Single-use Medical Devices

a report by
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Introduction

The increasing use of single-use medical devices is being driven by a growing awareness of iatrogenic (from the Greek: caused by the doctor) and nosocomial infections. Public health perceptions relating to transmissible spongiform encephalopathies, specifically variant Creutzfeldt-Jakob disease, HIV and hepatitis B, are high on the political agenda and a matter of concern to healthcare professionals in Europe and indeed across the Western world.

In 1999, the Department of Health in England issued advice to the National Health Service (NHS), describing contemporaneous understanding of the risks of transmission of vCJD, which included a very specific, unambiguous statement: "Devices designated for a single episode of use must not be reused under any circumstances"[1]

This article reinforces the position from a sterile service management perspective. Requests by healthcare professionals to reprocess medical devices designated for a single episode of use are frequent and may cause tensions between partners in the team committed to the provision of safe, effective devices for use on patients and handling by staff. Debates and discussions often surround economic and/or environmental concerns. These arguments are not new, having surfaced initially in the early 1960s when single-use syringes and needles were introduced. Similar concerns were rehearsed again when sterile disposable gloves were provided a decade later, only to resurface on the introduction of single-use, basic nursing procedure packs for wound care. Initial concerns regarding polypropylene tweezer-type forceps were entirely justified as forceps tips crossed and were quite incapable of meeting requirements.

Washing, patching, powdering and sterilising a surgeon's gloves was not a risk-free process. Nevertheless the introduction in terms of staff costs in the 1960s was still a point of discussion.

In addition to concerns regarding infection risks and economies of scale, industrial rather than in-house supply has also impacted on standardisation, specification and procurement of sterile single-use basic nursing procedure packs. Overall improvements in operating efficiency in hospital sterile services departments, along with effective management of the supply chain, present substantial opportunities to enable decontamination facilities to meet ever-increasing demands. Operating theatres and other healthcare facilities strive to meet the objectives of the NHS Plan and Clinical Governance. Freeing up technically trained clinical support staff enables additional throughput of complex devices to meet targets. However, major lessons learned from the recent introduction (and subsequent withdrawal) of single-use instrument sets for adeno-tonsilectomy, serve to highlight the need not to sacrifice quality.

Appropriate consultation, education and training, tempered by a rigorous risk assessment, to enable balanced well-informed decisions involving users and patient groups before any major changes are introduced, is a lesson that opinion-formers and decision-makers will have learned.

Surgical Drapes and Gowns

The Medical Devices Agency (MDA) in the UK has reinforced the view that surgical gowns and drapes are medical devices;[2] they are used to protect patients even though they may also protect the wearer. There has been an increased need for surgical drapes and gowns that afford effective barrier properties to protect the surgical team from liquid permeability and possess non-lining and non-particle-shedding properties. Regulatory issues with impending European standards for surgical drapes and gowns have reinforced the demand for quality products. Inevitably, new standards will stimulate growth in the market for disposables once they are ratified by EU Member States. High-tech reusable

1. *Health Service Circular (HSC 1999/179), "Controls Assurance in Infection Control: Decontamination of Medical Devices", London Department of Health: 1999.*
2. *Medical Devices Agency (MDA), "Surgical Gowns, Drapes and Coverings", MDA Notice, 11 December 2000.*

laminated and microfibre textiles may well meet the stringent requirements of standards, but many centres experience quality problems in terms of reprocessing and the integrity of supplies. Studies have also demonstrated major inadequacies in the packing of some processed reusable textiles, which obviously affect both their preservation and sterility. Faults imparting functionality include holes in critical areas, contaminants such as visible lint, adhesive residues, foreign bodies and translucent sites where the fabric is thinner than in the remainder of the material. Extant guidance issued in 1993 by the NHS Executive is certainly in need of major revision to meet contemporaneous infection control risks.[3]

Implications

The perceived benefits of reprocessing single-use devices are questionable and fly in the face of the European Medical Device Directive (MDD). In essence, the reprocessor, as a result of his/her actions, may assume legal responsibilities as a manufacturer and would need to comply with a whole host of regulatory requirements, risk assessments and, implicitly, the consent of the original manufacturer who placed the single-use device on the market. Users would need to be able to give absolute assurance that the device is safe and fit for its intended purpose. These are awesome responsibilities, which, in the worst-case scenario, may become the cause of litigation and cannot be devolved to the sterile services manager or other reprocessor tasked with decontamination.

Decontamination is the combination of processes including cleaning, disinfection and/or sterilisation used to render a reusable medical device safe for further episodes of use. In order to decontaminate medical devices effectively, all organic debris (e.g. blood, tissue and other body fluids) must be removed from the item before sterilisation or disinfection can occur. Single-use devices may not be designed to allow thorough decontamination and re-sterilisation in a hospital setting where steam under pressure is the process of choice. Reprocessing may affect the material's capabilities and the performance of the device giving a false sense of security to healthcare professionals who may not be aware of degradation of materials and deviations is the performance characteristics of a device.

Risks

Clinical risks associated with attempts at reprocessing include the following:

- inability to clean the device with any degree of assurance, potentially impairing the sterilisation process;
- material variation, chemicals used in the cleaning process causing corrosion and changes in the nature of the device;
- thermal degradation due to exposure to temperatures outside the design tolerance of the device during thermal disinfection and steam sterilisation;
- failure in use due to repeated stresses, leading to risk of fracture of orthopaedic drills, etc.; and
- batch, lot or serial numbers on devices to permit traceability in two directions: forwards to patients and backwards through the manufacturing process to enable recall in the event of a device alert or manufacturing problem; reprocessing risks invalidating the integrity of any look-back or recall exercise.

Policy

All too often, healthcare staff are unaware of the policy with regard to reprocessing or the 'single-use' symbol placed on medical device packaging or on the device itself. A written policy, which includes the relevant symbol, serves to avoid any ambiguities or misunderstandings that may occur. An example of a suitable policy will highlight the following:

- A statement of intent – it is the policy that medical devices designated for a single episode of use are not to be reused under any circumstances.
- The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of single-use devices has the following legal implications:
  - anyone who reprocesses or reuses devices intended by the manufacturer for use on a single occasion bears full responsibility for safety and effectiveness; and
  - anyone who reprocesses a single-use device and passes it to a separate legal entity (for example, the independent healthcare sector) has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.
- If a device is reprocessed and it is not fit for its

3. *Health Service Guidelines (HSG (95) 18), "Hospital Laundry Arrangements for Used and Infected Linen", London Department of Health: 1995.*

Figure 1

intended purpose, both the reprocessor and the professional user may be committing an offence under one or more of the following Acts:

- Health and Safety at Work Act 1974
- Consumer Protection Act Part 1
- General Product Safety Regulations 1994
- Medical Devices Regulations 1994

Technical Implications

The most important factor open to influence is device or instrument decontamination. A single-use device may be manufactured in such a way that decontamination may damage or alter the device to such an extent that further use is unsafe. The following problems have been identified:

- inadequate cleaning and sterilisation;
- material alteration;
- mechanical failure;
- potential vector of infection;
- hyperpyrexia due to residual endotoxins;
- chemical residues from washer/disinfection processes; and
- physical damage to sterilisers and other equipment.

Action by Healthcare Professionals

Look for the 'do not reuse' symbol on device packaging (see *Figure 1*), synonyms for which are 'single-use' and 'use once only'.

Single Patient Use

Some devices are designated for single patient use, which will be clearly stated on the packaging. These devices include such items as nebulisers, disposable pulse oximeter probes and certain specified intermittent catheters. The manufacturer's instructions should always be followed with regard to cleaning and disinfection between uses on a named patient only. Never reprocess and use on another patient.

Conclusions

Medical devices and associated equipment are used in the treatment and care of patients every day. Healthcare professionals play a vital role in ensuring that devices are used safely for the purpose intended, minimising risks to patients and any professional liabilities through misuse. To reuse a single-use device without being aware of the potential consequences could expose the patient and healthcare worker to risks that far outweigh perceived economic or environ-mental benefits. Explicit British United Provident Association (BUPA) Infection Control Policy prohibits the reprocessing of any medical device designated for a single use. This applies to devices that may have been opened but have not been used in the treatment or care of a patient. Patient safety is paramount. ■