THE IMPLICATIONS OF REUSING SINGLE-USE MEDICAL DEVICES

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The Medicines and Healthcare products Regulatory Agency (MHRA) has updated its advice on the implications of reusing single-use medical devices. This article discusses what constitutes a single-use device, the implications of reuse and the legal and safety issues.

It is long-standing practice for single-use medical devices to be reused in the NHS to cut costs or due to environmental concerns. However, many bodies including the Medicines and Healthcare products Regulatory Agency advise against the practice (MHRA, 2006).

In one recent high-profile case, a young boy died after breathing apparatus meant for single use was cleaned and used again. A subsequent investigation highlighted 13 other (non-fatal) cases where the same type of equipment had become blocked because the section of plastic used to connect tubing to patients’ face masks had come loose.

Other examples of problems that have occurred due to reuse of devices that were only meant to be used once include:

- Cardiac catheters whose tips had broken off in patients because they became brittle after resterilisation;
- Reuse of pressure domes used to cover the pressure transducers in urodynamic systems for assessing bladder pressure leading to patients being infected with Pseudomonas aeruginosa;
- Decontamination of single-use vaginal speculae with glutaraldehyde, which is absorbed by the plastic in the device and can leach out during subsequent use, causing chemical burns (Medical Devices Agency, 2002).

WHAT IS A SINGLE-USE DEVICE?

A single-use device is defined as one that should only be used on one patient during a single procedure then discarded. It should not be reprocessed and used again, even on the same patient. Examples include lancets, needle holders and infusion lines, and can vary between different products.

Single-use devices are marked with a symbol of a ‘2’ in a circle with a line through it, either on the packaging or on the device itself. This should not be confused with single-patient use devices, which may be used more than once on the same patient and can undergo reprocessing. Some single-use devices must be sterilised before use but they must not be resterilised.

GUIDANCE

The MHRA first issued advice in 2000 warning against the reuse of single-use devices because this may compromise their intended function or performance or encourage the spread of infection, and there are no guarantees from the manufacturer that the device can be reprocessed safely. The agency has published an updated version of the guidance, which states clearly that single-use devices must not be reused.

In Standards for Better Health, the Department of Health (2004) included proper use and decontamination of medical devices as a universal standard with which all healthcare organisations must comply. This includes a requirement to minimise risks associated with the acquisition and use of medical devices. Compliance with these standards is assessed by the Healthcare Commission (DH, 2004).

PROBLEMS ASSOCIATED WITH REUSE

- Potential for cross-infection – the MHRA states that infection is one of the greatest patient safety concerns associated with reuse of devices. The design of single-use...
devices may make it difficult to remove micro-organisms completely or the material used – such as plastics that are heat sensitive – may not be conducive to cleaning. These risk micro-organisms being transferred to the next patient. Also, abnormal proteins associated with prion diseases, such as variant Creutzfeldt-Jakob disease, are very resistant to conventional methods of decontamination. Therefore, the DH warned in a health service circular that single-use devices must not be reused under any circumstances whatsoever (DH, 1999).

● Inability to clean and decontaminate – if a device is to be cleaned satisfactorily, it must be possible to access all parts of the device. Some devices are difficult to clean because of the shape or material they are made out of, and complete decontamination cannot be guaranteed; these include devices with acute angle coils, long or narrow lumens and specialist surface coatings. If a device has been designed for single use, the manufacturer need not undertake any reprocessing validation studies.

● Residues from chemical decontamination agents – some materials used in the manufacture of devices can absorb chemicals used in the decontamination process. These chemicals can leach out of the object over time. Disinfectants such as glutaraldehyde may be absorbed by plastics and leach out during use, causing chemical burns or sensitisation in the user.

● Material alteration – exposure to chemical agents used in the decontamination process may damage the device through corrosion or other material changes. This also holds true for high temperatures and pressure used in sterilisation. For example, plastics may soften, crack or become brittle.

● Mechanical failure – stress can occur when some devices are being reprocessed, leading to fatigue-induced failure and fracturing. Single-use drill burners, saw blades and cranioectomy blades should not be reprocessed for this reason. One incident occurred with a single-use lithotripter stone retrieval basket that had been reused. During the procedure the cable was tightened and snapped. Further surgery was required to retrieve the device from inside the patient.

● Reactions to endotoxins – sterilisation will not inactivate toxins produced by the breakdown of Gram negative bacteria even if the bacteria themselves are killed. The MHRA says this is a significant problem if a device has a heavy bacterial load after use.

LEGAL AND REGULATORY IMPLICATIONS

If a device that carries the single-use symbol is reprocessed and used again, the legal responsibility for safe performance of the product may be transferred from the manufacturer to the user or the organisation that employs them.

If a reprocessed device is supplied to another legal entity (such as another trust) and the device is not fit for its intended purpose, the reprocessor and the user could both be committing an offence. There are several pieces of legislation and national guidance of which healthcare professionals should be aware:

● The Health and Safety at Work Act 1974 – reuse of a single-use device may be exposing patients or staff to risk contravening the provisions relating to the ‘general duties’ part of the act;

● Part 1 of the Consumer Protection Act 1987 – health professionals who reuse single-use devices could be exposing themselves or their employers to civil liability. Under the Consumer Protection Act, payment of damages could be awarded for injury caused by the device on the basis of negligence or because the device is defective;

● The General Product Safety Regulations 2005 – this applies when the device is intended for or likely to be used by a consumer. The regulations affect the producer, which can include any professional in the supply chain whose activities may affect the safety of the device. It also applies to other professionals in the supply chain (distributors) whose activities do not affect the device’s safety;

● The Medical Devices Regulations 2002 – medical devices manufactured and placed on the market in the UK and EU are subject to strict regulations, which require the product to carry a CE marking ensuring compliance with safety and performance standards;

● DH (2004) – Standards for Better Health states that all risks associated with the acquisition and use of medical devices must be minimised as a universal minimum core standard.

CONCLUSION

The MHRA states that single-use devices must not be reused under any circumstances and health professionals who do not comply with this may be putting themselves at legal risk. The agency has dealt with serious incidents relating to reuse, some of them fatal. Reuse is unsafe for several reasons, including cross-infection, patient injury and chemical burns. 

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