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# Reprocessing of Single-Use Medical Devices: A 2011 Update

Environmental Scan

## Context

The reprocessing of single-use medical devices (SUMDs) has gained wide popularity over the last decade, mainly because the practice is believed to be less expensive than using a disposable medical device only once.[1] SUMDs range from non-critical devices, such as disposable blood pressure cuffs, to critical devices, such as urinary catheters and biopsy forceps. Reprocessing involves cleaning, reconditioning, function testing, and disinfecting or sterilizing SUMDs.[2] SUMDs are not designed or licensed to be disassembled, cleaned, reassembled, and reused,[3] and doing so can jeopardize their performance, safety, and effectiveness. The reuse of SUMDs has evoked significant international interest in the creation of standards and legislation regarding their reuse.

Reprocessing of SUMDs takes place either within the central processing department of a health care facility, or is done by a third-party reprocessor. Third-party reprocessing is not regulated in Canada; reprocessing facilities used by some Canadian health care facilities are registered with the United States Food and Drug Administration, and are subject to the same regulatory requirements as the original equipment manufacturers.[4]

Accreditation Canada, a not-for-profit independent organization that assesses health organization services, does not support on-site reprocessing or sterilization of SUMDs. Licensed third-party reprocessing is regarded as acceptable, as long as processors are routinely monitored.

MEDEC, Canada's association for the medical technology industry, advocates banning the reprocessing of critical SUMDs that penetrate the skin or sterile tissue. MEDEC supports the position that single-use semi- and non-critical devices should not be reprocessed in house by any hospital or health facility, and reprocessing of these devices should be banned until such time as there are Canadian regulations that hold third-party reprocessors to the same regulatory standards as original device manufacturers.[5]

## Objectives

The purpose of this report is to provide an update on policies and practices across Canada and internationally on the reprocessing of critical, semi-critical, and non-critical SUMDs. This report will update information presented in a previous Environmental Scan, released in June 2010.[6] The following questions will be addressed:

- What are Health Canada's regulations regarding the reprocessing of SUMDs?
- What are the policies across Canada on the reprocessing of critical, semi-critical, and non-critical SUMDs in urban and rural hospitals?
- What are SUMD reprocessing practices outside of North America?

## Findings

It is not intended that the findings of this Environmental Scan provide a comprehensive review of the topic. Information on the reprocessing of SUMDs was provided by provincial and regional health authorities, and selected urban and rural hospitals. The results of this report are based on a limited literature search and communication with key informants. This report is based on information gathered as of August 2011.

## Federal

Health Canada does not have the authority to regulate the reuse and reprocessing of SUMDs by health care facilities or third-party reprocessors. Federal legislation governing the safety and effectiveness of medical devices is only intended to apply to the manufacturing and sale of devices. The reuse and reprocessing of SUMDs fall outside the governance of the *Food and Drugs Act* and *Medical Devices Regulations*. This year, Health Canada is developing a position that will distinguish between refurbished devices and reprocessed devices. The provincial and territorial governments and regional health authorities are responsible for reprocessing policies and practices, and these vary from one jurisdiction to another.

## Provincial

Three provinces (Saskatchewan, Prince Edward Island, and Newfoundland and Labrador) currently do not support the reprocessing of SUMDs. Newfoundland and Labrador is revising its policies on the reprocessing and reuse of SUMDs this year. In 2005, the Northwest Territories banned the reuse of any device labelled as single use.

Reprocessing and reuse of SUMDs by a licensed third-party reprocessor occur in six provinces (British Columbia, Manitoba, Ontario, Quebec, New Brunswick, and Nova Scotia).

Alberta does not currently reprocess critical and semi-critical SUMDs, in accordance with the Alberta Health and Wellness *Standards for Single-Use Medical Devices*. A ministerial directive to Alberta Health Services will allow it to develop criteria and a process to approve exemptions on a case-by-case basis for the reprocessing of SUMDs.

Manitoba's existing policy prohibits the reprocessing of critical SUMDs and provides criteria and process for the in-house safe reuse of specific semi-critical and non-critical SUMDs. Currently, one regional health authority outsources reprocessing of some non-critical SUMDs to a third-party reprocessor.

Manitoba's policy for reprocessing and reuse of SUMDs is actively under review.

New Brunswick and Ontario reprocess in house some non-critical SUMDs and outsource semi-critical and critical SUMDs to third-party reprocessors. Ontario has issued recommendations to health care facilities to encourage policy development and appropriate documentation associated with reuse and reprocessing of SUMDs.

Quebec does not support the reprocessing of SUMDs. Hospitals that do reprocess SUMDs are encouraged to outsource only critical and semi-critical SUMDs to third-party reprocessors. Quebec does not have a position on the reprocessing of non-critical SUMDs.

Information provided by Canadian health care officials who participated in the provincial scan is 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 | Reprocessing Policies and Practices |
|---|---|
| British Columbia | Reprocessing of non-critical, semi-critical, and critical SUMDs is outsourced to a licensed third-party reprocessor. In-house reprocessing is not allowed. *Best Practice Guidelines for the Cleaning, Disinfection and Sterilization of Medical Devices in Health Authorities*. BC Ministry of Health, 2007: http://www.health.gov.bc.ca/library/publications/year/2007/BPGuidelines_Cleaning_Disinfection_Sterilization_MedicalDevices.pdf |

| Canadian Jurisdiction | Reprocessing Policies and Practices | |
|---|---|---|
| Alberta | Critical and semi-critical SUMDs are not currently reprocessed for reuse in Alberta Health Services facilities, or in facilities providing health services under contract to Alberta Health Services.<br>*Standards for Single-Use Medical Devices: As Applied to Critical and Semi-Critical Medical Devices*. Alberta Health and Wellness, Government of Alberta, 2011: http://www.health.alberta.ca/documents/IPC-Medical-Device-Single-Use-2011.pdf | |
| Saskatchewan | Does not reprocess any SUMDs. Some RHAs have strengthened their own policies to ensure SUMDs are not reprocessed in their regions. | |
| Manitoba | Does not reprocess any critical SUMDs. Some non-critical SUMDs are reprocessed by a third-party reprocessor. | |
| Ontario | Rural hospitals: | |
| | Do not reprocess any SUMDs. | |
| | Urban hospitals: | |
| | A | Reprocessing of all types of SUMDs is outsourced to third-party reprocessor. |
| | B | Non-critical SUMDs are reprocessed by in-house facility. Semi-critical and critical SUMDs are reprocessed under certain conditions; no reprocessing currently. |
| | C | No SUMDs are reprocessed. |
| | *Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/ Devices in All Health Care Settings*. Ontario Ministry of Health and Long-Term Care, 2010: http://www.ontariochiropodist.com/Sites/1/Uploads/Images/56201091129AM.pdf | |
| Quebec | Reprocesses semi-critical and critical SUMDs by an outsourced third-party reprocessor.<br>*Reuse of Single-Use Medical Devices*. Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS), 2008: http://www.aetmis.gouv.qc.ca/site/phpwcms_filestorage/79c20f9940270fa69869b2336a70bec1.pdf | |
| New Brunswick | Rural/urban hospitals: Critical or semi-critical SUMDs that are labelled single use are reprocessed by a third-party reprocessor. Any RHA that wishes to have any SUMDs reprocessed by a third-party reprocessor must ensure the reprocessor's facilities are certified by a regulatory authority and meet US FDA standards, until Canadian regulatory standards are legislated. Some non-critical SUMDs are reprocessed in house.[7] | |
| Nova Scotia | DHAs | 9 of 10 DHAs do not reprocess any SUMDs.<br>4 of the 9 are introducing or are considering using third-party reprocessors.<br>1 DHA reprocesses only non-critical SUMDs by an outsourced third-party reprocessor. |
| Prince Edward Island | Rural/urban hospitals: Do not reprocess any SUMDs. | |
| Newfoundland and Labrador | • Rural/urban hospitals: Do not reprocess any SUMDs.<br>• Urban area revising the SUMD policy this year (2011). | |

BC = British Columbia; DHA = district health authority; FDA = Food and Drug Administration; RHA = regional health authority; SUMDs = single-use medical devices.

### International

The European Union permits the reprocessing of SUMDs,[8] although the practice varies across member countries. In France, the reuse of SUMDs is illegal.[8] In Germany, guidelines indicate that some SUMDs are permitted to be reprocessed and reused if product-specific validated procedures or quality standards are followed.[9] These guidelines include enhanced requirements for critical and semi-critical devices.[10] German reprocessing facilities must also be registered.[11] In Sweden, reprocessing is permitted, but hospitals that reuse SUMDs are considered to be manufacturers. Patient consent is also required for the reuse of SUMDs in Sweden.[11]

In the United Kingdom, the Medicines and Healthcare Products Regulatory Agency advises against reprocessing,[12] and United Kingdom health authorities have issued guidance that warns of the potential safety issues associated with the reuse of SUMDs.[8]

In 2010, the European Commission (EC) submitted a report to the European Parliament and Scientific Committee on Emerging and Newly Identified Health Risks on the reprocessing of medical devices.[13] The EC is currently developing policy options regarding the reprocessing of SUMDs that will be proposed in 2012, in context of the recast of the Medical Devices Directives.[14] These policy options will likely include either a complete ban on the reprocessing of SUMDs or a regulation of reprocessing facilities with the potential for the reprocessing of some critical devices to be banned.

Most EC member countries that do not currently have quality standards or legislation in place for the reprocessing and reuse of SUMDs are waiting for direction from the 2012 recast of the Medical Devices Directive before developing processes.

The EC's Scientific Committee on Emerging and Newly Identified Health Risks also produced a report on the safety of reprocessed SUMDs for the EC. The report concluded that not all SUMDs are suitable for reprocessing, and reprocessing practices must be evaluated and validated.[15]

While the reprocessing of SUMDs is not promoted in Australia, the practice still occurs. Australian reprocessors are required to apply the same conformity assessment procedures for a reprocessed product as the original equipment manufacturer.[13] The Australian Therapeutic Goods Administration is expected to revise its policy this year to allow the reprocessing and reuse of SUMDs.[16]

Japan and India practise the reprocessing of SUMDs; however, in Japan, a SUMD cannot be reprocessed if it is labelled single use and if the instructions for use contain the term "reuse is prohibited."[13] If a hospital's reuse of a SUMD results in a medical incident, liability is the responsibility of the hospital, as reuse of SUMD is considered to be "off-label use."

## Conclusion

Health Canada does not have the authority to regulate the reuse and reprocessing of SUMDs. Three provinces do not reprocess any SUMDs. Six provinces reprocess SUMDs through third-party reprocessors. Three provinces reprocess non-critical SUMDs within hospitals, and outsource semi-critical and critical SUMDs to third-party reprocessors. One province does not reprocess any critical or semi-critical SUMDs. Two provinces are currently reviewing their policies on the reprocessing of SUMDs. Internationally, there is considerable diversity in legislation and practice, with most countries sanctioning the reprocessing of SUMDs. Some countries have enforced quality standards and provide guidance.

Complementing this Environmental Scan, CADTH has published a Rapid Response report on guidelines and cost-effectiveness decision criteria for selecting SUMDs. CADTH published a Health Technology Assessment on the reprocessing of SUMDs in Canada in 2008, and a pan-Canadian Environmental Scan on reprocessing practices in 2010. These summaries are available for free on the CADTH website.[6,17,18]

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