Shropshire Community Health NHS Trust

Management of Medical Devices Policy

Document Details	
Title	Management of Medical Devices Policy
Trust Ref No	1536
Local Ref (optional)	NA
Main points the document covers	Management, Maintenance and Training for medical devices & equipment.
Who is the document aimed at?	All clinical and other staff who use medical devices and their managers
Author	Medical Devices Management Group
Approval process	
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Amendments History		
No	Date	Amendment
1	July 2015	Policy updated include role of groups and local recording arrangements
2	November 18	Review and minor update to roles and responsibility
3	July 2021	Review and update to include flowcharts
4	August 2022	Review and update to all sections
5	April 2023	Review and update to all sections
6	October 2024	Revised strategy and connected devices sections

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1. Introduction

This policy ensures that the Medical Devices within the Trust are:

- suitable for its intended purpose
- purchased following procurement processes that include clinical review, infection prevention and control
- used in line with the manufacturer's instructions
- used only by a competent member of Shropshire Community Health NHS Trust staff, a patient or carer who has received training in the use of the device
- traceable, where possible
- maintained in a safe and reliable condition, with associated records kept
- replaced having regard to the procedures and guidance contained in this policy
- disposed of at the end of their useful life

2. Overview

The policy covers the life-cycle management of medical devices:

- management of medical devices
- training
- maintenance and repair
- reporting adverse incidents
- decontamination
- decommissioning and disposal

3. Definition of a Medical Device

In simple terms a *medical device is* any instrument, apparatus, appliance material or healthcare product (re-usable or single use), excluding drugs used for, or by, a patient or service user.

MHRA defines a *medical device* as,
'... an instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body'

Medical devices can vary widely in complexity from simple devices such as a hypodermic needle, an oral thermometer, a disposable glove to more advanced devices such as defibrillators, x-ray machines and biopsy guns (and includes any software applications necessary for the device to function).

A medical device is any product used in the:

- diagnosis, prevention, monitoring and treatment of disease or disability
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy, or of a physiological process
- control of conception

4. Scope of Policy

This Policy applies to all staff employed by Shropshire Community Health NHS Trust who have access to and are required to use medical devices within their role. This includes students, patients, family or their representatives or carers.

The policy applies to all Medical Devices used by Shropshire Community Health NHS Trust.

5. Strategy

The SCHT strategy in relation to medical devices is to equip the Trust with innovative and secure, connected medical devices that empower better patient care, improve healthcare efficiency, and ensure long-term sustainability.

Strategic Goals:

Enhanced Patient Care:

- Facilitate faster diagnoses and more effective treatment plans through advanced diagnostics and remote monitoring.
- Improve patient experience by enabling remote consultations, self-management tools, and personalised care pathways.
- Prioritise devices that address unmet clinical needs and improve health outcomes.

Optimised Healthcare Delivery:

- Streamline workflows through data integration and interoperability across devices and healthcare systems.
- Reduce hospital readmissions through remote patient monitoring and preventative care.
- Enhance workforce productivity by automating administrative tasks and providing real-time data for informed decision-making.

Value for Money:

- Implement a robust cost-benefit analysis framework that considers total cost of ownership alongside upfront costs.
- Encourage innovation through partnerships with MedTech companies to develop cost-effective and clinically valuable devices.
- Standardise procurement processes, through the Integrated Care System, to ensure best value and efficient resource allocation.

Cybersecurity and Data Privacy:

- Prioritise robust cybersecurity measures to protect patient data and device functionality from cyberattacks.
- Ensure compliance with all relevant data privacy regulations (e.g., GDPR, NHS Data Security and Protection Toolkit).
- Foster a culture of cybersecurity awareness among staff through ongoing training and education.

Future-Proofing the NHS:

- Invest in devices with open architecture and modular designs to facilitate future integrations and upgrades.
- Encourage the adoption of digital health standards to ensure interoperability across different devices and systems.
- Build a skilled workforce with expertise in managing and utilising connected medical devices.

Implementation Strategies:

Collaborative Governance: Establish Groups/Meetings with representatives from Clinicians, Digital, Procurement and support services to oversee strategy development and implementation..

Needs Assessment: Conduct regular evaluations to identify unmet clinical needs and technological advancements that can benefit patient care.

Procurement Framework: Develop a standardised procurement process for connected medical devices that prioritises value, interoperability, cybersecurity, and futureproofing.

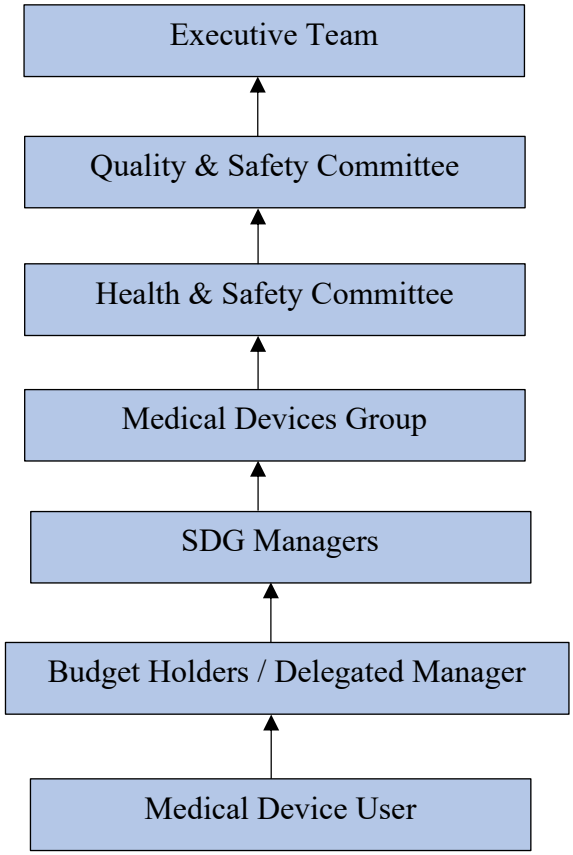
Training and Support: Provide comprehensive training programs for clinical staff on using connected devices securely and effectively. This includes cybersecurity awareness training.

Cybersecurity Infrastructure: Invest in robust cybersecurity infrastructure to protect NHS networks and connected devices from cyberattacks.

Innovation Partnerships: Foster collaboration with MedTech companies to develop innovative and cost-effective solutions that address specific Trust needs.

6. Management of Medical Devices

6.1. Roles & Responsibilities



The **Chief Executive** has overall responsibility to ensure all users of Medical Devices deployed under their auspices are competent to use the devices proficiently whilst minimising risk to patients, staff, visitors and the environment.

Responsibility for ensuring the efficient and effective planning, operation, management and disposal of medical devices and equipment has been delegated to the **Director of Governance.**

To provide assurance on compliance with this policy, **Divisional Clinical Managers** have responsibility:

- for ensuring training for equipment (including medical devices)
- for ensuring their department is equipped to carry out its function
- for ensuring staff members are trained to use and care for the medical devices they require to perform their duties
- to review and monitor medical device management within their Group
- to report any significant incidents or process failures through Datix system
- to review medical device incidents and implementing remedial actions where deficiencies have been identified.

- Continuity plans are maintained for all devices – see also Major Incident Policy.

The **Line/Unit/Ward Manager** who is the budget holder must:

- be the asset owner for all Medical Devices in their area
- ensure that they are aware of all equipment allocated to their department/ward
- ensure that their area has an up-to-date inventory of all equipment and devices
- Agree which staff are authorised to use the equipment identified on the inventory
- Establish a process for monitoring and recording staff competency in their area of responsibility
- Ensure staff are competent to use the medical devices within their area of responsibility
- Ensure that when they receive any new registered piece of equipment a user manual must be supplied and that the instructions are kept available to users

The Trust requires all staff to adhere to the following principles before using any medical device. The **Medical Device User** will**:**

- always visually check the piece of equipment for cleanliness and signs of damage and correct settings before each use
- ensure equipment has been serviced by checking service label
- Carry out user maintenance on the medical devices that they use
- Know how to safely and effectively operate the medical devices that they need to use to perform their duties
- Not use equipment they have not been trained on unless they are using the equipment under direct supervision of another competent individual and a risk assessment has been made
- if the equipment requires consumables, ensure they are correct, for the device and for its current settings and within expiry date
- not be afraid to ask for advice
- ensure that all equipment is thoroughly decontaminated in line with Infection Prevention and Control, cleaning schedules and manufacture instructions before and after use.
- Used within an appropriate environment
- Know how to report faulty medical devices
- Know how to report adverse events concerning medical devices

The **Procurement Team** will ensure that:

- Competitive financial tenders are obtained according to the Board's standing financial instructions and NHS regulations
- Procurement advice is available to all procurement exercises
- Best value for money and clinical outcome is obtained in the procurement of medical devices

The **Director for Infection Prevention and Control (DIPC)** will:

- Ensure that advice regarding appropriate decontamination and disposal of medical devices is available to purchasers and users
- Ensure that policies and procedures on decontamination and disposal of medical devices are appropriate and up to date

6.2. Medical Device Management supporting functions

Medical Devices Safety Officer (MDSO)

Within the Governance function, the Trust Medical Device Safety Officer co-ordinates the distribution of, and response to any received safety alert (National Patient Safety Alerts, MHRA safety messages and manufacturers' Field Safety Notices)

The Officer will undertake audits to assess the effectiveness of this policy. The MDSO will have oversight of all medical device related incidents reported via Datix, to review and determine whether MHRA reporting has been completed appropriately. The MDSO will provide a summary of incidents to the Medical Devices Group for sharing / learning.

Health and Safety Advisor / CAS Liaison Officer

The Health and Safety Advisor will support with the creation of business continuity plans and deputise for the MDSO with regards to their responsibility to distribute and follow up on alerts, in the absence of the MDSO.

It is the responsibility of the CAS Liaison Officer to acknowledge receipt of all safety alerts including Field Safety Notices when received within the Trust, disseminate as appropriate and within identified timescales and monitor responses ensuring that managers are aware of any recommendations required.

Medical Devices Management Group (MDMG)

The Group meets monthly to review the suitability and application of the Medical Devices Management Policy. The Group's role is to:

- fulfil their Terms of Reference – membership is in line with the ToR
- improve communication about medical devices within the organisation
- ensure involvement of clinicians, technical staff and users in relation to any proposed changes, including configuration settings relating to devices, where appropriate
- define persons responsible for device management tasks, training and safe device operation
- define and review the device management policy
- review incidents including governance issues relating to medical device management
- Support Service Leads and Local Managers with their Planned Preventative Maintenance and Replacement Programmes for Medical Devices
- Support Service Leads and Local Managers with training and competency review
- Approve new equipment requests prior to capital funding allocation and procurement
- Approving requests to modify devices or changes to device use.

Medical Engineering Services (MES)

As per the Service Level Agreement with the Trust, MES will oversee the general provision and requirements for Medical Devices requiring servicing, repair, and replacement
As per the Service level agreement with the Trust, MES will support the provision of training in the use of medical devices. This is arranged in co-ordination with the Trust's Clinical Education Team and Service Leads.

The responsibilities will include:

- Improving lines of communication between users and the Medical Engineering department i.e. the user / technical department interface.
- Carrying out customer satisfaction surveys.
- Liaising with external suppliers / contractors, users and appropriate professional staff, i.e. Infection Control and the MDSO.
- Overseeing the overall day-to-day function of the Medical Engineering department technical activities.
- Attending meetings which have related responsibilities or discussions with regards to medical devices
- Record all Trust held medical device assets via a database that is available (either live or via routine data export) for the Trust to integrate.
- Record high level information relating to the cyber risk of each device on the asset register.
- Record all interactions with the maintenance of medical devices, including, but not limited to, maintenance / servicing, repairs and software maintenance.
- Undertake urgent and routine software patching in line with CAS Alerts and routine maintenance respectively.
- Overseeing the full life cycle of medical equipment from its acquisition to decommissioning.
- Ensuring regulatory compliance for medical devices management.
- Reporting on a bi-monthly basis to the Medical Device Group with regards to performance.
- Report KPI's to the Medical Device Group.
- Report information that will assist with the Trust's device replacement programme, including, but not limited to, device age and device reliability.
- Accountability for the removal of sensitive data from devices before removal from service, escalating to the internal IT team where specialist knowledge is required.

The Trust appointed MESP will have a 'cradle to grave' approach to the way medical equipment is managed. The MESP will carry out the following procedures during the life of the medical device:

- Advise and / or evaluate proposed purchases.
- Acceptance test newly delivered devices.
- Issue unique equipment asset numbers and enter them onto a suitable equipment management database.
- Manage the equipment database to include changes in equipment additions and deletions (acceptances and retirements).
- Planned and remedial maintenance. A Planned Preventive Maintenance (PPM) schedule will be produced by the MESP each year and PPMs will be completed each month. Maintenance, including software updates, will be carried out as per the manufacturers instruction and at the frequency required and recorded on the equipment database. Planned preventative maintenance should be in accordance with the Table 8.3 checklist in the MHRA guidance 'Managing Medical Devices' January 2021.
- Make sure devices are adequately risk assessed and tested before being put back into use following maintenance/repair.
- Contract appraisal and monitoring of third party contractors obligations.
- Modifications and / or safety checks as required by the MHRA notices or equipment manufacturer.
- Ensure records of instructions are maintained and monitor any changes to the instructions for a device, ensuring that this is communicated to those using the device and appropriate training is

provided.
- Assist Ward/Department Manager with incident reports involving medical devices.
- Monitor equipment utilisation and if under-utilised consider redeployment
- Decommission / condemnation / retirement and disposal of equipment in accordance with equipment lifecycle management.

MESP, with ward / department managers, will risk assess all medical devices held on the register in accordance with the Trust risk assessment policy, and assign them with a risk level as appropriate. This will take into account the likelihood and consequence of failures giving an overall score for each device as well as the operational complexity of a device. Devices of significant risk will be entered into the Trust risk register. The information will be made freely available to Units/Service managers when required. The information will be used as part of a replacement policy.

Digital Services

Where a connected device automates the processes required to connect, store, transmit / delete data as required, Digital Services will take accountability for ensuring that these processes are working reliably.

Digital Services will offer subject matter specialist support when the Trust determines that a preferred medical device purchase involves introducing a device that connects to either the Trust internal network or the internet.

Support the Clinical Safety Officer and asset owner / potential asset owner to complete a risk assessment in line with the principles set out in Guidance on protecting connected medical devices - NHS England Digital

Assist or advise in setting up connected medical devices to ensure the device can reliably transmit data as required; this may include setting devices up with limited memory to back up data then delete, ensuring there is available memory for the next device use.

Will receive Medical Device Pre-purchase questionnaires and partake in decision making that allows or denies the purchase of items that require this assessment.

React to issues relating to data transmission of connected devices.

Clinical Safety Officer - CSO

Develop and implement clinical risk management activities that support the safe development, introduction and deployment of clinical digital systems.

Responsibilities of Medical Device Users

The User of the medical device has delegated responsibility for the following:

- No individual shall bring any medical device into the Trust under their own auspices without prior approval by the Medical Devices Group.
- No individual shall modify or use a medical device other than in accordance with manufacturer's instructions without a robust risk assessment **and prior approval**.
- Obtaining informed consent from the patient if a modified device is used.
- Undergone theoretical and practical training of medical devices used and kept their own record of training.
- Not using equipment for which they are not trained and competent.
- Having necessary proof of competence from accredited sources in the use of medical devices
- Equipment selected is suitable for the purpose required.
- Correct supplies (e.g. giving sets are selected for use with particular device).
- Devices are cleaned after use according to manufacturer's instructions and Trust Infection Prevention and Control Policy.
- Devices are appropriately stored in accordance with the manufacturer's instructions.
- Any incidents are reported via DATIX incident reporting module and in line with the Trust Incident Policy and to the MDSO, considering whether a yellow card escalation is required.

- Malfunctioning devices are removed from use immediately and labelled OUT OF USE / segregated from operational equipment and appropriately reported with clear, precise details of malfunction.
- Assessment of patient as to whether there is risk of the patient tampering with the device and tamper-proofing the device as appropriate. The patient's ability to use the device in accordance with manufacturer's instruction (taking into account any barriers to understanding or use) must also be assessed.
- When a device is in use it is regularly checked in accordance with manufacturer's instructions and be able to set any controls correctly.
- Able to recognise and, if competent, rectify malfunctions. If the device requires removal from service, know who to contact for remedial action.
- Able to assemble the device following cleaning and fit appropriate accessories when trained and competent to do so
- Be aware of differences between models of a given device type, where these affect safety and / or function.
- To be aware of any local policies and procedures appertaining to medical devices.
- Be aware of risks associated with device IT connectivity and mitigations that are required to ensure the safety of the patient, the Trust network and the device.
- Be aware of Trust and Ward/Department business continuity plans.
- Users of connected devices must be aware of their responsibilities as Information Asset Administrator, as described in the Information Governance Policy / Handbook.

6.3. Medical Device Management - Data Security and Protection Compliance

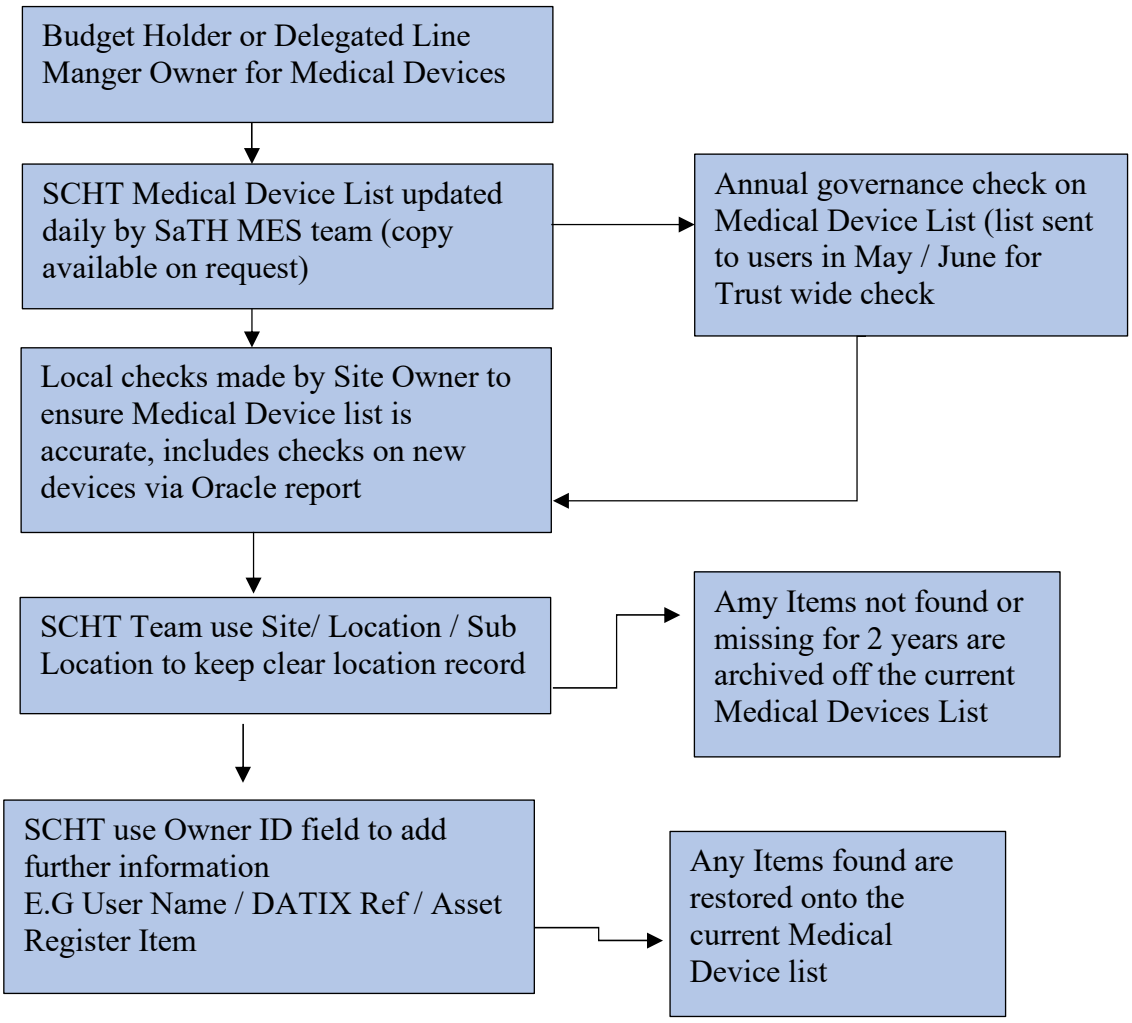
The organisation will comply with the UK General Data Protection Regulation (GDPR) by ensuring that any data processing activity that includes personal confidential data (PCD) is assessed against the Data Security and Protection Toolkit (DSPT). The Information Asset Owner (IAO), this is likely to be the same as the Medical Device Asset Owner, is responsible for ensuring that medical devices and their Users comply with the 10 Standards set out in the Data Security and Protection Toolkit (dsptoolkit.nhs.uk); and that evidence is documented and made available to the Data Security and Protection Assurance Group. The roles and responsibilities of the IAO are set out in the Trust's Information Risk Policy.

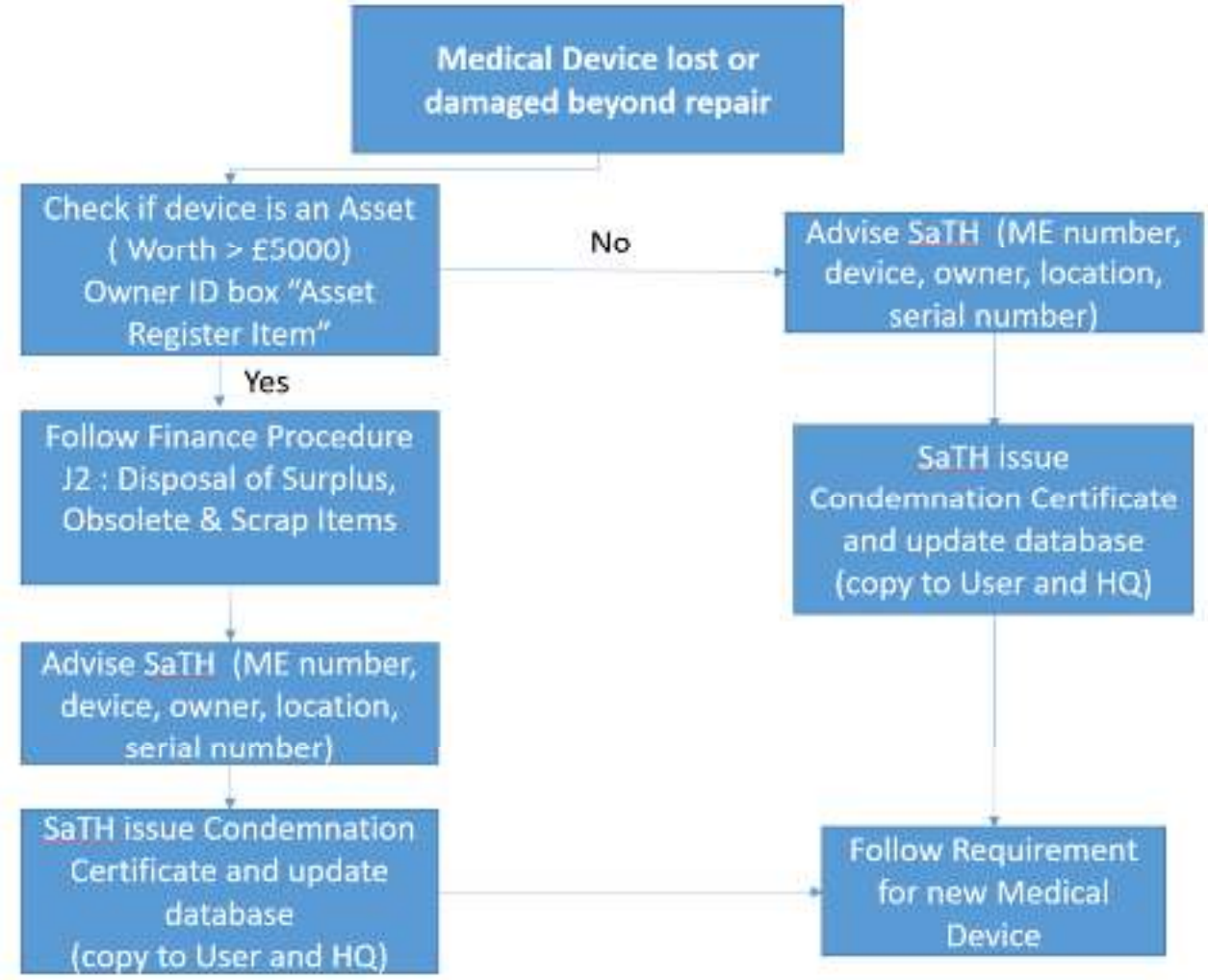
7. Ownership of Medical Devices

The MES database is the inventory of Medical Devices in use across the Trust. This database is updated daily by the MES Technologists. An updated copy of the inventory can be obtained on request by SCHT.

It is the responsibility of the Budget Holder or delegated Line Manager to ensure that the equipment database is an accurate representation of the equipment in use in their area.

There must be an annual review, to consist of the following:
- Ensure the equipment is within the department
- Ensure the entry details are correct
- Ensuring the best use of the descriptor fields (Site / Location / Sub-location / Owner ID)
- Ensure the device has been maintained
- Ensure that the authorisation and training information is up to date


Budget Holder or Delegated Line Manger Owner for Medical Devices
SCHT Medical Device List updated daily by SaTH MES team (copy available on request)
Annual governance check on Medical Device List (list sent to users in May / June for Trust wide check
Local checks made by Site Owner to ensure Medical Device list is accurate, includes checks on new devices via Oracle report
SCHT Team use Site/ Location / Sub Location to keep clear location record
Amy Items not found or missing for 2 years are archived off the current Medical Devices List
SCHT use Owner ID field to add further information
E.G User Name / DATIX Ref / Asset Register Item
Any Items found are restored onto the current Medical Device list



In addition:

For devices that are owned by Shropshire Community Health NHS Trust and loaned to end users in the community, the responsibility for ensuring that the device is delivered and is safe to use is our responsibility. Incident reporting to MHRA is also the responsibility of Shropshire Community Health NHS Trust. For devices that are owned and managed by a commercial supplier (such as enteral feeding pumps), the manufacturer's pre-dispatch tests in combination with end user pre-use checks will assure safety. Record keeping is the responsibility of the manufacturer with input from the end user as appropriate. Incident reporting to the MHRA is the responsibility of the manufacturer who must also inform the healthcare provider.

Services must put a robust process in place for the return of medical devices, accessories and equipment which have been loaned to patients.

7.1. General Rules for the Use of Medical Devices by Local Teams

- Medical devices must not be used if the 'next test due' date has been exceeded or if there is any doubt regarding the current service status of the device. MES Medical Technologists apply a sticker, as shown below, to show when the next test is due:
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- All medical devices will display a ‘Next Test Due’ or similar label which make it clear when the device should be tested
- Some medical devices are not subject to routine testing and are designated ‘repair only’.
- All devices should display an ‘ME’ number or other identification number (typically for older devices)
- The ME number should be noted and quoted in any correspondence with MES
- It is the responsibility of the end user to ensure equipment is safe to use, which includes ensuring it is not overdue any maintenance.
- Many locations are subject to a planned maintenance visit each year
- Devices can be sent to MES for service by using the transport service, if the device was unavailable during one of the planned site visits

7.2. Prescribing Medical Devices

Prescription of equipment including long-term loan to an individual user for their use only, is only to be undertaken by qualified and experienced staff.

Details of end users must be maintained, and equipment monitored to ensure that it is safe and maintained in line with this policy. There must be provision for training and contact details in the case of difficulties. The Trust remains accountable for collecting these items when they are no longer needed.

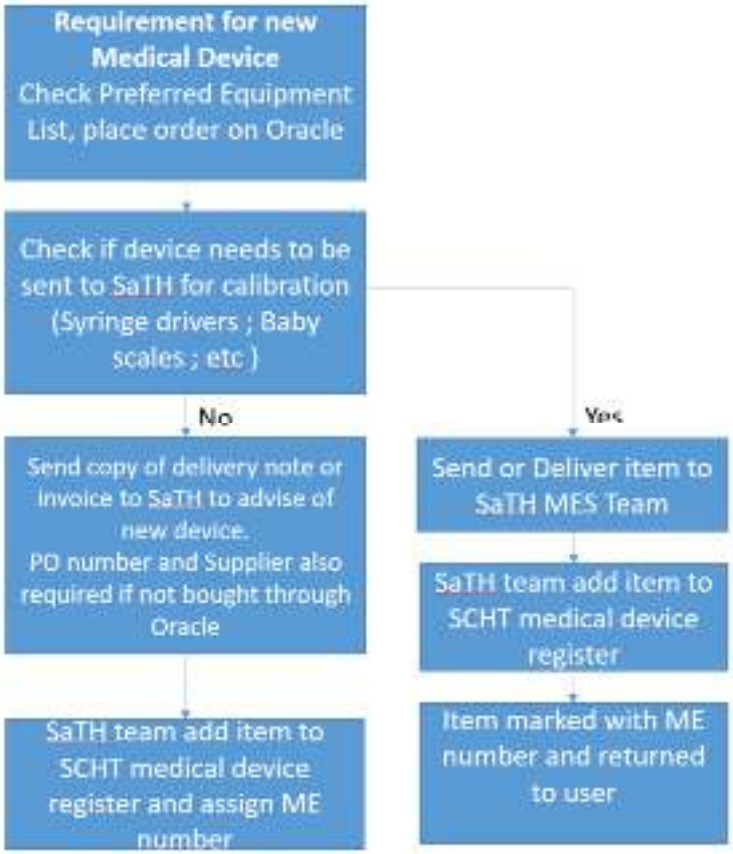
Some device management will transfer either to the individual end user or to a healthcare worker or other carer.

It is essential to be clear about where responsibility lies for the management and must be included in a letter to the patient or appointed representative.

This includes:

- decontamination procedures
- maintenance and associated record keeping
- availability of up-to-date instructions and other information, and passing to end users, where appropriate
- period and type of use
- device identification and traceability
- contact details (users and healthcare establishment)

8. Acquiring appropriate devices



8.1. Selection of Medical Devices

The Trust aims to minimise the number of different suppliers and model types of devices in use. MES are able to provide advice on suitable models and suppliers. Medical Devices must be purchased from regular suppliers through the Oracle procurement system.
Under no circumstances must medical equipment be purchased from third-party suppliers (for example, Amazon) without approval from the Medical Devices Management Group.

The current medical device inventory shows the model description in use, and the supplier name.

For a device at revenue level (<£5,000 Inc. VAT) it will be the responsibility of the budget holder.

The forum for Capital Medical equipment replacement (>£5,000 Inc. VAT) is via Capital Group.

8.2. Acceptance of New Medical Devices

All new Medical Devices will be subject to a formal acceptance and commissioning procedure in line with MHRA guidance. This includes whether it is leased, donated, hired or presented as a gift.

All medical devices purchased will be commissioned by MES.

MES, on commissioning will enter the equipment onto their asset database.

A nominated Trust member of staff and a trained Bio-Medical Engineer from the MESP will ensure that where appropriate: -

- Check the device matches the purchase order detail or tender specification and all necessary instructions and documentation is provided. If instructions for use of the device are inadequate then consideration should be made as to whether supplementary instructions are required. Any shortcomings in the instructions should be reported to the manufacturer for correction and to the MHRA as an adverse incident
- Make sure that delivery checks are carried out in accordance with Table 5.1 of MHRA guidance 'Managing Medical Devices' January 2021.
- A functional/acceptance test is conducted in accordance with Table 5.2 of the MHRA guidance 'Managing Medical Devices' January 2021.
- Safety checks are conducted and safety labels are in place on the device.
- Make sure test equipment for devices are working correctly and adequately demonstrate device safety, ensuring that they have the adequate training and experience to be able to satisfactorily test the equipment.
- Keep records of the delivery inspection, individual device or batch identifier and any safety or functional tests and make sure the name of the engineer who carried out the activities is recorded.
- The item is accepted into service by the MESP.
- Prior to first use, controls are set to standard values. In the case of IVDs it is vital that adequate user verification is carried out so any results obtained from the device are accurate.
- Conduct a risk assessment before first use where appropriate and in accordance with Section 5.3 of the MHRA guidance 'Managing Medical Devices' January 2021.
- Staff are properly trained in the use of the item and training recorded.
- Manufacturers interface / instructions are adhered to and are readily available to those who will be using the device.
- Make sure the device is appropriately installed in accordance with the manufacturers instructions and details of the device and instructions are entered into the appropriate device monitoring and tracking systems.
- Make sure a stock of suitable spare parts for devices are readily available and alternative devices are available for when a device is taken out of service for maintenance/repair.
- The device is adequately decontaminated before use on a patient.
- Where the device is reusable, maintenance has been scheduled and lifecycle recorded.
- Medical devices which have come to the end of their loan period are removed from use and collected by the manufacturer.

8.3. Replacement of Equipment

Department managers must formulate replacement programmes on devices in order to reduce the risk to the Trust via Risk Registers. The forum for Capital Medical equipment replacement is through Capital Management Group following approval of the Medical Devices Group or NEP. No bids for Capital monies will be considered without a Trust risk register entry.

Replacement of Devices will meet at least one of the following criteria:

- Recalled by manufacturer
- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliable through service history
- Clinically or technically obsolete
- Spare parts no longer available
- More cost-effective or clinically effective devices have become available
- Unable to be cleaned effectively prior to disinfection and/or sterilisation
- Other reasons

MESP may withdraw devices (Capital or Revenue), in consultation with the device owner and in conjunction with Finance as necessary, from service by issuing a 'Condemnation Certificate' stating the reason against the above criteria.

If a device meets any of the above criteria it will be decommissioned appropriately by the MESP in line with the guidance of MHRA Managing Medical Devices, retired on the equipment management database and removed from the PPM schedule.

Devices which are decommissioned / condemned will be either transferred to a Trust approved auctioneer or waste disposal agent in compliance of all National and legal requirements for the safe environmental disposal thereof in accordance with the Trust's waste disposal policy which will take into consideration the Waste Electrical and Electronic regulations (WEEE). Although the equipment will be removed from the Trust's asset register, service history will be retained by MESP.

Any patient identifiable data stored on a device should be certified as securely erased to an appropriate standard prior to disposal of the device. Data on any device should be forensically unrecoverable. MESP will take overall accountability for this process, escalating to the Digital Department where specialist knowledge is required.

To complete the process of replacement follow the steps laid out in Appendix 3.

9. Training and Information

9.1. Authorisation to Use Medical Devices

The Unit/Line or Ward Manager is responsible for identifying staff authorised to use medical devices. A record of individual staff members trained in the use of medical devices must be held by each department. Staff training level (number of staff trained as a percentage of staff who should be trained) must be recorded and monitored.

Only staff that have been trained and designated as competent may use that medical device.

Medical Devices on long term loan to be used in clinical service

The lender (SDG or clinical service) will provide the device and training. Purchase of consumables will be the responsibility of the clinical service. Maintenance arrangement will be agreed before the beginning of the loan period. The lender will remove the medical device immediately at the agreed end of loan date. When a medical device is issued to a patient or carer, responsibility for its safe use will transfer either to the individual or to a healthcare worker or carer.

MES will remain responsible for:

- maintenance and records
- availability of up-to-date user instructions

The relevant SDG or clinical service will remain responsible for:

- decontamination procedures
- information supplied to any discharged patients/users
- medical device identification
- passing on of manufacturer's user instructions to end users
- the users contact details

9.2. Medical Device Training

All staff must be competent in the use of the medical devices that they will be expected to use in the course of their work. They have a professional duty to ensure their own training and skills are up to date.

Training must encompass the operation of the medical device, user maintenance, cleaning and identification of faults. Staff must not attempt to use medical devices that they have not been trained to use unless under direct supervision of a competent staff member and following a risk assessment.

Managers must ensure that training is provided. Any user of a device must understand how the manufacturer intends the device/equipment to be used, and how it normally operates to be able to use it effectively and safely.

Training must include:

- to show end users how to use the device
- use of controls, displays, indicators, alarms etc.
- accessories and how they may increase or limit the use of the device
- requirements for maintenance and decontamination, including cleaning, in line with the manufacturer's instructions and relevant IPC policy
- troubleshooting, including potential issues including those identified in safety advice from the MHRA, manufacturers and other relevant bodies
- be able to recognise device defects or when a device is not working properly and know what to do
- understand the importance of reporting device-related adverse incidents

When a medical device is issued to a patient or carer, relevant training will be delivered by the relevant team so that they understand the intended use and normal functioning of the device in order to use it safely and effectively. Records must be kept of this training.

9.3. Training Records

Training records of medical devices must be kept by Managers that show users:

- know how to use the device safely
- can carry out routine checks and maintenance
- have been trained and had refresher training
- are confident and competent to use devices in their areas of work

9.4. Information about Medical Devices in Use

Unit/Line or Ward managers should ensure that they have instruction manuals/leaflets and that they are stored in a safe and easily accessible place available to all users.

10. Decontamination

Decontamination is the elimination of micro-organisms and other material which could otherwise be transferred to a susceptible site and cause infection. It is a collective term describing the three processes of cleaning, disinfection and sterilisation.

Consideration as to how devices are to be cleaned or decontaminated must be made before purchase of a Medical Device and consultation sought from the Trust Infection Prevention and Control Team and Medical Engineering Services. Items must not be purchased without clear cleaning and decontamination instructions.

Items subject to inspection, maintenance, repair or disposal must be decontaminated beforehand. Any loaned items being returned to a manufacturer or supplier must also be decontaminated following the manufacturers decontamination instructions.

Once decontamination has been completed, the items should be labelled accordingly using a green decontamination status label and a declaration of contamination status form/label completed, (if required). This should be readily accessible to the recipient of the device.
MES reserves the right to return a device if staff are not satisfied with the cleaning or disinfection process.

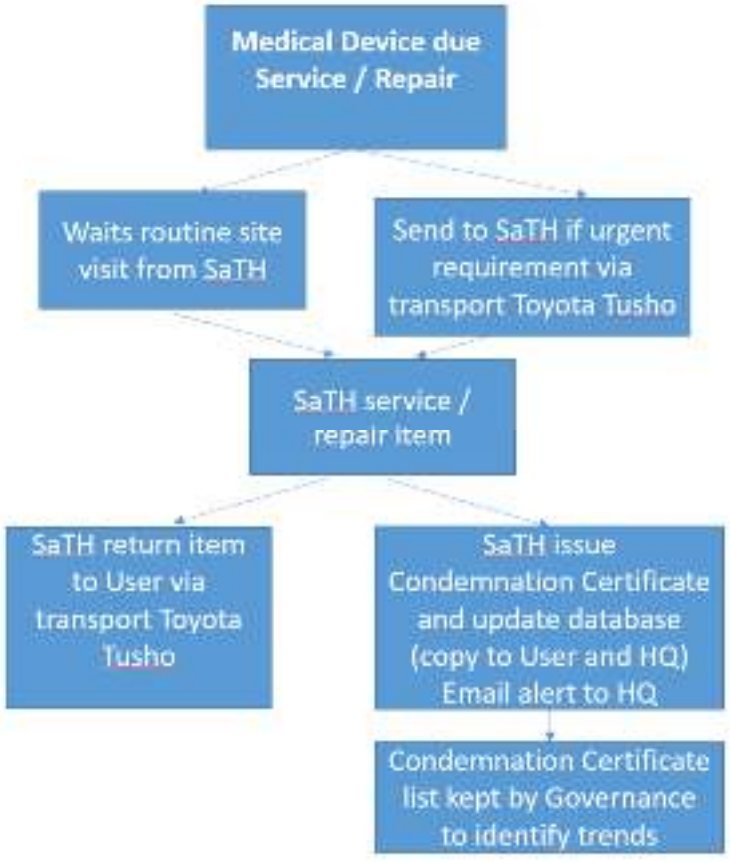
For Single Use Devices the Trust will adopt the appropriate MHRA guidance.

Refer to the Trust Infection, Prevention & Control Policy, and the specific decontamination policies which cover flexible endoscopes, reusable surgical and dental equipment.

11. Maintenance and Repair

The Trust has a service level agreement with Shropshire and Telford Hospitals (SaTH) MES for the maintenance and repair of medical devices.

All Medical Devices undergo regular performance and safety checks in line with the manufacturer's specifications. MES hold the Maintenance Record Cards which provide the relevant identification, type, history, and service history, and the annual schedule for Planned Preventive Maintenance (PPM).



11.1. Equipment Not Found on PPM visit

In the event of equipment not being found on the PPM visit, the database is marked "not found on PPM". The asset owner must be informed verbally on completion of the PPM Visit.

Any items not found or missing for two years are archived off the current Medical Device list. This is requested by the local site owner for the medical devices through the SaTH MES team.

11.2. Requirement for Service / Repair

Medical Devices which require repair are notified to MES and sent to the MES Workshop for assessment and repair:

- sath.medicalengineeringservices@nhs.net
- For Princess Royal Contact 01952 641222 ex 4260
- For Royal Shrewsbury Contact 01743 261000 ex 1149

For breakdowns/repairs, users must send equipment into the respective site Department via internal transport.

Ensure all relevant component parts are enclosed and a Decontamination status label is attached in compliance with Trust Policy.

Repairs are carried out, where possible, within 5 days, unless parts are unavailable. In these cases, the asset owner is notified of the reasons for the delay.

11.3. Decommissioning

In the event that a Medical Device is condemned following MES inspection then SCHT receive both an email and a condemnation certificate:

Asset Scrapped Information

The Asset ME008716 - MD300C2 - PULSE OXIMETER

Ownership SHROPSHIRE COMMUNITY TRUST - Value £250.000000

has just been removed from the RAM Asset Database.

A Decommissioning Certificate will follow for your records

This is a system generated message, please do not reply to this email

The MES asset database is updated, and the Maintenance Record Card/s are removed and stamped “Withdrawn from Service”, signed and dated.

The MDMG monitor items condemned using an excel report from MES that lists the assets condemned in the last 12 months to look for trends which may highlight issues with a device.

11.4. Record Keeping

MES keep a record of all medical devices for the Trust, which provides 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

- Where it was deployed and utilisation
- Scheduled maintenance
- Maintenance and repairs
- The end-of-life date

12. Decommissioning and Disposal

12.1. Disposal of Equipment/Devices

Medical Equipment with an MES asset number must be returned to the MES department for disposal in line with the guidance of MHRA Guidance.

Devices will be either transferred to a Trust approved auctioneer or waste disposal agent in compliance with all national and legal requirements for safe environmental disposal.

It is the responsibility of the asset owner to ensure all confidential/patient identifiable data is deleted from any device in accordance with the Trust's data protection Policy.

13. Reporting Adverse Incidents and Safety Alerts

For all incidents involving medical devices that occur within the Trust, in the first instance ensure that any patient and/or staff wellbeing and safety is not compromised, then immediately remove the item from use. The department manager must then be informed as soon as possible after the incident.

If the incident involves a number of devices, impacting service delivery, such as an incident affecting multiple connected devices, consider escalating via the Emergency Preparedness, Resilience and Response (EPRR) Policy as appropriate.

If an adverse incident occurs involving a medical device (including device failure at any stage), staff will report to the MHRA immediately and complete an online Datix Incident Reporting form.

Any reporting to the MHRA will be carried out by the Ward / Department Manager, with the assistance of the Trust's Medical Device Safety Officer.

The device(s) involved must be quarantined and labelled by the most senior member of staff at the scene of the incident and the incident reported to the Medical Device Safety Officer. If there is no further risk to patients, staff or visitors, then dials, indicators, switches and settings on the device will be recorded.

Where appropriate, all lines, giving sets, leads etc will be retained to assist in the investigation. MESP must be informed and the device removed for investigation and quarantined. MESP will produce an investigation report as appropriate detailing the serviceability of the device as per the manufacturers specifications.

This investigation report will be attached to the Trusts Datix – Risk Management Software ensuring there is feedback to the reporter / handler. MESP will keep a register of all reported incidents that involve medical devices and carry out a trend analysis on the results and act accordingly ensuring patients details are not deleted or affected.

Such incidents will be discussed with the Medical Devices Committee members

13.1. DATIX Incident Reporting Lost, Damaged, Adverse Event or Near Miss

If a Medical Device is lost, damaged or when a medical device is not returned from loan:

Record the following via Datix:

- Manufacturer and model of the device involved (and any other details you can find)

- Details of the incident

In the event of an incident with a medical device also record:

- Device settings
- Details of any error messages
- Date and time of the incident

Where a device has malfunctioned causing a serious risk to patient safety, the device concerned must be quarantined and labelled 'Do not use'. All material evidence relating to adverse events must be preserved, labelled and kept secure. This includes the medical device, consumables, packaging and any other means of batch identification. The evidence must not be interfered with in any way except for safety reasons or to prevent its loss. The MES team and SCHT MDSO are to be immediately contacted to progress any appropriate investigation which may include contacting the manufacturer/supplier.

13.2. Yellow Scheme Reporting

The Yellow Card scheme run by the MHRA and is the UK system for collecting and monitoring information on safety concerns such as suspected side effects or adverse incidents involving medicines and medical devices. The scheme relies on voluntary reporting of suspected side effects or medical device incidents to be reported by health professionals and the public, including patients, carers and parents. (See Appendix A)

Adverse incidents can be easily reported online through the Yellow Card scheme:
https://yellowcard.mhra.gov.uk/

13.3. Safety Alerts

The Trust Medical Device Safety Officer co-ordinates the distribution of, and response to, any received safety alert (National Patient Safety Alerts, MHRA safety messages and manufacturers' Field Safety Notices).
MES will advise on whether warnings concerning medical devices apply in Shropshire Community Health NHS Trust and will help ensure appropriate actions are issued and implemented.

14. Review and Consultation Process

This Policy has been developed in Consultation with members of the Medical Devices Management Group and Service Managers.

This policy will be reviewed in three years of approval date, or sooner if required through full consultation via the Medical Devices Management group.

15. Process for Monitoring Compliance with this Policy

- The Medical Device Management Group has overall responsibility for implementation and oversight of this document
- SDG Managers, Team Leaders and Line Managers have responsibility to ensure this policy is complied with operationally
- SDG Quality and Safety meeting agenda includes Medical Devices Management and Audit
- Audit results, action plans and monitoring is included in the Medical Device Management Group agenda as a standard item
- Medical Device Management Group Chairs report is provided to Health and Safety Committee for assurance and oversight

- A biannual Medical Devices Management Report is provided to the Health and Safety, and Quality and Safety Committees for assurance

16. References

MHRA, Managing Medical Devices, Guidance for Health and Social Care Organisations, 2021

Devices in Practice, Checklists for using Medical Devices, 2014

The Medicines Healthcare Regulatory Agency (MHRA) website provides further information safety warnings, alerts and recalls at: www.mhra.gov.uk.

Care Quality Commission CQC Regulation 15
The intention of Regulation 15 is to ensure premises where care and treatment are delivered are clean, suitable for the intended purpose, maintained and, where required, appropriately located. In addition, equipment used to deliver care and treatment is must also be clean, suitable for the intended purpose, maintained, stored securely and used properly.

The Health and Social Care Act 2008 Criterion 2
Provide and maintain a clean and appropriate environment in managed premises that facilitates the prevention and control of infections.

17. Associated Documentation

Health & Safety Policy

Incident Reporting Policy

Infection Prevention & Control policy

Decontamination Policy

Information Risk Policy

Records Management Policy

Data Protection Policy

Clinical Record Keeping Policy

Information Security Policy

Portable Electrical Equipment Management Policy

Appendix A: MHRA Yellow Card System

Yellow Card Scheme - MHRA

The Medicines and Healthcare products Regulatory Agency (MHRA) is the executive Agency of the Department of Health and Social Care that acts on behalf of the Ministers to protect and promote public health and patient safety, by ensuring that medicines and medical devices meet appropriate standards of safety, quality and efficacy. The Yellow Card scheme run by the MHRA and is the UK system for collecting and monitoring information on safety concerns such as suspected side effects or adverse incidents involving medicines and medical devices. The scheme relies on voluntary reporting of suspected side effects or medical device incidents to be reported by health professionals and the public, including patients, carers and parents.

The purpose of the scheme is to provide an early warning that the safety of a medicine or a medical device may require further investigation. It is important for people to report problems experienced with medicines or medical devices as these are used to identify issues which might not have been previously known about. The MHRA will review the issue and if necessary, take action to minimise risk and maximise benefit to the patients.

Reports can be made for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, all medical devices available on the UK market and reports of safety concerns associated with e-cigarette products.

The MHRA is also able to investigate counterfeit or fake medicines or devices and if necessary, take action to protect public health.

The scheme collects information on suspected problems or incidents involving

1. side effects (also known as adverse drug reactions or ADRs)
2. medical device adverse incidents
3. defective medicines (those that are not of an acceptable quality)
4. counterfeit or fake medicines or medical devices
5. safety concerns for e-cigarettes or their refill containers (e-liquids)