Summary

Reuse of Single-Use Medical Devices

Introduction

The various types of single-use medical devices (SUDs) that have emerged on the market over the last few decades help prevent disease transmission to other patients and device malfunction through wear and tear. However, for economic reasons, some health-care institutions have decided to reuse these devices, some of which are quite expensive. A recent survey showed that 28% of the Canadian hospitals and 44% of the Québec hospitals that responded to it reuse single-use devices—medical devices intended for one-time use are reused on several patients and reprocessed between uses. While the survey revealed that 17 Canadian acute-care hospitals, including 4 in Québec, subcontract to a U.S. company specializing in reprocessing SUDs, it did not mention whether any quality control was performed in the other hospitals. The survey did indicate that one of the main reasons for abandoning reuse was concern over patient safety. Indeed, the reuse of SUDs, as currently practised in Québec and elsewhere in Canada, raises clinical, economic, legal and ethical issues, which will be dealt with in this report.

Like all medical instruments, SUDs are classified according to the risk of infection posed by their use, that is, non-critical devices (that do not touch the patient or touch only intact skin), semi-critical devices (that come in contact with non-intact skin or mucous membranes without penetrating them) and critical devices (that penetrate the skin or sterile tissues). Critical medical devices present the highest risk because they can release multiple types of foreign matter directly into the patient's bloodstream, potentially causing adverse clinical reactions (infection, embolism, toxicity, etc.). Moreover, SUDs are not designed (in principle) to be reprocessed, since the small size or the acute angles of some models make them difficult to refurbish and inspect. Critical SUDs have the potential to remain contaminated after being reprocessed and to allow various types of aggressors to cross the human body's main protective barrier. The quality of reprocessing is therefore of paramount importance for maintaining the safety and effectiveness of reused SUDs. This chiefly means establishing validated reprocessing protocols that take into account the different types and models in use, implementing a device-tracking system, and ensuring compliance with them.

In the early 1990s, Québec's Ministère de la Santé et des Services sociaux (MSSS) asked the Conseil d'évaluation des technologies de la santé (CETS), the predecessor of AETMIS, to study the reuse of SUDs. Following the release of the CETS reports, the MSSS issued a position statement in 1994 declaring that reuse may "be justifiable and even desirable in some circumstances". The MSSS subsequently required hospitals wishing to reuse SUDs to develop a policy and procedures governing reuse and to have them approved by their board of directors.

Since then, several organizations and working groups both in Québec and elsewhere in Canada have revisited the issue of reusing SUDs and its potential risks. Two recommendations in particular were issued: to stop reusing critical and semi-critical devices or to use a licensed third-party reprocessor. In view of these recommendations, the regulatory gap on this issue and the new legislation on the safe delivery of health-care services in Québec, the MSSS asked AETMIS to re-examine the different issues surrounding the reuse of SUDs. A review of the ministerial position on this issue is in fact addressed in the MSSS's 2006–2009 action plan on preventing and controlling nosocomial infections (*Plan d'action sur la prévention et le contrôle des infections nosocomiales 2006–2009).*

Analysis of the efficacy and safety of single-use medical devices

Considering the potential risks cited above, a scientific literature review was undertaken to assess currently available evidence on the efficacy and safety of reusing certain reprocessed SUDs. This study covered nineteen types of critical or semi-critical devices and took into consideration the conclusions drawn in the assessments by the CETS, the New Zealand Health Technology Assessment (NZHTA) and the Canadian Agency for Drugs and Technologies in Health (CADTH).

Evaluation of that evidence led to the following conclusions:

- Like the NZHTA and the CADTH, AETMIS considers that the conclusions in the studies on the safety and efficacy of reused SUDs cannot be generalized to these devices as a whole because these outcomes differ from one device to the other.
- Regarding the different types of critical or semi-critical SUDs analyzed in the present report,
  a) there is sufficient evidence to conclude that it is safe and effective to reuse single-use hemodialysis membranes;
  b) the conclusions that can be drawn about the other types of SUDs are limited by the small number of scientific studies and by the poor quality, low level of evidence and in vitro nature of these studies.
- Nevertheless, if we were to set aside the criterion of having a "sufficient" number of studies and focus more on the in vitro or in vivo nature of the available studies and their level of evidence, we could conclude the following:
  a) In vitro studies on reused electrophysiological catheters showed that these instruments may be sterile and thus safe if they are properly reprocessed; however, even if an in vivo study supports that statement, evidence is still insufficient to justify reusing them in clinical practice.
  b) Among the studies on percutaneous transluminal coronary angioplasty (PTCA) catheters, the in vitro studies reported various problems with catheter integrity, the clinical effects of which need study. According to the in vivo studies and the CETS, the reuse of these catheters may be safe and effective if strict reprocessing and inspection protocols are followed.
  c) The studies on orthopedic external fixator components, all done in vivo, suggested that their reuse may be safe and effective, but these studies alone do not support this clinical practice.
  d) In vitro and in vivo studies on sphincterotomes showed that the reuse of these instruments may be safe if they undergo stringent reprocessing; however, there is insufficient evidence to support this practice in clinical settings.
  e) The in vitro studies on reused laparoscopy instruments indicated that they can remain contaminated after being reprocessed, while the in vivo studies (including one of a large number of patients and two with a high level of evidence) showed that instruments reused in clinical settings can be safe and effective if they are reprocessed according to stringent guidelines.
  f) The studies on reused biopsy forceps, all conducted in vitro, stated that they can remain contaminated and may therefore not be safe after being reprocessed.

Economic aspects of reusing single-use medical devices

It is true that reusing SUDs in principle allows for a more cost-effective use of resources and that this argument alone prompts hospitals to adopt this practice. However, most of the very few economic studies on this issue took into account only certain factors liable to affect the cost of this practice, not all of them as a whole. The economic benefits of reusing SUDs varies according to the device studied and how often it is reused. Reprocessing techniques and the effects of reusing SUDs in the Québec health-care system will need clinical studies, and the cost of such research will need to be taken into account.

Legal and administrative framework for reusing single-use medical devices

In 2006, Health Canada stated that it did not have the authority to regulate the use, cleaning or maintenance of medical devices after their sale. In fact, Canadian laws and regulations govern only the marketing of medical devices—their manufacture, advertising and sale—not their after-sale use. Reprocessed SUDs are therefore not subject to the requirements set out in current federal legislation on the safety and effectiveness of medical devices. However, the provinces do have jurisdiction over the use of medical equipment/devices, including the reuse of SUDs.

The governments of several provinces and territories have developed policies or directives on the reprocessing and reuse of SUDs. In general, the provinces and territories follow two different approaches: Some have banned the reuse of critical devices (Manitoba), including all single-use devices (Northwest Territories), while others have ruled that health-care facilities must cease their in-house reprocessing of critical and semi-critical SUDs, and, if they want to continue reusing these SUDs, they must subcontract to a third-party reprocessor licensed by a regulatory authority (such as the Food and Drug Administration for companies located in the U.S.) and qualified to supply a final product that meets the standards and requirements applicable to all manufacturers of SUDs (Alberta, British Columbia, New Brunswick and Ontario). The second approach was also favoured in a recent pan-Canadian framework.

In Canada's current legal context, if a Canadian company or a Canadian affiliate of a foreign company carried out reprocessing operations on Canadian soil, it would not be subject to any law or regulation in this area. There is also the question of whether or not the Canadian affiliate of a U.S. company would be subject to the requirements in force in the United States. Even if an affiliate could be obliged to meet those requirements and give a guarantee to that effect, it remains to be seen whether a contract signed in Canada could warrant the possibility of litigation against the company on Canadian soil.

Québec has no specific law or regulation directly governing this practice. Nevertheless, the Act respecting Health Services and Social Services explicitly states that, as of 2002 when Bill 113 came into force, health-care institutions are obliged to ensure users the safe provision of health services and to disclose to patients any accident or complication that may arise. Under that legislation and the principles of civil law, health-care institutions are liable for patients' safety and any injury potentially caused by reprocessed SUDs. With respect to the obligation to inform patients that a reprocessed SUD may be used in a medical procedure, in every case in which reuse increases the level of risk associated with the procedure, the patients would need to be given information about the nature, frequency and severity of the risk facing them in order to obtain their informed consent. If the level of risk stays the same, however, specific consent is apparently not required.

As a result, health-care institutions dealing with U.S. third-party reprocessors benefit from guarantees set out in their contracts but ultimately remain liable to their patients for any injury caused by the reprocessed medical devices provided to their practising physicians and other staff. If the reprocessing was performed by an independent company, the health-care institutions would still have recourse against that company to obtain compensation, where applicable.

Ethical considerations regarding the reuse of single-use medical devices

In considering the option of reprocessing and reusing certain SUDs, decision makers face the following dilemma: the obligation to make the most cost-effective use possible of resources in the delivery of services vs the need to protect the health and safety of patients undergoing procedures utilizing reused SUDs. Given the uncertainty that persists about the risks associated with this practice for most disposable devices after use, decision makers have two options: not to reuse SUDs (zero tolerance or risk prevention) or to opt for responsible risk management by ensuring safe practices based on a stringent reprocessing and reuse framework corresponding to the highest quality standards, as the U.S. FDA is currently doing.

The choice of either of these options must take into account the potential adverse effects of the risk actually materializing, including patient injury,

the costs of additional care from complications resulting from reuse, action for damages in the event that the health-care institution were to be found at fault, and the loss of patient and public confidence in the institutions and public authorities taking that risk. Moreover, it must be determined whether we are capable of meeting all the requirements for responsible risk management, given the current situation and the means available to redress identified shortcomings.

In the event that the option of responsible risk management is chosen with regard to the reuse of some SUDs, several points need clarification. Accordingly, the ethical reflection proposed in this report has identified certain requirements concerning quality assurance and transparency of practices that can serve to better guide responsible risk management.

Conclusions

In light of the analysis of the different issues raised by the reuse of critical or semi-critical SUDs, the acceptable options for the use of this practice are the following:

- continue reprocessing SUDs in-house by obliging health-care institutions to meet the highest recognized standards of quality; or
- 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.

In return, each of these options gives rise to certain requirements:

A. Any institution wishing to reprocess critical or semi-critical SUDs in-house in order to reuse them must ensure the following:
    - Reprocessing protocols must be developed by the professionals concerned and validated both inside and outside the institution, and their implementation must be closely monitored by a recognized authority.
    - Device-tracking mechanisms must be implemented to ensure disclosure of all necessary information in the event of any incident, accident or complication;
    - Policies and procedures for reprocessing and reusing SUDs must be adopted openly and officially by the health-care facility and endorsed by resolution of the board of directors.
    - Proof of the effectiveness and safety of this practice must be strictly based on scientific evidence or field studies.
    - Proof of the cost-effectiveness of this practice must be clearly established for each SUD, taking into account all the costs associated with the development of best practices for reprocessing them and its potential risks.

B. Any health-care institution that wishes to have its critical or semi-critical SUDs reprocessed by a certified reprocessor should ensure the following:
    - Reuse of reprocessed SUDs must meet the conditions for the safe provision of care and this practice must be formally approved by its board of directors;
    - The decision to reprocess and reuse SUDs must be made in accordance with good management principles and must demonstrate real and significant cost savings.
    - The contractual terms and conditions that it establishes with a third-party reprocessor (companies are solely in the United States for the time being) must comply with Canada's and Québec's regulations and guarantee that the company is applying the highest quality standards, that is, those defined by the U.S. FDA's regulatory framework.

Recommendations

- Given the conclusions drawn in this assessment and the general position adopted by Canadian organizations regarding the reuse of critical or semi-critical single-use medical devices (SUDs), and
- given the considerable requirements associated with the two possible avenues open to institutions opting to reprocess and reuse certain critical or semi-critical SUDs,

AETMIS recommends the following:

- 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 recognized 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 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.