Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

# Medical Equipment Policy

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| P100 | Medical Device Liaison Officer and Head of Risk and Compliance | Quality and Safety Committee | 3 years |

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## Contents

## 1. Introduction

The safe management of the use of medical devices is an essential requirement to ensure the safety of both service users and staff. The Trust is committed to effective medical device management and this policy document is based upon the requirements of the Medicines and Healthcare Products Regulatory Agency (MHRA).

This policy aims to ensure that recommended safety standards and legislation is adhered to in the use of medical devices and that it is the Trust's intention to adopt best practice standards in the management of medical devices.

Only medical equipment recommended and approved for use in healthcare settings may be used.

## 2. Purpose or aim

The Trusts owns and relies upon a range of medical equipment in order to carry out its function of service user care.

The policy describes the Trust's approach to the procurement, acceptance, commissioning, deployment and use of medical equipment as well as the arrangements for maintenance, repair and disposal.

The policy also addresses training issues in relation to medical equipment.

Decontamination of medical equipment is covered more thoroughly by the Trust's infection control policies.

## 3. Scope

For the purposes of this policy, the term 'medical device' encompasses medical devices as legally defined in the Medical Devices Regulations.

This policy applies to medical equipment which is either owned by the Trust or used in connection with patients who are being managed by the Trust.

The policy also applies to devices on loan or trial. The policy is applicable to all staff.

## 4. Definitions

### 4.1 Medical Devices

Medical devices are defined by the Medical Device Regulations. The Regulations define a medical device as any item that is placed on the market for medical use and covers all products, except medicines, used in healthcare for the diagnosis, prevention, monitoring, treatment or alleviation of illness or disability.

They include items from simple aids such as crutches to specialist equipment, such as ECT equipment. Disposable and consumable items such as continence aids are included as well as longer lasting items such as hospital beds and wheelchairs.

Due to the nature of mental health services, comparatively small ranges of medical equipment are used.

For the purpose of this policy, the terms medical device and medical equipment are inter-changeable.

# 5. Procedures

## 5.1 Evaluation and Selection of New or Replacement Medical Equipment.

New or replacement equipment will be selected and evaluated in accordance with the Procedure for Selection for New or Replacement Medical Equipment

## 5.2 Purchasing of New or Replacement Medical Equipment.

New or replacement equipment will be purchased in accordance with the Procedure for Purchasing for New or Replacement Equipment

## 5.3 Acquiring Medical Equipment by Other Means

On occasion it may be necessary to acquire equipment other than through a purchase. For example, equipment may be hired or loaned from a manufacturer

The same considerations apply to acquiring equipment as to those for evaluating and purchasing equipment.

## 5.4 Borrowing and Loaning of Medical Equipment

This is covered by the Procedure for the Borrowing and Loaning of Medical Equipment

## 5.5 Accepting Equipment into Use

This is covered by the Procedure for Accepting Equipment into Use

## 5.6 Instructions for Use

This is covered by the Procedure for Availability of Equipment Instructions for Use.

This is covered by the Procedure for Availability of Equipment Instructions for Use.

## 5.7 Maintenance and Repair of Medical Equipment

This is covered by the Procedure for the Maintenance and Repair of Medical Equipment.

## 5.8 Decontamination of Medical Equipment

This is covered by the Procedure for Decontaminating Medical Equipment.

## 5.9 Decommissioning and Disposal of Medical Equipment

This is covered by the Procedure for the Decommissioning and Disposal of Medical Equipment.

# 6. Safety and Incidents Involving Medical Devices

The safety of patients and staff is paramount at all times. It is the responsibility of all professional users to ensure that medical equipment is used in such a manner that the patient, visitors or any other person is not put at risk.

Before a new piece of medical equipment is commissioned, the manager responsible for the equipment should undertake a risk assessment to ensure that any possible hazards arising from the use of the equipment are identified and appropriate precautions undertaken.

On occasions, incidents involving the use of medical devices will occur. These will require reporting in accordance with the Incident Policy and may need to be reported to the MHRA.

## 7. Safety Alerts

The MHRA issue hazard and safety notices to Trusts as a result of reported incidents via an electronic system known as the Central Alerting System (CAS).

The Trust has a separate Managing Safety Alerts and Other Safety Communications Policy, and staff should refer to that policy to understand how to action and respond to such safety alerts.

## 8. Prescribing of Medical Equipment

Any professional user who prescribes medical equipment for use by a patient must be qualified to do so. Non-qualified staff who issue equipment must have the necessary written authority from a professional user before releasing the equipment or have been deemed competent to release it themselves.

Managers must ensure that medical equipment is not issued to patients or carers without the issue of the appropriate instructions and training and having ensured that facilities for maintenance and repair have been clarified.

## 9. Roles and responsibilities

### 9.1 Chief Executive

The Chief Executive has overall accountability for having effective medical device management systems and internal controls in place and for meeting statutory requirements.

### 9.2 Director of Nursing and Quality

The Director of Nursing and Quality is the executive director for medical device management. He is responsible for ensuring the Trust's overall duty for medical device management is discharged appropriately and has lead executive responsibility for all policy and guidance issues

### 9.3 Medical Device Safety Officer

The Medical Device Safety Officer has responsibility for supporting operational services in putting in place effective measures to manage medical devices, give clinical advice on safety alerts and the asset register. She will provide specialist advice in relation to medical devices, including training. The Medical Device Safety Officer will be the Trust's contact with the Medicines Healthcare Regulatory Agency (MHRA). She also oversees the f2 asset register of medical devices at a Trustwide level with admin support.

### 9.4 Head of Nursing

The Head of Nursing has responsibility for providing professional lead nursing advice in relation to medical devices across all services. She is the Trust's lead for resuscitation, infection control, decontamination and physical health monitoring and will work closely with the Medical Device Safety Officer to ensure that any medical equipment decisions are informed by best clinical practice.

### 9.5 Head of Procurement and Contracts

The Head of Procurement and Contracts is responsible for negotiating competitive purchasing arrangements for new equipment and their ongoing support and maintenance and for ensuring appropriate controls are in place to prevent the purchase of non validated equipment, acting in accordance with the Trust's Standing Financial Instructions and Standing Orders (SFI/SOs).

This person is also responsible for ensuring that suitable Service Level Agreements or alternative arrangements are in place from a specialist medical equipment service.

### 9.6 IT Systems Manager

The IT Systems Manager has responsibility for ensuring that technical support is available for the f2 asset management system so that it can be used effectively by the end users.

### 9.7 LDU/SDU Directors and Heads of Quality

Local and specialist Delivery unit Directors and Heads of Quality are responsible for ensuring that there is nominated staff responsible for equipment management to cover all clinical settings. These individuals will be known as “Equipment Leads” for the purposes of this work. A list of the duties of the equipment lead is included as Appendix 1.

### 9.8 Ward/Department Managers

The managerial ownership of an item of medical equipment lies with the relevant Ward or Department Manager who may chose to assume the role of Equipment Lead or delegate that responsibility to another individual. The Equipment Lead is responsible for ensuring that all medical equipment is maintained and used in a safe manner, for maintaining an inventory of equipment relating to their area of responsibility, and for helping to identify and address training needs. They will obtain professional advice on the ownership and use of their equipment via the Service Level Agreements or through third party arrangements. Together with the ward or department manager, they are responsible for maintaining their lists of equipment on the f2 management system and keeping instruction manuals and any other relevant documentation in a readily accessible place for staff use. Ideally the role of equipment lead would be allocated to a clinician but tasks can be delegated to an administrator. Appendix 1 defines the roles as clinical or admin.

### 9.9 All staff

The Trust requires that all staff are competent and confident in the use of any medical equipment that they are required to use.

### 9.10 Management Group oversight

The Trusts Infection Control and Physical Healthcare Monitoring Group has lead responsibility for medical devices, reporting through the Safety Management Group. It will set objectives for medical device management as part of its work plan and will monitor compliance with medical device standards.

## 10. Training

Most professional clinical staff will need to use medical equipment. Many episodes of patient treatment or diagnosis depend upon the correct use of such equipment. With the exception of sophisticated medical equipment such as ECT or resuscitation equipment, it is likely that the majority of training in the use of medical devices will happen on-the-job, through an experienced competent operator training other staff.

Managers should review the training needs of their staff when a new item of equipment is delivered, or when a new member of staff commences duty. If the item is unfamiliar to any member of staff then training/instruction must be provided for that member of staff and a record kept. Until such time as the training has been completed, the member of staff must use the equipment under supervision only.

No member of staff may operate any piece of equipment unless they and their immediate supervisor are confident that they are completely competent in its use.

Where medical equipment is passed onto a patient or carer, Managers will ensure that this end user has all the training necessary to ensure a level of safety and operation similar to that which would be expected in a healthcare setting.

All staff are orientated to the medical devices used in their workplace at induction and their manager completes and signs an induction checklist sheet to evidence that this is done. Any ongoing issues regarding the safe use of medical devices will be addressed through staff supervision.

The Medical Device Safety Officer will provide support and training to equipment leads, as required in the safe management of medical devices.

A competency skills framework covering medical devices is in place for staff to access with attendance recorded on MLE.

## 11. Standards

The Trust will follow the (MHRA) Medicines and Healthcare Products Regulatory Agency's guidance Managing Medical Devices. Guidance for healthcare and social services organisations (April 2015)

The Trust will adhere to the Care Quality Commission (Registration) Regulations 2009 (Part 4) and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 specifically:

- Regulation 12: Safe care and treatment
- Regulation 15: Premises and equipment

## 12. Monitoring and audit

The Trust will assess the efficacy of its medical device management arrangements through the following mechanisms:

- A review of medical device incidents
- A programme of medical device audits
- An Annual Assurance Report
- Feedback from Care Quality Commission (CQC) inspections
- Reports generated from the F2 asset management system.

# 13. Appendices

## 13.1 Appendix 1 – Defining Role of Equipment Leads as Clinical or Admin

| **Objectives** | **Clinical role** | **Admin Role** |
|---|---|---|
| Ensure that Medical equipment is fit for purpose and meets MHRA standards | To have knowledge and clinical experience with appropriate training of use of equipment.<br><br>Acquire new equipment in an informed way, following trust policy.<br><br>Liaise with Medical Device Safety Officer (MDSO) /SLA Provider/ Nurse directorate regarding preferred models / standards etc. | Ordering of new equipment after consultation / instructions from clinical staff<br><br>Arrange for acceptance testing with the SLA Provider on acquisition.<br><br>Ensure that instructions are available for each piece of equipment<br><br>Maintain a log book or equipment inventory system (F2)for medical devices |
| Enable staff to use medical devices safely and interpret results | Attend training events and cascade information to staff in your place of work | Keep and maintain a training record. Keep competency statements for all staff |
| Ensure that systems are in place to prevent cross infection and that decontamination of reusable equipment happens between patient use. | Establish decontamination regimes in your area based on the guidance by MHRA, local strategy and manufacturer's instructions and cascade information to relevant staff. | Ordering and maintaining stock of relevant stores e.g. detergent wipes to enable decontamination to take place |
| Maintenance and servicing of equipment | Check that all medical equipment complies with the servicing and maintenance regimes.<br><br>Report any breakdowns. Ensure decontamination and labelling of equipment before sending for repair. (this can be delegated within clinical team members)<br><br>Ensure there is a clear procedure in your place of work for staff to follow in the event of a breakdown or routine maintenance. | Arrange for routine maintenance to take place by the SLA Provider/ other provider and keep a log. |
| Report any adverse incidents regarding medical devices | Reporting is a clinical role as technical knowledge may be required, i.e. filling in adverse incident form or making decision when to report. The role of | Inform MDSO of incident by copying into email. |

| **Objectives** | **Clinical role** | **Admin Role** |
|---|---|---|
| | equipment lead would be to ensure that staff are aware of the responsibility to report adverse incidents and how to report them.<br><br>Also ensure staff are aware of the procedure to follow i.e. quarantine / decontaminate device | Information should be available for staff to follow in the event of an adverse incident involving a medical device. |
| Safety Alerts | Respond to alert by taking appropriate action if it applies to your place of work delegate feed back instructions to admin staff | Receive alert via email system and consult with clinicians.<br><br>Feed back response taken / required by email to LDU Directors.<br><br>Display relevant posters safety warnings issued by MHRA |
| Dispose of redundant equipment Appropriately | Ensure that staff are aware of the need to decontaminate, make safe and erase confidential data as necessary. Liaise with the SLA provider / MHRA regarding methods of disposal.<br><br>Arrange safe storage prior to disposal | Arrange for collection of equipment |
| Know what medical devices exist within place of work | Check that departments have minimum equipment recommended | Keep up to date log of equipment |
| Ensure appropriate and safe use of single-use / single-patient use items | Arrange for systems to be in place to make sure that stock is available and stock rotation so that there is never a need to reuse single use devices. | Ordering of stock, liaising with clinicians regarding stock levels |

## Version History

| Version | Date | Revision description | Editor | Status |
|---|---|---|---|---|
| 1.0 | 31 Dec 2005 | Approved – 31/12/2005 | LDH | Approved |
| 2.0 | 28 Feb 2008 | Revised to take account feedback from Safety Forum. Approved at Integrated Governance Committee 28/02/2008 | LDH | Approved |
| 3.0 | 10 Jan 2012 | Minor amendments by Quality and Healthcare Governance 10/01/2012 | LDH | Approved |
| 3.1 | 1 August 2015 | Reviewed and updated | AS | Draft |
| 3.2 | 15 December 2015 | Presented to Quality and Standards Committee for approval | HD | Draft |
| 4.0 | 15 December 2015 | Approved by Quality and Standards Committee | HD | Approved |
| 4.1 | 3 September 2019 | Extended until March 2020 | Nursing Director | Approved |