Section 1: Policy
Introduction

Ensuring patients are treated safely is our top priority. Effective reporting and analysis of Significant Adverse Events (SAE) allows the organisation, you and your team to highlight and learn from both strengths and weaknesses in the care we provide. Improving the quality and safety of patient care is a key clinical governance priority in healthcare and SAE reporting has an important role in contributing to this aim. This guidance on identifying, reporting and learning from SAEs will help us to focus on reliable, safe and effective systems of care allowing you and your team to provide the best care every time for patients and their families or loved ones.

A SAE is any event that resulted in the unexpected death or significant harm (harm includes negative physical and emotional impact) to a patient. All SAEs will be reviewed in accordance with Scottish Ambulance Service agreed process. Current thinking suggests that the causes of incidents cannot simply be linked to the actions of individual people, but are usually the result of system-wide issues. The Scottish Ambulance Service wants to encourage and support staff to do the right thing, first time and every time. The process is not designed to apportion blame, indeed no-one should be disciplined for making an honest mistake. But it is important for both individuals and organisations to learn from these mistakes, especially so when they are significant in nature. All staff have a responsibility to report incidents onto Datix and take appropriate remedial action where necessary (please refer to the Services Incident Reporting procedure).

Scope

This policy and process document applies to all activities conducted by the Scottish Ambulance Service whether conducted by employees, volunteers or contracted services.

Purpose

The purpose of this policy is to communicate the process of dealing with a SAE to all Service staff so that they can be safe, responsive and take control of a SAE if it occurs. Once implemented this will support:

- Safeguarding people (patients, public and staff), property, the service’s resources and its reputation;
- Understanding why the event occurred;
- Ensuring that steps are taken to reduce the chance of a similar incident happening again;
- Reporting to other bodies where necessary; and
- Sharing the learning with other NHSScotland organisations.
Commitments to patients and families involved in a Significant Adverse Event

The Scottish Ambulance Service is committed to ensuring that when a SAE occurs immediate, appropriate and effective action will be taken to ensure:

- The patient and their family are safe and supported;
- Staff members are safe and supported; and
- The organisation learns from the event and ensures any required improvements are made.

The Scottish Ambulance Service recognises the considerable impact that such an adverse event will have on patients and/or their carers/family. The organisational response to such an event will be:

- Compassionate;
- Transparent;
- Honest;
- Timely; and
- Consistent

with a focus on the needs of the patient and/or carers/family.

The Scottish Ambulance Service has agreed what patients and/or carers/families can expect to happen every time a SAE occurs. When an event occurs patients and/or their carers/families can expect the following:

- We will keep them informed of our actions from the time that the adverse event happens through to the point when we have identified the learning, if appropriate and improvements to be made;
- We will communicate with them respectfully and honestly, in a way that compassionately acknowledges and recognises the emotional impact of the adverse event on the patient and their family;
- We will support them by providing a consistent named contact person;
- We will work with them to involve them in the review process, taking account of their preferences and providing them with the opportunity to share details of their experiences with staff, if appropriate to support their learning; and
- We will provide them with a sincere and honest apology for identified failings.
Our commitments to staff

The Scottish Ambulance Service has agreed what staff can expect to happen every time a SAE occurs and what the organisation expects from staff.

The Scottish Ambulance Service is committed to developing and shaping our organisational culture with values, beliefs and behaviours that:

- Recognise the importance of our staff in delivering quality services;
- Support our managers and leaders to value staff, their health, safety and wellbeing; and
- Support an honest, fair and just culture underpinned by respect and dignity.

This requires every member of staff to play their part; and to understand their roles, responsibilities and commitments. For the NHS Board, the revised Staff Governance Standard sets out what it must achieve in order to continuously improve the fair and effective management of staff. The Scottish Ambulance Service recognises the importance of staff governance as a feature of high performance which ensures that all staff have a positive employment experience in which they are fully engaged with both their job, their team, and their organisation. Achieving such an outcome will not only have a positive impact on organisational performance (and therefore on the quality of the services we provide), it is also an important component in providing all employees with dignity at work. For staff, the Staff Governance Standard, together with existing staff Codes of Conduct, sets out the responsibilities, standards of performance and behaviours expected.

Our approach to supporting staff through SAEs will reflect these aims and has been agreed in partnership with staff through the National Partnership Forum.

Supporting staff

The Board recognises the impact that a SAE may have on staff and has listened to feedback from staff. Our commitment to staff is that the Board’s revised approach will be:

- Fair and thorough;
- Supportive and compassionate;
- Transparent;
- Honest;
- Timely and consistent;

while all the time being focussed on the needs of the patient, their family and staff.

The Board’s commitments to staff when a SAE occurs are:

- We will ensure that you are safe and fully supported throughout the process;
- We will communicate with you respectfully and honestly, in a way that compassionately acknowledges and recognises the emotional impact the event may have had on you. This communication will be provided by a named contact person;
- We will involve you in the review process, listening to your experience and ensuring this informs the process and the resultant learning;
Scottish Ambulance Service
Management and Review of Significant Adverse Events

- We will ensure that the review is completed thoroughly, openly, non-judgementally and as quickly as possible;
- We will keep you informed of progress of the SAE review, through your named contact, from the time that the event happens through to the point when we have identified the learning and improvements to be made; and
- We will ensure you receive feedback on the findings, recommendations and wider learning.

In return, the Board’s expectations from staff are:

- Ensure that you seek to fully understand the revised process and support its implementation within your area of work.

If you are required to participate in a review process we will need you to:

- Fully and actively engage throughout the process from initial review to developing and delivering improvement plans and identifying learning;
- Communicate openly, respectfully and honestly with everyone involved;
- Operate within all relevant professional code of conducts as well as the Board’s code of confidentiality;
- Fully implement any learning and education relevant to your role or sphere of practice; and
- Identify if you need help and support and accept this when it is offered.

Definitions

To minimise ambiguity and ensure consistency of approach the Service framework provides a definition of the term SAE. A SAE requiring review is defined as an incident that occurred in relation to Service operations and results in one or more of the following:

- Unexpected and avoidable death of one or more patients, staff, visitors or members of the public, i.e. Category 1 Events as identified in the National Framework for the management of SAEs;
- Serious harm to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolonged pain or psychological harm;
- A scenario that prevents or threatens to prevent the Service’s ability to continue to deliver healthcare services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, or ICT failure;
- Allegations of abuse (definition provided later in the document under “supplementary definitions”);
- Adverse media coverage or public concern about the organisation or the wider NHS;
- One of the core set of Never Events that results in death or serious harm
  1. Opioid overdose of an opioid-naïve patient
  2. Failure to recognise a misplaced or displaced ETT
  3. Failure to monitor and respond to SPO2 or EtCO2 saturation

Please Note- This document is uncontrolled once printed.
4. Misidentification of patients
5. Patient left at home outwith see and treat and no safeguarding in place
6. Patient falls or jumps from a moving vehicle
7. Patient falls from an ambulance trolley, patient chair or wheelchair
8. Ambulance involved in a fatal collision
9. Wrong medication given leading to adverse patient outcome
10. A patient suffering an immediately life-threatening condition does not receive a paramedic response
11. Non reported medication administration error
12. Preventable death in our care

A list of supplementary terms is provided within the National Patient Safety Agency (NPSA) guidance and provided later in the document under “supplementary definitions”

**Definition of Significant Adverse Events Requiring Further Review – Further Guidance**

The Service acknowledges that SAEs are not necessarily all clinical in nature and will include incidents such as data loss and serious breaches in confidentiality.

Any consideration of whether an incident meets the definition of Significant should consider the spirit of Service policy and the gravity of each incident. The definition of what constitutes a significant adverse event is not exhaustive and should not inhibit awareness of items which, although not listed specifically as SAEs, are SAEs.

It is assumed that any event involving death or serious harm will always be treated as a Significant Adverse Event Review (SAER) incident.
SAER Process Flowchart

1. Inform local GM during business hours, or On Call GM outwith business hours

2. SBAR requested by SAER Group 

3. Ensure incident recorded on Datix and inform SAER Group 

4. Core SAER Group must include a senior Medical Directorate member, a non clinician, and one other member 

5. Is incident an SAE? 
   - NO 
     - Critical incident? 
       - NO 
         - Normal review procedures locally 
       - YES 
         - Enhanced Review 
   - YES 
     - Director of HP & Nursing, or deputy informs appropriate Executive 

6. SAER Group convene or Conference Call 

7. SAER Group appoints a Review Coordinator, Lead and assistant Reviewers, and if applicable, a Liaison Officer for Family contact 

8. Ensure Reviewers and Liaison Officer have relevant information and Datix reference number, including Terms of Reference. Issue and commence Tracker. 

9. Weekly updates from Reviewer(s) with target completion within 30 days 

10. Family informed of outcome if involved, and staff given feedback 

11. Review shared with Chief Executive or Deputy 

12. Once completed, Reviewer presents Report with Action Plan to SAER Group 

13. Details shared with Board for noting 

14. Lessons learned shared with Clinical Governance Group/ Committee, SMT and Staff Governance Committee 

15. Ensure safety & welfare of Staff, Patients and other parties 

---

Please Note- This document is uncontrolled once printed.

Version: 2
Release Date: April 2014
Owner: Director of Health Professions and Nursing Care
Supplementary Definitions:

- **Adverse Event** - An adverse event is defined as an event that could have caused, or did result in, harm to people or groups of people.

- **Unexpected death** – where natural causes are not suspected. Local organisations should review these to determine if the incident contributed to the unexpected death.

- **Permanent harm** – directly related to the incident and not to the natural course of the patient’s illness or underlying conditions, defined as permanent lessening of bodily functions, including sensory, motor, physiological or intellectual.

- **Prolonged pain and/or prolonged psychological harm** – pain or harm that a service user has experienced, or is likely to experience, for a continuous period of 28 days.

- **Severe harm** – a patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care.

- **Major surgery** – a surgical operation within or upon the contents of the abdominal or pelvic, cranial or thoracic cavities or a procedure which, given the locality, condition of patient, level of difficulty, or length of time to perform, constitutes a hazard to life or function of an organ, or tissue (if an extensive orthopaedic procedure is involved, the surgery is considered major).

- **Abuse** – a violation of an individual’s human and civil rights by any other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal or psychological, it may be an act of neglect or an omission to act, or it may occur when a vulnerable person is persuaded to enter into a financial or sexual transaction to which he or she has not consented, or cannot consent. Abuse can occur in any relationship and may result in significant harm or exploitation of the person subjected to it. This is defined in *No Secrets* for adults and in Care Quality Commission (CQC) guidance about compliance. Working together to safeguard children (2006) states that "abuse and neglect are forms of maltreatment of a child. Somebody may abuse or neglect a child by inflicting harm or by failing to act to prevent harm".

- **Opioid Overdose of an opioid naïve patient** - Death or severe harm as a result of an overdose of an opioid given to a patient who was opioid naïve. Specifically this means:
  - Where a dose is used that is not consistent with the dosing protocol agreed by the healthcare organisation, or the manufacturer’s recommended dosage for opioid-naïve patients:
  - Where the prescriber fails to ensure they were familiar with the therapeutic characteristics of the opioid prescribed:
  - Excluded are cases where the patient was already receiving opioid medication.
Section 2: Procedure / Process
**Procedure**

The Significant Adverse Event Group (SAER Group) is directly responsible for overseeing the SAE process from inception to completion of recommendations as outlined in the action plan and to monitor and provide Board assurance in relation to the reporting and reviewing of SAEs involving the Service. The SAER Group will also:

- Provide strategic leadership and direction on all matters relating to the SAE;
- Ensure robust systems are in place and operating effectively for the identification, assessment and reviewing of all potential SAEs, both within the organisation and for independent contractor services;
- Be responsible for the decision and subsequent grading or down grading of all potential SAEs (must be Senior member of Medical Directorate, 1 non-clinical and any other Group member);
- Ensure process flow chart is followed;
- Receive and approve the final review report and associated action plan and be assured that the root cause of the Adverse Event has been established and learning has been realised;
- Sign off final reports and action plans (must be Senior member of Medical Directorate, 1 non-clinical and any other Group member);
- Monitor the progress and timely completion of the action plan.
- Identify themes and allocate them to appropriate owners to progress.

Incidents are reported to the SAER Group for consideration as to whether such incidents meet the definition of Significant. Incidents that may require additional review could come to the Service’s attention via a number of formal and informal routes including:

- Datix Reports
- Patient Concern
- Freedom of Information Request
- Central Legal Office
- Commendations process
- Never Event
- Whistle Blowing
- Exec Team
- ACC
- Patient Complaint
- Press Enquiry / Report
- Other NHSScotland body
- Scottish Government
- Trigger Tool
- Informal Conversations

The SAER group will use the initial incident review guidance (appendix 1) and the SBAR provided by Divisional Management (appendix 2) to determine if the incident is significant.

If the incident is a SAE, the SAER group members will inform the Chief Executive and launch a SAER.
**Review Process**

On receipt of information that an incident has occurred that may be a SAE, the SAER group will use the initial incident review guidance and an SBAR from the Division (appendix 2) to identify if the incident is a SAE. They will convene to decide if the incident is a SAE and if appropriate will invite local management. If it is classed as a SAE the SAER group will launch the SAER process and inform the CEO.

The incident will be assigned to a named member of the SAER Group who will act as the co-ordinator for the review. The SAER Group will assign two trained reviewers from the list of staff trained in Root Cause Analysis to carry out the review.

Once the reviewing officers have completed the review and developed an action plan they will forward these to the review co-ordinator who will quality control and present to SAER Group, the reviewing officers may also be asked to present to SAER Group.

The SAER Group will ensure that all completed reports are reviewed, redacted and forwarded to the National Clinical Governance Group and Staff and Clinical Governance Committees for information.

The Director of Health Professions & Nursing Care will share the completed SAER with the Chief Executive.

**Detailed process for reviewing officers when conducting a review**

This policy aims to establish a clear pathway for dealing with issues of adequacy of performance and competency of clinical staff, and any variations relating to clinical practice. It will establish a clear separation between these issues and those that pertain to matters of personal misconduct and capability.

The purpose of the policy is to encourage employees to openly discuss patient care issues in a supportive environment within the boundaries of justifiable accountability and to improve clinical practice for the future which will provide real benefits for patients and staff.

The policy is not intended to prevent issues of staff conduct and performance being dealt with by other appropriate service policies. Whilst no disciplinary sanctions are to be considered as part of this policy, there may be occasions whereby during the patient safety review or patient safety reflective meetings that issues come to light where it is deemed appropriate to invoke the Services Disciplinary Policy (Managing Conduct and Performance) rather than continue with this process.

This policy will allow the service to manage clinical performance issues without always having the need to refer to professional/registration bodies. However, there may be cases, for example, those where poor patient care was deemed to put the public at risk or the individual was deemed unfit to practice through lack of clinical competency. In these instances, the service would have a duty to refer the matter to the relevant professional/registration body.

This process is divided into 2 levels; Patient Safety Reflective (PSR) meetings and Root Cause Analysis (RCA).
Patient Safety Reflection Process

The appointed reviewing officers will have been given a set of terms of reference from SAER Group.

The first stage of the review is to conduct the Patient Safety Reflective Meeting. The reviewing officers should consider incorporating additional expert assistance within the debrief if it is deemed necessary. The members of staff will be invited to attend and be advised that they can be accompanied.

The reflective meeting should be conducted in an informal and relaxed atmosphere with the emphasis placed on learning lessons and improving clinical practice.

An action plan, if appropriate should be agreed with the individual at the end of the meeting, and recorded in writing on the Reflective Meeting Form.

The next stage of the process is to conduct the Root Cause Analysis. If at any point during the reflective meeting or the subsequent analysis of the incident it is considered more appropriate to deal with the matter under the Service’s Disciplinary Policy (Managing Performance and Conduct) the process will stop, this will be decided by the DHP&NC in conjunction with the Divisional Management. The employee will be informed in writing of the reason why and the more appropriate pathway will be followed.

The recording forms for the PSR are in Appendix 3 and the Root Cause Analysis template is in Appendix 4.

Root Cause Analysis Process

Root Cause Analysis investigation is a problem solving methodology for discovering the real, or root cause(s) of problems, or difficulties identified via a range of activities, including adverse incident management. It is a retrospective analysis of the sequence of events leading to an adverse incident and will sometimes include the way the incident has been managed. Please refer to Maria Dineen’s Six Steps to Root Cause Analysis guidance which was issued to trained reviewers within SAS.
Transfer to Disciplinary / Conduct Process

When considering whether an issue should be managed / controlled by the SAER framework or by the Service disciplinary / conduct process the following questions should be asked:

1. Is it alleged that there was a deliberate breach of a sound Service policy?
2. Is there concern about the health of the individual(s)?
3. Is the main concern about a clear lack of knowledge, skills, or significant unprofessional conduct?

If the answer to all of these questions is NO then the significant adverse event group process should be the first choice, if the answer is YES to any of the questions then the Service’s disciplinary or conduct processes should be used. In the latter case a patient safety exercise can be conducted after the conclusion of the formal process.

The NPSA decision support tree is attached in appendix 5, this tool can be used to support the decision to move into the disciplinary process.

There may be occasions where both processes need to run concurrently due to the severity of the incident, in such cases the Director of Health Professions and Nursing Care, or deputy shall approve the running of concurrent processes after discussion with the Director of HR, or deputy. In these cases appropriate processes will need to be in place to ensure information from either process does not adversely prejudice the other.

Monitoring SAER Group reviews and Action Plans

Once completed, reviews and action plans are passed to the review co-ordinator by the reviewing officers and the review co-ordinator shall pass all information to SAER Group.

The SAER Group will formally review the incident review and action plan at the next scheduled meeting.

On a quarterly basis the SAER Group shall compile reports for Service governance committees statistically detailing the status of all reviews and their subsequent action plans. In addition to this an executive summary for all completed reviews will be provided to the Staff and Clinical Governance committees.

Process for monitoring action plan effectiveness and implementation

To ensure the Board obtains adequate assurance that the SAE process is being followed, the SAER Group will regularly monitor the recommendations for improvement to ensure they have been implemented and sustained. Failure to sustain improvements could give rise to increased risk in relation to patient safety and further work may be necessary to re-communicate previously identified improvements.
Assurance will be provided to the Service that all procedures in respect of identifying and managing SAEs have been effectively implemented when the following have been evidenced:

- Full compliance with this policy has been achieved and evidenced;
- It is demonstrated that contributory factors of a SAE have been identified, action taken and recommendations communicated, implemented and reviewed in accordance with the Service Risk Management Policy;
- There is evidence that recommendations previously implemented have been sustained and maintained;
- There is evidence of public and patient involvement in the SAE process; and
- There is evidence that support offered reasonably met the needs and requirements of all those involved, including cultural and religious requirements.

**Sharing Lessons Learnt**

- The Director of HP and Nursing Care will ensure that all learning from Significant Adverse Events is published;
- The Director of HP and Nursing Care will liaise with managers and professional leads to ensure that any learning identified in the action plan is appropriately reflected in training and in policies and procedures;
- The Director of HP and Nursing Care shall provide a formal update to the Clinical Governance Committee at each meeting and to the Senior Management Team;
- Action plans will reflect any learning identified as part of the review and Heads of department / General Managers will ensure that action plans are fully implemented;
- Heads of department / General Managers will ensure that learning is appropriately discussed at team meetings, professional forums etc;
- If appropriate specific training / awareness sessions will be organised; and
- If considered appropriate the Service may decide to carry out audits to ensure that changes in practice have been embedded into the every day working practices of the organisation.

Examples of appropriate learning include:

- Solutions to address incident root causes that may be relevant to other teams, services and provider organisations;
- Identification of the components of good practice that reduced the potential impact of the incident, and how they were developed and supported;
- Potential impact of the incident;
- Lessons from conducting the review that may improve the management of reviews in future;
- Documentation of identification of the risks, the extent to which they have been reduced, and how this is measured and monitored; and
- An executive summary should be published and circulated for each incident containing learning points.
Document control and Retention

The SAER group will be responsible for maintaining a records database recording all significant decision points. In addition to this the SAER group shall maintain all records associated with this process in a secure environment appropriate for patient records.
**Roles and Responsibilities**

The roles and responsibilities of Service personnel and governance groups are briefly outlined below:

**Chief Executive:** Has overall responsibility for Service activities, and for the final approval of SAER.

**Medical Director:** Has overall responsibility for Clinical Governance and Patient Safety.

**Director of Health Professions and Nursing Care:** Has overall responsibility for health and safety, infection control and significant adverse events. The DHPNC chairs the SAER Group.

**Director of Finance:** Has overall responsibility for ensuring funding is available to support this policy.

**Director of Service Delivery:** Has the responsibility of ensuring action plans are implemented.

**General Managers (GM):** To release staff to conduct the review processes.

**Medical Directorate:** Contribute to SAER group and review processes.

**Team Leaders (TL) / Area Service Managers (ASM):** To complete SBARs and where appropriate patient safety reflections.

**All Service employees:** To report all incidents whether Significant or not onto Datix.

**Significant Adverse Event Group:** To receive signed off reviews and action plans at all stages and to confirm review has identified root causes and appropriate learning. To assist with developing action plans for national/regional themes that emerge from SAER, complaints, concerns, etc.

**Clinical Governance Committee:** To receive quarterly reports from the SAER group and to assure the board that appropriate reviews are taking place.

**Staff Governance Committee:** To receive quarterly reports from the SAER group.

**National Clinical Governance Group:** To receive signed off reviews and action plans at all stages and to confirm review has identified root causes and appropriate learning. To assist with developing action plans for national/regional themes that emerge from SAER, complaints, concerns, etc.

**Health and Safety Committee; and Infection Control Committee:** To receive quarterly statistical reports from the SAER group and where appropriate review signed off reviews and action plans in order to modify Service policy or procedures as required.
Appendices: Forms, records and decision tools
Appendix 1 – SAER GROUP – Initial Incident Review Record

<table>
<thead>
<tr>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Incident:</td>
</tr>
<tr>
<td>Datix Number:</td>
</tr>
<tr>
<td>SAER Group members</td>
</tr>
<tr>
<td>Summary of Incidents</td>
</tr>
<tr>
<td>(Note based on currently available information)</td>
</tr>
<tr>
<td>Division Occurred in:</td>
</tr>
<tr>
<td>North</td>
</tr>
<tr>
<td>SORT</td>
</tr>
<tr>
<td>Is the incident a SAE</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Is a SAER recommended</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Date Passed to Exec Team</td>
</tr>
<tr>
<td>Did Chief Executive approve SAER</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Date Exec Team Approved/Rejected</td>
</tr>
</tbody>
</table>

Description / Question

<table>
<thead>
<tr>
<th>With Regard to incidents not directly involving staff, patients or visitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Is the Service exposed to significant media interest (at the extreme level on Service risk matrix) due to the incident?</td>
</tr>
<tr>
<td>B Is the ability of the Service to deliver core services threatened due to the incident</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>With regard to incidents involving staff, patients or visitors,</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Has a “never event” occurred? Yes  No</td>
</tr>
<tr>
<td>2 Has “Unexpected or avoidable death” occurred? Yes  No</td>
</tr>
<tr>
<td>3 Was “Serious Harm” been caused? Yes  No</td>
</tr>
<tr>
<td>4 Are there allegations of “abuse”? Yes  No</td>
</tr>
</tbody>
</table>

Note: Any answer involving a yes response should lead to a recommendation to the Exec team that a SAER process is launched. The SAER group may recommend a SAER subject to Exec approval for incidents where no “yes” answer is provided.

If SAER process is approved for this incident complete the following details:

<table>
<thead>
<tr>
<th>Description</th>
<th>Name</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAER Group co-ordinator appointed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reviewing Officer appointed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date PSR required by</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date PSRev required</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date PSEA required</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 2 – SBAR Guidance for Managers

**Significant Adverse Event Group**

**SBAR - Datix Web Number:**

**IMMEDIATE ACTION**

**Situation**

What happened?
When did it happen?
Where did it happen?
Who was involved?
Who reported it?
To whom did they report it?
Include patient outcome if known.

Give a concise statement of the incident.

**Background**

Pertinent background information related to the situation.

Information may include but not limited to that obtained from C3, Sequence of Events, Patient Report Form, Datix, Viewpoint, written and verbal communications, ACC voice recordings (It may not be necessary to use all these elements).

**Assessment**

Is there a problem that requires further review?
Has there been a failure in relation with compliance with policy, procedure or system?
What is the severity of the incident using the risk matrix definitions?
  o Negligible – No impact to Organisation or Injury
  o Minor – Minor impact or injury requiring first aid
  o Moderate – Moderate impact to Organisation or injury requiring further treatment
  o Major – Major impact to Organisation or long term incapacity / disability (e.g. loss of limb), requiring extensive rehabilitation and support
  o Extreme – Extreme impact to Organisation or death or major permanent incapacity where rehabilitation will not improve outcome

**Recommendation**

Apart from further consideration by Significant Adverse Event Group, are there any other recommendations?
### Appendix 3 – Patient Safety Reflection Process

#### Patient Safety Reflection *

This template should be used to help you “reflect-on-action”, i.e. to think about what you (and others) did, how successful this was, and whether or not if any changes were made this would have resulted in any different outcomes.

<table>
<thead>
<tr>
<th>Report Author and Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Author</td>
</tr>
<tr>
<td>Report Date</td>
</tr>
<tr>
<td>Report Issued to SAER GROUP Date</td>
</tr>
<tr>
<td>SAER GROUP Ref Number ( eg:WebXXXX)</td>
</tr>
<tr>
<td>Incident Number:</td>
</tr>
</tbody>
</table>

#### Description

**What happened?**
Consider the entire event/patient journey not just a specific incident within it. For clinical incidents try and break this down into the component parts of the call i.e. dispatch, en-route, arrival, on scene, en-route/hospital/discharge etc.

---

Please Note- This document is uncontrolled once printed.

Version: 2
Release Date: April 2014
Owner: Director of Health Professions and Nursing Care
### Feelings

What were you thinking about?

<table>
<thead>
<tr>
<th>Feelings</th>
<th>What were you thinking about?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Evaluation

What do you think worked well and what didn't work as well?

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>What do you think worked well and what didn't work as well?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Analysis
Why do you think this happened? What other influences might there have been? Is there information that is missing?

### Conclusion
What else could you have done?
Patient Safety Reflection Action Plan

What could be done differently next time? Is there any wider organisational learning that can be taken from this event? How will this be shared? Who will be responsible? What are the timelines?

(Consider Incident Decision Tree)

<table>
<thead>
<tr>
<th>Ref No</th>
<th>Recommendation</th>
<th>Completion by whom</th>
<th>Completion Due Date</th>
<th>Complete and Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
</tbody>
</table>

*based on Gibbs (1988) Reflective Cycle
Patient Safety Reflection Report Template

Summary

Findings from Significant Adverse Event Group, Terms of Reference

Conclusion

Recommendations
Appendix 4 – Root Cause Analysis Report Template

Scottish Ambulance Service
Significant Adverse Event Group

Root Cause Analysis Review

Investigation in relation to: Datix Reference xxx
Author(s): xxx
Date submitted: xxx
## Executive Summary

### Incident Details

<table>
<thead>
<tr>
<th>Table</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Main Findings and Conclusions of Review

<table>
<thead>
<tr>
<th>Table</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Good Practice Identified

<table>
<thead>
<tr>
<th>Table</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Recommendations

<table>
<thead>
<tr>
<th>Table</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Full Report**

### Methodology and Terms of Reference

Please detail below the methods you used to conduct the review and all sources of data and information used to conduct this review. Also identify the terms of Reference.

As a minimum this will usually include:

<table>
<thead>
<tr>
<th>Source</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic Patient Report Form (ePRF)</td>
<td>ACC call recording to dispatch</td>
</tr>
<tr>
<td>Philips MRx Defibrillator Printout</td>
<td>ACC call recording to hospital</td>
</tr>
<tr>
<td>999 call recording – Incident number</td>
<td>Statements from</td>
</tr>
<tr>
<td>Sequence of Events – Incident number</td>
<td>Transcripts of interviews</td>
</tr>
<tr>
<td>Patient Safety Reflection Form</td>
<td></td>
</tr>
</tbody>
</table>
### Incident Details

Please detail below the story as explained to you:

```

```

### Findings

Insert your evidence based findings in this section

**Areas Where It Can Be Demonstrated That The Care And Treatment Of The Patient Met With Local And National Practice Standards**

```

```

**Areas Where The Care And Treatment Fell Significantly Below Local And National Practice Standards**

```

Please Note- This document is uncontrolled once printed.
Learning Opportunities Identified, But Which Do Not constitute Significant / Serious Lapses In Care And Treatment.

<table>
<thead>
<tr>
<th>Actions already completed following incident</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insert the conclusions you have made from all of the evidence gathered</td>
</tr>
<tr>
<td>Recommendations</td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td>Insert all recommendations in this section</td>
</tr>
</tbody>
</table>

Please Note - This document is uncontrolled once printed.
| Date | Time | Staff member involved | Event / step in chronology | Contextual Information e.g. Relevant background information, the detail of what is written in the clinical record, information obtained from staff statements but which is not in the records) | Were expected policy/practice standards met - if yes what is this evidence to support this assertion? | Are there significant concerns regarding care and treatment / standard/policy compliance. If yes what are they? | Questions that need to be asked about the patient's care and treatment (also identify to whom the question needs to be posed) these should be focusing on exploring the concerns identified and adhere to the principles of a human factors analysis framework. | Questions that need to be asked about systems, policies, supervision, training etc (also identify to whom the question needs to be posed) these should be focusing on exploring the concerns identified and adhere to the principles of a systems analysis framework. |

Please Note- This document is uncontrolled once printed.
Fish Bone Diagram / Contributory Factors

Please use this tool to identify factors contributing to the incident
For each of the factors please detail all relevant information in the table below

<table>
<thead>
<tr>
<th>Patient Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual Staff Factors</td>
</tr>
<tr>
<td>Task Factors</td>
</tr>
<tr>
<td>Communication Factors</td>
</tr>
<tr>
<td>Team Factors</td>
</tr>
<tr>
<td>Education and Training Factors</td>
</tr>
<tr>
<td>Equipment and Resource Factors</td>
</tr>
<tr>
<td>Working Conditions Factors</td>
</tr>
<tr>
<td>Organisational and Strategic Factors</td>
</tr>
</tbody>
</table>
## Five Whys Tool / Glasgow Grid

Please use the Glasgow Grid Below to examine all of the evidence gathered to reach a root cause.

For each of the columns ask a different “why question” derived from the previous question. Example below. Please replicate your questions in each column and the learning points from each question. These should be included in the action plan if one is required.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Why did HV (A) draw up the wrong vaccination?</td>
<td>Why did HV (A) administer the wrong vaccination?</td>
<td>Why did both HVs fail to double-check the vial or inform the guardians prior to vaccination?</td>
<td>Why was there no formal standard immunisation protocol in the practice?</td>
<td>Why did the practice make this assumption?</td>
</tr>
</tbody>
</table>

### Increasing Depth of Analysis

Superficial → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → → In-Depth

### 5 Why questions

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>↓</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
<td>↓</td>
</tr>
</tbody>
</table>

### Answers / Root Causes

### Identified Learning Points/Needs
### Action plan

<table>
<thead>
<tr>
<th>Ref No</th>
<th>Recommendation</th>
<th>Completion by whom</th>
<th>Completion Due Date</th>
<th>Complete and Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
</tbody>
</table>

Please Note- This document is uncontrolled once printed.

Version: 2
Release Date: April 2014
Owner: Director of Health Professions and Nursing Care
Appendix 5: Incident Decision Tree

**INCIDENT DECISION TREE**
Work through the tree separately for each individual involved

**Start Here**

**Deliberate Harm Test**
Were the actions as intended?
- **NO**
- **YES**
  - Were adverse consequences intended?
    - **NO**
    - **YES**
      - Consult NCAA or relevant regulatory body
      - Advise individual to consult Trade Union Representative
      - Consider:
        - Suspension
        - Referral to police and disciplinary/regulatory body
        - Occupational Health referral
      - Highlight any System Failures identified

**Incapacity Test**
Does there appear to be evidence of ill health or substance abuse?
- **NO**
- **YES**
  - Does the individual have a known medical condition?
    - **NO**
    - **YES**
      - Consult NCAA or relevant regulatory body
      - Advise individual to consult Trade Union Representative
      - Consider:
        - Occupational Health referral
        - Reasonable adjustment to duties
        - Sick leave
      - Highlight any System Failures identified

**Foresight Test**
Did the individual depart from agreed protocols or safe procedures?
- **NO**
- **YES**
  - Were the protocols and safe procedures available, workable, intelligent, correct and in routine use?
    - **NO**
    - **YES**
      - Were there any deficiencies in training, experience or supervision?
        - **NO**
        - **YES**
          - Were there significant mitigating circumstances?
            - **NO**
            - **YES**
              - Consult NCAA or relevant regulatory body
              - Advise individual to consult Trade Union Representative
              - Consider:
                - Referral to disciplinary/regulatory body
                - Reasonable adjustment to duties
                - Occupational Health referral
                - Suspension
              - Highlight any System Failures identified

**Substitution Test**
Would another individual coming from the same professional group, possessing comparable qualifications and experience, behave in the same way in similar circumstances?
- **NO**
- **YES**
  - Were there any System Failures identified?
    - **NO**
    - **YES**
      - System Failure
      - Review system

* Based on James Reason’s culpability model

Please Note- This document is uncontrolled once printed.

Version: 2
Release Date: April 2014
Owner: Director of Health Professions and Nursing Care

Page 35 of 49
Appendix 6

BEING OPEN POLICY AND PROCEDURE

This procedure applies to all significant adverse events as defined within the framework.

Guiding principles for being open (adopted from NPSA 2005)

The Principles

The following set of principles has been developed to help the SAS create and embed a culture of being open:

1. Acknowledgement
2. Truthfulness, timeliness and clarity of communication
3. Apology
4. Recognising patient and carer expectations
5. Professional support (for patients, carers their families and for staff?)
6. Risk management and systems improvement
7. Multidisciplinary responsibility
8. Clinical governance
9. Confidentiality
10. Continuity of care

Key Principles

Acknowledgement

All patient safety incidents should be acknowledged and reported as soon as they are identified through the Service’s incident reporting system, Datix. In cases where the patient and/or their carers inform staff when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all staff. Denial of a patient’s concerns will make future open and honest communication more difficult.

Truthfulness, Timeliness and Clarity

Information about a patient safety incident must be given to patients and/or their carers in a truthful and open manner by an appropriately nominated officer. Patients should be given a step-by-step explanation of what happened, which takes into account their individual needs, and is delivered openly.
Communication should be timely, please refer to timeline within the SAER GROUP framework. Patients and/or their carers should be provided with information about what happened as soon as this is practical. It is also essential that any information given is based solely on the facts known at the time. Staff should explain that new information may emerge as an incident review is undertaken, and the patient and/or carers should be kept up-to-date with the progress of the review. Patients and/or their carers should receive clear, unambiguous information and be given a single point of contact within the Service, for any questions or requests they may have. They should not receive conflicting information from different members of staff, and the use of medical jargon, which they may not understand, should be avoided. Staff should check that patients and/or their carers understand what is being said to them.

**Apology**

Patients and/or their carers should receive a sincere expression of sorrow or regret for the harm that has resulted from a patient safety incident. This should be in the form of an appropriately worded and agreed manner of apology, as early as possible. Both verbal and written apologies should be given. Based on local circumstances, senior managers should decide on the most appropriate member of staff to issue these apologies to patients and/or their carers. The decision should consider seniority, relationship to the patient, and experience and expertise in the type of patient safety incident that has occurred.

Verbal apologies are essential because they enable face-to-face contact between the patient and/or their carers and SAS staff. This should be given as soon as staff are aware an incident has occurred. It is important not to delay for any reason, including: setting up a more formal multi-disciplinary discussion with the patient and/or their carers; fear and apprehension; or lack of staff availability. Delays are likely to increase the patient's and/or their carers’ sense of anxiety, anger or frustration.

A written apology must also be given. This should clearly state that the Service is sorry for the suffering and distress resulting from the incident must also be given. Depending on the needs of the patient, carer or family members, alternative forms of communication may need to be considered and offered.

*For Information / Guidance see SPSO Guidance on Apology on page 60*

**Recognising Patient and Carer Expectations**

Patients and/or their carers can reasonably expect to be fully informed of the issues surrounding a patient incident, and its consequences, in a face-to-face meeting with representatives from the Service. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients and/or their carers should be provided with support in a manner appropriate to their needs. This involves consideration of special circumstances that can include a patient requiring additional support, independent advice, advocacy and support including communication support, such as foreign language or BSL interpretation. For further information please contact the Services Equalities Manager, Ann Tobin.

**Professional Support**
The Service encourages its staff, whether directly employed or independent contractors, to report patient safety incidents. Staff should feel supported throughout the incident review process because they too may have been affected by being involved. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.

Where there is reason for the Service to believe that a member of staff has committed a punitive or criminal act, steps will be taken to preserve its position, and the member(s) of staff will be so advised at an early stage to enable them to obtain separate legal advice and/or representation.

The Service encourages staff to seek support from their relevant regulatory / professional body such as the Healthcare Professions Council of Paramedics.

**Risk Management and Systems Improvement**

Patient Safety Reflection, Patient Safety Review and Root Cause Analysis (RCA) are the tools used within the Service to uncover the underlying causes of a patient safety incident, please refer to the PSL & I framework. The reviews and analysis should focus on improving systems of care, which will then be reviewed for their effectiveness by the Significant Adverse Event Group.

**Multi-Disciplinary Responsibility**

This policy on openness applies to all staff that have key roles in the patient’s care. Most healthcare provision involves multi-disciplinary teams and communication with patients and/or their carers following an incident that led to harm should reflect this. This ensures consistency with the philosophy that incidents usually result from system failures and rarely from the actions of an individual.

**Clinical Governance**

Being open is supported through the Service’s Significant Adverse Event Group, with accountability to the Executive Team to ensure required changes are implemented and their effectiveness reviewed. Findings will be disseminated to staff so that they can learn from patient safety incidents. Continuous learning programmes and audits will be developed to allow the Service to learn from the patient's experience of the policy of being open. The information used to share learnings will be treated appropriately, which may mean the incident and/or findings will be anonymised before being disseminated.

**Confidentiality**

The privacy and confidentiality of the patient and/or carer and staff privacy will be fully considered and respected. Details of a patient safety incident should at all times be considered confidential. It is good practice to ask the individual concerned for their consent prior to disclosing information beyond the clinicians involved in treating the patient. Where this is not practicable or an individual refuses to consent to the disclosure, disclosure may still be lawful if justified in the public interest or where
those investigating the incident have statutory powers for obtaining information. Communication with those outside the clinical team should also be on a strictly need-to-know basis and, where practicable, records should be anonymous. In addition, it is good practice to inform the patient and/or their carers about who will be involved in the review before it takes place, and give them the opportunity to raise any objections.

**Continuity of Care**

Patients are entitled to expect that they will continue to receive high standards of care and will continue to be treated with respect and compassion.
Being Open Process

*Being open* is a process rather than a one-off event. There are a number of stages in the process. The duration of the process depends on the incident, the needs of the patient, their family and carers, and how the investigation into the incident progresses. Please see the diagram and further detail below.

**Overview of the Being open process**

<table>
<thead>
<tr>
<th>Incident detection or recognition</th>
<th>Preliminary team discussion</th>
<th>Initial Being open discussion</th>
<th>Follow-up discussions</th>
<th>Process completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detection and notification through appropriate systems</td>
<td>Initial assessment</td>
<td>Verbal and written apology</td>
<td>Provide update on known facts at regular intervals</td>
<td>Discuss findings of investigation and analysis</td>
</tr>
<tr>
<td>Prompt and appropriate clinical care to prevent further harm</td>
<td>Establish timeline</td>
<td>Provide known facts to date</td>
<td></td>
<td>Inform on continuity of care</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Offer practical and emotional support</td>
<td></td>
<td>Share summary with relevant people</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Identify next steps for keeping informed</td>
<td></td>
<td>Monitor how action plan is implemented</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Respond to queries</td>
<td>Communicate learning with staff</td>
</tr>
</tbody>
</table>

**Being Open Procedure**

**Step 1: Incident Detection and Recognition**

Please refer to the SAER framework for information regarding this stage.

**Stage 2: Preliminary team discussion**

The SAER Framework identifies the level response for each type of incident.

1. **Timing**

The initial *being open* discussion with the patient, their family and carers should occur as soon as possible after recognition of the patient safety incident. Factors to consider when timing this discussion include:

- clinical condition of the patient
2. Choosing the individual to communicate with patients, their families and carers

The Service has trained a cross section of family liaison officers to carry out this function, with support from the Divisional Senior Manager, who has sufficient experience and expertise in relation to the type of patient safety incident.

Stage 3: Initial Being Open discussion

The initial being open discussion is the first part of an ongoing communication process with patients, carers and their families. Many of the points raised here should be covered in more detail in subsequent meetings with them.

The patient, their family and carers should be advised of the identity and role of all people attending the Being open discussion before it takes place. This allows them the opportunity to state their own preferences about which healthcare staff they want to be present. If, for any reason it becomes clear during the initial discussion that the patient would prefer to speak to a different healthcare professional, the patient’s wishes must be respected. A substitute with whom the patient is satisfied should be provided.

It should be recognised that patients, their families and carers may be anxious, angry and frustrated, even when the Being open discussion is conducted appropriately.

The content of the initial being open discussion with the patient, their family and carers should cover the following:

- An expression of genuine sympathy, regret and a meaningful apology for the harm that has occurred
- The facts which have been established to date, which have the consensus of the multi-disciplinary team reviewing the incident. Where there is disagreement on which facts have been established, communication relating to these should be deferred until after the investigation has been completed. This means that early dialogue can still be opened with the patient, carers and family members concerned, while further work is done to obtain clarity.
- The patient, their family and carers are informed that an incident investigation is being carried out and more information will become available as it progresses.
- Consideration is given of the understanding which the patient, family members and carer may have of what happened, as well as any questions they may have.
• Consideration and formal noting of the views and concerns of the patient, their family and carer and demonstration that these are being heard and taken seriously.
• Appropriate language and terminology are used when speaking to patients, their families and carers. For example, using the terms ‘patient safety incident' or ‘adverse event' may be meaningless or even insulting to some patients, their families and carers. If a patient’s first language is not English, it is also important to consider their language needs – if they would like the being open discussion to be conducted in French or Urdu, or for example via a sign language should be arranged.
• An explanation about what will happen next in terms of the short through to long-term treatment plan and incident analysis findings.
• Information on likely short and long-term effects of the incident (if known). The long-term effects may have to be presented at a subsequent meeting when more is known.
• In addition to direct assistance, an offer of practical and emotional support for the patient, their family and carers. This may involve getting help from third parties such as charities and voluntary organisations. Information about the patient and the incident should not normally be disclosed to third parties without consent.

Stage 4: Follow-up discussions

Follow-up discussions with the patient, their family and carers are an important step in the being open process. Depending on the incident and the timeline for the investigation, there may be more than one follow-up discussion. The following guidelines will assist in making the communication effective:

• The discussion occurs at the earliest practical opportunity.
• Consideration is given to the timing of the meeting, based on both the patient’s health and personal circumstances, as well as family commitments: e.g. a family member who is key to the meeting may have work commitments.
• Consideration is given to the location of the meeting, for example at the patient’s home.
• Feedback is given on progress to date and information provided on the investigation process.
• There should be no speculation or attribution of blame. Similarly, the healthcare professional communicating the incident must not criticise or comment on matters outside their own experience.
• The patient, their family and carers should be offered an opportunity to discuss the situation with another relevant professional, where appropriate.
• A written record of the discussion is kept and shared with the patient, their family and carers.
• All queries are responded to appropriately. If the query is likely to take more than a few days to collate a response, an acknowledgement of receipt of the query should be sent to the originator of the query.
• If completing the process at this point, the patient, their family and carers should be asked if they are satisfied with the investigation and a note of the response made in the patient’s records.
The patient is provided with contact details so that if further issues arise, it is straightforward for the patient to get back in touch with the relevant healthcare professionals or an agreed alternative contact.

Stage 5: Process completion

1. Communication with the patient, their family and carers
After completion of the incident review, feedback should take the form most acceptable to the patient. Whatever method is used, the communication should include:

- the chronology of clinical and other relevant facts
- details of the concerns and complaints of the patient, their family and carers
- a repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident
- a summary of the factors that contributed to the incident
- information on what has been and will be done to avoid recurrence of the incident and how these improvements will be monitored.

It is expected that in most cases there will be a complete discussion of the findings of the incident review and analysis. In some cases information may be withheld or restricted, for example, in the rare instances where communicating information will adversely affect the health of the patient; where investigations are pending coronial processes; or where specific legal requirements preclude disclosure for specific purposes. In these cases the patient must be informed of the reasons for the restrictions.

2. Communication with the GP
Wherever possible, it is advisable to send a brief communication to the patient’s GP advising them of the events.

3. Monitoring
Any recommendations for systems improvements and changes implemented should be monitored for effectiveness in preventing a recurrence.

The risk manager or equivalent should develop a plan for monitoring the implementation and effectiveness of changes.

4. Communicating changes to staff
Effective communication with staff is a vital step in ensuring that the recommended changes are fully implemented and monitored. It will also facilitate the move towards increased awareness of patient safety issues and the value of being open. Being open fits well with the Service’s own set of values, helping embed a culture of patient safety and continuous improvement in standards of clinical care. It will be important to ensure that communications channels are two-way, in order to for staff to feed back their views on patient safety.

5. Documentation
Throughout the *Being open* process it is important to record discussions with the patient, their family and carers as well as the incident review process. Required patient safety incident documentation includes:

- a copy of the Patient Report Form
- incident report(s)
- records of the incident review and analysis process.

The incident report and record of the investigation and analysis process should be filed separately to the patient’s medical records as a patient safety incident record, and kept as part of the healthcare organisation’s clinical governance reports.

Written records of the *Being open* discussions should include:

- the time, place and date, as well as the name and relationships of all attendees;
- the plan for providing further information to the patient, their family and carers;
- offers of assistance and the patient’s, their family’s and carers’ response;
- questions raised by the patient, their family and carers, and the answers given;
- plans for follow-up meetings;
- progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient, their family and carers;
- copies of letters sent to the patient, their family and carers, and the GP;
- copies of any statements taken in relation to the patient safety incident;
- a copy of the incident report.

A summary of the *being open* discussions should be shared with the patient, their family and carers.

**Conclusion**

It is vital that the Service is open and honest with any patient involved in a significant adverse event, as defined within the framework. It is also vital that the Service apologises for any errors made in the treatment of the patient.
When the Scottish Public Services Ombudsman (SPSO) investigates a complaint and finds unremedied fault, the Investigation Report will recommend what an organisation needs to do to put things right. A common recommendation is that an apology should be offered by the offending organisation. This guidance note sets out what is meant and what is required for an apology to be meaningful.
**what is an apology?**

The SPSO’s preferred definition is: ‘an encounter between two parties at which one party, the offender, acknowledges responsibility for an offence or grievance and expresses regret or remorse to a second party, the aggrieved’.

Whatever the definition, it is clear that an apology is much more than an expression of regret. An apology is an interactive exchange between two parties, so getting the process right is as important as saying the right things. However, in all cases, it is for the recipient to decide whether or not to accept the apology.

**why apologise?**

Not everyone finds it easy to apologise. However, a meaningful apology can have a powerful effect for both parties in diffusing emotion and moving forward to a new phase where resolution is possible. It is often the first step to repairing a damaged relationship. It can help to restore dignity and trust. It says that both parties share values about appropriate behaviour towards each other and that the offending party has regrets when they do not behave according to those values.

**what do complainants want?**

The experience of the SPSO is that complainants want and expect many different things from an apology, including:

- An acknowledgement of the wrong done;
- Confirmation that they were right;
- An understanding of why things went wrong;
- An acceptance of responsibility;
- A reassurance that the problem has been addressed and will not happen again;
- A reconciliation of a relationship, and;
- The restoration of their reputation.

**what is a meaningful apology?**

First and foremost, it is one which gives the complainant what he or she wants. Lazare’ and other authors consider that an apology has a number of integral and essential elements. Although their inclusion may not guarantee success, their absence is likely to result in failure. The importance and necessity of each element will vary depending on the nature of the offence and the overall apology should be proportionate to the harm done.
elements of a meaningful apology are:

- An acknowledgement of the wrong done. This is the naming of the offence. Whether or not it was intentional, an apology must correctly describe the offending action or behaviour. The description must be specific in order to demonstrate an understanding of the offence. It must also acknowledge the resulting impact on the aggrieved.

- Accepting responsibility for the offence and the harm done. This includes identifying who was responsible for the offence.

- A clear explanation as to why the offence happened. This should show that the offence was not intentional or personal. Although most people will want or need an explanation, it should be recognised that this is not always the case. Also, if there is no valid explanation, then one should not be offered. The offender may wish to say that there is no excuse for the offending behaviour.

- Expressing sincere regret. This demonstrates that the offender recognises the suffering of the aggrieved and is remorseful. It can be difficult to communicate sincere regret in writing. The nature of the harm done and needs of the aggrieved will determine whether the expression of regret should be made in person as well as being reinforced in writing.

- An assurance that the offence will not be repeated. This may include a statement of the steps that have or will be taken to address the complaint and, wherever possible, to prevent a recurrence of the harm.

- Actual and real reparations (or redress). This is making amends. The SPSO deals with this element in a separate Policy on Redress.

how should an apology be delivered?

When offering an apology, it is essential to understand how and why the complainant believes that they were wronged and what they want in order to put things right. It is impossible to construct a meaningful apology without this understanding.

The SPSO recommends that an organisation asks a complainant directly what they want and involves them in deciding the form and content of the apology.

Each complaint is unique and each apology needs to be tailored individually. There is no 'one size fits all', but here is some generic good practice:

1. The timing of an apology can be crucial. Once wrongdoing has been established, an apology delayed may be an opportunity lost.

2. A meaningful apology should be owned, active and unconditional (i.e. ‘it was my fault’ rather than ‘if mistakes have been made’).

3. The language used should be clear, plain and direct.

4. The apology should sound natural and sincere.

5. The apology should not question whether the aggrieved had been harmed (i.e. ‘I am sorry if you were offended!’)

6. The apology should not minimise the offence (i.e. ‘no-one else has complained’).

7. It is also essential to apologise to the right person(s).
who should apologise?

As a general rule, where the person who committed the offence is willing and able to apologise, they should be enabled and supported to do so.

If a personal or official apology is delivered by a third party on behalf of an organisation, then it should be delivered by the leader i.e. the person considered by the complainant to be the most accountable.

the benefits of apologising

Properly delivered, a meaningful apology can benefit the organisation as well as the complainant. It can take some heat out of the situation, dissolve anger and reduce stress for both the complainant and the staff dealing with the complainant. It can also help to repair the relationship between the complainant and the organisation.

It is important to remember that an apology is not a sign of weakness or an invitation to be sued. It can be a sign of strength and it can demonstrate a willingness to learn when something has gone wrong. It can also demonstrate a commitment to putting things right. To apologise is good practice and a vital part of any effective complaints management culture.


October 2005

For further information please contact:
SPSO, 4 Melville Street, Edinburgh EH3 7NS
Tel 0800 377 7330
Fax 0800 377 7331
Text 0790 049 4372
Email ask@spso.org.uk
Web www.spso.org.uk
## Review History

<table>
<thead>
<tr>
<th>Issue No</th>
<th>Reason for review and brief description of changes made</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Initial Issue</td>
<td>May 13</td>
</tr>
<tr>
<td>2</td>
<td>Reviewed policy in consultation with trained reviewers</td>
<td>April 14</td>
</tr>
</tbody>
</table>

- **Date of Release:** April 14
- **Date Intranet Posting:** April 14
- **Implementation:** April 14
- **Approved by:** SAER Group

**PFPI Checklist (available from W Mason):** Assessed as meeting the National Standards for Community Engagement checklist (Communities Scotland)

**Risk and Equality & Diversity Impact Assessment (available from A Tobin and Risk Manager):** No adverse impact has been detected - but under continuous review.

---

**Owner:** DHPNC  
**Version No:** 2  
**Doc & page:** SAER Framework  
**Review arrangements:** 2 yearly

---

**Important Information:**  
Prints of this document are uncontrolled and may not be extant or approved versions – check with the Service intranet and or document author/ owner. The Scottish Ambulance Service title, crest, uniform & vehicle design are variously protected in European, UK & Scottish law. In addition, all copyright is retained by the Service © Scottish Ambulance Service 2006 who will always act to redress any identified breach or non-authorised use. The Service adheres to Data Protection, Freedom of Information and Public Sector Information Regulations – further information on these; our licensing requirements and copying approvals are available on the Scottish Ambulance Service web site or on request. Note that this document may be liable to release to other parties under Freedom of Information legislation and the SAS use of email Policy.

---

Please support the Service’s Environmental Programme by not printing this document unnecessarily.

---

All preceding documents should be deactivated/ withdrawn by the recipient or local management, as per SAS disposal or records policy.

---

Please Note- This document is uncontrolled once printed.

**Version:** 2  
**Release Date:** April 2014  
**Owner:** Director of Health Professions and Nursing Care