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Evidence *in* Context

Health research — synthesized and contextualized for use in Newfoundland & Labrador

The Reprocessing and Reuse of Single-Use Medical Devices in Newfoundland & Labrador

S. Bornstein, J. Butler and R. Kean
with the assistance of R. Banken, G. Martin, L. Caron and J.-M. Lance of AETMIS

Newfoundland & Labrador Centre for APPLIED HEALTH RESEARCH
www.nlcahr.mun.ca

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Agence d'évaluation des technologies et des modes d'intervention en santé
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Canadian Agency for Drugs and Technologies in Health

Disclaimer

This report was prepared by the Newfoundland and Labrador Centre for Applied Health Research (NLCAHR), Memorial University, based on the French language report from the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) in Québec (March 2009).

It incorporates information provided by local health system partners with knowledge of the subject area as it relates to the province of Newfoundland and Labrador. This document may not fully reflect all the scientific evidence available. Other relevant scientific findings may have been reported since completion of this synthesis report. Memorial University, NLCAHR, and the CHRSP project team accept no legal liability for the use of the information contained herein.

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About NLCAHR

The Newfoundland and Labrador Centre for Applied Health Research (NLCAHR), established in 1999, contributes to the effectiveness of the health and community services system of the province and the physical, social, and psychological wellbeing of the population. NLCAHR accomplishes this mandate by building capacity in applied health research, supporting high-quality research, and fostering more effective use of research evidence by decision makers and policy makers in the province's health system. www.nlcahr.mun.ca

About CHRSP

In 2007, NLCAHR launched the Contextualized Health Research Synthesis Program (CHRSP) to provide research evidence to help guide decision makers in the provincial health system on issues of pressing interest to Newfoundland and Labrador.

CHRSP does not conduct original research, but rather analyzes the findings of high-level research (systematic reviews, meta-analyses and health technology assessments (HTA)) that have already been done on the issue in question. For special cases, the CHRSP Team at NLCAHR is developing a set of alternative approaches to meeting decision makers' needs for information support on topics of pressing interest. We call these rapid reports ***Expedited*** **Contextualized Health Research Syntheses (*E*-CHRSP).** In the present case, our report differs from full CHRSP reports in that the end-product is based, primarily, on the most recent synthesized evidence from a *single* HTA or systematic review. The findings are then synthesized and are subjected to a systematic process of 'contextualization' through which they are analyzed in terms of their applicability to the conditions and capacities of the unique context of Newfoundland and Labrador.

Our contextual analysis includes assessment of the specific forms that the issue takes in this province as well as the applicability of proposed solutions and methods to locally available physical and human resources, cultural conditions and financial capacities. CHRSP uses a combination of external experts and local networks to carry out and contextualize the research synthesis and to facilitate the uptake of the results by research users.

CHRSP focuses on three types of projects: health services/health policy projects; health technology assessment (HTA) projects; and projects that combine the two to examine processes for the organization or delivery of care involving a health technology.

About AETMIS

The Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) is an independent organization that reports to Québec's Minister of Health and Social Services. Its mission is to advise the Department and to support, by means of assessment, decision-makers in the Québec healthcare sector. Its assessments focus on the introduction, acquisition and use of health technologies, and on the methods of dispensing and organizing services. Promoting assessment, transferring knowledge, training and outreach activities are also at the heart of its mission. www.aetmis.gouv.qc.ca/site/en_agence.phtml

About CADTH

The Canadian Agency for Drugs and Technologies in Heath (CADTH) is a national body that provides Canada's health system decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies. The CADTH Exchange is a network of HTA producers that also works with granting and research organizations to support health technology innovation, evidence gathering and policy needs and priorities.

About CIHR-IHSPR

This CHRSP project was funded in part by the Canadian Institutes of Health Research (CIHR) - Institute of Health Services and Policy Research (IHSPR). IHSPR is committed to championing and supporting excellent health services and policy research and knowledge translation to identify, understand and address health system needs and challenges and to contribute to health system accessibility, responsiveness, effectiveness, efficiency and sustainability.

Who Should Read This Report?

This report is intended to inform and assist those making decisions about the reprocessing and reuse of medical devices intended for single-use in Newfoundland and Labrador. The report was produced in collaboration with colleagues from AETMIS who, in 2009, completed a study on the reuse of single-use medical devices. This report is specifically aimed at the Province of Newfoundland and Labrador, Canada, but decision makers from other jurisdictions may find the content helpful.

The e-CHRSP Research Team

- Dr. Reiner Banken**,** Deputy Chief Executive Officer, External Affairs, Partnerships and Networks, AETMIS
- Dr. Stephen Bornstein, Director, NLCAHR, Memorial University (CHRSP Program Director)
- Janice Butler, Research Officer, NLCAHR (CHRSP Program Coordinator)
- Rob Kean, Research Assistant, NLCAHR
- Geneviève Martin, Researcher, AETMIS
- Lorraine Caron, Researcher, AETMIS
- Jean-Marie Lance, Senior Scientific Advisor, AETMIS

External Reviewer

- Dr. Mark A. Miller, Chief of Clinical Microbiology, Head of Division of Infectious Diseases, Chair of Infection Prevention and Control Unit, Jewish General Hospital and Associate Professor of Medicine and Microbiology/ Immunology, McGill University

CHRSP Special Advisor

- Dr. Brendan Barrett, Professor of Medicine, Division of Clinical Epidemiology, Memorial University, and Nephrologist, Eastern Health

Advisors & Consultants

- Norma Baker, Vice President, Regional Acute Care Services, Eastern Health
- Pierrette Bugden, Infection Prevention and Control, Eastern Health
- Cathy Burke, Program Director, Emergency Ambulatory Care Services, Eastern Health
- George Butt, Vice President, Corporate and Support Services, Eastern Health
- Doreen Cave, Manager, Peri-operative Programs, Janeway Children's Health and Rehabilitation Centre, Eastern Health
- Joanne Collins, Quality Clinical Safety Leader, Eastern Health
- Beverly Griffiths, Regional Consultant, Board Services, Department of Health and Community Services, Government of Newfoundland and Labrador
- Lori Ings, Manager, Sterile Reprocessing Department, Central Health
- Ron Johnson, Director, Materials and Biomedical Equipment Support Services, Eastern Health
- Louise Jones, Senior Vice President & Chief Nursing Officer, Eastern Health
- Darlene Mahar, Clinical Care Coordinator, Endoscopy & Ambulatory Care Programs, Western Health
- Corenia Price, Regional Clinical Nurse Specialist, Labrador-Grenfell Health
- Dr. Daryl Pullman, Professor of Medical Ethics, Faculty of Medicine, Memorial University
- Penny Ralph, Regional Infection Control Coordinator, Central Health
- Paula Stagg, Regional Infection Prevention and Control Specialist, Western Health
- Merlee Steele-Rodway, Regional Director, Medical Device Reprocessing Services & Infection Prevention and Control, Eastern Health
- Ron Swain, Regional Manager, Medical Device Reprocessing Services**,** Eastern Health
- Janet Templeton, Regional Director, Medicine Program, Eastern Health
- Elaine Warren, Director, Regional Surgical Services (Surgery), Eastern Health
- Marion Yetman, Provincial Infection Control Nurse Specialist, Department of Health and Community Services, Government of Newfoundland and Labrador

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Glossary of Acronyms

AETMIS	Agence d'évaluation des technologies et des modes d'intervention en santé
CADTH	Canadian Agency for Drugs and Technologies in Health
CSA	Canadian Standards Association
CETS	Conseil d'évaluation des technologies de la santé
CHRSP	Contextualized Health Research Synthesis Program
E-CHRSP	Expedited CHRSP
FDA	Food and Drug Administration
HTA	Health Technology Assessment
MSSS	Ministère de la Santé et des Services sociaux
NL	Newfoundland and Labrador
NLCAHR	Newfoundland and Labrador Centre for Applied Health Research
NZHTA	New Zealand Health Technology Assessment
PIDAC	Provincial Infectious Diseases Advisory Committee
RHA	Regional Health Authority
SUD	Single-use device
U.S.	United States

The Research Question

Prior to the 1950s, medical instruments were mostly made of metal or other materials that can withstand steam sterilization, and hence were often reprocessed and reused on a routine basis. Advances in the plastics industry around the middle of the 20th century enabled the development of disposable medical devices.(1) At that time, use of disposable devices presented a number of compelling advantages: they eliminated the twin risks of disease transmission to other patients and device degradation through wear, and had the added bonus of reducing sterilization expenses.

However, in the last 20 years, the massive growth of health care costs has pressured hospitals into seeking savings through the reuse of certain medical devices intended for single-use only. A survey of Canadian hospitals was conducted by the Canadian Agency of Drugs and Technologies in Health (CADTH), between December 2006 and May 2007.(2) The report, released in February 2008, revealed that 28% of the sampled institutions routinely reused devices intended for single-use, sometimes in the absence of a written policy. On the other hand, among the other hospitals that reported not currently reusing single-use devices (SUDs), 81% had, in fact, engaged in this practice at some point in the past, but had since stopped doing so. The fact that such a high number had stopped suggests that concerns about SUD reprocessing and reuse had grown. The most commonly cited reasons for discontinuing the practice were growing concerns about patient safety and potential legal liability. Furthermore, it appears that when disposable devices are reused, this often takes place in the absence of a comprehensive evaluation of its possible economic benefits, environmental impact, and patient safety risks.

The practice of reusing single-use devices in NL, as in the rest of Canada, has evolved over time. Results from the first pan-Canadian survey of reuse of SUDs, conducted in 2000, showed that of the eight NL hospitals responding to the survey, only one had a reuse committee, despite the fact that reuse of SUDs was more widespread (Miller, M., personal communication, September 2010).[91] In 2006/07, only one of the nine hospitals in this province that responded to the survey by CADTH reported reprocessing SUDs. Reprocessing in NL was done in-house, as was the case in 85% of hospitals that reprocessed in Canada at the time of the survey. Only 60% of hospitals across Canada that reprocessed SUDs reported having a written policy, and the hospital in NL was one of them. As of 2010, all regional health authorities in the province have issued policies that essentially prohibit the reprocessing and reuse of SUDs. Variation exists, however, in the wording of such policies and the ways in which clinical practice aligns with written policies across the province.

As in other jurisdictions, there is a pressing need within Newfoundland and Labrador's health system to contain costs and derive maximum benefit from expenditures. At the same time, patient safety is an urgent concern. Health system decision makers need to strike the right balance between cost-effectiveness and the well-being of their clients. With these considerations in mind, the purpose of this Contextualized Health Research Synthesis is to answer the following question:

What does the best currently available scientific evidence say about the effectiveness, safety, and potential economic benefits of reusing certain reprocessed single-use devices (SUDs)?

Overview and Background

The Origins of this Report

Early in 2009, NLCAHR's partners in the provincial healthcare system identified the reuse of SUDs as an issue of pressing concern. From January to March, 2009, the CHRSP research team conducted an in-depth search of the published and unpublished literature to locate high-level research studies (health technology assessments and systematic reviews) on this topic.

The search process yielded two key pieces of review literature on SUDs: a 2008 health technology assessment (HTA) by the Canadian Agency for Drugs and Technology in Health (CADTH),[(3)] and an earlier 2004 assessment conducted by the New Zealand HTA organization (NZHTA).[(4)] We also learned that Quebec's major HTA organization, the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS), was in the process of producing a similar report on the topic.

In keeping with CHRSP methods, while searching the literature, the research team at NLCAHR sought a Team Leader, a scientific expert on the subject, whose role would be to synthesize the existing high-level research evidence on the reuse of SUDs. Despite an exhaustive search, it proved impossible to find a senior academic expert without a conflict of interest to lead the research team, since most of the Canadian experts were co-authors of the very same CADTH report we would be synthesizing. This made it impossible for us to undertake a standard CHRSP on this topic.

In March, 2009, AETMIS released a report entitled *La réutilisation du matériel médical à usage unique*[(5)]. The authors synthesized the evidence contained within the CADTH and New Zealand HTAs on SUDs, as well as previous reports published by CETS (the predecessor to AETMIS)[(61-64)] and recently published primary studies or studies that had not been reviewed in those reports. The AETMIS report is now the most comprehensive and up-to-date assessment of SUD reuse that we know of. It reports on the scientific evidence related to the reuse of both *critical*[a] and *semi-critical*[b] medical devices. There is a paucity of literature on the reprocessing and reuse of *non-critical*[c] devices; hence, these practices are not addressed in that report or in this one.

Unfortunately for health system decision makers in Newfoundland & Labrador, the full report is not available in English but AETMIS did provide an English translation of the four-page Executive Summary that accompanied the full report. With funding support from the CADTH Exchange and the gracious participation of the leadership and the research staff at AETMIS, the CHRSP research team has devised an innovative approach to providing evidence support to our system partners in the form of an *expedited* Contextualized Health Research Synthesis Project or E-CHRSP. This process differs from our full CHRSP reports (see www.nlcahr.mun.ca/chrsp) in that it is based, primarily, on the evidence from a *single* HTA or systematic review. We have taken the four-page English Executive Summary and augmented it by including translations of other components of the full report that were not included in the Summary but that seemed important for NL readers who would not have access to the full document. This augmented summary was used as the basis for a

[a] ***Critical devices*** *penetrate the skin or sterile tissues.*

[b] ***Semi-critical devices*** *come in contact with non-intact skin or mucous membranes without penetrating them.*

[c] ***Non-critical devices*** *do not touch the patient or touch only intact skin.*

contextualization effort involving a team of local experts from across NL and a meeting of those experts with the authors of the AETMIS report that took place in June 2010.

How to Read this Report

This first part of this report includes the augmented English-language Summary of the AETMIS report, on the *Reuse of Single-Use Medical Devices*. The CHRSP Research Team has, where appropriate, added selected parts of the full French-language report (translated into English) in textboxes in the right column, so as to provide the reader with a more complete summary of the evidence particularly as it might pertain to Newfoundland and Labrador. The Research Team has also inserted into the Summary relevant citations that are available in the full report so that the reader has the option of referring to the supporting evidence. In the second part of our report, we have contextualized the evidence in the AETMIS study, that is, we have examined it in reference to the specific circumstances relevant to the reuse of SUDs in NL.

Details about the methodology used by AETMIS to evaluate and synthesize the research evidence have also been translated into English and are presented in Appendix 1. A Glossary of the terms included in the full AETMIS report (translated into English) is provided in Appendix 2.

AETMIS Report Summary

La réutilisation du matériel médical à usage unique (Reuse of single-use medical devices)

Summary by AETMIS in the left-hand column with highlighted and additional components of the full French-language report translated and inserted by NLCAHR in the right-hand column.

NLCAHR Additions and Comments

Introduction

The various types of single-use medical devices (SUDs) that have emerged on the market over the last few decades help prevent disease transmission to other patients and device malfunction through wear and tear. However, for economic reasons, some health-care institutions have decided to reuse these devices, some of which are quite expensive. A recent survey[(2)] showed that 28% of the Canadian hospitals and 44% of the Québec hospitals that responded to it reuse single-use devices—medical devices intended for one-time use are reused on several patients and reprocessed between uses. While the survey revealed that 17 Canadian acute care hospitals, including 4 in Québec, subcontract to a U.S. company specializing in reprocessing SUDs, it did not mention whether any quality control was performed in the other hospitals. The survey did indicate that one of the main reasons for abandoning reuse was concern over patient safety. Indeed, the reuse of SUDs, as currently practiced in Québec and elsewhere in Canada, raises clinical, economic, legal and ethical issues, which will be dealt with in this report.

The reuse of medical devices, whether disposable or not, means the "use of a medical device in several patients or in the same patient (e.g., as in the case of hemodialysis membranes), and the reprocessing of the device between each use" (quotation taken from p. 4 of the AETMIS report).

Like all medical instruments, SUDs are classified according to the risk of infection posed by their use, that is, non-critical devices (that do not touch the patient or touch only intact skin), semi-critical devices (that come in contact with non-intact skin or mucous membranes without penetrating them) and critical devices (that penetrate the skin or sterile tissues).[(6)] Critical medical devices present the highest risk because they can release multiple types of foreign matter directly into the patient's bloodstream, potentially causing adverse clinical reactions (infection, embolism, toxicity, etc.). Moreover, SUDs are not designed to be reprocessed, since the small size or the acute angles of some models make them difficult to refurbish[(7)]

Non-critical devices *do not touch the patient or touch only intact skin*

Semi-critical devices *come in contact with non-intact skin or mucous membranes without penetrating them*

Critical devices *penetrate the skin or sterile tissues*

and inspect.[8] Critical SUDs have the potential to remain contaminated after being reprocessed and to allow various types of aggressors to cross the human body's main protective barrier. The quality of reprocessing is therefore of paramount importance for maintaining the safety and effectiveness of reused SUDs. This chiefly means establishing validated reprocessing protocols that take into account the different types and models in use, implementing a device-tracking system, and ensuring compliance with them.

In the early 1990s, Québec's Ministère de la Santé et des Services sociaux (MSSS) asked the Conseil d'évaluation des technologies de la santé (CETS), the predecessor of AETMIS, to study the reuse of SUDs. Following the release of the CETS reports, the MSSS issued a position statement in 1994 declaring that reuse may "be justifiable and even desirable in some circumstances". The MSSS subsequently required hospitals wishing to reuse SUDs to develop a policy and procedures governing reuse and to have them approved by their board of directors.

Since then, several organizations and working groups both in Québec and elsewhere in Canada have revisited the issue of reusing SUDs and its potential risks. Two recommendations in particular were issued: to stop reusing critical and semi-critical devices or to use a licensed third-party reprocessor. In view of these recommendations, the regulatory gap on this issue and the new legislation on the safe delivery of health care services in Québec, the MSSS asked AETMIS to re-examine the different issues surrounding the reuse of SUDs. A review of the ministerial position on this issue is in fact addressed in the MSSS's 2006 –2009 action plan on preventing and controlling nosocomial[d] infections (*Plan d'action sur la prévention et le contrôle des infections nosocomiales 2006–2009).*

Biofilms (combinations of proteins, lipids, mucopolysaccharides, cells and cell debris [87]) "can accumulate in these devices and can contain harmful micro-organisms that can prove impossible to remove [30]... In addition, the current practice of sterilizing critical devices using chemicals, and particularly ethylene oxide [92,93] rather than steam involves other challenges. These chemicals penetrate less completely than steam and are thus less effective.[94] Ethylene oxide, moreover, is toxic [95-97] and its tendency to bond strongly with plastics [86] means that even devices that have been aerated after sterilization may contain residues of ethylene oxide [98,99] and may cause adverse reactions in future patients... A final risk is that many of the materials used in single-use devices can deteriorate when reprocessed chemically and physically and this can seriously compromise their effectiveness," [100] especially when they are reused multiple times [42,101](quotation taken from pp. 5-6 of the AETMIS report).

"Contamination can occur, of course, during the medical procedure but also during reprocessing, because infectious agents can be transmitted by the reprocessing water or equipment.[8] Infectious agents include prions… [that] adhere strongly to materials such as stainless steel [102,103] and that are difficult to inactivate either by physical or by chemical methods" [104] (quotation taken from p. 5 of the AETMIS report).

[d] Nosocomial infections are hospital-acquired infections

Analysis of the efficacy and safety of single-use medical devices

Considering the potential risks cited above, a scientific literature review was undertaken to assess currently available evidence on the efficacy and safety of reusing certain reprocessed SUDs. This study covered nineteen types of critical or semi-critical devices and took into consideration the conclusions drawn in the assessments by the CETS, the New Zealand Health Technology Assessment (NZHTA) and the Canadian Agency for Drugs and Technologies in Health (CADTH).

See Appendix 3 for a summary of findings and Appendix 4 for definitions of the medical devices used.

Evaluation of that evidence led to the following conclusions:

- Like the NZHTA[4] and the CADTH,[3] AETMIS considers that the conclusions in the studies on the safety and efficacy of reused SUDs cannot be generalized to these devices as a whole because these outcomes differ from one device to the other.

- Regarding the different types of critical or semi-critical SUDs analyzed in the present report,

  a) there is sufficient evidence to conclude that it is safe and effective to reuse single-use hemodialysis membranes;[9-12]
  b) the conclusions that can be drawn about the other types of SUDs are limited by the small number of scientific studies and by the poor quality, low level of evidence, and in vitro nature of these studies.

"However, some authors argue that the existing patient studies do not provide the kind of high-level evidence necessary to confirm that reuse of hemodialysis membranes is equivalent to single use [105]. Furthermore, clinical studies are needed to determine whether or not potentially toxic products such as 4,4 '-methylenedianiline (MDA) are formed and accumulate within hemodialysis patients as a result of the wear on the polyurethane hemodialyzers during reprocessing" [106] (quotation taken from p. 58 of the AETMIS report).

- Nevertheless, if we were to set aside the criterion of having a "sufficient" number of studies and focus more on the in vitro or in vivo nature of the available studies and their level of evidence, we could conclude the following:

  a) In vitro studies on reused electrophysiological catheters showed that these instruments may be sterile and thus safe if they are properly reprocessed;[13-18] however, even if an in vivo study supports that statement,[19] evidence is still insufficient to justify reusing them in clinical practice.

In vitro *– Outside a living organism: e.g. physical evaluation of catheter guides by scanning electron microscopy.[70]*

In vivo *– Within a living organism: e.g. evaluation of infection frequency in patients treated with PTCA catheters.[26]*

In addition to the devices listed below, AETMIS also reviewed studies on reused PTA catheters, intra-aortic balloon catheters, angiography catheters, central venous catheters, guide-wires, angioscopes, arterial & venous cannulas, respiratory circuits, Combitube® intubation probes, bronchoscope stopcocks, argon plasma coagulation probes, and phacoemulsification needle tips. Only one study was available on each of these devices, and so AETMIS was unable to come to any meaningful or generalizable conclusion about their safety and effectiveness when reused in a clinical setting.

b) Among the studies on percutaneous transluminal coronary angioplasty (PTCA) catheters, the in vitro studies [20-23] reported various problems with catheter integrity, the clinical effects of which need study. According to the in vivo studies [24-26, 67, 81] and the CETS, the reuse of these catheters may be safe and effective if strict reprocessing and inspection protocols are followed.
c) The studies on orthopedic external fixator components, all done in vivo,[27,28] suggested that their reuse may be safe and effective, but these studies alone do not support this clinical practice.
d) In vitro [30, 31] and in vivo studies [29, 32] on sphincterotomes showed that the reuse of these instruments may be safe if they undergo stringent reprocessing; however, there is insufficient evidence to support this practice in clinical settings.
e) The in vitro studies [33-35] on reused laparoscopy instruments indicated that they can remain contaminated after being reprocessed, while the in vivo studies – including one of a large number of patients [36] and two with a high level of evidence [37,38] – showed that instruments reused in clinical settings can be safe and effective if they are reprocessed according to stringent guidelines.
f) The studies on reused biopsy forceps, all conducted in vitro,[39-41] stated that they can remain contaminated and may therefore not be safe after being reprocessed.

Economic aspects of reusing single-use medical devices

It is true that reusing SUDs in principle allows for a more cost-effective use of resources and that this argument alone prompts hospitals to adopt this practice. However, most of the very few economic studies on this issue took into account only certain factors liable to affect the cost of this practice, not all of them as a whole. The economic benefits of reusing SUDs vary according to the device studied and how often it is reused.[42] Reprocessing techniques and the effects of reusing SUDs in the Québec health-care system will need clinical studies, and the cost of such research will need to be taken into account.

"Factors that may affect the cost-effectiveness of SUD reuse include:
• Cost of using disposable equipment
•Cost of reprocessing SUDs, including the costs of program development, certification, and quality control
• Cost of additional care associated with an adverse clinical event (e.g. infection, injury, etc.) caused by a reused instrument
• Legal costs resulting from failure of a reused instrument" [86]
(quotation taken from p. 28 of the AETMIS report).

Legal and administrative framework for reusing single-use medical devices

In 2006, Health Canada stated that it did not have the authority to regulate the use, cleaning or maintenance of medical devices after their sale.[43] In fact, Canadian laws and regulations govern only the marketing of medical devices – their manufacture, advertising and sale – not their after-sale use. Reprocessed SUDs are therefore not subject to the requirements set out in current federal legislation on the safety and effectiveness of medical devices. However, the provinces do have jurisdiction over the use of medical equipment/devices, including the reuse of SUDs.[e]

The governments of several provinces and territories have developed policies or directives on the reprocessing and reuse of SUDs. In general, the provinces and territories follow two different approaches. Some have instituted a ban on reuse, whether of critical devices alone (Manitoba[44]), or all single-use devices in general (Northwest Territories[45]). Others have ruled that health-care facilities must cease their in-house reprocessing of critical and semi-critical SUDs, and, if they want to continue reusing these SUDs, they must subcontract to a third-party reprocessor licensed by a regulatory authority (such as the Food and Drug Administration for companies located in the U.S.) and qualified to supply a final product that meets the standards and requirements applicable to all manufacturers of SUDs (Alberta, British Columbia, New Brunswick and Ontario [46-49]). The second approach was also favored in a recent pan-Canadian framework.[f]

A 2010 CADTH scan of provincial SUD policies lists a few other jurisdictions that do not support SUD reuse under any circumstances – the Eastern Health and Central Health regional authorities in Newfoundland and Labrador, as well as PEI's Queen Elizabeth Hospital.[89]

In 2007, recognizing that it does not have the authority to regulate the reuse and reprocessing of SUDs, Health Canada convened a F/P/T Working Group to develop a Pan-Canadian position on this issue. The framework statement was finalized in February 2008. Each jurisdiction was responsible for developing its own implementation and related communication strategy, as appropriate.

In Canada's current legal context, if a Canadian company or a Canadian affiliate of a foreign company carried out reprocessing operations on Canadian soil, it would not be subject to any law or regulation in this area. There is also the question of whether or not the Canadian affiliate of a U.S. company would be subject to the requirements in force in the United States. Even if an affiliate could be obliged to meet those requirements and give a

[e] *British North America Act, 1867, art. 92*

[f] *Federal/Provincial/Territorial Working Group. Pan-Canadian framework statement on the reuse of single-use medical devices [working document, February 2008]. Information from a letter from David B. Riley, the Federal-Provincial-Territorial Secretariat addressed to the Federal Deputy Minister of Health (Health Canada) dated April 2, 2008 and sent to Geneviève Martin, AETMIS by the MSSS in May 2008.*

guarantee to that effect, it remains to be seen whether a contract signed in Canada could warrant the possibility of litigation against the company on Canadian soil.

Québec has no specific law or regulation directly governing this practice. Nevertheless, the Act respecting Health Services and Social Services explicitly states that, as of 2002 when Bill 113 came into force, health-care institutions are obliged to ensure users the safe provision of health services and to disclose to patients any accident or complication that may arise.[50] Under that legislation and the principles of civil law, healthcare institutions are liable for patients' safety and any injury potentially caused by reprocessed SUDs. With respect to the obligation to inform patients that a reprocessed SUD may be used in a medical procedure, in every case in which reuse increases the level of risk associated with the procedure, the patients would need to be given information about the nature, frequency and severity of the risk facing them in order to obtain their informed consent. If the level of risk stays the same, however, specific consent is apparently not required.

In response to the recommendations made in the AETMIS report, the Québec government in May of 2009 issued a formal ministerial position statement on SUD reuse. The statement recommends that health care institutions cease reprocessing SUDs in–house and subcontract their reprocessing activities to third parties. Furthermore, these third party firms should be recognized by a regulatory body, and the final product of their work should satisfy the norms and requirements applicable to all manufacturers of SUDs.[90]

As a result, health-care institutions dealing with U.S. third-party re-processors benefit from guarantees set out in their contracts but ultimately remain liable to their patients for any injury caused by the reprocessed medical devices provided to their practicing physicians and other staff.[51] If the reprocessing was performed by an independent company, the health-care institutions would still have recourse against that company to obtain compensation, where applicable.

Ethical considerations regarding the reuse of single-use medical devices

In considering the option of reprocessing and reusing certain SUDs, decision makers face the following dilemma: the obligation to make the most cost-effective use possible of resources in the delivery of services versus the need to protect the health and safety of patients undergoing procedures utilizing reused SUDs. Given the uncertainty that persists about the risks associated with this practice for most disposable devices after use, decision makers have two options: not to reuse SUDs (zero tolerance or risk prevention) or to opt for responsible risk management by ensuring safe practices based on a stringent reprocessing and reuse framework corresponding

to the highest quality standards, as the U.S. FDA is currently doing.

The choice of either of these options must take into account the potential adverse effects of the risk actually materializing, including patient injury, the costs of additional care from complications resulting from reuse, action for damages in the event that the health-care institution were to be found at fault, and the loss of patient and public confidence in the institutions and public authorities taking that risk. Moreover, it must be determined whether we are capable of meeting all the requirements for responsible risk management, given the current situation and the means available to redress identified shortcomings.

Additionally, leaving it up to individual institutions to decide whether or not to reuse single-use devices raises the problem of equity. "A transparent and uniform provincial policy for each type of device would be more equitable. Alternatively, if variation across institutions were permitted… equity could be preserved by requiring institutions to have a publicly available policy that would allow patients to make an informed choice" (quotation taken from p. 53 of the AETMIS report).

In the event that the option of responsible risk management is chosen with regard to the reuse of some SUDs, several points need clarification. Accordingly, the ethical reflection proposed in this report has identified certain requirements concerning quality assurance and transparency of practices that can serve to better guide responsible risk management.

Conclusions

In light of the analysis of the different issues raised by the reuse of critical or semi critical SUDs, the acceptable options for the use of this practice are the following:

- continue reprocessing SUDs in-house by obliging health-care institutions to meet the highest recognized standards of quality; or
- sub-contract reprocessing to a third-party processor certified by a regulatory authority and qualified to supply a final product that meets the standards and requirements applicable to all manufacturers of SUDs.

In return, each of these options gives rise to certain requirements:

A. Any institution wishing to reprocess critical or semi-critical SUDs in-house in order to reuse them must ensure the following:
    - Reprocessing protocols must be developed by the professionals concerned and validated both inside and

outside the institution, and their implementation must be closely monitored by a recognized authority.
- Device-tracking mechanisms must be implemented to ensure disclosure of all necessary information in the event of any incident, accident or complication;
- Policies and procedures for reprocessing and reusing SUDs must be adopted openly and officially by the health-care facility and endorsed by resolution of the board of directors.
- Proof of the effectiveness and safety of this practice must be strictly based on scientific evidence or field studies.
- Proof of the cost-effectiveness of this practice must be clearly established for each SUD, taking into account all the costs associated with the development of best practices for reprocessing them and its potential risks.

B. Any health-care institution that wishes to have its critical or semi-critical SUDs reprocessed by a certified reprocessor should ensure the following:
   - Reuse of reprocessed SUDs must meet the conditions for the safe provision of care and this practice must be formally approved by its board of directors;
   - The decision to reprocess and reuse SUDs must be made in accordance with good management principles and must demonstrate real and significant cost savings.
   - The contractual terms and conditions that it establishes with a third-party reprocessor (companies are solely in the United States for the time being) must comply with Canada's and Québec's regulations and guarantee that the company is applying the highest quality standards, that is, those defined by the U.S. FDA's regulatory framework

Recommendations

- Given the conclusions drawn in this assessment and the general position adopted by Canadian organizations regarding the reuse of critical or semi-critical single-use medical devices (SUDs), and
- given the considerable requirements associated with the two possible avenues open to institutions opting to reprocess and reuse certain critical or semi-critical SUDs,

AETMIS recommends the following:

- Health-care institutions should stop their in-house reprocessing of critical or semi critical SUDs until the requirements for making this practice comply with the highest recognized standards of quality can be met in the Québec context.
- Institutions wishing to reuse critical or semi-critical SUDs should subcontract reprocessing to a third-party reprocessor certified by a regulatory authority and qualified to supply a final product that meets the standards and requirements applicable to all manufacturers of SUDs, and should ensure that they meet the requirements related to this option.
- The Ministère de la Santé et des Services Sociaux
  - should closely keep track of ongoing federal, provincial and territorial initiatives regarding the regulatory and legislative framework for the reprocessing and reuse of SUDs; and
  - should amend its policy on the reuse of SUDs to make it more precise and better adapted to the context prevailing today, and should ensure its implementation.

Contextualization of the Evidence on the Reprocessing and Reuse of SUDs in NL

The AETMIS report is a synthesis of the latest up-to-date scientific evidence on the effectiveness, safety and potential economic benefits of reusing certain types of reprocessed SUDs, interpreted largely within the context of the Quebec health care system. The CHRSP research team at NLCAHR began its efforts to contextualize the evidence for NL by collecting background information from key stakeholders in the four regional health authorities (RHAs) of the province who work in infection prevention and control. Information was gathered about existing policies and practices, staff education needs, and communication strategies employed within various health settings.

On June 22, 2010, eighteen individuals including infection prevention and control specialists, directors of reprocessing, and senior directors and managers within the Newfoundland and Labrador RHAs and the Department of Health and Community Services met for a half-day meeting. One of the original authors of the report by AETMIS, Dr. Lorraine Caron, along with Mr. Jean-Marie Lance (scientific officer for this dossier), presented the findings and answered questions. The CHRSP Research Team reviewed federal, provincial and territorial positions on SUD reuse and the policies in place in the four NL RHAs on the reprocessing of SUDs. A local Professor of Medical Ethics, Dr. Daryl Pullman, guided the group through a discussion of the ethical considerations involved in the reprocessing and reuse of SUDs. The group discussed the findings of the AETMIS report, paying special attention to contextual factors affecting the way the issues present themselves in this province and the appropriateness of the proposed solutions. The resulting interpretation of the AETMIS report for the NL context follows.

Efficacy and Safety of Reprocessing and Reusing SUDs in NL

To summarize the conclusions of the AETMIS report, insufficient evidence was found to support, in clinical practice, the reprocessing and reuse of almost all of the 19 types of semi-critical and critical SUDs they reviewed. With the exception of the reuse on the **same patient** of single-use hemodialysis membranes, conclusions about the safety and efficacy of reusing the other device types were limited by the small number of studies and the poor quality of the evidence. While studies conducted in vitro on specific devices suggested that, if reprocessed according to stringent guidelines and closely inspected, a few of the reprocessed SUDs could be considered safe and effective, the paucity of testing within living organisms precluded support for the reuse of such devices in clinical practice. Furthermore, evidence gathered from the reprocessing and reuse of one type of SUD cannot be generalized to other SUDs.

The findings reported by AETMIS align well with recent policy developments in Newfoundland and Labrador. As of 2010, all provincial Regional Health Authorities have issued policies stating that the reprocessing or reuse of medical devices labeled as single use is not permitted. Labrador-Grenfell Health approved a policy in 2008 prohibiting the reprocessing of SUDs *except* under specific circumstances such as the reprocessing of a single-use device that has never been used but has passed the expiration date.[52] Labrador-Grenfell Health specifies that written instructions for reprocessing must be provided by the manufacturer, however, this approach should be viewed with caution since reprocessing instructions do not usually accompany devices intended for

single use. In September 2009, Eastern Health issued a policy stating that the reprocessing or reuse of products designated as single-use by the manufacturer is not permitted.[53] In September and October 2010, respectively, Central Health[54] and Western Health[55] updated their policies to closely align with those of Eastern Health.

While the scientific evidence supports the safe and effective reuse of single-use hemodialysis membranes in the same patient, local infection prevention and control specialists reported that this is not practiced in NL. The low cost of purchasing new membranes and the challenges of storing membranes, monitoring them for quality, and tracking their reuse combine to make reuse an impractical option.

Regional policies for all health authorities in the province thus explicitly forbid the in-house reprocessing and reuse of medical devices intended for single use and, currently, none of the provincial health institutions use third-party reprocessors. In practice, however, threats to policy adherence continue to emerge. Local stakeholders provided insight into areas where the risk of SUDs being reprocessed and reused still exists in NL. Some of the factors identified by our local stakeholders as potentially contributing to this risk are as follows:

- Manufacturers of medical devices, once intended for multiple use, have recently labeled the devices as SUDs, sometimes without adequate explanation and/or labeling changes.
- Some SUDs are clearly labeled as 'single-use' on the package, but once the packaging is discarded, it is difficult to see the single-use designation on the device itself.
- Some SUDs intended for 'single *patient* use' can be reused on the same patient but may be labeled as 'single use', a label that is confusing and that can sometimes lead to reuse of other devices that are correctly labeled 'single use.'
- Front-line workers report that they lack time to read and follow the labels on devices, or that the labels may be missing or hard to read. Hence, staff may resort to making judgments based on past experience or on local manuals that may not be fully up-to-date.
- Company representatives for medical devices sometimes provide confusing and/or misleading information to health professionals about the safety of reprocessing some SUDs.
- In clinical practice, if there is an inadequate supply of a particular SUD, then health professionals may opt to reprocess it in the same way they would reprocess a multiple-use version of the device, not realizing that these reprocessing procedures have not been validated for the single-use version.
- Confusion exists among health professionals about the existence of manufacturer's instructions for the reprocessing of SUDs. At least one local policy supports the reprocessing of SUDs when the manufacturer provides written instructions. By definition, however, if a device is sold as a single-use device, it should not be accompanied by instructions about reprocessing.
- Scientific evidence and best practice guidelines for the *reprocessi*ng and reuse of *non-critical* SUDs is unavailable. As a result, there are varying opinions among staff involved in direct patient care about the safety of reuse of such non-critical SUDs in the same patient and in other patients and this uncertainty can sometimes spill over into how other devices are used, especially when they might be seen to be on the borderline between non-critical and semi-critical.
- While compliance with accepted procedures has improved in recent years, there is still a need for continuing education of nurses, physicians, and other front-line workers on accepted practice regarding the reuse of SUDs.

In response to the above risks, one RHA in the province, Eastern Health, has established a stand-alone department for Medical Device Reprocessing and Regional Director is responsible for regionalizing and standardizing reprocessing practices, including auditing of performances and competencies and centralizing medical device reprocessing. An instrument tracking system is in place to enhance the tracking of instruments while also monitoring reprocessing and reuse of multiple use devices as well as any potential reuse of SUDs.

At present, no NL regions or institutions have contracts with third-party reprocessors. For the future, if third-party reprocessors are to be considered, local infection control and biomedical support professionals agree that they need better scientific evidence to support the reprocessing SUDs in clinical practice. This evidence should include: how often a device labeled as single-use can safely be reprocessed while maintaining its function and integrity; how to validate procedures for reprocessing, and; how best to track devices that are reused in the same and/or different patients.

Cost-effectiveness of Reprocessing and Reuse of SUDs in NL

The studies reviewed by AETMIS based their economic analysis of the cost-effectiveness of reprocessing and reusing SUDs primarily on economic models, many of which are acknowledged to have failed to take into account all the factors that would impact cost-effectiveness In the absence of comprehensive primary research in this area, it is not possible at this time to draw conclusions about the cost-effectiveness of reprocessing and reusing SUDs, in general. Moreover, analyzing the possible cost-effectiveness of such practices in NL would require extensive and costly scientific study specific to this province. For example, the cost of shipping to and from third-party reprocessors in the U.S. from the island portion of the province could differ significantly from costs in Quebec or other mainland provinces.

Moreover, the AETMIS authors advise that a valid economic analysis would require that each specific SUD be studied *separately* taking into consideration, among other things:

- the cost of the specific device under review
- how frequently it is used in clinical practice within the health institution or RHA
- all costs associated with reprocessing (e.g., costs of program development, cleaning of the device, packaging and shipping to a third-party reprocessor in the US, reprocessing and verification of device integrity and safety, repackaging and returning the device to NL, device tracking and monitoring, and quality control)
- cost of additional medical care associated with an adverse event, should one occur
- legal costs resulting from an adverse event, should one occur

In addition, the authors of the AETMIS report emphasize the importance, in any economic analysis, of including the cost of conducting research on the above factors in order to establish robust scientific evidence on the true cost-effectiveness of reprocessing SUDs.

Recognizing that colleagues in the other Atlantic Provinces might provide useful information pertaining to the economic analysis of reprocessing and reusing SUDs, the research team at NLCAHR contacted senior executives in the Departments of Health in both New Brunswick and Nova Scotia, including a Regional Health Authority representative from New Brunswick. Some regions in both provinces have, in the last year or so, considered the option of using third-party reprocessors in the U.S. New Brunswick recently contracted services to a company in Minnesota

that, according to the U.S. Federal Drug Administration, is considered a certified *manufacturer* of reprocessed devices. The New Brunswick RHA official interviewed cited both economic and environmental reasons for the province's decision to reprocess SUDs. At the time of writing this report, however, details about the type of SUDs to be reprocessed were still emerging and the contract had not been in operation long enough to confirm the anticipated cost-savings for the province (Suzanne Jones, Director of Hospital Operations, Hospital Service Branch, New Brunswick Department of Health, personal communication, June 24 2010).

To further inform our economic analysis , the research team contacted the Jewish General Hospital, in Montreal, where third-party reprocessing and reuse has been ongoing since 2005 (Pearl Orenstein, Infection Prevention and Control Coordinator, Jewish General Hospital, Montreal, Quebec, personal communication, September 22, 2010). Cost-savings attributed to third-party reprocessing of a select list of SUDs, range from approximately $88,000 to $128,000 per year since the program began. This cost-savings does not, however, factor in the salary of the program manager. The specific list of SUDs that are sent out for reprocessing in the U.S. has changed over time as the purchase prices for many new devices have been cut by the manufacturers in a deliberate attempt to compete with the reprocessing option.

Legal and Administrative Concerns Associated with Reprocessing and Reuse of SUDs in NL

a) **Regulations:** Health Canada has declined to accept any jurisdiction over the reprocessing and reuse of SUDs (as distinct from the manufacture and sale of new devices, which it does regulate) (43). While the pan-Canadian framework statement released in 2008 provides guidance on this issue, it was developed by an ad-hoc provincial/territorial working group for its members' consideration and possible, rather than mandatory, use. The practice of reprocessing/reusing SUDs remains entirely under provincial and territorial jurisdiction.

   Some provinces in Canada are moving toward reprocessing of SUDs by FDA-approved third-party reprocessors in the U.S.; however, doubt still exists about the extent to which FDA-approved reprocessing would stand up to challenges within the Canadian legal system should there be an adverse event associated with the use of such a device. Third-party reprocessors of SUDs are not subject to Health Canada regulations provided they do not sell the reprocessed device, but only provide a reprocessing service to a hospital that owns a device. Liability lies with the manufacturer only when the device is used as intended i.e., single-use.

b) **Legislation:** The Act respecting Health Services and Social Services (Bill 113) in Quebec specifically requires health care institutions to ensure the safe provision of health services and to disclose to patients if an adverse event arises.[50] The Newfoundland and Labrador Regional Health Authorities Act outlines the responsibilities of an authority for the delivery and administration of health and community services in its region but does not contain any specific safety provision similar to the 'safe provision' requirement of the Quebec legislation.[56]

c) **Standards**: An Accreditation Canada Standard (Standard 8.1), developed in 2008, states that: "The team prevents the on-site reprocessing or sterilization of single-use devices (SUDs)" and that, "If available, third-party reprocessors that meet accepted standards of practice and legal

requirements may be used to reprocess SUDs."[57] All publicly-funded health care institutions in NL are required to meet this standard for accreditation. Private clinics such as physicians' and dentists' offices, home-care nursing, and foot-care clinics, are supposed to meet the standards set by their own Associations.

d) **Provincial Policies**: Two Canadian provinces have issued directives for SUD reuse. In 2008, the then Minister of Health and Wellness in Alberta, Dave Hancock, issued a directive to all Regional Health Authority Boards to comply with the Standards for Single-Use Medical Devices (the 'Standards'), to ensure that third parties contracted to provide services also comply with the Standards, and that each RHA submit reports on its compliance with the directive to the Alberta health ministry.[58] The standard applies to all health care facilities and settings, including private clinics.

   In 2009, based on the conclusions and recommendations of the AETMIS report, the Quebec Ministry of Health and Social services issued a renewed position statement on the reprocessing and reuse of critical and semi-critical SUDs. The ministerial position called for the cessation of local in-house reprocessing and, instead, asked that establishments wishing to reuse SUDs use third-party reprocessors that are recognized by a regulatory body such as the FDA.

In NL, however, there are no province-wide regulations, laws or policies governing the reprocessing and reuse of SUDs. It is up to each RHA to make decisions about reprocessing and reuse of medical devices, including SUDs, and to verify the processes to be followed in each case. Regional policies apply only to publicly-funded health care settings. Private clinics such as those owned by doctors and dentists are subject to their own professional standards of practice, and there currently is no provincial mandatory auditing of these practices.

In response to the lack of national and provincial policies and regulations, at least one RHA in NL has begun to develop its own best practice standards and quality management systems for the reprocessing of all types of medical equipment and devices, based on CSA standards combined with the best practice document prepared by Ontario's Provincial Infectious Diseases Advisory Committee (PIDAC), first published in 2006 by the Ontario Ministry of Health and Long-Term Care.[59] The PIDAC best practices are intended for use in all settings where care is provided, across the continuum of health care. This includes hospitals, physician offices, dental offices, community health centres and long-term care facilities, to name a few.

In responding to the AETMIS report, NL's infection prevention and control specialists supported the need for a comprehensive province-wide policy, standards and regulations in NL for the reprocessing and reuse of medical equipment and devices, including those intended for single-use. Such a policy should govern all health care settings including publicly-funded health institutions and privately-owned clinics, and include mandatory auditing of reprocessing with regular reporting to the appropriate provincial body.

Ethical Considerations Regarding the Reprocessing and Reuse of SUDs in NL

As in other jurisdictions, policy makers in NL are faced with the dilemma of balancing the need to make cost-effective choices in health care with the requirements for protecting the health and safety of patients. The economic evidence on the reprocessing and reuse of SUDs is based largely on models that, at times, fail to take into account all costs. At this time, there is no clear case for

economic savings by reprocessing SUDs. The evidence on the safety and effectiveness of reprocessing and reusing SUDs in clinical practice is uncertain and cannot be generalized to all categories of SUDs. Moreover, there is virtually no scientific evidence on the reprocessing and reuse of non-critical SUDs. Ethical arguments in support of protecting the NL environment and reducing the disposal of medical devices and equipment in landfills are worthy of consideration. So are the opportunity costs associated with the decision not to reprocess and to continue purchasing SUDs when the limited financial resources of the province could be directed towards providing other much-needed health services. Hence, decisions about whether to reprocess and reuse SUDs in NL are value laden.

The potential legal consequences associated with the practice of reprocessing and reusing SUDs in patients are intertwined with the ethical dilemma. While current RHA policies in most parts of NL prohibit the reprocessing or reuse of SUDs in health institutions, the decision to move from a 'zero tolerance' approach to a 'responsible risk management' approach for certain types of SUDs, as described in the AETMIS report, would require a substantial commitment from the provincial government. The province would have to carefully assess the health care system's capacity to take all necessary steps to avoid an adverse event and be prepared to take responsibility for consequences should an adverse event occur in relation to the reuse of an SUD. The potential loss of public confidence in the health care system that could result from such occurrences would be particularly damaging in NL where the health system has recently been the subject of severe criticism associated with the Cameron Inquiry into faulty hormone receptor testing for breast cancer patients.[60]

Should the NL provincial government choose to move towards a responsible risk management approach by, for example, sending SUDs to third-party reprocessors in the U.S., then a general public disclosure would be advisable. Whereas in the American system with its largely private approach, it might make sense to require individual patient consent, our stakeholders felt that in a publicly funded system such as Canada's, our commitment to equity and universality overrides individual consumer preference and possibly also individual patient consent for the use of specific medical devices.

The existing variability in institutional approaches to the reprocessing and reuse of SUDs in Newfoundland and Labrador adds confusion to the related ethical issues and poses a potential problem of inequity in the treatment of patients. The general consensus among the stakeholders who participated in the discussion was that a transparent and uniform provincial-wide policy governing all health care settings had the potential to improve equity and to protect members of the general public who avail themselves of health services in private clinics such as physician offices and dental offices. RHAs that regularly refer patients to such clinics for treatment may also benefit from the assurance that accepted standards are being met regarding the reuse of medical equipment. Representation from the professional associations affected by a province-wide policy would be necessary to properly inform policy development.

Analysis and Implications for Decision Makers in NL

1. The Department of Health and Community Services should consider developing a comprehensive province-wide policy and regulations on the reprocessing and reuse of SUDs in all health care settings (public and private).

2. Such a policy, if developed, should be supported by the most up-to-date scientific evidence on the safety and efficacy of reprocessing specific categories of SUDs.

3. Regular audits and report mechanisms should be established and maintained in each Regional Health Authority to confirm compliance with the existing policies and regulations governing the reprocessing and reuse of SUDs. If the Department issues a province-wide policy governing all health care settings, this role should be assumed by the Department of Health and Community Services.

4. Where the existing research evidence is suggestive of the potential for reuse of specific devices or classes of device, primary research specific to the context of NL can assist policy makers in decisions. This should include research into the reprocessing and reuse of non-critical devices and the reuse of SUDs within the same patient.

5. All research on the reprocessing and reuse of SUDs should include both a clinical and cost-effectiveness analysis specific to NL.

6. If future research evidence lends support for the safety and efficacy of reusing certain types of SUDs, provincial health officials should work with the federal government (Health Canada) to push for a Canada-wide regulatory body.

7. Continuing education of health care providers on the reprocessing and reuse of medical equipment and devices in all health care settings is important.

8. Federal, provincial and territorial positions on the reprocessing and reuse of SUDs should be closely monitored as legal and regulatory changes elsewhere may have an impact on policy options in this province.

Appendix I– Research Methods

The following is an English-language translation of the methods employed by AETMIS to conduct the study.

The investigation of this issue by AETMIS was guided by an analysis of the rigorous scientific literature on the safety and efficacy of reusing critical or semi-critical medical devices intended for single-use. Reports by CADTH,[3] NZHTA,[4] and CETS [61-64] were reviewed and recently published studies or studies not included in those reports were analyzed. Analysis of the legal and ethical issues related to the reuse of SUDs is included, along with a brief account of the economics of reuse:

The questions under evaluation by AETMIS

1. Studies conducted in the laboratory (*in vitro*)
   Does the reuse of SUDs increase:
   - the deterioration or breakage of the devices, which may affect their efficacy and/or safety?
   - the concentration of infectious agents, pyrogens, particles, or cleaning/sterilization agents in the devices, which may affect their safety?

2. Studies conducted in patients (*in vivo*)
   Procedural efficacy - Does the reuse of SUDs increase:
   - the number of the same device used during an intervention
   - the duration of an intervention?

   Risk - Does the reuse of SUDs increase:
   - the frequency of infections?
   - the frequency of complications during an intervention (e.g., a wound caused by a damaged instrument, or a device component lost inside a patient's body)?
   - the frequency of accidents due to exogenous particles (e.g., embolism)?
   - the frequency of reactions to pyrogens?
   - the frequency of reactions to cleaning/sterilization agents?

Inclusion/exclusion criteria for additional studies

To answer the above questions, AETMIS searched for laboratory and patient research that was (a) conducted after 1997 and (b) available in English, French, or Spanish. In its review AETMIS included systematic reviews, meta-analyses, clinical trials (randomized, quasi-randomized, or non-randomized), comparative studies with or without control groups, pre-test/post-test studies, and case series. Included studies had to provide data on at least one of the following outcomes: frequency of infection, frequency of mortality, frequency of defects, frequency of accidents involving exogenous particles, and frequency of reactions to pyrogenic substances or cleaning/sterilization agents. Furthermore, included studies had to evaluate one of the following subjects:

- safety and efficacy of reusing SUDs on multiple patients
- safety and efficacy of reusing hemodialyzer membranes in the same patient
- reuse of single-use medical equipment that has been reprocessed by a health institution or a company that specializes in this field
- safety and efficacy of reprocessing medical equipment that has already been used
- use of single-use medical equipment in hospital settings

Among articles *not* eligible for inclusion were the following:

- the studies reviewed by NZHTA and CADTH
- studies on equipment labeled by the manufacturer as reusable

- studies on disposable medical equipment that had previously been unpacked but not yet used
- studies on disposable medical supplies that were reused on the same patient (with the exception of studies on hemodialyzers)
- studies evaluating adverse events caused by the initial use of a disposable medical device
- studies on the reuse of disposable medical equipment that had *not* been reprocessed (e.g., syringes in a developing country)
- studies comparing disposable with reusable medical equipment
- studies with insufficiently described methodologies and/or outcomes
- narrative reviews, expert opinions, editorials, commentaries, papers on conceptual/analytical frameworks, and magazine articles
- studies on the disposal of reused SUDs
- articles which described models for predicting physiological outcomes

Studies which satisfied the initial inclusion/ exclusion criteria were retained only if reviewers judged them to be "very good" or "good" in terms of methodological rigor (absence of bias/conflicts of interest and strength of the research design/statistical method). The critical review of the literature was completed first by one reviewer, then by a second reviewer.

Search strategy

The review of primary research articles (clinical and economic) was conducted using the following specialized health research database: MEDLINE (PubMed interface), EMBASE, Current Contents, CINAHL, and the Cochrane Central Register of Controlled Trials (Ovid interface). As with the NZHTA report, only articles published since 1997 were selected. The AETMIS reviewers also hand-searched the bibliographies of articles identified through the electronic search.

Literature Search Strategy
MEDLINE (1966 to present) by PubMed, research conducted September 4, 2007 (Limits: English or French or Spanish; 1997-2007) and updated June 30, 2008 1. disposable equipment[mh] OR single-use OR disposable 2. equipment reuse[mh] OR reprocess* OR reuse* 3. 1 AND 2 4. prospective studies[mh] OR comparative study[pt] 5. 2 AND 4 6. 3 OR 5
CURRENT CONTENTS by Ovid, research conducted June 12, 2007 (Limits: English or French; 1997-2007) and updated June 30, 2008 1. single-use.mp. OR disposable.mp. OR sud.mp. OR suds.mp. 2. reprocess$.mp. OR reuse$.mp. OR reusing.mp. 3. 1 AND 2
EMBASE by Ovid, research conducted June 12, 2007 (Limits: English or French; 1997-2007) and updated June 30, 2008 1. disposable equipment/ OR single-use.mp. OR disposable.mp 2. equipment reuse/ OR reprocess$.mp. OR reuse$.mp. OR recycl$.mp. 3. 1 AND 2

CINAHL by Ovid, research conducted June 12, 2007 (Limits: English or French; 1997-2007) and updated June 30, 2008 1. disposable equipment/ OR single-use.mp. OR disposable.mp. 2. equipment reuse/ OR reprocess$.mp. OR reuse$.mp. OR recycl$.mp. 3. 1 AND 2
Cochrane Central Register of Controlled Trials by Ovid, research conducted June 12, 2007 (Limits: English or French; 1997-2007) and updated June 30, 2008 1. disposable equipment.kw OR single-use.mp. OR disposable.mp. 2. equipment reuse.kw. OR reprocess$.mp. OR reuse$.mp. OR recycl$.mp. 3. 1 AND 2

The AETMIS reviewers triangulated several sources of information on the ethical aspects of SUD reuse in order to provide a comprehensive overview of the various stakeholder perspectives, practices, and inputs. This information came not only from scientific journals, but also from reports, guidelines, opinion pieces, and popular articles in medical journals and the mainstream press. The reviewers followed these steps:

- searched the relevant assessment reports already published (those of CETS and CADTH);
- conducted targeted literature searches in PubMed (since 1985), the ETHXweb database (Kennedy Institute of Ethics), and Google. They used both general keywords (such as single-use devices, reuse, risks, ethics, social, legal, etc.) as well as more accurate ones (consent, trust, risk management, etc.).
- searched the websites of the major manufacturers, reprocessing companies, regulatory authorities in Canada and the United States; and
- searched the reference lists of the various articles used for this analysis.

The analysis of legal aspects required the review of laws, regulations and relevant case law in Quebec, as well as the normative positions of relevant national-level organizations. The analysis concludes with an overview of the international context.

Levels of Evidence Included in AETMIS's Report[65]

Level	Evidence
I	Evidence obtained from a systematic review of all randomized clinical trials on the subject
II	Evidence obtained from at least one randomized clinical trial
III-1	Evidence obtained from quasi-randomized clinical trials
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent control groups: non-randomized experimental trials (including studies before and after with control group), cohort studies, case-control studies or time series studies interrupted with control group
III-3	Evidence obtained from comparative studies without concurrent control group: studies with historical control group, single arm studies or interrupted time series without control group
IV	Evidence obtained from a study of case series or retrospective pretest / posttest

Results of the literature search

AETMIS's search strategy produced an initial results list of 1,198 original research articles on the safety and efficacy of reusing medical devices intended for single use. From this initial list, 27 were excluded because they had already been assessed by the NZHTA or CADTH, and 1,084 were excluded after an appraisal of their titles and abstracts. Another 8 were reserved for other sections of the report. Of the remaining 79 articles, 61 were excluded on the basis of a detailed reading of the full text of each article. About two-thirds of these were excluded on methodological grounds, and the others were rejected because they were off-topic. Thus, there were a total of 18 studies from AETMIS's search that were ultimately included in the review. Combined with the 34 studies reviewed in the CADTH and NZHTA reports, this brings the total number of included studies to 52.

Included studies		
Alfa & Nemes, 2003 (30)	Feldman et al, 1999 (71)	Roth et al, 2002 (35)
Ayzman et al, 2002 (14)	Grabsch et al, 2002 (17)	Scherson et al, 2006 (79)
Bathina et al, 1998 (18)	Granados et al, 2001 (72)	Scott et al, 1999 (80)
Blomstrom-Lundqvist, 1998 (19)	Gundogdu et al, 1998 (37)	Shaw et al, 1999 (81)
Bloom et al, 1997 (66)	Hambrick, 2001 (39)	Srimahachota et al, 2000 (26)
Brown et al, 2001 (21)	Heeg, 2001 (40)	Sung et al, 2008 (28)
Browne et al, 1997 (67)	Karov, 2000 (23)	Tessarolo et al, 2007 (16)
Bryce et al, 1997 (68)	Kes, 1997 (12)	Tessarolo et al, 2006 (15)
Chan et al, 2000 (33)	Kinney et al, 2002 (73)	Ulualp et al, 2000 (34)
Chaufour et al, 1999 (69)	Kozarek et al, 1999 (29)	Unverdorben et al, 2005 (82)
Chuang et al, 2008 (9)	Kozarek et al, 1997 (31)	Unverdorben et al, 2003 (20)
Cogdill & Quaglia, 1998 (41)	Lipp et al, 2000 (74)	Vezina et al, 2001 (83)
Colak et al, 2004 (38)	Lujit et al, 2001 (75)	Wilcox et al, 1998 (32)
Da Silva et al, 2005 (70)	Ma et al, 2003 (13)	Wilson et al, 2000 (84)
DesCoteaux et al, 1995 (36)	Perry, 1996 (76)	Yang et al, 1997 (85)
Dirschl & Smith, 1998 (27)	Plante et al, 1994 (77)/Mak et al, 1996 (25)[g]	Zubaid et al, 2001 (24)
Fan et al, 2005 (10)	Port et al, 2001 (11)	
Fedel et al, 2006 (22)	Roach et el, 1999 (78)	

[g] Mak et al re-analyzed the data from the original study conducted by Plante et al in 1994.

Appendix 2– Glossary

(direct translation from the AETMIS report)

Cleaning
The use of a detergent to mechanically remove visible dirt, as well as visible and invisible organic material, in order to prevent the development, propagation, and transmission of microorganisms.[86]

Disinfection
Irreversible inactivation of microorganisms (vegetative bacteria, fungi, viruses or sporulating bacteria) present on all inanimate surfaces, on the skin, or intact mucous membranes. The disinfection is to minimize the risk of transfer of microorganisms. However, not all microorganisms are inactivated. Spore-forming bacteria, in particular, usually survive the disinfection process.[86]

Lumen
The space located within a tubular conduit

Pyrogen
A substance that causes fever, chills, and hypotension. An example of a pyrogenic substance is an endotoxin called lipopolysaccharide, a metabolite of certain wall-forming bacteria. Endotoxins are resistant to sterilization because inactivating them requires dry heat of 132 degrees Celsius for one hour.[87]

Reprocessing
Preparation (cleaning, sterilizing, etc.) of used medical devices for reuse.[59]

Reuse of a Single-use Device
Employment in several patients, or in the same patient (e.g., in the case of hemodialysis membranes), of a medical device intended for single use and reprocessing this device between each use.

Single-use medical devices
Disposable devices which are labelled as such by their manufacturer and designed for single-use, and not to be reprocessed or reused in another patient and, therefore, are not accompanied by reprocessing instructions from the manufacturer.[87]

Sterilization
Processes of inactivating microorganisms on an object, so that there is less than one chance in a million that a viable organism will be found therein.[86]

Sterilization by hydrogen peroxide plasma
Sterilization by oxidation using gaseous hydrogen peroxide, potentiated by the plasma form (the fourth state of matter) generated by the application of radio frequency on the gas. The plasma is comprised primarily of ions, electrons, and free radicals, and it facilitates the decomposition of hydrogen peroxide residues into water and oxygen.[88]

Appendix 3– Table of Nineteen Medical Devices Reviewed by AETMIS (translated and summarized by NLCAHR)

Single-Use Medical Device[i]	Class[ii]	Summary of Findings by AETMIS[iii]
Cardiovascular Devices		
1. Electro-physiological catheters	Critical	▪ Seven studies were reviewed; six were conducted in laboratories (*in vitro*[iv])[13-18] and one study was conducted on radio frequency ablation catheters (*in vivo*[v])[19] ▪ The only study involving humans in a clinical setting was based on a series of case reports, a relatively weak level of evidence ▪ The results were favourable to reuse if properly reprocessed ▪ However, there is insufficient evidence to justify reusing them in clinical practice
2. Percutaneous transluminal angioplasty catheters	Critical	▪ One study (*in vitro*)[75] found whose results were unfavourable to reuse ▪ Evidence is insufficient to determine safety and efficacy of reuse
3. Percutaneous transluminal coronary angioplasty catheters	Critical	▪ Most of the studies reviewed (many of which were *in vivo*[24-26]) indicated that reuse may be safe and effective provided that appropriate reprocessing methods and rigorous quality control are used ▪ One study[82] of patients came to the opposite conclusion, and recommended *de novo* stenosis of coronary artery not to be treated with reused catheters unless the intervention is limited to stent procedures ▪ The *in vitro* studies[20-23] found damage or breakage of catheters or the presence of residual particles but with varying degrees of severity and the authors insist on the necessity of evaluation of the clinical consequences
4. Intra-aortic balloon catheters	Critical	▪ One study (*in vitro*)[85] found whose results were unfavourable to reuse ▪ Evidence is insufficient to determine safety and efficacy of reuse
5. Angiography catheters	Critical	▪ One study (*in vivo*)[79] found whose results were favourable to reuse ▪ However, evidence is insufficient to determine safety and efficacy of reuse
6. Central venous catheters	Critical	▪ One study (*in vitro*)[72] found whose results were unfavourable to reuse ▪ Evidence is insufficient to determine safety and efficacy of reuse
7. Guide-wires	Critical	▪ One study (*in vitro*)[70] found whose results were unfavourable to reuse ▪ Evidence is insufficient to determine safety and efficacy of reuse
8. Angioscopes	Critical	▪ One study (*in vivo* in ducks infected with Hepatitis B virus)[69] found that rigorous reprocessing (involving adequate cleaning prior to disinfection or sterilization) of angioscopes poses no risk of infection transmission ▪ Evidence is insufficient to determine safety and efficacy of reuse in humans
9. Arterial and venous cannulas	Critical	▪ One study (*in vivo* in sheep)[66] found whose results were favourable to reuse up to five times ▪ However, evidence is insufficient to determine safety and efficacy of reuse in humans
Respiratory Devices		
1. Anesthesia breathing circuits (in combination with breathing filters)	Semi-critical	▪ One study (*in vitro*)[83] was found but the validity of the results is limited. It is therefore premature to conclude on the safety of using a filter to allow the reuse of disposable breathing circuits without rigorous disinfection or sterilisation. ▪ Evidence is insufficient to determine safety and efficacy of reuse of the anesthesia breathing circuits on more than one patient when using a sterile breathing filter
2. Combitube® Intubation tubes	Semi-critical	▪ One study (*in vitro*)[74] found whose results were favourable to reuse ▪ However, evidence is insufficient to determine safety and efficacy of reuse
3. Bronchoscope stopcocks	Semi-critical	▪ One study (*in vivo*)[84] found whose results were unfavourable to reuse ▪ Evidence is insufficient to determine safety and efficacy of reuse

Orthopaedic Devices		
1. Orthopaedic external fixator components	Semi-critical	▪ Two studies (*in vivo*)[27,28] showed that these devices remain safe and effective after reuse ▪ However, the low level of evidence of one of the studies and the small number of patients in the other preclude certainty about the efficacy and safety of reuse in clinical practice
Other Devices		
1. Sphincterotomes	Critical	▪ Four studies (two *in vitro*[30,31] and two *in vivo*[29,32]) demonstrated that reuse can be efficacious and safe provided that appropriate reprocessing methods and rigorous quality control are followed ▪ However, the low level of proof in the *in vivo* studies and the need for supplementary studies emphasized by the authors precludes certainty about the efficacy and safety of this practice in a clinical context
2. Various laparoscopy instruments	Critical	▪ The reused laparoscopy instruments examined in three *in vitro*[33-35] studies remained contaminated after reprocessing, while similar reused instruments proved to be safe and effective in 3 *in vivo* studies[36-38], one of which was a quasi-randomized trial[37] and the other a randomized trial.[38] The authors of two of the three *in vivo* studies insist on the need to govern reuse with strict guidelines.
3. Biopsy forceps	Critical	▪ Three studies (all *in vitro*)[39-41] showed that reprocessed biopsy forceps are not safe and should not be reused ▪ A fourth *in vitro* study showed that the contamination may have been caused by the endoscopes with which they came into contact[73] ▪ No study discussed the issue of efficacy
4. Argon plasma coagulation probes	Critical	▪ One study (conducted *in vitro* on beef steak)[78] found whose results were favourable to reuse ▪ However, evidence is insufficient to determine safety and efficacy of reuse
5. Phacoemulsification needle tips	Critical	▪ One study (*in vivo*)[76] found whose results were favourable to reuse ▪ However, evidence is insufficient to determine safety and efficacy of reuse
6. Hemodialysis membranes	Critical	▪ Four *in vivo* studies [9-12] confirm earlier findings that reuse *in the same patient* is generally safe and effective and helps reduce adverse clinical events associated with hemodialysis ▪ One other study,[71] however, showed that in units reusing membranes extensively, the use of a mixture of acetic and peracetic acids lead to a significant increase in hospitalization rates

Source: Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). *La réutilisation du matériel médical à usage unique*. A report prepared by Geneviève Martin and Lorraine Caron in collaboration with Alexandra Obadia. ETMIS 2009; 5(2):1-99.

[i] Single-Use Medical Device (SUD): A medical device that is intended for one-time use

[ii] Class: Medical instruments are classified according to the risk of infection posed by their use:
- Non-critical devices do not touch the patient or touch only intact skin
- Semi-critical devices come in contact with non-intact skin or mucous membranes without penetrating them
- Critical devices penetrate the skin or sterile tissues

[iii] The summary of the findings for each device is an English translation of selected material from Chapter 4 of the AETMIS report entitled, *La réutilisation du matériel médical à usage unique*, translated by NLCAHR and reviewed by staff at AETMIS

[iv] *in vitro*: experimentation outside of a living organism

[v] *in vivo*: experimentation within a whole, living organism

Appendix 4 – Definitions of Medical Devices Reviewed by AETMIS (translated and summarized by NLCAHR)

Single-Use Medical Device	Definition
Cardiovascular Devices	
1. Electro-physiological catheters	These are long flexible probes inserted into veins or arteries through to the heart, either to register intracardiac signals (diagnostic catheters) or to destroy a portion of the heart which is functioning abnormally (catheter ablation). Electrodes fastened to the surface of catheters permit recording of heart signals.
2. Percutaneous transluminal angioplasty catheters	These are long flexible tubes with a lumen of small diameter and a very small balloon that is inserted into a non-coronary artery. The balloon is inflated either to widen the narrowed segment of an artery or to deploy a stent previously mounted on the balloon.
3. Percutaneous transluminal coronary angioplasty catheters	Similar to the PTA catheters, these are inserted into coronary arteries.
4. Intra-aortic balloon catheters	These catheters have a lumen of medium diameter and a balloon that inflates in synchrony with the heart's beating. They are inserted in the aorta to increase both the irrigation of coronary arteries and cardiac output.
5. Angiography catheters	These are long flexible tubes with a lumen of small diameter. They are inserted into the arteries in order to inject a contrast medium.
6. Central venous catheters	These are short flexible tubes with a lumen of small diameter. They are inserted into a central vein (jugular, subclavian, or femoral, for example) in order to administer medications or fluids.
7. Guide-wires	These are long, flexible wires inserted into blood vessels and used to position catheters correctly.
8. Angioscopes	An angioscope is a long, flexible tube with a lumen of small diameter and a miniature microscope, which enables visual analysis of the inner surface of blood vessels.
9. Arterial and venous cannulas	These are semi-rigid plastic tubes with a lumen of small diameter which are inserted into either arteries or veins to aid drainage/perfusion.
Respiratory Devices	
1. Anesthesia breathing circuits (in combination with breathing filters)	This apparatus is composed of long flexible tubes with a lumen of medium diameter, a hollow Y-junction, a rigid angular tube, and an inflatable bag connecting the patient to an anesthesia machine, for example. In theory, a respiratory filter can be added and removed after each use to allow reuse of single-use circuits without the necessity of disinfection or sterilization procedures.
2. Comitube® Intubation tubes	These are hollow tubes which enclose both the oropharynx and nasopharynx in order to facilitate ventilation.
3. Bronchoscope stopcocks	Bronchoscopes are flexible tubes with a lumen of small diameter which enable visual exploration of the trachea and bronchi.
Orthopedic Devices	
1. Orthopedic external fixator components	These include rods, screws, and other components installed outside of limb and fastened to bone fragments with the aid of other bone-supporting devices
Other Devices	
1. Sphincterotomes	These are long, flexible tubes with one or many lumens of small diameter. They are fitted with a metal wire which is used to make incisions in sphincters.
2. Various laparoscopy instruments	These include trocars, dissectors, scissors, grasping implements, jaws, hooks, and clips. These metal devices are generally fixed to the end of a long hollow tube and, in the case of trocars, used to make punctures.
3. Biopsy forceps	These are long, hollow stems with a lumen of small diameter and mobile cutting jaws at the distal end.
4. Argon plasma coagulation probes	These probes with a lumen of small diameter. They emit argon gas which, when exposed to an electric current, causes blood to clot.
5. Phacoemulsification needle tips	These are spikes that penetrate the eye to remove cataracts.
6. Hemodialysis membranes	These membranes are placed within artificial kidneys to filter water and waste products like urea, creatinine, glucose, and electrolytes out of the patient's bloodstream.

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Newfoundland & Labrador Centre for Applied Health Research

www.nlcahr.mun.ca
nlcahr@mun.ca
1.709.777.6993