Portsmouth Hospitals NHS
NHS Trust

INTRODUCTION

This protocol is designed to assist staff in the investigation and analysis of a serious clinical incident (SCI). It is also designed to be read in conjunction with guidance from the South East Regional Office on the management of **Serious Untoward Incidents.**

It has been adapted from a process of analysis and investigation developed in a research context by clinicians and researchers and fits with recommendations made by the Clinical Negligence Scheme for Trusts. The chosen method is designed to promote a greater climate of openness and to move away from finger pointing and the routine assignment of blame.

1. WHAT IS A SERIOUS CLINICAL INCIDENT (SCI)?

"A Serious Clinical Incident is any incident that results in a potentially avoidable death or severe harm to a patient, visitor or staff member as a result of :-

- ***Poor clinical outcomes***
- ***Serious negligence/unprofessional conduct***
- ***Serious processes/ system failures that result in any of the above"***

OR

- ***Any clinical incident which could attract intense media attention and/or adversely effect the reputation of the Trust.***

2. INFORMING KEY STAFF

If a member of staff believes that any of the above might have occurred they must :-

1. Immediately contact:-
   - In hours - The Medical Director/Nursing Director or Head of Risk
   - Out of hours - Duty Manager

2. Complete an Adverse Incident Form

2.1 Within the first 24 hours of the incident occurring

The Duty Manager/Medical Director/Director of Nursing/Head of Risk (or their Deputy) must inform the following in the most expediant manner eg: Email or telephone:-

- The Executive Management Team
- Clinical Director/Divisional Senior Nurse and Divisional Manager of the Division where incident occurred. These staff will then decide who else in their Division needs to know this information.
- Portsmouth Health Authority Duty Officer

- NHS Executive South East Regional Office – Regional Communications team Press Officer Code A
- Code A
- Public Relations Manager
- Consultant and Senior Nurse in charge of the patient's care.

To ensure this action is taken the person responsible for the above should inform the Senior Nurse Advisor - Governance as soon as possible to ensure records are kept.

2.2 Supporting those Involved

The Clinical Director/Divisional Senior Nurse/Divisional Manager must offer support to the family/relatives and offer psychological support to staff involved in the incident.

Attached is a list of names of people who have experience and knowledge of handling serious incidents and would be happy to offer support and/or advice. For senior clinical staff this may be their peers and colleagues and for more junior staff their Clinical Tutor/Clinical Supervisor or, in the case of midwives, the Supervisor of Midwives. Alternatively, staff may wish to seek support outside of their clinical area or even outside of the Trust. The line manager must support this decision.

The Medical Director/Director of Nursing should arrange for either themselves or another Executive Director to attend and meet with the family, if this is deemed appropriate.

3. HOW AND BY WHOM IS THE DECISION MADE TO INVESTIGATE THE INCIDENT AS AN SCI ?

Following the submission of an Adverse Incident Report, a complaint, claim, telephone call, email or through the Whistleblowing process the Clinical Governance Senior Nurse Advisors will review the incident and if any of the above criteria seem to apply an initial investigation will be carried out by. The results of this preliminary report will be presented to :-

- Risk Manager/Deputy
- Director of Nursing/Deputy
- Medical Director/Deputy
- Senior Nurse Advisor – Governance

It may be necessary to gain further information from the clinicians involved to determine whether the event constitutes a serious clinical incident

4. WHO WILL INVESTIGATE?

Once a decision is made to investigate an SCI the **Serious Clinical Incident Review Team (SCIRT)** should be convened. The team should be a multi-skilled team led by the Governance Directorate, for example:-

- Risk/Legal Services Manager/Deputy
- Director of Nursing/Deputy
- Medical Director/Deputy
- Senior Nurse Advisor – Governance

NB: Clinical staff involved should not originate from the service/speciality under investigation. However, the speciality/service senior clinician/manager and the patient's named consultant should keep in close contact with the SCIRT.

If the named consultant is the 'lead' consultant, he or she should decide whether to request a colleague to take over either care of the patient or assisting with the SCI.

To ensure a degree of objectivity and independence, no parallel investigations should take place.

In certain circumstances (after the initial review has taken place) consideration might need to be given to the appointment of an external clinical investigator. This will be decided, jointly by the SCIRT and the senior clinician involved.

5. WHAT ACTIONS SHOULD BE TAKEN ONCE THE DECISION IS MADE?

As mentioned previously, it is essential to alert key staff/agencies that an SCI Review is to be undertaken, the SCIRT must therefore ensure the following have been notified:-

- Regional Health Authority
- Local Health Authority
- Duty Manager
- Executive Management Team
- Communications Manager
- Divisional Nurse/Divisional Clinical Director
- Consultant /Senior Nurse in charge of the patient's care.
- Other staff/agencies as decided by the SCIRT

The method of review implied by this model is to first examine the chain of events that leads to an SCI and consider the actions of those involved. The team then looks further back at the conditions and environment under which staff were working and the organisational context in which the incident occurred.

The first step in the analysis process is to identify active failures – unsafe acts or omissions by those at the 'sharp end' of the system whose actions have resulted in adverse consequences.

The second is to consider factors eg: high workload, fatigue and inadequate knowledge, which may have had a direct impact on the SCI. Each level of analysis will then be expanded to provide more detail.

6. PREPARING STAFF FOR REVIEW

It is essential that the reviewers acknowledge that the review is likely to be stressful for all involved therefore, it is crucial that they are sensitive in their approach to avoid undue stress. Staff need to be made aware that in itself, the review is **not** a disciplinary procedure. Therefore, staff involved in the incident should be supported and the review completed within an agreed timescale.

Interviews should be structured and pre-arranged, allowing staff to arrange for appropriate cover and to gather their thoughts in advance.

Staff being interviewed should be encouraged to bring a colleague/friend and be allowed time to ask questions as well as answer them.

During the review, the Manager in charge of the area must decide, early on, whether the staff involved need to be sent off duty if events have been or are becoming personally traumatic. This could occur immediately after the incident, any time following the incident before the review, during the review and immediately after completion of the review. **However, it must be emphasised that this does not constitute suspension from duty, and is simply a compassionate measure to enable recovery.**

7. ASSIGNING BLAME

In the event of an adverse incident or error, however serious the outcome, it is not the intention of the Trust to seek to assign blame. The Trust recognises that an incident/error is not necessarily evidence of neglect, carelessness or dereliction of duty. Identifying errors, which are common in health care, is only one step in the investigation process.

7.1 What Would Result in Retraining?

Serious errors/repeated errors of judgement, poor practice and non-compliance with policies and protocols.

7.2 When Could Disciplinary Action be Considered?

Only if evidence emerges of **repeated** poor performance that has not improved with retraining, or deliberate/wilful acts which breach professional standards of conduct, will action be considered in relation to any individual member of staff, be it retraining, or disciplinary. If, for any reason, disciplinary action is considered to be appropriate, this must be made clear as soon as this possibility emerges. If this situation arises advice should be sought from the Human Resources Department before proceeding any further.

8. INVESTIGATION PROCESS

Accounts of the incident may be taken from:-

- Written reports from staff members,
- Case notes/medical/nursing records/ or
- Interviews with staff.

8.1 Reviewing the Case Notes

Consideration should be given to gain the opinion of an expert if the case is of a complicated or specialist nature.

First Tasks – To be undertaken prior to interviewing staff

1. Case Note Review - record an initial summary of the SCI, identifying the key areas of concern (see Appendix 1) This must be documented in chronological order, as recorded in the notes.
2. List the key staff involved and decide who should be interviewed and in which order (see Appendix 2)

8.2 Undertaking the Interviews

Interviews should be undertaken in private, in a relaxed setting and always away from the immediate place of work.

Before starting the interview agreement should be reached on who will lead the process, who will listen and who will record responses.

The purpose of the interview is simply to find out what happened and this should be explained at the outset.

The style adopted should be supportive and understanding and not judgemental, critical or confrontational.

Where it becomes clear a professional shortcoming has occurred, this should be allowed to emerge naturally from the conversation and should not be extracted by cross examination.

It should always be remembered that errors and mistakes in clinical care are rarely wilful and most staff are genuinely disturbed when it becomes clear that something they have done, or failed to do, has contributed to an incident. The staff member will normally require additional support at this point and should be allowed, through supportive discussion, to start to come to terms with what has happened. Adverse comment and judgement at this stage is most unhelpful as it leads to demoralisation and defensiveness.

Firstly, establish the role of the member of staff in the incident as a whole. Then from the staff member :-

- Establish the chronology of events
- Identify the key concerns

- Identify any contributory factors
- Distinguish specific and general Contributory Factors, ie: common events or one specific event which led to the event
- Close the Interview (each interview should last a maximum of 30 minutes)
- Ask staff member if they wish to add any further comments
- Prompt the clinician in order to jog their memory about factors not mentioned in the account.

Compare this new information with what is known of the overall sequence.

8.3 Site Visits

If appropriate the SCIRT should undertake a site visit of the department/unit/area where the incident occurred. The Team should speak with staff and generally gain a view of:-

- The environment – fabric of buildings, space and facilities available
- Documentation – eg: nursing/medical notes, care plans, medicine charts, observation charts
- Communication – eg: Team Brief, notice boards, patient information, staff meetings
- Staff welfare – ward rosters, breaks, management of sickness absence, Performance Review
- Information technology – ward based terminals, access to Intranet/internet
- Staff training
- Adverse incident reporting/whistleblowing

Notes should be taken from each area visited

8.4 Adverse Incidents

The SCIRT should undertake a full review of all previous adverse incidents, complaints and claims related to the area being investigated.
Consider:-

- Previous incidents related or similar to event being investigated
- Action taken by line manager following event
- Implementation of actions identified
- Are there any claims against the Trust for similar events
- Has there been any previous claims against any individuals involved in the current event
- Has there been any complaints similar to current event being investigated
- What action was taken as a result of the complaints
- Have the action/s been implemented.

9. ANALYSING THE CASE

The core of the process is for the SCIRT to determine:-

- What happened?
- How did it happen?
- Why did it happen?

9.1 Establishing a Chronology of Events

Using both information obtained from casenotes, documentation, site visits, adverse incidents, claims, complaints and interviews:-

- Produce an agreed history of events, generally starting from when the patient is admitted to hospital, consider :-
- previous medical treatment
- misleading referral letters etc.
- any relevant clinical /administrative information that occurred prior to admission and/or MCIs
- Specify any areas of disagreement :-
- between accounts
- between case notes and recollection of staff

9.2 Identifying Key Concerns

- Identify the concerns noted by staff involved/concerns arising from the investigators knowledge and expertise
- List the main concerns on Form A (see Appendix 3)

This form is strictly for the recording of specific actions or omissions on the part of the staff involved, ie facts not opinion
NB: General observations on the quality of care should be recorded on Form B (see Appendix 4)

9.3 Identifying the Contributory Factors

Further distinction needs to be drawn to distinguish between specific factors and general, longstanding conditions within the workplace. The SCI Team should differentiate between those contributory factors that only exist on that particular occasion or those that are a permanent feature (see Appendix 5)

- Specify the conditions associated with each identified concern ie; any other factor that may have affected the process/es or system/s
- Judgements may need to be made regarding the most important causes
- Carry out a separate analysis for each concern

9.4 Complete Summary Forms for Each Key Concern

- Complete Analysis sheets (see Appendix 6)
- From each individual interview and other relevant records prepare a summary for each key concern (see Appendix 7)
- Examine the final list of general contributory factors and identify those that have implications for future action
- For each key concern record the implications and action points at the side of the summary form

9.5 Preparing the Report

Once the interviews and analysis is complete make a composite of them all detailing the whole incident from start to finish. In the process of undertaking the interviews, new concerns may have been identified. These should be added to

the list. When the composite is complete, there should be a clear view of the problem, the circumstances that led up to it and the flaws in the care process should be readily apparent.

9.5.1 What Happened

- Identify staff involved by grade and initials only
- Write a clear description of the SCI including:-
- summary of the analysis of the SCI
- summarise the chronology
- the circumstances leading up to the SCI

9.5.2 What went wrong

- Identify the key mistakes/errors in the process/system/people
- Any contributory factors
- Identify whether SCI was avoidable?
- Has the Trust experienced a similar SCI or near miss

9.5.3 Cost

- Where possible establish an estimate of quantum
- Include where possible human cost

9.5.4 Consequence

- Outcome eg: Death, permanent disability

9.5.5 Learning from the mistake

The report must consider what implications this incident has for the department and the organisation.

- What can be learnt from this?
- What changes should be made if any?
- A recommended Action Plan, including deadlines and Responsible Person/s for each identified risk treatment.
- Implications of Action Plan
- If the interviews suggest a need for follow up with a particular member of staff, return and use the same structured process, concentrating on the new concerns.

9.5.6 Performance Monitoring

Performance Monitoring should be by the Clinical Governance Committee as a stand agenda item – 'Status Report, Serious Clinical Incidents.

9.5.7 Effectiveness of Risk Treatment

Performance Monitoring should be by the Clinical Governance Committee as a stand agenda item – 'Status Report, Serious Clinical Incidents.

10. DISTRIBUTION/FEEDBACK

The SCIRT must ensure that the area involved is given in depth and final feedback, particularly in relation to future actions. The SCIRT should also ensure all areas, where a similar event may occur, are informed of the event and it's outcome. This will help minimise the chances of a similar event reoccurring.
Therefore, suggested distribution should include:-

- Divisional Clinical Director for division concerned
- Clinical Director for Speciality/Department
- Divisional Clinical Director for each division
- Divisional Senior Nurses
- All staff involved in the incident
- Clinical Governance Committee
- Trust Board
- All relevant health care staff

It may even be necessary to inform the Trust as a whole and local health agencies if the outcome of the review has far reaching implications

BIBLIOGRAPHY

UCL A protocol for the Investigation and Analysis of Clinical Incidents
Clinical Risk Unit & ALARM
September 1999. Royal Society of Medicine Press

Code A

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