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Incident management policy, including serious incidents

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AUTHOR / FURTHER INFORMATION:	Charlotte Bartlett, Head of Clinical Governance		
STAKEHOLDERS INVOLVED:	Clinical Governance team, Health & Safety team, Subject Matter Expert leads, Maternity Quality & Safety team, Divisional Triumvirates, patient safety leads, patient experience leads, Chief Nurse Officer.		

DOCUMENT REVIEW HISTORY:

Date	Version	Responsibility	Comments
April 2017	01	Quality & Clinical Governance	New, cross-site policy
April 2019	02	Charlotte Bartlett	Full revision of version 01
Jan 2020	03	Charlotte Bartlett	Expansion of section on external reporting; addition of section on human factors and support for staff
June 2021	04	Charlotte Bartlett	Addition of HSIB process and external scrutiny for maternity SIs; explicit detail around staff involvement

May 2022	05	Charlotte Bartlett	Scheduled review
NEXT REVIEW		March 2023	

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1.0 Summary

This policy describes how and why staff should report and investigate clinical and non-clinical incidents, including near misses, potential or actual incidents and serious incidents (SIs). It covers all incidents, whether they involve patients, relatives, visitors, members of staff, contractors, or the general public, or are associated with research.

2.0 Introduction

The Trust is committed to creating an open and fair culture in which staff are confident about reporting incidents, near misses and concerns. Evidence suggests that by creating a 'reporting culture', organisations can improve their ability to learn when things go wrong and improve safety.

Following the reporting of an incident, an investigation should be carried out which is proportionate to the incident and any associated risks, is open and evidence based and does not seek to apportion blame.

3.0 Objectives

- To describe the Trust's approach to the reporting, investigation and management of incidents, serious incidents and near misses
- To set out the responsibilities of Trust staff for reporting and investigation of incidents
- To explain how harm arising from an incident should be graded
- To provide assurance of the governance around incident management and learning

This policy is not intended as a manual or protocol for reporting incidents/use of Datix (the Trust's online incident management system), nor is it intended to replace the root cause analysis (RCA) investigation training that is in place.

4.0 Scope

This policy applies to all staff employed within the Trust and covers clinical and non-clinical areas. Incidents covered in the scope of this policy include those affecting patients, staff, visitors, contractors and members of the public on Trust premises.

This policy includes specific reference to serious incidents within Maternity Services and referral to the Healthcare Safety Investigation Branch (HSIB)

Exclusions:

This policy does *not* apply to the management of 'Major Incidents'. Please refer to separate policy.

This policy does not apply to issues around breaches of professional codes of conduct, disciplinary or HR processes. Please refer to appropriate workforce policies and processes.

5.0 Definitions

5.1. Incident

Any event that could have or did lead to harm, loss or damage associated with:

- Accidents / unexpected events
- Failure to deliver the expected standard of care or service delivery
- Patients, staff or the public being placed at unnecessary risk due to trust action or inaction
- Trust property or assets being placed at risk of loss or damage

5.2. Patient safety incident

Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients

5.3. Near Miss

Any event that did not lead to harm but could have; an occurrence which but for luck or good management, would in all probability have become a full blown incident.

5.4. Degree of harm

Degree of harm recorded must have occurred as a direct result of the incident. It does not relate to the patient's underlying medical condition OR the harm that could potentially have happened

5.5. No harm incident

The incident occurred, but no harm was caused to the people involved / affected. This is distinct from a near miss when the incident did not actually happen (see 5.3)

5.6. Low harm incident

Minimal harm caused by the incident that required extra observation or minor treatment

5.7. Moderate harm incident

Significant but not permanent harm caused by the incident that resulted in increased treatment, possible surgical intervention, cancelling of treatment, transfer to another area such as ICU, readmission, prolonged episode of care

5.8. Severe harm incident

Permanent or long-term harm caused by the incident e.g. lessening of bodily, sensory, motor, physiologic or intellectual functions

5.9. Death (in relation to incidents)

Person affected died as a direct result of this incident

5.10. Notifiable safety incident

Any unintended or unexpected incident that occurred in the patient's care that, in the reasonable opinion of a healthcare professional appears to have resulted in, or requires treatment to prevent:

- the death of a patient, where the death relates directly to the incident rather than to the natural course of the patient's illness or underlying condition
- severe harm, moderate harm, or prolonged psychological harm

The statutory Duty of Candour applies to all notifiable safety incidents (see section 11).

5.11. Incident level

5.11.1. Level 1 – an incident or near miss that does not meet the criteria for a serious incident (SI)

5.11.2. Level 2 – an incident or near miss where the potential for learning is so great, or the consequences so significant that a comprehensive serious incident investigation is warranted. However, this level of SI does not meet the NHSE SI Framework for external reporting. Approval is by the relevant Executive, i.e. the Chief Medical Officer, Chief Nursing Officer or CEO and the investigation process mirrors that for externally reportable incidents (see below).

5.11.3. Level 3 – an incident or near miss where the potential for learning is so great, or the consequences so significant that a comprehensive serious incident investigation is warranted. This type of SI meets the NHSE SI Framework for external reporting to our Commissioners and CQC via the Strategic Executive Information System (StEIS). Approval that an incident constitutes an externally reportable SI can only be by the relevant Executive, i.e. the Chief Medical Officer, Chief Nursing Officer or CEO.

5.12. Serious incident

See sections 5.11.2 and 5.11.3 above. The flowchart in Appendix A sets out the reporting and investigation of serious incidents in the Trust. Modified versions specific to Maternity and Tissue Viability are in Appendix B and C respectively.

In addition, there is no definitive list of events/incidents ('trigger lists') and lists should not be created locally as this can lead to inconsistent or inappropriate management of incidents:

- not appropriately investigating things that are not on a list even when they should be investigated
- undertaking full investigations of incidents where that may not be warranted simply because they seem to fit a description of an incident on a list

Serious incidents are defined in the SI Framework as acts and/or omissions that result in:

- Unexpected or avoidable death
- Unexpected or avoidable injury resulting in serious harm
- Unexpected or avoidable injury that requires further treatment to prevent death serious harm
- Actual or alleged abuse
- Never Events
- Incident(s) that prevent or threaten an organisation's ability to continue to deliver an acceptable quality of healthcare
- Major loss of confidence in the service (e.g. prolonged media coverage)

5.13. Never Event

Never Events are patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.

Each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death does not need to have happened as a result of a specific incident for that incident to be categorised as a Never Event.

In this context, it is important that when a Never Event occurs, regardless of the outcome, the problems in care are identified and analysed through full investigation using a systems-based investigation method (such as root cause analysis – RCA) to understand how and why they occurred (from a systems perspective), as described in the Serious Incident Framework. This will mean effective and targeted action can be taken to prevent recurrence.

The NHS list of Never Events is in Appendix E.

5.14. Root Cause Analysis

Root Cause Analysis (RCA) is a structured investigation that aims to identify the true causes of a problem and the actions necessary to eliminate it. RCA articulates the fundamental issues and what did, or what may have, caused the incident. It identifies the causal factors leading to the incident: care and/or service delivery failings and their contributory factors.

RCA produces a report with recommendations for system and process changes that are needed to mitigate the risk of recurrence and to improve performance. It provides in-depth understanding of events being investigated, enabling learning from mistakes.

5.15. Care and service delivery problems

Care delivery problems ('CDP') and service delivery problems ('SDP') are identified as part of root cause analysis. They may be defined as something happened that should not have happened, OR something that should have happened but did not happen.

5.16. StEIS

Strategic Executive Information System. Hosted by NHSI/E to report serious incidents and facilitate monitoring of investigations by Commissioners.

5.17. NRLS

National Reporting and Learning System. Managed and operated by NHSI/E. All patient safety incidents are uploaded to NRLS via Datix to support learning and improvement at a national level.

5.18. HSIB

Healthcare Safety Investigation Branch. Hosted by NHSE/I with a remit to conduct independent investigations of patient safety concerns across two programmes: national investigations and maternity investigations. The HSIB process is appended at Appendix D

6.0 Duties and Responsibilities

6.1. Chief Executive Officer (CEO)

Has overall responsibility for patient safety at the Trust, ensuring safe and effective systems are in place to meet statutory requirements. The CEO may also approve the declaration of a serious incident.

6.2. Chief Nurse Officer and Chief Medical Officer

Nominated Executives with overall responsibility for quality and safety, overseeing the work led by the Associate Director of Quality Governance. Responsible for review of all potential serious incidents and approving the declaration of a serious incident.

The Chief Nurse Officer is responsible for providing assurance to the Clinical Commissioning Group, the Coroner and other external agencies of the Trust processes and performance around patient safety and incident reporting.

6.3. Associate Director of Quality Governance

Provides day-to-day leadership on quality and safety activities, ensuring that the Trust's key objectives are met. Supported by the Head of Clinical Governance, he/she is responsible for ensuring that quality and safety processes are reviewed, updated and driven forward by the Trust.

The Associate Director of Quality Governance reports to the Chief Nursing Officer and both are accountable to the Chief Executive and the Board of Directors for ensuring effective implementation of this policy and the processes described.

The Associate Director of Quality Governance is responsible for discussing escalated incidents with the Chief Nursing Officer and Chief Medical Officer to enable an Executive decision to be made on the level of investigation and requirements for external reporting.

The Associate Director of Quality Governance is responsible for final review and sign-off of all serious incident investigation reports, following their approval by the Divisional Triumvirate and prior to submission to the Chief Nursing Officer for Exec approval. This may also be delegated to the Head of Clinical Governance.

In collaboration with the Chief Nursing Officer, the Associate Director of Quality Governance provides a point of liaison with the Clinical Commissioning Group, providing assurance of safe processes, responding to queries and when necessary, notifying them directly of any issues/incidents of concern, for example should a Never Event occur.

6.4. Divisional Triumvirates

Divisional Triumvirates and senior management are responsible for leading quality and safety strategies within their Divisions and ensuring appropriate structures and processes are implemented, maintained and delivered.

These include:

- Operational delivery of this policy and providing leadership in the Trust's approach to incident management
- Reviewing and monitoring incident trends and ensuring comprehensive investigation of serious incidents, with implementation of action plans to minimise the risk of recurrence
- Promoting an open culture within the division and facilitating/supporting Trust wide learning from (patient) safety issues
- Timely delivery and approval of serious incident investigation reports, prior to Executive sign-off
- Ensuring actions identified within incident and serious incident investigations are implemented and embedded within their Divisions

6.5. Clinical Governance Department (CG)

The CG team, led by the Head of Clinical Governance, supports the patient safety agenda, playing a key role in promoting an organisational safety culture to prevent harm by improved incident reporting, investigation and shared learning. Responsibilities include daily

monitoring of reported incidents, with timely escalation of incidents of concern together with support for incident investigators to enable timely delivery of SI reports. The CG team provide incident data to the Trust, undertaking thematic reviews and enabling monitoring of Divisional performance and incident trends.

The CG team are responsible for incident reporting to external bodies, namely the National Reporting & Learning System (NRLS) and the Strategic Executive Information System (StEIS). The CG team are responsible for submission of approved SI investigation reports to the CCG and for facilitating the response to any ensuing queries.

The CG team provide training to staff on use of Datix (the Trust's online safety and risk management system), both for reporting incidents and for interrogating data, for example via dashboards. The department is responsible for the Datix contract, liaising with IT in the event of problems and ensuring it is accessible to all staff.

6.6. Trust Mortality Surveillance Group and Divisional Mortality Review Groups

Where mortality review concludes that significant sub-optimal care occurred, the case must be escalated to the Clinical Governance team by the Chair of either Group for consideration of a comprehensive serious incident investigation. The findings of the mortality review will in turn be escalated to the Responsible Executive in line with the usual SI process.

6.7. Incident handlers

The incident handler is part of the management team of the person/area affected by the incident, for example the ward or department manager. Incident handlers are responsible for the immediate response to the incident report:

- Making safe when necessary and confirming the degree of harm caused to inform decisions about Duty of Candour
- Immediate escalation of potential serious incidents
- Identification of RIDDOR-reportable incidents, with escalation to the Health and Safety team
- Assigning a suitable investigator and ensuring review commences within two working days

The incident handler monitors the investigation, ensuring its completion within the appropriate timeframe: 10 working days for level 1 incidents and 60 working days for SIs.

6.8. Incident investigators (level 1 incidents)

Incident investigators are assigned by the Incident Handler and are responsible for:

- Completing the investigation within 10 working days and updating the Datix record accordingly
- Developing and implementing action plans to reduce the risk of recurrence
- Providing feedback, advice and support to patients and staff involved, including the reporter
- Sharing learning

6.9. Lead Investigators (serious incidents)

Serious incident investigators are assigned by an appropriate Director. They are responsible for:

- Scoping the incident to identify terms of reference of the investigation, evidence and documentation required and who may need to provide a witness account;
- Preparing a timeline of events following comprehensive review of the medical record;
- Liaising with subject matter experts when appropriate;
- Undertaking root cause analysis;
- Writing up their findings in the Trust/CCG approved SI investigation report template to enable timely submission to the SI panel;
- Ensuring factual accuracy of the report;
- Presenting their report at Divisional Panel and making any subsequent amendments prior to Executive approval of the final report.
- Providing feedback, advice and support to patients and staff involved, including the reporter
- Sharing learning

6.10. Health & Safety Department

The Health and Safety Department plays a key role in promoting organisational safety culture, with a primary focus on staff, visitor and public safety. Responsibilities include the review of non-clinical incidents, analysis of incident data to support the identification of safety opportunities, provision of a range of education and training sessions to support safety management improvement, providing expert guidance and support to incident investigators, and ensuring RIDDOR incidents are reported to the Health and Safety Executive within required time frames (see section 7.3.1).

6.11. Complaints Department

The complaints team should alert one of the governance managers or head of governance if they believe a complaint letter includes detail of a patient safety incident. Such situations need careful management and a flowchart is set out in Appendix E.

The complaints team should check if an incident has already been logged, in which case they should link the complaint record to the incident record within Datix. Conversely, if the complaint letter details a previously unreported incident, the CG team will log the incident and link the record to the complaint record.

6.12. Subject Matter Experts (SME)

These are individuals with specialist knowledge or responsibilities for certain subjects and incident types. They include but are not limited to: tissue viability, pharmacy, safeguarding, security, fire, H&S, infection control, thrombosis. SMEs are expected to provide specialist advice to the incident investigation and may also be required to attend SI panel meetings to enable assurance of accuracy and completeness of the report and associated action plan.

6.13. Responsible Officers for incidents with specific reporting requirements

There are a number of incident types that require reporting to regulatory or other bodies (see section 7.3). The designated leads for those areas have responsibility for advising on the correct protocols and ensuring the Trust complies with the relevant reporting framework.

6.14. Patient Safety Fellow

Incidents are notified via the Datix alerting system to the Patient Safety Fellow in the Postgraduate Medical Education Department. This individual is responsible for reviewing incidents to identify any Trainees who may need support in the event of their involvement, for example in the case of a serious incident.

6.15. All staff

All staff have a responsibility to report incidents and unsafe situations.

7.0 Incident Reporting

Incident reporting is a proxy measure of how safe an organisation is: it is well demonstrated that the more low and no harm incidents reported, then the more open and safe the organisation, with a better safety culture and more information available to enable action and implementation of safer systems and processes. Reporting incidents and near misses provides the opportunity to ensure the learning gained from the experience of patients, staff or members of the public is used to reduce the risk of something similar happening in future.

Robust incident reporting allows themes, trends and clusters in the data to be identified, forming the basis for further work to determine the scale and general severity of the issues highlighted. The output of this work supports local learning and changes to practice.

The focus of reporting should be on analysing the root causes of incidents, robust learning from them and identifying actions to mitigate risks to patients. It is therefore important that all staff, both clinical and non-clinical, have the confidence and knowledge to report incidents.

To support an open culture of reporting, the Trust also has a policy of open disclosure called 'Freedom to Speak Up' which supports staff to raise concerns. Details are on the Trust intranet.

7.1 Immediate action

Before the incident can be reported, some situations may require immediate action to make safe. This may involve:

- Emergency medical care or summoning assistance
- Moving individuals to a safe environment
- Removal or isolation of a piece of equipment
- Notifying an appropriate senior member of staff
- If appropriate, notifying a patient's family

7.2 Online incident reporting system

At CWNHSFT, incidents are reported on the online safety and learning system: Datix. This is accessible to all staff via the intranet; a log-in is not required.

All staff have a responsibility to report any incidents or unsafe situations. These include non-clinical incidents and incidents around staff safety.

7.2.1 Training for Incident Handlers and Investigators in use of Datix is available from the CG team (contact Datix Mailbox by phone or email) and Datix user guides are available. The online reporting and investigation form includes embedded guidance. Click on  to access the guidance or use the links at the top of the reporting page.

7.2.2 The flow of incidents through Datix is described in the flowchart in Appendix F

7.2.3 In the event of IT failure longer than 4 hours, the Datix downtime process will be implemented. The process is included in Appendix G.

7.3 Potential serious incidents

As soon as it has been identified that an incident may constitute a serious incident (refer to section 5.11 and 5.12), this must be escalated to appropriate senior members of staff in the clinical team and the clinical governance team who will flag within the incident record on Datix. Refer to the SI escalation flowchart in Appendix A.

7.3.1 'Rapid Reviews'

In most cases, the Clinical Governance and Exec teams will need further information to enable a decision as to whether the incident constitutes a serious incident or not. This is facilitated by a 'rapid review'.

A proforma is sent by the clinical governance manager to the appropriate clinician to undertake an assessment of the facts as they are known in the immediate aftermath of the incident.

To enable the Trust to fulfil its reporting requirements and log on StEIS within 48 hours, this must be returned within the first 24-36 hours of the incident occurring to enable a timely decision about the level of investigation needed and whether or not to report externally.

The rapid review must include detail of immediate action taken to minimise the risk of harm to others

7.3.2 '72-hr Reviews'

Once an SI has been logged on StEIS and is therefore visible to the CCG and CQC, our Commissioners may request a '72 hour review'. This is usually only requested for deaths or for incidents that threaten the organisation's ability to deliver its services (eg IT infrastructure). The proforma is the same as for the 'rapid review' and will be supplied by the governance team for onward submission to the CCG or, if requested, the CQC.

In practice, the information within the 72-hour review is likely to be identical to that within a rapid review and as such, the governance team will ensure streamlining of the process with no duplication of requests. It is their purpose that differs: the Trust's rapid review facilitates Exec decision-making, while the CCG's 72-hour review provides a level of assurance to our Commissioners and the CQC.

7.4 Incidents with specific reporting requirements

In addition to reporting all incidents on Datix, several specific incident types also require reporting to external agencies or regulators.

A number of incidents require notifying to the CQC; the majority can be notified via NRLS, but some require notifying directly. Details are in Appendix J.

7.5 Incidents requiring referral to HSIB

Incidents within Maternity Services meeting the criteria for HSIB referral follow a separate and defined process, as set out in Appendix D

The specific criteria are:

- Cooled baby/potential brain injury;
- Intrauterine death in labour;
- Early neonatal death;
- Maternal death

Once HSIB have accepted a case, any Trust investigation must stop.

8.0 Incident investigation

8.1. Summary and general principles of incident investigation

Incident investigations must be conducted with an appropriate level of independence;

The investigation process must be proportionate to the incident and any associated risks;

The investigation must begin and end in a timely manner;

The investigation process must be open and transparent;

The investigation team must keep relevant parties appropriately informed;

The investigation must be based on evidence;

The investigation must look for improvements and not to apportion blame.

8.2 Human Factors

Human Factors are organisational, individual, environmental, and job characteristics that influence behaviour in ways that can impact safety.

Human Factors principles and examination of the way that individuals behave, teams work, equipment and settings are designed, and organisations function should be applied to the analysis of incidents to identify learning and corrective actions. By taking Human Factors into account during incident investigation, learning and more robust corrective actions can be identified by focussing on optimising human performance through a better understanding of the behaviour of individuals, their interactions with each other and with their environment.

8.2.1 Some of the most common factors influencing human behaviours that should be taken into account during an incident investigation:

- Cognition and mental workload
- Distractions
- The physical environment
- Physical demands
- Device/product design
- Teamwork

- Process design

8.2.2 Examples of Human Factors include:

- Unfamiliarity with the task – and conversely, overfamiliarity with the task
- Information overload
- Misperception of risks or hazards
- Low self-esteem or poor morale
- Cultural norm of condoning violations and non-compliance with policy/process
- Overconfidence/lack of insight (Dunning-Kruger effect)
- Inattentional blindness - failure to notice a fully-visible, but unexpected object because attention was engaged on another task, event, or object
- Situational awareness - being aware of what is happening around you, where you are in relation to other people or things
- Expectation bias – hear/see what we expect to hear/see
- Confirmation bias – the processing of information (recall, search, favour, interpret) in a way that is consistent with existing beliefs
- Fixation error - concentration solely upon a single aspect of a case to the detriment of other more relevant aspects; 'tunnel vision'.

8.3 Lessons Learned

There may be occasions when nothing could have prevented the incident and no root cause(s) are identified. However, there are always lessons to learn and key safer practice issues may be identified which did not materially contribute to the incident.

8.4 Level 1 incident investigations

The purpose of the investigation is to:

- Gather / confirm information – what, where, when, who
- Consider the evidence – why did it happen, what was the impact / harm caused
- Based on the above, to make recommendations to minimise recurrence
- Implement an action plan that the Handler and/or Investigator will lead to reduce the risk of recurrence.

The timeframe for investigation of level 1 incidents is 10 working days. The above findings are then logged within the incident record in Datix.

8.5 Serious incident investigations

Investigation of a serious incident (SI) involves root cause analysis (RCA) to articulate the fundamental issues and causal factors contributing to the incident and provide an in-depth understanding of the events being investigated, with learning from mistakes.

SI investigation utilising root cause analysis is a structured process that involves:

- Identification of scope of investigation
- Review of evidence and documents (e.g. medical notes and charts, witness accounts)
- Compilation of a timeline of events based on the evidence

- Identification of good practice and identification of care delivery problems and service delivery problems
- Identification of contributory factors
- Identification of root cause(s) - the most fundamental underlying contributory factors that led to the incident. These should be addressed or escalated. Root causes should be meaningful, (not sound bites such as 'communication failure') and there should be a clear link, by analysis, between the root CAUSE and the EFFECT on the patient. Assess each CDP/SDP & ask if it had not occurred would the incident still have happened?
    - If yes, unlikely to be the root cause
    - If no, it is likely to be the root cause, or one of them
- Agreement of recommendations - recommendations and solutions should be designed to address the root causes and care/service delivery failings identified within the investigation
- Identification of an action plan – this must directly reflect the recommendations and must be precise and SMART (specific, measurable, achievable, realistic, timed). Action plans require identification and agreement of persons/groups responsible for actioning and for monitoring
- Specification of arrangements for shared learning locally and trustwide

8.5.1 Terms of reference and scope

The scope of the investigation should be agreed at the outset, as part of the initial investigation meeting. As a minimum include:

- what areas are being looked at, over what period of time
- who needs to be asked for witness accounts of events
- who needs to be involved in the investigation
- any issues raised as part of the mortality review process, if applicable.
- issues or queries raised by the patient/family, either within a complaint, or as part of the Duty of Candour process.
- details of support for staff, with consideration of A Just Culture Guide
- any necessary involvement of external agencies, e.g. safeguarding, police

Generic terms of reference should be adapted to include any objectives specific to the incident in question:

- To establish the facts i.e. what happened (*effect*), to whom, when, where, how and why (*root causes*)
- To establish whether failings occurred in care or treatment
- To look for improvements rather than to apportion blame
- To establish how recurrence may be reduced or eliminated

- To formulate *recommendations* and an *action plan,* with a means of *monitoring implementation*
- To provide a *report and* record of the investigation process & outcome
- To identify a means and routes of *sharing learning* from the incident
- To identify any trends or systematic failures
- When relevant, to ensure questions from patient or family are addressed by the investigation
- For surgical SI investigations: to identify any non-compliance with WHO surgical safety checklist or LocSSIP

8.5.2 SI Investigation reports

SI investigation reports provide a formal record of the investigation and its recommendations, together with a means of sharing learning. Trust serious incident investigation reports are documented within the approved template; this is based on the NPSA template and is approved by the Clinical Commissioning Group.

Investigation reports must be evidence based and include analysis of that evidence, with appropriate recommendations. They must not move into speculation.

In essence, the report should show a clear thread connecting:

1. the root cause(s);

2. how these directly resulted in the specific care and service delivery problems;

3. how these led to the documented actual or potential effect on the patient.

While they may be made available to the Coroner or a court, SI reports are not intended for that purpose. Rather, they are for the organisation to investigate what went wrong, to learn from that and put actions in place to prevent recurrence. Their function is for organisational learning.

8.5.3 SI reports and the NHSE SI Framework

Taken from the NHSE SI Framework:

'*Investigations carried out under this Framework are conducted for the purposes of learning to prevent recurrence. They are not inquiries into how a person died (where applicable) as this is a matter for Coroner.*

Neither are they conducted to hold any individual or organisation to account as other processes exist for that purpose including: criminal or civil proceedings, disciplinary procedures, employment law and systems of service and professional regulation, such as the Care Quality Commission and the Nursing and Midwifery Council, the Health and Care Professions Council, and the General Medical Council.

In circumstances where the actions of other agencies are required then those agencies must be appropriately informed and relevant protocols, outside the scope of this Framework, must be followed.'

SI investigations should never be used in place of a disciplinary or HR investigation, as specified within the SI Framework. Where concerns are raised regarding an individual's

performance due to a lack of capability in terms of skill, knowledge, experience or aptitude, the processes outlined within the Managing Performance (Capability) Policy and Procedure and Procedure for Handling Concerns about Doctors and Dentists will form the primary investigation.

8.5.4 Approval and sign-off

Once the SI investigation report is complete, has been proof-read and checked for factual accuracy, it is submitted to the Divisional Panel for review and approval. Panels are either monthly standing panels, or may be *ad hoc* to enable timely submission.

The report is presented by the lead investigator and the objective is to approve the final draft, including the action plan, prior to Executive approval.

The SI panel is also responsible for agreeing who is responsible for communicating the investigation findings to the patient/family/carer, in line with Duty of Candour.

Panel terms of reference may be found in Appendix I.

9 Support for staff following an incident: A Just Culture

A just and learning culture is the balance of fairness, justice, learning. It is not about seeking to blame the individuals involved when care goes wrong. It is also not about an absence of responsibility and accountability.

In order to achieve a just and learning culture when care has not gone as expected or planned, three questions should be asked:

- Who is hurt?
- What do they need?
- Whose obligation is it to meet that need?

These are three very powerful questions that refer to everyone: the staff involved, the patients and their loved ones.

The Trust has a responsibility to support its staff following an incident. Any staff involved in an incident may need support from their peers, colleagues and managers. It is the line manager's responsibility to ensure that individuals are supported appropriately.

The NHS Just Culture Guide (previously called 'The Incident Decision Tree') supports consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents. It is not intended to replace the incident investigation, nor any HR or disciplinary investigation. The actions of staff involved in an incident should not automatically be examined using the Just Culture Guide, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action.

A Just Culture Guide may be found at Appendix H.

Staff may also require external support from Occupational Health and/or the Trust's counselling service 'Dialogue' (available via Occupational Health). Individuals who have been away from work may require additional support and supervision to aid confidence when returning to work.

9.1 Patient Safety Education Fellow

This post is part of the Postgraduate Medical Education department and exists to provide support and advice for any trainee medical staff involved in patient safety incidents.

10 Feedback to staff

Staff involved in an incident, including reporters, must be kept informed of the progress of the investigation and its findings. Information sharing is important; individuals will need reassurance about management actions that may affect them.

An automatic feedback mechanism to reporters exists within Datix. Once the incident is closed, an email is automatically sent by the system to the reporter (providing they have given their Trust email), summarising the outcome and actions.

As part of serious incident investigations, the draft report should be shared with the staff involved and their feedback taken into account.

11 Duty of Candour

There is a general duty to act in an open and transparent way in relation to the care and treatment provided to our patients. This is referred to as Being Open. However, there is also a specific duty which applies to certain clearly defined patient safety incidents and requires us to be open, apologise, explain and document. This is Duty of Candour and the flowchart in Appendix K sets out the circumstances when it is applicable.

In practice, the Duty of Candour means that when a notifiable safety incident (see definitions – section 5.10) has occurred we must as soon as reasonably practicable:

- Notify patient or next of kin in person that an incident has occurred and apologise
- Provide an account of all the facts known about the incident
- Advise the patient or next of kin what further enquiries into the incident are being undertaken (i.e. how we are investigating)
- Provide reasonable support to the patient or next of kin
- Document all of the above
- Follow up with a written notification to include the key findings of further enquiries (i.e. outcome of any investigation) and a sincere apology.

Details of the process are found within the Trust's Duty of Candour policy and procedure on the intranet.

12 Involvement of patients and families

As part of the conversation with a patient/family/carer following a patient safety incident, there should always be discussion of any concerns or questions they may have about what happened. Any issues raised about the incident and its aftermath should be documented and addressed within the scope of the investigation and as part of the terms of reference.

Following the investigation and as part of the Duty of Candour process, a letter is sent by the Division which summarises the key findings, invites the patient to a meeting if they wish to discuss further and offers the full investigation report if they wish to see it.

Guidance on writing such letters is available from the Clinical Governance team, is included in the duty of candour policy (appendix) and on the intranet.

13 Governance framework and shared learning

Incident reporting and investigation is monitored through a number of different routes, both centrally and locally. The CG team monitor daily, with a view to identifying incidents of concern for escalation. A wide variety of dashboards within Datix are in place to enable easy tracking and visibility; bespoke dashboards can be developed for individuals on request.

The CG team produce monthly patient safety reports for each Division to be included in their quality reports. These cover a range of key metrics, both monthly snapshots and rolling 12-month data to identify themes and trends. In addition, ad hoc reports may be produced on request, depending on capacity. The CG team will also demonstrate how managers can produce their own specific reports from Datix according to need.

A comprehensive report on serious incidents is produced by the CG team every month. This is circulated to a wide range of groups, boards and committees at various levels across the Trust. It is also circulated to the Trust Board and its Quality Committee monthly. The content includes numbers, timeliness of reporting, closure rates, themes and trends, key issues, SI summaries.

A similarly comprehensive incident report is produced quarterly and annually by the CG team. Again, this is widely circulated.

The CG team provides support to enable thematic reviews of incidents to be undertaken. Key to this is the supply of data.

The learning from incident investigations is shared in a number of ways, including clinical governance half-days, divisional and directorate meetings, local and Trust newsletters, 'Lessons Learned' Grand Rounds.

Training and support in use of Datix is available from the CG team; enquiries should be directed in the first instance to DatixMailbox.

Training and support for incident investigation is available from the CG team. In the event of a serious incident, lead investigators are contacted by their divisional CG manager for 1-2-1 training. In addition, classroom training in root cause analysis is provided by the head of clinical governance.

13.1 Maternity serious incidents

Following publication of a number of national reviews, including the Ockenden Report in December 2020, serious incident investigations within Maternity Services undergo enhanced oversight, with external specialist scrutiny within a Local Maternity and Neonatal System (LMNS).

To facilitate this, a NW London LMNS has been established, with SI investigation reports submitted for review to the NWL Maternity Serious Incidents Oversight Group, to provide assurance of learning from mistakes and continuous quality improvement.

14 Monitoring compliance with this policy

Incident reporting, investigation and management are monitored in a number of ways. The Quality and Clinical Governance team monitor incidents logged on Datix on a daily basis, ensuring the record is appropriately graded and categorised and that any incidents of concern are escalated for consideration of the level of investigation required.

Further monitoring is undertaken quarterly whereby all incident data is collated by the Quality and Clinical Governance department into a high level report that includes details of incident numbers, types, harm caused, trends, learning and other key metrics. This report is circulated widely, including to Board-level committees who may request a thematic review of certain incidents showing a spike in numbers or high levels of harm.

Monitoring of incident management at Divisional level is undertaken monthly and reviewed at Divisional Quality Boards. It is also reported to the Trust Patient Safety Group.

Monitoring of serious incident management is undertaken by the Quality and Clinical Governance department. A monthly report is prepared that includes numbers, types, locations, summaries of root causes and actions. This report is shared widely across the organisation.

15 References

1. Serious Incident Framework, supporting learning to prevent recurrence, NHS England March 2015
2. Never Event policy and framework and Never Event list, NHS Improvement January 2018
3. National Patient Safety Agency – Root Cause Analysis investigation tools
4. A Just Culture, NHS Improvement March 2018
5. Being Fair: supporting a just and learning culture for staff and patients following incidents in the NHS, NHS Resolution, July 2019
6. Care Quality Commission: Notifications required by the Health and Social Care Act 2008
   https://www.cqc.org.uk/guidance-providers/notifications/notification-finder
7. The Ionising Radiation (Medical Exposure) Regulations 2017
   https://www.cqc.org.uk/guidance-providers/ionising-radiation/ionising-radiation-medical-exposure-regulations-irmer
8. Care Quality Commission: Mental Health Act notifications
   https://www.cqc.org.uk/guidance-providers/registration-notifications/mental-health-notifications
9. Human Factors in Healthcare
   https://chfg.org/
10. Incidents in NHS screening programmes
    https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes
11. Infection prevention and control incidents
    https://www.gov.uk/guidance/notifiable-diseases-and-causative-organisms-how-to-report
12. Healthcare Safety Investigation Branch:
    https://www.hsib.org.uk/

13. Ockenden Report:
https://www.donnaockenden.com/downloads/news/2020/12/ockenden-report.pdf

Appendix A
SI flowchart

Incident – potential SI?

Report on Datix and escalate to Clinical Governance (**SI email**)

Before end of shift

Within 24 hours

CG managers gather further information to support decision making: the 'rapid review'.

Alert Triumvirates & escalate

Within 48 hours

Within 1 working day

Clinical Governance escalates to CNO/CMO for agreement of level of investigation required

ON WORKING DAY 1
CG reports on StEIS & NRLS

Serious Incident declared: externally-reportable to CCG

Serious incident declared: requires comprehensive investigation but not externally reportable

Notify DMD/DN/DDO and request lead investigator
Duty of Candour – follow Trust process

WITHIN 24 hrs

Investigation Team
For example: Clinical/Service Director, General/Service Manager, Matron/Sister, CG manager, expert leads when needed e.g. VTE, TVN, resus, pharmacy etc.

Agreement of scope & terms of reference of investigation;
Notes & statements requested

BY WORKING DAY 2

Lead investigator reviews notes & statements; completes timeline

BY WORKING DAY 15

Draft report circulated to investigation team by lead investigator for comment

BY WORKING DAY 30

Following input from investigation team, final draft completed by lead investigator

BY WORKING DAY 35

BY WORKING DAY 60

Submit to CWHHE

PANEL MEETING - to sign-off final draft report

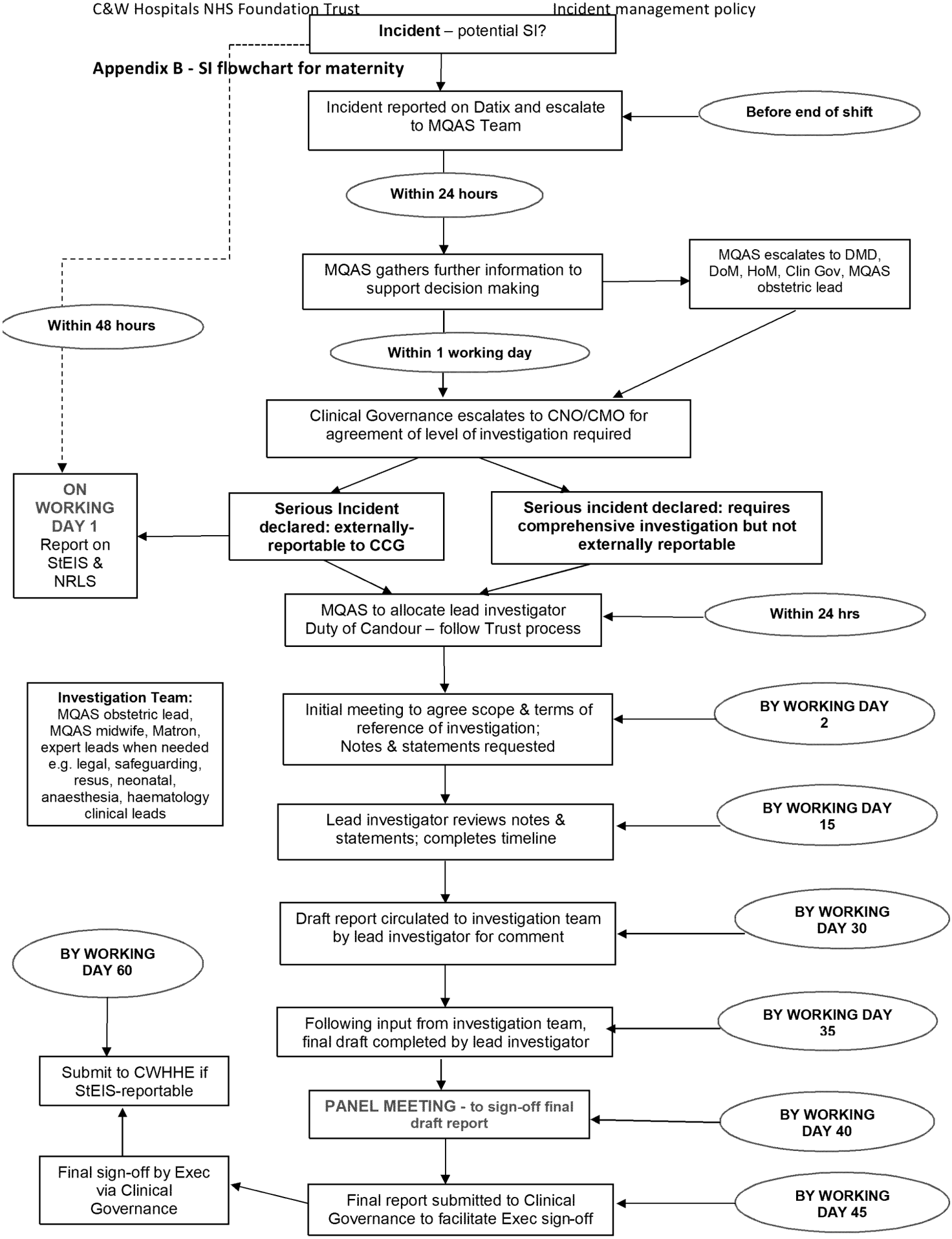
BY WORKING DAY 40

Final sign-off by Exec via Clinical Governance

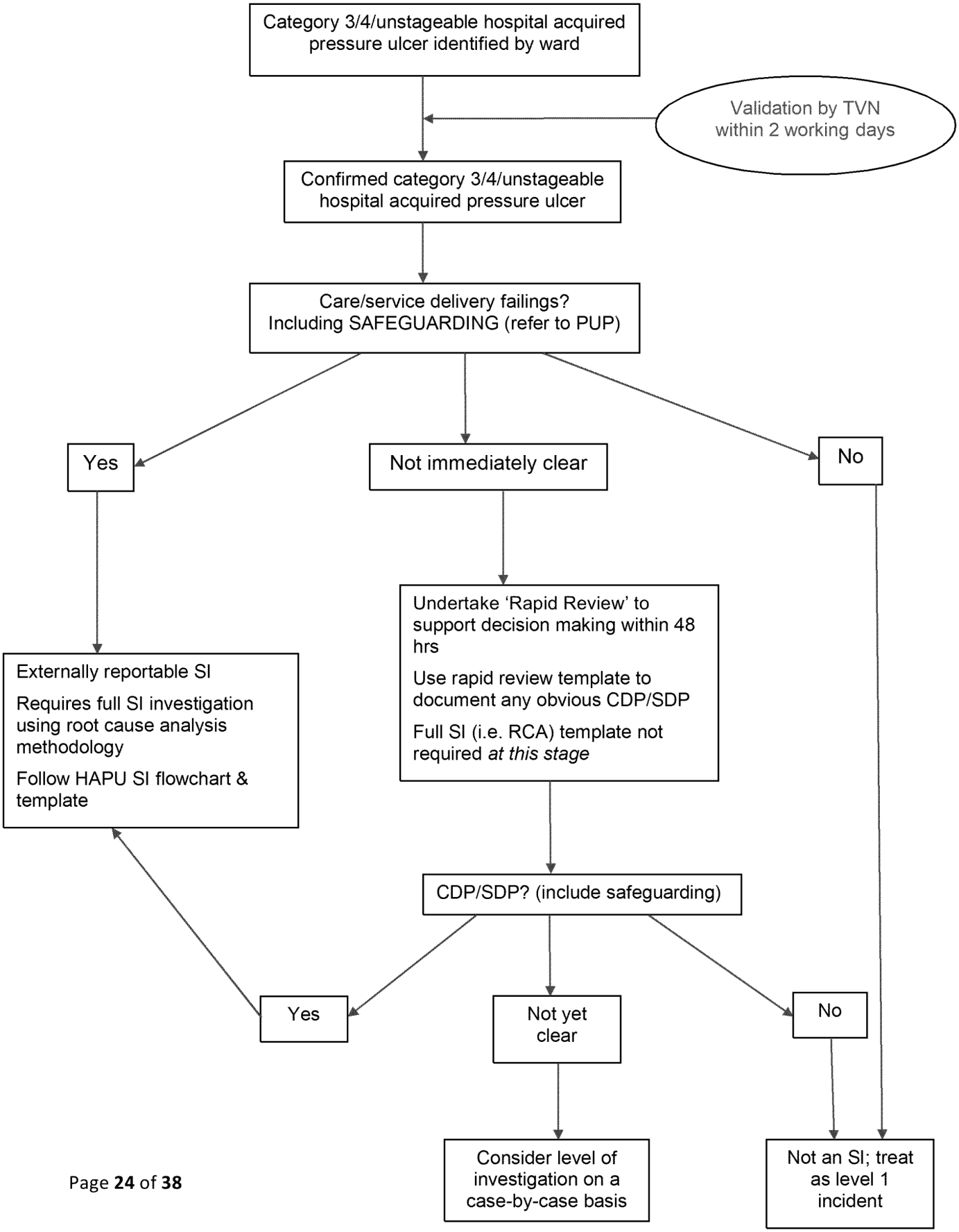
Final report submitted to Clinical Governance to facilitate Exec sign-off

BY WORKING DAY 45

Appendix B - SI flowchart for maternity



Appendix C – hospital acquired pressure ulcer SIs



Appendix D

HSIB SI process – Maternity Services

- Woman or baby meets HSIB referral criteria
- Duty of Candour to include information on HSIB, plus consent to pass on details to enable HSIB to make contact
- Notify HSIB of case details
- Undertake 72 hour review
- HSIB contact family to obtain consent for sharing of medical records
- If no consent given, or HSIB do not accept case, follow Trust SI process
- If consent given and HSIB accept case, 72 hour report and all relevant documentation uploaded to HSIB database
- HSIB send terms of reference and timeline to Trust for comment
- Staff identified for interviews
- Draft report shared with relevant staff for accuracy check
- Final report sent to Trust once approved by family (can take up to six months)

Appendix E

Never Events list

As at January 2018

For full details of inclusions and exclusions, refer to the NHS Never Event list 2018:

https://improvement.nhs.uk/documents/2266/Never_Events_list_2018_FINAL_v5.pdf

Surgical

1. Wrong site surgery
2. Wrong implant/prosthesis
3. Retained foreign object post procedure

Medication

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

Mental health

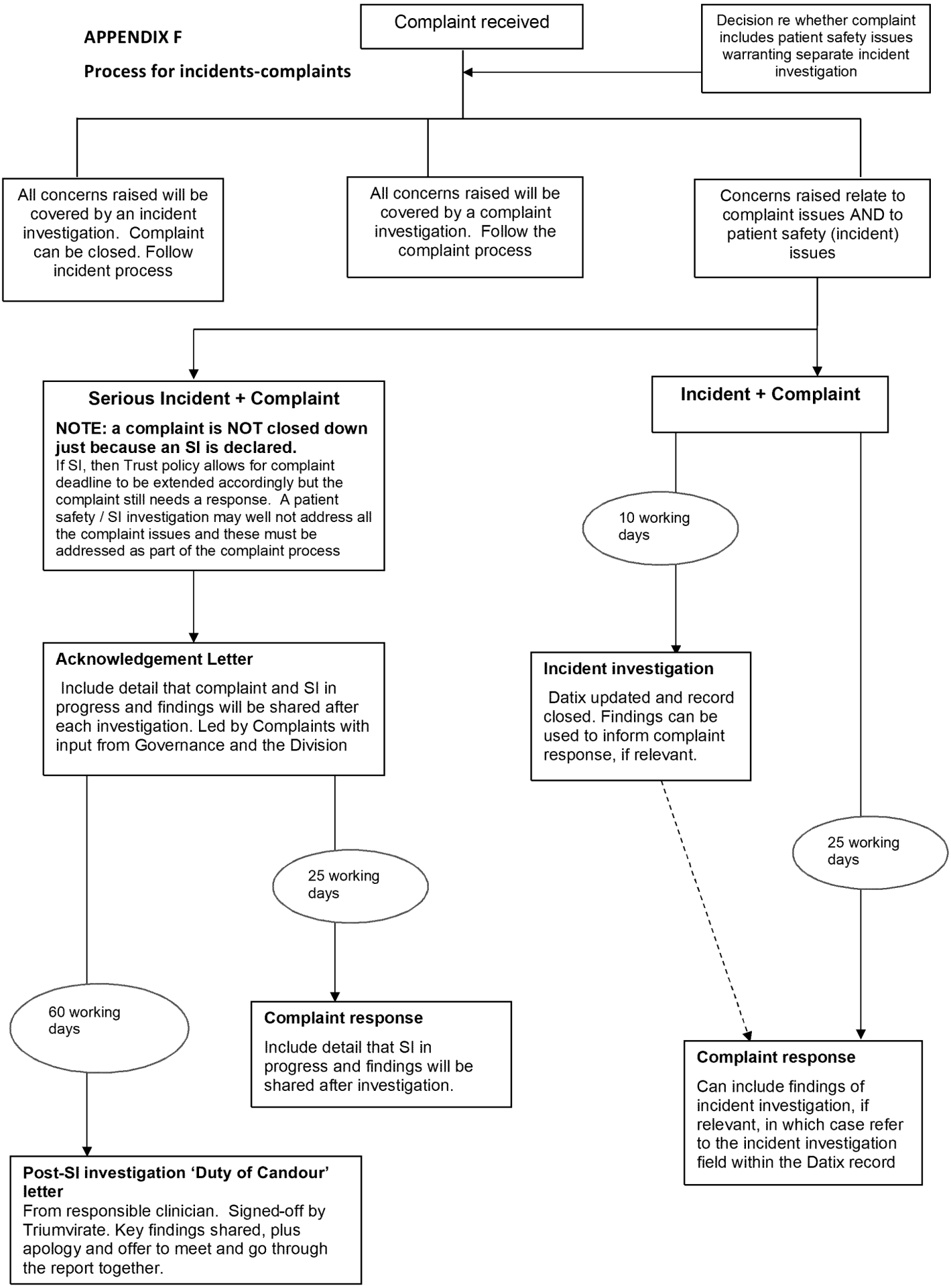
9. Failure to install functional collapsible shower or curtain rails

General

10. Falls from poorly restricted windows
11. Chest or neck entrapment in bed rails
12. Transfusion or transplantation of ABO-incompatible blood components or organs
13. Misplaced naso- or oro-gastric tubes
14. Scalding of patients
15. Unintentional connection of a patient requiring oxygen to an air flowmeter
16. Undetected oesophageal intubation - *Temporarily suspended as a Never Event*

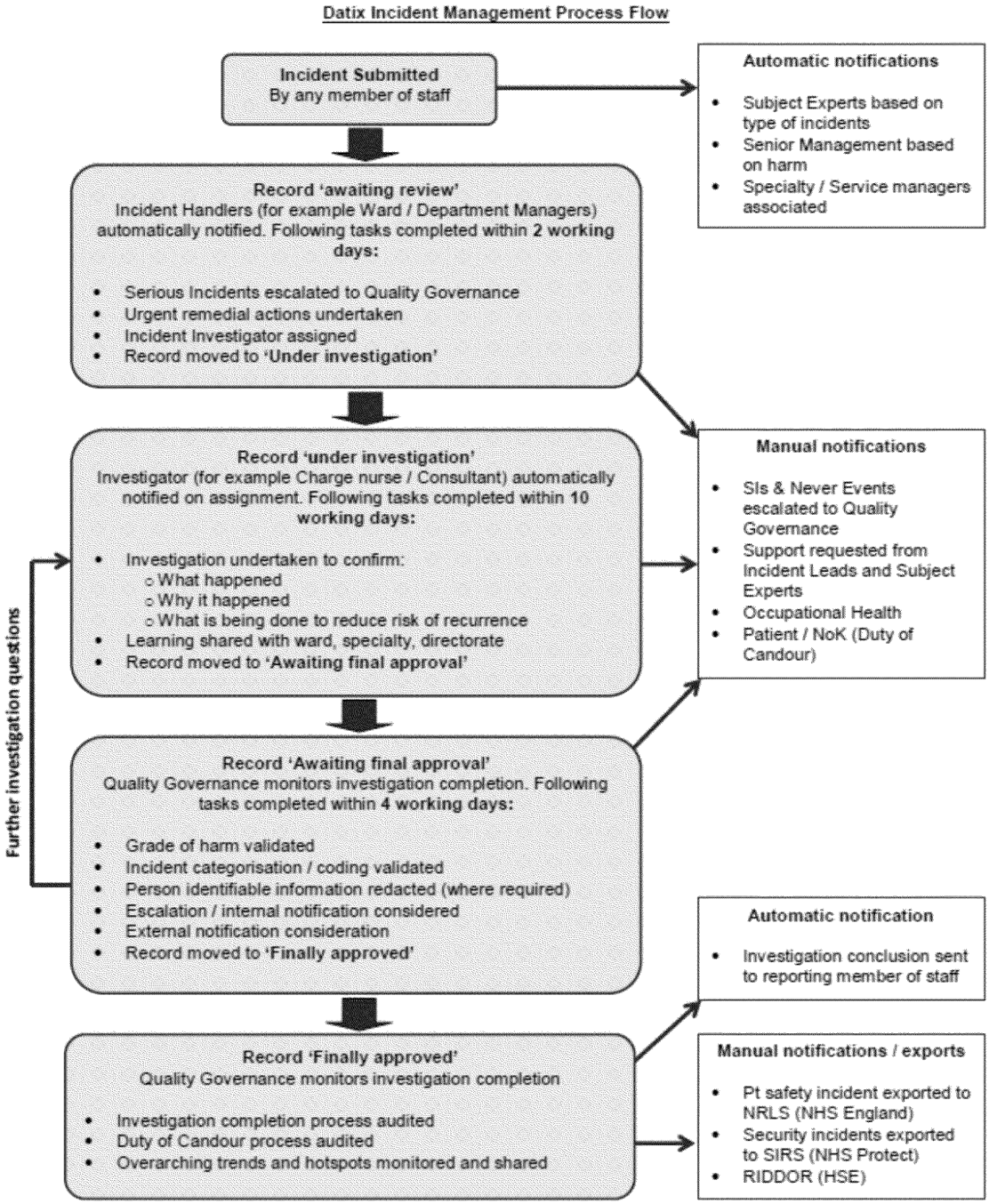
APPENDIX F

Process for incidents-complaints



APPENDIX G

Incident management in Datix - flowchart



APPENDIX H

Process for Datix downtime

In the event the Datix incident reporting module is unavailable due to server / network failures, the Datix contingency process will be initiated

Contingency Incident Reporting Form

The Contingency Incident Reporting Form contains the key mandatory questions required for incident reporting on Datix. This ensures the necessary information is provided for later upload by the Quality and Clinical Governance Team. The form is on the intranet.

Reporting Serious Incidents

In the event a serious incident needs to be reported during Datix downtime, it should be notified to the Quality and Clinical Governance team using the SI notification email (on the global address list:

SeriousIncidentNotificationGroup@chelwest.nhs.uk

Datix System and Network Downtime - Timeframes for Action

In the event of downtime during working hours (Mon-Fri 8am-5pm), a member of the Quality & Clinical Governance team will call the Sphere ICT Service Desk to log the issue as soon as possible on the following extensions:

From WMUH site: **72 58899**

From C&W site: **58899**

In the event of downtime outside working hours, staff should call the Sphere ICT Service Desk to log the issue as soon as possible on the following extensions:

From WMUH site: **72 58899**

From C&W site: **58899**

Actions for downtime of the online Datix Incident Reporting system are as follows:

1-4 Hours Downtime

If online reporting via Datix is unavailable for between 1 and 4 hours a notification from ICT should be cascaded to all staff informing them of the issue. Staff should discuss any incidents that occur during this time with their relevant Matron or line manager and report all incidents once the Datix system is back online.

Once ICT have resolved the issue a notification should be sent to staff informing them to resume reporting via online Datix as usual.

4 + Hours Downtime

If online reporting via Datix is unavailable for more than 4 hours then the following fall-back process must be followed.

- A second notification should be cascaded to relevant staff (e.g. site specific) informing them of the prolonged issue(s) and directing them to make use of the Contingency Incident Reporting Form (Appendix 1) link available within the communication.
- If emails are unavailable Contingency Incident report Forms should be stored safely until they are able to be emailed to Datix.Mailbox@chelwest.nhs.uk

Uploading Incidents Once Issues are Resolved

Once the issues affecting Datix are resolved, members of the Quality and Clinical Governance team will be responsible for uploading the incidents from Contingency Incident Report Forms onto the Datix system using the details of the staff member who completed the report form.

Contacts

If you have any issues or questions regarding the Datix incident reporting fall-back process please contact a member of the Quality Governance Datix Team via:

Telephone: 020 321 6073

Extension: (72) 6073

Email: chelwest.datix.mailbox@nhs.net

APPENDIX I

A Just Culture Guide

NHS Improvement

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this *just culture guide*, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. **Was there any intention to cause harm?**

Yes → **Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. → END HERE

No go to next question - **Q2. health test**

2a. **Are there indications of substance abuse?**

Yes → **Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. → END HERE

2b. **Are there indications of physical ill health?**

2c. **Are there indications of mental ill health?**

Yes → **Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. → END HERE

if **No to all** go to next question - **Q3. foresight test**

3a. **Are there agreed protocols/accepted practice in place that apply to the action/omission in question?**

3b. **Were the protocols/accepted practice workable and in routine use?**

3c. **Did the individual knowingly depart from these protocols?**

If **No** to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. → END HERE

if **Yes to all** go to next question - **Q4. substitution test**

4a. **Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?**

4b. **Was the individual missed out when relevant training was provided to their peer group?**

4c. **Did more senior members of the team fail to provide supervision that normally should be provided?**

If **Yes** to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. → END HERE

if **No to all** go to next question - **Q5. mitigating circumstances**

5a. **Were there any significant mitigating circumstances?**

Yes → **Recommendation:** Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. → END HERE

if **No**

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. → END HERE

improvement.nhs.uk

Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by: Academy of Medical Royal Colleges; avma; CareQuality Commission; General Medical Council; National Guardian Freedom to Speak Up; NMC Nursing & Midwifery Council; NHS England; Royal College of Nursing

collaboration trust respect innovation courage compassion

APPENDIX J

Serious Incident Panel Meetings

Terms of reference

1. Aim

The aim of the Serious Incident Panel is to ensure learning from incident investigations is identified and shared to enable prevention of future incidents and improvement in patient care.

The panel is responsible for reviewing the reports of serious incident (SI) investigations, ensuring a clear and logical flow leading from the facts of the incident, to the root causes and conclusion, to the recommendations, to the action plan.

The SI panel will ensure that any Duty of Candour is delivered in accordance with Trust Policy and statutory requirements.

2. Objectives

The SI panel will review and sign off the final draft of the investigation report prior to Executive approval. By the time the final draft reaches the Panel, it will be a complete document, ready for scrutiny and sign-off.

The panel will ensure the root cause has been identified, with appropriate recommendations and a robust plan for implementation of actions. This contributes to learning from incidents and improving both quality and safety of patient care.

Members of the panel are expected to provide a non-biased view, objectivity and professional challenge, drawing on their knowledge and expertise to critique the investigation and ensure the appropriate conclusions and findings have been drawn from the investigation and that the actions are robust and achievable: 'SMART'.

The SI panel is not an arena for judgment; it should be approached as a forum for learning for individuals as well as for the organisation and can provide positive feedback for revalidation or appraisals.

3. Membership

Chair

This will depend on the type of SI:

- Divisional Medical Director or nominated Clinical Director
- Divisional Director of Nursing or nominated Lead Nurse
- Divisional Director of Operations or nominated General Manager
- Never event panels are chaired by a member of the Executive team

Core members

- Divisional Medical Director or nominated Clinical Director
- Divisional Director of Nursing or nominated Lead Nurse
- Director of Midwifery (when appropriate)
- Divisional Director of Operations or nominated General Manager

- Clinical Governance Manager or head of Clinical Governance
- Lead investigator

Other Members (will vary with SI)

- General Manager
- Lead Nurse/Matron
- Service lead
- Expert Panel members for example Resuscitation, Information Governance, Human Resources, Pharmacy, Tissue Viability, Therapies, Thrombosis, NHS Screening Programme lead etc.
- Relevant representatives / senior leads from other divisions
- Non-Exec Director for never event panels
- Serious Incident Fellow

4. Quorum and attendance

Four members, to include at least one member of the Divisional Triumvirate or nominated deputy, the Clinical Governance manager, lead investigator, relevant expert lead when appropriate.

All members are to confirm their attendance to the meeting organiser one week before the meeting at the latest.

When a member cannot attend they should arrange for a fully briefed deputy of sufficient seniority to attend and contribute on their behalf.

5. Conflict of interest

Members should declare any conflict of interest in relation to the incident at the meeting outset.

6. Method of working and responsibilities

All reports must be reviewed by panel members and invitees prior to the meeting. By the time the Panel is convened, it will be in its final draft, ready for scrutiny and sign-off. Casenotes, statements and other supporting documents are not reviewed at Panel; these should have already been discussed during investigation meetings.

Reports are presented by the lead investigator or a deputy who has sufficient depth of knowledge to enable robust discussion of the incident and its cause(s). The incident should be only very briefly summarised, as members will have pre-read the report. The focus of the presentation is on the investigation findings.

The Divisional Triumvirate (Divisional Medical Director, Divisional Director of Operations, and Divisional Director of Nursing) will review and approve all serious incident investigation reports prior to final sign off at Exec level.

In the case of internal SIs this can be delegated to someone within division with the appropriate seniority, for example the relevant Clinical Director. All external SI investigation reports must be reviewed and approved by the Divisional Triumvirate prior to Executive sign off.

The Panel will:

- Determine if the investigation and report is sufficiently robust to enable agreement of the root cause(s)
- Determine if adequate information has been provided by specialist advisors or other expert leads
- Ensure the investigation has met all the requirements of the Duty of Candour, with involvement of patients and their families as appropriate
- Agree a communication plan for sharing the final report with the patient/family, identifying an appropriate member of staff to act as the family liaison (this would usually be the patient's consultant)
- Agree the action plan, ensuring nominated staff are aware of their actions and the timeframe for completion
- Ensure the Trust's obligations to the safeguarding process have been considered and undertaken as appropriate to the incident
- Ensure the report identifies the arrangements for sharing the learning from the investigation, not only with the staff involved in the incident, but other areas within the Division and trust wide.

Following the panel discussion, any changes are made by the lead investigator and resubmitted to the clinical governance manager for final quality check.

It will be agreed by the panel if the amended report needs to be reviewed again at a further panel, or if changes can be agreed electronically.

Following Divisional approval and sign off at panel, all external SI investigation reports are sent for Executive review and sign off prior to submission to the Commissioners. This is facilitated by the Head of Clinical Governance.

Via the monthly quality report, the Divisional Triumvirate will inform the Patient Safety Group of any themes identified by the Panel for further action.

7. Frequency of meetings

Monthly 'standing' panels on each site, or as required to align with the investigation timeframe and ensure timely submission to the Responsible Exec and Commissioners.

8. Papers

Clinical Governance managers will ensure the final investigation report is circulated by noon a minimum of two days before the meeting.

9. Secretariat support

Divisional Administrator

10. Accountability

Medical Director/Chief Nurse/COO

Appendix K – external reporting requirements

In addition to local reporting of incidents on Datix, the Trust is required to report certain incident types to specific external agencies or regulators. Details below.
Note: this excludes cases of professional misconduct which are reported via other routes.

Incident type	External/regulatory body	Responsible Officer	Detail
Death of a patient during or as a result of the care being provided	CQC	Clinical Governance (via NRLS)	
Serious injury to a patient during or as a result of the care being provided	CQC	Responsible Officer	
Death patient detained under the Mental Capacity Act (for example DOLS/LPS)	CQC	Responsible Officer	Lead nurse for mental health
Death of a person with learning disability	National Learning Disabilities Mortality Review (LeDeR)	Lead nurse for learning disability & transition	
Specific accidents and diseases that arise out of or in connection with work: • Death of a member of staff, whether or not they are at work • Over 7 day incapacitation of a member of staff as a result of an accident • Non-fatal accidents to non-staff • Reportable work-related diseases e.g. occupational dermatitis • Dangerous Occurrences e.g. gas leak or chemical spillage, needlestick injury or splash known to contain certain pathogens	Health and Safety Executive (Reporting of injuries, diseases and dangerous occurrences - RIDDOR)	Occupational Health in conjunction with the Trust Health and Safety Officer for Trust staff. Our contractors (e.g. ISS, JCA, Bouygues) are responsible for RIDDOR for their staff	Timeframes for reporting vary according to the incident; the Trust Safety Officer can advise
Infection control – certain healthcare associated infections and communicable diseases. Registered medical practitioners have a statutory duty to notify the 'Proper Officer' at their local council or local health protection team of suspected cases of certain infectious diseases.	Public Health England	Director of Infection Prevention & Control (DIPC) Can advise on specific diseases and HAIs that require reporting.	A notification form must be completed immediately on diagnosis of a suspected notifiable disease and sent to the Proper Officer within 3 days, or notify them verbally within 24 hours if the case is urgent
Incidents occurring within any of the NHS Screening Programmes. Examples of screening programmes include breast cancer, bowel cancer, cervical cancer and others	Public Health England	Responsible Officer for specified screening programme	Some screening programmes (eg cervical screening) have dedicated SI reporting procedures in addition to that via StEIS
Information Governance		Trust Data Protection Officer	The DPO can advise which IG incidents require reporting to the ICO
Information Governance Personal Data Breach that is likely to result in a risk to people's rights and freedoms Examples or personal data breaches • access by an unauthorised third party;	Data Security & Protection Toolkit (DSPT – NHS Digital). Automatically escalated to Information Commissioners Office if risk to data subject serious enough	Trust Data Protection Officer	The DPO can advise which IG incidents require reporting to the ICO

• deliberate or accidental action (or inaction) by a controller or processor; • sending personal data to an incorrect recipient; • computing devices containing personal data being lost or stolen; • alteration of personal data without permission; and • loss of availability of personal data			
Transfusion – specific adverse events and reactions must be reported to the UK haemovigillance scheme (SHOT)	Serious Hazards of Transfusion (SHOT)	Laboratory SHOT reportable errors – Blood Bank Managers. Clinical SHOT reportable errors - Transfusion Practitioner	Reported to SHOT via the MHRA Serious Adverse Blood Reactions and Events (SABRE)
Medicines/pharmaceuticals	MHRA	Relevant pharmacist	Via MHRA online Yellow Card scheme
Medical devices	MHRA	Head of clinical engineering	
Unexpected or unexplained death in hospital or during an operation	Coroner's Office	Responsible consultant or bereavement officer	
Fire – actual fire Fire/explosion incidents	NHSE RIDDOR	Director of Estates & Facilities Trust H&S Officer in conjunction with the Fire Officer	
Safeguarding incidents – child protection and safeguarding vulnerable adults Allegations involving staff as alleged perpetrators need to be reported to Commissioners and to CQC	Local Authority Commissioners CQC	Safeguarding leads (children/adults)	Suspected safeguarding incidents – child protection and safeguarding adults for example all categories of abuse, Prevent & counter-terrorism, pressure ulcers, alleged abuse by staff on patients & financial abuse
Actual or suspected assault (of a person using the service)	Police, Commissioners; CQC	Trust security advisor; Clinical Governance (via NRLS)	
Radiation: significant accidental or unintended exposure (SAUE) IR(ME)R 2017 incidents	CQC (responsible for enforcing IR(ME)R)	Radiation Protection Officer	Timeframes for reporting vary according to the incident; the Trust Radiation Protection Officer can advise.
Incidents in relation to the Trust's HFEA license	Human Fertilization and Embryology Authority	Designated Individual	
Incidents in relation to the Trust's HTA license	Human Tissue Authority	Designated Individual	
Events that stop the service running safely and properly	CQC	Clinical Governance (via NRLS)	Unable to meet people's assessed needs safety, for example, due to staff absence or damage to premises, or A utility, fire alarm, call system or other safety

			equipment fails for more than 24 hours.
Criminal activity e.g. theft, illicit drugs	Police	Trust security advisor	

APPENDIX L

Duty of candour – when to apply (see duty of candour policy for process detail)