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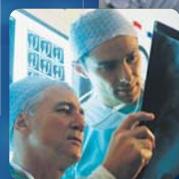
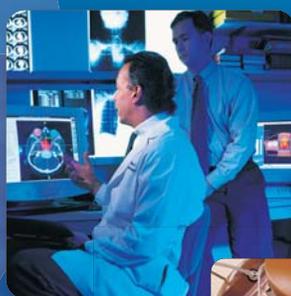


## T E C H N O L O G Y   R E P O R T

**HTA**

Issue 104  
February 2008

### Reprocessing of Single-Use Medical Devices: National Survey of Canadian Acute-Care Hospitals



*Supporting Informed Decisions*

Until April 2006, the Canadian Agency for Drugs and Technologies in Health (CADTH) was known as the Canadian Coordinating Office for Health Technology Assessment (CCOHTA).

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CADTH  
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Ottawa ON Canada K1S 5S8  
Tel. (613) 226-2553  
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**Cite as:** Polisen J, Hailey D, Moulton K, Noorani H, Jacobs P, Normandin S, Gardam M. *Reprocessing of Single-Use Medical Devices: National Survey of Canadian Acute-Care Hospitals* [Technology report number 104]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008.

Production of this report is made possible by financial contributions from Health Canada and the governments of Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, the Northwest Territories, Nova Scotia, Nunavut, Ontario, Prince Edward Island, Saskatchewan, and Yukon. The Canadian Agency for Drugs and Technologies in Health takes sole responsibility for the final form and content of this report. The views expressed herein do not necessarily represent the views of Health Canada or any provincial or territorial government.

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CADTH is funded by Canadian federal, provincial, and territorial governments.

Legal Deposit – 2008  
National Library of Canada  
ISBN: 978-1-897465-18-9 (print)  
ISBN: 978-1-897465-19-6 (online)  
H0334A – February 2008

PUBLICATIONS MAIL AGREEMENT NO. 40026386  
RETURN UNDELIVERABLE CANADIAN ADDRESSES TO  
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**Canadian Agency for Drugs and Technologies in Health**

**Reprocessing of Single-Use Medical Devices: National  
Survey of Canadian Acute-Care Hospitals**

Julie Polisena, MSc<sup>1</sup>  
David Hailey, MSc PhD Grad RIC<sup>2</sup>  
Kristen Moulton, BA<sup>1</sup>  
Hussein Noorani, MSc<sup>1</sup>  
Philip Jacobs, BCom DPhil CMA<sup>3</sup>  
Sarah Normandin, BSc MLIS<sup>1</sup>  
Michael Gardam, MSc MD CM MSc FRCP(C)<sup>4</sup>

February 2008

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<sup>1</sup>CADTH

<sup>2</sup>Department of Community Health Sciences, University of Calgary, Calgary AB

<sup>3</sup>Department of Medicine (Gastroenterology), University of Alberta, Edmonton AB

<sup>4</sup>Infection Prevention and Control, University Health Network, Toronto ON

## Reviewers

*These individuals kindly provided comments on this report.*

### **External Reviewers**

Michelle Alfa, PhD FCCM  
Assistant Director, Microbiology Lab  
St. Boniface General Hospital  
Winnipeg, Manitoba

John D. Shepherd, MD FRCP(C)  
Former Vice-President, Clinical Quality  
and Safety  
Vancouver Coastal Health Authority  
Vancouver, British Columbia

Hugh Grant, PhD Economics  
Professor  
University of Winnipeg  
Winnipeg, Manitoba

### **Reviewer for Development of Survey**

John Mahoney, BSc MD FRCSC FACS MSc  
Urologist  
OHRI  
Ottawa, Ontario

### **CADTH Peer Review Group Reviewers**

Chris Skedgel, MDE  
Research Health Economist  
Dalhousie University  
Halifax, Nova Scotia

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## Authorship

Julie Polisena, David Hailey, Hussein Noorani, and Philip Jacobs contributed to the conception and design of the project. Julie Polisena developed and piloted the survey instruments, and extracted and analyzed survey data. Kristen Moulton assisted with data entry and quality assurance of the survey results. Julie Polisena and David Hailey drafted the report, with assistance from Michael Gardam, who also provided clinical expertise. Sarah Normandin provided support in identifying literature that was relevant to the development and analysis of the survey.

All authors contributed to the revisions of the report.

## Reprocessing of Single-Use Medical Devices: National Survey of Canadian Acute-Care Hospitals

### Technology

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

### Issue

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

### Methods and Results

A survey was developed, drawing on information from previous Canadian surveys. The sample included 572 acute-care hospitals in Canada. It was pilot tested in November of 2006, in Ontario, with two community hospitals and one academic hospital. In December of 2006, a revised survey was mailed to contact persons in the sample. An electronic response was allowable. A modified Dillman approach was used for all contact and follow-up procedures. The useable response rate was 70% (398/572). Data were collected on the existence of a written institutional policy, the use of third-party reprocessing, types of devices reprocessed, and incident report mechanisms. Subgroup analyses were conducted by province or territory, hospital type, and size. Differences in proportions were tested using a chi-squared test, with a level of significance of 5%.

### Implications for Decision Making

- **Most hospitals do not reprocess SUDs.** The proportion of hospitals that reprocess (28%) is less than that reported in a 1986 survey (31%). Significant differences in reprocessing patterns were observed across provinces. Larger hospitals and academic centres were significantly more likely to reprocess SUDs.
- **In-house reprocessing is more common.** Most (85%) hospitals that reprocess SUDs do so in-house.
- **Documentation associated with SUD reprocessing has improved, but is still lacking.** Forty percent (40%) of hospitals that reprocess SUDs do not have a written policy, and 12% do not have an incident-reporting mechanism for SUDs adverse events at the hospital, suggesting a need for improved standards of documentation. The proportion of hospitals with written policies has improved compared to the number reported previously.

This summary is based on a comprehensive health technology assessment available from CADTH's web site ([www.cadth.ca](http://www.cadth.ca)): Polisen J, Hailey D, Moulton K, Noorani H, Jacobs P, Normandin S, Gardam M. *Reprocessing of Single-Use Medical Devices: National Survey of Canadian Acute-Care Hospitals*

Canadian Agency for Drugs and Technologies in Health (CADTH)

600-865 Carling Avenue, Ottawa ON Canada K1S 5S8 Tel: 613-226-2553 Fax: 613-226-5392 [www.cadth.ca](http://www.cadth.ca)

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# EXECUTIVE SUMMARY

## The Issue

There are concerns that the use of reprocessed single-use devices (SUDs) might be associated with 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.

## Objectives

In this report, our primary research objective is to obtain information on the current situation in Canada on the reprocessing and re-use of SUDs. The research question is: What are current practices in Canadian institutions for reprocessing of SUDs? A separate Canadian Agency for Drugs and Technologies in Health (CADTH) report, published concurrently, addresses the evidence on the safety, effectiveness, and cost-effectiveness of reprocessed SUDs.

## Methods

A survey instrument drawing on information from previous Canadian surveys was developed. Included items were related to the use of reprocessed SUDs. The survey was mailed to acute-care hospitals in all Canadian jurisdictions. Respondents could reply by mail or electronically, through CADTH's web site. In the analysis of the responses, differences in proportions were tested using the means of chi-square and were based on a level of significance of 5%. Subgroup analyses were done by jurisdiction, hospital type, and size. A logistic regression model was used to explore the effect of independent variables on the use of SUD reprocessing.

## Results

After a pilot test, the survey was sent to 572 Canadian acute-care hospitals. The survey's response rate was 72%, and 398 responses (70%) were used in the analysis. Among the hospitals, 72% do not reprocess SUDs. Of those not currently reprocessing, however, 81% have done so in the past. The most common reasons given for discontinuing the practice were concerns about potential legal liability (77%) and patients' safety (74%).

A logistic regression analysis indicated that larger hospitals were more likely to reprocess SUDs. Hospitals in Quebec, New Brunswick, the Prairies, British Columbia, and the Territories were more likely to reprocess SUDs than those in other jurisdictions.

Most hospitals that reprocess SUDs do so in-house (n=94, 85%) compared with hospitals that use a third-party reprocessor (n=17, 15%). The SUDs that were most commonly reprocessed were breast pump kits, ventilator circuits, and burrs. Among hospitals that reprocess SUDs through a third-party, 76% (13/17) are strongly satisfied or satisfied with the function of the device, cleanliness and sterility of the device, and customer service.

## Conclusions

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



# TABLE OF CONTENTS

<b>EXECUTIVE SUMMARY .....</b>	<b>IV</b>
<b>1 INTRODUCTION.....</b>	<b>1</b>
1.1 Background and Setting in Canada.....	1
1.2 Overview of Technology.....	1
<b>2 THE ISSUE .....</b>	<b>2</b>
<b>3 OBJECTIVES .....</b>	<b>2</b>
<b>4 METHODS .....</b>	<b>3</b>
4.1 Development of Survey .....	3
4.2 Survey Population .....	3
4.3 Data Collection.....	3
4.4 Statistical Analysis.....	4
<b>5 RESULTS .....</b>	<b>4</b>
5.1 Responses to Survey .....	4
5.2 Decision Making on Reprocessing SUDs.....	4
5.3 Hospitals that do not Reprocess SUDs .....	4
5.4 Reprocessing of SUDs and Written Policies .....	5
5.5 Incident Report Mechanisms for Adverse Events Associated with SUD Reprocessing.....	6
5.6 Location and Methods of Reprocessing .....	7
5.7 SUDs that are Reprocessed by Hospitals .....	8
5.8 Opinions and Decisions on Third-party Reprocessors .....	8
<b>6 DISCUSSION.....</b>	<b>9</b>
6.1 Results .....	9
6.2 Strengths and Weaknesses of this Assessment .....	9
6.3 Generalizability of Findings .....	10
6.4 Knowledge Gaps.....	10
<b>7 CONCLUSIONS.....</b>	<b>10</b>
<b>8 REFERENCES.....</b>	<b>11</b>

## **APPENDICES – available from CADTH’s web site [www.cadth.ca](http://www.cadth.ca)**

- APPENDIX 1: Survey and cover letter
- APPENDIX 2: Thank you and reminder postcard
- APPENDIX 3: Responses to the survey
- APPENDIX 4: Persons or groups used to decide on re-use of critical and semi-critical SUDs
- APPENDIX 5: Other reasons for discontinuation of SUD reprocessing
- APPENDIX 6: Year in which SUD reprocessing was discontinued by jurisdiction
- APPENDIX 7: Logistic regression analysis data
- APPENDIX 8: Written policies for hospitals that reprocess SUDs

- APPENDIX 9: Disinfection and sterilization methods used by hospitals that reprocess SUDs internally
- APPENDIX 10: Approaches to decisions on SUD reprocessing
- APPENDIX 11: Types of SUDs reprocessed by hospitals
- APPENDIX 12: Frequency of hospitals using third-party reprocessor by jurisdiction, hospital type, and size
- APPENDIX 13: Satisfaction with third-party reprocessors
- APPENDIX 14: Reasons for not selecting third-party reprocessor

# 1 INTRODUCTION

## 1.1 Background and Setting in Canada

Advances in synthetic materials such as plastics in the 1970s and 1980s led to an increase in medical devices that were produced, labelled, and marketed for single use only. The one-time use of single-use medical devices (SUDs) helps to ensure device function and sterility, and prevents cross-infection.<sup>1</sup> The use of reprocessed SUDs has become routine in some hospitals in an effort to reduce costs, and to improve the environment and waste management.<sup>2</sup> The reprocessing of medical devices can occur in a hospital or health region facility or can be contracted to a third-party reprocessing facility. No wholly Canadian third-party reprocessing facilities exist, although Canadian-based affiliates for US-based Food and Drug Administration (FDA)-regulated, third-party reproducers are used by some hospitals and health regions.

In 1996, the Canadian Healthcare Association (CHA) conducted a literature review on the re-use of SUDs and published guidelines for health care facilities. The document outlines issues with the re-use of SUDs, to assist in the development of policies and procedures on the practice.<sup>3</sup> The guidelines have served as a template for many agencies and policy-makers in Canada, but results from a 2001 survey suggest that many hospitals re-using SUDs do not follow the guidelines.<sup>4</sup>

Three surveys have been conducted on the re-use of SUDs in Canadian acute-care facilities.<sup>2,4,5</sup> The 1986 survey by Campbell *et al.* indicated that 41% of hospitals regularly re-used SUDs, while 38% of these hospitals had written procedures regarding re-use.<sup>5</sup> The survey also identified a list of SUDs that were reprocessed or re-used, the mechanisms established by hospitals to determine the number of times that SUDs were re-used, and whether the hospitals had done any cost analyses.

The 2001 survey by Miller *et al.* reported that the number of re-used SUDs per institution seemed to have “increased substantially” (data not given) since the Campbell *et al.* survey.<sup>2</sup> Despite this increase, most hospitals re-using SUDs did not have a re-use committee or written re-use protocols for most devices. Re-use committees are instrumental in obtaining expert advice regarding biomedical engineering, infection control, materials management, and sterilization.<sup>3,6</sup> Similar practices were reported by Mahoney for a survey published in 2001,<sup>4</sup> in which >50% of hospitals reusing SUDs reported that they did not have a re-use committee.

## 1.2 Overview of Technology

“Re-use” refers to the repeated use or multiple uses of a medical device, including devices that are intended for a single use, with reprocessing between uses. “Reprocessing” includes all the steps performed to make an original SUD previously used by one patient ready for use by another patient. The steps may include cleaning, functional testing, re-packing, re-labeling, pyrogenic (fever-producing) substance testing, and disinfection or sterilization.<sup>7</sup>

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 reproducers, except for implantable devices such as pacemakers, which are considered to be “sold” when permanently implanted in a patient.<sup>3,8</sup> Although third-party reproducers are not regulated by Health Canada, they are registered

with the FDA and, in the US, are subject to the same regulatory requirements as the OEMs. In Canada, provincial and territorial governments and health regions have been responsible for the policies, procedures, and recommendations for the organization, and delivery of health services, including the use of reprocessed SUDs. For example, the *Re-use of Single-Use Medical Devices* report published by the Ontario Hospital Association (OHA) in 2004 recommends that hospitals themselves do not reprocess critical and semi-critical SUDs, but supports the reprocessing of critical and semi-critical SUDs by Canadian regulated third-party reprocessors.<sup>8</sup> In Quebec, the Conseil d'évaluation des technologies de la santé du Québec published guidelines in 1991 and 1993 advising that the re-use of cardiac catheters, pacemakers, and hemodialyzers did not pose unacceptable risks to patients provided that hospitals had official policies and procedures on quality assurance and staff training.<sup>9,10</sup> Because of concerns about Creutzfeldt-Jakob disease, Quebec banned the re-use of cardiac catheters in 1996.<sup>11</sup> The Conseil d'évaluation des technologies de la santé du Québec then updated its position in 1997 by not allowing the re-use of cardiac catheters only on patients who were potential carriers of Creutzfeldt-Jakob disease.<sup>12</sup>

Policies and practices vary from one nation to another. For example, France prohibits the reprocessing of all SUDs. Other nations, such as 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 the 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.<sup>13</sup>

## 2 THE ISSUE

There are concerns that the use of reprocessed SUDs might be associated with increased risk of infection or other adverse events to patients. Other issues include legal liability, ethical concerns, safety of health care professionals, and cost-effectiveness of SUD reprocessing. To better understand the potential magnitude of this issue, current Canadian practices regarding the reprocessing of SUDs must be known.

## 3 OBJECTIVES

The objectives of this project are to obtain information on the current situation in Canada regarding reprocessing and re-use of SUDs, and to obtain information on the effectiveness and cost-effectiveness of such practices.

The research question is:

- What are the current practices in Canadian acute-care institutions for the reprocessing of SUDs?

Two other research questions have been addressed by CADTH in a separate report that has been published concurrently<sup>14</sup>:

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

## 4 METHODS

### 4.1 Development of Survey

A questionnaire on SUD reprocessing in Canadian acute-care hospitals was prepared by CADTH, drawing on details that had been included in earlier surveys<sup>2,4,5</sup> and on advice provided by the Ontario Hospital Association (OHA), and focusing on issues of interest to Canadian jurisdictions.

The Spaulding criteria are usually used to classify medical devices as critical, semi-critical, or non-critical.<sup>15</sup> Critical medical devices are intended to make contact with normally sterile tissue or body space during use, semi-critical devices are intended to touch mucous membranes but do not penetrate body surfaces, and non-critical devices are intended to make topical contact and not penetrate intact skin.<sup>15</sup> These criteria may be simplistic, but given their widespread historical use, they were used for this report. Our survey focused on critical and semi-critical medical devices.

### 4.2 Survey Population

The study sample consisted of 572 acute-care hospitals in Canada that were selected regardless of size and number of beds. The survey population was limited to Canadian acute-care hospitals to identify the trends in SUD reprocessing from past surveys.<sup>2,4,5</sup> All academic (teaching) and community acute-care hospitals across Canada, regardless of size, were asked to complete the survey.

### 4.3 Data Collection

The survey was pilot tested in November 2006 with two community hospitals and one academic hospital in Ontario. Minor revisions to the survey form were made after the feedback was received. In December 2006, the revised survey, available in English and in French, was mailed to an identified contact person (e.g., risk manager, infection control officer, sterile processing department coordinator) in each hospital (Appendix 1). The respondents also had an opportunity to complete the survey electronically, through the CADTH web site. A modified Dillman approach was used for all contact and follow-up procedures.<sup>16</sup> A reminder and a thank you postcard was mailed to all hospitals in our sample (Appendix 2). For non-responders, a follow-up package that included a cover letter and survey was sent in the second week of February 2007. Survey results were collected until May 2007. Incomplete responses were followed-up by e-mail or telephone.

Survey questions addressed the existence of a written institutional policy, location of reprocessing, types of devices reprocessed, and incident report mechanisms. All questions were closed-ended or partially closed-ended, and the respondents had an opportunity to add comments.

Participants who completed the on-line survey did so directly through CADTH's web site, and one author (JP) entered and maintained the postal survey results on the same server. Another author (KM) randomly compared 10% of the data records with the postal results for quality assurance. Data records that differed from the postal results were updated by KM.

## 4.4 Statistical Analysis

Differences in proportions were tested using a chi-squared test, with a level of significance of 5%. Subgroup analyses were done by jurisdiction (province or territory), hospital type, and size. A logistic regression model was used to explore the effect of independent variables on the use of SUD reprocessing. Explanatory variables in the model were hospital type and size, jurisdiction, and existence of a written policy on SUD reprocessing. Statistical analyses were performed using Intercooled STATA 8.2 for Windows.<sup>17</sup>

Qualitative data collected from questions with “other” as an option were organized into appropriate categories and assessed independently for relevant trends by two reviewers (JP, KM). Discrepancies were resolved through discussion between the reviewers.

# 5 RESULTS

## 5.1 Responses to Survey

The survey response rate was 72% (413/572). Of the 413 responses, 13 (2.2%) were from long-term care facilities with no acute-care beds, and two (0.3%) were incomplete. These were excluded from the analysis. Three hundred and ninety-eight responses, corresponding to 70% of the survey population, were used in our analysis. Survey responses appear in Appendix 3. Table 1 shows the usable responses by jurisdiction, hospital type, and size.

## 5.2 Decision Making on Reprocessing SUDs

The individual staff member(s) or committee(s) used by hospitals to decide on the re-use of critical and semi-critical SUDs are shown in Appendix 4. Central sterile processing units, infection control committees, infection control officers, operating staff members, and nursing departments make decisions in >30% of hospitals. Fewer hospitals involved hospital re-use committees, provincial organizations, regional health authorities, and local health integrated networks, or medical staff in the decision-making process. A few hospitals listed other staff members or committees that were excluded in our survey.

## 5.3 Hospitals that do not Reprocess SUDs

Of the hospitals in our survey, 72% (287/398) do not re-use or reprocess SUDs. Among the hospitals that do not re-use SUDs and that provided full responses, 19% (53/285) never reprocessed SUDs, and 81% (232/285) reprocessed SUDs in the past but have stopped doing so. The most common reasons given for discontinuing the practice were potential legal liability (77%) and concerns about patients’ safety (74%). Additional reasons given by hospitals for no longer reprocessing SUDs appear in Appendix 5.

The years in which hospitals discontinued the reprocessing of SUDs are shown by jurisdiction for 1995 to 2007 in Appendix 6. The rates of discontinuation varied between jurisdictions, but 70% of the hospitals ceased to reprocess SUDs between 2002 and 2005.

<b>Table 1: Survey responses used in analysis by jurisdiction, hospital type, and size</b>			
	<b>Number of Surveys Mailed</b>	<b>Number of Usable Responses (n=398)</b>	<b>% of Usable Responses by Jurisdiction</b>
<b>Jurisdiction</b>			
Alberta	96	84	88
British Columbia	44	40	91
Manitoba	52	37	71
New Brunswick	23	21	91
Newfoundland and Labrador	12	9	75
Nova Scotia	42	32	76
Ontario	126	92	73
Prince Edward Island	7	3	43
Quebec	109	52	47
Saskatchewan	43	23	43
Territories (includes Northwest Territories, Yukon, and Nunavut)	6	4	67
<b>Hospital Type</b>			
Academic		86 (22%)	
Community		312 (78%)	
<b>Hospital Size</b>			
<36 beds		107 (27%)	
36 to 74 beds		85 (21%)	
75 to 250 beds		105 (26%)	
>250 beds		101 (25%)	

## 5.4 Reprocessing of SUDs and Written Policies

Twenty-eight percent of hospitals in our sample (111/398) reprocess SUDs in-house or by third-party reprocessing. The proportions of hospitals that reprocess SUDs are shown in Table 2 by jurisdiction, hospital type, and size. A higher proportion of hospitals in New Brunswick, Quebec, and Saskatchewan reprocess SUDs compared with other jurisdictions.

A significantly lower proportion of community hospitals reprocess SUDs compared with academic hospitals. There is a positive association between hospital size and the proportion of hospitals that reprocess SUDs. The differences in proportions among hospitals that reprocess SUDs compared with those that do not reprocess SUDs are statistically significant by jurisdiction, hospital type, and size ( $p < 0.05$ ). Caution should be exercised, however, when interpreting the statistical significance of these differences because of the small numbers of hospitals in some jurisdictions (e.g., Newfoundland and Labrador, and the Territories).

The results of the logistic regression that was used to explore the effect of independent variables on SUD reprocessing are shown in Appendix 7. Most predictors in the model were statistically significant at the 0.05 level. The odds ratios indicated that the larger the hospital (i.e., the greater number of beds), the more likely that SUD reprocessing would occur.

**Table 2: SUD reprocessing by jurisdiction, hospital type, and size**

	Number of Hospitals (%)		
	Reprocess	Do not Reprocess	Total
<b>Jurisdiction*</b>			
Alberta	24 (29)	60 (71)	84
British Columbia	13 (32)	27 (68)	40
Manitoba	12 (32)	25 (68)	37
New Brunswick	12 (57)	9 (43)	21
Newfoundland and Labrador	1 (11)	8 (89)	9
Nova Scotia	1 (3)	31 (97)	32
Ontario	15 (16)	77 (84)	92
Prince Edward Island	0 (0)	3 (100)	3
Quebec	23 (44)	29 (56)	52
Saskatchewan	9 (39)	14 (61)	23
Territories (includes Northwest Territories, Yukon, and Nunavut)	1 (20)	4 (80)	5
<b>Hospital Type<sup>†</sup></b>			
Academic	32 (37)	54 (63)	86
Community	79 (25)	233 (75)	312
<b>Hospital Size<sup>‡</sup></b>			
<36 beds	19 (18)	88 (82)	107
36 to 74 beds	19 (22)	66 (78)	85
75 to 250 beds	31 (30)	74 (70)	105
>250 beds	42 (42)	59 (58)	101

\**P* value <0.001; <sup>†</sup>*P* value = 0.03; <sup>‡</sup>*P* value = 0.001.

Hospitals in Quebec, New Brunswick, the Prairies, British Columbia, and the Territories were also more likely to reprocess SUDs. Hospitals with a written policy were less likely to reprocess SUDs, although the findings were not statistically significant (*P* >0.05).

Our results showed that 40% of hospitals that reprocess (*n* = 44) are doing so without a written policy. The proportions of hospitals that reprocess SUDs and that have a written policy are shown in Appendix 8 by jurisdiction, hospital type, and size. There were significant differences between jurisdictions in the proportion of hospitals that have a written policy. These differences, however, were not statistically significant when examined by hospital type and size. The results suggest that the jurisdiction may have a greater influence on the existence of a written policy in hospitals, rather than the type or size of institution.

## 5.5 Incident Report Mechanisms for Adverse Events Associated with SUD Reprocessing

Eighty-eight percent (98/111) of hospitals that reprocess have a formal mechanism for reporting adverse events associated with a reprocessed SUD. Table 3 shows the number of hospitals with an incident report mechanism, by jurisdiction. Most of the hospitals use an internal reporting system (88/98), and 15 hospitals use Health Canada's voluntary problem system.<sup>18</sup> Some hospitals also use provincial, third-party reprocessors', manufacturers', or the Emergency Care Research Institute's report mechanisms.<sup>19</sup> A greater proportion of hospitals in Quebec (35%) and New Brunswick (30%)

do not have an incident report mechanism for SUD reprocessing in place compared with other jurisdictions. Among the hospitals that reprocess in-house, 87% (n=82) have an internal report mechanism compared with 94% (n=16) that use a third-party reprocessor.

<b>Table 3: Existence of incident report mechanism in hospitals that reprocess SUDs</b>			
<b>Jurisdiction</b>	<b>Number of Hospitals</b>		<b>Total</b>
	<b>Yes</b>	<b>No</b>	
Alberta	24	0	24
British Columbia	11	2	13
Manitoba	10	2	12
New Brunswick	9	3	12
Newfoundland and Labrador	1	0	1
Nova Scotia	1	0	1
Ontario	15	0	15
Prince Edward Island	NA		
Quebec	17	6	23
Saskatchewan	9	0	9
Territories (includes Northwest Territories, Yukon, and Nunavut)	1	0	1
Total (%)	98 (88)	13 (12)	

<b>Table 4: Single-use medical devices most frequently reprocessed</b>			
<b>Department</b>	<b>SUD</b>	<b>Number of Hospitals Reprocessing SUDs (n=111)</b>	<b>(%)</b>
Anesthesiology	Ventilator circuits	32	29
	Masks	16	14
Gastroenterology	Biopsy forceps	14	13
	Hot biopsy forceps/Gold probe electrohemostasis catheter	13	12
	Gastrointestinal guidewire	13	12
Ophthalmology	Endo Illuminator	11	10
	Gauge diamond dusted membrane scraper	11	10
	Phaco tip (straight and curved)	15	14
Orthopedics	Bite Blocks	16	14
	Blades and drill bits	14	13
	Burrs	24	22
Urology	Electrode rollerball	17	15
	Stone baskets	16	14
Miscellaneous	Breast pump kit	35	32
	Harmonic scalpel	12	11
	Electrosurgery cautery pencil	15	14

## 5.6 Location and Methods of Reprocessing

Most of the hospitals that reprocess SUDs do so in-house (n=94, 85%) compared with those that use a third-party reprocessor (n=17, 15%). Steam, peracetic acid, ethylene oxide, pasteurization, and gas

plasma are the most frequently used sterilization methods (Appendix 9). Some hospitals use >1 sterilization method.

Appendix 10 shows the approaches that hospitals take when considering whether to reprocess critical or semi-critical SUDs. Some hospitals use more than one approach. More than 75% of hospitals that reprocess in-house conduct cost (78%) and risk (92%) analyses before their decisions are made, and more than half develop reprocessing procedures for critical and semi-critical SUDs (67%) and periodically re-evaluate devices already approved for re-use (56%). Based on the responses, however, it is uncertain whether the effectiveness of the methods has been validated. Most hospitals may not have the resources or expertise to perform validation testing.

## 5.7 SUDs that are Reprocessed by Hospitals

A list of individual SUDs that are most frequently reprocessed by hospitals (i.e., by  $\geq 10$  hospitals) appears in Table 4. The devices that were most commonly reprocessed were breast pump kits, ventilator circuits, and burrs. A list of SUDs that are reprocessed by hospitals in our sample appears in Appendix 11.

## 5.8 Opinions and Decisions on Third-party Reprocessors

The number of hospitals using a third-party reprocessor by jurisdiction, hospital type, and size is presented in Appendix 12. As seen in Table 5, 86% of hospitals that use a third-party reprocessor started doing so in 2005 or later. Two hospitals that were using third-party processors did not indicate the year that they started using these services.

<b>Table 5: Start year for use of third-party reprocessors*</b>		
<b>Year</b>	<b>Number (n=15)</b>	<b>(%)</b>
2002	1	7
2003	0	0
2004	1	7
2005	8	53
2006	5	33

\*Missing data: 2 responses

Of the 17 hospitals that reprocess SUDs through a third-party reprocessor, 76% (13/17) were strongly satisfied or satisfied with the function of the devices, the cleanliness and sterility of the devices, and the customer service. Twelve hospitals (71%) were strongly satisfied or satisfied with the return of the original devices (Appendix 13). One hospital did not plan to continue to use the service of a third-party reprocessor because of less than anticipated cost savings and potential legal liability.

The reasons for not using a third-party reprocessor among those hospitals with a written policy that do not reprocess SUDs appear in Appendix 14. More than one-third of hospitals cited a lack of regulation in Canada (52%), potential legal liability (42%), and patients' safety (35%) as the primary reasons for not reprocessing SUDs.

Hospitals in our survey listed evidence of patients' safety (31%), introduction of regulation in Canada (30%), and potential cost savings (13%) as the most important factors that would lead them

to reconsider using a third-party reprocessor. More than half of the respondents (56%) stated that all the listed factors (i.e., regulation in Canada, patients' safety, cost savings, no potential legal liability, and short turnaround time) were equally important in considering the decision to be made.

## 6 DISCUSSION

### 6.1 Results

Our survey indicates that most of the acute-care hospitals in our sample (72%; n=287) do not reprocess SUDs. The factors influencing such decisions include concerns about patients' safety, cost savings, legal liability, and absence of regulation in Canada. The proportion of hospitals in our survey that reprocess SUDs (28%) is of the same order, though lower, than the 31% of hospitals reported to regularly reprocess SUDs in the 1986 Canadian survey.<sup>5</sup> A significant difference between jurisdictions in the proportions of hospitals undertaking reprocessing suggests that provincial and regional policies may have an impact on hospital practices. Most respondents, however, indicated that decisions on the re-use of SUDs were made at the hospital level. While governments or health regions may issue recommendations or guidance associated with SUD reprocessing, the ultimate decision rests with the hospital sector. A significantly greater proportion of academic hospitals reprocess SUDs (37%) compared with community hospitals (25%). The likelihood of SUD reprocessing is also affected by hospital size, with larger hospitals being significantly more likely to reprocess SUDs.

Of the 17 hospitals using a third-party reprocessor (n=11), 65% are strongly satisfied with the function, cleanliness, and sterility of the device. More than half (53%; n=9) are strongly satisfied with the customer service, and 40% (n=7) are strongly satisfied with the return of the original device. The results suggest that, in general, hospitals using a third-party reprocessor are pleased with the services.

Our results show increased documentation associated with SUD reprocessing when compared with those from the surveys by Miller *et al.* and by Mahoney.<sup>2,4</sup> Of hospitals that reprocess SUDs, however, 40% do not have a written policy. This is noteworthy, given the potential risks associated with the practice. Written policies assist in the development of planned and consistent procedures for SUD reprocessing and quality control that may reduce the risk of adverse events and device malfunction.<sup>3</sup> Most (88%) hospitals that reprocess have a formal mechanism for reporting the adverse events that are associated with a reprocessed SUD. For hospitals that reprocess SUDs and that do not have a formal incident reporting mechanism for SUD reprocessing, report mechanisms exist at the hospital level in some provinces for all adverse events so that the adverse events associated with reprocessed SUDs would be captured nonetheless.

### 6.2 Strengths and Weaknesses of this Assessment

This national survey provides a comprehensive view of current practices and opinions on SUD reprocessing in Canadian acute-care hospitals. The survey addressed several areas, including written policies and practices of SUD reprocessing, use of third-party reproducers, types of SUDs re-used, and incident report mechanisms. Because responses were obtained from hospitals in all provinces and territories, and because of the high response rate (72%), the survey results can be viewed with

confidence regarding generalizability across Canada. There is, however, a possibility that the 28% of hospitals that did not respond to the survey differed systematically in their approach to reprocessing SUDs. Thus, our results may reflect the practices of a selected group of hospitals, rather than those of the full target population.

Some responses were based on recall intervals that ranged from one week to one year (or longer in the case where a hospital stopped reprocessing), so that the data collected may have been subjected to recall bias. Given the complexity and nature of the topic, it was difficult for one respondent to answer all questions accurately. We had recommended that the survey be circulated in the hospital to ensure that all relevant perspectives were represented. We were unable, however, to accurately determine the number of hospitals that followed our recommendation.

To avoid a lengthy survey and to encourage responses, we excluded some items relating to the practices of SUD reprocessing. For example, “indicate the number of times that a SUD is reprocessed” was a potential question that was excluded. Also, it was beyond this report’s scope to assess whether appropriate sterilization methods were used on specific types of SUDs reprocessed, as reported in completed surveys.

It was a challenge to obtain comprehensive data on the average number of SUDs reprocessed per week, and on the numbers of adverse events and device malfunctions for each SUD reprocessed, because hospitals do not typically track these statistics.

### **6.3 Generalizability of Findings**

We were unable to determine how the proportions of hospital type and size in our survey sample were representative of hospitals across Canada. Despite this fact, the survey covered the majority of Canadian acute-care hospitals, as reflected by the response rate of 72% and the submission of completed surveys from all provinces and territories. Moreover, because the survey obtained a lot of details on the practices and opinions related to SUD reprocessing, our findings can be considered to be generally representative of current Canadian practice.

### **6.4 Knowledge Gaps**

Details about the numbers of SUDs reprocessed are not always available. There are also difficulties in obtaining information about device malfunctions and adverse events that are associated with the use of reprocessed SUDs. In principle, these limitations might be addressed by the establishment of more comprehensive systematic monitoring of SUDs use and by clinical studies that quantify the potential risks of adverse events. Also, because its focus was on critical and semi-critical devices, there are limited data on non-critical SUD reprocessing. Future research can focus on the current practices of non-critical SUD reprocessing because these devices may also contribute to infection transmission if they are inappropriately reprocessed.

## **7 CONCLUSIONS**

Our survey sought to assess the current practices of SUD reprocessing in Canadian acute-care hospitals. Most of the hospitals that responded to the survey do not reprocess SUDs. The reasons

given for not reprocessing include concerns about patients' safety, cost savings, legal liability, and absence of regulation.

Of the 28% of hospitals in the survey sample that reprocess SUDs, most do so in-house. The use of third-party reprocessors remains limited. A variety of devices are reprocessed. Of hospitals that reprocess SUDs, 40% do not have a written policy and 12% do not have an incident reporting mechanism, suggesting a need for improved standards of documentation in this area.

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## **APPENDICES**

**Available from CADTH's web site  
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