

Title:	Medical Devices Policy		
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Ownership:	Dr Cathy Jack, Medical Director		
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Date	Version	Author	Comments
21/03/2008	1	K Brookes	N/A
18/11/2009	2	K Brookes / R Henry	Policy updated from Version 1.0, after review of Policy by Medical Devices Management Committee. Changes to the Policy included the update of Section 3.0, 5.2, 6.1, 7.0, 8.1 and 8.2. A new Section was added under Section 13.0, titled 'Use of Medical Devices'.
11/07/2011	3	R Henry	Policy updated from Version 2.0. Changes to the Policy included the update of Sections 4.0, 7.0, 8.1, 8.2, 9.0, 10.0, 11.0, 12.0, 15.0, 16.0 & Appendix 2.
02/01/2014	4	E Doherty	Addition of guidance on dealing with Medical Devices company representatives. Updating of references, minor corrections of text content and formatting. Transfer to Trust Policies Template v2
01/02/2017	5	[REDACTED]	Revised terms of reference Clarification of Asset and capital asset registration Revised indemnity Arrangements for equipment on loan Links & references updated

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

Medical Devices are an integral part of the diagnosis, treatment, support and care of patients in acute and community settings. As part of an overall strategy for risk management the Trust has an obligation to make certain that it minimises the risks of using medical devices to as low a level as practicable by ensuring that it buys the most appropriate equipment for purpose, trains staff how to use it competently and safely, correctly decontaminates it, maintains it correctly, and disposes of it in an appropriate manner

1.2 Purpose

The Trust recognises the risks to patients, staff and others created by the use of medical devices. It therefore intends to ensure that there is a suitable operational system in place to manage the procurement, usage, traceability, maintenance and disposal of medical equipment, to meet the requirements of national legislation and NHS guidance and to make sure that equipment is used safely, competently and effectively for the care of patients.

1.3 Objectives

The Belfast Health and Social Care Trust will:

- Establish and maintain a register of medical devices within the Trust.
- Establish a system for identifying the risks associated with the procurement, use and disposal of medical devices within the Trust.
- Identify and support Department Equipment Controllers (DECs) who will be responsible for the Medical Devices within a designated area or department.
- Establish a system to ensure compliance of the Trust with all external standards.
- Establish suitable training programmes for staff to ensure competence in using medical devices.
- Establish a re-certification programme, where appropriate, to ensure continued competence in using medical devices.
- Establish a system for reporting incidents, disseminating information and learning concerning the use of medical devices.
- Standardise where possible the equipment in use across the Trust

2.0 SCOPE OF THE POLICY

This policy applies to all Belfast HSCT staff involved with the management of medical devices including choosing, using, servicing, decontaminating and disposing of medical devices

3.0 ROLES/RESPONSIBILITIES

3.1 Corporate Responsibility

The Chief Executive, on behalf of the Trust Board, carries overall responsibility for Risk Management, including the effective use of medical devices within the Belfast Trust.

Executive responsibility for the specific management of medical devices is delegated to the Medical Director. The Medical Director has been designated to direct the compliance of the Trust with external standards set for control of procurement, usage, maintenance and disposal of medical equipment.

The Chair of the Medical Devices Advisory Committee has been delegated to the Co-Director Redevelopment. It is the responsibility of the Chair to ensure that the Directorates have systems that will allow staff to purchase, use, maintain and dispose of equipment competently and safely. The Chair is also responsible for ensuring that Directorates have in place, appropriate training, guidance and information. The Chair is responsible for establishing a suitable monitoring framework to assure Trust Board that these arrangements are effective.

The Senior Manager Corporate Governance Services has been designated as the MDLO (Medical Devices Liaison Officer) for the Trust and is responsible for monitoring incidents involving medical devices, forwarding appropriate reports to NIAIC, distributing guidance and safety alerts to the relevant managers and ensuring they are actioned appropriately.

3.2 Medical Device Advisory Committee

The Medical Devices Advisory Committee is responsible for implementing the terms of reference listed in **Appendix 2**. The Advisory Committee will provide a bi-annual report to the Assurance group and will submit an annual report to Trust Board.

Operational Responsibility

3.3 Service Managers & Department Equipment Controllers (DECs)

It is the responsibility of all service managers & DECs to ensure that:

- All staff are suitably trained and deemed competent to use equipment
- Relevant training on use / handling / processing of medical devices is documented appropriately
- They assess the suitability of new equipment and seek advice from the appropriate departments prior to procurement (as detailed within the Trust Medical Devices Procedures & Guidelines document).
- Appropriate commissioning and acceptance testing is carried out on receipt of equipment.
- There are manufacturer's instructions held on file and accessible to staff, which should be reviewed to ensure they comply with Trust policies and procedures. Where these instructions are revised and updated the new versions are also made available to staff
- prescribing of medical devices is performed by staff with appropriate professional qualifications and suitable experience

- Equipment is registered on the Trust's Medical Devices Inventory system. This should include any updates regarding equipment that has been removed from service or transferred to another location or cost centre.
- There is a record of Equipment that is on-loan to other departments, hospitals and patient / clients.
- They undertake the mandatory *Medical Devices for Managers & DEC's* training
- All equipment can be appropriately decontaminated in accordance with the manufacturer's instructions.
- Equipment is adequately stored and maintained as per manufacturer's instructions. (Service maintenance contracts must be set up if required).
- Medical Devices are decontaminated as appropriate prior to any repair, service or investigation and that this is documented.
- Equipment is disposed of in the appropriate manner.
- All incidents involving medical devices are reported as per the Trust Incident Reporting system, and if necessary NIAIC are also notified.
- Safety alerts and bulletins are brought to the attention of staff in their area and appropriately actioned.

3.4 Staff

It is the responsibility of Trust staff to ensure that:

- they only use medical devices if they have received appropriate training and are competent and authorised to do so
- they follow procedures and protocols regarding the management and use of equipment
- they report any defects, faults or near misses with equipment immediately, clearly label defective devices and ensure they are taken out of use
- they immediately report any untoward incidents via the Trust incident reporting system, identify the medical device involved, record type and model and serial number(s) of the equipment

4.0 KEY POLICY PRINCIPLES

4.1. Medical Device Procurement

The procurement and purchase of medical devices will follow the guidance provided by the NHS Purchasing and Supplies contract.

Before proceeding to purchase any medical device the User must:

- Identify the need for the equipment
- Consider standardisation and rationalisation with devices already in use
- Ensure that the procurement process takes account of the needs and preferences of all interested parties including those involved in use, commissioning, decontamination, maintenance, delivery, collection and decommissioning
- Consider whole life costs during the procurement stage, including installation, training, consumables, servicing and disposal costs.
- Include Regional Supplies in all procurement processes to ensure that the Trust conforms with relevant legislation
- Ensure compatibility with existing systems

- Undertake a risk assessment(s) in the use and management of the device as appropriate

Trust staff should ensure that they exercise good judgement when dealing with representatives of Medical Devices Suppliers

Further guidance is available in the Trust *Medical Devices Procedures & Guidelines*, DB2006 (05) *Managing Medical Devices*, and the *ABHI CODE OF BUSINESS PRACTICE Guidelines on Interactions with Healthcare Professionals*

4.2. Maintenance and Repair

The manager or DEC in each service area shall ensure (where appropriate) that there is a suitable maintenance programme for equipment in place. Any non compliance should be identified to the appropriate manager for immediate action.

The service areas are responsible for ensuring revenue is identified for maintenance, repair and testing of equipment.

Managers and staff will ensure that when equipment requires maintenance and repair it is clean, safe and labelled in accordance with the guidance in the Trust *Medical Devices Procedures & Guidelines* and accompanied with a Decontamination Status Certificate. If a medical device cannot be cleaned or disinfected properly, this must be clearly indicated on the equipment and accompanying Decontamination Status Certificate. Engineers / technical staff must take appropriate precautions when undertaking repairs.

Manufacturers' guidance should be followed when disposing of equipment in addition to the directions outlined in the Trust *Medical Devices Procedures & Guidelines*. If no clear guidance is given then managers should contact the manufacturer or Infection Prevention Control for advice.

4.3. Equipment Loans

There are three main variations of loans in the use of medical devices:

- Inter-hospital loan
- Manufacturer loaned equipment
- Trust equipment loaned to patients

4.3.1. Inter-Hospital Loans and Manufacturer Loans

When loaning or borrowing equipment external to the Trust, Managers should ensure local protocols are followed, which include:

- Completion of indemnity agreement form (*Overarching Master Indemnity*) and Equipment loan form (*MIA Call Off Agreement*)
- Initial acceptance checking of loaned equipment
- Provision of manufacturer's instructions.
- Periodic checking of loaned equipment for functionality and safety and repair in accordance with manufacturer's instructions, whether by the hospital, owner/manufacturer or a third party.
- Clear definition of responsibilities for the maintenance, repair and regular safety checks of loaned equipment (including identifying the person(s) responsible for

initiating the testing of the equipment and those responsible for performing the testing).

- Adequate instructions regarding decontamination/sterilization of re-usable equipment and availability of appropriate equipment/facilities to carry out reprocessing.
- Provide any relevant traceability information if necessary
- A protocol by which the service area can identify medical devices on loan and ensure appropriate withdrawal or return of unwanted or obsolete loaned equipment.

See Trust Medical Devices Procedures & Guidelines for further details (§3.8)

4.3.2. Medical Device on Loan to Patient (& Carer)

Departments issuing patients (& carers) with devices for use both within the Trust and outside should ensure:

- Relevant details of the device are recorded against the patient to ensure traceability and retrieval
- Patients (& carers) are trained in the safe and effective use of the medical devices
- Instructions given to patients (& carers) are vetted for suitability by the prescribing professional, in consultation with the supplier if required.
- Patients are made aware of the administrative and technical support and relevant contact numbers (This should include out-of-hours support if necessary).
- Medical devices are collected after use by the service area or collection is organised through the commercial owner if required
- The professional advises carers/ patients of procedures to be followed if there is an equipment malfunction and any maintenance required.

See Trust Medical Devices Procedures & Guidelines for further details (§3.9)

4.4. Medical Device Inventory

A live equipment inventory is essential for ensuring effective and safe medical device management. Service areas are responsible for the management of all equipment inventories. The inventory must be up-to-date and contain make, model and asset number of all medical devices and equipment. The inventory should also reflect devices acquired via loan or lease and devices that have been loaned to other departments, hospitals or patients /clients. The Trust is committed to developing and maintaining a computerised database that will hold records including service and maintenance information of all devices. NB this requirement is in addition to capital asset registration for equipment valued at over £5000.

It is the responsibility of the Service manager / Department Equipment Controller to ensure that the Trust asset register inventory, and their own local inventory is up-to-date and reviewed on a regular basis.

4.5. Training

Each service area must ensure that medical device management is included in their local induction programme. Before using equipment staff / patients / clients must be

appropriately trained and deemed competent. Training may be provided in-house by staff who are deemed competent or via specialist training (via Trust / external providers). A full training record, including any updates, must be maintained. Recertification may be required for some medical devices to ensure continued competence.

See Trust Medical Devices Procedures & Guidelines for further information.

4.6. Incident Reporting

If an incident occurs with a patient, member of staff, contractor or member of the public, which involves a medical device, it is the responsibility of staff to report the event in line with the Trust Incident Reporting Policy. The person reporting the incident should record details of the equipment involved, including manufacturer, model, batch / serial number, date of manufacture etc and retain the equipment (if appropriate) in a secure environment until further notice. If the device cannot be moved, a notice should be placed on it warning against use.

If there is an ongoing issue with a medical device or if the incident is serious then the incident should also be reported to NIAIC. The Medical Devices Co-ordinator / Manager / Senior Manager Corporate Governance and applicable Governance lead should be copied into any such incident-related correspondence.

All equipment, including disposable equipment (e.g., IV lines, pump cartridges) should be retained if it is associated with a serious incident such as a death, even if it does not appear to be directly involved. This equipment must be retained and not disposed of. Release of this equipment to a third party must be authorized by the Medical Devices Team in Corporate Governance.

4.7. In-House Medical Device Manufacture

Medical Devices which are made by the Trust must be manufactured either in compliance with the Medical Devices Regulations, or in line with the spirit of the regulations, as stated in MDA/2010/001

4.8. Use of Medical devices

The Medical Devices Advisory Committee will agree and review, on a regular basis, the key performance indicators endorsed by the Trust Assurance Group. In addition the Medical Devices Advisory Committee will produce an annual report to the Assurance Committee via the Assurance Group, which may include identified areas of risk, for the Corporate risk register.

4.9. Performance Management

All staff involved in the use of medical devices must be aware of the risks associated with them, and where possible **avoid**:

- the off-label use of medical devices (i.e. used for a purpose other than that intended by the manufacturer)
- the modification of medical devices (unless such modifications are sanctioned in the manufacturer's instructions for use)
- the use of non-medical products for clinical purposes

Where a healthcare professional judges that there is no alternative to off-label use or modification of an existing medical or non-medical device they should:

- Consider the ethical and legal implications
- carry out and document a full risk assessment
- ensure the patient is fully informed through the consent period and the situation is documented in the patient's notes

See MDA/2010/001 for further guidance

“Devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient” (Medical Devices Directive 93/42/EEC)

The Medical Devices Advisory Committee will agree and review, on a regular basis, the key performance indicators endorsed by the Trust Assurance Group. In addition the Medical Devices Advisory Committee will produce an annual report to the Assurance Committee via the Assurance Group, which may include identified areas of risk, for the Corporate risk register.

4.10. Financial Implications

Completion of the medical devices inventory may identify the need for additional equipment or specialist training. However it is anticipated that this will be financed through the normal departmental budget. Where there is a gap in the equipment or training needs across a larger section of the Trust the service area / Directorate will be responsible for collating a bid for additional funding. Managers must include total whole life cycle costs when bidding for any medical devices which will include the cost of installation, training, maintenance, disposal and any associated consumable items.

If a new piece of equipment or a new Medical Device is purchased as a replacement, in most cases the associated service-maintenance costs will be to be transferred over. If the new equipment either has a significantly higher service-maintenance cost or is in addition to existing levels, the Service area / Directorate will need to identify additional funding for Estates to support the ongoing service-maintenance of this equipment.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

This policy is relevant to all staff involved with the use and management of medical devices and has previously been disseminated through *Medical Devices Awareness* and *Medical Devices for Managers & DEC*s training sessions, Trust intranet news pages, Corporate Governance newsletters and via MDAC members to their relevant staff groups

5.2 Resources

The *Medical Devices Awareness* and *Medical Devices for Managers & DEC*s training sessions are mandatory training required for all staff using medical devices and equipment, and this policy does not have any extra training requirements.

Any additional resource implications for implementation at a local level will be in line with safe use and management of the equipment, and should be considered as part of the whole-life costs prior to acquisition of the equipment

5.3 Exceptions

No areas or services using medical devices or medical equipment have been identified as being exempt from the requirements of this policy or the Medical Devices Procedures & Guidelines

6.0 MONITORING

Monitoring of compliance to the policy is undertaken by the Medical devices Advisory committee and tools used include the Controls Assurance Standard on Medical Devices Management and KPIs (key Performance Indicators) for medical devices management training provided, incidents reported and safety alerts distributed

7.0 EVIDENCE BASE / REFERENCES

- ABHI (2016) *CODE OF BUSINESS PRACTICE: Guidelines on Interactions with Healthcare Professionals*, Association of British Healthcare Industries
- BHSCT (2015) *How to submit a clinical investigation application for a non CE marked device or a CE marked device for a new purpose* (BHSCT/RG/SOP 017)
- BHSCT (2017), *Medical Devices Procedures & Guidelines (BHSCT Trust Policy, TP041/07)*
- *Health and Safety at Work (Northern Ireland) Order 1978, (SI 1978/1039 (NI 9))* Belfast: HMSO
- *Electrical Equipment (Safety) Regulations (NI) (1994)* London: HMSO
- Health Research Authority (2015), *NRES Guidance Notes for researchers, applicants and research ethics committees on the ethical review of medical devices (v2, March 2008)*
- HSC (2014) Controls Assurance Standard: Medical Devices And Equipment Management
- MHRA (2010), *MDA/2010/001 Medical Devices in General and non-medical products*
- MHRA (2015), *Managing Medical Devices*
- NIAIC (2015), *DB2010(NI)-01 (v.3) Reporting Adverse Incidents and Disseminating Alerts*
- NIAIC (2015), NIA/2015/001, *Reporting of Medical Device Adverse Incidents and Near Misses and Disseminating Alerts*
- NIAIC (2015), NIA/2015/002, *Reporting of Estates and Facilities Adverse Incidents & Near Misses and Disseminating Alerts*
- *Provision of Use of Work Equipment Regulations (NI) (1998)* Belfast: The Stationery Office

8.0 CONSULTATION PROCESS

Medical Devices Advisory Committee have been consulted throughout the creation and updating of this policy.

9.0 PROCEDURES

Refer to the Trust *Medical Devices Procedures and Guidelines (TP041/07)* for further details on the Management of Medical Devices

10.0 APPENDICES / ATTACHMENTS

Appendix 1 - Common Categories of Medical Devices
Appendix 2 - Medical Devices Advisory Committee Membership and Terms of Reference

11.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is:

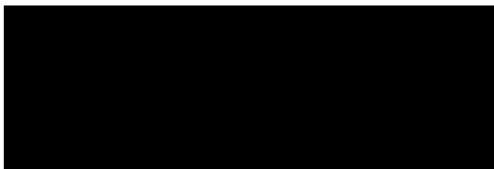
Major impact

Minor impact

No impact. X

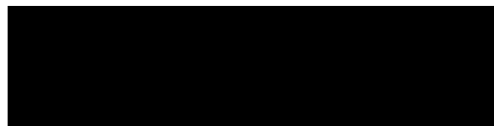
SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).



Author

Date: July 2017



Director

Date: July 2017

COMMON CATEGORIES OF MEDICAL DEVICES

This list is not exhaustive. It provides examples of common medical devices.

Equipment Used in the Diagnosis or Treatment of Disease, or Monitoring of Patients such as:

- Chiropody or podiatry equipment
- Dental instruments, equipment and materials
- Dressings
- Endoscopes
- Gastrostomy tubes
- Intravenous (IV administration sets and pumps
- Nebulisers
- Peak Flow meters
- Surgical instruments
- Suction Equipment
- Syringes and needles
- Sphygmomanometers
- Thermometers
- Urinary catheters

Equipment used in Life Support, such as:

- Defibrillators
- Domiciliary oxygen therapy systems
- Insulin injectors

In-vitro Diagnostic Medical Devices and their Associated Accessories such as:

- Blood glucose measuring devices
- Cholesterol test kits
- Pregnancy Test Kits
- Specimen collection tubes

Equipment Used by People with Disabilities such as:

- Bathing equipment and commodes
- External prostheses and othoses
- Hearing aids
- Communication aids including Apps
- Prescribable footwear
- Standing frames
- Urine Drainage Systems
- Walking aids
- Wheelchairs
- Equipment Used in Care such as
 - Adjustable beds
 - Patient hoists and lifting poles
 - Pressure relief equipment
 - Stoma care equipment

Other examples include

- Condoms and intra-uterine devices

MEDICAL DEVICES ADVISORY COMMITTEE MEMBERSHIP AND TERMS OF REFERENCE

Introduction

The Trust has established a Medical Devices Advisory Committee to ensure that systems and processes are in place to properly manage the procurement, usage, maintenance and disposal of all medical devices and to ensure their use and application does not create a risk to patients, staff and visitors.

Membership

The members will be responsible for providing expert advice and for co-ordinating or undertaking work at the request of the Committee. The Committee will draw membership from the following roles / services:

Medical Director

Co-Director, Planning & Redevelopment (Chair) Co-

Director of Information Technology

Quality & Governance Manager, Adult Social & Primary Care

Quality & Governance Manager, Specialist Hospitals & Women's Health

Quality & Governance Managers, Surgery & Specialist Services

Quality & Governance Manager, Unscheduled and Acute Care

Senior Manager, Corporate Governance Services

Senior Manager, Estates / Contracts

Podiatry Services Manager (representing AHP services, Unscheduled & Acute Care)

Consultant Scientist, Laboratories, Cancer & Specialist Services

Senior Manager, Community Child Health

Senior Infection Prevention & Control Nurse

Medical Devices Manager, Risk & Corporate governance

Head of Capital Development Finance

Senior Manager Theatres & Sterile Services

NB Other disciplines may be co-opted unto the group as and when appropriate.

All post holders and members will have nominated deputies who can attend meetings in their absence.

All appointments will be reviewed at a maximum interval of every three years.

Frequency of Meetings

The Medical Devices Advisory Committee will meet every four months.

Reporting Arrangements

The Committee will report to the Assurance Committee on a yearly basis and present a report to the Trust Board as part of the annual report.

Terms of Reference

The Medical Devices Advisory Committee will:

- Develop a Trust-wide approach to the management of medical devices ensuring that all aspects of procurement, usage, training, maintenance, decontamination and disposal are considered and assessed to ensure the safe and most effective use is made of every piece of equipment.
- Provide a forum to discuss and agree forward action regarding Trust-wide medical devices management issues as they emerge.
- Develop a Trust-wide policy and guidelines on managing medical devices.
- Establish KPIs and annual reporting on the management of medical devices.
- Develop a Trust-wide register of all medical devices across all Directorates.
- Assess the Trust needs and rationalise/standardise the use of equipment where appropriate.
- Monitor risks associated with medical devices as reported through medical device alerts and Trust risk management processes.
- Review serious untoward incidents involving medical devices and ensure appropriate action is taken and trends identified.
- Ensure Directorates have systems in place to monitor provision of training for all users of medical devices and equipment which will support their safe and effective use.
- Develop protocols and guidelines for procurement that focus on the life cycle of medical devices to ensure that they are fit for purpose, can be appropriately decontaminated and that funding is identified for all stages of the lifecycle including installation, acceptance tests, training, consumables, servicing and disposal.
- Provide the Committee an assurance update for their Directorates in advance of meeting