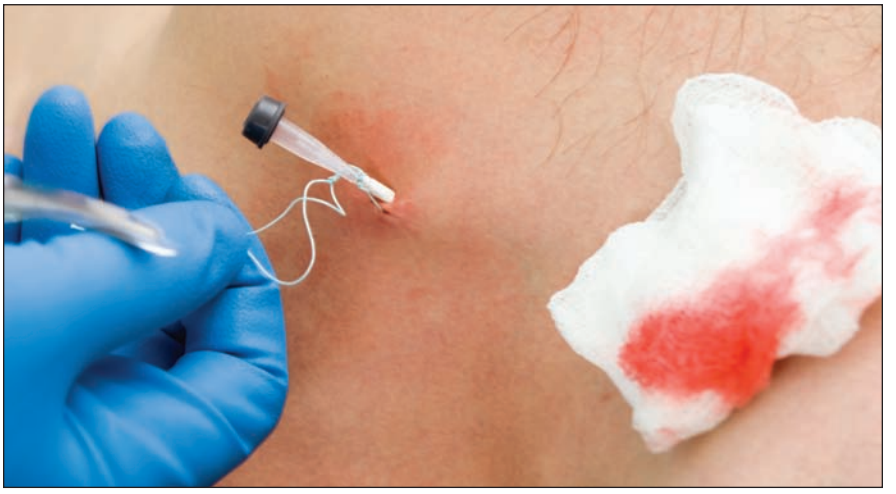
Reprocessing single-use devices: an international perspective

Do you dispose of the plastic baggie or save it for tomorrow's ham sandwich? Do you throw away the plastic fork or wash it and stick it in the drawer with your stainless steel cutlery? With respect to cost and safety, these are minor decisions. Matters become more complicated when the disposable item is a $5000 ultrasound catheter.

Reusing medical devices labelled as single-use is a common practice in many hospitals. Advocates of reprocessing say it is safe, if done properly, and good for the environment and hospital budgets. But concerns about patient safety and liability for adverse events make it a practice *non grata* in some hospitals.



Catheters, needles, syringes and other common devices are often reprocessed in developing nations.

In Canada, over a quarter of hospitals reuse single-use devices, similar to the rate in the United States. As for regulating reuse, however, the countries differ substantially. "Across Canada, there is no common regulation with regard to reprocessing single-use devices," says Julie Polisena, clinical research manager for the Canadian Agency for Drugs and Technologies in Health. "Provinces can provide direction, and regulations can be imposed or it may be up to hospitals or regional health authorities."

Polisena is the lead author of a survey indicating that 28% of Canadian hospitals reprocess single-use medical devices (www.cadth.ca/en/products/health-technology-assessment/publication/800). Of those that don't, 81% have done so before. Commonly reprocessed devices include breast pump kits, ventilator circuits and burrs. Most hospitals that reprocess such devices clean and sterilize them in-house, though only 60% have written policies on the practice. Also lacking was information on patient safety, such as adverse events linked to reprocessed devices. "They were reluctant to relay that information," says Polisena. "Or they didn't capture that information."

In the United States, the Food and Drug Administration (FDA) regulates which single-use medical devices can be reprocessed. It permits the reuse of about 70 devices, divided into three categories: high-risk (balloon angioplasty catheters, implanted infusion pumps), reprocessed only if there is sufficient evidence of safety and effectiveness and the reprocessing facility has been inspected; medium-risk (ultrasound catheters, laparoscopic equipment), which require the same evidence as high-risk devices but no inspection; and low-risk (elastic bandages, tourniquet cuffs), reprocessed without submission of efficacy or safety data.

In addition to these regulations, the "Medical Device User Fee and Modernization Act" states that all single-use devices prepared for reuse in the United States must be labelled as reprocessed and indicate the reprocessor (40%–50% of devices are reprocessed by third-party companies).

According to a 2010 report, reprocessing single-use items is also common in Spain (80% of hospitals), Germany (40% of hospitals) and Japan (80%–90% of hospitals), as well as in third-world countries (*IJHEH* 2010; 213:302-7). In developing nations, reprocessed items include needles, syringes and urinary catheters, often shared without being adequately cleaned, leading to infections of HIV and hepatitis B and C. In developed nations, only expensive, high-tech devices are reprocessed and the practice is safe if regulated and conducted carefully. "In developed countries it seems reasonable to validate reprocessing," the report states. "Clear guidelines and defaults for the reprocessing of medical devices including appropriate control mechanisms are the preconditions to using the medical devices safely and with economic advantage."

Still, some countries have moved away from the practice. In Australia, half of hospitals used to reprocess single-use devices, but that dropped sharply after the introduction of a law in 2005 that required all reprocessors, including hospitals that reprocess in-house, to meet the same regulatory standards as medical device manufacturers.

Other nations, the report states, have no national regulations, including Canada. Health Canada has collaborated with the Canadian Health Care Association to produce guidelines for reprocessing single-use items (www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/reprocess_retraitement_let-eng.pdf). The recommendations include the creation of a reuse committee, written reprocessing procedures, quality assurance and validation of sterility and functionality of devices. The Canadian Patient Safety Institute, a nonprofit advocate for patient safety, has not issued guidelines or policies in this area.

Any regulations that do exist in this area are set at the provincial level. "Nevertheless," the report states, "in some Canadian jurisdictions the practice occurs with little or no regulation." — Roger Collier, *CMAJ*

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