

Medical Devices Safety Officer Handbook V3

Supporting safe use of medical devices through reporting,
learning and action



Version Number	Date Approved	Summary of changes
V3	September 2026	A fully revised third release of the original MDSO Handbook

Joint Foreword – Medicines and Healthcare products Regulatory Agency (MHRA) and NHS England National Patient Safety Team

In March 2014, the MHRA and NHS England issued a joint National Patient Safety Alert calling for the establishment of the Medical Devices Safety Officer (MDSO) Network as a national forum to improve device safety. In the years since, the MDSO network has had a tremendous impact on the work of the MHRA and NHS England. MDSOs sustained engagement and advocacy have been instrumental in increasing device reporting over time. This is particularly so in promoting the Yellow Card scheme and patient safety incident reporting through the National Reporting and Learning System (NRLS) and more recently the Learn from Patient Safety events database (LFPSE).

We would like to extend our gratitude to MDSOs for your continued support in reporting via the Yellow Card scheme and LFPSE; your insights, expertise and reporting are more important than ever. By working in partnership with the MHRA and NHS England to co-produce systems and guidance, MDSOs help drive ongoing improvements to our surveillance systems. By identifying and reporting safety concerns relating to medical devices, MDSOs play a crucial role in enabling the MHRA and NHS as a whole to act quickly, prevent harm, and maintain confidence in the devices patients rely on every day. The intelligence shared by MDSOs from Yellow Card reporting, LFPSE and local investigations enables both the MHRA and NHS England to identify emerging issues and act quickly to protect patients nationally by taking the appropriate regulatory and alerting actions as needed.

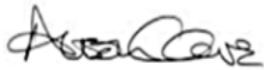
MDSOs act as the eyes and ears of both NHS England and the MHRA's safety surveillance system; working to manage complex safety alerts and implement actions within their local settings as well as the critical function of raising awareness of Patient Safety Incident and Yellow Card reporting. We recognise that reporting takes valuable time out of already demanding roles, but every single report makes a difference. The collective system of communication and collaboration between us at NHS England and the MHRA with MDSOs translates the care you have for the patients in front of you into a system that improves device safety nationwide.

As we move forward the Patient Safety Incident Response Framework (PSIRF) [[NHS England » Patient Safety Incident Response Framework](#)] will enable a wider system review of all incidents and your support and knowledge of medical device safety will be pivotal in creating enduring change in how care is delivered more safely.

The MHRA looks forward to implementing ongoing improvements to our systems to support Yellow Card reporting for medical devices. This includes upgrades to streamline the reporting process for MDSOs and future plans to strengthen our surveillance systems using data from healthcare records in tandem with data collected from reports to the Yellow Card scheme. The effectiveness of these surveillance systems relies on having

sufficient, high-quality reporting data. As MDSOs, you are key to this, helping to improve reporting cultures within your organisations so that safety concerns can be identified, shared and acted on.

Thank you for your ongoing commitment to promoting and strengthening reporting. The value of every report submitted to both organisations via LFPSE, and the Yellow Card scheme cannot be overstated. By continuing to champion reporting, you play a vital role in improving public health for all.



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Relationship between the MDSO network and the MHRA and NHS England

The MDSO Network is managed by the MDSO Editorial Board (see section 16.2 for further details). Support is provided by the MHRA and NHS England National Patient Safety Team to facilitate the effective operation of the Network. This includes secretariat activities such as organising Network meetings and maintaining MDSO Network contact information.

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1. Introduction

The Medical Devices Safety Officer (MDSO) role in England and the national MDSO Network were established in 2014 through the National Patient Safety Alert on [‘Improving Medical Device Incident Reporting and Learning’](#). Recognised as an enduring standard, the alert remains relevant to current practice and is required through the NHS Standard Contract, which mandates organisations providing NHS funded care to appoint an MDSO.

The alert set out a coordinated approach to improving the reporting, learning, and management of medical device incidents across healthcare organisations. Its focus was to strengthen patient safety by increasing the quality and timeliness of reporting, improving learning from incidents, and ensuring that action is taken to reduce the risk of harm. It introduced the MDSO role, strengthened expectations for local governance, and created the National MDSO Network to support shared learning and communication.

Over time, the MDSO Network has developed into a well-established national community. It supports collaboration between organisations, regulators, and manufacturers, enabling the sharing of learning and early identification of emerging risks. This collective approach has strengthened awareness of the role and contributed to improvements in reporting, learning, and patient safety.

However, differences in resourcing, organisational positioning, and local systems mean that the MDSO role is not experienced consistently across all healthcare providers. Where the role is well supported and integrated within governance structures, it demonstrates clear value in strengthening safety systems and improving learning from incidents, supporting organisations to better identify and manage risks associated with medical devices.

1.1. Handbook Purpose and Scope

This handbook provides MDSOs with clear, practical, and consistent guidance to support them in delivering their role effectively. It brings together national expectations, core responsibilities, and best practice approaches to incident reporting, governance, learning, and collaboration.

The handbook aims to strengthen the visibility and consistency of the MDSO role across healthcare providers, support safer use of medical devices through improved systems and shared learning, and provide both new and experienced MDSOs with resources that enhance competence, confidence, and patient safety.

If you are a new MDSO, please refer to Appendix A – Getting started as an MDSO for instructions on how to join the MDSO Network.



1.2. How to Use This Handbook

This handbook is designed to be used as both a reference guide and a practical support tool. MDSOs may use it to understand the expectations of the role, navigate key systems and processes, and support local implementation of medical device safety practices. It reflects the development of the national MDSO Network and highlights the importance of consistency, visibility, and leadership in strengthening medical device safety across organisations.

1.3. Devolved Nations

Healthcare in the UK is devolved. England, Scotland, Wales, and Northern Ireland each operate under different systems, policies, and governance arrangements. This handbook has been written to support MDSOs in England and therefore does not cover all national differences in detail. Safety Officers should refer to relevant national guidance within their own administration where appropriate.



2. The MDSO Role in Practice

Medical device safety sits within the wider activities of reporting, learning, governance and improvement. Medical devices are used across all areas of healthcare, and risks can arise from design, maintenance, use, or from the way devices are managed and supported in practice.

The MDSO role exists to strengthen how organisations manage these risks. It provides a focal point within the organisation to support the effective identification, assessment and reduction of patient harm associated with the use of medical devices.

The role was established to improve reporting, learning and communication relating to medical device incidents. It should therefore be understood as part of a coordinated approach that links local processes, national reporting and wider patient safety frameworks.

In practice, the MDSO supports how organisations bring together incident reporting, the use of data for learning, communication of safety information and coordinated action to reduce risk.

The role does not operate in isolation but helps ensure these activities are connected and that learning leads to improvement.

2.1. Purpose of the MDSO Role

The purpose of the MDSO role is to support the safe use of medical devices by strengthening how organisations report incidents, learn from information, communicate risk and coordinate responses.

This includes improving the quality and usefulness of incident data, supporting the flow of safety information between organisations and national bodies, and helping ensure that learning is translated into action.

The role provides an organisation wide view of medical device safety that may not exist elsewhere. By working across clinical, technical and governance functions, the MDSO connects information, identifies risks and supports coordinated responses. MDSOs should also work with Patient Safety Specialists (PSSs), Clinical Safety Officers (CSOs) and Medication Safety Officers (MSOs) when necessary (see section 9).

The MDSO acts as a bridge between local services, national regulators and manufacturers, helping to ensure that risks are recognised, understood and acted upon.



2.2. How the Role Operates in Practice

Medical device safety spans multiple areas within an organisation, including incident reporting, governance, technical services, procurement, training and regulatory compliance. The MDSO operates across these areas rather than within a single function. The role is therefore inherently collaborative.

The MDSO works with clinical teams, clinical engineering, governance and risk teams, procurement, training leads and others to support the safe use of medical devices.

In practice, the role involves working across the organisation to support how medical device safety is managed day to day. This includes:

- Supporting staff to report incidents effectively
- Reviewing information to identify patterns, trends, and risks
- Ensuring that safety information reaches the right people
- Supporting coordinated responses to safety alerts and Field Safety Notices
- Contributing to governance discussions and organisational decision making

The extent of involvement in each of these areas will vary depending on local structures and resources.

2.3. Role Boundaries and Responsibilities

It is important to recognise that the MDSO role is intended to support and enable existing processes, rather than to own them.

The MDSO does not replace clinical, technical or governance responsibilities. Instead, the role provides oversight, coordination and support. It helps ensure that processes are working effectively, that information is used for learning, and that risks are escalated and addressed appropriately.

A clear definition of role boundaries is essential. Where this is lacking, there is a risk that responsibility for medical device safety is placed disproportionately on the MDSO without sufficient authority or resource. This can reduce the effectiveness of safety arrangements and create gaps in accountability.

Healthcare organisations remain responsible for ensuring that processes are in place to report incidents, learn from those incidents, manage safety alerts and implement actions to reduce risk.



The MDSO supports these arrangements but does not replace organisational accountability.

2.4. Positioning the Role within the Organisation

For the MDSO role to be effective, it must be appropriately positioned within organisational structures.

This includes access to governance and risk forums, clear escalation routes, and the ability to engage with senior leadership when required. The role should enable influence and coordination across clinical, technical and operational boundaries. Where the role lacks visibility within governance structures, its ability to influence decision making and improve safety may be limited.

The level of resource and support available to the role is also critical. In medium to large organisations, the role should be a dedicated post with defined authority and resources. To support appropriate independence and objectivity of the role, it is recommended that the role sits within a governance structure rather than within a department responsible for medical device management.

Where the role is undertaken alongside other responsibilities, sufficient support is required to enable it to function effectively.

2.5. Diversity of professional backgrounds

The role of MDSO is undertaken by individuals from a wide range of professional backgrounds, each bringing valuable knowledge, skills and experience. These may include, for example, clinical engineering, governance, risk management, military service, logistics management, health and safety, and clinical roles, including both registered and non-registered professionals. MDSOs will therefore bring different perspectives and areas of expertise to the role; this diversity is also likely to be reflected within individual organisations.

MDSOs will work within their own scope of practice and should collaborate with peers and colleagues across other specialties where additional expertise is needed. For example, an MDSO with a background in clinical engineering may work with colleagues in governance or clinical teams to support specific aspects of the role, and vice versa.

2.6. Challenges in Delivering the Role

The MDSO role continues to face several challenges that can affect how effectively it operates in practice. These challenges are often shaped by how the role is understood and positioned within the organisation.



Visibility and recognition of the role can vary significantly. In some organisations, there is limited understanding of when to involve the MDSO or what the role contributes. This can reduce early engagement and limit its impact.

Resourcing and capacity are also significant factors. Many MDSOs undertake the role alongside other responsibilities, which can lead to competing priorities and a focus on reactive activity. Where protected time and support are limited, proactive safety work may be constrained.

The strength of local governance and infrastructure also affects delivery. Where processes for reporting, asset management or safety communication are underdeveloped, the MDSO may have to spend time compensating for these weaknesses rather than leading improvement.

Organisational culture plays an important role. Medical device safety requires collaboration across multiple professional groups, but engagement is not always consistent. Barriers such as organisational silos, limited leadership engagement or resistance to change can affect how effectively the role can influence practice.

The wider regulatory and technological landscape adds further complexity. Expectations continue to evolve, and the range and complexity of medical devices is increasing, particularly with the growth of digital and connected technologies. This reinforces the need for multidisciplinary working and continuous learning.

Training and professional development for MDSOs remain variable. MDSOs come from a range of backgrounds, and there is no single pathway into the role. Access to structured development, mentoring and protected learning time is inconsistent, and much learning takes place through experience and peer support.

2.7. Job Descriptions and Banding

The MDSO Network has been requested to provide example job descriptions for the MDSO role to support standardisation and guidance on banding. While the network recognises the value of this, this handbook does not include a generic job description. This reflects the reality that the MDSO role is delivered across a wide range of organisations, services, and healthcare settings, and is undertaken by individuals from diverse professional backgrounds and at different stages of their careers. As a result, the scope, seniority, and responsibilities associated with the role vary significantly between organisations.

The original National Patient Safety Alert that established the role did not define banding, competency requirements, or organisational positioning, which has contributed to this variation. For these reasons, a single “one size fits all” job description would not accurately reflect the role in practice and may be misleading. Instead, a range of example job descriptions has been shared within the MDSO Teams channel. MDSOs are encouraged to use these as a reference point, adapting them to reflect local organisational structures, governance arrangements, and the intended scope of the role.



2.8. Summary

The MDSO role supports the safe use of medical devices by strengthening reporting, learning, communication and coordination.

Its effectiveness depends not only on the individual in the role, but on the organisational processes, structures and culture in which it operates.

Where governance is clear, resources are sufficient, and leadership engagement is strong, the role can support proactive safety improvement and meaningful learning. Where these foundations are weaker, the role may become constrained to reactive or compliance driven activity and therefore be less impactful.

Understanding how the role fits within wider patient safety activity is essential to enabling it to deliver its full potential and to ensuring that medical device safety is effectively embedded within healthcare organisations.

2.9. MDSO Role Chapter Checklist

The following checklist highlights some key actions and considerations.

Knowledge

- ☐ Familiarise yourself with the original National Patient Safety Alert on [‘Improving Medical Device Incident Reporting and Learning’](#) and supporting information.
- ☐ Review the core functions of the MDSO role, including reporting, learning, communication, coordination, and support for local action.

Systems

- ☐ Familiarise yourself with the role of the MHRA, NHS England, and the National MDSO Network in supporting medical device safety.
- ☐ Participate in MDSO Network meetings and the MDSO Microsoft Teams channel where possible.
- ☐ Identify system challenges in delivering the MDSO role within your organisation.

Governance

- ☐ Familiarise yourself with how the MDSO role fits within wider patient safety, governance, and risk management systems within your organisation.
- ☐ Identify the Board level director responsible for oversight of medical device incident reporting and learning.



3. Medical Device Safety

Medical devices are integral to modern healthcare, enabling the diagnosis, treatment, and monitoring of millions of patients every year. While they bring significant benefits, their complexity means that failures, misuse, or poor systems of oversight can lead to harm.

Their safe use depends not only on design and manufacture but also on correct training, maintenance, and integration into clinical practice.

Adverse events may arise from device faults, inadequate servicing, use error, or systems that fail to support safe practice.

Medical devices are used in almost every area of healthcare, from commonly used consumables such as syringes to complex technologies such as ventilators, pacemakers and infusion pumps. When they are well designed, properly maintained and used correctly by trained staff, these devices support safe and effective care.

When systems fail, the consequences for patients can be severe. Safe medical device management spans the full lifecycle of medical devices, from initial planning and procurement through to use, maintenance, and final disposal. Medical devices include a wide range of products, from simple consumables to complex, networked, and implantable devices, each requiring different levels of control and oversight.

3.1. What is a Medical Device

The term medical device covers a wide range of products, defined in [The Medical Devices Regulations 2002](#) as:

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which

- a. *is intended by the manufacturer to be used for human beings for the purpose of-*
 - i. *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
 - ii. *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
 - iii. *investigation, replacement or modification of the anatomy or of a physiological process, or*
 - iv. *control of conception; and*



- b. *does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,*

The legal definition of a medical device is intentionally broad. It includes any item a manufacturer intends for human use to diagnose, monitor, treat, or alter the body or its functions, without relying on drugs, immunological, or metabolic means as its main effect. This definition covers thousands of different products, from simple consumables to complex implantable or software-based devices.

The table below provides a high-level summary of some common types of medical devices. The categories illustrate the wide range of products covered, from obvious devices such as surgical instruments and defibrillators to those that might be less immediately recognised as medical devices, including diagnostic software, assistive technologies, and remote patient monitoring systems.

Table 1: Table of example medical devices

Category	Purpose / Function	Examples (including less obvious ones)
Diagnostic Devices	Identify or monitor disease or physiological status	X-ray, MRI, ECG, laboratory analysers, blood glucose meters, urinalysis strips
In-Vitro Diagnostic (IVD) Devices	Tests performed on samples taken from the body	Blood tests, genetic tests, microbiology culture kits, pregnancy tests
Therapeutic / Treatment Devices	Deliver treatment or aid recovery	Infusion pumps, surgical instruments, defibrillators, dialysis machines, stents
Implantable Devices	Permanently or semi-permanently placed in the body	Hip replacements, pacemakers, vascular stents, cochlear implants
Monitoring / Critical Care Devices	Track patient status, support life in critical conditions	Pulse oximeters, ventilators, infant incubators, blood-gas analysers
Assistive / Mobility Devices	Support function or independence for patients	Wheelchairs, hoists, prosthetics, orthotics, walking aids, pressure care devices
Consumables	Used once or repeatedly replaced	Syringes, catheters, dressings, infusion sets, swabs
Home / Community Care Devices	Devices used outside hospitals	Domiciliary oxygen, urine drainage systems, home BP monitors, wearable health trackers



Emergency / Pre-hospital Devices	Support care in urgent situations	Ambulance stretchers, portable defibrillators, portable monitors, splints
Software & Digital Tools	Analyse, monitor, or manage health data	Diagnostic apps, remote monitoring platforms, device management software, clinical decision support systems
Custom-made Devices	Made for a specific patient or scenario	Orthodontic braces, prosthetic limbs, custom implants
Active Devices	Rely on energy to operate	Electric wheelchairs, ventilators, infusion pumps, pacemakers
Single-Use Devices	Designed for one-time use to reduce risk	Dressings, gloves, infusion sets, disposable instruments
Surgical Instruments	Tools used in surgical procedures	Scalpels, forceps, scissors, retractors, laparoscopic instruments

Devices range from commonly used devices such as dressings or thermometers through to advanced diagnostic scanners, implantable devices, and life-supporting technologies.

Their safe use depends not only on design and manufacture but also on correct training, maintenance, and integration into clinical practice. Effective oversight therefore requires both technical understanding and strong governance systems—areas where the MDSO role is uniquely positioned to add value.

3.2. Medical Device Modification

Unless a medical device is designed to be modified e.g. orthotics, it should not be modified unless directed by or approved by the manufacturer. If an organisation modifies a medical device without the manufacturer's approval, liability may be partly or wholly transferred to the organisation if the device is implicated in an adverse incident. Modification may also count as manufacture of a new device under the UK Medical Devices Regulations 2002.

Medical device modifications should also be explicitly addressed in an organisation's medical device management policies to ensure governance, oversight, and consistent risk management. See [MHRA – Managing Medical Devices](#) and [MHRA Guidance – Off Label Use](#) for further information.



3.3. Exceptional Circumstances: Off-Label or Modified Medical Device Use

In rare or exceptional cases where an appropriate medical device is not available for a procedure, an organisation may consider using an existing medical device for a different purpose, modifying a medical device for a new purpose, or using a product for a medical purpose that is not CE or UKCA marked as a medical device. In such situations, the organisation must balance the risks and benefits to the patient, taking into account legal liability risks and the following recommendations:

- Carrying out a risk assessment and documenting it
- Considering the ethical and legal implications
- Implementing suitable precautions to minimise the risk
- Reviewing the risk assessment at suitable periods
- Getting approval from MHRA for exceptional use of non-complying devices (if necessary)

Any modifications, alternative uses, or off-label applications should also be explicitly addressed within the organisation's medical device management policies to ensure governance, oversight, and consistent risk management. See [MHRA – Managing Medical Devices](#) and [MHRA Guidance – Off Label Use](#) for further information.

3.4. Borderline Devices

Not all products used in healthcare are clearly medical devices. Some products sit at the boundary between medical devices and other regulated products such as medicines, cosmetics, personal protective equipment (PPE), food supplements, consumer products, or general wellbeing technologies. These products are often referred to as borderline devices.

Determining whether a product is a medical device is important because different regulatory requirements apply depending on how the product is classified. A product that appears similar to a medical device may not be regulated as one, while some products that appear to be ordinary consumer products may fall within the medical device regulations because of their intended purpose.

The key factor in determining whether a product is a medical device is usually the manufacturer's intended purpose. Regulators will consider:

- the claims made by the manufacturer
- the instructions for use



- product labelling
- promotional and marketing material
- how the product achieves its intended effect

Table 2: examples of classification

Product	Possible Classification
Step counting fitness app	Consumer wellness product
App that analyses ECG recordings to detect arrhythmias	Medical device
Wound healing gel with a medical purpose	Medical device
Standard sunglasses	Consumer product
Protective eyewear intended for a medical procedure	Medical device or PPE
Compression sports socks	Consumer product
Compression stockings for treatment of venous disease	Medical device

Borderline questions are becoming increasingly common with the growth of digital health technologies, artificial intelligence, remote monitoring systems, wearable technologies, software, and products that combine elements of devices, medicines, and other regulatory frameworks.

The Declaration of Conformity, Instructions for Use, and manufacturer claims are often the quickest starting points when determining whether a product is likely to be regulated as a medical device.

Further Information

The MHRA provides guidance and resources that may assist when determining whether a product falls within the medical device regulatory framework:

- [MHRA Regulating medical devices in the UK](#)
- [MHRA Borderline Products Guidance](#)
- [MHRA Medical Devices Regulations 2002 Guidance](#)



- [MHRA Register Public Access Database \(PARC\)](#)
- [MHRA Software and AI as a Medical Device Guidance](#)

3.5. Medical Device Safety Checklist

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Familiarise yourself with the definition of a medical device and the wide range the definition covers
- ☐ Understand the risks of medical device modification and off label device use
- ☐ Familiarise yourself with what may be considered a borderline device

Systems

- ☐ Familiarise yourself with the documents and guidance from MHRA in supporting medical device safety around device modification and off-label use
- ☐ Identify the system challenges and areas where medical device modification and off -label device use may be undertaken within your organisation.



4. Medical Device Lifecycle Overview

This section introduces the medical device lifecycle and highlights how patient safety can be affected at each stage. It is intended to support understanding rather than provide detailed operational guidance.

Organisations and MDSOs should refer to the MHRA publication [‘Managing Medical Devices’](#) as the primary source of guidance for establishing and maintaining safe and effective systems. This document sets out expectations for managing medical devices across their lifecycle and should be used to inform local policies, procedures, and assurance arrangements.

The level of control applied at each stage of the lifecycle should be proportionate to the risks associated with the device, its intended use, and the environment in which it is used.

For simple devices, requirements may be minimal. For complex systems, each stage requires structured input, clear governance, and defined responsibilities. A failure at any stage may introduce risks that persist throughout the life of the device.

The lifecycle should be considered as a connected system rather than a series of isolated steps. Safe outcomes rely on the consistent application of controls across the whole lifecycle; supported by collaboration between clinical, technical, procurement, and governance functions.

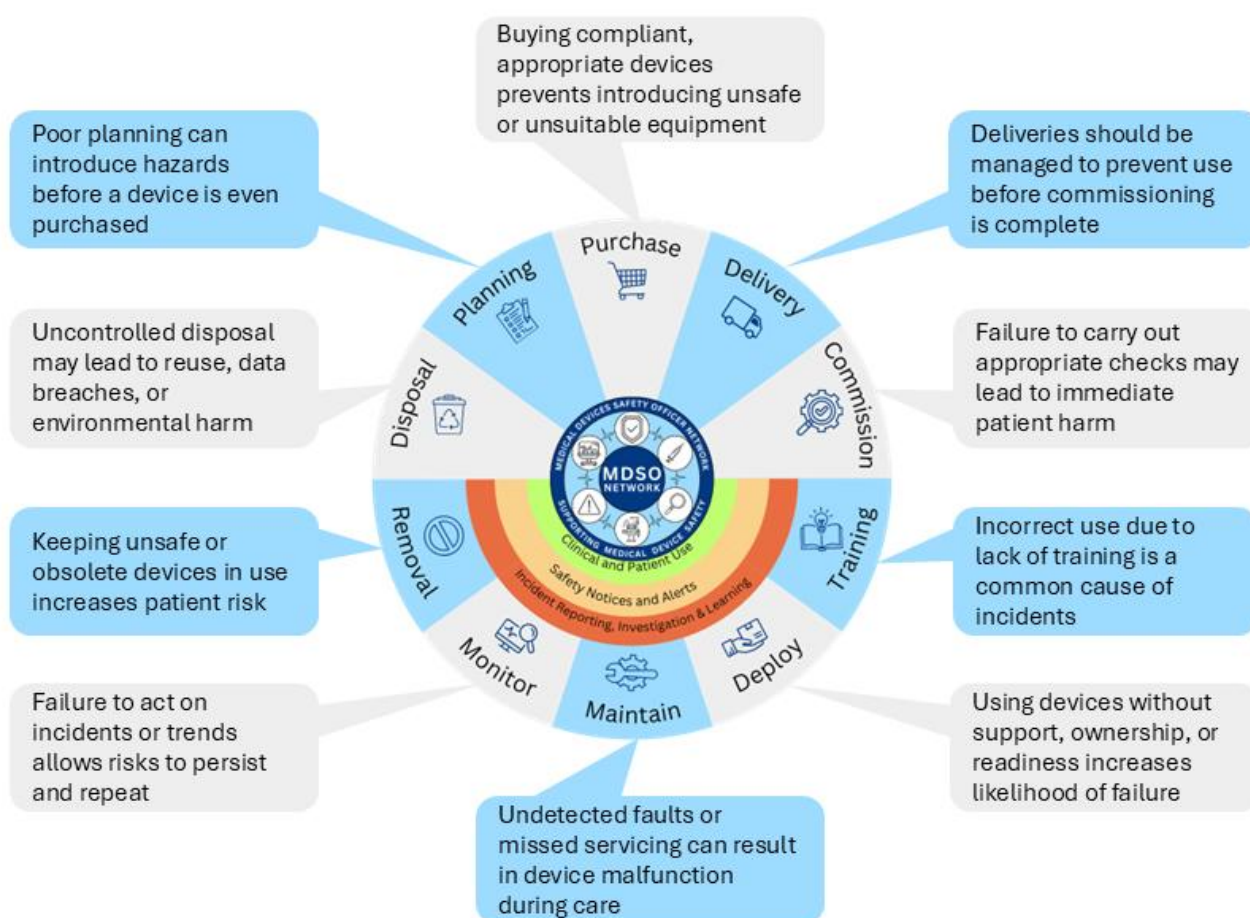


Figure 1: Simplified Medical Device Lifecycle

The diagram above illustrates the complexity and interconnected nature of the medical device lifecycle, covering stages such as purchase, commissioning, training, maintenance, and disposal. Each of these stages presents potential risks and opportunities to enhance safety. The medical device safety perspective brought by the MDSO can inform and influence processes across this lifecycle, even where direct operational responsibility sits elsewhere.

4.1. Planning

Planning should take a whole lifecycle approach, considering procurement, cost, commissioning, training, deployment, maintenance, monitoring, and disposal. Key considerations include defining clinical need, identifying stakeholders, determining training requirements, planning maintenance, support arrangements, establishing expected lifespan and replacement strategies. Contingency planning should also be considered, including potential disruption to supply chains. Inadequate planning may introduce risks that persist throughout the lifecycle. The level of detail required should be proportionate to the risk associated with the device, recognising the differences between simple consumables and complex or implantable devices.



4.2. Purchase

Only compliant medical devices should be purchased using approved routes to ensure traceability, regulatory compliance, and access to ongoing support. Procurement decisions should consider safety, compatibility with existing systems and consumables, cost, availability of maintenance and spare parts, and supply lead times.

Failure to follow appropriate procurement processes may result in delays, unsupported devices, or increased risk due to counterfeit or non-compliant products. Pre-Acquisition Questionnaires should be used (see section 4.11).

Standardisation should be considered where possible to reduce variation, improve user familiarity, support patient safety, and reduce costs. Using standardised medical devices can help reduce user error, simplify training, support maintenance, and improve consistency of practice across different clinical areas. However, standardisation can also create challenges, particularly during periods of supply chain disruption or product recalls. Where there is heavy reliance on a single manufacturer or device, shortages or safety concerns can affect multiple services at the same time and may have significant operational impacts. Organisations should therefore aim to maintain an appropriate balance between standardisation, resilience, and operational flexibility within their medical device management approach.

4.3. Delivery

Robust delivery, receipt, and control processes are required to ensure devices are not delivered to incorrect locations and are not used without commissioning, training, or documentation.

Centralised delivery processes are often appropriate to support control and traceability, although some devices may require direct delivery to clinical areas or patient homes where appropriate controls are in place. Receipt processes should confirm condition, completeness, and any decontamination requirements.

4.4. Commission

Commissioning ensures that devices are safe, correctly configured, and ready for use. The level of commissioning required will vary depending on device complexity, ranging from basic checks to detailed technical verification, configuration, and network integration.

This should include appropriate documentation and asset registration to ensure devices are traceable and managed effectively. Devices should not be used until appropriate commissioning is completed and staff are appropriately trained.

4.5. Training

Training is essential for the safe use of medical devices and should be proportionate to the level of risk associated with the device and its use. Training must be appropriately designed,



delivered, assessed, documented. Training should apply to all relevant users, including clinical staff, technical personnel responsible for maintenance, and (where applicable) patients and carers.

Inadequate training is a recognised contributory factor in medical device incidents. Organisations should therefore ensure that training supports users to understand device functionality, limitations, and associated risks, and that competency is assessed where appropriate. This supports safe practice, reduces the likelihood of misuse, and contributes to improved patient outcomes.

Training should not be considered a one-off activity. Competency must be maintained over time through ongoing use, supervision, and periodic reassessment. Local training arrangements are typically determined by risk, device complexity, and organisational policy; considering regulatory expectations around the safe use of equipment. For higher-risk or complex devices, more structured training and regular reassessment may be required.

Training should be reviewed and updated in response to changes in devices, software, clinical practice, or identified risks. This includes learning from incidents, safety notices, and manufacturer guidance. Refresher training is expected where significant changes occur, ensuring that users remain competent and that new risks are understood and managed.

Effective training systems are supported by clear governance, including defined responsibilities, competency records, and mechanisms for identifying gaps. This enables organisations to demonstrate assurance that staff are appropriately trained and that medical devices are used safely in practice.

The importance of training is reinforced within the wider medical device safety system, where organisations are expected to coordinate education and training to improve both reporting quality and the safe use of devices.

4.6. Deploy

Deployment represents the point at which devices enter active use. Devices should only be deployed once all preceding lifecycle stages have been completed and verified.

Deployment processes should ensure that devices are used in appropriate environments, correctly set up, and supported by clear ownership and responsibility. Maintenance arrangements and support processes should be established at this stage to ensure ongoing safe use.

4.7. Maintain

Maintenance ensures that devices remain safe and effective throughout their operational life. Maintenance must be carried out by appropriately trained personnel and recorded in accessible and auditable systems.



Maintenance strategies should be proportionate to risk and aligned with relevant legislation and guidance. Decisions regarding maintenance frequency or deviation from manufacturer recommendations should be documented and risk assessed. Failure to maintain devices appropriately can result in equipment failure and patient harm.

4.8. Monitor

Devices must be continuously monitored throughout their use. This includes incident reporting, trend analysis, performance monitoring, and monitoring of maintenance compliance and device performance.

Risks associated with medical devices should be formally recorded and maintained within risk management systems. Safety notices and alerts, including Field Safety Notices, should be actioned in a timely manner. Organisations should ensure appropriate governance oversight, with visibility of risks, and training and maintenance compliance at organisational level.

Learning from incidents should be systematically used to inform improvements across the lifecycle.

4.9. Removal

Devices that are no longer required or safe to use must be clearly and effectively removed from service (decommissioned). Removal processes should ensure that devices cannot be inadvertently reused.

Failure to remove devices appropriately may result in use by untrained staff, use of devices that have not been maintained, or use of obsolete equipment, creating avoidable patient safety risks.

4.10. Disposal

Disposal represents the final stage of the lifecycle and must be managed in accordance with relevant legislation and guidance, including decontamination and environmental requirements.

Robust disposal processes are required to ensure devices do not re-enter circulation inappropriately, including through resale or reuse outside controlled environments. This is particularly important for devices that pose ongoing safety risks if reused.

4.11. Pre-Acquisition Questionnaire (PAQ)

The [Pre-Acquisition Questionnaire \(PAQ\)](#) supports the safe management of medical devices by embedding lifecycle considerations at the earliest stage of planning and procurement. It requires structured information on regulatory compliance, risks, training, technical support, digital and cyber security requirements, maintenance, and end-of-life arrangements, ensuring that key safety and operational factors are identified before a device is introduced into use. This reflects the principle that risks introduced during planning and purchase can persist throughout



the lifecycle, and that safe outcomes depend on coordinated control across all stages. Used effectively, the PAQ acts as a critical control within the planning process, helping organisations confirm that devices are appropriate, supportable, and aligned with existing systems and governance arrangements. In doing so, it reduces the likelihood of introducing unsupported or unsafe devices and supports continuity of safe management across the full medical device lifecycle.

4.12. MDSO influence across the lifecycle

Training and competency are key contributors to safe device use. The MDSO may work with clinical, education, and technical teams to support proportionate training arrangements, particularly where incidents, safety alerts, or manufacturer communications identify increased risk. Strong collaboration in these areas supports the effective sharing of learning and helps ensure that lessons from incidents are embedded in practice.

Positioned at the intersection of clinical practice, governance, patient safety, and technical services, the MDSO can bring together different perspectives on medical device risk. This may include supporting the selection of new equipment, acceptance and commissioning processes, maintenance arrangements, risks associated with third-party providers, and issues escalated through governance routes.

The MDSO can help identify gaps between policy, practice, and assurance, and support timely action to reduce risk.

They may also support changes to policy, processes, or practice that are needed to strengthen safety and organisational assurance.

Incident learning may also inform maintenance planning and wider risk control measures. Where incidents, near misses, safety alerts, or recurring device faults identify increased risk, the MDSO may work with clinical engineering, service leads, and other relevant teams to review maintenance arrangements, inspection frequencies, replacement planning, or other mitigating actions, such as enhanced or refresher training to reduce the likelihood of harm.

The MHRA's [‘Managing Medical Devices’](#) guidance is a key reference document for understanding the medical device lifecycle and the systems needed to manage devices safely and effectively. MDSOs should become familiar with this guidance and use it as a practical resource to inform local arrangements.



4.13. Summary

The medical device lifecycle is complex, interconnected, and central to patient safety. Risks may arise at any stage, and failures early in the lifecycle can have long lasting consequences.

Safe management depends on a coordinated, system wide approach, supported by clear processes, defined responsibilities, effective governance, and ongoing learning. By ensuring that each stage of the lifecycle is appropriately controlled and that risks are visible and managed, organisations can support whole system assurance that medical devices are safe, effective, and appropriately managed.

4.14. Medical Device Lifecycle Chapter Checklist

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Familiarise yourself with the key stages of the medical device lifecycle.
- ☐ Familiarise yourself with the MHRA guidance document 'Managing Medical Devices' and its role in supporting safe lifecycle management.

Systems

- ☐ Identify how medical devices are approved, purchased, and introduced into use within your organisation.
- ☐ Understand how commissioning, asset registration, and traceability processes operate locally.
- ☐ Familiarise yourself with the purpose and use of the Pre-Acquisition Questionnaire (PAQ) process.
- ☐ Review how devices are removed from service and disposed of safely within your organisation.
- ☐ Review how systems for user training, competency assessment, refresher training, and training records support the safe use of medical devices within your organisation.



Governance

- ☐ Review how local incident learning, safety communications, and recurring device issues are used to inform safety improvements across the medical device lifecycle.
- ☐ Identify which teams and departments are involved with management of medical devices across their lifecycle in your organisation.



5. Governance and Organisational Systems

Clear governance and reporting structures are essential to ensure effective oversight of medical device safety within an organisation. The MDSO role should be supported by defined reporting lines and routes for escalation, enabling timely communication of risks, incidents and emerging issues.

The MDSO will typically contribute to, and receive assurance from, a range of organisational groups and committees. These may include medical device or equipment groups, patient safety committees, clinical governance forums, risk management groups, and other relevant operational or technical forums.

Effective reporting structures should support the flow of information from operational areas through to senior leadership and Board-level oversight. This includes regular reporting on medical device incidents, safety alerts, compliance with required actions, emerging risks, and themes identified through learning and assurance processes.

Reporting arrangements should also enable clear accountability for actions, support escalation where risks cannot be managed locally, and provide assurance that appropriate controls and mitigations are in place.

The MDSO may play a role in supporting these reporting processes by collating and presenting information, highlighting areas of concern, and ensuring that relevant issues are brought to the attention of appropriate governance forums.

5.1. Organisational Responsibilities

The MHRA [‘Managing Medical Devices’](#) document provides guidance for health and social care organisations on corporate and organisational governance, setting out a systematic approach to the acquisition, deployment, maintenance, repair and disposal of medical devices.

Below is a list of measures to help ensure that appropriate governance systems are in place:

- A Board Member or Director with overall responsibility for medical device management.
- An organisation-wide policy on the management of medical devices with clear lines of accountability throughout the organisation, leading to the board.
- A medical devices group with representation from a wide range of staff.



- An asset management system to facilitate a systematic approach to medical devices management including current location, servicing history and equipment lifecycle from purchase to disposal.
- Mechanisms for distributing manufacturer’s Field Safety Notices, MHRA safety information and other National Patient Safety Alerts relating to devices to the appropriate people in the organisation.
- A process for reporting incidents and managing risks associated with medical device use.
- Alignment between the healthcare organisation’s strategic plan and the operational management of the equipment lifecycle.

5.2. Medical Devices Safety Group

Organisations should have a multi-disciplinary Medical Devices Safety Group established to oversee and drive the safer use of medical devices within an organisation.

The name, membership and characteristics of this group will vary between organisations and in larger organisations, its functions may be split across more than one group, but the key responsibilities of this group are to:

- review medical device incidents and implement actions locally to improve patient safety;
- coordinate medical device education and training;
- provide advice and guidance on procurement and acquisition of medical devices (including consumable products where these are also medical devices); and
- assist in the development and review of medical device management policies and procedures.

This group may also link in with the Medicines Safety Group, Patient Safety or Risk Committees and local specialty or departmental clinical governance / risk groups.

5.3. Medical Device Policies

A policy sets out an organisation’s agreed principles, responsibilities and approach in relation to a particular area of practice.

As an MDSO, you may be asked to contribute to or lead the development of your organisation’s medical device management policy. This can feel daunting, particularly if you have not written this type of document before.

A clear policy helps support consistent decision-making; safe practice, effective governance, and the management of risks associated with the use of medical devices.



The MHRA's publication '[Managing Medical Devices](#)' sets out the areas that a medical device management policy should address.

When developing or reviewing a medical device policy, it is important to ensure that the document reflects relevant current legislation, national guidance and local organisational requirements. The document should be evidence-based, accurately referenced, and aligned with current practice. It should also be clear about responsibilities, processes and arrangements for managing medical devices safely within the organisation.

Most organisations will have their own policy development and document control processes. These usually set out requirements for format, approval, consultation, ratification, review and publication, and should be followed when developing a local policy. Examples of existing medical device policies may be available from other organisations, and some have also been uploaded into the NAMDET ([National Association of Medical Device Educators and Trainers](#)) library which can be accessed by NAMDET members following registration and approval as a NAMDET library User.

Above all, policies should help people do the right thing in a clear and practical way. A medical device management policy should therefore be proportionate, accessible and relevant to the organisation's needs.

The policy will be an evolving document. Review arrangements will depend on your organisation's requirements but also the need to ensure accuracy, relevance, and compliance with current legislation.

5.4. Risk Management

Effective risk management is essential to ensure that hazards associated with medical devices are identified, understood, and controlled in a proportionate and systematic way. Within healthcare organisations, risks may arise from device design, procurement decisions, maintenance arrangements, user training, operational use, or the wider systems that support safe practice.

Risk management should be embedded within organisational processes rather than treated as a standalone activity.

This includes integration with incident reporting systems, governance structures, safety alert processes, and decision-making forums. By bringing these elements together, organisations can ensure that risks are visible, prioritised appropriately, and managed in a coordinated way.

In practice, risk management for medical devices should include:

- identifying risks through incident reporting, audit, safety alerts, and user feedback



- assessing the realistic likelihood and potential impact of harm
- implementing controls or mitigations to reduce risk to an acceptable level
- recording risks within organisational risk management systems where appropriate
- monitoring risks over time, including review of incidents, trends and control effectiveness
- escalating risks that cannot be managed locally through defined governance routes. The level of formality and documentation required should be proportionate to the level of risk. For lower risk devices, simple controls may be sufficient. For higher risk or complex devices, a more structured and multidisciplinary approach may be required, including formal risk assessments and oversight through governance groups.

The MDSO may contribute to risk management by supporting the identification of device related risks, highlighting themes from incident data, and ensuring that relevant risks are visible within governance processes. This may include working with clinical, technical and governance teams to review risks, support appropriate escalation, and ensure that learning is translated into practical actions.

It is important to recognise that responsibility for managing risks sits with the organisation. The MDSO supports these processes but does not replace existing risk management, clinical, or operational responsibilities. Clear definition of roles, responsibilities and escalation routes is therefore essential to ensure that risks are managed effectively and that accountability is maintained.



5.5. Governance Chapter Checklist

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Understand your responsibilities for National Patient Safety Alerts, MHRA safety information, Device Safety Information, and Field Safety Notices.

Systems

- ☐ Confirm the process for receiving, assessing, distributing, actioning, and recording safety alerts within your organisation.
- ☐ Confirm how medical device inventory is tracked and how to access device location and history.

Governance

- ☐ Identify your CAS Liaison Officer and understand how you work together.
- ☐ Identify high risk devices or recurring device related issues within your organisation and review local risk management processes to support risk mitigation and safe use.



6. Investigating Medical Device Incidents

Medical device incidents provide an important source of learning for healthcare organisations. Learning from incidents helps organisations understand how harm occurs, identify risks, and implement improvements that reduce the likelihood of similar events happening again.

Many incidents involving medical devices are complex and arise from the interaction between people, devices, environments, processes, and organisational systems. Learning should therefore focus on understanding the wider circumstances and systems thinking surrounding an incident rather than simply determining whether a device failed.

Not every incident requires a formal investigation. Organisations should respond proportionately in accordance with local policies and the principles of the Patient Safety Incident Response Framework (PSIRF). However, all incidents and near misses should be viewed as opportunities for learning and improvement.

6.1. Medical Devices and Patient Safety Investigations

Medical device incidents may be identified through local reporting systems, patient safety investigations, complaints and maintenance activities.

In some cases, the involvement of a medical device will be obvious. For example, a ventilator that unexpectedly stops providing therapy or an infusion pump that delivers medication incorrectly. In other situations, it may be unclear whether a medical device contributed to an incident, or whether device information is simply needed to help understand what happened.

It is important to recognise that medical devices may provide valuable information even when they are not believed to be the cause of an incident. Device data may help establish timelines, confirm user interactions, identify environmental factors, or provide additional context that supports wider learning.

The purpose of learning is not simply to determine whether a medical device was at fault, but to understand whether it contributed to the event and, where appropriate, confidently exclude it as a contributory factor.

6.2. Preserving Evidence

The quality of learning that can be achieved from an incident is often heavily dependent on the quality of the evidence available. Early decisions made immediately following an incident can therefore have a significant impact on what can later be understood.

Many modern medical devices contain logs, alarm histories, trend data, configuration settings, and records of user interactions. However, many medical devices only retain information for a



limited period before it is overwritten during normal operation. In some cases, data may also be lost following software updates, configuration changes, or continued use of the device.

Where a medical device may be relevant to an incident, consideration should be given to preserving both the device and any associated evidence. This may include retaining accessories and consumables, recording device identifiers, documenting settings, and securing electronic information before it is lost.

In serious incidents, organisations should consider whether additional devices used in the patient's care may also contain relevant information. For example, an incident initially associated with a ventilator may also require information from physiological monitoring systems, infusion devices, or other equipment being used at the time.

The actions taken should always be proportionate to the circumstances and follow local organisational procedures.

6.3. Device Data and Technical Information

Medical devices increasingly generate large amounts of information that may assist learning and investigation activities. Depending on the device, this may include alarm histories, event logs, technical records, physiological trends, maintenance information, or evidence of user interaction.

This information can help establish timelines, identify contributory factors, and improve understanding of the circumstances surrounding an incident. In some cases, device data may provide insights that are not available from witness accounts or clinical records alone.

The absence of a device fault does not necessarily mean that a device is irrelevant to an investigation. Medical device information may still contribute significantly to understanding wider system factors and how care was delivered at the time of the event.

As healthcare technologies become increasingly digital and connected, organisations should ensure that appropriate systems, processes, and expertise are available to support the timely retrieval and preservation of medical device data when required. This may involve local clinical engineering, IT, digital, or specialist technical teams, or may require support from the manufacturer, depending on the technology involved.

Organisations should understand how data can be accessed from devices and associated systems before an incident occurs. This includes consideration of user access rights, system passwords, specialist software, data export capabilities, and any reliance on third-party suppliers or manufacturers. In some cases, delays may occur because the necessary expertise is unavailable, passwords are not accessible, data can only be viewed rather than exported electronically, or specialist support must be obtained from external organisations.



Failure to establish these arrangements in advance may result in delays obtaining information that is critical to learning and investigation activities. In some circumstances, delays may lead to important evidence being overwritten or becoming unavailable before it can be preserved.

6.4. Timeline Reconstruction

Developing an accurate understanding of the sequence of events is often an important part of learning from incidents. This frequently involves bringing together information from multiple sources, including patient records, incident reports, witness accounts, monitoring systems, and medical device data.

Medical devices can be particularly valuable when reconstructing events because many devices record alarms, parameter changes, user interactions, and other activities alongside timestamps. These records may help establish when interventions occurred and how devices were being used.

Investigators should recognise that different systems may record time differently. Medical devices, network servers, electronic patient record systems, and other sources of information may not always use synchronised clocks. Differences between Greenwich Mean Time (GMT), British Summer Time (BST), or local system settings may need to be considered when interpreting information and reconstructing events.

Bringing information together from multiple sources often provides a more complete understanding of an incident than reviewing any individual source in isolation.

6.5. Understanding Contributory Factors

Medical device incidents are rarely caused by a single factor. Whilst technical faults can occur, incidents may also arise from interactions between people, processes, environments, organisational systems, and medical technologies.

Learning should therefore consider factors such as training, competency, maintenance arrangements, workload, device configuration, consumable compatibility, local procedures, communication processes, and environmental conditions.

Investigations may conclude that a medical device functioned exactly as intended but that other factors contributed to the outcome. Equally, they may identify technical, organisational, or human factors that require action.

A systems-based approach supports more effective learning by helping organisations understand the wider conditions that influence safety.



6.6. Working with Manufacturers

Manufacturers may play an important role in supporting learning from medical device incidents. They can provide specialist knowledge regarding device design, intended operation, technical performance, and the interpretation of device logs or technical data.

Some organisations may have access to specialist clinical engineering or technical expertise capable of supporting investigations locally. Others may rely more heavily on manufacturer support, particularly for complex or highly specialised technologies.

6.7. Police, Coroner and External Investigations

Some incidents may be subject to investigation by external organisations, including the Police, Coroners, regulators, or independent investigation bodies.

In these circumstances, organisations should follow local procedures regarding evidence preservation and equipment handling. Devices may need to remain quarantined and should not be examined, tested, or altered unless authorised by the investigating authority.

Clear documentation and appropriate control of equipment can be important in maintaining confidence in the integrity of the investigation process.

6.8. The MDSO Role

The extent of MDSO involvement in investigations will vary depending on local arrangements. The role may provide valuable support by helping ensure that medical device considerations are recognised and appropriately addressed.

This may include advising on evidence preservation, supporting communication with manufacturers, contributing specialist knowledge regarding medical devices, supporting reporting arrangements, and helping identify wider learning opportunities.

By working across clinical, technical, governance, and patient safety functions, the MDSO can help ensure that learning from medical device incidents contributes to meaningful improvements in patient safety.

6.9. Learning and Improvement

The purpose of learning from medical device incidents is to improve safety. Learning may identify opportunities to strengthen training, improve maintenance arrangements, review procurement decisions, improve governance processes, or enhance local systems for reporting and communication.



The outcome of an investigation may be that a medical device functioned as intended and did not contribute to the incident. This remains an important finding because it helps organisations focus attention on other factors that may have influenced the event.

Learning should be shared appropriately so that improvements can be implemented locally and, where relevant, contribute to wider organisational and national learning.

6.10. Investigating Medical Device Incidents Checklist

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Understand incidents involving medical devices are often complex and arise from the interaction between people, devices, environments, processes, and organisational systems
- ☐ Familiarise yourself with local policies and how the principles of the Patient Safety Incident Response Framework (PSIRF) are used when investigating incidents

Systems

- ☐ Identify the team members within your organisation who may be involved in medical device investigations
- ☐ Understand that a systems-based approach supports more effective learning by helping organisations understand the wider conditions and contributing factors that influence safety.

Development

- ☐ Attend PSIRF training to gain the skills to lead system-based safety investigations, conduct compassionate family and staff engagement, and provide supportive framework oversight.



7. Reporting Medical Device Incidents

MDSOs play a critical role in ensuring that incidents involving medical devices are reported, reviewed, and learned from effectively. This role was formally established in the original 2014 National Patient Safety Alert on improving medical device incident reporting and learning. The alert recognised that while reporting systems existed, variation in reporting quality, delays in submission, and limited local review meant that important learning was being missed.

As an MDSO, you are responsible not only for supporting outward reporting of medical device incidents to national systems and third parties e.g. manufacturers, but also for improving the quality, consistency, and frequency of reporting within your organisation. This includes helping colleagues understand what should be reported, ensuring reports contain sufficient technical and clinical detail to support learning, and making sure incidents are reviewed by staff with appropriate medical device expertise.

By strengthening local reporting and acting as a link between local systems and national reporting routes, the MDSO helps ensure that individual incidents contribute to wider learning, risk reduction, and safer use of medical devices across the healthcare system.

Reporting and learning systems are used to capture information about patient safety incidents, near misses, and hazards so that organisations can understand what went wrong and reduce the risk of harm happening again. These systems support learning at local, regional, and national level by bringing together information from many individual events. For medical devices, effective reporting and learning systems are particularly important because risks may only become visible when incidents are reviewed collectively rather than in isolation. Strong reporting systems underpin a just culture, support improvement, and enable learning to be shared across the healthcare system.

7.1. Local Reporting

One of the primary reasons for the creation of the MDSO role was to improve medical device incident reporting and learning within healthcare organisations. The role was introduced in response to concerns that variation in the quality, frequency, and timeliness of local reporting meant that important opportunities for learning and risk reduction were being missed.

Local reporting allows staff to record patient safety incidents within their organisation. These reports are usually made through an electronic incident reporting system and should capture what happened, what device was involved, the outcome, and any immediate actions taken.

Local reporting is essential for identifying risks early, supporting local investigation, and enabling timely learning.



For medical devices, good quality local reports provide the information needed to support effective review, escalation, and onward reporting where needed. They also help organisations identify recurring themes, unsafe practices, device related trends, and emerging risks that may not be visible from isolated incidents alone.

Improving local reporting is not simply about increasing the number of reports submitted. It is also about improving the quality, completeness, consistency, and timeliness of reports so they can support meaningful local and national learning, identification of new safety issues, and implementation of actions to reduce harm. The MDSO therefore plays an important role in helping organisations strengthen reporting systems, improve data quality, support learning from incidents, and ensure that reporting leads to action that improves the safety of medical devices.

7.2. Local Risk Management Systems (LRMS)

A LRMS is the organisation's formal system for managing patient safety risks. This includes incident reporting, investigation, action tracking, trend analysis, and governance oversight. Medical device incidents should be recorded within the LRMS so they can be reviewed alongside other safety information. The LRMS supports assurance by helping organisations identify recurring issues, monitor controls, and demonstrate that learning has led to improvement. For MDSOs, the LRMS is a key source of intelligence for understanding medical device risk across the organisation.

7.3. Other Local Reporting Mechanisms

In addition to your organisation's LRMS, there are specific reporting systems for different issues, such as claims, complaints, and Patient Advice and Liaison Services (PALS). All of these may include medical device-related reports, which may or may not be captured in the incident reporting system. It is therefore important to be aware of these routes, and to work with colleagues in these areas to ensure relevant learning is not missed. Considering these sources together helps build a more complete picture of medical device incidents and risks within your organisation.

7.4. National Reporting

7.4.1. Learn From Patient Safety Events Service

The Learn from Patient Safety Events (LFPSE) service is a national NHS system for the recording and analysis of patient safety events that occur in healthcare. The service introduces a range of innovations to support the NHS to improve learning from the over 2.5 million patient safety events recorded each year, to help make care safer (see '[How LFPSE will improve patient safety learning](#)').



LFPSE is now in use across the NHS, and organisations have switched to recording patient safety events onto the new LFPSE service using [LFPSE-compliant local systems](#), rather than the National Reporting and Learning System (NRLS), which was decommissioned on 30 June 2024. The Strategic Executive Information System (StEIS) is still in use while the next version of LFPSE is rolled out to replace it – [see here for specific guidance](#).

7.5. Yellow Card Scheme



The MHRA is an executive agency of the DHSC and is responsible for protecting and promoting public health and patient safety by ensuring healthcare products including medicines and medical devices meet the appropriate standards of safety, quality, performance, and effectiveness.

The MHRA runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products. These include medication side effects, adverse medical device incidents, as well as concerns regarding defective, falsified or fake healthcare products.

The Yellow Card scheme relies on voluntary reporting of suspected problems with healthcare products by the public (including patients, parents, and carers), as well as by healthcare professionals. Healthcare professionals play an important role in raising awareness of the Yellow Card scheme and encouraging patients to report suspected problems. Reports based on first-hand experience can provide valuable information to support the investigation of safety concerns.

Healthcare products that can be reported to the Yellow Card scheme include:

- medical devices (including in vitro diagnostics, software, apps and artificial intelligence);
- medicines;
- vaccines;
- blood factor and immunoglobulin products;
- herbal products or complementary therapies such as homeopathies and;
- e-cigarettes including their refill containers (e-liquids).



The Yellow Card scheme provides an early warning that the safety of a product may require further investigation; helping the MHRA to monitor the safety of healthcare products in the UK. Yellow Card reports are used alongside other safety information to help the MHRA to take action if trends associated with the safety or efficacy of a healthcare product are identified.

7.5.1. What to report to the Yellow Card scheme?

You can submit a report to the Yellow Card scheme about an incident concerning a medical device that has had (or is suspected to have had) a negative impact on the health of a patient, their care or on wider public health. Even if the patient wasn't harmed during an incident, you can still report the event. For example, in the case of a near miss, interrupted treatment or delayed diagnosis that poses a risk to the safety of other patients in the future had the incident not been spotted early or handled appropriately. Equally, a medical device may only be suspected as a contributing factor of an adverse incident; this link does not need to be proven for a report to be made.

An adverse incident may have happened because of:

- poor usability due to product design;
- defective products caused by manufacturing issues;
- poor user instructions;
- inadequate training provision;
- inappropriate modifications made locally to a device;
- technical issues such as bugs, glitches or software malfunctions;
- inadequate servicing and maintenance; and
- unsuitable storage and use conditions.

If in doubt about reporting a suspected issue, the MHRA's advice is to please report it.

Sometimes an event that seems insignificant when viewed in isolation can be a sign of a wider issue. The MHRA also encourage reporting for repeat incidents; the frequency of an issue and the number of devices affected is factored in when determining whether a signal will be triggered. It is acknowledged, however, that organisations may not have the resources to report every incident to the Yellow Card scheme. Please prioritise reporting events that would be



considered particularly serious; fatal, life-threatening, disabling, incapacitating or results in hospitalisation.

7.5.2. How to report?

You can submit reports to the Yellow Card scheme at yellowcard.mhra.gov.uk. Alternatively, you can also report using the Yellow Card app available from the [Apple App Store](#), or [Google Play Store](#).

We recommend creating a user account so that you can easily view all your previously submitted reports, name and edit reports (e.g. to add any new information that you have collected), and view follow-up requests.

7.5.3. What happens after submitting a report?

After submitting a report, you will receive a confirmation email to acknowledge that the report has been received. A dedicated team of signal assessors will then review and process reports before being committed to the MHRA's database. Due to the volume of reports the MHRA receive, not every incident can be investigated. However, reports concerning fatalities or serious public health threats are routinely assessed. Every report received is shared with the device manufacturer for their own investigation, and they may contact you for additional information. It is important that when completing a report to the Yellow Card scheme, consent is provided to share the reporter's contact details with the manufacturer so that they can follow up with you about the concern. MHRA also encourage the manufacturer to update the reporter with investigation outcomes. It is the manufacturer's responsibility to investigate safety concerns raised within that report. In parallel, the MHRA has a unique role in reviewing reports collectively to identify broader safety signals, emerging trends, and potential risks that may not be apparent from individual reports.

Once your Yellow Card report is added into MHRA's database, it will be used to help analyse trends and detect future safety signals. The MHRA uses a process called signal detection to help prioritise what to investigate. A signal indicates a possible causal relationship between an adverse incident and a suspected product that warrants further investigation. Reports to the Yellow Card scheme are not the only source of signals. Signals can be generated from a variety of sources such as enquiries, other regulators, manufacturer reports, registries and literature reviews. Once a signal is identified, Signal Assessors will then collate evidence from different sources to try to validate the signal.

Following this initial assessment, Benefit Risk Evaluation teams will then support the manufacturer in their investigation with the aim of minimising risk and maximising benefit to patients. If we need assistance to review the manufacturers findings, MHRA might contact external stakeholders for advice, for a steer on how appropriate any planned action may be.



Please note that MHRA do not currently provide updates or notification of investigation outcomes directly to the reporter. You will only be contacted if the MHRA are requesting further information about an incident. In the meantime, follow local procedures within your organisation to best manage the risk in a proportionate way.

It is important to report as the more cases MHRA receives on an issue, the more likely a signal investigation will be undertaken

7.5.4. Additional resources

The Yellow Card scheme website contains a range of resources and information to support reporting. Key pages include:

- [The Yellow Card scheme: guidance for healthcare professionals, patients and the public - GOV.UK](#)
- [Medical devices](#) – guidance on what to report to the Yellow Card scheme.
- [Software, apps and Artificial Intelligence \(AI\) reporting](#) – specific guidance on Software, apps and AI.
- [Case studies](#) – real examples of Yellow Card reporting making a difference.
- [General awareness resources](#) – resources to share with colleagues and networks to help raise awareness of reporting to the MHRA Yellow Card scheme.
- [Campaign material](#) – campaign material to support annual patient safety awareness raising campaigns (e.g. World Patient Safety Day).
- [Free e-learning modules for healthcare professionals](#) – the [British Pharmacological Society Assessment](#) contains medical devices focussed content.

7.6. Incident Reporting in the Devolved Administrations

7.6.1. Scotland

In Scotland, healthcare professionals should report safety concerns involving medical devices to the [Incident Reporting & Investigation Centre \(IRIC\)](#) and their local incident recording system.

7.6.2. Northern Ireland

In Northern Ireland, healthcare professionals should report safety concerns involving medical devices to the Yellow Card scheme, via your Medical Device Liaison Officer, in accordance with your organisations medical device policies and procedures.

7.6.3. Wales

In Wales, healthcare professionals should report safety concerns involving medical devices to the Yellow Card scheme.



NHS Specifics: Within NHS Wales, incidents should follow internal clinical engineering or local risk management procedures (e.g. DATIX) in addition to the national MHRA report.

Yellow Card Centre Wales: The Yellow Card Centre (YCC) Wales is one of six regional adverse drug reaction (ADR) monitoring centres, acting on behalf of the MHRA. You can also use this portal to link to the MHRA Yellow Card scheme to report medical device issues. [About Yellow Card Centre Wales - All Wales Therapeutics and Toxicology Centre](#)

Product Defects: Defective products can also be reported to the Surgical Materials Testing Laboratory (SMTL). The Surgical Materials Testing Laboratory (SMTL) is part of the Welsh NHS, funded by the Welsh Government and is part of NHS Wales Shared Services Partnership (NWSSP). Their core service is to provide medical device testing and technical services regarding medical devices to the Welsh NHS, enabling Procurement Services and others in the NHS to undertake evidence-based purchasing. smtl.defects@wales.nhs.uk.

7.7. Manufacturers Online Reporting Environment

Manufacturers must submit post-market vigilance reports to the MHRA. Reports relating to adverse incidents involving medical devices are submitted through the MHRA's Manufacturers Online Reporting Environment (MORE) portal, which is intended for manufacturer use only. MDSOs and healthcare organisations cannot submit reports through MORE and do not have direct access to the portal.

A copy of the central MDSO contact list that the MHRA holds is stored in the resources area of the MORE portal. Manufacturers are encouraged to use this MDSO contact list to disseminate FSNs and other safety messages. Therefore, it is important to update the MHRA if your MDSO contact details change as this will be reflected on the MORE portal.

The MDSO Network has developed the following guidance, which is shared with manufacturers alongside contact details on how to use the 'MDSO Contact List':

"The contact details provided in this spreadsheet have been shared to enable effective communication of safety messages concerning medical devices (for example, Field Safety Notices) and must only be used for those intended purposes."

It is advised that manufacturers should use the listed MDSOs, IASOs and MDLOs as the primary contact point for medical device safety communications where possible. This national resource is intended to be used alongside manufacturers' own customer records and contact lists, rather than a sole source as the list is not comprehensive of every healthcare organisation across the UK.

This distribution list must never be used for marketing, as the health and safety of patients can be compromised if safety messages are diluted by non-safety related emails. Any other type of query should be directed to the MDSO network administration team



(MDSONetwork@mhra.gov.uk) who will be able to provide further advice on the most appropriate communication channel.

As good practice, when emailing network members, please follow the guidelines below:

- only contact organisations that the safety message affects;
- always ensure that the nominated 'Group Mailbox' for an organisation is included in correspondence as the primary point of contact;
- if sending an email to multiple organisations, please use the Bcc option; and
- in the email subject, clearly state the purpose of the email, whether it is for action, review or information and the deadline action is required by.

7.8. Reporting Quality

Good quality incident reporting requires being factual, objective, and complete, capturing exact core details while focusing on systemic learning rather than blame. Key elements to include are:

- Basic facts: Exact date, time, and precise location of the event.
- People involved: Full names, roles, job titles, and witness details. (these may need to be anonymised)
- Chronological description: Clear, unbiased record of what happened and immediate actions taken.
- Impact and damage: Details of any injuries, medical treatment given, medical device used (provide exact brand name, model number, serial number, lot and batch numbers of consumables and software version, if applicable))

Best practice for incident reporting quality includes:

- Objectivity: Record only observable actions and direct facts without personal judgments or assumptions.
- Timeliness: Write reports promptly while memory is fresh to prevent gaps.
- Continuous learning: Focus on root causes and preventative recommendations to stop future occurrences



7.9. Near Miss Reporting

Near Miss Reporting is vital for proactive safety management, system learning, and preventing patient harm. It stops future accidents, fixes hidden system flaws, and builds an open safety culture, enhancing patient safety through proactive learning, staff engagement and empowerment.

A Near Miss can be defined as an event that could have led to harm but did not, either by chance or timely intervention. Examples include faulty medical equipment used without harm and out of service equipment used on a patient.

There can be barriers to Near Miss reporting, which are considered, with ways to overcome these, in the diagram below:



Figure 2 Near Miss reporting



7.10. Reporting Checklist

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Understand your organisation's incident reporting process for medical devices.
- ☐ Promote the reporting of near misses as well as actual incidents.

Systems

- ☐ Ensure medical device incidents are reported through local systems in a timely and accurate manner.
- ☐ Support reporting to national systems, including LFPSE and the Yellow Card scheme where appropriate.
- ☐ Review medical device incident reports to ensure quality and completeness of data.
- ☐ Ensure learning from incidents is shared with relevant teams and stakeholders.

Governance

- ☐ Identify themes, trends, and emerging risks from incident data and ensure processes are in place within your organisation for these to be shared to improve learning.



8. Learning and Improvement

The primary purpose of reporting medical device incidents is not simply to record that an event occurred. Reporting exists to support learning and improvement.

Healthcare organisations collect large amounts of information relating to patient safety, including incident reports, complaints, claims, audits, investigations, maintenance records, safety alerts, and performance data. The value of this information is realised only when it is used to identify risks, understand contributing factors, and improve systems.

Medical device safety depends upon an organisation's ability to learn from both failures and successes. Effective learning helps prevent avoidable harm, supports safer use of medical devices, and strengthens confidence in healthcare systems.

The MDSO role was established primarily to improve medical device incident reporting and learning. One of the key functions of the role is therefore to help ensure that information relating to medical device safety is translated into meaningful action.

Learning should not be viewed as a separate activity that occurs after an incident. It should be a continuous process that informs decisions throughout the medical device lifecycle.

The principles described in this chapter align closely with the [NHS Patient Safety Incident Response Framework \(PSIRF\)](#), which promotes learning and improvement through understanding how systems influence outcomes.

8.1. Learning from Medical Device Incidents

Medical device incidents provide valuable opportunities to understand how and why harm occurred or could have occurred.

The purpose of reviewing incidents is not to identify blame but to understand the factors that contributed to the event and identify opportunities to improve safety.

Medical device incidents rarely result from a single failure. Contributory factors may include device design, equipment condition, maintenance arrangements, training and competency, clinical procedures, environmental conditions, communication failures, organisational processes, and human factors.

Modern patient safety approaches, including PSIRF, encourage organisations to focus on understanding how systems influence outcomes rather than concentrating solely on individual actions. This systems-based approach is also reflected in investigations undertaken by the [Health Services Safety Investigations Body \(HSSIB\)](#).



For the MDSO, learning from incidents may involve reviewing reports, identifying device-related factors, contributing specialist knowledge to investigations, and helping ensure that learning is shared appropriately.

8.2. Learning from Near Misses

Near misses often provide some of the most valuable learning opportunities available to organisations.

A near miss is an event that could have resulted in harm but did not, either through chance, timely intervention, or because safety controls functioned as intended.

Because no harm occurred, near misses can sometimes receive less attention than incidents resulting in patient injury. However, many serious incidents are preceded by multiple near misses that reveal underlying weaknesses within systems.

Examples may include:

- A device being selected incorrectly before the error is identified
- A damaged device being discovered during pre-use checks
- A maintenance issue being identified before patient use
- A software configuration error being detected before deployment

Near misses provide an opportunity to identify hazards before patients are harmed. Organisations with strong safety cultures encourage reporting of both incidents and near misses and treat both as valuable sources of learning.

8.3. Learning from Trends and Safety Intelligence

Individual incidents are important, but meaningful learning often emerges when information is viewed collectively.

Trend analysis can reveal recurring problems that may not be obvious when incidents are reviewed in isolation.

Safety intelligence extends beyond incident reports and may include information from local risk management systems, maintenance records, audit findings, complaints, national reporting systems, manufacturer communications, and safety alerts.

Information reported through the [MHRA Yellow Card Scheme](#) and the [NHS Learn from Patient Safety Events Service \(LFPSE\)](#) contributes to a wider understanding of emerging risks and supports learning across the healthcare system.



The MDSO can play an important role in bringing together information from multiple sources to support a broader understanding of medical device risks.

8.4. Organisational Learning

Learning only improves patient safety when it leads to meaningful and sustained change.

Organisational learning occurs when information from incidents, investigations, audits, safety communications, complaints, equipment performance data, or other sources is used to improve the systems that support safe care. The aim is not simply to identify what happened, but to understand why it happened and what can be done to reduce the likelihood of recurrence.

For medical devices, organisational learning may lead to changes in policies, procedures, training arrangements, procurement processes, maintenance programmes, governance arrangements, or the way safety information is communicated and acted upon. Examples may include revising local procedures, strengthening training programmes, sharing internal safety communications, introducing additional safeguards, improving maintenance arrangements, standardising equipment, or enhancing governance oversight.

Effective organisational learning requires more than identifying improvements. Organisations should have mechanisms to ensure that learning is translated into action, that actions are implemented and monitored, and that their effectiveness is reviewed over time. Without this feedback loop, opportunities to improve safety may be lost.

The MDSO can support organisational learning by helping to identify themes and trends from incident reports, safety communications, and other sources of safety intelligence. By working collaboratively with clinical teams, governance functions, clinical engineering services, patient safety specialists, and other stakeholders, the MDSO can help ensure that learning relating to medical devices contributes to wider safety improvement activities.

Healthcare organisations should maintain systems that support the review of learning, monitor the effectiveness of actions taken, and provide assurance that improvements have been embedded into practice. Organisational learning is most effective when it forms part of a continuous cycle of reporting, learning, action, review, and improvement.

These principles are consistent with wider patient safety approaches that emphasise learning from systems and processes rather than focusing solely on individual actions. They also reflect the broader expectation that organisations use information from incidents and safety communications to continually strengthen the safe management and use of medical devices.



8.5. National Learning

Many medical device risks are not unique to a single organisation.

National reporting systems allow information from multiple organisations to be combined, helping identify emerging risks that may not be visible locally.

National learning supports:

- Identification of previously unrecognised hazards
- Recognition of emerging trends
- Development of safety guidance
- Regulatory action by MHRA
- Improvements in device design
- Sharing of good practice

The quality of national learning depends upon the quality of local reporting. Accurate, timely and detailed reports increase the ability of national bodies to identify risks and take action to improve patient safety.

Learning published through [HSSIB Investigation Reports](#), MHRA safety communications, and NHS England patient safety programmes can provide valuable insight into system weaknesses and opportunities for improvement.

8.6. The Role of the MDSO Network

The National MDSO Network provides an important mechanism for sharing learning across organisations.

The network was established to support communication, collaboration, reporting and learning relating to medical device safety. It enables MDSOs to share experiences, discuss emerging risks, exchange good practice, and learn from incidents occurring elsewhere in the healthcare system.

Participation in network meetings, webinars, discussion forums, and national events helps MDSOs remain aware of emerging issues and supports the dissemination of learning across organisations.

The network also provides opportunities for peer support, discussion of complex issues, and sharing practical approaches to improving medical device safety.



8.7. Continuous Improvement

Learning should be viewed as part of a continuous cycle of improvement.

Improvement is rarely achieved through a single intervention. Instead, safety is strengthened through ongoing review, evaluation and refinement of systems and processes.

Continuous improvement involves:

- Identifying risks
- Understanding contributing factors
- Implementing improvements
- Monitoring effectiveness
- Reviewing outcomes
- Making further adjustments where necessary

This approach aligns with modern patient safety principles, systems thinking, and quality improvement methodologies.

For the MDSO, continuous improvement means maintaining curiosity, seeking opportunities to learn, sharing information openly, and supporting organisations to strengthen medical device safety over time.

[NHS England Quality Improvement Resources](#)



8.8. Learning and Improvement Checklist

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Familiarise yourself with how your organisation learns from medical device incidents, near misses, audits, and investigations.
- ☐ Familiarise yourself with PSIRF principles and how they support learning from patient safety events.
- ☐ Review how local and national learning contributes to improvements in medical device safety.

Systems

- ☐ Review how medical device incidents and near misses are analysed within your organisation.
- ☐ Identify sources of medical device safety intelligence available locally.
- ☐ Review how learning from safety communications is shared and acted upon.
- ☐ Participate in MDSO Network activities that support shared learning.

Governance

- ☐ Review how learning from medical device incidents is escalated through governance structures.
- ☐ Review how actions arising from learning are monitored and evaluated.
- ☐ Identify opportunities to strengthen organisational learning relating to medical devices.
- ☐ Consider how learning can be used to support continuous improvement across the medical device lifecycle.



9. Safety Communications

A wide range of medical device safety communications are issued throughout the healthcare system to help identify, communicate, and reduce risks associated with the use of medical devices. These communications may originate from manufacturers, regulators, national bodies, or other organisations with responsibilities for patient safety.

Safety communications vary considerably in their purpose, urgency, and required actions. Some address safety critical issues requiring immediate organisational action, while others provide information, recommendations, updates, or learning intended to support safer use of medical devices. Examples include National Patient Safety Alerts (NatPSAs), MHRA Device Safety Information, manufacturer Field Safety Notices (FSNs), Important Customer Notices (ICNs), and other safety related communications.

Regardless of their source or format, all safety communications should be reviewed and managed through appropriate organisational processes. The response required will depend on the nature of the communication, the level of risk identified, and the extent to which the affected devices are used within the organisation. Some communications may require urgent action, while others may require assessment, monitoring, local dissemination, or incorporation into training, policies, or risk management arrangements.

Effective management of safety communications is an important part of the wider medical device safety system. It helps organisations identify risks, implement corrective actions, share learning, and prevent avoidable harm. The role of the MDSO is often closely linked to these processes by supporting communication, coordination, learning, and visibility, although responsibility for managing safety communications may sit within different organisational structures depending on local arrangements.

MHRA have produced a helpful guide which explains the different types of safety communications and how to subscribe: ['Safety communications concerning medicines, medical devices and other healthcare products'](#).

To get emails from the MHRA about new safety communications, you can sign up on the website - [Alerts, recalls and safety information: medicines and medical devices emails - GOV.UK](#).

You can view the latest safety communications here: [Alerts, recalls and safety information: medicines and medical devices - GOV.UK](#) and a rolling list [here](#).

The following chapter provides an overview of the main types of safety communication that MDSOs are likely to encounter and explains how they fit within the wider patient safety and medical device safety landscape.



9.1. National Patient Safety Alerts (NatPSAs)

NatPSAs are for serious issues that will impact on patient safety and there are strict criteria that must be met for an alert to be issued.

In order to issue a NatPSA, an organisation must have an accredited process which meets 25 nationally agreed [criteria](#) overseen by the [National Patient Safety Committee](#). Accredited organisations include, but are not limited to: NHSE, MHRA, DHSC and UKHSA (UK Health Security Agency).

It is a requirement of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12 in England, Scotland, and Wales that healthcare organisations comply with relevant safety alerts as documented in the following:

- Regulation 12: Safe care and treatment of the CQC Fundamental Standards.
- Regulation 15: Standard 7 - Safe and Clinically Effective Care of the National Minimum Standards for Independent Health Care Services in Wales.
- Regulation 13: Quality of independent health care of the Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations.

Figure 3 below provides a practical overview of how National Patient Safety Alerts should be managed once received by an organisation. It illustrates the key stages involved, from initial receipt and identification of relevance, through to assessment, allocation of actions, implementation, and assurance. This process supports a coordinated and systematic response, ensuring that alerts are reviewed by the right people, actions are clearly defined and tracked, and progress is monitored to completion.

Although the diagram relates specifically to the management of alerts, the principles it describes are equally applicable to a wider range of safety communications, including Device Safety Information, Field Safety Notices, and other risk communications. Applying a consistent approach across these communications helps ensure that important safety information is not only received, but effectively translated into local action, supporting the reduction of risk and improvement of patient safety.

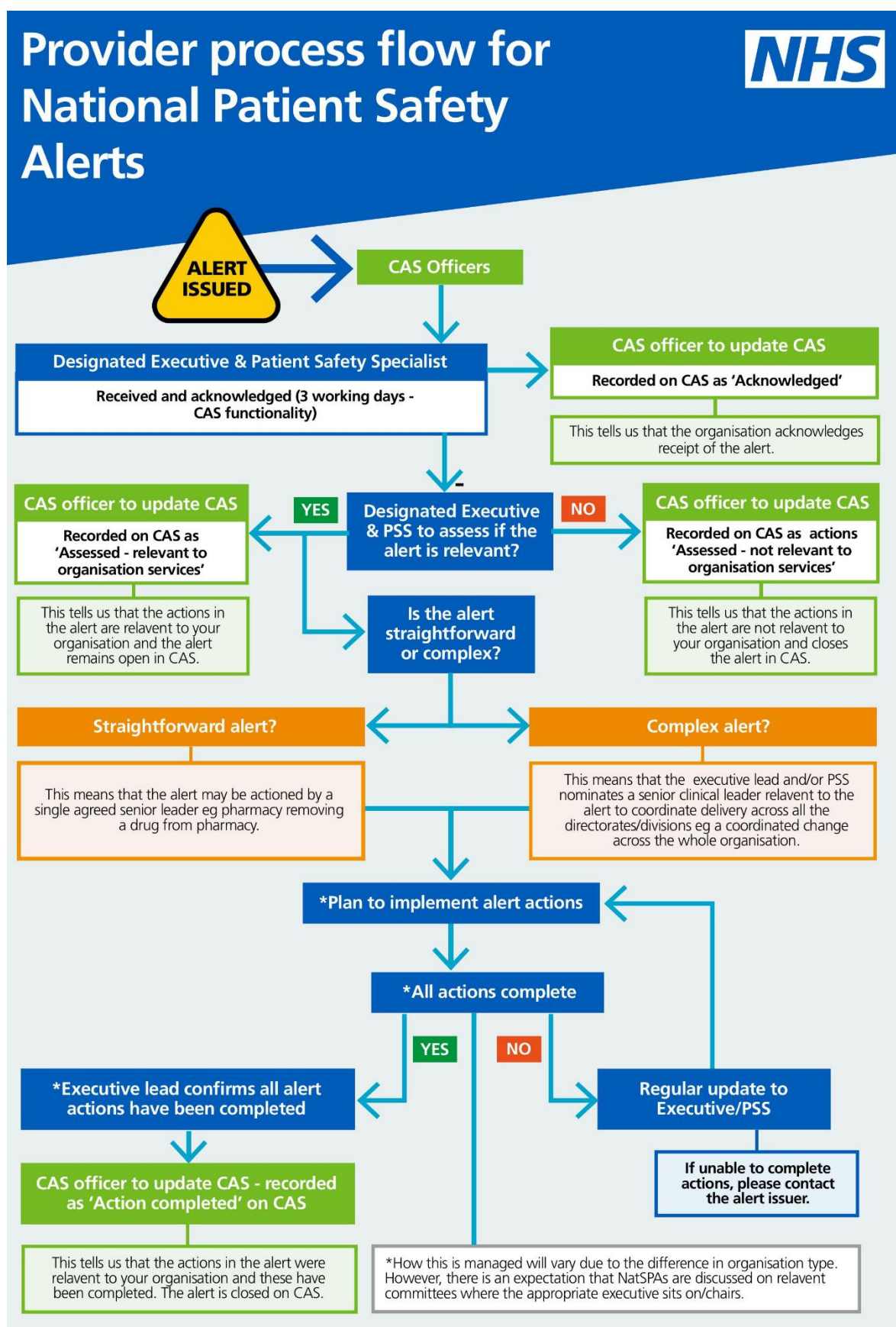


Figure 3: Provider process flow for National Patient Safety Alerts



To summarise, NatPSA are:

- written by an accredited organisation relevant to their remit;
- targeted at senior management in healthcare organisations for system-wide action; and
- sent to the healthcare sector through the Central Alerting System.

Useful NHS England resources are provided below:

- [National Patient Safety Alerts](#)
- [How we acted on patient safety issues you recorded](#)
- [Management of National Patient Safety Alerts](#)
- [Deciding if the patient safety issue, resources or intervention meet the criteria for an NHS Improvement Patient Safety Alert](#)
- [Response case studies by clinical speciality](#)
- [Enduring standards and general principles](#)

9.2. Field Safety Notices (FSNs)

When a manufacturer becomes aware of an issue with a medical device that they make, they must tell their customers what actions to take, using an FSN. This is an important communication about the safety of a medical device that is sent to customers by a device manufacturer, or their representative. These are not published on the Central Alerting System (CAS).

FSNs tell you what you need to do to reduce the specified risks of using the medical device. They give you either new information or highlight/remind you about existing advice. The actions are referred to as 'Field Safety Corrective Actions' (FSCAs). If you receive a field safety notice from a manufacturer, always act on it.

Do not wait for a communication from the MHRA before acting on an FSN.

It is important that your organisation takes the actions detailed in the FSN and that you tell the manufacturer that you have received the FSN. Your organisation's reply is the evidence that the manufacturer, and the MHRA, needs to monitor the progress of the corrective actions to ensure patient safety. Without your reply, the manufacturer can't know if their important message has been received and the MHRA may need to issue a safety communication.

The MHRA publishes a weekly list of FSNs. This list is provided for transparency purposes only and serves as an additional source of information. Manufacturers remain responsible for



ensuring that their safety communications are distributed directly to the intended recipients. Nevertheless, the weekly list can be a useful resource to review alongside direct safety communications, helping organisations confirm that all relevant FSNs have been received. As the published list is rolling, there may be a delay before a newly issued FSN appears on the weekly publication.

There is no need to respond to FSNs that are not relevant to your organisation. Manufacturers have a legal obligation to notify organisations directly when they have supplied a medical device that is affected by an FSCA or other relevant safety communication.

The MHRA publishes alerts, recalls and safety information for medicines and medical devices, including weekly summaries of FSNs [here](#). You can filter the published information by message type.

You can also sign up to receive specific MHRA email alerts [here](#), including the MHRA Safety Roundup. This monthly bulletin summarises the latest safety advice for medicines and medical devices.

MHRA also publish an excel spreadsheet containing all [FSNs published since January 2020](#) which can be filtered to find relevant FSNs. Folders organised by month and year of all FSNs published since November 2014 can be found [here](#). FSNs published before this date are available on the [National Archives website](#).

To summarise, FSNs are:

- written by manufacturers of medical devices, not by the MHRA;
- sent by manufacturers to relevant customers; and
- published on GOV.UK for information only.

9.3. MHRA - Device Safety Information

When an issue does not meet the criteria for a NatPSA, but still needs to be communicated, the MHRA can issue Device Safety Information (DSI) to reduce risks relating to a medical device.

The MHRA may also contact specific organisations known to use a particular device, or relevant bodies such as professional organisations or charities, where new information is relevant to their area of expertise or interest.

To summarise, DSIs are:

- written by the MHRA;
- targeted at healthcare professionals but may sometimes be directly relevant to patients; and
- published on GOV.UK for action and information.



9.4. NHS Supply Chain - Important Customer Notices (ICNs)

Important Customer Notices (ICNs) are formal communications issued by NHS Supply Chain to inform healthcare organisations of significant issues or changes affecting products and services supplied through national procurement routes.

[NHS Supply Chain](#) manages the sourcing, delivery and supply of healthcare products, services and food for NHS trusts and healthcare organisations across England and Wales. Their role is to source, deliver and supply healthcare products, services and food for NHS trusts and healthcare organisations across England and Wales.

ICNs support patient safety and operational continuity by ensuring organisations receive timely and consistent information about risks, supply issues, and required actions.

ICNs may include:

- Product disruptions such as shortages, delays, or supply constraints.
- Product recalls or safety concerns requiring removal or restricted use.
- Alternative products that have been clinically reviewed and approved.
- Changes to contracts or pricing that may affect procurement decisions.

9.5. MDSO Role in Safety Communications

Medical device safety communications form an important part of the wider medical device safety system. The MDSO should work collaboratively with clinical, technical, operational and governance colleagues to support an effective organisational response to safety communications relating to medical devices. The role helps ensure that medical device safety expertise informs decision-making and that learning from safety communications is used to improve the safe use of medical devices.

The extent of MDSO involvement will vary depending on the type of communication and local organisational arrangements.

National Patient Safety Alerts (NatPSAs)

National Patient Safety Alerts (NatPSAs) are typically managed through formal organisational governance processes and require senior leadership oversight, coordination and assurance. Where a NatPSA relates to medical devices, the MDSO may provide specialist advice and support as part of a multidisciplinary team, but responsibility for managing and assuring completion of the alert will usually sit within the organisation's established patient safety and governance systems.



Other Medical Device Safety Communications

For other medical device safety communications, such as Device Safety Information, Field Safety Notices (FSNs), Important Customer Notices (ICNs), manufacturer recalls and other advisory communications, the MDSO may have a greater role in supporting communication, coordination and implementation of local actions. The extent of involvement will depend on local arrangements and the nature of the communication.

It is important that you share your MDSO contact details with the MHRA so that your contact details can be uploaded to MORE to ensure that your organisation is kept informed of medical device safety communications from manufacturers. It is also essential that you keep MHRA updated of any changes to the MDSO contact details for your organisation.

Processes for receiving, assessing, distributing and monitoring safety communications vary between organisations and may involve governance, patient safety, risk management, procurement, clinical engineering, or other specialist functions.

Where the MDSO is expected to undertake significant operational responsibilities relating to medical device safety communications, organisations should ensure that appropriate resources and support are provided. This helps ensure that the core functions of the role, particularly those relating to medical device incident reporting, learning, communication and local safety improvement, continue to be delivered effectively.

9.6. Central Alerting System

The Central Alerting System (CAS) is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care. Field Safety Notices are not sent via this system.

Alerts relating to medical devices should be shared by the CAS liaison officer of the organisation, with the MDSO to support:

- appropriate onward cascade of information to key device users and technical staff;
- patient and staff safety measures are implemented in a timely and effective manner;
- a record of evidence of actions taken is maintained; and
- responses sent to the organisations CAS Liaison Officer/Administrator for uploading onto the website to ensure the organisation meets its regulatory requirements. (Please note: Currently there is no mechanism for non-NHS England organisations to report back into CAS. It is therefore important that local records of actions completed must be kept).



CAS is an NHS England system, hosted by MHRA; if you are an MDSO (or equivalent) working within the devolved nations you will have a different mechanism of distribution and will need to follow local guidance.

9.7. Central Alert System Liaison Officer / Administrator

The Central Alert System (CAS) Liaison Officer / Administrator role varies between organisations. It may be part of the MDSO, MSO role, health and safety team or governance departments. This role is responsible for managing safety alerts by disseminating them to the correct teams, monitoring the progress of required actions, and reporting back to the national database. This role is crucial for risk management, ensuring that patient and staff safety measures are implemented in a timely and effective manner, and that the organisation meets its regulatory requirements.

Responsibilities of the CAS Liaison Officer / Administrator may include:

- Ensuring the organisation is receiving alerts.
- Acknowledging and receipting alerts.
- Reviewing and distributing alerts to nominated leads in departments.
- Submitting updates and reports to the CAS website in response to alerts.
- Maintaining a record of notices sent, whom they were sent to, action taken and audit returns.
- Recording and escalating risks associated with CAS alerts.
- Auditing reports of alerts.

9.8. Assurance and Tracking

Maintaining full traceability of actions taken in response to safety communications is essential, particularly for FSNs, which are not tracked through the CAS. Where a safety action from a safety communication requires intervention on equipment, such as hardware modification, software upgrade or component replacement, it is good practice for the action taken to be recorded against the individual asset, ideally within the organisation's asset management database. Some organisations may also use incident management systems or other formal electronic tracking systems to record actions taken and retain supporting evidence relating to FSNs. Where such systems are not available, local records should still be maintained to provide assurance that actions have been completed and to support

In some cases, particularly where corrective actions relate to a large quantity of devices, organisations may find that a small number of affected devices cannot be located despite reasonable efforts. In these circumstances, it is important to assess the residual risk, agree any



necessary local mitigating actions, and consider escalation through relevant governance routes at a level proportionate to the risk. Any such approach should be undertaken in line with local organisational policies, procedures and governance arrangements.

Inventory Management Systems information is available here: [In-Trust Inventory Management Systems \(IMS\) » NHS Supply Chain](#) can assist in the effective management of recalls and maximising the potential of Unique Device Identifiers (UDIs) and also assist in uploading data to the Medical Device Outcome Registry ([MDOR](#))

9.9. Safety Communications Check List

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Familiarise yourself with the different methods of safety communication
- ☐ Understand how safety communications are received into your organisation
- ☐ Identify how safety communications are managed and understand your role in the process

Systems

- ☐ Familiarise yourself with the processes for reviewing and distributing safety communications within your organisation
- ☐ Understand how actions are captured and reported
- ☐ Identify system challenges in the safety communication process

Governance

- ☐ Identify the Board level director/Executive responsible for oversight of National Patient Safety Alerts (NatPSA)
- ☐ Identify how full traceability of safety communication review and action is achieved in your organisation



10. Delivering the Role in Different Settings

MDSOs work across a diverse range of healthcare organisations, each with their own unique challenges.

This section of the handbook has been written by members of the Editorial Board from different sectors, offering insight into how the MDSO role operates across these settings.

10.1. Acute and Tertiary Centre

Acute and tertiary centres deliver highly specialised care and often use advanced and complex medical devices, including imaging systems, surgical robots, Extracorporeal Membrane Oxygenation (ECMO) equipment and specialist diagnostic technologies. Services are wide-ranging and distributed across large estates, theatres, specialist units and research environments, creating a high reliance on robust medical device governance and coordination.

The MDSO role in acute and tertiary centres is usually embedded within established governance structures such as Clinical Engineering, Medical Physics, Patient Safety or Clinical Governance. While some organisations have a dedicated MDSO, the role is often combined with wider responsibilities relating to medical device governance, assurance and regulatory compliance.

A key part of the role is managing safety alerts, Field Safety Notices and recalls, ensuring affected services are identified quickly, actions are coordinated across multiple specialties, and assurance is gained that responses are completed. Clear record-keeping and traceability are essential due to the scale and complexity of devices in use.

Approaches to incident management vary: the MDSO may lead device related elements of investigations or act as an advisor supporting clinical, patient safety and engineering teams. Acute and tertiary centres often have device-related incidents involving software, connectivity or integration with digital systems, requiring collaboration with IT and specialist clinical teams.

Challenges in this sector include dispersed equipment, varied competency requirements, increasing software driven technologies, and the rapid pace of innovation, particularly when research or novel devices are involved. Maintaining consistent standards across multiple specialties and sites requires strong governance and clear escalation routes.

To be effective, MDSOs must build strong relationships with key stakeholders such as clinical leaders, Clinical Engineering/EBME, Medical Physics, Procurement, Digital/IT, Patient Safety, Training and Research & Development. Understanding which committees and groups oversee medical device governance helps ensure timely decisions and robust assurance across the organisation.



10.2. Community and Mental Health

In Community and Mental Health NHS Trusts, the MDSO role sits in a very different environment to acute care. Services are spread across wide geographical areas, with inpatient units, outpatient clinics, and multiple staff bases often a long distance apart. Medical devices are used not just in clinical areas, but in patient homes, where there is less visibility and less immediate support. In community services, the scale and spread of device use may make safe management of devices difficult. In mental health services, device use may be less frequent or less visible, but the risks are still present.

In this setting, communication becomes an essential tool. Safety information, alerts, and learning need to reach the right people, in the right place, at the right time, and that is not straightforward in a dispersed organisation. This often means working through local leads, existing governance routes, and simple, reliable communication channels.

Variation in practice is another challenge. Different services, different locations, and different ways of working can lead to inconsistency in reporting, training, and device management. The role here is to support a consistent approach across the organisation. In community services, this might mean making sure patients, carers and staff know how to report incidents and get support. In mental health services, it may be about raising awareness and making sure medical device risks are not overlooked.

Maintaining a clear view of risk across all of this is not easy. It relies on pulling together information from different sources, understanding how devices are used in practice, and spotting where things do not quite align. The reality is that the MDSO cannot be everywhere, so the focus should be on enabling local ownership, keeping things visible, and concentrating effort where it will make the biggest difference.

10.3. Ambulance and Emergency Medical Services

In Ambulance Trusts, medical devices are used in time-critical, high-risk environments to assess, stabilise and treat patients from first contact through to handover. Equipment such as defibrillators, ventilators, suction units, infusion/syringe pumps, oxygen delivery systems, monitoring equipment, powered stretchers and specialist devices must remain safe and reliable despite constant movement, vibration, temperature extremes, cleaning cycles and frequent handovers between crews and vehicles.

Across the sector, the MDSO function is usually embedded within wider governance arrangements (for example patient safety, risk, quality, clinical engineering, clinical governance or health and safety). It is often delivered alongside other responsibilities, rather than as a dedicated full-time post. As a result, the role is typically focused on coordination, assurance and communication.



A core part of the ambulance MDSO role is triaging and coordinating responses to safety communications. This includes CAS alerts, manufacturer Field Safety Notices and recalls, and other medical device safety communications. The MDSO helps ensure the right clinical, operational, and technical leads are engaged early, relevance is assessed quickly, and actions are communicated clearly. Good practice also includes tracking actions through to completion and keeping an auditable record of decisions and outcomes.

Local models vary in how adverse incidents are managed. In some Trusts, the MDSO leads or coordinates medical device safety investigations. In others, investigations are led by clinical, patient safety and engineering teams, with the MDSO supporting reporting and follow-up, including submitting reports to the Yellow Card scheme when required. New MDSOs should clarify early what sits within their remit locally, and what is owned by other functions.

Ambulance services have some distinctive challenges. Equipment is dispersed across vehicles, stations and specialist teams, and it is used in uncontrolled environments under time pressure. This can make assurance harder, particularly for consistent implementation of safety actions, traceability of affected devices, and maintaining competence and checking routines. Device reliability can also be impacted by vibration, temperature variation, frequent handling, battery dependence and increasing software/connectivity features.

To be effective, MDSOs need a clear understanding of local roles, responsibilities and escalation routes for medical device safety in their organisation. Key players commonly include clinical leaders, clinical engineering/EBME, procurement, infection prevention and control, education/training, risk/patient safety teams and operational leads. It is equally important to know which committees oversee device governance and where key decisions are made. Proactively building relationships with these key stakeholders helps the MDSO tailor support to local needs, speed up decision-making when alerts arrive, and strengthen assurance that actions have been implemented across the service.

10.4. Independent Sector

Independent healthcare in the UK refers to healthcare services not provided by the NHS, including private hospitals, clinics, GPs, and hospices run by companies, charities, or other organisations. Independent healthcare providers play a key role in the delivery of healthcare across the UK, treating millions of NHS and private patients every year across a range of services including acute hospital care, primary care, community care, hospice care clinical home healthcare, insourcing and diagnostics.

Being an MDSO in this sector can have its benefits and challenges. Depending on the size, complexity and geography of your organisation, you may be a MDSO across the whole of the UK or undertake to role of MDSO in addition to numerous other roles within a small organisation.



10.5. Care Homes

Care homes rely on a wide range of medical devices to support residents with complex and often changing needs. These range from basic consumables to more technical equipment such as hoists, beds and bed rails, thermometers, blood-glucose monitors, oxygen concentrators and syringe drivers. The MDSO role in this setting is to help ensure that devices are safe, suitable for purpose, advising on suitable training and used correctly. This includes encouraging effective incident reporting, supporting learning from device-related issues and helping staff recognise early signs of risk.

The sector faces several challenges that make this difficult. Many care homes do not have an MDSO, and in many areas there is little awareness that the role is needed at all. Where the role is absent, device safety practice can be fragmented, informal, or left to staff who may not have the time, knowledge or support to carry it out effectively.

Limited training budgets, high staff turnover and heavy reliance on agency workers add further pressure. Access to technical support is inconsistent, and procurement may be spread across multiple suppliers with no central oversight.

10.6. Hospices

Hospices use a wide range of medical devices to support residents with complex clinical needs, including end-of-life care, symptom management and rapid changes in condition. Equipment such as syringe drivers, oxygen therapy devices, monitoring equipment and pressure-relieving systems must be reliable and used safely, as errors can have serious consequences. The MDSO role helps hospices strengthen device governance by supporting incident reporting, promoting good practice and helping staff recognise and respond to emerging risks.

Hospices face their own challenges. Many do not have a dedicated MDSO and, as with care homes, awareness of the role remains limited across the sector. Teams are often small, with limited access to technical support and constrained funding for training. Variability in procurement routes and reliance on charitable income can further affect the consistency of device governance.

10.7. Community Equipment Services

Community Equipment Services provide medical devices and daily living equipment for people outside of hospital settings, usually in their own homes or community care environments. They support people to remain independent, safe, and cared for, often helping to prevent hospital admission or enable earlier discharge. The equipment can range from simple aids to daily living through to items such as patient hoists and suction devices for airway management, depending on the needs of the patient. As an MDSO, this means the scope of the role extends well beyond



traditional clinical areas, with devices in widespread use across a variety of settings that are not always visible or easy to oversee.

Services are typically commissioned jointly across health and social care and involve a mix of organisations, including NHS Trusts, local authorities, and external providers. They cover the full pathway of equipment provision, from assessment and delivery through to installation, maintenance, collection, cleaning, and reuse, often with significant reliance on third party providers. In practice, the role becomes about working across this system, building relationships and maintaining a network of stakeholders to ensure that risks are recognised, information is shared, and action is taken.

From an MDSO perspective, this creates a need to maintain visibility of risk across a pathway that is fragmented and spread across a large geographical area. This involves supporting reporting, understanding how devices are used in practice, and identifying where gaps exist between expected processes and what is actually happening. The role is about connecting information and people, making sure that learning is not lost across organisational boundaries, and supporting a consistent and safe approach across the whole system.

11. Patient Safety Systems

Patient safety is the avoidance of unintended or unexpected harm to people during the provision of health care. Ensuring patient safety is fundamental to your role as MDSO.

The core principles of Patient Safety can be listed as:

- **Prevention of harm:** Proactively minimising risks and preventing adverse events.
- **Culture of safety:** Creating an environment where staff and patients feel empowered to report errors and suggest improvements without fear of blame.
- **Learning from incidents:** Systematically reporting, analysing, and learning from medical errors and near misses to prevent recurrence.
- **Patient engagement:** Involving patients in their care to enhance their understanding and contribution to their own safety



This section of the handbook will provide you with an introductory insight into patient safety documents, frameworks and organisation that support patient safety across the healthcare.

11.1. NHS Patient Safety Strategy

The [NHS Patient Safety Strategy](#) sets out how the NHS will support staff and providers to share safety insight and empower patients and staff with the skills, confidence and mechanisms continuously to improve safety.

The strategy will evolve over time, building on the foundations of a safer culture and safer systems, to ensure it is supporting the NHS to meet its current challenges and priorities, remains relevant and can impact on the areas where need is greatest.



For information about the progress made since the strategy was launched in 2019 and some highlights of where the strategy is having an impact, along with a selection of case studies visit: [NHS Patient Safety Strategy: Progress so far webpage](#). You can also find further detail on the strategy's key initiatives via the links below:

- [Patient Safety Incident Response Framework \(PSIRF\)](#)
- [Learn from patient safety events service \(LFPSE\)](#)
- [Patient Safety Specialists](#)
- [Framework for involving patients in patient safety](#)
- [Patient Safety Syllabus](#)
- [National Patient Safety Alerts](#)
- [National Patient Safety Strategic Research Needs 2022/23](#)
- [Digital Clinical Safety Strategy](#)

It is important to acknowledge that the Patient Safety Strategy is not just relevant for NHS organisations but also non-NHS organisations, whether they are providing NHS funded care or not.

11.2. Patient Safety Incident Response Framework (PSIRF)

The [Patient Safety Incident Response Framework](#) (PSIRF) sets out a new approach to developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety. The framework represents a significant shift in the way organisations respond to patient safety incidents and is a major step towards establishing a safety management system across healthcare.

PSIRF aims to help providers continuously improve their safety cultures, systems and behaviours. The framework focuses on methods of investigation, the involvement of patients and families and the system changes needed for better patient outcomes.

PSIRF replaces the Serious Incident Framework (SIF). Unlike the SIF, PSIRF is not an investigation framework that prescribes what to investigate. PSIRF promotes a proportionate approach to responding to patient safety incidents by ensuring resources allocated to investigating and learning are balanced with those needed to deliver improvement. This means that organisations can choose which incidents they prioritise for a full investigation, and which they will respond to differently – for example, by conducting a multidisciplinary review, or facilitated debrief.

Please also see section 13 on MDSO training.



11.3. Patient Safety Culture

Safety culture is one of the two key foundations of the NHS patient safety strategy. A positive safety culture is one where the environment is collaboratively crafted, created, and nurtured so that everybody (individual staff, teams, patients, service users, families, and carers) can flourish to ensure brilliant, safe care by:

- Continuous learning and improvement of safety risks.
- Supportive, psychologically safe teamwork.
- Enabling and empowering speaking up by all.

Within safety culture, context is everything and improving safety culture is not just about what interventions happen, it is also about how these interventions happen – that is, how change is implemented.

You may hear the term 'Just Culture' or 'Being Fair'; this supports patient safety by creating a culture of fairness, transparency, and learning, where staff are not unfairly blamed for system failures or human error but are held accountable for reckless or wilful misconduct. It promotes an environment where people feel safe to report incidents and learn from mistakes by shifting the focus from "who is to blame?" to "what happened and why?".

11.4. Duty of Candour

Duty of Candour is the responsibility for health and care professionals and organisations to be open, honest, and transparent when a "notifiable safety incident" occurs in a patient's care, which is one that has, or could have, caused moderate harm or worse.

As an MDSO, you may be involved in this if there has been a medical device event has taken place. For example, sharing information with families.

Please refer to your local policy.

Healthcare staff may be fearful of upsetting the patient, saying the wrong thing or admitting liability however research has shown that being open when things go wrong can help patients and staff to cope better with the aftereffects of a patient safety incident.

For further information on Duty of Candour, including legal and professional requirements, please refer to the relevant national guidance available here: [Duty of candour](#)

11.5. Health Services Safety Investigations Body (HSSIB)

HSSIB is an organisation which investigate patient safety concerns across the NHS in England and in independent healthcare settings where safety learning could also help to improve NHS care. More information is available on the HSSIB website: [Who we are.](#)



Their investigations aim to reduce patient harm by:

- Supporting the involvement of patients, families and carers in healthcare.
- Supporting healthcare staff to carry out their roles and care for patients safely.
- Creating safer healthcare environments and processes.
- Making healthcare services more efficient.
- Sharing best practice and innovations in patient care.

Its core role is to carry out independent [patient safety investigations](#) that do not find blame or liability with individuals or organisations and to understand why patients may have been harmed or be at risk of harm. The investigations take a system perspective and aim to reduce the likelihood of patient safety incidents from happening. Learning is shared to support patient safety improvements across the whole healthcare system in England

11.6. SEIPS & Human Factors

11.6.1. Systems Engineering Initiative for Patient Safety (SEIPS)

PSIRF promotes a range of system-based approaches for learning from patient safety incidents. National tools have been developed that incorporate the well-established SEIPS framework (Systems Engineering Initiative for Patient Safety).

SEIPS was developed using human factors to emphasise the interactions between people and their environment that contribute to performance, safety, health, quality of working life and outcomes. It is a framework which can be used as a general problem-solving tool (e.g. to guide how we learn and improve following a patient safety incident, to conduct a horizon scan, and to inform system design).

Patient safety incidents result from multiple interactions between work system factors.

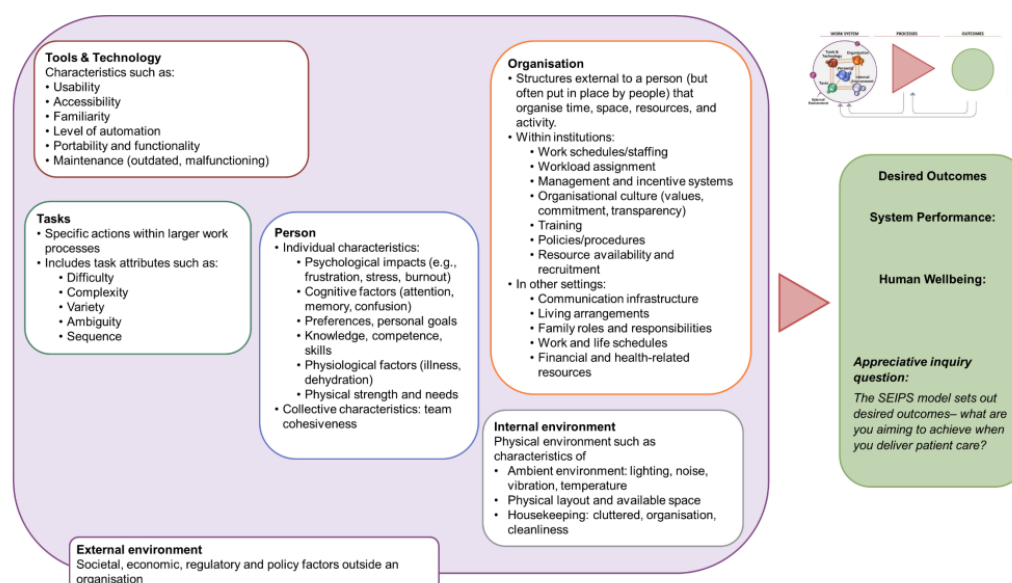


Figure 4: Overview of SEIPS work system

SEIPS prompts us to look for interactions rather than simple linear cause and effect relationships. A ‘work system’ as seen above in Figure 4 consists of six broad elements:

- external environment,
- organisation,
- internal environment,
- tools and technology,
- tasks
- people.

People cannot be separated from the work system; their deliberate placement at the centre of a SEIPS framework emphasises that design should support – not replace or compensate for – people.

SEIPS can be used as a general problem-solving tool (e.g. to guide how we learn and improve following a patient safety incident, to conduct a horizon scan, and to inform system design).

Patient safety incidents result from multiple interactions between work system factors. SEIPS prompts us to look for interactions rather than simple linear cause and effect relationships.

When a learning response thoroughly examines the different work system components and their interactions safety actions can focus on wider system issues, not individuals.



11.6.2. Human Factors

Human Factors (also called ergonomics) is a discipline that considers both the physical and mental characteristics of people as well as the organisational factors or wider socio-technical system. It is the application of scientific methods to the design and evaluation of tasks, jobs, equipment, environments and systems to make them more compatible with the needs, capabilities and limitations of people.

In healthcare Human Factors can improve human performance, optimise well-being, improve both staff and patient safety and experience and improve the overall system performance. Clinical Human Factors and Patient Safety are closely interlinked.

11.7. Patient Safety Learning Response Toolkit

The Patient Safety Learning Response Toolkit is a practical resource developed by NHS England to help organisations respond to patient safety incidents in a way that focuses on learning rather than blame. It supports the PSIRF approach by guiding teams to understand what happened, why it happened, and how care can be made safer in future. The toolkit provides clear methods, prompts and templates to support proportionate reviews, meaningful engagement with staff and patients, and the translation of learning into real improvement at local and system level.

[NHS England » Patient safety learning response toolkit](#)

11.8. Learning Response Review and Improvement Tool

The Learning Response Review and Improvement Tool is designed to help organisations reflect on the quality and impact of their patient safety learning responses. It supports teams to assess whether reviews are proportionate, fair and focused on understanding how work is done in practice, rather than on individual blame. The tool also helps identify strengths, gaps and opportunities for improvement, ensuring that learning responses lead to meaningful actions, shared learning and safer care over time.

<https://www.hssib.org.uk/education/learning-response-review-and-improvement-tool/>

11.9. NHS Patient Safety Syllabus Training Programme

When patients are harmed, it has an impact on them, their loved ones, the staff, and others who work in the healthcare system. It is crucial that all staff, whatever their roles, see safety not just as a collective *responsibility*, but as a key *priority*. We all need to *think differently* about what patient safety means and how we can make improvements.

Overall, we can make healthcare even safer by:

- Dealing with risks before they can cause harm.
- Working to create a positive patient safety culture.



- Building safer systems.
- Recognising everyone's role in patient safety.

The [NHS Patient Safety Strategy](#) will help deliver the changes needed. The Strategy includes a [patient safety syllabus](#) and training programme for the whole NHS. This is designed to help everyone who works in the NHS take all the necessary steps to ensure our patients are safe while they are in our care.

Click here to access the [NHS Patient Safety Syllabus](#) training programme

11.10. Patient Safety Systems Checklist

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Familiarise yourself with the core principles of Patient Safety
- ☐ Read the NHS Patient Safety Strategy
- ☐ Complete the NHS Patient Safety Syllabus Training Programme eLearning modules
- ☐ Familiarise yourself with the SEIPS Framework

Systems

- ☐ Understand how PSIRF has been launched and is working within your organisation
- ☐ Discover which systems learning and human factors methodologies are being utilised in your workplace

Development

- ☐ Undertake training on PSIRF, SEIPS and Human Factors and integrate these methodologies into your incident reviews and reports
- ☐ Familiarise yourself with the Learning Response Review and Improvement Tool



12. Internal Collaboration & Stakeholders

Collaboration improves the way all healthcare professionals can work together to support the safe use of medical devices. This can lead to improved communication, support system-wide change, encourages innovation and ultimately has the potential to reduce medical device related harm.

As an MDSO, you will collaborate with a range of key groups, stakeholders, and individuals within your organisation. Each of these parties brings valuable expertise and can provide you with advice and guidance relevant to their specific areas, supporting your role in promoting the safe use of medical devices. Please find examples below.

12.1. Governance and Risk Teams

Within an organisation there will be roles that focus on governance and risk, providing organisational oversight for assurance purposes.

Their understanding of the MDSO role and those individuals with a responsibility for supporting the safe use of medical devices, will ensure that medical device safety remains on the organisation's governance agenda, and that the value of the MDSO role reaches its full potential.

Your collaboration with these teams and attendance at these meetings will also provide an additional route for you to support medical device safety issues across your organisation.

12.2. Patient Safety Specialists

Patient Safety Specialists (PSSs) provide strategic leadership in advancing patient safety by implementing national safety strategies at the local level. They enhance safety systems, promote a culture of continuous learning and improvement, and ensure that principles such as a “just culture” are embedded throughout the organisation. PSSs also lead incident analysis, support improvement initiatives, and work closely with executive leadership to prioritise and champion patient safety. They also play a key role in the implementation of the NHS Patient Safety Strategy, supporting the development of a patient safety culture, safety systems and improvement activity.

You can read more about the role [here](#).

12.3. Medication Safety Officer (MSO)

An MSO is the named individual within an organisation responsible for encouraging medication error incident reporting and learning. The MSO can also offer medication safety specialist expertise and act as a centralised individual to work collaboratively on medication safety and



communication of medication risks and associated mitigation strategies within the organisation. You can read more about the role [here](#).

Effective collaboration between MDSOs and MSOs can improve organisational learning from incidents, particularly with drug-device combination products. Good communication between the MDSO and the MSO (or equivalent) will foster organisational learning and ensure a coordinated response to patient safety alerts and incidents.

Below are some examples of projects where MDSOs and MSOs have successfully worked together to effectively address safety issues from both sides:

- NRRFit NatPSA (ISO 80369-6 for neuraxial and epidural applications)
- ISO 80369-3 ENFit for enteral applications
- Infusion pumps and drug libraries
- Medical gas safety including cylinders
- Insulin safety and accuracy of delivery
- Field Safety Notice (FSN) management – Infusion consumables
- Managing lack of volumetric pumps during COVID
- Governance committee updates
- Incident investigations with crossover
- Device configurations

12.4. Clinical Safety Officer

A Clinical Safety Officer is a senior registered clinician required under DCB0160 to oversee the clinical safety of digital health systems in a deploying organisation. The CSO must hold current registration with a professional body such as the GMC, NMC, or GPhC, have completed accredited clinical safety training, and possess demonstrable experience in clinical risk management. Their core responsibilities include identifying and assessing hazards when digital systems are deployed, approving or rejecting system deployments, investigating safety incidents, and maintaining clinical safety documentation including hazard logs and safety case reports. The CSO has the authority to pause or stop any digital system deployment if they judge it to be unsafe — and that decision is final.

A Clinical Safety Officer (CSO) is a senior clinician responsible for assessing and managing the risks that digital health systems may pose to patients. The role exists because digital tools in healthcare carry potential hazards, and someone qualified must oversee whether those risks are being properly controlled.



The CSO's role spans the entire lifecycle of a digital health system, from initial procurement through to decommissioning (Risk Management, Change Governance, Incident Oversight, Supplier Assurance, Documentation.)

12.5. Additional Internal Stakeholders

As you can see from the list below (which is not exhaustive) in your role as MDSO you will collaborate with several key stakeholders within your organisation to support medical device safety:

- Clinical Engineer / Medical Physicist (either within your organisation or through a third-party provider)
- Board Directors for escalation of issues of operational and clinical issues
- Estates & Facilities Management Lead
- Waste Management Lead
- Infection, Prevention & Control Lead
- Decontamination Lead
- Learning & Development / Medical Device Trainers
- Medical Gases Lead
- Procurement / Clinical Procurement Specialists
- IT Lead
- Legal team
- Patient Safety Partners



12.6. Internal Collaboration Checklist

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Understand your local governance processes and identify key roles and responsibilities.
- ☐ Understand your local escalation routes and how issues reach Executive Board level.

Systems

- ☐ Identify your Medical Devices Management Group and/or Safety Committee and confirm your role within them.

Collaboration

- ☐ Meet key internal contacts, including:
 - ☐ Clinical Engineering, EBME, Maintenance Providers
 - ☐ Governance and Risk teams
 - ☐ Patient Safety Specialists
 - ☐ Medication Safety Officer
 - ☐ Procurement
 - ☐ Infection Prevention & Control
 - ☐ Sterile Services and Decontamination
 - ☐ Estates & Facilities
 - ☐ Medical Device Trainers
 - ☐ Digital & Information Technology
 - ☐ Clinical Safety Officer
- ☐ Learn how these stakeholders contribute to medical device safety within your organisation.



13. MDSO Training and Development

Effective training is required for MDSOs to carry out their role safely, confidently, and consistently. The MDSO role sits at the intersection of patient safety, clinical practice, technical systems, governance, and national reporting requirements. Without appropriate training, there is a risk that medical device incidents are poorly understood, inadequately investigated and not effectively reported locally or nationally, resulting in lost learning opportunities and missed opportunities to minimise or prevent patient harm.

Supporting learning from medical device incidents is a core function of the MDSO role.

MDSOs are expected to support high-quality reporting, contribute to investigations where appropriate, liaise with national bodies, and help organisations translate learning into safer practice.

Training is critical because medical device incidents are rarely caused by a single failure and usually involve interactions between people, technology, tasks and organisational systems. Investigations are now expected to align with the Patient Safety Incident Response Framework (PSIRF) and should use systems-based approaches to investigate.

Training for MDSOs should be planned, structured and proportionate, recognising that MDSOs come from a wide range of professional backgrounds. Training needs can broadly be divided into core training and supplementary training.

Continuing Professional Development (CPD) is the ongoing process by which healthcare practitioners maintain, develop, and broaden their knowledge, skills, and professional performance to ensure safe patient care. The monthly MDSO Network meetings and annual conference, which are held virtually, are an ideal learning, development and networking opportunity for MDSOs to hear from expert speakers, engage with peers in other organisations and share experiences.

13.1. Core MDSO Training

Supporting medical device incident investigations is considered a core part of the MDSO role. Core subject areas include SEIPS, PSIRF, risk management and governance, incident investigation, thematic analysis and patient safety science.

Recommended core training courses include:

- NHS Patient Safety Syllabus Levels 1–3
- Systems approach to investigating patient safety incidents



- Investigative interviewing
- Thematic analysis
- Writing investigation reports
- After Action Review

13.2. Supplementary MDSO Training

Supplementary training should be tailored to your background as an MDSO, the organisational profile, and the devices in use. This may include device-specific training, training linked to national patient safety alerts, and emerging areas such as ‘software as a medical device’ and AI.

Sources of supplementary MDSO training include:

- Local user or technical training
- Manufacturers and suppliers
- NHS Learning Hub

13.3. e4Equipment Medical Equipment Programme

The e4e medical equipment learning resource (Hosted by e-Learning for Healthcare; eLfh) has become a valuable platform for supporting consistent, high-quality training across healthcare organisations, offering practical guidance and structured learning on essential medical device topics. As the programme continues to evolve, its future development will focus on expanding content, improving usability, and aligning training more closely with national standards.

Recent additions include a national e-learning training programme for ‘*Medical Gas and Cylinder Safety*’ as well as ‘*Managing Risks around Beds, Bed Rails & Transfer Trolleys*’ to help support national patient safety alerts.

A key step in this progression is the transition of eLfh over to the NHS Learning Hub, which will provide a more integrated, accessible, and scalable environment for learners across the NHS, ensuring the resource remains sustainable and widely available for years to come.

13.4. Quality Improvement (QI) Tools

The Health Foundation (2021) ‘Quality improvement made simple - What everyone should know about health care quality improvement’ is a great document to read to start your QI journey, as are the free online learning resources available here [Quality improvement made simple | The Health Foundation](#)

QI is about giving the people closest to issues affecting care quality the time, permission, skills and resources they need to solve them. It involves a systematic and coordinated approach to



solving a problem using specific methods and tools with the aim of bringing about a measurable improvement.

However effective, QI is more than just a method. It is a systematic approach to personal and organisational learning, development and improvement, in the face of challenging problems.

There are many well-known approaches to QI, but no one approach appears to better than another. The key principles that they all have in common are:

- The concept of a cycle of improvement which involves:
 - problem definition and diagnosis;
 - stating a clear, unambiguous aim;
 - testing of change ideas before implementation;
 - measurement for improvement (not judgement); and
 - evaluation.
- Emphasis on small scale testing: test one change at a time.
- It is a continuous process of learning and adapting.
- The use of a set of tools and techniques to support implementation.
- Recognition of the need to identify and engage stakeholders.
- Recognition of the importance of culture and leadership.
- Consideration of sustainability.

Using a methodology helps to identify exactly what needs to change, generates creative solutions and can be tested quickly at small scale, refined and then spread at pace.

A very popular QI methodology is the [Institute of Healthcare Improvement \(IHI\) 'Model for Improvement' approach](#), which incorporates the Plan-Do-Study-Act (PDSA) cycle.

This is an approach to continuous improvement where changes are tested in small cycles that involve planning, doing, studying, acting (PDSA), before returning to planning, and so on. Done well, QI methods enable us to show meaningful improvements in patient care and share what was learnt. Your organisation is likely to have a QI team who can offer training, advice and support with Quality Improvement projects.



13.5. MDSO Training Checklist

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Consider your personal MDSO training and development plan
- ☐ Identify any gaps in your knowledge, skills, or experience relevant to the role

Systems

- ☐ Undertake core MDSO training, including:
 - ☐ NHS Patient Safety Syllabus
 - ☐ SEIPS and Human Factors
 - ☐ PSIRF learning response training

Development

- ☐ Seek opportunities for ongoing development, including network learning, mentoring, and peer support



14. Key References

14.1. Legislation

- Health and Safety at Work etc. Act 1974
- Management of Health and Safety at Work Regulations 1999
- Provision and Use of Work Equipment Regulations 1998
- Electricity at Work Regulations 1989
- Lifting Operations and Lifting Equipment Regulations 1998
- Manual Handling Operations Regulations 1992
- Control of Substances Hazardous to Health Regulations 2002
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013
- Health and Social Care Act 2008
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- Care Quality Commission (Registration) Regulations 2009
- Medical Devices Regulations 2002 (as amended)
- Medical Devices (Amendment etc.) (EU Exit) Regulations 2019
- Medical Device Regulation (EU) 2017/745
- In Vitro Diagnostic Medical Device Regulation (EU) 2017/746
- Consumer Protection Act 1987
- General Product Safety Regulations 2005
- Sale of Goods Act 1979
- Supply of Goods and Services Act 1982
- Unfair Contract Terms Act 1977
- Ionising Radiation (Medical Exposure) Regulations 2017
- Ionising Radiations Regulations 2017
- Electrical Equipment (Safety) Regulations 2016
- Pressure Systems Safety Regulations 2000
- Waste Electrical and Electronic Equipment Regulations 2013
- Hazardous Waste (England and Wales) Regulations 2005



- Employers' Liability (Compulsory Insurance) Act 1969
- Law Reform (Contributory Negligence) Act 1945

14.2. Guidance and Codes of Practice

- British Standards Institution. Medical devices. Application of risk management to medical devices. BS EN ISO 14971:2019
- British Standards Institution. Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements. BS EN ISO 15223-1:2021
- British Standards Institution. Requirements for Electrical Installations. IET Wiring Regulations. BS 7671 (current edition)
- Care Quality Commission. Guidance for providers on meeting the regulations (Health and Social Care Act 2008 Regulated Activities Regulations 2014)
- Department of Health and Social Care. The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance (latest edition)
- Department of Health. Device Bulletin. Single-use medical devices. Implications and consequences of reuse
- International Organization for Standardization. Medical devices. Quality management systems. ISO 13485:2016
- Medicines and Healthcare products Regulatory Agency. Managing medical devices. Guidance for healthcare and social services organisations
- Medicines and Healthcare products Regulatory Agency. Medical device stand-alone guidance and Device Bulletins (including management of in vitro diagnostic medical devices and point of care testing devices)
- Medicines and Healthcare products Regulatory Agency. Reporting adverse incidents and disseminating medical device alerts
- Medicines and Healthcare products Regulatory Agency. Managing medical devices prior to investigation, inspection, service or repair
- Medicines and Healthcare products Regulatory Agency. Devices in Practice. A guide for healthcare professionals
- NHS England and Medicines and Healthcare products Regulatory Agency. Improving medical device incident reporting and learning (Patient Safety Alert NHS/PSA/D/2014/006)



15. Glossary

Alert (Safety Alert)

A formal communication issued to healthcare organisations to highlight a safety issue and set out required actions.

Central Alerting System (CAS)

A national system used to distribute safety alerts and other safety-critical information to healthcare organisations. It allows organisations to receive, manage, and respond to alerts.

Clinical Governance

The system through which organisations are accountable for improving quality and safeguarding standards of care. It includes reporting, learning, and risk management.

Device Safety Information (DSI)

A communication issued by the Medicines and Healthcare products Regulatory Agency (MHRA) to provide safety information where a formal alert is not required.

Duty of Candour

A legal requirement for organisations to be open and transparent with patients when something goes wrong that causes harm.

Field Safety Notice (FSN)

A communication issued by a manufacturer to inform users of a safety issue with a medical device and the actions required to reduce risk.

Field Safety Corrective Action (FSCA)

An action taken by a manufacturer to reduce the risk associated with a device, such as modification, recall, or replacement.

Human Factors

The study of how people interact with equipment, systems, and environments, and how design can support safe and effective use.

Incident (Medical Device Incident)

An event involving a medical device that has caused, or could have caused, harm to a patient, user, or other person.

Incident Reporting

The process of recording and reporting safety incidents within local systems and, where appropriate, to national systems.



Learn from Patient Safety Events (LFPSE)

The national NHS system for recording and analysing patient safety events. It supports learning across organisations.

Local Risk Management System (LRMS)

An organisation's system for recording and managing incidents, risks, and actions.

Medical Device

Any instrument, apparatus, appliance, software, or material used in the diagnosis, monitoring, treatment, or care of patients.

Medical Device Lifecycle

The stages a medical device passes through, including planning, procurement, use, maintenance, and disposal.

Medical Device Safety Committee / Group

A multi-professional group responsible for reviewing medical device incidents, supporting learning, and overseeing actions to improve safety within an organisation.

Medical Device Safety Science

The application of systems thinking, human factors, and safety principles to understand and reduce risks associated with medical devices.

Medical Devices Safety Officer (MDSO)

The designated person within an organisation responsible for supporting medical device incident reporting, learning, and communication. The role was established by the national Patient Safety Alert.

Medical Devices Safety Network (MDSO Network)

A national network that supports communication, learning, and sharing of information between organisations and national bodies.

Medicines and Healthcare products Regulatory Agency (MHRA)

The UK regulator responsible for ensuring that medical devices and medicines are safe and effective.

Medication Safety Officer (MSO)

A designated individual responsible for medication safety within an organisation, working closely with the MDSO where medicines and devices interact.

National Patient Safety Alert (NatPSA)

A safety alert issued for serious risks requiring action across healthcare organisations.



National Reporting and Learning System (NRLS)

The previous national system for patient safety incident reporting, now replaced by LFPSE.

Never Event

A serious, largely preventable patient safety incident that should not occur if appropriate safety measures are in place.

Patient Safety Incident

An unintended or unexpected event that could have or did result in harm to a patient.

Patient Safety Incident Response Framework (PSIRF)

A national framework that supports a systems-based approach to learning from incidents, focusing on understanding how and why events occur.

Risk Management

The process of identifying, assessing, and controlling risks to patient safety.

Safety Communication

Any formal communication relating to medical device safety, including alerts, notices, and guidance.

Safety Culture

The shared values and behaviours within an organisation that prioritise safety, encourage reporting, and support learning.

SEIPS (Systems Engineering Initiative for Patient Safety)

A systems-based model that describes how people, tasks, equipment, environment, and organisational factors interact to influence safety.

Serious Incident

An incident that results in significant harm, requires investigation, or indicates a systemic failure.

Systems Thinking

An approach that considers how different parts of a system interact, rather than focusing on individual components in isolation.

Yellow Card scheme

The UK system run by the Medicines and Healthcare products Regulatory Agency (MHRA) for reporting safety concerns about medical devices and other healthcare products.



16. Appendix A - Getting Started as an MDSO

16.1. MDSO Network Registration

The MDSO Network is the main networking and collaborative group for MDSOs. The objectives of the Network are to:

- facilitate dialogue between all partners in the collaborative, including healthcare organisations, NHSE and MHRA;
- ensure effective reporting of medical device incidents throughout the health system;
- share learning from medical device incidents;
- educate and train MDSOs in medical device safety; and
- disseminate relevant research and information concerning new risks, safety alerts and best practice.

You must be an MDSO or closely support an MDSO to be eligible for joining the MDSO Network

It is important that you share your MDSO contact details with the MHRA so you can be granted access to the MDSO Network resources, to receive invites to the Network meetings and also so that your contact details can be uploaded to MORE to support medical device manufacturers to distribute FSNs. It is also essential that you keep MHRA updated of any changes to the MDSO contact details for your organisation.

To share and update your contact details with MHRA, the '[MDSO Contact Form](#)' must be completed and returned to the MDSO Network secretariat at MDSONetwork@mhra.gov.uk.

Please only use the MDSONetwork@mhra.gov.uk mailbox for MDSO registrations, updates to contact details, technical difficulties or questions specifically relating to the Network.

16.2. MDSO Editorial Board

The MDSO Network operates independently and is managed by the MDSO Editorial Board with support from the MHRA and NHS England National Patient Safety Team.

The MDSO Editorial Board comprises of volunteers from across the MDSO Network and aims to reflect the diversity of the Network's membership by representing a broad range of healthcare sectors, organisations, and professional backgrounds. The Editorial Board supports the operation and ongoing development of the Network and is led by a Chair and Deputy Chair.

Once you have joined the Network, there will be opportunities to apply to join the MDSO Editorial Board if you are interested. Vacancies and opportunities to join the Editorial Board will be



advertised to Network members during the monthly webinars as and when they arise. Where a vacancy arises on the MDSO Editorial Board, recruitment should seek to maintain representation across the breadth of the MDSO Network. Where sector representation is lacking, recruitment should aim to address this gap (for example, if an Acute sector Editorial Board member steps down, expressions of interest should be sought from individuals working within that sector). To be eligible, Network members must have held the role of MDSO for a minimum of one year.

Details of the application and selection process will be provided at the time of advertisement. Applications will be reviewed by the Editorial Board, and the successful candidate will be determined through an anonymous majority vote.

16.3. Leaving the role

When leaving the role, it's important to complete a handover to ensure that the roles and responsibilities of the MDSO are continued. This includes:

1. arranging access for the new postholder to the generic MDSO mailbox to ensure that essential communications are still received and acted on appropriately.
2. notifying the MHRA of changes to your organisations MDSO contact details via the MDSO Contact Form.

16.4. MDSO Contact List

MDSO contact details are held by the MHRA and stored on a central MDSO Contact List.

The MDSO Contact List is shared with:

- NHS England
- MHRA
- Other MDSOs to ensure effective network collaboration
- NHS Supply Chain (NHSSC) to support manufacturers with Field Safety Corrective Actions when the affected device has been supplied via NHSSC.
- Manufacturers of medical devices to provide contact points for the distribution of Field Safety Notices via the password protected MORE portal; a digital platform designed for medical device manufacturers to facilitate the reporting, monitoring, and management of medical device incidents.

Every organisation should maintain a generic MDSO mailbox as the main point of contact for all correspondence. This ensures continuity of communication during staff changes and allows messages to be accessed when team members are on leave.



Other safety communications may be shared directly with MDSOs via the MDSO Network mailbox, the MDSO Network MS Teams channel, or at the monthly Webex meetings.

16.5. Monthly MDSO Online Meeting

By sharing your contact details with the MHRA, you will receive invites to the monthly MDSO online meetings and other events. These meetings are organised by the Editorial Board and provide a platform for MDSOs to stay up to date with the latest safety updates, raise questions to the Editorial Board, listen to a series of expert speakers and network with other MDSOs.

The online meeting is held on the first Wednesday of every month (excluding January and August) and is hosted on Microsoft (MS) Teams. The main meeting runs from 13:00-14:00 and is followed by an open mic session from 14:00-14:30 to support open discussion between colleagues.

The standing agenda is detailed below:

Topic	Presenter	Time
Welcome and Introduction	MDSO Network Chair	13:00-13:05
Updates and What's New?	MDSO Network Update MHRA Update NHSE Update NAMDET Update	13:05 – 13:30
Guest Speaker	TBC	13:30-14:00
Open Mic Discussion (optional)	MDSO Network Chair	14:00-14:30

16.6. NatPSS Meetings

As an MDSO, you will also receive invitations to the monthly NatPSS meetings. These are forwarded by the Secretariats on behalf of the NatPSS team. Please note that meeting details are typically added closer to the meeting date by NatPSS and are outside the Secretariats' control. In the meantime, placeholder calendar holds will be shared. If you miss a session, all recordings will be uploaded to the MDSO MS Teams Channel.



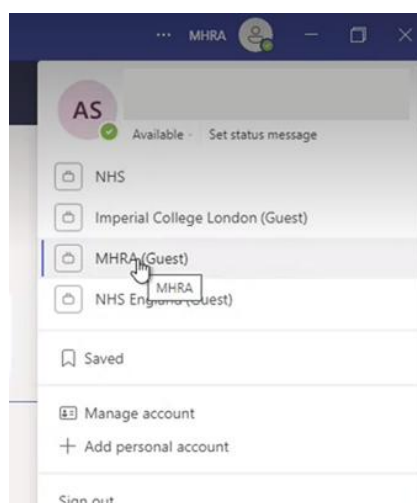
16.7. Teams Channel

The MDSO Network MS Teams channel is a private group intended for Network members, though equivalent Networks in the Devolved Administrations also have access to its resources.

16.7.1. How to join

You will be added to the MS Teams channel when you join the MDSO Network.

Please keep your eye out for an email with the subject line “AAD guest invitation” in your inbox (including the junk mail folder). Upon accepting this invite, you should be able to access the Teams channel via the following link: [MDSO Network - EXT.](#)



If you have any issues accessing, you may first need to be granted permission to access an external Teams channel by your IT helpdesk and / or switch your Teams profile to ‘MHRA guest’ if you have this option when you click on your name icon in the top right. Guidance on the M365 guest login process is available [here](#).

16.7.2. How to navigate

Within the MS Teams channel there are a number of forums and resources, including the following subchannels:



'General' – contains key administration documents, job descriptions, conference recordings, MDSO contact list, surveys, resources and more;

‘Monthly Webex’ – contains all the MDSO and MSO Webex recordings, slide decks and accompanying Patient Safety Updates. There is an ‘MDSO Webex Summary’ document stored with the meeting recordings where you can search for previous speakers and topics of interest to pinpoint the date they presented.



16.8. Getting Started Chapter Checklist

The following checklist highlights some of the key actions and considerations that may be relevant following review of this chapter.

Knowledge

- ☐ Explore MDSO Teams Channel resources

Systems

- ☐ Complete and return the 'MDSO Contact Form' to MDSONetwork@mhra.gov.uk
- ☐ Ensure your organisation has a generic MDSO mailbox and you have access
- ☐ Accept the MDSO Teams Channel invite

Development

- ☐ Add Monthly MDSO Meeting to your diary (first Wednesday each month, 13:00–14:00 plus Open Mic 14:00–14:30), holds will also be shared by the Secretariats.



17. Appendix B - Useful Links

This section provides a curated list of key national resources, tools and guidance to support Medical Devices Safety Officers. These include resources referenced within the handbook and additional useful links that can be used for further detail, training and implementation.

17.1. Core Systems

- Learn from Patient Safety Events Service (LFPSE): <https://www.england.nhs.uk/patient-safety/patient-safety-insight/learning-from-patient-safety-events/learn-from-patient-safety-events-service/>
- MHRA Yellow Card scheme: <https://yellowcard.mhra.gov.uk/>
- Central Alerting System (CAS): <https://www.cas.mhra.gov.uk/Home.aspx>

17.2. Safety Alerts and National Guidance

- National Patient Safety Alerts: <https://www.england.nhs.uk/patient-safety/patient-safety-insight/patient-safety-alerts/>
- MHRA Drug and Device Alerts: <https://www.gov.uk/drug-device-alerts>
- Managing Medical Devices (MHRA): <https://www.gov.uk/government/publications/managing-medical-devices>
- NICE About HealthTech Guidance: <https://www.nice.org.uk/what-nice-does/our-guidance/about-healthtech-guidance>
- Regulation of Medical Devices in the UK (MHRA): <https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk>

17.3. Investigation and Learning

- Health Services Safety Investigations Body (HSSIB): <https://www.hssib.org.uk/>
- 5 Whys: Finding the Root Cause: <https://www.ihl.org/library/tools/5-whys-finding-root-cause>
- Cause and Effect (Fishbone Diagram): <https://www.nhselect.nhs.uk/uploads/files/1/Cause%20Effect.pdf>



- Seven Steps to Patient Safety:
<https://webarchive.nationalarchives.gov.uk/20171030124342/http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/>

17.4. Safety Science and Systems Thinking

- NHS England Human Factors: <https://www.england.nhs.uk/wp-content/uploads/2013/11/nqb-hum-fact-concord.pdf>
- Yorkshire and Humber Improvement Academy – Human Factors: [Human Factors - Improvement Academy](#)
- The investigator's toolkit: SEIPS: <https://www.hssib.org.uk/news-events-blog/the-investigators-toolkit-seips/>
- WHO Patient Safety Curriculum:
http://apps.who.int/iris/bitstream/10665/44641/1/9789241501958_eng.pdf

17.5. Quality Improvement

- Quality Improvement Made Simple: [Quality improvement made simple | The Health Foundation](#)
- Q Community : <https://q.health.org.uk/>
- Healthcare Improvement Scotland:
<http://www.healthcareimprovementscotland.org/improvement.aspx>

17.6. Safety Intelligence and Databases

- Australian Database of Adverse Event Notifications (DAEN) – medical devices: [Health professional information and resources | Therapeutic Goods Administration \(TGA\)](#)
- American Manufacturer and User Facility Device Experience (MAUDE):
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>
- MHRA Public Access Registration Database (PARD): <https://pard.mhra.gov.uk/>
- ECRI Top 10 Health Technology Hazards: [ECRI Thought Leadership](#)



17.7. Networks and Collaboration

- NAMDET: <https://namdet.org/>
- Academic Health Science Networks: <https://healthinnovationmanchester.com/the-guide/the-ahsn-network/>
- Patient Safety Learning: <https://www.patientsafetylearning.org/>
- Clinical Human Factors Group: <https://chfg.org/>
- NHS Futures (Patient Safety, PSIRF, LFPSE, Patient Safety Specialists: <https://future.nhs.uk/>



18. Appendix C - Feedback

Constructive feedback regarding the Handbook is welcomed and will be taken on board by the Editorial Board for the next version.

If you would like to provide feedback on the content of the Handbook, ask a question about the Handbook or report a broken or out of date link; please submit this via email to

MDSONetwork@mhra.gov.uk.

Thank You