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Title **Reuse of Single-Use Medical Devices**

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Aim

To re-examine the clinical, economic, legal, and ethical issues surrounding the reuse of single-use medical devices (SUDs) in view of recommendations issued in Québec and Canada.

Results and conclusions

AETMIS considers that the conclusions of studies on the safety and efficacy of reused SUDs cannot be generalized to these devices as a whole. While the reuse of single-use hemodialysis membranes is considered safe and effective, the conclusions that can be drawn about other types of SUDs are limited by the small number of scientific studies and by the poor quality, low level of evidence, and in vitro nature of these studies. The reuse of electrophysiological catheters, orthopedic external fixator components, and sphincterotomes may be safe if properly reprocessed, but evidence remains insufficient to justify reusing them in clinical practice. Reused percutaneous transluminal coronary angioplasty (PTCA) catheters and laparoscopy instruments can be safe and effective if strict reprocessing and inspection protocols are followed. The studies on reused biopsy forceps show that they may not be safe after being reprocessed. The economic benefits of reusing SUDs vary according to the type of device and how often it is reused. Moreover, most of the very few economic studies are incomplete. Although Québec has no specific law or regulation directly governing this practice, healthcare institutions are liable for injury potentially caused by reprocessed SUDs. Given the conclusions drawn, the general position adopted by Canadian organizations, and the considerable requirements associated with reprocessing, hospitals and other healthcare facilities in Québec should stop in-house reprocessing of critical or semicritical SUDs until the requirements can be met for ensuring this practice complies with the highest recognized standards of quality. Hospitals wishing to reuse these devices should subcontract reprocessing to a third-party reprocessor certified by a regulatory authority and qualified to supply a final product that meets the standards and requirements applicable to all SUD manufacturers, and should ensure that they meet the applicable requirements.

Methods

A scientific literature review was undertaken to assess currently available evidence on the efficacy and safety of reusing reprocessed SUDs. Nineteen types of critical or semicritical devices were covered, and the conclusions drawn from assessments by the Conseil d'évaluation des technologies de la santé (CETS), New Zealand Health Technology Assessment (NZHTA) and the Canadian Agency for Drugs and Technologies in Health (CADTH) were taken into consideration.

Further research/reviews required

More in vivo studies on the safety and efficacy of reused SUDs are needed, specifically clinical studies on reprocessing methods and the effects of reusing SUDs in the Québec healthcare system. More studies on economic aspects of reusing SUDs are also required.

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