

Medical Device Alert

Action update

Ref: MDA(NI)/2009/001 Issued: 07 January 2009 at 10:00

Device

Please Note the NEW format for NIAIC Medical Devices Alerts (MDA's)

Medical Device Alerts in Northern Ireland are based on the format and content of the Medicines and Healthcare products Regulatory Agency's (MHRA) Alerts

Problem

Failure to implement adequate systems for ensuring that all reports of medical device related adverse incidents are submitted to the Northern Ireland Adverse Incident Centre (NIAIC) for recording nationally. This can act as a barrier to the identification of serious safety issues and prevent the NIAIC and the MHRA from pursuing corrective action with the device manufacturer.

Action by

- Chief Executives of HSC Trusts and Agencies.
- Safety Alert Broadcast System (SABS) and Medical Device Liaison Officers in Trusts.
- HSC Staff in Primary and Secondary Care Sectors.
- Owners and Managers of Private and Voluntary Health and Social care providers in the Regulated Sector.

SABS deadlines

Action underway: 12 January 2009
Action complete: 31 January 2009

Action

- Ensure that this and all subsequent Medical Device Alerts are disseminated locally by the SABS Liaison Officer to all those on the distribution list.
- Ensure that comprehensive and effective systems are in place for the reporting of medical device related adverse incidents to the NIAIC, and that these systems are regularly reviewed and maintained.
- Ensure that local reporting and risk management systems do not filter out medical device related adverse incident reports that should be sent directly to the NIAIC.
- Encourage staff and medical device users to report adverse incidents direct to the NIAIC in accordance with published NIAIC guidance.
- Ensure that a Medical Device Liaison Officer (MDLO) has been appointed to train staff and users to report adverse incidents and to advise the NIAIC of any changes to MDLO contact details (the role is often combined with the Safety Alerting Broadcast System (SABS) Liaison Officer).

Problem

The NIAIC through the MHRA is responsible for ensuring that medical devices are safe in Northern Ireland for patients, health and social care workers and all members of the public. Any failure to report the occurrence of an adverse incident to the NIAIC can undermine our efforts to review problems arising with medical devices, and can prevent or delay discussion of corrective actions with the manufacturer. It is only through effective review and investigation of incident reports that we can work with manufacturers to avoid repetition and to achieve resolution of safety problems.

The NIAIC has recorded a reduction in the number of adverse incidents reported to the medical device Adverse Incident Centre by healthcare professionals. Consultation with MDLOs at recent conferences and focus group meetings across the UK has indicated that this reduction does not reflect a similar change in the number of adverse incidents actually occurring.

It is important to ensure that local reporting and risk management systems are not used to filter out medical device related adverse incident reports that should be sent directly to the NIAIC. If a relevant incident report is submitted to another body (such as the Health & Safety Executive, the National Patient Safety Agency or the DHSSPSNI Serious Adverse Incident System), it is essential that a separate report is also sent to the NIAIC.

This Alert and the full NIAIC reporting guidance are underpinned by the performance framework for the Standards for Better Health and the Medical Device and Equipment Management Controls Assurance Standard. The framework demands that Health and Social care organisations protect patients through systems that:

- a) “identify and learn from all patient safety incidents and other reportable incidents, and make improvements in practice based on local and national experience and information derived from the analysis of incidents.”
- b) “ensure that patient safety notices, alerts and other communications concerning patient safety which require action are acted upon within required time-scales.”

Full guidance on the reporting of an Adverse Incident is updated on the NIAIC website annually. This information will be provided in the Device Bulletin DB2009(NI)001, published early in the calendar year and will supersede the previous published document; this document also includes information on the role of SABS Liaison Officers and Medical Device Liaison Officers.

Access to the latest NIAIC’s incident reporting forms can be obtained online at www.dhsspsni.gov.uk/niaic and attached with this Alert. All reporters should be encouraged to use the latest forms and email those directly to NIAIC at niaic@dhsspsni.gov.uk.

Distribution

The NIAIC has sent this MDA via SABS to:

- HSC Trust, HSS Board, and Agency’s Chief Executive’s
- HSC Trust, HSS Board, and Agency’s SABS Liaison Officer
- Selected members of the DPSSPSNI
- Hospitals in the independent sector
- Hospices

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- All ambulance staff
- All wards and clinical departments
- Allied health professionals
- Back care/manual handling advisors/trainers
- Care management team managers
- Children's services
- Clinical directors
- Clinical governance leads
- Clinical nurse specialists
- Community care staff in house day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Community hospitals
- EBME
- Educational establishments with beds for children
- Equipment stores & libraries
- Estates departments
- Health and safety managers
- Healthcare scientists
- Laboratory managers
- Loan store managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Medical device liaison officers
- Medical directors
- Medical physics
- Medical, dental and nursing staff
- Nurse consultants
- Nursing executive directors
- Occupational health departments
- Operating theatres
- Pharmacists
- Purchasing managers
- Residential special schools
- Risk managers
- Supplies managers
- Theatre managers
- Transport managers
- Wheelchair maintenance and seating service managers

The Regulation and Quality Improvement Authority (RQIA) to:

Headquarters for onward distribution to:

- All Nursing and Residential Home providers
- Domiciliary care providers
- Independent treatment centres
- Nursing agencies

Boards to:

SABS liaison officers for onward distribution to:

- Practice managers for onward distribution to GP's and nursing staff
- Consultants in communicable disease control
- Health protection nurses
- Regional epidemiologists
- Risk manager

Central Services Agency (CSA) to:

SABS liaison officers for onward distribution to all relevant staff including:

- Dentists
- Optometrists
- Private medical practitioners
- Pharmacists
- Staff with responsibility for purchasing

Northern Ireland

Enquiries in Northern Ireland, please send enquiries about this notice to the NAIC quoting reference number **MDA(NI)/2009/001** and addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523868
Fax: 02890 523900
E-mail: NIAIC@dhsspsni.gov.uk
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents

Incidents relating to medical devices in Northern Ireland must be reported to the Northern Ireland Adverse Incident Centre (NIAIC) as soon as possible.

Further information about reporting incidents can be found in DB(NI)2008-001; and downloadable report forms are available from the NIAIC's website (<http://www.dhsspsni.gov.uk/niaic>).

Alternatively, further information and printed incident report forms are available from: NIAIC at the address above.
(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the NIAC website

Further information about SABS can be found at <http://sabs.dhsspsni.gov.uk>

NIAIC is a agency of the DHSSPSNI
MHRA is an executive agency of the Department of Health (UK)
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