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Northern Lincolnshire and Goole NHS
NHS Foundation Trust

Directorate of Performance Assurance

POLICY FOR DEALING WITH SERIOUS INCIDENTS (CLINICAL AND NON-CLINICAL)

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Northern Lincolnshire and Goole NHS Foundation Trust actively seeks to promote equality of opportunity. The Trust seeks to ensure that no employee, service user, or member of the public is unlawfully discriminated against for any reason, including the "protected characteristics" as defined in the Equality Act 2010. These principles will be expected to be upheld by all who act on behalf of the Trust, with respect to all aspects of Equality.

Contents

Section ..... **Page**

1.0 Introduction 4

2.0 Purpose 4

3.0 Area 4

4.0 Definition of 'Serious Incidents' 4

5.0 Duties & Responsibilities 7

6.0 Procedure / Actions 11

6.1 Immediate Action to be Taken Following an Incident 11

6.2 Reporting a Suspected Serious Incident 12

6.3 Assessing whether an Incident is a Serious Incident 14

6.4 External Notification of Serious Incidents to Commissioners and Stakeholder 15

6.5 Follow up Information (72 hour review) 16

6.6 Investigation Process 17

6.7 Lead Investigator 17

6.8 The Investigation Team 18

6.9 Involving Patients, Victims and Their Families / Carers 19

6.10 Supporting Staff Involved in a Serious Incident 20

6.11 Link between Serious Incident and Potential Disciplinary Proceedings 21

6.12 Duty of Candour / Being Open requirements 22

6.13 Investigation Report & Action Plan 23

7.0 Submission of Report 24

8.0 Actions Plans 25

9.0 Tracking and Assuring Actions 25

10.0 Follow-up / 'Closing the Loop' 25

11.0 Record Keeping 26

12.0 Designation of Incident Room 26
13.0 Management of Information 27
14.0 Communications / Media Relations 27
15.0 Reporting and Investigation Requirements 29
16.0 Approval & Ratification 29
17.0 Review & Revision 29
18.0 Implementation 29
19.0 Dissemination 30
20.0 Monitoring Compliance & Effectiveness 30
21.0 Further Reading / Associate Documents 30
22.0 References 31
23.0 Consultation 31
24.0 Equality Act (2010) 31

Section:

Appendix A - SI Management Checklist Revised (2016) 32
Appendix B - Setting Up & Use of 'Helplines' 35
Appendix C - Helpline Pro-Forma 38
Appendix D - Reporting Requirements to External Bodies 40
Appendix E - A Guide to Serious Incident Grading for Investigation Purposes 45
Appendix F - SI Investigation Process 46
Appendix G - SI Reporting Procedure to Medical Education 48

1.0 Introduction

1.1 Serious Incidents (SIs) requiring investigations in healthcare are rare, but when they do occur, all healthcare provider organisations must make sure there are systematic measures in place to respond to them. Such measures are in order to protect patients and ensure that robust investigations are carried out, which result in learning to minimise the risk of recurrence.

1.2 All providers of health and social care in England have a statutory duty to report Serious Incidents to the body that commissioned the service where the incident occurred. Clinical Commissioning Groups (CCGs) and NHS England (as direct commissioners e.g. specialist services) are responsible for holding providers to account for managing responses to serious incidents. In addition, providers have a responsibility to report certain adverse events to the appropriate regulatory body. This includes the Care Quality Commission (CQC) and the Health and Safety Executive (HSE). As a foundation trust, NLAG has an additional responsibility to report to NHS Improvement.

2.0 Purpose

2.1 This policy is intended to formalise roles and responsibilities, for dealing with 'Serious Incidents', in order to ensure that such events are managed effectively and efficiently. It should be read in conjunction with the Trust's Incident Reporting Policy & Procedure and the NHS England Serious Incident Framework March 2015.

3.0 Area

This policy applies to all staff employed by or seconded to the Trust and to all Trust premises.

4.0 Definition of 'Serious Incidents'

4.1 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. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

4.2 The occurrence of a serious incident demonstrates weaknesses in a system of process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

4.3 The above includes incidents involving patients, members of staff (including volunteers), contractors and visitors to the Trust.

4.4 In accordance with the NHS England Serious Incident Framework (2015), there are certain circumstances in which a serious incident must be declared. Every incident must be considered on a case-by-case basis using the description below. Inevitably there will be borderline cases that rely on the judgement of the people involved.

4.5 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 of 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 of more people that requires further treatment by a healthcare professional in order to prevent:
  - The death of the service users 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 (see Part One; sections 1.3 and 1.5 of the NHS England Serious Incident Framework 2015 for further information):
  - A ‘Never Event’ – all ‘Never Events’ are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See the Revised Never Events Policy and Framework (March 2015) 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)
- Information Governance breaches classified as Level 2 as per the definition within the "Checklist Guidance for Reporting, Managing and Investigating Information Governance and Cyber Security Serious Incidents Requiring Investigation", published by the Health and Social Care Information Centre, Version 5.1, 29th May 2015. These incidents will be reported to the ICO via the Information Governance Toolkit
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation

4.6 The criteria within the framework describe the general circumstances in which Providers and Commissioners should expect Serious Incidents to be reported. There is no definitive 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 incidents. (Serious Incident Framework 2015).

4.7 All incidents meeting the threshold of a Serious Incident must be investigated and reviewed according to principles set out in the framework (which are reflected in this policy).

5.0 Duties & Responsibilities

5.1 Board of Directors

The principal accountability of all providers of NHS-funded care is to patients and their families/carers. In their fulfilment of the Trust's duty in this regard, the Board must ensure that an appropriate incident management system is in place for the reporting of incidents and monitoring of incident trends, including serious incidents, and Never Events. Provider organisations are also accountable for effective governance and learning following a serious incident, and it is the duty of the Board to ensure appropriate arrangements are in place throughout the Trust to meet this expectation.

5.2 Trust Governance and Assurance Committee

The Trust Governance and Assurance Committee (TGAC) ensures accountability from operational groups regarding implementation of actions and dissemination of leaning following serious incidents, or other incident trends highlighting emerging issues. The committee receive assurance that the Trust's Being Open policy and Duty of Candour is adhered to in terms of sharing Serious Incident reports with patients or family members and with individual staff involved in the incident.

5.3 Chief Executive

The Chief Executive is accountable and responsible to the Board for ensuring that resources, policies and procedures are in place to ensure the effective reporting, recording, investigation and treatment of incidents.

5.4 Director of Performance Assurance

The Director of Performance Assurance has overall responsibility for governance and risk management and ensuring the Trust has appropriate arrangements in place for the management of incident reporting and associated investigation. Responsibility for defining and verifying serious incidents rests with the Director of Performance Assurance who will discuss and 'second sense check' with the relevant professional leads e.g. the Medical Director and/or Chief Nurse, and/or other Leads as appropriate.

5.5 Medical Director and Chief Nurse

The Medical Director and Chief Nurse are responsible for ensuring that their respective professional groups are compliant with this policy and associated procedures in identifying, reporting and investigating incidents. This includes a responsibility to ensure professional practice obligations are maintained, learning is shared and any necessary changes implemented following the investigation of incidents. They will also provide professional advice and contribute to the decision making processes to identify serious incidents.

5.6 Deputy Director of Performance Assurance

The Deputy Director of Performance Assurance will deputise in the absence of the Director of Performance Assurance.

5.7 Director / Group Manager

5.7.1 The Director/Group Manager will assume specific responsibility* for managing the incident as detailed in the policy (if it is out of hours, the on-call Director/Senior Manager will assume this responsibility – see 5.8). The relevant Director/Manager will be supported by the Director of Performance Assurance and/or the Head of Risk and Clinical Audit, as appropriate.

*Note: dependent on the circumstances/scale of the incident (e.g. large scale patient re-calls) the Director of Performance Assurance and/or the Head of Risk and Clinical Audit may need to assume responsibility for the management of the incident. This will be decided at the time the incident occurs.

5.7.2 The Director/Group Manager will identify the Lead Investigator, Staff Liaison and Family Liaison Officer and inform Risk and Governance of that decision. They will ensure appropriate processes are in place for escalation, reporting, review and learning the lessons from serious incidents and near misses.

5.8 Out of Hours Site Manager

During out of hours all potential serious incidents will be notified to the respective Site Manager in the first instance. The Out of Hours Site Managers will ensure the on-call Director/Senior Manager is contacted immediately so that they can assume responsibility for the incident.

5.9 Associate Medical Directors (AMD)

The Associate Medical Directors along with the Associate Chief Nurses are accountable for the quality and safety of their services provided within their operational group. Each AMD has a joint responsibility therefore to ensure the principles and practice described in this policy is embedded within their directorate through clear communication with medical staff and effective Quality Governance arrangements. Where an incident involves a junior doctor in any way, the AMD should discuss with the Director of Postgraduate Medical Education so that appropriate support and guidance can be provided to the individual(s) at the earliest opportunity.

5.10 Associate Chief Nurses (ACN)

The Associate Chief Nurses along with the Associate Medical Directors are accountable for the quality and safety of their services provided within their operational group. Each Associate Chief Nurse has a joint responsibility therefore to ensure the principles and practice described in this policy is embedded within their directorate through clear communication with all nursing staff and effective Quality Governance arrangements. Associate Chief Nurses and the Head of Midwifery are responsible for the supervision of nursing staff and midwives within their operational group through Operational Matrons, Ward and Senior Sisters. They are expected to use visible leadership support to ensure that patient safety incidents are escalated, reported and investigated, working closely with their Senior Management Team and Risk and Governance. Where an incident involves nursing staff in any way, the ACN should ensure that the nursing staff member is supported and provided with the appropriate guidance.

5.11 Head of Therapeutic Services

The Head of Therapeutic Services is accountable for the quality and safety of their services provided within their operational groups and will have delegated responsibility to ensure the principles and practice described in this policy is embedded within their directorate through clear communication with all staff within therapy services and effective Quality Governance arrangements. They are expected to use visible leadership support to ensure that patient safety incidents are escalated, reported and investigated, working closely with their Senior Management Team and Risk and Governance. Where an incident involves an allied health professional in any way, the Head of Therapeutic Services should ensure that the staff member is supported and provided with the appropriate guidance.

5.12 Head of Risk and Clinical Audit

The Head of Risk and Clinical Audit has designated responsibility for ensuring that Serious Incident reporting and investigations are carried out in line with this Policy and the NHS Commissioning Board "Serious Incident Framework. March 2015. In particular, in respect of reporting on the Strategic Executive Information System (STEIS) and the National Reporting and Learning System. Serious Incidents must be reported without delay and no longer than 2 working days after the incident is identified. Following the initial reporting the Head of Risk and Clinical Audit will also be responsible for ensuring that the 72 hour update report is submitted to the CCG. Please see Appendix F.

5.13 Head of Communication and Marketing

The Head of Communication and Marketing will, if it is deemed necessary, facilitate and coordinate any communications with the media in accordance with the media relations' protocol described within the Trust's Communications Strategy.

5.14 All Managers / Heads of Service

Managers/Heads of Service have a duty to implement local systems to ensure that staff comply with this policy. In particular they must ensure that staff involved in a serious incident receive support, that serious incidents are identified on a timely basis and escalated accordingly, take immediate action within their scope to prevent recurrence and/or eliminate or reduce any identified risks. They must ensure duty of candour requirements are implemented and provide immediate and appropriate support to staff, patients and families following incidents. Managers/Heads of Service must ensure staff are allocated sufficient time to attend RCA meetings and write witness statements as appropriate.

5.15 All Staff

It is the duty of every employer to ensure, as far as is reasonably practicable, the health, safety and welfare of employees. This, together with the duty of care and cooperation imposed on each employee, requires that all serious incidents or near misses which do or could potentially result in harm should be reported to the appropriate level of management within the Trust and via the electronic incident reporting system available to all wards, service areas and departments. An employee's duty to report applies even if they are not directly or potentially affected.

5.16 Governance Groups

Operational Governance Groups are responsible for reviewing all serious incident reports, recommendations, and actions, together with monitoring implementation of improvements and clinical speciality learning.

5.17 Risk and Governance Facilitators

The Risk and Governance Facilitators will provide facilitation support to the Serious Incident process outlined in this policy and monitor and support RCA's to ensure they are undertaken within the required timeframe. They will receive, review and submit Serious Incident Investigation Reports for Director approval ensure dissemination of the reports and action plans, monitor progress of SI action plans providing regular updates to Governance Groups and submitting final signed action plans to risk management.

5.18 Director of Postgraduate Medical Education

When a patient safety incident involves a junior doctor, the Director of Postgraduate Medical Education should be made aware so that the appropriate support can be provided to the individual. Junior doctors will receive incident training as part of their induction. This will include their responsibilities to report patient safety incidents as well as how they may gain support should they be involved in any way.

5.19 Lead Investigator

In the event of a serious incident the Associate Chief Operating Officer will identify an appropriately trained Lead Investigator. The Lead Investigator, with support from risk management, will devise clear terms of reference within which to conduct the investigation. The Lead Investigator will facilitate a Root Cause Analysis (RCA) investigation and compile a report using the Trust templates. They should make all necessary decisions to manage the incident investigation effectively. The Lead Investigator should gain assurance that all staff involved in the incident and who may be interviewed are receiving appropriate support, including junior doctors and that, from the patient perspective, the duty of candour requirements are being met and they are being fully supported throughout the process. They will work with the identified investigation team to provide documentary evidence in support of the investigation findings and conclusions for safe keeping by the Risk and Governance Team (refer also to section 6.7).

5.20 Quality Matron – Falls Lead:

- Reviews all fall incidents reported via Datix and identifies those that have resulted in serious harm or death
- Notifies the Head of Risk and Clinical Audit of incidents that meet the SI criteria to enable prompt reporting
- Carries out a RCA in conjunction with the Ward manager

5.21 Quality Matron – Pressure Ulcer Lead

- Reviews all hospital acquired pressure ulcers in order to identify those that are category 3 or 4 and may meet the SI criteria
- Notifies the Head of Risk and Clinical Audit of any pressure ulcers that meet the criteria for reporting as Sis
- Contact the ward manager to request the RCA be undertaken

5.22 Infection Prevention and Control Lead

Informs the Head of Risk and Clinical Audit of all cases of hospital acquired Clostridium Difficile and MRSA bacteraemia that have contributed to the death of a patient and may meet the SI reporting criteria.

6.0 Procedure / Actions

6.1 Immediate Action to be Taken Following an Incident

6.1.1 It is an overriding responsibility of all employees to take immediate action at the scene of an incident to minimise injury and/or obtain appropriate treatment for individuals. Employees should consider what immediate action may be required to prevent further injury. Employees should have regard for their own health and safety at such times and should summon assistance whenever appropriate.

6.1.2 Individual employees, volunteers, contractors or students must report to their supervisor or head of department, as soon as practicable, any incident they have witnessed or been involved in. Following an incident, the person in charge of the ward/department/service area should ensure that all necessary and remedial actions have been taken and instigate any further actions as required to prevent recurrence.

6.1.3 Where relevant, a safe environment must be re-established, all equipment or medication quarantined, labelled and isolated, and all relevant documentation copied and secured to preserve evidence to facilitate the investigation and learning. To maintain product liability, no piece of equipment should be returned to the manufacturer for repair/examination until the Trust has carried out all necessary tests on the equipment as suggested by the MHRA.

6.1.4 Measurement, drawings or photographs of the location of the incident should be taken if necessary, appropriate and practical. The needs of patients and their family/carers must be made the first priority. Relevant documentation should be copied and secured to preserve evidence and facilitate investigation and learning. If there is a suggestion that a criminal offence has been committed, the organisation should contact the police (see 6.2.6).

6.1.5 The appropriate Consultant/Nurse in Charge should advise the patient (or where applicable the patient's relatives) of the circumstances of the incident and offer reassurances that a full investigation will be undertaken. Details of the patient safety incident and information provided to the patient/patient's family must be recorded contemporaneously and objectively within the patient's individual record. Facts not opinions must be documented.

6.1.6 Where the incident is serious, the manager responsible for the area where the incident occurred should make arrangements for all staff to document their recollection of the incident and sign it.

6.1.7 Serious incidents or suspected serious incidents should be escalated immediately as described in 6.2.

6.2 Reporting a Suspected Serious Incident

6.2.1 The occurrence of a suspected serious incident, with the exception of suspected fraud or corruption (see below), should be notified immediately to the Head of Risk and Clinical Audit. This should be by telephone or face to face.

6.2.2 It is recognised that the relevant Director or Manager may already have been informed as part of pre-existing departmental working arrangements. Where this is not the case, the member of staff reporting the incident should ensure appropriate escalation within the Group/Directorate to ensure that all relevant staff are aware.

6.2.3 The appropriate Director/Manager upon notification of a serious incident or potential serious incident should ensure all relevant staff within their group/directorate are fully briefed on the circumstances surrounding the incident and any immediate actions taken.

Note: Incidents of fraud and corruption must be dealt with in accordance with the Trust's Counter Fraud Policy, which is based on national guidance for counter fraud arrangements within the NHS.

Note: If a serious incident or never event occurs out of hours, during a weekend or bank holiday, the respective Site Manager should be contacted immediately by the person in charge of the area where the incident occurred. The Site Manager in turn will contact the on-call Director/Senior Manager (please also see point 6.2.8 below). The Head of Risk and Clinical Audit should be contacted by the Director/Senior Manager on the first working day following the incident to report the circumstances of the event and seek further guidance if so required.

Note: A child death should be notified immediately to the Head of Safeguarding as per Child Death Overview Panel (CDOP) Statutory Guidance and Service Level Agreement (SLA) with CCG/Local Safeguarding Children's Board. This relates to any child up to and including 17 years of age.

6.2.4 The Head of Risk and Clinical Audit will alert the Director of Performance Assurance (or designate in their absence) of the potential Serious Incident immediately following receipt of the verbal notification from the Directorate Manager/Head of Department.

6.2.5 Initial notification of a serious incident or potential serious incident should be followed up by the completion of an incident reporting form available on the intranet (including information on all persons involved and the immediate action taken after the occurrence and enclosing any statements obtained from all those involved in the incident).

Note: 'Guidelines on Preparing a Statement' are available from the intranet site under document control.

6.2.6 In respect of incidents, where foul play is suspected/has been confirmed, **early** consideration should be given, by the person in charge of the ward/department, in consultation with his/her Manager (or Site Manager if out of hours) if necessary, to involve the Police. In the event of such action being taken, the area should be isolated and any equipment involved should be retained until the Police have visited. Details of any witnesses to the incident should also be obtained in case this information is required by the Police. Should staff be unsure whether Police involvement is required, advice can be obtained from the Protecting Vulnerable Persons Unit between 7am-10pm on 01724 241700 or if out of hours, by ringing 101 (Police Non-Emergency). Note: It is recognised that the requirement to involve the Police may not become apparent until investigation of the incident has commenced/been completed. However, early contact with the Police is encouraged in order to obtain appropriate advice at an initial stage. Staff support should be considered in these early stages and advice can be obtained from Senior Management within the directorate and/or from the Human Resources Department. The individual's supervisor/line manager should be notified as soon as possible after the incident has occurred.

6.2.7 On notification of the incident, the Director of Performance Assurance/Head of Risk and Clinical Audit will ensure that the following staff are or have already been notified as appropriate:

- Trust Board, (including the notification of 'Never Events within 24 hours of the incident occurring with a detailed update provided to the next scheduled Board meeting)
- Appropriate Director
- Chief Executive
- Medical Director
- Chief Nurse
- Director of Strategy & Planning (Trust Information Security Manager)
- Director of Estates & Facilities, including Hotel Services General Manager (Head of Car Parking, Transport & Security and Trust Security Management Specialist)
- Head of Communications and Marketing
- Health & Safety Manager

6.2.8 **If out of hours,** the Site Manager will, in the first instance, notify the Director/Senior Manager on-call, who will then make a decision as to whether any of the above should be contacted. **In addition, there are certain Incidents which require reporting to an external authority – please refer to Appendix D. Please note: the notification to external authorities will be carried out by the office of the Director of Performance Assurance.**

6.2.9 The Director of Performance Assurance/Head of Risk and Clinical Audit, or Site Manager, will ensure that the necessary immediate action has been taken to prevent a recurrence of the incident(s) where this is possible and/or appropriate. In respect of incidents involving defective 'products' (i.e. drugs, equipment etc.), this will involve ensuring that the item(s) have been isolated and retained (where this has not already occurred for the purposes of a Police investigation) and the relevant in-house personnel contacted (this is in line with the requirement to report incidents caused by defects in medicinal products; buildings and plant; and other medical and non-medical equipment and supplies to the relevant external authority). Please refer to Appendix D.

6.2.10 In respect of clinical/patient safety incidents, the Director of Performance Assurance/Head of Risk and Clinical Audit, or Site Manager, will establish what information has already necessarily been communicated to the patient(s) and his/her relatives and agree with the appropriate Director (or if out of hours the Director/Senior Manager on-call) the approach for further communication and the responsibility for this (e.g. responsible Consultant, Ward Manager, etc). For further information on 'being open' and the legal requirement for 'Duty of Candour' – please refer to the Trust's **'Being Open and Duty of Candour Policy – Communicating with Patients and/or their Relatives/Carers Following a Patient Safety Incident'.**

6.2.11 Depending on the circumstances of the incident and, as appropriate, the Health & Safety Manager will advise whether it is necessary to inform the Health & Safety Executive (HSE) and whether the area involved needs to be isolated until a HSE Inspector has visited.

Note: Where the incident occurs out of hours, the Director/Senior Manager on-call, who at this point will assume responsibility for managing the incident from the Site Manager, will need to satisfy themselves that all necessary and appropriate action has been taken to prevent a recurrence and 'manage' the incident (points 6.2.1 – 6.2.11 above refer).

6.2.12 It may be that a potential Serious Incident has been identified via local reviews of the incident reports. Directorate Management Teams will be responsible for ensuring there are local procedures in place for the prompt review of incidents to ensure the identification of potential Serious Incidents on a timely basis.

6.3 Assessing whether an Incident is a Serious Incident

6.3.1 In many cases it will be immediately clear that a serious incident has occurred and further investigation will be required to discover what exactly went wrong, how it went wrong (from a human factors and systems based approach) and what may be done to address the weakness to prevent the incident from happening again. Whilst a serious outcome (such as the death of a patient who was not expected to die or where someone requires on going/long term treatment due to unforeseen and unexpected consequences of health intervention) can provide a trigger for identifying serious incidents, outcome alone is not always enough to delineate what counts as a serious incident.

6.3.2 In all instances, the Director of Performance Assurance will discuss and second/sense check the decision to escalate the incident as a serious incident or not with the relevant lead professional e.g. Medical Director, Chief Nurse.

6.3.3 Where it is not clear whether or not an incident fulfils the definition of a serious incident, the Trust will discuss with commissioners to agree the appropriate and proportionate response. It may be unclear initially whether any weaknesses in a system or process (including acts or omissions in care) caused or contributed towards a serious outcome, but the simplest and most defensible position is to discuss openly, to investigate proportionately and to let the investigation decide. If a serious incident is declared but further investigation reveals that the definition of a serious incident is not fulfilled – for example there were no acts or omissions in care which caused or contributed towards the outcome – the incident can be downgraded. This can be agreed at any stage of the investigation and the purpose of any downgrading is to ensure efforts are focused on the incidents where problems are identified and learning and action are required.

6.3.4 It may be appropriate for a 'near miss' to be classed as a serious incident because the outcome of an incident does not always reflect the potential severity of harm that could be caused should the incident (or similar incident) occur again. Deciding whether or not a 'near miss' should be classified as a serious incident should therefore be based on an assessment of risk that considers:

- The likelihood of the incident occurring again if current systems/process remain unchanged and
- The potential for harm to staff, patients, and the organisation should the incident occur again

6.3.5 This does not mean that every 'near miss' should be reported as a serious incident but, where there is a significant existing risk of system failure and serious harm, the serious incident process should be used to understand and mitigate that risk.

For further information – please refer to the National Serious Incident Framework, March 2015.

6.4 External Notification of Serious Incidents to Commissioners and Stakeholder

6.4.1 The Head of Risk and Audit will be responsible for notifying the commissioners of all Serious Incidents. Initial notification will be via completion of the computerised notification form on STEIS as soon as practically possible (within two working days of the incident being confirmed). Incidents falling into any of the categories listed below should be reported immediately to the commissioners upon identification. This should be by telephone as well as electronically:

- Incidents which activate the Trust or Commissioner Major Incident Plan
- Incidents which will be of significant public concern
- Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies

6.4.2 The serious incident report/notification must not contain any patient or staff names and the description should be clear and concise.

6.4.3 The Head of Risk and Clinical Audit will act as the liaison link between the Trust and the Commissioners during all stages of the incident investigation process. The Trust will keep the Commissioners informed of any significant developments in internal/external investigations, as appropriate.

6.4.4 Appendix D contains details of external stakeholders who should be considered prior to the commencement of the investigation. In all instances, reporting to the external stakeholders should be discussed and agreed with the Director of Performance Assurance. The notification to external authorities will be carried out by the office of the Director of Performance Assurance and the Director of Performance Assurance will assume responsibility for reporting to NHS Improvement/CQC as required. A record of the stakeholders who have been notified must be retained as part of the Serious Incident investigation.

6.4.5 Incidents reported as serious incidents when child or adult at risk issues are identified at any stage must be referred to the Head of Safeguarding who will ensure the appropriate procedure is followed. All serious incidents involving safeguarding issues will be investigated in accordance with the Trust's policies for safeguarding children and adults at risk.

6.4.6 All serious incidents which meet the definition for a patient safety incident should also be reported separately to the NRLS for national learning. This will be reported via Datix and will be undertaken by the Datix Manager.

6.5 Follow up Information (72 hour review)

6.5.1 An initial review (characteristically termed a '72 hour review') should be undertaken and submitted to the commissioners. This should be completed within 3 working days of the incident being reported on STEIS.

6.5.2 The aim of the initial review is to:

- Identify and provide assurance that any necessary immediate action to ensure safety of staff, patients and the public is in place
- Assess the incident in more detail (and to confirm if the incident does still meet the criteria for a serious incident and does therefore require a full investigation) and
- Propose the appropriate level of investigation. (For NLAG, all Serious Incidents undergo a comprehensive investigation)

6.5.3 The Lead Investigator (see 6.7) will be responsible for providing a 72 hour update and will be supported by the Risk and Governance Facilitator to do this. All ACOOs will be sent a copy of the 72 hour report for information and/or approval but due to the tight timescales, if approval has not been provided the report will be sent with Lead Investigator approval only. All 72 hour reports are reviewed by the Head of Risk and Clinical Audit.

6.5.4 The Head of Risk and Clinical Audit will submit the 72 hour report to the commissioners.

6.5.5 The information submitted as part of the initial review should be reviewed by the appropriate stakeholders and investigation team (once in operation) in order to inform the subsequent investigation.

6.6 Investigation Process

The relevant Director/Manager assuming responsibility for managing the incident will, at the earliest opportunity following confirmation of a Serious Incident, decide the Lead Investigator, Staff Liaison and Family Liaison. They will notify the relevant staff of this decision, confirming with them the expectations of their role as well as notifying the Risk and Governance Team.

6.7 Lead Investigator

6.7.1 The Lead Investigator will be responsible for establishing the investigation team, ensuring that all the relevant disciplines and departments are represented. If the Lead Investigator believes that an external expert is required, the decision to commission external help should always be referred to the Director of Performance Assurance. The reason for instructing an external expert must be documented in the Serious Incident file held by the Directorate of Performance Assurance. The Director of Performance Assurance will consider the degree of error and seriousness of outcome when debating whether to commission an external review.

6.7.2 The criteria that may result in commissioning an external review include:

- where on balance, a criminal charge is unlikely to follow, but could do so
- where there is a strong suggestion of clinical error
- where the effect of the error is to significantly harm the patient, or where the patient has died
- where the potential political ramifications are of national level
- when there is a reasonable belief that the action may be malicious and the Police have been informed

6.7.3 Although the Lead Investigator will have latitude to determine the conduct of the investigation and will be mandated to ensure that a single coordinated, multidisciplinary investigation takes place, they are expected to meet a number of essential requirements. A robust investigation requires a 'questioning attitude that never accepts the first response', and uses recognised tools and techniques to identify:

- The problems (the what?) including lapses in care/acts/omissions and
- The contributory factors that led to the problems (the how?) taking into account the environmental and human factors and
- The fundamental issues/root cause (the why?) that need to be addressed

- This includes:
  - a root cause analysis of incident
  - completion of chronology/time line of events
  - conducting exploratory interviews
  - collation of staff statements, as appropriate
  - ensuring there is timely and sympathetic liaison with the patient/patient's relatives and staff during the course of the investigation (refer to the Trust's Being Open Policy)
  - analysis of evidence
  - formulation of recommendations
  - compilation of report with action plan to prevent recurrence (using the Trust template)
  - learning lessons disseminated and shared with staff involved in the incident
  - learning lessons shared for wider learning

Note: For further information on investigation & RCA of incidents, please refer to the Trust's Incident Reporting Policy Appendix D and the Trust's RCA Toolkit, which are available on the Risk Management webpage under 'documents'.

6.7.4 They are responsible for developing and agreeing the terms of reference prior to commencement of the investigation, having regard for any previous internal investigations findings and the views of the patients and/or their carers/families (see 6.9.3).

6.7.5 In respect of clinical incidents, the Lead Investigator will ensure that medical records are or have been secured. Where records are required for the purposes of an external investigation, e.g. an inquest, criminal investigation or investigation by external experts, the Lead Investigator will ensure that copies are made and retained on the hospital site.

6.8 The Investigation Team

6.8.1 The Lead Investigator and investigation team will carry out the fact finding for the Trust response. They will gather and map the information, analyse the problems to identify the underlying contributory factors and generate robust solutions.

6.8.2 It is the responsibility of all members of the serious incident investigation team to keep the organisation fully briefed about the incident and actions being taken. The investigation team is also responsible for identifying valuable/safety-critical learning to be shared at any stage of the investigation process. The team should not wait until completion of the investigation to highlight system weaknesses/share valuable learning which may prevent future harm.

6.8.3 The investigation team will conduct the investigation in line with the terms of reference, ensure adherence to the timescale of a formal internal investigation and subsequently formulate a report/action plan using the Trust approved template. This will need to include any recommendations made by other agencies involved (i.e. HSE/Police) as well as identifying any actions that need to be implemented widely.

Note: There is no automatic bar on investigating incidents where criminal proceedings are underway. Wherever possible, serious incident investigations should continue alongside criminal proceedings. This should be considered in discussion with the police. Following a formal request by the police, a coroner or a judge, the investigation may be put on hold, as it may potentially prejudice a criminal investigation and subsequent proceedings (if any). Where this is the case, commissioners should review/agree the date for completion once the investigation can recommence.

6.8.4 Whilst staff involved in managing serious incidents should always refer to the full guidance outlined in this policy document, a management checklist has been provided and is attached at **Appendix A.**

6.8.5 In addition, the management of serious incidents including specific actions in respect of reporting, investigating and learning from incidents is attached at **Appendices F and G.**

6.9 Involving Patients, Victims and Their Families / Carers

6.9.1 The needs of those affected should be a primary concern for those involved in the response to and the investigation of serious incidents. It is important that affected patients, staff, victims, perpetrators, patients/victims' families and carers are involved and supported throughout the investigation.

6.9.2 Involvement begins with a genuine apology. The principles of honesty, openness and transparency (refer to the Trust's Being Open Policy) must be applied. All staff involved in liaising with and supporting bereaved and distressed people must have the necessary skills, expertise and knowledge of the incident in order to explain what went wrong promptly, fully and compassionately. The appropriate person must be identified for each case who will undertake the role of family liaison.

6.9.3 An early meeting must be held to explain what action is being taken, how they can be informed, what support processes have been put in place and what they can expect from the investigation. Those involved will want to know:

- What happened?
- Why it happened?
- How it happened?
- What can be done to stop it happening again to someone else?

- They must also have access to necessary information and should:
  - Be made aware, in person and in writing, as soon as possible of the process of the investigation to be held, the rationale for the investigation and the purpose of the investigation
  - Have the opportunity to express any concerns and questions. Often the family offer valuable insight into service and care delivery and can frequently ask key questions
  - Have an opportunity to inform the terms of reference to ensure their questions are reflected
  - Know how they will be able to contribute to the process of investigation, for example by giving evidence
  - Be given access to findings of any investigation, including interim findings – **Note: advice should be sought in relation to each case and this will be via the Trust's Caldicott Guardian**
  - Have an opportunity to respond/comment on the findings and recommendations outlined in the final report and be assured that this will be considered as part of the quality assurance and closure process undertaken by the commissioner
  - Be informed, with reasons, if there is a delay in starting the investigation, completing the investigation or in the publication of the final report; and be offered media advice, should the media make enquiries

6.9.4 Consideration needs to be given to support required during and after the investigation and whether there are any factors to consider such as language barriers. This needs to be done on an individual basis.

6.10 Supporting Staff Involved in a Serious Incident

6.10.1 Staff need support following any incident; however the more serious the incident, the more support is normally required. Being involved in an incident can be stressful for the individual, the team and the service. It is important that individuals should not feel isolated when involved in an incident. The Lead Investigator must ensure that adequate support mechanisms have been made available to staff. This may include referral to the Occupational Health department.

6.10.2 The Staff Liaison will be appointed to guide and support staff involved in the serious incident through the investigation process.

6.10.3 Where a serious incident raises concern in relation to an individual's capability or competence, the staff member must be treated with care and consideration and supported within the principles of a just culture.

6.10.4 The relevant Director/manager should ensure that the necessary arrangements are in place for individuals involved in incident(s) to receive the necessary counselling and support, as required/appropriate – for further information in this regard please refer to section 8.3 & Appendix D: 2.3.1 & 2.3.2 of the Trust's Incident Reporting Policy/Procedure.

6.10.5 Dependent on the circumstances of the incident, consideration should be given as to whether it is appropriate to report the incident to the relevant professional body (e.g. UKCC, GMC etc) or 'Confidential Enquiry'.

6.11 Link between Serious Incident and Potential Disciplinary Proceedings

6.11.1 In some particular circumstances the Trust may need to undertake separate disciplinary proceedings in respect of incidents that have been initially identified as a result of an investigation arising from a serious incident/safeguarding alert. It is recognised that serious incidents often occur as a result of an accumulation of a number of factors and events and staff are encouraged to report incidents without fear of disciplinary action in a culture of learning and reasonable accountability.

6.11.2 Possible disciplinary action will not routinely form part of a response **except** in cases where one or more of the following have been identified:

- Where the view from the Trust is that the actions causing/arising from the incident were far removed from acceptable standards of practice
- Where there was intent to harm and/or a criminal offence has taken place
- Where there is a failure to report an incident in which the member of staff was either involved or about which they were aware

6.11.3 The Incident Decision Tree (IDT) (available as part of the Trust's RCA Toolkit) can be used to help managers decide what initial action to take with staff involved in a patient safety incident. It is intended to promote a consistent and fair approach. Where a review of the circumstances using the IDT framework has demonstrated potential individual failings as detailed above, a formal investigation will be instigated in line with the Trust's General Disciplinary Policy.

6.11.4 This will be a separate disciplinary investigation led by a separate investigating officer who has not been involved in the serious incident investigation although all relevant information from the incident investigation can be referred through to the investigating officer for consideration as part of the disciplinary investigatory process. Terms of reference will need to be agreed by the allocated case manager in accordance with relevant Trust employment policies including clear boundaries for any disciplinary investigation.

6.11.5 A decision to undertake a formal disciplinary investigation can be undertaken at any point during the review of a serious incident where it is felt appropriate to do so by the lead manager who will involve the Human Resources Department as necessary. In some circumstances parallel investigations may need to be progressed. The SI investigation team will need to be informed on how the SI investigation can proceed in these circumstances by the Case Manager. If sharing of statements or interview notes is required, then permission will need to be obtained from the individual staff concerned by the Investigating Officer and HR representative leading the disciplinary investigation. Any information gathered as part of the serious incident investigation will be passed to those involved in the disciplinary. It should be noted that as both investigations are being investigated from different perspectives, separate information will be collected by the investigators as one does not rely on the other for evidence.

6.12 Duty of Candour / Being Open requirements

6.12.1 Patients and/or families (as appropriate) should be informed about patient safety incidents that result in moderate harm, severe harm or death and receive appropriate apologies, be kept informed of investigations and be supported to deal with consequences. This does not apply to low/no harm incidents. In these cases it is left to the judgement of the professional involved in their care or their supervisor.

6.12.2 In cases where the patient or their family/carer should be informed then this should occur with at most 10 working days of the incident being reported. The initial notification must be verbal (face to face where possible) unless the patient cannot be contacted or declines notification. Language barriers, communication difficulties, relevant disability and any other circumstances that will affect the ease of communication must be taken into account.

6.12.3 It may initially be unclear whether a patient safety incident has occurred, or what degree of harm was caused. This is not a reason to avoid disclosure. This conversation is the responsibility of the Lead Clinician however it may be appropriate for another member of staff to speak to the patient or their family on the clinician's behalf. The Trust's Being Open policy sets out the responsibilities of a named contact who is identified to provide information and support to the patient and family/carers in the event of a patient safety incident. A step-by-step explanation of what happened, in plain English, based on the facts, must be offered as soon as is practicable. This includes the provision of support to patients, relatives can carers and staff involved in the incident such as information regarding any support systems that are available to patients/relatives/visitors/contractors. Responsibilities include ensuring the Being Open conversation with the patient and/or family is clearly documented in the incident in the Datix system and that details of the incident are recorded in the patient's individual record.

6.12.4 Information that emerges during the investigation or subsequent to initial explanation must be offered to patients and their carers/families as soon as is practical. It is helpful to establish regular updates with affected individuals. Any incident investigation reports must be shared within 10 working days of being signed off as complete. This includes action plans and the details of investigations and means the actual written reports.

6.12.5 For relevant reportable incidents, the Trust has several responsibilities under the Duty of Candour, including:

- Within 10 working days of reporting the incident, Directorate Manager or Lead Clinician/Nurse must inform the service user or relevant person that the incident has occurred (or is suspected to have occurred). The Trust must ensure this is done verbally (preferably in person) and include an appropriate apology. This should be followed up with a letter using the Trust template (refer to the Trust's Being Open Policy)

- The Trust must provide the patient or relevant person with relevant information and support in relation to the incident

- The Trust must instigate and conduct a full investigation as soon as possible

- The Trust must offer the service-user or the relevant person a copy of the final report into the incident, within 10 working days of the investigation being signed-off as complete. Patients and relatives should be offered a meeting with senior staff involved in the investigation process to discuss and respond to the findings

Note: Refer also to the Trust's Being Open and Duty of Candour Policy available on the intranet

6.13 Investigation Report & Action Plan

6.13.1 The Lead Investigator must compile a written investigation report including conclusions and recommendations highlighting learning points and action required to prevent recurrence using the Trust's approved template. Action Plans should follow the SMART principles.

6.13.2 Reports should be drafted on the basis that they may become public documents and therefore must not contain patient identifiable information or staff name.

6.13.3 Serious Incident reports must clearly state that relevant bodies have been informed.

6.13.4 For all actions, agreement with the appropriate Head of Service/Manager for that service or clinical area should be sought by the Lead Investigator and they should be copied into the first draft of the Serious Incident Investigation Report.

6.13.5 All reports in the first instance will be sent to all those involved in the RCA meeting and to those who have provided statements to check for accuracy and to make any further amendments. Subsequent drafts will be resent to the all those involved as stipulated and to the relevant ACOO, AMD, ACN and to the relevant Group Managers, Governance Leads and Risk and Governance Facilitators.

6.13.6 Reports in final draft will be approved by the ACOO as per 7.1.

7.0 Submission of Report

7.1 Once the investigation is completed an RCA Investigation Report will be submitted to the Risk and Governance Team by the Lead Investigator within 50 working days of the incident accompanied by an action plan that has been shared with the relevant Associate Medical Director and/or Associate Chief Nurse and approved by the Associate Chief Operating Officer. The Head of Risk and Clinical Audit will review the completed report to ensure that the incident has been properly investigated, that there is a clear and timely action plan and that the report complies with the Serious Incident requirements.

7.2 Once the report has been quality assured by the Head of Risk and Clinical Audit, it will be sent for approval by the relevant Director/Directors before it is sent to the Commissioners and to the patient/relatives if applicable.

7.3 Serious Incident investigation reports must be submitted within 60 days of the incident being reported to STEIS, unless the incident requires an independent investigation in which case there is a 6 month timescale. The Trust will be notified by the Commissioners of the date the report is due. If, due to circumstances beyond the control of the investigation team (i.e. Police Investigation), an extension is required, the reasons must be submitted to the Head of Risk and Clinical Audit at least 2-3 weeks prior to the due date. The Head of Risk and Clinical Audit will be responsible for requesting an extension to the commissioners. The outcome of this request will be notified to the Lead Investigator as soon as it is received.

7.4 All Serious Incident Investigation Reports and Action Plans will be approved through the operational group governance framework and monitored accordingly until all actions are complete.

7.5 The Serious Incident central file will be held by the Directorate of Performance Assurance. The Head of Risk and Clinical Audit will be responsible for advising the Lead Investigator when the commissioners have agreed closure of the incident.

8.0 Actions Plans

8.1 All serious incident action plans are the responsibility of the area where the incident occurred to implement and monitor. Exceptions to this would be where the changes required the involvement of more than one group/directorate. In this instance it will be clear from the allocation of responsibilities within the action plan which group/directorate will be required to monitor and sign off specific actions as complete. Evidence for this will be stored in the Serious Incident central file by the Directorate of Performance Assurance.

8.2 It is the responsibility of the Lead Investigator to ensure all action leads are aware of the actions allocated to them and the expected timeframe of those actions.

9.0 Tracking and Assuring Actions

9.1 The Lead Investigator with support of the Risk and Governance Facilitator will track the delivery of all serious incident action plans. The group/directorate will be expected to provide regular updates on their achievement against any serious incident action plans and provide assurance evidence when actions are reported as 'complete'.

9.2 The nominated leads, as indicated through the action plan, will be requested to deliver their action(s) within the timescales agreed. Delivery of actions will be monitored and recorded at the relevant governance group(s) meeting.

9.3 Overall responsibility for this process lies with the management team where the incident occurred. In the event that actions cannot be completed within the given timescale this must be escalated by the action lead to the operational group management team and to the risk and governance facilitator who will notify the Head of Risk and Clinical Audit – see Appendix F.

10.0 Follow-up / 'Closing the Loop'

10.1 A key requirement of the follow-up/closing the loop process and, in order to bring about real improvements with the Trust's services, is the sharing of lessons learned arising from incidents with the staff involved and, where relevant, the wider organisation and external stakeholders.

10.2 Within NLAG, lessons learnt arising from incidents (including SIs) will be shared via the following routes:

- **Group/Directorate Level:**
  - Local Governance Groups/Minutes
  - Staff Meetings/Business Meetings
  - Quality and Safety Days/Audit Meetings
  - Local Newsletters etc

- **Trustwide:**
  - ‘Learning the Lessons’ Newsletter
  - Internal Safety Alerts
  - Risk Fora (e.g. Trust Governance and Assurance Committee, Health & Safety Committee, Learning Lessons Review Group etc)
  - Serious Incident Reports submitted to the Trust Governance and Assurance Committee and Trust Board (as agreed)
  - Staff Bulletins/Newsletters

10.3 Action plans should describe the ways in which learning from the individual incident will be disseminated. Audits/monitoring will be undertaken to strength test the learning/changes required from the serious incident to ensure improvements are being maintained.

11.0 Record Keeping

It is essential that records of the investigation/actions taken **throughout** the management of a serious incident are maintained and kept secure **(tips for information gathering and collection/collation are available in the Trust’s Root Cause Analysis (RCA) Toolkit)**. The relevant Director/Manager with responsibility for the management of the incident will ensure that:

- all documentation relating to the incident is retained/secured for future reference in the event of (i) an external independent investigation; (ii) legal proceedings being issued; and (iii) a criminal investigation
- (in respect of clinical/patient safety incidents) the medical records are ‘secured’. Where records are required for the purposes of an external investigation, i.e. an inquest or criminal investigation, copies should be retained on the hospital site. Where records may be required for ongoing treatment, copies may need to be provided for the purposes of the investigation process

12.0 Designation of Incident Room

Where it becomes apparent that the management of a serious incident is likely to generate large scale storage and management issues, for example where large numbers of patients are involved, the major incident room (Main Boardroom) on the respective site will be utilised as the 'incident room'.

13.0 Management of Information

In the event of a large-scale serious administrative and/or clinical error affecting large numbers of patients, the need to develop a dedicated database should be considered at an early stage. It should be stressed, however, that the process of setting up and managing such a database should be project managed from the outset by a local designated expert lead supported by a core group of relevant IT/information staff.

14.0 Communications / Media Relations

For some serious incidents, it may be necessary for a media/communication strategy to be developed and agreed. This will include:

- clarification of lead role responsibility of "media spokesperson" (although the Head of Communications and Marketing will be responsible for on-going liaison with the media)

- agreement of briefing responsibilities, requirements and timescales. This should include lead role for:

  (a) Contacting or further contacting the affected patient(s) and/or relatives or member(s) of the public (e.g. where the affected person may be a visitor) prior to release of statement/information to the media

  N.B. There should be no proactive release of information to the media until every effort has been made to contact affected patients and/or relatives or member(s) of the public. However, where there are tight timescales within which the Trust must contact patients and/or relatives, the need to balance the imperative of contacting affected patients and/or relatives against the likely sensitivities around the method and timing of the contact must be considered.

  (b) In the event of a serious incident affecting a member or members of staff, the same principles should apply as in (a) above

  (c) the setting up of an advice/'helpline' for dealing with enquiries from patients/relatives/the wider public, where this is considered necessary/appropriate (please refer to **Appendix B** for further information on setting up an advice/'helpline')

(d) as appropriate, briefing of:

- **Internally:**
  - Directors/Managers
  - Trust Governance and Assurance Committee
  - Trust Board
  - Trust Staff (including those directly involved)
  - PALS
  - Governors
  - Unions
- **Externally:**
  - MPs
  - other hospitals/Trusts
  - legal representatives – ongoing briefing
  - NHS Improvement
  - Care Quality Commission
  - Information Commissioners Office
  - NHS Commissioning Board
  - Medicines & Healthcare Products Regulatory Agency (MHRA)
  - Commissioner(s)/GPs (if patients affected)

    N.B. Given the wide catchment area covered by the Trust, care should be taken to ensure that all relevant Commissioners are briefed on the incident.
  - Emergency Planning Officer – Local Authorities
  - Local Authority Health Scrutiny Lead(s)
  - Social Services
  - Emergency Services
  - National Health Service Litigation Authority
  - Police

- Coroner
- Health & Safety Executive
- Public Health
- Local Supervising Authority (ref. maternal deaths – see Appendix D, page 42)
- Information Commissioner
- Care Quality Commission

15.0 Reporting and Investigation Requirements

The reporting and investigation requirements for serious incidents are provided in Appendices E and F of this policy for reference/information.

16.0 Approval & Ratification

The Trust Governance and Assurance Committee will be responsible for the ratification of this procedure.

17.0 Review & Revision

This procedure will be reviewed every three years or sooner should the need arise in the light of experiences/lessons learned in the management of serious incidents within the Trust.

18.0 Implementation

18.1 Training for staff in identifying and reporting, and the investigation of serious incidents, where this is a requirement of their role*, is provided via the Incident Investigation/Root Cause Analysis Training. *Staff that are new to post will need to be booked on this training as part of their local induction.

18.2 Staff that are RCA trained and are involved in Serious Incident RCA Investigations as part of their role will be deemed competent and will only require refresher training if they have not been involved in a Serious Incident investigation in the last 12 months or if current guidance/techniques have changed/been updated. For all other staff that are RCA trained, refresher training will be provided every 3 years (or sooner should the need arise). If they are regularly involved in RCAs, refresher training may not be necessary and this will be determined on a case by case basis by the Head of Risk and Clinical Audit.

18.3 All staff receive Incident Reporting Awareness Training at Corporate Induction on commencement in employment.

19.0 Dissemination

Copies of these procedures will be disseminated in hard copies and electronically via the intranet. Copies will also be issued to Directors/Senior Managers on-call.

20.0 Monitoring Compliance & Effectiveness

20.1 The Trust Governance and Assurance Committee (who have designated responsibility on behalf of the Trust Board) will be advised of all new SIs and will be kept informed of progress with and the outcome of the investigation/lessons learned and the action taken or proposed following SIs, including monitoring of overdue investigations and overdue actions. For further information – please refer to the Trust's 'Incident Reporting Policy/Procedure'. Where requested by the Trust Governance and Assurance Committee (i.e. in instances where there is the potential for significant media interest and/or the involvement of external agencies), the Trust Board will also be notified of SIs and will monitor progress with the implementation of agreed remedial actions.

20.2 Monitoring of agreed action measures will be undertaken as part of the wider Incident Reporting System arrangements via the Trust Governance and Assurance Committee. It will be the responsibility of the relevant Director/Manager to ensure escalation of significant risk issues/incidents to the Trust Governance and Assurance Committee and for keeping these committees advised of progress against agreed action plans.

20.3 Audit of performance against agreed targets for investigations and learning from Serious Incidents will be routinely undertaken and reports submitted to the Trust Governance and Assurance Committee. Embedding of the lessons learnt will be tested/monitored on at least an annual basis (as appropriate). This will be monitored by the Risk and Governance Team in conjunction with the relevant Operational Group.

20.4 The Trust's performance with regards to the management of SIs will also be undertaken as part of its commissioning arrangements with its local Commissioners and also by CQC and NHS Improvement.

21.0 Further Reading / Associate Documents

The following documents are available for reference in the management of serious incidents.

- Incident Reporting Policy
- Procedure for the Grading & Investigation of Incidents/Accidents, Complaints & Claims (Appendix D of the above document)
- Procedure for the Reporting of Adverse Incidents involving Medical Devices to the Medicines and Healthcare Products Regulatory Agency (MHRA)
- Guidelines on Preparing a Statement
- Root Cause Analysis Toolkit
- Policy on Being Open/'Duty of Candour' Policy (Communicating with Patients and/or their Relatives/Carers following a Patient Safety Incident)

- Serious Incident Framework, March 2015
- Revised Never Events Policy and Framework, March 2015

22.0 References

22.1 Department of Health (DOH). (2000). 'An Organisation with a Memory'. London: DOH.

22.2 National Patient Safety Agency (NPSA). (2000). 'Doing Less Harm'. London: NPSA.

22.3 Department of Health (DOH). (2001). 'Building a Safer MHS for Patients: Implementing an Organisation with a Memory'. London; DOH.

22.4 National Patient Safety Agency (NPSA). (2004). 'Seven Steps to Patient Safety'. London: NPSA.

22.5 Healthcare Commission (HCC). (2008). 'Learning from Investigations'. London: HCC.

22.6 Never Events Policy and Framework – March 2015.

22.7 National Framework for Reporting and Learning from Serious Incidents.

23.0 Consultation

Trust Governance & Assurance Committee.

24.0 Equality Act (2010)

24.1 In accordance with the Equality Act (2010), the Trust will make reasonable adjustments to the workplace so that an employee with a disability, as covered under the Act, should not be at any substantial disadvantage. The Trust will endeavour to develop an environment within which individuals feel able to disclose any disability or condition which may have a long term and substantial effect on their ability to carry out their normal day to day activities.

24.2 The Trust will wherever practical make adjustments as deemed reasonable in light of an employee's specific circumstances and the Trust's available resources paying particular attention to the Disability Discrimination requirements and the Equality Act (2010).

The electronic master copy of this document is held by Document Control, Directorate of Performance Assurance, NL&G NHS Foundation Trust.

Appendix A

Northern Lincolnshire and Goole NHS
NHS Foundation Trust

SERIOUS INCIDENT (SI) MANAGEMENT CHECKLIST – REVISED VERSION 2016

This document is intended as an 'aide memoir' for Directorate staff to be used throughout the management / investigation of an SI.
On completion of the SI investigation, a copy of this checklist Must be submitted to Risk Management along with the Investigation / RCA report and action plan.

Actions	**Completed** Answer (Yes / No / Not applicable) & Date (where applicable)
SI REFERENCE NO.	
Immediate Action:	
1. Has the immediate safety and care of the people involved been ensured?	☐ Yes ☐ No ☐ Not Applicable
2. Has the area been made safe / scene preserved?	☐ Yes ☐ No ☐ Not Applicable
3. Have the patient / relatives been informed and an apology given (& need for designation of ongoing 'family liaison' been identified)? **N.B.** Ensure documentation of discussion with the patients / relatives is done within 10 working days of the incident – refer to the ***'Being Open / Duty of Candour Policy'***	☐ Yes ☐ No ☐ Not Applicable
4. Have support mechanisms been identified for staff involved and the need for involvement of designated 'Senior Clinical Counsellor' been considered to support staff through the 'being open' process?	☐ Yes ☐ No ☐ Not Applicable
5. Was the incident notified immediately to the Director of Performance Assurance and Head of Risk and Clinical Audit or Site Manager (if out of hours) and to the relevant Director / General Manager and other appropriate staff within the Directorate / Group?	☐ Yes ☐ No ☐ Not Applicable
6. The relevant Clinical Director should also be notified as part of existing Directorate / Group escalation arrangements following SIs.	☐ Yes ☐ No ☐ Not Applicable
7. If a child death, has the Head of Safeguarding been notified immediately as per CDOP guidance and the SLA with CCG/LSCB?	☐ Yes ☐ No ☐ Not Applicable
8. Check if the incident involves any **training grade doctor**, if so immediate notification must be sent to the Head of Risk and Clinical Audit and Trust Medical Education Managers to enable a formal notification to be submitted to the Yorkshire & Humber Deanery. **NB** The timescale for notification to the PGME Managers is 5 working days from the date the SI is confirmed. Were the details of all Drs involved in the Serious Incident notified to the Medical Directors Office?	☐ Yes ☐ No ☐ Not Applicable ☐ Yes ☐ No ☐ Not Applicable
9. Have relevant 'interested parties' been notified of the incident? E.g. Facilities, Health & Safety, Unions, HR etc	☐ Yes ☐ No ☐ Not Applicable
10. Has the initial verbal reporting been followed up with an Incident Report Form on datix?	☐ Yes ☐ No ☐ Not Applicable
11. Was the Incident / Root Cause Analysis (RCA) Review Group convened? **N.B.** 'Incident / Root Cause Analysis (RCA) Review Group' convened particularly where large numbers of patients are involved and / or where the incident is cross-Directorate. Where the incident involves another Directorate or Group and where a Review Group is not convened – you MUST inform / involve the relevant staff within those areas, particularly where remedial action may be required.	☐ Yes ☐ No ☐ Not Applicable

12. Were the relevant staff within those areas contacted (particularly where remedial action may be required)?	☐ Yes ☐ No ☐ Not Applicable
13. Has the investigation / RCA commenced and statements/other relevant information / documentation obtained? **N.B.** Refer to NLG 'Incident Reporting Policy' (Appendix D – Incident Investigation), Root Cause Analysis Toolkit and Guidelines on Preparing a Statement.	☐ Yes ☐ No ☐ Not Applicable
14. Where incident involves large number of patients (e.g. patient recalls) was the following considered? • Did you consider setting up a 'helpline'? • Did you consider the designation of an 'incident room'? • Did you consider the development of a dedicated database?	 ☐ Yes ☐ No ☐ Not Applicable ☐ Yes ☐ No ☐ Not Applicable ☐ Yes ☐ No ☐ Not Applicable
15. Was a Debrief / Support / Counselling offered to staff involved (and this is ongoing as required)?	☐ Yes ☐ No ☐ Not Applicable
16. Was a notification of the incident sent to the Group Governance Group(s) or Directorate equivalent?	☐ Yes ☐ No ☐ Not Applicable

Actions	**Completed** Answer (Yes / No / Not applicable) & Date (where applicable)
17. Was an investigation / RCA commenced and statements and other relevant information / documentation obtained? **N.B.** 1. Where an investigation is not completed within the required **12** week deadline, an interim progress report should be submitted including details of expected date of completion. 2. The investigation / RCA report & action plan MUST be reviewed and agreed by all relevant parties / departments PRIOR to submission to Risk Management. 3. The final investigation report & action plan MUST have Director level sign-off.	☐ Yes ☐ No ☐ Not Applicable
18. Is the action plan being monitored via Group Governance Group or Directorate equivalent?	☐ Yes ☐ No ☐ Not Applicable
19. Has the SI Report and Action Plan been shared with the following: • Group Governance Group(s) or Directorate Equivalent • Staff involved in the incident • PGME Manager(s)	 ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
20. Lessons learned and any areas of 'good practice' shared (within immediate team & wider Directorate / Group) as follows: • Group Governance Group or Directorate Equivalent • Staff / Team Meeting • Staff Newsletter • Staff Noticeboard • PGME Manager(s) • Other (please include details) ……	 ☐ Yes ☐ No ☐ Not Applicable ☐ Yes ☐ No ☐ Not Applicable ☐ Yes ☐ No ☐ Not Applicable ☐ Yes ☐ No ☐ Not Applicable ☐ Yes ☐ No ☐ Not Applicable ☐ Yes ☐ No ☐ Not Applicable
21. Has the outcome of the investigation been conveyed to the patient / relatives – refer to the 'Being open / Duty of Candour Policy'	☐ Yes ☐ No ☐ Not Applicable
22. Does the action plan include audit/monitoring of the actions for implementation?	☐ Yes ☐ No ☐ Not Applicable
22. Is the action plan implemented and are all actions complete including any audits or monitoring requirements?	☐ Yes ☐ No ☐ Not Applicable

Name of person completing this checklist:
Designation of person completing this checklist:

Notes:

1. Not all of the above actions will be applicable to all SIs – a judgement will therefore need to be made based on the individual circumstances of the incident.
2. This checklist is not intended to be exhaustive – please also refer to the full 'Policy for Dealing with Serious Incidents (Clinical & Non-Clinical)' and other relevant documents referred to above as required.

Appendix B

SETTING UP & USE OF 'HELPLINES'

1.0 Introduction

1.1 It is recognised that the setting up of advice/information helplines by NHS organisations can be invaluable where there is likely to be large-scale public concern generated over a health related issue. This will usually be following an adverse incident or series of adverse incidents within an organisation/the NHS (please also refer to the Trust's Policy on the Management of Serious Incidents).

1.2 The primary purpose of a helpline will be to provide an immediate and accessible point of contact for the provision of information/reassurance to concerned patients and/or relatives who may be affected by a particular adverse incident or series of incidents. However, calls will also inevitably be received from patients/relatives/the wider public not directly affected but who may still be concerned.

1.3 Examples where a helpline may be used include:

- Healthcare worker found to be HIV positive
- Large scale public concern directed at a particular Trust but which impacts on other organisations within the NHS (e.g. organ retention issue)
- Large scale serious administrative and/or clinical errors affecting large numbers of patients (e.g. cervical cytology screening errors)
- Repeated serious complaints against an individual
- Closure of services/hospitals

1.4 This document has been provided as an 'aide memoir' where the setting up of a helpline is being considered within the Northern Lincolnshire and Goole NHS Foundation Trust. **Note: It will be the responsibility of the Director or Directorate Director/Directorate Manager in charge of managing the situation/incident, in conjunction with other key staff involved, to decide whether a helpline needs to be established and for ensuring that the necessary arrangements are made.**

2.0 Procedure

2.1 Ensure that the Head of Communications and Marketing is fully briefed on the issue/incident to ensure that he is prepared for media interest and can include the helpline number in any press release issued.

2.2 Co-ordinate the setting up of the helpline through the Switchboard as a dedicated/new number and extra phone lines may be required to be installed. Switchboard will also need to be aware so that any calls that are received on the general hospital number or by other areas can be re-directed to the designated helpline number.

2.3 Consideration will need to be given to the anticipated number of calls as this will dictate the hours during which the helpline may need to be available/which office the

helpline is managed from (if this is different from the 'incident room' – see section 12.0 of the Trust's 'Policy on the Management of Serious Incidents')/how many handsets/staff to manage the calls will be required. The length of time the helpline needs to remain in place should be kept under review. Depending on the number of calls and the duration of the helpline arrangements, a staffing rota may need to be devised.

2.4 Dependent on the issue/circumstances or where it may not be possible to provide an immediate response to callers, a recognised approach is to have 'front line' staff taking the calls/details with a view to the caller being contacted at a later time/date with a response. Clinical staff may however need to be on standby to answer queries where the caller may be distressed and/or requires an immediate response/reassurance. Again this will depend on the circumstances of the issue/incident. A judgement will also be required as to whether the circumstances of the incident dictate the need for clinical staff to take the calls.

2.5 Where 'front line' staff are taking the calls, ensure that the staff concerned have been fully briefed on the issue/incident, are prepared and able to deal with potentially difficult/distressed callers and know the answers which they are permitted to provide. It may be helpful to provide a list of Q&As and a copy of the press release to the staff concerned.

2.6 Ensure that a call pro-forma is available (see section 3 below). This will ensure that the maximum amount of relevant information on the call/caller is collected for reference/record/learning and follow-up and to ensure that a thorough response to all issues raised can be provided. **Note: Details of any advice/information given at the time of the call should also be recorded on the pro-forma. Similarly any subsequent communication with/correspondence to callers should be retained (with the incident file) for future reference/record. Consideration should also be given to developing a database of calls received/information given or alternatively including this information on the database set up as part of the management of the wider serious incident (see section 13.0 of the Trust's 'Policy on the Management of Serious Incidents').**

2.7 Where a full response cannot be given at the time of the initial call, it should be confirmed with the caller how they wish subsequent information communicating to them. This could be via a telephone call, face to face meeting or in writing. **Note: Where face-to-face meetings are planned, particularly off site, care should be taken to ensure the safety of the staff involved (i.e. the use of lone staff should be avoided).**

2.8 Where the caller has requested a written response to their enquiry, consideration should be given to the postal arrangements for this correspondence. For example, where the content of this correspondence is likely to cause significant distress, consideration should be given to the correspondence being 'double enveloped'. The inner envelope should contain the correspondence, the outer a letter explaining that the content of the correspondence in the inner envelope may cause distress and that consideration may need to be given by the recipient to having a relative/friend present for emotional support when opening. The letter in the outer envelope could also contain a telephone number to ring for access to counselling or support (if different to the helpline number). This method was used to respond to callers to the Trust's Organ Retention Helpline. **Note: The use of this method would be the exception rather than the norm. The timing of the sending of the correspondence should also be considered (e.g. where possible avoid sending correspondence which is likely to arrive over a weekend unless the helpline is**

still in place or other arrangements are in place to ensure that there is someone available to take follow-up calls from distressed/anxious callers).

2.9 Where the issue affects more than one organisation, agreement will need to be reached as to who will manage the helpline so as to avoid confusion.

2.10 It is essential that Caldicott principles be adhered to at all times throughout the handling of helpline enquiries. Issues which may need to be considered include:

- Where someone is calling on behalf of an affected patient, care must taken to ensure that the patient is aware of the enquiry and consents to the release of information to the caller

- Where information may need to be passed to other agencies, the patient's consent for this should be obtained save in exceptional circumstances. **(Note: There may be occasions where it is necessary in the patient best interests to disclose the information e.g. where there are possible child abuse allegations. Each case should be carefully considered)**

- Where information from the helpline is subsequently collated for the purposes of 'learning lessons'/'closing the loop', care should be taken to anonymise this information

  N.B. Patient identifiable information should only be shared on a strict 'need to know' basis.

2.11 Dependent on the circumstances of the issue/incident, the staff manning the helpline may require support and/or counselling. This should be managed/monitored throughout the period that the helpline is in place and at the conclusion of the exercise. **Note: Please refer to Organisational Development & Workforce for details of the counselling services available to the Trust ('Confidential Care').**

2.12 Further advice/assistance on the setting up of helplines can be obtained from within the Directorate of Performance Assurance and from the Head of Communications and Marketing (where the relevant staff are not already aware and involved with the issue).

3.0 Helpline Pro-forma

3.1 The pro-forma attached at Appendix C is an example of a form which has been used by the Trust where previous helplines have been put in place. This form can be used or adapted to suit the particular circumstances of the situation or incident.

Appendix C

Northern Lincolnshire and Goole NHS
NHS Foundation Trust

HELPLINE PRO-FORMA

CALLER DETAILS

CALLER _____

CALLER'S NAME & ADDRESS _____

_____

_____

DAYTIME PHONE NO: _____ **EVENING PHONE NO:** _____

DATE OF CALL _____ **TIME OF CALL** ____/____ (am/pm)

RELATIONSHIP TO PATIENT _____ (if applicable)

(NB. Is patient aware of call?) **YES** ☐ **NO** ☐

CALL TAKEN BY _____

PATIENT DETAILS

PATIENT'S NAME & ADDRESS (if applicable) _____

_____

_____

_____

DAYTIME PHONE NO: _____ **EVENING PHONE NO:** _____

HOSPITAL UNIT NO: A/ _____ **NAME OF GP:** _____

CONSULTANT PATIENT UNDER: (if applicable) _____

HOW CONCERNS RAISED (as applicable)

(a) I am one of the affected patients and was contacted by the Trust/my GP
(b) I am the relative of one of the affected patients
(c) I heard the news on the radio
(d) I saw the news on the TV
(e) I read the news in the paper
(f) Someone told me the news

Call referred to: (if applicable) _____

_____

_____

_____

ISSUES RAISED	RESPONSE GIVEN

OUTCOME:

1. Caller satisfied - no further information required ☐

2. Where response could not be given at time of initial call, does the patients want:-

   - ♦ telephone response ☐
   - ♦ written response ☐
   - ♦ face to face meeting ☐

Has patient/caller previously raised these issues. If so with whom/when/outcome, please detail:

Appendix D

REPORTING REQUIREMENTS TO EXTERNAL BODIES

Please note key personnel within Risk Management will report incidents to the following external authorities.

Full reporting requirements for provider organisations

Reporting to the regulator (CQC, NHS Improvement)

- Healthcare provider organisations are required to notify the appropriate regulator about incidents that indicate, or may indicate, risks to ongoing compliance with the registration requirements, or that lead, or may lead, to changes in the details about the organisation in the regulator's register.
- Most of the requirements for the CQC, as defined in current regulations[1] guidance[1], are met by providing incident reports to the NRLS. The NRLS will forward relevant information to the CQC.
- This exception does not apply to independent sector providers or primary care providers registered with CQC. They must report incidents directly to CQC.
- For more information on requirements for reporting to the CQC, refer to the CQC website.
- NHS Foundation Trusts are also required to report relevant serious incidents requiring investigation to NHS Improvement.
- Incidents must be reported without delay as defined in legislation.

Reporting a serious incident occurring in independent sector healthcare or other provider outside the NHS.

- Independent sector healthcare providers must report any serious incident involving a patient receiving NHS funded care to the commissioning organisation with responsibility for the contract.
- Independent sector healthcare providers should report to the NRLS via the eForm of the NRLS although this is voluntary; CQC must be notified directly of abuse, serious injury and all deaths.
- Independent sector healthcare providers are also responsible for reporting the incident directly to their appropriate regulator.
- NHS CB area teams can, if appropriate, provide access to STEIS for non-NHS providers for reporting purposes as long as those providers are on the NHS N3 network.

Reporting to the police

- The police are likely to investigate incidents where there is evidence, or suspicion of, a criminal offence having been committed, for example if an incident has arisen from or involves criminal intent, or gross negligence
- In the first instance the incident should be reported within the organisation in the normal way and to the commissioning body.
- Referral to the police should be undertaken by a senior member of staff in the reporting organisation.
- In circumstances of unexpected death or serious harm requiring investigation by the police, the incident should be managed in accordance with the Memorandum of Understanding (currently under review).
- This protocol should be activated when an incident requires investigation by the police and the Health and Safety Executive (HSE) jointly.

Reporting to the Health and Safety Executive (HSE)

- The HSE is responsible for the enforcement of the Health and Safety at Work Act 1974 (HSWA)[1] and ensuring that "risks to people's health and safety from work activities are properly controlled".
- Serious incidents may need to be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).
- The trigger point for RIDDOR reporting is over seven days' incapacitation (not counting the day on which the accident happened).
- Further information on reporting is available at http://www.hse.gov.uk/riddor/report.htm
- If the serious incident requires joint investigation by the organisation and the HSE and the police, the Memorandum of Understanding should be activated.

Work-related deaths

- Incidents involving work-related deaths (or cases where the victim suffers injuries in such an incident that are so serious that there is a clear indication, according to medical opinion, of a strong likelihood of death) should be managed in accordance with the Protocol on Work Related Deaths.[1]
- In the first instance the incident should be reported within the organisation in the normal way and to the commissioning organisation.

Reporting to the coroner

- An unexpected death (where natural causes are not suspected) and all deaths of detained patients must report to the coroner by the treating clinician.
- This should be done immediately, but recognising that, following an unexpected death, a serious incident may not be identified until the issuing of the coroner's report.

Reporting to Public Health England

PHE Centres:

- Where incidents have the potential to affect population health, the provider should seek advice from the local PHE Centre. Depending on the nature of the incident, other public health organisations such as local authorities, may need to be involved.
- Such incidents will include those with a health protection component, such as failures in decontamination.
- The PHECs' health protection staff will provide a risk assessment and advise on appropriate action

National screening programmes

- In the case of a serious incident in a screening programme, the NHS Commissioning Board Area Team Screening and Immunisation Lead is responsible for ensuring that the provider(s) respond to a serious incident in an appropriate and timely manner and take all necessary steps to mitigate any on-going risks . The Regional Quality Assurance Director (for NHS Cancer Screening Programmes) or the Regional Quality Assurance Lead (for NHS Screening Programmes) must be fully involved in the incident management process.
- The provider organisation must report all potential incidents and serious incidents to the Regional QA Director or Regional QA Lead. The Quality Assurance team will undertake initial fact finding with the screening provider and advise on next steps
- NHS England have issued Guidance for Managing Incidents in NHS National Screening Programmes in England, which the Trust is required to comply with in respect of reporting and investigating screening incidents.

Reporting to NHS Protect

- Where a serious incident occurs to a member of staff resulting from a physical or non-physical assault, there is a requirement to report this to NHS Protect via the Security Incident Reporting System.
- The same reporting requirement relates to incidents involving loss or damage to property and assets of NHS organisations, staff and patients.

Reporting to the Medicines and Healthcare products Regulatory Agency (MHRA)

- Any serious incident involving medication or medical devices should be reported to the MHRA. Details on how to do this are at: http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Reporting Health Care Associated Infection (HCAI) serious incidents

- The Health Protection Agency's guidance on *Health Care Associated Infection Operational Guidance and Standards for Health Protection Units* provides information on the steps that should be followed by providers in escalating concerns about the management of a HCAI situation, incident or outbreak and steps for informing commissioners and regulators about concerns. While this will need to be updated to reflect new responsibilities, the principles around recognising incidents, undertaking risk assessments and when to escalate serious HCAI situations / incidents and outbreaks remain valid.

  The guidance can be found at:
  https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/332051/HCAI_Operationalguidancefinalamended_05July2012.pdf

Reporting Serious Adverse Blood Reactions and Incidents (SABRE)

- The UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive require that serious adverse incidents and serious adverse reactions related to blood and blood components are reported to the MHRA, the UK Competent Authority for blood safety.

- This information is vital to the work that the Serious Hazards of Transfusion (SHOT) uses to compile its reports. Further details on reporting can be found at:
  http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood/index.htm

Maternal Deaths

Instances of maternal death will be classified as Serious Incidents and should be reported as such. It should be noted, however, that the Trust has in place a separate policy/procedure to be used following an instance of maternal death in accordance with National guidelines. These require that a 'confidential enquiry' is made into every maternal death and the Director of Public Health has responsibility for initiating this inquiry in conjunction with the Trust concerned. In the event of a maternal death the on-call Supervisor of Midwives is informed immediately. This individual starts the process of investigation as per Local Supervising Authority Guidelines. Maternal Deaths are then reported to the Local Supervising Authority Midwifery Officer who liaises with the nominated Supervisor of Midwives for Maternal Deaths for the Trust. This Supervisor of Midwives acts in a co-ordinator role for the Trust throughout the whole investigation. Documentation is completed in accordance with the Guidelines. The confidential enquiry held into a maternal death will therefore be in place of, or complimentary to, the Policy/Procedure for Dealing with Serious Incidents.

Part 8 Case Reviews – Children Act 1989

The Trust has a separate policy for discharging its responsibilities under the Children Act 1989, where a child dies or is seriously injured and abuse is suspected or confirmed. These are known as Part 8 Case Reviews. Where injury/harm to the child occurs on Trust premises, the Policy/Procedure for Dealing with Serious Incidents would apply.

Information Governance

Where a serious breach of confidentiality occurs – including loss of person identifiable information. There is no simple definition of a serious information governance incident. As a guide:

- Any incident which involves actual or potential failure to meet the requirements of the Data protection Act 1998 and / or the Common Law of Confidentiality.
- This includes unlawful disclosure or misuse of confidential data, recording or sharing of inaccurate data, information security breaches and inappropriate invasion of people's privacy.
- Such personal breaches which could lead to identity fraud or have other significant impact on individuals.
- Applied irrespective of the media involved and includes both electronic media and paper records.

such incidents will be dealt with in accordance with this policy and the national guidance issued by the Health and Social Care Information Centre "Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents". Those more serious incidents will be reported by the office of the Director of Performance Assurance to the Information Commissioner and NHS Improvement.

Safeguarding Adults / Safeguarding Children

- Ensure that local safeguarding adult board / local safeguarding children boards have been notified of relevant incidents and agreed arrangements for the management of Serious Case Reviews including action planning and Learning from incidents in line with local multi-agency safeguarding protocol and policies.
- Ensure robust communication between safeguarding boards, commissioners, regulators and providers. There should not be duplication of investigations and action planning within the health care provider organisations where external bodies like safeguarding boards are carrying out these activities and health care organisations are assured that actions are satisfactorily in hand and that there are robust processes for ensuring any outcomes from the external investigation will be communicated and acted upon.

Appendix E

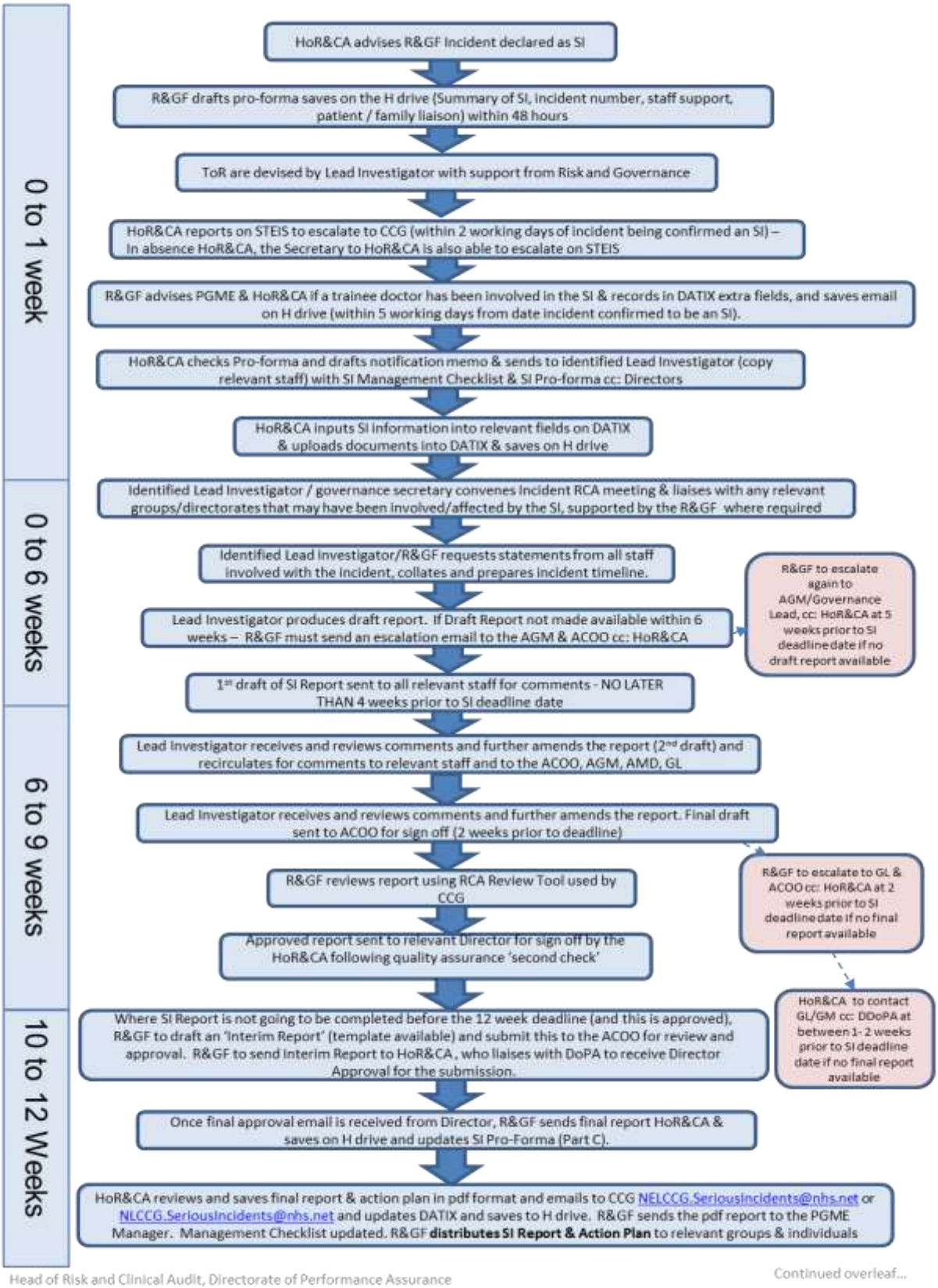
A guide to serious incident grading for investigation purposes

This table provides a guide to the grading of serious incidents for investigation purposes.

Level	Application	Product/ outcome	Owner	Timescale for completion
Level 1 **Concise internal investigation**	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld	Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner All internal investigation should be supported by a clear investigation management plan
Level 2 **Comprehensive internal investigation** (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity	
Level 3 **Independent investigation**	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved (see Appendix 1 and 3 for further details)	Comprehensive investigation report including all elements of a credible investigation	The investigator and **all** members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated.	6 months from the date the investigation is commissioned

Appendix F

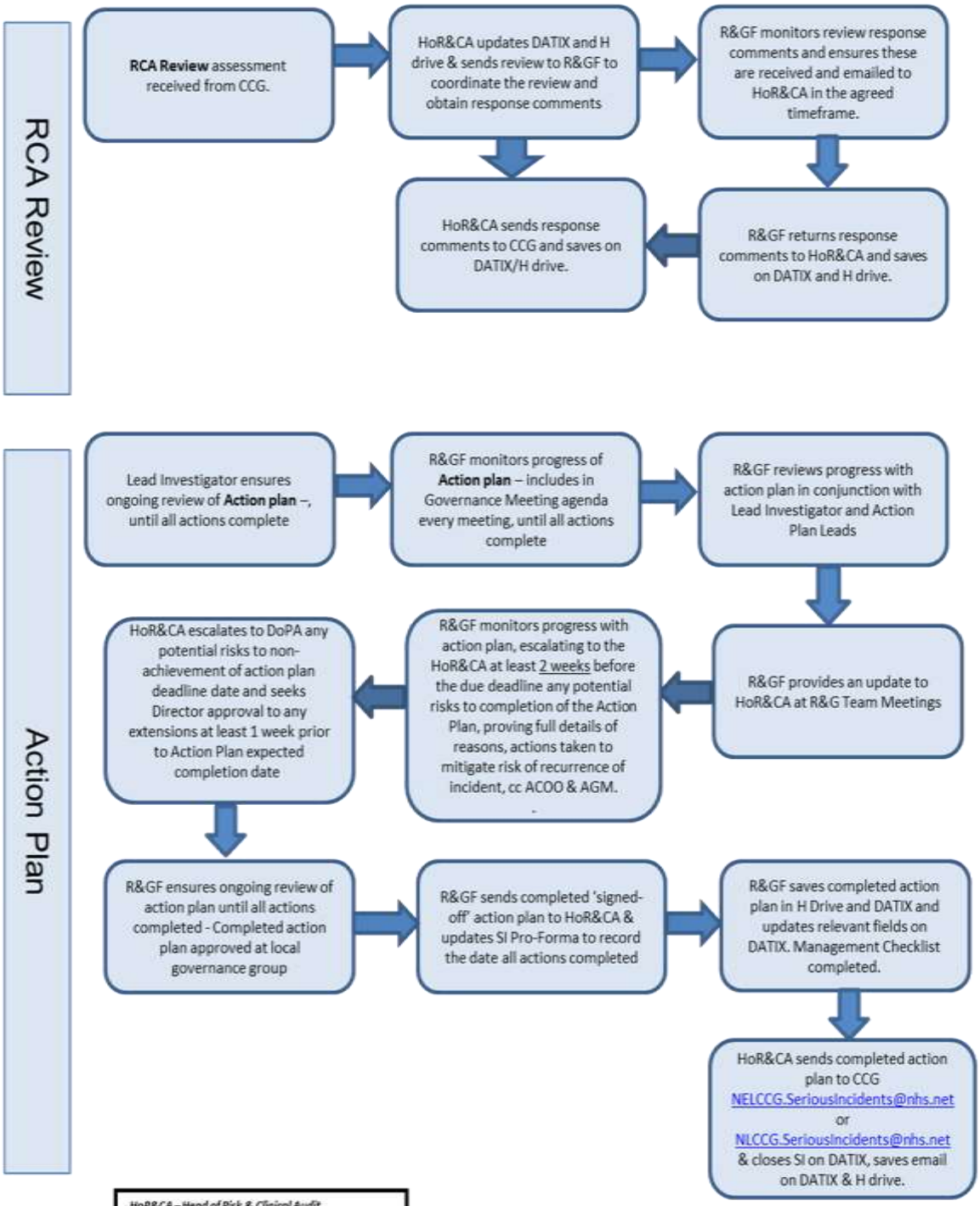
Serious Incident (SI) – Investigation Process



Head of Risk and Clinical Audit, Directorate of Performance Assurance

Continued overleaf...

Serious Incident (SI) – Investigation Process



Appendix G

Northern Lincolnshire and Goole Hospitals NHS
NHS Foundation Trust

SI REPORTING PROCEDURE TO MEDICAL EDUCATION