Directorate of Governance & Assurance

INCIDENT REPORTING POLICY AND PROCEDURE

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Appendices:

1.0   Introduction

1.1   As with any organisation, the NHS carries a number of hazards/risks which, if not properly managed/controlled, have the potential to cause harm, loss or damage.

1.2   **Risk is defined as a 'hazard/exposure to danger/chance of loss or harm'.**

1.3   It is self-evident that risk management requires risk identification and inevitably, through risk assessments, audits, workplace assessments, day-to-day practice, etc many risks will be identified and appropriate action taken before instances of loss, harm or damage have occurred. However, in an organisation as large and complex as the NHS, it is accepted that an element of risk management is reactive and that some risks will not be identified until something has gone wrong and therefore an essential part of any Risk Management Strategy is a system for identifying/reporting adverse incidents/accidents. As part of the Trust's commitment to the management of risk, in order to improve the quality of care and provide a safe environment for the benefit of patients, staff and visitors, an organisation wide Incident Reporting System for reporting adverse incidents/accidents is therefore in place within Northern Lincolnshire & Goole NHS Foundation Trust (NLG).

1.4   This policy outlines the purpose and benefits of the Incident Reporting System, the procedures to be followed for the reporting of incidents and the responsibilities of staff within those arrangements.

1.5   The effectiveness of the Trust's Incident Reporting System depends on the co-operation and involvement of all Trust staff.

2.0   Area

This policy applies to all staff employed by NLG.

3.0   Purpose of Incident Reporting

3.1   Incident Reporting Systems are considered to be a major tool in the way organisations manage risks; their purpose:

- To ensure that all incidents/accidents (actual and near miss) are reported, recorded and managed

- To prevent the recurrence of preventable adverse clinical and non-clinical events

- To provide 'early warning' of complaints/claims/adverse publicity

- To ensure that sufficient information is obtained:

  - to meet internal and external (e.g. NHS England, HSE) reporting requirements

  - to respond to complaints and litigation should these ensue

  - for trend analysis which in turn is intended to facilitate the identification and 'learning of lessons' from incidents/mistakes made

4.0   Benefits of Incident Reporting

4.1   If used effectively, the Incident Reporting System will:

- Enhance the Trust's ability to continually develop good practice and improve the quality of care

- Enable the Trust to learn lessons from mistakes made/take prompt action to prevent or minimise recurrence

- Protect individuals: patients, staff, contractors, volunteers and visitors through the provision of a safer environment

- Enhance the Trust's reputation

- Assist in utilising the Trust's resources more effectively (i.e. reduces the amount of money being spent on litigation)

- Assist in identifying training, education and resource needs

- Provide 'early warning' of actual and potential claims, complaints and/or adverse publicity and means that the Trust is 'prepared' for such occurrences

- Strengthen the Trust's position in the event of litigation (i.e. 'early warning' of incidents likely to lead to litigation enables the Trust to obtain the necessary information at the time of the incident when memories are fresh, before staff have left the Trust etc)

- Enable the Trust to meet National Health Service Litigation Authority (NHSLA) requirements

- Where actual incidents of loss/harm have occurred, enable early notification/explanation to the 'injured' party to occur and, where necessary, swift compensation to the justified claimant

5.0   'Fair Blame' Culture

5.1   "In an organisation as large and complex as the NHS, things will sometimes go wrong. When they do the response should not be one of blame and retribution, but of learning, a drive to reduce risk for future patients and staff. Blame cannot, and should not, be attributed to individual health care professionals. Identifying and addressing dysfunctional systems is, therefore, the key to reducing the risk of harm for many patients and staff and is the ethos behind the new National Reporting and Learning System (NRLS) for reporting adverse incidents run by NHS England.

5.2   It is understood that fear of disciplinary action and subsequent sanctions may deter staff from reporting incidents, and the Trust's Incident Reporting System, therefore, continues to be developed within a culture of 'fair blame'. The Trust's approach following incidents will therefore focus on '**what went wrong, not who went wrong**'. Where errors have occurred and are openly reported, an investigation into the facts may take place but the disciplinary process will not be instigated in respect of any member of staff, except in well-defined circumstances, as follows:

- an incident in which the Trust considers that a fundamental breach of professional practice has occurred, and/or an incident which might lead any professional registration body to review the individual's professional status

- further occurrences of actions involving an individual who has previously received counselling, or been subject to disciplinary action related to the type of error that might have led to the incident

- where it appears that staff may have been guilty of a criminal offence or some act or omission which may result in formal action by a regulatory or professional body

- failure or significant delay in reporting an incident in which a member of staff was directly involved or about which they were aware

5.3   It should be noted that when any error is being considered, whether within the Incident Reporting Policy structure or not, it is universally recognised that when a member of staff is open in admitting to the error and reporting it to the appropriate individual, a considerably more positive and supportive approach may be taken by the Trust in addressing the matter. Conversely, it is also the case that when a member of staff decides to either delay reporting, or to attempt to conceal the occurrence of an error, the Trust's response to it is likely to be less favourable and will indeed specifically address this delay or failure to report as a further element of the issue.

5.4   Guidance on raising concerns is also available by referring to the Trust's 'Speaking Out Policy' or by contacting the Human Resources Department. Staff can raise concerns verbally, by letter, email or by completing an incident form. Staff can also contact the Trust's Freedom to Speak-Up Guardian in confidence by email nlg.tr.ftsuguardian@nhs.net or by phoning 304141. More details about how to raise concerns with the Trust's Freedom to Speak-Up Guardian or with one of the Associate Guardians can be found on the Trust's intranet site.

6.0   Definitions

6.1   'Near Miss' Incidents

6.1.1   Where the incident did not result in harm, loss or damage, but could have, this is referred to as a 'Near Miss'. This may be clinical or non-clinical.

6.1.2   Near miss reporting is just as important in highlighting weaknesses in systems, policies/procedures and practices. If near misses are reported and learnt from and any necessary corrective action taken, they can help to prevent actual incidents of harm, loss or damage from occurring.

6.2   Adverse Incident (Clinical)

6.2.1   'An event or circumstance arising during clinical care of a patient that could have (i.e. 'near miss') or did lead to unintended or unexpected harm'.

6.2.2   Harm is defined as 'injury (physical or psychological), disease, suffering, disability or death'. In most instances, harm can be considered to be unexpected if it is not related to the natural cause of the patient's illness or underlying condition.

6.3   Adverse Incident (Non-Clinical)

'An event or circumstance that could have (i.e. 'near miss') or did cause unexpected or unwanted harm, loss or damage to any individual(s) involved (including patients but not related to clinical care, staff, visitors etc) or damage to/loss of property/premises for which the Trust is responsible'.

6.4   'Patient Safety' Incidents

Adverse incidents involving patients are also known as 'Patient Safety Incidents' (PSIs). The NPSA defines a PSI as 'any unintended or unexpected incident which could have or did lead to harm for one or more patient receiving NHS funded healthcare'.

6.5   Serious Incidents

6.5.1   'An incident or series of incidents which are likely to produce significant legal, media or other interest or give rise to large scale public concern and which, if not properly managed, may result in significant loss of the Trust's reputation and/or assets'.

6.5.2   The Trust also has in place a 'Policy for Dealing with Serious Incidents (Clinical and Non-Clinical)'. This outlines specific responsibilities of key individuals on identification of a serious incident including communication with patients and/or relatives or the wider public, notification to external stakeholders and investigation and follow-up of the incident. This policy also provides examples of the types of incidents which fall within the above definition.

6.5.3   In the event of a serious incident occurring, the requirement is for **immediate** reporting to the Director of Governance and Assurance and Head of Risk (preferably face to face or telephone). Both individuals can be emailed regarding escalation of a serious incident as long as the email is also sent to the Trust's serious incident email address: nlg-tr.nlagseriousincident.nhs.net. Out of hours the Site Manager should be contacted. The Site Manager, in turn, will contact the on-call Director/Senior Manager.

6.5.4   For further information, please refer to the Trust's 'Policy for Dealing with Serious Incidents (Clinical & Non-Clinical)', which is available on the Trust's intranet site.

6.6   'Never Events'

6.6.1   'Never Events' are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. The Trust has adopted a 'zero tolerance' approach to 'Never Events' and all such incidents will be escalated as Serious Untoward Incidents and be dealt with in accordance with the Trust's 'Policy for Dealing with Serious Untoward Incidents (Clinical & Non-Clinical)'. All 'Never Events' will be notified to the Trust Board. Where changes to the 'Never Events' Framework and 'Never Events' list occur, these will be considered and appropriate assurances on the robustness of the preventative measures will be sought via the Trust Quality and Safety Committee. The Committee will also receive reports of any 'Never Events' incidents which occur and will monitor progress with the implementation of agree actions / changes in practice.

7.0   'Trigger Lists'

7.1   In respect of clinically related events, particularly in high-risk specialities where a particular incident or event is a 'known litigation risk', 'trigger lists' of incidents, taking account of the relevant definitions above, which should always be reported should be developed.

7.2   In addition, events will often occur which are unexpected. These events are usually not related to negligence but may be viewed as such by the patient or their relatives. To the doctor or healthcare professional the unexpected event may be a recognised complication of a particular procedure or treatment. Given the potential for dissatisfaction, such events should also be added to specialty specific 'trigger lists'.

7.3   It should be emphasised, however, that such lists will not be exhaustive. An element of judgement is, therefore, required as to whether an incident should be reported but where doubt exists the safest option will be to report the incident. For areas wishing to develop their own 'trigger lists' a generic/core list of (clinical) codes is attached for reference at **Appendix A.** This can be adapted as appropriate. Advice can also be sought from the staff within Risk and Governance.

7.4   Trigger lists are already in place within specific areas and are incorporated into the Trust's wider list of Incident Codes (see section 11.0 'Incident Coding').

7.5   It should also be noted that specialty 'trigger lists' of non-clinical incidents, taking account of the relevant definitions above, could also be developed.

8.0   Incident Reporting Actions and Duties & Responsibilities

8.1   Staff generally

8.1.1   It is a requirement of all Trust staff that they report any incident, accident or potential (i.e. 'near miss') incident which has caused or has the potential to cause harm, loss or damage to any individual* involved or loss or damage in respect of property or premises for which the Trust is responsible. This includes any incident that has the potential to involve the Trust in either litigation or adverse publicity.

*This applies whether the 'affected' person is a patient, member of staff, contractor, volunteer or visitor to the Trust.

8.1.2 **Any** member of staff who is involved in, witnesses or discovers an adverse incident/accident or near miss incident/accident can complete an Incident Report Form.

8.2 As outlined in 6.5.3, in the event of a serious incident occurring, the requirement is for **immediate** reporting to the Director of Governance and Assurance and Head of Risk. Both individuals can be emailed regarding escalation of a serious incident as long as the email is also sent to the Trust's serious incident email address: nlg-tr.nlagseriousincident.nhs.net. Out of hours the Site Manager should be contacted. The Site Manager, in turn, will contact the on-call Director/Senior Manager. For further information, please refer to the Trust's 'Policy for Dealing with Serious Incidents (Clinical & Non-Clinical)', which is available on the Trust's intranet site.

8.3 **Person responsible for the immediate management of the incident**

The person responsible for the immediate management of the incident (e.g. the nurse in charge of the ward at the time an incident occurs), should undertake an immediate assessment of the situation, in order to determine any immediate treatment and/or ongoing care needs of the affected person, and/or the extent of any loss/damage to property and any other immediate action required (e.g. removal and isolation of faulty equipment). The situation/scene should be made safe.

8.4 **Managers**

8.4.1 Following every incident, whether a near miss or an incident resulting in injury, managers must take and record (on the incident report form) any required immediate and/or preventative actions.

8.4.2 Depending on the circumstances and severity of the incident, the action taken by managers following an incident may include:

- an appropriate level of investigation. (**N.B.** The level of investigation and resulting management action/preventative measures should be related to the severity grading of the incident – see also Section 12.0 below). Please also refer to the Trust's 'Investigation / Root Cause Analysis (RCA) Toolkit'

- ensuring patient/relatives have been informed of the incident, the investigation and action taken and apologies are offered, as necessary/appropriate – please also refer to the Trust's 'Policy on Being Open/Duty of Candour (Communicating with Patients and/or their Relatives/Carers following a Patient Safety Incident).

- ensuring appropriate follow-up treatment/care of the affected person. (Where this is a member of staff ensuring that he/she receives first aid and/or are advised to attend A&E or their GP)

- ensuring that faulty equipment has been taken out of use and isolated pending investigation by Medical Engineering and/or the MHRA prior to re-use

- ensuring feedback to staff raising the issue and reporting the incident. This includes staff who may have raised concerns with the Freedom to Speak-Up Guardian or Associate Guardians as per 5.4.

- debriefing/counselling and support of staff, as necessary appropriate (see also Appendix C – 2.3.1 & 2.3.2)

- implementing appropriate preventative actions

- monitoring and review of those actions to ensure they remain effective

8.5   Directors / General Managers

8.5.1 Directors / General Managers will be responsible for ensuring:

- that appropriate arrangements are in place within their Directorates / Groups for the reporting, investigation and follow-up of incidents in accordance with both this policy and the Trust's 'Policy for Dealing with Serious Incidents (Clinical & Non-Clinical)' and in accordance with their responsibilities for governance and risk management

- the review of data on incidents in order to identify and monitor trends/problems, and for taking appropriate action

8.6   The **Risk Management Department** will be responsible for:

- the overall management and co-ordination of the Trust's incident reporting arrangements including the central coding of incident data

- the reporting of incidents, as necessary, to the relevant external agencies

- the compilation of analysis reports (e.g. for Quality and Safety Committee, Trust Board, Local Governance Groups, Trust Health, Safety & Fire Sub-Committees, Information Governance Steering Committee, Healthcare Records Committee, Control of Infection Committee, Falls Group, Safer Medication Group etc)

- monitoring, as appropriate, that follow-up of incidents/changes in practice occur as necessary/appropriate. Ultimately, changes in practice and learning lessons are the responsibility of the area in which the incident occurred

9.0   Incident Reporting on-line - DatixWeb

The Trust has adopted an on-line incident reporting system using the **DatixWeb** system, which is accessible via the Trust's Intranet home page that is used for the reporting of **all** incidents/accidents (whether clinical or non-clinical) involving a patient, member of staff, contractor, volunteer or visitor to the Trust.

10.0   Reporting Incidents

10.1 As indicated in 8.1.2, **any** member of staff who is involved in, witnesses or discovers an adverse incident/accident or near miss incident/accident can complete an Incident Report in **DatixWeb**.

10.2 Incidents Report Forms should be completed as soon as possible after the incident/accident has occurred (whilst events can be clearly remembered). **Staff should not go off duty until they have completed the relevant sections of the form and passed it to their manager.** As indicated in section 6.5.3, Serious Incidents should be reported **immediately** to the Director of Governance and Assurance and Head of Risk (in addition to being escalated within the Directorate / Group). Out of hours the Site Manager should be contacted. The Site Manager, in turn, will contact the on-call Director/Senior Manager.

10.3   Incident Report Forms must be reviewed in **DatixWeb** by the relevant nominated manager ideally within 24 hours but no later than 7 days after the incident. **N.B.** The outcome of most incidents is immediately identifiable. However, it is just as important to report incidents where the outcome is identified at a later stage. For example, a back sprain resulting from manual handling may not become apparent for a few days.

10.4   The above reporting timescales enable timely escalation and investigation of such incidents internally but also mean that the relevant external reporting requirements can also be met. Details of the external stakeholders who require notification of certain incidents/accidents which occur within the Trust is attached at **Appendix B.**

11.0   Incident Coding

11.1   Once added to DATIX, all incidents are given a classification 'code'. This enables the same types of incidents to be grouped together, which in turn aides the analysis process in order to identify trends/problems. The coding of incidents in this way also enables the easy identification/selection of the incidents which must be reported externally.

11.2   Within NLG, the coding and grading of incidents is undertaken by a central team within Risk Management.

11.3   All incident report forms entered in to DATIX, are validated before being uploaded from DatixWeb to the NHS England National Reporting & Learning System (NRLS). This enables the collation and analysis of information on incidents and also aides the transfer of incidents to the relevant external stakeholders.

12.0   Incident Grading

12.1   In accordance with DOH guidance and good risk management practice, all incidents reported within NLG will be graded according to:

- the actual impact on the affected person(s), whether patient, member of staff or visitor to the Trust

- the actual or potential consequences for the organisation; and

- the likelihood of recurrence

12.2   The grading of incidents will assist in establishing:

- the level of risk associated with a particular incident; and

- the level of local investigation and root cause analysis required

12.3   The principles adopted for the grading of incidents will be consistent with those used for proactive risk assessment purposes and for the grading of complaints and claims.

12.4   The Trust's Risk Grading Matrix/Procedure for the Grading and Investigation of Incidents/Accidents, Complaints & Claims is attached at **Appendix C.**

12.5   Training for the relevant staff on incident grading/investigation and root cause analysis will be provided as part of the risk management training programme.

13.0   Investigation & Root Cause Analysis

13.1   Unless the causes of adverse incidents are properly understood, lessons will not be learned and suitable improvements will not be made to secure a reduction in the risk of harm to future patients, staff and visitors. However, not all incidents need to be investigated to the same extent or depth – as indicated in 12.0 above, the grading of incidents will assist in determining the level of investigation and root cause analysis required – see also **Appendix C.**

13.2   In the majority of instances, incidents will be minor or near miss and the cause of the incident will be clear and it will be the responsibility of the relevant manager to ensure that the appropriate remedial action is taken to ensure, as far as possible, there is no recurrence. Such incidents should then be the subject of aggregate review. Regular and timely trend analysis reports will be provided to Directorates / Groups, relevant committees and the Trust Board in order to facilitate this and to enable the learning of lessons from incidents which occur – see also section 14.0 below.

13.3   For other incidents and more serious incidents (actual and near miss) an appropriate level of investigation and root cause analysis will be required, involving key staff within the Directorate / Group, the Directorate of Governance and Assurance and other relevant departments as appropriate (see also the Trust's 'Policy for Dealing with Serious Incidents)'. The Trust's 'Procedure for the Grading and Investigation of Incidents/Accidents, Complaints & Claims' is attached at **Appendix C.**

13.4   '**Root Cause Analysis**' is a structured investigation process that aims to assist in the identification or the root or underlying cause(s) of a particular event or problem by determining **WHY** the failure occurred and the actions necessary to prevent or minimise the risk of recurrence.

13.5   A '**Root Cause**' is a failure in a process that, if eliminated, would prevent an adverse incident occurring.

13.6   Training for the relevant staff on incident grading/investigation and root cause analysis will be provided as part of the risk management training programme. The Trust also has in place an 'Investigation/Root Cause Analysis (RCA) Toolkit'.

14.0   Aggregate Analysis & Review

14.1   The Trust recognises that analysis and review of incident data is essential in order to inform the process of learning and change. Whilst Directorates / Groups will regularly review information on incidents which occur locally within their Governance Groups (or equivalent), central review of incident data will also be undertaken in order to:

- identify Trustwide patterns or trends not noticeable or seen as significant from analysis of incidents occurring in one area of the Trust

- provide additional valuable information for learning

- assure the Quality and Safety Committee and associated sub-committees and the Trust Board that risks of all kinds emerging from incidents are being identified and managed

14.2   Quarterly Trustwide analysis reports covering all areas and all incident types (including serious incidents) are therefore undertaken and submitted to the Quality and Safety Committee and Trust Board and include as a minimum the following qualitative and quantitative analysis:

- the overall total number of incidents for the quarter and the total for each category of incident (i.e. patient, staff, public (visitors and contractors), Trust (i.e. no person affected and serious incidents)

- analysis of data by site/unit, result and area (e.g. Directorate/Group/Specialty, highlighting any conclusions i.e. increases/decreases and particular trends or 'hotspots' and providing data for a 12 month period to enable comparison

- analysis of data for the quarter by patient safety incidents, incidents affecting staff, incidents affecting the public, incidents affecting the Trust and serious incidents and highlighting any conclusions i.e. increases/decreases and particular trends or 'hotspots'

- lessons learned/actions taken or proposed in respect of the issues identified – which in turn will be monitored by the Trust Quality and Safety Committee (and/or Trust Board where relevant)

14.3   Quarterly analysis reports on specific risks topics (e.g. falls, medication errors, inoculation incidents etc) are also undertaken and submitted to the relevant risk sub-committees.

14.4   Further, in order to identify common themes and determine the Trust's key risk issues, aggregate review of all **incidents, complaints/concerns and claims** will also be undertaken on an annual basis and a report submitted to the Trust Quality and Safety Committee. As a minimum the report will include a breakdown by site, unit, incident category, conclusions (i.e. increases/decreases and particular trends or 'hotspots' and details of actions taken or proposed).

14.5   Where actions are identified from the aggregate review of incidents, complaints/concerns and claims, the Trust Quality and Safety Committee will be responsible for monitoring progress and for ensuring that lessons learned are shared (see also 15.5 below) and that changes in practice and culture occur as necessary. This will include the lead for a particular risk issue being asked to provide regular formal updates to the Committee. Directorate / Group representatives on the Trust Quality and Safety Committee will, in turn, be expected to ensure that lessons learned from the wider incident analysis report and the aggregate review of incidents, complaints and claims, are shared and action taken, as required, within their individual areas.

15.0   Follow-up / 'Closing the Loop'

15.1   Follow-up/'closing the loop' following incidents is a **key** requirement of the incident reporting process. Without learning and change arising from incidents, aggregate review and wider experiences, the quality of care provided to patients and the safety of staff, patients and visitors will not improve.

15.2 As indicated above, in the majority of instances, incidents will be minor or near miss and the appropriate remedial action can be taken at the time the incident occurs. Where relevant, i.e. following more serious incidents, an action plan will need to be prepared by the relevant Directorate, in conjunction with other relevant parties, in order to reduce or eradicate the risk of recurrence.

15.3 Actions put in place will need to be monitored and reviewed to ensure they remain effective. At Directorate level, monitoring of agreed action measures will be undertaken via the appropriate Directorate Governance Group or Directorate equivalent.

15.4 In respect of more serious incidents, incidents will be notified to and action submitted to and monitored by the Trust Quality and Safety Committee – to whom responsibility for this function has been delegated by the Trust Board. The Trust Board will, however be notified of incidents and receive action plans in respect of incidents which have the potential for media interest and/or which may generate interest from external agencies (e.g. HSE, Information Commissioner etc).

15.5 A key requirement of the follow-up/closing the loop process and, in order to bring about real improvements, is the sharing of lessons learned arising from incidents with the staff involved including the person who reported the incident / concern either via datix, escalation to senior management or via the Trust's Freedom to Speak-Up Guardian (see 5.4) and, where relevant, the wider organisation and external stakeholders. Within NLG, lessons learned arising from incidents will be shared via the following routes:

- **Directorate / Group Level:**

  – Governance Groups (or equivalent)/Minutes

  – Staff Meetings/Business Meetings/Team Briefings/Huddles

  – Quality and Safety Days/Audit Meetings

  – Newsletters etc

- **Trustwide:**

  – 'Learning the Lessons' Newsletter, One Page Learning Lessons

  – Internal Safety Alerts

  – Risk Forums (e.g. Trust Quality and Assurance Committee, Health and Safety Committee etc)

  – Serious Incident Reports submitted to the Trust Quality and Safety Committee and Trust Board (as agreed)

  – Staff Bulletins/Newsletters

16.0 Risk Register

Where appropriate, risks highlighted via the Incident Reporting System will be added to the Trust's Risk Register, with details of the numbers and severity of related incidents which occur informing the grading/ranking of a particular risk on the Risk Register.

17.0   Consultation, Approval & Ratification Process

The Trust's Quality and Safety Committee will be responsible for the ratification of this policy.

18.0   Review & Revision

This policy will be reviewed every three years or sooner should the need arise.

19.0   Implementation

Training

The Trust provides ongoing awareness/training on incident reporting for all staff (and for new staff on induction) and investigation/root cause analysis training (where this is a requirement of the role).

20.0   Dissemination

This procedure will be disseminated to all wards and departments. Amendments to the policy will be communicated to the above as and when they occur. The policy will also be made available via the Intranet to ensure ease of access and to ensure that changes made are quickly communicated.

21.0   Monitoring Compliance & Effectiveness

21.1   The Trust will monitor compliance with its incident reporting arrangements through:

- the quarterly review and analysis of incident data to ensure that incidents are reported by all areas and by all staff groups;

- the annual review of aggregate incident, complaints/concerns, claims data in order to identify problems/trends;

- review of external NRLS reports to ensuring that levels and types of reporting are consistent with Trusts of a similar size;

- review of lessons learned/action taken further to incidents in order to ensure that this is effective and the risk of recurrence is minimised.

22.0   Further Reading / Associated Documents

22.1   It is recommended that this document be read in conjunction with the following Trust documents:

- 'Speaking Out' Policy

- Policy on the Management of Serious Incidents (Clinical & Non-Clinical)

- Risk Management Strategy

- Procedure for the Grading & Investigation of Incidents/Accidents, Complaints & Claims **(Appendix C)**

- Procedure for the Reporting of Adverse Incidents involving Medical Devices to the Medicines and Healthcare Products Regulatory Agency (MHRA)

- Guidelines on Preparing a Statement

- Nursing & Midwifery Policy for the Management of Medicines Incidents

- Root Cause Analysis (RCA) Toolkit

- Policy & Procedure for the Management of Complaints

- Claims Handling Policy & Procedure

- Policy on Being Open/Duty of Candour (Communicating with Patients and/or their Relatives/Carers following a Patient Safety Incident)

23.0 References

23.1   Estates and Facilities Trigger List (DCM128).

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

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

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

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

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

23.7   Never Events Framework (NHS). Update for 2017/18

23.8   Managing Safety Incidents in NHS Screening Programmes. (2017). Public Health England.

24.0 Equality Act (2010)

24.1   Northern Lincolnshire and Goole NHS Foundation Trust is committed to promoting a pro-active and inclusive approach to equality which supports and encourages an inclusive culture which values diversity.

24.2   The Trust is committed to building a workforce which is valued and whose diversity reflects the community it serves, allowing the Trust to deliver the best possible healthcare service to the community. In doing so, the Trust will enable all staff to achieve their full potential in an environment characterised by dignity and mutual respect.

24.3 The Trust aims to design and provide services, implement policies and make decisions that meet the diverse needs of our patients and their carers the general population we serve and our workforce, ensuring that none are placed at a disadvantage.

24.4 We therefore strive to ensure that in both employment and service provision no individual is discriminated against or treated less favourably by reason of age, disability, gender, pregnancy or maternity, marital status or civil partnership, race, religion or belief, sexual orientation or transgender (Equality Act 2010).

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

Appendix A

GENERIC/CORE LIST OF (CLINICAL) 'TRIGGER' CODES

- Failure/delay in referring/admitting to hospital

- Failure/delay in diagnosis

- Incorrect diagnosis

- Consent Issues (e.g. failure to warn, performance of unplanned, unconsented surgery/treatment)

- Treatment/operation delays

- Incorrect treatment (including operation on wrong patient/body part)

- Failure to recognise complication of treatment

- Foreign body left in situ

- Treatment/intra-operative problems

- Allergic reaction (including diathermy burns/reaction to prep agent)

- Post-operative complications

- Failure to carry out adequate post-operative observations

- Failure of follow-up arrangements

- Failure to act on abnormal test results

- Medication Errors

- Infusion problems

- Medical records problems

- Discharge Issues

- Infection Control Issues (e.g. MRSA, MDRTB)

- Lack of adequate facilities/equipment/resources

- Equipment malfunction

- Transfusion problems

- Unexpected re-admission to hospital

- Unexpected death

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Appendix B

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EXTERNAL STAKEHOLDERS REQUIRING NOTIFICATION OF INCIDENTS

The Trust will ensure that, where relevant, the following external stakeholders are informed of and, where appropriate, involved in the investigation of adverse incidents/accidents which occur. Unless, otherwise stated within each relevant section, reporting to the external stakeholders listed below will be undertaken centrally by the risk management department.

1.0   Health & Safety Executive (HSE)

1.1   Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) Incidents

1.1.1   Under RIDDOR, the Trust has a statutory responsibility to report to the HSE certain incidents / accidents which occur during the course of work activity.

1.1.2   Failure to comply with this regulation can lead to the Trust being prosecuted for a breach of regulations and further enforcement action being taken.

1.1.3   RIDDOR incidents are reported to the HSE by staff within Risk Management on receipt of the incident form.

1.1.4   Details of the incident need to be reported to the HSE within 10 days of the incident. Early notification of accidents/incidents means that the Trust is able to comply with this requirement.

1.2   Serious Incidents

1.2.1   There may be other instances where the HSE may need to be notified of incidents which occur. This will depend on the circumstances and severity of the incident. The Health & Safety Advisor will advise whether it is necessary to inform the HSE and whether the area involved needs to be isolated until a HSE Inspector has visited. For further information on this issue, please refer to the Trust's 'Policy on the Management of Serious Incidents (Clinical and non-Clinical)'.

2.0   NHS Improvement (NHSI)

2.1   The NHS Improvement (NHSI) is responsible for overseeing foundation trusts and NHS trusts, as well as independent providers that provide NHS-funded care. They offer the support providers need to give patients consistently safe, high quality, compassionate care within local health systems that are financially sustainable. Incidents are uploaded to the National Reporting & Learning System (NRLS), which is a central database of patient safety incident reports and is part of the NHSI. All information submitted is analysed to identify hazards, risks and opportunities to continuously improve the safety of patient care. 2.2 As well as making sure errors are reported in the first place, the NHSI is trying to promote an open and fair culture in the NHS, encouraging all healthcare staff to report incidents without undue fear of personal reprimand. It will then collect reports from throughout the country and initiate preventative measures, so that the whole country can learn from each case, and patient safety throughout the NHS can be improved.

2.3   All Trusts were required to commence reporting all 'patient safety' incidents to the NRLS by the end of December 2004. NL&G routinely report incidents (including serious untoward incidents or SIs) to the NRLS. The information submitted to the NRLS contains no staff or patient identifiers. From April 2010, in accordance with the Health & Social Care Act 2008 & Care Quality Commission (Registration) Regulations 2009, the requirement to report SIs to the NRLS database within a certain timescale will be a <u>statutory</u> requirement. The NHSI in turn will process these reports and pass on relevant information to the CQC – see also 8.0 below.

2.4   It should be noted that staff can also report incidents directly to NRLS, (although they will be encouraged by the NHSI to ensure that their local Trust are also made aware of the incident in order to ensure that lessons can be learnt and action can be taken local to prevent recurrence).

2.5   Reports received from the NRLS are routinely submitted to the Trust Quality and Safety Committee for review and consideration of actions required.

3.0   **NHS Litigation Authority (NHSLA)**

3.1   The NHSLA manages clinical negligence, third party liability and property risk pooling for NHS Trusts in England. In addition to managing claims that are made under these schemes, the NHSLA has a statutory duty to promote effective risk management within the membership with the objective of reducing the number and costs of claims to the pool.

3.2   The NHSLA requires member Trusts to report immediately:

- incidents or claims where the total cost of the case will approach or exceed the schemes deductible or excess;

- any serious adverse incident, and/or serious adverse outcomes representing a significant litigation risk, prior to an actual demand for compensation being made. These may come to light through an Incident Report Form or incident investigations, serious complaints, or risks highlighted through the risk management process.

4.0   **The Medicines and Healthcare Products Regulatory Agency (MHRA)**

4.1   The MHRA is the Executive Agency of the Department of Health responsible for protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely.

4.2   **Medical Devices**

4.2.1   The Trust is required to report to the MHRA, any adverse incident involving a medical device, especially if the incident has led to or, were it to occur again, could lead to death or serious injury, medical or surgical intervention (including implant revision), hospitalisation or unreliable test results.

4.2.2   It is the responsibility of all staff who use medical devices to report such incidents to the MHRA. Where incidents are reported to the MHRA, a copy of the MHRA report form should also be sent to Risk Management together with the original internal Incident Report Form. Where doubt exists as to whether incidents should be reported to the MHRA, advice can be sought from risk management and the Trust's Medical Devices Safety Officer (MDSO) who is also the Trust's Head of Engineering (and out of hours from the Site Manager and/or on-call Senior Manager/Director).

4.2.3   Other minor safety or quality problems should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems.

4.2.4   All adverse incidents should be reported to the MHRA as soon as possible. Serious cases should be reported by the fastest means possible. Initial incident reports should contain as much relevant details as is immediately available, but should not be delayed for the sake of gathering additional information.

4.2.5   Electronic reporting using the online form on the MHRA website is the preferred method. Reports may however also be sent by e-mail, fax or post. Report forms may be downloaded / printed from the MHRA website.

4.2.6   Any medical device involved in an incident needs to be taken out of use, quarantined and retained for inspection. It should not be repaired, returned to the manufacturer, or discarded until the MHRA has been given the opportunity to carry out its own investigation. The MHRA will advise when and if it is necessary to submit a device for examination. If responding to such a request, you must ensure that the device has been appropriately decontaminated, securely packaged and clearly labelled (including the MHRA reference number).

4.2.7   Medical Engineering should also be notified of such incidents.

4.2.8   For further information on the reporting of incidents to the MHRA, please refer to the Trust's 'Procedure for the Reporting of Adverse Incidents Involving Medical Devices to the MHRA'.

4.3   **Medicines**

4.3.1   Doctors, pharmacists or nurses can report suspected adverse drug reactions by completing the **suspected adverse drug reactions** form. This is a yellow coloured form which can be found in the back of the current edition of the British National Formulary. The form also includes the address to forward the report to the Medicines & Healthcare Products Regulatory Agency (MHRA). More detailed information on reporting and a list of drugs/products currently under intensive surveillance (black triangle list) can be found on the MHRA website: www.mhra.gov.uk/

4.4   **Defective Medicinal Products**

4.4.1   This is defined as:

• proves to be harmful under normal conditions of use;

• lacking in therapeutic efficacy;

• the qualitative and quantitative compositions of the product is not as declared;

- the controls on the medicinal products and/or on the ingredients and the controls at the intermediate stage of the manufacturing process have not been carried out, or if some other requirement or obligation relating to the grant of the manufacture authorisations has not been filled.

4.4.2 If a healthcare professional observes:

- a clinical symptom(s);

- or a patient event, which indicates that a defective medicinal product has been used or that a defective product might be the explanation of this observation;

- or who may recognise that a medicinal product may be defective prior to use should contact a member of the pharmacy department or pharmacist or pharmacist on-call immediately for further advice. The pharmacist should refer to a **Guide to Defective Medicinal Products** for guidance on how to proceed. Copies of the guidance are located in the pharmacy department.

5.0 **Serious Hazards of Transfusion (SHOT)**

5.1 SHOT invites reporting of major clinical incidents surrounding the transfusion of blood products (excluding coagulation factors, albumin and immunoglobulin).

5.2 If staff become aware of any incidents relating to blood transfusion, they should fill in an incident form. They then need to contact the Haematology Department during normal office hours, or if the incident is serious contact switchboard to inform the on–call haematologist. Incidents involving the transfusion of blood products will be highlighted at the Blood Transfusion Committee. Individual investigation and root cause analysis of all blood transfusion incidents will be undertaken by the Trust's Blood Transfusion Practitioners and recommendations for changes in practice forwarded to the areas concerned.

5.3 Reporting of incidents to SHOT will be undertaken by the Transfusion Practitioners.

6.0 **NHS Estates**

6.1 The following incidents, which involve defects and failures of buildings, plant, non-medical equipment or fire protection installations and equipment, will be reported to NHS Estates, via the office of the Director of Facilities Management, in accordance with the NHS Estates Procedure for the Reporting of Defects and Failures involving non-medical devices:

- Any adverse event involving the safety of patients, staff or others, arising from the defect or failure of equipment. These events may range from causing no actual harm (near miss) to serious harm and may include:

  - a fatal accident or serious injury

  - a reportable RIDDOR incident relating to equipment that contributed to an accident

  - an explosion or sudden fracture of any pressure vessel, pressurised system/high pressure water main

- a major electrical discharge or explosion (e.g. transformers or switchgear or failure of cable joints)
- a runaway lift or a lift crash

Incidents which result in the defect or failure of equipment that arise through:

- incorrect use of equipment
- Inappropriate modifications or adjustments
- inadequate servicing and/or maintenance
- design or manufacturing flaw

• Deficiencies in the technical or economical performance of equipment

• Failure of equipment designed to avoid patient harm (e.g. a person overcoming anti-ligature device

• Any defects in a product, or product instructions, identified by Health and Safety Executive Inspectors or Local Authority Inspectors e.g. Environmental Health

• Any utility or infrastructure failure in critical services (electricity, water, steam, gas, communications systems etc.), including the receipt of an enforcement order from the authorising authority

• Serious failure of building infrastructure, i.e. collapsed ceilings/walls, window restrictor failure/falls from windows, failure of hand-railing, etc

• Structural integrity of the building or associated structure is at risk. No actual failure has occurred, but there is a significant/material risk (e.g. damaged or rotting chimney, etc)

Incidents of plant or equipment failure, that meet the stipulated criteria, should be reported via the Defects and Failures module on the EFM-Information (part of NHS Digital) (http://efm.hscic.gov.uk). Refer to the Estates and Facilities Incident Trigger List (DCG299). Refer also to the Patient Safety Alert for reporting defects and failures (NHSI/2018/001)

7.0 **NHS Counter Fraud Authority (NHSCFA)**

7.1   The NHS Counter Fraud Authority (NHSCFA) is a Special Health Authority created to tackle fraud, bribery and corruption within the health service in England.

7.2   Any member of staff with a concern regarding fraud, corruption or bribery must at the earliest opportunity report their concerns to either:
- The Director of Finance
- The LCFS
- The Trust's 'Bad Apple' anonymous fraud reporting system can be found on the Trust intranet under Finance - Fraud on the department listing
- NHS FCRL on: **0800 028 40 60**
- www.cfa.nhs.uk/reportfraud

8.0   **Care Quality Commission (CQC)**

8.1   From April 2010, under the Health & Social Care Act 2008 & CQC (Registration) Regulations 2009, registered providers have a statutory duty to notify the CQC in writing, within certain timescales, about certain important events that affect people who user their services or the service itself – this will include notification of certain incidents, as follows:

- Certain deaths of people using the service (without delay). *

- Any abuse of allegation of abuse (without delay). *

- Events that stop or may stop the service from running safely and properly (without delay). *

- Serious injuries to people who use the service (without delay). *

- Deaths and unauthorised absences of people who use the service who are detained or liable to be detained under the Mental Health Act 1983 (without delay). **

- Applications to deprive a person of their liberty under the Mental Capacity Act 2005, and their outcomes (without delay). ** (For further information in this regard please refer to the Trust's Mental Capacity Act (MCA) 2005 & MCA Deprivation of Liberty (DOLS) Policy – MDP024 – which is available on the Trust Intranet.)

*   These incidents will be notified to the CQC via the NPSA.

**   These incidents must be notified directly to the CQC

Forms for providers to use when making notifications are available on the CQC website. These can be submitted electronically to HSCA_Notifications@cqc.org.uk or in hard copy to:

CQC HSCA Notifications, City Gate, Gallowgate, Newcastle upon Tyne, NE1 4PA

As outlined within the opening paragraph to this appendix, notification of incidents to the NPSA and directly to the CQC will be the responsibility of staff within governance / risk management.

9.0   **Cervical Screening Programme Quality Assurance Reference Centre (CSP QARC)**

9.1   Incidents surrounding the reporting of cervical cytology specimens or elsewhere in the screening programme should be reported to the Hospital Based Programme Co-ordinator who will liaise with QARC.

10.0   **Other**

10.1   **Depending on the circumstances and severity of the incident,** other external stakeholders may need to be notified, and in some instances involved in the investigation, of incidents which occur. (This is a decision which would normally be taken centrally*, as part of the response to the incident.)

These include:

- MPs

- Other hospitals / Trusts

- Legal representatives

- NHSI / CQC / NHS England (inc Public Health England)

- Media

- Police

- Coroner

- GMC / NMC

- Patient Forum(s)

- CCGs / GPs / Local Authority Environmental Health (includes SIs and 'Never Events')

- Public Health England

- Local Authorities

- Local Authority Health Scrutiny Lead(s)

- Social Services (as appropriate)

- Emergency Services (if appropriate)

- Ombudsman

- Information Commissioner Office

- Deanery

For further information on this issue, please refer to the Trust's 'Policy on the Management of Serious Incidents (Clinical and Non-Clinical)'.

Appendix C

PROCEDURE FOR THE GRADING & INVESTIGATION OF INCIDENTS/ACCIDENTS, COMPLAINTS & CLAIMS

1.0   **Incident Grading**

1.1   Incidents should be graded using the Trust's generic Risk Assessment Tool/Grading Matrix (Table 3) and the information in Tables 1 & 2.

1.2   All incidents will be graded in order to determine the actions to be taken at Directorate and Trust Level. The grading of the incident is determined by two factors:

- The actual consequence, outcome or severity of the incident
- The probability or likelihood of the incident occurring/reoccurring.

Both of these factors are assigned a numerical score ranging 1 – 5. A detailed description of the numerical scoring is illustrated in Table 1 and 2.

Determining Consequence

Table 1: Consequence scores (C)

	Consequence score (severity levels) and examples of descriptors				
	1	2	3	4	5
Domains	**1 None/Near Miss**	**2 Low**	**3 Moderate**	**4 Severe**	**5 Catastrophic**
Impact on the safety of patients, staff or public (physical/psychological harm)	Minimal injury requiring no/minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 1-3 days	Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days RIDDOR/agency reportable incident An event which impacts on a small number of patients	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients
Quality/complaints/audit	Peripheral element of treatment or service suboptimal Informal complaint/inquiry	Overall treatment or service suboptimal Formal complaint (stage 1) Local resolution Single failure to meet internal standards Minor implications for patient safety if unresolved Reduced performance rating	Treatment or service has significantly reduced effectiveness Formal complaint (stage 2) complaint Local resolution (with potential to go to independent review) Repeated failure to meet internal standards Major patient safety	Non-compliance with national standards with significant risk to patients if unresolved Multiple complaints/ independent review Low performance rating Critical report	Totally unacceptable level or quality of treatment/service Gross failure of patient safety if findings not acted on Inquest/ombudsman inquiry Gross failure to meet national standards

		if unresolved	implications if findings are not acted on		
Human resources/ organisational development/staffing/ competence	Short-term low staffing level that temporarily reduces service quality (< 1 day)	Low staffing level that reduces the service quality	Late delivery of key objective/ service due to lack of staff Unsafe staffing level or competence (>1 day) Low staff morale Poor staff attendance for mandatory/key training	Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>5 days) Loss of key staff Very low staff morale No staff attending mandatory/ key training	Non-delivery of key objective/service due to lack of staff Ongoing unsafe staffing levels or competence Loss of several key staff No staff attending mandatory training /key training on an ongoing basis

Determining Likelihood

Table 2: Likelihood score (L)

Likelihood score	1	2	3	4	5
Descriptor	Rare	**Unlikely**	**Possible**	**Likely**	**Certain**
Frequency How often might it/does it happen	Cannot believe this will ever happen again	Do not expect this to happen again but it is possible	May happen or recur occasionally	Will probably happen/recur but it is not a persistent issue	Will undoubtedly happen/recur,possibly frequently

Determining Incident Grading

Once the consequence and likelihood of an incident has been identified the grade of the incident must be determined using the risk assessment/grading matrix (Table 3 below). The grade of the incident is calculated by multiplying the consequence score by the likelihood score.

Table 3: Risk Scoring = consequence x likelihood (C x L)

Risk Assessment/Grading Matrix

Severity / Impact / Consequence

Likelihood of recurrence	None / Near Miss (1)	Low (2)	Moderate (3)	Severe (4)	Catastrophic (5)
Rare (1)	1	2	3	4	5
Unlikely (2)	2	4	6	8	10
Possible (3)	3	6	9	12	15
Likely (4)	4	8	12	16	20
Certain (5)	5	10	15	20	25

RISK	Green – Risk Score 1-3	**Very low**	Yellow – Risk Score 4-6	**Low**	Orange – Risk Score 8-12	**Moderate**	Red – Risk Score 15-25	**High**

1.3   The immediate assessment of the incident grade should be undertaken quickly, and it is not necessary for the person grading the incident to be in possession of all of the facts at the time of the grading. There is always scope for re-grading the incident as the facts and issues emerge.

1.4   Given the subjective nature of the grading process, it is essential that the person, or persons, designated with authority to grade incidents have been trained to do so and that their performance is periodically audited.

     NB. Training for the relevant staff on incident grading, investigation and root cause analysis will be provided. Thereafter, assistance with incident grading can be sought from the risk management team as the need arises.

1.5   The level of investigation and analysis required for individual events (whether complaint, claim or incident) should be dependent upon the grading (i.e. the nature and severity of the consequences) and not whether the event is an actual or a near miss, as follows:

Very Low (Green) – Risk Rating 1 - 3:

     Incidents graded as 'very low' (green) should be managed at operational level by ward/departmental manager in accordance with day-to-day operational management procedures. No formal, detailed investigation likely to be required, although 'closing of the loop' and feedback to staff / patients should occur as necessary/appropriate. Incidents to be subject of aggregate review in order to identify trends/problems.

Low (Yellow) – Risk Rating 4 – 6:

     Incidents graded as 'low' (yellow) should be notified to the relevant Line Manager & Governance Co-ordinator. Formal investigation requirement to be considered although may not be necessary. Action / 'closing of the loop' and feedback to staff / patients to occur as necessary/appropriate. Incidents to be subject of aggregate review to identify trends/problems.

Moderate (Orange) – Risk Rating 8 – 12:

     Incidents graded as 'moderate' (orange) must be investigated at senior level and an action plan developed. Action / 'closing of the loop' must occur plus feedback to staff / patients and lessons learned to be shared within the Directorate / Group and throughout the organisation. Judgement to be made as to whether to escalate as a Serious Incident – this will depend on the individual circumstances of the incident.

High (Red) – Risk Rating 15 – 25:

     Incidents graded as 'high' (red) must be escalated within the Directorate / Group and notified immediately to Director of Governance and Assurance and Head of Risk in accordance with the Trust's 'Policy for Dealing with Serious Incidents (Clinical & Non-Clinical)'. In depth investigation, full root cause

analysis and a formal action plan will be required. Action / 'closing of the loop' must occur plus feedback to staff and lessons learned to be shared within the Directorate / Group and throughout the organisation and to relevant external stakeholders.

1.6   The grading/investigation process should not delay the forwarding of the incident form, or immediate reporting in the case of serious incidents, to Risk Management.

1.7   Incidents with the potential to lead to complaints and/or claims will be notified to the Complaints and PALS Manager on receipt within Risk Management. This is in addition to already established communication links between key Directorate / Group staff and the Complaints and PALS Manager following such incidents.

1.8   Serious incidents (as defined in the Trust's Policy on the Management of Serious Incidents') will typically be regarded, in the context of the incident grading matrix, as 'severe' or 'catastrophic' events. Other types of adverse patients events may be deemed 'serious' and be immediately escalated locally or to external stakeholders. An element of judgement will be required in determining this. **NB.** In reality, incident grading and the decision to escalate will be a judgement call taken at the time an incident occurs and without the completion of the formal risk grading matrix.

1.9   Incidents should be re-graded once the improvement strategies/controls have been agreed in order to determine the potential reduction in risk. This process may also assist in prioritising the actions planned. The grading score (within the colour grading colour) will assist with the prioritisation of actions and the required allocation of resources.

2.0   Incident Investigation

2.1   Introduction

2.1.1 The main purpose of investigation is to establish how and why an incident or event occurred and to identify the corrective measures necessary to prevent recurrence of similar or related events. A prompt and effective investigation and response to an adverse incident/accident can also be beneficial in the management and defence of any subsequent complaint and/or claim.

2.2   Investigation Approach

2.2.1 In conducting an investigation the following factors should be considered / included:

- The investigation process and indeed the investigating officer(s) must be:

    - Sympathetic

    - Just and fair

2.2.2 **It is not the role of the investigating officer to apportion blame. The incident investigation, in accordance with the Trust's Incident Reporting Policy or Serious Incident Policy, should focus on 'what went wrong, not who went wrong'.**

2.2.3   Investigations should be led by someone with the status and knowledge to make authoritative recommendations.

2.2.4   Depending on the nature, circumstances and scale of the incident, an investigation team may need to be established. Ideally, an investigation team should consist of three to four members, facilitated by the investigation leader, with the appropriate knowledge and expertise. This may include an external expert view.

2.2.5   A good investigation is prompt and thorough. It recommends and assigns remedial actions. It should be undertaken as soon as practicable after the event and before memories have faded.

2.2.6   The investigation should:

- Identify reasons for substandard performance.

- Identify underlying failures in management systems/procedures and practices.

- Consider also the human factors that may have contributed to the incident occurring

- Learn from incidents and make recommendations.

- Implement improvement strategies to help prevent or minimise recurrences, thus reducing future risk of harm.

- Satisfy mandatory and reporting requirements.

2.3   **Investigation Process**

2.3.1   **On Scene**

- care for affected persons(s) including staff (consider need for de-brief / counselling / support including time-off etc. – see also 2.3.2 below);

- observe and take photographs as necessary/appropriate or sketch;

- Record scene description; include external factors e.g. weather conditions, visibility, environmental factors e.g. uneven path, congested work area etc.

- Take a statement or ask staff to complete a FACTUAL statement (with reference to the Trust's 'Guidance for Staff on Preparing a Statement', which can be found on the Trust's Intranet site).

- Ensure that any relevant records (including the patient's medical records) are secured. In respect of maternity or other incidents where CTG or other tracings may be relevant as evidence, ensure that these are retained and securely filed. **NB.** As originals are prone to fading in a relatively short space of time, consideration should be given to copying these.

2.3.2   When an adverse incident occurs, and in addition to the support to and follow-up of any affected patient(s), healthcare professionals involved may also require emotional support and advice. To support staff involved in incidents / traumatic events, the following arrangements are in place within NLG:

- the Trust has in place a fair blame culture that discourages the attribution of blame and, following adverse incidents, focuses on 'what went wrong, not who went wrong';

- arrangements are in place within Directorates / Groups for de-briefing of staff, as necessary, following incidents. Mechanisms are also in place to ensure that staff involved in adverse incidents receive feedback following incident investigations. This includes staff who may have raised concerns with the Freedom to Speak-Up Guardian or Associate Guardians

- counselling and support services are available via Occupational Health – please also refer to the 'Information and Guidance – Advice for Managers in the Event of a Traumatic Incident at Work' and via 'Confidential Care' – a confidential and anonymous support helpline – 0800 085 1376

- the Trust has in place guidance for a Professional Debrief following a Traumatic Event which can be accessed on the Trust's intranet site. Appendix A of this document outlines the Staff Support Services available within the Trust which includes the Counselling via Counselling in Care helpline mentioned above and also the following:

- Chaplaincy – This seeks to provide for the spiritual, religious and pastoral needs of all patients, their relatives and friends, as well as the staff. Details can be found on the Trust's intranet site, through switchboard or by emailing c.thody@nhs.net; Doctors' Support Line (08707650001). This is an independent service specifically for doctors. All calls are answered in confidence by doctor volunteers; Samaritans (08457 90 90 90). Samaritan volunteers listen in confidence to anyone in any type of emotional distress for any reason; In determining the support required by an individual member of staff, managers should consider:

  o the need for a 'lead' to be identified to co-ordinate the support required by individual or groups of staff (i.e. what if any support is required and who / how best can this be provided);

  o the need for clear documentation of that support;

  o that support needs will differ with each individual member of staff.

The above 'checklist should therefore be used, where appropriate, in conjunction with any advice received directly from Occupational Health where this has been required.

2.3.3   **Interview**

- Staff involved

- Witnesses

2.4   **Establish Bare Essential Facts**

2.4.1   The above will help in establishing:

- Who was involved

- What happened

- Where exactly

- Who experienced/did what (in accordance with e.g. policies/procedures)

- When

2.5   **Produce a Chronology of events**

A chronology involves the mapping of events to demonstrate the order and time(s) they occurred.

2.6   **Address More Fully (Root Cause Analysis)**

2.6.1   In order to determine:

- How the event happened

- Why the event happened

- **Underlying (or root) causes.**   This will include reviewing any relevant documentation e.g. medical records, statements, incident form, rotas etc and assembling and considering all gathered information. Compare the conditions and sequence of events against standards, policies and guidelines or what would have been accepted practice at the time the event took place. Determine if these were appropriate and applied.

2.6.2   A **root cause** is 'a failure in a process that, if eliminated, would prevent an adverse incident occurring'.

2.6.3   **Root cause analysis** is 'a structured investigation process that aims to assist in the identification of the root or underlying cause(s) of a particular event or problem by determining WHY the failure occurred and the actions necessary to prevent or minimise the risk of recurrence'.

2.6.4   Remember to examine the following possible causal factors:

- Individual factors / Human Factors (e.g. fatigue, general health, stress, overload, distraction, device/product design, process design, mental model, situational awareness etc.)

- Team and social factors (e.g. role clarity, leadership, team interactions etc.)

- Communication factors - verbal, written and non-verbal (e.g. correct use of language, information/directions to appropriate staff, availability and completeness of records, body language issues etc.)

- Task factors (e.g. availability, understand of and adherence to policies & procedures, access to senior / specialist advice, staff agreement with task / procedure etc.)

- Education and training factors (e.g. competence, adequacy of knowledge, skills, supervision, length of experience, availability / accessibility of training etc.)

- Equipment and resource factors (e.g. integrity, usability, positioning etc.)

- Organisation and strategic factors (e.g. accountability, responsibility, priorities, safety culture etc.)

- Environmental factors (working conditions) (e.g. noise, light, temperature, congestion, staffing levels, hours of work etc.)

- Patient factors (e.g. clinical condition, mental/ psychological factors etc.)

See full list attached at **Appendix E**.

2.6.5   The Trust has in place a RCA Toolkit to assist staff undertaking root cause analysis. RCA training is also provided for Trust staff involved in the investigation of incidents, complaints and claims.

2.6.6   Unless the real or root causes of adverse incidents are properly understood, lessons will not be learned and suitable improvements will not be made to secure a reduction in the risk of harm to future patients, staff and visitors.

<u>**Root Cause Analysis**</u>

Collect the facts	Analyse the facts	Establish causes	Make recommendations

		Draw conclusions	Validate conclusions

- What happened?
- **Staff involved**
- **Witnesses**
- **Physical/ observed evidence**
- **Sketches or photographs**
- **Records and documentation**
- **Medical evidence etc.**

- How did it happen?
- **Casual factors.**
- **Chronology?**
- **Focus on problem – solving not on blame**
- **System and process based – don't concentrate on the individual**

- Why did it happen?
- **Findings / conclusions**
- **Probable causes**

- Recommendations
- **Implement**
- **Monitor**
- **Review**
- **Lead / Timescales**

2.7   **Maternity Incidents**

In respect of maternity incidents, given the high risk nature of this specialty and the often complex nature of subsequent claims and in accordance with CNST requirements, additional actions as part of the investigation may be required. This should always include an assessment of care given in line with the relevant clinical guidelines and a further review of guidelines should take place following the incident

to identify any changes that need to be made to the guideline in light of new information.   Certain records will need to be copied and secured in the clinical records i.e. CTG's, fetal blood sampling/cord gas results. Record keeping should be assessed by a Supervisor of Midwives/responsible Consultant to ensure all information is recorded accurately.

A brief, not exhaustive guide is provided for specific investigations/documentation that is required.

- **Shoulder dystocia**

   Completion of shoulder dystocia document

   Copy CTG & secure original CTG in the clinical records

- **Persistent low Apgar scores (including neonatal death following low Apgar scores)**

   Cord blood gas analysis (arterial and venous). Write these results in the clinical records and store the fetal blood sample/cord gas analyser printout in the CTG envelope

   Placental examination and histology

   Copy CTG & secure original CTG in the clinical records

   Emergency caesarean section response times document (if appropriate)

- **Intra partum stillbirth**

   Copy CTG and store original in the clinical records

   Follow stillbirth guideline

- **Maternal death**

   Follow maternal death policy

- **3rd/4th degree tears**

   Perineal repair records

   Operative delivery record (If appropriate)

- **Hysterectomy**

   Operative delivery records

   Uterus for histology/pathology

- **Any birth injury to mother or baby**

   Assessment of bladder function

   Documentation that parent(s) have been advised of trauma if to the baby

2.8   **Communication**

2.8.1   Ensure that all relevant parties are kept informed throughout the investigation process, particularly   where the incident has been classified as a 'serious untoward incident'. Please also refer to the Trust's 'Policy on the Management of Serious Incidents (Clinical and Non-Clinical').

2.9   **Outcome of the Investigation**

2.9.1   At the conclusion of the investigation, a written report including conclusions and recommendations highlighting learning points and action required to prevent a recurrence should be developed.

2.9.2   A suggested layout for an investigation report is outlined below:

- Heading e.g. incident or issue being investigated.

- Introduction/history/background.

- Outcome for the patient including explanations and apologies given (for further information please refer to the Trust's 'Policy on Being Open/Duty of Candour – Communicating with Patients and / or their Relatives / Carers when Patients are Harmed').

- Incident synopsis (including who, what, where & when).

- Root cause analysis/causation.

- Conclusion.

- Recommendations/learning points.

- Improvement Strategy/Action Plan (including lead role responsibilities, timescales for completion, resource requirements, plans for monitoring/required evidence of completion).

- Plans for measuring/reviewing the effectiveness of the actions to be put in place.

- Name of Investigator.

- Date of report.

- Enclosures e.g. incident form, statements, risk assessments etc.

- Intended audience/dissemination of report - who the report is for and who else has received copies.

2.9.3   All documentation from the investigation should be preserved and filed for future reference and pending a possible complaint and/or claim. It is advised that this documentation be filed with the incident report form.

2.10   **Complaints/Claims Grading & Investigation**

2.10.1 Complaints and claims will be graded on receipt by the Complaints and PALS Manager, in line with the principles outlined within this procedure. The grading allocated in this way will then inform the level of investigations required within Directorates / Groups.

2.10.2 The investigation of complaints and claims will take place in line with the principles outlined within this procedure and with reference to the Trust's Policy & Procedure for the Management of Complaints, Concerns, Comments and Compliments and the Claims Handling Policy & Procedure.

Appendix D

CAUSAL / CONTRIBUTORY FACTORS

Consider:

Individual Factors

Individual Factors	Components
Physical issues	❑ General health (e.g. nutrition, diet, exercise, fitness) ❑ Physical disability (e.g. eyesight problems, dyslexia) ❑ Fatigue
Psychology issues	❑ Stress (e.g. distraction/preoccupation) ❑ Specific mental health illness (e.g. depression) ❑ Mental impairment (e.g. illness, drugs, alcohol, pain) ❑ Motivation (e.g. boredom, complacency, low job satisfaction) ❑ Cognitive factors (e.g. attention deficit, distraction, preoccupation, overload and boredom)
Social Domestic	❑ Domestic/lifestyle problems
Personality Issues	❑ Low self confidence over confidence ❑ Gregarious/interactive, reclusive ❑ Risk averse/risk taker

Team and Social Factors

Team Factors	Components
Role Congruence	❑ Is there parity of understanding ❑ Are roles definitions correctly understood ❑ Are roles clearly defined
Leadership	❑ Is there effective leadership – clinically ❑ Is there effective leadership – managerially ❑ Can the leader lead ❑ Are leadership responsibilities clear and understood ❑ Is the leader respected
Support and cultural factors	❑ Are there support networks for staff ❑ Team reaction to adverse events ❑ Team reaction to conflict ❑ Team reaction to newcomers ❑ Team openness

Communication Factors

Communication Factors	Components
Verbal communication	- Verbal commands/directions unambiguous - Tone of voice and style of delivery appropriate to situation - Correct use of language - Made to appropriate person(s) - Recognised communication channels used (e.g. head of service)
Written communication	- Are records easy to read - Are all relevant records stored together and accessible when required - Are records complete and contemporaneous (e.g. availability of patient management plans, patient risk assessments, etc) - Are memo's circulated to all members of team - Are communications directed to the right person
Non verbal communication	Body language issues (closed, open, aggressive, relaxed, stern faced)

Task Factors

Task Factors	Components
Guidelines Procedures and Policies	- Up-to-date - Available at appropriate location (e.g. accessible when needed) - Understandable/useable - Relevant; Clear; Unambiguous; Correct Content; Simple - Outdated; Unavailable / Missing; Unrealistic - Adhered to/followed - Appropriately targeted (e.g. aimed at right audience)
Decision making aids	- Availability of such aids e.g. CTG machine, risk assessment tool, fax machine to enable remote assessment of results - Access to senior/specialist advice - Easy access flow charts and diagrams - Complete information – test results, informant history
Procedural or Task Design	- Do the guidelines enable one to carry out the task in a timely manner - Do staff agree with the 'task/procedure design' - Are the stages of the task such that each step can realistically be carried out

Education and Training Factors

Education and Training	Components
Competence	❑ Adequacy of knowledge ❑ Adequacy of skills ❑ Length of experience ❑ Quality of experience ❑ Task familiarity ❑ Testing and Assessment
Supervision	❑ Adequacy of supervision ❑ Availability of mentorship ❑ Adequacy of mentorship
Availability / accessibility	❑ On the job training ❑ Emergency Training ❑ Team training ❑ Core skills Training ❑ Refresher courses
Appropriateness	❑ Content ❑ Target audience ❑ Style of delivery ❑ Time of day provided

Equipment and Resources factors

Equipment	Components
Displays	❑ Correct information ❑ Consistent and clear information ❑ Legible information ❑ Appropriate feedback ❑ No interference
Integrity	❑ Good working order ❑ Appropriate size ❑ Trustworthy ❑ Effective safety features ❑ Good maintenance programme
Positioning	❑ Correctly placed for use ❑ Correctly stored

Working Conditions

Work Environment Factor	Components
Administrative	❑ The general efficiency of administrative systems e.g. reliability ❑ Systems for requesting medical records ❑ Systems for ordering drugs ❑ Reliability of administrative support
Design of physical environment	❑ Office design: computer chairs, height of tables, anti-glare screens, security screens, panic buttons, pacing of filling cabinets, storage facilities, etc ❑ Area design: length, shape, visibility, cramped, spacious
Environment	❑ Housekeeping issues – cleanliness ❑ Temperature ❑ Lighting ❑ Noise levels
Staffing	❑ Skill mix ❑ Staff to patient ratio ❑ Workload/dependency assessment ❑ Leadership ❑ Use Temporary staff ❑ Retention of staff/staff turnover
Work load and hours of work	❑ Shift related fatigue ❑ Breaks during work hours ❑ Staff to patient ratio ❑ Extraneous tasks ❑ Social relaxation, rest and recuperation
Time	❑ Delays caused by system failure or design ❑ Time pressure

Organisational and Strategic Factors

Organisational Factors	Components
Organisational structure	❑ Hierarchical structure, not conducive to discussion, problem sharing, etc. ❑ Tight boundaries for accountability and responsibility ❑ Clinical versus the managerial model

Priorities	❑ Safety driven
	❑ External assessment driven e.g. Star Ratings
	❑ Financial balance focused
Externally imported risks	❑ Locum/Agency policy and usage
	❑ Contractors
	❑ Equipment loan
	❑ PFI
Safety culture	❑ Safety/efficiency balance
	❑ Rule compliance
	❑ Terms and Conditions of Contracts
	❑ Leadership example (e.g. visible evidence of commitment to safety)
	❑ Open culture

Patient Factors

Patient Factors	Components
Clinical condition	❑ Pre-existing co-morbidity
	❑ Complexity of condition
	❑ Seriousness of condition
	❑ Treatability
Social factors	❑ Culture/religious beliefs
	❑ Life style (smoking / drinking/drugs/diet)
	❑ Language
	❑ Living accommodation (e.g. dilapidated)
	❑ Support networks
Physical factors	❑ Physical state – malnourished, poor sleep pattern, etc.
Mental / psychological	❑ Motivation (agenda, incentive)
	❑ Stress (family pressures, financial pressures)
	❑ Existing mental health disorder
	❑ Trauma
Interpersonal relationships	❑ Staff to patient and patient to staff
	❑ Patient to patient
	❑ Inter family – sibling, parents, children