



Incident & Serious Incident Management Policy

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Learning**

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3.0	June 2022	Risk Team	A	Approved at TMG
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A = Approved D = Draft

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Associated Documentation:

- Risk Management Procedures
- Policy for Managing Compliments, Comments, Concerns and Complaints
- Safeguarding Policy
- Courts and Evidence Policy
- Claims Management Policy
- Freedom of Information Policy
- Supporting Staff Involved in an Incident, Complaint or Claim Policy
- Being Open (Duty of Candour) Policy
- Freedom to Speak Up (Raising Concerns) Policy
- Clinical Incident Review Policy
- Investigations & Learning Policy

- Post-Incident Care Guidance
- Disciplinary Policy
- Criminal Incident Policy

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Staff Summary

<p>The Incident & Serious Incident Management Policy is designed to provide structure and clarity around the process for receiving, investigating, responding, reporting and learning from incidents and SIs.</p>
<p>An incident can be defined as an adverse event that has caused harm to patients, staff or others or has had a negative impact on the organisation. Incidents also include 'near misses' where harm has not been realised however there was potential to do so. The Trust values near miss reporting to enable lessons to be learned at an early stage before harm has occurred.</p>
<p>It is important that incidents are investigated in a timely manner in order to ensure appropriate action is taken to resolve the incident and to ensure learning can take place and be applied across the Trust.</p>
<p>The aim of the investigation is to;</p> <ul style="list-style-type: none">▪ Understand what happened and establish the facts▪ Analyse the information and subsequently identify recommendations and learning that will help reduce the risk of recurrence
<p>In the case of grade 1 investigations, an 'After Action Review' (AAR) approach will be adopted in most cases which will be led by the investigator allocated to the case to ensure quality of information and understanding between all parties.</p>
<p>The Trust acknowledges that feedback to the reporter following investigation is vital in ensuring engagement with staff and for learning to be shared. All individuals reporting an incident will receive feedback following the investigation.</p>
<p>The Trust is committed to learning from incidents to help ensure the safety of patients, staff and others. Analysis should take place throughout the year, assessing the themes and trends arising from incident reports.</p>
<p>Serious Incidents are rare, however due to the nature of these incidents it is vital that the Trust investigates them thoroughly and most importantly learns from these to reduce the risk of recurrence.</p>
<p>Family engagement must be front and centre of any serious incident investigation, remembering that the family liaison may be handled by patient relations if the incident is the subject of a complaint or concern. Terms of reference should be established very early on in the process, and family's concerns taken into consideration when establishing the boundaries of the review.</p>
<p>For all serious incidents, a full comprehensive RCA should be undertaken and the incident will be investigated by someone trained in these methodologies and supported by the Quality & Risk Team.</p>
<p>The Trust has a statutory Duty of Candour to be open and honest with patients and carers and relatives when something has gone wrong.</p>

The vital element of conducting a serious incident investigation is to ensure that appropriate learning takes place and changes are made where necessary to avoid this happening again.

The Trust monitors learning on an individual basis from serious incidents as outlined above and theme and trend analysis is conducted in line with the principles outlined in the Investigations & Learning Policy to amalgamate themes and trends identified through other routes, for example complaints and claims.

1.0. Introduction

- 1.1. The Yorkshire Ambulance Service (YAS) NHS Trust is committed to making safety a priority and taking reasonable and proportionate steps to prevent any harm coming to patients, staff and others and to ensure the reputation of the Trust is upheld.
- 1.2. The management of incidents and Serious Incidents (SIs) is a vital process for the Trust to learn when things have gone wrong and to identify areas of improvement to prevent recurrence. It is a critical component of the Trust's approach to risk management and the Trust has clear processes in place for managing adverse events.
- 1.3. The Trust will undertake an investigation when an incident or a SI has occurred, and the level of investigation will be proportionate to the severity of the incident. The Trust will comply with the principles of the Duty of Candour and will operate in an open and transparent way with all those involved, encompassing the principles of 'Just Culture'.

2.0 Purpose/Scope

- 2.1 The Incident & Serious Incident Management Policy is designed to provide structure and clarity around the process for receiving, investigating, responding, reporting and learning from incidents and SIs.
- 2.2. The policy is part of the organisation's internal control system and provides assurance to the Board that robust processes are in place to mitigate the risks associated with the management of incidents and SIs.
- 2.3. The policy is aimed at all staff across the Trust and should be read in conjunction with the other relevant policies outlined at the start of this document.

3.0. Process – Incident Management

3.1. Reporting & Recording an Incident

- 3.1.1. An incident can be defined as an adverse event that has caused harm to patients, staff or others or has had a negative impact on the organisation. Incidents also include 'near misses' where harm has not been realised however there was potential to do so. The Trust values near miss reporting to enable lessons to be learned at an early stage before harm has occurred.
- 3.1.2. The Trust uses the Datix Cloud IQ incident management system to record all incidents and near misses. Staff can report an incident by;
 - Calling the 24/7 Datix phone line on 0300 330 54193
 - Submitting an incident form using the Datix Cloud IQ application on the Trust's intranet site

Appendix A outlines the process for reporting an incident.

- 3.1.3. All incidents and near misses should be reported as soon as possible (within 24 hours) using one of the above outlined methods.

- 3.1.4. If an incident is reported via the Datix phone line, this will be handled by a member of the Quality & Risk Administration team within office hours (07:00-18:00 Monday to Friday) or by Health Desk colleagues within EOC out of hours.
- 3.1.5. Following the reporting of an incident, the record will undergo a quality check by a member of the Quality & Risk Team within 2 working days to ensure that information has been entered correctly.
- 3.1.6. As part of the quality check process, the incident will be graded in accordance with the Risk Matrix (Appendix B) and will be assigned to an appropriate investigator. Investigators will be determined based on the geographical area, responsibility, and incident type. The allocation of an investigator is dependent on the incident category and the severity, and this matrix is held by the Quality, Governance & Performance Assurance directorate and is regularly reviewed and updated.

3.2. Timescales

- 3.2.1. It is important that incidents are investigated in a timely manner in order to ensure appropriate action is taken to resolve the incident and to ensure learning can take place and be applied across the Trust.
- 3.2.2. The quality check will take place within 2 working days of the incident being reported and during this process will be assigned to an investigator.
- 3.2.3. The investigator then has a further 2 working days to have an initial look at the incident, take any immediate action required, and change the status of the investigation on Datix to 'Being reviewed'.
- 3.2.4. As standard, all incidents will be investigated within a further 15 working days and will receive a final approval check within a further 15 working days. In exceptional circumstances this timescale may vary, based on the grading of the incident, if a more in-depth investigation is required.
- 3.2.5. Timescales for the incident investigation process can be found in Appendix A.
- 3.2.6. Adherence to the timescales in this policy will always be aspirational and may not always be achieved. This non-compliance can be due to a number of factors including, Trust reliance on external stakeholders to deliver necessary information, to support the identification of a conclusion, pending for example investigations by a Police force or through Court processes/directions from HM Coroner.

3.3. Investigating an Incident

- 3.3.1. The aim of the investigation is to;
- Understand what happened and establish the facts
 - Analyse the information and subsequently identify recommendations and learning that will help reduce the risk of recurrence
- 3.3.2. The level of investigation should be proportionate to the severity of the incident and reference should be made to the Investigations & Learning Policy which outlines the Trust's approach to grading investigations and provides a guide to the investigator on what the investigation should consist of.

- 3.3.3. Support will be provided to the investigator by the Quality & Safety Team if required and input may also be sought from specialist areas and/or managers across the Trust where appropriate.
- 3.3.4. In the case of grade 1 investigations, an 'After Action Review' (AAR) approach will be adopted in most cases which will be led by the investigator allocated to the case to ensure quality of information and understanding between all parties.
- 3.3.5. Patient safety specialists (PSS) are in post to support all learning directly involving patient care; these colleagues are a vital link between national methodology/steer and local implementation and should be accessed in all cases for specialist knowledge and expertise.

These colleagues are:

- ❖ Interim Executive Director of Quality, Governance and Performance Assurance
- ❖ Head of Investigations and Learning
- ❖ Head of Safety and Infection Prevention and Control Lead

- 3.3.6. Details of the investigation, including findings and recommendations, will be recorded on Datix and a guide is attached to each incident record on Datix to assist investigators in completing the investigation.
- 3.3.7. Where a patient related incident is graded as / or is suspected to have caused moderate or above harm (also referred to as a notifiable safety incident) the Duty of Candour applies. The Duty of Candour is the requirement upon the Trust to be open and transparent with patients and/or carers and relatives when something has gone wrong. Reference should be made to the Trust's Being Open (Duty of Candour) Policy for how this is applied.
- 3.3.8. With the planned introduction of the NHS Patient Safety Incident Response Framework (PSIRF) in Q3/Q4 of 2022, investigation methodology will be adjusted and enhanced to include any new and additional training which may come online whilst this policy remains in place. A full programme of learning for all NHS staff is expected to be launched in Q1/Q2 of 2022; this will include modules on Human Factors, Culture and investigation process with higher level modules available for colleagues involved directly with patient safety.

3.4. Final Approval of Incidents

- 3.4.1. It is important that investigations are approved by a specialist manager to ensure quality and consistency.
- 3.4.2. The Trust has determined a list of final approvers who are aligned to a specialist area and who will be able to apply their relevant knowledge, skills and experience to determine whether the investigation has covered all relevant areas.
- 3.4.3. It is the final approver's responsibility to ensure the investigation has been carried out adequately, to go back to the investigator if more information is required and have assurance that lessons have been learned and actions identified prior to approving. Appendix C outlines the process for final approval of incidents.

- 3.4.4. In some cases it will be appropriate to carry out the final approval of incidents via a batch update process. This would be for low level incidents which feed into a wider theme or trend work stream and these incident categories will be determined by the relevant specialist lead, with approval from a manager within the Quality & Safety Team.

3.5. Feedback

- 3.5.1. The Trust acknowledges that feedback to the reporter following investigation is vital in ensuring engagement with staff and for learning to be shared. All individuals reporting an incident will receive feedback following the investigation via the auto-feedback function on Datix Cloud IQ. This is an automated email that is generated by the system once the incident has been approved. The incident investigator is required to write a summary feedback message that is checked by the final approver and sent to the reporter.
- 3.5.2. Additional feedback may also be given via telephone or face to face if this is necessary or the preferred option.

3.6. Learning from Incidents

- 3.6.1. The Trust is committed to learning from incidents to help ensure the safety of patients, staff and others. Analysis should take place throughout the year assessing the themes and trends arising from incident reports.
- 3.6.2. Incidents should not always be reviewed as a stand-alone process and should be reviewed with other adverse events across the Trust such as complaints, coroners inquests, claims and safeguarding cases. Reference should be made to the Investigations & Learning Policy for guidance on how the Trust manages data analysis across these inputs in order to identify the appropriate learning and how this should be shared.
- 3.6.3. In addition to theme and trend analysis, individual actions should also be taken following investigation. This may be specific to the individual, team or organisation and should be identified during the course of the investigation as part of the Root Cause Analysis (RCA) or After-Action Review (AAR).
- 3.6.4. Reports will be produced to show theme and trend analysis and presented to the relevant committees and groups across the Trust throughout the year. The key reports to do this include the Integrated Performance Report (IPR) which is presented to Trust Management Group and Trust Board, the Significant Events & Lessons Learned Report that informs Quality Committee and Trust Board and the Quarterly Incident Management Report submitted to Commissioners and to the Trust Management Group. Quarterly analysis is also presented to the Clinical Quality Development Forum (CQDF) and the Clinical Governance Group (CGG). The relevant operational groups will receive theme and trend analysis appropriate to their areas.

4.0. Process – Serious Incident Management

4.1. Declaration & Reporting of a Serious Incident

- 4.1.1. Serious Incidents are rare, however due to the nature of these incidents it is vital that the Trust investigates them thoroughly and most importantly learns from these to reduce the risk of recurrence.

- 4.1.2. As defined in the National SI framework (SIF) 2015, in broad terms, serious incidents are events in healthcare where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response.
- 4.1.3. The SIF outlines that there is no definite list of events/incidents that constitute a serious incident and lists should not be created locally as this can lead to inconsistent or inappropriate management of serious incidents.
- 4.1.4. Guidance has however been provided to assist organisations in what should be declared as a serious incident and this is as follows:

Serious Incidents in the NHS include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
 - Unexpected or avoidable death of one or more people. This includes:
 - suicide/self-inflicted death; and
 - homicide by a person in receipt of mental health care within the recent past;
 - Unexpected or avoidable injury to one or more people that has resulted in serious harm;
 - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
 - the death of the service user; or
 - serious harm;
 - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
 - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
 - where abuse occurred during the provision of NHS-funded care;

This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident.

- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See national Never Events Policy and Framework for the national definition and further information;
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
 - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues;
 - Property damage;
 - Security breach/concern;

- Incidents in population-wide healthcare activities, like screening and immunisation programmes, where the potential for harm may extend to a large population;
 - Inappropriate enforcement/care under the Mental Health Act 1983 and the Mental Capacity Act 2005 including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
 - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
 - Activation of Major Incident Plan (by provider, commissioner, or relevant agency);
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.
- 4.1.4. The Safety Governance Manager will be alerted of a possible serious incident via several routes. This may be through the reporting of an incident or through escalation of an adverse event that has been received via another route, for example through a complaint or coronial investigation.
- 4.1.5. An early fact-find will be done to establish facts and a decision will then be made on whether the incident will be reported as a serious incident. Declaration of the serious incident will be done by the Executive Director of Quality, Governance & Performance Assurance or the Executive Medical Director and in the absence of both of these individuals; the Deputy Director of Quality & Nursing or the Deputy Medical Director.
- 4.1.6. The Trust holds a weekly multi-disciplinary meeting, the Incident Review Group (IRG), and it may be appropriate for the case to be discussed here prior to declaration if the incident is reported 1-2 days prior to the group meeting. However, to ensure timely reporting of a serious incident decisions may be made outside of this group. Any decisions made outside of this group will be carried forward to the next available group for inclusion and oversight. IRG will be responsible for agreeing that a Traditional SI approach should be taken, or if the case can be reviewed using After-Action Review (AAR).
- 4.1.7. The serious incident will be declared by the Quality & Safety Team via the Strategic Executive Information System (STEIS) within 2 working days of the serious incident being declared and this will alert commissioners.
- 4.1.8. A Significant Event Alert (SEA) form will be circulated by the Executive Director of Quality, Governance & Performance Assurance to an identified distribution group within the Trust to notify of the serious incident.
- 4.1.9. Relevant external bodies will be notified, as outlined in the National SI Framework 2015.
- 4.1.10 The overall purpose for conducting a Serious Incident investigation is to enable the organisation and the wider NHS to learn when something has gone wrong and improve systems and processes. It is not the aim of the investigation to apportion blame onto any individual or determine liability in any way. If at any point during the investigation process it is apparent that there has been any misconduct by a staff member this may instigate disciplinary proceedings and the Disciplinary Policy should be referred to.

4.2. Timescales for completion

- 4.2.1. During pressures associated with the global coronavirus pandemic, national reporting timescales have been relaxed in relation to serious incident submission. In May 2020, the NHS National Patient Safety Team outlined that the requirement for NHS Trusts to complete serious incident investigation within 60 working days had been removed. Going forward, Trusts are expected to continue to liaise with commissioning bodies and keep regular contact regarding progress, Trusts are also asked to pay close attention to investigation methodology and utilise alternative approaches which may be outside of the SIF framework, such as 'after action review', 'clinical case review' and timeline appraisal.

This temporary guidance was further underlined in September 2021 (Appendix G).

- 4.2.2. Based on the above, Trusts are expected to complete investigation work as soon as is practicably possible and to liaise closely with families and representatives in order to provide realistic and achievable timescales.
- 4.2.2. Following submission of the report to the commissioners, feedback will be received within 20 working days or as soon as is practicably possible to request any amendments are made where necessary.
- 4.2.3. Extensions should continue to be requested from the Clinical Commissioning Group (CCG) responsible for oversight of regional wide reporting; this is North Kirklees. A 20 working day extension, or multiples of, can be requested directly using the template provided by NKCCG. Given the amended guidance from the national patient safety team, mitigation must be included, detailing the reason for the request, and a comprehensive update on progress which should include patient safety actions already undertaken. A decision on extension of the SIF national timeframe remains with the CCG in all cases and their decision is final, the local agreement in place, based on the amended national guidance, is that extensions are acceptable based on the continued presence of uncontrollable external factors and will only be declined based on specific reasons, such as a time limited concern for future patient safety.

4.3. Investigating a Serious Incident

- 4.3.1. Family engagement must be front and centre of any serious incident investigation, remembering that the family liaison may be handled by patient relations if the incident is the subject of a complaint or concern. Terms of reference should be established very early on in the process, and family's concerns taken into consideration when establishing the boundaries of the review.
- 4.3.2. Close liaison with either the Trust duty of candour coordinator, or patient relations coordinator should be maintained through the period of investigation and regular updates provided as to progress and any unforeseen delays.
- 4.3.3. For all serious incidents, a full comprehensive RCA should be undertaken, and the incident will be investigated by someone trained in these methodologies and supported by the Quality & Safety Team.
- 4.3.4. The Investigations & Learning Policy outlines the level of investigation determined to be appropriate for a serious incident and this will always be a grade 1 investigation. This is the highest level of investigation determined locally by the Trust and conforms with the national guidance on conducting a comprehensive investigation. Where appropriate, the

serious incident may require independent investigation and this will be determined on a case by case basis.

- 4.3.5. The investigation will be led by a Lead Investigator, with input from a multi-disciplinary team made up of key specialists from across the organisation. The Lead Investigator will either be one of the Trust's Serious Incident Investigators or another appropriate individual. The investigator should be trained in RCA methodology and/or supported by an expert from the Quality & Safety Team who is suitably trained.
- 4.3.6. The investigation will look to establish the facts of the serious incident and identify appropriate learning.
- 4.3.7. A RCA toolkit or After Action Review (AAR) template will be provided to the investigator to assist in this methodology and a guide will also be issued to assist the investigator in completing the investigation and learning report which can be found in the Investigations & Learning Policy.
- 4.3.8. In cases where an After-Action Review (AAR) approach is taken, principles of the World Health Organization will be followed and guidance applied from NHS England in managing serious incidents during the global pandemic. Administration for the AAR process will be centralised within the Trust Quality and Safety function and attendance at the AAR event will be mandated to those involved in the timeline and/or representatives with enough knowledge of the incident to be able to provide valuable insight.

4.4. Working with Other Providers

- 4.4.1. In some instances it may be appropriate to involve other healthcare providers as part of the serious incident investigation if the care provided to that patient crosses over a number of care provisions.
- 4.4.2. The lead organisation should be established at the start of the investigation and this should be primarily based on who has reported the serious incident on STEIS. The organisations should work together to complete one investigation report that covers the incident from end to end.
- 4.4.3. The commissioners should be informed of this and be used to assist in facilitation of a joint investigation. An end to end review meeting may be deemed necessary in order to thoroughly investigate and analyse the incident. The Head of Investigations & Learning or an appropriate deputy would facilitate this.

4.5. Duty of Candour

- 4.5.1. The Trust has a statutory Duty of Candour to be open and honest with patients and carers and relatives when something has gone wrong.
- 4.5.2. The Trust has a Being Open (Duty of Candour) Policy and this should be applied in the management of a serious incident. The Trust's Lead for the Duty of Candour is the Head of Investigations & Learning and the being open process must be managed via this official route.
- 4.5.3. Early contact should be made with the patient and/or next of kin to inform them of the investigation and to give them an opportunity to be involved if they wish to do so.

- 4.5.4. In accordance with national guidance, the Trust will be open with all persons involved in serious incidents unless there is a specific reason to consider a different course of action, for example relating to the health or wellbeing of the patient or carer. The decision on communication with patients and/or carers should be made ultimately by the Executive Director of Quality, Governance & Performance Assurance with advice and input from other specialist experts across the Trust.

4.6. Approval & Submission

- 4.6.1. Following the completion of a serious incident investigation, the Safety Governance Manager will undertake a quality check of the investigation and work with the investigator to produce a final version of the report.
- 4.6.2. The report will be presented to the Trust Learning Group (TLG) by the investigator following prior circulation to ensure the investigation is comprehensive and the group will approve the recommendations and learning, including allocation of actions.
- 4.6.3. The report will receive a final quality check following TLG review by the Head of Investigations & Learning and/or the Safety Governance Manager and the report will be submitted to the commissioners once approved.

4.7. Closure & Monitoring

- 4.7.1. Following submission, a review will be undertaken by the commissioners to ensure the investigation has met its terms of reference and is comprehensive to identify learning that will improve safety.
- 4.7.2. The commissioners will determine when the serious incident is closed. This can be closed pending the action plan being completed, which is monitored via local commissioning arrangements.
- 4.7.3. The Trust monitors learning from SIs via the Trust Learning Group or other local groups identified as appropriate.
- 4.7.4. The commissioners monitor serious incidents via local commissioning arrangements and via the Joint Quality Board.
- 4.7.5. The Trust has an internal tracking system for ensuring all actions are completed and this is monitored by the Quality & Safety Team. Action updates are presented to the Quality Committee.

4.8. Learning from Serious Incidents

- 4.8.1. The vital element of conducting a serious incident investigation is to ensure that appropriate learning takes place and changes are made where necessary to avoid this happening again.
- 4.8.2. The Trust monitors learning on an individual basis from serious incidents as outlined above and theme and trend analysis is conducted in line with the principles outlined in the Investigations & Learning Policy to amalgamate themes and trends identified through other routes, for example complaints and claims.

- 4.8.3. Triangulation of learning enables the best action to be taken to improve safety across the Trust and it is vital that learning is shared across all levels of the investigation.
- 4.8.4. Learning is shared across the Trust via a number of forums, including key scrutiny committees and groups such as the Clinical Quality Development Forum (CQDF), the Clinical Governance Group (CGG), Trust Learning Group (TLG), Incident Review Group (IRG), the Trust Management Group, Trust Board & Quality Committee as well as local governance meetings.

4.9. Feedback

- 4.9.1. In line with the principles outlined within the incident section of this policy, feedback will be provided to all staff involved following the conclusion of an investigation.
- 4.9.2. For serious incidents, this should be done face to face by the investigating manager and, where appropriate, a review meeting should be considered for all persons involved to collectively review the findings and receive feedback.
- 4.9.3. In addition, all staff members involved in a serious incident will receive a letter from the Quality & Safety Team via their line manager at the start of the investigation to inform them of the process and to provide the necessary support.

5.0. Training expectations for staff

- 5.1. The Trust will provide RCA and Investigation Skills Training for managers across the Trust. This training is aimed at investigation leads who will undertake grade 1 investigations. Specialised training will be sought for colleagues directly involved in Serious Incident Investigation or for whom it is their primary function.
- 5.2. Further training and education will be provided to those undertaking lower level investigations.
- 5.3. Guidance documentation will be provided to managers undertaking incident and serious incident investigations and these are included as appendices to this policy.
- 5.4. eLearning from the national patient safety syllabus at Levels 1 and 2 is available via the Trust ESR function in relation to investigation principles and practice. Level 1 (and Board Level 1) will be mandated as statutory training for all colleagues in line with national expected standards from Q1 2022.
- 5.5. In cases where training cannot be provided internally, or for colleagues within the quality function who require specialist skills, external sources will be sought from the NHS Patient Safety - Training Procurement Framework.

6.0. Implementation Plan

- 6.1. The following stakeholders have been consulted in the development, consultation and review of this policy:

Clinical Quality Development Forum (CQDF)	Clinical Governance Group (CGG)	Legal Services Manager
Patient Relations Manager	Information Governance Manager	Information Systems Manager
Safety Governance Manager		

- 6.2. The policy has been agreed by members of the Clinical Governance Group and has been recommended to the Trust Management Group for approval.
- 6.3. The latest approved version of this Policy will be posted on the Trust Intranet site for all members of staff to view. New members of staff will be signposted to how to find and access this guidance during Trust Induction.
- 6.4. Archived documents will be stored electronically within the Document Library archive. A copy of previous versions of the policy will be additionally held by the policy author.

7.0. Monitoring compliance with this Policy

- 7.1. Regulatory compliance reports will be presented by the Head of Investigations & Learning throughout the year to a range of executive committees and groups. The committees review the reports, note any deficiencies and remedial actions in their minutes. Progress against relevant action plans associated with this policy will be monitored as part of routine business and will be subject to the Trust's performance management process.
- 7.2. The effectiveness of this policy is monitored against adherence to national frameworks and requirements, each of which will be specified within the individual investigation area policies. Key Performance Indicators (KPIs) based on national and local standards have been agreed and performance against these KPIs is monitored through reports to executive committees and through dashboards.

8.0. References

- 8.1. The following sources of information have been used in the creation of this document.

NHS Improvement 'A just culture guide'

[NHS England » A just culture guide](#)

Root Cause Analysis (RCA) report writing tools and templates.

<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59847>

CQC Regulation 20: Duty of Candour

[Regulation 20: Duty of candour | Care Quality Commission \(cqc.org.uk\)](#)

Serious Incident Framework 2015.

<https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incident-framework-upd.pdf>

NHS Patient Safety Incident Response Framework (2020) (Introductory Framework).

[Report template - NHSI website \(england.nhs.uk\)](#)

World Health Organization 2018 – After Action Review

[After Action Review \(AAR\) | Strategic Partnership for Health Security and Emergency Preparedness \(SPH\) Portal \(who.int\)](#)

World Health Organization 2019 – After Action Review Approach

<https://youtu.be/l61dcs45HDI>

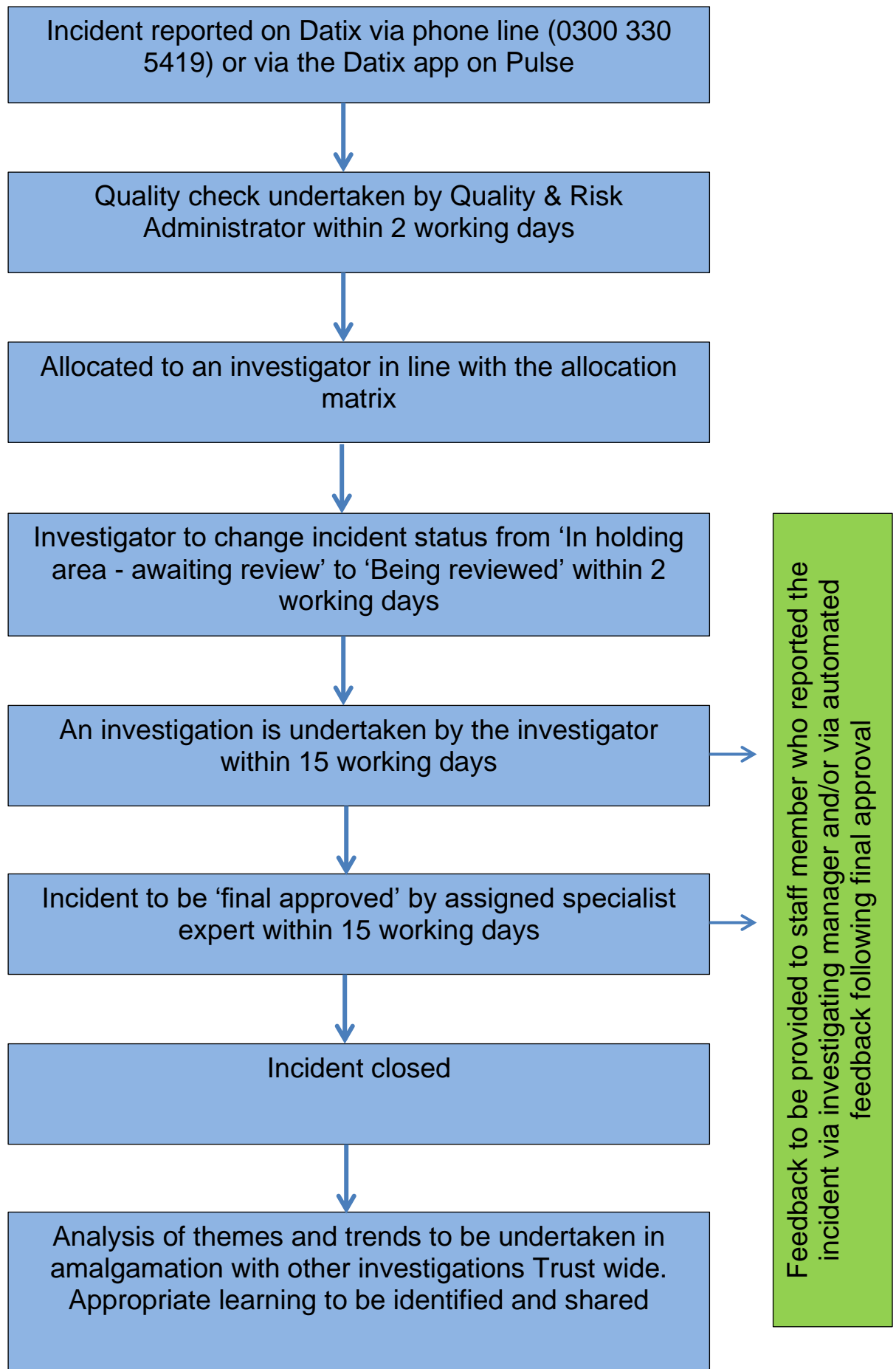
FutureNHS – Training Procurement Framework (2022)

9.0. Appendices

9.1. The following appendices are included within the document:

- Appendix A Incident Flowchart
- Appendix B Risk Matrix
- Appendix C Final Approval
- Appendix D Investigating a Serious Incident (SOP V6.3)
- Appendix E Definitions
- Appendix F Roles and Responsibilities
- Appendix G NHS Patient Safety Team Covid Update September 2021

Appendix A – Incident Flowchart



Appendix B – Risk Matrix

Risk Matrix

For grading risk, the scores obtained from the risk matrix are assigned grades as follows:-

Key to managing risk scores:		
Risk score of 1 - 6	Low	Managed at a local team/departmental level. Local management to determine and develop risk treatment plans or to manage through routine procedures; and consider including on the risk register. This level of risk may be short-lived or aggregated into a higher risk.
Risk score of 8 – 12	Moderate	Consider implications for Risk Register. Managed at local team/departmental level, unless escalated to Directorate or Trust/Subject specific group. Where there is a severity score of 4 or 5 alone, this may be considered for escalation to the Risk & Assurance Group regardless of the likelihood score.
Risk score of 15 – 25	High	Consider implications for Risk Register. Managed at local team/departmental level and/or Directorate or Trust/Subject specific group depending on management control, treatment plan, or wider strategic implications for the Trust. Risk Leads consider escalation and review at Risk and Assurance Group (RAG) where consideration is given to escalating the risk into the Corporate Risk Report and/or Board Assurance Framework (BAF).

Risk scoring = Consequence x Likelihood (CxL)

	Likelihood score				
Severity score	1	2	3	4	5
	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

Consequence Score (C) Guidance

Choose the most appropriate risk descriptor for the identified risk from the left-hand side of the table, then work along the columns in the same row to assess the severity of the risk on the scale of 1 to 5 to determine the consequence score, which is the number given at the top of the column.

	Risk Consequence score and examples of descriptors				
	1	2	3	4	5
Risk Descriptors	Negligible	Minor	Moderate	Major	Catastrophic
Safety	Minor injury not requiring first aid or no apparent injury	Minor injury or illness, requiring minor intervention	Moderate injury which impacts on an individual or a small number of people	Major injury leading to long-term incapacity/disability	Death /life threatening harm
Harm to patients/staff and/or public (including physical and/or psychological harm)		1-2 people affected No long term consequences.	Some degree of harm up to a year. RIDDOR/MHRA/agency reportable incident	Serious mis-management of care with long-term effects 16-50 people affected	Multiple permanent injuries or irreversible health effects More than 50 people affected
Staff	Insignificant effect on delivery of service objectives due to failure to maintain professional development or status	Minor error due to a lack of appropriate skills, knowledge and competence to undertake duties.	Moderate error due to limited skills, knowledge & competence to undertake duties	Major effect on delivery of service objectives due to failure to maintain professional development or status	Significant effect on delivery of service objectives due to failure to maintain professional development or status

Statutory duty/ inspections	No or minimal impact or breach of guidance/ statutory duty	Breach of statutory legislation Reduced performance rating if unresolved	Single breach in statutory duty Challenging external recommendations/ improvement notice	Enforcement action Multiple breaches in statutory duty Critical report	Multiple breaches in statutory duty Prosecution Severely critical report, zero performance rating
Service/business interruption	Loss of ability to provide services (interruption of >1 hour)	Loss of ability to provide services (interruption of >8 hours)	Loss of ability to provide services (interruption of >1 day)	Loss of ability to provide services (interruption of >1 week)	Permanent loss of service or facility
Business programmes/ projects	Temporary defects causing minor short term consequences to time and quality	Poor project performance shortfall in area(s) of minor importance	Poor project performance shortfall in area(s) of secondary importance	Poor performance in area(s) of critical or primary purpose	Significant failure of the project to meet its critical or primary purpose
Financial loss/Contracting	Small loss of budget (£0 -£5,000)	Medium financial loss (£5,000 - £10,000)	High financial loss (£10,000 - £50,000)	Major financial loss (£50,000 - £100,000) Purchasers failing to pay on time	Huge financial loss (£100,000 +), loss of contract / payment by results Unrecoverable financial loss by end of financial year
Information governance risks	Minimal or no loss of records containing person identifiable data. Only a single individual affected.	Loss/compromised security of one record (<i>electronic or paper</i>) containing person identifiable data.	Loss/ compromised security of 2-100 records (<i>electronic or paper</i>) containing confidential/ person identifiable data.	Loss/ compromised security of 101+ records (<i>electronic or paper</i>) containing person identifiable data.	Serious breach with potential for ID theft compromised security of an application / system / facility holding person identifiable data (<i>electronic or paper</i>).
Adverse publicity/ reputation/Public confidence	Rumours No public/political concern	Local media area interest – short-term reduction in public confidence	Extended local/regional media interest. Regional public/political concern.	Regional/national media interest with less than 1 day service well below reasonable public expectation	National media interest with more than 1 day service well below reasonable public expectation.
Litigation	Likely repudiation at pre-action stage.	Damages valued at less than £10,000 Minor concerns relating to care highlighted, no systemic issues identified Allegations not substantiated and claim likely to be successfully defended and discontinued at pre-action stage.	Civil action / Criminal prosecution / Prohibition notice-proceedings issued Likelihood of success at trial >50% Damages) valued between £10,000 and £100,000 Concerns relating to treatment/care/systemic issues identified which are not likely to have impacted on the outcome Low level risk of reputational damage.	Civil action / Criminal prosecution/Prohibition notice – proceedings issued Likelihood of success at trial <50% Damages between £100,000 and £1 million Major concerns as to treatment/care/systemic issues which are likely to have impacted on the outcome Reputational damage (local level) Raises individual employee failings and or Trust policy concerns	Civil action/Criminal prosecution/Prohibition notice – indefensible Damages >£1 million Catastrophic / significant systemic issues/concerns which have significantly contributed to the outcome Damage due to never event Reputational damage (national level)
Coroner's requests / inquests	No issues or concerns identified No identified risk of criminal or civil litigation No identified risk of reputational damage	Minor concerns identified unrelated to management of patient No identified risk of criminal or civil litigation No identified risk of reputational damage	Concerns relating to treatment/care/systemic issues which are not likely to have impacted on the outcome Does not raise significant individual or Trust policy failings	Significant concerns to treatment/care/systemic issues which are likely to have impacted on the outcome Areas of concern not addressed receiving a Coroner's Prevention of Future Death report (PFD).	Catastrophic / significant issues/concerns which are likely to have significantly contributed to the outcome High likelihood of a Coroner's Prevention of Future Death report-

	<p>Witness statements admitted under Rule 23</p> <p>YAS not an Interested Person</p>	YAS not an Interested Person.	<p>Low level risk of civil litigation claim</p> <p>Low level risk of reputational damage</p> <p>Family and/or other Interested Persons legally represented</p>	<p>Consideration given to legal representation at Inquest</p> <p>YAS has Interested Person Status</p> <p>Concerns raised by Coroner/other Interested Persons</p> <p>Potential for for Prevention of Future Deaths report- issues addressed pre- inquest</p> <p>Notification of civil claim- contemplated or actual</p> <p>Reputational damage (local level)</p> <p>Jury/Article 2 inquest</p> <p>Family and/or other Interested Persons legally represented</p>	<p>issues not addressed pre-inquest</p> <p>YAS has interested person status.</p> <p>Raises issues of national importance</p> <p>Potential to result in public national enquiry (i.e. London Bombings, Mid Staffordshire enquiry)</p> <p>Potential for criminal prosecution or civil claim proceedings issued</p> <p>Reputational damage (national level)</p> <p>Jury/Article 2 inquest</p> <p>Family and/or other Interested Persons legally represented.</p>
Complaint	<p>Minor injury not requiring first aid or no apparent injury</p> <p>Misunderstanding of an element of the service which can be corrected</p> <p>Local rapid resolution anticipated with no service change requirements</p>	<p>Minor injury or illness, requiring minor intervention</p> <p>Single failure to meet internal standards with no consequence</p> <p>Local resolution anticipated, local service change may be required</p>	<p>Moderate injury which impacts on a small number of people</p> <p>Single failing resulting in loss of appointment or care</p> <p>Resolution service wide with possible escalation of actions</p>	<p>Major injury leading to long-term incapacity/disability</p> <p>Repeated failure to meet internal standards within organisation</p> <p>Resolution service wide with possible escalation of actions</p>	<p>Death /life threatening harm</p> <p>Unacceptable level or quality of treatment/service . Grossly substandard care</p> <p>Resolution expected to be protracted, major trust wide service change may be required</p>
<p>Safeguarding children & Adults at Risk</p> <p><i>Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminatory and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery</i></p>	<p>No issues or concerns identified clinically or with reputation</p> <p>Progression to strategy meeting or multi-agency review unlikely</p> <p>No media interest</p> <p>Response to query responded to within 2 working days</p> <p>No, or minimal impact or breach of guidance/statutory duty</p>	<p>Minor concerns over patient care</p> <p>CDOP/Form B with uncomplicated information gathering</p> <p>Minor delay in response to external agency request (more than 5 working days)</p> <p>No allegations against Trust or employees</p> <p>Short term service impact from brief investigation involving discussions Police, Social care and HR</p>	<p>Moderate concerns about patient care, response times, clinical interventions</p> <p>CDOP requiring moderately complex information gathering and analysis</p> <p>Referral to LADO and Police. Disciplinary process commenced, suspension from front line duties</p> <p>Possible media interest anticipated</p>	<p>Major concerns with patient care that could have affected outcome</p> <p>Major injury leading to incapacity or disability</p> <p>Repeated failure to reach internal standards</p> <p>Regional media statement requested</p> <p>Abuse enquiry becomes public enquiry</p>	<p>Incident leading to death or permanent disability</p> <p>Healthcare did not take appropriate action/intervention to safeguard against abuse occurring</p> <p>Abuse that resulted in (or was identified through) a SCR, DHR, LLR</p> <p>Inquest requiring safeguarding information</p> <p>Staff/ex-staff member is found guilty of abuse and convicted</p> <p>Media interest highly likely</p>

Likelihood Score (L) Guidance

What is the likelihood of the consequence occurring?

The frequency-based score is appropriate in most circumstances and is easier to identify. It should be used whenever it is possible to determine the frequency.

Likelihood score	1	2	3	4	5
Descriptor	Rare	Unlikely	Possible	Likely	Almost certain
Probability	< 5% 1 in 100,000 chance	6-20% 1 in 10,000 chance	21-50% 1 in 1000 chance	50-80% 1 in 100 chance	>81% 1 in 10 chance
	This will probably never happen/recur Will only occur in exceptional circumstances	Unlikely to occur Do not expect it to happen/recur but it is possible it may do so	Reasonable chance of occurring Might happen or recur occasionally	Likely to occur Will probably happen/recur but it is not a persisting issue	More likely to occur than not Will undoubtedly happen/recur, possibly frequently

Appendix C – Final Approval

Category	Final Approval Lead
Trust Vehicle Related	Information Systems Manager
Care Pathway	Information Systems Manager
Violence and Aggression	Local Security Management Specialist
Moving and Handling	Moving and Handling Specialist
Response Related - EOC	Safety Governance Officer
Slips, Trips & Falls	Information Systems Manager
Response Related – IUC	IUC Governance Team
Security	Local Security Management Specialist/Violence Reduction Lead
Clinical Assessment	Information Systems Manager
Non-Medical Equipment	Information Systems Manager
Medical Equipment	Information Systems Manager
Medication – Controlled Drug	Area Clinical Governance Lead (MOG)
Medication – Non-Controlled Drugs	Area Clinical Governance Lead (MOG)
Clinical Treatment	Information Systems Manager
Consent Related	Information Systems Manager
Exposure to Harmful Substances	Information Systems Manager
IT Related	ICT Project Manager
Information Governance	Head of Risk and Assurance
IP&C	Head of Safety
Fire	Information Systems Manager
Response Related - PTS	PTS Governance and Training Coordinator
Self-Harm	Information Systems Manager
Environment & Estates	Information Systems Manager
Training	Head of YAS Academy
Adverse Publicity	Information Systems Manager
Financial Loss	Information Systems Manager

Appendix D – Investigating a Serious Incident



YAS Quality, Governance & Performance Assurance Standard Operating Procedure
A Guide for the Investigating Manager (Traditional SI Report and After-Action Review Approach)

Document Authors: Head of Investigations & Learning
Response Lead: Head of Investigations & Learning/Safety Governance Manager
Version: 6.3
Issue Date: April 2022
Review Date: August 2022 (or implementation of PSIRF)

Aim

The aim of this document is to provide the Investigating Manager with an easy-reference guide on how to complete a high level, quality investigation.

Role of the Investigating Manager

The role of the Investigating Manager is to undertake a thorough root cause analysis (RCA) investigation or after action review (AAR) into the adverse event that has taken place, understanding fully the reasons why the incident has happened and the actions taken by certain individuals. The manager should explore the systems and processes in place relating to the incident, assessing whether they provide sufficient support for staff following them. Contributory factors should be identified by the manager and corresponding recommendations made to help prevent recurrence of the incident. The manager should liaise with the relevant persons and departments to agree an action plan following the investigation.

Role of the Trust Patient Safety Specialists

Patient safety specialists (PSS) are in post to support all learning directly involving patient care; these colleagues are a vital link between national methodology/steer and local implementation and should be accessed in all cases for specialist knowledge and expertise.

These colleagues are:

- Interim Executive Director of Quality, Governance and Performance Assurance – Clare Ashby
- Head of Investigations and Learning – Simon Davies
- Head of Safety and Infection Prevention & Control Lead – Iffa Settle

1. First Steps – Getting Started (Traditional SI Report)

Upon being assigned as Investigating Manager you will receive an email from a member of the Quality, Governance & Performance Assurance directorate including:

- Investigation report template or After-Action Review template*
- Example report
- Key reminders for investigation
- YAS Glossary
- Datix reference (and access to this)
- The NHS Just Culture Guide
- Timescale for completion will be specified within the email

The Safety Governance Manager will arrange an initial meeting to go through the details of the case and the requirements of the investigation. Other relevant persons may also attend when required. The initial meeting should take place within three working days of the SI being allocated.

*The templates will have basic elements completed for you and will be saved as version 0.1.

2. Initial Meeting (Traditional SI Report)

At the initial meeting between yourself and the Safety Governance Manager, the Terms of Reference for the investigation will be agreed and key points highlighted for investigation. There will be an opportunity to discuss any queries you have in relation to the SI and to seek advice.

3. What information do you need? (Both Traditional and AAR Approach)

At the start of the investigation it is important to work out what information you will need to get to assist in your investigation. You should consider obtaining the following information (where applicable), although the Quality & Safety team will work with you to ensure this happens:

- Electronic Patient Record (ePR)
- Sequence of Events (SOE) log
- Adastral record
- Cleric record
- 999/111 call recording
- Statements from key staff involved
- Training records of staff involved
- Relevant policies & procedures
- Arrange interviews with the staff involved
- Equipment engineer report
- Resource information
- Demand information
- Call audit

- Identify appropriate persons to seek specialist information from (i.e. Pharmacist, Information Governance Team, Lead Paramedic)

NB - It is important to remember that for the After Action Review (AAR) approach, this material will be reviewed all together with all of the people who have been involved, therefore having an understanding of the material is key in order to get the most from discussion.

If it is identified that another organisation should input into the investigation, this will be facilitated by the Quality & Safety Team, with the Safety Governance Manager making contact with the relevant Trust in the first instance.

4. Completing the Investigation Report (Traditional SI Report)

You have 20-30 working days to complete the investigation report and return this to the Trust's Safety Governance Manager. The timescale will vary depending on complexity of the investigation and depending on alignment of deadlines to present the report to the Incident Review Group and its commissioner due date. It is important to remember when writing the SI report that this will be shared with commissioners and potentially other relevant persons including the patient and/or family of the patient involved, HM Coroner and other external bodies.

Your report should be clear, with acronyms explained and terminology appropriate for the lay person to understand. It is recommended you get a peer to review the report to ensure the wording and terminology is explicit and to check spelling/grammar prior to submission. All sections of the report **MUST** be completed.

Within the investigation report, guidance is included as to what you might consider including within each section.

The Trust adopts a 'team' approach led by the investigator allocated to the case to ensure quality of information and understanding between all parties. Regular contact will be expected, no less than monthly, to review the investigation and learning identified and this will take the form of either direct or virtual meetings.

Administration of this process will sit with the Quality, Governance, and Performance Assurance directorate and overall oversight will remain with the Safety Governance Manager to provide expert knowledge and guidance to the investigation process.

Suggested roles required to participate are as follows:

- Serious Incident Investigator or Nominated Trust Senior Manager
- Safety Governance Manager
- Relevant Heads of Department
- Relevant Audit/Compliance Leads
- Relevant Locality or Directorate Management Leads
- Relevant Executive colleagues responsible for Trust sign off

- Patient Safety Specialist

An Example for a case involving A&E Operations (South):

- Investigation Lead
- Locality Manager for South
- Safety Governance Manager
- Head of Investigations and Learning / Patient Safety Specialist
- Legal Services Department representative (if the incident involves coronial process, claim, or police request)

It is important that at least one team meeting be held before commencement of draft report writing to ensure that the focus and terms of reference are accurately reflected in the final document.

The action plan is submitted to the commissioners who will request evidence to demonstrate completion of the actions; it is therefore important that you set realistic actions and that these have been agreed by the individual they are assigned to prior to your first draft of the SI report coming to the Quality & Safety Team. If you are having difficulties with this aspect it is important you liaise with the Safety Governance Manager in the first instance who can aid facilitation.

There may be occasion where the recommendations you determine from your investigation cannot be delivered by the Trust into tangible actions. This may be due to financial constraints for example. You can record within the 'Recommendations' section what these would be and provide rationale as to why these cannot be delivered. The action plan within the report should be the final, agreed actions.

5. After Action Review

With the onset of coronavirus in 2019, and resource challenges across the public sector, NHS England gave NHS Trusts clear guidance in terms of investigation methodology going forward into the subsequent years.

Whereas traditionally serious incidents in the NHS were only reviewed by one method (RCA), Trusts were encouraged to consider alternative and less paper-based review methodology in order to manage the various challenges brought about by a national pandemic. Within YAS, we decided to take forward the concept of after-action review (AAR) which is a research based and simple format backed by various bodies including the World Health Organisation (WHO).

A short video can be accessed here which describes AAR in more detail:

<https://youtu.be/l61dcs45HDI>

TLG will decide if AAR is appropriate for the matter to be investigated, and if so we would like to refer you to the SOP entitled 'After Action Review Arrangement Process v1.0, which should be read in conjunction with this document.

Version Control

To ensure the appropriate version control of documents, these should be managed as follows:

Template sent to you with basic details completed = Version 0.1

Drafts that you work on prior to your final draft = Version 0.2, 0.3, 0.4 etc.

Your final draft that is sent to the Safety Governance Manager = Version 1.0

Versions updated by Safety Governance Manager, Head of Investigations & Learning and Area Lead with your input = Version 1.1, 1.2, 1.3 etc.

Version to be shared with IRG = Version 2.0

Any updates to report following IRG = Version 2.1, 2.2, 2.3 etc.

Report shared with commissioners = FINAL copy

6. Updating Datix Cloud IQ (Both Traditional and AAR Approaches)

As you are completing your investigation, you need to access the Datix Cloud IQ record and update the details of your investigation and all other fields on the record. You also need to ensure all the documentation you have reviewed as part of your investigation is uploaded onto Datix Cloud IQ.

Specific information relating to the national reporting of the incident can be found in section 5 of the Datix Cloud IQ report; this may not be visible to the investigating manager and will depend on the level of access provision granted to the individual.

Information relating to the national reporting can be obtained directly from the Safety Governance Manager if this is the case.

The screenshot displays the Datix Cloud IQ web application interface. At the top, a dark blue navigation bar contains the 'RLDatix' logo and a series of tabs: 'Capture', 'Evaluate', 'Strategy', 'Implement', and 'Assess'. Below this, a light blue header reads 'Search form (Advanced) - Search for Records'. On the left, a vertical sidebar lists navigation options: 'Back to Dashboard', '1. Incident Report Information', '1.1 Safeguarding', '1.2 Freedom to Speak up', '2. Duty of Candour', '3. Category Specific Information', '4. Investigation', '5. SIRC', '5.1 Serious Incident (SI)' (which is highlighted), '6. Progress Notes and Communication', '7. Documents', '8. Feedback and Approval Status', '9. Datix Administrators Only', 'Add a new incident', and 'My reports'. The main content area on the right is titled '5.1 Serious Incident (SI)' and contains several form fields: 'Serious Incident (SI)?', 'Date SI declared' (with a calendar icon), 'STEIS Reference', 'Quarter', 'First Final report due to Commissioner' (with a calendar icon), 'Report due to Quality & Safety' (with a calendar icon), 'Date to present to IRG' (with a calendar icon), 'Location:', and 'Incident Summary'.

6. What happens after you have completed your report? (Both Traditional and AAR Approaches)

Once you have completed your SI report, it then follows the below process:

- Review and approval – the report will be subject to a review from the Safety Governance Manager, who will liaise with you at this stage. Once an agreed report has been finalised, it will be sent to the Head of Investigations & Learning for review. Once approved, it will be sent to the area lead for approval and then circulated to members of the Trust Learning Group (TLG) ahead of the meeting. Only minor changes agreed in the meeting may be made after this time and the report is then ready for submission to commissioners.
- Submission – the report gets submitted to the Lead Commissioner who then shares it with the Clinical Commissioning Group (CCG) in which the patient involved resides/d.
- Feedback - the report or key findings should be shared with those who were involved in the investigation. This will be dependent on conversations that have been held earlier on in the investigation process and is an important part so that colleagues feel involved and that there is closure for them on a personal level. The SI closure letter template will be used to facilitate this. Summary feedback should also be provided to the colleague who reported the incident (if via the Datix route), ensuring that confidentiality is maintained. This should be carried out by the Safety Governance Manager upon approving the incident on Datix.
- Post TLG – if considerable review or changes are requested, the report must be taken back to TLG for approval before a final draft is submitted to the Safety Governance Manager. This may require an extension from the Clinical Commissioning Group (CCG), which can be organised via the Quality and Safety team.
- External review – the report will then undergo a review process with the commissioners where they will check that the report has met its Terms of Reference, identified appropriate learning, and helped reduce risk of recurrence. The report will be graded as 'accepted' or 'not accepted', as will the action plan. This feedback will be returned to the Quality & Safety Team.
- Response to external review – the Quality & Safety Team will share the feedback from the review with you and there may be further questions which need answering at this stage. If this is the case, the Safety Governance Manager will contact you. A response will then be formulated and returned to the commissioners for closure.

- Closure – providing the commissioners are satisfied at this stage with the report, they will confirm closure, subject to action plan evidence review.
- Action plan follow up – the commissioners will request evidence from the Quality & Safety Team once the action deadlines have passed. Evidence will need to be presented and the Quality & Safety Team monitor this regularly to ensure that actions have been completed and that evidence is available. This will be presented to Commissioners at the bi-monthly SI review meeting and, providing they are satisfied with the actions taken, the investigation will receive full closure.

At this stage you will not be required to do anything further with the report. As Investigating Manager, you may be asked to attend with the Head of Investigations & Learning (or other nominated person) to visit the patient and/or family of the patient, involved in the SI to feedback findings as part of the Being Open Process.

7. Support

Should you require any support throughout the duration of the investigation please do not hesitate to contact a member of the Quality & Safety Team on the following details:

Tracy Evans-Phillips (Safety Governance Manager)

t.evans-phillips@nhs.net

07517 549661

Simon Davies (Head of Investigations & Learning)

simon.davies14@nhs.net

07825 113004

Appendix E - Definitions

Investigation

A systematic approach to establish the facts about a case in order to understand the reason as to why something has happened.

Incident

An adverse event that gave rise to actual loss, damage or harm. See Near Miss definition also.

Adverse event

An unplanned event which has given rise to actual or possible personal injury, patient dissatisfaction, property loss or damage, or damage to the financial standing or reputation of the Trust.

Serious Incident (SI)

A serious incident (SI) requiring investigation is defined by the NPSA in the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation as an incident that occurred in relation to NHS funded services and care resulting in one of the following:-

- unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
- a never event - all never events are defined as serious incidents although not all never events necessarily result in severe harm or death. (See Never Events Framework);
- a scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
- allegations, or incidents, of physical abuse and sexual assault or abuse; and/or
- loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

After Action Review

An after-action review (**AAR**) is a structured review or de-brief process for analysing **what** was expected to happen and **what has happened**, **why** it happened and if there is any difference from expectation, and **how** learning can be taken forward to reduce the risk of reoccurrence.

Severity

Outcome or impact of an event.

Datix Cloud IQ

The system used by the Trust to amongst others, record risks and adverse events.

Root Cause Analysis (RCA)

A structured investigation that aims to identify the true causes(s) of a problem and the actions necessary to eliminate it.

Duty of Candour

Statutory duty meaning NHS providers must be open and transparent with service users about their care and treatment, including when it goes wrong.

Near Miss

An event that had potential to result in harm or injury but did not.

Never Events

An event defined nationally as something that should never occur in NHS healthcare provision. There is a list provided in the national Never Events Policy to outline that these are.

Trust Board

The Trust Board is responsible for ensuring that effective systems are in place for the management of incidents and serious incidents. The Trust Board seeks assurance regarding the Trust's response to incidents and serious incidents through the Chief Executive Officer and the Executive Director of Quality, Governance & Performance Assurance.

Quality Committee

The Quality Committee undertakes an objective scrutiny of the Trust's clinical governance and quality plans, compliance with external quality regulations and standards and key functions associated with this, including processes to ensure effective learning from incidents and serious incidents. The committee scrutinises bi-monthly reports provided by the Head of Investigations & Learning and supports the Board in gaining assurance on the effective management of incidents and serious incidents

Incident Review Group (IRG)

The IRG is a working group that meets weekly and which is responsible for reviewing and instigating appropriate action to address issues identified in relation to incidents, serious incidents, complaints and concerns, claims, coroners inquests, professional body referrals and safeguarding cases.

Chief Executive

The Chief Executive is ultimately accountable for the implementation of the process for managing the Trust's response to incidents and serious incidents. As the Accountable Officer the Chief Executive provides the Trust Board with assurance regarding the Trust's processes for managing these.

Executive Director of Quality, Governance & Performance Assurance

The Executive Director of Quality, Governance & Performance Assurance has responsibility for ensuring that adequate arrangements are in place to effectively manage incidents and serious incidents, and for ensuring that an appropriate system is in place to identify and implement learning following investigations. The Director has responsibility for providing the Trust executive and Trust Board with updates on significant developments and assurance on the incident and serious incident management process.

Deputy Director of Quality & Nursing

The Deputy Director of Quality & Nursing has responsibility for ensuring practical processes are in place to adequately manage incidents and serious incidents and ensure that the appropriate learning is identified. The Deputy Director will take direct management of the Head of Investigations & Learning.

Head of Investigations & Learning

The Head of Investigations & Learning has responsibility for the management of the processes associated with investigations and learning including the management of incidents and serious incidents. They will lead on learning arising from these functions, in conjunction with learning from other inputs such as complaints and will ensure the identification of appropriate recommendations and actions to ensure quality and safety is maintained.

Learning from Death Process (LFD)

The purpose of the Learning from Deaths Group is to support the Trust in delivering its obligations to monitor patient outcomes and ensure clinically effective care is delivered. Senior clinical leaders undertake strategic mortality reviews with cross directorate support, feeding back the learning within this forum. This is to ensure that lessons and actions are identified that

would not otherwise be commonly highlighted under other Trust processes for the purpose of reducing all avoidable deaths. The group operates as part of the Trust's wider integrated governance arrangements, with strategic links to both quality improvement and clinical care.

Patient Safety Specialist (PSS)

The requirement for NHS organisations in England to identify one or more person as their designated Patient Safety Specialist(s) is a key part of the [NHS Patient Safety Strategy](#). These specialists will work full time as patient safety experts, providing dynamic, senior leadership, visibility and support. In addition, they will support the development of a patient safety culture, safety systems and improvement activity. Specialists will also work in networks with Patient Safety Specialists from other organisations to share good practice and learn from each other, making them fundamental to patient safety across the NHS in England.

Safety Governance Manager

The Safety Governance Manager manages the day to day processes related to the management of incidents and serious incidents and will support the investigators throughout the course of investigations, will ensure actions are tracked following completion of a serious incident and will identify the relevant themes and trends arising from serious incidents.

All managers

All managers are required to co-operate with the Head of Investigations & Learning and the other responsible managers within the directorate, by responding in a timely manner to requests for any information or support required during the course of their business. Managers may also be asked to participate in investigations, and it is expected that they will apply due diligence to this process, provide support to affected staff, and facilitate effective organisational learning and improvement.

Staff

All Trust staff have a responsibility to co-operate with the Head of Investigations & Learning & the Risk Manager and the teams that sit within the Quality, Governance & Performance Assurance directorate by responding in a timely manner to requests for any information and by active participation in an investigation process.



Patient safety update – 28 September 2021

Patient safety update from the NHS National Patient Safety Team

This update pulls together key information that you or your clinical governance/patient safety leads might need to know but could otherwise miss. It is not intended for general circulation within your organisations.

Key messages	Information for safety leaders
<ul style="list-style-type: none">A new maternity principles document is available for organisations with maternity services	<p>1. A new maternity principles document has been published to support maternity services to provide safe care for women arriving in the UK from Afghanistan. The document will be updated as required</p> <p>A 12-month programme of trust board roadshows, led by Professor Jacqueline Dunkley Bent, Chief Midwifery Officer and Sascha Wells Munro, deputy Chief Midwifery Officer has commenced highlighting lessons learnt about maternity safety through their experiences of delivering the Maternity Safety Support Programme. Chief Executive Officers have been contacted directly about the roadshows which will also encourage trust boards to access and complete the revised maternity self-assessment tool launched in July.</p>
<ul style="list-style-type: none">New maternity equity and equality guidance has been issued with actions for local maternity systems	<p>2. The Equity and Equality: Guidance for Local Maternity Systems asks Local Maternity Systems to:</p> <ul style="list-style-type: none">by 30 November 2021, submit an equity and equality analysis (covering health outcomes, community assets and staff experience) and a co-production plan;by 28 February 2022, co-produce equity and equality action plans to cover five years from 1 April 2022. The plan should be agreed by the LMS board and the ICS partnership board and published.
<ul style="list-style-type: none">Read the latest HSIB investigation reports	<p>3. HSIB has published two recent reports:</p> <ul style="list-style-type: none">The Intrapartum stillbirth: learning from maternity safety investigations that occurred during the COVID-19 pandemic 1 April to 30 June 2020, national learning report was published 16 September 2021A report analysing patient safety themes from HSIB's first 22 national investigations was published 9 September 2021
<ul style="list-style-type: none">Declaring breaches in ambulance and Emergency Department target waiting time as Serious Incidents	<p>4. Please note there is no expectation to routinely report all breaches in ambulance and Emergency Department target waiting times as Serious Incidents (SIs), or to record them on StEIS.</p> <p>The Serious Incident Framework is clear that blanket reporting rules should not be created around certain incident types. Where data collection is needed, specific data collection processes should be put in place. Supplementary information is available in the Serious Incident Framework FAQ document.</p> <p>The Serious Incident Framework promotes identification and reporting of SIs based on the potential for learning, future risk reduction and the consequences of any recurrence of the incident as well as taking account of the views of the people involved, particularly patients and their families and carers.</p> <p>In line with guidance previously circulated:</p> <ul style="list-style-type: none">Healthcare teams should continue to use clinical and professional judgement when considering what to identify as a SI.Ongoing pressures on services may make it more difficult to undertake SI investigations. Organisations do not have to meet the 60-day timeframe for investigations during this period. Teams should be pragmatic about the sign off and closure of investigations, noting that formal panel meetings are not required to close investigations.

	<ul style="list-style-type: none"> Healthcare teams can also consider approaches for rapidly responding to patient safety incidents: Use huddles, after-action reviews, risk assessments and case record reviews, as well as investigations to identify ways to reduce future risk.
<ul style="list-style-type: none"> Thank you for supporting World Patient Safety Day 	<p>5. We'd like to say a huge thank you to all the staff and organisations that hosted events and activities to mark this year's World Patient Safety Day on 17 September. The National Patient Safety Team hosted a webinar on 'Improving patient safety in NHS maternity and neonatal care'; a recording is available on the Maternity and neonatal patient safety improvement programme Future NHS workspace https://future.nhs.uk/MatNeoQI/view?objectId=30638128.</p> <p>We also posted a short video on Twitter showing highlighting progress in the last 12 months in implementing the NHS patient safety strategy.</p>
<ul style="list-style-type: none"> Prepare for forthcoming launch of levels 1 and 2 of NHS Patient Safety Syllabus 	<p>6. Health Education England will be launching training in Levels 1 and 2 of the NHS patient safety syllabus, as e-learning resources, in October. Level 1 (Essentials) is designed to introduce all staff in the NHS to key patient safety concepts; while level 2 (Access to Practice) provides more detailed training in those areas for those who wish to progress further. We will notify the Patient Safety Specialists when the training goes live.</p>
<ul style="list-style-type: none"> Training and Developing framework now out to tender to support a systems approach to learning from patient safety incidents 	<p>7. As part of the development of the new Patient Safety Incident Response Framework (PSIRF), an upcoming Training and Developing framework is now out to tender, focusing on training to support a systems approach to learning from patient safety incidents. We hope to use this process to create a list of quality suppliers who offer training aligned with PSIRF expectations and PSII standards. If you work with a supplier that offers training in this area, please do make them aware. Deadline for bids is 11 October 2021 at midday. Further information is available here, and the procurement documents are available here.</p>
<ul style="list-style-type: none"> Patient safety podcast 	<p>8. We think you may find this podcast interesting. 'Stories from over 20 years in patient safety' – featuring Nippin Anand with Professor Suzette Woodward. If you would like to receive more of these in the future please get in touch using the email address below.</p>
Send any queries on this update to patientsafety.enquiries@nhs.net	

In focus: NHSX Digital Clinical Safety Strategy

On World Patient Safety Day (17 September 2021) NHSX published the NHS's first ever [Digital Clinical Safety Strategy](#). Safe digital health technologies are critical to COVID-19 recovery efforts. Building on the NHS patient safety strategy, the Digital Clinical Safety Strategy has been developed with NHS England and NHS Improvement, NHS Digital, frontline staff and patient bodies.

It sets out two clear aims.

- To improve the safety of digital technologies in health and care, now and in the future.
- To identify and promote the use of digital technologies as solutions to patient safety challenges.

The strategy makes a number of national commitments:

1. Collect information about digital clinical safety, including from the [Learn from patient safety events \(LFPSE\) service](#) and use it to improve system-wide learning.
2. Develop new digital clinical safety training materials and expand access to training across the health and care workforce.
3. Create a centralised source of digital clinical safety information, including optimised standards, guidelines and best practice blueprints.
4. Accelerate the adoption of digital technologies to record and track implanted medical devices through the [Medical Devices Safety Programme](#).
5. Generate evidence for how digital technologies can be best applied to patient safety challenges.

You can get in touch with the team by emailing nhsxdigitalsafety@nhsx.nhs.uk if you have any questions.