Cwm Taf Morgannwg University Health Board

Incident Management Framework

May 2022

For Revision July 2022

Chapter 1: The Framework Context

This incident framework has been developed to provide a structured overview of the incident management process within CTMUHB from start to finish. It is designed to guide staff in their decision-making and establish a standardised approach to incident management across the Health Board. It is important to remember that incident management and investigation is not intended to apportion blame, but to focus on essential learning that can be taken forward.

What is a concern?

A concern can include any complaint, claim or patient safety incident occurring from NHS funded care. A patient safety incident is "any unintended or unexpected incident which could have, or did, lead to harm for one or more people whilst in receipt of NHS-funded healthcare."

The Welsh Government's "Putting Things Right" guidance sets out how NHS bodies should effectively handle concerns according to the requirements of the NHS (concerns, complaints and redress arrangements) Regulations Wales (2011). You can access the regulations here: http://www.wales.nhs.uk/sites3/page.cfm?orgid=932&pid=50738. The guidance provides a single structure for the consistent, fair and transparent management of all concerns ensuring that the person affected is engaged and included according to the "Being Open" ethos. In accordance with the reporting requirements of the NHS Wales National Incident Reporting Policy (June 2021) https://du.nhs.wales/files/incidents/phase-1-policy-guidance-document-v1-0-pdf/. The Delivery Unit (DU) oversee and monitor the reporting duties on behalf of the Welsh Government.

How to report an incident?

The NHS in Wales uses a system called "DATIX Cymru" to log and manage all incident data. Anyone who has been given relevant access and associated training by the DATIX team can log an incident by opening the DATIX Cymru system, which can be found on SharePoint under the "Apps" section, or here http://ctuhb-intranet/dir/Datix/rai/_layouts/15/start.aspx#/SitePages/Home.aspx. Once logged in, staff are able to follow the simple instructions with boxes and drop-down menus to be completed. If you require further training or information on completing the form, or on managing incidents please contact the DATIX team or check their Sharepoint site http://ctuhb-intranet/dir/Datix/SitePages/Home.aspx where you can also find user guides.

TOP TIP! All staff identifiable information and all HB sites should remain anonymous throughout all reporting documentation and subsequent reports, whether this is internally to the HB or external. Use terms such as "Nurse A", "colleague" or "ward". In regards to patient identifiable information, the investigation team should consult with the patient/family at the start of the process and utilise whichever means of address they choose.

How to access support

You can gain support and advice from the ILG governance teams, they can be contacted here:

CTM.MerthyrCynonILG.Governance@wales.nhs.uk

CTM.RhonddaTaffElyILG.Governance@wales.nhs.uk

BridgendILGGovernanceIncidents@wales.nhs.uk

The central team are also happy to support with any further queries. They can be contacted via the Patient Safety Team inbox CTHB_Patient_Safety@wales.nhs.uk.

Chapter 2: The Process at a Glance

Immediate incident management

- Incident occurs - complete immediate make-safes.
- Datix submitted and escalation notification automatically sent via DATIX to senior management.
- Report to other bodies as relevant e.g. safeguarding
- Manager along with key stakeholders identifies what level of harm occured. If it is unclear, then proceed to RAPID review meeting. Where harm is moderate/severe/death, proceed to RAPID review meeting.
- **no/low harm** - complete level 1 (DATIX only) or level 2 (SBAR) investigation
- **moderate harm** - complete level 2 (SBAR) investigation or for more complex incidents, level 3 RCA investigation may be more sutiable.
- **Severe harm/death/Never Event** - complete level 3 (RCA) investigation.

Setting up the investigation

- RAPID review meeting to be held within 72 hours. To attend: senior nurse, CSG director, ILG representative, patient safety team representative (if required e.g. Never Events).
- During RAPID meeting, confirm level of harm. Does the incident meet criteria for NRI/LRI/ Never event?
- If the incident meets criteria for NRI/LRI/Never Event - notification to be completed within 7 working days and approved by ILG.
- ILG will submit notification to Central PS inbox. An LRI will be acknowledged and DATIX updated. An NRI/Never event will be forwarded for Executive sign off before submission to DU.
- RAPID meeting needs to decide: investigation team, lead investigator, level of investigation, patient/family liaison, staff liasion.

Undertaking the investigation

- Undertake the investigation:
- Investigation team should not be directly involved in the incident and at least one member must be RCA trained.
  - Complete a tabular timeline of events with clinical notes using CTMUHB template.
  - Collect and analyse information including any immediate actions/safety measures.
  - Collect and analyse staff statements from those involved using CTMUHB template.
  - Staff liaison and patient liaison to ensure both parties are kept up-to-date with the progress.
  - Generate report using appropriate template.
  - Generate action plan (SMART) using CTMUHB template.

Scrutiny and closure

- ILG Scrutiny of investigation report and action plan via QA process (CTMUHB template) and QA panel.
- Final sign off by ILG directors then sent to PS Inbox for processing.
- LRI acknowledged and approved for closure by PS team, DATIX record updated.
- NRI closure bundle collated and sent for Executive approval and final sign off before submission for closure to Delivery Unit. DATIX updated.
- Once reviewed by DU, either closure confirmation will be received or case returned to authors with queries. DATIX updated by PS team.

Chapter 3: Duty of Candour

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'.*

Every healthcare professional must be open and honest with patients when something that goes wrong with their treatment or care causes, or has the potential to cause, harm or distress. Research suggests patients expect to be told three things as part of an apology:

1. What happened?
2. What can be done to deal with any harm caused?
3. What will be done to prevent someone else being harmed?

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 body of the 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 something going wrong that was not their fault (such as system errors or a colleague's mistake). But 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.

Further information relating to duty of candour is set to be published shortly by the Welsh Assembly Government. A Bill has been prepared to bring the duty into effect in Wales in April 2023. The General Medical Council (GMC) and the Nursing and Midwifery Council (NMC) have produced joint guidance on the professional duty of candour: *Openness and honesty when things go wrong: the professional duty of candour.* This can be found here:

https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/openness-and-honesty-professional-duty-of-candour.pdf

Chapter 4: Safeguarding

Consideration of safeguarding must be made at the start, during and the end of any investigation and a report made and relevant referral form completed and sent to the Multi Agency Safeguarding Hub (MASH) if concerns are identified. We have legal duties 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. Useful links are also included for further reading. All this information is also available on the CTM intranet safeguarding page here:

http://ctuhb-intranet/dir/Safeguarding/SitePages/Safeguarding%20and%20Public%20Protection.aspx

Adults & Safeguarding

In CTM our aims are for adults, over the age of 18, to be protected from abuse, neglect or other kinds of harm and that they are prevented from becoming *at risk* of abuse. It is essential they live in an environment that promotes their wellbeing. It is essential that we comply with the below legislation: Social Services & Wellbeing (Wales) Act 2014 – Part 7, which can be accessed on the link below:

https://wcva.cymru/influencing/legislation/the-social-services-and-wellbeing-wales-act/#:~:text=The%20Social%20Services%20and%20Well-being%20%28Wales%29%20Act%20provides,promoting%20the%20integration%20of%20health%20and%20social%20care.

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.

Children & Safeguarding:

The Social Services and Well-being (Wales) Act 2014 defines a child at risk as a child who:

1. Is experiencing or is at risk of abuse, neglect or other kinds of harm;
2. 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.

Harm is defined as:

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

Child Death:

For any child deaths, the **Procedural Response to Unexpected Deaths in Childhood (PRUDiC, see Appendix 1)** process must be followed, the decision not to proceed with PRUDiC must be confirmed with Police**:**

- All PRUDiC cases should be reported to Welsh Government as an Early Warning (EW) notification;
- Not all PRUDiC cases need to be reported as a NRI;
- Some PRUDiC cases **may** need to be reported to the DU as an NRI, but this will depend on the individual circumstances of the case and whether it meets the criteria set out within Putting Things Right (PTR), which includes the incident being associated with NHS funded healthcare; for example: where a child has been actively involved with health services.
- Good practice recommendation is that a RAPID review meeting takes place within the ILG following the PRUDiC meeting to establish if NRI threshold is met. Please consider whether the circumstances surrounding the child death meets the criteria for referral for a Child Practice Review. http://ctuhb-intranet/dir/Safeguarding/Children/Supporting%20Documents/PHW%20PRUDiC%202018%20Final.pdf
- Each PRUDiC case should be assessed on an individual basis and where the NHS organisation considers the underlying incident meets the PTR criteria, then this should be reported as a NRI at the earliest opportunity. Cases can be reported retrospectively if the assessment changes at any time during, or following completion of the review.

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

For further support or questions:

- The Multi Agency Safeguarding Hub (MASH) **- 01443 742949 / 01656 643630** CTHBMashReferrals@wales.nhs.uk **CTMUHB Public Protection Nurse Specialists are based at each MASH**

- Emergency Duty Team (out of hours for immediate advice about safeguarding) 01443 743730

- Corporate Safeguarding Team are based at Ynysmeurig House - **01443 744800**

Chapter 5: The RAPID Review Meeting

The decision whether to convene a RAPID review meeting should be based around the nature, complexity and level of harm of each incident. The ILG governance teams can offer advice and support in assessing each incident on a case-by-case basis. See Appendix 2 for RAPID meeting terms of reference.

A RAPID review meeting, where at all 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 ILG governance team 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 clinical area within which the incident occurred, but who were not directly involved. This may include - but is not limited to - the ward manager, senior nurse, service Lead, medical and governance representatives. The level of accountability and staff who will be relevant to the seriousness of the incident needs to be clarified and agreed, for example a Never Event should be led by an executive chair.

Where an incident is of a serious nature, likely to require central Patient Safety Team involvement or advice in a complex case, a representative from the team can be invited to attend. The central Patient Safety Team can be contacted via email at CTHB_Patient_Safety@wales.nhs.uk

The RAPID meeting should follow the template outlined in Appendix 3, 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 as soon as possible following the meeting. The team should allocate this task at the beginning of the meeting to ensure it is completed.

Specific areas to be discussed during the RAPID meeting

1. Attendees should review all available information about the incident and agree the level of harm that occurred as a result (if any). The levels of harm: no harm, low, moderate, severe, death (see Appendix 4). **TOP TIP**: make sure you review the actual level of harm caused, rather than the eventual outcome for the patient.
2. The team should ensure that all *immediate* make-safes for both patients and staff have been clearly identified and that these have been sufficiently completed or allocated as actions to a designated individual.
3. Attendees should utilise all available information and the discussion around level of harm to decide upon the most appropriate level of investigation to be undertaken.
4. The team should discuss whether the incident meets the criteria for notification as either an LRI or NRI/Never Event, and where the threshold is met, designate an individual to complete and submit the notification to the ILG's governance team (for contact email addresses see chapter 1). This will then be submitted to the Patient Safety Inbox for acknowledgement and logging or onward referral where necessary.
5. Once the level of investigation has been decided, then the team should allocate an Investigation Lead, a designated staff and patient/family liaison.
6. The team should consider a possible breach of duty (BoD) and causation at the outset of the investigation process, although this may not be clear at this stage. Further training will be provided for staff on assessing BoD and causation.
7. The team should allocate any actions to specified staff members with clear timescales for completion, and agree on a schedule for reconvening to review investigation progress. The team should also agree on a timescale for the completion of the entire investigation (30, 60, 90 or 120 working days, ***90 and 120 working days are used ONLY in highly complex investigations or involving external bodies***).
8. The team should devise and agree Terms of Reference and scope to guide the subsequent investigation.

Chapter 6: Levels of Investigation and Investigation Tools

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. This could range from an investigation completed locally by one nominated individual, through to a complex, serious incident investigation managed by the Central Patient Safety Team. For some incidents, the level of investigation required may be obvious; however, where it is not clear this can be determined through a RAPID review meeting. The following levels of investigation give an indication of the proportionate response, however once the investigation has begun, this may be subject to change dependent upon the findings of initial enquiries.

Level 1 DATIX investigation

A concise investigation of non-complex, straightforward incidents, which can be investigated and documented within the DATIX incident record. A level 1 investigation is usually for incidents resulting in no or low harm.

Level 2 Concise, internal investigation

This is a concise investigation suited to less complex incidents, which can be managed, by individuals or small groups at a local level. The recommended investigation record tool for a level 2 investigation is the SBAR (see Appendix 2) alongside a chronology of events (see Appendix 1). Where an incident involves pressure damage or a fall, the nationally standardised investigation tool should be used (All Wales Pressure Ulcer Toolkit or falls investigation toolkit). Incidents requiring this level of investigation are usually Locally Reportable Incidents (LRI's) resulting in moderate harm.

Level 3 Comprehensive, internal investigation

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 and can be Nationally Reportable Incidents (NRI's). Where the incident is highly complex, involves cross-organisation issues or relates to a Never Event, this investigation may be undertaken by the Central Patient Safety Team. The recommended investigation tool for a level 3 investigation is a Root Cause Analysis (RCA) with the use of a chronology timeline and tools such as the "5-whys" or "fishbone" (see section on tools). The investigation requires documenting within a comprehensive RCA report.

Level 4 Comprehensive, independent investigation

This is an independent investigation of serious incidents where the integrity and objectivity of an internal investigation (such as undertaken at level 3) 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 a level 3 investigation, include incidents of high public interest, those attracting media attention or Mental Health related homicides. See Chapter 14 for further details on commissioning an independent investigation.

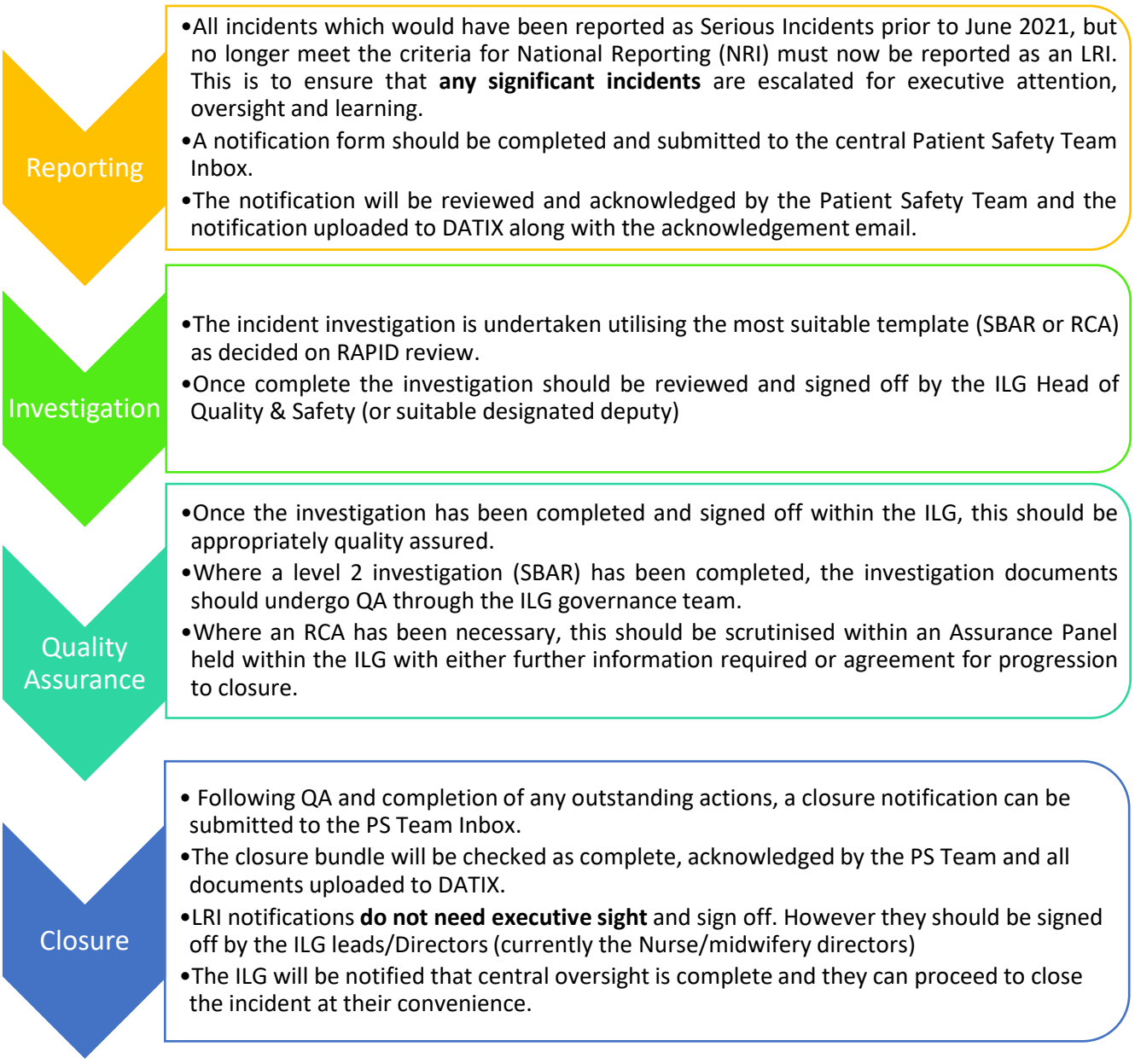
Choosing the timescale for the investigation.

The investigation team must indicate a predicted timescale for completion of the investigation, governed by the nature and complexity of the incident. Less complex incidents require a lesser timescale than those requiring RCA. As a flexible guide, level 2 investigations may take 30/60 working days and level 3 investigations 60 working days (in complex incidents, this may be extended to 90 working days) and level 4 investigations 90/120 working days.

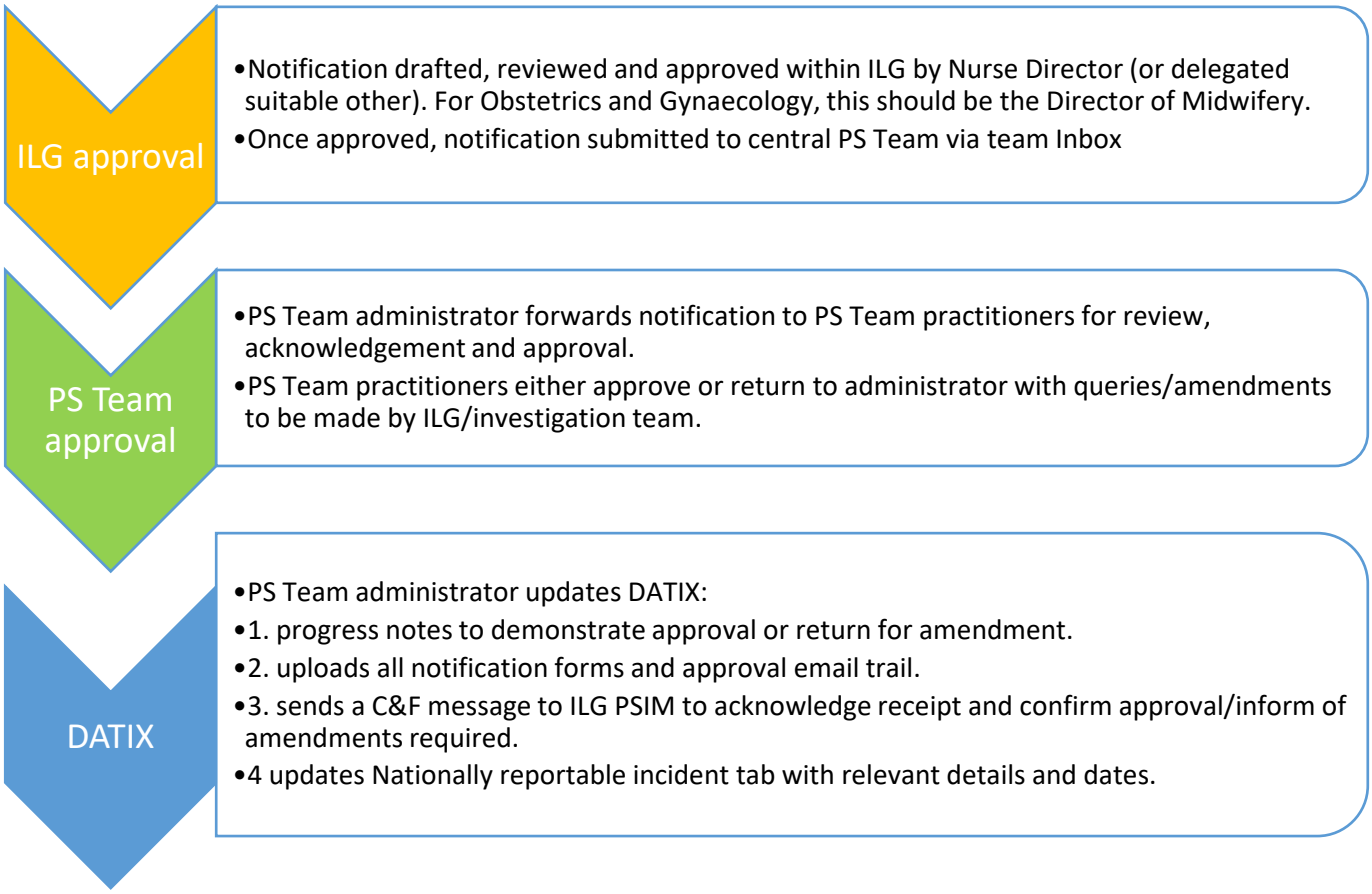
Chapter 7: Locally and National Reportable Incidents (LRI and NRI)

Locally Reportable Incidents (LRI) – LRI's replace what were known as Serious Incidents within the previous reporting system where they now no longer meet the threshold for reporting as Nationally Reportable Incidents. This includes, but is not limited to, avoidable falls of moderate severity, the death of a mental health patient in the community, drug errors where no harm was caused, admission of children to adult mental health ward admissions-guidance.pdf (gov.wales), AWOL with no harm. See Appendix 5 for a full outline of the process.

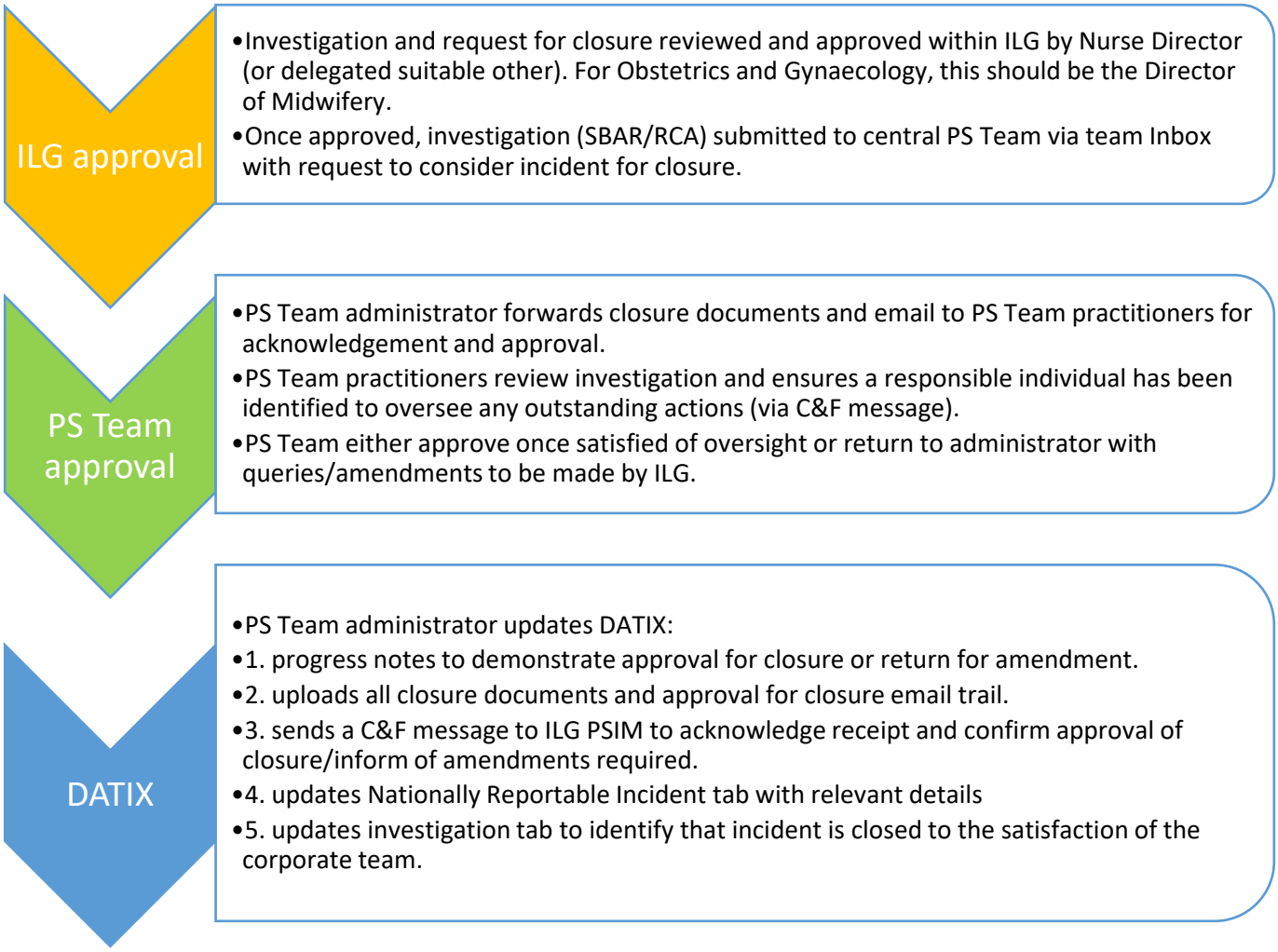
LRI's require a notification form to be submitted to the central Patient Safety Team Inbox (see chapter 1 for contact details) to ensure oversight and suitable notification processes (Appendix 6). The notification will be reviewed by the central team and acknowledged via email. The notification and acknowledgement email will be uploaded to DATIX by the PS Team. All LRI's are discussed within the weekly data meeting which includes the DATIX team and senior Quality and Safety and Governance representatives. It is important for patient safety and organisational learning that all incidents of significance are consistently escalated and investigated.



LRI notification process



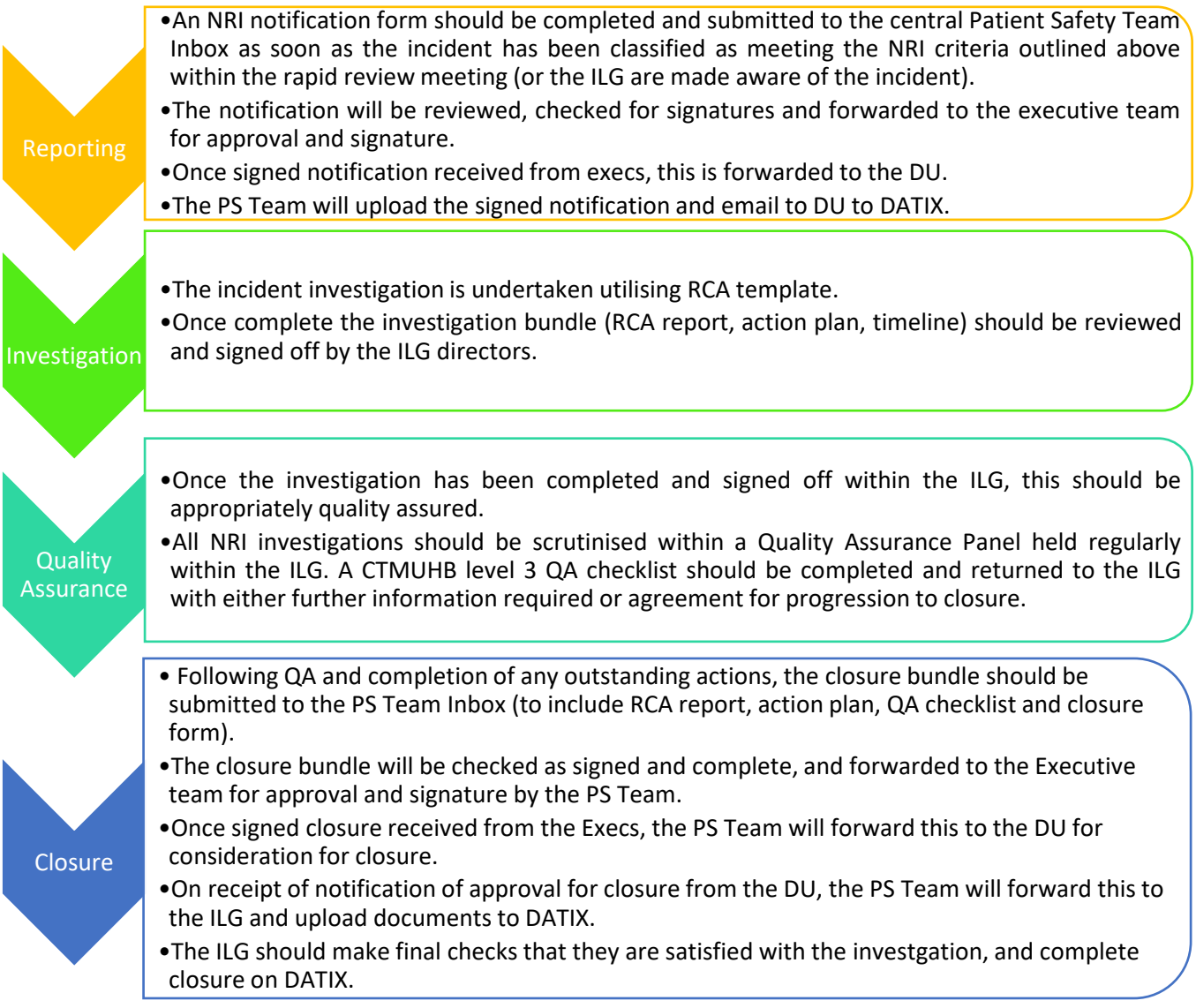
LRI closure process



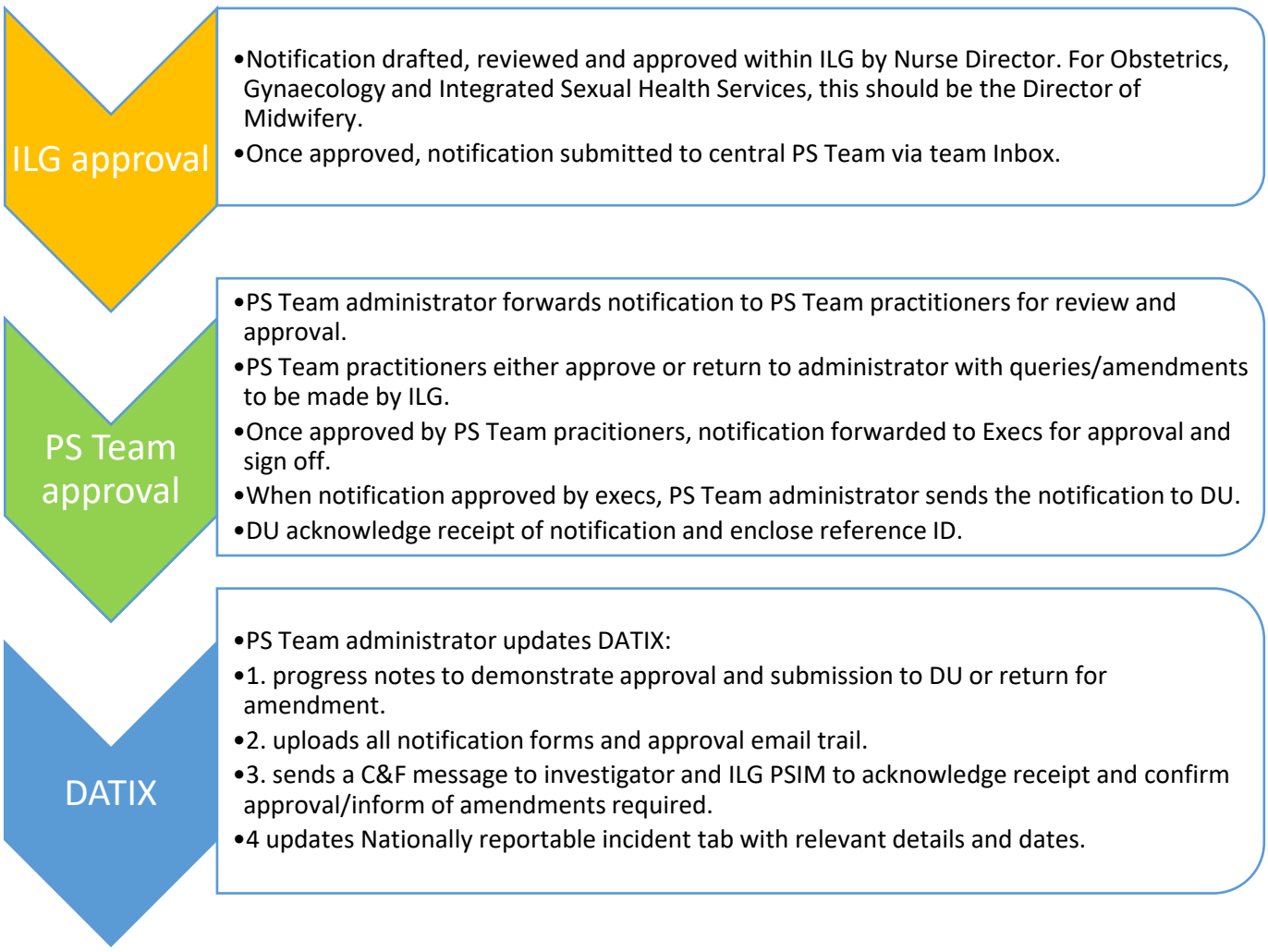
Nationally Reportable Incidents & Never Events (NRI/NE) - Where it is assessed or suspected that an action or inaction in the course of a service user's treatment or care, in any healthcare setting, has, or is likely to have caused or contributed to their unexpected or avoidable death, or contributed to severe harm, this should be nationally reported to the DU. There are several specific areas, which automatically meet the criteria for NRI:

- Suspected homicides where the alleged perpetrator has been under the care of the mental health service in the past 12 months.
- Inpatient suicides
- Maternal deaths
- Never events (a list of never events can be found here: never-events-list-2018-and-assurance-review-process.pdf (gov.wales))
- Incidents where the number of patients affected is confirmed to be significant.
- Unusual, unexpected or surprising incidents.

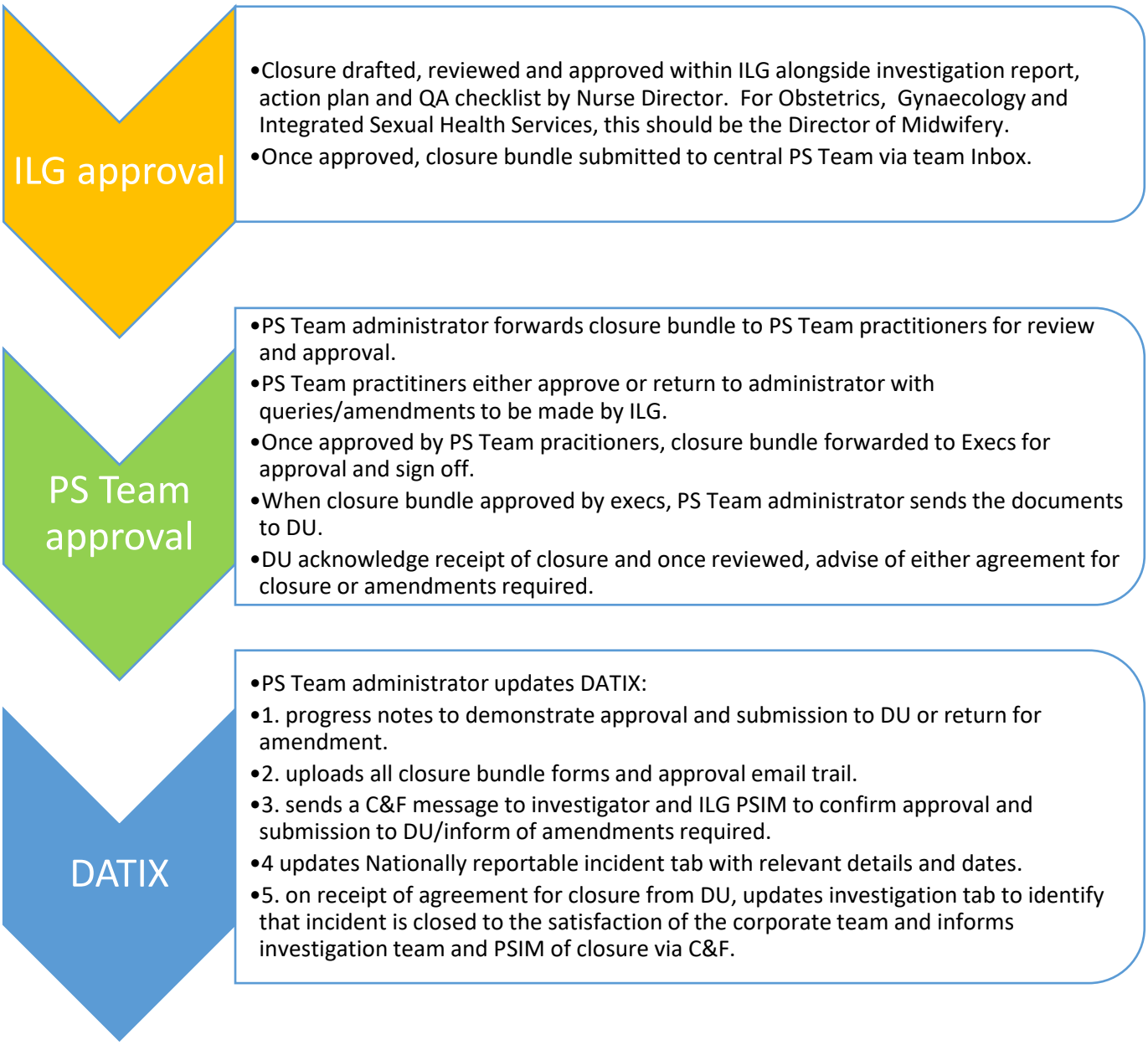
A notification of all NRI's should be submitted to the Patient Safety Team Inbox as soon as possible after an incident has been classified as NRI, or the ILG governance team is made aware of the incident. The notification form (Appendix 7) will (be checked by the PS Team for ILG and clinical director sign off prior to sending to the Executive team for approval. Once signed, this will be forwarded to the Delivery Unit (DU) who undertake the scrutiny of incidents on behalf of the Welsh Government. The notification and approval emails will be uploaded to DATIX by the Patient Safety Team. All NRI's are discussed within the weekly data meeting which includes the DATIX team, Quality and Safety and corporate governance representatives.



NRI notification process (to include Never Events)



NRI closure process (to include Never Events)



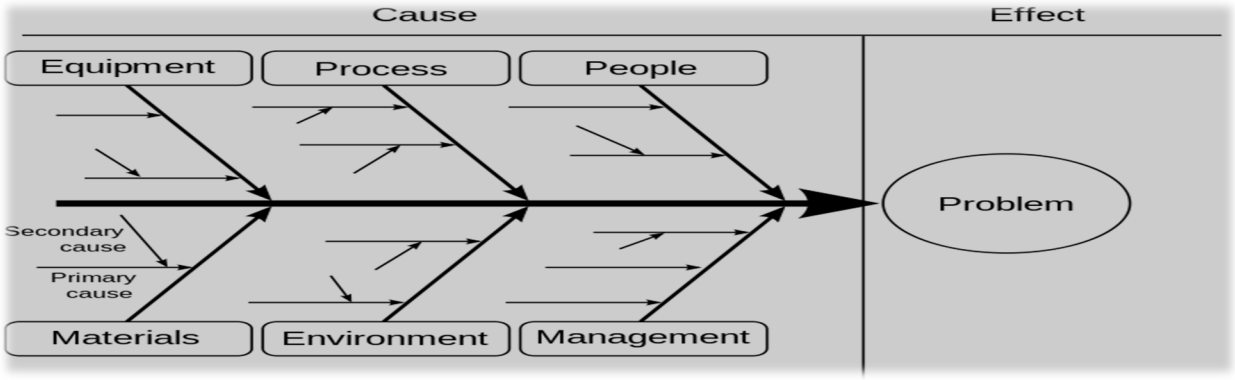
Chapter 8: Investigation Analysis Tools

There are several analysis tools available to support the investigation team in drilling down to identify root causes and contributory factors, however the following tools are recommended for their thoroughness and reliability. The team can choose which tool works best for them and the completed tool should be included in the report to demonstrate thought processes and decision-making.

1. 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 of 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?

The **Contributory Factor Classification Framework** must be used in conjunction with the Fishbone diagram. Select the relevant components which relate to the problem identified and add to the appropriate factor.

Patient Factors	Relevant to Incident?	Components
Clinical condition	☐ Yes ☐ Maybe ☐ No	❑ Pre-existing co-morbidity ❑ Complexity of condition ❑ Seriousness of condition ❑ Treatability
Social factors	☐ Yes ☐ Maybe ☐ No	❑ Culture / religious beliefs ❑ Life style (smoking / drinking / drugs / diet) ❑ Language ❑ Living accommodation (e.g. dilapidated) ❑ Support networks
Physical factors	☐ Yes ☐ Maybe ☐ No	❑ Physical state – malnourished, poor sleep pattern, etc.
Mental/ psychological factors	☐ Yes ☐ Maybe ☐ No	❑ Motivation (agenda, incentive) ❑ Stress (family pressures, financial pressures) ❑ Existing mental health disorder ❑ Trauma
Interpersonal relationships	☐ Yes ☐ Maybe ☐ No	❑ Staff to patient and patient to staff ❑ Patient to patient ❑ Inter family – siblings, parents, children

Individual (Staff) Factors	Relevant to Incident?	Components
Physical issues	☐ Yes ☐ Maybe ☐ No	General Health (e.g. nutrition, diet, exercise, fitness) ❑ Physical disability (e.g. eyesight problems, dyslexia) ❑ Fatigue
Psychological Issues	☐ Yes ☐ Maybe ☐ No	❑ Stress (e.g. distraction / preoccupation) ❑ Specific mental health illness (e.g. Depression) ❑ Mental impairment (e.g. illness, drugs, alcohol, pain) ❑ Motivation (e.g. boredom, complacency, low job satisfaction) ❑ Cognitive factors (e.g. attention deficit, distraction, preoccupation, overload and boredom)
Social Domestic	☐ Yes ☐ Maybe ☐ No	❑ Domestic / lifestyle problems
Personality Issues	☐ Yes ☐ Maybe ☐ No	❑ Low self confidence / over confidence ❑ Gregarious / interactive, reclusive ❑ Risk averse / risk taker

Team Factors	Relevant to Incident?	Components
Role Congruence	☐ Yes ☐ Maybe ☐ No	❑ Is there parity of understanding ❑ Are role definitions correctly understood ❑ Are roles clearly defined
Leadership	☐ Yes ☐ Maybe ☐ No	❑ Is there effective leadership – clinically ❑ Is there effective leadership – managerially ❑ Can the leader lead ❑ Are leadership responsibilities clear and understood ❑ Is the leader respected
Support and cultural factors	☐ Yes ☐ Maybe ☐ No	❑ Are there support networks for staff ❑ Team reaction to adverse events ❑ Team reaction to conflict ❑ Team reaction to newcomers ❑ Team openness

Communication Factors	Relevant to Incident?	Components
Verbal communication	☐ Yes ☐ Maybe ☐ No	❑ Verbal commands / directions unambiguous ❑ Tone of voice and style of delivery appropriate to situation ❑ Correct use of language ❑ Made to appropriate person(s) ❑ Recognised communication channels used (e.g. head of service)
Written communication	☐ Yes ☐ Maybe ☐ No	❑ Are records easy to read ❑ Are all relevant records stored together and accessible when required ❑ Are the records complete and contemporaneous (e.g. availability of patient management plans, patient risk assessments, etc) ❑ Are memo's circulated to all members of team ❑ Are communications directed to the right people
Non verbal communication	☐ Yes ☐ Maybe ☐ No	❑ Body Language issues (closed, open, aggressive, relaxed, stern faced)

Task Factors	Relevant to Incident?	Components
Guidelines Procedures and Policies	☐ Yes ☐ Maybe ☐ No	❑ Up-to-date ❑ Available at appropriate location (e.g. accessible when needed) ❑ Understandable / useable ❑ Relevant; Clear; Unambiguous; Correct Content; Simple ❑ Outdated; Unavailable/missing; Unrealistic ❑ Adhered to / followed ❑ Appropriately targeted (e.g. aimed at right audience)
Decision making aids	☐ Yes ☐ Maybe ☐ No	❑ Availability of such aids e.g. CTG machine, risk assessment tool, fax machine to enable remote assessment of results ❑ Access to senior / specialist advice ❑ Easy access flow charts and diagrams ❑ Complete information - test results, informant history
Procedural or Task Design	☐ Yes ☐ Maybe ☐ No	❑ Do the guidelines enable one to carry out the task in a timely manner ❑ Do staff agree with the 'task/procedure design' ❑ Are the stages of the task such that each step can realistically be carried out

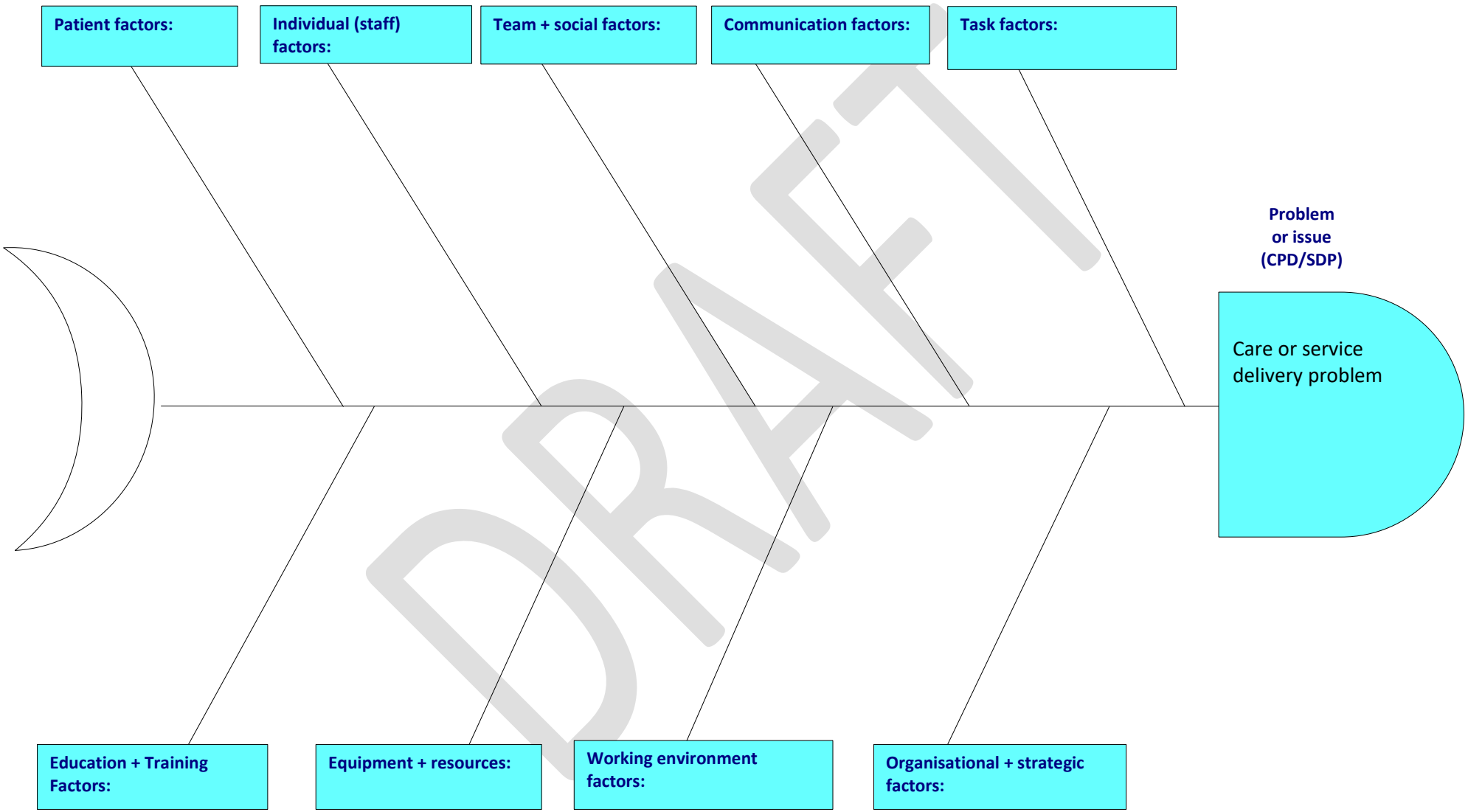
Education and Training Factors	Relevant to Incident?	Components
Competence	☐ Yes ☐ Maybe ☐ No	❑ Adequacy of knowledge ❑ Adequacy of skills ❑ Length of experience ❑ Quality of experience ❑ Task familiarity ❑ Testing and Assessment
Supervision	☐ Yes ☐ Maybe ☐ No	❑ Adequacy of supervision ❑ Availability of mentorship ❑ Adequacy of mentorship
Availability / accessibility	☐ Yes ☐ Maybe ☐ No	❑ On the job training ❑ Emergency Training ❑ Team training ❑ Core skills Training ❑ Refresher courses
Appropriateness	☐ Yes ☐ Maybe ☐ No	❑ Content ❑ Target audience ❑ Style of delivery ❑ Time of day provided

Equipment & Resources Factors	Relevant to Incident?	Components
Displays	☐ Yes ☐ Maybe ☐ No	❑ Correct information ❑ Consistent and clear information ❑ Legible information ❑ Appropriate feedback ❑ No interference
Integrity	☐ Yes ☐ Maybe ☐ No	❑ Good working order ❑ Appropriate size ❑ Trustworthy ❑ Effective safety features ❑ Good maintenance programme
Positioning	☐ Yes ☐ Maybe ☐ No	❑ Correctly placed for use ❑ Correctly stored
Usability	☐ Yes ☐ Maybe ☐ No	❑ Clear controls ❑ User manual ❑ Familiar equipment ❑ New equipment ❑ Standardisation

Working Environment Factors	Relevant to Incident?	Component
Administrative factors	☐ Yes ☐ Maybe ☐ No	❑ The general efficiency of administrative systems e.g. reliability ❑ Systems for requesting medical records ❑ Systems for ordering drugs ❑ Reliability of administrative support
Design of physical environment	☐ Yes ☐ Maybe ☐ No	❑ Office design: computer chairs, height of tables, anti-glare screens, security screens, panic buttons, placing of filing cabinets, storage facilities, etc. ❑ Area design: length, shape, visibility, cramped, spacious
Environment	☐ Yes ☐ Maybe ☐ No	❑ Housekeeping issues – cleanliness ❑ Temperature ❑ Lighting ❑ Noise levels
Staffing	☐ Yes ☐ Maybe ☐ No	❑ Skill mix ❑ Staff to patient ratio ❑ Workload / dependency assessment ❑ Leadership ❑ Use Temporary staff ❑ Retention of staff / staff turnover
Work load and hours of work	☐ Yes ☐ Maybe ☐ No	❑ Shift related fatigue ❑ Breaks during work hours ❑ Staff to patient ratio ❑ Extraneous tasks ❑ Social relaxation, rest and recuperation
Time	☐ Yes ☐ Maybe ☐ No	❑ Delays caused by system failure or design ❑ Time pressure

Organisational Factors	Relevant to Incident?	Components
Organisational structure	☐ Yes ☐ Maybe ☐ No	❑ Hierarchical structure, not conducive to discussion, problem sharing, etc. ❑ Tight boundaries for accountability and responsibility ❑ Clinical versus the managerial model
Priorities	☐ Yes ☐ Maybe ☐ No	❑ Safety driven ❑ External assessment driven e.g. Star Ratings ❑ Financial balance focused
Externally imported risks	☐ Yes ☐ Maybe ☐ No	❑ Locum / Agency policy and usage ❑ Contractors ❑ Equipment loan ❑ PFI
Safety culture	☐ Yes ☐ Maybe ☐ No	❑ Safety / efficiency balance ❑ Rule compliance ❑ Terms and Conditions of Contracts ❑ Leadership example (e.g. visible evidence of commitment to safety) ❑ Open culture

Fishbone Diagram Template (*NB: only to be used with classification framework)*



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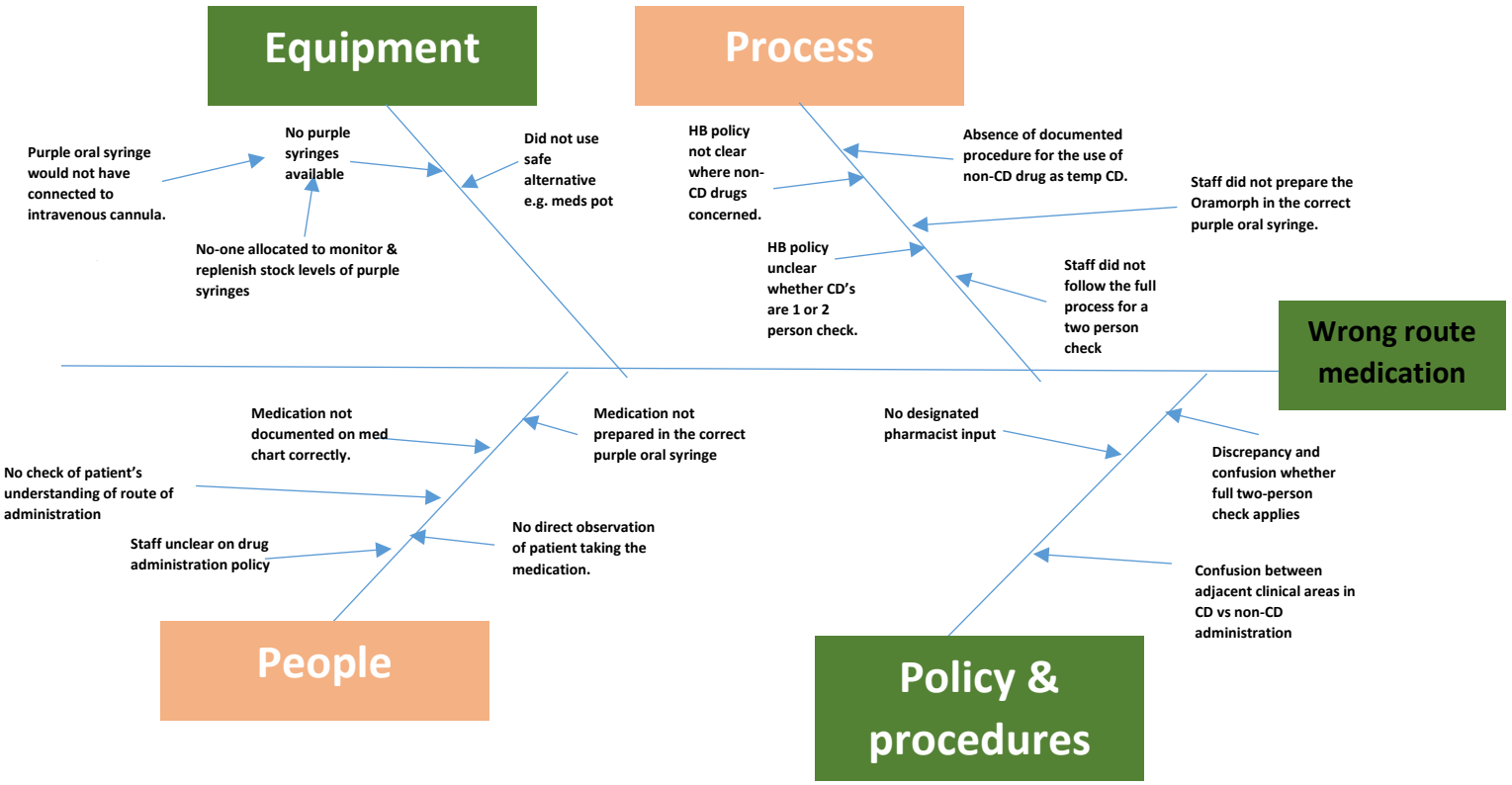
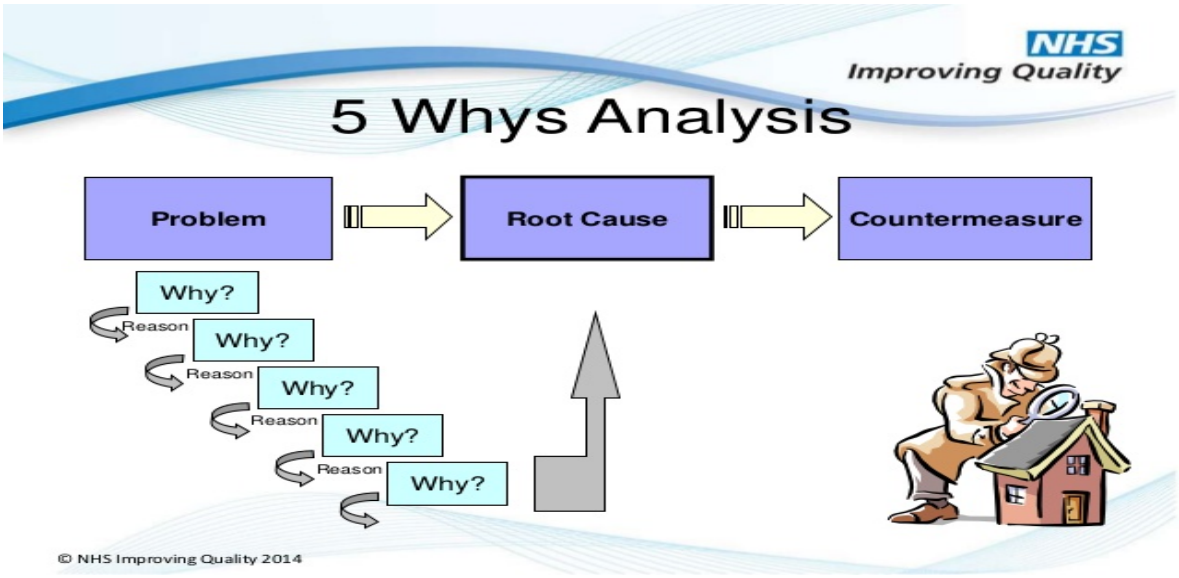
Fishbone analysis working example



2. "5 Whys" Analysis Tool

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?

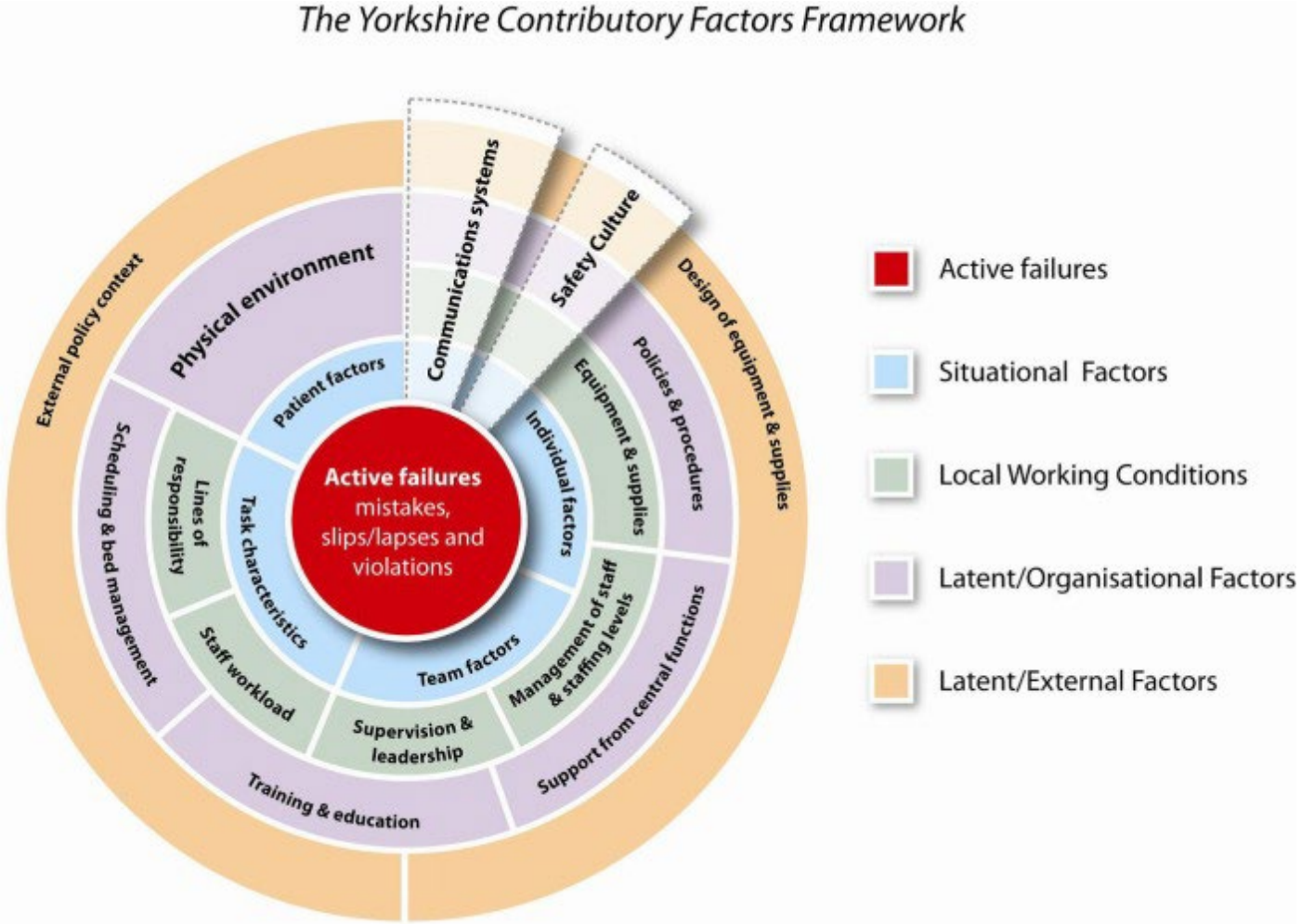
1. Agree on a problem statement and consider it in detail: who is involved, when and where it occurs. Engage your team to agree the problem statement. Include as much information as possible in the 'what', 'where', 'when' and 'how much' of the problem and use data to specify the problem if possible.
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.

5-why's working example:

1. Why did the patient receive the wrong medication? *The nurse did not complete patient identification*
2. Why did the nurse not complete patient identification? *The patient did not have a wristband.*
3. Why did the patient not have a wristband? *The wristband had been removed for a procedure and not replaced.*
4. Why was the wristband not replaced? *The print for the wristbands was not working.*
5. Why was the printer not working? *The staff needed to support IT had been reduced and was overworked*.

3. Yorkshire Contributory Factors Framework (YCCF)

The Yorkshire Contributory Factors Framework is a tool which has an evidence base for optimising learning and addressing causes of patient safety incidents (PSI) by helping clinicians, risk managers and patient safety officers identify contributory factors of PSIs. You may wish to use the associated forms below to help guide and documents all the relevant factors.



Framework for Patient Safety Incident Investigation: Yorkshire Contributory Factors Framework (YCFF)

The Yorkshire Contributory Factors Framework

Details of Incident	
Name of person completing form	**Date completed**
Brief description of incident	**Date of incident**

Domain 1: Situational Factors		
Team factors		
Was there any failure of team function? *For example:* • Conflicting team goals • Lack of respect for colleagues • Poor delegation • Absence of feedback	☐ Yes ☐ Maybe ☐ No	Notes
Individual staff factors		
Were there any reasons this incident was more likely to occur with the particular staff involved? *For example:* • Fatigue • Stress • Rushed • Distraction • Inexperience	☐ Yes ☐ Maybe ☐ No	Notes
Task characteristics		
Did the task features make the incident more likely? *For example:* • Unfamiliar task • Difficult task • Monotonous task	☐ Yes ☐ Maybe ☐ No	Notes
Patient factors		
Were there any reasons this incident was more likely to occur to this particular patient? *For example:* • Language barrier • Uncooperative • Complex medical history • Unusual physiology • Intoxicated	☐ Yes ☐ Maybe ☐ No	Notes
Domain 2: Local Working Conditions		
Workload and staffing issues		
Was there a mismatch between workload and staff provision around the time of the incident? *For example:* • High unit workload • Insufficient staff • Staff sickness	☐ Yes ☐ Maybe ☐ No	Notes
Leadership, Supervision and Roles		
Was there any failure of team function? *For example:* • Inappropriate delegation • Unclear responsibilities • Remote supervision	☐ Yes ☐ Maybe ☐ No	Notes
Drugs, Equipment and Supplies		
Were there difficulties obtaining the correct drugs and/or working equipment and/or supplies? *For example:* • Unavailable drugs • Equipment not working • Inadequate maintenance • No supplies delivery	☐ Yes ☐ Maybe ☐ No	Notes

Domain 3: Organisational Factors

Physical environment

Did the ward environment hinder your work in any way? *For example:* • Poor layout • Lack of space • Excessive noise/heat/cold • Poor visibility (e.g. position of nurses' station) • Poor lighting • Poor access to patient	☐ Yes ☐ Maybe ☐ No	Notes

Support from other departments

Were there any problems from other departments? *For example:* • This includes support from IT, HR, porters, estates or clinical services such as radiology, phlebotomy, pharmacy, biochemistry, blood bank, microbiology, physiotherapy, medical or surgical sub-specialities, theatres, GP, ambulances etc	☐ Yes ☐ Maybe ☐ No	Notes

Scheduling and Bed Management

Did any time or bed pressures play a role in the incident? *For example:* • Delay in the provision of care • Transfer to an appropriate ward • Difficulties finding a bed • Lack of out of hours support	☐ Yes ☐ Maybe ☐ No	Notes

Staff training and Education

Were there any issues with staff skill or knowledge? *For example:* • Inadequate training • No protected time for teaching • Training not standardised • No regular/yearly updates	☐ Yes ☐ Maybe ☐ No	Notes

Domain 4: External Factors

Design of Equipment, Supplies and Drugs

Was there any characteristic about the equipment, disposables or drugs that was unhelpful? *For example:* • Confusing equipment design • Equipment not fit for purpose • Similar drug names • Ambiguous labelling and packaging	☐ Yes ☐ Maybe ☐ No	Notes

National policies

Have any national policies influenced this incident? *For example:* • Commissioned resources • National screening policy • Interference by government organisations • National medical/nursing standards • 4 hour Emergency Department target	☐ Yes ☐ Maybe ☐ No	Notes

Domain 5: Communication and Culture

Safety culture

Did the lack of safety culture in your clinical area contribute to this incident? *For example:* • Patient safety awareness • Fear of documenting errors • Attitude to risk management	☐ Yes ☐ Maybe ☐ No	Notes

Verbal and Written communication

Did poor written or verbal communication worsen the situation? *For example:* • Poor communication between staff • Handover problems • Lack of communication/notes • Unable to read notes • Inappropriate abbreviations used • Unable to contact correct staff • Notes availability	☐ Yes ☐ Maybe ☐ No	Notes

Summary

Which are the most important contributory factors for this incident?

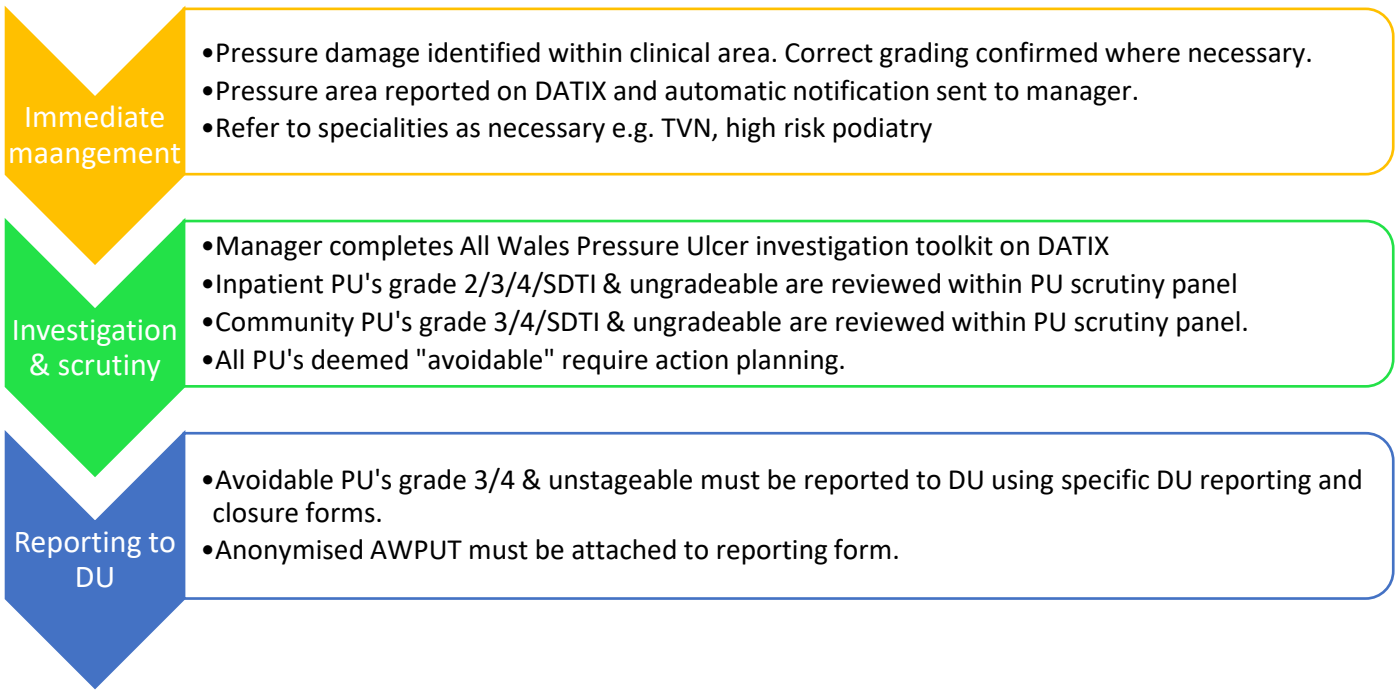
Feel free to adapt and share this document with acknowledgement to the Yorkshire and Humber Improvement Academy. Creative Commons Bradford Teaching Hospitals NHS Foundation Trust.

Chapter 9: Specific Investigation Tools

1. The All Wales Pressure Ulcer Toolkit (AWPUT)

The investigation of Pressure Ulcers (PU) falls under specific reporting measures assigned by the DU which are standardised nationally. There are bespoke investigation forms and processes in place to aid this, which can be accessed via DATIX. When entering the DATIX system, scroll down to the tab on the left of the screen marked "All Wales Pressure Ulcer Toolkit" and this will guide you through all the information needed for the investigation process. The process below should be followed, with both investigation and scrutiny panel (where applicable) occurring in a timely manner. Grade 3/4 and unstageable PU's should be reviewed in PU scrutiny panel within 7 days of occurrence. The AWPUT is sufficient to act as an RCA level of investigation where this is indicated and should be attached to the closure form.

The scrutiny panels consist of a MDT including senior nursing staff, TVN, safeguarding and central patient safety team representation. Attendance by ALL staff members involved in the care of individuals at risk of pressure damage is actively encouraged to aid learning at all levels. This can be arranged through negotiation with your ward/area manager.

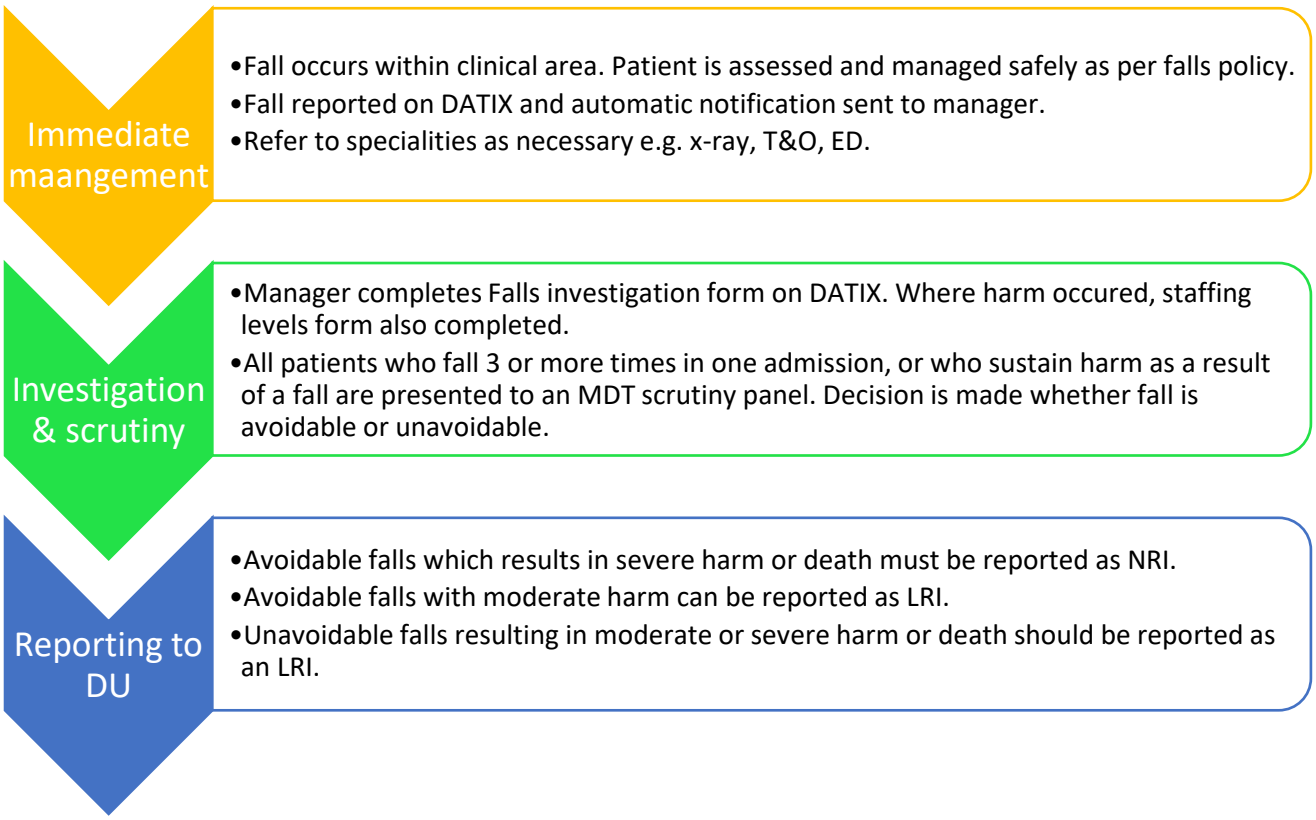


2. Falls investigation toolkit

There is currently no standardised national falls investigation toolkit such as there is with PU. However, there is a robust falls investigation tool, which can be found within DATIX, which should be completed for ALL falls. When entering the DATIX system, scroll down to the tab on the left of the screen marked “Patient Falls Investigation Tool” and this will guide you through all the information needed for the investigation. Where a fall results in harm, this should be accompanied by completion of the staffing levels tool also found on DATIX to demonstrate ward staffing at the time of the incident.

Where a patient has three or more falls within one admission, or sustains any level of harm as a result of a fall, the incident should be presented to falls scrutiny panel for multi-disciplinary discussion and decision on whether the fall was avoidable or unavoidable. Falls panels should be held regularly and incidents presented in a timely manner.

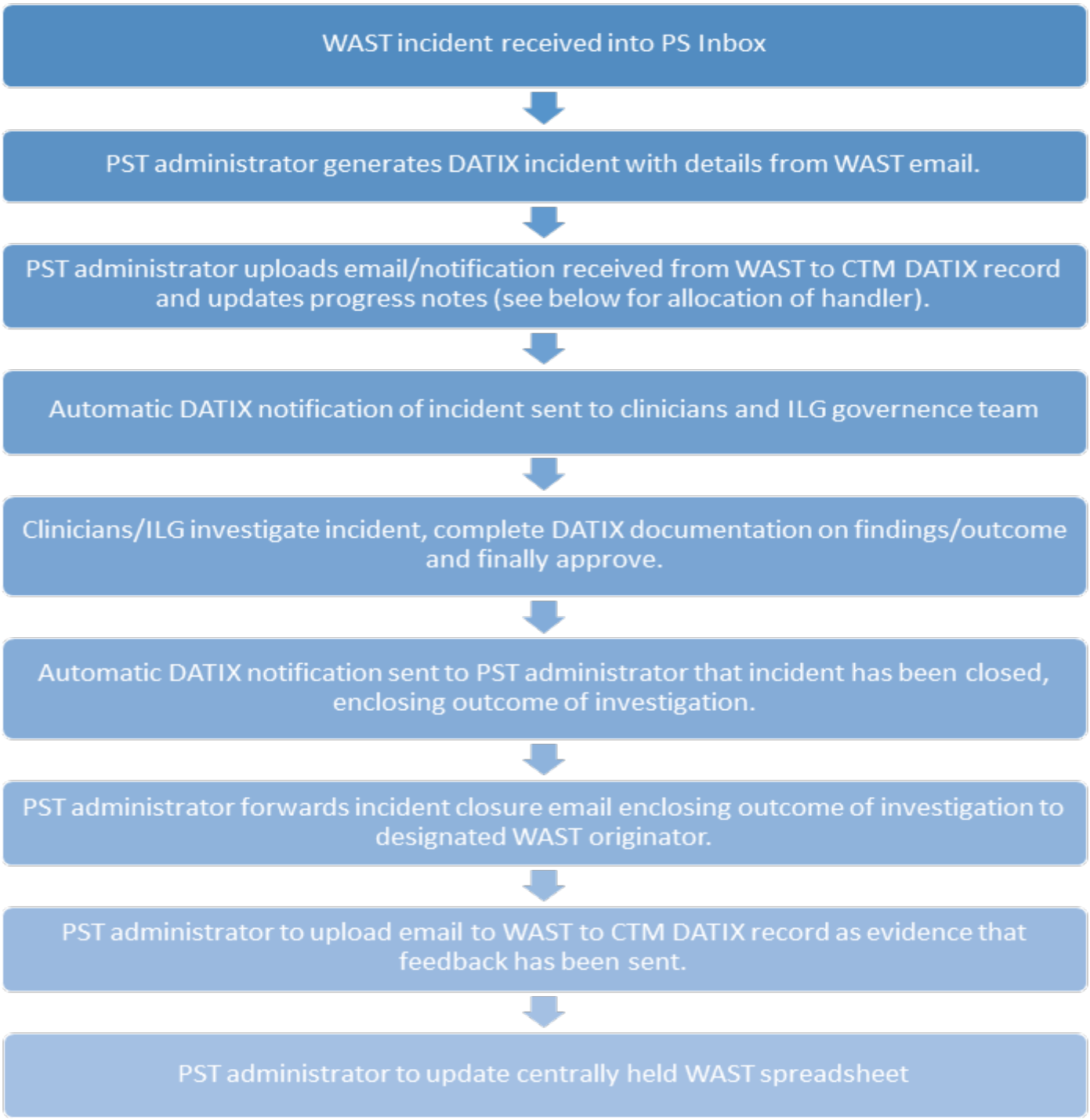
The scrutiny panels should, as a minimum, consist of an MDT including senior nursing staff, physiotherapy, pharmacy and medical representation. Attendance by ALL staff members involved in the care of patients at risk of falls is actively encouraged to aid learning at all levels. This can be arranged through negotiation with your ward/area manager.



3. Welsh Ambulance Service (WAST) investigations

All Appendix B incidents (where an incident has been classed as severe or death outcome) are forwarded to the central patient safety team (CPST) inbox by WAST. The current process is as follows:

1. CPST raise a DATIX incident and log the number in their shared files on the W drive.
2. DATIX incident is currently allocated to corporate.
3. The Delivery Unit (DU) and EASC are currently discussing how these incidents will be managed, so are all currently on hold for investigation and are not yet logged as NRI's (WAST has notified the DU, so that they are aware of the incidents).
4. The CPST meet monthly with WAST in the interim, to discuss incidents sent to and from the health board. An update on this process will be added to the framework once agreed and approved.



Chapter 10: Completing an RCA Investigation

An RCA is an evidence-based, structured investigation process that utilises tools and techniques to identify the true cause of an incident, by understanding what, why and how systems failed. There is comprehensive training available via the central Patient Safety Team to ensure staff are confident and equipped with all the knowledge and skills to undertake an RCA investigation. Fact-finding is the basis for a robust RCA and analysis can only begin once all of the facts are known. The process of an RCA investigation is fluid and should be approached in a flexible manner, however the following points should form part of every RCA investigation:

1. Terms of Reference should be available from the RAPID review meeting, however where not agreed these should be confirmed with the team prior to commencing an investigation.
2. Gather all available patient notes pertaining to the incident in question, this could include nursing notes, medical notes and online patient management systems such as CareVue and Welsh Clinical Portal.
3. Compile a timeline of events using CTMUHB template (Appendix 8), annotated with notable practice points and where care/service deviated from best practice/prescribed care.
4. Request written statements from all those involved in the incident. These should be completed on the statement template (Appendix 11) as a robust collection mechanism. Consider interviewing those directly involved in the incident where further information or clarification is required. If interviewing, these should be recorded to ensure an accurate recollection of discussions.
5. Utilise analysis tools such as the 5-whys or fishbone analysis to identify service delivery problems (SDP), care delivery problems (CDP) and contributory factors.
6. Utilise analysis tools in order to drill down to the root cause of the incident. This will be the cause with the greatest impact upon system failure and once resolved will most likely minimise the likelihood of recurrence.
7. Compile an RCA report utilising the CTMUHB template (Appendix 10). This will present all the work undertaken and should convey all the information in a concise, objective format.

DON'T

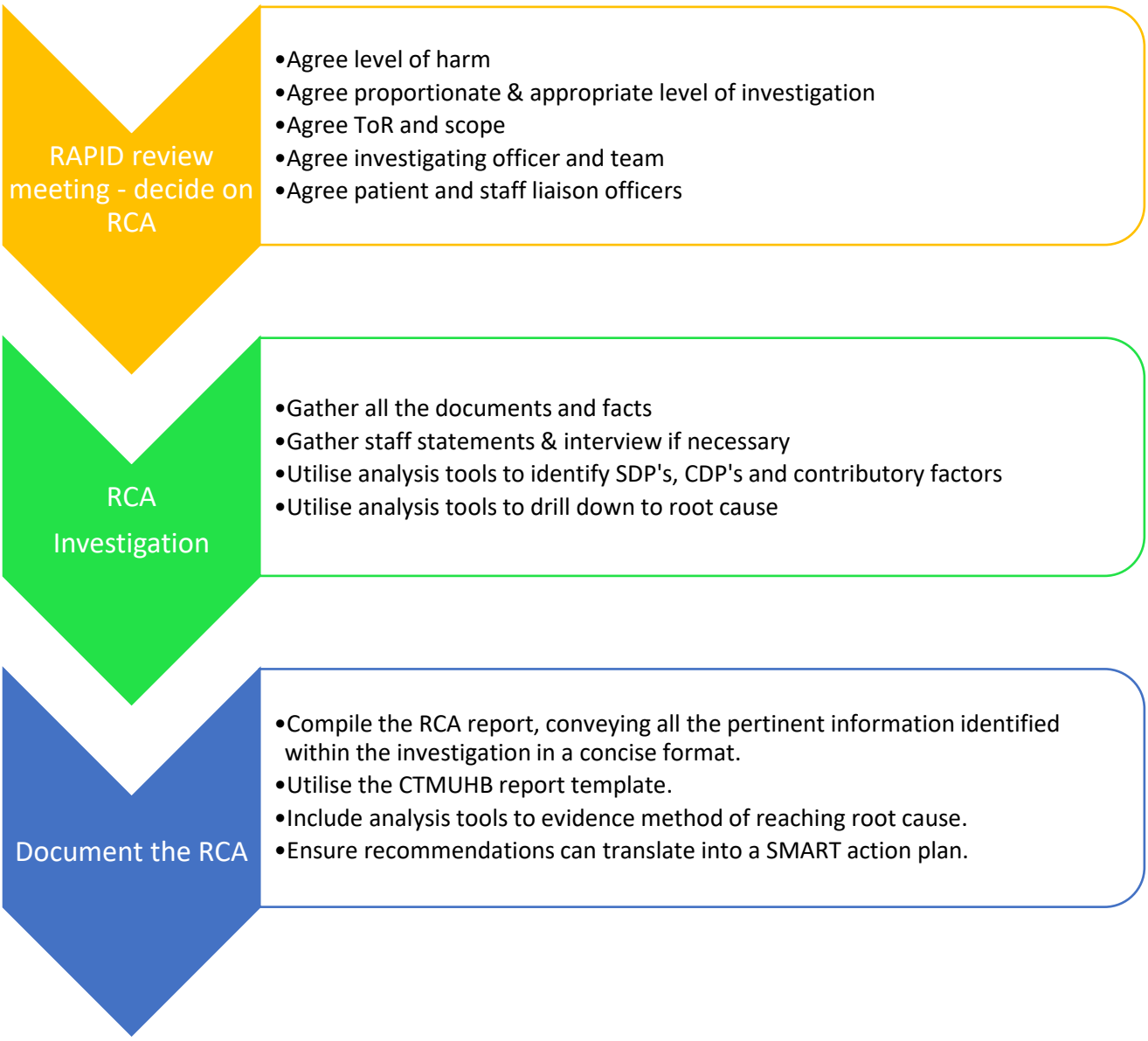
- Apportion blame to an individual, rather examine human factors, systems and services within which staff work.
- Use staff or patient identifiable information. The report should be anonymised.
- Work alone! The investigating officer should be supported by a team to ensure that all viewpoints are explored.
- Stop drilling down too early! Keep going until you come to the ultimate root cause and do not allow assumptions to influence the investigation.

DO

- Involve staff and key stakeholders in the investigation to utilise their expertise.
- Ask the patient (or their family) how they wish to be referred to within the report
- Ensure staff and the patient/family are kept up-to-date with the progress of the investigation and given many opportunities to comment and ask questions on the investigation.
- Be open to the views of others – do not become blinkered to possible causes.
- Seek advice and support where needed.
- Take note of and document good practice examples.
- Be open and honest! Offer an apology and remember an apology does not admit liability.
- Include references for all documents utilised during the investigation
- Utilise CTMUHB "a just culture guide" to support staff who are involved in an incident.
- Ensure that all documents, minutes, emails and other relevant items are uploaded to the DATIX record.

TOP TIP! All staff identifiable information and all HB sites should remain anonymous throughout all reporting documentation and subsequent reports, whether this is internally to the HB or external. Use terms such as "Nurse A", "colleague" or "ward". In regards to patient identifiable information, the investigation team should consult with the patient/family at the start of the process and utilise whichever means of address they choose.

The RCA process at a glance



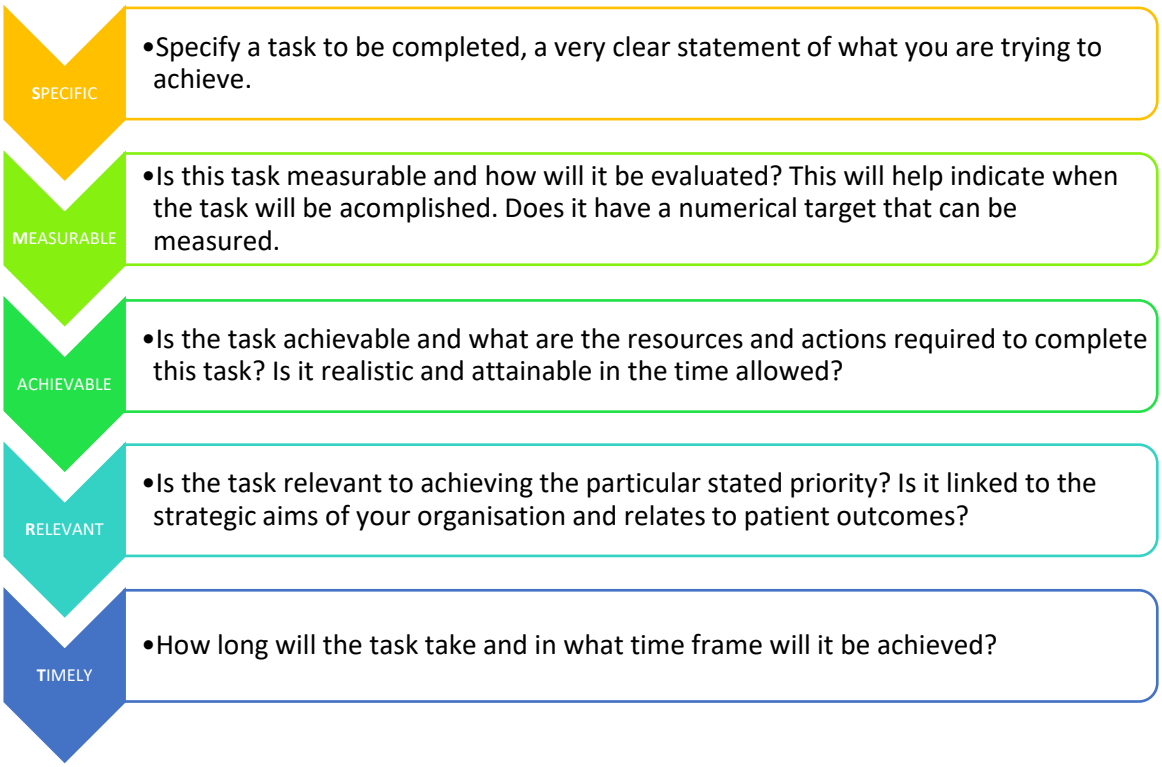
TOP TIP! Key DATIX actions should be completed by the lead investigator, or a designated investigation team member, in order to maintain robust documentation and audit trails. This should include as a minimum:

- Ensuring the DATIX record is appropriately changed from "in holding area" to "in progress" when the investigation is commenced.
- Ensuring the DATIX record is appropriately moved from "in progress" to "complete" when the investigation is completed and ready for QA and closure processes.
- Ensuring all associated contacts for the incident are logged and approved within the DATIX incident record.
- Ensuring all documents, meeting minutes, email trails etc. are uploaded to the "documents" section on the DATIX record.
- Ensuring all actions undertaken in relation to the investigation/incident are documented under "progress notes"

Chapter 11: Completing an Action Plan

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.

What makes an Action Plan SMART?



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

The action plan will need to be completed using the CTM template (see Appendix 12 and 13). These actions also need to be manually put into the Datix systems '*actions module'* under the specific incident number for the investigation in order monitor the completion. The evidence to support each action should be uploaded and saved to Datix for assurance and accessibility. The named individual on the action plan is responsible for ensuring the actions are completed and updating DATIX, including relevant evidence, accordingly.

NHS Improvement: An Overview of Action Planning; October 2011 https://www.england.nhs.uk/improvement-hub/wp-content/uploads/sites/44/2018/06/An-Overview-of-Action-Planning.pdf

Chapter 12 – Quality Assurance

Once the investigation is complete and the SBAR/RCA and action plan have been formulated and agreed by the investigation team, the document bundle should be submitted to the relevant ILG governance team for collation and approval. Where an investigation has been undertaken using an SBAR, the investigation documents should be forwarded to the Patient Safety Team who will complete a level 2 QA checklist (Appendix 14). This will be returned to the ILG with either an indication for further information or agreement to progress for closure. The PS Team will upload the QA checklist and agreement for closure email to DATIX.

Where an RCA has been completed, the ILG will organise the scrutiny of the report and action plan by a multi-disciplinary team within a Quality Assurance panel. Terms of reference and organisation of QA panels will be revised following the organisational change to Care Groups. The panel will decide whether the report meets key objectives according to the CTMUHB QA template (Appendix 15). The QA 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 panel have considered the documents, they will either return the bundle to the author for further amendments according to comments on the QA 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 ILG governance team will arrange for the bundle to be submitted for closure to the Central Patient Safety Team. The CPST will further scrutinise and approve the bundle for progression for closure or return to the ILG team for further amendment/additions.

In relation to Early Warning Notifications, the ILG will organise submission of the EWN form to the CPST Inbox, where a member of the CPST will first line approve or return to the author for any amendments/additions prior to sending to the Assistant Director of Quality and Safety for QA. Once QA is completed, this will then be submitted to the Executive team for final sign off prior to submission to Welsh Government.

Chapter 13: Closure

Once the investigation has been finalised to the satisfaction of the QA panel, ILG governance and investigation teams, the incident can be progressed to closure. For an **LRI**, a closure form should be submitted to the PS Team Inbox by the ILG for acknowledgement and an agreement for closure will be returned to the ILG. The PS Team will update DATIX with documents and agreement for closure email. The ILG should action closure when they are finally assured that the incident investigation is completed. DATIX should also be updated by the ILG for final closure.

An **NRI** closure bundle including the report, action plan and QA checklist should be signed off by the ILG directors then forwarded by the ILG 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 DU. only once closure confirmation has been received from the DU can the incident be fully closed.

The ILG governance team are responsible for finally closing each incident to ensure they are fully satisfied that all elements are completed and documented. The DATIX incident should also be closed.

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Chapter 14 – Putting Things Right

What is Putting Things Right?

The Health Board aims to provide very best treatment and care to all our patients. However, sometimes things might not go as expected – when this happens it is important for the Health Board to review what happened, what went wrong and how we can learn and improve to make things better for our patients. The *Putting Things Right arrangements* (PTR) is a method of handling and investigating any concerns about care and treatment provided by the NHS in Wales – a concern includes complaints, claims and patient safety incidents.

The PTR arrangements are set out in the ***NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011***. The principles of being open from the outset are at the heart of the PTR.

These Regulations apply to all Responsible Bodies in Wales, which include:

- Local Health Boards
- NHS Trusts
- Primary care providers and
- Independent providers providing NHS funded care

It is important for every concern to be handled and investigated by way of PTR. The benefits of this include:

- improved quality and standard of patient care and safety identified from lessons learnt
- a reduction in the likelihood of similar issues happening again
- better experience for people wishing to raise a concern
- reduction in the amount of concerns that are escalate
- better focus on specialist advice
- reduction in the amount of clinical negligence cases being pursued (reduction in settlement of damages and legal costs)
- increased public confidence in the services provided by the NHS

In accordance with Regulation 23 all concerns must be managed and investigated thoroughly and in the most appropriate, efficient and effective way. The Health Board must have regard to:

1. Initial assessment of concern to determine the type of investigation needed, which must be kept under review
2. The method, frequency and timing of communication
3. The most appropriate method of involving the persons involved with the investigation, including a discussion about how the investigation is going to be conducted
4. The level and type of support required by any member of staff who are involved
5. Whether the person investigating the matters raised by the concern required independent medical advice or legal advice
6. Whether the concern may be capable of resolution by making use of alternative dispute resolution
7. The making of decisions about the root cause of the matters
8. Any guidance from Welsh Ministers with respect to the exercise of the Health Board's functions
9. Where the investigation identifies harm may have been caused
10. The likelihood of any qualifying liability arising
11. The duty to consider Redress

The Health Board must be mindful of the financial limit in respect of any financial offers which may be considered under PTR/Redress – which is currently £25,000.00. This financial limit **MUST** be considered in every investigation regardless of whether or not there may be a qualifying liability. If it is clear from the outset that potential damages could exceed £25,000.00 the investigation should not proceed under PTR/Redress and advice should be given to the patient/family/person raising the concern to seek independent legal advice, and should also be given the contact details for the Community Health Council. *The Claims/Redress Team can provide some guidance in relation to potential value/quantum*, they can be contacted at CTM_Redress@wales.nhs.uk.

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What is a Qualifying Liability?

a. Breach of duty

All Healthcare Professionals owe a duty of care to each patient to provide treatment and care that meets the standard expected from them. In some circumstances, the standard of care expected is not provided to a patient – and this may constitute a breach in the duty of care owed to a patient. For instance, the Clinician may have omitted to do something a reasonable competent professional would have done, or carried out a procedure incorrectly and not in line with guidance or accepted practice, or provided incorrect care/treatment or maybe has not explained all the risks about a procedure.

During investigation, the team should consider the possibility of breach of duty and subsequently the early referral to the Redress team. A legal test is used to establish whether there has been a breach of duty, known as the "Bolam" test. The Bolam test states that there will be no breach of duty if a Clinician can prove they acted in accordance with a responsible/reasonable body of medical opinion in the circumstances. This has developed over the years, and the action/decision must withstand 'logical analysis'.

An adverse outcome does not necessarily mean there has been a breach of duty – there are recognised and known risks with some treatments and procedures. It is really important to rely on the protocols, policies and guidelines in place at the time of the incident, and not those is place at the time of the investigation.

When considering whether there has been a breach of duty it would be helpful to:

- Obtain and review relevant medical records and documents – to include the investigation report
- Identify staff and seek comments, including any witness statements provided in response to concern/investigation
- Always ensure the legal test for breach of duty (Bolam) is set out for internal/external experts when considering breach of duty.

If a breach of duty is not identified the Health Board will not take any further steps to investigate the case under the Regulations as there will be no any qualifying liability.

b. Causation/Harm

If a breach of duty is identified, the Health Board will carry out further investigations to establish whether the breach of duty has caused, and/or materially contributed to any harm.

The legal test for proving harm has been caused is the "but for" test i.e. "but for" the breach of duty the treatment the harm/injury would not have occurred. In some cases, despite there being a breach of duty in the care provided the outcome would have been the same in any event – so no harm caused.

When considering whether causation is established it would be helpful to consider:

- Whether any further medical records are needed – for instance GP records?
- Whether comments could be obtained internally from Clinicians – or whether external independent expert evidence is needed?
- Consider carefully which speciality is needed (whether internal comments or external independent expert evidence) – the speciality to consider causation is not necessarily the same as the breach of duty evidence
- Always set out the legal test for causation for internal/external experts

If the harm would have happened in any event, despite the breach of duty the Health Board will not take any further steps to investigate the case under the Regulations as there will be no qualifying liability. However, if there has been a breach of duty that has caused harm, the Health Board will accept a qualifying liability exists, and will consider whether Redress is appropriate (providing potential value of case is <£25,000.00).

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Redress

Whilst the Health Board is unable to change what has happened, there are a range of options the Health Board can consider under Redress to include:

- an explanation
- a written apology
- a report on actions taken to prevent similar situations occurring
- remedial care or treatment
- financial compensation (limit of £25,000), or
- a combination of both remedial treatment and financial compensation.

Referral for consideration for redress

Where the investigation team are unclear whether the quantum would exceed the £25,000 limit, the redress team can provide advice in relation to the probable level and subsequent response letter that should be drafted. The response letter should be drafted utilising the CTM UHB templates, adapted according to the specific incident details. Once the appropriate response has been drafted, this should be sent to the redress team for review and approval PRIOR to being sent to the patient/family.

All enquiries and submission of documents for review should be sent to the Redress team's email Inbox (see below) and accompanied by the Redress referral form (Appendix 16), outlining the details of the support required. The Redress team will endeavour to respond in a timely manner. See Appendices 17-23 for template response letters and flowcharts.

Independent Opinion/Investigator

There may be occasions when it is necessary to secure an independent opinion on a matter relating to a concern, with a view to resolving it. This is not done as routine, however sometimes an expert in a particular field can be commissioned to perform an external review/opinion. This also comes at a cost to the Health Board and will require senior approval for financing.

This may include:

- Obtaining a second opinion to aid a patient's understanding of their own care, or to see whether there are any other issues which need to be explored in terms of the provision of care and treatment, as part of the investigation of a concern by a Responsible Body;
- in instances when an allegation of harm has been made by the patient, and where a Welsh NHS body is unable to come to a determination itself as to whether there is a qualifying liability in tort, the securing of an expert opinion to answer questions in relation to the tests relating to breach of duty of care and/or causation, as part of an investigation under Part 5 of the Regulations; and
- where the Redress arrangements in Part 6 of the Regulations are triggered any instruction of medical experts must, in accordance with Regulation 32(1)(b), be carried out jointly by the person who notified the concern and the Welsh NHS body. Experts may be instructed to advise in relation to issues relating to causation, condition and prognosis and/or quantum to establish whether there is a qualifying liability in respect of which an offer of Redress should be made.

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Further information can be found on the HB intranet concerns page – or you can contact the Claims Team via email CTM_Redress@wales.nhs.uk.

Community Health Council contact details:
Telephone: 01443 403590
E-mail advocacy.ctmchc@waleschc.org.uk
Address: Cwm Taf Morgannwg Community Health Council
Tŷ Antur
Navigation Park
Abercynon
CF45 4SN
Website http://www.cwmtafmorgannwgcic.cymru (Welsh)
http://www.cwmtafmorgannwgchc.wales (English)

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Chapter 15 – Learning from Events Records (LFER)

What is an LFER?

Improvement to quality and safety in healthcare is aligned to learning which flows from case investigations, and the LFER (Learning from Event Report) provides a framework for regulators and inspection bodies to gather assurance that appropriate improvement has been implemented (see Appendix 24 for LFER template and guidance notes).

The Health Board is required to submit a signed LFER within **60 working days** of the **decision to settle a case**. For Clinical Negligence & Personal Injury claims, the decision to settle a case is identified as the point when the Health Board agrees to proceed to settlement. This includes making an offer or accepting an offer to settle or to admit liability. For a case, which is lost at trial, the trigger for the Learning from Events Report is the date that a trial judgement is received. For redress cases, the decision to settle a case is identified as the point that a Qualifying Liability is communicated to the complainant or representing solicitor.

All cases considered for reimbursement by the Welsh Risk Pool (WRP) will be scrutinised for evidence of the lessons learned and improvement actions taken by the Health Board. Reimbursement (both interim and final reimbursement) will be **deferred** until the WRP Committee is satisfied with learning and the actions taken in a case. Where reimbursement payment is deferred due to outstanding information, the Health Board will be notified of this decision. The Health Board should ensure that the information requested is submitted within **two calendar months**. Where the information requested has not been provided within **six calendar months**, the request for reimbursement will be struck out by the WRP Committee and reimbursement will be permanently deferred, resulting in a financial loss for the Health Board.

In exceptional circumstances, the Health Board can obtain an extension from the WRP for delay in submitting an LFER or for delay in providing further info in relation to a delay in submitting further information. Please note once an extension is granted, it is unlikely a further extension will be granted.

What should an LFER include?

- The LFER needs to provide a sufficient explanation of the circumstances and background to the events, which have led to the case, in order that colleagues who are scrutinising the report can identify the links to the findings and learning outcomes.
- Supporting information, such as action plans, expert reports and review findings may be appended to the LFER to evidence the learning activity this evidence should all be accessible via Datix. These should be referenced in the main document and the relevance of the attachments clearly outlined.
- The LFER must be signed by appropriate senior staff within the organisation.

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Learning From Events Reports- Procedures

Decision to settle a case or admission of liability

Early learning

It is likely CSG's & ILG's would have been involved in the investigation leading up to this decision, which provides many opportunities to process early learning.

Triggers 60 Working Days to submit LFER

A draft LFER will be forwarded with a target date to the CSG lead for learning and ILG governance team for monitoring.

Claims handler role

Sections 1-4 of the LFER will be completed by the Claims Handler and will need to confirm date they require the information returned and confirm date of 60 working day deadline.

Sections 5-9 of LFER is completed by the relevant CSG lead. The LFER will need to be signed by nominated CSG lead and sent to claims handler with evidence of learning attached.

Claims handler role

Responsible for chasing the signed LFER from ILG and submitting the LFER to WRP. Will sign case manager's declaration at section 9? Can also obtain extensions from WRP in exceptional circumstances.

Signed LFER submitted to WRP. **Learning Approved bv WRP?**

Deferred

Case handler will notify ILG lead/ CSG lead of deferment and will communicate further information required. Further information submitted to WRP ideally within 2 months. No later than 6 months to avoid permanent deferral!

Yes

Claim handler will notify relevant nominated lead and process case for reimbursement.

Once learning is approved by WRP after further review, claim handler will notify relevant nominated lead and process case for reimbursement.

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Chapter 16: Learning from Concerns, Safety II and Prevention

The Listening and Learning Framework

Cwm Taf Morgannwg University Health Board is committed to promoting a culture which values and facilitates learning and in which the lessons learned are used to improve the quality of patient care, safety and experience.

This Listening & Learning Framework demonstrates how learning will be identified, triangulated, disseminated and implemented in practice, in order to facilitate and embed a culture of appreciative enquiry and continually improving health care services.

All Staff are responsible for contributing and responding to learning and improvement activity in a timely manner.

The principles underpinning the Listening & Learning Framework are to consistently review our practice through the lens of quality and safety are:

- There is a culture of continuous learning and improvement across the health board, identifying opportunities to draw on good practice and minimise the risk of poor practice
- ILG's take ownership and responsibility for disseminating learning to all staff, using appropriate methodologies and evidence that this has been implemented appropriately
- Practitioners should be fully involved in learning activities and be invited to contribute their perspectives within a positive learning environment that fosters a safe space to learning
- Improvement is sustained through monitoring, and learning makes a real impact on quality, safety, experience and outcomes. Sustained improvement is evidenced through review and monitoring.
- People who use our services and our communities are fully engaged with health board service improvement and are encouraged and supported to contribute to our continuous learning processes

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The Health Board will use a variety of methods to share learning and disseminate this widely.

Feedback/Learning Events

7-Minute Briefings

Reports

E-Mail

E-Bulletins/Circulars and Updates

Team Meetings

CTMUHB Website & SM

Patient Stories at Board (live streamed)

Shared Listening & Learning Forum

Safety I and Safety II

Most people think of safety as the absence of accidents and incidents (or as an acceptable level of risk). In this perspective, which we term Safety-I, safety is defined as a state where as few things as possible go wrong. A Safety-I approach presumes that things go wrong because of identifiable failures or malfunctions of specific components: technology, procedures, the human workers and the organisations in which they are embedded. Humans—acting alone or collectively—are therefore viewed predominantly as a liability or hazard, principally because they are the most variable of these components. The purpose of accident investigation in Safety-I is to identify the causes and contributory factors of adverse outcomes, while risk assessment aims to determine their likelihood. The safety management principle is to respond when something happens or is categorised as an unacceptable risk, usually by trying to eliminate causes or improve barriers, or both.

Crucially, the Safety-I view does not stop to consider why human performance practically always goes right. Things do not go right because people behave as they are supposed to, but because people can and do adjust what they do to match the conditions of work. As systems, continue to develop and introduce more complexity, these adjustments become increasingly important to maintain acceptable performance. The challenge for safety improvement is therefore to understand these adjustments—in other words, to understand how performance usually goes right in spite of the uncertainties, ambiguities, and goal conflicts that pervade complex work situations. Despite the obvious importance of things going right, traditional safety management has paid little attention to this.

Safety management should therefore move from ensuring that 'as few things as possible go wrong' to ensuring that 'as many things as possible go right'. We call this perspective Safety-II; it relates to the system's ability to succeed under varying conditions. A Safety-II approach assumes that everyday performance variability provides the adaptations that are needed to respond to varying conditions, and hence is the reason why things go right. Humans are consequently seen as a resource necessary for system flexibility and resilience. In Safety-II, the purpose of investigations changes to become an understanding of how things usually go right, since that is the basis for explaining how things occasionally go wrong.

	Safety-I	**Safety-II**
Definition of safety	That as few things as possible go wrong.	That as many things as possible go right.
Safety management principle	Reactive, respond when something happens or is categorised as an unacceptable risk.	Proactive, continuously trying to anticipate developments and events.
View of the human factor in safety management	Humans are predominantly seen as a liability or hazard. They are a problem to be fixed.	Humans are seen as a resource necessary for system flexibility and resilience. They provide flexible solutions to many potential problems.
Accident investigation	Accidents are caused by failures and malfunctions. The purpose of an investigation is to identify the causes.	Things basically happen in the same way, regardless of the outcome. The purpose of an investigation is to understand how things usually go right as a basis for explaining how things occasionally go wrong.
Risk assessment	Accidents are caused by failures and malfunctions. The purpose of an investigation is to identify causes and contributory factors.	To understand the conditions where performance variability can become difficult or impossible to monitor and control.

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Transitioning to Safety-II

Look for What Goes Right

A key message is: look at what goes right as well as what goes wrong, and learn from what works as well as from what fails. Indeed, do not wait for something bad to happen but try to understand what actually takes place in situations where nothing out of the ordinary seems to happen. Things do not go well because people simply follow the procedures and work as imagined. Things go well because people make sensible adjustments according to the demands of the situation.

Focus on Frequent Events

A second message is: look for what happens regularly and focus on events based on their frequency rather than their severity. Many small improvements of everyday performance may count more than a large improvement of exceptional performance. The investigation of incidents is often limited by time and resources. There is therefore a tendency to look at incidents that have serious consequences and leave the rest for some other time—that never comes. The unspoken assumption is that the potential for learning is proportional to the severity of the incident or accident.

Remain Sensitive to the Possibility of Failure

A third message is: although Safety-II focuses on things that go right, it is still necessary to keep in mind that things can also go wrong and to 'remain sensitive to the possibility of failure'. But the 'possible failure' is not just that something may malfunction, but also that the intended outcomes may not be obtained. Making sure that things go right requires an ongoing concern for whatever works well, not only to ensure that it continues to do so but also to counteract tendencies to employ a confirmation bias or to focus on the most optimistic outlook or outcomes.

Be Thorough as well as Efficient

A fourth message is: do not privilege efficiency over thoroughness—or at least, not unduly. If most or all the time is used trying to make ends meet, there will be little or no time to consolidate experiences or understand Work-As-Done. It must be legitimate within the organisational culture to allocate resources—especially time—to reflect, to share experiences, and to learn. If that is not the case, then how can anything ever improve? Efficiency in the present cannot be achieved without thoroughness in the past. In addition, in the same way, efficiency in the future cannot be achieved without thoroughness in the present, i.e., without planning and preparations. While being thorough may be seen as a loss of productivity (efficiency) in the present, it is a necessary condition for efficiency in the future. In order to survive in the long run it is therefore essential to strike some kind of balance.

Investing in Safety, the Gains from Safety

A fifth and final message is making things go right is an investment in safety and productivity. Spending more time to learn, think, and communicate is usually seen as a cost. Indeed, safety itself is seen as a cost. This reflects the Safety-I view, where an investment in safety is an investment in preventing something from happening. We know the costs, just as when we buy insurance. But we do not know what we are spared, since this is both uncertain and unknown in size.

Instead of conducting investigations after the event or striving to reduce adverse outcomes, safety management should allocate some resources to look at the events that go right and try to learn from them. Instead of learning from events based on their severity, people should try to learn from events based on their frequency. Instead of analysing single severe events in depth, people should explore the regularity of the many frequent events in breadth, to understand the patterns in system performance. A good way to start would be to reduce the dependency on 'human error' as a near-universal cause of incidents and instead understand the necessity of performance variability.

Reference:

From Safety-I to Safety-II: A White Paper – NHS England
https://www.england.nhs.uk/signuptosafety/wp-content/uploads/sites/16/2015/10/safety-1-safety-2-whte-papr.pdf

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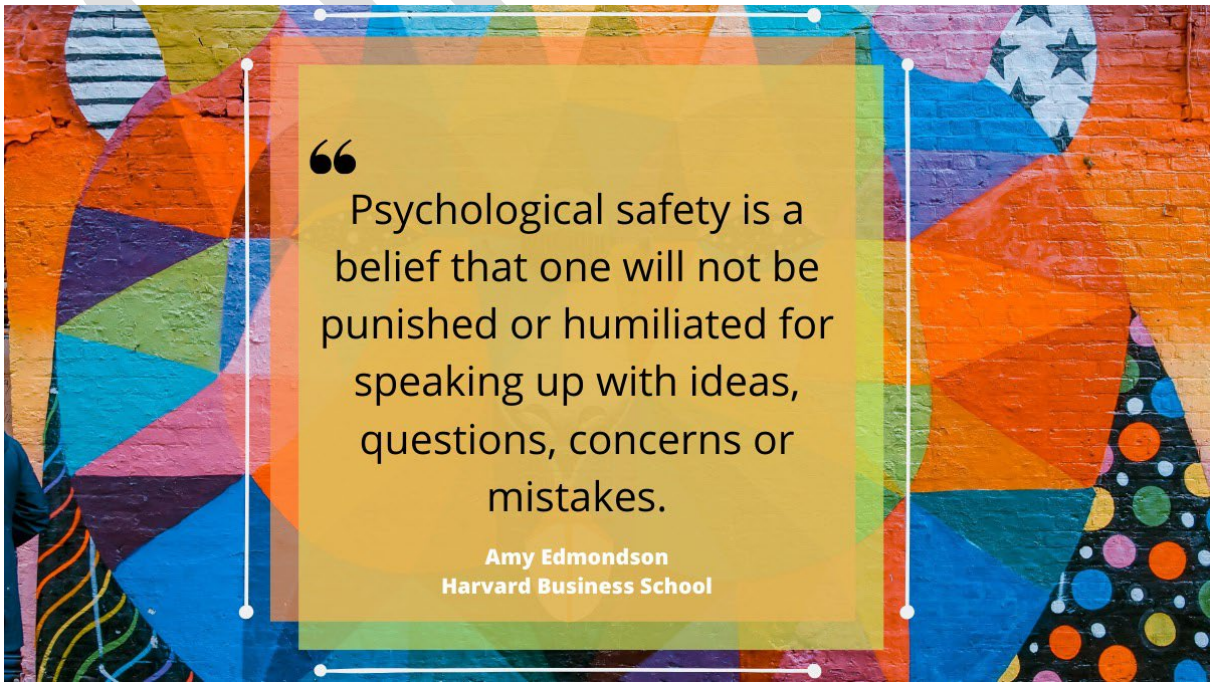
Chapter 17 - Human factors and psychological safety

Human factors are those things that affect an individual's performance. A human factors approach to patient safety starts with an understanding of the things that support or hinder the way people work. This can be seen in the diagram below:

Psychological safety

Psychological safety is a ''shared belief held by members of a team that the team is safe for interpersonal risk-taking.'' It describes a team climate characterised by inclusivity, interpersonal trust and mutual respect in which people are comfortable being themselves and expressing their views.



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Psychological safety plays a role in wellbeing by creating an environment in which change can be embraced, with confidence that there is a mechanism in which to resolve conflict. This supports new approaches being tested and reflected on without threat to the unity of the team as a whole. It also supports learning from those times care doesn't turn out as expected, allowing space for reflection without the fear of unjust blame.

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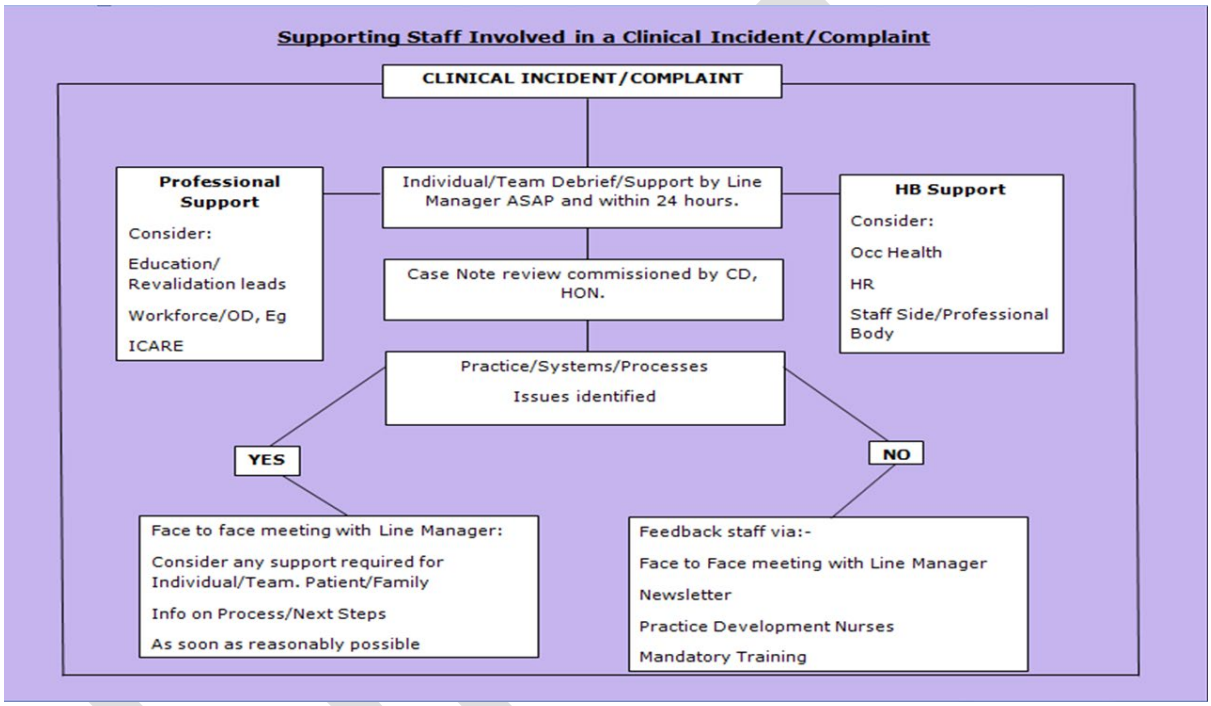
Chapter 18 - Colleague Support Following an Incident

This '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.

The Line Manager should arrange a "one-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. Workforce & OD, Occupational Health & Wellbeing Service, and/or Staff Side representatives.



Colleague Debrief Session

A debrief session should be arranged following a serious incident to help staff engage in true reflective practice to scrutinise and examine assumptions in professional work practices and seek practical solutions. It can be a mechanism whereby leaders can actively support frontline practitioners experiencing difficult situations. It is important that everyone has an opportunity to speak openly and honestly without feeling judged. There should be no apportioning of blame.

Aim of a debrief session:-

1. To find out what it is everyone wants from the session?

2. To have an understanding of how everyone is feeling…

(0 Worried/Petrified – 10 Not at all worried/Fine)

3. Is to identify what went well – what were the strengths

4. Identify what it is we are worried about

5. Identify what if any system failures/ incidental learning and that we have from you any suggested solutions/ recommendations

6. To discuss the next Steps

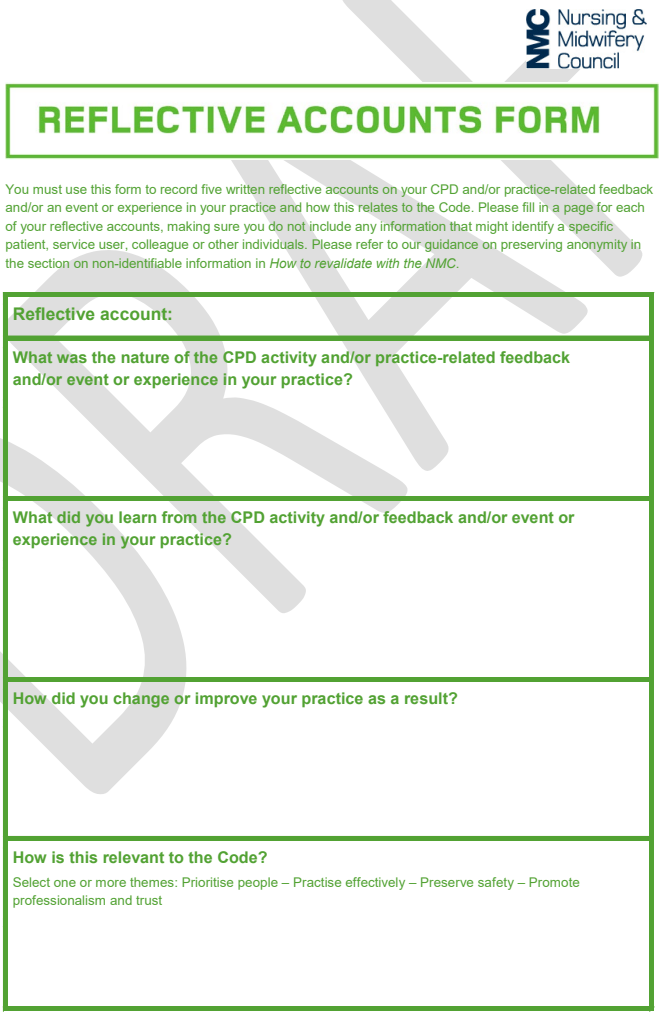
7. Ensure that everyone leaves the meeting feeling that they know what is expected of them

8. Know how to access support, wellbeing, Clinical Psychologist

Professional Reflection

Reflection allows staff to make sense of a situation and understand how it has affected them. It allows you to identify areas for learning and development to include in your professional development objectives and supports sharing and learning from other professionals. Reflective accounts can be completed within the 'assist me 'packs.

The Health and Care Professions Council have produced a guide to support effective reflection, which can be found here: What is reflection? | (hcpc-uk.org). Guidance on reflection for Doctors and medical students can be found here: The reflective practitioner - guidance for doctors and medical students - GMC (gmc-uk.org) Nurses and Midwives can also complete an NMC reflective account which can form part of their nursing revalidation:



NMC Nursing & Midwifery Council

REFLECTIVE ACCOUNTS FORM

You must use this form to record five written reflective accounts on your CPD and/or practice-related feedback and/or an event or experience in your practice and how this relates to the Code. Please fill in a page for each of your reflective accounts, making sure you do not include any information that might identify a specific patient, service user, colleague or other individuals. Please refer to our guidance on preserving anonymity in the section on non-identifiable information in *How to revalidate with the NMC*.

Reflective account:
What was the nature of the CPD activity and/or practice-related feedback and/or event or experience in your practice?
What did you learn from the CPD activity and/or feedback and/or event or experience in your practice?
How did you change or improve your practice as a result?
How is this relevant to the Code? Select one or more themes: Prioritise people – Practise effectively – Preserve safety – Promote professionalism and trust

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Staff Wellbeing/Support Services at CTM

Employee Experience and Wellbeing at CTM UHB can be found on social media "To keep staff updated with everything that is being done to improve your experience at CTM, and all of the wellbeing support we can offer you."

To access or enquire about any of the Health Board's wellbeing services email: CTM.WellbeingServices@wales.nhs.uk

Free Online Support

For a full range of free support and resources please visit https://people.nhs.uk/help/ . The services available to staff include: staff support line, PROJECT 5, wellbeing support and bereavement services.

- **Unmind** is a mental health platform that empowers staff to proactively improve their mental wellbeing. Using scientifically-backed assessments, tools and training you can measure and manage your personal mental health needs. Included are digital programmes designed to help with stress, sleep, coping, connection, fulfilment and nutrition. **Go to nhs.unmind.com/signup**

- **Headspace** is a science-backed app in mindfulness and meditation; providing unique tools and resources to help reduce stress, build resilience, and aid better sleep. **Go to https://www.headspace.com/nhs for NHS staff to access**

- **NHS Supporting our People** – Helps you manage your own health and wellbeing whilst supporting others. **Go to** https://people.nhs.uk/guides/health-and-wellbeing-conversations/steps/resilience-based-approaches-to-wellbeing/

- **Stress and you** (A free guide for Nursing Staff) https://www.rcn.org.uk/professional-development/publications/PUB-004967

- **Mindfulness Association** - The Mindfulness Association offers lots of online courses in the practice of mindfulness, compassion and insight meditation for relieving symptoms of stress, worry and anxiety. **FREE** daily online meditation is available 7pm – 8pm, 7 days per week. *(The* Mindfulness Association is *also available on App Store)*

- **Silver Cloud** - An on-line CBT resource on managing stress, sleep and resilience. NHS staff can sign up now at: https://cymru.silvercloudhealth.com/signup/.

- **BMA wellbeing services** available to all doctors, not just BMA members https://www.bma.org.uk/advice-and-support/your-wellbeing/wellbeing-support-services/counselling-and-peer-support-for-doctors-and-medical-students

- **RCM I Learn Resources** – Building resilient practitioners https://www.ilearn.rcm.org.uk/

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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 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.

Referral to the NMC or GMC

A referral to the NMC or GMC will only be made if following a robust investigation with the support of HR, evidence of behaviour or conduct that warrant referral is found. A full support system will be put in place for any members of staff who are referred and staff will be informed prior to any referrals being made. It is important to emphasise that this will only be in cases where significant harm has been identified. Any cases where it is felt there are immediate practice concerns will be escalated to the Director of Midwifery, Director of Nursing & Medical Director.

Family Support

Family liaison is to be identified and contact made to inform patient and or family that the incident has occurred, discuss investigation process, including any questions to be addressed and engagement. Ensure PTR guidance is addressed.
**Early, regular contact with family is advised.'*

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Chapter 19 – Support for Patients and their Family

Bereavement Support

CTM provides a professional, proactive and flexible service to relatives of patients who have died on the wards within Cwm Taf Morgannwg University Health Board's hospitals. We provide a service that is sensitive to the difficulties families may face at this time.

The death certification process is managed whilst ensuring that the Health Board's statutory obligations are fulfilled. Working closely with other key professionals, for example funeral directors, the Coroner's Office and Registrar of births and deaths to develop a seamless service and to ensure bereaved families are aware of the support available from outside agencies.

Who is it for?

The Bereavement Officer provides general non-clinical advice, information, and guidance to patients' relatives, for example providing the next of kin with guidance on what to do next once the medical certificate has been released.

Can anyone use this service?

The service is for bereaved families. The families are informed of the service by nurses and given the details of how to contact the Bereavement Officer.

Opening Hours

Opening Times

Monday to Friday

9:00am – 4:00pm (Excluding Bank Holidays)

The operating hours are between 08:00 and 16:00 on Mondays to Fridays (excluding Bank Holidays). Hours outside these and bank holidays are classed as 'out of hours'. The 'out of hours' service is limited. Refer to the policy for 'out of hours' mortuary service for more information.

Routine viewings are not performed "out of hours"

- The Bereavement Office at Prince Charles Hospital can be located in the Mortuary Department situated on the ground floor of the Hospital behind the Accident & Emergency Department.

- 01685 728625

- The Bereavement Office at the Royal Glamorgan Hospital can be located via the main entrance. Enter the South wing, walk down the corridor where the Pathology Department can be found on the left. On arrival, ring the bell, gain admission and ask for the Bereavement Office at the reception desk.

- 01443 443249

- The Bereavement Office at the Princess of Wales Hospital can be located at the back of the hospital.
  - 01656 754088

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Useful links

- Cruse – 0808 808 1677. Helpline@cruse.org.uk

Merthyr Tydfil and RCT – 01685 876020; Email: merthyr.rct@cruse.org.uk
Bridgend – 01792 462845 Email: morgannwg@cruse.org.uk

- Young People – www.hopeagain.org.uk
- Stillbirth and Neonatal Death Charity (SANDS) – 0808 164 3332 helpline@sands.org.uk
- 2 Wish Upon a Star – support for bereaved parents
- Support after Suicide – Help is at Hand booklet
- Winston's Wish – support for bereaved children – 08088 020 021

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Chapter 20 - Training and Resources

If you require any further information in relation to this, document, patient safety, or would like to enquire regarding further training for yourself or your team. Please contact the central Patient safety team on 01443 744 800 or by emailing: *insert new email address for training queries*

Further resources & support

- **Patient safety clinics –** the patient safety team are delivering Patient Safety Clinics across the HB, to focus on topical issues pertinent to different clinical groups. For further information, or to request a clinic within your area, contact the Learning from Concerns Coordinator or the Patient Safety Team Inbox.

- Patient Safety newsletters will be disseminated to capture key learning themes.

- A **support guide** is available alongside the full incident management framework, to specifically support those staff who are not directly undertaking investigations but who may still be called upon to contribute.

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