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Publications can be requested from:

CADTH
600-865 Carling Avenue
Ottawa ON Canada K1S 5S8
Tel. (613) 226-2553
Fax. (613) 226-5392
E-mail: pubs@cadth.ca

or download from CADTH's web site:
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Reprocessing of Single-Use Medical Devices in Canada

February 2008

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This overview is based on two technology reports commissioned by CADTH: Polisena J, Hailey D, Moulton K, Noorani H, Jacobs P, Normandin S, Gardam M. *Reprocessing of single-use medical devices: National survey of Canadian acute-care hospitals* [Technology report number 104]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008; and Hailey D, Jacobs P, Ries N, Polisena J, Normandin S, Noorani H, Lafferty S, Gardam M. *Reprocessing of single-use medical devices: Clinical, economic, and health services impact* [Technology report number 105]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008.

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Reprocessing of Single-Use Medical Devices in Canada

Technology

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

Issue

Reprocessing is less expensive than single use, but there are concerns that reprocessed single-use devices (SUDs) may have implications for patients' health and for legal liability; as well, there are ethical and health care environment concerns. There is uncertainty regarding the cost-effectiveness of SUD reprocessing.

Methods and Results

A sample of 572 acute-care hospitals in Canada was surveyed. The useable response rate was 70% (398/572). Data on the existence of a written institutional policy, the use of third-party reprocessing, types of devices reprocessed, and incident report mechanisms were collected. A systematic review of analytic studies was performed to examine the clinical impact of reprocessing. Twelve unique studies on five types of medical devices were identified. A break-even 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

- **Most hospitals do not reprocess SUDs.** Twenty-eight percent of hospitals surveyed indicated that they reprocess SUDs. Reprocessing was more likely to occur in large hospitals. Most (85%) hospitals that reprocess SUDs do so in-house.
- **The health impact of reprocessing is uncertain.** Few studies of variable quality were identified. There is insufficient evidence to suggest or rule out harm to patients from reprocessing SUDs. Only one study examined outcomes from third-party reprocessing.
- **Reprocessing may have other service delivery implications.** Model projections suggest that reprocessing can be cost saving, depending on the rates of adverse events. Liability risks, however, may cause additional costs to be incurred if patients who are harmed from 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 two comprehensive health technology assessments available from CADTH's web site (www.cadth.ca): Polisena J, Hailey D, Moulton K, Noorani H, Jacobs P, Normandin S, Gardam M. *Reprocessing of single-use medical devices: National survey of Canadian acute-care hospitals*; and Hailey D, Jacobs P, Ries N, Polisena J, Normandin S, Noorani H, Lafferty S, Gardam M. *Reprocessing of single-use medical devices: Clinical, economic, and health services impact*.

Canadian Agency for Drugs and Technologies in Health (CADTH)

600-865 Carling Avenue, Ottawa ON Canada K1S 5S8 Tel: 613-226-2553 Fax: 613-226-5392 www.cadth.ca

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1 Introduction

The reprocessing and re-use of single-use medical devices (SUDs), as an alternative to disposal, is practised 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.¹ 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 practice, however, is controversial.²

Reprocessing can occur in a hospital or health region facility, or it can be contracted to a third-party reprocessor. There are no Canadian third-party processing facilities, although Canadian-based affiliates for third-party reproducers regulated by the US Food and Drug Administration (FDA) are used by some hospitals and health regions. The manufacturing and marketing of medical devices in Canada falls under the control of the Medical Device Regulations administered by Health Canada. These regulations apply only to the original device manufacturers and not to hospitals or third-party reproducers (except implantable devices such as pacemakers).^{3,4} Although third-party reproducers are not regulated by Health Canada, they are registered with the FDA and are 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.

Information on the re-use of reprocessed SUDs in Canada is limited. Three surveys have been conducted (one in 1986 and two in 2001) on the re-use of SUDs in Canadian acute-care facilities.^{2,5,6} In 1996, the Canadian Healthcare Association published guidelines on the re-use of SUDs.³ These guidelines were considered in an Auditor General of Canada’s report on the regulation of medical devices in Canada.⁷ *Reuse of Single-Use Medical Devices*, a report published by the Ontario Hospital Association (OHA), recommends that hospitals do not reprocess critical and semi-critical SUDs, that Health Canada develop regulations for safe sterilization practices in hospitals for re-usable devices and SUDs and for third-party reproducers, and that hospitals should consider using third-party reproducers licensed by the FDA until Canadian regulations are established.⁴ The Ontario government, in its “Best Practices” guidelines, recommended that “critical and semi-critical [SUDs] ... must not be reprocessed and reused unless the reprocessing is done by a licensed reprocessor.”⁸

Health Canada has issued a letter referring to developments on the re-use of SUDs, including the establishment of a Medical Devices Reprocessing Working Group in Ontario and policy reviews by British Columbia and the Northwest Territories.⁹ Furthermore, Health Canada’s Scientific Advisory Panel on Reprocessing of Medical Devices endorsed a motion that Health Canada advise health care facilities and professionals that to minimize risks to patients: 1) Health care facilities and health care providers should not reprocess SUDs unless the facility has established quality systems for reprocessing that include a re-use committee to establish policies and ensure adherence to approved procedures; written procedures for each type of device that is reprocessed; validation of cleanliness, sterility, and function of the reprocessed devices; and continual monitoring of reprocessing procedures to ensure quality and 2) Health care facilities that wish to have their SUDs reprocessed by a third-party reprocessor should ensure that the reprocessor’s facilities and procedures have been certified by a regulatory authority or an accredited quality system auditor to ensure the cleanliness, sterility, safety, and functionality of the reprocessed devices.

The one-time use of a SUD ensures function and sterility and prevents cross-infection.¹⁰ There are concerns that the use of reprocessed SUDs may be associated with increased risks to patients of infection or other complications. Other issues include legal liability, ethical concerns, safety of health care professionals, and the cost-effectiveness of SUD reprocessing. To understand the implications of the re-use of SUDs, a survey of reprocessing practices in Canada and a review of the evidence for the effectiveness and cost-effectiveness of re-using SUDs would be valuable to Canadian policy and decision makers.

2 Objectives

The objectives of this project were to obtain information on the reprocessing and re-use of SUDs in Canada and on the safety, effectiveness, and cost-effectiveness of such practices. The research questions addressed were:

- What are the current practices in Canadian acute-care institutions for the reprocessing of SUDs?
- What is the evidence that reprocessed SUDs are safe and effective?
- What is the cost-effectiveness of reprocessing SUDs?

The first question was addressed by conducting a survey of Canadian acute-care hospitals, and the second and third questions were addressed by undertaking a systematic review of the literature and a primary economic analysis.

3 Survey

Methods

A questionnaire on the reprocessing practices of SUDs in Canadian acute-care hospitals was developed based partly on previous surveys.^{2,5,6} The survey focussed on critical devices (i.e., those intended to make contact with normally sterile tissue or body space during use) and semi-critical devices (i.e., those intended to touch mucous membranes but not penetrate body surfaces).¹¹ Questions focussed on the existence of a written institutional policy, location of reprocessing, types of devices reprocessed, and incident report mechanisms. A total of 572 Canadian acute-care hospitals (academic and community) were selected for participation, regardless of size.

After a pilot test, in December 2006 the survey was mailed to an identified contact person (e.g., risk manager, infection control officer, or sterile processing department coordinator) in each hospital. Respondents had the option of replying to the survey by mail or on-line, and reminder and follow-up procedures were carried out. A modified Dillman approach was used for all contact and follow-up procedures.¹² Survey results were collected until May 2007. The results were analyzed by comparing the differences in proportions using a chi-squared test at the 5% level of significance. Subgroup analyses were done by province or territory, hospital type, and size. A logistic regression model was used to explore the effect of independent variables on the use of SUD reprocessing. Explanatory variables in the model were hospital type and size, jurisdiction, and existence of a written policy on SUD reprocessing. Qualitative data were categorized appropriately and assessed independently for relevant trends by two reviewers. Discrepancies were resolved through discussion.

Results

The survey response rate was 72% (413/572). Of these, 398 responses (70%) were usable (i.e., 13 responses from long-term care facilities with no acute-care beds and two incomplete responses were excluded). Based on the included responses, 72% (287/398) of hospitals do not re-use or reprocess SUDs. Among hospitals that do not currently re-use or reprocess SUDs, 19% (53/285) never reprocessed SUDs, and 81% did so in the past but have since stopped. The most common reasons for stopping were potential legal liability (77%) and concerns about patients' safety (74%). More academic hospitals (37%) than community hospitals (25%) reprocessed SUDs ($p=0.03$); and the larger the hospital (i.e., the greater the number of beds), the more likely SUD reprocessing was done. Hospitals in Quebec, New Brunswick, Manitoba, Saskatchewan, Alberta, and British Columbia were more likely to reprocess SUDs than those in other jurisdictions.

Of the 28% of hospitals that reported reprocessing SUDs, 85% do so in-house as opposed to using a third-party reprocessor (15%). Of those using a third party, 76% were strongly satisfied or satisfied with the function, cleanliness, and sterility of the devices as well as with the customer service. In addition, 40% of hospitals that reprocess SUDs do so without a written policy, although 88% have a formal mechanism for reporting the adverse events associated with a reprocessed SUD. The SUDs that were most commonly reprocessed were breast pump kits, ventilator circuits, and burrs.

More detailed results can be found in the full report, *Reprocessing of Single-Use Medical Devices: National Survey of Canadian Acute-Care Hospitals*.¹³

4 Clinical Review

Methods

Published literature for the clinical and economic reviews was obtained by searching the Medline (1966 to 2006), EMBASE (1996 to 2006), BIOSIS Previews (1989 to 2006), and CINAHL (1982 to 2006) databases. Parallel searches were run in the HEED (Health Economic Evaluation Database) and the Cochrane Library. Monthly alerts and updates were reviewed for new literature up to July 2007. The searches were restricted to human studies published from 1996 onwards with no language restrictions. Grey literature was obtained by searching the web sites of health technology assessment (HTA) and related agencies, professional associations, and other specialized databases. Google and other search engines were used to search the Internet. Supplemental searches of bibliographies of key papers and abstracts of conference proceedings, and contact with appropriate experts and agencies were also carried out.

Reviewers independently selected studies for inclusion if the sample size was ≥ 20 for comparative (i.e., versus one-time use of SUDs) and non-comparative studies and if they reported the clinical outcomes after the use of reprocessed SUDs. Interventions were the use of medical devices manufactured and labelled for single-use that had undergone reprocessing by an institutional health care provider or a third-party reprocessor and the use of SUDs that had previously been opened but not used. The outcomes that were considered were infection, other identifiable adverse events, mortality, device damage or failure, and evidence of device contamination. Systematic reviews and HTAs were also reviewed. Reviewers independently extracted data from selected studies using a structured form. The quality of selected studies was evaluated independently by reviewers using a pre-specified approach that assigned studies to one of five categories (high to poor quality) based on

quality scores. Any differences between reviewers regarding study selection, data extraction, or quality assessment were resolved by consensus. Data analysis involved a series of non-quantitative reviews prepared by reviewers.

Results

A total of 856 citations were identified from the original search and other sources. Of these, 827 were excluded, resulting in 29 potentially relevant reports retrieved for scrutiny. A further 17 reports were excluded to yield 12 included reports describing 12 unique studies. Study sizes, designs, and quality varied. Details about the included studies can be found in the full report.¹⁴ There were five studies on coronary angioplasty catheters,¹⁵⁻¹⁹ three on devices used in laparoscopic surgery,²⁰⁻²² two on sphincterotomes,^{23,24} and one each on external skeletal fixation devices for the management of fractures²⁵ and on phacoemulsification needle tips.²⁶

The quality of the studies ranged from two high quality randomized controlled trials (RCTs) to three poor quality non-comparative case-series studies. The studies included small numbers of patients. As a result, the risk of adverse events with a low level of probability may not have been detected. In 11 of the 12 included studies, the re-use of reprocessed SUD was found to be safe and effective. All but one of eight comparative studies found no difference in the rates of adverse events between groups treated with reprocessed SUDs compared with new devices. In Plante *et al.*'s prospective, non-randomized study,¹⁶ there was a statistically significant higher incidence of cardiac events, clinical failure with adverse clinical events, and longer procedure times and hospital stays in patients who were treated with reprocessed single-use angioplasty catheters compared with those treated with new devices. A re-analysis of the data controlled for baseline clinical characteristics and found that the adjusted rates were similar between the two centres, suggesting that catheter re-use was not associated with an increased rate of in-hospital complications.²⁷

5 Economic Review

Methods

The same literature search strategy was used for the clinical and economic reviews. Reviewers independently selected studies for inclusion if they reported economic patients' outcomes data. The interventions and comparator were identical to those used in the clinical review. Outcomes were reported as an incremental measure of the increase from the comparator to the intervention (i.e., a cost difference or a difference in costs and consequences). Systematic reviews and HTAs were also considered. Reviewers independently extracted relevant information from selected studies using a structured form. The quality of selected studies was evaluated using an adaptation of the Drummond guidelines.²⁸ Any differences between reviewers regarding study selection, data extraction, or quality assessment were resolved by consensus. Data analysis was based on CADTH's economic evaluation guidelines²⁹ and involved a series of non-quantitative reviews prepared by reviewers. Quantitative (e.g., cost per patient or procedure and clinical outcomes) and qualitative results were reported.

Results

A total of 374 citations were identified from the original search. Of these, 363 were excluded resulting in 11 potentially relevant reports retrieved for scrutiny. From these, two reports were excluded to yield nine reports included in the economic review. The devices that were studied included those used in laparoscopic surgery and gastrointestinal procedures (e.g., trocars and

sphincterotomes), catheters for percutaneous transluminal coronary angioplasty (PTCA) and tracheostomies, and external skeletal fixators for fractures. Six studies were included in the clinical review.^{15,16,21,23-25} The other three studies, which investigated the re-use of tracheal suction tubes,²⁰ PTCA catheters,³⁰ and laparoscopic instruments for cholecystectomies,³¹ were not included in the clinical review. The study sizes, designs, quality, and clinical outcomes varied. Details on the included studies can be found in the full report.¹⁴

All studies were conducted in a hospital, and cost savings were calculated as the cost of using new devices each time a device was used minus the actual cost of re-using devices (i.e., cost of new devices and cleaning costs). Seven of the nine studies provided evidence of cost savings from the use of reprocessed SUDs, and the average savings was 44% of the cost of all new devices. Two studies reported positive net costs, one³² attributed to the unusual low cost of the device compared with cleaning and disposal costs and the other³⁰ because of the inclusion of costs of adverse events in the analysis, which favoured single-use. This changed, however, in a sensitivity analysis.

6 Economic Evaluation

Methods

A break-even analysis was conducted to compare the direct costs and dollar values of adverse health events that were associated with single-use and reprocessed (in-house or by a third-party) disposable laparoscopic instruments and coronary angioplasty balloon catheters. The analysis drew on data from two RCTs^{17,20} that were selected for their high quality. A hospital perspective was used in the analysis, and two target populations (adults undergoing laparoscopic cholecystectomy or coronary angioplasty) were investigated. The time horizon used was the physical life of a SUD. Discounting was not considered, because the useful lifetime of a device is likely a few weeks.

The economic model had three components: the manufacturer's price of the device, reprocessing costs, and costs of adverse events due to reprocessing. The sum was the total cost of using the device during its useful lifetime. Details on the cost calculations are provided in the full report,¹⁴ and all costs were expressed on a per-patient basis. The clinical outcomes that were measured were the probabilities of myocardial infarction, PTCA and coronary artery bypass graft (CABG) after coronary angioplasty,¹⁷ and hematoma after laparoscopic cholecystectomy.²⁰ Because of a lack of relevant information, the risk of infection was excluded from the analysis. The sensitivity analysis was contained to one key variable (i.e., the probability of an adverse event) and was conducted on the basis of a break-even value.

Results

In the base case analysis, the cost per patient for a coronary angioplasty catheter was C\$250 for single-use. The cost of re-use (assuming no adverse events) was C\$77 per case (a savings of C\$173 per patient). The cost per patient of instruments used for laparoscopic cholecystectomy was C\$1,233 for single-use and C\$262 for re-used devices (a savings of C\$971, assuming no adverse events). The break-even analysis revealed that the cost of re-use and single-use of coronary angioplasty catheters would be at parity if the probability of an adverse event due to re-use was 12.6 per 1,000 procedures. For laparoscopic instruments, the costs of the two strategies would be the same if the probability of an adverse event due to re-use was 445 per 1,000 procedures.

7 Limitations

Given the high survey response rate across all provinces and territories, the results can be assumed to be generalizable across Canada. Nonetheless, there is a possibility that non-responding hospitals could differ in their approach to reprocessing SUDs. Responses were based on recall intervals spanning from one week to one year or longer. Therefore, the data may be subject to recall bias. In addition, some items may have been excluded from the survey to keep it brief. It was also difficult to obtain comprehensive data on the average numbers of SUDs reprocessed, adverse events, or device malfunctions, because hospitals do not routinely track such data.

The clinical and economic reviews are limited by the available evidence on the clinical outcomes and costs associated with the re-use of reprocessed SUDs. Another complicating factor is that all reprocessing is not the same. It was difficult to group studies that reported on in-house, non-validated reprocessing procedures and those with well-documented, validated procedures performed by registered third-party reprocessors. The economic analysis took a narrow hospital perspective instead of a societal perspective, and in doing so it excluded the personal costs of adverse events. It is expected that the cost of adverse events would generate additional health care system and personal costs (including legal costs) that are not captured in the analysis. Furthermore, the economic analysis did not consider the opportunity cost of reprocessing associated with the need for hospitals to increase their stock of devices to compensate for those that are being reprocessed.

The generalizability of the results of the clinical review is unclear because of variable study quality, small numbers of patients, and reprocessing protocols that were specific to the hospitals in which the studies were conducted. Furthermore, only a few types of SUDs were represented in the literature, so there remains a lack of clinical and economic data for the reprocessing and re-use of most SUDs that are being used in Canadian hospitals.

8 Health System Implications

A budget impact analysis was conducted for Alberta (where the number of cases was assumed to be approximately 10% of the Canadian total) to determine what additional expenditures would result from eliminating the re-use of SUDs. As in the economic evaluation, the procedures chosen were coronary angioplasty and laparoscopic cholecystectomy. Because there were no increases in the number of adverse events identified in the base case analysis with the re-use of devices for these procedures (as in the literature review), adverse events were not considered in the analysis. In 2006, 1,824 laparoscopic cholecystectomies and 5,199 angioplasties were performed in Alberta. If 1% of these procedures were done with re-used SUDs, the corresponding numbers of procedures would have been 18 and 51 respectively. Applying the additional costs for single use of C\$971 for laparoscopic cholecystectomy and C\$173 for coronary angioplasty, derived from the economic analysis, the additional costs would be C\$17,500 for laparoscopic cholecystectomies and C\$8,800 for coronary angioplasties if the re-use of SUDs was eliminated. These increases would be less than one-tenth of 1% of the total costs of these procedures.

9 Legal, Ethical, and Psychosocial Issues

The practice of reprocessing and re-using SUDs raises legal and ethical questions. These pertain to liability for harms to patients, informed consent to treatment with reprocessed SUDs, duty to notify patients of past exposure to harm, and the appropriate balancing of the economic benefits of re-use against risks to the health and safety of patients. These questions focus on matters of law. In the absence of regulation and legal precedents, however, ethical principles must be used to guide decisions. Patients who are exposed to risks (especially undisclosed or poorly understood risks) may experience psychosocial problems such as heightened anxiety about their health and distrust in care providers, institutions, and regulators.

Although the re-use of SUDs is considered to be a cost-saving measure, the liability risks associated with it may lead to higher costs to health care facilities if patients who are harmed after using unclean or degraded devices successfully sue for damages. If scientific evidence reveals harms from the reprocessing and re-use of SUDs, patients may need to be informed of the risks proactively or retroactively, as circumstances warrant.

10 Conclusions

Survey responses suggest that 72% of hospitals do not reprocess SUDs. The reasons given for not reprocessing include concerns about patients' safety, cost savings, legal liability, and absence of regulation. Among the 28% of responding hospitals that reprocess SUDs, 85% do so in-house. Among hospitals that reprocess SUDs, 40% do not have a written policy, and 12% do not have an incident reporting mechanism. This suggests a need for improved standards of documentation.

The small numbers of studies that have considered the clinical outcomes associated with the use of reprocessed SUDs are of variable quality and provide insufficient evidence to establish safety and efficacy. The use of several types of reprocessed SUDs is cost-saving if it is assumed that there are no adverse effects. There are insufficient data to establish the cost-effectiveness of re-using SUDs. Legal, ethical, and psychosocial issues require consideration by those who fund and use SUDs.

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