POLICY ON THE
MANAGEMENT OF SIGNIFICANT CLINICAL INCIDENTS
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1. Introduction

The management of a Significant Clinical Incident forms part of the current Clinical Risk Management arrangements and should be recognised as a means of improving the quality of patient care and minimising risk. The key aspects to managing Significant Clinical Incidents are:

- Immediate action to limit harm and re-establish safety at a tolerable level
- Prompt sensitive and professional handling of incidents
- Prompt action to reporting incidents to all relevant authorities
- Establish details record of events surrounding the incident
- Review to ensure corrective measures are effective and likelihood of recurrence has been minimised

This policy addresses firstly the immediate action and communication following a significant clinical incident (see 3. Definition) then addresses the subsequent reporting, recording and investigation processes (See Sections 5 – 7 and appendices).

This policy does not cover non-clinical aspects of patient safety which should continue to be managed according to Health & Safety policy. The management of some incidents may require support from both Clinical Risk and Health & Safety teams, for example significant patient injury as a result of a fall. Routine incident reporting for both clinical and non-clinical incidents should be managed in line with the Board Incident Reporting policy.

2. Aims

The main aims of this policy are:

- To promote quality and reduce risk in patient care systems ultimately improving patient safety
- To ensure that immediate corrective action is taken in response to an incident
- To ensure that the incident is escalated via the relevant line management structure
- To ensure that an acceptable standard of investigation is consistently carried out for significant clinical incidents
- To create a culture of open reporting, learning and improving

It is expected that individual services will need to establish their local procedures to support this process and may wish to define their own communication set and flow chart to guide staff. Examples of localised processes from both Acute and Partnerships are included within appendix A.

3. Definition of a Significant Clinical Incident

A Clinical Incident is defined as any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS funded healthcare.

**Significant Clinical Incidents** are those events that have or could have significant or catastrophic impact on the patient and may adversely affect the organisation and its staff. Commonly these are referred to as level 4 or 5 incidents in line with the QIS severity descriptors.

The decision as to what constitutes a significant clinical incident depends on the characteristics of the event, the patient or the clinical service. The recognition and classification that a significant clinical incident has occurred will vary depending on a range of
factors but may include unexpected death of a patient, medication errors, incidents involving a child, homicide related to a patient’s mental health, etc.

As the definition suggests this policy applies also to near miss situations which could have led to harm. Near miss situations are those where no immediate harm, loss or damage was suffered, but could recur if conditions or causes are not remedied. As with actual incidents the decision over what constitutes a significant near miss will depend on the individual circumstances however it is important to recognise the learning potential within these situations and investigate appropriately.

4. Immediate Action

The person who discovers the incident must:

- Raise the alarm to secure the support from other clinical professionals
- Take immediate action to ensure the safety and well being of the patient involved, other patients and the public.
- Initiate communication by notifying Line Manager

Line managers must ensure that:-

- Senior clinical staff and appropriate managers are informed
- Immediate corrective action has been taken to secure safety and that the potential for further harm has been reduced to tolerable levels or eliminated
- Senior management staff are informed including out of hours as appropriate
- Other departments involved are notified as appropriate, please refer to appendix B for guidance
- Records, materials and equipment, including disposable equipment used in conjunction with any device, are retained.
- Any faulty medicine, equipment or device is removed from use immediately and labelled to prevent further use.
- Patients, relatives and other persons who need to have details of the events receive timely, adequate explanations / apologies from appropriate senior members of staff
- Personal support is given where necessary to staff who have been involved in a Significant Clinical Incident.

It is anticipated that the communication shown above would be face to face and/or via telephone. To ensure that the incident is communicated as widely as is needed throughout the organisation a Significant Clinical Incident Alert e-mail should be issued. This should be done as soon as is practicable after the incident has occurred. The Line Manager referred to above should issue this alert notice via the Board e-mail system using a previously agreed local distribution list. This list may have to be amended in light of the specific incident (e.g. to include pharmacy for medication errors).

All areas must develop their own rapid alert list which should include members of the Management Team. In developing this rapid alert list services may also wish to develop a template to be used for these communications – guidance on the minimum information that should be contained can be found below. Services must ensure that the information contained within a rapid alert meets the requirements of the Data Protection Act and Board Information Security Policies.
As an example within the Acute setting this list should include:

- Head of Nursing
- Director
- Associate Medical Director
- Clinical Director
- Lead Pharmacist for Directorate (if incident involves medication errors)
- Lead Nurse for Specialty
- Lead Consultant
- Clinical Risk Manager
- Clinical Service Manager
- General Manager
- Ward / Department Manager
- Quality Manager for Specialty (where available)

The e-mail should contain the following information:

- Directorate/ Partnership
- Location of incident (Site Ward/ Dept/ other)
- Date and Time of incident
- Synopsis of what has happened
- Any immediate action as a result of the incident
- Any ongoing hazard/ risk
- Any press release or communication information

5. Reporting

The appropriate incident report form should be completed, further guidance can be found within the NHS GG&C Incident Reporting Policy.

The flowcharts provided within appendix A show how the associated documentation is managed and how incidents are subsequently investigated and reported. As noted local services are expected to adapt the flowchart process to reflect local individual and committee roles within the process however the overall principles must be applied.

6. Investigation

It is the policy of NHS Greater Glasgow and Clyde that an investigation will be conducted into all Significant Clinical Incidents. The purpose of the investigation is to determine whether there are learning points for the Directorate / Partnership and wider organisation. All staff involved in commissioning/ conducting such investigations must adhere to the following principles:

- The investigation is not about establishing blame. If the investigation team considers that there are issues about the performance of an individual member of staff, this should be referred to the appropriate Line Manager and should not be part of the investigation (more details within Being Open section).
- The Management team should consider whether an external review is appropriate and commission accordingly.
- Terms of reference of investigators should be defined.
- The lead responsibility for establishing and meeting the communication requirements of patients or family members etc. should be clarified with the Lead Investigator.
- The support needs of staff involved in the incident must be considered.
- Case notes should be available to those being interviewed
Commissioning an Investigation

It is the Director’s responsibility to ensure an investigation is completed. Responsibility for instigating the investigation lies with the management team, though in practice this may be delegated to the lead for clinical governance within the Directorate / Partnership.

The level of investigation, basic or full analysis, should be established at this time and will inform the remit of the investigation. If a full analysis is not be carried out this should be communicated to the Clinical Risk Manager with details of the investigation to be undertaken.

At this stage it should be identifiable what Directorates/ Services have been directly involved in the incident and will therefore contribute to the investigation. Where an incident crosses multiple Directorates/ Services it is imperative that the leads for these services liaise and agree an overall lead for the investigation as soon as possible. The need to appropriately maintain communication across all Directorates/ Services involved during and following the investigation cannot be underestimated and the investigation lead must ensure this is achieved.

Where the investigation raises the possibility of external scrutiny, e.g. Fatal Accident Inquiry or Inquiry by The Mental Welfare Commission, senior staff should be made aware of this possibility. Where external inquiries are progressing, the scope and possible need for postponement of the internal investigation should be reviewed.

Investigation Team

A Lead Investigator will be appointed (by management team of delegated lead) who will be competent in Root Cause Analysis, or supported by a facilitator who is competent. The composition of the investigation team will be decided at a local level reflecting the circumstances of the event. It may be useful to include someone independent of the clinical area where the incident occurred.

Guidance is provided within Appendix C on specialist support staff within the Board who should be notified of significant clinical incidents and may provide support for the investigation process, including external notification where required.

The Investigation

An Investigation Toolkit is available from the Clinical Risk Management Team which provides guidance on tools and methods available to facilitate the investigation including guidance for staff on writing statements, factoral analysis tools and reporting template. This can be accessed via the CGSU Intranet site within Clinical Incident Reporting:

http://staffnet/Corporate+Services/Corp+Services/Clinical+Governance/Clinical+Risk/CG_Clinical_Incident_Reporting_CM_140207.htm

Where a full root cause analysis is commissioned then factoral analysis must be considered and reference to this made in the final report.

Investigations must be completed and reported within a maximum of three months following the incident.

All investigation reports will be anonymised. A copy of all final reports will be forwarded to the Clinical Risk Manager. Guidance for writing reports, including templates, is available within the Investigation Toolkit.
7. Being Open

Communicating effectively with patients and/ or their families is an essential part of the process when dealing with a significant clinical incident. Strongly linked to this is the need to ensure that staff are adequately supported through this process also.

NHS GG&C fully supports the principles of the NPSA guidance on being open in ensuring patients, their families and staff are appropriately informed and involved throughout a significant clinical incident.

**Informing Patients, Relatives and Staff**

The Boards Communication Strategy will be followed and Corporate Communications consulted before any public/external communication is made. Wherever possible patients, their relatives and/ or staff must be informed before the media becomes involved.

As soon as a significant clinical incident has been identified it is essential that an appropriate person is identified to inform patients and relatives. Who this person is will depend on the individual circumstances but is likely to be the consultant in charge of the overall patient care.

The responsibility for ensuring this communication is maintained appropriately through the investigation will lie with the Lead Investigator although it is acknowledged they may not be the person actually communicating with the patients/ relatives. Managers must ensure that staff are adequately advised and supported in undertaking this communication.

**Apologies**

It is both natural and desirable for those involved in treatment which produces an adverse outcome, for whatever reason, to sympathise with the patient or the patient’s relatives and to express sorrow or regret at that outcome. Such expressions of regret would not normally constitute an admission of liability, either in part of full, and where staff wish to do so GG&C encourage such expressions to patients and/ or relatives.

**Explanations**

Patients and their relatives increasingly ask for detailed explanations of what led to adverse outcomes. Closely linked to this desire for information is the frequently expressed view that they will feel some consolation if lessons have been learned for the future. GG&C are keen to encourage the sharing of appropriate information with patients and/ or families whether informally, formally or through mediation. The level of communication with patients and/ or relatives is an issue that needs to be addressed by the Lead Investigator to gain an overview of communication to date and the needs throughout the investigation. This will ensure further a consistent point of contact for the patient and/ or family and that their needs are met as far as possible in terms of receiving an explanation.

**Relationship of the Investigation to the Code of Conduct Procedure**

The spirit of the investigation into a clinical incident will be characterised by a *just* culture. ‘*Just* culture’ in this context means that the purpose of the investigation is to identify Root Causes or system failures. Staff will not be ‘blamed’ for such failures or their consequences; however, they retain individual responsibility for their own actions or inactions in accordance with the professional codes that apply to them and their professional practice. It is recognised that staff are expected to follow policies and procedures and that if there is wilful knowing departure from that then this is likely to be addressed through the established disciplinary procedures. Although the investigation is not in itself a disciplinary process it would always be open to staff providing information to be accompanied by a representative of their choice.
Any investigation into a serious clinical incident will not, and cannot, preclude use of the code of conduct process where there has been a serious breach of professional practice or organisational policy. However in the event that a disciplinary procedure is invoked, the Lead Investigator will be made aware and the reasoning for its use will be discussed with the Investigation Team. Similarly, if the Investigating Team believes there may be a need to undertake a disciplinary investigation under the Board's Code of Conduct, they should bring this to the attention of the Directorate/ Partnership Head of HR.

**Staff Support**

It is important that any staff involved in a significant clinical incident are fully supported both in terms of dealing with the incident and throughout the investigation process. The Occupational Health service are available to support staff and should always be offered as an option to staff involved in a significant clinical incident. As noted above any staff engaged in the investigation process through interview are entitled to be accompanied by a representative of their choice to provide support. It is also important that once an investigation has concluded a debrief is held for staff involved to advise them of the findings and outcomes. This should be co-ordinated via the Lead Investigator.

**8. Aggregated Incident Reports**

Aggregate analysis of incident reports involves quantitative review of all events on an ongoing basis, monitoring for any new trends e.g. increased levels of a type of incident or increases within a specific area. It also includes qualitative review of incident reports to identify common underlying themes or causes. This type of activity should form part of the routine activities of the Directorate / Partnership Clinical Governance Forum/Groups who may then commission further study on any of the following:-

- Common themes identified as problem areas in basic reports
- Groups of reports from a particular area
- Groups of reports for particular categories of patient

The Directorate / Partnership Clinical Governance Forum/Groups will make such decisions on the basis of the reports it receives.

**9. Monitoring the Policy and its Success in Improving Patient Safety**

The management, investigation and application of learning for significant clinical incidents should be a visible and explicit component of each Directorate or Partnership Clinical Governance work programme. The tracking and confirmation that improvements and agreed corrective measures are applied in practice should be apparent in the routine activities and reporting of Directorate / Partnership Clinical Governance Forum/Groups or Management Teams.

All investigation reports will be reviewed to identify themes and solutions that can be shared across services. An overview report of the NHS GG&C experience will be provided by the Head of Clinical Governance on a quarterly basis. This report will include promotion of issues and their solutions to highlight opportunities for shared learning.
**INCIDENT**
- Raise alarm
- Make safe area
- Institute related policy e.g. Sudden death policy

**NOTIFICATIONS**

Briefing Note – Operational Manager to Complete within 3 days of incident (Proforma Pg. 2)

- Notify Line Manager
- Incident Meets Definition of SCI

**GRADING INCIDENT**

HoMH and CD review briefing note and decide whether SCI review required (Pg. 18)

- Record Incident IR1/DATIX
- Notify Line Manager
- Document emailed to:
  - HoMH & CD
  - Clinical Risk & MHP
  - Other Senior Managers as appropriate
  - Other departments as appropriate
  - For example: Pharmacy manager in instances where incident involves medications

**INVESTIGATION AND REPORTING**

- CD/HoMH ensure:
  1. SCI Logged On Central Database (Clinical Risk Host Pg. 3)
  2. Review Chair Appointed with appropriate training, e.g. in root cause analysis (Pg. 13)

**RECORDS**

- Chair appoints Review Team & conducts investigation in <12 weeks (Pg. 4)
- Learning from incident implemented – Care Governance Operational Group (Refer Pg. 12 for guidance on dealing with requests for completed reports)

**REPORTS**

- To MHP and Care Governance Executive Group
- Rationale recorded
- Notification of decision not to proceed to SCI Review fed back to Exec Group
- Incident Trend Analyses
- Chair appoints Review Team & conducts investigation in <12 weeks (Pg. 4)
- Learning from incident implemented – Care Governance Operational Group (Refer Pg. 12 for guidance on dealing with requests for completed reports)
Appendix A – Flowchart Examples – Rehabilitation and Assessment Directorate

Incident Occurs - Secure Situation

Identify as non-clinical R1 completed (24 hours)

CSM & H&S Advisor
Discuss and agree if a H&S or clinical incident process – if clinical copy of form sent to clinical risk

Clinical Incident Form completed

Identify as Clinical Incident

Risk Assessment undertaken by Lead Nurse / CSM / Clinical Director / Professional Lead

Significant Incident 4 & 5

Rapid alert

Clinical implications dealt with immediately

Then immediately inform by phone

Line Manager

GM
CG Forum
Director

Strategic Management Group

Local Clinical Governance Forum to review action. No later than 2 months from incident.

Routine Clinical Incident Report

Clinical Risk Manager provides report on all incidents on ¼ basis

Non-Significant 1 - 3

Ward Manager / Team Leader

CSM / Ward Manager

Health & Safety (Allan Hughes) to assess risk of incident

Appendix A – Flowchart Examples – Rehabilitation and Assessment Directorate

Call GM / AHP Director then Email Alert

General Manager Clinical Risk Manager Clinical Director Director of RAD

Head of Nursing Director of AHP’s Associate Medical

**Out of Hours the clinical coordinator and consultant on call should be notified who informs Lead Clinician next morning.

**The local team will need to consider who undertakes email alert during a lead’s absence.
**OPERATIONAL LEAD**
Submit Clinical Incident Report to Clinical Director, Head of Nursing, Professional Lead GM and Clinical Risk Manager

**RISK MANAGEMENT TEAM**
For all Significant Incidents:
Monitor and review Action Plan progress.
Monitor Trends and Outcomes.
Division / Service wide communication and exception reporting as appropriate.
Share lessons learnt.

**DIRECTOR**

**HEAD OF SERVICE = General Manager / AHP Director**
Nominate investigation Team to carry out incident investigation.
Ensure Action Plan generated.

**CLINICAL RISK MANAGER**
Notify Management Team plus Communications Manager where appropriate. Support investigation as required.

**INVESTIGATION TEAM**
Prepare Incident Investigation Report and Executive Summary. Progress to full RCA if required. Copy including Action Plan to Directorate Management Team and CSM no later than 3 months from incident.

**DIRECTORATE MANAGEMENT TEAM**
Review full report, recommendations and action plan. Pass to CGC on approval.

**CLINICAL GOVERNANCE COMMITTEE**
For all significant incidents:
Exception reports to Board CG Committee
Appendix B – Communication & External Reporting

The following list provides an indication of the stakeholders (internal and external) who may require to become involved following an incident. Where relevant these contacts should be notified of an incident as soon as possible (for example by inclusion in the rapid alert).

This list is not exhaustive, if unsure if of reporting requirements or internal contacts advice can be sought from the Clinical Risk Manager.

<table>
<thead>
<tr>
<th>Incident type</th>
<th>Internal (GG&amp;C) Contact</th>
<th>External Requirements</th>
<th>Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Errors</td>
<td>Pharmacy</td>
<td>Committee of the Safety of Medicines – prescriber uses yellow card scheme to report adverse reactions to a medicine.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lead Pharmacist for each area who will advise.</td>
<td>Defective medicines require to be reported as per GEN (1991) 25 and updates.</td>
<td></td>
</tr>
<tr>
<td>Infection Control</td>
<td>Infection Control</td>
<td>Environmental Health</td>
<td>Food Standards Agency</td>
</tr>
<tr>
<td></td>
<td>Local Infection Control Teams will advise.</td>
<td>Scottish Centre for Infection and Environmental Health (SCIEH)</td>
<td>Scottish Government</td>
</tr>
<tr>
<td>Falls</td>
<td>Health &amp; Safety</td>
<td>RIDDOR – H&amp;S will advise.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H&amp;S Advisors aligned to each area who will advise.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Falls Co-ordinators</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 co-ordinators aligned to sites who can offer guidance/ support for Falls issues.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moving &amp; Handling</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Local co-ordinators assigned to services who will offer advice.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Transfusion</td>
<td>Blood Transfusion Service – local leads identified who can advise.</td>
<td>Serious Hazards of Transfusion (SHOT)</td>
<td></td>
</tr>
<tr>
<td>Incidents involving ionising radiation</td>
<td>Board Radiation Protection Advisor – Colin Martin, local advisors also available who can advise.</td>
<td>Radiation Protection</td>
<td></td>
</tr>
<tr>
<td>Any incident involving medical devices/equipment (i.e. fault with equipment)</td>
<td>Clinical Physics</td>
<td>Scottish Healthcare Supplies – either CP or H&amp;S will advise if required.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Local support staff who can advise.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Violence and Aggression</td>
<td>Health &amp; Safety</td>
<td>Police</td>
<td></td>
</tr>
</tbody>
</table>
Appendix C – Procurator Fiscal Notification Criteria

It is the responsibility of the doctor in charge of the patient at the time of death to consider whether the Procurator Fiscal needs to be informed. In the event of this an F89 Form requires to be completed. Please note that in addition to the following criteria, recent Home Office guidance would suggest that if the person is to be CREMATED, the Procurator Fiscal should be informed in respect of a death OCCURRING WITHIN 24 HOURS of an admission THAT IS NOT RELATED TO ANY PREVIOUS ADMISSION'S DIAGNOSIS. The area Fiscal Deaths’ Unit have advised that this is not an absolute requirement in Scotland but would reflect the extent of investigations and knowledge of the case in question. Therefore, for a death occurring within 24 hrs of admission, which is to be followed by cremation you are STRONGLY ADVISED to CONSIDER THE NEED TO CONTACT the Fiscal's death unit.

These are the categories :-
1. Any uncertified death.
2. Any death caused by an accident arising out of the use of a vehicle including an aircraft, a ship or a train.
3. Any death of a person whilst at work.
4. Any death from an accident in the course of work or arising out of industrial disease or poisoning.
5. Any death due to poisoning.
6. Any death where the circumstances indicate that suicide may be a possibility.
7. Any death where there are indications that it occurred as a result of medical mishap i.e.:

These include:
- Deaths which occur unexpectedly having regard to the clinical condition of the deceased prior to his receiving medical care;
- Deaths which are clinically unexplained;
- Deaths seemingly attributable to therapeutic or diagnostic hazard;
- Deaths which are apparently associated with lack of medical care;
- Deaths which occur during the actual administration of general or local anaesthetic; and
- Deaths which may be due to an anaesthetic
8. Any death resulting from an accident.
9. Any death following abortion or attempted abortion
10. Any death where the circumstances seem to indicate fault or neglect on the part of another person.
11. Any death occurring while the deceased was in legal custody as defined in section (14) of the 1976 Act.
12. Any death of a new born child whose body is found.
13. Any death (occurring not in a house) where a deceased's residence is unknown
14. Any death by drowning
15. Any death of a child from suffocation including overlaying
16. Any death which may be sudden death in infancy syndrome.
17. Any death occurring as a result of food poisoning or an infectious disease.
18. Any death by burning or scalding or as a result of a fire or explosion
19. Any death of a foster child
20. Any other death due to violent, suspicious or unexplained cause.
21. Any death where a complaint is received from the next of kin about the medical treatment given to the deceased, and where there is any suggestion that the medical treatment may have contributed to the death of the patient.

Other Information: The Crown Office has asked if attention can be drawn to those deaths which fall into category 21. Under this category any death where a complaint is received from the next of kin about the medical treatment given to the deceased and where there is any suggestion that the medical treatment may have contributed to the death of the patient, should be reported as soon as the complaint is received, if it has not already been reported under category 7. It is appreciated that such complaints may be unfounded, but Procurators Fiscal should be given the opportunity to investigate them.