MEDICAL DEVICES TRAINING FOR CLINICAL STAFF

Amendments

<table>
<thead>
<tr>
<th>Date</th>
<th>Page(s)</th>
<th>Comments</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2004</td>
<td>All</td>
<td>Document reviewed Appendix added</td>
<td>Director of Nursing</td>
</tr>
<tr>
<td>October 2007</td>
<td>3, 5, 6</td>
<td>Document updated</td>
<td>Director of Nursing &amp; Operations</td>
</tr>
<tr>
<td>Dec 2010</td>
<td></td>
<td>Document updated in line with NHSLA requirements</td>
<td>Medical Director</td>
</tr>
</tbody>
</table>

Complied by: Marty William Clinical Risk Manager

In Consultation with: Liz Taylor Clinical Governance Manager,
Ratified by: Clinical Governance Committee (Chairman’s Action)
Date Ratified: January 2011
Date Issued: January 2011
Review Date: December 2014
Contact name for comments: Training Department
1. **INTRODUCTION**

This document sets out the framework for clinical staff for medical device training. Medical Devices are:

“...any instrument, apparatus, 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 handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of contraception which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means. (MHRA 2007)

2. **PURPOSE**

This policy will ensure that there is a process whereby all permanent clinical staff are trained to safely use diagnostic and therapeutic equipment appropriate to their role. Clinical staff includes Doctors, Nurses, Midwives and all Allied Health Professionals. It is recognised that the use of medical devices and equipment may be delegated to a Health Care Assistant or other associated support staff, but the registered professional remains accountable at all times for ensuring the competence of individuals and that delegation is appropriate and safe.

3. **DUTIES WITHIN THE ORGANISATION**

It is the responsibility of the ward/departamental manager to ensure that they:

- Log all medical devices within their areas on the equipment inventory list (see example in appendix 1)
- Identify trainers on the equipment inventory list
- Make available instruction and user manuals

It is the responsibility of ward managers, departmental managers, divisional general managers or

- Assess individual training needs at initial local induction and/or annual appraisal using the Trust Equipment Inventory List for the appropriate area available from wards, departments and the Trust intranet.
• Identify and organise appropriate training programmes and/or training from ward/department trainers
• Retain completed individual training records (equipment inventory list)
• For Drs in training a generic equipment list has been designed and training is provided over the local induction period
• Consultants are expected to attend mandatory training to enable them to use category 2 equipment
• Each Division will offer speciality specific training to consultants where there is an identified need
• Explicit that all consultants have a professional/personal accountability to self competency for medical devices they use
• All consultant have an annual appraisal whereby CPD/CME attendance is discussed and any competency training identified
• Where new techniques are identified all medical/nursing /allied health professionals should follow the procedure outlined below
• When a new procedure requires a new piece of equipment the user will need to provide evidence to show that he/she has undergone the required training to carry out the new procedure or technique. Please refer to the Policy & Procedure for the introduction & Development of new interventional procedures.
• Frequency of attendance at specific training must be discussed individually at the annual appraisal or sooner if a problem is identified.

4. POLICY STATEMENT

The Trust aims to ensure that all clinical staff who operate diagnostic or therapeutic medical devices can do so in a safe and effective manner.

The Trust expects all clinical staff, including temporary clinical staff working in the Trust or those working in the Trust from other organisations to adhere to the following principles before using any medical equipment:

• Not to use equipment unless they have been trained to do so
• Identify their training requirements with ward manager / supervisor
• Having completed agreed supervised practice, be deemed competent by the supervisor to operate independently
• Always visually inspect the equipment for signs of damage prior to use.
• Ensure any accessories and/or disposables required are recommended by the manufacturer.
• Know where the user manual / instructions and Trust Medical Devices policy are located.
• Know how to clean the equipment
• Know what procedure to follow if equipment is broken, damaged or involved in an incident

5. CLASSIFICATION OF MEDICAL DEVICES

To identify which permanent staff are authorised to use the equipment identified on the equipment inventory the Trust’s medical devices are divided into 3 categories:
**CATEGORY 1**
Defined as basic equipment – items regularly used by all staff generally in the clinical area. For example tympanic thermometers, urinalysis machine, electric beds, dynamic mattress system.

Any clinical registered staff and non-clinical.

---

**CATEGORY 2**
Defined as competency based – items where staff require a competence, a certificate of practice or training forms part of a professional qualification. For example syringe drivers & volumetric pumps require the user to have the Intravenous Administration competency. Use of the defibrillator requires the user to be in possession of a current Advance Life Support / Immediate Life Support certificate.

Any staff holding a professional qualification, including Doctors, Other.

---

**CATEGORY 3**
Defined as a speciality specific – items used by staff in specialist areas, Theatres, Anaesthetics, Critical Care, NICU, Maternity, Therapies, Pathology, Imaging.

Any staff holding a professional qualification, including Doctors, Other.
6. **THE TRUST RECOGNISES TRAINING FACILITATED/ ORGANISED BY**

- Learning & Development Department
- Education Centre
- Equipment Resource Nurse
- Clinical Skills Education Manager
- Clinical Skills Laboratory
- Clinical Practice Educators
- Consultants / Specialist SPRs / Consultant & Specialist Nurses & Midwifery / Therapists / Manual Handling / Operating Dept Practitioner / Imaging / Staff holding a certificate/competency/logbook provided by the Royal Colleges
- Technical / Electro Medical Engineer
- Manufacturers / Suppliers of medical devices.
- Nominated competent ward/department practitioner

7. **TRAINING & EDUCATION**

- Training for any new medical device introduced into the Trust in the first instance is provided by the specific company and attendance records are kept locally and by the company.
- Training for a range of category 1 medical devices is provided on the Trust Medical Devices Study Day. Attendance records are kept by the equipment library staff.
- Training for infusion devices used for IV Therapy is provided on the Trust Intravenous Therapy Course. Attendance records are kept on the Clinical skills database by the Clinical Skills Education Manager.
- Training for category 3 medical devices is provided within specialist departments and attendance records are kept locally.
- Training for ward/department equipment is provided by the appropriate named trainer and training records kept locally.

8. **COMPETENCY**

Being competent to use a medical device is defined as:
‘Possessing the knowledge, skills and ability to safely and effectively practice without direct supervision’

Nursing staff must acknowledge the limits of their professional competence and only undertake practice for which they are deemed competent (NMC 2004)

Medical staff must provide good standards of clinical care, practise within the limits of their competence and ensure patients are not put at unnecessary risk (GMC 2006)

Competency will be revisited when:

- staff have not used a medical device for a period of time and professionally feel their knowledge or skill is limited
- where indicated by clinical practice
- an incident has been reported
- specific item where predetermined time scales have been agreed by the management/directorate team
9. **MONITORING**

The Trust equipment inventory lists are kept centrally on the Trust Intranet and locally on wards/departments and are updated and reviewed annually.

Permanent staff training needs will be reviewed annually during appraisal.

For category 2 medical devices where a competency is required, this will be recorded using either the Trust Competency Framework or other local competency documentation. Competency documentation will be kept by the individual in a Personal Portfolio.

10. **DISSEMINATION & IMPLEMENTATION**

This policy is available on the Trust intranet. All Managers are responsible for ensuring their staff are familiar with and comply with its content

11. **REVIEW**

This policy will be reviewed when statutory requirements/best practice guidelines dictate or no longer than 3 years after previous review

12. **ARCHIVING ARRANGEMENTS**

This policy will be archived with the Trust Quality Department

13. **REFERENCES**


MRHA (2007) [www.mhra.gov.uk](http://www.mhra.gov.uk)

Nursing and Midwifery Council (2004) [www.nmc-uk.org](http://www.nmc-uk.org)

National Health Service Litigation Authority (NHSLA) Risk Management Standards 2010/201
### Equipment Inventory List Example

**Department: Fracture Clinic**

**Name:** …………………………………………………………  **Signature:** …………………………………………………

**Designation:** …………………………………………………

Any person operating diagnostic or therapeutic equipment must have sufficient understanding of its use to do so in a safe and effective manner.

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Category</th>
<th>Equipment Trainer</th>
<th>Next Update Due</th>
<th>Signature of Supervisor / Mentor</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Glucosemeter - Ascencia Machine</td>
<td>1</td>
<td>Ann Fletcher</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bayer Trainer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Defibrillator Marquette 900</td>
<td>2</td>
<td>Paul Wills</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Resus Team</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECG Recorder Marquette Mac 8</td>
<td>1</td>
<td>Tina Kendall</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plaster Saw De Souter</td>
<td>3</td>
<td>M Wardle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resuscitation Trolley</td>
<td>2</td>
<td>M Wardle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suction Machine Sam12</td>
<td>1</td>
<td>J Larazo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinalysis M/C Bayer Clinitek 50</td>
<td>1</td>
<td>Ann Fletcher</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Bayer Trainer</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Please complete this form during the first week in your new post with your mentor / supervisor/ college tutor
- For Nurses, Midwives, Allied Health Professionals, Support Workers and non-clinical staff, copies of this document should be kept at Departmental level.
- For all Dr's in training, on completion of this form one copy should be sent to the appropriate Business Unit Manager or Medical College Tutor and another kept in the Learning Portfolio.
- For Consultants and staff grades, this document should be linked to the appraisal and kept in the Personal Development Portfolio.