University Hospitals Bristol NHS
NHS Foundation Trust

Terms of Reference – Medical Devices Management Group (MDMG)

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Document Abstract
This policy provides the terms of reference of the Medical Devices Management group (MDMG) to support the effective management of Medical Devices within UHB:

[1] Divide number of words (576) by 240 for average reading time and add 25% for specialist content.

Document Change Control				
Date of Version	**Version Number**	**Lead for Revisions**	**Type of Revision**	**Description of Revision**
July 2015	1		Major	First version
December 2017	2	[redacted]	Major	Review and update, review of activities, updated frequencies of meetings.

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1. Purpose

1.1 The Medical Devices Management Group (MDMG) is a statutory Group established by the Trust's Clinical Quality Group (CQG) to provide a multidisciplinary approach to the effective management of Medical Devices within the Trust.

1.2 It has responsibility for monitoring and ensuring compliance with both the Managing Medical Devices Safely Policy and also for ensuring that items are identified for the CQC Outcome 15 Baseline assessment.

1.3 For the purpose of this group a Medical device is defined as

(a) "Any electrically powered device or non-electrical equipment including related software used in the diagnosis, investigation, monitoring, treatment and care of patients."

(b) This group does not consider Consumable Medical Devices unless they are associated with the safe operation of a device which meets the definition above.

2. Role and Function

2.1 To assist the Trust in delivering the Care Quality Commissions guidelines outlined within

(a) Outcome 12: Safe Care and Treatment

(b) Outcome 15: Premises and Equipment.

2.2 Ensuring that the Managing Medical Devices Safely Policy is reviewed and updated annually as required and is implemented through the divisions.

2.3 To review incidents relating to medical devices to identify trends relating to devices and develop appropriate approaches to resolve Trust wide issues.

2.4 To formally approve and agree protocols and protocol changes for Medical Devices through the divisional representatives and other specialties within the group.

2.5 To review risks relating to Medical Devices and where possible support the remedial actions to minimise and mitigate these risks as far as reasonably practical

2.6 To support the effective procurement and standardisation of devices utilised within the Trust and support medical device purchases undertaken within the divisions. This will be completed through effective engagement with appropriate procurement processes and Standing Financial Instructions (SFI's).

2.7 To monitor agreed spend and capital schemes relating to Trust wide bids for equipment e.g. Patient Monitors, hoists etc. if agreed by the Capital Program Steering Group (CPSG)

2.8 To monitor divisional Medical Device training plans to ensure that Clinical Device training needs are met within the divisions and that any risks are flagged to the group to support the rectification of any issues raised.

2.9 To monitor governance around external maintenance agreements to ensure that contracts are set up within the divisions and monitor that the level of cover which is agreed is appropriate to meet the requirements of Medical Device Governance, operational needs and financial sustainability. Responsibility for level of cover will remain the responsibility of the budget holders within the divisions.

2.10 To monitor Health and Safety Regulations relating to Medical Devices including PUWER/LOLER and the associated requirements relating to these to ensure that the Trust complies with their requirements

2.11 To monitor the activities against the Trust's maintenance program undertaken by Clinical Engineering (MEMO), to create a multidisciplinary approach to ensure that devices within the Trust are appropriately maintained and rectified within appropriate timeframes.

3. Membership

3.1 Members of the Group shall be appointed by the Chair of the MDMG and shall include:

Role
??? (Chair)
Head of Clinical Engineering (Deputy Chair)
Divisional Representative (Surgery)
Divisional Representative (Medicine)
Divisional Representative (Trust Services)
Divisional Representative (W&C)
Divisional Representative (Specialised Services)
Consultant
Infection Prevention & Control Representative
Pharmacy representative
BWPC representatives
Point of Care Representative
Estates Representative
Medical Device Safety Officer
Medical Device Training Coordinator
Medical Physics and Bioengineering will provide Secretarial Support

4. Authority

4.1 The MDMG will report to the Clinical Quality Group (CQG) and is authorised to:

(a) Use the allocated Trust wide budget effectively to procure items agreed at the Trust's Capital Program Steering Group (CPSG)

(b) Provide guidance and approved specifications for the purchase of medical devices and standardise the procurement strategy relating to these devices on behalf of UHB

(c) To identify opportunities for rolling replacement programs of Medical Devices which can be recommended to CPSG or Procurement to minimise the risk of aging equipment within the Trust and present these within the appropriate forums.

(d) To agree and work within its authority to act to resolve risks relating to Medical Devices by working with Clinical Teams and make recommendations to CQG where these cannot be resolved by the group.

(e) Review information from suppliers and internal systems in order to review performance against KPI targets which relate to the effective management of Medical Devices within the Trust.

(f) To monitor risks associated with the devices within the remit of the group and put plans in place to prevent repeat occurrences.

(g) To approve on behalf of the Trust and implement updates to protocol's for Medical Devices utilised within the Trust

(h) To identify training needs across the divisions and put operational approaches in place to rectify any issues identified, through working with the divisional representatives and clinicians within the Trust.

5. Roles and Responsibilities

This section outlines the key roles and responsibilities for members of the group to ensure that the group is effectively delivered.

5.1 (Deputy) Chair of Group

(a) To review and monitor compliance on the implementation and delivery of the Management of Medical Devices within the Trust, identifying trends and key issues from reports generated by the divisions.

(b) To ensure that key actions are undertaken and progress is made on all key issues which arise within the group's scope of activity

(c) To ensure that the Medical Device's Policy and Terms of Reference are updated and reviewed

(d) To generate reports and escalate items which need to be sent through to the CQG as required by the group to report on activity from the group.

5.2 Divisional Representatives

(a) To cascade and collate divisional messages and communicate into and out of the group on items within the group's scope of activities

(b) To attend the group or send a nominated deputy to engage in the activity of the group

(c) To generate reports outlining their current status for Medical devices on a 2 monthly basis for their division, this should incorporate Risks, incidents, equipment purchases planned, contracts not being renewed etc.

5.3 Bristol and Weston Purchasing Consortium (BWPC)

(a) To support the development of rolling replacement programs and advise on best methods for putting contracts in place to support standardisation of devices within the Trust.

(b) To support the development of appropriate specifications for Medical Device's alongside the divisions in preparation for going out to market

(c) To provide specialist advice relating to appropriate procurement processes to ensure the most cost efficient process is undertaken and best value for the Trust is obtained.

5.4 Specialist Areas e.g. Infection Prevention and Control, Point of Care Coordinator, Estates, MDSO

(a) To provide reports on any device requirements or issues which may not be available to the Division's when generating their reports.

(b) To provide reports on training compliance, highlighting areas of non-compliance to divisions so remedial action can be implemented

(c) To provide specialist feedback on projects and group activities to ensure that all key requirements for delivery are addressed.

6. Reporting

6.1 The Chair of the Group shall report to the Clinical Quality Group (CQG) quarterly (or more if required by the CQG) on the activities of the Group and shall make recommendations the Group deems appropriate (on any area within the Group's remit where disclosure, action or improvement is considered necessary).

6.2 Sub-groups are expected to report to the group on a 4 monthly basis to meet the timetable of the group. These reports should contain details of the group's activity and any items which require escalation to the group or to CQG to ensure that they can be undertaken or addressed. Legislative changes and risks over 12 should always be reported as part of these reports.

6.3 Non delivery of reports will be escalated to the Clinical Quality Group and Divisional Directors to ensure that compliance can be appropriately monitored by the group.

7. Quorum

7.1 The quorum necessary for the transaction of business shall be five members of the group and it must include a minimum of three of the following Chair or Deputy Chair, Clinical/Divisional representation as well as one of the following Procurement, Manual Handling, Infection Control, Point of Care Testing and Pharmacy.

7.2 A duly convened meeting of the Group at which a quorum is present shall be competent to exercise all or any of the authorities, powers and discretions vested in or exercisable by the Group as set out in these Terms of Reference.

8. Duties

8.1 The duties of the Group are:

To consider and examine on behalf of the Trust:

- Key performance indicators (A list of these will be present within Appendix 1 of this TOR)
- To monitor and implement the requirements of the Managing Medical Devices Safely Policy and the baseline assessment for CQC outcome 15.
- Risks and Incidents relating to Medical Devices within the Trust
- Requests for protocol changes to devices within the Trust
- To review governance around external maintenance contracts and receive the report from the contracts group highlighting any challenges/issues relating to the setting up of contracts within the Trust.
- To target and develop Trust wide training programs to ensure appropriate monitoring and implementation of clinical competencies for Medical Devices

9. Secretariat Services

9.1 The allocated secretary shall co-ordinate secretariat services to the Group at the request of the Group Chair.

9.2 *Notice and Conduct of Meetings*

(a) Meeting of the Group shall be called by the secretary of the Group at the request of the Group Chair. Meeting invites to electronic diaries will be sent ideally at least 6 weeks in advance of any meeting being called

(b) Unless otherwise agreed, reminder notice of each meeting confirming the venue, time and date, together with an agenda of items to be discussed, shall be made available to each member of the Group and any other person required to attend, no later than 5 working days before the date of the meeting.

(c) Supporting papers shall be made available to Group members and to other attendees, no later than 5 days before the date of the meeting. A request for papers will be sent out 2 weeks in advance of the meeting date.

9.3 *Minutes of Meetings*

(a) The secretary shall minute the proceedings and resolutions of all Group meetings, including the names of those present and those in attendance and those who sent apologies.

(b) Draft Minutes of Group meetings shall be made available promptly to all members of the Group and will be formally agreed at the following meeting.

10. Frequency of Meetings

The Group shall meet every 2 months, and at such times as the chair of the Group shall require.

11. Review of Terms of Reference

The Group shall, at least once a year, review its own performance, constitution and Terms of Reference to ensure it is operation at maximum effectiveness and recommend any changes it considers necessary to the Chair for approval.

12. Appendix 1: KPI's to be reviewed by the group

To monitor the performance against the following KPIs:

1. Catastrophic incidents relating to Medical Devices < 1 per Annum?
2. Staff training percentages (TBC)