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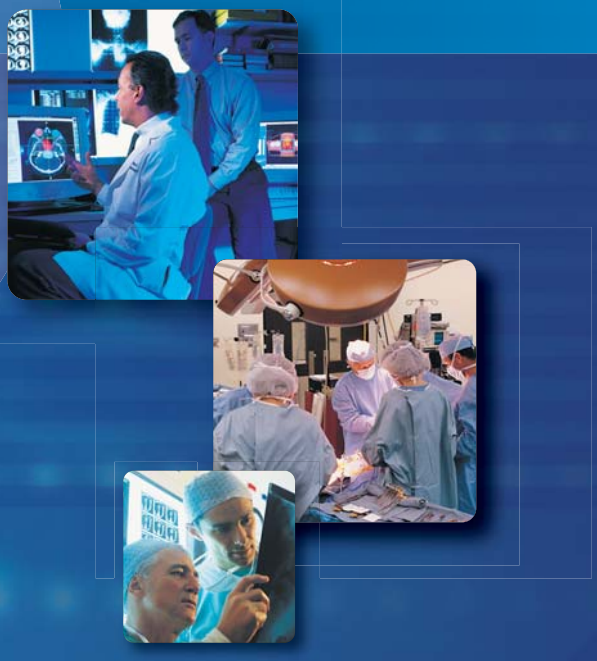

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Canadian Agency for Drugs and Technologies in Health

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

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David Hailey, Philip Jacobs, Hussein Noorani, and Julie Polisena contributed to the conception and design of the project, which was coordinated by David Hailey. David Hailey and Julie Polisena undertook the clinical review. Sarah Normandin designed and performed the literature search and verified bibliographic references. Philip Jacobs developed and implemented the economic analysis and the budget impact analysis with assistance from Susan Lafferty and Julie Polisena. Nola Ries developed the section on legal, ethical, and psychosocial issues. The report was written by David Hailey, Philip Jacobs, Nola Ries, Julie Polisena, and Sarah Normandin, with assistance from Michael Gardam, who also provided clinical expertise.

All authors contributed to the revisions of the report.

REPORT *IN BRIEF*

February 2008

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, Polisena J, Normandin S, Noorani H, Lafferty S, Gardam M. *Reprocessing of single-use medical devices: clinical, economic, and health services impact*

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EXECUTIVE SUMMARY

The Issue

The reprocessing and re-use of medical devices labelled and marketed as being for single use only is practised in some Canadian hospitals. There are concerns about the possible risk to patients of infection or other complications as a result of this practice, legal liability issues, and uncertainties regarding the cost-effectiveness of single-use device (SUD) reprocessing.

Objectives

The objective of this report was to assess the evidence that the use of reprocessed SUDs is safe, effective, and cost-effective.

Methods

The research questions were addressed through systematic reviews and a primary economic study using a cost-benefit analysis.

Results

Clinical Effectiveness

A systematic review of available literature was performed to identify studies that reported the clinical outcomes after the use of reprocessed SUDs in humans. Experimental studies and non-experimental studies with a sample size of 20 or more were considered. Outcomes included infection of patients, other identifiable adverse events occurring in patients, mortality, device damage or failure, and evidence of device contamination. Two authors independently applied the selection criteria for screening, and data from the included studies were extracted into evidence tables. The study quality was evaluated using an approach that takes into account study design and study performance.

Twelve studies covering SUDs for five areas of application were included in the review. The results suggested that SUD re-use could be safe and effective, but the quality of the studies varied. In 11 studies, the results suggested that SUD re-use could be safe and effective. Seven of eight comparative studies found no difference in the rates of adverse events between groups treated with reprocessed SUDs and those treated with new devices. The remaining study found more adverse events with reprocessed single-use angioplasty catheters than with new catheters, but a re-analysis of the data indicated that catheter re-use was not associated with an increased rate of complications.

Economic Analysis

A systematic review of economic studies was undertaken, using the same literature search strategy as that for the clinical effectiveness review. Studies were considered for review if they reported economic outcomes associated with the use of reprocessed SUDs for medical procedures in humans. Two authors independently applied the selection criteria for screening, extracted data from the included studies, and completed a quality assessment based on criteria determined a priori. Nine studies on five types of device were included in the review. Seven of the studies provided evidence of cost savings from the use of reprocessed SUDs. The reported savings per device ranged from 33% to 72% of the price of the medical device purchased from the manufacturer.

The direct costs and dollar values of adverse health events associated with SUD reprocessing were measured. The analysis drew on data from two studies included in the clinical review. These were

selected because they were of high quality and addressed the re-use of two frequently used types of SUD. The estimated decreases in cost per patient as a result of SUD re-use were $173 for coronary angioplasty catheters and $971 for instruments used in laparoscopic cholecystectomy, assuming that there were no adverse events.

The break-even analysis indicated that the cost of the re-use and single-use strategies would be the same for coronary angioplasty catheters 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.

Budget Impact

The results of the budget impact were obtained by considering laparoscopic cholecystectomy and coronary angioplasty, using data from the economic analysis. Alberta was the site of analysis. Eliminating the re-use of SUDs would add $17,500 and $9,200 respectively to the total costs of these procedures over a year. These increases would be less than one-tenth of 1% of the total costs of the procedures.

Legal, Ethical, and Psychosocial Issues

The liability risks associated with the reprocessing and re-use of SUDs may lead to higher costs, particularly in health care facilities, if the patients who are harmed by the use of unclean or degraded devices bring successful lawsuits. If scientific evidence reveals the risks of re-use, patients ought to be informed of these risks prospectively or retroactively, depending on the circumstances.

Conclusions

The small number of studies that have considered clinical outcomes associated with the use of reprocessed SUDs are of variable quality and provide insufficient evidence to establish the safety and efficacy of this practice. 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. Several legal, ethical, and psychosocial issues require consideration by those who fund and use reprocessed SUDs.

ABBREVIATIONS

CABG	coronary artery bypass graft
FDA	US Food and Drug Administration
HIV	human immunodeficiency virus
NSD	no significant difference
OEM	original equipment manufacturer
OHA	Ontario Hospital Association
PTCA	percutaneous transluminal coronary angioplasty
RCT	randomized controlled trial
RHA	regional health authority
SUD	single-use device

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1 INTRODUCTION

1.1 Background and Setting in Canada

Many types of medical devices are labelled and marketed by manufacturers as being for single use only. The one-time use of single-use medical devices (SUDs) helps to ensure device function and sterility and to prevent cross-infection.[1] There is also a financial advantage for a manufacturer to release SUDs rather than multi-use devices because they can be brought to market sooner and do not require the same degree of documentation and validation. There is no requirement for a manufacturer to prove that a device cannot be reprocessed. The re-use of SUDs after reprocessing has become a common practice in many Canadian hospitals because of perceived economic benefits, but the practice remains controversial. There are concerns about possible risks to patients, cost-effectiveness of SUD reprocessing, and legal liability issues.

A 2004 report by the New Zealand Health Technology Assessment concluded that:

> the evidence for the safety and effectiveness of re-using SUDs is anecdotal, with few studies evaluating outcomes directly related to patients. There is a lack of data on patient exposure to cross-infection, loss of device functionality, and resulting adverse patient outcomes. Much of the literature is set in laboratory contexts evaluating surrogate outcomes such as contamination and device integrity, so the overall evidence is indirect. The literature often forms more of a theoretical basis for these concerns than any firm scientific evidence.[1]

The report also noted that the reliability of the results was limited because of the diversity of SUDs and methods used to evaluate reprocessing and re-use.

The reprocessing of medical devices can occur in a hospital or health region facility, or it can be contracted to a third-party reprocessing facility. No Canadian-based third-party reprocessing facilities exist, although Canadian affiliates for US-based, third-party reprocessing facilities that are regulated by the US Food and Drug Administration (FDA) are used by some hospitals and health regions.

The re-use of SUDs was considered in a 2004 report by the Auditor General of Canada.[2] In July 2004, a letter was issued from the Therapeutic Products Directorate presenting Health Canada's recommendations to health care facilities on the reprocessing of re-usable and single-use medical devices.[3] The letter described Health Canada's 1996 collaboration with the Canadian Healthcare Association (CHA) to provide guidance to hospitals in making decisions on re-use.[4] It also stated that "Health Canada is concerned that re-using single-use devices may be hazardous to patients" and that Health Canada was addressing this issue in consultation with the provinces, territories, and stakeholders.

The letter referred to approval by the Ontario Hospital Association (OHA) of a report written by its ad hoc Working Group on Re-use of Single-Use Medical Devices.[5] The OHA's position statement on re-use included recommendations that hospitals not reprocess critical and semi-critical SUDs; that Health Canada should develop regulations for safe sterilization practices in hospitals for re-usable devices and SUDs; that Health Canada should regulate third-party reprocessors; and that until Canadian regulations are established, hospitals should consider using third-party reprocessors licensed by the FDA in the US.

In a 2005 letter, the Therapeutic Products Directorate referred to developments, including the establishment of a Medical Devices Reprocessing Working Group by Ontario and review of policies by British Columbia and the Northwest Territories. In addition, Health Canada's Scientific Advisory Panel on Reprocessing of Medical Devices had endorsed a motion that Health Canada advise health care facilities and professionals that to minimize the risks to patients:

- 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
  - continual monitoring of reprocessing procedures to ensure quality.
- 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.

Discussions with Health Canada in May 2006 indicated that these issues were still relevant to policy development and that a review was necessary to encourage the discussion of provincial and territorial policies among federal, provincial, and territorial deputy ministers.

1.2 Overview of Technology

Medical device re-use refers to the repeated use or multiple use of any medical device, including those intended for single-use, with reprocessing between uses. Reprocessing includes all the steps performed to make a device that has been used by one patient ready for use by another patient. The steps may include cleaning, functional testing, pyrogenic (fever-causing) testing, repacking, relabelling, and disinfection or sterilization.

The context and requirements for the reprocessing of medical devices have been outlined by the US General Accounting Office [now the Government Accountability Office (GAO)]. To successfully reprocess a device that has been used by a patient, institutions must be able to clean it thoroughly, sterilize it to acceptable standards, and ensure that reprocessing and re-use will not degrade its functioning. Cleanliness is important because even sterile devices can harbour biological material from previous uses that may be a health risk during subsequent uses. This biological residue may be toxic to new patients, and it also can form a crust to shield harmful bacteria from sterilization procedures.[6]

Reprocessors contacted by the GAO, both third-party firms and hospitals, followed similar reprocessing procedures. The devices to be reprocessed are collected following established procedures and are often rinsed or cleaned soon after use, before they are sent to the reprocessing facility. There, the devices are cleaned, refurbished, inspected, and sterilized. The third-party reprocessors said that they check the function of every device before it is sterilized and returned to the client. These firms also said that they do not mix devices from different hospitals, so that each hospital receives only devices from the batch that it sent to the reprocessor. According to the reprocessors, many devices are rejected during reprocessing because they have been damaged, even device models that are especially amenable to reprocessing.[6]

In Canada, the manufacture and marketing of medical devices are controlled by the Medical Devices Regulations administered by Health Canada. The regulations apply to the original equipment manufacturers (OEMs) but not to hospitals and third-party reprocessors, except for implantable devices such as pacemakers, which are considered "sold" when permanently implanted in a patient.[4,5] Although third-party reprocessors are not regulated by Health Canada, they are registered with the FDA and are subject to the same regulatory requirements as the OEMs in the US.

Individual governments and health regions have been responsible for the policies and procedures in the organization and delivery of health services in each jurisdiction, including SUDs. For example, Best Practice Guidelines published by the Government of Ontario in April 2006 recommend that "critical and semi-critical SUDs must not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor."[7]

Policies and practices vary from one nation to another. France prohibits the reprocessing of all SUDs. The US, Australia, and Sweden do not ban the re-use of SUDs; but all reprocessors, including hospitals that re-use SUDs, must comply with the same regulations as those for OEMs. Germany requires the registration of all reprocessors and proof of the reprocessing procedure's suitability. The UK has not instituted a regulatory ban, but a statement against the practice was issued in 2000 by the UK's Medical Devices Agency.[8]

2 THE ISSUE

The reprocessing and re-use of medical devices labelled and marketed as being for single use only has become routine in some Canadian hospitals. There are concerns that the use of reprocessed SUDs might be associated with an increased risk to patients of infection or other adverse events. Other issues include legal liability, ethical concerns, safety of health care professionals, and cost-effectiveness of SUD reprocessing.

3 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 former has been addressed in a report that has been published concurrently.[9]

The research questions addressed by this report are:

- What is the evidence that reprocessed SUDs are safe and effective?
- What is the cost-effectiveness of reprocessing SUDs?

These have been addressed through a systematic review and a primary economic study.

4 CLINICAL REVIEW

4.1 Methods

A protocol for the clinical review was written a priori and followed throughout the review process.

4.1.1 Literature search strategy

Literature searches were conducted for the clinical review and economic evaluation, and the results from both combined. All search strategies were developed by the information specialist (SN) with input from the project team. These searches were peer-reviewed by an internal information specialist not involved in the project.

The following bibliographic databases were searched through the OVID interface: Medline (1966 to November 2006 week 3; In-Process & Other Non-Indexed Citations, December 13, 2006), EMBASE (1996 to 2006 week 49), BIOSIS Previews (1989 to 2006 week 52), and CINAHL (1982 to December 2006 week 2). Parallel searches were run in the Health Economic Evaluations Database (HEED) and the Cochrane Library. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords focussing on the concepts of single-use medical devices and reprocessing or re-use. Methodological filters were applied to limit retrieval to randomized controlled trials, controlled clinical trials, systematic reviews, or economic studies. Appendix 1 shows the search strategy.

The search was restricted to human studies published from 1996 onwards. There were no language restrictions. OVID AutoAlerts were set up to send monthly updates with any new literature (to July 2007). Monthly updates were performed on the HEED and Cochrane Library databases.

Grey literature (literature that is not commercially published) was identified by searching the web sites of health technology assessment and related agencies, professional associations, and other specialized databases. Google and other Internet search engines were used to search for additional web-based materials and information. These searches were supplemented by hand searching the bibliographies and abstracts of key papers and conference proceedings and through contacts with appropriate experts and agencies.

4.1.2 Selection criteria

Studies were included for review if they reported clinical outcomes after the use of reprocessed SUDs in humans. Experimental studies and non-experimental studies with a sample size arbitrarily chosen as 20 or more were considered. Interventions were the use of medical devices manufactured for and labelled as single-use that had undergone reprocessing by an institutional health care provider or by a third-party reprocessor and the use of SUDs that had been previously opened but not used. The comparator in comparative studies was the one-time use of SUDs. The outcomes considered included infection of patients, other identifiable adverse events occurring in patients, mortality, device damage or failure, and evidence of device contamination.

Health technology assessments (HTAs) and systematic reviews that had considered the reprocessing of SUDs were also reviewed.

Excluded publications included those reporting studies that evaluated medical devices manufactured or labelled as re-usable, those evaluating adverse events caused by the first-time use of SUDs, studies evaluating re-used SUDs that had not been reprocessed, and studies that compared the safety or efficacy of SUDs with those of re-usable medical devices. Narrative reviews, experts' opinion, correspondence, and commentaries were also excluded.

4.1.3 Selection method

Two reviewers (DH and JP) independently applied the selection criteria to the title and abstract and selected abstracts for further review. Full-text articles were obtained for abstracts that met the selection criteria and for articles about which there was uncertainty. Articles were reviewed and included if they met the selection criteria. Any discrepancies were resolved by consensus.

4.1.4 Data extraction and abstraction strategy

A data abstraction form was created a priori (Appendix 2). Two reviewers (DH, JP) independently extracted data from the selected publications using this form. Any disagreements were resolved by consensus.

The information extracted included the medical procedure; study design, setting and duration; numbers of patients, procedures and devices; clinical outcomes related to adverse events associated with the use of reprocessed SUDs, including infections and mortality; and outcomes related to the device including failure or damage, non-sterility, or uncleanliness.

4.1.5 Strategy for validity assessment

The quality of the selected studies was evaluated independently by two reviewers (DH and JP) using an approach that takes into account study design and study performance and links both to judgments on study reliability. Studies were rated on a scale of 1 to 15 (e.g., 5 for study design and 10 for study performance) (Appendix 3). Any disagreements were resolved by consensus. On the basis of the quality scores, each study was assigned to one of five categories as follows:

- high quality (high degree of confidence in study findings)
- good quality (some uncertainty regarding the study findings)
- fair quality (some limitations should be considered in any implementation of study findings)
- poor to fair quality (substantial limitations in the study, findings should be used cautiously)
- poor quality (study findings have unacceptable uncertainty).

4.1.6 Data analysis methods

A series of non-quantitative reviews were prepared by two reviewers (DH and JP). For each selected study, the outcomes of interest associated with adverse events in patients and device malfunction were recorded and discussed. Any discrepancies were resolved by consensus.

4.2 Results

4.2.1 Quantity of research available

The report selection process is shown in Figure 1. The literature search identified 852 citations, and a further four were identified from other sources. Twenty-nine articles were retrieved for further scrutiny. The most common reasons for excluding citations from the review were that articles did not focus on device reprocessing and that issues were addressed only through narrative reviews or commentaries. Seventeen articles were excluded. Six of these were narrative reviews, five described in vitro studies, four articles reported studies that compared new SUDs with re-usable devices, and the other two were descriptions of non-experimental studies with <20 subjects.

Twelve articles met the selection criteria. These reported results from 12 unique studies on five types of medical devices.

4.2.2 Study characteristics

The selected studies are listed in Table 1. More extensive information is included in Appendix 4.

There were five studies on coronary angioplasty catheters,[10-14] three on devices used in laparoscopic surgery,[15-17] two on sphincterotomes,[18,19] and one each on external fixation devices for the management of fractures[20] and on phacoemulsification tips.[21] The study design varied. There were two large randomized controlled trials (RCTs) (>50 subjects in each arm), one small RCT (<50 subjects in each arm), two studies were prospective non-randomized comparative, three were retrospective comparative, and four were non-experimental (case series). External reprocessing was used in one study.[10]

The sources of funding were reported for three studies. Browne *et al.*[10] had support from a clinical research centre, Plante *et al.*[11] was partially funded by a university grant, and DesCôteaux *et al.*[17] was supported by a health technology assessment council. None of the articles included a statement about potential conflict of interest.

4.2.3 Data analyses and synthesis

All but one of the comparative studies found no difference in the rates of adverse events between groups treated with reprocessed SUDs and those treated with new devices. Plante *et al.*'s comparative study on coronary angioplasty catheters found that clinical failure with adverse clinical events was significantly higher in patients treated using reprocessed devices.[11]

The four non-experimental studies[17-19,21] did not identify any problems with the use of reprocessed SUDs. Three of the 12 studies used Canadian data[11,13,17] and five used US data.[10,18-21]

a) Coronary angioplasty catheters

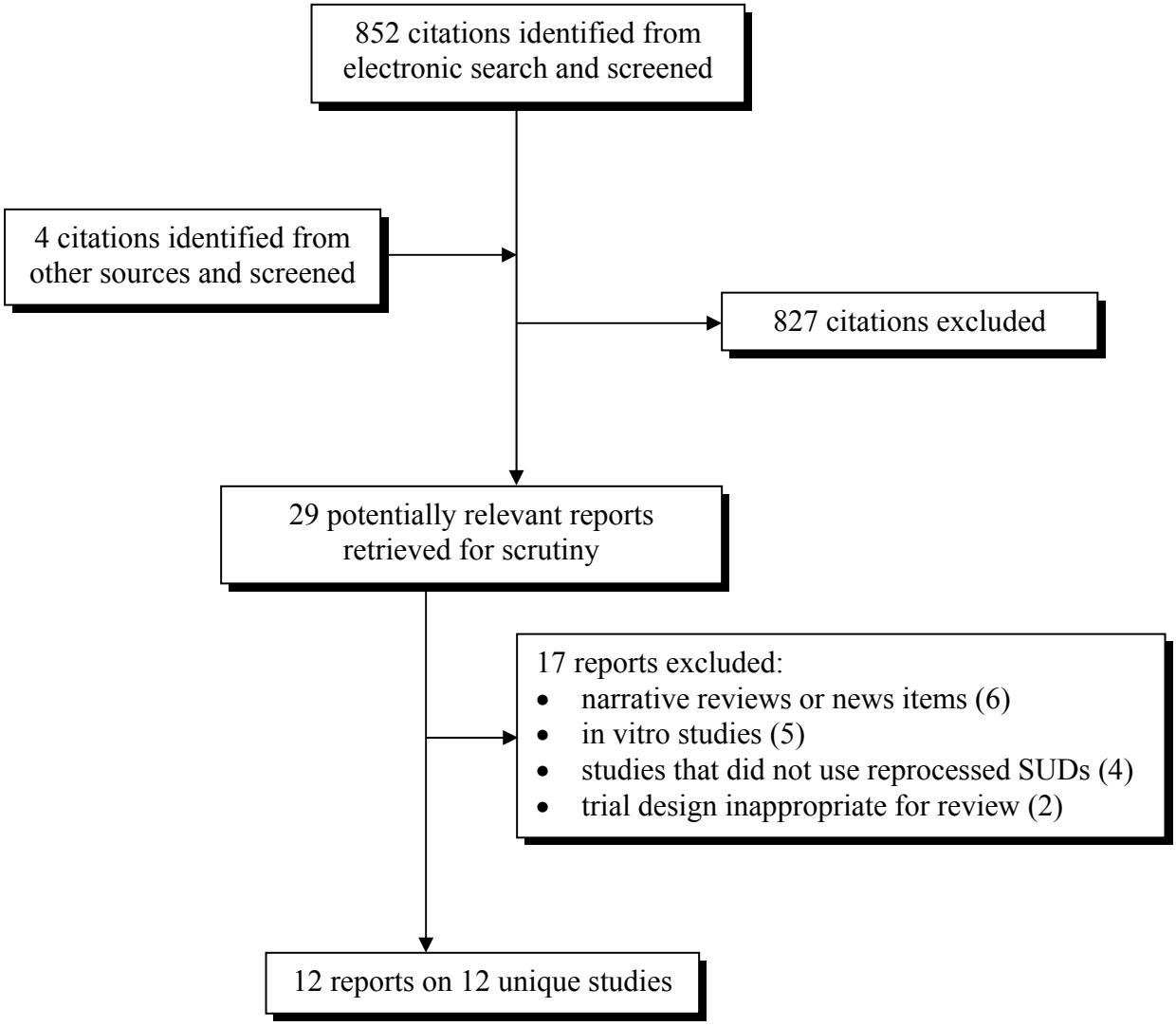
The study quality was high for the RCT, fair for three non-randomized comparative studies, and poor to fair for the fourth. Zubaid *et al.*[12] described a double-blinded RCT conducted at a university hospital over 12 months. All patients undergoing percutaneous transluminal coronary angioplasty (PTCA) were included except those with total occlusion of unknown duration or of more than one month. The

patient's lesion had to be crossed with a guidewire. Baseline clinical and angiographic characteristics of patients in the re-use group (n=178) were comparable to those in the single-use group (n=199).

There was no significant difference (NSD) in outcome between the two groups. At the 30-day follow-up, fever was noted in two individuals in the re-use group and four in the single-use group. The incidence of major adverse cardiac events was similar in the two groups — eight (4.5%) in the re-use group (one death) and 10 (5.2%) in the new devices group (two deaths). First balloon failure occurred in 12 individuals in the re-use group and 10 in the single-use group. The study quality was high.

Scherson and Dighero[14] measured the clinical effectiveness of single-use compared with re-used disposable angiographic catheters in a public hospital over a six-month period.

Figure 1: Selection of reports on clinical studies



There were 108 procedures with new SUDs and 313 with re-used catheters. Data about patients were collected from hospital registries and clinical files. Local infection or systemic pyrogenic reaction was observed in 4.3% of the patients. There was NSD between the group in which reprocessed catheters were used and the group with new catheters for any of the variables studied. The relative risk of complications associated with re-used catheters was 1.15 (95% CI=0.43 to 3.03; p=0.72). The study quality was poor to fair.

The prospective non-randomized study by Plante *et al.* compared effectiveness, safety, and the costs associated with the re-use of balloon catheters in one hospital (n=320) with those associated with single-use catheters in another hospital (n=373) over a 10-month period.[11] All those undergoing

PTCA were included in the study unless an alternative form of coronary intervention had been used initially. Data were collected after each procedure and before patient discharge. There was a higher incidence of unstable angina (70% versus 57%, p<0.005) in patients at the hospital that used reprocessed catheters. The re-use group had increased abrupt vessel closure (6.7% versus 3.3%, p<0.025), unsuccessful crossing with initial catheter (10.2% versus 3.3%, p<0.0001), clinical failure with adverse clinical events (7.8% versus 3.8%, p<0.025), and urgent coronary artery bypass graft (CABG) (4.1% versus 1.1%), p<0.025). Also, the re-use group experienced a longer procedure time (81 minutes versus 62 minutes, p<0.0001) and hospital stay (5.1 days versus 3.4 days, p<0.0001) compared with the single-use group. Fever was noted in three individuals in the re-use group and one in the single-use group. None of these occurrences appeared to be procedure-related. A higher incidence of initial balloon failure was observed in the re-use group compared with the single-use group (10.2% versus 3.3%).[11] A re-analysis of the data, controlling for baseline clinical characteristics, found that adjusted rates were similar for the two centres, suggesting that catheter re-use was not associated with an increased rate of in-hospital complications.[22]

The quality of the study was fair, but the validity of the findings that the use of reprocessed catheters was associated with a higher rate of adverse events is uncertain because the patients were treated in different hospitals. The authors of the paper note that this approach "may not be entirely suitable because of differences in patient groups, practice patterns and operator experience." The study authors consider that the operator's experience and skills were probably comparable between the two hospitals, but no reference is made to other potential factors such as differences in nursing staff or in catheter laboratory settings. The re-analysis of data from this study suggests that there was in fact NSD in adverse events between the re-use and single-use centres.[11,22]

The retrospective study in a general hospital by Shaw *et al.* compared the re-use of catheters with a single use protocol that was introduced after a Quebec government decision.[13] Consecutive patient cohorts before and after the date of the provincial policy change were considered. Those having atherectomy and patients whose PTCA was aborted because of a failure to cross the lesion with a guidewire were excluded. There were 53 patients with 64 lesions in the re-use group and 54 with 66 lesions in the single-use group. The angiographic success rate was similar in the re-use group (83%) and the single-use group (88%). Differences between the groups regarding in-laboratory complications (five versus three) and post-operation complications (five versus 11) were not statistically significant.

The study was of fair quality, but routine practice procedures may have changed during the study; for example, through the greater use of stents in the single-use group. No reference was made to the presence or absence of infection in the patients.[13]

Table 1: Clinical studies on reprocessed SUDs			
Study	**Study Design and Quality**	**Number of Patients**	**Outcomes**
Coronary Angioplasty Catheters			
Scherson and Dighero, Chile[14]	prospective non-randomized comparative, poor to fair quality	n=313 re-use, n=108 single use	NSD in local infection or systemic pyrogenic reaction between group with re-used catheters and group with new catheters
Zubaid *et al.*, Kuwait[12]	large RCT, high quality	n=178 re-use, n=199 single use	NSD in fever or major adverse cardiac events between re-use group and controls
Shaw *et al.*, Canada[13]	retrospective before-after study, fair quality	n=53 re-use, n=54 single use	re-used and new catheters gave similar rates of clinical success; NSD in complications
Browne *et al.*, US[10]	retrospective case control, fair quality	n=107 re-use, n=108 single use	NSD in frequency of fever, WBC count; no episodes of pyrogenic reaction or evidence of catheter-induced infection
Plante *et al.*, Canada[11]	prospective non-randomized comparative, fair quality	n=320 re-use, n=373 single use	abrupt vessel closure and clinical failure with adverse clinical events; SS higher in re-use group, but re-analysis suggested NSD between 2 groups[22]
Devices for Laparoscopic Surgery			
Colak *et al.*, Turkey[15]	large RCT, high quality	n=63 re-use, n=62 single use	NSD in infection and post-operative pain, no evidence of viral hepatitis, CMV, HIV, or syphilis at 6-month follow up
Gundogdu *et al.*, Turkey[16]	small RCT, poor to fair quality	n=30 re-use, n=15 new	no wound or intra-abdominal infection in any patient
DesCôteaux *et al.*, Canada[17]	prospective non-comparative, poor to fair quality	n=874	13 superficial and 3 deep infections, infection rate 1.8% no complications related to instrument malfunction
External Skeletal Fixators for Management of Fractures			
Dirschl and Smith, US[20]	before-after study retrospective, fair quality	n=65 re-use n=69 single use	rates of infection, re-operation, and complications unchanged after introduction of re-use program
Sphincterotomes			
Kozarek *et al.*, US[18]	prospective non-comparative, poor quality	n=534	cholangitis in 2 patients who had procedures using previously unused sphincterotomes
Wilcox *et al.*, US[19]	prospective non-comparative, poor quality	n=528	infection n=5, bleeding n=5
Phacoemulsification Needle Tips			
Perry, US[21]	prospective non-comparative, n=295, poor quality	n=295	no interoperative problems or complications during any procedure or at 0.5, 1, and 6 months

CMV=cytomegalovirus; HIV=human immunodeficiency virus; NSD=no significant difference; RCT=randomized controlled trial; SS=statistically significant; SUDs=single-use devices; WBC=white blood cell.

Browne *et al.*'s case control study evaluated the performance of reprocessed coronary angioplasty balloon catheters for patients undergoing PTCA in a regional medical centre.[10] The indications for PTCA were stable coronary insufficiency (n=69), unstable angina (n=22), and acute myocardial infarction (n=16). The control group of 108 patients had PTCA with new catheters. Clinical outcomes between the two groups indicated no statistically significant differences between the intervention and control groups in terms of frequency of fever (11 versus 12) or elevated white blood cell count (12 versus 14). There were no episodes of pyrogenic reaction or evidence of catheter-induced infection. The study was of fair quality.

b) Devices for laparoscopic surgery

Colak *et al.* investigated the efficacy and safety of reprocessed disposable instruments for laparoscopic cholecystectomy.[15] The study included patients with symptomatic cholelithiasis who were undergoing laparoscopic cholecystectomy under general anesthetic at a university hospital. Patients were recruited over an eight-month period and followed up at six months after the procedure. Patients were randomly assigned to a re-use group (n=62) or a single-use group (n=63). There was NSD in infection rates between the groups (two patients in the re-use group and one in the single-use group, p=0.57). There was one other complication in each group. There was no evidence of viral hepatitis, cytomegalovirus (CMV), human immunodeficiency virus (HIV), or syphilis at the six-month follow-up, and the tuberculosis skin test was negative in all patients. There was NSD in operating time, linear analogue pain scale score, and duration and amount of analgesic administration. The study was of high quality.

Gundogdu *et al.* described a small RCT that assessed the reusability of disposable plastic trocars in a general hospital for patients who underwent laparoscopic cholecystectomy.[16] There were 30 people in the re-use group and 15 in the single-use group. Patients were followed for seven days after the procedure. There was no wound or intra-abdominal infection in any of the patients. The study quality was poor to fair.

DesCôteaux *et al.*[17] conducted a prospective one-arm study over 41 months on the re-use of disposable laparoscopic instruments during various procedures at a university hospital. Data were obtained for 58 thoracoscopic and 816 laparoscopic procedures. Thirteen superficial and three deep infections were reported, giving an infection rate of 1.8%. No complications related to instrument malfunction were identified.

c) Sphincterotomes

Kozarek *et al.* conducted a prospective one-arm study at a medical centre on the use of reprocessed braided wire sphincterotomes for 536 cannulation or cutting procedures during a 12-month period.[18] Two patients with unrelieved ductal obstructions experienced postprocedural cholangitis, but both had had procedures with previously unused sphincterotomes. A total of 152 devices were discarded because of malfunction, in accordance with study criteria. Three devices were discarded after 10 uses with no malfunction. The study quality was poor.

In a second prospective one-arm study, Wilcox *et al.* evaluated the reprocessing of sphincterotomes for sphincterotomies or for cannulation alone in a university hospital during a 12.5-month period.[19] During the study, 528 endoscopic retrograde cholangiopancreatographies (ERCPs) were performed and 80 sphincterotomes were used 290 times. Infection was found in five patients, one of whom had been treated without a sphincterotome. Other complications included pancreatitis in 28 patients (considered to be unrelated to use of a sphincterotome), bleeding in five, and duodenal perforation in three. The study was of poor quality.

d) External fixation devices

In a before-after study, Dirschl and Smith measured the clinical and economic outcomes of a re-use program for selected components of external fixation devices for fractures at a university hospital trauma centre.[20] All patients who were fitted with external fixation devices 15 months before and after the establishment of a re-use program were included (n=69 before, single-use and n=65 after, re-use). There was NSD between the re-use and single-use groups in pin tract infection (n=4 versus 5) or in re-operation rate (n=9 versus 6). The quality of the study was fair.

e) Phacoemulsification tips

Perry investigated the re-use of phacoemulsification needle tips in 295 patients who had extracapsular cataract extraction in a community hospital.[21] In the 12-month prospective one-arm study, 182 units were used more than once. No inter-operative problems or complications occurred during any of the procedures or at postoperative examination at 0.5, one, and six months. The study quality was poor.

None of these studies considered the issue of late viral infections.

5 ECONOMIC ANALYSIS

5.1 Review of Economic Studies

5.1.1 Methods

The methods used in our economic review were written a priori, and the procedure was followed throughout the review process.

a) Literature search strategy

The literature search strategy was applied for the clinical review and the economic evaluation (Appendix 1).

b) Selection criteria

Studies were considered for review if they reported economic outcomes associated with the use of reprocessed SUDs for medical procedures in humans. Only studies in which patient outcomes data had been collected were included. The interventions were the same as those specified for the clinical review. The comparator was one-time use of SUDs. The 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). HTAs and systematic reviews that had addressed the reprocessing of SUDs were also considered. Excluded publications were the same as those specified for the clinical review.

c) Selection method

Two reviewers (PJ, JP) independently applied the selection criteria to the title and abstract for further review. Full-text articles were obtained for abstracts that met the selection criteria and for undecided articles. Articles were reviewed and included if they met the selection criteria. Any discrepancies were resolved by consensus.

d) Data extraction and abstraction strategy

Two reviewers (PJ, JP) independently performed the data extraction of relevant information based on a structured data extraction form (Appendix 5). Any discrepancies were resolved by consensus.

e) Strategy for assessing validity of included studies

A quality assessment was completed independently by two reviewers (PJ, JP) based on the criteria shown in Table 2. This was an adaptation of the Drummond guidelines.[23] The criteria include study design, sample size, clinical and cost variables measured, and whether an incremental analysis and a statistical or sensitivity analysis were conducted.

f) Data analysis methods

The analysis is based on the Health Economic Guidelines developed by the Canadian Agency for Drugs and Technologies in Health (CADTH).[24] According to these guidelines, an economic evaluation should have at least two alternative interventions, appropriate timelines, and measures of outcomes and costs.

The outcomes and costs should be expressed in terms of an incremental analysis, showing differences between the alternative interventions. We examined the economic literature by comparing the one-time use of SUDs and in-hospital SUD reprocessing.

Table 2: Quality indicators for assessing validity of included economic studies

Indicator	Explanation
Study design	An RCT provides the highest level of evidence. A two-arm prospective study provides higher quality estimates than a two-arm study with one prospective and one retrospective arm (i.e., before-after). Studies with one observational arm and one hypothetical arm have a very low quality.
Number of observations	A larger sample is better. For two arms, a balanced design is best.
Duration of observation	The best quality of study would include observation of the patient until there is no longer a risk of an adverse event because of the re-use of SUDs.
Inclusion of clinical outcomes	A complete analysis should include clinical outcomes and costs. These should be based on observational data.
Costs – items included	A complete cost-effectiveness or cost-consequences analysis of re-use should include cost per device, number of times the device was used, cleaning costs, costs of adverse events, and disposal costs.
Costs – method of estimation	The highest quality estimates are based on observed costs or standard costs that were derived from actual data. Hypothetical estimates are of lower quality.
Incremental analysis	An incremental analysis where differences in costs and outcomes are analyzed should be reported. This can be done without an actual cost-effectiveness ratio.
Statistics or sensitivity analysis	Variance analyses or sensitivity analyses should be conducted when there is uncertainty about the quality of the estimates.

There were no studies on third-party reprocessing that met our inclusion criteria.

Because the articles varied by study design, medical device, clinical outcomes, and costs measured, a series of non-quantitative reviews that summarized the characteristics and outcomes were undertaken by two reviewers (PJ, JP). Quantitative (i.e., cost per patient or procedure and clinical outcomes) and qualitative results were reported.

5.1.2 Results

a) Quantity of research available

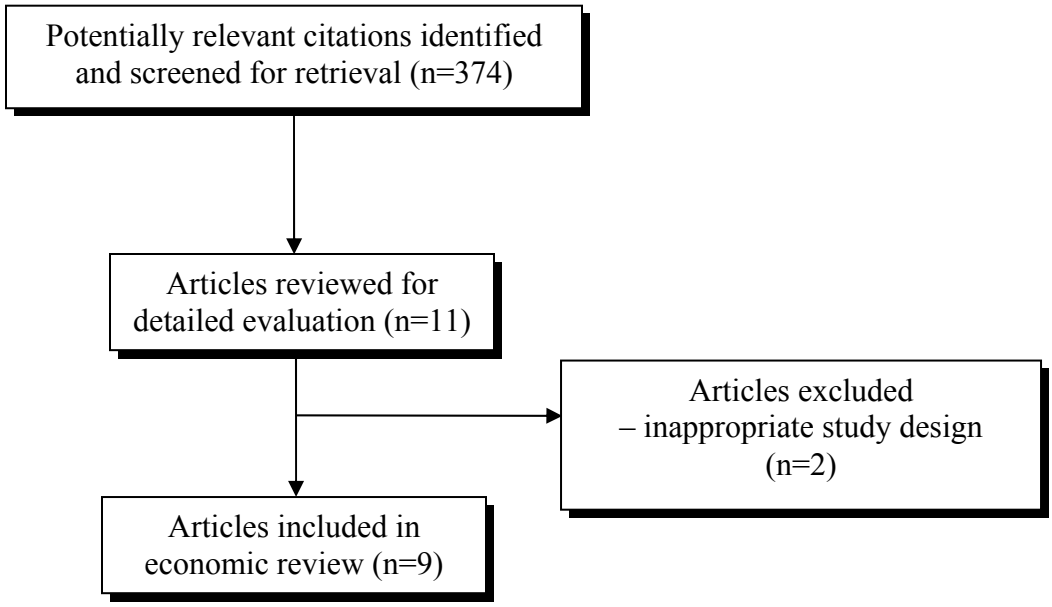
The literature search identified 374 potentially relevant citations. We selected 11 full articles for review, and nine met the selection criteria (Figure 2). Common reasons for the exclusion of articles were the same as those for the clinical review and included the absence of data on patients' outcomes. The devices studied include instruments for laparoscopic surgery and gastroenterological procedures (trocars and sphincterotomes), catheters for PTCA and tracheostomies, and external skeletal fixators for fractures.

b) Study characteristics

Of the nine studies in our economic review, six were included in the clinical review.[10,11,16,18-20]

Browne *et al.*[10] provided an estimate of device costs for single-use and re-used angioplasty catheters. Based on a price of $400 per device, the savings due to reprocessing were estimated to be $160 per device or 40% of the purchase price. There were no differences in outcomes between single-use and re-use groups.

Figure 2: Selection of reports on economic studies



Plante *et al.*[11] directly measured the device and cleaning costs in two hospitals and identified savings of 40% of the price of $644 per catheter from reprocessing. Because of possible differences in patients, clinical practice, and outcomes between the two centres, we could not incorporate costs and outcomes into one cost-consequences analysis.

Gundogdu *et al.*[16] presented the estimates of differences in device costs between the two study cohorts in an RCT but did not indicate how the costs were measured. Device costs for the single-use group were US$18,600, while savings were calculated at 95% of this amount. The cost-effectiveness

ratio would be highly favourable if the results were accurate, because there were no significant differences in clinical outcomes. The small sample size and lack of transparency of the cost measures, however, raise concern about the robustness of these results.

The one-arm trial by Kozarek *et al.*[18] examined the costs for 775 patients in a previous period when there was no reprocessing, but outcomes were reported for the re-use period. The results indicated that the savings would be 68% of the single-use price, but outcomes were not presented, so a full economic analysis could not be obtained.

Wilcox *et al.*[19] presented results for a one-arm trial. The cost data for single-use were hypothetical. The findings indicate considerable savings related to SUD reprocessing (72% of the original cost of $100 per device). Because of a lack of reported outcomes, a full economic analysis was not conducted.

Dirschl and Smith[20] directly measured the device costs and cleaning costs before and after the introduction of reprocessing. They reported charges and costs separately and included pin tract infections and re-operations before and after the introduction of reprocessing. There were fewer infections with re-use but more re-operations, but the differences were not statistically significant. The cost analysis indicated a 33% reduction from a single-use cost of $1,864 per procedure.

The remaining three papers were not included in the clinical review. DesCôteaux *et al.*[25] reported a single-arm prospective study that evaluated the re-use of laparoscopic instruments for cholecystectomies in a hospital. A total of 2,564 devices were included, and their costs were compared with those for a similar number of new devices. No health outcomes were measured. The results indicate a savings of 58% of the new single-use cost. Because outcomes were not reported, a full economic analysis could not be conducted.

Nanta *et al.*[26] assessed the re-use of tracheal suction tubes in a hospital. The study methods were not specified, and the authors measured costs for new SUDs and cleaning and discarding the devices. Suction tubes were low in cost, and as a result the reprocessed device costs were greater than those for single-use.

Mak *et al.*[27] studied the re-use of PTCA catheters, using data from Plante *et al.*[11] and observational data from a hospital. The model included device costs (including cases where there was >1 device per lesion), cleaning costs, and rates and costs of adverse events, which were primarily CABGs and late closures. Several scenarios were presented, allowing for a sensitivity analysis. All outcomes, including health outcomes, were expressed in terms of costs. The full cost per patient of the most likely case of re-use was US$8,929, compared to $8,800 for single use. In the best case scenario, the total cost per patient for re-use was US$8,320 and in the worst case scenario was US$9,875. This is the most complete cost analysis available, and the results favoured single use.

5.1.3 Data analysis and synthesis

Study characteristics appear in Table 3. All studies were conducted in hospitals. There is a wide variation in study design, sample size, and clinical outcomes measured (Table 3).
The quantitative results and qualitative aspects of the reviewed studies are shown in Table 4. In all studies, the cost savings were calculated as the cost of using new devices for every time that the device was used minus the actual cost of re-using devices (i.e., cost of new devices and the cleaning costs). Seven out of nine studies showed savings with re-use. The average saving was 44% of the

cost of all new devices. Two studies reported positive net costs. In Nanta *et al.*'s study,[26] the original price of the device was low compared with cleaning and disposal costs, which is unusual for such studies. Mak *et al.*[27] included the cost of adverse events in their analysis. Therefore, the results favoured single-use, although these changed in a sensitivity analysis.

Observational and comparative clinical data were reported in four studies. In Plante *et al*.'s study,[11] complications in the re-use arm were significantly greater than in the single-use arm, but re-analysis of the data suggested that there was in fact NSD between the groups.[22] In the other studies, the differences between groups in the number of adverse events were not statistically significant.

Table 4 includes comments on the quality of studies in our economic review. In two studies,[25,26] no clinical outcomes were measured. There was no clinical comparator in Wilcox *et al.*'s study,[19] and the number of patients observed was small in four studies.[10,16,18,20] In Mak *et al.*'s study, the method of observation was unclear.[27] Each arm in Plante *et al*.'s study[11] was treated in different hospitals, where practice patterns may have differed.

Table 3: Characteristics of economic studies									
Study	**DesCôteaux *et al.*[25]**	**Gundogdu *et al.*[16]**	**Kozarek *et al.*[18]**	**Wilcox *et al.*[19]**	**Browne *et al.*[10]**	**Plante *et al.*[11]**	**Mak *et al.*[27]**	**Nanta *et al.*[26]**	**Dirschl and Smith[20]**
Country	Canada	Turkey	US	US	US	Canada	USA	Thailand	USA
Year published	1996	1998	1999	1998	1997	1994	1996	2005	1998
Type of device	laparoscopic instruments	plastic trocars	sphincterotome	sphincterotome	PTCA balloon catheters	PTCA balloon catheters	PTCA balloon catheters	tracheal suction tubes	external skeletal fixators
Study design	prospective, 1 arm only	RCT	prospective for intervention, retrospective for control (cost data only)	prospective, 1 arm only	prospective for intervention, retrospective for control	prospective, 2 comparative study centres	model with retrospective and literature data	unspecified	prospective (re-use) versus retrospective (new use)
Number of observations (intervention/ control)	2,564 / 0 devices	30 / 15 patients	155 / 775 patients	80 / 0 patients	107 / 108 patients	693 / 452 patients	not applicable	unspecified	65/ 69 patients
Duration of observation	unspecified	after 1st or 2nd post-operative day, patients invited for follow-up on 7th post-operative day	unspecified	1 month after use	until hospital discharge	until hospital discharge	not applicable	unspecified	until hospital discharge
Clinical outcomes included	0	culture growth, gram-positive bacilli, strains, bile samples, wound infections	post-procedure infections	Complications	fever, white blood cell count, pyrogenic reaction, catheter-induced infection	clinical failure with adverse events; fever; urgent CABG; crossing with initial catheter	myocardial infarction CABG and mortality (all retrospective)	device function	re-operations
Cost items included	devices and cleaning	devices	devices and cleaning	Devices	devices	devices and cleaning	devices, cleaning and adverse events	devices, cleaning and disposal costs	devices and cleaning
Method of obtaining costs	observational	unstated	based on prior data	Estimated	estimated	observational	observational	not stated	observational
Type of analysis	incremental	incremental	incremental	not specified	incremental	not specified	incremental	incremental	incremental
Statistical test or sensitivity (yes or no)	no	no	no	no	yes	yes	yes	no	no

CABG=coronary artery bypass graft; PTCA=percutaneous transluminal coronary angioplasty; RCT=randomized controlled trial.

Table 4: Economic studies results			
Study	**Cost Results**	**Clinical Outcome Results**	**Comments on Quality**
DesCôteaux *et al.*[25]	Total costs reported only Cost of single use US$527,575 Cost of re-use US$218,944 Total savings (% of original manufacturer's price) US$308,630 (58%)	no clinical outcomes measured	no outcome data and no observed comparator weaken results
Gundogdu *et al.*[16]	Total costs reported only Cost of single use US$18,600 Cost of re-use US$1,240 Total savings (% price) US$17,630 (95%)	no patient developed clinical wound or abdominal infection	small numbers weaken results regarding outcomes
Kozarek *et al.*[18]	Cost of single use per device $435 Cost of re-use per device $138 Cost savings per device (% price) $297 (68%)	2 patients in study group had cholangitis but had been treated with new sphincterotomes; clinical outcomes not reported for retrospective group that provided cost comparison	small numbers weaken results regarding outcomes
Wilcox *et al.*[19]	Cost of single use per use $100 Cost of re-use per ERCP $28 Cost savings per ERCP (% price) $72 (72%)	infection n=5, 1 of whom treated without sphincterotome, bleeding n=5	no comparators
Browne *et al.*[10]	Hypothetical cost of single use per device US$400 Hypothetical cost of re-use per device US$240 Hypothetical cost savings per device (% price) US$160 (40%)	no statistically significant differences between groups in numbers of patients with elevated white blood cell counts or with fever	small numbers weaken results regarding outcomes
Mak *et al.*[27]	Hypothetical cost of single use per patient US$8,800 "Worst case scenario" of cost of re-use per patient" US$9,875 "Likely case scenario" of cost of re-use per patient US$8,929 "Best case scenario" of cost of re-use per patient US$8,320 Maximum potential cost savings per patient (% price) US$480 (9%)	clinical outcomes were hypothetical	model, methods of making calculations not clearly stated
Plante *et al.*[11]	Cost of single use per lesion C$644 Cost of re-use per lesion C$370 Cost saving per lesion (% price) C$274 (42%)	overall clinical success rates and rate of clinical failure without adverse clinical events comparable in both groups; rate of clinical failure with adverse events greater in re-use group, but re-analysis of data indicated NSD between groups	2 centres, practice patterns may differ between them
Nanta *et al.*[26]	Cost of single use per device US$0.217 Cost of re-use per device US$0.248 Cost savings per unit (% price) (US$0.031) (−14%)	no clinical outcomes measured	no clinical outcomes
Dirschl and Smith[20]	Mean cost of single-use per fixator US$1,864 Mean cost of re-use per fixator US$1,238 Overall mean cost savings per fixator (% price) US$626 (33%)	no changes in rates of infection, re-operation, or complications after introduction of re-use program	small numbers weaken results regarding outcomes

CABG=coronary artery bypass graft; ERCP=endoscopic retrograde cholangiopancreatography.

5.2 Primary Economic Evaluation

5.2.1 Methods

A protocol for the evaluation was written a priori and followed throughout the review process.

a) Type of economic evaluation

Economic models can be conducted in any of several formats: cost-minimization, cost-effectiveness, and cost-benefit. The first compares only costs and assumes that outcomes are the same between interventions. The second compares costs with physical outcomes. Cost-benefit analyses incorporate, in monetary terms, the production costs for care and health outcomes (in this case, adverse events). In this analysis, we placed a monetary value on adverse events and then compared the different scenarios. Single-use and reprocessing costs (in-house and third-party reprocessing) were compared for disposable laparoscopic instruments such as trocars, dissectors, curved scissors, and graspers and for coronary angioplasty balloon catheters. These interventions were chosen for analysis, because the best data were available for them.

b) Target population

Two population groups were used in our analysis. The first consisted of an adult population with symptomatic cholelithiasis undergoing laparoscopic cholecystectomy. The second target population included adults undergoing coronary angioplasty.

c) Comparators

The clinical effectiveness and cost of adverse events for the single-use of devices were compared with those for SUDs that are used after reprocessing in-hospital or by a third-party reprocessor.

d) Perspective

A hospital perspective was used in our analysis to provide the most appropriate assessment of direct costs for a health institution. The costs include those for devices and for the adverse events. Other costs included in a societal perspective, for example patients' personal costs (e.g., loss of employment) due to adverse events, are excluded.

e) Effectiveness

Results from our clinical review suggest that the evidence on the safety and efficacy of SUD re-use is limited and of variable quality. For the economic evaluation, we based the estimates of effectiveness on the outcomes from two high quality RCTs on the use of reprocessed instruments for laparoscopic cholecystectomy and of balloon catheters for coronary angioplasty.[12,15] Both studies compared the clinical-effectiveness of single-use with re-used SUDs that had been reprocessed in a hospital.

f) Time horizon

The time horizon for our analysis is the physical life of a SUD. Our objective was to compare the costs associated with multiple SUD re-uses before device malfunction with the one-time use of a SUD. Because the useful lifetime of a device is likely only a few weeks, the discounting of future period costs was not considered.

g) Modelling

The model has three components: the manufacturer's price of the device, reprocessing costs, and costs of adverse events due to reprocessing. These sum to the total cost of using the device during its

useful lifetime. The model applies to single-use, in-hospital reprocessing and third-party reprocessing.

The costs are expressed on a per-patient basis.

Single use: The relevant cost per patient for the single-use scenario is equal to the original price of the devices. Adverse events in the base-case analysis are considered to be equal between scenarios and are excluded in the base-case analysis. In a sensitivity analysis, the cost of discarding a device is the same in both strategies and not part of the model.

Re-use: The relevant cost per patient for the re-use scenario is equal to the price per patient of the devices, cleaning costs, and additional costs of adverse events (considered in the sensitivity analysis). Assuming one re-used device is used per patient, the device cost per patient is equal to the price of the device divided by the number of patients. If >1 re-used device is used per patient because of the possibility of faulty devices, then this must be factored in.

The device cost per patient is expressed as P/T, where P=price of SUD, and T=total number of times that a device is used. This assumes that one device is used for each procedure. If >1 device can be used per procedure, then the formula is $(P \times UP) / T$, where UP is the number of times per procedure that the device is used.

Reprocessing cost per patient: The device is not reprocessed on the first use but at each use thereafter. With one device used per patient, the reprocessing costs are $[R \times (T-1)] / T$, where R=cost of each cleaning, $R \times (T-1)$=total cleaning cost over the life of the device (each device is cleaned after the first use only), and T=number of procedures.

The formula for reprocessing when >1 re-used device is used for each patient is $[R \times (T-1)] / (T / UP)$.

Cost of adverse events: During one procedure, each patient has an adverse event probability (PROB) that will depend on the number of times that the device has been used. The probability is treated as a fixed rate after the first use (because the relative risk of the first use is zero). Each adverse event is assigned a cost, which is equal to the entire treatment cost of the original procedure, deducted from the cost of the procedure when there is an associated complication. The formula expressing the relevant adverse event cost is $PROB \times CSTAE$, where PROB=probability of an adverse event associated with a new SUD or average probability associated with reprocessed SUD, and CSTAE=cost of treating the adverse event.

If a device is reprocessed by a third party, the total cost is the cost of the first use, the cost of reprocessing multiplied by the cost of the device's subsequent uses, and the cost of adverse events after all subsequent uses.

5.2.2 Valuing outcomes

The clinical outcomes that were measured were the probabilities of myocardial infarction, PTCA, and CABG reported by Zubaid *et al.*[12] and the probability of hematoma reported by Colak *et al.*[15] Based on the results in our quality assessment, these studies provided the most accurate risk of patients' adverse events compared with other studies in the clinical review. In the absence of relevant information, the risk of infection was excluded in our analysis. In both studies, the relative risk of

reprocessing was assumed to be equal to 1, because there was no evidence of any adverse events due to reprocessing.

a) Resource use and costs

The original prices of devices and the data sources appear in Table 5. The prices are for non-re-usable devices. Reusable devices for laparoscopic cholecystectomy were placed into two groups – trocars and instruments. This is based on Demoulin *et al*.'s study.[28]

The costs related to the reprocessing of laparoscopic instruments in hospitals, such as materials, labour, and training, were obtained from DesCôteaux *et al*.'s study.[25] Plante *et al.* reported the total cost of preparing a disposable balloon catheter for re-use.[11] The contract prices of third-party reprocessing for trocars, dissectors, curved scissors, graspers, and balloon catheters were provided by Ascent Health Care Solutions, Phoenix, Arizona. The costs of dissectors, curved scissors, and graspers were expressed in one unit called "instruments" (Table 5).

Average number of re-uses: The average number of re-uses for a balloon catheter was derived from Plante *et al*.'s study.[11] The average number of re-uses for disposable laparoscopic instruments was based on Colak *et al*.'s study.[15] The number of times each instrument was used was averaged over the three types of instruments (Table 5).

b) Discount rate

Because the useful lifetime of a device is likely to be a few weeks, discounting future period costs was not considered.

c) Variability and uncertainty

Some of the key variables in the analysis – the price of the products, the number of times used per patient, and the number of re-uses – will not change the results if the values are kept within realistic bounds. We conducted sensitivity analyses for these variables, but we do not report the results. We contained our sensitivity analysis to one key variable — the probability of an adverse event. The value of this variable is a key element in deciding whether to re-use a device, and it is largely unknown. Therefore, it should be subjected to a sensitivity analysis. Although their study was not based on high quality data, Mak *et al*.[27] showed that the probability of an adverse event can influence the economic outcomes of a decision on whether to re-use catheters.

Our sensitivity analysis is conducted in light of a break-even value. We calculate the "full cost" (original equipment cost) of use under a single-use policy and the "full cost" (original equipment cost, cleaning, and adverse event cost) under a policy of re-use. The former cost will be greater than the latter in the absence of any difference in adverse events between the two policies. As the probability of an adverse event increases, however, the difference will diminish. At a "threshold" value of this probability, the full cost of single use will equal the full cost of re-use. This is the value that we seek.

If the threshold value of this probability is unrealistically high, then there are net cost savings from re-use. If the threshold probability is in a realistic range, then there may not be net savings from re-use.

Table 5: Values and sources of data for variables used in the economic model		
Variable	**Value**	**Data Source**
Angioplasty		
Price of catheter	$250	Corporate Contracting, Capital Health, Edmonton, June 2007
Price of third-party processed catheter	N/A	
Number of catheters used per procedure	Single use 1 Re-use 1.2	Plante *et al*.[11]
Number of times catheter used	Re-use 6.2	
Cleaning cost of second and subsequent uses	$35	DesCôteaux *et al*.[25]
Adverse event		Angioplasty without complication is CMG 189 Plx1. Adverse event of angioplasty assumed to result in CABG procedure with heart pump with cardiac catherization (CIHI CMG 178 Plex11) or major cardio-thoracic procedure without heart pump with cardiac catherization (CMG 183 Plx1). Plx1 refers to lowest complexity level in CMG.
Probability • single use • re-use	 0 0	Zubaid *et al*.[12] No differences in adverse events between interventions. Probability of adverse event assumed to be 0.
Cost per event	$13,755	Cost of angioplasty (CMG189 Plx1) that becomes coded as more severe CABG (CMG178 Plx1) is the difference in cost between them: $20,973 for CABG and $7,218 for angioplasty, or $13,755 (difference between angioplasty and CMG 183 Plx1 is $13,365).
Laparoscopic Cholecystectomy		
Price of device • trocar • instruments (dissector, curved scissors, jaw-grasper)	 $433 $800	Demoulin *et al.*[28] 1995 prices expressed in US dollars. Prices updated to 2006 using general Consumer Price Index for Canada, obtained from Statistics Canada.
Price of third-party processed device • trocar • dissector • curved scissors • jaw-grasper	 $9 to $30 (mid point $19.50) $38 $38 $38	Ascent Healthcare Solutions, Phoenix AZ
Number of devices used per procedure • trocar • instruments	 1 1	Assumption
Number of times device used • trocar • instruments	 5 5	Colak *et al*.[15]
Cost of cleaning device • trocar • instruments	 $4.10 $15.04	DesCôteaux *et al*.[25] ($5.31 + $4.90 + $4.83 for dissector, scissors, and jaw-grasper respectively)
Adverse event		Post-operative hematoma

Table 5: Values and sources of data for variables used in the economic model		
Variable	**Value**	**Data Source**
Probability of event • single use • re-use	 0 0.016	Colak *et al*.[15] No differences in adverse events between single-use and re-use groups.
Cost per event	$2,187	Laparoscopic cholecystectomy with low complexity level (CIHI CMG 137 Plx 1) costs $3,870. Post-operative hematoma increases complexity level to Plx 2, with associated cost of $6,057. Difference between case with or without hematoma is $2,187. Alberta Health and Wellness, Health Costing in Alberta, 2006 Annual Report, Schedule 1.[29]

CABG=coronary artery bypass graft; CMG=Canadian Institute for Health Information (CIHI) case mix group; Plx (1,2,3,4)=the complexity level associated with specific CMG, Plx1 being the lowest complexity level.

5.2.3 Results

a) Analysis and results

The results of the model appear in Table 6. For angioplasty catheters, the results in the base case indicate a cost per patient of $250 for single use. The cost of re-use, when there are no adverse events, is $77 per case, which includes an expected cost of $48 for the catheter [($250 × 1.2 catheters per patient) ÷ (6.2 uses per catheter)].

The cost per patient of laparoscopic cholecystectomy is $1,233 for single use and $262 for re-use, assuming no adverse events.

b) Results of uncertainty analysis

There are savings from re-use if there were no adverse events. These would be offset if there were adverse events. In the break-even analysis, we vary the probability of an adverse event due to re-use, to determine what the "threshold" adverse event would be for break-even (if the savings were just offset by the losses due to adverse events). The break-even analysis of the probability of adverse events after angioplasties indicates that the cost per patient is the same between re-use and single use if the probability of an adverse event due to the re-use strategy is 12.6 per 1,000 procedures.

As a secondary analysis, we compared the outcomes between the values of adverse events with single use and re-use, even though there was no significant difference between them.[12] For angioplasties, the rates of adverse events were 45 per 1,000 procedures and 50 per 1,000 procedures for single-use and re-use respectively ($p = 0.5$). While the results still favour re-use in this scenario, the differences in net costs is reduced. The net cost for re-use is $736 per patient, and for single use it is $869 — a difference of $133.

The break-even analysis of the probability of adverse events after laparoscopic cholecystectomies indicates that with a probability of an adverse event of 445 per 1,000 procedures, the cost of the two strategies would be the same.

Table 6: Results of economic model					
Intervention	**Cost per Patient**				
	Device Cost	**Cleaning Cost**	**Expected Cost of Adverse Events**	**Total Cost of Intervention**	**Break-Even Values**
Catheter for angioplasty, base case					
• single use	$250	$0	$0	$250	
• re-use	$48	$29	$0	$77	
Catheter for angioplasty, break-even value for probability of adverse events					break-even value of probability of adverse event is 12.6 per 1,000 procedures
• single use	$250	$0	$0	$250	
• re-use	$48	$29	$206	$283	
Laparoscopic cholecystectomy for base case values					
• single use	$1,233	$0	$0	$1,233	
• re-use	$246	$15	$0	$261	
Laparoscopic cholecystectomy break-even value for probability of adverse events					break-even value of probability of adverse event is 445 per 1,000 procedures
• single use					
• re-use	$1,233	$0	$0	$1,233	
	$246	$15	$973	$1,234	

As a secondary analysis, we applied the actual values for adverse events with or without re-use using data from Colak *et al.*'s study.[15] Using adverse events values of 0 and 16 per 1,000 for single use and re-use respectively, the net costs of single use were still greater.

6 HEALTH SERVICES IMPACT

6.1 Budget Impact

6.1.1 Methods

We conducted a budget impact analysis for Alberta. The costs per person in Alberta are similar to those in the rest of Canada. The number of cases will be approximately 10% of the Canadian total. In the budget impact analysis, we address the question of what additional expenditures would result from eliminating the practice of re-use of SUDs. We selected two types of procedures to answer this question — laparoscopic cholecystectomy and coronary angioplasty.

The additional expenditures due to single use are estimated as the cost to move from current re-use practice to 100% single-use practice. The cost will consist of the cost of extra devices used and the reduced cleaning costs. This is applied to the estimated number of patients who are treated with re-used devices. Because there were no identified increases in adverse events in the base case analysis

(a finding of the literature review), we have omitted consideration of these in the budget impact analysis. The additional expenditures from eliminating the practice of re-using SUDs are based on data in our economic analysis. We make the following assumptions:

- Currently, <1% (one of 111 hospitals) of each of the two types of procedures are being done with re-used SUDs. This figure is based on the survey results in the companion report on the re-use of SUDs in Canada.[9]
- The total number of procedures is the same as that reported for Alberta hospitals in 2005.[29] Canadian totals are about 10 times these volumes.
- The cost of SUDs and the per-patient cost of the practice of re-using SUDs are the same as those used in our economic analysis. The difference per patient indicates the additional expenditures due to the practice of re-using SUDs.
- The full cost of the entire procedure (including devices, nursing, drugs, and hospital overhead) are as reported in the Alberta 2006 health costing report.[29]

The additional costs are reported in dollar terms, as a percentage of the full cost of the procedure, and in terms of the impact on the entire costs for these procedures.

6.1.2 Results

The analysis appears in Table 7. There were 1,824 laparoscopic cholecystectomies and 5,199 angioplasties done in Alberta.

Table 7: Data and calculations used in budget impact analysis (Alberta data, 2005)

	Laparoscopic Cholecystectomy (CMG 137)	Coronary Angioplasty (CMG 188 and 189)	Data Sources and Notes
Number of procedures	1,824	5,199	Health Costing in Alberta 2006 Annual Report
Full cost per procedure	$9,737	$4,083	Health Costing in Alberta 2006 Annual Report
Total expenditures on procedure	$17,759,787	$21,227,517	product of above 2 rows
Percentage of cases re-using SUDs	1%	1%	CADTH survey of re-use practice in Canada
Cost of new devices	$1,233	$250	section 6
Cost of re-use	$262	$77	section 6
Additional cost for single use	$971	$173	difference between above 2 rows
Estimated number of procedures with re-use of SUDs	18	51	based on survey results (1%) applied to total number of procedures
Total additional expenditures from single use of SUDs	$17,500	$8,800	difference in costs between single use and re-use, per case, multiplied by number of cases
Additional expenditures from single use of SUDs as percentage of all costs of procedures	0.1%	0.04%	percentage of total costs of all procedures done as taken from previous row

If 1% of these were done with re-used SUDs, the number of procedures in which this practice was used would have been 18 laparoscopic cholecystectomies and 51 angioplasties respectively. The additional cost of the single use of SUDs, compared with the re-use of SUDs, would be $971 for laparoscopic cholecystectomy and $173 for coronary angioplasty.

If the practice of re-using SUDs were eliminated, the additional annual cost in Alberta would be $17,500 for laparoscopic cholecystectomies and $8,800 for coronary angioplasties. This would add less than one-tenth of 1% to the total costs of the procedures.

6.1.3 Discussion

Our results show that if current practice regarding the re-use of SUDs for these two procedures were discontinued, the additional cost to the health system would be minimal. There is also, however, the possibility that the practice of re-use would grow. The cost of new devices for these procedures represents a considerable portion of the total cost. For laparoscopic cholecystectomies, new devices cost $1,233 per patient, about 12% of the total cost of the procedure. The cost of a catheter is $250, about 6% of the total cost of a coronary angioplasty procedure.

The savings for re-use, using data from our model, are approximately $1,000 per case for cholecystectomies and $170 for angioplasties. The practice of moving from no re-use (which is current practice) to 100% re-use (an unlikely practice in the future) would increase costs by about 10% for laparoscopic cholecystectomies and approximately 5% for angioplasties.

6.2 Legal, Ethical, and Psychosocial Issues

While all medical devices may pose a risk of harm through problems such as defects in manufacturing or improper use, the reprocessing and re-use of SUDs pose specific concerns that are the focus of this report. The reprocessing and re-use of SUDs raises legal and ethical questions about liability for harms to patients, informed consent to treatment with reprocessed SUDs, obligations to notify patients of past exposure to harm, and appropriate balancing of the economic benefits of re-use against risks to the health and safety of patients. The cost savings of re-using devices are often emphasized, but concerns about the safety of the practice intensify, particularly regarding exposure of patients to preventable harms.

This section focuses on the following questions:

- What legal liability issues are involved in the processing and re-use of SUDs, and who bears legal responsibility if a patient is harmed by using a reprocessed SUD?
- To give legally valid informed consent to treatment, must patients be informed that a reprocessed SUD will be used as part of their treatment?
- If new evidence reveals harms associated with reprocessed SUDs, do health care facilities and providers have a duty to trace affected patients and notify them of risks?

These questions focus on matters of law, but ethical and psychosocial issues are intertwined in these legal problems. In the absence of clear regulation and legal precedents, ethical principles must guide decisions about how to ensure safe health care environments, protect patients from undue harm, and communicate risks and benefits. Patients who are exposed to risks — especially undisclosed or poorly understood risks — may experience psychosocial concerns such as heightened anxiety about their health and distrust in care providers, institutions, and regulators.

6.2.1 Liability issues related to negligence

The re-use of SUDs raises potential liability issues for several entities: the original manufacturer of the device; the reprocessor of the device: the health care institution where a patient receives care; and the care provider who treats the patient. These entities may face liability based on the legal principles of negligence (also called "malpractice for health care providers"). If government authorities regulate the reprocessing and re-use of SUDs, issues related to regulator liability may also arise.

In the health care context, negligence arises when an individual or organization that owes a "duty of care" to a patient fails to meet an appropriate standard of care and the patient suffers harm as a result. Negligence claims against health care providers and institutions can act as a "useful incentive for higher quality care and as a fundamental means of redress for injured patients."[30] To establish a claim of negligence, a plaintiff must establish four requirements:

- The defendant owed the plaintiff a duty of care.
- The defendant breached the relevant standard of care.
- The plaintiff suffered injury or loss.
- The defendant's conduct caused the injury or loss.

Specific to a claim of negligence in regard to SUDs, a plaintiff must prove:

- The defendant (manufacturer, reprocessor, health care facility, or health care provider) owed a duty of care to the patient.
- The defendant fell below an appropriate standard of care in its practices in regard to manufacturing, reprocessing, or re-using SUDs.
- The plaintiff was harmed. In the re-use of SUDs, a patient may be harmed in many ways. For example, the device fails or breaks and causes the patient physical injury or death, or the device is not cleaned properly and the patient is exposed to infectious agents and becomes infected or does not become infected but experiences emotional distress based on fear of infection.
- The plaintiff's harm resulted from use of a reprocessed SUD in the patient's treatment.

6.2.2 Liability of manufacturers and reprocessors

Manufacturers of medical devices and reprocessors of such devices owe a duty of care to patients who will be treated with the devices.[31] Manufacturers have legal duties to ensure that devices are fit for their intended use and may face legal liability for preventable manufacturing defects that cause harm to patients. Reprocessors must ensure that their processes are adequate to ensure proper functioning and cleanliness of devices intended for re-use. Emil P. Wang notes that reprocessors have a duty "to establish and maintain appropriate reprocessing protocols and to insure that re-use of the device is safe and presents no increased risk of harm or injury to the patient above and beyond those inherent in the original use of the SUD."[32]

Manufacturers and reprocessors have a legal duty to disclose the risks involved in using their products. This includes the obligation to warn of risks that are known or ought to be known, and the duty of disclosure is higher in the case of medical products.[31] Manufacturers discharge this duty through the use of labels advising that devices are for single use only. Conversely, reprocessors assert that devices may be safely re-used after appropriate reprocessing. If reprocessors learn, however, that their techniques may inadequately clean or restore devices to their original level of quality and safety, they have an ongoing duty to warn health care facilities of new information that reveals heightened risk.

The original manufacturer would likely face legal liability for defects present at original manufacture and would not be responsible for hazards that arise from the reprocessing and re-use of a device. Original manufacturers who label devices as single use only will rely on that warning to argue that they ought to bear no responsibility for harm: "deviation from product labeling constitutes a superseding, intervening cause and shifts all liability to the reprocessor or re-user."[33] Original manufacturers typically advocate against re-use, ostensibly based on safety concerns, but their economic interests are also affected by re-use because it diminishes the market for new devices. The past president of the Association of Disposable Device Manufacturers reportedly claimed: "The real issue is patient safety. Until you prove otherwise, these devices are safe and effective for one use. After that, they're garbage."[34]

The liability of health care institutions and care providers stems from the off-label use of SUDs.

a) Liability of health care institutions

Health care institutions have four primary legal responsibilities: to select competent staff and monitor their continued competence, to provide proper instruction and supervision, to provide proper facilities and equipment, and to establish systems necessary for the safe operation of the hospital.[35,36] The latter two points are most relevant in regard to institutional practices to re-use SUDs. In addition to direct liability for negligent conduct, health care institutions are also vicariously liable for the negligence of their employees, such as nurses, technicians, and salaried physicians.

The off-label use of reprocessed SUDs does not necessarily constitute a failure to provide an appropriate standard of care for patients, because institutions may argue that their activities are consistent with industry practice. Health care facilities may reprocess SUDs internally or, more commonly, send used devices to third-party reprocessors. A 2002 FDA survey found that most hospitals (84%) that re-use SUDs contract with third-party reprocessors.[37] In the first situation, the facility may be negligent if their internal processing methods are deficient. In the second situation, negligence may arise if the facility contracts with a poor quality reprocessor.

In addition to duties owed to patients, institutions have obligations to ensure safe working conditions for care providers and other staff. In using reprocessed SUDs, care providers may face risks that are not present when new devices are used. These risks are similar to those associated with disinfecting devices intended for multiple uses.[4] For example, there may be a heightened risk of exposure to debris that stays on the device after reprocessing. If hospitals reprocess devices in-house, employees who are responsible for disinfection may be exposed to chemicals such as formaldehyde, glutaraldehyde, and ethylene oxide, all of which require careful use in accordance with occupational health and safety rules.

Health care institutions mitigate their liability risks by complying with regulatory requirements and voluntary standards applicable to the re-use of reprocessed devices,[32] including providing appropriate training and equipment for staff who participate in device reprocessing.

b) Liability of health care providers

Health care providers must exercise "a reasonable degree of skill and knowledge and … a reasonable degree of care"[38] in treating patients. In a negligence claim against a health care provider, the practitioner's actions will be judged against those of his or her peers. For example, an orthopedic surgeon is held to the same standard of care as another orthopedic surgeon, and a nurse's conduct is compared against what another nurse would have done in a similar situation.

Does a health care professional fall below an appropriate standard of care in using reprocessed SUDs? The answer is complicated by several factors. First, a care provider may be unaware that a specific device has been reprocessed and cannot judge whether using the device increases risk to a patient. Care providers likely work from the assumption that equipment and devices bought and used in the facility are safe, and it would be burdensome to expect care providers to make independent inquiries about the safety of devices routinely. Second, off-label use does not automatically amount to negligence without other evidence of deficient practice. Third, negligence liabilities also arise from legal obligations to obtain informed consent from patients before treatment.

c) Regulator liability

Patients who are harmed by regulated products may sue the regulatory body for negligent regulation. These claims are difficult to advance, however, because courts are reluctant to find that regulatory agencies owe a "private law" duty of care to individual citizens. Rather, regulators have "public law" obligations to act within their legislated mandate to protect the health and safety of the population. As a Canadian court decision states:

> The relationship between the government and the governed is not one of individual proximity. Any, perhaps most, government actions are likely to cause harm to some members of the public. That is why government is not an easy matter. Of course, the government owes a duty to the public but it is a duty owed to the public collectively and not individually.[39]

Consequently, individual citizens often face difficulty in bringing legal claims against a government for alleged regulatory failures.

For example, in an Ontario case, a woman sued the federal government and the manufacturer and Canadian distributor of a device designed to alleviate or cure female incontinence.[40] She alleged that she suffered harm after the device was implanted in her body. Health Canada, in accordance with its authority to regulate medical devices under the *Food and Drugs Act* and the *Medical Devices Regulations*, issued a license authorizing the manufacturer to distribute the device in Canada. Before this case, Canadian courts had "not previously recognized a private law duty of care on the part of the federal government to individual members of the public with respect to the regulation of medical devices…."[39] In this case, the court concluded that "any duties imposed by the legislation with respect to the regulation of medical devices by Health Canada are duties owed to the public at large and not to private individuals."[39]

6.2.3 Informed consent

a) Disclosing risks of treatment with reprocessed SUDs

It is a fundamental principle of law that medical treatment may be administered only with the patient's fully informed consent, and a health care provider who treats a patient without consent faces legal liability. (Non-consensual treatment is permitted by law in some emergency situations and in situations involving mental health or public health protection.) For consent to be legally valid, it must be given voluntarily by a competent person who has been fully informed of the nature of the treatment and its relevant risks and benefits. Competence refers to the mental capacity to understand the nature of a treatment and its risks and benefits. Young children and patients who lose mental competence through injury, disease, or ageing lack an independent capacity to give consent, and a substitute decision-maker may act on their behalf.[35] The Supreme Court of Canada has emphasized the importance of consent from patients: "It should not be forgotten that every patient has a right to bodily integrity. This encompasses the right to determine what medical procedures will be accepted

and the extent to which they will be accepted.... This concept of individual autonomy is fundamental to the common law and is the basis for the requirement that disclosure be made to a patient."[41]

The legal requirement to disclose information to patients to enable them to make an informed choice about consent to treatment is complicated in the case of SUDs. It is not common practice to inform patients before medical procedures if devices that will be used are reprocessed SUDs. The practitioner may even be unaware about whether a device used in a patient's treatment is new or reprocessed. Even if the practitioner is aware, he or she may not believe that there is an increased risk associated with use of the device and therefore, believe there is no reason to disclose the information to the patient. As one commentator observes, "[t]he consent process is a communication between the patient and physician about the procedure itself, not the instrumentation."[42] Typically, "surgeons do not confer with patients preoperatively to discuss whether a hook electrosurgical instrument or a spatula will be used to remove the gallbladder during a laparoscopic cholecystectomy."[43]

A patient who is harmed through the use of a reprocessed SUD, however, may argue that he or she ought to have been informed that a reprocessed device would be used. Under Canadian law, a health care provider must disclose to a patient all information that a reasonable person in the patient's position would want to know. (The standard of disclosure is even higher in the research context. To give legally valid consent to participate in research, an individual must be informed of all risks, no matter how remote or rare.[44]) This includes information about common risks and rare but serious risks. This raises the question: Would a reasonable patient want to know if a reprocessed SUD will be used in his or her treatment? Some commentators argue that patients have a right to know if a reprocessed SUD will be used in their treatment and a concomitant right to refuse treatment unless a new device is used: "It is safe to assume that most patients prefer the procedure or surgery to be performed with the lowest possible risk. By inference, most patients would not want to increase their risks unnecessarily by allowing a re-used medical device to be used on them when that device was not manufactured, marketed or approved for more than a single-use."[45]

Canadian courts have not been confronted with a legal claim that raises this question. In the US, courts have handled cases where a patient sued for off-label uses of medical devices. In *Southard v. Temple University Hospital*,[46] a court ruled that "a prudent patient would want to know whether or not the FDA had approved a medical device as safe and effective for a particular use when deciding whether or not to give consent for a surgical procedure."[45]

In the absence of specific regulations governing the use of reprocessed SUDs, health care providers cannot turn to regulatory rules in determining what information must be disclosed to a patient during informed consent. Hogan and Colonna argue that an obligation to inform patients that a reprocessed SUD will be used depends on several factors:

- the SUD
- scientific evidence about its re-use
- the relative risk associated with reprocessed SUDs in comparison to alternatives
- whether reprocessing and re-use protocols contribute to increases in risk to the patient.[32,33]

If available evidence suggests that the re-use of specific devices may increase the risk of harm, health care providers may have a legal obligation to disclose this information to the patient before treatment.

If evidence indicates increased risk, however, it is legally and ethically tenuous to ask patients to accept that risk during informed consent. The economic benefit of re-using devices must be balanced against the patient's right to a safe health care environment, and care providers may face liability for adopting practices designed to protect budgets rather than patients. For example, in *Law Estate v. Simice*,[47] a physician was sued for failing to order a CT scan that could have prevented a patient's death. The physician argued that health care budget restrictions limited the number of scans that could be ordered, but the court rejected this defence: "If it comes to a choice between a physician's responsibility to his or her individual patient and his or her responsibility to the Medicare system overall, the former must take precedence in a case such as this."

If concerns about the safety risks of re-using SUDs are largely theoretical, questions arise about the ethics of informing patients of hypothetical risks. Advising patients that reprocessed SUDs will be used during their procedure, and that such devices could theoretically fail during use or expose the patient to infectious disease, will likely cause anxiety; and many patients may request that only new devices be used during treatment. If a health care facility re-uses SUDs to save costs, however, it may be illusory to suggest that a patient has a choice to consent to treatment only if new devices are used. Offering theoretical information and fictitious choice to patients may undermine the trust in health care providers and institutions.

b) Duty to notify of past exposure to harm

In addition to the issue of prospective disclosure of risks to patients before treatment, a duty to notify may arise when newly acquired evidence reveals that patients may have been exposed to harm in the past. For example, if exposure to an infectious disease is linked with re-use of a SUD, health care facilities and practitioners may have a duty to trace patients whose treatment involved the affected device to advise them about the risk of exposure.

There is a clear legal duty to trace patients and warn them of known risks that arise after treatment, such as exposure to HIV or hepatitis through contaminated blood products.[48,49] Notifying patients that they have been exposed to potential or theoretical harm from past treatment, however, presents ethical challenges. The literature related to the disclosure of theoretical risks, such as exposure to Creutzfeldt-Jakob disease, analyzes reasons for and against notification of patients.[50] A patient's right to know information about their health supports disclosure, as does the fact that information disclosure (even of uncertain or bad news) promotes trust between professionals and patients. Reasons for not disclosing hypothetical risks include a desire to avoid distressing patients, the difficulty in explaining such information, and in some circumstances, a lack of measures to confirm or deny exposure. Decisions to notify patients of hypothetical risks are often based on a case-by-case assessment in consultation with medical experts and clinical ethicists.

6.2.4 Conclusions

The re-use of SUDs is typically considered to be a cost-saving measure for health care facilities. However, "[h]ospitals and third-parties who are involved in the practice of reprocessing devices labelled as 'single-use only' need to balance carefully the regulatory and legal responsibilities and liabilities with the economic benefits associated with re-using these products."[32] The liability risks associated with the reprocessing and re-use of SUDs may result in costs, particularly for health care facilities, if patients who are harmed after using unclean or degraded devices bring successful lawsuits.

If scientific evidence reveals the risks of re-use, there is an argument that patients ought to be informed of these risks prospectively or retroactively, depending on the circumstances. Furthermore, the continued practice of reprocessing SUDs may ultimately diminish patients' trust in the health care system.

7 DISCUSSION

7.1 Results

The results of the clinical review are consistent with the findings of the 2004 New Zealand report[1] that few studies on the use of reprocessed SUDs have evaluated outcomes directly related to patients. Twelve studies covering SUDs for five areas of application reported clinical outcomes. The results suggest that SUD re-use could be safe and effective. The quality of the studies varied from two high quality RCTs to three poor quality non-comparative series. The results of the two high quality RCTs suggest that the use of reprocessed single-use coronary angioplasty catheters and instruments for laparoscopic cholecystectomy may be acceptable in terms of safety and efficacy. These studies, however, included small numbers of patients and cannot be considered to rule out the risk of adverse events that have a low level of probability.

One of the reviewed studies found that there were more adverse events with reprocessed single-use angioplasty catheters than with new catheters. The significance of the findings, however, is unclear because the two patient groups were treated in separate hospitals. A re-analysis of the data suggested that re-use was not associated with an increased rate of in-hospital complications.

Seven of the nine papers considered in the review of economic studies reported cost savings, some of them substantial, from the use of reprocessed SUDs. Although the studies provide decisive evidence of cost savings in the absence of adverse event costs, the methods of observing costs were vague, and the savings calculated did not reflect the marginal savings from SUD reprocessing. If one excluded clinical outcomes, the marginal savings from one extra time that a device is reprocessed would depend only on the original price and the cleaning cost. Each time that the device is re-used after reprocessing, the hospital saves the original price of buying a new item, less the cost of reprocessing. These savings are greater than those estimated by calculating the price less the average unit cost, which are the measures used in most studies to estimate the potential savings. They indicate that the incentive to re-use one more time is noteworthy.

The primary economic analysis indicates that the use of reprocessed single-use coronary angioplasty catheters and instruments for laparoscopic cholecystectomy would be cost saving, assuming no adverse events. In the model used, the cost of an adverse event is higher for coronary angioplasty than for laparoscopic cholecystectomy. Consequently, the break-even value of the probability of an adverse event, where costs of the single-use and re-use strategies are the same, is lower for coronary angioplasty catheters than for laparoscopic instruments (12.6 per 1,000 procedures compared with 445 per 1,000 procedures). A complication rate of 12.6 per 1,000 procedures for angioplasties is realistic, but one of 445 per 1,000 procedures for laparoscopic cholecystectomies is high. Therefore, including uncertainty, re-use would generate system-wide savings for laparoscopic cholecystectomies, but would be less likely to do so for angioplasties.

The review of legal, ethical, and psychosocial issues identified several issues of importance to health care funders, providers, and patients. Attention was drawn to the need to balance regulatory and legal responsibilities, and liabilities, with the economic benefits associated with re-using these products. The liability risks associated with the reprocessing and re-use of SUDs may lead to higher costs. Patients may need to be informed about the known risks from using reprocessed SUDs.

7.2 Strengths and Weaknesses of Assessment

The systematic reviews in the assessment have defined the available evidence on clinical outcomes after using reprocessed SUDs and available information from relevant economic analyses. The clinical and economic publications that were included in the reviews were appraised for study quality. The primary economic study has provided indications of likely cost savings for two categories of SUDs. Further context for this area was provided in an overview of legal, ethical, and psychosocial issues.

Weaknesses in the assessment are linked to the limited data available on clinical outcomes and costs associated with the use of reprocessed SUDs.

Another complicating factor is that not all reprocessing is the same. Studies that looked at in-house non-validated reprocessing are difficult to group with those looking at devices that have well-documented validated reprocessing procedures (i.e., those done by registered third-party reprocessors). Only one of the studies that were included in the clinical review actually reflects the state of affairs in the US. The low risk of adverse events indicated by post-marketing monitoring by the FDA of SUDs that are reprocessed by registered third party reprocessors[51] was noted, but has not been included in our analysis.

The economic analysis took a narrow hospital perspective rather than a broader, societal perspective. In doing so, we excluded the personal costs of adverse events. Although the net difference in adverse events between single-use and re-use has not been established, there remains the possibility that adverse events can result from the re-use of SUDs. If they did, they would then generate excess health system costs (borne by the health regions) and excess personal costs (e.g., the value of employment losses). We have focussed only on the former.

The ultimate assignment of excess personal costs will depend on how the legal system works. Patients can sue health regions or clinicians and be awarded a settlement that covers personal costs. On the other hand, losses borne by the health care system (for example, health regions) will be absorbed by the regions, so these costs are irrelevant to the liability issue.

If a societal perspective had been taken, the personal costs resulting from adverse events should be included in the analysis. The role of liability assignment is to shift the personal costs from one party to another. If the patient were made liable for his or her personal costs, for example, then these would be borne by the patient. If the health regions were liable, then they would bear the costs. The costs will be incurred regardless of who bears them.

We should comment on the likelihood of an adverse event attributable to the re-use of SUDs. Adverse events may be "routine" (e.g., occurring at predictable rates) or unpredictable. An unpredictable event is not insurable. It may be a rare event, but it can also be an event that occurs in bunches. For example, if one hospital has a lapse in cleaning procedures, several or many adverse

events can occur. These events will not show up in epidemiologic studies such as those included in this analysis.

The economic evaluation did not consider the opportunity cost of reprocessing associated with the need for hospitals to increase their stocks of devices to cover those that are out of commission.

7.3 Generalizability of Findings

The generalizability of the results of the studies included in the clinical review is unclear. Overall, the studies provide an indication that the use of certain reprocessed SUDs can be safe and effective, but the study quality varied, and the numbers of patients were limited in some investigations. Also, device reprocessing protocols and their application were specific to the hospitals in which the studies were conducted.

The economic findings from the reviewed papers and from the primary economic model showed that the use of reprocessed SUDs is cost-saving if there are no adverse events associated with this practice. These findings can be regarded as generalizable.

7.4 Knowledge Gaps

The available studies that report the clinical outcomes associated with the use of reprocessed SUDs provide only limited evidence on the safety and efficacy of this practice. In most of the studies in our review, the estimates were based on small numbers of observations in one hospital. Also, only a few categories of SUDs have been studied. There are no clinical outcomes data for many types of SUD.

Given that most single-use devices being reprocessed in Canadian hospitals were not represented in these studies and given that the reprocessing procedures for these devices are unknown, it is impossible to conclude from the existing literature that the current state of affairs is safe.

Furthermore, as almost all the safety and economic studies of reprocessed SUDs involve hospital reprocessing rather than reprocessing by a third party, as required in the US by the FDA, these studies are not representative of hospitals that have contracted with third-party reprocessors. The cost of in-house reprocessing is typically less than that performed by third parties. Requiring a validated reprocessing procedure and other safety requirements, as does the FDA, may largely negate any cost savings.

On the basis of what is available in the literature, the safety, efficacy, and effectiveness of the re-use of reprocessed SUDs remains unclear. Larger studies, and the systematic monitoring of SUD use and associated outcomes would be needed to arrive at confident conclusions.

The available evidence in the literature on the cost-effectiveness of SUD reprocessing and the re-use of reprocessed SUDs is inconclusive. Full economic studies would require additional data.

8 CONCLUSIONS

The small number 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 the safety and efficacy of this practice. The use of reprocessed SUDs is cost-saving for several types of devices, if it is assumed that there are no adverse effects. There are insufficient data to establish the cost-effectiveness of re-using SUDs. Several legal, ethical, and psychosocial issues require consideration by those who fund and use SUDs. The liability risks associated with the reprocessing and re-use of SUDs may lead to higher costs, particularly for health care facilities, if patients who are harmed from using unclean or degraded devices bring successful lawsuits. Also, if scientific evidence reveals the risks of re-use, there is an argument that patients ought to be informed of these risks.

9 REFERENCES

1. Day P. *What is the evidence on the safety and effectiveness of the reuse of medical devices labelled as single-use only?* [NZHTA Tech Brief Series vol 3, no 2]. Christchurch (New Zealand): New Zealand Health Technology Assessment (NZHTA); 2004. Available: http://nzhta.chmeds.ac.nz/publications/medical_devices.pdf (accessed 2007 Aug 2).
2. *Report of the Auditor General of Canada to the House of Commons. Chapter 2 Health Canada--regulation of medical devices*. Ottawa: Office of the Auditor General of Canada; 2004. Cat no FA1-2004/1-2E. Available: http://dsp-psd.communication.gc.ca/Collection/FA1-2004-1-2E.pdf (accessed 2004 Sep).
3. Peterson RG, Therapeutic Products Directorate, Health Canada. *Reprocessing of reusable and single-use medical devices* [letter]. Ottawa: Health Canada; 2004 Jul 30. Available: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/reprocess_retraitement_let_e.pdf (accessed 2007 Oct 25).
4. Canadian Healthcare Association. *The reuse of single-use medical devices: guidelines for healthcare facilities*. Ottawa: CHA Press; 1996.
5. Ontario Hospital Association. *Reuse of single-use medical devices* [executive summary]. Toronto: Ontario Hospital Association; 2004 Jan 12. Available: http://www.oha.com/oha/reports.nsf/($Att)/pspr5w8qex/$FILE/ReuseofSingleUse_Medical_Devices_Executive_Summary.pdf (accessed 2007 Jul 13).
6. United States General Accounting Office. *Single-use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted*. Washington: GAO; 2000 Jun. GAO/HEHS-00-123. Available: http://www.gao.gov/new.items/he00123.pdf (accessed 2007 Oct 26).
7. Provincial Infectious Diseases Advisory Committee. *Best practices for cleaning, disinfection and sterilization and in all health care settings*. Rev ed. April 2006. Toronto: Ontario Ministry of Health and Long term Care; 2006. Available: http://www.health.gov.on.ca/english/providers/program/infectious/diseases/best_prac/bp_cds_2.pdf (accessed 2007 Oct 26).
8. Health Canada. Therapeutic Products Directorate. *Issue analysis summary: the reuse of single-use medical devices* [Draft]. Ottawa: Health Canada; 2005 Apr 28. MECS #04-124643-474. Available: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/saprmd_ias_gcsrmm_raq_2005-06-09_e.pdf (accessed 2007 Jul 13).
9. Polisena J, Hailey D, Moulton K, Noorani H, Jacobs P, Normandin S, et al. *Reprocessing of single-use medical devices: national survey of Canadian acute-care hospitals* [Technology report]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2007.
10. Browne KF, Maldonado R, Telatnik M, Vlietstra RE, Brenner AS. Initial experience with reuse of coronary angioplasty catheters in the United States. *J Am Coll Cardiol* 1997;30(7):1735-40.

11. Plante S, Strauss BH, Goulet G, Watson RK, Chisholm RJ. Reuse of balloon catheters for coronary angioplasty: a potential cost-saving strategy? *J Am Coll Cardiol* 1994;24(6):1475-81.

12. Zubaid M, Thomas CS, Salman H, Al-Rashdan I, Hayat N, Habashi A, et al. A randomized study of the safety and efficacy of reused angioplasty balloon catheters. *Indian Heart J* 2001;53(2):167-71.

13. Shaw JP, Eisenberg MJ, Azoulay A, Nguyen N. Reuse of catheters for percutaneous transluminal coronary angioplasty: effects on procedure time and clinical outcomes. *Catheter Cardiovasc Interv* 1999;48(1):54-60.

14. Scherson BA, Dighero TH. Angiographic catheter reuse at the Hemodynamic Department of a public hospital in Chile. *Rev Chilena Infectol* 2006;23(1):45-9.

15. Colak T, Ersoz G, Akca T, Kanik A, Aydin S. Efficacy and safety of reuse of disposable laparoscopic instruments in laparoscopic cholecystectomy: a prospective randomized study. *Surg Endosc* 2004;18(5):727-31.

16. Gundogdu H, Ocal K, Çaglikulekci M, Karabiber N, Bayramoglu E, Karahan M. High-level disinfection with 2% alkalinized glutaraldehyde solution for reuse of laparoscopic disposable plastic trocars. *J Laparoendosc Adv Surg Tech A* 1998;8(1):47-52.

17. DesCôteaux JG, Tye L, Poulin EC, Lortie M, Murray G, Gingras S. Reuse of disposable laparoscopic instruments: a study of related surgical complications. *Can J Surg* 1995;38(6):497-500.

18. Kozarek RA, Raltz SL, Ball TJ, Patterson DJ, Brandabur JJ. Reuse of disposable sphincterotomes for diagnostic and therapeutic ERCP: a one-year prospective study. *Gastrointest Endosc* 1999;49(1):39-42.

19. Wilcox CM, Geels W, Baron TH. How many times can you reuse a "single-use" sphincterotome? A prospective evaluation. *Gastrointest Endosc* 1998;48(1):58-60.

20. Dirschl DR, Smith IJ. Reuse of external skeletal fixator components: effects on costs and complications. *J Trauma* 1998;44(5):855-8.

21. Perry EC. To reuse or not reuse: reuse of phacoemulsification needle tips, their efficacy, and patient response. *Insight* 1996;21(2):45-8.

22. Mak KH, Eisenberg MJ, Plante S, Strauss BH, Arheart KL, Topol EJ. Absence of increased in-hospital complications with reused balloon catheters. *Am J Cardiol* 1996;78(6):717-9.

23. Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. *BMJ* 1996;313(7052):275-83.

24. Canadian Agency for Drugs and Technologies in Health. *Guidelines for the economic evaluation of health technologies: Canada*. 3rd ed. Ottawa: The Agency; 2006. Available: http://www.cadth.ca/media/pdf/186_EconomicGuidelines_e.pdf (accessed 2007 Mar 12).

25. DesCôteaux JG, Tye L, Poulin EC. Reuse of disposable laparoscopic instruments: cost analysis. *Can J Surg* 1996;39(2):133-9.

26. Nanta P, Senarat W, Tribuddharat C, Danchaivijitr S. Cost-effectiveness and safety of reusable tracheal suction tubes. *J Med Assoc Thai* 2005;88(Suppl):86-8.

27. Mak KH, Eisenberg MJ, Eccleston DS, Brown KJ, Ellis SG, Topol EJ. Cost-efficacy modeling of catheter reuse for percutaneous transluminal coronary angioplasty. *J Am Coll Cardiol* 1996;28(1):106-11.

28. Demoulin L, Kesteloot K, Penninckx F. A cost comparison of disposable vs reusable instruments in laparoscopic cholecystectomy. *Surg Endosc* 1996;10(5):520-5.

29. Alberta Health & Wellness. *Health costing in Alberta: 2006 annual report*. Edmonton: Alberta Health and Wellness; 2006. Available: http://www.health.gov.ab.ca/resources/publications/Health_Costing_2006.pdf (accessed 2007 Jul 25).

30. Pritchard JRS. *Liability and compensation in health care: a report to the Conference of Deputy Ministers of the federal/provincial/territorial review on liability and compensation issues in health care*. Toronto: University of Toronto Press; 1990. p. 21.

31. Hollis v. Dow Corning Corp. 1995. S.C.J. No. 104.

32. Wang EP. Regulatory and legal implications of reprocessing and reuse of single-use medical devices. *Food Drug Law J* 2001;56(1):77-98.

33. Hogan JM, Colonna TE. Products liability implications of reprocessing and reuse of single-use medical devices. *Food Drug Law J* 1998;53(3):385-402.

34. Charatan F. Controversy erupts over reuse of "single use" medical devices. *BMJ* 1999;319(7221):1320. Available: http://www.bmj.com/cgi/content/full/319/7221/1320 (accessed 2007 Jun 26).

35. Picard E, Robertson G. *Legal liability of doctors and hospitals in Canada*. 3rd ed. Scarborough (ON): Carswell; 1996. p. 367.

36. Briffett v. Gander and District Hospital Board. N.J. No. 285. 1992.

37. Quirk M. Most US hospitals avoid reuse of single-use devices. *Lancet Infect Dis* 2002;2(12):714.

38. Crits v. Sylvester. 132, 508. 1956. O.R. aff'd [1956] S.C.R. 991.

39. A.O. Farms Inc. v. Canada. 288[101], para. 11. A.C.W.S. (3d). 2000.

40. Klein v. American Medical Systems Inc. 2006. O.J. No. 5181; Ont. S.C.

41. Ciarlariello v. Schacter. 119[2], 135. 1993. S.C.R.

42. Parsons M. The dilemma over the reuse of 'single-use' medical devices. A risk manager's perspective. *Todays Surg Nurse* 1997;19(3):17-21.

43. Dunn D. Reprocessing single-use devices--the ethical dilemma. *AORN J* 2002;75(5):989-99.

44. Reibl v. Hughes. 880[2]. 1980. S.C.R.

45. Carey D. Reprocessing and reusing single-use only medical devices: safe medical practice or risky business? *J Contemp Health Law Policy* 2001;17(2):657-85.

46. Southard v. Temple University Hospital. 603[731]. A. (2d). 1999.

47. Law Estate v. Simice. 1994. B.C.S.C.

48. Pittman Estate v. Bain. 482[112]. D.L.R. (4th); Ont. S.C. 1994.

49. Bailey TM, Ries NM. Legal issues in patient safety: the example of nosocomial infection. *Healthc Q* 2005;8 Spec No:140-5.

50. King SM, Watson H, Heurter H, Ricketts M, elSaadany S. Notifying patients exposed to blood products associated with Creutzfeldt-Jakob disease: theoretical risk for real people. *CMAJ* 1998;159(7):771-4. Available: http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=9805022 (accessed 2007 Jun 26).

51. Schultz D. *Statement of Daniel Schultz, M.D., Director, before Committee on Government Reform, House of Representatives*. Rockville (MD): Office of Legislation, U.S. Food and Drug Administration; 2006 Sep 26. Available: http://www.fda.gov/ola/2006/suds0926.html (accessed 2007 Nov 29).

52. Hailey D, Ohinmaa A, Roine R. Study quality and evidence of benefit in recent assessments of telemedicine. *J Telemed Telecare* 2004;10(6):318-24.

53. Rasanen P, Roine E, Sintonen H, Semberg-Konttinen V, Ryynanen OP, Roine R. Use of quality-adjusted life years for the estimation of effectiveness of health care: a systematic literature review. *Int J Technol Assess Health Care* 2006;22(2):235-41.

APPENDICES

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