Incident, Near Miss and Hazard Reporting and Management Procedure

Policy information

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Summary of document:
This procedure details the process for reporting incidents, near misses and hazards that arise in the course of Hywel Dda University Health Board (the Health Board) conducting its business. It should be read in conjunction with the '894 –'Putting Things Right' Management and Resolution of Concerns Policy (Incidents, Complaints and Claims) – opens in a new tab and, the 010 *Health and Safety Policy*. – Opens in a new tab. This procedure covers all incidents (both clinical and non-clinical) and near misses involving staff, service users, visitors, contractors or any others to whom the Health Board owes a duty of care.

Scope:
The procedure applies to all employed Health Board staff and contractual staff, including primary care contractors, who have a duty under the Regulations to report and investigate all incidents. Commissioned independent investigations or inspectorate driven investigations do not fall within the scope of this procedure.

These procedures do not take precedence where there is an identified Child or Adult at risk, who is experiencing or is at risk of abuse or neglect. In such instances these cases must be reported to the relevant Local Authority Safeguarding Team or Police in line with: the Social Services and Well-Being (Wales) Act 2014, and the Wales Safeguarding Procedures. The reporting and escalation of safeguarding concerns should run in parallel to this policy, however, incidents must not be investigated via this process unless authorised by Police or the Local Authority Safeguarding Team. Advice in relation to safeguarding incidents can be sought from the Health Board Corporate Safeguarding team. The procedure does not replace the duty and professional accountability of staff to report any adverse incident involving a medical device, hazardous product or unsafe procedure, in line with Health Board policies and other written control documents

To be read in conjunction with:
156 - Risk Management Strategy – opens in a new tab
674 - Risk Management Procedure – opens in a new tab
010 - Health & Safety Policy – opens in a new tab
894 –'Putting Things Right' Management and Resolution of Concerns Policy (Incidents, Complaints and Claims) – opens in a new tab
467 – Medical Devices Management Policy – opens in a new tab
435 - All Wales NHS staff to Raise Concerns Procedure – opens in a new tab

Patient information:
Include links to Patient Information Library

Owning group:
Task and finish group

Executive Director job title:
Director of Nursing, Quality and Patient Experience

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1 – new policy 1.6.2015
2 - minor changes 2.12.2015
3 - full review 13.8.2020
4 - full review 08.10.2024

Keywords
Alert, notice, safety notice, patient safety solution

Glossary of terms
The Health Board – Hywel Dda University Health Board
PSIs – Patient Safety Incidents
NPSA – National Patient Safety Agency
DI – Designated individual
PD – person designated
SHOT – Serious hazards of transfusion
SABRE - Serious Adverse Blood Reactions and Events
HTA – Human Tissue Agency
MHRA – Medicines and Healthcare Products Regulatory Agency
MDSO - Medical Devices Safety Officer

Contents

Introduction

This procedure details the process for reporting incidents, near misses and hazards that arise in the course of Hywel Dda University Health Board (the Health Board) conducting its business. It should be read in conjunction with the '894 –'Putting Things Right' Management and Resolution of Concerns Policy (Incidents, Complaints and Claims) – opens in a new tab and, the 010 *Health and Safety Policy*. – Opens in a new tab.. This procedure covers all incidents (both clinical and non-clinical) and near misses involving staff, service users, visitors, contractors or any others to whom the Health Board owes a duty of care.

It is the responsibility of all employees of the Health Board and, anyone attending Health Board premises for work, to provide a service, to follow this procedure and report any incidents, near misses or hazards, in which they were either directly involved or have witnessed. The Health Board seeks to encourage service users and other stakeholders to report incidents, near misses and hazards to enable the Health Board to obtain a more complete picture of the risks that face the organisation and to improve services.

Scope

The procedure applies to all employed Health Board staff and contractual staff, including primary care contractors, who have a duty under the Regulations to report and investigate all incidents. Commissioned independent investigations or inspectorate driven investigations do not fall within the scope of this procedure.

These procedures do not take precedence where there is an identified Child or Adult at risk, who is experiencing or is at risk of abuse or neglect. In such instances these cases must be reported to the relevant Local Authority Safeguarding Team or Police in line with: the Social Services and Well-Being (Wales) Act 2014, and the Wales Safeguarding Procedures. The reporting and escalation of safeguarding concerns should run in parallel to this policy, however, incidents must not be investigated via this process unless authorised by Police or the Local Authority Safeguarding Team. Advice in relation to safeguarding incidents can be sought from the Health Board Corporate Safeguarding team.

Aim

Hywel Dda University Health Board's aim is to ensure that all staff are able to identify incidents, take appropriate actions and reduce risks to service users and employees. Integral to this is the development of an organisational culture, which allows incidents to be reported in an open and fair environment.

Objectives

The overall objectives of the procedure are to:

- Ensure that all staff understand and recognise when an incident has occurred, are able to report it in a timely manner and provide advise if requested

- Ensure all staff understand their accountabilities and responsibilities for reporting incidents

Purpose of Incident Reporting

Incident Reporting Systems are considered to be a major tool in the way organisations manage risks.

Their purpose is to:

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

Benefits of Incident Reporting

If used effectively, the Incident Reporting System will:

- Enhance the Health Board's ability to continually develop good practice and improve the quality of care
- Enable the Health Board to learn lessons from mistakes made/take prompt action to prevent or minimise recurrence
- Protect individuals: patients, staff, contractors, volunteers and visitors through the provision of a safe environment
- Enhance the Health Board's reputation
- Assist in utilising the Health Board's resources more effectively (i.e. reduces the amount of money being spent on litigation)
- Assist in identifying training, education and resource needs
- Provide 'early warning' of actual and potential claims, complaints and/or adverse publicity and means that the Health Board is 'prepared' for such occurrences
- Strengthen the Health Board's position in the event of litigation (i.e. 'early warning' of incidents likely to lead to litigation enables the Health Board to obtain the necessary information at the time of the incident when memories are fresh, before staff have left the Health Board etc)
- Enable the Health Board to meet the legislative requirements such as Putting Things Right Regulations 2011 and Health and Safety at Work etc. Act 1974
- Where actual incidents of loss/harm have occurred, enable early notification/explanation to the 'injured' party to occur and, where necessary, swift compensation to the justified claimant

Just Culture

In an organisation as large and complex as the NHS, things will sometimes go wrong. When they do the response should not be one of blame and retribution, but of learning, a drive to reduce risk for future patients and staff. Blame cannot, and should not, be attributed to individual health care professionals. Identifying and addressing dysfunctional systems is, therefore, the key to reducing the risk of harm for many patients and staff.

It is understood that fear of disciplinary action and subsequent sanctions may deter staff from reporting incidents. Therefore, the Health Board's Incident Reporting System continues to be developed within a just culture– opens in a new ab. The Health Board's approach following incidents will focus on 'what went wrong, not who went wrong'. Where errors have occurred and are openly reported, an investigation into the facts may take place but the disciplinary process will not be instigated in respect of any member of staff, except in well-defined circumstances, as follows:

- an incident in which the Health Board considers that a fundamental breach of professional practice or gross negligence has occurred, and/or an incident which might lead any professional registration body to review the individual's professional status
- further occurrences of actions involving an individual who has previously received supervision, or been subject to disciplinary action related to the type of error that might have led to the incident where it appears that staff may have been guilty of a criminal offence or some act or omission which may result in formal action by a regulatory or professional body
- failure or significant delay in reporting an incident in which a member of staff was directly involved or about which they were aware

It should be noted that when any error is being considered, whether within the Incident Reporting Procedure structure or not, it is universally recognised that when a member of staff is open in admitting to the error and reporting it to the appropriate individual, a considerably more positive and supportive approach may be taken by the Health Board in addressing the matter. Conversely, it is also the case that when a member of staff decides to either delay reporting, or to attempt to conceal the occurrence of an error, the Health Board's response to it is likely to be less favourable and will indeed specifically address this delay or failure to report as a further element of the issue.

Guidance on raising concerns confidentially is also available by referring to the 435 - All Wales NHS staff to Raise Concerns Procedure – opens in a new tab . The Health Board also has Speak Up Safely Champions and Ambassadors and a Working in Confidence Platform. Staff can raise concerns verbally, by letter, email or by completing an incident form. More details about how to raise concerns can be found on the Health Board's SharePoint:

- Working in Confidence - opens in a new tab
- Speak Up Safely - opens in a new tab

Definitions

Patient Safety Incident or Clinical Incident

'An event or circumstance arising during clinical care of a patient that could have (i.e. 'near miss') or did lead to unintended or unexpected harm'.

Harm is defined as 'injury (physical or psychological), disease, suffering, disability or death'. In most instances, harm can be considered to be unexpected if it is not related to the natural cause of the patient's illness or underlying condition.

Incidents involving patients are also known as 'Patient Safety Incidents' (PSIs). The former National Patient Safety Agency (NPSA) defines a PSI as 'any unintended or unexpected incident which could have or did lead to harm for one or more patient receiving NHS funded healthcare'.

Incident (non-clinical)

'An event or circumstance that could have (i.e. 'near miss') or did cause unexpected or unwanted harm, loss or damage to any individual(s) involved (including patients but not related to clinical care, staff, visitors etc) or damage to/loss of property/premises for which the Health Board is responsible.'

Serious Incident

'An incident or series of incidents which are likely to produce significant legal, media or other interest or give rise to large scale public concern and which, if not properly managed, may result in significant loss of the Health Board's reputation and/or assets'.

Serious incidents include those where there is harm to the person affected is severe or catastrophic. Never events (see 'never events section') are also classed as serious incidents.

In the event of a serious incident occurring, the requirement is for immediate reporting to the ward manager and senior nurse / consultant (preferably face to face or telephone). Both individuals can be emailed regarding escalation of a serious incident as long as the email is also sent to the Health Board's Quality Assurance and Safety email address: patient.safety@wales.nhs.uk. Out of hours the Site Manager should be contacted. The Site Manager, in turn, will contact the on-call Director/Senior Manager.

Adverse Event

Any event that has given or may give rise to actual or possible personal injury, patient dissatisfaction, or to property loss or damage.

Near Miss

Any event or omission that could have potentially caused harm, but due to prompt action by a member of staff, or simply because of good fortune was prevented.

Never Events

"Never events" are very serious, largely preventable patient safety incidents that should not occur if the relevant preventative measures are out in place. These incidents will be reported onto the Datix Cymru system and the NHS Executive notified.

The current Never Event list is as follows:

Surgical Never Events

- Wrong site surgery
- Wrong implant/prosthesis
- Retained foreign object post procedure

Medication Never Events

- Mis-selection of a strong potassium solution
- Administration of medication by the wrong route
- Overdose of insulin due to abbreviations or incorrect device
- Overdose of methotrexate for non-cancer treatment
- Mis-selection of high strength midazolam during conscious sedation

Mental Health Never Events

- Failure to install functional collapsible shower or curtain rails

General Never Events

- Falls from poorly restricted windows
- Chest or neck entrapment in bed rails
- Transfusion or transplantation of ABO-incompatible blood components or organs
- Misplaced naso- or oro-gastric tubes
- Scalding of patients
- Unintentional connection of a patient requiring oxygen to an air flowmeter

'Trigger Lists'

In respect of clinically related events, particularly in specialities, where there is perceived higher-risk e.g. where a particular incident or event is a 'known litigation risk', 'trigger lists' of incidents which should always be reported should be developed.

In addition, events will often occur which are unexpected. These events are usually not related to negligence but may be viewed as such by the patient or their relatives. To the doctor or healthcare professional the unexpected event may be a recognised complication of a particular procedure or treatment. Given the potential for dissatisfaction, such events should also be added to specialty specific 'trigger lists'.

It should be emphasised, however, that such lists will not be exhaustive. An element of judgement is, therefore, required as to whether an incident should be reported but where doubt exists the safest option will be to report the incident. For areas wishing to develop their own 'trigger lists' a generic/core list of (clinical) codes is attached for reference at Appendix 1. This can be adapted as appropriate. Advice can also be sought from the Quality Assurance and Safety Team.

Trigger lists are already in place within specific areas and are incorporated into the Health Board's wider list of Incident Codes.

It should also be noted that specialty 'trigger lists' of non-clinical incidents, taking account of the relevant definitions above, could also be developed.

Incident Reporting Actions and Duties & Responsibilities

All Staff

It is a requirement of all Health Board staff that they report any incident, accident or potential (i.e. 'near miss') incident which has caused or has the potential to cause harm, loss or damage to any individual,* or, any property or premises, for which the Trust is responsible. This includes any incident that has the potential to involve the Trust in either litigation or adverse publicity.

**This applies whether the 'affected' person is a patient, member of staff, contractor, volunteer or visitor to the Health Board.*

Any member of staff who is involved in, witnesses or discovers an adverse incident/accident or near miss incident/accident can complete an Incident Report Form through Datix. The report should not wait until the affected person has returned to work and can be completed by a third person on the affected persons behalf if required.

As outlined in serious incident section, in the event of a serious incident occurring, the requirement is for immediate reporting to the Service Management Team e.g. consultant or senior nurse (preferably face to face or telephone).

Out of hours, the Site Manager should be contacted. The Site Manager, in turn, will contact the on-call Director/Senior Manager.

For serious patient safety incidents, the Health Board's Quality Assurance and Safety Team must also be notified by either telephoning 01267674010 (during office hours) or by emailing patient.safety@wales.nhs.uk.

For serious staff related incidents the Health Board's Health and Safety Team must also be notified.

Person responsible for the immediate management of the incident

The person responsible for the immediate management of the incident (e.g. the nurse in charge of the ward at the time an incident occurs) should:

- Undertake an immediate assessment of the situation;
- Determine any immediate treatment and/or ongoing care needs of the affected person; and/or
- Determine the extent of any loss/damage to property; and any other immediate action required (e.g. removal and isolation of faulty equipment).

The situation/scene should be made safe. Where possible the scene should be protected (e.g. cordoned off) and/or recorded (e.g. photograph). Medical devices and other equipment, if a factor in the incident, should be taken out of use and stored securely.

Managers

Following every incident, whether a near miss or an incident resulting in injury, managers must take and record (on the incident report form) any required immediate and/or preventative actions.

Depending on the circumstances and severity of the incident, the action taken by managers following an incident may include:

- Ensuring patient/relatives have been informed of the incident, the investigation and action taken and apologies are offered, as necessary/appropriate –also refer to the Health Board's 894 'Putting Things Right' Management and Resolution of Concerns Policy (Incidents, Complaints and Claims) – opens in a new tab.
- Ensuring appropriate follow-up treatment/care of the affected person. (Where this is a member of staff ensuring that he/she receives first aid and/or are advised to attend A&E or their GP);
- Ensuring that faulty equipment has been taken out of use and isolated pending investigation by a competent person for example, Estates or Clinical Engineering, and/or the MHRA prior to re-use;
- Ensuring appropriate escalation of the incident (certain incidents are reportable externally and/or have a requirement under *Putting Things Right Regulations* for an appropriate level of investigation. Therefore, there is a Health Board requirement to escalate certain serious incidents to corporate teams e.g. serious patient safety incidents must be escalated to the Patient Safety Team and RIDDOR reportable incidents escalated to the Health and Safety Team. For the full list of external reporting please see appendix 2
- Ensuring an appropriate investigation is undertaken; (*N.B. The level of investigation and resulting management action/preventative measures should be related to the severity grading of the incident*). Also refer to the Health Board's Concerns Investigation and Management Guidance – opens in a new tab
- Ensuring feedback to staff raising the issue and reporting the incident. – opens in a new tab
  This includes staff who may have raised concerns through the Speak Up – opens in a new tab - process;
- Debriefing/counselling and support of staff, as necessary appropriate;
- Implementing appropriate preventative actions; and
- Monitoring and review of those actions to ensure they remain effective.

Directors / General Managers

Directors / General Managers will be responsible for ensuring:

- That appropriate arrangements are in place within their Directorates / Services / Specialities / Departments for the reporting, investigation and follow-up of incidents in accordance with both this procedure and the Health Board's 'Procedure for Dealing with Serious Incidents' and in accordance with their responsibilities for governance and risk management; and
- The review of data on incidents in order to identify and monitor trends/problems, and for taking appropriate action

Quality Assurance and Safety Team and Health and Safety Team

The Patient Safety Team and the Health and Safety Team will be responsible for:

- The overall management and co-ordination of the Health Board's incident reporting arrangements including the central coding of incident data;
- The reporting of incidents, as necessary, to the relevant external agencies (see appendix 2);
- The compilation of analysis reports (e.g. for Quality, Safety and Experience Committee, Health and Safety Committee, Directorate Quality and Governance Groups) and provision of data for safety dashboards; and
- Monitoring, as appropriate, that follow-up of incidents/changes in practice occur as necessary/appropriate. Ultimately, changes in practice and learning lessons are the responsibility of the area in which the incident occurred.

Incident Reporting

- The Health Board currently uses the Datix Cymru system for incident reporting. The Datix Incident Report Form captures the detail of the incident, and the parts of the organisation and the people involved. It acts as a record of the incident and a prompt to support action planning and reporting.

- Any member of staff who is involved in, witnesses or discovers an adverse incident/accident or near miss incident/accident must complete the Datix Cymru Incident Report Form, which is available on the Health Boards intranet. If the incident involves a member of the public or someone who is external to the Health Board i.e. an Independent Contractor then the employee who witnessed the incident, or to whom the incident is reported, should complete the Incident Report Form.

- As indicated in section 'serious incident', Serious Incidents should be reported immediately to the department manager and senior nurse / consultant (in addition to being escalated within the Directorate Management Team). Out of hours the Site Manager should be contacted. The Site Manager, in turn, will contact the on-call Director/Senior Manager.

- It is understood that remedial action is often likely to take priority over the completion of the Incident Report Form. However, the incident should be reported as soon as possible, ideally within 24 hours but no later than 2 days after the incident. It is also just as important to report incidents where the outcome is identified at a later stage.

- The reporting timescales enable timely escalation, and investigation, of such incidents internally. This also mean that the relevant external reporting requirements can also be met. Details of the external stakeholders who require notification of certain incidents/accidents which occur within the Health Board is attached at Appendix 2.

- When completing the Incident Report Form, it is important to include as much information as possible and that a clear, sequential analysis of what failed is documented. However, person identifiable data must be excluded from the detail of the incident. There are appropriate fields, such as the contacts section, where this can be recorded.

- Once the Incident Report Form has been completed, it is submitted into Hywel Dda Health Board's Datix Cymru Concerns Management system. This enables the collation and analysis of information on incidents.
- If the incident is a result of faulty equipment the Manager must ensure that, it is taken out of use as soon as practically possible (see section: Person responsible for the immediate management of the incident).
- Incident Report Forms must be reviewed on Datix Cymru by the relevant nominated manager ideally within 24 hours but no later than 3 working days after the incident and the Management Review Form must be completed.

N.B. The outcome of most incidents is immediately identifiable. However, it is just as important to report incidents where the outcome is identified at a later stage. For example, a back sprain resulting from manual handling may not become apparent for a few days.

Incident Classification

- Once added to DATIX, all incidents are given a classification 'code'. This enables the same types of incidents to be grouped together, which in turn aides the analysis process in order to identify trends/problems. The coding of incidents in this way also enables the easy identification/selection of the incidents, which must be reported externally.
- Within the Health Board, the classification of incidents is undertaken by the reporter.
- The coding is reviewed at a number of investigation stages. It is first reviewed by the nominated manager when they undertake the initial review (within 3 working days).
- On conclusion of the investigation the code is reviewed by the manager responsible for approving closure of the incident record.
- Validation of the coding is undertaken by the Quality Assurance and Safety Team or Health and Safety Team (dependent on the type of incident).

Grading of Harm

- In accordance with national guidance and good risk management practice, all incidents reported within the Health Board will be graded using the principles adopted for the proactive risk assessment. Grading is undertaken according to the:
  - Actual impact on the affected person(s), whether patient, member of staff or visitor to the Health Board;
  - Actual consequences for the organisation.
- The grading of harm will also reflect whether there are any acts or inaction that led to the harm of the person affected by the incident. When reporting an incident, this may not be known and therefore the level of harm may change as the investigation progresses and concludes.

- The Datix Cymru Incident Reporting System allows for the level of harm to be captured at various stages:
  - On reporting - harm to the person affected at time of reporting the incident as perceived by the reporter of the incident (see table below showing levels of grading) This will allow the nominated manager to prioritise incidents for review when a significant number have been reported.
  - Initial management review - assessment of harm by the nominated manager. This will assist in establishing the level of:
    - Risk associated with a particular incident;
    - Whether duty of candour has been triggered; and
    - Investigation required.
  - Conclusion of the investigation. This grading will consider whether there were any acts or inactions (in healthcare) that lead to the outcome for the person affected.

Table showing levels (grades) of incidents on reporting

Level of Harm	Examples of concerns
Level 1 **No harm**	a) Concerns which normally involve issues that can be easily / speedily addressed; b) Potential to cause harm but impact resulted in no harm having arisen; c) Outpatient appointment delayed, but no consequences in terms of health;, d) Difficulty in car parking; e) Patient fall – no harm or time of work; f) Concerns which have impacted on a positive patient experience.
Level 2 **Minor Harm**	a) Concerns regarding care and treatment which span a number of different aspects/specialties b) Increase in length of stay by 1 – 3 days c) Patient fall – requiring minor treatment d) Requiring time off work – 3 days e) Concern involves a single failure to meet internal standards but with minor implications for patient safety f) Return for minor treatment, e.g. requiring local anaesthetic further treatment/monitoring by GP g) Samples taken from the wrong patient – not acted upon but require repeat venepuncture. h) Pathology labelling error detected post analytically before further intervention
Level 3 **Moderate harm**	a) Clinical / process issues that have resulted in avoidable, semi-permanent injury or impairment of health or damage that requires intervention

	b) Additional interventions required or treatment / appointments needed to be cancelled c) Readmission or return to surgery, e.g. requiring general anaesthetic d) Necessity for transfer to another centre for treatment / care (e.g. for an incident in a GP Practice, admission to hospital) e) Increase in length of stay by 4 – 15 days f) RIDDOR reportable incident (moderate harm) g) Requiring time off work 4 – 14 days h) Concerns that outline more than one failure to meet internal standards i) Moderate patient safety implication j) Concerns that involve more than one organisation (e.g. cross border incidents that may involve English providers or other Health Boards, incidents involving interface with Local Authority, or Ambulance Trusts)
Level 4 Major Harm	a) Clinical process issues that have resulted in avoidable, semi-permanent harm or impairment of health or damage leading to incapacity or disability b) Additional interventions required or treatment needed to be cancelled c) Unexpected readmission or unplanned return to surgery d) Increase in length of stay by >15 days e) Necessity for transfer to another centre for treatment / care f) Requiring time off work >14 days g) A concern outlining non-compliance with national standards with significant risk to patient safety h) RIDDOR reportable incident (significant harm)
Level 5 Catastrophic Harm	a) Concern leading to unexpected death, multiple harm or irreversible health effects b) Concern outlining gross failure to meet national standards c) Normally clinical/process issues that have resulted in avoidable, irrecoverable injury or impairment of health, having a lifelong adverse effect on lifestyle, quality of life, physical and mental well being d) Clinical or process issues that have resulted in avoidable loss of life

	e) RIDDOR reportable incident (catastrophic harm) f) Significant / consistent reporting errors i.e. malignant as benign.

Further examples are provided in the Duty of Candour – opens in a new tab - guidance.

Being Open/Duty of Candour

Being Open

A culture of openness, transparency and candour is widely associated with good quality care.

When an incident has occurred it is essential that all staff ensure that the patient's/relatives/carers are offered an apology and that they are informed of the next steps e.g. an incident investigation.

Any Being Open discussions must be documented in the patient's health records and in the "openness and transparency" section of the incident report form.

Whilst Being Open primarily applies to patients and service users, it is also good practice for staff related incidents.

Duty of Candour

When undertaking the initial management review of a patient safety incident, the nominated manager must consider whether Duty of Candour – opens in a new tab - has triggered.

The Duty of Candour – opens in a new tab - requires NHS providers to follow a process when a service user suffers an adverse outcome which has or could result in unexpected or unintended harm that is more than minimal, **and** the provision of health care was or may have been a factor**.** There is no element of fault, enabling a focus on learning and improvement, not blame.

When does the duty of candour apply?

The duty is triggered in relation to an NHS body if it appears to the body that both of the following conditions are met:

1. The first condition is that a person (the "service user") to whom health care is being or has been provided by the body has suffered an adverse outcome.
2. The second condition is that the provision of the health care was or may have been a factor in the service user suffering that outcome.

A service user is to be treated as having suffered an adverse outcome if the user experiences, or if the circumstances are such that the user could experience, any unexpected or unintended harm that is moderate or above.

The duty may be triggered by an action taken by a NHS body during the provision of health care or by a failure to take action.

The duty is not triggered where harm is related to the natural course of the service user's illness or underlying condition.

Further guidance is available on the Health Board's SharePoint – opens in a new tab - or within the 894 'Putting Things Right' Management and Resolution of Concerns Policy (Incidents, Complaints and Claims) – opens in a new tab.

Incident Investigation

Initial Management Review

Within 48-72 hours of an incident being reported, the manager of the area must review the incident report form.

When reviewing the initial report, the manager should consider whether there is an immediate patient safety issue, whether the action taken at the time of the event was sufficient and whether further "make safe" actions are required.

The manager will decide whether further investigation is required (the decision regarding investigation may be taken in conjunction with other managers / teams).

The findings of the manager's initial review must be documented on Datix Cymru in the relevant investigation section.

Issues identified during management review requiring further investigation

When further investigation is required, recognised investigation methodology will be used. Timely investigation is critical.

The principles of a good investigation are:

- Plan and outline the investigation before starting;
- Engage with those affected.
- Do not simply record the steps of the event;
- Take a system-based approach (safety arises from interactions and not from a single component)
- Capture multiple perspectives to reduce bias;
- Capture the view from inside the situation;
- Do not find fault, but find facts that can lead to corrective actions; and
- Be fair and objective.

Further guidance on investigation can be found on the Health Board's SharePoint Concerns investigation and management – opens in a new tab -

Severe or Catastrophic Incidents, Nationally Reportable incidents including Never Events

For incidents where there is severe or catastrophic harm or when an incident is a Never Event or nationally reportable, within 2 working days of the recommendation that an investigation be undertaken, an initial Incident Management Group meeting must occur.

The main purpose of the Incident Management Group meeting is to:

- Review and consider the findings of the initial scrutiny;
- Identify any immediate actions required to mitigate the risk of re-occurrence;
- Consider the 'Just Culture' tool;
- Set the Terms of Reference and scope for the investigation;
- Agreed the lead Investigatory and supporting investigation team;
- Confirm whether Duty of Candour has been triggers and agree the lead for the further Duty of Candour discussions;
- Confirm support arrangements for staff involved in the incident i.e. well-being support;
- Consider external reporting requirements.

Focussed Reviews

To assist investigation managers, a number of focussed reviews templates have been developed on an all Wales basis:

- Extravasation
- In-patient falls
- Manual handling
- Pressure damage
- Sharps

These focussed reviews must be completed by the investigating officer before conclusion of the investigation.

Documenting the findings of the investigation

The investigation report will be documented on Datix Cymru.

Investigation reports should be written in a way that is accessible and understandable to all readers (which will include the patient and/or family in most cases). The report must not contain any patient or staff names and the content should be clear and concise.

Concerns investigation reports, emails and any correspondence are disclosable documents, and may be used in a court of law (including at Coroner's Court) and as evidence during litigation.

The draft report should be shared with stakeholders (those who have been interviewed or who have provided information for the investigation). The purpose of sharing the report with stakeholders is so that they can check the report for factual accuracy. The stakeholders are not being asked to agree or disagree with the investigation conclusion but ensure that there is no information missing or incorrectly reported.

Closure of incident records

All investigation reports require formal sign-off before the incident record can be closed. This formal signoff process ensures the quality of the investigation.

An incident record should not be closed by the investigator of the incident.

Ensuring that there are improvement actions and learning are critical to ensuring that the likelihood of the event recurring is reduced. An improvement action plan should be developed and implemented in a timely manner following completion of the investigation. For some issues

identified during the incident investigation, there may be a need to use recognised quality improvement methodology.

The improvement action plan should be monitored to completion at the service or directorate quality and governance meeting (whichever is most appropriate for the event).

Feedback to the incident reporter

Feedback to the incident reporter is a critical for a positive safety culture and for staff to feel psychologically safe.

A positive safety culture is one where the environment is collaboratively crafted, created, and nurtured so that everybody (individual staff, teams, patients, service users, families, and carers) can flourish to ensure brilliant, safe care by:

1. Continuous learning and improvement of safety risks
2. Supportive, psychologically safe teamwork
3. Enabling and empowering speaking up by all

Psychological safety is a dynamic team-level phenomenon which exists when team members believe that it is safe to take interpersonal risks. In healthcare teams, the presence of psychological safety is critical to delivering safe care.

The Datix Cymru system sends an automatic email to the reporter of the incident (where the reporter has used an NHS Wales email address). The nominated manager must ensure that the specific field in the system is completed and that it includes the outcome of the investigation, the learning and the actions taken following the incident.

References

Welsh Government (2012) Putting Things Right: Guidance for dealing with concerns about the NHS - Version 2 FINAL.pdf (wales.nhs.uk)

Appendix 1: Generic 'Trigger' List

This list is not exhaustive

Access, admission

- Delay in admitting to hospital
- Referral not made as planned in patient pathway

Accident, Injury

- In-patient fall
- Contact with needles or medical sharps
- Manual handling injury
- Entrapment in bed rails

Assessment, Investigation and Diagnosis

- Delay in clinical diagnosis
- Missed diagnosis
- Specimen mislabelled or lost
- Test results / reports – delay in interpreting or acting upon

Behaviour

- Self harming behaviour of an in-patient
- Patient clinically challenging behaviour
- Violence or aggression

Consent

- Procedure undertaken without consent
- Lack of documentation of the patient's decision
- Lack of capacity assessment in accordance with the requirements of the Mental Capacity Act

Medical Devices

- Failure of a medical device
- Equipment malfunction
- Unauthorised use of a medical device

Infection Prevention and Control

- Healthcare Acquired Infection
- Increased incidence or outbreak

Information Governance, Confidentiality

- Patient records/information sent to wrong recipient.
- Staff/patient records inappropriately accessed

Medication

- Administration errors
- Prescription errors
- Lost/stolen medication

Monitoring, Observations

- Failure to carry out adequate observations (NEWS)
- Delay in requesting clinical assistance (escalation)
- Delay in assessing and recognising patient deterioration

Nutrition and hydration

- Failure to complete assessments
- Nil by Mouth issues – prolonged NBM, cancelled operations etc

Patient / service user death

- Unexpected death
- Maternal death (within 12 months)
- Death of service user known to learning disabilities
- Death of service user known to mental health services

Pressure damage, Moisture damage (see additional guidance on SharePoint)

- Pressure damage developed or worsened during clinical care;
- Pressure damage on admission from nursing home;
- Pressure damage on admission where there has been a delay in handover from ambulance to hospital
- Severe continence related moisture damage

Records, Information

- Missing, incorrect, incomplete documentation by healthcare professional
- Documents misfiled in healthcare record

Treatment, Procedure

- Delay in treatment/operation
- Incorrect treatment (including operation on wrong patient/body part)
- Foreign body left in situ
- Treatment/intra-operative problems
- Allergic reaction (including diathermy burns/reaction to prep agent)
- Post-operative complications
- Transfusion problems

Appendix 2: External Stakeholders Requiring Notification of Incidents

The Health Board will ensure that, where relevant, the following external stakeholders are informed of and, where appropriate, involved in the investigation of adverse incidents/accidents which occur. Unless, otherwise stated within each relevant section, reporting to the external stakeholders listed below will be undertaken centrally by the risk management department.

Health & Safety Executive (HSE)

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR)

Under RIDDOR, the Health Board has a statutory responsibility to report to the HSE certain incidents / accidents which occur during the course of work activity.

Failure to comply with this regulation can lead to the Health Board being prosecuted for a breach of regulations and further enforcement action being taken.

RIDDOR incidents are reported to the HSE by staff within the Health and Safety Team on receipt of the incident form.

Early notification of accidents/incidents means that the Health Board is able to comply regulatory requirements of RIDDOR. Details of the incident need to be reported to the HSE within strict timeframes based on the type of incident:

- **Without delay** - Deaths, major injuries, hospital treatment to non-workers and dangerous occurrences
- **Within10 days of the incident** - injuries, fatalities and dangerous occurrences full RIDDOR report
- **15 Days** – Over 7 day incapacitation

Serious Incidents

There may be other instances where the HSE may need to be notified of incidents which occur. This will depend on the circumstances and severity of the incident. The Health, Safety and Security Team will advise whether it is necessary to inform the HSE and whether the area involved needs to be isolated until a HSE Inspector has visited.

NHS Executive

The Health Board is required to report certain incidents to the NHS Wales Executive. Further guidance is detailed on the Nationally Reportable Patient Safety Incident SharePoint page. - – opens in a new tab

Principle 1 - 'Must Reports'

Incidents related to the following are always nationally reportable

- Never Events* even where no harm has occurred;

- 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, the incident should be nationally reported, 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.

In all cases the immediate management of the incident is paramount including the safety of the patient affected and other patients. The service management team e.g. senior nurse, must be informed of the incident and an incident report form submitted via Datix Cymru.

Reporting of nationally reportable incidents to the NHS Executive will be undertaken by the Quality Assurance and Safety Team.

Medicines

Doctors, pharmacists or nurses can report suspected adverse drug reactions by completing the suspected adverse drug reactions form. This is a yellow coloured form which can be found in the back of the current edition of the British National Formulary. The form also includes the address to forward the report to the Medicines & Healthcare Products Regulatory Agency (MHRA). More detailed information on reporting and a list of drugs/products currently under intensive surveillance (black triangle list) can be found on the MHRA website: www.mhra.gov.uk/

Defective Medicinal Products

This is defined as:

- Proves to be harmful under normal conditions of use;
- Lacking in therapeutic efficacy;
- The qualitative and quantitative compositions of the product is not as declared;
- The controls on the medicinal products and/or on the ingredients and the controls at the intermediate stage of the manufacturing process have not been carried out, or if some other requirement or obligation relating to the grant of the manufacture authorisations has not been filled.

If a healthcare professional observes:

- A clinical symptom(s); or
- A patient event, which indicates that a defective medicinal product has been used or that a defective product might be the explanation of this observation; or
- Who may recognise that a medicinal product may be defective prior to use should contact a member of the pharmacy department or pharmacist or pharmacist on-call immediately for further advice. The pharmacist should refer to a Guide to Defective Medicinal Products for guidance on how to proceed. Copies of the guidance are located in the pharmacy department.

Serious Hazards of Transfusion (SHOT)

SHOT collects anonymised reports from across the UK on adverse events related to transfusion of blood and blood components (red cells, platelets, fresh frozen plasma, cryoprecipitate, granulocytes), anti-D Immunoglobulin and cell salvage. More recently they have also started gathering evidence of exceptional transfusion practice by a team or department that was above and beyond routine practice and that has wide spread learning opportunities. All reporting to SHOT is recorded on the MHRA Serious Adverse Blood Reactions and Events (SABRE) reporting system.

If staff become aware of any incidents relating to blood transfusion they should contact the Blood Transfusion Department immediately. Incidents involving the transfusion of blood products will be highlighted at the Blood Transfusion Group. Individual investigation of all blood transfusion incidents will be undertaken by the Transfusion Practitioner and/or Blood Bank Manager and recommendations for changes in practice forwarded to the areas concerned.

Reporting of incidents to SHOT will be undertaken by the Transfusion Practitioner and/or Blood Bank Manager

Human Tissue Authority

The Human Tissue Authority (HTA) is the watchdog for tissue and organs. Their aim is to protect the public by licensing and inspecting organisations that store and use human tissue and organs for purposes including research, patient treatment, transplantation, post-mortem examinations, teaching and public exhibitions.

The HTA must be notified of all reportable incidents (HTARIs) that occur at licensed establishments in the post mortem sector. Notification of HTARIs must be submitted to the HTA within 5 working days of the incident occurring or being discovered. Establishments must not wait until any internal review or investigation is complete before notifying the HTA of a HTARI.

Notifications must be made using the HTARI form on the HTA web Portal.

https://portal/hta.gov.uk/ – opens in a new tab

This form can only be completed by a Designated Individual (DI) or Person designated (PD) named on the license who has a web Portal account. DIs are responsible for ensuring the HTA is notified of HTARIs, and must ensure systems are in place for reporting in their absence.

Refer to the Pathology Department *Standard Operating Procedure for Reporting to the Human Tissue Authority*

The Medicines and Healthcare Products Regulatory Agency (MHRA)

The MHRA is the Executive Agency of the Department of Health responsible for protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and

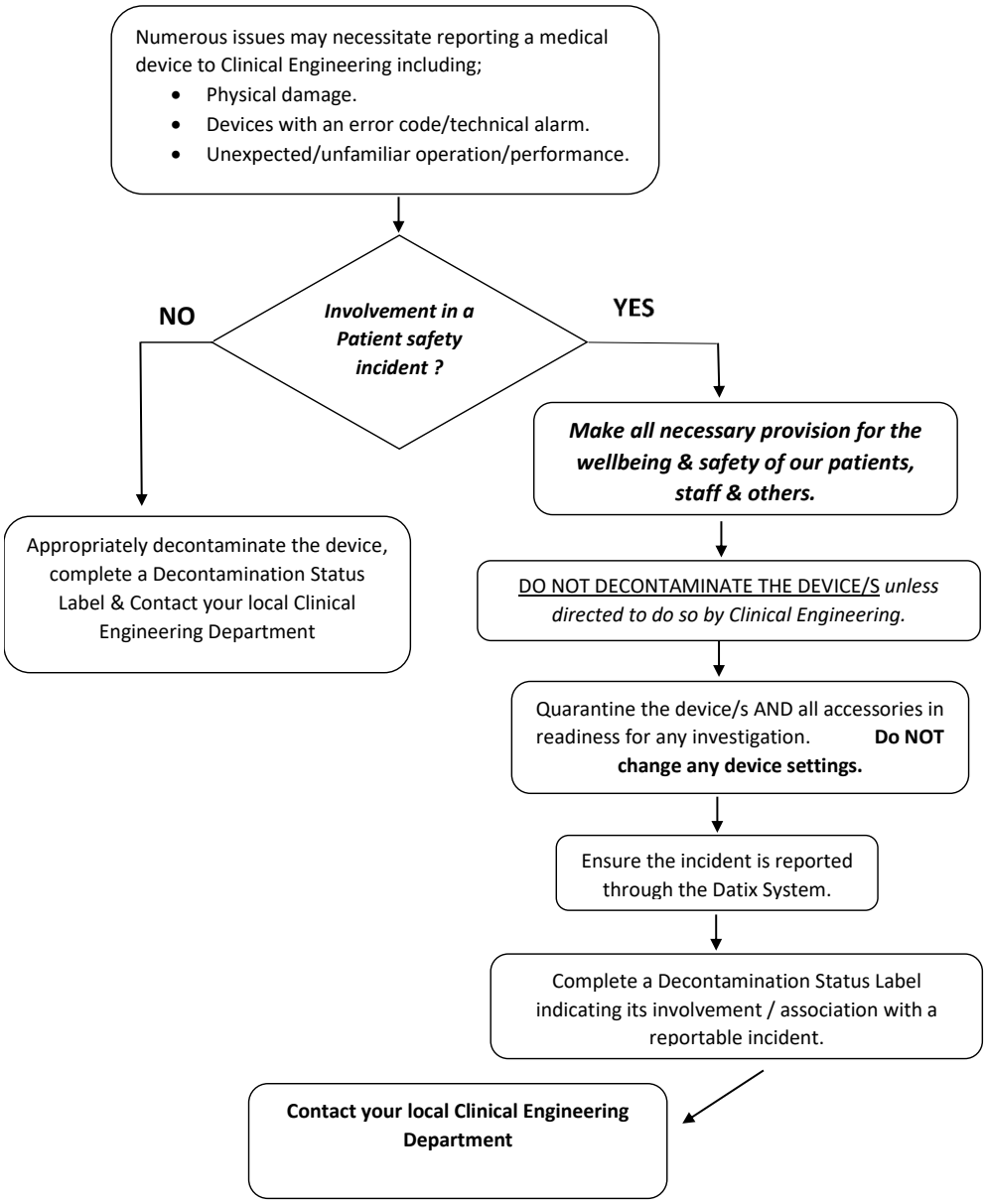
medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.

Medical Devices

The Health Board is required to report to the MHRA, any adverse incident involving a medical device via the UHB's Medical Devices Safety Officer (MDSO), especially if the incident has led to or, were it to occur again, could lead to death or serious injury, medical or surgical intervention (including implant revision), hospitalisation or unreliable test results.

The Head of Clinical Engineering acts as the Health Board's Medical Devices Safety Officer (MDSO) and all users of medical devices are requested to follow the process detailed below:

Medical Device Fault / Patient Safety Incident ?



Clinical Engineering will report to MHRA via the 'Yellow Card System' where appropriate.

Any medical device involved in an incident needs to be taken out of use, quarantined and retained for inspection. It should not be repaired, returned to the manufacturer, or discarded until Clinical Engineering and the MHRA have been given the opportunity to carry out their own investigation.