Northern Lincolnshire and Goole Hospitals NHS
NHS Foundation Trust

Medical Director

INCIDENT REPORTING POLICY / PROCEDURE

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Northern Lincolnshire and Goole Hospitals 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.

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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 Hospitals 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 potential) 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. NPSA, 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 that will be run by the National Patient Safety Agency (NPSA)"[1].

[1] 'Doing Less Harm – National Patient Safety Agency'

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.

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 Untoward 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 Untoward Incidents (Clinical and Non-Clinical)'. This outlines specific responsibilities of key individuals on identification of a serious untoward 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 untoward incident occurring, the requirement is for **immediate** reporting to the Head of Governance. 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 Untoward Incidents (Clinical & Non-Clinical)', which is available on the Risk Management webpage.

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 stressed, 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 Management.

7.4 Trigger lists are already in place within many 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.

8.1.3 As outlined in 6.5.3, in the event of a serious untoward incident occurring, the requirement is for **immediate** reporting to the Head of Governance. 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 Untoward Incidents (Clinical & Non-Clinical)', which is available on the Risk Management webpage.

8.2 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.

8.3 Managers

8.3.1 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.

8.3.2 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 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 reporting the incident

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

- implementing appropriate preventative actions

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

8.4 Directors

8.4.1 Directors will be responsible for ensuring:

- that appropriate arrangements are in place within their Directorates for the reporting, investigation and follow-up of incidents in accordance with both this policy and the Trust's 'Policy for Dealing with Serious Untoward 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

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

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

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

- the compilation of analysis reports (e.g. for Trust Governance Committee, Trust Board, Branch Governance Groups, Trust Health; Safety & Security Group, Information Governance Steering Group, Healthcare Records Committee, Complaints Group, Control of Infection Committee, Falls Group, Safer Medication Group etc)

- ensuring that follow-up of incidents/changes in practice occur as necessary/appropriate

9.0 Incident Report Form

9.1 The Trust has adopted a 'universal' Incident Report Form 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.

9.2 Supplies of these forms (which can be ordered from Stores, order reference code WVA049) are available in all wards & departments, from the Risk Management Department and from the Union Offices at Scunthorpe General Hospital and the Diana, Princess of Wales Hospital, Grimsby.

9.3 Each form contains a unique identifier (number), the purpose of which is two-fold. Firstly, to easily identify each specific incident and also if staff wish to enquire about receipt of the form and the follow-up taken at a later date.

9.4 For information on the completion of the Trust's Incident Report Form, please refer to **Appendix B.**

10.0 Reporting Incidents / Submission of Incident Report Forms

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 Form.

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 Untoward Incidents should be reported **immediately** to the Head of Governance (in addition to being escalated within the Directorate). 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 submitted to risk management, ideally within 24 hours but no later than 5 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 C.**

10.5 On receipt within risk management, incident report forms are entered in to DATIX, the risk management software system in place within the Trust. This enables the collation and analysis of information on incidents and also aides the transfer of incidents to the relevant external stakeholders. The Trust also has in place a data capture system which allows data from incident report forms to be scanned into the system electronically. This is intended to speed up the process of data capture and in turn speed up the provision of trend analysis reports to Directorates, Risk Forums and the Trust Board.

11.0 Incident Coding

11.1 Prior to being 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 incident report forms has been devolved to Directorates. To assist, an 'Incident Reporting – Coding & Grading Booklet' is in place to assist staff in completing this task.

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 D.**

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 D.**

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, 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 Division/Directorate, the office of the Medical Director and Head of Governance and other relevant departments as appropriate (see also the Trust's 'Policy for Dealing with Serious Untoward Incidents)'. The Trust's 'Procedure for the Grading and Investigation of Incidents/Accidents, Complaints & Claims' is attached at **Appendix D.**

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 will regularly review information on incidents which occur locally within their Branch Governance Groups (or Directorate 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 Trust Governance 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 untoward incidents) are therefore undertaken and submitted to the Trust Governance 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 untoward incidents)

- analysis of data by site/unit, result and area (e.g. Directorate, 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 untoward 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 Governance 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 Governance 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 Governance 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 representatives on the Trust Governance 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 Branch 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 Governance Committee – to whom responsibility for this function has been delegated by the Trust Board – a standard pro-forma has been implemented for this purpose. 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 and, where relevant, the wider organisation and external stakeholders. Within NLG, lessons learned arising from incidents will be shared via the following routes:

- **Directorate Level:**
  - Branch Governance Groups/Minutes
  - Staff Meetings
  - Newsletters etc
- **Trustwide:**
  - 'Learning the Lessons' Newsletter
  - Internal Safety Alerts
  - Risk Forums (e.g. Trust Governance Committee, etc)
  - Serious Untoward Incident Reports submitted to the Trust Governance Committee

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 Approval & Ratification Process

The Trust's Governance Committee will be responsible for the ratification of this policy.

18.0 Review & Revision

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

19.0 Implementation

19.1 Training

19.1.1 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:

- Incident Report Form
- 'Speaking Out' Policy (HRP025)
- Policy on the Management of Serious Untoward Incidents (Clinical & Non-Clinical) (MDP059)
- Risk Management Strategy (MDP029)
- Procedure for the Grading & Investigation of Incidents/Accidents, Complaints & Claims **(Appendix D)**
- Procedure for the Reporting of Adverse Incidents involving Medical Devices to the Medicines and Healthcare Products Regulatory Agency (MHRA) (MDR019)
- Guidelines on Preparing a Statement (MDG014)
- Nursing & Midwifery Policy for the Management of Medicines Incidents

- Root Cause Analysis (RCA) Toolkit (MDM002)
- Policy & Procedure for the Management of Complaints (MDP036)
- Claims Handling Policy & Procedure (MDP061)
- Policy on Being Open with Patients and/or their Relatives/Carers following a Patient Safety Incident (MDP006)

23.0 References

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

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

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

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

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

23.6 Never Events Framework (NPSA). Update for 2010/11. (2010).

The electronic master copy of this document is held by Document Control, Office of the Medical Director, 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

Appendix B

GUIDANCE ON COMPLETING AN INCIDENT REPORT FORM

These notes should be read (in conjunction with the Trust's Incident Reporting Policy) by all staff and be easily accessible for reference if guidance is required on reporting an incident.

1.0 Completion of the Incident Report Form

1.1 **General Requirements:**

1.1.1 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.

1.1.2 The completion of an incident form does not constitute an admission of liability, either on the part of the person making the report or any other individual involved. **It is important, however, that only the facts pertaining to the incident and not opinions are recorded.**

1.1.3 The Trust has in place data capture scanner which allows data from incident report forms to be scanned on to the incident reporting system electronically. This will speed up the process of data capture and in turn will speed up the provision of trend analysis reports to Directorates, Risk Forums and the Trust Board in order to facilitate the review of such incidents and enable the learning of lessons from incidents which occur. **To ensure the effectiveness of this system it is essential that staff ensure that the form is completed appropriately throughout. For example, it is essential that staff ensure that the information entered on to the form is only entered into the boxes provided. Where sections provide a number of options, a cross X should be used to select the appropriate option. Information which is entered outside of the boxes or which is not entered appropriately or is illegible may not be read by the scanner. The staff responsible for the coding / grading of incidents on to the form must also ensure that only the recognised codes are used.**

1.1.4 Each form contains a unique identifier (number) – this allows the easy identification of each specific incident. It also allows staff to enquire about receipt of the form/follow-up of an incident, if required, at a later date.

1.1.5 An Incident Reporting Telephone 'Hotline' is available for staff to report incidents (EXT 7751 at DPOWH and EXT 2438 at SGH/GDH). It should be stressed, however, that where staff routinely use incident forms to report incidents this practice should not change. The hotline has been set up (i) for anonymous reporting and (ii) for enquiring about receipt/follow-up of a particular incident form. **NB.** This can also be done via the Risk Management webpage – see section on incident reporting.

NOTE: Anonymous reporting is viewed as the exception rather than the rule but would be acceptable if the incident would not otherwise be reported. Please also refer to the Trust's Speaking Out Policy.

1.2 **Specific Requirements:**

1.2.1 **Side 1**

- **In the vast majority of cases, only Side 1 of the incident report form will need to be completed by the person reporting the incident.** The only exception to this will be where medication or equipment has caused or has the potential to cause harm to the individual(s) involved. In such instances, the relevant section of Side 3 of the incident report form will also need to be completed – see also section 1.2.7. below.

1.2.2 **Side 1: Section 1: Location & Identification of Incident / Accident**

- This section requests:
  - details of the hospital site where the incident occurred;
  - details of the ward / department where the incident occurred;
  - details of the specific location of the incident (e.g. Bay 1, Toilet etc.);
  - the date and time of the incident;
  - the personal details of the affected person and their status (i.e. whether patient, staff, visitor, volunteer etc. and, if staff, whether permanent, temporary etc and their occupation and whether absence from work is likely arising from the incident - **this latter information is required in order to determine whether the incident should be classed as a RIDDOR);**
  - the affected person's ethnic origin – please insert appropriate code – the ethnic origin codes are outlined on **Side 4** of the incident report form;
  - In respect of violence/aggression incidents, details of the affected person should be entered, however, the details of the 'aggressor' should also be included in the relevant space.

NB. If a person is not involved, the 'no person affected' box should be indicated.

1.2.3 **Side 1: Section 2: Details of the Incident**

- This sections requests:
  - confirmation of whether some loss, harm or damage occurred arising from the incident or whether it was a 'near miss' – please tick relevant box;

- a brief but accurate description of the incident. This should include details of any action taken and who was contacted and details of any injury and part of body injured. The 'brief description' box requires the entry of free text – a continuation sheet is provided on Side 3, if necessary. **To ensure that the details of the incident are captured by the scanner, it is important that staff ensure that this information is written legibly and within the boxes provided.**

- If it is considered that statements are required, these should be collected as close to the time of the incident as possible (when events are still clearly remembered) and attached to the incident form. For guidance on writing a statement, please refer to the Trust's Guidelines on Preparing a Statement.

1.2.4 **Side 1: Section 3: Person Completing Side 1 of the Form**

- This should be completed by the member of staff reporting the incident / completing the form and requires the inclusion of:

  - the name and occupation of the member of staff concerned;
  - whether permanent, temporary, bank, locum or agency staff;
  - their role in the incident (e.g. informed of incident, witnessed incident etc.);
  - their signature and the date of completion of the form.

NB. If medication or equipment are involved, please ensure that the relevant section(s) of Side 3 are completed. NOW FORWARD THE FORM TO YOUR MANAGER.

1.2.5 **Side 2 – Manager's Investigation Section**

- This section of the form should be completed by the Manager responsible for the investigation / follow-up of the incident.

1.2.6 **Side 2 – Incident Coding & Grading Section**

- This section of the form should **only** be completed by the 'designated' member(s) of staff within the Directorate responsible for coding & grading of incidents.

1.2.7 **Side 3 – Medication & Equipment Incidents and Continuation Sheet**

- Side 3 of the form only needs to be completed if medication or equipment has caused or has the potential to cause harm to the individual(s) involved.

- Side 3 also contains a continuation sheet for Section 2, Side 1, should this be required for recording further details of the incident.

1.2.8 **Side 4**

- Side 4 of the form contains some brief guidance notes for staff in how to complete the form.

2.0 Submission of Incident Report Forms

2.1 Incident 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.

2.2 Incident Report Forms must be submitted to risk management as soon as possible (ideally within 24 hours but no later than 5 days) after the incident. Serious untoward incidents should be reported immediately to the Head of Governance. Out of hours the Site Manager should be contacted. The Site Manager, in turn, will contact the on-call Director/Senior Manager.

2.3 Completed forms should be sent to:

Grimsby Site	**Scunthorpe & Goole Sites**
Risk Management	Risk Management
West Arch	Modular Build
Diana, Princess of Wales Hospital	Scunthorpe General Hospital

2.4 Whilst copies of incident report forms can be retained at ward / departmental level, original forms **must** be sent to Risk Management.

2.5 In respect of incidents involving patients, please note that incident report forms are **not** health records and copies should **not** therefore be filed in patients' notes.

Appendix C

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 Untoward 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 Untoward Incidents (Clinical and non-Clinical)'.

2.0 National Patient Safety Agency (NPSA)

2.1 The NPSA is a Special Health Authority created in July 2001 to co-ordinate the efforts of the entire country to report, to the new National Reporting & Learning System (NRLS), and learn from mistakes and problems that affect patient safety.

2.2 As well as making sure errors are reported in the first place, the NPSA 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 has successfully linked up to the NPSA and is now routinely reporting incidents (including serious untoward incidents or SUIs) to the NRLS. The information submitted to the NPSA contains no staff or patients identifiers. From April 2010, in accordance with the Health & Social Care Act 2008 & Care Quality Commission (Registration) Regulations 2009, the requirement to report SUIs to the NPSA within a certain timescale will be a statutory requirement. The NPSA 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 the NPSA, (although they will be encouraged by the NPSA 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 Governance 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 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 monitoring can be found on the CSM homepage: (www.open.gov.uk/mea/mcahome.htm).

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 event, which gives rise to or has the potential for unexpected or unwanted effects involving the safety of patients, staff and others;
- incidents that arise through incorrect use, inappropriate modifications or adjustments, or inadequate servicing and maintenance procedures;
- deficiencies in the technical or economical performance of equipment;
- any defects in product, instructions, identified by Health & Safety Inspectors or Local Authority Inspectors;
- failure in critical services (electricity, water, steam, gas, communication etc.) that would affect the safety of patients and others.

7.0 Counter Fraud and Security Manager Services (CFSMS)

7.1 The Counter Fraud and Security Management Service (CFSMS) is a Special Health Authority which has responsibility for all policy and operational matters relating to the prevention, detection and investigation of fraud and corruption and, following the implementation of the New Secretary of State Direction, the management of security (including violence & aggression) in the National Health Service.

7.2 The CFSMS manage the National Physical Assault Reporting System(PARS), which imposes on all Trusts the requirement to report all incidents of physical assault* regardless of the circumstances, thus enabling the Department of health (DOH) to determine the scale of and attempt to tackle the problem nationally. (*This includes incidents of assault involving patients with medical conditions which mean that they may not be responsible for their actions.)

7.3 The New Secretary of State Directions define a 'physical assault' as 'the intentional application of force to the person of another, without lawful justification, resulting in physical injury or personal discomfort'.

7.4 The Trust reports all incidents of physical assaults to PARS.

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 Other

9.1 **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
- Monitor
- Media
- Police
- Coroner
- GMC / GNC
- Patient Forum(s)
- Primary Care Trust(s) / GPs / Public Health (includes SUIs and 'Never Events')
- Emergency Planning Officer – Local Authorities
- Local Authority Health Scrutiny Lead(s)
- Social Services (as appropriate)
- Emergency Services (if appropriate)
- Ombudsman
- Information Commissioner etc.
- Deanery

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

Appendix D

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 (Tables 1) – which is printed on the Incident Report Form and using the information in Tables 2 & 3.

Table 1 – Risk 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

Table 2 – Definitions for likelihood of recurrence

Descriptor	**Description**
Certain	Will undoubtedly recur, possibly frequently
Likely	Will probably recur, but is not a persistent issue
Possible	May recur occasionally
Unlikely	Do not expect it to happen again but it is possible
Rare	Cannot believe that this will ever happen again

Table 3 – Definitions for severity/impact on affected person & consequence to organisation

(A) Level	(B) Descriptor	(C) Actual impact on affected person(s) (Examples Only)	D) Actual or potential consequence for organisation (Examples Only)
5	Catastrophic (including Death)	Death (including single or multiple fatalities).	• International adverse publicity/severe loss of confidence in the organisation • Extended service closure (i.e. 8 days+) • Litigation >£1 million • Other financial loss >£1 million • Significant lost staff working days • Definite notification to Strategic HA, NPSA, NHSLA/other external agencies (e.g. HSE, Police, Coroner etc.) • Probable external investigation/ interventions/sanctions by HCC, HSE etc. • Executive Officer Imprisoned • Removal of Executive control • Public enquiry
4	Severe	Permanent or long-term harm	• National adverse publicity/major loss of confidence in the organisation • Possible temporary service closure/disruption to service (i.e. 2-7 days) • Complaint • Litigation £500k - £1 million • Other financial loss > £500k • Increased length of stay >15 days • Increased level of care >15 days • Significant lost staff working days • Definite notification to Strategic HA, NPSA, NHSLA/other external agencies (e.g. HSE, Police etc.) • Possible external investigation/ intervention/sanctions/prosecution by HCC, HSE, Police etc. • Extended failure to meet national targets • Executive officer fined • Loss of major civil case • Loss of Human Rights Act (HRA) or Disability Discrimination Act (DDA) case • Critical CHI report
3	Moderate	Moderate/serious effect on care or wellbeing of any person Short-term harm requiring further treatment or procedure	• Moderate service disruption • Local adverse publicity/moderate loss of confidence in the organisation • Probable complaint • Probable litigation £50k - £500k • Other financial loss £100k-£499k • Increased length of stay 8-15 days • Increased level of care 8-15 days • Lost staff working days • Probable notification to Strategic HA, NPSA, NHSLA etc. • Failure to meet national targets 2 Qtr's • Improvement notice • Recruitment difficulties in key specialties • Persistent same issue complaints • HRA or DDA claim
2	Low	Minor effect on care or wellbeing, health & safety of any person Non-permanent harm requiring observation or minor treatment	• Minor impact/service disruption (i.e. up to 1 day) • Possible complaint • Possible litigation < £50k • Other financial loss <£99k • Increased length of stay 1-7 days • Increased level of care 1-7 days • Possible lost staff working days • Failure to meet national targets 1 Qtr • Minor civil case
1	None/ 'Near Miss'	No obvious harm/injury	• Minimal impact/no service disruption • No or low financial loss • No lost staff working days • No litigation

			• No loss of reputation • No loss of equity

1.2 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.

1.3 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.

1.4 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 & Clinical 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/Significant (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 Division/Directorate and throughout the organisation. Judgement to be made as to whether to escalate as a Serious Untoward 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 Division/Directorate and notified immediately to Risk Management in accordance with the Trust's 'Policy for Dealing with Serious Untoward

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 Division/Directorate and throughout the organisation and to relevant external stakeholders.

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

1.6 Incidents with the potential to lead to complaints and/or claims will be notified to the Complaints & Legal Services Manager(s) on receipt within Risk Management. This is in addition to already established communication links between key Divisional/Directorate staff and the Complaints & Legal Services Managers following such incidents.

1.7 Serious incidents (as defined in the Trust's Policy on the Management of Serious Untoward 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.

1.8 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, 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.
- 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 Risk Management webpage 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 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;
- 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.
- In determining the support required by an individual member of staff, managers should consider:
    - 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);
    - the need for clear documentation of that support;
    - that support needs will differ with each individual member of staff.

  The above 'checklist should therefore be used, where appropriate, in conjunction with the above OH Information and Guidance Sheet and having taken advice directly from Occupational Health where this may be 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 (e.g. fatigue, general health, stress, overload, distraction 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.

Root Cause Analysis

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 Untoward 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 – 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 & Legal Services Managers, 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.

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 and the Claims Handling Policy & Procedure.

Appendix E

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