Patient Safety Incidents Policy

Purpose

The purpose of this document is to set out expectations for patient safety incident reporting and learning in NHS Wales. In particular it describes new arrangements for the management of patient safety incidents at a national level. This builds on the extensive learning we have gained from the current process in order to maximise learning opportunities to improve patient safety, at both a local and national level.

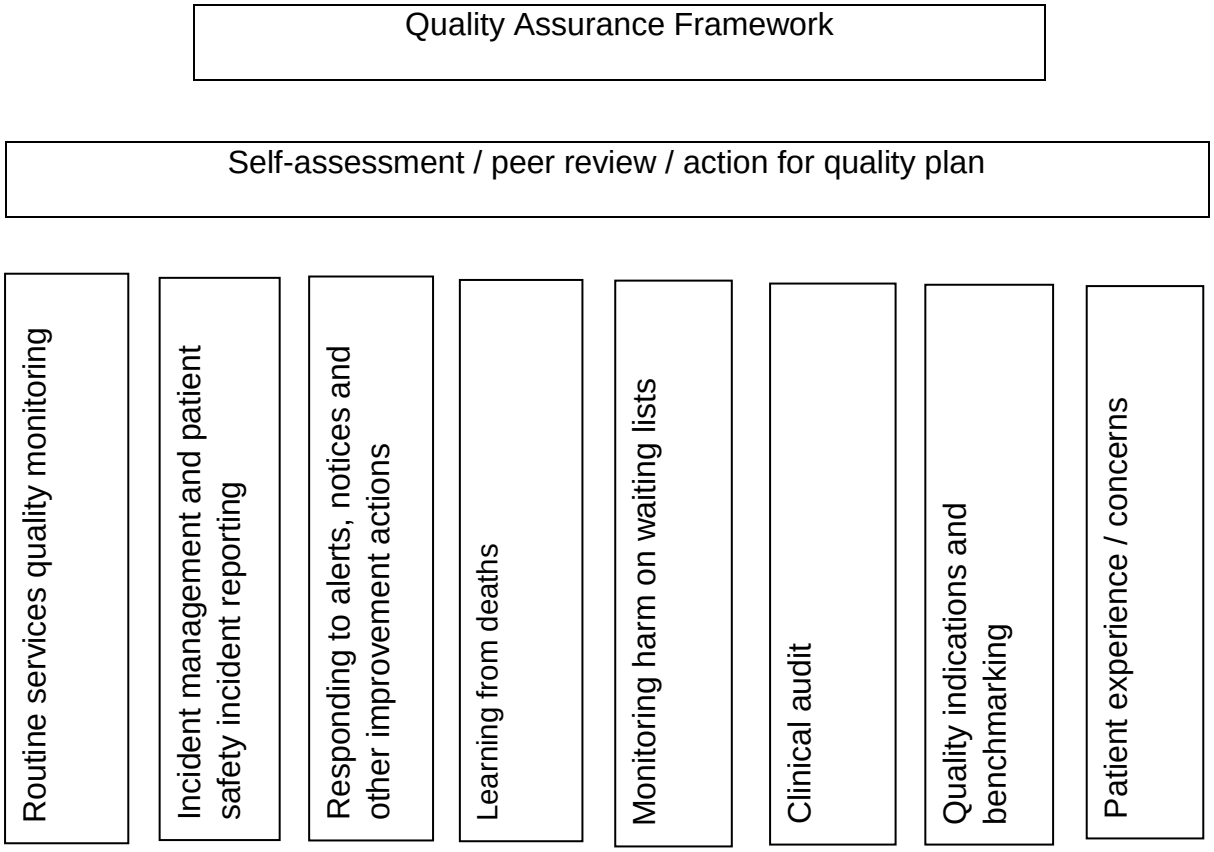
This policy should be used alongside the wider requirements when responding to concerns, including incidents, as set out in *Putting Things Right* (PTR). PTR applies to all local health boards, NHS trusts and independent providers providing NHS funded care[1] as well as primary care practitioners in Wales, in terms of patient safety reporting. The principle of being open is at the heart of PTR and that coupled with improved shared learning remain the drivers within this policy to improve the quality and safety of care provided.

Strategic context

Patient safety incident reporting is just one area where shared learning can help improve the quality of care provided. Patient safety alerts and notices will continue to be issued where specific actions have been identified, through the reporting of incidents, to strengthen safety systems. Learning must continue to be drawn from service inspection reports or reviews, including those undertaken by Healthcare Inspectorate Wales (HIW), Public Services Ombudsman Wales (PSOW) Reports and Regulation 28 reporting by Coroners.

All organisations will need to ensure this information is triangulated with a range of other qualitative and quantitative data sources submitted to their Boards, as part of their overall Quality Assurance Framework reporting processes.

[1] Putting Things Right (PTR) is the process for raising concerns or complaints in NHS Wales, https://gov.wales/nhs-wales-complaints-and-concerns-putting-things-right . Independent healthcare providers providing NHS funded healthcare and primary care providers must also follow the PTR process, apart from redress where this element of the Regulations does not apply to the.



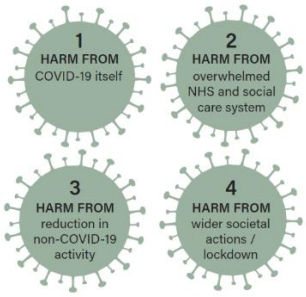
It is also important to take into account implementation of the forthcoming Duties within the Health and Social Care (Quality and Engagement) (Wales) Act 2020. The Duty of Quality requires organisations to set out all decisions that are taken to secure improvement in the quality of services provided within the NHS in Wales, in the journey towards ever higher standards of person-centred health services.

The Duty of Candour focusses on the need to be open with patients, families and carers when things go wrong, building on the requirements already set out in PTR. Evidence suggests that increased openness, transparency and candour are associated with the delivery of higher quality health and social care. When the duty of candour is implemented (projected to be in April 2023), the outcome of candour investigations will also be an important source of learning and improvement.

The Once for Wales Concerns Management System (OfWCMS) being rolled out across Wales from April 2021, will support the quality assurance agenda with timely access to patient incident and concerns related information which will help inform service planning and provision at a local and national level.

Covid-19 has and continues to have a huge impact on services as well as outcomes for patients. Organisations will need to ensure they have robust processes in place

to be able to track the impact of Covid-19 and the implications and outcomes for patients, relating to the four harms detailed below.



A separate NHS Wales national framework for managing incidents following nosocomial transmission of Covid-19 has been published and will ensure a consistent approach across Wales.

Patient safety incidents

A patient safety incident occurs when an unintended or unexpected incident could have or did lead to harm for one or more patients receiving healthcare. From the well-established incident reporting systems in the NHS we know the vast majority of incidents do not result in harm or significant harm, but do provide extensive opportunities for learning and improvements in safety to prevent future harm occurring. There will be occasions, however, when serious incidents do occur, resulting in serious harm, which can be life impacting or sadly result in an avoidable death.

In such cases the consequences for patients, families and carers, as well as the staff providing that care can be devastating. When incidents such as these occur a comprehensive response is required to ensure immediate make safe actions are taken. This must be prior to any wider learning identified from an investigation into the event and to ensure those affected are fully supported and involved in any investigation process as required. Sometimes a serious ‘near miss’ can provide important learning and therefore also needs careful consideration to prevent future harm.

Patient safety incidents can be single isolated events or multiple recurring events, which can signal more systemic failures in care, including omissions in care provision 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 in an IT system. Consequently there should be no definitive list of what constitutes a patient safety incident – but there will be a small number of events that will always be deemed reportable at a national level.

Local and national reporting

Local reporting requirements

All NHS organisations are accountable for the quality and safety of care provided to their respective populations. They must report all incidents of patient harm and near misses locally through their local risk management systems. This includes incidents across the whole patient pathway including primary and community care, emergency departments, out of hours' services, prisons and commissioned services including those in social care settings and those identified through medical examiner reviews. They should be investigated appropriately and proportionately with actions taken accordingly, in line with PTR requirements

National reporting requirements

The reporting of patient safety incidents at a national level will:-

- provide oversight and assurance relating to the most 'serious' incidents occurring in healthcare
- enable the identification of organisational and/or system risks
- inform learning and action, including the development of patient safety alerts and notices, policies and improvement programmes, national priorities, outcome measures and any potential service reforms.

Experience has shown that some incidents require rapid reporting on an individual basis in order to enable national oversight and assurance. In particular this will relate to incidents where significant harm has occurred or the incident otherwise represents a significant and serious risk to patients, the organisation and/or the delivery of care.

We also know there are a number of incident types where information would be better shared nationally as part of a thematic analysis. Taking this approach, where appropriate, enables better learning from all incidents, not just those where the outcome has led to significant harm or death and will support both local and national learning and improvement.

This policy change will be taken forward in two phases, allowing more detailed work to be undertaken regarding thematic reporting and what this will mean in practice to ensure a consistent approach across Wales.

Phase 1

Patient safety individual incident reporting – to be implemented from 14 June 2021

Phase 1 primarily relates to the reporting of individual incidents which have occurred during NHS funded healthcare and tend to result in significantly harmful outcomes.

Whilst there will remain a requirement to report specific types of incidents at a national level (to the NHS Wales Delivery Unit - NationalSIreports@wales.nhs.uk), as specified below, organisations will no longer report against specific incident categories. Instead NHS organisations must have systems and processes in place to review all incidents on an individual basis to determine what should be reported nationally. This will require a change in behaviour and approach with organisations using existing / preferred methods to assess incidents based on the level of harm caused, potential harm and likelihood or risk of recurrence. This applies to all service areas, not just acute services, across the patient pathway including primary care, out of hours, emergency departments and commissioned services.

The following patient safety incident types will continue to be reportable nationally:-

- unexpected or avoidable deaths (wherever they occur) and or severe / permanent harm of one or more patients, staff or members of the public, which could include, but is not limited to, incidents relating to the following (this is likely to be where an initial 'make safe'/ 72 hour review has identified issues to trigger a patient safety incident investigation, to then be reported within 7 days) :-
    - delays and omissions in care in any setting
    - maternity and neonatal including maternal death
    - children
    - serious medication errors

  The following must always be reported:
    - suspected homicides where the alleged perpetrator has been under the care of mental health services in the past 12 months
    - in-patient suicides in any clinical settings;
    - maternal deaths
- all Never Events, as specified within existing all Wales guidance;

- incidents where the number of patients affected is significant such as those involving screening, IT, public health and population level incidents possibly as the result of a system failure;

- occasionally 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. Incidents of this nature will be considered further through the implementation guide.

The above list may change as the thematic work relating to specific service areas develops.

Unexpected deaths of mental health / learning disability patients in the community (either open episodes of care or closed within the last year)

Any unexpected death in the community must be reported locally and investigated proportionately, including patients in contact with primary and/or secondary mental health and learning disability services, within the 12 months immediately preceding

their death. Proportionate investigations should seek to identify learning opportunities and/or identify any areas of concern in the care provided, which caused or contributed to the death, including concerns raised by the family.

Where an investigation confirms concerns in care were directly attributable to severe harm or an individual's death, an individual patient safety incident should be retrospectively reported at the earliest opportunity.

Incidents where the investigation does not identify concerns in care directly attributable to harm/death will be thematically reported in line with Phase 2.

Incidents which are already externally reportable

There is already a requirement for certain incidents to be reported to external organisations and this must continue. These include (but are not limited to):-

- Human Tissue Authority (HTA) and the Human Fertilisation and Embryology Authority (HFEA)
- Ionising Radiation (Medical Exposure) Regulations (IRMER) – reportable to HIW depending on the harm incurred
- Health and Safety Executive (HSE) - incidents including Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR)
- National audit programmes including Mothers and Babies: reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE), Joint Registry, National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH)
- Medicines and Healthcare products Regulatory Agency (MHRA), including Serious Adverse Blood Reactions and Events (SABRE)
- Professional regulators including General Medical Council, Nursing & Midwifery Council etc.

Where the external organisation has a mandatory reporting requirement, this should be followed. Incidents of this nature also need to be reported as patient safety incidents nationally where they meet the criteria set out above.

Phase 2

Phase 2 will be implemented throughout 2021/22 in accordance with the implementation plan published by the NHS Wales Delivery Unit.

The primary focus of Phase 2 is to instigate a shift from national reporting of individual incidents, to thematic reporting of certain incident types. These thematic reviews will take into account all incidents of a relevant type to draw out the learning which is often not always evident when reviewing individual incident cases, where themes or system failures may not be evident. It also helps reduce outcome bias by no longer focusing solely on incidents where significant harm is the outcome.

The Delivery Unit will work collaboratively with NHS organisations in Wales to develop thematic reporting processes which are fit for purpose for each incident type.

Thematic reporting

Thematic reporting will be undertaken for incident types which tend to occur more frequently and where learning and intelligence is more valuable on an aggregated or cluster basis rather than through a case by case analysis.

Thematic reporting and its practical implementation will be taken forward through the implementation plan. Incidents which will fall into this method of reporting will be:-

- healthcare acquired infections
- patient falls
- healthcare associated pressure damage
- maternity and neonatal incidents
- mental health and learning disability incidents:-
  - absconsions (includes leaving a ward without permission and failure to return at an agreed time) – consider early warning notification reporting at time of incident
  - admission of children and young people to adult mental health settings
  - unexpected deaths in the community of patients known to Mental Health and Learning Disability services (as stated above).

Periodic reporting / areas of focus

From time to time there may be a requirement for incidents to be reported on a specialty basis nationally to understand and consider any potential areas of concern / risk or to provide insight and learning into a particular area of interest. Organisations will be advised of this in advance.

Near miss reporting

Near misses can provide a valuable source of learning. All NHS organisations are expected to share learning from near misses as part of the national reporting and learning framework. This will be considered in more detail through the implementation guide and plan.

Patient safety incident investigations

All patient safety incidents must be investigated proportionately in line with PTR requirements. The depth of the investigation will vary according to the issues under

consideration and the level of harm caused. Organisations should 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 cases and so it is important to determine as accurately as possible from the outset what will be proportionate in the circumstances, with immediate make safes put in place as soon as possible and assurance the focus is on system safety at all times.

Where appropriate, joint investigations must be undertaken when patient safety incidents relate to two or more organisations e.g. patient handovers at emergency departments; system failures; cross border commissioned services; health and social care responsibilities etc.

The accountability for closing an incident investigation sits solely with reporting organisations. 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, patients and families are being engaged in the investigation process, appropriate actions are being taken and that learning is being shared across their organisations, to allow Boards to be assured that incidents have been dealt with appropriately and can be closed.

Investigation outcomes will need to be shared nationally as set out in the implementation guide.

Commissioned services

Most health boards and trusts will commission some NHS services, within their own boundary and from neighbouring health boards / NHS trusts (including WAST) or outside of Wales. Where this happens the following principles will apply to ensure equity:-

- the organisation where the patient safety incident occurred is responsible for reporting and investigating in line with its relevant national framework;
- when notified of an incident the service commissioner should liaise with the investigating organisation as appropriate as part of the investigation
- assurance should be sought that the patient and / or their family form part of the investigation process
- assurance must be obtained to confirm any immediate make safes have been put in place which protects the ongoing safety of patients or consideration is given to remove patients from a particular care setting where appropriate
- any incident learning should be shared with the service commissioner, as part of its internal assurance processes that commissioned services outside of its boundaries are safe and of high quality.

Early warning notifications

Early warning notifications will replace ‘no surprises’ and should be used in circumstances where the Welsh Government needs to be alerted to an immediate

issue of concern or prior warning of something due to happen which might relate to the following:

- has the potential to affect a number of patients/ staff / communities etc
- has a significant impact on service provision;
- may have an adverse impact in the media;
- might cause national or political embarrassment;
- following an inquest which has resulted in a Regulation 28 or public interest in a Public Services Ombudsman for Wales (PSOW) report OR
- a positive good news story.

NHS organisations are expected to work closely with local and national communications teams where required to mitigate potential impact through the media.

Early warning notifications will continue to be submitted to Welsh Government via the improving patient safety mailbox – improvingpatientsafety@gov.wales .