Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Selection and Procurement of Medical Devices Policy

This procedural document supersedes: CORP/PROC 3 v.5 - Selection and Procurement of Medical and Surgical Products Policy

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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 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 are used in providing healthcare to patients. All Medical Devices goods 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:-

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

2.2 To ensure that users are able to participate in decisions on the selection of Medical Devices, whilst maintaining appropriate Trust standards.

2.3 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 Medical Devices Management Policy and the 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 managed by the Medical Devices Management Group. This is an existing group but will now incorporate the previous roles and responsibilities of the Theatre Procurement Group and widens the remit to all Medical Devices across the Trust.

The Medical Devices Management Group will consist of the following staff cohort as and when required dependent on the nature of the agenda:

- Clinical Directors
- Consultants from each Care Group and where appropriate each Speciality
- Theatre Managers
- Theatre Sisters and or ODP for each Theatre

- Head of Nursing
- Matrons
- Patient Safety Review Group Lead
- Members of Medical and Technical Services
- Procurement Leads
- Clinical Educators
- Inventory Management Leads
- Business Managers
- Partnership Support Officer NHS Supply Chain

4. DUTIES AND RESPONSIBILITIES

4.1 Medical Devices Management Group

The Medical Devices Management Group 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 Care Group, 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 receive reports comparing the cost and features of alternative Medical Devices, and implement standardisation and rationalisation where appropriate across the Trust.

- To monitor and review the profile of Medical Devices used by the Trust, ensuring that the Trust continues to receive value for money and that standards remain appropriate in the light of new product development.

- To report to the Medical Devices Sub-Committee on implementation of Medical Devices

The Medical Devices Management Group will meet on a bi-monthly basis and feed into the quarterly Medical Devices Sub-Committee Meeting.

4.2 Care Groups

- Engage with the Procurement Department and 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 in the Gold Standard Folder on wards/departments.

4.3 Procurement Department

- Identify Medical Devices suitable for review via the annual work planning round.

- To develop Cost Improvement Plans (C.I.Ps) 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
    - NHS England Innovation Transformation Grant

- 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.

- Ensure that a training package is supported by the company if appropriate.

- To report to the Commercial Steering Group progress on identified and agreed C.I.P.S.

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 Procurement Director, 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

The 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 – NHS Improvement

NHSi 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 Director via an electronic requisition.

The Procurement Director 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 Director will determine the supply route of the new medical device and determine or advise on the stock control requirements e.g. reorder levels, reorder quantities.

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

Clear and precise protocols as to when the new medical device is to be used will be developed with the appropriate lead practitioner, thus avoiding inappropriate use.

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

6. TRAINING/ SUPPORT

This policy is available on the Trust's Intranet.

Care Groups 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 and stored in the Gold Standard Folder on wards/departments.

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	Any orders for new medical devices r will be checked by the Procurement Director 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 are used in providing healthcare to patients.

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 - Representatives 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

APPENDIX 1 – NEW PRODUCT FORM

New Product Form (available from the Procurement Department)

Product Request Information	
Name	
Department	
Date of Request	
Product	
Company	
Outline reasons for request	
Is this a new product or will it replace an existing product?	
What are the benefits of introducing this product?	
Are there any risks involved in introducing this product?	
Which depts. will require these medical and surgical consumables?	

Procurement Information	
NHS Supply Chain/Contract	
Pre- Purchase Questionnaire	
Infection Prevention & Control approval (Where applicable)	
Cost	
Funding	
Training	
Approval	

APPENDIX 2 – EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Care Group/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Selection and Procurement of Medical Devices Policy	Procurement	Elizabeth Tidswell	Existing Policy	July 2018

1) Who is responsible for this policy? Name of Care Group/Directorate – Finance and Healthcare Contracting

2) Describe the purpose of the service / function / policy / project/ strategy? Who is it intended to benefit? What are the intended outcomes?

3) Are there any associated objectives? Legislation, targets national expectation, standards

4) What factors contribute or detract from achieving intended outcomes? –

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: **August 2021**

Checked by: **Anthony Somerset** **Date: June 2018**