NHS
London North West
University Healthcare
NHS Trust

INCIDENT REPORTING AND INVESTIGATION POLICY
(Including Serious Incidents)

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Policy Number:	LNWHT/IGC/002/2016
Name of ratifying Committee:	Integrated Governance Committee
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Responsible Executive Director:	Chief Nurse
Name of author:	Head of Governance
Name of approving Committee:	Integrated Governance Committee
Equality Impact Assessment:	Yes, November 2015
Target audience:	All staff, Volunteers and Contractors

Associated documents/policies:	Risk Management Strategy & Policy. Health & Safety Policy. Being Open Policy. Violence & Aggression Policy. Raising Concerns Policy. Management of Medical Devices Policy. Guidance for Performing Risk Assessments. Trust RCA Investigation Guidance for Incidents, Claims and Complaints. Guidance on the Analysis and Learning from Complaints, litigation, Incidents & PALS [CLIPS] Datix - how to use Datix incident reporting system - reporters guide. Datix - how to use Datix incident reporting system - Managers guide. RIDDOR Reporting Policy. Support Arrangements for Staff Involved in Potentially Traumatic/Stressful Work Related Situations
Relevant legislation:	Health and Safety at Work etc., Act 1974. Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995, amended 2013.
Were comments sought from the Counter Fraud Service with regard to fraud and bribery?	Not applicable

VERSION CONTROL

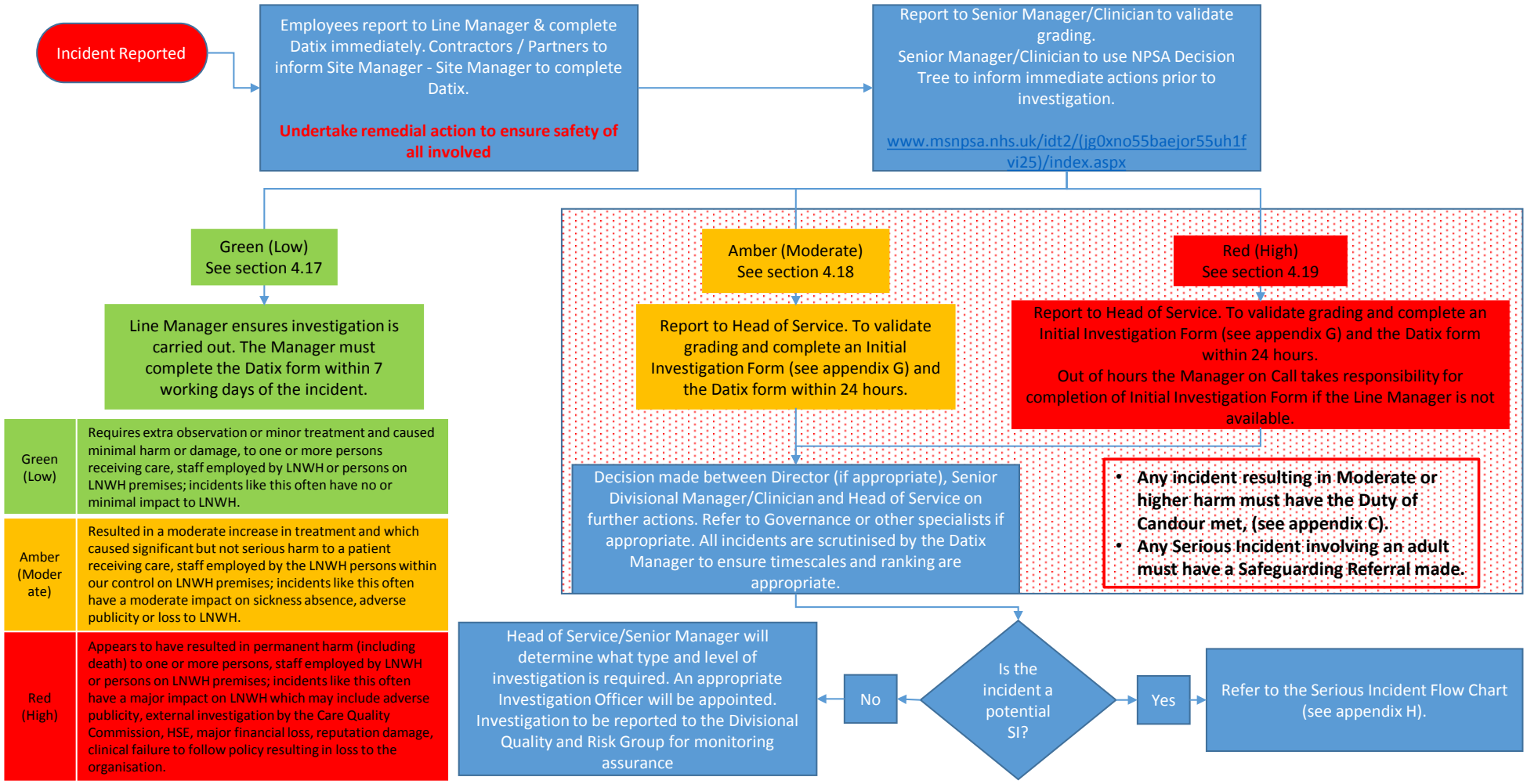
Version number	Date	Revision from previous issue
1	19.11.2015	New policy replacing the interim Incident Reporting Policies.
2	21.12.2015	Update to the SI Management Process
3	23.12.2015	Updates from review by Executive Team
4	07.01.2016	Review of responsibilities
4.1	08.01.2016	Removal of editing comments
5	26.01.2016	Changes required by the Integrated Governance Committee
6	02.02.2016	Removal of Liverpool References
7	04.02.2016	Reference made to independence of the investigation Chair Person from the process being investigated
8	29.03.2016	Updating of SI Flowchart
9	04.05.2016	Inclusion of comments by the Chief Nurse
10	05.05.2016	Inclusion of Reporting and Action Plan Templates as Appendices
11	06.05.2016	Addition of updated Action Plan Template
12	22.07.2016	Amendments to the flowcharts for reporting incidents and managing SI's
13	18.08.2016	Amendments to: • SI Flow Chart. • Initial Investigation form • SI Report Template
14-15	November 2016	Role and responsibility amendments.

16	11.01.17	Addition of PU SI Notification Form.
17	01.12.17	Change to the NHS Screening Programmes Guidance
18	22.05.18	Agreed extension (by IGC 21.05.18) to review date as work ongoing on update of policy.

CONTENTS

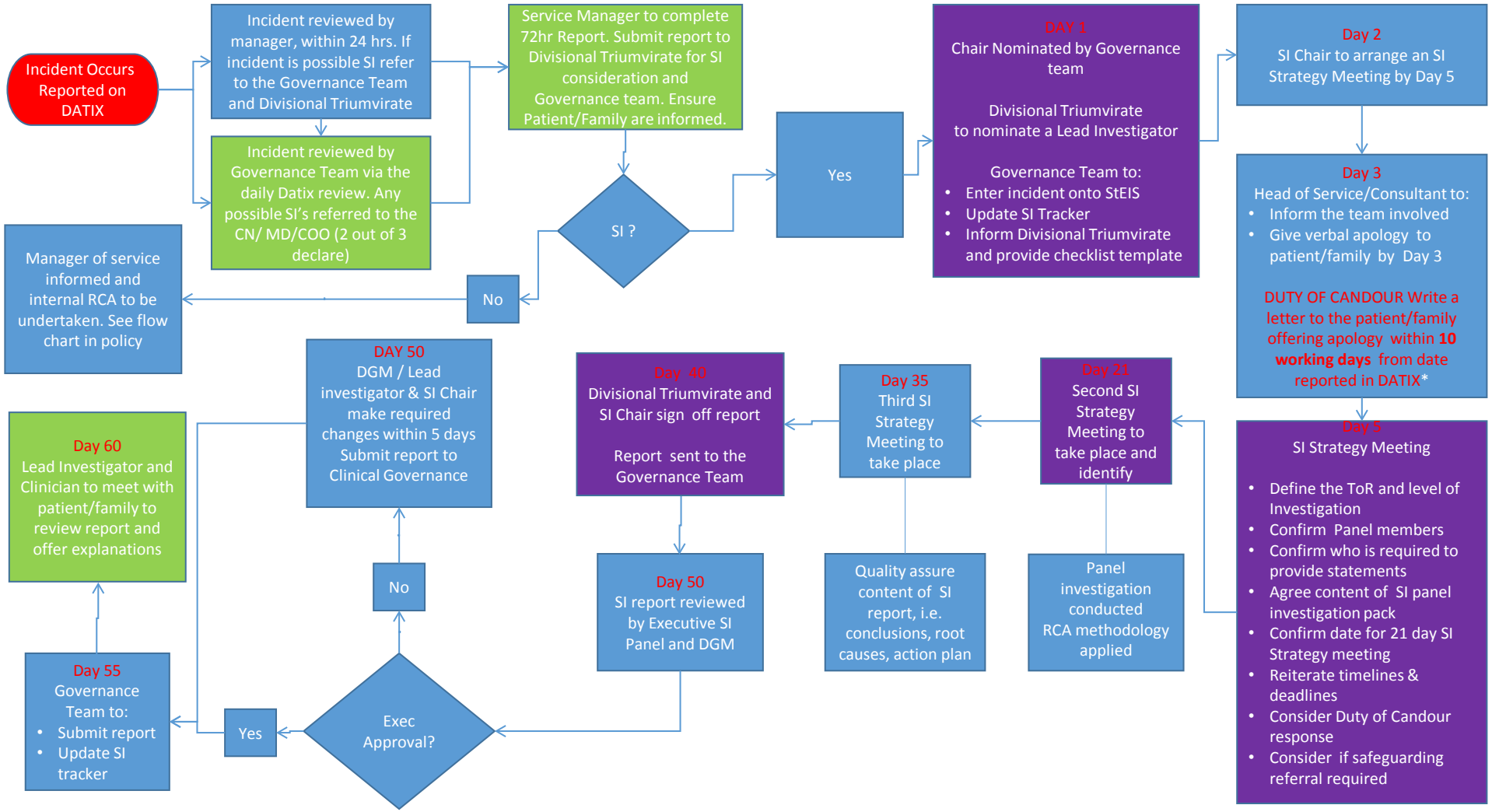
QUICK REFERENCE GUIDE – INCIDENT REPORTING PATHWAY

LNWH ORGANISATIONAL INCIDENT REPORTING PATHWAY v5 – (Incident Reporting and Investigation Policy)



Green (Low)	Requires extra observation or minor treatment and caused minimal harm or damage, to one or more persons receiving care, staff employed by LNWH or persons on LNWH premises; incidents like this often have no or minimal impact to LNWH.
Amber (Moderate)	Resulted in a moderate increase in treatment and which caused significant but not serious harm to a patient receiving care, staff employed by the LNWH persons within our control on LNWH premises; incidents like this often have a moderate impact on sickness absence, adverse publicity or loss to LNWH.
Red (High)	Appears to have resulted in permanent harm (including death) to one or more persons, staff employed by LNWH or persons on LNWH premises; incidents like this often have a major impact on LNWH which may include adverse publicity, external investigation by the Care Quality Commission, HSE, major financial loss, reputation damage, clinical failure to follow policy resulting in loss to the organisation.

QUICK REFERENCE GUIDE – SERIOUS INCIDENT (AND NEVER EVENT) PROCEDURE



1. POLICY STATEMENT

This policy covers both the reporting and investigation of clinical and non-clinical incidents, together with the processes for analysis and improvement. This policy should be read in conjunction with the Trust's Risk Management Strategy.

The Trust's risk management system is based on an open, honest, transparent culture of learning from experience underpinned by a systematic approach to incident management. This cultural approach fully adheres to national guidance from a staff and patient perspective, including the Management of Health and Safety at Work Regulations (1974) and the Sign up to Safety campaign.

The Trust aims to establish the causes of incidents, complaints and claims, understand these and make sure lessons are learnt and suitable improvements are made to minimise any further recurrence.

Serious incidents in healthcare are relatively uncommon but when they do occur the NHS has a responsibility to ensure that there are systemic measures in place for safeguarding people, property, NHS resources, and reputation. This includes responsibility to learn from these incidents in order to minimise the risk of them happening again. This organisation takes this reasonability very seriously and the importance of establishing a safety culture within an organisation; a reporting culture, which appreciates the significance of effective incident management. Incident reporting is a fundamental tool of risk management, the aim of which is to collect information about adverse incidents, including near misses, ill health and hazards, which will help to facilitate wider organisational learning. If incidents are not properly managed, they may result in a loss of public confidence in the organisation and a loss of assets.

The policy also includes information on the requirements arising from the Health and Social Care Act 2008 which means that organisations are required to notify the Care Quality Commission (CQC) about events that indicate or may indicate risks to ongoing compliance with the CQC registration requirements or that lead, or may lead to changes in the details about the organisation in the Commission's register.

2. PURPOSE

This policy allows concerns to be raised which may have an effect on the safety of patients and the public in general, and/or the safety of their personal data. This document sets out the adverse accident, incident, and near miss reporting, management, and investigation procedure for London North West Healthcare Trust (LNWH). It details the measures and procedures to be adopted when reporting, managing and investigating accidents, incidents and near misses. The management and investigation of accidents/ incidents/near misses will be based on the severity of their outcome, with the ultimate aim to learn and make changes as a result, in order to improve safety for patients, staff, visitors and contractors. Qualitative and quantitative data analysis will be used to highlight trends and identify any further need for action (see Guidance on the Analysis and Learning from Complaints, litigation, Incidents & PALS [CLIPS]). The purpose of an incident reporting system is to identify problems or potential problems, to prevent or

minimise a further recurrence. The intention of this policy is not to apportion blame but to identify system failures that may lead to human error, but recognises fair blame when individuals have acted beyond the scope of their employment and reference to Human Resources and Health & Safety Policies may need to be used in specific cases.

3. SCOPE

This policy and guidance is applicable in all cases of an adverse accident, incident and near miss that may occur on LNWH premises, premises not owned or managed by LNWH where employees of LNWH are undertaking their duties, contracted staff, students, volunteers and LNWH patients/service users.

4. DEFINITIONS

4.1. Incident An event or circumstance which could have resulted, or did result, in unnecessary damage, loss or harm to patients, staff, visitors or members of the public.

4.2. Clinical Incident is defined as "any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care." (NPSA, 2008).

4.3. Non-Clinical Incident is defined as any event or circumstance that does not involve a patient's treatment or care which leads to, or could potentially lead to, unintended or unexpected harm, loss or damage to staff, financial loss or injure the reputation of the Trust.

4.4. Near Miss is defined as any unexpected or unintended incident which was prevented either by intervention or by luck" (NPSA, 2001).

4.5. Serious incident (SI) requiring investigation is an incident that occurred during NHS funded healthcare. Not all SI's will result in harm to a patient; consideration must be given to the level of potential harm or disruption to service. These can include near misses, as well as looking at cluster events where a pattern of lower harm events are occurring. Clusters may become apparent during the management of individual incidents or whilst incident reporting is being reviewed at Divisional and Trust level.

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
    - Unexpected or avoidable death of one or more people. This includes
    - suicide/self-inflicted death; and
    - homicide by a person in receipt of mental health care within the recent past;
- Unexpected or avoidable injury to one or more people that has resulted in serious harm;
- Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
    - the death of the service user; or
    - serious harm;
- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:

- healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
- where abuse occurred during the provision of NHS-funded care.

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

- A Never Event - all Never Events (see section 4.6) are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See the Never Events list in Appendix B;
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
  - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues;
  - Property damage;
  - Security breach/concern;
  - Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
  - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
  - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
  - Activation of Major Incident Plan (by provider, commissioner or relevant agency)
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.
- Avoidable Grade 3 or 4 Pressure Ulcer.
- Specific maternity complications (including unexpected admission to NICU or unexpected admission to ITU).
- Information governance incidents Grade 1-5.

  (Contact Clinical Governance Team for further information.)

4.6. Never Events Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. These are updated on an annual basis by NHS England. See the Never Events list in Appendix B; (Contact Clinical Governance Team for further information.)

4.7. Security incident From April 2010 NHS Security Management Service introduced a Security Incident Reporting System (SIRS). This was developed to provide a clearer picture of security incidents across the health service in England, locally and nationally. The following security incidents must be reported using SIRS:

- any security incident involving physical assault of NHS staff;
- non-physical assault of NHS staff (including verbal abuse, attempted assaults and harassment);

- theft of or criminal damage (including burglary, arson, and vandalism) to NHS property or equipment (including equipment issued to staff);
- theft of or criminal damage to staff or patient personal property;
- property damage arising from these types of security incident.

4.8. Unexpected death

Where natural causes are not suspected, local organisations should investigate these to determine if the incident contributed to the unexpected death.

4.9. Permanent harm

Harm directly related to the incident and not to the natural course of the patient's illness or underlying conditions; defined as permanent lessening of bodily functions, including sensory, motor, physiological, or intellectual.

4.10. Prolonged pain and/or prolonged psychological harm

Pain or harm that a patient has experienced, or is likely to experience, for a continuous period of 28 days.

4.11. Abuse

It should be recognised that the term "abuse" can be subject to wide interpretation and that, when determining whether adult abuse is taking place, consideration will need to be given to a range of factors. "Abuse is a violation of an individual's human and civil rights by any other person or persons".

Abuse may consist of:

- A single act or repeated acts
- It may be physical, psychological, or emotional
- An act of neglect or omission to act
- Occur when a person is persuaded to enter into a financial or sexual transaction to which they have not, or cannot, consent.
- Abuse may be deliberate or unintentional or result from lack of knowledge.

4.12. External body / agency

An organisation that has an official advisory or regulatory role that has been mandated to regulate the corporate and professional activities of NHS Trusts.

4.13. RIDDOR is the Reporting of Injuries, Diseases, and Dangerous Occurrences Regulations 1995 (as amended). RIDDOR Incident is defined as any incident, disease, or dangerous occurrence reportable under the RIDDOR regulations by the Health and Safety Executive (HSE). (Contact Health and Safety Team for further information.)

4.14. Information Governance incident

Any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals.

The above definition applies irrespective of the media involved and includes both loss of electronic media and paper records.

All reported information governance incidents attributable to the actions of staff employed by LNWH, are risk rated in accordance with the Checklist guidance for reporting, managing, and investigating information governance serious incident requiring

investigation (Department of Health, 2013).Information Governance Incidents risk rated against the guidance and reaching a level 2 risk, are reported to the Department of Health and Information Commissioner's Office via the IG Toolkit Incident Reporting Tool. (Contact Information Governance Team for further information.)

4.15. Complaint/Claim

A complaint is defined is an expression of dissatisfaction (written or verbal) about a service provided or which is not provided, which requires a response. Examples of complaints include: Concerns about the quality of service provided, the following of standard procedures and good practice, poor communication and the attitude or behaviour of a member of staff.

4.16. Root Cause Analysis (RCA)

Is defined as the process by which the underlying cause(s) of patient safety and non-clinical incidents are established. The nature and extent of an RCA will be subject to the nature and level of incident. An action plan will be established for all root causes and issues identified which have contributed to/resulted in an incident.

4.17. Low Risk (Green Graded)

Any incident that required extra observation or minor treatment and caused minimal harm or damage, to one or more persons receiving care, staff employed by LNWH or persons on LNWH premises; incidents like this often have no or minimal impact to LNWH.

4.18. Moderate Risk (Amber Graded)

Any incident that resulted in a moderate increase in treatment and which caused significant but not serious harm to a patient receiving care, staff employed by the LNWH persons within our control on LNWH premises; incidents like this often have a moderate impact on sickness absence, adverse publicity or loss to LNWH.

4.19. High Risk (Red Grade)

Any incident that appears to have resulted in permanent harm (including death) to one or more persons, staff employed by LNWH or persons on LNWH premises; incidents like this often have a major impact on LNWH which may include adverse publicity, external investigation by the Care Quality Commission, HSE, major financial loss, reputation damage, clinical failure to follow policy resulting in loss to the organisation.

4.20. Strategy Meeting

A meeting convened at the request of the Line Manager/Senior Manager to: plan the route of the investigation, appoint an Investigating Officer and agree Terms of Reference.

4.21. Duty of Candour

In the wake of the Mid-Staffordshire Public Inquiry, the Government has introduced a range of measures to reinforce the value of openness, with sanctions for the most serious failings in candour and honesty.

The new statutory Duty of Candour on organisations, supported by strengthened guidance and codes for regulated professionals, champion's openness and safety across health and adult social care.

In line with National Patient Safety Agency (NPSA) guidance Being Open (2009) and the Duty of Candour Requirements (2014) the Trust has a Being Open Policy to ensure that when mistakes are made patients/relatives/carers receive an acknowledgement, apology

and a truthful and clear explanation as soon as a patient safety incident has occurred. Saying sorry is not an admission of liability it is the right thing to do. Communication with patients, carers and the public must be fully documented. Further detail on the Duty of Candour and links to resources are available in Appendix C.
Staff can also contact the Care Quality Commission (CQC) with concerns about care; details are available on the CQC website - http://www.cqc.org.uk/

5. PROCESS FOR THE REPORTING OF INCIDENTS

The process outlined in this policy should be used to report all accidents, incidents or near misses.

5.1 Reporting of Incidents Pathway (Appendix A)

The reporting procedure covers a wide range of situations. In general, all staff members must report:

- An event that has occurred contrary to LNWH accepted standard of patient care.
- An incident whereby a member of staff or the public has been injured or could have been injured or put at risk out of or in connection with LNWH work activity.
- An event that could place LNWH in an adverse legal or media interest position.
- All pressure ulcers grade 2 or above
- All cases of MRSA and Chlostridum Difficile

5.2 Completing the Datix Form

Datix - The Datix Incident Report Form should be completed immediately following an incident and be reported to your Line Manager. The Line Manager will then review approve and close the form within 72 working hours. http://eht-datix02v.xeht.nhs.uk/datix/live/index.php
Contractors and employees who do not have access to the web based form or work off LNWH premises should complete a web based form as soon as practicably possible.
The flow chart (see appendix A) shows the overall reporting and investigation procedure.

6. DUTIES, ROLES & RESPONSIBILITIES.

By not reporting an incident, staff may be putting themselves, their colleagues and patients at risks. If a member of staff reports an incident, it is LNWH Policy that any employee involved in the process are treated with respect and supported throughout the process. (see Support Arrangements for Staff Involved in Potentially Traumatic/Stressful Work Related Situations). If a staff member is uncomfortable about reporting a colleague or incident, consider seeking guidance from the Raising Concerns (Whistle Blowing policy);

6.1. Chief Executive

The Chief Executive is ultimately responsible for ensuring compliance with the Health and Safety at Work etc Act 1974, for associated NHS legislation and for ensuring this policy is effective.

6.2. Chief Nurse

The Chief Nurse is the Executive Director with responsibility for LNWH Governance & Quality and the process.

6.3. Medical Director

The Medical Director is the Executive Director with responsibility for LNWH Patient Safety.

6.4. The Chief Operating Officer (COO)

The COO is the Executive Director with responsibility for the provision of clinical services and works with the CN and MD to ensure the delivery of safe care.

6.5. Director of Estates and Facilities

Is the Executive Director with responsibility for LNWH Health and Safety and Security Management Director under the Counter Fraud Security Management Services.

6.6. Head of Governance

- Will provide expert advice on the Trust's risk management reporting system and processes.
- Ensure all relevant incidents are reported to the relevant agencies. e.g. National Reporting and Learning System (NRLS), Medicine & Healthcare Products Regulatory Authority (MHRA), Health & Safety Executive (HSE), Local Security Management Service (LSMS), Counter Fraud Management Service (CFMS).
- Oversee the production of regular incident reports, including frequency and severity of incidents and an overview of any trends to enable Divisions to evaluate what action(s) are in place and the effectiveness of these in reducing the likelihood of incidents reoccurring.
- Oversee the provision of reports to groups or committees, with a remit for risk management. This will include reports to the Trust Patient Safety and Quality Group, Clinical Quality and Risk Committee (CQ&RC) and external agencies as part of their governance and assurance process.
- Oversee all aspects risk management training to include:
    - Incident reporting training on staff induction.
    - Incident reporting to update staff in post.
    - Provide tools, advice and guidance on incident investigations [RCA]
    - Provide guidance and support for any SI investigation.
    - To maintain a database of Divisional SI trackers.

6.7. Head of Health & Safety

- To providing advice and guidance on all matters of Health and Safety Law, Regulations, Approved Codes of Practice and The Reporting of Injuries, Diseases & Dangerous Occurrences Regulations (RIDDOR).
- Ensure RIDDOR reportable incidents are reported to the Health & Safety Executive.
- Ensuring the provision of suitable Induction, Update and ad hoc Health and Safety Training is provided.
- Liaising with the Health and Safety Executive and other Enforcing Authorities as necessary.
- Undertaking Health and Safety monitoring, inspections and audits, in any Trust premises; of any work equipment; working environment / ward or department; work procedure/Safe Systems of Work.
- Liaising closely with Governance and Risk Managers, Occupational Health, Estates and Facilities, Unions and Safety Representatives, Infection Control, Community Services and all other clinical specialties and Contractors.

6.8. Line/Responsible Manager

People holding posts that have responsibility for a defined area and its resources e.g. Clinic Manager, District Nurse/Health Visitor Team Leader, Ward Manager, Supervisor, Department Manager, Team Leader Allied Health Professional. On notification of a completed Datix Form, the Line Manager will ensure that the form is completed correctly and all relevant information has been received and validated.

Following receipt of the Datix Form, the handler/Responsible Manager must log in and complete the Datix Form and an Initial Investigation Form (Appendix G) within 24 hours for red extreme incidents, 72 hours for Amber incidents and green incidents within 7 working days.

The Responsible Manager should also scrutinise the grade of the incident using the Grading Matrix (Appendix D) and amend if necessary or verify the risk grade made by the member of staff reporting the incident. This must be completed prior to being closed and submitted.

An investigation into an incident can only be carried out by the person who is reporting the incident if deemed low risk (green) and they are not directly responsible for the incident, otherwise an appropriate person will be appointed to investigate the matter dependent on the seriousness of the incident. If the incident is graded red, the Responsible Manager and Senior Manager/Clinician responsible for the area, service or department will be informed by the staff reporting the incident and via Datix. If the incident occurs that requires immediate action out of hours the Site Manager and the Director on call will take responsibility for the control measures within the specified time described above.

All incidents resulting in a Serious Incident will be reported immediately by the Responsible Manager to the Senior Manager/Clinician responsible for the area; and to the Governance Team in order for them to report the event on the StEIS system to the NHS England (Appendix H SI reporting chart). In office hours (09.00 – 17.00 hours, Monday to Friday) the incident should also be reported by the Governance Team to the Director of Nursing, the Medical Director or the responsible Executive Director. Out of hours it must be reported to the on-call member of the Management Team, via the Switch Board, who will escalate it as required.

6.9. Senior Manager/Clinician

For accidents, incidents and near misses graded red, in some cases amber, the Senior Manager/ Clinician will, following validation of the incident information, in conjunction with a member of the Divisional Triumverate/Executive Director decide on the next actions to be taken and organise a Strategy Meeting (in the case of a Serious Incident the meeting must be convened within 48 hours of the incident being known to the Senior Manager/Clinician) in order to establish the pathway that the investigation will follow. This meeting may include the:

- An Executive Director
- Line Manager
- Senior Manager/Clinician
- Head of Service
- Customer Services Team member (in the case where an investigation is required as a result of a complaint or claim)

The NPSA's Incident Decision Tree can assist in deciding what actions need to be taken following an incident. The Decision Tree can be found at the following link: http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59900

Under Duty of Candour requirements, the Senior Manager/Clinician is responsible for co-ordinating communication with the patient and their relatives/carers, liasing with the investigator and the Head of Service or Chair of the Strategy Group about the progress of the investigation and the future management of the patient. (See the Being Open Policy and the Complaints and Concerns Policy).

6.10. Affected/involved staff member

All staff who are involved in or witness an incident have a responsibility to report this via Datix. In the event of a serious incident a Datix MUST be completed immediately, in all other instances it should be completed by the end of the working shift.
The member of staff involved in or witness to any incident should take any necessary remedial action required to maintain the immediate safety of a patient or colleague etc. Any remedial action taken will be recorded on Datix. If remedial action includes medical/nursing/therapy care of a patient, this should be recorded in the patient's healthcare record.

6.11. Investigating Officer

A person within the organisation, who has undertaken Root Cause Analysis training or equivalent experience to act in the role of Investigating Officer and whose details are stored centrally within LNWH on a list of investigators. The current list of investigators is held by the Clinical Governance Department. The Investigating Officer must follow the RCA toolkit to undertake an investigation into a given incident, making recommendations to the Service involved. The Investigating Officer along with the patients clinician are responsible for ensuring that the Patient or their family receive feedback on the findings of the investigation and are offered a copy of the final SI Report.

6.12. Board, Committees and Sub-Committees

- **Role of London North West Health Care Trust Board**
  Has accountablity for effective risk management practices within the organisation, and to ensure that LNWH complies with its statutory obligations. The LNWH Trust Board will be assured that the organisation is managing the risk associated with incidents through the Integrated Governance reporting structure.
- **Role of the Integrated Governance Committee**
  Ensuring that appropriate strategies, frameworks and structures are in place across the organisation for risk management, health, safety and security including the monitoring and evaluation of actions taken and lessons learnt.
- **Role of Clinical Quality and Risk Committee and Corporate Quality and Risk Committee**
  To establish and maintain a system or mechanism for the precise and regular monitoring of incidents, SIs, investigations and lessons learnt. Assurance that mechanisms are in place will be gained through the clinical governance networks and sub groups.

6.13. External Stakeholder Information

Depending on the outcome or severity of the incident, certain government departments, NHS Institutions or Statutory bodies will need to be informed of the event. It is the responsibility of the Governance Team to report to external stakeholders. It is therefore essential that amber and red graded incidents are forwarded to the Governance Team within the standardised timescales (see below).

6.14. Health and Safety Executive (HSE) RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (1995) requirements

All incidents which fall within the catergory of RIDDOR should be reported to the HSE in accordance with guidelines. An event resulting in death will normally require police notification as well. The HSE and Police will then decide through their own reporting systems who will lead the investigation. Further details in relation to RIDDOR can be found in Appendix F.

Incidents that are reportable under (RIDDOR) will be notified to the HSE by the Governance Team when the incident report form is received or when contact is made if it is a major injury, or when an employee is off work for over 7 working days as a result of an accident.
Any absence of a member of staff for seven working days or longer following an adverse accident or incident at work is RIDDOR reportable. It is therefore essential that the Governance Team is informed as soon as it is known or suspected that a member of staff will be off work for more than 7 working days.

6.15. Strategic Executive Information System (StEIS)

NHS England (NHSE) require all NHS bodies within their area of responsibility to report all Serious Incidents (for SI definition see section 4.5) using the StEIS system. The Risk Manager is responsible for the reporting process and it is therefore essential that all SI's are reported to the Governance Team in order for them to meet these requirements.
All serious events must be reported to the Chief Nurse. Out of hours it must be reported to the on-call member of the Executive Team via the Hospital Switchboard. NHSE will then be notified immediately and at least within 48 hours of the event occurring. See SI flow chart Appendix H.

6.16. National Patient Safety Agency (NPSA)

All patient incidents are reported to the NPSA through the National Reporting and Learning System (NRLS) on a monthly basis by the Clincial Governance Team. Incidents resulting in severe harm or avoidable death and all allegations of abuse of a patient will also be reported within 48 hours to the NRLS.

6.17. NHS Counter Fraud Security Management Service (CFSMS)

All reported incidents involving violence to staff and patients will be sent electronically to the NHS Counter Fraud Security Management Service (CFSMS) using their SIRS.

6.18. Reporting of radiation exposures "greater than intended" to External Agencies

Under IR(ME)R (Ionising Radiation (Medical Exposure) Regulations 2000) If a patient (or volunteer, in the case of a research study) has received a radiation dose "greater than intended" or there has been a failure to follow a written protocol resulting in a dose being received where no dose was intended, LNWH must notify either the Department of Health, Care Quality Commission or HSE depending on the circumstances. Dose "multiplier

guidelines" have been published and these give advice on what constitutes "greater than intended". The Radiology Service Manager must be informed of the incident. The Radiology Service Manager will liaise with the Risk Manager as to determine whether an incident is to be investigated as a Serious Incident. The Radiology Service Manager may also liaise with the Director of Operations on sending out a letter of notification. For further detail on this, please see the Radiation Policy.

6.19. Reports to MHRA (Medicines and Healthcare products Regulatory Agency)

The reporting procedure to the MHRA is identified within the Medical Devices Policy.

7. COMMUNICATION AND NOTIFICATION

7.1. Communicating with the Patient and Family/Carers in the Event of an Incident

LNWH commits to openness and honesty, when communicating with patients and their carers, within the guidelines for consent (See Consent Policy) when an incident has occurred. (See Being Open Policy) (Duty of Candour – Appendix C). The patient and if appropriate their family must be informed if they are involved in an incident (Low, Moderate or High) and kept informed of the progress of any investigation. It is the responsibility of the Investigation Officer and the Patients Clinician to ensure that the Patient or their family are informed of the findings of the investigation and offered a copy of the final SI Report.

7.2. Media Management

In the event of a serious incident that is high risk (graded red) or an incident that involves a number of people, an Executive Director or on-call member of the Management Team must decide if the Communications Lead should be alerted and a media alert sent to the NHSM. Managers should be aware that red graded, high-risk events may attract public or media attention and managers should contact the LNWH Communication Lead for guidance on media handling within the Major Incident Plan.

7.3. Hotline arrangements

There may be circumstances where there are multiple enquiries needing to be responded to, or a complex, high profile incident needing well co-ordinated action planning and communications. In these events the Major Incident Room will be established, including hotline arrangements. Refer to the Major Incident Plan for further details.

8. INCIDENT INVESTIGATION

It is vital incidents are appropriately graded allowing the correct level of investigation to be undertaken. Service leads are required to look for trends and issues that may require further investigation. This will also be highlighted by the Aggregation of Compliments and Adverse Event Data document.

8.1. Incident Grading and Appropriate levels of investigations

- **Low Risk (Green Graded) Negligible and minor**
  Due to the low level of risk green graded incidents will form part of an aggregate review. Therefore only key information needs to be gathered. The Datix Incident

Form must be completed within 120 hours, further guidance is provided in Appendix D for investigating this level of incident.

- **Moderate Risk** (**Yellow graded**)
  Due to the level of risk, a local investigation will be required and findings together with any recommendations and lessons learnt to be recorded on Datix within 13 working days of the incident being reported.

- **Significant Risk (Amber Graded)**
  Due to the moderate level of risk, all amber graded incidents will be investigated using RCA investigation techniques in line with the RCA Guidance; this will be determined by the Senior Manager/Clinician. This allows the active failures (care/service delivery problems) and contributory factors to be indentified and recommendations to be made to address these. The Datix Incident form **and** Initial Investigation Report Form must be completed within 72 hours even if the full investigation is not yet complete.
  Any recommendations made will be brought by the Service involved to the Divisional Quality and Risk Group meeting to establish if organisational learning is appropriate.

- **High Risk (Red Graded)**
  Due to the high level of risk, the majority of red graded incidents should be investigated using RCA investigation techniques in line with the RCA Guidance; this will be determined by the Executive Director and appointed Chair dependant on the complexity and seriousness of the incident. A Non-Executive Director will be invited as the Chair or panel members for Never Event investigations. This allows the active failures (care/service delivery problems) and contributory factors to be indentified and recommendations to be made to address these. Datix Incident Report form **and** Initial Investigation Form must be completed within 24 hours of the incident. The Chair appointed must not be linked to the incident in such a way as to raise concerns about the independence of the investigation and its findings.

8.2. Responsibility for Investigation

There needs to be a degree of objectivity and independence in the investigation and for this reason those staff actively involved in the case will not be involved in conducting the investigation, unless this is deemed appropriate regarding some low risk green incidents.

- **Low Risk (Green Graded)**
  Accidents, incidents and near misses graded green will be investigated by the Responsible Manager with responsibility for the area or service involved, provided they are not directly involved in the incident, in such circumstances the Senior Manager will decide who will investigate the matter.
- **Moderate Risk (Yellow Graded)**
  Accidents, incidents and near misses graded yellow will also be investigated by the Responsible Manager or a nominated handler with responsibility for the area or service involved, provided they are not directly involved in the incident, in such circumstances the Senior Manager will decide who will investigate the matter.

- **Significant Risk (Amber Graded)**

The Responsible Manager/Senior Manager will determine what type and level of investigation is required and whether a Strategy Meeting is to be convened. An appropriate Investigation Officer will be appointed and if a RCA investigation is to be undertaken then the IO must be training in RCA techniques. An Investigation Pathway form must be completed by the Line Manager/Senior Manager during the meeting; which documents the route the investigation is to take and the Terms of Reference. This must be forwarded to the Governance Team.

- **High Risk (Red Graded)**
  A Strategy Meeting must be convened for confirmed red graded incidents (including Never Events); this will be arranged by the Senior Manager/ Clinician. An appropriate Investigation Officer, who must be trained in RCA techniques or have equivolent experience, will be appointed; LNWH have a list of trained investigators available from the Clinical Governance Team. To promote independence the Investigating Officer should be appointed from a different service to the one within which the incident took place. If the investigation is considered complex it may be appropriate to appoint an investigation team rather than an individual; this will be determined by the Senior Manager/Clinician. This offers independence and diversity of views and experience, counteracts bias and avoids traps that individuals might miss. In some cases it will be apparent that other organisations have been involved in the incident and the Senior Manager/Clinician will be responsible for liaising with other organisations with regard to inviting them to the Strategy Meeting and agreeing Terms of Reference.
  During the course of an investigation, it may become apparent that the issues first raised require a change in the direction of the investigation. In this instance, the Strategy meeting may need to reconvene in order to determine the route for the investigation. Where responsbility for implementation of any actions fall outside the Division, the Investigating Officer must notify and ensure the responsible Division takes ownership of the recommended actions before submitting the report for executive approval.

- **Serious Incidents (SIs)** See SI flow chart for process for reporting Appendix H. A member of the Divisional Triumverate/Investigation Chair will be responsible for convening a Strategy Meeting within the set timescales. An Investigating Officer will be appointed. The Lead Investigator must be trained in RCA investigation techniques or equivolent experience and to promote independence they should be appointed from a different service to the one within which the incident took place; there must be an investigator who has knowledge/expertise of the service and local procedures. The investigation may include an investigator from another Trust if there was another Organisation involved in the incident. The Lead Investigator will delegate various roles and responsibilities that will be accepted by the team and Terms of Reference agreed. The Investigation should be completed within the set timescales (see Appendix H). Where responsbility for implementation of any actions fall outside the Division, the Investigating Officer must notify and ensure the responsible Division takes ownership of the recommended actions before submitting the report for Executive approval. When complete the report will be approved by the Investigation Chair and a member of the Divisional Triumverate and then forwarded to the Governance Team to ensure it meets the Commissioners criteria, prior to it being forwarded to the Executive SI Review Panel. In addition to the above:

All incidents of reported MRSA and C Diff will be investigated.

The level of investigation undertaken into reported pressure ulcers will be determined by the Service Lead. For further information with regard to the process for investigation please see the RCA Guidance.

- **Trained Investigators**
  Each service area should have at least one person trained to undertake investigations at all levels. Within LNWH there are a number of experienced staff from various backgrounds who have undertaken appropriate training and are skilled and experienced in undertaking investigations; the list of trained investigators is maintained by the Governance Team.

  Staff who are trained investigators will be called upon on a cyclical basis to lead these investigations and are required to participate in red and amber graded investigations on a regular basis to maintain their competencies.

  An RCA Guidance and a toolkit is available for all investigators this includes standardised templates that must be followed and completed by all investigators.

8.3. Recommendations and Action Planning

For all investigations the Investigating Officer will compile a full report using the templates and guidance in the RCA Guidance. Root Causes and contributory factors will be identified and recommendations made. An action plan will be developed with the aim of eliminating or reducing the risk of the incident from recurring; this will include persons responsible for delivering the actions and the date for completion. The final report, recommendations, and action plan must be forwarded to the Senior Manager/Clinician in the area concerned, the SI Strategy Group, the patient and or family affected, all staff involved in the incident and the Divisional Quality and Risk Group meeting.

- **Monitoring of action plans and continual risk reduction**
  All action plans will be monitored via the Divisional Quality and Risk Group Meetings and learning will be disseminated through local established communication mechanisms e.g. team meetings. In addition, regular reporting on investigations will take place as a regular agenda item in all clinical governance networks and sub-groups. The investigation reports and recommendations from all incidents, green, amber and red, will be analysed on a regular basis to identify themes. Identified themes will be discussed and reported to the Clinical Quality and Risk Committee to provide assurance to the LNWH Board that appropriate actions are being taken and that there is a robust process for organisational learning. Regular reports will be prepared with the Clinical Quality and Risk Committee Groups and a report will be presented by the Divisiona to the Clincial Quality and Risk Committee.

  In addition, significant risks should be documented on Divisional Risk Registers for monitoring and the Divisional Quality and Risk Group and possible escalation to the Corporate Risk Register and escalation to the LNWH Board through the Integrated Governance Committee. The risk escalation process can be found in the Risk Management Strategy.
- **Lessons Learnt**

The sharing of lessons learnt following an investigation is a critical part of incident management. In order to prevent or reduce the likelihood of a further occurence, a systematic approach to the analysis of incidents, complaints and claims should be in place as part of the risk management process. This should include:

- Organisational sharing of learning.
- Local implementation of action plans.
- Links between claims, complaints and incidents management; - Aggregation of Compliments and Adverse Event Data.
- Identification of risks and inclusion on risk register.
- Reviewing and implementing best practice from other Trusts and organisations.

- Where a Department or area has successfully implemented an action plan or recommendations to reduce or remove care/system delivery failures, evidence must be presented to the Divisional Quality and Risk Group (and minuted) to demonstrate that lessons have been learnt.

- A number of methods will be used to disseminate information and communicate lessons learnt including:
  - Team meetings
  - LNWH Daily Bulletin
  - Governance Groups
  - Lessons Learnt/Audit Sessions
  - Intranet

9. TRAINING AND EDUCATION

9.1. Training in incident reporting procedures, guidance on how to complete the Trust's Datix incident reporting form, how to investigate and apply a grade, and identify action[s] required to reduce the risk of reoccurrence will form part of all staff induction to the Trust and the annual mandatory training for all staff. Training will be provided to update staff in post and the Risk Management team will on request provide advice and guidance on incident investigations.

9.2. Use of the Datix Incident Reporting System can be sought via the appropriate intranet guides in respect of reporting or investigating an incident. If a staff member requires further assistance they can contact the Risk Management Team.

9.3. Members of staff who may be called on to take part in an SI investigation Panel should access the root cause analysis training or seek advice and guidance from the Clinical Governance Team. The communications department will advise on any press/media interest.

9.4. Training, support and supervision to enable staff to implement the lessons learnt from investigations will be dependent on the findings of the investigation and will be available from professional leads and the Clinical Governance team.

10. POLICY GOVERNANCE

10.1. Monitoring and Review of Policy

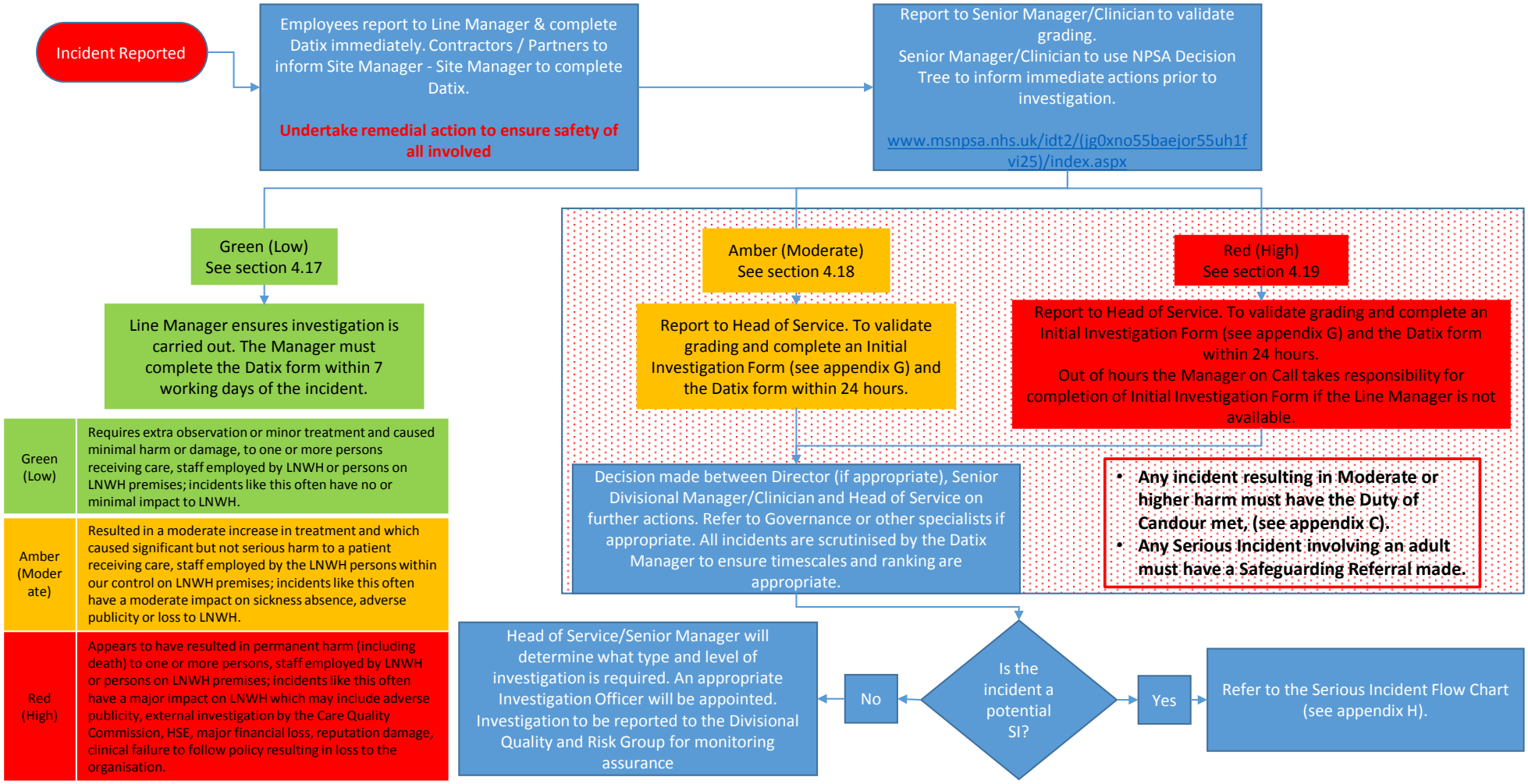
Implementation of this policy will be monitored via the Integrated Governance Committee.

11. LIST OF APPENDICES

Appendix A	Organisational Incident Reporting Pathway.
Appendix B	Never Event List.
Appendix C	Duty of Candour.
Appendix D	Grading Matrix.
Appendix E	Investigation Procedure for Adverse Accident, Incident and Near Misses.
Appendix F	The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (1995) RIDDOR.
Appendix G	Initial Investigation Form.
Appendix H	Flow chart for reporting Serious Incidents.
Appendix I	Process for Reporting to External Agencies.
Appendix J	SI Report Template
Appendix K	PU SI Notification Form

APPENDIX A

LNWH ORGANISATIONAL INCIDENT REPORTING PATHWAY v5 – (Incident Reporting and Investigation Policy)



APPENDIX B

NEVER EVENT LIST 2015/16

1. Wrong site surgery.
2. Wrong implant/prosthesis.
3. Retained foreign object post-procedure.
4. Mis–selection of a strong potassium containing solution.
5. Wrong route administration of medication.
6. Overdose of Insulin due to abbreviations or incorrect device.
7. Overdose of methotrexate for non-cancer treatment.
8. Mis–selection of high strength midazolam during conscious sedation.
9. Failure to install functional collapsible shower or curtain rails.
10. Falls from poorly restricted windows.
11. Chest or neck entrapment in bedrails.
12. Transfusion or transplantation of ABO-incompatible blood components or organs.
13. Misplaced naso- or oro-gastric tubes.
14. Scalding of patients.

Details of the Never Event categories can be found in the Never Events List 2015/16 (NHS England, 2015).

http://www.england.nhs.uk/ourwork/patientsafety/never-events/

APPENDIX C
DUTY OF CANDOUR

1. The contractual duty of candour applies to patient safety incidents that occur during care provided under the care of the London North West Healthcare NHS Trust and that result in moderate harm, severe harm or death that are reported onto the Datix risk management system. It does not apply to no harm/low harm incidents.

2. There should be an appropriate investigation by the Manager of the ward/department/team to establish the facts and determine whether moderate, severe harm or death has resulted.

3. The patient or their family/carer must be informed by the manager or senior manager of the ward/department/team or consultant that a suspected or actual patient safety incident has occurred within at most 10 working days of the incident being reported onto Datix, and sooner where possible. Incidents may be identified well after they take place but "the clock starts ticking" when the incident is reported onto Datix risk management system.

4. The initial notification must be verbal (face to face where possible) by the manager or senior manager of the ward/department/team or consultant, unless the patient cannot be contacted in person or declines notification. Providers must take into account any circumstances that will affect the ease of communication with the patient (language barriers, communication difficulties, relevant disability).

5. The verbal notification must be accompanied by a written notification the only circumstances the patient would not receive this is if a patient clearly notes they do not wish to receive a written notification. The verbal and written notifications must be recorded on the Datix Incident Form.

6. It may initially be unclear whether a patient safety incident has occurred, or what degree is harm was caused. This is not a reason to avoid disclosure. Patients or their carers/families must be told if there is a suspected patient safety incident that might involve moderate or severe harm or death within 10 working days of the incident being reported. They should be given all the facts that are known at the time, and be kept updated throughout the process of investigation.

7. An apology must be provided – a sincere expression of sorrow or regret for the harm caused must be provided for verbally and in writing by the manager or senior manager of the ward/department/team or consultant. This does not require fault to have been demonstrated. The Trusts Being Open policy provides more details on how to apologise. Expressing regret for harm caused is not the same as admitting liability and the risk of litigation should not prevent an apology.

8. A step-by-step explanation of what happened, in "plain English", based on the facts must be offered as soon as is practicable by the manager or senior manager of the ward/department/team or consultant. This may constitute an initial view, pending an investigation, but patients and families must be kept informed of progress.

9. Full written documentation of any meeting must be maintained, and attached to the Datix incident form by the lead manager or consultant. If the patient or their family/carer

explicitly decline any offers of meetings, this must be clearly recorded on the Datix incident form and a copy of any report can still be provided to the patient or their family/carer unless they decline this too, in which case this must be clearly recorded on the Datix incident form.

10. Information that emerges during an investigation or subsequent to the initial explanation must be offered to patients and their carers/families as soon as is practical by the manager or senior manager of the ward/department/team or consultant. It is helpful to establish regular updates with affected individuals. Any incident investigation reports (Serious Incident report) must be shared within 10 working days of being signed off by the Executive Team. This includes action plans and the details of investigations and means the actual written reports and, if necessary, plain English explanations of their contents. It is the responsibility of the Investigation Officer and the Patients Clinician to ensure that the Patient or their family are informed of the findings of the investigation and offered a copy of the final SI Report.

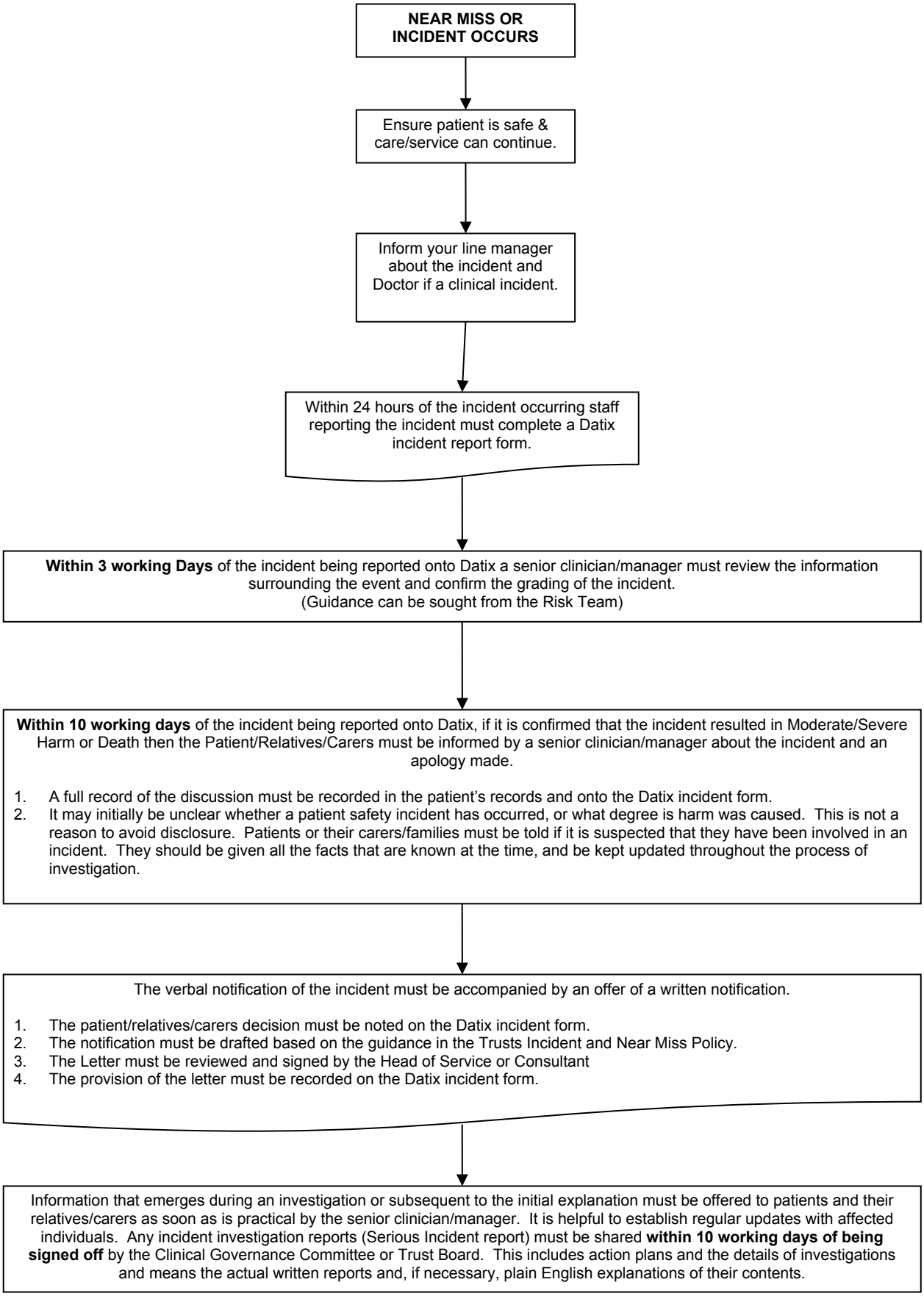
11. The Trust will make available to Commissioners upon request detail of incidents under the Duty of Candour and relevant auditable actions, i.e. communication with patients or their relatives/carers.

12. If the Commissioners become aware of an incident that was not reported, but should have been reported on the Trusts Datix Incident Reporting system. The original clinical incident should be reported and investigated, as well as reporting and investigating the failure to report the clinical incident. The Commissioners may refer the failure to report to the Care Quality Commission (CQC).

13. The Trust must inform the Commissioners if it learns, for example, through a complaint, that there has been a failure to report a clinical incident under the Duty of Candour. Consequences as highlighted above in section 11 may result.

14. Other consequences to not reporting and managing an incident under the Duty of Candour may include:
    - Requiring a direct written apology and explanation for the breach to the individual(s) affected from the Trusts Chief Executive;
    - Publication of the fact of a breach prominently on the Trusts website;
    - Notification to CQC by the Commissioner;
    - Recovery of the cost of the episode of care or £10,000 if the cost of the episode of care is unknown.

15. For further information please look at the Trusts intranet pages: http://lnwhintranet/departments/clinical-governance/duty-of-candour/


NEAR MISS OR INCIDENT OCCURS
Ensure patient is safe & care/service can continue.
Inform your line manager about the incident and Doctor if a clinical incident.
Within 24 hours of the incident occurring staff reporting the incident must complete a Datix incident report form.
Within 3 working Days of the incident being reported onto Datix a senior clinician/manager must review the information surrounding the event and confirm the grading of the incident.
(Guidance can be sought from the Risk Team)
Within 10 working days of the incident being reported onto Datix, if it is confirmed that the incident resulted in Moderate/Severe Harm or Death then the Patient/Relatives/Carers must be informed by a senior clinician/manager about the incident and an apology made.
1. A full record of the discussion must be recorded in the patient's records and onto the Datix incident form.
2. It may initially be unclear whether a patient safety incident has occurred, or what degree is harm was caused. This is not a reason to avoid disclosure. Patients or their carers/families must be told if it is suspected that they have been involved in an incident. They should be given all the facts that are known at the time, and be kept updated throughout the process of investigation.
The verbal notification of the incident must be accompanied by an offer of a written notification.
1. The patient/relatives/carers decision must be noted on the Datix incident form.
2. The notification must be drafted based on the guidance in the Trusts Incident and Near Miss Policy.
3. The Letter must be reviewed and signed by the Head of Service or Consultant
4. The provision of the letter must be recorded on the Datix incident form.
Information that emerges during an investigation or subsequent to the initial explanation must be offered to patients and their relatives/carers as soon as is practical by the senior clinician/manager. It is helpful to establish regular updates with affected individuals. Any incident investigation reports (Serious Incident report) must be shared within 10 working days of being signed off by the Clinical Governance Committee or Trust Board. This includes action plans and the details of investigations and means the actual written reports and, if necessary, plain English explanations of their contents.

APPENDIX D
GRADING MATRIX

Table 1 Consequence scores

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

See http://www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/risk-assessment-guides/risk-matrix-for-risk-managers/ for word version of the matrix

	Consequence score (severity levels) and examples of descriptors				
	1	**2**	**3**	**4**	**5**
Domains	**Negligible**	**Minor**	**Moderate**	**Major**	**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 if unresolved	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 implications if findings are not acted on	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

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
Statutory duty/ inspections	No or minimal impact or breech of guidance/ statutory duty	Breech of statutory legislation Reduced performance rating if unresolved	Single breech in statutory duty Challenging external recommendations/ improvement notice	Enforcement action Multiple breeches in statutory duty Improvement notices Low performance rating Critical report	Multiple breeches in statutory duty Prosecution Complete systems change required Zero performance rating Severely critical report
Adverse publicity/ reputation	Rumours Potential for public concern	Local media coverage – short-term reduction in public confidence Elements of public expectation not being met	Local media coverage – long-term reduction in public confidence	National media coverage with <3 days service well below reasonable public expectation	National media coverage with >3 days service well below reasonable public expectation. MP concerned (questions in the House) Total loss of public confidence
Business objectives/ projects	Insignificant cost increase/ schedule slippage	<5 per cent over project budget Schedule slippage	5–10 per cent over project budget Schedule slippage	Non-compliance with national 10–25 per cent over project budget Schedule slippage Key objectives not met	Incident leading >25 per cent over project budget Schedule slippage Key objectives not met
Finance including claims	Small loss Risk of claim remote	Loss of 0.1–0.25 per cent of budget Claim less than £10,000	Loss of 0.25–0.5 per cent of budget Claim(s) between £10,000 and £100,000	Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget Claim(s) between £100,000 and £1 million Purchasers failing to pay on time	Non-delivery of key objective/ Loss of >1 per cent of budget Failure to meet specification/ slippage Loss of contract / payment by results Claim(s) >£1 million
Service/business interruption Environmental impact	Loss/interruption of >1 hour Minimal or no impact on the environment	Loss/interruption of >8 hours Minor impact on environment	Loss/interruption of >1 day Moderate impact on environment	Loss/interruption of >1 week Major impact on environment	Permanent loss of service or facility Catastrophic impact on environment

Table 2 Likelihood score (L)

What is the likelihood of the consequence occurring?
The frequency-based score is appropriate in most circumstances and is easier to identify. It should be used whenever it is possible to identify a frequency.

Likelihood score	1	2	3	4	5
Descriptor	Rare	Unlikely	Possible	Likely	Almost certain
Frequency How often might it/does it happen	This will probably never happen/recur	Do not expect it to happen/recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen/recur but it is not a persisting issue	Will undoubtedly happen/recur, possibly frequently

Table 3 Risk Scoring = Consequence x Likelihood (C x L)

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

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

1 - 3	Low risk
4 - 6	Moderate risk
8 - 12	High risk
15 - 25	Extreme risk

Instructions for use – Grading Matrix

1 Define the risk(s) explicitly in terms of the adverse consequence(s) that might arise from the risk.

2 Use table 1 (page 27) to determine the consequence score(s) (C) for the potential adverse outcome(s) relevant to the risk being evaluated.

3 Use table 2 (above) to determine the likelihood score(s) (L) for those adverse outcomes. If possible, score the likelihood by assigning a predicted frequency of occurrence of the adverse outcome. If this is not possible, assign a probability to the adverse outcome occurring within a given time frame, such as the lifetime of a project or a patient care episode. If it is not possible to determine a numerical probability then use the probability descriptions to determine the most appropriate score.

4 Calculate the risk score the risk multiplying the consequence by the likelihood: C (consequence) x L (likelihood) = R (risk score)

5 Identify the level at which the risk will be managed in the organisation, assign priorities for remedial action, and determine whether risks are to be accepted on the basis of the colour bandings and risk ratings, and the organisation's risk management system. Include the risk in the organisation risk register at the appropriate level.

Appendix E

Investigation Procedure for Adverse Accident, Incident and Near Misses Graded Green (Low Risk)

Line Manager's Responsibility

Check Information

On receipt of the verbal report of the accident, incident or near miss or a completed Datix report form, ensure that the following information has been received and validated.

- Nature of the Incident.
- Outcome (i.e. the severity of the consequence of the accident, incident or near miss).
- Date and time of the incident.
- Any remedial action or communication taken to date.
- Using the information above, assess and record and grade the incident, using LNWHs Grading matrix, see Appendix D.

Immediate Actions

Line Manager's Responsibility

- Ensure that any implicated equipment is withdrawn from service and the item replaced. Do not let equipment be taken away keep safe for future reference if necessary.
- Discuss with Senior Manager if you feel that a particular procedure, process or intervention needs to be withdrawn, until the investigation is completed.
- Liaise with the incident reporter to verify facts.
- With appropriate Senior and Clinician support the Line Manager must inform the patient/family that they have been involved in an incident.
- Undertake a brief investigation, in line with the above principles, to establish the immediate and underlying causes of the incident.
- If during the brief investigation facts come to light that indicate a higher level of investigation is required, the investigation should be escalated to the next level (medium risk, amber graded) and reported to the Senior Manager for a decision on the level of investigation.

Post Investigation Actions

- Review the findings of the investigation and assess the information/evidence
- Re-assess the grading of the event based on the information/evidence gathered during the investigation.
- With appropriate Senior and Clinician support the Line Manager must inform the patient/family of the findings of the investigation.
- Provide recommendations and feedback to the staff member, team, service that reported the incident and develop an action plan to address any failings if appropriate.
- Report to Senior Manager who will record and identify trends within their area.
- Green graded incidents will be monitored through the Datix system to identify trends Trust wide.

THE REPORTING OF INJURIES, DISEASES AND DANGEROUS OCCURRENCES REGULATIONS (1995) (RIDDOR)

The following events are RIDDOR reportable and should immediately be reported to a member of the Health & Safety Team.

1. The **death** of any person as a result of an accident arising out of or in connection with work activity;

2. Any person at work suffering any of certain injuries or conditions as a result of an accident arising out of or in connection with work, including:
    - **Fracture of any bone** except in the hand or foot
    - **Amputation** of: a hand or foot; or a finger, thumb or toe
    - **Loss of sight** of an eye or serious injury to the eye
    - Injury as a result of **electric shock**
    - **Loss of consciousness resulting from lack of oxygen**
    - Acute illness requiring medical treatment, or loss of consciousness, resulting from **absorption of any substance by inhalation, ingestion or through the skin**
    - **Acute illness** requiring medical treatment resulting from exposure to a **pathogen (such as a bacterium or virus) or infected material**
    - Any other injury that results in the employer injured being **admitted immediately into hospital for more than twenty-four hours**

    Please note this list is not exhaustive

3. Any **dangerous occurrence,** i.e. collapse overturning or failure of load bearing parts of lifts and lifting equipment.

4. An employee or other person at work **being unable to perform their normal duties for normal work for more than 7 (seven) working days** as a result of an injury caused by an accident at work.

5. The **death of an employee** if this occurs sometime after the reportable injury that led to the employee's death, but not for more than one year afterwards.

6. Retain RIDDOR reports for a minimum of 3 years.

7. Diseases – Including Dermatitis, occupational Asthma etc.

8. Member of the public taken directly to hospital as a result of or in connection with a work activity.

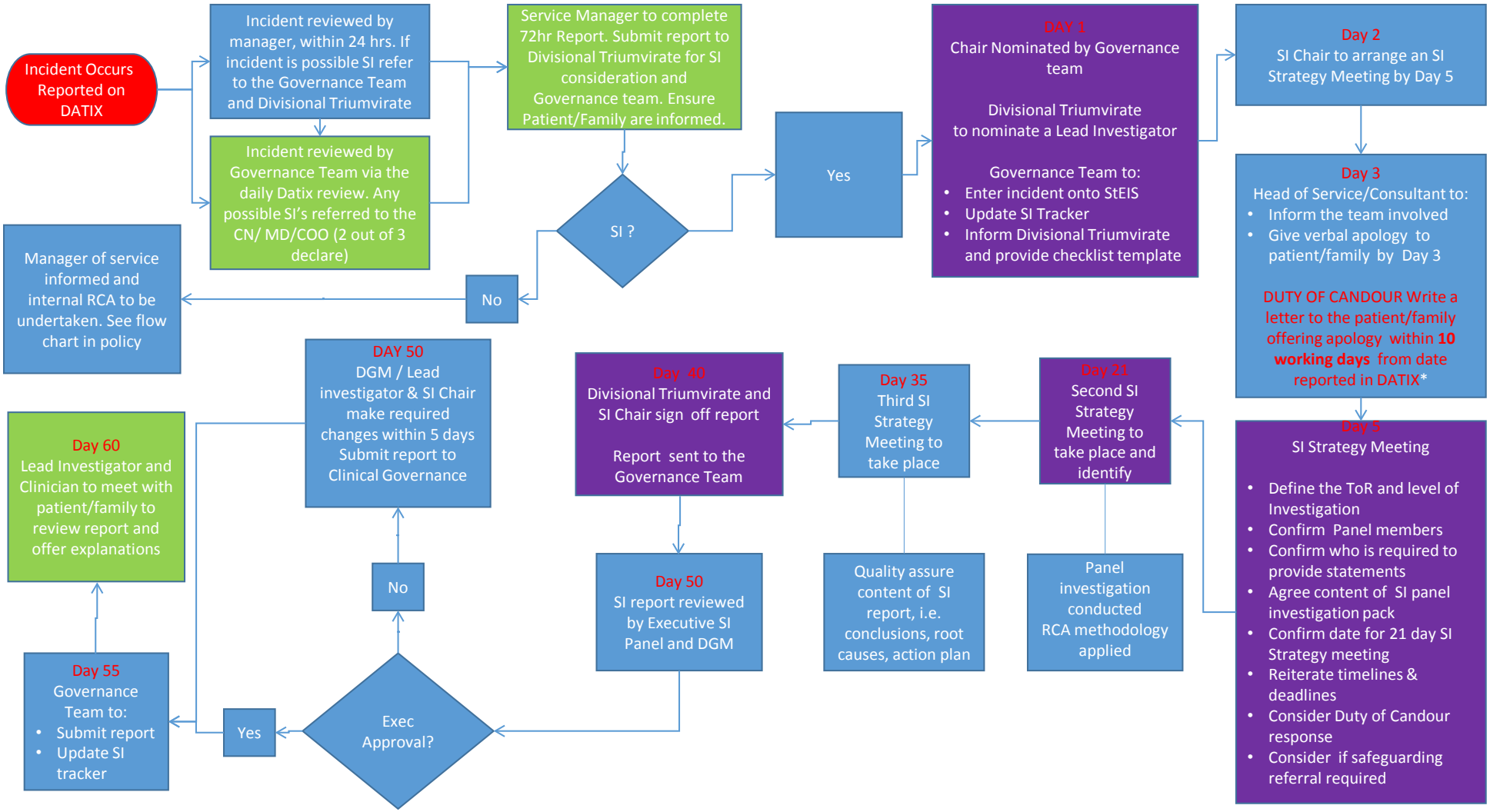
APPENDIX G
INITIAL INVESTIGATION FORM (72 HOUR REPORT)

INCIDENT INITIAL INVESTIGATION FORM
FOR ESCLATION OF POTENTIAL SERIOUS INCIDENTS

Details of the person completing the form	**Name**	
	Contact Details	
Datix Number		
Initial Grading of the incident		
Incident Date		
Location of the incident		
Lead Division for the investigation		
Details of the person affected by the incident	**Name**	
	Hosp/NHS N°	
	DoB	
	Borough of residence	
Duty of Candour	**Who informed the patient/NoK?**	
	Date	
	Has an apology been given?	
	Has an offer been made to provide follow up in writing to the patient/NoK?	
A CONCISE, clear and factual description of what happened. Clearly and briefly describe the incident – including an indication of any care or service issues identified which may have contributed.		
Describe the harm to the affected person		
Immediate mitigating actions taken		
List of concerns identified		
Name of proposed <u>Lead Investigator</u> (To be nominated by the Divisional Triumvirate)		
Proposed Link Patient Contact – requires regular updates on the investigation process for Duty of Candour		
Proposed Staff Debrief Lead (During and post the investigation)		
SI Chair (To be decided by the CG Team based on the SI Chair Rota)		
Any other comments		
StEIS Number		
Date Incident Reported on to StEIS (day 0)		
SI Chair and Lead Investigator to arrange a First SI Strategy Meeting by Day 5	**Due Date**	**Actual Date of Meeting**

Second SI Strategy Meeting (Day 21)	**Due Date**	**Actual Date of Meeting**
Third SI Strategy Meeting (if required) (Day 28)	**Due Date**	**Actual Date of Meeting**
Report due for Divisional Triumvirate sign off by (35 working days)		
Report due for Executive sign off by (40 working days)		
Report due for submission to the Commissioners by (60 working days)		

Appendix H – Serious Incident Procedure



APPENDIX I
PROCESS FOR REPORTING TO EXTERNAL AGENCIES

All identified Serious Incidents must be notified to relevant bodies within two working days of the incident occurring.

Type of Incident	Agency	Responsible Person	Reporting Requirements
All Patient Safety Incidents	NPSA via NRLS	Risk Manager	All patient safety incidents are downloaded to the NRLS on a monthly basis
Any accident or injury at work which results in an employee being unable to return to work or unable to carry out their normal duties for 7 days or more.	Health & Safety Executive RIDDOR	Head of Health & Safety or in their absence a nominated reporter	Staff/Incidents in Ealing Hospital Report to the Health & Safety Advisor and/or the Head of Health Safety. The Health & Safety Advisor /Head of Health & Safety will report to HSE accidents or injury occurring RIDDOR Staff/incidents in Community Services Report to the Health & Safety Advisor and/or the Head of Health Safety. The Health & Safety Advisor /Head of Health & Safety will report to HSE accidents or injury occurring RIDDOR Staff/incidents in Northwick Park, Central Middlesex or St Mark's Hospitals Report to the Health & Safety ManagerAdvisor and/or the Head of Health Safety. The Health & Safety ManagerAdvisor /Head of Health & Safety will report to HSE accidents or injury occurring RIDDOR RIDDOR events are not just to staff they occur to patients and visitors too.

Type of Incident	Agency	Responsible Person	Reporting Requirements
Safeguarding incidents	The LSAB/LSCB and Independent Safeguarding Authority (ISA) and professional bodies	Children – Trust Lead/Chief Nurse/Designated Doctor Adults – Chief Nurse	Where appropriate, referrals of incidents and/or individuals to the LSAB/LSCB and Independent Safeguarding Authority (ISA) and professional bodies are made Where the incident involves a child or young person, considerations should be given to raising the alert as a Serious Incident under section 8 of *Working Together to Safeguard Children*,7 which relates to the Children Acts 1989 and 2004 If the incident involves vulnerable adults, an alert should be raised as described in *No Secrets* Guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse. DH & Home Office 2000 NHS organisations in partnership with the SAB/ SCB should have local policies for implementing the findings from SCR, a process to report to their own boards and action plans to implement and monitor changes in practice.
Physical assaults on staff	NHS Protect	Local Security Management Specialist [LSMS]	Staff must report all incidents of assualt on Datix and report to the Local Security Management Specialist who will report all incidents of abuse the via the Security management reporting systems [SIRS]
Major injury and dangerous occurrences	Health & Safety Executive RIDDOR reporting	Director of Estates and Facilities	Reported to the Incident Contact Centre on 0845 30009923 in the case of a death Complete relevant RIDDOR form www.riddor.gov.uk Head of Health & Safety/ Health & Safety Manager/Advisor must be informed

Type of Incident	Agency	Responsible Person	Reporting Requirements
Abuse	Local Security Management Specialist [LSMS]	Local Security Management Specialist [LSMS]	Staff must report all incidents of abuse on Datix and report to the Local Security Management Specialist who will report all incidents of abuse the via the Security management reporting systems [SIRS]
Fire that results in injury to individuals or severe property loss	NHS Estates Health & Safety Executive	Fire Officer	Report to NHS Estates Complete relevant form on www.riddor.gov.uk
Equipment failure The equipment [including medical devices] should be retained untouched and in safe keeping for examination	MHRA	EBME Manager	Where immediate action is indicated the sequence of reporting should be made by telephone followed up by a written reports Any incident must be reported to the Risk manager who is responsible for reporting to the MHRA
		Risk Manager	Report must be made to the MHRA www.mhra.gov.uk Telephone reports ONLY for those involving death, serious injury or serious public harm concerns
Blood Transfusion incident	MHRA Serious Adverse Blood Reactions and Incidents (SABRE)	Transfusion Practitioner	Online reporting system **SABRE** Voluntary reporting to **SHOT**
Unexpected outcome from a drug	MHRA	Chief Pharmacist	Report must be made to the MHRA www.mhra.gov.uk Telephone reports ONLY for those involving death, serious injury or serious public harm concerns
Ionising Radiation	CQC and HSE	Radiation Protection Supervisor / Radiation Protection Advisor	As per requirements of IR(ME)R and Ionising Radiation Regulations

Type of Incident	Agency	Responsible Person	Reporting Requirements
All SI	NHS England / Commissioners. If required appropriate information to other relevant bodies e.g. CQC, TDA, HM Coroner, Police Health & Safety Executive, NPSA, Public Health England, GMC, NMC, other NHS agencies / organisations	Head of Clinical Governance	Incidents reported on The Strategic Executive Information System [STEIS] http://nww.steis.doh.nhs.uk/steis/steis.nsf/steismain?readform Out of hours urgent notification should be made to 08700 555 500 Pager #LON 01 **APPENDIX D** Flowchart for reporting
Serious Incident in Colposcopy	As with SI above.	Head of Clinical Governance	In addition to the SI process, there are specific processes to follow for Serious Incident involving Colposcopy Services. Please see the Trusts policy "Guidance on Serious Incidents [SI] in Cervical Screening" [NHS CSP No 11]
National Screening Programmes covering: • NHS Breast Screening Programme. • NHS Cervical Screening Programme. • NHS Bowel Cancer Screening Programme. • NHS Diabetic Eye Screening Programme. • NHS Abdominal Aortic Aneurysm Screening Programme. • NHS Foetal Anomaly Screening Programme. • NHS Infectious Diseases in Pregnancy Screening Programme. • NHS Sickle Cell and Thalassaemia Screening Programme. • NHS Newborn Blood Spot Screening Programme. • NHS Newborn Hearing Screening Programme. • NHS Newborn and Infant Physical Examination Screening Programme.	NHS Screening Programmes, NHS Cancer Screening Programmes and NHS England	Clinical Directors	Please use the Managing Safety Incidents in NHS Screening Programmes (updated August 2017).

APPENDIX J
SI REPORT TEMPLATE

Serious Incident Investigation Report

Incident Type	
Incident Date	
Incident Report Date	
StEIS Reference	
Datix Reference	
Author of report	
Divisional Approval (DGM, HoN or DCD and Date)	
Executive Approval (Title and Date)	

Please note an SI report should include the names of SI panel members but must not include the names or initials of any individuals, staff, patient or relative/ carer as this would be deemed a breach of confidentiality.

1 Reasons for the Inquiry - to include the incident severity, how the incident was detected and the level of Investigation

2 Incident description, consequences and incident date pre investigation risk assessment

3 Initial report – background and context

4 Inquiry panel's Terms of Reference
Members of the panel

5 Conduct of the Inquiry/Information and evidence gathering

6 Involvement and support of patient/relatives – Duty of Candour

7 Involvement and support provided for staff

8 Actual effect on patient/actual effect on service

9 Clear, fact based chronology of events leading up to the incident

10 Any Care and/or Service delivery problems

11 Contributory factors

12 Root Causes
Reference the RCA methodology used

13 Any Notable practice

14 Lessons learnt

15 Report considered for adult safeguarding concerns

16 Post investigation risk assessment

17 Conclusions

18 Recommendations

19 Identification of any Policies that have been review as a result of this investigation

20 Arrangements for shared learning

21 Comprehensive Action Plan

1. **Reason for the Inquiry to include the incident severity, how the incident was detected and the level of Investigation.**

2. **Incident Description, consequences, incident date and the pre-investigation risk assessment.**

3. **Initial Report, background and context**

4. **Inquiry Panel's Terms of Reference**

Members of the Panel

5. **Conduct of the Inquiry / Information and evidence gathering**

6. **Involvement and support of patient / relatives**

7. **Involvement and support provided for staff**

8. **Actual effect on the patient & actual effect on the service**

9. **Chronology of events leading up to the incident**

10. **Any Care and/or service delivery problems**

11. **Contributory factors**

12. **Root Causes**
    What RCA methodology was applied?

Factor	Root Cause
Patient Related	1.
Work Environment	1.
Staff-related	1.
Task Factors	1.
Communication	1.
Education and Training	1.
Team factors	1.
Strategic priorities	1.
Equipment	1.

13. Notable Practice

14. Lessons learnt

15. Report considered for adult safeguarding concerns

16. Post-investigation risk assessment

17. Conclusions

18. Recommendations

19. Identification of any Policies that have been review as a result of this investigation

20. Arrangements for shared learning

21. Monitoring arrangements for actions

Action plan – See Appendix A

Concerns (Identified by Root Cause Analysis Care & Service Delivery Problems Contributory Factors Effect on patient)	**Action** (List specific tasks required to mitigate the concerns)	**Senior Divisional Lead**	**Operational Lead** (Who is responsible for the Action)	**Timescale to complete**			**Output** (What evidence will be required (and saved to Datix) to demonstrate completion).	**Monitoring Group/ Committee** (Which Divisional group will monitor the progress of the Action)	**Signoff Committee** (Which Committee will Signoff to Endorse completion of the Action)
				Date Action Started	Date Action is to be Completed by	Date Completed the action was Completed			

Appendix A

An SI report will include a number of recommendations which aim to eliminate or reduce the risk of the incident reoccurring. The recommendations, based on the root cause(s), care and service delivery problems, contributory factors and the effect on the patient, will inform the action plan. The purpose of the action plan, which is the final and crucial stage in an SI investigation, is to identify, monitor and address tasks to improve patient / staff / environmental safety. The Directorate / Borough is responsible for monitoring SI investigation action plans.

1. The recommendations within an SI investigation report must be turned into actions with specific tasks stating clearly what is to be accomplished for each task.
2. A task must have a goal that is measurable and therefore it is possible to monitor progress.
3. The starting point must be clear so it is possible to tell what is to be achieved and when
4. To ensure a task is achievable break it down into step by step goals
5. The tasks / goals are relevant – consistent with what is to be achieved and within the scope of the operational leads to achieve them.
6. The action / task must have a timeframe in which the task will be completed and must be realistic taking all elements of the task/action into account when finalising a completion date.
7. The action plan must be reviewed at Directorate / Borough Clinical Governance meetings until all action are completed
8. Tasks which are passed completion date must be exception reported into the Trust ICO Clinical Governance Committee along with how the outstanding task will be completed.

APPENDIX K
PU SI NOTIFICATION FORM

Pressure Ulcer SI Notification

*Form to be completed and sent to Clinical Governance within **48hrs of incident being identified** for onward reporting*

Incident Date	
Datix reference	
Patient name / Hospital number	
Ethnic Background	
Borough of the patient	
Patient DOB	
GP Surgery Name /Postcode	
Site / Ward	
Speciality	
Was this a planned admission?	
Where was the patient at the time of SI notification (i.e. at home, still in hospital etc.)?	
StEIS reference *(to be completed by Patient Safety team)*	
StEIS due date *(to be completed by Patient Safety team)*	
Duty of Candour (Being Open) **Briefly comment has the family been informed of the incident? Who and when did the discussion take place? What was said etc.**	
Description of Pressure Ulcer:	
Pressure Ulcer Confirmed by (2 SENIOR NURSE or TVN): PRINT Name and Designation **Confirmer: Ward Manager or Matron plus Head of Nursing or another Matron** **Name: _____ Name: _____** **Designation: _____ Designation: _____** **Date of confirmation: _____** **PU Grade: _____** **PU Site: _____** **PU Origin (ward): _____**	
Planned RCA meeting date	