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26 October 2018

Freedom of Information Request – Ref: FOI 191-1819

Thank you for your recent Freedom of Information request about serious incidents. Please find the Trust's response below.

- Please can you share your serious incident reporting criteria and process.
  The incidents policy and procedure is attached

- Are all patients that are admitted to a caseload who die unexpectedly reported as a serious incident for the organisation? If not – what criteria do you use?
  Not all unexpected deaths are reported as serious incidents. Those which appear to be 'suspected suicides' are, others are considered via the mortality review process. If, as part of this process, or in the event of other findings via coroners inquires it transpires that we should investigate the death under the auspices of the serious incident process then we report & subsequently investigate at that juncture.

Yours sincerely,

Lisa Evans

LISA EVANS
Information Governance Officer
2gether NHS Foundation Trust

Incidents Policy & Procedure

(Including the Management of Serious Incidents, Clinical Incidents and Mortality Reviews)

Version:	17
Consultation:	Localities Executive Directors Information Governance Lead Heads of Profession Gloucestershire CCG Herefordshire CCG
Ratified by:	Governance Committee
Date ratified:	October 2017
Name of originator/author:	Gordon Benson / Paul Ryder
Date issued:	October 2017
Review date:	September 2019
Audience	All Trust employees

VERSION HISTORY

Version	Date	Reason for Change
10	11 June 2011	Updated to reflect new services in Herefordshire (Onward reporting to West Midlands SHA)
11	May 2012	Annual review. No significant amendments to process as national guidance has not changed. The formal of the document has been updated to reflect the requirement of the *" Policy, Procedure and Guidance for the Development and Management of Policy, Procedure and Guidance Documents" October 2012* Minor amendments to job titles/title of national bodies Recommendations from Internal Reviews have been included within this revision: 1. Para 6.2 (page 7) – managers to seek advice from the IG Manager in the event of loss of PID 2. Para 17.3 (page 13) – staff support if police are involved 3. Para 21.6 (page 15) – need to establish all known facts regarding serious incidents 4. Para 24.8 (page 19) – investigating officers to be RCA trained and have no involvement with the service user or team 5. Appendix 3 (page 36) – in the case of all deaths, families/carers to receive signposting for bereavement support.
12	Feb 2013	Updated to reflect the requirements of the Memorandum of Understanding; *Investigating patient safety incidents involving unexpected death or serious untoward harm* published by Department of Health, Association of Chief Police Officers, Health and Safety Executive (2006) – (seen in para.24.13) Appendix 3 –Support to Families amended to make specific the role of Family Liaison regarding the above requirements.
13	June 2013	Para 24.14 added to make explicit that care coordinators and responsible clinicians should not undertake the role of Appropriate Adult if requested to attend the custody suite by police. References to PCTs changed to CCGs. Procedure for reporting SIRIs to Herefordshire CCGs clarified in Appendix 9. Examples of harm classification of incidents e.g. #NOF or self-harm incidents provided in Appendix 10 to improve consistency.

14	June 2014	Procedure for reporting SIRIs to Herefordshire CCG updated in Appendix 9. References to the Clinical Risk Management Committee have been removed as this function is performed by the Governance Committee.
15	November 2014	Updated to include reference to the requirements of the Duty of Candour
16	July 2015	Incorporating updated elements of the Serious Incident Framework published by NHS England, March 2015
16.1	July 2016	Additions made to incorporate Clinical Incident management at 26.3 (i.e. those incidents which do not meet thresholds for SIRI but are considered sufficiently serious to require a local review) and recognition of changes in the role of H&S Advisor with regard to MHRA device alerts at 6.6 and 6.7 and also development of the Datix Systems Manager post. This policy will be reviewed in December 2016 on publication of awaited CQC guidance regarding Mortality Reviews.
17	October 2017	Additions made to Section 14 to incorporate the Learning from Deaths Policy which was ratified in September 2017.

TABLE OF CONTENTS

PART A: POLICY ON REPORTING AND MANAGING INCIDENTS

1. Policy Statement

1.1 In accordance with national guidance and legislation, the Trust is required to report all incidents and near misses irrespective of the outcome which affect one or more persons, related to service users, staff, students, contractors or visitors to trust premises; or involve equipment, buildings or property.

1.2 The Trust aims to take an integrated approach to learning from all incidents and deaths in order to improve and assure its services.

2. Introduction

2.1 [2]gether NHS Foundation Trust recognises the need for the prompt reporting of all incidents: deaths, clinical, non-clinical and 'near misses', as part of its Risk Management Strategy in order to improve service user and staff safety and its quality of care.

2.2 The Trust supports an active approach to managing incidents and places emphasis on lessons learnt rather than apportioning blame; there may however be occasions when the Trust's disciplinary procedures will need to be considered.

2.3 The Trust recognizes its particular obligations towards serious incidents and the need to follow strict reporting and investigation guidelines based on national and local commissioning guidelines as well as best practice. In particular, it has in place such systematic measures to:

- Safeguard people, property, the Trust's resources and its reputation
- Understand why the event occurred
- Ensure that steps are taken to reduce the chance of a similar incident happening again
- Report to other bodies where necessary
- Share the learning with other NHS organisations and providers of NHS-funded care

3. Purpose

3.1 This policy relates to the reporting, recording and investigating procedures which are to be adopted when any employee, patient, contractor or visitor experiences an incident, near miss or dangerous occurrence during the course of their work and/or whilst on Trust premises and/or receiving services from the Trust. It is also concerned with learning lessons from incidents to avoid similar occurrences.

3.2 In addition to all staff involved in the administering, investigating, reporting on and managing incidents, the policy applies to those that have:

- Witnessed an accident/incident
- Been directly involved in an accident/incident
- Discovered that an incident has occurred
- Have been told that an accident/incident occurred
- Experienced events that could have resulted in an incident/accident

3.3 The purpose of this policy is to support all staff by ensuring they have:

- Knowledge of the Trust incident reporting system (Datix)
- Guidance on procedure at individual, local and Trust level
- Information as to professional, statutory and legal duties

3.4 This policy will ensure that there is a structured, consistent and systematic approach to the reporting and investigation of adverse events, which have or could have led to harm. The process must be seen as non-threatening in order to promote a greater openness amongst staff where lessons learned from incident and near miss reporting is seen as an ongoing process within the organisation.

3.5 The procedures relating to this policy aim to simplify and streamline the incident reporting systems for staff, service users and visitors while ensuring the Trust meets its statutory duties under the Health and Safety at Work Act and the standards set by the CQC, National Reporting & Learning System (NRLS), NHS Litigation Authority and other such bodies.

3.6 This document is divided into two parts: the first covers the overall policy relating to incidents, whilst the second is a detailed set of procedures to manage incidents, particularly those judged as serious incidents.

3.7 When carrying out the procedures associated with this policy, there are certain elements common to other systems, such as when dealing with complaints. The major common components are:

- Guidelines for Investigating Incidents, Complaints and Claims
- Supporting Staff Involved in an Incident, Complaint or Claim
- System for Continuous Improvement Policy
- Policy on Learning from Deaths

4. Scope

4.1 This policy and procedure applies to all [2]gether NHS Foundation Trust staff, visitors and contractors. There are no limitations on its circulation within the Trust and the wider NHS community, and it can be made available to service users, their families and the public on request.

5. Context

5.1 The National Patient Safety Agency (NPSA) produced a national framework for reporting, investigating and learning from serious incidents in their publication *National Framework for Reporting and Learning from Serious*

Incidents Requiring Investigation. The revised ***Serious Incident[1] Framework 2015*** builds on and replaces the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation issued by the National Patient Safety Agency (NPSA, March 2010) and NHS England's Serious Incident Framework (March 2013). It also replaces and the *NPSA Independent investigation of serious patient safety incidents in mental health services, Good Practice Guide (2008).* This policy and the procedure in Part B describe our implementation of that updated framework.

5.2 Healthcare organisations are also charged with the reporting of a range of incidents to external bodies, as described in the NPSA document ***Information Resource to Support the Reporting of Serious Incidents***. A full, but non-exhaustive list of these is given in the Trust document ***Guidance for Staff Involved in Incidents***. These external reporting requirements are to assist in the learning from incidents and for the generation of alerts/solutions to minimize the risk of similar incident recurring.

5.3 The Health & Safety at Work etc. Act 1974 requires all employers to ensure that incident reporting systems are in place, and that they report certain incidents, dangerous occurrences and occupational ill health, to the Health and Safety Executive in accordance with RIDDOR regulations.

5.4 The Department of Health has produced a ***Checklist for Reporting, Managing and Investigating Information Governance Serious Incidents*** describing how information governance incidents should be managed.

6. Duties

6.1 All Members of staff

- Take initial, corrective actions (where safe) to prevent re-occurrence of accident/incident.
- Report all deaths, accidents, incidents and near misses in a timely manner using the designated procedure via Datix.
- Ensure incident forms (in the event that Datix is unavailable) are given to the line manager as soon as possible after the incident (within 72 hours)
- Report all serious incidents verbally within 24 hours
  The actions that the Trust expects staff to take in response to an incident are detailed in a separate Trust document: ***Guidance for Staff Involved in Incidents***
- Inform service users and their carers if a notifiable patient safety incident has occurred and provide reasonable support to them in relation to the incident in line with the requirements of **Regulation 20: Duty of Candour – Guidance for NHS Bodies** (This is covered in detail in the Trust ***Being Open Policy (including the Duty of Candour)***

[1] The terms 'serious incident requiring investigation (SIRI)', 'serious incident (SI)' or 'serious untoward incident (SUI)' are often used interchangeably. This document will refer to 'SIs' and serious incidents.

6.2 **Managers**

- Review incidents received and check the details for completeness.
- Authorise the Datix record (or countersign the completed paper form) and forward it, together with any supplementary documentation, to the Patient Safety Department within 5 days.
- Escalate the incident immediately if it is serious or potentially serious.
- Report incidents to the CQC without delay where appropriate.
- Are responsible for:
    - Undertaking or commissioning any necessary investigations
    - Obtaining witness statements
    - Identifying root causes
    - Re-evaluating risks following investigation
    - Remedying any immediate deficiencies e.g. change in procedure to minimize risk of re-occurrence
    - Determine if the incident has been recorded under the correct category in Datix
    - Seeking advice from the Information Governance Manager if the incident involves the loss of patient identifiable information.
- Support their staff that are or have been involved in incidents. Details are given in a separate Trust document: ***Guidance for in Supporting Staff Involved in an Incident, Complaint or Claim***
- Inform service users and their carers if a notifiable patient safety incident has occurred and provide reasonable support to them in relation to the incident in line with the requirements of **Regulation 20: Duty of Candour – Guidance for NHS Bodies**

6.3 **The Director of Quality**

- Has Board level responsibility for the development of this document and may delegate the authority to a subordinate.

6.4 **The Governance Committee**

- Receives and reviews quarterly reports of all incident reports and will monitor the implementation of action plans arising from these reports.

6.5 **Executive Team**

- The Chief Executive has overall responsibility to ensure that the Trust has a robust coordinated response to managing and learning from incidents. The Chief Executive is supported in this role by all Executive Directors.
- The Medical Director, Director of Quality and the Director of Service Delivery have responsibility for ensuring that internal reviews of serious incidents are held and that the learning from these reviews are shared across the organisation.

6.6 **Assistant Director of Governance & Compliance and/or Patient Safety Manager**

- Is responsible for producing Patient Safety Incident Reports: analysing the distribution, location, type and population involved in clinical incidents to identify trends, system or procedural failure.
- Is responsible for the production of quarterly reports of all incident reports
- Is responsible for the reporting of patient safety incidents including allegations of abuse to the appropriate commissioning and regulatory bodies.
- Is responsible for maintaining the Trust's incident database.
- Is responsible for the reporting of identified defective medical equipment to the Medicines & Healthcare Products Regulatory Agency (MHRA) and for notifying other agencies of Serious Incidents.
- Forwards details of all patient safety incidents, medical device failures or any incidents which might lead to claims to the Risk Manager.

6.7 **Health & Safety Advisor**

- Produces Health & Safety Reports detailing analysis of incidents affecting the workforce and presents to the Occupational Health & Safety Committee on a quarterly basis.
- Is responsible for reporting certain incidents, dangerous occurrences and occupational ill health to the Health and Safety Executive in accordance with Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) regulations.

6.8 **Local Security Management Specialist**

- Responsible for supporting staff and service users who have been subject to assault, and is responsible for the reporting acts of wilful violence against Trust staff to the Security Management Service.

6.9 **Health Records Managers**

- Responsible for notifying the CQC of deaths and unauthorised absences of people who are detained or liable to be detained under the Mental Health Act 1983.

7 Definitions

- **Clinical Incident**: an event or circumstance which could have resulted, or did result in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public which does not meet thresholds associated with Serious Incidents Requiring Investigation.
- **A Serious Incident Requiring Investigation** In broad terms, serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include

incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

Serious Incidents in the NHS include:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
  - Unexpected or avoidable death[2] of one or more people. This includes
    - suicide/self-inflicted death; and
    - homicide by a person in receipt of mental health care within the recent past[3] (see Appendix 1);
  - Unexpected or avoidable injury to one or more people that has resulted in serious harm;
  - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
    - the death of the service user; or
    - serious harm;
  - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
    - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring[4]; or
    - where abuse occurred during the provision of NHS-funded care.
  - This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident (see Part One; sections 1.3 and 1.5 for further information).
- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See Never Events Policy and Framework for the national definition and further information;[5]

[2] Caused or contributed to by weaknesses in care/service delivery (including lapses/acts and/or omission) as opposed to a death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice.

[3] This includes those in receipt of care within the last 6 months but this is a guide and each case should be considered individually - it may be appropriate to declare a serious incident for a homicide by a person discharged from mental health care more than 6 months previously.

[4] This may include failure to take a complete history, gather information from which to base care plan/treatment, assess mental capacity and/or seek consent to treatment, or fail to share information when to do so would be in the best interest of the client in an effort to prevent further abuse by a third party and/or to follow policy on safer recruitment.

[5] Never Events arise from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of a medicine via the incorrect route - for which the importance, rationale and good practice use should be known to, fully understood by, and robustly sustained throughout the system from suppliers, procurers, requisitioners, training units, and front line staff alike. See the Never Events Policy and Framework available online at: http://www.england.nhs.uk/ourwork/patientsafety/never-events/

- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:

    - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues (see Appendix 2 for further information);
    - Property damage;
    - Security breach/concern;[6]
    - Incidents in population-wide healthcare activities like screening[7] and immunisation programmes where the potential for harm may extend to a large population;
    - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
    - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services[8]); or
    - Activation of Major Incident Plan (by provider, commissioner or relevant agency)[9]
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation[10].

    - A serious **Information Governance Incident** is described as "Any incident which involves actual or potential failure to meet the requirements of the Data Protection Act 1998 and/or the Common Law of Confidentiality"
      (Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation published by the Health & Social Care Information Centre)
    - A "**near miss**" is any event which does not, but has the potential to, result in injury, damage or loss *(Department of Health).*
    - **Abuse**: a violation of an individual's human and civil rights by any other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal or psychological, it may be an act of neglect or an omission to act, or it may occur when a vulnerable person is persuaded to enter into a financial or sexual transaction to which he or she has not consented, or cannot consent. Abuse can occur in any relationship and may result in significant harm or exploitation of the person subjected to it.

[6] This will include absence without authorised leave for patients who present a significant risk to themselves or the public.
[7] Updated guidance will be issued in 2015. Until that point the Interim Guidance for Managing Screening Incidents (2013) should be followed.
[8] It is recognised that in some cases ward closure may be the safest/ most responsible action to take but in order to identify problems in service/care delivery , contributing factors and fundamental issues which need to be resolved an investigation must be undertaken
[9] For further information relating to emergency preparedness, resilience and response, visit: http://www.england.nhs.uk/ourwork/eprr/
[10] As an outcome loss in confidence/ prolonged media coverage is hard to predict. Often serious incidents of this nature will be identified and reported retrospectively and this does not automatically signify a failure to report.

- **Next Working Day**: If a serious incident occurs outside of normal working hours, 9 am – 5 pm, the next working day will be from 9am the following working day, i.e. if a Friday evening, then the following Monday morning
- **Datix –** the computer system used by the Trust to record and manage incidents
- **RCA** – Root Cause Analysis
- **NPSA** – National Patient Safety Agency
- **HSE** – Health & Safety Executive
- **RIDDOR** - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
- **MHRA** – Medicines & Healthcare Products Regulatory Agency
- **PALS** – Patient Advice & Liaison Service
- **PID** – Patient Identifiable Information
- **RLS** – Reporting & Learning Service – the system used by NPSA to record and analyse serious incidents.
- **SHA** – Strategic Health Authority
- **STEIS** – Strategic Executive Information System – the electronic system used to register serious incidents with the CCG & RHA. This is due to be superseded by a new system
- **CQC**- Care Quality Commission
- **DoH** – Department of Health
- **Commissioner** – the organisation/s who commission our services.

8. Ownership & Consultation

8.1 The Director of Quality has Board level responsibility for the development of this document and may delegate the authority to a subordinate.

8.2 Trust Localities, Executive Directors and Commissioners (as a minimum) must be consulted with prior to ratification.

9. Ratification Details

9.1 This document will be ratified by the Governance Committee.

10. Release Details

10.1 This document will be made available to all staff and managers via the Trust's policy section on the intranet.

10.2 The ratification and release of this document will be highlighted to managers and all staff via the weekly electronic news bulletin.

11. Review Arrangements

11.1 This document will be reviewed as determined by changes in:

- Legislation
- National guidance
- Local Trust needs

11.2 An annual review is required.

12 Process for Monitoring Compliance

12.1 This policy requires approval by the Governance Committee and will be reviewed at least annually and sooner if required.

12.2 The Governance Committee is responsible for ensuring that compliance against the standards defined by the NPSA within the National Framework for Reporting & Learning From Serious Incidents Requiring Investigations is followed by receiving a quarterly report from the Assistant Director of Governance & Compliance (for details see Appendix 5)

12.3 An audit of the implementation of the policy will be undertaken every two years, commissioned by the Director of Quality. The audit criteria will include assessing compliance against the following standards.

- Duties of individuals and committees
- Process for reporting all incidents/near misses, involving staff, service users and others
- The process for reporting to external agencies
- The processes for staff to raise concerns e.g. whistle blowing/open disclosure

12.4 It is expected that implementation of all these elements will comply with this guidance. The results of the audit will be presented to the Governance Committee who will be responsible for the development and monitoring of any identified actions within the scope of the audit.

13 Training

13.1 Staff will receive training in incident reporting as part of the health & safety programme in corporate induction. Additional training will be provided through Datix sessions run by the Datix Systems Manager.

14 Learning from Incidents

14.1 The process by which learning from incidents is embedded within the organisation is described in the Trust document ***System for Continuous Improvement.***

14.2 Additionally, all patient deaths will be reported on the Datix system. The process of categorisation, as described within the ***Policy on Learning from Deaths*** pathway at Appendix B of that policy will indicate one of six categories for the patient death. Deaths categorised as Expected Unnatural (EU) and Unexpected Unnatural (UU) will be considered for further investigation as directed within the ***Incidents Policy and Procedure*** following discussion with the Patient Safety Manager.

15 Raising Concerns

15.1 It is vital that any concerns with regard to professional competence or wrongdoing by an employee, or any individual undertaking work on the Trust's behalf, are reported and properly dealt with. This is described in the Trust's ***Whistle Blowing Policy, Procedure and Guideline.***

16 Trust Board Statement Regarding "Fair Blame"

16.1 The Trust Board recognises that the fear of disciplinary action (see ***Disciplinary Policy and Procedures***) may deter a member of staff from reporting an incident or near miss in which they are involved or have observed. It is the view of the Board that disciplinary action will not be invoked against that individual as part of the formal reporting system, except where one or all of the following situations apply:-

- Where in the view of the Trust and/or any professional registration body, the action causing the incident is malicious, criminal or constitutes gross misconduct.
- Failure to undertake remedial action as advised from a previous similar incident for which they were themselves responsible, and where the incident recurs

16.2 In addition to the above, failure to report a serious incident or near miss could also lead to disciplinary action.

16.3 Staff who may suspect or have evidence that their colleagues have acted in the ways described above, should report this in accordance with the ***Whistle blowing Policy, Procedure and Guideline***.

17 Staff Support

17.1 Staff who have experienced disturbing or distressing incidents in the workplace may require support and the opportunity to debrief. Staff members should be made aware of sources of individual and confidential support available to them, should they wish to further discuss their own response to the incident.

17.2 Details of how staff should be helped and supported are given in the Trust document: ***Guidance in Supporting Staff involved in an Incident, Complaint or Claim***.

17.3 In the event that Police are requesting statements, managers must ensure that staff are aware that they can/will be supported by senior managers or members of the executive team at the point of interview. Access to support can be arranged by the Service/Locality Director and/or the Manager on Call. **N.B Staff have the right to refuse to give a statement until they receive appropriate support.**

18 Confidentiality

18.1 The nominated senior manager/clinician will safeguard the Trust confidentiality policy and procedure, and will ensure those patients and their next of kin (if appropriate) are always informed before the media. Advice on upholding confidentiality may be sought from the Trust's Caldicott Guardian (Medical Director) or the Data Protection Manager (Information Governance & Registration Authority Manager)

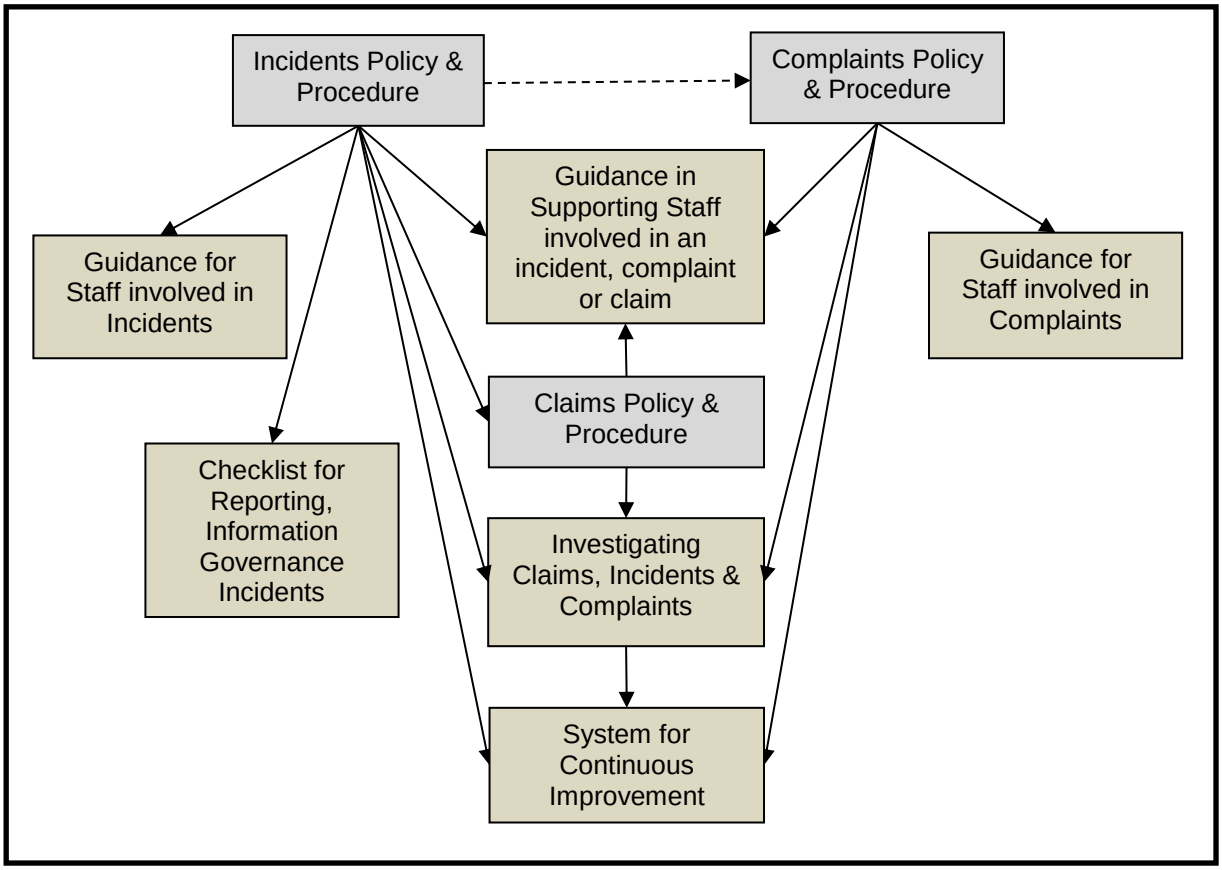
18.2 For further information refer to ***Confidentiality. NHS Code of Practice November 2003*** as this has been adopted as Trust policy.

19 References

Being Open: Communicating Patient Safety Incidents with Patients, their Families and Carers (NPSA 2009)
Seven Steps to Patient Safety (NPSA) 2004
Seven Steps to Patient Safety in Mental Health (NPSA) 2008
National Framework for Reporting and Learning from Serious Incidents Requiring Investigations. (NSPA) 2010
Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation (Health and Social Care Information Centre) 2013
Information Resource to Support the Reporting of Serious Incidents
NHS South of England: Process for reporting and learning from serious incidents requiring investigation
Department of Health, Association of Chief Police Officers, Health and Safety Executive (2006) *Memorandum of Understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm*
Regulation 20: Duty of Candour. Guidance for NHS Bodies. (CQC 2014)
NHS Improvement Serious Incident Framework (March 2015)
National guidance on Learning from Deaths https://www.england.nhs.uk/wp-content/uploads/2017/03/nqb-national-guidance-learning-from-deaths.pdf

[2]gether NHS Foundation Trust documents:

The following diagram shows how other documents relate to this current one:



Other Trust documents linked to this process include:

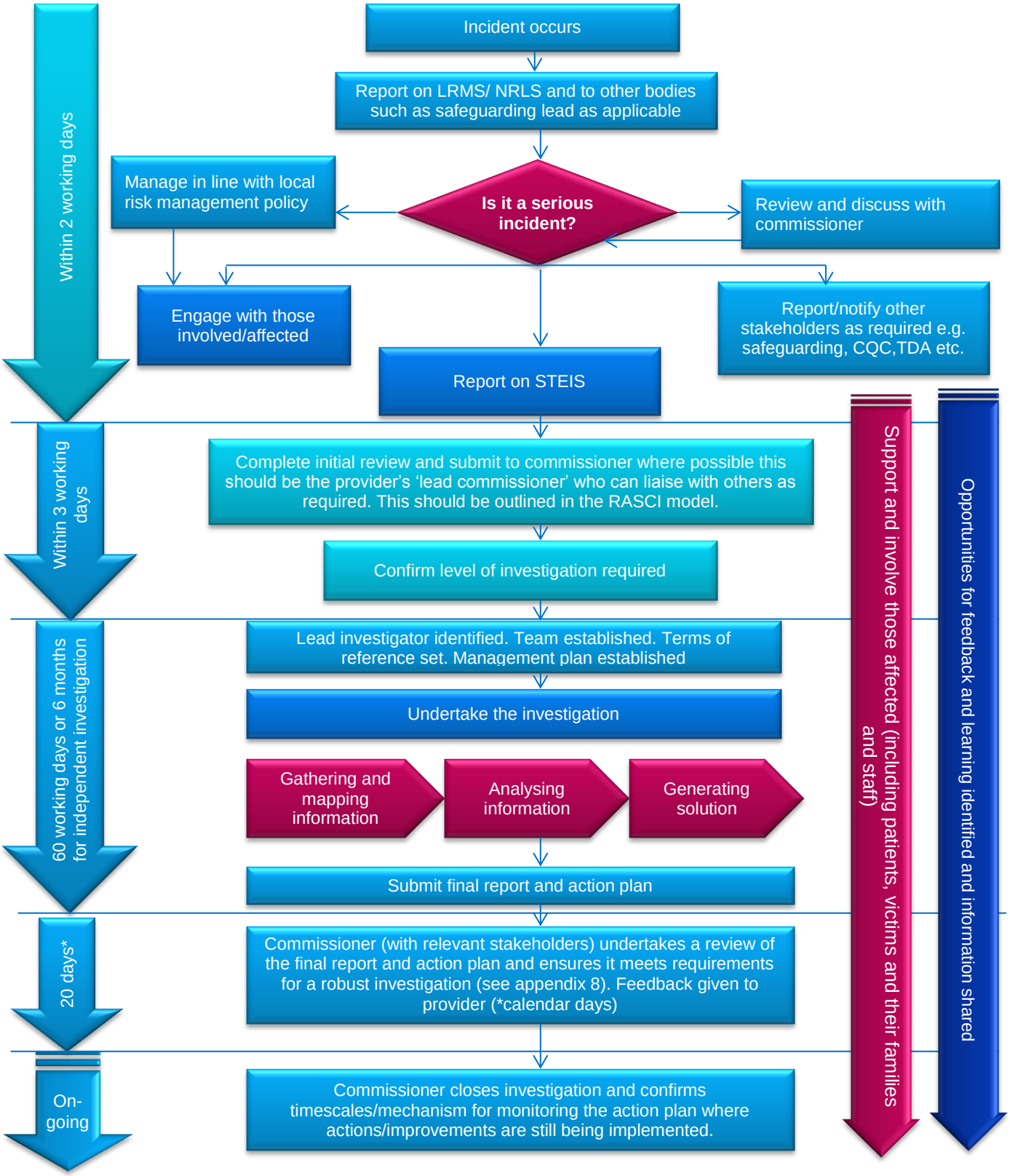
Disciplinary Policy and Procedures
Being Open Policy
Whistleblowing Policy and Procedure
Policy on Learning from Deaths

20 Associated Documentation

Equality Impact Assessment

PART B: PROCEDURE FOR REPORTING AND MANAGING INCIDENTS

21 Generalised Incident Procedure & Timescales



21.1 The generalised flow of events for handling incidents is shown in the above diagram. Each of the actions is described in the following sections, according to its number.

21.2 Note that an incident may be reported from an external source, such as:

- Coroner's report following an unexpected death
- Incidents involving national screening programmes
- GP surgeries
- 3rd-sector organisations

In the event of any member of staff being notified of an incident from any external source they must seek advice from the Assistant Director of Governance & Compliance or the Patient Safety Manager immediately in regard of the escalation process.

21.3 There are ***two*** types of incidents:

- **Serious incidents** for which there is a strictly defined procedure that follows national and regional guidelines
- Less serious incidents that are managed through local and less formal procedures – e.g. **clinical incidents**

21.4 The distinction between the two types is defined using a risk-based assessment of the nature and severity of the incident. A risk rating higher than "low", i.e. a risk grading of greater than 3, is regarded as a Serious Incident.

21.5 Depending on re-evaluation of the risk, or subsequent events, an incident may switch between the two types during its history, as appropriate.

21.6 In the event of an incident being considered serious, managers must triangulate all sources of information to ensure facts are established to ensure that the organisation and colleagues are enable to respond to accurate information rather than rumour or speculation.

21.7 Serious Incidents must be notified to the relevant bodies as soon as possible and within **two working days (maximum)** of the incident occurring or of being made aware of the incident. Serious incidents must be reported to Commissioners **within two working days (maximum)** of the incident occurring or being made aware of the incident. This allows time for internal discussion and consideration of the incident's management.

21.8 Incident grading has been removed from the Serious Incidents Framework 2015. All reported SIs are discussed with the appropriate Commissioner within 2 working days with a view to the level of investigation required to ensure appropriate allocation of resources. Concise (Level 1) and Comprehensive (Level 2) investigations must be completed internally **within 20 working days** and submitted to the relevant Service Director for review. These incidents must be fully completed and a Final Report submitted to Commissioners **within 60 working days**.

21.9 A Serious Incident where an independent (Level 3) investigation is carried out should be completed within **6 months**, although an extension can be requested if necessary.

21.10 Under exceptional circumstances these deadlines can be extended on agreement with the appropriate commissioner.

22 Taking Immediate Action

22.1 The first priority is to the safety of service users and staff and so any immediate remedial action must be taken before consideration of anything else.

22.2 If required, the staff member in charge will ensure that emergency services are called, and take any other immediate necessary action to ensure patient, staff and public safety.

The member of staff first aware that an incident has occurred will make an assessment of the event and if, in their judgement, it is either a serious or potentially serious incident initiate the Serious Incident procedure.

22.3 The staff member in charge will inform the Service/Locality Director (or on-call manager) immediately and others as directed.

22.4 Detailed duties and actions are given in the Trust document: ***Guidance for Staff involved in Incidents***

22.5 Inform service users and their carers if a notifiable patient safety incident has occurred and provide reasonable support to them in relation to the incident in line with the requirements of **Regulation 20: Duty of Candour – Guidance for NHS Bodies**

23 Recording of Incidents

23.1 All incidents, whether serious or not, must be formally recorded on the Datix incident system as soon after the incident as possible.

23.2 Where the member of staff is unable to access the web-based Datix system, an IR1 form will be forwarded immediately to the Datix Systems Manager who will transcribe it onto the Datix incident reporting system (this process is currently under review).

23.3 Statements from those staff that were involved in or witnessed the incident will be taken where possible (statements must be legible, timed, dated and signed). In the event that Police are requesting statements, managers must ensure that staff are aware that they can/will be supported by senior managers or members of the executive team at the point of interview. Access to support can be arranged by the Service/Locality Director and/or the Manager on Call.

N.B Staff have the right to refuse to give a statement until they receive appropriate support.

23.4 Health records documents are confidential. Incidents can become the subject of both internal and external scrutiny; therefore all information recorded on an incident report must be objective and factual. Any clinical details should only be recorded in the health records and do not need to be duplicated on the incident record.

23.5 Whenever any issue of staff or patient confidentiality is involved, such as suspected fraud or abuse by staff, with the consent of the senior manager, reports can be confidentially coded and details recorded without naming the staff involved on the incident form. It is expected that this confidential coding will ensure due regard to safeguard patient or staff confidentiality. Information relating to adverse events will only be passed on, and in a manner which is sensitive, on a need to know basis.

24 Managerial Decisions about Serious Incident Course of Action

24.1 On being notified, the Service/Locality Director (or on-call Manager) will inform:

- The Chief Executive, Director of Quality, Medical Director and Director of Service Delivery (or on-call Director out of hours).
- The Assistant Director of Governance & Compliance and/or Patient Safety Manager (for onward reporting to external agencies) and the Communications Manager.

24.2 The Service/Locality Director (or on-call manager) will also decide who will inform relatives, staff groups, patient groups, the patient's GP, day/residential services (if appropriate), and how this should occur. They may choose to consult with the patient's Consultant. Staff members will be made aware of arrangements for action and communication and of any expectations in this regard.

24.3 For 'serial' or 'multiple' incidents, the Service/Locality Director (or on-call manager) will initiate a strategy for responding to multiple enquiries. This may involve setting up telephone 'hot line' arrangements.

24.4 The Service/Locality Director will inform the Health & Safety Advisor if an incident or near miss occurs as a result of:-

- a failure of plant, machinery, medical or other equipment
- an adverse reaction relating to supplies of food
- a result of a breach of the Health and Safety at Work Act (1974) and associated regulations.

24.5 If the serious incident or near miss involves, or is suspected to involve, a medical device (e.g. hoist, ECT machine, suction machine, and defibrillator), the Service/Locality Director (or on-call manager) will also inform the Estates Manager. **The device must cease to be used immediately.** The Health &

Safety Advisor may wish to examine and photograph the device before it is removed and repaired or replaced by the Estates Department and report the event to the Medicines & Healthcare Products Regulatory Agency (MHRA).

24.6 When it is suspected that a claim may be brought against the Trust, staff should refer to the ***Claims Policy & Procedure*** for guidance.

24.7 Immediately an incident has been reported (this may be via the Trust incident reporting system, or from external avenues, e.g. the commissioner, media), the Service/Locality Director who is first informed of the incident will assign actions and responsibilities to other members of staff **and call an initial meeting within 72 hours of the incident** being reported to review the incident and develop a communication plan (see below). They will assign a senior manager or clinician to co-ordinate events and retain delegated responsibility for the management of the incident.

24.8 The purpose of the initial Service/Locality Director Meeting will be to review what information is known to date, coordinate the management of the incident and promote effective communication. The following information will aid these discussions

- Identify the nature of the incident, the time it was reported, who reported it and if all relevant parties within the Trust have been notified.
- Ascertain the extent and nature of involvement of the clinical team immediately prior to the incident and in the preceding 3 months (if relevant).
- Establish if there are any clinical assessments/outcomes which need to be considered.
- Establish if care has been documented appropriately.
- Establish if risk assessments are up to date and appropriate.
- Review if care went as planned. Were any concerns or deviations noted? What action was taken?
- What levels of support and supervision was the care-coordinator receiving?
- Which external agencies require access to notes, e.g. police, coroner? Are there any Information Governance issues that need to be considered?
- Is any contact with Trust solicitors required?
- Ensure that consideration is given to the support to the carer/family and the staff involved.
- Check that the initial care team review/debrief has been arranged.
- Establish a communication plan if necessary.
- Ensure notification to external agencies is underway.
- Appoint an Investigating Officer noting the need for the individual to be RCA trained and not involved in any way with the care of the patient or the team concerned.
- Ensure that the internal review process is underway in accordance with this policy.
- Ensure that the family liaison elements are undertaken and documented in accordance with the ***"Being Open Policy"***

24.9 The output from this meeting will be a series of meeting minutes and a chronology of the patient's contact with services or other relevant information regarding the incident.

24.10 Should a person be appointed to act in a Family Liaison role, details are given in Appendix 3.

24.11 The Assistant Director of Governance & Compliance and/or Patient Safety Manager will liaise directly with the nominated senior manager/clinician responsible for co-coordinating the serious incident response. This will ensure a proactive response to possible complaints or claims arising from the event.

24.12 When there is uncertainty regarding the threshold for classification of a serious incident the process detailed in Appendix 8 must be followed.

24.13 In the event of a patient in contact with services being arrested or charged with homicide specific courses of action must be taken as outlined in "Department of Health, Association of Chief Police Officers, Health and Safety Executive (2006) *Memorandum of Understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm"* The Director of Quality or the Assistant Director of Governance & Compliance will make immediate contact with the Head of Public Protection/Deputy Head of Public Protection (Gloucestershire and/or Herefordshire Constabulary) to enact the requirements of the Memorandum of Understanding. This will include the establishment of an incident coordination group, which requires representation ideally by the Chief Executive or nominated executive director, Assistant Director of Governance & Compliance and the Caldicott Guardian where appropriate. One of the functions of the incident co-ordination group will be to devise and agree a communications plan to ensure that appropriate service users and their families are communicated and supported in a co-ordinated way and are enabled the opportunity to take part in the Trust's internal investigation. Detailed requirements of the incident co-ordination group are contained within the Memorandum of Understanding and must be followed accordingly.

24.14 In the event of a patient in contact with services being arrested or charged with homicide, it is likely that the custody suite will approach the Trust to arrange for an appropriate adult to be available to ensure that the detainee understands the custody process, legal advice and any questions put to them by the police. This role should not be fulfilled by the patients care coordinator or responsible clinician to ensure that there is no conflict of interest. Additionally, psychiatrists involved in a patient's care should not undertake assessments in relation to criminal justice matters, as likewise this might create a conflict of interest.

25 Manager Review of Incident and Risk Assessment

25.1 On receipt of a notification of an incident, the manager should review the details and carry out an initial assessment, checking for missing information.

25.2 When it is suspected that a claim may be brought against the Trust, the manager should refer to **the *Policy for Managing Personal Injury, Social Care, Human Resources, Property Expenses and Clinical Negligence Claims* for guidance.**

25.3 The incident will be graded according to the severity, or impact, of the outcome and the likelihood, or probability, of reoccurrence of the incident using the risk evaluation matrices in Appendix 10.

25.4 The grading of incidents will determine the required level of response and investigation. As a general rule:

- A value of 1-3 will define this as a **non-Serious Incident**
- A value of 4 and above will define it as a **Serious Incident**

However, the circumstances of the individual incident may indicate that a low-graded incident should be treated as a Serious Incident and vice versa.

25.5 Managers, who on this analysis find that a suspected Serious Incident is not one, should inform the Service/Locality Director of this fact.

25.6 Similarly, an incident not thought to have been serious may prove to be a Serious Incident, in which case the Service/Locality Director must be informed immediately.

25.7 The Duty of Candour describes the following:

> "**moderate harm**" means -
>
> (a) harm that requires a moderate increase in treatment, and
>
> (b) significant, but not permanent, harm;

Service users and their families must be informed immediately of such incidents.

25.8 Service Managers, Service/Locality Directors, the Assistant Director of Governance & Compliance and/or Patient Safety Manager (and the Health & Safety Advisor – this process is currently under review) will also review the grading of incidents to determine the level of investigation to be carried out and the reporting requirements to external bodies. Additionally, incidents requiring investigation may be re-graded, where necessary, following investigation.

26 Local Resolution of non-serious Clinical Incidents

26.1 The majority of incidents will not meet the thresholds for a Serious Incident. The Serious Incident procedures for investigation will therefore not necessarily apply in these instances.

26.2 Consequently, the manager will resolve the incident as he or she sees fit, according to the circumstances of the incident, initiating and managing any investigation and resultant actions themselves.

26.3 This does not preclude more extensive investigations using, for example, root cause analysis, but it normally would not be necessary to go to that extent. When a **clinical incident** does require a more intensive response:

- The manager should raise the incident with the Patient Safety Manager and agree the level of investigation to be undertaken (Concise or Comprehensive).
- The resulting investigation should meet the standards and required elements of a Serious Incident Investigation and employ the principals of Root Cause Analysis.
- The incident will not be escalated nationally via STEIS although the investigation report will place the service in a good position to formally escalate to SIRI should that be required if thresholds become met.
- Reports, investigations and minutes of meetings held to develop learning from the incident must be forwarded to the Patient Safety Manager. Learning must be cascaded throughout the Trust as it would from a Serious Incident.
- The number of, type and other trends relating to non-SIRI Clinical Incidents needs to be established and this is best achieved through existing processes.

26.4 When resolved, the manager would close off the incident on the Datix system after completing the Investigation, Contributory Factors and Lessons Learned sections.

26.5 The manager may use statistics from the Datix system to analyse trends or other aspects of incidents to better manage their area.

27 Notification of Serious Incidents to Appropriate Bodies

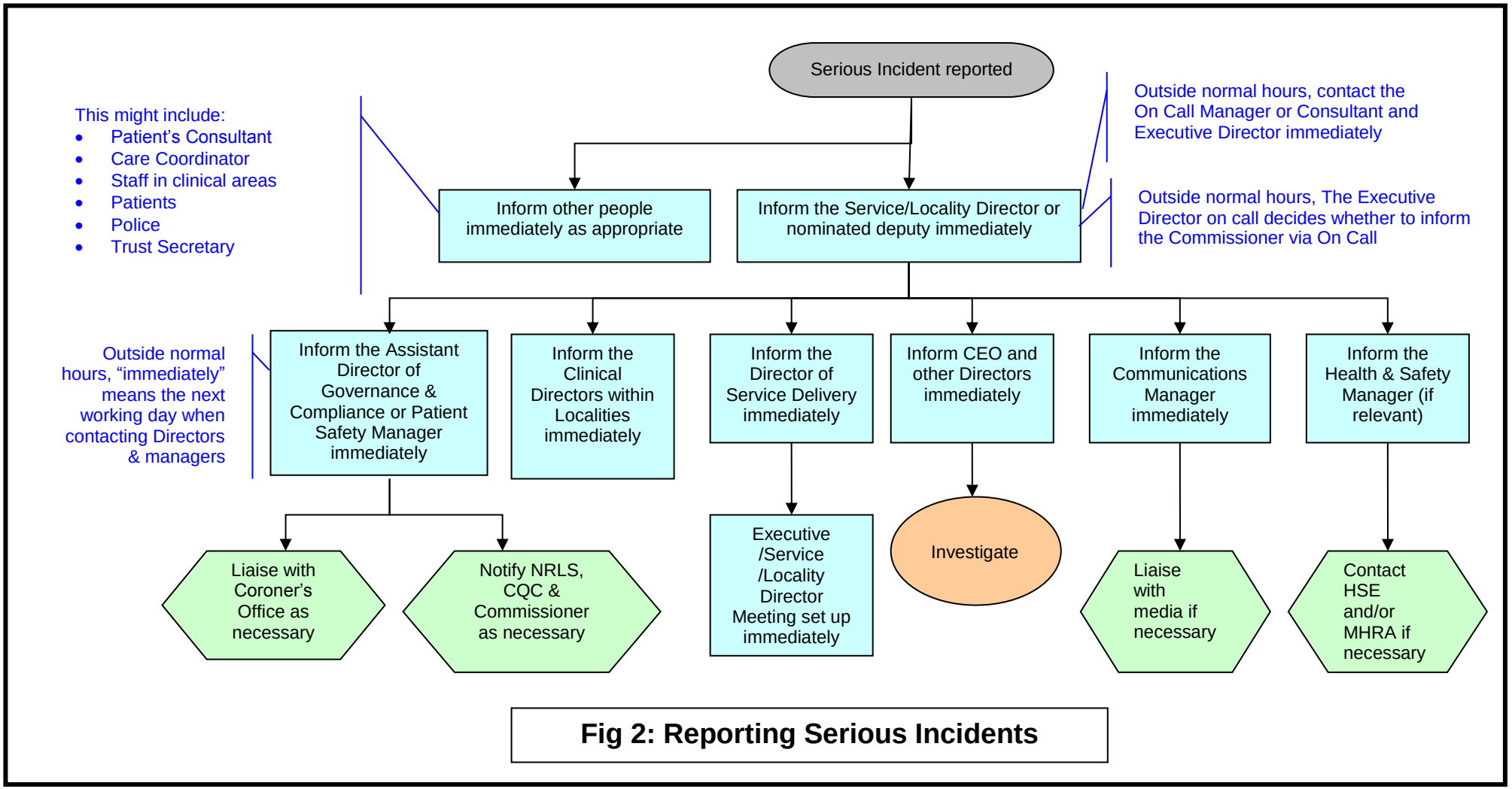


Fig 2: Reporting Serious Incidents

27.1 **General Statement**

All Serious Incidents must be reported to the appropriate external agencies within a given timeframe according to their grading. This includes all incidents that are deemed to be contentious, repercussive or likely to be of interest to the media. The following list of agencies is not exhaustive and is intended as guidance only. An element of judgement is inevitable, but where any doubt exists, the safest option is to report. A general schematic is shown in Fig 5.

27.2 **Grading of Serious Incidents / Level of Investigation**

The grading of Serious Incidents has been removed from the NHS England Serious Incident Framework.

The level of investigation must be agreed with the Commissioner. Details of the assessment, actions and monitoring of each level of investigation are given in Appendix 4.

27.3 **Reporting Of Incidents to External Agencies**

The Assistant Director of Governance & Compliance will ensure that the following agencies are informed where appropriate:

- The appropriate Commissioner
- NHS Litigation Authority
- Care Quality Commission (for detained patients- Health Records Department do this)

When a serious incident is seen as an exceptional incident as per the compliance framework, which is largely about adverse external criticism or potential for national media or reputational damage, the Chief Executive may take the decision to inform Monitor.

Reference should be made to the *Information Resource to Support the Reporting of Serious Incidents* published by the NPSA which gives details of the agencies that should or may need to be informed about specific categories of incidents. A simplified checklist according to the incident category is given in Appendix 1.

27.4 **Procedure for Reporting to Gloucestershire CCG**

All potentially high profile events must be notified on the **same working day (Monday-Friday 9.00-5.00)**. All other serious incidents must be notified within **48 hours** or the next working day.

Reporting serious incidents to Gloucestershire CCG during office hours will be the responsibility of the Assistant Director of Governance & Compliance (or nominated deputy) and will be achieved initially by verbal contact and subsequently by logging the incident, including its level of investigation, on the STEIS system. Where there is uncertainty regarding who should lead on reporting and investigating incidents (particularly within Primary Mental Health Services where patient contact can be limited), the Assistant Director of

Governance & Compliance and/or Patient Safety Manager will agree who the lead agency will be via discussion with the relevant CCG.

Out of Hours, the responsibility lies with the Executive on call. The seriousness of the incident will determine whether the on-call Executive for the relevant CCG is contacted or if contact is made the next working day. All contact numbers are held in the on-call folder. Out-of-hours arrangements for Gloucestershire CCG are given in their document *Process for reporting and learning from serious incidents requiring investigation.*

Where incidents are regarded as homicides as defined by HSG 94 (27), then liaison with Gloucestershire and/or Herefordshire CCG and NHS South of England should follow the procedure given in the document *Process for reporting and learning from serious incidents requiring investigation.*

27.5 Procedure for Reporting to Herefordshire CCG

The procedure is broadly similar to that for Gloucestershire CCG and is shown in diagrammatic form in Appendix 9.

27.6 Procedure for Reporting to the Care Quality Commission

Deaths and unauthorised absences of people who are detained or liable to be detained under the Mental Health Act 1983 must be notified to the Care Quality Commission without delay by the Health Records Manager or MHA Administrators. All other incidents will be reported to the CQC via the NPSA's Reporting & Learning Service (RLS).

27.7 Reporting of incidents via the National Reporting & Learning System

The Patient Safety Manager will routinely report such incidents via the NRLS at least once a month by uploading relevant incidents from Datix. The types of incidents to be reported via the NRLS without delay are shown in Appendix 6.

27.8 Reporting of Incidents to the Medicines & Healthcare Products Regulatory Agency (MHRA)

The role of the MHRA is to protect and promote public health and patient safety. It does this by ensuring that the manufacture and use of medicines and medical devices meet appropriate standards of safety, quality, performance and effectiveness.

It aims to minimise the risks of new adverse incidents involving medical devices, and reduce the risk of those that have already occurred from happening again.

The Health & Safety Advisor is responsible for the reporting of identified defective medical equipment to the MHRA within 14 working days of the incident being reported.

27.9 **Reporting of Incidents to the National Confidential Inquiry into Suicide and Homicide**

The National Confidential Inquiry into Suicide and Homicide by People with Mental Health Illness (NCISH) was established in its present form in 1996. The remit of the Inquiry is to collect detailed clinical information on people who have had contact with specialist mental health services before committing suicide or homicide.

Usually the Inquiry identifies the Consultant Psychiatrist required to complete the return and will write to the trust requesting that this occur.

27.10 **Reporting of Incidents to the Local Multi-Agency Safeguarding Team**

Allegations of abuse are referred immediately to the local multi-agency safeguarding arrangements for adults by the Specialist Practitioner for Safeguarding and a safeguarding alert raised. Investigations are coordinated by those arrangements and should not begin independently of them.

27.11 **Reporting of Incidents to the NHS Security Management Service**

The Security Management Service (SMS) is part of NHS Protect. It provides a central support to those charged with undertaking security management work in NHS bodies. It aims to help tackle violence against NHS staff and ensuring the security of NHS property and assets.

The Local Security Management Specialist is responsible for the reporting acts of wilful violence against Trust staff to NHS Protect and will routinely report such incidents.

27.12 **Reporting of Incidents to Monitor**

Monitor need to be informed of any incidents that may affect the reputation of the Trust or the NHS. The Director of Quality in discussion with executive colleagues will decide and undertaken this action.

27.13 **Reporting of Incidents to the Health & Safety Executive**

The Health & Safety Executive has a role in ensuring that risks to people's health and safety from work activities are properly controlled. This includes investigating incidents in which people are harmed

The Health & Safety Advisor is responsible for notifying the of incidents that fall under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) within 10 working days but immediately (verbal - by phone) in event of death.

27.14 **Liaising with the Information Commissioner**

The Trust Secretary is responsible for reporting applicable Information Governance incidents via the IG Incident Reporting facility within the IG Toolkit. Level 2 and Level 3 incidents reported through this route will automatically be escalated to the Information Commissioner and the

Department of Health. The Trust Secretary will also liaise with the Director of Quality in the event a serious information governance incident may need reporting to Monitor.

Guidance on reporting such incidents is given in the document *Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation* published by the Health & Social Care Information Centre.

27.15 **Liaising with the Coroner**

In the event of unexpected/sudden death it is possible that staff may be asked to provide a report for the Coroner and also be summoned to give evidence in person. Appendix 2 details the required information for inclusion in such reports.

Liaison with the Coroner's Office is via the Assistant Director of Governance & Compliance and/or Patient Safety Manager. The Assistant Director of Governance & Compliance will receive all requests for statements/reports from the Coroner's Office and disseminate these to the relevant staff. Advice will be provided concerning the content of such documents and the Assistant Director of Governance & Compliance will review all such documents prior to them being forwarded to the Coroner. **If staff are approached directly by the Coroner's Office they should notify the Assistant Director of Governance & Compliance immediately**.

To assist the internal review process, the Assistant Director of Governance & Compliance and/or Patient Safety Manager will seek information from the Coroner's Office as to the circumstances of the death. This information will then be shared with the Lead Investigator for the preliminary report and the Team Manager.

Staff required to attend inquests for the purpose of giving evidence will be supported throughout the process by the Assistant Director of Governance & Compliance, who may on occasion request representation from the Trust solicitors.

In line with the requirements of **Regulation 20: Duty of Candour – Guidance for NHS Bodies** where a reported serious incident relates to the death of a service user, the final investigation report will be shared with the Coroner to assist with the inquest process.

27.16 **Liaising with the Media**

The Communications Manager (in working hours) will liaise directly with the nominated senior manager/ clinician with regard to dealing with the media and also liaise with Commissioners and Monitor if deemed appropriate.

27.17 **Other Provider Organisations**

Where the Trust identifies that more than one provider organisation is involved in a Serious Incident, the Assistant Director of Governance & Compliance and/or Patient Safety Manager will make contact with the other parties, making

contact with the originating organisation first wherever possible. In such cases, a lead organisation is mutually identified as the main co-ordinator of the incident.

28 Serious Incident Investigation Procedure

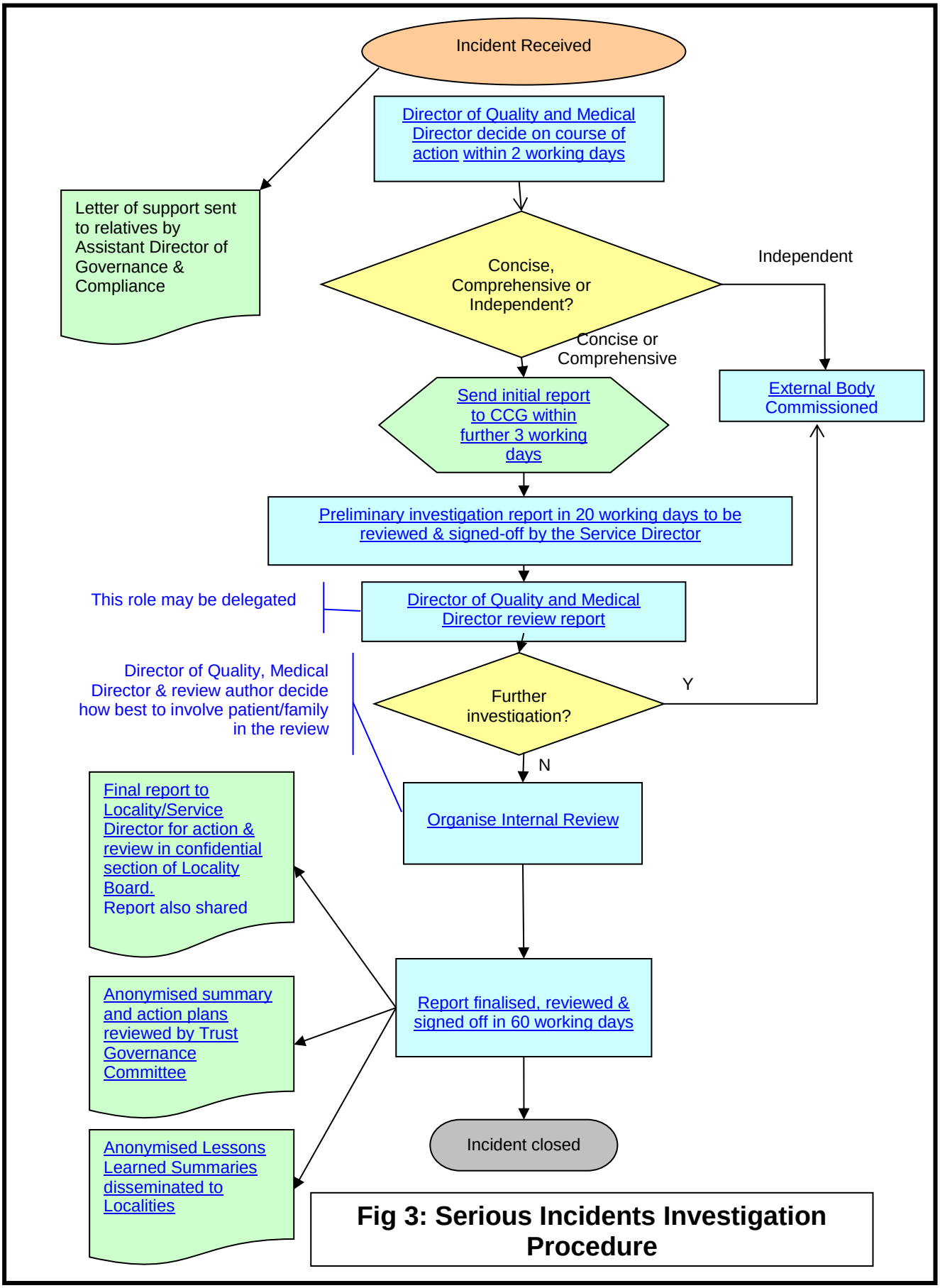


Fig 3: Serious Incidents Investigation Procedure

28.1 Following the initial Service /Locality Directors' meeting (as described in 24.8), the following information will be provided to the Assistant Director of Governance & Compliance and/or Patient Safety Manager within 3 working days

- the principal facts/description of the incident (including date, description, location, background and consequences)
- level of investigation and whether a Never Event;
- details of the initial investigations undertaken including the scope, methodology and the individuals involved (including relatives/carers);
- immediate action taken
- initial recommendations
- proposals for the full investigation (including scope, methodology and details of the review team with clear timeline and accountability).

This report may be in the form of minutes of a meeting as long as the meeting takes place within 3 days and does cover the key issues set out above.

When communicating information within the trust regarding a serious incident, any email should include in the body of the email (NOT the subject line) the following:

- Name of the patient
- Date of the incident
- Status of the patient (the degree and nature of harm)

This will help to reduce unnecessary distress and inappropriate actions by staff.

28.2 External investigations may need to be established when:-

- Suspected homicides are committed by a mentally ill person in contact or recent contact with services,
- Where there have been several in-patient suicides within the Trust within any twelve month period, or
- Where there have been an unexpectedly large number of serious incidents in a single provider unit, such as to warrant public concern.

It is the responsibility of Strategic Health Authorities and/or local Commissioners to establish any such inquiries. Where the incident prompting consideration of an inquiry involves a specialist unit subject to lead purchasing arrangements, the "responsible Strategic Health Authority" is:-

- The lead Purchaser where the object of concern is a series of incidents/suicides occurring in a Provider Unit over a recent period (the costs would be shared across Purchasers who use the Unit).
    - The Strategic Health Authority and/or Commissioner from an individual patient's "home" area, where the incident prompting concern is focusing on an individual.

It is expected, before an external inquiry is set up, that:-

- An internal review will have been established and have reported promptly following notification of a serious incident.
- This will have demonstrated local agencies commitment to examine their own practice and should assist agencies in their preparation for an external inquiry.
- All incidents prompting an inquiry will have been reported to the relevant Strategic Health Authority(s)/Commissioner/CQC
- The involvement of other relevant agencies in such an inquiry will have been secured and
- Any relevant criminal proceedings will have been concluded.

The Strategic Health Authority has the responsibility to brief Ministers on the outcome and likely impact of the enquiry report. They may involve the Care Quality Commission and the relevant criminal justice agencies where they are involved.

28.3 The Assistant Director of Governance & Compliance and/or Patient Safety Manager sends immediate notification to the relevant external agencies, and will supply relevant commissioners within 3 working days with the following information:

- STEIS identification number
- the principal facts/description of the incident (including date, description, location, background and consequences)
- gender and date of birth of the client, where appropriate;
- Level of investigation and whether a Never Event;
- details of the initial investigations undertaken including the scope, methodology and the individuals involved (including relatives/carers);
- immediate action taken
- initial recommendations; and
- proposals for the full investigation (including scope, methodology and details of the review team with clear timeline and accountability).

28.4 The Service/Locality Director/Clinical Director will be responsible for commissioning an investigation report, including a tabular timeline (staff trained in root cause analysis techniques are required to undertake this) and submitting this to the Medical Director, Director of Quality and Director of Service Delivery and Assistant Director of Governance & Compliance within 20 working days. The template for this preliminary report is contained within the document ***Guidelines for Investigating Incidents, Complaints and Claims*** (this policy is under review).

If an incident indicates a prima facie need for referral to any of the following:

- one of the professional regulatory bodies;
- an independent inquiry into a serious incident under Section 84 of the National Health Service Act 1977;
- an investigation of a criminal offence;
- the alleged physical abuse of patients/children`
- the Health & Safety Executive

The Assistant Director of Governance & Compliance and/or Health & Patient Safety Manager will notify the Medical Director and/or Director of Human Resources who will initiate appropriate action. This referral may be made at any stage of the incident reporting procedure. On all such occasions the Chief Executive will be informed.

Abuse involving a child must also be notified to the Trust Named Nurse/Named Doctor for Child Protection for referral through to the appropriate safeguarding committee. Safeguarding Committee procedures will be applied.

The Medical Director/Director of Human Resources must refer the matter to the Police if a possible criminal offence has occurred. If the criminal offence is fraud or theft then the Director of Finance would undertake this action.

For serious clinical incidents/adverse events the Medical Director & Director of Quality may wish to involve the CQC in the investigation.

Where incidents indicate professional misconduct of a practitioner the appropriate Trust director can refer the matter to the relevant regulatory agency.

• General Medical Council	Medical Director
• Nursing & Midwifery Council	Director of Quality
• Health Professions Council	Director of Quality
• Social Care Council	Director of Quality

28.5 The Internal review meeting to be organised by the Medical Director's Office; to include Medical Director (Chair), Director of Quality (Nursing, Social Care & Therapies) (or nominated deputy), a Non-Executive Director, Assistant Director of Governance & Compliance or Patient Safety Manager as well as all staff involved in the incident or treatment of the patient concerned. The patient and relatives (with the consent of patient where possible) will subsequently be invited to take part in a separate element of the process with appropriate support.

28.6 The review will follow root cause analysis processes. Documentation required for the meeting includes the preliminary report, tabular timeline and coroner's report (when appropriate) and patient notes. Following internal review the notes of the review will be checked for accuracy firstly by the Medical Director (or the Chair, if different) and then sent to the Director of Quality (or nominated deputy) and the relevant Non-Executive Director. The Assistant Director of Governance & Compliance and/or Patient Safety Manager will be responsible for the collation of the final report in line with the *Policy and Guidelines for Investigating Incidents, Complaints and Claims.* The final report must be completed, signed off by an Executive Director and submitted to the appropriate Commissioner within 60 working days.

28.7 When approved the report will be sent to the Service/Locality Director/Clinical Director for action and review in the confidential section of the Locality Governance Committee Meeting.

28.8 A brief summary of each review, including the ID number, Locality and recommendations/actions will be submitted to the Trust Governance Committee on a quarterly basis. (This will also a RAG rating regarding the impact of delayed completion of actions)

28.9 To promote learning, an anonymised “Lessons Learned Summary” sheet will be produced for review at each of the Locality Governance Committees and onward cascade to teams.

28.10 The Trust Board will be kept informed of all reported serious incidents on a monthly basis within its confidential section.

29 Serious Incident Investigations

29.1 For Serious Incidents, the principles of Root Cause Analysis (RCA) will be applied to all investigations, but the scale and scope of investigation should be appropriate to the incident itself. The scope and terms of reference will be formulated by the Service Director to aid and assist the Investigators.

29.2 Investigations will follow the Trust document: ***Guidelines for Investigating Incidents, Complaints and Claims***

29.3 The Training Department maintains an up-to-date list of competent staff within the Trust familiar with the organisation’s investigation policies and protocols, skilled in good practice root cause analysis methodologies and techniques

30 Action Plans and Lessons Learned

30.1 When an adverse event or incident results in major permanent harm or the death of a patient, serious violence towards staff, patients or members of the public, it is necessary to review, in detail, the patient’s care and make any recommendations for changes in practice. The development of action plans and process for disseminating learning is described in the separate Trust document ***System for Continuous Improvement.***

31 Closure of Incident

31.1 The nominated senior manager/clinician will liaise regularly with the Chief Executive (or Executive Director if “out of hours”) and agree when to finally close the incident. Internal care review panels will be established in accordance with this policy.

31.2 Serious Incidents can only be closed with the agreement of the appropriate Commissioner, following the receipt of a robust investigation report that has been generated following a root cause analysis to include lessons learned and an action plan.

31.3 The Assistant Director of Governance & Compliance and/or Patient Safety Manager will ensure that the appropriate other bodies are informed and that the records are updated on both the local Datix system and the STEIS system.

APPENDICES

Appendix 1: Summary Checklist for Notifying Incidents to the Appropriate Authority

This is for guidance only and is neither comprehensive nor exhaustive. For more details, refer to ***National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*** and ***Information Resource to Support the Reporting of Serious Incidents***.

	Commissioner	SHA	Local Authority	CQC	HSE	MHRA	NHS SMS	HPA	Information Commission	Health Protection Agency	Monitor	Coroner	
Safeguarding/Abuse	✓		✓										
Deaths/homicide/suicide		✓		✓	✓							✓	
Work related death	Refer to the Work Related Deaths Protocol												
Unauthorised absence				✓									
Major emergency	✓						✓				✓		
Notifiable infection	✓				✓					✓			
Assault/ violence by patient	✓				✓								
Assault/ violence on NHS staff	✓				✓		✓						
Never events	✓	✓		✓							✓		
Loss or damage to property or assets	✓						✓						
Defective Medical Equipment	✓					✓							
Information Governance	Refer to *Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents* published by the DoH												
Serious Incidents Reported in the Media	✓										✓		

Appendix 2: Compiling a Report for the Coroner

The purpose of compiling a report/statement for the Coroner is to

1. Inform the Coroner
2. To assist in understanding “how” death occurred
3. To inform the basis of evidence in court.

Provision of such information is a statutory requirement.

Consideration should be given to the following key issues

1. Clarity
2. Honesty
3. Completeness

When constructing the report/statement the following information should be included

Introduction

- Who you are
- What are your qualifications
- What is your experience
- Who employs you

Connection with the case

- What is your connection to the care and treatment of the person
- Who were you answerable to
- Who was answerable to you

The Facts- 6 Key Elements

- Date
- Time
- The documented position (what information does the health record contain e.g. risk assessments, levels of observation, contemporaneous notes etc)
- What did you do
- Why did you do it
- What was the result

The Systems

- Identify the relevant systems
- Identify the policies in place at the time
- Identify any changes since

Appendix 3: Support for Families affected by a Serious Incident (including the role of Family Liaison Officer)

- The Service/Locality Director will appoint a person to liaise with the family or partner of a patient seriously affected by an incident. When deciding on which clinician/practitioner to appoint, the team manager/ward/unit manager should consider seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred. Where unexpected death has occurred it is good practice for the Family Liaison Officer to write to the family expressing sympathy and contact if required, and signpost families to the appropriate avenues of support for bereavement. All contacts with families must be documented in accordance with record keeping procedures and the ***"Being Open Policy (including the Duty of Candour)".***

- This person can be any appropriate member of staff, but will usually be a senior professional or the care-coordinator. They may have existing links with the family (e.g. Consultant, Community Mental Health Nurse), or they may be involved with the review of the incident (e.g. Ward Manager, Unit or Team Manager, Operational Manager). Family Liaison Training is now available via the Trust's Training Department to equip staff with the skills and knowledge required to fulfil this important function.

- The purpose of family liaison is to ensure that the family are not 'left in the dark' following an incident. They will be told about the review process, and will be kept updated on the stage that the review has reached. Should the family have concerns about the incident, they will be told how they can contact PALS or make a complaint.

- The family should not be given detailed information until the review process is complete, but may be told of any general areas of policy or practice relevant to the review. The liaison person will not reveal or discuss any identified deficiencies in the service until the review process is fully complete. Families will have the opportunity to be involved in the review process and the decision as to how this is achieved will be decided on a case by case basis by the Medical Director and/or Director of Quality.

- Family liaison may reveal a need for family support. The liaison person may indicate possible sources of support from services or agencies external to the Trust. The Assistant Director of Governance & Compliance holds a list of these resources and should be approached in the first instance for access to this. The liaison person may also, after consultation with their Service/Locality Director indicate possible sources of support from within the Trust e.g. IAPT. In all instances where death has occurred, the Assistant Director of Governance & Compliance will also write to families/carers outlining the support available and (if appropriate) the investigation process.

- Where a service user has taken their own life, staff appointed to act in a liaison role should make themselves familiar with the document *"Help is at Hand – A resource for people bereaved by suicide or other sudden, traumatic death"*. This document is available on the trusts intranet and should be shared with the family.

- In the event of patient in contact with services being arrested or charged with homicide, a Family Liaison Officer will be identified to provide support to the family of

the victim, and enable the them opportunity to take part in the Trust's internal investigation. In these instances the multi-agency incident co-ordination group (as described in para 24.13) will identify the member of staff to fulfill this function noting that the person **must** be a senior manager. In these circumstances the identified Family Liaison Officer will receive supervision/support from either the Director of Quality or Assistant Director of Governance & Compliance for the duration of their involvement in the case.

Appendix 4: Levels of Investigation

Information in this table provides an outline of the levels of systems-based investigations recognised in the NHS (currently referred to as RCA investigation). Within the NHS, most serious incidents are investigated internally using a comprehensive investigation approach. Resources to support systems-based investigation in the NHS are available online from: http://www.england.nhs.uk/ourwork/patientsafety/root-cause/ **For further information relating to the circumstances and requirements for commissioning independent investigations see appendix 3.**				
Level	**Application**	**Product/ outcome**	**Owner**	**Timescale for completion**
Level 1 **Concise internal investigation**	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld	Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner All internal investigation should be supported by a clear investigation management plan
Level 2 **Comprehensive internal investigation** (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Provider organisation (Trust Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity	
Level 3 **Independent investigation**	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved (see Appendix 1 and 3 for further details)	Comprehensive investigation report including all elements of a credible investigation	The investigator and **all** members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated.	6 months from the date the investigation is commissioned
National reporting templates should be used unless agreed that adaptions are required. National templates will be reviewed on a continuous basis. Recommendations to inform changes should be sent to england.RCAinvestigation@nhs.net				

Appendix 5: Quality Standards for Serious Incidents & Reporting Requirements

The following table defines the quality standards in managing Serious Incidents as defined within the contract with our commissioners:

Standard	Detail	Data Source
Incidents should be reported as soon as practicable after the incident occurs	Time from incident occurred date to incident reported on STEIS	STEIS
Incidents will be reported within 2 working days of the identification of the incident	Time from date of knowledge to incident reported on STEIS	STEIS
An initial report (the 72-hour report) will be submitted to Commissioners within 3 working days of the incident being reported	Initial fact-finding meeting held with Service Director and care team will inform Commissioners	Local database
All incidents will be investigated and reported on within 60 working days (excluding agreed extensions)	Time from incident reported date to receipt of a quality investigation report	STEIS
Incident investigations will follow the structure and process of RCA methodology	Investigation structure to follow the NPSA RCA guidance & template or similar robust framework determined at local level	Investigation reports
The STEIS will be kept up to date and incidents closed according to timescales	STEIS will reflect the current status of investigation	STEIS

To assist in monitoring compliance against the above standards, a quarterly report will be produced including (as a minimum):

Quantitative Section

- No. of Serious Incidents occurring during the quarter reported
- No. of Serious Incidents closed during the quarter
- No. of Serious Incidents remaining open with the reason why.

Qualitative Section

- Root causes and lessons learned of each incident closed in the quarter
- Any themes emerging over the current and previous quarters, with actions take to reduce the likelihood of recurrence
- How learning has been shared across the Trust
- Any exemplar reports that can be shared across the Trust and with others.

Appendix 6: Incidents that must be reported to NPSA without delay

- Injuries that lead to or are likely to lead to permanent damage – or damage that lasts or is likely to last more than 28 days – to:
  - A person's sight, hearing, touch, smell or taste
  - Any major organ of the body (including the brain and skin)
  - Bones
  - Muscles, tendons, joints or vessels
  - Intellectual functions, such as:
    - Intelligence
    - Speech
    - Thinking
    - Remembering
    - Making judgments
    - Solving problems

- Injuries or events leading to psychological harm, including:
  - Post traumatic stress disorder
  - Other stress that requires clinical treatment or support
  - Psychosis
  - Clinical depression
  - Clinical anxiety
  - The development after admission of a pressure sore of grade 3 or above that develops after the person has started to use the service (European Pressure Ulcer Advisory Panel Grading)
  - Any injury or other event that causes a person pain lasting or likely to last for more than 28 days
  - Any injury that requires treatment by a healthcare professional in order to prevent:
    - Death
    - Permanent injury
    - Any of the outcomes, harms or pain described above.

- Apparent or actual suicides
  - All apparent or actual suicides of people with an open episode of care (either community or inpatient) at the time of death;
  - Actual or apparent suicides of former patients (inpatients or community patients) ONLY where a patient safety incident is believed to have contributed to the death (for example, a failure to provide community care or inappropriate discharge from inpatient care);
  - Deaths of inpatients, community patients or former patients from alcohol or use of street drugs ONLY in circumstances where a patient safety incident is believed to have contributed to the death (for example, a delay in access to addiction services) and/or where there has been an actual or apparent suicide;

NOTE the terminology is *'apparent or actual suicide'* i.e. we should report suicides where, in our reasonable opinion, the death appears to be due to suicide. We are not expected to report all unexpected deaths, but only unexpected deaths related to our provision of care and treatment. Incident reports should be updated when evidence of apparent suicide emerges where they were previously not regarded as apparent suicides. Similarly, if evidence is found that the death was not due to suicide the reported apparent suicide should be updated.

Appendix 7: Initial Serious Incident Checklist

Serious Incident Checklist

Name	
Address	
Date of Birth	
Ethnicity	
NHS/GO no	
CPA status	**S117:** Y or N
Diagnosis	
NoK and consent	

Serious Incident Details

Date	
Time	
Location of Incident	
Locality/Speciality	
Team Involved	
Incident Details	
Immediate Action Taken	

Executive Action

Lead Executive	
Initial Review Details (Meeting or phone conference)	
Staff Involved	
Investigating Officer Identified	
Family Liaison Person appointed	

Communication

(These people must receive a copy of this form or be contacted by phone with the above details within 24 hours or the next working day)

Who	Date	Time	Medium (phone, copy, fax, email)
Chief Executive			
Assistant Director of Governance & Compliance			
Assistant Director of Communications			

Appendix 8: Thresholds for Classification of Serious Incidents

There are occasions when there is uncertainty if a particular incident or event should be classified as a serious incident, and therefore managed as such. The following guidance will assist with classifying these incidents/events and lead to greater consistency in reporting and managing serious incidents.

In all instances the national framework will be applied, this defines serious incidents requiring investigation as;

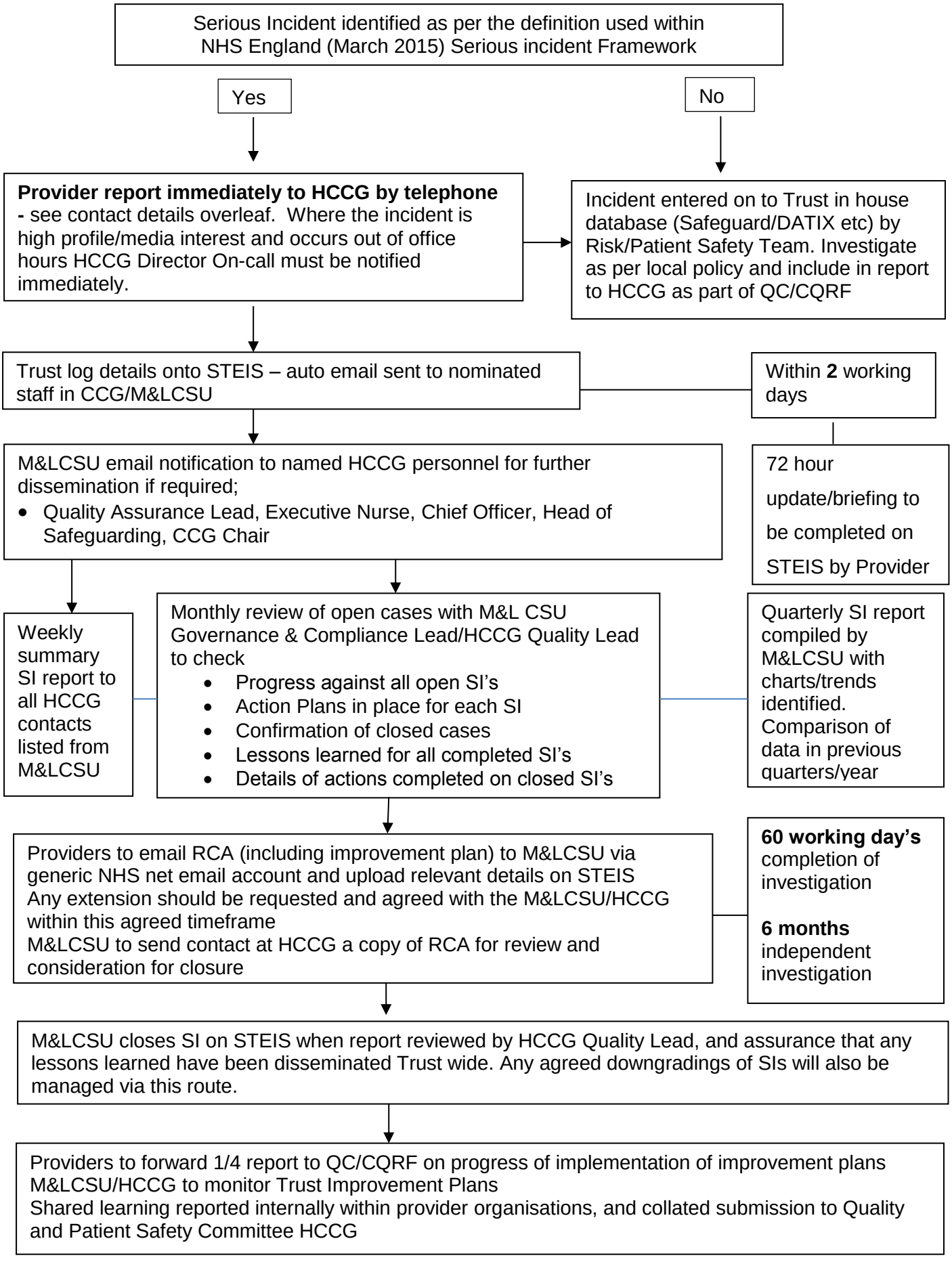
"A serious incident requiring investigation is defined as an **incident** that occurred in relation to **NHS-funded services and care** resulting in:

- **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 or where the outcome requires **life-saving intervention**, **major surgical/medical** intervention, **permanent harm** or will shorten life expectancy, or result in **prolonged pain or psychological harm** (this includes incidents graded under the NPSA definition of severe 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/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 set of 'Never Events' as updated on an annual basis"

Where there remains uncertainty regarding the threshold for incidents which may meet any of the above criteria, the Assistant Director of Governance & Compliance and/or the Patient Safety Manager **must** be approached for advice. They will liaise with the Director of Service Delivery and/or Director of Quality and consider if the incident meets the threshold referred to in the NPSA *Information Resource to Support the Reporting of Serious Incidents.* Responsibility for the classification of such incidents rests with these individuals.

Appendix 9: Serious Incidents Procedure for Herefordshire CCG

Process for Reporting Serious Incidents (SI's) to Herefordshire Clinical Commissioning Group (HCCG)



Appendix 10: Evaluation of Risk/Classification of Harm

IMPACT SCORE					
	1	**2**	**3**	**4**	**5**
	Negligible	**Minor**	**Moderate**	**Major**	**Catastrophic**
SAFETY • SERVICE USERS • STAFF • PUBLIC	Minimal injury requiring no/minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention (e.g. First Aid) Takes 1 month to heal Requiring time off work for < 3 days An event which impacts on a small number of patients or Staff (1 or 2 people) ***Practical examples*** Self-harm- e.g. cutting requiring cleaning or dressing of wound Overdose requiring no intervention Fall – causing bruising Physical assault - causing bruising/superficial lacerations	Moderate injury requiring professional intervention (e.g. A&E or GP) Takes 1 year to heal Requiring time off work for 4-14 days Hospitalization by up 15 days RIDDOR / agency reportable incident An event which impacts on a small number of patients or Staff **(< 10%**) ***Practical examples*** Fall – leading to fracture/fractured neck of femur Overdose - requiring hospitalization and Parvalax treatment Grade 3 pressure ulcer Physical assault - causing fracture/plating of bones or non-fatal stabbing in which full recovery is made	Incident leading to death Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Hospitalization >15 days An event which impacts on a large number of patients or Staff (**10% to 50%)** ***Practical examples*** Self-harm which leads to the loss of a limb Self-harm – e.g. jump from high place causing major permanent harm to one or more limbs Overdose – requiring organ transplant or lifelong dialysis	Multiple fatalities Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients or staff **(> 50%)** ***Practical examples*** Suicide/suspected suicide Homicide

GOVERNANCE - COMPLAINTS	Informal complaint/inquiry	Formal complaint (stage 1) Local resolution Single failure to meet internal standards Minor implications for patient safety if unresolved Reduced performance rating if unresolved	Treatment or service has significantly reduced effectiveness Formal complaint Local resolution (with potential to go to independent review) (stage 2) Repeated failure to meet internal standards Major patient safety implications if findings are not acted on	Non-compliance with national standards with significant risk to patients if unresolved Multiple complaints/ independent review internal/external independent review (PHSO/CQC) Public inquiry Litigation Low performance rating Critical report	Totally unacceptable level or quality of treatment/service Gross failure of patient safety if findings not acted on Coroners inquest Public inquiry Litigation Internal/external independent review (PHSO / CQC) Gross failure to meet national standards
STAFFING & COMPETENCY	Short-term low staffing level that temporarily reduces service quality (< 1 day)	Low staffing level that reduces the service quality	Unsafe staffing level or competence (>1 day)	Unsafe staffing level or competence (> 5 days)	Ongoing unsafe staffing levels or competence
GOVERNANCE - LEGAL & REGULATORY	No or minimal impact or breech of guidance/ statutory duty	Breach of statutory legislation Reduced performance rating if unresolved	Single breach in statutory duty Challenging external recommendations/ improvement notice	Enforcement action Multiple breaches in statutory duty Improvement notices Low performance rating Critical report	Multiple breaches in statutory duty Prosecution Complete systems change required Zero performance rating Severely critical report
MEDIA & REPUTATION	No interest	Local media coverage x 1 day	Local media coverage (up to 1 week).	National media coverage < 3 days	National media coverage with > 3 days. MP concerned (questions in the House)
FINANCIAL	Small loss Risk of claim remote	Loss of £500k to £1m	Loss of < £1m Claim(s) > £1 million	Loss > £10m	

SERVICE	Loss/interruption of >1 hour	Loss/interruption of < 8 hours	Loss/interruption of 1 to 5 working days	Loss/interruption of > 5 working days	Permanent loss of service or facility
ENVIRONMENT	Minimal or no impact on the environment	Minor impact on environment	Moderate impact on environment	Major impact on environment	Catastrophic impact on environment

PROBABILITY SCORE					
Likelihood score	**1**	**2**	**3**	**4**	**5**
Descriptor	**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost certain**
Frequency How often might it/does it happen	This will probably never happen/recur	Do not expect it to happen/recur but it is possible it may do so	Might happen in the next 12 months	Will probably happen in the next 12 months	Will undoubtedly happen in the next 12 month
Additional clarification	This event has not occurred in the Trust and would only occur in exceptional circumstances	The risk has occurred in the Trust however a strong control environment exists making it unlikely that the risk will occur	The risk has occurred in this Trust / other trusts in the past and an adequate control environment exists making it possible that the risk will occur in the next 12 months	The risk has occurred in this Trust / other trusts in the past and an inadequate control environment exists making it likely that the risk will occur in the next 12 months	The risk has occurred in the Trust in the past and the control environment provides little confidence and it is almost certain that the risk will occur

Risk scoring = IMPACT x PROBABILITY

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

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

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