POLICY ON THE MANAGEMENT OF SIGNIFICANT CLINICAL INCIDENTS

NHS GREATER GLASGOW & CLYDE	Custodian: Head of Clinical Governance
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1. Overview

Introduction

NHS Greater Glasgow and Clyde aim to provide high quality care which is safe, effective and person centred. For the majority of patients requiring healthcare this aim is satisfied but on occasion care does not proceed as planned. From the full range of clinical incidents reported in NHS GG&C there is a smaller set of instances where there is a risk of significant harm to patients. We have a responsibility to ensure these incidents are appropriately investigated to minimise the risk of recurrence through learning. This opportunity for learning exists at times without a significant adverse outcome for the patient, e.g. a near miss or a lower impact incident which exposes potential system weaknesses that could lead to further significant harm. Such events have been traditionally referred to as Significant Clinical Incidents.

It is the policy of NHS Greater Glasgow and Clyde that a robust 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/Sector/Partnership and wider organisation. It is then our responsibility to implement those improvements that we identify as producing a greater level of clinical safety for our patients. The management of a Significant Clinical Incident forms part of the current Clinical Risk Management arrangements and should be recognised as an important means of improving the quality of patient care and minimising risk.

This policy document advises on the definition of a Significant Clinical Incident and addresses firstly the immediate action and communication following a Significant Clinical Incident. It then focuses on the subsequent reporting, recording and investigation processes including monitoring of actions.

This policy has been developed to take cognisance of literature on best practice on the management of Significant Clinical Incidents and the Healthcare Improvement Scotland Learning from adverse events through reporting and review: A national framework for Scotland (2015). It is the intention that compliance with this policy framework will meet the requirements of the national framework in relation to significant events.

A toolkit has been developed to support implementation of this policy (appendix E). This contains templates for all documents referred to within the policy, guides for local procedures and also guidance on tools and process as well as key information links. A list of the items within the toolkit is included within the appendix. The toolkit can be found within the Clinical Governance Support Unit Staffnet site at the following link:

http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Clinical%20Risk/Pages/SCIInvestigationToolkit.aspx

Scope

This policy applies to all services within NHS Greater Glasgow and Clyde health board. Routine incident reporting for both clinical and non-clinical incidents should be managed in line with the NHS GG&C Incident Management Policy.

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 could be within the scope of this policy.

The following incidents, which can often be associated with a severe patient outcome, have investigation processes in place which are automatically triggered when an event occurs to quickly establish if the appropriate care assessments and interventions were in place to minimise the event. These events will be considered potential Significant Clinical Incidents and subject to screening using the appropriate tool to support decision making as to whether the incident should be confirmed as an SCI.

- Any deaths associated with severe Clostridium Difficile Infection (CDI)*
- Any deaths associated with Staph. Aureus Bacteraemias (SAB)*
- Avoidable Grade 3 and 4 Pressure Ulcers developed under NHS Care*
- Serious Falls with harm*
- Patient Suicide where there has been contact with Mental Health Services
- Clinical incidents reported with a severe consequence (severity 4/5)

In some cases the review may not be sufficient enough to provide an answer and SCI Investigation can be used to support a more detailed review. The severity 4/5 screening tool will ensure for those that do not progress as a Significant Clinical Incident there is a formal record of the review undertaken to inform this decision making. More information on the guidance and tools can be found within the toolkit. Directorates/Sectors/Partnerships must ensure these review processes are implemented within service.

Please note this stage does not have to be used for all incidents before they can be classed as a significant. If it is clear from the outset the incident requires investigation as a Significant Clinical Incident then it can be declared by escalation using a rapid alert template to initiate the process.

*Separate guidance in place to support the review process external to CGSU

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 including appropriate patient involvement and support for staff involved.
- To ensure robust governance of significant clinical incident management and develop good behaviours and practices.
- To create safety practices which promote openness, learning and improvement.
- To meet Duty of Candour requirements so patients / families are informed of serious events relating to their care / treatment.

Individual services must establish their own local procedures to support implementation of this policy and may wish to develop a flowchart to guide staff; the policy highlights the mandatory requirements that must be met within local procedures.

Basic Principles

All staff involved in commissioning/ conducting SCI investigations must adhere to the following principles:

- The investigation is not about apportioning blame but establishing causality and unless there are immediate professional/practice concerns this process should be concluded before any formal HR involvement.
- The SCI investigation is a transparent process and there must be evidence of appropriate staff/patient/family involvement.
- Staff members directly involved in the incident should not be involved in the investigation team but may contribute to the investigation.
- There is no requirement for the investigation team to be independent of the service but management teams should consider whether this is appropriate and may ask a clinician from another site / department if further independence is required.
- There is a robust process in place to ensure SCI investigations are appropriately supported from commissioning to conclusion.
- All staff who contribute to the investigation will have the opportunity to review draft reports for factual accuracy, a final report will then be agreed by the investigation team and submitted to the investigation commissioner.
- The SCI investigation is to investigate the clinical care of the patient and does not relate to other issues which may be declared in a complaint.
- If the incident involves more than one service a joint review is required involving both parties. There should not be two separate investigations for the same event.

Key Requirements

All SCI investigations must meet the following key requirements:

- All incidents should be reported on Datix.

- Attached to the incident record will be the rapid alert or 4/5 review and a PDF copy of the final investigation report and associated action plan (when available). Clinical Risk should be sent all rapid alerts, 4/5 reviews and final reports using the generic email account.

- A central file can be stored by Clinical Risk separate to Datix which may include:
    - Any staff recollection of events submitted as part of the investigation
    - Any reports/documented information provided to support investigation
    - Any photographs taken as part of the investigation
    - Details of any equipment involved in the incident including location of equipment
    - Investigation timeline
    - Key of names

- Local procedures must define the process for ensuring this core file is maintained; all files must be kept in line with records retention guidelines.

- SCI investigations should aim to be completed within 3 months of confirmation of SCI status. It is recognised there may be cases where this timescale is not achievable however this timescale is felt to be a reasonable aim for the expected date of conclusion.

Definition and Immediate Response

Description of a Significant Clinical Incident

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 and have potential for wider learning (i.e. learning that can be gained for future care delivery).

In the national framework these are referred to as Category One events and subject to investigation in line with this Board Policy. However, it must be stressed that a severe or tragic patient outcome is not the only indicator of a Significant Clinical Incident. Near miss events with no adverse outcome and complex lower severity incidents can also warrant investigation within this process due to the potential for learning that has been exposed. The following are events that should be considered but is not an exhaustive list:

- Any retained swab or surgical item
- Maternal death
- Any fetal loss meeting the MBBRACE criteria*
- Avoidable return to theatre
- Patient Suicide where there has been contact with MHS
- Wrong patient blood transfusion
- Re-use of a non sterile instrument
- Homicide (where perpetrator is a patient)
- Medication incident with a serious or potentially serious patient outcome.
- Delay in treatment or diagnosis that has significantly influenced health or life expectancy.
- Child protection incident with potential learning for health

* **Late fetal losses** – the baby is delivered between 22^{+0} and 23^{+6}weeks of pregnancy showing no signs of life, irrespective of when the death occurred.
Terminations of pregnancy - resulting in a pregnancy outcome from 22^{+0} weeks gestation onwards.
Stillbirths – the baby is delivered from 24^{+0} weeks gestation showing no signs of life.
Early neonatal deaths – death of a live born baby (born at 20 weeks gestation of pregnancy or later or 400g where an accurate estimate of gestation is not available) occurring before 7 completed days after birth.
Late neonatal deaths – death of a live born baby (born at 20 weeks gestation of pregnancy or later or 400g where an accurate estimate of gestation is not available) occurring between 7 and 28 completed days after birth.

The decision as to what constitutes a Significant Clinical Incident depends on the characteristics of the event, the patient or the clinical service and the potential for learning. It is acknowledged that there can be delay with post mortem/toxicology results. The prompts below can be used to aid decision making regarding whether the investigation should commence before the results are available.

The following prompts, used in the 4/5 review template are useful in considering if an incident requires investigation as an SCI:

- Has the patient suffered any harm?
- Is the patient outcome a known complication of a disease/ treatment?
- Has there been a breach in policy or procedure?
- Are you satisfied everything was done as it should have been done, or are there unknowns?
- Do you feel there is learning to be gained (would something be done differently next time)?
- Are there patient/ family concerns regarding the care/ treatment/ outcome?
- Is there management concern?
- Is there interest from the fiscal?
- Has there been a serious equipment, system or process failure?

If there is any uncertainty as to whether an incident falls in the scope of the policy the Directorate/Sector/Partnership Clinical Governance lead should be involved in the decision; advice can also be sought from Clinical Risk in such occasions.

All reviews of events being considered as an SCI must be completed and documented using the defined template, which is then attached to the reported incident in Datix.

An event being declared a Significant Clinical Incident does not indicate any causal link between the care and patient outcome but reflects the perceived need to investigate an event in detail to establish this and/ or that there is potential for learning on a wider level. An investigation may conclude that the care delivered was appropriate and an event unavoidable; this is still logged as a Significant Clinical incident as the investigation process has been enacted to inform this conclusion. An investigation conclusion code is applied to all incidents to indicate the findings of the investigation in relation to the link between care and patient outcome which will allow identification of those events where improvements are required.

Immediate Response
The **person who discovers** the incident must**:**

- Raise the alarm to secure 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:-

- 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 clinical staff and the service senior management are informed including out of hours as appropriate.
- Patients, families 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
- Any faulty medicine, equipment or device is removed from use immediately and labelled to prevent further use.
- Other departments involved are notified as appropriate; please refer to appendix C for guidance.
- Records, materials and equipment, including disposable equipment used in conjunction with any device, are retained.
- If records being sent externally to Fiscal ensure a copy is retained.
- A Datix report is made (if more than one service is involved one incident should be recorded and teams should discuss and agree who will record and lead the incident review).

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 rapid alert (or severity 4/5 template) should be e-mailed. This should be done as soon as is practicable after the incident has occurred by the Line Manager referred to above.

All areas must develop their own rapid alert distribution list as part of their local procedures which should include appropriate members of the Senior Management Team and may have to be amended in light of the specific incident (e.g. to include pharmacy for medication incidents).

In implementing this rapid alert list services can refer to the template within the SCI toolkit which contains the core information that should be included, services can amend to include additions specific to local requirements. Services must ensure that the information contained within a rapid alert meets the requirements of the Data Protection Act and Board Information Security Policies and that the distribution list is appropriate.

Reporting and Escalating a Significant Clinical Incident

All incidents in NHS GG&C should be reported via Datix in line with the NHS GG&C Incident Reporting Policy. This includes SCI's and the line manager must ensure this has been completed as soon as possible.

Datix is the system utilised to support monitoring and reporting of SCI's and it is therefore imperative the information within here is up to date and accurate. Local SCI procedures should outline how the Datix record will be subsequently managed. Clinical risk will attach the final report at conclusion of investigation. Datix is at this time the prescribed data store for Significant Clinical Incidents and must be used so we have a single repository of all Significant Clinical Incidents.

Within local procedures services will wish to define a list of incidents that should automatically be escalated. As noted services should have a rapid alert system in place separate to the Datix report to support rapid communication to senior staff.

This rapid alert should be reviewed by the commissioner and must be confirmed as SCI within 10 working days. This should trigger the SCI investigation process within the service.

Directors must consider within their process, and agree, arrangements for immediate communication/ escalation of events to Division/Board level. Escalation to senior staff is intended to create transparency and to generate support around the ongoing management of Significant Clinical Incidents. The Clinical Senior Management Team are provided with copies of all rapid alerts.

The Boards Communication Strategy will be followed and Corporate Communications consulted before any public/external communication is made.

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.

Informing and Involving Patients/ Families (Duty of Candour)

The Duty of Candour procedure, and regulations to be made using the power in the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill (2016) will require organisations to make sure that they are open and honest with people when an unintended or unexpected incident resulting in death or harm has happened. In principle all patients/ families should be informed if they are involved in a Significant Clinical Incident.

As soon as a Significant Clinical Incident has been identified it is essential that an appropriate person is identified to inform patients and families. Who this person is will depend on the individual circumstances but is likely to be the consultant in charge of the overall patient care, where this person is not available a suitable senior clinician should be identified.

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 family and to express sorrow or regret at that outcome. Such expressions of regret would not normally constitute an admission of liability, either in part or full, and where staff wish to do so NHS GG&C encourage such expressions to patients and/ or families.

Patients should also be advised of the intention to undertake an SCI investigation and where appropriate offered the opportunity to input to this process. This may be in the form of a face to face discussion, letter or may on occasion involve a further meeting with patients/ families. It is good practice to document this interaction in the patient record including any queries patient or family may have.

It is important that the process and remit of an investigation is carefully explained to the patients/ families. It may be that there are issues/ concerns they have outwith the scope of the SCI investigation and if this is the case then support should be given to ensure these are addressed via the appropriate channels. At this stage agreement should also be made on the level of contact the patient/ family wish during the process and on the type of feedback. It is acknowledged that not all patients/ families will wish to be involved in the process and this should also be respected.

In all instances those decisions relating to the involvement of patients and families must be recorded by the investigation team and made visible in the report. Datix has also been updated to allow the service to log whether the patient was informed. This will allow the board to monitor patient involvement in line with Duty of Candour legislation.

The requirements for Duty of Candour are listed below:

Type of unexpected or unintended incident (not related to the natural course of someone's illness or underlying condition)
A person died
A person incurred permanent lessening of bodily, sensory, motor, physiologic or intellectual functions
A person's treatment increased
The structure of a person's body changed
A person's life expectancy shortened
A person's sensory, motor or intellectual functions was impaired for 28 days or more
A person experienced pain or psychological harm for 28 days or more
A person needed health treatment in order to prevent them dying
A person needing health treatment in order to prevent other injuries as listed above

An SCI process guide with timescales can be found at appendix A.

It is acknowledged that there may be rare occasions where it is felt appropriate to deviate from this position due to assessment of the risks/benefits to the individual patient/ family; in these cases agreement must be reached with the investigation commissioner and rationale reflected in the final report. These decisions must be agreed by the senior management team of the

sector/directorate/HSCP. There should however no exceptions for any SCI which is concluded as an investigation conclusion code of 4 (Issues identified that directly related to the cause of the event) with a severity 4 or 5; in these cases patients/families must be informed even if this is done retrospectively.

If the SCI review is not complete within the three month timescale then the lead investigator should discuss and agree with the commissioner the requirement to contact patients/families to inform them of the delay and offer an expected completion date.

Informing and Involving Staff

Line managers should inform staff of any incidents escalated under this process and of the investigation process. (Supporting information is available within the toolkit.)

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. Being involved in such an event can have an impact on an individual and it is important they are offered a full opportunity to immediately debrief and discuss any concerns.

The Occupational Health service is available to support staff and should always be offered as an option to staff involved in a Significant Clinical Incident. Although the process is not within the HR remit any staff engaged in the investigation process are entitled to seek advice and be accompanied by a colleague or friend where they are not a member of a trade union or a professional organisation and where they are a member they have a right to be represented by that trade union or professional organisation.

Colleagues can be a very useful support mechanism to staff and local managers should consider appointing a designated colleague to discuss matters in a supportive manner and provide ongoing support to an individual.

Managers should ensure staff are kept updated on the SCI process and take opportunity to offer further support. If the need for an individual debrief is identified through the investigation the line manager will be informed and can make arrangements to progress.

It is also important that once an investigation has concluded a general debrief is held for staff involved to advise them of the findings and outcomes. This should be arranged by local management teams. Local procedures will set out how the final outcome is communicated to management and senior clinicians to ensure wider discussion takes place.

Links to other Formal Proceedings

Staff should be aware that incidents of this nature can at times be involved in other formal proceedings linked to the incident specifically Procurator Fiscal reviews, HR reviews and legal claims. In these named examples copies of the core file may be shared if requested.

In cases where there is a formal complaint linked to an incident a final copy of the SCI report can be used to support the complaint response. A complaints and SCI flowchart can be found in the toolkit.

<u>Relationship of the Investigation to the Code of Conduct Procedure</u>
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 which cannot be justified or explained in terms of root causes then this is likely to be addressed through the established disciplinary procedures.

Any investigation into a serious clinical incident will not, and cannot, preclude use of the code of conduct process where there has been an obvious serious breach of professional practice or organisational policy. In the event that a disciplinary procedure is invoked, the lead investigator will be made aware.

In all other cases the appropriate HR processes should not be instigated until an SCI investigation has been completed and causal factors identified.

Information gathered as part of an investigation may be shared if the incident is subject to further investigation, this includes a staff recollection of events document. All staff should be advised at the time of submitting a staff recollection of events document that this may be the case. This is a supportive action to prevent staff being asked to submit multiple recollections of events.

Relationship to the Freedom of Information (Scotland) Act 2002 (FOISA)
Significant Clinical Incident information is within the remit of the Freedom of Information legislation and we may be required to disclose if requested under the Act information relating to SCIs, either as high level information or in relation to specific incidents. This could include key documents such as:

- SCI Final Reports
- Action Plans
- Investigation Timelines

The position in relation to information that must be released under FOI legislation is constantly evolving in line with decisions made by the Information Commissioner and all requests will be reviewed and considered on an individual basis; full redaction principles will be applied to any information released. It is our view that the final SCI report contains the findings of the investigation and all relevant information gathered through that process therefore would be regarded as the key information source for any requests. It is acknowledged that action plans and timelines can provide additional factual information in relation to the investigation process and conclusion. Any change to the position as to what information we are required to disclose will be communicated and guidance amended to reflect.

Significant Clinical Incident Investigation

Aim of Investigation

The investigation aims to examine the processes of care to identify if any system failures occurred which contributed to the incident and the patient outcome. This understanding is vital if the learning from these incidents is to be realised.

Where system failures are identified, causal analysis should be undertaken to further understand why and how these can be managed to prevent recurrence. An investigation should consider how significant this failure has been in the overall incident (i.e. if multiple failures how they relate to each other) and also how they impacted on the patient and subsequent outcome. This may be difficult at times depending on the circumstances of the incident but should be considered and included within the final conclusions of the report.

It is recognised that not all incidents investigated will identify system failures and may find appropriate care was delivered, the potential for learning in these cases should also be recognised and areas of good practice shared appropriately.

To support this part of the process, all investigations will conclude one of the following investigation causation codes:

1 Appropriate care: well planned and delivered
2 Issues identified but they did not contribute to the event
3 Issues identified which may have caused or contributed to the event
4 Issues identified that directly related to the cause of the event

Any incident investigation conclusion of "Appropriate care: well managed" will not be monitored by Clinical Risk. Those cases where system of care issues are identified will be reported to the Board Medical Director as Board Clinical Governance lead.

SCI Investigation

All incidents will receive an investigation to identify the root cause. The level of investigation and therefore write up required will vary dependant upon the nature and complexity of the event. In most instances we expect use of the full RCA toolkit and investigation report template.

Commissioning an Investigation

Directors should establish who within service has the responsibility to commission the investigation process. This individual must ensure confirmation of SCI status and a clear remit for the investigation team and appropriate nomination of the investigation team in line with the circumstances of the incident. The commissioning manager must also ensure that the managers of staff involved and the patient's consultant are notified of the investigation.

At this stage it should be identifiable which Directorates/Sectors/Partnerships have been directly involved in the incident and will therefore be required to contribute to the investigation.

Where an incident crosses multiple Directorates/Sectors/Partnerships 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/Sectors/ Partnerships involved during and following the investigation cannot be underestimated and the investigation lead must ensure this is achieved. Partnerships must also consider the need for joint investigations with social work services where services are jointly managed and how to link in independent contractors including GP's. A flowchart describing joint investigations can be found in the toolkit.

Where the investigation raises the possibility of external scrutiny, e.g. Fatal Accident Inquiry or Inquiry by The Mental Welfare Commission/HIS/HSE, 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 considered along with the service responsibility to ensure safe systems of care.

The commissioner has a responsibility to ensure action plans are discussed at the appropriate level within the service to ensure completion.

Investigation Team

A lead investigator will be appointed (by management team or 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. A core team can be established and specialist input sought to support this as required if particular issues are identified.

There is an expert resource available within the Clinical Risk team to support investigations, with direct involvement targeted at the most critical or complex events. At commissioning stage the level of support required from Clinical Risk team should be agreed with your aligned Clinical Risk contact.

Staff members directly involved in the incident should not be involved in the investigation team but may contribute to the investigation. There is no requirement for the investigation team to be independent of the service though where it is felt involvement of local leads will compromise the objectivity of an investigation then external input should be sought. It must also be noted that external expertise can be sought as part of the review and not require the individual to form part of the investigation team as noted above.

Staff involved in an investigation team should be supported to ensure they can adequately fulfil the role in the required timescales. Consider planned leave, staff must have the capacity to participate in the review.

The Investigation Process

The supporting toolkit provides guidance on tools and techniques that can be used to support the investigation process and also specialist support staff within the Board who should be notified of Significant Clinical Incidents and may provide support.

The process generally involves gathering of all relevant information and analysis of this to understand not only what happened but why and the relationship between the care delivery processes and outcome. The investigation should clearly conclude on the link between the two and identify the causal factors.

The Report

The final report of an SCI investigation is a key document and presents the findings, conclusions and recommendations of the investigation team. It is important that the report clearly demonstrates the links between causal factors and the outcome evidencing any root cause analysis tools utilised. The recommendations made should be consistent with the conclusions ensuring a clear understanding by the reader and assurance of the identified issue and remedial response. It is acknowledged that on occasion investigation teams may not be able to explore an issue in the depth required to produce a solid recommendation and that further analysis/ investigation may be recommended in these situations. In this instance the issue and further analysis required should be clearly framed in the recommendation and taken forward through action planning.

The SCI report template must be used; this contains additional information required and how to complete. The review team should establish who will take the lead in writing the report.

All SCI reports must be anonymised so that no staff members involved can be identified from the report, patient names must also be removed (this includes initials). The use of different letters such as Dr A and Dr B or numbers such as Nurse 1 and Nurse 2 is suggested to help identify different key personnel within the description of events within the report. Where multiple staff are involved it may also be helpful to include a key at the beginning of the report describing the main role of the coded staff e.g. Mr G – patient's main Consultant, Nurse 1 – night duty nurse etc.

Any staff who have contributed to the report should have an opportunity to review and comment on factual accuracy prior to final sign off. It may be appropriate to share the draft with the patient/family for comment on factual accuracy at this point.

It is important that reports are appropriately signed off; the following steps are key in this process and must be reflected in local procedures:

- Factual accuracy check by key contributors.
- Report submitted to commissioner by lead investigator.
- Review by management structure of final report and agreement on how to progress recommendations.
- If at management review there is any disagreement over the findings and/ or decision not to progress recommendation(s), an addendum to report can be made.
- Action plan development, where required, with clear agreement on owners and tracking.
- Quality assurance of report (i.e. does it meet requirements of remit/ issues explored enough?).
- Local management teams should not make any changes to the report without consultation with the review team.

Once a report has been quality assured it is considered final and is submitted to the commissioner (the commissioner may be involved in the QA process). If there is any disagreement over the findings at QA stage then a view should be sought from a third party independent to the process. Once established as a final report it should not be amended. A PDF copy of the final report should be attached to Datix by Clinical Risk.

Final reports must be shared with all staff involved in the incident and where agreed the patient/ family. The lead investigator will ensure the local line manager(s) receives a copy of the report and they are then responsible for ensuring this is shared appropriately. Arrangements for sharing of the report with patients/ families should be agreed at the commissioning stage with the Management Team and the lead investigator.

Reports may be shared with external agencies, for example the Procurator Fiscal, SGHD, NMC, GMC and with other NHS Scotland Boards. It must be confirmed that the report has been finalised prior to release and that a named lead is agreed to manage any ongoing contact. Any reports to be shared in the public domain (i.e. via an FOI request) must be redacted in line with Board procedures as outlined in earlier section.

Action Planning and Monitoring

Following submission of the report, services have responsibility to develop action plans considering any recommendations from the report. A completed action plan should be recorded on Datix. If actions have already been taken this should be reflected in the final report.

Where a recommendation is not being progressed there should be clear reasoning as to why and a record of this should be made using the progress field of the Datix actions module. It may be appropriate to transfer actions that are not able to be progressed at the time to the risk register.

Services must ensure a robust process is in place to monitor completion of actions including updating of Datix on completion of all actions. Further guidance on developing action plans can be found in the SCI Toolkit. Clinical Risk will contact services following completion of an SCI investigation for an update of the status of recommendations, if issues are outstanding a revised completion date must be provided or the issue escalated for further investigation if completion is not possible.

Once all actions are completed it is the responsibility of the service manager to ensure that the action plan is updated on Datix.

Shared Learning

NHS Greater Glasgow and Clyde would encourage the use of the learning summary template which can be used both locally within departments, GG&C wide and we also have the facility to share learning nationally via an adverse events community of practice website which has been set up by Health Improvement Scotland to support Boards.
The learning summary should focus on what can be done to prevent recurrence rather than just highlighting the issue / problem. It is helpful if the last section gives an indication of what can be done to reduce the risk.

All learning summaries should be submitted to Clinical Risk who will share wider across GG&C and post those that are appropriate on the national site.

The template for the learning summary with the national guidance can be found on Staffnet as part of the toolkit.

Ongoing Analysis and Reporting

Aggregate analysis of incident reports involves quantitative investigation 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 investigation of incident reports to identify common underlying themes or causes.

Service Level

This type of activity should form part of the routine activities of the Directorate/Sector/ 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/Sector/ Partnership Clinical Governance Forum/Groups will make such decisions on the basis of the reports it receives.

Clinical Risk will support an annual analysis of SCI activity highlighting any trends and outstanding issues and will advise on any policy compliance issues.

Specialist/Division/Board Level

Specialist committees will also undertake regular analysis of appropriate clinical incidents supported by Clinical Risk and other support staff as appropriate e.g. infection control, pharmacy, falls. As above, further study may be commissioned on investigation of reports by these committees.

Clinical Risk will produce a quarterly report which will include an update on SCI activity and cross service learning points including recommendations for action where appropriate; this will be shared at Division and Board level. Division and Board wide committees should ensure such reports are received and considered as appropriate.

Monitoring Implementation

The management, investigation and application of learning for Significant Clinical Incidents should be a visible and explicit component of each Directorate/Sector/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/Sector/Partnership Clinical Governance Forum/Groups or Management Teams. The aforementioned action plan tracking is an essential component in assessing the success of improvements.

Monitoring of Basic Policy Requirements

As noted in the introduction the policy highlights several areas that must be evidenced within an SCI investigation. All services must submit to Clinical Risk their procedure for SCI investigation including any supporting documentation to ensure policy requirements are met; this must be completed within 8 weeks of the policy publication. The toolkit contains a list of the mandatory elements to be met and evidenced including templates.

Clinical Risk will monitor the timeline of investigations on a regular basis and highlight potential breaches to service for investigation. This information will also be included in the quarterly risk report produced at Division level. Again it is acknowledged that there are legitimate reasons as to why an investigation may exceed 3 months but this should always serve as a prompt to review the status.

All final reports must be attached to Datix. Clinical Risk will do this and enter a closed date on Datix on confirmation of this report.

Directorate/Sector/Partnerships Clinical Governance work plans will be reviewed by Clinical Governance to ensure evidence of policy application.

Learning Review

Clinical Risk will support services to ensure SCI investigations are reviewed to identify themes and solutions that can be shared across services. This and the aforementioned aggregate reports will support ongoing monitoring of the learning from Significant Clinical Incidents.

The Board Annual Clinical Governance Report will also include consideration of learning.

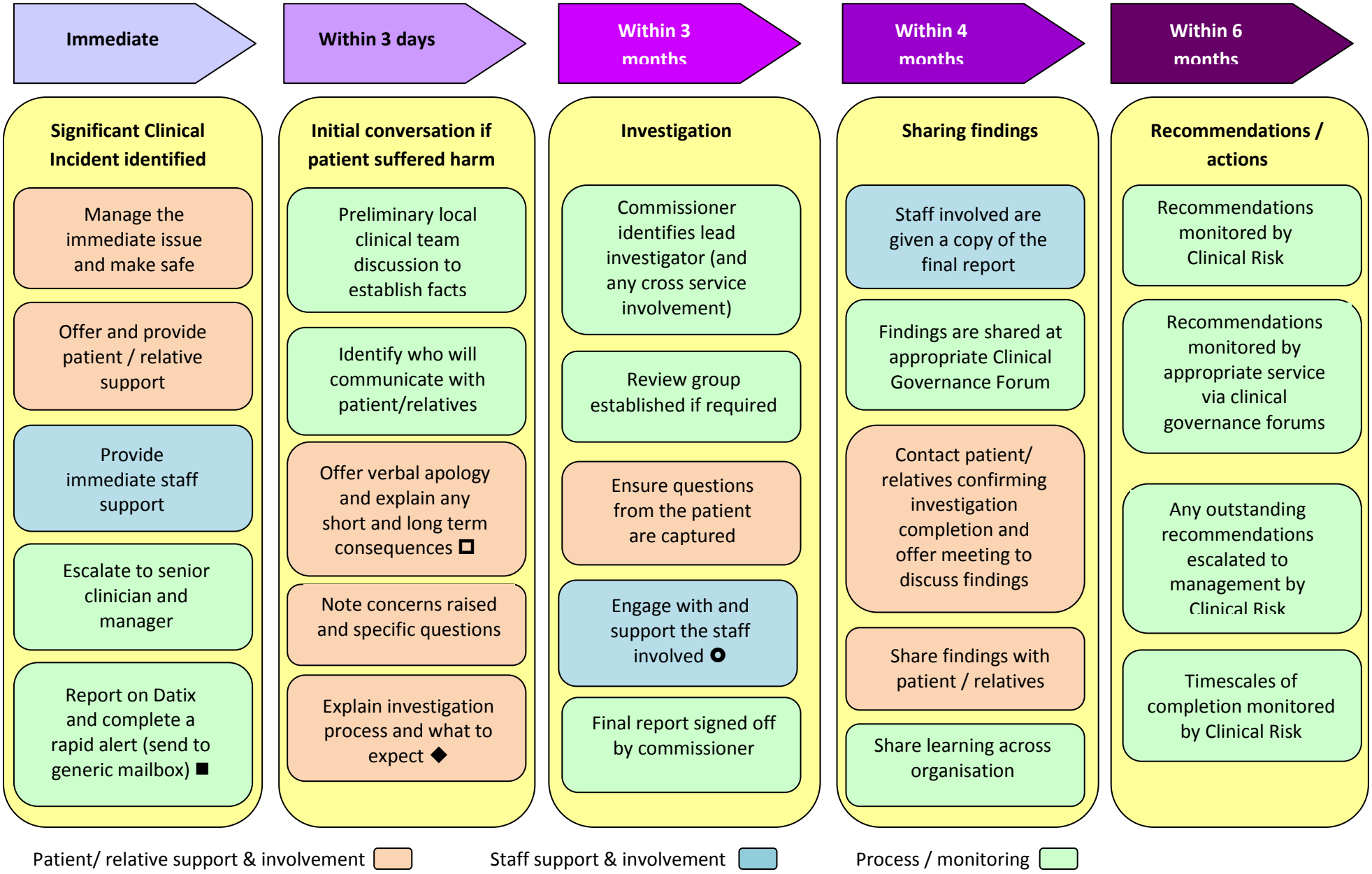
HIS Framework and Investigation Process

As noted earlier HIS have a national framework in place and we are required to demonstrate compliance with the principles of this framework. To date a self assessment and inspection visit have taken place; future monitoring arrangements have to be confirmed.

The policy and supporting guidance has been developed in line with the key principles and requirements of the framework; compliance with the policy will support the Board in meeting the requirements of the framework.

Clinical Risk will randomly sample at least 5 investigations from each Directorate/Sector/ Partnership per year to review against the key requirements as an internal test of the scrutiny process; this will be built into the annual SCI analysis.

Appendix A - SCI Process Guide



Appendix B – NHSScotland Risk Assessment Matrix

Descriptor	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Patient Experience	Reduced quality of patient experience/clinical outcome not directly related to delivery of clinical care.	Unsatisfactory patient experience/ clinical outcome directly related to care provision – readily resolvable.	Unsatisfactory patient experience/ clinical outcome; short term effects – expect recovery <1wk.	Unsatisfactory patient experience/ clinical outcome; long term effects – expect recovery >1wk.	Unsatisfactory patient experience/ clinical outcome; continued ongoing long term effects
Objectives / Project	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over-run.	Inability to meet project objectives; reputation of the organisation seriously damaged.
Injury (physical and psychological) to patient/visitor/ staff.	Adverse event leading to minor injury not requiring first aid.	Minor injury or illness, first aid treatment required.	Agency reportable, e.g. Police (violent and aggressive acts). Significant injury requiring medical treatment and/or counselling.	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling.	Incident leading to death or major permanent incapacity.
Complaints / Claims	Locally resolved verbal complaint.	Justified written complaint peripheral to clinical care.	Below excess claim. Justified complaint involving lack of appropriate care.	Claim above excess level. Multiple justified complaints.	Multiple claims or single major claim Complex justified complaint
Service / Business Interruption	Interruption in a service which does not impact on the delivery of patient care or the ability to continue to provide service.	Short term disruption to service with minor impact on patient care.	Some disruption in service with unacceptable impact on patient care. Temporary loss of ability to provide service.	Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being invoked.	Permanent loss of core service or facility. Disruption to facility leading to significant "knock on" effect
Staffing and Competence	Short term low staffing level temporarily reduces service quality (< 1 day). Short term low staffing level (>1 day), where there is no disruption to patient care.	Ongoing low staffing level reduces service quality. Minor error due to ineffective training/implementation of training.	Late delivery of key objective / service due to lack of staff. Moderate error due to ineffective training/implementation of training. Ongoing problems with staffing levels.	Uncertain delivery of key objective/ service due to lack of staff. Major error due to ineffective training/ implementation of training.	Non-delivery of key objective/service due to lack of staff. Loss of key staff. Critical error due to ineffective training/ implementation of training.
Financial (including damage / loss / fraud)	Negligible organisational/ personal financial loss. (£<1k). (NB. Please adjust for context)	Minor organisational/personal financial loss (£1-10k).	Significant organisational/personal financial loss (£10-100k).	Major organisational/personal financial loss (£100k-1m).	Severe organisational/personal financial loss (£>1m).
Inspection / Audit	Small number of recommendations which focus on minor quality improvement issues.	Recommendations made which can be addressed by low level of management action.	Challenging recommendations that can be addressed with appropriate action plan.	Enforcement action. Low rating. Critical report.	Prosecution. Zero rating. Severely critical report.
Adverse Publicity / Reputation	Rumours, no media coverage. Little effect on staff morale.	Local media coverage – short term. Some public embarrassment. Minor effect on staff morale/public attitudes.	Local media – long-term adverse publicity. Significant effect on staff morale and public perception of the organisation.	National media/adverse publicity, less than 3 days. Public confidence in the organisation undermined. Use of services affected.	National/international media/adverse publicity, more than 3 days. MSP/MP concern (Questions in Parliament). Court Enforcement. Public Inquiry/ FAI.

Appendix C – Communication & External Reporting

The following list provides an indication of the stakeholders (internal and external) who may require to be 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 of reporting requirements or internal contacts advice can be sought from the Clinical Risk Manager. Also consider if the patient is involved in a research trial, the need to inform the Research & Development unit.

Incident type	Internal (GG&C) Contact	External Reporting Requirements
Medication Incidents	**Pharmacy** Lead Pharmacist for each area who will advise.	• Committee of the safety of Medicines – yellow card scheme to report adverse reactions to medicines' • Defective medicines require to be reported as per GEN (1991) 25 and updates.
Infection Control	**Infection Control** Local Infection Control Teams will advise.	• Environmental Health • Food Standards Agency • Scottish Centre for Infection and Environmental Health (SCIEH) • Scottish Government
Falls	**Health & Safety** H&S practitioners aligned to each area who will advise. **Falls Co-ordinators** Co-ordinators aligned to Acute sites who can offer guidance/ support for Falls issues. **Moving & Handling** Local Practitioners assigned to services who will offer advice.	• RIDDOR – H&S will advise.
Blood Transfusion	**Blood Transfusion Service** – local blood transfusion practitioners.	• Serious Hazards of Transfusion (SHOT) • Serious Adverse Blood Reactions and Events (SABRE)
Incidents involving ionising radiation	**Board Radiation Protection Advisor** –local advisors also available who can advise.	• Radiation Protection
Any incident involving medical devices/ equipment (i.e. fault with equipment)	**Clinical Physics** Local support staff who can advise. **Health & Safety**	• Scottish Healthcare Supplies – either CP or H&S will advise if required.
Violence and Aggression	**Health & Safety**	• Police • RIDDOR – H&S will advise.
Suicide mental health	**Clinical Risk**	• Healthcare Improvement Scotland (HIS) • RIDDOR – H&S will advise.
Detained patient deaths	**Clinical Risk**	• Procurator Fiscal

Appendix D – Procurator Fiscal Notification Criteria

The Scottish Fatalities Investigation Unit (SFIU) is a specialist unit of Crown Office and Procurator Fiscal Service (COPFS). SFIU has responsibility for receiving reports of deaths occurring in Scotland which are sudden, suspicious, accidental or unexplained and fall within the categories set out below and deaths which give rise to public anxiety.

Further information and guidance can be found on staffnet using the link below: http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Clinical%20Risk/Pages/SCI%20Policy.aspx

Appendix E – Investigation Toolkit

Significant Clinical Incident Investigation Toolkit
http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Clinical%20Risk/Pages/SCIInvestigationToolkit.aspx

This toolkit has been developed to assist in the investigation process and contains a range of guidance documents and templates.

The SCI Guide details each stage in the process highlighting links to the toolkit.

Templates marked with a * are mandatory in use.

It is recognised not all tools will be relevant in every case, but you can select to assist your particular need. Further advice can be sought from Clinical Risk.

General Guidance:
SCI Guide
Severity Matrix
Policy Mandatory Requirements
Yorkshire Contributory Factors Framework
Human Factors Basic Guide
Developing Recommendations
Action Plan Guide
Guidance on the use of Investigation Conclusion Codes
Multi Board Approach to SCIs
Cross Service SCI Process
Frequently Asked Questions

Patient/Family Tools/Guidance:
Guidance to Support Communication with Patient/Family
Letter Templates for Communication with Patient/Family
Patient Information Leaflet

Staff Support Tools/Guidance:
Writing Staff Recollection of Events Guidance*
Staff Support Guidance for Managers
Decision Tree
Staff Support Checklist
Staff Leaflet
Role of Lead Investigator

Templates/Tools:
Rapid Alert Template*
Severity 4/5 Review Template*
Investigation Report*
Timeline
Cause Effect Model (also known as Accident Causation)
Reactive Barrier Analysis
Time Person Analysis
SCI Checklist
Local Investigation Template