GIG CYMRU NHS WALES | Y Weithrediaeth Executive

Supporting Section 3 – guidance on nationally reporting specific incident types

This section aims to provide clarity around some particular types of incidents which may require national reporting. It is not intended to be an exhaustive or even illustrative list of patient safety incidents which require national reporting.

As set out in the Policy, organisations are responsible for ensuring that they are considering **all** patient safety incidents widely, and making informed decisions on whether or not they think they should be nationally reported, in line with the principles set down in the Policy.

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1. Guidance on 'must reports'

1.1. Never Events

Never Events are defined as "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".

The NHS Wales Never Event list is maintained by the NHS Wales Executive and is issued as part of this Policy (Supporting Section 1).

All Never Events are reportable regardless of harm caused.

When reporting a Never Event, the list in effect at the time the incident was identified should be used.

1.2. Suspected mental health homicides

In line with the proposed definition in the draft statutory guidance for the Single Unified Safeguarding Review process (consultation version launched 6 March 2023), a mental health homicide is when a homicide is committed, and the alleged perpetrator has been in contact with primary, secondary or tertiary Mental Health Services within the last year. In this criteria, 'contact' may include an assessment or intervention.

This definition will be reviewed on completion of the SUSR statutory guidance consultation to ensure alignment as far as possible.

1.3. Suspected suicide or self-inflicted death

- **in any clinical setting; or**
- **during authorised/agreed leave, following recent planned discharge, or following unplanned leave/discharge**

In any clinical setting

All completed suspected suicides and any self-inflicted death, regardless of apparent intent in any NHS Wales Health Board or Trust premises, are reportable. This applies across all NHS Wales healthcare provider inpatient and outpatient environments.

The requirement extends to all service users, not just those being treated for mental health needs, either within a Mental Health setting or otherwise.

During authorised/agreed leave, following recent planned discharge, or following unplanned leave/discharge

The suspected suicide or self-inflicted death of any patient during an episode of authorised/agreed leave from hospital OR following recent planned discharge OR following

a recent unplanned/unauthorised discharge from in-patient care. The definition of 'recent' will depend on individual circumstances, including the clinical condition that the patient was being assessed or treated for.

This includes:

- patients who are legally detained (e.g. under the Mental Health Act) and die unexpectedly whilst on authorised leave
- patients who are not legally detained and die unexpectedly whilst on agreed leave
- patients who knowingly discharge themselves against medical advice
- patients who leave hospital care of their own volition without prior notification (e.g. without signing a Discharge Against Medical Advice form)
- patients who are discharged from hospital without the care team having full assurance of safe discharge arrangements (possibly at times of high operational pressures)

The requirement extends to all service users, not just those being treated for mental health needs, either within a Mental Health setting or otherwise.

1.4. Maternal, perinatal and infant deaths

The requirement to report maternal, perinatal and infant deaths as an NRI will be aligned with the current reporting definitions as set out by MMBRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK) - https://www.npeu.ox.ac.uk/mbrrace-uk/data-collection.

Where the MMBRACE-UK reporting definition is met, the underlying incident should also be reported as an NRI.

Some neonatal deaths meet the criteria for PRUDiC and will also need to be managed through this pathway (see also section 3 below).

2. Incidents reportable to other external organisations

There is already a requirement for certain incidents to be reported to external organisations and where these requirements exist, they must be followed. 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) – incidents of accidental or unintended radiation exposure reportable to HIW

- Health and Safety Executive (HSE) - incidents including Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR)

- Medicines and Healthcare products Regulatory Agency (MHRA), including Serious Adverse Blood Reactions and Events (SABRE)
- National audit programmes and Confidential Enquiries for example: Joint Registry, National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH) etc.
- Professional regulators including General Medical Council, Nursing & Midwifery Council etc.

Except in the case of MMBRACE-UK, there is no requirement within the Policy for responsible bodies to routinely generate a National Incident Report by virtue of the incident being reportable to an external organisation.

However, each incident must be assessed on the basis of the principles set out in the policy to determine if it requires NRI reporting in addition to any other external reporting. Where the responsible body determines that the NRI threshold is met, then the incident must be reported an NRI in addition to the external organisation.

3. Safeguarding incidents, including Procedural Response to Unexpected Death in Childhood (PRUDiC)

Reporting
Safeguarding incidents must be reported and managed in keeping with current national safeguarding procedures and requirements.

Where a safeguarding incident **also** meets the definitions and thresholds in this policy, then it will **also** need to be reported nationally as an NRI. The requirements of both processes will need to be met.

For clarity, there is no routine requirement to report PRUDiC cases as a NRI. Where there is an element associated with the unexpected death related to the provision of healthcare that meets the definitions described in this policy, this must be considered in line with this policy and where the principles of this policy are met, reported as an NRI.

Investigation
Wherever possible, the investigation into an incident which is both (a) a safeguarding incident and (b) a patient safety incident, should be as cohesive as possible i.e. ideally a single investigation covering all relevant aspects, although it is recognised that this may not always be possible.

At the outset of a safeguarding review/investigation (including e.g. an adult/child practice review), consideration should be given at the earliest opportunity to ensuring that the Terms of Reference for the investigation meets the requirements of an investigation under PTR.

4. Healthcare Acquired Infections (HCAIs)

Context

The COVID-19 pandemic has seen a shift in national reporting of HCAIs across Wales, in particular given the establishment of the National Nosocomial COVID-19 Programme (NNCP) through which all cases of nosocomial COVID-19 were reported. As we transition from the NNCP into Business-as-Usual reporting processes, this policy will set out the new reporting requirements for any new cases of nosocomial COVID-19.

Additionally, throughout the pandemic period, national reporting of non-COVID-19 HCAIs has been inconsistent.

The detail below aims to provide clarity of expectation around national reporting requirements of all HCAIs.

Reporting requirement

Local reporting, management & investigation: All HCAIs (including nosocomial COVID-19) and increased incidences of HCAIs (formerly known as outbreaks) are patient safety incidents. They should therefore be locally reported, managed and investigated in line with the Policy and the Duty of Candour once it has come into effect.

National reporting: National reporting in relation to HCAIs should take place in line with this policy, with individual cases and increased incidences assessed in line with the principles set down in the policy to determine whether the national reporting thresholds have been met.

- Individual cases – at a minimum, where a patient or service user has acquired an infection that has caused or contributed to severe harm or their death would be reportable in line with the "outcomes" principles described in the Policy.

- Increased incidences - at a minimum, where an increased incidence of HCAIs has been identified and has caused a significant service disruption (e.g. a ward closure, inability to deliver expected services etc.), this would be reportable in line with the "number of people involved" principle described in the Policy.

National Nosocomial COVID-19 Programme

The requirements of the NHS Wales national framework – Management of patient safety incidents following nosocomial transmission of COVID-19 (accessible from Health in Wales | COVID-19 Essential Services Guidance) still apply for all cases of nosocomial COVID-19 contracted prior to 01 May 2022.

5. Retrospective reporting of certain types of patient safety incidents

Some incident types are designated as acceptable for retrospective reporting, in order to allow the NHS organisation to undertake a fuller local investigation to determine the national reporting requirement.

In these cases, the expectation is that these will be locally reported as soon as possible, consistent with local reporting of all other incident types. An appropriate investigation must then be undertaken in a timely manner.

Where the local investigation identifies a causal or contributory factor in line with the definitions set out in this policy, it must be retrospectively reported in line with Supporting Section 2 of this policy.

The relevant incident types which can be retrospectively reported are detailed below:

5.1. Avoidable pressure damage

The detail of what types of pressure damage should be reported nationally are set out in the version of the All Wales Pressure Ulcer Reporting and Investigation guidance document in effect at the time the incident was identified.

Incidents relating to pressure damage are retrospectively reported following the process set out in Supporting Section 2 of this policy.

5.2. Avoidable falls resulting in harm

Feedback from across NHS Wales during 2021/22 is that there is significant difficulty in determining the severity of harm from falls at the outset of the incident, particularly where it will take some time to determine the permanence of harm from a fall in an elderly patient.

Accordingly, to provide national clarity, patient falls which result in any fracture or significant injury, where the investigation has identified causative or contributory factors, will be reportable as an NRI.

NHS organisations will need to consider other falls resulting in harm to determine whether they require reporting nationally in line with the principles set out in the policy.

5.3. Medically unexpected deaths in the community of patients known to MH&LD services

It is not possible to provide guidance for all eventualities of unexpected deaths in the community of service users known to Mental Health & Learning Disabilities (MH&LD) services. Accordingly the following is provided as broad guidance for organisations.

The cohort of patients and service users relevant to this section are those individuals who have been in contact with primary, secondary or tertiary Mental Health or

Learning Disability Services within the last year. In this criteria, ‘contact’ may include an assessment or intervention.

MH&LD services include:

- substance misuse services e.g. community drug and alcohol teams
- neurodevelopmental services

It does NOT include deaths of service users where the cause of death is immediately known and not relevant to the healthcare being provided (e.g. the service user dies unexpectedly in a car accident, or as the result of a diagnosed terminal illness).

6. Incidents where the number of patients affected is significant

The key wording in this reporting requirement is “the number of patients affected **is** significant”. The word ‘is’ has been purposely included to prevent unnecessary reporting where emerging issues, which could have resulted in harm, were avoided through corrective action or risk mitigation.

Where any incident has, or is likely to have caused an unexpected or avoidable death, and/or severe harm, this should be reported as a national incident within seven days from the point of knowledge that harm has been caused (regardless of timeframe). It should be reported by the organisation responsible for coordinating the care and treatment of the affected patient(s) or service user(s), regardless of whether the underlying incident was within that organisation’s control. Reporting organisations can identify at the time of reporting who the appropriate investigating organisation should be where the incident is considered beyond their control.

7. Unusual, unexpected or surprising incidents, where the seriousness of the incident requires it to be nationally reported and the learning would be beneficial

The nature of patient safety incidents makes it impossible to define a list to which all reportable incidents would comply – this is one of the problems observed with traditional ‘category based’ or ‘trigger list’ reporting methods. All organisations will have incidents occur that do not strictly meet the criteria set out in the policy or this guidance, but should still be reported. This may be because the incident was a significant near miss or because the circumstances of the incident make it impossible to determine a level of harm with any certainty.

The purpose of including this category within the policy was to help make it clear that organisations should be reporting any incident they consider should be reported, even where the national reporting criteria are not met. This is in keeping with the spirit of the policy that a mature approach to assessing and reporting incidents should allow organisations to make decisions and, following assessment, report any such incidents they feel should be reported.

There is therefore an expectation that, as part of the systems and processes specified above, responsible bodies will consider all incidents, and where an incident of significant concern occurs, will report those incidents nationally even if they do not strictly meet the criteria set out in the Policy. Whilst it is a decision for each organisation about serious patient safety incidents reported in this way, advice can be sought from the NHS Wales Executive to support decision making.