NHS
Greater Glasgow
and Clyde

NHS Greater Glasgow & Clyde
Mental Health Services

Significant Adverse Event (SAE) Guidance

Important Note:

The Intranet version of this document is the only version that is maintained.

Any printed copies should therefore be viewed as ‘Uncontrolled’ and as such, may not necessarily contain the latest updates and amendments.

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MHS CP&G Revision/Amendments Form

Significant Adverse Event (SAE) Guidance

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date	Brief Summary of Changes	Author(s)
	Nov 20	Change of language from SCI to SAER	
	Nov 20	Change of language from rapid alert to briefing note	
	Nov 20	Reference to updated Incident Management policy	
	Nov 20	Reference to new clinical risk generic email account	
	Nov 20	Reference to gathering statements	
	Nov 20	Reference on how to book RCA training	
	Nov 20	Reference to collecting patient/family feedback	
	Nov 20	Updated QA form	
	May 22	Added summary of key points to page 5	
	May 22	Local investigation to page 5 and definitions page 6	
	May 22	Removed line relating to restricted patients Page 7	
	May 22	Added new GGC generic email address for liaison with PF	

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Summary of key points

This document supports NHSGGC Management of Significant Adverse Events Policy.

Examples of what may be considered significant adverse events (SAE) are provided as a guide.

The Board policy notes "Patient Suicide where there has been contact with MHS" as an event that should be *considered* for SAER. For clarity, "contact with MHS" means cases open to MHS or within one year of discharge.

For all patient suicides in MHS:

- As a minimum, a local investigation should be undertaken. This can then be converted to a SAER if significant systemic concerns are identified.
- A SAER should always be considered (but not necessarily triggered) if any of the briefing note checklist items are positive. If the decision is made not to proceed to a SAER, the rationale for this must be clearly documented on the briefing note.

Guidance on who makes up a review team are included but are given as example. Review teams will be dependent on the incident and the expertise required for review.

Deaths should be recorded as severity 5 on Datix. Near miss incidents should also be reviewed and any learning shared across the service.

If other services have been involved, e.g. acute services, then a joint review should be commissioned and any recommendations should be agreed with the other service prior to submitting the action plan.

Section 1

1. Introduction

This document is a guide to identifying Significant Adverse Events (SAEs) in Mental Health Services (MHS), and conducting an appropriate review. The NHS GG&C Policy on the management of Significant Adverse Events is available on Staffnet and should be used in conjunction with this guidance (link available at Appendix 1).

SAE reviews are important processes. A well written SAE Report helps the organisation to learn from adverse events, may relieve some of the distress and uncertainty experienced by relatives, and can avoid the need for further, external investigation. SAE Reports will be read by colleagues, clients and families. They may also be seen by lawyers acting for the family, HIS, the MWC and by the Procurator Fiscal.

The purpose of an SAE Review is to help all mental health staff, clinical and managerial, to improve the service for others by recognising where risk can be reduced, where clinical practice and service improvements can be made, and also by sharing the good practice that is often found during reviews.

1.1 Definition of a Significant Adverse Event

Some incidents are significant enough to be considered "Significant Adverse Events". Such incidents:

- are defined in the NHS Greater Glasgow & Clyde Policy as "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."[1]
- would usually rate 4 or 5 on the severity rating of Datix
- any legal duty of candour event

The Board policy notes "Patient Suicide where there has been contact with MHS" as an event that should be *considered* for SAER. For clarity, "contact with MHS" means cases open to MHS or within one year of discharge.

For all patient suicides in MHS:

- As a minimum, a local investigation should be undertaken. This can then be converted to a SAER if significant systemic concerns are identified.
- A SAER should always be considered (but not necessarily triggered) if any of the briefing note checklist items are positive. If the decision is made not to proceed to a SAER, the rationale for this must be clearly documented on the briefing note.

Patient Suicide where there has been contact with MHS" as stated in the Board SAER policy, "contact with MHS" means cases open to MHS or within one year of discharge.

Common incidents also appropriately reported include:

- Assault
- Inpatient absconding – including informal patients when there are major concerns.

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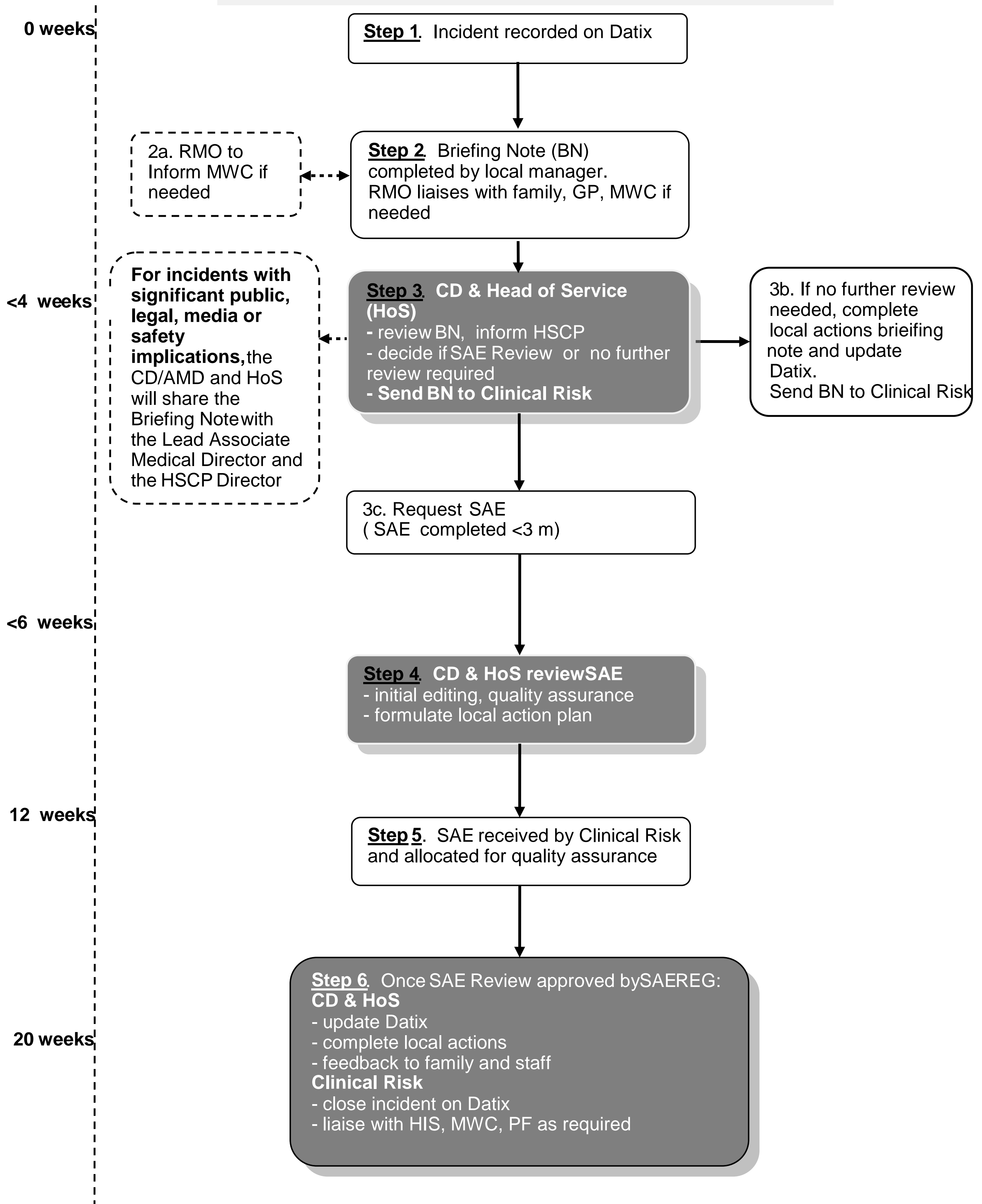
[1] http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Clinical%20Risk/Pages/CG_Cl inical_Incident_Reporting_CM_140207.aspx

- Fire, attempted fire raising and other significant Health and Safety concerns.
- Significant client to client and client to staff assault.
- Theft, illegal drug supply in wards.
- Homicide – please contact Clinical Risk prior to commencing investigation. Clinical Risk will liaise with Procurator Fiscal to confirm plea has been entered
- Adverse medical emergencies and medicine administration error
- Incidents involving restricted patients

Note that ‘moderate’ or ‘minor’ incidents (i.e. those rating 3 or less on the severity rating of Datix) should usually trigger a ‘local investigation’ (see GG&C Incident Management Policy 2020).



Significant Adverse Event (SAE) Flowchart NHS GG&C Mental Health Services
0 weeks
Step 1. Incident recorded on Datix
2a. RMO to Inform MWC if needed
Step 2. Briefing Note (BN) completed by local manager.
RMO liaises with family, GP, MWC if needed
<4 weeks
For incidents with significant public, legal, media or safety implications, the CD/AMD and HoS will share the Briefing Note with the Lead Associate Medical Director and the HSCP Director
Step 3. CD & Head of Service (HoS)
- review BN, inform HSCP
- decide if SAE Review or no further review required
- Send BN to Clinical Risk
3b. If no further review needed, complete local actions brieifing note and update Datix.
Send BN to Clinical Risk
3c. Request SAE
(SAE completed <3 m)
<6 weeks
Step 4. CD & HoS review SAE
- initial editing, quality assurance
- formulate local action plan
12 weeks
Step 5. SAE received by Clinical Risk and allocated for quality assurance
20 weeks
Step 6. Once SAE Review approved by SAEREG:
CD & HoS
- update Datix
- complete local actions
- feedback to family and staff
Clinical Risk
- close incident on Datix
- liaise with HIS, MWC, PF as required

1.2 Significant Adverse Event flowchart guidance notes

The numbers for each paragraph below relate to the boxes on the flowchart on page 5:

Step 1: Record incident on Datix

All incidents, regardless of severity, require a Datix form to be completed as soon as practicable following the event, regardless of whether further reporting is required

All unexpected or potentially avoidable deaths require Datix notification but death following terminal illness or from life limiting health conditions do not.

Datix forms should be:

- Completed by staff member witnessing incident or by person in charge (Reporters)
- Reviewed by immediate senior as identified within Datix scheme of delegation (Reviewer)
- Approved by Heads of Department as identified in Datix scheme of delegation (Approver)

Step 2: Complete and share the Briefing Note

A "Briefing Note" should be completed for significant incidents on the same day as the incident occurred. The Briefing Note template is available on staff net at http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Clinical%20 Risk/Pages/ClinicalIncidentR.aspx

'Briefing Notes' have 2 distinct functions:

1. Notification to the service that an incident has occurred.

- The Briefing Note should be completed by the clinical, managerial or staff with the best knowledge of the case. The Briefing Note must be signed off by the Service Manager for that area.

- It should be sent immediately by email to the relevant Clinical Director (CD) and to the local Head of Service (HoS).

- All Briefing Notes should be sent to Clinical Risk (clinical.risk@ggc.scot.nhs.uk)

- **NB For incidents with significant public, legal, media or safety implications,** the CD/AMD and HoS will share the Briefing Note with the Lead Associate Medical Director, Deputy Medical Director and Nurse Director for Mental Health Services, and the Chief Officer for the HSCP in which the incident takes place. In situations where there may be media interest in an incident, the Press Office should also be informed. In cases with significant legal implications or which may result in a Fatal Accident Inquiry, the Risk and Litigation manager should also receive a copy.

2. To inform subsequent investigation of the incident.

- Information in Briefing Notes form the basis for local managers to decide whether or not an SAE should be commissioned.

- That decision should be taken within two weeks, and the Briefing Note may be updated during that period as more information is obtained.

- Where a decision is taken to conduct an SAE, Clinical Risk should be informed by the CD/HoS

- Clinical Risk will inform the Lead Associate Medical Director for Mental Health, Deputy
  Medical Director, Director of Nursing for Mental Health, Head of Clinical Governance, Board Director of Nursing and Board Medical Director in an email with the subject heading "notification of SAE"

The Service or local operational manager should:

- Ensure that the Briefing Note is completed appropriately
- **Ensure that all immediate actions required have been carried out.**
- Ensure senior staff are informed, including Out Of Hours staff as appropriate.
- Ensure that the Briefing Note includes relevant details, including local managerial action that has already been put in place.
- Check that any clients and carers involved have been given any necessary explanation.
- Ensure that any appropriate personal support is given to staff and patients affected by the incident.
- Check that the incident has been logged on Datix.
- Forward the Briefing Note to Clinical Risk

A lack of information should not delay the production of a Briefing Note. It can be updated later if required.

The RMO must:

- Liaise as appropriate with the family (including Named Person if detained under the Mental Health Act). This includes the following actions: o in cases involving a death, the RMO should usually write to the family. It is particularly important to express sympathy and offer to meet a family to discuss the care received by the deceased, and to discuss any questions or concerns they may have. A template 'letter to the family' is available at:
  http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Clinical%20Risk/Pages/SCIInvestigationToolkit.aspx o In the case of suicide, the family should also be sent a copy of the information leaflet
  "After a Suicide" Available at http://supportaftersuicide.org.uk/wpcontent/uploads/2016/09/Scotland-after-a-suicide.pdf
  o what to do after a death in Scotland provides practical advice for times of bereavement, available at http://www.gov.scot/Resource/0041/00417212.pdf
- Ensure that GP is made aware of the incident whether in an inpatient or community setting
- Ensure that the Mental Welfare Commission (MWC) is informed where appropriate. This includes all deaths of people subject to compulsory treatment or guardianship or

where there is concern that a patient has been subjected to ill treatment, neglect or some other deficiency in care.
Appendix 2 gives more detail on the criteria for involving the MWC.

- Ensure that the Procurator Fiscal is made aware of all sudden deaths of detained patients – guidance for staff is available at http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Clini
ni
cal%20Risk/SCI%20Policy%20and%20Toolkit/Reporting%20Deaths%20to%20Procura
t or%20Fiscal%20Guidance.pdf

Step 3: Incident review- what actions need to be taken?

The relevant CD/AMD and HoS have joint responsibility for deciding on the appropriate response to a Significant Adverse Event. In areas where there are local multidisciplinary Clinical Governance Groups which have responsibility for the SAE process, they may delegate or share that responsibility with them. It is critical, however, that decisions are taken promptly.

The actions that can be taken are as follows:

3a: Where there has been a death, there may be a "pause" to defer a decision on actions if the cause of death is unknown and more information is required to make a decision. In that event, the CD should arrange for the Procurator Fiscals' office to be informed that an SAER is being considered in the case, and that early release of Post Mortem findings would be helpful. Such requests should be made to NHSGGC generic email at ggc.pfreporting@ggc.scot.nhs.uk. The Procurator Fiscal's office will expedite the release of this information in such cases (see Appendix 3)

3b: In the event of a death which does not appear to be suicide or in non-fatal incidents where it is clear after initial information gathering that an SAE is not required, this information should be shared with the family, any local actions completed and Datix updated. The reasons why further investigation is not thought to be necessary should be recorded on the Briefing Note and sent to Clinical Risk.

3c: Local Management Team Commission SAE Review

The decision to commission an SAE Review should be communicated by the CD/AMD and HoS to the Clinical Risk Department, GP, and Partnership Director/Sector Director.

Who should investigate?

The investigating team must include a minimum of 2 senior members of staff. The lead investigator should have the experience and authority to make informed comment about the decision making of the involved clinicians and must 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. Additional specialist input can be sought to support the core team if required during the course of the investigation.

If the RMO is a General Adult CD, it is good practice for the investigation to be carried out in another Division with the support of another CD or HoS. Where the RMO is a CD in other Directorates the HoS should commission the investigation taking into account the need to ensure the investigating team has both the required expertise and independence to give an informed view.

Clinical Directors should not be part of a review team in their own service area.

What should the method of investigation be?

- Supporting tools and templates can be found on staffnet – link available at Appendix 1)

- Review the case notes and prepare timeline
- Seek feedback from the GP
- Involve the family (see below)

In addition, it may be appropriate to
- Involve other services
- Gather any available statements
- Interview relevant staff members; this would usually be face to face but telephone contact where interview not possible
- Conduct Root Cause Analysis (RCA)

While investigators are not seeking to apportion blame for an incident, situations may arise in which evidence of misconduct or negligence comes to light. SAE investigators have a responsibility to report such issues to local managers.

There are ‘External Chairs’ and members of SCIREG (see Section 2.1.1) available to assist with the most complex reviews in particular those involving:
- Inpatient Suicide
- Homicide
- Complex care involving multiple agencies

CD’s/HoS should request the assistance of External Chairs by contacting Dr Brian Gillatt by email.

Involving patients and/or families

In cases that progress to an SAE Review, the patient and/or their family should be invited to express questions or concerns they would like the review to address, and receive a leaflet about the NHS GG&C SAE Process (See hyperlink on SAE Toolkit for letter / leaflet templates on Staffnet at Appendix 1)

Support for the investigation

The CD/AMD and HoS should ensure that investigators have support if required through this process. They should ensure that there is an adequate pool of staff who have undertaken Incident Investigation training, (including RCA) and maintain a register of staff with this experience. Experienced investigators may occasionally be needed to act as lead investigators for SAE Reviews in other Divisions or Directorates. (Places on Incident Investigation training can be booked on eESS)

Where incidents involve more than one agency or sector (e.g. Social Work, Primary Care, Acute Services) then the relevant CD or HoS should liaise with the other service to ensure that the lead agency is identified and that duplication of work is avoided.

Support is available from Clinical Risk. This can include telephone contact to support staff with template letters, tools required or be part of review teams where necessary.

Conducting the SAE Review

A suggested Timetable for an SAE Review is set out below:

Week 1

- Ensure membership of the investigation team members and terms of reference are clear
- The review team usually consists of senior staff with relevant experience in the area e.g. ○ a Doctor, ○ a Senior Nurse/Service Manager ○ One other person
- Review case notes and EMIS notes in collaboration with co-investigator(s) to identify relevant staff (including those from primary care and other services) who will need to be approached during the review process
- Set a date or dates for any meetings with relevant staff in 1-2 weeks' time.
- Liaise with the RMO about family contact. The family should be informed by letter that an SAE review has been commissioned and invited to raise questions or concerns that the SAE should address.
  Contact with the family should be made sensitively, and could be carried out through the RMO, local manager or other staff if more appropriate. If the family do not respond or indicate they do not wish to be involved, this should be documented clearly in the Report. See also 'Involving the family' on page 13.

Week 2/4

- Investigators meet.
- Investigators may find it helpful to refer to the RCA map at Appendix 4. Steps 1-3 are relevant to the first meeting in Week 2: ○ **Step 1 – Gather information** ○ **Step 2 – Sort and map the information** ○ **Step 3 – Identify and prioritise problems.**
- Information from the case notes should be supplemented during Week 2 by feedback from the GP and a meeting or correspondence with the family.
- Investigators should decide how any interviewing tasks are divided.
- Minuted interviews should be taken with all relevant staff members. It may be appropriate to conduct a group interview with staff involved in the incident.
- Staff involved in the incident should have the opportunity to check the timeline and written accounts of interviews for factual accuracy prior to meeting to discuss the final report.

Week 5

- Investigation team should discuss any problems identified, highlight positive practice points, identify areas for improvement and note these issues in a first outline of the report.
- One member of the team, usually the lead investigator, will take responsibility for generating the report using the SAE report template and drafting recommendations.
- Investigators may choose to meet with the CD/AMD who commissioned the report at this point to discuss their findings or any areas of uncertainty.

Week 6

- Investigators finalise the draft report and submit to the CD/AMD and HoS

Week 7/8

- The CD/AMD, HoS may have questions about details of the investigation or suggestions about the recommendations made which they will discuss with the investigators. In most cases, the investigators and commissioning group will be able to come to an agreement about the wording of the report and its conclusions.
- In cases where findings or recommendations are not agreed, it may be useful to note:

    - Where the facts are unclear, more information should be sought; where that is not available, the body of the report should reflect uncertainty about the facts of the case.
    - The report should take care to separate “information” from “interpretation”, and ensure that any conclusions drawn are based on the information set out earlier in the report
    - While investigators should make recommendations, these will not always reflect the views of MH services as a whole. It is for the CD/AMD and HoS to convert recommendations into an action plan. The action plan should comment on any recommendation that is not reflected in the service response.
    - See also ‘dispute resolution’ Page 12

Complete quality assurance process by CD/HoS and submit to SCIREG with an Action Plan prepared by CD/HoS

Writing a SAE report using RCA

The initial process for gathering information, meeting to sort and map information and to identify and prioritise problems with feedback from the GP, family and interviews with relevant staff will be the same as for an SAE report without RCA. However, having established during the preliminary investigation that the root cause(s) for the incident are not apparent, the investigating team should use their training in RCA to explore the problem in more depth.

In this more extensive investigation, it may be necessary to meet on several occasions and it is worth planning these meetings in advance. Any difficulty in meeting with the staff concerned should be shared with the CD/AMD by the lead investigator as soon as possible. Investigators should also consider whether additional expertise will be required on the review team or whether Clinical Risk could help to support the investigation process.

Step 4: Submission of SAE Report to CD/AMD and HoS

The responsibilities of the Commissioner (**CD/AMD and HoS)** in relation to SAE reviews are as follows.

- Send reminders to the lead investigator of an SAE a month before, when the report is due, and if necessary monthly thereafter. The Lead AMD for MH should be informed if reports fall more than three months overdue. Partnerships Directors will be informed of reports are more than 4 months overdue.

- Where there are delays in report completion, the family should be kept updated about the reasons for the delay and estimated completion date (see letter templates on staffnet, link at Appendix 1)
- Arrange to meet with the investigators six weeks after commissioning the report to discuss its contents.
- In the rare event of a disagreement between investigators and commissioning management about final conclusions and recommendations, dispute resolution would take place through the SAE Review Group (SCIREG).
- Complete an Action Plan on Datix. This may contain details of a local action plan and/or suggest MHS or Board wide policy or system review.
- Ensure that the Action Plan is updated in Datix
- Send the report with Action Plan and learning summary if applicable to the Clinical Risk Department. NB All paperwork including documentation of interviews with staff can be sent with the final report for storage by Clinical Risk.
- All reports submitted to SCIREG will be pre-screened for Datix ID number, anonymisation, family and GP contact, and completed action plan, learning summary if applicable, Data Collection Template and final approval by CD/HoS. Any reports without this information will be returned for completion prior to screening at SCIREG.
- Reports should only be amended by the review team. This will usually be in consultation with the commissioning management team. Local management should not independently amend or update SAE reports.

The **Action Plan** should make clear:

- What action is to be taken.
- Who is responsible for taking the action forward.
- The time scale for the action to be completed.
- How and where the action plan progress is to be reported.

- Where there are recommendations made by the investigators which the CD/AMD or HoS decide not to action, the reasons for this must be clearly documented in the progress field on Datix.

- The actions must be clearly marked as Local, Partnership (MH) wide or Board wide (action plan guidance is available on staffnet, link at Appendix 1)

Step 5: NHS GG&C Clinical Risk Department and SCIREG

The Clinical Risk Department are currently based at Dykebar Hospital. They are responsible for overall administration and organisation of the SAE process within Mental Health Services. They are experienced in reviewing SAEs and form part of the SAE Review Group (SCIREG). All SAE reports and correspondence should be directed to – clinical.risk@ggc.scot.nhs.uk available on the global e-mail directory under. Further information is available from the Clinical Risk website on Staffnet.

SCIREG is jointly chaired by a Consultant Psychiatrist and Head of Service. Members of the group include Consultant Psychiatrists, senior clinical staff and Clinical Risk staff.

SCIREG meets monthly to review all GG&C MHS SAE Reports with a view to identifying appropriate learning and ensuring that lessons are shared across the Board. It reports to the Mental Health Quality and Clinical Governance Executive Group chaired by the Lead Associate Medical Director and Partnership Nurse Director.

SCIREG has several functions:

- Scrutinising report findings and recommendations to identify system error and appropriate responses
- Return reports that do not meet quality assurance criteria to local management teams for further action
- Approving reports and returning the report to the originating Divisions or Directorate to implement outstanding action plan items.

Clinical Risk will feedback to local management teams following SCIREG meetings and close the incident on Datix. Clinical Risk will ensure relevant external agencies receive copies of Reports.

Where there is a divergence of opinion between investigators, Local Management Teams or with SCIREG and agreement cannot be reached, SCIREG will send the report to the Lead Associate Medical Director.

Clinical Risk will store SAE Report Appendix information including records of staff interviews where required

Step 6: Completion of Process

The CD/AMD and HoS should ensure there are arrangements in place to:

- Feedback recommendations from report to the staff concerned
- Liaise with the family to outline the findings of the report and actions in response to those findings (see 'Involving the Family' – page 14).
- Liaise with the patient/family to obtain feedback from the SAE process
- Ensure that support is available to staff affected by the incident – the 'Employee Counselling Service' is a free, confidential service independent of the NHS available by self-referral or through Occupational Health http://www.empcs.org.uk
- Update Datix when feedback to family and staff is completed.
- Ensure a local system for tracking the development and completion of Action Plans.
- Coordinate local learning.
- Ensure HSCP Directors are informed of SAE recommendations and action plans

Section 2

2.1 General points on completing SAE Reviews

2.1.1 Role of the External Chairs, Lead Investigator and the Investigating team.

‘External Chairs’ are Consultant Psychiatrists with expertise in the quality assurance of SAEs and investigation of complex incidents. The decision to appoint an External Chair is initially made based on the likely complexity of the investigation from ‘Briefing Note’ information. If on further review of the notes, the incident is not thought to require their assistance then the ‘Chairs’ reserve the right to stand down from the investigation team. This is to ensure that they are involved in only the most complex SAEs.

A Consultant Psychiatrist from the local area should also be on the investigating team

Their remit is to:

- Support the investigation of more complex SAE reviews timeously throughout GG&C MHS
- Conduct the review in keeping with terms of reference determined by HoS and CD

Occasionally External Chairs may be asked to review SAE reports where

- There are queries about the impartiality of a local team
- There are difficult judgements to be made about decisions made as part of clinical care
- The investigation requires to be re-opened

The External Chair should not be asked to:

- Liaise with family or with the PF other than to conduct the investigation itself
- Manage other aspects of family or staff liaison arising from the incident, including disciplinary issues

Where there are ‘disputes’ about report findings or other issues between an External Chair and local Management, these should be raised at SCIREG in the first instance, thereafter with LAMD.

The lead investigator should:

- Have been trained in Root Cause Analysis (or ensure 1 member of the team has been trained)
- Make time to prepare for the review, to carry it out, and to write the final report
- Be independent, objective and accurate

The investigating team should have:

- Knowledge of relevant policies and procedures

2.1.2 Involving the family

Families should always be given the opportunity to contribute in SAE investigations, and be provided with the results of those investigations.

- The investigating team and CD/AMD and HoS should operate in a transparent and open way in particular with regard to engaging with relatives and carers.
- A minimum of 2 members of staff should meet with the family. SAE investigators should carefully document concerns raised by the family as well as any positive feedback about care.
- It is important that reports are produced in a timely way to avoid adding to any frustration or sense of grievance that the family may already have with the care received.
- Where there are delays in report completion, the family should be kept updated about the reasons for the delay and estimated completion date. (template letters can be found on Staffnet – see Appendix 1)
- Once the SAE is completed, best practice would be for the CD/AMD and HoS to offer to meet with the family. The meeting could take place with the lead investigator if appropriate. The purpose of meeting is to go through the report findings and recommendations with the family and to inform them of local or service wide Action Plans to address any issues raised.
- Sometimes a family may wish to see the report prior to a meeting and should be offered this option.
- The family may ask for a copy of the report and if so, the CD/AMD should be informed. Ideally, it is preferable to have the opportunity to discuss the report and recommendations prior to giving the report to the family. Release of the report is a decision for the CD/AMD and the HoS.
- If the SAE does not involve the death of a patient, he or she must consent to the release of the SAE report to the family.
- It is good practice for the CD/HoS to ask the patient/family for feedback on the SAE process. The process for evaluating the experiences of the SAE process is put;ined in the SAE toolkit.

2.1.3 Writing the report

Investigators should ensure that:

- The terms of reference are clearly stated in the SAE Report.
- All the information relevant to conclusions and recommendations is contained in the main body of the report.
- Opinion and interpretation are limited to the conclusions, and clearly linked to the relevant sections of the main body of the report.
- The report is accurate, informative and succinct.
- The report is anonymised; include a key, and identify names in a separate document
- Reports are submitted in a suitable condition to leave the organisation, for instance to the Procurator Fiscal, to HIS or the Mental Welfare Commission as well as to the family. It is important to carry out final checks on grammar, punctuation and a spell check.

The following are common difficulties with reports:

- **Delay**
  Long-delayed reports are hard to write, because it becomes increasingly difficult to locate staff, and for them to recall events accurately. The potential for system learning decreases over time. Perhaps most importantly, grieving families find it much more

difficult to come to terms with their loss while questions about care remain unanswered.

- **Factual errors**
  Staff involved in the incident (and also families, when appropriate) should have the opportunity to check the timeline and report for factual accuracy before the final report is submitted.

- **Drift**
  It is important to answer the Terms of Reference as specified at the top of the report, and to take care that investigation or conclusions that fall outwith those terms remain relevant to the investigation of the incident.

- **Over inclusive**
  Reports can become very long documents, and sometimes that is necessary. However the Terms of Reference do not usually require an exhaustive case review of a patient's entire medical history. A brief outline of the background should be sufficient, followed by a detailed timeline beginning at an appropriate point. Most reports should be less than 20 pages long.

- **Too negative**
  SAE Reviews do not have to find fault. It is as important for service development that positive aspects of care are shared as well as negative aspects. It is important to try to avoid "hindsight bias". As a Sheriff once said of an FAI: 'As for hindsight, it should not be employed in deciding whether a precaution was reasonable, or whether, if implemented, it might have avoided the death in question'.

- **Misleading**
  Reports must be scrupulously accurate- especially when information is incomplete, or accounts of events differ. Adjectives and adverbs must be carefully chosen with this in mind. Phrases implying a judgement (e.g. "this *pleasant* gentleman", "*sadly* was not received", or "*inevitably* led to delay") often creep into reports, but are usually not substantiated. Authors writing "care was excellent" must be able to justify that conclusion with reference to information in the report.

- **Unsubstantiated**
  Reports should ensure that any conclusions are well evidenced and are materially important or thought to have had a significant effect on the outcome. Any conclusions drawn from an investigation should be related to relevant material in the body of the report.

- **Unchecked**
  All reports should be reviewed using the screening form in Appendix 5 before submission. Please do not require your colleagues in SCIREG to return reports for correction of spelling and grammatical errors!

2.1.4 Communication with the Procurator Fiscal

Requesting a cause of death may often be quicker than requesting the full post mortem report.

Post mortem reports are usually available between 8 and 12 weeks after death, the latter because of delays in receiving toxicology reports. The Procurator Fiscal have advised that

they will not release copies of Police reports but may be able to release information from reports to assist in decision making.

Requests should be made through NHSGGC generic email at ggc.pfreporting@ggc.scot.nhs.uk Any requests should explain the reason for the request.

All PF requests to Divisions or Directorates for access to SAE or other reports should be forwarded to ggc.pfreporting@ggc.scot.nhs.uk.

2.1.5 Relationship to the Freedom of Information (Scotland) Act 2002 (FOISA)

Significant Adverse Event 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 SAEs, either as high level information or in relation to specific incidents. This could include key documents such as SAE reports, Action Plans and 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 SAE 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.

2.2 Drawing conclusions from an SAE review

The SAE Review will need to make a judgement on what was appropriate care in relation to the incident. Such judgements are often difficult, since it may be unclear whether faults or errors stem from individual mistakes or broader system problems. When considering these issues the National Patient Safety Agency (NPSA) Incident Decision Tree http://www.ncbi.nlm.nih.gov/books/NBK20586/ may also be a useful tool.

In many cases, the investigating team may have no recommendations to make and conclude that care has been good; investigators should make this clear in the report. However, almost all reviews do generate some insights into the functioning of the system, even if these are not critical. It is important that these insights are described to help with system learning.

Carefully summarising the findings, making judgements and drawing conclusions are key to producing an effective review report as is the ability to write **SMARTER** recommendations that will lead to actions for service change and improvement.

Specific
Measurable
Accountable/**A**greed
Reasonable
Timely
Effective
Reviewable

This ensures that the local Clinical Governance group can take these recommendations forward into Action Plans at a local, Mental Health Service or even Board wide level.

2.3 Learning from SAE Reviews

Timely feedback to the individuals or team involved would usually be the responsibility of the CD/AMD and HoS. This is perhaps the most important aspect of learning and should be a priority for local management teams.

Issues identified in SAEs may be specific to an individual, a team, a Division or Directorate or a discipline, or common to staff MHS-wide or Board-wide. Learning summaries should be produced following the SAE report.

SCIREG members are responsible for recognising recurring or thematic issues arising within SAEs and for collating information from the Data Collection Template and ensuring this learning is available to frontline staff through learning events or through the Patient Safety Bulletin.

SCIREG and MHS GCE have responsibility for ensuring that lessons are learning at the MHS level.

Further information about learning lessons from SAEs is available on staffnet clinical governance page at http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Clinical%20Risk/Pages/ClinicalRiskBulletinsPage.aspx

Appendix 1 Link to SAE Toolkit

Copies of all SAE templates can be found by following the SAE Investigation toolkit link on the GG&C Staffnet website at:

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

Appendix 2

<u>NOTIFYING THE COMMISSION</u>

<u>Guidance for Staff in NHS/local authority/independent sector services</u>

We are often asked about what issues and incidents should be reported to the Mental Welfare Commission. It is difficult to be prescriptive as each and every circumstance will be different. However, the following guidance is intended to assist staff in the NHS/local authority/independent sector services in determining whether an incident or issue should be notified to us and the form that notification should take. Any such notification is in addition to any other notification required by, for example, the Care Inspectorate, Adult Support and Protection Officer, or Healthcare Improvement Scotland. The term “individual” is used throughout this guidance to refer to a person with mental illness, learning disability or a related condition. On receipt of such a notification, the Commission will determine whether any further information is required or any action is to be taken.

Despite this guidance, it is not possible to be prescriptive about all cases which should be reported to the Commission as circumstances vary so much. Anyone in doubt as to whether a matter is significant enough to report to the Commission should contact the Commission (0131-313-8777) to discuss the situation.

Specific

- The death of any individual who is subject to compulsory treatment under the Mental Health (Care and Treatment) (Scotland) Act 2003.
- The suicide of any in-patient receiving psychiatric care at the time of death or who has been discharged from inpatient psychiatric care within the preceding month
- The death of any individual where there is a significant concern regarding any aspect of their care and treatment prior to death.
- Where it is felt that a Fatal Accident Inquiry should or will be held
- All cases where an individual who is receiving care from mental health or learning disability services is accused of or convicted of, a serious crime, e.g. homicide, serious physical assault or sexual assault.
- Where it appears that an individual is being/has been detained in any care setting without appropriate legal authority

General

- Incidents where it appears there has been a deficiency in care or treatment and, as a result, an individual suffers a serious injury or adverse physical effects, including as a result of restraint, or where the injury has been caused deliberately by another person.
- Where an individual is living alone or without care and is unable to look after him or herself or his or her property or financial affairs and no intervention is taking place to remedy the situation.

- Incidents or circumstances in which a deficiency in care has led to the property of an individual suffering significant loss or damage or has led to it being at risk of significant loss or damage.

In addition to the above, local authorities should notify the Commission of:

- Any significant investigation the local authority carries out under Section 33 of the Mental Health (Care and Treatment) (Scotland) Act 2003 or Section 10(1) (c) of the Adults with Incapacity Act 2000 or where a Protection Order under the Adult Support and Protection (Scotland) Act 2007 has been taken out in relation to an individual.

Information required by the Commission

The information provided to the Commission should be relevant and proportionate to the circumstances of the case and would normally include:

- A brief account of the circumstances of the incident or situation, its antecedents and any other relevant information

- Information on the diagnosis, treatment and the mental state of the person

- Information on any other person involved

- What further action is being taken or considered, including any changes in procedure, policy or the physical environment

- An indication of any further investigation, enquiry or review that is being carried out or considered, and a copy of the outcome of these when available.

20 August 2018

Appendix 3

Post Mortem and Police Reports and the Procurator Fiscal

A recent scoping exercise indicates there is different practice in contacting the Procurator Fiscal to request post mortem reports following Significant Adverse Events.

Most areas usually 'phone the Procurator Fiscal rather than write to request a post mortem report. Phoning for or requesting the cause of death may often be quicker than requesting the full post mortem report.

***Post mortem reports** are usually available between 8 and 12 weeks after death, the latter because of delays in receiving toxicology reports.

The Procurator Fiscal have advised that they will not release copies of ****Police reports** but may be able to release information from reports to assist in decision making.

Any requests to or from the Procurator Fiscal should be sent to NHSGGC generic email account at ggc.pfreporting@ggc.scot.nhs.uk

Please see below a suggested template for requesting PM reports or information from Police reports.

Dear

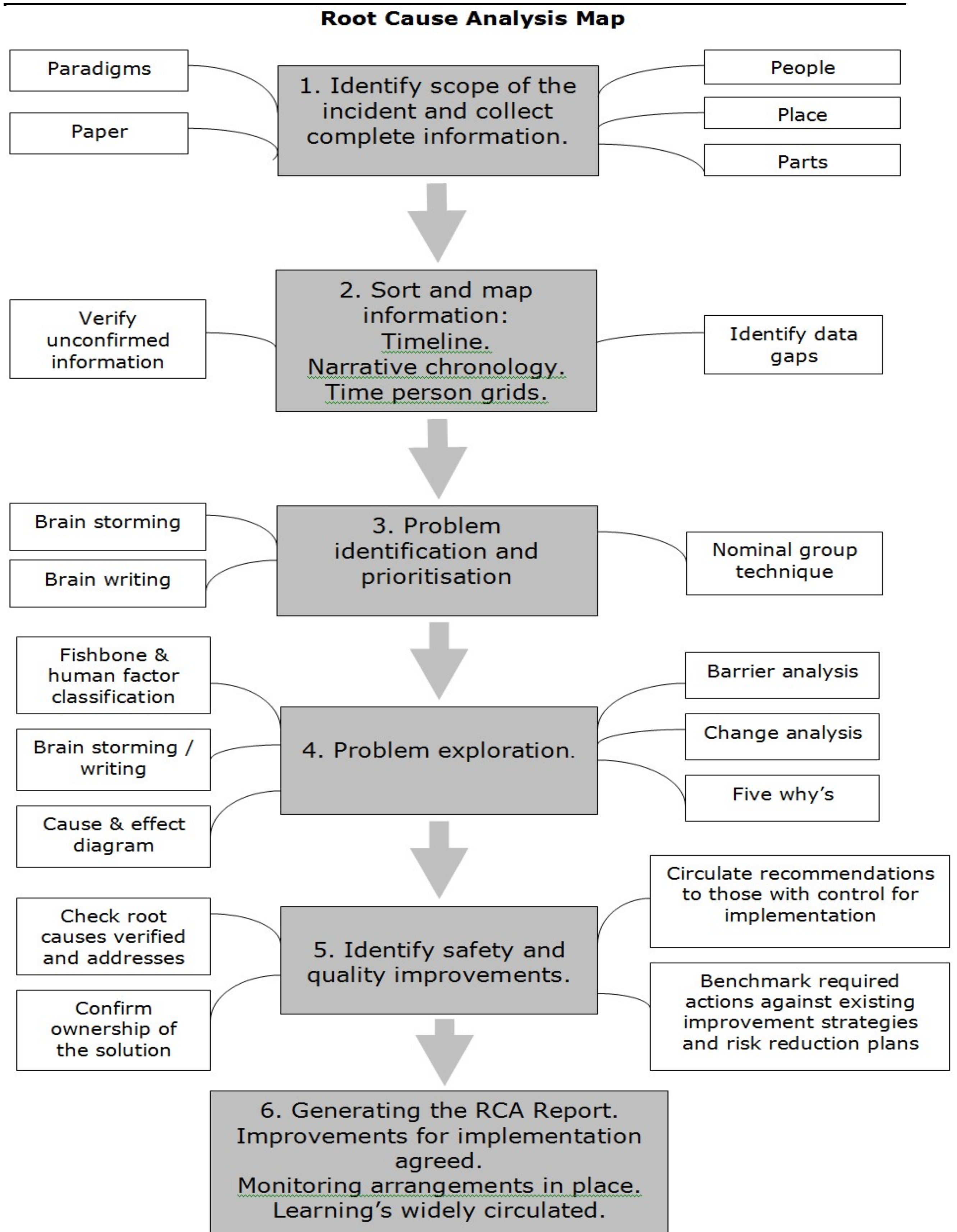
I am a Clinical Director in……………………, Mental Health Services NHS Greater Glasgow and Clyde. I have commissioned an investigation into the death of …….. DOB…………

**Please could you send a copy of the Post Mortem report when it is available to assist us in deciding what form of investigation is appropriate*
OR
*** We would like to commission an investigation as soon as possible and would be grateful for any information from the Police report which could suggest that the patient took his/her own life.*

This information will be used solely to assist us in commissioning the incident report. Please let me know if you require any further information,

Many thanks.

Appendix 4



Appendix 5 Significant Adverse Event Report QA Screening Form

NHS Greater Glasgow and Clyde

Quality Assurance Checklist for Significant Adverse Event Review (SAER) Reports

Datix ID		Date Received	

Section A: Pre-Screening

Criteria	Yes	No	NA
The incident details in the report match the details on Datix	☐	☐	
The report is on the correct template	☐	☐	
All sections of the report have been completed	☐	☐	
Family/patient involvement has been considered	☐	☐	
GP Involvement has been considered	☐	☐	☐
No names are present in the report, including the Review Team	☐	☐	
Recommendations are present	☐	☐	☐
An action plan is present and is on the Datix Action Plan Module	☐	☐	☐
Arrangements for shared learning have been listed	☐	☐	☐
An Outcome Code has been selected	☐	☐	
The report has been signed and dated	☐	☐	
A learning summary has been received	☐	☐	☐
A timeline is present (which contains no names)	☐	☐	
A key of names is present and includes the review team and the patient/family	☐	☐	

If 'no' has been selected against any item please request that all documents be resubmitted to clinical.risk@ggc.scot.nhs.uk within 3 days.
Once 'yes' or 'NA' has been selected for all items, the report and this form may be submitted for detailed screening.

Section B: Detailed Screening

All Sections	Yes	No	NA
The report is on the correct template	☐	☐	
The report flows well and is free from spelling and grammatical errors, jargon and abbreviations.	☐	☐	
The report is written in prose and not note form	☐	☐	
The report and timeline are anonymous	☐	☐	
Formatting and font are consistent	☐	☐	
There are no tracked changes in the report or timeline	☐	☐	
Cover Page	**Yes**	**No**	**NA**
Information is fully completed and matches Datix	☐	☐	
Contents page	**Yes**	**No**	**NA**
The contents page is accurate	☐	☐	
Section 1: Terms of Reference	**Yes**	**No**	**NA**
The Terms of reference is described and deemed to be acceptable	☐	☐	
Section 2: Patient and Family Involvement	**Yes**	**No**	**NA**
This section is fully complete and the reasons provided for 'no' are valid.	☐	☐	
Section 3: Investigation Process	**Yes**	**No**	**NA**
The Investigation Process is adequately detailed and deemed to be appropriate	☐	☐	
Names and titles mentioned in the report match those in the key	☐	☐	
Section 4: Detailed Description of Events	**Yes**	**No**	**NA**
The description gives a full account of the incident and it is clear what happened	☐	☐	
The description contains facts and not opinions	☐	☐	
Risk management is considered in the report	☐	☐	☐
All relevant individuals have been interviewed or have provided statements	☐	☐	
The description correlates with the timeline	☐	☐	

Section 5: Key Issues Identified & Lessons Learned	Yes	No	NA
The findings reflect the issues raised in the description of events	☐	☐	
The findings correlate with identified contributory factors	☐	☐	
The findings correlate with the timeline	☐	☐	
Section 6: Conclusion	**Yes**	**No**	**NA**
The conclusion reflects the issues raised in Section 5	☐	☐	
The outcome code has been completed	☐	☐	
The outcome code reflects the information in the report	☐	☐	
The severity score, the outcome code and duty of candour information match	☐	☐	
Section 7: Recommendations	**Yes**	**No**	**NA**
There is a recommendation which adequately addresses each of the issues identified	☐	☐	☐
The recommendations indicate whether the action is ongoing or already complete	☐	☐	☐
The recommendations detail whether they are Local, Acute, Partnership or Board	☐	☐	☐
Actions are SMART (***S****pecific,* ***M****easurable,* ***A****ttainable,* ***R****elevant,* ***T****ime-related*.)	☐	☐	☐
Section 8: Arrangements for Shared Learning	**Yes**	**No**	**NA**
If cross sector/directorate all appropriate Clinical Governance Meetings are included	☐	☐	☐
If to be shared with specific specialist groups this is included *(Nutrition, Falls, VTE, MCN)*	☐	☐	☐
The Learning summary is of high quality and adequately captures learning from the report	☐	☐	☐
Sign Off	**Yes**	**No**	**NA**
The report has been approved and signed off locally	☐	☐	
Data Collection Template (MH only)	**Yes**	**No**	**NA**
The Data Collection Template is completed accurately	☐	☐	☐

Comments/Actions Required

Screener		Date Screened	

Appendix 6 Links to NES Resources

Fatal Accident Inquiries (FAIs) for NHS staff

An NHS Education for Scotland (NES) resource for staff who may have to attend a Fatal Accident Inquiry is now available on StaffNet.

NHSGGC is the only Health Board in Scotland to have a nominated lead who manages FAIs, and Procurator Fiscal Investigations, and who also provides one-to-one witness support/guidance to staff throughout these processes. You can contact our lead by email: MargaretAnn.MacLachlan@ggc.scot.nhs.uk

Support Around Death (SAD)

The following links to 5 short animated films are from the NES Support Around Death (SAD) website:

- Talking to children who are bereaved https://vimeo.com/167887527 o Discussing Dying https://vimeo.com/170436673
- Discussing Adult (Authorised) Hospital Post Mortem Examination https://vimeo.com/167899265
- Dealing with a failed neonatal resuSAEtation https://vimeo.com/167898800 o Understanding the processes which occur after a sudden or unexplained death https://vimeo.com/167901377

All the films are also freely available on the SAD website at this link http://www.sad.scot.nhs.uk/education-learning-resources/

A further two films will be launching soon – ‘Breaking the news of intrauterine death’ and ‘Discussing authorised (hospital) post mortem examination after stillbirth or neonatal death’.

If anyone uses twitter they might want to access NES_Bereavement to see any new developments

NHS Greater Glasgow and Clyde

Appendix 7 Data Collection Template

Mental Health Services (including Addictions, LD, OPMH, Forensic)
Section 17 Data Collection Tool for SAE Reviews

Section A: General

Primary | Secondary | No mental illness | Diagnostic Uncertainty

☐ EDC ☐ STDC ☐ CTO ☐ Compulsion Order ☐ Care Programme Approach
☐ CORRO ☐ ASP ☐ AWI ☐ MAPPA ☐ Child Protection
☐ Criminal Procedure Act ☐ N/A

☐ Employment ☐ Relationships ☐ Financial ☐ Social Isolation ☐ Physical Health
☐ Bereavement ☐ Features of BPD (self harm) ☐ Dissocial PD (violence)
☐ Other (specify)

☐ Yes ☐ No

☐ Yes ☐ No

Section B: Community Patients

☐ Within 7 days ☐ Within one month ☐ Within three months ☐ More than three months
☐ Never admitted **(If more than 3 months or never admitted proceed to 5f)**

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Patient presented ☐ MHS were informed

☐ Patient presented ☐ MHS were informed

☐ Patient presented ☐ MHS were informed

☐ Patient presented ☐ MHS were informed

☐ Patient presented ☐ MHS were informed

Section C: In-Patients

☐ In-patient psychiatry ☐ On pass - community (agreed time off ward)
☐ On pass – other acute site ☐ Absconded

☐ Same day ☐ 1-30 days ☐ Over 30 days

☐ Special ☐ Constant ☐ General

Days ☐ NA

	☐ Yes ☐ No ☐ NA
	☐ Yes ☐ No ☐ NA
	☐ Yes ☐ No
	☐ Yes ☐ No

☐ Yes ☐ No

	☐ Yes ☐ No
	☐ Yes ☐ No

Section D: Transitions of Care/Joint Working

☐ At point of transition ☐ during joint working between ☐ N/A (proceed to 7d)

☐ Yes ☐ No ☐ N/A

☐ General Adult Psychiatry	☐ Old Age Psychiatry	☐ Addictions
☐ CAT	☐ Forensic	☐ LD
☐ CAMHS	☐ CRISIS	☐ OOH Service
☐ Addictions Psychiatry	☐ Liaison Psychiatry	☐ Esteem
☐ Perinatal	☐ Social Services	☐ Primary Care
☐ Voluntary/3rd Sector	☐ Acute Hospital	☐ Police
☐ CMHT	☐ PCMHT	☐ Other (specify)

	☐ Yes ☐ No

☐ General Adult Psychiatry	☐ Old Age Psychiatry	☐ Addictions
☐ CAT	☐ Forensic	☐ LD
☐ CAMHS	☐ CRISIS	☐ OOH Service
☐ Addictions Psychiatry	☐ Liaison Psychiatry	☐ Esteem
☐ Perinatal	☐ Social Services	☐ Primary Care
☐ Voluntary/3rd Sector	☐ Acute Hospital	☐ Police
☐ CMHT	☐ PCMHT	☐ Other (specify)

☐ Yes ☐ No

Section E: Thematic Learning (select all that apply)

1. Deteriorating patient

- ☐ Vital signs not recorded frequently enough
- ☐ EWS not calculated
- ☐ EWS calculated wrongly
- ☐ Issue with/failure to escalate high EWS
- ☐ Issue with/failure/delay to respond to escalation
- ☐ Inappropriate response to escalation – treatment
- ☐ Inappropriate response to escalation – senior help
- ☐ Issue with/failure to increase level of observation
- ☐ Issue with/failure to adequately observe
- ☐ Issue with/failure to communicate deterioration at handover
- ☐ Issue with/failure to recognise a clinical indication
- ☐ Issue with/failure to monitor long term physical health indicators

2. Communication and Joint Working (select whether at Assessment, Ongoing care, Discharge, Transition)

	A	O	D	T
Issue with/failure to share clinical information within a service	☐	☐	☐	☐
Issue with/failure to share clinical information between Acute services	☐	☐	☐	☐
Issue with/failure to with share clinical information between Boards	☐	☐	☐	☐
Issue with/failure to share clinical information between NHS and external agencies	☐	☐	☐	☐
Issue with/failure to share clinical information on handover	☐	☐	☐	☐
Inadequate information shared with patient	☐	☐	☐	☐
Inadequate information shared with relatives	☐	☐	☐	☐
Issue with/failure to follow up (e.g. 7 day follow up)	☐	☐	☐	☐
Issue with/failure with multidisciplinary working	☐	☐	☐	☐
Issue with/failure with working between teams or services	☐	☐	☐	☐
Issue with/failure to share clinical information between Secondary and Primary Care	☐	☐	☐	☐
Issue with/failure to share clinical information between Mental Health and LD/OPMH	☐	☐	☐	☐
Issue with/failure to share clinical information between Mental Health and Addictions	☐	☐	☐	☐
Issue with/failure to share clinical information between HSCP services	☐	☐	☐	☐
Issue with continuity of care	☐	☐	☐	☐

3. Risk Assessment & Care Planning

- ☐ Issue with/failure to perform Risk Assessment
- ☐ Incomplete Risk Assessment
- ☐ Inappropriate response to Risk Assessment
- ☐ Issue with/failure to review Risk Assessment
- ☐ Inadequate environment
- ☐ Issue with assertive Engagement
- ☐ Issue with care planning and/or CPA
- ☐ Issue with staffing levels, training and skill mix
- ☐ Issue with risk assessment documentation and information sharing

4. Documentation & Admin Issues

- ☐ Written information illegible
- ☐ Issue with/failure to record clinical information
- ☐ Poor quality of Electronic Patient Record
- ☐ Transcription error
- ☐ Wrong information recorded
- ☐ Delay in admin
- ☐ Admin errors

5. Results

- ☐ Result not acted on
- ☐ Issue with/failure to with to interpret result
- ☐ Issue with/failure to escalate result
- ☐ Delay in responding to result

6. Medicines optimisation and Side Effects Monitoring

- ☐ Prescribing errors, dispensing errors, administration errors, monitoring errors
- ☐ Issue with adherence and shared decision-making
- ☐ Issue with structured medicine reviews/regular medical reviews - “a critical examination of a person's medicines with the objective of reaching an agreement with the person about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste”
- ☐ Inadequate side-effects monitoring

7. Carer and family involvement

- ☐ Issue with early recorded and consistent contact with carers
- ☐ Issue with information sharing and confidentiality
- ☐ Issue with information provision for patients and carers