Ref: QS24

MEDICAL DEVICES AND EQUIPMENT MANAGEMENT POLICY

Executive Sponsor & Function	Chief Operating Officer Health and Safety Function
Document Author:	Health and Safety Manager
Approved by:	Quality, Safety and Performance Committee
Approval Date:	January 2021
Date of Equality Impact Assessment:	20th October 2020
Equality Impact Assessment Outcome:	This policy has been screened for relevance to equality. No potential negative impact has been identified.
Review Date:	January 2024
Version:	Version 4.1

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1. Policy Statement

Velindre University NHS Trust attaches great importance to the health, safety and wellbeing of its patients, donors, staff and visitors whilst fulfilling its statutory obligations within the law.

The purpose of this policy is to put systems in place which ensure that all risks associated with the acquisition, use and disposal of Medical Devices and Equipment are controlled and minimised, that medical devices and equipment purchased are suitable for intended use and offer best value and to monitor and validate those systems.

2. Scope of Policy

This policy applies to all staff employed by or contracted to the Trust, including those within Hosted Organisations. It applies to all areas where medical devices and medical equipment is purchased, used or stored or manufactured in-house.

3. Policy Aims and Objectives

The aims of this policy are to: -

- outline the management of medical devices and equipment arrangements within Velindre University NHS Trust,
- minimise the health and safety risks arising from the use of medical devices and equipment
- to reflect the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA) document *Managing Medical Devices* – *Guidance for healthcare and social services organisations April 2015*.

The policy objectives are to ensure that whenever a medical device is used, it is: -

- Suitable for its intended purpose.
- Used according to its “intended use” as outlined by the manufacturer.
- Maintained in a safe and reliable condition.
- Disposed of appropriately at the end of its useful life.

4. Responsibilities

4.1 Chief Executive

The Chief Executive has overall accountability for health and safety within the organisation, making sure that arrangements are in place for:

- ensuring that there is a Director appointed as a lead for the management of medical devices and equipment.
- ensuring that the Trust Board and Executive Management Board is informed as required on matters related to the procurement, use and disposal of medical devices and equipment
- ensuring that the Trust’s Medical Devices and Equipment Management Policy

is implemented
- ensuring that there are sufficient resources for the implementation of this policy

4.2. Chief Operating Officer

The Chief Operating Officer has delegated responsibility at Trust Board level for the management of medical devices and equipment and is responsible for ensuring that:

- the Trust's Medical Devices and Equipment Management Policy, is reviewed in accordance with the Trust policy review programme
- regular updates on medical device and equipment issues are reported to the Executive Management Board and the trust Quality and Safety Committee.

4.3. Trust Medical Devices Officer

The Trust has appointed a Medical Devices Officer (MDO) who is responsible for coordinating medical device safety and management arrangements across the Trust and is the key point of contact for all medical devices related queries for frontline staff and managers

The MDO ensures Trust compliance with the Medicines and Healthcare products Regulatory Agency (MHRA) Devices Bulletin "Managing Medical Devices – Guidance for Healthcare and social services organisations V1.1 (MHRA 2015)" and supports the development and delivery of care in relation to the safe use of medical devices and works collaboratively with internal and external stakeholders.

The MDO works closely with all staff and the procurement service regarding the procurement and performance management processes in respect of contracts and service level agreements for medical devices management and safety**.**

The organisation has procured an Asset Management Database and all medical devices and equipment should be recorded on the system. The MDO is responsible for the overall management and maintenance of the database.

4.4. Trust Accountability

The Trust Medical Devices Group monitors trust-wide activity and provides a quarterly highlight report to the Trust Quality and Safety Committee. The group is chaired by the Medical Physics lead for Medical Devices and the Terms of Reference are attached (Appendix 1). The group receives regular updates on MHRA Device Alerts and other safety notices and the actions taken, reports on any incidents involving medical devices and the procurement of new devices into the organisation.

Medical Devices management is audited through standard 2.9 of the Health and Care Standards, Medical Devices, Equipment and Diagnostic Systems and the associated action plan is a standing agenda item of the group.

5. Definitions and Examples

Article 2(1) of Regulation (EU) 2017/745, the Medical Devices Regulation defines a medical device as: -

“any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices …”

All such devices on the market must be CE marked in accordance with the Medical Devices Directive 93/42/EEC (as amended), or the EU Medical Devices Regulation or the associated UK regulations. [1]

Medical devices play an increasingly important role in the assessment and management of patients in clinical practice today. The term “medical device” covers a broad range of products, which are used for: diagnosis or treatment of disease, monitoring of patients and assistive technology. Medical devices include both passive devices, e.g. dressings and powered medical devices sometimes simply referred to as medical equipment. Also covered within the scope of this policy are *In vitro* diagnostic medical devices (IVDs).

Examples of Medical Devices and IVDs are given below but these are not exhaustive lists: -

[1] As of July 2020, the UK regulations based on the three EU Directives (for active implantable, general and in-vitro diagnostic devices) are still in force as S.I. 2002/618 as amended from time to time since.
The EU Medical Devices Regulation 2017/745 is also in force and can be applied but will not automatically become directly applicable EU legislation. New UK regulations are under development https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021
This policy with then be updated as appropriate.

Function	Examples
Diagnosis or Treatment of Disease	Anaesthetic equipment, catheters, diagnostic laboratory equipment, dressings, implants, scanners, surgical instruments, surgical gloves, syringes, x-ray machines.
Monitoring of patients	ECG, pulse oximeter
Critical Care and Community based Healthcare	Baby incubators, blood gas analysis, defibrillators, ventilators, pressure relief mattresses and pressure care equipment, catheters, dressings, domiciliary oxygen therapy systems, glucose tests, syringe, urine drainage systems

Function	Example
Improve Function and Independence of people with Physical Impairments	Communication aids, environmental controls, hoists, orthotic and prosthetic appliances, supportive seating and pressure care, walking aids, wheelchairs
Emergency services	Stretchers, trolleys, resuscitators

Within the Trust, there are many pieces of equipment that fall within the above types. Usage is commonplace and very often training is part of an employee's education. The Trust expects all staff to adhere to the following principles before using ANY medical device:

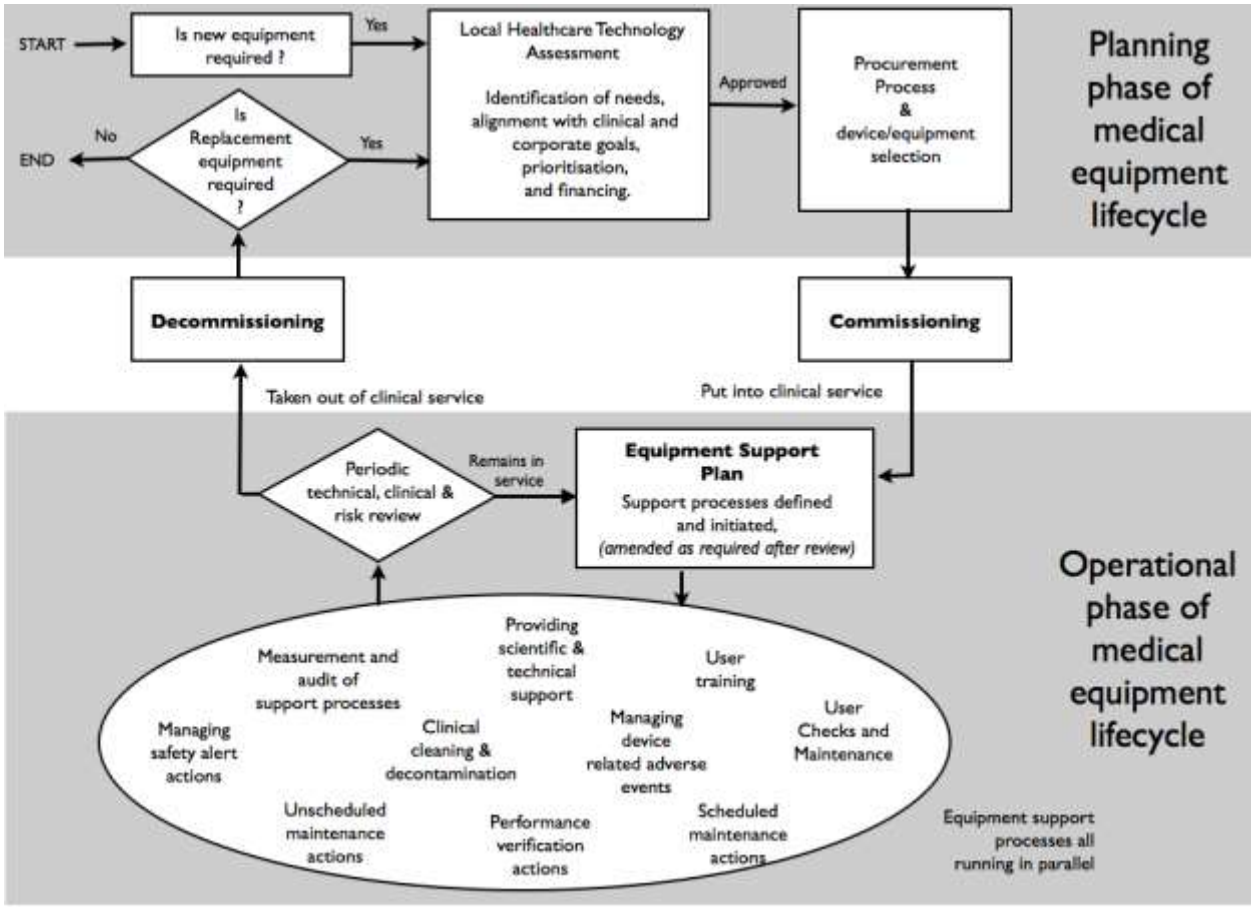
- Always visually check the device or equipment for cleanliness and signs of damage or incorrect settings before each use.
- Ensure equipment has been serviced where appropriate by checking the service label.
- If the equipment requires disposables, ensure that they are correct for the device and for its current settings.
- Do not use a piece of equipment unless you have been trained to do so
- Do not be afraid to ask for advice.

6. Systems of Management

6.1. Equipment Life Cycle

A key feature of all effective equipment management is that a life-cycle approach is taken. This involves careful strategic consideration of needs and options before equipment is purchased / procured, appropriate operational management of that equipment while it is in use, and the legal and economic disposal of the equipment when the decision is taken to remove it from service. This brings the cycle back to the starting point again. A useful illustration of this is shown below:

Equipment Life Cycle – (adapted with permission; cited in McCarthy et al, 2020) [1]: -



6.2. Adverse Incidents – Device related

Medical Devices liaison is undertaken by the Trust Medical Devices Officer, ensuring the effective reporting of adverse incidents involving medical devices to the Medicines and Healthcare products Regulatory Agency (MHRA) and Health and Safety Executive (HSE), by the relevant managers of Divisions or Hosted organisation, where appropriate.

Managers and staff should report any medical device incidents e.g. failures, faults and non-compliance issues into the Datix incident reporting system, following the Trust Incident Reporting Policy and the MHRA publication on Reporting Adverse Incidents and Disseminating Medical Advice Alerts DB 2011(01) should be consulted.

Incidents that involve non-powered medical devices e.g. dressings, disposables should be reported to the Surgical Materials Testing Laboratory (SMTL) using their medical device defect reporting form, following local reporting procedures.

6.3. Interaction with other products e.g. mobile phones, chemicals and safety devices

6.3.1. Electromagnetic Interference from mobile phones and other sources

The most up to date guidance from the MHRA, issued in December 2014 is titled Electromagnetic Interference: sources: -

https://www.gov.uk/government/publications/electromagnetic-interference-sources/electromagnetic-interference-sources (Updated 17 January 2020; accessed 21 July 2020)

The guidance does not recommend a ban on the use of mobile phones in health care premises however, it advises that a mobile phone can effect sensitive equipment if it is in close proximity to devices and recommends that Healthcare organisations develop local policies to minimise the risk of interference in places such as:

- treatment areas
- by the patient's bedside when the patient is connected to any electro-medical device
- other areas where interference with a device could have a detrimental effect on patients

Communication devices that use only Wifi or Bluetooth may be used without restriction. Examples are: -

- Tablets without a sim card
- E-readers without a sim card

****Note** If a communication device has mobile phone functionality (e.g. 3G / 4G), the device may be used without restriction, provided that it is switched to "Airplane Mode", to ensure that the mobile phone signal is disabled. Otherwise, the restrictions noted in section 6.3.1. apply.**

6.3.2. Chemical Interactions

Consideration must to be given to any processes that need to be in place to ensure that any potential risks from chemicals used in conjunction with a medical device or the delivery of a substance via a medical device are minimized. For example, the use of grease / oil based products in close proximity to Oxygen may increase the risk of auto ignition.

6.3.3. Interactions with products and systems used to enhance safety

Where products or systems are introduced to enhance safety to either an employee or a service user, an assessment of the risk with the new device or product must be undertaken to ensure that an alternative risk is not introduced. For example, the inability to use an existing radiation shield with a safety engineered needle.

6.4. Actions required on MHRA's Medical Device Alerts and Manufacturer's Corrective Notices

The Quality and Safety Department is responsible for dissemination of medical device alerts in accordance with the policy QS 02 – Safety Notices and Important Documents Management Procedure. The Quality and Safety Manager is the Trust lead for the Health and Care Standards, which incorporates the trust-wide management of safety notices, alerts and other such communication.

In addition, any Operating System (OS) or software security updates must be deployed to any associated computer system in line with Trust Policy and Procedures. If such "Patches" or upgrades cannot be deployed then a Risk Assessment for the underlying vulnerability must be undertaken and where appropriate reported into the Datix Risk Management system. For further information on risk assessment please seek advice from the Trust Quality and Safety Department or follow the Risk Assessment and Risk Register Policy.

Should the manufacturer be required to up-grade or "patch" their application within any computer system, a degree of user acceptance testing must be undertaken prior to the acceptance of this change. This process should follow the Trust's Change Management Policy if appropriate.

6.5. Divisional Level Responsibilities

Divisional directors should ensure that appropriate equipment management and reporting structures are identified and are in place. This may include a designated lead in each division to co-ordinate the local management processes. Systems must be developed, validated and monitored to ensure all staff are aware and take ownership of their responsibilities concerning the management of equipment in accordance with national guidelines including the MHRA *Managing Medical Devices – Guidance for healthcare and social services organisations April 2015*.

Departmental Managers must: -

- Identify individuals for specific tasks and responsibilities.
- Set objectives, standards and timescales and monitor performance in relation to equipment management in their areas of work.
- Report problems / areas of concern to senior managers.
- Implement the policy for equipment management and monitor compliance with the Medical Devices and Equipment Management Policy in their area.
- Take part in the business planning process relating to equipment.
- Check competence of staff upon induction and monitor / review competence of all staff as part of appraisal and risk management process.
- Identify training and support for departmental leads. Ensure all training and competence is documented.
- Set up systems to ensure periodic decontamination is carried out according to manufacturer's guidance.

Professional users must: -

- Work only within sphere of professional / personal competence.
- Use equipment in a safe authorised manner, only for its intended or designated purpose, following manufacturers' guidelines and local policies and standard operating procedures.
- Ensure that equipment is appropriately decontaminated both before and after use.
- Work to all Trust policies and procedures relating to the procurement, use and disposal of equipment.
- Report any adverse incidents and concerns relating to the use of equipment to line manager.
- Equipment must not be used or maintained without appropriate training.
- Staff have a responsibility to identify and report any training needs to their line manager.
- Not purchase any equipment without specific consultation with the Infection Prevention and Control Department, the Trust Medical Devices Officer and the Procurement Team

Procurement Team must: -

- Ensure all purchases are made in accordance with the *MHRA Managing Medical Devices – Guidance for healthcare and social services organisations April 2015* including that all medical devices are specified to be CE marked.
- Ensure that equipment matches the planned level of service.
- Ensure that the equipment to be purchased can be decontaminated appropriately and in line with local decontamination process.
- Co-ordinate information regarding the condition of equipment, received from the relevant maintenance department – e.g. age / state of repair / maintenance histories.
- Ensure equipment is disposed of in accordance with the appropriate Trust Policies, manufacturer's guidance and relevant legislation (see 12.2)

- Associated Computer Systems which contain Personal Identifiable Information (PII) or Trust information must have a recognised and approved hard drive encryption product installed. Exceptions to this must be through a formal, documented risk assessment in line with Trust Policy.
- Develop strategies to ensure that the Trust learns from any purchasing mistakes and identify any training needs concerning procurement & disposals of equipment.
- Ensure that the Official Journal of the European Union (OJEU) procurement rules are followed.

Maintenance

Service Divisions must ensure that there is adequate maintenance provision for medical devices and equipment and appropriate maintenance schedules are put in place. This should include planned preventative maintenance programmes. The following should be considered where appropriate: -

- Ensure service contracts are in place and establish follow-up systems to ensure contracts are reviewed well before renewal date to ensure best value is achieved.
- Devise and monitor systems to ensure equipment which is loaned to patients / other departments etc., is regularly tested for safety and appropriately maintained.
- Set up and monitor systems to ensure that maintenance contracts are carried out to the required standard.
- A suitable anti-virus product must be installed to any associated computer system and maintained to a current level to protect against all identified vulnerabilities.

6.6. Audit

Random audits should be carried out locally on all elements of maintenance, repair, record generation and storage to ensure that the correct procedures are in place and being adhered to. Audits should be carried out by staff with appropriate knowledge and experience of managing medical devices.

The application of the policy should be regularly reviewed to ensure that, whenever a medical device is used, it is:

- Suitable for its intended purpose
- Used in line with the manufacturer's instructions
- Traceable, where possible
- Maintained in a safe and reliable condition, with associated records kept
- Disposed of appropriately at the end of its useful life

7. Acquiring Equipment – Safety Quality and Performance

Appropriate acquisition and selection of devices should be undertaken in accordance with section 3 of the MHRA's *Managing Medical Devices* – *Guidance for healthcare*

and social services organisations April 2015. In addition, reference should be made to the MHRA's publication dated June 2014 - Devices in Practice – Checklists for using medical devices, which includes a series of checklists that can help in the purchase, use and maintenance of medical devices and training.

7.1. Procurement

Various parties in the Trust are responsible for the procurement process. Divisions and Hosted Organisation of the Trust should develop medical device procurement procedures that link with and complement the Trust process for the selection and acquisition of medical / equipment which are outlined in Appendices 2 and 3. Taken together, these processes will ensure:

Value for money – equipment that meets the needs of its professional and end users and compliance with Standing Financial Instructions / Standing Orders.

To comply with the Trust's Standing Financial Instructions, competitive tendering or quotes will be obtained when necessary. Device / equipment specifications should be provided by the requisitioning department to allow competitive quotes / tenders to be obtained.

This process covers both new and replacement devices such as renting, borrowing, in-house manufacture, modification of in-house devices, refurbishment or "cannibalising". Cannibalising is NOT to be considered a method of equipment procurement, merely a short term reaction to given changes in circumstance.

Procurement Checklist – should be drawn up and followed in the specification / quotation / tendering stages of the procurement process. This will often be needed in addition to a technical equipment specification where that specification looks only at the primary functions and capabilities of a device.

Some examples of questions likely to be asked could include: -

	Yes / No
Will this replace existing equipment?	
Will it meet department's requirements? (as per business case)	
Are there Installation costs? (E.g. electrical sockets, workbenches, communication cables etc.)	
Have all accessories been requested? (e.g. stands, trolleys etc.)	
Have running costs been considered? (Disposables, extra staff, capital charges)	
	Yes / No
Are there any training costs involved?	
Is regular maintenance or decontamination required?	
If yes, is funding available (on average 10% of purchase cost)	
Does the supplier require remote access to any computer system to maintain the equipment?	
If yes, then a Code of Connection agreement is required for access to the NHS Wales Network	

Will the equipment be in contact with intact skin, non intact skin, mucous membranes?	
What are manufacturer guidelines for decontamination (cleaning, disinfection, sterilisation) and can this be met within current Trust policy or existing facilities?	
Is the equipment CE marked and does it comply with relevant Standards?	
Overall, is equipment considered satisfactory?	
Have safer alternatives been considered (as required by the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013?	
Have disposal costs been calculated and impact assessment completed	

The Trust procurement department will send a Pre-Acquisition Questionnaire (PAQ) form to the prospective supplier; the form includes information relating to safety and infection control to enable the purchaser to make an informed decision as to whether to proceed with the particular purchase. Guidance should be sought at the tendering stage of procurement from the manufacturer concerning decontamination (cleaning, disinfection, sterilisation), to ensure the manufacturer's instructions can be met. This must be carried out for every purchase of medical devices, regardless of funding route or cost. A link to the PAQ form can be found here. The completed PAQ form will require a pass response from relevant specialists (e.g. Medical Devices Officer, Medical Physics, Infection Prevention and Control) before proceeding to purchase. A link to the Pass / Fail Form can be found here.

Example equipment procurement flowcharts are attached at Appendix 2 and 3.

7.2. Records

Good record keeping is essential for the safe management of medical devices. The detail and complexity of the records will depend on the type of device and its usage during its lifetime. It should also include any specific guidance provided in the manufacturer's instructions and supporting information. Records must be protected to ensure their accuracy is maintained and that any changes do not obscure previously recorded information.

The Engineering Section of Medical Physics have responsibility for the management of the Asset Management database system which will enable comprehensive records to be kept and analysed. All medical equipment must be recorded on this system.

Records should provide evidence of: -

- A unique identifier for the device, where appropriate.
- A full history, including date of purchase and, where appropriate, when it was put into use, deployed or installed.
- Any specific legal requirements and whether these have been met.
- Proper installation.
- The purchase price of the equipment
- Where it was deployed.

- Where appropriate, identification in patient notes of devices used in individual patient episodes.
- Scheduled maintenance.
- Details of Maintenance and repairs.
- Decontamination dates.
- The end-of-life date.

Records should also show that users: -

- Have been trained and had relevant refresher training.
- Know how to use the device safely.
- Can carry out routine checks and maintenance.
- Are confident and / or competent to use devices in their area of work
- Know who is responsible for cleaning the equipment.

7.3. In-House Manufacture or Modification of Medical Devices

Where equipment or devices are manufactured or modified in-house and used exclusively within the Trust, it is essential that relevant standards, regulations and guidance are followed and suitable records and documentary evidence, including documented risk assessments and a technical file, are maintained throughout the lifecycle of the equipment. Software applications running on standard platforms such as PCs or smart phones can be medical devices in their own right and are subject to these requirements.

Legislation under development is likely to regulate in-house manufactured or modified and used devices more formally, including the requirement for such developments to be carried out under formal quality management systems.

In-house manufactured devices (including software as a medical device) that are then used outside of the Trust's control are legally 'placed on the market' and the full regulations must be applied.

8. Introduction of a New Piece of Equipment

8.1. Loan Equipment Procedures

Equipment borrowed from others for clinical trials or equipment trials, for example

- Provided by an external company for research purposes.
- Borrowed from a manufacturer or supplier.
- Borrowed from another organisation.

In all cases, a Loan Indemnity agreement, based on the master indemnity agreement, must be completed as a record for the Trust or check if a blanket agreement has been signed by the supplier which may need to be used against any incident resulting from faulty equipment. Advice and appropriate forms can be obtained from the Trust Medical Devices Officer.

All borrowed devices must go through the same acceptance procedure / acceptance tests as new equipment. The same standards of training, competence, maintenance, repair and calibration apply to loaned, trial or purchased equipment.

It is important that at the end of its loan period the equipment is decontaminated and removed from use or accepted as part of the inventory of equipment. Should it cease to be on loan but still in use, full responsibility must be assumed for the equipment and its acquisition treated as if it were new equipment.

Reference should also be made to Welsh Health Circular WHC (2008) 015 Effectively managing "On Loan" surgical Instruments and any other current guidelines that are released during the lifespan of this policy.

8.2. Device Acceptance Procedures

Each service division will have documented acceptance testing procedures in place and these must be in accordance with the guidelines contained in section 5 of the *MHRA Managing Medical Devices – Guidance for healthcare and social services organisations April 2015*.

For portable equipment a variety of acceptance testing procedures may be necessary – electrical safety tests for example.

8.3. Internal Loans

When a piece of equipment is loaned to another department, it is the responsibility of the borrower to ensure that they have been trained and are competent to use the equipment. The borrower will be responsible for and be aware of the maintenance / care requirements whilst in their possession and must ensure the device is returned in safe working order having been cleaned / decontaminated / sterilised as appropriate and is accompanied by a completed decontamination certificate.

8.4. External Loans to Carers / Patients

Some equipment may be loaned to patients / carers upon discharge from hospital as part of their on-going care needs or as part of their outpatient treatment.

It is important to assess whether those being loaned the equipment are capable of taking responsibility for it, i.e. that they are competent to use and maintain the equipment and will return it in good condition.

It is essential that a proper record is kept of the make, model and identification number of loaned equipment and the responsible person to whom it has been loaned. This is important so that equipment can be followed up for maintenance or recall.

It is essential to be clear about where responsibility lies for each aspect of device management, including: -

- Decontamination procedures.
- Maintenance and its records.
- Availability of up to date instructions.
- Period and type of use.
- Information supplied to any discharged patients / users.
- Device identification and traceability.
- Passing on of manufacturers' instructions to end users.
- Contact details (users and healthcare establishment).

The organisation remains accountable for collecting these items when they are no longer needed. It is essential that all individuals are aware of the local medical device management system and the part that they play within the system to ensure that medical devices are managed correctly.

8.5 Clinical investigation of a non-CE marked medical device

If the Trust wishes to carry out a clinical investigation of a prototype medical device as part of a clinical evaluation with a view to obtaining a CE mark, the regulations and guidance issued by MHRA must be followed. This applies whether the evaluation is being carried out in cooperation with a manufacturer or as part of an in-house development. Ethical approval will be required.

Section 4 of the *MHRA Managing Medical Devices – Guidance for healthcare and social services organisations April 2015* has a checklist of the factors that must be addressed. More detailed guidance, application forms etc. are available from MHRA.

9. Training

9.1 Training of staff in the use of Clinical Equipment

The Trust must ensure that the potential risk of harm to patients is reduced to a minimum. In seeking to achieve this it is essential that staff using diagnostic or therapeutic equipment are appropriately trained and are competent to undertake the duties for which they are employed.

This section applies to all grades and disciplines of staff that are employed directly or indirectly within relevant Trust service divisions.

9.2. Identification of Training Need

All departments will identify equipment within their areas for which staff will require specialist training. Departmental managers will identify which staff are able to use each device following successful completion of a programme of training. This may include setting up a device, preparing for its use, checking the device and decontamination where appropriate.

Consideration must be given to the possible need to develop new Standard Operating Procedures.

Training records for Agency and Bank staff will also be checked to establish current levels of knowledge and skills and to identify any additional training that may be required.

- Upon local induction ensure all appropriate staff, including bank and agency staff, receive appropriate training before using equipment.
- Ensure competence is measured, documentation maintained and training recorded and reviewed as part of staff's individual performance review. (IPR).
- Ensure designated storage space for manufacturer's instruction manuals.
- Review training plans and organise regular refresher training when necessary.
- Ensure training / induction includes an understanding of relationships with other departments (e.g. Maintenance Department, Infection Prevention and Control Department etc.).

Individuals are responsible for ensuring they are competent for any equipment they use. Anyone who does not feel competent must not use equipment until they have undertaken the appropriate training and assessment.

Competence will be monitored and reviewed through staff appraisal and risk management process or when staff have not used a piece of equipment for 12 months or earlier if indicated by clinical practice.

9.3 Training for users of medical devices and their carers

Consideration must also be given to the training requirements of device users and their carers. End users need to understand the intended use and normal functioning of the device in order to use it safely and effectively.

9.4 Training for other staff

Training may also be required for maintenance and repair staff, to enable them to undertake the required level of in-house maintenance. They may need access to technical support from the manufacturer.

9.5 Training Documentation

Evidence that suitable instructions and training have been given will be required. Users of a device should be asked to sign / electronically confirm statements confirming that they have received and understood written and / or oral instructions.

Details of training given should be recorded and a test at the end of training may also be included, to check that the information has been understood.

10. Manufacturer's Instructions

Manufacturer's Instructions must be readily available for each piece of equipment and it is essential that they are followed. Any deviation from the instructions may not only invalidate any warranty but could also cause an injury to the employee or service user.

Single-use and multiple-use medical Devices should be used in accordance with manufacturer's instructions. Where this remains unclear, additional supporting information has been provided at Appendix 4, following advice from the All Wales decontamination and sterilization advisory group.

11. Appropriate Prescription of Devices

The prescription of devices is the selection of the most appropriate device to use for a given clinical situation and will only be made by staff with the appropriate professional qualifications. Competency to prescribe must be assessed, recorded and audited to ensure consistency and accuracy of prescribing procedures.

Technical support and advice is available from relevant Maintenance Departments, Infection Prevention and Control Department and the Procurement Department and by the PAQ process

11.1 Rationalisation to Single Models where possible

Consideration should be given to the rationalisation to single models where possible as some devices may have a similar appearance but very different operating parameters which could lead to dangerously inappropriate treatment.

12. Maintenance and Repair

It is Trust policy to keep medical devices safe and effective, through both user maintenance procedures, supervised by professional users, and planned preventative maintenance and repair carried out by suitably trained technical staff. All maintenance and equipment management will be undertaken using the guidelines contained within section 8 of the *MHRA Managing Medical Devices – Guidance for healthcare and social services organisations April 2015* and any other relevant publications.

Each service division must ensure that maintenance is carried out by suitably qualified staff whether internal or external e.g. Clinical Engineering departments who will maintain certain medical devices, and that all aspects of the technical specification are met and maintained.

12.1 Routine Maintenance by Users

Routine maintenance by users should ensure that the device continues to function correctly. It entails regular inspection and care, as recommended by the manufacturer or within local procedures. This should clearly show the routine tasks and how they should be carried out. Instructions for the user maintenance of medical devices should be provided to the user, which should include: -

- Checking that it is working correctly before use
- Regular cleaning
- Specific daily / weekly checks
- Noting when it has stopped working properly or when obvious damage has occurred, and then discontinuing use

- Reporting or arranging for servicing as per local procedures.

Users may need to be trained to carry out routine user maintenance.

12.2. Planned Preventative Maintenance (PPM)

Service Divisions should have arrangements in place for planned preventative maintenance and, where necessary, calibration of medical devices and equipment and relevant staff should be aware of maintenance procedures including timescales for maintenance checks based on the manufacturer's recommendations. How the device is used and how often must also be considered when determining service intervals.

12.3. Storage of Devices

It is important that adequate and appropriate storage arrangements are in place for safely storing equipment including accessories. Particular attention should be given to any device that requires to be on charge whilst not in use by ensuring that it is not stored alongside combustible materials and by ensuring that the area is suitable and safe for charging the equipment, in order to reduce the risk of fire by separating an ignition source from combustible materials, particularly where these areas are within close proximity to inpatient areas.

13. Decontamination

Micro-organisms will always be present in the healthcare environment and employees of Velindre University NHS Trust have a responsibility to be aware of methods to prevent their transmission. The choice of decontamination method depends on a number of factors, which include the type of material to be treated, the organisms involved, the time available for decontamination and the risks to staff and patients and donors.

Decontamination of equipment and the environment is a key infection prevention and control measure.

The effective decontamination of re-usable devices is essential to reduce cross infection risks.

Decontamination methods used will depend on the nature of the micro-organisms present and the infection risk associated with the surface, equipment, device or procedure.

Medical devices must be decontaminated between each patient and donor. Use only the decontamination method advised by the manufacturer- using any other process might invalidate warranties and transfer liability from the manufacturer to the person using or authorising the process. If there are any doubts about the manufactures recommendations seek further advice from the infection prevention and control team.

For full guidance on decontamination all staff must refer and comply with the Decontamination of Equipment Policy IPC 04.

When transferring medical devices from site to site from consignor to consignee the medical devices must be decontaminated with a completed attached decontamination certificate, signed by both parties.

14. Decommissioning and disposal of devices

14.1. Replacement Criteria

Depending on fiscal circumstances, medical devices / equipment will be replaced following consideration by the users and, where appropriate, advice from the Trust Medical Devices Officer, based on the following criteria: -

- Worn out beyond economic repair.
- Damaged beyond economic repair.
- Unreliability (service history).
- Clinically or technically obsolete.
- Spare parts (manufacturers support) no longer available.
- More cost-effective or clinically effective devices have become available.
- Unable to be decontaminated effectively.
- Medicines and Healthcare products Regulatory Agency (MHRA) notifications – hazards etc.
- The availability of safer alternatives as required by the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013.

14.2. Disposal / Transfer of ownership of Equipment

The purpose of this section is to ensure that all equipment is disposed of with due regards to safety and to ensure managers consider appropriate legal implications. (See Trust Disposal Policy Black 124 and contact the Trust Procurement Department for copies of the relevant forms.)

14.2.1. Financial Considerations

All equipment sold or disposed of must be done so in accordance with relevant Welsh Government circulars and the Trust's Financial Corporate Governance policy to ensure financial probity and in consideration of any capital charges which may be relevant.

Failure to follow appropriate guidance or legislation when selling medical devices and other equipment could lead to prosecution or liability for damages.

14.2.2. Trust's liabilities when ownership is transferred

In the event of a sale or donation all new owners must sign a disclaimer to limit any future legal liabilities of the Trust. It should be noted however, that this disclaimer does not absolve the Trust of all legal liabilities and could still be left liable to prosecution e.g. where Health and Safety legislation has been breached. In general the more comprehensive the information supplied to the new owner the more the Trust's liability is reduced.

14.2.3. Information supplied to the new owner

Manufacturer's instructions and any other information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely must be provided to the new owners.

The new owner must also be furnished with any safety information provided by the Medicines and Healthcare Regulatory Agency (MHRA) such as product safety updates. The new owner should also be advised to regularly check if there are any future product updates.

As a minimum, the following information should be provided: -

- Record of any reconditioning work carried out, including a record of replacement parts.
- Copy of all maintenance and servicing that has been carried out including the name of maintenance / servicing organisation. Original service records must be retained.
- Record of usage.
- Fault log.
- Decontamination status.

14.2.4. Confidentiality

Some equipment may have the capacity to hold electronic information which may compromise a patient's confidentiality. Any such equipment must have memories fully erased or data storage / retrieval capacity destroyed before disposal or transfer of ownership in accordance with the Trust's I.T. policies.

Computer system hard drives must be wiped/erased to a recognised standard to ensure no Personal Identifiable Information (PII) or Trust information is retained within the system.

15. Equality

This policy has been screened for relevance to equality. No potential negative impact has been identified.

16. Getting Help

Advisors for certain aspects of Medical Devices and Medical Equipment have been incorporated within the Trust structure, to provide specialist advice as outlined below:-

Chief Operating Officer	Ms. Cath O'Brien Velindre NHS Trust Headquarters 2 Charnwood Court Heol Billingsley, Parc Nantgarw, Cardiff CF5 7QZ Tel: 029 20196138 WHTN 01875 6138 E-mail: Cath.OBrien@wales.nhs.uk

Medical Devices Officer	Mr. Jignesh Raiyani, Medical Physicist Velindre Cancer Centre, Whitchurch, Cardiff CF14 2TL Tel: WHTN 01875 4321 E-mail: jignesh.raiyani@wales.nhs.uk
Infection Prevention and Control	Karen Jones, Senior Infection Prevention and Control Nurse Velindre Cancer Centre, Whitchurch Cardiff CF14 2TL Tel: WHTN 01875 6342 E-mail: Karen.Jones65@wales.nhs.uk
Radiation (Ionising)	Mr Arnold Rust, Head of Radiation Protection Service Velindre Cancer Centre, Whitchurch Cardiff CF14 2TL WHTN 01875 6270/6268 E-mail: Arnold.Rust@wales.nhs.uk

17. Legislation and Best Practice Guidance

This policy is based on statutory requirements produced by the Health and Safety Commission, Department of Health and Social Care, Medicines and Healthcare Products Regulatory Agency and the Welsh Government including:

The Medical Devices Regulations 2002
The Medical Devices (Amendment) Regulations 2008 and 2012
EU Medical Devices Regulation 2017
Health and Safety at Work etc Act 1974
Electricity at Work Regulations 1989
Management of Health and Safety at Work Regulations 1999
Provision and Use of Work Equipment Regulations 1998
Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

Best Practice Guidance:
MHRA, 2015. *Managing Medical Devices – Guidance for healthcare and social services organisations V1.1* [online]. London: MHRA. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf
[Accessed 21July 2020]

MHRA Safeguarding Public Health Device Bulletin DB2011(01) Reporting Adverse Incidents and Disseminating Medical Device Alerts March 2011

MHRA, 2014. Devices in Practice- checklists for using medical devices

18. References

1 McCarthy J, Hegarty F, Amoore J., Blackett P., Scott R*. Healthcare Technology Asset Managemen*t. In: Taktak A., Ganney P., Long D., Axell R., editors. *Clinical Engineering: A handbook for clinical and biomedical engineers*. 2nd ed. London: Academic Press; 2020. p. 17-30.

Appendix 1

Terms of Reference
Medical Devices Group

Name of Group/Committee/Board:	Velindre University NHS Trust Medical Devices Group
Summary of Role:	To ensure that risks of all types associated with the lifecycle of medical devices (including acquisition, in-house manufacture or development, decontamination, use, maintenance and disposal) are controlled and minimised.
Remit:	Provide a forum for the identification and management of any issues with medical devices in use or being maintained, including any relevant MHRA or manufacturer alerts. Provide a forum for the identification and management of any procurement issues and procedures, including advising and receiving advice from the procurement officer. Provide a forum to ensure any manufacture of medical devices including software as a medical device, conforms to the requirements of the current Medical Devices Regulations & In-vitro Diagnostic Devices Regulation. Receive incident reports relating to medical devices and provide recommendations on preventing re-occurrence. The monitoring, active completion and approval for submission of the Health and Care Standards 2.9, Medical Devices for each division. To provide support on: • Medical devices and equipment selection. • Tracking of equipment and maintenance of inventory. • Medical devices and equipment management procedures. • Medical devices and equipment evaluation and costing prior to acquisition. • Procurement procedures. • Medical device manufacture (including software). • Decontamination processes (in conjunction with infection prevention and control specialists)
Reporting to: **Communicates with:** **Monitoring of:**	Trust Quality, Safety and Performance Committee, Divisional Senior Management Teams. Medical Gases and Electrical Safety groups Trust Safety Alerts Group Infection Prevention & Control Committee Water Safety Group Divisional H&S Groups Action plans for the NHS Wales Health and Care Standard 2.9, Medical Devices, Equipment and Diagnostic Systems, Medical Device incidents, Actions from safety alerts, Medical Device Legislation, Audit & KPIs

<table>
<tr><td>Sub Committees:</td><td colspan="2">Electrical Safety Group
Medical Gases Group</td></tr>
<tr><td>Chaired by:</td><td colspan="2">Appointee from Membership.

Current Chair is Mr Tim Register, Medical Physics Engineering Manager
Current Deputy Chair is Simon Lawrence, Radiology Senior Radiographer</td></tr>
<tr><td>Membership:</td><td colspan="2">Nursing
Patient Safety
Estates
Infection Prevention & Control
Medical Physics
Medical Devices Officer
Procurement
Health & Safety
Pharmacy
Radiotherapy
Radiology
Cardiff & Vale Clinical Engineering
Welsh Blood Service
NWIS
SMTL
Consultant Clinical Engineer
Other members co-opted as required according to speciality.

Attendance for a quorum must be a minimum of 6 and must include representation from each Division (VCC, NWIS, SMTL & WBS), and also include Medical Devices Officer and Infection Prevention & Control and Nursing representatives
Each nominated representative should send a deputy if they are unable to attend.</td></tr>
<tr><td>Meeting Frequency:</td><td colspan="2">Bi-monthly.</td></tr>
<tr><td rowspan="2">Documentation Required/Submitted From:</td><td>Documentation</td><td>Submitted From</td></tr>
<tr><td>Minutes of meetings
Medical Devices Alerts and Field Safety Notice Reports
HCS reports and Incident reports</td><td>Secretary
MDO</td></tr>
<tr><td>Outputs (i.e. minutes of meeting submitted to other committee meetings)</td><td colspan="2">Highlight reports to Quality, Safety and Performance committee.
Divisional reporting structure – VCC, WBS, SMTL, NWIS & Clinical Engineering C&V</td></tr>
<tr><td>Contact:
Claire Power, MDG Admin Support Officer</td><td>Date ToR Last Revised

06/08/20</td><td>Next Review Date

Aug 21</td></tr>
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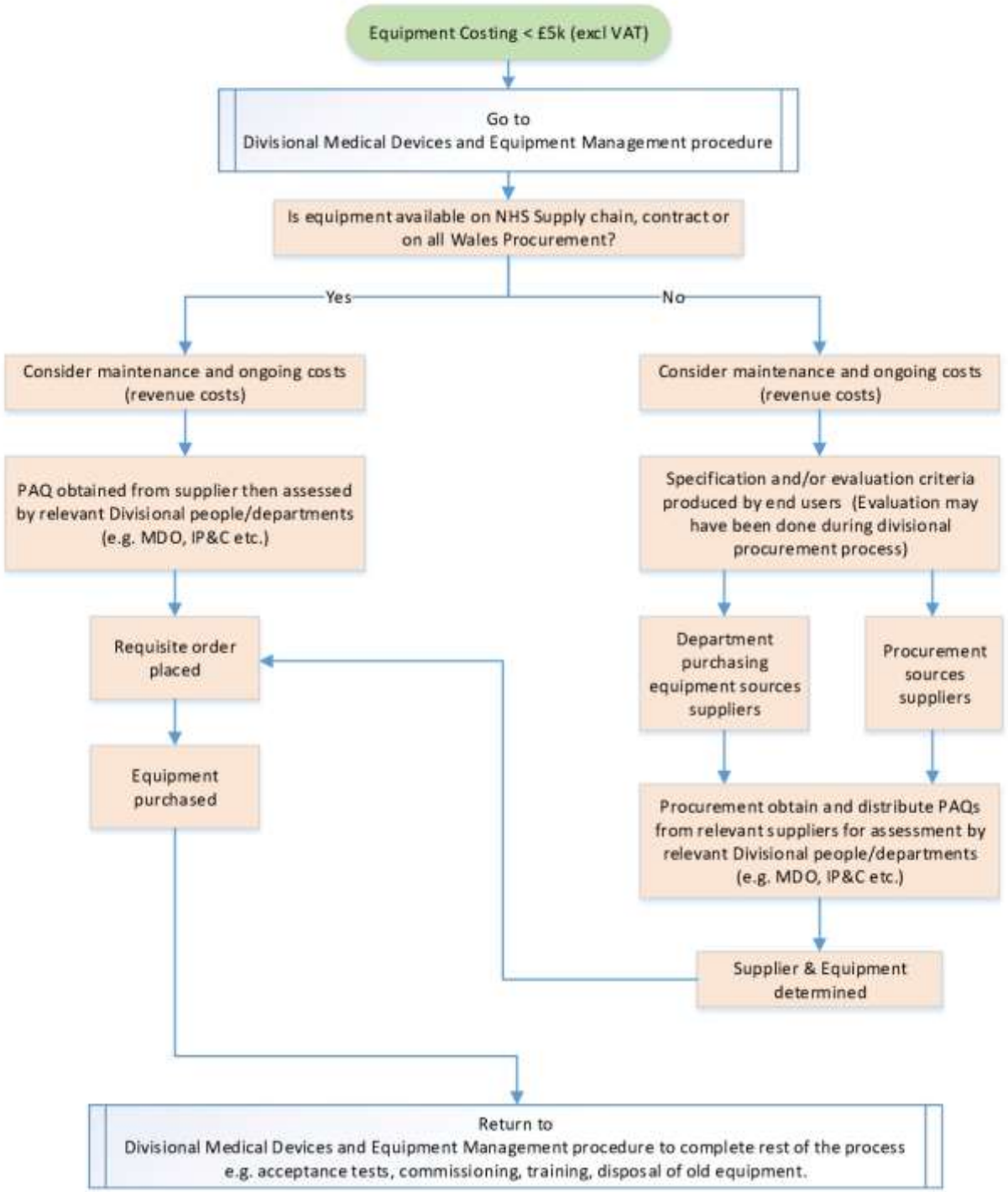
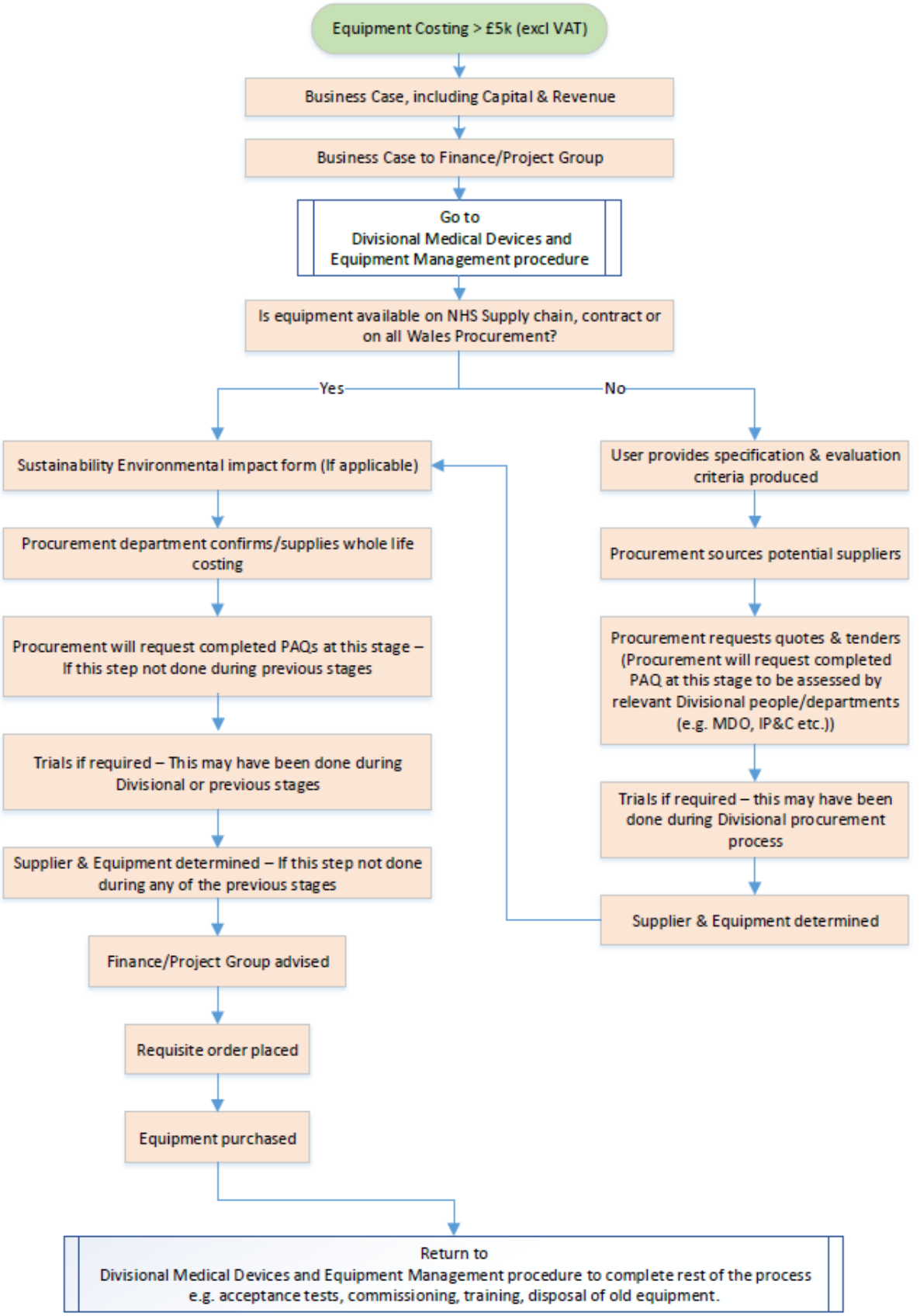
Trust Medical Devices and Equipment Procurement Flowchart

Appendix 2



Trust Medical Devices and Equipment Procurement Flowchart

Appendix 3



Appendix 4

Single-use and multiple-use of Medical Devices

Revision 0.7 01/10/2019

Mike Simmons[2], Pete Phillips[3], & Matthew Alderman[4]

Introduction

Convenience, difficulty with cleaning, and logistics have all resulted in a move from traditional reusable devices to single-use devices in some areas of the Health Service.

The All Wales decontamination and sterilization advisory group have been asked on a number of occasions to provide advice regarding single use items. The questions are generally:

- Does single-use imply single use within a determined period of time on more than one patient?
- Can the device be used more than once on a single patient?

This document is intended to guide Welsh NHS users when faced with these questions.

Single-use labelling and legislation

This section deals with interpretation of the labelling and the medical device legislation.

The MHRA provide some useful guidance documents on single-use medical devices.

MHRA Single-use medical devices document:

> *A device designated as 'single-use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.*

MHRA leaflet on single use devices:

> ***What does single-use mean?***
> *Do not reuse. A single-use device is used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.*

The Medical Device Regulations (EU 2017/745, April 2017) (MDR) define single-use as follows, which is now consistent with the MHRA definitions above:

> *'single-use device' means a device that is intended to be used on one individual during a single procedure;*

Previously the Medical Device Directive (2007-47-EC) (MDD) stated:

> *'single use device' means a device intended to be used once only for a single patient.*

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2 *Lead Clinical Microbiologist, Public Health Wales Microbiology, Carmarthen, Chair of the All Wales decontamination and sterilization advisory group.*
3 *Director, Surgical Materials Testing Laboratory, NWSSP, Princess of Wales Hospital, Bridgend.*
4 *Operations Manager, Surgical Materials Testing Laboratory, NWSSP, Princess of Wales Hospital, Bridgend*

The MHRA appear to concentrate on the reprocessing element of single-use – i.e. all of their definitions mention reuse linked to reprocessing. It is not clear from these documents whether a single *procedure* encompasses the act of using the device for multiple actions within the same procedure.

Questions

Q1: Can a single use device be used for one episode of care on more than one patient.

The answer to this question is straightforward – No.

All of the documents above are very clear that a single use device must not be used on more than one patient.

Q2: Can a single use device be used more than once on a single patient?

This is a more complex question to answer. First of all we should look at the manufacturers' instructions.

Manufacturers' instructions

The first element which requires clarification is what the manufacturers say about their device in the Instructions for Use (IFUs) i.e., what claims or instructions do they make/provide?

The MDD states:

> *As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.*
>
> *Instructions for use must be included in the packaging for every device.*
>
> ***By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.***

The MDR states:

> *23.1. General requirements regarding the information supplied by the manufacturer*
>
> *Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website....*
>
> *…*
>
> *(d) Instructions for use shall be provided together with devices.*
>
> ***By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section.***

The last sentence is, of course, subjective – who decides whether you need instructions to use the device safely? This means that many medical devices, appropriately CE marked to the MDD or MDR, may not have instructions for use.

If instructions are included, users should check whether the IFUs specifically mention what single-use

means in the context of the device described, or whether they do not make reference to this at all. For example, do they specifically state that the device may be used multiple times during a single episode of patient care?

Some devices will be labelled with the phrases 'disposable' or 'for single patient use', which for some devices is a more helpful term than 'single-use', although as discussed below, the NHS has a wide interpretation of what 'single-use' actually means. **If the IFUs make clear recommendations, then they should be followed.** An organisation who wishes to ignore the IFUs would probably be liable in the case of litigation, and therefore should deal with the matter through their local risk management and governance systems.

If the IFUs don't help, we need to look elsewhere for an answer.

How is 'single use' interpreted for other devices?

A sensible interpretation may be that we should look at this in the same way that a single use scalpel would be used multiple times in an operation by a surgeon – we would not expect the surgeon to use the scalpel for a single incision and then discard it.

The MDD appears to be less open to interpretation, using the phrase

> "*used once only for a single patient*",

which, if interpreted strictly, could mean any single-use device should be used for a single action and then disposed of. Clearly this is not happening in theatres with scalpels, gloves, gowns and other similar medical devices.

The MDR language is more akin to the MHRA documents,

> "*used on one individual during a single procedure".*

Thus it appears we have an accepted interpretation of single-use already – surgeons' gloves are not changed after every action in theatre, and scalpels will be used for more than a single incision, and both of these usage patterns accord with the principle of a "single procedure" (which is not actually defined in the MDR, so is open to interpretation). Thus, the 'use' appears to be accepted as covering multiple actions on the same patient within a defined period.

This would also make sense for the example of a patient having oxygen therapy through a face mask where they want a drink, and who removes the mask from their face and then replaces it after drinking. This is all clearly part of a single procedure even though it has been interrupted for the drink, and therefore there would be no need for the face mask to be replaced.

This appears to answer our question – if we consider a "**single procedure**" to be a series of consecutive actions on a single patient within a short or defined time period, then it is probably acceptable to use the device multiple times. We should, however, consider the device itself, and whether we are introducing any risks by using it for more than a single action.

Where are the risks?

Another way of approaching this is to try to identify the potential risks.

If we accept that multiple actions on a single patient is, in principle, acceptable for certain single-use devices, then the only other issues to be dealt with are whether the multiple actions cause a problem for the patient, for the member of staff, or for the device or its intended actions.

Consideration should be given to:

1. **Infection risk** – for example, does normal clinical handling compromise the device in use? For example:
    - In some theatres, gloves are changed **during** the operation (intra-operatively), as

there is some evidence that the longer gloves are used, the more likely they will develop pinholes, exposing patient and surgeon to an increased risk. This decision is usually a local one, agreed as part of a local policy.

    - How long is it acceptable to use a face mask for before it becomes unhygienic?

2. **Mechanical/performance risks**: for example, will the device degrade in some manner after multiple actions? For example:
    - Cutting devices may become gradually blunter after each action, and a decision may be made to limit the number of actions, or the surgeon may just stop using the device when it is no longer performing acceptably.
    - Biopsy guns may be designed to take multiple samples, but may cause additional pain/discomfort to the patient after a certain number of uses, and it may be decided to limit the number of samples which are taken with each gun.

Many of these decisions are already being made on a pragmatic basis without formal assessments. It may therefore be helpful to think of a similar type of procedure and/or device, and whether devices are used for multiple actions within those procedures.

Conclusion

When trying to decide whether a medical device can be used for multiple actions during a single procedure on a single patient, it can be useful to take account of the following:

- Check whether the instructions for use (IFUs) for the medical device limit the use of the device for a single action on the single patient, or do they give clear instructions.
- Consider whether there are similar devices or procedures where multiple actions are acceptable or not acceptable, and use this to guide your analyses.
- Consider whether there is evidence of performance degradation, contamination/infection or other risks to the user, device, or staff related to multiple actions on a single patient.

Following this process should help decide whether a single-use device can or cannot be used for multiple actions on a single patient, during a single procedure.

Bibliography

1. "Single-use medical devices: implications and consequences of reuse", MHRA, Dec 2018.
2. "Medical Device Directive", Council Directive 93/42/EEC, 14 June 1993, amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007.
3. "Medical Device Regulation", Council Regulation 2017/745 of 5 April 2017.
4. "Single-use medical devices", MHRA leaflet, Dec 2013.

If you have any thoughts/comments on this document please email Pete Phillips, Director, Surgical Materials Testing Laboratory (pete@smtl.co.uk).