Bundle Public Quality, Safety and Performance Committee 24 March 2022

0.0.0 10:00 - PRESENTATIONS

0.0.1 Welsh Blood Service - Donor Story

To be led by Alan Prosser, Interim Director, Welsh Blood Service, supported by Andrew Harris, Interim Head of Donor Engagement
Link: https://youtu.be/CdWj3kHPxq0

1.0.0 10:15 - STANDARD BUSINESS

To be led by Vicky Morris, Quality, Safety & Performance Committee Chair

1.1.0 Apologies

To be led by Vicky Morris, Quality, Safety & Performance Committee Chair

1.2.0 In Attendance

To be led by Vicky Morris, Quality, Safety & Performance Committee Chair

1.3.0 Declarations of Interest

To be led by Vicky Morris, Quality, Safety & Performance Committee Chair

1.4.0 10:20 - Review of Action Log

To be led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science

1.4.0 Public QSP Action Log March 2022.docx

Action 2.2.8 - SBAR for Oral SACT education service (QS&P Committee).pdf

2.0.0 CONSENT ITEMS

To be led by Vicky Morris, Quality, Safety & Performance Committee Chair

2.1.0 10:25 - ITEMS FOR APPROVAL

To be led by Vicky Morris, Quality, Safety & Performance Committee Chair

2.1.1 Draft Minutes from the meeting of the Public Quality, Safety & Performance Committee held on 17th February 2022

To be led by Vicky Morris, Quality, Safety & Performance Committee Chair

2.1.1 NOTES - Public Quality Safety Performance Committee 17.2.22(v4 approved).docx

2.1.2 Infection Control Policies

To be led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science
• (IPC01) – Gastro-Enteritis Policy (revised)
• (IPC04) – Decontamination Policy (revised)
Other policies:
To be led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science & Nigel Downes, Deputy Director of Nursing, Quality & Patient Experience
• Complaints Policy
• Incident Policy

2.1.2a IPC Policies.pdf

2.1.2b Incidents & Concerns Policy.docx

2.1.3 Wales Quality Bill Preparedness Update

To be led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science

2.1.3 Quality Act preparedness.docx

2.2.0 ITEMS FOR ENDORSEMENT

To be led by Vicky Morris, Quality, Safety & Performance Committee Chair

2.2.1 Radiation Protection Committee Highlight Report (deferred from January 2022 Committee)

To be led by Dr Hilary Williams, Assistant Medical Director for Quality & Safety

2.2.1 QSP Ionising Radiation Governance.docx

2.2.1a Terms of Reference - Radiation Protection Operational Group.docx

2.2.1bTerms of Reference - Radiation Protection Strategic Group.docx

2.3.0 ITEMS FOR NOTING

To be led by Vicky Morris, Quality, Safety & Performance Committee Chair

2.3.1 Trust Vaccination Programme Board Highlight Report

Led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science

2.3.1 Vaccination Programme Board Update QSP 24.3.22.docx

2.3.2 Infected Blood Enquiry Update

Led by Cath O'Brien, Chief Operating Officer

2.3.2 IBI_QSP Update_ March 2022 FINAL PUBLIC.docx

2.3.3 Highlight Report from the Trust-wide Patient Safety Alerts Group

To be led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science & Nigel Downes, Deputy Director of Nursing, Quality & Patient Experience

2.3.3 Patient Safety alert audit outcome Final Paper 2022-03-15 4.docx

2.3.4 RD&I Sub Committee Highlight Report

Led by Professor Andrew Westwell, Chair of the RD&I Sub Committee

2.3.4 RDI Public Highlight Report 13-01-22_FINAL.docx

2.3.5 Highlight Report from the Trust Estates Assurance Group

Led by Carl James, Director of Strategic Transformation, Planning and Digital

2.3.5 Trust Estates Assurance Highlight Report.docx

2.3.6 Transforming Cancer Services Programme Scrutiny Sub Committee Highlight Reports

Led by Stephen Harries, Interim Vice Chair and Chair of the Transforming Cancer Services Scrutiny Committee

2.3.6a PUBLIC TCS Programme Scrutiny Committee Highlight Report Dec 2021.docx

2.3.6b PUBLIC TCS Programme Scrutiny Committee Highlight Report Jan 2022.docx

2.3.7 Medical Devices Report (deferred from January 2022 Committee)

To be led by Cath O'Brien, Chief Operating Officer

2.3.7 QSP Medical Devices Report v0.5 - WBS - VCC combined.docx

2.3.8 Trust Operational Annual Plan 2021/2022 – Q3 Progress Report (deferred from January 2022 Committee)

Led by Carl James, Director of Strategic Transformation, Planning and Digital

2.3.8 IMTP 2021-2022 Progress Update Report - Quarter 3.docx

2.3.8a Annex 1 VCC Progress Update Q3.docx

2.3.8b Annual Plan 2021.22 WBS objective.docx

2.3.9 Medical Examiner's and Mortality Report (deferred from January 2022 Committee)

Led by Dr Hilary Williams, Assistant Medical Director for Quality & Safety

2.3.9 QS&P 240322 MES Paper_FINAL.docx

3.0.0 10:35 - Velindre Quality & Safety Committee for NHS Wales Shared Services

Led by Gareth Tyrrell, Head of Technical Services, NHS Wales Shared Partnership

3.0.0.a Quality Safety Performance Committee - CIVAS@IP5 March 2022.docx

3.0.0.b CIVAS@IP5.pptx

4.0.0 MAIN AGENDA

4.1.0 10:45 - Gold Command Report

Led by Lauren Fear, Director of Corporate Governance and Chief of Staff, supported by: Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science, Cath O'Brien, Chief Operating Officer and Jacinta Abraham, Executive Medical Director

4.1.0 GOLD COMMAND_ QSP Highlight Report March 2022_FINAL_17.03.2022.docx

4.2.0 10:50 - Workforce and Organisational Development Performance Report / Financial Report

To be led by Sarah Morley, Executive Director of Workforce and Organisational Development and Matthew Bunce, Executive Director of Finance

4.2.0a QSP Month 10 Finance Workforce Key Risks Paper Final.docx

4.2.0b M10 Finance Report.pdf

4.2.0c Workforce January Data.docx

4.3.0 11:10 - January Quality, Safety & Performance Update

Led by Cath O'Brien, Chief Operating Officer

4.3.0 VUNHST JANUARY PERFORMANCE COVER PAPER QSP MARCH Final 15.3.22.docx

4.4.0 Welsh Blood Service Quality Safety & Performance Divisional Report

Led by Alan Prosser, Interim Director of Welsh Blood Service

4.4.0a WBS Quality report for MARCH QSP 2022 final 15.3.22.docx

4.4.0b WBS Jan PMF 2022 QSP March 15.3.22.pdf

4.5.0 Velindre Cancer Service Performance Report

Led by Cath O'Brien, Chief Operating Officer

4.5.0a VCC JANUARY Performance Report FINAL QSP 15.3.22.docx

4.5.0b Radiotherapy referrals to Rutherford Cancer Centre (RCC (002 QSP final UPDATED.pptx

4.6.0 11:45 - Digital Service Operational Report

Led by Carl James, Director of Strategic Transformation, Planning and Digital and David Mason-Hawes, Head of Digital Delivery

4.6.0 Digital Service Operational Report.pdf

4.7.0 11:55 - Trust Risk Report

Led by Lauren Fear, Director of Corporate Governance and Chief of Staff

4.7.0 QSP PUBLIC Risk Paper March 2022 - FINAL VERSION.docx

4.7.0a Appendix 1 - V14 Data.pdf

4.7.0b Appendix 2 - V12 Data.pdf

4.8.0 12:05 - Quarter 3 Putting Things Right Report

To be led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science & Nigel Downes, Deputy Director of Nursing, Quality & Patient Experience

4.8.0 Putting Things Right Report - Q3.pdf

4.9.0 12:15 - Review of Information Governance Incidents & Trends

Led by Matthew Bunce, Executive Director of Finance

4.9.0 QSP IG Assurance Report Q4 21-22 - UPDATE FOLLOWING EMB.docx

4.10.0 12:25 - Freedom of Information Requests Report (deferred from January 2022 Committee)

Led by Lauren Fear, Director of Corporate Governance and Chief of Staff

4.10.0 FOI Report March 2022 -QSP Final.docx

5.0.0 INTEGRATED GOVERNANCE

5.1.0 12:30 - Health Care Standards Self-Assessment Action Plan / Improvement Plan

To be led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science & Nigel Downes, Deputy Director of Nursing, Quality & Patient Experience

5.1.0 Health & Care Standards QSP paper.docx

5.2.0 12:35 - Trust-wide Policies and Procedures Report

Led by Lauren Fear, Director of Corporate Governance & Chief of Staff

5.2.0 Policy Compliance Report March 2022 QSP.pdf

5.3.0 12:40 - Analysis of triangulated meeting themes

Led by Vicky Morris, Quality, Safety and Performance Committee Chair supported by all Committee members
Analysis of Quality, Safety & Performance Committee effectiveness
Led by Vicky Morris, Quality, Safety and Performance Committee Chair supported by all Committee members

6.0.0 12:50 - HIGHLIGHT REPORT TO TRUST BOARD

Members to identify items to include in the Highlight Report to the Trust Board:
- *For Escalation*
- *For Assurance*
- *For Advising*
- *For Information*

7.0.0 12:55 - ANY OTHER BUSINESS

Annual Quality Statement
To be led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science

8.0.0 DATE AND TIME OF THE NEXT MEETING

The Quality, Safety & Performance Committee will next meet on the:
12th May 2022 from 10:00 – 12:30 via Microsoft Teams

Minute ref	Action	Action Owner	Progress to Date	Target Date	Status (Open/Closed)
Actions agreed at the 18th January 2021 Committee					
2.1.2	Review Policy for Policies to incorporate requirements of the Well-being Future Generations Act	Lauren Fear	**Update 16/03/2022 -** A fundamental review of the Policy for Policies incorporating the Wellbeing Future Generations Act requirements has been completed and APPROVED by the Executive Management Board on 7th March 2022. This has now been included in the Policy Compliance report for completeness, which is on the agenda for the March QS&P Committee.	24/03/2022	CLOSED
Actions agreed at the 13th May 2021 Committee					
2.2.6	Update regarding plan to take part in national Medical Examiner Service following paper to VCC SMT to be presented at July Committee.	Jacinta Abraham/Paul Wilkins	**Update 10/02/2022** - It was confirmed that a paper would be presented at March EMB followed by submission to the March QS&P Committee.	24/03/2022	CLOSED
Actions agreed at the 15th July 2021 Committee					
2.1.4	Interim Handling Concerns Policy to receive a comprehensive review for completion by September Committee.	Annie Evans	**Update 08/03/2022** - This item is on the agenda for APPROVAL at the March QSP Committee and can be closed.	24/03/2022	CLOSED

2.2.8	BT to update the Committee on status of patients' education in relation to oral SACT at January 2022 Committee.	Bethan Tranter	**Update 08/03/2022** - This item has been deferred to March QS&P Committee and a paper has been provided and is included as an appendix to the action log.	24/03/2022	CLOSED
Actions agreed at the 18th November 2021 Committee					
4.7.0	Deep dive review of emerging themes in relation to complaints/concerns to be undertaken to gain further understanding and instigate meaningful resolution.	Annie Evans	**Update 08/03/2022** - This item will be contained within the Putting Things Right Report which is on the agenda for March QS&P Commitee.	24/03/2022	CLOSED
Actions agreed at the 20th January 2022 Committee					
5.1.0	Deep dive to be undertaken into Radiation Services to be undertaken to explore factors impacting service development opportunties within Radiotherapy.	Cath O'Brien	**Update 03/03/2022 -** The deep dive exercise will be undertaken in the April 2022 Board Development Session. This is on the April agenda and a presentation is currently being prepared.	12/05/2022	CLOSED
5.4.0	Workforce report to outline timescales in relation to job planning and supporting narrative to be provided for areas of concern.	Sarah Morley	**Update 10/02/2022** - Data provided via ESR on job planning currently being validated to ensure that it reflects the accurate picture of activity. This work will be completed and brought back to March QS&P Committee.	24/03/2022	OPEN
6.1.0	Overview of the wider picture and development in a number of areas to potentially be demonstrated via a presentation. COB to take forward and discuss this with LF.	Cath O'Brien	**Update 03/03/2022** - A meeting has been scheduled to discuss this in March.	24/03/2022	OPEN

Actions agreed at the 17th February 2022 Committee					
	A Public Health Wales representative to be invited to a future Board Development Session to facilitate a discussion in relation to the Trust's role / requirements & public health. A summary paper will be presented to the July 2022 Committee.	Lauren Fear/Nicola Williams	**Update 16/03/2022** - As referenced, a summary paper is to be reported to the July Committee.	14/07/2022	OPEN
3.2.0	MB to update Financial Report to reflect that the Committee NOTED but could not APPROVE the report, before publication on Trust website for accuracy.	Matthew Bunce		24/03/2022	OPEN
3.4.0	NW to investigate whether colour scheme within the CIVICA report can be amended to avoid confusion.	Nicola Williams	**Update 08/03/2022** - Discussions are currently underway with CIVICA.	24/03/2022	OPEN
3.8.0	SfM to update the Committee on position with 10 staff with outstanding DBS checks.	Sarah Morley	**Update 09/03/2022** - 5 DBS checks remain outstanding and divisional senior leadership teams have been advised. A formal process under the disciplinary policy will now take place. This action can be closed.	24/03/2022	CLOSED
4.1.0	LF to liaise with Communications colleagues to ascertain the most appropriate method of communicating positive feedback to staff from the February Extra-ordinary Committee meeting, in particular the staff experience story.	Lauren Fear	**Update 16/03/2022** - Communication has been drafted and is awaiting sign off.	24/03/2022	OPEN

Canolfan Ganser Felindre
Velindre Cancer Centre

Evaluation of Pharmacy Bespoke Oral SACT Education Service

Meeting Date:	16.02.2022
Author:	Usman Malik
Sponsor:	Bethan Tranter
Report Presented by:	Usman Malik
Committee/Group who have received or considered this paper:	VCC – Quality, Safety and Performance Management Committee

Trust Resolution to: (please tick)							
Approve:	**X**	**Endorse:**		**Discuss:**		**Note:**	
Recommendation:							

This report supports the following Trust objectives as set out in the Integrated Medium Term Plan: (please tick)	
Equitable and timely services	**X**
Providing evidence based care and research which is clinically effective	**X**
Supporting our staff to excel	
Safe and reliable services	**X**
First class patient /donor experience	**X**
Spending every pound well	

SITUATION

The Medicines Management Group have been requested by the Trust Quality, Safety and Performance Committee to undertake an evaluation of the oral Systemic Anti-Cancer Therapy (SACT) education service that is currently provided by the pharmacy dept. In particular, the QS&P committee have identified a potential 'unmet need' for those patients who have been initiated on oral SACT but do not have a bespoke education delivered by pharmacy.

Alongside this SBAR, a risk assessment has been performed (attached) which explain the next steps to be undertaken to further the work done to date.

BACKGROUND

Background of oral SACT education Service
All patients initiated on oral SACT have a baseline level of education. This baseline education includes:

1. **Written patient information** – all patients are given either a VCC or Macmillan patient information leaflet specific to their regimen. These leaflets include information of the oral SACT, how to take it, common side effects and when to contact a health professional. The patient will also receive the manufacturer's patient information leaflet contained within the medication box.
2. **SACT consent** – patients are consented on their treatment by their prescriber. This involves discussing with the patient the nature and intent of the oral SACT, the more common and serious side effects, after which the patient has to sign to state that they agree to proceed.
3. **Treatment alert card** – there are currently 3 different types of treatment alert card that relate to the different forms of SACT treatment (chemotherapy, targeted therapy and immunotherapy). These 'credit-cards sized' alert cards highlight serious side effects, when to contact the treatment helpline along with the contact details of the helpline.
4. **Standard pharmacy 'hatch' education** – when patients pick up their oral SACT medication from the pharmacy dispensary, pharmacy undertake a standard education of their SACT along with an explanation of any supportive medications (e.g. medications used for sickness, diarrhoea, mouth-care etc.).

However, as part of its clinical service, pharmacy also undertakes an additional 'bespoke education' service for patients who are initiated on certain 'higher risk' oral only SACT regimens. Patients on either parenteral or combination oral / parenteral SACT regimens receive SACT education via the nursing team.

This bespoke oral SACT education service first started in 2001 resulting from the prescribing of capecitabine (Xeloda ®) which was the first oral chemotherapy agent licensed for the treatment of metastatic colorectal cancer. The resource for this bespoke education service come from the existing pharmacy team at the time. Since 2001, the number of oral SACT that have had an additional bespoke education has increased; and the specific oral SACT regimens that have a bespoke education have been agreed between pharmacy and the specific SST.

However, as the number and complexity of 'oral only' SACT regimens increased across all SSTs, the demand for this service also increased. This led to a business case for a dedicated oral SACT education service lead whose role was to formalise the service, review all new 'oral only' SACT regimens for suitability of the service, to develop educational materials and checklists, undertake training of other staff to deliver and help in the delivery of the oral SACT education service. Despite this 1.0 WTE dedicated resource, the number of 'oral only' SACT regimens available and prescribed has continue to increase such that the current resource is not sufficient enough to undertake education on ALL oral only SACT regimens.

Background of SBAR

In April 2021, the Medicines Management Group (MMG) approved its annual 'Medicines Management Strategy Highlight Report' which identified all the achievements of the MMG over the 2020/21 financial year. This report was then presented at the VCC Quality and Safety Management Group, and then at Trust Quality, Safety and Performance (QS&P) Committee in July 2021.

One of the several achievements highlighted in the report was an approximate 30% increase in the number of patients that had received an oral education by the pharmacy team; which was due to the increase in the number of patients being prescribed oral only SACT regimens over this period (overall there was a 21.5% increase in the number of 'oral only' SACT prescribed in the 2020/21 financial year compared to 2019/20).

The QS&P Committee identified that although there had been an increase in the number of bespoke oral SACT education sessions that were undertaken, pharmacy do not undertake a bespoke oral SACT education for all patients initiated on 'oral only' SACT regimens, but only those that have been agreed between the pharmacy team and the SST to be considered 'higher risk', and therefore required an additional bespoke education. Following this, Trust QS&P Committee have requested a review of this service to identify if there is an 'unmet need'.

ASSESSMENT

Due to current resource available within the pharmacy oral SACT education team, it is not possible to undertake a bespoke education on all patients initiated on 'oral only' SACT. Therefore, an assessment was undertaken to ascertain the following:

1. Whether the 'oral only' SACT regimens that currently have an education package are the most appropriate regimens? *This would require some form of 'risk categorisation' to ascertain which regimens are a higher risk and which a lower risk, based on some form of criteria*.
2. For those regimens that do not have an associated bespoke education undertaken, a risk assessment will be undertaken to investigate whether the lack of this additional bespoke education will result in patients being non-concordant with their oral SACT, which will result in a compromise to patient safety and treatment outcomes.

Categorisation of Risk

A. Literature Search

A comprehensive literature search was undertaken by the VCC library service on the different models of oral SACT education. This search included whether there was any criteria in

existence on how different oral SACT were categorised, especially in accordance with their level of risk that could affect the patient's compliance.

The literature search did not identify the existence of a 'risk categorisation criteria' that can be used to identify which oral SACT regimens are more likely to require a higher level of education. Wiengart et al undertook survey of US cancer centres identified chemotherapy-related adverse drug events in one quarter of centres, and serous near-miss errors in a third. They highlighted toxicity of treatment and complexity of cancer treatments as risk factors to medication safety.

Schneider et all noted multiple risk factors that affected adherence to oral SACT treatment categorised into condition related factors such as:

- cognitive impairment,
- co-morbidities,
- psychopathology and other medications, and
- therapy related factors such as:
  - adverse events,
  - length of treatment
  - patterns of dosing
  - polypharmacy
  - complex regimens
  - safety and handling

Several other papers eluded to similar therapy related risk factors that potentially result in poor compliance. Therefore it could be argued that these factors may be able to form the basis of risk criteria to identify oral SACT regimens that may be of a high risk and therefore have a greater need for education.

B. Expert discussion

Alongside the literature search, one to one discussions were held with several different pharmacy technicians that currently undertake oral SACT education along with several pharmacists, some of which work as independent prescribers, to obtain their professional opinions on what they feel are factors that could potentially put an oral SACT regimen into a higher risk category and therefore require additional education. The risk factors highlighted are identified in the table below:

'Risk Criteria' identified by expert staff
Toxicity of treatment / side effects - especially those toxicities that the patient must action immediately. These include: • Nausea and vomiting (to prevent dehydration) • Signs / symptoms of infection (to prevent potential sepsis) *Note: for those oral SACT that have the above listed as very common (> 1 in 10) side effects on their Summary of Product Characteristics.*
Complex regimens, which include:

• Regimens whereby oral SACT is taken for a certain number of days of the cycle from the date of issue(i.e. take for X days followed by a break for Y days, e.g. palbociclib, capecitabine) • Regimens whereby oral SACT is issued by pharmacy but not taken immediately (i.e. vinorelbine taken on day 8 or lonsurf taken on days 1-5 and then again on days 8-12, temozolomide starting on day 10 when given in combination with capecitabine)
Oral SACT that require additional blood tests mid cycle (i.e. patients starting / changing doses of niraparib)
Specific administration instructions, such as: • Taken within a certain time period of food (i.e. capecitabine – within 30mins of food) • Minimal timing between dosing (i.e. capecitabine – at least 9 hours between doses)
Where dosing commonly involves different strengths of tablets to obtain the final dose (i.e. capecitabine)
Oral SACT regimens that also have several additional supportive co-prescribed and issued (i.e. polypharmacy and education around when to take these other medications)

In addition to these named factors, there were several other patient specific factors also identified such as those patients with cognitive impairment or learning needs, and those patients on several other medications that could impact on compliance and concordance.

Risk Stratification of current oral SACT

Using a combination of the risk factors highlighted in the literature and by the expert staff, an exercise was undertaken whereby all current oral SACT regimens was subjected to a 'risk stratification' to identify which agents were categorised at a 'higher level of risk'. Alongside this, those SACT agents that are currently subject to a bespoke oral education are also highlighted – see Appendix 1.

Medicines Management Group (MMG) meeting – 24th Nov 2021

This SBAR along with the 'Risk Stratification' document (appendix 1) have been reviewed by the MMG on 24th November 2021. Alongside this, a risk assessment has been undertaken to rate the level of risk attributed to patients who initiated on oral SACT agents that do not have this additional bespoke education service in addition to the baseline level of education (appendix 2).

The recommendations of MMG was to develop a task and finish group that comprises of pharmacy, nursing, treatment helpline staff and medical staff to agree the risk categorisation criteria, agree the level of risk allocate to the individual oral SACT regimens (e.g. the risk score) and to agree the level of risk categorisation that would warrant a bespoke education to be delivered. Work can then be undertaken to calculate the resource requirements needed to deliver the agreed level of education.

RECOMMENDATIONS

The recommendations of this SBAR for the VCC Quality and Safety Group are as follows:

1. Note the recommendations of the MMG as per above
2. An update to these recommendations will be presented back to MMG in April/May 2022; which will then be presented to Q+SMG.

Appendix 1

Oral SACT education - Risk Stra

Appendix 2

Oral SACT education - Risk Ass

Ymddiriedolaeth GIG Prifysgol Felindre
Velindre University NHS Trust

Minutes

Public Quality, Safety & Performance Committee

Velindre University NHS Trust

Date: 17th February 2022
Time: 10:00 – 11:45
Location: Microsoft Teams
Chair: Vicky Morris, Independent Member

ATTENDANCE		
Prof. Donna Mead OBE	Velindre University NHS Trust Chair	DM
Hilary Jones	Independent Member	HJ
Stephen Harries	Interim Vice Chair and Independent Member	SH
Steve Ham	Chief Executive Officer (in part)	SHa
Cath O'Brien	Chief Operating Officer	COB
Jacinta Abraham	Executive Medical Director	JA
Lauren Fear	Director of Corporate Governance and Chief of Staff	LF
Carl James	Director of Strategic Transformation, Planning and	CJ
Nicola Williams	Executive Director of Nursing, Allied Health Professionals & Health Science	NW
Matthew Bunce	Executive Director of Finance	MB
Sarah Morley	Executive Director of Organisational Development &	SfM
Alan Prosser	Interim Director of Welsh Blood Service	AP
Nigel Downes	Deputy Director of Nursing, Quality & Patient Experience	ND
Peter Richardson	Head of Quality Assurance, Welsh Blood Service	PR
Emma Stephens	Head of Corporate Governance	ES
Kyle Page	Business Support Officer (Secretariat)	KP

0.0.0	PRESENTATIONS	Action Lead
0.0.1	**Staff Story** Led by Nicola Williams, Executive Director Nursing, AHP & Health Science supported by Matthew Walters, Operational Senior Nurse, Velindre Cancer Service A video had been received in advance of the Committee outlining Velindre Cancer Centre First Floor Ward staff experiences, wellbeing and team working efforts to overcome the challenges faced during the fourth wave of the COVID pandemic. MW highlighted the following: • Staff had consistently endeavoured to support one another, often at very short notice, working additional shifts wherever necessary and supporting each other's out of work commitments and essential periods of rest.	

	• Informal 'de-briefs' following challenging situations provided mutual emotional and mental support. • Staff had applied rapid learning during COVID, improving processes and the environment for both patients and staff, with the patient at the forefront of decision making. • Shifts and skill mixes had been appropriately organised and managed. • Provision of support from mental health staff / clinical psychologists. • Improving communication with patients isolating following admission, providing the best possible care in relation to both physical patient comfort and mental health support, including the provision of technology to allow patients to communicate with loved ones in the absence of visiting. MW confirmed that in terms of patient comfort, 8 cubicles are available for isolating patients, with modern facilities including television / emergency call facility. iPads are also available to facilitate virtual communication between patients and their friends and families. NW thanked the team for their performance as a whole and commitment to ensuring that the patient remained at the heart of decisions and processes, often under difficult circumstances due to the complex nature of caring for patients on the Ward. SfM queried the availability of wellbeing support for staff who may be suffering long term effects of working in such circumstances for an extended period of time. MW confirmed that support can be accessed through Occupational Health, in addition to the current supporting mental health team. DM suggested that to support any future stories measurable outcome data should be used to demonstrate 'good care' such as infection rates, falls and pressure ulcers. It was noted that this data was included in separate papers provided to the Committee and demonstrated good patient outcomes in respect of these. The Committee welcomed the openness of staff and powerful nature of the video and commended their ongoing commitment during an extended period of many challenges. It was acknowledged that the service had continued to develop during this time and VM thanked MW and his team on behalf of the Committee.	
1.0.0	**STANDARD BUSINESS**	
1.1.0	**Apologies** Apologies were received from: • Paul Wilkins, Interim Director of Velindre Cancer Service	

1.2.0	**Additional Attendees** • Jennie Palmer, Quality & Safety Manager • Katrina Febry, Audit Lead, Audit Wales • Sarah Thomas, Healthcare Inspectorate Wales • Stephen Allen, Chief Officer, South Glamorgan CHC • Kathy Ikin – Head of Radiation Services, VCC • Laura Howells – Principal Auditor, NWSSP • Matthew Walters – Operational Senior Nurse, VCC • Alice Grove – Clinical Sister, VCC	
1.3.0	**Declarations of Interest** Led by Vicky Morris, Quality, Safety & Performance Chair There were no declarations of interest.	
1.4.0	**Review of Action Log** Led by Nicola Williams, Executive Director of Nursing, AHPs and Health Science The Committee reviewed all actions identified as having closed since the previous meeting and those whose completion date was due or overdue. In addition to confirming the closed actions the following was agreed: **5.1.0: Deep dive exercise into Radiation Services** – It was agreed that this was closed. The Deep Dive will be undertaken in the April 2022 Board Development Session. **5.1.0: COSC patient pathways** – It was agreed that this could be closed as will be addressed as part of the Performance Management Framework discussion on today's agenda. VM suggested reviewing how closures and the status of actions are documented on the action log including dates of defined actions to ensure efficient progression through future Committees. **Legacy Action – Request a Public Health Wales Representative for Trust Board** – DM commented that the action had been present on the log for an extended period of time and had discussed with Executives how this action can be taken forward. It was agreed that this would be discussed at a future Board Development session where a Public Health Wales Representative would be invited to facilitate a conversation in respect of the Trust's potential role in all aspects of public health. LF confirmed that a summary paper would be presented by the July Committee to provide assurance and the Committee agreed to close the current action on this basis. The Committee **AGREED** the status of all actions as noted above.	**KP** **LF** **KP**
2.0.0	**CONSENT ITEMS**	

	(The consent part of the agenda considers routine Committee business as a single agenda item. Members may ask for items to be moved to the main agenda if a fuller discussion is required).	
2.1.0	**ITEMS FOR APPROVAL**	
2.1.1	**Draft Minutes from the meeting of the Public Quality & Safety Committee held on the 20th January 2022** Led by Vicky Morris, Quality, Safety and Performance Committee Chair The minutes of the Public Quality & Safety Committee held on the **20th January 2022** were **APPROVED** as a true reflection of the meeting.	
2.2.0	**ITEMS FOR ENDORSEMENT**	
	There were no items for endorsement.	
2.3.0	**ITEMS FOR NOTING**	
2.3.1	**Draft summary of the minutes from the meeting of the Private Quality, Safety & Performance Committee held on 20th January 2022** Led by Vicky Morris, Quality, Safety & Performance Committee Chair The Committee **NOTED** the summary minutes from the **20th January 2022** Private Committee.	
2.3.2	**Trust Vaccination Programme Board Report** Led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science DM advised the Committee that prior to the meeting she had requested previous influenza comparative data and that although the influenza vaccination percentage for 2021/22 was slightly lower than last year (an extraordinary year) it was greater than pre pandemic levels. NW advised that the 60% national influenza vaccination target had been exceeded at 71% for 2021/22 and that this figure excluded staff who had acquired an Influenza vaccination elsewhere. The Trust vaccinated 79% of staff in 2020/21 and pre-pandemic average was 66%. The Committee **NOTED** the contents of the report and actions being taken.	
2.3.3	**Datix Project Highlight Report** Led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science *(Removed from the consent section of the agenda by VM to allow for fuller discussion)* VM noted that issues had been identified by the Welsh Blood Service in aligning systems with the previous coding categorisation structure adopted with the new Once for Wales system, presenting challenges when entering incidents and extracting information for reporting	

	purposes. VM queried how this is being managed to ensure that no incidents are missed due to system updates / amendments, and how comparisons can be made to ensure there are no safety concerns in the relevant areas of applicable Datix reports, which are not escalated. NW advised that items for resolution are escalated to Once for Wales' representatives involved in the project and tracked to ensure progression. Additionally, an escalation point to Shared Services is in place to troubleshoot any resolution issues. The challenges have arisen due to the specific nature of the Welsh Blood Service and PR provided assurance in relation to the oversight that WBS have where all incidents reported into Datix and Q-pulse are reviewed daily by a triage team and all information is considered / risk assessments undertaken before investigation. An exercise to integrate the additional coding requirements for the Welsh Blood Service is also currently underway. The deficits in coding mainly affects WBS ability to have effective reporting as the current themes and trends must be produced manually whilst the codes are being worked through nationally. VM requested that this level of supporting assurance detail is included in future reports. The Committee **NOTED** the contents of the report.	
2.3.4	**Executive Director Nursing Update** Led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science The Committee **NOTED** the contents of the Executive Nursing report covering the period November to December 2021. DM commended the report.	
2.3.5	**Quality, Safety & Performance Committee deferred papers** Led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science The Committee **NOTED** the current position in relation to the status of papers deferred from the January 2022 Committee. The paper detailed that some deferred papers had been recieved at this meeting and the remaining were due to come to the March 2022 meeting.	
3.0.0	**MAIN AGENDA** (This section supports the discussion items for review, scrutiny and assurance).	
3.1.0	**Gold Command Report** Led by Lauren Fear, Director of Corporate Governance and Chief of Staff, supported by: Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science, Cath O'Brien, Chief Operating Officer and Jacinta Abraham, Executive Medical Director	

	The Gold Command Highlight Report provided an overview of the key issues and items considered by Gold Command at its meetings held between 17/01/2022 and 09/02/2022. The following was highlighted: • The frequency of Gold Command meetings has been reduced to once weekly based on the reduction in overall risk to the organisation. • Infection prevention and control - In relation to the First Floor Ward COVID outbreak initially reported, a review with Public Health colleagues had concluded that it had been categorised as a 'cluster', rather than an outbreak. The Cluster had been managed as an outbreak to ensure robust management. Daily infection control audits undertaken with 100% compliance with all standards (including PPE, donning and doffing, isolation and screening of all patients upon admission). • The number of new patients waiting to commence their SACT (Systemic Anti-Cancer Treatment Therapy) within 21 days during January 2022 is under validation and is currently identified as 24. All those waiting over 21 days are the lowest risk patients and commenced treatment within a few days of the 21 day deadline. The Committee were advised that SACT demand capacity is under continual review (daily review meetings) and additional weekend clinics are being held when staffing is available. • COB advised that an urgent Task & Finish Group has been established to urgently review SACT provision, looking at immediate options and ways to increase capacity. • All planned inpatients are screened prior to admission. All patients admitted are isolated and screened on arrival, obtaining results within hours via fast track PCR (Polymerase Chain Reaction) tests. Screening is also carried out on day 5 of their stay. The Committee **NOTED** the contents of the report and actions being taken.	
3.2.0	**Financial Report** Led by Matthew Bunce, Executive Director of Finance The Financial Report was received, outlining the financial position and performance for the period ended 31st December 2021 (month 9). The following was highlighted: • It is anticipated that all KPIs in relation to Revenue, Capital and Public Sector Payment Performance will be met and the year-end forecast is set to achieve financial break-even. • Following a request for the Executive team to review areas of non-recurrent spend agreed in April 2021, feedback had been provided from the Executive team and the year-end forecast will be updated to reflect this.	

	• The request for a reduction in recharges to Charitable Funds of £800k due to redeployment of staff in areas where the Trust had bid for funding into COVID response related work was approved by the Executive team and a similar paper will be presented to VCC SMT to agree the reduction in charges for the year. • Options in relation to how Charitable Funds may be utilised during 2022/23 in relation to the following risks: o The significant shortfall in provision of COVID-related funding from Welsh Government (via Health Boards) to assist local response and additional capacity necessary for addressing the backlog and general growth in demand; o Increased levels of sickness and lost productivity due to enhanced infection prevention and control measures; o Maintaining current levels of delivery, treatments and services. MB advised that the new integrated Finance and Workforce report (to be presented at March Committee) would include a review of how funding is utilised in terms of staffing (including agency costs). The Committee **NOTED** the contents of the report (pending minor amendments noted during the meeting), in particular the financial performance to date and year-end forecast to achieve financial break-even. For governance purposes, VM requested that the paper be updated to record that the Committee **NOTED** but could not **APPROVE** the report. This would be updated and included with re-published papers available on the Trust website for accuracy.	**MB**
3.3.0	**Quality, Safety & Performance Reporting** Led by Cath O'Brien, Chief Operating Officer The Trust Performance report was discussed and the following key items were highlighted: • Further improvements are required to the narrative within the report in relation to the improvement actions being taken when performance is off track. • Continued delivery of SACT despite considerable absences within the team. A level of cover from a number of other departments has been welcomed to sustain service provision and reduce the number of breaches. • Circulation of a paper to Committee members, providing an overview of Radiotherapy targets (historic JCCO (Joint Collegiate Council for Oncology) and new COSC (Clinical Oncology Sub-Committee)) had been circulated prior to the Committee. • The current position in relation to the development of Radiation Services, including work undertaken to facilitate meeting the COSC targets once they have become a formal requirement, will be	

	discussed in detail during the April 2022 Board Development Session. • The current position in relation to pathway work will also be presented at the April 2022 Board Development session followed by a summary / record to be presented at the Quality, Safety & Performance Committee. • The Brachytherapy Business Case remains under development with completion anticipated within the next few weeks. • COB reported that a detailed step by step analysis of the Head and Neck pathway had been undertaken; however implementation of core changes to all pathways will be required. The Committee **NOTED** the contents of the report.	
3.4.0	**Velindre Cancer Service Quality, Safety, Performance & COVID Report** Led by Cath O'Brien, Chief Operating Officer The Velindre Cancer Service report provided an update on key quality metrics, outcomes and performance against key metrics for the period to the end of December 2021 and the following items were highlighted: • Analysis of the significant number of open Radiotherapy incidents had confirmed that many had been identified as low risk and therefore not been prioritised. The Committee was provided with **ASSURANCE** that all risks are currently undergoing review and prioritisation. • NW advised that there had been six Radiotherapy (IRMER) incidents reported late to HIW (Health Inspectorate Wales). These were all low exposure / low harm incidents. The delays were a result of internal delays in assessing if low additional exposure incidents met the reporting thresholds. A number of changes have been made across radiation services to prevent such delays in the future. NW had liaised with the HIW relationship manager re these incidents. • KI noted that a number of historic issues related to a change in categorisation by HIW resulting in non-reportable incidents. Incidents are being upgraded to high risk to ensure timely reporting to HIW (and relevant manufacturers if necessary). • VM asked HIW representatives (in attendance at the Committee) if they had any concerns or were satisfied with the late reporting process. They confirmed they were satisfied. • In order to mitigate the risk of predicted shortfall of Oncologists, a review of skill mix is currently underway to enable an increase in capacity, in addition to the recruitment of two Physicians' Associates upon qualifying in autumn 2022. Work is currently at scoping stage, however further reporting on this will follow at a future Committee. • The transition to DHCR (Digital Health & Care Record) from CANISC (Cancer Network Information System Cymru) and analysis of its implementation on ways of working remain in progress with further clarity expected imminently.	

	• All actions resulting from recommendations following 15 step challenge visits undertaken within VCC Outpatients Department and SACT Outreach Unit at Prince Charles Hospital are in progress or have been completed and will be included as part of regular reporting. Procurement for new flooring within the Outpatients' Department is underway with anticipated completion by the end of March 2022. • An option appraisal has been undertaken for the relocation of Phlebotomy and a business case is currently under development. • It was recognised that far more compliments had been received by the Cancer Centre than are currently being captured on the Datix system (30 for period October to December 2021). As the compliment section is new, further awareness raising of this is required across all services so that compliments are captured at source. • The report included the new CIVICA (patient feedback) system reports for the period October to December 2021 from across a number of services within VCC. The feedback was in the main extremely positive. NW highlighted that the report did also include some areas/issues requiring improvements for patients that are being reviewed by departmental teams and where patient contact can be made,(if details are available) a review and follow up also acted on. SA noted that although the CIVICA report provided assurance, the colour scheme may cause confusion and amendment of this will be investigated. • COB advised that the implementation of DHCR is also exploring the collation of the booking teams with the aim to reduce waiting times. COB was confident that improvements would be seen within a few months. The Committee **NOTED** the contents of the report.	**NW**
3.5.0	**Welsh Blood Service Quality, Safety, Performance & COVID Report** Led by Alan Prosser, Interim Director, Welsh Blood Service The Welsh Blood Service report provided an update on performance against key metrics for the period to 31st January 2022 and the following items were highlighted: • Challenges presented during December 2021 had been overcome without the requirement for importation and the position had improved during January 2022, particularly in relation to stock levels (now 2,000 units in comparison to 1,000). The blue alert instigated during December 2021 was lifted at the end of January 2022. • Donor feedback remains very positive in the main (96%), with 6 concerns received all managed in line with national timescales. • Recruitment of bone marrow donors continues to be challenging, partly due to restricted access to schools and universities as a result of the Omicron wave; however a new strategy is currently being considered to increase numbers.	

	• Closeout of incidents within the required timeframe had dropped below target for the first time since May 2021. Despite adhering to reporting, risk assessment and instigation of the appropriate level of investigation, the target had not been met due to delays in review and closure by the Manager as a result of competing pressures due to Omicron. The Committee was provided with an assurance that this had now been escalated and resolved and that potentially extending the deadline for decisions would help avoid a reoccurrence. • The Committee was verbally advised of a recent incident that has been investigated involving the deterioration and unfortunate death of a patient during a red cell transfusion within a Health Board. The Welsh Blood Service has undertaken a robust internal investigation and worked with the Health Board in respect of the overall incident. The outcome is that there is no evidence that the blood transfusion related to the patients' death. The Committee **NOTED** the contents of the report.	
3.6.0	**Workforce & Organisational Development Performance Report** Led by Sarah Morley, Executive Director of Organisational Development and Workforce The Workforce and Organisational Development Performance Report provided information in relation to PADR (Performance Appraisal & Development Review), Statutory & Mandatory compliance and staff sickness / absence. The following was highlighted: • Presentation of data within the report continues to be developed and a Finance / Workforce triangulation report will be presented at the March Committee. • It was recognised that although PADR performance had decreased from pre-COVID levels, the level remains high across divisions, with the exception Corporate Services. Current discussions are focusing on improvements within this area in particular Corporate teams and Executive Directors are taking urgent action to ensure full PADR compliance across all teams. • Sickness levels have remained at 0.6% above pre-COVID levels of 4.5% for the last 18 months and detailed analysis and monitoring has enabled focused work in recognised areas to actively reduce this. The Committee **NOTED** the contents of the report.	
3.7.0	**Infection Prevention and Control Management Group (IPCMG) Highlight Report** Led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science The IPCMG Highlight Report provided details of the key issues considered during its meeting held on 20th January 2022 and the	

	following was highlighted: • Overall healthcare acquired infection rates remain low across all areas and is in contrast to most Health Boards where increases have been seen. Staff were commended for this. • There has been no MRSA bacteraemia for over 8 years. • There remain three Infection Prevention and Control related Policies out of date. The plan for each is: o IPC01 - Gastro-Enteritis Policy – will be presented at the March Committee for **approval**. o IPC04 - Decontamination – will be presented at the March Committee for **approval**. o IPC07 – MRSA – currently under review and will be presented at the May Committee for **approval** (further delayed due to COVID taking priority). NW advised that no other Infection Prevention and Control policies are out of date. The Committee **NOTED** the contents of the report and actions being taken.	
3.8.0	**Safeguarding & Vulnerable Adults Management Group (SVAMG) Highlight Report** Led by Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science The SVAMG Highlight Report provided details of the key issues considered during its meeting held on 3rd December 2021. The following areas were highlighted: • Safeguarding training compliance - It was noted that Safeguarding training compliance remains below target and that the training needs analysis had been delayed due to the Omicron wave. This will be revisited imminently and will include ESR data cleansing and a role by role training needs analysis. Workforce & Organisational Development are supporting this work. • Tier 2 Dementia training – A historical gap in the Trust's assurance mechanisms in respect of dementia, older persons and learning disability standards has been recognised and plans put in place to address this. One element identified was the provision of tier 2 Dementia training. Arrangements have been put in place with Cardiff & Vale University Health Board to provide this training. The wider remit is now being addressed by broadening the role of the Senior Nurse Safeguarding to include Vulnerable Groups and the broader remit of the Safeguarding Management Group. • The annual Safeguarding Maturity Matrix peer review had been undertaken. The report is awaited and will be provided to the	

	Committee as part of the next Safeguarding Report. • HJ suggested the inclusion of a target date for the improvement of Safeguarding training compliance, in addition to a target date for the implementation of the chaperone policy plan. • VM queried the current Trust Disclosure & Barring Service (DBS) position, which remains unclear. Following the recent DBS governance checks it has been identified that 10 staff are yet to submit their DBS. SfM advised that Management action had been taken to pursue this and that an update would be provided as soon as possible. The Committee **NOTED** the contents of the report and the actions being taken to address training compliance.	**SfM**
3.9.0	**Trust Risk Report (COVID-related risks only)** Led by Lauren Fear, Director of Corporate Governance and Chief of Staff The Trust Risk Report provided information on the current status of COVID-19 related risks, scoring level 15 and above. LF advised the Committee of the following: • There are currently three risks scoring level 15 and above, involving changes to service within Radiotherapy due to continued COVID-19 response, the potential significant impact on ability to provide SACT due to COVID-19 related staff absences and implementation of the Digital Health & Care Record system. • A new function within Datix now enables the identification of COVID related risks. • Feedback received in relation to the overall presentation of data is currently being worked through via weekly meetings across the Trust. This will be evidenced in the March 2022 report provided to the Committee. • Where mitigating actions for risks are unclear, this will be comprehensively covered going forward. The Committee **NOTED** The COVID-19 risks scored above 15.	
4.0.0	**INTEGRATED GOVERNANCE** (The integrated governance part of the agenda will capture and discuss the Trust's approach to mapping assurance against key strategic and operational risks)	
4.1.0	**Analysis of meeting outputs** Led by Vicky Morris, Quality, Safety and Performance Committee Chair NW noted that the overriding theme is the level of performance and efforts of teams to maintain the core functions of the Trust during the pandemic.	

	It was recognised that while several areas of performance require improvement, the Trust has and continues to deliver exceptionally, evidenced by reports and low levels of complaints. Focused work on underperforming areas is already planned and outcomes will be demonstrated at future Committee meetings. SH suggested sharing this positive feedback with staff across the divisions and LF agreed to liaise with Communications colleagues to consider the most appropriate manner of doing so. VM also advised that as a significant number of papers will be brought to the March 2022 Committee, Colleagues were advised to ensure that cover papers are written succinctly to highlight the key items and matters for consideration by the Committee.	**LF**
5.0.0	**HIGHLIGHT REPORT TO TRUST BOARD**	
7.1.0	Members were asked to identify items to include in the Highlight Report to the Trust Board: • For Escalation • For Assurance • For Advising • For Information	
6.0.0	**ANY OTHER BUSINESS**	
	No other business was received.	
7.0.0	**DATE AND TIME OF THE NEXT MEETING**	
	The Quality, Safety & Performance Committee will next meet on **Thursday 24th March 2022 @ 10:00h-13:00h via Microsoft Teams.**	
CLOSE		
The Committee is asked to adopt the following resolution: That representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest in accordance with Section 1(2) Public Bodies (Admission to Meetings) Act 1960 (c.67).		

QUALITY SAFETY & PERFORMANCE COMMITTEE

Decontamination of Equipment Policy (Ref: IPC04) & Viral Gastroenteritis Policy (Ref: IPC01)

DATE OF MEETING	24th March 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable

PREPARED BY	Infection Prevention and Control Team
PRESENTED BY	Nicola Williams, Executive Director of Nursing, Allied Health Professionals & Health Science
EXECUTIVE SPONSOR APPROVED	Nicola Williams, Executive Director of Nursing, Allied Health Professionals & Health Science

REPORT PURPOSE	FOR APPROVAL

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Infection Prevention and Control Divisional Group – Velindre Cancer Centre	16/02/2022	ENDORSED FOR APPROVAL
Infection Prevention and Control Divisional Group - Welsh Blood Service	16/02/2022	ENDORSED FOR APPROVAL
Executive Management Board	7th March 2022	APPROVAL

1. SITUATION

This paper is provided to the Quality, Safety & Performance Committee to **APPROVE** the following revised Infection Prevention & Control related Policies:

- IPC04: Decontamination of Equipment Policy
- IPC01: Viral Gastroenteritis Policy.

2. BACKGROUND

Due to the impact of the pandemic and staffing challenges there were three Infection Prevention & Control Policies that were out of date. All required significant changes, rather than minor reviews.

Two of the three have been reviewed. The MRSA Policy remains out of date. The review is almost complete. It is anticipated that this will come to the Committee for approval in May 2022.

3. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

3.1 Decontamination of Equipment Policy (Ref: IPC04)

The purpose of this policy is to ensure the safety of both Velindre University NHS Trust staff and outside contractors who are employed to use, maintain and repair medical equipment. The policy applies to all staff within Velindre University NHS Trust who are involved with decontamination of medical devices/ healthcare or who are involved with decontamination of healthcare equipment prior to inspection, service, maintenance or repair.

Wide engagement and consultation has taken place in respect of this policy review including Divisional Teams, microbiology, Infection Prevention & Control Management Group attendees. The Policy was endorsed by the Executive Management Board on the 7th March 2022.

3.2 Viral Gastroenteritis Policy (Ref: IPC01)

The purpose of this policy is to provide the required information for staff across the Trust to promptly recognise and take appropriate actions when a patient or staff member is suspected of having gastroenteritis.

This policy applies to all Trust staff (including contracted, volunteers and community) and service users.

Wide engagement and consultation has taken place in respect of this policy review including Divisional Teams, microbiology, Infection Prevention & Control Management Group attendees. The Policy was endorsed by the Executive Management Board on the 7th March 2022.

An Equality Impact Assessment was undertaken on both policies on the 13th September 2017. The outcome was that '*No potential negative impact has been identified'.*

Once approval is sought both Policies will be published on the Trust Intranet site and circulated to the policy distribution list.

4. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
RELATED HEALTHCARE STANDARD	Safe Care
	If more than one Healthcare Standard applies please list below:
EQUALITY IMPACT ASSESSMENT COMPLETED	Yes
	An Equality Impact Assessment was undertaken on both policies on 13th September 2017. The outcome was that '*No potential negative impact has been identified'.*

LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	There is no direct impact on resources as a result of the activity outlined in this report.

5. RECOMMENDATION

The Quality, Safety and Performance Committee are asked to **APPROVE:**

- IPC04: Decontamination of Equipment Policy
- IPC01: Viral Gastroenteritis Policy.

Ref: IPC 04

DECONTAMINATION POLICY

Executive Sponsor & Function	Executive Director of Nursing, AHPs and Health Sciences
Document Author:	Infection Prevention and Control Team
Approved by:	Trust Executive Management Board Quality, Safety & Performance Committee
Approval Date:	March 2022
Date of Equality Impact Assessment:	September 2017
Equality Impact Assessment Outcome:	*This policy has been screened for relevance to equality. No potential negative impact has been identified.*
Review Date:	3 years from Approval Date
Version:	5

CONTENTS

ABBREVIATIONS

IPCMG	Infection Prevention and Control Management Group
HCAIs	Healthcare Associated infections
IPCT	Infection Prevention and Control Team
HCW's	Healthcare Workers
HTM	Health Technical Memorandum
HBN	Health Building Note
EMB	Executive Management Board
MHRA	Medicines and Healthcare products Regulatory Agency
WHTM	Welsh Hospital Technical Memorandum
VCC	Velindre Cancer Centre
NIPCM	National Infection Prevention and Control Manual

1 POLICY STATEMENT

1.1 Medical devices play a key role in healthcare, vital for diagnosis, therapy, monitoring, rehabilitation, blood collection and care. Effective management of this important resource is required to satisfy high quality patient and donor care, clinical and financial governance, including minimising the risks of adverse events.

Decontamination of reusable devices is a combination of processes, which if not correctly undertaken, individually or collectively, may increase the likelihood of micro-organisms being transferred to patients, donors or staff. This combination of processes includes acquisition, cleaning, disinfection, inspection, packaging, sterilisation, transportation and storage.

2 SCOPE OF POLICY

2.1 This policy applies to all staff within Velindre University NHS Trust who are involved with decontamination of medical devices/ healthcare equipment. It is also applicable to staff who are involved with decontamination of healthcare equipment prior to inspection, service, maintenance or repair.

2.2 Cleaning and environmental cleanliness is not addressed in this policy and reference should be made to Policy IPC 05 National Infection Prevention and Control Manual

2.3 Please refer to local Standard Operating Procedures for decontamination of specific reusable medical devices.

3 AIMS AND OBJECTIVES Eliminating preventable healthcare associated infections (HCAIs) requires the proactive involvement of every member of staff across all healthcare settings. In conforming to the principles of Prudent Health and Care, healthcare organisations and individuals involved in providing services are obliged to prevent cross infection when using medical devices in patient care. It is essential that medical devices and care equipment are managed safely to ensure they are used within manufacturer guidance, cannot harbour organisms and can be effectively decontaminated in accordance with this policy. This policy has been produced to ensure the safety of both Velindre University NHS Trust staff and outside contractors who are employed to use, maintain and repair medical equipment.

3.2 To ensure that there is a system in place that ensures as far as is reasonably practicable all reusable medical devices are appropriately decontaminated prior to use and after use and the risks associated with decontamination facilities and processes are adequately managed. (Appropriately = in alignment with manufacturer's instructions and National guidance).

3.3 Effective decontamination of medical devices/ healthcare equipment will be carried out to ensure the device is:

- Safe for further use
- Safe for staff to handle
- Safe for use on the patient/ donor
- Safe for disposal

3.4 The policy objectives are to:

- Provide guidance on the appropriate decontamination of medical devices and healthcare equipment
- Establish processes to ensure that equipment is kept clean, fit for purpose and in a good state of repair at all times during its operational life
- Identify individuals' responsibilities for cleaning and maintaining medical devices/ healthcare equipment within Velindre University NHS Trust, ensuring consistency

- Ensure safe systems of work are adopted to protect patients, donors and staff from the transmission of infection from medical devices and other equipment that comes into contact with patients and donors

4 RESPONSIBILITIES Trust Roles and Responsibilities

Trust Accountability

The Chief Executive has overall responsibility to ensure this policy is adhered to. Other responsibilities are outlined below.
The Trust Executive Management Board is collectively responsible for minimising the risks of infection to patients, donors, healthcare workers (HCW's) and the public. The Executive director for Director of Nursing, AHP's & Health Science is board lead for the IPC organisational structure for the service.

Trust Responsibilities

The Trust has a responsibility to ensure that:

- All Divisional Directors make staff aware of the policy and provide appropriate equipment and training in the use and decontamination of devices.
- An Executive Board Decontamination Lead (representing the Chief Executive) and the Operational Decontamination Lead are identified.
- The Infection Prevention and Control Team (IPCT) will assist with training as appropriate.
- The IPCT will advise on the use of decontamination processes and products as well assess new devices to ensure they comply with this policy.
- Facilities and equipment used by the Trust for decontamination comply with relevant Health Technical Memoranda (HTM) and Health Building Note (HBN) requirements for good practice as well as Medicines and Healthcare products Regulatory Agency (MHRA) directives.
- Medical devices are managed in accordance with Health Safety & Welfare Policy (QS 18).
- Incidents relating to decontamination processes are monitored and reviewed in a timely manner.

4.2 Decontamination Executive Lead/ Operational Decontamination Lead

The Executive Decontamination Lead will provide the strategic lead for decontamination and will be responsible in ensuring that this policy is implemented in relation to the organisation and takes proper account of relevant national guidelines.

The Operational Decontamination Lead with support from the Consultant microbiologist and the IPCT will be responsible for the production, review and audit of evidence-based policy to provide the Trust with up-to-date information on the decontamination or reusable medical devices and will provide staff with training on this policy where needed.

Assess risks associated with ineffective decontamination processes; determine remedial action and recognise areas for development. Report risks on the Boards Risk Register.

Identification and implementation of lessons learnt to inform and improve future practice.

4.3 Infection Prevention and Control Management Group

The role of the Infection Prevention & Control Management Group is to provide strategic direction and develop a structured approach to the decontamination of reusable medical devices that eliminates or reduces as far as possible the risks associated with the decontamination processes to the patient, user and third parties. The Group is accountable to the Trust and reports to the Quality & Safety Committee and Executive Management Board.

4.4 Authorised Engineer (Decontamination)

The Authorising Engineer (Decontamination) will undertake the duties set out in NHS Wales documents Welsh Hospital Technical Memorandum (WHTM), WHTM 01-01 Part A, WHTM 01-05 and WHTM 01-06 Part A.

4.5 Infection Prevention & Control Team

- Provide specialist advice for the suitability of equipment prior to purchase and during use. This will include approving the design of equipment e.g. difficult to clean areas, dust traps etc. Such advice must be copied to the Decontamination lead.
- Provide information and advice to enable managers and users to undertake risk assessments on levels of decontamination required.
- Assist in and undertake risk assessments as required by the Infection Prevention & Control Management Group.
- Conduct investigations into areas of special risk advising on safe practice.
- Audit practice and monitor standards in line with current legislation and guidance.

4.6 Manager Responsibilities

Managers/supervisors have responsibility to ensure that:

- All staff are notified of this policy and must have access to and understand the contents and local procedures derived from this policy.
- All relevant staff are trained on how to decontaminate equipment and reusable devices as well as manage single use devices appropriately.
- Staff are trained to recognise the symbol for single use and other packaging marks) and expiry dates on all products are checked before use.
- Single use devices are used in accordance with (MHRA) guidance– Single-use medical devices: implications and consequences of reuse (2013) and chosen according to risk over reusable.
- The manufacturer guidance and Trust Waste Policy are followed in the disposal of such devices.
- Failure or inappropriate use of a medical device is reported accordingly via the incident reporting mechanisms i.e. DATIX
- New equipment is not purchased until it has been risk assessed against this policy to ensure it can be adequately decontaminated.

4.7 Staff responsibilities

All staff are responsible for ensuring effective decontamination takes place and they are competent to carry out the appropriate process. Staff involved in any aspect of the decontamination process of reusable medical devices are responsible for adhering to this policy.
In addition, key persons and responsibilities as defined in detail in WHTM 01:01 Part A are in place as follows.

The Executive Lead is identified as the person with ultimate management responsibility for the operation of the premises and the decontamination process.

The Microbiologist is designated to be responsible on microbiological aspects of decontamination.

4.8 Distribution

The policy will be available via the Trust intranet site, Where the staff do not have access to the intranet their line manager must ensure that they have access to a copy of this policy.

5 DEFINITIONS

5.1 Please see Appendix 1.

6 IMPLEMENTATION/POLICY COMPLIANCE

6.1 Requirements for Effective Decontamination

To undertake decontamination effectively all the processes illustrated in the life-cycle (below) must be implemented correctly and consistently –with all appropriate controls and monitoring in place.

The reusable surgical instrument cycle

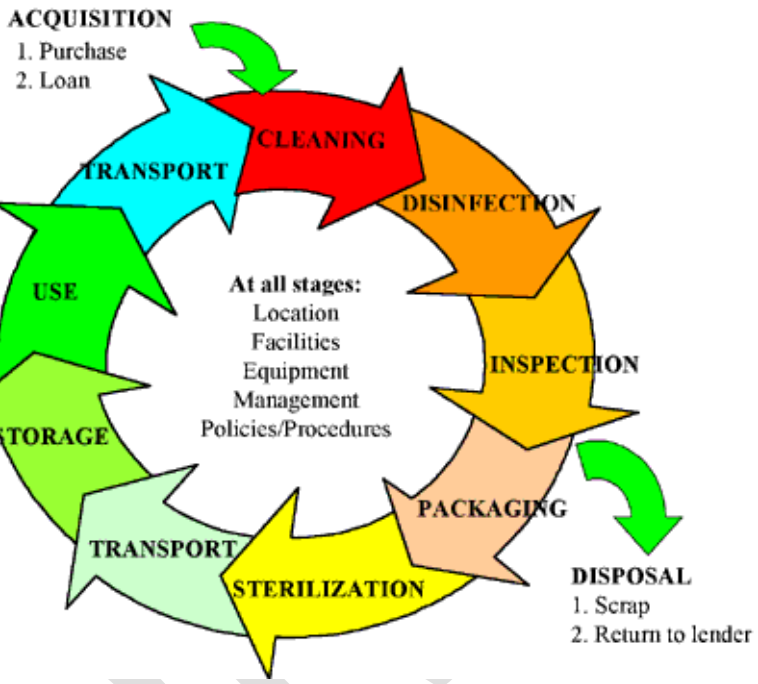


Fig 1.1

The essential requirements for good decontamination practice are:

- Management controls are in place
- Medical devices are used appropriately and are:.
    - fit for purpose;
    - in accordance with manufactures' instructions;
    - properly maintained, monitored and validated;
    - used by staff who are fully trained and competent;
    - conforming to standards and requirements;
    - track and trace systems link device usage to individual patients;
    - robust records are maintained throughout the process;
        - appropriate facilities are provided for the decontamination process
        - single use instruments are not re-used
        - decontamination is undertaken in a dedicated Sterile service Department accredited to the Medical Device Directive department wherever possible (WHTM 01:01 Part A)

Risk Assessment

The decontamination methods must be chosen according to the risk of infection associated with the use of a particular piece of equipment and according to the risk that inadequate

decontamination poses to patients and staff (Table 1).

	Application	Recommendation	Examples
HIGH	• Items in close contact with broken skin or broken mucous membrane • Items which penetrate the skin or are introduced into sterile body cavities • Invasive devices	• Use sterile single use devices where available • Thorough cleaning followed by: • Sterilisation in accredited SSU or high level disinfection using approved chemicals and processors	IV cannula Vaginal or rectal probes Flexible endoscopes e.g. bronchoscopes, nasoscopes Dental equipment Theatre instruments Implants/prostheses
MEDIUM	• Items in contact with intact mucous membranes • Items/ environment contaminated with particularly virulent or readily transmissible organisms • Items prior to use on immuno-compromised patients	• Thorough cleaning followed by disinfection and/or sterilisation or high level disinfection • Single use	Shared patient equipment (as below) after use on any known or suspected infected patient e.g. MRSA, *C. diff.*
LOW	• Items in contact with healthy intact skin • Items/environment not in contact with the patient/ donor	• Thorough cleaning with detergent solution or detergent /disinfectant impregnated wipes	Shared patient equipment e.g. BP cuffs, Tourniquets, Commodes, Stethoscopes, Beds, IV Pumps, Mattresses

Table 1 Risk Stratification for Decontamination of Medical Devices

Decontamination processes are referred to in Appendices.

6.2 Purchasing Medical Devices

Please refer to Quality and Safety Policy QS 24: Medical devices and Equipment Management Policy.

6.2.1 Storage

All devices following decontamination should be stored correctly in a designated area that is controlled and secure and inaccessible to the public.

Sterile packs

- Strict rotation of stock (first in, first out) to control inventory.
- Shelving should be easily cleaned and allow the free movement of air around the stored product.
- Products must be stored above floor level away from direct sunlight and water in a secure, dry and cool environment. Do not store clean or sterile supplies:
    - in corridors
    - on window sills
    - on the floor

- under sinks

Before being used the sterile product should be checked to ensure that:

- The packaging is intact and the product is still within expiry date.
- The sterilization indicator confirms the pack has been subjected to an appropriate sterilization process.

6.2.2 Decontamination of equipment prior to inspection, service or repair.

Anyone who inspects, services, repairs or transports medical, dental or laboratory equipment, either on hospital premises or elsewhere, has a right to expect that medical devices and other equipment have been appropriately decontaminated; appropriate documentation must be provided to indicate the decontamination status of the item (MHRA 2021)

6.2.3 Transportation of Contaminated/Sterile medical equipment.

Contaminated medical instruments are regarded as UN2814 Clinical Waste, on the basis they are being transported as healthcare waste for the purpose of recycling. Where contaminated instruments are to be transported outside of the healthcare premises onto a public highway, they must be handled collected and transported to their decontamination area in a way that avoids the risk of contamination to patients, staff and any area of the healthcare facility. Those responsible for such transportation must refer to the requirements of the Health and Safety at Work Act 1974 and The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 bring into UK law the alternative dispute resolution (ADR) 2015 regulations.

Medical Instruments subject to inspection, maintenance, repair or disposal, either on site or at the manufacturer's or agent's premises, should be decontaminated beforehand. Any loaned items being returned to a manufacturer or supplier should also be decontaminated (see Table.1). Devices intended for single-use only do not require decontamination, except where they are implicated in an adverse incident and may need to be sent to the manufacturer for investigation. In this situation, contact the manufacturer to find out the most appropriate method of decontamination.

If the manufacturer’s instructions appear inappropriate or incomplete, the organisation should report this to the MHRA as an adverse incident

Adverse incidents can be easily reported online through the Yellow Card scheme:
https://yellowcard.mhra.gov.uk/

Once decontamination has been completed, the items should be labelled accordingly and a declaration of contamination status form/label completed.

6.2.4 Decommissioning and disposal of devices

Please refer to QS 24: Medical devices and Equipment Management Policy.

6.2.5 Single Use / Single Patient Use Devices

Single-use medical devices

The expression single use on the packaging of medical devices means that the manufacturer:

- Intends the device to be used once and then discarded.
- Considers the device is not suitable for use on more than one occasion.
- Has evidence to confirm that reuse would be unsafe.

Single- use:

The above symbol is used on medical device packaging indicating '**DO NOT RE-USE'** and may replace any wording.

Single Patient Use Devices
Some devices are designated for **Single Patient Use.** This will be clearly stated on the packaging. These devices include such items as nebulisers, disposable pulse oximeter probes, and certain specified intermittent catheters.

Always follow the manufacturer's instructions regarding cleaning and disinfection between uses **on a named patient only. Never reprocess and use on another patient.**

6.3 Audit and Monitoring

Audits as per Annual Audit programme for Infection Prevention & Control.

6.4 Implementation

This policy will be implemented and maintained by the Infection Prevention and Control Team (IPCT).

Please refer to the responsibilities section for further information in relation to the responsibilities in connection with this policy.

7 GETTING HELP

7.1 Further information and support

Infection Prevention and Control Team: 02920196129.

8 RELATED POLICIES

This policy should be read in conjunction with:

- Welsh Health Technical Memorandum WHTM 01-01 Decontamination of Medical Devices within Acute Services Part A: Management & Environment (2016) http://www.nwssp.wales.nhs.uk/sitesplus/documents/1178/WHTM%2001-01%20Decontamination%20Part%20d%20protected%200119.pdf

- Welsh Health Circular (2016) Decontamination of medical devices: A development plan for healthcare organisations https://gov.wales/sites/default/files/publications/2019-07/decontamination-of-medical-devices-a-development-plan-for-healthcare-organisations.pdf

- Managing Medical Devices (2021) Guidance for healthcare and social services organisations. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf

- National standards for cleaning in Wales – ADDENDUM

Key Standards for Environmental Cleanliness Revision 2.0 – December 2021

https://phw.nhs.wales/topics/latest-information-on-novel-coronavirus-covid-19/information-for-health-and-social-care/addendum-key-standards-for-environmental-cleanliness/
ttps://phw.nhs.wales/topics/latest-information-on-novel-coronavirus-covid-19/information-for-health-and-social-care/sup-029/

- Medical Devices and Equipment Management Policy (QS 242021) https://phw.nhs.wales/about-us/policies-and-procedures/policies-and-procedures-documents/clinical-governance-and-infection-control-policies/medical-devices-and-equipment-management-policy/

- QS33 Control of Substances Hazardous to Health (COSHH) Policy https://www.hse.gov.uk/cleaning/topics/coshh.htm

9 INFORMATION, INSTRUCTION AND TRAINING

9.1 Training

Whilst there are no formal training programmes in place to ensure implementation of this policy, each Executive Director, Divisional Director, Clinical Director, Divisional General Manager, Divisional Nurse, Departmental Manager, Head of Nursing and Head of Departments must ensure that managers and all staff, clinical and non-clinical, are made aware of the policy provisions and that they are adhered to at all times.

10 MAIN RELEVANT LEGISLATION

Legislation considered in the development of this policy includes:

- WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part A: Management and Environment (2018)
- WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part B: Common Elements (2018)
- WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part C: Steam Sterilisation and Steam for Sterilisation (2018)
- WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part D: Washer Disinfectors (2018)
- WHTM 01-01 Decontamination of Medical Devices Within Acute Services Part E: Alternatives to Steam for the Sterilisation of Reusable Medical Devices (2018)
- WHTM 01-06 Parts A-D Decontamination of Flexible Endoscopes (2018)
- Health Building Note (HBN) 13: Sterile Services Department, NHS Estates, Department of Health (2021).
- Medical Device Regulation (EU) 2017/745
- Provision and Use of Work Equipment Regulations (PUWER), 1998
- Managing Medical Devices, Guidance for healthcare and social services organisations, MHRA, January 2021.

Appendix 1 - Definition in Terms

Medical Device	Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability — investigation, replacement or modification of the anatomy or of a physiological or pathological process or state — providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means The following products shall also be deemed to be medical devices: — devices for the control or support of conception — products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point
Cleaning	A process that physically removes contaminants but does not necessarily destroy micro-organisms**.** The reduction in microbial contamination will depend upon many factors including the efficiency of the cleaning process and the initial level of contamination.
Disinfection	A process following cleaning that is used to reduce viable micro-organisms but not necessarily inactivate some bacterial agents, such as viruses and bacterial spores. Once disinfected, equipment should be stored in a clean environment to prevent recontamination.
High-Level Disinfection	A process following cleaning that is used to significantly reduce the number of viable micro-organisms including viruses and bacterial spores using designated chemicals in a validated reprocessing machine e.g. washer disinfector.
Sterilization	A process following cleaning and disinfection used to render an object free from all viable micro-organisms including viruses and spores but not necessarily prion proteins. Sterilization can be achieved using steam or gas.
Single Use	Items labelled "single-use" or "not for reuse" or with the international single use sign that must not be reused or reprocessed in any way (QS 24).
Single Patient Use	A medical device labelled as 'single patient use' that may be use for more than one episode on **one patient/donor only** which can undergo some sort of reprocessing as specified by the manufacturer guidance e.g. nebuliser.
Reusable or Multi Use	May be used more than once for different patients/ donors subject to proper decontamination. This may include care equipment that is shared e.g. BP cuffs, stethoscopes, beds, infusion pumps etc., or surgical instruments, endoscopes that require a higher level of decontamination.

Appendix 2 – Decontamination Methods (Velindre Cancer Centre)

Operator Protection

Staff should be instructed on how to handle disinfectants carefully and advised what protective clothing is required. Reference should always be made to the COSHH risk assessment for each product and COSHH advisor for further advice. Disinfectants should never be mixed with other products and always be used in the correct dilution: higher or lower concentrations are wasteful and potentially harmful.

Expiry dates
Certain disinfectants will bear expiry dates and they should not be used after that date. Where chemicals need to be diluted or mixed always use freshly prepared solutions that are dated and labelled accordingly with strength and do not store for longer than advised (usually 24 hours but refer to manufacture guidance).

Note: Welsh Blood Service methods are written into operational procedures

1. Cleaning
Please refer to Cleaning Standards Manual for specific details on cleaning products for clinical and non-clinical areas.
Cleaning removes organic material and many, but not all, microorganisms.

1.1 General purpose detergent and water or detergent wipes
This is the preferred method of decontamination for the vast majority of items such as furniture, fittings and general equipment e.g. mattresses, bed frames, washing bowls etc.

1.2 General principles:
- Where possible immerse the item in a designated bowl or sink of warm water and detergent. If immersion is not possible surface clean with detergent wipes.
- If using detergent wipes, use a sufficient number to prevent drying out.
- Do not use wash-hand basins in ward areas for cleaning equipment. Use a designated sink or bowl.
- Dry thoroughly.
- Store items dry.
- When cleaning equipment check for signs of damage e.g. covers on mattresses, pillows, cushions. If there are signs of damage report this to the department manager who can initiate replacement or repair.

1.3 Cleaning of Surgical Instruments before Sterilization
Effective cleaning to remove all organic material is an essential pre-requisite for sterilization or high level disinfection. **Automated cleaning** in a washer disinfector is the **preferred option** however; some instruments cannot be processed in a washer disinfector or may need manual cleaning prior to processing in a washer disinfector.

To minimise the contamination risk to personnel, splashing and the creation of aerosols must be avoided at all times.

- Always wear appropriate protective clothing when cleaning contaminated equipment e.g. gloves, apron and eye protection
- Fill the clean sink or container (not hand wash basin) with the appropriate amount of water and enzymatic detergent or other appropriate detergent to achieve a working solution (refer to manufacturer's instructions)
- Dismantle or open instrument
- With the exception of power tools*, fully immerse the instrument in the solution for a minimum of 2 minutes
- Drain any excess detergent prior to rinsing with clean water
- Drain the item before drying with a clean non- linting clean cloth
- Visually check to ensure organic material has been removed
- Complete any relevant documentation
- If cleaning solution or rinse water is obviously soiled or contaminated, replace immediately

* Power tools must not be immersed but should be surface cleaned only using a non- linting cloth impregnated with an enzymatic detergent solution. This should be followed by a non- linting cloth dampened with clean water and then dried using a dry non -linting cloth. Alcohol impregnated wipes can be used following the manual cleaning procedure.

2. Disinfection

Disinfection reduces the number of micro-organisms to a safe level for a defined procedure but does not kill bacterial spores and does not necessarily inactivate all viruses.
The following disinfection methods and products are used locally. The use of alternative methods/products must be approved by the Infection Control Team prior to introduction.

2.1 Heat Methods

2.1.1 Washer/Disinfectors

Washer disinfectors can be used to clean and disinfect equipment, such as bed pans, that can withstand wet heat.

2.1.2 Steam cleaners

Steam cleaners can be used to clean and disinfect fabric that cannot be laundered and surfaces that require surface disinfection. To achieve this a steam cleaner with a continuous vacuum extraction facility must be used.

The steam cleaner produces dry steam at temperatures exceeding 130ºC. The water is turned into high temperature microfine vapour, the microscopic water particles penetrate the surface of the item being decontaminated and are subsequently removed by continuous vacuum extraction. The contaminated water then goes into a separate dirty water tank.

2.2 Chemical Methods

Chemical disinfectants are often irritant when allowed contact with skin and mucous membranes or when inhaled as vapor. They can also be corrosive and flammable. A risk assessment, under the Control of Substances Hazardous to Health (COSHH) Regulations, must be undertaken before chemical disinfectants can be introduced.

There is a potential fire hazard associated with all chemical disinfectant products. It is advisable that these products are stored in appropriate sealed containers/cupboards.

Chemical disinfectants may also be damaging to equipment. It is vital, therefore, that equipment manufacturers instructions are reviewed to ascertain compatibility. This should be clarified prior to purchase of new equipment and a decontamination procedure written by the users and approved by the Infection Prevention & Control Team.

2.2.1 Low level chemical disinfection

Alcohol

- Usually in the form of ethyl or isopropyl alcohol this is most active at a concentration of 60 – 90%. It has good bactericidal and fungicidal activity but whilst ethyl alcohol is effective against most viruses, isopropyl alcohol is not.
- Alcohol is available as a bottled solution or, more commonly, as wipes, in tubs or individually wrapped sachets e.g. Cliniwipes, Sanicloth 70.
- Alcohol is useful for surface disinfection of instruments such as power tools, prior to sterilization.
- Alcohol does not penetrate well into organic matter and must only be used on visibly clean surfaces. If an item is obviously contaminated with organic matter it must be cleaned before disinfection.

Chlorine releasing agents

- This includes sodium hypochlorite and di-isochlorocyanurate (NaDcc).
- Wide range of bactericidal, virucidal and fungicidal activity.
- Corrosive to some metals
- A chlorine-based disinfectant solution at a dilution of 10,000 parts per million (ppm) should be used for the disinfection of any equipment contaminated with blood or blood stained body fluids.

- A chlorine-based disinfectant solution at a dilution of 1,000 ppm should be used for the disinfection of equipment that has been in contact with an infected service user, non-intact skin, body fluids (not blood stained) or mucous membranes.

Chlorine dioxide
This is sporicidal disinfectant that can be used in a wipe system i.e. Tristel Trio, for cleaning and disinfecting non lumened flexible endoscopes e.g. nasoendoscopes.

2.3 High level disinfection
This process must be preceded by thorough cleaning.

2.3.1 Vaporised Hydrogen peroxide for disinfection of the environment
Vaporised hydrogen peroxide may be used to achieve high level disinfection of the environment following outbreaks of infection such as Clostridioides *difficile* and Norovirus. It will only be used with the agreement of the IPCT and operated by housekeepers/domestic assistant who have received training to operate the vaporiser. The area to be treated must be free of people when the vaporiser is in use.

2.3.2 Ultraviolet (UV) Light Systems for disinfection of the environment
Ultraviolet light systems aid in reducing environmental contamination after terminal cleaning and disinfection and can be used following outbreaks of infection such as *Clostridioidesdifficile* and Norovirus. It will be used with the agreement of the IPCT and operated by housekeepers/ domestic assistants and nursing staff who have received training to operate the system.

2.3.3 Heat labile endoscope disinfection
There are no flexible endoscopes at VCC.

3. Sterilization
Sterilization is the complete removal or destruction of all viable microorganisms including viruses and bacterial spores. All reusable medical devices used in acute healthcare settings requiring sterilization will be reprocessed in a Medical Device Directive (MDD) accredited facility.

Autoclaving for VCC will be carried out in the Sterile Services Unit at Llandough Hospital as part of the Service Level Agreement.

4. Tracking and Traceability of Surgical Instruments
It is important to be able to trace products through the decontamination processes and also to the patient on whom they have been used. The ability to track and trace surgical instruments and equipment enables corrective action to be taken when necessary. For example in the unlikely event of a sterilisation cycle failure products can then be recalled.

Records should be maintained for all the sets cleaned and sterilised identifying:
- The cleaning and sterilisation method used.
- The name of the person undertaking the decontamination.
- Details of the item being processed.
- Records should be maintained for a minimum of eleven years.

5. Transportation of contaminated surgical instruments and associated equipment

All contaminated reusable medical devices must be handled collected and transported to their decontamination area in a way that avoids the risk of contamination to patients, staff and any area of the healthcare facility. All contaminated surgical instruments present a risk of infection.
To minimise this risk:

- The instruments must be placed in closed, secure containers and transported to the decontamination area as soon as possible following use.
- Contaminated medical devices and equipment are kept separate from clean during transportation; this is achieve by using separate containers to provide physical barriers between clean and dirty items.
- Personnel are trained to handle collect and transport contaminated medical devices/equipment and should wear protective clothing as appropriate.
- Contaminated and clean/sterile instruments must be segregated during transportation. (Records should be kept of vehicles and containers used).
- Transport containers must protect both the product during transit and the handler from inadvertent contamination and therefore must be:
    - Leak-proof
    - Easy to decontaminate
    - Rigid
    - Capable of being closed securely
    - Lockable where appropriate, to prevent tampering
    - Clearly labelled to identify the user and the contents
    - Robust.
    - Labelled

Appendix 3 - Spills of blood and body fluids (Velindre Cancer Centre)

Note: Welsh Blood Service methods are written into their organisational standard operational procedures

Spills of blood or body fluids must be removed immediately. The removal of blood and bodily fluid spills is the responsibility of the clinical staff in that department, not the cleaning staff. Domestic supervisors are responsible for spillage in non-clinical areas within the building. Estates staff are responsible for the grounds of the hospital. However, some common sense and flexibility must be adopted with the priority being to remove the spill as soon as possible.

Do not use your hands if a spillage contains broken glass or sharps use a brush and pan for example and discard into an appropriate sharps container.

Sodium hypochlorite should be used to disinfect equipment or surfaces contaminated by blood or body fluids.

When a spillage occurs, if practical, close off the immediate area.

WEAR APPROPRIATE PROTECTIVE CLOTHING. (Standard Infection Control Precautions (SIPCs) Policy PC 05 National Infection Prevention and Control Manual)
Note: Welsh Blood Service methods are written into operational procedures

Spills of blood
Make up a solution of Sodium Hypochlorite 10,000ppm - pour on to spillage, leave for 5 mins before mopping up with disposable paper towel then cleaning with detergent and water

Sodium Dichloroisocyanurate (NaDCC) Granules
These granules are stocked in Velindre Pharmacy and can be used to soak up larger spillages of body fluids. Use protective clothing and follow directions on containers.

Do not use on urine spillages for these soak up urine in paper towels discard into clinical waste and clean the area with Sodium Hypochlorite 1000ppm or Chlor clean Tablets diluted to 1000 ppm. Wear appropriate protective equipment.

Spillage Kits
Spillage Kits are available in some divisions; the instruction on the kits should be followed.

Spills of body fluids not visibly contaminated with blood

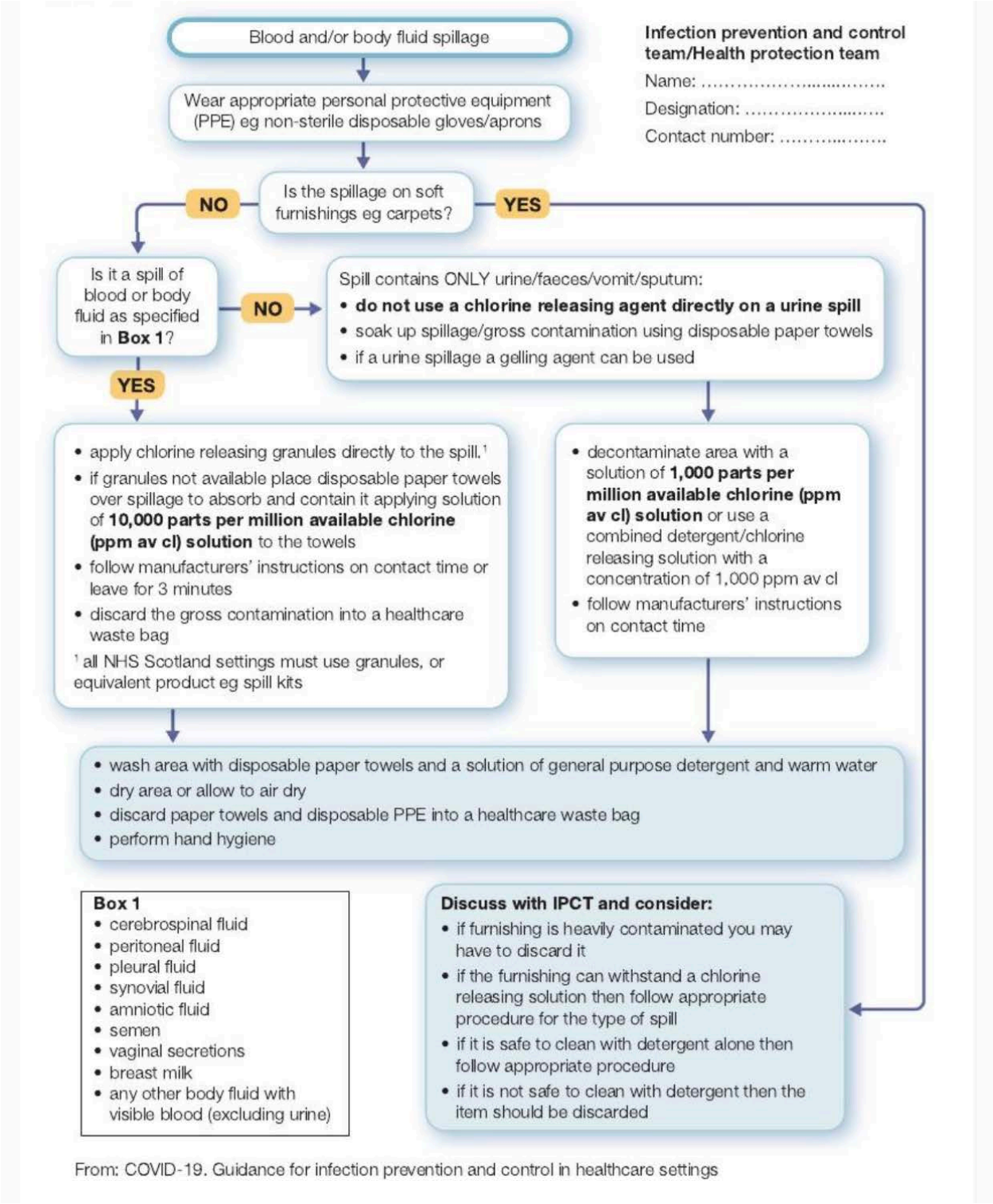
- These include spills of faeces, vomit, urine and sputum.
- Soak up the spill as thoroughly as possible with paper towels.
  Discard the paper towels and any other waste from the spillage into a clinical waste bag.
- Clean and disinfect the area.
- Discard personal protective equipment into the clinical waste bag.

Divisions should follow their Standard Operating Procedures.

Appendix 4. Best Practice: Management of Blood and Body fluid spillages

Part of the updated 4 Nations Guidance on infection prevention and control for seasonal respiratory infections including SARS-CoV-2.

Available at:

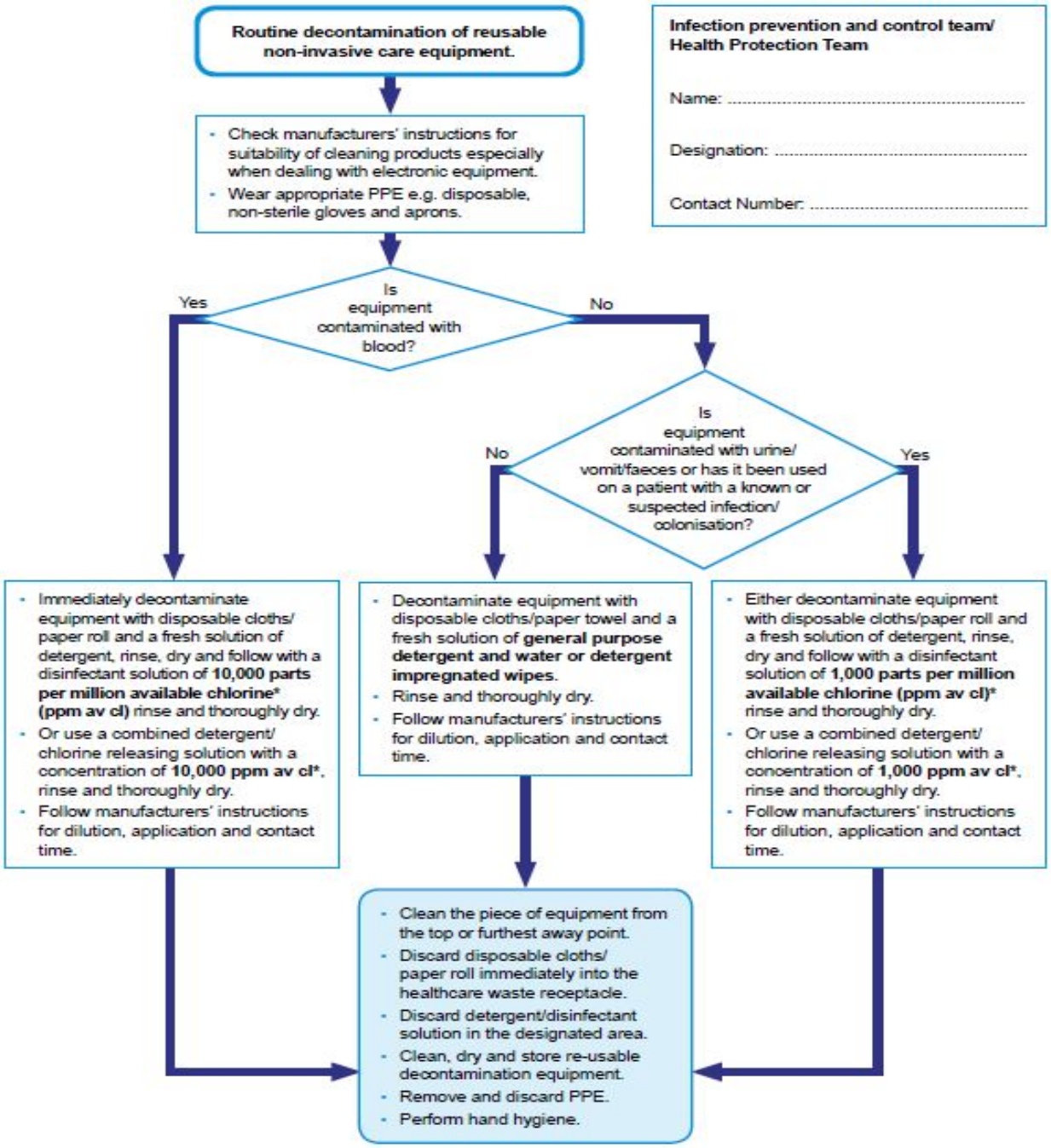


From: COVID-19. Guidance for infection prevention and control in healthcare settings

Appendix 5 - Decontamination of reusable non-invasive equipment

Part of the National Infection Prevention and Control Manual (NIPCM)

Available at: http://www.nipcm.hps.scot.nhs.uk/



Ymddiriedolaeth GIG Prifysgol Felindre
Velindre University NHS Trust

Ref: IPC 01

VIRAL GASTRO-ENTERITIS (INCLUDING NOROVIRUS)

Executive Sponsor & Function	Executive Director of Nursing, AHPs and Health Sciences
Document Author:	Infection Prevention & Control Team
Approved by:	Trust Executive Management Board Quality, Safety & Performance Committee
Approval Date:	TBC
Date of Equality Impact Assessment:	31st August 2021
Equality Impact Assessment Outcome:	*This policy has been screened for relevance to equality. No potential negative impact has been identified.*
Review Date:	3 Years after approval date
Version:	5

CONTENTS

ABBREVIATIONS

IPCT	Infection Prevention and Control Team
IPC	Infection Prevention and Control
PPE	Personal Protective Equipment
UHW	University Hospital of Wales, Cardiff

1 POLICY STATEMENT

1.1 This policy describes the infection control best practice for management of sporadic cases and outbreaks of patients and staff with confirmed or suspected viral gastroenteritis.
All staff working must be aware of the contents of the policy and;

- Appropriately assess patients with suspected viral gastroenteritis
- In line with this policy commence correct infection prevention & control precautions, implement appropriate management and follow effective lines of communication.

Managing outbreaks of gastroenteritis is a common event within any healthcare setting especially during the winter months. An outbreak can be defined as two or more cases associated in time and place, therefore the early detection and appropriate management of episodes is therefore essential to minimise service disruption.

Norovirus is highly transmissible, requiring ingestion of as few as 10-100 viral particles to cause illness. The incubation period is usually 24-48 hours although as little as 12 hours has been reported. The period of infectivity of norovirus is considered to be from the onset of symptoms until 48 hours after the last symptom e.g. diarrhoea, vomiting and abdominal pain although infectivity may precede clinical illness and viral shedding may be prolonged in immunocompromised patients.

Norovirus is the most common cause of outbreaks of gastroenteritis in hospitals and outbreaks can often lead to ward area closure and cause major disruption in service activity. Norovirus can be airborne and can also be spread through direct and indirect contact. Viruses may also be introduced into the service environment via any of these routes.
Symptoms typically consist of nausea, diarrhoea and/or vomiting, but may also include headache or abdominal pain. The condition is self–limiting with symptoms usually lasting between one to three days.

2 SCOPE OF POLICY

2.1 This policy applies Velindre Cancer centre however it is relevant to all Trust staff (including contracted, volunteers and community) and service users.

3 AIMS AND OBJECTIVES

3.1 The purpose of this policy is to provide the required information for staff across the Trust to promptly recognise and take appropriate actions when a patient or staff member is suspected of having gastroenteritis through;

- Ensuring prompt identification of possible cases
- Ensuring required Infection Prevention and Control measures are in place to prevent transmission
- Management of cases in line with national guidance
- Ensuring each patient with viral gastroenteritis is cared for effectively and appropriately in line with national guidance
- Prompt and effective measures are essential in controlling the spread of infection between patients, staff and visitors
- Detect outbreaks quickly and initiate outbreak measures promptly.
- Effective management of possible viral gastroenteritis among staff groups.
- Prevention of outbreaks

4 RESPONSIBILITIES

The Infection Prevention & Control Management Group is responsible for the ongoing updating of this policy as national guidance changes.

Trust Roles and Responsibilities

The overall responsibility for the implementation and promotion of the policy lies with the Chief Executive who will ensure there are effective arrangements for infection prevention and control within the Trust. The Trust Executive Management Board is collectively responsible for minimising the risks of infection to patients, HCW's members and the public. The Executive director for Director of Nursing, AHP's & Health Science is board lead for the IPC organisational structure for the service.

Manager Responsibilities

Managers/supervisors have responsibility to ensure that:

- Staff have access to this policy
- Local risk assessments are carried out where necessary, e.g. to identify the use of appropriate personal protective equipment (PPE), to ensure adherence to safe practices, including the provision of resources and that any incidents that occur are reviewed and subsequent actions taken where appropriate
- Work in partnership with Infection prevention and Control colleagues
- Undertake appropriate actions in response to cases/outbreaks
- Ensuring staff members have compliance with Infection prevention and control training
- Have access to equipment required to manage cases of gastroenteritis
- Ensure that staff are appropriately skilled and trained in line with the requirements of this policy
- Provide support and guidance to staff members reporting possible gastroenteritis symptoms
- Follow workforce and infection prevention and control policies and procedures
- Enforce medical exclusion requirements of staff members

Staff responsibilities

Staff have responsibility to ensure that they:

- Maintain skill and knowledge to be able to manage cases of gastroenteritis in line with this policy
- Undertake required IPC training appropriate to role
- Do not attend work if symptomatic
- Report any signs of gastro enteritis to their line manager as soon as practically possible
- Provide samples, if required, as advised by Occupational Health Departments and the Infection Prevention and Control Team
- Follow Medical Exclusion requirements

Medical exclusion following infectious/notifiable disease (as per WF 08 Sickness Absence Policy)

- Where the absence is the result of diarrhoea and vomiting or other relevant notifiable infectious disease and whilst the employee is suffering from the effects of the disease, the absence will be recorded as a period of sickness in the usual way.
- The manager must obtain information regarding the nature of the illness and obtain advice, if necessary, from the Infection Control or Occupational Health Department as to whether a period of further exclusion is required after the symptoms have subsided and sick leave has ended.
- Where the advice requires the employee, for purposes of infection control to remain off work, this subsequent period will be regarded as a medical exclusion with pay, and not be recorded as sick leave, e.g. 48 hour period following last reported symptoms.

Distribution

The policy will be available via the Trust intranet site, Where the staff do not have access to the intranet their line manager must ensure that they have access to a copy of this policy.

5. CLINCIAL FEATURES

There is an incubation period of 12-48 hours and the symptoms may last 24-72 hours on average. Symptomatic individuals are infectious for up to 48 hours after the last episode of diarrhoea and/or vomiting and abdominal pain. Other symptoms may include abdominal pain and/or nausea, headaches, muscle aches and fever. Recovery usually takes place within 72 hours of onset of symptoms

Outbreak control measures – key points

Routes of Transmission:

- Airborne – inhalation or ingestion of virus particles when a patient vomits.
- Contact via contaminated hands.
- Person to person via faecal-oral route.
- Ingestion of contaminated food and drink usual prepared by an individual with SRSV illness.
- Environmental contamination of viral particles due to patients shedding.

Patient Management

- A patient with symptoms of suspected gastroenteritis should be isolated in a single room (preferably en-suite) with appropriate infection control measures until at least 48hours symptom free. Refer to Policy IPC 02 SICPs & TICPs.
- In an outbreak situation the numbers of affected individuals may be high, therefore if a case is suspected, it is essential to implement appropriate infection control measures immediately to prevent the spread of infection.
- During the outbreak you must regard all patients, staff and visitors who present with symptoms as infectious.

In patient departments
Single Cases

- **Isolate patients as soon as they become symptomatic.**
- All patients admitted with or who develop diarrhoea and/or vomiting, should be nursed in a single room and remain isolated until asymptomatic for 48 hours
- Inform a member of the IPCT as soon as possible.
- Inform housekeeping services to possible infection to ensure correct cleaning measures
- Reduce footfall to the room and review and visiting to the patient
- Keep doors to cubicle closed and where possible open windows to promote ventilation
- During office hours, contact IPCT or out of hours contact the on-call Consultant Microbiologist at UHW (via switchboard), who will carry out a risk assessment and advise the ward of further infection control measures to be implemented.
- Strict Transmission based precautions should be adhered to including the use of personal protective equipment and hand washing with soap and water as per WHO 5 moments (Appendix 1).
- Facemasks may be considered if there is a risk of droplets or aerosol contamination – following discussion with the infection prevention and control team.

5.1 Outbreak

- If a department has two cases connected to place or time then a meeting will be called of the outbreak team:
  - Microbiologist
  - Department manager
  - General manager of site
  - Infection prevention and control team
  - Operational services manager/supervisor
  - Medical representation
  - Senior nurse/bed manager
- Where the numbers of symptomatic patients exceeds the number of single rooms, the IPCT will provide advice as cohorting patients may be required – IPCT to advise
- In some cases, bays or the entire ward will need to be closed to new admissions. This will only occur after consultation with the Infection Control Doctor and discussion with other relevant personnel.
- Close affected bay(s) to admissions and transfers.
- Keep doors to single room(s) and bay(s) closed.
- Place signage at ward entrance informing all visitors of the closed status and restricting visits to essential staff.
- Daily assessment will take place to ascertain earliest date for terminal clean and reopening.
- Seek advice from IPCT if a patient needs to leave the ward for investigations in other departments. A patient's treatment should not be compromised whilst the ward is closed, but risk assessments need to take place to reduce the risk of cross infection.
- Communication with the receiving department is essential. The IPCT can be consulted to give advice to minimise the risk of spread of infection.
- Unless unavoidable where ever possible allocate staff to duties in either affected or non-affected areas of the ward.
- Visiting staff such as Physiotherapists, Occupational Therapists and Phlebotomists should if possible, visit the affected ward(s) last or allocated an individual to visit affected wards. Only essential procedures should be carried out on symptomatic patients.
- Ensure all staff receive effective communication of the outbreak situation and how viral gastroenteritis is transmitted.

Staff Cases Across the organisation

- Staff with symptoms of possible gastroenteritis should inform their line. Affected staff should be immediately excluded from work until 48 hours symptom free.

Patient and Visitors Information

- Provide all affected patients with information on the outbreak and control measures they should adopt – available from IPCT.
- Patients'/visitors information leaflets are available from the Infection Prevention and Control Team. Copies of these will be issued to ward staff which is then the responsibility of the nurse in charge to make sure these are distributed to patients and visitors.
- Visitors may contribute to an outbreak of viral gastroenteritis and should be advised to refrain from visiting if they are symptomatic or have not been free of symptoms for 48 hours.
- Elderly visitors, immuno-compromised individuals and young children may be more susceptible to infection and should be advised to refrain from visiting during the outbreak.
- Visitors should be instructed to decontaminate their hands prior to, and after visiting their relative/friend using the ward facilities.
- Visitors should not sit on beds or use patient only toilets.

- An IPC Nurse will visit the ward daily as a minimum in order to review and reassess the situation. Out of hours the ward will be reviewed by telephone by the on call Consultant Microbiologist who can be contacted via switchboard.
- Do not accept admissions while the ward is closed unless approved by the IPCT or medical director.
- A patient's treatment must not be compromised whilst the ward is closed, but risk assessments must take place to reduce the risk of cross infection. Communication with the receiving department is essential. The IPCT can be consulted to give advice to minimise the risk of spread of infection.
- During the working shift, where possible do not transfer staff to other wards if they are working on an affected ward. Agency staff must not work on other wards once exposed to an outbreak ward situation.
- Leaflets are available for patients with Norovirus from the IPCT. The leaflets give details of the action that is being taken and why. (https://phw.nhs.wales/services-and-teams/harp/infection-prevention-and-control/infections1/norovirus-information-leaflet/)
- Information on other types of gastro-enteritis can be obtained from the Public Health Wales site: http://howis.wales.nhs.uk/sitesplus/888/page/34204

When is the patient/ward clear of infection?

- Patients are usually but not always deemed non-infectious 48 hours after their last episode of diarrhoea or vomiting. In the elderly or immunocompromised patient they may continue to excrete the virus for a longer duration.
- Further stool specimens are not required once a confirmed positive sample has been detected or to check if an agent has cleared.
- Usually the ward can be opened when the last patient with symptoms has had no diarrhoea or vomiting for 48 hours. A thorough terminal clean of the ward (environment and equipment) must take place prior to beds being re-opened.
- Following each outbreak a multidisciplinary evaluation should take place to review the outbreak and learn lessons in order to strengthen future plans.

What happens if symptoms recur?

- Contact a member of the IPCT immediately for a further risk assessment.

Patients Discharge

Patients discharge to their own home

This can take place as long as they are medically fit for discharge and do not require nursing or social care at home. **Please note:** if a patient is being 'fast tracked' home for palliative care contact the Infection Control Team for advice.

Patients discharge to another hospital

- It is not necessary to delay the discharge of symptomatic patients or those who may be incubating gastroenteritis.
- Advise them to inform the admitting Doctor/ Nurse if they are readmitted within 48 hours of discharge.
- Patients from closed wards should be discharged directly from the ward.

Patients discharge to nursing or residential homes

- Discharge to a home known not to be affected by an outbreak of diarrhoea and or vomiting should not occur until the patient has been asymptomatic for more than 48 hours.
- However, discharge to a home known to be affected by an outbreak at the time of discharge should not be delayed providing the home can safely meet the individual's care needs.

- Those who have been exposed but asymptomatic patients may be discharged only on the advice of the IPCT.

6 Clinical Settings Infection Prevention and Control Measures

Hand Hygiene

- Hand hygiene is essential in the prevention of cross infection and hand decontamination is compulsory before and after contact with all patients and their immediate environment.
- Patient hand washing should not be forgotten. All patients should be reminded about good hand washing practices and non-ambulant patients must be offered means of decontaminating their hands before eating and after using bedpans/commodes, for example.
- Handwashing with soap and water is recommended over alcohol gel in the presence of diarrhoea.

Personal Protective Equipment (PPE)

- Personal protective equipment must be used when handling faeces and/or vomit, other body fluids and for direct patient contact.
- Disposable aprons and gloves must be removed before leaving the patients room and disposed of as clinical waste.
- Hands should be decontaminated immediately using soap and water.

Environment

- It is essential that environmental cleaning is performed to a high standard and cleanliness is maintained. The operational services department should be notified at the earliest point when an outbreak occurs (Appendix 2).
- Supervisors & Housekeeping staff responsible for undertaking the cleaning must liaise with the ward manager & the infection control team.
- Cleaning procedures should be increased to reduce the accumulation of bacteria in the environment. Special attention must be paid to toilet and bathroom areas, commodes, all horizontal surfaces and frequent touch surfaces such as door handles, flush handles, sinks, taps and nurse call systems.
- Remove exposed foods e.g. fresh fruit in bowls on lockers.
- Staff should not consume food or drink at the nurses' station during an outbreak of viral gastroenteritis. Any exposed food and drink is likely to have been contaminated.

Equipment

- Use single-patient use equipment wherever possible
- Decontaminate equipment immediately after use i.e. commodes
- Red Clinell sporicidal wipes should be used to decontaminate commodes
- Consider use of UVC to decontaminate high use equipment after manual cleaning
- Dispose of soiled bedpans/vomit bowls immediately

Linen

- While clinical area is closed, discard all linen in a water soluble (alginate) bag and then a secondary bag.
- Leave empty beds unmade

Spillages

- Diarrhoea/vomit must be covered immediately, removed and the area decontaminated.
- Decontamination of all vomit or faecal spillage is vital to ensure viral particles are destroyed.
- See appendix 2 for instruction on cleaning solutions.

7. Audit and monitoring

- The IPC Annual Programme of work contains audit programme which incorporates audits of clinical practices to ensure compliance with standard precautions use of PPE, hand hygiene etc.
- In cases of outbreak the outbreak meeting will require results from daily audit of use of PPE, recent environmental cleaning audit, hand hygiene.

8. Implementation

- This policy will be implemented and maintained by the Infection Prevention and Control Team (IPCT).

9. References

National Infection Control Policies

- http://howis.wales.nhs.uk/sites3/page.cfm?orgid=379&pid=30427
- Guidelines for the management of norovirus outbreaks in acute and community health and social care settings: Produced by the Norovirus Working Party: an equal partnership of professional organisations. Published March 2010
- Preparedness, control measures & practical considerations for optimal patient safety and service continuation in hospitals. HPS Norovirus Outbreak Guidance Published 2013

10. Getting Help

a. **Further information and support**

Infection Prevention and Control Team: 02920196129.

11. Related Policies

This policy should be read in conjunction with:

- IPC 02 Policy for Standard Infection Control and Transmission Based Precautions (including isolation of patients)
- IPC 03 Policy for Care of patients with diarrhoea (chemo-induced and Clostridium difficile)
- Workforce 08 Sickness Absence Policy
- IPC 05 - National Infection Prevention and Control Manual

12. INFORMATION, INSTRUCTION AND TRAINING

Training

- Training about the reporting of staff sickness should be carried out as part of induction training.
- An element of Standard infection control precautions should be included in induction training.
- Full training in Standard Infection Control Precautions & Transmission Based Precautions is carried out during all levels of infection prevention and control training.

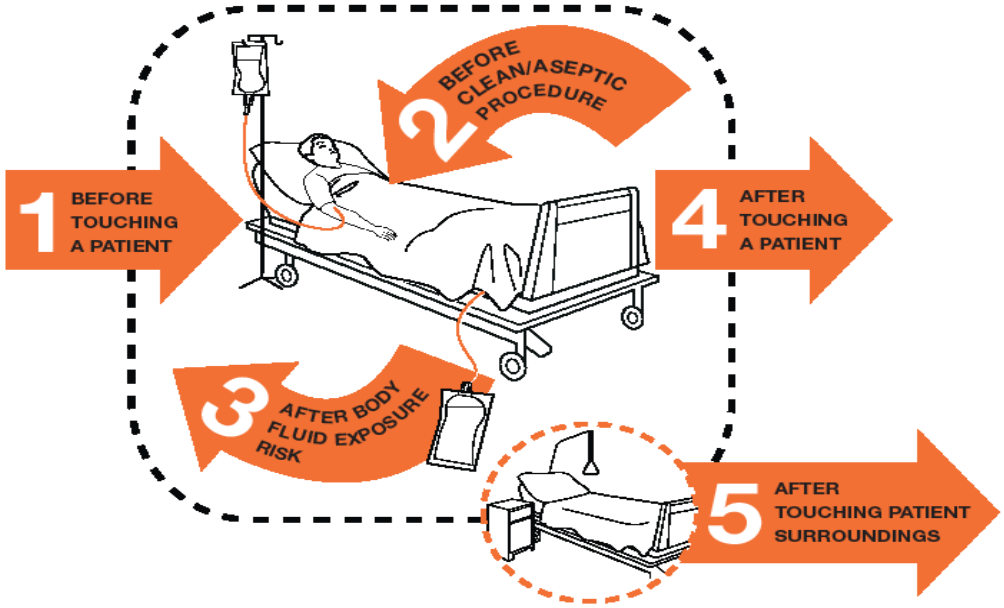
13. MAIN RELEVANT LEGISLATION/GUIDANCE

Legislation considered in the development of this policy includes:

- Health and safety at Work Act (1974)
- The Management of Health and Safety at work Regulations (1999)
- Control of Substances Hazardous to Health (COSHH) Regulations (2002) (as amended 2003 & 2004)
- Management of Health and safety at Work regulations (1999)
- Personal Protective Equipment (PPE) at Work Regulations 1992 (as amended 2002)
- Healthcare Standards for Wales (2015)
- NICE Guidelines for the Management of Gastroenteritis (Adults) 2020 - https://cks.nice.org.uk/topics/gastroenteritis/management/adult-gastroenteritis/
- Guidance for the Management of Gastrointestinal infections 2019 - (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/861382/management_of_gastrointestinal_infections.pdf)

Appendix 1 – Five Moments of Hand Hygiene

Your 5 Moments for Hand Hygiene



1	BEFORE TOUCHING A PATIENT	WHEN?	Clean your hands before touching a patient when approaching him/her.
		WHY?	To protect the patient against harmful germs carried on your hands.
2	BEFORE CLEAN/ ASEPTIC PROCEDURE	WHEN?	Clean your hands immediately before performing a clean/aseptic procedure.
		WHY?	To protect the patient against harmful germs, including the patient's own, from entering his/her body.
3	AFTER BODY FLUID EXPOSURE RISK	WHEN?	Clean your hands immediately after an exposure risk to body fluids (and after glove removal).
		WHY?	To protect yourself and the health-care environment from harmful patient germs.
4	AFTER TOUCHING A PATIENT	WHEN?	Clean your hands after touching a patient and her/his immediate surroundings, when leaving the patient's side.
		WHY?	To protect yourself and the health-care environment from harmful patient germs.
5	AFTER TOUCHING PATIENT SURROUNDINGS	WHEN?	Clean your hands after touching any object or furniture in the patient's immediate surroundings, when leaving – even if the patient has not been touched.
		WHY?	To protect yourself and the health-care environment from harmful patient germs.

World Health Organization | Patient Safety — A World Alliance for Safer Health Care | SAVE LIVES Clean Your Hands

WHO acknowledges the Hôpitaux Universitaires de Genève (HUG), in particular the members of the Infection Control Programme, for their active participation in developing this material.

May 2009

Appendix 2 – Environmental Cleaning Recommendations during an Outbreak

Environmental decontamination during an outbreak

• Increase frequency of cleaning using dedicated domestic staff where possible and avoiding transfer of domestic staff to other areas, as directed by the Infection control team.

• Clean from unaffected to affected areas, and within affected areas from least likely contaminated areas to most highly contaminated areas

• Use disposable cleaning materials including mops and cloths

• Where reusable microfibre cloths suitable for use with chlorine releasing disinfectants are in use, the system must be supported by a robust laundry service and adherence to manufacturer's instructions

• Dedicate reusable cleaning equipment to affected areas and thoroughly decontaminate between uses e.g. mop handles and buckets

• After cleaning, disinfect with 0.1% sodium hypochlorite (1000ppm available chlorine - Chlorclean)

• Pay particular attention to frequently touched surfaces such as bed tables, door handles, toilet flush handles and taps

• Cleaning staff and other staff who undertake cleaning tasks should follow standard infection control precautions and wear appropriate personal protective equipment (PPE) including disposable gloves and apron

• National and local colour coding for PPE and cleaning equipment should be adhered to, in order to avoid cross contamination

QUALITY, SAFETY & PERFORMANCE COMMITTEE

Handling Concerns Policy (Ref. QS03) (Complaints, Claims and Patient Safety Incidents) & Incident Reporting and Investigation Policy

DATE OF MEETING	24th March 2002

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Nigel Downes, Interim Deputy Director of Nursing, Quality and Patient Experience Jennie Palmer, Interim Head of Quality and Safety
PRESENTED BY	Nigel Downes, Interim Deputy Director of Nursing, Quality and Patient Experience
EXECUTIVE SPONSOR APPROVED	Nicola Williams, Executive Director of Nursing, Allied Health Professionals & Health Science

REPORT PURPOSE	FOR APPROVAL

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Management Board	07/03/2022	APPROVAL

1. SITUATION

This paper is provided to the Quality, Safety & Performance Committee to **APPROVE** the following revised policies:

- Handling Concerns Policy (Complaints, Claims and Patient Safety Incidents) (Ref. QS03)
- Incident Reporting and Investigation Policy

2. BACKGROUND

The Handling Concerns and Incident Reporting and Investigation policies are in place to ensure that the Trust is meeting its legislative and national requirements with respect of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, and the Putting Things Right Guidance (PTR) (2013).

Both policies have been updated to reflect enhanced arrangements within the Trust: the Handling Concerns Policy (Complaints, Claims and Patient Safety Incidents) reflects ongoing changes within the handling and investigation of concerns; and the Incident Reporting and Investigation Policy reflects the changes of the digital provider of the reporting system and the additional functionality provided.

Both policy will require considerable re-review by April 2023 when the Health and Social Care (Quality and Engagement) (Wales) Act 2021 comes into force placing a Duty of Quality and Duty of Candor on NHS bodies. In addition, there will also be minor amendments made to the Putting Things Right Regulations. Both policies will therefore have a review date of April 2023.

3. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

3.1 Handling Concerns Policy (Complaints, Claims & Patient Safety Incidents)

The purpose of this policy is to ensure that Velindre University NHS Trust fulfils the requirements for the robust management of concerns, ensure there is organisation wide learning and improvement and also provides assurance to the Board and

external bodies about the commitment of the Trust to implement the legislation: the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, and the Putting Things Right Guidance (PTR) (2013).

This policy applies to all employees, including temporary or contracted staff who work within or for Velindre University NHS Trust (The Trust) and covers the service divisions and hosted organisations including all patients, donors or members of the public who are utilising Trust services.

3.2 Incident Reporting & Investigation Policy

The purpose of this policy is to provide a structure for the management of incidents, near misses and hazards though the digital platform provided by RLDATIX Once For Wales Concerns Management System (OfWCMS), ensuring a single system for reporting, investigation and feedback. This policy reflects the current working assumptions in relation to the new Duty of Quality requirements and the systems available to support data collection and analysis.

This policy applies to all employees, including temporary or contracted staff who work within or for Velindre University NHS Trust (The Trust) and covers the service divisions and hosted organisations including all patients, donors or members of the public who are utilising Trust services.

4. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	These policies are critical to effective Quality & Safety arrangements within the Trust
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	These policies span across all the Health & Care Standards domains

EQUALITY IMPACT ASSESSMENT COMPLETED	Yes
	As these policies are only revisions to existing policies, a new EQIA is not required.
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	There is no direct impact on resources as a result of the activity outlined in this report.

5. RECOMMENDATION

The Quality, Safety and Performance Committee are asked to **APPROVE** the Trust**:**

- Handling Concerns Policy (Complaints, Claims and Patient Safety Incidents) (Ref. QS03)
- Incident Reporting and Investigation Policy.

Ymddiriedolaeth GIG Prifysgol Felindre
Velindre University NHS Trust

Ref QS03

Handling Concerns Policy (Complaints, Claims and Patient Safety Incidents)

Executive Sponsor & Function:	Executive Director Nursing, Allied Health Professionals and Health Science
Document Author:	Trust Quality & Safety Manager
Approved by:	Quality, Safety & Performance Committee
Approval Date:	TBC
Date of Equality Impact Assessment:	31.08.2020
Equality Impact Assessment Outcome:	
Review Date:	April 2023
Version:	2

TABLE OF CONTENTS

1. Executive Summary

This policy has been developed to ensure that Velindre University NHS Trust "the Trust" fulfils the requirements for the robust management of concerns, ensure there is organisation wide learning and improvement and also provides assurance to the Board and external bodies about the commitment of the Trust to implement the legislation. National Health Service (Concerns, Complaints and Redress Arrangements (Wales) Regulations 2011 ''the Regulations'', and the Putting Things Right Guidance (PTR) (2013) set out the requirements that all Health Bodies must make arrangements in accordance with the Regulations for the handling and investigation of concerns.

This policy will be implemented in accordance with the following:

- Welsh Government Putting Things Right Guidance on Dealing with Concerns about the NHS (Version 3 – November 2013)
- National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.
- The Trust's Concerns' Toolkit 2021
- Public Service Ombudsman for Wales Act (April 2019)
- The Health and Social Care Quality and Engagement (Wales) Act 2020 (particularly Part 3 – Duty of Candour)

2. Policy Statement

The Trust acknowledges that, as a provider of specialist clinical and non-clinical services, there will be occasions where things will go wrong. The Trusts response to such events will be openness, transparency and to ensure we so everything we can to minimise the potential for reoccurrence of similar incidents in the future. The overriding principle, when concerns are reported, is to be able to understand fully what happened and learn from them rather than attribute blame.

In line with the Health and Social Care Quality and Engagement (Wales) Act 2020, the Trust will implement an open and transparent approach to the management of concerns aligned to the Duty of Quality and the Duty of Candour, and ensure procedures are in place to enable delivery against the Regulations. This policy has been developed in conjunction with a number of key principles:

Handling Concerns Key Principles

A culture of openness will **be promoted**

Staff will be actively encouraged to report incidents and near misses, and patients/donors will be supported to raise feedback & concerns.

Robust & proportionate Investigations will be undertaken

Investigate once investigate well: Concerns will be investigated in accordance with the all Wales concerns grading matrix.

Local concerns arrangements will be in place

Local procedures will be in place to support delivery against the Regulations, which will be communicated to all staff.

Concerns training will be provided to all staff

A range of concerns & Datix training will be made available to all staff based upon their role and responsibility.

Individuals raising concerns will be engaged in the process

Expectations of the person raising the concern will be established and their involvement in the process sought.

Support will be available for staff involved in, or the subject of a concern

A variety of support mechanisms will be available for staff involved in, or are the subject of a concern.

Datix will be used to record all concerns

All investigation information including outcomes and action plans will be recorded in Datix.

Risks will be mitigated to avoid re-occurrences

Actions will be identified to mitigate the risks identified from concerns.

A bi-lingual service will be provided when required

Concerns relating to the Welsh Language will be managed via the language of choice.

Learning will be identified to improve services

Arrangements will be in place to ensure learning from concerns is identified and shared across the Trust.

Early resolution of concerns will be promoted

Wherever possible, concerns will be resolved by the end of the next working day to avoid unnecessary escalation of concerns.

80% of responses will be provided with 30 working days

80% of concerns will be responded to within 30 working days, and none later than 60 working days.

3. Scope of Policy

This policy applies to all staff, permanent and temporary, employed by or working within the Trust (including hosted organisations).

The Policy covers concerns about:

- Services, care & treatment provided by the Trust.
- Services provided by the Trust's employed staff.
- Services provided by independent contractors.
- Services provided by independent or voluntary sector(s) funded by the Trust.
- This policy does not apply to clinical services provided privately, even when provided within Trust premises.

Matters excluded are set out in Regulation 14 of Putting Things Right, including:

- A concern notified by any member of staff relating the contract of employment.
- A concern that is being or has been investigated by the Public Services Ombudsman.
- A concern arising out of an alleged failure of the Trust to comply with a request for information under the Freedom of Information Act 2000 – these would be dealt with by the Information Commissioners Office.
- Disciplinary proceedings that the Trust is taking or proposing to take, arising from the investigation of a concern.
- A concern that becomes the subject matter of Civil Proceedings.
- A concern that is/becomes the subject of a concern related to an Individual Patient Funding (IPFR) Request. Reference should be made to the Welsh Health Shared Services Committee IPFR policy;
- Police criminal investigations.

The Trust will advise the complainant (person who notified the concern), as soon as reasonably practicable, in writing, of the reason(s) for any decision that the concern is excluded from the scope of the Regulations and, thereby, this Policy. If any excluded matter forms part of a wider concern, then there is nothing to prevent the other issues being looked at under the Regulations, so long as they are not excluded as well.

4. Aims & Objectives

The Trust is committed to dealing with concerns in an open, accessible and fair manner, ensuring that learning ad improvement takes place.

The aim of this Policy is to outline how the Trust will comply with the Putting Things Right Regulations (2011) and the Health and Social Care Quality and Engagement (Wales) Act 2020 and ensure systems are in place for the investigation and handling of concerns in a variety of media, formats and languages.

5. Definitions

Adverse event/incident	An adverse incident is an event which causes or has the potential to cause unexpected or unwanted effect involving the safety of the patients, users or other persons.
Claim	Allegations of negligence and/or demand for compensation made following an untoward incident resulting in clinical negligence or personal injury to a member of staff, a patient or a member of the public or damage to property
Complainant	A person notifying the concern/complaint
Complaint	An expression of dissatisfaction, requiring a response.
Concern	Patient/Donor/service user safety incident or expression of dissatisfaction (incorporates safety incidents, complaints, claims)
Duty of Candour	Candour means the quality of being open and honest: transparency, fairness; impartiality. Placing a duty of candour on NHS bodies and primary care providers, through the Health and Social Care (Quality and Engagement) (Wales) Act 2020 [1] ('the Act'), highlights the Welsh Government's commitment to safe, effective and person-centred health services.
Duty of Quality	The Duty of Quality seeks to improve the health services for the people of Wales providing evidence based around the 6 domains of Quality (as defined by the Institute of Medicine)
Early Resolution	Concerns that could potentially be resolved immediately or within 2 working days through discussion, explanation or the provision of information. These generally relate to relatively easy to address issues and as such are handled outside of the PTR regulations
External body / agency	An organisation that has an official advisory or regulatory role that has been mandated to regulate the corporate and professional activities of NHS Trusts
Investigation	A formal approach of gathering information in a systematic and methodical way
Nationally Reportable Incident	An incident or accident where a patient, member of staff, or member of the public suffers serious injury, major permanent harm or unexpected death (or risk of serious injury) on premises where health care is provided, or whilst in receipt of health care, or where the actions of health service staff are likely to cause serious injury.
Never Event	"Never events" are defined as 'serious, largely preventable patient safety incidents' that should not occur if the available preventative measures have been implemented by healthcare providers
Near Miss	A near miss is a situation in which an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as a result of compensating action, thus preventing injury
Qualifying Liability	A liability in tort owed in respect of, or consequent upon, personal injury or loss arising out of or in connection with breach of duty of care owed to any person in connection with the diagnosis of illness, or in the care or

[1] https://www.legislation.gov.uk/asc/2020/1/contents

	treatment of any patient/donor/service user in consequence of any act or omission by a health care professional and which arises in connection with the provision of qualifying services
Redress	The making of an offer of compensation in satisfaction of any right to bring civil proceedings in respect of a qualifying liability in tort; the giving of an explanation; the making of a written apology and the giving of a report on the action that has been, or will be, taken to prevent similar occurrence
Root Cause Analysis	A process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a sentinel event.

6. Roles and Responsibilities

The Regulations specifically require every NHS organisation to clarify who is responsible in their organisation, for the undertaking of the distinct roles and regulatory responsibilities as set out below:

6.1 Chief Executive Officer

The Trust Chief Executive Officer has overall responsibility for dealing with concerns and ensuring investigations are undertaken in an appropriate manner, within appropriate timescales and that lessons learned are implemented within the Trust.

6.2 Responsible Officer

The Responsible Officer is accountable for the effective day to day operation of the Trust's arrangements for dealing with concerns in an integrated manner. The Director of Nursing, Allied Health Professionals and Health Science is the Responsible Officer for the Trust and ensures arrangements are in place to:

- Deal with concerns in line with the Regulations.
- Allow for the consideration of qualifying liabilities; and
- For incidents, complaints and claims to be dealt with under a single governance arrangement.

6.3 Strategic Oversight

A nominated Independent Member is responsible for maintaining a strategic overview of the Putting Things Right arrangements and their operation, including:

- Overseeing how organisational arrangements are operating at a local level.
- Ensuring that concerns are dealt with in compliance with the regulations.
- Ensuring arrangements are in place to review the outcome of all investigated concerns to ensure that any failure in provision of service identified during the investigation are acted upon, improved and monitored in order to prevent recurrence

The nominated Independent Member is the Independent Member with responsibility for the Quality, Safety & Performance Committee.

6.4 Trust Quality and Safety Manager

The Trust Quality & Safety Manager is also responsible as Senior Investigations Manager (SIM) as described in the PTR regulations. The SIM is responsible for;

- Oversight of the handling and consideration of concerns in accordance with this Policy.
- Auditing of Trust and Divisional concern management arrangements.
- Robust interface arrangements with the Divisions in relation to effective divisional concern management processes and outcomes.
- The development, integration and embedding of a comprehensive investigation and redress system for concerns.
- Providing assurance to the Executive Management Board (EMB) and Quality, Safety and Performance Committee on the Trust performance regarding concerns.
- Ensuring mechanisms are in place for lessons learnt to be shared across the Trust.

6.5 Corporate / Divisional Directors (including hosted organisations)

Divisional Directors are responsible for ensuring the necessary processes and structures are in place across their Division and to ensure compliance with the PTR Regulations, and this policy. They are required to ensure robust processes are in place within Division for proportionate and timely investigations and to ensure that all earning identified from investigations is appropriately implemented across the division so that the required improvements are embedded, patient / donor experience is enhanced and potential for harm reduced.

Corporate / Divisional Directors, Clinical Directors / Medical Directors, Chief Scientific Officers and Heads of Nursing are responsible for ensuring (within respective Divisions):

- that all concerns are recorded on datix at source including those received verbally;
- that a culture of openness is promoted and encouraged to ensure that staff report all concerns that are patient safety incidents and that concerns are robustly and promptly investigated in line with the Regulations and acted upon;
- effective and practical local arrangements are in place across all provided and commissioned services to ensure full implementation of and compliance with this policy and that these are communicated to staff;
- that staff receive concerns handling, investigation and Datix training pertinent to their roles and responsibilities;
- that there is appropriate cross-divisional and Trust co-ordination and liaison to achieve compliance with this policy;
- that adequate and appropriate support is made available to staff who are involved in/are the subject of a concern;
- that staff trained in investigations analysis within the Trust and are released or have their duties appropriately adjusted to enable them to undertake or support investigations when required;
- that all information pertaining to individual concerns including the outcomes of all investigations are fully and accurately recorded in Datix, that all documents are saved against the Datix record, and all action plans are completed through the Datix system so that compliance can be easily monitored and reviewed;
- that all necessary actions are taken to prevent re-occurrence of issues arising from both individual and aggregated concerns;

- appropriate communication and reporting of relevant information to all appropriate Boards and Committees;
- that lessons are shared across services and the Trust as relevant;
- the creation of a culture across the Divisions where issues are resolved as they arise and informally resolved as far as possible – not allowing unnecessary escalation or protraction of concerns;
- that 80% of concerns being managed through the Division are responded to within 30 working days and no concerns receive a response later than 60 workings days (Regulatory maximum time period);

6.6 Every manager in the Trust is responsible for:

- ensuring all staff, volunteers and contractors are made aware of this policy and the requirements within it;
- creating and maintaining a culture where patient feedback is encouraged and timely action is taken to make any changes required;
- creating and maintaining a culture where all staff are supported and trained to address issues and concerns as they arise as to nip issues in the bud and to ask for help and assistance when required and not allow issues to fester and escalate;
- creating and sustaining an environment whereby staff feel supported to report concerns that are patient safety incidents and feel that these will be taken seriously and dealt with appropriately;
- ensuring appropriate feedback is given to the reporters of patient safety incidents and all staff involved with or the subject of any concern, including any investigation outcomes and actions taken and to ensure that this feedback is clearly documented;
- identifying the training needs of individual members of staff, in relation to use of Datix and the handling of concerns, and ensuring that these training needs are met;
- ensuring that how to raise a concern and Community Health Council posters and leaflets are visible within all patient / donor areas;
- Ensuring that all identified improvement action is taken or if unable to do so, this is escalated through to the Divisional Quality Team;
- Ensure all verbal concerns are recorded in 'real time' on Datix; and,
- ensuring staff are made aware of how to access copies of the Trust's arrangements for handling concerns, in all the formats, so that they may satisfy any reasonable request made of them for this information.

6.7 Responsibility of all Staff

All staff must:

- Treat persons notifying/reporting concerns with respect and courtesy;
- Treat all concerns confidentially;
- Co-operate fully and openly in the investigation of concerns;
- Address issues and concerns as they arise and escalate for assistance if unable to manage any issue affecting the progress of the concerns raised;
- Attend incident/concerns training and Datix training pertinent to their roles and responsibilities;

- Ensure they are aware of the importance of reporting safety incidents, including near misses, and that all staff are aware of their responsibilities for reporting and escalating incidents and near misses;
- Ensure they are aware of the Trust's arrangements for handling concerns, and where to seek advice and information where appropriate, to enable them to satisfy any reasonable request made of them for this information; and,
- Be open, honest and transparent and adhere to this Policy and the supporting procedures that accompany it, at all times.

6.8 Corporate Quality and Safety Team

The Corporate Quality & Safety team is responsible for ensuring the Trust has appropriate policies, procedures, support and training in place for the management of Concerns across the organisation. In particular they are responsible for:

- Receipting and grading Concerns and provision of acknowledgement letters within required timescales
- Development of Concerns / Putting Things Right related policies and procedures
- Provision of appropriate Concerns Management, investigation and DatixTraining
- Overseeing appropriate divisional investigative processes and adherence with national timescales
- Leading on 'serious Harm' investigations
- Leading on all Public Services Ombudsman Reviews / investigations
- Leading on all Redress processes
- Leading on all Duty of Candour and Duty of Quality reporting
- Lead on Vexatious Concerns Management
- Auditing compliance with all Concerns / Putting things Right Standards
- Oversight of learning and dissemination of learning
- Provision of Executive Management Board and Quality, Safety & Performance Committee report Lead on liaison and meeting requirements of other external bodies such as: Coroner's Office; Shared Services – Legal and Risk, Police; and Community Health Council.

6.9 Executive Management Board

Concerns are a gift as they offer a valuable opportunity for us to learn and improve. Regular quarterly reports are provided to Executive Management Board. The Executive Management Board is responsible for overseeing the Trusts Concerns Management process and outcomes. This will include appropriate: policies, procedures and reporting in line with legislative and national requirements; training; identification of and compliance with key performance indicators; meaningful analysis; investigative processes; audit and operational assurance mechanisms; that all remedial action is taken; Duty of Candour mechanisms in place; and, appropriate lessons identified and shared.

A quarterly Putting Things Right Report will be presented to Executive Management Board in respect of the above areas as well as an annual report which is also published to ensure full transparency. Following Executive Management Board deliberation appropriate amendments are made and submitted for assurance to the Quality, Safety & Performance Committee.

6.10 Quality Safety and Performance Committee

The Quality Safety and Performance Committee is responsible on behalf of the Board for scrutinising and receiving assurance and / or any exceptions in relation to Putting Things Right and Concern Management. This will include appropriate: policies, procedures and reporting in line with legislative and national requirements; training; identification of and compliance with key performance indicators; meaningful analysis; investigative processes; audit and operational assurance mechanisms; that all remedial action is taken; Duty of Candour mechanisms in place; and, appropriate lessons identified and shared.

The Quality, Safety and Performance Committee provide assurance reports to the Board in respect of how the Trust is meeting its Putting Things Right and Wales Quality and Engagement Act Responsibilities highlighting any exceptions, risks or potential risks in respect of this.

7 Notification of a Concern

7.1 Who May Notify a Concern

Almost anyone may raise a concern. Regulation 12 (PTR Regulations) notes a concern may be notified by:

- People who are receiving or have received services from the Trust.
- Any person who is affected, or likely to be affected by the action, omission decision of the Trust, in relation to the functions of the Trust.
- Any non-officer member of the Trust, e.g. an independent member.
- Any member of staff of the Trust.
- Any person acting on behalf of any person from the above categories (a to d) who has died, is a child, lacks the capacity under the Mental Capacity Act (2005) to notify the concern themselves or has requested the person to act as their representative.
- Assembly Members and Members of Parliament.

Some concerns will not be handled under the formal arrangements for raising a concern under the Putting Things Right regulations. These include concerns that are relatively easy to address and can are normally dealt with by way of early resolution. Such concerns are required to be resolved within 48 hours (or the next working day) from receipt of the concern. Where Early Resolution concerns cannot be addressed within the 48 hour timeframe, provided that the complainant expressly wishes for the concern to remain as an informal complaint, the Trust has five days in which to resolve the concern in accordance with the Early Resolution requirements. After this time, the concern is treated as formal. Concerns that can be dealt with as they arise (informally) should be recorded locally on the Datix OFW Feedback module. A written record of the concern must be made together with the outcome. A copy of the outcome will be given to the person raising the concern, if appropriate.

7.2 Concerns Notified by a third party

When a third party acts as a representative on behalf of another e.g. a child or someone who lacks mental capacity if there are reasonable grounds to conclude that they are not suitable to act on their behalf, for example because it does not appear to be in the persons best interests, then they must be advised in writing. However, an investigation into the

issues raised may still need to be undertaken. In this instance the Trust is under no obligation to provide a detailed response to the person who raised the concern, unless it is reasonable to do so.

7.3 Concerns Received from Assembly Members/Members of Parliament

Concerns received from the Welsh Government or via an Assembly Member/Member of Parliament or other elected members on behalf of their constituent, must be dealt with as soon as possible and a response provided at the earliest opportunity.

For the sharing of personal data, the Trust will rely on The Data Protection (Processing of Sensitive Personal Data) (Elected Representatives) Order 2002, which also covers the disclosure of such data by organisations responding to Members.

7.4 Concerns Relating to Children

Any child or young person under the age of 16 is able to raise a concern if they are considered as having sufficient competency. Where a concern is notified by a child or young person, the Trust has a duty to support and assist in responding to the concerns raised.

Advocacy is to be offered to assist the child or young person and this should be arranged in accordance with the Welsh Government's 'Model for Delivery Advocacy Services to Children and Young People in Wales' (2004) through the local authority services provided. The investigation process will be consistent with the principles of the Carlisle Report (2002) and with appropriate involvement of named advocates and others with nominated responsibility for a child's health and welfare where appropriate.

In instances where child protection issue arise, staff involved should seek advice from their Head of Nursing or the Trust Head of Safeguarding & Vulnerable Groups. The Putting Things Right Procedure for handling concerns should run independently of any child protection investigation. The concern should be investigated by the Investigation Lead; however, advice should also be sought from the Head of Safeguarding & Vulnerable Groups. Where the concern alleges child abuse or neglect by an employee, a multi-agency child protection referral must be made to the appropriate social services department in line with the All Wales' Child Protection Procedures and the Trust Child Protection policy and procedures.

In many cases, a carer (parent/carer/guardian) may raise a concern on behalf of a child. This does not remove the right of the child to take the concern forward by him/herself with appropriate support. The Trust must satisfy itself as to whether the child wishes to raise a concern with assistance and support from a relevant carer/advocate or if they prefer to be represented with appropriate consent to do so.

If the child is unwilling to allow a concern to be investigated, a decision will need to be taken regarding the investigation. Specialist advice will need to be sought if appropriate from the Trust Head of Safeguarding & Vulnerable Groups where issues arise concerning

safety/safeguarding of a child. In such circumstances, it may be necessary to proceed with an investigation even if a child is unwilling.

7.5 Concerns Raised by Prisoners

Prisoners have access to the same quality and range of healthcare services as the general public. Where a prisoner raises a concern, the Trust will handle and investigate the concern in the same way as it does for all concerns in accordance with the PTR regulations. Prisoners must also be informed that they have the right of access to advocacy services provided by Community Health Councils and/or mental health advocates as appropriate.

7.6 Concerns raised by individuals Lacking Capacity or Vulnerable Adults

All concerns are treated seriously, whether an individual lacks capacity or not. This includes people who are also deemed vulnerable adults.

The Trust is aware of the importance of the complaints process being accessible to all. Therefore, the Trust will make reasonable adjustments and/or consider the ways people access the complaints process and how this may affect an individual's ability to make a complaint.

When a person lacks capacity or is deemed a vulnerable adult, such concerns should be processed in compliance with the Mental Capacity Act (2005). Where necessary, the Trust will use a consent process that allows complaints to be made on behalf of people who may lack capacity. This process may include clinical assessment of capacity, whilst ensuring equality and equity processes are followed.

The Trust will also need to be satisfied that the complaint is being made in the best interests of the person on whose behalf the complaint is made. In such instances, and where doubts exist about the reasonableness of the concern, discussion should take place between medical and nursing staff with a relative, friend or advocate, who has permission to act on the persons behalf, and a decision made as to whether the concern should be formally investigated. There is also a need to ensure that a person who lacks capacity or is vulnerable, has access to appropriate advocacy services.

Care must be taken not to overlook a real and serious underlying concern, which may be masked by the patient's disability or incapacity. Investigation Leads must remain alert to any possibility of vulnerable adult abuse, and take immediate advice from relevant senior professional staff, or the Trust Head of Safeguarding & Vulnerable Groups, in cases of doubt.

Where it is deemed appropriate for the issues raised in the concern to be dealt with via the Protection of Vulnerable Adults Policy, the person raising the concern should be informed and the necessary steps taken.

7.7 Concerns raised through Advocacy Services

It is important that those who raise concerns are informed of their right to have involvement of an advocacy service. Advocacy promotes social inclusion, equality and social justice.

Community Health Councils (CHCs) across Wales are responsible for representing independently and without bias, the interests of patients, families and third parties, in order to influence and improve the NHS. CHCs will listen to views expressed about the health service and represent people who wish to raise concerns regarding the health service. They also work closely with the health service to improve the quality of care that is delivered.

Advocacy Support Cymru (ASC) is a registered charity that specialises in the provision of professional, confidential and independent advocacy for those eligible in secondary care and community mental health settings across South Wales.

Independently Mental Health Advocacy (IMHA) support patients with issues relating to their mental health and care. Mental health advocates have a duty to ensure that patients are eligible in accessing IMHA services. The service takes action on behalf of patients to ensure that their interests are represented and that services that are required are obtained for patients.

The Trust recognises the importance of advocacy in the concerns process and encourages patients to take advantage of advocates when raising a concern. This ensures that patients who require support are provided with the necessary access for appropriate representation.

7.8 Concerns from Solicitors / Intention to Litigate /Requests for Compensation

People have a right to raise their concern via a solicitor, provided that the appropriate consent is given to ensure that the solicitor is able to act on the person's behalf. Any concerns that are received via a solicitor are dealt with in accordance with the governance and framework of the PTR regulations. Exceptions to this relate to the following:

When legal proceedings or notification of proceedings have been issued
When the solicitor has issued a letter before claim
Pre-action protocol (eg letter before claim/letter of notification)
Conditional Fee Arrangement (CFA)
After the Event Insurance (ATE)
Part 36 offer
Claim form
Particulars of Claim
Acknowledgement of Service
Response Pack
Defence
Consent Order
Case Management Conference
If there is mention of instructing a barrister.

The above provides an indication that the matter is being pursued as a civil claim under the pre-action protocol. Any letters or communication received from a solicitor should be passed to the Claims Manager and alerted to the possibility that the solicitors are not conducting the matter in accordance with PTR.

Where there is an intention to proceed with a claim and the matter is able to be dealt with in accordance of the PTR Regulations, this should be conveyed to the solicitor via the Claims Manager and a request made to inform the client via the solicitor that PTR is considered appropriate. There is provision with the scope of the PTR Regulations that allows for the time limit to be suspended during the PTR investigation of a concern.

The Trust Claims Manager should be notified immediately of any concern which has the potential to be considered under Redress or which is likely to result in a legal claim over the financial threshold applicable under the PTR regulations (£25,000).

In the event that legal proceedings are instigated during the PTR process the matter no longer proceeds under the Putting Things Right Regulations and the person raising the concern is duly notified in writing.

Where the Trust accepts, in the absence of legal proceedings, that there is a breach of duty which has potentially or otherwise resulted in harm, the matter is considered under the Redress arrangements to determine if a qualifying liability exists.

7.9 Concerns from people with a disability

In line with the Equality Act 2010, the Trust will make reasonable adjustments to ensure that the concerns process is accessible to service users who have a disability. Advice on reasonable adjustments should be sought from the Trust Equality & Diversity Manager.

7.10 Concerns involving contracted service

The Trust recognise that it remains responsible and accountable for ensuring that the services provided on behalf of a contractor meet current standards in relation to the complaints policy and procedures by ensuring that:

- the contractor complies with this policy and complaints handling procedures and/or
- the contractor has their own complaints handling procedure in place, which fully meets the standards outlined in this procedure.
- The Trust is responsible for ensuring that there is appropriate provision for information sharing and governance oversight involving contracted services to ensure the safe delivery of services that is provided on behalf of the contractor.

7.11 Concerns and Welsh Language

Language plays a vital part in the quality of care and the treatment a person receives. The Trust recognises the need to provide Welsh language services, whereby Welsh language users are able to access the complaints processes fairly, without prejudice or discrimination.

Upon establishing the need for communication in Welsh, the Trust will ensure:

- All written communication is provided in Welsh
- Arrange Welsh interpretation for over the phone or face-to-face meetings.
- Ensure there are bilingual complaints leaflets/forms that include the Public Service Ombudsman for Wales guidance and CHC support made available both on the intranet and across sites across the Trust where service users frequent
- Adopt a proactive approach to language choice and need in Wales by:
  - ✓ Ensuring the language needs of Welsh speakers are met.
  - ✓ Ensuring Welsh language provision/services for those who need it.

7.12 Concerns and British Sign Language

The Trust acknowledges that not being able to communicate well with health professionals can affect health outcomes, increase the frequency of missed appointments, the effectiveness of consultations and patient experience.

The Trust is committed to providing high quality, equitable, effective healthcare services that are responsive to all patients' needs and recognises that the British Sign Language (BSL) is a recognised language.

The Trust will take steps to ensure:

1. That there is equality for BSL users to raise concerns
2. That there is access to interpretation and translation services to enable appropriate communication to take place.
3. That there is the opportunity to liaise with an individual via their preferred means of communication.
4. Concerns information is available in alternative formats.
5. Access to an interpreter when required

"Interpreter" is used to mean registered, qualified bilingual and bicultural professionals who facilitate communication between BSL Users and those who use only spoken languages, such as Welsh or English and provide a service for patients, carers and clinicians to help them understand each other**.**

7.13 Concerns and Blind and Partially Sighted Disabilities

The Trust recognises the need for equality and fairness for those who wish to raise concerns who are registered blind or partially sighted and will ensure that there is flexibility within the complaints process that allow for individual needs to be taken into account.

The Trust will also ensure that it has in place alternative methods for communication, with access to Braille information and ability for an individual to raise complaints orally, in addition to ensuring that appropriate services are available for the individual to access and raise concerns.

8. Reporting Concerns

The Trust is required to have a single point of contact for Concerns that should be advertised. This includes concerns relating to Velindre Cancer Service and the Welsh Blood Service. For all concerns the Trusts point of contact is:

Executive Director Nursing AHP's & Health Science
Velindre Trust Head Quarters
2 Charnwood Court
Heol Billingsley
Parc Nantgarw
Cardiff, CF15 7QZ
handlingconcernsvelindre@wales.nhs.uk
Telephone: 029 20196161

8.1 Time limits for notification of a concern

A concern must be notified no later than **12 months** from:

- The date on which the concern occurred, or if later,
- 12 months from the date the person raising the concern realised they had a concern (Where a patient has opted to have a representative act on his/her behalf, this date is the patient's date of knowledge, NOT the date that the representative was informed of the concern by the patient).

To investigate a concern after the 12-month deadline, the Trust must consider whether the person raising the concern has good reason not to provide notification of the concern earlier and whether, given the time lapse, is it still possible to investigate the concern thoroughly and fairly.

A concern under these regulations may not be notified 3 or more years after the date on which the subject matter occurred or after the date that the subject matter came to the notice of the patient/donor. The Trust may, therefore, refuse to consider any such concern under the regulations. (Where a patient/donor has opted to have a representative act on his/her behalf, this date is the patient's /donors date of knowledge, NOT the date that the representative was informed of the concern by the patient/donor).

If the person who raised the concern is a child at the time of injury the three year period does not begin to run until the individual reaches the age of 18years and runs out on their 21st birthday.

If the Trust makes an exception to this it must make it clear to the person who raised the concern that the investigation is not being undertaken under the PTR regulations. In addition, that the investigation will be limited in some aspects based on the information available as key staff may have left the Trust and given the time elapsed memory in relation to the circumstances will be poor and unreliable.

8.2 Withdrawal of Concerns

A concern may be withdrawn at any time by the person who notified the concern. The withdrawal of the concern can be made:

- in writing;
- electronically; or
- verbally in person or by telephone.

If a concern is withdrawn verbally, the Trust will write to the person as soon as possible to confirm their decision. However, even if the concern has been withdrawn, if it is felt that the investigation of the concern is still appropriate, the Trust will continue to investigate.

9. Handling a concern process

9.1 Acknowledging Concerns

All concerns managed under the PTR regulations should be acknowledged in writing within 2 working days of receipt. This written acknowledgement should be done by the corporate Quality & Safety team.
If the concern is not from the patient, consent must be sought from the patient/donor/user. The template acknowledgement letter is available from the Trust Quality and Safety team and includes:

- Name and telephone number of a named contact (not usually the Investigation Lead) for use throughout the handling of the concern
- The offer of an opportunity to discuss with the named contact, either in a meeting or over the telephone, any specific needs and the way in which the investigation will be handled
- The opportunity to meet with relevant staff involved in relation to the concern/s raised
- When a response is likely to be received i.e. 30 days from the date of receipt of the concerns raised
- The availability of advocacy and support, i.e. Community Health Council
- Information advising that a patient's clinical records will need to be accessed as part of the investigation
- A copy of the Putting Things Right leaflet is to be provided at the outset

The concern lead will then refer the concern for investigation. The progress of the concern is monitored by the Trust Quality and Safety Team to ensure the investigation is completed within an appropriate timescale, commensurate with the grading and complexity of issues raised by the concern.

9.2 Time limit for formally responding to a concern

30 working days from the date the concern is received is the deadline for providing ma response/interim report to the complainant.

If this is not possible, the Trust will:

(a) notify the complainant and outline the reason for the delay; and
(b) send the interim report as soon as reasonably practicable and within 6 months
(c) a Regulations 33 response and disclosure of the investigation report must be sent no later than 12 months

9.3 Concerns received from Medical Examiners

Medical examiners are a core part of the process of investigating patient deaths across the NHS in England and Wales. The role of the medical examiners will speak with bereaved families and discuss the cause of death. Where there are concerns raised by bereaved families in relation to any aspect of care or treatment, these are referred to the appropriate NHS provider for consideration.

The Trust has set up the Medical Examiners Panel which sits bi-weekly to look at cases referred by the Medical Examiner. Where it is identified that a concern arises, the Trust's co-ordinator for mortality will write to the family to ascertain if they wish for the concern to be investigated and provide an opportunity to discuss these concerns with the clinical team involved. If the concerns warrant an investigation under the Regulations, the matter is passed to the Trust Quality & Safety Team and thereafter to the relevant Divisional Concerns Lead to investigate and provide a response within the timescales outlined by the PTR Regulations.

9.4 Concerns Referred to Coroner's Inquest

An investigation into a concern should continue regardless of the inquiries of the Coroner, whose role is to determine the cause of death. However, in cases where there is a National reportable incident and/or statements are being taken from staff for the purpose of inquest proceedings, the person raising the concern may need to be informed that the investigation may not comply with the 30-day timeframe to provide a response under the PTR regulations.

A formal response may be issued relating to concerns raised, independent of the inquest if it is appropriate to do so. However, if an outcome from a Coroner's inquest is needed to complete the response, the person raising the concerns is required to know the reason for the delay in the process and must be notified of the expected delay. Where statements are taken as part of the inquest process, the concerns investigation should include reference to these.

The Investigation Lead should discuss the case with the Trust Claims Manager and the Quality and Safety Manager to determine the most appropriate action.

10 Investigation of Concerns

10.1 Concerns Flowchart

Regulation 23 provides that all concerns must be managed and investigated in the most appropriate, efficient and effective way, having regard to the matters that are set out in Regulation 23(1) (a) to (i).

A concern which alleges (implicitly or explicitly) harm or impact experienced by the patient will generally be graded 3, 4 or 5 (see Appendix A) and will be investigated

under the PTR guidance. In such circumstances, a relevant and proportionate investigation will be undertaken following the scoping of the concerns and key issues identified.

The Trust notes in particular Regulation 23(1) (i) which provides that where the concern notified includes an allegation that harm has or may have been caused it will consider:

- the likelihood of any qualifying liability arising;
- the duty to consider Redress in accordance with Regulation 25; and
- where appropriate, consideration of the additional requirements set out in Part 6 of the Regulations.

When considering the "additional requirements of Part 6", the Trust will be mindful of the current financial limit of £25,000 applied to offers of Redress under Regulation 29. Where it is clear from the outset that if a qualifying liability were to be established damages would exceed £25,000, the Redress arrangements will not be triggered. In this situation the Trust will serve a Regulation 24 response, which will not comment on whether or not there is or may be a qualifying liability, and the person who notified the concern will be advised to seek legal advice and will be given the contact details for their local CHC.

10.2 Initial Assessment of a Concern

An initial assessment and grading of the concern is undertaken to determine the level of investigation required.

All concerns will be graded on receipt in terms of severity, from 1(No Harm) to 5 (Catastrophic Harm) in accordance with the All Wales' Grading Framework (see Appendix A). This will determine the level of investigation required in dealing with the issue(s) raised.

The grading of a concern should be kept under review throughout the investigation in case the level of investigation needs to change. For example, the seriousness of a concern may only become evident once an investigation has commenced or has been completed. The grading of a concern may therefore be upgraded or downgraded by the Investigation Lead during the course of the investigation. The Trust procedure for the investigation of concerns should be followed when investigating the concern (complaint/incident).

All concerns (complaints, claims and incidents) must be recorded on Datix upon receipt (formal and early resolution). This ensures robust recording and oversight.

Concerns are managed by the Velindre Cancer Centre Head of Nursing, Deputy Head of Nursing and Quality and Safety Manager with appropriate assistance from Service Leads.

Concerns raised by donors or those acting on behalf of donors to Welsh Blood Service is managed by Donor Experience Manager

10.3 Obtaining independent clinical or other advice

There may be occasions when the Trust considers it is necessary to secure an independent opinion on a matter relating to a concern, with a view to resolving it. The Trust incident and concerns investigation procedure should be followed in these situations.

10.4 Consent to Investigate Concerns

In the majority of cases, the investigation of a concern requires access to medical records and therefore the issue of consent will need to be considered. When consent is required, the Trust procedure for Consent to Investigate a Concern must be referred to thereby ensuring that the appropriate consent is obtained before the sharing of information.

If there is any doubt as to whether the processing of sensitive personal data without the consent of the data subject is unlawful, appropriate legal advice should be sought. Further information regarding consenting issues is set out in the all Wales Guidance (Putting Things Right Regulations) on dealing with concerns.

In the event that the patient/donor contacts the Trust after raising the concern to say that they are unwilling to provide consent for their records to be accessed, then the Trust must take a view on whether the issues raised is of sufficient seriousness to merit an investigation without access to the medical records.

10.5 Consent Involving Other Organisations

Where the Trust is notified of a concern that involves the functions of more than one responsible body/another organisation, it is required to seek the consent of the person notifying the concern to contact the other organisation before sharing information in relation to the concerns raised.

Consent should be sought within 2 working days of when the concern is received. Templates for the consenting process is available from the Trust Quality and Safety team.

Once consent is received, the Trust is required to contact all other relevant organisations involved in the concern within 2 working days of the consent being received.

The Trust must agree with the NHS organisations and person raising the concern, which organisation will take the lead, co-ordinate the investigation and provide the response. All relevant organisations should be included in any meetings arranged to discuss the concern.

11 Nationally Reportable Incidents

A concern which is raised by a complainant may already have been raised by staff as a nationally reportable incident and an investigation may already be underway.

The investigation into the incident should continue to ensure that action is taken to reduce the risk of recurrence and improve patient safety. In this situation the Trust Procedure on the Management of Nationally Reportable Incidents should be relied upon, and the person raising the concern must be kept informed of any delays in regard to the final response.

Where a letter raising a concern is received and it becomes apparent that there has been a serious incident that the Trust was previously unaware of, an on-line incident form should be submitted via OFW Datix Incident Module. The serious incident process will commence and the person raising the concern should be informed that it may not be possible to achieve the 30-day timeframe in which to provide a response. Regular updates should be provided throughout the course of the investigation and the likely timing of when a response will be envisaged.

12 Response

12.1 Delays to the Complaint Response

Regulation 24 requires the Trust to take all reasonable steps to send the response to the person who notified the concern within 30 working days, beginning on the day that the notification of the concern was first received. It is essential the Trust advises the person who raised the concern of the predicted timescale for a response. If the Trust is unable to provide a response within 30 working days, the following actions are required:

1. A written explanation setting out the explicit reasons for the delay must be provided to the person who raised the concern, with estimation or anticipated date for completion of response.

2. Some responses may take up 60 working days (3 months), where a serious patient safety investigation is required. Rarely an investigation may take up to 6 months, however where this is the case close contact with the complainant must be maintained to provide regular updates of the stage of the investigation. Responses should not be sent later than 6 months, from the day that the notification of the concern was first received.

3. Timescales are reported at a divisional and corporate level through the Trust's management structures.

12.2 No Qualifying Liability – Regulation 24

Where appropriate, the lead investigator prepares a written report and drafts a response to the concern under investigation for the responsible officer which:

- Summarises the nature and substance of the matter or matters raised in the concern
- Describes the investigation
- Contains copies of any expert opinions (internal or external) relied upon to inform the investigation
- Contains an offer to provide copy relevant medical records, as appropriate
- Contains an apology as appropriate
- Identifies what action will be taken in light of the outcome of the investigation
- Contains details of the complainant's right to notify the concern to the Public Services Ombudsman for Wales and aligns with provision of section 36 of the Public Services Ombudsman (Wales) Act 2019
- For complaints relating to the Welsh Language, the right to notify the Welsh Language Commissioner
- Offers the complainant the opportunity to discuss the content of the response with appropriate clinical/nursing/administration teams.

The letter is to be written in a language that the person raising the concern will easily understand and must avoid medical or technical jargon. Where there may be difficulties in understanding the response, the Trust will make every effort to provide the appropriate support. Where necessary, people raising concerns should be given the opportunity to receive their response in an appropriately accessible format, e.g. Braille, large print, electronically or on an audio device.

In respect of a concern that alleges that harm has or may have been caused and this has been found not to be the case, the letter must also contain an explanation of the reasons why no qualifying liability exists.

Written responses determined as grade 1 and 2, where no harm is alleged, are signed by the service/hosted organisations director or a person acting on their behalf as their deputy. If the investigation has determined that there is no qualifying liability the response must provide an explanation as to how it reached this decision.

Where approval/sign off is required by the Executive Director Nursing, AHP's and Health Science, the response must be agreed both with the relevant senior professionals involved in the investigation and the Divisional Director. As a matter of good practice, it should also be shared with any staff involved in investigating the concern.

Following approval by the Divisional Director, the draft response and a copy of the original concern is subject to quality assurance by the Trust Quality and Safety Manager and/or Deputy Director of Nursing before forwarding to the Executive Director Nursing, AHP's and Health Science for final approval and signature.

Following issue of the final response, further correspondence may be received when the person raising the concern does not feel that all the issues in the original concern have been addressed. Every effort will be made to address these further issues

satisfactory at a local level including, where appropriate, the setting up of a meeting between the person raising the concern and relevant staff where this has not yet happened. Notes should be taken at such meetings and these will be shared with the person raising the concern.

Further correspondence received from the person raising the concern expressing dissatisfaction will be reopened on the OfW Datix Feedback Module and will be acknowledged within 2 days with a further investigation undertaken of any new issues that are raised.

In the event that a complainant is dissatisfied with their response and there are no new issues to investigate then the complaint will not be reopened but a meeting with the complainant will be offered. Where the complainant remains dissatisfied then he/she will be advised to refer to the Public Services Ombudsman of Wales. Contact details of this must be provided in acknowledgement or response letter to the person raising the concern.

12.3 Interim Report (Regulation 26) – When a Breach of Duty is identified and harm has or likely to have occurred resulting in a possible qualifying liability

If, at the end of an investigation, it is established that harm has occurred and a qualifying liability exists or likely to exist, the matter will be considered by the Trust's Putting Things Right Panel.

Where there is the potential that harm has occurred or has been identified from the investigation, a draft interim response will be prepared for the complainant with input from the Trust Claims Manager, as appropriate.

The interim response will include:

- A summary of the nature and substance of the issues contained in the concern;
- A description of the investigation undertaken so far;
- A description of why in the opinion of the Trust there is or may be a qualifying liability;
- A copy of any relevant medical records;
- An explanation of how to access legal advice without charge;
- An explanation of advocacy and support services which may be of assistance;
- An explanation of the process for considering liability and Redress;
- Confirmation that the full investigation report will be made available to the person seeking Redress;
- An offer of an opportunity to discuss the contents of the interim report with appropriate staff.
- The interim report should receive final approval and signed off by the Executive Director Nursing, AHP's and Health Science.

Once the interim response has issued, the matter is to be forwarded to the Trust Claims Manager for further investigation under the Redress arrangements as referenced within the Putting Things Right Regulations.

12.4 Trust Putting Things Right Panel

The Trust's Putting Things Right panel consists of multi-disciplinary team members who hear presentations to:

- Determine and or validate whether a breach of duty has occurred;
- Determine whether the breach of duty described has caused harm;
- Consider the engagement of an independent clinical expert if a decision on breach of duty cannot be reached;
- Consider the engagement of an independent clinical expert in collaboration with the person raising the concern where causation is in question or further clarity as to the degree of harm is required;
- Agree how the decision of the panel will be communicated to the person raising the concern, and by whom;
- Agree how the decision of the panel will be communicated to staff affected by the concern, and by whom;
- Agree an award of financial compensation in cases where a Redress remedy applies
- Ensures there is a robust system in place for recording the decisions made.

12.5 Post Closure contact - Public Service Ombudsman of Wales

In accordance with the Public Services Ombudsman (Wales) Act 2019, when an individual remains dissatisfied with a response, he/she has the right to contact the Public Service Ombudsman for Wales, who will review the matter on their behaf. The Ombudsman can accept complaints through his website, by e-mail, in writing, or over the phone.

The Ombudsman's contact details are:
Phone: 0300 790 0203
Email: ask@ombudsman.wales
Website: www.ombudsman.wales
Address: Public Services Ombudsman for Wales, 1 Ffordd yr Hen Gae, Pencoed, CF35 5LJ.

The complainant, or an individual acting on behalf of the complainant, must be advised that if they wish to contact the Ombudsman with a complaint, this will need to be done so promptly. The Ombudsman is able to consider complaints made to him within one year of the matters complained about (or within one year of when it became aware that the complaint could be made). Upon receipt of a response to a concern, the individual will need to inform the Ombudsman within twelve weeks if he/she wishes for the matter to be investigated further.

The Ombudsman will determine on a case-by-case basis whether to consider a complaint. However, he will not generally consider a complaint in relation to matters which happened more than a year ago, unless the complaint to the Trust was made within a year, and the complaint is referred to the Ombudsman within twelve weeks of a response.

12.6 Investigation by the Public Service Ombudsman of Wales (PSOW) - timeframes

In 2019, the legal powers of the PSOW were extended. The PSOW can now accept oral complaints, undertake their own initiative investigations, including the investigation of medical treatment, including nursing care, as part of a patient's health pathway and also investigate the way a complaint was handled by an NHS provider. The new powers also extend to the publication of complaints handling by an NHS provider.

When a complaint is received from PSOW, the Trust has 5 days in which to acknowledge the complaint and 20 days to investigate and respond to PSOW with their findings. If there are difficulties in meeting the timescale and more time is needed, an extension can be requested from PSOW, following discussion with their senior management team. If agreed, PSOW will write to the complainant advising that the issues that have been raised will take longer than expected and will aim to provide an expected timeframe upon which the response can be expected.

12.7 Redress

Redress comprises:

- The making of an offer of compensation in satisfaction of any right to bring civil proceedings in respect of a qualifying liability
- The giving of an explanation
- The making of a formal apology
- The provision of a report on the action/s which has been, or will be, taken to prevent a similar occurrence from arising
- Care/remedial treatment

An initial valuation of the concerns raised is required to ensure that any likely liability will not exceed that of £25,000. Where it is likely that financial compensation will exceed that of £25,000 if liability is admitted, the Trust Claims Manager will discuss with NWSSP Legal and Risk Services and the Welsh Risk Pool to determine if the matter is capable of remaining in Redress in an attempt to reduce litigation costs. Where the value of the case exceeds that of £25,000 and cannot continue under Redress, the person raising the concerns will be advised to seek independent legal advice and no qualifying liability will be admitted.

However, if it is considered that initial valuation is within the remit of Redress and it is established that both a breach of duty and harm has occurred that results in a qualifying liability, it is the duty of the Trust's PTR Panel to confirm a breach of duty and approve whether the breach caused or materially contributed to harm suffered by the patient.

If the Panel determines that no breach of duty exists, the Division is notified and a response under Regulation 24 is issued identifying the reasons why no qualifying liability exists.

If it is not possible to determine whether a breach of duty exists following in-house comments, the Trust can commission an external expert to provide an opinion on breach of duty. Terms of Reference will be undertaken by the Lead Investigator with assistance from the Trust Claims Manager, where appropriate.

Following an opinion from an independent expert, the report findings are shared with the appropriate division and relevant staff members involved in the investigation, as required. If a breach of duty exists, a Regulation 26 response is issued and the matter is referred to the Trust Claims Manager for ongoing management of the concerns under the Redress arrangements.

When a breach of duty is identified and harm remains uncertain, further investigation will be required. This may include obtaining in-house comments from staff members to inform the decision-making on qualifying liability or by way of obtaining an expert opinion on causation/condition/prognosis to determine liability and quantum.

The Terms of Reference to request an expert report is prepared by the Trust Claims Manager in conjunction with relevant staff members involved in the investigation. The Terms of Reference is shared with the person raising the concern or with the person's legal representative and is undertaken on a joint basis.

The Trust Claims Manager will provide a list of experts in the relevant speciality, together with a copy of expert CVs and terms and conditions for reference and agree the expert list with the directorate prior to sharing with the person raising the concern or their legal representative acting on their behalf. The decision to instruct an expert of choice will be taken by the person raising the concern or the legal representative.

Where a person is seeking Redress, the findings of the investigation must be recorded in an investigation report. The investigation report, in accordance with Regulation 31, must be provided to the person who raised the concern and is seeking Redress within 12 months of first receipt of the concern. The investigation report must contain:

- copies of any independent expert advice used to determine whether or not there is a liability;
- a statement by the Trust confirming whether or not there is a liability and
- the rationale for the Trust decision.

However, it is not necessary to provide a copy of the investigation report before

- an offer of Redress is made;
- before a decision not to make an offer of Redress is communicated
- if the investigation of Redress is terminated for any reason or
- if the report contains information which is likely to cause the person or other applicant for Redress significant harm or distress.

Where an investigation report cannot be provided within the set 12 month timescale, then the person raising the concern must be informed of the reason for the delay and given an expected date for response.

Once further investigations have been completed, the case will be re-presented to the Panel to agree the findings and, where harm has been established seek approval at the Panel for an appropriate Redress remedy/remedies to be made. In the event a financial compensation is considered appropriate, the Panel will be asked to agree an offer of financial compensation, which reflects the harm suffered following quantification by the Trust Claims Manager.

12.7.1 Regulation 33 Response

If financial compensation is due, the Trust Claims Manager will be responsible for preparing a Regulation 33 response making an appropriate financial offer to settle the matter on a full and final basis with approval from the Executive Director of Nursing, Allied Health Professionals and Health Science. The person raising the concerns will have six months to accept the offer from the time the response is issued. If, after that time, no response is received, the concern is closed down within 9 months.

12.7.2 CRU Certificate

The Trust Claims Manager is responsible for requesting a CRU certificate from the Department of Work and Pensions where it is established that harm may have occurred. This is in accordance with the Trust's statutory obligation. Where harm is found to have occurred in relation to the NHS Charges/recoverable benefits (CRU), the Trust Claims Manager will arrange the appropriate payment and discharge of the CRU Certificate as necessary. Where the NHS charges/CRU amounts to over £3,000 the matter is passed to NWSSP Legal and Risk Services for advice in accordance with the Welsh Risk Pool guidance.

13 Behaviour, Conduct and Unreasonable Demands during a concerns investigation

People raising concerns have the right to be heard, understood and respected. On occasions there may be times when persons raising the concern acts out of character and become determined, forceful, angry and make unreasonable demands of staff.

The Trust, however, recognises that persons who complain despite being advised on other avenues available to them may be abusive toward, show aggression to and make unreasonable demands of staff or continue to persistently pursue their concern by telephone, in writing, or in person. Behaviours that escalate into actual or potential aggression towards staff are not acceptable. The Trust has a zero tolerance policy on unreasonable, unacceptable abusive or aggressive, or violent behaviour.

Unreasonable, unacceptable abusive or aggressive, or violent behaviour is:

- Behaviour that produces damaging or harmful effects, physically or emotionally on other people.

- Persistent unacceptable behaviour is behaviour that is deemed unacceptable within one event or on a number of occasions within a period of time.

Examples of unacceptable or aggressive or abusive behaviour:

- Verbal threats unsubstantiated allegations or offensive statements can also be termed as abusive violent behaviour.
- Threatening remarks e.g. both written and oral.
- Unreasonable demands e.g. Demands for responses within unrealistic timescales, repeatedly phoning, writing or insisting on speaking to particular members of staff.

If staff encounter situations where a person raising a concern behaves in an unacceptable manner towards staff, appropriate action should be taken in line with the Trust's Zero Tolerance policy.

14 Monitoring Arrangements

It is essential that all responses are full, comprehensive, clear and answer the concerns raised. The response needs to be in layman's terms ensuring a meeting is offered on receipt of the responses. All concerns are monitored to ensure the concern has been adequately investigated, remedial actions put in place and lessons have been learned. The Trust Quality & Safety Performance Committee is responsible for the Trust's arrangements for learning from concerns, and that the Trust has robust processes to drive continuous improvement in the quality of services and care.

For the purposes of monitoring the operation of the arrangements for dealing with concerns Velindre must maintain a record of the following matters:

- Each concern notified to it;
- The outcome of each concern;
- The time period taken to investigate the concern;
- The reasons where any investigation exceeded the 30 day time period.

This record will be reported to the Executive Management Board and Trust Quality and Safety Performance Committee on a quarterly basis.

The Executive Management Board will receive quarterly reports giving an overview of complaints received, setting out what changes have been made as a result of complaints information and, following monitoring of their implementation, what results have been received.

An annual report will also be produced using the template provided in the Putting Things Right guidance, to include:

- An overview of arrangements in place for dealing with Concerns
    - Any planned developments
    - Reference to working with other responsible bodies

    - Effectiveness of the arrangements, and how this has impacted on patients/service user and staff
    - An indication of services used, for example expert advice, legal advice, alternative dispute resolution, advocacy services.
- Concerns Statistics and analysis
- Themes, trends, performance and key issues
- Lessons learnt, demonstrating how they have contributed to improved service delivery.
- Conclusion and priorities for improvement

The report will be placed on the Trust's internet site and published as part of the organisation's Annual Quality Statement.

15 Learning from Concerns

The Trust will ensure that it has arrangements in place to review and assess the outcome of any concern that has been subject to an investigation under the Regulations, in order to ensure that any deficiencies in its actions or its provision of services, identified during the investigation, are:

- Recognised, acknowledged, owned and acted upon
- Where improvement requires embedding, an improvement plan will be developed using the template action plan within the complaints manual
- Identify learning for wider sharing across the Trust and share as appropriate, including the means to share across the wider NHS sector if suitable.
- Reviewed and reported regularly within the service divisions and Trust wide to ensure improvements are established minimising the risk of reoccurrence.
- Ensure that learning is used to target any problem areas and consider if there is potential to improve policies, procedures and services.

Learning lessons throughout the Trust and taking action to ensure any necessary improvements are made is critical to avoid such deficiencies recurring. The Trust has a number of mechanisms for sharing learning from patient experience and concerns, e.g. Alerts, newsletters, intranet, training, divisional meetings, SCIF, Shared Listening and Learning Committee for shared learning and improvement.

16 Supporting Staff

16.1 Staff involved in concerns

To support staff involved in concerns investigations the Trust will:

- Actively promote an open and fair culture that fosters peer support and discourages the attribution of blame. Velindre University NHS Trust will work towards a culture where human error is understood to be a consequence of flaws in the systems, not necessarily the individual

- Educate all staff to understand that apologising to service users is not an admission of liability
- Provide advice and training on the management of concerns, including the need for practical, social and psychological support, as part of a general training programme for all staff in risk management and safety
- Provide information on the support systems currently available for staff including counselling services offered by professional bodies, stress management courses for staff who have the responsibility for leading investigation discussions, and mentoring for staff who have recently taken on a lead investigations manager role.

Further information can be located in the Trust procedure for supporting staff involved in an incident complaint or claim and on the Trust intranet site under 'staff support services'.

16.2 Concerns Containing Allegations against Staff

Where concerns raised contain allegations against a staff member / staff members, the relevant staff member/s should receive a copy of the key issues identified at the beginning of the investigation and support offered where appropriate, including appropriate signposting to support. The line manager will be responsible for discussing the nature of the allegations with the staff member and for identifying and signposting any required support. The member/s of staff will need to be actively involved in investigation. All staff have a duty to actively participate as deemed appropriate by the investigator in this process.

Any staff member identified in the investigation process should have an opportunity to review the response before the relevant Divisional/Hosted Organisation Director/Lead approves it.

17 Concerns and Disciplinary Procedure

If an investigation into a concern indicates the need for a disciplinary investigation, the Investigation Lead must discuss these issues with the staff member's line manager. A decision to initiate a Disciplinary Investigation, rests with the relevant line manager with advice from the relevant professional Head of Service.

If a disciplinary investigation begins before the investigation has been completed, consideration will need to be given as to how far the investigation under the Trust's Handling Concerns Policy and Procedures can continue and whether a disciplinary investigation can run alongside the concerns investigation.

The person raising a concern may not be entitled to know of disciplinary sanctions imposed on any staff member other than action has been taken. A judgement will need to be made between reassuring the complainant that the matter that has been raised has been taken seriously and dealt with satisfactorily, while protecting the confidentiality of the staff member.

18 Equality Impact Assessment

This policy has been screened for relevance to equality. No potential negative impact has been identified so a full equality impact assessment is not required.

The Trust will develop an understanding of why some members of the community who may wish to raise a concern might not feel able to do so. This may be due to cultural, social, gender and other reasons, including sensory loss, any of which might result in ineffective communication. Staff should be mindful of the issues which might act as a barrier to people raising a concern and look for ways to assure people that it is safe for them to raise an issue.

19 Policy Compliance

On an ongoing basis, the Trust will actively promote awareness and understanding of this policy, linking to existing organisational development programmes, where possible.

Service/hosted organisation Directors will implement the policy within their area and ensure local procedures exist to support the policy. The Trust Quality & Safety Manager will advise and oversee the development of local procedures to ensure compliance with the Regulations.

20 Confidentiality – Information Governance

Confidentiality is an important aspect in relation to the concerns handling of a matter. All Trust Staff are required to maintain the complainant's confidentiality and are required to protect personal data as outlined by the Data Protection Act 2018. The Act sits alongside the General Data Protection Regulation (GDPR) 2018, which sets out the key principles, rights and obligations for processing personal information.

The Trust acts as “controller” of information and staff responsible for using personal data has to follow strict rules called 'data protection principles'. They must also make sure that the information is used fairly, lawfully and transparently. There is also the requirement to protect information as outlined by the Caldicott principles, Human Rights Act 1998 and the Freedom of Information Act 2000.

Information in relation to complaints should not be disclosed/copied/ shown to any external agency without the permission of the Responsible Officer or nominated deputies on a “need to know basis”.

All requests for access to such information should be directed to the appropriate manager, or nominated deputy or service lead for the subject of the concern, in the first instance.

In addition to the above, NHS Wales has adopted the Confidentiality Code of Practice for Health and Social Care in Wales. All staff have an obligation of confidentiality regardless of their role and are required to respect the personal data and privacy of others. Staff must not access information about any individual who they are not providing care or treatment for, or in relation to the administration of services unless in a professional capacity. Rights to access information are provided only for staff to undertake their professional role and for work related purposes only. If in doubt, staff must contact their line manager or the Trust Information Governance Manager, regarding concerns relating to the sharing of information.

The Information Commissioner's Office has also prepared detailed guidance on data sharing and has issued a data sharing code of practice.

Further information can be found in the Trust's Privacy Policy and Information Governance Policy available on the Trust's intranet site.

21 Training

The level of training required is outlined in the Training Needs analysis (TNA). Staff need to be informed about and received appropriate training in respect of the operation of the arrangements for the reporting, handling and investigation of concerns. Training should be considered in relation to areas such as:

- Customer care
- Safeguarding
- Records management
- Root Cause Analysis training
- Human Factors
- Being Open
- Legal Training/Awareness

Training will take the form of one or more of the following:

- Online training
- Self-learning: guides, procedures, policies and legislation
- Videos
- Meetings and conferences
- Induction
- E-learning

22 Storage and Management of Concerns Files

The concerns files should include the investigating lead's file and any other relevant information concerning the investigation. The (paper and Datix) concerns file must be kept for a period of 10 years and in the case of children, until the child attains the age of 25 (with the minimum 10 year provision).

The concerns file including the investigating lead file should be combined into one full file. It is the responsibility of the Division to ensure that the file is complete and accurate and holds no contentious remarks.

23 Complaints and legal action

The limitation in relation to bringing a claim under the Civil Procedure Rules is 3 years from the date of the incident or from the date when the complainant knew or ought to have known he could bring a claim.

During a PTR investigation, the limitation period to bring a claim under the Civil Procedural Rules is stopped. However, the limitation period resumes once the investigation is completed and the findings shared with the complainant.

If, during the process of the PTR investigation into the concerns raised by an individual, a letter of claim or service of proceedings is received, the matter is no longer suitable to be dealt with by the PTR Regulations and the matter is to be passed to the Trust Claims Manager.

If an individual threatens legal action or a pre-action letter is received from an individual's solicitors, the matter is to be referred to the Trust Claims Manager who will advise as appropriate. The matter is also to be passed to the Trust Claims Manager if any correspondence is received from solicitors concerning a request for medical records on behalf of the patient or patient's representative.

24 Managing Media Interest / Media Communications

The management of media interest/ in relation to incidents, either individually or generally, will be undertaken by the Trust's Communications Department.

25 References

- The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011
- Health & Care Standards Wales
- Putting Things Right
- Civil Procedural Rules

VELINDRE NHS TRUST

REF: QS 01

Trust Policy

INCIDENT REPORTING & INVESTIGATION POLICY

Executive Sponsor:
Executive Director of Nursing, Allied Health Professionals and Health Science

EXECUTIVE SUMMARY

Overview	The incident reporting policy outlines the: • Process involved following all incidents, near misses and work-related injury or ill health and provides guidance on the actions that need to be taken to effectively investigate and to ensure a safe working environment is provided for staff, patients and service users. • Reporting arrangements required to comply with the Health and Safety at Work Act 1974. • Reporting process for notifying external agencies including, Delivery Unit Welsh Government, Medicines and Healthcare products Regulatory Agency and the Health and Safety Executive.
Who is the policy intended for:	All Velindre University NHS Staff, including Service Divisions and Hosted Organisations.
Key Messages included within the policy:	Velindre University NHS Trust outlines a standardised approach for incident reporting and investigation across the organisation. The key messages are: • All incidents / near misses should be reported immediately the occur/are known about using the Once for Wales Concerns Management System (OfWCMS) DATIX • All staff should be aware of their responsibilities to report incidents and near misses • Manager's are responsible for: o Reviewing the incident & grading- identifying level of investigation required and commencing timely investigation o Making safe, taking necessary immediate remedial action to prevent a re-occurrence o Checking on patient / donor / staff safety & wellbeing o Provide investigation outcome feedback to relevant staff, patients/donors o to ensure all actions to prevent a re-occurrence are taken and sustained o Sharing lessons learned • Highlighting those incidents that need reporting to external agencies
For more information or advice in relation to the Incident Reporting Policy. Please contact the Trust Quality and Safety team	
Please note this is only a summary of the policy and should be read in conjunction with the full policy document and with local procedures.	

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1. INTRODUCTION

Velindre University NHS Trust is committed to ensuring the health, safety and welfare of its staff, patients, donors, visitors and all users of its premises and services, and its impact on the environment by being pro-active in its approach to reduce the number of incidents and near misses.

Incidents are those unplanned or uncontrolled events or a sequence of events that lead to or result in injury, damage or loss. Near misses are similar but no harm, injury or loss has occurred although there was potential for this to occur. The Trust has a duty to protect its' assets from all threats whether internal, external, deliberate or accidental.

It is essential that all incidents near misses, cases of work-related injury or ill-health and hazards are reported in a consistent manner, this policy outlines the overarching process that all service divisions/hosted organisation will follow. However, further local procedures that support this policy may be in place where additional guidance for staff is required.

Incident Reporting Systems are a major tool in the way organisations manage risks and improve safety. Their purpose is to:

- Ensure that all incidents/accidents (actual and near miss) are reported, recorded and managed
- Prevent the recurrence of preventable adverse clinical and non-clinical events
- Provide 'early warning' of complaints/claims/adverse publicity
- Ensure that sufficient information is obtained:
  - to meet internal and external (e.g. Welsh Government, HSE) reporting requirements
  - to respond to complaints and litigation should these ensue
  - for trend analysis which, in turn, is intended to facilitate the identification and 'learning of lessons' from incidents/mistakes made

This policy is developed in line with the requirements of the following legislation:

- The NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulation 2011
- The Health and Safety at Work etc. Act 1974
- Reporting of Injuries Diseases and Dangerous Occurrences Regulations 2013

If used effectively the incident reporting system will ensure action is taken when incidents / near misses occur to prevent a re-occurrence and enable the Trust to quickly and effectively learn and improve reducing the impact and likelihood of future harm.

The Trust engenders an open and fair culture where staff are comfortable with reporting incidents, near misses and hazards. The aim of reporting and investigating incidents is to prevent reoccurrence, identify the immediate and root cause and learn lessons, and not to blame individuals. This policy also outlines the management responsibilities for reviewing and identifying appropriate investigation and feedback mechanisms to the incident reporter and for sharing lessons learned.

The Policy also highlights the reporting arrangements required for the Trust to comply with its statutory duty in notifying external agencies including the Welsh Government, Healthcare

Inspectorate Wales (HIW), Information Commissioners Office (ICO), Medicines and Healthcare products Regulatory Agency and the Health and Safety Executive (HSE).

2. POLICY STATEMENT

Velindre University NHS Trust is committed to ensuring the health, safety and wellbeing of all its staff, patients, donors and service users, by providing a safe and secure environment and safe systems of work in which staff can deliver safe and effective services.

All staff / contractors are required to report any incident or near miss that occurs during their working activities. When an incident occurs that causes an injury medical advice and /or first aid should also be sought. The incident must be reported immediately on the Datix system and reported verbally to the person in charge / Manager/supervisor prior to leaving site. The person in charge/Manager/supervisor will discuss the incident, undertake an immediate review, take any required remedial action to prevent a re-occurrence and ensure the wellbeing of all involved.

The Trust promotes an 'open and fair' culture where reporting an incident or near miss will not normally lead to instigation of the Trust Disciplinary Policy unless under exceptional circumstances for example:

- where there is criminal or malicious activity (including malicious reporting)
- acts of gross misconduct or gross negligence
- and repeated unreported errors or violations of procedure.

3. AIMS

To ensure the Trust and all its staff report, investigate, feedback and learn from incidents and near misses in a timely way in order to reduce risk and harm through a culture of openness, transparency, robust enquiry / investigation and no-blame. Therefore that Velindre University NHS Trust will have a positive reporting and learning culture.

4. OBJECTIVES

- To ensure that all incidents, near misses and hazards are reported and managed appropriately and effectively within a supportive framework.
- To promote an open and transparent culture in where incidents are reported and investigated appropriately and to ensure lessons learnt are shared across the Trust.
- To ensure that the Trust is able to effectively manage the risks to which it is exposed, which may arise from hazards or result in incidents and near misses.
- To enable the Trust to comply fully with legislation and mandatory requirements in relation to incident reporting.
- To ensure the Trust proactively monitors incidents to identify emerging patterns or trends so that required system changes can be identified.
- To ensure reflection and learning at an individual, team and wider level.

5. SCOPE

This policy applies to all employees, including temporary or contracted staff who work

within or for Velindre University NHS Trust (The Trust) and covers the service divisions and hosted organisations including all patients, donors or members of the public who are accessing Trust services.

6. OPEN & FAIR CULTURE

In line with the Health and Social Care Quality and Engagement (Wales) Act 2020, the Trust will implement an open and transparent approach to the management of incidents, and ensure procedures are in place to enable delivery against the Regulations. This will enable lessons to be learnt and risks reduced as far as is reasonably practicable.

The Trust encourages all staff to report incidents without fear of personal reprimand or detriment. The emphasis is on the "how" and “why” rather than the "who".

To achieve this, the incident investigation process must be:

- Fair and equitable
- Consistent and systematic
- Focused on learning and change
- Focused on identifying contributory factors and root causes
- Timely

In accordance with the principles of clinical governance, disciplinary action would not normally result from reporting incidents, mistakes or near misses but other procedures may apply.

7. DEFINITIONS

These definitions apply throughout the policy.

The Trust: Velindre University NHS Trust policy and terminology covers all Service Divisions and Hosted Organisations.
Service Division: Defined as any Service Division or Hosted Organisation that have their own internal management structure.
Accident: Any unplanned, unwanted event that results in injury or ill-health to employees, patients, donors or service users visitors, contractors, members of the public on Trust property or results in property damage. **Incident:** An event that does not cause harm but has the potential to do so in many organisation termed as near misses **Please note:** Only incidents that are related to, or in connection with the Trust activities should be reported. Throughout the policy the term ‘incident’ covers all incidents, serious untoward incidents and near misses that affect the whole of the Trust regardless of the Service Division or Hosted Organisation.

Nationally Reportable Incident: In general terms an NRI is defined as: *"Something out of the ordinary or unexpected or likely to attract public or media interest."* An incident may be declared as an NRI if it involves a large number of patients/service users, there is a question of poor clinical or management judgment, a service has failed, a patient/service user has died under unusual circumstances or there is a perception that any of these has occurred. Examples of Serious Incidents and the procedure to be followed in the event of such an incident occurring appears **in Appendix 1**
Never Event: Are very serious, largely preventable patient safety incidents that should not occur if the relevant preventable measures have been put in place. Examples appear **in Appendix 9**
Near Miss: A 'near miss' as defined by the Health and Safety Executive (HSE), is any incident, accident or emergency which did not result in an injury but has the potential to
HSE: Health and Safety Executive
Hazard: Anything with the potential to cause harm, injury or loss as defined by the HSE
Risk: A risk is the chance, high or low, of somebody being harmed by the hazard, and how serious the harm could be, as defined by the HSE. Impact x Likelihood= Risk Rating.
RIDDOR: Abbreviation for Reporting Injuries, Diseases and Dangerous Occurrences Regulations.(2013)
Root cause analysis: A method used in investigation process to identify underlying causes of an incident. E.g. Incident Decision Tree, 5 WHYS, Fishbone, Fault Tree Analysis, Failure Modes and Effect analysis.
Risk Assessment: A careful examination of what in the workplace or work activity could cause harm, a documented process that uses a numerical calculation to identify the risk rating. For full details see Trust Risk Assessment Policy
Competence: To establish if a person is competent: The person must have the appropriate and relevant qualification, knowledge, skills and experience to perform their duties.
Duty of Candour: Candour means the quality of being open and honest: transparency, fairness; impartiality. Placing a duty of candour on NHS bodies and primary care providers, through the Health and Social Care (Quality and Engagement) (Wales) Act 2020[1] ('the Act'), highlights the Welsh Government's commitment to safe, effective and person-centred health services.
Duty of Quality: The Duty of Quality seeks to improve the health services for the people of Wales providing evidence based around the 6 domains of Quality (as defined by the Institute of Medicine)
OfWCMS: Once for Wales Concerns Management System DATIX. This is the hosting platform on which incidents, feedback, claims, alerts, mortality review and learning can be capture in a central repository.

[1] https://www.legislation.gov.uk/asc/2020/1/contents

8. ROLES & RESPONSIBILITIES

8.1 Chief Executive: The 'Chief Executive', carries overall accountability for ensuring compliance with the Health and Safety at Work etc. Act 1974 and associated legislation and for ensuring that the risk management, governance and incident reporting systems are in place and functioning effectively.

8.2 Executive Director of Nursing, Allied Health Professional and Health Science: The Executive Director of Nursing, Allied Health Professionals and Health Science has Board level responsibility for ensuring that a robust and effective quality and safety infrastructure is in place that includes an incident reporting system is in place. The board level role also includes:

- Advising the Chief Executive and Executive Directors regarding incidents that may constitute a Nationally Reportable Incident
- Ensuring there are robust systems in place that relevant external agencies are notified when required
- Ensuring that systems are in place for incident trends to be monitored and reviewed
- Ensuring robust processes for identification of learning.

8.3 Corporate / Divisional / Hosted Organisation Directors: Directors are responsible for ensuring effective incident management systems within their areas of responsibility. Directors are also responsible for ensuring that reporting of incidents and trends to an appropriate Divisional Senior Management Committee or Team takes place and for ensuring that any required local procedures are in place to support the overarching Trust Policy.

8.4 Trust Quality and Safety Department: The Trust Quality and Safety department is responsible for:

- Taking the lead investigators role in all incidents resulting in severe harm or death.
- Providing support to the Service Divisions in relation to the maintenance of the OfWCMS- Once for Wales Concerns Management System-DATIX
- The appropriate reporting to external organisations /agencies
- Providing assistance, support and advice on the investigation process
- Ensuring that Trust wide incident analysis and identification of trends are reported and shared
- Ensuring that demonstration of learning has taken place
- Auditing compliance with this policy and incident processes
- Providing appropriate incident, investigation and Datix training for those that require it.

8.5 Managers: All Managers are responsible for:

- Engendering a positive incident / near miss reporting culture across all areas of responsibility;
- Ensuring all recorded incidents are reviewed and investigated within required time periods and that all such records are held on Datix. This will include;

- to review any incidents occurring in their area
- to identify any remedial action required though an initial management review
- to review and record the severity of actual injury or harm
- to identify those incidents requiring a proportionate review and the appropriate person to conduct the review
- to identify any lessons learnt that can be shared with other departments or committees
- to review in a timely manner
- to record all outcomes and feedback to staff

- Ensuring that staff have received any required Datix, investigation training;
- Ensuring that investigations are undertaken by trained and competent staff and are independent from staff directly involved in the incident;
- Ensuring that their area is a safe environment for staff patients, donors, visitors and service users and where incidents have been reported for ensuring any faulty equipment and estate defects are taken out of use if appropriate and reported to the appropriate personnel for remedial action to be implemented;
- Ensuring prompt identification of any incident that should / may need reporting to an external regulatory body / Organisation and ensuring that this is undertaken within the stipulated time period

8.6 All Staff: All staff are responsible for reporting incidents / near misses that occur during their working activities or shift, in a timely manner via the approved procedure and for making the area safe unless they are injured and ensure they have received the required training / support to be able to do this.

9. TRAINING & AWARENESS

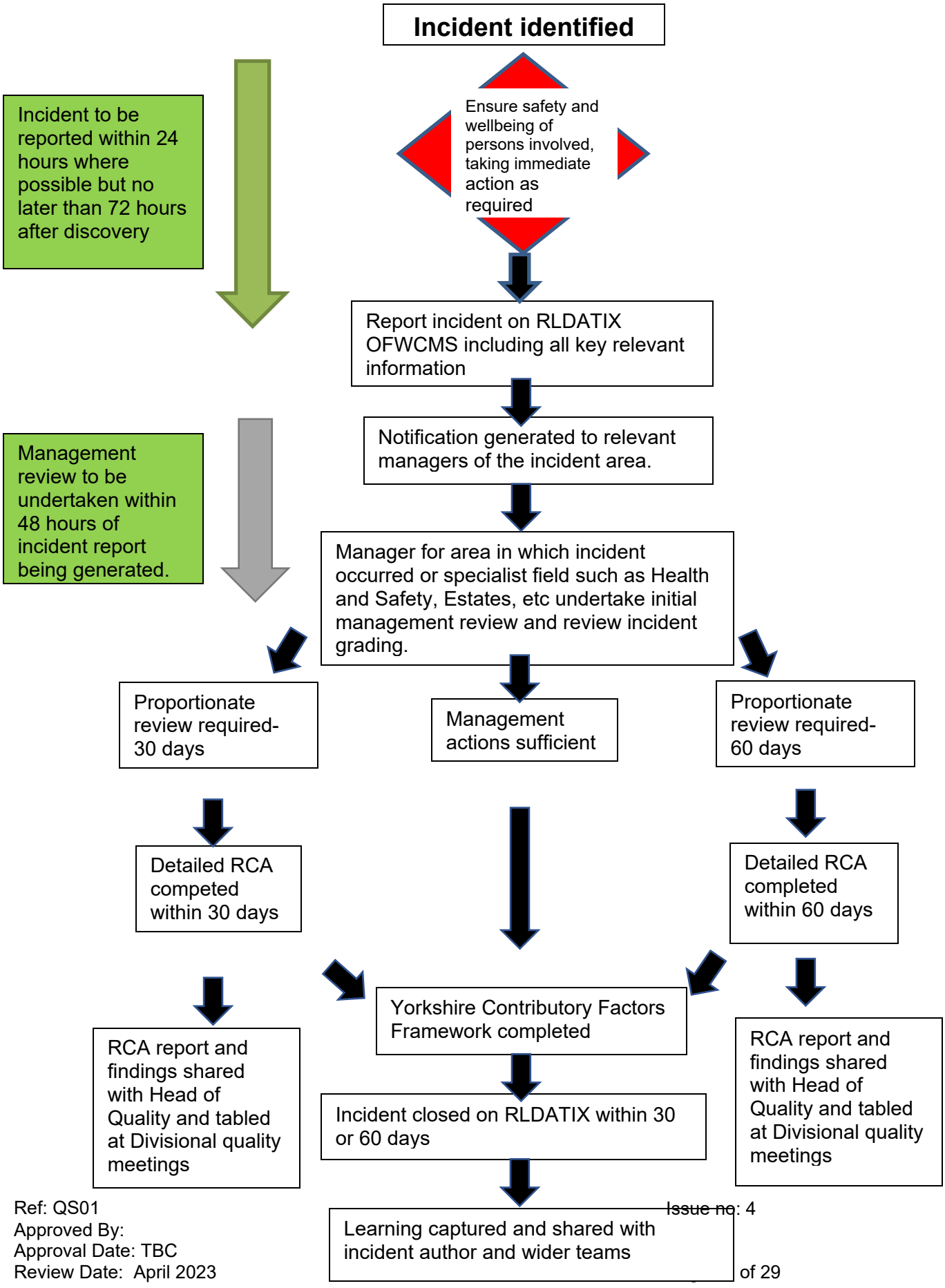
It is the responsibility of all staff to report incidents on the RLDATIX system with the Trust providing training to enable staff to understand where and how this can be done. There is a range of training available across the Trust which includes online e-learning packages and support guides on the intranet pages.
Additional training is provided to staff who will be investigating and managing the review of an incident. This includes access to a suite of short training sessions to include areas around human factors, handling difficult conversations, investigation training, root cause analysis and report writing.
Further specific training is provided within IOSH managing safely and working safely upon request. Competence to deliver training must be in line with core skills framework and reviewed during annual appraisals.

10. INCIDENT REPORTING

The priority on the discovery of an incident is to ensure and maintain the safety and wellbeing of any persons involved and minimizing the risk of harm. If required immediate action such be taken such as escalation emergency services.

The following flow chart, overleaf, captures the process to be undertaking on the discovery of an incident:

10.1 Incident reporting mechanism - OfWCMS- Once for Wales Concerns



Management System-DATIX
All incidents are recorded into a single incident reporting system (OfWCMS). Any staff member may report directly into an online web based form, which is available via the Velindre UNHST Intranet. An incident for should be completed ideally within 24 hours but no later than 72 hours following the identification of the incident. The form is available on the Trust intranet pages. The RLDATIX user guides are available on the VUNHST intranet and can be reference to support the completion of an incident.

It is important to include all key information relevant to the incident. All sections of the form with a * are mandatory and must be completed. Failure to do so before you submit the form will revert you back to the required section. Once you have input and submitted your form an automatic notification is issued to the relevant Manager of the incident area. It is important to include factual information and including supporting documentation such as photographs where applicable. Patient or donor identifiable data should not be included in any of the free text boxes and capture in the patient information section of the form.

10.2 Incident Coding
Once added to DATIX, all incidents are given a classification 'code'. This enables the same types of incidents to be grouped together, which in turn aides the analysis process in order to identify trends/problems. The coding of incidents in this way also enables the easy identification/selection of the incidents, which must be reported externally.

Within the Trust, the coding and grading of incidents is undertaken by the reporter.

The coding and grading is reviewed by the nominated manager and the Quality and Safety Team or Health and Safety Team.

10.3 Incident Grading
In accordance with national guidance and good risk management practice, all incidents reported within the Trust will be graded using the principles adopted for the proactive risk assessment. Grading is undertaken according to the:

- Actual impact on the affected person(s), whether patient, member of staff or visitor to the Trust
- Actual or potential consequences for the organisation, and
- Likelihood of recurrence

The grading of incidents will assist in establishing the level of:

- Risk associated with a particular incident; and
- Investigation required, for example, concise or comprehensive / root cause analysis.

Table showing levels (grades) of incidents

Level of Harm	Explanation
Level 1:- No harm	A situation where no harm incident occurred, either a prevented patient safety incident or a no harm patient safety incident.
Level 2:- Minor Harm	Any unexpected or unintended incident which required extra observations or minor treatment and caused minimal harm, to one or more persons.
Level 3:- Moderate harm	Any unexpected or unintended incident which resulted in further treatment, possible surgical intervention, cancelling of treatment, or transfer to another area and which caused short term harm, to one or more persons.
Level 4:- Major Harm	Any unexpected or unintended incident that caused permanent or long-term harm, to one or more persons.
Level 5:- Catastrophic Harm	Any unexpected or unintended incident which caused the death of one or more persons.

10.4 Manager's responsibility and guide

The Manager is responsible for incidents occurring in areas under their direct control, e.g. office, department etc. In certain circumstances the estates or facilities Manager will be responsible for the area but not the staff. E.g. Staff member has a fall on the stairs, this is not normally related to their own area it is a shared communal space any investigation will be done by the Estates or Facilities Manager or appointed person.

When an incident has been submitted into the system, the Manager of the incident area should receive an automated notification from OfWCMS that an incident has occurred. The Manager will discuss the incident with the staff member and review the incident, ensuring it is factual and any remedial action is input into the report.

The Manager is responsible for grading the incident based on the actual injury or harm caused, using the risk matrix see **Appendix 2.** The manager will record the grading in the DATIX incident record, where there is no injury or harm caused this must also be recoded.

The Manager will instigate an investigation where required and may decide to perform the investigation or identify an appropriate competent Investigating Officer to perform the investigation.

Where the incident involves a patient, the Manager should consider if the incident is referred to a review group such as the Falls or Pressure Ulcer review panels.

Levels of Investigation within the OfWCMS- Once for Wales Concerns Management System-DATIX are:

- Management Review and Make it Safe Plus - It is the responsibility of the allocated manager to review the incident record and complete the management review/make it safe plus section. This involves checking the information included in the incident

record, to ensure that it is accurate, complete, relevant, reliable and timely. If following Management Review/Make it Safe Plus it is sufficient to close, the Yorkshire Contributory Classification Framework* and conclusion will appear for completion.

- Proportionate Investigation - If following Management Review/Make it Safe Plus a proportionate investigation is required, the form will trigger the following options for the allocated manager to complete.

    - Proportionate Investigation – 30 days
    - Proportionate Investigation – 60 days

If the incident is ready to close following the Proportionate Investigation, the Yorkshire Contributory Classification Framework and Conclusion will appear for completion.

10.5 Reporting a Nationally Reportable Incident (NRI's)
Initially, Nationally Reportable Incidents (NRI's)'s are also reported in the same way as all other incidents. If the reporter or Manager suspects the incident may be an NRI they must take further action. Guidance is available on categorisation of an NRI although the list is not exhaustive see **Appendix 1.**

If the incident is categorised as an NRI, the Service Division will inform and brief the Executive Director of Nursing, Allied Health Professionals and Health Science or the Chief Executive (or other Executive Director in their absence). The Executive Director of Nursing, Allied health Professionals and Health Science will identify the required action.

It is important that NRI's are identified quickly for an investigation to commence, in some circumstances an NRI will not be initially identified, however they may later be re-categorised. This is a preferred option rather than delaying until an investigation has been completed. Exceptionally an incident may only be recognised as an NRI some time after the event. In such cases the member of staff for whom such evidence comes to light must report it immediately.

NRI's will be scored for severity on the potential impact and the potential likelihood, due to their nature. All NRI's will require full investigation using an appropriate root cause analysis technique.

Further information is available from the Wales Delivery Unit.

11. INVESTIGATION

It is important to emphasise that the benefits of the investigation process are to prevent further incidents from occurring. The investigation process will identify failings and underlying causes without apportioning blame and by putting appropriate control measures in place will ensure a safe working environment and improve staff morale.

The Manager will determine the severity of the incident based on actual harm using the matrix in **Appendix 2** and will also identify the level of investigation required and identify a

competent Investigating Officer (IO) or will investigate the incident themselves.

A proportionate investigation may not be needed for all incidents, where incidents have no injury or harm the Manager will discuss the incident with the person affected and identify if any remedial action is required and ensure it is implemented. This information will be recorded in the OfWCMS.

The Manager will collect physical evidence immediately or may identify an appropriate person to do so. This is particularly important where incidents are serious, complex or could result in litigation or prosecution. Evidence to be collected may include physical, documentary and supporting information, and is not limited to the following:

- Photographs of the environment where the incident occurred and of any items contributing to the incident E.g. equipment, machinery, labels on medicines or substances, warning signs etc.
- Maintenance records, for equipment
- Relevant pages of patient notes
- Material safety data sheets
- Documented risk assessments
- Safe systems of work and written instructions given to staff
- Training records
- Observations noted at the time of the incident e.g. weather, lighting, wet floors
- Comments from witnesses who overheard an incident, but may not have seen it
- Witness statements

A systematic process is advised when performing an investigation which is proportionate to the incident. The OfWCMS DATIX system supports the use of the Yorkshire Contributory Tool to support the investigation with information captured on the relevant section on the form.

All additional information that is not directly inputted on to the incident report form must be scanned or uploaded into the documents section of the incident report within OfWCMS. These will include all the correspondence, photographs and documents related to the incident.

12. STAFF SUPPORT

All staff involved in an incident must be offered appropriate support or guidance to ensure staff wellbeing is maintained.

Staff involved in or witnessing significant incidents may become distressed and suffer psychological harm and become anxious when returning to work. Staff may need support and counselling there are a number of support mechanisms in place across the Trust.

Managers and colleagues may offer informal support. Where staff may need professional

help, advice and support is available from Occupational Health, there are two ways to access this service either by speaking to your Manager or HR who may refer you or self-referral is available. The Trust has subscribed to Workplace Options who provide the Employee Assistance Programme which offers a range of counselling services 24/7 and is a free and confidential service. For more advice on staff support see your local procedure/notice boards and the Trust intranetsite.

13. REPORTING

13.1 Internal Committees

13.1.1 Divisional

Incident reporting activity will be used to inform quality, safety and governance agendas at departmental and divisional level to enable trend analysis and learning in support of the Duty of Quality and Duty of Candour agendas. Local managers are encourage to use incident data to ensure that those reporting are aware of outcomes and learning.

13.1.2 Trust

The Trust Quality and Safety Committee will receive incident activity reports and analysis of output and learning that has informed service delivery and development.

The Trust Quality and Safety Committee will provide evidence based and timely advice to the Trust Board to assist with discharging its functions and meeting its responsibilities.

The Trust Quality and safety Committee will receive assurance that services are delivery safe care aligned to the evolving requirement under the Duty of Quality and the Duty of Candour.

Specific Trust Board Committees such as the Health, Safety and Fire Management Board will monitor a range of health and safety topics and receive a quarterly health and safety incident report and the health and safety dashboard that includes relevant key performance indicators for discussion and review.

The Health Safety and Management Board will be chaired by the Director of Strategic Transformation, Planning and Digital who will ensure that the Health and Safety Committee meets it statutory obligations and disseminates relevant health and safety information to the Trust Quality and Safety Committee.

Attendance at the Trust Health, Safety and Fire Management Board is attended by the Trust Health and Safety Manager and management representatives from each Service Division/Hosted Organisation, with authority to discuss and explain their Divisional reports.

13.2 External Agencies

All incidents reported to external agencies must be raised and discussed at the appropriate Trust-wide committees to ensure incidents are appropriately discussed internally and any lessons learned can be identified and disseminated. E.g. The Trust Health, Safety and Fire or the Quality and Safety Committee. For advice and guidance on external reporting contact

the Trust Quality and Safety Department.

13.2.1 Health and Safety Executive (HSE)

Reporting Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)

All Divisions/Hosted Organisations are responsible for ensuring that an approved process is in place that ensures a competent person is identified to report Divisional incidents directly to the incident reporting centre. All incidents identified as potentially RIDDOR reportable should be discussed with the Trust Health and Safety Manager prior to a report being submitted to HSE. The Trust Claims Manager should also be informed of any incidents reported under this legislation.

Failure to report a reportable injury or a dangerous occurrence or disease in accordance with the requirements of RIDDOR is a criminal offence and may result in prosecution.

Reporting an incident is **not** an admission of liability.

13.2.2 Medicines and Healthcare Products Regulatory Agency (MHRA)

All Divisions/Hosted organisations are responsible ensuring a competent person is identified to reporting directly to the MHRA in line with local procedures.

13.2.3 Welsh Government

The Trust are required to provide the Welsh Government with a range of incident information and statistical report which are co-ordinated via the Trust Quality and Safety Department on a quarterly basis. The Divisions are required to assist in this process upon request.

13.2.4 Delivery Unit

The Trust Datix Support Manager will compile reports from the OfWCMS- Once for Wales Concerns Management System-DATIX of all Patient Safety Incidents, these reports are submitted via the NHS Wales Delivery Unit on a monthly basis.

14. LEARNING FROM INCIDENTS

It is important that learning from incidents is shared throughout the Trust. Divisional/Hosted Organisations information on incidents and trends should be reported and discussed and lessons learned shared at the appropriate Divisional Senior Management Team meeting or other appropriate Health and Safety/Risk Management meeting.

Other appropriate means for learning to be shared Trust wide include:

- Internal alerts disseminated to Service Divisions by the Trust Quality & Safety Department
- Reports and action plans to be monitored at the Organisational Learning Committees
- Feedback from Union Safety Representatives following attendance at

15. FEEDBACK

It is the Manager's responsibility to feedback on any outcome or action to any person reporting and involved in an incident. This will include patients and donors. It is essential to thank the person for reporting the incident and also to provide an update on any action proposed or taken, to demonstrate that their incident was taken seriously.

The feedback process will highlight any repair, replacement or changes to working practices and any outcome of an investigation. This will demonstrate that the learning process is being completed.

It is preferable that the manager provides the feedback with all involved and the person who reported the incident in person. This affords the opportunity for two way dialogue and discussions in relation to the appropriateness and effectiveness of improvement actions that have been put in place. If this is not possible feedback should be provided electronically via email. This feedback should also be recorded in the incident record on Datix.

16. MONITORING

It is necessary to ensure that this policy is disseminated and promoted across the Trust to ensure that a standard approach to incident reporting and investigation is implemented. The Quality and Safety department will monitor compliance by using various methods, a review of incident forms input in a timely manner, completion of the severity of incident closure of incidents etc. The results will be reported to the Service Divisions and discussed in the Trust Health, Safety and Fire Management Board and at the Trust Quality and Safety Committee.

17. EQUALITY IMPACT ASSESSMENT

The Trust is committed to ensuring, as far as is reasonably practicable, the way it provides services to the public and the way it treats its staff reflects their individual needs and does not discriminate against individuals or groups. An equality impact assessment was completed and found that there was **no impact** against individuals or groups.

18. IMPLEMENTATION

The Trust will actively promote awareness and understanding of this policy, linking to existing organisational development programmes, where possible.

Service Directors will implement the policy within their division and ensure where appropriate that local procedures generated support this policy. Additionally, there will be supporting guidance available the intranet site and information disseminated via internal communication channels and dedicated awareness training available upon request.

19. DISTRIBITION

The Incident Reporting and Investigation Policy will be available via the Trust intranet and internet sites. Where staff do not have access to the intranet their line manager must ensure that they have access to a copy of this policy.

20. SUPPORTING POLICIES

The following policies should be read in conjunction with this Policy:

- Trust Health & Safety and Welfare Policy.
- Trust Risk Assessment Policy
- Trust Being Open Policy
- Trust Handling Concerns Policy
- The Whistleblowing/Right to Raise Concerns in the Public Interest Policy for staff to raise specific concerns as identified in the policy.
- Guidance document – Once for Wales Concerns Management System DATIX incident reporting

Appendix 1

Nationally Reportable Incidents (NRI)

Delivery Unit/NHS Executive

The Trust is required to report certain incidents to the NHS Wales Delivery Unit. The following definition of a nationally reportable patient safety incident applies:

> "A patient safety incident which caused or contributed to the unexpected or avoidable death, or severe harm, of one or more patients, staff** or members of the public, during NHS funded healthcare*"

The above definition of an incident is applicable to all NHS funded services, regardless of speciality, delivered in all secondary or primary care settings, including community based services.

A patient safety incident will be nationally reported within seven working days from the occurrence, or point of knowledge, if it is assessed or suspected an action or inaction in the course of a service user's treatment or care, in any healthcare setting, has, or is likely to have caused or contributed to their unexpected or avoidable death, or caused or contributed to severe harm.

The following specific categories of patient safety incidents must be reported:

- Suspected homicides where the alleged perpetrator has been under the care of mental health services in the past 12 months
- In-patient suicides
- Maternal deaths
- Never Events (see section 8.6)
- Incidents where the number of patients affected is significant such as those involving screening, IT, public health and population level incidents, possibly as the result of a system failure
- Unusual, unexpected or surprising incidents where the seriousness of the incident requires it to be nationally reported and the learning would be beneficial

The Trust is also required to report the following in specific circumstances:

- Pressure Ulcers (avoidable - Grade 3 / Grade 4 / Unstageable)
- Unexpected deaths in the community of patients known to MH&LD Services
- Safeguarding
- Procedural Response to Unexpected Death in Childhood (PRUDiC)
- Abuse / Suspected Abuse
- Healthcare Acquired Infections (HCAIs)

In all cases the immediate management of the incident is paramount including the safety of the patient affected and other patients. The Divisional Director must be informed of the incident and an incident report form submitted via Datix.

Reporting of nationally reportable incidents to the Delivery Unit will be undertaken by the Trust Quality and Safety Team.

Appendix 2

Please record in Datix Risk Management System.

The **Actual** severity level of the injury sustained. Where there is no injury sustained, please record no injury.

Severity Rating =	1	2	3	4	5
Domains	**Negligible**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Impact on the safety of patients, staff or public (physical or psychological harm)	Minimal injury requiring no /minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 1-3 days	Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days RIDDOR reportable incident. An event which impacts on a small number of patients	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients

Likelihood – MATRIX

	LIKELIHOOD DESCRIPTION
5 Almost Certain	Likely to occur, on many occasions
4 Likely	Will probably occur, but is not a persistent issue
3 Possible	May occur occasionally
2 Unlikely	Not expected it to happen, but may do
1 Rare	Can't believe that this will ever happen

Risk Rating Matrix = Impact x likelihood

	LIKELIHOOD				
IMPACT	**Certain 5**	**Likely 4**	**Possible 3**	**Unlikely 2**	**Rare 1**
5 Catastrophic	**25**	**20**	**15**	**10**	**5**
4 Major	**20**	**16**	**12**	**8**	**4**
3 Moderate	**15**	**12**	**9**	**6**	**3**
2 Minor	**10**	**8**	**6**	**4**	**2**
1 Insignificant	**5**	**4**	**3**	**2**	**1**

Risk score and Action timetable.

Risk Score	Risk Level	Action and Timescale
1-3	LOW	No action required providing adequate controls in place.
4-6	MODERATE	Action required to reduce/control risk within 12 month period
8-12	SIGNIFICANT	Action required to reduce/control risk within 6 month period
15-25	CRITICAL	Immediate action required by Senior Management

Appendix 3

Categories and types of incident.
General guidance (Not an exhaustive list):

Type	Category	Sub category
Health and Safety	Fire Ill health- work related Manual handling (patient) Manual handling inanimate load Sharps Violence and Aggression	Fire alarm activation Work related stress Lifting a patient Lifting a load Needle-stick clean/dirty Verbal abuse
Information Governance	Confidentiality Data protection Freedom of information Records management	Breach of confidentiality Breach of DPA principles Request not processed Consent issues
Clinical Patient & Clients	Blood transfusion issues Chemotherapy issues Communication Complications of treatment Diagnosis error Dignity issue Radiotherapy patient specific Safeguarding issue POVA issue Unsafe clinical environment	
Operational and Organisational	Buildings and plant incident Equipment Security	Buildings fault or failure Equipment failure or fault Information or building security and theft
Quality Assurance	Product defect Research and Development issues	

Appendix 4

Witness Statement

Witness Name:
Job Title:
Work Telephone Number:
Date and Time of incident:
Exact Location of the incident: …… E.g. NWIS Reception, VCC Ward, Corporate HQ first floor open plan, WBS mobile unit Tesco Llantrisant:
FACTUAL ACCOUNT OF EVENT: Please make a note of all FACTS relating to the incident including what you saw, what you heard, what the environment was like and what the weather conditions were (if appropriate).
…… …… …… …… …… …… …… …… …… …… …… ……
This is a factual statement of events: Signature …… date……..

Appendix 5

Investigation Process – Guidance

It is important to emphasise that the benefits of the investigation process is about preventing the incident from happening again and identifying the failings and underlying causes and not apportion blame. Reviewing the Safe Systems of Work with the underlying causes will identify any gaps. Sharing the findings is as important as ensuring the quality of the investigation.

The Manager will determine the level of severity of the incident and will identify a competent Investigating Officer (IO) and in some cases will perform the investigation themselves.

The IO will lead the investigation and will facilitate any assistance required where necessary identifying who will support the review depending on circumstances the following should be considered:

- □ Someone familiar with the work location
- □ Supervisor or Manager of the work location
- □ Senior manager with authority or influence
- □ Health and safety expert and or technical expert
- □ Employee representative
- □ Person involved if possible

The IO or team will collect any further information and will complete any interviews with witnesses, patients, service users and staff. Ensuring documented statements are taken.

The IO or team will analyse all evidence collected as part of the immediate response and ensure where required that an appropriate specialist examines any equipment thought to be faulty and that a report is provided by the specialist on the outcome.

The IO or team will analyse all the evidence collected and using an appropriate root cause analysis tool e.g. Incident Decision Tree, 5 WHYS, Fishbone, Fault Tree Analysis, Failure Modes and Effect analysis. The IO will use the best tool for the incident and identify direct causes and any underlying causes.

Where the incident is general the IO will conduct a proportionate review and capture the content using the Yorkshire Contributory Framework on the DATIX record.

The aim of the review is to identify any immediate or underlying causes and consider any gaps in the process or procedures and recommend remedial action and share information to learn lessons from the incident.

Appendix 6

Never Events as identified by the Department of Health

Never events are very serious, largely preventable patient safety incidents that should not occur if the relevant preventable measures have been put in place. The UK Government has identified a list of 25 Never Events. Velindre has reviewed this list and identify with 21 Never Events.

- □ either resulted in severe harm or death or had the potential to do so
- □ there is evidence that the never event has occurred in the past and is a known source of risk (for example through reports to the NRLS or other serious incident reporting system).
- □ there is existing national guidance or safety recommendations, which if followed, would have prevented the incident from occurring.
- □ occurrence of the never event can be easily identified, defined and measured on an ongoing basis.

It is the Managers responsibility to identify if the incident is a never event and to ensure that the incident is classified and reported to NRLS via the Datix Risk Management System.

The manager will also ensure the incident is investigated to identify compliance and the robustness of systems and processes, and also human factors using an appropriate root cause analysis tool and where possible to examine and identify how the issues can be mitigated to prevent recurrence.

The term should not be used for incidents that do not meet these criteria.

1. Wrong site surgery (existing)
2. Retained foreign object post-operation (existing)
3. Wrongly prepared high-risk injectable medication (new)
4. Maladministration of potassium-containing solutions (modified)
5. Wrong route administration of chemotherapy (existing)
6. Wrong route administration of oral/enteral treatment (new)
7. Intravenous administration of epidural medication (new)
8. Maladministration of Insulin (new)
9. Overdose of midazolam during conscious sedation (new)
10. Opioid overdose of an opioid-naive patient (new)
11. Inappropriate administration of daily oral methotrexate (new)
12. Suicide using non-collapsible rails (existing)
13. Falls from unrestricted windows (new)
14. Entrapment in bedrails (new)
15. Transfusion of ABO-incompatible blood components (new)

16. Misplaced naso- or oro-gastric tubes (modified)
17. Wrong gas administered (new)
18. Failure to monitor and respond to oxygen saturation (new)
19. Air embolism (new)
20. Misidentification of patients (new)
21. Severe scalding of patients (new)

QUALITY, SAFETY & PERFORMANCE COMMITTEE

Health and Social Care (Quality and Engagement) (Wales) Act 2020 Trust Preparedness

DATE OF MEETING	24th March 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Nicola Williams, Executive Director Nursing, AHP & Health Science
PRESENTED BY	Nicola Williams, Executive Director Nursing, AHP & Health Science
EXECUTIVE SPONSOR APPROVED	Nicola Williams, Executive Director Nursing, AHP & Health Science

REPORT PURPOSE	For Assurance

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Management Board	07/03/2022	Noted & Endorsed

ACRONYMS	

1. SITUATION

This paper provides the Quality, Safety & Performance Committee with an overview of the time lines for the NHS in Wales in respect of the Wales Health and Social Care (Quality and Engagement) (Wales) Act 2020 and preparedness plans to ensure the Trust is able to meet the Act requirements.

This paper will focus on two of the four elements of the Act: The Duty of Quality & Duty of Candour.

The Quality, Safety & Performance Committee are requested to **NOTE** the current national plans and timescales in respect of the Act and to **APPROVE** the Trust preparedness plans.

2. BACKGROUND

2.1 Act Overview

The Act aims to improve the quality of health services and ensure the citizens of Wales are kept at the heart of ever-improving health and social care services and has four main objectives:

- Greatly **strengthen the existing duty of quality** on NHS bodies and extend this to Welsh Ministers (in relation to their health service functions);
- **Institute a duty of candour** on NHS bodies in Wales (including primary care providers who provide NHS services), requiring them to be open and honest with patients and service users as soon as they are aware that things have gone wrong - or may have gone wrong, with their care or treatment;
- Strengthen the voice of citizens, by replacing Community Health Councils with a new, **all-Wales Citizen Voice Body** ('the CVB'), to represent the views and interests of people across health *and* social care;
- Enable the appointment of **vice chairs for NHS trusts**, bringing them into line with health boards.

The implementation of the Duty of Quality and Duty of Candour elements of the Act was initially planned for April 2022 but due to the impact of the pandemic this was delayed to April 2023.

There is a robust national Act Implementation infrastructure in place. This includes a National Oversight Group – Chaired by Dr Chris Jones, Deputy Chief Medical Officer and a National Duty of Candour & Duty of Quality Steering Group established to develop the relevant statutory guidance so that WG / Ministers & NHS Wales can execute their responsibilities – Chaired by the Executive Director Nursing, AHP & Health Science, Velindre University NHS Trust. There are a number of workstreams taking forward elements of the Act and Velindre has meaningful representation on these. To date, despite the pandemic there has been a good level of engagement from across all areas and disciplines within the NHS.

2.2 Duty of Quality

Requires health services & Welsh Minsters to demonstrate that quality is at the heart of all they do, ensuring they are **delivering services with a system-wide approach to achieve quality of care in a way that secures continuous improvement** in quality and improved outcomes for the population.

- Focusses on the **6 domains of quality**: Safe, Effective, Person-centred, Timely, Efficient, Equitable. It seeks to strengthen these domains across a maturing Quality Management System.
- Applies to all health service functions, not just clinical functions.
- Also applies to the Welsh Ministers with regard to their health related functions
- Ministers and NHS bodies will have to actively consider whether their decisions will improve service quality and secure improvement in outcomes.
- This approach supports the five ways of working in The Well-being of Future Generations (Wales) Act 2015 to achieve a healthier Wales.

NHS bodies must publish an annual report setting out how they have complied with the new Duty. This will build on and replace the current Annual Quality Statements. The report must include an assessment of the extent of any improvement in outcomes achieved. Welsh Ministers must also produce an annual report and lay this before the Senedd for scrutiny.

2.3 Duty of Candour

Strengthens the fundamental principles of 'Putting Things Right' and provides a robust process to support 'Being Open'.

The legal duty of candour will help achieve a position of consistent and routine practice whereby openness and transparency with people in relation to their care and treatment becomes a normal part of daily healthcare practices. The key intention is to promote the ethos of openness, learning and improving, which must be *owned at*

organisational level. The candour procedure and reporting framework encourages reflective learning and prevention of incidents occurring again.

3. ASSESSMENT

3.1 Duty of Candor & Duty of Quality Implementation Plans

The statutory guidance documents for both elements of the Act are under development. The timeline is as follows:

- May 2022 – Formal Consultation of Duty of Quality & Duty of Candor Statutory Guidance.
- October 2022 - Non Statutory launch
- April 2023 – Statutory launch.

The NHS Wales Putting Things Right (PTR) Regulations are being reviewed to ensure they are fully congruent with the Duty of Candour requirements. This is a minimal review rather that a substantial review.

It is proposed that the Health & Care Standards will be replaced by new Quality Standards – aligned to the six domains of Quality. This proposal will be widely consulted on in forthcoming months and if accepted will come into place in April 2023. The Quality Standards will apply to all Health related Welsh Government departments e.g. planning, performance, finance etc. putting quality at the centre of all decision making.

A suite of duty of quality performance standards / indicators are under development. These will be widely consulted on.

3.2 Proposed Act Preparedness Plans

3.2.1 *Establish a Trust Quality & Engagement Act Implementation Group*

Reporting Formally to Executive Management Board and feeding into Divisional SMT's and Hosted Organisations Senior Team Meetings. Chaired by the Deputy Director Nursing, Quality & Patient Experience. Attendance:

- Senior Quality Leads Divisions & hosted organisations
- Senior Clinical Leaders both Divisions including Scientific, Nursing, Pharmacy, AHP's, Radiation Services

- Assistant Medical Director Quality
- Corporate Governance Manager (inc. Risk)
- Director Welsh Blood Service
- Health & Safety Manager
- Claims Manager
- Quality & Safety Manager
- Information Governance Manager
- Deputy Director Organisational Development & Workforce
- Trust Quality & Safety Facilitator
- Communications
- Informatics
- Performance

Co-option – Other people will be co-opted on as required e.g. finance

The initial core roles of this group is to:

- Identify relevant policies, procedures that need review in light of Act / statutory guidance and oversee reviews
- Ensure relevant systems and processes are reviewed to ensure Act requirements are met
- Review Trust meeting infrastructure, propose any changes required to meet Act requirements
- Review current improvement infrastructure in line with Duty of Quality requirements
- Review Trust Performance Framework & informatics feed in line with Act requirements
- Identify training requirements and put training plan in place
- Produce monthly Trust wide preparedness communications – to include written, video, briefing sessions.
- Produce formal reports into Executive Management Board, Divisional SMT's, Hosted Organisation Senior Teams & Trust Quality, Safety & Performance Committee.

These will be reviewed and updated when the draft statutory guidance is produced.

3.2.2 *Trust Wide Senior Briefing Session* (April / May 2022)- Facilitated by the National Duty of Quality & Duty of Candor leads undertake a Trust wide briefing session. Audience to include: implementation Group, Executive Directors, Deputy Directors, Divisional Senior Management Teams.

3.2.3 *Board Briefing Session (Summer 2022)* - Facilitated by the National Duty of Quality & Duty of Candor leads.

4. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	Significant Quality & Safety implication – positive implication if requirements fully enacted.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below:
EQUALITY IMPACT ASSESSMENT COMPLETED	Yes
	Will be undertaken nationally.
LEGAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Trust has a legislative requirement to fully implement the Duty of Quality & Duty of Candour.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	There may be additional resources required for the full implementation of the Duty of Quality & Duty of Candour. The full requirement is not known until consultation statutory guidance documents are produced. The requirements have been factored in as far as known to the Quality & Safety Team OCP & the Quality Framework.

5. RECOMMENDATION

The Quality, Safety & Performance Committee are requested to **NOTE** the current national plans and timescales in respect of the Act and to **APPROVE** the Trust preparedness plans.

QUALITY SAFETY & PERFORMANCE COMMITTEE

IONISING RADIATION GOVERNANCE

DATE OF MEETING	24th March 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Dr Matthew Talboys
PRESENTED BY	Dr Matthew Talboys
EXECUTIVE SPONSOR APPROVED	Jacinta Abraham, Executive Medical Director
REPORT PURPOSE	FOR APPROVAL

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
N/A	N/A	Choose an item.

ACRONYMS	
IRR17	The Ionising Radiations Regulations 2017
IR(ME)R17	The Ionising Radiation (Medical Exposure) Regulations 2017
EPR16	The Environmental Permitting (England and Wales) Regulations 2016 as amended

1. SITUATION/BACKGROUND

The use of ionising radiation in healthcare is highly regulated through a number of Statutory Instruments. These primarily include:

- The Ionising Radiation (Medical Exposure) IR(ME)R Regulations 2017 which provides a framework intended to protect patients from the hazards associated with ionising radiation.
- The Ionising Radiations Regulations 2017 (IRR17) which provides a framework intended to protect staff and members of the public from the hazards associated with ionising radiation.
- The Environment Permitting (England and Wales) Regulations 2016 which provides a framework intended to protect the environment from the hazards associated with ionising radiation.

The Trust is either routinely subjected to or can be inspected by regulatory authorities including Healthcare Inspectorate Wales (HIW), Natural Resources Wales (NRW) and the Health and Safety Executive (HSE).

Legally, the Employer carries the overall responsibility for implementing the requirements of the regulations governing work involving ionising radiation throughout all Services managed by the Trust. This responsibility is discharged via the Chief Executive to the Executive Medical Director. Roles and responsibilities are define in the Trust Ionising Radiation Safety Policy (QS19).

To provide executive assurance regarding compliance with the use of ionising radiations, the Trust has established a Radiation Protection Committee (RPC), which incorporates the functions of a Medical Exposures Committee (MEC). The purpose of the RPC/MEC is to formulate appropriate policies, monitor the level of compliance in the various components of the Trust, identify areas of non-compliance and initiate remedial action, and to keep the Chief Executive informed of specific issues that require their attention. The RPC/MEC meets on a six monthly cycle with reports submitted to the Quality, Safety and Performance Committee.

Although Velindre University NHS Trust is small compared to Health Board equivalents, the use of ionising radiation within the Trust is disproportionately large, especially in the Radiation Sciences Directorate. With the current RPC/MEC structure, the RPC/MEC has become predominately operational in nature and has limited time for strategic oversight and direction setting. The governance model adopted by other Health Boards, are to have a more operational radiation protection group, dealing with operational issues, and a strategic group, which deals with the strategic direction of radiation protection governance and assurance. This provides a clear distinction between dealing with routine radiation protection issues and strategic setting of Trust wide policies and procedures.

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 In line with similar radiation protection governance structures in local Health Board equivalents, it is recommended that the governance meeting structures for radiation protection in the Trust is revised.

2.2 A Radiation Protection and Medical Exposures Operational Group is created within the Radiation Sciences Directorate to oversee operational compliance issues within the directorate. This will be chaired by the Head of Radiation Sciences and will meet on a three monthly cycle.

2.3 A Radiation Protection and Medical Exposures Strategic Group is created to receive assurance reports, escalate radiation protection issues and setting the direction of the operational divisions. This will be chaired by the Executive Medical Director and will meet on a six monthly cycle.

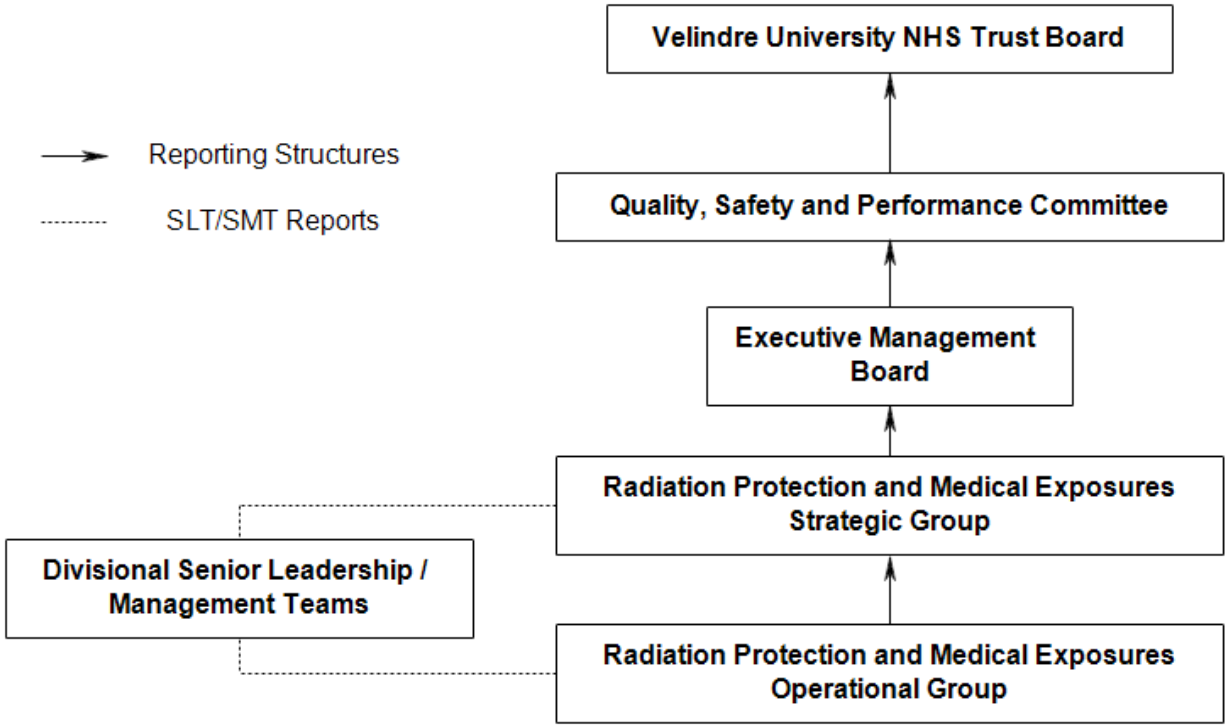
2.4 The operational Group will report directly to the strategic group. A highlight report will firstly be presented to EMB and then subsequently to the Quality, Safety and Performance Committee.

3. Action Points from EMB Run 6th December 2021 & 7th February 2022

The proposal has been agreed in principal by EMB on the 7th February 2022. The following points were discussed and have either been addressed or will shortly be completed.

- There needed to be clarity in relation to the governance infrastucture and reporting arrangements, as the flow charts were confusing and mixed individual responsibilities with the meeting reporting structure. There needs to be a separation in relation to the responsibilities and accountabilities for individuals and of the groups, in particular, how the operational group links and feeds into Nuclear Medicine and services at VCC, the relationship with the SLT at VCC and where the EMB sits within the governance arrangements.

  Reply: The governance infrastructure is noted in the diagram below.



- The title of the strategic group would need to be changed to subcommittee.

  Reply: Following discussions with the Director of Corporate Governance, it is suggested that the strategic group remains a group to ensure it is chaired by the Medical Director and does not require independent membership. Across the region, radiation protection committees / groups are exclusively professional led and this appears to be a departure to convention of radiation protection governance across the region to require independent membership.

- There was also a need to consider that ionising radiation and radiation protection was more than just the VCC, it also included the WBS.

  Reply: Yes, there will be representation on the strategic group of WBS.

4. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below:
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	There is no direct impact on resources as a result of the activity outlined in this report.

5. RECOMMENDATION

4.1 To endorse the new radiation protection governance structure.

Velindre University NHS Trust

Radiation Protection and Medical Exposures Operational Group (RPMEOG)

Terms of Reference

1.1 Introduction and Purpose

The use of ionising radiation in healthcare is highly regulated through a number of Statutory Instruments. These primarily include:

- The Ionising Radiation (Medical Exposure) IR(ME)R Regulations 2017 which provides a framework intended to protect patients from the hazards associated with ionising radiation.
- The Ionising Radiations Regulations 2017 which provides a framework intended to protect staff and members of the public from the hazards associated with ionising radiation.
- The Environment Permitting (England and Wales) Regulations 2016 which provides a framework intended to protect the environment from the hazards associated with ionising radiation.

In addition, the use of non-ionising radiations (e.g. MRI) can pose hazards to staff and the public which requires additional assurance.

The operational group has been created to provide operational updates and escalate issues from the radiation sciences directorate to the Radiation Protection and Medical Exposures Strategic Group. The group will manage the operational delivery and compliance with the Trust policies and procedures.

1.2 Objectives

The primary objective of the operational group is to provide assurance to the Strategic Group of the safe and effective use of radiation and to escalate compliance issues through the committee structures.

In addition the operational group will:

- Report on compliance with the regulations and Trust policies and procedures in radiation services.
- Discuss operational issues and agree escalation when required.
- Seek the advice of the appointed RPAs / RWAs / MPEs on regulatory compliance.
- Receive the outcome of audit reports and escalate contentious issues.
- Prepare for regulatory inspections and provide summary reports for the strategic Group regarding preparations and outcomes.
- Produce and agree local procedures dealing with the compliance with the regulations and Trust policies and procedures.

- Receive non-ionising radiation reports from Radiology and escalate issues identified.

1.3 Accountability

The Operational Group will be accountable to the Head of Radiation Services who reports to the strategic Group.

1.4 Membership

Head of Radiation Services (VCC - chair)
Appointed Radiation Protection Adviser(s)
Appointed Radioactive Waste Advisers(s)
Appointed Medical Physics Expert(s)
Appointed Radiation Protection Supervisors
Departmental Radiation Leads
Senior Leadership Team Representative

1.5 Quorum

Business will only be conducted if the meeting is quorate. The group will be quorate with 5 members including the chair.

1.6 Attendance by Members

The Chair and a representative of the Radiation Protection Service (Radiation Protection Adviser or Medical Physics Expert), or their nominated deputy will be expected to attend 100% of the meetings. Other group members and mandatory participants will be required to attend a minimum of 80% of all meetings and be allowed to send a Deputy to one meeting per annum.

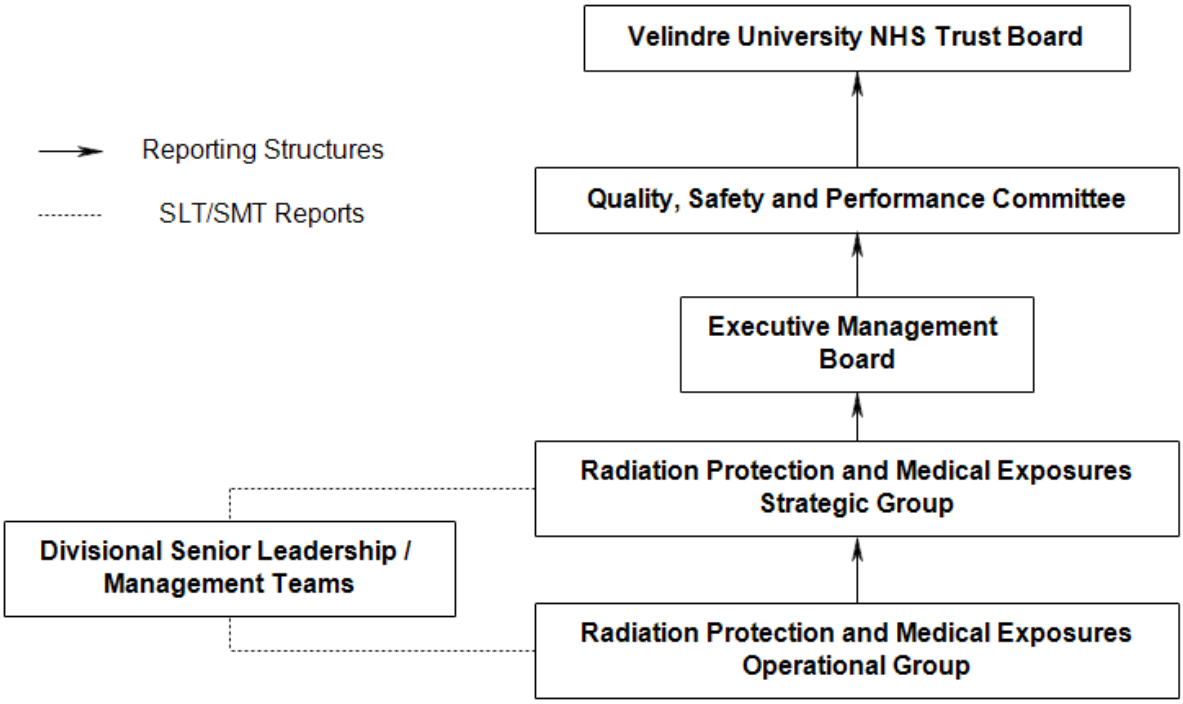
1.7 Frequency

The Operational Group will meet every 3 months.

Additional meetings may be arranged when required to support the effective and safe functioning of the services.

1.8 Reporting

The overall responsibility of ensure compliance with the regulatory requirements falls with the Chief Executive. The operational group will have links with the senior leadership team to ensure appropriate medical and non-medical senior representation on the Group. A report will be sent to the Radiation Protection and Medical Exposures Strategic Group. Any immediate actions needing executive input will be escalated to the executive management board.



1.9 Monitoring Effectiveness

The operational group will undertake an annual review of its performance against it Terms of Reference and work plan in order to evaluate the achievement of its duties. This review will be presented to the Radiation Protection and Medical Exposures Strategic Group.

2.0 Review

These terms of reference will be reviewed at least annually as part of the monitoring effectiveness process.

Velindre University NHS Trust

Radiation Protection and Medical Exposures Strategic Group (RPMESSC)

Terms of Reference

1.1 Introduction and Purpose

The use of ionising radiation in healthcare is highly regulated through a number of Statutory Instruments. These primarily include:

- The Ionising Radiation (Medical Exposure) IR(ME)R Regulations 2017 which provides a framework intended to protect patients from the hazards associated with ionising radiation.
- The Ionising Radiations Regulations 2017 which provides a framework intended to protect staff and members of the public from the hazards associated with ionising radiation.
- The Environment Permitting (England and Wales) Regulations 2016 which provides a framework intended to protect the environment from the hazards associated with ionising radiation.

In addition, the use of non-ionising radiations (e.g. MRI) can pose hazards to staff and the public which requires additional assurance.

The governance of radiation safety within the Trust is managed by the Quality, Safety and Performance Committee. The strategic Group is responsible for setting the direction for how the operational divisions, (Velindre Cancer Centre, and Welsh Blood Service) will operate to ensure compliance with regulatory compliance. This will include defining Trust level policies and procedures and facilitating compliance within the operational departments. At an operational level the Medical Director has established a Radiation Protection and Medical Exposure Operational Group, which will manage the operational delivery and compliance with the operational policies and procedures.

1.2 Objectives

The primary objective of the Strategic Group is to provide assurance to the Board that the key systems, pathways and processes are efficient, safe, effective, responsive and robust through the work of the Strategic Group and the operational group. The work of the Strategic Group encompasses all work undertaken on Trust managed premises.

In addition, the Strategic Group will:

- Identify and monitor all current activities and co-ordinate all future developments related to the use of ionising and non-ionising radiation and the use of radioactive substances in Velindre UNHS Trust.

- Consider external and internal assurance reports and monitor action plans, in relation to all aspects of radiation protection, resulting from improvement reviews/notices from HIW, Health and Safety Executive, RPA/MPE and other external assessors.
- To review and act upon any actions arising from the Radiation Sciences Radiation Protection and Medical Exposure Operational Group, other radiation departments and advice received from the Radiation Protection Advisers / Radioactive Waste Advisers / Medical Physics Experts Report.
- To ensure that these activities are carried out in accordance with national legislation, published guidance and local policies and procedures; with patient, public and staff safety at the heart.
- To ensure that the Trusts activities adhere to the Health and Safety, Risk Management and Clinical Governance arrangements of Velindre University NHS Trust.
- To manage the review and generation of Trust radiation safety policies and relevant procedures.
- To note radiation safety incidents and identify trends which interventions can be made to improve Trust compliance.
- To review radon monitoring in the Trust.
- To receive updates and assurances from non-ionising radiation groups.

1.3 Accountability

The Group will be accountable to the Medical Director who reports to the Chief Executive.

1.4 Membership

Medical Director (Chair)
Director of Cancer Services (VCC)
Director of the Welsh Blood Service (WBS)
Head of Radiation Services (VCC)
Appointed Radiation Protection Adviser(s)
Appointed Radioactive Waste Advisers(s)
Appointed Medical Physics Expert(s)
Head of Estates

1.5 Quorum

Business will only be conducted if the meeting is quorate. The Group will be quorate with 5 members, including at least the Chair, Radiation Protection Adviser and Medical Physics Expert.

1.6 Attendance by Members

The Chair and a representative of the Radiation Protection Service (Radiation Protection Advisor or Medical Physics Expert), or their nominated deputy will be expected to attend 100% of the meetings. Other Group members and mandatory participants will be required to attend a minimum of 80% of all meetings and be allowed to send a Deputy to one meeting per annum.

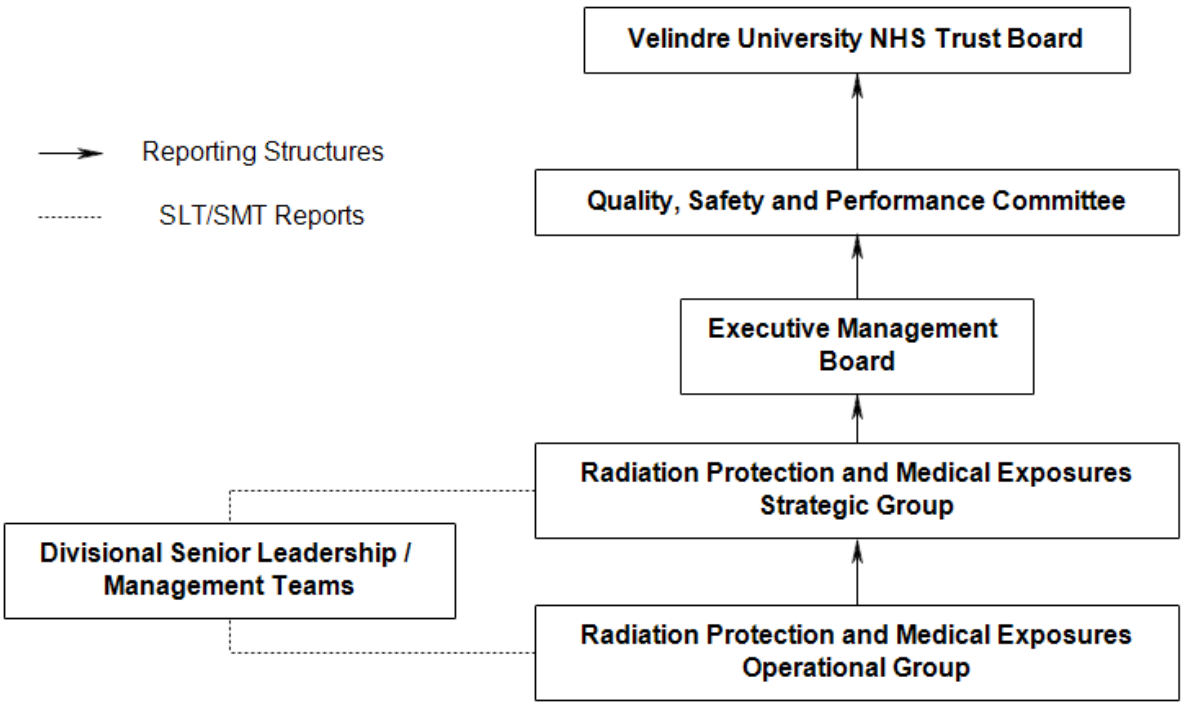
1.7 Frequency

The strategic Group will meet every 6 months.

Additional meetings may be arranged when required to support the effective and safe functioning of the services across both divisions.

1.8 Reporting

The overall responsibility of ensure compliance with the regulatory requirements falls with the Chief Executive. The strategic group will provide summary reports to the senior leadership / management teams of each of the divisions and the executive management board. Any immediate actions needing executive input will be escalated to the executive management board. Highlight assurance reports will be provided to the Quality, Safety and Performance Committee, which will then report to the Trust Board.



1.9 Monitoring Effectiveness

The Group will undertake an annual review of its performance against it Terms of Reference and work plan in order to evaluate the achievement of its duties. This review will be presented to the Trust Quality, Safety and Performance Group.

2.0 Review

These terms of reference will be reviewed at least annually as part of the monitoring effectiveness process.

Quality, Safety & Performance Committee

VELINDRE UNIVERSITY NHS TRUST VACCINATION PROGRAMME BOARD UPDATE

DATE OF MEETING	24th March 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	N/A

PREPARED BY	Kyle Page, Business Support Officer
PRESENTED BY	Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science
EXECUTIVE SPONSOR APPROVED	Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science

REPORT PURPOSE	FOR NOTING

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Trust Vaccination Programme Board	16/02/2022	Items for discussion approved
Executive Management Board	07/03/2022	NOTED

ACRONYMS	
JCVI	Joint Committee on Vaccination and Immunisation

1. SITUATION

This paper is to provide the Quality, Safety & Performance Committee with an update in relation to the Trust's COVID-19 Booster and Influenza vaccination progress and plans as discussed and agreed at the Trust's Vaccination Programme Board held on the 16th February 2022.

The Quality, Safety & Performance Committee is asked to **NOTE** the progress of the Velindre University NHS Trust COVID booster and influenza Vaccination Programme during Autumn/Winter 2021 and plan for 2022.

2. BACKGROUND

The purpose of the Trust wide Vaccination Programme Board is to assume responsibility for planning and safely delivering the Public Health Wales Vaccination Programmes for the Trust, to include vaccines for Influenza and the COVID-19 virus in line with Joint Committee on Vaccination and Immunisation (JCVI) guidelines, frontline categories and age groups on an ongoing basis as required.

3. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

3.1 National COVID Booster Vaccination Requirements

The Trust COVID booster vaccination programme commenced in October 2021 and has been delivered in line with JCVI eligibility criteria.

A number of staff were also deployed to assist the vaccination programme within other Health Boards, via a Mutual Aid agreement, while others had joined banks.

3.2 Velindre University NHS Trust Vaccination Status

3.2.1 COVID 19 Booster

To date, 1,418 staff (83%) have received a COVID-19 booster vaccination, 1,250 of which were administered by Velindre University NHS Trust, with any remaining staff still requiring a booster transferred to their respective Health Boards to receive the booster. Surplus vaccines were transferred to Cardiff & Vale University Health Board for use before their expiry date (early December 2021).

3.2.1 Influenza Vaccinations

To date, 1,214 staff (71%) have received their influenza vaccination via Velindre

University NHS Trust (excluding staff who had received a vaccination elsewhere.) This has exceeded the Government target of 60%.

3.3 Clinically Vulnerable Patients

Arrangements for the vaccination of patients within the Extremely Clinically Vulnerable Category (including cancer patients on immunosuppressant treatment) were put in place for the identification and vaccination of these patients within their Local Health Boards.

3.4 Further Vaccination Plans for 2022

3.4.1 Immediate term

Recent updated guidance published by JCVI during February 2022 advised that a second booster will be offered during Spring 2022 to **adults aged 75 and over, residents in care homes for older adults and individuals aged 12 years and over who are immunosuppressed**. The decision was taken to transfer any staff eligible for vaccination to their respective Health Boards due to the narrow eligibility criteria and very low numbers predicted.

3.4.2 Longer term

Recent advice received from Welsh Government indicates the most likely scenario will include the offer of an Autumn / Winter annual booster for cohorts 1-9, with a main vaccination window of September to December and an emergency surge response (similar to delivery during the Omicron booster surge) should there be a need to respond to a new variant of concern or should vaccine waning prompt urgent action. An option appraisal is currently under development to facilitate a Trust response.

4. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	No
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.

FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Any COVID-19 vaccination costs for the financial year will be funded centrally.

5. FINANCIAL IMPLICATIONS

A letter received from Welsh Government, dated 14 February 2022, notes that financial cover was provided for the first six months of the next financial year in recognition of the crucial role vaccination teams play, giving certainty on contract lengths. There is also further confirmation in a health board allocation letter to Chief Executives and Directors of Finance, issued before Christmas 2021, that any COVID-19 vaccination costs in the next financial year will be funded centrally.

It is also noted that this should provide assurance that, in planning for the coming months and into 2022/23, the funding required can and will be made available to support this important work, including funding to secure venues, workforce and consumables. In providing this assurance, Welsh Government notes there is the expectation that every opportunity to secure a more sustainable workforce and adapt the delivery models to be as efficient as possible, demonstrating value for money is explored.

6. RECOMMENDATION

The Quality, Safety & Performance Committee is asked to **NOTE** the progress to date in relation to delivery of the Velindre University NHS Trust COVID-19 booster and Influenza Vaccinations and potential plans for 2022.

QUALITY, SAFETY AND PERFORMANCE COMMITTEE

INFECTED BLOOD INQUIRY

DATE OF MEETING	24/03/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	

PREPARED BY	Suzanne Jones, Business Support Officer
PRESENTED BY	Cath O'Brien, Chief Operating Officer
EXECUTIVE SPONSOR APPROVED	Cath O'Brien, Chief Operating Officer

REPORT PURPOSE	FOR NOTING

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
EMB	07/03/2022	The Report was Noted

ACRONYMS	
IBI	Infected Blood Inquiry
NHSBT	National Health Service Blood and Transplant (England)
NIBTS	Northern Ireland Blood Transfusion Service

SNBTS	Scottish National Blood Transfusion Service
WBS	Welsh Blood Service

1. SITUATION/BACKGROUND

1.1 The Infected Blood Inquiry is the independent public statutory inquiry into the use of infected blood.

1.2 The Inquiry has been established to examine why men, women and children in the United Kingdom were given infected blood and / or infected blood products; the impact on their families; how the authorities (including government) responded; the nature of any support provided following infection; question of consent; and whether there was a cover-up.

1.3 The Inquiry has been in operation for over 3 years and has been taking evidence from those affected and infected together with a number of individuals representing relevant organisations.

1.4 The Welsh Blood Service (WBS), VUNHST has core participant status in the Inquiry.

1.5 The activity of the IBI has continued during the COVID 19 pandemic, but ways of working have been adapted.

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 VUNHST Engagement with the IBI team

The Trust continues to engage with the IBI team. The lead and deputy solicitors to the Inquiry have recently left the team and have been replaced with a lead solicitor and 3 deputies. The Inquiry team continues to send documents through giving the Trust the opportunity to request a redaction. None have been requested to date.

2.2 Hearings

The Inquiry is currently taking evidence from the 4 UK Blood Services. The former Director of WBS – Dr Tony Napier was the first witness to give evidence in relation to his time as a Regional Director. He is the only former director of WBS who has been asked to submit a formal statement and provide evidence in person to the Inquiry. Former Directors continue to provide evidence, which is expected to continue until the end of March and will include examining evidence in relation to question of Self Sufficiency and whether the UK should have been able to rely solely on UK donations to provide blood fo the population

sooner. The hearings will then recommence in May when they will be examining the government response and also reporting on the compensation framework study. The Chair of the Inquiry has stated that he hoped that 2022 would be the year when the hearings end and if they don't then they will be very close to that goal.

The Inquiry Team have indicated that they will not be requiring the current Blood Service Directors to give evidence at the Hearings (unless they were in post during the relevant period).

2.3 UK Forum

Meetings have continued to take place with the UK Forum, including NIBTS – Northern Ireland Blood Transfusion Service, SNBTS – Scottish National Blood Transfusion Service and NHSBT – NHS Blood and Transplant. Fortnightly meetings during the blood service evidence have been set up to enable all services to respond quickly to any issues raised. Traditional and social media are being monitored to enable a response should one be needed.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
	The Inquiry relates to historic timelines.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	Standard 2.8 Blood Management
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
	The Inquiry relates to historic timelines.
LEGAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	The Inquiry will identify in relation to its' Terms of Reference, any individual responsibilities as well as organisational and systematic failures.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)

	Funding for this work was confirmed with the Welsh Government to continue for the duration of the Inquiry

4. RECOMMENDATION

4.1 The Quality, Safety and Performance Committee is asked to **NOTE** the content of the report.

QUALITY, SAFETY & PERFORMANCE COMMITTEE

PATIENT SAFETY ALERTS GROUP SAFETY ALERT AUDIT

DATE OF MEETING	24 March 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Non Applicable

PREPARED BY	Jade Coleman, Quality and Safety Officer
PRESENTED BY	Nigel Downes, Deputy Director Nursing, Quality & Patient Experience
EXECUTIVE SPONSOR APPROVED	Nicola Williams, Executive Director of Nursing, AHP's and Health Care Scientists

REPORT PURPOSE	FOR ASSURANCE

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Management Board	07/03/2022	ENDORSED FOR APPROVAL

ACRONYMS
Non Applicable

1. SITUATION

The purpose of this paper is to provide the Quality, Safety & Performance Committee with the outcomes from a Safety Alert audit that was completed by the Trust Quality and Safety Team for Alerts received by Welsh Government between the 1st April 2021 – 31st December 2021 and to provide details of any exceptions to complying with Safety Alert requirements.

2. BACKGROUND

The Velindre University NHS Trust regularly receives various types of Safety Alerts which include:

- Patient Safety Notices (advising the Trust on changes to practices and procedures to prevent possible harm to patients)
- Dangerous Incident notifications (which relate to Estates concerns such as high voltage hazards)
- Medicine updates (such as shortages of particular drugs and medications)
- Medical device notifications
- Covid-19 risk reduction measures, treatment and vaccinations update alerts

The Trust must be able to demonstrate that it has responded appropriately to the requirements of each applicable Safety Alert in order to reduce the risk of harm occurring to patients, staff and service users.

The Trust Quality & Safety Team undertake an immediate review, dissemination and escalation of any Safety Alerts that the Trust receives. This ensures that prompt action is taken to assess applicability and levels of compliance and areas of action required. In addition, the Trust is a member of the All Wales Patient Safety Solution Reference Group so that it is fully involved in discussions of any 'Alerts of concern', the sharing of best practice and ongoing national network support.

To increase assurance and ensure a robust approach is taken toward Safety Alerts received by Welsh Government, the Executive Management Board requested that an audit of Safety Alerts was carried out to further explore the systems and processes that are in place and evaluate steps taken when a Safety Alert is received. A range of Safety Alerts were selected to ensure that all types of Alerts that the Trust receive were able to be audited.

3. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

3.1 Alerts Received 1st April 2021 – 31st December 2021

115 Safety alerts were received between the 1st April 2021 to the 31st December 2021. Each alert received is uploaded onto the Datix version 14 database and distributed to specific Safety Alert leads across the Trust.

3.2 Audit

Only 21 of the 115 Safety alerts received were applicable to the Trust. These comprised of Patient Safety Alerts, Notices and Pharmacy updates. The Trust audited 11 of the 21 safety alerts. The methodology used to audit each is summarized in the table below. The remaining 10 alerts will be audited by 31st May 2022.

An assurance rating matrix was used to provide an overall score for each (attached in ***Appendix 1)***. A summary of findings are detailed below:

Substantial Assurance		
Alerts below had few matters requiring attention and following action the Trust was noted as being compliant. These alerts were:		
Alert received	**Alert subject**	**Details of Alert**
21/05/21	Pharmacy alert (918)	MHRA Class 3 Medicines Recall: Advanz Pharma Carbimazole 10mg and Carbizamole 15mg tablets, EL (21)A/13
17/06/2021	Pharmacy Alert (926)	Recall of Co-codamol 30/500 Effervescent Tablets, Batch 1K10121, Zentiva Pharma UK Ltd
23/04/2021	Patient Safety Alert (911)	Deterioration due to rapid offload of pleural effusion fluid from chest drains
05/07/2021	Personal Protective Equipment (934)	Fang Tian Ft-045a Ffp3 Masks
16/08/2021	Pharmacy alert (945)	MHRA Class 2 Medicines Recall: UPDATE - Various Marketing Authorisation Holders and parallel distributor companies, Irbesartan-containing products, EL (21)A/19

25/08/2021	Covid related alert (980)	Infection risk when using FFP3 respirators with valves or Powered Air Purifying Respirators (PAPRs) during surgical and invasive procedures.

Reasonable Assurance		
Alert received	**Alert subject**	**Details of Alert**
23/10/2020	**Patient Safety Notice (819)**	**The Safe Storage of Medicines: Cupboards**
Description of actions and steps taken: • An audit of all areas that stock medication was undertaken in January 2021 using the national audit tool associated with the alert. • Audit findings were reported back to the Medicines Management Group in March 2021. • The Trust deems itself to be non-compliant however work continues in order to improve the compliance status and includes, undertaking risk assessments in all the areas that store medication against the criteria set out by the alert. • The Safety alert remains an ongoing Agenda item at the Medicine Management Group. • Individual risk assessment of all clinical areas that store medication within VCC were completed by November 2021. • The assessments have been used to produce a gap analysis document that highlights all the breaches against the recommendations within the alert. • The breaches have been categorised as either major, moderate or minor, and this document continues to be reviewed at the Medicine Management Group meeting. • The vast majority of work is complete to address all concerns identified in the risk assessments. • Clinical areas have been a priority for action and information fed back to the Medicine Management Group. • A risk matrix has been produced clearly listing outstanding actions as well as actions that have been completed. • One area causing concern following the review of the Safety Alert is the need to completely relocate the Outpatients treatment room as it currently does not comply with the alert. The impact of Covid has resulted in this work not being progressed. The Safety Alert remains open whilst management review the risk matrix. The alert will continue to be monitored through the Medicine Management and Safety Alert Groups.		
11/10/2021	**Patient Safety Notice (967)**	**Reducing the Risk of Inadvertent Administration of Oral Medication by the Wrong Route**

Description of actions and steps taken:

- An administrative plan was completed as part of the actions to comply with the Safety Alert.
- Work has already been completed in relation to the safety notice as well as colleagues in other HB's who the Trust collaborate with. Outstanding actions include training and linking in with the nursing staff within the clinical areas.
- Compliance form sent to the Delivery Unit on the basis that we cover most of the actions in the alert.

Will remain open until the training plan has been executed and the Standard Operating Procedures are aligned.

Limited Assurance		
Alert received	**Alert subject**	**Details of Alert**
24/06/2021	**Patient Safety Alert (928)**	**Ligature and ligature point risk assessment tools and policy**

Description of actions and steps taken:

- Compliance form sent to Patient Safety Wales on the 20th September 2021 advising that the Trust are compliant and the below information details work carried out by the Velindre University NHS Trust to demonstrate compliance for Ligature points.
- Risk assessment (DATIX 2342) is in place to capture risk around curtain tracks being used as a ligature point. Controls are in place including approved contractors being used to install and validate anti-ligature curtain rails. A yearly review of the risk assessment was last completed on the 03/08/2021.
- Walk around of inpatient ward was conducted on the 3rd August 2021 to identify any high risk areas of the ward. All areas deemed safe however opportunities were highlighted to improve the environment.
- A plan is in place to refurbish 1 cubicle as an anti-ligature cubicle.
- Business case is being developed and costed.
- All patients are assessed on an individual basis and actions taken in response to each patients need.

Whole site assessment to be conducted using the Manchester Hospital Ligature Audit Tool, with outcomes being shared with Health and Safety Groups and Quality and Safety Management Group.

27/5/2021	**Patient Safety Notice (920)**	**Revised National Steroid Treatment Card**

Description of actions and steps taken:

- The majority of actions within the alert have been completed.

- A multidisciplinary working group including nursing, medical and pharmacy representatives working through the actions.
- The All Wales Procurement for emergency packs are underway and to support the project a Task and Finish group has been set up to work through this alert on an All Wales basis, confirmed via collaboration at the Delivery Unit Safety alert meeting held on the 22.9.21.
- Responsible persons have been named within the SBAR for each step of the process and the information leaflets are being finalised.
- The kits have not become commercially available as yet and are being manufactured by Cardiff Aseptic specialty services. As soon as they are available, the Trust will procure via the All Wales contract.

The Delivery Unit have been informed that given the delays with the national work the Trust is currently non-compliant.

Assurance Not Applicable		
Alert received	**Alert subject**	**Details of Alert**
13/7/2021	**Patient Safety Notice (936)**	**Urgent assessment/treatment following ingestion of 'super strong' magnets**

Initially identified as applicable, however on further review this Safety Alert was noted as not applicable to the Trust.

Description of actions and steps taken:
Although the Safety Notice does not apply directly to the Trust, the following steps were undertaken:

- All staff made aware that an absolute ban from MRI scanner is in place for hazardous magnetic environment already.
- Reminders sent to Radiographers (Operators) and Radiologists (Practitioners) about AP and Lateral Plain film Xray. Following an email to all staff regarding Abdomen X rays, urgent CT and avoidance of MRI being reiterated.

3.3 Next Steps

The next steps for each of the above audits is summarized in the table above.

A further status report of the Alerts marked 'Reasonable Assurance' and 'Limited Assurance' will be obtained for the next Safety Alert Management Group meeting on the

24th April 2022, The outcome of this will be reported to the Executive Management Board and the Quality, Safety & Performance Committee in the next Safety Alert Highlight Report.

In addition, as outlined above, the remaining 10 alerts will be audited by the 31st May 2022.

3.4 Status against all safety alerts

There are currently 3 safety alerts open within the Trust. The Trust has met the reporting requirements of the delivery unit for each of these alerts and is working toward improving the Trust compliance in each of the 3 areas.

4 IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	Effective communication. Timely review of safety alerts
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Legal requirement to comply with mitigating the risk of safety alerts
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Financial impact, fines etc

5 RECOMMENDATION

The Quality, Safety & Performance Committee is asked to **NOTE** this assurance report and the next steps.

Appendix 1

Assurance Matrix

Green	**Substantial Assurance**	Few matters require attention and are compliance or advisory in nature. Low impact on residual risk exposure.
Yellow	**Reasonable Assurance**	Some matters require management attention in control design or compliance. Low to moderate impact on residual risk exposure until resolved.
Orange	**Limited Assurance**	More significant matters require management attention. Moderate impact on residual risk exposure until resolved.
Red	**No Assurance**	Action is required to address the whole control framework in this area. High impact on residual risk exposure until resolved.
Grey	**Assurance Not Applicable**	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

QUALITY, SAFETY AND PERFORMANCE COMMITTEE

PUBLIC RESEARCH, DEVELOPMENT & INNOVATION SUB-COMMITTEE HIGHLIGHT REPORT

DATE OF MEETING	24/03/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Emma Stephens, Head of Corporate Governance
PRESENTED BY	Professor Andrew Westwell, Chair of the Research, Development & Innovation Sub-Committee
EXECUTIVE SPONSOR APPROVED	Dr. Jacinta Abraham, Executive Medical Director

REPORT PURPOSE	FOR NOTING

ACRONYMS	
RD&I	Research, Development and Innovation
QSP	Quality, Safety and Performance Committee

1. PURPOSE

This paper has been prepared to provide the Quality, Safety and Performance Committee with details of the key issues and items considered by the **Public** meeting of the Research, Development and Innovation Sub-Committee on the 13/01/2022.

Key highlights from the meeting are reported in Section 2.

The Quality, Safety and Performance Committee is requested to **NOTE** the contents of the report and actions being taken.

2. HIGHLIGHT REPORT

ALERT / ESCALATE	There were no items identified for **ALERT** or **ESCALATION** to the Quality, Safety & Performance Committee.
ADVISE	**Velindre Futures Research and Development Cancer Strategy Update** The Sub-Committee received an update on the progress made in taking forward the **Velindre Futures Overarching Cancer Research, Development & Innovation Ambitions 2021-2031.** The following was highlighted: - There is now a strategic leadership group in place for Velindre Futures. - The implementation team have all now been appointed. - There are ongoing discussions with other Health Boards and a piece of work has been created to look at the research activity that happens in Aneurin Bevan. - The priority over the last few months has been to focus on the Cardiff Research Hub. This is a **Tripartite Agreement** between Cardiff and Vale Health Board, Cardiff University and Velindre and the purpose is for this to be able to deliver high risk early phase trials and in time advanced therapeutics. **Cardiff Cancer Research Hub** The Sub-Committee received a report on the joint proposal and clinical specification that links with the Cardiff Cancer Research Hub. The Sub-Committee were advised that the joint proposal represented a huge step forward in getting to this point in the process with the three complex organisations working together. The **Tripartite Agreement** sets out the context, strategic ambitions, case for change, pillars of work associated with the Cancer Research Hub and the infrastructure needed. The Sub-Committee were advised that the finer details now need to be refined in order that the Cancer Research Hub can be fully established.

ASSURE	**Breast Cancer Research within Velindre University NHS Trust** *(Presented by Dr Annabel Borley, Consultant and SST Lead, Clare Boobier, Lead Research Nurse and Carys Evans, Patient Participant in the Breast SST Clinical Trial)* The Sub-Committee received a presentation from staff leading the work of the Breast Clinical Trials Unit at Velindre Cancer Service and were joined by a patient participant of the Breast SST Clinical Trial. The following key highlights were noted: - Circa 1.6 million in income for the Trust has been generated over the last 6 years. - The trials serve to improve patient treatments and outcomes. - Support learning and development that can often lead to routine clinical practices. - Provide the opportunity to access novel therapies and gain experience. - Promote job satisfaction amongst staff. - Support a high-profile reputation for the Trust. The Sub-Committee also learned about the many challenges with clinical trials that have to be overcome, including how they are becoming increasingly complex with fewer eligible patients and resource capacity increasingly constrained by the ongoing pandemic. The Sub-Committee welcomed learning firsthand more about the recent experience of a participant in one of the clinical trials and how this had been an extremely positive experience in what was one of the most difficult and challenging periods of their life. The Sub-Committee commended the ongoing commitment of staff working in the Breast Clinical Trials Unit and the excellent work they are undertaking. **Trust Research, Development and Innovation Performance Report, Quarter 3 2021/2022** The Sub-Committee received the second iteration of the fully integrated Trust Research, Development & Innovation Performance Report that is continuing to mature and develop in format, content and overall structure to aid triangulation.

	Key performance highlights for the reporting period included but were not limited to the following: - The Joint Research Office (JRO) has been established between CVUHB and CU and the heads of both organisations have formally opened the office on the Heath Park site and staff have moved in. Velindre are currently in discussions with the JRO with a view to establishing a footprint within the office, sharing expertise and actively seeking opportunities to deliver studies that are being run from the tripartite Cardiff Cancer Centre Research Hub in a streamlined and efficient way. A member of the Trust R&D office staff has been seconded into the JRO for 12 months to improve joint working between the organisations. - The R&D Small Grant Scheme is currently supporting 4 projects. The Sub-Committee were assured of the projected strong financial outturn position against the allocated budget. The Sub-Committee also received an update on the Nursing and Interdisciplinary Research Highlights over the last twelve months. The following key achievements were highlighted: - 18 Velindre Healthcare researcher led, Research, Innovation and Improvement Projects. - 23 Velindre healthcare researcher authored outputs. - 10 funding applications have been submitted and 5 have been successful. - An outline application for research for patient and public benefit has also been invited through to full application. - Celebration event held for education initiatives and the group continue to meet to develop education training to support capacity building in healthcare research within the cancer centre.
INFORM	The Sub-Committee were informed that Seema Arif has been awarded an MBE and extended their congratulations.
APPENDICES	**NOT APPLICABLE**

3. RECOMMENDATION

The Quality, Safety & Performance Committee is asked to **NOTE** the key deliberations and highlights from the **Public** meeting of the Research, Development & Innovation Sub-Committee held on the 13/01/2022.

QUALITY, SAFETY & PERFORMANCE COMMITTEE

Highlight report from the Chair of the Trust Estates Assurance Meeting

DATE OF MEETING	24/03/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Jason Hoskins, Assistant Director of Estates, Environment and Capital Development
PRESENTED BY	Jason Hoskins, Assistant Director of Estates, Environment and Capital Development
EXECUTIVE SPONSOR APPROVED	Carl James, Director of Strategic Transformation, Planning and Digital

REPORT PURPOSE	FOR NOTING

ACRONYMS	
VCC	Velindre Cancer Centre
WBS	Welsh Blood Service
NWIS	NHS Wales Informatics Service
CSTF	Core Skills Training Framework
NWSSP	NHS Wales Shared Services Partnership
HTW	Health Technology Wales
HSE	Health and Safety Executive
RIDDOR	Reporting of Diseases and Dangerous Occurrences Regulations

1. PURPOSE

1.1 This paper had been prepared to provide the Quality, Safety & Performance Committee with details of the key issues considered by the Trust Estates Assurance Meeting.

1.2 The Trust Estates Assurance meeting replaces previously separate meetings for Health and Safety, Fire Safety, Environment and Statutory Compliance and as such, this report now gives a more comprehensive overview.

1.3 Key highlights from the meeting are reported in section 2.

1.4 The Committee is requested to **NOTE** the contents of the report and actions being taken.

2. HIGHLIGHT REPORT

ALERT / ESCALATE

Health and Safety

Mandatory Training levels are below acceptable levels across the board. Action has been taken to address the situation.

Fire Safety

Nil to Escalate

Environmental / Sustainability

Utility costs are vastly inflated due to the conflict in Ukraine raising market uncertainty. The trust has representatives attending regular meeting with NWSSP and Health Board colleagues to review costs. Based on current market conditions tit is anticipated that this could present a cost pressure of circa £600K for the coming financial year

Estates and Statutory Compliance

Nil to escalate

ADVISE

Health and Safety

A new Trust Health and Safety Policy was agreed at the February H&S Board an

Training

CSTF Subject	TCS	RDI	WBS	VCC	Corp	Trust
Health & Safety	*79.1%*	*85.7%*	*84.9%*	*85.7%*	*75.1%*	*82.7%*
Manual Handling (Level 1/A)	*70.8%*	*81.0%*	*69.9%*	*81.0%*	*54.8%*	*71.5%*
Manual Handling (Level 2)		*70.6%*	*91.4%*	*72.2%*		*78.0%*
Violence & Aggression (Mod A)	*89.6%*	*80.0%*	*90.5%*	*86.3%*	*90.5%*	*87.4%*
Violence & Aggression (Mod B)			*90.1%*	*80.0%*	*45.5%*	*71.9%*
Overall Compliance	*79.8%*	*79.3%*	*85.4%*	*81.0%*	*66.5%*	78.3%

Training compliance has dipped slightly in conjunction with onset of Omicron variant, which created staffing pressures regarding release for training
Education and Development, the Trust Health and Safety manager and Clinical Nurse Education working group are set to meet in April to plan the future strategy for training.

Work is being progressed to roll out IOSH accredited courses - Managing Safely, Managing Safely Refresher and Working safely, picking up plans which were originally in place before the pandemic. Meeting arranged with The Education Steering Group in April.

Fire Safety

Overall fire safety training compliance has dropped below 85% benchmark; as noted below, the fire safety manager in partnership with Trust OD team is continuing with the targeted approach for departments to address local issues such as service need, absence etc. to address issue.

Also refer to ongoing work to develop more interactive, accessible means of delivering fire safety training in ASSURE / INFORM sections below.

Environmental / Sustainability

An external audit of the Trust ISO14001:2015 System was undertaken in Q3. The Trust was successful in gaining recertification for ISO 14001 with no major issues raised.

Updated Sustainability Strategy completed

Estates and Statutory Compliance

VCC annual asbestos re-inspection has taken place in January 2022. Minor issue were highlighted in the report which mainly centered around slight deterioration of products. Abatement works scheduled for February 2022.

Water Hygiene Risk Assessments were undertaken at VCC in October 2021 and we are currently working through the defects register. Medium and low risk registers and an action plan have been compiled to address defects.

Water Hygiene Risk Assessment Reports and the Velindre Cancer Centre and Headquarters Audit Report have been shared with the WSG.

The WBS HQ Risk Assessment has been received and will be issued to the group shortly.

All actions with regard to the WS documents have been closed apart from the review of the Trust WS Policy and Appendices format which sits as an agenda item for the next meeting.

The Water Safety Policy has been reviewed and amended and will be submitted for formal acceptance in April

	The Asbestos Policy has been reviewed and will be submitted for formal acceptance in April Statutory Compliance Audit The Estates team has completed statutory compliance audit on all Trust sites to provide a further level of assurance to the Board. o This will include an exercise to gather asset information. o This is scheduled to be completed in the next eight weeks. o An update will be provided in due course.
ASSURE	**Health and Safety** VCC have employed a H&S Advisor to support legislative obligations **Fire Safety** Trust fire safety policy (PP01) reviewed and ratified As part of integrated management system, the Trust fire safety manager developing relevant protocols to support implementation of policy. Fire Safety Manager continues to be actively involved in development of nVCC and Neville Hall SRU with regard to fire strategy and design. Continuation of remedial works at VCC and WBS headquarters with regard to the fire safety BJC; all works progressing to plan. Fire safety Manager and Trust Education and Development Team continue to work with divisions and individual teams to explore alternative methods of training delivery to overcome issues associated with staff homeworking – also refer to comment under INFORM below. **Environmental / Sustainability** A draft action plan has been designed in response to the NWSSP/WG NHS Wales Decarbonisation Plan, which will support implementation of the Trust Strategy As previously reported, the Trust was successful in obtaining bids in Welsh Governments Decarbonisation grant funds. The Trust has successfully obtained funding for the following – o Velindre Cancer Centre Building Management System Upgrade o Trust Headquarters LED Lighting Upgrade Work is completed, and benefits being recorded. The Trust Sustainability Manager is working with divisional leads to populate A Welsh Government Carbon Net Zero Reporting. The content is under development, and will be how carbon is captured going forward to ensure a full & detailed account is available

	The document will be 'live' in the ISO Green Group Teams channel and all data will be captured in here and audited on a quarterly basis **Estates and Statutory Compliance** Capital works programme for 2022/23 although ambitious will be closed out over the coming weeks with all committed works expected to be delivered. VCC Compliance is at 81% WBS HQ Compliance is at 73 % This dip in compliance is attributed to turn over of staff and challenges presented through Omicron, although this is expected to improve going forward as replacement staff are recruited. Funding has been approved to recruit new posts within the estates team to focus on compliance. A water safety audit has been completed within the quarter reporting no issues of note
INFORM	**Health and Safety** Nil to Escalate **Fire Safety** The Fire Safety Manager continues to represent Trust on All-Wales Fire Safety Managers' forum with focus on the fire training task & finish group. Renewed emphasis on the development of interactive fire training project for Nursing as reported previously. Annual fire safety audit under way with submission due at the end of May 2022. **Environmental / Sustainability** A number of initiatives have been progressed through the quarter; VALUE-ADDED SPONSORSHIP PROGRAMME (VASP) Programme launch to begin to monitor / celebrate the 'value add' projects in the TCS project and across the Trust Workshop launch in January, which will be held quarterly going forward GREEN SOCIAL PRESCRIBING PROJECT – Ray of Light Endorsement from Dignity group on 15.02.2022, approval from SLT on 09.03.2022 Green Social Prescribing project will start in the next month SINGLE USE PLASTIC VCC Reintroduced reusable metal cutlery, mugs and plates in canteen

	Exploring the option to incentivise reusable products (e.g. bringing your own container) by providing a discount Introducing VegeWare products (replacing the plastic/polystyrene products) all of which are compostable Relaunch of Eco to Go cups to get back the momentum pre pandemic WBS Trialling compostable cups for the West Teams on collection – following a project review will be rolled out **Estates and Statutory Compliance** A full asset collection has been completed with cross reference undertaken with industry compliance standards. A new facilities management platform has been purchased with a view to populate with the updated asset information. This will allow automation of the management of estates deliverables, providing an automated audit trail to underpin assurance reporting. This will support development and implementation of KPI's for the service.
APPENDICES	**YES - (Please Include Appendix Title in Box Below)**

QUALITY, SAFETY & PERFORMANCE COMMITTEE

HIGHLIGHT REPORT FROM THE CHAIR OF THE TRANSFORMING CANCER SERVICES SCRUTINY SUB-COMMITTEE

DATE OF MEETING	24th March 2022
PUBLIC OR PRIVATE REPORT	Public
IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report
PREPARED BY	Jessica Corrigan, Business Support Officer
PRESENTED BY	Stephen Harries, Independent Member
EXECUTIVE SPONSOR APPROVED	Carl James, Director of Strategic Transformation, Planning & Digital
REPORT PURPOSE	FOR NOTING

ACRONYMS	
OBC	Outline Business Case
FBC	Full Business Case
TCS	Transforming Cancer Services
WG	Welsh Government
IRS	Integrated Radiotherapy Solution
IM	Independent Member

1. PURPOSE

1.1 This paper has been prepared to provide the Quality, Safety & Performance Committee with details of the key issues considered by the Transforming Cancer Service (TCS) Programme Scrutiny Sub-Committee at its public meeting on 21st December 2021.

1.2 This is not considered a full update on the Programme but a high-level record of the matters of business conducted by the TCS Programme Scrutiny Sub-Committee.

1.3 Key highlights from the meeting are reported in section 2.

1.4 The Quality, Safety & Performance Committee is requested to **NOTE** the contents of the report and actions being taken.

2. HIGHLIGHT REPORT

ALERT / ESCALATE	There were no items identified for Alert / Escalation to the Quality, Safety & Performance Committee.
ADVISE	**Finance Report** A summary of the Capital and Revenue budget forecasts costs for all projects within the TCS Programme were provided. The forecasting position shows within budget for the end of the year for TCS Programme. The sub-committee were advised all legal fee requirements for next year have been included in the budget. The sub-committee were assured the team are monitoring the spend of the legal fees. It was confirmed a session will be arranged to go through all the risks and funding for each project. This will allow everyone to be sighted on all the project resources. This Board Development Session will be arranged for the New Year. The sub-committee **noted** the finance report. **TCS Programme Risk Register** The TCS Programme Risk Register report was presented. The latest risk positions for the TCS programme and projects were reviewed and discussed.

	The sub-committee **noted** the Risk Register. **TCS Programme Managers Update** • nVCC – Competitive Dialogue An update was given on the Competitive Dialogue. The progress was noted. • Workshop on Developing the South East Wales Cancer System An update was given on the workshop on developing the South East Wales Cancer System. The workshop has been postponed due to unavailability of key personnel across the region. There might be a chance this will be postponed again depending on the impact Covid / Omicron variant has. But everyone is keen for this workshop to be held as soon as possible. • Radiotherapy Satellite Centre The detailed design presentation is scheduled for 27th January 2022 which will include SMART hospital requirements. The Full Business Case completion is now anticipated for April/May 2022. The Sub-Committee highlighted their concerns hopefully the presentation date doesn't get delayed due to the COVID Omicron variant situation. The Sub-Committee **Noted** the Paper. **Project 4: RSC Progress Update and Full Business Case (FBC) Timelines** The RCS Progress update and Full Business Case (FBC) timeline paper was presented to the Sub-Committee. The expected completion date for the scheme is now July 2024. The sub-committee were informed of the recommended several mitigations to reduce the impact of delays. These have been approved and the works started on site in October 2021 with a planned completion date of the first week in April 2022. The FBC is currently due to go to boards in May 2022 with Welsh Government FBC approval anticipated for end of June 2022. However, the project is considering whether it is possible to bring the business case to boards in April 2022. The Sub-Committee **Noted** the Paper.
ASSURE	**Nuffield Trust Report – Progress Update** The Nuffield Trust Report – Progress Update paper was presented to the Sub-Committee. The sub-committee noted the good progress being made.

	The Sub-Committee **Noted** the Paper. **Velindre @ UHW – Progress Update** The Velindre @ UHW – Progress Update paper was presented to the Sub-Committee. • The Cardiff Cancer Research Hub @ UHW: The Project Implementation Team has been appointed. The Strategic Lead has also been appointed and in post. Project Support Officer will start in January 2022 and admin support has been identified. Posts are short-term funding through charitable funds. • Haemato-oncology The workstream is currently delayed whilst internal clinical capacity to support is reviewed. The Sub-Committee **Noted** the Paper. **Communications & Engagements** An update was given on communication and engagements. The Sub-Committee **Noted** the Paper.
INFORM	There were no items identified to inform the Quality, Safety & Performance Committee.
APPENDICES	NOT APPLICABLE

QUALITY, SAFETY & PERFORMANCE COMMITTEE

HIGHLIGHT REPORT FROM THE CHAIR OF THE TRANSFORMING CANCER SERVICES SCRUTINY SUB-COMMITTEE

DATE OF MEETING	24th March 2022
PUBLIC OR PRIVATE REPORT	Public
IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report
PREPARED BY	Jessica Corrigan, Business Support Officer
PRESENTED BY	Stephen Harries, Independent Member
EXECUTIVE SPONSOR APPROVED	Carl James, Director of Strategic Transformation, Planning & Digital
REPORT PURPOSE	FOR NOTING

ACRONYMS	
OBC	Outline Business Case
FBC	Full Business Case
TCS	Transforming Cancer Services
WG	Welsh Government
IRS	Integrated Radiotherapy Solution
IM	Independent Member

1. PURPOSE

1.1 This paper has been prepared to provide the Quality, Safety & Performance Committee with details of the key issues considered by the Transforming Cancer Service (TCS) Programme Scrutiny Sub-Committee at its public meeting on 19th January 2022.

1.2 This is not considered a full update on the Programme but a high-level record of the matters of business conducted by the TCS Programme Scrutiny Sub-Committee.

1.3 Key highlights from the meeting are reported in section 2.

1.3 The Board is requested to **NOTE** the contents of the report and actions being taken.

2. HIGHLIGHT REPORT

ALERT / ESCALATE	There were no items identified for Alert / Escalation to the Quality, Safety & Performance Committee.
ADVISE	**Finance Report** The TCS Finance Report highlights the TCS Programme are on track to break even on Revenue and Capital by the end of the financial year. The sub-committee **noted** the finance report. **TCS Programme Risk Register** The TCS Programme Risk Register report was presented. The latest risk positions for the TCS programme and projects were reviewed and discussed. The sub-committee **noted** the Risk Register. **Verbal Updates:** The TCS Programme Scrutiny Sub-Committee received a verbal update on the following: - Nuffield Trust Report – Progress Update - Project 1: Enabling Works Update - Competitive Dialogue Update - Project 3a: Integrated Radiotherapy Solution Update **Value Add Engagement Programme** TCS Programme Scrutiny Sub-Committee received the **Value Add Engagement Programme presentation. The following was outlined:** - In building a new hospital, it intensifies the opportunities for further areas in which the Trust can lead or collectively sponsor to add further value. - In addition, there are opportunities to enhance the site itself.

	- Within the organisation, there will be a sponsorship group to lead collaboration across the matrix of activities. - We will be led by engagement with our patients, staff and community as to what matters most to them. The Sub-Committee **Noted** the Paper.
ASSURE	There were no items identified to assure the Quality, Safety & Performance Committee.
INFORM	There were no items identified to inform the Quality, Safety & Performance Committee.
APPENDICES	N/A

Quality, Safety and Performance Committee

MEDICAL DEVICES REPORT

DATE OF MEETING	24th March 2022
PUBLIC OR PRIVATE REPORT	Public
IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report
PREPARED BY	Peter Richardson, Head Of Quality Assurance and Regulator Compliance, WBS Tim Register, Head of Engineering, Radiotherapy Physics, VCC
PRESENTED BY	Choose an item.
EXECUTIVE SPONSOR APPROVED	Cath O'Brien, Chief Operating Officer
REPORT PURPOSE	FOR NOTING

ACRONYMS	
VUNHST	Velindre University NHS Trust
VCC	Velindre Cancer Centre
WBS	Welsh Blood Service
MDG	(VUNHST) Medical Devices Group
UKAS	The United Kingdom Accreditation Service
MHRA	Medicines and Healthcare Product Regulatory Agency
MDR	Medical Device Regulations
MDD	Medical Devices Directive
The Sharps Regulations	The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

1. PURPOSE

1.1 This paper had been prepared to provide the Quality, Safety & Performance Committee with a review of Medical Devices and compliance with the Medical Devices regulations across both operation divisions of Velindre University NHS Trust (VUNHST)

1.2 The Committee is requested to **NOTE** the contents of the report and actions being taken.

2. SITUATION/BACKGROUND

Medical Devices in healthcare is regulated through a number of Statutory Instruments. These primarily include:

- Medical Devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and are based on 3 EU directives as listed below that cover Medical Devices.

  Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
  Directive 93/42/EEC on medical devices (EU MDD)
  Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

  The MDR regulations are intended to improve the safety and performance of medical devices and intends to provide a high level of protection for the health of patients and users of these medical devices.

- The EU introduced updated medical devices regulations in 2017, but the regulations did not come fully into force until 2021. The UK decision to leave the EU means that the latest EU regulations have not been enacted into UK law.

  The Medicines and Healthcare Products Regulatory Agency, recognising the need for updated legislation has recently consulted on the matter and updated regulations are expected to be laid before parliament later this year. VUNHST responded to the consultation. The Welsh Government working party convened to oversee NHS Wales input into the MHRA decision making process.

  A specific area of focus for this consultation is the use of software as a medical device either in its own right or embedded within equipment, and the exemptions to be applied when a suitable, approved medical device or diagnostic reagent is not available to meet the needs of patients. Other area of focus is in-house manufacturing.

- The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013, known as 'The Sharps Regulations', build on existing health and safety law and provide specific detail on requirements that must be taken by healthcare employers and their contractors. The Sharps Regulations include a statutory requirement to carry out a post-implementation review (PIR) to assess the effectiveness of the regulatory regime after they have been operational for a period of time.

The Trust is either subjected to or can be inspected by regulatory authorities including Healthcare Inspectorate Wales (HIW), Medicines and Healthcare Product Regulatory Agency (MHRA), the Health and Safety Executive (HSE) and Wales Audit Office (WAO).

Legally, the Employer carries the overall responsibility for implementing the requirements of the regulations governing work involving MDR and The Sharps Regulations throughout all Services managed by the Trust. The Chief Operating Officer has been delegated responsibility at Trust Board level for the management of medical devices and equipment. Roles and responsibilities are define in the Trust Medical Devices and Equipment Management Policy (QS24).

3. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

3.1 The Welsh Blood Service uses a large number of medical devices for the collection, processing and storage of blood and stem cells, testing and analytical services use in vitro medical devices. In compliance with the regulations, WBS uses CE-marked medical devices and In Vitro Diagnostic devices where available. In the small number of cases where suitable CE marked products are not available, WBS develops a validated process which is documented and audited as permitted by the regulations.

In cooperation with other UK blood services, suppliers of the most critical medical devices used by WBS are audited by representatives of one or more UK blood services, and the findings shared across all UK blood services under relevant non-disclosure agreements.

3.2 From both WBS and VCC, MHRA and Manufacturer Medical Device Safety Alerts/Notices and other relevant issues are reviewed at quarterly MDG group meetings and appropriate actions undertaken as and when necessary. The group receives periodic reports from the Medical Gases Committee and Electrical Safety User Group for note of any medical device specific issues or actions.

3.3 The Welsh Blood Service continues to comply with the 2002 Medical Devices regulations. This is evidenced through extensive divisional policies and procedures and has been subjected to regular audit by both the internal audit team at WBS and by external regulators including the MHRA and the UK Accreditation Service (UKAS). In 2021/22 both of these regulators inspected the main WBS facility in Talbot Green. The MHRA found no major deficiencies and renewed the Blood Established Authorisation for the maximum 2 years, UKAS conducted a full reaccreditation of the diagnostic laboratories to ISO 15189 and found

no deficiencies with respect to medical devices legislation. The ISO 15189 registration was renewed for the maximum 4 years.

To provide assurance regarding compliance appropriate regulations and safe use of medical devices throughout their lifecycle (as defined in QS24), the Trust has established a Medical Devices Group (MDG).

The purpose of the MDG is to deals with the strategic direction of the medical devices governance and assurance by formulating appropriate policies, identification and management of any issues with medical devices in use or being maintained, including any relevant MHRA or manufacturer alerts and to keep the Chief Operating Officer informed of specific issues that require their attention. The MDG meets on a quarterly cycle with highlight reports submitted to the Executive Management Board (EMB).

To provide assurance regarding safety alerts and notices relating to the medical devices, quarterly alerts report is presented at the MDG meeting and any action taken is discussed with the group. Safety alerts are received via MHRA or manufacturer/supplier either in electronics or paper form. There are many alerts that are issued by MHRA which are scanned weekly, and appropriate action is taken with any applicable alerts. In this financial year, 2 Patient safety alert (NatPSA), 10 Field Safety Notices (FSN), 2 product recall and 1 product defect were dealt with. **At the present there is no outstanding action**.

In relation to The Sharps Regulations, the requirement to use a safety device if one is available is subject to ongoing review as we are required to use a device if one is available. **There are no outstanding items of concern.**

3.2 Key Actions / Areas of focus during next period

It is expected that new, draft legislation, will be laid before the UK parliament during 2022 and VUNHST must remain alert to the potential impacts of this. Whilst the legislation has yet to be published, it is anticipated that there will be a high level of alignment with existing US and EU legislation, and this may impact both divisions in particular around the costs of diagnostic reagents and the use of software as a medical device in such areas as automated support for diagnosis, treatment planning/dose calculations, and interpretation of diagnostic tests such as cross-matching.

The latest EU and US legislation requires all such software to have an appropriate Quality Certification such as a CE mark, and where suitable software is not commercially available, any in-house development must be done under a suitable quality management system – ISO 13485 is the suggested standard. Given the highly specific nature of both VCC and WBS operations, and the current levels of reliance on bespoke software, the trust must be prepared for a level of impact from this legislation. A cross-divisional working party has already been set up to co-ordinate activities in both divisions and to interface with the Chief Scientific Officer's team at the Welsh Government who are coordinating activity across the whole of

NHS Wales. In addition, WBS is working with the other UK Blood Services to coordinate the specific impacts on Blood and Transplantation across the UK.

It should also be noted that any tightening of regulations around the in-house manufacture of diagnostic reagents (including simple dilutions) and In-house manufacturing of the Medical Devices. Any new regulatory barriers introduced as a result of UK legislation would have a potentially significant cost implication for analytical services across NHS Wales.

4. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	Compliance with the latest regulatory standards is a significant element of the overall system which assures the safety of patients and donors
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below: • Staff and Resources • Safe Care • Effective Care • Health and Care Standard 2.9 - Medical Devices, Equipment and Diagnostic Systems
EQUALITY IMPACT ASSESSMENT COMPLETED	Yes
LEGAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Noncompliance with the Regulations once new UK legislation is introduced may impact.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Compliance with the Regulations may require investment however the potential financial impact has not been assessed at present.

5. RECOMMENDATIONS

The Quality, Safety & Performance Committee is asked to **NOTE** the information in this report.

QUALITY SAFETY AND PERFORMANCE

QUARTERLY ACTION PLAN 2021/22 – QUARTER 3 PROGRESS UPDATE

DATE OF MEETING	24/03/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Phil Hodson, Deputy Director of Planning and Performance
PRESENTED BY	Cath O'Brien, Chief Operating Officer / Carl James, Director of Strategic Transformation, Planning, Performance and Estates
EXECUTIVE SPONSOR APPROVED	Cath O'Brien, Chief Operating Officer / Carl James, Director of Strategic Transformation, Planning, Performance and Estates

REPORT PURPOSE	FOR NOTING

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Management Board - Run	7/03/2022	NOTED

ACRONYMS	
VUNHST	Velindre University NHS Trust
QSP	Quality Safety and Performance Committee

VCC SMT	Velindre Cancer Centre Senior Management Team
WBS SMT	Welsh Blood Service Senior Management Team
EMB	Executive Management Board
IQPD	Integrated Quality Planning and Delivery (Welsh Government review meeting)
RAG	Red Amber Green – quarterly action progress rating

1. SITUATION/BACKGROUND

1.1 The Quarterly Action Plan for this financial year was developed as part of the Annual (IMTP) Plan for 2021/22 which was approved by the Trust Board on 28th June 2021. The action plans *(see Annex 1 (VCC) / Annex 2 (WBS)*) monitor progress against the Trust's operational planning intentions by quarter for the current financial year.

1.2 Regular progress reports are presented to Executive Management Board (EMB) and Quality Safety and Performance (QSP) Committee. Updates are also provided to the bi-monthly Welsh Government Integrated Quality Planning and Delivery (IQPD) review meetings.

1.3 The purpose of this paper is to provide assurance to the QSP Committee on progress being made against our quarterly actions for 2021/22 and will form the basis of information shared with IQPD.

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 Whilst good progress has been made against 2021/22 quarterly actions, due to recent Omicron COVID-19 operational pressures, a number of 2021/22 actions have been *'delayed'* in Q3.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	All plans are subject to the Trust quality assurance framework and the processes established during the Covid 19 outbreak.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below: • Staff and Resources • Safe Care • Timely Care • Effective Care • Staying Healthy
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Financial impact of all service changes are being monitored and reviewed with finance colleagues for onward engagement with Welsh Government on Covid related costs.

4. RECOMMENDATION

4.1 The Quality Safety and Performance Committee is asked to **NOTE** the content of this report.

Ymddiriedolaeth GIG Prifysgol Felindre
Velindre University NHS Trust

ANNEX 1 VELINDRE CANCER CENTRE

	VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTIONS BROUGHT FORWARD FROM 2021/22 ANNEX 1 - VELINDRE CANCER CENTRE								Progress Updates from Action Leads
ID	**Covid Harm**	**REF**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**February 2022**
VQ2	Covid	VQ 2.3	Continue to manage repatriated patient activity until safe plans are agreed with HBs	VCC	SACT Lead	Q1	Q4	**Green**	We are delivering SACT across VCC site, maximizing capacity and productivity, covering all HB area patients.
VQ2	Non Covid	VQ 2.4	Develop plans with all HB partners to deliver a safe return of SACT outreach services	VCC	SACT Lead	Q1	Q3	**Amber**	PCH has returned to 50% capacity. Increase in Tenovus mobile unit sited in ABUHB from 2 to 3 days. All other patients continue to be treated at VCC. There are plans for a new unit at Neville Hall, however no absolute deadline has been agreed. Discussions continue between ABUHB and VUNHST.
VQ2	Over Whelm	VQ 2.6	Implement capacity delivery options to meet demand changes	VCC	Senior Management Team.	Q1	Q4	**Green**	Targeted delivery plans in place supporting all areas to meet demand growth, supported by detailed demand forecasts.
VQ2	Societal	VQ 2.10	Workforce development and recruitment plan to be developed to support options	VCC	W & OD Lead	Q1	Q3	**Green**	Workforce plans in place for recruitment, retention.
VQ2	Covid	VQ 2.20	Gather patient feedback on the use of virtual appointments	VCC	Patient Experience/OPD Business Manager	Q1	Q4	**Green**	Survey tool developed and patient feedback process now in place.

	VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTIONS BROUGHT FORWARD FROM 2021/22 ANNEX 1 - VELINDRE CANCER CENTRE								Progress Updates from Action Leads
ID	**Covid Harm**	**REF**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**February 2022**
VQ3/4	Covid	VQ 3/4.8	Deliver and manage the private sector additional capacity provision in line with contractual requirements	VCC	Director of Cancer Services	Q1	Q3	**Green**	All private sector capacity secured through formal contracts and managed in accordance with those requirements.
VQ3/4	Covid	VQ 3/4 12	Relocate Phlebotomy service to support effective social distancing in outpatient department and to increase OP throughput	VCC	Director of Cancer Services	Q2	Q4	**Amber**	Phlebotomy service repositioned along with wider OP department patient flow changes. Permanent plan to move Phlebotomy is part of OP development plans which require major investment programme tba with WG.
VQ3/4	Covid	VQ 3/4 12	Continue to offer Phlebotomy services and monitor activity levels while initiating discussions on sustainable service model with Health Boards	VCC	Director of Cancer Services	Q2	Q4	**Amber**	Limitations on DGH and GP surgery access. Pressure on OP space as a result. Little progress on HB's repatriating phlebotomy to local provision. Being picked up by OP task and finish group commenced February 2022.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ 1-4	Covid	V01	VCC Priority 1: Ensuring that Staff and Patients are Safe at our Treatment Locations and Minimising the Risk of COVID-19 transmission – including enhanced infection control measures, vaccination and testing strategies during 2021/22	To maintain safety of patients and staff through ensuring appropriate range of measures relating to infection prevention, site access, social distancing, communication and engagement strategies (including the provision of advice and information), vaccination and testing.	Continued roll out of lateral flow testing and patient testing in accordance with WG guidance	VCC	General Manager	Q1	Q4	**Green**	The Trust continues to implement the use of Lateral flow testing in line with WG guidance for all staff in healthcare settings and all patients before they commence a course of treatment.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ 1-4	Covid	V04	VCC Priority 1: Ensuring that Staff and Patients are Safe at our Treatment Locations and Minimising the Risk of COVID-19 transmission – including enhanced infection control measures, vaccination and testing strategies during 2021/22	To maintain safety of patients and staff through ensuring appropriate range of measures relating to infection prevention, site access, social distancing, communication and engagement strategies (including the provision of advice and information), vaccination and testing.	Revise and implement new Home Working plan	VCC	General Manager	Q1	Q4	**Green**	Trust established Agile Working Board. Detailed analysis of home working activity, space availability and utilisation undertaken. Staff survey and focus groups on 'workspace' requirements undertaken. Recovery actions to follow WG advice on continued home working and workplace rules regarding 1 or 2 metre rule.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ 1-3	Covid	V05	VCC Priority 1: Ensuring that Staff and Patients are Safe at our Treatment Locations and Minimising the Risk of COVID-19 transmission – including enhanced infection control measures, vaccination and testing strategies during 2021/22	To maintain safety of patients and staff through ensuring appropriate range of measures relating to infection prevention, site access, social distancing, communication and engagement strategies (including the provision of advice and information), vaccination and testing.	Establish staff wellbeing unit	VCC	General Manager	Q1	Q4	**Amber**	Detailed accommodation requirements developed. Some digital equipment has been purchased and wider capital bid under development.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ 1 -4	Non Covid	V07	Priority 2: Delivery of appropriate capacity to meet patient demand and continue to operate in a COVID-19 pandemic environment responding to further phases and government guidance including adaptation our clinical model as appropriate and reinstatement of local services with Health Boards.	To provide sufficient capacity to meet patient demand in 21/22 and to plan for future service requirements.	Develop the demand and capacity modelling infrastructure	VCC	Head of Planning	Q1	Q4	**Green**	Detailed demand model completed to ensure that we are able to predict demand at various points in patient pathways. This gives us early operational warnings of increases /decreases in volumes. We are also able to model overall demand projections impacting on OP, Radiotherapy and SACT services.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ 1-2	Non Covid	V08	Priority 2: Delivery of appropriate Outpatient capacity to meet patient demand and continue to operate in a COVID-19 pandemic environment.	To provide sufficient capacity to meet patient demand in 21/22 and to plan for future service requirements.	Return outreach provision to Local Health Board sites.	VCC	General Manager	Q1	Q4	**Amber**	We have maximised the use of virtual consultations to keep patients safe and accommodate the initial HB outreach activity at VCC. We have now returned over 80% of outpatient outreach back to HBs. Further work is required in partnership with HB's to address some of the gaps in clinic support when delivering services in outreach settings. This is impacting on our ability to fully return to our outreach clinical model.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ 1-4	Non Covid	V10	VCC Priority 2: Delivery of appropriate Radiotherapy capacity to meet patient demand and continue to operate in a COVID-19 pandemic environment.	To provide sufficient capacity to meet patient demand in 21/22 and to plan for future service requirements.	Fully explore and deliver capacity through third party suppliers as appropriate	VCC	Head of Radiotherapy	Q1	Q4	**Green**	Formal agreement with Rutherford Cancer Centre in place for radiotherapy provision. First patients using this pathway treated in July 2021. SACT agreement with Rutherford commenced in April 2022.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ 1-4	Non Covid	V11	VCC Priority 2: Delivery of appropriate capacity to meet patient demand and continue to operate in a COVID-19 pandemic environment.	To provide sufficient capacity to meet patient demand in 21/22 and to plan for future service requirements.	Work with each SST to revise and optimise clinical pathways	VCC	Clinical Director	Q1	Q4	**Green**	Work continuing on Single Cancer Pathway (SCP) implementation which involves pathway review and improvement. Review sessions planned for each SST.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ 1 - 3	Covid	V15	VCC Priority 2: Delivery of appropriate SACT capacity to meet patient demand and continue to operate in a COVID-19 pandemic environment.	To provide sufficient capacity to meet patient demand in 21/22 and to plan for future service requirements.	Establish supressed demand capacity for SACT	VCC	Head of SACT	Q1	Q4	**Green**	The primary driver for SACT demand is the internal increase in cycles of treatment for existing patients. This is as a result of improving patient's response to new/combination treatment regimes. Additional capacity has been in place throughout 21/22, however service pressure due to staff absence levels has increased in 2022. A task and finish group has commenced to scope further actions to support increased SACT capacity options.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ3	Non Covid	V17	VCC Priority 2: Delivery of appropriate capacity to meet patient demand and continue to operate in a COVID-19 pandemic environment.	To successfully deliver the Digital Health and Care Record replacement for CANISC and the next stages in the procurement of the Integrated Radiotherapy Solution. To further develop the Velindre Futures Initiative as the vehicle for service transformation.	Delivery of DHCR project including operational change in system use	VCC	Director of Cancer Services	Q1	Q4	**Amber**	DHCR plan slipped in year and has been delayed until 2022/23. IRS progressing to contract award stage. Velindre Futures programme embedded in each directorate.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ 1 - 4	Non Covid	V19	VCC Priority 3: Deliver business critical initiatives through Velindre Futures as well as the outputs of the first phase and our service development plans.	To successfully deliver the Digital Health and Care Record replacement for CANISC and the next stages in the procurement of the Integrated Radiotherapy Solution. To further develop the Velindre Futures Initiative as the vehicle for service transformation.	Establish VF staff engagement programme	VCC	Director of Cancer Services	Q1	Q4	**Green**	Velindre Futures Programme structure in place with associated communication and engagement plan under constant review. Programme embedded in each directorate and delivering against agreed priorities.

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
VQ 1 - 3	Non Covid	V21	VCC Priority 4: Engagement with Health Boards and Regional Service Planning – including developing the regional approach in line with Nuffield recommendations	Regular meetings with each Health Board operational and cancer leads to address the challenges of service delivery and working with the CCLG to develop a regional service planning approach to cancer services in SE Wales.	Regular meetings with each Health Boards	VCC	Head of Planning	Q1	Q4	**Amber**	Regional Partnership Board meeting regularly with full Programme governance structure in place. Planning and operational meetings have commenced with HBs.
VQ 1-2	Covid	V22	VCC Priority 5: Patient Experience and Engagement – recognising and responding to the impact of COVID-19	To further develop our patient engagement approach and our patient experience gathering capability.	Establish project to develop a few Patient Engagement Framework for VCC Implement the new NHS Wales system for Patient Experience	VCC	General Manager	Q1	Q4	**Green**	Significant work undertaken to gain patient and staff views on development of the framework. CIVICA Once for Wales Patient Experience System went live on 29th July 2021. Ongoing phased plan for roll-

VELINDRE UNIVERSITY NHST OPERATIONAL PLAN QUARTERLY ACTION PLANS 2021/22 ANNEX 1 – VELINDRE CANCER CENTRE											Progress Updates from Action Leads
ID	**COVID Harms**	**REF**	**Priority Areas**	**Key Objectives**	**Agreed Quarterly Actions**	**Work Area**	**Action Leads**	**Start Date**	**End Date**	**BRAG Rating**	**Last updated: February 2022**
											out and optimisation.
VQ2	Covid	V03	VCC Priority 1: Ensuring that Staff and Patients are Safe at our Treatment Locations and Minimising the Risk of COVID-19 transmission – including enhanced infection control measures, vaccination and testing strategies during 2021/22	To maintain safety of patients and staff through ensuring appropriate range of measures relating to infection prevention, site access, social distancing, communication and engagement strategies (including the provision of advice and information), vaccination and testing.	Delivery of vaccination programme	VCC	General Manager	Q1	Q3	**Green**	Trust Programme Board ensured delivery of COVID19 booster and flu vaccination as planned. Trust stepped down as part of wider NHS Wales vaccination programme.

objective	ID	Deliverables	op lead	SMT lead	Delivery date	Current position	Status at 28/02/2022
Strategic priority 1.		**Excellence in service delivery**					
To provide a modern, safe and sustainable blood and transplantation service	**1.01**	Review and develop revised WBS 5-year strategy, supported by an approved IMTP 2021/22	Rachel Hennessy	Rachel Hennessy	Q4	5-Year strategy approved by SMT 9/02/2022 to be considered by EMB 21/02/2022	**CLOSED**
	1.02	Ensure structure and project plan is in place to support the development of OBCs for Infrastructure PBC and implementation of phase 1 'ventilation' Ensure Models developed and OBC to support implementation of further phases including sanitation and renewable energy and lab modernisation	Jason Hoskins	Rachel Hennessy	Q4	OBC writer appointedFeb 2022. Lab modernisation to be excluded from the OBC for infrastructure Prgramme. OBC to be submitted April 2022	
	1.03	To consider and implement the findings of the clinical services review in line with clinical & service priority ensuring effective use of clinical and scientific resources	Zoe Gibson/Janet Birchall	Janet Birchall	Q4	Paper for Consultancy approved by SMT, actions to follwing post March 2022	

objective	ID	Deliverables	op lead	SMT lead	Delivery date	Current position	Status at 28/02/2022
	1.04	Develop a prioritised capital plan which reflects service requirements, secure funding and ensure clear plans are in place for delivery of approved programme.	Angela Robins	Rachel Hennessy	Q3	Capital plan supported by SMT, Trust Capital Group and by Trust EMB	**CLOSED**
	1.05	To develop a plan to ensure patient and donor testing platforms in the transfusion labs are updated including implementation of: - blood grouping/Immunohematology analysers - flow cytometers - bacteriology monitoring equipment - HbS Testing solution	Emma Cook/ Georgia Stephens/Deb Pritchard	Tracey Rees	Q4	Flow Cytometers are undergoing validation. BactAlert – procurement process underway. ABO Analysers- procurement process underway - now in implementation Phase HbS – paper received by SMT Feb 2022, implementation end of Q3 2022/23	

objective	ID	Deliverables	op lead	SMT lead	Delivery date	Current position	Status at 28/02/2022
						Bacteriology monitoring equipment due to be delivered in Q4 21/22, expected to be completed in Q1 22/23 Primary analysers expected to be completed by end of Q2 22/23	
	1.06	Scope and develop a Fleet Strategy and implementation plan in line with the revised strategic intent for the Collection model	Clive Francis/Simon Davies	Jayne Davey	Q4	TCV order now placed. Delivery forecast by March 2023 Electirc Vehicle - recieved	

To ensure the support functions that operate as part of the General Services Department are fit for purpose and integrated within service delivery across WBS.	**1.07**	To review the service model for estates and facilities in collaboration with wider Trust service model	Jason Hoskins	Rachel Hennessy	Q4	Service model in process of being developed for consideration by SMT	
	1.08	To review the service model for Business Intelligence in collaboration with wider Trust service model	Rachel Hennessy	Rachel Hennessy	Q4	Further discussions to take place across VUNHST	
	1.09	To review the service model for IHub and programme management in collaboration with wider Trust service model	Sarah Richards	Rachel Hennessy	Q2	Service model reviewed and considered by SMT April 2021.	**CLOSED**
To ensure compliance with regulatory and clinical governance standards across all service areas, where gaps are identified, plans are	**1.1**	Implementation of actions to support compliance with Fire safety requirements in line funding received as part of WG business case	Jonathan Fear/Jason Hoskins	Rachel Hennessy	Q4	Fire alarm upgrade complete Fire Doors have to be retendered due to lack of interest from the market and required updates to scope. This work will roll	

developed and implemented						over into the next finacial year.	
	1.11	Initiate donor individual review findings	Stuart Blackmore	Janet Birchall	Q2	FAIR Implementation due to go live on the 14.6.21 FAIR has gone live	**CLOSED**
	1.12	Scope wider QA role across NHS Wales including cell & gene and other pathology	Peter Richardson	Peter Richardson	Q2	Provide advise on regulator framework on ongoing basis. Cell and Gene therapy is not a deliverable for QA	**CLOSED**
Support UK Infected Blood Inquiry and delivery of its Terms of Reference	**1.13**	Continued engagement with UK Infected Blood Inquiry (IBI)	Cath O'Brien	Cath O'Brien	Q4	Blood inquiry continues. It has taken evidence from blood services in Q3 and Q4 and timeline has been extended to 2023	
To provide a National External Quality Assessment Scheme (NEQAS) service	**1.14**	Evaluate reporting and quality of samples distributed	Deb Pritchard	Tracey Rees	Q4	Complete	**CLOSED**
Ensure availability of plasma derived	**1.15**	Develop a project plan to support the future expansion of plasma	Peter Richardson	Peter Richardson	Q4	Formal request from WG to support All wales programme board	**CLOSED**

medicines across Wales in immediate to longer term		derived medicine across Wales				which will define the strategy and operation al planning required. Discussion are ongoing regarding the resources required, WBS to respond Backfill position has been advertised.	
	1.16	IVIG Strategy – scope & interrogate data to reduce variation across NHS Wales IVIG strategy – translate data insight to reduce variation	Chloe George	Peter Richardson	Q4	WBS providing IVIGs to BCUHB effectively creating a national service for Wales. Now complete	**CLOSED**
Meet service development needs to address changes in practice in line with evidence base	**1.17**	New Foetal D screening service model to be scoped and pilot implemented	Deb Pritchard	Tracey Rees	Q4	Agreed start of project May 2022 Awaiting update from Antenatal Screening Wales.	
	1.18	Clinic digitalisation, link up heamaflows to ePROGESA	Sally Gronow	Jayne Davey	Q4	Not able to pursue Capital funding due to delivery time exceeding March 2022. To be added	

						to capital plan for 2022/23 - no further update	
	1.19	Review and update the platelet, plasma and Cryo component strategy and implement changes to include - the production of male only derived cryo - requirements of solvent/detergent plasma and transition to FFP - apheresis/pooled ratio	Georgia Stephens	Tracey Rees	Q4	1. Male only derived cryo production is implemented, the e-ePROGESA controls configuration being planned with IT, estimated work timescale for this work to be completed is Jan-Feb 2022 due to competing priorities on the IT Backlog. Will be followed up via the ongoing change process. 2.A SBAR for the requirements of solvent/detergent plasma and transition to FFP was submitted and accepted in RAGG meeting in August. Phased implementation planned to start in September, with	

						ongoing evaluation of impact on stocks as implementation is rolled out to each Health Board. Implementation delayed to October due to stock assessment and change control activities. This has now been implemented 3. The need to review the WBS platelet strategy was discussed in the Demand Planning Group meeting in August. The group agreed to take this topic forward for scoping with view to develop a new platelet strategy subject to SMT approval. This item is expected to be 'in progress' at end of Q3. It was agreed that a project/T&F Group will be established	

						to review the WBS strategy. No timelines available to date. Progress now expected in Q4. Plan to take forward via Demand Planning not agreed, awaiting SMT lead and prioritisation. Omicron variant pressures means that this objective is further delayed and will not be delivered by end of March 2022.	
To ensure staff have the skills, competencies and opportunities to develop themselves within WBS and beyond	**1.2**	Management and leadership development needs identified and implemented as appropriate	Angela Voyle-Smith	SMT	Q4	Management and leadership development needs identified and implemented as appropriate. Inspre programme has begun and currently on Cohort 3, with cohort 4 planned for April/May and cohort 5 in September	**CLOSED**

Ensure there is a planned and sustainable workforce model that supports and shapes WBS now and in the future	**1.21**	Developing the talent management /succession planning process that supports flexible career pathways	Sue Price (Donna Dibble)	SMT	Q4	Career Pathways have been developed for Nurses and Scientist and are ready to be uploaded to the new WBS website, when this is launched. New website luanch at end of March. Initial meeting staged with the porduction company and further detail of filiming needs now provided and being evalauated. Still working to 31/03/2022	**CLOSED**
	1.22	Develop a clear recruitment strategy and plan for implementation targeting specific areas of shortage and using a range of communication channels, focussing on Bi-lingual recruitment to grow our Welsh speaking workforce, flexibility	Sue Price (Donna Dibble)	Alan Prosser	Q4	Delivery plan to be agreed	
	1.23	Ensure each department has a workforce plan that reflect service needs,	Sue Price (Donna Dibble)	SMT	Q4	delivery plan to be developed	

		including skill mix, new roles and responsibilities, values and behaviours					
To ensure a healthy and engaged workforce, whereby work life balance is actively encouraged and supported	**1.24**	Welsh Language internal audit findings received and actions addressed, ensure Welsh Language and Welsh culture embedded in all programmes of work	Ceri Thomas	Rachel Hennessy	Q4	Compliance audit completed awaiting discssion with Trust W/l to confirm final gradin/scoring outcome, meeting to be arranged beofre 31/03/2022. Will be closed at 31/03/2022	
Implement Blood Stem Cell collection centre at VCC	**1.25**	Implement Blood Stem Cell collection centre at VCC	Emma Cook	Tracey Rees	Q2	PBSC phase now completed, remaining work on bone marrow collection to be completed. Bone marrow phase paused in response to Covid Pressures	
To ensure provision of blood and blood products to meet surge activity in health Boards	**1.26**	Ensure structures are in place to meet the demand from Health Boards for blood and blood products to support delivery of Health Board recovery plans	Simon Davies/Georgia Stephens	Jayne Davey/Tracey Rees	Q2	Risk assessment completed for next finanical year in light of reduced covid monies. Demand continues to be met & action will be extended into 22/23	**CLOSED**

Strategic Priority 2.		**Deliver a state of the art supply chain**					
	2.01	Review and evaluate Impact/benefits realisation of BSC2020 programme	Sarah Richards	Rachel Hennessy	Q4	Programme officially closed following final Programme Board meeting in August 2021. After Action Reviews and Benefits Realisation Reviews underway. Dec this year, PMs holding after actions reviews and expected to complete Dec 21.	
To work in partnership with donors, citizens & organisations to shape our services	**2.02**	Implementation of phased approach to improved donor interaction functionality within eDRM, including donor app	Andrew Harris/David Mason-Hawes	Jayne Davey	Q2	Donor engagement is ready, test (UAT) system available; unable to progress due to competing work priorities / COVID (see notes). Currently paused. Completion of project estimated for 2022 New software proposed to SMT (future), which will	

						aid the analysis, reviewing and speed of query responses. Due to competing work priorities & COVID, re-commencement of eDRM	
	2.03	Full implementation of recommendations from FAIR study.	Stuart Blackmore	Janet Birchall	Q1	FAIR went live 14th june 2021	**CLOSED**
Maintain healthy, prudent & sustainable donor panels to maximise the frequency people in Wales are able to donate blood	**2.04**	Scope and implement workstream(s) in line with strategic intent to improve donor health & increase donor personalisation	Edwin Massey/ Emyr Adlam	Janet Birchall	Q4	Project work to manage transgender donors in an improved way is ongoing. Completion of this task is reliant on a substantial upgrade to the ePROGESA system by MAK-Systems, which is not expected to be undertaken in the immendiate future - No further update Semester patch now expected post 2022, to be confirmed when prioritised by	

						orgainsation. Timelines to follow.	
To plan & coordinate blood collection activity across Wales, optimising clinic flow and ensuring provision of an effective & efficient cycle of clinics & processes for blood donation	**2.05**	Review the options for the potential introduction of electronic rostering system in line with NHS Wales implementation timeline and make recommendations to SMT to support a preferred way forward.	Simon Davies	Jayne Davey	Q4	Rota's from W/C 23/08/2021 went live in the E-rosta system, and the system now fully Live. Only task that remains for the initial phase is adding users from outside of the department. Awaiting Cyber Security Report from IT before this can happen.	**CLOSED**
	2.06	OCP undertaken to support the implementation of the new collection team model	Sally Gronow	Jayne Davey	Q3	In communications with Union reps to discuss next steps re: Implemtnation phase **- no further update**	
To optimise transport and logistics to effectively meet stakeholder requirements	**2.07**	Proposed model for make ready service reviewed as part of wider facilities/stores/estates model, recommendation made on service for West and North Wales and implementation if required	Michael Thomas/Carol Morgan	Rachel Hennessy	Q4	Recommendation being done as part of the facilities and estates review which is now underway. SMT decison March 2022 No update at present .	

						Make ready service on hold until further notice	
	2.08	Review, evaluate and refine Ambient Overnight Hold facilities and workflow model for maximum efficiency	Sarah Richards/Georgia Stephens	Rachel Hennessy	Q4	Ambient and overnight hold has now been transitioned to BAU and can now be closed as part of the programme closure.	**CLOSED**
To work collaboratively with our hospital partners to provide an assured distribution service for blood components and products	**2.09**	Work with Digital services to Review, develop and implement Hospital Web Based Ordering system	Georgia Stephens/David Mason-Hawes	Tracey Rees/Stuart Morris	Q4	Unable to progress - delayed due to COVID-19, work will not be undertaken in 2021/22 - deferred.	
	2.1	BHNOG KPI report to be developed, ensuring data is provided, warehoused and verified to BI recommended standards and dashboards produced	Lee Wong	Janet Birchall	Q1	KPI dashboard approved by BHNOG meeting 30/06/2021	**CLOSED**
Strategic Priority 3.		**Provision of progressive Histocompatibility and**					

		Immunogenetics services in support of transplantation, transfusion and advanced therapies					
Develop services that are evidenced based and in line with best practice	**3.01**	Review an update antibody testing strategy for solid organ transplantation and commence work required to inform future strategy	Deb Pritchard	Tracey Rees	Q4	Ccomplete	**CLOSED**
	3.02	Implement changes required for compliance with NHSBT-ODT donor characterisation project	Deb Pritchard	Tracey Rees	Q4	Complete	**CLOSED**
	3.03	Undertake a review of the virtual crossmatching policy to identify opportunities to extend further in order to benefit more patients, making recommendations for implementation	Deb Pritchard	Tracey Rees	Q4	Data collection complete. Analysis of data to take place in Q1 2022-23	
	3.04	Full implementation of NGS technology in transplant services	Deb Pritchard	Tracey Rees	Q2	Complete	**CLOSED**
	3.05	Development of platelet immunology and granulocyte antibody testing in support of transfusion services	Deb Pritchard	Tracey Rees	Q4	Delays to project due to IT resource avaliability and competing priorities.	

						Estimated completion May 2022.	
To ensure the Welsh Bone Marrow Donation Registry (WBMDR) contributes at a national and international level	**3.07**	WBMDR strategy to be delivered in full, Evaluate WBMDR donor panel to assess required growth / service developments	Emma Cook	Tracey Rees	Q4	Pending the workshop being held which has been delayed until April 2022.	
	3.08	Undertake a workforce review of the WBMDR and develop an action plan which support optimise of the service and succession planning	Emma Cook	Tracey Rees	Q4	Pending the workshop being held which has been delayed until April 2022.	
Strategic Priority 4.		**Digitally enabled to deliver in the modern world**					
Optimisation of the core Blood Establishment Computer System (BECS) & Appointments System	**4.01**	Routine enhancement of BECS via 'delta' release programme	Emyr Adlam	David Mason-Hawes	Q3	Delayed due to competing priorities. Implementation of the maintenance patch on 03/10/2021 - updated IT work plan to be considered via Business Planning Group and SMT -	

						to include consideration for timing of next 'delta' release. - No further update	
	4.02	Commence re-procurement / extend current BECS contract	David Mason-Hawes	David Mason-Hawes	Q4	Agreement in principle with Procurement to pursue a 2+1 extension to current contract. T&F Group established; however, currently unable to meet due to COVID pressures. Aim to seek SMT, EMB and Trust Board approval by end of March 2022, with contract renewed by end of May 2022.	
Optimisation of the core Blood Establishment Computer System (BECS) & Appointments System	**4.03**	Initiate integration of clinic equipment & full roll out of live connectivity	Dan Rainbird	David Mason-Hawes	Q4	Launch of the project has been delayed due to COVID-19 pandemic. Meetings have recently been re-established to revisit the Project Brief with the goal	

						of launching a proof of concept later this year. The results of this will determine the scope of the wider deployment to all Collection Teams.	
	4.04	Deploy transition state labelling functionality - UK wide go-live	Emyr Adlam	David Mason-Hawes	Q4	Position now known, meeting took place w/c 23/08/2021 agreement on specification now awaiting approval from JPAC. - No further update	
	4.05	Refresh existing WBS external & BH Team websites	David Mason-Hawes/Andrew Harris	David Mason-Hawes	Q4	Work progressing. Full go-live for both BH Team and WBS websites by end of March 2022.	
Establishment of industry standard Business Intelligence (BI) services	**4.06**	Ongoing delivery of advanced 'self-service' BI dashboard and reporting capabilities Automation of core data set refresh; dimensional modelling of core datasets; migration to new infrastructure; migration of published datasets from Excel to PowerBI	Zoe Wilder	Rachel Hennessy	n/a	Core data set refresh completed for Q1, Dimensional modelling of core datasets is ongoing but expecting it to be completed in parallel with migration of published datasets from Excel to PowerBI aiming to	**CLOSED**

						complete end of Q3. Migration to infrastructure still at has specification stage, completion date for this element unknown at present, but not expecting this to be completed before Q4	
Delivery of modern, resilient, secure IT infrastructure services supporting organisational objectives incorporating innovative developments	**4.07**	Upgrade telephony infrastructure to include replacement of existing call centre software - Trust programme	Dan Rainbird	David Mason-Hawes	Q4	Digital Services team reviewing current telephony provision across VUNHST. Telephony Strategy document being developed, for future review by Divisional SMTs / Trust Board.	
	4.08	Progress deployment of Office 365 and define use	Dan Rainbird	David Mason-Hawes	Q4	Complete in terms of initial migration. Office 365 fully adopted across all staff groups using core features like Outlook, Teams and OneDrive. On track and expected to be delivered as	**CLOSED**

						planned - work underway to migrate VCC users onto OneDrive. Deployment of Microsoft InTune Mobile Device Management (MDM) started, ongoing.	
	4.09	Explore opportunities to utilise AI / machine learning to support business processes	David Mason-Hawes	David Mason-Hawes	Q4	If required, further features will be enabled as part of a Trust O356 project – current recruitment ongoing to build adoption of wider range of O365 services. Plans to deliver AI / Machine Learning to be reviewed against available resources and prioritised work plan, following publication of pan-Trust Digital Strategy (March 2022).	PAUSED

Strategic Priority 5.		**Building our business on a foundation of research, development and innovation**					
Implement the research, development & innovation strategy	**5.01**	Review WBS RD&I strategy in line with Trust RD&I strategy	Sian James	Peter Richardson	Q4	14 Jul No action to date Overarching Velindre UNHST strategy still to be produced Further clarification required from COO on preferred direction of travel	**CLOSED**
	5.02	Plan to operationalise outputs of exiting KESS studentships	Sian James	Peter Richardson	Q3	A programme of knowledge transfer has taken place, Next end of studentship Winter 2021 - Completed 30/09/2021	**CLOSED**
	5.03	Review opportunities for ongoing engagement of KESS students	Sian James	Peter Richardson	Q3	Replacement programme for young donor motivation September 2021 and a studentship in Component Development - which will utilise the IMTP allocation	**CLOSED**

						for FY 2021-22 is in hand	
Actively seek partners for collaborative projects	**5.04**	Scope the opportunity enabled by our University status in improving our capability in RD&I and the opportunities enabled as a result of collaborations with academia	Sian James	Peter Richardson	Q4	Remains on Target	**CLOSED**
	5.05	Deliver goals outlined in new component development plan	Chloe George	Peter Richardson	Q4	Component development laboratory now performing several pieces of research work. Component Development Board established to prioritise work plans in line with organisational objectives. Component development awaiting estates expansion in line with original agreed business case.	**CLOSED**
Strategic Priority 6.		**Implementing effective clinical systems to support improved outcomes**					

To support to the clinically safe, effective and appropriate use of blood and blood products, working in conjunction with partner agencies	**6.01**	Review and update the Blood Health Plan in line with national guidelines	Lee Wong	Janet Birchall	Q3	Blood Health plan issued on 30/09/2021 from WG	**CLOSED**
	6.02	Develop and deliver Blood Health Education Strategy, facilitated by BHT with delivery by end users	Lee Wong	Janet Birchall	Q3	Draft BHNOG Education Strategy was submitted to BHNOG meeting for approval/ratification in September 30th.Currently out to consultation for sign off BHNOG meeting in December 2021. **Approved 21/12/2021**	**CLOSED**
	6.03	Review current arrangements for NABT Programme, clarifying service requirements and agreeing contracting arrangements	Lee Wong	Janet Birchall	Q4	WBS **Action is now Null and Void** as HEIW will now own NABT Course. A steering group being established including WBS which includeds all key stake holders	**CLOSED**

						to review current arrangement for NABT programme.	
	6.04	Working with All Wales LINC project to develop a core dataset for transfusion e.g. demographics, unit distribution etc.	Lee Wong	Janet Birchall/David Mason Hawes	Q4	LINC Contract now awarded Working with programme team to review benefits realised. Delivery will be via the national programme anticipated deadlines 23/24	
	6.05	Oversee the implement SHOT recommendations with HBs and identified opportunities to meet recommendations	Lee Wong	Janet Birchall	Q4	Gap analysis of SHOT recommendations completed by HBs . Agreed action planby Transfusion Lab Managers & Transfusion Practitioner meetings in December. Actions compelted fpr 2020 SHOT recommendations completed. New cycle to start in July 2022. to be inlcuded in 2022/23 IMTP	**CLOSED**
	6.06	Work with Health Board partners to develop a pre-op	Lee Wong	Janet Birchall	Q4	Anaemia Pathway approved Health	

		amenia strategy, whereby reducing the need for blood transfusions resulting in reduced hospital lengths of stay and fewer post surgery complications				Board Anaemia leads and ratified at BHNOG meeting in December 2021. Presentation to agree testing strategy at NPOMG meeting,on 10th February 2022. No funding available from WHSSC, alternative funding pathwaySBAR completed and awaiting approval from WBS SMT using interoperative cell salvage funding. Working with DHCW to develop audit collection tool Expected to completed against original timeline	
Work in partnership with DHCW to facilitate the delivery of WLIMS modules across WBS	**6.07**	Deliver WLIMS modules for Blood Transfusion (BT) which facilitate appropriate use and real time audit - national decision awaited on progressing	David Mason-Hawes	Tracey Rees/David Mason-Hawes	Q4	Internal project remains on hold; however, confirmation now received that ABHB, Cwm Taf and SBU health boards are all planning to go live	**PAUSED**

						with BT LIMS in early-2022. WBS supporting this activity, as required. These implementations require no change to existing operational management arrangements in WBS. Advice from DHCW is that no other HBs are currently planning to go live with BT LIMS.	
	6.08	Deliver WLIMS modules for H&I & DCS to include: procurement and deployment of transplant centre IT system and phase 2 WTAIL IT solution	David Mason-Hawes	Tracey Rees/David Mason-Hawes	Q4	Prometheus go-live delayed to January 2022 (from December 2021) - re-testing and validation underway. Refreshed URS for H&I system being drafted, Labs Digitisation Programme Board ToR agreed, first meeting August 2021. WTAIL H&I Systems Project	

						Group due to meet 15/12/2021.	
Inform and support the national procurement for LINC (WLIMS2)	**6.09**	Complete development & testing of LINC - as part of national programme	David Mason-Hawes	Tracey Rees/David Mason-Hawes	Q4	Procurement completed - Citadel Health selected supplier. Testing to commence Q2/Q3 2021/22. Local Deployment Project will be handled under Labs Digitisation Programme Board. Development & Testing phase due to extend into 2022/23, as per national programme plan	
WTAIL IT System development	**6.1**	Implement systems to support Donor Characterisation requirements	Deb Pritchard	Tracey Rees/David Mason-Hawes	Q4	Update from ODT that electronic HLA result transfer element of donor characterisation has been pushed back from April 22 to April 23 go live date.	
	6.11	Develop bespoke application to support recruitment of non-blood Bone Marrow volunteers	Chris Harvey/ David Mason-Hawes	Tracey Rees/David Mason-Hawes	Q1	Application delivered for operational use by WTAIL staff.	**CLOSED**

QUALITY, SAFETY & PERFORMANCE COMMITTEE

THE MEDICAL EXAMINER SERVICE AND VELINDRE UNIVERSITY NHS TRUST

DATE OF MEETING	24/03/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Viv Cooper, Head of Nursing & Integrated Care Dr Jillian MacLean Consultant Oncologist/MES Medical Lead
PRESENTED BY	Dr Hilary Williams, AMD Quality & Safety
EXECUTIVE SPONSOR APPROVED	Jacinta Abraham, Executive Medical Director

REPORT PURPOSE	FOR NOTING

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
SLT	06/01/2022	NOTED
EMB	04/03/2022	NOTED

ACRONYMS	
MES	Medical Examiner Service
SACT	Systemic Anti-Cancer Therapy
RT	Radiotherapy

SST	Site Specific Teams
VCC	Velindre Cancer Centre
OfW	Once for Wales

1. SITUATION / BACKGROUND

1.1 This purpose of this report is an update to the Quality, Safety & Performance Committee on the implementation of the requirements of the Medical Examiner Service in Wales at Velindre Cancer Centre.

1.2 The Medical Examiner Service (MES) is being implemented in England and Wales in response to The Shipman Inquiry and Mid Staffordshire NHS Foundation Trust Public Inquiry. These proposed a common approach to death certification and independent scrutiny of all deaths to allow the cause of death to be more accurately identified, and the circumstances surrounding the death to be more objectively assessed in order to identify any concerns about the treatment or care provided that may require further investigation.

1.3 Previously, the death certification and mortality review process of patients who die at Velindre Cancer Centre was undertaken in-house, as has been the case across all of the UK until recently. Since autumn 2021, this process has changed as part of the England and Wales' national rollout of the MES. The MES now reviews the medical records for all patients who die at Velindre and consults with the treating team to determine the cause of death for the death certificate to be completed at VCC. As a part of this process the MES completes a comprehensive mortality review and feeds back any issues they identify to VCC. As part of this process the MES will contact the Next of Kin to discuss the cause of death and allow them the opportunity to raise any issues about the care the patient may have received (at any point in their illness). Any issues/concerns/positive feedback identified are fed-back to VCC. The aim is for the MES to be fully operational across Wales for secondary care by April 2022.

This paper is provided for the Committee to:

- Report high level outcomes
- **NOTE** the progress that has been made in implementing the revised Mortality Review process and governance arrangements that have been put in place
- **NOTE** the priorities and plans for the next period and to receive regular updates at future meetings.

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 The introduction of the MES for death certification and Part 1 mortality reviews for patients who die in Velindre University NHS Trust was introduced in October 2021, using an incremental approach to allow time for capacity and processes to be put in place.

2.2 To support the introduction of the new MES process and improved mortality reporting within VCC, the VCC MES and Mortality Project Group has been established and led by Dr. Jillian MacLean. The group meets monthly and the work of the group underpinned by a robust project plan and support from the Programme Management Office.

2.3 A six-week pilot was undertaken in Velindre Cancer Centre on the First Floor ward which commenced in October 2021. The pilot included the reporting of all deaths occurring in VCC to the MES and the sharing of all relevant documentation for death certification and Part 1 mortality review.

2.4 The pilot included training of relevant administrative staff, development of new documentation, and the establishment of dedicated mailboxes for use by the MES and relevant VCC staff.

2.5 The pilot was successful and positive feedback has been received from the Medical Examiner's office.

2.6 The pilot also identified that additional resources will be needed to meet the MES requirements.

2.7 Implementation of the Once for Wales (OfW) DATIX Mortality Module encountered some national delays but is available now in the 'sandpit' environment and will be implemented at VCC.

2.8 As the MES continues its roll out across primary and secondary care, the MES will increasingly discuss the circumstances of patients' deaths with the treating teams at Velindre (even when patients die outside of Velindre) to facilitate the MES mortality reviews, learning and improvement.

2.9 The MES continues to send and share information with VCC regarding:

a) Certain patients under the care of Velindre who die in the Health Boards (in hospital, hospice or at home) to facilitate Velindre reviews of deaths within 30 days of systemic anti-cancer therapy (SACT), or where non-surgical cancer treatments are a cause of death.

b) They also feedback findings they have identified concerns or questions regarding care at Velindre Cancer Centre from mortality reviews they have carried out elsewhere. In certain circumstances these findings will also be reported to Welsh Government and Velindre will be required to demonstrate actions and learning from this feedback.

c) Key VCC staff meet fortnightly with the Trust Q&S team to discuss details of referrals from the MES in circumstances where a patient has died outside of Velindre Cancer Centre.

2.10 Priorities for the Next Period

The MES & Mortality Project Group are developing a Standard Operating Procedure for the new process and reviewing the Terms of Reference for the MES Case Review Panel
The Quality and Safety Team will continue to engage with the OfW DATIX work stream to implement the new Mortality Module to further support the new process.
Re-establish a formal mortality review process utilising the MES review for VCC inpatient death.
Undertake the pilot for death within days of SACT mortality reviews with the colorectal SST.

Velindre University NHS Trust is meeting the requirements of the Medical Examiner System and has received feedback from the MES service on a small number of cases.

2.11 Outcomes, Reporting and Learning

We have met with the MES to discuss the pilot and they feel that it has gone well. Their only issue was that the patient information from Velindre comes to them in multiple emails due to size limit on the data transfer. This does not seem to be the case in other health boards and IT colleagues have been asked to investigate and feedback on this issue.

We have not received any feedback regarding concerns about standards of care for patients who die within VCC. As standard the MES do not automatically send their mortality reviews to the hospital where the death occurred unless issues were identified. However, they have agreed to do this for patients who die at VCC to facilitate our governance processes. We are liaising with the MES to arrange this. We plan to discuss these reviews within our mortality review process and encourage input from other healthcare professionals involved in the patient's care.

To date we have received feedback from the MES regarding a small number of patients with cancer who have died elsewhere (<10). These cases have all been to highlight comments made by the patient's Next of Kin (NoK) where the MES requested clarification. They often related to either the NoK's understanding of the patient's disease, communication during treatment or community support following the end of active treatment. One related to a death within 30 days of SACT, though no deficiencies in care were noted. These cases were all reviewed within the MES and Mortality Group, with input from the patient's clinical team. Responses were sent to the MES and retained at VCC.

Reporting of all VCC deaths is ongoing with regular reports being submitted to the VCC Quality & Safety Management Group and the Trust QSP Committee. Deaths within 30 days of SACT are also reported via the SST Annual Review and the Trust's Quality & Safety function. Themes from each MES response will be included in future reports.

2.12 **Learning**

We continue to refine our process to receive Medical Examiner referrals ensuring a robust investigation is undertaken with any learning identified and shared. Referrals are all reviewed by the MES and Mortality Group with input from the patient's treating team. Generally, the feedback requests clarification of certain aspects of care. Appropriate cases that require more in-depth review are referred to SCIF.

For cases where the MES requests VCC review due to NoK comments, a letter has been drafted to send to the NoK to invite them to contact us or request feedback if they wish to. We are acutely aware that the MES feedback comes to us at a very early point after a patient's death and, as such, we feel that sensitively writing to families offering contact is the correct course of action.

2.13 **Resources**

The administrative resource needed to meet the requirement of this MES has been identified by the pilot project. There is also a co- ordination resource required that is currently being quantified to ensure good links between the Wales Medical Examiner Service with Velindre University NHST Trust. The VCC Quality & Safety team and the MES & Mortality Project Group are currently scoping the resource requirement. It is anticipated that a dedicated resource will be needed to support the increasing requirements of the MES as this process develops alongside the additional mortality reporting requirements, a full business case to ensure sustainable delivery of all aspects of this MES for VUNHST will be developed by the end of May 2022.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS / IMPACT	Yes (Please see detail below)
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability

	Staff and Resources, Safe Care, Individual Care, Timely Care, Dignified Care, Effective Care
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Currently scoping out the need for resourcing to fulfill this implementation

4. RECOMMENDATION

The Quality, Safety and Performance Committee are asked to **NOTE** the contents of this report.

QUALITY, SAFETY & PERFORMANCE COMMITTEE

(CIVAS@IP5)

DATE OF MEETING	24/03/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Choose an item.

PREPARED BY	GARETH TYRRELL – HEAD OF TECHNICAL SERVICES - CIVAS@IP5
PRESENTED BY	GARETH TYRRELL
EXECUTIVE SPONSOR APPROVED	LAUREN FEAR, DIRECTOR CORPORATE GOVERNANCE & CHIEF OF STAFF

REPORT PURPOSE	FOR NOTING

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
		Choose an item.

ACRONYMS	
CIVAS	Centralised Intravenous Additives Service
IP5	Imperial Park Building No.5, Celtic Way, Newport, NP10 8BE
TMU	Temporary Medicines Unit

GMP	Good manufacturing Practice https://ec.europa.eu/health/documents/eudralex/vol-4_en
GDP	Good Distribution Practice https://ec.europa.eu/health/documents/eudralex/vol-4_en
MHRA	Medicines and Healthcare products Regulatory Agency
MS	MHRA Manufacturers' "Specials" license
WDA	MHRA Wholesale Distribution Authorisation

1. SITUATION/BACKGROUND

1.1 Health Boards in Wales have increased the number of Intensive Care beds as part of contingency planning for the COVID 19 pandemic. Welsh Government has anticipated increased demand for intravenous infusions as a result of this expansion and established a Temporary Manufacturing Unit (TMU) to supplement existing UHB CIVAS capacity. The staff and non-staff costs were initially funded to 31/3/21. In January 2021, Welsh Government confirmed extension of funding to 31/3/23. Welsh Government advised that "Temporary" should be removed from the name of the unit. The alternative name CIVAS@IP5 has been adopted. The necessary variations to HO and MHRA licences will be made to change the name, in the meantime both the names TMU and CIVAS@IP5 will be used as appropriate.

1.2 The TMU application for General Pharmaceutical Council (GPhC) Premises registration was accepted in June 2020. The GPhC registration was required for cross boundary supply of medicines under Section 10 Exemption From the medicines Act (1968), pending MHRA license application. The TMU has obtained Home office Domestic Controlled Drugs license, MHRA Manufacturers' "specials" license (MS) and Wholesale Distribution Authorisation (WDA). Following the award of MHRA MS licenses, the GPhC Premises registration is no longer required. A Voluntary Withdrawal of GPhC Premises registration application has been made and accepted.

1.3 The CIVAS@IP5 service has prepared over 20000 doses of ready to administer intravenous infusions, which have been supplied to each of the health boards to support critical care during the COVID-19 Pandemic

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 January sees the CIVAS@IP5 unit having been open and licenced by the MHRA for 12 months.

2.2 Attached to this document is the CIVAS@IP5 Service Board Report for Q3. This report identifies the following

- Performance metrics for operational output
- Regulatory performance against EU GMP
- Service development progress

2.3 Operational output has fluctuated, largely as a result of staff shortages resulting from sickness and loss to other sectors, it is anticipated that all posts be recruited into by end Jan 2022.

2.4 Production output and yield is above 95% (industry and NHS standard) despite capacity pressures

2.5 Wholesale dealing of Rixathon continues to provide cost savings across Wales and the development of a ready-to-administer product from CIVAS@IP5 will support clinical and financial pressures further

2.6 CIVAS@IP5 has packed down under the MHRA Specials Licenced just over 170000 vaccine doses to support booster roll out, with a projection of >200000 by the end of Jan 2022.

2.7 Regulatory performance shows excellent adherence to expected EU GMP guidance, and initial MHRA feedback regarding the Quality Management System is further evidence of regulatory compliance

2.8 Current service developments are:

- Development of additional Noradrenaline strength syringe for critical care
- Standardised Potassium Chloride syringe (50mmol in 50mL)
- Rituximab dose banded infusions provided in ready to use format
- Calcium Folinate infusions provided in ready to use format
- Procurement of semi-automated device for preparation of insulin syringes and OPAT pilot

2.9 As well as the regulatory, compliance and assurance framework for the activity itself, it was also important to consider the wider quality governance framework in which this part of the NWSSP model operates in. To support consideration of this, appendix one was compiled which outlines, from various internal and external sources, key elements which make up an Organisational quality governance framework. The right-hand column then articulates how TMU and NWSSP fulfill these elements. The document has been previously discussed and approved in advance of the Committee with Medical Director NWSSP, Executive Medical Director Velindre University NHS Trust and Executive Director of Nursing, AHPs and Health Science.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below:
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
	The CIVAS@IP5 was specifically commissioned to ensure equality of access to medicines by supplementing existing aseptic manufacturing capacity.
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
	CIVAS@IP5 is operating in compliance with relevant legislation, specifically the Medicines Act (1968), The Human medicines regulations (2012) and the misuse of Drugs act (1971)
FINANCIAL IMPLICATIONS / IMPACT	There is no direct impact on resources as a result of the activity outlined in this report.
	Welsh Government has confirmed continuing funding of revenues for the project to 31/3/23.

4. RECOMMENDATION

4.1 The Quality, Safety and Performance Committee is asked to **note** current levels of service performance against the framework of standards set out in EU GMP and which we are legally required to comply with as an MHRA “Specials” and Wholesale Dealer licence holder. Further update on new products introduced into the CIVAS@IP5 portfolio will be provided in future meetings.

4.2 The MHRA inspected the service in February 2022. Provisional findings have been provided and an action plan in response submitted for acceptance. Once a final action plan has been accepted by the MHRA the inspection findings will be presented back to QS&P

Appendix - TMU Governance Arrangements – notes

1.1	Quality as drive for organisational strategy	Quality and safety priorities clearly defined, documented and periodically reviewed	CIVAS@IP5 operates in compliance with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) these internationally recognised standards designed to ensure safe manufacturing, storage and distribution of medicines are clearly defined: https://ec.europa.eu/health/documents/eudralex/vol-4_en https://ec.europa.eu/health/human-use/good_manufacturing_distribution_practices_en The facility and its operation are clearly defined in the CIVAS@IP5 site master file and in standard operating procedures. The CIVAS@IP5 was inspected by the MHRA against GMP and GDP on 15-16th December 2020, AND FOR PACK DOWN OF covid VACCINES ON THR 6TH Sept 2021. All newly licensed manufacturing units are inspected within 12 months of the first inspection a further inspection is anticipated in December 2021. The CIVAS@IP5 will be inspected against GMP and GDP on behalf of WG and the Welsh Chief Pharmacists Group by the All Wales QA Pharmacist during 2021.
1.2		These priorities are reflected in organisation's IMTP	The CIVAS@IP5 development is fully supported by the Shared Service Partnership Committee and Welsh Government. The Minister has provided funding for the TMU project in response to COVID requirements and

			continuity of supply. It is also integral to supporting the COVID vaccination Programme. Given the success and future potential additional funding has been provided by the Minister for a further two-year period and it will form part of the next iteration of the NWSSP IMTP which is due to be agreed by the NWSSP Committee in March 2021.
1.3		Quality and safety strategic risks are reflected in Board Assurance Framework	The CIVAS@IP5 Board Agenda includes an agenda item on project risk. Any significant quality and safety risks will be also highlighted and discussed at the Shared Service Partnership Committee and the NWSSP Senior Leadership Team as part of the normal operational management and reporting within NWSSP. A separate paper outlines the proposed addition of NWSSP business, including CIVAS@IP5, into the Velindre University NHS Trust Quality, Safety & Performance Committee going forwards, the agenda will include a section on associated risks.
1.4		Quality and safety risks central in the risk management strategy and processes of the organisation	Quality and Safety is integral to GMP and GDP quality improvement and quality by design are inherent within the approach to processes within CIVAS@IP5. As above in terms of reporting risks within NWSSP and to the NWSSP part of the Velindre University NHS Trust Quality, Safety & Performance Committee if approved.
2.1	Leadership of quality and safety	Collective responsibility for quality and patient safety across the	The CIVAS@IP5 lines of accountability are clearly defined. There are clearly defined professional roles.

		executive team and clearly defined roles for professional leads	The CIVAS@IP5 Head of Technical Services now reports to the NWSSP Service Director for TrAMS managerially and to the Chief Pharmaceutical Advisor to WG professionally. The CIVAS@IP5 Head of Technical Services also reports to the Service Board, which in turn reports to the Shared Services Partnership Committee. The CIVAS@IP5 Head of Technical Services is the Superintendent Pharmacist for the CIVAS@IP5 General Pharmaceutical Council Premises Registration, and the Site lead, and Person Responsible for Security on the Home Office Domestic Controlled Drugs license. A suitably qualified and experienced individual is employed in the Accountable Pharmacist role. A new accountable pharmacist has been appointed to take over from the incumbent's retirement. The QA and Production Leads report to the CIVAS@IP5 Head of Technical Services. The QA and Production lead are named on the MHRA Manufacturers' "specials" (MS) license as being responsible for Quality and Production respectively. The QA lead is the named Responsible Person on the MHRA Wholesale Distribution Authorisation (WDA). All staff working in the CIVAS@IP5 will be formally engaged to job roles within NWSSP, to ensure

			accountability for the work undertaken. These engagements will be a mixture of: • Honorary Secondments of staff already employed by Health Board or Trust Pharmacy units • Bank Staff engagements • Permanent or where appropriate temporary employment contract All staff have a quality element to their role and an understanding of quality assurance of the operation of the service.
2.2		There is sufficient capacity and support, at corporate and directorate level, dedicated to quality and safety	The CIVAS@IP5 board provides scrutiny of safety, quality and performance and of the service. The board also provides strategic and operational support. The board has met monthly since the service was envisaged in April 2020. The capacity of the board to carry out the oversight and support roles is evidence by the successful MHRA license applications and service delivery, respectively, within the projected project timescales. All health boards through the support of Chief Pharmacists have helped support the creation of the TMU and they are fully supportive and committed to the Unit. NWSSP is about collaboration and support service provision.
3.1	Organisational scrutiny of quality and patient safety	The roles and function of the Quality and Safety Committee is fit	It is proposed that the following are submitted to the Quality and safety Committee

		for purpose and reflects the Quality Strategy, Quality and Safety Governance Framework and key corporate risks for quality and safety	• Annual Quality Statement • Inspection reports (as and when received) • MHRA Update/Action plan
3.2		Independent/Non-Executive Members are appropriately supported to meet their responsibilities through the provision of an adequate induction programme and ongoing development so they can effectively scrutinise the information presented to them	A separate paper outlines the proposed addition of NWSSP business, including CIVAS@IP5, into the Velindre University NHS Trust Quality, Safety & Performance Committee going forwards. Regular updates will be provided as part of the normal course of business to the Shared Service Partnership Committee, which includes representatives from every NHS organisation as the responsible body for shared services.
4.0	Clinical Audit	There is visibility and oversight of clinical audit and improvement activities across divisions/groups/directorates and at corporate level. This includes identification of outliers and maximising opportunities for sharing good practice and learning	The CIVAS@IP5 service is a professional technical service whereby all clinical decisions are made by health board clinicians and not the CIVAS@IP5 staff. The unit is an accredited production unit which has a self-inspection programme for GMP and GDP. The unit is independently inspected by the All Wales QA Pharmacist. Best practice is shared through the Welsh Chief Pharmacists Group's pharmacy technical services sub-group (CPTS) and lessons learned from the development of the TMU have been captured. A number of senior health board technical pharmacy staff have been

			involved in putting in place the quality and operating procedures.
5.1	Organisation promotes a quality and safety focused culture	Organisational values and behaviours support a quality and safety focused culture	The organisational structure of CIVAS@IP5 is designed to ensure adequate supervision of all processes. All grades of staff are empowered and supported in identifying process deviations. The service will operate in line with the values and culture of NWSSP
5.2		Organisation actively participating in quality improvement initiatives	The service has a robust Corrective Action/Preventative Action (CAPA) system built into it's Pharmaceutical Quality System (PQS). This ensures lessons are learnt and appropriate actions taken, within an appropriate timescale. The CAPA system also ensure continuous quality improvement.
5.3		Organisation takes steps to listen to staff and involve them in monitoring service change/improvement	All grades of staff are empowered and supported in identifying process deviations, during manufacturing process or at daily pre and post manufacturing session meetings. Feedback is provided on issues raised.
5.4		Strong culture of learning lessons from staff feedback or concerns	The CAPA system is an essential component of the Pharmaceutical Quality system. Staff training encompasses the PQS and the role of team members in its operation. The management recognise the importance of responding appropriately to staff concerns and providing feedback.

5.5		Quality and safety an integral part of workforce management processes	Quality and safety are pre-requisites for compliance with GMP and GDP
6.1	Organisational structures and processes support delivery of high-quality, safe and effective services	Clear lines of accountability for quality and patient safety across the organisational structure ie 'floor to Board'	Included as point 9 of PQS in Internal Assurance section
6.2		Effective corporate and operational controls to support delivery of high-quality and safe services	Operational controls in PQS in Internal Assurance section Current corporate and operational controls have been extended to cover the operation in line with existing processes. Once fully established the Q&S Committee for Shared Services will also provide an additional level of assurance for NWSSP Committee members
6.3		The oversight and governance of DATIX and other risk management systems ensures they are used as an effective management and learning tool. This should also include triangulation of information in relation to concerns, at a divisional/group/ directorate or corporate level, and formal mechanisms to identify and share learning	The DATIX is used to report clinical incidents and health and safety incidents. It is recognised that the DATIX system does not have the level of detail in classification of incidents for a CAPA system which meets the expectation of the MHRA. The Q-Pulse system is therefore used in addition to DATIX for management of CAPA and other components of the PQS. Complaints will be managed through Q-Pulse, the NWSSP Complaints Management Protocol and if these relate to product quality and or patient safety the MHRA's Defective Medicines Report Centre (DMRC). There is a Recall Procedure, the effectiveness of which is tested annually.

6.4		Enough resource and expertise to support and improve quality governance arrangements	The CIVAS@IP5 Head of Technical Services is an appropriately qualified and experienced Pharmacist. The CIVAS@IP5 Head of Technical Services is supported by QA lead, Production Lead and Production Managers with the necessary qualifications, skills and experience. The senior team is supported by a workforce designed, recruited and trained specifically for the operation of the service. The team has a clear understanding of their required contribution to the PQS. Capacity planning carried out as part of workforce design has ensured that the PQS is appropriately resourced.
6.5		Organisation has comprehensive and timely information for monitoring and reporting on quality and safety	Q-pulse is used to manage the PQS. This system is used to record, monitor and report on information relevant to the PQS: CAPA, facilities and equipment, customer, suppliers, external audit and self-inspection, The working environment is monitored by the team. End of batch tryptone soya broth fills are carried out at the end of each manufacturing batch. Public Health Wales provides Microbiological services, including incubation, species level identification and reporting for the environmental monitoring and end of batch testing. Finished product is quarantined pending confirmation of satisfactory environmental and end batch testing data.

6.6		Quality and patient safety receives effective coverage at both corporate and operational management meetings	The Board receives and reviews a monthly operational report, which includes both quality, safety and operational performance.

CIVAS@IP5 Service Board

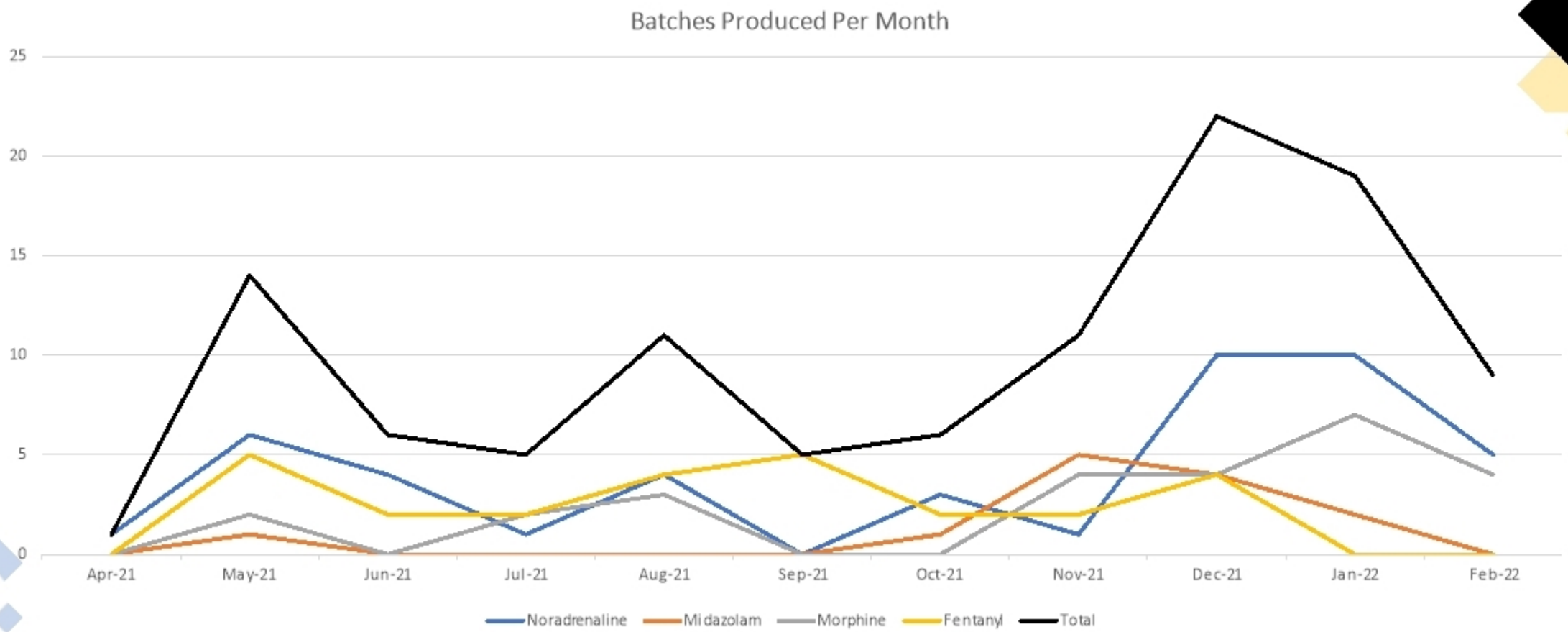
March 2022

CONTENT

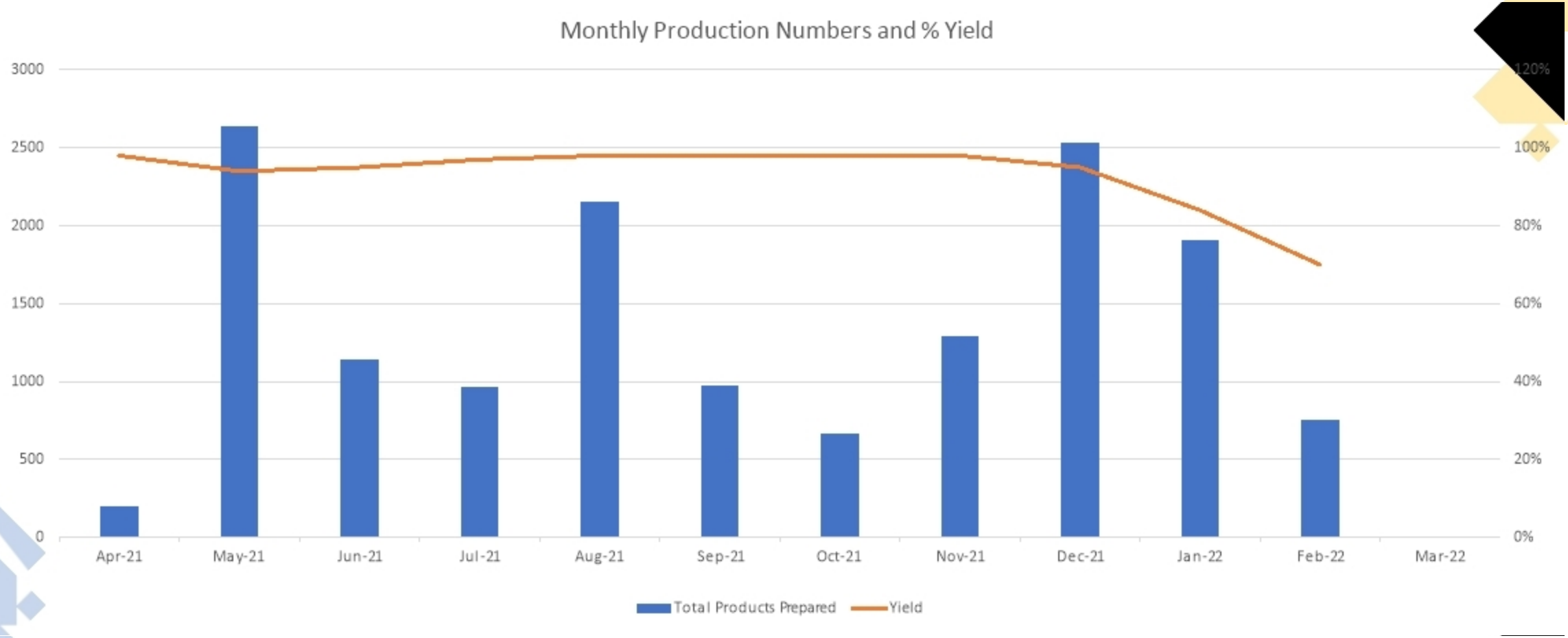
- SERVICE PERFORMANCE METRICS
- QUALITY METRICS
- SERVICE SUMMARY
- QUESTIONS

SERVICE PERFORMANCE

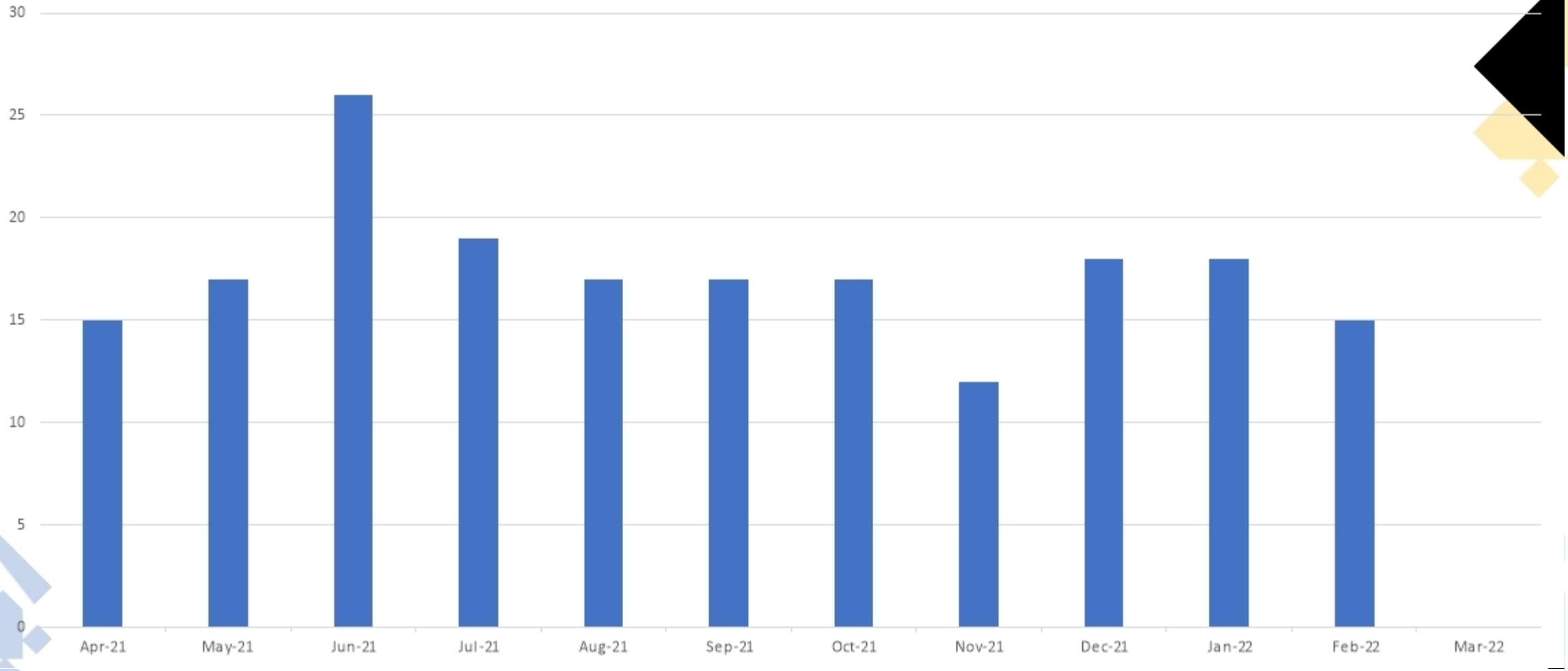
BATCH PRODUCTION



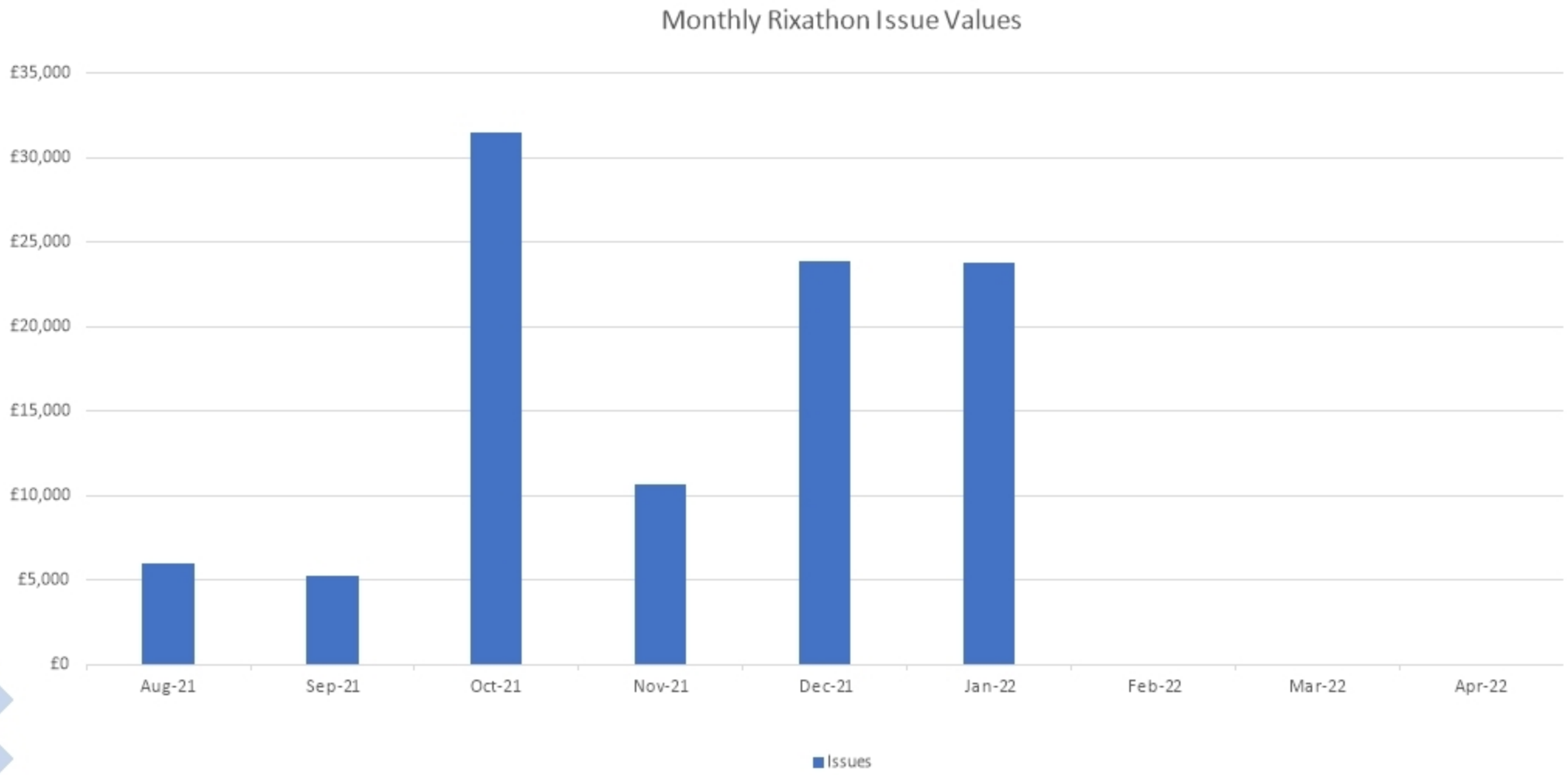
TOTAL PRODUCTION & % YIELD PERFORMANCE



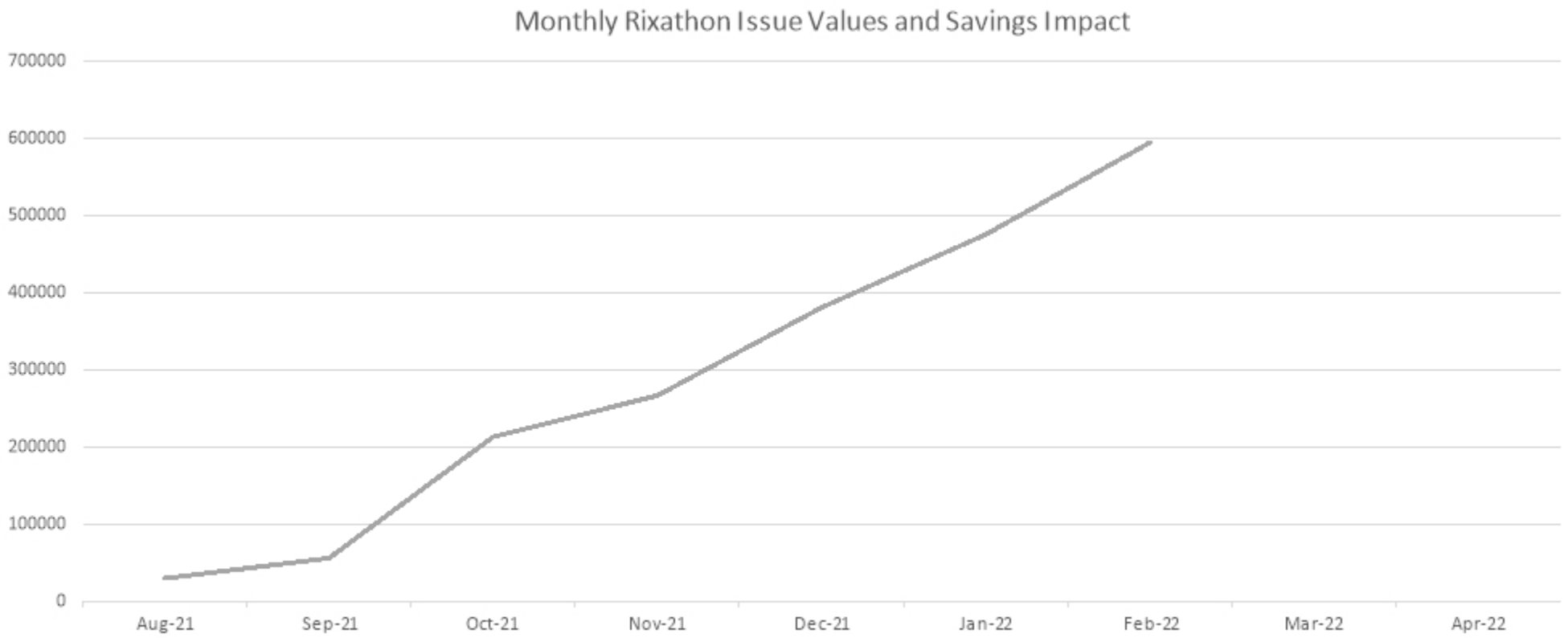
UHB ORDERS RECEIVED



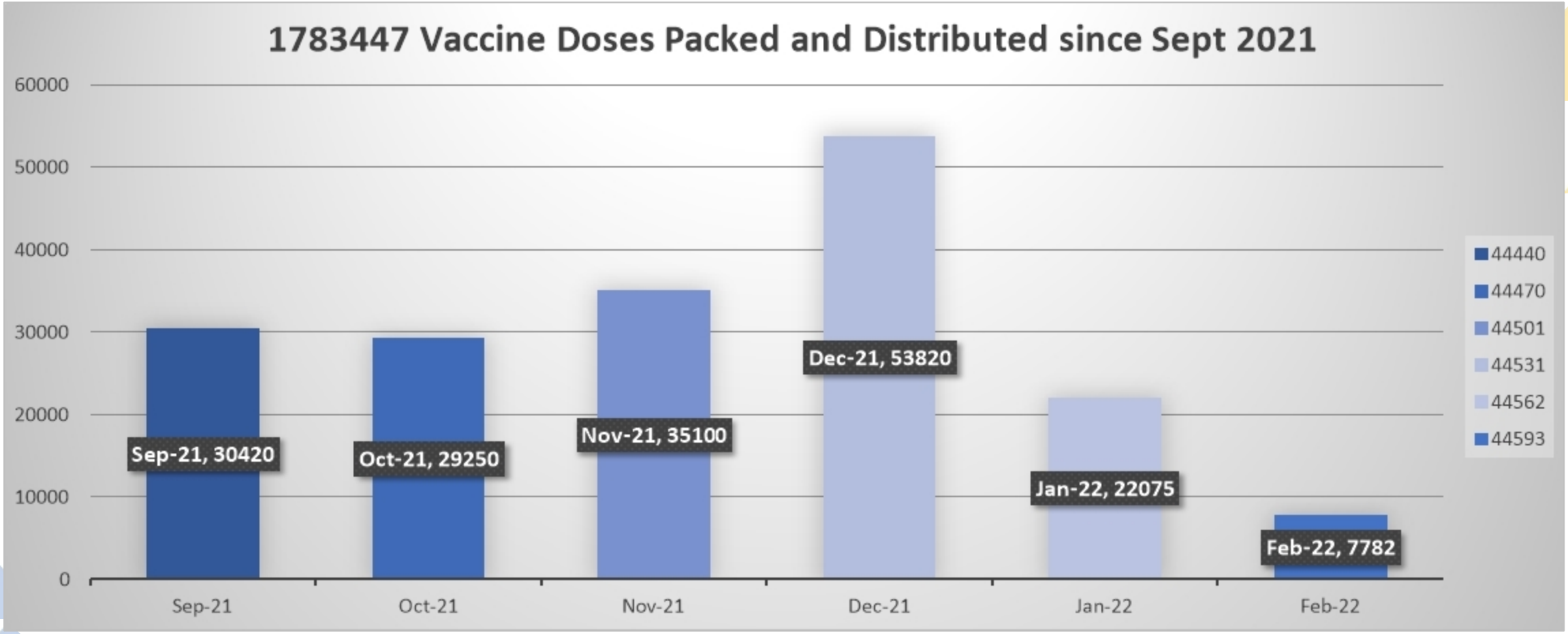
RIXATHON WDA SERVICE



CUMULATIVE RIXATHON SAVINGS

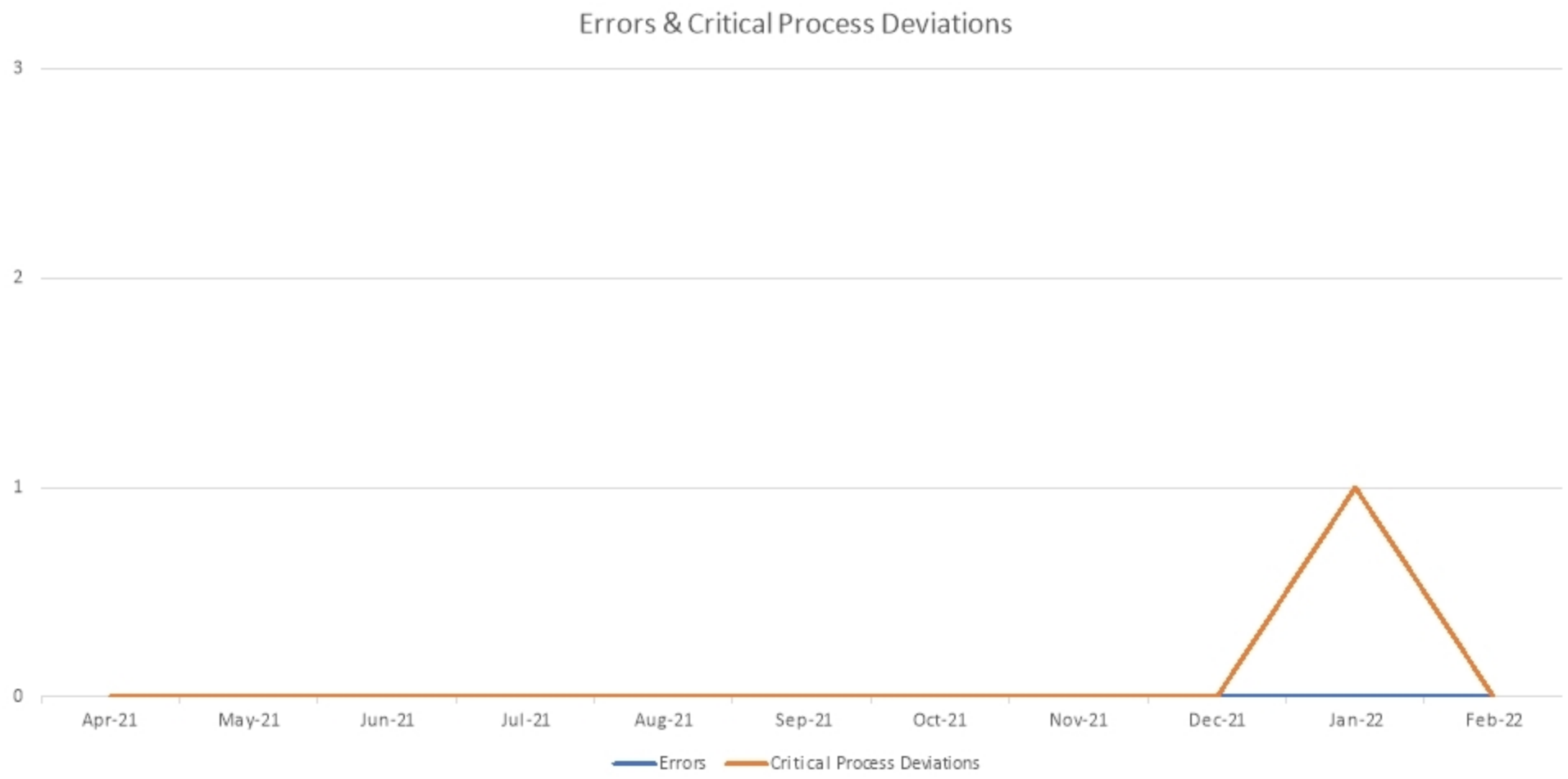


COVID-19 VACCINE BOOSTER PACK DOWN

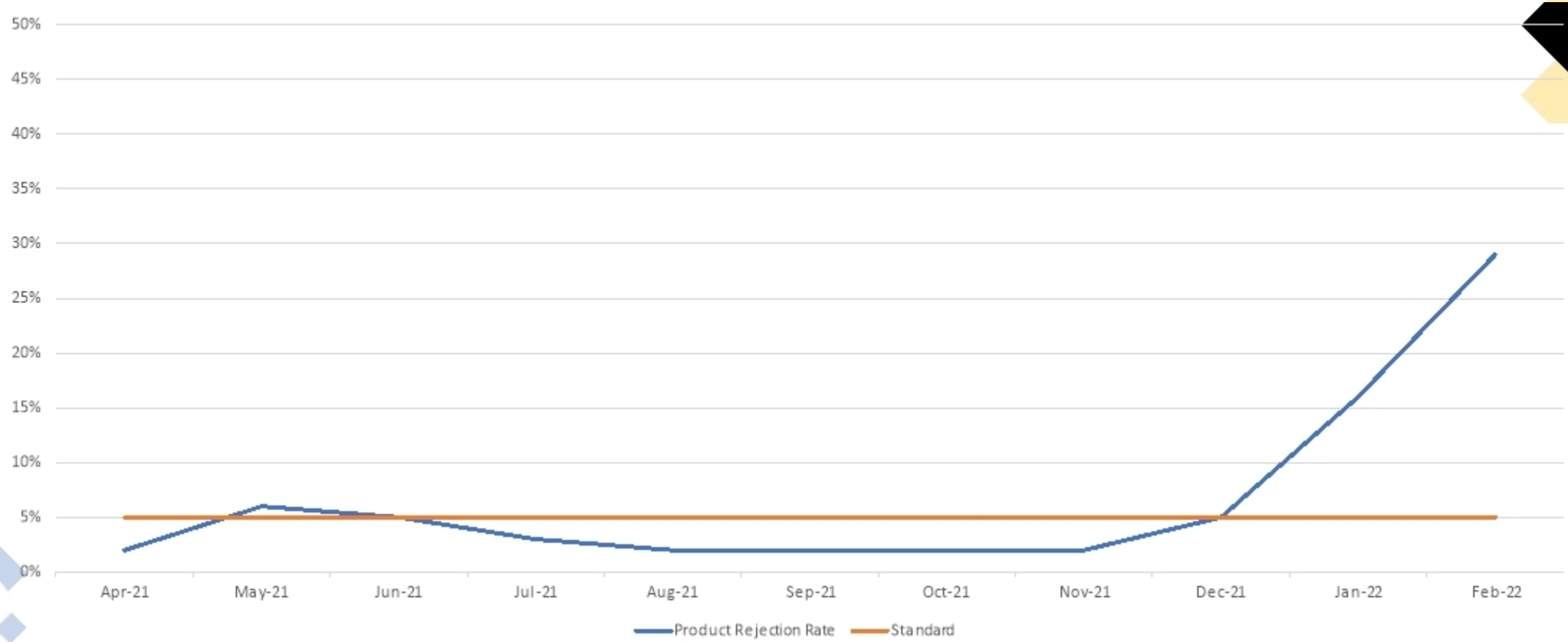


SERVICE PERFORMANCE REPORT CIVAS@IP5

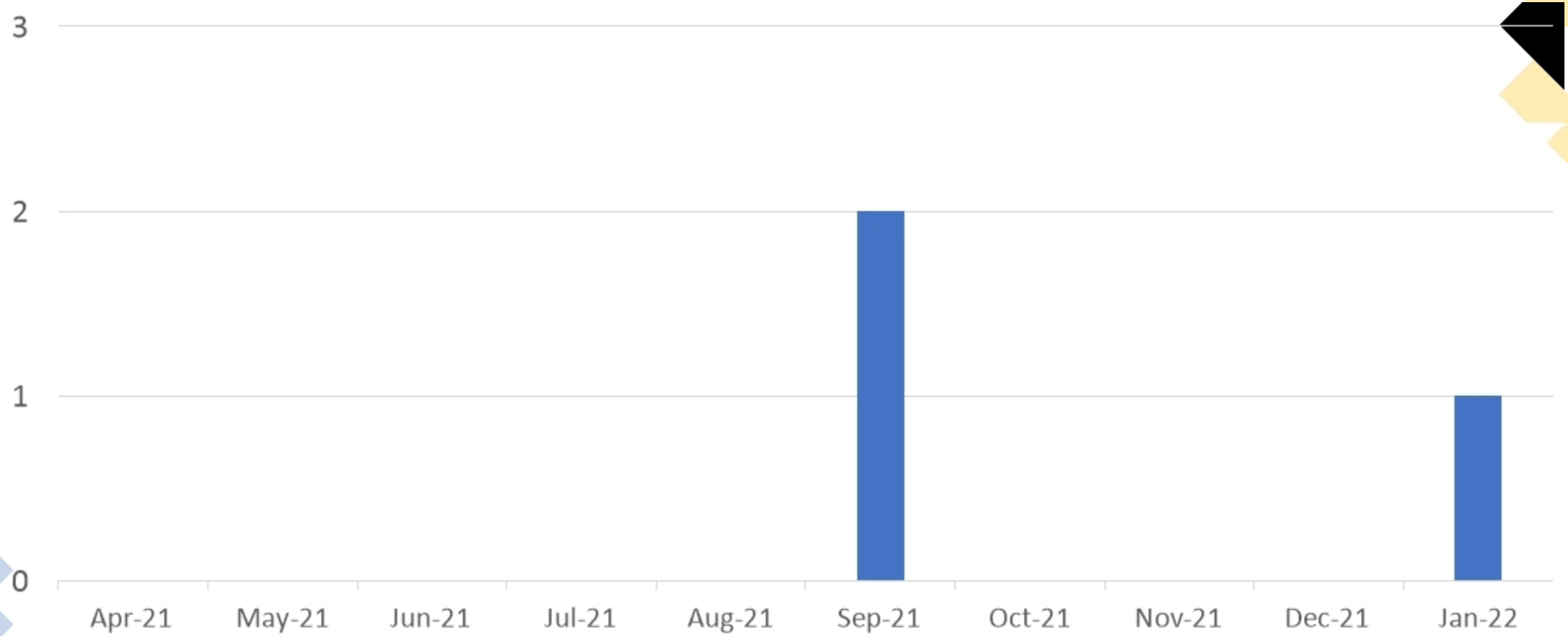
ERRORS & CRITICAL DEVIATION PROCESS



PRODUCT REJECTION RATE

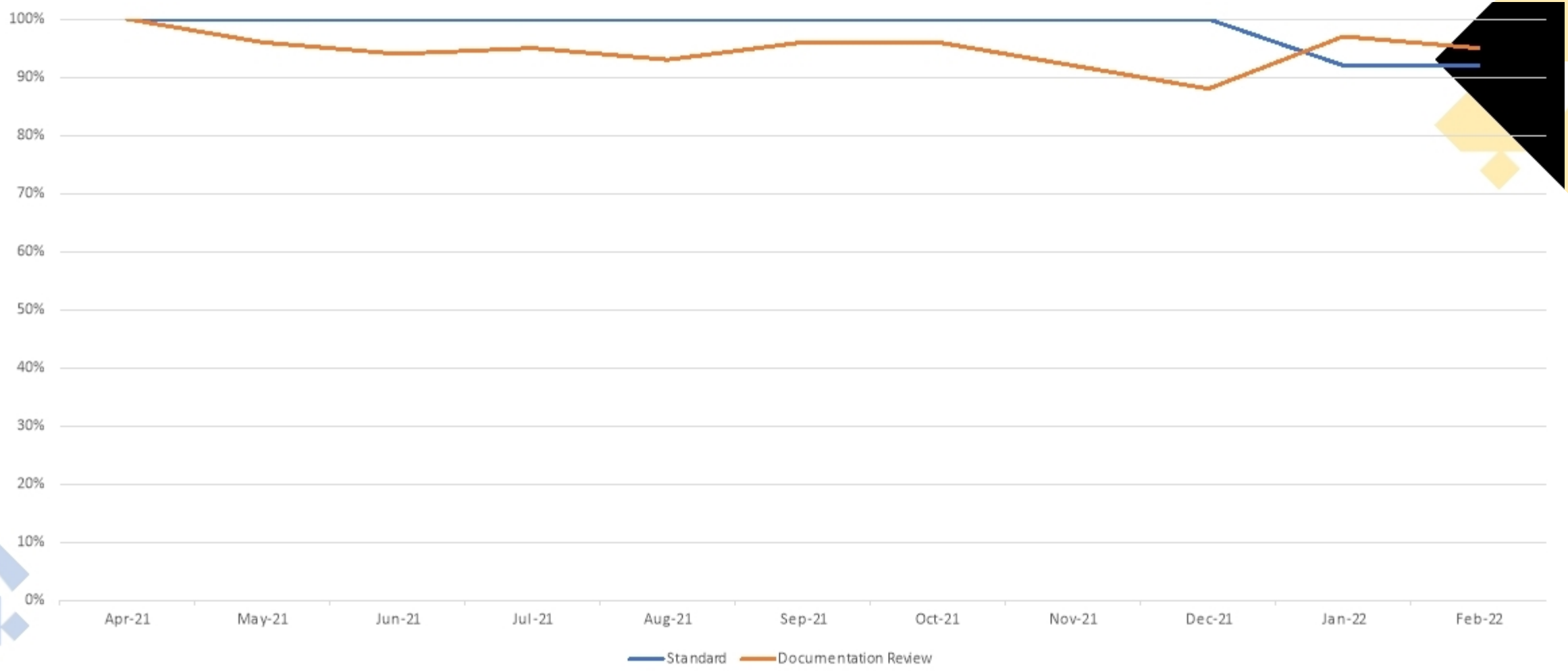


FACILITIES DEVIATIONS

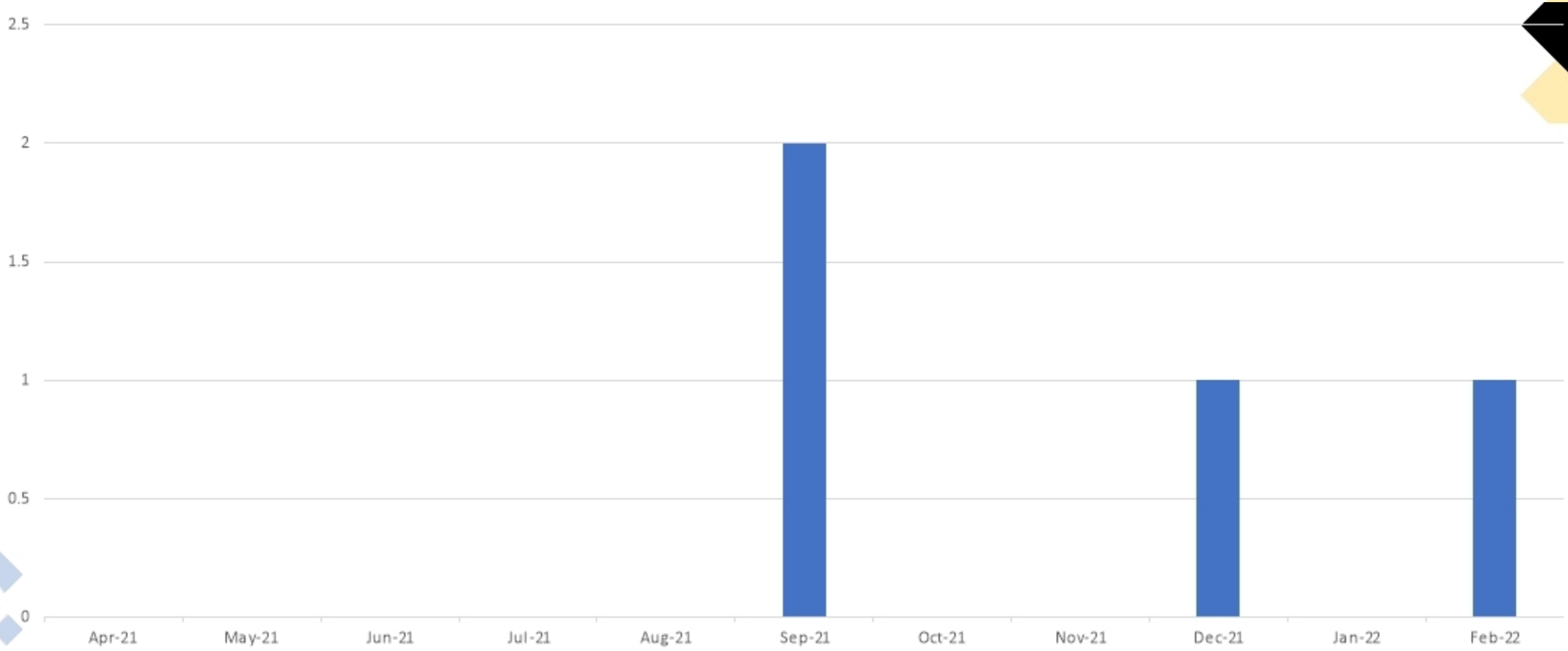


INTERNAL AUDIT COMPLIANCE

DOCUMENTATION REVIEW TARGET



SERVICE COMPLAINTS



SERVICE SUMMARY

Notable reduction in yield % resulting from new staff in production process. This is a recognised industry response to new operators

High sickness absence rate combined with supplier quality issues led to a drop in production – reviewed ordering patterns will avoid future issues in this regard.

All capital purchases receipted or with confirmation of contracted delivery

Batch rejection due to poor handling of samples in PHW Lab – this has been investigated and reported back to PHW

QUALITY, SAFETY & PERFORMANCE COMMITTEE

GOLD COMMAND HIGHLIGHT REPORT

DATE OF MEETING	24 March 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Emma Stephens, Head of Corporate Governance
PRESENTED BY	Lauren Fear, Director of Corporate Governance & Chief of Staff Nicola Williams, Executive Director Nursing, AHPs & Health Science Cath O'Brien, Chief Operating Officer Dr. Jacinta Abraham, Executive Medical Director
EXECUTIVE SPONSOR APPROVED	Lauren Fear, Director of Corporate Governance & Chief of Staff Nicola Williams, Executive Director Nursing, AHPs & Health Science Cath O'Brien, Chief Operating Officer Dr. Jacinta Abraham, Executive Medical Director

REPORT PURPOSE	**FOR NOTING**

ACRONYMS	
COVID	Coronavirus
SACT	Systemic Anti-Cancer Treatment

1. PURPOSE

This paper has been prepared to provide the Quality, Safety & Performance Committee with details of the key issues and items considered by **GOLD COMMAND** at its meetings held between the **16/02/2022** to **16/03/2022**.

The Quality, Safety & Performance Committee is requested to **NOTE** the contents of the report and actions being taken.

2. BACKGROUND

To ensure a combined and coordinated response to the emergence and prevalence of the Omicron variant the Velindre University NHS Trust re-activated its agreed dedicated incident Command and Control structure on the **15/12/2021**. The structure provides a formal escalation and de-escalation path and is consistent with the nationally recognised three tiered Command and Control structure. This has included a strengthened clinical support infrastructure, ensuring effective agile decision making with robust clinical oversight, placing clinicians (Medical, Nursing, AHP's, & Health / Clinical Scientists) firmly at the centre of risk based decision making.

3. HIGHLIGHT REPORT

The following areas were highlighted for reporting to the Quality, Safety & Performance Committee from the GOLD COMMAND meetings held between the **16/02/2022** and **16/03/2022**.

ALERT / ESCALATE	There were no items identified to **ALERT / ESCALATE** to the Quality, Safety & Performance Committee.
ADVISE	• **GOLD COMMAND** The frequency of GOLD COMMAND meetings is continually assessed and flexed in line with the needs of the incident and its interface with the Welsh Blood Service and Velindre Cancer Service SILVER COMMANDs. Since the **24/01/2022** GOLD COMMAND has reduced its meeting frequency to once a week. The requirement for GOLD COMMAND to continue to remain in place was reviewed and discussed on the

16/03/2022. It was agreed that GOLD COMMAND and its supporting incident structure arrangements will continue to remain in place until at least the end of March 2022, due to the increasing number of staff absences and operational pressure in both of the core divisions relating to the current increasing prevalence of the new variant. The situation will be further reviewed in the last week of March 2022. This will also align with the imminent revised guidelines from Welsh Government expected by the end of March 2022.

- **COVID RISKS**

The risk profile associated with the prevalence of the Omicron variant continues to reduce and continues to be carefully monitored. The key risks continue to be associated with staffing levels with ongoing COVID related absence and the end of year period and associated increased take up of annual leave presenting some increased difficulty within both of the core operating divisions of the Trust. This remains intermittently acute in the Systemic Anti-Cancer Treatment (SACT) service and the Blood Collection teams and daily monitoring and planning are in place. Arrangements to enable buy back and carry-over of annual leave to 2022/23 has enabled further flexibility, although staff wellbeing remains a focus.

- **DELIVERY OF SYSTEMIC ANTI-CANCER TREATMENT THERAPY (SACT) WITHIN TARGET TIMESCALES (21 DAYS)**

GOLD COMMAND has continued to receive regular updates providing a detailed analysis of the current position in relation to the Velindre Cancer Service ability to meet demand for SACT as a result of the combined impact of COVID and non-COVID related staff absences.

GOLD COMMAND were advised of all the enhanced business continuity measures that remain in place to mitigate the risks as far as possible to SACT delivery, including the establishment of a Task Force Group to oversee this, working across the service to maximise patient treatment. GOLD COMMAND received ASSURANCE that the Task Force is adopting a flexible and agile approach to delivery to review and assess all options available on the SACT treatment pathway, in order to secure the required nurse staffing and also fully consider the wider workforce capacity, to ensure effective optimisation and consideration of all key elements.

	In addition to the above business continuity measures, daily patient prioritisation exercises are undertaken each morning in line with the agreed Clinical Prioritisation Framework, Organisational Change Process documentation is at final stages of preparation for approval to secure routine opening of SACT Daycase Services on bank holidays and extended opening hours of Pharmacy. As staffing across the Directorate enables, ad-hoc Saturday clinics are established to ease capacity pressures.
ASSURE	• **UPDATE ON 28/01/2022 FIRST FLOOR WARD COVID OUTBREAK** GOLD COMMAND were assured that following review of the 4 in-patients who tested positive for COVID post admission it had been concluded that only one, on the balance of probability was First Floor Ward acquired. It was therefore concluded that it had been a 'cluster' rather than an outbreak. Individual nosocomial patient reviews have been undertaken. • **VELINDRE CANCER SERVICE** o ***Staff Absence:*** Main impact of COVID Wave 4 for the Velindre Cancer Service remains staff absence and the resulting impact on ability to provide services to all patients within the required timescales. As outlined above GOLD COMMAND commissioned a Task Force to address key risks in respect of SACT delivery. o ***Health Boards:*** In order to ensure that the operational leads within the Velindre Cancer Service have a clear and up to date view of the current COVID position within each of the Health Boards, meetings have been established with cancer team leads across each of the Health Boards. • **WELSH BLOOD SERVICE** o ***Blood / Blood Products Stock levels:*** Overall decreasing blood stock position reported over the past few weeks. This is due to increasing non-attendance of donors as community rates of Covid-19 have increased. Targeted blood group collection is underway to reduce the risk to A and O neg position, and will continue to be proactively monitored and extra sessions are planned.

	– Over the last 4 weeks, the demand for red cells has averaged at 1440 units per week, this was slightly below last year's average (1459). However, collections for the same period were approximately 1380 units per week. This shortfall of approximately 60 units per week has resulted in a slow decline in blood stocks. – The change in guidance in relation to physical distancing provides the opportunity to increase the Donor chair capacity within clinics and additional clinics (subject to staff availability) which will be enacted in forthcoming weeks. ○ ***Staff Absence:*** throughout late February and into March 2022, Collections has seen an increase in the allocation of annual leave, however the allocation has not exceeded maximum allowance for service delivery. There is a continued decrease in sickness absence and a focus on recruitment into funded vacancies. Collection teams are maintaining full operation, however proactive monitoring is being undertaken to manage stock levels. Daily resourcing meetings are being conducted and resulting adjustments to clinics are made wherever necessary. Appointment booking is specific blood type focused to refine supply demand alignment. ○ Preparations are underway on the introduction of self-service triage facility to release this resource and a reduction in social distancing. It must be noted that clinic capacity increases resulting from any reduction in social distancing will require additional staff on some occasions (clinic size dependent). Full advantage of this increased capacity will only be realised where staffing levels are sufficient to maintain safe service delivery.
	• **COVID RESPONSE CELL** The COVID response cell has been considering the step down plans from some of the current COVID restrictions in line with National, Public Health guidance. Public Health and Welsh Government held NHS Wales wide seminars week of the 7th March 2022 to support the NHS in the work to move towards a new business as usual approach. Current Infection Prevention and Control guidance supports the introduction of a risk based approach balancing need for service delivery with current restrictions. Public Health has advised that these Infection Control guidance documents will cease to exist from 1st April 2022 and NHS

	bodies will revert to using the pre-pandemic national Infection Control Manual. In line with the risk based flexibility that the current guidelines have and, given the current capacity challenges, and the change in the balance of risk, the COVID Cell made a number of recommendations which were approved by both Strategic Clinical Advisory Group and GOLD COMMAND on the **09/03/2022** that will need to be operationally planned and worked through carefully by divisional SILVERS. The main changes are summarised below: ○ ***Cease front door COVID triaging*** (although recognising that high volume areas such as Velindre Cancer Service Outpatient Department may need to retain this role in some form in order to control the footfall). ○ ***Reduce social (physical) distancing*** *to 1M* in all clinical and non-clinical areas. The exception being the in-patient ward at Velindre Cancer Service which should remain at 2M for the short term. ○ ***Reinforcing to staff*** that unless they have direct contact with extremely vulnerable patients they do not need to isolate if a COVID contact. Changes will be assessed and implemented on a divisional basis utilising a risk based approach tailored to local situation and needs. Velindre Cancer Service and Welsh Blood Service SILVER COMMANDs and Senior Management Teams will implement these changes in a planned way, prioritising clinical services. Further changes will be required in forthcoming weeks upon receipt of further revised national guidance. It is anticipated that these changes will enable additional capacity within both divisions, whilst still ensuring that we continue to work within the existing guidelines. However, it is also recognised that to implement the social distancing changes, this will need to be carefully planned alongside the return of staff to working on site and flexible working. As such, de-escalation of the COVID measures will be undertaken adopting a phased approach to support the necessary operational arrangements, this will include collaboration with the established Agile Project Group, underpinned by a clear and comprehensive staff communication and engagement plan across the Trust.

	• **UKRAINE CRISIS** ○ ***Supplier disruption:*** *T*here is no current evidence of supply chain impact, however work is being undertaken on the global supplier position in relation to the potential risk of increased supplier disruption due to the Geo-political events (Ukraine-Russia). Assurance has been received from the existing supplier of blood packs, who has a manufacturing plant in Poland that supply will continue. WBS are closely monitoring the critical supplier position with procurement and continuing to engage with other UK Blood services and aligned Donor Registries in relation to any potential impact on service provision. ○ ***Fuel Shortage:*** whilst there has been no formal shortage of fuel declared, WBS have received reports of disruption to fuel supplies in some parts of Wales. Concerns have been raised regarding the increasing cost of fuel, the disparity with the rate of business mileage and the timeline for reimbursement. The reduction in physical distancing will provide some mitigation as this will increase the capacity available on the minibuses, reducing the need for all staff to utilise their own transport to venues. Further consideration may need to be given to balancing the requirement for physical distancing against maximizing the capacity available in the minibus whilst maintaining other infection prevention and control measures should access to fuel become an issue.
APPENDICES	~

QUALITY, SAFETY & PERFORMANCE COMMITTEE

WORKFORCE & ASSOCIATED FINANCE RISKS

DATE OF MEETING	24th March 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Matthew Bunce, Executive Director of Finance & Susan Thomas, Deputy Director of W&OD
PRESENTED BY	Matthew Bunce, Executive Director of Finance
EXECUTIVE SPONSOR APPROVED	Matthew Bunce, Executive Director of Finance

REPORT PURPOSE	FOR NOTING

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Team via e-mail	15th March 2022	Approved

ACRONYMS	
IMTP	Integrated Medium Term Plan
HB	Long Term Agreement
LTA	Health Board
WBS	Welsh Blood Service
WTAIL	Welsh Transplantation and Immunogenetics Laboratory
WG	Welsh Government

VCC	Velindre Cancer Centre

1. SITUATION/BACKGROUND

1.1 The purpose of this report is to highlight the key workforce and associated financial risks that the Trust is currently facing and that might crystalise in 2022-23, together with the required management action to ensure risk mitigation and performance improvement.

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 Key Workforce & Associated Financial Risks

Key issues currently and expected to continue into 2022-23 are:

Workforce

- **Workforce Supply and Shape**.
    - Clear service and workforce plans are required to articulate the skills required to meet both current and future demand. Particular areas of focus are Radiotherapy and Medical staff, Velindre Futures/TCS projects and Laboratory Modernisation in the Welsh Blood Service

    - The supply of staff, due to the funding streams supporting a number of projects over the years the Trust, has resulted in a significant number. of staff (c185) on fixed-term contracts. The Workforce team is currently reviewing all contracts with operational teams to provide a current and updated picture of contractual status in order to quantify risk of any redundancy cost associated with these contracts

- **Wellbeing**

  The COVID pandemic has resulted in a generally higher levels of sickness absence compared to pre-Covid. The main reason for absence remains stress and anxiety. The Trust, throughout COVID, has provided a raft of wellbeing interventions to support staff and the Workforce teamwork with hotspot areas to ensure targeted interventions are provided

- **Recruitment and Retention**
    - The Trust has 141wte vacancies, 97wte in clinical roles. A Recruitment and Retention plan is being developed with targeted specific intentions in hotspot areas

Actions:

- **Workforce Supply and Shape**
    - Robust 5-year workforce plan to enable timely recruitment to fill vacancies reducing agency, TOIL and overtime payments accordingly in the short term and also looking at skill mixing and role re-design in the medium term.

- **Wellbeing**
    - Continue to provide support to teams to manage sickness, with particular focus on hotspot areas. A Trust wide Health and Wellbeing Steering group has been established to provide a holistic overview and assurance to the Executive Board that effective interventions are being undertaken and good practice is shared across the Trust. During COVID staff have often needed to adapt to a hybrid working model. This work will be progressed over the forthcoming months with a focus on supporting staff's wellbeing in different working environments.

- **Recruitment and Retention**
    - Work ongoing to:
        - Ensure robust baseline recruitment data in line with effective recruitment processes
        - Deliver effective attraction strategies
        - Develop pilots of new ways of working (in line with effective workforce planning)
        - Create retention strategies to improve retention rates

Financial

- The Trust has reported a cumulative year to date position of £477k (Jan '22) underspent on pay and is forecasting an outturn underspend of circa £552k. However, whilst the Trust pay budgets are underspent due to significant vacancies, the cumulative spend on agency to date is £1,524k and a forecast outturn spend of circa £1,821k. **Of the forecast annual agency cost of £1,821k, c£500k is estimated to be premium cost that could be saved if the Trust were able to recruit permanently.**

- The cost of sickness is reflected in the pay costs through use of agency and overtime and provision of TOIL. Reduction in sickness absences rates has a direct impact on reducing the variable pay bill to cover absences.

- Covid response & recovery funded posts are the key financial risk for the Trust given the uncertainty regarding the Covid income sum for 2022-23:

    - 72.5wte staff have been recruited permanently to respond and recover from Covid with a cost of £3,600k p.a. A further 38wte staff with a cost of £2,659k p.a. are in the process of being recruited, a total of 110.5wte staff and £6,263k cost p.a.
    - Of the 72.5wte staff, 33wte relate to Covid response which Commissioners have indicated they can't provide funding for amounting to £1,300k.
    - Commissioners have included funding in their IMPTs for the Trust Covid recovery plans, however the risk to the Trust is that funding will flow as marginal income based on activity the Trust treats above its baseline 19-20 levels. The costs are already committed to establish extra capacity which presents a financial risk to the Trust should the activity not flow as forecast. The Chief Exec and DoF are seeking recognition from commissioners to this in terms of the flow of funds.

    - A further risk relates to the outsourced activity for which the Trust must pay a premium cost of x3 times its own marginal rates. Agreement with commissioners is being sought on the mechanism to enable the premium cost element to be funded.

- Correspondence on 14.03.22 from Director General for H&SC to Chief Executives has set out that WG will provide funding cover for specific Covid response costs. This is being worked through to assess if there remains any risk around funding of Covid response staff costs.

- The W&OD and Finance team will work with departments to manage any associated workforce risk regarding Covid staff recruited permanently where funding is no longer available. This will be through re-deployment into vacancies or redundancy. However, given that the Commissioner funding is recurrently provided to them by WG for Covid recovery and WG has recently confirmed as noted above that they will fund Covid response costs, the Trust is better placed to plan for and manage these risks.

Actions:

- The finance team are working with W&OD to support departments with high use of agency to recruit permanently into substantive vacancies as quickly as possible, subject to market conditions.

- The finance team are working with W&OD to support departments to implement alternatives to agency where possible, such as establishment of Bank staffing and agreeing overtime, however these options may be considered unsustainable given the high level of vacancies and sickness levels

- Over the past 4 weeks service leads / department heads have been reviewing all Covid costs to identify:

  - Posts and associated costs that can be removed as will no longer be required in 2022-23 to deliver the Trust Covid response & recovery, with date by when this will occur

  - For posts that are required in 2022-23 to deliver the Covid response & recovery, what the implications are of cessation on the service, to provide

Commissioners and WG with a clear understanding of the impact of not providing funding.

This work is ongoing and updates will be provided in future reports, including the potential financial risk around permanently recruited posts and funding.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below:
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Covid staff costs that may not be fully covered by WG or Commissioner income Ongoing premium cost of agency

4. RECOMMENDATION

4.1 The Committee is asked to **NOTE** the contents of the report

QUALITY, SAFETY & PERFORMANCE COMMITTEE

FINANCE REPORT FOR THE PERIOD ENDED 31ST JANUARY 2022 (M10)

DATE OF MEETING	24 March 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Matthew Bunce, Executive Director of Finance
PRESENTED BY	Matthew Bunce, Executive Director of Finance
EXECUTIVE SPONSOR APPROVED	Matthew Bunce, Executive Director of Finance

REPORT PURPOSE	FOR NOTING

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
EMB	7/03/22	Noted

ACRONYMS	
IMTP	Integrated Medium Term Plan
WBS	Welsh Blood Service
WTAIL	Welsh Transplantation and Immunogenetics Laboratory
WG	Welsh Government
VCC	Velindre Cancer Centre

1. SITUATION/BACKGROUND

1.1 The attached report outlines the financial position and performance for the period to the end of January 2022. The detailed report is attached at **Appendix 1.**

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 Performance against Key Financial Targets:

	Unit	Current Month £000	Year to date £000	Year End Forecast £000
Revenue	Variance	(2)	3	0
Capital (To ensure that costs do not exceed the Capital Expenditure limit)	Actual Spend	1,306	4,974	10,650
Public Sector Payment Performance (Administrative Target – To pay 95% of non NHS invoices within 30 days measured against number of invoices paid).	%	93.0%	94.7%	95.0%

2.2 Revenue Budget

The overall revenue budget continues to remain broadly in line with expectations as planned within the IMTP, with a projected forecast outturn position of breakeven.

The overall position against the profiled revenue budget to the end of January is an underspend of **£3k**, with a pay underspend offsetting a non-pay overspend and Income under achievement.

A large element of the underachievement on planned income relates to WBS WTAIL and Blood Components due to the impact of Covid above the level of forecast reduced income which the Trust is receiving WG funding to cover.

Cost pressures which have / will surface during the year, in line with normal budgetary control procedures, are managed by budget holders to ensure the delegated expenditure control limits are not exceeded.

The Trust is currently planning to fully achieve the savings target during 2021-22. There remain £200k of schemes relating to post Covid savings that are RAG rated as amber. Although these savings are being partly generated, they have been replaced with non-recurrent vacancy factor savings whilst we are in the pandemic as the cost reductions are being offset against the additional costs of Covid as required by WG for Covid funding.

Any slippage or non-delivery against savings targets will be managed through implementation of alternative savings / cost avoidance measures, which may be non-recurrent in nature such as additional vacancy factor.

The Trust has now invoiced WG for all Covid related expenditure relating to 2021-22.

The Trust is therefore reporting a year end forecast breakeven position on the assumption that the savings target for the year is achieved.

2.3 PSPP Performance

PSSP performance for the whole Trust is currently 95.4% against a target of 95%, however the performance against the Core Trust excluding NWSSP is presently falling just short of the target at 94.7%.

PSPP compliance levels had significantly recovered following a temporary dip in performance, however both January and December did see another drop. Urgent investigations are ongoing however early signs point to reduced levels of receipting on orders which is most likely due to the high levels of sickness which currently being experienced in the Trust.

The finance teams continue to work with the service and NWSSP colleagues with a view to improve performance and ensure the target is met for this financial year.

2.4 Covid Expenditure

Covid-19 Revenue Spend/ Funding	YTD Actual £000	Plan 2021/22 £000	Funding Recevied / Allocated £000	Balance Remaining £000
Mass & Booster Covid Vaccination	345	392	213	179
Cleaning Standards	653	769	367	402
PPE	158	226	147	79
Covid Recovery	2,158	3,227	3,479	(252)
Other Covid Related Spend & Cost Reduction	1,549	1,526	1,176	350
BFWD Savings Loss	580	700	700	0
Return of Bonus Payment (over allocated)	(83)	(83)	(83)	0
Total Covid Spend /Funding Requirement 2021/22	**5,360**	**6,757**	**5,999**	**758**

The overall gross funding requirement related to Covid is £6,757k which includes £6,140k of directly associated expenditure or cost reduction, £700k in relation to the non-achievement of savings carried forward from 2020/21, and the return of surplus NHS bonus payment £(83)k.

The Trust has now invoiced WG for the balance of £758k, with the income expected to be received during February.

2.5 Reserves

The financial strategy for 2021-22 facilitated the development of a recurrent and non-recurrent reserve in support of the Trust transformation and delivery agenda. These reserves could only be accommodated on the basis that all income expectations are received, planned savings schemes delivered and new emerging cost pressures managed. In addition, the Trust holds an emergency reserve of 522k.

2.5.1 Recurrent Reserves (budget unallocated):

Summary of Total Reserves Remaining Available in 2021-22	£k
Recurrent Reserve Available 2021-22	617
Slippage on BFWD Commitments	*125*
Further Exec Commitment 2021-22	(144)
Slippage on Further Exec Support	*144*
Forecast remaining Balance 31 March 2022	**742**

The forecast remaining balance expected on the recurrent reserves as at 31 March is £742k which is a result of further slippage against investment decisions during 2021-22, **however this funding has now been committed into future years so is not available for further investment.**

2.5.2 Non Recurrent Reserves (budget unallocated):

Summary of Total Non-Recurrent Reserves Remaining Available in 2021-22	£k
Anticipated Slippage on N/R Allocated Reserves	550
Emergency Reserve	522
Forecast Remaining Balance 31 March 2022	**1,072**

The Emergency reserve of £522k is set every year and used non-recurrently to deal with any in year unforeseen unavoidable cost pressures. To date none of the Emergency reserves have been utilised.

In addition to the recurrent and emergency reserves, the Executive Management Board (EMB) agreed to make available £1,545k of non-recurrent funding for investment during 2021-22 from the release of accountancy gains. The current spend to January '22 is £657k (includes £104k of new commitments). The anticipated slippage against the £1.5m is currently expected to be circa £550k during 2021-22 due to delays in implementation of several investments which are mainly fixed term posts, although this balance is under constant review with potential further slippage. EMB has agreed that non-recurrent funding of £550k will be re-provided in 2022-23 to enable all the approved investments to be fully implemented.

It is important that the Executive Team consider what plans can be implemented in the remaining weeks of 2021-22 to utilise as much of the available non-recurrent funding to support the significant service challenges in 2022-23.

2.6 Financial Risks

All new operational financial risks are expected to be managed or mitigated at divisional level. Where this is not possible, or the risk is Trust wide and can not be mitigated the Emergency Reserves will be utilised.

2.7 Capital

a) All Wales Programme

The Trust previously received confirmation of £675k funding from WG towards Capital related Covid recovery. This will be used to support additional donor chairs in WBS, urgent ventilation work, and increased capacity in VCC such as improvements to the outpatient area and Bobarth building which now forms part of the CEL.

In addition, following a communication from WG of the availability of additional end of year capital monies, the Trust was successful in receiving £838k of funding against the £1,396k of schemes it submitted. The request was based on prioritised divisional bids of clinical equipment in VCC, equipment to establish a component development Laboratory in WBS, and several Digital / IT refresh & infrastructure requirements.

The Capital Programme is significantly underspend for the period year to date which is a combination of procurement capacity constraints and impact of pandemic on supplier lead times. The Trust has appointed external contractors to support the tender and award of contracts in order to help delivery of Estates approved schemes. Despite the challenges performance against the current agreed All Wales Programme budget allocations are at this stage expected to deliver to budget.

Other Major Schemes in development that will be considered during the remainder of 2021-22 and in 2022-23 in conjunction with WG include, Integrated Radiotherapy Solution (IRS), WBS HQ, VCC Ventilation & Infrastructure/ Outpatients, and WBS Plasma fractionation (for medicines).

b) Discretionary Programme

Due to supply chain issues we are starting to see an emergence of slippage against some of the discretionary schemes that were previously approved. This was discussed at the internal Capital Planning Meeting on the 18th October where other Organisational priorities were discussed and agreed to replace the schemes that were would not be fully delivered during 2021-22.

The year-end forecast outturn is currently expected to be managed to a breakeven position, with any further slippage being managed through the Capital Planning and Delivery Group.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below:
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	The Trust financial position at the end of January 2022 is an underspend of £3k with a year-end forecast break-even position in accordance with the approved IMTP

4. RECOMMENDATION

4.1 The Committee is asked to **NOTE** the contents of the January 2022 financial report and in particular the financial performance to date, and the year-end forecast to achieve financial break-even.

FINANCIAL PERFORMANCE REPORT

FOR THE PERIOD ENDED JANUARY 2021/22

QUALITY, SAFETY & PERFORMANCE COMMITTEE 24/03/2022

1. Introduction

The purpose of this report is to outline the financial position and performance for the year to date, performance against financial savings targets, highlights the financial risks, and forecast for the financial year, outlining the actions required to deliver the IMTP Financial Plan for 2021-22.

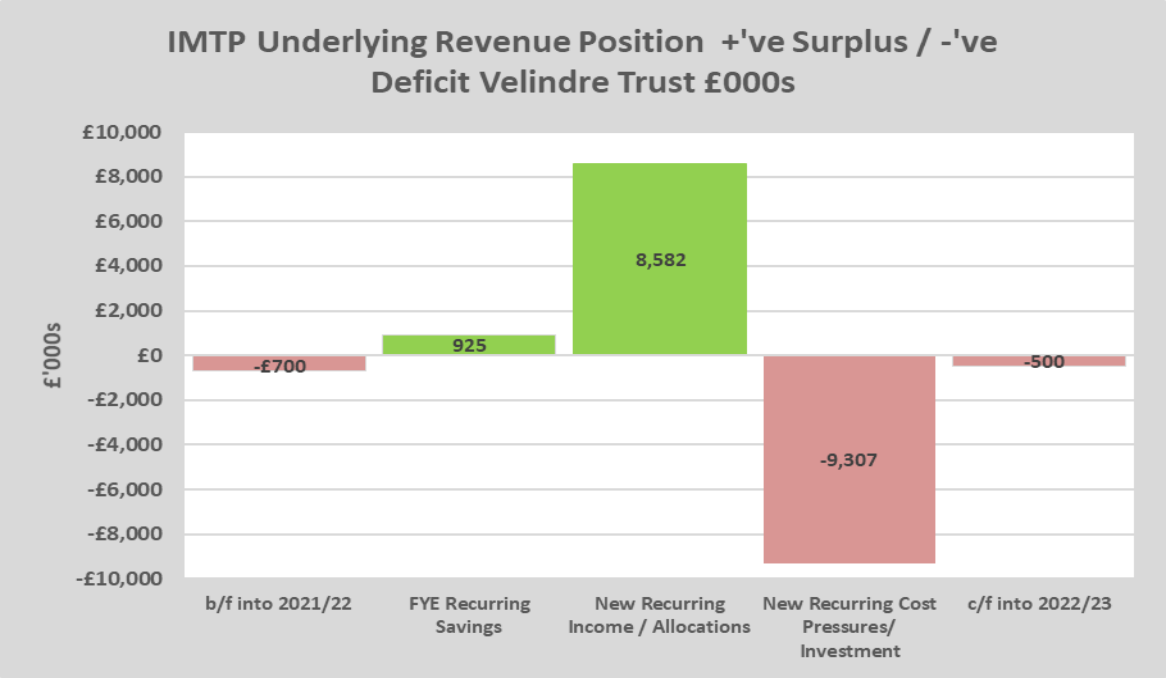
2. Background / Context

The Trust Financial Plan for 2021-22 was set within the following context.

- The Trust submitted a balanced one-year financial plan, covering the period 2021-22 to Welsh Government on the 30 June 2021.

- For 2021-22 the Plan (excl Covid) included;
  - an underlying **deficit of -£700k brought forward from 2020-21,**
  - FYE **of new cost pressures / Investment** of -**£9,307k,**
  - offset by **new recurring Income** of **£8,582k,**
  - and Recurring FYE **savings schemes** of **£925k.**

- Due to the ongoing pandemic and the inability to fully enact savings schemes & cost reduction, the Trust is not expecting to be able to fully eliminate the underlying deficit during 2021-22, however in line with the submitted financial plan the Trust will be aiming to reduce the deficit by £200k to carry forward an underlying position of £500k into 2022-23.
- **To reduce the underlying deficit, the savings target set for 2021-22 must be achieved.**



Underlying Position +Deficit/(-Surplus) £000s	b/f into 2021/22	Recurring Savings	New Recurring Income / Allocations	FYE New Cost Pressures/ Investment	c/f into 2022/23
Velindre NHS Trust	- 700	925	8,582	- 9,307	- 500

3. Executive Summary

Summary of Performance against Key Financial Targets (Excluding Hosted Organisations)

(Figures in parenthesis signify an adverse variance against plan)

Table 1 - Key Targets

	Unit	Current Month £000	Year to date £000	Year End Forecast £000
Revenue	Variance	(2)	3	0
Capital (To ensure that costs do not exceed the Capital Expenditure limit)	Actual Spend	1,306	4,974	10,650
Public Sector Payment Performance (Administrative Target – To pay 95% of non NHS invoices within 30 days measured against number of invoices paid).	%	93.0%	94.7%	95.0%

Performance against Planned Savings Target

Efficiency Savings	Variance	0	0	0

Revenue

The Trust has reported a **£(2)k** in-month overspend position for January '22, with a cumulative position of **£3k** underspent, and an outturn forecast of **Breakeven**.

Capital

The approved Capital Expenditure Limit (CEL) as at January 2021 is **£10,650k** for 2021-22. This represents all Wales Capital funding of **£8,739k**, Discretionary funding of **£1,911k.** The Trust reported capital spend to January '22 of £4,794k and is forecasting to remain within its CEL of £10,650k.

The capital programme is significantly underspend for the period year to date which is a combination of procurement capacity constraints and impact of pandemic on supplier lead times. The Trust has appointed external contractors to support the tender and award of contracts in order to help delivery of Estates approved schemes.

PSPP

During January '22 the Trust (core) achieved a compliance level of **93%** (December 21: 91.8%) of Non-NHS supplier invoices paid within the 30-day target, which gives a cumulative core Trust

compliance figure of **94.7 %** to the end of January, and a Trust position (including hosted) of **95.4%** compared to the target of 95%.

Like in December the PSPP compliance levels in January have again not achieved the target which is following a significant recovery in performance between September and November. Urgent investigations are ongoing however early signs point to reduced levels of receipting on orders which is most likely due to the high levels of sickness which currently being experienced in the Trust. The finance teams continues to work with the service and NWSSP colleagues with a view to improve performance and ensure the target is met for this financial year.

Efficiency / Savings

The Trust is currently planning to fully achieve the savings target during 2021-22. Any slippage or non-delivery against savings targets will be managed through implementation of alternative savings / cost avoidance measures, which may be non-recurrent in nature such as increased vacancy factor. Where non-recurrent savings schemes are implemented this will require additional recurrent savings schemes to be delivered in 2022-23.

4. Revenue Position

Cumulative				Forecast		
£2,604 Underspent				Breakeven		
Type	YTD Budget (£'000)	YTD Actual (£'000)	YTD Variance (£'000)	Full Year Budget (£'000)	Full Year Forecast (£'000)	Forecast Variance (£'000)
Income	(134,830)	(134,457)	(374)	(164,805)	(164,427)	(378)
Pay	59,923	59,446	477	72,057	71,535	522
Non Pay	74,908	75,008	(101)	92,748	92,891	(144)
Total	(0)	(3)	3	0	(0)	0

The overall position against the profiled revenue budget to the end of January is an underspend of **£3k**, with a Pay underspend offsetting a non-pay overspend and Income under achievement.

The Trust has now invoiced WG for all Covid related expenditure relating to 2021-22.

4.1 Revenue Position Key Issues

Income Key Issues

- Income underachievement to January is **£(374)k** and is largely where activity is lower than planned on Bone Marrow and Plasma Sales in WBS which is resulting in income loss above Covid support, with assessments as to scale and sustainability ongoing.
- The underperformance in WBS is being partly offset within VCC via an increase in VAT savings from providing additional SACT Homecare.

Pay Key Issues

The Trust has reported a cumulative year to date position of **£477k** underspent on Pay and is forecasting an outturn underspend of circa **£552k**.

The total Trust vacancies as at December is 141wte, (VCC 80wte), (WBS 35wte), (Corporate 2 wte), R&D (18wte), TCS (1wte) and HTW (5wte).

The WTE by pay category is provided within the table below:

Pay WTE By Category			
Pay Type	WTE Budget	WTE Actual	WTE Variance
ADD PROF SCIENTIFIC AND TECHNICAL	58.40	53.80	(4.60)
ADDITIONAL CLINICAL SERVICES	260.78	228.23	(32.55)
ADMINISTRATIVE & CLERICAL	536.23	492.11	(44.12)
ALLIED HEALTH PROFESSIONALS	136.06	126.22	(9.84)
ESTATES AND ANCILLIARY	64.81	65.19	0.38
HEALTHCARE SCIENTISTS	161.56	150.67	(10.89)
MEDICAL AND DENTAL	98.69	77.82	(20.87)
NURSING AND MIDWIFERY REGISTERED	221.90	203.25	(18.65)
PAY BUDGET ADJUSTMENTS	0.00	0.00	0.00
Total Pay by Category	**1,538.43**	**1,397.29**	**(141.14)**

*The total number of staff directly relating to Covid is 76.12wte (VCC 50.72, WBS 25.4)

- Allied Health Professionals are experiencing a small overspend to date £(99k) which is due to the use of agency in both Radiotherapy and Medical Physics. VCC is aiming to recruit on a permanent basis against some of these posts which commenced in September. This is expected to create a saving going forward from the removal of the premium cost for agency, however due to the difficulty being experienced in recruiting into these posts along with the requirement to cope with the expected surge capacity, the majority of agency staff will be re-directed to support Covid recovery which is funded by WG during 2021-22.
- Medical costs have increased and are reflecting a year to date overspend of £(261)k due to additional temporary staff recruited at risk to ensure that all Jnr Dr rotation placements are filled and to provide additional resilience against pressured consultants. In addition, enhanced out of hours service, for advanced life support which will be nursing led is currently being covered by Jnr Dr's.
- Each Division of the Trust holds a savings and vacancy factor target which is delivered in year via establishment control. Any forecast adverse variance against the target will be offset through various underspends across numerous staff groups due to vacancies as illustrated in the WTE table above.

<u>Non Pay Key Issues</u>

The Trust has reported a cumulative year to date position of **£(101)k** overspend on Non-Pay and is forecasting an outturn underspend of circa **£(144)k**.

- Large underspend in WBS due to reduced costs from suppressed activity, underspend on Collections Services, Laboratory Services, WTAIL, and General Services
- There are underspends on general drugs in VCC from reduced activity and temporary closure of outreach clinics.
- Large overspends in VCC on One Wales and rise in consumable across Pharmacy.
- Facilities Management, along with Maintenance & Repairs are under review in WBS with Trust Estates following increased compliance requirements against new contracts which is pushing the outturn into a forecast overspend position.

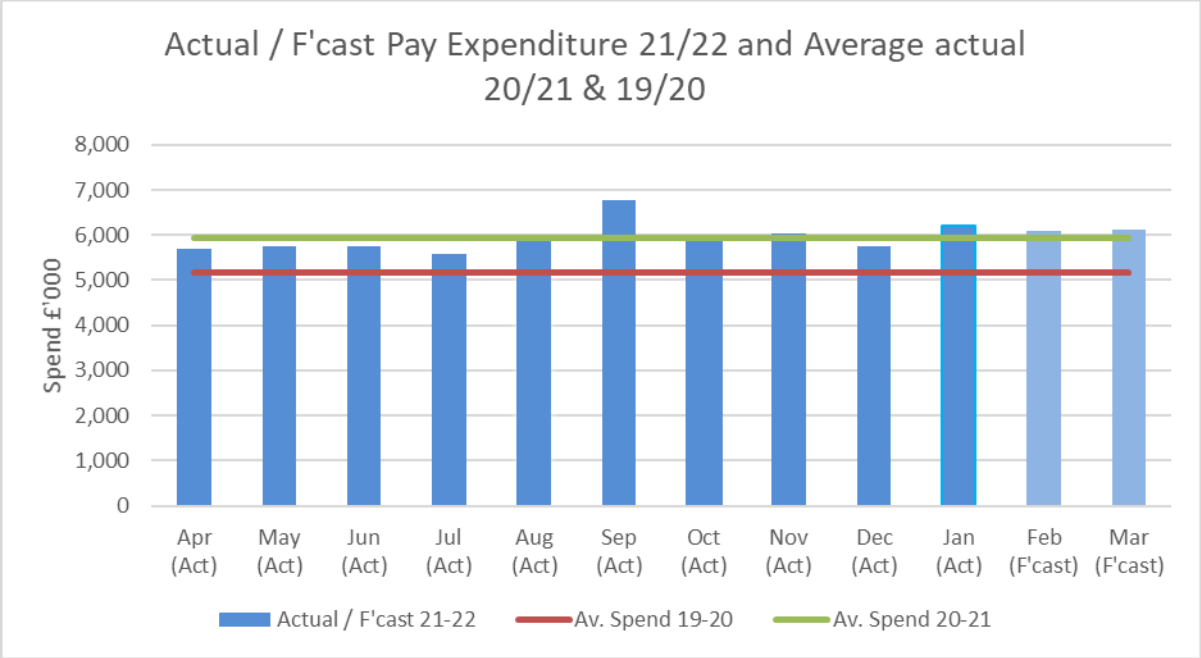
- Transport underspend is due to non-recurring fuel savings and consequently maintenance costs relating to the fleet following reduction of vehicle use related to Covid.
- Starting to experience additional travel & subsistence costs in relation to increased travel of WBS collections team to clinic. This is starting to offset the savings generated from general staff travel & subsistence which has been a benefit since the pandemic hit and the use of IT resources to conduct meetings.
- Printing / Stationary & Postage is underspending due to a reduction in office-based activity and paper-based communications given the increased homeworking. A proportion of this underspend is anticipated to be permanent and will be taken as recurrent saving once the Trust has agreed the operating model of future working arrangements.
- General Reserves / Savings Target relates to the Cost improvement Plan (CIP) targets that are held centrally within divisions. These CIP's will be achieved through the underspends in several areas of non-pay. Additionally, as noted above further alignment of staff underspends to the CIP should result in an underspend within non-staff.
- The Trust reserves and investment funding is held in month 12 and will be released into the position to match spend as it occurs. A significant proportion of the reserves is remaining following slippage against investment decisions which will now be managed in the overall Trust position this financial year.

Further details on performance against Income, Pay and Non-Pay is provided within the Divisional analysis later in the paper.

4.2 Pay Spend Trends (Run Rate)

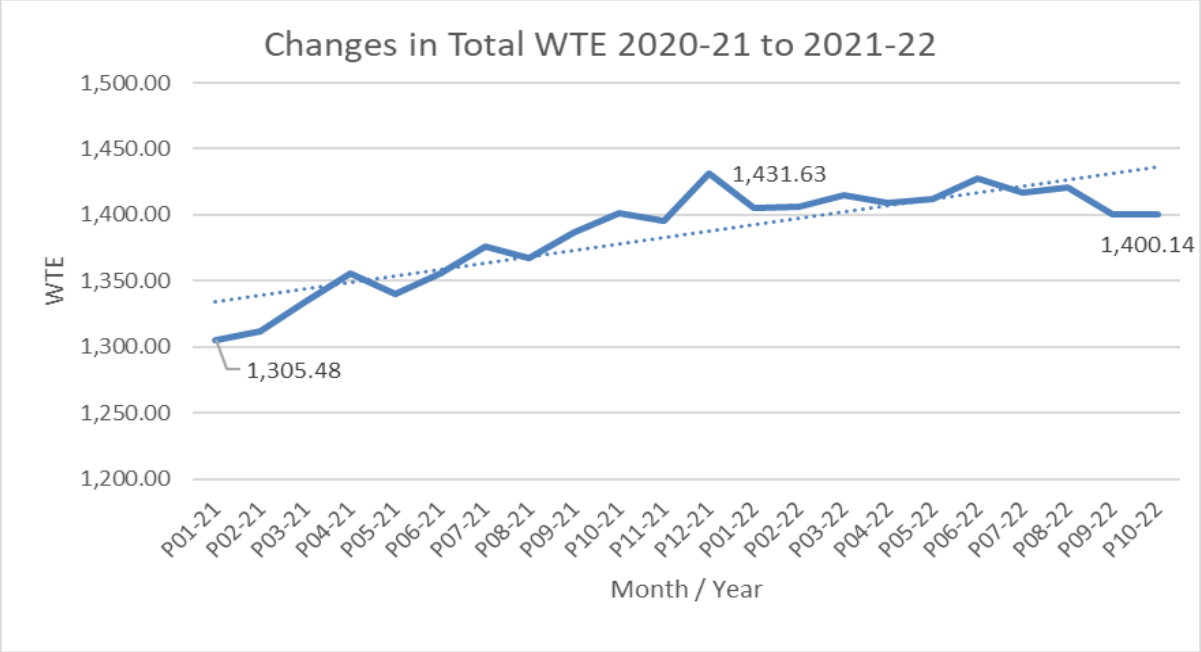
The pay spend for 2020-21 was 14.82% above av. pay in 2019-20. 3% was accounted for by the pay award, 1.14% can be accounted for by an increase in use of agency, 2.3% related to the NHS Bonus Payment with the remaining being the additional staff recruited over the course of 2020-21 (c.126 wte), and the pay costs associated with Covid.

Staff received the 2021-22 pay award of 3% and arrears dated back to April 2021 in their September pay. Excluding the Pay award, spend is still expected to increase with the recruitment of additional posts to meet 'surge' capacity in both VCC and WBS which is in response to Covid recovery. Whilst the plan was to reduce agency costs within the Trust Core staffing structure, due to the difficulty being experienced in recruitment, the agency staff replaced with substantive recruits will now be utilised as part of the Covid recovery.

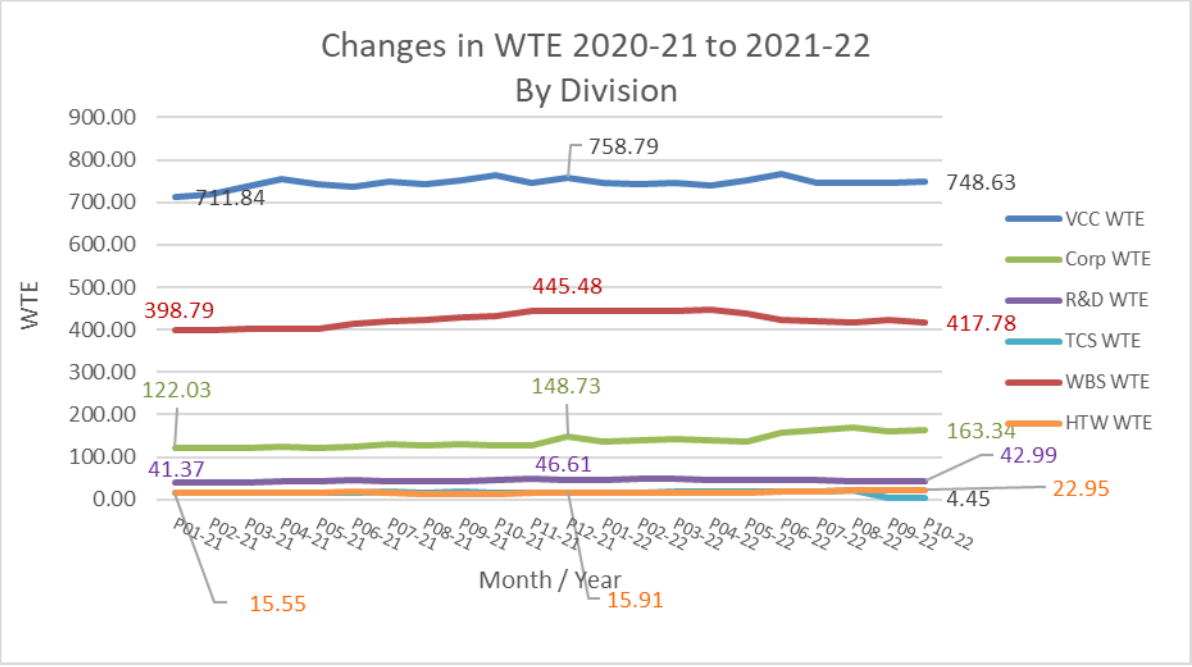


*Sep costs include Pay Award (3%) backdated to April. The perviously reported £2.6m additional pension has been removed as this will be a nominal charge from WG.

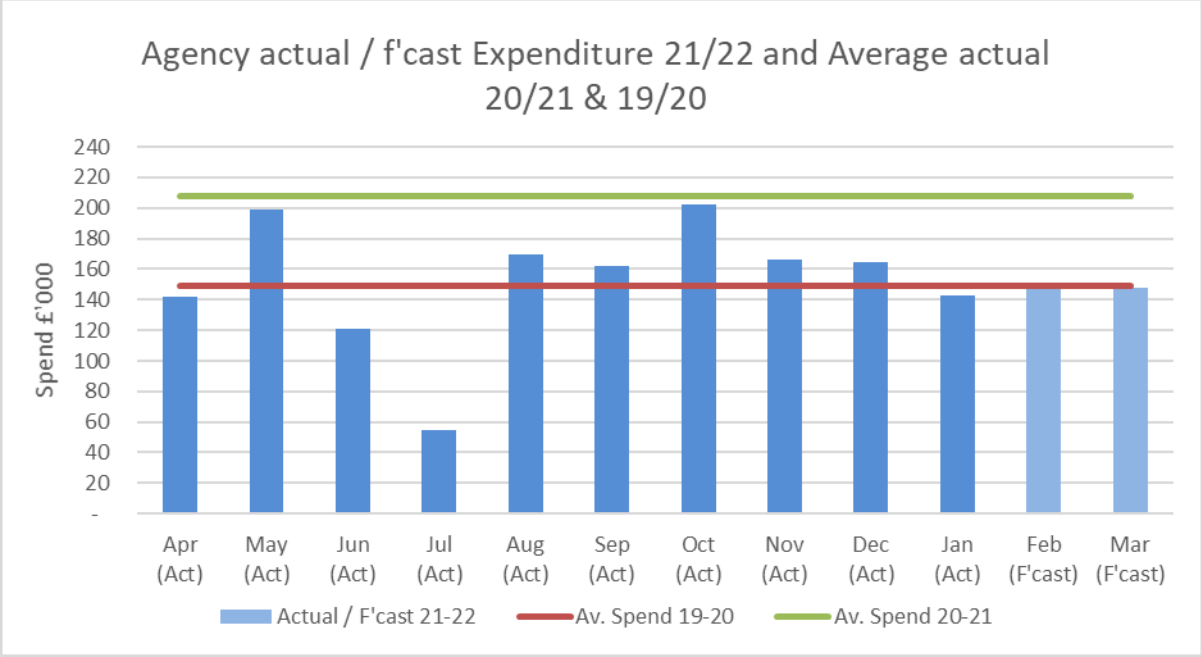
*During January Staff who were on bands 1-5 received a 1% non consolidated pay award.



* Reduction in WTE since March 21 is largely due to ceasing of the Patient Vaccination programme.



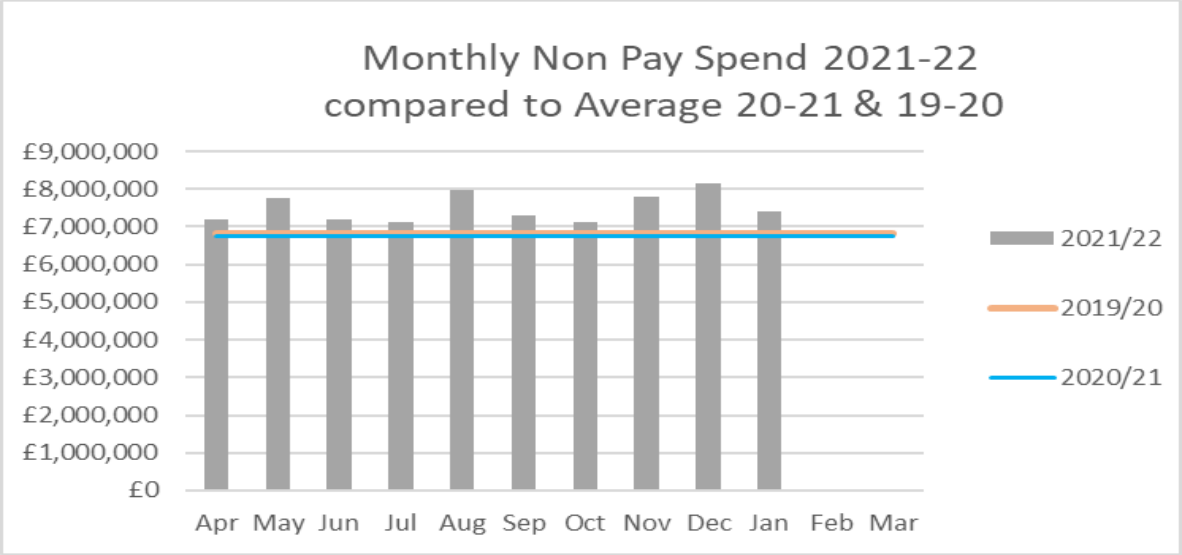
The spend on agency for January was £147k (December £165k), which gives a cumulative year to date spend of **£1,524k** and a forecast outturn spend of circa **£1,821k.** Of these totals the year to date spend on agency directly relating to Covid as at the end of January is £644k and forecast spend is circa £765k.



*The increase in May costs has been reviewed and corrected in July following a full review of agency invoices received against orders raised within VCC.

4.3 Non Pay

Non-pay 20-21 (c£81.2m) av. monthly spend remained static between 19-20 and 20-21 at £6.8m. The average monthly spend for 21-22 is currently £735k (9.81%) more than 20/21, which is largely due to the increase NICE / High-Cost drug usage following the recovery and surge related to Covid.



4.4 Covid-19

Covid-19 Revenue Spend/ Funding				
	YTD Actual £000	Plan 2021/22 £000	Funding Recevied / Allocated £000	Balance Remaining £000
Mass & Booster Covid Vaccination	345	392	213	179
Cleaning Standards	653	769	367	402
PPE	158	226	147	79
Covid Recovery	2,158	3,227	3,479	(252)
Other Covid Related Spend & Cost Reduction	1,549	1,526	1,176	350
BFWD Savings Loss	580	700	700	0
Return of Bonus Payment (over allocated)	(83)	(83)	(83)	0
Total Covid Spend /Funding Requirement 2021/22	**5,360**	**6,757**	**5,999**	**758**

The Trust has currently received or been allocated funding from WG to the sum of £5,999k, £3,479k towards Covid recovery, £1,903k to cover the first six months of Covid response and £700k to cover the underlying savings loss bfwd from 2020/21. The Trust has returned £83k which was surplus money received toward the NHS bonus payment. This leaves funding to be allocated by WG of £758k.

The Trust has now invoiced WG for the final £758k with the income expected to be received during February.

Covid Recovery

The spend and funding requirement to deliver Covid Recovery and Surge Capacity comprises direct outsourcing and enablement of additional clinical sessions within VCC, and an additional

collection team within WBS. The resources required will provide coverage for an anticipated surge in capacity of up to 20% above pre-Covid levels for VCC and 10% for WBS, although slippage in the current financial year is already being experienced.

Covid recovery funding has been flexibly managed with Covid response requirements, whilst delivering the capacity intended by the funding. This has maintained the overall funding envelope though recovery has been re-categorised to £3,227k via a reduction in outsourcing to date, but forecast to have a sustained increase in utilisation to the end of the Financial Year.

The Trust has received confirmation that the increase in NICE/ High cost drugs will be funded by commissioners. Latest estimate has been updated to circa £1,800k above existing forecast which is based on potential demand should the additional capacity be fully utilised. These figures are excluded from the table above.

The Trust has been informed that £4.5m will be made available to the Hospices for 2021-22, which will pass through the Trust in the same way as it did in 2020/21. Following discussions with WG and Audit at the last financial year end it was agreed that the Trust should not include the Hospice income and expenditure within the Velindre accounts, and therefore they have also been excluded for reporting purposes from the Trust Financial ledger and the tables above. Following a recent request from WG the figures are being included within the Trust monthly financial monitoring returns.

Vaccinations

The Trust is expecting to spend circa £392k on the Covid Mass & Booster Vaccination programme during 2021-22. The £392k revenue spend requirement largely relates to the WBS storage and distribution for NHS Wales (£297k), delivery of vaccinations to front line staff in both Velindre and WAST, and the rollout of the Patient Vaccination programme which has now ended (£63k), with the balance being ringfenced for the booster programme which is also drawing to a close (£32k).

WG have provided reassurance that the ongoing Vaccination programme is a priority and that any costs that may be incurred during 2022-23 will be funded.

5. Savings

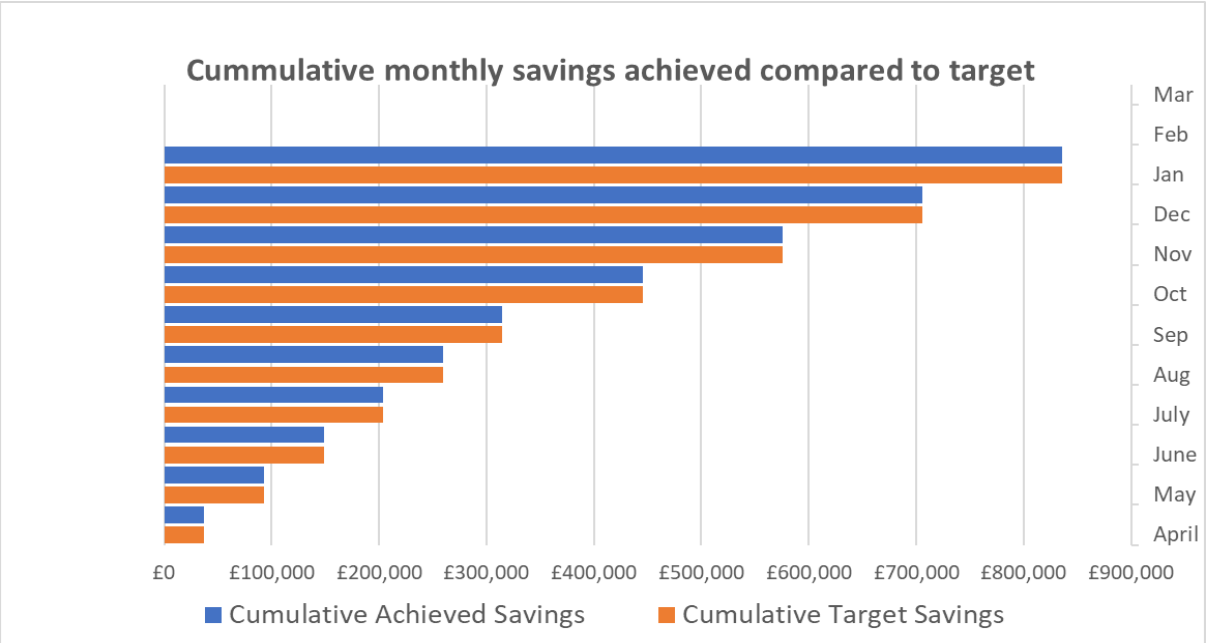
The Trust established as part of the IMTP a savings requirement of £1,100k for 2021-22, £525k recurrent (£925k full year recurrent) and £575k non-recurrent, with £1,050k being categorised as actual saving schemes and £50k being income generating schemes.

The YTD achievement on the 'Post Covid' Savings is £54k and forecast full year is £90k. These savings are not reflected in the tables below as they are being netted of against Covid Spend which is not being drawn down from WG whilst still in the pandemic. The Trust is expected to realise the benefit of these savings post Covid following the new ways of working such as reduced Travel expenses and office consumable spend. For this financial year the savings has been replaced with non-recurrent vacancy factor savings which gives an overall balanced savings position

Any slippage or non-delivery against savings targets between now and the financial year end will be managed through implementation of alternative savings / cost avoidance measures, which may be non-recurrent in nature. Any non-recurrent schemes will need to be replaced by additional recurrent savings schemes in 2022-23.

ORIGINAL PLAN	TOTAL £000	Planned YTD £000	Actual YTD £000	Variance YTD £000	Full Year Actual £000	Variance Full Year £000
VCC TOTAL SAVINGS	413	208	208	0	300	(113)
			100%		73%	
WBS TOTAL SAVINGS	368	250	250	0	300	(68)
			100%		82%	
CORPORATE TOTAL SAVINGS	119	83	83	0	100	(19)
			100%		100%	
TRUST TOTAL SAVINGS IDENTIFIED	900	542	542	0	700	(200)
TRUST ADDITIONAL NON-RECURRENT SAVINGS	200	292	292	0	400	200
TRUST TOTAL SAVINGS	1,100	834	834	0	1,100	0
			100%		100%	

Scheme Type	RAG RATING	TOTAL £000	Planned YTD £000	Actual YTD £000	Variance YTD £000	F'cast Full Year £000	Variance Full Year £000
Savings Schemes							
Premium of Agency Staffing	Green	150	100	100	0	150	0
Premium of Agency Staffing	Green	100	67	67	0	100	0
Post Covid Savings (VCC)	Red	113	0	0	0	0	(113)
Blood Supply Chain 2020	Green	75	63	63	0	75	0
Blood Supply Chain 2020	Green	25	21	21	0	25	0
Stock Management	Green	200	167	167	0	200	0
Post Covid Savings (WBS)	Red	68	0	0	0	0	(68)
Establishment Control	Green	100	83	83	0	100	0
Post Covid Savings (Corporate)	Red	19	0	0	0	0	(19)
Total Saving Schemes		**850**	500	500	0	650	(200)
Income Generation							
Maximinsing Income Opportunities	Green	50	42	42	0	50	0
Total Income Generation		**50**	42	42	0	50	0
TRUST ADDITIONAL NON-RECURRENT SAVINGS - VACANY FACTOR		200	292	292	0	400	200
TRUST TOTAL SAVINGS		1,100	834	834	0	1,100	0
				100%		100%	



6. Reserves

The financial strategy for 2021-22 facilitated the development of a recurrent and non-recurrent reserve in support of the Trust transformation and delivery agenda. These reserves could only be accommodated on the basis that all income expectations are received, planned savings schemes delivered and new emerging cost pressures managed. In addition, the Trust holds an emergency reserve of 522k.

The current remaining available funding is shown below: -

Summary of Total Reserves Remaining Available in 2021-22	£k
Recurrent Reserve Available 2021-22	617
Slippage on BFWD Commitments	*125*
Further Exec Commitment 2021-22	(144)
Slippage on Further Exec Support	*144*
Forecast remaining Balance 31 March 2022	**742**

The forecast balance of the recurrent reserves as at the end of 2021/22 is expected to be £742k, however this funding is either ringfenced or has now been committed into future years so is not currently available for investment.

Summary of Total Non Recurrent Reserves Remaining Available in 2021-22	£k
Anticipated Slippage on N/R Allocated Reserves	550
Emergency Reserve	522
Forecast Remaining Balance 31 March 2022	**1,072**

In addition to the recurrent and emergency reserves, the Executive Management Board (EMB) agreed to make available £1,545k of non-recurrent funding for investment during 2021-22 from the release of accountancy gains. The current spend to January '22 is £657k (includes £104k of new commitments). The anticipated slippage against the £1.5m is currently expected to be circa £550k during 2021/22 due to delays in implementation of several investments which are mainly fixed term posts, although this balance is under constant review with potential further slippage. EMB has agreed that non-recurrent funding of £550k will be re-provided in 2022-23 to enable all the approved investments to be fully implemented.

7. End of Year Forecast / Risk Assessment

The Trust is currently reporting a year end breakeven position against its revenue budget, however there are a few risks which are being managed and closely monitored at Divisional level.

8. CAPITAL EXPENDITURE

Administrative Target

- *To ensure that net Capital expenditure does not exceed the Capital Expenditure Limit (CEL) approved by the Welsh Government.*
- *To ensure the Trust does not exceed its External Financing Limit*

	Approved CEL £000s	YTD Spend £000s	Committed Orders Outstanding £000s	Budget Remaining @ M11 £000s	Full Year Actual Spend £000s	Year End Variance £000s
All Wales Capital Programme						
VCC - Transforming Cancer Services	3,711	2,564	0	1,147	3,711	0
VCC Radiotherapy Procurement Solution	312	249	0	63	312	0
IT - WPAS (CANISC replacement phase 2)	993	802	0	191	993	0
Fire Safety	600	175	63	363	600	0
National Programmes - Decarbonisation	109	30	76	3	109	0
National Programmes - Imaging	1,020	0	924	96	1,020	0
Covid Recovery	675	9	90	576	675	0
DHCW - NDR Funding	350	350	0	0	350	0
DHCW - VCC Careflow	60	0	0	60	60	0
HTW Capital	5	5	0	0	5	0
Linc ETR Funding	25	0	24	1	25	0
Additional DPIF Capital Allocations	41	0	0	41	41	0
End of Year Capital						
Multileaf Collimator (MLC) Motor Replacements	120	0	0	120	120	0
(CDR) function within the WBS.	83	0	44	39	83	0
Patient Specific Quality Assurance (PSQA) Phantom	100	0	0	100	100	0
Digital IT Client tech refresh	450	324	87	39	450	0
Digital Server Infrastructure Tech refresh	85	0	28	57	85	0
Total All Wales Capital Programme	8,739	4,506	1,335	2,897	8,739	0
Discretionary Capital	1,911	468	604	839	1,911	0
Total	10,650	4,974	1,939	3,736	10,650	0

The approved 2021-22 Capital Expenditure Limit (CEL) as at January 2022 was £10,650k. This includes All Wales Capital funding of £8,739k, and discretionary funding of £1,911k.

The Trust previously received confirmation of £675k funding from WG towards Capital related Covid recovery. This will be used to support additional donor chairs in WBS, urgent ventilation

work, and increased capacity in VCC such as improvements to the outpatient area and Bobarth building which now forms part of the CEL.

In addition, following a communication from WG of the availability of additional end of year capital monies, the Trust was successful in receiving £838k of funding against the £1,396k of schemes it submitted. The request was based on prioritised divisional bids as provided for in the table above.

Performance to date

The actual cumulative expenditure to January 2021 on the All-Wales Capital Programme schemes was £4,506k, this is broken down between spend on the TCS Programme £2,564k, Integrated Radiotherapy Procurement Solution £249k, IT WPAS £802k, Fire Safety £175k, Decarbonisation £30k, Covid recovery £9k and HTW £5k.

The Trust Discretionary funding has now been allocated for 2021-22 and was approved at EMB on the 2nd August. The contingency that was being held has now been released, resulting in all funds being fully committed to schemes.

Spend to date on Discretionary Capital is currently £468k with a further £604k committed.

Due to supply chain issues we have seen slippage against some of the discretionary schemes that were previously approved. This was initially discussed at the internal Capital Planning Meeting on the 18th October where other organisational priorities were discussed and agreed to replace the schemes that were would not be fully delivered during 2021-22.

The capital programme is significantly underspend for the period year to date which is a combination of procurement capacity constraints and impact of pandemic on supplier lead times.

Year-end Forecast Spend

The year-end forecast outturn is currently expected to be managed to a breakeven position, with any further slippage being managed through the Capital Planning and Delivery Group.

Major Schemes in Development

The Trust has also been in discussions with WG over other projects which it is seeking to secure funding from the All-Wales Capital programme.

Other Major Schemes in development that will be considered during 2022-23 and beyond in conjunction with WG include:

	Scheme	Scheme Total	Stage (i.e. OBC development, FBC development, scoping etc.)	22/23 £'000	23/24 £'000	24/25 £'000	25/26 £'000
1	VCC Outpatients	1,250	Feasibility & design study currently being undertaken although unlikely to gain WG funding to supprt during 2022/23	1,250			
2	WBS HQ	22,000	PBD approved by WG OBC end of February.	1,000	11,000	10,000	
3	Ventilation	2,490	BJC to be submitted (paused during pandemic) Likely costs will shift into 23/24.	2,490			
4	IRS	37,929	OBC & PBC approved by WG, FBC under development (Phasing of costs under review)	4,711	8,234	14,254	10,730
5	Plasma Fractionation	TBC	Feasibility study to be developed				

*Cash flow of these schemes is under review alongside WG with slippage into further years expected.

9. BALANCE SHEET (Including Hosted Organisations)

The Balance Sheet in NHS Financial Statements is known as the Statement of Financial Position (SoFP). It provides a snapshot of the Trust's financial position including the hosted divisions at a point in time.

The statement shows the Trust's assets and liabilities. As part of the Trust SFIs there is a mandatory requirement to report movement in working capital.

The Trust has now formally removed DHCW from the Trust SoFP, following the transfer of assets and liabilities that took place on the 31 December'21.

Non-Current Assets

The balance on PPE and intangible assets will move up and down depended on the agreed purchases from the Trust Capital programme (including hosted), offset against the depreciation charges on owned assets.

Trade debtors and receivables will move up and down each month depending on timing of when invoices are raised and consequently paid by organisations.

Current Assets

NWSSP continues to hold high levels of stock in response to Covid which will be passed out to the HB's. In addition, the Trust is still holding £7,000k of contingency stock from 2018-19 which WG asked both NWSSP and WBS to purchase in preparation for Brexit.

The Trust was intending to unwind the contingency stock during 2021-22 and repay the £7,000k cash provided by WG to purchase the Brexit stock, however given the uncertain situation around supply chains which has arisen due to Covid the Trust is currently continuing to hold this stock.

The balance on receivables will move up and down each month depending on the timing of when invoices are raised, and when the cash is physically received from debtors. The Trust actively chases its debts to ensure prompt payment.

Due to the high levels of purchases relating to Covid within NWSSP, the cash levels are fluctuating significantly on a daily / weekly basis. Cash levels are being continually monitored using a cash flow forecast to maintain appropriate levels.

Current Liabilities & Non-Current Liabilities

Liabilities will move up and down each month depending on timing of when commitments are made, and invoices are received and paid.

Taxpayers Equity

The movement on PDC and revaluation reserves relates to the transfer of Capital assets relating to DHCW.

	Opening Balance Beginning of Apr 20	Closing Balance End of Jan-22	Movement from 1st April Jan-22	Forecast Closing Balance End of Mar 21
Non-Current Assets	**£'000**	**£'000**	**£'000**	**£'000**
Property, plant and equipment	136,558	127,149	(9,409)	124,700
Intangible assets	20,821	5,398	(15,423)	5,481
Trade and other receivables	817,142	818,998	1,856	818,998
Other financial assets	0	0	0	0
Non-Current Assets sub total	974,521	951,545	(22,976)	949,179
Current Assets				
Inventories	95,564	81,206	(14,358)	85,187
Trade and other receivables	548,836	403,148	(145,688)	443,213
Other financial assets	0	0	0	0
Cash and cash equivalents	43,263	60,844	17,581	18,518
Non-current assets classified as held for sale	0	0	0	0
Current Assets sub total	687,663	545,198	(142,465)	546,918
TOTAL ASSETS	1,662,184	1,496,743	(165,441)	1,496,097
Current Liabilities				
Trade and other payables	(353,136)	(220,412)	132,724	(212,743)
Borrowings	(8)	0	8	0
Other financial liabilities	0	0	0	0
Provisions	(316,959)	(316,346)	613	(316,374)
Current Liabilities sub total	(670,103)	(536,758)	133,345	(529,117)
NET ASSETS LESS CURRENT LIABILITIES	992,081	959,985	(32,096)	966,980
Non-Current Liabilities				
Trade and other payables	(7,301)	0	7,301	(7,000)
Borrowings	0	0	0	0
Other financial liabilities	0	0	0	0
Provisions	(818,782)	(818,782)	0	(818,782)
Non-Current Liabilities sub total	(826,083)	(818,782)	7,301	(825,782)
TOTAL ASSETS EMPLOYED	165,998	141,203	(24,795)	141,198
FINANCED BY:				
Taxpayers' Equity				
General Fund	0	0	0	0
Revaluation reserve	27,978	30,963	2,985	31,052
PDC	122,468	94,597	(27,871)	94,597
Retained earnings	15,552	15,643	91	15,549
Other reserve	0	0	0	0
Total Taxpayers' Equity	165,998	141,203	(24,795)	141,198

10. CASH FLOW (Includes Hosted Organisations)

As part of the Brexit emergency planning an additional £5m of stock had been purchased by NWSSP and an additional £2m of commercial blood products were purchased by WBS, to provide resilience for NHS Wales due to the uncertainty around supply chain reliability because of Brexit.

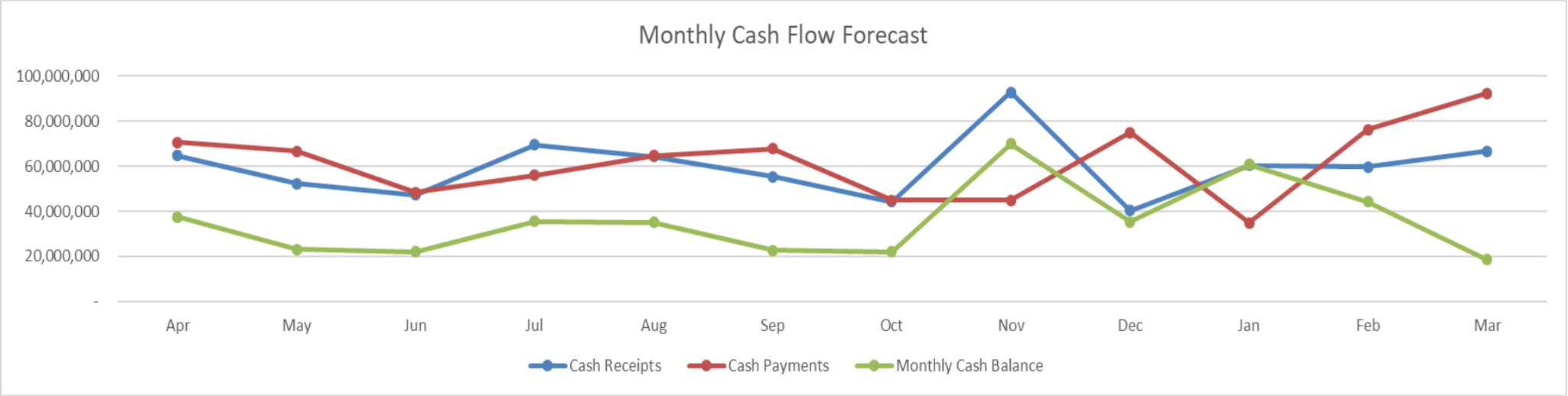
To aid the Trust's cash flow while the additional stock was being held for Brexit, Welsh Government (WG) provided the Trust with additional cash of £7m during 2019/20. WBS did intend to run down the commercial blood stock, however given the uncertain situation with Covid and potential impact on supply chains the Trust will continue to hold this stock and assess the situation throughout the year. NWSSP are continuing to liaise with WG regarding the level of Brexit stock to maintain but it is anticipated that the repayment to WG of the additional £7m cash will take place in March '22.

Due to the high levels of purchases relating to Covid within NWSSP, the cash levels over the past year or so have been significantly higher than usual and may continue to be above average with ongoing need for Covid related purchases. Due to this, the cash balance can fluctuate significantly on a daily / weekly basis.

WG have asked the Trust to manage the £5.6m transfer of cash into the Escrow holding account for the nVCC programme which will need to take place before the 31st March. This will be done on the basis that the Trust can draw down the funds from the 1st April which ensures that there is no cash risk to the organisation.

Cash levels are monitored daily using a detailed cash flow forecast to ensure the Trust has sufficient cash balances to meet anticipated commitments.

		Apr £'000	May £'000	Jun £'000	Jul £'000	Aug £'000	Sep £'000	Oct £'000	Nov £'000	Dec £'000	Jan £'000	Feb £'000	Mar £'000	Totals £'000
	RECEIPTS													
1	LHB / WHSSC income	23,348	22,492	30,672	34,078	32,225	28,886	33,252	33,603	30,431	31,820	29,860	33,280	363,947
2	WG Income	33,807	26,132	11,582	30,431	27,512	21,398	6,388	56,520	693	26,150	27,650	22,457	290,720
3	Short Term Loans													0
4	PDC												8,714	8,714
5	Interest Receivable										3	3	3	9
6	Sale of Assets													0
7	Other	7,643	3,682	4,973	5,006	4,613	5,004	4,673	2,719	9,139	2,454	2,182	2,300	54,388
8	**TOTAL RECEIPTS**	**64,797**	**52,306**	**47,227**	**69,515**	**64,350**	**55,288**	**44,314**	**92,842**	**40,263**	**60,427**	**59,695**	**66,754**	**717,778**
	PAYMENTS													
9	Salaries and Wages	15,189	22,734	22,015	20,181	19,284	24,383	25,582	24,544	25,089	25,614	25,221	26,554	276,390
10	Non pay items	52,989	43,749	25,742	35,377	45,158	42,830	18,755	19,768	49,260	7,089	47,850	48,680	437,248
11	Short Term Loan Repayment												7,000	7,000
12	PDC Repayment													0
14	Capital Payment	2,375	277	540	453	225	623	631	499	612	2,181	3,220	10,250	21,886
15	Other items													0
16	**TOTAL PAYMENTS**	**70,552**	**66,760**	**48,297**	**56,011**	**64,667**	**67,836**	**44,968**	**44,811**	**74,961**	**34,884**	**76,291**	**92,484**	**742,523**
17	Net cash inflow/outflow	(5,755)	(14,454)	(1,070)	13,504	(317)	(12,548)	(655)	48,031	(34,698)	25,543	(16,596)	(25,730)	
18	Balance b/f	43,263	37,508	23,054	21,984	35,488	35,171	22,623	21,968	69,999	35,301	60,844	44,247	
19	Balance c/f	37,508	23,054	21,984	35,488	35,171	22,623	21,968	69,999	35,301	60,844	44,247	18,518	



DIVISIONAL ANALYSIS

(Figures in parenthesis signify an adverse variance against plan)

Core Trust

	YTD Budget £000	YTD Actual £000	YTD Variance £000	Annual Budget £000	Full Year Forecast £000	Year End Variance £000
VCC	30,412	30,412	0	36,522	36,522	0
RD&I	66	66	0	(365)	(365)	0
WBS	16,874	16,874	0	20,691	20,691	0
Sub-Total Divisions	**47,352**	**47,352**	**0**	**56,848**	**56,848**	**0**
Corporate Services Directorates	7,598	7,603	(5)	8,959	8,959	0
Delegated Budget Position	**54,950**	**54,955**	**(5)**	**65,807**	**65,807**	**0**
TCS	553	546	7	669	669	0
Health Technology Wales	(22)	(23)	0	28	28	0
Trust Position	**55,481**	**55,478**	**3**	**66,504**	**66,504**	**0**

VCC

	YTD Budget £000	YTD Actual £000	YTD Variance £000	Full Year Budget £000	Full Year Forecast £000	Year End Projected Variance £000
Income	**50,068**	**50,397**	**329**	**61,941**	**62,341**	**400**
Expenditure						
Staff	33,786	33,752	35	40,704	40,804	**(100)**
Non Staff	46,693	47,057	(364)	57,759	58,059	**(300)**
Sub Total	**80,480**	**80,809**	**(329)**	**98,463**	**98,863**	**(400)**
Total	**30,412**	**30,412**	0	**36,522**	**36,522**	**0**

VCC Key Issues:

The reported financial position for the Velindre Cancer Centre as at the end of January 2022 was **breakeven**, and an expected outturn position of **breakeven**.

Income at Month 10 represents an overachievement of **£329k**. This is largely from an increase in VAT savings from providing additional SACT Homecare, an over achievement on private patient income due to drug performance, which is above general private patient performance, additional funding for senior medical non-surgical workforce, increased income against the Radiation protection SLA, and HSST income within Physics Management, along with a number of smaller areas representing income growth. This is offsetting the divisional savings target and loss of income from closure of gift shop and volunteer's office in response to Covid.

VCC have reported an underspend of **£35k** against staff for January. The division continues to have a high level of vacancies, sickness, and maternity leave predominantly in Nurse Management, Inpatients, Pharmacy and Radiotherapy which is above the divisional vacancy factor target and is offsetting the cost of agency (£1,080k to end of January) although £558k is directly related to Covid. Inpatients underspend relates to the holding off on recruitment due to reduced bed capacity from social distancing measures. Medical costs have increased due to additional temporary staff recruited at risk to ensure that all Jnr Dr rotation placements are filled, and to provide additional resilience against pressured consultants. In addition, enhanced out of hours service, for advanced life support which will be nursing led is currently being covered by Jnr Dr's.

Non-Staff Expenditure at Month 10 was **£(364)k** overspent. There are underspends on general drugs from reduced activity and temporary closure of outreach clinics, Nuclear medicine warranty savings, along with cost avoidance generated from closure of gift shop and volunteer's office. This is in part offsetting the one off spend on uniforms and consumables in Pharmacy, One Wales cost pressure, and cost from NWSSP for sponsorship of overseas students, along with reporting fees and oncotype in Senior Medical. The increase in price for utilities is starting to have an impact and is expected to be significant next year, which is being factored into the Trust IMTP, and will be managed through the discretionary uplift in funding.

WBS

	YTD Budget £000	YTD Actual £000	YTD Variance £000	Annual Budget £000	Full Year Forecast £000	Year End Projected Variance £000
Income	**18,693**	**18,036**	**(657)**	**21,982**	**21,269**	**(713)**
Expenditure						
Staff	14,194	14,010	185	17,126	16,830	**296**
Non Staff	21,373	20,900	473	25,547	25,131	**416**
Sub Total	**35,567**	**34,910**	**657**	**42,673**	**41,961**	**712**
Total	**16,874**	**16,874**	**0**	**20,691**	**20,692**	**(0)**

WBS Key Issues:

The reported financial position for the Welsh Blood Service at the end of January 2022 was **breakeven** with an outturn forecast position of **breakeven** expected.

Income underachievement to date is **£(657)k**, where activity is lower than planned on Bone Marrow and Plasma Sales, due to freezer breakdown and Covid suppressed activity. Plasma sales recovery to business-as-usual levels following hire of freezers, although delayed further from original expected return date of November 21 with partial recovery during December '21. Transitional operating sites for Bone Marrow and increasingly curtailed procedures is resulting in income loss above Covid support, with assessments as to scale and sustainability ongoing.

Staff reported a year-to-date underspend of **£185k** to January, which is above the division's vacancy factor target. Vacancies remain high albeit reducing at 31 as at end of month 10. Long standing vacancies in donor contact centre and transport have been recruited, resulting in reduced vacancy factor. Plasma fractionation staffing costs to be supported by division during 2021-22.

Component development staffing costs incurred as a divisional cost pressure with no WHSSC funding secured.

Trust approval to appoint a 4th collection team in response to NHS Wales surge capacity and meeting blood demand commenced on 6th September 2021 and continues. Confirmation received that these costs will be met by WG in 2021-22.

Potential risks due to implications of cessation of Convalescent Plasma (CVP) Funding where WG initial funding ended 31st March 2021, Part Year Effect funding agreed for 21-22, tenure of Registered Nursing posts significant as appointed on permanent contracts. SMT approval to partially mitigate the financial risk by transferring CVP permanent posts into team vacancies (where available).

Non-Staff underspend of **£473k** is largely due to reduced costs from suppressed activity, underspend on Collections Services, Laboratory Services, WTAIL, and General Services such as building maintenance and MAK business systems, which is offsetting the divisions savings target.

Corporate

	YTD Budget £000	YTD Actual £000	YTD Variance £000	Annual Budget £000	Full Year Forecast £000	Year End Projected £000
Income	**1,105**	**1,141**	**36**	**1,238**	**1,321**	**82**
Expenditure						
Staff	8,039	7,868	170	9,568	9,361	**207**
Non Staff	664	875	(210)	630	919	**(289)**
Sub Total	**8,703**	**8,743**	**(40)**	**10,197**	**10,279**	**(82)**
Total	**7,598**	**7,602**	**(4)**	**8,959**	**8,959**	**0**

Corporate Key Issues:

The reported financial position for the Corporate Services division at the end of January 2022 was a small overspend of **£(4)k**. The Corporate division is currently expecting to achieve an outturn position of **breakeven**.

Forecast Income underachievement is due to vacancies within fundraising including a period for the Charity Director where the costs were not recharged to the Charity, which is offset by a forecast underspend against the staff in post. Year to date income overachievement relates to income received upfront in IM&T but is expected to be utilised later in the year.

Staff is forecasting a large underspend due to vacancies being held, including the Chief Digital Officer and the Deputy Director of finance which will offset the CIP target and other pressures within non-staff.

The forecast Non pay overspend circa **£(289)k** is mainly due to the divisional savings target £(158)k which is expected to be met in year via staff vacancies. Other main cost pressure relates to the estates budget in VCC which is under immense strain due to the increased repair and maintenance costs of the hospital, recently added costs for statutory compliance and increased material prices, along with general inflation. In addition, several departments have little or no non pay budget to allow for unforeseen and unexpected spend.

RD&I

	YTD Budget £000	YTD Actual £000	YTD Variance £000	Annual Budget £000	Full Year Forecast £000	Year End Projected Variance £000
Income	**2,469**	**2,387**	**(82)**	**3,389**	**3,241**	**(148)**
Expenditure						
Staff	2,293	2,211	82	2,700	2,581	**119**
Non Staff	242	243	(1)	324	296	**28**
Sub Total	**2,535**	**2,453**	**82**	**3,024**	**2,877**	**0**
Total	**66**	**66**	**0**	**(365)**	**(364)**	**0**

RD&I Key Issues

The reported financial position for the RD&I Division at the end of January 2022 was **breakeven** with a current forecast outturn position of **breakeven**.

Currently no issues to report.

TCS – (Revenue)

Hosted Other - TCS

	YTD Budget £000	YTD Actual £000	YTD Variance £000	Annual Budget £000	Full Year Forecast £000	Year End Projected Variance £000
Income	**0**	**0**	**0**	**0**	**0**	**0**
Expenditure						
Staff	439	434	5	527	527	**0**
Non Staff	114	112	2	142	142	**0**
Sub Total	**553**	**546**	**7**	**669**	**669**	**0**
Total	**553**	**546**	**7**	**669**	**669**	**0**

TCS Key Issues

The reported financial position for the TCS Programme at the end of January 2022 is a small underspend of **£7k** with a forecasted outturn position of **breakeven.**

HTW (Hosted Other)

	YTD Budget £000	YTD Actual £000	YTD Variance £000	Annual Budget £000	Full Year Forecast £000	Year End Projected Variance £000
Income	**1,351**	**1,351**	**0**	**1,625**	**1,625**	**0**
Expenditure						
Staff	1,171	1,171	0	1,433	1,433	**0**
Non Staff	157	157	0	220	220	**0**
Sub Total	**1,329**	**1,329**	**0**	**1,653**	**1,653**	**0**
Total	**(22)**	**(23)**	**0**	**0**	**28**	**0**

HTW Key Issues

The reported financial position for Health Technology Wales at the end of January 2022 was **breakeven,** with a forecasted outturn position of **breakeven** on the basis that any potential slippage which is starting to emerge will be handed back to WG**.**

TCS PROGRAMME DELIVERY BOARD

TCS PROGRAMME FINANCIAL REPORT FOR 2021-22 JANUARY 2022

DATE OF MEETING	15th February 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Mark Ash, Assistant Project Director
PRESENTED BY	Mark Ash, Assistant Project Director
EXECUTIVE SPONSOR APPROVED	Matthew Bunce, Executive Director of Finance

REPORT PURPOSE	FOR NOTING

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
N/A		

ACRONYMS	
TCS	Transforming Cancer Services
Trust	Velindre University NHS Trust
PBC	Project Business Case
PMO	Programme Management Office
EW	nVCC Enabling Works
nVCC	New Velindre Cancer Centre
WG	Welsh Government
IRS	Integrated Radiotherapy Solution
SDT	Service Delivery and Transformation

1. PURPOSE

1.1 The purpose of this report is to provide a financial update to the TCS Programme Delivery Board for the financial year 2021-22, outlining spend to date against budget as at Month 10.

2. BACKGROUND

2.1 In January 2015 the Minister for Health and Social Services approved the initial version of the Strategic Outline Programme 'Transforming Cancer Services in South East Wales'. Following the completion of the Key Stage Review in June/July 2015, approval was received from the Minister to proceed to the next stage of the Programme.

2.2 As at March 2021, the Cabinet Secretary for Health, Well-being and Sport, had approved capital and revenue funding for the TCS Programme and associated Projects of £20.710m and £1.678m respectively.

2.3 Included in this approval was funding for the IRS Procurement Project (Project 3a). The PBC for this project was endorsed by WG in 2019-20, providing capital funding of £1.110m from July 2019 to December 2022. The provision was £0.250m in 2019-20, £0.548m in 2021-22, and £0.312m in 2021-22.

2.4 In addition to WG funding, NHS Commissioners agreed in December 2018 to provide annual revenue funding towards the TCS Programme. £0.400m was provided in the initial year of 2018-19, with £0.420m annually thereafter.

2.5 Further revenue funding was provided by Trust in 2019-20 and 2020-21 from its own baseline revenue budget. Funding of £0.060m and £0.030m respectively was provided for nVCC Project Delivery (previously provided by WG until March 2019). Another £0.039m (2019-20) and £0.166m (2020-21) was provided to cover the costs of staff secondment from Velindre Cancer Centre.

2.6 The total funding and expenditure for the TCS Programme and associated Projects by the end of March 2021 was £23.923m: £20.710m Capital, £3.213m Revenue.

3. FUNDING

3.1 Funding provision for the financial year 2021-22 is outlined below.

3.2 In August 2021, the Trust Board approved that the nVCC Project provide interim funding of **c£0.350m** to the EW Project. The funding is to support the work packages associated with tree and vegetation clearance (c£0.250m) and site management and security (c£0.100m). The EW Project has secured the funding from the approval of its FBC in January 2022.

3.3 The Trust has provided revenue funding of **£0.110m** to the nVCC Project.

Description	Funding	
	Capital	Revenue
Programme Management Office There is no capital funding requirement for the PMO at present Allocation of £0.240m from £0.420m funding provided from Commissioners for 2021-22 to cover direct clinical/management support and Programme Management was provided in April 2021 Allocation from WG 2021-22 revenue pay award funding was provided in September 2021	**£ nil**	**£0.246m** £0.240m £0.006m
Project 1 – Enabling Works for nVCC Capital funding from WG was provided on 24 March 2021	**£0.250m** £0.250m	**£ nil**
Project 2 – New Velindre Cancer Centre Capital funding from WG was provided on 24 March 2021 The Trust provided revenue funding in September 2021 for Project Delivery The Trust has provided revenue funding for the Judicial Review costs incurred between August 2021 and December 2021	**£3.460m** £3.460m	**£0.110m** £0.026m £0.084m
Project 3a – Radiotherapy Procurement Solution Final 9 months of a 28 month project, running from 1st August 2019 to 31st December 2021, with a funding allocation of £0.312m for 2021-22 from an overall funding allocation of £1.110m, provided in April 2021 Additional funding provided by the Trust for the Project's increased legal and staff costs November 2021.	**£0.576m** £0.312m £0.264m	**£ nil**
Project 4 – Radiotherapy Satellite Centre The project is led and funded by the hosting organisation, Aneurin Bevan University Health Board; no funding requirement is expected from the Trust for 2021-22	**£ nil**	**£ nil**
Project 5 – SACT and Outreach A review of all the Trust Programme & Project resources is being undertaken to identify how these are deployed against Trust priorities. This project is on hold pending this review.	**£ nil**	**£ nil**

Description	Funding	
	Capital	Revenue
Project 6 – Service Delivery, Transformation and Transition	**£ nil**	**£0.313m**
Allocation of £0.180m from £0.420m funding provided from Commissioners for 2021-22 to cover direct clinical/management support and Programme Management was provided in April 2021		£0.180m
Funding provided from the Trust's core revenue budget towards the costs of the Project Director post and the Project Manager post in April 2021		£0.116m
Allocation from WG 2021-22 revenue pay award funding was provided in September 2021		£0.009m
Additional funding provided from the Trust's core revenue budget towards the cost of the Project Manager post in November 2021		£0.008m
Project 7 – VCC Decommissioning A review of all the Trust Programme & Project resources is being undertaken to identify how these are deployed against Trust priorities. This project is on hold pending this review.	**£ nil**	**£ nil**
Total funding provided to date	**£4.286m**	**£0.669m**
	£4.955m	

4. FINANCIAL SUMMARY AS AT 31ST JANUARY 2022

4.1 The summary financial position for the TCS Programme for the year 2021-22 as at 31st January 2022 is outlined below:

- **CAPITAL** spend of **£2.815m to M10** with a forecast outturn of **£4.282m and variance of £0.004m underspent;** and

- **REVENUE** spend is **£0.546m to M10** with a forecast outturn of **£0.669m and variance of £nil**

TCS Programme Budget & Spend 2021-22

CAPITAL	Cumulative to Date			Financial Year		
	Budget to Jan-22	Spend to Jan-22	Variance to Jan-22	Annual Budget	Annual Forecast	Annual Variance
	£	£	£	£	£	£
PAY						
Project Leadership	157,702	157,580	123	193,000	191,641	1,359
Project 1 - Enabling Works	100,000	178,503	-78,503	100,000	215,121	-115,121
Project 2 - New Velindre Cancer Centre	698,098	595,077	103,021	1,008,500	795,649	212,851
Project 3a - Radiotherapy Procurement Solution	301,514	301,158	356	362,675	361,606	1,069
Capital Pay Total	**1,257,314**	**1,232,318**	**24,997**	**1,664,175**	**1,564,017**	**100,158**
NON-PAY						
nVCC Project Delivery	53,410	53,084	326	78,500	78,204	296
Project 1 - Enabling Works	144,167	458,957	-314,791	150,000	880,294	-730,294
Project 2 - New Velindre Cancer Centre	1,205,204	915,105	290,098	2,180,000	1,545,215	634,785
Project 3a - Radiotherapy Procurement Solution	164,792	155,226	9,566	213,165	214,234	-1,069
Capital Non-Pay Total	**1,567,572**	**1,582,372**	**-14,800**	**2,621,665**	**2,717,946**	**-96,281**
CAPITAL TOTAL	**2,824,887**	**2,814,690**	**10,197**	**4,285,840**	**4,281,963**	**3,877**

REVENUE	Cumulative to Date			Financial Year		
	Budget to Jan-22	Spend to Jan-22	Variance to Jan-22	Annual Budget	Annual Forecast	Annual Variance
	£	£	£	£	£	£
PAY						
Programme Management Office	178,612	167,918	10,694	224,833	224,833	0
Project 6 - Service Change Team	260,528	265,825	-5,297	312,633	312,367	266
Revenue Pay total	**439,139**	**433,742**	**5,397**	**537,466**	**537,200**	**266**
NON-PAY						
nVCC Project Delivery	21,381	20,991	389	26,000	26,000	0
nVCC Judicial Review	82,904	82,904	0	84,000	84,000	0
Programme Management Office	6,423	8,263	-1,840	21,534	21,534	0
Project 6 - Service Change Team	0	222	-222	0	266	-266
Revenue Non-Pay Total	**110,708**	**112,380**	**-1,673**	**131,534**	**131,800**	**-266**
REVENUE TOTAL	**549,847**	**546,123**	**3,725**	**669,000**	**669,000**	**0**

5. FINANCIAL POSITION FOR TCS PROGRAMME AND ASSOCIATED PROJECTS AS AT 31ST JANUARY 2022

CAPITAL SPEND

Project 1 – Enabling Works

5.1 There is a cumulative capital spend to date of **£0.637m** against a budget of **£0.244m**, with a forecast spend for the year of **£1.095m** against a budget of **£0.250m with a forecast variance of £0.845m overspend**.

Work package	Spend to 31st January 2022 £m	Forecast Annual Spend £m
Pay	**£0.179**	**£0.215**
Third Party Undertakings	£nil	£0.058
Technical Advisers	£0.265	£0.423
Works	£0.134	£0.605
Legal Advice	£0.122	£0.122
Enabling Works Reserves	-£0.063	-£0.328
Non-pay	**£0.459**	**£0.880**
Total	**£0.637**	**£1.095**

5.2 The forecast overspend within the Project has been mitigated by the use of underspends from the nVCC Project.

Project 2 – nVCC

5.3 There is a cumulative capital spend to date of **£0.968m** against a budget of **£2.114m**. The forecast spend for the years is **£2.611m** against a budget of **£3.460m with a forecast variance of £0.850m underspent**.

Work package	Spend to 31st January 2022 £m	Forecast Annual Spend £m
Pay	**£0.753**	**£0.987**
Project Delivery costs	£0.053	£0.078
Competitive Dialogue – PQQ & Dialogue	£0.878	£1.377
Legal Advice	£0.012	£0.053
Planning	£0.051	£0.141
nVCC Reserves	-£0.026	-£0.026
Non-pay	**£0.968**	**£1.623**
Total	**£1.721**	**£2.610**

5.4 The forecast underspend will be used to cover the Enabling Works forecast overspend for the year.

Project 3a – Integrated Radiotherapy Procurement Solution

5.5 There is a cumulative capital spend to date of **£0.456m** for the IRS Project against a budget of **£0.466m**. The Project is currently forecasting a spend of **£0.576m** against a budget of **£0.576m**.

Work package	Spend to 31st January 2022 £m	Forecast Annual Spend £m
Pay	**£0.301**	**£0.362**
Legal Advisors	£0.143	£0.175
Financial Advisors	£nil	£nil
Business Case Advisors	£0.010	£0.019
Procurement Advisors	£nil	£nil
IRS Reserves	£0.002	£0.019
Non-pay	**£0.155**	**£0.214**
Total	**£0.456**	**£0.576**

REVENUE SPEND

Programme Management Office

5.6 The PMO spend to date is **£0.176m** (£0.168m pay, £0.008m non-pay) against a budget of **£0.185m**. The Project is forecasting a spend of **£0.246m** (£0.225m pay, £0.022m non-pay) in the financial year 2021-22 against a budget of **£0.246m**.

Projects 1 and 2 Delivery Costs

5.7 There is a revenue project delivery cost to date for the nVCC and Enabling Works Projects of **£0.021m** against a budget of **£0.021m,** with a budget and expected spend for the year of **£0.026m**. This spend relates to costs associated with office costs and project support, such as audit, training and Competitive Dialogue support.

nVCC Judicial Review

5.8 There is a revenue spend to date of **£0.083m** against a budget of **£0.084m** for the legal advice to deliver the requirements of the judicial review process as the Trust is an interested party. This is also the current forecast spend for the year.

Project 6 – Service Delivery, Transformation and Transition (Service Change)

5.9 Service Change spend to date is **£0.266m** against a budget of **£0.261m,** made up of pay costs. The Project is currently forecasting a spend of **£0.313m** for the year against a budget of the same.

6. Financial Risks & Issues

6.1 There are no current financial risks or issues for the TCS Programme.

7. CONSIDERATIONS FOR BOARD

7.1 This report is included as an appendix to the Trust Board Finance Report.

8. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
RELATED HEALTHCARE STANDARD	Staff and Resources
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	See above.

9. RECOMMENDATION

9.1 The TCS Programme Board are asked to **NOTE** the financial position for the TCS Programme and Associated Projects for 2021-22 as at 31st January 2022.

At a glance

Velindre (Excluding Hosted	Current Month	Previous Month	Target
	Jan-22	Dec-21	
PADR	69.21	70.83	85%
Sickness	5.66	5.54	3.54%
S&M Compliance	85.97	86.40	85%

Key	85%-100%		50% - 84.99%		0% - 49.99%								
These figures exclude Trainee Doctors, those on Maternity, Starters within first 6 Months, those currently off on sickness absence.													
PADR	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Corporate	39.82	41.74	43.44	45.00	49.58	47.01	48.33	50.43	45.69	46.58	44.59	45.64	44.08
Research, Development & Innovation	42.22	34.04	58.33	60.00	64.58	62.50	61.70	65.96	66.67	72.09	90.91	88.37	84.09
Transforming Cancer Services	40.00	64.29	60.00	66.67	68.75	71.43	66.67	60.00	56.25	43.75	62.50	75.00	63.16
Velindre Cancer Centre	78.68	77.53	79.78	81.07	78.88	76.52	74.31	75.17	76.40	73.77	70.90	67.61	65.16
Welsh Blood Service	67.97	73.19	77.25	78.65	82.41	81.74	79.78	78.27	77.93	77.52	82.19	83.06	83.73
Velindre Organisations	70.19	71.32	74.64	76.07	76.77	75.09	73.28	73.58	73.67	71.69	72.11	70.83	69.21
Target 85%	85	85	85	85	85	85	85	85	85	85	85	85	85

Key	85%-100%		50% - 84.99%		0% - 49.99%								
These figures exclude those on Maternity and those currently off with sickness absence													
Stat and Mand Compliance (10x CSTF)	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Corporate	71.61	70.62	69.47	69.06	70.08	69.08	69.26	70.45	71.36	74.54	72.32	74.40	72.17
Research, Development & Innovation	77.45	82.50	83.73	82.59	83.08	85.69	86.00	85.80	86.25	84.89	84.58	85.83	84.26
Transforming Cancer Services	71.18	69.38	64.12	65.29	70.00	76.00	76.84	85.26	82.50	82.86	83.33	81.43	77.86
Velindre Cancer Centre	80.69	81.53	81.57	80.98	81.77	82.45	82.70	83.16	82.89	83.11	84.91	84.93	84.73
Welsh Blood Service	90.43	89.54	90.90	90.43	92.23	92.39	93.38	92.66	92.21	92.54	93.36	93.56	93.78
Velindre Organisations	82.81	83.06	83.39	82.92	84.09	84.59	84.97	85.24	84.95	85.10	86.06	86.40	85.97

Key	0% - 3.54%		3.55% - 4.49%		4.5 % & Above								
Sickness Rolling %	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Corporate	5.24	5.13	4.84	4.58	4.50	4.42	4.31	4.11	4.13	4.18	4.41	4.67	4.72
Research, Development & Innovation	4.37	4.23	4.01	3.73	3.46	3.16	3.34	3.55	3.96	4.29	4.41	4.31	4.49
Transforming Cancer Services	2.41	2.41	2.01	1.34	0.88	0.41	0.32	0.33	0.40	0.86	1.27	0.99	0.95
Velindre Cancer Centre	5.88	5.97	5.77	5.40	5.38	5.41	5.47	5.47	5.52	5.58	5.65	5.55	5.58
Welsh Blood Service	4.44	4.38	4.24	4.19	4.37	4.58	4.82	5.11	5.42	5.72	5.98	6.26	6.45
Velindre Organisations	5.28	5.29	5.10	4.84	4.85	4.91	5.01	5.09	5.24	5.39	5.53	5.58	5.66
Target 3.54%	3.54	3.54	3.54	3.54	3.54	3.54	3.54	3.54	3.54	3.54	3.54	3.54	3.54

Monthly Sickness Rolling Covid Only Absence %	0%		0.01% - 0.49%		0.50 % & Above								
Sickness Leave Covid Related	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Corporate	0.55	0.60	0.58	0.53	0.58	0.62	0.67	0.78	0.90	0.97	1.02	1.04	1.06
Research, Development & Innovation	0.45	0.46	0.42	0.35	0.44	0.45	0.45	0.43	0.43	0.43	0.42	0.37	0.40
Transforming Cancer Services	0.26	0.26	0.21	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Velindre Cancer Centre	1.39	1.44	1.31	0.96	0.89	0.86	0.87	0.88	0.85	0.87	0.85	0.73	0.78
Welsh Blood Service	0.42	0.44	0.39	0.31	0.29	0.28	0.29	0.29	0.36	0.39	0.38	0.36	0.39
Velindre Organisations	0.96	1.00	0.91	0.68	0.65	0.63	0.64	0.66	0.68	0.70	0.69	0.62	0.66

Monthly Special Leave Absence Rolling %	0%		0.01% - 0.49%		0.50 % & Above								
Special Leave Non Covid Related	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Corporate	0.30	0.23	0.17	0.11	0.05	0.04	0.06	0.05	0.03	0.09	0.09	0.09	0.08
Research, Development & Innovation	0.74	0.65	0.50	0.46	0.42	0.51	0.60	0.74	0.92	1.08	1.26	1.38	1.54
Transforming Cancer Services	0.51	0.51	0.51	0.51	0.51	0.51	0.53	0.56	0.55	0.54	0.40	0.24	0.07
Velindre Cancer Centre	0.42	0.43	0.43	0.41	0.41	0.42	0.44	0.47	0.49	0.54	0.57	0.65	0.72
Welsh Blood Service	0.63	0.61	0.62	0.58	0.59	0.58	0.60	0.61	0.63	0.65	0.64	0.62	0.59
Velindre Organisations	0.49	0.48	0.47	0.44	0.43	0.44	0.46	0.48	0.51	0.55	0.57	0.60	0.63

Monthly Special Leave Absence Rolling %	0%		0.01% - 0.49%		0.50 % & Above								
Special Leave Covid Related	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Corporate	0.58	0.57	0.48	0.32	0.25	0.18	0.11	0.03	0.01	0.00	0.00	0.00	0.00
Research, Development & Innovation	1.96	1.95	1.45	1.04	0.76	0.49	0.21	0.13	0.13	0.15	0.10	0.15	0.27
Transforming Cancer Services	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Velindre Cancer Centre	2.27	2.36	2.13	1.71	1.40	1.16	0.99	0.88	0.88	0.89	0.83	0.82	0.92
Welsh Blood Service	1.71	1.75	1.65	1.33	1.06	0.82	0.68	0.62	0.67	0.67	0.68	0.65	0.62
Velindre Organisations	1.90	1.96	1.77	1.41	1.15	0.92	0.77	0.68	0.69	0.70	0.66	0.65	0.70

Quality, Safety and Performance Committee

JANUARY PMF COVER PAPER

DATE OF MEETING	24/03/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Anna-Marie Jones, Business Support Manager Wayne Jenkins, Head of Planning and Performance Alan Prosser, Director WBS Sue Thomas Ass Director WOD
PRESENTED BY	Cath O'Brien, Interim Chief Operating Officer Sarah Morley, Director WOD
EXECUTIVE SPONSOR APPROVED	Cath O'Brien, Interim Chief Operating Officer

REPORT PURPOSE	FOR DISCUSSION / REVIEW

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
WBS SMT MEETING	9.02.22	Reviewed and Noted
VCC INDIVIDUAL DIRECTORATE MEETINGS	18.2.22 -24.2.22	Reviewed
WBS PERFORMANCE REVIEW	16.02.22	Reviewed and Noted
VCC PERFORMANCE REVIEW	25.02.22	Reviewed and Noted

ACRONYMS	
VUNHST	Velindre University NHS Trust
UHB	University Health Board
VCC SLT	Velindre Cancer Centre Senior Leadership Team
WBS SMT	Welsh Blood Service Senior Management Team
RCR	Royal College of Radiologists
JCCO	Joint Council for Clinical Oncology
PADR	Performance Appraisal and Development Review
KPIs	Key Performance Indicators
SACT	Systemic Anti-Cancer Therapy
WTE	Whole Time Equivalent (staff)
EMB	Executive Management Board
COSC	Clinical Oncology Sub-Committee
IPC	Infection Prevention Control
SPC	Statistical Process Control

1. SITUATION/BACKGROUND

1.1 The attached Trust performance reports provide an update to the Quality, Safety & Performance Committee with respect to Trust-wide performance against key performance metrics through to the end of January 2022 for the Velindre Cancer Centre, the Welsh Blood Service and for VUNHST Corporate Services respectively.

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 The reports set-out performance at Velindre Cancer Centre **(*appendix 1*),** the Welsh Blood Service **(*appendix 2*)** and the Workforce **(appendix 3).** Each report is prefaced by an '*at a glance*' section which is intended to draw attention to key areas of performance. A number of areas from the reports are highlighted below.

2.2 Velindre Cancer Centre:

Covid continues to impact our service planning and delivery. Covid related absences, capacity reductions due to IPC measures and increasing patient numbers are all having an impact on our service provision and waiting times. We are continuing to experience high staff absences in SACT; some staff are off for an extended period of time. We have reallocated staff from other areas, moved patients to inpatients and the RD&I department are also providing facilities and staff. We are also expecting the situation to remain challenging in radiotherapy during the next couple of months. It is important to note that despite all the challenges we continue to respond in providing excellent care for our patients with only 1 target reporting red.

There was only one current target reporting red in January's performance report. This was healthcare acquired infections, where one C.difficile infection was reported. The patient fully recovered from the infection and there was no transmission to other patients in the ward environment.

Since April 2021, we have been requested by the Welsh Government to report against the COSC (Clinical Oncology Sub Committee) targets. These targets align more closely with the direction of travel for reporting against the Single Cancer Pathway. In addition to the JCCO measures, which we are also reporting on COSC measures for Radiotherapy are red and not yet achieved, as we continue to work towards these. These measures are still to be formally mandated by Welsh Government and a data standard agreed so they remain indicative.

The COSC targets present different criteria and different time points of reporting (Scheduled, Urgent and Emergency- within 1 day). Work is underway to ensure that we can appropriately manage patients and report against these COSC measures. Our patient pathways are being redesigned to support health system wide adoption of the nationally agreed optimised clinical pathways, whilst development of the Digital Health and Care Record will in future support automation of reporting against these new definitions and criteria. Data capture and reporting remains a manual process and administrative overhead in the meantime.

Radiotherapy Waiting Times

The total number of referrals received in January 2022 (342) represented an increase from the previous month, which is expected following the Christmas break. The number of new referrals in January exceeded the average number received in any given month in 2020/21 (315).

IPC measures continue to restrict Linac capacity by c20%, resulting in growth in waiting times as referrals are returning to pre Covid levels, thereby exceeding available capacity. The number of patients breaching waiting time targets is expected to continue over next 6 months as demand grows and is forecast to exceed capacity.

Whilst addressing the immediate capacity challenges from the 4th wave of COVID we are also planning a range of activities to maximise our capacity in the medium and long term.

We are maximising the use of private sector capacity in the short term, and we are also reviewing utilisation of the Linac fleet in order to align tumour site groupings to maximise efficiency and flexibility of the use of each pair of machines. Please find additional information on the Rutherford in ***Appendix 4.***

We are maximising the use of hypofractionation to reduce Linac demand, although this does increase workload for the planning team.

We are working with each SST to develop a tailored capacity plan based on demand projections and treatment options eg Brachytherapy, molecular radiotherapy.

The Brachytherapy plan is progressing with agreement on the resource envelope with WHISC to fully fund the service. There remains a small number of challenges most notably the additional Anaesthetics input required from C&V team which requires an extra day to support. They are working through those options to provide the support required. We are targeting a start date around 6 months from now.

Weekly capacity planning meetings are in place reviewing patient prioritisation and resolving live operational issues.

These short term actions are being delivered alongside the major change programmes to introduce a new fleet of machines and the development of the satellite centre. The short terms actions have now been completed and all the operational interventions in terms of increasing capacity have been undertaken and we are now concentrating on the medium to long term actions to sustain this capacity.

SACT Waiting Times

The waiting times target for emergency SACT was met against a background of increasing demand above pre-covid levels, plus the additional patients who were not treated in December as a result of the holiday season. Performance decreased to 94% for non-emergency patients treated within 21 days. This has been delivered in the most difficult circumstances against a background of significant staff shortages which were Covid and non Covid related. This performance has been achieved by the hard work of the staff by improving the booking processes, increasing the utilisation of chair capacity, redeployment of SACT trained nurses, and an additional day on the Tenovus mobile unit. Support for the SACT service has come from all areas at VCC, with primarily ward based teams and clinical research providing nurses or treating patients in their areas. Staff also cancelled their leave at the beginning of the month in January, so they could ensure that the capacity of work that had planned for was completed. Weekend clinics have also been held to increase capacity with the next one scheduled on the 5thth of March.

In February, a task and finish SACT group was set up to support the service and identify solutions to the increasing capacity challenges. This is being led by the deputy director of nursing Nigel Downes. In terms of third party providers the task and finish group are looking at bringing forward the start date of April for the extra capacity at the Rutherford and prioritising the provision at Neville Hall. The delivery timescale of the task and finish group is still being finalised.

Outpatients

Data collection paused during December and January due to operational pressures and staff absence

Therapies

Physiotherapy and Dietetic in the All Therapy waiting times targets were reporting amber. 2 patients were not seen by a physiotherapist within the six week target due to staff absence. No patient harm was reported. There are challenges covering specialist staff absences within a small team. One patient was not seen within the two week urgent referral target in dietetics. The patient replied to their appointment email and their email was directed to the junk folder. The process for checking emails has now been amended.

Other areas

Falls

During January 2022, 3 falls was reported on first floor ward. Of these three falls, 1 was deemed to be avoidable. The patient tested positive for COVID-19 and was moved to an isolation cubicle. The COVID-19 protocol requires the door of the cubicle to be shut, resulting in a limit to the observation required under the falls assessment. The patient had been identified as being at risk of a fall. The patient mobilised within the cubicle without assistance and fell. They suffered a minor abrasion as a result of the fall. Moving forwards a supervision policy is being developed to assess falls and Covid risks together.

Pressure Ulcers

No Velindre acquired pressure ulcers were reported in January 2022

Healthcare Acquired Infections

One case of C.difficile was reported in January 2022. The patient had no previous history of C Diff. The indications are that the C Diff infection is related to treatment with multiple courses of antibiotics. The patient fully recovered from the C Diff infection. There was no transmission to other patients in the ward environment.

An investigation has since been carried out and was discussed at MDT on the 7th of March where it was agreed that this case could have been caused by either antibiotic usage and/or radiotherapy treatment and was deemed unavoidable.

SEPSIS bundle NEWS score

Six patients met the criteria for administration of the sepsis treatment bundle in January 2022. All six received all elements of the bundle within one hour. Five of the patients subsequently received a diagnosis of sepsis or neutropenic sepsis.

Delayed Transfers of Care (DTOC's)

There was one delayed transfer of care reported in January 2022.
The patient was due to be discharged home, but they required a nasogastric (NG) tube and had no close family to support them, so a decision was taken to transfer them to UHW. There was no bed available. When the patient no longer required the NG tube, they were discharged to their own home with a revised care plan.

Further detailed performance data is provided in Appendix 1

2.3 Welsh Blood Service

Supply Chain Performance

The WBS service recovered well in January in terms of the stock position and was able to increase stock by 11% thanks to suppressed hospital demand, additional clinics at weekends and by working closely with blood banks across Wales.

All demand for red cells was met, and all stock groups continued to be maintained above 3 days. Clinical demand for platelets was also met.

2.3.1 Recruitment of new bone marrow volunteers

The Welsh Bone Marrow Donor Registry (WBMDR) has seen an increase of 89 donors in the month of January. The service has also put together a detailed communications and engagement plan to support increasing and sustaining the recruitment target. The service also used World Cancer Day (4th Feb) to promote swab kits and engage with Universities and the impact of this campaign should be reflected in February's performance.

2.3.2 Reference Serology

Turnaround times have not met the target for January. Work continues to be prioritised based on clinical need, and all compatibility testing (>52% of referrals) is completed to the required time/date. The complexity of referrals and sickness absence continues to impact performance in January. An audit of this service has now completed and benchmarking across UK blood services was undertaken. The findings of the audit is currently with the Clinical Service team for review, with implementation of any agreed actions is expected by end of April 2022. A new testing strategy for samples suitable for automated testing is due to be completed by the end of March 2022, Validation of a new automated analyser and incorporation into routine use is planned to be in place by the end of March 2022 which will improve efficiency.

2.3.2 Quality

Incidents reported to Regulator/Licensing

There were no Serious Adverse Events (SAE) reported to regulators during January.

Incidents closed within 30 days

There was a slight decrease in performance in this activity with breaches increased from 10 in the previous three-month rolling period to 13 in this reporting period. These are low

risk investigations which have been difficult to complete in the current extremely challenging operational environment, however they are being actively managed.

Whole Blood Collection Productivity

The productivity for January is the same as December and continues to be below target. This target will not improve under Covid restrictions as the additional resources to operate in this environment are included in the productivity data. Work is in hand with the Infection Prevention and Control team to assess removal of triage and reducing social distancing within collections which should help improve this position as Wales begins to lift COVID restrictions.

Time Expired Platelets

Platelet expiry was above target for January as a result of prudently managing the stock over the bank holidays that resulted in higher wastage. Wastage levels are compounded by a 7 day shelf life for this blood component.

Number of Concerns Received

There were six concerns reported in January 2022, from approximately 7,700 donors attending clinics in the month. Five of these were managed within timeline as 'Early Resolution' whilst the one formal concern was managed under 'Putting Things Right' (PTR) regulations.

Donor Satisfaction

Continues to perform strongly at a national level despite the COVID restrictions in place.

Further detailed performance data is provided in Appendix 2

3. WORKFORCE

3.1 PADR

Trust wide performance shows compliance levels at 69.21% for the year to January against a target of 85%.

Despite a steady rise in PADR for most of 2021 (Jan – Nov average 73.49%) the figure has dropped to below 70% for the first time in the past 12 months. This is due in part to the winter pressures experience through the rising omicron situation in December 2021 and January 2022.

WBS, 83.73%: Overall WBS has seen a significant rise in PADR compliance since this time last year (Jan 21, 67.97%). Discussions continue at every SLT to stress the importance of PADR compliance.

VCC, 65.02%: Workforce Operational Team continue to highlight PADR compliance in regular meetings with managers.

3.2 Sickness Absence

Rolling absence levels are 5.66% for the year to January against a target of 3.54%.

Over the 12 month period sickness absence remains relatively stable across the Trust with an average rate of between 5.1 and 5.3%. In comparison to Jan 21 (5.28%) and Jan 22 there has been a slight rise in sickness absence of 0.38% points.

WBS, 6.40%: Both long and short term sickness has declined in January 2021 however sickness absence is still reporting at least 2% points higher when compared with a year ago.

VCC, 6.33%: short-term sickness, despite being relatively low across the division on average continues to rise this month, reporting at 3.18%

3.3 Statutory & Mandatory Compliance

Compliance with the 10 subjects of the Core Statutory Training Framework is at 85.97% against a target of 85%.

Statutory and Mandatory compliance has reported over target for 4 consecutive months within the Trust. WBS compliance sits at 93.78% with emphasis now to continue to maintain target compliance across the Division.

VCC compliance is at 84.73% which continues to improve with targeted intervention and support from WOD. Overall increase in compliance of 4.04% points since Jan 2021.

4.0 IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	The current performance reporting and monitoring system is predicated upon identifying performance issues and supporting effective decision making at service and operational levels to drive forward continuous improvement in quality, safety and the overall experience of patients and donors.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below: • Staff and Resources • Safe Care • Timely Care • Effective Care.
EQUALITY IMPACT ASSESSMENT COMPLETED	Yes
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Delivery against the performance metrics presented in the attached reports and the work associated with delivering improved performance supports sound financial governance across the Trust.

5.0 RECOMMENDATION

5.1 The Quality, Safety and Performance Committee is asked to **NOTE** the contents of the attached performance reports.

Appendices

1. VCC December PMF Report
2. WBS December PMF Report
3. Workforce KPI data
4. Rutherford information

QUALITY SAFETY AND PERFORMANCE COMMITTEE

WELSH BLOOD SERVICE QUALITY SAFETY AND PERFORMANCE REPORT

DATE OF MEETING	24/03/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not applicable

PREPARED BY	PETER RICHARDSON, HEAD OF QUALITY ASSURANCE AND REGUALTORY COMPLIANCE, WELSH BLOOD SERVICE
PRESENTED BY	Alan Prosser, Interim Director Welsh Blood Service & Peter Richardson, Head of Quality and Regulatory Compliance
EXECUTIVE SPONSOR APPROVED	CATH O'BRIEN, CHIEF OPERATING OFFICER

REPORT PURPOSE	FOR ASSURANCE

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Welsh Blood Service Senior Management Team	09/03/22	Discussed & actions agreed Approved for submission to QSP

ACRONYMS	
WBS	Welsh Blood Service
WTAIL	Welsh Transplant and Immuno-genetics Laboratories
MHRA	Medicines and Healthcare products Regulatory Agency
RAGG	Regulatory assurance and governance group
SAE	Serious Adverse Events
CA/PA	Corrective Action/Preventative Action
SABRE	Serious Adverse Blood Related Event

1. SITUATION

This assurance paper is to provide the Quality, Safety & Performance Committee with an overview of the key quality, safety and performance outcomes and metrics for the Welsh Blood Service for February 2022. The report summarises:

- Key performance outliers and associated actions to resolve
- Key quality and safety related indicators and remedial action identified
- Feedback from Donors and the responses to it.
- Regulator and Audit Feedback, assurance and learning themes
- An outline of key service developments in WBS

The Quality, Safety & Performance Committee are asked to **CONSIDER** and **NOTE**:

- Performance against the six domains of Quality
- Issues, corrective actions and monitoring arrangements in place
- Service developments within Welsh Blood Service.

2. BACKGROUND

This report is usually provided to the Quality, Safety & Performance Committee quarterly. The frequency of reporting has increased periodically during the last two years due to increased risks at peak times throughout the pandemic. The last report covered the period up to January 2022 and was reported to the Committee in February 2022.

3. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

3.1 Triangulated Analysis

The report provides assurance to the Quality, Safety and Performance Committee that the Welsh Blood Service is continuing to meet its Quality, Safety and Performance standards. The key areas contained for February 2022 are:

- 41 of incidents reported were closed within the required 30 days.
- One Serious Adverse Event (SAE) was reported to the Medicines and Healthcare products Regulatory Agency (MHRA). This related to a transposition error in the patient's date of birth entered onto a cross-match label. There was no patient harm as a consequence of this error.
- All clinical demand was met for red cells and platelets, with no imports.
- All blood stock groups were maintained above the required 3 day target.
- Reference Serology turn-around times remain below the target.
- 10 concerns were received: 2 managed as formal concerns, the remaining 8 managed as early resolution (within 48 hours).
- Overall donor satisfaction remains positive and above target position at 97.5%.
- Equity of access for donors to attend donation venues remains a challenge under COVID restrictions.
- A new plan to support Bone Marrow Volunteer recruitment is being finalised

3.2 Key Actions / Areas of focus during next period

Quality and safety and patient experience remains at the heart of our service during this period in all aspects of service delivery as well as the well-being of our staff.

A key area of action is the working through and implementing the reduced restrictions across Collections such as reducing from 2 meters to 1 meter.

4. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)

	The current performance reporting and monitoring system is predicated upon identifying performance issues and supporting effective decision making at service and operational levels to drive forward continuous improvement in quality, safety and the overall experience of patients and donors.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below: • Staff and Resources • Safe Care • Timely Care • Effective Care.
EQUALITY IMPACT ASSESSMENT COMPLETED	Yes
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)

5. RECOMMENDATIONS

The Quality Safety and Performance Committee are asked to **NOTE** the information in this report.

WELSH BLOOD SERVICE - QUALITY, SAFETY & PERFORMANCE COMMITTEE REPORT

February 2022

INTRODUCTION

This paper outlines the key Welsh Blood Service Quality, Safety and Performance related issues being monitored, reviewed and acted upon within the service and is aligned with the Six Domains of Quality as defined by the Institute of Medicine namely:

1. Safety
2. Effectiveness
3. Patient-centeredness
4. Timeliness
5. Equity
6. Efficiency

1. Safety

1.1 Safety Incidents linked to donors are reported into the Donor Clinical Governance Group and scrutinised at the Regulatory Assurance and Governce Group, These include failed venepuncture where a needle is not properly sited in a vein, and part bags where a donation stops before the full quantity is collected. All of these measures have remained at low levels and within tolerance during February 2022:

1.1.1 Failed Venepuncture 1.41% (Tolerance 2%)
1.1.2 Part bags 2.36% (Tolerance 3%)

1.2 For reporting purposes, WBS sub-divides incidents into two types:

- **Good Manufacturing Practice (GMP) Incidents**, in which our routine process monitoring and checking identifies non-compliance with expected processes or outcomes and responds to prevent further processing or harm to patients. These are reported into the Q-pulse electronic Quality Management System and monitored as a critical part of the overall Quality Management System (QMS) in line with regulatory standards.

  There were 24 GMP incidents occurring in February have been reported via QPulse. 3 of these were reported outside of the 48-hour reporting time frame (excluding weekends); a rationale for late reporting is provided and assessed by the Quality Assurance team. Where the rationale is deemed unacceptable the relevant Head of Department is advised.

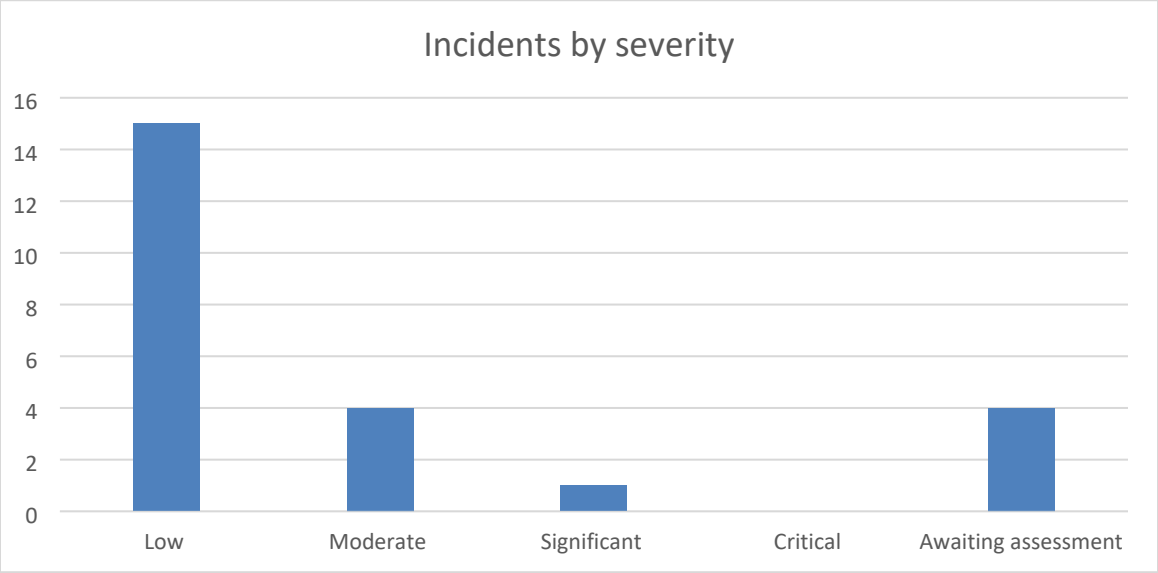
- **Incidents which may lead to redress or could result in harm to donors, patients or staff** these are reported in Datix Once for Wales (OfW) for consistency across the trust.

  There were 21 incidents reported via Datix (OfW) that could potentially affect the quality and safety of blood/blood components, however, coding of the events within the Datix (OfW) system remains a challenge for easily identification of such incidents so these have not been included in the pie chart detailing incident by category.

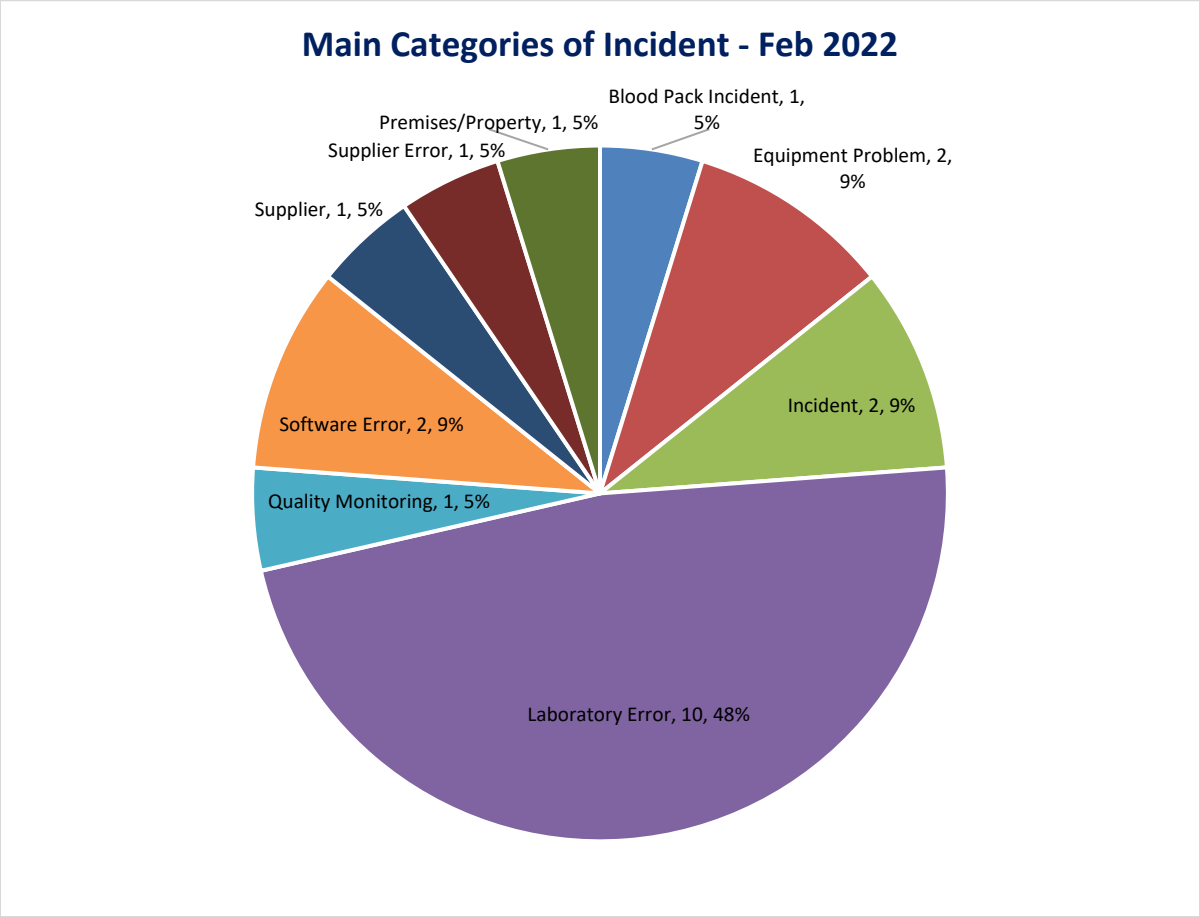
1.3 Areas of concern:

There was one incident with a significant risk rating in this reporting period. Details are included in section 2.4.1. A full root cause analysis investigation has been undertaken and is under review.

At the end of the reporting period 4 events were awaiting risk assessment, these have since been assessed as low or moderate risk events.



The chart below depicts the broad categorisation of incidents reported via QPulse in February 2022:



No trends have been noted this month; laboratory errors occurred across several laboratories, with no identifiable trends.

In the 3 months to the end of February 2022, 92% of reported incidents were investigated and closed within 30 days (including GMP incidents reported via Datix OfW). This is an improvement in performance compared with previous months (87%).

The number of incidents not closed within the required timeframe has reduced from 13 in the previous three-month rolling period to 8 in this three-month reporting period. Further to the decline in performance against this measure in January, steps have been taken to ensure incidents that may take longer than 30 days to investigate and review are recognised in advance and reported

to the relevant Head of Department and Senior Management Team Lead. This provides assurance that the investigation is being undertaken as swiftly as possible and any risks imposed to operational activity are identified and managed effectively.

1.4 Serious Incidents Reportable to Regulators

1.4.1 There was one serious incident reported to MHRA via the Serious Adverse Blood-Related Events (SABRE) portal in February. SABRE Reports are used by the MHRA to identify incidents of concern and national trends. Key learnings from these reports are shared with all blood services

IR-219: Date of birth incorrectly entered onto cross-match labels for 4 units sent to Glangwlil Hospital Blood Bank (HBB). The error was not identified in the WBS checking procedure but was noted at the bedside check. The unit(s) were returned from the ward to the Hospital Blood Bank.

There was no patient harm as a result of this error, however this is a near miss event and is SABRE reportable because the WBS quality check did not identify the error; the hospital blood bank add their own labels to the units prior to issue to the ward, these contained the correct date of birth.

A full Root Cause Analysis investigation has been undertaken and is being reviewed by the Quality Assurance and Laboratories management teams prior to submission to the regulator.

1.4.2 During February WBS was notified of a patient death that was thought to have been potentially due to bacterial contamination in transfused red cells. Standard procedures were followed to recall all associated blood components as the transfused pack.

The transfused pack was sent for microbial culture and analysis which failed to find evidence of infection. Subsequent information received indicates that the timeline of the patient’s symptoms did not indicate contaminated red cells and that other significant clinical conditions were now under investigation.

WBS has continued to provide information to the coroner as requested, and the recalled unused components were destroyed as a precaution.

2 Effectiveness

2.1 Blood Supply

WBS continues to face challenges in collecting blood and predicting demand for blood products as a result of the ongoing pandemic. In particular, the availability of venues large enough to support stock-building donation sessions has been limited by competition from the vaccination program for such facilities. The Blue alert issued to hospitals on December 16th was lifted mid-January and WBS has continued to maintain stock levels equivalent to at least 3 days' demand throughout February. There has been no requirement to import.

2.2 Bone Marrow / Stem Cell collections

The pandemic has impacted on unrelated donor stem cell transplants globally, which has reduced the number of stem cell collection requests. In addition the Service is experiencing a cancellation rate of around 30% compared to 15% pre COVID pandemic levels. This is due to patient fitness and the need for collection centres to 'work up' two donors simultaneously due to a reduction of selected donors able to donate at a critical point in patient treatment.

The move to the new Velindre Cancer Centre (VCC) collection model has enabled WBS to offer more options for collections, moving to four day availability compared to two previously available.

A 5 year strategy is being developed which will seek to enhance the Donor Panel and offer potential collaborations with other Donor registry partners.

2.3 Audit Summary

The planned audit schedule has not been maintained in order to comply with the Welsh Government guidance on social distancing. The plan has been risk assessed and audits postponed where safe to do so. Two planned audits were cancelled following the risk assessment as these areas and procedures had been covered by external audits earlier in the year.

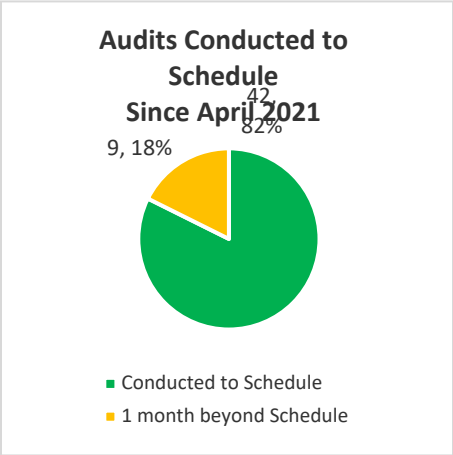
Total number of audits originally scheduled for completion in February: 6 Procedural Audits = 3 ISO 15189 = 3 ISO 17043 = 0 HTA Internal = 0	Conducted 1	Total Audits conducted 1
Audits due to be conducted in Feb but risk assessed and closed: 2 Audits postponed from Feb to Mar as a result of Covid Restrictions: 3	-	

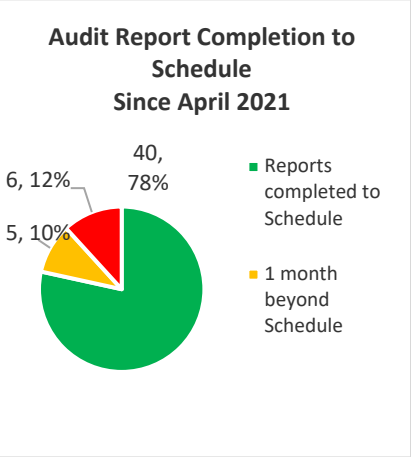
1 Audit Conducted within February – 3 Audits Postponed to March	Findings
21/31 Audit of Service Point requests: Database Amendments and Standard Changes	Under discussion/ approval
2 Audits Risk Assessed and Closed	**Findings**
21/27 – MP-003 Audit (due to extent of coverage within MHRA and UKAS Inspections) 21/30 – MP-007 Product Recall and Adverse Incidents (previously audited Feb 2021 and reported April 2021, also covered within MHRA inspection in May. The procedure is currently undergoing a full review under Project Management)	N/A

Reports outstanding/received from audits conducted in previous months	Findings
21/06 ISO 15189 – Automated Testing Laboratories (Audit conducted December – Report received 03/03/2022) (Delay in submission of audit report due to auditors current work commitments)	Under discussion/ approval

Risk by late completion: Low
The above audits have been conducted. Findings are fed back to auditees/Heads of Department at the time of audit, by completion and approval of Summary of Findings Sheet.

Audit Completion to Schedule, Since April 2021:





3 Service-User Centred

3.1 WBS invites every blood donor to complete a feedback survey in the month after their donation. This is available online, by text message or by completion of a feedback form. The feedback highlights are:

a. During February 2022 897 responses were received (14.7% response rate)
b. Donor satisfaction for those who had successfully donated was:
   - Overall (827) 97.5%
   - N.Wales (135) 98.5%
   - S.Wales (692) 97.3%

c. Donor satisfaction for every respondent, including incomplete donations was:
   - Overall (876) 95.2%
   - N.Wales (143) 96.5%
   - S.Wales (733) 95%

d. In total 751 donors scored themselves as 'Totally Satisfied' and were invited to provide more details.

e. **Out of 6,093 donation attendances in February a total of 9** donors described themselves as 'Dissatisfied' or 'Totally Dissatisfied' and were invited to provide more details. The responses will be analysed and followed up by the Collections Leadership team through their monthly operational service group:

3.2 Changes in response to Donor Feedback

3.2.1 An updated version of the 'Putting things Right' Leaflet is now available for use on donation clinics.

3.2.2 A new donor invitation letter has been created following donor and staff feedback to help donors understand why our current operating model is in place. A short animation video is also in production and will be ready to share with donors alongside their SMS invitations.

3.2.3 Three donors referenced they weren't receiving invites, all three contacted, and information updated where appropriate.

3.3 Concerns

3.3.1 In February 2022, 10 concerns (0.16%) were reported, eight were managed within timeline as early resolution as detailed in the table below. One formal

complaint was dealt with and closed within 30 days, a second one is being managed under 'Putting Things Right' (PTR) regulations and is expected to be closed within 30 working days:

You Said	We did
Donor unhappy with conversation had with Staff member feels it was inappropriate	Clinic Lead RN to support staff member and identify areas of concern (Senior staff made aware of situation)
Donor deferred at clinic due to performed Lateral Flow test for potential Covid-19 symptoms	Apologies given to donor at clinic, staff following current guidelines when assessing donors who are symptomatic for possible Covid-19 infection
Donor booked appointment online, received confirmation text, then received text message on route to donation session as to soon to donate	DCC have a process in place to identify donors who book too soon to donate, donor used middle name to book appointment so was not picked up by eProgesa as too soon to donate, apologies and explanation given to donor
Donor declared a number of issues with last donation visit: • lack of signage at venue, • no support from staff/walking stick user, • bruising to venepuncture sight	Clinic RN's advised to address all action with team staff whilst monitoring and controlling the situation
Member of public raised concern about driver of one of WBS vehicles	Transport Manager conducted investigation, including reviewing dash cam footage and photographic evidence, no evidence to suggest WBS staff acted outside of what would have been expected
Donor unhappy staff asked them to use WBS hand gel before entering the donation clinic, whilst donor has sore hands	Operations Manager advised Clinic RN's to inform staff, to refer any donors who are unable to use WBS hand sanitiser to them for full explanation of the importance of IPC & individualised assessment
Donor unhappy staff member did not take her advice to call on a more experienced Nurse to cannulate due to difficult vein access	Donor advised to ensure she requests an RN to cannulate in future, staff reminded not to attempt cannulation if not confident
Donor unhappy for being turned away from session for having received a blood transfusion (TX) and the lack of information on WBS website around TX	Apologies and explanation given to donor at session, donor booked online and skipped the eligibility quiz where the information can be found for donors who have received a blood transfusion previously
Formal concern – raised by Senedd Member on behalf of Constituent, would like to know what WBS plans are to re-start a timetable that will include regular visits to an area of North Wales	Formal concern - Current Covid-19 guidelines permits the use of the North Wales 3 bed blood mobile, ongoing risk assessments being undertaken
Formal concern - Donor raised concern about having to take a day off work resulting financial loss due to receiving a bruise and pain to venepuncture site dost donation	Formal concern -A full investigation was conducted which including working with corporate team to identify if redress was just, no breach in process identified, donor informed of finding

4 Timeliness

4.1 Reference Serology Turn-around times

The service conducts specialist tests to confirm hospital results that are difficult to interpret or will undertake additional testing which is not performed in the hospital blood banks. These tests must be performed within 7 days of the sample being taken and are prioritised appropriately to ensure the fastest turnaround possible. In February 2022 76% of these tests were completed within 7 days which is in improvement on January but still below target.

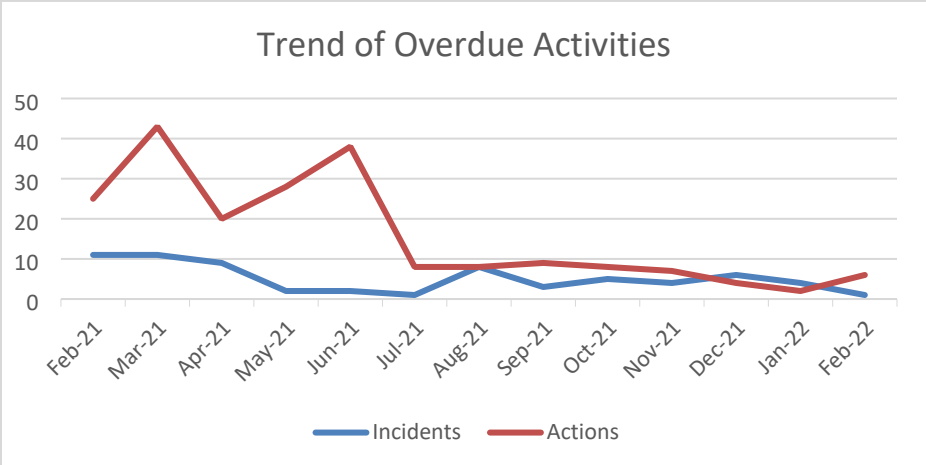
All referrals are prioritised based on clinical need and all Compatibility Testing (>52% of referrals) is completed to the required time/date. These requests are time critical and require provision of blood for transfusion, the tests are prioritised and patient care was not affected.

The actions being taken to improve the performance against this measure include:

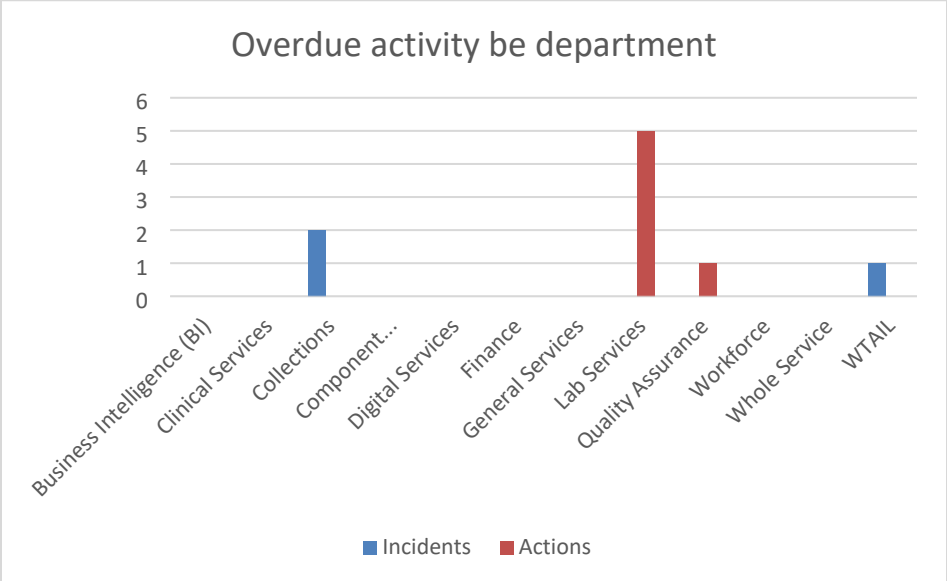
- Continued prioritisation of compatibility referrals and safe provision of red cells for transfusion.
- Validation the new automated analyser and incorporation into routine use by the end of March 2022.
- Development of a new testing strategy for patient samples that are suitable for automated testing, due to complete by the end of March 2022.

4.2 Overdue activity performance trends

The following graph provides an overview of the overdue activity performance trends for incidents and preventive actions overdue for closure over the past year. The reduction in incidents overdue for closure since the revised incident management process was introduced in May 2021 has been sustained. This in turn has allowed the Service to concentrate on completing follow-up actions in a timely manner.



The following graph provides an overview of the overdue activity performance trends for incidents, preventive actions and change proposals over time, and by department:



4.3 Areas for concern:

There are no quality deviations (incidents) more than 3 months overdue.

There were 6 overdue actions recorded in QPulse, 5 of which were assigned to one individual. These have since been discussed and addressed. The 6th was due to be completed during a meeting which was postponed, thereby causing a short delay. This action is now closed.

One incident under investigation by WTAIL is complex and reliant on the availability of a specific antibody used in the flow crossmatch test, there was limited antibody available whilst a new delivery was being received and validated. Timescales for investigation have been further impeded by staff shortages due to sickness (Covid and non-Covid related) and isolation due to Covid requirements. The investigator is in regular contact with QA regarding progress of the investigation, and although the potential severity of this incident is high, the likelihood of a recurrence is low.

Following the drop in performance during January 2022, the Quality Assurance team now send advisory notifications on a weekly basis, these include notice of actions that are overdue and those due for completion the following week; moving forward those

with assigned actions will be requested to advise the Quality Assurance team of any potential delays and subsequent risk imposed by the delay.

Quarterly Corrective and Preventative Actions (CA/PA) effectiveness monitoring is ongoing for previously reported significant risk incidents; no concerns have been identified to date.

5 Equity

The Welsh Blood Service strives to give everyone in Wales the opportunity to donate, this has traditionally been achieved through a peripatetic model of collection teams based in regional hubs and visiting visiting community venues across Wales, supplemented by mobile collection vehicles where suitable premises are not available.

The Covid Pandemic has severely limited the options for collection venues due to social distancing and ventilation requirements and has led to the mobile collection vehicles being taken off the road entirely. The service has introduced regional hubs. This means that donors in urban areas have more options for donation venues then those in more rural locations. In additon, all donors are being asked to travel further to donate, in some cases traveling upto 15 miles to their nearest donation venue. Unfortunately, some loyal donors are unable to make such a journey. This has limited the collection capacity in some areas and has led to some complaints from those donors who feel unable to donate under these arrangements.

As Covid 19 restrictions ease, WBS will need to review the collection model to address these issues, but must also recognise that some venues will be too small or too poorly ventilated for us to return to safely. This review is a priority for the Welsh Blood Service during quarter 1 2022/23.

6 Efficiency

6.1 Whole Blood Collection Efficiency (Target 1.25 units by WTE per hour)

At 0.95 collection productivity for February is same as January but continues to be below target. Covid and Infection Prevention Control (IPC) measures continue to limit donation centre capacity. Donor sessions are operating on 2m distancing therefore impacting on a reduction of available donor slots in most venues. Donors are allocated planned appointment times impacting on availability of walk in donors. There are also regional variations in productivity across collection teams which the Service is reviewing, and in part is attributable to skill mix and regional team location.

The service has now reviewed the risk assessments around triage and social distancing in collection venues. The proposed lifting of face to face triage will reduce the need for staff on reception, and reduced spacing to 1.5 or 1m where it is safe to do so will, if approved, increase the collection capacity of some venues.

6.2 Manufacturing Efficiency (392 Components per WTE)

A higher manufacturing efficiency reading was observed for February. This was primarily as a result of increased staff absence within the month (short term, long term sickness, training in Hospital Services). Manufacturing efficiency is calculated by dividing working time available by the amount of work completed.

NOTE: The work completed relates to clinical components and does not include other work (such as commercial plasma sales) performed by the department. The Service is currently reviewing its Key Performance Indicators as part of the wider review of the VUNHST Performance management Framework and will address this anomaly.

6.3 **Manufacturing Losses (Tolerance 0.5%)**

Controllable losses for February were extremely low at 0.03% (2 units of whole blood) and remain within tolerance.

6.4 **Time Expired Red Cells (Target 1%)**

Red cell expiry for February remains negligible at 0.04% and significantly lower than the 1% target. The Covid 19 challenges continue to affect the blood collection numbers resulting in faster stock turnover preventing red cells stocks from ageing in storage. This metric is well within the target and there are no concerns around expiry of red cells.

6.5 **Time Expired Platelets (Target 10% expired)**

Platelet expiry was above target for February, the reasons were:

- Overall lower average issues for platelets in February (188 per week)2.
- High weekly variation in platelet demand (weekly range was 154 - 217 units)
- This meant that it was not appropriate to reduce platelet production which resulted in excess expiry.

The Platelet shelf life of 7 days is a contributing factor to fluctuations in platelet stocks as well as the requirement for to meet differing specifications such blood group, and other specialist requirements. This adds uncertainty to the system and requires robust stock numbers to also allow and absorb normal variations in clinical demand. Platelets are made

in advance and take 2.5 days from Manufacture before becoming available. Taken together along with the impact of insufficient platelets (patient harm or importing) versus the impact of oversupply (excess time expiry) results in a cautious approach to reducing platelet production.

Expiry for end February was significantly reduced compared with expiry at the start of the month.

Welsh Blood Service Monthly Report

January 2022

Gwasanaeth Gwaed Cymru
Welsh Blood Service

- All hospital demand for red cells was met, and stock levels increased by 11.1%. 1450 units were issued on average per week.
- All clinical demand for platelets was met, with average demand at 195 units per week, slightly below the year average, and due to low demand (158) week commencing 3rd January 2022.
- The number of new bone marrow volunteers added to the Welsh Bone Marrow Donor Registry (WBMDR) reached 206 in January compared to 177 the previous month. A communication and engagment action plan to improve performance going forward has been drafted.
- At 96%, the turnaround time for routine Antenatal tests in January remains above target but slightly lower than in December (98%).
- At 68% the Red Cell Testing metric is below target (80%). This is due to a number of contributory factors. An audit has been undertaken alongside benchmarking at a UK level, a plan to address this will be available in March 2022.
- At 0.95 collection productivity for January is the same as December. Covid and Infection Prevention Control (IPC) measures continue to limit donation centre capacity. The service will be actively reviewing the socially distancing requirements with the Infection Prevention Control (IPC) team in the coming months as social distancing restrictions are reduced at a national level.
-The combined 'Part Bag' rate for all whole blood teams remains within the required tolerance at 2.3% in January. The overall trend on all teams is stable, however the increase in January part bag rates of the East A and East C teams is being reviewed to ensure no repeat issues
-The combined Failed Venepuncture (FVP) rate for all whole blood teams for January remains within the required tolerance at 1.3%, and is set against a previously upward trend in the previous 3 months.
- At 88% the performance against the 'Incidents closed within 30 days' measure did not meet target (90%) for the three month rolling period to January. The number of incidents not closed within the required timeframe has increased to 13 in this reporting period. Four of these incidents remain under investigation and are categorised as low risk.
- There were no external audits, inspections undertaken or Serious Adverse Events (SAE) reported to regulators during January.
- The manufacturing efficiency performance exceeded the target (392) for January is 418.5. The increased efficiency performance for January is due to the increased number of donations processed as a result of additional collections clinics planned to boost stock levels.
- In January 2022, approximately 7,700 donors were registered at donation clinics. Six concerns (0.07%) were reported within this period, five were managed within timeline as 'Early Resolution' with one formal concern being managed under 'Putting Things Right' (PTR) regulations.
- In January overall donor satisfaction continued to exceed target at 96.0%. In total there were 1,096 respondents, who had made a full donation, 168 were from North Wales and 872 were from South Wales.

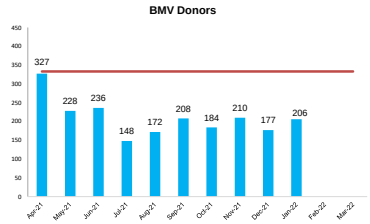
Reference Table

Measure	Target	Timeframe	National / Local
Number of new bone marrow donors aged 18-30 recruited to the Welsh Bone Marrow Donor Registry (WBMDR)	4,000	Annual	Local
Number of days when the Red Blood Cell (RBC) stockholding for O, A & B- fell below 3 days cover	0 days	Monthly	Local
Number of bags of RBCs manufactured as a % of the number of issues to hospitals **(% Red Cell Demand Met)**	100%	Monthly	Local
Number of bags of platelets manufactured as a % of the number of issues to hospitals **(% Platelet Demand Met)**	100%	Monthly	Local
Number of Confirmatory Tests (CTs) requested and bled as a % of the total CTs requested **(Confirmatory Tests Bled)**	65%	Monthly	Local
Number of Stem Cell Collections	80	Annual	Local
Number of antenatal patient results provided to customer hospitals within 3 working days from receipt of sample **(Antenatal Turnaround Times)**	90%	Monthly	Local
Number of samples referred for red cell reference serology work ups provided to customer hospitals within 2 working days. **(Reference Serology Turnaround Times)**	80%	Monthly	Local
% of Quality Incident Records (recorded in DATIX), closed within 30 days over a rolling 3 month period	90%	Rolling	Local
Number of critical non-conformances through external audits or inspections	0	Annual	Local
Number of Serious Adverse Blood Reactions & Events (SABRE) reported to the Medicines and Healthcare products Regulatory Agency (MHRA)	0	Annual	Local
Number of whole blood donations that are collected on session which are below the minimum viable volume, as a % of the total number of whole blood donations collected **(% Part Bags)**	3%	Monthly	Local
Number of donors where venepuncture is attempted to be performed on but no blood enters the bag, as a % of the number of donors who have reached the donation chair **(% Unsuccessful Venepuncture)**	2%	Monthly	Local
The number of blood components (weighted) collected per Standardised FTE (**Blood Collection Efficiency)**	1.25 WTE	Monthly	Local
Number of components manufactured per Standardised FTE. **(Manufacturing Efficiency)**	392	Monthly	Local
Number of platelets which have time expired as a % of the total number of platelets manufactured **(Time Expired Platelets)**	10%	Monthly	Local
Number of RBC units which become non-viable during the manufacturing process which could have been avoided, as a % of the number of complete whole blood donations **(Controllable Manufacturing Losses)**	0.5%	Monthly	Local
Number of bags of RBC, including Paediatric bags, which have time expired as a % of the total number of RBC bags manufactured **(Time Expired Red Cells)**	1%	Monthly	Local
Number of donors that scored 5 or 6 out of 6 (6 being totally satisfied and 1 being totally dissatisfied with their overall donation experience after they have been registered on clinic to donate **(Donor Satisfaction)**	71%	Monthly	Local
Number of 'formal' and 'informal' concerns received from blood donors	~	~	~
% of 'formal' concerns received and treated under 'Putting things Right Regulations within 30 working days	100%	Monthly	National
% of all concerns (formal and informal) acknowledged within 2 working days as required by the 'Putting things Right' Regulations	100%	Monthly	National
Number of new Whole Blood Donors recruited to the donor panel	2,750	Quarterly	Local
Number of new Apheresis Donors recruited to the donor panel	14	Quarterly	Local
Number of Deceased Donor Typing / Cross Matching reported within given period	80%	Quarterly	Local
Number of Anti D & -c Quantitation patient results provided to customer hospitals within 5 working days	90%	Quarterly	Local

Monthly Reporting

Equitable and Timely Access to Services

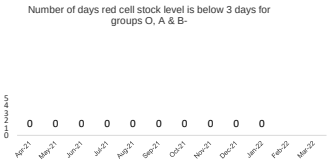
Jan-22



Annual Target: 4000 (ave 333 per month)	SMT Lead: Jayne Davey / Tracey Rees	
What are the reasons for performance?	**Action (s) being taken to improve performance**	**By When**
The number of new bone marrow volunteers added to the Welsh Bone Marrow Donor Registry (WBMDR) reached 206 in January compared to 177 the previous month. Whilst conversion of 17-30 blood donors to bone marrow volunteers has remained consistent throughout Covid-19, the reduction in blood collection due to reduced demand for blood has reduced the number of new blood donors available to convert to bone marrow volunteers. During Covid-19, appointment slots have been reduced to match hospital demand. The reduction has resulted in fewer available opportunities for new donors to donate. The current demand for blood is being sustained despite the decrease in new donors. As new donors' blood type is unknown, reserving slots for new donors is not prudent as this will increase the number of unknown blood types bookings and decrease the efficiency of blood collection. The ability to recruit new donors has also been complicated by the reduction of post-5pm donation slots and the pause on the majority of venues with high numbers of new donors (e.g. Universities). The feasibility of reintroducing universities	The Service is preparing a two-pronged approach: a) promoting swab kits and b) supporting the Service to increase the number of younger donors donating blood. In Q4, the Service will increase the visibility of WBMDR using World Cancer Day (4 Feb) to promote swab kits and engage with Universities as they are slowly reintroduced to the blood collection model. A website task and finish group was set up in January to review and improve the WBMDR sign up process for 17-30-year-olds.	Reviewed weekly

Safe and Reliable Service

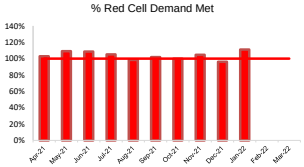
Jan-22



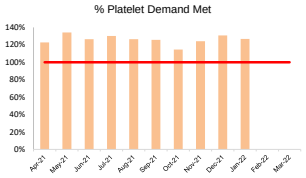
Monthly Target: 0	SMT Lead: Jayne Davey / Tracey Rees	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
O, A and B+ groups continue to be maintained above 3 days. Following a challenging Christmas period, the blood stocks position steadily improved during January. The two main contributory factors for the January performance include; increased collections from staging additional weekend clinics, and reduced hospital demand due to the spread of the Omicron variant (SARS-Cov-2 virus).	The Welsh Blood Service constantly monitors the availability of blood for transfusion through its 'Resilience Group'. Meetings are held on a daily basis and include representatives from all departments supporting the 'blood supply chain' and include the Collections, Manufacturing, Distribution and Blood Health teams. At the meetings business intelligence data is also reviewed and facilitates operational responses to the challenges identified at daily review meetings. Appropriate operational adjustments are then made in order to maintain adequate stock levels and minimise blood shortages.	Business as Usual, reviewed daily

Safe and Reliable service

Jan-22

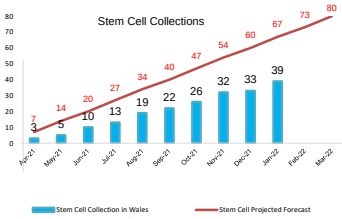


Monthly Target: 100%	SMT Lead: Jayne Davey/ Tracey Rees	
What are the reasons for performance?	**Actions(s) being taken to improve performance**	**By When**
All hospital demand for red cells was met. The Collections reading reached 111.1% demand meaning stock levels increased by 11.1% Factors continuing to affecting the supply chain include; Covid restrictions, winter pressures and staff absence. Continued collaboration between the Collections and Laboratory teams continues to enable responses to variations of stock levels and service needs. Demand in January (full weeks) averaged at 1450 units per week, in line with the	The Welsh Blood Service constantly monitors the availability of blood for transfusion through its 'Resilience Group'. Meetings are held on a daily basis and include representatives from all departments supporting the 'blood supply chain' and include the Collections, Manufacturing, Distribution and Blood Health teams. At the meetings business intelligence data is also reviewed and facilitates operational responses to the challenges identified at daily review meetings. Appropriate operational adjustments are then made in order to maintain adequate stock levels and minimise blood shortages.	Business as Usual, reviewed daily



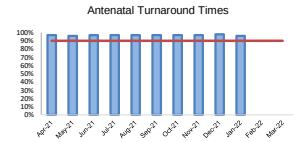
Safe and Reliable service — **Jan-22**

Monthly Target: 100%	**SMT Lead: Jayne Davey / Tracey Rees**	
What are the reasons for performance?	**Actions(s) being taken to improve performance**	**By When**
All clinical demand for platelets was met. Platelets are being produced by two different methods: Donor Apheresis and Manufactured Pools from whole blood. In combination, they provide the total number of units available each month. Due to their short shelf life (7 days), platelet stocks are monitored on a daily basis to ensure adequate response time to any 'spikes' in demand. In January platelet demand averaged 195 units per week, slightly below the year to date average of 201. For the week commencing 3rd January demand was low, at 158 units which reduced the January average and contributed to the surplus.	The Ambient Overnight Hold (AONH) production process allows flexibility in the production plan for platelets. Adjustments on the weekly production continue to be made to align with demand.	Reviewed daily



Safe and Reliable service — **Jan-22**

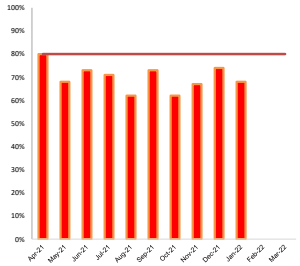
Annual Target: 80 (ave 7 per month)	**SMT Lead: Tracey Rees**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
The pandemic has impacted on unrelated donor stem cell transplants globally, which has resulted the number of stem cell collection requests. In addition the Service is experiencing a cancellation rate of around 30% compared to 15% pre COVID pandemic levels whch is in line with the global trend. This is due to patient fitness and the need for collection centres to 'work up' two donors simultaneously, as a result of a reduction of selected donors able to donate at a critical point in patient treatment.	The move to the new Velindre Cancer Centre (VCC) has enabled WBS to offer more options for collections, moving to four day availability compared to two previously available at Nuffield. A five year strategy is being developed seeking to increase the Donor Panel and offer potential collaborations with other Donor registry partners. In addtion as part of the strategy the WBMDR is working closely with the WBS communications team to increase the number of donors recruited to the panel via blood donor sessions and swab recruitment. The service is doing this through social media, attendance at blood clinic via planned bespoke recruitment drives for swab only collection, and use of World Cancer Day (4th Feb) to promote swab donation and engage with Universities.	30/06/2022



Safe and Reliable service — **Jan-22**

Monthly Target: 90%	**SMT Lead: Tracey Rees**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
At 96%, the turnaround time for routine Antenatal tests in January remains above the target of 90% Continued monitoring and active management remains in place.	Efficient and embedded testing systems in place. Continuation of existing processes are maintaining high performance against current target.	Business as Usual, reviewed daily

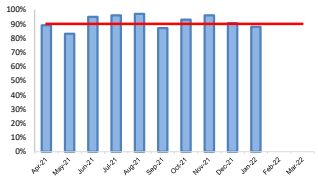
Reference Serology



Safe and Reliable service — **Jan-22**

Monthly Target: 80%	**SMT Lead: Tracey Rees**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
Contributory factors to the January performance of this measure include; staff vacancies, sickness, Covid related absence, compensatory rest due to 'out of hours call out' (47% increase compared to 2021, Pre covid) and an increased training commitment due to the inability to recruit qualified staff.	The service conducts specialist tests to confirm hospital results that are difficult to interpret or will undertake additional testing which is not performed in the hospital blood banks. These tests must be performed within 7 days of the sample being taken and are prioritised appropriately to ensure the fastest turnaround possible. All referrals are prioritised based on clinical need and all Compatibility Testing (>52% of referrals) is completed to the required time/date. These requests are time critical and require provision of blood for transfusion, the tests are prioritised and patient care was not affected. There were 231 hospital patient referrals in January, with the average number of Hospital Patient referrals at 226/month for 2021, compared to 181 in 2020. The list below details the actions being taken to improve the performance against this measure: 1. Continued prioritisation of compatibility referrals and safe provision of red cells for transfusion. 2. Validation the new automated analyser and incorporation into routine use by the end of March 2022. 3. Development a new testing strategy for patient samples that are suitable for automated testing, due to complete by the end of March 2022. 4. A review of the WBS audit aimed to identify the appropriateness of 'out of hours' hospital referrals. The Clinical Team review of the Audit is expected by week beginning 7th March 2022 and implementation of any agreed actions by end of April 2022.	April 30th 2022

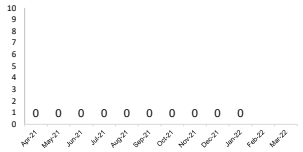
Quality Incidents closed within 30 days (rolling 3 months)



Safe and Reliable service — **Jan-22**

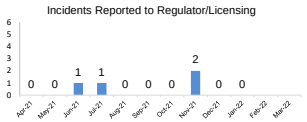
Monthly Target: 90%	**SMT Lead: Peter Richardson**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
The reason that incidents have not been completed on time is due to competing pressures of the Collections Management Team as a result of the ongoing 'Blue Alert'. The number of incidents not closed within the required timeframe has increased from ten in the previous three-month rolling period to thirteen in this reporting period. Five 'Datix' incidents two required collection of sensitive information in order to close, requiring a review of data collected over a number of weeks. There were seven 'Q-Pulse' events four of which indicated a trend in hospital issues, needing further time to investigate. Two events were due to errors outside of the control of WBS and required input from external organisations, and one event was an investigation of a trend in packing errors at donation clinics which required a review of clinical data and staffing rota. These incidents remain under investigation by the Clinical Governance team, and are categorised as low risk investigations which have been difficult to complete during the current extremely challenging operational environment.	The revised process for managing low-impact incidents was implemented on 1st June, new reports are reviewed and risk assessed daily and the majority of incidents are fully closed within a few days of reporting. The QA team to review incident management process to include weekly alerting of owners of incidents likely to breach time deadlines. Datix User Access and Reporting issues remain with the Datix Project Board for resolution.	Continue with close monitoring.

Critical Findings



Safe and Reliable service — **Jan-22**

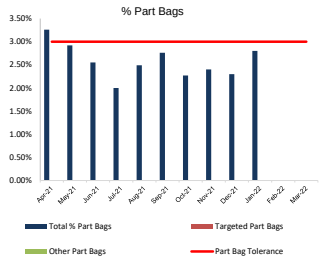
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
There were no external audits or inspections undertaken during January.	Actions from previous MHRA inspections are being managed as business as usual via action plans. MHRA have been informed of delays to completion of three long-term actions and have accepted the rationale for delay and the revised timelines for completion. The three outstanding actions noted by MHRA all required IT or equipment upgrades, and the original timelines for the upgrades were based on the most optimistic assumptions. Two of the above actions have now been closed. The original proposed solution for the remaining action has proved difficult to achieve technically, and work is underway to find a simpler resolution. The revised timeline has been approved by the MHRA.	N/A



Safe and Reliable service

Jan-22

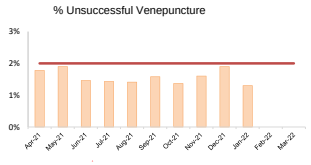
Annual Target: 0	SMT Lead: Peter Richardson	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
There were no Serious Adverse Events (SAE) reported to regulators during January.	N/A	N/A



Spending Every Pound Well

Jan-22

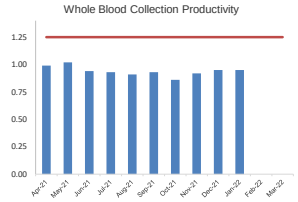
Monthly Target: Maximum 3%	SMT Lead: Janet Birchall	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
The combined 'Part Bag' rate for all whole blood teams remains within the required tolerance level at 2.8% in January 2022. The overall trend on all teams is stable, however East A and East C teams have seen an increase in January with both teams being over tolerance at 3.3% and 3.4% respectively. Causes of Part Bag are various and include: needle placement, donor is unwell, donor request to stop donation, and equipment failure. This is a separate factor to Failed Venepuncture (FVPs).	Analysis of venepuncturist performance on East A and C teams will be undertaken to ensure no repeat venepuncturist issues. Operation Managers & the Training Team will be provided with the relevant information, and should it be required, further interventions (I.e. Individual Support Plans and or Additional Training /Supervision) can be actioned.	Continue with close monitoring and intervention where required



Spending Every Pound Well

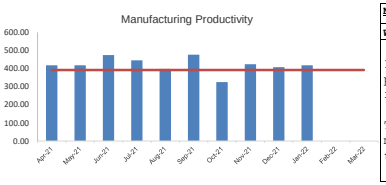
Jan-22

Monthly Target: Maximum 2%	SMT Lead: Janet Birchall	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
The combined Failed Venepuncture (FVP) rate for all whole blood teams for January 2022 remains within the required tolerance at 1.3%. This reduced rate is set against a previously upward trend in the previous 3 months. Wrexham is the only team to be over tolerance for this factor in January 2022. (2.6% - 19 FVP events).	A review of the Wrexham team venepuncturist performance will be undertaken to determine if there are any trends linked to individual venepuncturists. Operation Managers & the Training Team will also be provided with the relevant information, and should it be required further interventions (I.e. Individual Support Plans and or Additional Training /Supervision) can be actioned.	Continue with close monitoring and intervention where required



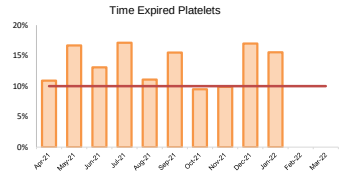
Spending Every Pound Well — **Jan-22**

Monthly Target: 1.25	**SMT Lead: Jayne Davey**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
This target measures collection productivity by assessing the staffing levels against the collections made. Covid and Infection Prevention Control (IPC) measures continue to limit donation centre capacity. Donor sessions are operating on 2m distancing therefore impacting on a reduction of available donor slots in most venues. There are also regional variations in productivity across collection teams which the Service is reviewing, and in part is attributable to skill mix and regional team location.	Whilst the Service continues to operate under Covid conditions, it is extremely limited in being able to improve this performance which is based on a pre COVID operating model. The service will be actively reviewing the socially distancing requirements with the Infection Prevention Control (IPC) team in the coming months as social distancing restrictions are reduced at a national level.	Review end of Quarter 1 2022



Spending Every Pound Well

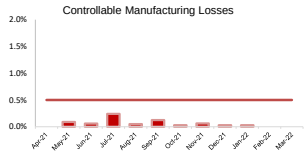
Monthly Target 392	**SMT Lead: Tracey Rees**	
What are the reasons for performance?	**Actions(s) bring taken to improve performance**	**By When**
Increased productivity was observed in January. The manufacturing efficiency performance for January is due to the increased number of donations processed as a result of additional collections clinics planned to boost stock levels. The number of units manufactured is assessed against the staff resource for the month. At 418.50, figure reflects the increased laboratory activity which enabled the successful production of additional blood components.	This target measures the manufacturing productivity by assessing the staffing levels against the number of blood components being manufactured. As the Service continues to operate under Covid conditions, it is extremely limited in being able to improve this performance which is based on a pre COVID operating model. The service will be actively reviewing the socially distancing requirements with the Infection Prevention Control (IPC) team in the coming months as social distancing restrictions are reduced at a national level.	Quarter 1 2022



Spending Every Pound Well

Jan-22

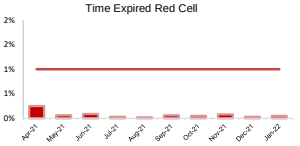
Monthly Target: Maximum 10%	**SMT Lead: Tracey Rees**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
Platelet expiry was above target for January, the two main reasons were: 1. Increased production at the end of December in preparation for the Christmas period and at the beginning of January to recover form the lower platelet position following Christmas and New Year holidays. 2. Reduction in platelet demand (at 158 units for week starting 3rd January, usually at approximately 200 units per week) which led to excess platelet wastage from that week. NB. The Platelet shelf life of 7 days is a contributing factor to fluctuations in platelet stocks as well as the requirement for to meet differing specifications such blood group, and other specialist requirements. This adds uncertainty to the system and requires robust stock numbers to also allow and absorb normal variations in clinical demand.	Platelets are being produced by two different methods: Donor Apheresis and Manufactured Pools from whole blood. In combination, the methods provide the total number of units available each month. The introduction of Ambient Overnight Hold process for the manufacturing of blood components has increased flexibility in production of pooled platelets. Daily communications between the Collections and Laboratory teams enables agile responses to variations of stock levels and service needs. Adjustments to the platelet manufacturing targets are made in the laboratory to better align with demand, and take into account the apheresis appointments and donor attendance. Although it should be noted that demand can fluctuate significantly on a daily basis. NB: All demand has been met without the requirement to import routine stock.	Ongoing and reviewed daily



Spending Every Pound Well

Jan-22

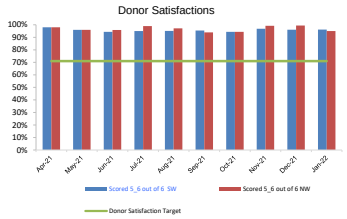
Monthly Target: Maximum 0.5%	**SMT Lead: Tracey Rees**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
Controllable losses for January were extremely low at 0.03% and remain within tolerance to be below 0.5%. The losses were (units): Manufacturing & Distribution Operator - Blood Presses :2 units	Active management of the controllable losses in place, including vigilance and reporting of all units lost. Ongoing monitoring of losses when occurring in order to understand the reasons and consider appropriate preventative measures thus continuously improving practice through lessons learned and analysis.	Business as Usual, reviewed monthly



Spending Every Pound Well

Jan-22

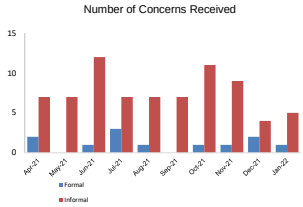
Monthly Target: Maximum 1%	**SMT Lead: Tracey Rees**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
Red cell expiry for January remains negligible at 0.05% and significantly lower than the 1% target. The Covid 19 challenges continue to affect the blood collection numbers resulting in faster stock turnover preventing red cells stocks from ageing in storage.	Daily monitoring of age of stock as part of the resilience meetings. Red Cell Shelf life is 35 days, with all blood stocks stored in Blood Group and Expiry Date order and issued accordingly. Continued effective management of blood stocks to minimise the number of wasted units.	Business as usual, reviewed daily



First Class Donor Experience

Jan-22

Monthly Target: Minimum 71%	**SMT Lead: Jayne Davey**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
In January overall donor satisfaction continued to exceed target at 96.0%. In total there were 1,096 respondents, who had made a full donation and shared their donation experience (some of which are non attributable), 168 were from North Wales and 872 were from South Wales (where location was able to be defined).	Findings are reported to management at the Collections team meeting for actioning by individual teams.	Business as usual, reviewed monthly

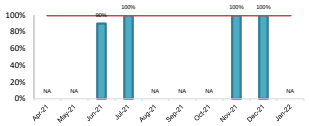


First Class Donor Experience

Jan-22

Target: N/A	**SMT Lead: Alan Prosser**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
In January 2022, approximately 7,700 donors were registered at donation clinics. Six concerns (0.07%) were reported within this period, five were managed within timeline as 'Early Resolution' whilst the one formal concern was managed under 'Putting Things Right' (PTR) regulations. The formal concern was first managed as Early Resolution, then logged as a formal concern on 11/01/2022 as it was unable to be resolve to the concern within the 2 working day threshold. This is due to donor refusing to provide telephone number or digital means of contact with correspondence is issued via the post. This issue is logged as a 're-opened' concern and remains within PTR timeline. 1. Formal Concern - The donor does not wish to provide additional contact details such as email or phone number and is unhappy that he is regularly asked to do so. 2. The donor was concerned that donors are not provided with one to one attention during donation where possible. 3. The donor was unhappy that he was only able to provide a 'part bag' and was not offered the opportunity to provide the donation from the other arm. 4. The donor was unhappy that she was not accepted for donation at clinic following travel abroad following a previous conversation with DCC staff had deemed her eligible and an appointment made. 5. The donor was unhappy about being turned away at clinic because she attended with her baby and also complained of a lack of signage to session at UHW making the venue difficult to find. 6. The donor was frustrated that he was only able to provide a 'part bag' donation.	Actions taken to address concerns include; 1. A formal acknowledgement letter was issued to the donor within timescale. 2. Several attempts to invite the donor to contact WBS have been made in order to discuss the issue and to provide explanation of current model. At the time of writing there has been no reply received from donor. 3. Contact has been made with the donor to explain the reason for not agreeing to his request to donate from his other arm following a part bag donation. 4. At donation the donor declared that she had been unwell following travel abroad - this meant that the donor was ineligible to donate. A review of the collections booking telephone call confirmed that the discussion at collection was inconsistent to information provided by the Donor to the DCC when booking the appointment . The correct decision was made by DCCA and clinic staff at clinic, and the explanation was provided to donor. 5. The donor has been contacted to discuss their complaint. The WBS website does provide information regarding children attending clinics and the donor has since read this. Collections teams have reminded to ensure venue signage is clear, correct and visible. 6. The donor has been contacted and full discussion took place regarding his experience.	Business as usual, reviewed daily

% Responses to Concerns closed within 30 Working Days



First Class Donor Experience

Jan-22

Monthly Target: 100%	**SMT Lead: Alan Prosser**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
During January 2022 one formal concern was received. This concern was acknowledged on time and is on target for closeout within PTR timeline. * Under PTR, Organisations have 30 working days to address/ close formal concerns. This can result in concerns being received and subsequently closed within separate reporting periods.	Continue to monitor Formal complaint response progress, and 30 day target compliance.	Business as Usual, reviewed daily

% Concerns Acknowledged within 2 Working Days

First Class Donor Experience

Jan-22

Monthly Target: 100%	**SMT Lead: Alan Prosser**	
What are the reasons for performance?	**Action(s) being taken to improve performance**	**By When**
All initial responses to all early resolution and formal concerns received in January 2022 were managed within timeline.	Continue to monitor initial complaint acknowledgement progress against the 'two working day' target compliance.	ongoing, reviewed daily

Velindre Cancer Centre Monthly Performance Report Summary Dashboard (January 2022)

The table below includes two measures for the performance for radiotherapy service provision. The JCCO is the measure that has historically been reported. It defines patients into certain categories as detailed below. The newer COSC measure has been introduced in 2020 and sets a reduction in the days target for treatment commencing that we and other centres are working towards. The measure is based on different categories of patients and new definitions and as a result the two data sets are not directly comparative. We will continue to report both sets of measures to provide the board assurance that we are maintaining service while also providing progress against the new target. The detailed narrative reports against the JCCO target.

			Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-21
Radiotherapy	Patients Beginning Radical Radiotherapy Within 28-Days (page 8) ***(JCCO Measure)***	Actual	97%	92%	89%	95%	94%	97%	96%	97%	96%	92%	78%	92%
		Target	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%
	Patients Beginning Palliative Radiotherapy Within 14-Days (page 10) ***(JCCO Measure)***	Actual	97%	90%	85%	95%	85%	82%	82%	82%	82%	74%	84%	90%
		Target	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%
	Patients Beginning Emergency Radiotherapy Within 2-Days (page 12) ***(JCCO Measure)***	Actual	97%	100%	97%	100%	100%	97%	100%	97%	100%	85%	89%	100%
		Target	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%
	Scheduled Patients Beginning Radiotherapy Within 21-Days (page 13) ***(COSC Measure)***	Actual			35%	28%	37%	35%	31%	27%	36%	36%	33%	34%
		Target	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
	Urgent Scheduled Patients Beginning Radiotherapy Within 7-Days (page 13) ***(COSC Measure)***	Actual			41%	48%	40%	54%	52%	52%	35%	41%	57%	37%
		Target	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
	Emergency Patients Beginning Radiotherapy Within 1-Day (page 13) ***(COSC Measure)***	Actual			83%	88%	85%	82%	86%	82%	86%	77%	84%	90%
		Target	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

			Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-21
SACT	Patients Beginning Non-Emergency SACT Within 21-Days (page 14)	Actual	77%	88%	98%	98%	98%	99%	99%	98%	99%	99%	99%	94%
		Target	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%
	Patients Beginning Emergency SACT Within 2-Days (page 15)	Actual	100%	100%	100%	100%	100%	100%	100%	100%	100%	86%	100%	100%
		Target	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%
Outpatients	New Patient, other Outpatient and Chemotherapy Assessment Appointments Where Patients Were Seen Within 30 minutes of the Scheduled Appointment Times (National Target) (page 19)	Actual	65%	57%	66%	79%	76%	76%	53%	53%	65%	65%	Data collection paused during December and January due to operational pressures.	
		Target	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%		
	Did Not Attend (DNA) Rates	Actual	2%	3%	3%	4%	4%	5%	5%	5%	5%	5%	3%	3%
		Target	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
Therapies	Therapies Inpatients Seen Within 2 Working Days (page 22)	Actual (Dietetics)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
		Actual (Physiotherapy)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
		Actual (Occupational Therapy)	100%	100%	100%	100%	100%	100%	100%	100%	95%	100%	100%	100%

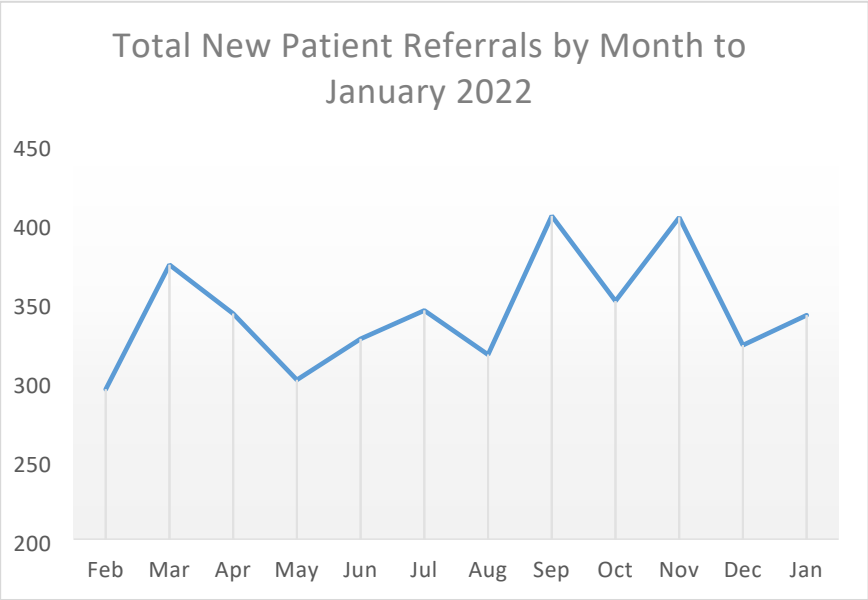
			Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-21
		Actual (Speech and Language Therapy)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
		Target	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
	Therapies Outpatient Referrals Seen Within 2 Weeks (page 22)	Actual (Dietetics)	100%	100%	100%	100%	84%	94%	94%	98%	97%	100%	95%	98%
		Actual (Physiotherapy)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
		Actual (Occupational Therapy)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
		Actual (Speech and Language Therapy)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
		Target	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
	Routine Therapies Outpatients Seen Within 6 Weeks (page 22)	Actual (Dietetics)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
		Actual (Physiotherapy)	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	86%
		Actual (Occupational Therapy)	100%	100%	100%	100%	100%	100%	96%	33%	78%	100%	100%	100%
		Actual (Speech and Language Therapy)	100%	100%	100%	100%	100%	96%	100%	100%	96%	100%	100%	100%
		Target	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

			Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-21
Safe and Reliable Care	Number of VCC Acquired, Avoidable Pressure Ulcers (page 24)	Actual	0	0	1	0	0	0	2	1	1	0	1	0
		Target	0	0	0	0	0	0	0	0	0	0	0	0
	Number of Pressure Ulcers Reported to Welsh Government as Serious Incidents	Actual	0	0	1	0	0	0	0	0	0	0	0	0
		Target	0	0	0	0	0	0	0	0	0	0	0	0
	Number of VCC Inpatient Falls (page 26)	Actual (Total)	1	1	2	3	1	3	4	2	3	1	4	3
		Unavoidable	1	1	1	3	1	3	4	1	3	1	4	2
		Avoidable	0	0	1	0	0	0	0	1	0	0	0	1
		Target	0	0	0	0	0	0	0	0	0	0	0	0
	Number of Delayed Transfers of Care (DToCs)	Actual	0	0	0	0	0	0	1	0	4	0	0	1
		Target	0	0	0	0	0	0	0	0	0	0	0	0
	Number of Potentially Avoidable Hospital Acquired Thromboses (HAT)	Actual	0	0	0	0	0	0	0	0	0	0	0	0
		Target	0	0	0	0	0	0	0	0	0	0	0	0
	Patients with a NEWS Score Greater to or Equal to Three Who Receive all 6 Elements in Required Timeframe (page 28)	Actual	100%	100%	100%	100%	100%	80%	100%	75%	100%	100%	100%	100%
		Target	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

			Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-21
	Healthcare Acquired Infections (page 29)	Actual	0	0	0	0	0	1 (*C.diff*)	0	0	0	0	0	1 (*C.diff*)
		Target	0	0	0	0	0	0	0	0	0	0	0	0
Percentage of Episodes Clinically Coded Within 1 Month Post Episode End Date		Actual	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	98%	%
		Target	95%	95%	95%	95%	95%	95%	95%	95%	95%	95%	95%	95%

RAG rating above indicates: Green - Target was achieved. Amber - 85% Compliance or above. Red - Target not achieved.

Radiotherapy Referral Trends - Overall

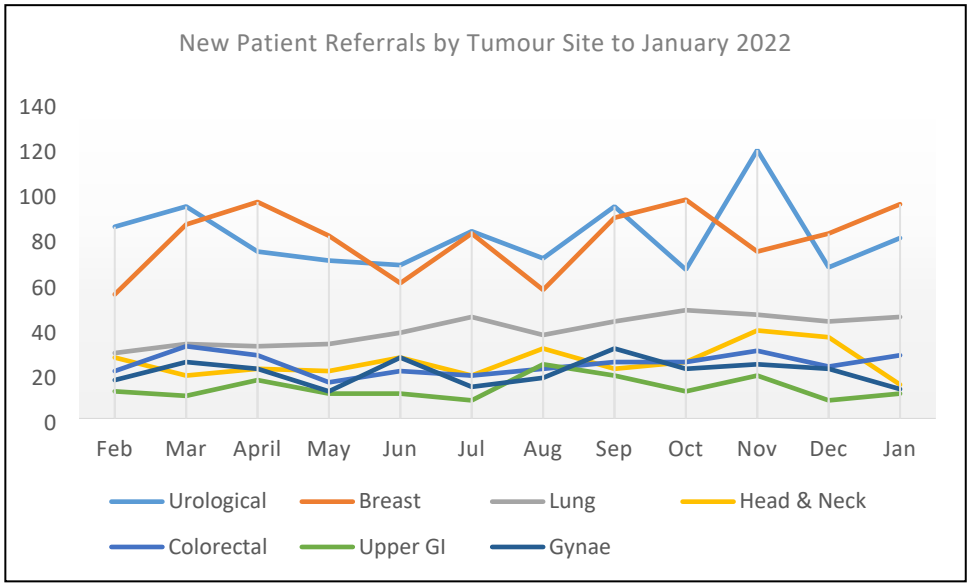


Monthly Average (2019-20)	Monthly Average (2020-21)	Total New Patient Referrals (January 2022)
357	315	342

The total number of referrals received in January 2022 (342) represented an increase on the number received in December 2021 (322). It is typical to observe a rise in referral numbers following a relative low in December. This pattern is reflective of changing activity in health boards. The number of new referrals in January exceeded the average number received in any given month in 2020/21 (315).

Radiotherapy – Operational Context

Referral Trends - Tumour Site

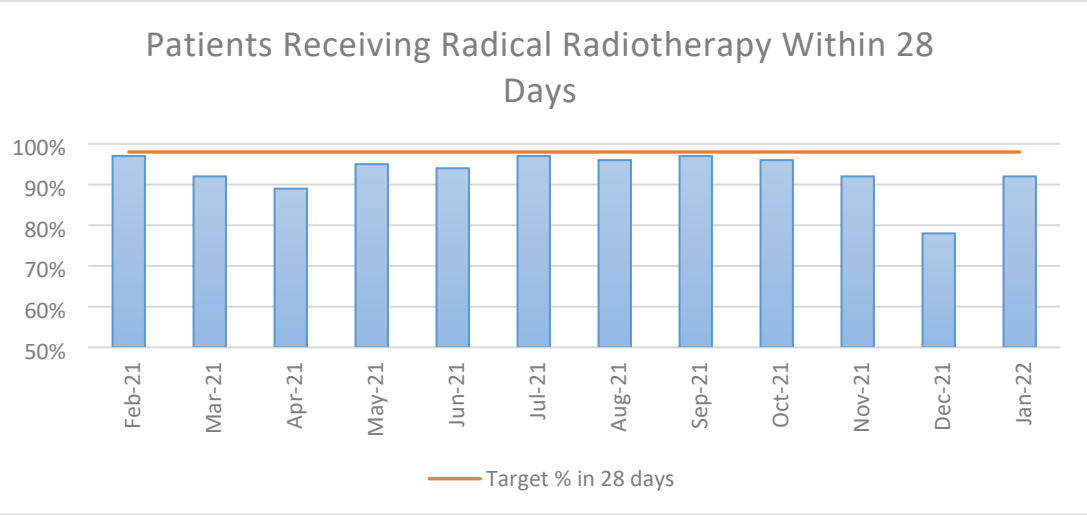


Site	Monthly Average (2019-20)	Monthly Average (2020-21)	2020-21 Average Relative to 2019-20 Average	New Patients (January 2022)
Breast	**88**	**60**	**-32%**	95
Urology	**82**	**82**	**0%**	80
Lung	**47**	**38**	**-19%**	45
Colorectal	**20**	**22**	**+10%**	28
Head and Neck	**23**	**23**	**0%**	15
Gynaecological	**18**	**18**	**0%**	13
Upper Gastrointestinal	**16**	**13**	**- 19%**	11
Top 7 Tumour Sites by Number of Referrals as Percentage of Total Referrals	**82%**	**81%**		84%

The graph and table show the number of patients scheduled to begin treatment in January by the tumour sites most commonly referred for radiotherapy treatment.

- Referrals overall and across some tumour sites now returning to pre Covid levels.
- Demand up from 82% to 87% against the 2019/20 baseline (in the tumour sites most commonly referred for radiotherapy, with maximum 80% capacity due to IP&C measures. Prior to staff absences rising during 4th COVID wave.
- Weekly variation in referrals from health boards, across individual tumour sites, is impacting on our ability to meet demand in a timely fashion. Engagement with health boards ongoing to understand their backlog clearance plans.
- All options being explored by SSTs to meet short term surges and to respond to health board backlog clearance.

Patients Receiving Radical Radiotherapy Within 28-Days	
Target: 98%	**SLT Lead: Radiotherapy Services Manager**
Trend	Current Performance



The number of patients scheduled to begin radical radiotherapy treatment in January 2022 (155) exceeded the monthly average observed in 2020-21 (150) and was higher than the number scheduled to begin treatment in December 2020 (114).

Social distancing and other infection control measures present particular challenges in the delivery of radiotherapy. Capacity has been reduced by 20% due to these COVID precautions.

The reduction in the number of patients beginning treatment within 28 days is also impacted by the loss of routine capacity from the additional bank holidays, when service is reduced to high priority Category 1 patients and emergency patients only.

13 patients referred for radiotherapy treatment with radical intent did not begin treatment within the 28 day target constituting an overall performance rate of 92**%.**

3 patients began treatment in excess of 50 days:

Treatment Intent	≥ 50 days
Radical (28-day target)	3

Additional staffing pressures due to sickness during January as a result of Omicron variant resulted in a curtailment of the service.
Summary of delays:
Planning complexity, and capacity for kilo Voltage, brachytherapy, Space OAR and other specialist treatments alongside general Linac capacity due to staff omicron, were the main reasons for breaches.
3 patients too unwell to commence treatment.

IPC measures continue to restrict Linac capacity by 20%, resulting in growth in waiting times as referrals are returning to pre Covid levels, thereby exceeding available capacity.

Breaches expected to continue over next 6 months as demand grows and will continue to exceed

Intent	Monthly Average (2019-20)	Monthly Average (2020-21)	Patients Scheduled to Begin Treatment (January 2022)
Radical	167	150	155
	Patients Scheduled to Begin Treatment (January 2020)	Patients Scheduled to Begin Treatment (January 2021)	
	162	114	

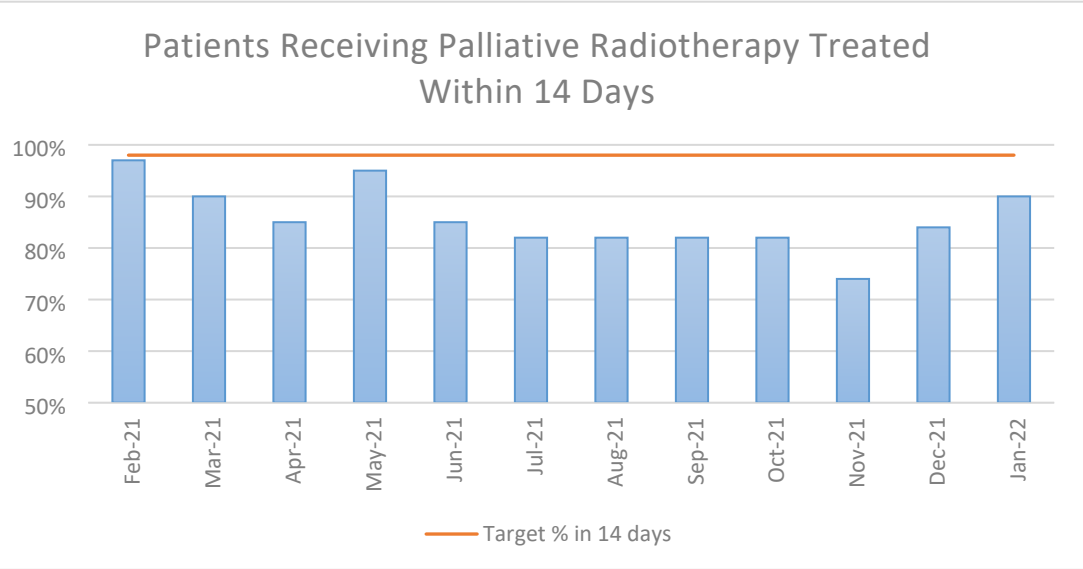
available capacity, generally and in respect of specialist treatments such as DXR and STS.

We have completed the short term actions and are now in the detailed planning stage. All operational intervention in terms of increasing capacity have now been undertaken. We are now moving to medium and longer term actions to sustain our capacity.

Medium Term Actions

- We are working with each SST to develop a tailored capacity delivery plan based on demand projections and treatment options eg Brachytherapy, molecular radiotherapy.
- Recruitment and appointments in progress for additional front line resources, however capacity increases predicted throughout 2nd half of 2022 due to lead in time, maximising capacity from Sept-Dec 2022.
- Peer review with Clatterbridge Trust underway to identify options/service models to put service demand and capacity in balance for Brachytherapy March/April 2022
- Brachytherapy expansion business case being written to obtain support for increased capacity with WHSCC. submission Mar 2022
- Assess the options to escalate some or all of the longer term capacity solutions. March 2022.

Patients Receiving Palliative Radiotherapy Within 14-Days	
Target: 98%	**SLT Lead: Radiotherapy Services Manager**
Trend	Current Performance



The number of patients scheduled to begin palliative radiotherapy treatment in January 2022 (60) was below the monthly average observed in 2020-21 (74), but exceeded the number scheduled to begin treatment in January 2021 (50).

Intent	Monthly Average (2019-20)	Monthly Average (2020-21)	Patients Scheduled to Begin Treatment (January 2022)
Palliative	82	74	80
	Patients Scheduled to Begin Treatment (January 2020)	Patients Scheduled to Begin Treatment (January 2021)	
	83	50	

80 patients referred for radiotherapy treatment with palliative intent were scheduled to begin treatment in January. Of this total, 8 patients did not begin treatment within the 14 day target constituting an overall performance rate of **90%.**

Additional staffing pressures due to sickness during January as a result of Omicron variant resulted in a reduction of the service. Impact on staffing is ongoing and has resulted in Breach data not being fully validated due to absence of key staff members.

Summary of delays:
The major contributor to the breach position is the requirement of 3D conformal plans and the overall lack of capacity.

IPC measures continue to restrict Linac capacity by 20%, resulting in growth in waiting times as referrals are returning to pre Covid levels, thereby exceeding available capacity.

Breaches expected to continue over next 6 months as demand grows and will continue to exceed capacity.

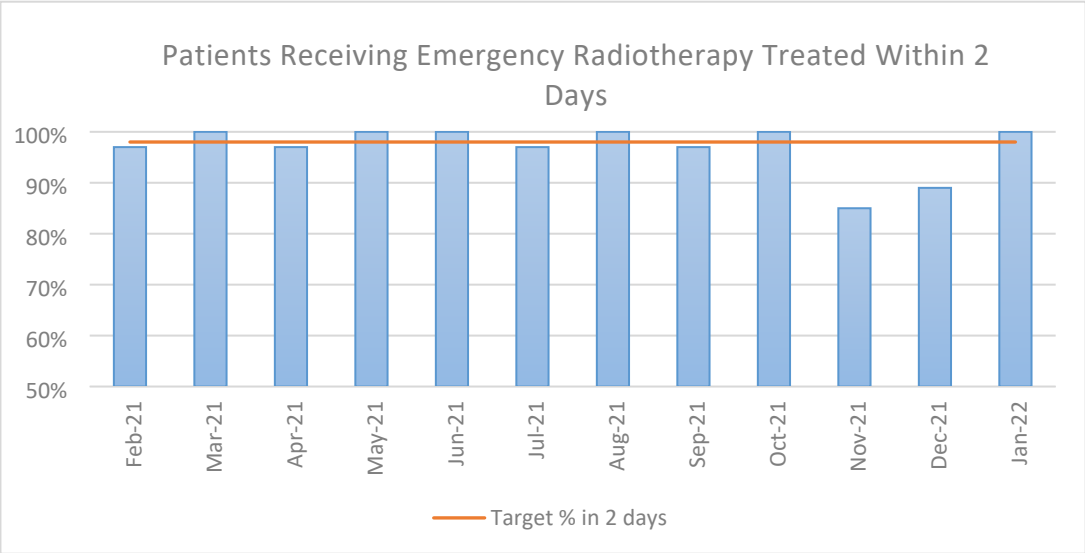
	Medium Term Actions
	• Recruitment and appointments in progress for additional front line resources, however capacity increases predicted throughout 2nd half of 2022 due to lead in time, maximising capacity from Sept-Dec 2022. • Peer review with Clatterbridge Trust underway to identify options/service models to put service demand and capacity in balance. March 2022 • Brachytherapy expansion business case being written to obtain support for increased capacity with WHSCC. Feb 2022 • Assess the options to escalate some or all of the longer term capacity solutions. March 2022

Patients Receiving Emergency Radiotherapy Within 2-Days

Target: 98%

SLT Lead: Radiotherapy Services Manager

Trend



The number of patients scheduled to begin emergency radiotherapy treatment in January 2022 (19) was lower than the monthly average observed in 2020-21 (27), but was marginally greater than the number scheduled to begin treatment in January 2021 (18).

Intent	Monthly Average (2019-20)	Monthly Average (2020-21)	Patients Scheduled to Begin Treatment (January 2022)
Emergency	25	27	22
	Patients Scheduled to Begin Treatment (January 2020)	Patients Scheduled to Begin Treatment (January 2021)	
	29	18	

Current Performance

22 patients referred for emergency radiotherapy treatment were scheduled to begin treatment in January 2022. All of the patients begin radiotherapy treatment within 2 days of referral constituting an overall performance of **100%.**

Wider Actions as above for 21 and 14 day targets

Radiotherapy – Operational Context

Latest Performance Consolidated

Measure		Target	VCC Jan-22	SBUHB Dec-21	BCUHB Aug-21
Scheduled (21-day target)	COSC	80%	**34%**	**37%**	**52%**
Urgent (7-day target)	COSC	80%	**37%**	**37%**	**34%**
Emergency (within 1-day)	COSC	100%	**90%**	**100%**	**50%**

The table shown here sets out the latest available performance of the 3 Wales centres relative to the Clinical Oncology Sub-Committee (COSC) stretch targets.

Clinical Oncology Sub-Committee (COSC) Time to Radiotherapy Targets

- Velindre Cancer Centre continues to report good Radiotherapy performance against UK agreed targets as set by the Royal College of Radiologists (RCR), particularly given that we are continuing to deliver services within a COVID driven reduced capacity.
- Since April 2021, we have been mandated by the Welsh Government to also report against the Clinical Oncology Sub Committee (COSC) targets. These targets align more closely with the direction of travel for reporting against the Single Cancer Pathway.
- The COSC targets present different criteria and different time points of reporting (Scheduled, Urgent and Emergency- within 1 day). Our systems are not currently designed to intuitively respond to both the criteria and time points for COSC as the patient pathways and the Radiotherapy planning and scheduling systems, have been designed to respond to the original RCR targets.
- The relatively low performance within Velindre Cancer Centre and the other cancer centres across Wales against the COSC targets currently, does not mean that patients are waiting any longer than they were previously under the RCR targets, only that we have changed the way in which we now categorise patients. We are continuing to report against both measures for comparison at present.
- Work is underway to ensure that we can accurately manage patients and report against these newly adopted COSC measures and to ensure our patient pathways are redesigned in order to meet the new criteria definitions.
- Current data published and reported highlights significant issues in consistency of application across the cancer centres.
- Work is underway through a COSC sub group nationally to standardise and mandate data quality in reporting across Wales to inform accurate comparison and to drive improvement.

The table below describes the allocation of individual patients scheduled to begin treatment in terms of the new COSC definitions for January 2022

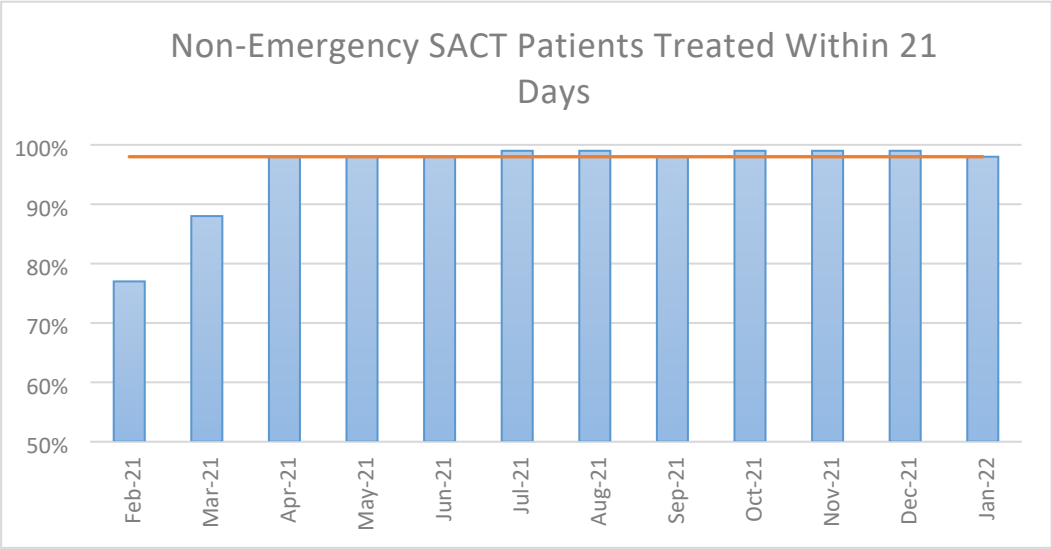
Scheduled (21 day target)	Urgent (7 day target)	Emergency (within 1 day)
168	57	18

Non-Emergency SACT Patients Treated Within 21-Days

Target: 98%

SLT Lead: Chief Pharmacist

Current Performance



The number of patients scheduled to begin non-emergency SACT treatment in January 2022 (334) was considerably larger than both the monthly average observed in 2020-21 (298) and was greater than the number scheduled to begin treatment in January 2021 (318).

Intent	Monthly Average (2019-20)	Monthly Average (2020-21)	Patients Scheduled to Begin Treatment (January 2022)
Non - emergency	328	298	361
	Patients Scheduled to Begin Treatment (January 2020)	Patients Scheduled to Begin Treatment (January 2021)	
	290	318	

Trend

334 patients were referred for non-emergency SACT treatment scheduled to begin treatment in January. Of this total, 19 patients did not begin treatment within the 21 day target, constituting an overall performance rate of 94%.

Of the 19 patients who did not begin treatment within 21-days, 12 were treated within 28 days and all had begun treatment before day 42:

Treatment Intent	≤ 28 days	≤ 28 days	≤ 42 days
Non-emergency (21-day target)	12	6	2

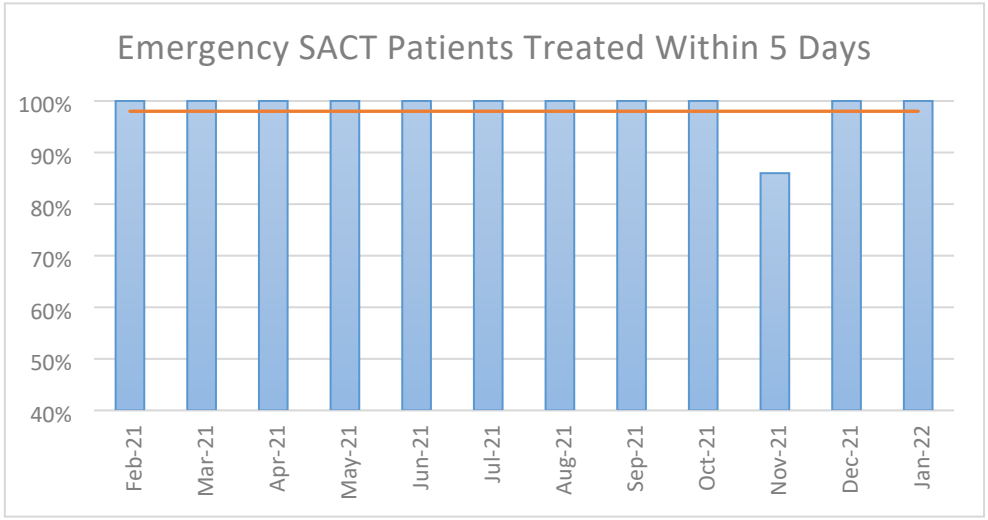
A number of category 5 and 6 patients treatment, had been carried over from December 2021 and some of these contributed to the January breaches when treated. This was due to demand exceeding capacity in month where capacity was reduced by bank holidays.

Actions

- Additional capacity being secured from Rutherford cancer centre. April 2022 is the predicted commencement, however discussions have commenced to try and bring this forward.
- Streamlined management of non-SACT chair activity, e.g. simple injections are being moved out of unit to specific weekend clinics, creating extra capacity. March 2022.
- A task and finish group has been established to identify solutions to support the service in increasing capacity, productivity, sustainability. Commenced March 2022 and ongoing.

	• Discussions are being escalated to prioritise the Neville Hall provision, which is the medium term plan for increasing capacity. Next update April 2022

Emergency SACT Patients Treated Within 5-Days	
Target: 98%	**SLT Lead: Chief Pharmacist**
Current Performance	Trend



The number of patients scheduled to begin emergency SACT treatment in January 2022 (5) was higher than the monthly average observed in 2020-21 (4).

Intent	Monthly Average (2019-20)	Monthly Average (2020-21)	Patients Scheduled to Begin Treatment (January 2022)
Emergency	4	4	5
	Patients Scheduled to Begin Treatment (January 2020)	Patients Scheduled to Begin Treatment (January 2021)	
	3	6	

5 patients referred for emergency SACT treatment were scheduled to begin treatment in January 2022. All patients began treatment within the 5-day target.

- Ring fencing of emergency chair capacity has allowed us to improve the compliance in this area. This took a number of months until the correct balance between ring fencing and chair utilisation was achieved.

Actions

- Continue to balance demand and ring fencing with capacity.

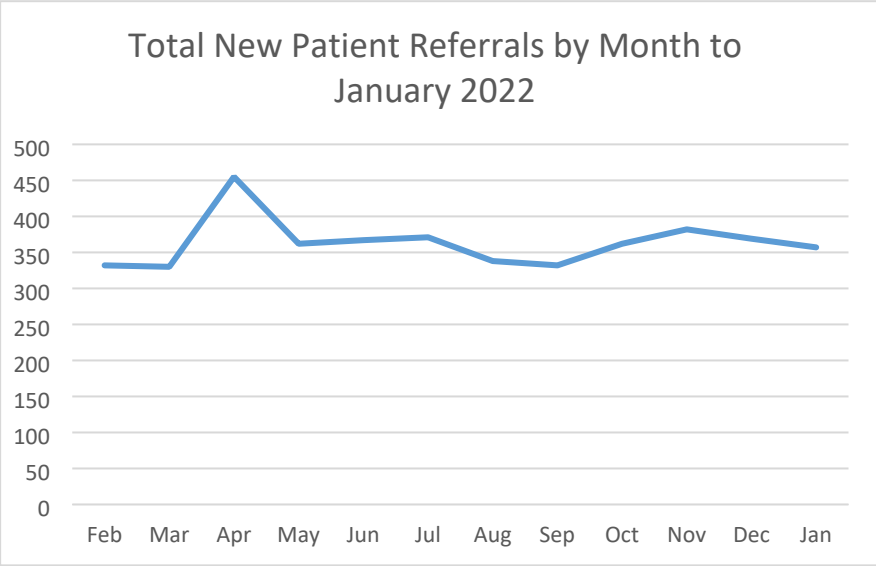
SACT – Operational Context	
Current Performance Consolidated	

Measure	Target	Jan-22
Non-emergency (21-day target)	98%	**94%**
Emergency (5-day target)	98%	**100%**

The table shown here sets-out performance relative to the extant time to SACT targets.

Social distancing and other infection control measures present particular challenges in the delivery of SACT. Additionally, overall delivery capacity remains restricted. All services, previously delivered in outreach contexts, were repatriated to VCC in response to the pandemic. With the exception of a reduced service at the Macmillan Unit at the Prince Charles Hospital in Merthyr Tydfil, this remains the case.

Referral Trends - Overall



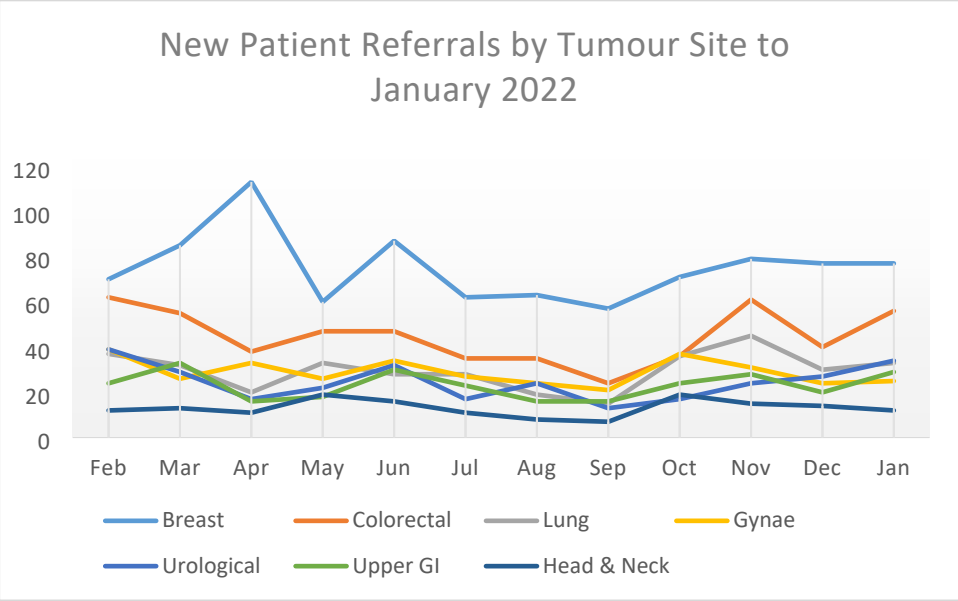
Monthly Average (2019-20)	Monthly Average (2020-21)	Total New Patient Referrals (January 2022)
325	301	357

The total number of referrals received in January 2022 (357) was above the average number received in any given month during 2020-21 (301) and marginally below the number received in December 2021 (369). The number of referrals received in January also exceeds the average number received per month in 2019-20.

Referrals fell dramatically following the first national lock-down in March 2020. Subsequently, referrals have returned to pre-pandemic levels.
Referrals include new patients for 1st definitive treatment and repeat treatments for patients mid cycle or on a revised treatment cycle.

SACT – Operational Context

Referral Trends - Tumour Site



Site	Monthly Average (2019-20)	Monthly Average (2020-21)	2020-21 Average Relative to 2019-20 Average	New Patient Referrals (January 2022)
Breast	**92**	**76**	**-17%**	77
Colorectal	**54**	**55**	**+2%**	56
Lung	**33**	**32**	**-3%**	33
Gynaecological	**31**	**31**	**0**	25
Urological	**36**	**26**	**-28%**	34
Upper Gastrointestinal	**18**	**26**	**+44%**	29
Head and Neck	**16**	**14**	**-12%**	12
Top 7 Tumour Sites by Number of Referrals as Percentage of Total Referrals	**86%**	**87%**		75%

The graph and table show referrals for the tumour sites most commonly referred for SACT treatment.
SACT referrals are being driven by a high level of internal demand as a result of new/combination regimens, increasing patient treatment cycles etc.

Equitable and Timely Access to Services - Therapies

Target: 100% | **SLT Lead: Head of Nursing**

Current Performance

Percentage of Therapies Referrals (Inpatients) Seen Within 2 Working Days

	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Dietetics	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Physiotherapy	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
OT	100%	100%	100%	100%	100%	100%	100%	100%	95%	100%	100%	100%
SLT	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Percentage of Urgent Therapies Referrals (Outpatients) Seen Within 2 Weeks

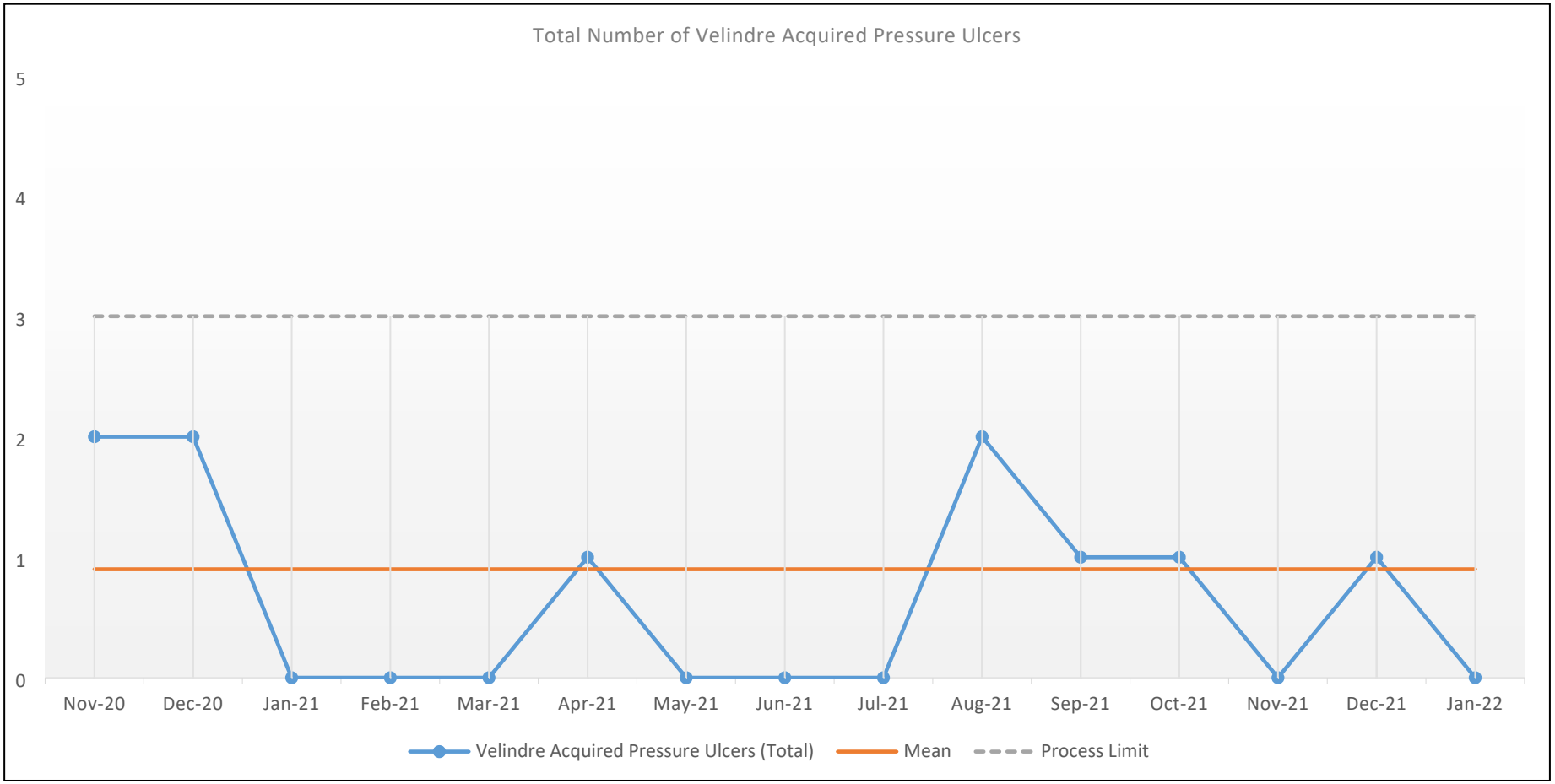
	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Dietetics	100%	100%	100%	100%	84%	94%	94%	98%	97%	100%	95%	98%
Physiotherapy	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
OT	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
SLT	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Percentage of Routine Therapies (Outpatients) Seen Within 6 Weeks

	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Dietetics	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Physiotherapy	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	86%
OT	100%	100%	100%	100%	100%	100%	96%	33%	78%	100%	100%	100%
SLT	100%	100%	100%	100%	100%	96%	100%	100%	96%	100%	100%	100%

In January, it was reported that 1 patient was not seen by a dietician within the two-week urgent outpatient referral target. This was due to a communication issue when the patient replied to the appointment offer, their e-mail was directed into a spam folder. The patient was seen on day 1 of the third week following referral. No harm to the patient was reported.	The process for checking incoming appointment confirmations to now include regular review of spam/junk folders.
It was reported that 2 patients were not seen by a physiotherapist within the six-week routine outpatient referral target. Both patients were referred to a scheduled physical activity programme which was delayed due to staff absence. No patient harm was reported.	Specialist services in a small team can result in challenges to cover absences. There is a limit to how much cover can be provided within existing resources.

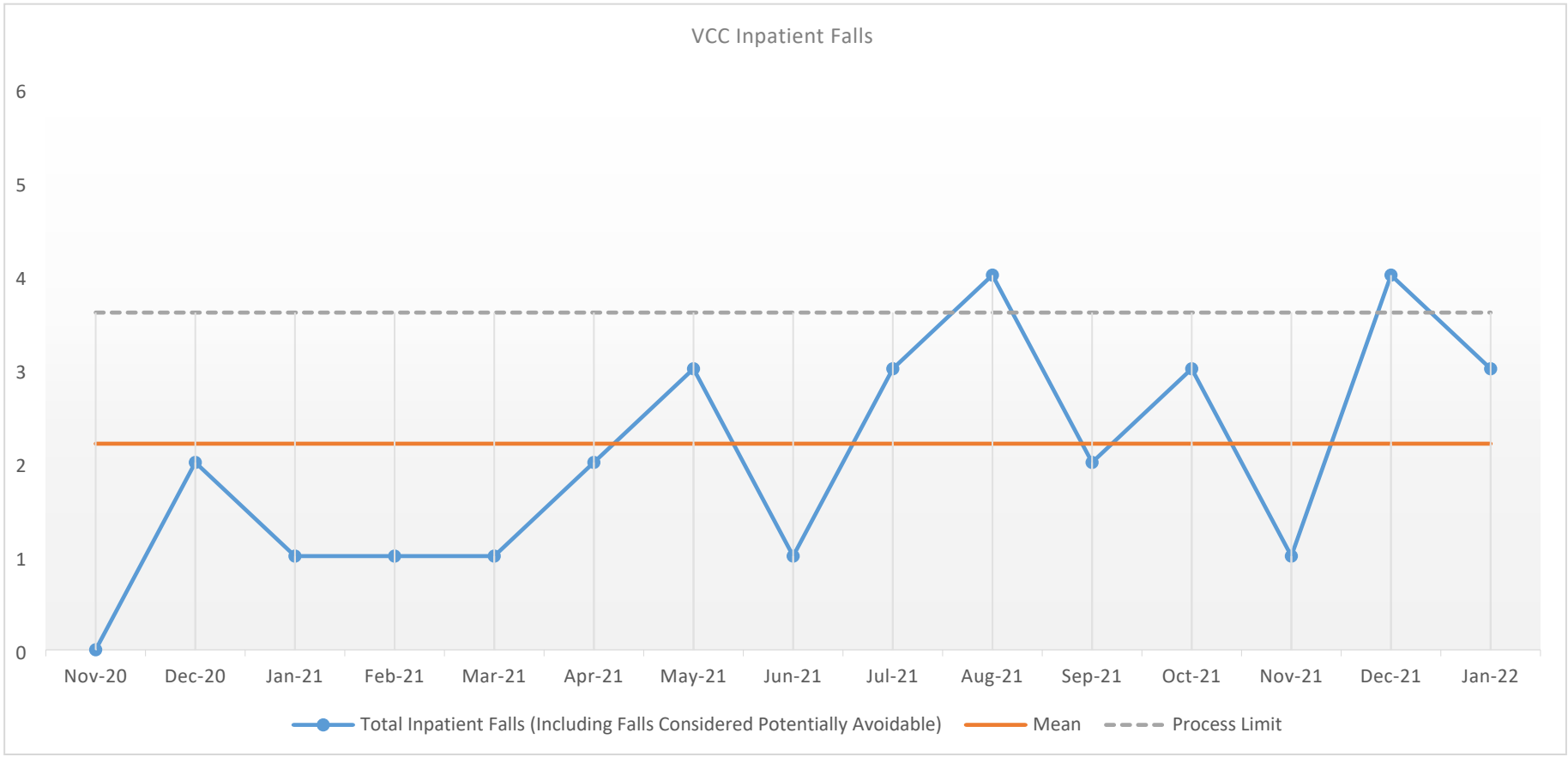
Velindre Acquired Pressure Ulcers	
Target: 0	**SLT Lead: Head of Nursing**
Current Performance	



	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Velindre Acquired Pressure Ulcers (Total)	2	2	0	0	0	1	0	0	0	2	1	1	0	1	0
Potentially Avoidable Velindre Acquired Pressure Ulcers	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0

Trend	Action
No Velindre acquired pressure ulcers were reported in January 2022 No Velindre acquired ulcers were reported to Welsh Government as a Serious Incident (SI).	No specific action required.

Velindre Inpatient Falls	
Target: 0	**SLT Lead: Head of Nursing**
Current Performance	

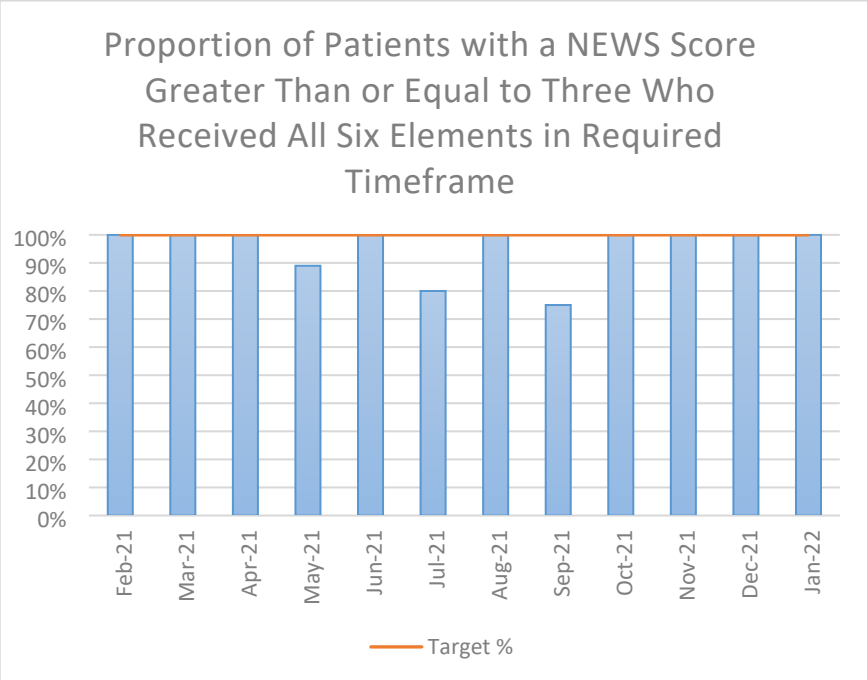


	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov - 21	Dec - 21	Jan - 22
Total Inpatient Falls	0	2	1	1	1	2	3	1	3	4	2	3	1	4	3
Potentially Avoidable Inpatient Falls	0	0	0	0	0	1	0	0	0	0	1	0	0	0	1

Trend	Action
During January 2022, 3 falls was reported on first floor ward. Of these three falls, 1 was deemed to be avoidable. A full investigation was undertaken by the VCC Falls Scrutiny Panel. Following investigation, 1 fall was deemed to have been avoidable. In this case the patient tested positive for COVID-19 and, as per protocol, was moved to an isolation cubicle. The patient had been identified as being at risk of a fall. The COVID-19 protocol requires the door of the cubicle to be shut, resulting in a limit to the observation required under the falls assessment. The patient mobilised within the cubicle without assistance and fell.	Falls risk assessments were undertaken, on admission, in each case. • In each case, following the incident the falls pathway was completed and the patient reviewed by a medic. • In one instance, the patient suffered a minor abrasion, otherwise no harm was identified. • Patients who are cared for in an isolation cubicle will be subject to increased level of observation. A supervision policy will be developed to ensure the falls risk and the COVID-19 risks are both addressed.

Delayed Transfer of Care	
Target: 0	**SLT Lead: Head of Nursing**
Current Performance	

There was one delayed transfer of care reported in January 2022.
The patient was due to be discharged home. They required an NG tube, but refused to engage with respect to its care and there was no close family to support. The decision was taken to transfer to UHW, but no bed was available at the time. When the patient no longer required the NG tube, they were subsequently discharged to their own home with a revised care plan.

Patients with a NEWS Score Greater Than or Equal to Three Who Receive All 6 Elements in Required Timeframe	
Target: 100%	**SMT Lead: Clinical Director**
Current Performance	Trend
	Six patients met the criteria for administration of the sepsis treatment bundle in January 2022. All six received all elements of the bundle within one hour. Five of the patients subsequently received a diagnosis of sepsis or neutropenic sepsis.
	Actions
	No specific action required.

Healthcare Acquired Infections (HAIs)	
Target: 0	**SLT Lead: Clinical Director**

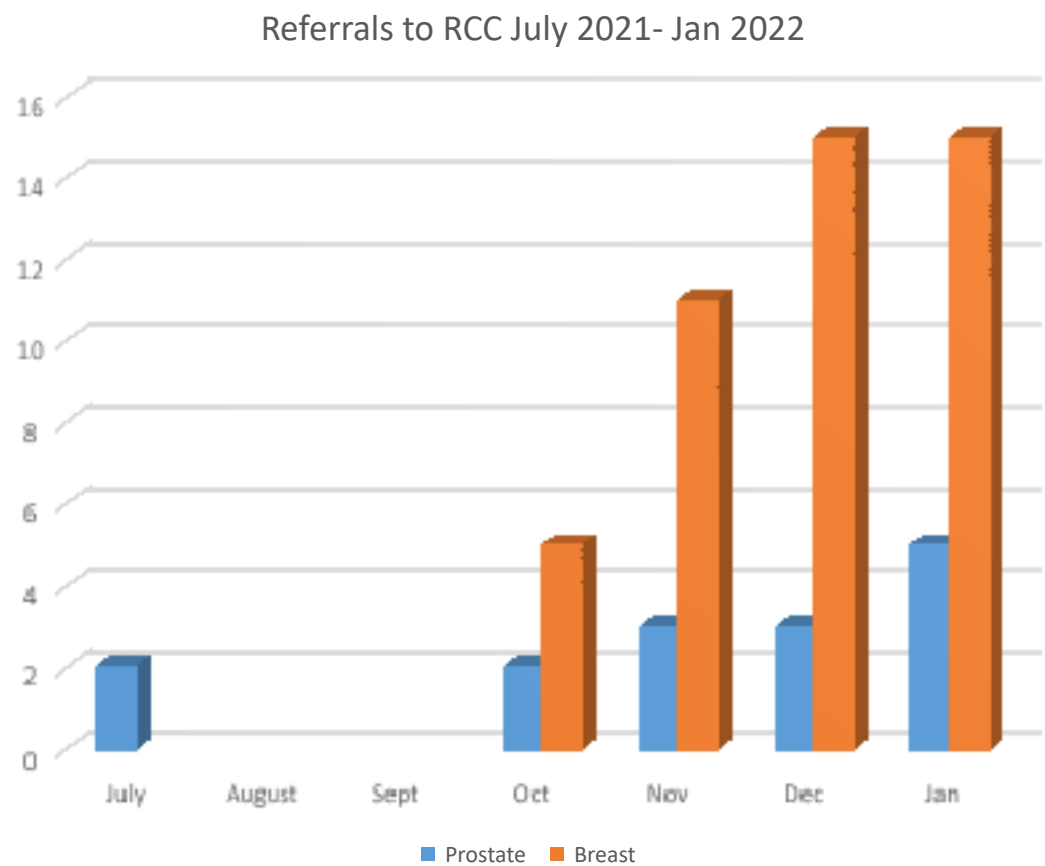
Current Performance

	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
C.diff	1	0	0	0	0	0	1	0	0	0	0	1
MRSA	0	0	0	0	0	0	0	0	0	0	0	0
MSSA	0	0	0	0	0	0	0	0	0	0	0	0
E.coli	0	0	0	0	0	0	0	0	0	0	0	0
Klebsiella	0	0	0	0	0	0	0	0	0	0	0	0
Pseudomonas Aeruginosa	0	0	0	0	0	0	0	0	0	0	0	0

Trend	Action
1 *C.diff* infection was reported in January 2022. This is the 2nd infection since April 21.	An investigation has been initiated and a full MDT discussion took place on the 7.3.22 where it was agreed that this could have been caused by either antibiotic usage and/or radiotherapy. It was deemed unavoidable. The patient had no previous history of C Diff. The patient fully recovered from the C Diff infection. There was no transmission to other patients in the ward environment.

Radiotherapy referrals to Rutherford Cancer Centre (RCC)

- Pilot breast patient commenced in July 21
- Pilot prostate patient referred to RCC started treatment 9/8/2021
- Outsourcing breast and prostate patients to RCC commenced Sept 2021 following successful completion of pilot.
- RCC capacity plan : up to 4/week till Nov. up to 6/week till Jan. Now up to 10 /week no more than 50% prostate
- Total of 61 patient have been referred to RCC (46 breast & 15 prostate) from the commencement of the pilot to 31/1/22.



Radiotherapy referrals to Rutherford Cancer Centre (RCC)

- Referral criteria set in accordance with RCC constraints.
- 46 patients have been referred to RCC for radiotherapy to the breast.
- 15 patients have been referred to RCC for radiotherapy to the prostate.

Radiotherapy referrals to Rutherford Cancer Centre (RCC)

Continued developments:

- VCC are working with RCC to maximise referrals - to enable referral from all VCC entitled referrers under IR(ME)R
- VCC are working with RCC to maximise referrals – by expanding the staff groups who are accepted by RCC as able to consent patients for radiotherapy

QUALITY & SAFETY COMMITTEE

DIGITAL SERVICES OPERATIONAL REPORT

DATE OF MEETING	24/03/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	David Mason-Hawes, Head of Digital Delivery
PRESENTED BY	Carl James, Director of Strategic Transformation, Planning, Performance & Estates David Mason-Hawes, Head of Digital Delivery
EXECUTIVE SPONSOR APPROVED	Carl James, Director of Strategic Transformation, Planning, Performance & Estates

REPORT PURPOSE	FOR DISCUSSION / REVIEW

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Management Board (EMB)	07/03/2022	Noted

1. SITUATION/BACKGROUND

1.1 This paper has been produced to inform and update the Quality, Safety & Performance Committee of key projects/programmes of work underway for digital services, this includes but is not limited to:

1.1.1 Digital Delivery & Programme Update.

1.1.2 Any significant incidents during the period October 2021 to February 2022.

2. ASSESMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 Please refer to the report for the full summary of all operational Digital Services activity from October 2021 to February 2022.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	Capacity within the Digital Services team to support timescales for various Trust-wide projects may delay the realisation of the benefits of those programmes of work.
RELATED HEALTHCARE STANDARD	Effective Care
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
	N/A
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Further investment could be required to deliver against some timescales outlined within this report.

4. RECOMMENDATION

4.1 The Quality, Safety, Planning & Performance Committee are requested to **DISCUSS / REVIEW** the contents of this report.

ACRONYMS	
ABUHB	Aneurin Bevan University Health Board
BAU	Business As Usual
CANISC	Cancer Information System Cymru
DHCR	Digital Health & Care Record
DHCW	Digital Health & Care Wales
EMB	Executive Management Board
NCSC	National Cyber Security Centre
NGS	Next Generation Sequencing
NIS	Networks & Information Systems Directive
nVCC	Radiology Information System
RADIS	New Velindre Cancer Centre
VCC	Velindre Cancer Centre
VUNHST	Velindre University NHS Trust
WCP	Welsh Clinical Portal
WLIMS	Welsh Laboratory Information Management System
WPAS	Welsh Patient Administration System
WTAIL	Welsh Transplant & Immunogenetics Laboratory

1. SITUATION/BACKGROUND

1.1 This paper has been produced to inform and update the Quality, Safety & Performance Committee of key projects/programmes of work underway for digital services, this includes but is not limited to:

1.1.1 Digital Delivery & Programme Update.

1.1.2 Any significant incidents during the period October 2021 to February 2022.

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 Digital Delivery & Programme Update

The table below outlines the key digital deliverables within the Trust Annual Plan

Action	Timeframe
ePROGESA Developments & Enhancements	
Re-procurement of the Blood Establishment Computer System (ePROGESA)	**Ongoing – aim to confirm contract extension in May 2022**
Implement FAIR (MSM Blood Donors) functionality	**Completed**
Implement ePROGESA Maintenance Patch 14	**Completed**

Action	Timeframe
Implement ePROGESA Delta Patch	**Deferred to 2022/23 – est. May / June 2022**
Implement eDRM (Donor Relationship Management)	**Deferred to 2022/23 – work due to re-start May 2022**
Laboratory Enhancements	
Implement functionality for non-blood Bone Marrow Volunteers (BMVs)	**Completed**
Implement Phase 1 of Next Generation Sequencing	**Completed**
Implement Transition State Labelling	**Deferred to 2022/23 – agreed by all UK Blood Establish-ments**
Support the procurement of the Laboratory Infor-mation Network Cymru (LINC)	**Completed**
Develop requirements specification for WTAIL La-boratories (H&I)	**Ongoing – aim to produce specification in Q1 2022/23**
Implement SACT & Medicines management func-tionality	**Deferred – business case to be developed in 2022/23**
Chemocare version 6 implementation	**Deferred until Q3 2022/23 due to DHCR**
Complete implementation of Electronic Test Re-questing (Pathology)	**Completed**
Implement national Pharmacy solution	**Completed**
Implement SACT Virtual Assessment Pathways	**Ongoing – pilot planned for March / April 2022**
Procurement of Chemocare eScheduling	**Completed**
Infrastructure	
Full roll out of live connectivity	**Deferred to 2022/23**
Upgrade telephony infrastructure to include replace-ment of existing call centre software	**Completed**
Implement Estates Management Software	**Completed**

Action	Timeframe
Deployment of improved Business Intelligence / Data Warehouse infrastructure	**Ongoing – NDR IT infrastructure purchased, awaiting installation**
Implement enhanced networking capability and improved infrastructure resilience	**Completed – ongoing (BAU)**
Digital Programmes	
Initiate Single Sign-on Pilot for Clinicians within Velindre Cancer Centre	**Deferred to 2022/23**
Digital Health & Care Record Implementation (Canisc Replacement)	
Implement Clinical Functionality into the Welsh Clinical Portal	**Deferred – due to be delivered by end of 2022**
Implement the Welsh Patient Administration System	**Go-live planned for 2022/23**
Digital Innovation for Out of Hospital Care	
Pilot of Patient Held Record	**Deferred to 2022/23**
Pilot of Keep Me Safe App	**Ongoing**
Implement the principles of the Digital Inclusion Charter	**Deferred to 2022/23 – to be aligned with Digital Strategy**
Transforming Cancer Services	
Procurement of Integrated Radiotherapy Solution	**Ongoing – aim for contract award Q1 2022/23**
Implementation of Oncology Information System for Radiotherapy	**Ongoing – aim for contract award Q1 2022/23**
Development of Digital Specification for Radiotherapy Satellite	**Completed**
Development of Digital Specification for new Velindre Cancer Centre CC	**Completed**

2.1.1 **Digital Health & Care Record (DHCR)**

Digital Services resources continue to be prioritised towards the delivery of the DHCR (Canisc Replacement). Following a delay in the delivery of the required software development for the Welsh Patient Administration System (WPAS) and Welsh Clinical Portal (WCP) by Digital Health & Care Wales (DHCW), the implementation timelines for this programme are currently being revisited by the VUNHST and DHCW Programme Leads.

The prioritisation of this work programme has resulted in limited capacity to support other programmes of work across the Trust.

2.1.2 **nVCC Competitive Dialogue**

The digital work stream of the nVCC competitive dialogue phase continues to progress at pace. Several formal dialogue meetings have been held with both bidders through the winter, to support their planned submission of draft final tenders in mid-March 2022.

In January, dedicated resource was appointed into the Digital Services team in support of the nVCC programme. Ian Taylor – nVCC Head of Digital Infrastructure Design will be coordinating discussions and feedback in respect of the design of the digital infrastructure for the nVCC between the nVCC Programme Team, Digital Services and the various clinical and operational services across VCC.

2.1.3 **Next Generation Sequencing (NGS)**

In the latest period, the Digital Services team worked with the colleagues in the WBS Welsh Transplantation & Immunogenetics Laboratory (WTAIL) to deploy new technology to enable NGS within the WTAIL Molecular Genetics function.

Whilst further work is required to fully interface the new platform, the new approach replaced all legacy sequencing techniques and has made significant improvements to laboratory workflows and the services the team provides to both Hematopoietic stem-cell transplantation and solid organ transplantation centres in Wales.

The completion of this work closes out one of the digital objectives on the Trust Annual Plan.

2.1.4 **Cyber Security**

As reported previously, the Cyber Security Strategic Delivery Plan was approved by the Strategic Development Committee in September 2021. The Digital Services team continue to take forward a wide-ranging workplan , to align the Trust to the NCSC's 'Top 10 Steps to Cyber Security'. A twice-yearly review / update to our compliance score in planned, which will be reported in the next Digital Services Operational report.

The Digital Services team have completed a joint review with the Cyber Resilience Unit – based in DHCW – to assess Trust compliance against the Networks & Information Systems (NIS) Directive. The CRU reported its findings to the team in mid-February 2022. The report is currently being reviewed by the Digital Services team, with a view to building in any recommended actions into the strategic delivery plan, to ensure the Trust's cyber security agenda is appropriately aligned to the relevant national guidance and standards.

In late-2021, the Digital Services team commenced a programme of engagement with the Trust Board, which started with an introductory session at the Board Development Session on 26 October 2021. Further sessions are planned (delayed due to the winter pressures associated with COVID-19 / Omicron) to ensure the Board are appropriately informed on the risks of cyber security and have the required knowledge and understanding to challenge and question the Trust's ongoing cyber security plans.

In February 2022, the Trust was made aware that from 1st April 2022 the cyber awareness ESR e-learning will not be available. This is due to an issue with the contract for the current e-learning tool, which is managed by Digital Health & Care Wales. Work is being progressed nationally to procure a new solution, to continue this essential training which forms part of the Trust's statutory and mandatory suite of training. Once a new solution is procured, the Digital Services will communicate details to staff.

Finally, the Digital Services team continue to communicate to staff across via Trust communication channels on the need to remain alert and vigilant to various cyber threats, especially phishing. These threats have escalated in recent weeks because of the unfortunate events in Ukraine. Through the Cyber Security Officer, the Trust is actively engaged in national discussions to ensure we are aware of the latest information about such threats and are coordinating our local response in accordance with advice from DHCW and the NCSC.

2.1.5 **System Developments**

Despite significant pressures within the service, a number of key system enhancements have taken place over recent months, summarised below:

- The Digital Services team have coordinated work with several other health boards in the southeast Wales region, to fully deploy the '**GovRoam**' service for VUNHST staff working across other sites. GovRoam , much like the 'Eduroam' service used in UK universities, is a network that allows staff to connect into their corporate network when working in other enabled locations. In the context of NHS Wales, this means staff can connect to the local GovRoam network when working on another site and can work as if they were sat at their desk in the VCC, with full connectivity to all the apps and digital services they use during their normal day-to-day work, without the requirement to connect using VPN.

- The Digital Services team are continuing to develop its **business continuity** / major incident response plans, to ensure more effective response from the Digital Services team in the event of a significant IT incident. Review of any revised procedures will be managed via relevant Divisional and/or Trust Business Continuity Group(s).

- Following the completion of work to upgrade the WBS and Trust HQ network, work is ongoing with BT to **upgrade the VCC PSBA network**. The work will significantly improve network performance and overall resilience, providing faster connections and general performance of IT services that work across the VCC network, including the use of those services from home. Work was intended to be completed in January 2022 but was delayed on account of Omicron pressures and the associated temporary changes to working arrangements. Work is now intended to be completed in late-March / April (specific date TBC).

- A number of changes were deployed to the WBS Blood Establishment Computer System – **ePROGESA** – over recent months, including changes to ensure the WBS aligned with national standards for assessing donors who carry a potential malaria risk and to ensure our management of donors aligned to current COVID-19 guidance.

- In December 2021, the Digital Services team supported an upgrade to the **Welsh Nursing Care Record** (WNCR), which delivered a number of improvements to the system. The main benefits of the upgrade include the ability to easily identify all open assessments for discharged patients, alerts notifying staff of upcoming and overdue assessments and enabling multiple users the ability to edit assessments. Further upgrades are planned over the next 6 months to increase the number of assessment types that can be created within the system.

Unfortunately, the planned January 2022 go-live of the **Prometheus** application into the Welsh Transplantation & Immunogenetics Laboratory (WTAIL) was not successful, following a number of technical issues experienced during the final phases of re-validation of the system. The project has been paused to allow for further assurances to be provided by the supplier and DHCW, before a revised go-live date is confirmed.

As reported previously, like many parts of the Trust capacity within the Digital Services team to support projects requiring digital support in both divisions remains a significant challenge. In particular, the prioritisation and intensity of work associated with the DHCR programme leaves limited time for other project work within the VCC. Similarly, a growing number of emerging projects in the WBS is creating a challenge for the Application Services team. A proposed digital services work plan for the 2022 calendar year was recently presented to and endorsed by both Divisional SMT/SLTs, clearly stating the priorities to which the Digital Services team will focus resource in over the coming 12 months. This plan will be presented to EMB in due course. Discussions are ongoing in respect of the release of additional funding to develop further capacity within the Digital Services team, so that it can meet the growing digital needs of the organisation.

2.1.6 **Capital Spend During 2021/2022**

Digital Services have been allocated an initial £225k to support the capital purchase of a range of IT equipment, client devices and other IT equipment, licences and services. An additional £576k was made available via Welsh Government funding. As of 3 March 2022, all but £25k was either already committed or with spend plans confirmed. The team have plans toe sure the remaining £25k is fully committed before year end.

2.1.7 **ABHB Satellite Radiotherapy Site**

The Digital Services team continue to support the design and costing of the ABUHB satellite centre, with work continuing to finalise the business case ahead of its submission to Welsh Government.

2.2 Significant Incidents during the period (October to February 2022)

2.2.1 There were no IT business continuity incidents between 1 October 2021 and 31 January 2022. The following incidents took place in February 2022:

2.2.2 **4 February 2022 – National network outage**

Problems associated with the national firewalls – managed by DHCW – resulted in intermittent disruption to the NSH Wales PSBA network. These outages occurred intermittently over an approx. 16-hour period from 6pm on 4 February 2022 until just before 10am on 5 February 2022, when DHCW applied configuration changes to the national firewalls to resolve the issue. Outages were mostly brief, although there was around ½ hour of network downtime during the night. Because of the out of hours nature of the incident and the fact that most of the service outages were brief, users may not have noticed any material impact on the use of affected national IT services, such as the Welsh Clinical Portal.

Whilst no issues were reported via the Digital Service Desk and there was no reported patient impact, this incident is reported here to reflect the risk this incident posted had it escalated across the NHS Wales network.

2.2.3 **8 February 2022 - Loss of results integration from RADIS and WLIMS into WCP**

At around 5pm on 8 February 2022, DHCW reported an issue with the national 'Fiorano' integration engine, which seeds results from various national IT systems into the Welsh Clinical Portal (WCP). As a result, results from RADIS and WLIMS were not viewable within WCP for approx. 3 hours. 'All Users' communications were issued to the Service, to notify staff of the issue.

DHCW resolved the issue at around 8pm, although full visibility of all results in WCP was not restored until around 10.30pm as the results queue that had developed during the downtime was retrospectively processed.

No patient impact / harm was caused.

2.2.4 **17 February 2022 – multiple national IT services unavailable**

At approx. 12.45pm on 17 February 2022, the Digital Services team received reports of multiple Trust IT systems being unavailable – i.e. WCP, WNCR, Wellsky (Careflow), Trust intranet and ServicePoint. This was a national issue, associated with disruption to networking arrangements in the national data centres managed by DHCW. Services were down for approx. 45mins, with confirmation that all services were restored at approx. 1.30pm.

No formal business continuity arrangements were invoked, no patient impact / harm was caused.

2.2.5 VCC Wi-Fi Issues

The intermittent, ongoing issues with the Wi-Fi service in VCC continued through December into January 2022. Connectivity issues were experienced with both the private (NHS Wales) and 'the_cloud' public Wi-Fi services. After further work with our Wi-Fi service providers, those issues are now resolved. However, the Digital Services team intend to replace the public Wi-Fi service in VCC with a new Trust-wide service in Q1 2022/23 – this was originally due to be completed in Q4 2021/22 but has been delayed due to COVID-19 and other work pressures.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	Capacity within the Digital Services team to support timescales for various Trust-wide projects may delay the realisation of the benefits of those programmes of work.
RELATED HEALTHCARE STANDARD	Effective Care
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
	N/A
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Further investment could be required to deliver against some timescales outlined within this report.

4. RECOMMENDATION

The Quality, Safety, Planning & Performance Committee are requested to **DISCUSS / REVIEW** the contents of this report.

QUALITY, SAFETY & PERFORMANCE COMMITTEE

TRUST RISK REGISTER

DATE OF MEETING	24/3/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not applicable

PREPARED BY	Lauren Fear, Director of Corporate Governance & Chief of Staff and Mel Findlay, Business Support Officer
PRESENTED BY	Lauren Fear, Director of Corporate Governance & Chief of Staff
EXECUTIVE SPONSOR APPROVED	Lauren Fear, Director of Corporate Governance & Chief of Staff

REPORT PURPOSE	FOR NOTING

Committee/Group who have received or considered this paper PRIOR TO THIS MEETING		
Committee or Group	DATE	OUTCOME
Executive Management Board	7/3/22	NOTED

ACRONYMS	
VCC	Velindre Cancer Centre
WBS	Welsh Blood Service
TCS	Transforming Cancer Services
SLT/SMT	Divisional Senior Leadership Teams / Senior Management Teams
EMB	Executive Management Board

1. SITUATION AND BACKGROUND

The purpose of this report is to:

- Share the February extract of risk registers to allow Quality, Safety and Performance Committee to have effective oversight and assurance of the way in which risks are currently being managed across the Trust.
- Summarise the feedback, and progress against that to date, on the process from the previous cycle of Committees and Trust Board.
- Summarise the final phase in implementing the Risk Framework.
- Provide the Committee with assurance on the steps agreed by the Executive Management Board during this reporting period.
- Outline approach to risk appetite review for May-June.

2 ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

Key points for the Committee:

Risk Register:

- The action plans for Velindre Cancer Centre and Corporate risks needs clearer articulation. This will be prioritised for the risks scoring 20 and 16 for the next reporting cycle. Welsh Blood Service and Transforming Cancer Services risks already clearly articulate actions in their reporting.

- Executive Management Board have asked that the Digital Health and Care Record project team review again the calibration of the level of granularity and the scoring of the project risk profile. This will be actioned and reflected in the next reporting cycle.

- The geo-political risks relating to the war in Ukraine are being assessed by the business continuity team, will be reviewed in Executive Management Board and shared with the Committee. It may be appropriate that this is reported out of cycle to provide the Committee with this analysis before the next meeting.

Implementation of Risk Framework:

- The final stages of implementation of the Risk Framework are dependent on the Policy and the Training being finalised. Once these are complete, the final milestones, particularly from a Welsh Blood Service migration into version 14, can

be agreed upon.

2.1 THE TRUST RISK REGISTER

2.1.1 Total Risks

As discussed in the January reporting cycle, there has been a thorough review of the risks, scoring and associated records of management of those risks completed for all risks scoring 15 and above across the Trust.

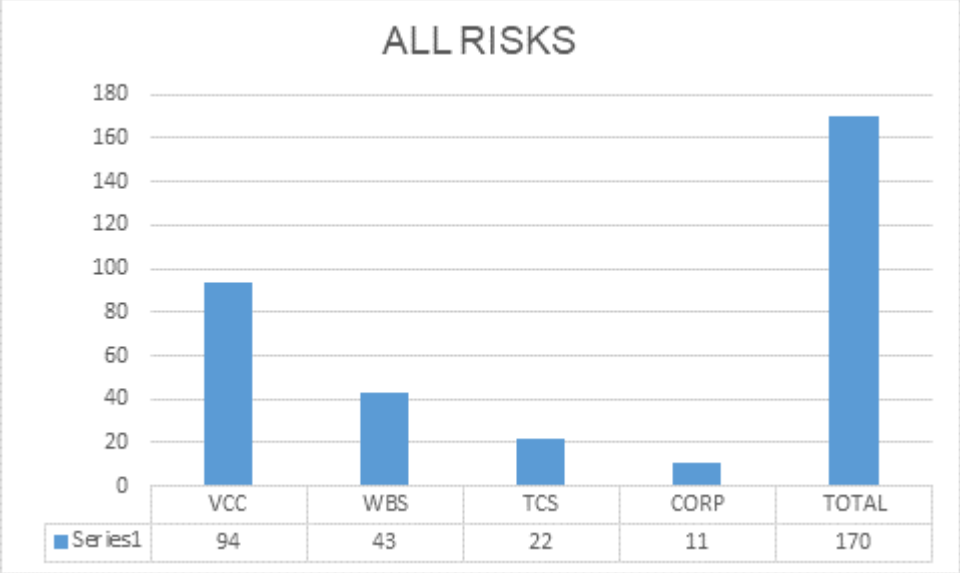
The same in-depth review will not take place for those scored 12 and above, phased over the next couple of reporting cycles.

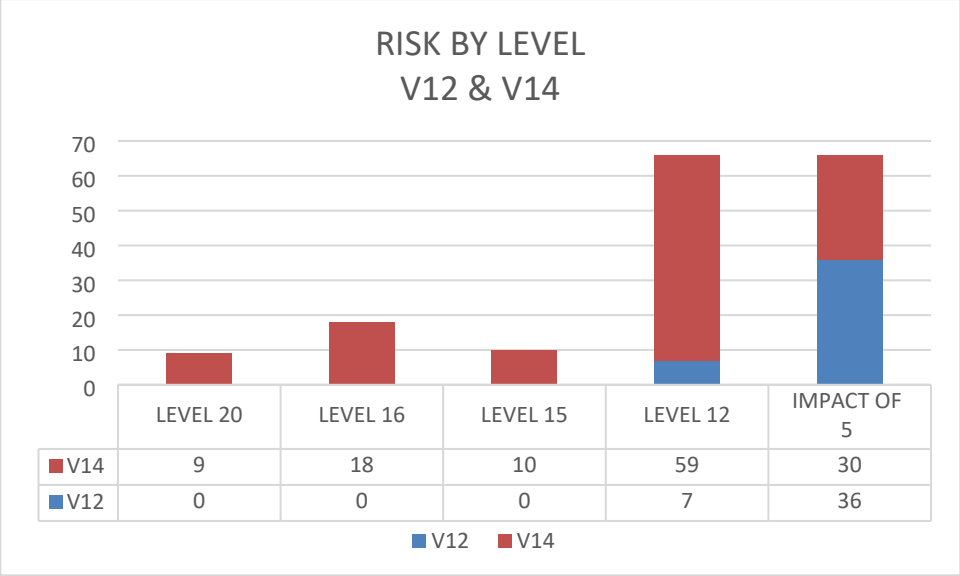
As a result of reviewing the reporting in the weekly risk Trust meetings, the key aspect that has come to light following this review has been that the “actions” field is not being used consistently across departments and divisions. This is going to be a focus for the next reporting cycle. Therefore in this report, the controls column is displayed, to provide some insight into the approach to mitigating the risk. Clearly this needs to be augmented with the specific, measurable, owned and time bound actions that will achieve the target risk score. The completion of this information in this way will be prioritised initially for the 20s and 16 for the next reporting cycle. For the Welsh Blood Service reporting in version 12, this information is clearly displayed in the Senior Leadership Team reporting.

There are a total of 170 risks recorded in Datix Trust Risk Registers, 44 in version 12 and 126 in version 14. This is the same amount of total risks recorded in the February 2022 reporting cycle. The graph below provides a breakdown of the total number of risks by Division.

2.1.2 Risks by level

The graph below provides a breakdown of risks by level across the Trust. A further breakdown of risks by level and Division is also included.


ALL RISKS
180
160
140
120
100
80
60
40
20
0
VCC
WBS
TCS
CORP
TOTAL
Series1
94
43
22
11
170


RISK BY LEVEL
V12 & V14
70
60
50
40
30
20
10
0
LEVEL 20
LEVEL 16
LEVEL 15
LEVEL 12
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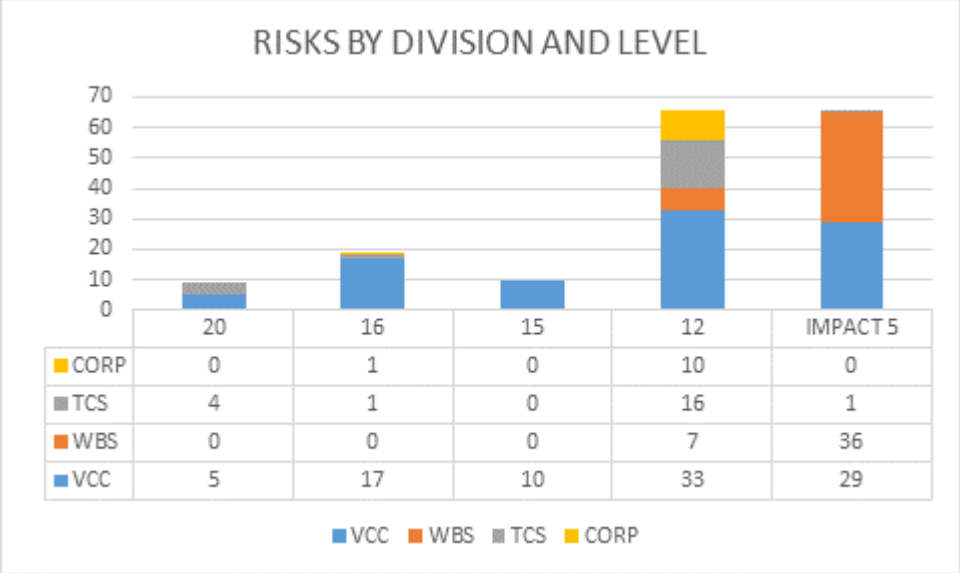
V14
9
18
10
59
30
V12
0
0
0
7
36
V12
V14


RISKS BY DIVISION AND LEVEL
70
60
50
40
30
20
10
0
20
16
15
12
IMPACT 5
CORP
0
1
0
10
0
TCS
4
1
0
16
1
WBS
0
0
0
7
36
VCC
5
17
10
33
29
VCC
WBS
TCS
CORP

2.1.3 Analysis of risks

An analysis of risks by level is provided below. Tables provide detail of each risk including risk type, risk ID, review date and title of the risk.

Risks level 25

There are no level 25 risks to report in the March cycle. This is as per the January reporting cycle.

Risks level 20

The table below provides a breakdown of risks level 20. There are currently 9 risks with a current risk rating of 20 recorded, 5 for Velindre Cancer Centre and 4 for Transforming Cancer Services. This compares to 9 in the January 2022 reporting cycle, although there has been some movement within this:

- The risk regarding implications from Brexit has been closed by the Business Continuity Group and agreed by Executive Management Board.
- The Digital Health & Care Record team have reviewed their risk profile and some of the resulting changes are evident in this report:
    - 2206 – Digital Health & Care Record Project – Information Management and Technology Department - Covid-19 Pandemic – has increased from a 12 in January reporting cycle to 20 in March.
    - 2499 – Digital Health & Care Record Project - There is a risk that not all interfaces will be delivered timely for sufficient testing – is a new risk at score 20.
    - Previously risk 2437 was regrading delays in Radiographer graduates starting which has now been closed.
        - As referenced in the developments section on page 13 of this report, as agreed in the January committee cycle of Quality, Safety & Performance and Audit Committees, the closure rationale is now a set automatic field to be completed on Datix when a risk is closed. This data is now being collated and will be reported from the system in the next reporting cycle.
    - It is important for the Committee to note that in reviewing the risk profile in March Executive Management Board, there was an action agreed to request that the Digital Health & Care Record Project team reconsider the calibration of their scoring and the granularity of their project risk profile.
- Risk 2513 is a new risk with a score of 20; the risk is a Performance and Service Sustainability Risk relating to the number of practitioner's licenses held by staff for prostate brachytherapy.
- Transforming Cancer Services Risks 2501, relating to cost pressure risk as a result of increased inflation and 2421, relating to the risk of disruption caused by direct action, following appropriate challenge in the January Committee reporting cycle, are being reported in the public version of this paper.
- Risk 2360 is a new Transforming Cancer Services Programme level risk regarding the interdependencies between projects which was agreed to in the March Programme Delivery Board meeting.

Risks reported from V14:

ID	Risk Type	Division	Title	Rating (current)	Rating (Target)	RR - Current Controls
2206	Performance and Service Sustainability	Velindre Cancer Centre	Digital Health & Care Record DHCR003(R) - IM&T Departement - Covid-19 Pandemic	**20**	**9**	Following guidance from VUNHST & Government Project team are all enabled to work from home as required. Early engagement and communication plan in place to keep staff updated and included in the process. Departmental leads being identified to ensure that all departments have a voice at the table and a mechanism to feed in their requirements. DHCR producing Contingency plans as part of COVID-19 response. Canisc will be moved as part of the data centre project, if this failed the contingency would be a single instance of Canisc running in Newport data centre.

2499	Performance and Service Sustainability	Velindre Cancer Centre	Digital Health & Care Record DHCR051(R) - There is a risk that not all interfaces will be delivered timely for sufficient testing	**20**	**8**	Pressure on DHCW to provide interface on schedule. Testing window is fixed and protected not used as development contingency
2191	Performance and Service Sustainability	Velindre Cancer Centre	Inability to meet COSC / SCP targets	**20**	**4**	Plans are prioritised by start date to minimise delays. Physics staff are redirected to physics planning during periods of high demand. Weekly RT service capacity and demand meetings monitor position. Increased checkers rostered for a Friday to mitigate Monday starts. Plan to increase capacity is in progress. 4 additional surge posts have been created in treatment planning with recruitment ongoing (2 surge posts filled internally with backfill recruitment active, 2 filled externally but 1 staff member moved Trust).
2200	Performance and Service Sustainability	Velindre Cancer Centre	Radiotherapy Capacity	**20**	**6**	Ongoing monitoring of capacity, demand breaches and waiting times targets. Development of breach escalation process to ensure, where needed patients are prioritised effectively. - Extended working hours are in place on the treatment machines and in many other areas of service. - Agency Radiographers are in place to support additional hours. Assessment of potential Agency staff experience at point of hire to ensure that Agency staff are able to rotate around more than one work area / linac type / OMS type within department. - Outsourcing to The Rutherford centre for prostate and breast patients is underway. - Changes made to RT Booking processes, and staff flexibility used to maximise use of resources. - Understand and prioritise activities that promote wellbeing in the team. Diverse training sessions held to enhance mindfulness, wellbeing, and resilience. - Review of dose & fractionation, plan complexity and recruitment at clinical trials is being reviewed by SST's and Clinical Director.
2513	Performance and Service Sustainability	Velindre Cancer Centre	There are a lack of staff holding a practitioners licence for prostate Brachytherapy	**20**	**10**	Clinical service is dependent on one consultant - another is in training and about to apply for an ARSAC licence
2400	Workforce and OD	Transforming Cancer Services	Risk that there is lack of project support for Project 5, outreach model development, which could result in impact on the overall clinical model assumptions in the programme.	**20**	**6**	Executive agreement on priority of agreeing final plan and implementation of that. SRO escalation and awareness. To see further detail in new risk 360 below.
2501	Financial Sustainability	Transforming Cancer Services	Risk of inflation leading to increased costs	**20**	**12**	Specific actions reported in private paper, due to commercial nature.
2421	Performance and Service Sustainability	Transforming Cancer Services	Risk of direct action disputing enabling works and future new Velindre cancer centre build.	**20**	**6**	Interim injunction obtained and full injunction trial 26th April.

2360	Performance and Service Sustainability	Transforming Cancer Services	There is a risk that as a number of Projects remain 'On Hold' and/or incur delays impacts on interdependencies with projects which are progressing resulting in Programme Master Plan objectives / outcomes being delayed / not being met	**20**		1) Stocktake of all Projects and Programme to be undertaken 2) Refreshed Project Self-Evaluation toolkit 3) Refresh of Master Programme Plan 4) Review Programme and Project resources /gaps and make appropriate investments where required. 5) Fully implement new ways of working – Velindre Futures & Strategic Infrastructure Board

Risks level 16

The table below provides information of level 16 risks as per the Risk Register. There are currently a total of 18 risks with a current risk rating of 16, 1 for TCS, 16 for VCC, 0 for WBS and 1 for Corporate. This compares to 15 in the February 2022 reporting cycle. The three new risks included are:

- A new risk, 2514; relating to out of date Standard Operating Procedures (SOP) within the Brachytherapy area.
- A new risk, 2454, workforce risk relating to Digital Services Capacity / Skill Mix
- Following the review of Covid-19 related risks, as reported in the extraordinary meeting of the Quality, Safety & Performance Committee in February, there was a new risk, 2505, that Covid-19 related absences for staff could significantly impact on ability to provide core SACT and Radiotherapy Service.

Risks reported from V14:

ID	Risk Type	Division	Review date	Title	Rating (current)	Rating (Target)	RR - Current Controls
2190	Performance and Service Sustainability	Velindre Cancer Centre	31/03/2022	BI Support for reporting of Breaches	**16**	**10**	Large amount of BI is occurring, with better understanding of RT BI and complexity of internal RT processes
2211	Performance and Service Sustainability	Velindre Cancer Centre	03/03/2022	Digital Health & Care Record DHCR004(R) - Requirements for Standardisation process redesign & agreed Ways of Working	**16**	**12**	Ways of Working sessions to be held. Key advocates for change, standardisation and process redesign to be involved in the project Project Governance - Workstreams will be established to ensure key decisions are made with all involved in a timely manner required by the project. SMT and Clinical Lead support on standardisation of Ways of Working
2203	Performance and Service Sustainability	Velindre Cancer Centre	03/03/2022	Digital Health & Care Record DHCR013(R) - Accelerated Timelines of the DHCR Programme	**16**	**8**	Data Migration Phase 1 near completion and there are dedicated WPAS team resources working hard to complete all phase 2 activities by the end of April 2021, in line with the current DH&CR Project Plan which has been approved by the DH&CR Project Board.
2221	Performance and Service Sustainability	Velindre Cancer Centre	03/03/2022	Digital Health & Care Record DHCR019(R) - Clinical Coding Copy Functionality within WPAS	**16**	**12**	The proposed interim solution will enable 'manual selection instead of automated selection and copy'. This will enable the user to select multiple episodes across multiple admissions, within a single patient's record, and copy the coding from the 'coded' episode, to all other episodes selected. The user will have to verify that they want to complete this transaction to ensure the correct admissions is selected

2324	Performance and Service Sustainability	Velindre Cancer Centre	03/03/2022	Digital Health & Care Record DHCR024(R) - SACT & Medicines Management – DH&CR Project Support	**16**	**8**	Continuous review of service capacity of SACT and MM clinical team to support clinical prioritisation process. Twice-weekly review undertaken. Daily contact can be made with the booking team if required. If the workstream operational lead is required by the service, this resource would not be able to be replaced.
2326	Performance and Service Sustainability	Velindre Cancer Centre	03/03/2022	Digital Health & Care Record DHCR030(R) - Service unable to significantly reduce the capacity of clinics over the Go-Live period	**16**	**9**	1. Service managers and teams to be available on site. 2. Training champions/super users to support on site during the Go-Live period. 3. Minimise annual leave as much as possible.
2329	Performance and Service Sustainability	Velindre Cancer Centre	03/03/2022	Digital Health & Care Record DHCR034(R) - SACT & Medicines Management – Cashing Up Daycase Clinics	**16**	**16**	SACT, Clinical Trials, Supportive care an OP daycase are all scheduled via Chemocare therefore the patient record will be complete in Chemocare Explore requirements for administrative role Attendance data is reviewed manually by the nursing administration team when they process the daycase clinics to change certain attendances to WACs as necessary. This is not comprehensive and does not cover all of the clinics at present.
2328	Performance and Service Sustainability	Velindre Cancer Centre	03/03/2022	Digital Health & Care Record DHCR035(R) - SACT & Medicines Management – processes of booking/admitting patients	**16**	**16**	SACT, Clinical Trials, Supportive care and OP daycase are all scheduled via Chemocare therefore the patient record will be complete in Chemocare Explore requirements for administrative role
2440	Performance and Service Sustainability	Velindre Cancer Centre	03/03/2022	Digital Health & Care Record DHCR046(R) - unable to significantly reduce the capacity of SACT daycase clinics	**16**	**6**	Regular capacity review meetings by SACT & MM leads to discuss ongoing capacity constraints23/08/21 - There are a small amount of specific regimens where there is scope to reschedule treatment dates and therefore reduce patient numbers for go-live week. Decision to reduce capacity at go live is a strategic level decision requiring project board/SMT/Exec approval. Risk can only be fully considered when go live date is agreed.
2454	Workforce and OD	Corporate Services	01/05/2022	Digital Services Capacity / Skill Mix	**16**	**8**	Regular review of IT work plan, to ensure delivery is aligned to Trust / Divisional priorities. VCC and WBS IT work plans regularly reviewed, to be shared via relevant channels (BPG, SMT/SLT etc.). 'Agile' utilisation of Digital Services resource, to ensure focus on prioritised work.
2193	Performance and Service Sustainability	Velindre Cancer Centre	30/04/2022	Medical Physics Expert cover for Molecular Radiotherapy (Nuclear Medicine)	**16**	**2**	Current control measures include:- Not participating in clinical trials involving MRT Not implementing any new MRT until a safe, sustainable service can be provided Organising workload to minimise the impact of a lack of MPE back-up. Expectation to date has been to ask C&V Medical Physics to provide any additional MPE cover. However, the depth of MPE cover has been critically eroded over the years and recent resignations mean the current position is there will be only 2.5 WTE physicists left by the end of April (only 2.0 WTE being MPEs). One of those MPE is already providing 1 WTE support to VCC under an SLA for over >30 years. This leave 1.0 WTE MPE at C&V. (C&V provides MPE support to other HB as well as its own).

2196	Performance and Service Sustainability	Velindre Cancer Centre	01/04/2022	Radiotherapy Department -COVID Isolation Impact	**16**	**4**	Ability to work from home with relevant IT equipment on completion of DSE risk assessmentIsolations rules to be reviewed regularly.7/5/2021 – risk reviewed by HP & CRD. The risk due to COVID -19 remains despite the relaxation of national regulations. The need to maintain the controls mentioned above continue to ensure safety of staff, patients and the radiotherapy service.1/11/2021 – risk reviewed by CRD. The risk due to COVID -19 remains despite the relaxation of national regulations. The need to maintain the controls mentioned above continue to ensure safety of staff, patients and the radiotherapy service.7/2/2022 - risk reviewed by CRD. The risk due to COVID -19 remains despite the relaxation of national regulations. The need to maintain the controls mentioned above continue to ensure safety of staff, patients and the radiotherapy service.
2345	Performance and Service Sustainability	Velindre Cancer Centre	06/12/2021	Radiotherapy Dept - Change to service due continued response to Covid19	**16**	**1**	Continuing to work through recover phase towards business as usual. Covid contingency plan in place to be deployed if required, ie, deferral of benign, prostate monotherapy, prostate external beam and skin if necessary'Pod' working in place across radiotherapy clinical delivery service to minimise risk of cross infectionDevelopment of outsourcing contract to private provider to deliver external beam for prostate and breast5/11/2021 - UpdateCurrently we have insufficient capacity to meet demand. The number of hours available is restricted due to safe staffing and skills mix.Mitigation1.Department is currently working under business continuity, with 2x weekly meeting with SLT, Radiation Service and Radiotherapy Service managers to discuss departmental position and actions being undertaken.2.Undertaking escalation work to minimise breaches.3.SST's being asked to review current dose/# offered to patients.4.Review of trials.5. All vacancies out to advert.6. Outsourcing to Rutherford Cancer Centre.
2505	Performance and Service Sustainability	Velindre Cancer Centre	31/01/2022	Risk that Covid-19 related absences for staff could significantly impact on ability to provide core SACT and Radiotherapy Service	**16**	**6**	-SACT staffing - realignment from wards, senior staff deployed, RD&I capacity utilised to full; increased virtual appointments-Radiotherapy - major limitations on capacity due to reduction in workforce but maintaining service with increase in breaches with prioritisation based on clinical need; Changes made to Prostate pathway based on agreed framework; maximising third party provision.
2428	Compliance	Velindre Cancer Centre	31/03/2022	There is a risk of increased infection transmission due to poor ventilation.	**16**	**9**	UPDATE 14.02.22 from Mark David - A temporary air con solution will need to be installed for this summer (as per last year setup) with the hope of the ventilation BC being signed off later this Summer.Next steps will be for service to sign off decant plan so it can be included in the BC, this can then be signed off by SMT, EMB and then forwarded on to WG.UPDATE 03.11.21 - Further detailed planning to be undertaken by estates and operational services teams in conjunction with nursing team with timescales and decant plan.* Infection control and prevention measures in line with Trust polices. Including regular audit, training, enhanced cleaning etc.* Additional COVID19 precautions - Use of PPE, regular testing of patients and staff etc.* Full root cause analysis undertaken to ascertain cause(s) of any infections.* Business Case currently under development to seek funding for compliant ventilation system.
2514	Quality	Velindre Cancer Centre	29/04/2022	There is a risk that Standard Operating Procedures (SOPs) within Brachytherapy are not up to date	**16**	**4**	Following the retirement of the former Head of Brachytherapy Physics, ownership of RT physics documents has transferred to another member of staff who is reviewing SOPs. Similarly a review of documentation is taking place within Radiotherapy

2198	Financial Sustainability	Velindre Cancer Centre	13/12/2021	VCC may face financial loss, legal action, inadequate service provision as a result of no coordinated system for SLAs, contracts	**16**	**6**	Specialist procedure advice via NWSSP Agreement for planning team to take ownership (delayed due to COVID) VCC Planning team to take responsibility for establishing database and monitoring mechanism
2402	Performance and Service Sustainability	Transforming Cancer Services	31/01/2022	Risk of time-consuming infrastructure work	**16**	**9**	1) Identify location 2) Identify refurb / new build required 3) Establish level of local engagement with CHCs/public required 4) Identify appropriate resources from all HBs & VUNHST (inc Project Leads, Planning etc) to ensure project is supported and managed to align with project & programme timelines 5) Establishment of ownership and governance of Project within TCS/VF environment

3. **Development of Risk Framework**

Update on the progress during latest reporting cycle, in particular highlighting the action against feedback received by the Quality, Safety & Performance Committee, Audit Committee and Trust Board in the January reporting cycles:

- Closure rationale
    - Datix now has hard coding making rationale for risk closure a compulsory field.

- Committee mapping of oversight:
    - Currently Audit Committee, Quality Safety & Performance Committee and Trust Board receive full register.
    - Going forwards, Research and Development category of risks to Research, Development & Innovation Committee. Research and Development risks are reported and Datix currently, therefore specific reports can be developed for the committee.
    - There have been preliminary discussions with the Charity Director regarding the migration of the Charity risk register onto Datix. There is agreement in principle around this action, however a further meeting is planned in March to confirm the process, anticipating completion by end April for incorporation in risk reporting overall.
    - Transforming Cancer Services Programme risks will be continued to be reported to the Transforming Cancer Services Programme Sub-Committee.

- Private risks – review of all completed – see Private paper

- Link to Trust Assurance Framework – scheduled further development over coming months, in line with the further development of the Trust Assurance Framework, for completion and reporting Q3-4 2022/23.

- Reporting of actions – as articulated in the key points for the Committee on page 2: The action plans for Velindre Cancer Centre and Corporate risks needs clearer articulation. This will be prioritised for the risks scoring 20 and 16 for the next reporting cycle. Welsh Blood Service and Transforming Cancer Services risks already clearly articulate actions in their reporting.

- Colours for reporting of score – formatting changes completed.

- Articulation of risks in Datix and way in which summary of title pulls through to this cover paper.
    - All 20 and above risks have been reviewed for WBS, VCC, TCS and Corporate and where appropriate updated on Datix and therefore will be reflected in this report.
    - Level 16 risks have been reviewed and amended on Datix for WBS, TCS and Corporate. The review is still ongoing at VCC and will be completed by the next reporting cycle.

- Initial view on approach to risk appetite review for May-June discussed in Executive Management Board.
    - Important to link to strategy discussions and will therefore bring back to next Executive Management Board Shape meeting in April.
    - May want to change a number of the categories thresholds so more calibrated at 16/15 rather than 12 for reporting residual level of risk to Board level.
    - Executive leads for risk categories to then discuss with Independent Member leads prior to bringing to Board for sign off and approval.

3 IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	Is considered to have an impact on quality, safety and patient experience
RELATED HEALTHCARE STANDARD	Safe Care
	If more than one Healthcare Standard applies please list below.
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
	Completed for individual risks as appropriate
	Yes (Include further detail below)

LEGAL IMPLICATIONS / IMPACT	Risks open for extended periods of time without indication that work is being undertaken could expose the Trust that may have legal implications.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	If risks aren't managed / mitigated it could have financial implications.

4 RECOMMENDATION

The Quality, Safety and Performance Committee is asked to:

NOTE the risks level 20 and 16 reported in the Trust Risk Register and highlighted in this cover paper.

NOTE the on-going developments of the trust's risk framework.

ID	Is this a Private & Confidential Risk?	Risk Type	Division	Area	Handler	Manager	Approval status	Service	Opened	Review date	Closed date	Title	Risk (in brief)	Rating (initial)	Rating (current)	Rating (Target)	RR - Current Controls
2187		Performance and Service Sustainability	Velindre Cancer Centre	Medical Physics	Windle, Rebecca	Millin, Tony	Accepted	Medical Physics (previously Radiotherapy Physics)	14/09/2020	31/03/2022		Radiotherapy Physics Staffing	There is a risk of the radiotherapy physics team being unable to complete core and developmental tasks due to inadequate staffing. This may result in - patient treatment delay - Radiotherapy treatment errors. - key projects not keeping to time e.g. commissioning of essential systems - suboptimal treatment - either due to lack of planning time or lack of developmental time Example of areas of the service currently considered as routine that are detrimentally impacted by the lack of resource include i. Completion of incident investigations, reports and learning, essential to prevent future radiotherapy errors and incidents and improve local practice ii. Inability to provide engineering cover during weekend quality control activities iii. IMPE advice on, and review of, treatment protocols to ensure they are in line with national guidelines whilst also appropriate for local practice iv. Development of workflow processes to increase efficiency v. Delays to the commissioning of new treatment techniques / service developments e.g., Partial Breast Irradiation (PBI) and Internal Mammary Node Irradiation (IMN) vi. Delays in performing local RTQA slowing opening of new trials and thus reducing recruitment of Velindre patients to trials compared with other centres (e.g. PACE C) vii. IMPE support for imaging activities providing imaging to the radiotherapy service inside and outside VCC. Background The ATTAIN report highlighted that in comparison to the Institute of Physics and Engineering in Medicine (IPEM) guidance, Radiotherapy Physics were under resourced by approximately 25%. The IPEM recommendations for the provision of a physics service to radiotherapy are recognised as a benchmark for minimum staffing guidance. The Engineering Section in particular is identified as an area of risk to the radiotherapy service. Not only are staffing numbers significantly under those recommended by IPEM but the age profile of this team is of concern, with up to 6 engineers planning to retire within 5 years. Linac engineering is a specialist area requiring in depth knowledge of complex machines and requires training to work at high voltages in a radiation environment. This is particularly critical with the age profile of our current linac fleet. The effects of incorrect repairs and / or maintenance can be significant on the patient and it is vital that this area is sufficiently resourced. Skill mix within physics enables most staff to be redirected to physics planning in order to meet fluctuating demand in the pre-treatment pathway and minimise patient delays and breaches. However, this negatively impacts on other essential core duties.	25	15	5	Radiotherapy Physics workforce remains below recommended (IPEM) levels. Additional surge funding has been utilised alongside IRS funding to increase recruitment in the short term. The service head has developed an outline workforce plan, looking at roles and responsibilities and demands on the service, mapping out the essential BAU activity, critical projects and programmes of service development to implement a prioritisation if activity and resource utilisation. Whilst the situation to establish a full complement of staff in the service remains a challenge, development of a medium term workforce planning, and long term workforce strategy, with HEIW and W&OD colleagues continues alongside recruitment there will need to be support to focus on service critical projects. These have been determined as DHCR replacement, IRS and nVCC. Recruitment is underway to mitigate this risk, currently at 15, as this resource will cover the business critical programmes. This is subject to dynamic risk assessment due to the anticipated shortage of appropriate candidates.
2419		Safety	Velindre Cancer Centre	External Departments/Areas	Jones, Helen	Buswell, Stuart	Accepted	Operational Services	01/09/2021	31/01/2022		Risk Assessment of Marquee erected outside Out Patients Department	To manage the number of people in the Outpatients Department and to comply with Covid19 2m social distancing requirements additional waiting area space is required. In October 2020 a marquee was erected by County Marquees to provide additional waiting space. The marquee is provided with an electrical supply by the Trust Estates Department. There is a wooded floor covered by carpet. Patients are triaged on entering the marquee and then are able to wait there sitting on socially distanced chairs until it is their turn to enter the department. August 2021 the wooden floor was noted to have become uneven after a patient fell in the area. This is a temporary structure which is likely to remain on the VCC hospital site for some time and will require maintenance and inspection. Hazards identified: Deterioration in the structural condition of the Marquee over time A fault occurring with the structure of the marquee An electrical fault occurring within the marquee The marquee being damaged by inclement weather, antisocial behaviour or other damage	12	12	3	Bollards have be put in place to protect the marquee and people walking near it from being struck by vehicles. A hedge has been removed and replaced by concrete to increase the turning circle in the road adjacent to the entrance to the Out Patients Department. The edge of the flooring in the marque is demarcated with batons and high visibility tape. The marquee is fitted with fire detection and is situated 2m from the main building. Additional control measure are required to maintain and monitor the condition of the marquee.
2475	N	Performance and Service Sustainability	Velindre Cancer Centre	No Further Coding Required	Seary, Sarah	Cooper, Mrs Vivienne	Accepted	Whole Service	19/11/2021	31/03/2022		A risk that increase in COVID and the Winter pressures period potentially impacts Int. Care project delivery	COVID-19 and Winter Pressures - A risk that increase in COVID-19 pressures and the Winter pressures period potentially impacts project delivery Cause: Increase in demand that requires project resource to focus solely on clinical work Increase in staff sickness leading to gaps in capacity/back fills requirements/prioritisation of clinical requirements	16	12	8	Update 14.02.22 - Most projects have continued with minimal impact from staff absence. Progress of projects is closely monitored by the PMO office and weekly meetings take place with the Project Manager and IC service staff Update 10.12.21 - Regular meetings continue to take place with PMO to review status of projects and work plan. Activity monitored via the ICOG and sickness levels monitored by HODs. Mitigating actions: 1. Monitor staff sickness through the IC Operational Group 2. Monitor increase in demands via IC Operational Group 3. Update PM with resourcing issues for further escalation and re-prioritisation. Logged as a Project risk also for Integrated Care as may impact on project work streams
2523	N	Performance and Service Sustainability	Velindre Cancer Centre	Outpatients	Baker, MRS Kate	Baker, MRS Kate	New risk	Therapies	24/02/2022	18/03/2022		A risk to the delivery of the Physiotherapy Gynae-Oncology service	With monies successfully secured from Velindre Charitable Funds, and more specifically the Rhian Griffiths Forget Me Not Fund, a 0.8 FTE 3-year trainee Advanced Practice Gynae-oncology Physiotherapist role was recruited into in April 2020 with the primary aim of helping women to manage side effects from their cancer treatment. The staff member in post in unfortunately off work sick for at least the next month (4 weeks). The role is a single point of failure as we do not have any other physiotherapists who are trained in gynae-oncology to be able to review the patient caseload. Therefore the service will be put on hold for this period of time. The interventions provided for these patients can't be seen in general physiotherapy outpatient clinic due to the specialist nature of interventions delivered.	12	12	6	The VCC Gynae team are made aware of the service being put on hold for the time period of 4 weeks with the potential this may increase. Any new referrals to the physiotherapy clinic will be received and a waiting list letter sent to the individual patients
2503	N	Compliance	Velindre Cancer Centre	No Further Coding Required	Johnston, Sam	Gallop-Evans, Eve	Accepted	Medics	14/01/2022	01/02/2022		ALS Training Compliance	CTUHB have made the decision to cancel their Feb and March 2022 ALS training courses for external attendees. A number of SHO's, Registrars and Consultants who were booked on the course or have training expiring in the near future will be effected. This carries the risk of immediately impacting service such as the On Call rota for existing VCC staff. This will carry further impact when Junior Doctors join VCC as part of the next rotation. Junior Doctors are required to be ALS trained to enable them to work on the wards and assessment unit. Backlogs in training expired medical staff could result in further medical staff being out of compliance in the near future.	12	12	3	Business team has contacted the Resuscitation Council to query extension periods during COVID times. Made contact with Malcolm Jones, First Response Medical Training Ltd. with whom Nursing have an SLA contract to organise an additional training session for medical staff. Potential to undertake a RA to extend current compliance in the absence of future training courses, needs to be agreed and signed off by SLT.
2253	N	Performance and Service Sustainability	Velindre Cancer Centre	Information and Technology	Mason-Hawes, David	Mason-Hawes, David	Accepted	Digital Services	27/10/2020	01/05/2022		Availability of CANISC System	There is a risk that clinical/patient services across VCC would be critically endangered as a result of the prolonged loss of CANISC, which may lead to significant patient harm and treatment delays due to the lack of availability of critical clinical information for VCC clinical staff. In the event of a catastrophic CANISC system failure, Velindre Cancer Centre would have no electronic patient record and radiotherapy workflow management systems. In this scenario patient care would be seriously compromised, for inpatient admissions and /or outpatient appointments. Electronic access of patient medical histories would not be available or limited to a point in time to guide care decisions. This would lead to the unavailability of clinical information to support decision making. As well as loss of patient administration activities tasks including the booking and processing of outpatient and inpatient activity, clinic lists etc.	15	15	5	Full geographical resilience for CANISC was restored in August 2021 following completion of the migration of national IT services out of the Blaenavon Data Centre (BDC) by DHCW. This means the CANISC service can be 'failed over' to the new 'CDC' data centre in the event of there being issues in the primary 'NDC' data centre. This significantly reduces the risk of the permanent loss of CANISC services. In the event of CANISC becoming unavailable for short periods of time, access to relevant clinical documentation is avialable via alternative systems - e.g. - WCP CANISC Case Note Summary to provide historic record - Chemocare (existing patients) - Welsh Clinical Portal (WCP) for viewing all results, documents and Canisc CaseNote Summary. - WCP is linked to Master Patient Index (MPI) to access patient demographic information - Welsh Results Reporting Service (WRRS) for all VCC radiology reports - Paper Radiotherapy Workflow (IRMER) - Manual Registration - new patients on Chemocare - Manual Registration - new patients on Aria and Mosaiq - Availability of Clinical correspondence created at VCC in Document Management System (DMS) from April 2019 that feeds into Welsh Clinical Record Service (WCRS) - Access to paper record that holds inpatient documentation, charts etc
2190		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Payne, Mrs Helen	Powell, Emma	Accepted	Radiotherapy Services	14/09/2020	31/03/2022		BI Support for reporting of Breaches	BI Support for reporting There is a risk that lack of high quality data informing in real time key activity (demand/ capacity) Key data inputs (RTDS) are done manually Different staff groups only understand their own systems. Resulting in a lack of ability to accurately forecast and model future demand for services which may impact on accurate capacity planning for the scheduling of patient pathways	16	16	10	Large amount of BI is occurring, with better understanding of RT BI and complexity of internal RT processes
2511	N	Workforce and OD	Velindre Cancer Centre	No Further Coding Required	Johnston, Sam	Gallop-Evans, Eve	Accepted	Medics	28/01/2022	28/02/2022		Calculation of Medic A/L allowances	There is a risk that part time consultant A/L entitlements have been calculated incorrectly as a result of business processes which may lead to numerous risks including financial, reputational and compliance. A part time consultant queried that their A/L entitlement was incorrect due to the incorrect B/H A/L entitlement being issued. This was investigated by the medical business team and identified that the B/H A/L entitlement hadn't been included within the consultants A/L entitlement. Further investigation identified this wasn't an isolated case and that numerous part time consultants B/H entitlements were not included in the overall A/L. Other peripheral issues have been identified around medic A/L allocation and processes such as full time medics not being allocated or booking B/H A/L via the Intrepid system resulting in no audit trail or governance. Certain medics having various contractual arrangements without formal documentation (SLA/secondment documentation) in place detailing whose responsibility it is for A/L to be calculated and allocated by. This may lead to issues with up and coming guidance in relation to carryover/sell back of A/L.	12	12	2	Business team have added the risk to the directorates risk register. Business team have contacted and sought advice and support from WF colleagues. Business team have communicated has escalated the issue identified to the CD, MD and Director of Cancer Services Business team are currently exporting and requesting data to identify all part time medics who may be affected. Working group have met to discuss and identify all scenarios which could be present and affect medic A/L entitlement i.e. B/H allocation, contractual changes (years of service, role). WF currently reviewing contractual obligations and case law which is relevant. Working group have met to discuss current process, information sources and initial plan to resolve. Working group to develop SBAR detailing the above information for SLT. Raised for discussion at JLMC for discussion. --
2205		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Johns, Dewi	Wilkins, Paul	Accepted	Digital Services	14/09/2020	31/01/2022		CANISC failure	Currently the CANISC electronic IR(ME)R form is the only way for the Oncologist to request a CT simulation scan and subsequent radiotherapy treatment for all patients bar emergencies. It is also the system used to manage the complex radiotherapy pre-treatment workflow and to document and authorise the detailed dose information for a patient plan prior to treatment. This documentation and authorisation is required under the IR(ME)R 2017 regulations. If CANISC is unavailable, there is no "fall-back" method for the above tasks. Business Intelligence (BI) data is also sourced from the electronic IR(ME)R form in CANISC, the loss of which will reduce the ability for BI reporting, forecasting and modelling. CANISC will no longer be available from September 2021, with the long-term IR(ME)R form replacement (part of the IRS) not being fully procured and in-house until around this time. CANISC will no longer be available from September 2021, with the long-term IR(ME)R form replacement (part of the IRS) not being fully procured and in-house until around this time. No longer applicable - can be removed	25	15	9	Engagement with NWIS & DCHR to develop MVP ongoing. DCHR-led project underway. Initial option appraisal highlighted high likelihood of gap between CANISC and OIS; several discussions occurring to confirm this and identify optimal bridging solution. Approved Design in place for WCP IRMER as an interim solution - this now is subject to acceptance testing of the software delivery by VCC service leads
2202		Workforce and OD	Velindre Cancer Centre	Velindre Hospital	Sully, Nicola	Gallop-Evans, Eve	Accepted	Medics	23/02/2021	01/02/2022		Consultant cover for long term absences	Two consultants will be taking Maternity Leave in 2021 in Urology and Breast tumour sites. One Consultant is planning a career break in Spring 2022. One Consultant on Long Term Sick Covid related from Mar 2020.	20	12	4	The Directorate has employed a Consultant for a 1 year post to cover the Urology gap for Mat Leave in 2021 but may require extending the contract to Mid 2022 depending on how long the Consultant will be off on Mat Leave and also to cover the sabbatical in 2022. An additional temporary consultant will be required to cover the breast sessions for the 2nd Mat Leave.

2189		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Tranter, Bethan	Tranter, Bethan	Accepted	SACT	15/04/2020	01/05/2022		Covid - SCT - VCC Futures: Clinical plan for SACT Services through the COVID 19 pandemic	VCC Futures: Clinical plan for SACT Services through the COVID 19 pandemic As a stand-alone cancer centre, VCC has a vital role to play in ensuring continuation of essential cancer services throughout the pandemic and effective and rapid recovery of services afterwards. This will be essential to prevent worsening cancer outcomes from occurring as 'collateral damage' from the pandemic. VCC will be a 'cancer treatment hub' for the population of South-East Wales during the COVID-19 pandemic. Systemic Anti-Cancer therapy (SACT) is a highly effective cancer treatment, which can be given to cure cancer as primary treatment (with or without radiotherapy), to reduce the risk of relapse (after surgery) and to palliate symptoms and reduce complications. It is imperative that this service continues as comprehensively as possible throughout the pandemic and beyond. Clinical/Medical oncologists, pharmacists and nurses with SACT competencies are highly specialist NHS staff who will continue to utilise their skills throughout the pandemic to treat cancer patients. As the Covid-19 pandemic changes through the three identified phases (Acute phase (early & late pandemic), Recovery Phase (early & late recovery) and Reactivation Phase), there is a risk that VCC will be unable to match capacity with demand for SACT Services. This would result in patients being unable to receive the cancer care they require in a timely manner	20	12	9	Document providing strategic oversight of core documents produced by the Velindre Cancer Centre (VCC) SACT Strategic Group (SSG) and national bodies during Covid-19 and beginning to explore future adaptation to these as the risk from the pandemic changes, as well as a perspective on the recovery phase as the pandemic wanes - submitted to Silver Command 24.04.20 (Velindre Futures plan for SACT through COVID-19_Final Version 1.1 April 27 2020.docx) It is assumed that this evolution will happen over approximately six to nine months (March to December 2020), although the timings may vary. It is also accepted that there will be peaks and troughs in demand over this period so we need a system that will be agile. The aim is for VCC to be able to deliver a centralised, high quality, specialised SACT service, adapting quickly to the needs of cancer patients / services in SE Wales whilst minimising patient harm. VCC Futures: SACT Operational Plan currently in the final stage of production. This plan details options for how VCC will be able to operationally manage demand through the Recovery phase of the pandemic. Recovery of the SACT service is dependent on multi-professional capacity across the whole of Velindre Cancer Centre. In early Recovery, VCC will endeavour to adequately manage the predicted surge in demand for SACT Services and: A - Re-start SACT treatments that have been deferred in whom therapy is still appropriate (will need clinical review) B - Continue to deliver SACT in place of surgery for patients who cannot have surgery, as listed in the early phase plan C - Continue use of all adapted SACT regimens implemented during phase 1 and 2 of the response, to manage demand on the SACT service, until a phased adaptation is possible without impact upon new or existing patients D - Re-initiate outreach daycase services potentially following a different model, key areas to be considered. E - Embed changes to models of pre-SACT assessment clinics made during the peak of the COVID-19 crisis and to build on these through progress of the Virtual Assessment Pathways (VAP) project and continued SST leadership. 01.08.20 - Strategic and Operational papers have been approved. Pace of recovery has been unable to match demand with resultant impact on service. This is likely to be an ongoing issue and is included on the SACT SG general register Update - 29.10.20 - As we enter the second wave of COVID-19, demand is exceeding capacity and the number of target breaches has increased. PCH Outreach Unit now re-opened for 3 days a week and the MAH Parenteral Service on the Mobile Unit is being expanded as of November to help ease capacity issues - likelihood score raised from 2 to 3 Update - 12.01.21 - Mobile Unit with 3rd party provider service expanded to 2 days per week from mid-December. Proactive systems of SACT escalations introduce to manage urgent new referrals and on treatment demand. Current performance including and demand and capacity closely review in light of increased community incidents and effect impact on staffing service Update - 23.06.21 - Funding for SACT Surge approved and staff recruitment in progress. Timescales for recruitment will determine date for opening Outreach Unit at NHH - currently estimated as Sept / Oct 21 in coordination of obtainment of trained SACT staff - key pieces of work currently progressing to enable this
2504	N	Safety	Corporate Services	Infection Control	Wright, Lenisha	Fear, Lauren	New risk	Whole Service	18/01/2022	31/01/2022		Covid-19: Changing profile of Covid-19 infection risk, impacting our patients, donors and staff	Response to COVID-19 and the controls that need to be put in place. The Action plan: -Finalise operational review of Clinical Principles, including trigger points --governed through Gold 13.12.2022 via: -Strategic clinical advisory group -WBS risks based social distancing paper to be completed and approved	20	12	6	-Re-establishing command structure -Clinical governance strengthened, with establishment of Strategic Clinical Advisory Group at Gold level and Clinical Development Group at Silver level -Covid Cell established -Decision making framework refreshed, approved by Trust Board and reinstated -Changes to Board and Executive Meeting Structure, including increase frequency of Quality, Safety & Performance Committee
2480	N	Workforce and OD	Velindre Cancer Centre	No Further Coding Required	Sully, Nicola	Button, Mick	Accepted	Medics	23/11/2021	01/02/2022		Current and predicted shortfall of oncologists by 2025	A recent census (RCR 2021) has predicted a shortfall across Wales in clinical oncologists by 2025. Medical oncologist were not included in the census but should also fall under this risk due to overlapping clinical roles. There is a current shortfall with predictions that this will worsen over the next 5 years (NB this is likely to be a gradual worsening over a period of time; the census predictions only go up to 2025 so no data suggests sudden improvement after that time). Due to the nature of clinical work, these gaps may fall unevenly, for example one team/tumour site could be seriously affected while others are not. Drivers behind this are: increasing clinical care/complexity (increase in patient numbers, increase in treatment options/complexity for each patient), new demands (eg regional AOS delivery), increasing trend to LTFT working and predicted retirements. On top of this there are potential impacts from Covid (ill health), pension tax impact. This is likely to lead to: difficulties seeing new patients on time, managing all aspects of care (OP review, SACT, RT), delivering a regional model of care, supporting new areas such as AOS, impact on clinician health, wellbeing and teamworking. It may also impact on non clinical roles, ability to recruit/retain staff. Recruitment is challenging as this shortfall will be felt across the UK. Due to the nature of clinical work, finding backfill through re-allocations of individual sessions is challenging.	15	15	4	Training places have increased however will not feed through by 2025. Actively seeking to recruit Developing new multi-professional ways of working (but there are also workforce limitations in other professional groups and the time taken to train new colleagues is a challenge)
2395		Safety	Corporate Services	Estates Management	Fear, Jonathan	Fear, Jonathan	Accepted	Quality and Safety	26/05/2020	01/10/2022		Deficiencies in compartmentation (fire-resisting construction, fire doors and fire dampers) – Velindre Cancer Centre	Deficiencies in compartmentation (fire-resisting construction, fire doors and fire dampers) – Velindre Cancer Centre	15	12	9	1.As noted above, site has holistic fire strategy where compartmentation plays a key role 2.Site has high level of fire detection to WHTM 05 (Firecode) 3.Provision of fire safety training to support implementation of fire safety strategy 4.Program of fire safety risk assessments and annual fire safety audits including the identification and assessment of compartmentation 5.Inspection of compartmentation by 3rd party accredited surveyors and receipt of report and remedial actions in 2020 6.In support of management and prevent, Department managers responsible for regular workplace inspections including the monitoring of local fire precautions 7.Fire doors subject to regular visual inspection as part of Estates planned preventative maintenance regime 8.Consideration of fire risk assessment findings (including compartmentation issues) as part of Capital Refurbishment schemes.
2223		Performance and Service Sustainability	Velindre Cancer Centre	Outpatients	Bell, Mrs Tracy	Miller, Lisa	Accepted	Operational Services	21/07/2020	12/01/2022		Delay in re-starting outreach activity	The delay in re-starting outreach activity which is as a result of the COVID-19 pandemic, is impacting on outpatients resources and the availability of clinic rooms in VCC. This is because all outreach services have been repatriated to the cancer centre for the duration of the COVID-19 pandemic.	12	12	12	UPDATE June 21 - Discussions to repatriate outpatients clinics continue with health boards. Previously agreement from ABUHB to re-start outreach clinics in Nevill Hall but subsequently notified that space is not available, although not Royal Gwent. VCC group established to manage repatriation of clinics and SACT to NHH. Continue with ongoing discussions with other HBs as this remains a priority for VCC. SSTs have been asked to review all their clinics and highlight priority clinics for repatriation. Undertake surge planning and discuss impact with health boards
2185		Safety	Velindre Cancer Centre	Radiotherapy	Windle, Rebecca	Johnston, Sam	Accepted	Medics	14/09/2020	31/03/2022		Delination Risk treatment delay (16284)	There is a risk of Radiotherapy physics planning rework and patient delay as a result of errors in tumour volume delineation / margin growth, which may lead to a reduction in physics capacity and inability to meet planning targets. There is a lower risk that errors are missed at physics check and make their way to treatment. These errors are generally not picked up at medic peer review or during the physics planning process but by more experienced Clinical Scientists at final physics check, often the day before treatment. There have been a number of Datix incidents attributed to this - with Radiotherapy Physics previously trying to communicate the issues. Action is required to ensure these errors do not propagate to treatment.	12	12	6	Discussions, initiated by physics, have been held at the RMG quality focused meeting to ensure the medical workforce are aware of the issues and to enable discussions and learning within SSTs. Medic peer review processes (for some treatment sites). A physics quality improvement project categorised the errors - this information is available for learning. Further controls required – ensure volume peer review is in line with RCR recommendations and a Datix medic representative is available to ensure learning within medical teams. Also consider transferring PTV volume growth to the physics team.
2224		Performance and Service Sustainability	Velindre Cancer Centre	Outpatients	Bell, Mrs Tracy	Miller, Lisa	Accepted	Operational Services	07/11/2019	12/01/2022		Demand for services outstripping capacity	Demand for services outstripping current capacity resulting in patients not being seen in a timely manner and waiting time breaches. Also results in overbooked clinics which are extremely busy. In addition, many of the outreach clinics continue to be run from VCC which is adding to the pressure on clinic rooms.	16	12	16	UPDATE June 21 - Risk rating increased to reflect current situation. Increasing referrals are leading to an increase in outpatient attendances resulting in very busy clinics. Continue with planning for any surge in activity due to cancer backlog and latent demand from health boards is being undertaken by VCC. Continue with weekly monitoring of outpatient referrals and activity. Progress with the work of the Demand Modelling group being led by the BI team. Continue to have discussions with health boards re. outreach clinics and likely demand for services.
2206		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Evans, Fran	Rodgers, Suzanne	Accepted	Digital Services	09/10/2020	03/03/2022		Digital Health & Care Record DHCR003(R) - IM&T Dept - Covid-19 Pandemic	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR003(R) - Could impact on key project team members capacity due to service requirements being prioritised, childcare needs, the need to self-isolate etc. The ongoing impact of the Covid 19 outbreak continues to have a significant impact of staff in terms of their well-being, their availability and their ability to absorb new ways of working and new systems within an already stretched environment. Also, additional clinical pressures/ demand on; clinics, inpatient activity, treatments and the presentation of potentially sicker patients, resulting from the impact of COVID19.	20	20	9	Following guidance from VUNHST & Government Project team are all enabled to work from home as required. Early engagement and communication plan in place to keep staff updated and included in the process. Departmental leads being identified to ensure that all departments have a voice at the table and a mechanism to feed in their requirements. DHCR producing Contingency plans as part of COVID-19 response. Canisc will be moved as part of the data centre project, if this failed the contingency would be a single instance of Canisc running in Newport data centre.
2211		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Evans, Fran	Rodgers, Suzanne	Accepted	Digital Services	09/10/2020	03/03/2022		Digital Health & Care Record DHCR004(R) - Requirements for Standardisation process redesign & agreed Ways of Working	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR004(R) - Requirements for standardisation, process redesign and agreed Ways of Working - Business Change The scope of the deliverables for the workstreams will change after being signed off and planned and may cause delays. There is a risk that without an element of standardisation; process redesign and agreed ways of working; system configuration, testing and training becomes very complicated and time consuming.	16	16	12	Ways of Working sessions to be held. Key advocates for change, standardisation and process redesign to be involved in the project Project Governance - Workstreams will be established to ensure key decisions are made with all involved in a timely manner required by the project. SMT and Clinical Lead support on standardisation of Ways of Working
2296		Performance and Service Sustainability	Velindre Cancer Centre	Information and Technology	Evans, Fran	Rodgers, Suzanne	Accepted	Digital Services	11/01/2021	03/03/2022		Digital Health & Care Record DHCR010(R) - Data Migration Resource	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR010(R) - The Head of Information who manages the Business Intelligence (BI) Service within VCC is actively involved with the Data Migration work. This includes assisting the Data Migration Specialist with the development and testing of data migration extracts from Canisc to WPAS. In addition, the Head of Information provides subject matter advice and guidance to the whole project team. There are currently competing priorities on the Head of Information time due and the need to delivery Capacity and Demand planning, ad hoc information requests etc. during the COVID pandemic, whilst supporting a new team. The impact of these competing demands and a number of new team members is the reduced availability of focused time for the Head of Information to undertake the complex data migration work. This has impacted directly on the capacity of the Head of Information to assist in the development and testing of the data migration extract and provided support/guidance in a timely manner.	15	15	6	Clear prioritisation of the BI Service work and Head of Information's workload is required. Notification to service users of unavoidability of BI Head for 3 weeks period in April 2021. A deep dive is planned to support this prioritisation. 09/06/2021 - LM & JH reviewed risk - situation still stands. LM to discuss with WJ.
2203		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Evans, Fran	Rodgers, Suzanne	Accepted	Digital Services	12/01/2021	03/03/2022		Digital Health & Care Record DHCR013(R) - Accelerated Timelines of the DHCR Programme	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR013(R) - Due to the accelerated timelines of the DH&CR Programme, the data migration phase is having to be compressed from 18 months to 6 months. Data Migration Phase 1 (Patient Demographics and casenotes) and Phase 2 (Referrals, activity, Clinics, pathways and waiting lists) both need to be completed by prior to UAT testing which is due to commence in July 2021. There is a risk that any delay to these data migration activities could have a direct impact on the quality of the patient data migrated from Canisc into WPAS as there will be no time to review and cleanse the data prior. There is also a risk that any delay to the data migration activities will have a direct impact on the WPAS implementation date which may lead to the Service having to rely on an unstable and unsupported Canisc instance for a longer period of time.	16	16	8	Data Migration Phase 1 near completion and there are dedicated WPAS team resources working hard to complete all phase 2 activities by the end of April 2021, in line with the current DH&CR Project Plan which has been approved by the DH&CR Project Board.

2221		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Evans, Fran	Norman, Sarah	Accepted	Health Records	24/02/2021	03/03/2022		Digital Health & Care Record DHCR019(R) - Clinical Coding Copy Functionality within WPAS	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR019(R) - Clinical coding require a 'Copy Coding Functionality' within WPAS. Currently within Canisc VCC Clinical Coding staff are able to choose an option to 'copy exact coding to all linked Radiotherapy (RT) Regular Day Admissions (in same sequence of admissions)'. This means that if a patient has received 10 episodes of radiotherapy the coder can code the first episode and then click the copy function to copy to the other 9 episodes. This saves the coder time and ensures the accuracy of the coding. This functionality is not available within WPAS; therefore it is requested that the functionality be developed. There is a risk that NWIS are unable to deliver an exact replica of the functionality within the timescales - there is also a prerequisite on the Radiotherapy Admissions work completing and the eRMER development. This could affect the implementation timescales. DHCW confirmed that they can replicate the copy coding functionality but that it could take up to 12 months. They have confirmed a temporary manual copy coding function that will be used in the interim. This will require 2 staff (or equivalent overtime) for up to 12 months. Without the ability to copy the RT Regular Day Admissions (in same sequence of admissions) will have a resource and financial impact. Without the use of a copy coding function coding quality could be compromised as there would be great chance of human error. It could also compromise VCC achieving their current coding levels/standards. At present, 2 coders code 60,000 episodes of RT Regular Day Admissions. Without the function to copy the coding team would need additional resource to maintain deadlines. A full time coders would generally code approx. 6,000 episodes per year. Therefore an additional 8 full time coders would be required to maintain current levels of productivity. Financials can be calculated if necessary. Without the use of a copy coding function coding quality could be compromised as there would be great chance of human error. It could also compromise VCC achieving their current coding levels/standards.	16	16	12	The proposed interim solution will enable 'manual selection instead of automated selection and copy'. This will enable the user to select multiple episodes across multiple admissions, within a single patient's record, and copy the coding from the 'coded' episode, to all other episodes selected. The user will have to verify that they want to complete this transaction to ensure the correct admissions is selected
2512		Performance and Service Sustainability	Velindre Cancer Centre	Outpatients	Evans, Fran	Lloyd, Gareth	Accepted	Whole Service	02/02/2022	03/03/2022		Digital Health & Care Record DHCR022(R) - Business Continuity Risk following Implementation	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR022 - A potential business continuity risk following implementation. Currently the WCP is used to access case note summaries for patients in order to provide business continuity when Canisc is unavailable. The impact in this risk would be felt after go-live but could impact on service delivery. This is potentially a service risk but will be considered and summarised for the project risk register and discussed further at the next Project Board Meeting	15	15	12	DHCW to develop a solution as this would have an effect on every HB when they have an Electronic Patient Record
2324		Performance and Service Sustainability	Velindre Cancer Centre	Chemotherapy Day Unit (CDU)	Evans, Fran	Tranter, Bethan	Accepted	SACT	09/06/2021	03/03/2022		Digital Health & Care Record DHCR024(R) - SACT & Medicines Management – DH&CR Project Support	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR024(R) - DH&CR project support: There is a risk regarding the availability of SACT support for the DH&CR project, due to increased demand on the SACT service if & when SACT surge demand occurs or SACT capacity reduces The SACT DH&CR operational lead also provides clinical leadership for SACT booking services. Impact on clinical patient escalation & prioritisation process for SACT scheduling with potential impact on clinical outcomes if SACT DH&CR operational lead is unable to provide sufficient time to this element of service should SACT demand increase or capacity reduce. Conversely, there is the potential impact on the DH&CR SACT project progressing if resource is focussed on clinical prioritisation	16	16	8	Continuous review of service capacity of SACT and MM clinical team to support clinical prioritisation process. Twice-weekly review undertaken. Daily contact can be made with the booking team if required. If the workstream operational lead is required by the service, this resource would not be able to be replaced.
2325		Performance and Service Sustainability	Velindre Cancer Centre	Chemotherapy Day Unit (CDU)	Evans, Fran	Tranter, Bethan	Accepted	SACT	09/06/2021	03/03/2022		Digital Health & Care Record DHCR026(R) - SACT & Medicines Management – Affect of Canisc Shutdown on the Department	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. There is a Risk of Canisc being shut down on 17/09/21 before SACT & MM have completed required activity in Canisc. Clinical teams will be unable to access patient records during Canisc switch off, leading to delays in decision making and potential error, along with poor patient experience There could also be an impact on data migration if all SACT switch off activities are not completed in time	20	12	8	All clinical teams and SACT administration to complete all work before switch off deadline. During this time, SACT & MM have requested that switch off of Canisc be delayed until 19:00 on Friday 17/09/2021. This aligns with RT & OP clinics
2326		Performance and Service Sustainability	Velindre Cancer Centre	Outpatients	Evans, Fran	Stockdale, Ann Marie	Accepted	Operational Services	24/05/2021	03/03/2022		Digital Health & Care Record DHCR030(R) - Service unable to significantly reduce the capacity of clinics over the Go-Live period	There is a risk that the Service will be unable to significantly reduce the capacity of clinics over the Digital Health & Care Record go-live. A Minimal amount of outpatient activities can be paused due to the nature of the service provision. Some non-cancer and follow-up clinics can be reduced however. Clinics will be running at normal capacity - ideal situation on a large go-live would be for reduced clinics for a few days after go-live to allow users a little additional time to get used to the new system.	16	16	9	1. Service managers and teams to be available on site. 2. Training champions/super users to support on site during the Go-Live period. 3. Minimise annual leave as much as possible.
2329		Performance and Service Sustainability	Velindre Cancer Centre	Chemotherapy Administration (inc Bookings)	Evans, Fran	Tranter, Bethan	Accepted	SACT	09/06/2021	03/03/2022		Digital Health & Care Record DHCR034(R) - SACT & Medicines Management – Cashing Up Daycase Clinics	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. There is a risk that the 'cashing up' of the daycase clinics in WPAS (including SACT, Clinical Trials, OPs and ambulatory and supportive care) will not be completed as required. Documentation and performance data will not be accurate. Protracted administrative process causing stress to clinical teams whose primary focus is clinical care.	16	16	16	SACT, Clinical Trials, Supportive care an OP daycase are all scheduled via Chemocare therefore the patient record will be complete in Chemocare Explore requirements for administrative role Attendance data is reviewed manually by the nursing administration team when they process the daycase clinics to change certain attendances to WACs as necessary. This is not comprehensive and does not cover all of the clinics at present.
2328		Performance and Service Sustainability	Velindre Cancer Centre	Chemotherapy Day Unit (CDU)	Evans, Fran	Tranter, Bethan	Accepted	SACT	09/06/2021	03/03/2022		Digital Health & Care Record DHCR035(R) - SACT & Medicines Management – processes of booking/admitting patients	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR035(R) - The process of booking / admitting patients as they arrive in real time on the unit is time consuming and complex whilst clinical staff are concentrating on safe delivery of care Potential risk to patient safety because clinical staff are distracted by the administrative task Documentation will not be accurate impacting on clinical decision making Protracted administrative process causing stress to clinical teams whose primary focus is clinical care	16	16	16	SACT, Clinical Trials, Supportive care and OP daycase are all scheduled via Chemocare therefore the patient record will be complete in Chemocare Explore requirements for administrative role
2432	N	Workforce and OD	Velindre Cancer Centre	Information and Technology	Evans, Fran	Seary, Sarah	Accepted	Whole Service	05/10/2021	03/03/2022		Digital Health & Care Record DHCR036(R) - DHCR Project Support from Service	Risk that DHCR work may be delayed as result of staff prioritising service demands & patient care DHCR036(R) - DHCR project support: Availability of Inpatient Staff, Psychology, Therapies, Infection Control, Clinical Coding, Assessment Unit and Supportive Care staff and CNSs, to support DHCR project due to continued increased demand across all these services. 1. Project timelines could be delayed as training, testing may be seen as secondary to providing clinical care. 2.Once ways of working have been identified, time required to employ, train any additional resource required could impact project implementation.	16	12	4	Update 14.02.22 - Monthly Project Group meetings taking place along with fortnightly Inpatient meetings. Process Maps now completed and signed off by service. Currently looking at resources that may be required to support the new ways of working. Update 10.12.21 - Regular meetings continue to take with project leads. Ways of working almost completed for IC. Some process maps completed and signed off by service. Update 03.11.21 -Regular update meetings scheduled with project team leads to review progress and outstanding work. Attendance at Project Team meetings. Update 27/10/2021 -Dedicated time made available for operational lead. Continuous review of service capacity across the inpatient workstream prioritisation process. Weekly reviews with the Department Leads to monitor progress in DHCR project, but also to sense check the demands of the services.
2440		Performance and Service Sustainability	Velindre Cancer Centre	Chemotherapy Day Unit (CDU)	Evans, Fran	Tranter, Bethan	Accepted	SACT	18/08/2021	03/03/2022		Digital Health & Care Record DHCR046(R) - unable to significantly reduce the capacity of SACT daycase clinics	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR046(R) - SACT & MM service are unable to significantly reduce the capacity of SACT daycase clinics and concern re: reducing pre-assessment clinics over the Go-Live period due to cyclical nature of SACT treatment and potential consequences of delays for SACT patients Mimimal amount of SACT treatments can be paused due to nature of service provision. Clinics are monitored regularly to manage ongoing constraints with capacity.	16	16	6	Regular capacity review meetings by SACT & MM leads to discuss ongoing capacity constraints 23/08/21 - There are a small amount of specific regimens where there is scope to reschedule treatment dates and therefore reduce patient numbers for go-live week. Decision to reduce capacity at go live is a strategic level decision requiring project board/SMT/Exec approval. Risk can only be fully considered when go live date is agreed.
2498		Performance and Service Sustainability	Velindre Cancer Centre	Chemotherapy Day Unit (CDU)	Evans, Fran	Lloyd, Gareth	Accepted	Digital Services	11/01/2022	03/03/2022		Digital Health & Care Record DHCR050(R) - There is a risk that Chemotherapy treatment information is not sent to Canisc post go	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR050(R) - There is a risk that Chemotherapy treatment information is not sent to Canisc post go live. During cutover this interface will be redirected to WCDS and WCRS. However it has been questioned whether this feed would still be required in Canisc, post DHCR golive i.e. would Chemo treatment information still be required for RT and Palliative Care (viewable in Canisc). The assumption would be that as the information would be available as a PDF in WCP, like the other results feeds, if we can get them elsewhere, let's turn the feed off. Additional development/cost maybe CIS,the ChemoCare, provider do not support multiple feeds, InSe would need to do additional work do send messages to multiple systems.	15	15	1	Two decisions required. 1. Turn off the interface (on the proviso that the results are available via PDF in WCP). 2. When should the interface be turned off – a.Precut over with suggested date. b. during cutover c. defined date post cutover
2499		Performance and Service Sustainability	Velindre Cancer Centre	Information and Technology	Evans, Fran	Lloyd, Gareth	Accepted	Digital Services	11/01/2022	03/03/2022		Digital Health & Care Record DHCR051(R) - There is a risk that not all interfaces will be delivered timely for sufficient testin	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR051(R) - There is a risk that not interfaces will be delivered in a timely manner for sufficient testing. * Clinical information will not be available in WCP/WPAS. * VCC runs a clinical safety risk if data is not available for decision support. *Not enough time will be available to provide adequate assurance.	20	20	8	Pressure on DHCW to provide interface on schedule. Testing window is fixed and protected not used as development contingency
2438		Performance and Service Sustainability	Velindre Cancer Centre	Radiotherapy	Evans, Fran	Ikin, Kathy	Accepted	Radiotherapy Services	21/06/2021	03/03/2022		Digital Health & Care Record Risk DHCR043(R) - Completion of process maps and ways of working	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR043(R) - Further maps now having to be drafted due to development of e-IRMER and migration issue. e-IRMER workflow maps required, increased workload for project team, with limited resource.	20	12	9	Project team structure undergoing revision & recruitment planned. Workshop to be arranged to finalise workflow process maps with clinical input
2454	N	Workforce and OD	Corporate Services	No Further Coding Required	Mason-Hawes, David	Mason-Hawes, David	Accepted	Digital Services	29/10/2021	01/05/2022		Digital Services Capacity / Skill Mix	There is a risk that the Digital Services team are unable to support agreed Divisional and/or Trust strategic and operational objectives as a result of limited capacity within the team, which may lead to a delay in the delivery of new / updated digital services.	20	16	8	Regular review of IT work plan, to ensure delivery is aligned to Trust / Divisional priorities. VCC and WBS IT work plans regularly reviewed, to be shared via relevant channels (BPG, SMT/SLT etc.). 'Agile' utilisation of Digital Services resource, to ensure focus on prioritised work.

2461	N	Performance and Service Sustainability	Corporate Services	No Further Coding Required	Mason-Hawes, David	Mason-Hawes, David	Accepted	Digital Services	29/10/2021	01/01/2022		Failure of Building Management System (BMS)	There is a risk of failure to the Building Management System (Trust wide). This is for multiple reasons including being run on legacy operating system (Windows 7), no patch management and faulty hardware - this has led to multiple issues previously.	12	12	4	No controls relevant to suppressing the risk. Machine either requires upgrading, replacing or migrated to a virtual machine.
2394		Performance and Service Sustainability	Corporate Services	Executive Management Team	Wright, Lenisha	Fear, Lauren	Accepted	Governance	21/04/2016	28/10/2021		Fundraising Income Targets	This risk applies to external charities as well as those based on site at Velindre Cancer Centre. However, the control measures and focus of the remainder of this risk assessment relates to onsite charities.	12	12	3	The Trust has a clear fundraising strategy in place. Velindre Cancer Centre's branding guidelines introduced in July 2015 states that: - The Velindre University NHS Trust, NHS Wales, Velindre Cancer Centre and Velindre Fundraising will be the prominent brands on Velindre Cancer Centre premises. - Only 'Velindre Fundraising' and 'Friends of Velindre', charities which raise funds exclusively for Velindre NHS Trust, will be allowed to display publications, materials or media alluding to any form of fundraising on Velindre Cancer Centre premises. - Non-fundraising materials from other charities and organisations will be promoted where there are clear benefits for patients and carers.
2191		Performance and Service Sustainability	Velindre Cancer Centre	Radiotherapy	Maggs, Rhydian	Ikin, Kathy	Accepted	Radiotherapy Services	14/09/2020	31/01/2022		Inability to meet COSC / SCP targets	There is a risk of poor compliance against COSC time to treat targets, potentially affecting patient outcomes and Trust reputation, due to inefficiencies in the current pathway and staffing issues. Staffing risks are raised separately for RT Physics, Radiotherapy and Medical directorate.	20	20	4	Physics mitigation described below: Plans are prioritised by start date to minimise delays. Physics staff are redirected to physics planning during periods of high demand. Weekly RT service capacity and demand meetings monitor position. Increased checkers rota'd for a Friday to mitigate Monday starts. Plan to increase capacity is in progress. 4 additional surge posts have been created in treatment planning with recruitment ongoing (2 surge posts filled internally with backfill recruitment active, 2 filled externally but 1 staff member moved Trust).
2393		Safety	Corporate Services	Health and Safety	Evans, Annie	OBrien, Cath	Accepted	Quality and Safety	19/06/2020	28/10/2021		Infection control	There is a risk that staff could contract COVID-19 in their working environment as a result of poor social distancing or hygiene Majority of control measures in Welsh Government guidance now in place. However the work on site utilisation and linking of this to the capacity planning framework is complex.	12	12	9	To be inserted
2397		Safety	Corporate Services	Health and Safety	Evans, Annie	Evans, Annie	Accepted	Quality and Safety	18/05/2018	28/10/2021		Infection Prevention & Control Service including staff attendance	1.Reduced capacity in the Infection Prevention and Control Team (IPCT) will reduce service provision within Velindre NHS Trust as operational workload will be prioritized. 2.Reduction in microbiology consultant ward rounds due to decreased capacity within the Public Heath Wales laboratories (PHW). Core service continues but educational opportunities will be missed and robust antimicrobial review may not occur. 3.Multi-disciplinary approach to root cause analysis investigation will not occur due to reduced medical input driven by a reduction in the number of doctors within VCC. This will compromise the quality of the clinical review as medical expertise will be absent and opportunities for learning to inform practice will be missed. 4.There has been persistently poor medical attendance at core IPC meetings such as RCA review, AMT / sepsis leading to reduced engagement. This will hinder required service improvement in clinical audit.	16	12	9	Control Measures in place: 1.Risk assessment in place for ICNet and duplication of data entry but it doesn't take into account additional demands of imminent National Enhanced surveillance. 2.Core Microbiology service provision continues but opportunities for learning and clinical review missed as reduction in weekly microbiology ward rounds to every 3/ 4 weeks
2452	N	Performance and Service Sustainability	Velindre Cancer Centre	Information and Technology	Mason-Hawes, David	Daniels, Gareth	Accepted	Digital Services	29/10/2021	01/02/2022		Intermittent IP telephony failure	There is a risk of ongoing (intermittent) IP telephony failures as a result of a recent upgrade to the Wi-Fi central controller, which does not fully support the older Cisco 7925 Wi-Fi IP phones in use across VCC, which may lead to telephony disruption for around 150 users.	15	12	3	New Wifi phones are in stock to replace the critical areas that require upgrades immediately. New Batteries are required to install these which will be ordered ASAP. Plan to replace all 149 handsets ASAP Attempt to fix the issue with the 7925 in the interim.
2456	N	Performance and Service Sustainability	Corporate Services	No Further Coding Required	Mason-Hawes, David	Mason-Hawes, David	Accepted	Digital Services	29/10/2021	01/05/2022		Lack of agreed software development standards	There is a risk that internal / 3rd party software development activity will fail (or be difficult to support) as a result of a lack of agreed software development standards, which may lead to inconsistent approaches to delivery of new software applications Outdated policies and procedures to support software development practices and processes within WBS have resulted in audit failures and the development of software products outside of existing procedures.	16	12	4	Currently software development follows existing guidelines. A Temporary SOP has expired but this is also being followed. Where possible peer review establishes validity of developments and stringent User Acceptance Testing is always followed.
2457	N	Performance and Service Sustainability	Corporate Services	No Further Coding Required	Mason-Hawes, David	Mason-Hawes, David	Accepted	Digital Services	29/10/2021	01/05/2022		Lack of dedicated web / SharePoint development resource within Digital Services	There is a risk that priority strategic / operational web / SharePoint developments cannot be supported as a result of a lack of dedicated web / SharePoint development resource within the Digital Services team, which may lead to a degradation of existing VUNHST websites and/or an inability to develop new website / SharePoint content to meet service needs. Current web development being managed on an ad-hoc basis by WBS Digital Services staff and Corporate Communications team. No dedicated full time support available to be responsive to the demands of the service	12	12	3	Ad-hoc support by trained individuals.
2254		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Fear, Jonathan	Wilkins, Paul	Accepted	Estates	16/06/2020	01/07/2022		Lack of mechanical ventilation at the VCC site (including inpatient ward areas)	This risk has 3 elements – 1. Potential for increased risk of infection due to a lack of mechanical ventilation, 2. Staff and patient discomfort in hot weather due to sub-optimal ventilation, and 3. Breach of Health & Safety regulations and Health & Safety Executive regulation to provide ventilation systems that are sufficient to ensure that high risk patients are protected from exposure to potentially harmful airborne microbiological organisms	12	12	4	Taking each of the three key elements of the risk: 1.Increased potential for infection due to sub-optimal ventilation •Full infection prevention processes are in place, and any patient with suspected infection is cared for in a side room which usually has a window for natural ventilation (in the summer months). 2.Staff and patient discomfort in warm weather due to sub-optimal ventilation •Some mitigations are in place, but further work is required with pace to ensure the well-being of staff and patients during the rest of this summer. •An external specialist will be commissioned to provide recommendations to reduce the heat, and a Task & Finish group has been set up w/c 15/06/20 to develop a hot weather business continuity plan •Further mitigations are being assessed, including use of theatre scrub uniforms for nursing staff and washable cooling blankets and mattresses for patients. 3.Non-compliance with Health & Safety standards due to sub-optimal ventilation across the VCC site •In order to address the sub-optimal ventilation at VCC, an external specialist been commissioned to provide recommendations to feed into the business case.
2252		Performance and Service Sustainability	Velindre Cancer Centre	Radiotherapy	Staffurth, Mr John	Miller, Lisa	Accepted	Whole Service	14/09/2020	01/04/2022		Large number of development projects in Radiotherapy	Large number of development project Multiple development and research projects exist There is no single point of oversight or prioritisation of resource There is poor linkage between projects and the risk register or strategic service/ VCC/ Trust priorities. there is a risk that specialist and scarce resources will be required for multiple project simultaneously as a result of which there will be a reduction in patient pathway resource or a delay in the implementation of a number of projects which may lead to patient pathway breaches or delivery delays agreed within the programs Some Physics developments delayed as redirected resource into paperless planning project and increasing resilience in treatment planning. This enabled staff to work from home and prepared for potential staff absences / future increase in demand	20	15	10	Prioritisation process underway. Program to support delivery Medical Physics and RT Ongoing review of major projects. Core team with resilience approach identified to allow scientists back to project work Program plan for Radiation Services being developed will require resourcing input from IRS nVCC and DHCR
2222		Performance and Service Sustainability	Velindre Cancer Centre	Outpatients	Arndel, Karen	Gent, Carolyn	Accepted	Nursing	07/11/2017	31/03/2022		Loss of CANISC - compromise patient care	There is a risk that as Canisc is an 'end of life' system, it could fail which could compromise patient care. It could mean that some patients cannot be seen in clinic or some would experience long delays. This can lead to increased patient anxiety, frustration and stress for staff, overcrowding in waiting areas and a possible delay in prescribing chemotherapy.	16	12	12	Update June 2021 – DH&CR project continues at pace which includes plans to replace CANISC with WPAS. Regular meetings taking place to review OPD processes and clinics. CANISC BCP remains in place. Implementation of the Document Management Solution – copy of correspondence available electronically on local infrastructure. Correspondence viewable in the Welsh Clinical Portal. Correspondence sent to the GP electronically (via WCCG). Welsh Clinical Portal to link to the Master Patient Index – in the event of Canisc being unavailable this version of the WCP would be invoked enabling access to documents, test results and the GP Summary. Authorised staff members have direct access to Synapse (local infrastructure) – VCC radiology images and reports available to view. Aria and Mosaiq not reliant on Canisc – Radiotherapy treatment can continue in the event of a Canisc outage. ChemoCare decoupled from Canisc and held of local infrastructure – SACT prescribing, dispensing and delivery can continue
2193		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Hooper, Sue	Ikin, Kathy	Accepted	Nuclear Medicine	05/02/2021	30/04/2022		Medical Physics Expert cover for Molecular Radiotherapy (Nuclear Medicine)	Medical Physics Experts (MPEs) for Nuclear Medicine. This risk combines 8438 (submitted by S Hooper – MPE cover for clinical trials) and 15684 (submitted by M Talboys – Ra223 service) on the current risk register and has been expanded to encompass new developments on the immediate horizon. There is a significant risk is that Velindre Cancer Centre will not be in a position to safely and sustainably offer the Molecular Radiotherapy (MRT) demand, likely to be required in the next 12-18 months. This arises because of a lack of experienced Medical Physics Experts (MPEs), the timescales over which the implementation of new MRTs may be required, the predicted increase in workload and the anticipated number of other significant developments which will lead to not being able to implement MRT MPE cover within Nuclear Medicine for MRT has been extremely stretched for a number of years. There has been a large reliance on a single point of failure, for several molecular radiotherapies within Nuclear Medicine. An additional MPE was appointed in November 2018 but the individual appointed had no previous experience in radionuclide therapy (MRT). A temporary solution was implemented to provide MPE support for Ra223 by two individuals not employed within Nuclear Medicine. That offer of support was withdrawn (Jan 2021). Some experience has now been gained by the individual appointed in 2018 but there is now a requirement to provide back-up to that MPE (for Ra223). This is not feasible for the experienced MPE, who is already working in breach of working time directive and trying to respond to a predicted increase in MRT in the next 1-2 years at VCC. (This increase includes repatriation of a therapy to Cardiff from London, a potential large increase in prostate MRT 2022/23 (if NICE approved), personalised dosimetry for MRT patients to comply with legislation and involvement in a clinical trial). Wales is already behind England in implementing some of these treatments into routine clinical care, due to a lack of resilience in MPE support in recent years. Current predictions for MRT is that there will be an 18% compound annual growth (Journal of Clinical Oncology -Feb 2021).	20	16	2	Current control measures include:- Not participating in clinical trials involving MRT Not implementing any new MRT until a safe, sustainable service can be provided Organising workload to minimise the impact of a lack of MPE back-up. Expectation to date has been to ask C&V Medical Physics to provide any additional MPE cover. However, the depth of MPE cover has been critically eroded over the years and recent resignations mean the current position is there will be only 2.5 WTE physicists left by the end of April (only 2.0 WTE being MPEs). One of those MPE is already providing 1 WTE support to VCC under an SLA for over >30 years. This leave 1.0 WTE MPE at C&V. (C&V provides MPE support to other HB as well as its own).
2258		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Walters-Davies, Rhiannon	Tranter, Bethan	Accepted	SACT	17/05/2021	28/02/2022		Medicines at Home Service:	There is a risk that patient pathways and supporting professional procedures and practices (eg SOPs) will not be appropriately or adequately reviewed because of a lack of resource OR that pharmacist attempts to review in the absence of an alternative suitable clinician are clinically insufficient which may lead to patient safety incidents There is a risk to service continuation and sustainability because of limited alternative clinical leadership within pharmacy (or wider SACT and MM Directorate) for the MaH service which may lead to the service needing to be reduced or discontinued with resultant negative impact on SACT and MM capacity and cost savings opportunities. There is a risk to financial sustainability because lack of service resilience may result in the service prematurely ceasing either because of governance issues which could have been avoided OR because of lack of strategic leadership to continue to grow the service. There is a risk to patient experience and patient outcome if the benefits of released SACT service capacity provided via the Medicines at Home Service (oral and parenteral) cannot be maintained and increased There is a risk to VCC reputation because of an inability to progress action plan from RPS audit There is a risk to patient safety because of limited capacity for engagement by medical or nursing to review incidents, learn lessons and instigate remedial actions to reduce the likelihood for future reoccurrence There is a risk to patient safety because of limited resource within current team to review to manage oversight of all complaints and incident	16	12	4	Chief Pharmacist and MaH technician have sufficient baseline knowledge of service to enable short to medium term continuation of the CURRENT service provision
2396		Performance and Service Sustainability	Corporate Services	Executive Support Team	Morley, Sarah	Morley, Sarah	Accepted	Workforce and OD	20/04/2017	28/10/2021		PADRs	Not all employees are receiving meaningful PADRs -PADRs do not underpin the requirement of the Velindre NHS Trust Integrated Medium Term Plan (IMTP) and the Trust Values. -Failure to complete quality PADRs will have direct impact on the All Wales Pay Progression Policy. -Employees do not understand what is expected of them in their role (objectives not agreed for next 12 months) and do not take responsibility for their own performance and development. -Personal Development Plans are not established for next 12 months - missed development opportunities for employees. -The Trust are not easily able to audit the quality of PADRs undertaken.	9	12	6	-PADRs do not underpin the requirement of the Velindre NHS Trust Integrated Medium Term Plan (IMTP) and the Trust Values. -Failure to complete quality PADRs will have direct impact on the All Wales Pay Progression Policy. -Employees do not understand what is expected of them in their role (objectives not agreed for next 12 months) and do not take responsibility for their own performance and development. -Personal Development Plans are not established for next 12 months - missed development opportunities for employees. -The Trust are not easily able to audit the quality of PADRs undertaken.
2255		Financial Sustainability	Velindre Cancer Centre	Private Patients	Stockdale, Ann Marie	Miller, Lisa	Accepted	Private Patients	24/02/2021	31/03/2022		Private Patients Debt	An internal audit under in 20/21 reviewed debt management as one of its objectives. A key area requiring attention was the management of aged debtors by the Private Patient Service. The conclusion was that the aged debtors are not monitored or acted upon and there was no action plan in place to improve the situation. Also that there is no liaison between the private patient service and the corporate finance team. Analysis has shown that debtors go back a number of years and include self paying individuals as well as insurance companies. As at the time of submitting this risk the outstanding amount is £328,791.	12	12	4	1. Full review of all debtors in 2017 and 2018 to assess current situation and recommendation for follow up to be provided to Director of Finance. 2. Action plan developed for Trust Audit Committee which will be monitored by weekly meetings. 3. All debtors to be written to by 5th March 2021 providing 14 day payment period requirement. 3. Meeting arranged to discuss automation of process options. 4. Private Patient Manager to benchmark systems with other organisations. 5. Private Patient Manager to review current Standard Operating Procedures (SOP's) to improve current process. 6. Head of Operations and Delivery to work with Deputy Director of Finance to review Trust SOP's and engagement process. 7. Regular meetings with Private Patient Manager and corporate Finance lead to be established.

2200		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Jenkins, Paul	OBrien, Cath	Accepted	Radiotherapy Services	01/05/2011	31/03/2022		Radiotherapy Capacity	Availability of sufficient radiotherapy capacity within available financial resource affects achievement against national cancer standards. Patients may not be treated to optimum treatment timescales, which may affect the overall patient experience and lead to poorer outcomes. 2/7/19 update Hazards broken down into safety / quality and service sustainability sections. Narrative clarified – risks defined (PJ). This will be linked to Risk 2245 5/11/2021 - Update Currently we have insufficient capacity to meet demand. The number of hours available is restricted due to safe staffing and skills mix. 23/11/2021 - Update Currently we have insufficient capacity to meet demand. The number of hours available is restricted to a maximum due to safe staffing, skills mix, and the age and configuration of the fleet. Any delay in the development of the radiotherapy Satellite centre will significantly limit capacity within the radiotherapy service	20	20	6	Ongoing monitoring of capacity and demand Ongoing monitoring of breaches of waiting times targets Reports and business cases have been prepared Radiotherapy strategy Discussion underway regarding future radiotherapy configuration through the TCS programme Extended working hours are in place on the treatment machines and in many other areas of the service Agency radiographers in place to support additional hours Updated 23/5/19 (PJ) Ongoing monitoring of capacity, demand breaches and waiting times targets. Extended working hours are in place on the treatment machines and in many other areas of service. Agency Radiographers are in place to support additional hours. Changes made to radiotherapy booking processes, and staff flexibility used to maximise use of resources. Project to be commenced to address ongoing capacity led by COO. Implementation of the above measures will not mitigate this risk- further measures required from escalation to Trust board 22/4/20 - We have sufficient capacity at this moment in time due to covid. We have taken 2 linacs out of routine use. One due to it acting as the machine for treating covid + patients, the other is removed as we have halted treating prostate patients. We are working 7-7 shifts on one machine to compensate for the large amount of H+N patients being treated at present. 5/11/2021 - Update Currently we have insufficient capacity to meet demand. The number of hours available is restricted due to safe staffing and skills mix. Mitigation 1.Department is currently working under business continuity, with 2x weekly meeting with SLT, Radiation Service and Radiotherapy Service managers to discuss departmental position and actions being undertaken. 2.Undertaking escalation work to minimise breaches. 3.SST's being asked to review current dose/# offered to patients. 4.Review of trials. 5. All vacancies out to advert. 6. Outsourcing to Rutherford Cancer Centre. 23/11/2021 Update - Ongoing monitoring of capacity, demand breaches and waiting times targets. Development of breach escalation process to ensure, where needed patients are prioritised effectively. - Extended working hours are in place on the treatment machines and in many other areas of service. - Agency Radiographers are in place to support additional hours. Assessment of potential Agency staff experience at point of hire to ensure that Agency staff are able to rotate around more than one work area / linac type / OMS type within
2196		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Payne, Mrs Helen	Payne, Mrs Helen	Accepted	Radiotherapy Services	14/09/2020	01/04/2022		Radiotherapy Department - COVID Isolation Impact	COVID Isolation Impact Staff isolation as a result of coming in to contact with a COVID positive person, exhibiting COVID symptoms or receiving a COVID positive test result will affect the capacity (Linac & Pre-Treatment hours) of the radiotherapy department as the majority of staff are patient facing and are unable to work from home. Resulting in the need to contract the radiotherapy service.	16	16	4	Ability to work from home with relevant IT equipment on completion of DSE risk assessment Isolations rules to be reviewed regularly. 7/5/2021 – risk reviewed by HP & CRD. The risk due to COVID -19 remains despite the relaxation of national regulations. The need to maintain the controls mentioned above continue to ensure safety of staff, patients and the radiotherapy service. 1/11/2021 – risk reviewed by CRD. The risk due to COVID -19 remains despite the relaxation of national regulations. The need to maintain the controls mentioned above continue to ensure safety of staff, patients and the radiotherapy service. 7/2/2022 - risk reviewed by CRD. The risk due to COVID -19 remains despite the relaxation of national regulations. The need to maintain the controls mentioned above continue to ensure safety of staff, patients and the radiotherapy service.
2345		Performance and Service Sustainability	Velindre Cancer Centre	Radiotherapy	Payne, Mrs Helen	Payne, Mrs Helen	Accepted	Radiotherapy Services	14/09/2020	06/12/2021		Radiotherapy Dept - Change to service due continued response to Covid19	There is a risk that there will be a continued change to service as a result of Covid 19 measures which may lead to contraction of the service and the creation of a waiting list As the service moves in to the recovery phase there is a continued risk of the availability of staff being impacted through infection prevention and control measures, thus potentially impacting on the service ability to deliver the required capacity to meet demand 5/11/2021 - Update Currently we have insufficient capacity to meet demand. The number of hours available is restricted due to safe staffing and skills mix. □	9	16	1	Continuing to work through recover phase towards business as usual. Covid contingency plan in place to be deployed if required, ie, deferral of benign, prostate monotherapy, prostate external beam and skin if necessary 'Pod' working in place across radiotherapy clinical delivery service to minimise risk of cross infection Development of outsourcing contract to private provider to deliver external beam for prostate and breast 5/11/2021 - Update Currently we have insufficient capacity to meet demand. The number of hours available is restricted due to safe staffing and skills mix. Mitigation 1.Department is currently working under business continuity, with 2x weekly meeting with SLT, Radiation Service and Radiotherapy Service managers to discuss departmental position and actions being undertaken. 2.Undertaking escalation work to minimise breaches. 3.SST's being asked to review current dose/# offered to patients. 4.Review of trials. 5. All vacancies out to advert. 6. Outsourcing to Rutherford Cancer Centre.
2361		Performance and Service Sustainability	Velindre Cancer Centre	Radiotherapy	Jenkins, Paul	Jenkins, Paul	Accepted	Radiotherapy Services	12/06/2020	01/04/2022		Radiotherapy Dept - COVID Social distancing	COVID Social distancing – Radiotherapy In response to national guidance to reduce the risk of contraction of COVID-19 due to close contact with persons and objects, social distancing measures have been introduced into the radiotherapy department in line with COVID-19 guidance. This may result in reduced capacity and the contraction of the radiotherapy service.	16	12	2	21/5/2021 – Risk reviewed by PJ & CRD. The risk due to COVID -19 remains despite the relaxation of national regulations. High risk staff are no longer required to shield, but are advised to continue to work from home where possible if a safe working environment with VCC cannot be provided. The need to maintain the controls mentioned above continue, to ensure safety of staff, patients and the radiotherapy service. 1/11/2021 – Risk reviewed CRD. The risk due to COVID -19 remains despite the relaxation of national regulations. High risk staff are no longer required to shield, but are advised to continue to work from home where possible if a safe working environment with VCC cannot be provided. The need to maintain the controls mentioned above continue, to ensure safety of staff, patients and the radiotherapy service. 7/2/2022 – Risk reviewed CRD. The risk due to COVID -19 remains despite the relaxation of national regulations. The need to maintain the controls mentioned above continue, to ensure safety of staff, patients and the radiotherapy service.
2502	N	Performance and Service Sustainability	Transforming Cancer Services	No Further Coding Required	Hinton, Tracy		Accepted	New Velindre Cancer Centre	14/01/2022	01/03/2022		Risk of delay to start on site	There is a risk that the start of construction is delayed beyond the date stipulated in the outline planning permission decision notice 17/01735/MJR (27th March 2023), leading to delays to the project and a possible loss of planning permission.	12	12	4	1. Submit section 73 application to extend the date by which start on site must occur, to reduce the impact of any delays to the start of construction. Started 2. Regular monitoring and management of other projects/workstreams which may affect start on site date including enabling works and nVCC procurement. Ongoing
2501	N	Financial Sustainability	Transforming Cancer Services	No Further Coding Required	Hinton, Tracy		Accepted	New Velindre Cancer Centre	14/01/2022	04/03/2022		Risk of Inflation leading to increased costs	There is a risk that increased rates of inflation lead to the capital costs of the project exceeding the affordability envelope.	20	12	12	1. Paper on affordability submitted to WG. Ongoing
2401	N	Workforce and OD	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Bryce, Gavin	Accepted	Integrated Radiotherapy Solution	26/02/2021	03/03/2022		Risk of insufficient resources being made available to the Project	There is a risk that insufficient resources (people) being made available to the project will have an adverse impact on the quality of the procurement process	16	12	8	1) Detailed project Plan to identify resource requirements 2) Approved Capital Budget for the Legal & Staffing Costs 3) Regularly monitor staff availability (annual leave & sickness)
2407	N	Performance and Service Sustainability	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Hague, Andrea	Accepted	Radiotherapy Satellite Centre	17/01/2020	20/05/2022		Risk of overlapping timeframes and interdependancies between RSC & IRS Projects	There is a risk that as the IRS Project needs to be phased in parallel with RSC Project, due to overlapping timeframes and interdependancies resulting in the RSC project being restricted to planning assumptions until the Equipment Project is concluded which has an inherent risk.	16	12	4	1) RSC project requires a clear view IRS Project Risk landscape and links between the 2 projects in terms of risk registers and project plans 2) Ensure design is flexible and futureproof to allow for IRS solution 3) Review impact of delays to IRS Project on RSC Timeline
2249		Financial Sustainability	Velindre Cancer Centre	Finance	Wilkins, Paul		Accepted	Operational Services	27/02/2020	20/12/2021		Risk of service disruption due to number of posts funded by soft monies leading to financial instability,recruitment difficulties	A high proportion of VCC workforce are funded via 'soft monies' from the Trust Charity or Third Sector. This leads to risks around service continuity, recruitment and retention and staff wellbeing. It also poses a financial and reputational risk for the Trust should funding be ceased. For 20/21 there is approximately £2.8 million of charity/3rd sector funding which is supporting service delivery.	12	12	4	Funding ending in the next year to be included in cost pressures for 2020/21. Review posts funded externally to establish: Number of posts, length of funding, contribution to service, and contractual position of postholder. Establish Financial contingency. Through the scrutiny process ensure future risks are considered for all new and extended posts. Prioritise work in order of funding stream end date
2402	N	Performance and Service Sustainability	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Williams, Nicola	Accepted	Transforming Cancer Services	10/05/2021	31/01/2022		Risk of time-consuming infrastructure work	There is a risk that time-consuming infrastructure work i.e. the refurbishment of a current site or identification of a new build is required to deliver the agreed outreach model of care. This could lead to delays in outreach services not being established or operational ahead of the new VCC as agreed within Programme objectives	16	16	9	1) Identify location 2) Identify refurb / new build required 3) Establish level of local engagement with CHCs/public required 4) Identify appropriate resources from all HBs & VUNHST (inc Project Leads, Planning etc) to ensure project is supported and managed to align with project & programme timelines 5) Establishment of ownership and governance of Project within TCS/VF environment
2424	N	Safety	Velindre Cancer Centre	Therapies Areas	Baker, MRS Kate	Baker, MRS Kate	Accepted	Therapies	28/07/2021	25/02/2022		Risk of WT breaches & poor patient experience as a result of reduced Dietetic staffing levels	There is a risk that there could be breaches of waiting times, reduced patient experience and outcomes as a result of reduced staffing levels in the Dietetics department which may and stress on the remaining staff members. Due to x1 maternity leave (Clinical Lead DT) and x1 LTS (band 6 PSU cover) with the Dietetic department the workforce is currently reduced from 5wte qualified staff to 3.5wte. Scrutiny approved 1.0wte band 6 DT and an internal upgrade band 6-7. Unfortunately we did not recruit into either of these posts. Our locum also finished on 7th July 2021. Scrutiny have however approved an external band 7 Clinical Lead DT 1.0wte, which is currently out to advert and in the recruitment process. There is therefore a current risk on the workforce that will hopefully be mitigated by recruitment into the vacant post. For the next 2-3 months, there will not be the required capacity to deliver a high quality, timely DT service. This will lead to breaches of waiting times, reduced patient experience and outcomes and stress on the remaining staff members. We are currently trying to recruit a Locum to cover this period however at present we are unable to secure one.	12	12	6	Remaining DT staff are trained to appropriate levels and clear re what they can and cannot do Clear prioritisation criteria is in place Discussions with Senior managers and exec colleagues to make them aware of situation Locum agency searches. Temporary cessation of some services will be required. Recruitment for the 1x external Clinical Lead Dietitian vacancy is underway
2416	N	Quality	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Williams, Nicola	Accepted	Transforming Cancer Services	30/06/2020	31/01/2022		Risk that COVID may lead to delays on Project progress	There is a risk that potential further waves of COVID may lead to delays that effect the development & key activity of the outreach project	20	12	6	Agreement with HBs of ways of working during any possible covid resurgence to ensure that project is able to continue making progress

2505	N	Performance and Service Sustainability	Velindre Cancer Centre	Human Resources	Wright, Lenisha	Miller, Lisa	Accepted	Whole Service	18/01/2022	31/01/2022		Risk that Covid 19 related absences for staff could significantly impact on ability to provide core SACT and Radiotherapy Servic	Further focus on demand and capacity modelling, linked to current action plan – subject to Gold review 19th January	20	16	6	-SACT staffing - realignment from wards, senior staff deployed, RD&I capacity utilised to full; increased virtual appointments -Radiotherapy - major limitations on capacity due to reduction in workforce but maintaining service with increase in breaches with prioritisation based on clinical need; Changes made to Prostate pathway based on agreed framework; maximising third party provision.
2507	N	Safety	Velindre Cancer Centre	No Further Coding Required	Wright, Lenisha	Miller, Lisa	Accepted	Medics	18/01/2022	31/01/2022		Risk that current regulations in Wales regarding isolation has impacted on patients being able to commence treatment	current regulations in Wales regarding isolation has impacted on patients being able to commence treatment	16	16	9	-Research underway into practices nationally conducted via Silver Command for reporting into Gold -Finalise recommendation for Gold decision, as appropriate, on any changes
2403	N	Quality	Transforming Cancer Services	No Further Coding Required	Pinocci, Francesca		Accepted	Enabling Works	08/06/2020	04/03/2022		Risk that enabling works construction exceeds timescale	There is a risk that enabling works construction, including bridges, exceeds 15 months, leading to delays to nVCC construction and incurring financial loss claims from the MIM contractor.	12	12	9	1. Regular review of possible areas which may cause delay: Most recent review of the plan shows only minimal slack between the end of the enabling works construction and beginning of MIM construction Ongoing 2. Partial mitigation through normal contract condition re liquidated and ascertained damage – where events in the contractors control can result in compensation for costs incurred by the client resulting from time or cost overruns. Need to be within expected reasonable limits. Care required in setting that limit to steer away from punitive damages as few contractor would price the works, pushing up tender prices. Scaling delay damages clause added to tender documentation to ensure contractor is incentivised to complete work on time. Complete 3. Focus to be applied to detailed construction programme following return of EW D&B bids. Complete
2423	N	Performance and Service Sustainability	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Bryce, Gavin	Accepted	Integrated Radiotherapy Solution	08/09/2021	03/03/2022		Risk that IRS evaluation process is delayed due to resource pressures	There is a risk that as the nVCC Competitive Dialogue clashes with the IRS Final Tender evalutation, there is pressure on resource availability leading to delays in finalising the evaluation process	12	12	6	1) Works has started to understand which staff and resource are impacted to explore availability and potential impact of this to the Project
2408	N	Performance and Service Sustainability	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Bryce, Gavin	Accepted	Integrated Radiotherapy Solution	22/04/2021	03/03/2022		Risk that IRS Project FBC is delayed or not approved	There is a risk that the approval for the FBC for the IRS Project is delayed or not approved, due to changes in approval timescales which would lead to delays to project delay, project abandonment impacting on other TCS Projects (nVCC & RSC) deliverables	16	12	8	1) Engagement with Capital & Treasury teams - ongoing 2) Previous presentations to IIB - complete 3)OBC shared with WG Officers for comment - complete 4)WG notified of timescales for FBC so they can align resources - complete 5)Specialist advisors used to support delivery of Business Case - ongoing
2389	N	Safety	Velindre Cancer Centre	Therapies Areas	Seary, Sarah	Cooper, Mrs Vivienne	Accepted	Therapies	28/05/2021	25/02/2022		Risk that patients with altered airways may not receive appropriate care from the MDT clinical team	There is a risk that patients with altered airways may not receive care from the MDT clinical team with the necessary skills and competencies due to the frequency of staff being required to use these competencies (months between patients) and therefore their ability to train and maintain. This situation has been exacerbated by the retirement of a specialist nurse with expertise in airways management. Definition of these patients fall into 3 groups; • Head and neck patients with tracheostomy or laryngectomy stoma. • Respiratory patients requiring suction • Palliative patients requiring suction	12	12	6	Update 10.12.21 - Recruitment underway for a Head & Neck Advanced Nurse Practitioner with interviews taking place w/c 13.12.21. MDT discussions take place pre-admission for this group of patients to assess needs and treatment requirements. Update 03.11.21 - additional mitigating actions: We are currently in the process of recruiting a Head & Neck Advanced Nurse Practitioner whose role will be to provide training for staff in the management of altered airways and ensure that there is appropriate cover for this service. MDT discussions take place pre-admission for this group of patients to assess needs and treatment requirements. Additional training has been sourced from C&V UHB and a Speech & Language Therapist with the relevant skills and expertise has recently been appointed to the VCC Therapies team. •Group 1 patients •1 x SLT works Mon/Tues and Thursday and able to see these patients with good skill level • Advice available from PSU nursing team Mon-Fri in basic competency levels - needs scoping as there is potential for enhancing straining and assessment through this service. •Ward Nursing staff – some basic skills – training needs analysis needs to be completed •H&N CNS and consultant radiographer – skills need scoping but these work Mon-Fri, what are the opportunities for cover across the 7 days? •Training being sourced by nurse education lead •Group 2 & 3 patients •Recent survey of competencies of VCC physios (available on request) with an action plan for roll out to the other disciplines •Establish competencies and work out how best to complete/maintain them •Link with Pall Care to determine a clearer pathway for when suction is required •Benchmark as to what other areas do, i.e. Rookwood, Hospices, Cancer centres. •Explore research further to identify clear precautions/contraindications for certain respiratory techniques for oncology patients •Link with C&V physios and critical care team to access competency based training. •Staff competencies across the organisation to be scoped and potentially access the C&V training for all. •Re-instate the Altered Airways training for clinical staff asap
2405	N	Quality	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Williams, Nicola	Accepted	Transforming Cancer Services	30/06/2020	31/01/2022		Risk that projected growth assumptions for Outreach will be less than required	There is a risk that the projected growth assumptions for outreach delivery of SACT, ambulatory care and outpatients is less than will be required, leading to undersized locations.	16	12	6	1) Re-run projections around growth assumptions. 2) Activity model will be re-run with outputs presented to project Board. Any additional requirments will be presented to the Programme Delivery Board with recommendations. Individual meetings with Health Boards to ascertain their requirments will be undertaken.
2413	N	Performance and Service Sustainability	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Hague, Andrea	Accepted	Radiotherapy Satellite Centre	29/06/2020	30/06/2022		Risk that Radiotherapy Satellite Centre will not have required skilled staff in place to run facility	There is a risk that the Radiotherapy Satellite Centre will not have required skilled staff in place to run the facility once ready to be operational. This would impact on radiotherapy capacity and resilience for the Trust.	15	12	6	1) An integrated Radiotherapy and Physics workforce plan is required to consider the service as a whole taking account of a full operating model that includes current activity, projected activity, IRS and RSU. 2) Provisions from across the whole service will be reconfigured to meet the requirements of the satellite unit.
2418	N	Reputational	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Fear, Lauren	Accepted	Programme	05/10/2020	14/01/2022		Risk that TCS Programme does not have support from Stakeholders	Risk that the TCS Programme does not have support from Stakeholders (pts, HB, politicians, WG, clinicians) Causes - Lack of engagement with all relevant stakeholders/ Misinformation shared from external sources / Inconsistent engagement from specialist resource / Change of views over a period of time / Lack of alignment between TCS programme and other strategic priorities across the organisation and individuals / Political leadership change Consequences - WG and LHBs do not support key decisions / Reputational damage for Velindre Trust as an organisation / Petitions & opposition to plans for TCS Programme / Delays to programme and project progress / Failure to deliver some/all of programme benefits	16	12	4	1) Further engagement is being planned with specialist stakeholders – broader and more targeted who are not fully supportive. Programme Communications resource in place & recruitement of additional comms resource to support comms/engagement activities 2) Better use of technology being reviewed and rolled out to share key messages 3) Variety of stakeholder events held over a number of years - complete 4) Clinical workshops held throughout Programme lifetime - ongoing 5) Professional meeting forums held e.g. DoPs, MDs, CEO's etc - ongoing 6) Ongoing engagement with local elected members (MS, MP, Councillors) 7) Dialouge beteen exisiting cancer forums e.g. cancer leads in SE Wales HBs - ongoing through CCLG 8) Monthly meeting with WG Head of Capital and Director General - ongoing
2400	N	Workforce and OD	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Williams, Nicola	Accepted	Transforming Cancer Services	30/06/2020	31/01/2022		Risk that there is lack of project support	There is a risk that the lack of appropriate project support from the programme will lead to delays in developing the solutions required for the project success.	20	20	6	1) Programme Board will look to allocate resources as appropriate. Funding request to WG to support ongoing work - Ongoing 2) Clarification required on whether Outreach Project is an Operational or an Infrastruture Project - Ongoing TBC
2417	N	Reputational	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Fear, Lauren	Accepted	Programme	08/07/2020	14/01/2022		Risk that there is lack of TCS Programme Comms Plan	There is a risk that there is a lack of TCS Programme wide communications plan resulting in the objectives of projects and interdependant links are not communicated effectively and the wider networked clinical model not understood.	12	12	4	1) Revise TCS website - complete 2) Improve internal TCS teams Comms - complete 3) Improvements to intranet - started 4) Improvements to the link between Programme Governance and Comms - tbc
2410	N	Workforce and OD	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	Morley, Sarah	Accepted	Programme	05/10/2020	18/03/2022		Risk that there will be inadequate and / or insufficient workforce capability and capacity to meet needs of the TCS Programme	Risk that there will be inadequate and / or insufficient workforce capability and capacity to meet the needs of the TCS Programme outputs. Causes - Workforce supply not available in required professionals groups or with required skills / Requirements for workforce capacity and capability no longer accurate. Consequences - Inadequate staffing of Velindre facilities across the SE Wales region / Impact on providing treatment and care to patients	12	12	2	1) Service planning is sufficiently developed to facilitate effective workforce planning techniqies to be applied 2)Ensuring each project has clear and well developed workforce plans which are predicated on clear service plans 3) Clarity of expectations for workforce team involvement 4) Clarity of Role & Responsibility for Workforce planning input team in relation to Project & Programme need 5) Workforce team to support service to ensure the right people are available and allocated to support
2229		Workforce and OD	Velindre Cancer Centre	Velindre Hospital	Miller, Lisa	Miller, Lisa	Accepted	Operational Services	12/03/2019	24/01/2022		Risk to timely communication /engagement activities as a result of dedicated resource leading to low morale, reputational damage	There is a risk that positive communications are not distributed in a timely manner as a result of lack of dedicated VCC resource therefore positive communication is not provided in a timely manner to staff or externally. VCC has no dedicated specialist communication resource to support the patient and staff experience. This limits the processes that can be developed and also poses a risk to media handling. There is no dedicated support to develop social media policy or channels which limits communication options.	12	12	4	Resource increased within corporate communications and TCS teams.

2256		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Tranter, Bethan	Tranter, Bethan	Accepted	SACT	26/03/2020	28/02/2022		SACT / Divisional	Reporting on treatment pathway changes As a result of the COVID-19 Pandemic, it is likely that some patients will not be initiated on a new Systemic Anti-cancer Treatment (SACT) treatment regimen, whilst others will have their current SACT regimens deferred or discontinued earlier than originally planned. It is expected that VCC will be requested to report on the number of patients whose treatment pathway has been affected by the COVID-19 Pandemic. Thus, the number of patients that require deferral or cancellation of their SACT or who are not offered / do not accept SACT must be captured. There is a risk that this data will not be captured correctly / adequately which will result in VCC being unable to report the information	16	12	12	A paper providing an overview of the possible methods which are available to capture this data along with the challenges of doing so was submitted to the VCC Clinical Group on 26.03.20 and accepted. Staff guidelines for clinical staff were sent out in the daily Coronavirus Staff Update via e-mail and also made available in the Coronavirus section of the VCC Intranet 1 - All Clinical Staff to be directed to (where appropriate): - utilise the drop down reason code "COVID-19" on ChemoCare, - include COVID-19 in all Canisc annotations and - include "COVID-19" as the "Description" title when utilising the "Other" tab in Canisc 2 - Clinical Audit Department to lead on the capture on this data and to ensure compliance with these recommendations 3 - Recognition that a solution to identify patients whom have not been referred for treatment to VCC due to COVID-10 has not been identified. 1st Aug 2020 Solutions as identified within the paper were not consistently utilised throughout service. SST Lead and SACT Clinical Lead leading on pieces of work to identify all patients whom have had treatment pathway altered due to COVID. Work of clinical leads continues to endeavour to undertake this work and Head of P and P with BI support providing additional support and insight. This is an important piece of work which will help to identify future SACT demand and thus capacity requirements 12.01.21 - work to identify impact of first wave COVID on patient pathway was subsequently led by planning and performance colleagues and future demands work in on-going. For 2nd wave, clinical colleagues have the message reinforced that use of term COVID-19 is to be used (see above). No further mitigation available to the SACT service.
2243			Velindre Cancer Centre	Velindre Hospital	Membury, Rebecca	Tranter, Bethan	Accepted	SACT	30/06/2021	01/05/2022		SACT staff turnover	There is a risk that SACT Daycase may not be able to deliver care at the current level as a result of staff turnover which may lead to SACT reducing capacity at the SACT Daycase Unit which will impact on patient care and patient experience.	16	12	3	Senior SACT management working in the numbers Clinical trainer working alongside junior staff closed mobile unit on MONDAY Senior staff working on helpline Deputy Director of Nursing undertaking a review on the turnover/retention and education pathways Daily meetings to ensures that staffing levels are appropriate and that if needed patients are clinically prioritised.
2244		Workforce and OD	Velindre Cancer Centre	Medical Physics	Windle, Rebecca	Wilkins, Paul	Accepted	Medical Physics (previously Radiotherapy Physics)	14/09/2020	12/02/2021		Senior Management Capacity	Senior Med Physics Management Capacity is under pressure due to some staff being utilised on IRS Multiple major programmes pull senior staff away from service delivery. COVID exacerbates the situation Separation between service and major programme means there is a loss of continuity and ownership	12	12	4	Deputies for the programs to be identified without affecting service delivery
2245		Performance and Service Sustainability	Velindre Cancer Centre	Radiotherapy	Jenkins, Paul	Jenkins, Paul	Accepted	Radiotherapy Services	12/04/2019	31/03/2022		Service impact of delay in equipment replacement	Service impact of delay in equipment replacement Current provisions for Radiotherapy Services at VCC are based on the assumption that a new Cancer Centre and associated Satellite Centre will be clinical by 2021/22. Delays on these projects will impact negatively on the Radiotherapy Department at VCC. Linear Accelerators have a recommended clinical life of 10 years. In 2019, there are currently 3 (out of 8 (38%)) linacs aged 10 years or above. In 2021 there are currently 5 (out of 8 (62%)) linacs aged 10 years or above. Identified hazards are to be found in the risk assessment attached as a document.	15	12	3	Timely / effective communication with Commissioners / Government re. Linac life, performance etc. Older linacs can receive deep services / upgrades with the intention of extending clinical life. Ability to add functions / services to older linacs / equipment such as RPM / DIBH make this viable. Uptime is maximised by good in-house engineering support. Engineers are very experienced at VCC. Service contracts allow access to Manufacturer's engineers when required. Complaints procedure in case of issues with quality of service. Gaps procedure assist with direction in times of breakdown. Experience and skill of staff allow effective dealing with delays and patient issues. RCR guidelines guide protocols for acceptable prolongation of treatment courses prior to compensation (NB. Latest update suggests that standard 3-week course of breast treatment should ideally not be prolonged for more than 2 days). Regular update of staff from management re. New centre / satellite sites. TCS website, events to publicise new centres. Prioritisation list of latest technologies / innovations, to ensure that patients receive most prudent treatment. 22.7.20. New VCC - IRS cycle 5 ongoing. No update at this point. New linacs for current department tied up with IRS. Satellite - OBC submitted. 20.10.20. New VCC - IRS cycle 5 ongoing. No update at this point. New linacs for current department tied up with IRS. Satellite - OBC submitted. PJ. 25.1.21. Awaiting formal updates on IRS. Currently appraising options for maximising capacity PJ 21/5/2021 – Risk reviewed by PJ & CRD. Risk remains Awaiting formal updates on IRS. New linacs for current department tied up with IRS. Satellite – working on full business case, to be submitted Autumn 2021 1/11/2021 - Risk updated by CRD. Risk remains. IRS evaluation still to be completed. Work started on Breast service contingency to ensure resilience in the event La6 is no longer available.
2455	N	Performance and Service Sustainability	Corporate Services	No Further Coding Required	Mason-Hawes, David	Daniels, Gareth	Accepted	Digital Services	29/10/2021	01/05/2022		TAO Windows Server 2003 Failure (VUNHST Finance)	There is a risk that key Finance activity may be disrupted as a result of a failure of a Windows Server 2003 which hots a key IT application used by Finance, which may lead to an ability to perform critical finance activity (payroll, invoicing etc.). There is currently no resilience / business continuity arrangement in place for this server.	16	12	4	RegKey changes applied to change/add ProviderFlags to 1. New VM has been built to the latest supported version - DO to liaise with Finance for an appropriate upgrade time.
2513	N	Performance and Service Sustainability	Velindre Cancer Centre	Theatres	Millin, Tony	Gallop-Evans, Eve	New risk	Whole Service	09/02/2022	01/08/2022		There are a lack of staff holding a practitioners licence for prostate Brachytherapy	Currently only one staff member has a practitioners licence for Prostate Brachytherapy	20	20	10	Clinical service is dependent on one consultant - another is in training and about to apply for an ARSAC licence
2388		Safety	Velindre Cancer Centre	Outpatients	Stockdale, Ann Marie	Miller, Lisa	Accepted	Nursing	18/06/2021	31/03/2022		There is a risk of high temperatures, increased spread of infection a result of lack of ventilation	OPD Environment - Temperature of the Outpatients department There is a risk that during the summer months, due to a lack of ventilation and air conditioning in the outpatients department, the temperature exceeds that which is comfortable or safe for patients and staff. There is a risk that due to the extremes of heat, patients and staff could become unwell. Wall mounted fans should not be used due to covid restrictions.	12	12	8	Doors and windows left open where possible to increase ventilation. Staff providing cold drinks to patients in the department throughout the day. Increased seating outside the OPD entrance. Staff issued with lightweight scrubs. Staff to take regular breaks to ensure they remain hydrated.
2428	N	Compliance	Velindre Cancer Centre	First Floor	Miller, Lisa	Wilkins, Paul	Accepted	Nursing	02/08/2021	31/03/2022		There is a risk of increased infection transmission due to poor ventilation.	Concerns have been raised around the poor ventilation and seasonal extremes of temperature that exist within inpatient areas at VCC impacting both staff and patients, this risk assessment relates to First Floor (FF) ward. Patients receiving care in the inpatient ward at VCC are often immunocompromised and/or neutropenic and therefore would benefit from improved air quality which can only be guaranteed through a compliant mechanical ventilation system. See document for full description	16	16	9	UPDATE 14.02.22 from Mark David - A temporary air con solution will need to be installed for this summer (as per last year setup) with the hope of the ventilation BC being signed off later this Summer. Next steps will be for service to sign off decant plan so it can be included in the BC, this can then be signed off by SMT, EMB and then forwarded on to WG. UPDATE 03.11.21 - Further detailed planning to be undertaken by estates and operational services teams in conjunction with nursing team with timescales and decant plan. * Infection control and prevention measures in line with Trust polices. Including regular audit, training, enhanced cleaning etc. * Additional COVID19 precautions - Use of PPE, regular testing of patients and staff etc. * Full root cause analysis undertaken to ascertain cause(s) of any infections. * Business Case currently under development to seek funding for compliant ventilation system.
2236	N	Quality	Velindre Cancer Centre	Outpatients	Miller, Lisa	Stockdale, Ann Marie	Accepted	Operational Services	08/04/2019	31/03/2022		There is a risk of poor patient experience as a result of insufficient space and poor environment	The design of the OPD department is not fit for purpose, there is a lack of available accommodation, insufficient space in waiting area, the reception desk is not ideally placed and the fabric of the area is in poor condition.	15	12	12	1. Nurse 'rounding' in place to monitor patients on regular basis 2. External 'canopy' waiting area 3. Information provided explaining visiting restrictions but process in place to call relatives into consultation if appropriate 4. High level of virtual consultations 40-50% 5. Clinic planning and preparation undertaken daily 6. Task and Finish Group to lead repatriation of OPD and phlebotomy to HB's 7. Service improvement programme to reduce waiting times, improve experience etc 8. Appointment system implemented for phlebotomy appointments
2248	N	Safety	Velindre Cancer Centre	Velindre Hospital	Seary, Sarah	Cooper, Mrs Vivienne	Accepted	Nursing	29/10/2020	31/03/2022		There is a risk that non-compliance with COVID-19 Health Regulations may place staff and patients at higher risk of infection	There is a risk a risk that that non-compliance with the Health Protection (Coronavirus Restriction Wales) Regulations 2020 could place patients and staff (FFW, CIU) at increased risk of infection and contracting COVID-19, resulting in illness. Regulation 7A of the Health Protection (Coronavirus Restrictions) (Wales) Regulations 2020 dictates: - that all reasonable steps have been taken for staff to work from home; - when they are in work environment, all reasonable steps have been taken to maintain a 2m distance; - and where people cannot be 2m apart, everything practical done to manage transmission risk.	16	12	12	Update 14.02.22 - Social distancing still in place; enhanced cleaning and full IPC measures still mandated. IPC team continue to monitor compliance and undertake regular clinical practice and environmental audits in all departments. Update 10/12/21 - Regular updates and guidance given by IPC Team to all staff to remind them of IPC requirements. Enhanced cleaning still in place; social distancing measures remain in place; cleaning wipes and sanitiser freely available along with face masks. Mitigation -Cleaning regime reviewed as part of changes made, e.g. all ward staff including visiting staff wearing suitable PPE (e.g. cleaners, admin, pharmacy, RT etc.) -Hand Sanitiser stations installed -Hand washing posters at sinks -Sterilising materials, wipes, spray etc available for all staff -Enhanced hand washing regime -Staff who can work from home being assessed and if applicable currently doing so -Care taken to manage 2m space where applicable -Social distancing posters -If appropriate reduce amount of staff in working area where applicable. The FFW offices, are areas where social distancing is unable to be maintained for hand overs etc.PPE is provided for use on the FFW at all times. Process constantly reviewed against guidance. Analysis and then clear signage of occupancy levels in appropriate areas if applicable Enhance cleaning practices for all equipment as per standard and covid regulations. UV cleaning of rooms for high infections. Testing for staff with symptoms as per covid guidelines. Zoning during outbreak. COVID Patient pathway to minimise interaction with staff and other patients. Reduction of beds Restricted visiting in lines with All Wales Guidance. Patients are triaged on admission and rapid testing prior to admission to FFW

2188		Compliance	Velindre Cancer Centre	Velindre Hospital	Miller, Lisa	Miller, Lisa	Accepted	Operational Services	18/04/2018	24/01/2022		There is a risk that services cannot be expanded to meet demand as a result of lack of accommodation which may affect service de	Lack of physical space to accommodate the current service requirements, statutory building note requirements, health and safety standards and other legal requirements at Velindre Cancer Centre. This risk affects all areas within VCC. A number of internal and external audits have demonstrated a significant lack of physical space within all areas of VCC. COVID 19 pandemic has further reduced available site capacity by 40-50%. Increased provision of clinical services and workforce requiring additional space. Requirement for Digital Programme Team to return to VCC site in view of DHCR replacement programme, testing and training requirements etc.	12	12	6	1. Ongoing review of current accommodation to ensure best use and maximisation. 2. Review service models and the balance between on site and outreach services to make best use of all resources. 3. Implement changes in working practices where appropriate (e.g. working from home, extend the working day) 4. Office sharing principles reviewed in light of COVID19 which has led to reduction in available office accommodation due to 2m rule. 7. Open plan and flexible working. 8. Additional space within CRW to be utilised as a temporary measure for Digital Programme Team as part of DHCR Programme. 9. Non-critical staff relocated from VCC site or WFH under COVID principles. 10. Capital bids placed and timelines produced. 11. Business case submitted to WG for Fire Improvement work. 12. Business case being produced for ventilation improvements in clinical areas. 13. Trust has entered into formal lease agreement with for additional accommodation (Bobath). This has provided space for some staff displaced due to social distancing and to allow wellbeing space for staff. 14. Reassessment underway of corporate and other staff on VCC site that can be relocated to other Trust premises. 15. SACT and ambulatory care services operating extended hours, bank holidays and some Saturday working.
2515		Performance and Service Sustainability	Velindre Cancer Centre	Radiotherapy	Millin, Tony	Millin, Tony	New risk	Whole Service	09/02/2022	27/05/2022		There is a risk that staffing levels within Brachytherapy services are below those required for a safe resilient service	"Brachytherapy Staffing Levels at Velindre are low and recruitment and retainment of staff is not at the level required. There are a number of staff nearing retirement. There are also staff on maternity leave, sick leave, sabaticals etc. affecting staffing levels day to day." "There are a number of single points of failure within the service with a lack of cross cover, loss of single members of key staff could interupt patient treatment. Loss of trained staff leaves the service with a number of additional single points of failure. Training times are often long and impact on staff's current role. Staff can be sought from university cohorts but these are limited and the time required to train them to work within the Velindre service means they are not direct replacement for lost staff"	15	15	5	Capacity is managed by careful examination of rotas, refusing leave and redeployment of staff from other areas. A programme of training sufficient staff to cover all areas and a review of staff numbers is taking place
2514	N	Quality	Velindre Cancer Centre	Radiotherapy	Millin, Tony	Millin, Tony	New risk	Whole Service	09/02/2022	29/04/2022		There is a risk that Standard Operating Procedures (SOPs) within Brachytherapy are not up to date	Key staff have not been available to review the SOPs due to work pressures and reviews are not routinely undertaken at an operational management level SOPs could be outdated which could potentially lead to the standard operating procedures at Velindre not aligning to National requirements, or requirements for patient safety. Staff could be operating in a sub-optimal way to treat patients.	16	16	4	Following the retirement of the former Head of Brachytherapy Physics, ownership of RT physics documents has transferred to another member of staff who is reviewing SOPs. Similarly a review of documentation is taking place within Radiotherapy
2517	N	Financial Sustainability	Transforming Cancer Services	No Further Coding Required	Hinton, Tracy		Accepted	New Velindre Cancer Centre	14/02/2022	01/03/2022		There is a risk that the competitive dialogue participants tenders excced the CAPEX limit leading to increase project costs and	CAPEX There is a risk that the competitive dialogue participants tenders excced the CAPEX limit leading to increase project costs and potential delays.	12	12	12	1. Discuss with Welsh government.
2431	N	Performance and Service Sustainability	Transforming Cancer Services	No Further Coding Required	Lewis, Bethan	James, Carl	Accepted	Programme	23/07/2021	31/12/2021		There is a risk that the impact of Covid-19 on Programme activity will continue to cause longer-term disruption	There is a risk that the impact of Covid-19 on Programme activity will continue to cause longer-term disruption resulting in potential misalignment of project activity and as such further impacts to Programme Plans and Deliverables	16	12	4	1) Project plans being reviewed with programme support to ensure they are up to date and where projects are now 'unpaused' to bring plans in line with more mature projects. Complete 2) Master Programme Plan updated to reflect update to projects and to show dependencies across projects and programme activity. Complete 3) Review and reporting on Master Plan to PDB and Scrutiny committee. Ongoing
2486	N	Quality	Transforming Cancer Services	No Further Coding Required	Pinocci, Francesca		Accepted	Enabling Works	07/12/2021	04/03/2022		There is a risk that the Section 278 application takes longer than expected to be approved,	S278 Application There is a risk that the Section 278 application takes longer than expected to be approved, meaning that works traffic accessing the 'straight' TCAR are delayed, leading to a delay to construction and longer overall construction timeline.	9	12	6	This application process has started.
2220		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Windle, Rebecca	Maggs, Rhydian	Accepted	Medical Physics (previously Radiotherapy Physics)	07/11/2018	28/02/2022		Treatment Planning System End of Life	There is a risk that some patient treatment plans cannot be completed as a result of the OMP treatment planning system breaking down and being past end of life, which may lead to inability to plan / treat sites not transferred from OMP. The Oncentra MasterPlan treatment planning system is end of life and is no longer be supported by the manufacturer. A replacement treatment planning system, RayStation, is being commissioned but due to understaffing within physics, and a change of priorities due to Covid, commissioning is taking longer than initially estimated. Should a catastrophic failure of OMP occur at this point in time (March 2021) the centre will be without a planning system for the Varian 2100 machines (breast patients), and 10 MV treatments on Truebeam and Elekta machines. There is a risk that the existing treatment system will fail and without the implementation and alternative no planning system for all breast patients to be treated	15	15	1	Most physics developments are on hold to redirect resource to the commissioning of RayStation. Commissioning plan is in place. Outsourcing contract in place and being utilized with Rutherford Detailed contingency plan is being worked through
2198		Financial Sustainability	Velindre Cancer Centre	Velindre Hospital	Miller, Lisa	Miller, Lisa	Accepted	Operational Services	29/12/2017	13/12/2021		VCC mayface financial loss, legal action, inaequate service provision as a result of no coordinated system for SLAs, contracts	VCC has numerous contacts and SLA's for services delivered by NHS organisations and external companies. To manage such legal agreements it is crucial to have robust governance structures for the development, management, monitoring and renewal of such documents. There are a lack of processes, clarity regarding responsibility regarding responsibility, management etc and a varied level of monitoring.	16	16	6	Specialist procedure advice via NWSSP Agreement for planning team to take ownership (delayed due to COVID) VCC Planning team to take responsibility for establishing database and monitoring mechanism
2213		Performance and Service Sustainability	Velindre Cancer Centre	Velindre Hospital	Evans, Fran	Daniels, Gareth	Accepted	Digital Services	09/07/2018	01/05/2022		VCC Phone System - External Phone Lines	There is a risk that external telephony services in VCC may be disrupted as a result of the ongoing use of the 'end of life' PBX gateway ISDN30 line, which may lead to the inability to make inbound and outbound external calls, resulting in significant disruption to clinical / patient and administrative services.	16	12	4	22 phone lines are strategically placed around VCC site to enable dialling to public telephones in the event that an ISDN30 line is lost. Discussion with supplier commenced. Capital funding to be secured for delivery of resilient SIP.
2251		Compliance	Velindre Cancer Centre	Radiotherapy Physics	Windle, Rebecca	Jarvis, Richard	Accepted	Medical Physics (previously Radiotherapy Physics)	18/03/2016	30/03/2022		XVI imaging termination faults resulting in repeat acquisitions	There is a risk that the patient will require an additional CBCT scan to confirm treatment position as a result of a known fault with XVI which may lead to additional patient imaging dose. Under new IRMER guidance if 3 scans are required to achieve 1 usable dataset this becomes reportable. This fault is known UK wide issue. When using XVI CBCT (Elekta only), faults are occurring intermittently during the image acquisition. This is resulting in repeat image acquisitions needed which increases the overall dose the patient is receiving from imaging. It is also worth noting that these scans usually terminate part-way into the scan. If a full additional scan is acquired the patient will receive a maximum of 2 - 20 mGy additional dose, which is <0.1% of a typical treatment dose. CBCT imaging is essential to verify correct patient position during treatment, ensuring the radiotherapy treatment targets the tumour and spares Organs at Risk and critical structures. This is a known issue nationally and Public Health England and HIW are aware.	15	12	6	1. If a patient is having a routine offline XVI CBCT and the unit faults during acquisition attempts should be made to clear the fault and carry on. If the radiographers cannot clear the fault themselves the engineers should be contacted for advice. One further attempt at a full scan is permitted. If this fails then the CBCT should be repeated on the next fraction on an alternate unit. A Datix should be completed for all failed scans that cannot be continued from the point of failure. Scans that can be continued should still be recorded in the machine log. 2. For online scans the same as above applies but if a second scan fails then the patient should be moved to an alternate machine prior to treatment. 3. When a patient receives a total of 2 extra partial scans due to faults, then a superintendent must be informed, and the patient must be moved by the radiographers on-set to another LA for the remaining imaging fractions. 4. All partial scans to be recorded on the imaging form. 5. Radiotherapyl Physics and the treatment superintendents must be informed if the units are regularly failing during a day, and these failures recorded in the unit log book. 6. Additional dose contributions are calculated for all patients affected and recorded in the Datix incident system. 7. Failure rates are reviewed weekly during the multidisciplinary linac status meeting and fault causes are actively investigated.

ID	Risk Type	Division	Approval Status	Review date	Title	Risk (In Brief)	Rating (Initial)	Current Rating	Rating (Target)	RR - Current Controls
2187	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	31/03/2022	Radiotherapy Physics Staffing	There is a risk of the radiotherapy physics team being unable to complete core and developmental tasks due to inadequate staffing. This may result in - patient treatment delay - Radiotherapy treatment errors. - key projects not keeping to time e.g. commissioning of essential systems - suboptimal treatment - either due to lack of planning time or lack of developmental timeExample of areas of the service currently considered as routine that are detrimentally impacted by the lack of resource include i. Completion of incident investigations, reports and learning, essential to prevent future radiotherapy errors and incidents and improve local practice ii. Inability to provide engineering cover during weekend quality control activities iii. MPE advice on, and review of, treatment protocols to ensure they are in line with national guidelines whilst also appropriate for local practice iv. Development of workflow processes to increase efficiency v. Delays to the commissioning of new treatment techniques / service developments e.g., Partial Breast Irradiation (PBI) and Internal Mammary Node Irradiation (IMN) vi. Delays in performing local RTQA slowing opening of new trials and thus reducing recruitment of Velindre patients to trials compared with other centres (e.g. PACE C) vii. MPE support for imaging activities providing imaging to the radiotherapy service inside and outside VCC. Background The ATTAIN report highlighted that in comparison to the Institute of Physics and Engineering in Medicine (IPEM) guidance, Radiotherapy Physics were under resourced by approximately 25%. The IPEM recommendations for the provision of a physics service to radiotherapy are recognised as a benchmark for minimum staffing guidance. The Engineering Section in particular is identified as an area of risk to the radiotherapy service. Not only are staffing numbers significantly under those recommended by IPEM but the age profile of this team is of concern, with up to 6 engineers planning to retire within 5 years. Linac engineering is a specialist area requiring in depth knowledge of complex machines and requires training to work at high voltages in a radiation environment. This is particularly critical with the age profile of our current linac fleet. The effects of incorrect repairs and / or maintenance can be significant on the patient and it is vital that this area is sufficiently resourced. Skill mix within physics enables most staff to be redirected to physics planning in order to meet fluctuating demand in the pre-treatment pathway and minimise patient delays and breaches. However, this negatively impacts on other essential core duties.	25	15	5	Radiotherapy Physics workforce remains below recommended (IPEM) levels. Additional surge funding has been utilised alongside IRS funding to increase recruitment in the short term. The service head has developed an outline workforce plan, looking at roles and responsibilities and demands on the service, mapping out the essential BAU activity, critical projects and programmes of service development to implement a prioritisation if activity and resource utilisation. Whilst the situation to establish a full complement of staff in the service remains a challenge, development of a medium term workforce planning, and long term workforce strategy, with HEIW and W&OD colleagues continues alongside recruitment there will need to be support to focus on service critical projects. These have been determined as DHCR replacement, IRS and nVCC. Recruitment is underway to mitigate this risk, currently at 15, as this resource will cover the business critical programmes. This is subject to dynamic risk assessment due to the anticipated shortage of appropriate candidates.
2253	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Availability of CANISC System	There is a risk that clinical/patient services across VCC would be critically endangered as a result of the prolonged loss of CANISC, which may lead to significant patient harm and treatment delays due to the lack of availability of critical clinical information for VCC clinical staff. In the event of a catastrophic CANISC system failure, Velindre Cancer Centre would have no electronic patient record and radiotherapy workflow management systems. In this scenario patient care would be seriously compromised, for inpatient admissions and /or outpatient appointments. Electronic access of patient medical histories would not be available or limited to a point in time to guide care decisions. This would lead to the unavailability of clinical information to support decision making. As well as loss of patient administration activities tasks including the booking and processing of outpatient and inpatient activity, clinic lists etc.	15	15	5	Full geographical resilience for CANISC was restored in August 2021 following completion of the migration of national IT services out of the Blaenavon Data Centre (BDC) by DHCW. This means the CANISC service can be 'failed over' to the new 'CDC' data centre in the event of there being issues in the primary 'NDC' data centre. This significantly reduces the risk of the permanent loss of CANISC services. In the event of CANISC becoming unavailable for short periods of time, access to relevant clinical documentation is aviable via alternative systems - e.g. - WCP CANISC Case Note Summary to provide historic record - Chemocare (existing patients) - Welsh Clinical Portal (WCP) for viewing all results, documents and Canisc CaseNote Summary. - WCP is linked to Master Patient Index (MPI) to access patient demographic information - Welsh Results Reporting Service (WRRS) for all VCC radiology reports - Paper Radiotherapy Workflow (IRMER) - Manual Registration - new patients on Chemocare - Manual Registration - new patients on Aria and Mosaiq - Availability of Clinical correspondence created at VCC in Document Management System (DMS) from April 2019 that feeds into Welsh Clinical Record Service (WCRS) - Access to paper record that holds inpatient documentation, charts etc
2205	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	31/01/2022	CANISC failure	Currently the CANISC electronic IR(ME)R form is the only way for the Oncologist to request a CT simulation scan and subsequent radiotherapy treatment for all patients bar emergencies. It is also the system used to manage the complex radiotherapy pre-treatment workflow and to document and authorise the detailed dose information for a patient plan prior to treatment. This documentation and authorisation is required under the IR(ME)R 2017 regulations. If CANISC is unavailable, there is no “fall-back” method for the above tasks. Business Intelligence (BI) data is also sourced from the electronic IR(ME)R form in CANISC, the loss of which will reduce the ability for BI reporting, forecasting and modelling. CANISC will no longer be available from September 2021, with the long-term IR(ME)R form replacement (part of the IRS) not being fully procured and in-house until around this time. CANISC will no longer be available from September 2021, with the long-term IR(ME)R form replacement (part of the IRS) not being fully procured and in-house until around this time. No longer applicable - can be removed	25	15	9	Engagement with NWIS & DCHR to develop MVP ongoing. DCHR-led project underway. Initial option appraisal highlighted high likelihood of gap between CANISC and OIS; several discussions occurring to confirm this and identify optimal bridging solution. Approved Design in place for WCP IRMER as an interim solution - this now is subject to acceptance testing of the software delivery by VCC service leads
2260	Compliance	Velindre Cancer Centre	Accepted	01/01/2022	Control of Asbestos at VCC	Working on the infrastructure or fabric of the building and causing the release of asbestos which may endanger patients, staff, visitors and contractors.	15	10	5	Large areas of Asbestos have already been removed from Velindre Cancer Centre. Trust Asbestos Policy and Management Action Plan in place. Supervision on site has received “Management of Asbestos in Building Training” (P405). VCC has and maintains an asbestos register which Estates staff can access. The maintenance ducts have been identified as having asbestos material within them; maintenance staff have been informed not to enter these ducts. Safe systems of work are in place at VCC, all jobs competed by Estates staff are automated through the FACTS system which locates any asbestos in the working area and records them on the job sheet identifying the risk as Level 1, 2, or 3. Estates staff have completed Asbestos Awareness Training within the last 12 months. Estates staff complete Health and Safety training. Contractors are given tool box talks before being allowed to work on site which includes information on Asbestos and known locations. Prior to any destructive works on site Refurbishment and Demolition Surveys are completed. Socotec are the appointed consultants to support professional advice and assistance. Annual asbestos inspections are also undertaken. Annual staff Asbestos Awareness Training delivered.
2447	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Cyber Security - Cleartext credentials stored in memory	There is a risk of a cyber security breach as a result of due to the storage of account credentials in 'cleartext' format, which can be leveraged and result in a loss of IT services across VCC.	20	10	5	Controls in place to prevent attackers from reaching the network i.e Firewalls, ACLs etc. However, if an attacker did access the network there are very little controls in place that would prevent lateral movement.
2444	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Cyber Security - CVE-2019-0708 BlueKeep Vulnerability	There is a risk of a cyber security breach as a result of the presence of the CVE-2019-0708 BlueKeep vulnerability within the VCC network, which may lead to the disruption or loss of IT services across VCC.	20	10	5	Affected Radiology services are protected behind IT security (firewalls - external to NHS Wales) with access to those systems limited to a small number of named access.

2442	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Cyber Security - End of Life Desktop/ Client Operating Systems on the VCC network	There is a risk of a cyber security breach as a result of the ongoing presence of devices within the VCC network running the legacy Windows Operating System (Windows 7, XP etc.), which may lead to the disruption or loss of IT services across VCC.	20	10	5	National Firewalls. Anti-virus controls in place.
2458	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Cyber Security - End of Life Server Operating Systems on the VCC Network	There is a risk of a cyber security breach as a result of the ongoing presence of servers within the VCC network running the legacy Operating Systems (Server 2003, Server 2008 etc.), which may lead to the disruption or loss of IT services across VCC. There are numerous end of life server operating systems within Velindre Cancer Centre (including Windows 2003 & 2008), which increases the risk of a successful cyber-attack as these devices are not appropriately patched and vulnerable to exploit.	20	10	5	Current controls in place include Firewalls (DHCW), Antivirus software (Mcafee and Defender), access control lists and network segmentation.
2450	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Cyber Security - Inactive Edge Firewalls on VCC Servers	There is a risk of a cyber security breach as a result of VCC server firewalls being in 'passive' mode (meaning communications are not filtered), which may lead to the disruption or loss of IT services across VCC.	20	10	5	National firewalls used as protection for VUNHST.
2451	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Cyber Security - No Client Firewalls on VCC devices	There is a risk of a cyber security breach as a result of the lack of client firewalls on VCC devices, which may lead to the disruption or loss of IT services across VCC.	20	10	5	National firewalls in place. Anti-virus may mitigate malicious software, if attempted.
2448	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Cyber Security - NTLM hashed credentials stored in memory	There is a risk of a cyber security breach as a result of NTLM hashed credentials being stored in memory, which can be leveraged and result in the disruption or loss of IT services across VCC.	20	10	5	Controls in place to prevent attackers from reaching the network i.e Firewalls, ACLs etc. However, if an attacker did access the network there are very little controls in place that would prevent lateral movement.
2445	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Cyber Security - Risk of malicious payloads not being blocked by anti-virus (McAfee)	There is a risk of a cyber security breach as a result of malicious payloads not being blocked by VCC anti-virus (McAfee),, which may lead to the disruption or loss of IT services across the VCC.	20	10	2	VCC currently migrating to Defender Anti-Virus and will be moving towards Defender DLP. Mcafee still in use on various servers and DLP enabled.
2460	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Cyber Security - Risk of privilege escalation on local user accounts	In the event of a successful cyber attack against Velindre Cancer Centre there is a risk that a local user account could be leveraged, to the spread the attack further due to excessive privileges.	20	5	5	Controls in place include national firewalls, Anti Virus & ACLs.
2446	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/05/2022	Cyber Security - Weak Passwords in use on Admin / Privileged IT accounts	There is a risk of an external agent compromising VCC admin/privileged IT accounts as a result of the use of weak passwords in use within the VCC Digital Services team, which may lead to a cyber security breach and/or the loss of IT services across VCC, resulting in the disruption or loss of IT services across VCC.	20	10	5	Various Cyber Security tools in place including national firewalls, AV and ACLs which provides defence in depth. Work ongoing to remove weak passwords.
2512	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	03/03/2022	Digital Health & Care Record DHCR022 (R) - Business Continuity Risk following Implementation	Please note this risk has been raised as part of the Digital Health & Care Record (DH&CR - Canisc Replacement) programme and is ratified and managed via the DH&CR Project Board. DHCR022 - A potential business continuity risk following implementation. Currently the WCP is used to access case note summaries for patients in order to provide business continuity when Canisc is unavailable. The impact in this risk would be felt after go-live but could impact on service delivery. This is potentially a service risk but will be considered and summarised for the project risk register and discussed further at the next Project Board Meeting	15	15	12	DHCW to develop a solution as this would have an effect on every HB when they have an Electronic Patient Record

2261	Safety	Velindre Cancer Centre	Accepted	30/09/2022	Lack of electronic prescribing at Teenage Cancer Trust	There is a potential safety risk to Teenagers and Young Adults who are under the care of VCC and TCT and therefore can be admitted to either facility. Currently VCC and TCT have two different systems, VCC operate an e-prescribing system whilst TCT still use paper prescriptions.	16	10	4	Experienced medical and nursing staff - familiar with both processes. TCT staff have access to CANISC but any changes to dose etc. would be via chemocare. The actual dose prescribed will be transferred to Canisc in the next version of chemocare. Pharmacy staff clinically check script(only if access to medical records/prior treatment). Inpatients will receive visit from pharmacist/med recs/clerking but this is not always the case for outpatients so its probably a highter risk for outpatients. Business case is being developed for an all Wales National e-Prescribing solution (single solution). VCC to provide input and implement procured solution. Timescales to be confirmed. 31.08.20 - Working group has been established between VCC Pharmacy, UHW Pharmacy and wider UHW TCT reps since Feb 2020. An interim work around solution has been developed to enable TCT access to VCC ChemoCare and thus for the prescribing of regimens to occur electronically. Development of the SLA continues TCT to be included within VCC version 6 training and roll out programme subject to SLA agreement. With interim work around solution in place, risk= 5x2=10 11.05.21 – Workaround in place between UHW and VCC Pharmacy Dept continues to be supported with no safety issues or concerns noted. ChemoCare version 6 roll out will be paused in June 2021 due to overlap of implementation of DH and CR replacement and Wellsky and impact on staff training. Roll out (to include TCT) will re-commence post implementation and embedding of these 2 systems which is likely to be Autumn 2021 (date TBC). 27.05.21 – UHW informed that implementation is temporarily paused as above. VCC will continue to install and test latest patch (version j). Subject to successful UAT, VCC and UHW will liaise to determine if there is a) an immediate need for roll out to TCT ahead of the VCC programme, b) whether VCC can resource such a roll out and c) consequences to VCC of VCC clinicians utilising version 6 ahead of VCC site rollout.
2252	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/04/2022	Large number of development projects in Radiotherapy	Large number of development project Multiple development and research projects exist There is no single point of oversight or prioritisation of resource There is poor linkage between projects and the risk register or strategic service/ VCC/ Trust priorities. there is a risk that specialist and scarce resources will be required for multiple project simultaneously as a result of which there will be a reduction in patient pathway resource or a delay in the implementation of a number of projects which may lead to patient pathway breaches or delivery delays agreed within the programs Some Physics developments delayed as redirected resource into paperless planning project and increasing resilience in treatment planning. This enabled staff to work from home and prepared for potential staff absences / future increase in demand	20	15	10	Prioritisation process underway. Program to support delivery Medical Physics and RT Ongoing review of major projects. Core team with resilience approach identified to allow scientists back to project work Program plan for Radiation Services being developed will require resourcing input from IRS nVCC and DHCR
2262	Safety	Velindre Cancer Centre	Accepted	01/07/2022	Releasing passenger lift release	In the event of a person being trapped in a lift, they will need to be released in a manner that will not endanger themselves or others.	10	10	5	The lift release key has been removed from Switchboard and has been placed in the Estates key safe to prevent unauthorised use. Staff will not release people or the lift be lowered by manually hand winding unless they have been trained on that lift in accordance with BS 7255 (training has been provided by OTIS). Furthermore there must be at least three members of staff available if the lift is to be lowered by manually hand winding. Persons trapped within a lift are only to be assisted out of a lift if they are within 200mm of a landing. A maintenance contract for lifts at VCC which includes the releasing of persons have been set up with OTIS Lift Company. Any derogation from the above in an emergency situation must be discussed with a senior member of the Estates Management team prior to any action. British Engineering insurance inspections are also undertaken on all lift throughout the Trust.
2336	Safety	Velindre Cancer Centre	Accepted	01/01/2022	Risk of injury or ill health to Estates staff whilst working in a lone working environment	Risk of injury or ill health to Estates staff whilst working in a lone working environment and a possible delay in receiving medical treatment in the event of an adverse event. Due to slips, trips and falls, contact with machinery, contact with electricity, serious illness, overcome by noxious fumes, falls from height or coming into contact with an aggressive violent person.	15	5	5	Safety shoes with non-slip soles provided. Hard hat areas identified or hazard tape used to identify bump hazards. Toughened gloves available. Two way radios are available should the Estates worker deem them necessary. Machinery has guards to prevent entrapment. Trained qualified staff to work within their capabilities. Staff carry Cisco WIFI phones and/or mobile phone. Some plant rooms have telephones Permit to work required for electrical work. Ongoing program to barrier roof areas. Violence and aggression training is provided. Health and Safety training is provided. All plant rooms have automatic smoke detection. Co2 detector is fitted in the main boiler house. All boiler rooms have ventilated doors. Regular boiler maintenance is carried out. Basic Life Support training level 1 with practical CPR for maintenance technicians is delivered. Outside stairs are illuminated. Medical staff available on site should a medical emergency occur. Maintenance staff will assess the need to use a safety person when required (out of hours Security may be used or a member of Estates staff may be requested to return to work to assist). All chemicals being used will have a COSHH risk assessment.
2338	Safety	Velindre Cancer Centre	Accepted	01/07/2022	Risk of injury or ill health to staff whilst working in subterranean ducts (confined space)	Maintenance staff working in confined spaces such as the subterranean service ducts to either run in new services or to maintain existing ones. The ducts are not full height and therefore staff will have to crawl along these spaces. In the event of a person collapsing, difficulties would arise with emergency evacuation. Issues noted when working in confined areas include, but are not exclusively, cramped conditions, heat, gas, fire/explosion, radon gas, exposure to asbestos and problems carrying out an emergency evacuation in the event of injury or illness.	15	5	5	Staff not trained in confined spaces are prohibited from entering confined spaces under any circumstances, therefore should an occasion arise when entry to a confined space is required out of hours and an untrained Estates worker is on call, he will have to contact one of the confined space trained tradesman to assist. Members of the Estates department have received confined space training and two have received confined space supervisory training. Lighting has been upgraded in the ducts. An asbestos removal has taken place in the ducts, however residual asbestos is still in the Horseshoe and main duct therefore Estates workers are not to enter either the Horseshoe or main duct. An asbestos survey was carried out in the Whitchurch duct and no asbestos was recorded (additional sampling is to take place). Staff have completed Health and Safety training. Hot works permit to works are in use on site. PPE is available for all members of Estates (this includes CAT B disposable suits and over boots, FP3 masks, safety shoes, and gloves). A personal gas monitor is used by the Estates team. Sub-contractors competency to access confined spaces is confirmed prior to any works being undertaken by sub-contractors within the confined space. Risk assessments and method statements are provided for all tasks undertaken by sub-contractors. Currently, access to the main service ducts has been prohibited to the Estates staff.

2339	Safety	Velindre Cancer Centre	Accepted	01/01/2022	Risk of injury to staff whilst using single and double extension ladders and steps	Risk of injury to staff whilst using single and double extension ladders and steps.	15	5	5	Operative using ladder will inspect before use and report any defects. Safety man should be utilised when required. Barriers are available should they be required. Steps and ladders are regularly inspected and results are documented. Ladder training provided to staff.
2340	Compliance	Velindre Cancer Centre	Accepted	01/01/2022	Risk of injury to staff, patients, visitors if equipment hasn't been PAT tested	There is a potential risk of injury to building users if equipment have not been PAT tested.	15	5	5	No equipment to be used on site unless it has a valid PAT sticker. Patients equipment is tested and PAT sticker is applied (staff are responsible for informing Estates via the FACTS system of patients' equipment which requires testing. Industry Guidelines consulted to decide frequency of testing for IT equipment (every three years). Medical equipment is tested by Bio engineering (outside of the Estates remit). All other equipment is tested annually. Asset register of appliances created during testing by contract labour. Department managers are informed prior to annual testing taking place within their department. Any incidents regarding portable electrical equipment are raised on DATIX and discussed at the Electrical Safety Group.
2341	Safety	Velindre Cancer Centre	Accepted	01/01/2022	Risk of injury to staff/contractors when working at height where there is a lack of edge protection	Injury to persons from falling from roof, and exposure to radiation whilst being on the roof.	5	5	5	Method statements and permits to access roofs from contractors. Working at heights has been a topic during team meetings to raise Estates staff awareness. Roof edge protection fitted to commonly accessed areas. Access to roof areas controlled through gate and locking system.
2342	Safety	Velindre Cancer Centre	Accepted	01/07/2022	Risk of patient using curtain track as ligature point	Risk of patient using curtain track as ligature point.	10	5	5	Approved contractors will install and validate anti ligature curtain rails where it has been identified via discussions with department managers as they are required.
2400	Workforce and OD	Transforming Cancer Services	Accepted	31/01/2022	Risk that there is lack of project support	There is a risk that the lack of appropriate project support from the programme will lead to delays in developing the solutions required for the project success.	20	20	6	1) Programme Board will look to allocate resources as appropriate. Funding request to WG to support ongoing work - Ongoing 2) Clarification required on whether Outreach Project is an Operational or an Infrastruture Project - Ongoing TBC
2513	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	01/08/2022	There are a lack of staff holding a practitioners licence for prostate Brachytherapy	Currently only one staff member has a practitioners licence for Prostate Brachytherapy	20	20	10	Clinical service is dependent on one consultant - another is in training and about to apply for an ARSAC licence
2515	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	27/05/2022	There is a risk that staffing levels within Brachytherapy services are below those required for a safe resilient service	Brachytherapy Staffing Levels at Velindre are low and recruitment and retainment of staff is not at the level required. There are a number of staff nearing retirement. There are also staff on maternity leave, sick leave, sabaticals etc. affecting staffing levels day to day." "There are a number of single points of failure within the service with a lack of cross cover, loss of single members of key staff could interupt patient treatment. Loss of trained staff leaves the service with a number of additional single points of failure. Training times are often long and impact on staff's current role. Staff can be sought from university cohorts but these are limited and the time required to train them to work within the Velindre service means they are not direct replacement for lost staff	15	15	5	Capacity is managed by careful examination of rotas, refusing leave and redeployment of staff from other areas. A programme of training sufficient staff to cover all areas and a review of staff numbers is taking place

2472	Safety	Velindre Cancer Centre	Accepted	31/03/2022	There is a risk that there is a traffic accident on site which may lead to someone being injured or damage to vehicles	All car parking areas on site. Vehicle movements on site including Staff, patients, deliveries and contractors. Pedestrian walkways on site. Specific risks include adverse interaction of vehicles and or pedestrians, slips trips/ falls, theft and vandalism.	15	10	5	Hazards identified: LPG storage cage close to road with no bollard protection (behind LA 2 and 3) Large vehicles encroach on coming traffic on narrow roads Pedestrians getting hit by cars Poor lighting resulting in slips, trips ,falls List control measures in place: Car park: 5mph speed restriction. Directional flow traffic system and road marking in place. Information signage directing visitors to the different departments on site. Designated ambulance parking areas and Ambulances fitted with audible reversing warning signals. Designated patient drop off/ pick up areas. Designated disabled parking spaces and pharmacy collections. Patient parking located near entrances allowing easier access for users. No parking zones are in place around the site and clearly visible. Dropped kerbs in place with tactile surface for pedestrians. Road and pavement surfaces in good condition. Drainage is good with no evidence of excess water holding during period of heavy rain. Junctions are clearly marked for right of way. Digital speed signs in place to show drivers their speed. Pedestrian crossings in place. No contractor parking on site unless essential to works and prior agreement must be made, with areas/ spaces agreed for use. Bollards are in place to protect the temporary waiting area (Marquee) from any traffic at the entrance to out-patients. Max height signage in place at main entrance to warn drivers because of canopy. Deliveries: Any planned deliveries using large vehicles are arranged to take place outside of patient hours, usually 6am with bollards/ barriers removed where needed and vehicles martialled into place. Any un-planned large vehicles/ deliveries are martialled through the site where possible, the junction to radiotherapy/ stores can be used to turn them around. Large vehicles might have difficulty accessing stores area for delivery so unloading may take place on road near the junction to the stores, and items moved by pallet truck to the stores. However, deliveries to the stores are mostly vans, they reverse un-aided to stores entrance. Waste: Waste contractor collections are mostly before 7am there are exceptions to this with SDCL
2220	Performance and Service Sustainability	Velindre Cancer Centre	Accepted	28/02/2022	Treatment Planning System End of Life	There is a risk that some patient treatment plans cannot be completed as a result of the OMP treatment planning system breaking down and being past end of life, which may lead to inability to plan / treat sites not transferred from OMP. The Oncentra MasterPlan treatment planning system is end of life and is no longer be supported by the manufacturer. A replacement treatment planning system, RayStation, is being commissioned but due to understaffing within physics, and a change of priorities due to Covid, commissioning is taking longer than initially estimated. Should a catastrophic failure of OMP occur at this point in time (March 2021) the centre will be without a planning system for the Varian 2100 machines (breast patients), and 10 MV treatments on Truebeam and Elekta machines. There is a risk that the existing treatment system will fail and without the implementation and alternative no planning system for all breast patients to be treated	15	15	1	Most physics developments are on hold to redirect resource to the commissioning of RayStation. Commissioning plan is in place. Outsourcing contract in place and being utilized with Rutherford Detailed contingency plan is being worked through
2343	Compliance	Velindre Cancer Centre	Accepted	27/07/2021	Water Systems - Legionella	Maintaining the water systems free of Legionella at the Velindre Cancer Centre using a range of monitoring and control systems for water treatment and flushing across the VCC site. Continual improvement to remove redundant pipework and upgrade water systems where possible.	20	5	5	Regular monitoring of water temperatures. Regular testing and sampling. HEPA filters on shower outlets in the patient areas. Risk assessment and audit of water system by external consultant. Water Safety Group in place with appropriate members which meet regularly. Water Safety plan and written scheme are in place. Pre-planned preventative maintenance are also on FACTS and are routinely undertaken by competent staff. Removal of redundant pipe work where possible. Legionella management policy in place. Responsible person trained. Water sampling regime has been constructed and reviewed by Water Safety Group members and is currently in place on all sites.

ID	Division	Approval status	RA Date	Title	Description	Controls in place	Current Risk Rating	Review date
16894	Welsh Blood Service	Final approval	28/10/2021	Transfusion associated acute lung injury risk reduction strategy	WBS supply of apheresis platelets from female or previously transfused donors, not screened for HNA antibodies	Donor screening identifies donors that may have experienced sensitising events (previous transfusion/pregnancy) but without HNA antibody screening is not able to mitigate the risk of these antibodies being present.	5	07/05/2022
16900	Welsh Blood Service	Final approval	18/10/2021	Apheresis Premises at Velindre cancer Centre	Velindre Cancer Centre Hospital building	Hospital facilities are inspected by an external contractor (Hurley & Davies). The VCC collection suite has been licenced by the HTA and will be regularly inspected by the WBS. H&S, Fire inspections regularly undertaken.	5	18/10/2022
16809	Welsh Blood Service	Final approval	06/09/2021	Malaria Risk – Delay in Implementation of the Process to Support Amended Malarial Testing for a Specific Donor Group	Non-compliance with donor assessment based on the JPAC Donor Selection Guidelines for donors with MALR, MALF and MALP risks. No malaria discretionary test is undertaken following re-exposure to a malarial risk for donors in this group.	This issue has been fully discussed at JPAC / SACTTI-(Parasites) group. The MHRA have laisied with the Chair of JPAC- the conclusion is that whilst WBS practice is safe, the recommendation is to align WBS practice with other UK Services. By definition all these donors will have tested negative for malaria at their first donation - this part of the process is robust. It is the subsequent testing post re-exposure that is missing.	5	06/09/2022
16762	Welsh Blood Service	Final approval	13/08/2021	Supply Chain disruption of Blood Collection tubes	All other tubes not on the shortage list (10ML, 6ML etc)Update-17/08/2021	"Internal stock take and regular monitoring and management of WBS stock position. Stock holding of 8 weeks supply at present. Stock projection received from BD for coming months and identification of WBS allocation."	10	18/03/2022
16780	Welsh Blood Service	Final approval	22/04/2021	Transport of Donor Records to and From WBMDR Collection Centre	Transport of paperwork that may contain donor personal identifiable information (PII)	Paperwork transported by WBMDR staff is kept to the minimum required (note: all WBMDR documentation only contains the minimum required PII to facilitate the collection). Staff are aware of the GDPR requirements, and have received training in Information Governance. Information and training provided by the WBMDR and stated in the standard operating procedure for the stem cell/PBL collection (SOP HUB-903). Staff advised to drive directly between the WBS and the collection centre unless absolutely necessary to stop or divert. Paperwork stored together securely (in a closed folder or bag) and out of sight in the vehicle.	5	22/04/2022
16788	Welsh Blood Service	Final approval	16/03/2021	Apheresis Premises at Nuffield The Vale Hospital	Nuffield the Vale Hospital building	Hospital is HIW inspected, HTA licenced and inspected by the WBS. H&S, Fire and HIW inspections regularly undertaken.	5	16/03/2023
16398	Welsh Blood Service	Final approval	11/12/2020	Review of modules used in Oracle Finance & Procurement System - GxP impact	Purchasing - used to manage the procurement of both stocked items (using the Inventory module), and non-stocked items (using the IPROC module).	Functionality verified in CQ test scripts for IPROC and Inventory (Note: issues would only be identified in the Live environment during CQ testing)	12	25/04/2022
16467	Welsh Blood Service	Final approval	27/11/2020	Receipt, Storage and Distribution of Covid 19 Vaccines	Recording time of vaccine removal from -80 freezer	Labels printed with time Print labels before removal of vaccine from freezer risk treatment - validate printed labels	5	22/10/2022
16295	Welsh Blood Service	Final approval	22/09/2020	Use of Female Plasma for Manufacturing Pooled Cryoprecipitate	WBS Cryoprecipitate made from female donors not tested for HLA/HNA antibodies	"Prevention 2) Low level of plasma from each donor, reducing any potential antibody concentration"	5	12/04/2022
16266	Welsh Blood Service	Final approval	15/09/2020	Inability to secure venues during response /recovery plan for Covid-19 - Impact to Blood Supply Chain	Inability to operate clinics at the same efficiency verses pre-Covid 19 due to social distancing and IPC measures/amount of donors able to attend venue due to social distancing measures.	Escalated to the Director of WBS And Chief Operating Officer for VUNHST, Head of Planning Logistics and Resource to submit SBAR outlining emerging situation and required support. Explored with MOD available venues. Ongoing dialog with PHW and WG about conflict between vaccination and WB venues. Update 28/01/2021 - A number of Health Boards have not yet responded to email , those that have showed that there will be some conflict with venues in certain regions. Working on proof of concept for use of trailers in a socially distanced environment, Also looking at options around a potential fixed site.	12	01/08/2022
15973	Welsh Blood Service	Final approval	19/05/2020	Exposure to Potential Pre-symptomatic, Asymptomatic Individuals at Verification Sample Procurement, Donor Information, Medical A	Donor Exposure to potential pre-symptomatic, asymptomatic individuals at VT sample collection - Performed by a Health Care at Home under contract to the WBMDR.	Assurances received from Health Care at Home that correct protocols are being implemented with regards to social distancing and use of appropriate PPE.	5	06/03/2022

16009	Welsh Blood Service	Final approval	18/05/2020	Social Distancing measures within the Laboratory environment (Lab Services and WTAIL)	See attached FMEA	See attached FMEA. Reviewed FMEA attached. Risk further reduced by staff vaccination program. All other measures remain in place. GS, 27/05/21	5	27/05/2022
15937	Welsh Blood Service	Final approval	04/05/2020	Covid-19 implications of handling biological samples within the WBS	Handling of untested or presumed COVID-19 negative samples for laboratory testing	Appropriate staff training, supervision and comptetence. Good laboratory practice. Use of standard laboratory PPE including nitrile gloves and labcoats. Risk treatment plan and recommended actions: All staff should be aware that there is the potential for any sample to be positive for COVID-19, as patients or donors may be asymptomatic. If appropriate, all primary samples should be centrifuged and left for at least 10 minutes before decapping to reduce aerosol risk. Centrifuge bucket lids must be used to reduce aerosol production risk in the event of tube breakage. Aerosol-generating or potential splashing procedures should be performed in a Class-2 microbiological safety cabinet if possible and appropriate. If these cannot be performed in a cabinet these procedures must be identified and additional proportionate controls put in place, such as capping of tubes, safety screens or PPE. Local Risk assessment within each laboratory should be performed to identify these procedures. Update 06/01/2021. Vaccination for all front line/lab staff has ben tolled out, Increased UK testing capability, increased use of PPE for all staff. No evidence of laboratory COVID-19 transmission has been seen, and no evidence (either locally or worldwide) that COVID-19 has been transmitted by aerosol from laboratory samples.	5	05/10/2022
15932	Welsh Blood Service	Final approval	23/04/2020	Impact of COVID-19 stabilisation phase to WBS	Re-introduction of elective procedures including Haematology activities. WBS are aware that WG have written to all Health Boards regarding the re-introduction of this work.	VUNHST planning team and WBS blood health team are liaising with hospitals to determine future demand. Existing MOU with the UK blood services to support in the event of a shortage in a blood component. WBS planning team have forecasted future collection models based on potential scenarios. Currently working on a proof of concept around trailer use in a socially distanced environment and also considering fixed site options.	12	12/08/2022
15533	Welsh Blood Service	Final approval	27/09/2019	Manual Double Entry of Test Results in Automated Testing - Contingency Process	Manual entry of test results which are normally interfaced directly from an analyser into BECS.	Components from a positive donation are physically removed from the supply chain by Automated Testing staff.	5	14/06/2022
15456	Welsh Blood Service	Final approval	11/07/2019	Clinical RA for not providing HbS negative red cells	HbS negative blood not supplied by WBS as recommended by JPAC guidance	"- low incidence of HbS in Welsh population (0.02% in 2013) '- Most HbAS units block leucodepletion filters and don't make it to a usable donation"	5	25/08/2022
15373	Welsh Blood Service	Final approval	27/06/2019	Risks associated with MAK-System introduction of new interfacing policy for devices connected to ePROGESA	Increased complexity of networking / integration architecture in respect of the middleware used to interface devices that require interfacing to MAK-System products (e.g. ePROGESA). Additional costs incurred for establishment and maintenance of interfaces to MAK-System products (e.g. ePROGESA).	Ability to liaise with suppliers during procurement to advise on WBS preferences in respect of middleware arrangements for connected devices. MAK have recently confirmed "non partners" will still be permitted to interface devices to ePROGESA and other related MAK services. Subject to ongoing monitoring and discussion via International MAK-System User Group (IMUG).	12	31/08/2022

15398	Welsh Blood Service	Final approval	06/06/2019	Facilities Infrastructure	Electrical circuitry is not installed to current standards	Not installing any new equipment until power supply has been updated..	10	19/08/2022
15297	Welsh Blood Service	Final approval	29/04/2019	WBS Cyber Security Attack or Breach	WBS Systems and Services	Antivirus software deployed to detect threats. Device control deployed to limit access to removable devices. E-mail messages are scanned for threats and spoofing by NWIS. Web browsing is via a proxy server that scans for viruses and malicious content. Software updates are rolled out to address vulnerabilities in operating systems and key applications. Firewalls are enabled at device level as well as network levels to restrict access from unwanted systems. Newer operating system deployments are harden against security baselines recommended by suppliers and NCSC. Regular backups of critical and key data. Vulnerability scanning conducted against WBS devices. Phishing exercises targeted at WBS users	10	22/04/2022
15261	Welsh Blood Service	Final approval	01/04/2019	Microsoft Windows 7 and Server 2008 R2 End of Support	Windows Server 2008 R2 server operating system (ePROGESA)	Server operating systems are protected by local and network firewalls - this limits which devices can access the servers. Antivirus software provides detection and remediation against known threats. Internet usage and E-Mail is generally blocked from servers. System have been hardened against best practices. General users are only able to access limited parts of the ePROGESA environment, for example, Database Servers are not accessible	10	04/01/2023
15262	Welsh Blood Service	Final approval	01/04/2019	Oracle Java 8 End of Support	Oracle Java Runtime Environment	Java environment has been hardened to limit where applications can be launched from. Client operating systems are protected by local and network firewalls - this limits which devices can access the clients. Antivirus software provides detection and remediation against known threats. Removable media controls limit threats from USB/DVD drives. Internet usage is monitored to protect from web and downloadable threats. E-mail messages are scanned for threats. System have been partially hardened against best practices	5	22/04/2022
15189	Welsh Blood Service	Final approval	22/01/2019	Red Cell Antibody detection on the PK7300	Failure to detect high level anti-D on PK7300 - impact on Apheresis donations - not neonatal	None	5	13/01/2023
14764	Welsh Blood Service	Final approval	09/10/2018	Brexit - Implications of Exiting the EU - No Deal Situation	Increased expenditure	Public Contract Regulations Budgeting and financial controls	20	06/04/2022
14744	Welsh Blood Service	Final approval	03/09/2018	Abbott Microbiology Platform	Result Transfer to eProgesa	WBS Procedures Peer Review	5	13/01/2023
14508	Welsh Blood Service	Final approval	09/07/2018	Management of Work Place Related Stress	Could affect every activity within WBS including collections, processing and distribution etc. of blood products	Policy (Trust wide Mental Health , Wellbeing and Stress Management WF43) Toolkit to support Good Mental Health, Wellbeing and Reduce Stress. Employee assistance programme All Wales Wellbeing Tool Kit Stress risk assessment (completed by manager with staff member) Sickness absence policy Manager Training Mindfulness / complementary therapy Team Assistance Organisation Development facilitated discussion and mediation Organisation change RA Blood Supply 2020 relating to stress. Work life balance - flexible working. Health and wellbeing - Cycle to work scheme to promote healthy activities. Monitoring of sickness and absence reasons and levels. PADR process - clear roles and responsibilities. Manager support. Update Oct 2019 Continue to monitor sickness and absence levels WBS Sickness and Absence Deep Dive Stress Related Absence document produced Dec 2018 Ongoing wellbeing initiatives Initiatives introduced to look at finances - Home finances impact on stress Menopause Policy developed and initiatives to look at this introduced (Menopause Café) which impacts on work place stress	12	01/08/2022

14215	Welsh Blood Service	Final approval	06/03/2018	Risks associated with the implementation of Prometheus into WTAIL	Failure of WTAIL to meet its regulatory obligations (e.g HTA)	URS signed off and agreed. Regular meetings with supplier to ensure URS requirements are fulfilled. Regular communication with supplier in respect of changing/ new regulatory requirements. Development complete. Update 13/10/2020 UAT is complete.	10	01/04/2022
13311	Welsh Blood Service	Final approval	08/11/2017	Reprinting Group Labels for overweight imported red cells	Reprint group label for imported red cell which is overweight (outside maximum volume parameter)	"NHSBT & SNBTS have an automatic discard set for components that are overweight/ over-volume (i.e. all Blood Services comply to the Red Book Guidelines and have their processes controlled accordingly). Laboratory staff identify non-conforming donations.	5	12/04/2022
12342	Welsh Blood Service	Final approval	29/03/2017	Use of the External Plasma Freezer	Safety of staff whilst using the freezer	None (PPE)	5	01/11/2022
12104	Welsh Blood Service	Final approval	02/02/2017	Movement of WBS personnel within the service yard area	Staff movement in the service yard .	Designated speed limit of 10 mph within the service yard area. Entrance gate controlled from central point (reception). Entrance gate is kept closed and access to the service yard is via intercom. Adequate lighting located in service yard area. All transport department staff and CCA drivers who use the service yard are provided with a service yard awareness briefing. This is undertaken as part of their training and is detailed in the training booklet prepared by transport department. Donor Services personnel and facilities staff are issued with hi visibility jackets /vests to wear when working on service yard area and this is a compulsory requirement. Transport and Facilities staff provide hi visibility jackets/vests to visitors and these visitors are escorted whilst on the service yard. Additional controls include hi vis paint work, periodic service yard inspections, contractor leaflet read and understood before work commences. CCTV coverage of the service yard.	10	01/08/2022
11522	Welsh Blood Service	Final approval	17/10/2016	Antibody detection by Luminex based technology	Detection of HLA antibodies by Luminex based methods	sample collection requirements are stated in WTAIL user guide. samples are only taken by trained phlebotomists and nursing staff. Acceptance of results based on review of patient history as and when available and take into consideration patient own type. Platelet cases require increment data for review of increment levels to determine further support required. Multiple samples are tested for those patients requiring long term support.	10	29/10/2022
9515	Welsh Blood Service	Final approval	03/07/2015	WBMDR Sterile Tube Welder	Sterility	Documented system at Collection centre (by two individuals) to check docking undertaken correctly (recorded on form WBM-551). Use of standard concession system (SOP 566/HUB) in the event of a dock failure. Routine sterility testing of all HPC products (100% testing)	5	04/11/2022
8719	Welsh Blood Service	Final approval	17/12/2014	GMP-0273 (Premises)	Storage area	Restricted access to authorised staff only. Physical segregation of product from routine blood stocks. Clear identification as HPC product	5	20/11/2022
8706	Welsh Blood Service	Final approval	15/10/2014	GMP-0062 (PBSC Collection)	Collection of product	pre-assessment of veins by 2 different healthcare practitioners. BM collection available as possible back-up	5	09/02/2023
8712	Welsh Blood Service	Final approval	15/10/2014	GMP-0066 (Assess Donor Fitness)	Failure to receive completed report in time for 'Final Clearance'.	None	5	09/02/2023
8717	Welsh Blood Service	Final approval	15/10/2014	GMP-0071 (HPC Storage & Transport)	Storage of PBSC/PBL	Stored in GMP monitored area of WBS. Stored in secure area. Controlled product release.	5	05/11/2022
8713	Welsh Blood Service	Final approval	15/10/2014	GMP-0067 (G-CSF administration)	Incorrect dose.	Prescription calculated according to SOP by consultant with nurse. Dosage actually given is recorded on prescription at time of administration.	5	03/03/2023
8715	Welsh Blood Service	Final approval	15/10/2014	GMP-0069 (Final Release)	Product Inspection	Visual inspection of each bag in accordance with documented procedure. Documentation to allow audit trail. Formal concession system to account for any sterile docking failures. 02/11/2016 No change to control measures required.	5	09/02/2023
8707	Welsh Blood Service	Final approval	15/10/2014	GMP-0063 (PBL Collection)	Collection of product.	IDM Testing and Lifestyle questionnaire performed	5	09/02/2023
8708	Welsh Blood Service	Final approval	15/10/2014	GMP-0064 (Whole blood for immunotherapy)	Donor Fitness for purpose	IDM testing and lifestyle questionnaire	5	26/11/2022

7746	Welsh Blood Service	Final approval	02/04/2014	Liquid Nitrogen supply system for TT1-17.	DATIX 2725 - transferred from paper assessment	Wall mounted oxygen depletion sensors- which are regularly serviced and tested (SOP: 008/FAC), linked to an audible and visible alarm in the area and an alarm on the Environmental monitoring system (EMS). In the event of an alarm staff are instructed to leave room TT1-17 immediately: Calibrated personal oxygen depletion monitors in use; Exhaust ventilation for the room, which alarms on the EMS system if it fails; Two emergency stop buttons, one inside the room, one outside to cut-off liquid nitrogen feeding to cryogenic vessels in the event of an over-fill; Overfill or fan failure will cause nitrogen supply to be stopped by emergency cut-off valves, PPE including eye protection BSEN166 (2002) goggles and full-face safety masks (supplied in area), special blue cryoprotective gloves of various sizes. and Lab coats; Safety rules detailed in POL(S)009, including a “buddy system” outside normal hours; Restriction of access, cleaners instructed not to work in the area unless supervised by WTAIL laboratory staff; Safety Training given to new staff at induction; Staff trained to POL(S)-009, and SOP 001/TTY for working with biological agents; Regular servicing of cryogenic refrigerators, and system pipe work by specialist external contractors; Warning signs; Overfill and low pressure alarms on individual units linked to EMS; On-call staff available to respond to alarms out of hours; Laboratory Safety procedures POL(S)-009 instructions on spillages; COSHH assessment completed; First aid; Management of liquid nitrogen system covered by SOP: TTY/112. Annual insurance inspection, CCTV in yard and alarmed external doors near external tank.	5	15/04/2022
7736	Welsh Blood Service	Final approval	31/03/2014	Liquid nitrogen storage and retrieval of frozen cells - room TT1-17	DATIX 3482 - transferred from paper assessment	Wall mounted oxygen depletion sensors- which are regularly serviced and tested (SOP: 008/FAC), linked to an audible and visible alarm in the area and an alarm on the Environmental monitoring system (EMS). In the event of an alarm staff are instructed to leave room TT1-17: Calibrated personal oxygen depletion monitors in use; Exhaust ventilation for the room, which alarms on the EMS system if it fails; Two emergency stop buttons, one inside the room, one outside to cut-off liquid nitrogen feeding to cryogenic vessels in the event of an over-fill; PPE including eye protection BSEN166 (2002) goggles and full-face safety masks (supplied in area), special blue cryoprotective gloves of various sizes. and Lab coats; Safety rules detailed in POL(S)009, including a “buddy system” outside normal hours; Restriction of access, cleaners instructed not to work in the area unless supervised by WTAIL laboratory staff; Safety Training given to new staff at induction; Staff trained to POL(S)-009, and SOP 001/TTY for working with biological agents; Regular servicing of cryogenic refrigerators, and system pipe work by external contractors; Warning signs; Written instructions on safe manual handling displayed on wall; Steps available to aid access to vessels for staff as required; Risk assessment on manual handling carried out by Hu-tech; Laboratory Safety procedures POL(S)-009 instructions on spillages; COSHH assessment completed; First aid; Management of liquid nitrogen system covered by SOP: TTY/112.	5	04/02/2022
7137	Welsh Blood Service	Final approval	07/11/2013	Electrophoresis in WTAIL Molecular Genetics - analysis of PCR-SSP reactions by agarose electrophoresis	DATIX 3486 - transferred from paper assessment	SOP: MOL/022 Safety policies POL(S)-009, POL(S)-007 Training PAT testing Visual inspection during cleaning Intact lids prevent access to energised liquid or electrodes whilst in use. Annual H&S inspection Use of electrophoresis will significantly reduce due to implementation of new technologies - will only be used for HPA typing. Technique will probably be fully superseded in a few years.	5	15/04/2022

7026	Welsh Blood Service	Final approval	03/10/2013	WTAIL liquid nitrogen automated filling system (low pressure) TT1-17	DATIX 3467 - transferred from paper assessment	Cryostorage refrigerators are sited so their open lids cannot damage the piping; The system has a regular Insurance inspection (Zurich); Piping, valves and controllers have regular maintenance by specialist contractors; Room has mechanical ventilation (monitored and alarmed by the EMS system); Laboratory Safety procedure POL(S)-009; Oxygen depletion sensors are present in the room, with audible and visual alarms; Induction training; Liquid Nitrogen emergency cut-off switches present both inside and outside of room to stop flow in event of problem: SOP 112/TTY, Management of the liquid nitrogen system in the Welsh Transplantation and Immunogenetics Laboratory. CryoVent system bleeds Nitrogen gas from lines before filling to prevent splashing. Use of cryo-protective gloves, coats, enclosed shoes and goggles mandatory. Laboratory safety procedures (POL-S 009), includes 'buddy system' for out of hours access.	10	02/08/2022
6987	Welsh Blood Service	Final approval	23/09/2013	Operation of the BacT/ALERT	Operation of the System	Staff trained to SOPs Good Laboratory Practise Process Design Competency Assessment Appraisal Controls	5	06/01/2022
5394	Welsh Blood Service	Final approval	21/05/2012	Remove the class I HLA-A, HLA-B, PCR-SSP result from the UBM database for stem cell donor 15568709	Remove incorrect HLA type from UBM Database	IT working instructions Post implementation check performed	5	15/11/2022
2556	Welsh Blood Service	Final approval	23/04/2010	Missing Hazardous Items	9-4-10:The standard procedures for storage and transportation of all hazardous material created during a blood donation clinic should ensure that none of these items go missing. Hazardous material is defined for the purposes of this SOP as:- "Sharpsafes containing used items e.g. needles "Boxes containing contaminated waste "Vacutainers containing blood samples "Blood transportation boxes containing full blood donations/Non Conforming Donations	9-4-10: Standard operating procedure SOP: 014/BCT. WBS Transport record sheet (SOP: 022/BCT).Donor are health screened, before giving blood, which reduced the risk of contamination with blood borne pathogens. Training to SOP's. Agency Drivers have ID checks.	5	06/09/2022

QUALITY SAFETY AND PERFORMANCE COMMITTEE
2021 / 2022 QUARTER 3 PUTTING THINGS RIGHT REPORT

DATE OF MEETING	24th March 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Non Applicable

PREPARED BY	Jade Coleman, Quality and Safety Coordinator
PRESENTED BY	Nigel Downes, Deputy Director of Nursing, Quality and Patient Experience
EXECUTIVE SPONSOR APPROVED	Nicola Williams, Executive Director of Nursing, Allied Health Professionals and Health Science

REPORT PURPOSE	FOR ASSURANCE

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Management Board	07/03/2022	Endorsed for submission to QSP Committee

ACRONYMS	
N/A	

1. SITUATION

The 2021 / 2022 Quarter 3 Putting Things Right report is provided to the Quality, Safety and Performance Committee to provide a summary of concerns (complaints) and incidents received, themes and improvements made during the 1st September 2021 to the 31st December 2021.

The paper is provided to provide the Committee with **ASSURANCE** in relation to how the Trust is executing its responsibilities in relation to the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

2. BACKGROUND

All NHS bodies in Wales must ensure that they have effective processes for managing concerns raised by patients and staff in accordance with the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

Velindre University NHS Trust is committed to ensuring the provision of an effective and timely process for responding to concerns. This ensures that concerns (including incidents) are appropriately investigated, and that learning takes place in order that the Trust can improve the quality and safety of its services, and the patient and donor experience.

3. ASSESSMENT/SUMMARY OF MATTERS FOR CONSIDERATION

The following are the key highlights as detailed within the quarter 3 report:

- 44 concerns were raised during the Quarter, 89% of which were graded at level 1.
- 73% of the concerns raised were managed via the Early Resolution process, with 27% of the concerns raised managed via the Putting Things Right process.
- Concerns relating to the COVID-19 Pandemic were significantly reduced.
- 75% of the formal concerns raised were closed within the 30 working day timeframe, which is an increase from the previous quarter and equate to the Welsh Government target of 75%.
- The top three themes of the concerns raised continue to be: appointments, attitude and behavior, and Clinical Treatment.
- 468 incidents were raised during the Quarter – 367 from the Cancer Centre and 101 from the Welsh Blood Service.
- 85% of incidents raised were graded as no harm or low harm
- There was one National Reportable Incident reported to Health Inspectorate Wales on the 23rd November 2021 which related to a secretary conducting clinical conversations with patients which does not fall under the remit of the job description.

- The Welsh Blood Service continues to manage the investigation and closure of incidents in a timely manner. Targeted improvement work is currently taking place at the Cancer Centre in respect of this target.
- The outcome of the 'deep dive' undertaken into incidents and concerns from quarters 1 and 2 is attached to the report. In summary this demonstrated that the methods of communication, behaviours and attitudes displayed within our services have a significant impact on our service users. Having reviewed the findings of the deep dive, the Divisions are working with their Quality and Safety leads to develop local action plans to support the reduction of complaints and incidents. The data shared is also being used to inform additional work streams, such as the treatment helpline, to improve patient and donor experience. A further deep dive review will be undertaken in September 2022.

4. IMPACT ASSESSMENT

RELATED HEALTHCARE STANDARD	Yes
	Safe Care and Individual Care
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	Yes
	The Putting Things Right legislative implications of the management of incidents across the Trust
FINANCIAL IMPLICATIONS / IMPACT	Yes
	Possible financial implications in the event of complaints and claims as a result of an incident and where errors have occurred or system failures are evident.

5 RECOMMENDATION

The Quality, Safety and Performance Committee is asked to **DISCUSS** and **NOTE** the 2021 / 2022 Quarter 3 Putting Things Right Report.

Ymddiriedolaeth GIG Prifysgol Felindre
Velindre University NHS Trust

Gwasanaeth Gwaed Cymru
Welsh Blood Service

Canolfan Ganser Felindre
Velindre Cancer Centre

Putting Things Right Report

Quarter 3
2021/2022

Learn it Lead it Live it

LEARN TODAY FOR A BETTER TOMORROW

Contents

Acronyms

VCC	Velindre Cancer Centre
WBS	Welsh Blood Service
SLT	Senior Leadership Team
Q&S	Quality and Safety

Executive Summary

This is the Trust's Quarterly Putting Things Right report where the concerns raised and incidents reported during the Quarter are presented within one overarching report. Due to sensitivities, a separate claims and redress report will continue to be presented.

This quarter 3 report reflects the period 1st September 2021 to 31st December 2021. The key messages / highlights are:

- 44 concerns were raised during the Quarter, 89% of which were graded at level 1
- 73% of the concerns raised were managed via the Early Resolution process, with 27% of the concerns raised managed via the Putting Things Right process.
- Concerns relating to the COVID-19 Pandemic were significantly reduced.
- 75% of the formal concerns raised were closed within the 30 working day timeframe, which is an increase from the previous quarter and equate to the Welsh Government target of 75%.
- The top three themes of the concerns raised continue to be: Appointments, Attitude and behaviour, and clinical treatment.
- 468 incidents were raised during the Quarter – 367 from the Cancer Centre and 101 from the Welsh Blood Service.
- 85% of incidents raised were graded as no harm or low harm
- There was one National Reportable Incident reported to Health Inspectorate Wales on the 23rd November 2021 which related to a secretary conducting clinical conversations with patients which does not fall under the remit of the job description.
- The Welsh Blood Service continues to manage the investigation and closure of incidents in a timely manner. Targeted improvement work is currently taking place at the Cancer Centre in respect of this target.
- The outcome of the 'deep dive' undertaken into incidents and concerns from quarters 1 and 2 is attached to the report.

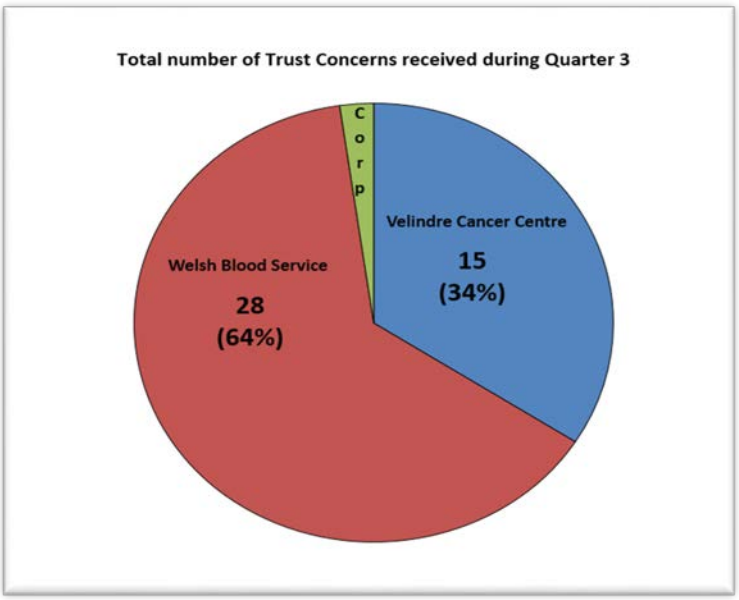
The report is presented in two parts:

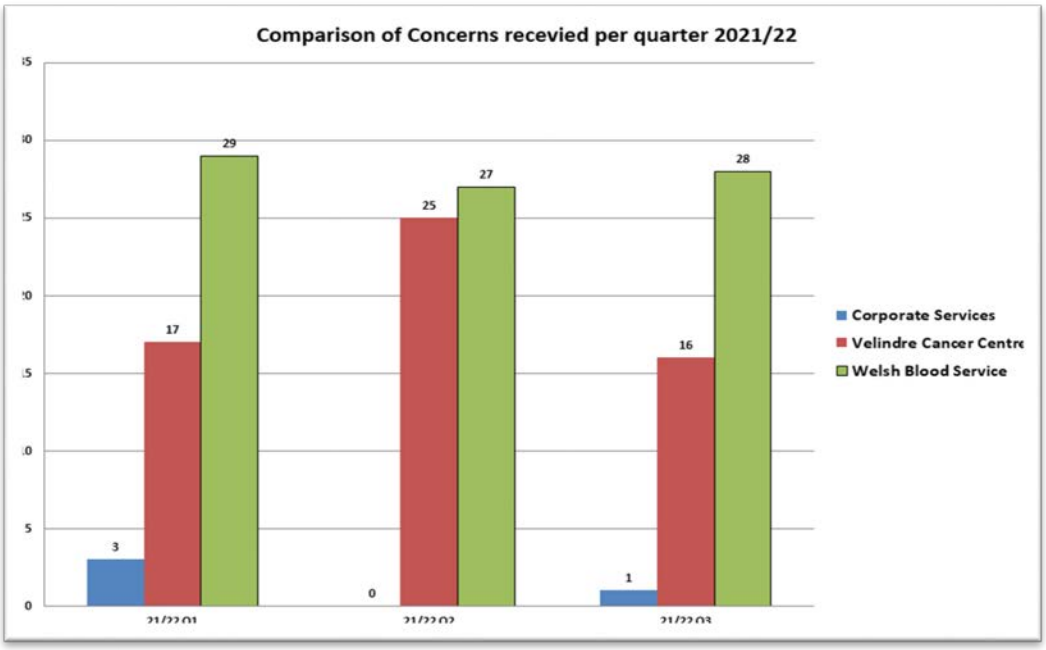
- Part 1: Concerns, which are presented under the heading of the Trust's Concerns Pledge which can be viewed in ***Appendix 1***
- Part 2: Incidents for the Welsh Blood Service and the Velindre Cancer Centre

1. CONCERNS RECEIVED IN QUARTER 3

Raising a concern will be easy and information will be widely accessible.
Put the complainant at the centre of the process and provide support for individual requirements.
Listen to concerns and treat everyone with dignity and respect.

44 concerns were received by the Trust during Quarter 3. The below pie chart outlines where in the Trust the concerns originated:

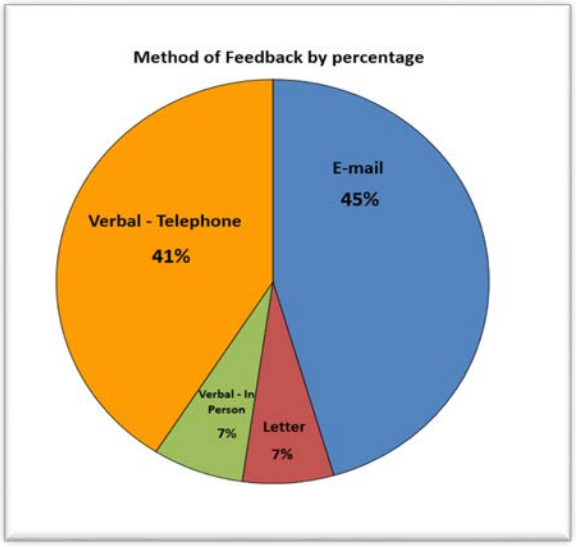


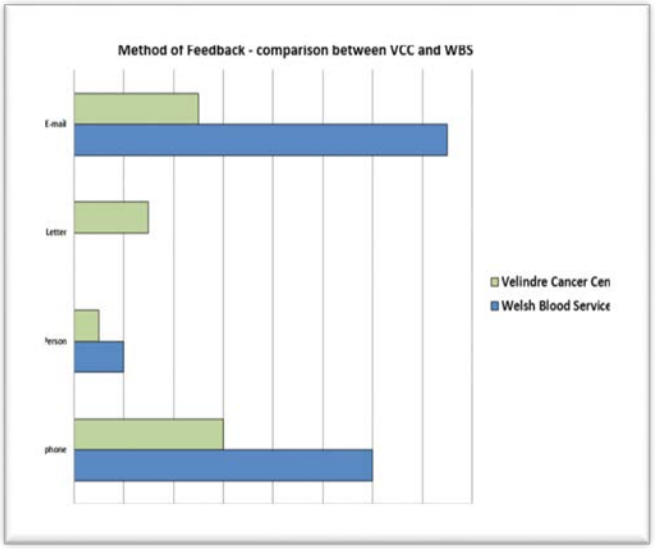


There has been a small decrease in the number of Trust concerns received during Quarter 3, from the beginning of the financial year 2021/22.

1.1 Method of receipt for concerns received in Quarter 3

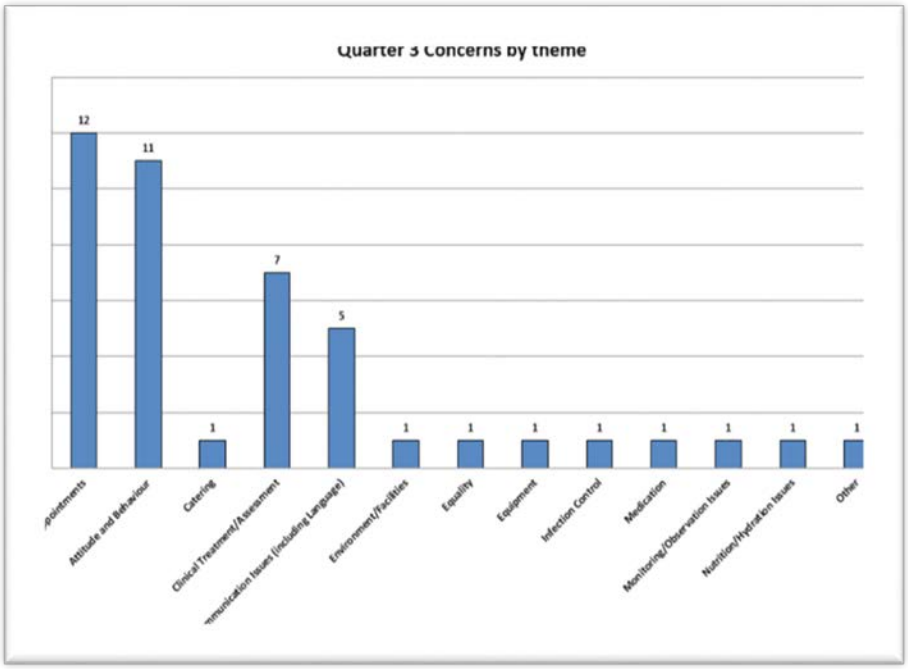
45% of the concerns were received via email, and this continues to be the preferred method adopted to receive feedback by patients and donors. The pie chart below displays a further breakdown of other methods used to contact the Trust to feedback concerns.





1.2. Thematic review of the concerns received in Quarter 3

Of the 44 reported concerns received, the main themes remain the same as in the previous Quarter: appointments, attitude and behavior.



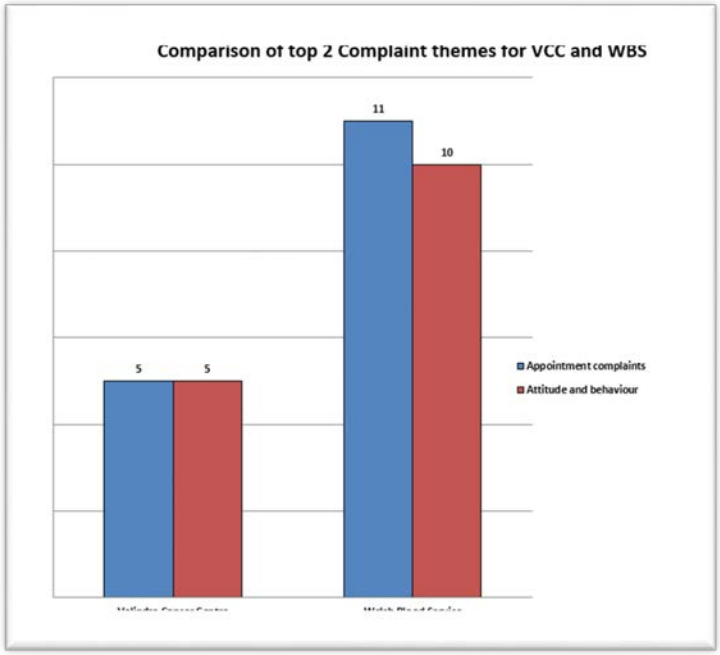
Following the presentation of the Quarter 1 & 2 2021/22 Putting Things Right report at the November 2021 Quality, Safety and Performance Committee, the Committee requested that a deep dive review be conducted to further explore the top three themes emerging from complaints and incidents: attitude; communication; and clinical treatment. It was noted that

attitude and communication were recurring themes and a deep dive was requested to further understand these issues and provide assurance around actions taken to minimise reoccurrence. A summary of the deep dive into the trends of concerns is attached in **Appendix 2.**

Analysis of the 3 main themes arising from the Quarter 3 concerns:

- **Attitude and Behaviour :** This is a continued theme arising through concerns.

Both the Velindre Cancer Centre and Welsh Blood Service face concerns that relate to appointments, attitude and behavior. Both Divisions have identified that a contributory factor to this has been the high pressure and demand on the operational teams.



- **Appointments:** This was the highest theme for the Trust during the quarter.

  There has been a large increase in the number of appointment concerns raised for Welsh Blood Service during the Quarter. An increase to 11 in Quarter 3 compared with 4 in Quarter 2. Most of these relates to the unavailability of walk in appointments. Welsh Blood has enhanced its communications and explanations to donors in relation to the reasons for this (clinics being run at 100% appointments to utilize and manage the flow of clinics and optimize efficiency).

  Within Velindre Cancer Service an Outpatient Improvement Programme, led by the Clinical Transformation Lead that includes appointments is well underway.

- **Clinical Treatment:** These mainly related to treatment provided by Velindre Cancer Service.

  The ‘clinical treatment’ field on the Once for Wales system which captures the themes of concerns received is very broad and can be difficult capture specific incidents/occurrences.

The Cancer Centre understand that Radiotherapy and SACT remain the highest number of reported “incidents” within the system and these are routinely reviewed at the Velindre Cancer Centre Quality Safety and Management Group meeting. The UK Health Security Agency require all SACT, hypersensitivity and extravasation occurrences to be recorded and reported which in turn displays high reported incident figures within the Once for Wales system even though they are not incidents as such.

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1.3 COVID-19 related concerns

There were 5 concerns related to COVID (13% of all concerns received). This is an increase by 1 from the previous Quarter, the details of the 5 Covid Concerns are included below:

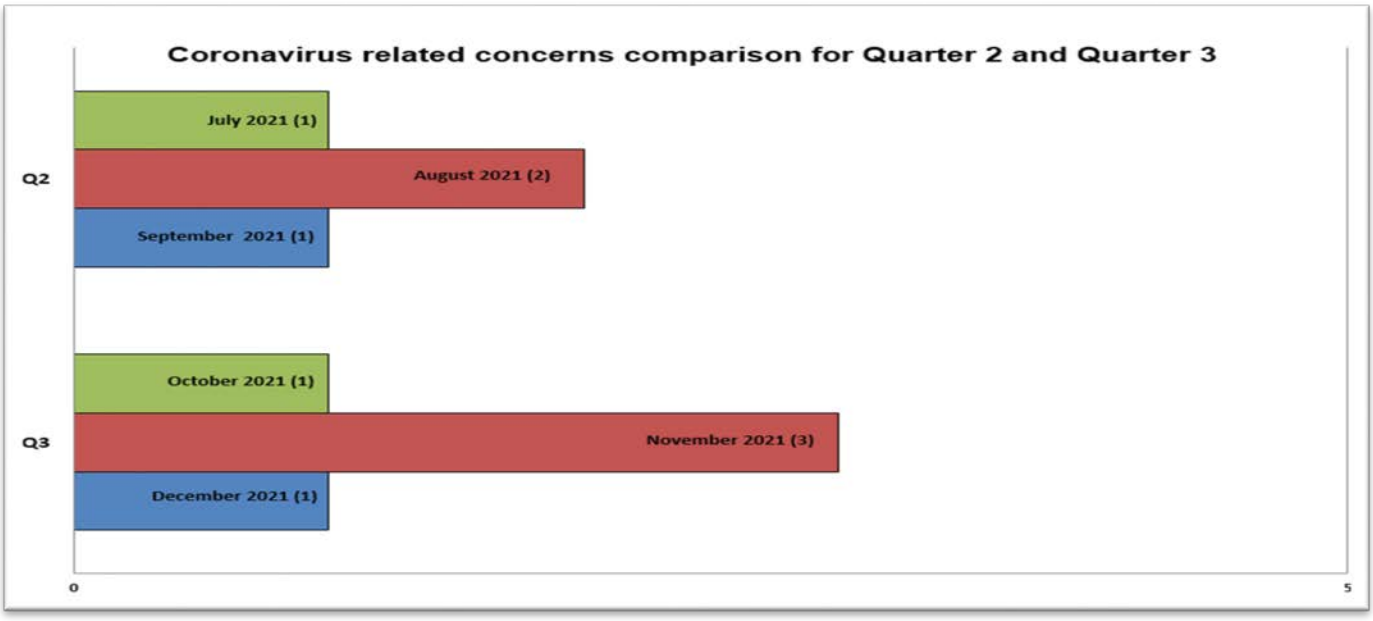
- There were ***2 complaints relating to the closure of mobile donation units***. The use of the mobile units were paused due to the pandemic.
  During the pandemic WBS has had to make use of large regional collection venues that enable the provision of services in line with Public Health advice whilst maintaining the required blood supply for NHS Wales. The re-introduction of the mobile units is now under consideration.

- The ***attitude of WBS staff towards a Donor who is exempt from wearing a mask***.
  A sincere apology was provided and occurrence discussed with staff involved. Work on going to introduction of donor experience survey (CIVICA) at reception. Donor has offered to give feedback following his next donation experience to ensure lessons have been learnt.

- Donor had ***not been able to give blood for 18 months due to Covid restriction concerns***. When Donor tried to book an appointment they were told they could not because they were over 70 years of age.
  A sincere apology provided to the donor will full explanation of current guidelines relating to donors over the age of 70 years, who have not donated blood within a two year period. Donor fully acceptance of reason for guidelines, following a full investigation and screening process it was deemed as donor was just outside of the deferral period and otherwise healthy and well the deferral was lifted, donor happy to continue to donate.

- ***Donor turned away following a negative PCR test*** one week before appointment. No indication prior to the appointment that this would cause a problem. Donor had taken time off work.
  Full explanation given to donor around blood donation acceptance relating to the use of PCR testing/ Covid-19 in line with Public Health Wales guidance. SOP COL-027 Triage Flow chart updated to reflect process to follow. -Website has been updated to include information around PCR testing

Many reviews have taken place for Covid related incidents within the Cancer Centre which have included meetings with other Health Boards on the correct processes to follow when patients are transferred from Velindre for emergency and routine care. A Covid incident which effected a small number of staff members following a Christmas party in December 2021 was quickly recognised and further Christmas celebratory plans were swiftly discouraged Trust wide.

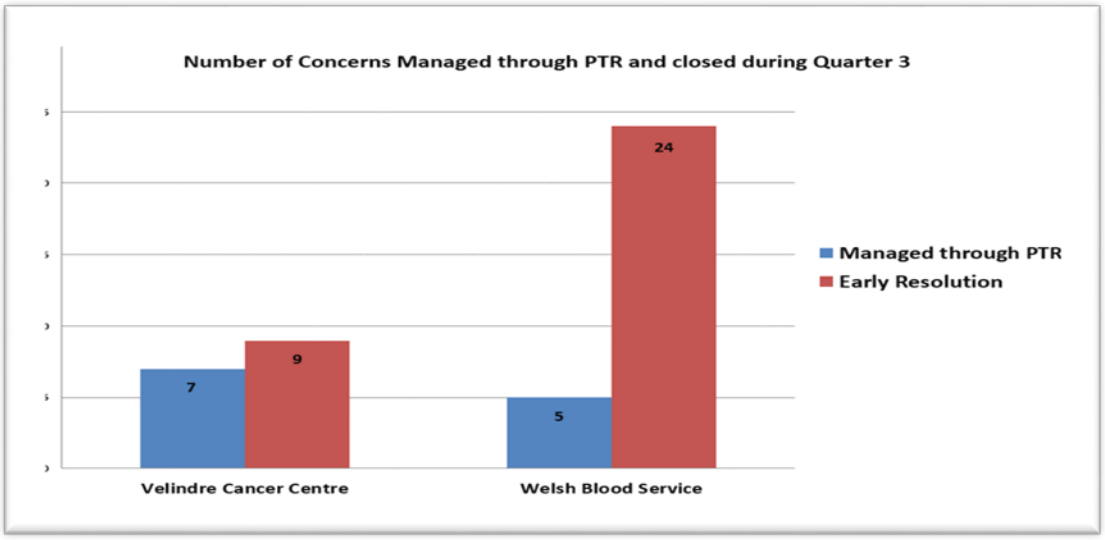


1.4 Concerns investigated and closed during the Quarter

Acknowledge all concerns within 2 working days.
Aim to resolve concerns at source, or by the end of the next working day.
Responses required under PTR will be provided within the legislative timescales.

All concerns raised during Quarter 3 were closed during the same Quarter: 73% were closed as an Early Resolution, and 27% under the Putting Things Right regulations.

Welsh Blood Service complaints remain low in number considering the service had approximately 6,500 donor contacts. The majority of Welsh Blood concerns were managed as Early Resolutions. Overall donor satisfaction continues to exceed target. During the month of December 1108 donors responded shared their donation experience.



1.5 Level of investigations undertaken

	Concerns will be assessed to determine the level of investigation required *Undertake robust investigations by trained staff* *Being open and transparent throughout the investigation*

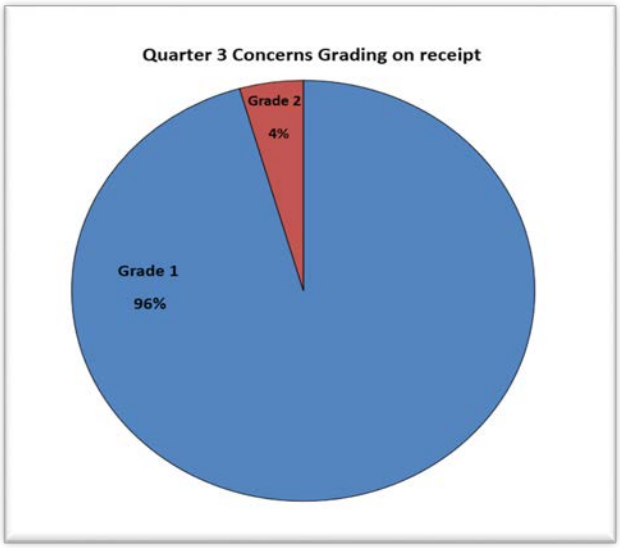
	Provide an apology where required and confirm what has been done to Put Things Right *Redress will be considered where appropriate* *Offer concerns meetings and details of the Public Services Ombudsman Wales*

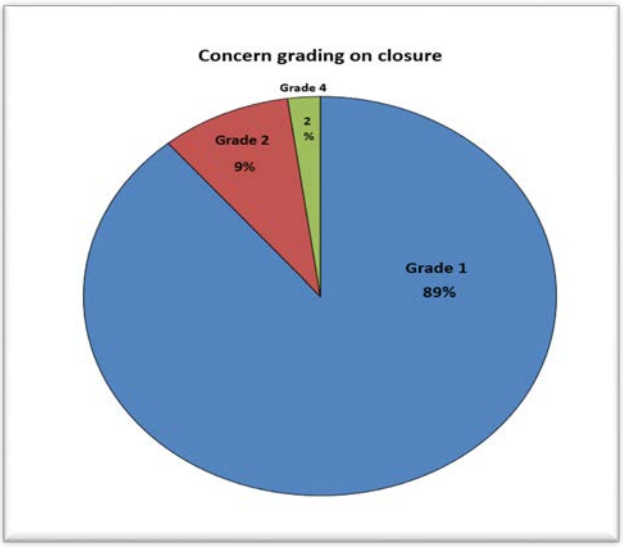
All concerns graded level 2 – 5 undergo an assessment of harm to determine whether the Trust has breached its duty of care, whether a qualifying liability in tort exists and to ensure that the appropriate level of investigation is undertaken. Relevant cases are discussed at the Trust's Putting Things Right Panel.

All concerns are graded upon receipt and the Complaints grading table is included as **Appendix 1** in this report. During the Quarter 89% of all concerns were graded as level 1, 9% as grade 2 and 1 concern was graded at a level 4.

The Grade 4 concern was an extremely complex case which was investigated and managed by the Trust Corporate Team. The complaint related the Cancer management of a patient, where concerns were raised over delays in the patient's treatment care plans and decision making. This concern accounted for the one re-opened concern during Quarter 3 2021.

Wherever possible, all concerns graded as level 1 should be resolved as an Early Resolution. During the quarter 40 concerns were graded as level 1 and 33 concerns were resolved as an Early Resolution, suggesting 82.5% of level 1 concerns were resolved within 2 working days via the Early Resolution process. The below pie charts further displays this data:





At the end of Quarter 3, the number of open claims and redress cases have reduced.

1.6 Quality of investigations undertaken

1.6.1 Public Service Ombudsman: During the Quarter:

- The Trust received one new Ombudsman case (case 3 below)
- There was one Ombudsman case closed
- There were 3 ombudsman cases under investigation:

    - ***Case 1:*** Relating to a failure to discuss prognosis and incorrect information provided for the suitability of different drug treatment. The final report from the Ombudsman is anticipated.

    - ***Case 2*****:** Relating to: a failure to communicate essential information to the medical practice which impacted on the last days of life for the patient; communication issues with the family; and, the postponement of treatment. The Trust awaits the specific learning requests from the Ombudsman.

    - ***Case 3*****:** Related to the transfer of a patient from Velindre to Cardiff and Vale Health Board. The Ombudsman investigation is underway.

1.7 Learning Arrangements

Identify and implement learning from concerns raised
Updating patients and donors as to how learning has improved services

Through the investigation and management of concerns, the Trust has been able to identify a number areas for service improvement. The Divisions have mechanisms in place to share learning from complaints, and for monitoring the implementation of recommendations and actions. Work continues across both Divisions to better understand the feedback being received in relation to attitude and behavior and the treatment that patients receive.

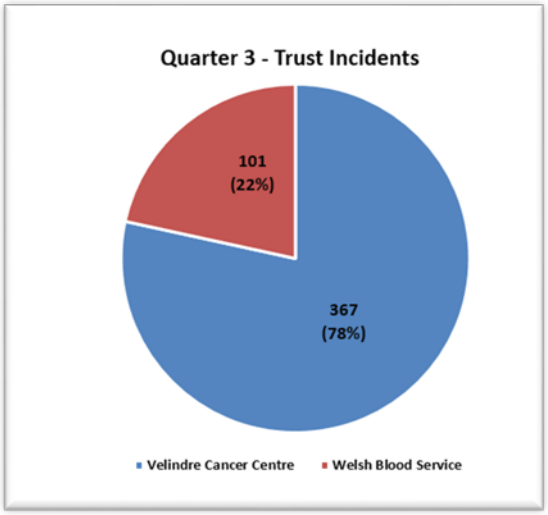
The attached deep dive learning exercise included in this report in **Appendix 2** has been completed in order to better understand the root cause of the issues so that meaningful improvements can be made. Furthermore, work continues to review the access to clinical treatment to ensure timely access and equitable care.

A task and finish group is exploring how the Cancer Centre's Treatment Helpline can be improved to support decision making and sign posting. The deep dive review also includes concerns raised within this category in order to better understand the issues raised.

2. QUARTER 3 INCIDENTS

2.1 General Overview

468 incidents were reported during the Quarter.



Nationally reportable Incidents (replaced Serious Incidents in June 2021)

The Cancer Centre reported one National Reportable Incident to Health Inspectorate Wales on the 23rd November 2021. This met the criteria for reporting due to the volume of patients involved and no harm to date has been determined. The incident is under investigation and is relating to the mechanism of clinical consultations for some patients during COVID.

Early warning notifications (replaced 'No Surprises' in June 2021)

There were no Early Warning Notifications submitted to Welsh Government.

Regulatory Incidents

There were no regulatory incidents reported during the quarter

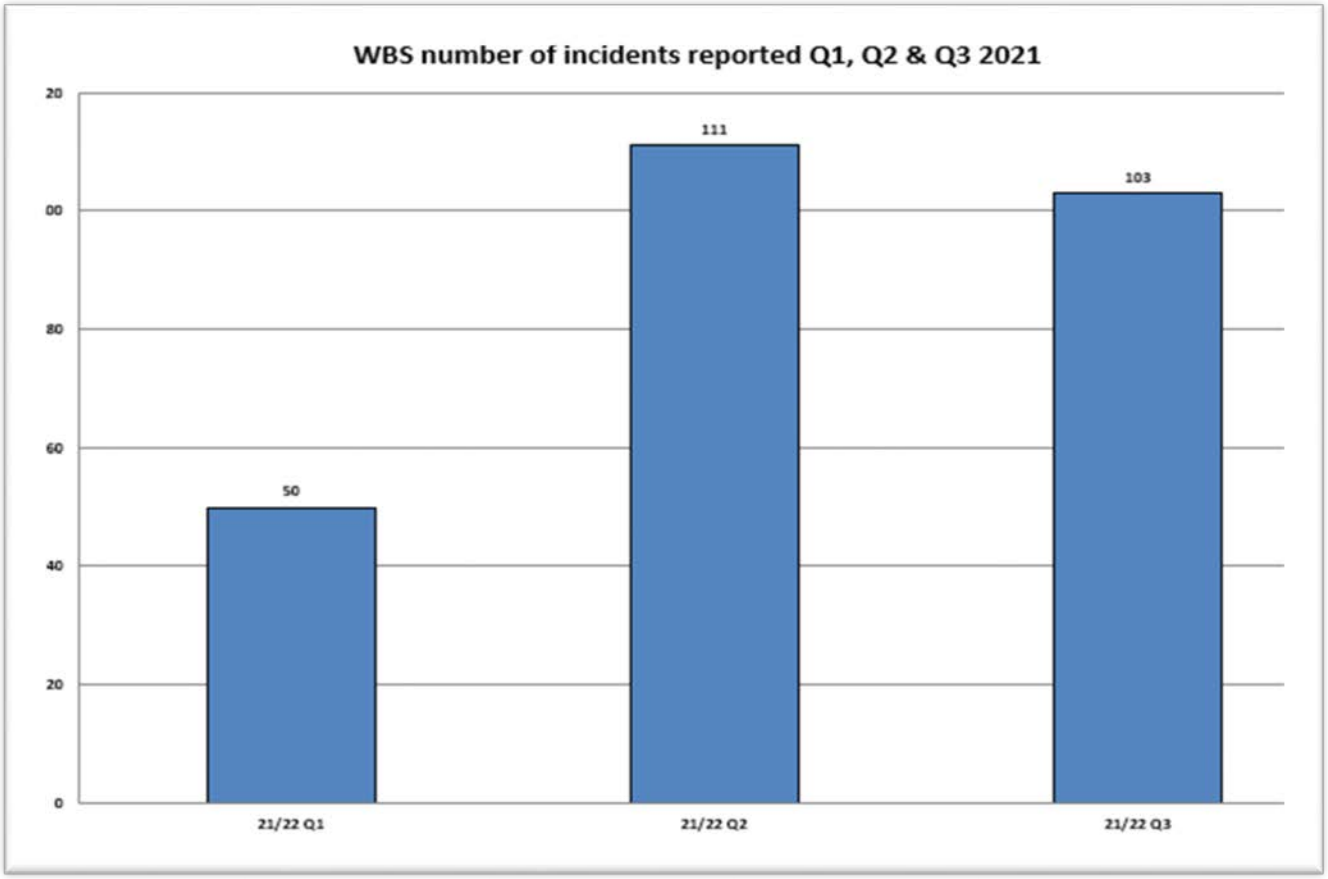
2.2 Welsh Blood Service Incidents

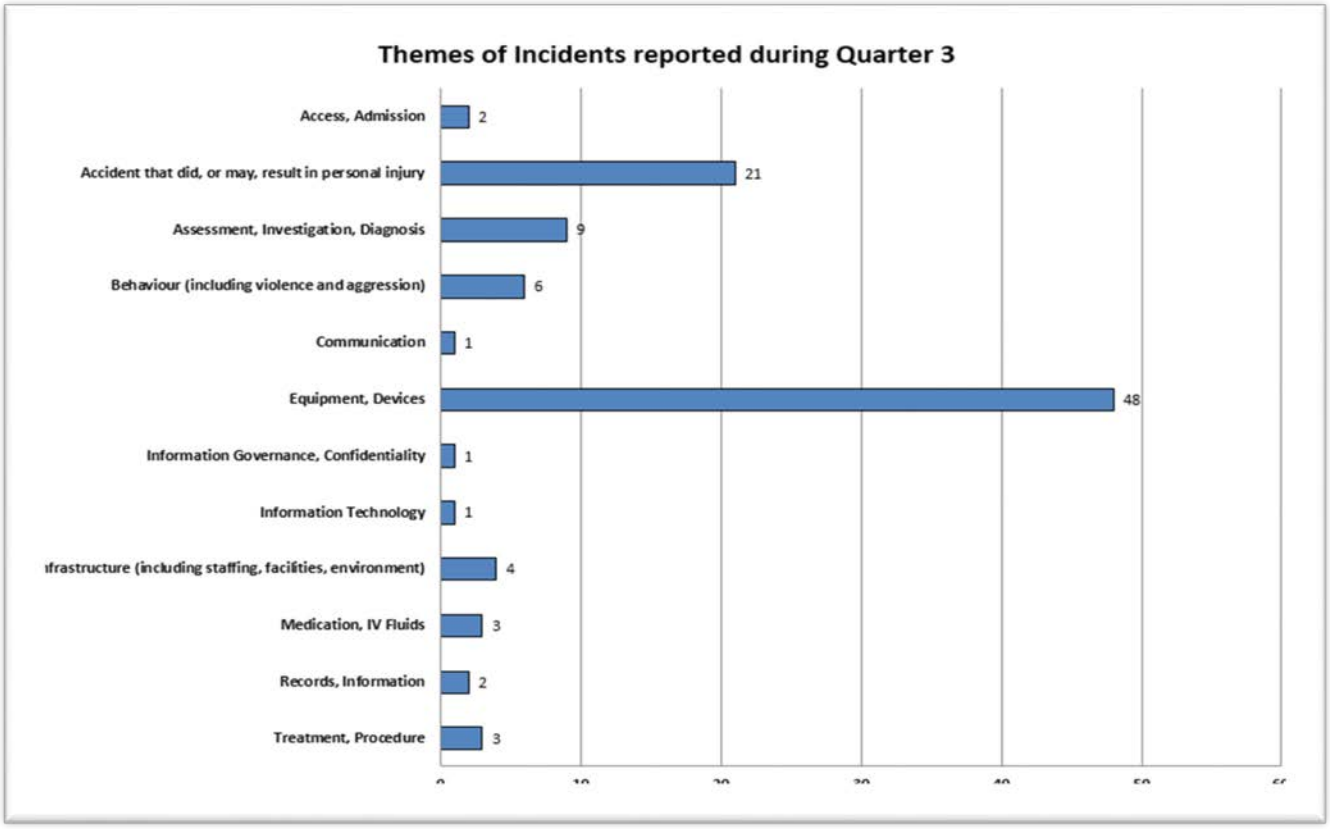
The Welsh Blood Service reports incidents in accordance with the Trust incident management policy. As part of their quality management system, the Welsh Blood Service is also required to report incidents defined as 'quality deviations'. These incidents relate mainly to operational or process issues, and enable the service to identify and manage risks that could impact on the safety of blood products.

A project plan was developed to facilitate the transition of 'quality deviations' into Q-Pulse (Quality Management System), and to report all other incidents into Version 14 of Datix. These types of incidents are no longer captured in the Trust quarterly report now that Q-Pulse is fully implemented.

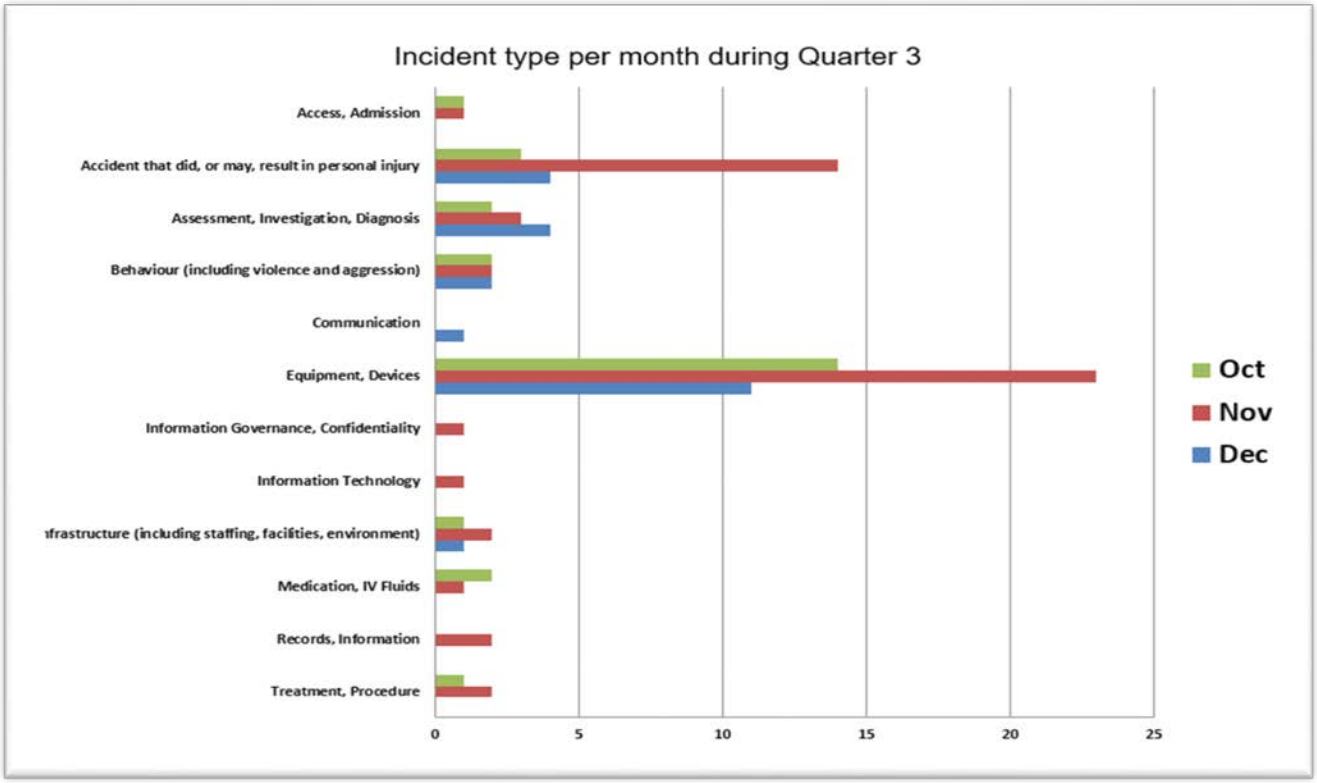
This report does not include Donor Adverse Events (known complications related to blood donation e.g post donation fainting) as these events are not currently categorised as incidents, and are reviewed via the Welsh Blood Service clinical services department.

The Welsh Blood Service reported 103 incidents, which is consistent with the previous quarter, a summary of themes is provided in the diagram below.





Further breakdown is provided in the graph below to display the type of incident reported and what month those incidents occurred.



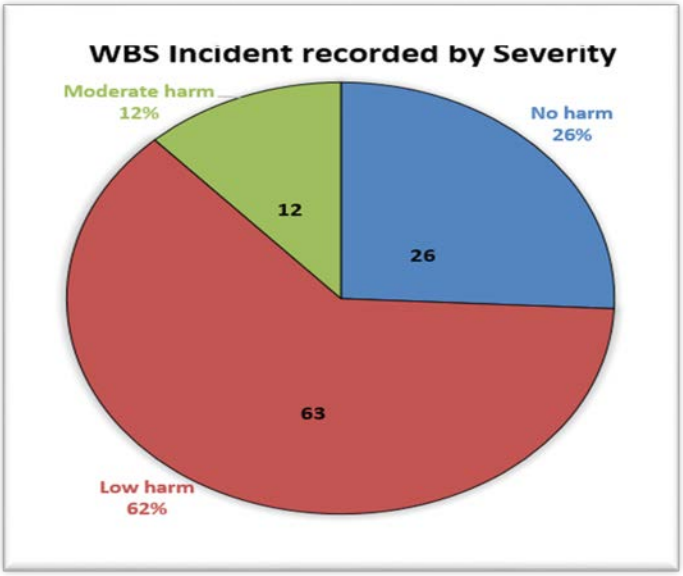
Equipment and device related incidents continue to be the highest number of incidents reported for the Welsh Blood Service, 48 reported in quarter 3, 47.5% of total of Welsh Blood Incidents.

These incidents relate to Centrifuge failures and other equipment failures. One of the main themes from the incidents reported during Quarter 3 relate to the collection of blood whereby an electronic process requires a blood bag to be clamped and then tilted back and forth. If the clamp on the bags does not clip on correctly it may result in an overweight bag. Clip incidents relate to a manual process carried out by a member of staff. Staff members techniques are monitored and if the same staff member has 3 tolerance breaches within a month there is an intervention and review of that persons competency.

The Welsh Blood Service have a low tolerance for breaches and bleed 7000 units a month with a total of 20 as the maximum tolerance level.

Clips incidents are within normal process variation and continued to be monitored to ensure no variance in activity.

The below pie chart displays how many incidents were reported for the Welsh Blood Service and the severity of each incident recorded post investigation. The majority of incidents, 88% were recorded as low/no harm.



There were 12 incidents assessed as moderate harm. These included: two donor's fainting; appointments needing to be cancelled due to staffing issues; a staff member trapping their hand whilst reversing through a door pulling a blood stacker; and, an Information Governance related issue relating to a Nadex and password being used by 2 different members of staff simultaneously.

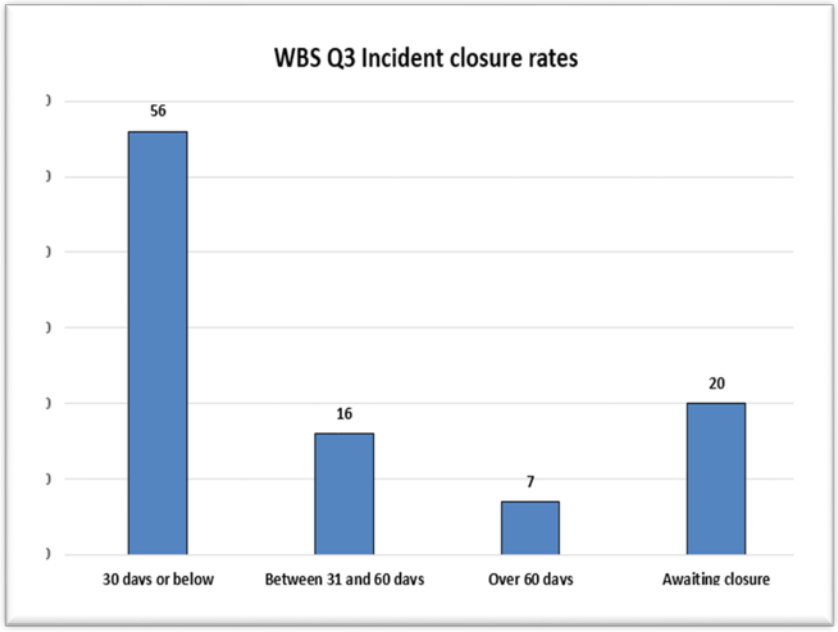
2.2.1 COVID-19 related Welsh Blood Service Incidents

There was one Covid-19 related incident reported which related to a staff member receiving both the Influenza and Covid vaccination as part of the immunisation schedule that was rolled out in November 2021, the staff member had previously received the Influenza vaccine at an earlier date.

2.2.2 Incidents closed within 30 days

The Trust requires 80% of incidents to be investigated and closed on the Datix system within 30 days. 79 incidents were closed within the period within the Welsh Blood Service, 56 of which were closed within 30 days (71%). The longest open incident was for 87 days.

A number of the open incidents are under investigation by the Divisions Clinical Governance team; these are low risk investigations which have been difficult to complete due to the pandemic priorities.



2.2.3 Learning from Incidents

When investigating incidents, the Welsh Blood Service identifies learning and preventive actions to reduce the risk of the incident happening again. A number of operational processes and procedures have been reviewed and updated as a result of learning from incidents.

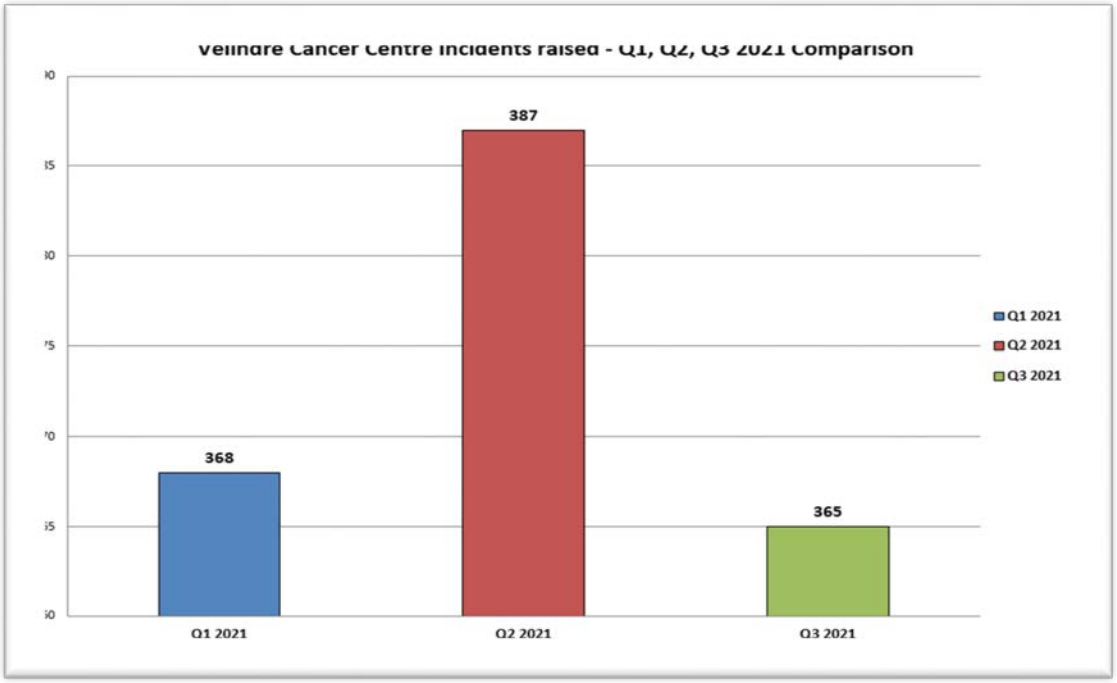
During December 2021, 91% performance was recorded against the 'Incidents closed within 30 days' which shows a positive direction against the target of 80%.

The revised process for managing low-impact incidents was implemented on 1st June 2021 and since then, new reports are reviewed and risk assessed daily to ensure the incidents are fully closed within a few days of reporting. Datix User Access and Reporting issues remain with the Datix Project Board for resolution.

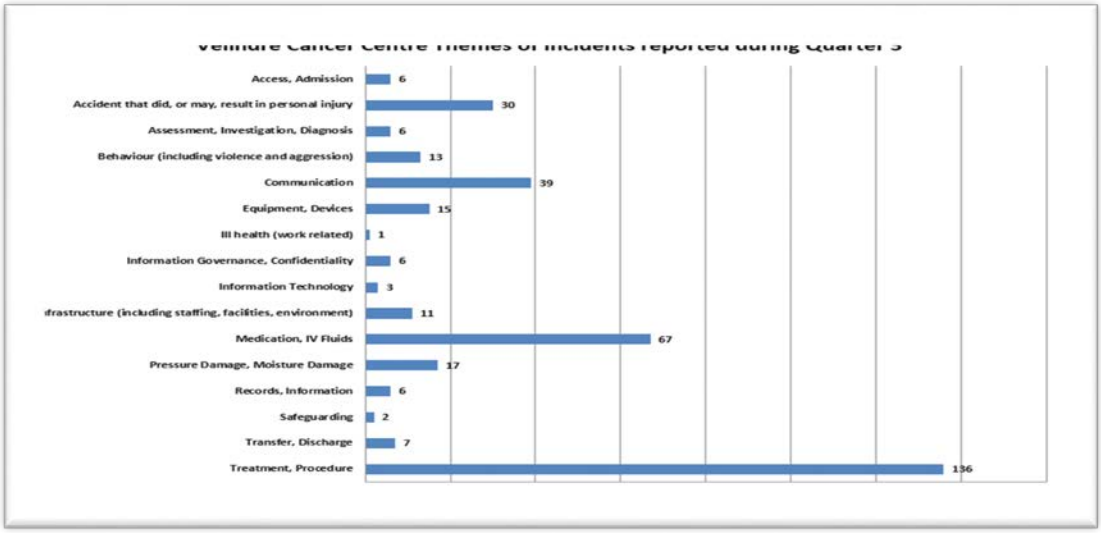
During the Quarter, there has been a commitment to improve the timeliness of implementing actions identified from incidents. The Service implemented a ‘zero tolerance’ approach towards overdue actions. As result, those staff with overdue actions have been contacted directly with an explanation requested as to the cause of the delay and an expected completion date. This process will be evaluated to assess effectiveness.

2.3. Velindre Cancer Service Incidents

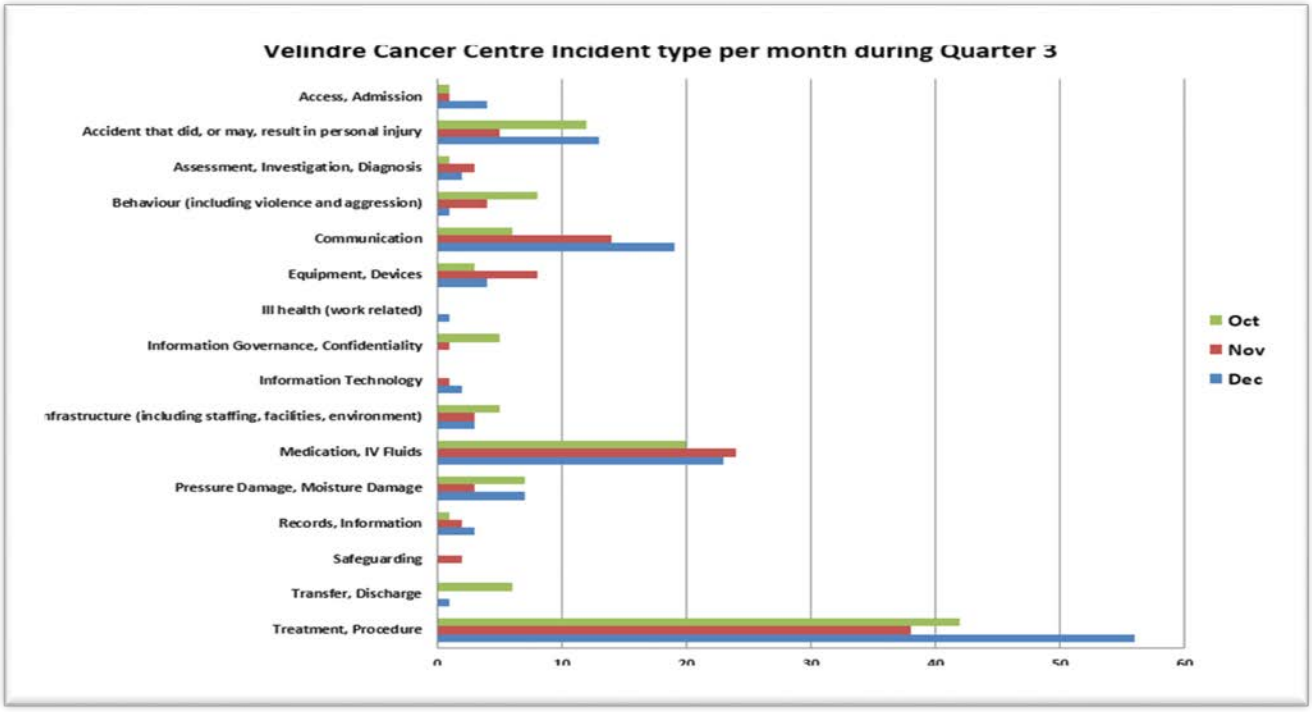
365 Incidents were recorded relating to Velindre Cancer Service during Quarter 3. Generally the number of incidents being reported is remaining stable. The below graph shows incident figures from the 1st April – 31st December 2021.



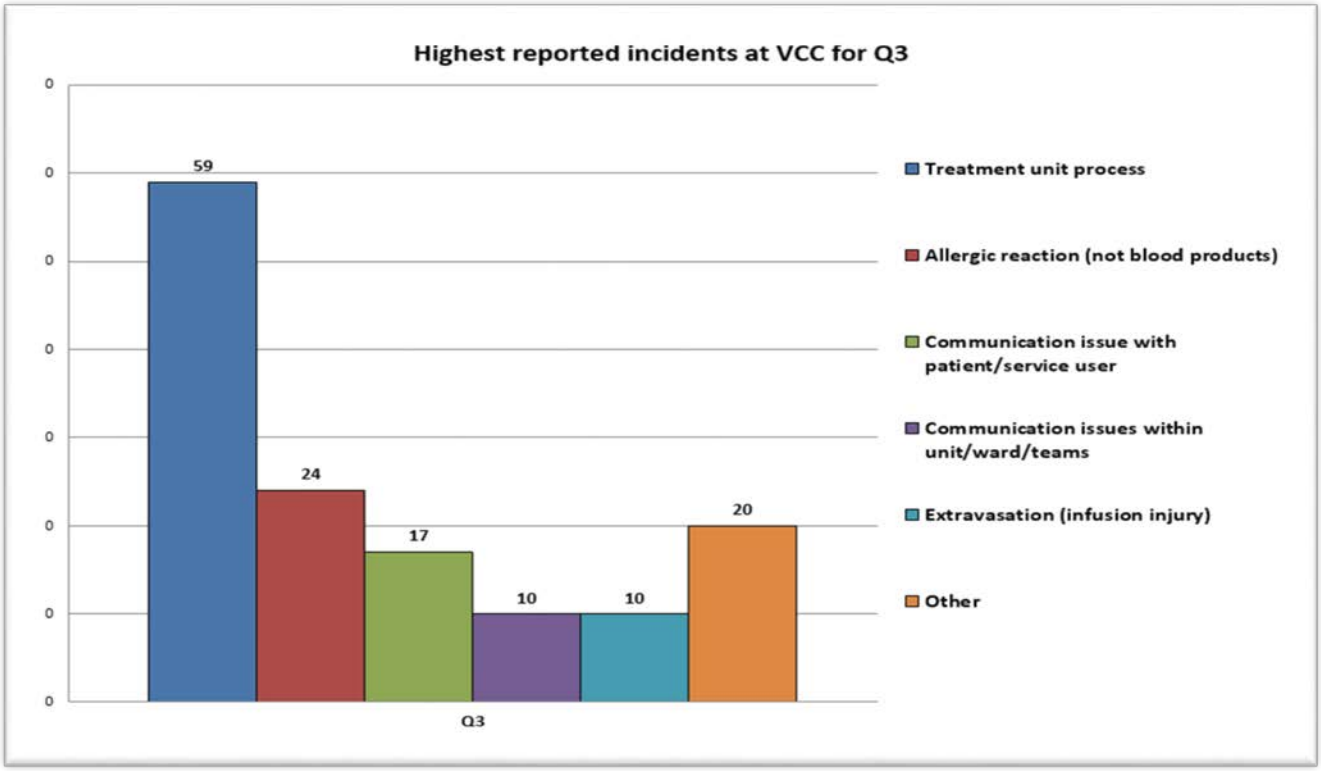
The below bar chart displays the number of incidents recorded by theme for Velindre Cancer Centre.



Further breakdown and key themes of the number of incidents raised per month during the Quarter are shown below:



The highest number of reported incidents relates to procedures and treatments received at the Velindre Cancer Centre. The below graph displays a breakdown of the highest numbers of incidents reported.



2.3.1 COVID-19 related incidents

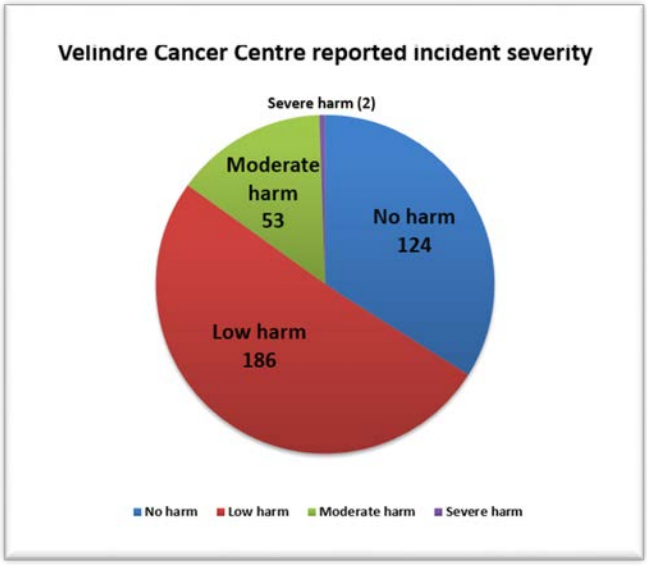
There were seven incidents relating to Covid reported. These included: staff members and patients testing positive for Coronavirus; Covid related absence impacting on routine administration checks due to the lack of trained staff availability; and the breakdown of correct Covid related communication routes between the Trust and Health Boards when transferring patients.

2.3.2 Incident severity

The majority of incidents reported caused low or no harm which is a consistent theme (85%). 53 were graded as causing moderate harm, and 2 as severe harm. The 2 severe harm incidents are detailed below however following investigation were subsequently downgraded and both incidents were re-categorised as low.

- ***Case 1*:** Related lack of an available bed for a patient at Velindre and Local Health Board who required potassium treatment. Oral treatment was commenced as an alternative to intravenous. Following review the incident was downgraded as alternative outpatient treatment was given which was effective and there was no harm to patient.

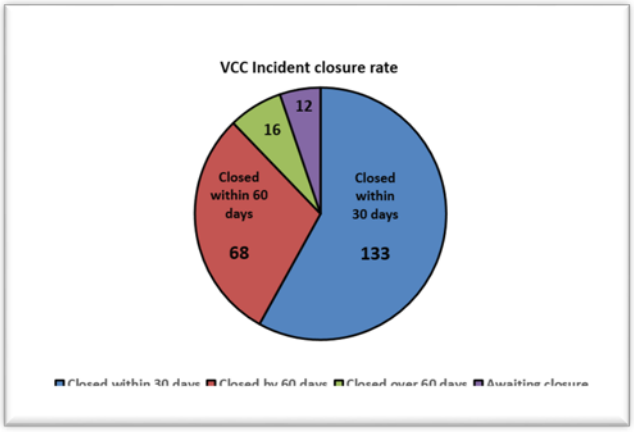
- ***Case 2*:** Related to a delay in reviewing a patients CT scan (undertaken in patients' Health Board) prior to commencing SACT. The case was downgraded following review as the Consultant had reviewed the scan and had started patient on SACT and there was no patient harm. It was identified that documentation required improvement.

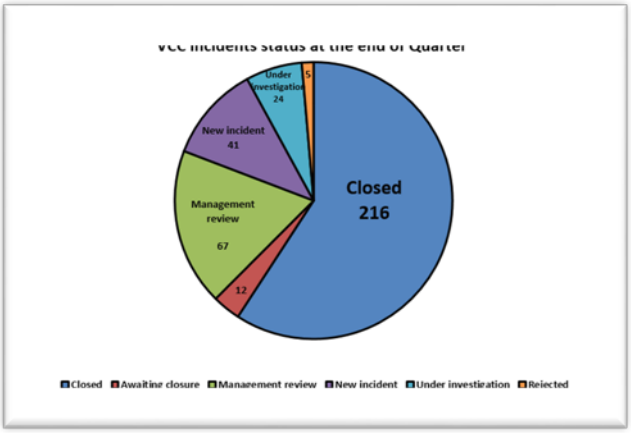


Themes that were evident amongst moderate harm incidents reported, consisted of patient falls, pressure damage incidents and treatment concerns along with some administrative errors. The attitude and behavior of both patient and staff continues to be a theme reported within the Velindre Cancer Centre.

2.3.3 Closed incidents during the Quarter

216 of the 365 Incidents reported during the Quarter were closed, 133 within the 30 day timeframe (36%). The longest open incident was open for 98 days.





3. LEARNING

A summary of the key learning identified from incidents reported and investigated by the Cancer Centre during the Quarter is provided below:

SACT booking Centre	An action plan has been presented to VCC Quality Safety Management Group from the SACT directorate. There is now a process in place whereby an answer phone service is available and messages are checked at the end of each working day. All chemo booking staff have received training by the Information Governance lead and all online training has been completed. The SACT manager is reviewing all SOP's that relate to the service. The SACT directorate are also working with service improvement and clinical audit to improve the processes in place.
IV Access	Examples of service improvement from the IV Access team: *Community Nurse Education for PICC care and Management*. Due to Covid, we have had to adapt how education is delivered to community nurses. Working with all the Health Boards in southeast Wales region, an on line educational programme was devised including documentation for a formal assessment of the practitioners in the community. In addition, as part of the programme a TEAMS training sessions is provided by Velindre to educate and inform the assessors in the community. This will ensure robust training and assessment to improve patient care. *Extravasation training for Radiographers*. Working with the Radiology leads, we standardised the use of one contrast in both departments and to cease using a contrast that could cause more significant extravasation injury. The extravasation guidelines were reviewed and updated, including an easy to follow flow chart to provide instant and accurate guidelines for the management of extravasation. In addition, a training programme was devised specifically for the Radiographers to be delivered by TEAMS. This will improve knowledge and increase their confidence when dealing with extravasation injuries. Ultimately, this will leads to better management and outcomes for patients.

Incidents still "open"	A number of these are incidents are categorised "for reporting purposes only" such as transport issues, extravasation, and hypersensitivity reactions. The Datix team are looking at the possibility of a "for reporting purposes" only drop-down option.

4. SUMMARY OVERVIEW OF INCIDENTS RAISED IN QUARTER

- 85% of incidents reported across the Trust resulted in no or low harm.

- One National Reportable Incident was raised during the quarter and two severe incidents were raised at the Velindre Cancer Centre. The National Reportable Incident related to a secretary undertook clinical conversations with patients and the 2 severe incidents that were reported were subsequently downgraded to low harm following the investigation. Work continues to embed the new processes aligned to nationally reportable Incidents and Early Warning Notifications.

- Work is being conducted on a continuous basis to ensure the timely investigation and closure of Incidents. Improvements have been seen at the Welsh Blood Service, and the Cancer Centre is now having a concerted focus on improving compliance with the national timeframes for the investigation of incidents. Dashboards have been created within Datix to show all open incidents and for every directorate. These Dashboards will be shortly included in the monthly directorate meetings.

- Formal training for undertaking investigations and learning from any incidents raised is has been procured and will be delivered during March 2022.

5. CONCLUSION: CONCERNS AND INCIDENTS IN QUARTER 3.

The following overarching conclusions have been drawn for the Trust for Quarter 3:

- Directorate leads are being asked to focus their efforts on learning, retraining and intervention where we have high numbers of incidents and concerns.

- There are many improvement plans in place across the Trust to address some of the themes, these improvement plans are monitored through the Velindre Futures, and Senior Management Teams.

- Quarter 3 was a very busy period clinically with services seeing an increase in pre-covid demand and restrictions due to the 3rd Covid wave.

- Quality and Safety as a department has been engaged in work to support the upgrades to the OfW Datix system for incidents, setting up systems and processes for managing complaints and concerns and developing as a new team.

- There is evidence that incidents, concerns and compliments are managed appropriately and compliant with the PTR regulations. Lessons learnt and actions are implemented and monitored by Directorate leads and their teams, we recognise there is always room to improve in this area.

- The after-action review database is a central learning database where learning from our complaints are visible and accessible to inform our quality indicators, clinical audits, internal and external audits. The learning database is shared at the Quality Safety Management Group meetings with departments being asked to provide an update on their learning.

- The Trust remains committed to learning from all concerns and incidents raised, and investigation training is currently being procured for all key staff to strengthen our ability to objectively and comprehensively investigate and learn from all concerns and incidents.

APPENDIX 1

GRADING FRAMEWORK FOR DEALING WITH ALL CONCERNS

The All Wales grading framework is based on a risk matrix developed by the National Patient Safety Agency [2] and has been used to assess and manage risks and incidents. This approach has been built on to develop a framework for determining the level of investigation required in dealing with all types of concerns in order to promote a consistent approach across NHS Wales. The impact or harm experienced by the patient is always the overriding factor for grading concerns. The harm grading is dynamic in nature and must be considered throughout the investigation. Due consideration should also be given to the potential for litigation, regardless of the harm grading. However there may be situations where the grading of harm is low i.e. a grade 2, but there is indication there they will be pursuing a claim. **The examples listed are meant only to be a guide and not an exhaustive list.**

Grade	Harm	Examples of concerns	Consider potential for qualifying liability / Redress
1	None	a) Concerns which normally involve issues that can be easily / speedily addressed; b) Potential to cause harm but impact resulted in no harm having arisen; c) Outpatient appointment delayed, but no consequences in terms of health;, d) Difficulty in car parking; e) Patient fall – no harm or time of work; f) Concerns which have impacted on a positive patient experience.	Highly unlikely
2	Low	a) Concerns regarding care and treatment which span a number of different aspects/specialities; b) Increase in length of stay by 1 - 3 days; c) Patient fall - requiring treatment; d) Requiring time off work - 3 days; e) Concern involves a single failure to meet internal standards but with minor implications for patient safety; f) Return for minor treatment, e.g. local anaesthetic or extra investigations.	Unlikely
3	Moderate	a) Clinical / process issues that have resulted in avoidable, semi permanent injury or impairment of health or damage that require intervention; b) Additional interventions required or treatment / appointments needed to be cancelled; c) Readmission or return to surgery, e.g. general anaesthetic; d) Necessity for transfer to another centre for treatment / care; e) Increase in length of stay by 4 -15 days; f) RIDDOR Reportable Incident; g) Requiring time off work 4 -14 days; h) Concerns that outline more than one failure to meet internal standards; i) Moderate patient safety implications; j) Concerns that involve more than one organisation;	Possible in some cases
4	Severe	a) Clinical process issues that have resulted in avoidable, permanent harm or impairment of health or damage leading to incapacity or disability; b) Additional interventions required or treatment needed to be cancelled; c) Unexpected readmission or unplanned return to surgery; d) Increase in length of stay by >15 days; e) Necessity for transfer to another centre for treatment / care; f) Requiring time of work >14 days; g) A concern, outlining non compliance with national standards with significant risk to patient safety; h) RIDDOR Reportable Incident;	Likely in many cases
5	Death	a) Concern leading to unexpected death, multiple harm or irreversible health effects; b) Concern outlining gross failure to meet national standards; c) Normally clinical/process issues that have resulted in avoidable, irrecoverable injury or impairment of health, having a lifelong adverse effect on lifestyle, quality of life, physical and mental well-being; d) Clinical or process issues that have resulted in avoidable loss of life; e) RIDDOR Reportable Incident;	Very likely

Appendix 2: Concerns Pledges

GIG CYMRU NHS WALES
Ymddiriedolaeth GIG
Prifysgol Felindre
Velindre University
NHS Trust

Valuing Concerns - Our Pledge

Concerns will be valued.

- We will ensure information on raising a concern is widely accessible.
- We will provide support to raise concerns, taking account of individual requirements.
- We will listen to your concerns and review our services to Put Things Right.

Concerns will be dealt with quickly and efficiently.

- We will acknowledge concerns within 2 working days.
- We will aim to resolve concerns at source, or by the end of the next working day.
- Where a concern cannot be resolved at source, we will aim to provide a full response within 30 working days.

Investigations will be proportionate and robust.

- We will assess all concerns and determine the level of investigation required.
- We will undertake robust investigations by trained staff with the required skills and knowledge.
- We will be open and transparent throughout the investigation of the concern.

Responses will be easy to read and will address all of the issues.

- We will provide an apology where appropriate.
- We will consider forms of Redress where we have not met our highest standards of care.
- We will advise you of next steps, offer a meeting with key staff and provide details of the Public Services Ombudsman Wales

Learning will be identified to improve our services.

- We will identify and implement learning from concerns raised with us.
- We will let our patients and donors know how their experience has changed the way we deliver services.

Appendix 3

DEEP DIVE- Q1/Q2 (2021/22) COMPLAINTS AND INCIDENTS

1. SITUATION

The purpose of this paper is to provide the outcome of the deep dive undertaken into the top three themes emerging from the complaints and incidents for the period 1st April 2021 – 30th September 2021. (Data was shared in the Putting Things Right report produced in November 2021).

2. BACKGROUND

Following the presentation of the Quarter 1 and 2 2021/22 Putting Things Right report at the November 2021 Quality, Safety and Performance Committee, the Committee requested that a deep dive review be conducted to further explore the top three themes emerging from complaints and incidents. These were identified as: ***attitude; communication; and clinical treatment.*** It was noted that attitude and communication were recurring themes and therefore a further review was required to better understand these issues and provide assurance around actions taken to minimise reoccurrence. The aim was to identify sub themes and issues with teams or services that would trigger need for further review and possibly system / team improvements.

All complaints and incidents in the above categories were reviewed in detail. This further analysis was to explore more specific criteria including:

- Service level,
- Service location,
- Operational group,
- Staff group.

3. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

3.1 Complaints

Of the 104 complaints received between 1 April and 30 September 2021 97 were reviewed for this deep dive as the concern raised included attitude, communication or treatment solely or in part of the concern.

Three of the 97 concerns have been categorised as corporate concerns, as they relate to communications around the building of the new Velindre Cancer Centre. This area is being closely monitored and managed by the Corporate Governance team and is included in this report for transparency.

3.1.1 Welsh Blood Service (WBS)

51 of the complaints were linked with services delivered by WBS. Although all are included in the overarching themes of communication, further review and analysis provide a more specific breakdown within these themes, including:

Team/Service area	Number	Theme	Action/Learning
East A	8	Donors expressed concerns how some team members communicated changes or problems with their donation.	Discussions with all Staff identified through the concerns, have been undertaken and extra support provided. Where appropriate action plans have been issued and file notes made.
East B	3	Donors felt like they were not listened to and staff were condescending.	Discussions with all Staff identified through the concerns have been undertaken, and extra support provided. Where appropriate action plans have been issued and file notes made.
East C	3	Problems during blood collection which donors felt could have been better communicated.	All Team leaders at WBS required to ensure all staff have completed and are up to date with relevant training re: risk of pain or bruising for donors. Concerns shared with clinical teams to support learning.
West 2	2	Communication with younger and first-time donors.	Concerns shared with all teams across WBS to support changes to communication approach.
Wrexham	4	Response of staff to donors experiencing pain. Dignity of donor compromised.	All WBS staff who communicate directly with donors have been reminded of importance of good communication skills such as tone of voice and how information can be perceived by donors.
Bangor	1	Lack of concern around environmental impact of service. Poor response for staff when questioned.	Details shared with corporate services to support wider conversations around sustainability.
Apheresis	2	Lack of compassion when seeking personal information from donors.	All WBS staff who communicate directly with donors have been reminded of importance of good communication skills such as

			tone of voice and how information can be perceived by donors.
Direct Clinical Contact/ Communication	28	Themes identified donors were able to schedule their next blood donation appointment online, without any suggestion they were too soon to schedule. Donors being turned away form clinic as they had not presented at their appointment time. Too many requests to ask donor to donate. Unable to donate due to donor criteria but not communicated this prior to attending a session.	New process put in place following the feedback to identify donors who attempt to schedule their next donor appointment online too early, which include: - Review of the donors with scheduled appointments prior to clinic so that contact can be made if they fall outside of the time criteria. - Review of messaging on web pages to ensure that time restrictions between donations are clearly stated and in an appropriate area on the website for viewing. This has reduced the number of donors who are turned away on arrival. A more efficient IT process is being considered to improve the timeliness and reliability of this process.
Blood service reception	1	Attitude of reception staff.	All WBS staff who communicate directly with donors have been reminded of importance of good communication skills such as tone of voice and how information can be perceived by donors.

The deep dive did not identify a trend that focuses on any individual collection' team; with feedback focusing on service delivery and access to donor sessions. However, it is of note that staff do rotate between/across teams in response to the demands of the service, therefore feedback from complaints is shared with all teams.

The Welsh Blood Service Donor Engagement Manager has engaged with this deep dive process and will continue to review concerns that are raised, including themes of communication and attitude. The Donor Engagement Manager is continuing to work with the Clinical Education Lead to ensure that effective communication is included in the education programme for all WBS staff.

3.1.2 Velindre Cancer Centre (VCC)

43 of the complaints related to communication and attitude in some services delivered by VCC and in the VCC outreach services. These have been further explored to determine if there are any site-specific teams or staff groups that have particular high incident of this type of complaint.

SST/Staff group	Consultant	Number	Themes	Actions/Learning
Gynaecology	Doctor A	1	Lack of empathy.	Concerns shared with medical directorate to provide a response and to identify and support learning within the clinical teams.
	Doctor B	1	Lack of referral onto a different specialist.	
Lower Gastrointestinal	Doctor C	2	Lack of collaborative working across health providers.	The medical directorate are aware of the concerns and are working with the team to address the concerns and support learning.
	Doctor D	1	Lack of treatment options.	
	Doctor E	4	Lack of contact with patient. Abrupt manner. Lack of apology	
	Doctor F	1	Lack of communication with hospice.	
Urology	Doctor G	1	Inconsistent around disease progression messaging Lack of candour	Concerns shared with clinical staff involved in delivering care to patient
	Doctor H	1	Communication was monosyllabic and evasive	
	Doctor I	1	Care not escalated and patient required hospital admission	
Breast	Doctor J	2	Lack of information shared. Unable to speak with team.	Concerns shared with staff involved. Staff continue to monitor impact of new working arrangements put in place in response to COVID-19

Sarcoma	Doctor K	1	Unable to access team to raise concerns around investigations and treatment.	Staff continue to monitor impact of new working arrangements put in place in response to COVID-19
Unspecified Site Specific Team		3	Lack of information sharing.	Concerns shared with team members for learning. Concerns share with treatment helpline working group to inform review of services
Chemo booking		2	Unable to speak with team to change appointment.	Staff continue to monitor impact of new working arrangements put in place in response to COVID-19
Nursing		10	Ability to communicate with Clinical Nurse Specialist (CNS). Uncaring behaviour towards patient from a CNS (1 case).	The working pattern for the Clinical Nurse Specialist workforce has been affected by COVID-19 and work continues to ensure that phone calls are able to answered and returned in a timely manner. The navigator role is being embedded in the CNS service and roles shared across more than 1 SSTs are being introduced to ensure full coverage. Work continues to review the treatment helpline to ensure it is fit for purpose and staff are trained to support the queries that are posed by patients.
Information governance		2	Sensitive information left in public view (1 case). Multiple calls to member of public's landline (1 case).	Level 1 Information Governance (IG) mandatory training available to all staff. Managers to ensure and monitor IG compliance.

Other services		10	Unable to contact VCC via telephone (2 cases). Inappropriate comments shared on social media platforms (2 cases). Communication with transport services (6 cases).	An upgrade to the telephone network is has taken place (August 2021). Regular meetings are held with transport services and feedback shared during these meetings to inform impact of service delivery.

A theme of complaints across the Service Specialist Teams and the staff groups identified above is around timeliness of communication with other health providers to access additional services or investigations. These concerns reference a lack of information being provided to the patient and their family in relation to the referrals and/or a perceived lack of timeliness to refer the patient to specialist teams and services. There is opportunity for staff to ensure that patients and their families understand the referral process and an indication of the time this may take. The deep dive review has been received by the medical directorate and the Velindre Cancer Centre Quality and Safety team. The Quality and Safety team will be attending the Service Specialist Team meetings to work with the clinicians to review the findings of the deep dive and develop a learning plan.

Within the medical directorate some site specific teams share all written communication with patients. There is no consistency to this approach as some teams have found that patients do not always like to have this information shared with them. However, there would be prudence in patients being asked how they would like to be kept up to date with any changes to their planned care. The Quality and Safety team will support the clinical teams through the Service Specific Team meetings to standardise this approach and put an audit plan in place to understand effectiveness.

The Lower Gastro-intestinal team have had 8 complaints raised with them that have involved elements of communication. The complaints have been raised with 4 different consultants. Within the medical directorate new processes were put in place during Q1 to monitor any trends within Site Specific Teams and ensure that the information is fed back to the teams to support their learning. Whilst there has been no evidence that this change has impacted on the number of communication concerns received, the engagement within the teams has improved and work continues to develop.

Training has been provided by for clinicians to support their understanding of the impact of poor communication for patients and their families. This work is being supported by a new Directorate Support Manager who is engaging with the handling of concerns and providing direct feedback to the teams.

There is a specific piece of work being undertaken in partnership with Welsh Ambulance Service as detailed in the Integrated Care workplan, to understand the requirements of the transport services for patients. Learning identified through incidents and complaints is informing this work. Regular meetings are held with Welsh Ambulance service with the

incidents and complaint data used to guide reviews of the service to ensure that it is meeting the needs of the patients.

3.2 Incidents

98 incidents were reported during this period relating to communication or attitude as the subject of the incident. The categories identified for further analysis reflect the 'sub-subtype' area chosen when the incident was generated. This has allowed for data to be explored at departmental level, however, some incident data may have been recorded in a manner that does not allow for a specific department or service to be identified.

A summary of these is detailed below:

Category	Area	Number	Issue	Action
Velindre Cancer Centre				
Infection Protection and Control	Systemic Anti Cancer Therapy (SACT)	2	Timely sharing of COVID-19 test results impacting on timing of treatment	
	Radiotherapy	1	COVID-19 screening	
With another care setting or hospital	Pharmacy	7	Medication provision by Homecare. Delay in blood results impacting on SACT prep.	
	Portering	6	Delay in porters attending a job. New electronic portering request system was introduced in March 2021 and has had some initial interface challenges.	
	Information Governance	1	Patient received a letter not intended for them.	
	Transport	4	Delay in transport arriving and challenge in accessing transport.	
	Treatment	2	Poor communication in changed to patient treatment plan.	
	Access to care	16	Incorrect appointment times. Patients presenting to VCC when changes have been made to their appointment.	

With patient/Service user			Communication between departments.	
	Information Governance	2	Incorrect blood labelling.	
	Virtual activity	5	Timeliness of call. Access to Information Technology to support virtual activity.	
	Transport	4	Patients arriving for treatment via Welsh Ambulance Service Transport at incorrect times.	
	Portering	1	Timely attendance.	
	Consent	1	No consent form available.	
	Pharmacy	3	Changes to treatment plan not communicated.	
	Outpatients	3	Noise level in the department. Tone used by staff member.	
	First Floor Ward	9	Bed availability. POC not cancelled. Discharge planning. Access to blood products.	
Clinical area	Operational services	8	Portering availability. Timely access to Welsh Ambulance Service Transport.	
	Medical Secretaries	1	No letters generated.	
	SACT	4	Hypersensitivity reaction. Timeliness of SACT preparation for patient treatment	
	Medical	3	No Clinical outcome forms. No communication of treatment plan.	
	VCC	4	Poor capture of care and treatment plan. Staff not handing over care	

Handover of care	VCC	4	Verbal abuse by patient towards staff	
Welsh Blood Service				
Behaviour/attitude	WBS	1	Donor not accepted for donation	
Lack of information	Welsh Blood Service	1	Polar bags not collected.	
With another care setting or hospital	WBS	1	Donor presenting at incorrect time.	

Whilst there are no areas that have a particular spike in incidents that are categorised as communication or attitude there are clear opportunities for staff to be reminded of the impact of their communication with within teams and with patients.

The introduction of the new electronic portering request system Symbiotix in March 2021 has had an impact on the service with any change taking time to embed into practice. The operational services team are reviewing the impact of the new system regularly and a service improvement manager has been appointed to support staff training around the best use of the new system with a view to reduce the number of reported incidents. There are continued challenges however as the system runs on the public wi-fi network which causes issues with connectivity and notifications via the portering handheld units.

4. CONCLUSION

The methods of communication and the behaviours and attitudes displayed within our services have a significant impact on our service users. Adopting a suitable approach can be difficult with adaptations being required frequently in response to the situation. The Divisions have reviewed and received the findings of the deep dive and are working with the Quality and Safety leads to develop local action plans to support the reduction of complaints and incidents. The data shared is being used to inform work streams such as the treatment helpline and transport with this work being managed through departmental work plans and assurance being provided to Senior Management and Leadership teams.

5. NEXT STEPS

- Share deep dive findings with wider clinical and operational teams
- Deliver suite of training during which deep dive findings will be used as examples.
- Use CIVICA data and ‘real time’ feedback as an opportunity to monitor impact of communication, attitude and behaviours for our patients and donors
- Repeat deep dive review in 6 months

QUALITY, SAFETY AND PERFORMANCE COMMITTEE

INFORMATION GOVERNANCE ASSURANCE REPORT

DATE OF MEETING	24th March 2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Ian Bevan, Head of Information Governance & Matthew Bunce, Executive Director of Finance
PRESENTED BY	Matthew Bunce, Executive Director of Finance
EXECUTIVE SPONSOR APPROVED	Matthew Bunce, Executive Director of Finance

REPORT PURPOSE	FOR DISCUSSION / REVIEW

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING

COMMITTEE OR GROUP	DATE	OUTCOME
EMB Run	7 March 2022	Amend report in line with recommendations from EMB Run

ACRONYMS

IG	Information Governance	NWSSP	NHS Wales Share Service Partnership
VCC	Velindre Cancer Centre	ICO	Information Commissioners Office
WBS	Welsh Blood Service	NIIAS	National Intelligent Integrated Audit Solution
DHCW	Digital Health and Care Wales	M&S	Mandatory and Statutory

HoIG	Head of Information Governance	DPIAs	Data Protection Impact Assessments
GDPR	General Data Protection Regulation	AOS	Acute Oncology Service
MHRA	Medicines and Healthcare products Regulatory Agency	SAR	Subject Access Requests
AHRA	Access to Health Record Act 1990	IGMAG	Information Governance Management Advisory Group
SIRO	Senior Information Responsible Officer	DPO	Data Protection Officer
FOIA	Freedom of Information Act	EIR	Environmental Information Regulation
NCSC	National Cyber Security Council	CISP	Cyber Information Sharing Partnership
VUNHST	Velindre University NHS Trust	IMTP	Integrated Medium-Term Plan

1. SITUATION/BACKGROUND

1.1 The purpose of this report is to provide assurance about the way Velindre University NHS Trust (VUNHST) manages its information in respect of patients, donors, service users and staff highlighting compliance with Information Governance (IG) legislation and standards, actions to improve management of IG risks and report IG incidents and actions from lessons learned.

1.2 The report sets out how IG supports the delivery of VUNHST's statutory functions and contributes to delivering its Integrated Medium-Term Plan (IMTP) and associated Strategy. It does this through 8 domains of IG:

1.3 The report outlines key assurance activities and IG Incidents for the reporting period of 1 January 2022 to 28 February 2022. There may be some instances where reporting is from 1 December 2021 to 28 February 2022, this is to ensure that a full picture of activity is provided where previously reported up to 30th November. Relevant updates from this reporting period are provided based on the core responsibilities of the Trust:

1.3.1 Compliance with the IG Toolkit and improvements in managing information risks

1.3.2 Organisational compliance with legislative and regulatory requirements relating to the handling of information, including compliance with the Data Protection Act (2018) (General Data Protection Regulation (GDPR)), Freedom of Information Act (2000) and Environmental Information Regulations (2004)

1.3.3 Any IG Incidents relating to any losses of personal data or data security breaches within the reporting period.

1.3.4 Any IG work during the reporting period and future work planned to improve IG and data security

1.3.5 The key impacts that the IG assurance Framework aims to mitigate against are:

- rights and freedoms of individuals being breached

- loss of confidence in the Trust, harm or financial impact to patients, donors and staff
- possible impact on safety & quality of clinical care or day-to-day operational functions of the Trust
- Trust reputational damage
- financial impact through ICO fines and cost of recovery of information & systems, legal advice etc.

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 SPECIFIC MATTERS FOR CONSIDERATION (ASSESSMENT)

The committee is reminded of the definition of an Information Governance Incident:

> "a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, all personal data, whether Employee or Patient, Donor, Service User held on computer or held manually and whether communicated verbally, electronically or in writing"

2.2 TRUST COMPLIANCE – LEGAL & REGULATORY FRAMEWORK

The following provides an update during the reporting period against the Information Governance (IG) Assurance Framework that ensures the Trust meets its statutory obligations and other standards. There are a number of areas of Risk Management & Assurance in relation to IG that are in place included at **Appendix 1** and form part of the ongoing IG workplan included at **Appendix 2**.

The three key aspects of assurance that are being brought to the Committee's attention are:

- IG Toolkit – a self-assessment providing an overview of the Trust compliance against national Information Governance (IG) standards and legislation through assessment against the eight domains of IG

- Data Protection Impact Assessment (DPIA) – this is how we identify processing risk in a privacy by design methodology for electronic and manual systems in operation and also importantly how we continue to review that risk on a regular basis

- IG incident investigations – these articulate the impact of any losses of personal data or data security breaches on the rights and freedoms of individuals and the being taken and lessons learned

2.2.1 Information Governance Toolkit Self-Assessment

The Welsh Information Governance Toolkit (IG Toolkit) is an online self-assessment tool managed by DHCW enabling organisations to measure their level of compliance against national Information Governance (IG) standards and legislation. The tool is completed annually and provides evidence of areas of improvement achieved and identifies actions for the following year.

The IG Toolkit annual assessment will be completed and upload to the DHCW site by the end of March '22. Last year's submission is being used by the HoIG to identify previous areas for improvement and provide background information. However, to ensure that the Trust has a fully updated picture the 2021/22 assessment is being completed without incorporation of the previous year's self-assessment. To provide assurance the 2021/22 assessment will be compared against the previous year's assessment identifying any key differences. The priority areas for improvement will form the basis of the IG workplan for 2022/23.

Action

- Completion of the IG toolkit by 31st March and update of the IG workplan to reflect new areas of improvement required
- Identification of differences from previous years assessment
- Sharing of assessments across Wales to support learning & improvement

2.2.2 Data Protection Impact Assessments (DPIAs)

A DPIA is a process to help analyse, identify and minimise the data protection risks of a system (both electronic and manual records). Under UK GDPR DPIA's are a legal requirement for processing data that is likely to result in high risk to the rights and freedoms of individuals being breached and good practice when processing personal data. A DPIA does not have to eradicate all risk but should help to minimise and determine whether the level of risk is acceptable in the circumstances.

Under UK GDPR, failure to carry out a DPIA when required may leave the Trust open to enforcement notice where the ICO will tell the Trust that it MUST carry out an action and if it does not, the ICO may impose a financial penalty of up to 20 million Euros (£16.52m).

A review is being undertaken by the HoIG and Head of Digital Delivery of the Trust key systems to assess the status of the DPIA's. An initial finding is that where systems were in place pre-GDPR (25 May 2018) DPIA's were not undertaken for some.

Due to the volume of systems in use across the Trust work will remain ongoing throughout 2022/23 to obtain a full picture of the DPIA status. The DPIA's will be prioritised and activity planned throughout 2022/23.

DPIAs are completed by the staff in each of the Trust departments who are responsible for systems that store and process information. The responsible officer is identified as Information Asset Owners (IAOs). As a risk assessment methodology, the DPIA process articulates IG risk which the IAO needs to take action to remove or mitigate.

The HoIG has employed a workshop approach to reviewing new DPIA's with information owners to ensure that understanding is as thorough and detailed as possible. The same approach will be taken with the owners of legacy systems to review and update DPIAs or complete new DPIA where required due to a high risk to the rights and freedoms of individuals being breached.

The following sets out the number of new DPIAs commenced since October '22 both for Internal Trust systems and External National systems the Trust uses and whether the DPIA has been approved by the HoIG:

No. DPIA's	**Internal Trust Systems**	**External NHS Wales National Systems**	**Commenced by Data Owner / Approved by HoIG**
11	9	2	Commenced by data Owner
4	4	0	Approved by HoIG

The Record of Processing Activity (ROPA) is another are of substantial work that needs to be progressed, which will record formally DPIA activity and the type of data being processed.

Action

- All systems either in use or proposed for adoption across the Trust where personal data is processed and considered a high risk to the rights and freedoms of individuals being breached will undergo a DPIA screening process in line with ICO best practice.

- Work ongoing to obtain a clearer picture of existing systems and associated DPIA's across the Trust

- Work ongoing to obtain a full picture of all Trust systems and their DPIA status during 2022-23

- DPIA's will be prioritised and activity planned throughout 2022/23.

2.2.3 DPA requests, Data Security incidents & investigations

Members of the public are entitled to request information from public authorities, these are known as Subject Access Requests (SAR). Information requested may include information about themselves - Data Protection Act, or information held by public authorities - Freedom of Information (FOI) Act and Environmental Information Regulations (EIR). The Trust is required to respond to any requests in line with legislation:

- FOI/EIR – 20 Working Days (if received on a bank holiday/Saturday/Sunday – next working day)
- DPA 2018 – 1 calendar month from date of receipt

Note: FOI/EIR requests, incidents and investigations are included in a separate report.

Data Protection SARs for clinical information and requests from third parties

During the period of 1 December 2021 – 28 February 2022 a total of 47 requests for access to health records were received with **0% breaches against the one calendar month response timeframe.**

Data Protection SARs for non-clinical information

During the period 1 December 2022 – 28 February 2022, 2 requests were received for access to information held on an individual with **0% breaches against the one calendar month response timeframe**

Data Security Incidents

Analysis
Under GDPR there are 3 types of data breaches:

Confidentiality breach – where data or private information is disclosed to 3rd parties without the owner's consent

Integrity breach (Data protection) – unauthorised or accidental alteration of personal data

Availability breach (Data Protection) – accidental or unauthorised loss of access to, or destruction of, personal data

A number of incidents reported, relate to patient / donor record confidentiality; these incidents include failure to secure records, records misfiled, sent/delivered to the wrong recipient and disclosed in error.

It is a legal obligation under GDPR to notify personal data breaches within 72 hours to the Information Commissioner's Office if the breach is likely to result in a high risk to the rights and freedoms of individuals being breached. Organisations must also inform those individuals without undue delay.

During the reporting period one incident involving personal data breaches (multiple patient records) was assessed as requiring reporting to the Information Commissioner's Office, WG and nationally. All members of the EMB were informed immediately due to the seriousness of the incident which remains ongoing and is one of the 5 open investigations. This incident is subject to a separate paper included in the private QS&P agenda.

Velindre Cancer Centre (VCC) Incidents

Quarter 4 (1 Jan 22 – 28 Feb 22)

Reported via Datix
There have been 16 Data security incidents reported within Datix this period, however, following review the correct number of incidents is 14, as 1 of the incidents has been raised twice in Datix by differing departments and one of the incidents relates to an estates/pharmacy issue and not IG.

- Of the 14 incidents 9 relate to data protection and 5 to confidentiality.
- 1 incident was reported to the ICO.
- All 14 IG incidents were investigated by the HoIG and 8 remain open.

All 6 incidents after investigation with the reporter presented no risk of harm to the continuity of patient care from an IG perspective. 8 incidents are still in the process of investigation with 6 of those presenting a low risk which is expected to present no harm to the continuity of patient care, for this reason priority is being given to the investigation of other higher risk incidents. These remaining 2 incidents are subject to Root Cause Analysis. Preliminary results for 1 incident shows that the risk of harm may be lower than

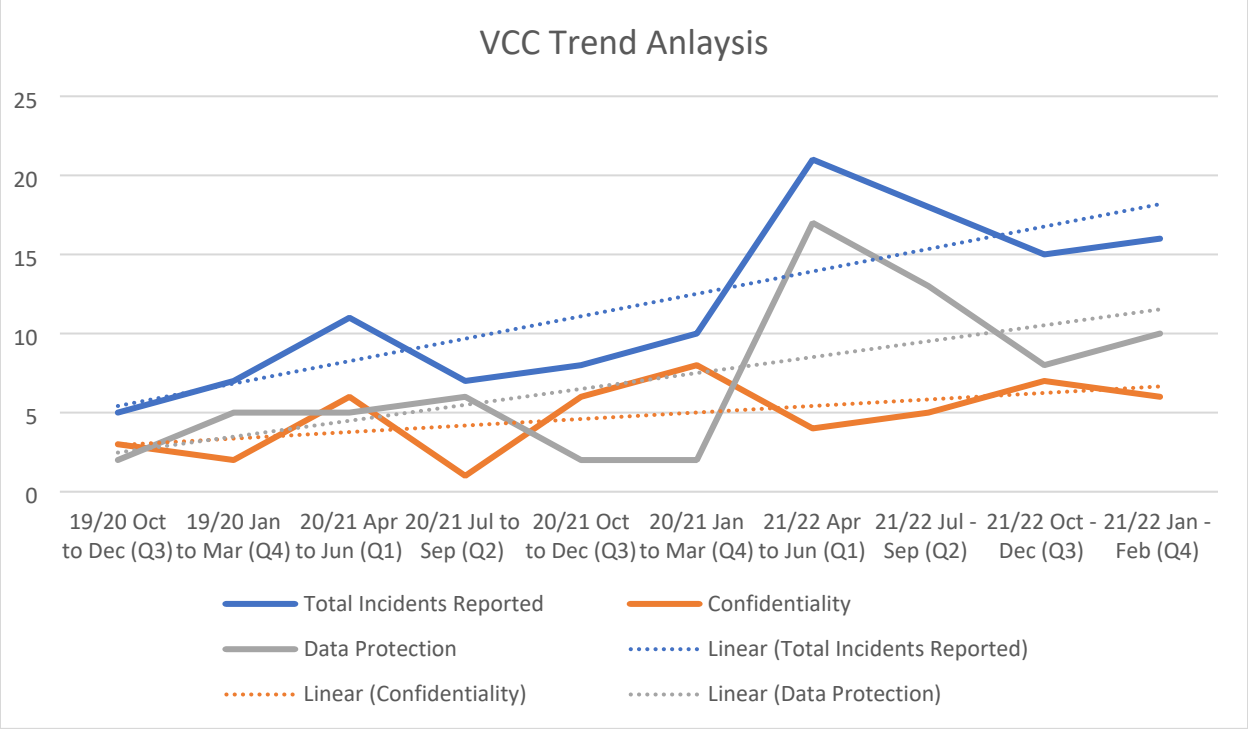
originally thought, as most information is already recorded within electronic patient systems. The remaining incident is under investigation and is the subject of a separate report.

Not reported via Datix

There have been 2 Data security incidents reported directly to the HoIG due to their sensitivity.

- Of the 2 incidents 1 relates to data protection and 1 to confidentiality.
- 1 incident was reported to the ICO.
- 1 IG incidents was investigated by the HoIG and closed, the other remains open.

Incident Trend



The increase in incidents identified since April ’21 is across all categories and teams. It appears that the core reasons for the increase could be:

- Incidents that were not primarily identified as IG, but which had an IG aspect not previously being flagged as IG.

- New version of Datix has added functionality of an IG flag, which has increased reporting due to an active campaign by DATIX trainers encouraging individuals to report incidents even if unsure whether the incident requires reporting or not.
- No additional IG training & awareness sessions for 5 months from Jun 21 when the IG Manager departed Velindre, until Dec 21 when HoIG commenced.
- Outcomes of incidents and lessons learnt are shared at team meetings and IG training awareness sessions

Welsh Blood Service (WBS)

During 21-22 incidents previously only reported on QPulse have also been reported on DATIX so that the Trust has full visibility of all incidents, including IG related.

There were 2 IG incidents reported during the period 1 Jan 22 – 28 Feb 22. One incident is closed, the other remains open which is expected to present no harm to continuity of patient care, for this reason priority is being given to the investigation of other higher risk incidents within VCC.

NHS Wales Shared Services Partnership (NWSSP)

There has been a total of 9 incidents reported during month 1 (Jan 22) of Qtr 4 2021-22. All incidents are closed.

IG Root Cause Analysis Investigations

During the reporting period, 5 incidents reported via DATIX required a Root Cause Analysis Investigation. In addition, 4 incidents were not reported via DATIX due to their sensitivity but reported directly to the HoIG and required a Root Cause Analysis Investigation.

Of the 9 Root Cause Analysis Investigations undertaken, 4 investigations were closed and 5 remain open.

Action

- Actions identified through the Root Cause Analysis for each incident are being implemented by the relevant leads

Lessons Learned / Actions

Initial analysis of incidents is that most cases could be avoided with improved IG awareness & training of staff as human error appears to be the common factor

Where human error has been assessed as the main contributory factor, the following actions have been taken:

- The person who has made the error required to undertake ESR IG awareness training
- Enhanced IG training delivered by HoIG to teams using a risk-based assessment i.e. no. of incidents from each team balanced against impact
- If an incident is assessed as potentially having a serious impact on the patient/donor or the family of a patient/donor a Root Cause Analysis investigation is undertaken in addition to the investigation template within DATIX

2.2.4 Other IG Assurance

Other areas of IG assurance are included in **Appendix 1.**

The summary IG workplan is included at **Appendix 2**.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	The loss or disclosure of personal information should be an important consideration for all staff on a day-to-day basis as it can seriously damage the Trust's reputation and undermine patients, donors and/or service user's trust.
RELATED HEALTHCARE STANDARD	Effective Care
	Standard 3.4 Information Governance and Communications Technology
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	The accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, all personally identifiable data may lead to a breach of security and the noncompliance with Data Protection Legislation. Where there is an impact on the rights and freedoms to the Data Subject, this may be reportable to the ICO

	within 72 hours of the discovery of the breach. Unauthorised access to systems may also lead to further legal ramifications (Computer Misuse Act 1990)
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	In recent years the Information Commissioners Office powers have been strengthened including the power to impose financial penalties (fine of up to 20 million euros) and issuing enforcement action. It should be noted that the ICO has launched its review of the Regulatory Action Policy which is due to close in March 2022. A watching brief will be kept, and the Committee informed as appropriate, but there may be changes to the powers of the ICO because of the consultation.

4. RECOMMENDATION

4.1 The Committee is asked to **DISCUSS & REVIEW** the contents of this report

Appendix 1: Other areas of IG assurance

Requests for Information - Compliance with Legal and Regulatory Framework

Subject Access Requests (SARs)

Members of the public are entitled to request information from public authorities, these are known as Subject Access Requests (SAR). Information requested may include information about themselves - Data Protection Act, or information held by public authorities - Freedom of Information (FOI) Act and Environmental Information Regulations (EIR). The Trust is required to respond to any requests in line with legislation. Freedom of Information Act compliance is subject to a different report. DPA 18 Subject Access Request data is below:

- DPA 2018 – 1 calendar month from date of receipt.

Data Protection Subject Access Requests for clinical information and requests from third parties

During the period of 1 December 2021 – 28 February 2022 a total of 47 requests for access to health records were received with **0% breaches against the one calendar month response timeframe**:

Access to Health Records	**Total**
Type of SAR	
Data Protection (Live Patients)	41
Access to Health Records Act 1990 (AHRA) [Deceased Patients]	6
Total requests received	**47**
Timeframe Breached (Total number of responses issued outside the one calendar month timeframe)	**0**
% Breaches	**0%**

Data Protection Subject Access Requests for non-clinical information

During the period 1 December 2022 – 28 February 2022, 2 requests were received for access to information held on an individual with **0% breaches against the one calendar month response timeframe:**

Access to Non-Health Records	Total
Type of SAR	
Data Protection – own data	2
Data Protection – someone else's data	0
Total requests received	**2**
Time breached (total number of responses issued outside the one calendar month timeframe for response)	**0**
% Breaches	**0%**

Data Protection Subject Access Requests Non-Health Records received 1 Dec 21 – 28 Feb 22			
Data Protection (Own data)	**Data Protection – (someone else's data)**	**Total Breached**	**Breach rate %**
2	0	0	0%

The non-clinical Subject Access Requests were for own records from individual employees of the Trust. Due to complexity of providing the information for both requests the timescales for provision of the information have been extended.

Action / Mitigation

- The Trust aims to maintain compliance performance with Data Protection requests.

IG Awareness Training

The Trusts compliance with IG awareness training is 82.56% which is just below the required target of 85% of all staff to complete training within the financial year. However, the Corporate Departments are achieving significantly lower percentage attainment (71.17%).

Action / Mitigation

- The Trust will continue to deliver and monitor the uptake of IG awareness training which will target hotspots such as Corporate Departments and those staff who have not completed training in the last two years and provide support to achieve compliance.

- The HoIG will continue to provide suitable training for Information Asset Owners (IAO's) and Information Asset Administrators (IAA's) within each business area. IAO's are responsible for managing information risks to assets in their control.

- Where there has been a reported IG incident, the HoIG has taken an approach of increased training regardless of the current status of the IG awareness training of the person responsible for the breach. In addition, where there is a wider team undertaking the same functionality where the incident occurred, IG training completion regardless of current status is also required of the wider team. This approach means that IG Training and impact of errors are highlighted to everyone.

- Proactive increased training by the HoIG has been offered to teams to help their understanding of how IG impacts on their day-to-day function.

- It is anticipated that the re-fresh of the areas within the workplan in Q4 2021/22 to Q1-3 2022/23 will lead to a positive impact across the Trust by the end of 2022/23

Information Governance and data security Incidents

Analysis

The main difference between data protection and confidentiality is that data protection secures data from damage, loss, and unauthorized access while confidentiality allows accessing the data only by the authorized users.

TA number of the incidents reported relate to patient records confidentiality; these incidents include failure to secure records, records misfiled, sent/delivered to the wrong recipient and disclosed in error.

It is a legal obligation to notify personal data breaches of the General Data Protection Regulation under Article 33 within 72 hours, to the Information Commissioner's Office, if the breach is likely to result in a high risk to the rights and freedoms of individuals. Organisations must also inform those individuals without undue delay.

During the reporting period one incident involving personal data breaches (multiple patient records) was assessed as requiring reporting to the Information Commissioner's Office, WG and nationally. All members of the EMB were informed immediately due to the seriousness of the incident which remains ongoing. This incident is subject to a separate paper.

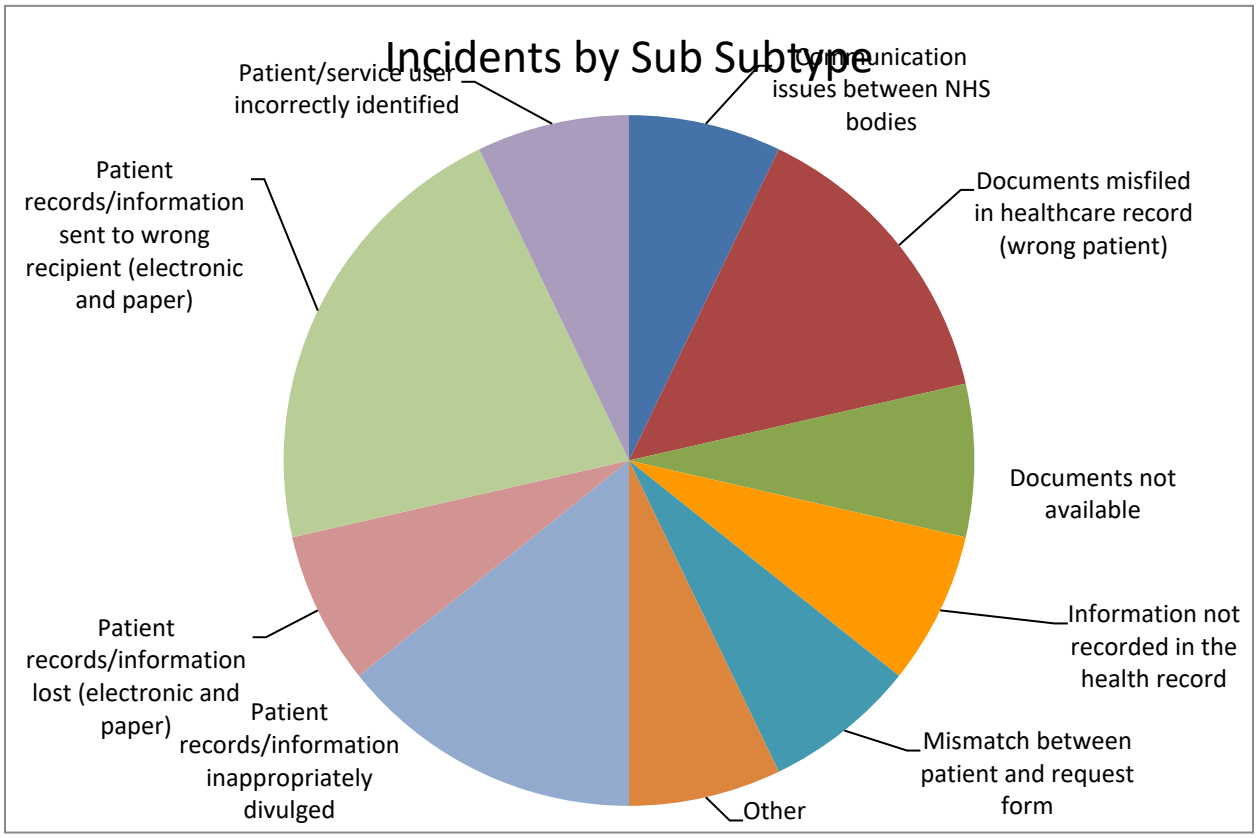
Velindre Cancer Centre (VCC)

Quarter 4 (1 Jan 22 – 28 Feb 22)

There have been 16 IG incidents reported within Datix this period, however, following review the correct number of IG incidents is 14, as 1 of the incidents has been raised twice

times in Datix by differing departments and one of the incidents relates to an estates/pharmacy issue and not IG.

Of the 14 incidents 10 relate to data protection and 3 to confidentiality. The type of incident is sub categorised as follows:



Department / Team IG incident occurred in	No. Incidents
Outpatients	1
Medical Records	6
Radiology	1
SACT / Chemo Booking	3
Radiotherapy	1
CNS	1
Nuclear Medicine	1
Total	**14**

IG Incidents not reported via Datix

Quarter	Total incidents	Reported to ICO / ICO Case
2021/22 - Q3	2	2
2021/22 – Q4(1 Jan 22 – 28 Feb 22)	2	1

All 4 incidents were investigated by the HoIG, 3 are closed and 1 incident remains under investigation.

Lessons Learnt / Actions Taken

The HoIG is working to clear the backlog of 8 incidents (Jun - Dec 21). Review and closure of DATIX IG incidents is included in the HoIG weekly activity.

Initial analysis of DATIX IG incidents is that most cases could be avoided with improved IG awareness & training of staff as human error appears to be the common factor. Where human error has been assessed as the main contributory factor, the following actions have been taken:

- IG Training for the person who has made the error be undertaken regardless of their current training attainment
- IG training for all team members be undertaken regardless of the current training attainment – this is as a learning point to reinforce the need to ensure that everyone acts compliantly
- If deemed an incident where there may be a serious impact on the patient/donor or the family of a patient/donor then a Root Cause Analysis investigation is undertaken in addition to the investigation template within DATIX
- Outcomes of incidents and lessons learnt are shared at team meetings and IG training awareness sessions

In addition to IG training and awareness provided within ESR, enhanced IG training is now being delivered to teams where risk has been identified. Risk being assessed based on the number of incidents (liklihood) from each team balanced against incident impact.

Attendance records and feedback for each session of training provided will be collected to ensure that the training delivered is appropriate to individual team requirements and ensure the Trust has evidence of what traiing has been given to which staff.

To date the the following enhanced IG training to teams has been delivered:

Team	Date
Medical Records Team	28 Jan 22
SACT	31 Jan 22
Pharmacy Administration	21 Feb 22
Chemo Bookings	28 Feb 22

Further enhanced IG training is planned for delivery to the following teams during March 2022:

Team	Date
PA Students	7 Mar 22
SHO's who begain their time in the Trust on 4 Feb 22 (as a result of an IG Incident)	7 Mar 22
Rutherford Nurses (commencement of contracted work as no access to ESR)	8 Mar 22
RITA Project Manager	9 Mar 22
Rutherford Nurses (commencement of contracted work as no access to ESR)	11 Mar 22
SSC Induction	14 Mar 22
Rutherford Nurses (commencement of contracted work as no access to ESR)	16 Mar 22

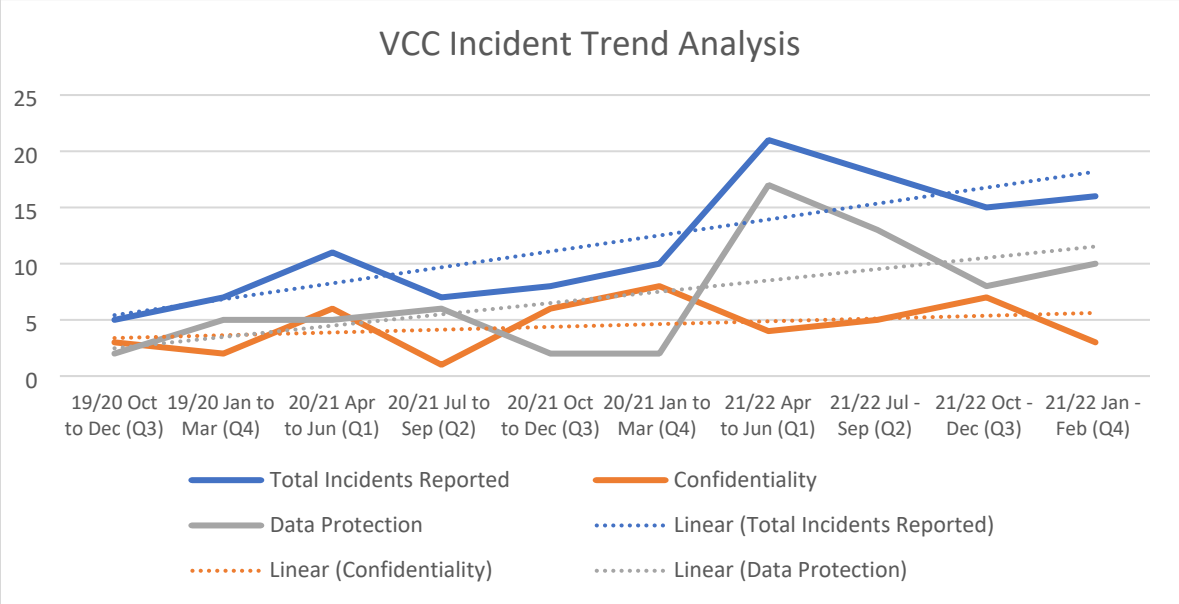
- Refresh IG Training & Awareness in ESR - The current ESR training content is pre-pandemic and pre-EU Departure. VUNHST is now registered within a ESR Refresh sub-section as part of the All Wales Information Management Advisory Group (IGMAG) that will be working on the refresh of IG training within ESR.

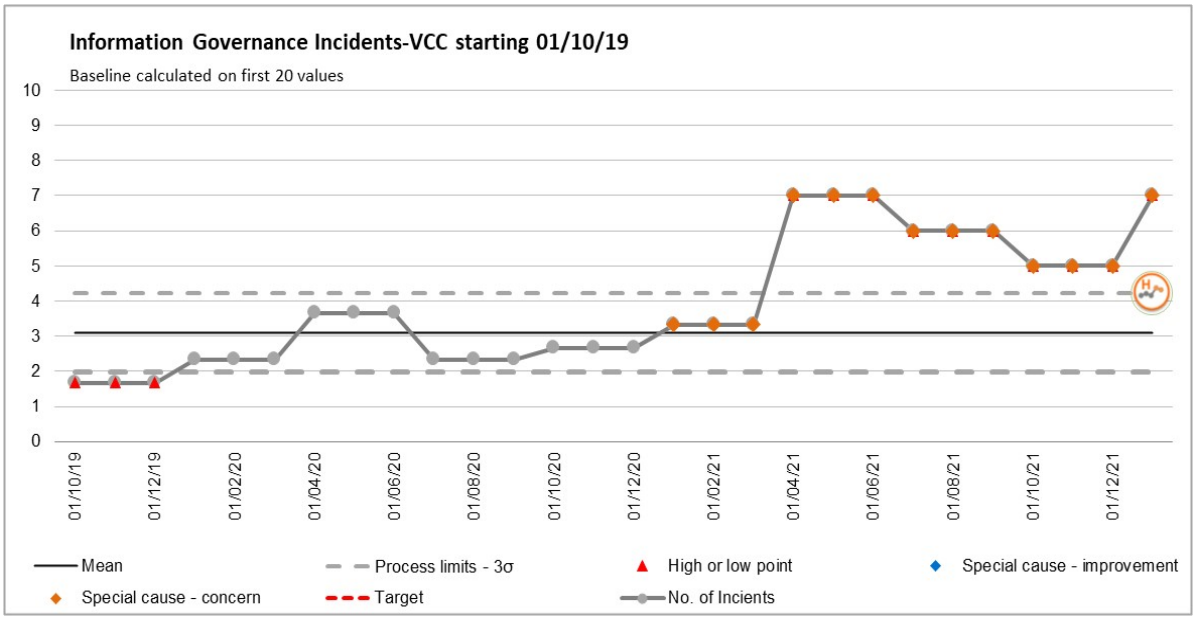
- Continue delivery of enhanced training to teams on a risk based approach

- Continue delivery IG staff induction training so that a positive IG culture is encouraged across the Trust.

IG Reported Incidents Trend Analysis

The graph and table provide the Committee with a trend analysis from Oct '19 to Jan '22 of all VCC IG reported incidents broken-down by Confidentiality & Data Protection.





Further analysis of IG incidents over eight weeks (7 Jan 22 – 28 Feb 22) has not changed the assessment from the last quarter report that there has been an increase in incidents reported since April ’21 across all areas. The increase in data protection incidents reported is greater.

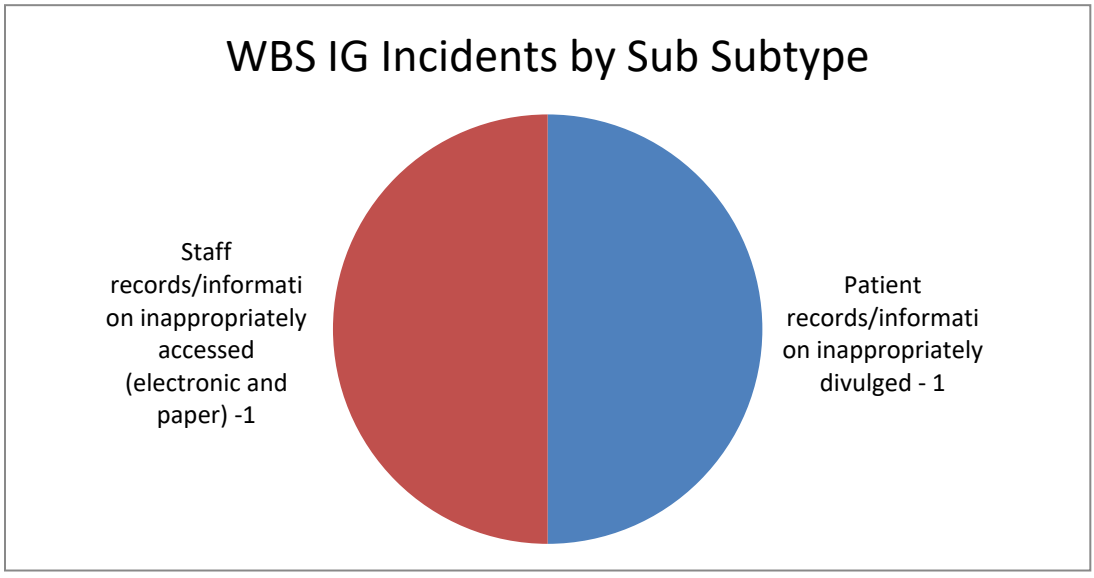
The increase in incidents identified since April '21 is across all categories and teams. It appears that the core reasons for the increase could be:

- Incidents that were not primarily identified as IG, but which had an IG aspect not previously being flagged as IG.
- Transition from Version 14 of DATIX to the Once for Wales version has added functionality of an IG flag, which has increased reporting due to an active campaign by DATIX trainers encouraging individuals to report incidents even if unsure whether the incident requires reporting or not.
- No additional IG training & awareness sessions for 5 months from Jun 21 when the Information Governance Manager departed Velindre, until Dec 21 when new HoIG commenced.

Welsh Blood Service (WBS)

During 21-22 incidents previously only reported on QPulse have also been reported on DATIX so that the Trust has full visibility of all incidents, including IG related.

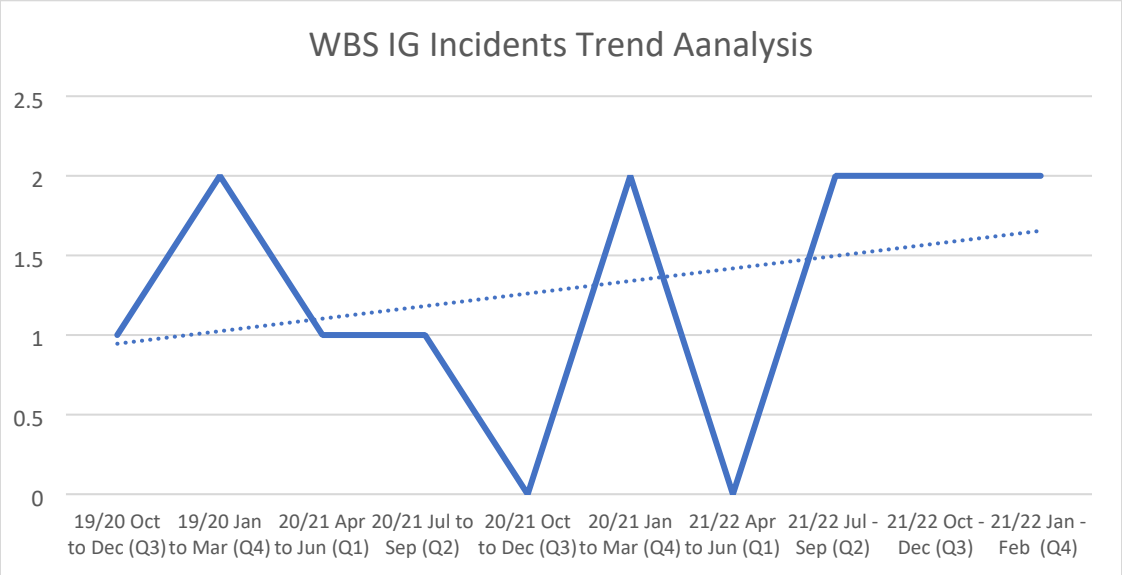
There were 2 IG incidents reported during the period 1 Jan 22 – 28 Feb 22.



Note: DATIX does not differentiate between donor/patient, so reference to patients means donors.

IG Incidents Trend Analysis

The chart below provides the Trend Analysis of WBS IG reported incidents from Oct '21 to Jan '22.



Lessons Learnt/Actions Taken

Initial analysis for the 1 donor information incident reported within the quarter to 28 Feb 22 is that it was a misdirection of information.The line manager contacted the HoIG immediately who advised the incident be recorded on DATIX. A simple investigation was undertaken and the following action taken by the line manager upon advice from the HoIG:

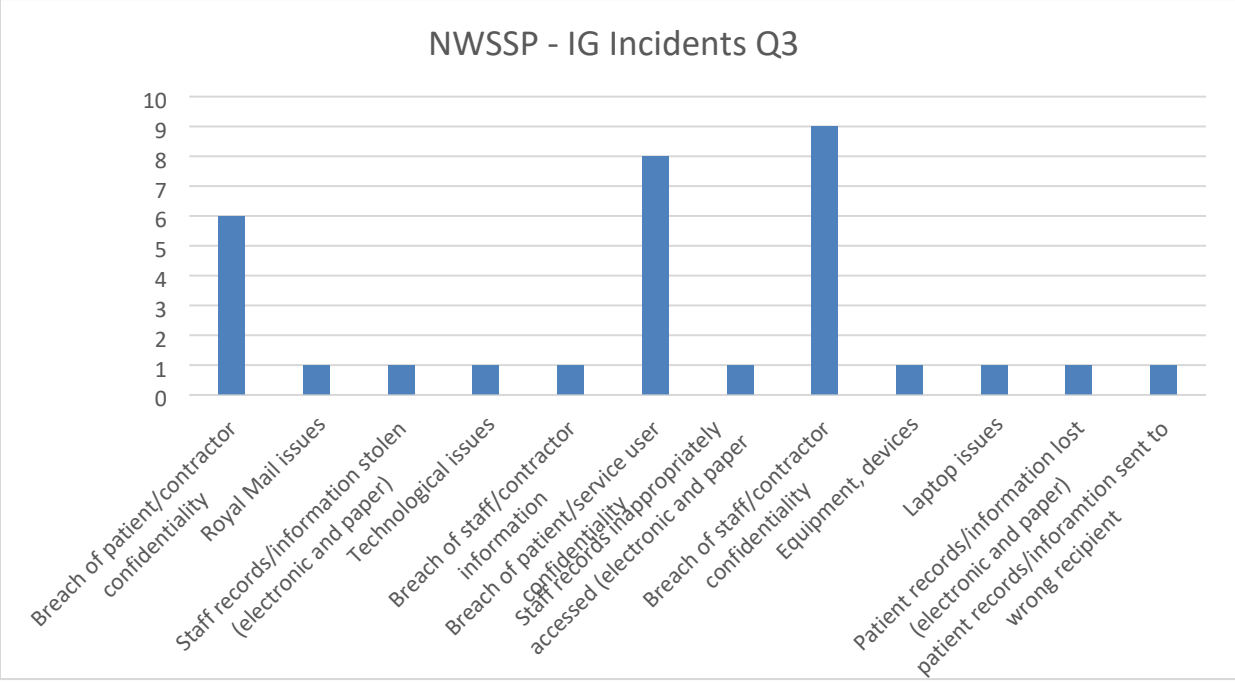
- IG Training for the person who made the error be undertaken regardless of their current training attainment, and;
- IG training for all team members be undertaken regardless of the current traiing attainment – this is as a learning point to reinforce the need to ensure that everyone acts compliantly

It was deemed by the line manager that this action would be sufficient to ensure that the individual had an appropriate level of warning in relation to the incident.

The staff related incident relates to inappropriate access to a member of staffs record and is currently under investigation.

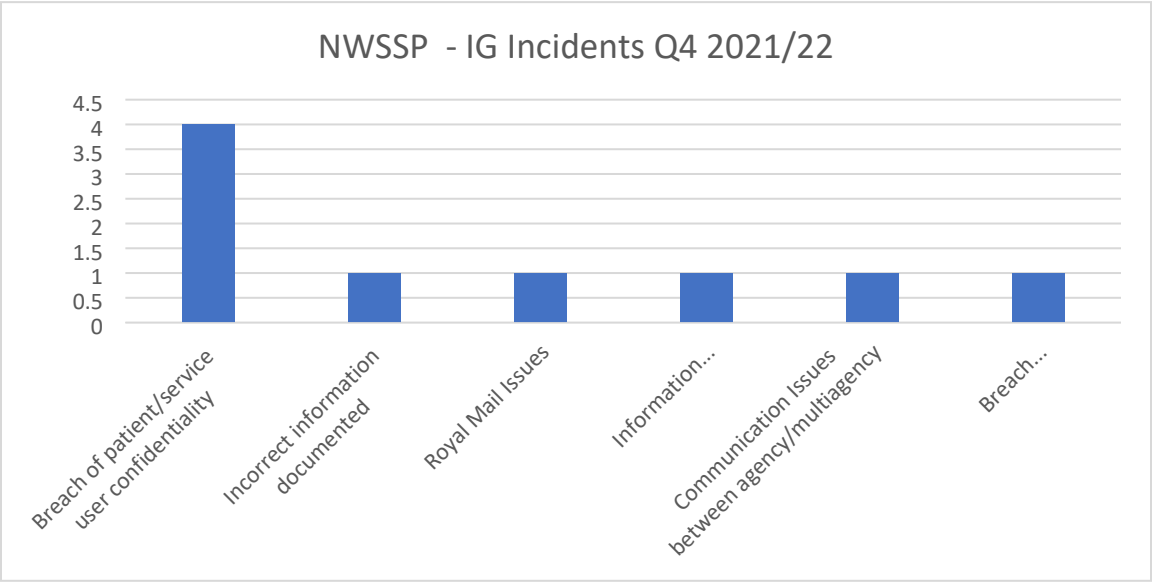
NHS Wales Shared Services Partnership (NWSSP)

There have been in total 32 IG incidents reported during Quarter 3 2021-22, and these are categorised as follows:



Note: the bar chart illustrates the main sub-categories of incidents, further detail is available within sub-categories

There has been a total of 9 incidents reported during month 1 (Jan 22) of Quarter 4 2021-22, these are categorised as:



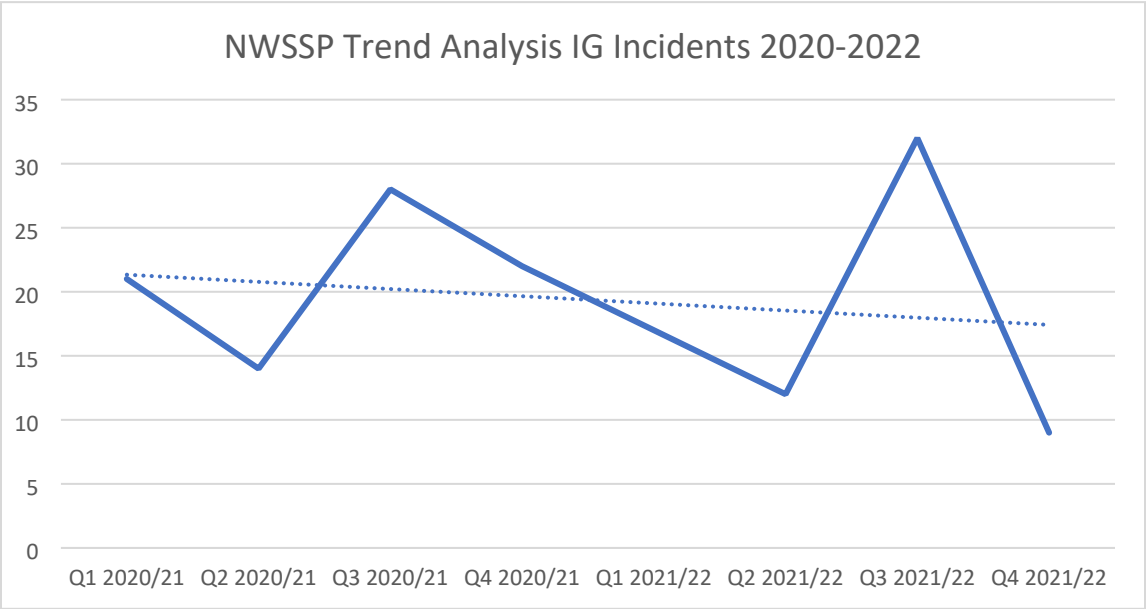
Lessons Learnt / Actions Taken

- NWSSP reports the incident and where it occurred across all the NWSSP services for awareness. Advice/Guidance on how to prevent / mitigate incidents is given to the reporter and is articulated against incident.

- The HoIG has noted that increased training and awareness to individuals or teams where an incident has occurred does not currently feature as a standard action. The HoIG is meeting with NWSSP IG Manager on 11 Mar 22 to discuss the Trust approach to IG processes and procedures and to scope the possibility of NWSSP adopting VUNHST approach to increasing awareness through a risk-based approach to additional focused training.

Incidents Trend Analysis

Trend analysis for NWSSP incidents over the last two years:



October 2020 (21 incidents) and October and November 2021 (10 and 14 incidents respectively) saw large rises which impacted on the overall figures for Quarter 3 in each financial year respectively.

Action / Mitigation

- The HoIG is liaising with the NWSSP IG Manager to try and understand the cause of these increases. The main area for most IG incidents is within Employment Services, so initial focus will be directed here.

IG Breach Root Cause Analysis Investigations

Analysis

During the reporting period, some incidents reported via DATIX required a Root Cause Analysis Investigation. In addition, some incidents were not reported via DATIX due to their sensitivity but were reported via other means. In such cases they were a direct approach to the HoIG to commence a Root Cause Analysis Investigation.

10 Root Cause Analysis Investigations were undertaken 5 not reported as Datix incidents and 5 Datix incidents. 5 investigations were closed and 5 remain open.

Action / Mitigation

- Various actions are identified through the Root Cause Analysis for each incident which are being implemented by the relevant lead

Assurance Framework

Issue

- Lack of clarity on IG Assurance Framework and which committees and individuals are accountable & responsible for IG can lead to the Trust not being sighted fully on IG risks and therefore not taking appropriate actions to remove or mitigate those risks

Analysis

The Trust's Information Governance Management Framework was reviewed in January 2022. It identifies the roles and responsibilities of key staff within the Trust and the reporting structures.

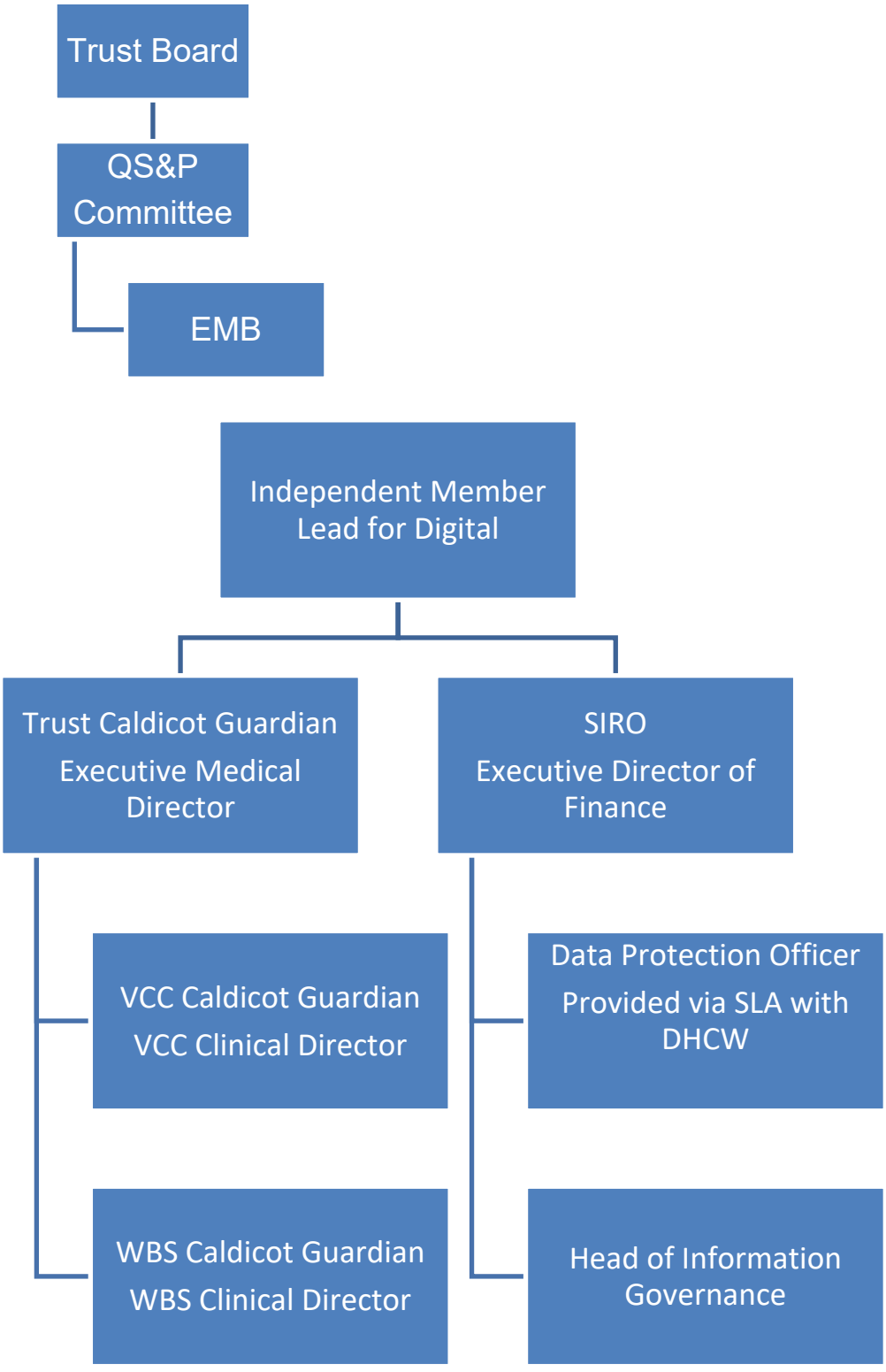
The Trust's Senior Information Risk Owner (SIRO) who is the Executive Director of Finance reports on IG and data security assurance to the Executive Management Board (EMB), which reports to the Quality, Safety & Performance (QS&P) Committee and from QS&P into the Board.

The SIRO is supported in this by the Data Protection Officer, HoIG and by Information Asset Owners (IAOs) and Information Asset Administrators (IAAs) within each business area. The IAOs are responsible for managing information risks to the assets within their control. Support is also provided through Head of Digital Delivery, Health Records Manager, Communications and W&OD.

The Trust Caldicott Guardian (Executive Medical Director) has responsibility for protecting the confidentiality of people's health and care information and making sure it is used properly. This is an important advisory role and the Trust Caldicot Guardian is supported by a VCC and WBS Caldicot guardian which are the Clinical Directors for the two Divisions.

The is an Independent Member lead for Digital which includes taking a lead on behalf of all Independent Members in assuring that the Trust is meeting its IG responsibilities in terms of compliance with legislation and standards, actions are being taken to improve management of IG risks and lessons are learned from IG incidents.

The Committee & Officer reporting framework is as follows:


Trust Board
QS&P Committee
EMB
Independent Member Lead for Digital
Trust Caldicot Guardian
Executive Medical Director
SIRO
Executive Director of Finance
VCC Caldicot Guardian
VCC Clinical Director
Data Protection Officer
Provided via SLA with DHCW
WBS Caldicot Guardian
WBS Clinical Director
Head of Information Governance

Note: The Executive Medical Director is the Trust Caldicott Guardian for all areas within the Trust except for VCC and WBS.

Action / Mitigation

- IG Assurance Framework to be included in IG training for Executives and Board members
- IG Assurance Framework included as part of additional IG training & awareness provided by HoIG
- re-invigorate the Caldicott function by:
    - Process map roles within the Trust so that the linkage between IG related roles (clinical and non-clinical) can be clearly understood
    - Assess compliance with Data Protection and Health Records Legislation thereby providing assurance as to whether the Trust is meeting its statutory obligations
    - Deliver IG training to clinicians including a refresher on the 8 Caldicott Principles

Policies

Issue

- Policy review deadlines missed may result in out-of-date legislation or best practice guidance being followed leading to an IG breach and associated risk

Analysis

The Trust has x8 policies that relate to Information Governance the status of the review of these policies as of 28th February 2022 is:

Policy Title	Sponsor	Author	Approval Date	Date Due Review	Date Reviewed
Records Management	DOF	HoIG	Feb 18	Feb 21	Dec '21
Data Protection and Confidentiality	DOF	HoIG	Feb 18	Feb 21	Dec '21
Software	DOF	Head of Digital	Feb 19	Feb 22	Expect completion Mar '22

Policy Title	Sponsor	Author	Approval Date	Date Due Review	Date Reviewed
Anti-Virus	DOF	Head of Digital	Feb 19	Feb 22	Expect completion Mar '22
Freedom of Information Act	DOF	HoIG	Feb 18	Feb 21	Dec '21
Data Quality	DOF	Head of Digital	Dec 18	Dec 21	Expect completion Mar '22
Confidentiality and Breach Reporting	DOF	HoIG	May 18	May 21	Dec '21
Information Asset	DOF	HoIG	May 18	May 21	Dec '21

Of the 5 polices authored by the HoIG, x3 had Feb '21 and x2 May '21 review dates. Due to the transition between the Information Governance Manager leaving and HoIG starting, the reviews for all x5 policies slipped to Dec '21, with update completed in Feb '22.

For the x3 policies authored by the Head of Digital one has a review date of Dec '21 and x2 a review date of Feb '22. The review and update of these x3 policies is currently nearing completion.

Action / Mitigation

- Reviewed and updated policies will be approved through the Trust governance processes.

- Once all the updated Policies are approved, it is expected that they will not require updates until 2024 which is the review date of the UK's Data Protection regime as part of the post-transition deal agreed on 30 December 2020.

- Should there be any changes to the UK Data Protection legislation or best practice codes before 2024 relevant polices will be reviewed and updated sooner.

Information Governance Training

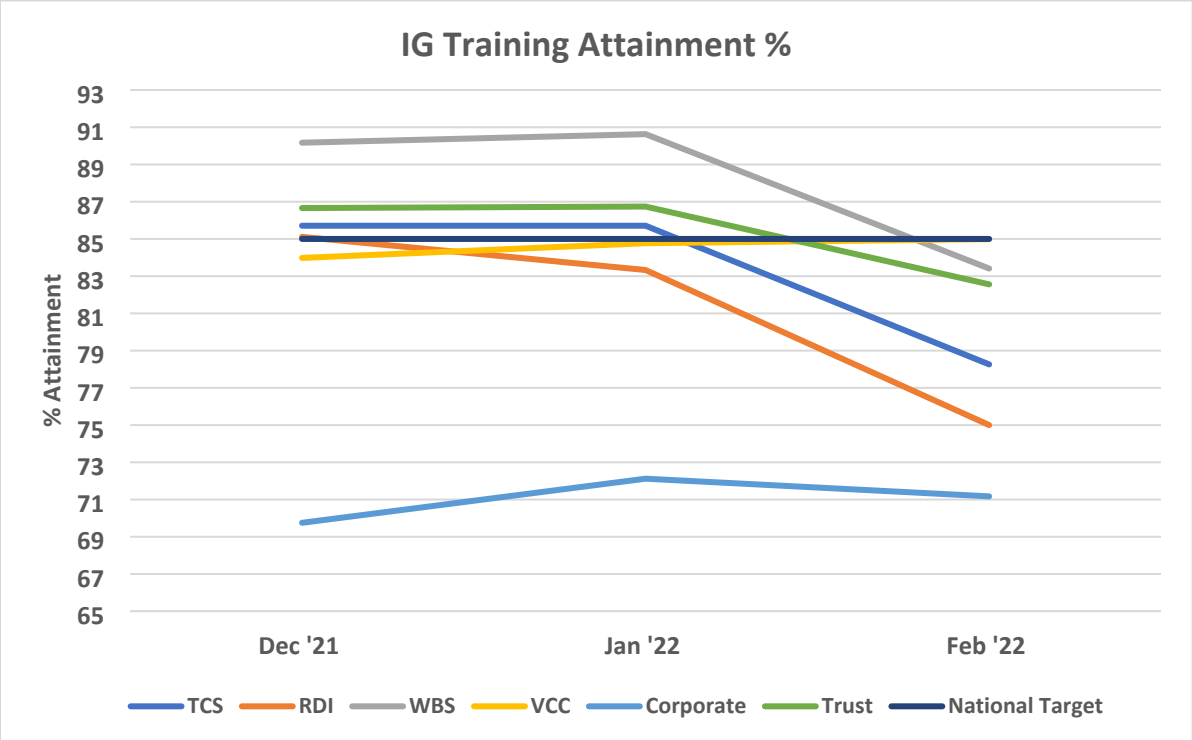
Issue

- The effective delivery of Trust services requires the substantial collection, processing, and exchange of personal data. Ensuring the appropriate collection, use and security of this information is a major legal responsibility for the Trust and its staff

- Information Governance training is mandatory for staff on a bi-annual basis to ensure they are aware of their role and responsibilities

Analysis

For Dec ’21, Jan ’22 & Feb 23 the IG Training Mandatory & Statutory Compliance figures for each Division and Total for the Trust were:



Historical performance data to show a 12 month rolling performance will be included in the next report to demonstrate trend analysis.

The Trust overall performance in Dec ’21 and Jan ’22 was c86% and meeting the National target of 85%. In Feb ’22 the Trust performance has dropped to c83% below the National target largely due to a reduction in performance mainly in WBS, but also in TCS & RD&I.

The Corporate performance remains significantly below other Divisions of the Trust at c72%.

The IG Toolkit has three levels in terms of attainment against standards for IG Training:

- Level 1 - IG training has been provided to staff in line with the core skills framework. Processes are in place to ensure temporary staff, volunteers and students have received appropriate IG Training
- Level 2 - The organisation has increasing compliance with IG mandatory training. There is a training strategy in place to identify the need and provision of specialist IG training
- Level 3 - The organisation has a high level of mandatory IG training compliance. Training content is regularly reviewed and updated. Feedback is requested where appropriate

When assessing percentage attainment against each level, the attainment levels are further defined in the IG Toolkit as:

- Level 1 - Organisation is able to meet 50% compliance of mandatory IG Training for Staff
- Level 2 - Organisation is able to meet 70% target for compliance on mandatory IG training for staff as a minimum
- Level 3 – The organisation meets the national target compliance of 85% for mandatory IG training – 85% attainment or higher

Action / Mitigation

- all Directors to urgently address the low compliance with their teams to improve attainment to achieve the 85% National Target.

Cyber Security

Analysis

Ransomware and Cyber-attacks have been around for many years, however during the Covid 19 pandemic, attacks have increased globally and the National Cyber Security Centre (NCSC) recorded an unprecedented 777 incidents in the last year a rise from 723 the previous year with around 20% of organisations linked to the health sector and vaccines.

There is an increased risk that NHS Wales will be attacked either directly or in directly due to a malicious or 'drive by' attack.

Warnings have been issued by the NCSC around the increasing threat landscape, and in the last few weeks, UK organisations were advised to bolster their cyber security resilience due to the Ukraine war.

The attack against the Health Service Executive (HSE) in Ireland in May 2021 was introduced by a phishing email/excel attachment which led to the encryption of 80% of its systems. It was over 5 months before their systems were fully back up. Investigators identified 700 Gb of data (including confidential health data) was exfiltrated from the networks and sent to servers owned by the threat actors. **A key finding from the report was that "HSE also had no security monitoring solutions deployed to help investigate and respond to security threats detected across its IT environment**".

Effective Cyber Security contributes to the security of information across the Trust. Accountability for fostering an information security culture is held by the SIRO who is responsible for overseeing the development and implementation of the Trust's cyber risk strategy. Accountability for operational delivery of Cyber Security sits with the Director for Strategic Transformation, Planning and Digital, with day-to-day responsibility sitting with the Chief Digital Officer and the Head of Digital Delivery. There are operational links between the HoIG and the Cyber Security Officer within Digital with regular touch points with contact increasing in reaction to incidents that require both functions to collaborate on an issue.

The HoIG and the Cyber Security Officer are members of the NCSC Cyber Information Sharing Partnership (CISP). CISP provides intelligence on current threats to information and systems from a UK perspective.

Basic Cyber Security awareness is included in the suite of IG training materials that has been put together to enhance VUNHST staff awareness as much of the online threat is now linked to cyber activity by criminals which in turn presents information risk.

Microsoft have allowed NHS Wales to enable its Security and Threat Prevention software at no cost until the end of February '22. There is a requirement to continue this service until 1st July 2022 at additional cost, at which point the new Microsoft Enterprise Agreement will commence which includes the cost of this service.

Action / Mitigation

- Fund the Microsoft cyber security software licenses from 1st March '22

- Cyber security officer to continue to deliver awareness training across the Trust

- Ongoing use of CISP intelligence on current cyber threats to focus discussions internally to ensure that required actions are taken to protect information and system.

Information Management

Issue

- In August 2021, the Lord Chancellors Information Management Code of Practice was superseded by the Information Management Code of Practice 2021 which is sponsored by the Department of Digital, Culture, Media, and Sport.

- The NHS Wales 2016 code of Practice for Information Management, which was adopted by the Trust, was based on the Lord Chancellors Information Management Code of Practice and has not yet been updated to reflect the Information Management Code of Practice 2021.

- Possible risk of following outdated code of practice leading to an IG breach

Analysis

NHS England reviewed and replaced their existing Code of Practice to reflect the Information Management Code of Practice 2021 which was published by NHSX on 4 August 2021.

All hyperlinks and references to the Lord Chancellors code have been removed from the NHS Wales 2016 Code of Practice, but no longer reflects current best practice.

Welsh Government is leading work to review and adapt this new Code of Practice in conjunction with the Health Records Management Advisory Group (HRMAG) which is a national group consisting of NHS Wales Trust and Health Boards members. The HoIG has joined the group, membership allows the Trust to influence the development of the Code of Practice and be aware of timelines for delivery. It is hoped the delivery timeframe of the new NHS Wales Records Management Code of Practice will be clearer in the next few months.

Informal enquires across the Welsh NHS has provided a mixed picture of what organisations are using whilst he Welsh Code of Practice is agreed; Powys Teaching Health Board dare not using the NHSX Code of Practice, however, Cardiff and Vale University Health Board are doing so until the new Code of Practice is published in Wales.

Action / Mitigation

- Participate and influence the work of the Health Records Management Advisory Group (HRMAG) reviewing and adapting this new Code of Practice

- Work is ongoing to consider whether the Trust should adopt the NHSX code of practice as a stopgap until the publication of the NHS Wales Records Management Code of Practice.

National Intelligent Integrated Audit Solution (NIIAS)

Issue

- Inappropriate access to clinical information not being identified and consequential risk of IG breach not being mitigated:
  - Due to the gap between the departure of the departure of the Information Governance Manager and commencement of new HoIG the Trust has not accessed the NIIAS system since March 2021.
  - VCC no longer have the capacity to undertake this activity, which was previously undertaken by the medico—legal officer who is no longer in post

Analysis

To undertake the proactive monitoring of staff access to records held on national clinical systems, Velindre has implemented the National Intelligent Integrated Auditing Solution (NIIAS) which is managed by DHCW. Velindre receives NIIAS notifications the following national systems:

- Canisc
- Welsh Clinical Portal
- Welsh Demographic Service

The NIIAS system provides live information regarding staff accessing records within the systems listed above. However, the Trust has not accessed the NIIAS system since March 2021. From Jan '22 the HoIG has been reviewing the NIIAS reports & system as regularly as possible, however the HoIG does not have sufficient resourced time to undertake daily review.

Action / Mitigation

- A full update will be provided in the next report by which time the HoIG will have undertaken a focused review of the NIIAS reports and whether there have been an IG breaches and actions taken in response

Ymddiriedolaeth GIG Prifysgol Felindre
Velindre University NHS Trust

Appendix 2 - Workplan Table – updated 3 Mar 22

Item	Q4 2021/22	Q1 2022/23	Q2 2022/23	Q3 2022/23
Review time expired IG Policies/Equality Impact Assessments and republish	X			
Refresh Data Protection Impact Assessment (DPIA) Screening Process	X			
Review existing DPIA's in relation to legacy systems in operation across VCC to ensure that they are reviewed in line with legislation				X
Review legacy systems in operation across VCC to ensure that where required a DPIA is in place				X
Review existing DPIA's in relation to legacy systems in operation across WBS to ensure that they are reviewed in line with legislation				X
Review legacy systems in operation across WBS to ensure that where required a DPIA is in place				X
Review existing DPIA's in relation to legacy systems in place across RD&I, TCS & HTW to ensure that they are reviewed in line with legislation				X
Review legacy systems in operation across RD&I, TCS & HTW to ensure that where required a DPIA is in place				X
Review existing DPIA's in relation to legacy systems in place across Corporate Departments to ensure that they are reviewed in line with legislation				X
Review legacy systems in operation across Corporate departments to ensure that where required a DPIA is in place				X
Instigate and maintain annual review process for all DPIA's created since 1 Dec 21	X			

Item	Q4 2021/22	Q1 2022/23	Q2 2022/23	Q3 2022/23
Instigate and maintain annual review process for all Data Processing/Sharing Agreeements		X		
Maintain current Record of Processing Activity (ROPA) for all divisions of the Trust, cross referring to DPIA tracker appropropriately				X
Create new Information Asset Register - reporting risks to SIRO annually and Corporate Governance as appropriate		X		
Ensure that the new Information Asset Register contains a risk treatment plan presenting the plan annually to the SIRO for review		X		
Create and maintain a central register of Non-Disclosure Agreements		X		
Review all Subject Access Request (SAR) activity so that the Trust can be assured that it is compliant with Data Protection/FOI/EIR legislation	X	X	X	X
Review and re-publish the Standard Operating Procedure for FOIA	X			
Clear backlog of DATIX incidents	X			
Conduct reviews of DATIX incidents where IG is a factor – making recommendations and tailoring training proposals as appropriate	X	X	X	X

QUALITY, SAFETY & PERFORMANCE COMMITTEE

FREEDOM OF INFORMATION REQUESTS

DATE OF MEETING	24.3.22

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable - Public Report

PREPARED BY	Julie Mann – Communication and Compliance Officer
PRESENTED BY	Lauren Fear – Director of Corporate Governance and Chief of Staff
EXECUTIVE SPONSOR APPROVED	Lauren Fear – Director of Corporate Governance and Chief of Staff

REPORT PURPOSE	FOR DISCUSSION / REVIEW

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Management Board	07/3/22	NOTED

ACRONYMS	
	• FOI – Freedom of Information • IG – Information Governance • QSP – Quality, Safety and Performance Committee • EMB – Executive Management Board

	• ICO – Information Commissioners Office

1. SITUATION/BACKGROUND

1.1 The purpose of this report is to provide assurance to the Quality, Safety & Performance Committee in relation to the Trust's compliance with the requirements of the Freedom of Information Act 2000 and Environmental Information Regulations 2004 (known as the Act).
.

2. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

Key Points for the Committee:

1. Although there continued to be non-compliance with the timeliness of requests in 2021, this was in line with the national expectations set by the Information Commissioner's Office regarding the impact of the pandemic on health organisations. Management processes and controls in place, and discussed in Executive Management Board, to ensure at least 80% compliance in 2022.

2. The analysis of requests in 2021 continues to show the three most significant volumes on renewal dates of digital contracts (19 requests); drug treatment data from healthcare organisations (12 requests); and matters relating the new hospital build (12 requests).

2.1 The Trust has a corporate responsibility under the Act to provide a general right of access to the Public to information held in the Trust's Information Management systems.

2.2 Specific requests for information not listed in the Trust's Publication Scheme or on the Trust website will be processed by the Trust's Communication and Compliance Officer specific responsibility for formulating responses rests with the Executive Team within each Division. This role forms part of the Corporate Governance portfolio in the Trust.

2.3 The Trust and/or respective Divisions or Hosted Organisations must acknowledge a request within 2 working days and respond to any request within 20 working days. Where clarification of a request is needed, further reasonable details can be requested in order to identify and assist in locating the information.

2.4 The Trust reports its Freedom of Information data into a weekly report that is sent to Welsh Government in respect of the requests received by all Health Boards and Trusts in Wales.

2021 Overview and Context

2.5 During 2021 calendar year the Trust received 151 Freedom of Information requests. The figure has increased over that received in 2020, the COVID-19 pandemic had an effect on the Trusts ability to respond to requests within the FOI timescales. As a result, the Trust failed to respond to 72 out of 151 completed requests within the 20 working day deadline.

2.6 The impact of the pandemic on response times has been explicitly acknowledged by the Information Commissioner's Office and during 2021 the standard wording was clearly displayed on the Trust website, as advised for all health organisations in UK by the Commissioner's Officer, around attempting to comply with the timescales when we can but acknowledging that there may be other clinical priorities which could impact timeliness.

2.7 In addition to impact that the pandemic had on the Trust's ability to provide timely response to all Freedom of Information requests, it also received a number of requests relating to the New Cancer Centre, the requests (**12** in total received in 2021) were complex in nature, therefore taking more time to gather and formulate a response, some of these requiring Exemptions to be considered, formal advice received and then applied.

Review and Complaints

2.8 If the requestor is not content with the reply or the processed by which the trust replied, they are advised in the response, and on website, that they can request a review by the Trist Information Governance Officer. If the requestor continues to be not content, they can refer to the Information Commissioner's Office.

2.9 During 2021, two requests were referred to an internal review stage and two were referred by the requestor to the Information Commissioner's Office without first requesting an internal review, which the requestor is also entitled to do. Those referred to the Information Commissioner's Office were on timeliness.

Website Publication

2.10 During transition to the new internet platform at start of 2021, it came to light that there was a backlog of Freedom of Information Requests which were loaded on the trust

website. This has not been addressed and the controls in place to support timely management going forwards are operating effectively.

Process Improvements

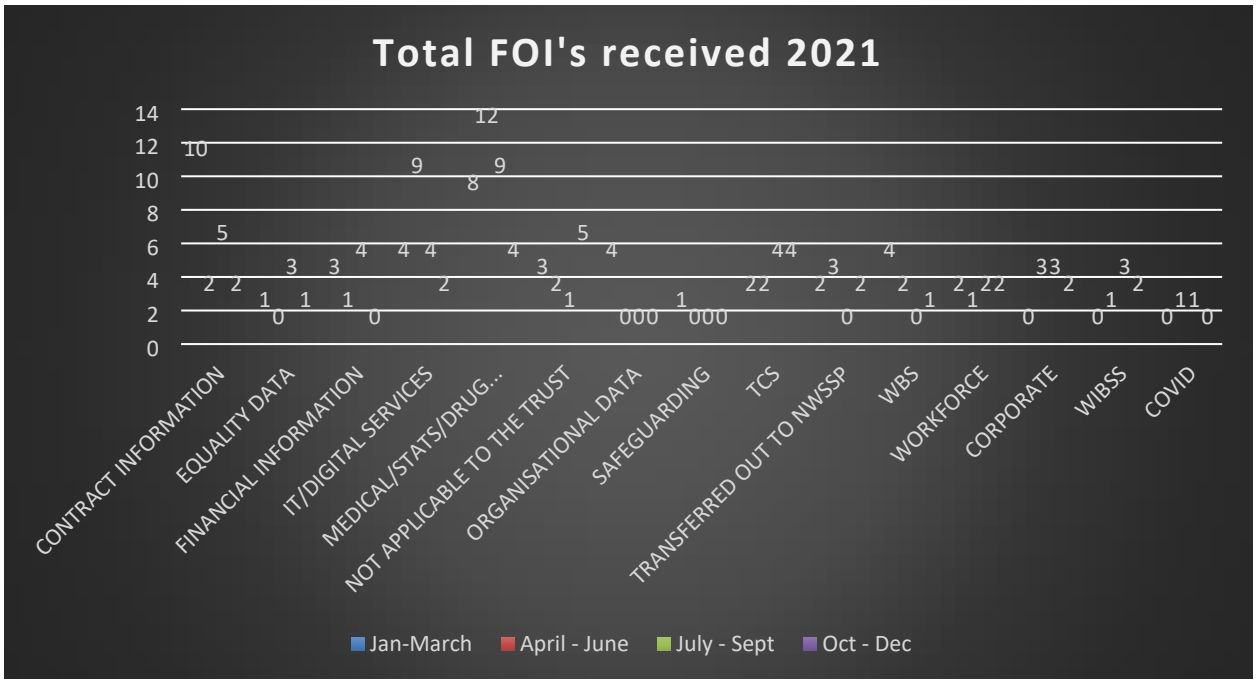
2.11 The discussion in the Executive Management Board in March on this paper focused on the various process improvements that are being implemented by the Corporate Governance team. As assurance for the Committee in this respect, this included:

- In weekly review meeting of all outstanding Freedom of Information requests continue to be reviewed with the Director Corporate Governance & Chief of Staff, the Assistant Communications and Engagement Director and the Communications and Compliance Officer. These meetings have tended to focus on those coming up to timeframe for response. However in recent months, the emphasis has changed to also include review of the new requests. This is following learning that where there is narrative required, in many instances, it is important to ensure the accountable executive for that subject area is aware promptly and that the overall response outline can be agreed upfront. This is already having a positive impact on approach as helping to ensure there is not delay at senior review stage towards the end of the process which then often results in questions about whether response is effectively meeting the requestor's overall question/ meaning etc.

- Continue to enhance the join up between NHS organisations where many/ all organisations may be receiving similar or the same requests.

- Continue to ensure that where appropriate and possible, the types of questions being asked through a Freedom of Information route are informing the information which the Trust is proactively publishing, for instance in "Frequently Asked Questions" relating to new hospital matters etc.

3. 2021 DATA



3.1 Overview of 2021 Requests

3.2 Further Analysis for 2021 Requests

Drug Treatments

The Trust received 12 drug treatment FOI's from a variety of healthcare companies.

Transforming Cancer Services

The Trust received 12 requests relating to the new Velindre Cancer Centre and Enabling Works projects.

Contract information

The Trust received 6 requests from the same requestor seeking renewal dates and costs of facility management contract information. To note, that a process is now underway to assess the application of further exemptions in this respect going forwards, catered for in the Act.

WIBSS Information

6 requests were received in relation to the Wales Infected Blood Support Scheme.

Workforce Information

Of the 12 requests received seeking Workforce information, 3 were seeking information in relation to the Trust's membership of Stonewall.

IT & Digital Information

Of the 19 requests, 12 were contract requests seeking renewal dates and costs of existing contracts.

4. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	There are no specific quality and safety implications related to the activity outined in this report.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below:
EQUALITY IMPACT ASSESSMENT COMPLETED	Not required
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	Yes (Include further detail below)
	Any financial impact will be captured in the detailed report relating to the Trust FOI's.

5. RECOMMENDATION

The Quality, Safety & Performance Committee are asked to **NOTE** the contents of this report.

QUALITY SAFETY & PERFORMANCE COMMITTEE

HEALTH AND CARE STANDARDS SELF-ASSESSMENTS

DATE OF MEETING	24th March 2022

PUBLIC OR PRIVATE REPORT	Public
IF PRIVATE PLEASE INDICATE REASON	Not Applicable
PREPARED BY	Jade Coleman, Quality and Safety Facilitator
PRESENTED BY	Nigel Downes, Deputy Director Nursing, Quality & Patient Experience
EXECUTIVE SPONSOR APPROVED	Nicola Williams, Executive Director Nursing, Allied Healthcare Professionals and Health Science

REPORT PURPOSE	For Assurance

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Management Board	07/03/2022	Noted & Endorsed

ACRONYMS	
HCS	Health and Care Standards
VCC	Velindre Cancer Centre
WBS	Welsh Blood Service

1. SITUATION

The purpose of this report is to provide the Quality, Safety & Performance Committee with the 2021/22 position in relation to the Trust's compliance with the Health and Care Standards for Wales (2015). In particular, it provides:

- An overarching Trust compliance self-assessment with the Health and Care Standards
- A progress update against the 2021 / 22 Trust Improvement plan by exception.

2. BACKGROUND

The 'Health and Care Standards' programme for NHS Wales provides a framework for ensuring compliance and ongoing improvements in the provision of high quality, safe and effective care.

In 2020, the Trust reviewed its internal self- assessment process with the Health Care Standards, and it was recognised that in order to drive quality improvement at the Trust, the Health and Care Standards needed to be more firmly embedded into the core business of the Divisional and Corporate Teams. As such, it was agreed by the Executive Management Team that the Trust would adopt a more rigorous approach to the Health and Care Standards, which would include a quarterly review and progress update at a Divisional level, and a bi-annual Executive review.

2021/2022 is the first year in which the Trust has implemented the strengthened process for the Health and Care Standards. The Divisional and Corporate Teams have undertaken a comprehensive review of their compliance with the Health and Care standards during each quarter of 2021 / 2022, and have also ensured that the Improvement Plan has been updated.

There will be a further Divisional and Corporate Team review and update regarding the Health and Care Standards during Quarters 3 and 4, and an Executive Management Team review towards the end of Quarter 4. The Internal Audit Team have taken the decision not to undertake an independent review of the Trust's compliance against the Health and Care Standards at the end of Quarter 4, 2021/2022.

A national review of the Health and Care Standards has commenced in order to ensure they reflect the requirements of the Wales Quality and Engagement Act (2020) and the national Quality & Safety Framework (2021) requirements. The revised standards are not expected until well into 2022.

3. ASSESSMENT / SUMMARY OF MATTERS FOR CONSIDERATION

3.1 Compliance across the Trust with the enhanced quarterly Health and Care Standards self-assessment process

Following the end of each quarter during 2021/2022, the Corporate and Divisional Teams have fully engaged in the new quarterly self-assessment process, and have actively sought to ensure that improving compliance with the Health and Care Standards is becoming embedded into their 'business as usual'. This is a credit to the teams as it is recognised that this work has been undertaken at the same time as increasing operational pressures and ongoing challenges relating to the COVID Pandemic.

The Divisional Senior Management Teams have reviewed and approved the compliance data, and the progress against the Improvement Plans.

3.2 Overview of the compliance status at the end of Quarter 3

Despite the challenges of operational service delivery during the third quarter of 2021/22, the teams have reported continued good results in the compliance with the Health and Care Standards. The compliance has been reviewed and approved via the following internal process:

1. Health and Care Standard Operational Lead
2. Divisional Senior Management Teams
3. Executive Health and Care Standard Lead

The aggregated Trust wide self-assessment scores for each Health and Care Standard is attached in ***Appendix 1.***

The overarching aggregated Trust compliance score with the entire Health Care Standards remains a level 4 i.e. '***we have well developed plans and processes, and can demonstrate sustainable improvement throughout the organisation/business'***.

In order to further enhance the self-assessment process, work has been commenced to align performance indicators to each standard and this has been further progressed during Quarter 3.

The Divisional assessments are available if required from paper author.

3.3 Progress with the 2021/ 2022 Health and Care Standards Improvement Plan

The Health Care Standards Improvement Plan details the actions that are required per Standard in order to improve compliance, and to ultimately improve the quality of care provided within the organisation.

Despite the ongoing operational challenges, positive progress has been made with the improvements that had been identified at the outset of the year with continued improvement actions listed being on track to be completed by the end of Quarter 4. The

following table provides an overview to the exceptions to this and includes revised timescales:

	Due for completion	Reason for delay	Revised completion date
Disability Confident accreditation	Quarter 2 2021/22	Action was on hold due to the need to replace the Equality Manager post.	This post is now filled. Will achieve Disability Leader Level 3 by ***Sept 2022*** – a task and finish group will be established and led by Head of OD
Virtual Reality Learning project	Quarter 2 2021/22	Stood down because of pandemic however plan to ***restart in Q4 2021/22 – plan to complete by December 2022.***	Re-established with Swansea Uni and will be delivered in December 2022
Development of the HealthCare Support Worker role at the Cancer Centre	Quarter 4 2021/22	Delayed due to the pandemic – will be completed by Quarter 2 2022/23	Project will be recommenced in June 2022.

4. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	The areas considered to have an impact on quality and safety are identified in the Health and Care Standards
RELATED HEALTHCARE STANDARD	All related to the Health and Care Standards.
EQUALITY IMPACT ASSESSMENT	All areas considered to have an impact on equality are identified in the Standards.
LEGAL IMPLICATIONS / IMPACT	There would be potential legal implications of non-delivery of these core standards.
FINANCIAL IMPLICATIONS / IMPACT	There would be financial implications aligned to both delivery and non-delivery of the Health and Care Standards. The non-delivery will be in relation to possible litigation due to non-compliance. Delivery of financial requirements will be worked through as part of local implementation/delivery plans.

5. RECOMMENDATION

The Quality, Safety & Performance Committee is asked to **NOTE** the**:**

- current status and progress being made year to date in respect of the Health and Care Standards
- status in respect of the Health & Care Standard Improvement Plan
- the overarching Trust compliance scoring table for the Health and Care Standards.

Appendix 1

OVERARCHING TRUST COMPLIANCE WITH THE HEALTH & CARE STANDARDS FOR Q3 2021

	HCS Standard	VCC self-assessment rating	WBS self-assessment rating	Overarching Trust assessment rating post Executive Review	Comment 2021/22
Governance, Leadership and Accountability	Effective governance, leadership and accountability in keeping with the size and complexity of the health service are essential for the sustainable delivery of safe, effective person centred care.	**4**	**4**	**4**	**Working towards 5**
STANDARD 1 Staying Healthy	**Standard 1.1 Health Promotion, Protection and Improvement** People are empowered and supported to take responsibility for their own health and wellbeing and carers of individuals who are unable to manage their own health and wellbeing are supported. Health services work in partnership with others to protect and improve the health and wellbeing of people and reduce health inequalities.	**4**	**4**	**4**	**Working towards 5**
STANDARD 2 Safe Care	**Standard 2.1 Managing Risk and Promoting Health and Safety** People's health, safety and welfare are actively promoted and protected. Risks are identified, monitored and where possible, reduced or prevented.	**4**	**4**	**4**	**Working towards 5**
	Standard 2.2 Preventing Pressure and Tissue Damage People are helped to look after their skin and every effort is made to prevent people from developing pressure and tissue damage.	**4**	**NA**	**5**	**Overarching score increased to 5 following Exec review**
	Standard 2.3 Falls Prevention People are assessed for risks of falling and every effort is made to prevent falls and reduce avoidable harm and disability.	**4**	**NA**	**5**	**Overarching score increased to 5 following Exec review**
	Standard 2.4 Infection Prevention and Control (IPC) and Decontamination Effective infection prevention and control needs to be everybody's business and must be part of everyday healthcare practice and based on the best available evidence so that people are protected from preventable healthcare associated infections.	**4**	**4**	**4**	**Working towards 5**

	Standard 2.5 Nutrition and Hydration People are supported to meet their nutritional and hydration needs, to maximise recovery from illness or injury.	**4**	**NA**	**4**	**Working towards 5**
	Standard 2.6 Medicines Management People receive medication for the correct reason, the right medication at the right dose and at the right time.	**5**	**NA**	**4**	**Working towards 5**
	Standard 2.7 Safeguarding Children and Safeguarding Adults at Risk Health services promote and protect the welfare and safety of children and adults who become vulnerable or at risk at any time.	**4**	**4**	**4**	**Working towards 5**
	Standard 2.8 Blood Management People have timely access to a safe and sufficient supply of blood, blood products and blood components when needed.	**4 to 5**	**4**	**4**	**Working towards 5**
	Standard 2.9 Medical Devices, Equipment and Diagnostic Systems Health services ensure the safe and effective procurement, use and disposal of medical equipment, devices and diagnostic systems.	**4**	**5**	**4**	**Working towards 5**
STANDARD 3 Effective Care	**Standard 3.1 Safe and Clinically Effective Care** Care, treatment and decision making should reflect best practice based on evidence to ensure that people receive the right care and support to meet their individual needs.	**4**	**5**	**4**	**Working towards 5**
	Standard 3.2 Communicating Effectively In communicating with people health services proactively meet individual language and communication needs.	**4**	**4**	**3**	**Change to score following Exec Review** **Working towards 4**
	Standard 3.3 Quality Improvement, Research and Innovation Services engage in activities to continuously improve by developing and implementing innovative ways of delivering care. This includes supporting research and ensuring that it enhances the efficiency and effectiveness of services.	**5 to 4**	**5**	**4**	**Changed following Exec Review** **Working towards 5**
	Standard 3.4 Information Governance and Communications Technology Health services ensure all information is accurate, valid, reliable, timely, relevant, comprehensible and complete in delivering, managing, planning and monitoring high quality, safe services.	**5 to 4**	**5**	**5**	**Change to overall score following CDO review** **Needs review**

	Health services have systems in place, including information and communications technology, to ensure the effective collection, sharing and reporting of high quality data and information within a sound information governance framework.				**Working towards 5**
	Standard 3.5 Record Keeping Good record keeping is essential to ensure that people receive effective and safe care. Health services must ensure that all records are maintained in accordance with legislation and clinical standards guidance.	**4**	**5**	**4**	**Working towards 5**
STANDARD 4 Dignified Care	**Standard 4.1 Dignified Care** People's experience of health care is one where everyone is treated with dignity, respect, compassion and kindness and which recognises and addresses individual physical, psychological, social, and cultural, language and spiritual needs.	**4**	**5**	**5**	**Work towards maintaining 5**
	Standard 4.2 Patient Information People must receive full information about their care which is accessible, understandable and in a language and manner sensitive to their needs to enable and support them to make an informed decision about their care as an equal partner.	**4**	**5**	**3**	**Change to overall score following Exec review** **Working towards 4**
STANDARD 5 Timely Care	**Standard 5.1 Timely Access** All aspects of care are provided in a timely way ensuring that people are treated and cared for in the right way, at the right time, in the right place and with the right staff.	**4**	**NA**	**4**	**Working towards 4**
STANDARD 6 Individual Care	**Standard 6.1 Planning Care to Promote Independence** Care provision must respect people's choices in how they care for themselves as maintaining independence improves quality of life and maximises physical and emotional wellbeing.	**3**	**NA**	**3**	**Changed to 3 at VCC following consultation with Exec Lead**
	Standard 6.2 Peoples Rights Health services embed equality and human rights across the functions and delivery of health services in line with statutory requirement recognising the diversity of the population and rights of individuals under equality, diversity and human rights legislation.	**4**	**5**	**3**	**Changed to 3 following Exec review** **Working towards 4**
	Standard 6.3 Listening and Learning from Feedback People who receive care, and their families, must be empowered to describe their experiences to those who provided their care so there is a clear understanding of what is working well and what is not, and	**4 to 3**	**4**	**4**	**Working towards 5**

	they must receive an open and honest response. Health services should be shaped by and meet the needs of the people served and demonstrate that they act on and learn from feedback				
STANDARD 7 Staff and Resources	**Standard 7.1 Workforce** Health services should ensure there are enough staff with the right knowledge and skills available at the right time to meet need.	**4**	**4**	**3**	**Assessed by Exec Lead** **Working towards 4**

QUALITY, SAFETY AND PERFORMANCE COMMITTEE

VELINDRE UNIVERSITY NHS TRUST
POLICY MANAGEMENT REVIEW AND COMPLIANCE
STATUS: MARCH 2022

DATE OF MEETING	24/03/2022

PUBLIC OR PRIVATE REPORT	Public

IF PRIVATE PLEASE INDICATE REASON	Not Applicable

PREPARED BY	Lenisha Wright, Business Support Officer Kay Barrow, Corporate Governance Manager Emma Stephens, Head of Corporate Governance
PRESENTED BY	Lauren Fear, Director of Corporate Governance & Chief of Staff
EXECUTIVE SPONSOR APPROVED	Lauren Fear, Director of Corporate Governance & Chief of Staff

REPORT PURPOSE	For **DISCUSSION & REVIEW**

COMMITTEE/GROUP WHO HAVE RECEIVED OR CONSIDERED THIS PAPER PRIOR TO THIS MEETING		
COMMITTEE OR GROUP	**DATE**	**OUTCOME**
Executive Management Board	07/03/2022	APPROVED

ACRONYMS	
VUNHST	Velindre University NHS Trust
QSPC	Quality, Safety and Performance Committee

1. SITUATION

1.1 A comprehensive review is currently being undertaken of the existing arrangements in place for the management and reporting of Velindre University NHS Trust (VUNHST), Trust wide Policies. The purpose of which is to identify any areas for improvement to strengthen the operation of the governance framework, increase control to enable effective assurance arrangements and build firm foundations for a step change in the management and reporting of all Trust wide Policies.

1.1.1 The scope of the audit applies to all Trust wide policies. As such, any locally managed controlled documentation, for example Standard Operating Procedures that only apply to one of the core Divisions of the Trust are excluded from the scope of this work.

1.1.2 Currently there are circa **157** Trust wide policies that need to be assessed as part of the audit underway. As such, due to the scale and rigor required to complete a comprehensive and robust audit, a phased approach has been undertaken. The first phase of the work has focused initially with a review of the Trust wide policies that fall within the remit of the Quality, Safety and Performance Committee.

1.2 To date, the initial phase of the review has included:

i. Complete review and refresh of the existing Trust Policy for the Management of Policies and Other Written Control Documents, following a Pan-Wales benchmarking review of the 'Policy on Policy Management' from other Health Boards and Trusts.

ii. Root and branch audit of the status of the Trust wide policies that fall within the remit of the Quality, Safety and Performance Committee as at **01/03/2022**.

iii. Creation of a new Document Control Register to accurately record the status and risk profile of all Trust wide policies that fall within the remit of the Quality, Safety and Performance Committee, to underpin future reporting and enhanced governance arrangements.

iv. Assessment of the existing document control management systems in operation across the Trust to consider options available for the electronic management of all Trust wide Policies going forward, and action required to facilitate this.

1.3 The Quality, Safety and Performance Committee is asked to:

a. **NOTE** the revised Policy and Procedure for the Management of Trust wide Policies and other Trust wide written control documents **(GC01)** following **APPROVAL** at the Executive Management Board (RUN) on 7 March 2022, included at ***Appendix 1***.

b. **DISCUSS AND REVIEW** the findings of the Policy Management Review and compliance status for those policies that fall within the remit of the Quality, Safety and Performance Committee.

c. **NOTE** the Quality, Safety & Performance Committee Policies Extract Compliance Report as at **01/03/2022,** included at ***Appendix 2***.

BACKGROUND

1.3 Trust wide Policies are an essential component in ensuring the Trust meets all of its statutory responsibilities, is able to achieve its strategic objectives and consistently deliver high quality standards of care to our donors and patients.

1.4 A preliminary review undertaken by the Head of Corporate Governance, identified that there were areas in the existing policy management arrangements that needed to be addressed to strengthen the systems and processes in place to provide increased, assurance and effective oversight.

2. ASSESMENT / SUMMARY OF MATTERS FOR CONSIDERATION

2.1 Review of Current Trust Policy GC01 – Policy for the Production, Consultation, Approval, Publication and Dissemination of Strategies, Policies, Protocols, Procedures and Guidelines

The policy framework of the Trust is complex and diverse and is continually changing and being updated due to national and/or local changes. The Trust's Policy for the Production, Consultation, Approval, Publication and Dissemination of Strategies, Policies, Protocols, Procedures and Guidelines (GC01), has been in place since January 2017, and was passed its review date. As such, a root and branch review of the existing Policy has been undertaken and included the following key aspects:

2.1.1 NHS Wales Benchmarking Exercise

A benchmarking exercise was undertaken to review the policy approach across NHS Wales and, as such a number of policies and procedures were reviewed from the various Health Boards and Trusts across Wales.

The review highlighted a number of key themes and principles that have been captured to support and enable adoption of best practice in the revised Policy including:

- Step by Step Process and Flowchart
- Approval Process
- Where to Seek Advice
- Roles and Responsibilities
- Referencing compliance and statutory obligations as part of the Policy Development Process
- Engagement and Consultation
- Publication, Dissemination and Distribution
- Review Process
- Review Period
- Training, Implementation and Policy Compliance

2.1.2 Changes to Statutory Requirements

The review has encompassed an assessment of the requirements regarding compliance with the Health and Care Standards, Welsh Language Standards and changes to statutory requirements of a wide range of legislation, in particular, the Equality Act 2010, Socio-

Economic Duty, Well-being and Future Generations (Wales) Act 2015 and Health and Social Care (Quality and Engagement) (Wales) Act 2020.

2.1.3 Key Changes to the Policy

As outlined above, following the benchmarking review and assessment of any changes to statutory requirements, a number of key changes were required to the existing policy, this included but was not limited to the following:

- Development of a fully integrated impact assessment process to guide development and initiation of any new or revision to existing policies in place that encompasses the:
    - Equality Act 2010
    - Socio-Economic Duty
    - Well-being of Future Generations (Wales) Act 2015
    - Health and Social Care (Quality and Engagement) (Wales) Act 2020
- Utilisation of visual process flow charts to support effective operationalisation.
- Refinement and clear guidance around the required governance pathway.
- Strengthened guidance around the statutory obligations and requirements for effective policy management.

The updated and revised Policy was **APPROVED** at the Executive Management Board on 7 March 2022 (ref. ***Appendix 1.***)

2.2 Policy Compliance Status

A risk-based phased approach has been adopted for the Policy Compliance Audit. The first phase of work has concentrated on a review of the Trust wide policies that fall within the remit of the Quality, Safety and Performance Committee. These policies govern and control areas of practice across the Trust that manage any risks to patients, donors and staff, health and safety and well-being, as well as information governance and information security.

The Corporate Governance team have reviewed the latest policies held on record in order to collate a report including information on document control, review dates, policy status and risk assessments for the following directorates:

- Infection, Prevention and Control
- Information Governance, Corporate Communications and Digital
- Quality and Safety
- Estates, Planning and Performance
- Health and Safety

Note: Workforce and OD policies although these fall within the remit of the Quality, Safety & Performance Committee, these will form part of the next tranche of the audit programme due to the volume held (circa 55), and as such are not captured in the audit work as at **01/03/2022**.

Following the collation of data and information based on the review of the policies for the above, a comprehensive preliminary compliance report was compiled to highlight key information. Further validation and analysis was then undertaken through collaborative engagement with all of the relevant policy leads to determine status, risk profile and any ongoing actions required or underway. A summary of the outcome of this exercise is included at ***Appendix 2*****,** and a more detailed overview is provided below under section **3.3.4 'Collaborative Engagement'**.

2.2.1 Policy Status

In recording the policy status, the key below was used to assess and capture various aspects of the policies status, including whether policies were in date or if review dates had passed. For those policies where review dates had passed, actions currently underway and other actions required were also captured which will form part of the ongoing monitoring by the Corporate Governance Team for assurance.

POLICY STATUS KEY:
Policy in date
Policy review date passed – action underway/required
All Wales Policy review date passed – awaiting national review

2.2.2 Policy Risk Assessment

The key below was developed to assess any risks associated with policies with review dates that have passed, and the associated actions required to address this.

POLICY RISK ASSESSMENT KEY:
Policy in date with no risk assessment required
Policy review date passed with low risk
Policy review date passed with moderate risk
Policy review date passed with high risk

2.2.3 Document Control Register

A document control register has been compiled to explain the outcome of the audit for effective monitoring and reporting purposes. This is included at ***Appendix 2***. Ongoing updates and progress will be captured and recorded on the Document Control Register and reported against on a monthly basis with immediate effect.

2.2.4 Collaborative Engagement Exercise

As indicated earlier, following an assessment of the policies currently held on record, collaborative engagement was undertaken with each of the respective Policy leads, namely:

Directorates	Policy Lead(s)
Health and Safety	Health and Safety Manager
Quality and Safety	Quality & Safety Manager, Claims Manager, Chief Pharmacist, Quality & Safety Facilitator, Senior Nurse Safeguarding & Public Protection, Interim Deputy Director of Nursing, Quality & Patient Experience
Infection, Prevention & Control	Head of Infection Prevention and Control, Interim Deputy Director of Nursing, Quality & Patient Experience
Information Governance and Digital	Head of Information Governance Head of Digital Delivery & Business Systems
Estates	Assistant Director of Estates

The purpose of this engagement exercise was to confirm and validate the following:

- Whether the versions of the policies held on file were correct.
- Clarification on existing policies review dates.
- A risk assessment of policies passed their review date.
- Ongoing actions underway or actions required.

A summary is provided below of information gathered from the engagement exercise:

Quality and Safety

Focussed work is underway by the Quality and Safety Team to progress a number of key policies that have passed their review date. This is evidenced by the Handling Concerns Policy and the Incident Reporting Policy that were **ENDORSED** by the Executive Management Board at its March 2022 meeting, in readiness for approval by the Quality, Safety and Performance Committee (QSPC). The remainder of the policies passed their review dates will be taken through consultation in quarter 1 of 2022/23 in readiness for approval by the QSPC thereafter.

Health and Safety

All Health and Safety Policies on record are in date with no risk assessment required. Clarification and confirmation of this has been established in discussions with the Health and Safety Manager for the Trust.

Infection, Prevention and Control (IPC)

The newly appointed Head of IPC together with the IPC Team have commenced a review to update policies passed their review date; some of which are included in the agenda for the March 2022 meeting of the QSPC for **APROVAL**.

As part of this Policy Management Review, the IPC Team has been provided with a full list of those policies held by the Corporate Governance Team and validation of document control including those listed on the Trust Intranet.

Through the review process, two policies have been reallocated, two policies archived and superseded by the National IPC Manual and two policies endorsed by the Executive Management Board at its March meeting for approval by the QSPC, as outlined below.

Policies reallocated	○ Policy for the Management of Prevention and Control of Legionellosis ○ Management and Control of the Environment (Cleaning)
Policies archived	○ Standard Infection Control and Transmission Based Precautions ○ Outbreak Management Policy
Policies endorsed by Executive Management Board	○ Viral Gastro Enteritis (including Norovirus) Policy & Addendum ○ Decontamination Policy

Information Governance (IG), Digital and Corporate Communications

The newly appointed Head of Information Governance has undertaken a review of the status of the Trust's current IG policies. This has included an assessment of whether those policies are passed their review date and also a review of the remit of these policies that were previously all grouped together and listed as 'Information Governance, Information Management and Technology'. Through discussion and engagement with the IG, Digital and Communication Teams, the remit of these policies has been revised to be more specific and aligned with each of the respective executive portfolios. The full list of policies is now split as follows:

Digital	Email Use Policy
Digital	Software Policy
Digital	Anti-Virus Policy
Digital	Data Quality Policy
IG	Records Management Policy
IG	Data Protection & Confidentiality Policy
IG	Confidentiality Breach Reporting Policy
IG	Information Asset Policy
Corporate Communications	Social Media Policy
Corporate Communications	Freedom of Information (FOI) Act Policy

Estates, Planning & Performance (EPP)

The EPP Team are currently reviewing the list of policies provided to them by the Corporate Governance team to validate document control and status.

Further engagement will continue through March 2022 to complete the review of these policies and risk profile status, with the outcome to be reported to the QSPC in May 2022.

To date, confirmation status and risk assessment has only been confirmed and completed in respect of the Fire Safety Policy within the EPP Directorate.

2.2.5 Policy Audit Compliance Status

The findings of the Policy Audit Compliance Status for each of the directorates outlined above is reported below against the following categories:

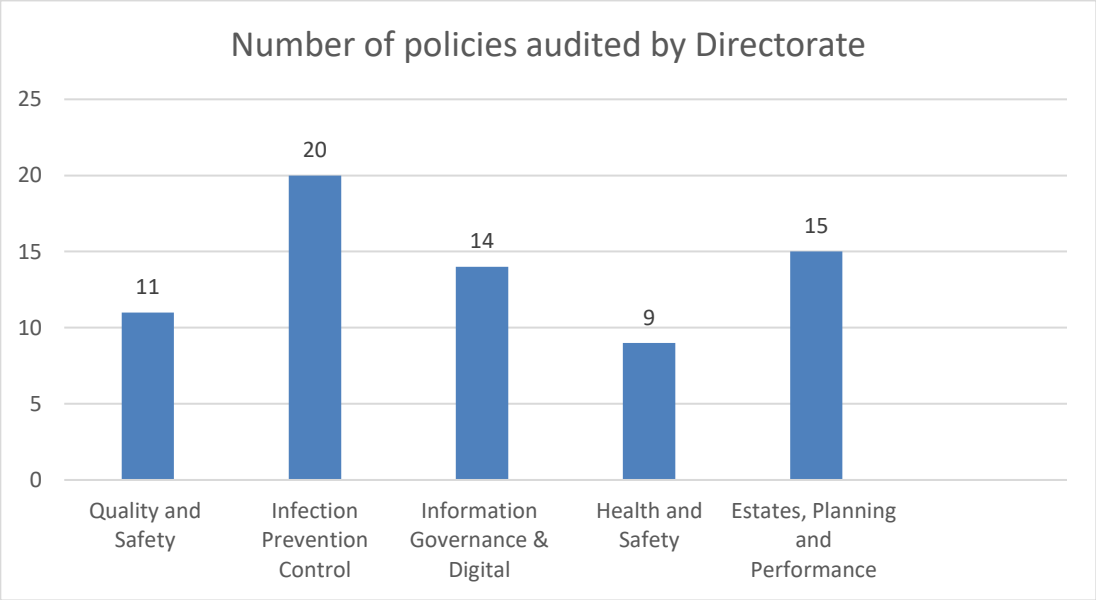
- Number of policies audited
- Policy status
- Policies passed review dates
- Policy risk assessment

- ***Number of Policies audited***

As at 01/03/2022, **69** Trust wide Policies have been subject to a comprehensive audit for the above directorates.

The chart below provides a breakdown of the number of policies reviewed across each of the directorates.

Figure 1: Number of Policies audited by Directorate



- ***Policy Status***

The table below provides an overview of the overall policy status. In terms of the **69** policies audited, **36** (**52%)** policies are in date, **31(45%)** are passed their review date and **2(3%)** policies have been archived.

Table 1: Overall Policy Status

Policy Status	Number of Policies	Percentage
Policy in date	36	53%
Policy review date passed – action underway/required	30	44%
All Wales Policy review date passed – awaiting national review	1	1%
Policies Archived	2	3%

The table below provides an overview of the status of the **69** policies audited per Directorate.

Table 2: Overall Policy Status by Directorate

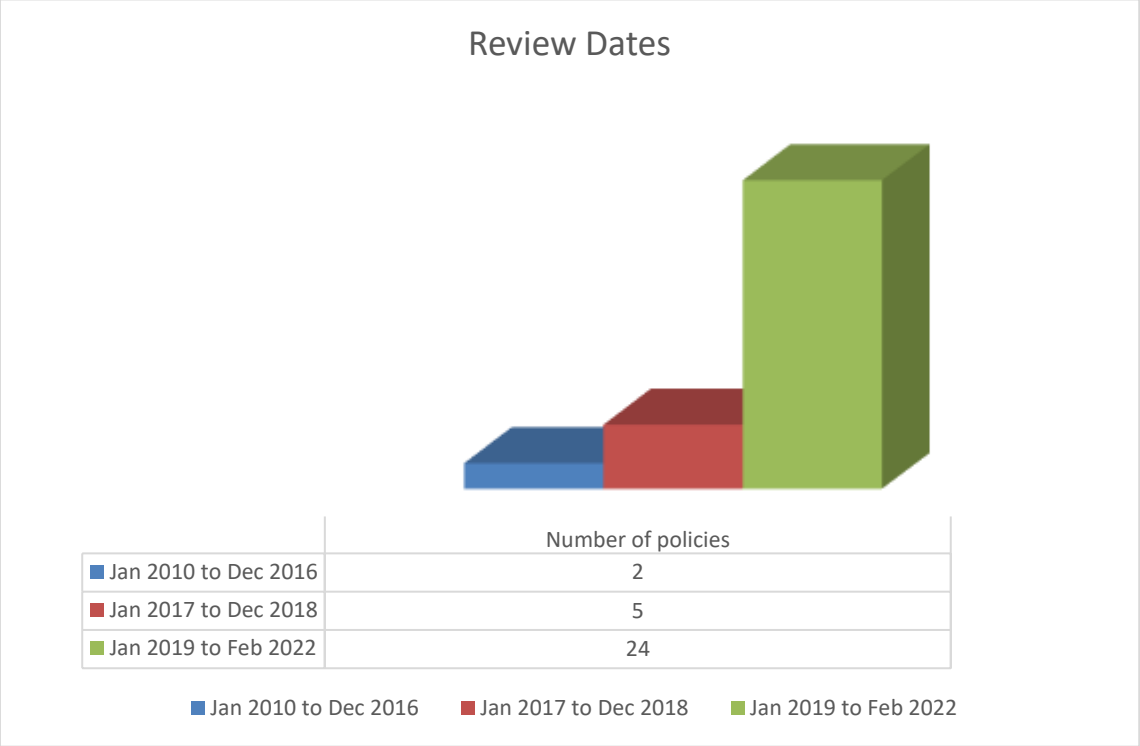
Policy Directorate	Policy in date	Policy review date passed – action underway/ required	All Wales Policy review date passed – awaiting national review	Policies Archived
Health and Safety	9	0	0	0
Quality and Safety	5	6	0	0
Information Governance and Digital	4	10	0	0
Infection, Prevention & Control	12	5	1	2
Estates, Planning & Performance	6	9	0	0
Total	**36**	**30**	**1**	**2**

- ***Policies Passed their Review Dates***

  Of the policies that have passed their review dates, **2 (6%)** have recorded review dates between January 2010 and December 2016 ref. ***Appendix 2.*** However, confirmation is currently being sought by the Policy Leads of whether these policies now need to be archived, or if the policy contents and detail has transferred and has now been captured in a different policy.

  5 (16%) of the policies that have passed their review dates, have recorded review dates of between January 2017 and December 2018 and **24 (77%)** between January 2019 and February 2022 ref ***Appendix 2***. These policies are currently under review, the progress of which will be reported to the QSPC in May 2022. A breakdown is provided in the graph below.

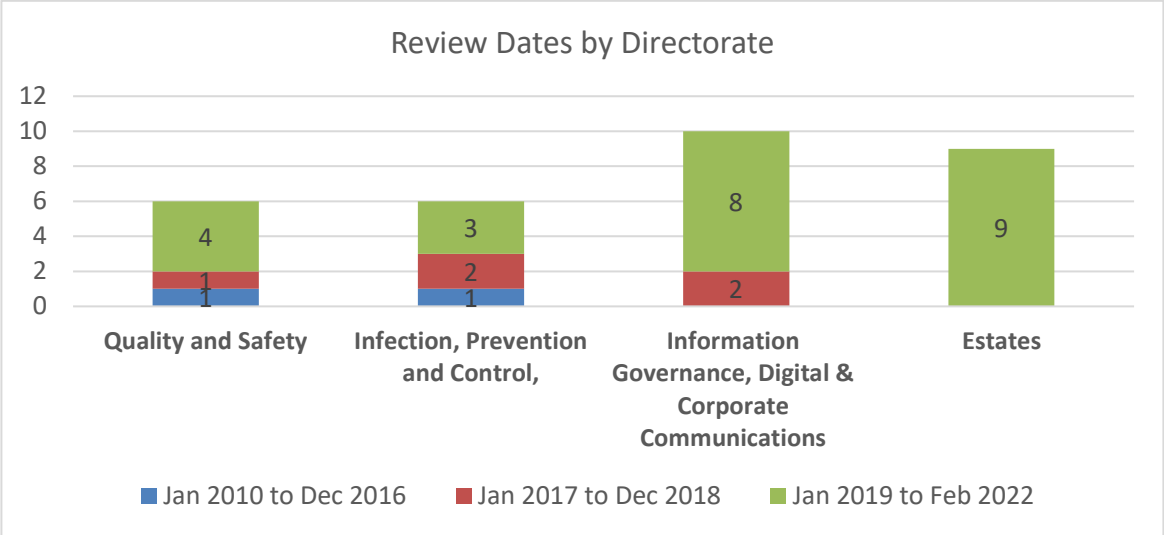
Figure 2: Review Dates



Note: Of the two policies listed with a review date passed between 2010 to 2016, it should be noted that one of these policies, Incident Reporting and Incident Investigation Policy & Appendices has now been reviewed and is to be approved by QSPC at its March meeting. The policy for the Management and Control of the Environment (Cleaning) Accountable Officer has reallocated and is currently being reviewed by the Chief Operating Officer.

A further breakdown of policies passed their review dates per Directorate is provided below.

Figure 3: Review Dates by Directorate



- ***Policy Risk Assessment***

The policy audit has also included an exercise to establish any risks associated with policies that have passed their review date.

- Of the 69 policies audited, **54%** were in date with **no risk** assessment required.
- **34%** with review dates that that had passed with **low risk**.
- **12%** with review dates that had passed with **moderate risk**.
- **Zero** policies with review dates passed with **high risk**

The table below provides a breakdown by Directorate/Department and the associated

risk assessments.

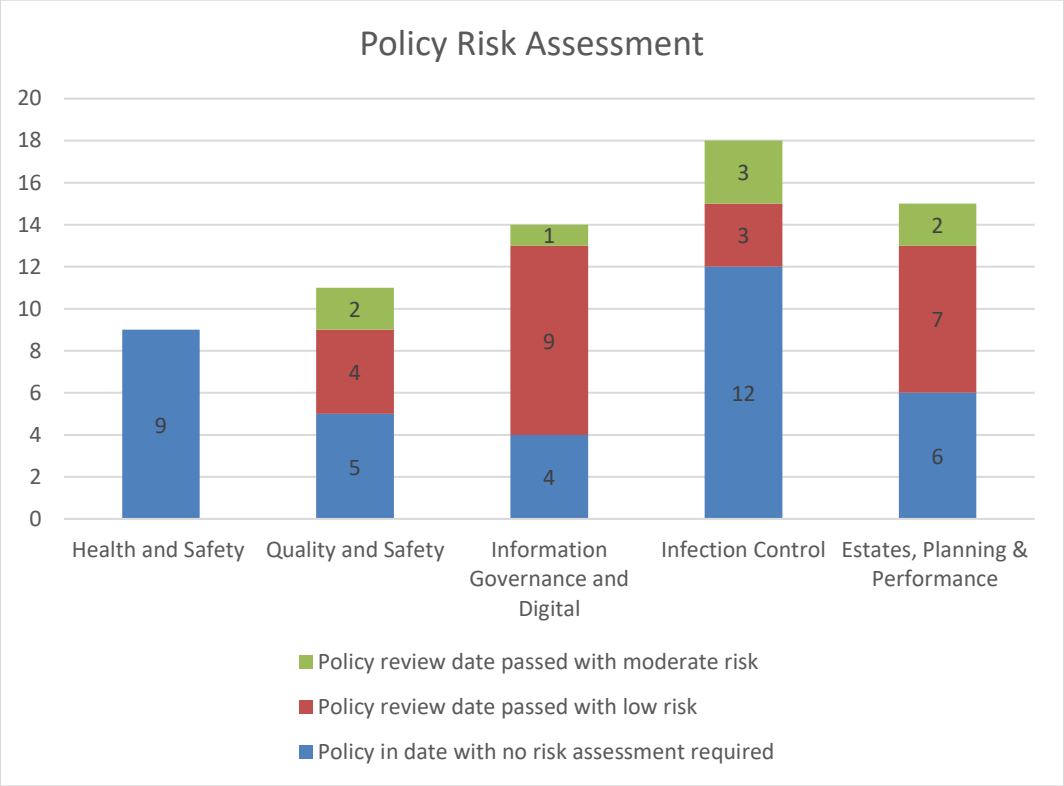
Table 3: Policy Risk Assessment

	Health and Safety	Quality and Safety	Information Governance, Corporate Communications and Digital	Infection Control	Estates, Planning & Performance	Total
Policy in date with no risk assessment required	9	5	4	12	6	36
Policy review date passed with low risk	0	4	9	3	7	23
Policy review date passed with moderate risk	0	2	1	3	2	8
Policy review date passed with high risk	0	0	0	0	0	0

Note: the total number of policies in the table above is 67 due to the two policies that have been archived and therefore do not require a risk assessment.

The Chart below provide an overall breakdown of policies audited that have passed the review date as well as a breakdown by Directorate/Department.

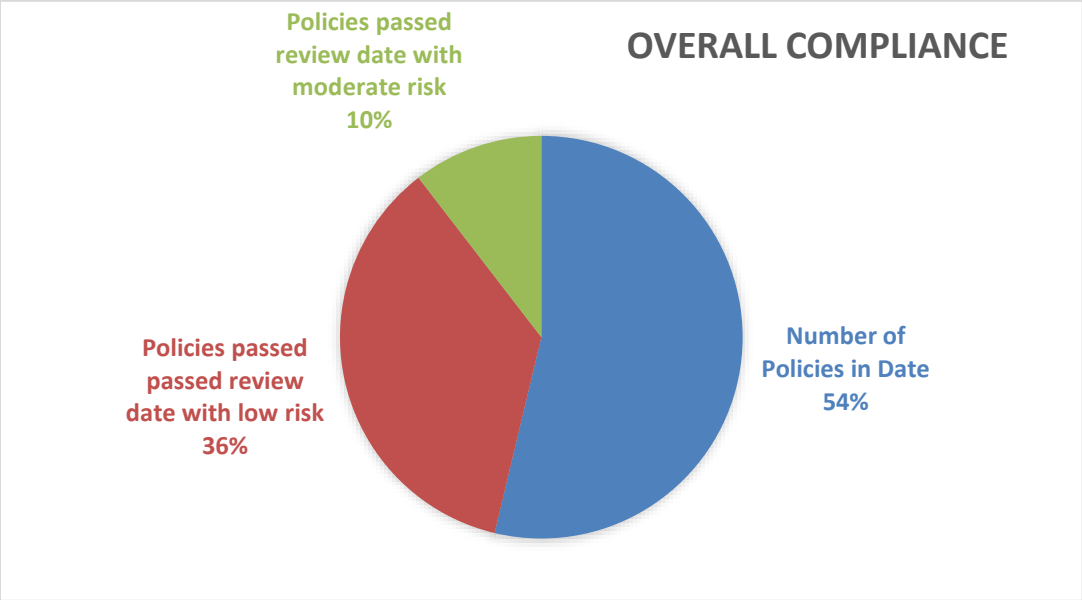
Figure 4: Policy Risk Assessment by Directorate



2.2.6 Overall Policy Compliance Status

The chart below represents the overall compliance status of the audit work on policies as at 01/03/2022 that fall within the remit of the Quality, Safety and Performance Committee.

Figure 5: Overall compliance



2.3 Document Control Management Systems

A comprehensive review is underway to assess the existing document control management systems currently in use both within the Trust and across NHS Wales to identify best practice, to support and enable effective policy management going forward.

Q-Pulse is currently used by the Trust, predominantly with the Welsh Blood Service where it has been in operation for a number of years as part of their wider Quality Management System. Q-Pulse is utilised to a lesser extent within the Velindre Cancer Service, mainly by the Medical Physics Department.

Through discussion and engagement with the Head of Quality Assurance and Regulatory Compliance within the Welsh Blood Service, there is support to further review and establish a programme of work to identify a document control management system that can be utilised on a Trust wide basis. This should also extend to include a review of best practice beyond the NHS within the Private Sector. Further discussion and engagement with the Head of Digital Delivery and leads both within the Welsh Blood Service and the Velindre Cancer Service will be taken forward over quarter 1 of 2022/23 to help progress and take this forward.

A preliminary review has also been undertaken across NHS Wales which has identified that SharePoint, a web-based collaborative platform that is part of the Microsoft Office suite, is adopted by some NHS organisations as their preferred document control management system. A demonstration of this system will also form part of the wider review to be enacted over quarter 1 of 2022/23.

3. IMPACT ASSESSMENT

QUALITY AND SAFETY IMPLICATIONS/IMPACT	Yes (Please see detail below)
	A robust and clear governance framework for the management of policies is essential to minimise risk to patients, employees and the organisation itself; therefore, the Trust has developed a system to support the development or review, approval, dissemination and management of polices.
RELATED HEALTHCARE STANDARD	Governance, Leadership and Accountability
	If more than one Healthcare Standard applies please list below:
EQUALITY IMPACT ASSESSMENT COMPLETED	Yes
LEGAL IMPLICATIONS / IMPACT	There are no specific legal implications related to the activity outlined in this report.
FINANCIAL IMPLICATIONS / IMPACT	There is no direct impact on resources as a result of the activity outlined in this report.

4. NEXT PHASE OF POLICY AUDIT COMPLIANCE STATUS

The next phase of the Policy Management Review Audit will concentrate on a review of the 54 Workforce and OD policies that fall within the remit of the Quality, Safety & Performance Committee in **April 2022,** the results of which will be reported in the **May 2022 QSPC** together with an updated compliance report on the remainder of those policies that fall within the QSPC remit.

5. RECOMMENDATIONS

5.1 The Quality, Safety and Performance Committee is asked to:

a. **NOTE** the revised Policy and Procedure for the Management of Trust wide Policies and other Trust wide written control documents **(GC01)** following its **APPROVAL** at the Executive Management Board on 7 March 2022 **ref. *Appendix 1***.

b. **DISCUSS AND REVIEW** the findings of the Policy Management Review and compliance status for those policies that fall within the remit of the Quality, Safety and Performance Committee.

c. **NOTE** the Quality, Safety & Performance Committee Policies Extract Compliance Report as at **01/03/2022, ref. *Appendix** 2*.

APPENDIX 1

Ref: GCO1

POLICY AND PROCEDURE FOR THE MANAGEMENT OF TRUST WIDE POLICIES AND OTHER TRUST WIDE WRITTEN CONTROL DOCUMENTS

Executive Sponsor & Function	Director of Corporate Governance Governance and Chief of Staff Communications Function
Document Author:	Head of Corporate Governance
Approved by:	Executive Management Board
Approval Date:	7 March 2022
Date of Equality Impact Assessment:	August 2013
Equality Impact Assessment Outcome:	Approved
Review Date:	March 2025
Version:	Version 2

1. INTRODUCTION AND AIM

1.1 Velindre University NHS Trust, subsequently referred to in this policy as the 'Trust', has a statutory duty to ensure that appropriate policies and supporting strategies procedures, protocols, or guidelines (referred to collectively as other Written Control Documents) are in place. Policies and other Written Control Documents help ensure that the Trust complies with legislation, meets mandatory requirements, and provides services that are evidenced-based, safe and sustainable, enabling all staff to fulfil their roles safely and competently to provide effective and appropriate care and services for patients, donors and their colleagues.

1.2 Policies describe the Trust's guiding principles that underpin its decisions, behaviours and actions for everything it does. A Policy statement is a public commitment of our intent. Other written control documents translate these principles into more detailed instructions or guidance including individual responsibilities

1.3 Policies and other Written Control Documents provide the Trust with a clear governance framework to operate within and provide a process of internal control. They define what the organisation does and how it is done, support effective decision making and delegation and provide guidance for staff to follow.

1.4 To ensure the Trust delivers its aims, objectives, responsibilities and legal requirements transparently and consistently, it will develop and describe its "ways of working" in Policies and other Written Control Documents. In this regard, the Trust has approved the Policy and Procedure for the Management of Trust Wide Policies and other Trust Wide Written Control Documents (GC01), commonly referred to as the "*Policy on Policies"*.

1.5 Through this Policy the Trust ensures that there is a process whereby all policy documentation is consistent in format, compilation and dissemination. In addition, there is an effective process for managing and reviewing policies and any other written control documents on a regularised basis, to ensure that documentation remains legally compliant and actions are undertaken in a safe and efficient manner.

1.6 The principles of the policy management process including individual responsibilities for developing and reviewing policies and other written control documents, is summarised in the flow chart on page 7.

2. OBJECTIVES

2.1 This Policy ensures consistency in the format, compilation, approval and dissemination of all Policies and other Written Control Documents, so that they are:

- Developed and reviewed when required;
- "Owned" – each document will have an owner who has responsibility for making sure that it is regularly reviewed and kept up to date;
- Written in plain language so that they can be understood, and people are clear of what is expected;
- Subject to an Integrated Impact Assessment where required;

- Recorded, stored and archived in accordance with the Trust's Records Management Policy;
- Appropriately co-produced and consulted on;
- Considered and approved at the appropriate level within the Trust by the appropriate advisory group, forum, sub-committee or committee (with delegated powers and authority to do so);
- Shared with staff and stakeholders where required;
- Supported by appropriate learning, education and development where required; and,
- Available to the public, in line with Freedom of Information Act requirements and the Trust's Publication Scheme.

3. SCOPE

3.1 This policy applies to all staff employed by the Trust in all locations including those with honorary contracts.

3.2 This policy applies to all Trust wide Policies and other Trust wide Written Control Documents which fall within the definitions contained in this policy, both clinical and non-clinical.

3.3 Where written control documents relate to a single Directorate or Division and there is no wider impact on the Trust, they may be approved by the relevant Senior Management/Leadership Management Team.

3.4 In addition to the responsibilities detailed within the Policy, staff also have a responsibility for making sure that they meet the requirements of their role profiles and any other responsibilities delegated to them, which includes the development, review, publication and implementation of Policies and other Written Control Documents within their role.

4. POLICIES AND OTHER WRITTEN CONTROL DOCUMENT PROCESS AND FLOWCHART

4.1 The reason to develop a new or review an existing Policy or Written Control document can come from a variety of sources, i.e. legislation, national guidance, external reviews, audits, to clarify/improve working practice, to mitigate an identified risk or to adopt an all Wales Policy or other Written Control Document. It is up to managers of a service, staff or function to recognise when a Policy or other Written Control Document is required to minimise risk to patients, donors, staff and the organisation. An example is, as a result of an investigation following incident reporting, which recommends additional system controls to prevent the risk of reoccurrence of a similar incident. This can equally apply to action required following the investigation of a complaint and claims management.

4.2 The first step in the development/review of a Policy or other Written Control Document is the completion of the Document Approval Checklist. The Document Approval Checklist must be completed when the Policy or other Written Control Document is multi-disciplinary and/or multi-agency in nature. The Document Approval Checklist must also be completed for all Wales or jointly developed Policies and other Written Control Documents.

4.3 Any local Written Control Document, which is a local/divisional procedure or guideline which sets out the requirements for staff in a discrete department or professional group and does not have wider implications across the Trust, may not require a Document Approval Checklist. Further clarity can be sought from the Corporate Governance Team.

4.4 The overarching rationale for completion of the Document Approval Checklist is to aid the responsible document author (see section 10) in being clear about the reason for the document, the potential impacts of the document and the support required to facilitate the implementation of the document. It is best practice to consider these prior to developing or reviewing all Policies or Written Control Documents.

4.5 Whilst most Policies and other Written Controls Documents are developed internally for internal use within the Trust, there will be occasions when a Policy or other Written Control Document requires to be developed jointly with another organisation, for example, the Local Authority or other partner agencies. These must follow the process as Trust only Policies and Written Control Documents (page 7).

4.6 Some Policies and other Written Control Documents are issued on an all Wales basis with the expectation of local adoption. These documents must also be subject to formal adoption for use in the Trust (refer to section 6).

4.7 When the requirement for a developing a new or reviewing an existing Policy or other Written Control Document arises, it is recommended that contact is made with the Corporate Governance Manager, subsequently referred to as the 'Policy Process Manager', who will able to provide advice and support about each stage of the Policy and other Written Control Document development/review process.

4.8 The most important thing to note is that the development of a new or review of an existing Policy and other Written Control Document must not be undertaken in isolation and that it must be owned and overseen by the appropriate advisory group, forum, sub-committee or committee. Policies and other Written Control Documents are best developed/reviewed in collaboration with others to ensure that the final document is one that is in line with current legislation, guidance and evidence and can be implemented seamlessly within the organisation.

4.9 In addition, Strategies and Policies only must be sponsored by an Executive/ Director. If not already identified, the advisory group, forum, sub-committee or committee must nominate an author who will be responsible for ensuring that the process outlined in this policy is adhered to, starting with the completion of the Document Approval Checklist (Appendix 1).

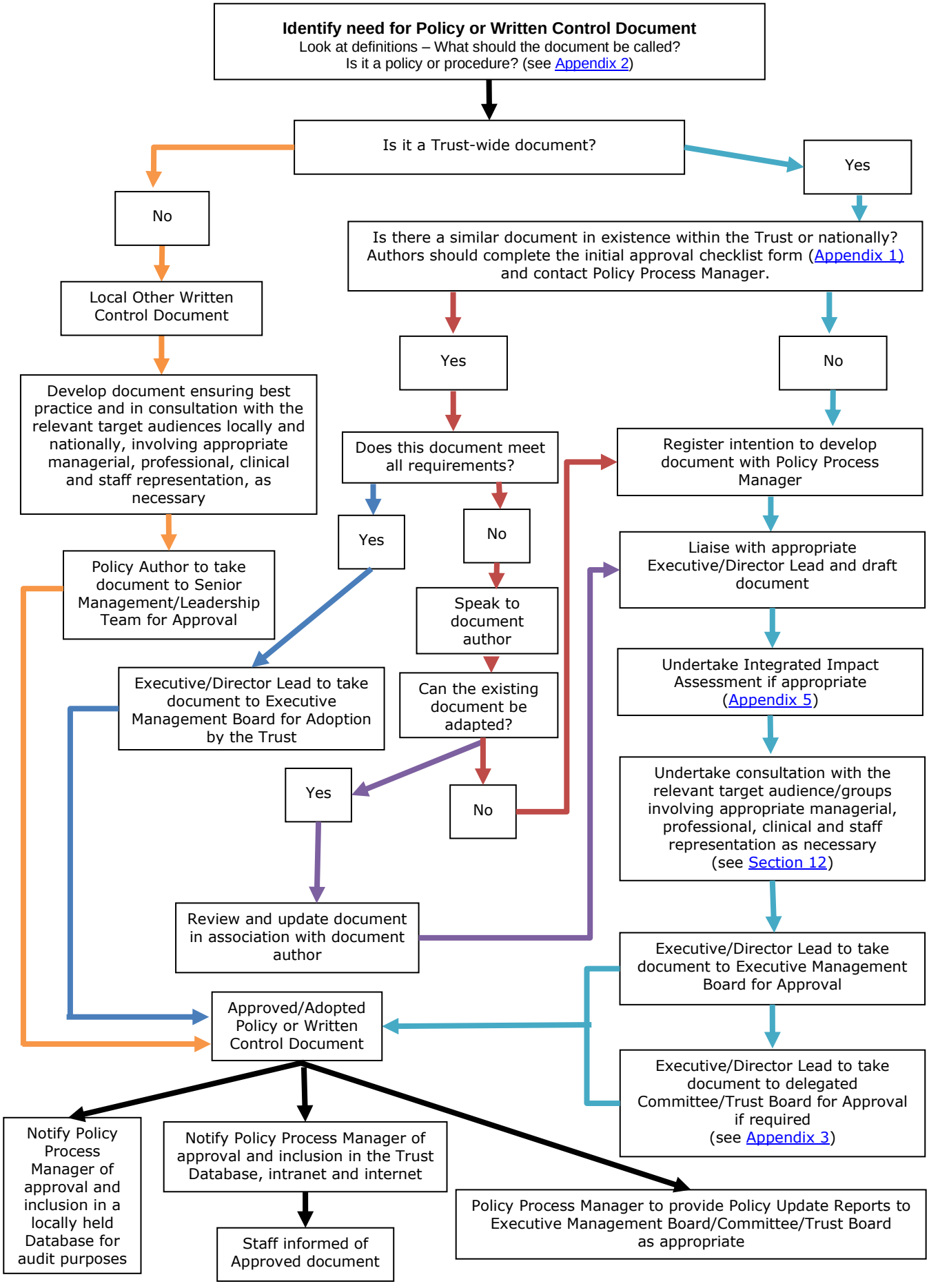
4.10 In accordance with the Equality Act 2010, all policies will be subject to Integrated Impact Assessment (refer to Section 10 for further detail and Appendix 5).

4.11 The flow chart on the following page explain the steps to be taken when considering the development of a Policy or Written Control Document. It is important that appropriate engagement and consultation takes place. In the case of employment

policies, (excluding those enforced from Welsh Government following national negotiations and other “All Wales policies”), staff representatives and management will jointly negotiate a draft policy for submission to the appropriate Committee for approval. If there are any issues that cannot be resolved at Committee level, the Policy will be brought to the Trust Board for final consideration and approval.

4.12 The development of Policies and other Written Control Documents must not be undertaken in isolation and will be based on sound evidence, and take account of current legislation, mandatory requirements and national/professional guidance. Sources of information used should be appropriately referenced.

PROCESS FLOWCHART



5. DEFINITIONS

5.1 Policies and other Written Control Documents are essential in the delivery of a high quality and safe health services and to ensure the Trust operates within the law. They form an integral element of the governance and assurance framework by which the Trust regulates its activities to achieve its goals and are used as reference points to assist staff in their day to day working.

5.2 Terminology across the range of documentation can often be confusing for both those that develop the documents and to those that use them. Clear definitions for these terms, highlighting the differences and similarities and the appropriate use of each is provided Appendix 2.

6. WHO CAN APPROVE THESE DOCUMENTS AND WHERE ARE THEY PUBLISHED?

6.1 The Standing Orders set out a Scheme of Delegation for the Trust and for organisation-wide documents. Strategies are a matter on which Trust Board approval is required. Certain key policies also require approval by the Trust Board (see Appendix 3) whilst others are delegated to the appropriate advisory group, forum, sub-committee or committee or Executive based Group (see Appendix 3). Any delegated approvals must also be submitted through the relevant Executive Sponsor to the Policy Process Manager. A copy of the relevant minute confirming the approval may be required. Documents that have not gained the required approval **will not be published.**

6.2 **Directorate and Division Specific Documents:** Where written control documents relate to a single Directorate or Division and there is no wider impact on the Trust, they may be approved by the relevant Senior Management/Leadership Management Team. Such documents will still need to be recorded in a suitable database at a local level and subjected to strict version control, issued with a unique reference number and meet the standards set within this policy. There must also be a clearly documented audit trail to indicate where and by whom the document has been considered.

6.3 Some “All Wales” policies are developed by the Welsh Government or by Health Boards and Trusts working together. For some of these documents the Trust must adopt them. Where this is the case, they will be reported to the appropriate advisory group, forum, sub-committee or committee and Trust Board so that there is a record of their adoption.

6.4 Where a document requires only a small amendment which is not material to the aims or objectives of the document, e.g. to reflect a change in working practice, content of supporting documents etc, an interim review may be undertaken. This will be agreed in advance with the Policy Process Manager to ensure that the completion of an interim review does not expose the Trust to an increased level of risk. The change will be reported to the next available meeting of the approving body.

6.5 Once approved, centrally recorded documents are published on the Trust Intranet and Internet sites. Under limited circumstances it may be necessary to redact

[remove or hide] information from a document prior to publication on the Internet e.g. direct dial telephone numbers within the Business Continuity Policy. The advisory group, forum, sub-committee or committee approving the document will determine if it is necessary to redact information prior to publication. Where this has been agreed it will be made clear within the body of the text on the document made available via the Internet.

6.6 The diverse nature of health care means there will be a large number of policies and other Written Control Documents in place. Some will apply across the Trust and be relevant to all staff, and others will be specific to certain areas or activities.

6.7 For ease of reference, all policy documentation will be listed and numbered under a series of headings. An index of Policies and other Written Control Documents will be maintained as part of the on-line database that is in place and maintained to manage the review process. The database will become the central register for all Policies and other Written Control Documents in the Trust.

7. WHO CAN PROVIDE ADVICE ON WHAT TO DO AND HOW DO WE KNOW WHAT DOCUMENTS HAVE ALREADY BEEN DEVELOPED?

7.1 The Director of Corporate Governance and Chief of Staff is responsible for making sure that the Trust has arrangements in place to ensure effective development and management of Policies and other Written Control Documents.

7.2 The Corporate Governance Manager is part of the Corporate Governance team and undertakes the function of Trust-wide "Policy Process Manager", who can provide advice and assistance on any aspect of document development and review. They can be contacted via the generic Policy email account [insert email address when set up].

7.3 The Policy Process Manager maintains a register of all documents that are centrally recorded and will be able to advise if a document already exists. All of these documents are also published on the Trust's Intranet and can be found through either the A-Z Listing or by searching on key words. Most documents are also published on the Trust's Internet site.

7.4 They Policy Process Manager will arrange for approved documents and the accompanying Integrated Impact Assessment (if applicable) to be published on the intranet/internet as appropriate within ten working days of receipt from the policy author or advisory group, forum, sub-committee or committee Secretariat.

8. WHAT ARE THE ROLES AND RESPONSIBILITIES OF EXECUTIVE/DIRECTOR LEADS

8.1 The Chief Executive, as Accountable Officer, has overall responsibility for ensuring the Trust has appropriate Policies and other Written Control Documents in place to ensure the Trust works to best practice and complies with all relevant legislation.

8.2 The delegated responsibilities of Executive/Director Leads are set out in the Scheme of Delegation. They have responsibility for:

- making sure that appropriate Policies and Written Control Documents are produced and kept up to date by identifying a document author (including reallocating responsibility if the author leaves or moves to another role);
- personally checking for accuracy of content prior to submission to an advisory group, forum, sub-committee or committee for approval;
- maintaining a list of these Policies and Written Control Documents, supported by the Policy Process Manager and making sure that these documents are up to date;
- making sure that there are arrangements in place to capture as appropriate, respond to and review documents when external organisations, e.g. Health and Safety Executive, Royal Colleges, publish new and updated information which require action by the Trust;
- making sure that consultation has taken place and an Integrated Impact Assessment, which includes the equality and health impact assessments, have been completed where necessary. Where these have not been undertaken a reason for this will be provided;
- making sure that any training requirements specific to the document have been referenced; and,
- making sure that where a process of audit and/or review has been agreed this is maintained and reported on.

9. WHAT ARE THE RESPONSIBILITIES OF DOCUMENT AUTHORS?

9.1 Authors are employees who have been given the task of writing or reviewing Policies and Written Control Documents. Employment documents should always have at least two authors i.e. a management representative and a staff representative. Authors must:

- liaise with Executive/Director Leads to make sure Policies and Written Control Documents are implemented appropriately and, where necessary, compliance with these documents is formally audited;
- make sure that documents are reviewed in line with the review date or as a result of changes to practice, organisational structure or legislation;
- work with the Executive/Director Lead and the Policy Process Manager to make sure that appropriate engagement and consultation has taken place with the relevant individuals and groups;
- inform the Executive/Director Lead of any learning, education or development needs and resource implications which must be considered before approval can take place;
- undertake the necessary impact assessments, including equality and health impact assessments, in consultation with the Equality, Diversity and OD Manager and Equality Impact Assessment (EQIA) Group, as required (Appendix 5);
- consider the findings and make sure that appropriate action has been taken in response to equality and health impact assessments.
- send the approved document to the Policy Process Manager for publication within ten working days of approval.

9.2 Authors are responsible for the review of their documents. If an author leaves the Trust or takes up another post, the responsibility for the ongoing maintenance of the

document is taken on by their replacement. Where no direct role replacement is appointed, responsibility reverts to the post holder's line manager. The Executive/Director Lead will be informed of the situation to allow them to identify a replacement author if it is not appropriate for the responsibility to stay within that department.

10. POLICY DEVELOPMENT

10.1 Each Trust-wide policy will be sponsored by a lead Executive. At Directorate/ Departmental level, Policies and other Written Control Documents will be sponsored by the appropriate Director/Head of Department. The Director of Corporate Governance and Chief of Staff will ensure that all Policies and Other Written Control documents are reviewed and appropriately monitored.

10.2 The development of new Policies and other Written Control Documents, or the amendment of existing documentation, will be overseen by the appropriate lead Executive/Director. They will be responsible for ensuring that content and scope are fit for purpose before being presented for approval.

10.3 When the need for a new policy document arises, the Policy Process Manager should be informed before preparation commences to ensure there is not a Policy or other Written Control Document already in existence locally or nationally on the same or similar subject, thus avoiding duplication of effort. Authors should complete the initial Document Approval Checklist (Appendix 1) and send to the generic Policy email account [insert email address when set up].

10.4 Once the need and type of Policy or other Written Control Document is identified, the process for production and approval must follow that contained within this Policy. A flowchart depicting this process is set out on page 7.

10.5 The language used should be plain English, using short sentences and where possible avoiding technical terms. If technical terms are used, they should be explained using a glossary or footnotes. In accordance with the requirements of the Data Protection Act 2018, the names of individuals will not be contained within policies and other written control documents. Individuals with particular responsibilities will be identified by their job title only.

10.6 All Policy and Written Control Document development should be undertaken in line with current legislation, national and professional guidance. Documentation should also be based on sound evidence and be appropriately referenced.

10.7 **Health and Care Standards**
All Policies and other Written Control Documents should outline how they contribute to compliance with the Health and Care Standards and should also indicate to which Standards this area of activity is linked.

10.8 **Well-being of Future Generations (Wales) Act 2015**
The Well-being of Future Generations (Wales) Act 2015 is about improving the social, economic, environmental and cultural well-being of Wales. As a listed body, we are mandated to assess our long-term impact, work better with people and communities and each other, look to prevent problems and take a more joined-up

approach. This will help us to create a Wales that we all want to live in, now and in the future. To make sure we are all working towards the same vision, the Act puts in place seven well-being goals:

- A Prosperous Wales
- A Resilient Wales
- A Healthier Wales
- A More Equal Wales
- A Wales of Cohesive Communities
- A Wales of Vibrant Culture and Thriving Welsh Language
- A Globally Responsible Wales

The Act also lists the 5 Ways of Working:

- Long Term
- Collaboration
- Prevention
- Involvement
- Integration

All Policies and other Written Control Documents must consider provisions and demonstrate that all key goals were considered in the development of the document.

Each Well-being Goal and the 5 Ways of Working are incorporated into the Integrated Impact Assessment, refer to Appendix 5 for further detail. All documentation is required to highlight how it contributes to at least one Well-being Goal and assesses the whether the documentation adheres to the 5 Ways of Working.

10.9 **Integrated Impact Assessment**

The Equality Act 2010 requires the undertaking of various impact assessments and all Trust Policies and other Written Control Documents will require the completion of these before the document is consulted upon. The impact assessments are a process to find out whether a ‘policy’ will affect people differently on the basis of their 'protected characteristics': age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion, sex or sexual orientation and if it will affect their human rights. It also takes account of Welsh Language issues. It is designed to ensure that the Trust is taking into consideration the needs of all individuals who work for it and/or access its services.

The Trust has adopted an integrated approach to impact assessment, which combines the equality and health assessment alongside environmental impacts, Welsh Language whilst assessing the document against the requirements within the Well-being of Future Generations (Wales) Act 2015 and the Socio-Economic Duty.

A health impact assessment is a process that considers how the health and well-being of a population may be affected by a proposed action, be it a policy, programme, plan, project or a change to the organisation or delivery of a particular public service. Some impacts of policies on health may be direct, obvious and/or intentional, whilst others may be indirect, difficult to identify and unintentional. A health impact assessment is a systematic, objective, flexible and practical way of

assessing both the potential positive and negative impacts of a proposal on health and well-being and suggests ways in which opportunities for health gain can be maximised and risks to health minimised. Health impact assessment looks at health in its broadest sense, using the wider determinants of health as a framework.

Where another Written Control Document has been developed in support of a policy it may not be necessary to undertake a further Integrated Impact Assessment. If an Integrated Impact Assessment has not been completed the reason for this will be explained at the beginning of the document. Where an Integrated Impact Assessment has been completed the impact will be included in the document.

10.10 **Environmental Management**

The Trust is accredited to the Environmental Management System (EMS) ISO 14001:2015 which is the internationally recognised standard for managing the environment. The EMS provides a framework for managing environmental impacts associated with the Trust's activities.

The system applies to both the public and private sectors and demonstrates that the organisation has a formal system in place for managing the environment.

The system is based on the principle of continual improvement and requires the Trust to demonstrate this by the use of Key Performance Indicators and progress towards environmental objectives and targets. This framework allows an organisation to understand, describe and control its significant impacts on the environment, reduce the risk of potentially costly pollution incidents, ensure compliance with environmental legislation and continually improve its business operations.

An environmental impact assessment is undertaken as part of the Integrated Impact Assessment process and is an assessment of the possible positive or negative impact that a proposed project may have on the environment, together consisting of the natural, social and economic aspects.

The purpose of the assessment is to ensure that decision makers consider the ensuing environmental impacts when deciding whether to proceed with a project. Advice on areas that require an environmental impact assessment can be obtained from the Trust's Environmental Development Officer.

11. DOCUMENT FORMAT

11.1 A document template has been developed to provide guidance on what information should be contained in which policy/other written control document along with some standard clauses that can be used as appropriate (Appendix 4) and indicates fields that are mandatory. It also contains the standard front cover which is to be applied to Trust Policies and other Written Control Documents, together with some specific points regarding formatting. See Appendix 4 and the Policies Intranet page.

11.2 This Template must be used for all Trust-wide, Divisional or multi-departmental documents. Where a document is only applicable within a single Department or, for example consists of a flow chart, an alternative format is acceptable and a "basic

template" is also shown below. As a minimum the principles listed below must still be followed:

- Document must have a clear heading.
- The scope and objectives must be defined.
- The status of the document must be clear e.g. guidance/mandatory requirement.
- Instructions/guidance must be logically recorded.
- Date of approval shown.
- Date of review shown.
- Author's details.
- Pages numbered.

11.3 The language used for all documents should be plain English, using short sentences and where possible avoiding technical terms. If technical terms are used, they should be explained using a glossary or footnotes.

11.4 Policies and other written control documents will not be routinely translated into other languages. However, where staff are aware that this may cause difficulty for patients, donors or their families, they will ensure that the content is explained to them by an interpreter or translated if necessary.

11.5 In accordance with the requirements of the Data Protection Act 1998, the names of individuals will not be contained within policies and written control documents. Individuals with particular responsibilities will be identified by their job title only.

11.6 If the Trust is adopting an externally approved document it will not need reformatting providing it meets the standards set above. These documents will be given a reference number, recorded and uploaded as if they were a Trust document.

12. ENGAGEMENT AND CONSULTATION

12.1 Policies and other Written Control Documents must not be written in isolation.

12.2 Engagement and consultation on all Policies and other Written Control Documents should take place with the target audience including appropriate stakeholder, service user/carer, managerial, clinical and staff representation. Where appropriate, documents should be co-produced with that target audience.

12.3 The Trust has a range of mechanisms to involve patients, carers, donors and members of the public in its work. This will strengthen the stakeholder involvement with the Trust and demonstrate our commitment to working with the local community and develop our services and policies jointly. Where appropriate, the relevant patient and donor Engagement Leads should be contacted.

12.4 When a final draft has been developed the formal consultation can start. The consultation period should allow enough time to enable the key stakeholders to have had an opportunity to consider and input into the consultation. If necessary, the Policy Process Manager can provide advice.

12.5 The policy author should send the document and Integrated Impact Assessment (if applicable) to the Policy Process Manager who will arrange for the documents to be

uploaded onto the Trust's Policy Page on the Intranet. They will also make sure that they are brought to the attention of appropriate stakeholders in a timely manner. This will include the Community Health Council in accordance with mutually agreed principles.

12.6 The author, in association with the appropriate Executive/Director lead, must document the consultation arrangements and provide assurance to the approving advisory group, forum, sub-committee or committee that this has been conducted thoroughly and that comments have been incorporated into the policy or written control document where appropriate. The groups/individuals consulted will be clearly identified in the report presented to the approving advisory group, forum, sub-committee or committee.

13. REVIEW PROCESS

13.1 The Policy or other Written Control Document Author who owns the Policy or Written Control Document is responsible for ensuring it remains in line with current legislation, guidance and evidence and therefore is required to review the Policy or other Written Control Document in light of new or updated legislation and/or guidance (NICE, Professional bodies) as it is published.

13.2 All Policies and Written Control Documents should be reviewed on a minimum cycle of three years. With the exception that a small number of documents need to be reviewed annually (and this requirement will be identified in individual documents by their authors). Sometimes, a document which was subject to a three-year cycle will also need to be reviewed earlier in the light of changing practice or Welsh Government guidance/ policy changes etc. However, if no revisions have occurred in the preceding three years, it must be subject to the full Policy or other Written Control Document process. The author of the individual document is responsible for ensuring this takes place.

13.3 Nine months prior to the review date, the Policy Process Manager will contact the document author who owns the Policy or other Written Control Document to notify them that their document is due for reviewing. The author, in conjunction with the Executive/Director lead who owns the Policy or other Written Control Document, is responsible for ensuring that the document is reviewed by the review by date. If it is foreseen that the review date will not be met, the approving advisory group, forum, sub-committee or committee must receive assurance that the current version of the Policy or other Written Control Document is still fit for purpose and agree an extension of up to a maximum of six months. Any material or significant changes to an existing Policy or Written Control Document will require it to be re-approved by the approving advisory group, forum, sub-committee or committee following the Policy and other Written Control Document process.

13.4 Until a document is reviewed, it will remain the extant policy document of the Trust until replaced. It is the responsibility of the policy author to ensure that documents are reviewed in line with their review dates.

13.5 Organisational change can lead to more than one version of a document on a given subject area existing. In such instances the author will take steps to develop a

single version of the document. Should this not be achieved prior to the document reaching three years post approval it will be archived.

13.6 To assist Executive/Director leads to maintain an oversight of the documents approaching three years post-approval, a bi-annual report will be sent to the Executive Management Board and relevant advisory group, forum, sub-committee or committee by the Policy Process Manager providing a summary of the position.

14. PUBLICATION, DISSEMINATION AND DISTRIBUTION

14.1 The Policies and other Written Control Documents which are approved through the Scheme of Delegation for the Trust are centrally managed through the Corporate Governance Department. A Trust Policy database is in place and once a document has been entered onto the database, approved and published on the internet, this should be regarded as the only official Trust version for dissemination to and use by Trust employees.

14.2 Where a Policy or Written Control Document has been superseded, the archived copy will be held on file by the Policy Process Manager but will no longer be available via the internet. The Trust is required to keep a record of all archived, out of date Policies and other Written Control Documents, in line with WHC (2000) 071 for the Record and Records Management Policies.

14.3 Each department/service which develops/reviews Policies and other Written Control Documents must set up their own local document management system. This must hold all current and out of date Policies and other Written Control Documents. All out of date documents must be kept for **a period of 30 years in line with the WHC (2000) 071 For the Record.**

14.4 All policies and other written control documents that have been ratified appropriately must be forwarded to the Policy Process Manager within ten working days of approval. They will then ensure that the document is:

- Added/updated on the Trust Policy database;
- Cascaded in line with the Trust's communications system;
- Included within the Executive Management Board and Trust Board regular reporting;
- Uploaded onto the intranet;
- Included in the Freedom of Information Publication Scheme.

14.5 The Trust's intranet site will be the primary location for all Policies and other Written Control Documents to ensure that staff can access the most up to date versions. Where hard copies need to be circulated, these should be downloaded from the intranet site by the appropriate Line Manager.

14.6 Relevant documentation will also be published on the Trust's internet site, in line with Freedom of Information Act requirements.

14.7 All documents will be subject to version control and archived in line with legal requirements. Once revised Policies and other Written Control Documents are

approved, the Policy Process Manager will e-mail the author/policy lead to inform them in order that they can ensure appropriate dissemination to their staff.

14.8 Once issued, individual Line Managers will be responsible for ensuring that all staff are aware of the revisions and that any out of date versions are taken out of local circulation. Each Directorate/Department will put in place a robust controlled documentation system to ensure that records of distribution of policies and other written control documents are maintained.

14.9 Information on new and revised policies will be cascaded in line with the Trust's communications system. Where appropriate other communication channels may be used to inform staff of policy development (for example, inclusion with payslips).

14.10 It is the responsibility of the author of a Policy or Written Control Document to ensure that when a document is revised, a copy of the original is forwarded to the Policy Process Manager for audit purposes.

14.11 The Director of Corporate Governance and Chief of Staff will ensure that the register of all Policies and other Written Control Documents is reported bi-annually to the Executive Management Board, relevant advisory group, forum, sub-committee or committee and Trust Board.

15. TRAINING

15.1 All Executive/Director leads will work with the Executive Director of Organisational Development and Workforce to ensure that there is an ongoing training programme for all staff that incorporates the implementation of Policies and other Written Control Documents. Key subject areas will be included at local induction and as part of staff development processes.

15.2 Line Managers must ensure that new starters are aware of this policy, induction arrangements and of their individual departmental processes.

15.3 It is the responsibility of individual Line Managers to inform the Executive Director of Organisational Development and Workforce of the requirement where specific staff training needs are identified, particularly in relation to the implementation of new or updated documents.

15.4 Executive/Director leads will ensure that responsibilities for policy development are clearly outlined in each individual Job Description, in accordance with their role.

16. IMPLEMENTATION AND POLICY COMPLIANCE

16.1 Any advice required on implementation of this policy should be obtained via the Policy Process Manager.

16.2 All policies should be part of the Trust and/or Directorate/Department auditing process to ensure that they:

- have been implemented effectively;
- are fit for purpose; and
- are being complied with.

16.3 Information regarding the frequency of the monitoring arrangements should be included within the main policy document. If appropriate, questionnaires can be used for staff feedback to evaluate any policy and supporting written control documentation.

16.4 It will be necessary to ensure that all documents are being produced, vetted, approved and disseminated in accordance with this policy. Periodical 'spot checks' will be carried out in all areas to ensure that all policies and other written control documents comply with this policy.

16.5 Compliance will also be monitored as part of the Health and Care Standards for Wales Annual Review process.

16.6 Where documents are submitted for publication but do not meet the pre-publication requirements they will be **not be published**. Such documents will be returned to the Executive Sponsor for action.

17. REVIEW PERIOD

17.1 This policy will be reviewed every three years, or sooner should the author or legal requirements deem it to be relevant or required.

18. ACKNOWLEDGEMENTS

18.1 This policy has been developed following benchmarking with the following:

Aneurin Bevan University Health Board, (ABUHB001) Policy and Procedure for the Management of Policies, Procedures and other Written Control Documents – approved May 2017

Cardiff and Vale University Health Board, (UHB 001) Management of Policies, Procedures and Other Written Control Documents Policy – approved November 2017

Hywel Dda University Health Board, (190) Written Control Documentation Policy and Procedures – approved February 2021

Public Health Wales, (PHW47/TP01) Policies, Procedures and Other Written Control Documents Management Procedure – approved September 2019

Swansea Bay University Health Board, (HB76) Policy for the Management of Health Board Wide Policies, Procedures and Other Written Control Documents (WCD) – approved July 2019.

APPENDIX 1

DOCUMENT FOR APPROVAL CHECKLIST

This form should be completed and approval to proceed obtained before you start producing your document. The Equality and Health Impact Assessment, known as the Integrated Impact Assessment, should also have been started and any Welsh Language requirements considered.

To be completed by document author.

1. Proposed/existing title of document

2. 'Owning group' – which advisory group, forum, sub-committee or committee will own the document?

Name of Group		**Chair of Group**		
Please indicate (further details may be requested if applicable)	**Internal Trust Group**		**Yes**	**No**
	Multi-Agency Group		**Yes**	**No**
	Regional Group		**Yes**	**No**

3. What type of document are you proposing/adopting/reviewing? Please select

Policy		**Strategy**		**Procedure**		**Guideline**	
Protocol		**Other**	**Please describe**				

New		**Existing**	

4. Which category will it be/is it?

Clinical		**Corporate**	

If it is a corporate document will/does it impact on patient/donor care?

Yes		**No**	

5. What is the reason for developing/adopting/reviewing this document?
Please tick the box that is most relevant. If there are no relevant boxes, please tick other and ensure that you specify the reason in the box

	Insert tick for most relevant
Improve/standardise clinical care/organisational procedures	
In response to complaint, incident or claim	
In response to alerts, safety notifications, WHCs, etc.	
Re-organisation of service/department	
New/amended legislation	
All Wales documents / national guidance documents to be adopted for use	
Replacing/updating existing written control documents. If so, which ones (Please include policy reference and full name:	
Other (please specify):	

6. What will be/is the aim of the document? What risks are being mitigated?

7. Which other written control documents will be/are relevant to the document?

Document Number	**Document Name** List all document names and numbers that are relevant to this document

8. **What will be/is the scope of this document?**
What service area is covered by the document? Who does it affect? What patient groups? What professional groups or individuals does it affect? What competence is required by staff to use this procedure, e.g. completion of specific training, e-learning, formal qualification, competency framework, is required from users of the procedure?

9. Collaboration with Key stakeholders – What staff groups/professional groups/clinical specialities/services will be/are responsible for implementing/complying with this document?

These key stakeholders' will need to be involved in the development/adoption/review of the document to eliminate any barriers to its implementation prior to approval (see policy for guidance).

10. Collaboration with others

Involvement is an essential component of developing/adopting/reviewing the document.

Please indicate which of the following need to be considered when developing/reviewing this document

Compliance with legislation / regulation / alert	**Please tick √**
Consent	
Deprivation of Liberty Safeguards (DOLS)	
Mental Capacity Act (MCA)	
Mental Health Act	
Safeguarding	
Data Protection/Records Management and Information Governance	
Welsh Language	
Counter Fraud	
Equality, Diversity and Inclusion	
Socio Economic Duty	
National Safety Standards for Invasive Procedures (NatSSIPs)	
Alert/NCEPOD	
Interested Parties	
NICE Guidance	
Patient/Donor Information	
Training / Learning and Development	
Legal	
Financial	
Workforce	
Medicines Management	
Medical Devices	
Infection Prevention & Control	
Business Continuity / Emergency Planning / Major Incident	
Health and Social Care (Quality and Engagement) (Wales) Act 2020	

11. Who will be/is the sponsoring Executive/Director Lead and date they agreed to own this document?

Job Title	
Date	

12. Who will be/is the lead author/main contact for this document?
An individual's name and details will need to be provided as a contact for this document for any queries arise both during development and after approval.

Name	
Job Title	
Email Address	

Date of Completion:		**Name of person completing this form**	
Chair of the Owning Group:		**Signature of the Chair of the Owning Group:**	

PLEASE SEND COMPLETED CHECKLIST FORM TO THE POLICY PROCESS MANAGER [insert Policy inbox email address link]

APPENDIX 2

TYPES OF WRITTEN CONTROL DOCUMENTS (DEFINITIONS)

Written Control Document – Is a supporting strategy, procedure, protocol, guideline or standard referred to collectively as other Written Control Documents within this Policy.

Strategy - A strategy is a broad statement of an approach designed to accomplish the desired objectives or goals and can be supported by other Written Control Documents. Strategies are always organisational wide and required to be approved by the Board via the Scheme of Delegation.

Policy – A written statement of intent, describing the broad approach or course of action that the Trust is taking with a particular issue. Policies are underpinned by evidenced based procedures and guidelines and are mandatory. Policy documents may be used to support the Trust during legal action.

The formulation of policies allows the Trust to produce formal agreements, which clearly defines the commitment of the organisation and the obligations of individual staff.

Procedure - A standardised method of performing clinical or non-clinical tasks by providing a series of actions to be conducted in an agreed and consistent way to achieve a safe, effective outcome. This will ensure all concerned undertake the task in an agreed and consistent way. These are often the documents detailing how a policy is to be achieved.

Procedures can be written as part of a policy document (in which case they are mandatory) or as ‘stand-alone’ documents (in which case they are discretionary).

Where procedures are formulated utilising evidence-based knowledge and best practice guidelines, they must include reference of any researched evidence used.

‘Stand-alone’ procedures give the user the means to carry out specific tasks. This may be within the overall control framework of the organisation or to regulate activities to achieve a quality outcome. ‘Stand-alone’ procedures do not have the same status in law as a policy; however, failure to follow a specific procedure may prejudice the successful defence of a claim against the organisation.

Protocol - A written code of practice, including recommendations, roles and standards to be followed, which can also include details of competencies and delegation of authority.

Protocols are different from policies as they lack the ‘mandatory’ element and by allowing for professional judgement, individual cases and competency to play a role they are flexible working documents.

Within a protocol it must be clear by whose authority is it being implemented, what the scope of the protocol is and what procedure is to be followed if practice is to be outside of the protocol.

In the case of clinical protocols, clinicians must be advised in every document that it is for their guidance only and the advice should not supersede their own clinical judgement.

Guidelines - Give general advice and recommendations for dealing with specific circumstances. They differ from procedures and protocols by giving options of how something might be carried out. They are used in conjunction with knowledge and expertise of the individual using them.

Guidelines are not prescriptive. However, whilst guidelines are not mandatory, it could prove difficult to defend a case where agreed guidelines had not been followed.

National Clinical Guidelines - The National Institute Health and Clinical Excellence (NICE) defines guidelines as:

> *"systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. Research has shown that if properly developed, disseminated and implemented, guidelines can lead to improved patient care" (NICE 1999).*

Standards - The Royal College of Nursing definition is:

> *"to provide a record of service or representation of care which people are entitled to experience, either as a basic minimum or for use as a measure of excellence" (RCN 1997)*

> The Health and Care Standards define standards as:
> *"Standards are a means of describing the level of quality health care organisations are expected to meet or to aspire to. The performance of organisations can be assessed against this level of quality" (Welsh Government 2015).*

Standard statements are accompanied by a description of the structure and process needed to attain specified observable outcomes.

Standards are not generally prescriptive; it could prove difficult to defend a case if a standard is not adhered to.

CLASSIFICATION OF DOCUMENTS

Clinical – Clinical Written Control Documents relate to the care and treatment of patients within the organisation and offer an evidence-based approach to making a series of clinical decisions for patients with a given condition.

Corporate – Corporate Written Control Documents relate to the management of the organisation and formulate the organisation's response to known situations and circumstances.

Employment – Employment Written Control Documents relate specifically to the management of employees (however defined) within the organisation and are a written source of guidance on how a wide range of issues should be handled within an employing organisation, incorporating a description of principles, rights and responsibilities for managers and employees.

APPENDIX 3

DOCUMENTS RESERVED FOR APPROVAL BY THE TRUST BOARD AND OR ONE OF ITS COMMITTEES, GROUPS OR FORUMS

AREAS COVERED	DOCUMENT SPONSOR	ENDORSING GROUP	ENDORSING BODY	APPROVING BODY
Standing Orders	**Director of Corporate Governance and Chief of Staff**	**Executive Management Board**	**Audit Committee**	**Trust Board**
Risk Management Trust Assurance Framework	**Director of Corporate Governance and Chief of Staff**	**Executive Management Board**	**Audit Committee**	**Trust Board**
Citizen Engagement & Involvement Partner & Stakeholder Engagement Corporate Governance	**Director of Corporate Governance and Chief of Staff**	**Executive Management Board**	**Quality, Safety & Performance Committee**	**Trust Board**
Standing Financial Instructions Financial Management Financial Governance Commissioning Arrangements	**Executive Director of Finance**	**Executive Management Board**	**Audit Committee**	**Audit Committee**
Information Governance Health Records	**Executive Director of Finance**	**Executive Management Board**	**Quality, Safety & Performance Committee**	**Quality, Safety & Performance Committee**
All aspects of Workforce and Organisational Development including Wellbeing, Equality, Diversity & Human Rights (including all-Wales workforce policies on behalf of the Trust Board). Welsh Language	**Executive Director of Organisational Development and Workforce**	**Executive Management Board**	**Local Partnership Forum** **Quality, Safety & Performance Committee**	**Trust Board**

AREAS COVERED	DOCUMENT SPONSOR	ENDORSING GROUP	ENDORSING BODY	APPROVING BODY
Clinical Audit & Effectiveness Inquests Clinical Strategy	**Medical Director**	**Executive Management Board**		**Quality, Safety & Performance Committee**
Research & Development Innovation Intellectual Property Policy	**Medical Director**	**Executive Management Board**		**Research, Development & Innovation Sub Committee**
Medicines Management Civil Contingency/Emergency Planning Arrangements	**Chief Operating Officer**	**Executive Management Board**		**Executive Management Board**
Major Incident Plan/Business Continuity	**Chief Operating Officer**	**Executive Management Board**	**Strategic Development Committee**	**Trust Board**
Quality, Safety and Performance of patient and service user centred healthcare Patient Experience including Complaints, Incidents & Litigation Safeguarding Human Tissue Act	**Executive Director of Nursing, Allied Health Professionals & Health Sciences**	**Executive Management Board**		**Quality, Safety & Performance Committee**
Infection Prevention & Control	**Executive Director of Nursing, Allied Health Professionals & Health Sciences**	**Infection Prevention & Control Management Group**	**Executive Management Board**	**Quality, Safety & Performance Committee**
Nursing Services Nutrition Allied Health Professional Services Health Sciences	**Executive Director of Nursing, Allied Health Professionals & Health Sciences**			**Executive Management Board**

AREAS COVERED	DOCUMENT SPONSOR	ENDORSING GROUP	ENDORSING BODY	APPROVING BODY
Integrated Medium Term Plan Performance Management Framework	**Director of Strategic Transformation, Planning & Digital**	**Executive Management Board**	**Strategic Development Committee**	**Trust Board**
IM&T Arrangements and Digital Delivery Health & Safety Performance Arrangements Estate Plans	**Director of Strategic Transformation, Planning & Digital**	**Executive Management Board**		**Quality, Safety & Performance Committee**
Strategy Planning Sustainability/Environment Management	**Director of Strategic Transformation, Planning & Digital**	**Executive Management Board**		**Strategic Development Committee**
Investments Fundraising Bequests Donations	**Executive Director of Finance**	**Executive Management Board**		**Charitable Funds Committee (in conjunction with Charitable Fund Trustees)**

APPENDIX 4

POLICY OR WRITTEN CONTROL DOCUMENT TEMPLATE

Ref: ( )

(DOCUMENT TITLE)

Executive Sponsor & Function

Document Author:

Approved by:

Approval Date:

Date of Equality Impact Assessment:

Equality Impact Assessment Outcome:

Review Date:

Version:

TEMPLATES FOR DOCUMENTS

The template and control sheet should be used by anyone wishing to formulate any written control system. Documents should be formatted in line with Corporate Style as follows:

Electronic format	Microsoft Word - PDF Read only
Front cover	Corporate template
Audit trail	Use Policy process
Body text	Arial 12
Headings	Arial 12 (UPPER CASE)
Tables and charts	Arial (size as appropriate)
Use of bold	Headings only
Alignment	Justified
Line spacing	Body text single
Paragraph spacing	One line between paragraphs. Two lines between main sections.
Underlining	None
Contents page Contents page if >3 pages	As template Use judgement - help reader to find relevant information more easily.
Staff Names	Use titles rather than names.
Logo	Use Trust logo.
Headers and footers	Arial 9
Margins	Top and bottom of page 2.5cm, sides 2.5cm.
Document Title	To be included in the header on every page
Page numbering	To be included in the footer (e.g. page x of x)
Bullets	• Use standard bullets only, as they do not always format across different systems.
Abbreviations	State in full in first usage with abbreviation in brackets.
Printing	A4/double sided.
Referencing	All reference material should be listed in full at the end of every document in Harvard style.
Glossary of terms	As all policy documents are subject to the Freedom of Information Act, they need to be user friendly as they are documents that can be held up to public scrutiny. Therefore, all abbreviations, jargon and specific wording must be clearly explained to the reader.
Version Control	Reference Number provided by the Corporate Governance Manager. Documents to state ‘Draft’ whilst in development.

COMPONENTS OF A POLICY

All Policies must include the following headings as a minimum

Introduction/Aim	What is the purpose of the document? What is it about? Why is it needed? This should include where necessary reference to external regulations or other relevant guidance. This may require information relating to audit, risk management, quality and safety.
Objectives	What will the document achieve?
Scope/Area of Application	Exactly who the policy applies to and the consequences for non-compliance where appropriate: • All staff? • Directorate/Clinical Department/Corporate Department specific?
Roles and Responsibilities	• Who is responsible for implementation? • Which groups of staff are able to carry out the procedures required? • What action points does the document raise? • Who is responsible for ensuring action points are undertaken? • Who is accountable if the responsibilities are not followed?
Main Body	Show how the document aims and objectives will be achieved. Reference evidence appropriately.
Resources	Are there any resource issues in order for the document to be implemented? Financial/Time/Training – these must be identified as if there are no resources the document will not be achievable.
Training	• Are there any training issues and if so, who is responsible for the training programme? • Who will keep a record of those members of staff who have been trained? • Will there be update training? How often? If the document compliance is not carried out for any length of time at what stage will the person cease to be authorised to carry out that policy? Where appropriate, specify the grade and required education and training of staff implementing the document.

Implementation and Policy Compliance	How will the document be implemented? • Action Plan? • Timescales? • What level of training should they have? This will be the main part of the policy, generally divided into sections and describe in detail what has to be done in order to comply with the policy and achieve the policy objective. The document needs to set out how compliance with the policy is to be measured and reported.
References	Policies must be based on sound evidence and be appropriately referenced. Name any recognised relevant professional body, for example the source of your evidence base. Where appropriate, specify what is required to be documented in patients' notes. Clinical policies should also include a review of the evidence used and a reference list of that evidence.
Health and Care Standards	This section should outline how the policy or written control document contributes to compliance with the Health and Care Standards and should also indicate to which Standards this area of activity is linked.
Integrated Impact Assessment	Has an equality and health impact assessment been carried out? If 'no' the reason for this will be explained at the beginning of the document. If 'yes' the impact will be included in the document and appended. Explain how the document promotes equality of opportunity and/or good relations between different groups. For further information contact the Equality, Diversity and OD Manager
Environmental Impact	Does an Environmental Impact Assessment need to be carried out? For further information contact the Trust's Environmental Development Officer.
Audit	This is required to ensure that the document is appropriate and achievable and that there is compliance with the document by staff. An audit tool must therefore be built into the policy document.
Review	Generally, 3 years unless legislation requires differently – check with Corporate Governance Manager.
Getting Help	Details of the specific office or department to contact for interpretations, resolution of problems and other special situations.

A policy may also need to contain the following additional components	**Related Policies and/or written control documents** Where other policies are relevant these should be listed. **Information, Instruction and Training** This section is relevant where instruction, training and supervision is necessary for to meet the policy requirements. It should detail when, how often and by whom the action will be taken and any requirement for keeping training records should be indicated. **Main Relevant Legislation** A list of the relevant statutory provisions which influence the organisation's operation in relation to the policy.

CHARACTERISTICS OF POLICIES AND WRITTEN CONTROL DOCUMENTS

The overall goal is for the design to be simple, consistent and easy to use.

Writing Style:

- Factual - accuracy should be double checked
- Should not provide information that may be quickly outdated
- If an acronym is used, it should be in full initially
- Not excessively technical, must be simple enough to be understood by a new member of staff

Policies should:

- Be written in clear, concise and simple language wherever possible
- Identify the rule rather than how to implement the rule
- Be based on sound evidence and be appropriately referenced.
- Be readily available and their authority should be clear.
- Indicate designated "experts" who can interpret documents and resolve problems
- Represent a consistent, logical framework for action

Written Control Documents should:

- Be clear in terms of how the procedure helps the organisation achieve its aims and objectives.
- Be developed with the client/patient/relative/carer/objective in mind. Well-developed and thought-out procedures provide benefits to the procedure user.
- Involve users in their development where appropriate to engender a sense of ownership

Design and Layout of Policy and Written Control Documents

- Use Arial text
- Number paragraphs and pages
- Generous use of white space
- Structure the presentation so that the reader can quickly focus on the aspect of policy relevant to the decision in hand
- Headings need to be consistent, e.g. location on each page, type size, bold etc.
- Footer should contain: the page number

APPENDIX 5

Integrated Impact Assessment Process and Form

The Equality Act 2010 requires the undertaking of equality and health impact assessments and all Trust policies will require the completion of such before the policy is consulted upon. This is a process to find out whether a ‘policy’ will affect people differently on the basis of their 'protected characteristics': age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion, sex or sexual orientation and if it will affect their human rights. It also takes account of Welsh Language issues. It is designed to ensure that we are taking into consideration the needs of all individuals who work for us and/or access our services.

The Integrated Impact Assessment (IIA) is a process that considers how the health and well-being of a population may be affected by a proposed action, be it a policy, programme, plan, project or a change to the organisation or delivery of a particular public service. Some impacts of policies on health may be direct, obvious and/or intentional, whilst others may be indirect, difficult to identify and unintentional. The IIA is a systematic, objective, flexible and practical way of assessing both the potential positive and negative impacts of a proposal on health and well-being and suggests ways in which opportunities for health gain can be maximised and risks to health minimised. HIA looks at health in its broadest sense, using the wider determinants of health as a framework. This will ensure that any negative or indirect discrimination which could be an outcome of the policy, etc. is identified and risk assessed, linking to the Trust Risk Management Policy and Strategy. All final policies must include reference to the Integrated Impact Assessment that has been undertaken.

Where a procedure or other written control document has been developed in support of a policy it may not be necessary to undertake a further Integrated Impact Assessment. If an IIA has not been completed the reason for this will be explained at the beginning of the document. Where an IIA has been completed, the impact will be included in the document.

IIAs will be published as part of the consultation process and they will be available on our internet and intranet sites alongside the relevant policy or written control document.

One of the key requirements is the need to involve stakeholders in the process, whether internal or external. This ensures that any potential areas for discrimination are identified and solutions are sought to prevent discrimination.

In addition, the Trust’s IIA process also includes the Welsh language and carers as well as adopting a human rights-based approach, ensuring dignity and respect are also evaluated in the process.

Equality Impact Assessment (EQIA) Group

The Trust has established an Equality Impact Assessment Group, which has representation from each division and hosted organisations, as well as Sustainability, Quality and Risk, Governance, Workforce and Occupational Development, Finance, Welsh Language and Staff side representation. The group meets monthly to undertake assessments with the relevant policy leads etc. Once the IIAs are complete, the policy/ procedure/ guidance/ business plan/proposed service change can then go out to full

internal consultation, before being submitted to the relevant advisory group, forum, sub-committee or committee and, where required to the Trust Board for approval. This process ensures that the Trust does not approve documents or services changes which have not been appropriately impact assessed and enables the Trust to meet its statutory duties as part of the Equality Act 2010.

The group meets monthly to conduct assessments with the policy or service lead. It you are planning to write a policy, change a procedure and develop a service you need to ensure that it undergoes and assessment and that you attend one of the meetings.

An Integrated Impact Assessment form must be completed as part of the assessment process. Prior to attending the EQIA Group meeting the policy author/lead will be required to complete and forward the first page of the Integrated Impact Assessment form to the Equality, Diversity and OD Manager.

To arrange for your policy or written control document to be assessed at a future EQIA Group, or to attend one of the meetings, please contact the Trust's Equality, Diversity and OD Manager.

Integrated Impact Assessment		
Ref no:		
Name of the policy, service, scheme or project:		
Service Area		
Preparation		
The purpose and aims of the policy, procedure, strategy or decision required Please include: • the overall objective or purpose • the stated aims (including who the intended beneficiaries are • a broad description of how this will be achieved • the measure of success will be • the time frame for achieving this • a brief description of how the purpose aims of the policy are relevant to equality and intended beneficiaries.		
Who is the Executive Sponsor?	**Please Select**	
We have a legal duty to engage with people with protected characteristics under the Equality Act 2010 identified as being relevant to the policy. • What steps will you take to engage and consult with stakeholders, (internally and externally)?		

• How will people with protected characteristics be involved in developing the policy, procedure, strategy and or decision from the start? • Outline how proposals have/will be communicated? • What are the arrangements for engagement as the policy/procedure/strategy or decision is being implemented?	
Does the policy assist services or staff in meeting their most basic needs such as; • Improved Health • Fair recruitment etc.	
Who and how many (if known) may be affected by the policy?	
In review of the Well-being of Future Generations Act Which Well-being Goals does this contribute to and how? Please select from drop down box, if multiple, please list. If none, how will it be adapted to contribute to one?	**Please Select**
Evidenced used/considered Your decisions must be based on robust evidence. What evidence base have you used in support? Evidence includes views and issues raised during engagement; service user or citizen journeys, case studies, or experiences; and qualitative and experience-based research, not just quantitative data and statistics.	

Please list the source of this evidence; • Identify and include numbers of staff, broken down by protected characteristics and other relevant information • What research or other data is available locally or nationally that could inform the assessment of impact on different equality groups? Is there any information available (locally/nationally) about how similar policies/procedures/strategies or decisions have impacted on different equality groups (including any positive impact)? Do you consider the evidence to be strong, satisfactory or and are there any gaps in the evidence?	
Who is involved in undertaking the Integrated Impact Assessment?	

Equality Duties, Sustainable Development Principles

Does the policy/procedure, strategy, e-learning, guidance etc meet • Public Sector & specific duties - Equality Act 2010 • Welsh Language Standards (2011) • Sustainable Development Principles?	Protected Characteristics									Additional		Ways of Working				
	Race	Sex/Gender	Disability	Sexual orientation	Religion and Belief	Age	Gender reassignment	Pregnancy and Maternity	Marriage/ civil Partnerships	Welsh Language	Carers	Long Term	Collaboration	Involvement	Prevention	Integration
To eliminate discrimination and harassment	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Promote equality of opportunity	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓					
Promote good relations and positive attitudes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓					
Encourage participation in public life	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓					
In relation to disability only, should the policy/service/project or scheme take account of difference, even if involves treating some individuals more favourably?			✓													

Key	
✓	Yes
x	No
-	Neutral

Human Rights Based Approach – Issues of Dignity & Respect

The Human Rights Act contains 15 rights, all of which NHS organisations have a duty. The 7 rights that are relevant to healthcare are listed below.			
Consider is the policy/service/project or scheme relevant to:	**Yes**	**No**	**N/A**
Article 2: The Right to Life	✓		
Article 3: the right not to be tortured or treated in an inhumane or degrading way	✓		
Article 5: The right to liberty	✓		
Article 6: the right to a fair trial	✓		
Article 8: the right to respect for private and family life	✓		
Article 9: Freedom of thought, conscience and religion	✓		
Article 14: prohibition of discrimination	✓		

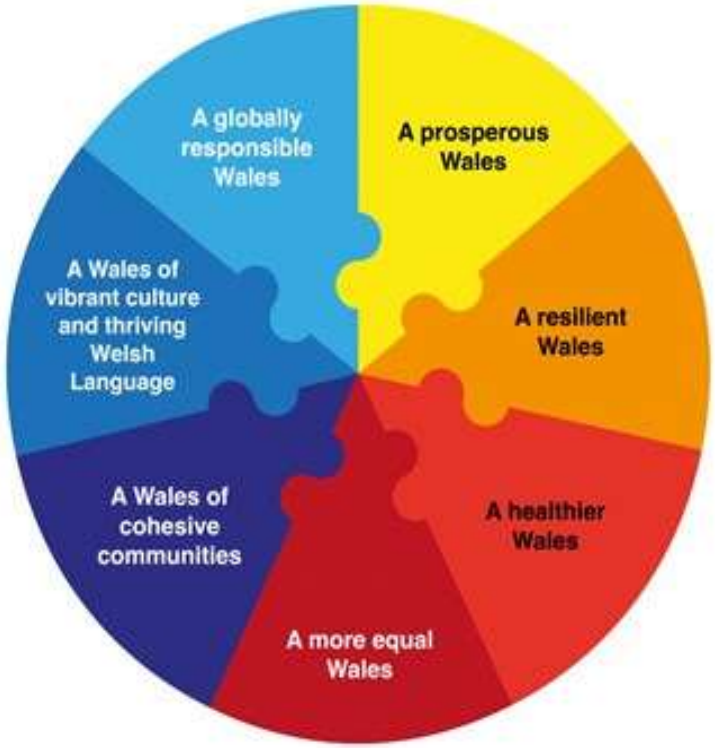
Measuring the Impact

Reason for your decision (including evidence used). Include details of how it might impact on people from this group and how opportunities to advance equality and good relations have been maximised.	
Protected Characteristics & Other Areas	**Impact – operational & financial**
• **Race** • **Sex** • **Disability** • **Sexual orientation** • **Religion belief & non belief** • **Age** • **Gender Identity** • **Pregnancy & maternity** • **Marriage & civil partnership** • **Carers**	
Welsh Language Standards	**Impact – Operational & Financial**
Does the policy, service, or project have positive or negative effects on: a) Opportunities for persons to use the Welsh language? b) Does it treat the Welsh language less favourably than the English language? The Welsh language Standards are: 1. Operational Standards – how we operate 2. Service Delivery – how we deliver our services 3. Record Keeping – how we keep a record of our services e.g. language needs of patients or donors 4. Policy making – how we develop our policies 5.Supplementary Standards – how we report on our services	

Wellbeing Goals

How does the policy/procedure, strategy, e-learning, guidance etc. embed, prioritise the Well-being Goals and Sustainability Development Principle of the Well-being of Future Generations (Wales) Act 2015?

Please describe and provide evidence below of how the 5 ways of working have been met, inclusive of the 7 well-being goals, to maximise the social, economic, environmental and cultural wellbeing of people and communities in Wales.



Sustainable Development Principles	
 Balancing short term with long term needs	
 Working together to deliver aims and objectives.	
 Involving those with an interest and seeking their views	

 Putting resources into preventing problems occurring or getting worse	
 Considering impact on all wellbeing goals together and on other bodies	
Social Economic Impact	**Impact – Operational & Financial**
How does the policy/procedure, strategy, e-learning, guidance etc. ensure transparent and effective measures to address the inequality of outcome that result from socio-economic disadvantage? Examples of inequality of outcome might include for example, education attainment, employment and earning potential, health and mental health access to services and goods, opportunity to participate in public life, housing.	

Positive Action	Impact – Operational & Financial
If the policy, procedure, strategy and or decision is intended to increase equality of opportunity through positive action, does it appear to be lawful? **Positive action** is defined as voluntary **actions** employers can take to address any imbalance of opportunity or disadvantage that an individual with a protected characteristic could face.	

Outcome report

Equality Impact Assessment: Recommendations Please list below any recommendations for action that you plan to take as a result of this impact assessment					
Action Required		Potential Outcomes	**Timescale**	**Lead Officer**	**Resource implications**
1					
2					
3					
4					
5					

Risk Assessment based on above recommendations – if policy is approved in original format refer to grading in Annex 1

Recommendation	Likelihood	Impact	Risk Grading
1	3	3	9
2	3	2	6

Reputation and compromise position	**Monitoring Arrangements**
The Trust recognizes the importance of inclusivity and accessibility for patients, their families as well as staff. So, they feel respected and valued and dignity is a priority. Potential discrimination can lead to negative attention as be costly in respect to reputational as well as in monetary terms.	Part of annual benefits review
Training and dissemination of policy	
Training needs to be identified throughout project.	

Is the policy etc. lawful?	**Yes** ☐	**No** ☐	**Review date**
Does the EQIA group support the policy be adopted?	**Yes** ☐	**No** ☐	
Signed on behalf of Trust Equal Impact Assessment Group		Signed Lead Officer	
Date:		Date:	

Annex 1

	Impact, Consequence score (severity levels) and examples				
	1	**2**	**3**	**4**	**5**
	Negligible	**Minor**	**Moderate**	**Major**	**Catastrophic**
Statutory duty	No or minimal impact or breach of guidance/statutory duty Potential for public concern Informal complaint Risk of claim remote	Breech of statutory legislation Formal complaint Local media coverage – short term reduction in public confidence Failure to meet internal standards Claims less than £10,000 Elements of public expectations not being met	Single breech in statutory duty Challenging external recommendations Local media interest Claims between £10,000 and £100,000 Formal complaint expected Impacts on small number of the population	Multiple breeches in statutory duty Legal action certain between £100,000 and £1million Multiple complaints expected National media interest	Multiple breeches in statutory duty Legal action certain amounting to over £1million National media interest Zero compliance with legislation Impacts on large percentage of the population Gross failure to meet national standards

LIKELIHOOD DESCRIPTION	
5 Almost Certain	Likely to occur, on many occasions
4 Likely	Will probably occur, but is not a persistent issue
3 Possible	May occur occasionally
2 Unlikely	Not expected it to happen, but may do
1 Rare	Can't believe that this will ever happen

APPENDIX 2

Compliance Status by Directorate

Directorate/ Department	Policy Reference	Version	Policy Title	Policy Lead	Accountable Executive Lead	Approving Body	Policy Review Date (3 year cycle)	Updated Policy Approval Status	Policy status	Policy Risk assessment
Quality & Safety	QS 08	Version 2	Policy for the management of Safeguarding Allegations/ Concerns about Practitioners and those in a position of trust	Senior Nurse SafeGuarding & Public Protection	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsing QSP - Approval Trust Board - Policy Update	Mar-23		Policy in date	Policy in date with no risk assessment required
Quality & Safety	QS 12	Version 2	Safeguarding & Public Protection Policy	Senior Nurse SafeGuarding & Public Protection	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsing QSP - Approval Trust Board - Policy Update	Mar-23		Policy in date	Policy in date with no risk assessment required
Quality & Safety	QS 04a&b	Version 8	Compensation Claims Policy & Compensation Claims Procedure	Claims Manager	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsing QSP - Approval Trust Board - Policy Update	Sep-22		Policy in date	Policy in date with no risk assessment required
Quality & Safety	All Wales	Not indicated	All Wales Model Policy Consent to Examination or Treatment	VCC General Manager	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsing for adoption QSP - Approval for adoption Trust Board - Noting	Jun-22		Policy in date	Policy in date with no risk assessment required
Quality & Safety	QS 02	Version 2	Safety Alert Procedure	Quality & Safety Facilitator	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsing QSP - Approval Trust Board - Policy Update	Jun-22		Policy in date	Policy in date with no risk assessment required
Quality & Safety	QS 03	Version 2	Handling Concerns Policy	Quality & Safety Manager	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsing QSP - Approval Trust Board - Policy Update	Jan-22	7 March 22 to EMB	Policy review date passed – action underway/required	Policy review date passed with low risk
Quality & Safety	QS 07	Version 1	Medical Gas Cylinders Policy	Chief Pharmacist	Executive Medical Director Consultant Clinical Oncologist	EMB - Endorsing QSP - Approval Trust Board - Policy Update	Dec-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Quality & Safety	QS 19	Version 4	Ionising Radiation Safety Policy	Head of Radiation Protection Services	Executive Medical Director Consultant Clinical Oncologist	EMB - Endorsing QSP - Approval Trust Board - Policy Update	Nov-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Quality & Safety	QS 31	Version 1	International Health Partnership related Activity Policy	Interim Deputy Director of Nursing, Quality and Patient Experience	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsing QSP - Approval Trust Board - Policy Update	Dec-19	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Quality & Safety	QS 25	Version 3	Preceptorship Policy for Newly Registered Nurses and Allied Health Care Professionals	VCC General Manager	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsing QSP - Approval Trust Board - Policy Update	Mar-18	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with moderate risk
Quality & Safety	QS 01	Version 3	Incident Reporting and Incident Investigation Policy & Appendices	Quality & Safety Manager	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsing QSP - Approval Trust Board - Policy Update	Sep-16	7 March 22 to EMB	Policy review date passed – action underway/required	Policy review date passed with moderate risk

Directorate/ Department	Policy Reference	Version	Policy Title	Policy Lead	Accountable Executive Lead	Approving Body	Policy Review Date (3 year cycle)	Updated Policy Approval Status	Policy status	Policy Risk assessment
Infection, Prevention and Control	IPC 05	Missing	National Infection Prevention & Control Manual (NIPCM)	All Wales	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Missing		All Wales Policy review date passed – awaiting national review	Policy review date passed with low risk
Infection, Prevention and Control	IPC 02	Version 2	Standard Infection Control and Transmission Based Precautions	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Feb-15		Archived Policy & superceded by National IPC manual	N/A
Infection, Prevention and Control	IPC 14	Version 3	Outbreak Management Policy	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Sep-13		Archived Policy & superceded by National IPC manual	N/A
Infection, Prevention and Control	IPC 00	Version 5	Framework Policy for Infection Prevention and Control	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsing QSP - Approval Trust Board - Policy Update Noting	Jul-22		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 03	Version 1	ANNT IPC Policy	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Jun-22		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 06	Version 4	Policy for the Management of Occupational Exposure to Blood and High Risk Body Fluids	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Sep-22		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 09	Version 4	Sharps Safety Policy & Addendum	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Jun-22		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 10	Version 5	Hand Hygiene Policy	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Jun-22		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 11	Version 4	Specimen Collection, Handling and Transport Policy	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Dec-22		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 12	Version 1	Guidelines on Single Use Medical Devices	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Jun-22		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 13	Version 5	Policy for the Prevention and Control of Transmissible Spongiform	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Sep-22		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 15	Version 2	Control and Management of Multi Drug Resistant Bacteria	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Jun-24		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 18	Version 4	Tuberculosis Management	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Dec-24		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 19	Version 4	Infection Prevention and Control within Building Development, Change and Adaptation Policy	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Sep-22		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 21	Version 3	Infection Prevention and Control Policy for the Management of Respiratory Infections and Addendum	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Jun-22		Policy in date	Policy in date with no risk assessment required
Infection, Prevention and Control	IPC 01	Version 4	Viral Gastro Enteritis (including Norovirus) Policy & Addendum	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Dec-20	7 March 22 to EMB	Policy review date passed – action underway/required	Policy review date passed with low risk
Infection, Prevention and Control	IPC 07	Version 3	Meticillin Resistant Staphylococcus Aureus (MRSA)	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Jun-17	Q1 22/23 to EMB	Policy review date passed – action underway/required	Policy review date passed with low risk
Infection, Prevention and Control	IPC 04	Version 3	Decontamination Policy	Head of Infection Prevention and Control	Executive Director of Nursing, AHPs and Health Sciences	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Jun-21	7 March 22 to EMB	Policy review date passed – action underway/required	Policy review date passed with moderate risk
Infection, Prevention and Control	IPC 16	Version 3	Policy for the Management of Prevention and Control of Legionellosis	Head of Estates	Director of Strategic Transformation, Planning & Digital	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	Jun-18	Ongoing Engagement	Policy review date passed – action underway/required	Policy review date passed with moderate risk
Infection, Prevention and Control	IPC 22 (previous IP	Version 1	Management and Control of the Environment (Cleaning)	Business Support Manager	Chief Operating Officer	EMB - Endorsement QSP - Approval Trust Board - Policy Update Noting	May-10	Ongoing Engagement	Policy review date passed – action underway/required	Policy review date passed with moderate risk

Directorate/ Department	Policy Reference	Version	Policy Title	Policy Lead	Accountable Executive Lead	Approving Body	Policy Review Date (3 year cycle)	Updated Policy Approval Status	Policy status	Policy Risk assessment
Corporate Communications	IG 08	Version 4	FOI Standard Operating Procedure	Assistant Director Communications	Director Corporate Governance and Chief of Staff	EMB - Endorsement QSP - Noting	Apr-22		Policy in date	Policy in date with no risk assessment required
Digital	All Wales	Version 3	Internet Use Policy	All Wales Policy	Director of Strategic Transformation, Planning & Digital	EMB - Endorsing for Trust Adoption QSP - Approval for Adoption Trust Board - Policy update report	Jan-23		Policy in date	Policy in date with no risk assessment required
IG	All Wales	Version 2	Information Governance Policy	All Wales Policy	Executive Director of Finance	EMB - Endorsing for Trust Adoption QSP - Approval for Adoption Trust Board - Policy update report	Jan-23		Policy in date	Policy in date with no risk assessment required
IG	All Wales	Version 2	Information Security Policy	All Wales Policy	Executive Director of Finance	EMB - Endorsing for Trust Adoption QSP - Approval for Adoption Trust Board - Policy update report	Jan-23		Policy in date	Policy in date with no risk assessment required
Corporate Communications	All Wales	Version 1	Social Media Policy	All Wales Policy	Director Corporate Governance and Chief of Staff	EMB - Endorsing for Trust Adoption QSP - Approval for Adoption Trust Board - Policy update report	Jan-18		Policy review date passed – action underway/required	Policy review date passed with moderate risk
Digital	All Wales	Version 2	Email Use Policy	All Wales Policy	Director of Strategic Transformation, Planning & Digital	EMB - Endorsing for Trust Adoption QSP - Approval for Adoption Trust Board - Policy update report	Jun-18		Policy review date passed – action underway/required	Policy review date passed with low risk
Digital	IG 05	Version 3	Software Policy	Head of Digital Delivery	Director of Strategic Transformation, Planning & Digital	EMB - Endorsement QSP - Approval	Feb-19	April/May Consultation June/July Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Corporate Communications	IG 08	Version 1	FOI Act Policy	Assistant Director Communications	Director Corporate Governance and Chief of Staff	EMB - Endorsement QSP - Noting	Feb-21	April/May Consultation June/July Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
IG	IG 01	Version 1	Records Management Policy	Head of Information Governance	Executive Director of Finance	EMB - Endorsement QSP - Approval	Feb-21	April/May Consultation June/July Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
IG	IG 02	Version 1	Data Protection & Confidentiality Policy	Head of Information Governance	Executive Director of Finance	EMB - Endorsement QSP - Approval	Feb-21	April/May Consultation June/July Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
IG	IG 13	Version 1	Confidentiality Breach Reporting Policy	Head of Information Governance	Executive Director of Finance	EMB - Endorsement QSP - Approval	May-21	April/May Consultation June/July Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
IG	IG 14	Version 1	Information Asset Policy	Head of Information Governance	Executive Director of Finance	EMB - Endorsement QSP - Approval	May-21	April/May Consultation June/July Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Digital	IG 11	Version 1	Data Quality Policy	Head of Digital Delivery	Director of Strategic Transformation, Planning & Digital	EMB - Endorsement QSP - Approval	Dec-21	April/May Consultation June/July Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Digital	IG 06	Version 3	Anti Virus Policy	Head of Digital Delivery	Director of Strategic Transformation, Planning & Digital	EMB - Endorsement QSP - Approval	Feb-22	April/May Consultation June/July Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk

Directorate/ Department	Policy Reference	Version	Policy Title	Policy Lead	Accountable Executive Lead	Approving Body	Policy Review Date (3 year cycle)	Updated Policy Approval Status	Policy status	Policy Risk assessment
Estates, Planning & Performance	PP 10	Version 1	Medical Gas Piped Systems Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Aug-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 11	Version 1	Operational Policy for High Voltage Electricity Supply Systems using a contractor as the Authorised Person	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Aug-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 12	Version 1	Operational Policy for High Voltage Electricity Supply Systems	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Aug-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 14	Version 1	Ventilation Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Aug-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 01	Version 4	Fire Safety Policy	Fire Safety Manager	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Sep-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 13	Version 1	Electrical Low Voltage Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Sep-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 09	Version 1	Water Safety Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Sep-20	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 04	Version 1	Asbestos Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Dec-20	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with moderate risk
Estates, Planning & Performance	PP 01a	Version 1	Safety and Protocol Prevention of Fire and Arson	Fire Safety Manager	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Feb-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 03	Version 1	Environmental Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Mar-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 08	Version 1	Waste Management Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Mar-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 06	Version 2	Business Continuity Policy	Interim Director WBS	Chief Operating Officer	Quality, Safety & Performance Committee	Apr-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 07	Version 2	Protocol for dealing with suspect packages and bomb threats	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Jul-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 02	Version 1	Security Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Nov-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 05	Version 1	Control of Contractors	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Nov-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk

Directorate/ Department	Policy Reference	Version	Policy Title	Policy Lead	Accountable Executive Lead	Approving Body	Policy Review Date (3 year cycle)	Updated Policy Approval Status	Policy status	Policy Risk assessment
Estates, Planning & Performance	PP 10	Version 1	Medical Gas Piped Systems Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Aug-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 11	Version 1	Operational Policy for High Voltage Electricity Supply Systems using a contractor as the Authorised Person	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Aug-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 12	Version 1	Operational Policy for High Voltage Electricity Supply Systems	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Aug-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 14	Version 1	Ventilation Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Aug-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 01	Version 4	Fire Safety Policy	Fire Safety Manager	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Sep-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 13	Version 1	Electrical Low Voltage Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Sep-23		Policy in date	Policy in date with no risk assessment required
Estates, Planning & Performance	PP 09	Version 1	Water Safety Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Sep-20	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 04	Version 1	Asbestos Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Dec-20	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with moderate risk
Estates, Planning & Performance	PP 01a	Version 1	Safety and Protocol Prevention of Fire and Arson	Fire Safety Manager	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Feb-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 03	Version 1	Environmental Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Mar-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 08	Version 1	Waste Management Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Mar-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 06	Version 2	Business Continuity Policy	Interim Director WBS	Chief Operating Officer	Quality, Safety & Performance Committee	Apr-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 07	Version 2	Protocol for dealing with suspect packages and bomb threats	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Jul-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 02	Version 1	Security Policy	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Nov-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk
Estates, Planning & Performance	PP 05	Version 1	Control of Contractors	Assistant Director of Estates	Director of Strategic Transformation, Planning & Digital	Quality, Safety & Performance Committee	Nov-21	May/June Consultation July/August Approving Body	Policy review date passed – action underway/required	Policy review date passed with low risk