The Tavistock and Portman NHS
NHS Foundation Trust

Maintenance of Medical Devices and Equipment Procedure

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Bodies consulted:	SIRO
Approved by:	PASC
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Lead Manager:	Health and Safety Manager
Responsible Director:	Medical Director
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Maintenance of Medical Devices and Equipment Procedure

1 Introduction

It is a requirement that all NHS trusts have in place an organisation wide policy on the deployment, monitoring and control of medical devices, as set out in the Medical Devices Regulations 2002 (as amended).

Whist recognising that the Trust has a very low use of any piece of physical equipment that falls within the scope of the regulations, the Trust Board is fully committed to ensure that patient safety is a maintained when devices and/or equipment are used. Of increasing importance is the use of software applications used for health purposes, this is dealt with in separate guidance as part of the management of information assets.

2 Purpose

This document sets out the procedures that are to be followed to ensure the safe selection and maintenance of physical equipment and the procedures in place to ensure that staff using any medical devices are competent in their use.

3 Scope

The procedure applies to all clinical and managerial staff who order, arrange maintenance or use physical medical devices and equipment in the course of their work for the Trust. Hereafter, references to devices refers to the physical devices in table 1 below and excludes software applications.

4 Definitions

'Equipped to Care1' sets out the wide range of medical devices that can be deployed within the NHS. This includes medical and surgical equipment, disability equipment and disposable items. The term 'Medical device' encompasses medical devices as legally defined in the Medical Devices Regulations 2002.

Few devices are in use in the Trust and the table below shows the category of devices and those which may be used by Trust clinicians:

[1] Equipped to Care: Medical Devices Agency. A guide for health care professionals, support workers and managers 2000

Table 1: Medical devices and equipment categories

Equipment uses in diagnosis or treatment of disease, or monitoring or patients	Syringes &needles Sphygmomanometers Thermometer Examination gloves
Equipment used in life support	Defibrillators First aid kit
Aids to daily living: Equipment used in the care of Older Adults or those with a disability	not applicable
In vitro medical devices and their accessories	not applicable

5 Duties and responsibilities

Board Level Accountability for Medical Devices

The Board member with responsibility for safe use of medical equipment and devices is the Medical Director. The Director will be supported in this role by the Patient Safety and Clinical Risk Lead. The Director will seek assurance that the Trust maintains a suitable procedure for the use of medical devices; in the event of any adverse event relating to medical devices investigates each incident and put in place actions to reduce risk of recurrence.

Health and Safety Manager

The Health and Safety Manager will be the nominated individual who acts as the Trusts central point of contact in relation to all matters relating to the selection, servicing and decommissioning of all medical devices owned and in the use in the Trust. The Health and Safety Manager will be responsible for ensuing all equipment in the Medical Room at the Tavistock Centre is effectively maintained and in good working order.

Any incidents involving medical devices or equipment will be reported to the Health and Safety Manager who will be responsible for investigation and follow up as set out in the Trust's Incident Reporting Procedure[2]

The Central Alerting System (CAS) is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care. All alerts are sent directly to the Health and Safety Manager who will respond in a timely manner and report the results to the Corporate Governance and Risk Lead on a quarterly

[2] For most up to date incident reporting form and procedures see Trust Intranet and website

basis.

The Health and Safety Manager reports to the Associate Director of Quality and Governance for medical devices matters and will inform the Patient Safety and Clinical Risk Lead of any incidents reported that relate to the use of devices and/or equipment in the course of patient care.

Patient Safety and Clinical Risk Lead

The PSCR Lead is responsible for reporting on an exception basis any incidents that involve medical devices or equipment to the Clinical Quality Governance and Risk Committee to provide assurance that patient safety reporting is well-managed.

All clinical staff using any medical device or equipment

Clinical staff using medical devices and equipment supplied by the Trust are responsible for ensuring that they are competent in the use of the equipment and to seek supervision and or advice from their manager if the equipment is unfamiliar[3].

6 Procedures

Procurement
Any member of staff wishing to procure an item that is defined as a 'medical device or piece of equipment used for patient care' should seek advice from the Health and Safety Manager who will then ensure that the device is being purchased from an NHS approved supplier.

Device deployment

When equipment is allocated to a department, clinical staff has primary responsibility for the way they treat the equipment and the state in which it is left. These responsibilities can also include performance checks before use and routine maintenance, such as charging batteries. Any problems with any device and/or piece of equipment should be reported to the manager without delay and not used until the device/equipment is fully tested as safe. If a piece of equipment or device is removed from service, then an incident form should be completed and sent to the Health and Safety Manager.

Maintenance and Repair

All devices should be maintained and repaired in accordance with the manufacturer's instructions which should be helped locally for reference. All electrical equipment should have an in date PAT test safety certificate.

[3] Due to then nature of the equipment supplied e.g. weighing scales, BP machines etc. no specific training is provided as a level of competence is expected of staff in basic equipment

7 Training Requirements

At the current time the Trust does not deploy any medical device or equipment that requires specific training, beyond standard clinical training of doctors and nursing staff. Individual clinical staff are expected to ensure that they maintain their competence on any piece of equipment that they use and to refer.to manufacturer's instructions for further information.[4]

8 Process for monitoring compliance with this policy

Compliance with this procedure will be by exception reporting via incident reporting to the Clinical Quality, Governance and Risk Committee via the Health and Safety Manager and the Associate Director of Patient Safety

9 References

- The Medical Devices Regulations 2002.
- Health and Safety at Work Act 1974.
- Management of Health and safety at work Regulations 1999
- Provision and Use of working Equipment Regulations 1998

10 Associated documents[5]

- Health and Safety Policy
- Incident Reporting Procedure
- Infection Control Procedure
- Information Asset Acceptance and Registration Procedure
- Tavistock Health Application Assessment Tool Usage Guidelines

[4] In the event that new services require non-standard equipment this procedure will be expanded and updated to meet new requirements

[5] For the current version of Trust procedures, please refer to the intranet.

11 Appendix: Equality Impact Assessment

Completed by	**Jonathan McKee**
Position	**Governance Manager**
Date	**20.5.16**

The following questions determine whether analysis is needed	**Yes**	**No**
Does the policy affect service users, employees or the wider community? The relevance of a policy to equality depends not just on the number of those affected but on the significance of the effect on them.	X	
Is it likely to affect people with particular protected characteristics differently?	X	
Is it a major policy, significantly affecting how Trust services are delivered?		X
Will the policy have a significant effect on how partner organisations operate in terms of equality?		X
Does the policy relate to functions that have been identified through engagement as being important to people with particular protected characteristics?		X
Does the policy relate to an area with known inequalities?	X	
Does the policy relate to any equality objectives that have been set by the Trust?		X
Other?		X

If the answer to *all* of these questions was no, then the assessment is complete.

If the answer to *any* of the questions was yes, then undertake the following analysis:

	Yes	**No**	**Comment**
Do policy outcomes and service take-up differ between people with different protected characteristics?		X	
What are the key findings			Na

of any engagement you have undertaken?			
If there is a greater effect on one group, is that consistent with the policy aims?		X	
If the policy has negative effects on people sharing particular characteristics, what steps can be taken to mitigate these effects?			Na
Will the policy deliver practical benefits for certain groups?			It will make the use of devices safer
Does the policy miss opportunities to advance equality of opportunity and foster good relations?		X	
Do other policies need to change to enable this policy to be effective?		X	
Additional comments			

If one or more answers are yes, then the policy may unlawful under the Equality Act 2010 – seek advice from Human Resources (for staff related policies) or the Trust's Equalities Lead (for all other policies).