Medicines &
Healthcare products
Regulatory Agency

NHS

Medical Device Safety Officer

Contents

Revision history

Version	Date published	Changes
V2.1	October 2020	Amended to include reference to National Patient Safety Alerts instead of PSAs and MDAs.
V2.0	September 2019	Major revision of v1

Executive Summary

The purpose of this handbook is to support new as well as established MDSOs to fulfil their role by signposting to relevant information and resources.

The Medical Device Safety Officer role was created on 20th March 2014 following the publication of an NHS England Patient Safety Alert that aimed to help healthcare providers increase the quality and frequency of incident reporting for medical device related problems and medication errors. The alert called on large healthcare provider organisations across both public and independent sectors, along with healthcare commissioners, to identify named responsible persons in both medical device and medication safety roles.

A new National Network was set up to support Medical Device Safety Officers in England. Wales, Scotland and Northern Ireland have similar networks and are linked together. Its aim was improved communication and feedback on reported safety issues, monthly webinars, online forums, conferences and workshops. An editorial board was established to provide expert and strategic clinical support for the Medical Device Safety Officers and the National Network.

This handbook provides practical information and resources to support those who have been designated the Medical Device Safety Officer in their organisation. It is particularly relevant to people new in post or as a quick reference for established staff.

1 Introduction

This chapter provides the context and background to the Medical Device Safety Officer role.

Medical devices play a key role in healthcare, vital for diagnosis, therapy, monitoring, rehabilitation and care and can be an instrument, appliance, apparatus, software and even an 'app'.

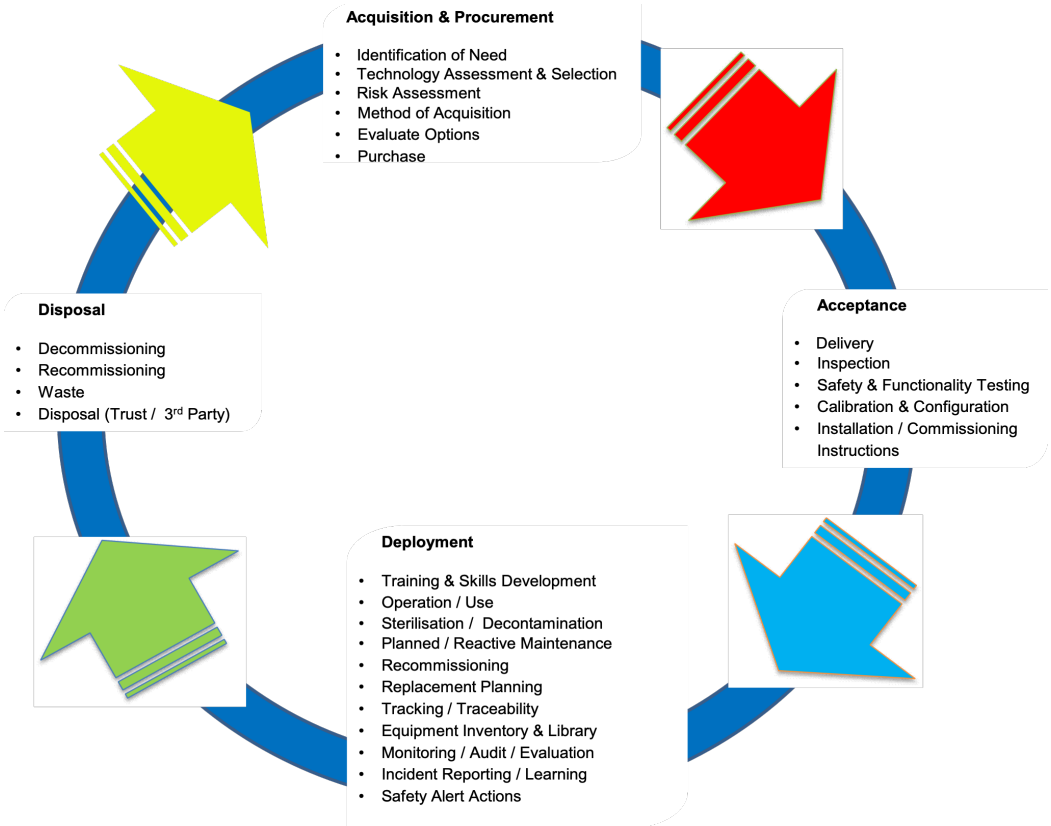
Table 1 Examples of medical devices (not an exhaustive list)

Function	Examples
Diagnosis or treatment of disease	Diagnostic laboratory device, X-ray machines, magnetic resonance imaging (MRI) scanners, vascular catheters, dressings, surgical instruments, syringes, hip replacement implants, standalone software for diagnosis
Monitoring of patients	ECG, pulse oximeter
Critical care	Infant incubators, blood-gas analysers, defibrillators, ventilators, vascular stents
Improve function and independence of people with physical impairments	Hoists, orthotic and prosthetic appliances, pressure care devices, walking aids, wheelchairs
Community-based healthcare	Dressings, domiciliary oxygen therapy systems, urine drainage systems
Emergency services (ambulances)	Stretchers, trolleys, defibrillators

Effective management of this important resource is required to satisfy high quality patient care, clinical and financial governance, including minimizing risks of adverse incidents.

The role of the Medical Devices Safety Officer (MDSO) was established primarily to ensure effective reporting and response to adverse incidents involving medical devices and, that lessons are learnt and shared within the organisation. In addition, the MDSO is expected to be the organisation's contact for a national Medical Devices Safety Network – see background below for more information. Many of you will also play an active role in the advising and monitoring of the management of different aspects of the medical device lifecycle which, together with learning from adverse incidents including near misses, will greatly assist in reducing their potential for harm (Figure 1).

Figure 1: Management of the Lifecycle of a Medical Device



Background to Network Formation

To reduce the frequency and severity of medical device related incidents in England, despite improvements in manufacturing and regulations surrounding medical device safety, incidents can still occur. Recognising this, NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA) jointly issued a Stage 3, Directive Alert to improve medical device incident reporting and learning. A key aspect of this Alert was the designation of Medical Device Safety Officers (MDSO).

A complementary Stage 3 Directive Alert set up a raft of Medication Safety Officers (MSO). It should be noted that many medicines are inexorably linked to devices for delivery, and synergies through collaboration with Safety Officers is an expectation of the role.

Similar positions for reporting have been established in NI (NIA-2014-001) and Scotland(CEL 43 (2009)) with Medical Devices Liaison Officers (MDLO) and Equipment Coordinators respectively.

A survey following the set up of the network showed that medical device safety officers' experience in medical device patient safety roles was more than 5 years. 40% spent less than 3 hours per week dedicated to the role but most felt 5-8 hours per week would be more appropriate.

2 Getting Started

Trying to get a business case to fund a Medical Device Safety Officer post? Or just new to the Medical Device Safety Officer role and unsure of your responsibilities? Read on for some basic steps to get you started.

If you are looking for examples of job descriptions you can find these on the MDSO forum.

Role and Responsibilities of the MDSO

One of the MDSO key roles, as set out in the Alert, is to promote the safe use of medical devices across their organisations and be the main point of reference for medical device safety. The MDSO is expected to:

- manage medical device incident reporting within the organisation and, improve the reporting and learning from these
- provide insight and feedback to the MHRA and NHS England & Improvement that may contribute to national medical device related alerts
- be an 'expert' in understanding how national medical device patient safety actions and field safety notices have and should be acted upon within your organisation
- know how to escalate issues from the Medical Device Safety Committee to your organisation's Executive Board
- be an active member of the National Medical Device Safety Network
- be responsible for implementing national learning shared through MDSO network WebEvents and the Forum to improve local medical device safety;

MDSOs are the essential link to implement National initiatives by providing local actions to improve Medical Device Safety.

Practicalities

One of the first things a MDSO needs to do is make sure that their organisation's details are up to date on the Central Alerting System (CAS) using the MDSO contact form (Appendix F) which should be sent to the CAS team. CAS is managed by MHRA and the team can be emailed at SafetyAlerts@dh.gsi.gov.uk. Legitimacy for the role and its responsibility is linked to being identified on the CAS list of MDSOs. Being on the list is essential to make sure you receive all the relevant communication, including invites to meetings and events, from the National MDSO Network.

The National Patient Safety Alerting Committee (NaPSAC) is working to align all bodies and teams that issue national alerts, and make sure that a future system of National Patient Safety Alerts set out clear and effective actions that providers must take on safety-critical issues. MHRA and NHS England & Improvement issue these alerts.

In Northern Ireland you should be registered with NIAIC; in particular the Northern Ireland Central Alert System (NICAS) system. In Scotland you need to be registered with IRIC.

Next, work through the following questions, which will begin to introduce you to key individuals within your organisation and start you off fulfilling your responsibilities.

Fact finding: Do you know…

1. How do I access the generic MDSO mailbox?

All organisations with an MDSO should have a generic mailbox address. Find out what yours is and make sure you can access this. Please note that it is your responsibility to disseminate and communicate within your organisation, whether you have a generic email, a direct email address or both.

2. How do I access my organisational incident reporting system?

Where possible, access to the reporting system is a requirement of the post. This is because the Alert makes the MDSO responsible for the quality and frequency of the organisation's reporting. Without access it is not readily feasible to review and confirm the accuracy of the data or the device incident.

In secondary care trusts you will need to access the incident reporting system as an 'expert' or 'super-user' with the ability to review, revise, and in some organisations approve medical device incidents before they are uploaded to the National Reporting and Learning System (NRLS) and MHRA's Yellow Card incident reporting system. The Alert underpins that as the organisation's nominated MDSO you are responsible for the quality and frequency of reporting in your organisation. It is also useful to be able to interrogate and create reports from these systems to help you monitor trends and identify themes. Please ensure that you report individual incident and not just observed trends.

Your organisation may not have implemented electronic reporting direct to the NRLS and this is not possible with Yellow card yet. In such cases, it is still important to report and to have a plan to develop reporting mechanisms.

You also need to ensure that there is local learning from incidents and continuous safety improvement within the organisation. Where the learning is considered to be of national importance then this should be communicated directly to devices.queries@mhra.gov.uk.

For the purposes of the Alert it is still necessary to be able to demonstrate that there is a system for compiling incident reports, learning from them and progressively making care safer for patients.

3. How do I complete a Yellow Card Report to MHRA?

See Chapter 4.

4. Who is my organisation's incident reporting system manager/lead?

Organisations with reporting systems are likely to have a dedicated incident reporting system manager or lead who will be a key contact to enable your access and use of your local system as described above. The Alert provides the authority for you to engage with this person(s).

5. How often are incidents uploaded to the NRLS?

One of the Alert requirements was to improve the timeliness of reporting to the NRLS, so knowing how often incidents are uploaded from your organisation, and influencing this if necessary, will help you with this responsibility. There are rules for reporting serious harm within 48 hours [https://www.england.nhs.uk/patientsafety/serious-incident/]. A benchmark for other levels of harm would be under a month from the date of incident.

6. How are medical device related categories in the local incident reporting system mapped across to the NRLS codes for medical device?

Improving the quality of reports and minimising the use of categories such as 'other' and 'unknown' was a driver for the alert. Many organisations use local categories, which if not mapped properly, may get reported as 'other' and 'unknown' when uploaded to the NRLS. Check what categories are in use at your organisation and how these map across to the NRLS categories.(Chapter 4).

7. Who is my organisation's Medication Safety Officer (MSO)?

Medication administration often involves the use of devices and equipment such as infusion pumps. Some products, for example, flushes may also be licensed as a medical device. It is therefore important to work closely with your MSO to ensure a comprehensive review and understanding of incidents involving both medicines and medical devices. In some organisations, the same individual may be the MDSO as well as the MSO. We estimate that 20% of non-serious harm medication errors involve medical devices and this rises to nearly 50% for serious harm. Through the Safety Officer Alerts strong links have been forged with medicines and the devices staff at the MHRA. You can engage with them through the MDSO/MSO forum.

8. Which board director or equivalent has oversight responsibility for Medical Device Safety?

The individual with oversight responsibilities is your 'go-to' person for escalating issues to the board, so make sure you know them, and they know who you are (see Infrastructure and support).

9. Who is my organisation's Central Alerting System Officer?

This varies in organisations. It may be part of the MDSO or MSO role or it may be help by Health and Safety or Governance departments. You will need to know how alerts are disseminated and your role within this for medical device related alerts, or for other alerts that would benefit from a medical device aspect.

Infrastructure and Support

To be able to fulfil the requirements of the role, the MDSO needs support from others within the organisation. It is important you are represented within your organisation's structure in a way that allows you to take the learning from local incidents and follow through with subsequent actions.

The Alert requires a Board Director (medical or nursing) to have oversight responsibilities for medical device incident reporting and learning systems. The individual with oversight responsibilities is your 'go-to' person for escalating issues to the Board.

TIP: Arrange a meeting with this person as soon as you can so you can introduce yourself and they know who you are. Use the opportunity to remind them about your role and responsibilities and the importance of their input in:

- fostering a safety culture
- ensuring systems for reporting and learning are operating effectively and that important patient safety issues identified are addressed adequately at local level.

Do you know the other key personnel in patient safety and risk management in your organisation? For example, Governance leads, MSO, CAS Officer, incident reporting lead, Risk lead, Health and Safety lead. Also see Key Working Relationships.

Committees

An existing or new multi-professional group should be identified to review medical device incidents locally and implement actions to improve safety for patients. Usually this is the Medical Devices Group/Committee who have clear Terms of Reference and responsibility for ensuring the organisation's medical devices policies meet current legislation, guidance and best practice.

The Group/Committee should be multi-professional and include the MDSO, MSO, medical and nursing staff, those in risk and general management and a

patient representative. Your organisation's Medical Devices Group / Committee may also include others not listed here.

The Medical Devices Committee should also: provide advice and guidance on a procurement and acquisition programme for medical devices; regularly review medical device incidents locally and, implement actions to improve patient and staff safety.

TIP: Find out how your Medical Device Safety Group or Committee links in with other committees within your organisation. This may include the Medicines Safety Committee, Patient Safety or Risk Committees and local specialty or departmental clinical governance/risk groups. **Remember**: committees often have multiple functions.

Key Working Relationships

The MDSO will be expected to work with staff across a wide range of departments and services, all of whom can offer you advice and guidance about their specific area of expertise. Here are some of the main ones you might work with but remember, there may be others not listed here.

- Central Alert System (CAS) Administrator/Officer
- Clinical Engineering / Medical Physics
- Estates & Facilities Management/Waste Management
- Infection, Prevention & Control
- Decontamination lead
- Learning & Development/Medical Device Trainer
- Medical Gases
- Pharmacy (especially the Medicines Safety Officer (MSO))
- Procurement
- Medical Devices Committee
- Medical Devices Incident Review Committee
- Patient Safety Committee(s)
- Risk Management, Quality & Governance

The MDSO editorial board

oversees activities of the network and provides expert and strategic support for MDSOs.

National Safety Network

The main networking and collaborative group for MDSOs is the National Medical Device Safety Network (NMDSN). The objectives of the Network are to:

- improve reporting and learning from medical device incidents by educating and training MDSOs in patient safety science, and disseminating relevant research and information concerning new risks and best practice;
- provide an environment for sharing best practice and for highlighting nationally risks that are identified locally;
- provide a platform for disseminating knowledge and understanding of patient safety issues and for refining instructions such as National Patient Safety Alerts.

Every MDSO is expected to be an active member of the MDSO network and to participate in monthly web meetings [webexes]. These webexes which are organised by the MDSO editorial board, allow for information sharing and the chance to share experiences and ask questions of the organisers, presenters and other attendees.

In Northern Ireland there is also a quarterly webex organised by NIAIC to allow MDLOs to update themselves on current device related issues and exchange learning from recent incidents on a regional basis. Scottish Equipment coordinators also have their own communication network.

Connecting On-Line with the Network

8

MDSO Forum

To access the online forum, use your registered MDSO email address and contact details to register at: http://forums.mhra.gov.uk/usercp.php.

Remember: you will only be able to access and interact on the forum after you have received a confirmation email.

Collaboration

These activities include:

- a joint MDSO/MSO annual conference;
- NAMDET regional meetings should also have an Agenda item on MDSOs.

At the time of publication of this handbook, a number of patient safety interest groups and initiatives also exist with overlapping interests. Some of these are highlighted below:

- Patient Safety Collaboratives
- Academic Health Science Networks

- Sign up for Safety Campaign
- Patient Safety Learning
- Clinical Human Factors Group

Have you been involved in investigating an incident or developing innovative solutions to improve Medical Device Safety? Contact the MDSO editorial board via devices.queries@mhra.gov.uk or patientsafety.enquiries@nhs.net for a session to share the learning at a monthly webex.

3 Tools

To be an effective MDSO you will need to acquire and develop specialist knowledge and skills.

The field of patient safety, human factors and medical device safety continues to grow. In this chapter, you are signposted to a range of resources that will help your knowledge and skill development. Other formal taught courses (masters, postgraduate certificate and diploma) in the broader areas of quality and patient safety are delivered by a number of universities. However, the focus of this chapter highlights a range of resources that can assist with development of knowledge and skills for the MDSO role.

World Health Organisation Patient Safety Curriculum

The aims of the World Health Organisation (WHO) curriculum for Patient Safety are: *"highlights the key risks of health care and how to manage them, shows how to recognize adverse events and hazards, report and analyse them.*

It teaches about team-work and the importance of clear communication across all levels of health care whilst emphasizing the importance of engaging with patients and carers to build and sustain a culture of patient safety."
Materials and course guide is available here.

Although designed as a guide for teachers it is a useful

tool to learn from. You can then use it to teach others!

7 Steps to Patient Safety

This resource can be used by MDSOs to work through the '7 steps' to patient safety in the context of medical devices to reduce the risk of harm to patients and staff.

The 7 Steps to Patient Safety resource is available via the NRLS archived website so use with caution: https://webarchive.nationalarchives.gov.uk/20171030124342/http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/ .

Root Cause Analysis

A fundamental aspect of the MDSO role is to lead or at least be involved in investigating medical device safety incidents. One of the tools which can be used during the investigation process is a root cause analysis (RCA). RCA helps to *'identify **how** and **why** patient safety incidents happen and to identify areas for change and development of recommendations which deliver safer care for patients.'*

NHS Improvement has produced a series of resources including:

https://improvement.nhs.uk/resources/root-cause-analysis-using-five-whys/

https://improvement.nhs.uk/resources/cause-and-effect-fishbone-diagram/

The forum also has resources in this area.

Quality Improvement Tools

Improving and learning from incidents is core to the MDSO role. If changes need to be made these should be planned with the involvement of relevant stakeholders and then assessed for impact.

Quality improvement tools allow interventions to be planned and tested on a small scale. They enable a systematic approach that can be applied quickly often with minimal resources. Some examples include:

- Quality improvement made simple.
- Healthcare Improvement Scotland.
- Q Community

Design for Patient Safety and Human Factors

Devices should be designed in such a way to minimize the likelihood of use error (human factors) and hence improved safety for patients. There are

resources for manufacturers on user testing in the development of medical devices and human factors.

Resources for users (not medical device specific) include:
NHS England - human factors
Human Factors in Healthcare
Royal College of Nursing – Patient Safet and Human Factors

ECRI Top 10 Health Technology Hazards

ECRI collates the latest hazards identified worldwide and provides some guidance.

TIP: Find out what training is available within your organisation which can help to broaden your knowledge of managing, risk assessing and auditing medical devices.

4 Being Effective

How does all this translate to the daily job? What do you need to do to be effective, and how will you demonstrate that you are?

As the MDSO you should be leading or involved in the following areas within your organisation:

- ✓ Pro-active risk assessment and analysis using tools such as Failure Modes Effect Analysis (FMEA) and Fault Tree Analysis (FTA).
- ✓ Liaising with managers and senior clinical colleagues to ensure the organisation's infrastructure supports dissemination of learning as well as improvement strategies.

✓ Setting the strategy and vision for Medical Device Safety within your organisation

How Will I Know Whether I Am Being Effective?

For any initiative, evaluation and demonstration of effectiveness is imperative. This is especially the case for the MDSO role, which is relatively new and has a limited evidence base.

To make your mark as the MDSO and to show the impact you have within your organisation and beyond, remember to:

✓ **Use the title**! As well as being the MDSO you may have other roles and titles. However it is important to publicise and use the title of MDSO. It gives you the authority and identity to lead on Medical Device Safety matters and is recognized nationally. Even when you are collaborating with others it is important to emphasise the MDSO title. Publicity and branding are important;

✓ **Monitor and measure the outcomes** of any interventions that you implement. This may include KPIs for the Medical Devices Safety group, feedback from participants of education and training sessions, or actual patient outcome data;

✓ **Publish any initiatives** that have resulted in patient safety improvement. You can publish the outcomes within your organisation, as presentations to the MDSO web event, at national and international conferences and as manuscripts in peer reviewed journals.

✓ **Audit medical device safety initiatives** based on local trend or national guidance. An example could include auditing of a ward to see if air flowmeters are in general use. If so, you may need to provide additional guidance and support to that area to understand the reasons behind the alert and assist them in developing a system to meet it

✓ **Medical device safety is extensively linked to medical device training**. Find out what medical device training happens in your organization and who is responsible for it. Remember users are accountable for the use and misuse of a medical device

No Training; No Touching

5 Reporting & Monitoring Systems

Healthcare systems are complex involving multiple individuals and settings as well as information technology and reporting systems. Medical Device Safety forms part of this wider system of patient care and safety. This section highlights the overlap and interaction between different reporting and monitoring systems.

A number of national and local medical device safety and patient systems exist. As MDSO you need to know and understand these to facilitate your role.

Organisational Reporting Systems

Each organisation will have specific reporting systems for different issues, such as claims, complaints, Patient Advisory and Liaison Services (PALS) and incidents. All of these may include medical device related reports, which may or may not be reported in the incident reporting system.

Additionally, even within an incident reporting system, medical device incidents may be categorised as something else. For example, medical device unavailability or delays due to lack of staff may be categorised as 'infrastructure' or 'inadequate staffing.'

To get a full picture of Medical Device Safety reports you need to find out how the different reporting systems interact. It is also advisable to gain a good understanding of the full coding structure of the incident reporting system.

National Reporting & Learning System

For the majority of MDSOs data from your organisational reporting system will be uploaded to the NRLS. The frequency of reporting will vary by organisation, so find out how often reports are uploaded at your organisation.

The NRLS is a 'relational database' that is dynamic meaning, organisations can upload, change, amend, delete or add to any of its reported incidents. So even if an incident is being reviewed, it is possible for the preliminary report to be uploaded within a month and the full report to be finalised once the details have been completed.

Some MDSOs work for organisations that do not currently upload to the NRLS nevertheless, there will be a mechanism for reporting and the same principles apply.

TIP: By mapping 'local' codes to appropriate NRLS codes, if you are using different classification or categorisation, will minimise the use of automated mapping to the code 'other'. [Appendix 1]

***Remember** to check mapping to NRLS codes and minimise the number of incidents categorised as 'other'.*

Your local data will provide the richest source of information identifying local trends and themes which can be used for learning across your organisation.

If you are interested in benchmarking on a wider level, you can gain access to the NRLS database which allows comparison with other organisations.

NRLS data is published regularly and data workbooks of Organisation Patient Safety Incident Reports are available.

You should be able to request access to the NRLS directly through your organisational co-ordinator or via the NRLS reporting homepage. You can compare your data with up to 6 peer group organisations after logging in. Note, data from the other organisations will be presented as an aggregate.

A new patient safety incident management system (PSIMS) is being developed to replace the NRLS. This content will be updated once PSIMS is fully operational

Yellow Card Reporting

In England and Wales, medical device incidents should also be reported to MHRA via the Yellow Card system. This may be done directly by the reporter or via their organisation's MDSO/Risk Manager depending on local policies

In Northern Ireland equipment and estates related adverse incidents should be reported to the Northern Ireland Adverse Incident Centre (NIAIC) subject to their reporting criteria.

In Scotland, adverse incidents are reported to Incident reporting and investigation centre (IRIC).

6 Frameworks and Legislation

As a MDSO you may be asked to review your organisation's medical device related policies and procedures so you will need to be aware of various frameworks and legislation for managing the medical devices lifecycle including reporting and learning.

A number of additional frameworks and legislative requirements exist, which you may need to contribute to. The key ones are listed below but always liaise with your governance and risk leads to make sure you are fully aware of any external or legal reporting requirements.

- Acquisition and Management of Medical Devices
- Dissemination of Alerts/Notices (CAS)(CCR105)
- Incidents/Near Misses, Serious Incidents Requiring Investigation
- Infection Prevention & Control (ICC001)
- Manual Handling (HS025)
- Medical Devices Training Policy (CCR049)
- Portable & Fixed Electrical Equipment (HS015)
- Standing Financial Instructions

The Patient Safety Strategy

The Patient Safety Strategy was launched as part of the NHS Long Term Plan 2019 and it describes how the NHS will continuously improve patient safety, building on the foundations of a safer culture and safer systems.

Never Events Policy and Framework

Never Events are serious incidents which should not occur if proper safety procedures are followed. The Never Event list is updated regularly so please check this is the latest list. There are five medical device related incident types in the 2018 Never Events list:

- Wrong implant/prosthesis
- Retained foreign object post-procedure
- Chest or neck entrapment in bedrails

- Misplaced naso- or oro-gastric tubes
- Unintentional connection of a patient requiring oxygen to an air flowmeter

Serious Incidents Framework

The Serious Incident Framework builds on previous guidance that introduced a systematic process for responding to serious incidents in NHS-funded care. The focus of the framework is learning from incidents.

Duty of Candour

Duty of Candour is a legal duty on hospital, community and mental health trusts to inform and apologise to patients if there have been mistakes in their care that have led to significant harm

Being Open

Open and **honest** communication with patients is at the heart of health care. Research has shown that being open when things go wrong can help patients and staff to cope better with the after effects of a patient safety incident.

NRLS has reviewed the guidance and developed a **Being Open** framework and alert (now archived).

Healthcare staff may be fearful of upsetting the patient, saying the wrong thing or admitting liability. This guidance and the associated actions outlined in the alert, provide reassurance that Being Open is the right thing to do, and encourage NHS boards to make a public commitment to openness, honesty and transparency. It explains the principles behind Being Open and outlines how to **communicate** with patients, their families and carers following harm.

The Just Culture Guide encourages managers to treat staff involved in a patient safety incident in a consistent, constructive and fair way.

A Week in the Life Of…..

The Role of Medical Device Safety Officers (MDSO) in the UK - presented by Paul Lee

Please provide other examples for other areas e.g. CCG, Mental Health, Community

The Last Words

It is hoped that this handbook provides you with some practical tips and suggestions, no matter what your starting point is in the MDSO role.

It is intended to be an evolving resource by an MDSO for other MDSOs, so please feel free to send through any feedback, comments and suggestions to any of the MDSO Editorial Board.

Good luck in the MDSO role!

Glossary

Here are some common terms and phrases you may come across whilst carrying out your role

Accessory: an article or item(s) which, whilst not being a device is intended by the manufacturer to be used in conjunction with the device to enable the device to be used for its intended purpose.

Adverse incident

Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, user or of other persons or, to a serious deterioration in their state of health. (Article 10 of the Medical Device Directive)

Examples include:

- someone's injured (or almost injured) by a medical device, either because its labelling or instructions aren't clear, it's broken or has been misused
- a patient's treatment is interrupted because of a faulty device
- someone receives the wrong diagnosis because of a medical device
- you think a medical device is fake or counterfeit

Care Quality Commission (CQC): the Care Quality Commission (CQC) is an executive non-departmental body of the United Kingdom (UK) Department of Health and is responsible for the monitoring, regulation and inspection of health and social care services in England and ensures these services meet the fundamental standards of quality and safety.

Central Alerting System (CAS): National Patient Safety Alerts are sent centrally via the Central Alerting System (CAS). They are distributed locally by the Trust CAS Liaison Officer (CLO/CASLO) who also has responsibility for tracking the completion of the necessary actions in accordance with the Trust's CAS Policy and reporting to the Medical Devices Group (MDG). The postholder can vary across different Trusts

Clinical Engineering Contractor: The company providing clinical engineering maintenance services to the Trust.

Clinical Engineering Staff: staff in clinical engineering who provide support for the maintenance of medical devices.

Clinical Staff: staff involved in delivering patient care in ward/clinical area/ community setting.

Corrective (Reactive) Maintenance: repair/maintenance of a medical device in response to identified fault and/or device failure.

Chemical burns or sensitisation: residues from chemical decontamination agents on materials that can adsorb/absorb chemicals

Cross-infection: the transfer of micro-organisms from one person/equipment/ environment to another

Decontamination: this is the combination of processes including cleaning, disinfection and sterilisation used to render a reusable item safe for further use on patients and handling by staff.

Electrical Safety Test (EST): an essential test to ensure safe operating standards for medical devices which use electricity. The electrical safety test for medical devices is different from the portable appliance test (PAT) for domestic appliances.

End User: a patient, carer or client who uses a medical device unsupervised at home eg. wheelchair user.

Fixed Medical Device: equipment which is fastened or otherwise, secured at a specific location in a building or a vehicle and can only be detected by a tool

Limited Use Device: a medical device intended only for a specified number of uses. There is therefore a requirement for the number of uses to be recorded. The item shall be discarded after being used for the maximum recommended number of times.

Manufacturer: natural or legal person with responsibility for the design, manufacture, packaging or labelling of a medical device, assembling system or adapting a medical device before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.

Medical Device: a medical device is, according to Medical Device Regulation, any instrument, apparatus, appliance, material or health care product (excluding drugs), used for a patient or client for the purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease

- diagnosis, monitoring, treatment or alleviation of or compensation for, any injury or handicap
- diagnosis, prevention, monitoring, treatment or alleviation of disease
- investigation, replacement or 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.

Medical device prescribers: a person who decides which is the appropriate device for a given patient or client e.g. occupational therapist.

Medical Equipment: mobile electrical equipment, intended to diagnose, treat or monitor the patient under medical supervision and which makes physical or electrical contact with the patient and/or, transfers energy from the patient and/or, detects such energy transfer to/from the patient.

Medicines & Healthcare products Regulatory Agency (MHRA): an executive agency of the Department of Health and is responsible for protecting and promoting public health and patient safety by ensuring medicines, healthcare products and medical equipment meet the appropriate standards of safety, quality, performance and effectiveness and they are used safely.

National Patient Safety Agency (NPSA): a special health authority within the NHS and is responsible for monitoring patient safety incidents, including medication and prescribing error reporting.

National Patient Safety Alerting committee (NaPSAC): The National Patient Safety Alerting Committee (NaPSAC) has been established to improve the effectiveness of safety critical communications and to support providers to better implement the required actions. The key way NaPSAC is doing this is through the introduction of National Patient Safety Alerts. More information is available here: https://www.england.nhs.uk/patient-safety/national-patient-safety-alerting-committee/

National Patient Safety Alerts: nationally distributed safety alerts and notices relating to medical devices includes those issued by NHS England & Improvement and MHRA (replacing Medical Device Alerts [MDAs] over the course of 2020). Other organisations such as NHS Estate will be issuing this style of alert shortly.

National Reporting & Learning System (NRLS): a central database of patient safety incident reports

Patient safety incident - any unintended or unexpected incident which could have lead to harm (a "near miss"), or resulted in actual harm, for one or more patients receiving NHS-funded healthcare.

Planned Preventative (Routine) Maintenance (PPM): scheduled maintenance/servicing of medical devices as determined by the Estates & Facilities Department taking into account the manufacturers recommendations.

Portable Medical Device: transportable equipment intended to be moved from one location to another while used or between periods of use while being carried by one or more persons.

Professional User: qualified person using devices as tools who prescribe and use medical devices such as:

- healthcare assistants
- nurses
- matrons
- clinical site practitioners
- doctors
- physiotherapists

Reprocess: to make good the device for reuse by any or a combination of the following processes:

- cleaning
- disinfection/decontamination
- sterilization
- refurbishment
- repackaging

Reprocessor: person who undertakes the reprocessing of a medical device.

Re-usable Medical Device: a medical device intended, by the manufacturer, to be used more than once and by more than one patient. The device shall need to be decontaminated or sterilised appropriately between each episode of use in accordance with the manufacturer's guidelines for cleaning and decontamination of the product.

RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences regulations) is regulated by HSE.

Serious incidents- events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response.

Single Patient Device: a device or item which can be used for more than one episode on **one patient only** (e.g. oxygen mask, BP cuff). The device shall be cleaned and/or decontaminated between each use according to manufacturer's instructions. The manufacturer must state how the device should be decontaminated and how many times the device can be used prior to disposal. The device **shall never** be used on more than one patient.

Single Use Device: a device or item intended to be used on an individual patient during a single procedure and then discarded. It **shall never** be reused or reprocessed under any circumstances.

Supplier: a person or organisation who provides the medical device. This may not be the manufacturer but the manufacturer's representative who holds the licence to sell the product.

Key References

Legislation & Guidance

Legislation

- Control of Substances Hazardous to Health Regulations 2002
- Consumer Protection Act 1987 (Consumer Safety and Product Liability) [8]
- Electricity at Work Regulations 1989 [5]
- Electrical Equipment (Safety) Regulations 1994 [22]
- Employers' Liability (Compulsory Insurance) Act 1969 [14]
- General Product Safety Regulations 2005 [9]
- Health and Safety at Work Act 1974
- Health and Social Care Act 2008 Regulation 2010:16.
- Ionising Radiation (Medical Exposures) Regulations 2000 [27]
- Ionising Radiations Regulations 1999 [12]
- In Vitro Diagnostic Medical Devices Regulations 2000 [26]
- Law by the Medical Devices Regulations (MDR) June 1998
- Lifting Operations and Lifting Equipment Regulations 1998 [13]
- Management of Health and Safety at Work Regulations 1999 [28]
- Manual Handling Operations regulations 1992
- Medical Devices Regulation (MDR) 2017/745
- Medical Devices Regulations 2002. (as amended)
- Pressure Systems Safety Regulations 2002 (Amended 2003) [11]
- Provision and Use of Work Equipment Regulations (PUWER) 1998
- Reporting of Injuries, Diseases and Dangerous Occurrences regulations (RIDDOR)
- Restriction of Hazardous Substances (RoHS) Directive 2011/65

- Sale & Supply of Good Act 1994

- Special Waste Regulations 1996
- Pressure Systems Safety Regulations 2002 (Amended 2003) [11]
- Sale and Supply of Goods Act 1994 [20]
- Special Waste Regulations 1996
- The Health and Social Care Act 2008 (Regulated Activities) Regulations
- The Care Quality Commission (Registration) Regulations 2009
- The Common Law of Negligence: Law Reform (Contributory Negligence) Act 1945
- Trade Descriptions Act 1968 [21]
- Unfair Contract Terms Act 1977 [23]
- Waste Electrical and Electronic Equipment (WEEE) Regulations 2013

Guidance/Codes of Practice

- British Standards Institute. *Medical Devices. Application of risk management to medical devices*. BS EN ISO 14971:2012
- British Standards Institute. *Medical Devices- Symbols to be used medical devices, labelling and information to be supplied. Part 1: General requirements.* ISO 15223-1:2016
- British Standards Institute. *Requirements for electrical installations. IET Wiring Regulations*. BS 7671 2008 + A3:2015
- Care Quality Commission. *Regulation 15: Premises and Equipment (previously Outcome 11: Safety availability and Suitability of equipment)*: 2014

- Care Quality Commission. *Guidance about Compliance: Essential Standards of Quality & Safety*: 2010
- Care Quality Commission. *Regulations for Service Providers and Managers. Regulation 15:2017*
- Department of Health. *The Health & Social Care Act (2008) Code of Practice on the prevention and control of infections and related guidance*: 2015
- Department of Health Device Bulletin: *Single-use Medical Devices: Implications and Consequences of Reuse*: 2011
- International Standard for Organization. *Medical Devices Quality Management Systems*. ISO 13485:2016
- *Management of In-vitro Diagnostic Medical Devices and Management and use of IVD Point of Care Test Devices (MHRA)*
- Medicines Healthcare products Regulatory Agency. Device Bulletin. *Managing medical devices: Guidance for healthcare and social services organisations*. (DB005): November 2015
- Medicines Healthcare products Regulatory Agency. *Reporting Adverse Incidents & Disseminating Medical Device Alerts*:
- Medicines Healthcare products Regulatory Agency. *Management of In-vitro Diagnostic Medical Devices*: 2013
- Medicines Healthcare products Regulatory Agency. *Management of Medical Devices prior to investigation, inspection, service or repair.* MHRA DB 2003 (05) June 2003
- Medicines Healthcare products Regulatory Agency. *Devices in Practice 'Checklist for using Medical Devices:* June 2014
- Medicines Healthcare products Regulatory Agency/NHS Improvement. *Improving Medical Devices incident Reporting and Learning*. NHS/PSA/D/ 2014/006: March 2014

Appendix 1 – NRLS Codes for Medical Devices

DE01	Please select from the following choices to indicate the type of device:	0	Please select...
		A	Administration and giving sets
		B	Anaesthetic machines and monitors
		C	Anaesthetic and breathing masks
		D	Autoclaves
		E	Bath aids
		F	Beds and mattresses
		G	Blood pressure measurement
		H	Commodes
		I	Contact lenses and care products
		J	CT systems
		K	Dental appliances
		CF	Dental materials
		L	Dialysis equipment
		M	Diathermy equipment and accessories
		N	Dressings
		O	Endoscopes and accessories
		P	Endotracheal tubes and airways
		R	External defibrillators
		S	External pacemakers
		Q	Feeding systems - enteral
		T	Feeding tubes
		AA	Gloves
		AB	Guidewires
		AC	Hearing aids
		CC	Heart lung bypass machine

		AD	Hypodermic syringes and needles
		AE	Implants – active (general)
		AF	Implants – breast
		AG	Implants – cardiovascular
		AH	Implants – hip and knee
		AI	Implants – non-active
		AJ	Implants – pacemakers, defibrillators and leads
		AK	Implant materials
		AL	In vitro medical devices
		AM	Infant incubators
		AN	Infusion pumps, syringe drivers
		AO	Insulin syringes
		AP	Intravenous catheters and cannulae
		CD	Laryngoscopes
		AQ	Lasers and accessories
		AR	Magnetic resonance equipment and accessories
		AS	Mobile X-ray systems
		BT	Mobility devices- wheeled, seating aids and accessories
		CE	Mobility devices - non-wheeled
		AT	Monitors and electrodes
		BA	Ophthalmic equipment
		BB	Orthotics
		BC	Patient hoists
		BD	Patient monitoring equipment
		BE	Physiotherapy equipment
		BF	Prostheses – external limb
		BG	Radiotherapy equipment
		BH	Radionuclide equipment
		BI	Resuscitators
		BJ	Staples and staple guns
		BK	Stretchers
		BL	Surgical instruments

		BM	Surgical power tools
		BN	Sutures
		BO	Thermometers
		BP	Ultrasound equipment
		BQ	Urinary catheters
		BR	Ventilators
		BS	Walking sticks / frames
		CA	Wound drains
		CB	X-ray equipment, systems and accessories
		Z	Other
	Please define here:	Z-TXT	[Free Text]
DE02	Current location of the device(s):	A	[Free Text]
DE03	Product name:	A	[Free Text]
DE04	Model:	A	[Free Text]
DE05	Catalogue number:	A	[Free Text]
DE06	Serial number:	A	[Free Text]
DE07	Manufacturer:	A	[Free Text]
DE08	Supplier:	A	[Free Text]
DE09	Batch number:	A	[Free Text]
DE10	Expiry date:		
DE10-A		0	Year...
		X	[Years from (Current Year+20) – (Current Year-50)]
DE10-B		0	Month...
		A	Jan (01)
		B	Feb (02)
		C	Mar (03)
		D	Apr (04)
		E	May (05)

		F	Jun (06)
		G	Jul (07)
		H	Aug (08)
		I	Sep (09)
		J	Oct (10)
		K	Nov (11)
		L	Dec (12)
DE10-C		0	Day...
		X	[Numbers from 01 – 31]
DE10-D		A	Date unknown
DE11	Date manufactured:		
DE11-A		0	Year...
		X	[Years from Current Year – (Current Year-50)]
DE11-B		0	Month...
		A	Jan (01)
		B	Feb (02)
		C	Mar (03)
		D	Apr (04)
		E	May (05)
		F	Jun (06)
		G	Jul (07)
		H	Aug (08)
		I	Sep (09)
		J	Oct (10)
		K	Nov (11)
		L	Dec (12)
DE11-C		0	Day...
		X	[Numbers from 01 – 31]
DE11-D		A	Date unknown
DE12	Quantity defective:	A	[Free Text]

Medication triggers for medical device inclusion

MD02	**For this Patient Safety incident involving medicine, please select the appropriate description:**	**0**	**Please select...**
		A	**Adverse drug reaction (when used as intended)**
		B	**Contra-indication to the use of the medicine in relation to drugs or conditions**
		C	**Mismatching between patient and medicine**
		D	**Omitted medicine / ingredient**
		E	**Patient allergic to treatment**
		F	**Wrong / omitted / passed expiry date**
		G	**Wrong / omitted patient information leaflet**
		H	**Wrong / omitted verbal patient directions**
		I	**Wrong / transposed / omitted medicine label**
		J	**Wrong / unclear dose or strength**
		K	**Wrong drug / medicine**
		L	**Wrong formulation**
		M	**Wrong frequency**
		N	**Wrong method of preparation / supply**
		O	**Wrong quantity**
		P	**Wrong route**
		Q	**Wrong storage**
		Z	**Other**
	Please define here:	**Z-TXT**	**[Free Text]**
		U	**Unknown**
MD03	**Were there other important factors? If so, please select one or more from the following choices:**	**0**	**Please select...**
		A	**Failure to refer for hospital follow-up**

		B	Poor transfer / transcription of information between paper and/or electronic forms
		C	Poor communication between care providers (verbal or written)
		S	Use of abbreviation(s) of drug name / strength / dose / directions (e.g. MTX, .1 mg, 1 po)
		D	Handwritten prescription / chart difficult to read
		E	Omitted signature of healthcare practitioner
		F	Patient / carer failure to follow instructions
		G	Failure of compliance aid / monitored dosage system (MDS)
		H	Failure of adequate medicines security (e.g. missing CD)
		I	Substance misuse (including alcohol)
		K	Medicines with similar looking or sounding names
		J	Poor labelling and packaging from a commercial manufacturer
		T	Healthcare practitioner undertaking supplementary prescribing
		L	Variance to guidelines for sound clinical reasons
		M	Involving a medicine supplied under a Patient Group Direction (PGD)
		N	Involving an over-the-counter (OTC) medicine
		O	Failure in monitoring / assessing medicines therapy
		P	Failure of clinical assessment equipment
		INSTR	>> Device Incident Trigger
		Q	Issues associated with an infusion pump / syringe driver
		INSTR	>> Device Incident Trigger
		R	Failure to order laboratory test
		Z	Othe
	Please define here:	Z-TXT	[Free Text]

		U	**Unknown**
		Y	**Not applicable**

IN05 is shown below:

- **Medical device / equipment**
  - ☐ Please select sub-category...
  - ☐ Failure of device / equipment
  - ☐ >> Device Incident Trigger
  - ☐ Lack / unavailability of device / equipment
  - ☐ >> Device Incident Trigger
  - ☐ User error
  - ☐ >> Device Incident Trigger
  - ☐ Wrong device / equipment used
  - ☐ >> Device Incident Trigger
  - ☐ Other
  - ☐ [Free Text]
  - ☐ >> Device Incident Trigger

The first stop for professional medical device advice