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To: Hospital Administrators
Hospital Risk Managers
Hospital Infection Control Practitioners
Hospital Biomedical Engineering Departments
Provincial Hospital Associations
Canadian Healthcare Association
Provincial Health Ministries
Canadian Medical Protective Association
Canadian Medical Association
Colleges of Physicians and Surgeons
Canadian Dental Associations

RE: REPROCESSING AND REUSE OF SINGLE-USE MEDICAL DEVICES

Dear Sir/Madam:

This letter is to advise you of recent developments on the issue of the reuse of single-use medical devices.

BACKGROUND

On July 30, 2004, Health Canada issued an advisory letter to health care facilities entitled "Reprocessing of Reusable and Single-Use Medical Devices", stating that Health Canada is concerned that reusing single-use devices (SUDs) may be hazardous to patients ¹.

RECENT DEVELOPMENTS

Ontario

Ontario has established a Medical Devices Reprocessing (MDR) Working Group, a collaborative effort between the Ontario Ministry of Finance and the Ministry of Health and Long-Term Care. Among the Working Group's tasks are to:

- Establish regulations on the reprocessing of SUDs

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- Establish an entity to coordinate third-party reprocessing of SUDs on behalf of Ontario hospitals
- Helping hospitals establish a framework to evaluate alternatives for reprocessing SUDs and re-useable devices

The Working Group has initiated discussions with two US-based third-party reproducers to ascertain their interest in expanding their Canadian business and establishing a reprocessing facility in Ontario.

British Columbia

British Columbia's Patient Safety Task Force has announced that it will establish a short-term provincial committee to review the reuse policies in each of the Province's health authorities and to make recommendations for the development of a single process at the Provincial level.

Northwest Territories

The Northwest Territories Department of Health and Social Services is planning to revise the Hospital Standards Regulations to include a requirement that a single-use device shall not be used on a patient for more than one procedure and shall not be used on another patient. It is expected that the new regulations will come into force in April, 2005.

Health Canada

Health Canada is concerned that reusing single-use devices, as it is currently practised in many Canadian hospitals and other health care settings, may be hazardous to patients. Few of the hospitals that reuse critical-contact SUDs have reuse committees, written procedures, or systems to track usage of the devices.^{2, 3}

Health Canada's Scientific Advisory Panel on Reprocessing of Medical Devices (SAP-RMD), held its first meeting on February 10 and 11, 2005, in Ottawa. Although the final recommendations of the SAP-RMD have not yet been submitted, the members endorsed a motion that Health Canada advise healthcare facilities and professionals of the following:

In order to minimize the risks to patients:

1. Health care facilities and health care providers should not reprocess single-use devices unless the facility has established quality systems for reprocessing that include:
 - (a) A reuse committee to establish policies and ensure adherence to approved procedures
 - (b) Written procedures for each type of device that is reprocessed
 - (c) Validation of cleanliness, sterility and function of the reprocessed devices
 - (d) Continual monitoring of reprocessing procedures to ensure their quality

2. Health care facilities that wish to have their SUDs reprocessed by a third-party reprocessor should ensure that the reprocessor's facilities and procedures have been certified by a regulatory authority or an accredited quality system auditor to ensure the cleanliness, sterility, safety and functionality of the reprocessed devices.

Yours sincerely,

Original Signed by

Omer Boudreau
Director General

References

1. Health Canada letter to hospital administrators, "Reprocessing of Reusable and Single-Use Medical Devices", July 30, 2004.
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/letter_reprocess_e.html
2. Mahoney, J et al. Reuse of Medical Devices Labeled by the Manufacturer for 'Single Use' Only, contract report to the Advisory Committee on Health Services, May, 2001.
3. Miller MA, Gravel D and Paton S, Reuse of Single-use Medical Devices in Canadian Acute-care Healthcare Facilities Canada, Communicable Disease Report, vol. 27-23, Dec.1, 2001.
(<http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/01vol27/dr2723ea.html>).