

Ref QS03

**Handling Concerns Policy
(Complaints, Claims, Patient Safety Incidents and
Duty of Candour)**

Executive Sponsor & Function:	Executive Director Nursing, Allied Health Professionals and Health Science
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1. Executive Summary

This policy has been developed to ensure that Velindre University NHS Trust (the Trust) discharges its statutory responsibilities for the robust, effective, and timely handling of concerns (complaints, claims, and patient safety incidents) through ensuring organisation wide learning and continuous improvement, in line with the requirements set out within:

- The Health and Social Care (Quality and Engagement) (Wales) (2020) (Duty of Quality and Duty of Candour).
- National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations ('the Regulations') (2011).
- The Putting Things Right Guidance (PTR) (2023).
- Public Service Ombudsman for Wales Act (2019).
- Duty of Candour Procedure (Wales) (2023).
- NHS Wales National Policy on Patient Safety Incident Reporting & Management (2023).

2. Policy Statement

The Trust fully acknowledges that, as a provider of specialist and complex healthcare services, there will be occasions where things will go wrong.

When such occasions occur the Trust will ensure a robust response that is in line with the key principles and statutory requirements of Health and Social Care Quality and Engagement (Wales) Act (2020), the Duty of Quality (2020), the Duty of Candour (2022) and National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations ('the Regulations') (2011), to ensure an open and transparent concerns handling, with and a strong focus upon learning and continuous improvement, required to ensure the provision of safe, timely, effective, efficient, equitable and person centred care.

2.1 Policy Key Principles

A culture of psychological safety, openness, and transparency.	Robust & proportionate Investigations.	Local procedures will be in place to support delivery in line with the requirements of National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations (2011). Putting Things Right Guidance.
Staff will be equipped with role appropriate concerns handling knowledge and information.	Individuals raising concerns will be engaged in the handling process.	Staff involved in a concern will be able and encouraged to access support.
Consistent concern management and reporting Systems in place across the Trust.	Continuous improvement through learning.	A bi-lingual service will be provided through an active Welsh Language offer.
Learning will be shared across the Trust.	Early resolution of concerns will be promoted, and unnecessary escalation avoided.	Concerns will be managed in a timely manner in line with Putting Things Right Regulations.

3. Scope of Policy

This policy applies to all people engaged in work for the Trust and host organisations, including those employed on a contract of employment and those working on a bank or agency contract

There is an acknowledgement that the Putting Things Right Regulations and Duty of Candour may not apply in their entirety to some hosted organisations, however, the principles and requirements of the Regulations should be adopted where appropriate as good practice.

The Policy relates to concerns regarding:

- Services, care, and 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 concerns relating to:

- Clinical services provided privately, even when provided within Trust premises.
- Staff contract of employment, e.g., concerns raised through the Respect and Resolution Policy or The Procedure for NHS Staff to Raise Concerns (whistleblowing).
- Public Services Ombudsman investigations.
- Alleged failure of the Trust to comply with a request for information under the Freedom of Information Act (2000).
- Trust disciplinary proceedings arising from the investigation of a concern.
- Civil Proceedings.
- Individual Patient Funding Request (IPFR).
- Police criminal investigations.

If a concern raised is excluded from the scope of Putting Things Right Regulations (PTR) the Trust will advise the complainant, in writing as soon as reasonably practicable of the reason(s) for the decision. If any excluded matter forms part of a wider concern, the issues within scope of the Putting Things Right Regulations can be managed under this policy.

4. Aims & Objectives

The Trust is committed to dealing with concerns in a timely, open, honest, transparent, accessible, and equitable manner, with a strong focus upon ensuring that organisational learning and continuous improvement takes place, in accordance with the NHS Wales Duty of Candour.

The aim of this Policy is to:

- Ensure the Trust has robust arrangements in place for the effective handling and monitoring of concerns.
- Provide assurance to the Board and external bodies of the commitment to implement the requirements of the regulations National, the Health and Social Care Quality and Engagement (Wales) Act 2020 and Duty of Candour Procedure (2023).
- Define concern handling roles, responsibilities, and processes.

5. Definitions

Adverse event/incident	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, patient, member of the public or damage to property.
Complainant	A person notifying the concern/complaint.
Complaint	Any expression of dissatisfaction.
Concern	Any complaint, claim or reported patient/ donor incident to be handled under the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.
Duty of Candour	A requirement to ensure healthcare providers are open and transparent with people who use services when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.
Duty of Quality	A legal responsibility for Welsh Ministers and NHS bodies secure improvements in the quality of services they provide, supporting the achievement of ever higher standards of person-centred care services in Wales. represents our ambition of achieving ever-higher standards of person-centred health services in Wales.
Early Resolution	Concerns that could potentially be resolved to the complainant's satisfaction either immediately or within 2 working of receipt.
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	A patient or donor 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.
Never Event	Serious Incidents that are wholly preventable because guidance or safety recommendations are available at a national level and should have been implemented by all healthcare providers.
Near Miss	An occurrence, which but for the luck or skilful management would in all probability have become an incident.
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 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

In line with the Regulations the roles and responsibilities for Concern Handling at VUNHST are:

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.
- Ensure a Duty of Candour is applied where appropriate.
- 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 the Duty of Candour 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 the Duty of Candour is triggered where relevant.
- 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, learnt from, and monitored to prevent recurrence. The nominated Independent Member is the individual with responsibility for the Quality, Safety & Performance Committee.

6.4 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 through.

- Receipting and grading PTR Concerns and providing acknowledgement letters within required timescales.
- Developing Concerns / Putting Things Right/ Duty of Candour related policies and procedures.
- Providing/sourcing concerns handling, investigation and Datix Cymru training to ensure staff across the organisation are equipped with the knowledge and skills to undertake their role in concerns handling and investigation.
- 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 reporting
- Leading on Vexatious Concerns Management
- Auditing compliance with Putting Things Right and Duty of Candour
- Oversight of learning and dissemination of learning
- Development of Concern reports for Executive Management Board, Quality, Safety & Performance Committee and Trust Integrated Quality and Safety Group
- Development and Publishing Trust Annual Concern Report
- Leading on liaison and meeting requirements of other external bodies such as: Coroner's Office; Shared Services – Legal and Risk, Police; and Citizen Voice Body for Health and Social Care, Wales
- Representing the Trust at National Concern related meetings.

6.5 Executive Management Board

The Executive Management Board is responsible for overseeing the Trust's Concerns Management process and outcomes, including policies, procedures, and reporting in line with legislative and national requirements; training provision and compliance; identification of and compliance with key performance indicators; meaningful analysis; investigative processes; audit and operational assurance mechanisms; ensuring that remedial action is taken; Duty of Candour mechanisms are in place; and appropriate lessons are identified and shared.

6.6 Quality Safety and Performance Committee

The Quality, Safety and Performance Committee provide assurance reports to the Trust Board in relation to how the Trust is meeting its responsibilities under the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations ('the Regulations') (2011) and Duty of Candour Procedure (Wales) (2023), whilst highlighting any exceptions, risks, or potential risks in respect of this. The Committee's oversight includes ensuring the provision of appropriate training, policies, procedures, and reports in line with legislative and national requirements; identification of and compliance with key performance indicators; meaningful analysis. investigative processes; audit and operational assurance mechanisms; ensuring remedial action is taken and appropriate learning identified, addressed, and shared

6.7 Corporate Head of Quality, Safety and Assurance

The Head of Quality, Safety and Assurance is responsible as the Senior Investigations Manager (SIM) for the Trust in line with the requirements of the PTR regulations, and is responsible for:

- Oversight of the handling and consideration of concerns in accordance with this policy.
- Auditing Trust and Divisional concern handling arrangements.
- Ensuring robust interface arrangements with the Divisions are in place to ensure effective divisional concern handling processes and outcomes.
- Development, integration and embedment of a comprehensive concern investigation and redress systems.
- Embedment of robust Duty of Candour processes and procedures.
- Providing assurance to the Executive Management Board (EMB) and Quality, Safety and Performance Committee on the Trust concern management performance.
- Ensuring mechanisms are in place for learning, and continuous improvement initiatives to be shared across the Trust.

6.8 Service Directors (including hosted Organisations)

(Corporate / Divisional Directors, Clinical Directors, Medical Directors, Chief Scientific Officers, and Heads of Nursing.)

Service Directors are responsible for achieving compliance with the Regulations, the Duty of Candour, and this policy through ensuring:

- The provision of robust local concern handling arrangements across all provided and commissioned services.
- Concerns are managed within required timescales and performance measures.
- Datix Cymru is the primary repository for all concerns and associated documentation
- All investigations are fully and accurately recorded and stored in Datix Cymru.
- A culture of openness, transparency, psychological safety, learning, improvement is promoted, encouraged, and embedded into practice.
- Employees receive role appropriate concerns handling training
- Employees understand their individual roles and responsibilities in concerns handling.
- Cross-divisional and Trust wide approach to concern handling, communication, co-ordination, liaison, and reporting.
- Adequate and appropriate support is available and offered to employees who are involved in, or are the subject of a concern
- Availability and release of employees trained in investigations analysis to support required investigations.
- All identified learning is addressed and shared to enable continuous improvement to prevent re-occurrence of issues arising and optimise quality and safety of service provision.

6.9 Departmental Managers

All managers across the Trust are responsible for ensuring:

- Employees and volunteers are aware of this policy and their roles and responsibilities within it.
- A culture of openness, transparency, psychological safety, empowerment, learning, improvement, and timely concerns handling is promoted, encouraged, and sustained in practice.
- Processes are in place to ensure effective management of concerns and discharge responsibilities in line with Putting Things Right Guidance and Duty of Candour Procedure.
- Ensuring all concerns and associated communications and documentation are recorded at time of report and stored within Datix Cymru system.

- Provision of robust and timely feedback of concern outcomes, lessons learnt and improvement opportunities with colleagues.
- Employees are provided with role specific training for both concerns handling and operation of Datix Cymru system.
- Display and provision of relevant patient/ donor concern reporting information and sign posting within clinical areas e.g. 'How to raise a concern' and Llais (Citizen Voice Body for Health and Social Care).
- All identified lessons learnt, and improvement actions are addressed, implemented, or escalated as appropriate.

6.10 Putting Things Right Panel

The Trust Putting Things Right panel are responsible for the consideration and progress of Regulation 26 concerns where a breach in the duty of care has been identified. Responsibilities identified include:

- Determination and or validation of whether a breach of duty has occurred.
- Determination of whether the breach of duty described has caused harm.
- Consideration of engaging an independent clinical expert if a decision on breach of duty cannot be reached.
- Consideration of engaging 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.
- Agreement of communication pathways to communicate the decision of the panel to both the person raising the concern and staff affected by the concern.
- Agreement of award of financial compensation in cases where a Redress remedy applies.
- Ensuring robust systems to capture and record decision making processes and outcomes.

6.11 Responsibility of all Staff

All staff must ensure:

- Adherence to this policy, divisional/ departmental concerns, and Duty of Candour procedures.
- All individuals notifying/reporting concerns are treated with honesty, transparency, respect, and courtesy.
- All concerns are treated confidentially.
- Understanding of their individual role and responsibilities for reporting, handling and escalating concerns, incidents, and near misses.
- Awareness of available supportive resources.
- Co-operation and engagement in investigation processes.
- All concerns are addressed or escalated at time of report.
- Role specific concern management and Datix Cymru training and education is undertaken.
- Report all near misses, safety incidents and concerns in line with divisional and departmental processes.

7. Duty of Candour

The Trust will adhere to the legal requirements and discharged its responsibilities in line with the Health and Social Care (Quality and Engagement) (Wales) Act (2020) and Duty of Candour Procedure (Wales) (2023).

7.1 When does the Duty of Candour apply?

For the Duty of Candour to be triggered the following two conditions must be met:

- **A service user experienced, or may have experienced, unintended, or unexpected harm (physical or psychological harm or in the case of an individual that is pregnant, loss or harm to the unborn child) that is “more than minimal.” Although there is no legal definition of minimal harm, in practice this relates to moderate harm or above:**

“Moderate Harm: A service user experiences a moderate increase in treatment and significant but not permanent harm, e.g., being given medication, that they have a known allergy to, and this leads to a significant reaction requiring 4 or > days in hospital before recovery.”

‘Severe Harm: A service user experiences a permanent disability or loss of function e.g., being given medication, that they have a known allergy to, and this leads to brain damage or other permanent organ damage.’

‘Death: A service user dies e.g., being given medication, they have a known allergy to, and this leads to their death.’

- **The provision of healthcare “was” or “may have been” a factor in the patient or donor suffering that outcome.**

To ensure appropriate consideration of the Duty of Candour requirements the Trust will consider each event upon an individual basis and determine whether a ‘notifiable adverse outcome’ has occurred, and the Duty triggered.

7.2 Requirements of Duty of Candour

- The trust is legally required to adhere to the conditions of the Duty of Candour and will therefore ensure that Duty of Candour Procedure (Wales) 2023 is followed.

7.3 Duty of Candour Procedure

- To ensure the Trust fulfils its legal obligations it will ensure the following robust process is in place:

7.3.1 Stage 1 – Rapid Review- Identification of a ‘Notifiable Adverse Outcome’

Incidents or Concerns graded at moderate harm or higher will receive a rapid review that is undertaken within 48 hours of report to determine whether a notifiable adverse outcome has occurred, and the Duty of Candour triggered. All rapid reviews will be recorded in the Datix Cymru system in line with Trust Incident Reporting policy and processes.

7.3.2 Stage 2 – ‘In Person Notification’

The Trust will ensure that the ‘In Person Notification is undertaken in line with the Duty of Candour procedure (2023), by a suitably trained and skilled individual, either in person, via telephone or audio visually, and completed at the time the Trust first become aware the Duty of Candour procedure has been triggered.

The in-person notification will consistently include:

- A meaningful apology
- An explanation of the actions and further enquiries that the Trust will undertake to investigate the circumstances of the notifiable adverse outcome
- Details of the nominated point of contact,
- An offer of support and details of any appropriate support information
- If the in-person notification is made later than 30 working days after the Trust first became aware of the notifiable adverse outcome an explanation for delay should be included.

7.3.3 Stage 3 - Written Communication

The Trust will ensure a formal letter is issued by the Service Director or nominated deputy to the service user/ person acting on their behalf within five working days of the “in-person” notification.

The formal letter will include:

- Reiteration of the verbal apology
- Date of notification
- An account of the incident to date and explanation of the actions that the organisation will take as part of the procedure and the investigation
- Point of Contact details
- Details of available support
- If “in-person” notification was later than 30 days after the date on which the incident occurred, an explanation of the reason for the delay is required.

7.3.4 Stage 4 - The Review/Investigation

The division in collaboration with the service user or person acting on their behalf will conduct an open, transparent, and proportionate investigation of the incident in accordance with the Regulations and Duty of Candour procedure (2023). Once complete the investigation outcome will be communicated to the service user or their representative in accordance with regulation 24 or regulation 26 and 31, where the Redress arrangements apply.

7.4 Record Keeping

The Trust will ensure that all correspondence, decisions made, actions and relevant documents are kept in accordance with the Duty Candour Procedure within Datix Cymru. Documentation should include but is not limited to:

- Outcomes of Rapid Review to establish whether the duty has been triggered.
- Notification of the Duty.
- Attempts to contact the service user/person acting on their behalf.
- Any decision by the service user/person acting on their behalf not to be contacted in relation to the Duty of Candour
- Investigation of the notifiable adverse outcome, which is undertaken by the Trust, including the response or interim report issued under regulations 24, 26 or 31 of the 2011 Regulations.

7.5 Consent

The Trust will ensure that relevant consent procedures are followed in line with the Putting Things Right guidance and Duty of Candour procedure. In cases where a representative is acting on behalf of a service user with capacity, consent for the representative to act will be obtained from the service user and will be kept under review throughout the process.

In situations where the service user/person acting on their behalf indicate that they do not wish to engage or communicate with the Trust, the individuals wishes should be respected, but investigation of the incident must continue so that lessons can be learned, and quality improvements made.

7.6 Serious Case Reviews

In the event of adverse outcomes effecting large numbers of patients/ donors are identified following retrospective serious case reviews, or following a decision made by the medical examiner service or a coroner's inquest, where the cause of death attributed was not known at the time of the incident, the Trust will ensure Duty of Candour Procedures are followed for all affected individuals.

7.7 Incidents that occurred before 1st April 2023

The Duty of Candour is not intended to operate in respect of adverse outcomes which occurred before the 1st of April 2023.

7.8 Reporting to External Bodies

The Trust will fulfil its external reporting responsibilities in line with the requirements of the Health and Social Care (Quality and Engagement) (Wales) (2020) ((Duty of Quality and Duty of Candour), National Serious Incident reporting procedure, regulators, Medical Examiner Service, His Majesty's Coroner and Welsh Government.

7.9 When more than one NHS organisation is involved in the Duty of Candour Procedure

In situations where the Trust is part of an episode of care with other NHS Organisation(s) in which the Duty of Candour is triggered, the Trust will fulfil its responsibilities in line with the Duty of Candour procedures (Wales) (2023).

8. Concerns Management

8.1 Early Resolution Concerns

The Trust will manage Early Resolution Concerns in line with The Putting Things Right Guidance, ensuring resolution achieved to the satisfaction of the complainant within 2 working days from receipt. In circumstances where resolution has not been achieved within this period, but the complainant does not wish to raise a formal concern, the Trust will aim to resolve the concern(s) within 5 working days from receipt. If following this time, the concern remains unresolved, the concern(s) will be managed in line with the regulations as a formal concern.

8.2 Concerns Notified by a Third Party

The Trust will ensure that concerns notified by a third party acting as a representative on behalf of another are handled in line with the Regulations ensuring a best interest assessment is completed and proportionate response considered.

8.3 Concerns Received from Assembly Members/Members of Parliament

The Trust will ensure that concerns received from the Welsh Government, an Assembly Member, Member of Parliament, or other elected members on behalf of their constituent, are dealt with as soon as possible and a response provided at the earliest opportunity. For the sharing of personal data, the Trust will adhere to the requirements of The Data Protection (Processing of Sensitive Personal Data) (Elected Representatives) Order (2002).

8.4 Concerns Relating to Children and Young People.

Where a concern is notified by a child or young person, the Trust will ensure it meets its support, assistance, and advocacy responsibilities in line with the Welsh Government's 'Model for Delivering Advocacy Services to Children and Young People in Wales.'

In the event of concerns being received on behalf of a child or young person the Trust will determine whether the child or young person wishes to raise a concern themselves, or if they are happy for the person who raised the concern to represent them. In cases where the child or young person is not willing to allow the concern to be investigated, the Trust will assess the individual situation and where appropriate seek specialist advice to support decision making. In any circumstance where safeguarding issues are identified the Trust will evoke the Wales Safeguarding procedures.

8.5 Concerns Raised by Prisoners

The Trust will handle and investigate concerns raised by prisoners in the same manner as all concerns, in accordance with the Regulations and with the offer and right of access to advocacy services provided by Llais, Social Care or mental health services as appropriate.

8.6 Concerns raised by individuals Lacking Capacity or Vulnerable Adults

The Trust will ensure that all concerns raised by individuals lacking capacity or vulnerable adults and handled in an equitable and accessible manner with reasonable adjustments and enhanced support and advocacy services provided as required.

In circumstances where concerns regarding mental capacity are raised the Trust will ensure all assessments align with the requirements of Mental Capacity Act (2005). During this process, if any safeguarding and public protection issues are identified the Trust will evoke the All-Wales Safeguarding Procedures.

8.7 Concerns raised through Advocacy Services

The Trust will work in collaboration with Advocacy services and ensure that concerns raised on behalf of patients/ donors are managed in line with the Regulations.

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

The Trust will ensure that concerns, litigation intents and compensation requests are managed by the Corporate Quality and Safety Team, in accordance with the governance and framework of the regulations, with exception of a concern in respect of which court proceedings have already been issued, including the pre-action stage of those proceedings which should not be further investigated.

8.9 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, and reasonable adjustments provided for service users who have a disability.

8.10 Concerns and British Sign Language (BSL)

The Trust recognises BSL as a recognised language and will ensure the concerns process is accessible to service users who communicate through BSL through the provision of services and reasonable adjustments as appropriate.

8.11 Concerns from Blind and Partially Sighted Individuals

The Trust will ensure that it has in place alternative methods for communication, including access to Braille and large print versions to support and enable concerns to be raised by individuals who are blind or partially sighted.

8.12 Concerns involving Contracted Services

The Trust will ensure that all contracted services are aware of and understand this policy, its application in practice, and their role and responsibilities in concerns management and adherence with the Regulations.

9. Welsh Language

When dealing with concerns the Trust will take account of its statutory duties in relation to the provision of services in Welsh and will ensure compliance with the duties set under the Welsh Language (Wales) measure (2011) and Welsh Language Standards. All concerns received in Welsh will be responded to in Welsh under the regulations and the Trust will ensure:

- All written communication is provided in Welsh.
- Welsh interpretation for telephone or face-to-face meetings.

- Provision of bilingual information resources.
- Adopt a proactive approach to language choice and need in Wales.
- Ensure Welsh Language Needs are met.

10. Reporting Concerns

In line with the Regulations, the Trust has a single point of contact for raising a concern:

Executive Director Nursing AHP's & Health Science Velindre Trust Head Quarters
2 Charnwood Court
Heol Billingsley
Parc Nantgarw
Cardiff
CF15 7QZ

Email: handlingconcernsvelindre@wales.nhs.uk

Telephone: 029 20196161

10.1 Management and Investigation of Concerns

The Trust will ensure that concerns are managed and investigated in the most relevant, proportionate, efficient, and effective way in line with the Regulations, Duty of Candour Procedure, this policy, and local procedures.

10.2 Acknowledging PTR Concerns

The Trust will ensure that all concerns managed under the Regulations and Duty of Candour Procedure with acknowledgement being issued in writing within 5 working days of receipt and will include:

- Point of Contact details
- An offer of a meeting or discussion to review and discuss their concern and the concerns process.
- The opportunity to meet with relevant staff involved in relation to the concern/s raised.
- Response timescales.
- Details of advocacy and support services.
- 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.

10.3 Formal Response Timescales limit

The Trust will provide a full and comprehensive response/interim report within 30 working days from the date the concern is received, if the Trust is unable to comply with this standard, the Trust will:

- (a) notify the service user, outline the reason for the delay, and advise when the response will be available; and
- (b) send the comprehensive response/interim report as soon as reasonably practicable and within 6 months, or 12 months for concerns being handled under Regulation 33 of the Regulations.

10.4 Concerns received from Medical Examiners

The Trust will ensure robust corporate procedures are in place to receive and respond to concerns received from the Medical Examiner's office.

10.5 Concerns Referred to Coroner's Inquest

The Trust will ensure that robust procedures are in place to investigate concerns referred to HM Coroners Service in line with the Regulations.

10.6 Consent to Investigate Concerns

The Trust will ensure that the consent policy is followed, and patient/ donor consent obtained for all concern investigations that require access to medical records, if the patient/donor does not provide consent the Trust will take a view on whether an investigation without access to the medical records would be possible and beneficial.

10.7 Consent Involving Other Organisations

Where the Trust is notified of a concern that involves the functions of more than one responsible body/organisation, it will firstly seek the consent of the complainant (within 2 working days of concern receipt), Within 2 days of consent receipt the Trust will contact all relevant organisations and the lead organisation will be identified in discussions with the complainant and involved organisations.

11. Time limits for notification of a Concern

The Trust aligns the time limits for notification of a concern with the Regulations and requires concerns to 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. Concerns received after these timescales will be considered by the Trust to determine the reason for the delay in reporting and the possibility of investigation being thorough and fair due to the time lapse.

12. Withdrawal of Concerns

The Trust acknowledges that a concern can be withdrawn at any time by the complainant, with such withdrawal requests can be provided in writing or verbally and will be acknowledged in writing by the trust. Despite withdrawal the Trust will ensure the concern continues to be investigated.

13. Nationally Reportable Incidents

The Trust will ensure a concern raised by a complainant that has already been reported and investigation commenced as a nationally reportable incident will be managed in accordance with the Regulations, with the investigation progressing in line with Nationally Reportable Incident policy, ensuring the person raising the concern is kept informed of investigations and outcomes.

Where a concern is received, and it becomes apparent that there has been a serious incident that the Trust was previously unaware of, the Trust will ensure the incident is reported within Datix Cymru system and the National Reportable incident process followed, whilst informing the complainant of the process, the potential that 30-working day response timeframe will not be achieved, and details of expected timing of response.

13.1 No Qualifying Liability – Regulation 24

The Trust will ensure that requirements of the Regulations and associated investigations and reporting requirements are met.

In events where further correspondence is received from the person raising the concern, expressing dissatisfaction, the Trust will ensure the concern is reopened, investigated, and acknowledged within 2 days. If a complainant is dissatisfied with their response and there are no new issues to investigate, the Trust will manage in accordance with the Regulations with the concern not being reopened and a meeting with the complainant offered, if the complainant remains dissatisfied following this the Trust will advise the complainant to refer their concerns to the Public Services Ombudsman of Wales.

13.2 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

- The Trust will ensure compliance with the Regulations, in cases where the Trust considers following investigation that both breaches in the duty of care have been identified and potential for harm, or actual harm identified in line with the requirements of establishing a qualifying an interim report under Regulation 26 will be issued within 30 working days from whichever is the later from: The day upon notification of the concern was received or
- Where the Duty of Candour is triggered, the day upon which the “in person” notification under Regulation 4(1) of the Duty of Candour Regulations was given.

The Trust will ensure that in cases where a breach in the duty of care is identified that the case will be progressed and considered by the Trust’s Putting Things Right Panel to inform the interim Regulation 26 response, ensuring the inclusion of the following detail:

- A summary of the nature and substance of the issues contained in the concern.
- A description of the investigation undertaken to date
- 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.

If it is not possible to issue a Regulation 26 interim response within the required 30 working day timeframe, the Trust will ensure the person raising the concern will be informed of the reason for the delay and the interim response sent within 6 months of whichever is the later, either:

- The day upon notification of the concern was received or
- Where the Duty of Candour is triggered, the day upon which the “in person” notification under Regulation 4(1) of the Duty of Candour Regulations was given.

Once the interim response is issued, the Trust will ensure the matter is forwarded to the Trust Claims Manager for further investigation under the Redress arrangements as referenced within the Regulations.

13.3 Post Closure contact - Public Service Ombudsman of Wales

The Trust will ensure compliance with the Public Services Ombudsman (Wales) Act (2019) and inform any individuals that are dissatisfied with the Trust final response of their right to contact the Public Service Ombudsman for Wales, who will review the matter on their behalf.

The Ombudsman’s contact details are:

Phone: 0300 790 0203

E-mail: ask@ombudsman.wales

Website: www.ombudsman.wales

Address: Public Services Ombudsman for Wales

1 Ffordd yr Hen Gae

Pencoed

CF35 5LJ

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

On receiving a complaint from the PSOW, the Trust will provide an acknowledgement of receipt to the PSOW within 5 days and will investigate and respond to the PSOW within 20 days. If for any reason required timescales are difficult to achieve the Trust will request an extension from PSOW.

In response to conclusions received from the PSOW the Trust will ensure that identified opportunities for learning and improvement are actioned and shared.

13.5 Redress

The Trust will ensure compliance with the Redress requirements of the Regulations, including.

- 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.

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.

In circumstances when a person is seeking Redress, the Trust will ensure findings of the investigation are recorded in an investigation report in accordance with Regulation 31, with the report that contains:

- copies of any independent expert advice used to determine whether there is a liability.
- a statement by the Trust confirming whether there is a liability and
- the rationale for the Trust decision.

The Trust will ensure the report is provided in line with the Regulations to the person who raised the concern.

Where an investigation report cannot be provided within the set 12-month timescale, the Trust will inform the person raising the concern of both the reason for the delay and expected date for response.

13.6 Regulation 33 Response

The Trust will ensure compliance with Regulation 33 ensuring that when financial compensation is due, a Regulation 33 response will be completed by the Trust Concern Manager, to provide 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. Following the issue of this response the person raising the concerns will have six months to accept the offer, If, after that time, no response is received, the concern will be closed within 9 months.

13.7 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.

14. Behaviour, Conduct and Unreasonable Demands during a Concerns Investigation

The Trust will ensure that people raising concerns are 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, in such circumstances the Trust has a zero-tolerance policy on unreasonable, unacceptable abusive or aggressive, or violent behaviour.

For the purpose of this policy, unreasonable, unacceptable, abusive, or aggressive, or violent behaviour is considered as:

- Behaviour that produces damaging or harmful effects, physically or emotionally on other people.
- Persistent unacceptable behaviour is demonstrated on several occasions within a given period of time.

Examples of unacceptable or aggressive or abusive behaviour recognised by the Trust include:

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

15. Monitoring Arrangements

The Trust will ensure a record is held of the following matters:

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

The Trust will ensure that this information, and comprehensive analysis of concerns activity and learning will be reported to the Executive Management Board and Trust Quality and Safety Performance Committee on a quarterly basis. The Trust Integrated Quality & Safety group will provide oversight for the quarterly reports and will ensure the triangulation and robust analysis of data.

The Trust will prepare and publish an annual PTR report annually by the 31st of October regarding the delivery of the Regulations and application of the Duty of Candour in line with the requirements of the Regulations, Duty of Candour, and PTR Guidance, and will be clearly displayed on the Trusts internet site.

16. 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, 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 complaint's 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.

17. Supporting Staff

17.1 Staff involved in Concerns

The Trust will ensure it discharges its responsibilities for staff involved in concerns and will provide a psychologically safe environment for staff involved in Concerns investigations through:

- 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.
- Providing ongoing support via Line Managers, Clinical Supervisors, Workforce department, Occupational health colleagues and Trade Union representatives.
- Ensuring the provision of mentorship and coaching as required.
- Signposting staff to their Employee Wellbeing Service/Occupational Health/Employee Assistance Programmes.
- Providing and maintaining up to date information on the support systems currently available for staff including counselling services offered by professional bodies.

17.2 Concerns Containing Allegations against Staff

Where concerns raised contain allegations against a staff member(s), the Trust will ensure relevant staff member/s receive a copy of the key issues identified at the beginning of the investigation and provide support as required throughout the process.

18. Concerns and Disciplinary Procedure

Any Disciplinary Proceedings undertaken in relation to a concern will be managed under the Trust Disciplinary policy. 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

The Trust and its Divisions will ensure adherence to this policy and will provide role specific concern and Duty of Candour training to enable staff to possess the required knowledge to fulfil both their concern management roles and responsibilities and compliance with the Regulations and Duty of Candour procedure.

20. Information Governance

The Duty of Confidentiality is an important aspect in relation to concerns handling. All Trust Staff are required to maintain the complainant's confidentiality and are required to protect personal data as outlined by legislation including the Common Law Duty of Confidentiality and the Data Protection Act 2018 which includes the retained EU GDPR 679/2016 (known as UK GDPR). UK GDPR sets out the key data protection principles, rights of individuals (known as Data Subjects), and obligations for processing personal information.

The Trust acts as a “Data Controller” in respect of personal data as defined in Article 4 UK GDPR. Staff responsible for processing personal data are to follow the 'seven data protection principles' which are contained in Article 5 UK GDPR, this means that whenever they process Personal Data, they must do so; lawfully, fairly and transparently; Only process it for specific, explicit and legitimate purposes; Ensure that in relation to the purposes of processing that the data is adequate, relevant and limited for that purpose; Ensure that the data processed is accurate, kept up to date and stored in a format which permits the data subject to be identified and kept for no longer than is absolutely necessary. Staff must also ensure that when the data is processed that appropriate technical and organisational measures are in place to protect the integrity and confidentiality of the Data. The final data protection principle is accountability; all Staff are accountable for the data that they process. The obligation to comply with the data protection principles sits alongside the eight Caldicott principles, Section 8 of the Human Rights Act 1998, Section 40 of the Freedom of Information Act 2000, and Section 13 of the Environmental Information Regulations 2004.

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 in the first instance to the appropriate manager or nominated deputy or service lead for the subject of the concern.

The Trust has adopted the NHS Wales Records Management Code of Practice Health and Social Care 2022, as well as supporting the development of the Wales Accord on the Sharing of Personal Information (WASPI) as a legally binding framework.

All staff are bound by their Contractual Duty of Confidentiality regardless of their role and are required to respect the personal data and privacy of others. All 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. They are not permitted to access their own data, any request for their own personal data must be made as a Subject Access Request. The Trust Head of Information Governance can provide further information and advice if required in relation to access rights and the lawful sharing of personal data.

The Information Commissioner's Office (ICO) has detailed guidance on data sharing on its website and has issued a data sharing code of practice, the Code of Practice can be accessed

<https://ico.org.uk/for-organisations/guide-to-data-protection/ico-codes-of-practice/data-sharing-a-code-of-practice/>

It must be noted that the threshold for reporting a data breach to the Information Commissioner is much higher than that contained within the Duty of Candour, this is because Article 33(1) UK GDPR states:

“In the case of a personal data breach, the controller shall without undue delay and, where feasible, not later than 72 hours after having become aware of it, notify the personal data breach to the Commissioner, unless the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. Where the notification under this paragraph is not made within 72 hours, it shall be accompanied by reasons for the delay”.

The Trust Head of Information Governance must be contacted where a data breach has occurred so that an assessment of risk to the rights and freedoms of the natural person (data subject) can be made, this is to ensure alignment between Duty of Candour and Data Protection legislation requirements.

Advice and guidance in relation to any aspect of Information Governance considerations can be obtained from the Trusts Head of Information Governance.

VelindreInformationGovernance@wales.nhs.uk

21. 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.

22. References

- The Health and Social Care (Quality and Engagement) (Wales) (2020) (Duty of Quality and Duty of Candour).
- National Health Service (Concerns, Complaints and Redress Arrangements) Regulations (“the Regulations”) (2011).
- The Putting Things Right Guidance (PTR) (2013).
- Putting Things Right Guidance update (2023)
- Public Service Ombudsman for Wales Act (2019).
- Duty of Candour Procedure (Wales) (2023).
- NHS Wales National Policy on Patient Safety Incident Reporting & Management (2023).
- Civil Procedural Rules