Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Selection and Procurement of Medical Devices Policy

This procedural document supersedes: CORP/PROC 3 v.6 - Selection and Procurement of Medical and Surgical Products Policy

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Executive Sponsor/a:	Jon Sargeant, Director of Finance
Author/reviewer: (this version)	Claire Burns, Deputy Head of Procurement
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Target audience:	Trust Wide

Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 7	November 2021	• Updated introduction to include Medical Devices Regulations 2002. • Updated details on purpose and role of Medical Devices Management Group • Updates to duties and responsibilities of Medical Devices and Management Group. • 'Care Groups' amended to 'Divisions' • Update to add Trust Procedure for the Procurement of Non-Medical Devices Used in Patient Care (2021). • Updated definitions and references to other relevant policies • Updated New Product Form.	Claire Burns
Version 6	22 October 2018	• Trust Title amended • Policy name changed • Introduction updated • Job Titles amended • Addition of membership section • Merge of Theatre Procurement Group and Medical Devices Management Group • Duties and Responsibilities amended • Procedure Amended • Product Evaluations DH amended • Associated Trust Procedural Documents additions included	Elizabeth Tidswell
Version 5	1 July 2015	• New document template • Contents Page amended • Job Titles amended • Training/Support added • Associated Trust Procedural documents added • New product form included	Andrea Smith

Version 4	December 2011	• Title change. • Amendment form and contents page added. • Item 2 - Policy Objectives - Note – Policy dates changed • Item 4 – General Manager Supplies and Procurement changed to Trust Clinical Procurement Specialist • Paragraph 4.7 removed • Item 7 – Equality Impact Assessment added • Item 8 – Monitoring of Policy added	Ian Allcock

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1. INTRODUCTION

Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust has a responsibility to ensure that Medical Devices used by the Trust meet all relevant standards, are suitable for their intended purpose are safe to use, cost effective and efficient. For avoidance of doubt, medical devices are classed as equipment or goods that comply with the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and are defined 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 is intended by the manufacturer to be used for human beings 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.
- Control of conception.

All Medical Devices purchased for the delivery of healthcare to patients must be ethically sourced and be from a supply source which can demonstrate that they maintain ethical standards throughout their supply chain.

2. PURPOSE

The objectives of this policy are:-

- To identify the lines of responsibility for the selection and purchase of Medical Devices, the application of which is not restricted to a particular Division, Ward or Department.

- To ensure that users are able to participate in decisions on the selection of medical devices, whilst maintaining appropriate Trust standards.

- To confirm that existing and new medical devices are safe to use, cost effective and meet the Trust's quality requirements to assist in patient treatment.

Note: This Policy should be read in conjunction with the Supplier and Manufacturer Representative Policy. Reference to The Provision and Use of Work Equipment Regulations 1998 should also be made.

3. MEMBERSHIP

3.1 Medical Devices Management Group

The Selection and Procurement of Medical Devices will be overseen/audited by the Medical Devices Management Group (MDMG). The purpose of the committee is to advise the trust on matters relating to the management/governance of medical devices used within the organisation. The committees work is based upon recommendations of the Medicines & Healthcare products Regulatory Agency (MHRA) document – Managing Medical Devices, guidance for healthcare and social care organisations (January 2021).

The MDMG comprises of:-

- Medical Devices Safety Officer (Chair)
- Consultant Microbiologist.
- Neonatal Matron.
- ED Deputy Matron.
- IPC Lead Nurse.
- Principal Clinical Physiologist.
- Divisional Director of Nursing
- Head of Estates.
- IT Security & Continuity Manager.
- HSDU Manager
- MTS Deputy Manager.
- Clinical Specialist – Procurement.
- Clinical Education Manager.
- Also any individuals co-opted onto the group from time to time for their expertise in a particular field of medical devices management.

4. DUTIES AND RESPONSIBILITIES

4.1 Medical Devices Management Group

The Medical Devices Management Group shall advise the trust on matters relating to the management/governance of medical devices used within the organisation. It will lead the Trust's strategy for the selection and procurement of medical devices by reviewing existing and new devices in accordance with evidence based practice and national guidelines and will undertake the following roles:-

- To approve the specification and evaluation of new medical devices which are not restricted in their application to a particular Division, Ward or Department.

- To receive reports on the evaluation of new medical devices and to make decisions based on a mixture of clinical acceptability (quality) and value for money criteria.

- To audit the Trusts governance arrangements for medical devices in-line with Section 2.6 of Medicines & Healthcare products Regulatory Agency (MHRA) document – Managing Medical Devices, guidance for healthcare and social care organisations (January 2021).

- Act as the Trust's authorising body for the standardisation of medical devices.

- Act as the Trust's authorising body for the inclusion of equipment onto the Trust's Radio Frequency Identification (RFID) system.

- Review and give advice upon the Premises Assurance Model (PAM) with respect to medical devices.

The Medical Devices Management Group will meet on a quarterly basis and report to the Medical Equipment Group (MEG).

4.2 Divisions

- Engage with the Procurement Department and Medical Technical Services (MTS) to play an active role in the selection of medical devices.

- Engage with the Procurement Department at the earliest opportunity if there are any changes to services or clinical procedures which involve the use of medical devices.

- Advise the Procurement Department of any national guidance which may require the review of the medical device in use.

- Ensure that clinical staff have the opportunity to attend training if required to implement new medical devices. Details of person performing training and members of staff trained should be recorded and stored on wards/departments.

4.3 Procurement Department

- Identify medical devices suitable for review via the annual work planning round.

- To develop Cost Improvement Plans (CIPs) in relation to medical devices.

- Initiate product switches in line with recommendations made under the following work streams

    - Nationally Contracted Products (NHSI led)
    - Working Together Programme

- Procurement Transformation Plan – Category Tower provider recommendations
- NHS England High Cost Tariff Excluded Devices Programme

- Engage with clinical staff regarding the selection of medical devices via the Medical Devices Management Group.

- Engage with specialist clinicians and practitioners to support them with the selection of specialist medical devices.

- Support clinical staff in the evaluation of medical devices.

- Guide and support clinical staff through the procurement procedures.

- Keep staff informed of all product changes.

- To report to the Commercial Steering Group progress on identified and agreed CIPs.

5. PROCEDURE

5.1 Management of Medical Devices Evaluations

Evaluations sponsored or requiring the approval of the Medical Devices Management Group will be processed as follows:-

5.1.1 Specialist practitioners may initiate requests directly to the Medical Devices Management Group or by using a New Product Request form which is available from the Procurement Department. All request must be accompanied with a specification

5.1.2 All other requests will be made via Departmental Managers to the Head of Procurement, who will request the Clinical Procurement Specialist to review and make recommendations to the Medical Devices Management Group as appropriate.

5 .1.3 If the request for medical devices evaluation is approved the Medical Devices Management Group will identify suitable sites to ensure that the product is evaluated appropriately.

5.1.4 All product evaluations are to be co-ordinated with the support of the Trust's Clinical Procurement Specialist.

5.1.5 The Trust's Clinical Procurement Specialist will ensure, in conjunction with Medical Technical Services that NHS Indemnity Agreement documents are completed before the evaluation proceeds.

5.1.6 The Departmental Manager or the Clinical Educators of evaluation sites will be responsible for ensuring that the users of the Medical Devices have the knowledge and skills for the safe use of the item and agree the % of staff to be trained prior to implementation. Clear instructions supporting the Medical Devices used will be provided if required, and any training needs identified will be provided in a timely and effective manner.

5.1.7 If the evaluation of the new product is by the use of free samples, the Trust's Clinical Procurement Specialist will ensure that there are no hidden costs of using the samples and that the Trust is not committed to the company concerned.

If the evaluation product is not free then an understanding of the financial implications should be evident before the start of any evaluation. If there is a net additional cost as a consequence of undertaking the evaluation, then approval of this additional expenditure would need to be obtained from the appropriate General Manager/Director prior to the evaluation commencing.

It should be possible to either return all unused Medical Devices to the supplier with no financial penalty or the replenishment levels should be co-ordinated to ensure that the Trust is not left with any unusable stock.

Any changes resulting in significant additional financial consequences over £5k per annum will require a business case to be completed and approved by the Commercial Investment Group before purchasing of any alternative medical devices.

Where the financial consequences are not considered significant the budget holder (General Manager/Director) must identify the funding source within their budget in order to ensure financial balance.

5.1.8 A report on the outcome of each evaluation will be submitted by the user to the Medical Devices Management Group for approval.

5.2 Management of Product Evaluations – Working Together Group

A Clinical Reference Group leads on the clinical decisions for the Working Together Group. The ethos is that if a medical device is used or evaluated by one of the Working Together Group Trusts then it is fit for purpose in any other of the Working Together Group Trusts, provided clinical practice is the same and can be implemented without trial. Where medical devices do require a trial then they may be trialled by one or more of the Trusts and implemented throughout all member Trusts.

5.3 Management of Product Evaluations – NHSE/I

NHSE/I has initiated a 'Nationally Contracted Product' (NCP) programme to introduce standardised medical devices nationally. These medical devices have already undergone clinical evaluation and are recommended for implementation within Trusts without further evaluation. Procurement will facilitate the communication and implementation of NCP's within the Trust. Where an NCP is considered not clinically acceptable this shall reported via the NCP exception reporting process managed by the Head of Procurement.

5.4 Purchase

After approval by the Medical Devices Management Group the request to purchase will be passed to the Procurement department via an electronic requisition.

The requesting department must complete an electronic Medical Devices Purchase Form before the purchase order can be raised. This can be found here: http://dbhmts/forms/MDF/MDF_Form.php. This form must be signed by Medical Technical Services.

The relevant Procurement lead will ensure that the supplier can demonstrate that the medical device is ethically sourced and that they have robust business continuity plans in place.

The Procurement lead will determine the supply route of the new medical device. The department and the Inventory Management team will determine and advise on the stock control requirements e.g. reorder levels, reorder quantities.

The Procurement lead shall not place any order for any 'reusable' medical device without assuring themselves that:

- The Trust holds a valid Pre-Acquisition Questionnaire (PAQ) on its PAQ database for that medical device or the current PAQ is not older than 5 years.
- Where the device requested is NOT listed on the Trusts Medical Devices Standardisation List.
- Also the Procurement lead shall not place any order for any non-medical devices that is intended to be used for patient treatment where it has not listed in the Trust Procedure for the Procurement of Non-Medical Devices Used in Patient Care (2021).

Existing stocks of the current medical device must be used prior to the introduction of the new medical device.

The Procurement lead will process the request in accordance with the Trust's Standing Orders and Standing Financial Instructions.

5.5 Probity

All employees of the Trust must maintain the highest standard of public accountability; therefore this policy should be read in conjunction with the Trust's Standards of Business Conduct and Employees Declarations of Interest Policy (CORP/FIN 4) and the Fraud, Bribery and Corruption Policy & Response Plan (CORP/FIN 1 D). Where there are concerns in regard to the conduct or probity of any member of staff or external parties in regard to the selection or procurement of medical devices, then it should be reported without delay to the Trust's Local Counter Fraud Specialist (LCFS) or via the NHS Fraud and Corruption Reporting Line on 0800 028 40 60 (online at: www.cfa.nhs.uk/reportfraud).

6. TRAINING/ SUPPORT

This policy is available on the Trust's Intranet.

Divisions must ensure that clinical staff have the opportunity to attend training if required to implement new medical device. Details of person performing training and members of staff trained should be recorded.

7. MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
New medical devices are not ordered without going through the correct process.	Inventory Management Assistants and Buyers	Daily or when requisitions are raised	Any orders for new medical devices will be checked by the Clinical Procurement Specialist and Head of Procurement and before order is processed.
Process for medical devices evaluation is followed correctly.	Medical Devices Management Group	Bi-monthly	Reported at Medical Devices Management Group meetings

8. DEFINITIONS

Medical Devices - medical devices are classed as equipment or goods that comply with the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and are defined 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 is intended by the manufacturer to be used for human beings 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.
- Control of conception.

Ethical sourcing – Ensuring that the medical devices being sourced are created in safe facilities by workers who are treated well and paid fair wages to work legal hours. The supplier respects the environment during the production and manufacturing of the medical and surgical consumables.

Specialist Practitioner - For the purpose of this policy, a member of staff whose role is working within a specialist team or clinical area, for example Tissue Viability or Resuscitation.

9. EQUALITY IMPACT ASSESSMENT

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment for All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. See Appendix 2.

10. ASSOCIATED TRUST PROCEDURAL DOCUMENTS

CORP/PROC 1 - Use of Medical Equipment used on Trial/Loan

CORP/PROC 2 - Supplier and Manufacturer Representative Policy

CORP/PROC 4 - Medical Devices Management Policy

CORP/HSFS 17 (A) - Waste Management Policy

CORP/HSFS 1 - Health and Safety Policy

CORP/RISK 2 - Medical Equipment Training for Trust Staff

CORP/PROC 8 - Procurement Policy

CORP/FIN 4 – Standards of Business Conduct and Employee Declarations of Interest Policy

CORP FIN 1 (D) – Fraud, Bribery and Corruption Policy & Response Plan

11. DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

APPENDIX 1 - New Product Form (available from the Procurement Department)

Product Information	
Name of Requestor	
Department/Deliver to Location	
Date of Request	
Supplier Name and Relevant Rep Name	
Product code and Description	
Unit of Measure and Unit Cost	
Min. / Max. stock levels, Anticipated Monthly Usage or One Off?	
Total Cost per Annum £	
Outline reasons for request	
New Product or Replacement?	New Product ☐ Replacement ☐
Code of product being replaced	Code: .....
What are the clinical benefits of introducing this product?	
IPC Lead approval checked	Yes ☐ No ☐
COSHH Lead approval checked	Yes ☐ No ☐
Decontamination Lead Checked	Yes ☐ No ☐
Training requirements?	Yes ☐ No ☐
Name of Training Lead	
Ward Manager/ Clinical Lead Approval Name	
Ward Manager/ Clinical Lead Approval Signature	
Date of Approval	

Procurement Information (For Procurement Use Only)	
Contract / Business Case / STW Reference	
Pre-Acquisition Questionnaire required	Yes ☐ No ☐
Will it need adding to Genesis?	Yes ☐ No ☐
E-Class Code and Description	
Where will the funding come from?	Revenue ☐ Capital ☐ Trust Fund ☐
Procurement Approval Name	
Procurement Approval Signature	
Date	
Deputy Head of Procurement Name	
Deputy Head of Procurement Signature	
Date	

APPENDIX 2 – EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Division/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Selection and Procurement of Medical Devices Policy	Procurement	Claire Burns	Existing Policy	October 2021

1) Who is responsible for this policy? Procurement

2) Describe the purpose of the service / function / policy / project/ strategy? To ensure that Medical Devices used by the Trust meet all relevant standards, are suitable for their intended purpose are safe to use, cost effective and efficient.

3) Are there any associated objectives? No

4) What factors contribute or detract from achieving intended outcomes? – None

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? Details: [see Equality Impact Assessment Guidance] - No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] –

6) Is there any scope for new measures which would promote equality? [any actions to be taken] No

7) Are any of the following groups adversely affected by the policy? No

Protected Characteristics	Affected?	Impact
a) Age	No	
b) Disability	No	
c) Gender	No	
d) Gender Reassignment	No	
e) Marriage/Civil Partnership	No	
f) Maternity/Pregnancy	No	
g) Race	No	
h) Religion/Belief	No	
i) Sexual Orientation	No	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form in Appendix 4

Date for next review: November 2024

Checked by: Richard Somerset Date: November 2021