Canadian Agency for Drugs and Technologies in Health
Issue 8 • June 23, 2010

Reprocessing Single-Use Medical Devices: An Update of the Clinical Evidence and an Environmental Scan of Policies in Canada

Environmental Scan

Context and Policy Issues

Numerous types of medical devices are labelled and marketed by manufacturers as being for single-use only to help ensure device functionality and sterility and to prevent cross-infection.[1] The reuse of single-use (medical) devices (SUDs) after reprocessing in health care facilities is perceived to have some economic benefits, but there are concerns about patient safety, cost-effectiveness of SUD reprocessing, ethical obligations, and legal liabilities. Reprocessing involves all the steps performed, including cleaning, function testing, disinfection, and sterilization, to make a device that has been used by one patient ready for use by another patient.[1,2]

In February 2008, the Canadian Agency for Drugs and Technologies in Health (CADTH) published a national survey of Canadian acute-care facilities and a health technology assessment on the reprocessing of SUDs.[1] The useable response rate for the survey was 70% (398 of 572). Twenty-eight per cent (111 of 398) of hospitals that responded reprocessed SUDs. Most hospitals that reprocessed did so in-house (85%) instead of using third-party reprocessors; and 40% of them did not have a written SUD policy, with 12% reporting no incident report mechanism for adverse events related to reprocessing or reuse of SUDs at the hospital.[2] According to the limited evidence available on SUD reprocessing, the assessment suggested an uncertain health impact of reprocessing. Few studies of mixed quality were identified, and the authors were unable to suggest or rule out harm to patients from reprocessing.[1]

Health Canada does not regulate the reuse and reprocessing of SUDs. The provincial and territorial governments and health regions are responsible for the policies, procedures, and recommendations for the organization and delivery of health care services, including the use of reprocessed SUDs.[2] Policies and practices vary from one jurisdiction to another.

Objectives

The objectives of this report are to provide an update of the clinical evidence and information on the policies and regulations across Canadian jurisdictions about the reuse and reprocessing of SUDs. The following questions will be addressed:

- What is the evidence, since the last CADTH review, that reprocessed SUDs are safe and effective?
- What are the policies and recommendations across Canada on the reuse and reprocessing of SUDs?

Methods

An update of the literature search of the clinical evidence was performed and the selection criteria were applied based on the original CADTH report.[1] Studies that measured the clinical effectiveness, safety and device functionality, and contamination of new SUDs compared with reprocessed SUDs or SUDs that had been previously opened but not used in human subjects were included. In addition, an environmental scan of SUD policies and regulations in the Canadian provinces and territories was conducted through communication with the appropriate contact person or examination of websites, such as those related to the provincial ministry of health, for each jurisdiction.

Summary of Findings

Clinical Evidence

Two new studies that compared the safety, efficacy, and function of new SUDs with the reuse of reprocessed SUDs were identified.[3,4] One study evaluated the efficacy and complications of pin tract infections, loss of fixation, or loosening of components of new versus reprocessed external fixations.[3] A second study compared the handling and functionality of new versus reprocessed single-use ultrasound scissors.[4] In both studies, the medical devices were reprocessed by a third-party reprocessor, and the patient safety, effectiveness, and functionality were similar between the new and reprocessed SUDs.[3,4] The study characteristics and outcomes appear in Appendix 1. As the sample size was 100 devices in each study, it is difficult to determine if true differences in outcomes between new and reprocessed SUDs exist. Also, Gartner et al. provided limited information on how randomization and blinding were conducted and the sterilization procedure used on the ultrasound scissors.[4] Taken together with the previous review, the clinical evidence remains insufficient.

Environmental Scan of SUD Policies in Canada

Information on the regulatory context on the reuse and reprocessing of SUDs provided by the regional health authorities and jurisdictions that participated in our environmental scan or for which information was available on the Internet is presented in Appendix 2. Five out of 10 provinces (British Columbia, Alberta, Saskatchewan, New Brunswick, and Nova Scotia) do not permit the reprocessing and reuse of SUDs unless they are reprocessed by a licensed third-party reprocessor. The Eastern Health and Central Health authorities in Newfoundland and Labrador, the Northwest Territories, and the Queen Elizabeth Hospital in Prince Edward Island do not support the reuse or reprocessing of SUDs under any circumstances. In-house SUD reprocessing is not forbidden entirely in Ontario and Quebec, but these provinces have issued position statements or recommendations to health care facilities to encourage policy development and appropriate documentation associated with the reuse and reprocessing of SUDs.

Limitations

There remains a dearth of evidence on the effectiveness and patient safety associated with the reuse and reprocessing of SUDs, and newly available studies are of mixed quality. We did not receive responses from all health ministries given the short time frame of this scan.

Conclusions

There is insufficient evidence to support or rule out harm to patients from the reuse and reprocessing of SUDs. Moreover, the policies and regulations on SUDs vary by jurisdiction. Some jurisdictions do not support the reprocessing of SUDs unless it is performed by a third-party reprocessor, while others do not support the reuse and reprocessing of SUDs under any conditions.

References

1. Hailey D, Jacobs PD, Ries NM, Polisena J. Reuse of single use medical devices in Canada: clinical and economic outcomes, legal and ethical issues, and current hospital practice. Int J Technol Assess Health Care. 2008;24(4):430-6.
2. Polisena J, Hailey D, Moulton K, Noorani H, Jacobs P, Normandin S, et al. Reprocessing of single-use medical devices: national survey of Canadian acute-care hospitals [Internet]. Ottawa: Canadian Agency for Drugs and Technologies in Health (CADTH); 2008. [cited 2010 May 21]. (Technology report number 104).

Available from: http://www.cadth.ca/media/pdf/334A_Reprocessing-SUDs%20National-Survey_tr_e.pdf

3. Sung JK, Levin R, Siegel J, Einhorn TA, Creevy WR, Tornetta P. Reuse of external fixation components: a randomized trial. J Orthop Trauma. 2008 Feb;22(2):126-30.
4. Gartner D, Munz K, Huckelheim E, Hesse U. Ultrasonic scissors. New vs resterilized instruments. Chirurg. 2008 Feb; 79(2):175-9.
5. Update on reprocessing and reuse of single-use medical devices [Internet]. Ottawa: Health Canada, Therapeutics Product Directorate; 2007. [cited 2010 Jun 3]. Available from: http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/lthsud_md_lahimj_im-eng.php
6. Standards for single-use medical devices [Internet]. Edmonton: Alberta Health and Wellness; 2008 Jan 16. [cited 2010 Jun 3]. Available from: http://www.health.alberta.ca/documents/IPC-Medical-Device-Single-Use-2008.pdf
7. Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization in all health care settings [Internet]. Toronto: Ontario Ministry of Health and Long-Term Care; 2009. [cited 2010 Jun 3]. Available from: http://www.health.gov.on.ca/english/providers/program/infectious/diseases/best_prac/bp_cds_2.pdf
8. Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) [Internet]. Montréal: AETMIS; 2009. Reuse of single-use medical devices; 2008 Mar 17 [cited 2010 Jun 3]. Available from: http://www.aetmis.gouv.qc.ca/site/250.1131.0.0.1.0.phtml
9. Summary: reuse of single-use medical devices [Internet]. Montréal: Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS); 2009. [cited 2010 Jun 3]. Available from: http://www.aetmis.gouv.qc.ca/site/phpwcms_filestorage/79c20f9940270fa69869b2336a70bec1.pdf Extract from the report prepared for AETMIS by Geneviève Martin and Lorraine Caron with the collaboration of Alexandra Obadia.
10. Hospital and health care facility standards regulations, N.W.T. Reg. 036-2005 [Internet]. Yellowknife (NWT): Territorial Printer, Northwest Territories; 2009. [cited 2010 Jun 3]. Available from: http://www.canlii.org/en/nt/laws/regu/nwt-reg-036-2005/latest/nwt-reg-036-2005.html

Appendix 1: Study Characteristics and Outcomes

First Author, Year, Country	Study Design	Number of Patients	Outcomes	Conclusions
Gartner, 2008, Germany[4]	Blind, randomized, single-centre trial	New ultrasound scissors = 51 Resterilized ultrasound scissors = 49	• Optimal force of activation: new = 94.1% (48/51) versus resterilized = 95.9% (47/51), P = 1.000 • Optimal cutting action: new = 86.3% (44/51) versus resterilized = 87.8% (43/49), P = 1.000 • Optimal coagulation effect: new = 88.2% (45/51) versus resterilized = 87.8% (43/49), P = 1.000 • Number of unacceptable error messages: new = 4 versus resterilized = 4, P = 1.000 • Number of error messages and disturbing noises: new = 7.8% (4/51) versus resterilized = 6.1% (3/49), P = 1.000 • Number of scissors to be replaced during operation due to persistent problems: new = 11.8% (6/51) versus resterilized = 4.1% (2/49), P = 0.269	The functionality and handling of the new versus resterilized ultrasound scissors was comparable.
Sung, 2008, US[3]	Randomized controlled trial	New external fixation frames = 50 Refurbished external fixation frames = 46	• Incidence of pin tract infections: new = 46% (23/50) versus refurbished = 52% (24/46), P = 0.32 • Loss of fixation: new = 4% (2/50) versus refurbished = 4% (2/46), P = 0.70 • Loosening of components: new = 1% (5/413) versus refurbished = 1% (4/333), P = 1.0	The refurbishment of external fixation devices is safe and effective. The authors indicated a potential cost savings of 25% for the cost of all new external fixation frames.

Appendix 2: Environmental Scan of SUD Policies in Canada

Jurisdiction	Position on Reuse and Reprocessing of SUDs (verbatim)
British Columbia	Policy: • All health authorities must eliminate the reprocessing and reuse of critical contact single-use devices unless they have been reprocessed by a licensed third-party reprocessor, certified by a national regulatory authority, such as Health Canada or the US Food and Drug Administration (FDA).[5]
Alberta	Standards:[6] • Critical or semi-critical single-use medical devices that are labelled by their manufacturers as single-use shall not be reused on any client unless reprocessed by a third-party reprocessor in a manner that ensures that the devices is safe and will function as intended by the manufacturer. • Exception: Semi-critical single-use medical devices may be reused for a single client, where appropriate as determined by the health professional, in the client's home, if the device can be cleaned and maintains function. o The semi-critical single-use medical device reused for a single client shall be cleaned between each use.
Saskatchewan	• Developing a policy on reprocessing SUDs that is consistent with Accreditation Canada standards — prohibiting on-site reprocessing, while potentially allowing use of licensed third-party reprocessors under specific circumstances. (Valerie Phillips, Patient Safety Project, Health — Government of Saskatchewan, Regina: personal communication, 2010 May)
Manitoba	Policy:[5] • Hospitals are not permitted to reuse "critical contact" SUDs (those that contact the bloodstream or a sterile body activity).
Ontario	Recommendations:[7] • The health care setting must have written policies regarding single-use medical equipment/devices. • Critical and semi-critical medical equipment/devices labelled as single-use must not be reprocessed and reused unless the reprocessing is done by a licensed reprocessor. • Needles must be single-use and must not be reprocessed. • It is strongly recommended that catheters, drains, and other medical equipment/devices with small lumens (excluding endoscopy equipment) must be designated single-use and not be reprocessed and reused, even if designated as reusable by the manufacturer. • Home health care agencies may consider reusing single-use semi-critical medical equipment/devices for a single client in their home when reuse is safe and the cost of replacing the equipment/device is prohibitive for the client.
Quebec	Position statements:[8] • Reuse may be justifiable and even desirable in some circumstances. • Hospitals wishing to reuse SUDs are required to develop a policy and procedures governing reuse and to have them approved by their board of directors. Recommendations:[9] • 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 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

Jurisdiction	Position on Reuse and Reprocessing of SUDs (verbatim)

	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.

Nova Scotia	Policy: • Critical and semi-critical medical devices that are labelled by their manufacturers as being represented for single-use must not be reprocessed in hospitals and health care facilities. • Should it be necessary to reprocess these devices for use in hospitals or health care facilities, they must be reprocessed by a certified third-party reprocessor in a manner that ensures that the device is safe and will function as intended by the manufacturer. (Patsy Rawding, Department of Health, Halifax: personal communication, 2010 Jun)
New Brunswick	Policy: • Regional health authorities (RHAs) will not reprocess critical or semi-critical medical devices, which are labelled single-use. • RHAs that wish to have any SUDs reprocessed by a third-party reprocessor must ensure that the reprocessor's facilities and procedures have been certified by a regulatory authority to ensure the cleanliness, sterility, safety, and functionality of the reprocessed devices. • FDA, US standards will be used to ensure patient and staff safety until Canadian regulatory standards have been developed and are in legislation. (Suzanne Jones, Department of Health, Fredericton: personal communication, 2010 Jun)
Prince Edward Island	• The Queen Elizabeth Hospital does not reprocess any single-use devices. (J. David White, Queen Elizabeth Hospital, Charlottetown: personal communication, 2010 Jun)
Newfoundland and Labrador	Policies: • In the Eastern Health Authority, no reuse or reprocessing of single-use devices is permitted. (Merlee Steele-Rodway, Eastern Health, St. John's: personal communication, 2010 Jun) • The Central Health Authority does not support the reprocessing or reuse of medical devices labelled as single-use by the manufacturer. (Penny Ralph, Central Health, Grand Falls-Windsor: personal communication, 2010 Jun) • No response received from the Western and Labrador-Grenfell Health Authorities.
Nunavut	• No response received.
Northwest Territories	Regulation:[10] • A disposable device, intended to be used on a patient during a single procedure, shall not be used on a patient for more than one procedure and shall not be used on another patient.
Yukon	• No response received.

Cite as: Polisena,J. *Reprocessing Single-Use Medical Devices: An Update of the Clinical Evidence and an Environmental Scan of Policies in Canada* [Environmental Scan issue 8]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2010.

****

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, Northwest Territories, Nova Scotia, Nunavut, 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.

****

Canadian Agency for Drugs and Technologies in Health (CADTH)
600-865 Carling Avenue, Ottawa, Ontario K1S 5S8