NHS
Yorkshire
Ambulance Service
NHS Trust

Incident & Serious Incident Management Policy

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1.0	February 2016	Rebecca Mallinder (Head c Investigations & Learning)	A	Policy Approved
1.1	January 2018	Rebecca Mallinder (Head c Investigations & Learning	D	Full review - Process updated, job titles and committees/groups & New visual identity
2.0	April 2018	Levi MacInnes	A	Policy approved at April TMG
2.1	August 2020	Ruth Parker	D	Date agreed by TMG for review date extension

A = Approved D = Draft

Document Author = Rebecca Mallinder (Head of Investigations & Learning)

Associated Documentation:

- Risk Management Procedures
- Policy for Managing Compliments, Comments, Concerns and Complaints
- Safeguarding Policy
- Claims Management 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

Staff Summary

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 & SIs.
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.
It is important that incidents are investigated within 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.
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
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.
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.
Serious Incidents are rare however due to the nature of these incidents it is vital that the Trust investigates these incidents thoroughly and most importantly learns from these to reduce the risk of recurrence.
All serious incidents should undertake a full comprehensive RCA and will be investigated by someone trained in these methodologies and supported by the Quality & Risk Team.
The Trust has a statutory Duty of Candour to be open and honest with patients and carers and relatives when something has gone wrong.
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.

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 & 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 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 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 a NHS 111 call handler out of hours (18:00-07:00 Monday to Friday and all day on weekends).

3.1.5. Following 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 have been 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 within 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.

3.3. 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. 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.

3.3.5. Where a patient related incident is graded as having caused moderate or above harm 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.

3.4. 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. 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, 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).

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 these incidents thoroughly and most importantly learns from these to reduce the risk of recurrence.

4.1.2. As defined in the National SI framework 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 framework 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.

4.1.5. As a supportive tool to aid decision making in relation to SIs that involve excessive response times, the Time Related Decision Tree should be referred to (Appendix E). This is an internal tool that has been developed in line with national requirements by the Trust to enable more consistent reporting of SIs.

4.1.5. 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.

4.1.6. 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.

4.1.7. The Trust holds a fortnightly 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 a decision will be made outside of this group where necessary with the input of the relevant individuals.

4.1.8. 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.

4.1.9. 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.

4.1.10. Relevant external bodies will be notified as appropriate as outlined in the National SI Framework 2015.

4.1.11 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. 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. All serious incidents must be investigated within 60 working days of it being reported.

4.2.2. Following submission of the report to the commissioners feedback will be received within 20 working days and amendments made where necessary.

4.3. Investigating a Serious Incident

4.3.1. All serious incidents should undertake a full comprehensive RCA and will be investigated by someone trained in these methodologies and supported by the Quality & Safety Team.

4.3.2. 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.

4.3.3. 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 the Trust's Serious Incident Investigator or other 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.

4.3.4. The investigation will look to establish the facts of the serious incident and identify appropriate learning.

4.3.5. A RCA toolkit 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 & learning report which can be found in the Investigations & Learning Policy.

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 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 IRG 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 IRG 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 Incident Review Group or other local group 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), 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 & Investigation Skills Training for managers across the Trust. This training is aimed at investigating leads who will undertake grade 1 investigations.

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.

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
- 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.

Root Cause Analysis (RCA) report writing tools and templates. Available at: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59847

Statutory Duty of Candour. Available at: https://www.gov.uk/government/consultations/statutory-duty-of-candour-for-health-and-adult-social-care-providers

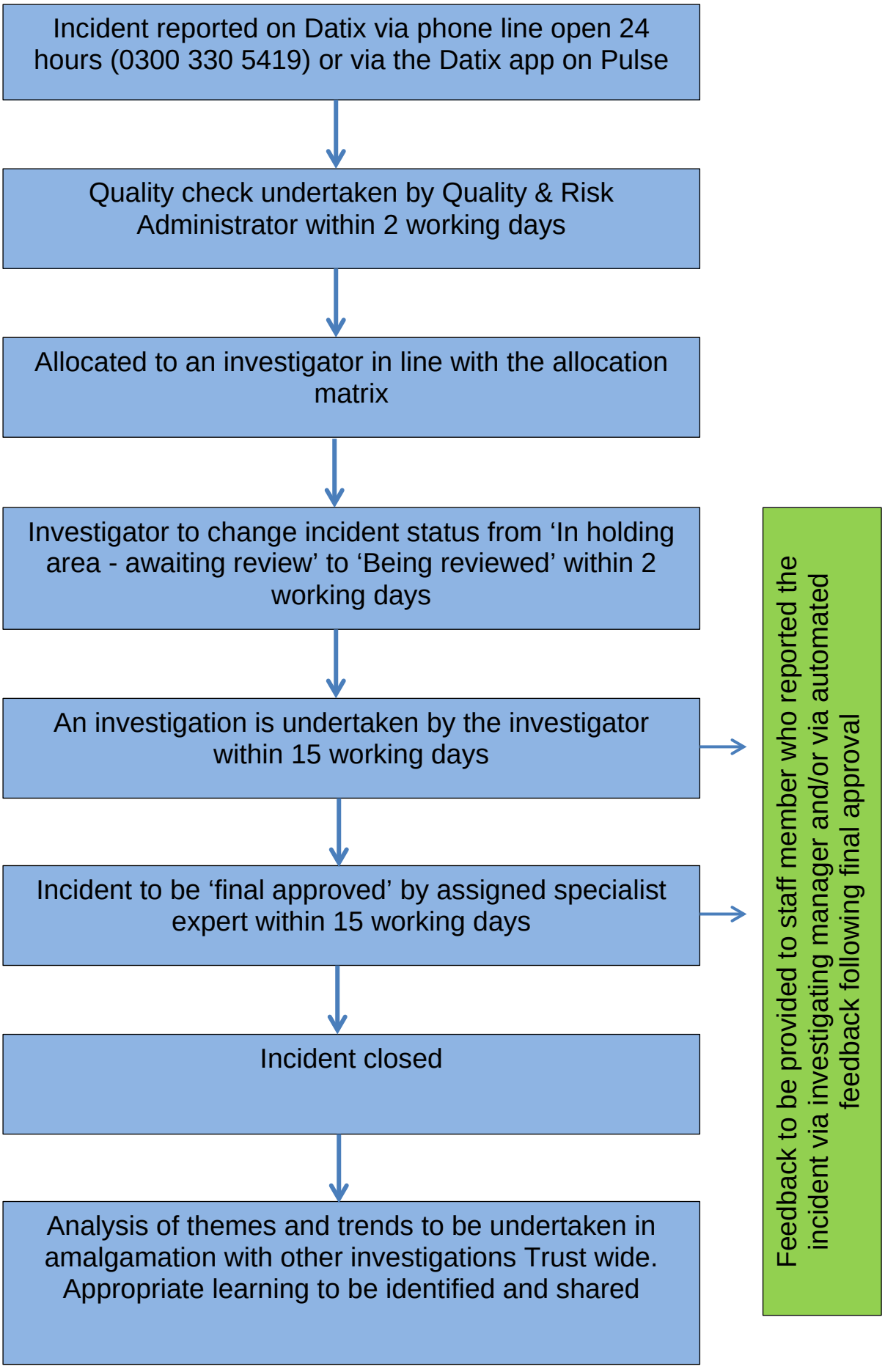
Serious Incident Framework 2015. Available at: https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf

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
- Appendix E – Time Related Decision Tree
- Appendix F – Definitions
- Appendix G – Roles & Responsibilities

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 **Harm to patients/staff and/or public (including physical and/or psychological harm)**	Minor injury not requiring first aid or no apparent injury	Minor injury or illness, requiring minor intervention 1-2 people affected No long term consequences.	Moderate injury which impacts on an individual or a small number of people Some degree of harm up to a year. RIDDOR/MHRA/agency reportable incident	Major injury leading to long-term incapacity/disability Serious mis-management of care with long-term effects 16-50 people affected	Death /life threatening harm Multiple permanent injuries or irreversible health effects More than 50 people affected
Staff **Competence and training, poor staff attendance for mandatory/key training**	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 breech of guidance/ statutory duty	Breech of statutory legislation Reduced performance rating if unresolved	Single breech in statutory duty Challenging external recommendations/ improvement notice	Enforcement action Multiple breeches in statutory duty Critical report	Multiple breeches 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 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 *(electronic or paper)* containing person identifiable data.	Loss/ compromised security of 2-100 records *(electronic or paper)* containing confidential/ person identifiable data.	Loss/ compromised security of 101+ records *(electronic or paper)* containing person identifiable data.	Serious breach with potential for ID theft compromised security of an application / system / facility holding person identifiable data *(electronic or paper).*
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 Witness statements admitted under Rule	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 Low level risk of civil	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). Consideration given to	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-issues not addressed

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

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	Fleet Services Manager
Care Pathway	Care Pathways Advisor & Clinical Manager (Pathways)
Violence and Aggression	Local Security Management Specialist
Moving and Handling	Health & Safety Manager
Response Related - EOC	EOC Governance / Management
Slips, Trips & Falls	Health & Safety Manager
Response Related – 111, LCD, OOH	111 Governance Team
Security	Local Security Management Specialist
Clinical Assessment	Clinical Managers (Quality)
Non-Medical Equipment	Health & Safety Manager
Medical Equipment	Medical Equipment Technician
Medication – Controlled Drug	Pharmacist
Medication – Non Controlled Drugs	Pharmacist
Clinical Treatment	Clinical Managers (Quality)
Consent Related	Clinical Excellence Manager
Exposure to Harmful Substances	Health & Safety Manager
IT Related	ICT Project Manager
Information Governance	Information Governance Manager
IP&C	Head of Safety
Fire	Fire Safety Officer
Response Related - PTS	PTS Manager
Self-Harm	Mental Health Lead
Environment & Estates	Estates Manager
Training	Head of Learning & Development
Adverse Publicity	Communications Manager
Financial Loss	Finance Manager

Yorkshire Ambulance Service NHS Trust

YAS Quality, Governance & Performance Assurance Standard Operating Procedure
A Guide for the Investigating Manager

Document Authors: Tina Medlock (Safety Governance Manager)
Response Lead: Karen Warner (Deputy Director of Quality & Nursing)
Version: 3.0
Issue Date: December 2017
Review Date: December 2018

This document has been approved by:

Name	Title	Date
Rebecca Mallinder	Head of Investigations & Learning	December 2017

Aim

The aim of this document is to provide the Investigating Manager with an easy-reference guide on how to complete a high level investigation. This document should be used in conjunction with the RCA tools provided by the Quality & Safety Team which provides specific guidance in more detail of certain aspects of the investigation.

Role of the Investigating Manager

The role of the Investigating Manager is to undertake a thorough root cause analysis investigation 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.

1. First Steps – Getting Started

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
- Example report
- Key reminders for investigation
- YAS Glossary
- Datix reference (and access to this)
- 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 3 working days of the SI being declared.

2. Initial Meeting

At the initial meeting between yourself and the Safety Governance Manager, the Terms of Reference for the investigation will be discussed 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?

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:

- Patient Care Record (PCR)
- Sequence of Events (SOE) log
- Adastra 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 Manager, Lead Paramedic)

4. Completing the Investigation Report

You have 20 working days to complete the investigation report and return this to the Trust's Safety Governance Manager. 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, the 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 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 a relevant person.

5. Updating Datix

As you are completing your investigation, you need to access the Datix 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 updated onto Datix.

6. What happens after you have completed your report?

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 circulated to members of the Incident Review Group (IRG) ahead of the meeting. Changes may be made after this time after review and then submitted 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.

- 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 helps 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 submitted to commissioners 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

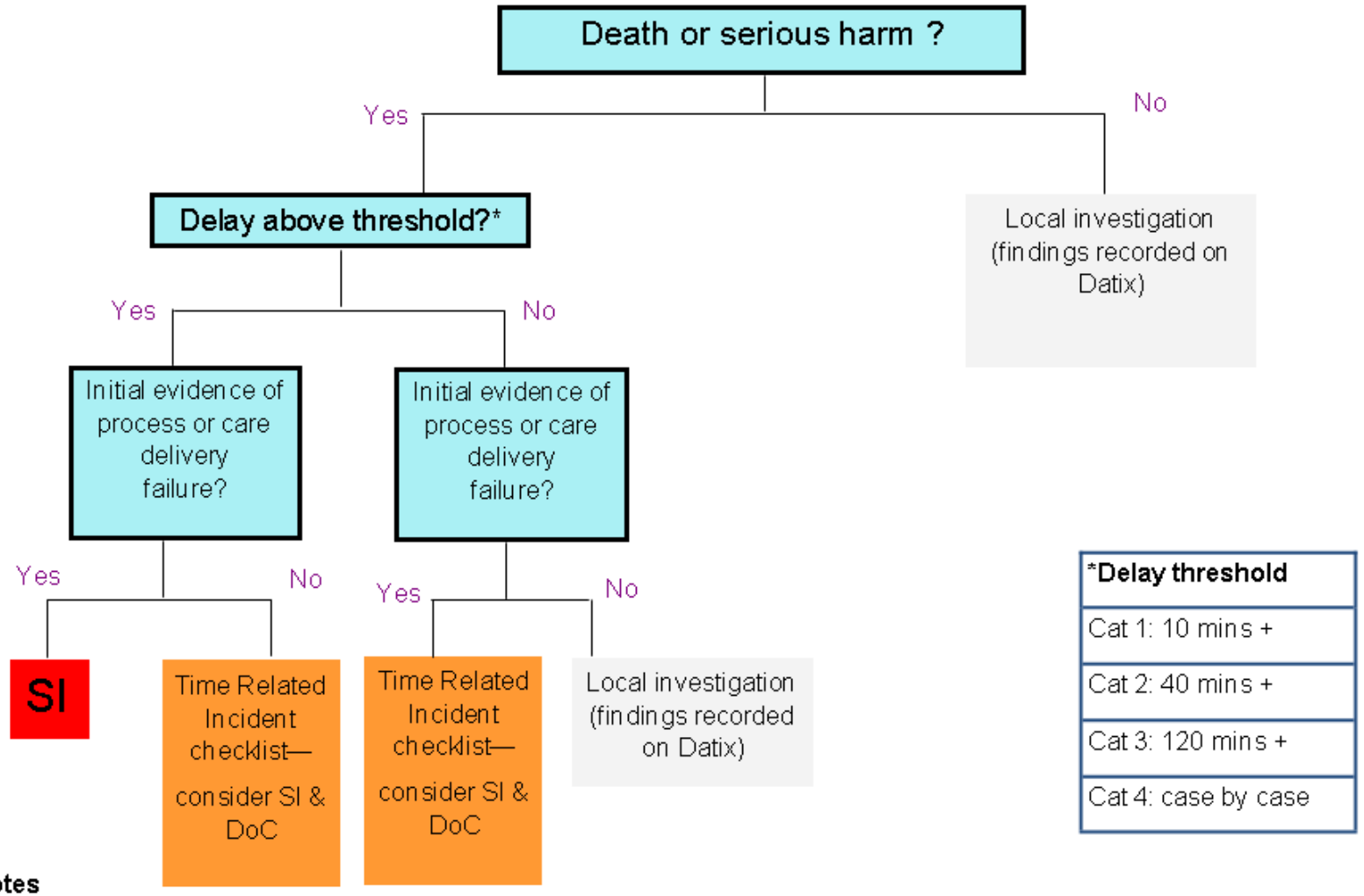
Should you require any support throughout the duration of the investigation please do not hesitate to contact a member of the Quality & Safety Team on the following details:

Tina Medlock (Safety Governance Manager)
tina.medlock@yas.nhs.uk
01924 584048/07825 113004

Rebecca Mallinder (Head of Investigations & Learning)
rebecca.mallinder@yas.nhs.uk
01924 584085/07789 922838

Appendix E – Time Related Decision Tree

INCIDENTS ASSOCIATED WITH A RESPONSE OUTSIDE THE TARGET TIMEFRAME



*Delay threshold
Cat 1: 10 mins +
Cat 2: 40 mins +
Cat 3: 120 mins +
Cat 4: case by case

Notes

- All potential SIs and use of the Decision Tree are monitored through the Incident Review Group.
- Safety netting of Datix reporting through the 'real time' EOC process and consideration of other sources of reporting including complaints, service to service feedback and inquests, as at present.
- Duty of candour criteria are applied to all incidents as specified in the national guidance.

Appendix F - 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.

Severity
Outcome or impact of an event.

Datix
The system used by the Trust to 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.

Appendix G – Roles & Responsibilities

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 fortnightly 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.

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.