Healthcare Improvement Scotland

Adverse Events:

Guidance on national notification data

Purpose of this document

The purpose of this document is to provide guidance to the NHS boards in Scotland on the specific dataset that Healthcare Improvement Scotland (HIS) requires for the national notification system in relation to Category I, Significant Adverse Event Reviews (SAER). The aim is to make sure that there is consistency of process and quality in the data submitted.

Data is essential for quality management purposes at national, regional and local levels. The national notification system will allow data to be collated and analysed centrally which will facilitate the recognition of trends and themes at a national level and to inform the planning of national improvement programmes.

The initial dataset submitted to HIS will change over time. Improvement in the data set will be informed by review of the outputs in partnership with stakeholders to achieve the aims of the national notification system. Data will initially be reviewed monthly to assess the quality of the data.

Background

This document should be read alongside Learning from adverse events through reporting and review: A national framework for Scotland, published by Healthcare Improvement Scotland, and revised in December 2019. The national framework aims to support a consistent approach in health and care services to reviewing and learning from adverse events, and to facilitate learning and improvement at national level. It recognises that adverse events can have a major effect on the people who are involved in them. An **adverse event** is defined as **an event that could have caused or did result in harm to people or groups of people.**

In September 2019 HIS published Adverse Event Management: NHS boards self-evaluation report.

This report highlighted areas of good practice in adverse event management within NHS boards in Scotland but also identified variations and inconsistencies between these organisations.

In response to the report the Cabinet Secretary for Health and Sport instructed Healthcare Improvement Scotland (HIS) to work with all NHS Boards to ensure that NHS boards notify HIS when a category I, SAER is commissioned, and to move towards standardising terminology and definitions, including the implementation across all NHS boards of the consistent use of SAER.

This document was informed by engagement with representatives from NHS boards, including an expert reference group, and discussions with Scottish Government officials.

Aim

Establish a robust national notification system for the NHS boards in Scotland to report the commissioning of any SAERs for Category I adverse events.

Objectives

The primary objective of this work is to support improvement, and achieve greater consistency, in the management and review of the most serious adverse events (Category I) that occur in healthcare services; and to enable effective learning at national level. This in turn should support the aim of safe, effective and person-centred healthcare services, and a culture of openness and learning.

The national notification system will develop and evolve over time and the first year will enable an initial dataset to be tested and refined to meet the primary objective outlined above.

Operational objectives

- To achieve the aim, review data submitted monthly to assess consistency and appropriateness of the information.

- Seek feedback from users with a review of the submission process after 3 months of launch.

- Analyse data to understand the national harms across Scotland which result in Significant Adverse Event Reviews.

- Identify patterns of national consistency and variation in the data reported from NHS boards, to determine the reasons for these patterns and generate actions that will support improvement in collective practice.

- Engage and collaborate with relevant stakeholders, including NHS boards and national organisations with a shared interest in this work, to develop and refine the approach, and to seek opportunities to maximise impact of any work undertaken. Assess for national trends, and identify recurring national themes which could support national improvement work.

- Develop a clearer national picture of significant adverse event processes in healthcare in Scotland.

- Develop a revised guidance document to improve consistency with regard to nationally submitted data.

- Share good practice relating to the process of significant adverse event reporting nationally utilising information from the national notification data.

What will the data be used for?

The data will be used to meet the objectives outlined above. NHS boards will submit non-identifiable data to protect patient confidentiality. HIS will use this data to inform existing improvement programmes nationally including Scottish Patient Safety Programme (SPSP) and the wider work done by the Improvement Hub (iHub).

There will be a future focus on the learning from the data submitted by the boards that will be shared nationally.

HIS will provide feedback and support to boards on areas of improvement identified from data collected through the notification system, with the potential to commission national pieces of work in response to identified improvement opportunities.

The data will help inform an evolving list of key harms to further assist NHS boards in Scotland to reduce any unacceptable variation regarding the application of the national adverse events framework.

A national view of adverse events reporting will support NHS boards in Scotland to continuously improve adverse event management approaches.

Data and submission process

Data will be submitted monthly via a reporting spreadsheet template until a national digital solution is available.

In the event of an NHS Multi-Board Significant Adverse Event Review, the NHS board leading the review will be responsible for notifying Healthcare Improvement Scotland of the commissioning of the review and the outcome of the review process.

NHS boards will notify HIS of **all Significant Adverse Event Reviews commissioned for category I events from 01.01.20**.
The first data submission will be expected to be received by **06.02.20**.
The deadline for data submission in subsequent months will also be by the 6th of the subsequent month, for example:

Commissioned SAERs	Deadline for initial notification to HIS
1 January – 31 January 2020	6 February 2020
1 February – 29 February 2020	6 March 2020
1 March – 31 March 2020	6 April 2020

Boards will be asked to submit their data monthly, via a newly created email address: his.adverseevents@nhs.scot with reminders sent out by HIS in advance of the submission date.

If no SAERs have been commissioned in that month, then a nil report is expected to be returned to HIS to signify this.

It is recognised that notification of an SAER at point of commission alone will not support national learning and therefore there will be a two-stage data submission process to support national learning. Once a review has been completed, boards will be asked to update the initial notification record, and submit the outcomes from the SAER process. This will be reported as part of the monthly return.

All SAERs commissioned for a Category I event will require notification to HIS, as per the cabinet secretary's instruction.

Definitions as per national Framework

Adverse event category	Suggested minimum level of review	Review team	Reporting of findings and learning	Guidance timescale
Category I – events that may have contributed to or resulted in permanent harm, for example unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as major or extreme impact on NHS Scotland risk assessment matrix, or Category G, H or I on National Coordinating Council for Medical Error Reporting and Prevention (NCC MERP) index).	**Level 1:** Significant Adverse Event analysis and Review. Use of validated analysis tools or evidence of screening and clear rationale for any not progressing to analysis.	Full review team: commissioning manager to agree review lead and Terms of Reference (the review team should be sufficiently removed from the event, and have no conflict of interest, to be able to provide an objective view).	Via division/service governance structures with evidence of improvement plans as required. The development of the improvement plan should sit within the team/department where the adverse event took place.	Commission review within 10 working days of the adverse event being reported on incident management system. Commence and close review (report submitted for approval) within 90 working days of the commissioning date. Final approval should take place as soon as possible and no later than 30 working days from report submission. Develop improvement plan within 10 working days from report being approved.

Two stage data submission

Initial notification: date the decision is made to commission an SAER	Learning and outcomes: outcome of the event after review completion

Stage 1

Initial notification system

Data	Definition/ explanation
Month/year	Notification month and year.
Unique identifier	Datix number or other identifier from local board incident reporting system
Date SAER commissioned	Date decision made to progress to SAER
Incident/Event Type	Free text summarising the type of event e.g. suicide, medicines
Incident/Event Sub-type	Further detail and context of event for example Unexpected death: suicide or sepsis. If device involved please specify the device.
Speciality related to event	Area of speciality if relevant (free text) for example mental health, obstetrics, gynaecology, surgery
SRLS scope	Would this event/incident be reported into the SRLS system previously?
Level of review applied	For suicide events which would have been reported into the SRLS system. What level of review was commissioned?
PLEASE ENSURE * **NO PATIENT IDENTIFIABLE DATA IS SENT TO HIS**	

Stage 2

Learning and outcomes

POTENTIAL DATA FIELDS FOR DISCUSSION

Data	Definition/ explanation
Date review completed	Date final sign off by appropriate governance group
Main learning points	tbd
Outcome Code	Refer to Appendix 1, and grade outcome code accordingly
Reason for removal of event	Where an adverse event becomes out of scope, the reason for removal is required (free text)
Confirmed incident/event type	Confirmation/correction of type of event following original notification or review
***PLEASE ENSURE *** **NO PATIENT IDENTIFIABLE DATA IS SENT TO HIS**	

Appendix 1: Review Outcomes

[Learning from adverse events through reporting and review: a national framework for Scotland (Page 23)](#)

Review outcomes

Not all adverse event reviews will identify system failures and may find proper care was delivered. A review may conclude that the care delivered was appropriate and event was unavoidable. The potential for learning in these cases should still be recognised and areas of good practice shared appropriately. An outcome code can be applied to adverse event reviews to indicate the findings of the review in relation to the link between care and outcome which will allow identification of those events where improvements are required. The following codes can be used.

1. **Appropriate care** - The adverse event review concluded that the care and/or service was well planned and appropriately delivered; no care or service delivery problems were identified; and the adverse event outcome was ultimately unavoidable. However, it is likely there are still learning points (especially good practice points).

2. **Indirect system of care issues** - The adverse event review identified indirect or incidental sub-optimal care or service issues and lessons that could be learned (and good practice points). However, these were unlikely to have affected the final outcome. For example, a protocol was not strictly followed or there was a delay in accessing the case notes, but these were unlikely to have affected the final outcome.

3. **Minor system of care issues** - The adverse event review identified minor or sub-optimal care or service provision and that a different plan or delivery of care/service may have resulted in a different outcome. For example, system or management factors were identified (such as incomplete records or a delay in transferring the patient or service user), but there was uncertainty regarding their impact on the final outcome. Learning points have been identified and improvement plans developed.

4. **Major system of care issues** - The adverse event review identified that a different plan and/or delivery of care or service would, on the balance of probability, have been expected to result in a more favourable outcome. Factors were identified which negatively influenced or contributed to the adverse event outcome. For example, how the case was managed had a significant impact on the level of harm. Learning points have been identified and improvement plans developed.