GIG CYMRU NHS WALES | Y Weithrediaeth Executive

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NHS Wales

National Policy on Patient Safety Incident Reporting & Management

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Contents

Supporting sections:

1. Changes from previous version

- Merged the content of the policy and the guidance document into a single document
- Removed references to “Phase 1” and “Phase 2” of policy implementation. Phase 2 related to the establishment of systems to thematically analyse incident data, this work has been superseded by the plans to undertake thematic analysis at a national level through the use of the Once for Wales Concerns Management system (Datix Cymru)
- Clarification of the scope of applicability of the policy, particularly with regard to independent service providers
- Improved clarity of roles & responsibilities of all organisations involved in policy delivery, alongside use of more inclusive terminology throughout the document
- Improved clarity on the requirements of the initial assessment process following identification of a patient safety incident
- Strengthened references to the use of Datix Cymru for the reporting and management of patient safety incidents, including the use of the in-built Yorkshire Contributory Factors Framework tool
- Clarified the principles for NHS organisations to consider in determining whether an incident should be nationally reported
- Incorporated the NHS Wales Never Events list
- Endorsement of the just culture guide as a supporting tool
- New/strengthened sections on:
    - Duty of Candour, including alignment of harm definitions
    - Joint safety incident investigations
    - Incidents occurring in relation to commissioned services
- Clarification of accountability for completion (closure) of an incident investigation
- Provision of introductory guidance relating to the use of Safety-II thinking into current incident management processes
- Updated guidance and definitions in relation to specific incident types based on feedback throughout 2021/22 including:
    - patient & service user falls to be retrospectively reported where the investigation has determined the fall was avoidable
    - alignment of reporting requirements associated with maternal & perinatal and infant deaths to National Confidential Enquiry (MMBRACE-UK) definitions
- Clarity on the relationship between Nationally Reportable Incident (NRI) reporting and Welsh Government (WG) Early Warning Notifications

2. Introduction

Patient safety incident reporting is changing across Wales. Historically, incident reporting has been used as a key safety indicator in healthcare to attempt to understand where things go wrong to learn and improve safety, experience and outcomes for future patients and service users. As a nation, our understanding of how to best use intelligence from incident data is continuing to evolve. New conceptual approaches to safety, such as Safety-II, will help us shift the narrative from focusing purely on "what went wrong?" and balance this line of inquiry alongside "what goes right, and how can we learn from that as well?" (see Supporting Section 5 for more information on Safety-II). These new approaches require us to think differently and consider how incident reporting is one component of a whole safe system of care. We must continue to ensure our national processes and approaches to this complex and sensitive area of healthcare are aligned to maximise learning opportunities for the benefit of patients, service users, their families, carers and loved ones, staff and our NHS organisations.

To achieve these ambitions, our national processes must support a just culture for organisations and staff to feel supported to identify, report and learn from patient safety incidents, without the fear of punitive response or action throughout all levels of NHS Wales.

The previous version of this policy (in effect from 14 June 2021) aimed to empower organisations to think differently about what should be reported, taking more ownership and accountability for incident reporting and management. Through this updated version of the Policy, the NHS Wales Executive will take these aims further and continue to work collaboratively with NHS Wales organisations and other key stakeholders in delivering a new system for collecting and analysing incident data which is for the NHS, by the NHS.

3. Purpose of this policy

A patient safety incident occurs when an unintended or unexpected incident could have or did lead to harm for one or more patients or service users receiving NHS-funded healthcare.

While many incidents will not result in significant harm to an individual, the exploration of incident reports can help provide a source of intelligence which can be used by healthcare providers for a variety of purposes, including:

- to **learn** from what has gone wrong and what could have been done differently, by using the incident as a prompt to undertake an investigation and take action in order to make changes to improve the safety of patients;
- to identify and address **emerging risks** by looking for trends, themes and patterns of incident reports; and
- as a mechanism for oversight and **assurance** particularly where significant harm has occurred in the delivery of healthcare, in line with *The National Health Services*

(Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011- also known as 'Putting Things Right' (referred to forthwith as 'the Regulations').

Incident reports can be a valuable signal to healthcare providers about where to focus resource and attention to improve patient safety. However, they are only one part of the puzzle and should be examined in the wider context of other sources of safety intelligence. This includes triangulation with other data sources (for example, patient experience and complaint data) as well as looking at what goes well the majority of the time, and what we can learn from that (e.g. Safety-II). Throughout 2023 and beyond, the NHS Wales Executive will be working to improve how this triangulation of multiple data sources is undertaken at a national level.

The purpose of this Policy is to set out clear expectations for patient safety incident reporting and management across NHS Wales. It supersedes and replaces the section on "Serious Incidents" within the 2013 'Putting Things Right' (PTR) guidance document.

4. Strategic policy context

The following national programmes and concepts provide context to this Policy:

- **Health and Social Care (Quality and Engagement) (Wales) Act 2020**, which underpin the statutory **Duties of Candour and Quality**:
    - The **Duty of Candour** is intrinsically linked to incident management. The Duty focusses on the need to be open with patients and service users and anyone acting on their behalf when things go wrong, building on the requirements already set out in the Regulations.
    - The **Duty of Quality** has two aims – to improve the quality of services, and to improve outcomes for people in Wales.
- **Quality & Safety Framework: learning and improving**: the overarching national Framework setting out the national ambitions for Wales in relation to quality and safety in the NHS. In particular, this Policy relates to Action 4 – **the development of a new National Incident Reporting Framework focussing on maximising and sharing learning from incidents**.
- **National Clinical Framework: A Learning Health and Care System**: the overarching national Framework setting out the national ambitions for Wales in relation to the development of clinical services across NHS Wales.
- **NHS Wales Executive**: in fulfilment of an objective set down in A Healthier Wales, a number of organisations have brought together under the banner of the NHS Wales Executive from 1 April 2023. National systems for incident reporting will be established, maintained and developed by the NHS Wales Executive.

- **National Quality Management System (NQMS)**: a visionary system for NHS Wales which will ultimately bring together data from a number of sources, including patient safety incidents, for triangulation and to inform a range of activities in relation to learning and assurance.
- **Once for Wales Concerns Management System**: the national IT system enabling consistent approaches to a range of processes across NHS Wales. In relation to incident reporting and management, this system is also known as **Datix Cymru.**
- **COVID-19 pandemic & the National Nosocomial COVID-19 Programme (NNCP):** NHS Wales is still recovering from the effects of the COVID-19 pandemic and this must continue to be taken into consideration in relation to patient safety incident reporting and management. Importantly, learning and changes to process which were brought about by the pandemic must be capitalised on, including in particular learning from the NNCP, which will be incorporated into this and future versions of the policy as applicable.

5. Scope of Policy

This Policy applies to **all** services directly provided or managed by a Health Board, Trust or Special Health Authority in NHS Wales.

NHS Wales organisations that contract, agree or arrange for care to be provided by a non-NHS Wales provider (independent provider) on their behalf, retain responsibility for national incident reporting. This is in keeping with position outlined in the *Health and Social Care (Quality and Engagement) (Wales) Act 2020* for Duty of Candour reporting. The requirement to report extends to Primary Care services providing care as part of NHS Wales.

6. References and related documents

- Health and Social Care (Quality and Engagement) (Wales) Act 2020
- The National Health Services (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 as amended by National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2023
- The Duty of Candour Procedure (Wales) Regulations 2023
- The Duty of Candour Statutory Guidance 2023
- Putting Things Right guidance document (v3, 2013)

7. Aims and objectives of this policy

- Provide a clear and consistent national approach to incident reporting, management and investigation across NHS Wales.
- Provide clear guidance on what types of incident should be nationally reported, and how this should occur.

8. Responsibilities in relation to this policy

Welsh Government:

- Setting legislation, statutory guidance and government policy.
- Ensuring that intelligence and learning derived from the outputs of this policy are taken into account in setting legislation, statutory guidance and government policy.
- Publishing official statistics based on reported incidents.

NHS Wales Executive:

- Oversee and deliver national policy and processes in relation to reporting, management and investigation of safety incidents.
- Identification of cross-system learning, ensuring that learning is disseminated.
- Ensuring consistency of application of this policy, including provision of assurance mechanisms in relation to incident reporting, management and investigation.
- Provide national analysis on nationally reported incident data.
- Provide advice, guidance and support to organisations in relation to implementation of this policy, including the reporting, management and investigation of safety incidents.

Health Boards, NHS Trusts and Special Health Authorities

- Accountable for the quality and safety of care and services provided to their respective populations, including care that they contract, agree or arrange for their populations.
- Implementing this policy including endorsement through their Quality & Safety governance framework.
- Ensuring there are appropriate governance and assurance mechanisms in place, facilitating a flow of information across all parts of the organisation.

- Ensuring local systems and processes for incident reporting are in place and embedded.
- Ensuring that there are systems and processes for incident reporting, management and learning for any health care they contract, agree or arrange on behalf of their populations.
- Undertaking analysis of locally reported incidents, including identifying trends and themes from incident data.
- Establishing mechanisms to extract and share learning from incidents, and taking action to reduce the risk of recurrence and improve patient and service user safety, experience and outcomes.
- Ensuring staff are familiar with the requirements of this Policy.

Primary Care (General Medical Services) contractors in NHS Wales

- Accountable for the quality and safety of care and services provided to their respective populations
- Required to locally report incidents that have occurred within their organisations using the Datix Cymru system. The Health Body whose system they report into is responsible for assessing whether incidents have met the NRI threshold and undertaking any subsequent reporting.
- Primary Care Contractors must notify the relevant Health Board of occurrences where the Duty of Candour is triggered in respect of the health care they provide under a contract or other arrangement.
- Establishing mechanisms to extract and share learning from incidents, and taking action to reduce the risk of recurrence and improve patient and service user safety, experience and outcomes.

Once for Wales Concerns Management System programme:

- Responsible for overseeing the development and delivery of relevant Datix Cymru modules to support the implementation of this Policy.

9. Key Definitions

General definitions:

Policy Term	Applicable Definition
Concern	As defined in the *NHS Wales (Concerns, Complaints and Redress Arrangements) (Wales) (Amendment) Regulations 2011,* a concern is any complaint, claim or reported patient safety incident
Patient Safety Incident	An unintended or unexpected incident that could have or did lead to harm for one or more patients or service users receiving NHS-funded healthcare Note: the term "patient safety incident" refers to an incident occurring in the course of the delivery of healthcare. It is recognised that this may not always be to a patient but can also affect other service users in receipt of NHS-funded healthcare. The language throughout this document has been updated where possible to reflect this but for the avoidance of doubt, the definition of a patient safety incident applies equally to a service user in receipt of NHS funded healthcare even if they are not classified as a patient.
Patient or Service user	A person to whom healthcare is or has been provided Healthcare includes services for the prevention, diagnosis or treatment of illness as well as the promotion and protection of public health. It also includes NHS staff accessing treatment and care through wellbeing/occupational health services
Action	Something done intentionally or unintentionally
Inaction	Something **not** done intentionally or unintentionally including as a result of indecision, unnecessary delay, failure to act
Nationally Reported Incident (NRI)	A patient safety incident which is nationally reportable in line with this policy
"Must report"	A sub-set of Nationally Reportable Incidents where national reporting is mandated through this Policy

Harm definitions

The following definitions align with the definitions set out in the Duty of Candour Statutory Guidance

No harm	Any patient safety incident that had the potential to cause harm but impact resulted in no harm having arisen
Low harm	Any patient safety incident that resulted in a minor increase in treatment and which caused minimal harm to one or more persons receiving NHS-funded care
Moderate harm	Any significant but not permanent harm, or harm that requires a 'moderate increase in treatment' relating to the incident. A 'moderate increase in treatment' is further defined as an unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient or transfer to another treatment area such as intensive care
Severe Harm	The permanent lessening of the bodily, sensory, motor, physiologic or intellectual functions, including the removal of the wrong limb or organ or brain damage, which is related directly to the incident and not related to a natural course of the service user's illness or underlying condition
Death	A death caused or contributed to by a patient safety incident, as opposed to a death which occurs as a direct result of the natural course of the patient or service user's illness or underlying condition

10.Governance & assurance requirements

Organisations must ensure they have robust systems and processes in place in relation to local and national incident reporting, including:

- systems and processes to enact this policy in all areas of the organisation;
- all incidents should be reviewed within an appropriate governance framework to determine required risk management activities as well as any national reporting requirement. Whilst advice and support can be sought from the NHS Wales Executive, it will be expected that organisations are responsible and accountable for their judgements and decisions in line with the policy;
- integration with other relevant clinical and corporate governance processes e.g. management of complaints and claims, mortality review processes etc.;
- internal oversight, scrutiny and quality assurance of all incident reporting and investigation processes, including Executive level sign off on national incident notification and investigation outcome forms;
- clear and demonstrable lines of reporting across all parts of the organisation, including through relevant Committees of the Board;

- mechanisms for ensuring joint investigations with other responsible bodies and external agencies where applicable and appropriate;
- mechanisms for recording the outcomes of decisions around national reporting and investigation, including decisions on appropriate investigation methodology. In particular, organisations must ensure they keep robust records around the decisions not to report/investigate incidents as this will be needed for quality assurance purposes;
- mechanisms for capturing and demonstrating shared learning;
- mechanisms for ensuring engagement with any affected patient or service user or anyone acting on their behalf, in line with the legal Duty of Candour.

11. Local incident reporting, management & investigation requirements

11.1. Context

Patient safety incidents can be single isolated events, or multiple recurring events which can signal more systemic failures in care or demonstrate system weaknesses. They can also include events which indirectly impact patient safety or an organisation's ability to deliver a service, such as a failure of an IT system. Consequently, there is no definitive list of what constitutes a patient safety incident and accordingly NHS organisations will need to apply judgment when considering what should be reported, both at a local and a national level.

11.2. Systems and processes

All organisations are required to ensure that they have systems and processes for local incident reporting, management and investigation in line with this Policy. This must include systems and processes to analyse incident data, extract learning and disseminate it throughout the organisation, with relevant actions taken to improve patient and service user safety, outcomes and experience.

Organisations should also have systems in place for monitoring and nationally reporting incidents that occur within services that are provided on their behalf by non-NHS Wales providers.

These processes must include the use of Datix Cymru where available to ensure a consistent national approach to data collection and analysis. These processes should be sufficient to capture and analyse data from across all parts of the patient or service user pathway, including (but not limited to):

- secondary and acute care settings
- primary and community care, including community pharmacy, optometry, dentistry services

- urgent and emergency services including emergency departments & ambulance services
- out of hours' services
- public health services
- relevant IT services
- prisons
- commissioned services, and
- incidents identified through the course of other clinical and corporate governance processes, for example Medical Examiner and Mortality Reviews.

The systems and processes must fully align with the organisation's governance and assurance mechanisms, ensuring clear reporting across the entire organisation for relevant information.

Organisations must ensure local processes are reviewed, amended and/or adapted to incorporate the requirements of this Policy.

11.3. Initial assessment to determine risk management activities and next steps

All patient safety incidents will require an initial assessment in order to assess the circumstances, identify the relevant make safe actions required, and determine the next steps to manage the incident. This initial assessment should take place as soon as practicable after the incident has occurred or otherwise been identified.

This initial assessment must include:

- review of known information about the incident and consideration of further information to be obtained to inform the next steps;
- assessment of risk and determination of make safe actions in relation to:
    - all patient(s) or service user(s) affected by the incident, and
    - the organisation, or other safety systems, to prevent recurrence in similar circumstances;
- determination of the depth and parameters of an appropriate investigation;
- consideration of engagement with the patient or service user and anyone acting on their behalf as appropriate. This assessment will need to balance the desire to engage transparently and compassionately with all affected by the incident whilst having due regard for legal matters of consent and capacity.

- consideration and, where required, escalation e.g.:
    - as a Nationally Reported Incident (NRI);
    - through to relevant national frameworks (e.g. multiagency safeguarding processes); and/or
    - through to relevant external bodies;
- any relevant communications handling required;
- next steps in terms of incident management.

The depth of the initial assessment will vary depending on the circumstances of the incident. The initial assessment must be undertaken by someone of sufficient seniority and experience in incident management proportionate to the circumstances of the incident, and in many cases will require a multi-disciplinary approach. In some cases, including where the incident requires reporting as an NRI, this may require Executive level oversight.

Depending on the circumstances of the incident, this may be the point at which the organisation considers whether the Duty of Candour has been triggered and if so, who should make the initial "in person" notification – see Section 4 of the Statutory Guidance.

11.4. Use of Datix Cymru

All patient safety incidents should be reported through Datix Cymru (part of the Once for Wales Concerns Management System) in line with the applicable User Guide operational at the date of reporting.

Employees of Health Boards, Trusts and Special Health Authorities should have access to report directly into their employer's Datix Cymru system.

Primary Care Contractors in NHS Wales are required to report incidents that have occurred within their organisations. More information can be obtained from the Primary Care Wales Incident Reporting - NHS Wales Shared Services Partnership website.

11.5. Welsh Government Early Warning Notifications (EWN)

Early Warning Notifications (EWN) (previously No Surprise Reporting) is a communication function established by Welsh Government. Its purpose is to provide rapid information to Welsh Government on a range of issues, which may or may not relate to patient safety incidents.

The EWN process is independent of the incident reporting systems described in this Policy, which are overseen and managed by the NHS Wales Executive.

For clarity, where a patient safety incident meets both the requirements of a EWN and a NRI, then both processes must be followed.

12. National incident reporting requirements

12.1. Context

A subset of patient safety incidents will require national reporting to the NHS Wales Executive. The reporting of patient safety incidents at a national level:

- provides oversight and assurance relating to incidents that cause the most harm to patients and service users during healthcare;
- provides oversight and assurance relating to incidents that cause high levels of service impact, disruption or risk;
- enables the identification of organisational and/or system risks; and
- informs learning and action, including e.g. development of patient safety alerts and notices, policies and improvement programmes, national priorities, outcome measures and potential service reforms.

Building on the foundation of the previous version of the Policy, there is a need to move away from prescriptive "trigger list" approaches to determining what incidents require national reporting. This is because of the complexity of healthcare and the incidents that can occur, it would never be possible to determine and list all the types of incidents which should be reported.

Accordingly, NHS organisations must have systems and processes in place to review all incidents on an individual basis and apply judgement to determine what should be reported nationally.

12.2. Nationally Reportable Incidents (NRIs)

As part of the initial assessment process described above, NHS organisations will need to consider whether an incident requires reporting nationally, taking the following principles into account:

Principle 1 - 'Must reports'

Incidents related to the following are always nationally reportable (please see Supporting Section 3 for more guidance on definitions):

- Never Events, as specified within this Policy, even where no harm has occurred. The current NHS Wales Never Event list can be found in Supporting Section 1 of this Policy;
- suspected mental health homicides;
- suspected suicide or self-inflicted death
    - in any clinical setting; or

    - during authorised/agreed leave, following recent planned discharge, or following unplanned leave/discharge; and

- maternal, perinatal and infant deaths.

Principle 2 - outcome/harm

A safety incident should be nationally reported if it is **assessed or suspected** an **action or inaction** in the course of a patient or service user's treatment or care, in any healthcare setting, **has**, or **could have caused or contributed** to their **severe harm** or **death**.

It will not always be possible to rapidly determine the extent to which a safety incident caused or contributed to the harm or death of a patient or service user within seven working days. In this case, organisations should nationally report the incident, specifying that the position is unclear and/or investigations are ongoing. Incidents can be downgraded at a later date.

Acts and inactions can relate equally to human interactions, technical failures and/or delays in systems and processes.

Principle 3 - number of patients or service users involved

Special consideration must be given to incidents where the numbers of patients or service users affected is significant, even where direct harm has not been, or is difficult to, identify. This includes but is not limited to incidents involving significant:

- screening services;
- IT failures;
- data breaches;
- national system failures; and/or
- service disruptions.

Principle 4 - learning opportunities

Incidents should be nationally reported where they present new learning opportunities, particularly where a similar risk may be present in other NHS organisations. This may include:

- near misses and/or no or low harm incidents where the learning would be beneficial to be shared nationally with other organisations to help raise awareness and mitigate risks for other patients or service users; and/or

- incidents may present which are unusual, unexpected or surprising, where seriousness of the incident requires it to be nationally reported and the learning would be beneficial for others.

Principle 5 - joint decision making around reporting and investigation

Some patient safety incidents will require joint investigation with another organisation. Early consideration must be given to involving relevant stakeholders in any discussions around incidents potentially requiring joint investigation, to ensure relevant information is obtained from all sources in order to inform the discussion. Guidance on the joint investigation process can be found in Supporting Section 4.

12.3. Reporting process

A patient safety incident will be nationally reported to the NHS Wales Executive within seven working days from the date of knowledge of the incident.

The reporting process is set out in Supporting Section 2.

13. Duty of Candour

The provisions of the statutory Duty of Candour, as set out in the Health and Social Care (Quality and Engagement) (Wales) Act 2020 came into effect on 1 April 2023. This is an organisational duty on all NHS bodies and primary care providers. More information on the Duty of Candour, including the statutory guidance, can be found on the Welsh Government website.

Incident reporting, management and investigation is intertwined with the principles of *Being open: communicating patient safety incidents with patients and their carers* and must adhere to the Duty of Candour, so in practice these activities should be fully integrated. In preparation for the Duty of Candour, NHS organisations have been reviewing their systems and processes in relation to concerns and incident reporting, investigation, and management to ensure that they are aligned as far as possible, in order to provide a seamless patient or service user experience.

The Duty of Candour is triggered when:

- an adverse patient safety event (usually an incident) occurs, and the service user sustains or could sustain harm which is
    - unintended or unexpected, and
    - more than minimal e.g., moderate, severe or death, and
- the provision of healthcare was or could have been a factor in that harm occurring.

At the point the incident is reviewed, and it is recognised that the above triggers for the Duty of Candour have been met, the organisation becomes 'aware'. It is at this point that the Duty of Candour procedure should be initiated.

The Duty of Candour is not intended to operate retrospectively and therefore will only apply where the conditions triggering the Duty of Candour as set out in Section 3 of the Health and Social Care (Quality and Engagement) (Wales) Act 2020 occur after the date on which Section 3 was brought into force (i.e. 1 April 2023). In practical terms, this means that the provision of health care and the harm which ensued, must have taken place after 1 April 2023.

For the avoidance of doubt, the Duty of Candour may be triggered following a retrospective case review but that the conditions which gave rise to the notifiable adverse outcome must have occurred after Section 3 was brought into force.

14. Patient safety incident investigations

14.1. Legislation

All concerns reported in NHS Wales, including patient safety incidents, must be subject to an appropriate and proportionate investigation in line with the *NHS Wales (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011*. In particular,

Regulation 23 outlines the requirements of the investigation to be undertaken and requires the organisation to undertake the investigation in the manner that appears, to that organisation, to be most appropriate to reach a conclusion in respect of those matters thoroughly, speedily and efficiently.

14.2. Methodologies

NHS organisations must have systems and processes for determining the appropriate and proportionate investigation to be undertaken in response to each reported safety incident, taking into account considerations such as scale, complexity and type of incident.

Organisations should therefore ensure they have access to a range of suitable investigation approaches/tools to support a proportionate approach across a range of outcomes. It will not be appropriate to conduct in-depth investigations for all incidents, and so it is important to determine as accurately as possible from the outset what will be proportionate in the circumstances.

Methodologies in use by an organisation should ensure the involvement throughout the investigation of appropriate staff and patient, service user or a person acting on their behalf.

For certain incident types, to support a consistent national approach there are a number of focussed review tools built into Datix Cymru, which should be used where they are available. This includes safety incidents relating to:

- Falls
- Pressure damage
- Extravasation

This section will be expanded during 2023 in line with the NHS Wales Executive's work.

14.3. Use of Yorkshire Contributory Factors Framework

The Yorkshire Contributory Factors Framework (YCFF) has been built into Datix Cymru to support a consistent approach to the analysis of incidents, including the identification of cross-cutting themes to enable targeting of improvement activities.

Accordingly, the use of the YCFF is required for NRIs and encouraged for other patient safety incidents.

14.4. Just culture guide

Staff who have been involved in a patient safety incident should be treated in a consistent, constructive and fair way.

NHS Wales endorses the use of the NHS England just culture guide as a tool to support the fair treatment of staff who have been involved in an incident. It supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely.

The just culture guide should **not** be used as a routine or integral part of a patient safety investigation – it should only be used when consideration needs to be given to whether an individual member of staff requires support or management to work safely.

The just culture guide, along with supporting reference materials, can be found on the NHS England website - https://www.england.nhs.uk/patient-safety/a-just-culture-guide/

14.5. Joint investigations

Some safety incidents will require joint investigations, including between:

- different departments within the same organisation;
- where patients have been moved between organisations, including patient handovers at emergency departments; and

- where services have been commissioned, including relating to social care.

NHS organisations should have systems and processes in place to manage these types of investigations.

For joint investigations involving multiple organisations, please refer to the joint investigation process in Supporting Section 4.

15. Investigation of incidents occurring to a patient or service user while in receipt of commissioned services

Whilst the reporting of patient safety incidents at a national level remains the responsibility of the NHS Wales organisations that provided, managed or commissioned the care at the time of the incident, guidance on the investigation of such incidents is provided within the *The National Health Services (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011* ("the Regulations"). The Regulations require all 'responsible bodies' to investigate incidents which occur to services users in receipt of NHS funded care.

A responsible body is defined under the Regulations as:

- a Welsh NHS body:
  - a Health Board;
  - an NHS Trust managing a hospital or other establishment or facility wholly or mainly in Wales;
  - a Special Health Authority
- a primary care provider; or
- an independent provider:
  - a person or body who provides healthcare in Wales under arrangements made with a Welsh NHS body; and is not an NHS body or a primary care provider.

When a patient safety incident occurs, Regulation 23 states that "the responsible body must investigate the matters raised in the notification of a concern in the manner which appears to that body to be most appropriate to reach a conclusion in respect of those matters thoroughly, speedily and efficiently, having particular regard to additional criteria set out in the Regulations". The Regulations also detail what actions responsible bodies must take in terms of *redress*[1], when harm is deemed to have been 'caused' to a patient or service user through a 'breach in duty of care' to that patient or service user.

When healthcare is funded by another Welsh NHS body (Health Board or Trust), the Regulations require a full investigation up to and including consideration of qualifying

[1] Redress is a range of actions which include an apology, learning lessons, and/or in certain circumstances, financial compensation.

liability (QL). Organisations are required to undertake a joint investigation with a lead organisation agreed.

There are however distinct differences in how the Regulations are applied when healthcare provision has not been provided by a 'Welsh NHS body' (Health Board or Trust) through NHS funding arrangements. The degree in variation is predicated on which other type of 'responsible body' provided the healthcare, and particularly when the healthcare has been provided outside of Wales.

The way in which the Regulations vary can be divided into two categories;

1. NHS Wales funded healthcare provided by another UK NHS provider, i.e.:
    - NHS England; or
    - NHS Scotland; or
    - NHS Northern Ireland; and
2. NHS Wales funded healthcare provided by an 'independent provider', either:
    - provided in Wales under arrangements made with a Welsh NHS body and is not an NHS body or a primary care provider; or
    - provided outside of Wales.

NHS Wales funded healthcare provided by another UK NHS provider

When the Regulatory duty is applied to other UK NHS organisations through cross-border and other commissioning arrangements, it is anticipated that local procedures for managing concerns and investigations will be of a sufficient standard to support investigations in keeping with the Regulations. The Regulations require other UK nations to consider a qualifying liability (QL) and refer the matter back to the NHS Wales commissioning organisation where they consider a QL **does**, or **may** exist. However, there is no requirement on other UK NHS organisations to inform an NHS Wales commissioning organisation where they **do not** consider a QL exists.

NHS Wales funded healthcare provided by an 'independent provider'

The Regulations state any responsible body, who provides healthcare **in Wales** under arrangements made with a Welsh NHS organisation, and who is not an NHS Wales Health Board or Trust, must have arrangements in place to manage and undertake investigations when a concern, including a patient safety incident, is raised.

The first element to highlight is that the Regulations do not apply to private provision of healthcare *outside* of Wales.

The second element relates to private provision *within* Wales. In this regard, this will include healthcare provision in care and residential home settings through continuing healthcare

(CHC) and funded nursing care (FNC) arrangements, including local authority managed, third sector/charitable/not for profit sector, and private business. This also extends to any other privately provided healthcare which is NHS funded.

Responsibility to Investigate

Whilst the Regulations require an investigation to be undertaken when a patient or service user is subject of a concern during funded provision of healthcare, there are two key differences when a concern is raised in this regard:

1. the investigation is to be **undertaken by the provider** and not the NHS commissioning organisation, in keeping with the requirement on them to have arrangements in place to do so; and
2. there is no requirement on the provider to consider a QL as part of the investigation process.

Joint investigations in relation to commissioned services

Although the Regulations require the provider to undertake investigations when a concern is raised (including a patient safety incident), it is envisaged that when a concern is raised both in respect of the commissioned healthcare provider, and the commissioning organisation, it will be for the NHS Wales organisation to lead a joint investigation. The Regulations still however limit the independent provider element of the investigation to a factual response and not as far as considering QL, but the NHS element of the investigation is required to consider QL.

Post discharge

Concerns which occur during healthcare provision by an NHS Wales body prior to, or during a transfer of care to an independent provider through NHS funding arrangements, will remain the responsibility of NHS commissioning organisation to manage and investigate, fully in keeping with the Regulations up to and including consideration or QL.

16.Investigation outcomes

16.1. Learning from incident investigations

A fundamental part of undertaking incident investigations is to learn from previous experience in order to identify areas for improvement to reduce the risk of similar incidents occurring in the future.

NHS organisations should ensure they have robust systems and processes in place to support the extraction and dissemination of learning from incident investigations throughout the organisation, and include key learning as part of sharing investigation outcomes with the NHS Wales Executive.

This section will be expanded during 2023 in line with the NHS Wales Executive's work.

16.2. Completing (closing) an incident investigation

The accountability for completing (closing) an incident investigation sits with the NHS organisation who undertook the investigation.

NHS organisations must ensure there are robust processes in place to ensure the timely completion of incident investigations in line with this policy, which incorporate processes for patient or service user involvement, quality assurance, and Executive sign off.

To allow Boards to be assured that incidents within their organisation have been dealt with appropriately, all NHS organisations must ensure robust processes are in place to inform and assure their Boards that:

- the quality of their investigation processes is of a high standard;
- investigations are being undertaken and completed in a timely manner;
- patients or service users or anyone acting on their behalf are being engaged and supported during the investigation process and the findings and outcomes of the investigation are shared with them; and
- appropriate actions are being taken and learning is being shared across the organisation.

16.3. Process for reporting outcomes of an investigation into an NRI

Detailed guidance on the process for reporting NRI investigation outcomes to the NHS Wales Executive is in Supporting Section 2.

16.4. NHS Wales Executive's role in relation to investigation outcomes

The NHS Wales Executive does not "close" incident investigations related to NRIs. As stated above, the completion of an incident investigation is the responsibility and accountability of the NHS organisation who undertook the investigation.

The NHS Wales Executive has an assurance function to ensure that the information shared in relation to the investigation outcomes is of good quality, using a suitable approach, and undertaken in a timely manner. This is to support a patient or service user focussed approach, as patients or service users affected by safety incidents and people acting on their behalf require good quality information to be provided to them in a timely manner. Where gaps in assurance are identified, the NHS Wales Executive will liaise with the relevant NHS organisation to seek further assurance.

In addition to the extraction and utilisation of learning from incidents, data and intelligence from NRIs will be used to inform local and national assurance activities.

17. Future thinking in relation to incident reporting and analysis

As described in the introduction section, new conceptual approaches to safety including resilience in healthcare and Safety-II, will be increasingly considered by the NHS Wales Executive to determine how these new ways of thinking can help support continual improvement and evolution of our safety management systems in healthcare.

Some preliminary guidance on how to incorporate elements of Safety-II thinking into current incident management practices is included in Supporting Section 5.

This section will be expanded during 2023 in line with the NHS Wales Executive's work.

18.Getting Help

Please contact PatientSafety.Wales@wales.nhs.uk if help and support in application of this policy is required.