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Reprocessing of Single-Use Medical Devices: A 2015 Update

Environmental Scan

Background and Context

Health Canada encourages medical device manufacturers to design and seek authorization to sell their products according to their intended use. Therefore, it is up to each manufacturer to decide how to design and label each medical device. Single-use medical devices (SUMDs) that are licensed by Health Canada are intended by their manufacturers to be used once during a single procedure and not to be disassembled, cleaned, reassembled, and reused, where doing so can jeopardize their performance, safety, and effectiveness. In contrast to reusable devices, manufacturers of SUMDs are not obliged to provide instructions for proper cleaning and sterilization.[1]

Provincial and territorial policies regarding the reprocessing of medical devices are typically based on the device category. The internationally accepted classification scheme described by Spaulding, which groups devices according to the risk of infection associated with the device, categorizes medical devices, as follows:[2]

- Critical – Devices that come in contact with blood or normally sterile tissue, such as surgical forceps
- Semi-critical – Devices that come in contact with mucous membranes, such as endoscopes
- Non-critical – Devices that come in contact with unbroken skin, such as stethoscopes.

Reprocessing a medical device encompasses cleaning, reconditioning, function testing, and disinfection or sterilization to ensure that a medical device can safely be reused.[3] According to the responses to a 2007 national survey of Canadian hospitals, a little more than a quarter of health care facilities across Canada reprocessed SUMDs on economic and environmental grounds. Among the facilities that did not report reprocessing SUMDs in that year, the majority (81%) had done so in the past.[4] The reprocessed SUMDs most commonly used by hospitals in Canada include breast pump kits, ventilator circuits, and burrs (drill bits used to cut teeth or bone). Most of the health care facilities (85%) reprocessed SUMDs in-house within a central reprocessing department.[4]

As a result of recent provincial policies banning the in-house reprocessing of SUMDs, health care facilities are increasingly using services offered by commercial third-party reprocessors. Given that there are no commercial single-use device reprocessors in Canada, many Canadian hospital facilities outsource their reprocessing to FDA-licensed, third-party reprocessors in the US.[4] Canadian hospitals using commercial reprocessors have adopted either a closed-loop procurement model (the hospital receives only its own devices back from the third-party reprocessor) or an open-loop model (the hospital does not get its own devices back but rather buys them from a pool of reprocessed devices).

MEDEC, the Canadian association for the medical technology industry, has advocated for federal regulatory oversight for reprocessed SUMDs. MEDEC's position is that Health Canada should regulate third-party reprocessing companies as manufacturers, in the context of Canada's *Medical Devices Regulations*.[5] As part of its advocacy efforts, MEDEC suggested amendments to Bill C-17 (*An Act to Amend the Food and Drugs Act*) to address the issue of Health Canada not having the authority to regulate the reuse and reprocessing of SUMDs by health care facilities or third-party reprocessors.[6]

Objectives

The objective of this report is to provide a summary of the policies and practices across Canada and internationally on the reprocessing of critical, semi-critical, and non-critical SUMDs. It is an update to a previous Environmental Scan that was published in September 2011.[7] The following questions will be addressed:

- What are Health Canada's regulations regarding the reprocessing of SUMDs?
- What are the current policies and practices across Canada on the reprocessing of critical, semi-critical, and non-critical SUMDs in hospitals? If a policy has changed since 2011, what was the rationale for the change?
- What are SUMD reprocessing regulations, policies, and practices outside of Canada?

Findings

It is not intended that the findings of this Environmental Scan will provide a comprehensive review of the topic. Information on the reprocessing of SUMDs is based on a limited literature search and communication with key informants. This report is based on information current as of February 2015.

Federal

Under the *Food and Drugs Act* and *Medical Devices Regulations*, Health Canada has the authority to govern the safety and effectiveness of medical devices, including the manufacturing and sales of SUMDs. Over the past eight years, the federal regulatory approach toward the commercial reprocessing of SUMDs has evolved as the business model of reprocessing has evolved.

2007

In 2007, Health Canada communicated to stakeholders the conclusions of an internal review of its authority to regulate the reprocessing of SUMDs by hospitals or third parties. The review concluded: "*The Food and Drugs Act* is not intended to apply to the use of a device after its sale. Therefore, Health Canada does not have the authority to regulate reuse."[8] At that time, the majority of SUMD reprocessing was being done on-site by hospitals.

2014

By 2014, hospitals were increasingly relying on the services of commercial reprocessors. In spring 2014, through discussions on proposed patient safety legislation (Bill C-17), Health Canada concluded that it had authority, under its existing medical devices regulatory framework, to regulate the commercial reprocessing of SUMDs. In July of that year, Health Canada notified stakeholders that it had received its first licence application to sell a reprocessed SUMD, and had licensed it under the existing regulations. Health Canada approved the application from an original device manufacturer for the sale of a reprocessed, non-invasive, inflatable compression sleeve, which was labelled and authorized for sale for "single-use."[1]

Health Canada applied the current medical device regulatory framework criteria that follows to assess the reprocessor's application:[1]

- The reprocessor supplied Health Canada with the same level of evidence of safety and effectiveness of the reprocessed device that is required for a newly manufactured device.
- The reprocessor provided additional information on the reprocessing methods.

In addition, Health Canada imposed the following conditions on the reprocessed device:[1]

- The reprocessed SUMD will have a different licence number than the original device.
- The reprocessed SUMD will have the single-use symbol removed and be clearly labelled as a reprocessed device.
- The reprocessed SUMD will clearly identify the reprocessor as the manufacturer and provide reprocessing instructions in the label.

Health Canada also indicated that it would apply its existing regulatory framework to anticipated future licence applications. Health Canada's practice of accepting the original manufacturer's reprocessing application aligns with that of other countries, such as the US and Australia, where commercial reprocessors are subjected to the same regulatory requirements as the original manufacturer.

2015

In February 2015, Health Canada issued a "Notice to Stakeholders — Health Canada's Regulatory Approach to Commercial Reprocessing of Medical Devices Originally Labelled for Single Use."[9]

According to the notice, the department would be regulating commercial reprocessing of devices originally labelled for single use by holding reprocessing companies to the same requirements as manufacturers of new devices. This would ensure that commercially reprocessed devices met appropriate standards for safety and effectiveness.[9]

Therefore, commercial reprocessors of medical devices "must meet requirements for licensing, quality system management, labelling, investigating and handling complaints, maintaining distribution records, conducting recalls, reporting incidents and informing Health Canada of any changes to the information in their licence application. To fulfill labelling requirements, reprocessed devices should clearly identify the reprocessor as the manufacturer and contain instructions for safe reuse, such as how or by whom the device should be reprocessed. In addition, the single-use symbol should be removed from the label." Health Canada has stated it will work with commercial reprocessors over an anticipated 18-month period to bring industry activities and products into compliance with the new regulations; including meeting with industry associations to "promote awareness of the regulatory requirements and determine their readiness to meet them."[9]

Commercial reprocessors will need to prepare to phase out the supply of non-compliant devices. By September 1, 2016, commercial reprocessors distributing reprocessed medical devices to Canadian health care facilities are expected to have applied for licences, as appropriate.[9] The regulations will apply to all commercially reprocessed SUMDs, regardless of whether they are reprocessed within or outside of Canada. The oversight of in-hospital reprocessing will continue to be provided at the provincial and territorial levels.

Provincial

Provincial and territorial health authorities have the power to develop their own policies and guidelines related to reprocessing of SUMDs, and these policies vary greatly from one jurisdiction to another.

Prince Edward Island, Newfoundland and Labrador, and all three territories (Northwest Territories,[10] Yukon, and Nunavut[11]) have maintained their positions described in the 2011 CADTH Environmental Scan.[7] That is, these jurisdictions continue to prohibit, regardless of device class and type, both in-house and commercial third-party reprocessing, and hence ban the reuse of medical devices labelled for single-use.

Alberta, similar to what was described in the 2011 CADTH Environmental Scan, does not reprocess or reuse any critical or semi-critical SUMDs, in accordance with the Alberta Health and Wellness *Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices*.[12] However, under the current policy, an exemption can be granted to allow a critical or semi-critical SUMD to be reprocessed following a defined multi-level evaluation of an exception request.[13] The one approved exemption request to date has been for Medela Breast Pump Kits.

Quebec and New Brunswick have maintained their policies from 2011 regarding the reprocessing of semi-critical and critical SUMDs. The current policy for both provinces prohibits

the reuse of semi-critical and critical SUMDs unless the reprocessing is performed by a licensed reprocessor. No explicit directive on the reprocessing of non-critical SUMDs was identified in the Quebec or New Brunswick provincial policies.

In Ontario in 2011, some urban hospitals were reported to be reprocessing non-critical SUMDs via in-house facilities. Concerned with the legal liability, increased risk of patient adverse events, and ethics associated with this practice, the Provincial Infectious Diseases Advisory Committee has since updated its guidelines on *Best Practices for Cleaning, Disinfection and Sterilisation of Medical Equipment/Devices in All Health Care Settings, 3rd edition* (May 2013), as follows: "health care settings must not internally reprocess single use medical equipment/devices" and secondly, "if a facility enters into a contract with a 3rd party reprocessor, the liability for adverse outcomes in the event of improper sterilization or changes to equipment functionality must be clear to both parties."[14] All Ontario hospital contracts with third-party reprocessors include an indemnification clause for device malfunction, as long as it is used for its intended purpose as per the original manufacturer.[14]

British Columbia updated its policy after the publication of the 2011 Environmental Scan. While the policy still allows for the reprocessing of critical SUMDs by licensed third-party reprocessors, exceptions are now mentioned. Hence, needles and "sharps" (i.e., any item capable of cutting or piercing the skin) shall not be reprocessed.[13]

Manitoba revised its policy on the reprocessing and reuse of SUMDs in 2012 in order to end in-house reprocessing of semi-critical and non-critical SUMDs. It now permits FDA-regulated third-party reprocessing of critical, semi-critical, and non-critical SUMDs.[15]

Nova Scotia is currently in the process of issuing an SUMD policy to permit only licensed third-party reprocessing for critical and semi-critical devices. In some jurisdictions, for non-critical SUMDs, a risk assessment is performed for each non-critical device and some may be reprocessed in-house if the risk assessment deems it to be a reasonable option. (Suzanne Rhodenizer Rose, Nova Scotia Health and Wellness, Halifax: personal communication, 2014 November 17).

Saskatchewan has maintained its 2011 policies, which prohibit any in-house reprocessing and requires health care facilities to outsource reprocessing, regardless of the class and type of SUMD, to an FDA-licensed third-party reprocessor.

Information provided by participating Canadian health care leaders on provinces' SUMD reprocessing policies and practices are summarized in Table 1.

TABLE 1: PAN-CANADIAN POLICIES ON THE REPROCESSING OF CRITICAL, SEMI-CRITICAL, AND NON-CRITICAL SINGLE-USE MEDICAL DEVICES

Canadian Jurisdiction	SUMD Reprocessing Policies			Practices[a]
	Device Type	2011	2015	
British Columbia[13,16]	Non-critical	FDA-licensed TPR	FDA-licensed TPR	Reprocessing of critical SUMDs by third-party reprocessors is allowed with exceptions: no reprocessing of sharps and needles. A third-party reprocessor (Stryker Sustainability Solutions) is expanding its reprocessing services offered; however, no information exists on whether these services are being explored and/or acted upon by hospitals.
	Semi-critical	FDA-licensed TPR	FDA-licensed TPR	
	Critical	FDA-licensed TPR	FDA-licensed TPR	
Alberta[12]	Non-critical	Not reprocessed	Not reprocessed	Reprocessing of all SUMDs is prohibited. Exemptions can be granted; however, at the time of the survey, only the Medela Breast Pump Kits were approved for single-patient reuse.
	Semi-critical	Not reprocessed	Not reprocessed	
	Critical	Not reprocessed	Not reprocessed	
Saskatchewan	Non-critical	FDA-licensed TPR	FDA-licensed TPR	Saskatchewan Health prohibits on-site reprocessing of any SUMD. RHAs may use the FDA-licensed reprocessors. At the time of the current survey, none of the RHAs were using third-party reprocessors.
	Semi-critical	FDA-licensed TPR	FDA-licensed TPR	
	Critical	FDA-licensed TPR	FDA-licensed TPR	
Manitoba[17]	Non-critical	In-house	FDA-licensed TPR	Following 2012 changes in Manitoba's policy direction to cease internal reprocessing of all SUMDs, the Winnipeg Regional Health Authority in 2013 signed a procurement agreement with Sterilmed Inc. (an FDA-licensed reprocessor of SUMDs), in partnership with Medique Medical Supply Inc., a Canadian medical device distributor), for SUMD reprocessing that stipulates closed-loop procurement. In contrast, the MHHLS single-use device reprocessing policy does not require procurement agreements to stipulate a closed-loop procurement. The majority of the reprocessed SUMDs are high-cost, critical medical devices.
	Semi-critical	In-house	FDA-licensed TPR	
	Critical	Not reprocessed	FDA-licensed TPR	
Ontario[14]	Non-critical	In-house	FDA-licensed TPR	Several hospitals in Ontario are contracting third-party reprocessors for SUMD reprocessing services under a closed-loop procurement model.
	Semi-critical	FDA-licensed TPR	FDA-licensed TPR	
	Critical	FDA-licensed TPR	FDA-licensed TPR	

Canadian Jurisdiction	SUMD Reprocessing Policies			Practices[a]
	Device Type	2011	2015	
Quebec	Non-critical	In-house	In-house	The Quebec government supports the recommendations from a 2009 report issued by AETMIS (now INESSS), which states that health care institutions should stop their in-house reprocessing and sub-contract reprocessing to a third-party reprocessor recognized by a regulatory authority. Since 2009, all Quebec hospitals require a closed-loop procurement model for devices reprocessed by a third party.
	Semi-critical	FDA-licensed TPR	FDA-licensed TPR	
	Critical	FDA-licensed TPR	FDA-licensed TPR	
New Brunswick	Non-critical	In-house	In-house	New Brunswick is working with Sterilmed as a third-party reprocessor. High-cost devices are more likely to be reprocessed because of cost-savings. *SUMDs currently being reprocessed:* Non-critical SUMDs — oxygen sensors and tensor stockinets, sequential compression devices, bed alarms, external fixation devices Semi-critical SUMDs — respiratory equipment Critical SUMDs — trocars; tissue coagulation devices; harmonic scalpels; laparoscopic instruments; and saw, shaver, and surgical blades
	Semi-critical	FDA-licensed TPR	FDA-licensed TPR	
	Critical	FDA-licensed TPR	FDA-licensed TPR	
Nova Scotia	Non-critical	In-house	In-house	Risk assessment is performed for non-critical devices to establish the appropriateness of in-house reprocessing.
	Semi-critical	FDA-licensed TPR	FDA-licensed TPR	
	Critical	FDA-licensed TPR	FDA-licensed TPR	
Prince Edward Island	Non-critical	Not reprocessed	Not reprocessed	N/A
	Semi-critical	Not reprocessed	Not reprocessed	
	Critical	Not reprocessed	Not reprocessed	
Newfoundland and Labrador	Non-critical	Not reprocessed	Not reprocessed	N/A
	Semi-critical	Not reprocessed	Not reprocessed	
	Critical	Not reprocessed	Not reprocessed	

Canadian Jurisdiction	SUMD Reprocessing Policies			Practices[a]
	Device Type	2011	2015	
Northwest Territories[10]	Non-critical	Not reprocessed	Not reprocessed	N/A
	Semi-critical	Not reprocessed	Not reprocessed	
	Critical	Not reprocessed	Not reprocessed	
Nunavut[11]	Non-critical	Not reprocessed	Not reprocessed	N/A
	Semi-critical	Not reprocessed	Not reprocessed	
	Critical	Not reprocessed	Not reprocessed	
Yukon	Non-critical	Not reprocessed	Not reprocessed	N/A
	Semi-critical	Not reprocessed	Not reprocessed	
	Critical	Not reprocessed	Not reprocessed	

AETMIS = Agence d'évaluation des technologies et des modes d'intervention en santé; FDA = Food and Drug Administration (US); INESSS = Institut national d'excellence en santé et en services sociaux; MHHLS = Manitoba Health, Healthy Living and Seniors; N/A = not applicable; RHA = regional health authority; SUMDs = single-use medical devices; TPR = third-party reprocessor.
[a] Policies and practices have been informed by publicly available documents and input from key jurisdictional informants.

International

This Environmental Scan did not identify any changes in SUMD reprocessing policies and practices for the international countries included in the 2011 CADTH Environmental Scan.[7]

In 2000, the US FDA started regulating hospitals — defined as acute health care facilities — and third-party reprocessors of SUMDs by subjecting them to all of the regulatory requirements applicable to original device manufacturers.[18] Furthermore, the FDA assesses the quality and adequacy of supporting evidence to regulate the reprocessing of SUMDs. As of August 2011, the FDA had permitted the reuse of about 70 devices,[19] divided into the following three categories:

- High-risk (e.g., balloon angioplasty catheter, implanted infusion pumps); reprocessed only if sufficient evidence of safety and effectiveness is available and the facility has been inspected
- Medium-risk (e.g., ultrasound catheters, laparoscopic equipment); requires the same evidence of safety and effectiveness as high-risk devices but facility inspection is not required
- Low-risk (e.g., elastic bandages, tourniquet cuffs); reprocessed without having to submit any evidence.

In Australia, the Therapeutic Goods Administration introduced regulations in 2003 for hospital and third-party reprocessors of SUMDs. Reprocessors, or "remanufacturers" as described in the legislation, must conform to the same regulatory standards as the original manufacturer and are required to demonstrate that the reprocessed SUMDs are as equally safe and perform as well as the original manufactured device.[20] According to the Association of Medical Device Reprocessors, both the US and Australia have seen a sharp decline in the number of hospitals reprocessing SUMDs in-house, likely because of the high costs and stringent regulatory requirements.[19,21]

The European Union's medical devices directive currently does not include regulation regarding the reprocessing of SUMDs and therefore each nation's legislation regulates this practice differently throughout Europe. For example, in Germany, the existing regulatory framework addresses only quality standards and validated procedures for reprocessing and makes no legal distinction between single- and multiple-use medical devices.[22] Both in-house and third-party reprocessing are allowed but must conform to German regulations on reprocessing, which stipulate that institutions reprocessing SUMDs must adopt and implement a quality management system in accordance with the recommendations by the Commission for Hospital Hygiene and Infection Prevention. In the United Kingdom, the Medicines and Healthcare Products Regulatory Agency cautions against reprocessing and emphasizes the legal responsibilities of organizations preparing SUMDs for reuse.[15] In contrast, the reuse of SUMDs is considered off-label in France, and it is therefore illegal; such practice is thought of as deceptive to the patient.[23] The aforementioned examples illustrate the policies and guidelines of a few European countries — the majority of member states have not issued regulations on the reuse of SUMDs.

In 2010, the European Commission submitted a report to the European Parliament highlighting that not all SUMDs are suitable for reprocessing and calling for the regulation of the entire reprocessing cycle of SUMDs, from collection of the SUMD until final delivery of the SUMD, to ensure health and safety protection.[24] As a result, the European Parliament is considering an amendment to the current legislation that would regulate the reprocessor as if it was the manufacturer of the reprocessed SUMD (i.e., a first-time submission). The proposed amendments would also authorize the Commission to establish and regularly update a list of devices or types of SUMDs that are unsuitable for reprocessing.[25]

Finally, although reprocessing and reuse of SUMDs is practised in numerous countries in Asia, Africa, and the Middle East, the practice is currently not regulated.[21] The vast majority of the reprocessing is done at the facility level because there is an absence of third-party reprocessors.

Conclusion

Canadian jurisdictions that allow the reuse of SUMDs have two forms of reprocessing: either in-house, which may be regulated by existing provincial policies and guidelines; or outsourcing to commercial third-party reprocessors based in the US, and which are regulated by the US FDA.

Traditionally, the reprocessing of SUMDs was done in-house by hospitals, with oversight provided at the provincial and territorial levels. Increasingly, hospitals rely on the services of commercial reprocessors to clean and sterilize their SUMDs for reuse. In 2014, through discussions on proposed patient safety legislation, Health Canada concluded that it had authority, under its existing medical device regulatory framework, to regulate the commercial reprocessing of SUMDs. In July 2014, for the first time, Health Canada received an application and issued a licence for a reprocessed device. In February 2015, Health Canada communicated that it would be requiring all commercial reprocessors that distribute devices to Canadian health care facilities to meet the same regulatory requirements as manufacturers of new devices, regardless of whether they are reprocessed domestically or outside Canada. This is to help ensure that these devices meet appropriate standards for safety and effectiveness and will be implemented over an anticipated 18-month transition. Oversight of in-hospital reprocessing departments will continue at the provincial and territorial levels.

Regarding provincial practices, since CADTH's last Environmental Scan in 2011,[7] Ontario,[14] Manitoba,[17] British Columbia,[13] and Nova Scotia

have new policies and guidelines on the reprocessing of SUMDs. As of 2012, Manitoba no longer allows in-house reprocessing but permits commercial third-party reprocessing of all SUMDs.[17] Similarly, the 2013 guidelines released by the Ontario Agency for Health Protection and Promotion (Public Health Ontario) strongly discourage in-house reprocessing.[14] In contrast, Nova Scotia permits only commercial third-party reprocessing of semi-critical and critical SUMDs but allows in-house reprocessing of non-critical devices. In British Columbia, some critical devices are now excluded from reprocessing based on their intended use.[13]

Currently, the following provinces utilize commercial third-party reprocessors: British Columbia, Manitoba, Ontario, Quebec, New Brunswick, and Nova Scotia. While British Columbia, Manitoba, and Ontario outsource the reprocessing of all SUMDs, Quebec, Nova Scotia, and New Brunswick outsource the reprocessing of only semi-critical and critical SUMDs. In contrast, Alberta, Prince Edward Island, and Newfoundland and Labrador, as well as the three territories (Northwest Territories, Yukon, and Nunavut), do not reprocess any SUMDs.

There is considerable diversity internationally in the legislation and practice of reprocessing SUMDs, with only a few countries formally regulating the reprocessing, including the US, Australia, and New Zealand.

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