

Reprocessing Single-Use Medical Devices: Clinical, Economic, and Health Services Impact

Technology

Reprocessing as an alternative to discarding medical devices intended for single use.

Issue

While reprocessing is less expensive than single use, reprocessed single-use devices (SUDs) may have implications for patients' health and be cause for legal liability, ethical, and health care environment concerns. There is uncertainty regarding the cost-effectiveness of SUD reprocessing.

Methods and Results

A systematic review of available analytic studies was performed to examine the clinical impact of reprocessing SUDs. The quality of the selected studies was evaluated independently by two reviewers using an approach that takes into account study design and study performance and links both to judgments on study reliability. Twelve articles were selected that reported results from 12 unique studies on five types of medical devices. An economic analysis from a health care system perspective was conducted using two scenarios to measure the direct costs and dollar values of adverse health events associated with SUD reprocessing. The budgetary implications of eliminating the practice of re-use and legal and ethical issues related to liability were examined.

Implications for Decision Making

- **The known health impact of reprocessing is still uncertain.** Few studies of variable quality were identified. There is insufficient evidence to suggest or rule out harm to patients from reprocessing. Only one study examined outcomes from third-party reprocessing.
- **Reprocessing can lead to cost savings for health care systems.** Model projections suggest that the reprocessing of angioplasty catheters or laparoscopic instruments in a Canadian setting is cost saving, unless adverse events occur in patients at a rate of 12.6 or 445 per 1,000 respectively.
- **Reprocessing may have other service delivery implications.** The liability risks associated with reprocessing SUDs may lead to additional costs that were not captured in the economic analysis if patients harmed from using unclean or degraded devices bring successful lawsuits. If scientific evidence reveals harm from reprocessing, patients may need to be informed prospectively or retroactively, depending on the circumstances.

This summary is based on a comprehensive health technology assessment available from CADTH's web site (www.cadth.ca): Hailey D, Jacobs P, Ries N, Polisen J, Normandin S, Noorani H, Lafferty S, Gardam M. *Reprocessing of single-use medical devices: clinical, economic, and health services impact*