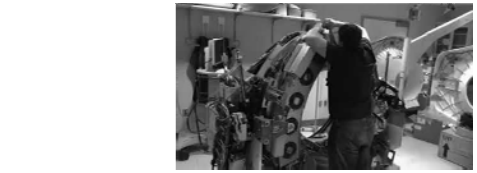
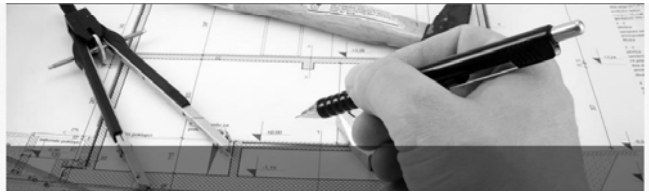
Management of Digital Imaging in Contemporary Healthcare

Slavik Tabakov





Medical device - definition

'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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,

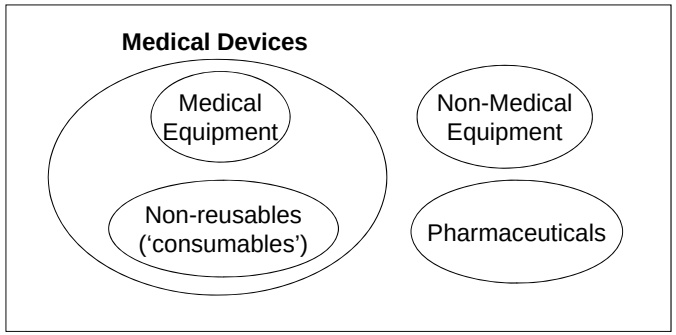
— investigation, replacement or modification of the anatomy or of a physiological process,

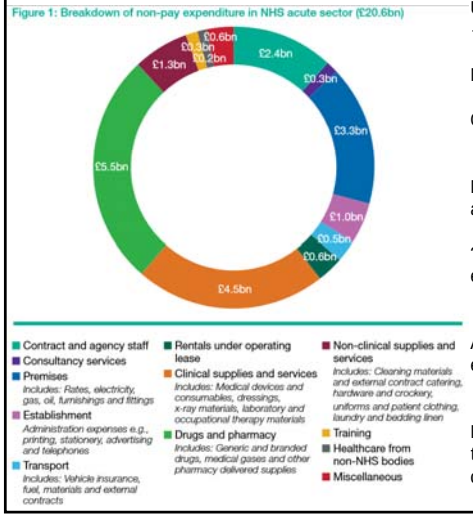
— control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

Medical Equipment as part of Medical Devices

Medical Device Directive

Medical environment





UK NHS budget 2011-12 (total ~£100bn) incl.~£20bn non-pay

Non-pay: equipment ~£4.5bn

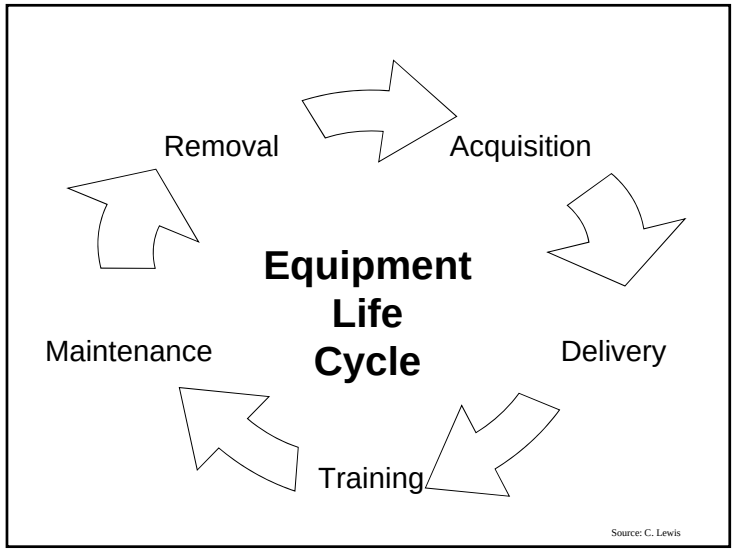
Comparison: in Africa ~£2bn

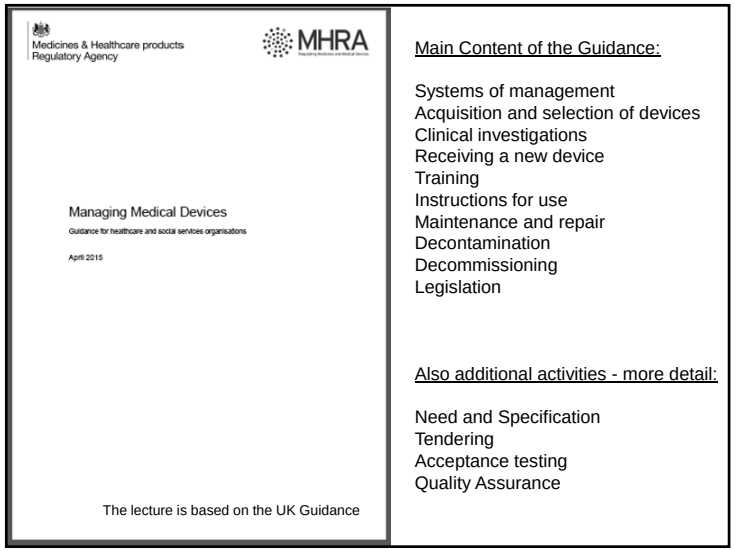
Most expensive (%): Imaging and RT equipment

? Ratio: Maintenance/New equipment (often equal)

Adverse Incidents related to equipment : x1000 pa

Manpower: engineers, technicians, physicists, other clinical scientists, managers





Main Content of the Guidance:

Systems of management
Acquisition and selection of devices
Clinical investigations
Receiving a new device
Training
Instructions for use
Maintenance and repair
Decontamination
Decommissioning
Legislation

Also additional activities - more detail:

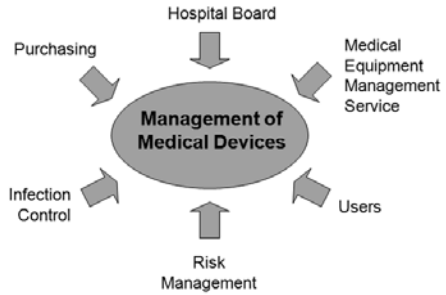
Need and Specification
Tendering
Acceptance testing
Quality Assurance

System of Management

Person (Director) with responsibility for medical device management

Medical Device Safety Officers (MDSO)

Medical devices management group – covering various aspects from clinical engineering to decontamination, purchasing, training, etc



Device management policy - ensuring that risks associated with the use of medical devices are minimised or eliminated. To address:

- responsibilities in relation to medical device management
- decontamination
- the equipment life cycle (including: selection, acquisition, acceptance, maintenance, repair, monitoring, traceability and disposal/replacement) of all medical devices
- risk management including adverse incident reporting and actions required on MHRA's Medical Device Alerts and manufacturers' field safety notices
- training and access to manufacturer's instructions
- records, including device inventory.
- outsourcing
- equipment deployment, tracking and utilisation
- equipment financing.

POLICY

This policy should be regularly reviewed to ensure that, a medical device is:
- suitable for its intended purpose
- used in line with the manufacturer's instructions
- traceable, where possible
- maintained in a safe and reliable condition, with associated

Records

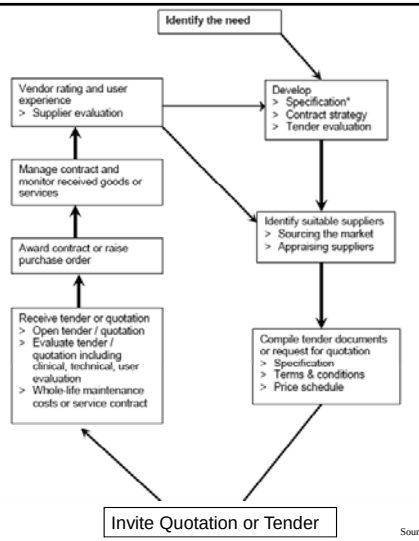
The device records should provide evidence of:

- a unique identifier for the device, where appropriate
- the purchase price of the equipment
- a full history, including date of purchase and where appropriate when it was put into use, deployed or installed
- any specific legal requirements and whether these have been met
- proper installation and where it was deployed
- schedule and details of maintenance and repairs
- the end-of-life date, if specified.

RECORDS

Healthcare organisations must ensure records are kept of training of users of medical devices. These should show that users:

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



Acquisition cycle Flow chart

or Factors to consider BEFORE the acquisition of the device - see Specifications

Source: MHRA Managing Medical Devices, April 2015

Receiving a new device

Acceptance checks/tests

Record keeping

Skills required for, and scope of, checks and tests

Delivery checks

- Paperwork
- Visual inspection
- Configuration
- Functioning test
- Electric tests
- Calibration and measurements

Safety test limits

Special considerations

- Risk assessment before first use
- Legal requirements in relation to electrical safety testing
- Other

Maintenance and repair

Management policy for medical devices

- How each device should be maintained and repaired, and by whom
- Arrangements for maintenance/repair - part of the assessment process
- Arrangements for the most suitable providers to carry out the work
- Arrangements to ensure items subject to inspection, maintenance, repair or disposal should be decontaminated
- The timescale for planned maintenance
- The timescale for repairs to be completed
- Maintenance databases

Choosing appropriate maintenance and repair services

- manufacturer service organisation
- authorised service agents
- generic/third-party service providers
- in-house maintenance departments
- users.

The service contract

- reference to manufacturer's written instructions
- availability, source and traceability of spare parts
- notification of any changes, including the use of alternative spare parts or methods
- training of staff
- quality management systems
- requirement for adequate record keeping
- who is responsible under information governance when third parties and manufacturers are taking patient data from the premises
- use of sub-contractors
- response times
- loan devices
- disposal of obsolete devices, parts and waste.

Spare parts and other components

- the device manufacturer
- other manufacturers
- healthcare organisations
- service providers
- pre-used.

Planned preventive maintenance

Legal liabilities and Insurance

Training

Policy on training

- Adequate training programmes - generic and specific (periodic review).
- How will training be delivered (face-to-face, e-learning)?
- Is it competency based?
- Who should receive the training offered by the manufacturer or supplier?
- Inclusion of new staff, agency, locum staff, contractors, engineers, etc.
- Continuing professional development.
- Training for service end users and carers.
- Planned training before a new medical device is introduced to the organisation.
- Appropriate record keeping of training both centrally and by individuals.
- Access to manufacturer's instructions for all users.
- Have you considered future training needs (in-house or by the manufacturer)
- How will training updates be managed for device/software upgrades?
- How will end users or staff in the community be trained?

Training (continue)

Training for professional users

Training for end users

Training for repair and maintenance service providers

Documentation

Instructions for use

Decontamination

Decommissioning and disposal of devices

Planning for replacement

Replacement criteria

Decommissioning

Disposal

Sale or donation for reuse

Liability issues

Refurbishment

Legislation