

Safety Action Notice

Reference **SAN(SC)20/01**

Issued **13 January 2020**

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National adverse incident reporting and safety alert systems for medical devices, estates & facilities, and social care equipment

Summary

NHS Boards and local authorities must have local systems for managing adverse events and safety alerts¹. Local systems must integrate with national incident reporting and safety alert systems including those operated by Healthcare Improvement Scotland (HIS) and NHS National Services Scotland (NSS IRIC).

Action

- Annually review the effectiveness of local systems for:
 - recording and reviewing adverse events
 - identifying trends and sharing learning from adverse events
 - notifying Serious Adverse Event Reviews (SAERs) to HIS
 - reporting incidents involving medical devices, estates & facilities, and social care equipment to NSS IRIC ([how to report an adverse incident](#)).
 - managing the receipt, assessment, distribution and implementation of safety alerts.
- For medical devices, estates & facilities, and social care equipment:
 - ensure that an Equipment Co-ordinator has been appointed with the ability to function at corporate level and that there is continuity of cover - [CEL43 \(2009\)](#).
- NHS Boards - ensure the Equipment Co-ordinator has suitable links to:
 - Executive lead for management of serious adverse events
 - Quality Improvement lead
 - Medical devices committee and/or medical physics department

Action by

Chief Executives

Equipment Co-ordinators

Health & Safety Managers

Medical Directors

Nurse Directors

Directors of Estates & Facilities

Risk Managers

Background

Local authorities and NHS Boards must have suitable arrangements in place for the safe provision of care supported by local systems for managing adverse events and safety alerts.

Healthcare Improvement Scotland (HIS), which regulates NHS care, manages the national framework for learning from adverse events¹. The framework requires that NHS Boards manage all adverse events, regardless of their nature, through reporting, review and improvement planning. HIS must be notified of all category 1 Serious Adverse Event Reviews (SAERs) commissioned from 01 January 2020.

Background (continued)

The framework supports NHS boards to standardise processes of managing adverse events across all care settings in Scotland. It is supported by the [Adverse Events Community of Practice](#) website which contains policies, tools, templates, learning summaries and other items which Boards are able to share.

NHS National Services Scotland (NSS) operates the national adverse incident reporting and safety alert systems for medical devices, estates & facilities, and social care equipment. These systems cover services provided by local authorities, NHS Boards, partnership organisations and contractors.

NSS has a partnership arrangement through which it shares information on adverse events with the MHRA, the UK competent authority for medical devices. NSS also works closely with Scottish Government, Healthcare Improvement Scotland, NHS Improvement, and counterparts in devolved administrations in Wales and Northern Ireland.

The safe provision of care also requires suitable arrangements for the provision and use of medical devices, estates & facilities, and social care equipment. These arrangements are set out in [CEL 43 \(2009\)](#) and its [Addendum](#). Local and national systems should integrate clearly and effectively.

These arrangements do not apply to patients and members of the public who may instead report adverse incidents involving medicines and medical devices to MHRA, the UK's regulatory authority, using the Yellow Card scheme: <https://yellowcard.mhra.gov.uk/>.

References

1. Learning from adverse events through reporting and review. A national framework for Scotland. Healthcare Improvement Scotland, July 2018.
http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx

Enquiries

Enquiries in Scotland should be addressed to:

Incident Reporting & Investigation Centre (IRIC)

NHS National Services Scotland

Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB

Tel: 0131 275 7575 Email: nss.irc@nhs.scot

Report options are available on the HFS website: [How to report an Adverse Incident](#)
Further information about reporting incidents can be found in [CEL 43 \(2009\)](#) or by contacting IRIC at the above address.