Reuse of Single Use Medical Devices

During the ten years that I have worked at the Canadian Nurses Protective Society, we have had numerous calls from Operating Room nurses questioning the practice of re-using single use medical devices in their facilities and voicing their concerns about possible harm to patients, themselves and potential liability exposure. Interest in this topic has been rekindled by the recent Saskatchewan case involving the death of a patient from variant Creutzfeld-Jakob Disease (vCJD) and possible transmission of vCJD to 71 patients who may have been exposed to the same endoscope as the deceased while in hospital. In this article, I propose to address some of the concerns related to the reuse of single use medical devices by focusing on the prevalence of this practice, the legal risks involved, regulation of this practice, and risk management.

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PREVALENCE

Just how prevalent is this practice in Canada? In 2001, a study addressing reuse practices in Canada was conducted for the Advisory Committee on Health Services (ACHS). The findings from this study were released in May of 2001 and reveal that of the 802 Canadian hospitals surveyed 7% do not reuse and 40% of the hospitals indicated that they reused items from the list provided.

RISKS

Reuse is a concern because reuse of single use devices is not without risks. There are primarily three major risks related to this practice. First, there can be damage to the device's functional integrity because of the effects of resterilization on the physical and mechanical properties of the device, which could result in device failure or patient injury. Second, infection or transmission of disease may result from devices exposed to high levels of contamination during first use, build up of toxic residues and ineffective reprocessing. And, third, there may be health risks for health care personnel exposed to additional blood and body fluids, or reprocessing chemicals and gases.

LIABILITY ISSUES

Because of the risks, litigation may be initiated if a patient suffers injury as a result of the reuse of a single use item. And, if a number of patients suffer similar injuries a class action could be commenced. From a liability perspective, the two main areas of concern relate to the potential for actions in negligence against an institution for reuse of disposables and against health care providers for failure to obtain informed consent.

It is quite clear in the Canadian case law that in order to provide patients with reasonable and safe care a hospital owes its patients a duty to provide adequate and safe facilities and equipment. This legal duty incorporates the appropriate maintenance of equipment including the procedures for decontamination, resterilization and reuse of devices that have been designated by manufacturers as single use items. Consequently, if a patient suffers an injury or develops an infection or disease related to the reuse of a disposable, and the harm suffered can be attributed to the handling or reprocessing of the reused device, then the hospital may be found liable for its breach of the duty to provide patients with safe equipment.

As in all medical negligence cases involving hospitals, the court will hold the institution to a reasonable standard of care. In a reuse case, factors the court will look at include the practice in other comparable institutions, the foreseeable risk to a patient and the manufacturer's advice concerning reuse. In most cases, manufacturers of single use devices do not approve of the reuse of single use devices. This is the position taken by Medical Devices Canada (MEDEC), the main trade association for the medical device industry in Canada. MEDEC has stated that it "strongly disapproves of the reuse of single use devices. Organizations or individuals that choose to reuse single use products do so at their own risk and should be prepared to assume some liability. Institutions that reprocess and reuse single use devices contrary to labelled indications should be required to validate the procedure to the same standards as industry."

The second area of concern involves informed consent. The case law and provisions in consent to treatment legislation clearly state that health care providers have a legal obligation to obtain a patient's informed consent before providing medical treatment. In a case involving the reuse of disposables, the main issue will be whether the patient's informed consent is needed for the reuse of single use items. And if, yes, whether the duty to inform was met.

The seminal case in the informed consent area is Reibl v. Hughes. In that case, the Supreme Court of Canada stated that a patient must be informed of all the risks related to the procedure or course of treatment that would be material to the patient's decision to proceed or not proceed. When addressing the issue of materiality the court has indicated that factors that must be considered include the likelihood of the occurrence of a risk and the gravity of the potential consequences. Therefore, in a reuse case, in order to convince a judge that informed consent had not been given, the patient must establish that had he/she been informed of the risks related to the reuse of a single use medical device then he/she would not have agreed to proceed with the procedure or treatment.

If a hospital has reasonable protocols in place and research based evidence that there is no significant increase in risk from the use of the reprocessed item/device, compared to the single use of the same device/item, it is unlikely that a judge would find that reuse of a single use medical device is a material risk which must be disclosed to the patient for the purposes of obtaining an informed consent. Conversely, if the institution's research reveals that the reuse of the medical device poses a significant increase in risk to the patient, a judge would probably find that this information must be disclosed to the patient as part of the informed consent process.

REGULATION

Are there laws or guidelines relating to reuse? In the US, the Food and Drug Administration (FDA) regulations provide comprehensive requirements that must be complied with before single use items may be reused. These regulations place the responsibility for the safety of the reuse on the shoulders of the institution or individuals undertaking the reuse and require these parties (i.e. hospitals and third party processors) to comply with the same quality standards and all the regulatory requirements as the original device manufactures. The FDA regulations establish three device classes that are based on risk. Class I (least risk) devices are subject to general controls, Class II (moderate risk) are subject to special controls and Class III (greatest risk) must undergo pre-market approval.

In Canada, we do not have legislative requirements similar to the American FDA regulations. Health Canada has legal authority to regulate the sale of medical devices based on the provisions in the federal Food and Drugs Act. Because the Food and Drugs Act and its regulations set no requirements on the user of

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medical devices, reuse of disposables is not a violation of the act or its regulations. Use is governed by provincial legislation. Health Canada is, however, in the process of examining their authority to regulate reuse and repro-cessors and is developing options for policies and/or regulatory action in this area.

At the provincial level, since February 24, 1999, Manitoba has placed a ban on the reusing of all "critical products" (one that penetrates skin or invades normally sterile parts of the body i.e. products with blood contact, or invasive into sterile body cavities). Quebec has also taken a position on this issue. In 1996, the Minister of Health for Quebec declared a moratorium on the reuse of single use cardiac catheters because of concerns that patients might be at risk of contracting CJD.. This position was modified in 1997 based on a report prepared for the Minister of Health by the Conseil D'Évaluation des Technologies de la Santé du Quebec (CÉTS). Based on the scientific evidence available at that time, CÉTS concluded that cardiac catheters should not be reused if they had come in contact with patients considered to pose a risk of being a vector for CJD. If the catheter was used on patients not within that category, CÉTS concluded that "given the current state of knowledge, the reuse of single use angioplasty and angiography catheters does not pose any unacceptable risks as regards the possible transmission of Creutzfeldt-Jakob disease."

Although there is no current Canadian federal or provincial/territorial legislation governing reuse of single use devices, there are comprehensive guidelines on reuse published by the Canadian Health Care Association. These documents set out factors that should be considered before establishing a reuse program. They provide a framework that can help an organization make an informed decision about the risks and benefits of setting up this type of program. The guidelines also contain a comprehensive review of the literature and suggested parameters for the development of a reuse program. A classification system, similar to the system set out in the American FDA regulations, and guidelines for resterilization are also included.

RISK MANAGEMENT

How can an organization limit the risks related to reuse of single use medical devices? The best method of limiting risk is to **not** reuse. Many hospitals have decided to take this position. If a decision is made to reuse, or to continue to reuse, the CHA guidelines suggest that the first step is to set up an interdisciplinary reuse committee. This committee would be responsible for setting up the framework for the reuse program and overseeing its implementation and ongoing evaluation.

An effective program should include: a cost analysis at the outset to demonstrate the cost effectiveness of reusing; a formal written reuse policy which is endorsed by management; written protocols emulating industry standards by setting up step-by-step reprocessing procedures which produce outcomes that are quantifiable, documented and supported by test data; consistent application of these protocols to each disposable item that is to be reused; and a quality assurance component which ensures that the reused product can be safely used for patient care and does not expose health care workers to increased risks. The program should also include staff education and incorporate audits to ensure that the protocols are being applied consistently and appropriately.

If your hospital is reusing single use medical devices, or, is considering whether to do so, it is important to remember that reuse should **not** be done on an ad hoc basis. Your reuse program should demonstrate that single use devices that are reprocessed are as safe as reusable medical devices that have been appropriately reprocessed.

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