GIG CYMRU NHS WALES

Bwrdd Iechyd Prifysgol Cwm Taf Morgannwg University Health Board

Incident Management Framework

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Section 1: Introduction & Overview

Definition

An incident is defined as any unexpected or unintended occurrence, which could have, or did, lead to harm, damage or loss for one or more patients receiving NHS funded care, staff or member of the public on NHS premises. This definition includes any unexpected or unintended incident, which could have led to harm but that harm was prevented by way of some intervention.

The Incident Management Framework has been developed to provide a comprehensive structured guide to incident reporting and management within Cwm Taf Morgannwg University Health Board (CTMUHB). The document will outline the process to be followed in order to:

- Report incidents
- Maximise the learning from incidents
- Ensure that all incidents are investigated appropriately
- Identify any actions to prevent recurrences
- Ensure robust monitoring of incident reporting, investigation and relevant actions.

It is intended that this will be an interactive reference document to be used as a toolkit in conjunction with the Incident Management SharePoint Pages and Concerns Policies and Procedures. Implementation of the document is supported by a training strategy.

The Health Board recognises its responsibilities to have effective incident management systems as well as implement Health and Safety legislation as it affects the workplace.

The effective reporting and management of incidents, near misses and hazards, by all staff working in the health community and directly employed in Cwm Taf Morgannwg University Health Board, is a key component of Quality, Safety and Governance to ensure safe and effective care for patients and maintain staff safety.

It is important to remember that incident management and investigation is not intended to apportion blame, but to focus on essential learning that can contribute to continuous improvement. In addition incident reporting:

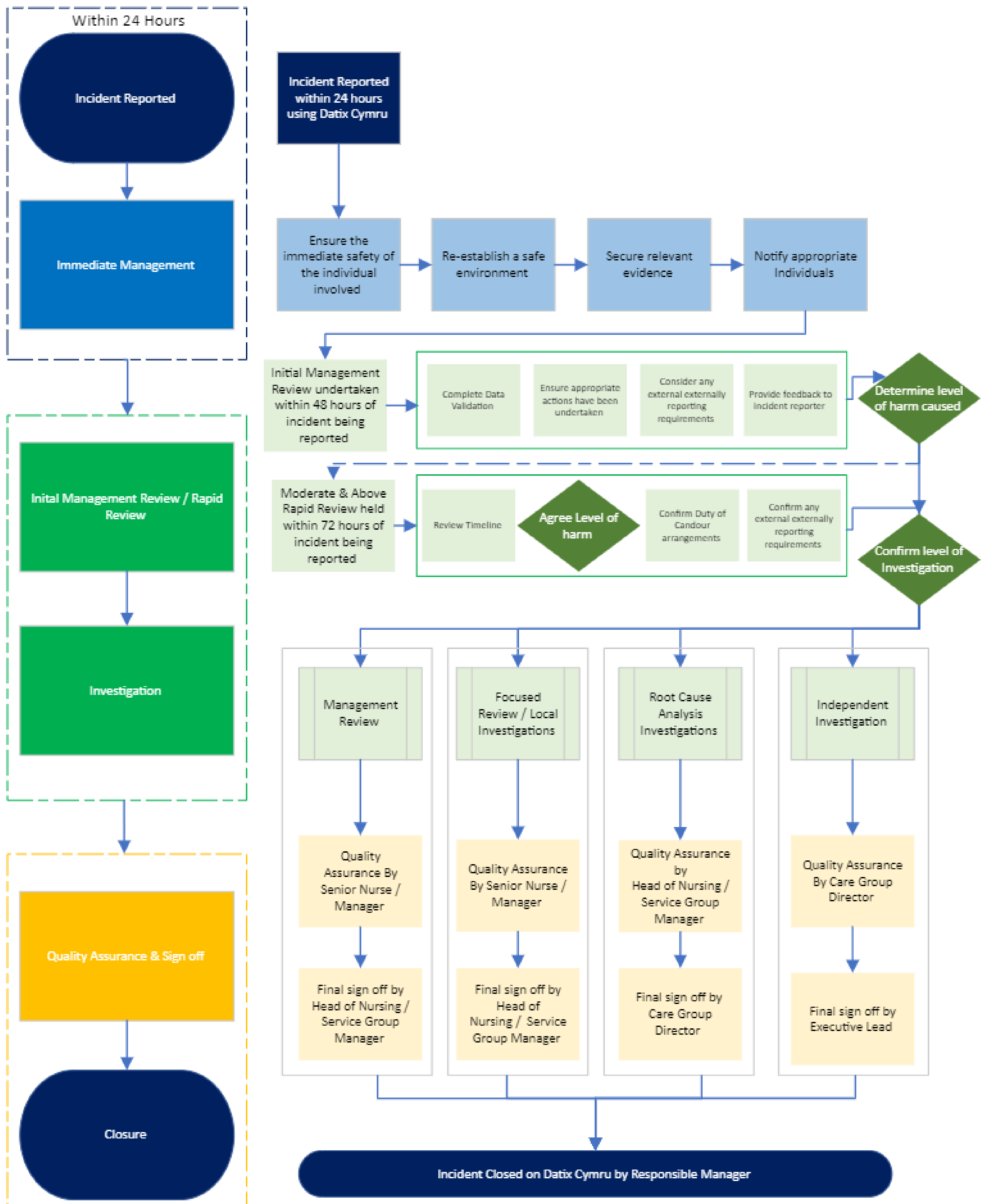
- Enables early action to occur so that likelihood of recurrence is reduced;
- Enables a review of what measures are in place to prevent incidents;
- Fulfils the Health Board's legal and statutory obligations to record and report certain defined incidents;
- Provides an early warning of potential complaints or litigation and helps identify any likely litigation cost to the Health Board;
- Alerts the Board to conditions of risk.

Essential to an effective incident management process is the timely and accurate updating of the Datix Cymru Incident Functionality. This MUST be undertaken at all stages of the process.

Support, Training and Resources

Support in relation to incident management can be obtained from the Business Intelligence Team (Datix Cymru), Quality & Safety Teams and Health & Safety Teams.

Section 2: Incident Reporting & Management At A Glance



Section 3: Roles & Responsibilities

The Board

Statutory responsibility for ensuring compliance with the incident reporting system lies with the Health Board, with the following reporting arrangements to provide assurance:

- All Major or Catastrophic incidents must be immediately reported to the appropriate Executive Lead and Chair of the Health Board.
- The Health Board will be provided with an Annual Concerns Report
- The Quality & Safety Committee and relevant Sub-Committees will receive quarterly reports detailing trends, themes and lessons learnt
- Care Groups will receive regular reports detailing trends, themes and lessons learnt.

Chief Executive

The Chief Executive has overall accountability, on behalf of the Health Board, for ensuring the implementation of this policy throughout the organisation.

Executive Directors

Executive Directors delegate their responsibilities for day to day matters to the designated Care Group Directors, Service Managers and professional leads for accurate reporting, investigation and ensuring that learning is identified and appropriate action is taken to reduce incidence of similar issues arising again.

Responsible Directors / Managers

Care Group Directors, Service Managers and professional leads will be responsible for ensuring that appropriate arrangements are in place within their areas for the reporting, investigation and follow up of incidents in accordance with this policy. Furthermore these Directors / Managers are responsible for the review of data on incidents in order to identify and monitor trends/problems, and for taking appropriate action. In addition they will be responsible for sharing Organisational Learning and ensuring that lessons are shared across the Health Board i.e. across Care Groups.

All Staff

Staff are responsible for:

- Reporting and escalating incidents in accordance with this policy and cooperating where appropriate in any subsequent investigations
- Engaging in learning and outcomes from investigations
- Raising concerns to their line manager through the incident reporting system or as outlined within 'Speaking Up Safely' regarding the delivery of care / services to patients
- Raising concerns about the safety of their environment or work activities, in line with the Health Board's Health & Safety policy.

Executive On Call

The Executive on call is responsible for the application of this policy in the event of incidents occurring out of hours. All major or catastrophic incidents should be reported immediately to the Executive on call.

Independent Contractors and Commissioned Services
There is no contractual obligation for Independent Contractor Services to report incidents to the Health Board. However, they are encouraged to work with the organisation in promoting safer working practices and sharing lessons learned. These include:

- Incidents which have occurred in a particular practice, where others would benefit from the shared learning and
- Incidents which have occurred in secondary care, and need to be referred back for investigation, but have become evident in primary care

Independent contractors and Commissioned Services are requested to:

- Complete the electronic incident report form
- Investigate, and discuss if appropriate in the practice team meetings
- Implement changes if appropriate
- Share lessons learned

It is the responsibility of the Independent Contractor Services and Commissioned Services to have systems in place for reporting and managing incidents as part of their governance arrangements. The Health Board is required to monitor this as part of their contractual arrangements.

Section 4: Incident Reporting
All Incidents should be reported using the on-line incident reporting system (Datix Cymru) **within 24 hours** of the incident being identified unless there are exceptional circumstances. The online form is accessible from the **Health Board intranet**. A guide for all staff, on how to use the online incident report form, is accessible from the same location.

Where/if there are exceptional operational circumstances that present difficulties in accessing the online reporting facility, an electronic (attached to an email) or paper based version should be completed and forwarded to the line manager, who will ensure that the information is subsequently reported using the online reporting system.

As far as possible, the person most directly involved in the incident should complete the incident report.

The reporter will make a judgement on the actual outcome of the incident using the Level of Harm Grading Framework.

The assessment of the severity should not delay the completion / submission of the incident report. The reporter should make the most reasonable assessment possible based on the information available at the time. In determining the severity of the incident, the reporter should consider the harm attributed by an action or inaction by the Health Board. The grading of an incident is subject to review throughout the review and investigation process as facts and issues emerge.

On clicking the 'Submit' button, the reporter of the incident will receive an instant, on screen, acknowledgement of the incident report having been received.

Section 5: Immediate Management of Incidents

a. Notifications / Initial Contacts

Each Department, Service, Care Group Leads should define its specific arrangements for the following:

- Incidents occurring within normal working hours (Monday-Friday, 09.00 – 17.00)
- The senior person on duty to be informed of any safety incident
- The process of escalation for externally reportable incidents
- Incidents occurring outside normal working hours
- Notifying the On-Call Manager of serious incidents occurring outside of normal hours and the action being taken.

These arrangements should be communicated to all staff.

b. Immediate Safety of the individual involved

The responsible manager will ensure the immediate safety and care of the individual involved. Where the person has sustained an injury, an appropriate level of examination and treatment must be offered.

Where the person involved is a patient consider if any safeguarding action and referral is required. If the patient is not an inpatient, this might include referral to inpatient services. If the referral is declined, this should be documented in the medical records.

The consultant or lead professional in charge of the patient's care must be informed, who should consider the communications with the patient/relatives/carers at this time (refer to Duty of Candour).

If the incident occurs in a community setting, and it is considered that the GP should be made aware, the patient should be advised to contact the GP, or the member of staff should personally notify the GP as soon as practicable after the incident. If the incident is sufficiently serious, the GP should be notified immediately and/or an ambulance should be called.

If the incident relates to the use of equipment, disconnect or isolate the equipment and refer to Clinical Engineering for medical devices or contact the Estates Department in relation to non-medical devices. Refer to equipment section.

A record of a patient safety incident should be written in the patient’s clinical notes in addition to completion of an incident report on Datix Cymru. However, the incident report itself and any subsequent investigation notes do not form any part of the patient’s record and it should not be printed and filed in the patient’s clinical notes.

When an inpatient has been the subject of an incident, the discharge letter sent to the patient's GP should contain summary details of:

- the nature of the incident and related care and treatment
- the current condition of the patient
- key investigations
- recent results
- prognosis

c. Re-establishing a safe environment

Appropriate action must be taken to contain the situation, as agreed with the responsible manager/senior person on duty. If a significant event has occurred, the scene may need to be protected to undertake the investigation. There should be notification to or advice sought from specialist advisors/departments, as necessary (e.g. Health & Safety, Infection Control, Pharmacy, Clinical Engineering etc). Consideration should be given in relation to the safety and impact on other patients, public, staff and other services.

d. Secure relevant evidence

1. Equipment

It is important that there is a common sense approach and that there is discussion within the Care Group/Unit or with relevant specialists in any given situation.

Where it is suspected that drugs may be defective/contaminated/out of date etc, they must be taken out of use and contact made with Pharmacy for advice.

If the incident is serious all the relevant evidence must be preserved and kept secure. There may be a police investigation as well as a Health Board investigation. If necessary, secure the area, to ensure that everything is left untouched. Lock doors and put up signs clearly stating that no-one is permitted to enter the area. Explain the reason for the closure to patients, relatives, visitors and staff in the vicinity, ensuring that confidentiality is not breached.

If the incident involves the use of medical equipment, the item(s) of equipment must be removed from use, appropriately labelled and retained for inspection by the Clinical Engineering Service or other specialist departments.

If the incident involves the use of non-medical equipment, it must be removed from use, appropriately labelled and retained for inspection by Estates or IT. All accessories and disposables/consumables must be retained intact. Settings must not be adjusted. The equipment must be clearly labelled as 'Evidence - Not To Be Used' and it must be stored in a place and manner such that it cannot be accidentally or intentionally brought back into use in the intervening period until all investigations are complete and formal approval has been given for the re-introduction of the item. The supplier or manufacturer of an item should not be contacted at this particular time.

Advice can be sought from specialist departments, the Patient Safety or Health & Safety Teams.

2. Witness recollection of events

Any witnesses to an incident should complete a recollection of events form on which they should record the facts of what they witnessed. These can be found on the SharePoint site.

These can be attached as a 'Document' to the on-line incident report, by the incident reporter. If this is not yet available at the time of completing the on-line incident report, it should be attached to the incident record in the Datix Cymru system, when it is available, in accordance with the arrangements defined by the Care Group.

Witnesses should be reminded that no allegations are being made against them and that the purpose of providing a report is simply to obtain factual information that could be of assistance in establishing the facts leading up to the incident.

A formal statement may also be requested later, as part of an investigation of an incident.

Section 6: Management Review & RAPID Review

Incidents should be thoroughly investigated as appropriate to ensure that lessons are learned and, the risk of recurrence removed if possible, or minimised. A robust and timely investigation will also provide reassurance to patients, their families, carers and colleagues. The level of investigation will be proportionate and determined by key factors including the level of severity (actual or potential) and the mechanism for investigations available i.e. clinical review, RCA methodology, referral to safeguarding. The Patient Safety or Health & Safety team should be consulted for advice and support if there are any concerns in relation to the level of investigation required.

The purpose of the investigation is for learning from events. The investigation will determine fully the issues involved, identify the cause, ascertain the circumstances, identify consequences and implement improvements to ensure the risk of similar incidents is minimal.

a. Initial Management Review & RAPID Review

The initial review of an incident must be completed on the Datix Cymru system by the responsible manager within 48 hours of the date that the incident is reported and include as a minimum:

- Confirmation that the matter reported constitutes a reportable incident
- Determine the perceived level of harm caused as a result of the incident
- Data validation to ensure all the information is accurate and comprehensive. A data validation checklist is available **here**
- Ensure that all appropriate actions in response to the incident have been taken or are underway. This includes commissioning an appropriate proportionate investigation
- Ensure that all appropriate communications are undertaken
- Ensure that appropriate and timely feedback is provided to the incident reporter
- Consider any externally reportable requirements i.e. NHS Executive, Health & Safety Executive, Healthcare Inspectorate Wales, Human Tissue Authority, Information Commissioner

As part of the review, the incident should be assessed for future risk potential in line with the Health Boards Risk Assessment Procedure.

b. Rapid Review

The decision whether to convene a RAPID review meeting should be based around the nature, complexity and level of harm of each incident. As a minimum a RAPID review will take place for all incidents identified as moderate and above following initial management review. The Care Group Quality & Safety Team or your local Health and Safety Coordinator can offer advice and support in assessing each incident on a case-by-case basis. Details of the Care Group Quality & Safety Teams can be found **here** and Health & Safety Teams can be found **here**

A RAPID review meeting, where possible, should be held within 72 hours of an incident being identified to ensure the discussion and investigation process is commenced in a timely manner. The incident is reported to the Care Group Quality & Safety Team or your local Health and Safety Coordinator who will organise the RAPID review alongside the clinical lead for the area in which the incident occurred. This can be held either in person or virtually to maximise the opportunity for attendance. Those in attendance should be drawn from the local area within which the incident occurred, but who were not directly involved. This may include, but is not limited to, Head of Nursing, Lead Nurse, Senior Nurse, Ward Manager, Service Lead, Medical and Governance representatives. The level of accountability and staff present will be relevant to the seriousness / impact of the incident and will need to be agreed, for example a Never Event should be led by an Executive Level chair or nominated Deputy. Terms of Reference for the Rapid Review Meeting can be found **here**.

Where an incident is of a serious nature, likely to require central Patient Safety Team or Health & Safety Team involvement or advice in a complex case, a representative from the team can be invited to attend. Details for the central Patient Safety Team can be **here** and Health & Safety Teams can be found **here**.

The RAPID review should follow the agreed **template**, although remain flexible to allow for the flow of discussion between attendees. Minutes should be kept of all discussions and documented within the proforma, and this should be uploaded to the documents section of Datix Cymru as soon as possible following the meeting. The team should allocate this task at the beginning of the meeting to ensure it is completed.

The tabular timeline must be completed prior to the RAPID review meeting taking place.

The main purpose of the RAPID Review meeting is to:

- Review and consider the findings of the initial scrutiny of the incident
- Agree the perceived level harm that has occurred as a result of an action or inaction by the Health Board
- Identify any immediate actions required to mitigate the risk of re-occurrence
- Confirm Duty of Candour arrangements have been made and agree the lead for further Duty of Candour discussions
- Set the Terms of Reference (ToR) and scope for the investigation
- Agree the lead Investigator and supporting investigation team
- Identify any risks associated with the incident / complex complaint
- Consider whether an early warning notification requires submission
- Lay out arrangements for any further investigation team meetings
- Confirm timescales for the investigation (this will be between 30 and 120 working days)
- Identify a Family / Staff Liaison Officer

The outcome of this meeting will be summarised on the management review form on Datix Cymru (under incident investigation) or on a Rapid Review **document** which must be uploaded onto Datix Cymru by either the responsible lead from the area or the Patient Safety Improvement Manager (to be agreed during the RAPID Review Meeting. This documentation acts as a source of assurance for the Care Group Triumvirate Team and Executive Directors that appropriate actions have been taken to ensure the immediate safety of the patient(s)/staff following an incident and to mitigate risk of re-occurrence.

Section 7: Duty of Candour for Patient Safety Incidents
All healthcare professionals have a duty of candour. This is a professional responsibility to be honest when things go wrong, providing truthful information and an apology. An apology *'means an expression of sorrow or regret in respect of a notifiable safety incident'.*

The Duty of Candour is a legal requirement for NHS Organisations in Wales to be open and honest with patients receiving care and treatment. This is outlined in the Health and Social Care (Quality and Engagement) (Wales) Act 2020.

The Duty of Candour applies if the care we provide has, or may have contributed to unexpected or unintended moderate or severe harm, or death.

A summary of the Duty of Candour procedure is outlined below:

- On first becoming aware that the Duty of Candour applies, the NHS must notify the patient or a person acting on their behalf. This contact should be 'in person' which means by telephone, video call or face to face.
- The purpose of the 'in person' notification is to offer an apology, provide an explanation of what is known at that time, offer support, explain the next steps and provide point of contact details.
- Once the 'in person' notification has been made, a written notification must also be sent to the patient or the person acting on their behalf within five working days. The purpose of the written notification is to confirm everything that was said in the 'in person' notification.
- The NHS will undertake an investigation of the incident to determine what happened and why and what can be done to prevent it from happening again. This will be undertaken in accordance with the NHS Wales 'Putting Things Right' Procedure.

These discussions can form part of the initial meeting with the family which should take place as soon as possible following the incident. It is important to provide the family with an opportunity to ask questions. It is essential that you do not have to wait until the outcome of an investigation to speak to the patient and/or family, but you should be clear about what has and has not yet been established.

The questions raised by the patient and/or family should be reflected and answered within the investigation and final report.

It is essential the patient knows whom to contact in the healthcare team to ask any further questions or raise concerns. You should also give patients information about independent advocacy, counselling or other support services that can give them practical advice and emotional support. You should record the details of your apology in the patient's clinical record. Note that an apology is not an admission of culpability and will not be viewed as such. It is simply the right thing to do when something goes wrong.

When apologising to patients and explaining what has happened, it is essential that staff realise that there is not an expectation to take personal responsibility for the incident, however the patient has the right to receive an apology from the most

appropriate team member regardless of who or what may be responsible for what has happened.

Healthcare professionals (colleagues) must be open to take part in reviews and investigations when requested. They must support and encourage each other to be open and honest, and not stop someone from raising concerns. They must encourage a learning culture by reporting adverse incidents that lead to harm, as well as near misses.

Full Information in relation to the Duty of Candour requirements can be found **here**

Section 8: Support for Patients & Families

At the start of the investigation a patient / family liaison officer who will act as the single point should be identified where appropriate. The Family Liaison Officer will support the patient or family with any questions that they wish to include in the investigation, provide regular progress updates in relation to the process and an expected timescale for completion.

A range of services are available to support patients and families, details of which can be found **here**.

Section 9: Support for Staff

The 'assist me' pack has been designed to assist managers to support colleagues when involved in a traumatic/stressful incident, complaint or claim. In the majority of cases this will be through their Line Manager as the first point of contact. In cases where this is not appropriate, a point of contact 'staff liaison' will be identified by the Line Manager. 'Assist me' information and documentation can be found on the **Incident Management SharePoint Pages.**

The Line Manager should arrange a "one to one" meeting with the individual member of staff concerned to discuss the issues identified, offer support and determine the level and type of further support required by the member of staff which may be through internal or external sources i.e. People's Services, Occupational Health, Wellbeing Services, and/or Staff Side representatives.

Debrief Sessions

Following an incident, particularly those resulting in significant harm, a debrief session should be arranged to support staff through the process, providing a safe space for everyone to speak openly and honestly without feeling judged. It will also provide an opportunity for staff to engage in reflective practice and identify practical solutions in the immediate aftermath of the incident occurring.

The aim of the session will be to identify:

- What it is everyone wants from the session?
- How everyone is feeling
- What went well – what were the strengths
- What individuals are worried about
- Any system failures or incidental learning
- Suggested solutions or recommendations
- The next steps

In addition it should be ensured that everyone leaves the meeting feeling they know what is expected of them and how to access support, wellbeing, Clinical Psychologist.

Information for Health Board staff wellbeing and support services can be accessed by visiting the **Wellbeing SharePoint Services** .

Feedback following an incident

Following the completion of an incident investigation, staff involved should be contacted via phone/email/letter to be given the opportunity to be invited to receive formal feedback and discuss the findings of the investigation. It is important to emphasise that feedback from an investigation will not be a punitive process, but one of support and learning in a non-judgemental way and will be confidential. If there are any concerns about an individual's professional competency or conduct, education, support and learning will be provided by the Health Board for the individual and wider team learning. Staff may also be invited to attend a learning event, created from the findings of the incident and investigation.

Section 10: Externally Reportable Incidents

The Health Board has a duty to inform certain external agencies of specific types of incidents. These include the Health and Safety Executive (HSE) and National Reporting to NHS Executive. Details of other types of incidents where external reporting should be considered can be found here.

Health and Safety Executive (RIDDOR)

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) requires employers and others to report certain types of injury, some occupational diseases and dangerous occurrences that **"arise out of or in connection with work"**. Generally, this covers incidents associated in some way with work activities, equipment or environment, including how work is carried out, organised or supervised.

RIDDOR places a legal duty on employers, self-employed people and people in control of premises to report:

- **Death** - the death of any person, whether or not they are at work if it results from a work accident or occupational injury;
- **Major Injury** – accidents or incidents which result in an employee or a self employed person suffering a major injury;
- **Over-seven-day injuries** - accidents or incidents which result in an employee or a self-employed person dying, suffering a major injury, being absent from work or unable to do their normal duties for more than **seven** consecutive days (not counting the day of the accident but including non-work days such as weekends, rest days or holidays);
- **Injuries to people not at work** - accidents or incidents which result in a person not at work (e.g. a patient, service user, visitor) suffering an injury and being taken to a hospital, or if the accident happens at a hospital, suffering a major injury which would otherwise have required hospital treatment;
- **Occupational Diseases** - an employee or self-employed person suffering one of the specified occupational diseases;
- **Dangerous Occurrences** - specified dangerous occurrences (near miss accidents or incidents), which may not result in a reportable injury, but have the potential to do significant harm.

When there has been an incident which is RIDDOR reportable the Health, Safety and Fire Team must be contacted with the incident reference number. A RIDDOR form will be sent to the Manager to fill in. This must be completed and returned to the Health, Safety and Fire Team as soon as possible so that the Health and Safety Executive (HSE) can be informed. Staff who are absent from employment for over-seven-days due to injuries must be reported to the HSE within fifteen days. All other RIDDOR reportable injuries must be reported to the HSE within a maximum of ten days of the incident occurring.

The Regulations require that the Health Board keeps a record of an incident if the employee has been incapacitated for more than **three** consecutive days (absent from work or unable to do their normal duties for over-three-days). This is recorded via the incident reporting system. It is important that the Health, Safety and Fire Team is notified of the length of time an employee is off work or has been incapacitated.

More detailed information can be found on the **Health & Safety SharePoint Pages**.

National Reporting to NHS Executive

The following definition of a nationally reportable patient safety incident applies:

A patient safety incident which caused or contributed to the unexpected or avoidable death, or severe harm, of one or more patients during NHS funded healthcare.

The above definition of an incident is applicable to all NHS funded services, regardless of speciality, delivered in all secondary or primary care settings, including community based services. When considering whether to report an incident, the following should be applied:

- a patient safety incident will be nationally reported within seven working days from the occurrence, or point of knowledge, if it is assessed or suspected an action or inaction in the course of a patient's treatment or care, in any healthcare setting, has, or is likely to have caused or contributed to their unexpected or avoidable death, or caused or contributed to severe harm
- as it will not always be possible to determine the extent to which a patient safety incident caused or contributed to the harm or death of a patient within seven working days, responsible bodies should report in line with the criteria where it is known, and/or suspected, that a patient safety incident has caused or contributed to harm or death. In this scenario, for clarity, the responsible body should specify on the form that the position is unclear and/or investigations are ongoing. Incidents can be downgraded at a later date as outlined **here**
- all such incidents must be reported to the NHS Executive within seven working days from the occurrence, or point of knowledge.

Specific National Incident Categories

Whilst these fall under the broad definition of a nationally reportable incident as set out above, they have been drawn out in the policy to ensure clarity on expectations around national reporting.

- Suspected homicides where the alleged perpetrator has been under the care of mental health services in the past 12 months
- In-patient Suicides
- Maternal Deaths
- Never Events (current list is available **here**)

- 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
- Unusual, unexpected or surprising incident

In addition to those incidents identified above, avoidable pressure damage and patient falls should be reported retrospectively following approval at the appropriate scrutiny panel.

Once approved by the Care Group Director, Nationally Reportable Incident Forms should be submitted to the Corporate Patient Safety Team for processing and submission to the NHS Executive. The Care Group should outline their arrangements for the completion and approval of Nationally Reportable Incident Notifications Forms.

Section 11: Safeguarding Considerations

Consideration of safeguarding must be made at the start, during and the end of any investigation. Where concerns are identified a report must be made, with the relevant referral form completed and sent to the Multi Agency Safeguarding Hub (MASH).

The Health Board has a legal duty to report safeguarding concerns so if there is any doubt in relation to whether there is a safeguarding element or not to an incident, please contact the Corporate Safeguarding Team, the MASH or the Emergency Duty Team if out of hours to discuss.

A brief overview of adults and children's safeguarding is outlined below to help with consideration during investigations.

An adult at risk is defined as anyone:

- Over 18
- Is, or may be, in need of community services due to having a mental or other disability
- Is, or may be, unable to take care of him/herself or are unable to protect him/herself.

A child at risk is defined as a child who:

- Is experiencing or is at risk of abuse, neglect or other kinds of harm;
- Has needs for care and support (whether or not the authority is meeting any of those needs).

It is important to note:

- The use of the term 'at risk' means that actual abuse or neglect does not need to occur, rather early interventions to protect a child at risk should be considered to prevent actual harm, abuse and neglect.
- The two conditions necessary to demonstrate a child is at risk of abuse or neglect ensures that protection is provided to those with care and support needs who also require actions to secure their safety in the future.
- Risk of abuse or neglect may be the consequence of one concern or a result of cumulative factors.

In relation to Safeguarding, harm is defined as:

- Ill treatment including sexual abuse, neglect, emotional abuse and psychological abuse.
- Impairment of physical or mental health (including that suffered from seeing or hearing another person suffer ill treatment).
- Impairment of physical intellectual, emotional, social or behavioural development (including that suffered from seeing or hearing another person suffer ill treatment).

Child deaths

Reporting of a child death in line with the Procedural Response to Unexpected death in Children (PRUDiC) process are outlined below:

- An Early Warning Notification should be submitted to Welsh Government for all PRUDiC cases
- Not all PRUDiC cases need to be reported as a Nationally Reportable Incident
- Some PRUDiC cases **may** also need to be reported to the NHS Executive as a Nationally Reportable Incident if the criteria is met. This will depend on the individual circumstances of the case and whether it meets the criteria set out above.
- Good practice recommendation is that a RAPID review meeting takes place within the Care Group following the PRUDiC meeting to establish if the Nationally Reportable Incident threshold is met. Please consider whether the circumstances surrounding the child death meets the criteria for referral for a Child Practice Review.
- Each PRUDiC case should be assessed on an individual basis and where the NHS organisation considers the underlying incident meets the criteria, then this should be reported as a Nationally Reportable Incident at the earliest opportunity. Cases can be reported retrospectively if the assessment changes at any time during, or following completion of the review.

All child deaths will be subject to notification to the Child Death Review programme and will be completed by the Corporate Safeguarding Team.

Full information and contact details in relation to Safeguarding and Public Protection can be found on the Health Board's **SharePoint Pages**.

Section 12: Proportionate Investigation

The level of the investigation should always be proportionate to the issue identified and should be considered on a case-by-case basis. The nature, severity and complexity of each incident will determine the appropriate level of investigation.

The levels of investigation can be broadly categorised as the following:

- Management Review
  Initial management review will be sufficient for non-complex, straightforward incidents, normally resulting in no or low harm that are completed fully within the Datix Cymru system.
- Focused Review / Local Investigations
  A proportionate investigation for less complex incidents, which can be managed, by individuals or small groups at a local level. For this type of investigation a focused review investigation tool must be completed within the Datix Cymru system. Where a focused review tool is not available the proportionate

investigation screen must be completed within the Datix Cymru system. It is recommended that is supported by a timeline of events and SBAR report.
- Root Cause Analysis (RCA) Investigations
  This is a comprehensive investigation suited to complex issues, which should be managed by a multidisciplinary team involving experts and/or specialist investigators. Incidents requiring this level of investigation usually result in severe harm or death.
- Independent Investigation (Internal or External)
  This is an independent investigation of serious incidents where the integrity and objectivity of an internal investigation would be difficult to maintain. The investigator and team are all independent of the organisation where the incident occurred. Examples of incidents, which may indicate an independent investigation, include incidents of high public interest, those attracting media attention or Mental Health related homicides.

For some incidents, the level of investigation required may be clear from the outset, however, where it is not clear this can be determined following the initial management review or a RAPID review meeting. A never event must always have an RCA investigation as minimum.

Investigation tools
There are several analysis tools available to support the levels of investigation highlighted above and these should be uploaded to Datix Cymru or included in the report to demonstrate thought processes and decision-making.

These tools support in:
- Gathering information
- Identification of care or service delivery issues, contributory factors & good practice
- Analysis of findings, identification of causal factors, root causes and lessons learned
- Documenting the investigation findings

The team should choose which tools are required for the type of investigation being undertaken to identify root causes and contributory factors, however the following tools are recommended for their thoroughness and reliability.

Fishbone or Cause and Effect Diagram
A fishbone diagram, as the name suggests, mimics a fish skeleton. The underlying problem is placed as the fish's head (facing right) and the causes extend to the left as the bones of the skeleton; the ribs branch off the back and denote major causes, while sub-branches branch off the causes and denote root causes. You may wish to use the contributory factors classification framework below to help you.

Use this tool when you are trying to determine why a particular problem is occurring. It will help you to fully understand the issue and to identify all the possible causes – not just the obvious.

How to use it?
1. Agree on a problem statement (effect) and consider it in detail: who is involved, when and where it occurs. Engage your team to agree the problem

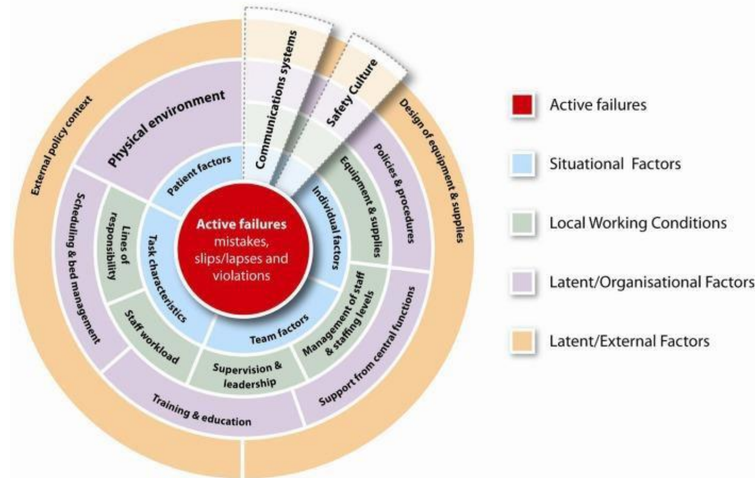
statement. Include as much information as possible in the 'what', 'where', 'when' and 'how much' of the problem and use data to specify the problem if possible.
2. Write the problem in a box and draw an arrow pointing towards it.
3. Aim to construct the diagram with the people involved in the problem.
4. Explore the major categories of causes of the problem. Write the categories of causes as branches from the main arrow.
5. Further explore all the possible causes of each major category branch
6. Keep exploring causes for each branch until you cannot delve any deeper.
7. You can use a cause and effect diagram as a working document that is updated as and when you collect more data, or to test possible solutions.
8. Where contributory factors are clustered most heavily on one spine of a fishbone diagram, are these linked to a single underlying cause?

<u>"5 Whys" Analysis Tool</u>
The simplest way of conducting the 'Five Whys' test is to simply write it down on a piece of paper. However, the fishbone above can help during the initial process of identifying problems. The diagram can reveal problems that may need the five whys for a deeper look. Then, you can gather all of the root-cause-effect relationships and evaluate which of them had the greatest impact on the original problem.

How to use it?

1. Agree on a problem statement and consider it in detail: who is involved, when and where it occurs. Engage your team to agree the problem statement. Include as much information as possible in the 'what', 'where', 'when' and 'how much' of the problem and use data to specify the problem if possible.
2. Write the problem in a box at the top of a page
3. Aim to construct the diagram with the people involved in the problem. You may get different answers from different people, but this will help you to evaluate all angles.
4. Now ask yourselves why did this happen and write the answer below your problem statement.
5. Keep asking 'why' until you exhaust all the underlying reasons behind the problem. You may not need five whys but be careful not to stop too early, otherwise you may not reach the ultimate root cause. If the problem is complex, you may need many more levels of why before you have exhausted them all.

<u>Yorkshire Contributory Factors Framework (YCCF)</u>
The Yorkshire Contributory Factors Framework is a tool which has an evidence base for optimising learning and addressing causes of safety incidents by helping reviewers and investigation identify contributory factors of incidents. Whilst a form is available for completion during the investigation, the contributory factors <u>MUST</u> be completed on Datix Cymru.



All template investigation tools are available on the **Incident Management SharePoint Pages.**

Redress arrangements for Patient Safety Incidents

In line with the requirements set out in Putting Things Right and Duty of Candour, investigations should consider if any failings identified constitute a breach of duty of care and require further investigation under Redress processes. Further guidance on breach of duty and qualifying liability investigations is included in the Concerns Policy & Procedures. Advice should be sought from the Health Board's Legal Services Team as part of the process.

Section 13: Action Planning and Completion of Learning

A SMART action plan should be aligned to the investigation that clearly sets out the actions that will need to be taken in response to the report to provide assurance. These actions should be pulled from the learning and recommendations that have been identified in the investigation.

Components of an Action Plan include:

- A well-defined description of the goal to be achieved
- Tasks/ steps that need to be carried out to reach the goal
- People who will be in charge of carrying out each task
- When will these tasks be completed (deadlines and milestones)
- Resources needed to complete the tasks
- Measures to evaluate progress
- Arrangements for sharing learning arising of out incident investigations

These actions should be added to Datix Cymru under the specific incident number for the investigation in order to robustly monitor completion. The evidence to support each action should be uploaded and saved to Datix Cymru for assurance and accessibility. The named individual on the action plan is responsible for ensuring the actions are completed and updating Datix Cymru, including relevant evidence.

Section 14: Quality Assurance & Final Sign Off

All incidents will be subject to quality assurance linked to the type and level of investigation undertaken. Whilst Care Groups will determine the granular detail of their

quality assurance, sign off and closure process they should be in the line with the following parameters:

Level of Investigation	Quality Assurance to be completed by	Final Sign off & Closure by
Management Review	Senior Nurse / Manager / Lead Nurse / Operational Manager	Head of Nursing / Service Group Manager
Focused Review / Local Investigations	Senior Nurse / Manager / Lead Nurse / Operational Manager	Head of Nursing / Service Group Manager
Root Cause Analysis Investigations	Quality & Safety Team Lead Nurse / Head of Nursing / Service Group Manager	Quality Assurance Panel Care Group Director
Independent Investigation	Care Group Director	Executive Lead

Quality Assurance Process & Sign off for Nationally Reportable Incidents

The quality assurance process differs slightly according to the level of investigation undertaken, with the depth of scrutiny and breadth of panel attendees increasing according to the level of investigation. Once the investigation is complete, the report and action plan will be submitted to the relevant Care Group Quality & Safety Team who will undertake quality assurance of the investigation using the agreed checklist and support the scrutiny of the report and action plan by a multi- disciplinary team within a Quality Assurance panel. The Terms of Reference Template can be found **here**.

The panel will decide whether the report meets key objectives according to the Health Board Quality Assurance template.

Once the panel have considered the documents, they will either return the bundle to the author for further amendments according to comments on the Quality Assurance template or confirm the bundle is suitable to proceed for closure. On agreement that the bundle is complete and ready for consideration for closure, the Quality & Safety Team will arrange for the approved bundle to be submitted for closure to the Central Patient Safety Team.

Once the investigation has been finalised to the satisfaction of the Quality Assurance Panel, Quality & Safety Team and Investigation teams, the incident can be progressed to closure.

A Nationally Reportable Incident closure bundle including the report, action plan and Quality Assurance checklist should be signed off by the Care Group Directors then forwarded by the Care Group Quality & Safety Team to the Patient Safety inbox, alongside the closure notification form. It will then be collated and forwarded to the Executives for sign off prior to submission to the NHS Executive.

Section 15: Escalation & Monitoring

Delays with process outlined within the framework will be escalated via the appropriate Care Group hierarchy.

Monitoring of the implementation of the Incident Management Framework will be undertaken via a number of mechanisms including:

- Corporate review by the Quality & Safety, Patient Safety, Health & Safety and Business Intelligence Teams
- Weekly audits of closed cases
- Reporting of incident management compliance via the Health Board's Governance Structure.