Family Nursing & Home Care

Standard Operating Procedures

(Learning Events Investigation)

April 2021

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Date	Version	Summary of changes made
March 2021	1	New SOP

Contents

Introduction

Learning from experience is vital to the safe and effective delivery of services at Family Nursing & Home Care (FNHC). Staff are committed to providing safe, high quality care to patients, clients and families. On the rare occasion that something may go wrong, the organisation wants to ensure that it learns from what happened to avoid the same thing happening again.

A report in 2018 by Professor Sir Norman Williams concludes:

> *"A just culture considers wider systemic issues where things go wrong, enabling professionals and those operating the system to learn without fear of retribution"*

The report goes on to say:

> *"…generally in a just culture inadvertent human error, freely admitted, is not normally subject to sanction, to encourage reporting of safety issues. In a just culture investigators principally attempt to understand why failings occurred and how the system led to sub-optimal behaviours. However, a just culture also holds people appropriately to account where there is evidence of gross negligence or deliberate acts"*

Investigations are necessary to provide a retrospective review of events to identify what, how and why an event happened. Learning will then be identified to help improve services and prevent re-occurrence.

The purpose of these Standard Operating Procedures (SOP) is to set down the process for investigating all incidents, events and complaints, ensuring that a systematic approach to the analysis and organisational learning of these events is undertaken alongside the relevant organisational policies and procedures, for example:

- Policy for the management of complaints
- Incident reporting policy
- Serious Incident framework

It is acknowledged, at the time of writing that the NHS is introducing the Patient Safety Incident Response Framework (PSIRF) which will replace the Serious Incident Framework (2015) (SIF). These SOPs have been developed using some of the principles from the PSIRF, however, may be revised when FNHC implement the PSIFR which will supersede the existing SIF.

FNHC is committed to embedding an organisational culture that is open, transparent and focussed on learning rather than blame.

Disciplinary procedures are only likely to apply in the following circumstances for staff personally involved in incidents, events or complaints:

- Where the Just Culture Guide (Appendix 1) deliberate harm test indicates a staff member had intention to cause harm.
- Failure to report a serious incident.
- Failure to co-operate with an investigation or review.
- Criminal actions.
- Actions so far removed from reasonable practice that any competent practitioner would have been able to predict the adverse outcome.

Investigations carried out under these Standard Operating Procedures will be conducted for the purposes of learning and should not be used to hold any individual or organisation to account as other processes exist for that purpose including criminal/civil proceedings, professional regulation and disciplinary procedures.

Learning from investigations may be directed towards individuals, services/teams or the whole organisation. Examples of learning along with responsibilities for monitoring and reporting are shown in Appendix 2.

Key resources and references

Health and Community Services (2019) Patient Safety Learning Event Policy.
Health and Community Services (2017) Policy and Procedures for the management of serious incidents.
Healthcare Quality Improvement Partnership.
NHS (2020) Patient Safety Incident Framework.
NHS (2015) Serious Incident Framework.
NHS Improvement (2018) After Action Review.

Regulatory requirements

Under the Regulation of Care, Home Care Standards (Standard 4) Accidents and incidents must be reported and investigated. Learning from incidents will be actioned and monitored where appropriate to help prevent a similar situation from occurring.

SOP 1 - Just culture guide

Purpose

The Just Culture guide (Appendix 1) was developed by the NHS and is supported by the Nursing and Midwifery Council (NMC), the Royal College of Nursing (RCN) in addition to other professional/regulatory bodies and unions. It supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Click on the link above for further information.

Scope

The NHS just culture guide should be used where the investigation of an incident/event, begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

Core Requirements

A just culture guide is useful when assessing concerns about individuals to ensure they are treated consistently, constructively and fairly. Such assessments must be:

- used only when there is reason to believe the deliberately malicious, negligent or incompetent actions or decisions of an individual contributed to an incident, and not routinely whenever an incident is reported or investigated
- managed completely separately from any activity to examine an incident for the purposes of learning and improvement
- led by a colleague of appropriate seniority and with relevant human resources, individual management review or fitness to practise investigation training.

Inappropriate blame is extremely damaging to individuals and an organisation's safety and culture. Staff should never be automatically suspended or their duties restricted or changed unless that is required to support their wellbeing or to protect patients, irrespective of whether they have been involved in other patient safety incidents. These actions should only be taken after a skilled assessment (NHS 2020).

SOP 2 Incident investigations (Assure)

Purpose

This SOP identifies the process for the handling of incidents reported on Assure (incident reporting system).

Scope

This SOP applies to any incident reported on Assure. Incidents may be reported via the web portal (no login) or through the incident module (login required). Incidents should be managed/escalated appropriately prior to reporting on Assure.

Core Requirements

The portal will be checked twice daily during office hours. Incidents reported through the portal will be reviewed by a member of the Governance Team and released which will send a notification email to the relevant parties (see table below).

Notifications of incidents reported through the Assure incident module will be sent upon submission of the incident report and will not be reviewed by the Governance Team prior to release.

Notifications of incidents reported on Assure will be sent via email as per the table below:

Director of Governance, Care and Regulation	All incidents
Head of Quality, Governance and Care	All incidents
Clinical Effectiveness Facilitator	All incidents
Operational Leads/Departmental Managers	Incidents occurring within their service/department only.
Team Leads/Deputies/Managers	Incidents occurring within their teams only.

Timeframes for incident investigation (Assure)

Stage	Timeframe	Responsibility
Review of incident	Within 3 working days of notification	Team leader / deputy / manager
Investigation	Within 2 weeks from date of notification	Team leader / deputy / manager
Approval	Within 4 weeks from date of notification	Operational / departmental manager

SOP 2a Decision Not to Investigate

Purpose

This SOP has been developed to help team leaders/managers decide when an investigation is not required for an incident reported on Assure.

Scope

This is for use by all Team Leads / Managers who receive notifications of incidents reported on Assure where there is **no learning** for FNHC.

Core Requirements

Team Leads / Managers should:

- Open the incident record upon receipt of the notification.
- Review the content to ensure that all sections have been completed.
- Consider the incident severity – Has this been appropriately graded?
- Gather further information where necessary.
- Complete risk matrix (where necessary)

Where **there is no learning** for FNHC then an investigation may not be required. (Please note, where appropriate, it may be necessary to notify other agencies of incidents e.g. HCS – Datix incident report).

Examples:

- Patient admitted onto caseload with pressure ulcer
- Positive Covid-19 case

The team leader/deputy/manager will record their decision not to investigate in the Investigation Findings and Outcome sections of the Investigation & Conclusion section on Assure and where appropriate will inform the person who produced the incident report with the outcome.

This decision will be reviewed by the Operational Lead/Department manager and approved or referred back for further information/investigation prior to approval.

Action	Timeframe	Responsibility
Review notification of incident (complete any immediate action)	Within 3 working days from notification.	Team leader/manager
Decision not to investigate recorded	Within 2 weeks from notification	Team leader/manager
Review of decision and approval	Within 4 weeks from notification	Operational lead/departmental manager

SOP 2b Assure Investigation (within incident report)

Purpose

This SOP has been developed to help identify when and how an investigation should be carried out using the investigation features on the Assure Incident Report.

Scope

This is for use by all Team Leads / Managers who receive notifications of incidents reported on Assure where a comprehensive investigation is not required. Please note that there are separate procedures for pressure trauma investigation (category 2 and above) in SOP 2c (further details in the Pressure Ulcer Reporting Pathway Appendix 3).

Core Requirements

Team Leads / Managers should:

- Open the incident record upon receipt of the notification.
- Review the content to ensure that all sections have been completed.
- Consider the incident severity – Has this been appropriately graded?
- Gather further information where necessary.
- Complete risk matrix
- Complete Investigation and Conclusions section on Assure Incident Report by:
  - Reviewing records
  - Discussion with relevant people
  - Summarising findings (Investigation Findings)
  - Identifying causal factors (What were the root causes)
  - Identifying learning and actions to help prevent reoccurrence. (Learning and Actions)

Action	Timeframe	Responsibility
Review of incident	Within 3 working days of notification	Team leader / deputy / manager
Investigation	Within 2 weeks from date of notification	Team leader / deputy / manager
Approval	Within 4 weeks from date of notification	Operational lead / departmental manager

SOP 2c Pressure Ulcer Root Cause Analysis (PURCA)

Purpose

This SOP has been developed to help identify when and how a Pressure Ulcer Root Cause Analysis (PURCA) should be carried out.

Scope

A PURCA is required where a patient/client develops a pressure ulcer (Category 2 or above) whilst in the care of FNHC (all child and adult services). Further details in the Pressure Ulcer Reporting Pathway Appendix 3).

Core Requirements

Upon receipt of a notification of a pressure ulcer through Assure, the team leader/deputy should:

- Review the categorisation of the pressure ulcer (seeking advice from the Tissue Viability Nurse (TVN), when necessary).
- Identify the need for a PURCA - where a pressure ulcer has been categorised as 2 or above, including suspected deep tissue injuries and unstageable ulcers **and** it developed whilst in the care of FNHC.
- Complete or delegate completion (action via Assure) of the PURCA on Assure.
- Identify that a PURCA is being completed within the Investigation and Conclusion section of Assure.
- Review completed PURCA and action the TVN via Assure to inform them that the PURCA has been completed and reviewed by a Grade 5/6.

The PURCA will be reviewed at the PURCA panel where:

- The TVN will add any recommendations regarding individual patient care to the patient's EMIS record.
- The team lead/deputy will be actioned via Assure to review recommendations on EMIS.
- Service wide/organisational learning will be captured and an action plan will be developed and updated quarterly.

The PURCA panel (see terms of reference) will:

- Consist of the TVN, governance representative and operational lead(s)
- Meet at least monthly, or more frequently as necessary
- Report findings and learning quarterly to the Governance and Performance Board

Action	Timeframe	Responsibility
Review notification of incident (complete any immediate action)	Within 3 working days from notification.	Team leader/manager
Delegate/complete RCA and Action TVN	Within 2 weeks from notification	Team leader/manager
Review at PURCA Panel	Within 4 weeks from notification	TVN

SOP 3 Comprehensive Investigation

Purpose

This SOP has been developed to identify how and when to complete a comprehensive investigation, it should be read alongside any relevant policy i.e. Serious Incidents, Complaints etc.

Scope

A comprehensive investigation may be required for undertaking:

- Serious incident investigation/Patient Safety Incident Investigation
- Thematic reviews
- Complex incident investigation
- Comprehensive complaint investigation

Alternative methods to identify learning may be more suitable depending on the circumstances of the incident/event for example: audit, case review, safety huddle.

The table below provides examples of and responsibilities for commissioning comprehensive investigations.

Type	**Examples**	**Commissioner of investigation**
Serious Incident	Refer to NHS Serious Incident Framework	Director of Governance, Care and Regulation
Thematic review	Following pattern of incident/events	Operational Lead / Department Manager / Director of Governance, Care and Regulation
Complex incident/events	Significant risk / more than one team/service involved	Operational Lead / Department Manager / Director of Governance, Care and Regulation
Comprehensive complaint	Complaints with a number of issues/factors	Head of Quality, Governance and Care.

Core Requirements

A decision to commission a comprehensive investigation should be made within 1 week of an incident/event occurring or when the findings from initial investigation highlight complexities which require further review.

The commissioner of the investigation will:

- Identify lead investigator(s) and admin support where required (this may include use of external investigators where necessary).
- Provide clear and concise terms of reference on the comprehensive investigation report template (Appendix 5).
- Provide a timeframe for the investigation.
- Write to the affected parties, informing them of the investigation process and lead investigator where appropriate.
- Consider informing the organisation's insurers of the incident/event.

Investigations should be completed within 30 days from their commission (unless a specific timeframe is prescribed within the relevant policy) however, the commissioner has discretion to increase/decrease the timeframe dependent upon the complexity of the investigation.

The lead investigator must inform the commissioner at the earliest opportunity if they expect any delays so that time frames may be revised. The lead investigator(s) will be responsible for communicating any delays to relevant parties including patients/clients where necessary.

The lead investigator(s) will agree the method of investigation with the commissioner this will depend upon the context of the incident/event. Comprehensive investigation can be carried out either by the investigator(s) working alone, meeting with individuals as necessary (SOP 3a) or by facilitating an After Action Review where relevant staff, involved in the incident/event come together to review what happened and identify learning (SOP 3b).

Support for patients/clients/relatives

It is essential that the needs of those affected remain the primary concern of those involved in the response to and the investigation, see the relevant policy for Duty of Candour and communication requirements.

Support for Staff

Incidents/events and involvement in investigations can have a significant impact upon staff. Where necessary, staff should be offered StRaW, TRiM or support through Occupational Health. All staff involved with an investigation must be provided with a point of contact, so that they can address any questions to the appropriate person.

SOP 3a Comprehensive Investigation (meetings)

Purpose

This SOP will set out how a comprehensive investigation will be undertaken using the template in appendix 5. It should be read alongside any relevant policy i.e. Serious Incidents, Complaints etc.

Scope

This applies to any staff involved in a comprehensive investigation and provides a process for investigation that should be used in line with the relevant policy.

Core Requirements

Lead investigators will:

- Review and agree the terms of reference and expectations set out by the investigation commissioner within the comprehensive investigation report template.
- Develop an investigation plan which details:

    - What information/documentation will need to be accessed
    - Where and how consent will be obtained (where applicable)
    - Who will be invited to meetings/discussions
    - Dates of discussions/meetings/visits
    - How to keep relevant parties informed of progress

- Prepare appropriate questions for investigation meetings
- Invite individuals to an investigation meeting (which may be done in writing, via email or discussion where appropriate). Appendix 4 contains an investigation meeting invitation template that can be used to ensure that staff understand the purpose of the investigation.

Investigation meetings

Investigation meetings will follow a set process (see below). In some circumstances, meetings may be conducted virtually, by telephone or by sending the questions to the relevant person by letter or email (consider confidentiality).

Staff asked to attend meetings must be aware of the reasons for the meeting before it takes place. The aims of the investigation should be made clear to staff so as not to confuse the investigation with any other legal or disciplinary process (see appendix 4).

Staff involved in investigation meetings should be informed that there is no requirement for them to be accompanied when they meet members of the investigation team. However, although the meetings are conducted as informally as possible it is acknowledged that they may be a cause for anxiety and staff are,

therefore, welcome to have someone present, such as a colleague or member of their trade union/professional union at their meeting.

If someone accompanies a member of staff they must understand and agree that all information regarding the meeting and investigation must remain confidential. The member of staff must not be accompanied by someone who was involved in the incident/event or investigation.

During investigation meetings a second investigator (or note taker) will note key points. It is important that these points are clarified and agreed during the meeting (or as soon as possible after, where the meeting is held virtually).

Investigation meeting process

1. Welcome to meeting, housekeeping

2. Introduction:
    - To investigation team
    - Purpose of investigation
    - Purpose of meeting
    - Confidentiality
    - Note taking

3. Summary of incident/event

4. Questions by investigators

5. Questions from attendee

6. Conclusion
    - Clarify and agree key points recorded in investigation meeting notes. (Where meeting is held virtually, notes will be sent to the attendee immediately after the meeting, they will be asked to review and return within 7 days)
    - Explain whether any further contact likely

7. Close meeting

SOP 3b Comprehensive Investigation Using 'After Action Review'

Purpose

This SOP will set out how a comprehensive investigation may be undertaken through After Action Review (AAR) using the Comprehensive Investigation Report Template (appendix 5). An after action review usually takes the form of a facilitated discussion following an incident/event. It enables understanding of the expectations and perspectives of all those involved and it captures learning, which can then be shared more widely.

Scope

This applies to any staff involved in a comprehensive investigation and provides a process for investigation using AAR that should be used in line with the relevant policy.

Core Requirements

The Lead Investigator will:

- Review and agree the terms of reference and expectations set out by the investigation commissioner within the comprehensive investigation report template.
- Arrange an AAR
- Facilitate the AAR
- Complete the comprehensive investigation report template

AAR arrangements

The lead investigator will identify members of staff who were involved in the incident/event and arrange a date where they are available to meet together (length of session will depend upon complexity of incident/event).

It is important to include as many people as possible who were involved in the incident/event so that a wide range of viewpoints can be explored. A prerequisite of an AAR is that everyone feels able to contribute without fear of blame or retribution. AAR's are about learning, not holding people to account.

The lead investigator/facilitator will guide the group through the discussion and help create a safe and open atmosphere to answer the following questions to create a common understanding of the incident/event under review which will provide the content of the investigation report.

AAR preparation

Depending on the complexity of the incident/event, the lead investigator may choose to complete some of the sections of the investigation template prior to the AAR. For example, the factual information that is readily available, and/or a chronology of events. However, in some cases it may be beneficial to complete the investigation template during the AAR.

The lead investigator will need to make available any relevant documentation, policies, procedures etc. for the AAR and may choose to use additional tools for example; change analysis or tabular time frame (see comprehensive investigation report template for further information) to help facilitate the discussion.

The lead investigator will need to ensure that confidentiality is maintained and information governance/data protection is considered.

AAR questions

- What happened that we want to learn from?
- What did we set out to do?
- What actually happened?
- Why were there differences?
- What went well? Why?
- What could have gone better? Why?
- What would we do differently?

The table below demonstrates how the AR questions can inform the report.

Question	Considerations	Template section
What happened that we want to learn from?	Facts	Description of incident/event
What did we set out to do?	Standard operating procedures / systems	Care and service delivery
What actually happened?	Tabular timeline / Change analysis	Chronology of events Care and service delivery
Why were there differences?	Contributory and mitigating factors	Contributory and mitigating factors
What went well? Why?	Good practice / strengths in procedures/systems	Notable practice/system strengths
What could have gone better? Why?	What happened to cause the incident/event	Causal factors and root causes
What would we do differently?	Reduce likelihood of recurrence.	Learning and Recommendations

Family Nursing & Home Care

Appendix 1

NHS Improvement

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this *just culture guide*, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. Was there any intention to cause harm?

Yes → **Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. **END HERE**

No go to next question - Q2. health test

2a. Are there indications of substance abuse?

Yes → **Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. **END HERE**

2b. Are there indications of physical ill health?

2c. Are there indications of mental ill health?

Yes → **Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. **END HERE**

if No to all go to next question - Q3. foresight test

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

If No to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. **END HERE**

if Yes to all go to next question - Q4. substitution test

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

If Yes to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. **END HERE**

if No to all go to next question - Q5. mitigating circumstances

5a. Were there any significant mitigating circumstances?

Yes → **Recommendation:** Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. **END HERE**

if No

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. **END HERE**

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Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by:

Academy of Medical Royal Colleges · BMA · Care Quality Commission · National Guardian's Office · General Medical Council · NHS England · Nursing & Midwifery Council · Royal College of Nursing · Royal Pharmaceutical Society · UNISON · Unite

Appendix 2 - Learning, Monitoring and Reporting

Learning for:	How learning takes place:	Examples:	Recorded and monitored on:	Held by:	Reported to and when
Organisation	Themes / recommendations shared at Quality Assurance, Governance and Performance meetings	Changes to policies/ procedures, etc. Introduction of service wide training Quality/improvement initiatives	Organisational Learning Data Base	Director of Governance, Regulation and Care	Quarterly Governance Committee meetings
Service/team specific	Themes / recommendations shared at Team Lead/service meetings.	Changes to standard operating procedures Practice development Clinical audit Evidence based practice	Service/Team Learning Database	Operational Lead/Service Manager	QAG&P monthly meetings
Individual	Reflection and support	Skills / knowledge development	Team learning database	Team Leader	Monthly 1:1 with Operational Lead

Appendix 3


Pressure Ulcer Reporting Pathway
February 18, 2021
Category 1 Complete Assure
Pressure Ulcer Identified
Category 2, 3, 4, Unstageable SDTI occurred whilst in care FNHC
If Category 3 or 4 consider SI
Assure/JCC Reporting
Nurse to complete RCA on Assure
Multiple Category 2 or 3 or 4 Seek Safeguarding Supervision & TVN support
Team Leader/ Deputy implement early learning from RCA
Team Leader/ Deputy review RCA on Assure
Safeguarding Lead/TVN will complete adults PU decision tool With practitioner
Safeguarding threshold not met
TL/Deputy Action Assure TVN when RCA reviewed
If safeguarding threshold met refer adult safeguarding
Record Score/ Actions in EMIS
RCA Panel Individual recommendations/ Organisational Learning
Review care plans risk assessments etc
Any actions for patients recorded on EMIS. Assure actions sent to Teamleader to review RCA EMIS template
Organisational learning feedback op lead for action

Appendix 4

Invitation to comprehensive investigation meeting

Dear

RE: Investigation meeting invitation

I have been asked to complete a comprehensive investigation which aims to provide a retrospective review of **[incident/event etc.]** to identify what, how and why it happened. You are invited to attend an investigation meeting **[where, when]**

Learning will then be identified to help improve services and prevent re-occurrence. Please see the **enclosed Standard Operating Procedures** which detail the investigation process.

Investigations carried out under these procedures will be conducted for the purposes of learning and are not used to hold any individual or organisation to account. **This is not a disciplinary investigation.**

There is no requirement for you to be accompanied during the meeting. However, although meetings will be conducted as informally as possible it is acknowledged that they may be a cause for anxiety and staff are, therefore, welcome to have someone present, such as a colleague or member of their trade union/professional union at their meeting.

If someone accompanies you they must understand and agree that all information regarding the meeting and investigation must remain confidential. You cannot be accompanied by someone who was involved in the incident/event or investigation.

During the meeting, notes recording the key points will be taken. You will be asked to clarify and agree them either during the meeting or shortly afterwards.

If you have any questions, please do not hesitate to contact me.

Yours sincerely

Appendix 5

Comprehensive Investigation Report Template

Investigation Reference	
Type of investigation i.e. Serious Incident / Comprehensive / Thematic etc.	
Commissioned by:	
Date Commissioned	
Timeframe for investigation	
Lead Investigator	
Investigation Team	
Date of Report	

Contents

1. Description of incident/event

What happened?
Which department/service?
What were the effects on the person involved?
What was the impact (severity)?

2. Risk assessment

Assess the realistic severity and likelihood of recurrence using the appropriate risk matrix (appendix 1).

A Likelihood of recurrence of harm (1-5)	B Level of harm (1-5)	C Risk rating (C=AxB)

3. Background and context

Brief description of service type, size, team, care etc.

4. Terms of reference

Purpose

To identify causes and learning to use information to reduce likelihood of future harm/recurrence.

Objectives

To establish facts – what happened (effect) to whom, when, where, how and why (root causes).
To identify learning and recommendations/action plan to reduce likelihood.
To provide a report and record investigation process and outcome.
To identify routes of sharing learning

Key questions/issues to be addressed
Specific to the case

Scope
Start and end points, depth

Investigation process
Investigation meetings/learning event
Mapping/Tabular timeline (appendix 3)

Change analysis (appendix 2)
Contributory/mitigation factors (appendix 4)

Arrangements for communication, monitoring, resources etc.

5. Involvement and support of patients/clients/relatives

Who is involved?
What are their wishes?
Detail discussions etc.

6. Involvement and support of staff involved

Refer to staff anonymously, and to support offered/provided to staff involved in the incident/event (StRaW / TRiM)

7. Information and evidence gathered

Summary of relevant local/national policy/guidance in place at time of incident/event
List of data accessed – care records, staff rotas, training records, etc.
Dates of meetings – persons seen

8. Chronology of events

Date/time	Event

9. Care and service delivery

Refer to change analysis (appendix 2) or tabular timeline (appendix 3)
What happened?
What should have happened?

10. Contributory and mitigating factors

Refer to appendix 4

11. Notable practice/system strengths

Highlight good practice, strengths in procedures/systems

12. Causal factors and root causes

What happened to cause the incident/event and why

13. Learning

What has been learned?

14. Recommendations

What can be done to reduce the likelihood of recurrence or improve quality/safety?

15. Arrangements for sharing learning

How will the learning be shared?

16. Appendix 1

Risk Matrix; Determining the Likelihood of Harm

This must be estimated over a stated period or related to a given activity.

Level	Descriptor	Description
1	Rare	This will probably never happen/recur
2	Unlikely	Do not expect it to happen/recur but it is possible it may do so
3	Possible	Will probably happen/recur but it is not a persisting issue
4	Likely	Might happen or recur occasionally
5	Certain	Will undoubtedly happen/recur, possibly frequently

Determining the Consequences of Harm

For example catastrophic means death or debilitating permanent injury and minor means requiring first aid.

Level	Descriptor	Description
1	Negligible	No/minor injuries, no time off work required, Informal complaint, rumours, low financial cost
2	Minor	First Aid Treatment, minor intervention, requiring time of work <3 days, verbal complaint, minor implications for patient safety if unresolved, breech of statutory legislation, local media coverage, Medium financial loss.
3	Moderate	Moderate injury requiring professional intervention, requiring time off work for 4-14 days, an event which impacts on a small no. of patients/staff, written complaint, low staff morale, single breech in statutory duty, local media coverage – long term reduction in public confidence.
4	Major	Major injury leading to long-term incapacity/disability, requiring time off work for >14 days, multiple complaints, unsafe staffing level or competence (>5 days), multiple breeches in statutory duty, National media coverage <3 days.
5	Catastrophic	Incident leading to death, multiple permenant injuries, inquest / ombudsman enquiry, prosecution, National media coverage >3 days.

A Simple Risk Level Estimator

	Likelihood				
Consequence	**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

17. Appendix 2

Change analysis

Prescribed/expected/accepted procedure or action	Procedure or action at time of incident	Was there a change (Y/N)	If yes, was this a care/service delivery strength (S) or weakness (W)
		Y/N	S/W
		Y/N	S/W
		Y/N	S/W
		Y/N	S/W
		Y/N	S/W

(NHS Patient Safety Incident Response Framework 2020)

18. Appendix 3

Tabular Timeline (Excel version available)

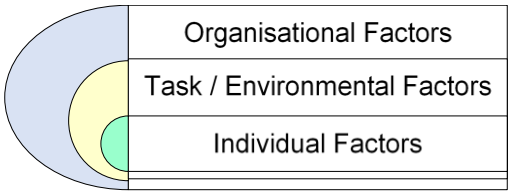
Instructions: Begin by stating why the tabular timeline is needed (e.g. details of the problem under consideration). Review the available information to populate the grid. This is a simple process and starts with the dates and times and details of what happened in chronological order. This is followed by completion of the 4 additional rows (what should have happened, any other information, missing information and good practice).

Reason for tabular timeline				
Event date/time				
What happened?				
What should have happened?				
Any other information				
Missing information				
Good practice				

(Healthcare Quality Improvement Partnership, 2016)

19. Appendix 4

NHS Patient Safety Incident Response Framework (2020)
Contributory and mitigating factors classification



External context factors	Components
National guidelines and policies	• Impact of national policy/guidance (DHSC/professional colleges, etc.) • Locum/agency policy and usage • Contractor related
Economic and regulatory context	• Service provision • Bed occupancy levels (opening/closures) • Private finance initiative related • Equipment loan related • Financial constraints • Resource constraints
Societal factors	• Values • Beliefs
Organisational and strategic	Components

Structure	• Hierarchical structure (discussion, problem-sharing, etc.) • Roles, responsibilities and accountability • Multidisciplinary working • Clinical/managerial approaches • Maintenance • Service-level agreements/contractual arrangements • Safety terms and conditions of contracts
Priorities/resource	• Safety focus • Finance focus • External assessment focus • Workforce resource management • Estates and technology resource management
Safety culture	• Safety/efficiency balance • Commitment to safety • Openness of culture and communication • Risk tolerance • Approach to escalation of concerns • Leadership response to whistleblowing
Policy, standards and goals	• Organisational processes (formal) • Organisational processes (informal) • Processes between/spanning organisations
Operational management factors	Components
Safety focus	• Rule compliance • Dealing with risks from past incidents • Awareness of current practice • Adherence to current practice • Empowerment of staff to act

Work planning and delivery	• Risk management plans • Scheduling • Incentive schemes • Contingency planning
Staffing levels and skill mix	• Skill mix • Staff to patient ratio • Workload/weighting/dependency • Temporary staff • Staff turnover
Workload, shift patterns, hours of work	• Working hours • Work breaks • Workload (under/over/balanced) • Extraneous tasks • Social relaxation, rest and recuperation
Training design	• Training needs analysis • Training design • Training/education content • Targeted training • Style of delivery • Time of day provided
Training availability/accessibility	• Training availability/accessibility • Core skills training • On the job training • Emergency scenario training (skills drills) • Team training • Refresher training
Staff supervision	• Orientation • Personal supervision • Monitoring of supervision (assessment) • Mentorship

Staff competence	• Knowledge • Skill • Experience • Familiarity with task • Competence testing and assessment

Workplace factors	Components
Environmental factors	• Capacity • Fixture or fitting • Separation • Safety • Cleanliness/hygiene • Temperature • Lighting • Noise levels • Distractions (audio) • Distractions (visual) • Ligature/anchor points
Design of physical environment	• Work area design (e.g. size, shape, visibility, screens, space, storage) • Security provision • Lines of sight • Use of colour contrast/patterns (walls/doors/flooring, etc.) • Space design (adjustable furniture, panic buttons, positioning, etc.)
Administrative factors	• Administrative work systems • Administrative infrastructure (phones, bleep systems, etc.) • Administrative support

Equipment and technology factors	Components
Displays	• Information/feedback available • Information clarity • Information consistency • Information legibility • Information Interference • Information displays (colour, contrast, anti-glare screens, etc.)
Integrity and maintenance	• Working order • Reliability • Safety features (fail to safe, etc.) • Maintenance programme • Emergency back-up services (power, water, piped gases, etc.)
Positioning and availability	• Availability • Accessibility • Position/placement • Storage • Emergency backup equipment
Usability/design	• Controls • Intuitiveness • Use of colour • Use of symbols • User manual • Detectability of problems • Use of items which have similar names or packaging • Compatibility
Team and social factors	Components

Culture	• Approach to newcomers • Approach to adverse events • Approach to conflict • Approach to rules/regulations • Approach to seeking support • Approach to interprofessional challenge • Interpersonal relationships • Power relationships
Team structure and consistency	• Shared understanding • Familiarity • Mutual respect • Clarity of roles and responsibilities • Congruence of roles and responsibilities • Informal support networks
Leadership	• Clinical leadership • Managerial leadership • Leadership impact • Leadership decision-making • Timeliness of leadership action • Respect for leadership • Formal support networks for staff

Communication management	• Communication strategy and policy documents • Involvement of patient/family/carers in treatment and decisions • Communication of risks to patient/family/carers • Communication of risks to staff • Communication of risks to the board • Information from patient/family/carers • Communication flow to staff up, down and across • Communication with other agencies (partnership working) • Measuring effectiveness of communication
Verbal communication	• Tone of voice • Style of verbal communication delivery • Use of language • Specificity • Direction • Channel/route • Verbal communication aids/equipment
Written communication	• Readability • Accessibility/availability • Collated • Completeness • Contemporaneous • Accuracy • Currency • Circulation of written information • Patient identification • Information to patients
Non-verbal communication	• Body language/gestures/facial expression
Task factors	Components

Clinical condition	• Pre-existing co-morbidities • Complexity of condition • Seriousness of condition • Options available to treat condition
Plans, guidelines, policies, procedures and protocols	• Informative • Instructional • Representative • Routine use • Usability • Currency • Accuracy • Availability • Accessibility (ambiguous, complex, irrelevant, incorrect) • Monitoring • Review • Targeting/focus (i.e. audience)
Decision-making aids (information/results/ tools/machines, etc.)	• Available • Accessible • Working • Accurate • For prioritisation of tasks • Access to specialist advice • Access to technical information, flow charts and diagrams
Procedural or task design and clarity	• Task complexity • Task memorability • Understandable • Agreed with staff (feasibility) • Time allocation

	• Task sequencing/stage sequencing • Workload (under/over/balanced) • Compatibility of tasks/task stages • Competing task demands • Feedback from the task • Transferability to/from other situations • Influence on task/outcome • Automation • Audit, quality control, quality assurance
Individual patient factors	Components
Physical factors	• Physical health/condition • Nutrition/hydration • Age related • Body mass related
Social factors	• Cultural/religious beliefs • Language/communication • Lifestyle choices • Life events • Living accommodation • Support networks • Social protective factors (relevant to mental health services) • Risk tolerance • Engagement/motivation/compliance/concordance • Interpersonal relationships (staff-patient; patient-family; staff-family)
Psychological factors	• Mental health • Mental capacity • Learning disability • Intent (relevant to mental health services)

Individual staff factors	Components
Physical health	• General health (nutrition, hydration, wellness, fitness) • Health related conditions (e.g. eyesight, dyslexia)
Psychological/mental health	• Mental health • Mental alertness • Motivation level (boredom, complacency, low job satisfaction)
Social domestic factors	• Domestic (family related) • Lifestyle (financial, housing, etc.) • Language
Personality factors	• Confidence • Risk awareness/risk tolerance
Social factors	• Motivation and values • Beliefs and expectations • Attitudes • Habits
Cognitive factors	• Focus/attention • Perception • Reasoning and decision-making • Group influence • Workload (underload/overload/well-balanced)