A NATIONAL APPROACH TO LEARNING FROM ADVERSE EVENTS

Being Open National Guidance

Background

Through the Culture Working Group, we have been developing a package to support boards implement the NPSA Being Open principles to ensure a consistent approach to engaging with patients/families/carers. There are two strands to this work:

- The principles within the NPSA Being Open Framework have been drafted into a reference document for NHSScotland
- A 12 month pilot is underway within NHS Lothian and the National Waiting Times Centre to support staff in implementing the principles of being open when an adverse event occurs

Being Open Guidance

The draft Being Open paper (appendix 1) presents a refresh of the NPSA Being Open Framework (2009) to support a standardised approach to communicating and engaging with patients, families and carers when an adverse event occurs. The standard approach would apply across all care settings within NHSScotland.

The learning and outcomes from the pilot will also help inform the content and provide case studies that can be used as practical examples of the ‘how’. We are also working on developing national information leaflets for patients/families/carers and for staff which can be used as a tool to support implementation.

This paper was issued for consultation to key stakeholders in July to facilitate further engagement and discussion ahead of publishing as guidance with the refreshed adverse events framework later in 2014. 17 responses were received and the comments are summarised in the attached table (appendix 2).

The Programme Board is asked to consider the feedback received, and in particular advise on the following comments/issues that have been raised:

- How the principles interact with existing policies on whistle-blowing/confidentiality/grievance/disciplinary and complaints
- Reflecting/referencing primary care settings
- Reflecting all adverse events not just those involving a patient (eg member of staff, information governance, health and safety)
- Supporting the required ‘culture shift’.
Learning from adverse events through reporting and review:
Being Open in NHSScotland
Consultation paper – June 2014
1. INTRODUCTION

The adverse events national framework aims to support NHS boards to standardise processes for managing adverse events across NHSScotland to enable learning and improvement.

This paper presents a refresh of the NPSA Being Open Framework (2009) to support a standardised approach to communicating and engaging with patients, families and carers when an adverse event occurs. The standard approach would apply across all care settings within NHSScotland.

This paper aims to facilitate further engagement and discussion ahead of publishing as guidance with the refreshed adverse events framework later in 2014.

A response form is provided at Appendix 1 and we welcome responses from all organisations and individuals. Please send your responses to this consultation by Friday 15 August 2014 to: hcis.adverseevents@nhs.net

It is not our intention to publish individual consultation responses. Any requests for detailed information on the consultation responses will be responded to in line with the Freedom of Information (Scotland) Act 2002.

2. BACKGROUND

NHSScotland is committed to delivering high quality healthcare for the people of Scotland. The national approach to learning from adverse events aims to support everyone in NHSScotland effectively manage adverse events, to learn from them, and allow best practice to be actively promoted across Scotland in order that we can continually improve the safety of our healthcare system for everyone.

Open and effective communication with patients, and their family and carers, should begin at the start of their care and continue throughout all the care they receive. This should be no different when an adverse event occurs. Being open when things go wrong is key to the partnership between patients and those who care for them. Openness about what happened and discussing adverse events promptly, fully and compassionately can help patients and staff cope better with the after-effects of adverse events.

Being open involves:
- Acknowledging, apologising and explaining when things go wrong
- If appropriate, conducting a thorough review into the adverse event which involves patients, their families and carers, and aims to identify lessons that will support improvements and help prevent the adverse event being repeated
- Providing proportionate support for those involved to address any physical and/or psychological consequences of what happened.
We are committed to an open and honest approach and fully endorse the principles outlined in the National Patient Safety Agency’s (NPSA) Being Open Framework 2009:

- Acknowledgement
- Truthfulness, timeliness and clarity of communication
- Apology
- Recognising patient and carer expectations
- Culture and professional support
- Risk management and systems improvement
- Multidisciplinary responsibility
- Clinical governance
- Confidentiality
- Continuity of care

This document provides guidance for all staff to support openness with patients, their families and carers following an adverse event. As part of our work to support implementation of these principles, NHS Lothian and the NHS National Waiting Times Centre are undertaking a year long pilot project to:

- test opportunities for application of the principles by establishing a robust process for engaging patients/ families more fully and reliably in adverse events
- establish an improved culture of openness by developing mechanisms for communicating more actively with patients and their families and to ensure staff are supported when adverse events happen
- inform discussions nationally on the scalability of a training package across boards in Scotland and the infrastructure required at a local and national level.

The learning and outcomes from the pilot will be shared over the next 12 months and we will share good practice that is identified in other board areas. This document will be updated and re-issued accordingly.

Senior managers and Board Directors should ensure the infrastructure is in place to support an open and just culture where the overall approach expected within the organisation is one of help and support rather than blame and recrimination, where it is safe to report adverse events from which lessons can be learned and patient safety improved.
<table>
<thead>
<tr>
<th>1</th>
<th>Acknowledgement</th>
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<tbody>
<tr>
<td><strong>I.</strong> <strong>Policy.</strong> The Adverse Event policy must be clear with regards to the delegation and responsibilities of key staff for informing the patient and their family.</td>
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<td><strong>II.</strong> <strong>Process.</strong> Adverse Event documentation (electronic or otherwise) should be configured to ensure interactions with the patient and family are recorded and embedded in the process.</td>
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<tr>
<td>(a) All adverse events should be acknowledged and reported as soon as they are identified.</td>
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<td>(b) In cases where the patient, their family or carers inform healthcare staff when something untoward has happened, it must be taken seriously from the outset.</td>
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<td>(c) Any concerns should be treated with compassion and understanding by all healthcare professionals.</td>
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<th>2</th>
<th>Truthfulness, timeliness and clarity of communication</th>
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<tr>
<td><strong>I.</strong> <strong>Communication.</strong> Should be delivered in an open manner by a nominated person. Where possible this person should remain the primary point of communication through the duration of the engagement with the patient and their family.</td>
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<tr>
<td><strong>II.</strong> <strong>Equality and Diversity.</strong> The individual needs of the patient and their family should be considered. For example if required be prepared to provide interpretation services or advocacy support.</td>
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<tr>
<td>(a) Information about an adverse event must be given to patients, their families and carers in a truthful and open manner.</td>
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<tr>
<td>(b) Patients should be provided with a step-by-step explanation of what happened, in a manner that they can understand.</td>
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<tr>
<td><strong>III.</strong> <strong>Communication.</strong> This should:</td>
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<tr>
<td>• Be timely.</td>
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<td>• Be clear and not ambiguous?</td>
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<tr>
<td>• Provide facts about what has happened. There should be no speculation.</td>
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(a) Patients, their families and carers should receive a meaningful verbal apology as soon as possible after the adverse event.

(b) A written apology, which clearly states the healthcare organisation is sorry for the suffering and distress resulting from the adverse event.


I. **Spoken apologies.** These;
   - Will allow face-to-face contact between the patient, their family and carers, and the healthcare team.
   - Should be given as soon as staff are aware an adverse event has occurred.
   - Should be a sincere expression of sorrow or regret for the harm that has resulted.
   - Should be delivered by a senior clinician involved in the patients care and as agreed by the health care team.

II. **Written apologies.**
   - This should be appropriately worded, based on known facts and delivered as early as possible.
   - Support may be provided by Board Complaint Managers.

Example wording:
"I regret the discomfort experienced .........".
"I apologise for the anxiety this adverse event has caused to you and your family"
"I am sorry that......."

III. **Engaging with the family.**
   - Local teams should agree on the member of staff to give both verbal and written apologies. The decision should consider seniority, relationship to the patient, and experience and expertise in the type of adverse event that has occurred.

IV. **Promptness.** Teams should not delay in giving a meaningful apology for any reason, including:
| Setting up a more formal multidisciplinary *Being open* discussion;  
| Fear and apprehension  
| Lack of staff availability.  

NB. Evidence suggests that delays are likely to increase the patient’s, their families and their carers’ sense of anxiety, anger or frustration.

| 4 Recognising patient and carer expectations  
| (a) Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding an adverse event, and its consequences although this should be based on the needs of the patient and their family.  

| I. Engage and communicate in line with NHSScotland’ shared values:  
| a. Care and compassion  
| b. Dignity and respect  
| c. Openness, honesty and responsibility  
| d. Quality and teamwork.  

| II. All staff should treat the patient and their family empathetically, with respect and consideration.  

| III. Identify expectations. When meeting with the patient and their family explicitly ask their preferred methods of communication and engagement.  

| IV. Identify needs as appropriate to the patient. Ask if the patient requires additional support, such as an independent patient advocate or a translator  

| V. Other support. Where appropriate, information on local area support groups, advocacy providers and other relevant support groups should be given to the patient as soon as it is possible. |
| 5 | Culture and Professional support |  
|   | (a) Boards must create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report adverse events and supported following such events. |  
|   | I. **Culture.** All Boards as part of their broader risk management activity are expected to foster a fair and just culture. |  
|   | II. **Staff support.** Staff should |  
|   | • Feel supported throughout the adverse event review process because they too may have been traumatised by being involved. |  
|   | • Not be *unfairly* exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration. |  
|   | III. **External support.** Boards should also encourage staff to seek support from relevant professional bodies such as the GMC, royal colleges, the MDU, the MPS and the Nursing and Midwifery Council. |  
| 6 | Risk management and systems improvement. |  
|   | (a) Root Cause Analysis, Significant Event Audit (SEA) or similar techniques should be used to uncover the underlying causes of an adverse event. |  
|   | I. **Integration.** Being open principles highlighted in this guidance should be integrated into Board adverse event reporting and risk management policies and processes. |  
|   | II. **Engagement.** The patient and their family will have a unique perspective on the adverse event and should be offered the opportunity to contribute to the review if they so wish. |  
|   | III. **Improvement.** The review should focus on improving systems of care and outputs should be linked to the Boards quality improvement framework. |  
| 7 | Multidisciplinary responsibility. |  
|   | (a) Most healthcare provision is through multidisciplinary teams and the *Being open* process is consistent with the philosophy that adverse events usually result from systems failures and rarely from the actions of an individual. |  
|   | I. **Ensure multidisciplinary involvement.** This is critical to the *being open* process. It is important for Boards to identify clinical, nursing and managerial opinion leaders who will support it. Both senior managers and senior clinicians who are local opinion leaders must participate in adverse event reviews and clinical risk management. |
| 8 | Clinical governance.  
(a) **Being open** requires the support of patient safety and quality improvement processes through clinical governance frameworks in which adverse events are reviewed and analysed to find out what can be done to prevent their recurrence. | I. **Learning.** It is important that;  
- Findings from reviews **must** be disseminated to healthcare professionals so that they can learn from adverse events.  
- Continuous learning programmes and audits should be instigated that allow Boards to learn from the patient’s experience of **Being open**, and that monitor the implementation and effects of changes in practice following an adverse event review.  
II. **Accountability.** There must be a system of accountability through the Chief Executive to the Board to ensure changes are implemented and their effectiveness reviewed. This system must be transparent and open to scrutiny by everyone. |
|---|---|---|
| 9 | Confidentiality.  
(a) When applying the principles of **Being open** Boards must give full consideration of, and respect for, the patient’s, their families and carers’ and staff privacy and confidentiality. | I. **Awareness of information sharing**  
- Patients, family, carers and staff should be made aware that adverse event review reports will be shared for the purpose of learning and improvement.  
- Assurance should be provided that information will be anonymised as far as possible (consent is not needed for sharing of anonymised data).  
II. **Communication.** It is good practice to inform the patient, their family and carers about who will be involved in the investigation before it takes place, and give them the
| 10 | Continuity of care.  
(a) Patients are entitled to expect that they will continue to receive all usual treatment and continue to be treated with dignity, respect and compassion. | opportunity to raise any objections.  
III. See Guidance for sharing information from adverse event reviews. | I. Alternate care provision. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere. |
<table>
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<tr>
<th><strong>Action for NHS Boards.</strong></th>
<th><strong>Guidance for implementation (NB this section will be enhanced through consultation with NHS Boards to include real examples/case studies and with the learning and outcomes from the pilot work)</strong></th>
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</table>
| **Core responsibilities** | **I.** Ensure that across the Board appropriate policies and procedures (i.e. adverse event reporting, risk, claims and complaints, communications and media policies,) acknowledge and identify how to engage and communicate with patients, their families and carers when an adverse event has occurred so that a consistent approach comes from across the Board.  
II. Ensure that all staff who are accountable for management of the policy documents noted in (i) fully understand the principles of being open and able to provide assurance that these are embedded within the appropriate documents. This should be captured through existing KSF and objective setting through the personal development review process.** |
| **(1) Local Policy.** | **(a) Review and strengthen local policies to ensure they align with the Being open framework and are embedded with the Boards risk management and Clinical Governance processes.**  
I. Boards should have available clear concise information, in appropriate formats, which can be given to patients and their families following an adverse event.  
II. Ensure all core staff understand their responsibilities within the being open framework and have received appropriate training to implement being open.  
III. The Boards Complaints Manager in conjunction with the Head of Clinical Governance (or equivalent) should ensure support services are aware of the being open and have stocks of patient information available.** |
| **(2) Patient and family support.** | **(a) Patients and their families should be aware of the Boards approach to being open when they are in care settings.**  
(b) Staff in corporate support functions (i.e. those in Clinical Governance and Quality Improvement teams) should have the information, skills and processes in place to support patients and frontline clinical staff through the Being open process.** |
|                      | **I.** Ensure that across the Board appropriate policies and procedures (i.e. adverse event reporting, risk, claims and complaints, communications and media policies,) acknowledge and identify how to engage and communicate with patients, their families and carers when an adverse event has occurred so that a consistent approach comes from across the Board.  
II. Ensure that all staff who are accountable for management of the policy documents noted in (i) fully understand the principles of being open and able to provide assurance that these are embedded within the appropriate documents. This should be captured through existing KSF and objective setting through the personal development review process.** |
### Leadership

(a) Make a board-level public commitment to implementing the principles of *Being open*.

(b) Ensure senior clinical staff from all professional groups are empowered to promote and implement being open principles when this is appropriate.

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### Responsibilities

(a) Nominate executive and non-executive leads responsible for leading implementation promoting being open across the NHS Board.

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### Training and support

(a) There should be a specific section within the Boards Learning and Development strategy that outlines how the Board will proportionally train its staff to implement being open. This strategy

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<table>
<thead>
<tr>
<th>I.</th>
<th>The Board makes a publicly visible and recordable commitment to implement the principles of <em>being open</em>. Consider; (a) Commitment to ‘being open’ should be explicit in the Boards vision and values programme which should be publically available on the Boards website. (b) There should be an explicit commitment in materials used to promote <em>being open</em> across the organization and patient information leaflets. (c) Patient stories, including those where patients may have died or come to significant harm should be shared at the start of Board, Senior Team and Quality and Clinical Governance meetings.</th>
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<tbody>
<tr>
<td>I.</td>
<td>Boards should name executive and non-executive leads responsible for <em>being open</em>. These could be leads with existing responsibilities for clinical governance.</td>
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<td>II.</td>
<td>Responsibilities for operational implementation of being open should be clearly defined within annual objectives for appropriate senior managers.</td>
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<td>III.</td>
<td>Existing policy and procedures should be updated with staff responsibilities as noted in (i) and (ii)</td>
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<td>IV.</td>
<td>The Board should clearly publicise who are the leads for Being open so that staff and patients are able to identify them.</td>
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<td>I.</td>
<td>Work with Learning and Development teams to conduct an audit of current training (adverse event reporting, communication skills, Complaints etc) to understand how this relates to being open.</td>
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<td>II.</td>
<td>A proportionate approach should be developed for how all staff,</td>
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Potential disciplinary circumstances. Whilst it is extremely rare, where there is reason for the Board to believe a member of staff has committed a punitive or criminal act, it should take steps to preserve its position, and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation.

| Potential disciplinary circumstances. Whilst it is extremely rare, where there is reason for the Board to believe a member of staff has committed a punitive or criminal act, it should take steps to preserve its position, and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation. | 
---|---|
should also indicate how the Board will provide ongoing support to staff who may require it during or following adverse events. | dependant on their role will be trained and supported |
III. Identify senior clinical counselors within the Board who can provide the required support to staff should this be required. These staff should be openly accessible to those who may need to use their support. |

(6) **Metrics for improvement.**

(a) The Board should utilise indicators that show compliance with local process and quality of outcomes. |

(6) **Visibility**

(a) Raise awareness and understanding of the *Being Open* principles among staff, patients and the public in general. |

I. Promote the *Being open* principles amongst staff through newsletters, team meetings, intranet, special interest meetings, governance meetings. |

II. Explicitly include reference to the Boards approach to being open in staff induction programmes. |

III. Promote the Board commitment and approach to *Being open* through local media and patient and public forums |
### Adverse Events Consultation Questions/Answers

<table>
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<tr>
<th>Respondent</th>
<th>Question 1 – Do you have any generic comments on the paper</th>
<th>Question 2 – Do you have any comments on the principles identified to support implementation</th>
<th>Question 3 – do you have any comments on the actions for the Boards</th>
<th>Question 4 – Do you have examples of good practice that we could consider?</th>
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<tr>
<td>Individual</td>
<td>Pleased with the approach outlined therein. I do feel it was worth highlighting the ethical obligation, as articulated by the GMC, on the professional duty to acknowledge when something has gone wrong and provide the patient/relatives with an honest explanation. Also an expression of dissatisfaction requiring a response is de facto a complaint. This can be verbal or something raised as a ‘concern’ but still should be dealt with inside the NHS complaints procedure.</td>
<td>No, but the nature of apology/acknowledgement has to be genuine rather than a legalistic expression of regret abrogating liability.</td>
<td>Any apology needs to be prompt as a failure to [adequately] address this at the earliest opportunity (and I’d never advocate saying sorry when that clinician has not done anything wrong) is perceived as tokenistic and designed to minimise the financial consequences form litigation that may subsequently flow rather than truly addressing a legitimate grievance.</td>
<td>No, but over the years I’ve had plenty of examples of bad practice where the doctor wanted to say sorry, the Medical Defence Organisation directed them to the GMC guidance and the Board dragged its heels.</td>
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<tr>
<td>Royal College of Nursing Scotland</td>
<td>The Being Open principles are a positive move towards an open and supportive culture enabling learning from adverse events. They align with NHSScotland’s key values of openness and honesty and with the RCN’s own principles of nursing practice Principle E - Nurses and nursing staff are at the heart of the communication process: they assess, record and report on treatment and care, handle information sensitively and confidentially, deal with complaints effectively, and are</td>
<td>NHS Boards must have policies and practices in place that protect whistle-blowers and foster a culture of transparency and openness among staff and patients. Staff must be able to trust their employers and feel confident, supported and encouraged to report on adverse events. There are confidentiality and employment issues for staff involved in adverse events that need to be taken into consideration. In our previous response to “Building a national approach to learning from adverse events through reporting and review: A consultation paper – January 2013”, we recommended that the</td>
<td>We are pleased to see a focus on Boards providing training, guidance and support for staff in implementing the being Open principles. In relation to culture and professional support (p.6): - We agree that “Staff should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration”. This builds on the important principles of a “just culture” and “personal, professional and organisational accountability” set out in the 2013 national</td>
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conscientious in reporting the things they are concerned about. We recognise that informing patients about adverse events is not as widespread as it should be. There is a complex range of factors that may explain this, including fear of litigation, disciplinary action, difficulties in communicating, staff unaware of their rights/protections and the culture of the employing organisation not encouraging disclosure.

Confidentiality is a key issue for staff involved in adverse events and a confidential approach will help encourage an open reporting culture. A “no fault approach” as opposed to a “blame culture” will encourage reporting and maximise information disclosure in relation to the adverse event. In order to feel comfortable reporting on adverse events staff will need assurances that disclosure of this information will not have negative implications for them.

While we support the principles of Being Open, there are a number of points we think need to be clarified or addressed:

Further clarity on how the principles will interact with existing policies and procedures on confidentiality, whistleblowing and grievances.

Providing quality,

NHSScotland whistleblowing PIN Policy is widely promoted and that the protections available to staff under the Public Interest Disclosure Act (1998) are made explicit. Although staff reporting in relation to adverse events may not always equate to “whistleblowing”, appropriate support must still be in place to protect and reassure workers that speak up and encourage a culture of openness to help improve services.

We feel that the following comments (on p.11 of this consultation and paragraph 9 of the consultation on data redaction), need further explanation:

- **Potential disciplinary circumstances.** Whilst it is extremely rare, where there is reason for the Board to believe a member of staff has committed a punitive or criminal act, it should take steps to preserve its position, and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation.

- “We also need to protect the identity of individual staff involved in the adverse event notwithstanding cases involving negligence”.

Even if it turns out that an adverse event involves potential negligence or disciplinary circumstances, staff are still entitled under the Data Protection Act to the protection of their personal data contained in an adverse event review report. Not to do so would discourage staff from coming forward and reporting events as they occurred. Will information framework on adverse events

- To fully support the being open principles, there needs to be an organisational shift towards a culture that fosters open and effective patient-professional relationships, removing the fear of individual blame and the threat of litigation. Although a no blame culture which encourages reporting should not be confused with a no responsibility culture, staff need to be reassured that they will be supported through admission of genuine error. Staff must be given training on how the review/reporting procedure works and be entitled to receive feedback in relation to any report they make, including information about any action taken or reasons for not acting.

- There should be greater clarity on how this will interact with the Board’s whistleblowing policy.

In relation to clinical governance and learning (p.7):

- It should be clearer which healthcare professionals the reviews should be shared with and at what level (local, national etc)

- Liaison with patients and families around adverse events is sensitive and boards should be continually seeking to improve their performance. We agree that Boards should instigate continuous learning programmes and audits (p.7).

However there is also a need for wider national learning from
comprehensive training for all staff on their rights and obligations arising out of this consultation. Assurances that reporting under the being open principles will not jeopardise staff’s position in the case of any further proceedings disciplinary or otherwise.

reported as part of an adverse event review be used against staff in any subsequent disciplinary proceedings or accusations of negligence? Unions should be available to provide advice/representation and staff must be protected and supported from the outset of the adverse event review process. There should be no negative implications for staff who choose not to engage in the reporting process if they fear the it will incriminate them or adversely affect them in any subsequent disciplinary or other legal proceedings.

adverse events, for example from the current pilot projects, which we hope that Healthcare Improvement Scotland will be supporting.
- There must also be quality improvement processes and clear lines of accountability in relation to adverse events within services that are delegated to integration authorities. The responsibilities of executive and non-executive leads in implementing the Being Open principles (p.10) must also be considered in the context of integration.

In relation to confidentiality (p.8):
- As noted in our response to the consultation on data redaction, this is a particularly complex issue. There must be detailed guidance for staff, along with training and support for staff carrying out anonymisation of reports in particular. Though we agree a standardised approach can be a useful guide, there will still need to be individual consideration for each adverse event review report.
- "Patients, family, carers and staff should be made aware that adverse event review reports will be shared" See our points in the consultation on data redaction about it being best practice to seek consent for sharing information in adverse event review reports.

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| individual | In general the paper seems to focus too much on the right to staff to remain anonymous, while not allowing patients/family/carers to decide whether the process has been fair, open and reached appropriate conclusions prior to information about them to be distributed to the general public, ignoring the patients/family/carers right to control access to their information. | I feel that the following changes are needed to improve the principles:  
- Page 4, Point 2: Truthfulness, timeliness and clarity of communication, Part 3: Communication.  
Add communication should be at regular intervals to ensure family are engaged with process.  
- Page 6, Point 4: Recognising patient and carer expectations Part 3: Identify expectations.  
Add clearly state whether patient's expectations can be met, and if not explain why this will not be possible.  
- Page 6, Point 5: Culture and Professional support, Part 2: Staff support: Remove Not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.  
- Page 7, Point 6 Risk management and systems improvement, Part 2: Engagement.  
The patient and their family will have a unique perspective on the adverse event and should be offered the opportunity to contribute to the review if they so wish.  
Change offered to encouraged  
- Page 7, Point 7, Multidisciplinary responsibility. Part 1: Ensure multidisciplinary involvement. This is critical to the being open | I feel that the following changes are needed to improve the action for the boards:  
- Page 9, Point 2: Patient and family support, Part 1  
Boards should have available clear concise information, in appropriate formats, which can be given to patients and their families following an adverse event.  
Change following to prior to adverse events.  
- Page 9 Point 2: Patient and family support, Part 3  
The Boards Complaints Manager in conjunction with the Head of Clinical Governance (or equivalent) should ensure support services are aware of the being open and have stocks of patient information available.  
Change to should ensure support services proactively make staff and patients aware of what an adverse incident is, how to report these, and what support is available for staff and patients.  
- Page 11 below final table: Potential disciplinary circumstances. Whilst it is extremely rare, where there is reason for the Board to believe a member of staff has committed a punitive or criminal act, it should | Not at present, but as we are experiencing the SCI process at present as and when something positive occurs I might be in a position to change that opinion. |
process. It is important for Boards to identify clinical, nursing and managerial opinion leaders who will support it. Both senior managers and senior clinicians who are local opinion leaders must participate in adverse event reviews and clinical risk management.

Add independent monitors should supervise senior staff to ensure that they are being open about failures in their organisation.

- Page 8, Point 9, Confidentiality. Part 1: Awareness of information sharing
  Patients, family, carers and staff should be made aware that adverse event review reports will be shared for the purpose of learning and improvement. Assurance should be provided that information will be anonymised as far as possible (consent is not needed for sharing of anonymised data).

Add no review reports should be shared until the patient/family/carer has accepted the findings of the review, or the findings have been externally reviewed and accepted by an independent investigation team.

- Page 8, Point 9, Confidentiality. Part 2: Communication.
  It is good practice to inform the patient, their family and carers about who will be involved in the investigation before it takes place.

Change to patients and their family and carers must be informed of who will be involved in the investigation at the earliest possible moment.

take steps to preserve its position, and advise the member(s) of staff at an early stage to enable them to obtain separate legal advice and/or representation.

Change to it should publicly advise that the board have reason to believe that there could have been a punitive or criminal act committed and that the relevant external agencies have been informed and disciplinary procedures have begun.
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<tr>
<th>Patient</th>
<th>As the Next of Kin currently involved in a review – this document builds on the Ayrshire and Arran recommendations particularly relating to communication with patients/family and other stakeholders. Our only desire was for those involved in our son’s care to be open and transparent about where things could have been done differently.</th>
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<tr>
<td>Care needs to be taken to avoid a tick box culture in relation to contact with patients and families. One directorate involved in the review of our son’s death decided that meeting with us once was sufficient, followed up by sending us a draft report to consider including basic factual errors about names and relationships that had been pointed out in the meeting. We have recently discovered that the final report was released to staff involved in the care of our son two weeks before we were given sight of this. This felt very disrespectful and demonstrated a lack of openness. Having a named person responsible for contact with families is key to gaining their confidence. Providing clear support for patients and families involved in adverse events is also key. For us this wasn’t bereavement support – but someone who could talk us through the process, regularly contact us to tell us what was happening and explain any delays.</td>
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<td>At an early stage I arranged a meeting with my son’s GP (who was unknown to me). The GP and Practice manager were a little nervous but from the start were very open. After speaking with them and realising that their responses matched what my son had said before he died I felt considerably more confident about the actions taken by the GP. At a later date I received information regarding contact between the GP and a clinician. Having established confidence in the GP as a result of his initial openness I felt able to approach him again and seek clarification. This in turn enabled me to accept the response from the clinician. Dealings with senior health board managers felt less than open, often with feelings of hidden agendas. Meetings require considerable preparation to ensure that the right questions are asked. This would be an exhausting process at any time – but even more when you are recently bereaved. Our experience is that NHS managers will only respond to direct questions, they will not present unasked for information.</td>
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<td>Respondent</td>
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<tr>
<td>Royal college of Physicians of Edinburgh</td>
<td>The Royal College of Physicians of Edinburgh (&quot;the College&quot;) supports the overall aims of the paper and welcomes the proposal to provide guidance to all NHS Scotland staff to support openness around adverse events. We strongly support the stated aim in the background section of that paper that senior managers and Board Directors should ensure that the infrastructure is in place to support an open culture and the improvement of patient safety. The College agrees that a pilot project is sensible before implementing the principles more widely, and we would suggest a phased introduction of a national approach. However, since the principles set out in the paper are largely beyond dispute – openness, fairness, honesty, timeousness – it is hoped that the phased introduction could be rapid after a brief pilot.</td>
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<tr>
<td>NHS Borders</td>
<td>The paper does not consistently reflect the adverse event management framework in its approach to ALL types of adverse events, this consultation addresses being open when it is a patient related event, what if</td>
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<td>NHS Highland</td>
<td>We thought the paper was very helpful. It confirms the approach we are aspiring to. We fully endorse the principles of being open, however sometimes the practical application can be challenging so it will be useful to see the outcome of the pilot work around this. A national approach to training and learning will also</td>
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| | it’s a staff related event? Or healthcare partner eg GP, Local Authority. Is separate guidance being developed? If yes does this devalue staff as not having exactly the same principles applied to them and their relatives? To be consistent with the definitions within the HIS adverse event management framework Being Open should apply to all significant adverse events involving harm to people. Current experience suggests that there is a potential for some patients/relatives/carers to interpret an apology as being an admission of guilt/liability and raises expectations of an ‘easy claim’. There is a clear need in certain SAEs to seek legal advice from CLO before engaging fully with patients/relatives/carers, would suggest this is clearly stated at the beginning of the principles. | undermine patient community confidence in services if all adverse events are disclosed automatically. Section 5 culture and professional support: ii) staff should not be unfairly exposed to punitive action, increased medico-legal risk or any threat to their registration. What does this mean? The risk of damage to reputation and legal action is increased as a result of involving the public: Health Boards cannot control what the public will do when they are given increased information as to how the event took place, how they will react and who they will tell, its naive to think otherwise. Is this fair rather than unfairly exposed to this risk? | This should be clarified to read following a significant adverse event that has caused the patient harm. Health Boards could not give out this information after every event as defined in the HIS framework, adverse events are too numerous however where harm has occurred is less so. When no harm has occurred then it may cause un-necessary distress. | |
be helpful. I think we have to consider this as a journey. We should also not underestimate the support that both patients, families and staff will need in openly discussing adverse incidents in a valuable and constructive way.

| NHS Grampian | This paper will prove to be invaluable in setting out the context to reporting and learning within all Health Boards in Scotland. Needs still to be greater clarity on adverse events eg a missed medication dose. It is probably clear at serious end of continuum where patient has suffered harm. Risk that system becomes overwhelmed if every small incident included. Under the heading of ‘Background’ as noted on the third point - Providing proportionate support for those involved to address any physical and/or psychological consequences of what happened. How do we define proportionate? This can lead to variation in practice (support) offered by Health Board with individuals raising concerns of unfair treatment. This is laid out well and addresses the relevant points. Principles seem comprehensive. Under section 8, point 1 – Learning. Findings from reviews must be disseminated to healthcare professionals so that they can learn from adverse events. Reviews should be conducted in a timely manner and feedback must be disseminated to healthcare professionals promptly and effectively to ensure errors/ near misses are not allowed to continue whilst front line staff await a complex process to run its course. |
| General Surgery Datix-M&M Process Aberdeen Royal Infirmary | Adverse outcome or incident reporting is vital in creating a safe, effective and reliable healthcare system. However, having carried out a study analysing the reporting behaviours and barriers to reporting amongst surgeons, an integrated reporting process encompassing a structured web based reporting form and a more standardised and structured Mortality and Morbidity meetings was established in General Surgery. The objectives of the integrated reporting process is to • Improve the reporting of adverse outcomes and near |
etc. Perhaps this can be replaced with 'adequate', or simply removed.

- Standardise the structure of discussions at mortality and morbidity meetings
- Improve the dissemination of data from the reported adverse outcomes
- Ensure that the appropriate actions are taken where required and lessons are learnt from the reported adverse outcomes

The Datix reporting tool was modified and simplified to create a speciality specific reporting form. With the support of all the surgeons and management team in NHSG, the General Surgical Mortality and Morbidity meetings were restructured to a weekly one-hour process. The meetings were standardised according to the redesigned Datix forms. Each ward/unit (out of a total of four) would present their reports on a weekly basis. Emphasis is placed on the lessons learned and action outcomes based on the consensus of all those present and these are recorded onto the Datix system. A Datix consultant from each ward was nominated to ensure cases reported were
highlighted at these meetings. As the volume of cases do occasionally exceed the time of these meetings, the Datix consultant also has the responsibility of signing off any cases he/she feels does not merit further discussions at these forums.

A PDF summary of cases discussed, lessons learned and action outcomes is disseminated to all the consultants at the end of the meeting. Details of cases discussed can be accessed at any time for audit or learning purpose. Regular audits and Quality Improvement meetings can be organised to ensure lessons are learned and there is improvement in outcomes.

A training day for surgical registrars in the region utilising this database of cases has also been carried out with positive feedback from trainees and trainers.

This system has since been emulated in the other specialties and there is evidence of significant improvement in reporting amongst medical staff across the health board.

Conclusion
- Appropriate improvements are being made to support the process.
The integrated reporting system has improved adverse outcome reporting.
• It has resulted in a structured and compelling learning process.
• Adverse outcomes or near misses can be monitored and key themes identified to focus local and national improvement initiatives.
• Addressing adverse outcomes and providing timely feedback, helps prevent errors from repeating. This process translates into improved patient outcomes.
• This process can be aligned to the principles set out by HIS (Learning from adverse events through reporting and review).

Scottish Public Services Ombudsman

The Scottish Public Services Ombudsman very much welcomes the development of this guidance and the inclusion of the reference to SPSO’s guidance on apology. Two key considerations that the SPSO would wish to highlight here are:
• The status of such guidance in relation to complaints about the handling of an adverse event. SPSO’s focus here would be in the event that a patient or their family made a complaint about a
• Our view is that the Principles are clear and reflect the key considerations with regards to being open during the adverse events process. In terms of the table, it could benefit from more clarity as to the purpose of the LHS and RHS columns. For example, is the purpose of the LHS to describe the principle in more detail and the RHS to establish the requirements that fall under that principle?
• Under principles 2 and 4, the focus is on how information will be communicated to patients and families. We would suggest
• It would be helpful to clarify if this document is a time bound action plan, and if so, what the process for updating will be.

The SPSO publishes all its findings, including highlighting areas of best practice and would be happy to work with HIS to identify relevant cases in this area.
<table>
<thead>
<tr>
<th>NHS Fife</th>
<th>Not sure if this is so much a consultation as an update on the work of Culture Group with recommendations to prompt Boards to undertake a gap analysis of their local frameworks. Content is straightforward and reasonable, clear and easy to understand.</th>
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<td>To have better effect, the practicalities of implementing this guidance at operational and strategic levels need to be taken into account. “This is how we do business”, echoing the points made above. This must take cognisance of the shift in culture and mindset that may be required in some areas and by some professional groups. NHS Fife developed a Being Open strategy.</td>
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<td>Boards will require to categorically state that “Being Open” is an expectation and make an explicit commitment to this. The actions for the Board seem reasonable; however they highlight the need for us as a Board to clarify a number of points, i.e., who is responsible for what - who is the Exec Lead and Non Exec Lead.</td>
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|          | Awareness at The Board
NHS Fife Board is developing the strategic framework which is underpinned by vision and values, which will reflect the Board commitment to being open. Since Oct 2013 a set of data is presented at the Board on key indicators relating to safe, patient care satisfaction, and complaints handling. |
understand. It provides food for thought on implications for local implementation. Need to ensure that 'Being Open' is seen as integral to good day to day practice. Not separate or different. Care must be taken not to disable or desensitize 'routine communications with patients, families and carers. Accountability and ownership must be maintained. Policy in response to NPSA guidance several years ago. While it served a useful purpose in terms of setting out principles, expected behaviours and examples of Being Open in action, its impact was limited to some extent by the challenge of supporting implementation in a meaningful way to ensure that these principles are core to all aspects of our work. These principles are sound and fundamental to successful implementation.

Success of the national framework will depend on many factors, not least, Board level strategic frameworks which clearly articulate the organisation's aspirations, and expectations for exemplary leadership behaviours (eg 5 High Impact Leadership Behaviours (Swensen, S.et al, 2013) and supporting actions (Seven Leverage Points (Reinertsen, JL.et al, 2008). who is responsible for training, are all our policies and procedures consistent, what about the clear concise information for families. A gap analysis is likely to be needed to identify the extent to which Boards' existing 'frameworks' - documentation and existing polices - relating to eg adverse events, complaints, communications and media, align with Being Open principles.

In terms of patient and family support and provision of apologies and information, there would perhaps be merit in developing criteria that would state under which circumstances we would provide written information to patients and their families. A national suite of information which could be provided to patients and families in a range of situations could be most helpful. This would ensure a consistent standard in terms of information quality and presentation and reduce the risk of variation in practice. effective and person centred care. In addition to bring some of these data to life a story is presented to the Board. from a patient/family perspective and from a staff perspective; the stories have been a mixture of good and bad news stories.

Patients /Families/Carers As part of the management of significant adverse events, we are developing our approach to 'being open' without naming it as such. In addition to the expectation that appropriate members of staff provide an explanation and apology close to the time of the event, we write to inform the patient, (family/carers as appropriate), SAER has been commissioned. We offer them the opportunity to meet, and/or contribute to the review as they wish. They are invited to identify any issues that they wish the review to consider. We have recently agreed that we will share draft SAER reports with patients/families prior to these being finalised. At the concluding stage of the review family and carers are asked to assist with developing this further by evaluating the review process for them and
how it felt. The form/set of questions is still being tested.

Staff
‘Fair and just culture’
We continue to strive to foster a fair and just culture in all aspects of our business, including:
• Supporting staff through the adverse event review process. At the concluding stage of the review staff are asked to assist with developing this further by evaluating the review process for them and how it felt. The form/set of questions is still being tested
• Providing information on sources of support and advice

‘Second Victim’ Project
We recently commissioned a piece of work on ‘second victim’ in relation to the impact of adverse events on staff.

LEARNS Summaries
These capture key elements of SAER reviews.

Local Issue
Emerging Themes
Action Taken
Review
Now
Share
These are currently being tested but early feedback has been positive. As a Board we are now exploring options for sharing the learning across the organisation
and as with all such developments, we must consider the circulation and impact of the summaries. We need to consider how we monitor the extent to which the principles of being open in relation to adverse events are being met.

**Mortality Newsletter**
Highlights issues emerging from adverse events and mortality reviews. To date issues covered include The Deteriorating Patient, VTE and In-patient Falls.

**Inter-specialty CG Meetings**
Programme designed to look at the processes of data feedback, sharing of lessons learned from reviews and involving departments in improvement. Initial event held May 2014, further sessions scheduled August and November 2014.

**Metrics for Improvement**
Through SPSP measures can be seen in the majority of areas which relate to process measures. Currently under development in NHS Fife is an electronic dashboard which has some outcomes measures included. This Quality Dashboard relates indicators under safe, effective and person-centred.
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<th>Question 4 – Do you have examples of good practice that we could consider?</th>
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<tr>
<td>NHS Tayside</td>
<td>Agree that it is vital to promote and overall approach of “help and support”. Fully support the NPSA Being open Framework.</td>
<td>Clearly sets out the key actions that need to be addressed</td>
<td>NHS Tayside already comply with several elements of this guidance and are currently reviewing systems and processes to ensure that all elements of this guidance is fully complied with. How will evidence of compliance be established? Metrics for Improvement: what indicators? Are Boards allowed to devise their own, if so how will cross-Scotland comparison/evaluation work?</td>
<td>AEM Policy Guidance Appendix 1 – Excerpt from NHS Tayside Adverse Event Management Policy SCEA Leaflet Appendix 2 – NHS Tayside SCEA Leaflet April 2014 Frequently Asked Questions for staff Appendix 3 – SCEA Frequently Asked Questions SCEA Communication SOP Appendix 4 – SCEA Patient Family Contact Revised April 2014</td>
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<tr>
<td>NHS Lothian</td>
<td>Outdated language/concept used in places, not in line with national framework eg Root cause, incidents. Project currently being undertaken in Lothian and Golden Jubilee will inform and provide evidence so this could only be seen as interim guidance.</td>
<td>Some of this section is repetitive and 5-8 are not directly related to being open with patients – see also tracked changes / comments on paper.</td>
<td>As stated in response to data reductions and reporting documents, guidance on reporting to FOIs would help with national consistency. Some of this section is prescriptive – should identify the ‘what’ rather than the ‘how’ – the pilot work will inform the ‘how’. Once this has reported, it would be helpful to have more specific actions so that a consistent change is achieved.</td>
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<td>State Hospital</td>
<td>For the State Hospital it is not always appropriate to ‘be open’. As a high secure mental health hospital, over half the reported incidents (2013/14) were on patient behaviour - verbal aggression, attempted assaults on patients/staff. In this context, we would not routinely consider ‘Being Open’ as communication. When reviewing more serious adverse events, we take advice from the patient’s RMO as to whether there would be benefit to speak with the patient. The majority of times this is not appropriate given the patients mental health post-incident. This is documented within the report. We would also not routinely call families to advise them that their relative has been subject to a more minor adverse event. Some patients do not have much contact with their families. It is decided on a patient by patient basis. At the next contact, any significant issue would be passed on to the named person for their information. Should harm be ‘caused’ to the patient, as would occur in the main in other NHS organisations, then this would be followed.</td>
<td>No issues with the principles suggested but would suggest this should be implemented proportionately.</td>
<td>Again, this should be proportionate. Would an e-learning module be provided to support staff training?</td>
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<td>National Services Scotland</td>
<td>The guidance is focused on the openness in the management of adverse events involving patients/families/carers. It is important to recognise that the guidance can be applied in the management of other adverse events including information governance (involving person identifiable data) or serious health and safety incidents. In both cases guidance about how to apply the Being Open guidance to support the affected individual would be welcomed. We would also welcome the inclusion of blood donors in the guidance. Typically NSS policies and guidance refer to ‘patients and donors’. A definition of an adverse event should be included in the paper along with guidance on: • Dealing with adverse events associated with 3rd party supplies of medicines that may be defective • Dealing with events and impact discovered several years after treatment • Whether or not these principles will apply to a clinical trial We suggest that more emphasis</td>
<td>We support the principles identified in the document</td>
<td>No comments</td>
<td>None</td>
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National Services Scotland
is placed on improvement, trending events and managing repeat events under section 6. We would also suggest the inclusion of guidance on metrics for improvement.

Under clinical governance it might be useful to state some specific considerations e.g. does a national alert regarding practice or equipment need to be considered by MHRA, should the incident change any current threat assessment.

<p>| NHS Forth Valley | A good expansion of the original ‘Being Open’ paper. The tabulated layout is easy to follow and less ‘texty’ than the original paper. Couple of typos on page 8 Section 9. Font size on page 5 varies – website Inconsistent use of italics in column 2. Page 9 Being - capitalize first letter | The document gives good guidance on attaining the principles identified in the document. It will be interesting to hear how the pilot in Lothian goes – is there any detail around theork being done? | It would be helpful to benchmark the resources that each Health Board has in place to manage SAE Reviews. Agree that it is important for the Board to pursue a consistent approach to communicating with patients, families and carers. This might possibly include an early indication that a review will take place before a decision has been made to progress to s SAER. We invite patients, families, carers to attend part of a review meeting to allow them to meet the team and to communicate what concerns and ask questions that they would like the review to address. This helps to strengthen the communication interface and for the team to express sincerity around the process. There are leaflets for patients/families/carers and for staff which follows the principles of ‘Being Open’. In addition, a framework letter personalised the process following the initial discussion. Additional, we drafted guidance based on the Being Open document. The format here is probably easier to follow. |</p>
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<td>NHS Shetland</td>
<td>The paper is timely. A key message from the National Approach to learning from Adverse Events Conference in May was the need to understand the consequences of adverse events from the patient perspective and to balance the reporting and review process with compassion, empathy and support for those affected. Murray Anderson-Wallace in particular emphasised the necessity to urgently improve the quality of our response after harm has occurred. We used to make specific reference to the Being Open guidelines in previous versions of our Risk Management Strategy and Incident Reporting, Investigation and Management Policy however not in the most recent versions (although these do reflect the general principles of the Being Open framework).</td>
<td>NHS Shetland’s revised Adverse Event Policy was approved by the board’s Strategy and Redesign Committee in May 2014 to comply with the timescale specified in the national framework but on the understanding that it would be seen as a ‘holding policy’ and subject to immediate review. It was recognised that the policy document needs to be simplified and contain clearer messages and guidance as well as reflecting feedback from staff and learning across Scotland as a consequence of the development of the national approach. The aim is to have a rewrite completed by the end of October 2014 and this will take cognisance of the principles identified to support implementation of Being Open outlined in the consultation paper.</td>
<td>We would envisage incorporating actions required into our Risk Management Action Plan 2015/16. Following an information-sharing visit to the Quality, Governance and Risk Unit at NHS Grampian in June 2013, we adopted their practice of recording patient/family contact on the Datix electronic risk management system. Following our system upgrade in April this year, we have included the question ‘Family, Carer etc contacted?’ on the adverse event reporting form. This is a compulsory question and answering ‘Yes’ prompts the reporter to add contact details. Answering ‘No’ brings up another question asking for a reason.</td>
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<td>Scottish Ambulance Service</td>
<td>I welcome guidance on this as an appendix to the National Framework, however I have concerns regarding the assumption within the paper that you would disclose to the next of kin or patient on every occasion. Under section 3 - Apology – ‘A senior clinician involved in the patient’s care to provide the apology’ is not appropriate for the SAS, however a senior manager would carry this out nonetheless.</td>
<td></td>
<td>How are Healthcare Improvement Scotland planning to support Boards to implement such actions - ‘Identify senior clinical counselors within the Board who can provide the required support to staff should this be required’.</td>
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as its not always appropriate, there is never a black and white on this, therefore the guidance should read ‘if appropriate’. However a very strong presumption that we will be open in the majority of cases is necessary to change the culture of the NHS.

It is important to note that in SAS there are times when we don’t identify a SAER has occurred until we are notified by a third party, therefore delays are unavoidable. It can sometimes be difficult to locate the patient.

Under section 5 Culture and Professional Support - External support. Boards should also encourage staff to seek support from relevant professional bodies such as the GMC, royal colleges, the MDU, the MPS and the Nursing and Midwifery Council. I don’t think the purpose of the GMC, NMC etc is to provide support. It is to protect the public. Royal Colleges covers nurses and midwives. College of paramedics?

Under section 9 Confidentiality - Communication. ‘It is good practice to inform the patient, their family and carers about who will be involved in the investigation before it takes place, and give them the opportunity to raise any objections’ I do not agree with this statement, it is the responsibility of the Board to nominate the most appropriate people to carry out the review based on expertise and experience in the relevant field.

For example, are HIS planning on supporting the above action by organising training courses for staff?