

## Action

Ref: NIA/2015/001 Issued : 16 Feb 2015 at 14:00

## Reporting of Medical Device Adverse Incidents & Near Misses and disseminating Alerts

### Information

The purpose of this document is to act as a reminder that:

- In the interests of patients, staff and visitor safety **all** regulated healthcare providers, Ophthalmic, Pharmaceutical & Dental practices and GP surgeries have a requirement to report Adverse Incidents (AIs) involving medical devices to the Department via the Northern Ireland Adverse Incident Centre (NIAIC). The aim of this reporting and any subsequent investigation is to identify learning that can be shared across all healthcare service providers and work towards reducing the chances of the incident reoccurring, thereby improving safety for all.
- All adverse incidents or near misses involving any medical device must be reported to the NIAIC via the appropriate Adverse Incident reporting form (copy attached in Appendix) as per section 4 below.
- All Medical Device Alerts issued via the Safety Alert Broadcast System (SABS) need to be disseminated to the key relevant people in your organisation, to ensure senior stakeholders are engaged and involved.

This document provides guidance on:

- 1) What constitutes a Medical Device Adverse Incident
- 2) When to report an Adverse Incident
- 3) Actions required by all providers of healthcare services.
- 4) How reporting should be carried out.
- 5) Other actions and responsibilities.
- 6) What should happen to an item involved in an Adverse Incident.
- 7) What actions the NIAIC will take.

## 1. What constitutes an Medical Device Adverse Incident

A Medical Device Adverse Incident can be classed as:

- a) Any adverse event involving the safety of patients, staff or others, arising from the defect or failure of equipment. These events may range from causing no actual harm (near miss) to serious harm and may include:

- death, life-threatening illness or injury
- deterioration in health or permanent impairment of body structure or function
- the necessity for medical or surgical intervention (including implant revision)
- hospitalisation or prolongation of existing hospitalisation
- unreliable test results and associated risk of mis-diagnosis or inappropriate treatment
- fetal distress, fetal death, congenital abnormality or birth defect
- ongoing faults that successive service/maintenance visits have failed to rectify.

b) Adverse Incidents that arise through:

- design or manufacturing problems
- inadequate servicing and maintenance
- inappropriate use of a device for self-harm
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice or decontamination problems).

c) Conditions of use may also give rise to adverse incidents:

- environmental conditions (e.g. electromagnetic interference)
- location (e.g. devices designed for hospitals may not be suitable for a community or ambulance setting).

## 2. When to report an Adverse Incident.

Incidents should be reported as soon as possible, usually within 24 hours. Serious incidents should be reported to us by the fastest means available either by fax or email and should be confirmed with a telephone call. Where the first report is by telephone, a written report (email or fax) should follow as soon as possible.

The initial report of an incident should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information.

## 3. Actions required by all providers' of healthcare services.

The provider organisations Chief Executive / Board Member / nominated person with special responsibility for adverse incident safety must ensure that, in accordance with local procedures, this alert is brought to the attention of appropriate staff within their organisation(s) (this includes PFI and any external contractors as appropriate) for information purposes.

The following arrangements should already be in place:

- a) Ensure a designated person is responsible for receiving and disseminating Estates and Facilities related alerts from the Safety Alert Broadcast System (SABS).
- b) Regular review of monitoring procedures to ensure there is a person in place, with backup arrangements, that has responsibility for promptly reporting appropriate estates and facilities adverse incidents at all times.
- c) Communication arrangements to ensure personnel are aware of the reporting system available.

- d) Ensure relevant personnel are familiar with the SABS website where alerts are posted <http://sabs.dhsspsni.gov.uk/>
- e) Advising the NIAIC Office on Tel 028 9052 3868 or email [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk) of changes to SABS liaison officer or point of contact.

## 4. How reporting should be carried out.

Anyone may submit an adverse incident report to the NIAIC – clinicians, healthcare workers, carers, patients and members of the public.

Reporters should, however, familiarise themselves with their organisation's local incident reporting procedures and risk management systems, as these may require reports to be submitted via, or copied to, medical device liaison officers and/or patient safety managers.

Forms for reporting incidents may be downloaded from the NIAIC website and when completed can be electronically emailed as a .doc or .pdf file to [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk) . They may also be printed and sent by post or fax. Copies of forms are also available from:

### **Northern Ireland Adverse Incident Centre**

Department of Health and Social Service & Public Safety  
CMO Group  
Room 17, Annex 6  
Castle Buildings  
Stormont Estate  
Dundonald  
BT4 3SQ

Tel: 028 90523868

Fax: 028 90523900

Web: [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

Email: [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk)

Telephone reports must always be followed up by a written (post, email or fax) confirmation. In urgent cases outside of normal office hours an answering machine at the NIAIC carries a message giving the contact telephone number for the duty officer. The duty officer is able to contact senior NIAIC staff.

Alternatively, telephone messages may be left on the answering machine for the next working day.

## 5. Other actions and responsibilities.

This reporting system does not affect the duty of local staff to take actions as required by legislation and / or by line management, because of an adverse incident. Additional actions may be required as follows:

- a) Prevent further use of equipment that may be defective.
- b) Reporting of incidents to the most appropriate officer within the organisation (e.g. radiation hazards to the Radiation Protection Advisor, infection issues to Infection Control).
- c) Reporting to the Health and Safety Executive (HSENI) "Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR 2013)".

- d) Reporting under “Ionising Radiation Regulations 1999”.
- e) The manufacturer / supplier should also be contacted by the originator of the report and supplied with a copy of the incident report, in order that the two parties can establish the reason for the Adverse Incident.
- f) The outcome of any investigation, either by the healthcare provider or jointly with the manufacturer, should be added forwarded to the NIAIC quoting the incident reference number supplied following the initial report.
- g) When an incident occurs it must be reported to all relevant bodies. It is important to ensure that the use of local reporting and risk management systems does not result in the reporting of relevant adverse incidents being overlooked. If a relevant incident report is submitted to another body (for example the Health & Safety Executive Northern Ireland), an entry must also be made to NIAIC as detailed above.
- h) Health and Social Care (HSC) Trusts, Family Practitioner Services (FPS) and Independent Service Providers (ISP) must report Serious Adverse Incidents (SAIs) arising during the course of the business of an HSC organisation/Special Agency or commissioned service to the Health and Social Care Board (HSCB) who are working in close partnership with the Public Health Agency (PHA) and the Regulation Quality Improvement Authority (RQIA) for the recording and follow up of SAIs. All SAI's that involve Medical Devices **must also** be reported to the NIAIC as well as the HSCB utilising the NIAIC adverse incident form.

## 6. What should happen to an item involved in an Adverse Incident.

- a) All defective devices are potential legal evidence and should be treated as such by the most senior person on site at the time. It should not be modified, cleaned or dismantled, unless immediate repair is the only possible option.
- b) All material evidence shall be identified and kept secure under the charge of a named responsible officer.
- c) If possible photographs (ideally digital and dated and timed) should be taken of the incident scene and / or the damage.
- d) Defective / failed items should not be interfered with in any way except for safety reasons or to prevent injury, damage or loss.
- e) Where appropriate a record, which should be signed and dated, should be kept of all readings, settings and position of switches, dials, gauges and indicators etc.
- f) In serious cases a detailed incident report shall be compiled and if necessary timed and signed. Eyewitness reports should also be obtained as soon as reasonably possible, these reports should be signed and dated in front of witnesses.
- g) The manufacturer/supplier should be promptly notified directly by the healthcare provider and shall be allowed accompanied access with a responsible officer, to inspect the equipment. Care must be taken to ensure the manufacturer does not exchange, interfere or remove any part, as this could prejudice any subsequent investigations by other official bodies.
- h) The devices should not be handed over to the supplier, repaired or discarded before there has been an opportunity to investigate and a course of action agreed.
- i) Where there is a clinical need for the device to be kept in use, any defective parts must be clearly identified. They can be removed, secured and identified for later inspection and the equipment can be repaired (and where necessary inspected and re-certified) for re-use after due consultation with a named responsible officer.
- j) If a device is contaminated and constitutes a bio hazard, advice contained in Device Bulletin, DB(NI)-2014-02 “Managing Medical Devices” – Section 9, should be followed.

**NB:**

- 1) It is illegal to send contaminated items through the post.
- 2) Health and Safety Inspectors have legal powers under the Health and Safety at Work Order 1978 ,to enter property at a reasonable time, and take possession or samples of any equipment, material or article, make examinations, take measurements, photographs, order dismantling, question personnel and take copies of documents.
- 3) Health and Safety Inspectors may also act or investigate on behalf of HM Coroner.

## 7. What actions the NIAIC will take.

When the NIAIC receives an Adverse Incident report, the following action(s) are taken:

- a) If the NIAIC is notified of an adverse incident via a different route the originator will be prompted to complete the appropriate AI form for inclusion on the Adverse Incident Register. (See section 4)
- b) An acknowledgement will be sent by the NIAIC to the originator and the appropriate Liaison Officer with a unique reference number that should be quoted in all correspondence.
- c) The NIAIC or their representative may contact the originator, to discuss the incident and then may liaise with the manufacturer and other bodies as appropriate.
- d) The report is evaluated by NIAIC Officer to identify any appropriate action required.
- e) Based on historical data within the Adverse Incident Register system, the nature of the incident, the manufacturer's report and the originator's own investigations, the NIAIC may discuss with the MHRA the need for the manufacturer to produce a Field Safety Notice (FSN). Where there is no national interest the NIAIC may still consider a Northern Ireland Alert or Early warning notice.

## Suggested onward Distribution

- Chief Executives
- Medical Device Liaison Officer
- Clinical and Nursing Directors
- Governance and Risk Management Leads
- Health & Safety Manager's
- PFI/PPP staff
- Staff involved in the procurement, management or maintenance of medical devices
- Others as deemed appropriate

## Additional information for Northern Ireland

This Alert was compiled by the NIAIC for circulation in Northern Ireland only.

Action required by this alert should be **underway by: 1<sup>st</sup> March 2015**  
Action required by this alert should be **completed by: 31<sup>st</sup> March 2015**

Enquires should quote reference number NIA-2015-001 and be addressed to: [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk)

A copy of this Alert can be found on <http://sabs.dhsspsni.gov.uk>

## NIAIC ADVERSE INCIDENT REPORT FORM

<b>Details of the report:</b> Reporting Body: Address :  Post Code : Reporter : Position : Tel No : Email :  Your or Hospital IR1 Reference:	<b>Location of the incident:</b>  As Reporter : <input type="checkbox"/>  Facility/Building: Ward/Dept :  Local Contact : Position : Tel No : Email :
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<b>Details of device:</b>			
Product		Catalogue No	
Model		Serial No	
Manufacturer			
Supplier			
Batch No		Expiry date	
Date of mfr		Quantity defective	
Location of device now			
Is there a CE-mark? Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/>		If YES, was the manufacturer or supplier contacted? Yes <input type="checkbox"/> No <input type="checkbox"/>	

<b>Incident Details :</b>	Date of Incident
Nature of Injury :    Fatality <input type="checkbox"/> Serious <input type="checkbox"/> Revision <input type="checkbox"/> Distress <input type="checkbox"/> Minor <input type="checkbox"/> None <input type="checkbox"/>	

<b>Injury details:</b>
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<b>Nature of defect / details of incident:</b>
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<b>Action taken by staff :</b>
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PLEASE NOTE IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST.  
 If you still have the incident device please retain it and await further instructions from the NIAIC.

Signed	Date
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**Please send completed form to:** Northern Ireland Adverse Incident Centre, CMO Group, DHSSPSNI, Annex 6, Castle Buildings, Stormont Estate, Dundonald, BT4 3SQ, Tel 028 90523868 | Fax 028 90523900

Preferred method e-mail : [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk)

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