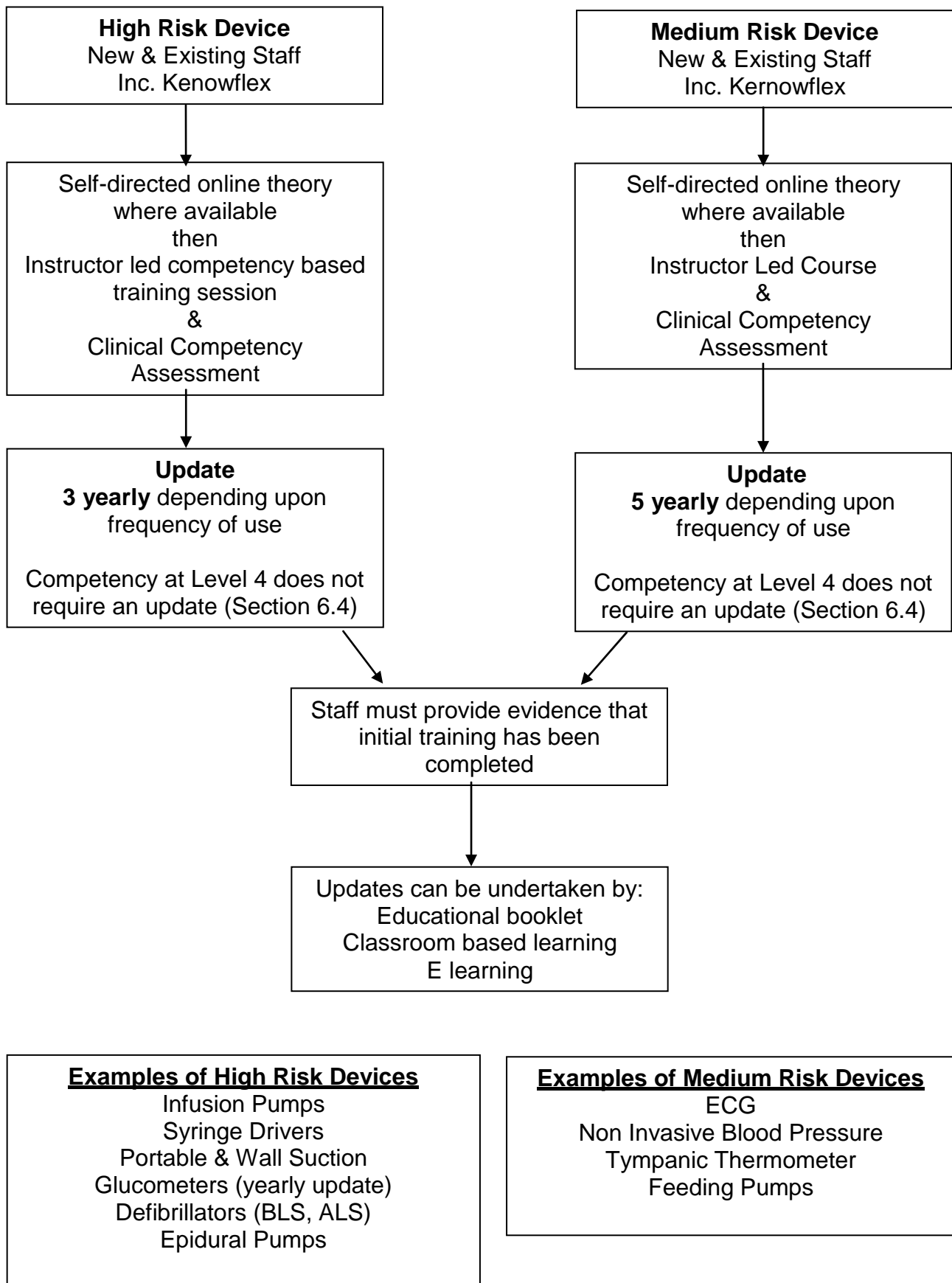


Medical Devices Training Policy

V2.0

August 2019

Summary 1: Medical Device Training Pathway



Summary 2: Medical Device Training Pathway for New Devices

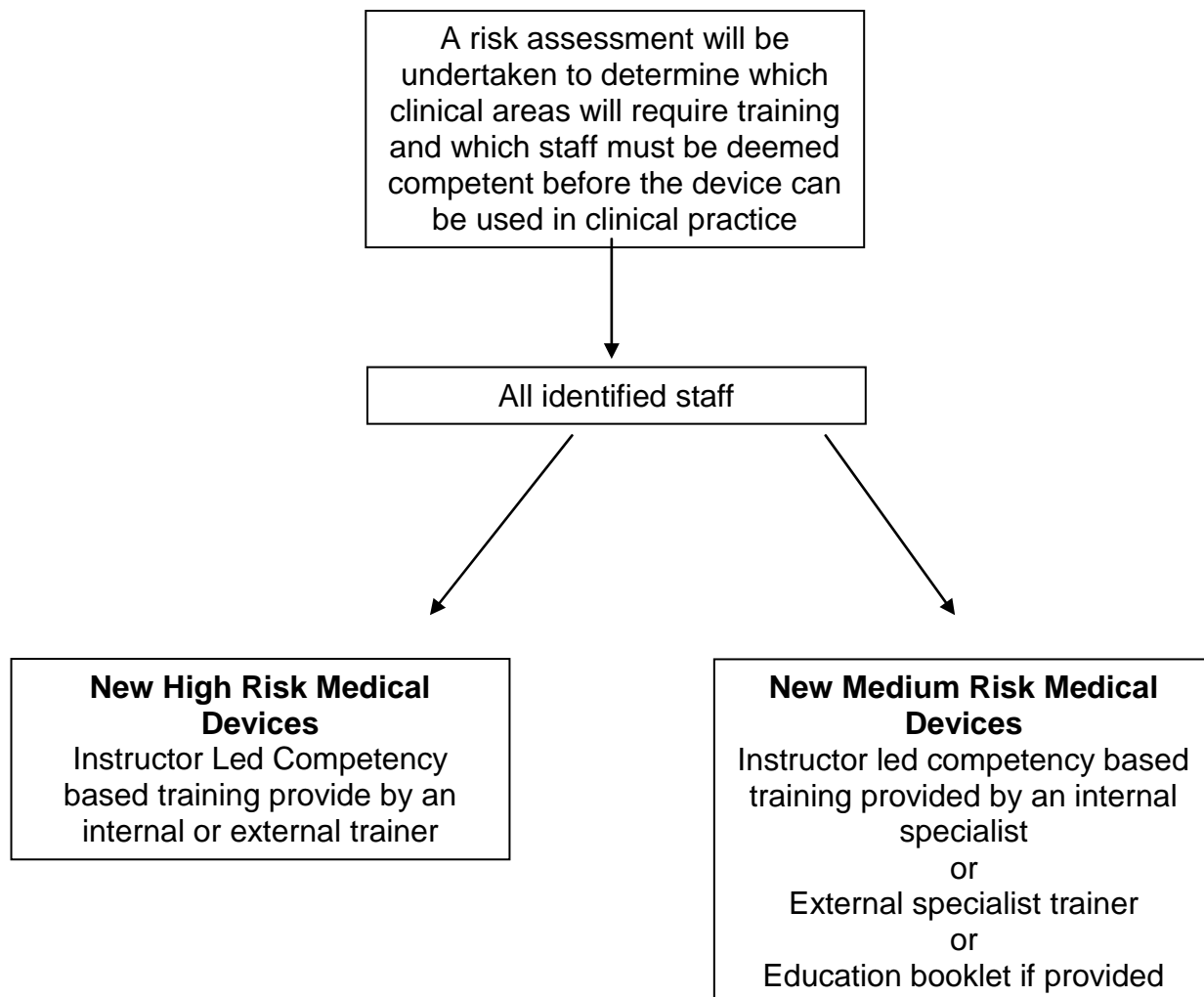


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1. Introduction

1.1. Medical devices are used every day by many healthcare professionals to support and assist in the care and treatment of patients. This policy sets out the framework for the safe and effective use of medical devices within the Trust.

1.2. This policy has been implemented to complement other established programmes within the Trust e.g. Corporate Induction, Local Induction, Mandatory Training, Personal Development Plans and Appraisal Programmes.

1.3. This version supersedes any previous versions of this document.

1.4. **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We can't rely on Opt out, it must be Opt in.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the 'information use framework policy', or contact the Information Governance Team rch-tr.infogov@nhs.net

2. Purpose of this Policy

2.1. The purpose of this policy is to assist the Trust in ensuring that medical devices under its control are effectively and properly used based on the requirements of the Care Quality Commission (CQC), National Health Service Litigation Authority (NHSLA). This policy incorporates recommendations from the Medicines and Healthcare Products Regulating Agency (MHRA) and the NHS Commissioning Board.

2.2. And also:

- Provide a clear framework for training requirements and the use of medical devices
- Ensure that a consistent approach to training is in place for all appropriate disciplines within the Trust
- Help identify and minimise hazards and reduce risk, related to the use of medical devices
- Ensure that the appropriate staff receive suitable training and are competent in the use of medical devices prior to its application in the clinical setting

3. Scope

This policy applies to all RCHT staff members who use medical devices or are responsible for managing staff members who use medical devices.

4. Definitions / Glossary

4.1. Medical Device: “any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application 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 disability
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception

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

4.2. Risk Levels

4.2.1. **Low Risk**

Devices whose failure or misuse is unlikely to result in serious consequence.

4.2.2. **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.

4.2.3. **High risk**

Devices that have the potential to cause a serious adverse consequence or death should they fail or be misused. Devices recently associated with serious injury.

4.3. **Clinical Staff**

Doctors, Nurses, Midwives and all Allied Health Professionals (AHPs).

5. Ownership and Responsibilities

5.1. **Role of the Trust Board**

The Trust Board has overall responsibility for the safe use of medical device which includes medical device training. The Chief Operating Officer has overall responsibility for the Trust’s management of Medical Devices, incorporating medical device training, and compliance with the relevant external Assurance Standards.

- Provide adequate resources to enable instruction, training and supervision to takes place that will minimise risk and safeguard patients and staff from the hazards associated with the use of medical devices
- Ensure that an inventory of medical devices is maintained, kept up to date and monitored to ensure its integrity
- Ensure that suitable policies and procedures are in place and

communicated to staff ensuring compliance with Health and Safety Regulations, NHSLA Risk Management Standards and Standards for Better Healthcare with regards to the safe use of medical devices.

5.2. Role of the Cornwall NHS Procurement Service

Ensure provision of appropriate training, including initial and on-going clinical training, plus technical and decontamination processes training is included in all contract specifications relating to the purchase of medical devices

5.3. Role of the Medical Devices Training Officer / Lead Educational Trainer

- Provide assistance to Care Groups in identifying and co-ordinating medical device training needs
- Develop standards of training for professional users relating to medical device equipment used within the Trust
- Plan and co-ordinate the development and coverage of Trust wide training programmes
- Assist clinical areas to develop learning plans, training packages and ensure good practice is shared
- Audit compliance with the Medical Devices Training Policy e.g. checking data on the medical devices shared drive
- To review clinical incidents involving medical equipment
- Chair quarterly meetings with the Local Medical Device Links and provide updates on medical devices, changes to policy and training data collection
- To provide competency reports at a local and Care Group level

5.4. Role of the Clinical Manager

- Ensure training needs of staff have been identified that staff are competent on the Medical Devices in their area and that training records are well documented. This responsibility will extend to the induction of new staff, Locum, Agency and Kernowflex staff.
- Ensure training records and training requirements are reviewed during Personal Development Reviews (PDR) in accordance with the current PDR policy.
- Appoint one Local Medical Devices Link (LMDL) for each clinical area to assist in identifying staff training needs and to provide contact with the Medical Devices Training Officer
- Bring to the attention of staff this policy and ensure that staff understand roles and responsibilities
- Ensure 'New staff' as part of their local induction programme review what medical device training they require and ensure they complete a "high risk" device training programme accordingly
- Maintain a concise and up to date department/ward medical device asset register
- Maintain Staff Medical Device training records in accordance with the Trust's Training Database e.g. personnel files and Medical Device Shared Drive
- Staff follow Trust procedures where a concern regarding medical

- device training is identified and contact the Medical Device Training Officer to enable an action plan to be formulated
- All end-users are given suitable training in the safe and effective use of medical devices; where instructional literature is provided ideally this should be approved/endorsed by the original supplier; or appropriate specialist wherever possible
- Ensure the MD11 'End user Documentation' is used with all loaned equipment: The MD11 form is accessible on the Sister Shelf /Discharge Tab and CEMS tab

5.5. Role of the Care Group Quality Managers

- Have a system in place to ensure all staff in their Care Group using Medical Devices are adequately trained on the relevant equipment
- Keep appropriately documented evidence of staff training on ward
- Establish local procedures for the management of devices to comply with the requirements of this policy
- Appoint a Local Medical Device Link (LMDL) to assist the area manager and the Medical Devices Training Officer with training needs analysis, training, risk assessments and maintenance issues
- Maintain an equipment inventory, to be reviewed quarterly, noting new equipment and equipment disposed of or re-located. (Refer to the Medical Device Management Policy).
- Complete risk assessments on devices which may pose a significant risk to patients or staff
- Ensure equipment is kept in an appropriate state of maintenance and repair and is cleaned according to Trusts policy (refer to Section 8 and the RCHT Decontamination Policy)
- Ensure staff are aware of their responsibilities regarding the safe use of medical devices

5.6. Role of the Local Medical Devices Link (LMDL)

5.6.1. Roles and Responsibilities of Local Medical Device link and Key Trainers)

A Local Medical Devices Link (LMDL) will be identified for each ward or departmental area (See Appendix 6). This is a crucial role in ensuring the safe and efficient use of medical devices throughout the hospital

5.6.2. A LMDL will:

- Gain advanced skills with medical devices through training programmes
- Develop valuable teaching experience
- Support Key Trainers
- Ensure training records are accurate and update in-line with the ward manager

5.6.3. Additional staff may be identified as key trainers of specific devices, as it is recognised that one person may not be able to train all staff on all devices within an area.

5.6.4. The main responsibilities of an LMDL are:

- To identify training needs for their area (in conjunction with the area's senior manager)
- To assist in record keeping for their area (in conjunction with the area's senior manager)
- To provide update training on medical devices in their clinical area to healthcare workers including agency/locum staff. LMDL must be identified as a qualified trainer for the devices they teach. .
- Ensure that any training provided by either the LMDL or Key Trainer is recorded on a MD07, (See Appendix 5) and sent to the Medical Device Training Officer.

5.7. **Role of the Key Trainers (See Appendix 6A)**

- Key Trainers must be a minimum of band 5 qualified/registered practitioner and on permanent contract with the Trust. Band requirement is based on a risk assessment of the device or performed by the Medical Device Training Officer.
- Identify specific devices for which they will provide training (number of devices at the discretion of the MDTO)
- To deliver competence-based update training to existing staff on the safe use of specific medical devices in their clinical area to healthcare workers including agency/locum staff by using training packages facilitated by the MDTO to ensure standard training throughout the Trust
- To assist the ward/department manager and LMDL with updating their local area's training records and provide evidence of training
- To report issues, concerns or proposed improvements directly to the LMDL.

5.8. **Role of Individual Clinical Staff**

- Staff have a legal obligation to take reasonable care for their own health and safety and that of others who may be affected by what they do or conversely fail to do whilst at work (Ref. Section 7 (a) Health and Safety at Work Act 1974).
- Staff have a legal obligation to assist the Trust to meet with any statutory duty or requirement imposed upon it in regards to health and safety and to cooperate in such a manner as to ensure that approved Trusts policy and procedure is properly applied. Additionally healthcare professionals are bound by their Code of Ethics and Scope of Professional Practice, which clearly set out the individual's responsibilities and duty of care when using medical devices and of the situation that may arise when undertaking actions that they are not trained to perform.
- All staff are required to report any suspected or known breaches of this procedure through the correct channels and cooperate in any subsequent actions as may arise.

5.8.1. When considering using any medical device, it is the duty and responsibility of each individual to ensure that:

- They are deemed competent by the Trust to use the medical device. If in any doubt they should seek advice on the matter; and more importantly do not use the device until their competency has been confirmed. Any shortcoming

- in regard to individual skills or competences should be reported to and/or acted upon by their Ward/Unit/Department Manager as soon as is practical.
- Medical devices must be used in the manner for which training has been received and in line with manufacturer's guidelines. Arbitrary adjustment or modification of an approved training competence is not permitted. Failure to follow correct procedure may lead to disciplinary action.
 - Where it is felt that a change in practice may improve procedures this should be raised with Line Management in the first instance; and with the Medical Devices Training Officer as to whether a change in training competence may be appropriate. Where it is agreed that a new training competence would be appropriate Trust policy and procedure will be followed to ensure the proper introduction of the revised training competence.
 - Where practical individuals should make themselves aware of the content and location of Manufacturer's user manuals/guidelines, competency and other appropriate information; and make due reference to as an aide memoir as and when necessary.
 - Refer to Medical Device Management Policy in regards to Faults with medical devices and Reporting Faults. Decontamination Policy in regards to cleaning and decontaminating medical devices.

5.9. Role of the Medical Equipment Procurement Group

The Medical Devices Group is responsible for:

- Reviewing maintenance, training and risk & safety issues in regards to Medical Devices
- Providing advice to the Trust Board via the Care Group Quality Group, or equivalent, on the procurement, management and deployment of Medical Devices
- Assisting formulation of common policy/procedures
- Ratifying a Recommended List of Medical Devices
- Reviewing trials and evaluations of new medical devices as a replacement for existing devices or new to the trust

6. Standards and Practice

6.1. A training strategy has been devised to support continuing improvements in clinical quality and reduce the risks/adverse incidents relating to the use of medical devices within the Trust.

- The medical devices training strategy incorporates risk assessment and user feedback to ensure that training is targeted to those areas highlighted by adverse incident reporting, complaints, and user experience.
- The maintenance of training records is an important part of the training strategy, consistent with recommendations from the National Audit Office and the requirements Care Quality Commission and NHSLA Risk Management Standards (2008).
- In order to meet with the agreed levels of accreditation of the NHSLA Risk Management Standards, evidence is required to enable the Trust to reasonably demonstrate that it manages the training processes in a manner consistent with the standard. In following the procedure it is

intended that the following five headline elements will be met i.e. To:

- Identify all medical devices for which specialist training is required.
- Assess all users of such medical devices for training needs. Ensure that 'suitable' training programmes are in place Maintain training records for all users.
- Monitor the procedure for evidence that it is being operated effectively.

This policy is for all Clinical Staff. It is recognised that the use of medical devices and equipment when delegated to a Health Care Assistant or other associated support staff by a registered staff member - accountable will remain with the registered professional. They must ensure the competence of individuals and that delegation is appropriate and safe.

6.2. Training Delivery

6.2.1. Users of medical devices are responsible for ensuring their own training is appropriate and up to date; advice can be sought from the Medical Device Training Officer, Local Medical Device links and Ward Managers. All staff that use medical devices are encouraged to use all training routes available to them.

- Clinical Skills
- Mandatory Training
- Company Representative courses
- Instruction manuals.
- In-house training provide by specialist trainers
- E-learning packages

6.2.2. **End User Training:** Any professional user delivering medical device training to end-users must have the appropriate skills, knowledge and experience to train patients and home carers on the safe and proper use of the device and advice the patient on how to contact the appropriate support if required. (See Appendix 3, MD11 form for details)

6.2.3. **Medical Devices Training Courses:** Medical device training is based upon clinical risk assessment and the medical devices common to most clinical areas. Training for specialist areas will be organised on a local level with the Medical Devices Training Officer. The training prospectus is located on the hospital intranet. Staff may book onto the training courses directly or with the assistance from Employee support team.

6.2.4. **Student nurses and midwives:** In accordance with the recommendations laid out in the Standards of proficiency for registered nurses Annexe B (2018) all students are expected to be introduced and have exposure to intravenous pumps, feeding pumps and patient observation devices. Student nurses and midwives in their final year of training will attend classroom based medical device training on these devices. Following successful completion of this classroom training the students will be expected to use the equipment under direct clinical supervision. Upon entering the NMC register nurses and midwives will be competency assessment for the high risk intravenous devices within their preceptorship status prior to using the devices independently.

6.3. Training Competencies

Level of training required is based on the risk level of the device (See Appendix 4). The training pathway can be seen on page 2. Further information on risk level can be seen in Appendix 6: Definition of Medical Device Risk Levels

6.3.1. **High Risk:** Where a device is assessed as being high risk the Trust requires any training provided to be competency based with evaluation and assessment following training. Recognised experts and/or staff who have received device specific training and can demonstrate they have the aptitude, skill, knowledge and experience to do so may train/instruct and assess others. Competency is judged against agreed assessment criteria. Competency may need to be re-assessed:

- Where indicated by an alteration in clinical practice (change of responsibilities or section)
- If staff have not used a particular high risk device for over a period of 3 months, a review of its functions is required with a competent staff member
- An incident has been reported within the Trust or externally that links the device to misuse, poor design or poor practice
- Any specific item where a predetermined time scale for frequency of training updates has been agreed to by the Medical Devices training officer

6.3.2. **Medium Risk:** Where a device is assessed as being medium risk the Trust requires any training provided to be competency based with evaluation and assessment following training. Recognised experts and/or staff who have received device specific training *and* can demonstrate they have the aptitude, skill, knowledge and experience to do so may train/instruct and assess others. Competency is judged against agreed assessment criteria.

6.3.3. **Low Risk:** Training is not required for frequent regular (Section 6.10) users who can demonstrate they have the aptitude, skill, knowledge and experience in using the devices.

6.4. Self-Assessment

6.4.1. Existing Healthcare professionals who are identified by their manager as long-term 'expert users' and use the device as part of their job role e.g. Clinical staff that use devices where competency has been inferred from professional qualification; may self-certify on low, medium and most high- risk equipment.

6.4.2. To self-assess competency, each professional member of staff is required to read and complete a competency statement using form MD05s (See Appendix 3). The statement gives recognition to professional accountability of trained staff; and those staff who are able to self-assess and self-regulate their competency are authorized to do so on most items. In order to ensure that the self-assessment is as accurate as possible and to maintain a balanced and consistent approach, personal profiles (MD04 See Appendix 3) will be countersigned as appropriate by one (or more) of the following: ward/department manager, speciality/clinical tutor or designated trainer.

6.4.3. NOTE: Some high-risk devices require specialist training and staff are required to attend training courses, e.g. defibrillators. Each Care Group should develop their own list relevant to their areas and staff should be made aware of these items.

6.4.4. Where staff use the following Medical Devices:

- Defibrillators
- Epidural Equipment
- Infusion Pumps
- Neonatal Incubators
- Patient Controlled Administration
- Patient Lifting and Handling equipment
- Point of care equipment provided by Pathology (e.g. blood gas machines)
- Renal Dialysis Equipment
- Specialist Theatre Equipment
- Syringe Drivers/pumps
- Ventilators

This is not an exhaustive list

6.4.5. This equipment may not be self-certified unless the user is deemed at level 4 (Table 1.0) competencies by a specialist user, clinical manager or the MDTO. If staff are not deemed a level 4 competency they are required to attend specific training programmes before being authorised to use the equipment.

6.5. **Transferral of Competency**

Devices where competency has been inferred from professional qualification must be checked against the specific model of the devices in use in this Trust. This should take place at induction and any training needs identified on high-risk equipment should be addressed within a reasonable amount of time from when commencing work in a clinical area. It is the individual staff member's responsibility to ensure training is obtained.

6.6. **Processes for Identifying Training Needs**

6.6.1. **New staff - Substantive**

Training needs of new staff will be assessed and training plans agreed with their relevant Induction Leads during the induction period giving particular emphasis to **high-risk medical devices**. Staff must not use these medical devices until they have been successfully trained or are deemed competent.

6.6.2. New staff will receive appropriate training, in relation to high-risk medical devices that they are required to use during their work in the shortest possible time, usually within 6 months.

6.6.3. Staff should complete this form with their induction lead during assessment at local induction when applicable. It is essential that once any training has been successfully completed that a record of the training is given to the manager to update the MD03 form on the Medical Devices Share Drive. Staff are required to update their MD04 individual record of training after training has been completed (Appendix 3).

6.6.4. Training programmes for medium risk medical devices will be carried through in a prioritised and timely manner. If it is felt appropriate by the Induction Lead, an assessment of competency can be determined on the ward once it has been established it is safe to do so.

6.6.5. **Existing staff – Substantive**

All users of medical devices, at the time of their annual appraisal, must check their competencies are up to date in accordance to their role using the MD06 form. Staff must refer to Ward Manager or appropriate person to ensure that their competencies are current on the functionality and safe use of existing medical devices and any new item(s) that may have arrived in the previous 12 months. Should any training requirement be identified, a training programme should be requested and agreed with the staff member and by the relevant Manager(s) to ensure that their skills, knowledge and competencies are maintained. Any agreed training (and subsequently its completion) should be recorded in their personal development plan (PDP) as well as their MD04 form (Appendix 1).

6.7. **New ‘Medical Devices’ Training**

6.7.1. Training on new medical devices will be provided where ever possible by the supplier/ manufacturer and identified and agreed at the procurement stage. Due to resource limitations it may necessary to have “Key Trainers (the person trained by supplier/manufacture) as the initial trainer (e.g. when the amount of training in the use of the new medical devices exceeds required implementation timescales).

6.7.2. Medical Devices will not be put into operation without there being sufficient numbers of trained staff to ensure its safe and effective use (Appendix 4A). This should be at the discretion of the Medical Devices Training Officer in conjunction with clinical management. The risk level of the device and the usage, according to individual ward needs, must be taken into consideration. A review of device risk levels can be found in Appendix 6.

6.8. **Process for Identifying Authorised Users**

6.8.1. In clinical areas, the Ward Manager shall keep a list of Key Trainers for specific medical devices approved for that area

6.8.2. All ward/department managers and other designated staff will have access to the Medical Device Shared drive to review staff training and competencies. The Medical Devices Shared drive will include all high-risk medical devices identified in that area along with the approved users of the medical devices.

6.9. **Level of Training**

Training level achieved is determined by the role in which the staff member is required to use a specific medical device. There are three levels of training achievable (See Appendix 5).

6.10. Frequency of Training Update

6.10.1. Refresher/Update training will always 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 that may affect the safe operation of the device
- When a Safety Alert recommended actions requires it.
- When a clinical trust policy requires it e.g. (Point of Care Testing Equipment)
- The Medical Device Training Pathway on page 2 will assist staff to identify the correct pathway of training according to risk of the device

6.10.2. **High Risk Devices:** Staff may require updating to ensure competence is maintained with the relevant model. Frequency of update required depends on the amount of use on the equipment. A frequent user with a level 4 competency may be deemed competent by a qualified assessor (Appendix 4A). A competency assessment form (MD06) must be completed and signed by the clinical manager and sent to the Medical Devices Training Officer. The Clinical Manager/LMDL must update the training records in the medical device share drive folder with the date of the completed competency assessment.

The *minimum* requirement for refresher training on 'High Risk' medical devices should be based on the frequency that a professional uses a device and their level of competency: Table 1 and Table 2

Table 1.0 High Risk Update Only

COMPETENCY LEVEL	Required Minimum Frequency update for High Risk			
	Level 4	Level 3	Level 2	Level 1
	I am able to use the device easily and I can recognise and interpret information and troubleshoot without hesitation.	I am able to use this device safely but some concentration is required.	I can use this device with a lot of concentration. I cannot be distracted by conversation.	I may have received training but do not feel competent to use this device
Frequent User	Update not required	3 yearly	Annual	User not authorised
Occasional User	Update not required	2 yearly	Annual	User not authorised

Example: If you are an occasional user but can sustain a competency level 4, an update will not be required. If you are level 3, a 2 yearly update applies.

6.10.3. **Medium Risk Devices:** The minimum requirement for refresher training Medium risk medical devices should be based on the frequency that a professional uses a device and their level of competency. A frequent user with a level 4 competency may be deemed competent by a qualified assessor (Appendix 4A).The form must be signed by the clinical manager and sent to the Medical Devices Training Officer. The clinical manager/LMDL must update the training records in the medical device share drive folder with the date the self-assessment was completed.

Table 2.0: Medium Device Risk update

COMPETENCY LEVEL	Required Minimum Frequency update for Medium Risk			
	Level 4	Level 3	Level 2	Level 1
	I am able to use the device easily and I can recognise and interpret information and troubleshoot without hesitation.	I am able to use this device safely but some concentration is required.	I can use this device with a lot of concentration. I cannot be distracted by conversation.	I may have received training but do not feel competent to use this device
Frequent User	Update not required	5 yearly	Annual	User not authorised
Occasional User	Update not required	5 yearly	Annual	User not authorised

6.10.4. **Low Risk Devices:** No update is required
All permanent clinical staff are expected to access refresher training/updates for medical devices as a matter of course according to their own professional accountability.

Frequent User: Devices are used several times per shift.

Occasional User: Devices are used less than 7 times weekly.

6.11. **Reviews of Risk Levels:**

Details of risk levels are outlined in Appendix 4.

6.12. **Training Records**

6.12.1. **Responsibility of staff member**

Each individual staff member in the Trust that is involved with medical devices requires a personal profile **MD04** (Appendix 3) form to record the training achieved. This provides an overview of evidence of their competency level on all the devices they use, whether training is by a company rep, an in-house course or self-assessment. Update the MD04 frequently to keep the record up to date. This may be used in the annual PDP review and must be stored in the area they are working.

6.12.2. **Responsibility of Ward/department**

An inventory of medical devices (MD01 Asset Register, Appendix 3) is a pre-requisite for all training forms to identify which devices are used in a specific

area.

6.12.3. Each Department must have an **MD03** form located on the Medical Device Shared drive as an overview of the current staff training level and when their training was achieved (Appendix 1). The Medical Devices Shared drive will include all high-risk medical devices identified in that area along with the approved users of the medical devices.

6.12.4. **Registers for training received:** Where an approved Training Provider (including LMDL or key trainer) delivers training, either on a one to one basis or to a group, a record of the training given must be made that will include as a minimum:

- Name of the course
- Date of training
- Level of training received
- Name of staff that attended with signature
- Trainers Name and details

The MD07 Form must be used to record in-house training sessions (Appendix 3). Employee support provide registered for formal classroom teaching. Company representative may use their own registers or the MD07 form. All training registers, once completed, should be sent to the Medical Device Training Officer, Medical Physics Department, Tower Block.

6.12.5. **Recognised Expert:** Person accountable to use the MD07 training form:

- Key Trainer
- Specialist User
- Company Representative Clinical trainer when applicable
- Medical Devices Training Officer

7. Dissemination and Implementation

7.1. This policy will be published on the Trust Document Library following authorisation by the Executive Director. Immediately following publication the Medical Physics Department will ensure that its publication is highlighted across the Trust using various media including the Daily Bulletin. Implementation of this policy will be supported through a series of briefings, departmental visits and training as required highlighting differences from the preceding policy and resolving medical device training issues as they arise.

7.2. The training aspects relating to the implementation of this policy are contained within the main body of this document.

8. Monitoring compliance and effectiveness

Element to be monitored	Trust Compliance level in regards to High Risk device training and training records
Lead	Medical Device Training Officer
Tool	Quarterly Reports from Electronic Staff Records and Training Database
Frequency	The Medical Device Training officer will undertake an audit every 6 months to verify compliance and the efficacy of evidence. Training records should be reviewed quarterly by the Ward/Department Managers to ensure records remain up to date.
Reporting arrangements	All areas will be audited on a rotational basis. A report will be produced for the Care Quality Group. The information will be summarized on the annual IPR report to the executive board. Concerns will reported and acted upon through the Learning & Development Committee.
Acting on recommendations and Lead(s)	Senior Matrons, Medical Device Links and Medical Devices Training Officer will formulate an action plan and allocate actions to staff accordingly within an appropriate time scale.
Change in practice and lessons to be shared	Changes will be disseminated through Ward Managers and the Local Medical Devices Links. Action to be completed will be address through the Medical Device Link Meetings and completed within the appointed time stated in the action plan.

9. Updating and Review

This policy will normally be reviewed no less than every three years unless an earlier review is required.

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the '[Equality, Diversity & Human Rights Policy](#)' or the [Equality and Diversity website](#).

10.2. **Equality Impact Assessment**

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Medical Devices Training Policy V2.0		
Date Issued/Approved:	3rd July 2019		
Date Valid From:	August 2019		
Date Valid To:	August 2022		
Directorate / Department responsible (author/owner):	Elizabeth Anderson- Medical Device Training Officer. Learning & Development Department.		
Contact details:	01872 252275. Bleep 3018		
Brief summary of contents	Outline of all aspects of training staff in the safe use of Medical Devices		
Suggested Keywords:	Medical, Devices, Baxter, Alaris, T34, McKinley, pump, training, observations		
Target Audience	RCHT	CFT	KCCG
	✓		
Executive Director responsible for Policy:	Medical Director		
Date revised:	3rd July 2019		
This document replaces (exact title of previous version):	Medical Devices Training Policy V1.10		
Approval route (names of committees)/consultation:	The Learning Committee		
Department Manager confirming approval processes	Helen Lewis Associate Director of People Development		
Name and Post Title of additional signatories	Not Required		
Name and Signature of Care Group Governance Lead confirming approval by specialty and Care Group management meetings	{Original Copy Signed}		
	Name: Elizabeth Anderson		
Signature of Executive Director giving approval	{Original Copy Signed}		

Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only	
Document Library Folder/Sub Folder	e.g. Clinical / Medical Physics			
Links to key external standards	CQC Regulation 15			
Related Documents:	<ul style="list-style-type: none"> • Standards of proficiency for registered nurses Annex B: Nursing procedures NMC (2018) • Health and Social Care Act 2008 • Care Quality Commission 2009 • NHSLA Standards for Acute Trusts Department of Health (2008) - Standards for Better Health • NHSLA Risk Management standards for Acute Trust (2008) • Medical Device Agency (MDM) Devices in Practice • MDM Equipped to Care- The safe use of medical devices in the 21st century • Medicines and Healthcare Product Regulatory Agency (MHRA) (2015) Managing Medical Devices 			
Training Needs Identified:	Yes. Training aspects relating to the implementation of this policy are contained within the main body of this document			

Version Control Table

Date	Version No	Summary of Changes	Changes Made by (Name and Job Title)
15 th Dec 2004	V1.0	Initial Issue	Scott Brown
15 th Dec 2006	V1.2a	Minor amendments	Scott Brown
1 st June 2008	V1.3a	Minor Amendments	Richard Cranage
23 rd January 2009	V1.4a	Amended	Sally-Ann Rundle
7 th April 2011	V1.5a	Major amendments were made to reflect current practice and new guidelines	Janine Webster
7 th May 2011	V1.8	Policy reformatted to conform to Trust Template	Andrew Rogers Corporate Records Manager
15 th May 2013	V1.9	Changes to self-assessment criteria	Janine Webster
11 th July 2016	V1.10	Policy reformatted to conform to Trust Template. Contact Numbers updated. Addition Training Pathway on page 2	Elizabeth Anderson Medical Device Training Lead
3 rd July 2019	V2.0	Changes to Divisional Governance structure to realign with new Care Groups. Additional section 6.2.4 detailing training for student nurses & student midwives.	Elizabeth Anderson Medical Device Training Lead

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.

This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Initial Equality Impact Assessment Form

Name of the strategy / policy /proposal / service function to be assessed Medical Devices Training Policy V2.0						
Directorate and service area: Medical Physics			New or existing document: Existing			
Name of individual completing assessment: Elizabeth Anderson			Telephone: 01872 252275			
1. <i>Policy Aim*</i> <i>Who is the strategy / policy / proposal / service function aimed at?</i>		To help staff identify the requirements of medical device training within the remit of their role.				
2. <i>Policy Objectives*</i>		To ensure staff use medical devices competently and confidently and staff are working within the guidelines of the NHSLA and Care Quality Commission				
3. <i>Policy – intended Outcomes*</i>		Ensure all clinical staff are adequately trained in Medical Devices, improve patient safety and patient experience.				
4. <i>*How will you measure the outcome?</i>		Compliance Monitoring Tool				
5. <i>Who is intended to benefit from the policy?</i>		All clinical staff and patients within the care of RCHT.				
6a Who did you consult with		Workforce	Patients	Local groups	External organisations	Other
		X				
b). Please identify the groups who have been consulted about this procedure.		Please record specific names of groups The Learning Committee				
What was the outcome of the consultation?		Agreed.				

7. The Impact

Please complete the following table. **If you are unsure/don't know if there is a negative impact you need to repeat the consultation step.**

Are there concerns that the policy could have differential impact on:					
Equality Strands:	Yes	No	Unsure	Rationale for Assessment / Existing Evidence	
Age		X			
Sex (male, female, trans-gender / gender reassignment)		X			
Race / Ethnic communities /groups		X			
Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.		X			
Religion / other beliefs		X			
Marriage and Civil partnership		X			
Pregnancy and maternity		X			
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		X			
<p>You will need to continue to a full Equality Impact Assessment if the following have been highlighted:</p> <ul style="list-style-type: none"> You have ticked "Yes" in any column above and No consultation or evidence of there being consultation- this <u>excludes</u> any <i>policies</i> which have been identified as not requiring consultation. or Major this relates to service redesign or development 					
8. Please indicate if a full equality analysis is recommended.			Yes	No	X
9. If you are not recommending a Full Impact assessment please explain why.					
Not indicated					

Date of completion and submission	3 rd July 2019	Members approving screening assessment	Policy Review Group (PRG) APPROVED
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This EIA will not be uploaded to the Trust website without the approval of the Policy Review Group.

A summary of the results will be published on the Trust's web site.

Appendix 3. A Guide to Medical Devices Forms

Ward forms		Responsible staff	Location	Update
MD01	Local inventory list of medical devices in ward/department	Ward/ departmental manager or delegated staff	Ward/ departmental folder	On receipt/ disposal of equipment
MD03	Register of competencies of all staff in ward/department	Ward/ departmental manager or delegated staff	Ward/ departmental folder	Yearly or sooner if required; start of new staff / update of staff training.
MD04N	Personal competency record for staff not state-registered	All MD04 forms: All staff are responsible for their own training records. Ward/ departmental manager to ensure yearly update (eg: at PDR)	All MD04 forms: Staff personal folder. Copy kept in Ward/ departmental folder Copy kept after staff have left Trust	As required; on training updates. Yearly review in PDR
MD04R	Personal competency record for professionally registered staff			
MD04K	Personal competency record for agency and Kernowflex staff			
MD08i TNA	Induction form for new staff and TNA for existing staff	Ward/ departmental manager and new staff member (optional form at local induction)	To be kept by Ward/ departmental manager until listed training requirements complete	Information transferred onto MD04 form
MD05	Self-assessment competency sheets specific to a medical device	Key Trainer to provide staff with relevant sheet (for training purposes only)	Staff personal folder	As required; on training update
MD06	Medical Devices Assessment Form Equipment list for Registered and Non Registered staff General Ward Equipment	Ward/ departmental manager to ensure yearly update (e.g. at PDR)	Ward/ departmental folder Copy sent to Medical Device Training Officer	Staff are out of compliance with their medical device training
MD07	Attendance sheet for training sessions	In-house course trainer/ Key Trainer/ company representative	Return completed form to: rch-tr.MedicalDevices@nhs.net	When training courses are completed
MD11	Record sheet to be used when Issuing Medical Devices to End-Users (patients/carers)	Staff who issue medical device	Ward/ departmental folder If item belongs to Equipment Library, copy to be sent to them for information	On issue of device, and on its return. (Escalation process to be followed if item not returned)

All forms are located on the Medical Physics intranet site

Appendix 4. Medical Device Risk Level

Category	Definition	<i>Level of risk of harm to patient due to user error</i>	Training Requirements
Low risk	Devices whose failure or misuse is unlikely to result in serious consequences.	None too low. None – little or no adverse effect on patient Low – discomfort, delay and inconvenience to patient	Training is informal, ‘in-house’ or linked to professional qualifications. No formal records are required, but the user must be able to demonstrate knowledge of the specific model, equipment use, 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 Unless fully competent, the user must seek advice from staff competent with the device prior to using the medical device. This should be followed by a formal or informal training program, provided by an experienced practitioner.
High risk	Devices that have the potential to cause serious adverse consequences or death should they fail or be misused. <i>Devices recently associated with serious injury</i>	Severe – Serious harm leading to disability or death	Training and competency records must be maintained. The user must undertake competency-based training prior to using the device.

Appendix 5. Levels of Training

Level 1: Basic (Awareness) Training

WHO: This applies to all medical equipment that medical, nursing, professions allied to nursing or ancillary staff may use or handle.

WHY: This level of training is intended to provide an **overview** including a basic understanding of the equipment, providing an awareness of the principles of the equipment. This level of training may be given to support staff who would not be expected to operate the equipment clinically but will need an appreciation of it for safety, to set it up for others, to clean the item or to perform routine maintenance checks.

HOW: Training may be provided by self-assessment, ward/department based **key trainers**, in-house training providers or supplier/manufacture's representatives.

Level 2: Full Training

WHO: This applies to all medical equipment that medical, nursing, professions allied to nursing or ancillary staff may use.

WHY: This level of training is intended to provide comprehensive and detailed instruction in the use of the equipment, covering all aspects of the equipment including pre use Testing, setting up, operation, user problems and decontamination. This will allow the staff to operate the equipment correctly and safely for a clinical procedure.

HOW: Training may be provided by self-assessment, ward/department based key trainers, in-house training providers or supplier/manufacture's representatives.

Specialist Training (Key Trainers)

WHO: This level of training is intended for those members of staff who use specialist equipment to a higher level than general clinical use, or have been designated as key trainers for the equipment.

WHY: This level of training identifies equipment requiring specific training and provides the key trainer with information on how to train others.

HOW: Key trainers must have been trained by the supplier/manufacture representative, a specific in-house course or be identified as an expert in use on a particular item. Key trainers will be expected to complete the Course Register form (MD07) when conducting in house training sessions and forward this to the Medical Devices Training

Appendix 6. Local Medical Device Link and Key Trainer

Identifying Roles and Responsibilities

Local Medical Device Links (LMDL) and Key Trainers (KT) are essential roles in ensuring the safe and efficient use of medical devices throughout the Trust. They will be involved in assisting in the training of their colleagues, identifying training needs in their area, and become the link between their ward and the Clinical Equipment Management Service.

This link will facilitate will inform the Medical Device Training Officer for (MDTO) the improvement of staff competencies through by recording competencies on the training database.

LMDL Requirements:

- Must be a qualified/registered practitioner on a permanent contract within the Trust
- Can also become a Key Trainer provided they commit to the Key Trainer Program and the requirements of a Key Trainer.

Ward/Dept Managers must identify a Local Medical Link within the ward/department

Responsibilities:

- Work in association with the Medical Devices Training Officer to improve the competencies of RCHT staff on Medical Devices
- Identify the Medical Device training needs of healthcare workers in their local are and convey them to the MDTO in conjunction with the ward/department manager.
- Identify Key Trainers (KT) in their area who can assist with update training of specific devices
- Assist Key Trainers by communicating to Ward Level Managers and Care Group Leads the necessity for time allocation within working hours to permit training and attend Key Trainer Training
- Attend meetings organised by the MDTO to share experiences, identify training needs and promote good training practice within the Trust.

Appendix 6A: Key Trainer Requirements

Key Trainer Requirements:

Key Trainers must be a minimum of a band 5 and a qualified/registered practitioner and on permanent contract with the Trust. Key Trainer person specification can be found in Table 1.0 below.

Ward/Department Managers must recommend appropriate staff members for the Key Trainer Program.

Responsibilities:

- Commit to the Key Trainer Program
- Attend Key Trainer Days (relevant devices)
- Commit to a signed Key Trainer Agreement.
- Identify specific devices for which they will provide training (number of devices at the discretion of the MDTO)
- To deliver competence-based update training to existing staff on the safe use of specific medical devices in their clinical area to healthcare workers including agency/locum staff by using training packages facilitated by the MDMT to ensure standard training throughout the Trust
- To assist the ward/department manager and LMDL with updating their local area's training records and *provide evidence of training*
- To report issues, concerns or proposed improvements directly to the LMDL.

In reference to the Key Training Program guidelines, if the KT is unable to fulfil training duties or attend Key trainer training days they must inform the MDTO or LMDL immediately, failure to do so may result in their key training status being revoked.

Table 1.0 Key Trainer- Person Specification (Clinical Assessor):

		Essential		Desirable
Qualifications	Q1	Appropriate Healthcare professional qualification for the device in question or equivalent level of knowledge, skills and experience	Q2	Teaching/Assessing related qualification at NVQ3 or above
Experience	E1	Ability to demonstrate sound clinical expertise and knowledge of clinical issues relating to device usage and/or	E4	Have attended a key trainer session.
	E2	Demonstrate in depth knowledge of the device.		
	E3	Proven experience of teaching and mentoring staff.		

Skills/Abilities/Knowledge

Attributes

SA1	Operating device at Competency Level 4
SA2	Ability to troubleshoot problems with the device
SA3	Awareness of professional responsibilities to self and others.
SA4	Ability to demonstrate a safe and supportive working environment for staff
SA5	Able to articulate all training aspects relating to the safe use of the device to team members including those less confident in the use of the technology
SA6	Able to judge the understanding of students and assess competency when required.
SA7	Able to identify staff requiring further support and training
SA8	Able to review and develop clinical competencies/learning packages for specialist equipment

A1	Approachable
A2	Enthusiastic
A3	Manual Dexterity
A4	Demonstrate an aptitude for technology