

Medical Devices Policy

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Distributed via:	Staff intranet pages

**Lincolnshire Community Health Services NHS Trust
Medical Devices Policy**

i) Version Control Sheet

Version	Section/Para/Appendix	Version/Description of Amendments	Date	Author/Amended by
1		New Policy	August 2008	K A Russell/K Rossington
2		Review and Update	December 2009	Medical Devices Committee
3		Review and Update	April 2010	Medical Devices
4		Review and Update	January 2012	Matthew Smith and Ali Biegaj
5		Review and Update	August 2014	Lisa Green
5.1		Extension agreed	February 2015	QSG
5.2		Extension agreed	July 2015	Dr P Mitchell
5.3		Extension agreed	October 2015	QSG
6		New document V6 Replaces P-CS-09 v5.3	December 2015	Interim/Acting Medical Devices Safety Officer
7	P8/9	Reference to asset log added	January 2017	Interim/Acting Medical Devices Safety Officer
	P9 sec 5.3	Reference to annual report added		Interim/Acting Medical Devices Safety Officer
8	P10 sec 7	Reference to annual audit added	May 2017	Interim/Acting Medical Devices Safety Officer
	P17	Updated TOR appended	July 2017	Head of Medical Devices and Technology
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Lincolnshire Community Health Services NHS Trust

Medical Devices Policy

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Lincolnshire Community Health Services NHS Trust

Medical Devices Policy

ii) Policy Statement

Lincolnshire Community Health Services NHS Trust (the "Trust") is committed to ensuring that there are robust processes for effective device medical device management for the whole life cycle of the device - from determining the justification of the need to purchase a device through to its ultimate disposal.

This document has been developed to set out the essential key aspects of the systematic approach required to ensure that the Trust does deliver services that promote the safe use of medical devices and that ensures that the Trust complies as a minimum with its statutory legal requirements.

This document must be read in conjunction with associated portfolio of core documents as detailed on page 12 appendix A that serve to provide detailed guidance and to ensure that the Trust responsibilities in relation to MHRA (2015) *Managing Medical Devices* are embedded.

Responsibilities

This document applies to all staff employed (or contracted) by the Trust who use, repair or procure medical devices in the course of their work.

All staff are required to ensure that they work within the boundaries set out by this policy

Dissemination

This policy will be available/accessible via the staff intranet.

Links with other policies

This policy should be read in conjunction with other local and national documents to include:

- Medical Devices "How to guides" (accessed via the Medical Devices pages on the Trust Staff intranet)
- P_RM_02 Risk management strategy (and other associated local guidance)
- P_GIG_03 Central Alert System (CAS) Policy
- P_IPC_01 Infection Prevention Policy (and other associated local guidance)
- P_HS_02 Corporate health and safety policy
- P_HS_07 Health and Safety Risk Management Policy (and other associated local guidance)
- P_HS_12 Healthcare waste policy
- P_CoG_02 Standing Orders, Reservation and Delegation of Powers and Standing
- P_CIG_16 Open and Honest Care (including duty of Candour) Policy
- CQC Essential Standards of Quality and Safety
- Clinical Negligence Scheme for Trusts (CNST) Clinical Risk Management Standards
- MHRA (2014) Regulatory Guidance for Medical Devices

Resource Implications

The resource implications of this policy are primarily related to procurement and contractual costs associated with maintenance, servicing and repair of medical devices.

Failure to meet regulatory standards could lead to imposition of financial penalties, patient harm and reputational damage.

iii) NHSLA Monitoring Template

Minimum requirement to be monitored	Process for monitoring	Responsible individual	Frequency of monitoring /audit	Responsible committee (multidisciplinary) for review of results	Responsible individuals / committee for development of action plan	Responsible individuals / committee for monitoring of action plan
Policy is current and available to staff	Policy is reviewed, updated and approved	Head of Medical Technology and Patient Safety	Min every 3 years	Medical Devices Committee	Medical Devices Committee	Medical Devices Committee
Standards of safety in medical device management are attained	Exception reports	Service Leads	Quarterly	Medical Devices Committee	Service Leads	Medical Devices Committee
Annual report	Report is received by the Medical Devices Committee	Head of Medical Technology and Patient Safety	Annually	Medical Devices Committee	Medical Director	Medical Director

iv) Equality Analysis

A.	Briefly give an outline of the key objectives of the policy; what it's intended outcome is and who the intended beneficiaries are expected to be	This document sets out the key requirements for the safe management of medical devices. Ensures that risks associated with their use is effectively managed.		
B.	Does the policy have an impact on patients, carers or staff, or the wider community that we have links with? Please give details	Not directly – but serves to ensure/support a robust governance framework.		
C.	Is there is any evidence that the policy/service relates to an area with known inequalities? Please give details	No		
D.	Will/Does the implementation of the policy/service result in different impacts for protected characteristics?	No		
		Yes	No	
	Disability		X	Applies to all persons equally
	Sexual Orientation		X	Applies to all persons equally
	Sex		X	Applies to sexes equally
	Gender Reassignment		X	Applies to all persons equally
	Race		X	Applies to all persons equally
	Marriage/Civil Partnership		X	Applies to all persons equally
	Maternity/Pregnancy		X	Applies to all persons equally
	Age		X	Applies to all persons equally
	Religion or Belief		X	Applies to all persons equally
	Carers		X	Provides advice on how to reduce /identify risks
	If you have answered 'Yes' to any of the questions then you are required to carry out a full Equality Analysis which should be approved by the Equality and Human Rights Lead – please go to section 2			
The above named policy has been considered and does not require a full equality analysis				
Equality Analysis Carried out by:		Cheryl Day		
Date:		14 th Dec 2015 (reviewed Jan 2017 v1.1)		

Medical Devices Policy

1. Medical Device...towards a definition

The term *medical device* covers a wide range of products used every day in primary and secondary care settings.

MHRA defines a *medical device* as,
'... an instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body'

In simple terms a *medical device* is any instrument, apparatus, appliance material or healthcare product, excluding drugs used for, or by, a patient or service user.

Medical devices can vary widely in complexity from simple devices such as a hypodermic needle, an oral thermometer, a disposable glove or even a tongue depressor to more advanced devices such as defibrillators, x-ray machines and POC or EAT related devices and does include any software applications necessary for the device to function.

2. Medical Device management... key principles

The management of medical devices is an important pre-requisite of a safe clinical service. Effective management requires a process that is agreed across all areas that contribute to the assurance and safe operation processes and requires organisational sign up to the core management principles to include Clinical Service Managers, Procurement, Clinical Engineering, Inventory control, and all staff using equipment.

3. Aim and purpose of this document

This document sets out to establish a governance framework for the management of *medical devices* used by staff working for and on behalf of Lincolnshire Community Health Services NHS Trust ("the Trust").

It must be read in conjunction with associated portfolio of core documents detailed on page XX that serve to ensure that the Trust responsibilities in relation to *MHRA (2015) Managing Medical Devices* are understood and embedded.

The overarching aims of the policy and associated documents is to ensure that whenever a Medical Device is used it is managed in concordance with MHRA and manufacturers requirements and

- that the device is suitable and used only for its intended purpose that its operation and purpose and risks associated to its use, are properly understood by the User, who has undertaken appropriate training and deemed competent.
- That it is maintained in a safe and reliable condition
- That it has been appropriately assessed, procured and the benefits of standardisation considered.
- That the procedures to be adopted in the event of an adverse or potentially adverse incident involving the *medical device* are understood.

4. Key Responsibilities

4.1 Chief Executive

The Chief Executive has the overall accountability for the management of *medical devices*.

4.2 Medical Director

The Medical Director is the Trusts nominated Executive Director accountable for the management of *medical devices*. The Medical Director is the chair of the Medical Devices Group.

4.3 Head of Estates and Facilities Management

The Head of Estates and Facilities Management has the delegated responsibility for the management of the central inventory for *medical devices*. The post holder is additionally responsible to provide assurance to the Board that appropriate PAT testing and maintenance arrangements for *medical devices* are in place.

4.4 Head of Medical Technology and Patient Safety

The Head of Medical Technology and Patient Safety is a newly developed position for the Trust. Although currently the post is vacant the purpose of the role is to provide strategic leadership and expert advice in relation to all aspects of *medical device* management, to support the Medical Director and clinical and corporate services in those activities associated to medical device management.

4.5 Medical Devices Safety Officer

The Lead Matron for Infection Prevention is the Trusts nominated Medical Devices Safety Officer (interim post). The key purpose of this role is to promote learning and safe use of *medical devices* across the organisation and provide the expert clinical resource. This role will be encompassed with that of Head of Medical Technology and Patient Safety role on appointment to the vacant post.

4.6 Risk Managers

The Risk Managers are the nominated MHRA/CAS liaison officers and are responsible for the dissemination and co-ordination of and for maintaining the local inventory for MHRA/CAS alerts and local action responses. The risk managers will provide CAS status update reports to the Medical Devices Group detailing alerts received, alerts relevant to the Trust, alerts sent out and responses

4.7 Heads of Service (or their nominated representatives)

Heads of Services are responsible for ensuring that

- Training needs of staff are identified, learning needs met and recorded in staff personnel files and training records (e.g. local records, TNA, ESR)
- Instructions for *medical devices* use are available at point of use of that device
- Appropriate clinical policies and risk assessments, associated with the use of medical equipment, are in place within each ward/ department area
- All *medical devices* are appropriately maintained, tested and properly stored.
- They actively participate in the dissemination and any relevant action of *medical device* alerts published by the MHRA and in reporting adverse or potentially adverse incidents.
- That proper procurement processes as set out in this document are adhered to
- That local asset registers are maintained and up to date for their areas of responsibilities.
- That local asset registers are forwarded at agreed frequencies to the central asset inventory

clerk.

4.8 Medical Device users

A member of staff using the *medical device* is known as the user.

The user is ultimately responsible for ensuring that

- the device is safe to use and that any deficits are reported promptly and where appropriate the *medical device* is taken out of use and quarantined until service/repair or replacement has been completed.
- that they have sufficient knowledge and training to operate the device safely
- All staff have a responsibility with regard to adverse incident reporting and should follow the Incident Reporting Policy in respect of *medical devices*.

Under Health and Safety regulations staff must also take reasonable care for their own health and safety and also of other people who may be affected by their acts or omissions. It is the responsibility of each individual member of staff to ensure that they are conversant with the content of this policy and are appropriately trained and competent to use the *medical devices* which they are required to use as part of their duties. They should report any problem relating to use, maintenance, servicing or decontamination as contained in this policy to their line manager.

5. Governance arrangements

5.1 Trust Board

The Trust Board will receive and consider the annual report and agree content. The Board will ensure that adequate resources are available to facilitate the effective management of *medical devices*.

5.2 Risk and Quality Committee

The Quality and Risk Committee will oversee all risks within the organisation and will incorporate any issues relating to the management of medical devices in the annual report to the board.

5.3 Medical Devices Group

The group will meet formally every 3 months.

The group will be chaired by the Medical Director (or nominated deputy). The terms of reference may be located at appendix D.

The Medical Devices Group will be responsible

- For the review and update of the medical devices policy
- To identify, develop, propose and promote activities that serve to minimise risks associated with the acquisition, use, decontamination and disposal of *medical devices*.
- Will review MDSO report and other data as available to identify, prioritise and address *medical device* risk and minimise harm to patients
- Oversee the production of the Medical Devices Annual report
- The group will act as a forum to discuss complex medical device alerts and will propose and co-ordinate processes and system changes that will reduce the likelihood of occurrence of harm and never events resulting from *medical device* use.
- To receive minutes from local quality meetings and to escalate inadequacies in attendance or unmanaged risks through the organisational governance routes (reporting to the Safeguarding

and Patient Safety Committee to the Trust Board)

5.4 Local Quality Meetings

Will ensure that *medical devices* are a standing agenda item. The review of risks and the compliance with the operational management of medical devices will be the devolved responsibility of the local service line quality meetings. Minutes from the meetings detailing medical devices management or risks will be received by the Medical Devices Group.

6. Training

Training for *medical devices* will be available via several mechanisms

- staff Induction
- device specific training from the device manufacturers
- device specific training local lead clinicians/educators
- Workforce and Transformation team will support organisational training needs.

See accompanying document (Medical Devices: Training) for details.

7. Policy Monitoring

Elements of this policy will be monitored by a number of established groups within the Trust such as;

- Medical Devices Group
- Quality and Risk Committee
- Procurement Sub-Group
- Infection Prevention Committee
- Training and Development

In line with P CIG 01 Clinical Audit Policy, an audit to assess compliance with the policy will be undertaken by service leads as determined by the Medical Devices Group. The Medical Devices Group will agree and monitor an annual programme of audit that will serve to appraise compliance with policy.

Any deficiencies identified will be actioned and changes implemented accordingly. The action plans will be monitored by the Medical Devices Group.

7. Dissemination

This policy will be distributed via the Trust intranet.

8. Policy review

This policy will be reviewed in 12 months.

V6.1 was reviewed/approved Jan 2017

V6.2 was reviewed/approved 3rd July 2017

Appendix A: Medical devices document portfolio: Key associated documents

This policy sets out to establish a governance framework for the management of *medical devices* used by staff working for and on behalf of Lincolnshire Community Health Services NHS Trust (“the Trust”).

It should be read in conjunction with the associated portfolio of documents - “How to Guide” (this list is not exhaustive):

- Medical Devices: How to Guide no 1. Acquisition and selection of medical devices
- Medical Devices: How to Guide no 2. Single use medical devices
- Medical Devices: How to Guide no 3. Adverse incidents
- Medical Devices: How to Guide no 4. Decontamination
- Medical Devices: How to Guide no 5. Maintenance and Repair
- Medical Devices: How to Guide no 6. De-commissioning and disposal
- Medical Devices: How to Guide no 7. Training
- Medical Devices: How to Guide no 8. Instructions for use
- Medical Devices: How to Guide no 9. Point of Care Testing
- Medical Devices: How to Guide no 10. Equipment on loan to patients
- Medical Devices: How to Guide no 11. The Use of non-Trust supplied clinical measurement devices by Sub-contractors
- Medical Devices: How to Guide no 12. Donated Medical Devices (awaiting final approval)

Appendix B: Useful definitions

MDA	Medical device alerts
Adverse incident	An event which gives rise to, or has the potential to produce, unexpected or unwanted effects involving the safety of patients, users or other persons.
CAS	Central Alerting System
MDSO	Medical Device Safety Officer
Medical Device	<p>an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which is intended by the manufacturer to be used for the purposes of:</p> <p>Diagnosis, prevention, monitoring, treatment or alleviation of disease;</p> <p>Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or physical impairment;</p> <p>Investigation, replacement, or modification of the anatomy or of a physiological process; or</p> <p>Control of conception.</p> <p>Note a list of a medical devices may be located at appendix A</p>
MHRA	Medicines and Healthcare Products Regulatory Agency
PPQ	Pre-purchase questionnaire

APPENDIX C:

Types of Medical Devices

This list is not exhaustive but provides examples of medical devices.

Equipment used in the diagnosis or treatment of disease, or monitoring of patients, such as:

- Administration sets and pumps
- Bathing aids
- Beds/Trolleys and mattresses
- Bed rails
- Blood glucose measuring devices and associated equipment
- Commodes
- Communication aids
- Condoms
- Contact lenses and care products
- Defibrillators
- Dental instruments, equipment and materials.
- Domiciliary oxygen therapy systems
- Doppler's
- Dressings
- Endoscopes
- Examination gloves
- External prostheses
- Gastrostomy tubes
- Hearing aids
- Hoists and slings
- Insulin injectors
- Intra-uterine devices (IUDs)
- Near patient testing devices (such as INR, pregnancy test kits, blood gases etc)
- Nebulisers
- Ophthalmic equipment
- Peak flow meters
- Prescribed footwear/orthoses
- Pulse oximeters
- Standing frames
- Sphygmomanometers
- Surgical instruments
- Suction equipment
- Syringes and needles
- Thermometers
- Ultrasound
- Urinary catheters and urine drainage systems
- Ventilators used in the home
- Walking aids
- Wheelchairs and special support seating
- X-ray machines

Appendix D: TOR Medical Devices Committee V1.2

MEDICAL DEVICES COMMITTEE

TERMS OF REFERENCE V1.2

PURPOSE OF THE GROUP

To minimize all risks associated with the acquisition, use, decontamination, maintenance and disposal of medical devices by monitoring and advising on the evidence base and cost effectiveness of medical devices for Lincolnshire Community Health Services NHS Trust.

ACCOUNTABILITY

The Medical Devices Committee is a sub-committee of the Quality and Risk Committee and has links to the Health and Safety Committee.

RESPONSIBILITIES

1. To consider the range, type and location of medical devices being used across LCHS NHS Trust and co-ordinate an equipment inventory.
2. To oversee the development of the Medical Devices policy and provide the expert body of knowledge to ensure its maintenance and suitability.
3. To implement and review a policy for the purchase, acceptance, decontamination, maintenance, repair, monitoring, and replacement of devices, and for the training of users.
4. To produce an annual report on the efficacy of the medical devices process for submission to the Trust Board through the Safeguarding and Patient Safety Committee as a sub-group of the Quality and Risk Committee. The Chair of the Committee has the responsibility to ensure that the report is produced and received by the Committee by the end of Q2.
5. To receive and consider documentation such as pre purchase questionnaires (PQQ's) and business cases etc associated with the purchase medical devices with a view to ensuring effective procurement decisions and comparisons of alternative devices are considered.
6. To advise on technical specifications, regulatory compliance information and related issues.
7. To advise on standardisation to single models where possible.
8. To advise on the financial implications when preparing an equipment purchase bid.
9. To advise on risk management considerations in relation to medical devices (to include PID where appropriate).
10. To advise on the evaluation of medical devices/equipment
11. To advise on guidelines for equipment decontamination

12. To advise on training issues
13. To advise on equipment management and maintenance procedures.
14. To develop key indicators capable of showing improvements in medical devices management and/or providing early warning of risks.
15. To ensure compliance with Care Quality Commission Outcome 11 – Safety, availability and suitability of equipment.
16. To monitor the provision of equipment supplied from external agencies and contracted suppliers.
17. To consider and monitor all Central Alerts System alerts (CAS) and incident reports relating to Medical Devices.
18. To establish, monitor and receive reports/minutes from specialist sub groups and local quality meetings as and when required.
19. The Service Line representatives will have responsibility for decision making in liaison with their Finance Lead.
20. Compliance with ToRs is monitored on an annual basis by this Committee who will identify any deficiencies and nominate a responsible member to produce and monitor implementation of an Action Plan to ensure future compliance. Progress on all Action Plans should be reported to this Committee on a regular basis.
21. Papers to be submitted to the minute taker no later than 10 days prior to the meeting. Reports can be by exception should the committee require additional papers.

CONSTITUTION

Chair - Medical Director

Deputy Chair – Head of Medical Devices and Technology

Clinical Governance Manager

Medical Device Officer

Infection Prevention Representative

Clinical Engineering (ULHT) Representative

Estates and Facilities Department Representative (Asset co-ordination)

Senior Clinical Service Representatives (i.e. one nominee from each of the clinical service lines)

Procurement Representative

Resuscitation Lead

Finance Representative

Health and Safety Representative

Workforce and Education Representative

Representation from each of the clinical service lines is required at every meeting.

Should the main representative not be able to attend, a designated deputy/representative is to attend.

Additional members with knowledge for advice on specific matters may be co-opted with the agreement of the Chair.

Any inadequacies in representation will be reported to the Safeguarding and Patient Safety Committee via the exception reporting route

QUORUM

The quorum is
Chair or Deputy Chair,
Clinical Engineering,
Estates and Facilities.
Each of the LCHS Clinical Service line must be represented.

FREQUENCY OF MEETINGS

To meet on a quarterly basis. If a decision needs to be made on a Medical Device before a meeting is due, a virtual group will be formed to comprise of representation from the Chair, Finance, Procurement, Clinical Service lines, Infection Control and Clinical Engineering.

SECRETARIAL SUPPORT

Secretarial support to the Committee will be provided by a member of the LCHS Beech House Administrative Team.

V1.1 Due for review January 2017- Reviewed and approved 21/10/16 via virtual committee

V1.2 Reviewed 31/05/2017 & Approved 03/07/2017