Canadian Agency for Drugs and Technologies in Health

Agence canadienne des médicaments et des technologies de la santé

Reprocessing of Single-Use Medical Devices: Current Practice, Safety, and Cost-Effectiveness

Research Highlights — February 2008

This document highlights key findings from two Canadian Agency for Drugs and Technologies in Health (CADTH) health technology assessment reports on the reprocessing of single-use medical devices in Canada — a summary of findings from a national survey of Canadian acute-care hospitals and an examination of the clinical, economic, and health services impact.

The one-time use of single-use medical devices (SUDs) ensures function and sterility and prevents cross-infection.

The reprocessing and re-use of SUDs, as an alternative to disposal, is practiced by some Canadian hospitals.

Reprocessing refers to all the steps needed to make a SUD previously used by one patient ready for use by another. These steps may include cleaning, functional testing, repackaging, relabelling, pyrogen testing, and disinfection or sterilization. Reprocessing can occur in a hospital or health region facility or it can be contracted to a third-party reprocessor.

Re-use is the repeated or multiple use of a medical device (including SUDs) with reprocessing between uses. The rationale underlying the re-use of SUDs is to reduce costs and assist with environmental and waste management issues.

The use of reprocessed SUDs is controversial because of concerns regarding increased risks to patients of infection or other complications. This leads to other questions: What are the legal and ethical issues in using reprocessed SUDs? Is the reprocessing of SUDS cost-effective? What is the situation in Canada — Are SUDS re-processed here? If so, how and where?

Third-Party Reprocessors:

- There are no Canadian third-party processing facilities.
- There are Canadian-based affiliates for third-party reprocessors regulated by the US Food and Drug Administration (FDA).
- Third-party reprocessors are not regulated by Health Canada but are registered with the FDA and therefore subject to the same regulations as the original device manufacturers in the US.

In Canada:

- The policies, procedures, and recommendations for the re-use of reprocessed SUDs are the responsibility of provincial and territorial governments or health regions.
- Health Canada's Scientific Advisory Panel on Reprocessing of Medical Devices has endorsed advice to health care facilities and professionals on how to minimize the risks to patients.

KEY FINDINGS

- **Most hospitals in Canada do not reprocess SUDs.**
- **The health impact of reprocessing is uncertain.**
- **Reprocessing can be cost-saving — but there are significant legal and ethical implications that require consideration.**

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What are current practices in Canadian institutions for reprocessing of SUDs?

A National Survey

- A survey instrument on the use of reprocessed SUDs was developed, drawing on information from previous Canadian surveys.
- After a pilot test, the survey was sent to 572 acute-care hospitals in Canada.
- The response rate was 72%, with 70% (398 responses) used in the analysis.

Survey Results

- 72% of hospitals do not reprocess SUDs.
- 81% of hospitals not currently reprocessing have done so in the past.
- Reasons for discontinuation:
  - Concerns about legal liability (77%)
  - Patient safety concerns (74%)
- More likely to reprocess SUDs:
  - Larger hospitals
  - Hospitals in Québec, New Brunswick, the Prairies, British Columbia, and the Territories
- In-house reprocessing is more common:
  - 85% of hospitals that reprocess SUDs do so in-house
  - 15% use a third-party processor (76% of which are satisfied or strongly satisfied with the reprocessed devices and customer service)
- SUDs most commonly reprocessed:
  - Breast pump kits
  - Ventilator circuits
  - Burrs
- Among hospitals reprocessing SUDs:
  - 40% have no written policy for reprocessing
  - 12% have no mechanism for incident reporting.

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Is the use of SUDs safe, effective, and cost-effective?

A Clinical Systematic Review and Economic Analysis

Safety and Effectiveness

- There is insufficient evidence to establish safety and effectiveness.

Cost-effectiveness

- There is evidence of cost savings from the use of reprocessed SUDs.
- Reported savings per device ranged from 33% to 72% of the original price when purchased from the manufacturer.
- Estimated cost decreases with SUD re-use (assuming no adverse events):
  - $173 for coronary angioplasty catheters
  - $971 for instruments used in laparoscopic cholecystectomy.

Budget Impact

- Eliminating the re-use of SUDs would add less than one-tenth of 1% of the total costs of the procedure.

Project Information

CADTH's full-length Technology Reports, *Reprocessing of Single-Use Medical Devices: National Survey of Canadian Acute-Care Hospitals* and *Reprocessing of Single-Use Medical Devices: Clinical, Economic, and Health Services Impact*, as well as a Technology Overview and this Research Highlights tool, are available at www.cadth.ca.

About CADTH

CADTH is a national body that provides Canada's federal, provincial, and territorial health care decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies.

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