Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Northern Ireland Adverse Incident Centre (NIAIC)

Reporting Medical Device and Estates Adverse Incidents

Version Control

This document is owned and controlled by the Head of Medical Device and Estates Safety Policy Branch

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1.0	Issue date	Oct 2017	
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Contents

1. Introduction

1.1 The Northern Ireland Adverse Incident Centre

The Northern Ireland Adverse Incident Centre (NIAIC) operates as part of the Chief Medical Officers (CMO) Group within the Department of Health (DoH). The key aim of the NIAIC is to seek learning from investigations into reported adverse incidents involving medical devices, non-medical equipment, plant and buildings used within the healthcare environment across Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient, staff, client or user injury. As it is part of the Department of Health the NIAIC inputs to the development and monitoring of the implementation of policy, standards and guidance, as appropriate, concerning medical devices and technical estates safety.

The importance of open reporting of adverse incidents in the healthcare environment has been proven in many instances with additional learning and improvement being achieved. Therefore part of NIAIC's work is in encouraging a shift to a safety culture, where open reporting and balanced analysis are encouraged in principle and by example. This is in contrast to a blame culture, which encourages people to cover up errors for fear of retribution. Open reporting and a balanced analysis allows for focus on the true cause of the incident and any role of the underlying systems which enables improvements, if identified, to be made.

The introduction of effective clinical governance means that there is a shared goal between the individual and the organisation to minimise risk related to the use of medical devices, equipment and plant and thereby ensure that everyone who needs to is able to use equipment safely and effectively.

The NIAIC works closely with the Medicines and Healthcare products Regulatory Agency (MHRA) - the UK Competent Authority for Medical Devices, in relation to issues concerning medical device safety. The NIAIC also liaises closely with the NHS Improvement - England, Health Facilities Scotland and NHS Wales Shared Services Partnership - Facilities Services for safety issues concerning non-medical equipment, plant and building items.

Learning is conveyed to individuals and organisations through reported findings of individual investigations and to the wider healthcare environment by the use of Alerts, which are issued via the Northern Ireland Central Alerting Systems (NICAS). The NICAS is a web based application to notify users about new or updated safety information and to provide an assurance pathway to the DoH of the appropriate safety actions taken by the HSC and large acute service providers across the region in response to an alert.

2. Reportable Events

2.1 What is an adverse incident?

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users including staff, patients or other persons

For example:

- a patient, user, carer or professional is injured as a result of a medical device failure or its misuse.
- a patient's treatment is interrupted or compromised by a medical device failure.
- a misdiagnosis due to a medical device failure leads to inappropriate treatment.
- a patient's health deteriorates due to medical device failure.
- the reduction in service due the failure of a device or part of the estate.

Causes can include: design aspects, poor user instructions or training, inappropriate modifications, inadequate maintenance, and unsuitable storage and use conditions.

2.2 What is a medical device?

A medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

General workshop equipment such as power or machine tools, general purpose laboratory equipment or aids for daily living are not considered as medical devices. A list of examples of Medical Devices is provided in Appendix 1.

Note: **An accessory is not considered to be a medical device. However, where an accessory is intended specifically by its manufacturer to be used together with the 'parent' medical device to enable the medical device to achieve its intended purpose, it should be considered as a medical device in its own right.**

2.3 What are non-medical equipment, plant and building items?

Non-medical equipment, plant and buildings are items directly managed and controlled by an Estates and Facilities Department. This does **not** include general IT systems, except where they are classified as a medical device (see above). Examples of non-medical equipment, plant and building items are provided in Appendix 2.

2.4 What should be reported to the NIAIC?

Any adverse incident involving a medical device and estates, plant, equipment or buildings should be reported to the NIAIC. It is important to note that relatively minor incidents can have a greater significance if aggregated with other similar reports. This should include incidents thought to be due to human error, minor safety issues or potential problems. Potential problems that are identified with a device or piece of equipment could lead to an adverse incident occurring.

2.5 Why report?

The information from adverse incident reports can help identify safety issues with medical devices or equipment and can prevent similar incidents happening again through analysis of the incident in order to identify possible learning, that can then be disseminated in order to prevent a reoccurrence.

2.6 Who should report?

Anyone may submit an adverse incident report to the NIAIC – clinicians, healthcare workers, carers, patients and members of the public. Reporters from the Health and Social Care sector should copy their report to or submit via their Medical Device Liaison Officers and follow the incident reporting procedures of their organisation. Submitting a report of an adverse incident to the NIAIC does not negate the need to report to other systems/ bodies including organisational local incident registers or statutory bodies including the Health and Safety Executive (RIDDOR requirements).

2.7 When should an incident report be made?

All incidents should be reported to the NIAIC as soon as possible. Serious cases should be reported by the fastest means possible. Initial incident reports should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information.

2.8 How do I report an incident?

Complete the appropriate NIAIC AI Form and return it via email or hard copy by post. AI Report forms may be downloaded/printed from the NIAIC pages of the DoH website.

Postal Address: Northern Ireland Adverse Incident Centre
Medical Device and Estates Safety Policy Branch
Safety Strategy Unit, CMO Group
Department of Health
Room D1
Castle Buildings
Stormont Estate
Belfast
BT4 3SQ

Telephone: +44 (028) 90523744
Email: niaic@health-ni.gov.uk
Website: https://www.health-ni.gov.uk/niaic

2.9 What do I do with devices or equipment that has been involved in an adverse incident?

When a device has been involved or implicated in an adverse incident it is necessary to ensure that the device or equipment is clearly identified, its location is recorded and any history (event logs, settings, accessories, etc.) are maintained for investigation.

The following non exhaustive information is provided for guidance only:

- If the adverse incident is likely to be the subject to a police or coroner's investigation you should completely quarantine any devices associated with the incident, including all accessories. The quarantined equipment should not be released for service until you are provided with confirmation from the police or the coroner that the devices are no longer required and may be released to service.
- If there is no police or coroner investigation the device can be made available to the manufacturer or their service agent for analysis. In doing so they should be advised that the device was implicated in a reportable adverse incident and they may be asked to provide a full report of their findings to the NIAIC.
- If the failure to return the device to operational service would affect service delivery and possibly other patients' safety, the device should be checked/repaired as required and verified safe by a competent person before being returned to service. All work carried out on the device and service records should be documented and maintained. Faulty devices should not be returned to service.
- Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. The manufacturer/supplier should be contacted for advice prior to any further action being taken. The MHRA publication 'Managing Medical Devices' contains advice on decontaminating healthcare equipment. For additional information contact your local Infection Control Specialist, particularly if the item requires examination prior to any decontamination.

Important: **If you are in any doubt about what to do with a device, contact your medical device liaison officer or the NIAIC.**

Do not send medical devices to the NIAIC unless specifically requested by the NIAIC. Please note that it is illegal to send contaminated items through the post

2.10 What does the NIAIC do when it receives a report?

When an adverse incident report is received the details are recorded on a database. The NIAIC will assess the report to see if the report relates to a medical device or estates related plant or equipment. For medical device related incidents the MHRA will be notified and the incident reported to the manufacturer for investigation. The NIAIC will monitor and review the manufacturer's investigation and findings and if felt necessary may request additional information from the manufacturer and or highlight the issue to the MHRA. If thought necessary, the NIAIC may visit site to gather further information to assist in the identification of learning.

All reports are acknowledged and reporters advised of the nature and outcome of the investigation.

2.11 Reporting multiple occurrences of an incident

Although single reports have on occasion (by themselves) enabled the NIAIC and the MHRA to bring about changes to the design or instructions for use of a device, multiple reports give much more leverage when working with manufacturers to initiate change. Hence we would recommend that you report each occurrence of an incident and do not assume that because a similar event was previously reported that there is no further need for additional reporting.

2.12 How long does the investigation take?

On average, 50% of monitored investigations will be concluded within 10 weeks.

For general enquiries about adverse incidents involving medical devices contact our Adverse Incident Centre: niaic@health-ni.gov.uk or 028 90523868.

2.13 Confidentiality, data protection and the provision of information to third parties

Unless notified to the contrary, the submission of a report to the NIAIC provides us with the authority to use the information it contains as we consider appropriate in the interest of safeguarding public health. Please see the NIAIC Privacy Notice (NIAIC Privacy Notice)

The NIAIC does not require patient names or other identifying information in order to carry out an investigation. Healthcare staff reporting incidents should, therefore, ensure that such details are not provided in their reports or our deleted or redacted from their any accompanying attachments or any other form of correspondence.

The details that we do require are clearly detailed on the NIAIC Adverse Incident report forms. The reporter's full contact details (name, post held etc.) are essential, as this allows us to contact the reporter to acknowledge receipt of the report , to request any further information that may be needed and provide the outcome of the investigation.

When the reporter is a patient/private individual, these contact details are still required. The NIAIC shall consult directly with the individual for their consent if the sharing of their personal identifying information to the manufacturer or the MHRA is thought necessary to aid the investigation.

Technical and scientific information relevant to our investigations may be sought or shared with bodies such as the MHRA and/or the Department of Health as well as with the supplier or manufacturer of the device concerned.

3. Safety Information

3.1 Safety Alerts

Safety Alerts are the NIAIC's prime means of communicating important safety information to the healthcare environment in Northern Ireland. The NIAIC issues three types of alert – Medical Device Alert, Estate and Facility Alert and a Northern Ireland Alert.

3.2 Medical Device Alerts (MDAs)

Medical Device Alerts (MDAs) are produced by the MHRA, the UK Competent Authority for Medical Devices, and distributed in Northern Ireland by the NIAIC. Each Medical Device Alert will contain a series of actions with dates of when these should be underway and completed. The completion date is based on the perceived level of risk.

MDAs are reviewed on a regular basis and updated or deleted. The Departmental and the NICAS websites provide a list of MDAs that are still in force with links to the original document. If a notice is not listed on these sites, it may have been either superseded or withdrawn.

3.3 Estates and Facilities Alerts (EFAs)

Estates and Facilities Alerts (EFAs) are used to communicate safety information on estates issues to the health and social care environment.

EFAs were introduced from the start of 2010 as a national alert, with similar information simultaneously published in England, Wales, Scotland and Northern Ireland. They will carry the same reference number across the UK. EFAs replaced safety advice on estates, plant and buildings previously provided under the Medical Device/Equipment Alert (MDEAs) numbering system. The NIAIC website provides lists of EFAs that remain in force. If a notice is not listed, it may have been superseded or withdrawn.

3.4 Northern Ireland Alerts (NIAs)

Northern Ireland Alerts (NIAs) are the NIAIC's means of communicating safety information for either medical devices or Estate and facilities which is primarily focused on an issue applicableto Northern Ireland.

NIAs were introduced from the start of 2010, they are ONLY published in Northern Ireland and are designed to give advice on local issues or advanced notification of safety problems still under national investigation i.e. they may be superseded by national advice at some point in the future.

4. Field Safety Corrective Actions and Field Safety Notices

4.1 What is a FSCA?

Under the terms of the Medical Devices Regulations, the manufacturer is responsible for the safe functionality of the devices they manufacture. If they find an issue related to the safe functionality and use of their device which could potentially cause serious harm or death they must report this to the MHRA (the UK Competent Authority for medical devices) along with an action plan on how they are managing the risk. The problem and their proposed action is detailed in a document called a Field Safety Corrective Action (FSCA). If this action plan requires the end user to take action on devices in their possession, the manufacturer will distribute a Field Safety Notice (FSN).

4.2 What is a FSN?

A Field Safety Notice (FSN) is a safety communication issued by a medical device manufacturer, or their representatives, to all of their known customers and users of the device. An FSN details the immediate actions being taken by the manufacturer, such as what the manufacturer proposes to do reduce the risk of patient harm associated with the known issue; the time scale for their action; and most importantly a reply slip for the customer/user to acknowledge they have received the information found in the FSN.

4.3 What should an organisation do if it receives an FSN?

It is essential that organisations undertake the actions detailed in the FSN and reply to the manufacturer, acknowledging receipt and providing any other information requested in the FSN. An organisation's reply to the manufacturer is the evidence that the manufacturer requires to provide assurance to the MHRA that the problem is being addressed in accordance with the FSCA. Without adequate assurance from the manufacturer that appropriate action has been taken on devices in service, the MHRA may take action and issue a Medical Device Alert.

If an organisation has provided receipt of the FSN to the manufacturer, the organisation could be found liable if something goes wrong as a result of not acting on the safety information provided within the FSN.

In accordance with medical device alert (MDA-2014-037) organisations should ensure that they have systems and procedures in place for the appropriate dissemination of FSNs to relevant personnel and to ensure that the appropriate action has been taken. The above indicates that organisations should centrally record FSNs sent to them and monitor the required action.

The MHRA currently place manufacturers' FSNs on its website for information only.

5. Northern Ireland Central Alerting System (NICAS)

5.1 The Northern Ireland Central Alerting System (NICAS)

The Northern Ireland Central Alerting System is a web based application utilised by the DoH for the issue of relevant safety information, including links to alerts applicable to the Northern Ireland healthcare environment. The application provides an assurance loop to the DoH from relevant HSC organisations that the safety information has been received and that action is being taken.

The NICAS has four user access levels:

Actioner:	This type of user receives an email to notify them that a new Alert has been published on NICAS. This email also contains a copy of the published alert. Actioners will have a secure login, which provides full access to all the information on the NICAS website. They are required to acknowledge they have received the information and to provide assurance that the actions contained within the Alert have been completed within their organisation. Actioners are generally persons working within HSC Organisations. The actioner is typically the MDLO or a person designated by them to carry out the assurance function on behalf of their organisation. All users are responsible for ensuring that they keep their own contact details up to date.
Secure User:	This type of user receives an email to notify them that a new Alert has been published on NICAS. This email also contains a copy of the published alert. The Secure user will have a secure login, which provides full access to all information on the NICAS website, however they cannot update assurance information for their organisation.
Registered User:	This type of user receives an email to notify them that a new Alert has been published on NICAS. This email also contains a copy of the published alert. Registered users have web access to public facing information on the NICAS.
Public:	Safety information issued by NICAS can be viewed by the public on the public facing web pages.

For general enquiries about NICAS contact our Adverse Incident Centre by email at niaic@health-ni.gov.uk or by telephone on 028 90523868.

6. Medical Device Liaison Officer (MDLO)

6.1 Role of medical device liaison officers (MDLOs) in HSC Trusts

The MDLO role is integral to improving medical device incident reporting and learning from incidents within HSC organisations. One of the MDLO's key roles is to promote the safe use of medical devices across their organisation, by encouragement and training in the reporting of adverse incidents, so that learning can be identified. As well as improving the quality of reporting, the MDLO will be the essential link between the identification and implementation of (local and national) medical device safety initiatives and investigating device related incidents in order to improve the safety of medical devices.

Roles and responsibilities should include:

- improve reporting of and learning from medical device incidents in the organisation;
- manage medical device incident reporting in the organisation; review all medical device incident reports to ensure data quality for local and national learning; where necessary investigate and get additional information from reporters;
- make sure that medical device incidents are sent to the NIAIC as soon as possible;
- receive and respond to requests for more information from the NIAIC about medical device incident reports;
- active membership of the regional Medical Devices Safety Network (NIAIC Webex);
- support the dissemination of medical devices and estates safety communications from the NIAIC throughout the organisation;
- provide assurance on NICAS that their organisation has acted on medical devices and estates safety communications;
- act as an additional senior point of contact for manufacturers regarding Field Safety Notices and support the local action required by the organisation in relation to a Field Safety Notice
- maintain knowledge of issues arising regarding medical device safety – e.g. participate in national Medical Device Safety Officer Webex and chat forums.

7. Other reporting systems

7.1 Serious Adverse Incidents (SAIs) Reporting

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 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 SAIs that involve Medical Devices, non-medical devices plant or building equipment **must also** be reported to the NIAIC utilising the NIAIC adverse incident form.

7.2 The MHRA Yellow Card Scheme

The Yellow Card Reporting Scheme is operated by the MHRA. The scheme enables safety reporting to be made for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, and all medical devices available on the UK market.

Within Northern Ireland any incident involving medical devices must be reported to the NIAIC as per the guidance in this document. HSC Staff who report or are informed of any reporting via the Yellow Card scheme should ensure that their MDLO is notified and the NIAIC are copied in on the incident report.

7.3 SABRE (reporting blood safety and quality incidents)

With the introduction of the Blood Safety and Quality Regulations 2005 No. 50 and The Blood Safety and Quality (Amendment) (No.2) Regulations 2005 No. 2898 (effective for the purposes of regulation on 8 November 2005), the MHRA became responsible for ensuring that blood products, blood establishments and blood banks are acceptably safe.

Incidents relating to blood safety and quality should not be sent to the NIAIC. Reports under these regulations are submitted to the MHRA using the dedicated online reporting system, SABRE (Serious Adverse Blood Reactions & Events). SABRE is accessible via the MHRA website (www.mhra.gov.uk). The system also prompts reporting to SHOT (Serious Hazards Of Transfusion http://www.shotuk.org/).

Enquiries concerning the reporting of blood safety incidents should be directed to:

MHRA
Email: sabre@mhra.gsi.gov.uk
Tel: 020 7084 3336 Fax: 020 7084 3109

SHOT
Email: shot@nhsbt.nhs.uk
Tel: 0161 423 4208 Fax: 0161 423 4395

7.4 RIDDOR

In addition to reporting medical device related incidents to the NIAIC, incidents involving certain types of injury, occupational disease or dangerous occurrence, whether involving medical devices or not, should also be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR '95) to the relevant enforcing authority for the premises at which the incident occurred. For healthcare premises, this will usually be the Health and Safety Executive Northern Ireland (HSENI). All notifications under RIDDOR should be sent to:

HSENI	Tel: 028 9024 3249
83 Ladas Drive	Fax: 028 9054 6896
Belfast	E-mail: mail@hseni.gov.uk
BT6 9FR	www.hseni.gov.uk

Online reporting and copies of report forms are available via their website.

8.0 Contacts

Enquiries concerning the content of this document should be addressed to: niaic@health-ni.gov.uk or by telephone on 028 90523868.

Annex 1

Examples of medical devices

Anaesthetic equipment
Blood warming cabinets
Catheters (e.g. urinary, cardiac)
Chiropody equipment
Dental equipment and materials
Dressings
Endoscopes
Examination gloves
Hospital beds
Implants – powered (e.g. implantable defibrillators, pacemakers) and non-powered (e.g. heart valves, orthopaedic implants, bone cements)
Incontinence products
IV administration sets and pumps
Ophthalmic equipment
Patient monitoring equipment (e.g. cardiac monitors)
Physiotherapy equipment
Radiotherapy equipment (brachytherapy, external beam)
Sphygmomanometers
Surgical instruments and equipment
Syringes and needles
Thermometers
Urine drainage systems
Vaginal specula
X-ray systems, ultrasound imagers and CT/MR scanners

For patient transportation or moving (but **not** including ambulance vehicles themselves):
Carry chairs
Hoists and slings
Portering chairs
Slider boards and standing aids
Stretchers and trolleys

For critical care:
Defibrillators
Resuscitators
Ventilators

For people with reduced mobility or physical impairment:
Communication aids
Environmental controls
Hearing aids
Orthotics
Prosthetic limbs
Pressure relief mattresses, cushions or pads
Supportive seating
Walking aids
Wheelchairs (powered and non-powered)

For daily living:
Bathing and showering equipment
Commodes
Incontinence products
Prescribable footwear
Special chairs
Urine drainage systems

In vitro diagnostic medical devices and their accessories:
Blood gas analysers
Blood glucose meters
Hepatitis and HIV test kits
Pregnancy test kits
Specimen collection tubes
Urine test strips

Also included are:
Condoms
Contact lenses and care products
Intra-uterine devices (IUDs)

We are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices. For example:
Benchtop sterilizers
Blood and tissue storage systems
Disinfecting and sterilizing equipment
Chemical and biological indicators used in sterilization processes

Annex 2

Examples of estates equipment and plant

Building, building components and lifts.

Demolitions and construction carried out under CDM regulations, including plant.

Engineering plant and services of all types (e.g boilers, generators, heating, ventilation, water, drainage, electrical installations) and any other fixed plant equipment, but not medical devices.

Fire protection installations and equipment.

Permanently installed sterilizers, bedpan washers and disposal units.

Equipment in laundries, catering departments, workshops and any other plant or equipment used for maintenance or cleaning.

Piped medical gas and vacuum systems, cryogenic liquid systems (CLS) including vacuum insulated evaporators (VIE's) and anaesthetic gas scavenging systems.

Fixed luminaries including examination lamps.

Communications equipment (e.g. telephone and bed head services, nurse call systems, paging systems, alarm and audio equipment).

Lightning protection and electrostatic discharge systems.

Incinerators and other clinical waste treatment equipment.

Environmental aspects (buildings) and the Control of Substances Hazardous to Health (COSHH) Regulations.

Installation aspects of fume cupboards and microbiological safety cabinets, including ductwork and their interaction with ventilation systems.

Fixtures and fittings which have been installed to prevent patients self-harming.

Poor design or incorrect installation.