Great Ormond Street Hospital for Children NHS Foundation Trust

Incident Reporting and Management Policy

LEAD EXECUTIVE DIRECTOR:	**Medical Director**
POLICY APPROVED BY:	Policy Approval Group
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	Document Control Sheet
Policy Title	**Incident Reporting and Management Policy**
Purpose of Policy/ Assurance Statement	Incident reporting provides an opportunity for adverse events to be documented, analysed and used for learning and improvements in practice. It is a key requirement to improve patient safety and is an important way of assuring staff, patients and the public that systems for managing risk are robust and effective. This policy defines the procedures and actions to be taken by staff in response to an incident and details individual and organisational responsibilities. The overriding emphasis is to identify why mistakes have occurred and to learn from the process, not to attribute blame and punish.
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Lead Executive Director	Medical Director
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Circulated for Consultation to (*Please list Committee/Group Names*):	Patient Safety team Patient Safety and Complaints team Health and Safety team Legal team Pals team Directorate Management teams PSOC committee members Infection Prevention and Control team
Amendments:	Change in departmental names and titles Changes to the SI management flowchart Incorporation of clinical audit in the aggregated analysis Flowchart Incorporation of the Duty of Candour legislation Incorporation of the updated requirements for registration with the CQC.
Links to other policies or relevant documentation	See section 18.
If draft	**[only complete remaining boxes]**
Draft Number	
Comments to	
By	

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1. Introduction

In late 2017, the Trust developed its strategy: *Fulfilling our potential.* The strategy identifies the vision for the Trust and the key 8 priorities:

Those four priorities are

- We will achieve the best possible outcomes through providing the safest, most effective and efficient care
- We will attract and retain the right people and through creating a culture that enables us to learn and thrive
- We will improve children's lives through research and innovation
- We will transform care and the way we provide it through harnessing technology

The Trust is committed to achieving the best possible outcomes through proving the safest, most effective care and to create a culture that enables us to learn and thrive.

The Incident reporting and management policy outlines how adverse events to be documented analysed and used for learning and improvements in practice. The Trust actively supports and encourages a positive and non-punitive approach to incidents, accidents and near miss reporting in a culture of openness and learning.

Incident reporting is a key requirement to improve patient safety and is an important way of assuring staff, patients and the public that systems for managing risk are robust and effective. This policy defines the procedures and actions to be taken by staff in response to an incident and details individual and organisational responsibilities. The overriding emphasis is to identify *why* mistakes have occurred and to learn from the process, not to attribute blame and punish. This does not absolve staff from professional accountability but it is important that all the facts of an incident are reviewed. Research shows that it is rarely due to one person when a mistake occurs, but usually a combination of events, requiring consideration of all contributory factors and a thorough investigation prior to deciding any action required. Balanced in this approach is the need to counsel and support staff and families through any incident, potential or actual, and ensure appropriate action is taken to reduce the risk of the event occurring again.

This policy is not part of the Trust disciplinary process and all staff, both medical and nursing, are expected to report incidents when they occur as part of their roles as responsible professionals. As required by Health Education England under the *Framework for the Management of Trainees in Difficulty (2013)* all Serious Incidents (SI) involving medical trainees, regardless of their level of involvement in this incident, will be shared with the relevant post graduate Dean via the Medical Director.

Although the main focus of this policy is the reporting of clinical incidents, the procedures, assessment tools and documentation used are also applicable to non-clinical incidents. This reflects the Trust's aim to integrate the management of all risks in a co-ordinated and consistent way. Specific information on the management of Health & Safety and data or information loss[1] can be found in the health & safety policy and the confidentiality and information security policies. Further guidance and sources of information are given within the policy and below.

2. **Aims and objectives**

Incident reporting is a key part of the safety culture at Great Ormond Street Hospital (GOSH). It is the way in which the Trust collects information about adverse incidents, including near misses and hazards to support organisational learning to prevent harm to patients, staff and others. It underpins the safety culture in the Trust to ensure that the safety of patients is paramount. As such, this policy identifies:

- the process for reporting all internally and externally reportable incidents/near misses involving staff, patients and others

[1] For incidents regarding data or information loss, please refer to the Data Loss Policy. Data or information loss may need to be reported to the Information Commissioner. The loss may be of data in any format eg paper, electronic, loss of USB stick etc. If in doubt, advice can be sought from the IT Security Officer, Head of Information Governance, Company Secretary or Head of Quality and Safety.

- the types of incidents to be reported
- the importance of intervening quickly to reduce the effects of an incident that affects a patient, visitor or member of staff
- how the information from reported incidents is used to improve patient care and the learning shared across all levels of the organisation
- the process to ensure lessons learned from an incident in one part of the Trust will be applied generally wherever appropriate, so that recurrence is reduced and subsequent risk reduced
- the systems in place to analyse trends, provide feedback to each ward/ unit/ department, monitor progress against action plans and assess effectiveness and sustainability of any action required as a result of an incident whether affecting patients, staff, visitors or contractors
- the process for identifying, assessing, grading and monitoring an incident consistently and documenting any required actions regardless of whether the incident is clinical or non-clinical. All incidents will be graded and actioned according to their significance (actual or potential)
- the system for incorporating risks at local level into the risk registers, including risks from reported incidents, and reviewing and reporting on actions in line with the risk management strategy
- how the local risk registers are combined to form the Trust wide risk register, with high risks incorporated into the board assurance framework for consideration by Trust board
- the process for effective reporting to statutory and relevant external agencies
- the process to monitor compliance with the requirements of this policy

3. **Definitions**

Glossary of Terms

Near Miss

Within the remit of this policy a near miss is an incident that did not occur put could have done if actions were not taken to prevent it.

Incident

Within the remit of this policy, an incident is defined as any event or circumstance that could have or did lead to unintended or unexpected, harm, loss or damage. These may be clinical or non-clinical events and can affect staff, patients or visitors while on the Trust premises.

Datix

Datix is the risk management database used by the Patient Safety team , Complaints team and PALS team. Incident reporting at the Trust is electronic and is housed on the Datix server.

Abbreviations

NPSA	National Patient Safety Agency
CDOP	Child Death Overview Panel
ICU	Intensive Care Unit
EPP	Expert Patients Programme
COSHH	Control of Substances Hazardous to Health
LSCB	Local Safeguarding Children Boards
PSOC	Patient Safety and Outcomes Committee
NRLS	National Reporting and Learning Service
QS&AC	Quality Safety and Assurance Committee
RCA	Root Cause Analysis
SI	Serious Incident
Q&S	Quality and Safety team
RAG	Risk Action Group

4. **Being open and the `Duty of Candour**

Being open with patients and their families when something goes wrong is a key component of developing a safety culture; a culture where all incidents are reported, discussed, investigated and learned from.

The Trust has legal and contractual requirements to ensure that patients and/or their families are told about patient safety incidents that affect them, receive appropriate apologies, are kept informed of investigations and are supported to deal with the consequences.

The contractual duty of candour applies to patient safety incidents that occur during care provided under the NHS standard contract and that result in moderate harm, severe harm or death. Communication with the family must happen within 10 working days of the incident being reported on Datix. The initial notification must be verbal (face to face where possible) unless the patient/family cannot be contacted in person or declines notification. This conversation must be conducted by a senior member of the clinical team and documented in the medical records and an offer to have the conversation followed by a letter must be made.

On some occasions it may be initially unclear whether a patient safety incident has occurred, or what degree of harm, was caused. This is not a reason to avoid disclosure. Patient or their 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. Irrespective of the incident's grading the Trust encourages staff to commit to open and honest communication with patients and their families.

Full written documentation must be maintained according to the principles of the *Being Open* guidance.

Please see the Being Open and Duty of Candour policy for further guidance.

5. Duties and responsibilities

All staff members employed at the Trust

All staff who are employed at the Trust have a responsibility to report incidents, whether they are clinical or non-clinical, regardless of whether there were other people who could also have seen it. Staff should not worry about multiple reporting as the Patient Safety team have a process to filter out repeated incidents if necessary.

Staff Member involved

Ensure the safety of the individual involved in the incident as a priority.

For errors involving patients, inform the person in charge of the ward / department. If applicable, contact the relevant medical team to assess the child's clinical condition and likelihood of any detrimental effect on their care, or immediate action required. Ensure that the patient and or their parents/carers are informed of the incident if the patient suffered harm in line with the being open and Duty of Candour policy.

Document the effect, any treatment necessary and any communication with the patient / family in the patient's medical record.

Complete an incident form using the Datix on line incident reporting system as soon as practicable. Consider whether it may be necessary to retain any equipment involved (appendix 3)
If requested to provide a written account of your involvement by either your management team or the Patient Safety team it is expected that this should be provided within 5 working days of the request being made.

Line Manager of staff involved in the incident

Support staff member and discuss incident with them. The purpose of the discussion is to provide support to the individual and to identify exactly 'what' happened and 'why'. Consideration should be made of the contributory factors in relation to incidents, for example, training needs, lack of supervision, interruptions. Consideration also needs to be taken into how likely the incident is to recur. This will form the basis of what action (if any) is needed.

Investigate the incident locally and consider using tools designed to assist including the DIARY toolkit, incident decision tree, root cause analysis toolkit (all available on Q&S website) dependent on the harm or risk level of the incident.

In the rare event that the incident has resulted in a criminal investigation and the line manager, as well as, the staff member are witnesses the law prevents the two staff members from discussing the incident. On this occasion the line manager will appoint an individual to support the staff member in order to avoid 'witness contamination'.

Grade 3, 4 or 5 (Moderate harm, Long term damage, Major harm or unexpected death)
If the incident is graded as 3 the Directorate Management team must ensure that the appropriate level of investigation is taking place. Advice can be sought from the Patient Safety team.

When the severity of the incident is grade 4 or 5 the Patient Safety team must be notified on the day of the incident during normal working hours via Datix or via ext. 8572. Thought must be given to the accessibility and availability of the Patient's medical records to assist in the investigation.

Outside of office hours inform clinical site practitioners (CSPs) immediately. Discuss with staff, head of nursing and clinical team any on-going support or additional action required.

'Handler' on Datix

- Review the incident to ensure accuracy
- Completion of all mandatory fields, including lessons learned from the incident
- The Handler is solely responsible for ensuring that the incident is investigated and closed within the allocated timescales.
- Nomination of additional investigators when appropriate
- Ensuring that appropriate action plans are developed following incidents.
- Submitting the incident for final approval once all fields are complete

'Investigator' on Datix

Responsible for investigating the appropriate aspects of an incident which has taken place when requested to by the incident handler and to update the action taken and lessons learned field on Datix. However the handler retains responsibility for reviewing the investigator's comments and finalising the Datix form.

Other members of staff who are notified of an incident/have access to an incident

Other members of staff may be notified of incidents for information purposes. It is the responsibility of these staff to ensure that they are monitoring these incidents for trends and themes.
Ensure that when trends and themes are identified that they are escalated appropriately via the local risk action group (RAG) or senior management.

Head of Nursing /Matron / Department Head

- Review the incident to ensure all relevant fields have been completed appropriately on Datix
- Check that relevant people have been contacted/been involved.
- Check that the lead consultant has been informed if the incident is graded 3, 4 or 5
- Ensure that the right level of investigation (in view of harm level or risk level) is being undertaken. Advice can be sought from the Patient Safety team
- Check staff support provision is adequate
- Review recommendations to ensure that they are robust and that they will mitigate the risk of re-occurrence.
- Ensure that communication routes have been established. i.e. family, staff
- Identify any additional risks which need to be added to the risk register
- Co-ordinate local investigations and obtain statements for relevant incidents within agreed timescale
- Facilitate staff to meet with the Patient Safety team or other agency as appropriate
- Review investigation reports prior to being sent to family.
- Monitor action plans and recommendations relevant to the local area (from incidents and root cause analysis)

Consultant involved in the Patient's care

- Mitigate any adverse effect as far as possible for incidents graded 3, 4 and 5

- Ensure that the incident and any treatment required is documented in the medical records where appropriate.
- Maintain open and regular communication with the patient and their family.
- Support junior medical staff involved and other members of the ward team.
- Ensure other consultants involved in child's care are informed.
- Communicate with other relevant health care professionals.
- Ensure the Patient Safety team are notified immediately of any event graded 3, 4 or 5.
- Contribute to investigations into the incident and support more junior staff members to do so.
- Encourage staff to report incidents to promote learning and foster an open approach.
- Act as professional liaison with external agencies as appropriate, e.g. safeguarding, professional colleges.
- Review and comment on relevant investigation reports i.e. where the incident has affected their patient or is of relevance to their area/practice.
- Support the implementation of relevant recommendations.
- In the event of major harm or unexpected death ensure that the incident is discussed at the relevant morbidity and mortality meetings, RAG, team / departmental meetings as appropriate to share learning.
- Check whether the incident has been reported to any relevant external agency e.g. Coroner
- For incidents and prevented incidents graded 0-2, support clinical team to identify why they may have occurred, consider what information will be required by the family and whether any change in practice is required.

Risk Management and/ or Health and Safety Team

- Review incidents and ensure that appropriate investigations/actions have been taken
- Ensure that the form is anonymised before closing for submission to the NRLS (National Reporting and Learning Service).
- Check whether the patient/family have been informed in line with the Duty of Candour policy.
- Depending on each individual case, consideration will be given to the need to report externally according to the notification and communication procedures will be followed as stipulated by those organisations. See appendix 7 for specific requirements and responsibilities.
- Seek additional information from the clinical team as required.

Where the incident is Grade 3 or a significant near miss –

The need for further local investigation will be considered including:

- Concise/aggregated root cause analysis investigation/infection control RCA
- DIARY toolkit
- Incident decision tree
- Further actions required to reduce risk

Where the incident is Grade 4 or 5 the above should be considered and <u>additionally:</u>

- Check that the patient / and or family are aware of the incident
- Report as an SI if it meets the requirements
- Consider whether the incident needs to be reported externally and if so ensure that this takes place
- Facilitate a root cause analysis investigation where this is required.
- Inform members of Executive team and senior managers in the relevant clinical units.
- Inform staff of timescales
- Monitor compliance with timescales
- Ensure that the family are kept informed during the course of the investigation including any delays which are anticipated
- Seek other expertise within the Trust as appropriate to ensure the incident is fully investigated
- Finalise report/action plan and share with relevant external agencies including the family.
- Arrange and facilitate meeting with family following incident if appropriate.

All lessons learned as a result of all RCA's (irrespective of level of incident) undertaken will be added to the Datix system.

Ensure that arrangements for sharing the lessons learned as a result of investigation are included in final reports and that all action plans, and progress against them, should be submitted to the Patient Safety and Outcomes Committeefor information and monitoring as per the reporting schedule.

Reports to Committees as per reporting schedule.

Information obtained through an SI investigation will not be shared with any external agencies, unless we are requested to do so by law. This includes requests under the Freedom of Information act and the data

protection Act. It is important that statements and timelines that have been created soon after the incident is kept confidential to ensure openness and honesty. Any requests for information by other bodies, including the Coroner, Police and Solicitors should be requested/managed independently of the SI process.

Monitor the following in line with the policy:

- Severity of incidents reported
- High risks identified locally are being reviewed (See risk management strategy)
- Compliance with timescales for externally reportable incidents

Level of investigation appropriate to incident

- Reports to Executive team to ensure that they are aware of level 4 and 5 incidents.
- Send monthly reports with analysis of incident trends to Divisions/specialty areas.
- Quarterly reports with Trust wide analysis of incident trends to the learning, implementation and monitoring board.
- Quarterly Reports containing aggregated quantitative and qualitative analysis of incidents complaints and claims.
- Quarterly reports to divisions with analysis of incident trends
- Other reports/analysis as required by the Trust.

Clinical Site Practitioners (CSP's)

When contacted regarding incidents of level 4 or 5 out of hours, the CSPs should ensure:

- That all necessary action has been taken to ensure the safety of the patient
- That there has been communication with the family
- That there is support for staff involved
- That the incident is escalated to duty managers and executive on call if necessary
- Consideration is given to whether the incident needs to be reported externally e.g. NHS England, police, coroner, NHSLA for property damage etc.
- That the Patient Safety team are notified by Datix, via telephone or via email address.
- Where the CSP has been involved in the incident or the period immediately following the incident they will provide statements and co-operate with investigations as appropriate.

Duty Manager

When the Duty Manager is alerted to an incident graded 4 or 5 out of hours their duties include*:*

- Alerting the executive director on call
- Establishing the status of patient.
- Ensuring that arrangements are in place to speak to staff regarding statements.
- Ensure that family are involved and ascertain what information they have been given.
- Where necessary, contact the relevant consultant to request that they communicate with the family. If the relevant consultant has been involved in the incident consideration should be given to finding another consultant to discuss the incident.
- Consider whether the incident should be escalated/managed as a major incident
- Log the incident in duty manager's log book (and update accordingly)
- Email relevant staff documenting actions already taken and the names of people involved.
- Determine the level of investigation required initially and ensure confirmation in conjunction with Patient Safety Manager during next working day. Consider whether the incident needs to be reported externally as required (See 7.0)
- Alert the press office, if there is a risk that there may be press interest.
- Update executive director on call and agree roles and responsibilities for actions required

Executive Director on call

- Ensure that all relevant actions have been taken
- Provide advice and support as required
- Ensure that relevant staff, including external agencies if necessary, are aware
- Consider and decide whether it should be managed as a major incident.

Communications team

In the case of an incident which may be reported in the press, a press statement will be prepared immediately by the press office. The statement will be circulated to the Chief Executive, Head of Quality and Safety (or deputies) and other relevant staff for comment and approval. The press statement will be updated as appropriate, subject to prior approval by the same parties. Internal updates and de-briefs may be provided for staff as appropriate.

Chief of Service / General Manager

- Act on escalated incidents/risks identified
- Lead on investigations that are required for grade 4 and 5 incidents
- Ensure that staff involved in the investigation or undertaking the investigation are supported
- Ensure that relevant action plans are implemented
- Ensure that risks are added to the clinical unit risk register as appropriate
- Review reported incidents at division boards as per reporting schedule

Deputy Chief of Service

- Will be aware of incidents relevant to their speciality
- Will assess the need for actions to mitigate risks identified
- Will act on escalated issues
- Will ensure that all serious incidents are discussed at the specialty morbidity and mortality meeting.

Medical Director and/or Chief Nurse

- Will request an independent review of an incident if this is considered necessary.
- Escalates issues to executive colleagues as necessary
- Ensures appropriate risks identified through incident reporting, aggregated analysis or from external drivers are added to the assurance framework
- Meet with parents and families following SIs where appropriate
- Ensure the investigation meets the timescales required by NHS England and support the investigating lead to prioritise the investigation over other work
- Monitor progress of the SI via weekly reports from the Patient Safety team
- Escalate/resolve obstacles to completion of the investigation
- Approve the SI report

Chief Executive

- Will be aware of all incidents Grade 4 & 5's

- Public Liaison

Infection Control

- Receive notification of all infection prevention and control incidents reported on Datix
- Provide advice and support for incidents relating to Infection prevention and control
- Update Datix as required
- Report identified infection incidents via the Datix system (if not already reported by the clinical team)
- Request infection control RCA to be undertaken by the relevant ward as appropriate
- Report to external agencies as appropriate. (DoH, HPA etc.)

Consider further actions including:

  - Ward closure
  - Isolation
  - Deep cleans
  - Swab checks/environmental cleaning

Blood Transfusion Service

- Identify any incident relating to blood transfusion (clinical or laboratory)
- Report using the Datix system
- Report to external agencies as appropriate (see 'reporting to external agencies')
- Consider further actions which may be necessary to mitigate risk

Reporting an Incident

Each member of staff employed by the Trust is expected to comply with all aspects of this policy and ensure that all incidents, including near misses, are reported in a timely manner. The safety of the child/young person is paramount and without reporting no learning can take place to identify the means to reduce the risk of an incident occurring again.

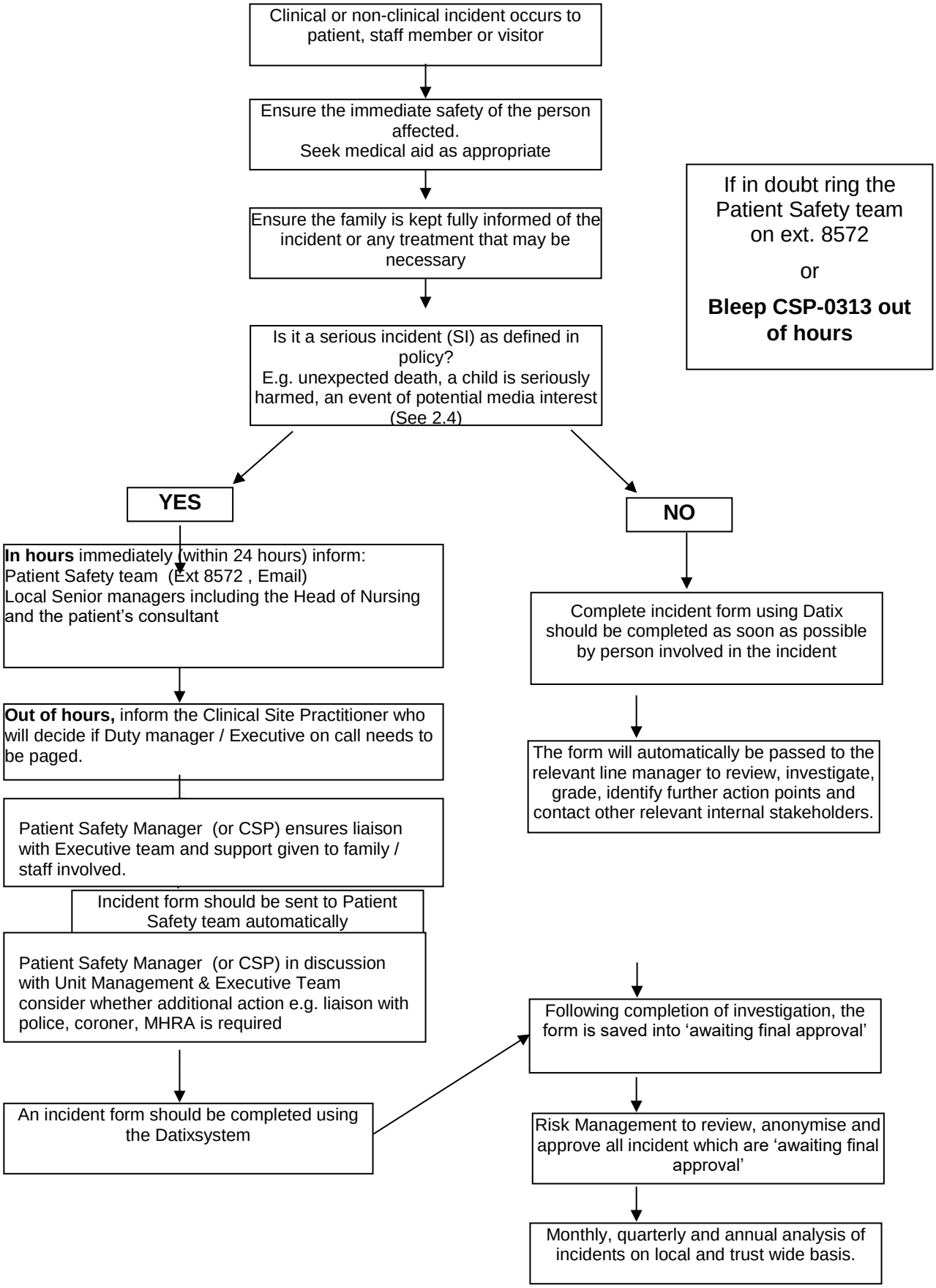
Incident forms will be shared with the patients and families upon request, or through a 'access to records request'. Incidents must be fully investigated and updated prior to be released.

NB. **Low levels of incident reporting do not indicate a safe system.**

Evidence of an effective reporting system is one where the number of incidents increases but the severity of the events goes down. This indicates that staff are risk aware and can identify events early, often before they cause permanent harm, at the stage where interventions can be made to reduce the adverse effect.

The following flow chart identifies the process for reporting all incidents/near misses involving staff, patient and others. Incident report forms are available in hard copy in ward and departments and on line by accessing Datix from the front page of the GOSH intranet site. If in doubt, contact the Patient Safety team on ext. 8572.

Process for reporting internal incidents



For incidents regarding data or information loss, please refer to the Data Loss Policy and SI reporting below. For health & safety incidents, see health & safety policy. For major incidents see major incident policy.

Examples of Incidents to be reported
(**Patient Safety team must be notified immediately or within 24 hrs of event).

Access *Admissions, Transfers, Discharge, Appointments* Delays, Refused, Unplanned re-admissions due to complications Transport, Bed blocked not available, Complication after Discharge	**Blood Transfusion** *Reaction/Recall* Delay Collection/Storage Prescription/Administration Laboratory Error Inappropriate Wrong patient, wrong blood	**Consent & Documentation** *Procedure performed without consent*** Not obtained for that procedure Incomplete Not requested Not received Not fully understood Withheld
Death *Unexpected*** Peri-operative death (24hours either side of anaesthetic/op) 24hrs post discharge Brain death (within 24hrs of admission), Due to complication(s) Due to infection	**Drugs** *Errors* Prescription, Administration (overdose/under dose), Reaction Dispensing, storage (CD's) Inappropriate method of delivery Site, route, Unavailable, expired	**Communication** *Interpreter* Needed but not requested Breakdown between departments, staff, families, other services, complaints, Crash call – wrong number Feeding when Nil by Mouth Unable to contact parents in an emergency
Documentation *Allergies – not recorded, no armband* Incomplete, Not available (medical records), Missing follow up letters Missing referral	**Chemicals (use of)** *Spillage, storage, inhalation*** Non-compliance with COSHH No EPP used, available Non-compliance with guidelines	**Confidentiality** *Breaches* Computer, Data protection, Patient information, Professional conduct Data loss – any format
Deterioration in condition *Sudden or unexpected* Inadequate/inappropriate monitoring Apnoea, aspiration, arrests** Choking, collapse, Compartment syndrome Delay in admission to ICU area Delay in senior attending Inadvertent catheter/tube removal	**Equipment** *Dislodgement, disconnection of invasive equipment* ETT, chest drains, CVP lines, ECMO Unavailability of equipment, Complications using Inappropriate use Inappropriate storage	**Infection Control** *Non isolation of infectious patient*** Central line infection Unclean equipment Post-operative infection Contamination Cross infection (pt-pt, pt-staff, visitor-pt) Housekeeping
Staff *Unavailability of appropriate staff* Clinical Non clinical Shortages Latex/Dermatitis	**Injuries** *Slips, trips, manual handling, spills* Musculoskeletal Stress Needle sticks**, sharps, Falls including from height Workplace design	**Skin marks/ Corneal abrasions** *Pressure sores* Extravasation Related to intubations/reduced mobility, equipment Bruising-explained/unexplained Burns during procedure or hospital stay

Procedures/Operations	**Violence/Abuse**	**Tests (scans, x-rays, reports)**
*Wrong site surgery**, cancelled surgery, unplanned return to theatre***	*Towards staff, patients members of the public, contractors*	*Not undertaken, not followed up*
Complications, malignant hyperpyrexia, Anaesthetic – awake / aware or pain during procedure**	Alleged	Lost
Incorrect procedure** Wrong sample sent Excessive blood loss related to surgery**	Actual	Delayed or missing specimens/ results
Hearing or other sensation loss	Verbal	Misdiagnosis
Wrong Patient	Physical	Mislabelled
	Phone calls/emails/letters	Failure to follow up on abnormal test
		Wrong/inappropriate test ordered/done
		Over or unintended exposure to ionising radiation

This is a guide only. If you think something should be reported then complete an incident form[2]. Events involving staff injuries are reported using the same incident form. See health & safety policy for additional information and appendix 3 for reporting equipment errors; for incidents involving defective medicines (rather than wrong, dose, wrong, route, wrong time, wrong patient) please refer to the administration of medicines policy.

Incidents (SIs)

A serious incident requiring investigation is defined as an incident that occurred in relation to NHS funded services and care resulting in:

- Unexpected or avoidable death of one or more patients, staff, visitors or members of the public
- Serious harm to one or more patients, staff, visitors or members of the public where the outcome requires lifesaving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy, or result in prolonged pain or psychological harm.
- A scenario that prevents or threatens to prevent a provider organisation's ability to continue to deliver health care services, for example, actual or potential loss of personal or organisational information, damage to property, reputation or the environment or IT failure.
- Allegations of abuse
- Adverse media coverage or public concern for the organisation or the wider NHS
- One of the core sets of 'never events' as updated on an annual basis

A list of all the SI categories set out in the NHS England Patient Safety Domain 'Serious Incident Framework' based on the previous guidance Information Resource to Support the Reporting of Serious Incidents'

[2] The Patient Safety team can be contacted by phone, or email to prevent delays

If you are unsure as to whether something should be reported as an SI, please contact the Lead Patient Safety Manager on x0158 or the Patient Safety team on x8572

SIs are reported to NHS England, via STEIS, by the Patient Safety team who provide a summary of the incident, the actions taken so far and update reports within set time scales as and when investigations into SIs are completed. Responsibility for reporting to external agencies is listed in 7.0.

Communication and Notification Patient/relative/visitor/contractor communication & support

Trust policy is always to be as open and honest with families as possible. The Trust encourages staff to be able to acknowledge, explain and apologise when things go wrong. (See Being Open and the Duty of Candour policy)

All communication with families and other relevant parties should be clear and honest and should occur as soon as possible after the incident occurred by within 10 days of the incident being reported on Datix. . Where there are likely to be delays in communication or information, patients and their families should be advised of this.

During the root cause analysis investigation period a nominated person will be responsible for ongoing verbal / written communication with the family and other relevant parties. If the patient is receiving clinical care from the Trust in the interim, normal clinical communication should continue at the same time. All communication must be fully documented. Other patients, both inpatient or outpatient, and their families who are either closely affected by the incident or get notice of the incident via the hospital network or the media may also require support and information. Meetings should be held in appropriate areas to allay fears and give relevant information whilst observing the principles of the data protection act and preserving confidentiality.

Process by which to raise concerns

The Trust is committed to meaningful and effective communication with its staff and encourages a climate of openness and honesty in all of its services and business dealings. Individual members of staff are encouraged to raise with their manager(s) any matters of concern that they may have about health care issues related to the delivery of care or service to a patient or any concern relating to the possible existence of fraud or corruption in the Trust. (See Raising Concerns in the workplace policy).

Every manager has a duty to ensure that staff are easily able to express their concerns through all levels of management in the Trust. Managers must ensure that any staff concerns are dealt with thoroughly and fairly, and that reference to their management is made quickly where appropriate

Process for supporting staff affected by an incident

All staff involved will need support from their peers, colleagues and managers. They may also require external support such as bereavement counselling or Care First. Staff should be kept informed at regular intervals as to the progress of the investigation. In some instances, for their own benefit, staff involved may require to be given time off work, usually in the form of suspension on full pay, or offered the possibility of working in a different area of the Hospital for a period of time. Efforts will be made to meet these needs. Further advice can be sought from the HR department, Occupational Health or Patient Safety team . (See Supporting Staff policy)

Reporting to external agencies

Depending on the nature and severity of the incident, there may be a need for the findings of an incident to be reported to relevant external bodies. The Trust has a duty to comply with external reporting systems.

The following table outlines the process, responsibilities and timescales for the external reporting systems most frequently used. This is a non-exhaustive list. More detail is given in appendix 7.

External Body	Process	Responsible	Timescale
NHS England Patient Safety Domain	All clinical incidents are reported anonymously to the NHS England Patient Safety Domain using the National Reporting and Learning System. Within two weeks of incident being entered on Datix system all clinical incidents are uploaded onto the NRLS system.	Patient Safety team	Within two weeks
NHS England	The Trust reports all relevant serious incidents to NHS England via the STEIS system. The process can be found in Appendix 1.	Patient Safety team	Within 1 working day of becoming aware of incident
MHRA	The previous month's incidents which involve equipment failure or user error are reviewed by the Patient Safety Manager and Biomedical engineering to identify the incidents that need to be reported to the MHRA.	Patient Safety team	Within 1 month of incident being logged on Datix.
	All staff are able to report incidents to the MHRA regarding Equipment or Medication incidents via the website or by phone. Staff should provide details of confirmation of reporting to the Patient Safety team . This can accompany an incident form or be used in place of an incident form providing all relevant details are included	All staff	Within 5 days of incident occurring.
SHOT/SABRE	Blood Transfusion is informed of all incidents involving the transfusion of blood components and relevant incidents are then reported to SABRE (MHRA) and/or SHOT in line with legal requirements.	Transfusion Practitioner/ the Blood Transfusion Laboratory Manager	Within 1 working day of being notified of incident.
CARE QUALITY COMMISSION	All unintended radiation exposures are reported via the incident reporting system. The Radiation Protection Supervisor (RPS), Trust appointed Radiation Protection Advisor (RPA) and Radiology head of Service are notified. The modality Lead in conjunction with the RPS investigates the incident and the Radiation Protection Advisor provides dose and risk assessment and identifies recommendations. The incident is reported to the Care and Quality Commission if the exposure is much greater than intended in line with Ionising Radiation (Medical Exposure) Regulations (IRMER).	Radiology – Head of Service	Within 2 weeks of being notified.
HEALTH AND SAFETY EXECUTIVE	All incidents are reported via the incident reporting system. The incident form requires the person completing it to specify whether the staff member has been off for more than seven days. Incidents are reviewed upon receipt and reported in line with RIDDOR requirements. Ionising radiation exposures much greater than intended caused by Equipment malfunction or defect.	Health and Safety Advisor Radiology –Head of Service	Within 10 days of incident
COMMISSIONERS/INFORMATION COMMISSIONER	By direct contact re any serious untoward incidents (Grade 4 & 5) including data loss incidents. The process can be found in Appendix 1.	Chief Finance Officer	Within 1 working day of becoming aware of the incident
Environment Agency	Serious Radionuclide incidents involving Sealed or Unsealed Radioactive isotopes	RPA	Within 10 days of incident
HSCIC and ICO	All Information Governance related SI's including data loss and breaches of confidentiality are reported to the HSCIC and ICO via the HSCIC IG toolkit online reporting tool	Head of Information Governance	Within 5 working days of the incident being reported as an SI

Where the external body does not specify a timescale for reporting the Trust aims to report any relevant incident within seven days of the incident occurring unless otherwise specified.

Investigation and Training

The Patient Safety team provides training on root cause analysis to all staff and additional training to managers who may be required to lead investigations as identified in the training needs analysis. All training undertaken and attended is recorded on the central training database and non-attendance reported by the Education and Training team.

Incident grading

Incidents are graded in terms of their outcome (potential or actual). Incidents are graded from 0-5 using the risk matrix and assessment process (appendix 5).

Incident rejection

Datix has, by default, an incident rejection function. The Trust encourages all staff to report incidents in the safety of the knowledge that the information will be reviewed and used as set out in this policy. It is not the intention that any staff will 'reject' incidents and Incidents reported can only be 'Rejected' after discussion and agreement with a member of the Patient Safety team .

Investigation

The level of investigation required will vary according to the severity or nature of the incident. Investigations are conducted on a level appropriate and proportionate to the incident under review and facilitated by the Patient Safety team using the NPSA Three levels of Investigation Tool.

A guide as to the levels of investigation which may be required is given below.

Grade	Actual or potential impact	Level of investigation	Responsible for Co-ordinating the investigation	Process for following up action plan
5	Unexpected death of one or more persons, national adverse publicity, potential litigation, major health and safety incident e.g. toxic gases, fire, bomb, catastrophic financial loss	Root cause analysis unless there is a decision by the Lead Patient Safety manager in consultation with the clinical team that a different technique is more applicable	Directorate Management team supported by a Patient Safety Manager from Q&S	Reported via Directorate board, monitored by PSOC
4	Permanent injury, long term harm or sickness, involving one or more persons, potential litigation, extensive injuries, loss of production capability, health and safety incident, some toxic release, fire, major financial loss	Root cause analysis unless there is a decision by the Head of Quality and Safetyin consultation with the clinical team that a different technique is more applicable	Directorate Management team supported by a Patient Safety Manager from Q&S	Reported via Directorate board, monitored by PSOC
3	Semi-permanent injury, one or more persons, possible litigation, medical treatment required, health and safety incident, moderate financial loss	Decision will be made regarding type of investigation required by Patient Safety Manager following discussion with clinical team.	Head of Nursing/Consultant/ Department Head with support from Patient Safety team	Risk action group or Directorate Board and monitored by PSOC
2	Short term injury following incident, first aid treatment required, on-site toxic release immediately contained, minor financial loss	Local concise investigation	Ward / departmental manager, with support from their senior manager and advice from Patient Safety team if necessary	Risk action group
1	Incident occurred but resulted in no injury, and no treatment required; no financial loss	Local concise investigation	Ward / departmental manager, with support from their senior manager and advice from Patient Safety team if necessary	Risk action group
0	Incident did not happen but could have, if an intervention had not taken place; no financial loss	The level of investigation will depend on the risk of re-occurrence or the level of harm that was prevented. The Divisions should discuss with the Patient Safety team if there are any uncertainties	This will depend on the level of investigation required.	Risk action group will decide whether the incident should be reported to the Directorate Board and PSOC

In addition to incidents which have caused a significant level of harm (3, 4 & 5) a root cause analysis should be undertaken if:

- Despite local concise investigation it has not been possible to establish why the incident occurred
- The incident was a high risk near miss
- A trend of low/medium grade incidents requiring greater analysis

The incident decision tree & DIARY tool (available on Q&S website) should be used in the event of a medication error which

- Has caused harm (level 2, 3, 4 & 5)
- Is considered by the ward sister/Patient Safety Manager to be a high risk near miss.

Any disagreement regarding the level must be discussed with the Head of Quality and Safety who is responsible for ensuring appropriate levels of investigation for any incident are undertaken. The local team, supported by the Patient Safety team , will undertake the investigation unless there is a conflict of interest in which case the lead investigator will be agreed with the Medical Director.

Root Cause Analysis

The Root Cause Analysis (RCA) is a structured investigation which aims to identify the true cause of a problem and the actions that are necessary to either eliminate or significantly reduce the risk. An RCA investigation will be held for all Serious Incidents (SIs). The decision to undertake a root cause analysis for incidents not reportable as SIs will be taken by a member of the Patient Safety team in discussion with senior clinicians and managers within the relevant specialty. The Infection Prevention and Control team will provide advice and support when an RCA is required for investigating incidents relating to Infections. Please see the Infection Prevention and Control (IPC)Assurance Framework and Operational Policy for further information.

A concise RCA may be carried out for incidents which are not reportable as SIs. Such incidents may include incidents of a moderate severity or near misses. The purpose of the concise RCA is to assist in departmental and organisational learning. Concise RCAs will be managed locally with support from Patient Safety team as appropriate. Action plans developed following a concise RCA will be monitored locally and the risk action group structure may be used for this purpose. A copy of the completed concise RCA will be sent to the Patient Safety team to be incorporated in organisation-wide analysis and learning. These investigations and ensuing reports are still reviewed via the Learning, Implementation and Monitoring Board.

Recommendations, action planning and risk reduction

Following an investigation into an incident, recommendations can be made about actions that should be taken to mitigate the risk of reoccurrence. These recommendations must form an action plan. The action plans must be updated on Datix by the Directorate management team. Not all incidents will require actions to be taken but this should be clearly documented on Datix

Process following Local Concise Investigations

Following local concise investigation the staff reporting the incident, in conjunction with their manager, should recommend actions that can be taken locally to reduce the risk of re-occurrence. This should be documented on Datix. This information will be included on monthly ward reports and quarterly Directorate reports accessed on Datix by the local unit or provided by the Patient Safety team.

These action plans will be followed up by the local risk action group either through review of reported incidents or by adding the issue to the local risk registers for on-going review and monitoring in accordance with the Trust risk management strategy.

Process following Root Cause Analysis

Following an RCA, recommendations will be made regarding the actions that need to be taken to address the lessons learned as part of the investigation.

Recommendations which only require action at a local level can be managed by the risk action group who will be monitored by the Directorate board (or equivalent).

Recommendations which require organisational change will be sent to the Patient Safety and Outcomes Committee for a decision on actions that need to be taken. These action plans will be followed up via the committee 3 months after being presented at the PSOC.

Risk Reduction

The process for risk reduction following identification of risk in incidents or the aggregation of incidents, complaints and claims is included in appendix 4.

Staff do not have to use this template, but any action plan designed to reduce risk should:

- identify the level of the risk,
- note any controls already in place to control the risk
- state the agreed course of action to manage the risk further
- identify who is responsible for leading on this work
- the timescale for the completion of the action

Investigations across organisational boundaries

If an incident occurs across a number of organisational boundaries, it may be necessary to work together in a joint investigation. In such a case the investigation within GOSH will normally be co-ordinated by one of the Patient Safety Manager s as allocated by the Head of Quality and Safety. Agreement with other parties involved will identify which organisation will act as overall coordinator for the investigation with input from colleagues and timescales for reporting agreed.

Sharing of lessons learnt

Internal

Local Learning

The Patient Safety team trains all relevant clinical and non-clinical staff on the use of Datix and how to run reports from the database. The Patient Safety team will provide any reports upon request. Managers will use the reports identifying learning which are submitted to the Patient Safety and Outcomes Committeeand other Trust committees to identify relevant learning points from incidents in other areas, and ensure these are discussed in their local risk action group in conjunction with learning identified from complaints or claims. The local areas should keep a record of lessons learned locally and actions taken.

For incidents graded 0, 1, 2 local managers are responsible for identifying relevant learning and ensuring that appropriate action is taken to prevent these incidents locally.
For incidents graded 3, 4 and 5 the lessons learned from investigations which are relevant to a local area will be brought to the risk action group by the local risk link or by the allocated Patient Safety Manager .

Organisational Learning

Where lessons learned from either incidents, complaints or claims, including aggregated analysis of these (see also the Complaints policy and the Legal policy) that require changes in organisational practice or culture, then the recommendations/action plans will be submitted to the Patient Safety and Outcomes Committee for discussion and approval. The Patient Safety and Outcomes Committee will monitor progress against actions plans via reports submitted by the Quality and Safety team in accordance with the reporting schedule or through the committee action log. In addition members of the Patient Safety and Outcomes Committee are responsible for ensuring that key learning is disseminated to relevant staff members in their units as appropriate.

In addition to the Patient Safety and Outcomes Committee there are other groups and committees in the Trust who have a role in ensuring that lessons learned as a result of incidents or the aggregated analysis of incidents, complaints and claims are shared and actioned. These groups include but are not limited to:

- Risk action groups
- Directorate Boards
- Specialty meetings
- Guideline approval group
- Records management committee
- Hospital transfusion committee
- Drugs and therapeutics committee
- Clinical ethics committee
- Radiation protection committee
- Infection Prevention and control committee
- Nursing practice educators group
- Resuscitation committee

See appendix 6-Analysis and learning from incidents, complaints, PALS and claims.

External

Opportunities to share learning across the local health community

Following the completion of an RCA it may be that there are lessons learned which can be shared with the wider healthcare community. The Trust will identify opportunities to share learning from incidents, complaints and claims (or the aggregation of these) on an anonymised basis and will engage with other Trusts/Agencies who seek to share learning in this way. This may include (but is not limited to):

- Participation in Patient Safety Manager s Groups/Forums,
- Development of communication links with the patient safety managers at NHS England and the NRLS ,
- Attendance at relevant national events and conferences.
- Sharing of anonymised reports or executive summaries with relevant organisations.

Incident & Causal Factor Analysis

Responsibility for incident analysis

Each specialty and all grades of staff are expected to report clinical incidents and prevented incidents. Data from the reported incidents will be reviewed internally in accordance with the following schedule:

Type of Report	Level of Analysis	Frequency	Received by	Responsible
Ward / Department	Anonymised datix report for each specific ward / department including qualitative analysis regarding categories of incidents and high risk incidents reported by that area	Monthly	All ward sisters/ heads of departments/risk links as appropriate	Person identified by local unit or Patient Safety Manager
Quarterly Reports	Includes top 3 types of incidents reported for each specialty/ Unit/ department. Key learning and analysis of data including complaints and claims, serious incidents	Quarterly	Directorate boards, PSOC Summary report discussed at QSAC quarterly.	Patient Safety team

Any team who wish to review their incidents can do so via the Datix on line database. Both qualitative and quantitative data can be obtained from the Patient Safety team. All reports will be anonymised.

Aggregated analysis of Incidents, Complaints, Claims and PALS

In order to support learning and identify early trends which may need action or further investigation, the data from incidents, complaints, claims and PALS including root cause analysis data, will be used to learn lessons and improve and/or make changes to practice following aggregated analysis. This supports a proactive

approach to risk management to use previous learning to mitigate the risk of similar situations occurring in the future. See appendix 6- Analysis and learning from incidents, complaints claims and PALS.

Coordinated Approach

Weekly safety meetings between the Medical Director, Chief Nurse, Head of Quality and Safety, Lead Nurse for Infection, Prevention and Control, Lead Nurse in Resuscitation and others will take place to identify and action trends that arise. Key themes across the areas represented will be documented by the Quality and Safety team and will be circulated to the Executive team within 24 hours.

The Patient Safety Managers, Patient Safety and Complaints Manager, PALS Manager and a member of the legal team will meet on a weekly basis to analyse and record key themes across incidents, PALS, complaints & claims. During this meeting the information is minuted

Aggregated reports including recommendations on risk reduction measures required will be presented quarterly to the Patient Safety and Outcomes Committee or Risk Assurance and Compliance Group as appropriate. The risk reduction process is outlined in appendix 4.

Any key themes identified through aggregated analysis which do not already appear on the Trust risk register will be added to the Assurance Framework in accordance with the Risk Management Strategy.

Hotline Arrangements

If an incident involves multiple incidents or a major incident, which requires a hot-line, this will be set up by Switchboard and there will be a designated incident room in line with the Major Incident policy or the attached protocol, as shown in Appendix 8, depending on the specific incident which has occurred.

A Fair Culture

The Trust believes that:

- Competent and caring professionals will make mistakes and staff should not fear punishment for reporting them.
- Many errors result from inadequate or complex systems.
- Errors and accidents will be analysed and aggregated in an attempt to establish trends and patterns to learn from them and prevent reoccurrence, thus improving patient safety.
- The Trust provides a supportive environment for all staff to report errors and prevented incidents.
- In the process of evaluating errors and prevented incidents, healthcare providers participate in reporting and developing improved processes.

- Incident reporting is a critical component of the Trust's patient safety and risk management programme.

A thorough investigation will be carried out to ensure facts of an event are available and to inform any decisions regarding additional action that may be required. This does not detract from the professional accountability of individual practitioners as required by their professional, registration organisations.

If it becomes clear that staff competency is the root cause for a pattern of errors; management will make every reasonable effort to ensure staff can reliably deliver safe care. If it becomes clear that a staff member cannot practice in a reliably safe manner, in spite of education and counselling, this situation will be treated as a staff competency issue through normal disciplinary procedures. The Trust has adopted the 'incident decision tree' (devised by the National Patient Safety Agency) to guide staff and managers in reaching a decision as to whether disciplinary action should be considered, or whether extra training and support is required.

Knowingly intentional acts with intent to harm or deceive.

If there is any concern that there has been an intentional act to harm or deceive by a member of staff the 'Allegations against staff member' procedure within the Safeguarding Policy should be consulted. If staff would like to discuss such a situation contact can be made with either the Head of Safeguarding, the Head of Quality and Safety, Deputy Chief Nurse or through the relevant management structure.

Process for implementation

This policy will be available to all staff through the Trust's document library. All staff are notified of updates to the policy via the postmaster email system. Key points from the policy are included in mandatory, supplementary and ad hoc training provided by the Quality and Safety team to all staff.

14. Equality impact statement

This policy has been assessed for its impact on equality and will not have an (specify level of impact as appropriate e.g. minimal, moderate, etc.) level of impact on the protected groups below:

- Age
- Disability (including learning disability)
- Gender reassignment
- Marriage or Civil partnership
- Pregnancy and maternity
- Race
- Religion or belief
- Sex
- Sexual orientation

15. Other policies of relevance

- Risk Management Strategy
- Being Open and the Duty of Candour Policy
- Legal Policy
- Falls Policy
- Complaints Policy
- Health and Safety Policy
- Major Incident Policy
- Raising concerns in the workplace policy
- Supporting Staff Policy
- Newborn Screening Standard Operating Procedure (SOP)

16. References

- Health and Safety Executive (HSE) The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR), HSE Books.
- NPSA Three Levels of investigation Guidance September 08
- Department of Health. (2001). Building a Safer NHS for Patients: Implementing an Organisation with a Memory. London: Department of Health. Available at: www.dh.gov.uk
- National Patient Safety Agency (NPSA). (2004). Seven Steps to Patient Safety. London: NPSA. Available at: www.npsa.nhs.uk/
- National Patient Safety Agency (NPSA). (2005). Building a Memory: Preventing Harm, Reducing Risks and Protecting Patient Safety. London: NPSA. Available at: www.npsa.nhs.uk
- National Patient Safety Agency (NPSA). (2005). Patient Briefing - Saying Sorry When Things Go Wrong. London: NPSA. Available at: www.npsa.nhs.uk

- National Patient Safety Agency (NPSA). (2005). Safer Practice Notice - Being Open When Patients are Harmed. London: NPSA. Available at: www.npsa.nhs.uk
- National Patient Safety Agency (NPSA). (2009). Never Events – Framework for 2009/10: Process and action for Primary Care Trusts 2009/10. London: NPSA. Available at: www.npsa.nhs.uk
- NHS London (2009) Serious Untoward Incident Reporting Policy. London

Appendices

Appendix 1: Guidance for Serious Incident (SI) Reporting[3]

What is an SI?

The principle definition of an SI is something out of the ordinary or unexpected, with the potential to cause serious harm, and/or likely to attract public and media interest, that occurs on NHS premises or in the provision of an NHS or a commissioned service. This may be because it involves a large number of patients, there is a question of poor clinical or management practice, a service has failed, a patient has died under unusual circumstances, or there is the perception that any of these has occurred. SIs are not exclusively clinical issues, for example an electrical failure may have consequences that make it an SI.

In deciding whether or not the incident being dealt with constitutes an SI the possible impact the incident could have is considered, including in the media. If it could be damaging to the Trust or the NHS in general, it should be reported as an SI. NHS London and the Department of Health work on the principle of "no surprises". It is better to report something early and then de-escalate it than delay reporting.

Reporting is done by the Quality and Safety team using the STEIS system. If you are unsure as to whether something should be reported as an SI, then contact the Patient Safety team on 8572 or the Head of Quality and Safetyon 8185 who can advise and who will check with NHS England's Patient Safety Action Team if there is any doubt.

As the risk assessment process that evaluates whether incidents are SIs is fundamentally subjective this may be open to interpretation and guidance is given below as to the type of risk event which will be reported to NHS England. For reporting child protection events advice can be sought from the Safeguarding team on ext 5126.

Types of incidents to be reported to NHS England as SIs

There are many types of incidents which need to be considered as reportable to NHS England. The full NPSA listing which has been adopted by NHS London is listed in the Serious Incident Framework and the Never Events List 2015/16.

In addition there are 25 never events which are also reportable as SIs.
A never event is a serious, largely preventable, patient safety incident that should not occur if the available preventative measures have been implemented by healthcare providers. The incident will fulfil the following criteria:

- Has the clear potential for or has caused serious harm/death
- Evidence of occurrence in the past (i.e. known source of risk)
- There is national guidance and/or national safety recommendations on how the event can be prevented
- The event is largely preventable if the guidance is implemented
- Occurrence can be easily defined, identified and continually measured.

The occurrence of a never event is seen as an indication that the organisation may not have put in place the right systems and processes to prevent incidents from happening and thereby prevent harmful outcomes.

The Never Events Policy and Framework 2015-16 indicates that while the Government will continue to maintain and increase the focus on safety in the NHS, serious failure will not be tolerated.

[3] Based on NHS London Reporting SI's (2009)

When do they need to be reported?

This should be completed as soon as the incident becomes known to the Trust and on the same working day wherever possible. Limited information early is better than full information late so that SIs can be briefed to the DoH where necessary. This will be followed up with full information at the earliest opportunity.

How are they reported?

SIs are reported via the DoH Strategic Executive Information System (STEIS) system. This is a secure site which requires a login and password. In the event of a Major Incident or an incident which has resulted in serious harm, death or may create intense media interest, NHS England must be contacted as soon as possible. This is done by the CSP, Duty Manger or Patient Safety team who hold relevant contact numbers. This must then be followed up by an electronic report on STEIS (See 1.1 below)

Who reports and where to?

The Patient Safety team is responsible for reporting on STEIS. A member of the Major Incident Team will be responsible for notifying NHS England
by phone in the event of a major incident. If an SI is reported the following people must be notified: Head of Quality and Safety – Risk Management, Executive team, Commissioning PCT and Host PCT, Chief of Service and General Manager of areas concerned.

Why do we report SIs?

1. To ensure that the correct people are informed of SIs promptly so that there are 'no surprises'. This includes ministerial briefings and the briefing of concerned organisations on potential media interest.
2. To ensure that the number and type of SIs which occur in an organisation are identified so that trends and learning can take place across the health community.
3. To monitor the outcomes and action plan implementation from SI RCA investigations where these are undertaken to share the learning locally.

What Information is required?

Full anonymised details including when and how it happened, how it's being managed including media handling arrangements. The guidance notes that limited information early is better than full information late. The NHS England recommends that information should be supplied in accordance with: **I**ncident – **B**ackground - **A**ction

When does the report get updated?

Three days after the incident is reported, the STEIS form should be updated with further details to confirm whether the incident is an SI. If it is no longer felt to be an SI after initial investigation, the possibility of de-escalation can be discussed with the NHS England

The STEIS form should also be updated if:

- Situation deteriorates
- If the level of media interest changes (especially if it increases)
- If the 'line to take' changes
- When the situation is resolved
- If there is police interest
- Where there is an increased level of family concern
- Further high profile coroner's inquests
- If there is a court case
- In the event of a publication of an inquiry or investigation.
- outcome within one working day of a serious case review panel meeting

- outcome of third party review e.g. POVA panel, OFSTED judgment for child protection serious case review

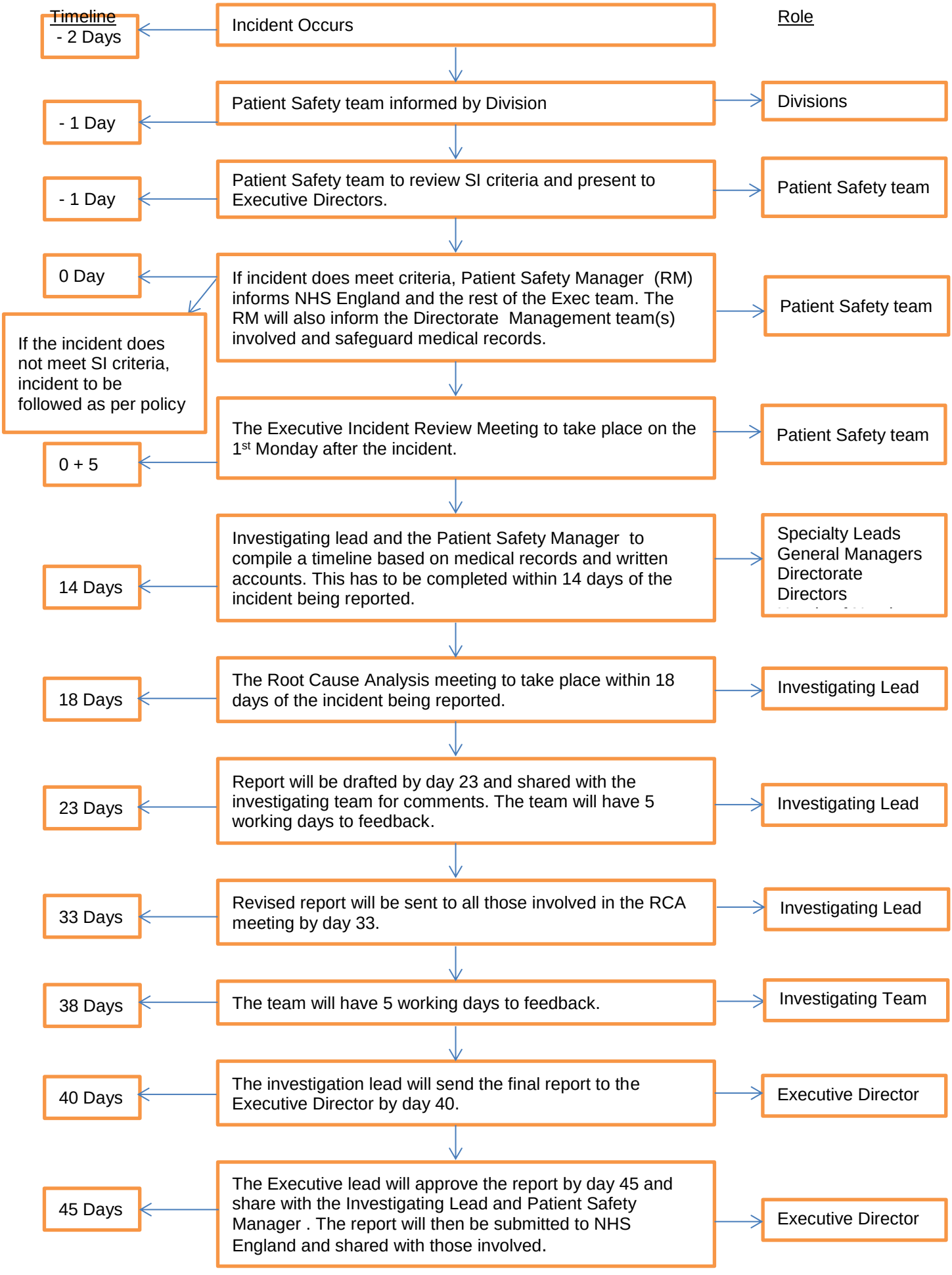
What if more than one organisation is involved?

If more than one organisation is involved in an SI, the organisation which has discovered the incident can make the initial SI report to NHS England having first made contact, wherever possible, with the organisation from whence it originated. Where this relates to an incident involving the HSE or the Police, the Memorandum of Understanding should be followed. The organisations involved will agree on who will take the lead role in investigating the SI updating STEIS. The reporting organisation must notify NHS England of this decision via STEIS and email.

What if investigation shows it was not within the definition of an SI?

SIs reported based on limited information and which on further investigation do not meet the criteria for an SI can be de-escalated. A request is sent to NHS England with the detail as to why it should be de-escalated. NCL will review the de-escalation request and inform the Trust of its decision within 10 working days. As de-escalation on STEIS means the record is deleted from the system, NCL may take the decision to close the SI without a report rather than deescalate it. NCL may decide that the SI should not be de-escalated and a full SI report is required. Where the SI is to be closed without a report this will be noted on the NHS England comments section of the STEIS record.

SI Reporting Process Flowchart



Roles & Responsibilities

Chief Executive

- Will be notified of all Serious Incidents by the Patient Safety team
- Public liaison

Executive Director (Exec lead for Investigation)

- Approves the decision to declare an SI
- Chair the Executive Incident Review Meeting on the first Monday following the incident as per the terms of reference.
- Appoints the lead investigator with the Chief of Service
- Reviews progress of investigation on a regular basis through receipt of weekly update reports from the Quality and Safety team
- To ensure that obstacles to completion of the SI within the timescales are addressed and timescales are met
- Provides support to investigating team
- Reviews and approves all SIs reports before they are submitted to NHS England.

Investigation Lead (a member of the Directorate management team)

- SI process becomes highest priority in their workload
- Attend the Executive Incident Review meeting on the first Monday following the incident.
- Ensure that on-going support is provided and available to all staff involved in the SI.
- Along with the allocated Patient Safety Manager , request written accounts from those involved giving staff 7 working days to submit. If by day 8 the written accounts are not received the Executive Lead must be informed.
- By day 14 a timeline, based on the medical records and written accounts, must be completed and disseminated to those attending the RCA meeting.
- Arrange and attend the RCA meeting, ensuring that all relevant parties attend and that the meeting is adequately recorded. This must be completed by day 18 of the reported incident.
- By day 23, the first draft of the report must be compiled and circulated with the investigating panel for comment and feedback. The investigating panel should be given 5 working days to review and feedback.
- By day 33, the revised report must be circulated to all staff involved in the incident for comments. The staff should be allocated 5 working days to review and feedback comments.
- By day 40, the Executive lead must be sent the final draft of the report for approval.
- By day 45, the Executive lead must review and approve the report for submission.
- Send the final draft to all staff involved for completion.
- Lead the investigation and development of recommendations from the SI
- Ensure all timescales are achieved

- Attend the Patient Safety and Outcomes Committee(PSOC) and ensure that all learning & risks identified at the committee are implemented locally
- Escalate corporate wide issues to the Executive

Patient Safety team

- Review criteria and advise the Executive team on whether the incident needs to be reported as an SI
- Inform NHS England of the SI via STEIS
- Consider whether the incident needs to be reported to any other organisation and ensure that this takes place
- Allocate a named Patient Safety Manager to the SI to support the Investigation Lead during the whole process.
- Safeguard the medical records and arrange for them to be scanned or copied for ease of access to those involved.
- Along with the lead investigator, request written accounts from those involved giving 7 working days for the statements to be received. At 5 days a reminder should be sent to those involved.
- By day 14 a timeline, based on the medical records and written accounts, should be completed and ready to disseminate.
- Attend and facilitate the RCA meeting, ensuring that the methodology is used appropriately and the relevant information is obtained. The Patient Safety Manager will arrange for an administrator to take notes of the meeting.
- Liaise with NHS England over de-escalation where decided by the Head of Quality and Safetyand the Executive Lead
- Send report to NHS England and ensure the family have received a copy of the report.

Additional Information on the Management of Specific SI's

A. Death of a Child

For full details on information sharing when a child dies please refer to the Child Death Overview Information Sharing Policy available on the Document Library.

1. Expected Death of a child which is anticipated
Definition: The death of the child was anticipated within a 24 hour period.

Action required:

- Report through the LSCB Child Death Review Process
- Case is managed according to Chapter 7 of Working Together, which monitors all child deaths in the LSCB area.
- No SI report is generated for this category.

2. Unexpected Death of a child which is not anticipated. No suspicious concerns
Definition: When the death of the child was NOT anticipated as a significant possibility 24 hours before the death, or when there was a similarly unexpected collapse leading to or precipitating the events that led to the death.

Action required:

- No suspicious circumstances in the history and the causation of death is known, report immediately to single point of contact for child death at GOSH (Bereavement services)
- Bereavements Service to notify Local CDOP within one working day
- Managed according to Chapter 5 of Working Together to safeguard children 2013. The case will be reviewed by the LSCB Child Death Overview Panel (CDOP) and a rapid response led by them will be held if required
- Attendance at the Rapid response meeting or report to be sent via the medical lead if they can't attend.

3. Unexpected Death of a child and possible suspicious circumstances or child protection concerns are identified
Definition: Where the death of the child that was NOT anticipated as a significant possibility 24 hours before the death, or when there was a similarly unexpected collapse leading to or precipitating the events that led to the death. In addition the presentation or initial enquiries indicate that there may be suspicious circumstances or factors relating to abuse or neglect.

Action required:

- Report immediately to single point of contact for child death review
- Report immediately to designated professionals expressing clearly the concerns that have been identified. Consideration should be given to whether the Police should/need to be informed.
- Complete STEIS report and notify NHS England of SI.

B. Information Security Incidents

All incidents relating to breaches of confidentiality involving person identifiable data and data losses are reported in line with Health and Social Care Information Centre (HSCIC) guidance[4]. Incidents that meet the criteria for a 'level 2' Serious Incident Requiring Investigation must be reported using the HSCIC incident reporting tool on the IG Toolkit, which in turn reports to NHS England and the Information Commissioner's Office. This is done by the Head of Information Governance. In addition the incident should be reported on STEIS as per other types of serious incidents, this is done by the Patient Safety team . Internally, the Senior Information Risk Officer, IT Security Officer (where IT related), Company Secretary as Data Protection Officer, Division Director, Head of Department / General Manager are informed and the Caldecott Guardian executive lead.

The following is assessed as a minimum:

- Nature of the loss- Theft, accidental loss, inappropriate disclosure, procedural failure etc.
- The number of patients / staff (individual data subjects) involved
- The number of records involved
- The media (paper, electronic) of the records
- If electronic media, whether encrypted or not
- The type of record or data involved and sensitivity
- Where and when it was lost
- Whether the information could damage the reputation of an individual, a work-team, an organisation or the NHS as a whole
- Whether there are legal implications for the trust
- The distress, embarrassment, detriment (including financial) or risk of physical harm caused to the individual's concerned

An action plan is agreed with the local team to notify patients and manage any subsequent queries or press interest.

The loss or theft of removable media (including laptops, removable discs, CDs, USB memory sticks, PDAs and media card formats) upon which data has been encrypted to the approved standard, is not a Serious Incident reportable to the NHS England but is reportable internally.

[4] Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation, June 2013

Appendix 2: Reporting Injuries to staff[5]

Contamination injuries

"**Contamination injuries**" must be reported to Occupational Health. These are:
Accidental punctures of skin by:

- a used needle (i.e. needle stick incidents); or
- a used instrument;
- a human bite
- Splashing of blood or body fluids into an eye, mouth or abraded skin (i.e. an open cut).

If a member of staff incurs any of these injuries, an Incident Form must be completed and he/she must take it with him/her to Occupational Health. Occupational Health will complete the relevant part of the Incident Form, after which the usual procedure for completing and sending in an Incident Form will be followed.

The injured member of staff must ring first and then go to Occupational Health as soon as possible after the incident. Out of hours, the on-call microbiologist should be contacted via switchboard. If in doubt, the member of staff must obtain advice from their manager in hours or the CSP's out of hours.

Any other injury

For any injury other than a contamination injury (e.g. a back injury, sprain etc.), the member of staff should go to accident and emergency at UCH or to his/her GP if advised to do so in accordance with the Health & Safety policy, taking the incident form with him/her to be completed by the doctor he/she sees. After this, the usual procedure for completing and sending in an Incident Form will be followed.

RIDDOR Reporting

If a member of staff is off sick for more than 7 days, he/she must state this on the incident form. This is to enable the Health and Safety Adviser to report the incident to the Health and Safety Executive (a legal requirement under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995). There are statutory time scales in which this must occur therefore it is important that all staff injuries are reported appropriately. Advice can be sought from the Health & Safety Adviser on Ext. 7885.

[5] See Health & Safety Policy

Appendix 3: Instructions for dealing with Equipment[6] involved in an incident

Basic Principles

The following basic principles are taken from the guidance given by the Medical Devices Directorate at the Department of Health (Doing No Harm, 1994). It is the responsibility of ward / department managers to ensure that these principles are observed:

- Ensure the patient is safe and complete an incident form; the form should include full details of the equipment (e.g. serial number, batch number, settings); A copy of the form should be sent with the equipment to BME.
- Keep the device involved in the incident, including packaging and instructions, where appropriate - if it is a machine, ensure that all settings at the time of the incident are documented but try to leave all switches and controls as they were at the time of the incident, unless they have to be changed to make them safe;
- Do not return the device to the manufacturer, before it is examined by an appropriate person eg Clinical Supplies Advisor, Biomedical Engineer;
- If the item is part of a batch, check the remaining stock and ask if the defect has arisen due to faulty storage. The batch may need to be withdrawn.

Who to return equipment to

Biomedical devices will be sent in a safe condition to the Biomedical Engineering Department (BME). BME will evaluate the equipment and establish whether the MHRA need to be notified, depending on their findings.

Disposable devices involved in an incident which may be needed as part of an investigation will be sent for decontamination. A copy of the incident form will be sent with the equipment.

Follow up may include contacting the manufacturer and reporting the defect to the MHRA. Advice can be sought from BME.

Situations may occur where staff feel that the equipment cannot be removed from the ward or decontaminated before investigation, e.g. in the context of child protection concerns. Advice must be sought immediately from the Lead for Child Protection, Legal team or the Patient Safety team (the CSPs out of hours) in these circumstances.

External reporting

The Medicines and Healthcare products Regulatory Agency (MHRA)

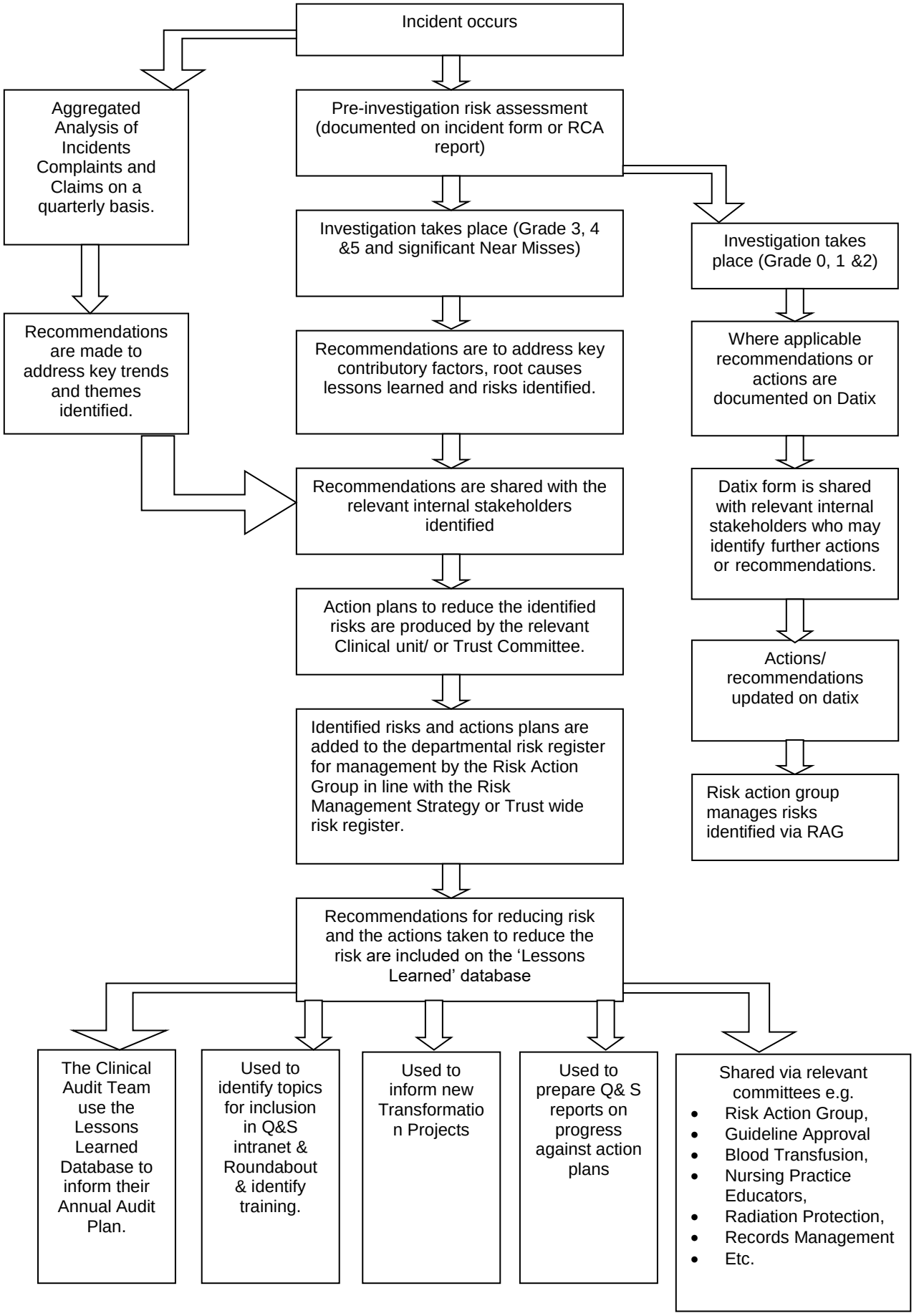
The MHRA will be notified of incidents involving devices, equipment or related procedures including:

- Any safety related incident.
- Problems arising through incorrect use, inappropriate modification, adjustment or maintenance.
- Minor accidents or anomalies which may indicate inadequate quality assurance or instruction on the part of the manufacturer or supplier.

Incidents categorised as device failure or user error will be reported to the MHRA on a monthly basis following review by the Patient Safety Manager and Biomedical Engineering.

[6] See Equipment Policy for routine repair of faulty equipment not involved in an incident

Appendix 4- Risk Reduction Process



Appendix 5- Risk Assessment Tool

Introduction

Risk assessments are the corner stone of any safety management system. Undertaking risk assessments is a fundamental part of the process whereby the necessary arrangements for controlling risks are identified, implemented and monitored. The Trust has therefore established a Trust wide tool for recording risk assessments. Risk assessments are a legal requirement for all NHS Trusts. The purpose of this tool is to help staff undertake any risk assessment in any field where a specific tool is not otherwise available. The principles are the same but the techniques may vary from issue to issue.

It is the department manager/Directorate director's responsibility to ensure that risk assessments are undertaken and risks to patients, staff and others are reduced to acceptable levels. These assessments must be reviewed on a regular basis. The action plans will be used to inform the division and Directorate boards/departments on progress to reduce risk at least every quarter.

How to undertake a Risk Assessment

A risk assessment is best undertaken by a multi-disciplinary team. The process of undertaking a risk assessment is the same for clinical, non-clinical, research projects and moving and handling assessments. Please follow the steps below:

Identify the hazard.
A hazard is anything that has the potential to cause harm. The important thing is that you identify those hazards.

Decide who can be harmed and how?
GOSH has many vulnerable groups that need to be taken into account when undertaking a risk assessment. Consider what particular risks there may be to each of the different groups of people involved (or exposed) to the hazards identified and how this will affect the level of risk.

Assess the risks and decide if measures currently in place are adequate to prevent harm or should more be done?
Risk is the chance that an identified hazard will cause harm.

State the risks that are involved with the work/ event and establish how likely it is that these will cause harm, and how severe this harm is likely to be. The matrix below will help you determine the severity of the risk and whether or not you need to try and reduce the risk.

Risks can be measured by assessing the likelihood of harm occurring and the possible severity of the consequences to provide a score, which can assist in identifying whether a risk is low, medium or high. These need to be documented on the risk register. Even after all safety measures have been implemented, some risk usually remains. Your aim is to make all risks smaller by implementing adequate control measures. If the existing risk is medium or high then you should implement additional measures to reduce the risk to 'Low' as far as possible or practicable. Please see the Accepted Risk process in the Risk Management Strategy. These should be documented on a separate action plan, if necessary with the options you have taken to either control or accept this risk or the risk register updated regularly with progress against the actions taken.

If a risk is to be accepted this must be decided in conjunction with the Directorate director/ head of department and documented on the risk register to ensure regular review. If in doubt, advice must be sought from the Head of Quality and Safety

Risk Assessment Matrix

SEVERITY	LIKELIHOOD				
	1 **Very Unlikely** ***(Freak event – no known history- 1 in 100,000 or less)***	**2** **Unlikely** ***(Unlikely sequence of events1 in 100,000 to 1 in 10,000)***	**3** **Possible** ***(Foreseeable under unusual circumstances 1 in 10,000 to 1 in 1000)***	**4** Likely ***(Easily foreseeable – 1 in 100 - 1000)***	**5** **Very Likely** ***(Common occurrence – 1 in 100 chance in any one year)***
1 **No harm** ***(No injury, no treatment required, no financial loss.)***	Low	Low	Low	Low	Low
2 **Minor** ***(Short term injury, first aid treatment required, minor financial loss)***	Low	Low	Low	Medium	Medium
3 **Moderate** ***(Semi permanent injury, possible litigation, medical treatment required, moderate financial loss)***	Low	Low	Medium	High	High
4 **Major** ***(Permanent injury, long term harm or sickness, potential litigation, fire, major financial loss)***	Low	Medium	High	High	High
5 **Catastrophic** ***(Unexpected death, potential litigation, catastrophic financial loss)***	Low	Medium	High	High	High

Record Your Findings

The risk register will show all the risks you have identified. For clinical and non-clinical risks, it is good practice to ensure that this information is disseminated through the RAG so that all your colleagues are aware of the same risks. As these risks are reviewed, some of them will be removed from the risk register, and new risks will be highlighted. Changes to the risk register must be recorded on Datix. If issues arise that require disseminating across the Trust, they will facilitate this process. The higher and more complicated risks will have achievable action plans documented, to show whether you are going to try and reduce, eliminate, accept or transfer the risk to someone else.

The Datix system which is accessible to all clinical and non-clinical units is overseen by the Patient Safety team must be used to store and update the risk register. It is important that action plans are documented so that progress against them can be monitored effectively by named committees or time limited groups, including the number and outcome of risk assessments undertaken.

Review your assessments

Risk reduction is an on-going process and as such periodic reviews of risk assessments and action plans are required to evaluate its success. Sometimes, when you introduce steps to reduce risks, you may introduce further hazards. It is important that this process is reviewed on an on-going basis so that staff and patients are not vulnerable.

Further Guidance on Risk Assessments

Clinical Risk Assessments

These include anything that you think could potentially cause harm or have a negative effect on patient safety. It is also extremely useful if you think there is a potential problem but you are not sure whether you should do anything about it or not. A good example of this is 'should tracheal dilators be kept at a patient's bedside or not?' A risk assessment was undertaken looking at the risks of having tracheal dilators at the bedside and not having them. Each risk was scored for their likelihood and severity, and action plans were drawn up as the best way to deal with the issue.

Risks assessments are required as part of any proposed business case for the development or improvement of a clinical service. If you consider something is a risk within your department, but is quite costly to fix, a risk assessment must be one of the first steps you take in order to highlight the problem. It will also help you look at how you can manage the risks in the short term, until your business case is/is not accepted. This is one of the most important reasons as to why risk assessments are multi-disciplinary- so that all avenues can be explored and the effect considered from a different perspective.

Non-Clinical Risk Assessments

It is a legal requirement for every employer to make an assessment of the health and safety risks arising out of their work. The purpose of the assessment is to identify what needs to be done to control health and safety risks.
The findings must be added to the risk register. Although the department/ division managers in each area will ensure that risk assessments are carried out for all work activities, the risk assessment process is a team exercise and must involve those people affected by the activity.

Moving and Handling Risk Assessments

It is the law to undertake a moving and handling risk assessment before moving a load (e.g. box, child, and equipment) At Great Ormond Street we have three moving and handling assessment tools to help you undertake these assessments.

- **Loads**. Most staff move and handle items as part of their job. It is therefore essential that objects and/or systems or work, which present a risk of injury, be identified, recorded and the information disseminated amongst the relevant staff.
- **Patients/Children**. All patients must have a risk assessment completed on admission; this must be reassessed if the child's ability, mobility or condition changes.
- **Generic Patient and Non-Patient Area and Safe Systems of Work Assessments**. All areas in the trust must undertake, annually, a moving and handling risk assessment of work activities in their area to ensure that new hazards or risks are identified, recorded and disseminated amongst the relevant staff.

High risks or on-going risks must be transferred onto the unit's risk register, so that the unit and departmental teams are aware of them. Further information on the Trust's processes for monitoring risk can be found in the Risk Management Strategy.

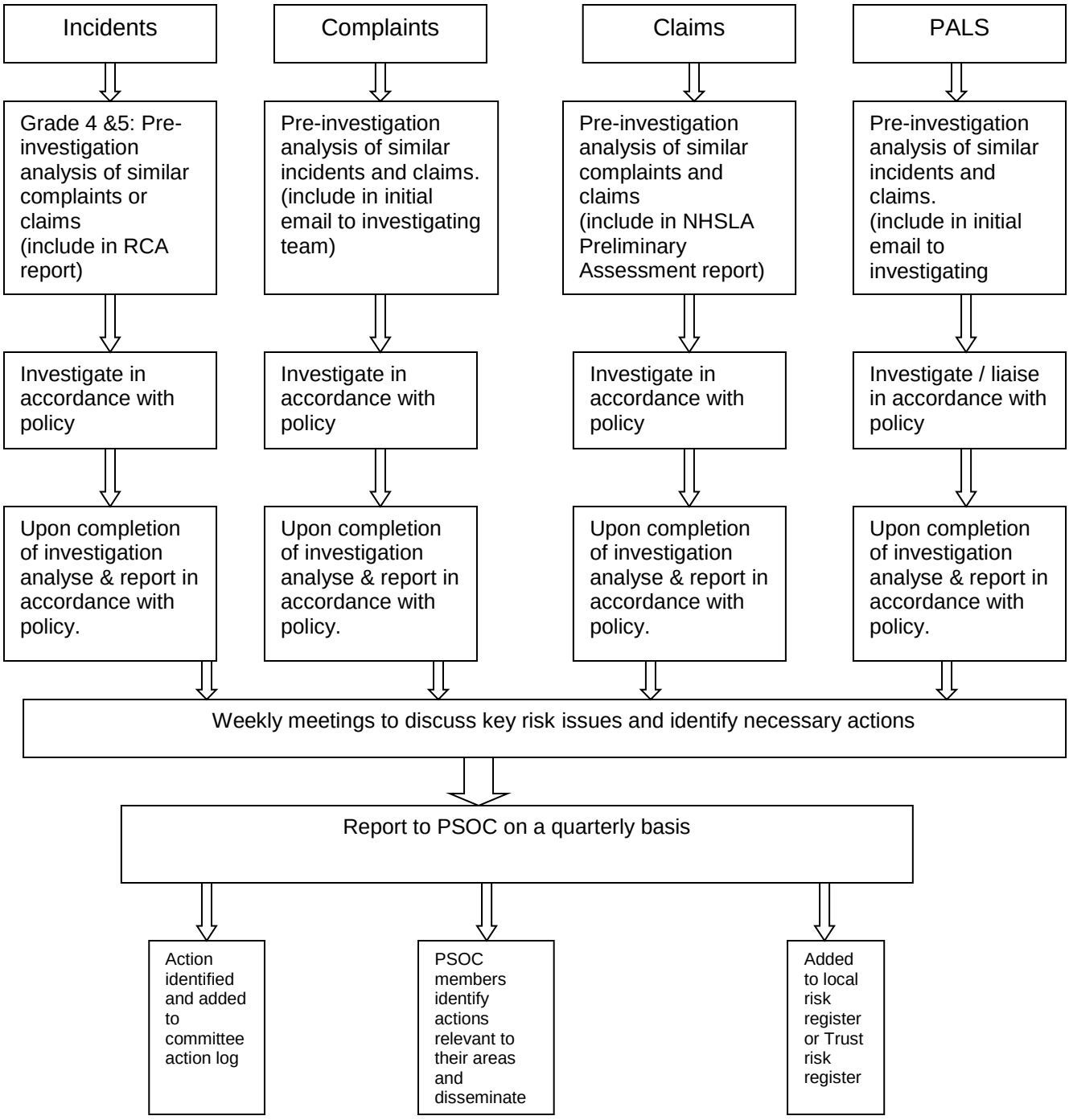
Appendix 6- Analysis and Learning from Incidents, Complaints PALS & Claims

All incident, complaints, PALS and claims data will be held centrally on the Trust's risk management system [Datix]. This database provides an interface between risk management, incident reporting, PALS, complaints management and claims handling and enables a coordinated approach to managing risks identified as a result of incidents, complaints, pals and claims.

Minimum Content

All incidents, complaints, PALS and claims will be analysed and reported separately in accordance with their respective policies. This chart demonstrates the minimum content of the quarterly reports:

	Minimum content of report includes aggregation of:	**Actioned By**	**Summary report goes to:**
Incidents	Number of incidents reported in the preceding quarter, level of severity of incidents reported, top 5 categories of incidents, top 10 categories of high risk incidents	Patient Safety Manager s	1.PSOC to identify outcomes of analysis, make recommendations regarding actions required to Clinical Governance Committee to provide assurance on progress against actions Trust Board to confirm review process in place and working. If identified risks are not already on a local departmental risk register, then the risk will be added to the Trust wide risk register. 5. Agreed actions are added to Datix
Complaints	Number of complaints closed in the previous quarter, top three themes raised in complaints, details of any high risk complaints.	Patient Safety and Complaints Manager	
Claims	Top three themes identified through preliminary assessment of claims	Trust Solicitor	
Risks	Any correlations between the risk registers and key themes identified in the aggregated analysis	Patient Safety Manager s	
Pals	Key themes in all cases	PALS Manager	


Incidents
Complaints
Claims
PALS
Grade 4 &5: Pre-investigation analysis of similar complaints or claims (include in RCA report)
Pre-investigation analysis of similar incidents and claims. (include in initial email to investigating team)
Pre-investigation analysis of similar complaints and claims (include in NHSLA Preliminary Assessment report)
Pre-investigation analysis of similar incidents and claims. (include in initial email to investigating
Investigate in accordance with policy
Investigate in accordance with policy
Investigate in accordance with policy
Investigate / liaise in accordance with policy
Upon completion of investigation analyse & report in accordance with policy.
Upon completion of investigation analyse & report in accordance with policy.
Upon completion of investigation analyse & report in accordance with policy.
Upon completion of investigation analyse & report in accordance with policy.
Weekly meetings to discuss key risk issues and identify necessary actions
Report to PSOC on a quarterly basis
Action identified and added to committee action log
PSOC members identify actions relevant to their areas and disseminate
Added to local risk register or Trust risk register

Appendix 7: External Stakeholders: Reporting Roles and Responsibilities

The National Reporting and Learning Service

The Trust will comply with the requirements of the NRLS. All clinical incidents are reported anonymously using the National Reporting and Learning System. Staff can report on line to the NRLS instead of via the Trust incident reporting system if they wish. Staff who do this must understand that the incident report will be logged only, and no feedback will be given to them by the NRLS.

The Patient Safety team are responsible for reporting all relevant incidents to the NRLS. The Head of Clinical Governance monitors compliance.

NHS England

The Trust reports all relevant serious incidents to the NHS England via the STEIS system. The CQC also has access to and monitors the incidents reported via the NRLS.

The Patient Safety team are responsible for reporting all relevant incidents to the NHS England.

The Coroner

There are a range of situations where a death must be reported to the coroner (eg cause of death is unknown, due to violence or poisoning). Practitioners should consult the guidelines for referring deaths to the Coroner available on GOSHWEB. Referrals must be made electronically via coroners.referrals@gosh.nhs.uk. A Coroner's Officer will call back to advise whether or not a death certificate may be issued. . The Legal team will liaise closely with the Coroner's Office and staff to ensure that statements are provided in a timely manner. They will also accompany staff to inquests, if necessary. If Risk Management are informed of a coroners referral they will refer the case on to the Legal team who manage the process.

Where the death meets the criteria for reporting, clinical staff have the responsibility for reporting this to the Coroner. Advice can be sought from the Legal team and the Patient Safety team .

MHRA Serious Adverse Blood Reactions and Events (SABRE) and Serious Hazards of Transfusion (SHOT)

Reporting of all serious adverse reactions and events relating to Blood Transfusion is mandatory, to comply with UK legislation. Reporting is facilitated by the MHRA via the SABRE reporting system. SABRE provides a single reporting point for both the MHRA and SHOT, where the reporter can choose to submit a report to only one organisation or both. Information reported using SABRE that is shared with SHOT remains anonymous.

Blood Transfusion is informed of all incidents involving the transfusion of blood components and the Transfusion Practitioner, or the Blood Transfusion Laboratory Manager has the responsibility for reporting to SABRE and/or SHOT.

The Medicines and Healthcare products Regulatory Agency (MHRA)

See appendix 3.

Health and Safety Executive (HSE)

The Health and Safety Advisor will report under the RIDDOR requirements to the HSE on behalf of the Trust. Health and Safety is part of the Estates and Corporate Facilities team.

NHS Estates

The Trust reports all relevant estates incidents through the Health & Safety Advisor or senior manager within the Estates Department.

The NHS Litigation Authority (NHSLA)

The Trust Solicitor has responsibility for ensuring that any relevant incidents are reported to the NHSLA. Third party investigation could be required if there is a high probability of litigation. The NHSLA may choose to undertake an independent investigation if this is the case. Any incident which may compromise compliance with the risk management standards will also be reported to the NSHLA.

The Police

The police may be contacted as a result of allegations of criminal events committed against a child, child protection concerns of physical or actual abuse, where the clinical presentation of a child is not as expected (e.g. possible line tampering, interference with child's equipment or environment). The child protection policy will be referred to in these instances.

The police may be called if there are cases of unexpected death, which do not fit with the clinical picture. Their advice may also be sought where there is any doubt regarding the care or treatment of a child. The responsibility for contacting the police lies with any staff member who suspects a criminal event has occurred. Support is available from the Legal team, Risk Management, the Clinical Site Practitioners, the Child Protection team, the Social Work department and the Security staff as appropriate. If a police investigation is instigated, the Quality and Safety team or the Legal team will co-ordinate the process, depending on the nature of the case. This is to ensure appropriate levels of support to staff providing statements.

Care Quality Commission

As part of its assessment to determine whether the organisation is safe, the CQC considers whether there are effective and embedded arrangements for reporting safety incidents and allegations of or actual abuse, which are in line with national and statutory guidance. It also reviews whether there is a consistency of reporting across services and consistent approach to reporting across services and whether the Trust is actively engaged in applicable external reporting systems. Incidents of unintended exposure to radiation will be reported in line with IRMER.

Information Commissioner's Office

In the event of loss of personal, identifiable data the Information Commissioner's Office may need to be informed. This is done by the Head of Information Governance via the HSCIC Incident reporting tool. The loss may be of data in any format e.g. paper, electronic, loss of USB tick etc. If in doubt, advice can be sought from the Head of Information Governance, Data Protection Officer or Head of Quality and Safety

Appendix 8 - Procedure for establishing a telephone hot line[7]

Summary and Guidance

In some instances it may be necessary to establish a 'hotline' as a result of an adverse event or issue of patient safety which will impact on patients / patient services and raise questions of public concern.
While having similarities to establishing a communication centre, as outlined in the Major Incident Procedure, the key difference is that there may be some warning that a hotline will need to be established eg as a result of a government report due to be published such as prior to the organ retention issues; as a result of a known serious adverse clinical event e.g. where harm has occurred to a child; or as a result of queries regarding a certain practitioner or practice e.g. Hepatitis contamination of patients by staff. The procedure outlined below is based on previous experience the Trust has had in responding to national enquiries both on a continuous basis and in response to major incidents.

Aim of the hotline

To provide clear and consistent information as a result of an adverse event or issue of patient safety which will impact on patients / patient services and will raise questions of public concern. This information may be provided for:

- Patients and /or families directly affected
- Other patients and members of the public who may be concerned
- Others working in the NHS or with the NHS
- Provide direct advice or make appropriate referral to expert advice for patients and/or families and NHS staff directly affected or concerned
- Sign post or reassure people who are concerned or distressed about a health issue not related to the event

Definition of an event

Using the existing risk management classifications of adverse events a hotline may be needed for example in the event of a **grade 5 catastrophic** incident occurring. This is defined as an event where:

- the death of one or more persons has occurred
- the event is likely to cause national adverse publicity
- litigation will occur
- the event has a risk of huge financial loss/ reputation to the organisation or its staff

Management Responsibility

The responsibility for deciding to establish a hotline rather than use existing services rests with the Executive team. The decision will be based on:

- the nature of the incident
- the potential number of multiple enquiries which are anticipated
- the length of time a hotline may need to be available
- the resource implications required.
- whether the event requires multi agency or multi organisational involvement

A core group of staff will be established to take calls to ensure that the correct expertise is available and to keep disruption of normal service delivery to a minimum. This group will retain management responsibility for the hotline with direct reporting to the Chief Executive and Executive team. Additional staff may be added to the group if appropriate and depending on the nature of the incident. The system to record contacts will be the same as used in the event of a major incident wherever possible. The Executive team will agree the information to be given, will be consistent and in line with any press statements and reviewed on a daily basis or more frequently if necessary, depending on the nature of the event.

Location of the Hotline

The hotline will be located through from switchboard to a central contact point. This may be within existing offices of the staff allocated to respond to external queries or within the most appropriate alternative area of the Trust. Depending on the number of calls received, arrangements may be needed to increase the number of lines available at short notice or to establish an '0800' number via BT. This responsibility will lie with the Executive team in liaison with NHS London and relevant press offices.

Maintaining Contact

Depending on the nature of the incident, and the number of queries, press, public or national interest, briefings will occur between the Executive team and those staff designated to receive enquiries.

Establishing the hotline as a result of an internal event at GOS

If the hotline needs to be activated as a result of an internal event e.g. as a result of a known serious patient safety incident, or as a result of queries regarding a certain practitioner or practice by a member of GOS staff, there will be an additional need to advertise how this information can be obtained.
This process will need to link into that established by NHS England which ensures they are informed of any such major incident and can provide an immediate response. This ensures their communications lead is able to brief upwards to the Department of Health as necessary. The Chief Press Officer and other members of the Executive team will action this process and ensure that any other external agencies are informed.

A lead will be identified at local level, usually the division chair, to co-ordinate any local response. Information internally will be provided by means of targeted Trust wide email to be cascaded to staff and parents and families as necessary, once the Executive team has assessed the situation. This will identify contact sources for internal and external enquiries, which may need to include postal as well as electronic means. The level of action taken will be agreed by the Executive team based on an assessment of the type of incident and its possible effect on public confidence.

Appendix 9- Equality Analysis Form

INCIDENT REPORTING AND MANAGEMENT

COMPLETED BY
Salina Parkyn

DATE COMPLETED
February 2015

POTENTIAL EQUALITY IMPACTS AND ISSUES IDENTIFIED

Protected group	Potential issues identified	Actions to mitigate/Opportunities to promote
Age	None	
Disability (including learning disability)	Those who may have difficulty with literacy	Policy can be viewed in easy to read format and discussed if required
Gender re-assignment	None	
Marriage or civil partnership	Marriage does not automatically give someone the right to patient information	Those with PR for the patient will be openly communicated with
Pregnancy and maternity	None	
Race	None	
Religion or belief	None	
Sex	None	
Sexual orientation	None	

ASSESSMENT OF EQUALITY IMPACT
Patients, parents and carers will be communicated with openly