Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Single Use Policy

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P013	Medical Device Safety Officer	Quality and Standards	3 Years

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Contents

1. Introduction

Healthcare organisations are required to have systems in place to minimise the risks associated with the acquisition and use of medical devices in accordance with guidance issued by the Medicine and Healthcare Product Regulatory Agency (MHRA) and The Care Quality Commission (CQC). This include single - use devices.

Reprocessing and re-use of medical devices is a long-standing practice. Infection control protocols have been developed to ensure that risks associated with cross infection are minimised due to adequate decontamination of medical devices. Using single-use devices is a further safeguard in minimising the risks.

Healthcare organisations are encouraged to select single-use medical devices wherever practical the Trust has adopted this approach.

We have no facility in this Trust or Service Level Agreement in place for decontamination of instruments used in medical or surgical procedures. Therefore we will rely on Single-use devices in many circumstances.

2. Purpose or aim

This policy was prepared to ensure awareness of best practice in the use of single-use and single patient-use medical devices and to assist staff to maintain a high standard of infection prevention and control and cost effective use of equipment

This policy is based on current recommendations made by the Medicine and Healthcare Product Regulatory Agency (MHRA) Single-use medical devices: implications and consequences of reuse December 2018 which clearly states that 'devices designated for single use must not be re-used '

3. Scope

This policy applies to all staff and is relevant for all clinical settings.

4. Definitions

The following terms have been defined for the purpose of this document:

- The term single-use means a device used on an individual patient during a single procedure and then discarded. It is not intended to be used again even on the same patient.
- Single-patient use is not the same as single use it means the medical device may be used for more than one episode on one patient only. The device may undergo some reprocessing between each use.
- Reprocessing – to make good the device for re-use by cleaning, disinfection or decontamination, sterilisation, refurbishment or repackaging.
- Legal entity – An individual, institution, or organisation that has its own existence for legal or tax purposes e.g. a corporation partnership or trust.
- Adsorb - Adsorption occurs when one substance holds another via physical bonds.
- Absorb - Absorption is the chemical integration of one chemical into another.
- Endotoxin - A toxin produced by certain bacteria and released upon destruction of the bacterial cell.

5. Policy description

5.1 Single-use and Single Patient-use Devices

Single-Use

This expression means that the medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient. Reprocessing single-use devices may compromise their intended function.

Single-use devices may not be designed to allow thorough decontamination and (if applicable) resterilization processes.

Reprocessing a single-use device may alter its characteristics so that it no longer complies with the original manufacturer's specifications and, therefore, the performance may be compromised.

Single-use devices have not undergone extensive testing, validation and documentation to ensure the devices are safe to reuse.

A device that is designed for single-use will have this symbol on the packaging or the device.

Or it will bear the phrase "single-use". These items should not be re-used under any circumstances. The MHRA has published this leaflet to help clarify the term 'single-use' and the symbol that is used by manufacturers to designate a medical device as single-use. It is also the end users responsibility to be familiar with other symbols on the packaging of the device and their meaning.

Where ever possible wards and clinical teams should adopt the Productive Ward approach in the clinic rooms and areas where medical devices are stored.

Single-use devices might include:

- Syringes and Needles (Safer Sharps should be used in line with EU directive EU law (the "Sharps Directive"– European Council Directive 2010/32/EU)
- Dressings
- Foley Catheters and Urine Drainage bags
- Gallipots and other sterile CSSD items
- Intravenous giving sets
- Suction Catheters
- Personal protective equipment e.g. gloves, aprons
- Medicine pots
- Pulp urinals and commode pans.

Many pieces of equipment including patient monitoring equipment like ECG recorders, tympanic thermometers, suction machines; nebulisers and oxygen have single-use attachments.

This list is not exhaustive and staff must be responsible for checking the label on products when using and purchasing devices. Details of approved single use devices (including Safer Sharps) can be found on the Clinic List and Safer Sharps List on Ourspace

It is also essential to check the use by date on devices and ensure that they are not used after their expiry date or if the packaging for items intended for sterile procedures were already opened beforehand.

Risks Associated with the re-use of single-use devices.

- Cross infection

Potential Cross Infection is one of the greatest patient safety concerns. The risk of cross infection is greater due to the design of a device e.g. narrow tubes and types of material that cannot withstand heat and a reprocessing system would not completely remove micro-organisms and if re-used they would be transferred to the next patient..

- Device Design

A single-use device may be made in such a way that reprocessing may damage or alter it to the extent of making it unsafe. If a device has been designed for single use the manufacturer need not undertake any reprocessing validation and is not required to provide such information. This would put patients at risk.

- Material Alteration

Exposure to chemicals such as cleaning agents may cause corrosion and / or changes in the material of the device. Or exposure to elevated temperatures or pressure during a sterilisation process may alter the properties or degrade the device material for example plastics may soften or become brittle and crack.

- Residues from Chemicals and Decontamination Agents

Materials used in Device Manufacture can absorb or adsorb certain chemicals, which can gradually leach from material over time. For example, some disinfectants may be absorbed by plastics resulting in chemical burns or risk of sensitisation of the patient or user.

- Mechanical Failure

Some devices may experience stress if re-used leading to fatigue induced failure e.g. single-use blades.

- Reactions to Endotoxins

Endotoxins are Gram-negative products of bacterial breakdown and can be a problem if the device has a heavy bacterial load after use which cannot be adequately removed by cleaning. The sterilisation process will not inactivate the toxins even when cleaning and sterilisation is effective in killing bacteria.

- Prion Disease

The abnormal proteins associated with Prion Disease e.g. Creutzfeldt- Jacob disease (CJD) and variant Creutzfeldt- Jacob disease (vCJD) are very resistant to all conventional methods of decontamination. The Department of Health have issued advice describing the present state of knowledge of the risk of transmission of v CJD from one patient to another. Health Service circular 1999/178, variant Creutzfeldt- Jacob Disease 9v CJD): Minimising the risk of transmission states that ‘Devices designated for single episodes should not be reused under any circumstances whatsoever.

- Legal Implications

If staff reprocess medical devices that are designated for single-use, they may be transferring legal liability from the manufacturer to themselves or to the Trust. They would be committing an offence or contravening one of the following:

- Health and Safety at Work Act 1974.
- Part one of the Consumer Protection Act
- The General Product Safety Regulations 2005
- The Medical Device Regulations 2005

Single-Patient use Devices

This term refers to devices that can be used on more than one occasion on one patient only.

Examples of single-patient devices may include:

- Oxygen or nebuliser masks
- Nasal specs
- Hoist slings or slide sheets
- Custom made appliances e.g. splints and prostheses.
- Hearing aids
- Hip protectors
- The device may undergo some form of reprocessing between each use, and the manufacturer's instructions should be followed.
- In addition to the above, the use of single–patient medical devices within the clinical environment must address the following:
- Device labelling which clearly identifies the patient it will be used for
- Pre-use checks, which ensure that the device is only used by the intended patient.
- Appropriate and timely device cleaning / replacement in line with agreed recommendations.
- Some single-patient use items will have a limited life span which will be indicated in the manufacturer's instructions

The device should be disposed of appropriately on completion of use for that patient and under no circumstances re-used on another patient.

Disposal of Single-use and Single-patient use Medical Devices

All equipment should be disposed of as per The Waste Management Policy and The Waste Policy updated Guidance March 2010 according to the nature of the product e.g. sharps, hazardous and non-hazardous waste.

6. Roles and responsibilities

6.1 The Chief Executive

The Chief Executive has overall accountability for having effective medical device management systems and internal controls in place and for meeting statutory requirements.

6.2 The Director of Nursing and Quality/ Director of Infection Prevention and Control (DIPC)

The Director of Nursing and Quality is the Executive Director for medical device management and is responsible for ensuring the Trust's overall duty for medical device management and infection control is discharged appropriately and has lead executive responsibility for all policy and guidance issues.

6.3 The Director of Operations

The Director of Operations has responsibility for ensuring that appropriate medical device systems are implemented throughout Local Delivery Units. The Medical Director is responsible for ensuring that all medical staff are competent to use the medical equipment in place in the Trust and that they abide by this policy.

6.4 The Medical Device Safety Officer

The Medical Device Safety Officer (MDSO) has responsibility for supporting operational services in putting in place effective measures to manage medical devices. The MDSO will be the Trust's contact with the Medicines Healthcare Regulatory Agency (MHRA) and will

disseminate and receive information to wards and departments regarding new information on single-use and single-patient use devices used in the Trust. The MDSO will also be responsible for advising on the issuing safety alerts regarding single-use and single-patient use items and for reporting related adverse incidents to the MHRA. The MDSO will provide a network facility to disseminate and receive information from Wards and departments. The MDSO will link with the Head of Nursing Physical Health Care to raise awareness of the implications of this policy and ensure compliance among all staff involved in the use of Medical Devices.

6.5 The Patient Safety Team

The Patient Safety Systems Team is responsible for the dissemination and feedback of relevant Safety Alerts concerning Single-use devices.

6.6 The Head of Physical Health Care

The Head of Physical Health Care has responsibility for providing professional advice in relation to medical devices across all services. He will work closely with the Medical Device Safety Officer to ensure that any medical equipment decisions are informed by best practice.

6.7 The Head of Contracts and Procurement

The Head of Contracts and Procurement is responsible for negotiating competitive purchasing arrangements for single-use equipment and enabling ease of provision.

6.8 LDU Clinical Directors

LDU Clinical Directors are responsible for ensuring that staff in their areas are able to order sufficient stock of single use items so that staff do not have to consider re-use. They are also responsible for ensuring there is provision for storage so that controls are in place to avoid over stocking on individual wards

6.9 Ward or department managers

Ward or Department Managers will be responsible for ensuring that supplies of single-use equipment are replenished and ready for use and staff in their units are aware of this policy and the guidance is followed within their departments.

6.10 All staff

All Staff who are involved in the use of medical devices must adhere to this policy and have an understanding of single-patient use and single-use medical devices and the implications of re-use on patient safety.

Staff must also report all incidents relating to single-use and single-patient use devices to their line manager in accordance with the Incident Policy 6. Single Use Devices

7. Training

Registered practitioners are responsible for ensuring their knowledge is up to date regarding the use of single use equipment.

8. Monitoring or audit

The Trust will monitor compliance with this policy by:

- Reviewing incidents reported that involve single-use or single patient-use items.

- Auditing and inspecting local arrangements on an ad hoc basis and during six monthly infection control audits.

9. References

The following documents were used to develop this policy:

- Single-use Medical Devices: Implications and Consequences of Re-use MHRA December 2018
- The Department of Health's The Health and Social Care Act 2008 Code of Practice for the Prevention and Control of Health Care Associated Infections and related guidance.
- The Care Quality Commissions (Registration) Regulations 2009 (Part 4) and The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 12 Safe Care and Treatment and Regulation 15 Premises and Equipment
- EU law (the"Sharps Directive"– European Council Directive 2010/32/EU) http://www.hse.gov.uk/pubns/hsis7.htm

10. Appendices

10.1 Associated and Related Documents

- Infection Control Policies
- The Waste Management Policy
- Medical Equipment Policy

10.2

Version History

Version	Date	Revision description	Editor	Status
1.0	May 2009	Board approved	LDH	Approved
2.0	25 Nov 2012	3 year review. Approved by Quality & Safety Committee	LDH	Approved
3.0	4 Jan 2016	3 year review	AS	Approved
4.0	19 April 2016	The Q & S Committee approved the Single Use Policy. It was noted that it should have gone through the Physical Health Group	AS	Approved
5.0	10th April 2019	Full revision	AS	Approved DoN