What is the purpose and focus of the review?

Reviewing NHS boards’ governance arrangements and processes for managing adverse events helps us to identify whether appropriate learning and improvement is taking place to reduce the risk of events happening again.

Our reviews focus on the six key recommendations (18–23) for NHS boards from the NHS Ayrshire & Arran report (2012) to provide assurance that NHS boards are effectively managing adverse events. We measure NHS boards against the recommendations within the NHS Ayrshire & Arran report and against their own policies.

The review process has two key phases:

- pre-visit analysis, and
- the review visit.

When will the board be notified of our review visit?

Healthcare Improvement Scotland will notify NHS boards 10 weeks prior to the visit date.

What information will NHS boards be asked to provide and how much time will be given to return the information?

All boards have already provided policies and procedures relating to the management of adverse events as part of the baseline returns received in September 2012.

Healthcare Improvement Scotland will ask for the following additional information before the visit date:

10 weeks before visit with 1 week to return

A list of your ‘significant’ (or however described locally) adverse events over the last 18 months. The list should include:

- Local case reference
- Date of event
- Directorate /department where event happened
- Status / stage of review e.g. investigation underway / action plan being implemented / changes implemented & evidenced
- Description of event – an overview to the event e.g. the ‘description of incident’ provided within Datix
The purpose of this initial request is to allow the review team to select a number of adverse event cases from which we will ask for more detailed information (see below).

8 weeks before the visit with 2 weeks to return

- Documentation relating to the cases selected. This should be comprehensive in nature and should include identification reports, investigation reports, action plans, learning summaries, meeting notes/minutes, emails and so on associated with the individual incident throughout the management process.
- All the relevant governance committee minutes e.g. clinical governance committee (and related papers) over the last 18 months. To include where specific adverse events are presented including, but not restricted to, the cases referred to above.
- Evidence of measurement and presentation for example, governance committee minutes and papers against any Key Performance Indicators. Where available please include information relating to any further assurance mechanism’s you may have in place regarding decision making and escalation.
- A statement providing information regarding the application and implementation of your NHS board adverse event policy and related procedures in how they apply to primary care - including independent contractors, for example GPs, Community Pharmacy & Dentistry.

We will ask you to invite the staff either involved in the selected adverse event cases to a discussion on the review visit day. Please note that the case discussions are to explore the process of managing adverse events within the organisation, using the case as an example, and are NOT about any clinical decisions or judgement within that particular case.

We will also provide you a draft programme for the review visit day. Healthcare Improvement Scotland staff will liaise with the NHS board's nominated contact to confirm the detail of the programme.

What does the programme of the review visit include?

There are a number of planned sessions which will allow the review team to talk to various members of staff about the NHS board’s adverse event arrangements. The sessions include:

- A discussion with senior management
- Discussions about the process followed in the selected cases with staff that were involved in either the incident and/or investigation (see Appendix A)
- Demonstration of information systems (see Appendix B)
- Visit to clinical areas - this session is intended to give the review team the opportunity to speak with frontline staff (not necessarily associated with a particular event) to understand their perspective on the management of adverse events.
Please note that the closing session will not include any feedback from the visit. It is merely a wrap up session to enable us to thank the NHS board for its involvement.

**Who are the members of the review team?**

The review team comprises individuals with experience and knowledge of adverse event management. Typically the review team will have a senior clinician, a senior NHS manager, a public partner and members of the adverse event team from Healthcare Improvement Scotland.

**What happens after the review?**

The review team will collate the information we have read and heard to develop a report of our findings. The review team will feedback any high level finding to the NHS board’s chief executive within one month after the visit. After this meeting a clearance draft will be sent to the board for factual accuracy checks.

The reports will be published throughout the programme on the Healthcare Improvement Scotland website.

We will expect NHS boards to develop a plan to address the NHS board recommendations outlined within the NHS Ayrshire & Arran report as well as those specific board recommendations. It is important that the recommendations are carefully considered and a detailed action plan developed, with appropriate timescales, ownership, accountability and measures of improvement incorporated. Healthcare Improvement Scotland should be kept informed of the development of the improvement plan and notified when it should be agreed through local governance structures. The review teams would be happy to provide support through the development of this document.
Appendix A

Adverse Event Management Review

Visit guidance – discussions with NHS board staff

Below is some general guidance on what the Review Team may wish to discuss with NHS board staff within the operational team discussion sessions and on the clinical area/ward visit. Please note this guidance is not prescriptive but merely provides examples to help support staff in advance of the visit. The Review Team may choose to ask alternative questions on the day of the visit.

Operational Team discussions

Within these sessions, the Review Team will want to discuss the selected cases with members of staff involved in the event and in the subsequent investigation, to gain a perspective from front line staff’s experience of adverse event management. The purpose of this discussion is not to dissect or appraise the specific case or clinical judgements, but to provide the Review Team with an operational viewpoint of how the process for adverse event management is applied within the NHS board.

The questions posed to staff members will be based upon the information we have received from the NHS board to allow us to understand how the defined organisational process is implemented. Therefore, the questions will be set around the following:

- Adherence to local adverse event management policy (using the cases chosen as an example)
- Involvement and engagement of key stakeholder (eg staff, patients and families)
- Governance arrangements including reporting, decision making, roles and responsibilities etc
- Learning and making improvements

As a minimum, we would expect the following staff to be invited to attend:

Operational staff involved in event:
- staff that were present during or immediately after the event
- Staff that were involved in recording/reporting the event
- Staff involved in ensuring it was safe to continue to treat patients

Staff investigation/actions
- Investigation team (if different from above)
- Support staff eg risk management/Datix coordinator
- Staff involved in reporting/action planning/monitoring
Staff involved in learning and follow-up

Clinical Area/ Ward visit

The aim of the Review Team visit to a ward area is to enable the team to gather staff views of the adverse event management process, in an informal way particularly from staff not necessarily involved in a previous significant adverse event. We would like to be able to ask staff to voluntarily come and spend a few moments discussing the areas listed below. The views would be completely anonymous and are likely to include the following themes:

- Awareness and accessibility to the significant adverse event review policy
- How you report incidents
- Where would you get advice and guidance on significant incidents
- Staff training
- Feedback provided following the reporting of an incident
- Learning from other significant events
Appendix B

Adverse Event Management Review

Visit guidance - systems demonstration

Below is some general guidance on what you may wish to include in the NHS board session – “Support team demonstration of systems in place eg Datix, record storage, staff training”. The list includes examples and is not intended to be prescriptive.

The aim of the session is to help the review team to understand how document control and related information systems are used to provide an audit trail of adverse event management and to capture improvements and learning.

Live demonstration of the system used to record adverse incidents

- How the system is used - what modules/areas/data are populated
- How widely the system is used within the NHS board
- Who is responsible for inputting and keeping the database up-to-date – is it person dependent?
- Who checks progress of actions
- Who checks the audit trail
- What reports are generated from the system
- Whether there are linkages with other systems eg complaints
- If there is a process for checking significant adverse event trends on the system
- How learning is disseminated from the system

Record storage

- Other ways significant adverse event information is managed and stored eg manual recording, where information is kept, who manages the documentation
- Whether the NHS board has a single repository for significant adverse events and associated documentation
- Whether the NHS board has a tracking system for significant adverse events to monitor involvement of patient/family/carers
- What procedures/policies are in place to support appropriate document control and records management.

Staff training

- What training staff currently receive eg training on Datix, use of risk matrix, records management, undertaking reviews etc