NHS
University Hospitals of North Midlands
NHS Trust

# Medical Equipment Strategy

## 2021 - 2025

Together Compassion Safe Improving

# Contents

# 1. Introduction

**Medical devices play a crucial role in the delivery of safe effective care for patients. With advances in technology and the increased use of medical devices, it is paramount that the safety of the patient and staff is maintained.**


**The purpose of this Medical Devices strategy is to set out a plan for the future development and management of medical devices at the University Hospitals of North Midlands NHS Trust (UHNM), in line with national standards and guidance from the CQC, MHRA and NPSA and aligned with our overarching Strategic Priorities.**

This strategy focuses on ensuring that our Medical Devices are fit for purpose as they represent a substantial investment by any NHS trust. However, reliance on medical devices introduces new risks to patients and our staff. Therefore we must ensure, through delivery of this strategy, that:

- The use of medical devices meets relevant **safety and quality standards**
- They are **fit for purpose** and represent **value for money**
- That they are **operated competently** in accordance with national regulations and guidance
- That they are **maintained** within safe working conditions
- There are **effective risk management** processes in place to respond and learn from adverse incidents
- That they promote **a digital first agenda** where the data from these devices flows into clinical systems, to **improve decision making**

# 2. Background

**The terms 'medical device' or 'medical equipment' relates to any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used in clinical care for the purpose of:**

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process

As one of the largest acute Trusts in the country, we invest heavily in our medical equipment, which directly supports the provision of health care to our patients. We currently use over 50,000 pieces of re-usable medical equipment, worth in excess of £55 million.

With such a vast inventory of medical technology, it is clear that the proper use and management of medical devices and equipment is critical to the delivery of effective and safe healthcare.

# 3. Context – where are we now?

## 3.1 The National Framework

Deficiencies in the management of medical devices can be hazardous to patients and to staff, and can result in harm to both groups. The potential risks associated with the management of medical devices have been recognised nationally by the Care Quality Commission and NHS England / Improvement and there are clear regulatory expectations in place, including:

| Regulatory Requirement | |
|---|---|
| **Care Quality Commission Regulations (12e)** | Providers must make sure that equipment is suitable for its purpose, properly maintained and used correctly and safely. This includes making sure that the staff using the equipment has received adequate training, competency and skills needed' |
| **MHRA/NHS England Patient Safety Alert 20th March 2014)** | 'Improving medical device incident reporting and learning', |
| **Medicines and Healthcare Products Regulatory Agency April 2015** | Managing Medical Devices – Guidance for healthcare and social services organisations on managing medical devices in practice, , |

## 3.2 Local Arrangements

The management of medical equipment at UHNM is overseen by a multi-disciplinary group collectively known as the 'Medical Device Strategy Committee (MDSC). The function of the Medical Devices Strategy Committee is to:

- Manage medical devices in a safe, clinically and cost effective manner
- Ensure compliance with recognised standards of clinical governance
- Support the Trust in meeting is Strategic Objectives
- Act as the Medical Devices Capital Sub Group

This multi-disciplinary approach combines the knowledge, skills and expertise from a range of services within the organisation, as illustrated below and some of the key components of this approach are described further.

### 3.2.1 Clinical Technology

**Clinical Technology provides corporate services for the management and safe use of medical equipment, providing compliance with the CQC standards and MHRA guidance referred to above. Clinical Technology provides a strong governance culture delivering assurance to satisfy any external regulation.**

This assurance is given by a combination of in-house and externally contracted service provision, this service provides specialist involvement with the specification, procurement and life-cycle management.

Clinical Technology manages more than 53,000 assets, the same processes/procedures and regulations are applied to all of these assets to make the most effective use of resource in order to provide value for money.

The numbers of Trust owned medical devices is split across both of our sites, as follows:

| Medical Equipment Assets by Site | |
|---|---|
| **County Hospital** | 8749 |
| **Royal Stoke University Hospital** | 44967 |

Clinical Technology has a highly skilled and flexible workforce which responds rapidly to changing service requirements. It comprises of six teams of specialist engineers based in clinical locations to provide fast responsive support to acute clinical areas.

Clinical Technology utilise an **Equipment Management System (EMS)** to manage and record maintenance of equipment across the Trust. All records of a repair, maintenance, acceptance testing etc. are retained as part of the Quality Records on the EMS. These details will clearly indicate if the equipment has passed final testing, the results of the tests and the condition and follow up action of any equipment that fails the test.

**Planned Preventative Maintenance (PPM)** is carried out according to manufacturer's recommendations and MHRA guidance. Equipment is serviced at the recommended intervals (usually annually). PPM will include an appropriate electrical safety check, calibration, safety advice, any parts fitted as part of the service schedule, as well as general user advice and data audit. Clinical Technology will schedule all PPMs on the departmental Equipment Management System (EMS). Clinical Technology has developed an in house performance verification procedure (PVP) which allows a standardised approach to all maintenance events. The PVP is derived from the devices service manual, regular checks are undertaken to ensure the manual and service instructions are up to date.

A **comprehensive corrective maintenance** service is also provided. Which consist of the PPM service described above and any corrective/repair activity that is required to maintain the equipment and keep it in excellent operating condition.

Clinical Technology review **Medical device alerts (MDA's), Field Safety Notices (FSN's)**, identify equipment on EMS database related to each alert and create relevant actions. We have a dedicated specialist engineer whose duty is to disseminate all incoming alerts and distribute accordingly. Where immediate action is required, this is escalated to team leaders and priority set to achieve completion as soon as practicable. Clinical Technology has a quality procedure in place to cover the Department's response to alerts.

### 3.2.2 Medical Device Safety Team

**Working within the Quality Safety & Compliance Department, the Medical Device Safety Team (MDST) comprises the MDSO (Medical Device Safety Officer), Senior Medical Device Trainer and two Medical Device Trainers.**

The team are responsible for:

- Ensuring that systems and processes are in place to disseminate and **respond to device safety notices** and to confirm that the required action is taken in response. The MDSO reviews all medical device related alerts received at UHNM and advises the CAS (Central Alerting System) Liaison Officer on appropriate actions and targeting.
- Ensuring that **adverse incidents and near misses** involving medical devices are appropriately investigated and the necessary actions taken to minimise or eliminate further risk (including external reporting to MHRA/ NHS Supply Chain etc. to ensure national learning)
- Developing and maintaining processes to ensure that **staff training** on the use of medical devices is effective, in line with UHNM policy and external regulations

### 3.2.3 Data, Security & Protection

The Trust must continue to respond to latest DSP developments, whilst still providing health care to the standard we are accustomed to. The Clinical Technology Department continue to work closely with the DSP Team and moving forward are looking to embed a DSP framework into the lifecycle of a medical device; ensuring due diligence is undertaken with our suppliers, identifying and adopting appropriate security controls during the use of the device and seeking assurance destruction/ removal of personal data is in line with national guidance when a device is retired/ removed from service.

### 3.2.4 Funding Mechanisms

Expenditure falls into two categories, Capital and Revenue. The vast majority of medical devices fall within the definition of ‘Capital’, that is purchase of assets with a life of greater than 12 months and a value in excess of £5,000 (including VAT where applicable). Groups of assets individually under £5,000 may also be grouped to form a single asset over £5,000 where they are co-dependent and meet the capital definition. All other items of smaller value or of a disposable nature are classified as ‘Revenue’.

Revenue items are funded through departmental budgets agreed with Divisions prior to the start of each financial year and divisions will need to make appropriate cases to increase spending beyond historic levels adjusted for inflation as part of the planning process.

# Where do we want to get to?

**In developing and consulting upon this strategy we have identified our Strategic Aim and Objectives for the development of medical equipment management in the medium term (5 years). Our Aim and Objectives have been designed to support our overarching Trust Strategic Priorities and below we illustrate how these align.**

## STRATEGIC AIM

**"To provide safe, high quality care for our patients, supported by the competent and efficient use of the latest medical equipment and technology."**

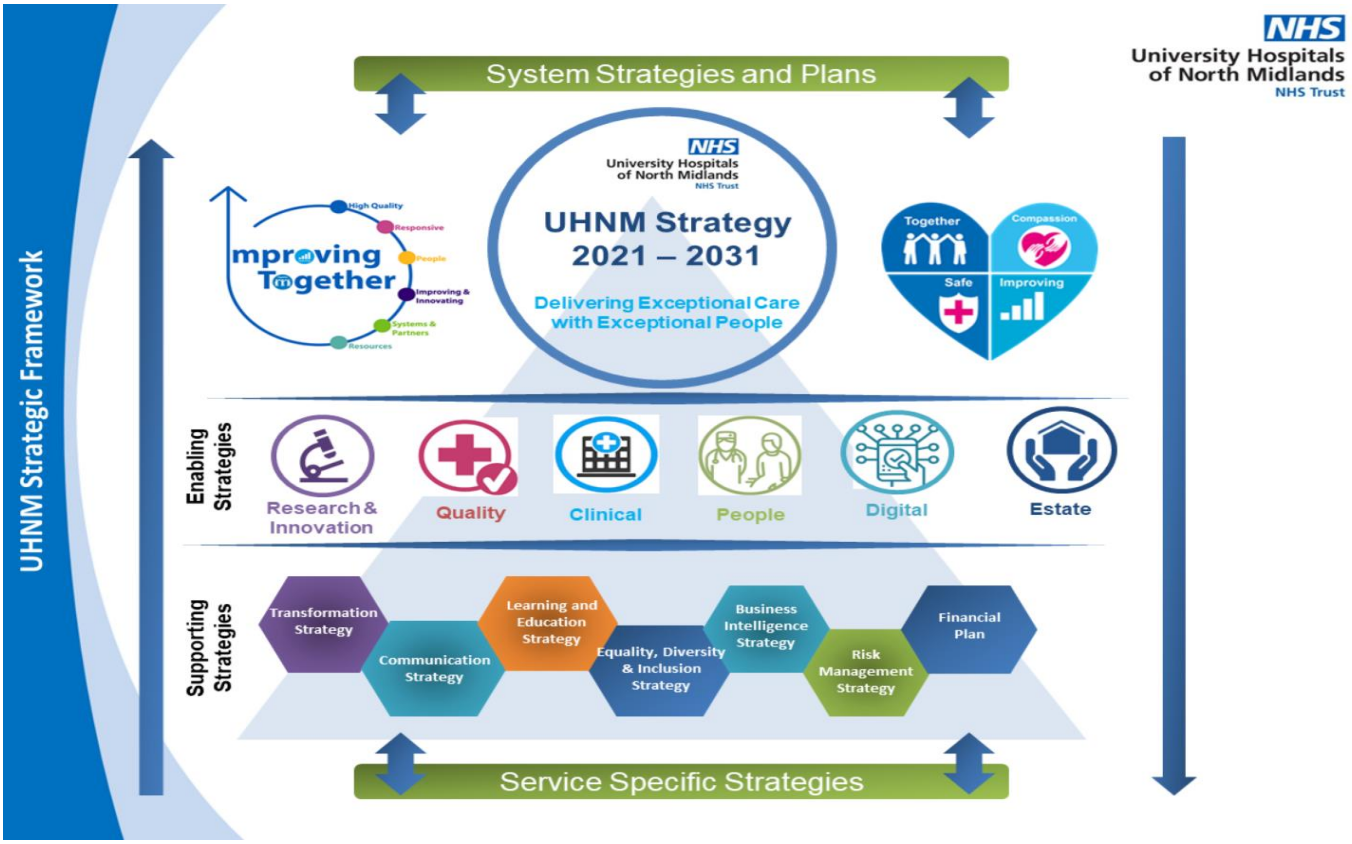
| No. | Medical Equipment Strategic Objective | Alignment with Strategic Priorities | |
|---|---|---|---|
| 1. | Enhanced quality of care for patients through use of the latest medical technology available | Quality | ● |
| | | Responsive | |
| | | People | |
| | | Improving | ● |
| | | System | |
| | | Resources | ● |
| 2. | Ensuring value for money and efficient use of our technological resources | Quality | ● |
| | | Responsive | ● |
| | | People | ● |
| | | Improving | |
| | | System | |
| | | Resources | ● |
| 3. | Supporting our staff in the safe and competent use of medical equipment | Quality | ● |
| | | Responsive | |
| | | People | ● |
| | | Improving | ● |
| | | System | |
| | | Resources | ● |


# 4. How we will get there?

| No. | Medical Equipment Strategic Objective | Work streams to Enable Delivery | |
|---|---|---|---|
| 1. | **Enhanced quality of care for patients through use of the latest medical technology available** | 1.1 | Robust engagement with Divisions for procurement planning and horizon scanning. Identification of equipment that presents a risk due its age profile or where technological advances have been significant and the device is no longer fit for purpose. |
| | | 1.2 | Maximise functionality of technology in medical equipment and maximise extraction of information in real time, utilising this information to support informed decision making in other systems e.g. iPortal. |
| | | 1.3 | Ensure we are maximising our medical devices to their full technical potential. |
| 2. | **Ensuring value for money and efficient use of our technological resources** | 2.1 | Maximising capital options across 5 year cycles for focussed equipment replacement |
| | | 2.2 | Robust equipment evaluation processes. Including cyber security and system interoperability, additionally infrastructure and dependent systems will also require consideration. |
| | | 2.3 | Co-ordinated approach to managing major equipment supply disruption |
| | | 2.4 | Ensure medical device inventory is fully functional, downtime of essential equipment is minimised. |
| 3. | **Supporting our staff in the safe and competent use of medical equipment** | 3.1 | Ensure appropriate training is made available for all devices requiring formal training records as per policy MDM02 |
| | | 3.2 | Ensure all medical device adverse incidents are reviewed by a multidisciplinary group as per MHRA/NHSE guidance |
| | | 3.3 | Ensure all medical device related alerts received at UHNM are targeted and actioned appropriately |

# 5. Alignment to our Trust Strategy

**The UHNM Strategic Framework is set out below. The Medical Equipment Strategy is a 'Service Specific Strategy' which supports the delivery of a number of key Enabling Strategies, in particular the Quality Strategy, Clinical Strategy and the Digital Strategy.**




# 6. How we have developed this strategy

**This strategy has been developed at the request of the Medical Director on behalf of the Executive Infrastructure Group.**

A number of key stakeholders have contributed to its development, including representatives of those services involved in the Medical Devices Strategy Group, along with input from clinical divisions.

Executive approval of the strategy is the responsibility of the Executive Infrastructure Group which is accountable to the Performance and Finance Committee (PAF).

# 7. How we will measure our success

Metrics / KPI's / benchmarking that will be used to measure progress against the objectives

| No. | Medical Equipment Strategic Objective | Work streams to Enable Delivery | | Key Performance Indicators |
|---|---|---|---|---|
| 1. | **Enhanced quality of care for patients through use of the latest medical technology available** | 1.1 | Robust engagement with Divisions for procurement planning and horizon scanning. Identification of equipment that presents a risk due its age profile or where technological advances have been significant and the device is no longer fit for purpose. | Clinical Technology to meet annually with divisions to discuss and align 5-10 capital plans.<br><br>This will subsequently produce an annual highlight report. |
| | | 1.2 | Maximise functionality of technology in medical equipment and maximise extraction of information in real time. | Health informatics group agenda item. |
| | | 1.3 | Ensure we are maximising our medical devices to their full technical potential. | MDSC agenda item. |
| 2. | **Ensuring value for money and efficient use of our technological resources** | 2.1 | Maximising capital options across 5 year cycles for focussed equipment replacement. | Agenda item for Business intelligence group and Finance Committee. |
| | | 2.2 | Robust equipment evaluation processes. | Agreed process via MDSC. |
| | | 2.3 | Co-ordinated approach to managing major equipment supply disruption. | Operations group chaired by MDSC Chair and directly reporting to Executive Lead. |
| | | 2.4 | Ensure medical device inventory is fully functional, downtime of essential equipment is minimised. | Clinical Technology to provide report on PPM compliance. |
| 3. | **Supporting our staff in the safe and competent use of medical equipment** | 3.1 | Ensure appropriate training is made available for all devices requiring formal training records as per policy MDM02. | Senior Medical Device trainer to provide reports to MDSC on training provision. |
| | | 3.2 | Ensure all medical device adverse incidents are reviewed by a multidisciplinary group as per MHRA/NHSE guidance. | MDSC meeting record of Datix incident review. |
| | | 3.3 | Ensure all medical device related alerts received at UHNM are targeted and appropriately managed. | Head of Quality Safety & Compliance CAS report to Patient Safety Group. |

# 8. How we will monitor our progress

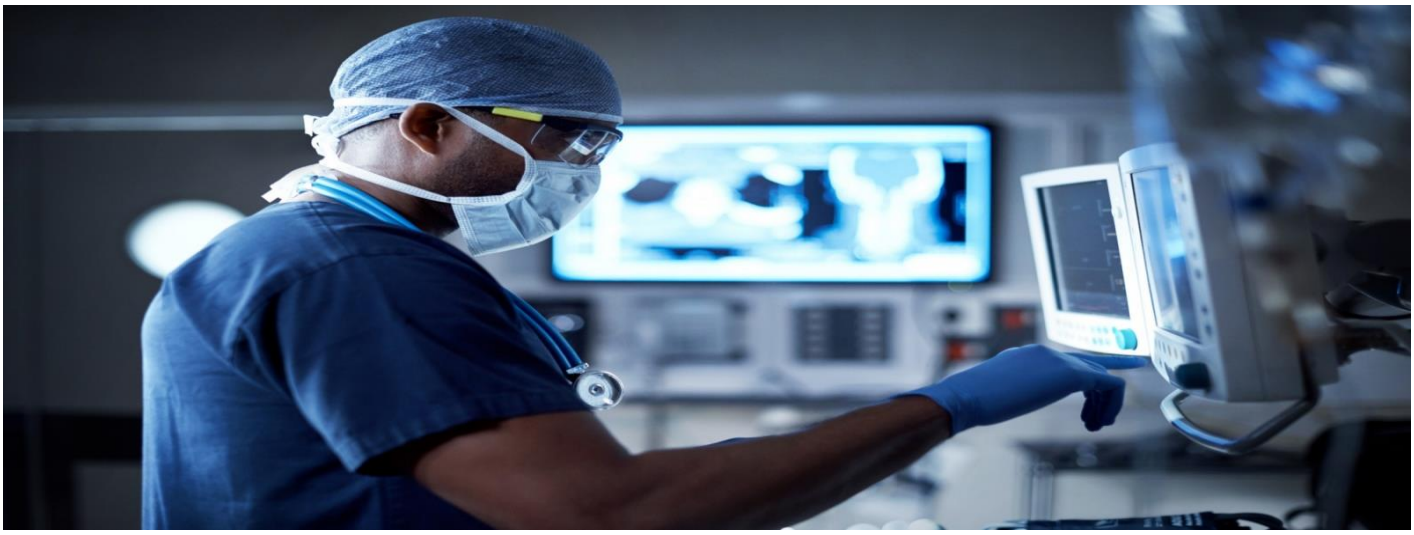
Progress against the delivery of this Strategy will be monitored through a number of mechanisms:

- Strategic progress reports based on the Key Performance Indicators agreed.
- Adverse Incident Reporting.
- Feedback from our patients and service users.
- Risk management and action planning.
- Capital expenditure reports.
- Regulatory inspection reports.

The Executive Infrastructure Group will receive quarterly reports on progress against the delivery of this strategy, which will be reported by exception to the Performance and Finance Committee.

# 9. How we will communicate this strategy

This strategy will be communicated with all key stakeholders via email dissemination, once approved by the Executive Infrastructure Group. It will be made available to staff via the Trust Intranet and will be highlighted through corporate communications, supported by the Communications Department.



# Appendix 1: Plan on a Page

# Appendix 2: Strategic Delivery Plan

| No. | Strategic Objective | Action Required | Intended Benefit | Measure of Success | Delivery Date | Lead | Progress Report | BRAG |
|---|---|---|---|---|---|---|---|---|
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