Yeovil District Hospital NHS
NHS Foundation Trust

INVESTIGATION PROTOCOL

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Policy Owner	Director of Nursing & Clinical Governance		
Author	Trust Risk Manager		
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Staff/Groups Consulted	Associate Director of Patient Safety and Quality Medical Director Strategic Business Unit Management Team Health & Safety Committee Clinical Governance Delivery Committee		
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INVESTIGATION PROTOCOL

1. AIM

1.1 In order to manage risk and learn from adverse events, near misses and serious incidents, it is necessary to identify the underlying root cause/s that led to the event occurring. The aim of this protocol is to identify the different levels of investigation required and to provide a structured approach to the process in line with the National Patient Safety Agency (NPSA) guidelines.

1.2 This document complements the Trust's **Incident Reporting policy** and the Clinical Commissioning Group (CCG's) Serious Incidents Requiring Investigation (**SIRI**) policy. It is to be used as a reference for investigation to take place for all Serious Incidents.

2. DEFINITIONS

- **Root Cause Analysis (RCA)**: a Root Cause Analysis is a systematic review of an incident identifying immediate (root causes) and underlying (contributing) factors associated when an incident occurs. As a result of an RCA recommendations and lessons learned are made.

- **Serious Incident** – a Serious Incident Requiring Investigation (SIRI), or Serious Untoward Incident (SUI) is defined as an **incident** that occurred in relation to **NHS-funded services and care** resulting in one of the following:

    - **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**;
    - A scenario that prevents or threatens to prevent a provider organisation's ability to continue to deliver healthcare 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;
    - One of the core set of '**Never Events**' as updated; Department of Health, Never Events Framework 2012/13 (as updated)

- **Patient Safety Root Cause Analysis (RCA) Investigation Levels -** RCAs should be conducted at a level appropriate and proportionate to the incident, claim, complaint or concern under review. There are 3 Levels defined in the NPSA RCA toolkit www.npsa.nhs/rca

    - **Level 1** – **Concise** investigation, most commonly used for incidents, claims, complaints or concerns that resulted in no, low, or moderate harm to the patient.
    - **Level 2** – **Comprehensive** investigation, commonly conducted for actual or potential 'severe harm or death' outcomes from incidents, claims, complaints or concerns.
    - **Level 3** – **Independent** investigation, as per Level 2, but in addition, must be commissioned and conducted by those independent to the organisation

3. INVESTIGATION CRITERIA

3.1 Levels of Investigation

The risk category assigned determines the level of investigation required.

- **Green Incidents** – as identified in the Incident Reporting policy, it is the responsibility of managers to identify the underlying causes and identify actions to prevent a recurrence if appropriate and inform staff of the outcome to eliminate the risk of recurrence. This should be documented in the incident report.

- **Orange Incidents** – these are classified as serious incidents in respect that learning needs to take place but are not always mandated for external reporting, reference should be made to the CCG SIRI policy. They are investigated within the Business Unit (SBU) and reports feed into the incident reporting system for action planning.
    - All Orange incidents are **Level 1** - **Concise** investigations with a brief investigation report developed, this will be based around the Trusts Incident Investigation report and specialist reports such as the pressure ulcer and falls report format.

- **Red Incidents** – these are categorised as Serious Incidents which fall under the CCG's SIRI policy and are reported externally. They are investigated within the BU and actions as a result of the investigation are reviewed through the governance meetings.
    - All Red incidents are **Level 2 or 3** - **Comprehensive** investigations carried out by an independent team where possible from outside the area in which the incident occurred. The investigation report is detailed by nature and will most likely include statements from those involved. A Level 3 investigation this is normally carried out by individuals from outside the Trust and is by nature independent and may involve multi agencies.

Note: In line with the Duty of Candour all Orange and Red investigations must include the concerns of the patient, family, carer and the report should be offered to them as part of openness and transparency in line with the Incident Reporting policy.

3.2 Purpose of an Investigation

3.2.1 The purpose of an investigation is to:

- Establish the full facts and sequence of events that led to the adverse event; this will include contributory factors (e.g. organisational and management factors)
- Identify the concerns of patients, families, carers to be addressed
- Determine why it happened, how it happened and what can be learned
- Determine what went well and identify examples of good practice
- Identify the 'root cause' of any error, omission or concern and 'contributory factors'
- Identify the actions required to prevent recurrence and the persons responsible for implementing change

3.2.2 As a result of an investigation it may be apparent that HR involvement is required which should be actioned at the earliest stage so that reviews can take place jointly with the BU management team and HR.

4 PROCESS FOR INVESTIGATING SERIOUS INCIDENTS

4.1 Immediate Management of a SUI Incident

4.1.1 Once a serious untoward incident has been reported the Manager / Matron or their deputy will obtain key details and work with the Incident Reporting coordinator / Quality Improvement lead to update the incident report within **2 days** of identifying the incident including:

- Patient details confirmed including Name, Date of Birth and Hospital number, address and Next of Kin
- Identify the level of harm or seriousness
- Identify the exact location of incident and if necessary take picture evidence of the location
- Identify any additional events at the time of the incident that may be contributory to the event
- Retain any equipment that may have been at fault and if applicable check any medical devices with the Medical Electronics department for serviceability, maintenance and identify faults if applicable
- Check that the patient and their family/carer has been informed of the incident and that a Being open lead has been identified. Under the Duty of Candour for any harm moderate or above the patient / family must be informed within 10 days and an apology provided
- Check the names, job titles and contact details of those involved (Medical Staff, Nursing staff and other healthcare professionals)
- Identify the Consultant lead for the patient, or the senior manager in charge

4.1.2 Where it is unclear if an incident is to be classed a serious incident, a medical notes review will be carried out to clarify the status of the incident, this will be led by the manager / matron with support from the Quality Improvement Lead. An incident investigation may be downgraded at this time.

4.1.3 The Manager / Matron or their deputy with the Quality Improvement Lead will work with the Incident Reporting Coordinator to ensure the following information is collected no more than **5 days** after the incident was identified:

- For Red Incidents, copy the patients notes, for Orange incidents determine if a copy is needed, or check the availability and copy if they are going to be unavailable for some time to allow the investigating team to access the records
- Obtain access to scans and test results as available
- Identify the staffing numbers and duties rotas at the time of the incident
- Obtain a copy of any Health and Safety risk assessment, and / or audit inspection reports in place
- Obtain copies of relevant policies, procedures, guidelines and protocols etc.
- Identify a member of the investigating team to start a timeline of the events

4.1.4 The Incident Reporting Coordinator will ensure that relevant external / internal reports have been made (such as informing Executive Team, External agencies etc)

4.2 Initiating an Investigation

4.2.1 Once an investigation is confirmed as being required (within **2 days** of the incident being reported) the terms of reference will be set by the Associate Director for Patient Safety and Quality through the Incident Reporting Coordinator and the Quality Improvement lead. Within **4 days** the Quality Improvement lead should identify the investigator/s. A list of trained staff is maintained by the governance team.

4.2.2 Once staff have been identified the Incident Reporting Coordinator / Quality Improvement lead will send out the terms of reference within **6 days** including the details of the incident to be reviewed and the timescale for reporting by email to those involved in the review, at the same time notifying the area and speciality leads

of the investigation being commenced. The investigation template and chronology will be provided to the lead investigator along with additional information gathered relevant to the incident.

4.2.3 The Incident Reporting Coordinator in conjunction with the Quality Improvement lead will maintain an investigation folder linked to the incident report on the incident reporting system. All correspondence, files and emails must be saved in the folder.

4.3 Investigating Team Preparation and Meetings

4.3.1 The Incident Reporting Coordinator and the Quality Improvement lead will co-ordinate with the aim of bringing the investigating team together to review the evidence gathered no later than **8 days** after the incident has been reported.

4.3.2 At this meeting all the evidence gathered including the patient's notes should be reviewed. A timeline / chronology should be developed for all investigations and the care or service delivery issues should be identified at that time for further investigation and interviews to take place.

4.4 Investigation Tools and Techniques

4.4.1 The following tools can be used to systematically identify any care delivery or service delivery issues, any violations and all relevant contributory factors. These tools are available on the Clinical Governance Intranet site on YCloud:

- **Timeline / Chronology** – used to identify the events around the incident that identifies key areas for further investigation by establishing what happened against what should have happened including reference to supplementary information such as policies and guidelines.
- **Fishbone Diagram** (causational analysis) – used to evaluate specific issues by asking what contributed to an event.
- **Five Whys Technique** – used to identify the underlying cause why an event happened

Further resources can be found at:
http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/

4.5 Analysis of the Evidence

4.5.1 Once the investigation team are in possession of the full facts and have a detailed understanding of what happened and why, they can begin to establish the 'contributory factors' and 'root causes', to identify what aspects of the adverse event were managed well and what aspects give cause for concern.

- ***Establish the Timeline / Chronology of Events***
  When interviewing staff it is important to establish the chronology of events leading up to and immediately after the adverse event. The investigator needs to take a pragmatic look at the problem and decide what timescale is to be the focus of the investigation.

- ***Identify the issue(s) that need to be addressed***
  These are the actions or omissions (Care and Service Delivery problems) that arose during the adverse incident that need to be explained. They were elements in the event that had, or could have had, a material influence on the ultimate outcome.

- ***Identify the Contributory Factors***
  There are many possible elements that bring about actions or omissions contributing to an adverse event. These may be active failures and / or latent conditions. It is part of the task of root cause analysis to identify these elements.

Some of the most important to consider are listed as follows:

***Organisational and Management Factors**:*
- Organisational structure.
- Policies, Procedures, Standards
- Risks imported/exported
- Safety Culture
- Financial Resources and Restraints

***Work Environment Factors**:*
- Administration
- Building and Design
- Equipment and Supplies
- Environment
- Staffing
- Education and Training
- Workload/Hours of Work
- Time Factors

***Team Components**:*
- Verbal Communication
- Written Communication
- Supervision and seeking help
- Congruence/Consistency
- Leadership and Responsibility
- Staff Colleagues Response to Untoward events

***Individual (staff) Components**:*
- Competence
- Skills and Knowledge
- Physical and Mental Stressors

***Task Component**:*
- Availability and Use of Protocols/Procedures
- Availability and Accuracy of Medical Records/Test Results
- Decision Making Aids
- Task Design

***Patient Components**:*
- Condition
- Personal circumstances
- Treatment/Care Plans
- History
- Staff-Patient Relationship

- ***Identify the underlying reasons for the adverse event occurring**:*
  Having taken into account all the above factors and issues, it can be very effective to use the "5 Whys" technique to reveal the reason why things went wrong. This can also be an effective and simple way of explaining what happened and why

4.6 Conducting Interviews

4.6.1 The nominated investigation lead is to arrange for staff to be interviewed and should decide whether to interview staff individually or on a group basis; whichever is appropriate in the circumstances.

4.6.2 Arrange a time for the interview should be arranged to allow staff to make arrangements for appropriate cover and to gather their thoughts in advance.

4.6.3 All key members of staff should be made aware of the incident report details and why the investigation is taking place. It should be made explicit that the purpose of the review is to identify areas of concern as well as good practice, and that the focus of the review is on 'learning lessons'.

4.6.4 All staff will be advised that they may have a work colleague or union representative present during the interview process if they wish.

4.6.5 All identified staff should be asked to complete a post incident questionnaire as part of the investigation process. Recommendations suggest no written statements should be taken for RCA's.

Note: Where a formal witness statement is required staff should refer to the guidance entitled 'Making a Witness Statement' which is available through the governance team. In certain situations formal statements may be required for HM Coroners investigations, or statements taken as part of a Police investigation.

4.6.6 As part of the investigation process the patient and their family / carer should be interviewed as part of the investigation process to establish the facts if appropriate; they are entitled to have a relative / carer or advocate present during this process.

4.6.7 It may be useful to speak to other members of staff who were not directly involved in the untoward event to clarify cultural issues and accepted practice within the unit / team.

4.7 Record Keeping

4.7.1 Written evidence, in the form of post-incident questionnaires, forms, etc., is important information. Records will be kept during and after a serious incident by the governance team. The Incident Reporting Coordinator is to scan all documents that are use

4.7.2 Any written evidence may become "disclosable" in the event of subsequent legal action and as part of any disciplinary process and so care should be to include only relevant facts of what actually happened, not what people thought happened. There should be no opinion on who is at fault or any speculation on causes.

4.7.3 The governance team is responsible for the security of all documents and information and must have due regard to Caldicott principles on patient confidentiality and Data Protection Act 1998 requirements when undertaking investigations.

4.8 Completing the Investigation Report (key headings)

4.8.1 The draft report should be written within **30 days** using the template provided by the governance team, and in any statements, other documents such as tabular timelines and action plan should be appended to the final report. The report should include as a minimum the following:

- Details of the person/s investigating and the person whom the investigation is about what was the consequence of the incident realised
- Incident description and background to events, patient relevant history
- Full factual account of the adverse event including a timeline / chronology of key events
- Staff, patients and visitors involved in the review, and if the Being open process has been followed
- Good practice points identified

- Issues of concern (Care and Service delivery problems)
- Contributory factors related to the incident
- The Root cause of the incident
- Recommendations
- Author of the report, dated and signed, and to whom the report is sent

4.8.2 All investigation reports should be reviewed by those persons who have been involved with providing evidence and who have had involvement in the investigation to agree the factual detail.

4.9 Reports and Action Plans*

4.9.1 The draft investigation report and recommendations should be sent to the Associate Director of Patient Safety and Quality via the Incident Reporting Coordinator / Quality Improvement Lead. The report should be sent out and agreed with comments as necessary from those involved and within the BU team by the **30 day** period for all investigations unless complications and delays are identified.

4.9.2 Delays for Level 2 / 3 reports must be reported to the Associate Director for Patient Safety and Quality.

4.9.3 The actions identified as a result of recommendations should be agreed by the **40 day** point and the final report should be reviewed at the appropriate meeting / committee with monitoring of action plans.

4.9.4 Level 2 / 3 reports must be submitted externally to the CCG through STEIS within the **45 day** period. This will be reviewed and monitored through the quality monitoring meetings. Notification will be provided to the Trust when this has been closed down on STEIS through the CCG.

4.10 Identifying and Sharing Lessons Learned*

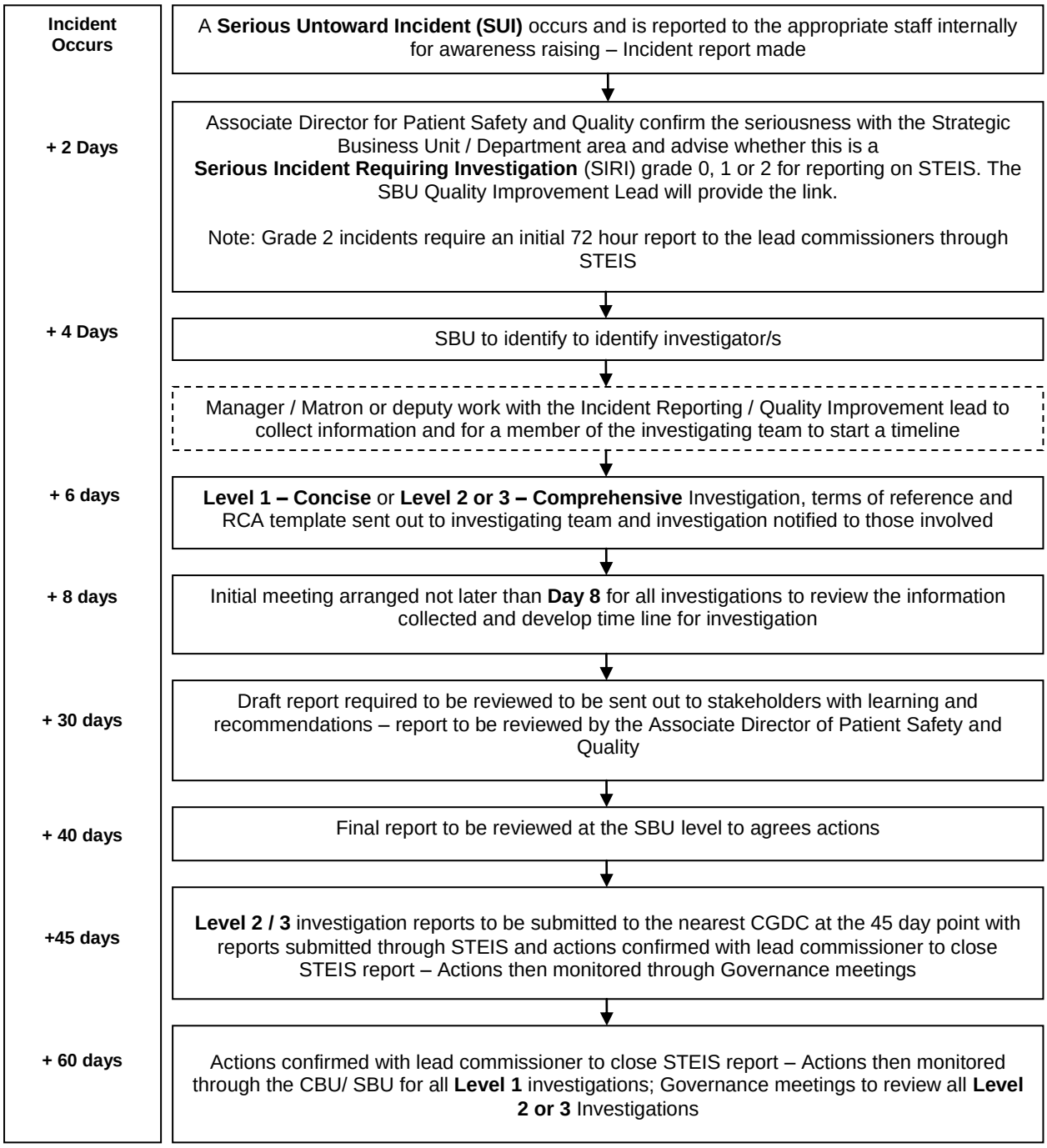
4.10.1 The process of 'root cause analysis' will enable the investigator/team to identify the lessons to be learned from the adverse event, and thus the recommendations that need to be made to improve the safety and quality of the service provided.

4.10.2 The sharing of lessons learned from the investigation will be managed through the appropriate Business Unit and through appropriate governance meetings. Shared learning opportunities will be identified within the Trust and reports may be shared with the lead commissioner as part of wider learning.

4.10.3 In line with the Duty of Candour all incident investigations should be offered to the patient, family, carer for openness and transparency.

*Refer to Section 18 of the Incident Reporting policy and Annex A1 of this protocol for the timeline.

ANNEX A1 – TIMELINE FOR REPORTING AND INVESTIGATING INCIDENT



Note: This timeline support the process identified in the Incident Reporting Policy including Annex A of the policy.