South East Coast Ambulance Service NHS
NHS Foundation Trust

Medical Devices Training Standard Operating Procedure

Contents

1 Scope

1.1. South East Coast Ambulance Service NHS Foundation Trust (SECAmb, or 'the Trust') recognises that there are risks associated with the use of medical equipment. The Trust seeks to mitigate these risks through the provision of an appropriate programme of education for all staff who may be responsible for using such equipment in clinical practice. This procedure describes a framework for the governance and provision of that training.

1.2. The Trust is committed to providing high quality patient care whilst maintaining the safety of its staff and volunteers.

1.3. This procedure is applicable to all staff and volunteers in the Trust using medical devices provided by the Trust and sets out the principles which must be adhered.

1.4. It is recognised that whilst this procedure specifically refers to medical devices, the same methodology can be applied to non-medical and other devices in use within the Trust to provide a governed approach to training and familiarisation.

2 Procedure

2.1. Authorised users of medical devices

2.1.1. Staff are authorised to use medical devices based on their grade and scope of practice, as identified within the Scope of Practice and Clinical Standards Policy. The Clinical Equipment and Consumables Working Group (CECWG) will identify which grades of staff are authorised to use each medical device and this will be recorded on the medical device inventory – e.g. authorised users of Otoscope are Paramedic Practitioners.

2.1.2. All operational staff grades are recorded on the Electronic Staff Record (ESR). In order to identify which equipment a specific member of staff is authorised to use their clinical grade will be determined from ESR and then cross-referenced with the medical device inventory.

2.1.3. It is recognised that an individual's scope of practice may change during employment, either temporarily or permanently. Authority to use medical devices is based on the scope of practice an individual is working to at the time of using the medical device.

2.2. **Risk assessment**

2.2.1. Each medical device will have a unique risk associated with use. This risk will be assessed by considering the likelihood of a device causing harm to staff, patients or others and the severity of the harm which may be caused. When assessing risk it is important to consider the complexity of the equipment; the circumstances in which it is likely to be used; the frequency of use and therefore familiarity; and any inherent hazards.

2.2.2. Each medical device should have a risk assessment completed by the Head of Health and Safety or their nominated delegate prior to introduction – this will identify a risk rating (low, medium, high) for the equipment as well as any mitigations which should be considered. Mitigations may be standard or device specific and will dictate the training and competency requirements.

2.2.3. Risk assessments should be reviewed periodically by the Health and Safety department. Each risk assessment should be reviewed every three years, or sooner if there are changes to the medical device in question (for example an upgraded version or change in supplier).

2.3. **Training and competency requirements based on risk assessment**

2.3.1. The training and competency requirements should be determined through completion of a Training Needs Analysis. This will be completed by a nominated Clinical Education Lead and will consider information from a range of sources, including but not limited to: the risk assessment completed for the medical device; the manufacturer's user instructions and training recommendations; the Quality Impact Assessment (QIA) completed for introduction of a new device; the outcome of any trials for new equipment; feedback from users; and recorded adverse events involving devices currently in use.

2.3.2. There is no prescribed format for the Training Needs Analysis, however the outcome will be one of the following standard mitigations which should be considered to manage the risk associated with use of medical devices and are as follows, from low to high risk:

2.3.2.1. **Information dissemination** – risk can be managed by distributing information and / or instructions to all staff who will be using the equipment and recording that it has been read and understood. The method of collating this record may vary depending on technology available at the time, but it must be recorded on the Trust's Learning Management System (LMS).

2.3.2.2. **One off familiarisation training** – risk can be managed by attending a single familiarisation training session which should take place prior to using the medical device. Note that this may take place as part of an induction training course (for example the Emergency Care Support Worker course).

2.3.2.3. **One off competency training and assessment** – risk can be managed by attending a single training session and undertaking a competency-based assessment which should take place prior to using the medical device.

2.3.2.4. **Ongoing familiarisation training** – risk can be managed by attending regular familiarisation training, the frequency of which will be determined by the risk assessment. Note that update training may be less in-depth than initial training and may be undertaken as part of the Trust Key Skills Programme.

2.3.2.5. **Ongoing competency training and assessment** – risk can be managed by attending regular training and undertaking a regular competency-based assessment, the frequency of which will be determined by the risk assessment.

2.3.3. Device specific mitigations should be listed within the risk assessment for the medical device, and may include the clear availability of instructions, warning labels placed on the device, or any other additional recommendations.

2.3.4. Where information dissemination is the accepted mitigation (this will generally be for low risk devices as per the risk assessment), this will take the form of an information pack with an appropriate 'sign off' process to confirm understanding. The information pack must be reviewed and approved by the CECWG prior to distribution.

2.3.5. Where training and / or assessment is the accepted mitigation (this will generally be for medium and high-risk devices as per the risk assessment), the format and materials associated with this training must be reviewed and approved by the Clinical Education Sub-Group (CESG) prior to implementation.

2.3.6. Consideration should be given to:

2.3.6.1. Who will deliver the training, including ensuring they are appropriately qualified to do so;

2.3.6.2. The length of training required, and the appropriate learner to teacher ratio;

2.3.6.3. The format and method of any assessment required – this may include peer assessment or review by line manager if appropriate;

2.3.6.4. The inclusion of appropriate learning outcomes and how these will be assessed. These should include (but are not limited to): equipment selection (indications and contra-indications); preparing equipment for use; using the equipment; monitoring patient safety during equipment use; cleaning and disinfection procedures; adverse incident reporting.

2.3.6.5. A recommendation of how time for training will be achieved (for example through Key Skills, abstractions, or ad-hoc release whilst on shift) and consideration of at what stage the device should be introduced (e.g. immediately, alongside established devices, or once a sufficient majority of individuals have been trained).

2.4. Recognising prior learning

2.4.1. Where an individual joining the Trust can evidence prior learning relating to the use of a medical device, for example a direct entry Newly Qualified Paramedic who has been taught to use a device on their university course, or an experienced technician who has been taught to use the device in another Trust, the acceptance of this will be based on the risk rating and expected standard mitigation.

2.4.1.1. For low risk devices, where information dissemination has been considered an appropriate mitigation, a declaration of competency will be considered sufficient (although the information pack should be made available to the individual to ensure they are familiar with any SECAmb-specific requirements).

2.4.1.2. For medium risk devices, where one-off training and assessment has been considered appropriate, the individual will not be required to repeat the training however must successfully complete assessment prior to using the medial device. Where the individual is unsuccessful at assessment they will be required to undertake the full training.

2.4.1.3. For high risk devices, where ongoing training and assessment has been considered appropriate, the individual will be required to undertake all elements of training and assessment and recognition of prior learning will not be applied.

3 Definitions

3.1. A medical device is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other

similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one of more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- Supporting or sustaining life;
- Control of conception;
- Disinfection of medical devices;
- Providing information by means of in vitro examination of specimens derived from the human body;

And does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means (World Health Organisation, 2019).

3.2. The Key Skills Programme is the Trust approach to providing annual updates and development training to all operational staff, in order to ensure compliance with statutory and mandatory requirements.

4 Responsibilities

4.1. The **Chief Executive Officer** has overall accountability for this procedure.

4.2. The **Medical Director** has responsibility for the implementation and monitoring of this procedure.

4.3. The **Head of Logistics** is responsible for maintaining an accurate, up-to-date and complete inventory of medical devices which are in use throughout the Trust.

4.4. The **Head of Health and Safety** is responsible for ensuring appropriate risk assessments are written, recorded and reviewed for all medical devices within the Trust.

4.5. The **Consultant Paramedic (Clinical Education)** is responsible for ensuring that staff receive appropriate and sufficient training and assessment related to medical devices.

4.6. The **Consultant Paramedics** are responsible for identifying, amending or developing the scopes of practice to be followed by operational staff.

4.7. The **Clinical Equipment and Consumables Working Group (CECWG)** is the organisational focus for advice and best practice relating to the acquisition, use and management of medical devices. In regard to medical device training, the group has responsibility for:

4.7.1. Determining the risk assessment and appropriate mitigations for managing risk for all items on the medical device inventory;

4.7.2. Identifying which grades of staff, as per their scope of practice, or authorised to use each item on the medical device inventory;

4.7.3. The ongoing effectiveness of this procedure.

4.8. The **Clinical Education Sub-Group (CESG)** is the gatekeeper of educational quality and assurance for clinical teaching with the Trust. In relation to medical device training, the group has responsibility for:

4.8.1. Reviewing the Training Needs Analysis for any new or existing medical devices used within the Trust;

4.8.2. Ensuring teaching and learning materials are appropriate to the device in question, quality assured, and accessible for use as required.

4.9. **All employees** are responsible for:

4.9.1. Adhering to this procedure in its entirety;

4.9.2. Ensuring they are aware of which medical devices they are authorised to use as per their scope of practice;

4.9.3. Ensuring they are confident and competent in the operation of the medical devices they are authorised to use.

4.9.4. There is the expectation that any employee who does not feel confident and competent to use a medical device correctly will identify this training need to their line manager and not use the relevant device until sufficient training has been provided to demonstrate competence.

5 Audit and Review (evaluating effectiveness)

5.1. All procedures have their effectiveness audited by the responsible Management Group at regular intervals, and initially six months after a new policy is approved and disseminated.

5.2. Effectiveness will be reviewed using the tools set out in the Trust's Policy and Procedure for the Development and Management of Trust Policies and Procedures (also known as the Policy on Policies).

5.3. This document will be reviewed in its entirety every three years or sooner if new legislation, codes of practice or national standards are introduced, or if feedback from employees indicates that the policy is not working effectively.

5.4. All changes made to this procedure will go through the governance route for development and approval as set out in the Policy on Policies.

5.5. The effectiveness of this procedure and its application will be assessed using information from audit systems, adverse incidents, user feedback and external alerts.

6 References

6.1. World Health Organisation (WHO), 2019. *Medical devices – full definition* [online]. Available at: <https://www.who.int/medical_devices/full_deffinition/en/> [Accessed 5th August 2019].

7 Equality Analysis

7.1. The Trust believes in fairness and equality, and values diversity in its role as both a provider of services and as an employer. The Trust aims to provide accessible services that respect the needs of each individual and exclude no-one. It is committed to comply with the Human Rights Act and to meeting the Equality Act 2010, which identifies the following nine protected characteristics: Age, Disability, Race, Religion and Belief, Gender Reassignment, Sexual Orientation, Sex, Marriage and Civil Partnership and Pregnancy and Maternity.

7.2. Compliance with the Public Sector Equality Duty: If a contractor carries out functions of a public nature then for the duration of the contract, the contractor or supplier would itself be considered a public authority and have the duty to comply with the equalities duties when carrying out those functions.

8 Quality Impact Assessment

8.1. A Quality Impact Assessment (QIA) has been undertaken on this procedure.