



devices in practice

.....

a guide for health
and social care
professionals



HEALTH ESTATES

ESTATE POLICY

*An Executive Agency of the Department of
Health, Social Services and Public Safety*

*Áisíneacht Feidhmeannach don Roinn Sláinte,
Serbhísí Sóisialta agus Sábháilteacht Phoiblí*



The Medical Devices Agency helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.

Our primary responsibility is to ensure that medical devices achieve their fullest potential to help healthcare professionals give patients and other users the high standard of care they have a right to expect.

The Medical Devices Agency is an Executive Agency of the Department of Health

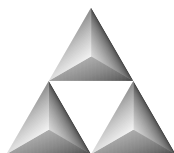


The key aim of the Northern Ireland Adverse Incident Centre (NIAIC), part of Health Estates, is to record and investigate reported adverse incidents involving Medical Devices and equipment used in the delivery of Health and Personal Social Services care in Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient or user injury. NIAIC has direct links with MDA who co-ordinate across the adverse incident centres in England, Scotland, Wales and Northern Ireland. NIAIC also disseminates safety information in Northern Ireland, including information provided by MDA.

Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety.

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Safeguarding Public Health

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1 Introduction

Medical devices play a crucial role in care and treatment. This booklet provides a practical guide to medical devices for all health and social care service professionals involved in primary care.

This booklet is for:

- health and social care professionals working in a range of primary care settings including residential and nursing homes
- health and social care organisations as they develop policies and protocols for the use of medical devices
- voluntary and charitable organisations who provide medical devices direct to individuals or Health and Social Care organisations.

Within these groups, people will have different levels of knowledge, expertise, responsibility and accountability concerning the use of medical devices. Increasingly individuals are buying their own medical devices privately. In these circumstances, health and social care professionals need to be aware that it is the responsibility of the owner to ensure that the medical devices are appropriately used and maintained.

Changes in health care technology and clinical practice mean that increasingly complex devices are being used in primary care. This is against a background of legal requirements with which devices and users must comply, together with an increased concern about the quality of care by the public and professionals.

The booklet contains a series of checklists to help ensure informed procurement and the safe use of medical devices.

2 What is a medical device?

The term 'medical device' covers a wide range of products used everyday in primary care settings, such as General Medical Practices, General Dental Practices and Residential and Nursing homes. Devices include items such as needles, syringes, infusion pumps, endoscopes, examination gloves, dressings, walking sticks and blood glucose meters. In other words, any instrument, apparatus, appliance, material or health care product, excluding drugs, used for, or by a service user for:

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

A list of some of the products covered by the definition of medical device is provided opposite.

Common categories of medical device

This list is not exhaustive. It provides examples of medical devices.

Equipment used in the diagnosis or treatment of disease, or monitoring of patients, such as:

- Chiropody and podiatry equipment
- Dental instruments, equipment and materials
- Dressings
- Endoscopes
- Examination gloves
- Gastrostomy tubes
- Intravenous (IV) administration sets and pumps
- Nebulisers
- Ophthalmic equipment
- Peak flow meters
- Surgical instruments
- Suction equipment
- Syringes and needles
- Sphygmomanometers
- Thermometers
- Ultrasound dopplers
- Urinary catheters

Equipment used in life support, such as:

- Defibrillators
- Domiciliary oxygen therapy systems
- Insulin injectors
- Pulse oximeters
- Ventilators used in the home

***In vitro* diagnostic medical devices and their accessories, such as:**

- Blood glucose measuring devices
- Cholesterol test kits
- Pregnancy test kits
- Specimen collection tubes
- Urine test strips

Equipment used in care, such as:

- Adjustable beds
- Lifting poles
- Patient hoists
- Pressure relief equipment
- Stoma care equipment

Equipment used by people with disabilities, such as:

- Bathing equipment
- Commodes
- External prostheses and orthoses
- Hearing aids
- Incontinence aids
- Prescribable footwear
- Standing frames
- Urine drainage systems
- Walking aids
- Wheelchairs and special support seating

Other examples include:

- Condoms
- Contact lenses and care products
- Intra-uterine devices (IUDs)

3 Procuring medical devices

A policy for procuring medical devices should be established in consultation with the professionals who will be prescribing or using them. Factors that need to be considered in developing a policy include:

- what equipment and accessories need to be provided and why
- the range of particular devices available to cover requirements
- purchasing arrangements for new products
- the tendering process for equipment supply, where applicable
- what is included in a procurement package, e.g. backup, training, servicing and maintenance requirements
- total costs
- compatibility with accessories and other devices
- a system of record keeping to include use, maintenance and tracking where appropriate.

Case Studies

Inappropriate selection of device

A walking frame was selected for an elderly woman. However, the frame broke because it was not strong enough for her weight.

Incompatibility of accessories

A number of deaths each year result as a consequence of cotsides and beds being incompatible.

Procuring medical devices

This checklist will help in making a decision about procuring the most appropriate device.

THE DEVICE

- What functions must the device perform?
Consider its fitness and suitability for purpose
- What similar devices do we already have?
Keep range of any type of device limited
- What is the evidence for the choice of this device?
Consider whether any research on effectiveness has been carried out
- How easy is the device to use and maintain?
Previous experience, feedback from users
- What is the life expectancy of the device?
- Is a single-use or a multiple-use device most appropriate?
- Has the device a CE marking?
Note: CE marking demonstrates compliance with the Medical Devices Regulations. In vitro diagnostic medical devices do not require to be CE marked until June 2005. Custom-made devices do not require CE marking
- What accessories are necessary for the intended function of the device?
Consider whether they are easy to obtain and compatible with the existing device
- Where is the device to be used?
Consider location, e.g. health centre, residential home, user's home
- Are decontamination processes required and are facilities available?
Consider whether any infection control measures are needed
- Where can unbiased information on the range of available devices be obtained?
 - consult documents, e.g. Medical Devices Agency (MDA) Evaluation reports, Northern Ireland Clinical Resource Efficiency Support Team (CREST) Equipment Evaluation Subgroup reports, Disabled Living Foundation reports, Hamilton Index
 - consult Regional Supplies Service of the Central Services Agency, servicing contractors, hospital supplies departments, hospital specialists
 - seek advice from colleagues, professional associations, experts in the field

COSTS INCURRED

- What is the cost of the device and installation, if applicable?
- What maintenance is required and what is the cost?
- Are maintenance and servicing costs included in the price?
- What are the purchase, lease and finance options?
- Is servicing insurance cover available and at what cost?
- What is the cost of consumables?
- Does the device represent value for money?

TRAINING REQUIREMENTS

- Are special clinical and technical training requirements necessary?
- Are initial and updating training programmes provided by the manufacturer?

4 Using medical devices safely

Health and social care professionals use medical devices themselves and also provide devices which are then used by others, e.g. by a service user or carer. Health and social care professionals are personally accountable for their use of the device and therefore must ensure that they have appropriate training. They are also personally accountable for ensuring service users and carers have received appropriate training and know how to use the device that has been provided.

Note: An individual health care professional who advises against manufacturer's instructions may take on liability for that device.

Using devices safely

Use this checklist to ensure that you use medical devices safely.

BEFORE USE: assessment

- What are the service users clinical and social needs?
- Which of the medical devices available best meets those needs?
- Has a risk assessment been undertaken?
- Are the risks associated with this device acceptable and can they be minimised?
- If the device has been bought privately, is the service user aware of their personal responsibility?
- If the medical device is to be used by patients and/or carers, have the following been taken into account:

- *physical capabilities, e.g. manual dexterity*
- *sensory capabilities, e.g. vision, hearing*
- *ability to understand and remember*
- *previous experience with the medical device*
- *the patient's or client's expectations*
- *the environment in which the device will be used*

BEFORE USE: knowledge of device

- Is the way the device is to be used that intended by the manufacturer?
- What are the limitations and contra-indications for use?
- Has the device been regularly maintained?
- When was the device last serviced and when is the next service due?
- Has the device been checked after servicing?
- Is the device within its expiry or use-by date?
- Are there any signs of wear, damage or faults?
- Where can a replacement device be obtained?

Ask yourself:

- Do I know how to set up and use this device?
- Have I read the user instructions, and are they attached to the device [if this is possible]?
- Have I been trained in the use of the device?
- How was my competency in relation to this device assessed?
- Do I know how this device should perform and the monitoring that needs to be done to check its performance?
- Am I using the correct additional equipment, e.g. disposable infusion sets for an infusion pump?
- Do I know how to recognise whether the device has failed?
- Do I know what to do if the device fails?
- Do I know how and to whom to report a device-related adverse incident?
- Have I or others modified the device, if so, has liability been checked with the manufacturer?

DURING USE

- Does checking the medical device indicate it is functioning correctly and to the manufacturer's specifications?
- What action should be taken if the device is not functioning properly?
- Has this been documented?
- Is there up-to-date documentation to record regular checking of the device?
- What are the details (name and serial number) of the device being used?
- Is the equipment still appropriate in the light of changing needs of the service user, e.g. children can physically outgrow equipment?

AFTER USE

- If used in the home, how will the medical device be returned to the owner, disposed of, or safely stored?
- What cleaning and/or decontamination is required?
- Does the medical device show any signs of wear, damage or faults that should be reported?
- Is any servicing, maintenance or repair required?
- Were there any problems in using this device which should be noted and could be rectified for the future? e.g. was any information missing from the patient/carer guidance which would have been useful?

Service users and carers

In primary care settings health and social care professionals will often provide medical devices to be used by service users and carers. It is important to ensure that service users and carers have adequate information about the use of the device. Health and social care professionals are personally accountable for ensuring that service users and carers have appropriate training in the use and maintenance of the device provided.

Individuals who purchase a device privately need to be made aware of their personal responsibility to ensure the device is appropriately used and maintained.

Advising service users and carers

Use this checklist to make sure that service users and carers are fully aware of their responsibility for medical devices.

- Has the service user or carer been appropriately trained in the use of the device?
- Have they been given written guidance which supports the use of the device and covers:
 - the name of the device
 - the operation of the device
 - their responsibility for checking the device while in use
 - recognition of the device failure and fault
 - action to be taken in the event of a device failure or fault
 - their responsibility for reporting an untoward event to the supplier of the equipment
 - telephone numbers of contact points in an emergency, including out of hours
 - their responsibilities if they have bought the device themselves?

5 Record keeping

Good records are important in effective device management. Records should provide evidence that the device has been maintained in good condition and that staff know how to use it properly.

Paper-based systems can be used if you have only a few devices; computer-based system may be better if you have a number of devices.

Record keeping

Use this checklist to ensure your record keeping is adequate.

Ensure that your records provide evidence of:

- a unique identification of the device, where appropriate
- an appropriate history of the device, including date of purchase and installation
- having met any legal requirements concerning the use of the device
- proper installation
- routine maintenance.

Your records should show that staff:

- know how to use the device safely
- can carry out day-to-day checks and routine maintenance
- have been trained and had relevant refresher training.

6 Maintenance and repair

Routine maintenance and planned preventative maintenance should ensure that your equipment will work safely when you need to use it, and should increase its working life.

Case Study

Lack of maintenance of regularly-used devices

A bench-top steriliser in a health centre had not been regularly or appropriately maintained. As a result, staff were unaware that it was not sterilising properly.

Maintenance and repair

Use this checklist to ensure that your maintenance and repair systems are appropriate.

- Routine maintenance will include:
 - regular cleaning of the device
 - preparation of the device for use
 - checking and calibrating the device.
- Planned preventative maintenance:
 - should follow the device manufacturer's guidance
 - is usually done by the manufacturer, supplier or agent
 - may be done by third party repairers, provided the work of the sub-contractor is of a sufficiently high standard, is audited and reviewed regularly.
- Procedures for routine maintenance should ensure that:
 - instructions are documented and available
 - staff know how to check that the device is working properly before it is used on a patient
 - staff can identify when a device is faulty and know how to get it repaired
 - staff know how to decontaminate the device after use
 - devices are stored safely in accordance with the manufacturer's instructions.
- Procedures for planned preventative maintenance should ensure that:
 - there is a contract which sets out responsibilities and repair and maintenance requirements
 - there is evidence to show that the service organisation is competent to maintain the device to the manufacturer's specification
 - any changes to the manufacturer's maintenance recommendations have been agreed and documented
 - following maintenance or servicing, the device is checked before it is used with a patient
 - there is a planned replacement policy
 - times for preventative maintenance on individual devices are brought to users' attention regularly and automatically
 - there is a system to display the date of the last and the next service, if this is appropriate.
- Back-up equipment should be available if the device is defective or requires servicing or maintenance.

7 Training health and social care professionals

All practices and organisations in the public and private sectors must provide adequate arrangements for training in the safe use of medical devices. This also includes agencies providing staff to the care sector. Employers are responsible for ensuring that staff who use medical devices have appropriate training. Equally, all health care professionals and support workers have a personal responsibility and accountability to ensure that they are trained in the safe use of the medical devices they need to use.

Assessment of training needs

An assessment of training needs should be undertaken for individual staff and should address both clinical and technical matters. Training should then be planned to meet the identified needs. This should include whether individual staff:

- understand the principles underlying the use of devices
- are familiar with the practical aspects of the devices they are likely to encounter
- have had their competence assessed in relation to the safe use of devices.

Content of programmes

Use this checklist to ensure that the key issues have been covered when participating in or developing training programmes.

Programmes addressing *general principles* concerning medical devices should include:

- relevant regulations
- the purpose intended by the manufacturer
- performance specifications
- frequency of maintenance and servicing
- checks required following maintenance and servicing
- importance of complying with the manufacturer's instructions for use
- setting up a device
- pre-use checks
- monitoring and checking during use
- reporting an adverse incident
- importance of cleaning and decontamination
- the importance of consulting the manufacturer if considering using or processing the medical device in any way not covered by the manufacturer's instructions.

Programmes addressing the use of *specific devices* should include:

- purpose of the device
- principles of how it operates
- device specifications
- setting up the device
- safety features and the rationale for them
- reliance to be placed on the device
- reliance to be placed on results obtained from the device
- reliance to be placed on the safety features of the device
- importance of 'double checking' by observing the patient and device
- use of any relevant alarms
- difficulties in the use of the specific device and any likely causes of failure
- monitoring and checking of device
- recognising when the device has failed
- common faults in the use of the device
- importance of the user consulting the manufacturer's instructions
- cleaning and decontamination

Note: Collection, storage, cleaning and decontamination of devices have safety implications not only for patients and users, but also for servicing and maintenance personnel.

- assessing competence in the safe use of the device.

8 The importance of reporting adverse incidents

What is an adverse incident?

A device-related adverse incident is an event which can produce, or have the potential to produce, unwanted effects involving the safety of patients, users or other people. An adverse incident can arise from shortcomings in the device, its accessories, its operating instructions, user practice, servicing and maintenance and conditions of use. However, many adverse incidents are the result of user error.

If an incident occurs, what should I do?

- Check and take steps necessary for the well-being of the patient.
- Take device(s) involved out of action and label, together with other material evidence, e.g. packaging if available. If this is not possible the state of the device at the time of incident should be recorded.
- Record:
 - date and time of the incident
 - device settings if relevant
 - details of incident (how it happened and any outcomes for the person affected)
 - details of device affected and any others (type, make, model and serial numbers)
 - details of any error message or failures.
- Report incident to relevant manager and to the Northern Ireland Adverse Incident Centre (NIAIC).

Northern Ireland Adverse Incident Centre

Department of Health, Social Services and Public Safety

Health Estates, Stoney Road, Dundonald, Belfast BT16 1US

Telephone 028 9052 3704

Fax 028 9052 3900

E-mail NIAIC@dhsspsni.gov.uk

Reporting Forms are available from the NIAIC and will be available from the DHSSPS website www.dhsspsni.gov.uk.

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