Trust Policy

University Hospitals Plymouth NHS Trust

Medical Devices Training Policy

Issue Date	Review Date	Version
January 2021	January 2025	6

Purpose

This policy applies to **all** staff employed by University Hospital Plymouth NHS Trust i.e. permanent, temporary, bank and those in training, both professional and support workers who have access to, and are required to use and maintain medical devices within their role.

It is pertinent to all medical devices used by staff for the delivery of treatment, care, diagnosis, monitoring etc.

Who should read this document?

All users of medical devices and all managers who have responsibility for staff who use medical devices.

Key Messages

- All staff are responsible for ensuring that they are trained and assessed as competent, where necessary, to use any medical device that they are designated to use as part of their role.

Clinical managers must ensure that their staff are trained and assessed as competent, where required, in the use of the medical devices that they are designated to use as part of their role

Core accountabilities	
Owner	Medical Device Training Lead
Review	Medical Device Strategy Group
Ratification	Medical Director (Executive Lead)
Dissemination (Raising Awareness)	Head of Clinical Governance Systems
Compliance	Medical Device Training Lead & Director of Healthcare Science and Technology

Links to other policies and procedures

The Management & Use of Medical Devices Policy
Workforce Induction & Training Policy
Clinical Engineering Medical Equipment Users Guide
Clinical Risk Classification Scheme for Medical Devices
Point of Care Testing Policy
Point of Care Testing Training Policy
Performance and Conduct Policy
Appraisal Policy

Version History		
2.1	July 2009	Reviewed by the Clinical Governance Steering Group.
3	April 2012	Comprehensive review, supporting structural change within the Trust and seeking to deliver compliance with CQC and NHSLA expectations.
3.1	July 2012	Amended Job Titles in Appendix C
4	April 2013	Review date of Policy
5	November 2014	Comprehensive Review
5.1	January 2020	Extended to April 2020 by Richard Struthers
5.2	June 2020	Extended to July 2020
6	January 2021	Comprehensive review

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Contents

1 Introduction

The Trust is committed to providing education and training to ensure users of reusable medical devices have the necessary clinical and technical knowledge, skill and competencies to safely and effectively fulfil their duties.

2 Purpose

The aim of this policy is to ensure that the benefits to patients from the use of medical devices are maximised and risks minimised; and to ensure safe and best practice is applied in relation to the management and use of medical devices.

The Trust recognises its responsibilities as an employer to ensure that staff are competent and safe in the roles that they are performing. The Trust has a legal and moral duty to provide adequate training in medical devices in order to minimise the risk of harm to patients, staff and the organisation. Employees of the Trust must ensure that they attend training provided by the Trust and ensure that they are competent in using the medical devices that they are designated to use.

To achieve this, the organisation will:

- Ensure all who use or maintain medical devices in this organisation attend induction training in the first instance and retain competency by accessing training and updates.
- Introduce competency training for all staff using or maintaining high and moderate risk devices throughout the trust.
- Support standardisation of medical devices
- Ensure all users have access to training, retraining, updates and support to develop and
- Maintain knowledge, skill and competency levels
- Maintain records of training.

Compliance with external regulations

Training programmes will be designed to incorporate the recommendations from the Medicines and Healthcare Products Regulating Agency (MHRA) and the National Patient Safety Agency (NPSA). This policy will assist in ensuring the use of medical devices is based on the requirements of the Care Quality Commission (CQC) and the National Health Service Litigation Authority (NHSLA).

3 Definitions

Medical devices have been defined by the Medicines and Healthcare Products Regulatory Agency as:

a medical device is described as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or

therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

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

A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these

For the purpose of this standard, the term '**Medical device**' should be taken to include:

Active implantable medical devices

These types of devices are powered implants or partial implants that are left in the human body.

General medical devices

First aid bandages

Hip prostheses

X-ray equipment

ECG monitors

Heart valves

Dental materials

Spectacles

Depressors

in vitro diagnostic medical devices:

This type of medical device is usually a:

reagent

reagent product

calibrator

control material, kit, instrument, apparatus

equipment or system intended for use in vitro to examine specimens including blood and tissue donations from the human body

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4 Duties

The following responsibilities apply to the Trust's existing medical devices, newly purchased, donated or loaned devices and devices transferred between departments or specialties:

Trust Board and Chief Executive have an overall responsibility*:*

- For the provision and safe use of medical devices, incorporating medical device training and compliance to relevant assurance standards.
- To provide adequate resources to enable instruction, training and supervision to take place that will minimise risk and safeguard patients and staff from the hazards associated with the use of medical devices.
- To ensure that suitable policies and procedures are in place and communicated so as to ensure that compliance with Health and Safety Regulations, NHSLA Risk Management Standards with regards to the safe use of medical devices, is achievable.

Service Line Directors, Cluster Managers, Heads of Departments and Matrons are:

- Accountable for ensuring that the service is provided by staff who are adequately trained and competent in using the medical devices that they are designated to use.
- Responsible for ensuring that all new clinical staff have received medical devices training as part of the Trust's corporate and local induction.
- Responsible for ensuring records of medical devices competencies and training are maintained for each clinical area/department and for each member of staff and that they are available for inspection when requested.
- Responsible for ensuring that when a new or updated/upgraded medical device is introduced to an area; sufficient numbers of staff have been trained to ensure its safe and effective use before it is put into use.

Ward and Department Managers are responsible for:

- Maintaining an inventory of Medical Devices used in their area including Risk Category (assigned by Clinical Engineering) of the devices. The e-QUIP asset management list from Clinical Engineering is the basis of the inventory. The inventory must also include medical devices used in the ward/department not listed on EQUIP for that ward/department e.g., Medical Equipment Library (MEL) equipment and specific pain devices.
- Reviewing the Medical Devices inventory at least annually or when new or upgraded medical devices are purchased or used.
- Identifying and supporting a suitable member of staff as Medical Device Link Practitioner (MDLP). Identify key trainers for specific medical devices to support the MDLP.
- Completing a Medical Device Training Needs Analysis (Appendix D) for the ward/department and arrange appropriate training for staff.

- Ensuring that training needs are identified for each member of staff using the Medical Device Training Needs Analysis (Appendix D) and reviewed at individual annual appraisal**.**
- Ensuring that all staff that require training and competency assessment on the devices that they are designated to use have received appropriate training and assessment. Any staff that are not trained and assessed as competent have an action plan (Appendix F) put in place to ensure attainment. Where necessary the performance management route may need to be followed. An Individual Medical Device Training Record for each member of staff should be maintained (Appendix G)
- Designating authority for their staff to use the medical devices required for their roles.
- Ensuring that new clinical staff receive the relevant required training on the Trust's corporate and local induction.
- Ensuring that for High and Very High Risk Medical Devices that evidence of competence is maintained for staff who are designated to use these Medical Devices.
- Maintaining a recording system of Medical Device training and competency assessment, defining who have received training and evidence of competency so that it is available for scrutiny by the Trust, Clinical Education Manager, Service Line Director/Matron and any external monitoring authority, e.g., CQC.
- Responding to Medical Device Alerts, patient safety bulletins and Datix incidents if the medical device is used in their clinical area.
- Ensuring that up to date user manuals and instructions for use are available for reference by end users (hard copy or electronic versions).
- Ensuring staff only use those medical devices for which they have been trained / assessed as being competent to use, unless closely supervised by staff competent in the use of the medical device.
- Monitoring staff attendance at Medical Device training and completion of assessment and competency.
- Support staff to attend training and to allow time for competency assessments to be completed.
- Taking action on staff who do not attend training or complete competency assessment. Where necessary, the performance management route may need to be followed.
- Ensuring that any patient/carer who is discharged with a Medical Device has received adequate training in the intended use and normal functioning of the device in order to use it effectively and safely. Ensure that the 'End user Training and Tracking Checklist' (Appendix H) has been completed evidencing that training has taken place, and that it is stored in the correct place. See Section 5: 'Training of End uses' for more information.
- Completing the "Self verification of competence for Very High Risk and High Risk Medical Devices" form for relevant medical devices which should be reviewed within staff personal appraisal (Appendix E) along with the original competency documents and other medical device training records.

Medical Device Link Practitioner (MDLP) is responsible for:

- Keeping up to date with medical device training issues via Medical Device Link Practitioner meetings or minutes. Ensure access to MDLP drive (access available from

Medical Device Training Team).

- Attending train the trainer sessions for specific medical devices or identify an appropriate link to attend relevant to equipment in use in their area.
- Assisting in coordinating training and assessment of staff in the use of medical devices; ensuring the use of the most up to date competency document and planning that the training is accessible to all relevant staff. In the case of unsuccessful competency assessment of a member of staff, a 'Medical Device Training Action Plan' (Appendix F) with specific learning objectives and timeframes must be completed.
- Informing line managers of staff nonattendance or non-completion of assessment, updates or training sessions and avoidance of training/assessment.
- Assisting in the production of competency documents for Medical Devices either locally or Trust wide with support and verification from the medical device training team.
- Assisting the ward/department manager in maintaining an inventory of medical devices used in that area.

Registered and non-registered Staff/Medical Staff are responsible for:

- Only using medical devices they are competent to use and designated to use, unless closely supervised by staff competent in the use of the medical device.
- Completing the relevant induction training in the safe use of medical devices, as part of their corporate and local induction.
- Ensuring that they are competent to operate medical devices in a safe and effective manner and ensuring that they have been assessed as competent for relevant medical devices. Maintain an Individual Medical Device Training Record (Appendix G) for any Medical Device training received.
- Keeping up to date with training and competency of the medical devices they are designated to use within their individual role. Seek further training and updates as required by contacting their manager, Clinical Educator, Medical Device Link Practitioner or Clinical Education Manager.
- Report any untoward or adverse incidents to line manager and complete Datix.
- Completing the "Self verification of Competence for Very High Risk and High Risk Medical Devices" form (Appendix E) for relevant medical devices which should be reviewed within their personal appraisal along with the original competency documents and other medical device training records.

Clinical Educators are responsible for:

- Assisting the Ward/Department Manager and MDLP to maintain records of medical device training and competency used in their area.
- Attending train the trainer sessions for specific medical devices or identify an appropriate link to attend relevant to equipment in use in their area.
- Assisting in coordinating training and assessment of staff in the use of medical devices; ensuring the use of the most up to date competency document, and planning that the training is accessible to all relevant staff. In the case of unsuccessful competency

assessment of a member of staff, a ‘Medical Device Action Plan’ (Appendix F) with specific learning objectives and timeframes must be completed.

- Supporting managers with reviewing competence of staff in use of medical devices, ensuring that they are up to date and inform manager of non-attendance, non-completion of training/assessment and avoidance of training/assessment.
- Assist in the production of competencies for High/Very High Risk medical devices either locally or Trustwide with support from the Medical Device Training Lead.

Human Resources are responsible for:

- Ensuring that staff working in the organisation that are not directly employed by the Trust, i.e., NHSP, and agency staff, only use medical devices that they have been trained/assessed as competent to use. Their employer should be able to provide evidence and give assurance that they have been trained and are competent to use the medical devices that are required for their role prior to booking them to work for the Trust.

Procurement Department is responsible for:

- Ensuring the users specified educational and training requirements for clinical and technical staff (including for those undertaking decontamination) are included and assessed as part of the tender process and included in any contracts awarded.
- Informing the Medical Device Training Lead of any plans to introduce a new medical device within the Trust.

Medical Device Training Lead is responsible for:

- Providing and facilitating a standardised approach to education and training for medical devices used within the Trust.
- Ensuring that training in medical devices is part of annual mandatory training and appraisal.
- Providing support and advice Trustwide regarding medical device training and competency assessment.
- Reviewing clinical incidents involving medical devices and monitoring ALERT publications to identify training needs.
- Implementing regular MDLP meetings providing updates on medical devices, changes to policy and support for training.
- Organising training for medical devices for all staff, provided in accordance with contractual agreements. This applies to all medical devices including new and upgraded/updated devices and devices received on trial, or on loan from another organisation.
- Ensuring that training programmes are repeated regularly where necessary.
- Monitoring compliance and the effectiveness of this policy through the audit process.
- Report to MDSG (Medical Device Strategy Group) and via the Service Line route.

5 Main Body of Policy

Patients and/or carers must be appropriately trained in the use of any medical device provided on discharge. Staff providing this training must ensure the user is competent in the use of the device. Staff providing training must be competent and confident to use the medical device themselves and be able to demonstrate their own competency assessment documentation as evidence of their own competency. End users need to understand the intended use and normal functioning of the device in order to use it effectively and safely. Where relevant, training should cover:

- Any limitations on use.
- How to fit accessories and to be aware of how they may increase or limit the use of the device.
- How to use the controls appropriately.
- The meanings of any displays, indicators, alarms etc and how to respond to them.
- Requirements for maintenance and decontamination, including cleaning.
- Recognise when the device is not working properly and know what to do about it.
- Understand the known pitfalls in the use of the device, including those identified in safety advice from the MHRA, manufacturers and other relevant bodies.
- Understand the importance of reporting device-related adverse incidents to the MHRA.
- Training must be delivered by a member of staff who is competent to use the device. The "**End user training and tracking checklist**" (Appendix H) or equivalent form should be completed and stored in the patients' medical notes. The patient or carer is required to sign a statement confirming receipt of this training.

Clinical Risk Classification of Medical Devices and Levels of Training and Competence Required

The level of training required is determined by the clinical risk classification of the medical device. Each medical device used within PHNT will have an assigned risk category as defined in the Trust Equipment Management System Asset Register (f2) by MEMs.

Risk Category	Definition	*Level of risk of harm to patient due to user error*	Training Requirements
Low risk	Devices whose failure or misuse is unlikely to result in serious consequences.	None to low. **None** – little or no adverse effect on patient **Low** – discomfort, delay and inconvenience to patient	**Training is informal, 'in-house' or linked to qualifications. Where training has taken place, ensure records are maintained.** The user must be able to demonstrate knowledge of the specific model, equipment use and application and associated potential risks.

Medium risk	Devices whose failure or incorrect use would have a significant impact upon patient care or temporary adverse health consequences, but would be unlikely to cause direct serious injury.	**Moderate** – semi-permanent harm to patient or increased length of stay	**Training records must be maintained** The user must be able to demonstrate knowledge of the specific model, equipment use and application and associated potential risks.
High risk **Very high risk devices**	Devices that have the potential to cause serious adverse consequences or death should they fail or be misused. *Devices recently associated with serious injury* Life support and resuscitation devices, this is sub-category of high risk devices to specifically capture life-support and resuscitation devices**.**	**Severe** – Serious harm leading to disability or death	**Training and competency records must be maintained.** The user must undertake competency-based training and assessment prior to using the device. Assessment must be carried out by an identified trainer. **Annual Appraisal:** Following initial training and assessment of competence, users must complete the self verification of competence statement with regard to medical devices at least annually at appraisal when assessment of formal training and competence will be reviewed. A formal update is required at least every 3rd year unless more frequent updates are necessary for specific medical devices

Key Principles of using a Medical Device

Prior to using any medical device, the user should ensure that they adhere to the following criteria:

- Ensure that the device is appropriate for the patient, their condition and required treatment.
- Ensure that the device is suitable for the purpose (i.e. not using equipment in a manner other than that intended by the manufacturer) and can explain the use of the equipment within the remit of their role.
- Ensure that the device is in good working order.
- Inspect device for up to date ‘safety test label’ and any signs of damage.
- Do not use any device unless assessed as competent/trained to do so.
- Know where to access user manuals or locally written instructions.
- Know the Risk category of the medical device as determined by Clinical Engineering and as listed on the e-Quip asset management system.
- Be aware of personal limitations. Declare if not competent or confident to use a particular piece of equipment or have not used the equipment regularly to a senior staff member.

- Understand how to operate the controls, carry out pre use checks and associated accessories, single use items and know how to respond to alarms and troubleshoot issues with the medical device.
- In the event of failure, know how to safely disconnect the device and remove from service.
- Aware of the Trust procedure for incident reporting.
- Able to clean and prepare the medical device for future use.

Process for Identifying Training Needs

Each clinical area is required to maintain a local inventory of medical devices. The e-QUIP asset management system from Clinical Engineering will be the basis of the inventory but must also include medical devices used in the ward/department not listed on e-QUIP for that ward/department e.g., Medical Equipment Library (MEL) equipment and specific pain devices.

The Medical Device Training Needs Analysis document (Appendix D) must reflect the medical devices listed in the inventory for each clinical area. It will also define what medical devices are required for each individual's role.

The identification of training needs may also occur in direct response to adverse clinical incidents, MHRA Medical Device Alerts and at any individual's performance review or request.

Documentation and evidencing of Training and Competence

Evidence that suitable instructions and training were provided are needed should a legal case be brought. Users of medical devices should be asked to sign to confirm that they have received and understood written/oral instructions and training.

Details of training should also be recorded along with who delivered the training.

Evidence of competency assessment should be maintained locally for departmental information and in case competency of staff needs to be scrutinised or inspected.

How the organisation follows up those who do not complete training / competency assessment

Individual managers have a responsibility to ensure that their staff have the appropriate training and competency assessment to use medical devices that they have been designated to use.

All employees have responsibility for their own personal development and must identify and communicate areas of training and development need to their manager.

Where medical device training falls within mandatory training i.e. Basic Life Support, Manual Handling, Clinical Trust update and induction. Non-attendance is reported to ward/departmental managers and matrons via the Trust learning management system which produces monitoring reports on a monthly basis, and in turn, is taken to the Trust Board.

Line Managers will discuss any non attendance highlighted by these reports with the employee and ensure that training is re-booked.

All other medical device training and competency assessment must be reviewed by the manager at annual appraisal. Completion of the appraisal process is reviewed through monthly monitoring reports which are available to all managers.

Staff who do not complete training/ competency assessment will be followed up by the Line manager in accordance with the Performance and Conduct Policy. Persistent non-attendance or non-completion of training/competence assessment will also be managed through the Performance and Conduct Policy.

Frequency of Training Update

Users of medical devices are responsible for ensuring their own competence and training is up to date. Training updates should be accessed appropriate to the individual staff need and under the direction of the line manager**.** A review of competency in the use of medical devices required for the individual's role should be undertaken at least on an annual basis. This should preferably be undertaken at a personal appraisal whereby an action plan can be devised and agreed by the line manager. However, training needs may be identified at any stage, e.g. performance review or when an individual requests training, or an incident with a specific medical device occurs.

Refresher/Update training will be required by all users in the following circumstances:

- When manufacturers advise that there are software/version changes that may affect the safe operation of the device.
- A new model or upgrade is purchased with differing/additional features from the model staff have been using and that may affect the safe operation of the device.
- When a Safety Alert regarding a medical device requires action.
- When learning arising from an incident, complaint, clinical negligence claim or inquest indicates a deficiency in the content, quality or frequency of training provided.
- When a clinical trust policy determines frequency of training.
- An update should be undertaken if the individual has not used the medical device on a regular basis or when there are performance issues concerning a medical device competency, or when an individual lacks confidence in using a medical device.
- An update is required on Very High Risk /High Risk medical devices at least every 3rd year, unless more frequently specified for specific medical devices.
- An 'Individual Medical Device Training Record' for each member of staff should be maintained (Appendix G).

The Medical Device Self Verification of Competence

Health care professionals who use High and Very High Risk medical devices must be assessed as competent in using them and there must be documentary evidence available to demonstrate this. Following this initial training and assessment of competence, a **Self Verification of Competence for Very High Risk and High Risk Medical Devices Form** (Appendix E) must be completed at each annual appraisal or performance review or when the practitioner believes he/she lacks the knowledge and skill to use a specific device. This document will assist in identifying specific training needs. Individuals must update themselves by attending training at least every 3rd year in medical devices that they self-verify their competence in.

Registered Practitioners are accountable for ensuring competence in the use of any medical device required for their role. Non registered staff must have their verification of competence countersigned by a Registered Practitioner who understands the implications of professional accountability in providing staff authority to use the named medical device required for their role.

Very high risk/high risk devices which require regular updates should be identified on the local Medical Devices Training Needs Analysis and on the staff member's medical device training records (electronic and/or hard copy).

Medical Devices introduced to the Trust

Medical Devices will not be put into operation without sufficient numbers of trained staff to ensure safe and effective use**.** Service Line Leads and Departmental Managers must take into consideration the risk level of the device and the usage according to individual department/ward needs. Training on new medical devices to the Trust will be provided wherever possible by the supplier/manufacturer and identified and agreed at the procurement stage.

Training in the use of Medical Devices on Trial or Loan

Clinicians wishing to loan or trial equipment within the Trust will in the first instance follow guidance in the Medical Devices Policy and ensure that representatives from companies inform the Clinical Engineering Department and the Medical Devices Training Team of the intended equipment to be loaned or trialled. This is to allow the Trust to monitor the provision and adequacy of training for staff in the use of these devices and for companies to recognise the need for an educational commitment in the Trusts purchasing activity.

6 Overall Responsibility for the Document

This Policy is reviewed and ratified by the Medical Device Steering Group and ratified by the Medical Director.

7 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the medical device steering group and ratified by the Medical Director.

Non-significant amendments to this document may be made, under delegated authority from the Medical Director, by the nominated owner. These must be ratified by the Medical Director.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

8 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document owner will be responsible for agreeing the training requirements associated with the newly ratified document with the named Medical Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

9 Monitoring Compliance and Effectiveness

Element to be monitored	Trust compliance with this policy in relation to the identification of training needs, fulfilment of those training needs and assessment of competence will be monitored with particular focus on training requirements for very high and high risk devices.
Leads	Medical Device Training Lead
Tool (s)	Monitoring will be achieved as part of the Trust Annual Internal Audit Programme and as part of auditing programme designed and carried out by the Medical Device Training Lead
Frequency	Annual audits of medical device training and competence across all departments.
Reporting arrangements	The Medical Device Training Lead will report to the Medical Device Strategy Group.
Acting on recommendations and Lead(s)	Staff including, (but not limited to) Service Line Directors, Cluster Managers, Heads of Department, Matrons, Clinical Educators, Medical Device Link Practitioners and the Medical Device Training Lead will create actions to be taken when required.
Change in practice and lessons to be shared	Changes will be disseminated via the Medical Device Training Lead, Clinical Educators and Medical Device Link Practitioners. Action(s) to be completed will be addressed through the Clinical Educator and Medical Devices Link Practitioner meetings. These should be completed within the appointed time stated in the action plan.

10 References and Associated Documentation

The following documents are referred to in this policy, or provide additional sources of reference material:

‘Essential standards of Quality and Safety’ **Care Quality Commission**, March 2010

‘NHS Resolution Risk Management Policy and Procedure’ **NHS Resolution** November 2020

‘NHSLA Risk Management Standards for NHS Trusts providing Acute, Community or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care, 2011/12’ **NHS Litigation Authority**, January 2011.

‘MHRA Managing Medical Devices: Guidance for healthcare and social services organisations’ **MHRA** April 2015

Dissemination Plan and Review Checklist | Appendix 1

Dissemination Plan	
Document Title	Medical Device Training Policy
Date Finalised	2021
Previous Documents	
Action to retrieve old copies	Via dissemination of revised policy

Dissemination Plan

Recipient(s)	When	How	Responsibility
All Trust staff		Information Governance StaffNet Page	Information Governance Team
Service Line Directors, Cluster Managers, Ward Managers and Heads of Department, Matrons, Clinical Educators and Medical Device Link Practitioners	2021	Electronic	Sarah Dormor
Daily Email	2021	Electronic	Sarah Dormor

Review Checklist		
Title	Is the title clear and unambiguous?	Yes
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Yes
	Does the style & format comply?	Yes
Rationale	Are reasons for development of the document stated?	Yes
Development Process	Is the method described in brief?	Yes
	Are people involved in the development identified?	Yes
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Yes
	Is there evidence of consultation with stakeholders and users?	Yes
Content	Is the objective of the document clear?	Yes
	Is the target population clear and unambiguous?	Yes
	Are the intended outcomes described?	Yes
	Are the statements clear and unambiguous?	Yes
Evidence Base	Is the type of evidence to support the document identified explicitly?	Yes
	Are key references cited and in full?	Yes
	Are supporting documents referenced?	Yes
Approval	Does the document identify which committee/group will review it?	Yes
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	Yes
	Does the document identify which Executive Director will ratify it?	Yes
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Yes
	Does the plan include the necessary training/support to ensure compliance?	Yes
Document Control	Does the document identify where it will be held?	Yes
	Have archiving arrangements for superseded documents been addressed?	Yes
Monitoring	Are there measurable standards or KPIs to support the monitoring of	Yes

Compliance & Effectiveness	compliance with and effectiveness of the document?	
	Is there a plan to review or audit compliance with the document?	Yes
Review Date	Is the review date identified?	Yes
	Is the frequency of review identified? If so is it acceptable?	Yes
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes

Equalities and Human Rights Impact Assessment | Appendix 2

Core Information	
Date	2021
Title	TRW.MED.POL.325.6 Medical Device Training Policy
What are the aims, objectives & projected outcomes?	The aim of this policy is to ensure that the benefits to patients from the use of medical devices are maximised and risks minimised; and to ensure safe and best practice is applied in relation to the management and use of medical devices. The Trust recognises its responsibilities as an employer to ensure that staff are competent and safe in the roles that they are performing. The Trust has a legal and moral duty to provide adequate training in medical devices in order to minimise the risk of harm to patients, staff and the organisation. Employees of the Trust must ensure that they attend training provided by the Trust and ensure that they are competent in using the medical devices that they are designated to use.

Scope of the assessment
The assessment covers all protected characteristics The EIA was produced by the Trust's Equality & Diversity Lead Incidents and complaints are monitored via datix and reported as necessary

Collecting data	
Race	There is no evidence to suggest there is disproportionate impact on race regarding this policy. However, data collected from Datix incident reporting and complaints will ensure this is monitored. Consideration will be made if information provided is required in a different language for patients/carers receiving training.
Religion	There is no evidence to suggest there is a disproportionate impact on religion or belief and non-belief regarding this policy. However, data collected from Datix incident reporting and complaints will ensure this is monitored.

Disability	There is no evidence to suggest there is a disproportionate impact on disability regarding this policy. However, data collected from Datix incident reporting and complaints will ensure this is monitored. Consideration will be made for staff requiring reasonable adjustments for training purposes. Consideration will be made for patients/carers who require training who require information in different formats or where translations services are required.
Sex	There is no evidence to suggest there is a disproportionate impact on sex regarding this policy. However, data collected from Datix incident reporting and complaints will ensure this is monitored.
Gender Identity	There is no evidence to suggest there is disproportionate impact on gender identity regarding this policy. However, data collected from Datix incident reporting and complaints will ensure this is monitored.
Sexual Orientation	There is no evidence to suggest there is disproportionate impact on sexual orientation regarding this policy. However, data collected from Datix incident reporting and complaints will ensure this is monitored.
Age	There is no evidence to suggest there is a disproportionate impact on age regarding this policy. However, data collected from Datix incident reporting and complaints will ensure this is monitored.
Socio-Economic	There is no evidence to suggest there is a disproportionate impact on socio-economic regarding this policy. However, data collected from Datix incident report and complaints will ensure this is monitored.
Human Rights	Carers will be involved in the medical device training for patients who require support due to disability on incapacity.
What are the overall trends/patterns in the above data?	No comparative data has been used to date which means that no trends or patterns have been identified.
Specific issues and data gaps that may need to be addressed through consultation or further research	No gaps have been identified at this stage but this will be monitored via data collected from Datix incident reporting and complaints.

Involving and consulting stakeholders	
Internal involvement and consultation	Medical Device Strategy Group Peter Wright, Director of Healthcare Science & Technology
External involvement and consultation	
Impact Assessment	
Overall assessment and analysis of the evidence	Consideration will be made if information provided is required in a different language for patients/carers receiving training. Consideration will be made for staff requiring reasonable adjustments for training purposes. Consideration will be made for patients/carers who require training who require information in different formats or where translation services are required. Carers will be involved in the medical device training for patients who require support due to disability on incapacity.

Action Plan

Action	Owner	Risks	Completion Date	Progress update
Collect and monitor data collected from Datix on incidents and complaints. Quarterly reports to be produced.	Sarah Dormor		Ongoing	