Fourth CCOHTA Regional Symposium
in collaboration with
Conseil d'évaluation des technologies de la Santé du Québec
and
Hôpital du Sacré-Coeur de Montréal

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INTRODUCTION

The topic of Reuse of Disposable Medical Devices was selected by CCOHTA for its fourth Regional Symposium because it is the subject on which most requests for information have been received over the past two years or so. These requests have come from hospitals across the country, as well as from other countries. Reuse is becoming a more widely accepted practice in Canadian hospitals, and is causing concern in many quarters. There are gaps in what is known about the implications of reuse, e.g. risk/safety, about patients’ rights as far as reused devices are concerned, and about the true cost-effectiveness of the practice. Also, there is little precedent in case law that gives definitive answers regarding liability.

The Symposium was intended to have a *practical* focus, not an academic, abstract or theoretical one. It was intended that attendees would leave with an understanding of pressing current issues of reuse and with concrete results or practical tools that would help them be better and more efficient health care providers without jeopardising patient safety and well-being.

The first day of the Symposium was intended to focus on the identification of relevant issues, e.g. regulatory, economic (industry and provider perspectives), safety and risk, ethics and liability. Three case studies on the reuse of specific device types were then presented.

The second (half) day was originally designed to be in a "workshop" format, with the hope that some form of guideline policy document would be developed for consideration by hospital administrators. The large number of participants (over 250) made this impractical. The presentations on the second day dealt with economic evaluation methods, biomaterials and testing and with a discussion of the necessary elements of a hospital reuse programme.

The Workshop was conducted in collaboration with the Conseil d’évaluation des technologies de la santé du Québec and l’Hôpital du Sacré-Coeur de Montréal.

**Note:** These Proceedings were compiled without review by the speakers. CCOHTA therefore takes full responsibility for the transcription.

Dr. D. Menon  
Executive Director  
CCOHTA  
February 1995
A PROGRAM MODEL FOR REUSE

Ms. Marimargaret Reichert

The program model introduced in this presentation was developed in 1982 following an investigation of cardiac catheter reuse. With the proper collaboration, and a scientific approach, many single-use devices can be safely and effectively reused under the right conditions.

*Reuse* is a term that is interpreted in many ways; however, there are three distinct components. *Resterilization* refers to the sterilization of a sterile device that is still in its (unopened) package. *Reprocessing* is the packaging and sterilization of a device whose package has been opened, but has not been used. Finally, *reuse* really refers to the cleaning, packaging and sterilization of a single-use device which has been used on a patient, and which is then used again on the same or another patient. This presentation deals with *reuse*.

Several issues need to be considered for a reuse program.

**Design and shape compatibility**

The design and shape of the device must be compatible with existing processes in the hospital. It must be possible to disassemble it for thorough cleaning. There may be specific coatings on the device that need consideration; some coatings may prevent the sterilant or disinfectant from contacting all surfaces of the devices, internal and external. Some devices have complex structures (e.g. specialty cardiac catheters), and disassembling and assembling may be difficult. Also, many devices are heat sensitive, and cannot withstand high-temperature sterilization. Ethylene oxide (EtO) is therefore commonly used, and in this case, residues of EtO and its by-products have to be reduced to safe levels following sterilization.

**Cleaning**

Devices must be cleaned before packaging and/or sterilization. It is not always easy to ensure that a device is clean, since hospital sterilization/processing departments receive various types of devices in various conditions. Nonetheless, it is important to be able to ensure that all visually apparent gross debris has been removed by
cleaning. But it is still possible that proteins and fat films that may not be visible or felt remain, potentially compromising the patient.

Materials compatibility

Several materials used in single-use devices have never been tested for reuse compatibility in hospitals. It is important to ensure the compatibility of such materials with the cleaning methods and detergents used in the hospital. Cleaning agents must be rinsed from the device so that there are no enzymatic detergent residues remaining. Employee safety in this area is also of concern, particularly with biocidal processes being used in decontamination.

Testing and documentation

There are few accepted protocols and documentation requirements for testing of a single-use device for acceptibility for reuse. The hemodialyzer is an exception; however, this device is unique in a number of ways. For example, a hemodialyzer is always reused on the same patient, while cardiac catheters and other devices considered for reuse end up being used on other patients.

There are considerable hospital-to-hospital variations in knowledge and experience of capabilities for testing. Hospitals have developed reuse practices fairly independently of each other, often without appropriate documentation. There is also a lack of written instructional material available from manufacturers. It would be preferable to have more networking and cooperation among hospitals. Appropriate documentation of practices is also important from the perspective of institutional liability.

Technological ramifications

This is an era of rapid technological change both in reprocessing technologies and in medical devices. It is important to anticipate product, material or design changes in devices, as processes may require re-validation. Changes in the sterilization technology itself will have ramifications on costs of reuse. The planned replacement of 12% EtO/88% freon sterilant, perhaps with new plasma technology, will have to be addressed. There may also be a need for new specialized decontamination equipment, if complex medical devices continue to be produced. In some cases,
new preventative treatments (e.g. medication) may eliminate the need for a particular device; all expenses related to reusing the device would then need to be written off.
Cost analysis

Perceived cost savings are generally cited as the main reason for reuse. However, this is not often proven to be the case. Hospitals do not take into account all relevant costs when determining whether a particular device is cost-effective when reused. For example, it is assumed that using a device five times is five times cheaper than using it once. But there is more than just the purchase price of the original device to consider. One has to include costs of testing, time of hospital staff involved in reuse, time to develop procedures, training time and cost, etc.

Volume of potential use of a device is also a critical factor in determining cost-effectiveness. An 850 bed hospital with an annual volume of 8000 cardiac catheterizations may benefit from economies of scale that are not available to a smaller hospital performing 200 procedures a year. If there are insufficient volumes of procedures to offer such economies of scale, the costs of developing a reuse programme may not be recoverable. A comprehensive model for cost analysis of reuse will need input from financial experts and economists in the hospital.

Reuse procedures

Appropriate and consistent processing procedures should be developed by hospitals intending to reuse single-use devices. There are numerous components in a processing system, and all of these have to be controlled for the end product to be consistently safe. For example, it is important to specify what is meant by the term "clean", and it may be necessary to specify explicitly the amount of liquid used to irrigate the device, the type of water required for cleaning, etc.

The procedures should also take into account the users of the device being reprocessed. The transportation to the processing department, and subsequent return to user department, both need to be considered. It is also important to record the number of reuses of each individual device.

Packaging of the devices is also an important step in reprocessing. While a manufacturer usually has high volumes of a minimal number of products, making customized packaging possible, the hospital is a very different environment. It may be necessary to recognize that at the present time, industry standards cannot be duplicated in all health care facilities. Neither the technical sophistication nor the resources required exist in hospitals. However, hospitals must still ensure that the packaging will protect the device and meet the standards of quality required.
Validation

The first step in developing a reuse programme is establishing protocols for validation of processes. The effectiveness of the recommended processes (e.g. for sterilization or cleaning) must be validated by testing. Hospitals, unlike industry, have to process low volumes of a large number of devices, and these devices have an unknown bioburden. These differences from industry must be recognized, and it should be possible to design a hospital system that compensates for, or at least recognizes these differences.

A model of reuse

To illustrate these various aspects of a reuse programme, the example of the reuse of an electrical pacing probe for cardiac catheters is provided.

This is a non-lumened device with electrical leads at the tip. At first, the care and handling of such probes by users was observed. The probes were very fragile and could be damaged if not handled properly while being delivered to the processing department. To reduce this likelihood, a plastic basin was introduced.

The initial cleaning was performed after the catheter arrived at the processing department along with other products. When a batch of 30 catheters had accumulated, they were cleaned again, this time at five in the morning. It was felt that at this time, there would be the lowest level of airborne particulates and bioburden. All counters were cleaned, and sterile sponges were used to maintain a controlled environment.

During the inspection and preparation step, gloves were worn to minimize deposition of oils or organisms on the device. The device was inspected under a lighted magnifying glass, and an electrical test (with specifications provided by the manufacturer) was administered.

Instrument marking tape was used to keep track of number of reuses, so that catheters would not be reprocessed more than five times; after five times, they were discarded. To ensure consistent packaging, a template was designed, so that the positions of the tips and ends of the catheter and of the coil were identifiable. This provided assurance and a measurable criterion that the product was wrapped appropriately each and every time, and that it was a usable product.

Catheters were wrapped in one wrap, secured with a piece of tape and placed into a plastic pouch, which was then heat-sealed. To standardize the load, a container was designed for the sterilization process, and the pouches were distributed uniformly in this container.
Validation was performed on a half-cycle. It was verified that the catheters could be sterilized in 90 minutes and the exposure time was then doubled to three hours. After 12 hours, however, there were substantial EtO residues and byproducts. This meant that the procedure had to be completed over a weekend in order to assure acceptable residue levels.
This presentation focussed on the applicability of the *Food and Drugs Act* and the *Medical Devices Regulations* to the reuse of single use devices. Although federal regulations do not specifically address the concept of reuse, this discussion is necessary as there are several misconceptions. The following remarks are based on the Medical Devices Bureau's interpretations of the regulations and on the legal opinion of Health Canada. It is important to note that the final interpretation on the meaning of the regulations has to be by a judicial ruling. To date, however, the application of the *Food and Drugs Act* and *Medical Devices Regulations* to the issue of the reuse of disposable devices has not been tested in court.

Central to the *Act* and *Regulations* are the requirements for the manufacturing, advertising, and sale of devices. Manufacturers are expected to:

- conduct testing before the sale of the device to establish its safety;
- notify the Branch of the sale of the device;
- provide adequate labelling, instructions for use, warnings and contraindications for the use of the device;
- maintain records of problems and corrective actions;
- inform the Branch of recall actions.

It is often assumed that these same regulations apply to the users of the devices. For example, if the device is used contrary to the manufacturer's instructions (sometimes referred to "off-label" use) then it is sometimes interpreted that this must be a violation of federal regulations. In actual fact, the *Act* and *Regulations* set forth no requirements for the user of the device. The off-label use of a device may increase a hospital's liability and weaken its defence in a civil litigation, but it is not in violation of the *Act* or *Regulations*.

It may also be assumed that since sterilization is a step in the manufacturing process, a hospital which resterilizes and re-packages a disposable device becomes a manufacturer and thus is subject to all the legal requirements defined by the *Act* and *Regulations*. This argument arises from a misunderstanding of the legal definition of "manufacturer" in the *Regulations*. A manufacturer is defined as:

"any person, partnership, or unincorporated association that manufactures and, under its own name or under a trade mark, design, trade name or other name or mark owned or controlled by it, sells a device..."

Therefore, carrying out a step in the manufacturing process does not make one a manufacturer. This appears to be a reasonable definition. A complex medical device might contain components made by several different sub-contractors and it...
would be impractical to regard each of these as a manufacturer of the device. For that reason, the responsibility is assumed solely by the person or organization which sells the final product under its own trade mark. In the instance of a hospital reprocessing or re-packaging a device, the hospital would be considered the manufacturer only if it distributes the device under its own name or trade mark.

The operative word in the previous definition and throughout the Act and Regulations is "sell". Federal law controls the sale of medical devices. The issue then revolves around the question of whether the use of a device on a patient can constitute sale. The Act states that to "'sell' includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for considerations." Money need not change hands.

It is the inclusion of the word "distribution" in this definition which broadens the scope enough to cause problems for hospitals. Although "distribution" is not defined in the Regulations, a reasonable interpretation would be that the hospital or medical professional who "gives" a device to a patient to take away and use without further medical supervision has "distributed" and therefore "sold" the device to the patients. Examples of such distributed devices are artificial limbs, colostomy aids, crutches, and prescription eye glasses.

Another very important class of devices that are distributed are implants in which there is a general agreement that the implant becomes the property of the patient. This view has also been upheld in legal cases where the ownership of an implanted device has come into question. This argument has led some to believe that it is the operation of implantation that assumes a sale has taken place.

There is nothing in the Regulations to indicate that implantation is a factor in determining whether distribution or sale has taken place. In the absence of regulatory guidance, it is reasonable to assume that the deciding factor is whether the patient leaves medical supervision with the device in possession. For example, the hospital which purchases a central venous catheter from the manufacturer is the owner of the device. Using, resterilizing, re-packaging, and reusing that device does not constitute sale.
The reuse of single-use medical devices is a contentious issue with two diametrically opposed points of view. Manufacturers of these devices state unequivocally and repeatedly that single use products may not be reused and end-users argue in favour of the practice. The motivation to reuse single-use devices is purely economical in nature, however there has been no cost/benefit analyses completed. If there is a benefit, it appears that it is not for the patient but for the health care system. This presentation will describe how industry manufactures products that are safe and effective for their intended use and how industry responds to market demands for new and innovative products.

A single-use device is a device that may be used only once for its intended purpose and then disposed of. On the other hand, a disposable device may be used a number of times following resterilization and/or reprocessing. A single-use device must not be resterilized and reprocessed and must not be reused on another patient, according to industry.

Background

Thirty years ago, nearly all medical devices were reusable. For example, hypodermic needles were cleaned, sharpened, and resterilized for reuse and sterile drapes used in the operating room were washed, resterilized, and reprocessed before use in the next case. This practice placed a considerable burden on the sterile processing departments, particularly in terms of time and money. There was also the concern of cross contamination from one patient to the next. Eventually, health care institutions requested that industry develop single use devices that would eliminate the costs involved in reprocessing and reduce the potential for cross contamination.

Industry responded to this request by developing new materials and technologies that could be applied toward the construction of single-use products. So these products could be made more economically, new plastics and polymers were developed. These products were not designed to withstand the rigours of repeated use.

Along with the development of new materials came the development of products for new and evolving medical techniques. For example, soft pliable materials were used to develop catheters that could traverse and negotiate major blood vessels for cardiovascular diagnostic and interventional procedures. These products are designed to very precise specifications that reflect the delicate procedures they are
intended for. Such devices can perform efficiently once but they are not designed nor have they been validated to duplicate their performance characteristics a second or third time.

Once again, hospitals facing pressures to implement cost control, began to look to the reuse of single-use devices as a cost saving measure. In 1994, several institutions acknowledge that they reuse certain products as a means of controlling costs.

Design, manufacture, and validation of single-use devices

There are several steps taken by manufacturers of single-use devices to ensure that their products will perform both safely and effectively. From initial design to delivery, the manufacturing process must be consistent and is audited to verify that there are no deviations from established procedures. Verification is achieved by an elaborate quality assurance program and Good Manufacturing Practices (GMP), which are required by law in several countries.

Product materials should be chosen based on biocompatibility for human use and proven by physical tests that simulate use under natural conditions. Devices sold as sterile have been validated to ensure the sterilization technique will result in a sterility assurance level of $10^{-6}$. Certain product types (e.g. condoms) must meet product specific standards. All these factors and more are necessary for the manufacturer to justify the safe and effective use of their product as intended. For a single-use product, it is the safe and effective use of the product for one time only. Beyond that, the manufacturer has no design criteria, no quality assurance program, no GMPs, no biocompatibility studies, no physical testing and no sterilization validation to support the reuse of the product after it has been used on a patient.

Hospital studies

Various institutions have performed studies that seem to suggest that the reuse of certain single use devices is safe and therefore acceptable. An example is the dialyzer; however, in this case, reuse is restricted to the same patient. There are some studies that indicate if the product is effectively cleaned, it can be safely sterilized and reprocessed for subsequent use. There is no evidence from hospitals or otherwise to demonstrate that the physical properties have not been altered. This means that product integrity following reprocessing and resterilization remains questionable.

If hospitals choose to ignore the manufacturers' recommendations against reuse, industry believes institutions should follow the same standards and requirements
for process validation. Control measures will need to be carried out to ensure the process is performed both effectively and consistently.

Redesign of the single-use product-- the limited reusable product

For manufacturers to claim multiple use from a single-use product, it is necessary for multiple uses to be validated using all the criteria previously mentioned. If any of the validation requirements could not demonstrate safety and efficacy for more than one use, the manufacturer would not be able to claim multiple use. Then, the design of the product would need to be reviewed to determine if any changes were required to meet expectations of use. If, for example, the material could not withstand repeated sterilization, new material would have to be used or developed. A complete review of the quality assurance program would have to be undertaken as well as safety and efficacy studies encompassing biocompatibility and clinical trials. Essentially, industry would produce a limited reusable product that would be different from the current single use product.

Revalidating the product will not come without increased costs. Even minor changes in the design and function of a product will be reflected in an increase in cost. These costs will have to be recovered somewhere within the system and in 1994, if the manufacturers cannot pass on the costs to the consumer (given the current fiscal environment), the costs will have to be absorbed by the manufacturers themselves. This will translate into either lost jobs within the industry or decisions not to bring the product to market. Either way, society will suffer because less service and innovation will be available to the health care community.

If the redesign of single-use products incurs higher costs, it would appear to defeat the whole purpose of reusing a single-use product and would therefore support the principle of disposing the product after one use. This is indeed a paradox since single-use products were originally designed and introduced with cost savings in mind.

ISO 9001

The International Standards Organization (ISO) has developed a general manufacturing standard called ISO 9001. This is a quality system standard that can be applied to the manufacture of a wide range of products. Medical devices are no exception to these standards, and the international medical device community is moving towards the adoption of ISO 9001 as a mandatory requirement. In Europe there is a Medical Device Directive that requires devices to be manufactured in accordance with EN 46001 which is a standard based on ISO 9001. The U.S. FDA has proposed incorporating ISO 9001 into their GMP requirements and Health Canada are also considering the requirements for ISO 9001 in device manufacturing.
ISO 9001 specifies design control requirements for the design process. When developing the specified requirements, the supplier should consider other likely uses of the device, and the needs for labels and customer training. Manufacturers with ISO 9001 certification for products designed for single-use would be required to revisit their design validation for multiple use thereby ensuring that the product meets user requirements. Manufacturers who do not undertake validation of their design may be at risk of losing their certification and/or violating regulatory requirements.
Medical devices regulations

The *Medical Devices Regulations* stipulate that medical devices sold in Canada are to be supported by safety and efficacy studies and the Minister of Health has the authority to request that data. Manufacturers who are unable to produce the data may be requested to stop the sale of their products until such time as the information is received. Manufacturers do not perform safety and efficacy studies which support the reuse of single-use devices and expect that Health Canada would require safety and efficacy studies to demonstrate multiple use.

Risk based classification system

Health Canada will be implementing a regulatory system based on risk as a result of a comprehensive review of the Medical Devices Regulations. Although this system is still several years from implementation, it will encompass all medical devices, including single use devices.

It is expected that some single-use devices will be classified as high risk and will be required to undergo an extensive regulatory review. The costs to industry will be high and time to market entry will be delayed by the extensive review processes. This will force manufacturers to seriously consider the marketability of their products in Canada with a possible result of fewer treatment options for Canadians.

Hospital practices

A frequent argument heard by industry in support of reuse is that it is cost effective, however, it is not apparent if any substantial cost recovery studies on the reuse of single-use devices have been performed. It is very simple to state that if one can get five uses out of a single-use device, the savings is five times the cost of a new product. What is not usually considered is the cost of reprocessing and resterilizing the product. These include labour costs, the cost of the sterilant, and the cost of repackaging the device. There is also the high cost of liability assumed by all parties should the device fail on subsequent reuse and cause injury or death. A thorough cost-benefit analysis is necessary to show the long term savings, if any.

Liability

Manufacturers of single-use devices state on their labels that the product is for single-use only. Labelling alone may not be sufficient to absolve the manufacturer of liability. If a manufacturer is aware that a single-use product is being reused, it may be necessary to take further steps in preventing reuse. This may place the manufacturer in a very precarious and conflicting situation with a valued customer.
Medical Devices Canada (MEDEC) believes institutions, organizations, or individuals who choose to reuse single-use devices do so at their own risk. MEDEC feels that the liability resulting from product mishaps because of reuse should fall entirely on the organization or individual reusing the product. Furthermore, MEDEC expects institutions or individuals that reprocess and resterilize single-use devices against the manufacturers’ instructions to comply with process validation requirements. This would include such activities such as sterilization, validation, quality assurance audits, performance characteristics studies and compliance with existing standards (HPB, CSA, ISO). Essentially, industry demands that hospitals should be made to follow the same validation requirements as industry.
ETHICAL ISSUES

Dr. Hubert Doucet

There are three realities regarding the reuse of single-use medical devices:

1. Reuse is a fact of life
2. Studies of reuse have not had negative conclusions, provided the reuse is done under certain conditions
3. Manufacturers, despite this, continue to label their products as "single-use"

There are no writings in biomedical ethics that deal with the situation described by these realities. There may be legal opinions, but no one has reflected on these issues from an ethical perspective. Two ethical questions in particular spring to mind. First, is there an ethical dimension to this dilemma, and second, what can ethics contribute to the resolution of this problem?

Ethics has been defined by Ricoeur as "The aim for good life, with and for fellow humans within equitable institutions". Clearly there is an ethical dimension to reuse. The reality of reuse creates tension between social groups, with obvious negative consequences. Each group (hospitals or manufacturers or health care professionals, for example) wants to protect itself, and to throw the responsibility to another group. It is a social problem, being put forth in a context of conflict. For instance, on the one hand, one may say that manufacturers originally developed single-use devices as an answer to needs and requests identified by users. On the other hand, however, these manufacturers are not telling the whole story. At the same time, hospitals and government agencies now find themselves in a position of facing increased costs; thus they take risks in order to have their questions regarding safety and efficacy of re-use addressed. The problem is transferred to another level, and hospitals are having a burden placed on their shoulders that should not be there.

What, then, can ethics contribute to the issue? It can take an all-inclusive view of the issue, and it can propose elements for an "acceptable practice". Taking this broad view entails determining the purposes of the various existing practices in an institution, uncovering what does not work in the system, and in finding out who has to act. The role of ethics is at the "political" level.

Ethics would argue that an "acceptable practice" for hospitals should involve the development of a set of internal procedures. These should be adopted by the hospital's governing board, and the hospital's policy should be made public. The set of internal procedures should take a number of things into account: the available studies on safety, cost and risk, done to date; the accumulated experience; and the specific context of the particular hospital. This process of developing policy...
must include representatives of as many stakeholders as possible in order to take into consideration the broad perspective. It must also recognize that reuse is a viable option so that it does not remain a continuing source of tension. Finally, it should address the issue of what should be said to individuals concerned.

The overriding consideration, from an ethical perspective, is concern for the patient. This could be addressed by using devices that are appropriate for the particular application, and ensuring the quality of information provided to patients regarding informed consent.
CASE STUDY 1: CARDIAC CATHETERS
(a) CARDIAC CATHETERS

Dr. Carl Juneau

Introduction

There are various kinds of cardiac catheters and distinctive issues surround the reuse of each type: The specific use to which they were put, whether it was for cardiac catheterization, coronary angiography, coronary dilatation, or valvuloplasty (in which case it cannot be reused). The same holds true for coronary dilatation catheters, whether they are conventional balloon catheters or products of new technologies.

Protocol for the reuse of cardiac catheters

Diagnostic Catheters and Guide Wires
1. Immediately after use, rinse with a physiologic heparin solution
2. Soak in a detergent solution for 30 minutes
3. Insert a guide in the lumen of the catheter in order to remove all biological debris
4. Hand rinse for 5 minutes with a detergent solution
5. Clean for 15 minutes in an ultrasound bath with a detergent solution
6. Rinse and irrigate for 5 minutes with water under pressure
7. Dry with compressed air
8. Inspect the catheter in great detail (apply a quality control)
9. Mark the use with indelible ink
10. Package and label the catheter
11. Gas sterilize for 120 minutes at 54 - 60°C (ethylene oxide 12%, freon 88%)
12. Aerate for 24 hours at 49°C

Coronary Dilatation Catheters
1. Inspect and rinse immediately after use with a physiologic heparin solution
   - irrigate the distal lumen with a special needle
   - purge the balloons of their contents by flushing repeatedly with sterile water then close the tip with a Luer-Lock
2. Soak in a lukewarm detergent solution for 30 minutes
3. Insert a guide in the lumen of the catheter to remove all biological debris
4. Hand rinse for 5 minutes with a detergent solution
5. Clean for 15 minutes in an ultrasound bath with a detergent solution
6. Rinse and irrigate for 5 minutes with water under pressure
7. Inspect the catheter in great detail (apply a quality control)
8. Mark the use with indelible ink
9. Dry
10. Soak in a bath of Formac solution
   - irrigate the distal extremity
   - irrigate the balloon
11. Soak in a Formac solution for at least 10 hours before use
12. Renew the Formac solution once a week
13. Prepare for re-use by:
   - Removing from Formac bath and rinsing repeatedly with sterile water
   - Irrigating the tip with sterile water
   - Purging the balloon repeatedly

Trial results

During the period of April 1, 1993 to March 31, 1994, there were 64 catheterizations, 971 coronary angiographies, 125 coronary angiography/coronary & bypass graft angiograms, and 485 coronary dilatations performed in Sacré-Coeur Hospital as part of the experiment on re-use.

The details pertaining to the 485 coronary dilatation procedures are as follows.

### Coronary dilatation

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<th>No. of Procedures Performed</th>
<th>Success Rate</th>
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<td>No.</td>
<td>%</td>
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<td>New stenosis</td>
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<tr>
<td>Restenosis</td>
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<tr>
<td>De-obstruction</td>
<td>44</td>
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<tr>
<td>Total</td>
<td>485</td>
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### Comparison of actual results with anticipated results

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<th>Complications</th>
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<th>Anticipated</th>
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<td>Success rate</td>
<td>-</td>
<td>95.5</td>
</tr>
<tr>
<td>Occlusion (acute or sub acute)</td>
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<td>1.45</td>
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<tr>
<td>Infarction</td>
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<td>0.41</td>
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<tr>
<td>Urgent bypass</td>
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<td>0.62</td>
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<tr>
<td>Ventricular fibrillation</td>
<td>1</td>
<td>0.21</td>
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<tr>
<td>Death</td>
<td>0</td>
<td>0.00</td>
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<tr>
<td>Rupture of balloon (1 new, 1 used)</td>
<td>2</td>
<td>0.41</td>
</tr>
</tbody>
</table>
* Acute occlusion only

**Equipment used and procedure time**

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Number</th>
<th>Average per case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guide wires - total</td>
<td>536</td>
<td>1.11</td>
</tr>
<tr>
<td>New</td>
<td>164</td>
<td>0.34</td>
</tr>
<tr>
<td>Balloon catheters - total</td>
<td>2.19</td>
<td>1,060</td>
</tr>
<tr>
<td>New</td>
<td>253</td>
<td>0.52</td>
</tr>
<tr>
<td>monorail</td>
<td>201</td>
<td>-</td>
</tr>
<tr>
<td>integrated</td>
<td>49</td>
<td>-</td>
</tr>
<tr>
<td>perfusion</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Dye used (volume)</td>
<td>-</td>
<td>167 cc</td>
</tr>
<tr>
<td>Procedure time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 vessel</td>
<td>-</td>
<td>54 minutes</td>
</tr>
<tr>
<td>2 vessels</td>
<td>-</td>
<td>81 minutes</td>
</tr>
</tbody>
</table>

**Discussion**

Reusing balloon catheters allows a reduction in the cost per procedure and gives flexibility in the choice of size of balloon. On the other hand, the use of a larger number of catheters lengthens the duration of the procedure and increases the use of dyes. In addition, there might be a loss in the balloon's profile because of a possible alteration in the catheter's coating. This may restrain the use of reused ones in cases of acute stenosis. Similarly, reuse might increase the fragility of devices and impose tighter safety margins on users.

A strategy for reuse should be developed with respect to the selection of cases. New balloons should be used whenever there is patient instability, whenever the flexibility of the guide wire has been altered, whenever the stenosis to be passed is tight or obstructed, when the stenosis is very distal or the passage is awkward, or when kissing of balloons is required when treating bifurcations.
Some of the conclusions of our present experiences at Sacré Coeur Hospital on the reuse of both diagnostic and balloon catheters still need confirmation from larger studies in order to be generalized. For instance, while we noticed that some of the results reached in our study on diagnostic catheters were confirmed by the present experience on balloon catheters, generalizations need to be confirmed. The question of evaluating each individual type of catheter or not separately is still under debate. Questions regarding the rate of complications also need to be further explored and so are the questions regarding the increased length of time and dyes required by each procedure.

(b) EXPERIMENTS CONDUCTED ON CARDIAC CATHETERS

Ms. Patricia Bentolila

Historic overview

Reuse of devices is increasingly widespread in hospitals. It developed as a cost saving measure in a time of limited resources. In particular, reuse of cardiac catheters is not new. Originally, Sacré-Coeur Hospital reused reusable catheters, and then it began to reuse disposable ones. However, there were no written cleaning and sterilization protocols. In 1986, because a number of incidents occurred, surgeons no longer approved of the reusing of catheters. A committee formed to investigate the matter concluded that the incidents were related to the cleaning procedures. As a result a cleaning protocol was put in place as well as a program of personnel training.

Feasibility of catheter reuse

The reuse of single-use devices should be subject to the same evaluation process as new technology is, that is, considerations of efficacy, safety and benefits should be evaluated. This evaluation should be done for each device to be reused, and by each institution that seeks to reuse. No generalization should be permissible.
In addition, other aspects need to be considered such as official standards, policies and norms, ethical and legal considerations, manufacturers recommendations, the position of insurers, and environmental aspects.

Risks associated with catheter reuse

The most significant risks associated with the practice of reuse include:

- the risk of infection - possibility of introducing infectious organisms into a patient
- the risk of pyrogenic reactions - possibility that a reused catheter becomes contaminated with endotoxins originating from the rinsing water
- the risk of toxicity - potential chemical reaction between polymers and sterilization products or potential absorption of contaminant products
- the risk of particulate contamination - potential introduction of undesirable particles associated with the manufacturing and the cleaning processes
- the risk of catheter breakage - potential alteration in the physical integrity of the catheter
- issues of bio-compatibility

Experiments conducted at Sacré-Coeur hospital (1987 - 1992)

Mechanical Tests

*Purpose:* to determine the effect of reuse on the physical characteristics of catheters.

*Sampling:* a sample of 132 catheters consisting of 5 different types of new catheters and of catheters reused up to 10 times was used. Tests were carried out on 10 mm sections taken from the linear part of the catheter body as well as from either the bond between the body and the tip of the catheter or the curved portion of the catheter tip. Re-use protocol included soaking in detergent water, manual rinsing, drying, ethylene oxide sterilization, aeration.

*Methods:* the standard test protocol ASTM D-882-83 was followed. The maximum tensile load and the elongation of the sample at rupture were measured and recorded.
Results: results indicated that the mechanical properties of the catheters were not adversely affected by the cleaning and sterilization procedures associated with reuse.

Tests for Particulate Contamination

Purpose: to verify the efficacy of the catheter cleaning procedure and to determine the extent of particulate contamination in re-used catheters in comparison to new catheters.

Methods: the methodology used was based on the one described in the US pharmacopoeia (USP) for intravenous liquids as adapted by Health and Welfare Canada for medical devices. It consisted of rinsing with ultra pure water 5 new and 5 reused catheters and then counting and classifying by size (≥10µm and ≥25µm) the particles contained in the rinsing water. Rinsing water should satisfy the standards of a maximum of 5 particles ≥25µm per ml, a maximum of 50 particles ≥10µm per ml.

Results: all tested catheters satisfied the accepted standards.

Electron Microscopy Tests

Purpose: to examine and compare the internal surface of new and re-used catheters.

Methods: 10 new catheters and 22 catheters reused up to 10 times were examined. A 10 mm section was taken from the linear part of each catheter body and observed with a scanning electron microscope.

Results: Some debris were found on some catheter lumens but they appeared to be sufficiently adherent to the lumen surface, and so the clinical consequences are hard to evaluate. It should be remembered that electron microscopy examination is not performed on all reusables, e.g. surgery devices.

Microbiological Tests

Purpose: to verify whether the conventional ethylene oxide sterilization procedure can sterilize catheters which have been subjected to extreme contamination as well as to improper handling during the cleaning process.
Methods: extreme conditions of contamination were simulated by two protocols. In protocol a, catheters were soaked in contaminated blood (with "staphylococcus aureus", "pseudomonas aeruginosa" and "bacillus subtilis") and sterilized with ethylene oxide without being washed; protocol b was the same as protocol a but in addition, blood was deliberately dried on the inside and outside of the catheter prior to sterilization. For each protocol, three separate lots of 10 reused catheters each used 10 times were used. After sterilization, the catheters were cut into several small sections and placed in an enriched culture broth at 37°C for 96 hours.

Results: none of the 30 catheters submitted to protocol a tested positive for any of the 3 strains mentioned above. 18 of the 30 catheters submitted to protocol b presented growth of either one or all of the three strains. These results suggest that for ethylene oxide sterilization procedure to be effective, the lumen should not be obstructed. In any event, however, a catheter whose lumen is obstructed by any particle should never be used.

Economic impact

Savings associated with the reuse of catheters depend on the number of times a catheter is reused. However, the biggest savings are achieved with the first few reuses. Marginal savings decrease as the number of reuse increases. Cleaning and sterilization costs should be taken into account when calculating savings.

As an example, Sacré Coeur hospital realised savings of about half a million dollars in 1992-93 by reusing catheters; savings coming mostly from the reuse of angioplasty catheters.
New developments

In the coming years, new developments will occur that will affect the practice of reuse. New legislation is expected concerning the use of CFCs which are presently used for sterilization. The resulting new standards will impact the technologies, and consequently new experiments will have to be undertaken. Ecological concerns are increasing and biomedical waste management will gain prominence. In addition, globalization and generalization of the practice of reuse will bring automation of procedures.
CASE STUDY 2: THE REUSE OF LAPAROSCOPIC INSTRUMENTS

Dr. Eric Poulin

Overview

Reuse of single-use devices is a common practice today. It is estimated that 86% of hospitals with 200 beds or more reuse single-use medical devices such as cardiac catheters, arterial pressure domes, needles and syringes. Therefore the practice is neither new nor necessarily unsafe. St-Sacrement Hospital turned to the reuse of disposable instruments as a measure to curb rising costs. This presentation was a review of the St-Sacrement Hospital's experience with reuse and an assessment of the safety and the effectiveness of reuse as a cost-reduction measure.

There are many reasons to reuse disposable laparoscopy instruments. First, certain specific instruments are not available in reusable form such as linear staplers or multiple clip applicators. Second, the disposable instruments are sometimes better and sharper than their reusable counterpart, such as laparoscopy scissors which remain sharp even when cautery is applied. Third, it makes "economic sense" such as in the case of Veress needles used to inflate the abdomen. Fourth, disposable instruments provide improved security and convenience as in the case of working ports.

Selection of instruments for reuse

A preliminary step in a program of reuse is the selection of devices that will be reused. So many issues surround the practice of reuse (structural and functional integrity of the device, toxicity, pyrogenicity, sterilization, economics, ethical and legal issues) that it was decided not to reuse devices that are especially hard to clean. For example, at St-Sacrement hospital, disposable trocars were not reprocessed, not because they could not be sterilized, but because they are hard to clean. Only the sleeves have been reprocessed. On the other hand, multiple clip applicators, linear staplers, hand held instruments such as graspers, retractors, dissectors, clamps and scissors as well as devices such as needles, sleeves, cannulas and reducers have been reused. It was a committee of surgeons which
selected from the basic tray of 21 laparoscopy instruments the instruments that were to be re-used for each surgery type. For example, it was decided to reuse 9 of the disposable instruments for laparoscopic cholecystectomy.

Cleaning and sterilization protocols

A cleaning and sterilization protocol has to be developed for each laparoscopy instrument to be reused, and the process has to be validated for each device specifically. It is only then that the instrument can be reused. The protocol developed at St-Sacrement Hospital covers the enzymatic solution to be used, the ultrasound procedure, the rinsing protocol, drying, packaging, sterilization and the aeration procedures as well as indicators. The protocol has been validated three times, in 1990, 1992 and 1994. Instruments were deliberately contaminated with \textit{B. Subtilis} spores and sterilized according to the protocol developed. No instrument failed the chosen indicators.

The study and its results

A retrospective study of all laparoscopic cholecystectomy cases performed between August 1990 and February 1994 was conducted, in order to determine the safety of the practice of reuse as applied at the hospital, and to evaluate the costs and the savings that were associated with this practice. An attempt was also made to determine the optimal number of reuses for each device. Our analysis revealed that the practice is not only safe but also cost beneficial. Considerations of both savings and efficacy indicate that optimum results are achieved by using a combination of disposable and reusable instruments for each surgery.

In order to determine the safety of the practice, we analyzed all patient charts for each type of surgery. On occasion, it was necessary to follow up with patients. A study of the 30 day post operative period indicated that the cumulative rate of infection both deep and superficial was 1.8\%. In the 874 cholecystectomy cases that were examined, 13 cases of superficial infection (1.5\%) and 3 cases of deep infection (0.3\%) developed. No toxicity or other instrument breakage that was detrimental to patients was reported. Although this is a retrospective study with no control, these
rates are within the reported ranges. It is interesting to note that 11 of the infections were infections of the umbilicus region; the trocars were not reused.

The cost of reuse was estimated by calculating the costs incurred at each step of the cleaning and sterilization process. The program of reuse did not require any acquisition of new equipment or hiring of additional personnel, and sterilizers were not used more intensively. In the analysis, the cost of reuse included only the costs that were directly attributed to the practice of reuse such as material and personnel handling plus an allowance for personnel training. This costing exercise revealed that the cost of reusing one single device ranged between $2.64 and $4.86 depending on the particular device.

A calculation of the total savings generated by the program of reuse was then attempted. To do this, total savings were taken to be the difference between what would have been spent in new acquisition minus the amount that was actually spent plus an allowance for cost congruent to reuse. For example, laparoscopic scissors were used in 172 cases. However, only 9 new pairs were bought. The savings associated with the reuse of scissors were then calculated to be around $19,000 over the 4 year period of the experiment. When all instruments that were reused are considered, the total savings over the entire period is estimated to be approximately $300,000. For the 874 procedures, a total of 8,130 disposable surgical instruments were used. Of these only 2,566 were newly purchased instruments.

An analysis to determine the optimum number of uses was then undertaken for each instrument. In the majority of cases, it was found that the greatest savings were achieved when the devices were used between 10 and 20 times. In general, the biggest the difference between the purchase price and reprocessing costs, the larger the savings that will be achieved. For example, reprocessing camera bags is not necessarily very efficient. On the other hand, it was noticed that if reprocessing costs were doubled, the conclusions about the savings associated with the reuse of expensive items would not change much. It was also determined that for some instruments that could break, such as linear staplers, reusing them 5 to 6 times is sufficient to allow for the bulk of the savings to materialize.

The average number of times an instrument was used varied by instrument. Veress needles were used on average 68 times each, while reducers were used on average 13 times, scissors 20 times, linear staplers 6 times, camera sleeves 7 times.
Throughout the whole process, the collaboration of a number of departments was essential. Coordination is required between the department of surgery, management of nursing services, operating room personnel, the sterilization department, microbiologists and infectious disease specialists.
CASE STUDY 3: CARDIAC PACEMAKERS

Dr. Michael Rosengarten

Introduction

Cardiac pacemakers are generally comprised of an electronic pacing system and flexible leads that are attached to the atrium or the ventricle of the heart. It is important to recognize that once inserted, the leads cannot be removed and are considered to be part of the patient. This presentation discussed the reuse of the electronic component of the pacemaker and the findings of a prospective controlled study on the use of new and refurbished pacemakers.

There are many different types of pacemakers with different life spans. Some pacemakers start to decline after three or four years while several other pacemakers may function for up to 9 or 10 years. In fact, some of the newer pacemakers are expected to last 15 or 20 years. The bottom line is that there are a number of implanted pacemakers with long lives and a life span of 10 years is not unreasonable to expect from a pacemaker.

A pacemaker is considered to be part of a system; another component of that system is the patient being paced. For that reason it is important to determine if the two are being matched properly. Sometimes a mismatch may occur such as the patient outliving the pacemaker or the pacemaker outliving the patient. Two-year mortality for patients with pacemakers is 15-20%; therefore such patients could be a source for used pacemakers. However, this is not the only source. Patients may also be "upgraded" to another more appropriate pacemaker although the previous one may only have been in use for a few months.

Because of this mismatch being quite significant, perhaps clinical practice is being influenced by the lack or availability of reuse. Harken reiterates this by the following statement, "The harvesting of cadaver organs such as kidneys, liver, and heart is widely applauded. We now live in an era of mechanical organs. Does not a similar obligation and opportunity apply to precious artificial organs such as lungs and pacemakers?"
As mentioned previously, there is a wide variety of pacemakers and many manufacturers. Therefore, each pacemaker needs to be considered individually. Independent of the mechanical characteristics of the pacemaker, it is also very important, for ethical reasons, to consider how the pacemaker actually works. For example, a pacemaker which would maintain atrial synchrony and prevent a decrease in blood pressure may cost $3,000. A pacemaker that does not maintain atrial synchrony may cost only $1,500. If it is desirable to reduce the price of the pacemaker to be used in half, the latter will be implanted but unfortunately at a very heavy price to the patient. This is one of the driving forces behind trying to find better ways of making pacemaker implantations more economical.

The actual cost of a pacemaker varies and may range from $300 to $18,000 for a defibrillator. This illustrates that the savings obtained by reusing pacemakers may be quite large. For example, to reuse a defibrillator may cost $1,000 while using a new one may cost up to $20,000.

The Montreal General Hospital study

A prospective trial of new versus refurbished cardiac pacemakers was undertaken at the Montreal General Hospital. The purposes of this study were to determine if pacemakers could be recycled, to see if there was any difference in performance between the new and recycled devices, and to estimate cost savings for the Montreal General Hospital.

All patients requiring a pacemaker during the study were considered candidates for either a reused pacemaker or a new pacemaker. For many reasons, it was decided to let the physician who was implanting decide whether to refer the patient for a used pacemaker or for a new one. It resulted that as patients got older, and particularly in the over-90 age group, the implant rate of recycled devices increased. All patients implanted with new pacemakers on the same day were followed as the control group. In total, of the 68 patients who received pacemakers, 18 were implanted with recycled pacemakers, and 54 patients were part of the control group.

At 20 months after the first implant, there was really no difference in the complication rate between the two groups. In the group of patients receiving refurbished pacemakers, four experienced complications and one pacemaker was
removed because of an erosion. In the control group there were 11 complications for a rate of 21% and 2 pacemakers had to be removed in that group, one for an erosion and one for a suspected malfunction. During the whole study there was no pacemaker-related death and no pacemaker malfunction.

The mortality rate of the control group at two years was 25%. This figure is slightly higher than the average but may reflect the fact that patients treated were quite ill. It also means that there are 25% of devices that may be reused in our population. There was an increase in mortality as well in the reused pacemaker group, however, it was not related to the pacemaker but to the older, sicker patients in this group who died from other causes. Overall, there was a very clear relationship illustrating that the number of people alive varied directly with the decade of the age when they were implanted.
LEGAL ISSUES REGARDING REUSE
OF DISPOSABLE DEVICES

Dr. Bernard Dickens

The reuse of medical devices raises a number of unresolved issues of legal definition, manufacturers' design and intention, and hospital liability. The central problem is relatively uncomplicated, since it arises when a health professional reuses a medical device that the manufacturer intends to be used only once. Legal liability for negligence is easily established when reuse by the health professional is unintended and results in some form of injury to the patient. On the other hand, when reuse is deliberate (e.g. if the user considers a device safe after sterilization, or if the hospital has a policy on economy in purchase of supplies) the matter is more complex. The issue is further complicated when the supplier or manufacturer knows or reasonably should have known that the devices marketed as disposable are being reused.

This presentation addressed Canadian law which is fault-based in this area. In the United States, however, the principles of no-fault or strict liability are applied. Potential litigants therefore should consider the merits of suing in an appropriate U.S. jurisdiction. The law applied in the nine Common law provinces of Canada (was the basis of the presentation) rather than the articles of the Civil Code of Québec, and only devices classified as such in the law were considered. Finally, the presentation addressed primarily the reuse of a device on a patient by a health care practitioner, not a purchaser's reuse of a device on himself or herself.

Product liability law

One of the first questions regarding the reuse of a device sold as disposable, is whether the device may be designed and manufactured as strictly non-reusable (i.e. if it could be created to be incapable of reuse). If a device that could be designed to be incapable of reuse is not so designed or manufactured, the patient that is injured as a result of reuse may not only have a claim against the actual reuser, but the manufacturer as well for a design or production defect. A manufacturer may also be liable if prices are kept competitive by not adding costly elements that could
render a device non-reusable, thereby inviting reuse. This is so unless adequate warning against reuse is given.
Misuse of a device

If a device is being used in unexpected or unusual ways, in principle the manufacturer or seller of a device is not liable. If it is known or should be reasonably known that a device cannot be safely sterilized for reuse (e.g. if there is continued contamination or if the device is rendered unsafe after sterilization, there is risk of operator error) a manufacturer or seller may not bear liability for injury to patients after reuse.

If a manufacturer foresees or should reasonably foresee a use of a device that departs from the use for which the device was intended, liability may arise. The reuse of devices seeming fit for reuse, such as after sterilization, may be considered to be reasonably foreseeable. This may be more so when the device is expensive to replace (e.g. a cardiac pacemaker) than if the device is deemed to be relatively inexpensive (e.g. a tongue depressor). It may also be considered to be reasonably foreseeable that as health facility budgets lose purchasing power, devices may be reused. The greater the risk of misuse and the risk to patients from misuse, the more demanding will be the legal requirements on manufacturers and sellers to use warning labels and other precautions against reuse.

A court could be persuaded that a manufacturer or supplier only needs to state that a device is disposable to avoid legal liability for injury and to in fact, transfer accountability for injury to the user. In this case, it would be better for the manufacturer and seller to give information on how reuse might be undertaken safely, in a manner that is not unreasonably dangerous, and describe what dangers could arise from failure to follow specified procedures or from allowing reuse by unskilled personnel. The user, however, bears the risk of determining that a manufacturer's or seller's statement on reuse is only an attempt to increase sales.

Warnings

A device that is dangerous to reuse can be securely distributed with a proper warning. Warnings against reuse printed only in catalogues or circulars may be insufficient. If it is not possible to place a legible warning right on the device, package labelling may be required. The actual method of packaging may vary from device to device.
When a device appears to be sound for reuse on another patient after sterilization but is actually unfit in another way, courts may be more demanding on manufacturers and sellers for the adequacy of labelling. If, for example, sterilization will cause a device to explode or become harmful to the handler, a clear warning may be expected. A court may determine the legal standard of warnings against reuse by reference to how other manufacturers or sellers give warning. The size, colour, design, and placement of warnings are also matters of law. It is also necessary for the language of the warning to be understood by the users of the device, including minority populations.

Hospital liability

The hospital is at risk of liability if hospital staff fail to observe defects in a device or if they do not read of the warning or underestimate its significance. This is even more so the case if hospital administrators or senior staff require that devices be reused despite the warnings, unless, of course the warnings are considered to be insincere or liability shifting strategies. If manufacturers, suppliers, and hospitals all contributed to a patient's injury from reuse, the liability may be apportioned among them.

An exception from hospital liability was recognized by the Ontario Court of Appeal when an erroneous decision was made by a physician who, although working in a hospital, was not a salaried staff member but was paid on a fee-for-service basis by OHIP. If a physician makes a policy to use disposable devices on behalf of the hospital, the hospital will probably be liable. On the other hand, if it is decided to reuse only within the physician's own practice in the hospital, the hospital may not be liable. The hospital is liable, however, for decisions of salaried physicians and of other staff members who do not act as independent contractors but are servants of the hospital.

A hospital may be held vicariously liable for a salaried staff member's fault even if it is in deliberate defiance of hospital orders. The hospital may have a legal claim against the staff member to be indemnified for its loss through legal liability, but what the indemnity is worth usually depends on the staff persons' insurance coverage or membership in a self-protection association.
If it is decided within a hospital, department of a hospital, or by a physician to reuse certain disposable devices, the hospital department or physician is required to inform patients before reusing devices, particularly if that knowledge will affect the choice of a reasonable patient in deciding whether or not to accept the treatment from the hospital, department, or physician. This is a matter of law relevant to informed consent. The Supreme Court of Canada has maintained that failure to provide adequate information may be negligence, but a patient must actually be able to show injury in order to claim negligence. Therefore, if no disclosure is made and no injury results from reuse, a plaintiff cannot succeed in a negligence action.

Under recent guidance from the Supreme Court of Canada, however, courts are developing principles of legal liability for breach of fiduciary duty. This means the duty of conscientious conduct of full and frank disclosure, even where no conventional injury has been suffered. A court may find that even in the absence of infection or other injury from reuse of a disposable device, a fiduciary duty of disclosure owed to a patient had been violated and then award damages. A professional licensing authority may also impose a disciplinary sanction for professional misconduct.

Provincial health ministries, conscious of hospitals' strained resources and rising costs of purchasing disposable devices, may propose legislation giving immunities or limiting legal liability to particular circumstances. Any provincial legislation to this effect would be liable to scrutiny under the Canadian Charter of Rights and Freedoms, for instance for denying injured patients the equal protection of the law without discrimination (section 15 (1) of the Charter) or their security of the person (section 7).
Economic issues are among the many factors that institutions contemplating reuse must consider. The CETS experience in this matter has been acquired with hemodialysis equipment, cardiac pacemakers, cardiac catheters and laparoscopy instruments. This presentation highlights the economic aspects of reuse, dwells on the general role of economic evaluation, identifies the principal steps involved in economic evaluation and indicates how these steps can be applied in a hospital context.

General consideration

Hospitals face the challenge of maintaining accessibility and quality service in a context of increasingly tight budgets. The constraints imposed by collective agreements leave in the hands of managers few options, among them to look toward the medical and surgical equipment budget, which, for certain hospitals in Quebec, can reach $220 million, or 3.4% of total expenditures.

In this context, the potential for savings generated by reuse is very appealing. Among other things, reuse allows a reduction in budgets and the maintenance or increase in priority services. It brings about new approaches without increases in budgets and allows increases in service volumes. However, savings must be estimated in order to make decisions.

Economic analysis in the decision making process

Economic analysis, or the determination of efficiency, enters the decision making process along with considerations of equity, ethics, politics, regulation and organization. It entails the evaluation of options in consideration of the specificities of each (efficacy, safety, functional integrity).
In a broad sense, economic analysis is the analysis of a spectrum of options having comparable costs and consequences. Options can be programs, equipment, interventions, instruments, or application modalities. It is conducted principally because resources are limited and choices have to be made. By being systematic, economic analysis allows an adequate and complete comparison of options. It also highlights the essential elements for the purpose of decision making.

Economic analysis can take many forms. It can be a cost minimisation analysis - used when options yield identical results. It can be a cost effectiveness analysis - used when results are similar but of different magnitude. It can be a cost benefit analysis - used when results are different, or it can be a cost utility analysis - used when results are different and the impact on the quality of life is taken into consideration. Cost minimization analysis (with due assurance that results are identical) is the preferred approach to evaluate reuse options.

Economic analysis should be on-going. It should be performed prior to re-use in order to assist decision making, during reuse, as a pilot experiment, and after reuse in order to validate the preliminary evaluations and to take into account changes in parameters. In addition, medical equipment keeps evolving. New medical interventions constantly appear, and so does new equipment. New materials are developed and sterilisation techniques keep evolving. As a result economic analyses need to be revisited periodically.

Steps involved

**Problem Definition**

A general portrait of the situation within the hospital that indicates the type of reuse being done, volume of use per instrument, budget situation, sterilization activities and capacity should be drawn, and saving objectives for each department should be selected.

A preliminary list of target instruments should be made based on such criteria as the price of a device, patterns of use, and whatever outside information concerning its reuse is available.
A work group representing the different departments involved should be formed, and a work plan elaborated. A protocol for the gathering and dissemination of the information within and outside the hospital should also be developed.

**Identification of Options**

The reference option against which reuse options are to be evaluated is the case where single-use devices are only used once. Reuse options could be sterilization, reconditioning, and normal reuse. For each of these options, basic technical information should be assembled. This should include information on recuperation, cleaning, sterilization and aeration procedures, information on the theoretical and practical efficacy of each option, on the risks involved for patients, medical personnel and the environment, on each option's impact on the functional integrity of devices, and on the optimal number of reuse times, if available.

**Estimation of Costs and Benefits**

**Identification of Cost and Benefit Elements:**
A detailed description of the process should be elaborated. It should include for the reference case the purchase, storage, utilisation and disposal of the device. For the options being evaluated, it should include in addition to the items involved in the reference case, the steps included in the cycle of the recuperation, cleaning, inspection, performance monitoring, packaging, sterilization, aeration, storage, distribution and reuse of the device, and this for as many times as reuse is contemplated.

In each of these steps, the cost elements are direct human and material costs (personnel, instruments, equipment utilized, sterilization products, energy consumed, installation, purchase of services) as well as the costs associated with the consequences of these steps such as possible increases in surgery time.

**Cost elements should also include:**

- Cost of the analysis: administrative costs, pilot experiment costs, costs of information gathering;
- Set up costs: organization of installation, equipment, personnel training, elaboration of the quality control and other processes;
Operational costs: direct costs, indirect costs such as supervision and management, capital costs, depreciation of capital equipment;

Costs associated with risks to patients: increased surgery time, cost of treating complications, incremental insurance costs, costs of litigation; and

Costs associated with effects on personnel health and the environment: cost of de-polluting and treatment of contaminants, possible absenteeism of personnel, increased workers compensation contribution charges.

Benefits are then the difference between costs of the different options compared to the reference option plus indirect benefits. Indirect benefits are the effects on non-hospital resources such as possible benefits on patients' health.

Valuation of cost elements:
Once cost elements are identified, they should be valued. To do this, first, the "quantity" used of each cost element should be estimated, and second, a "dollar value" should be assigned. To measure "quantities", a detailed description of all steps involved is necessary. This can come either from outside sources or can be internally developed and performed with the aid of activity charts. Units of measurement are usually specific to each cost element. For example, devices are measured in units of each type, and personnel in man hours.

The dollar value assigned to each cost element is usually the actual cost paid. When not available, realistic estimates should be made. Some elements are intangible and cannot be evaluated. They should nonetheless be mentioned and their effect on the conclusions discussed. Financial statements can serve as a basis for measuring capital cost and overhead costs.

Consideration of Time and Uncertainty:
Proper accounting for time preference and discounting of future costs and benefits should be performed when costs and benefits are spread over many years.

Uncertainty as to the exact value of each parameter should be dealt with by sensitivity analysis. This involves identifying the parameters critical to the conclusions, and assessing the impact of varying their estimated value on the conclusions reached.

Elaboration of Decision Rules:
This entails putting forward the essential workable propositions and conclusions (summary of the analysis). These would include (a) estimates of the potential savings (reference option minus the reuse option), (b) estimates of the average cost of the device reused (total cost of reuse / number of reuse times) and possibly (c) a determination of the optimal number of reuses within the accepted safety and efficacy constraints (such as a maximum number of complications tolerated, a maximum risk factor tolerated).

Information Presentation for Decision Making:
It is advisable that the analysis and its conclusion be put together in a report accepted by all members of the evaluation work group. The report should make reference to all assumptions, all cost and benefit elements, estimation techniques and decision criteria used.
EFFECT OF REUSE ON MATERIAL PROPERTIES

Mr. Bob Petrosenko

This presentation addressed some of the practical considerations regarding the effects of reuse on materials, particularly those materials found in disposable medical devices. It included a description of the Committee in University Hospital, London, that is responsible for managing reuse.

In University Hospital, reuse of single-use devices has increased over the past few years, mainly because it has been seen as a cost-saving measure. This increase has taken place despite the absence of hospital policies and procedures to guide the practice of reuse. The Reuse of Medical/Surgical Devices Committee was established three years ago in response to this growing practice of reuse.

The Committee is multidisciplinary, and is chaired by an epidemiologist, who is responsible for validating cleaning and sterilization methods. Other members include two biomedical engineers and a risk analyst, who provides legal guidance to the Committee and serves as liaison with hospital legal counsel. The manager of the Materials Management department also sits on the Committee, and provides information and advice on reprocessing costs and other issues related to the reprocessing and reshelving of materials. The final member of the Committee is an operating room nurse who provides the perspective of the users of the devices. In addition, when the Committee is considering a specific device, it seeks the advice of appropriate hospital physicians as well as managers of the relevant areas. The Reuse Committee is a subcommittee of the hospital's Risk Management Committee, and reports to it through the chair of the Reuse Committee.

The Reuse Committee has developed a classification scheme for disposable items available in University Hospital. There are three categories:

1. Critical: Instruments or objects that are introduced directly into the bloodstream or any other sterile part of the body, and whose failure can be catastrophic, e.g. cardiac cannulae, hemodialyzers.
2. Semi-critical: Items inserted into a natural orifice or intact mucous membrane, e.g. endotracheal tubes, anesthesia breathing circuits.
3. Non-critical: Items typically in contact with intact skin e.g. blood pressure cuffs, surface electrodes and leads.
The classification scheme has allowed the Committee to examine devices in priority order.

Cleaning and sterilization

Cleaning and sterilization methods are important from a materials perspective, since the temperatures, times and the chemical nature of the process can all affect different materials in different ways. The process could be done with steam, ethylene oxide (EtO), liquid chemicals, ionizing radiation, or gas plasma.

The temperature with steam sterilization is quite high (120°C). Disposables are often made of thermoplastics, which soften around 100°C. They are therefore unsuitable for steam sterilization. There are some high density plastics, such as Delrin, however, that will withstand steam.

EtO, when used for sterilization requires a lower temperature (54°C). The sterilant used is a mixture of 12% EtO and 88% freon. By January 1996, freon will be phased out, and this mode of sterilization will no longer be available. However, at present, it is widely used, and there are issues to be aware of.

EtO has very good penetrating ability, but all parts, stopcocks, cannulae, etc. on the device must be open during sterilization. The process is lengthy, since the device must be aerated, generally for one day, to remove residual EtO gas. It is also essential that the device is dry, since EtO can produce poisonous compounds when mixed with water or saline.

For plastics that soften even at 54°C, there is the option of using cold EtO. However, a cold EtO cycle takes longer, and so in most cases, it would be done over a weekend. This will restrict reprocessing and re-use of a device to once a week.

Liquid chemical sterilants are available which use hydrogen peroxide and gluteraldehyde. They are generally used at room temperature. The process is quite time consuming, and as these are active chemicals, there may potentially be various problems with specific materials.

Ionizing radiation may affect the molecular structure of plastics. It may cause polymer cross-linking, making the plastic less flexible, perhaps stronger, and more
brittle. Devices like cardiac cannulae require flexibility for manoeuvring during use, and hence this form of sterilization may be detrimental. There is a paradox in that ionizing radiation may also cause de-linking, which makes the plastic more flexible, but less strong.

Gas plasma sterilization uses hydrogen peroxide, which does not penetrate as well as EtO. Therefore, when sterilizing certain devices, special fittings may be necessary to help move the plasma through ports and stopcocks.

No matter what the mode of sterilization is, all devices must be thoroughly cleaned to remove bioburden. They must also be thoroughly rinsed to remove chemical cleaners, which, when subjected to the heat of sterilization, can damage materials in the device.

Common materials in medical devices

Three types of metals used in medical devices are stainless steel, brass or chrome-plated brass. However, these are not found often in disposable medical devices. More commonly, such devices contain polymers or plastics which are typically combinations of carbon, hydrogen and oxygen. They can be low-density or high-density, depending upon the composition; low-density polymers are less resistant to temperature compared to high-density ones.

The chemical structure of plastics by itself does not determine its properties, since manufacturers commonly add many additives to the plastic for various reasons. Certain additives are heat and light stabilizers; fillers are used to help reduce cost and enhance properties such as abrasion, resistance and strength. Plasticizers increase flexibility and pigments are added for colour. Other additives include lubricants, fungicides and bactericides. Reprocessing and reuse can cause leaching out of such substances, thereby reducing performance. Exposure to light, especially ultraviolet light, can break certain chemical bonds, and soften or harden certain plastics.

Mechanical testing
Mechanical testing helps determine the integrity of devices, and there are objective and subjective test methods. Various standards organizations have developed standardized protocols, such as the International Standards Organization (ISO), the American National Standard Institute (ANSI), the American Society for Testing and Materials (ASTM) and the Association for the Advancement of Medical Instrumentation (AAMI). Few, if any, tests apply directly to any particular medical device, and so they need to be adapted and modified to suit the particular device.

A key mechanical test is the tensile test. The force required to stretch a specimen through a given extension is measured, and this yields a stress/strain curve. The curve’s shape depends on properties of the material. When looking at reuse, the stress-strain curve of the reprocessed device is compared to that of a new device.

Other objective tests include tests of hardness, flexibility and fatigue. In the hardness test, for example, a standardized steel ball is pressed into the material with a known force for a certain amount of time, and the resulting indentation is measured to determine hardness.

If objective testing is not possible, subjective or visual testing can be quite helpful. It is also important to test for functionality. In a visual inspection, it is important to look for cuts, abrasions, unusual stiffness or flexibility. Colour changes could be evidence of deterioration, and there could be corrosion from liquid sterilant.
A PROTOTYPICAL POLICY ON REUSE

Mr. Roger Jacob

The state of knowledge

The major advantages of re-use are: directly, savings accruing to hospitals, and indirectly, to patients and society as a whole. Although cost savings are the main reason for reuse, it has other advantages as well, such as reduced inventories and reduced solid wastes. Although there are examples in the literature on costs and savings associated with specific devices in particular institutions, no macro-economic evaluation of reuse is available.

Risks include: infection and toxicity, pyrogenic reaction, instrument breakage, particulate contamination, and potential legal action against hospitals and hospital staff.

Ethical issues include informed consent and establishment of acceptable safety and performance levels; financial interests of governments and of third party payers are also relevant. These ethical issues have to be addressed in the context of patient autonomy, well-being and welfare, and of societal justice and utility.

Clinical efficacy of the practice of re-use has not been examined in detail. The few controlled trials which have been conducted suggest that efficacy is not compromised. In particular, efficacy does not seem compromised by the reuse of hemodialyzers, cardiac catheters or pacemakers.

Environmental concerns seem to be reduced with reuse, e.g. direct pollution appears to be reduced. Less energy and material seem to be consumed and less manufacturing processes are involved, thus involving fewer rejects, less packaging, transportation, storage and waste. On the other hand, reuse requires the use of cleaning and sterilization agents, which in turn could create more waste.

Sterilization methods include:
1. EtO. The use of EtO/CFC will eventually be banned. EtO at 100% and EtO/CO$_2$ have also been used.
2. Heat and steam. Known technology but has limitations.
3. Glutaraldehydes. For specialized purposes e.g. endoscopes.
5. Peracetic acid. New and interesting product.
7. Gamma radiation. Use limited to manufacturers to date.
8. Ozone. To come?

The position of various parties on reuse

Legal status: Under Canadian law, devices are regulated through the *Food and Drugs Act*, and there is no clear definition of its position on re-use. The Quebec *Civil Code* requires hospitals and medical practitioners to ensure well being and avoidance of unnecessary risks. Use of the label "single-use" does not in itself constitute proof that re-use is risky. Quebec's *Bill 120* (on health care and social services) requires health care centres to provide quality health care, and to this end they must administer their human, material and financial resources efficiently.

Other positions: The Canadian Standards Association recommends reusing disposable devices only in cases where explicit recommendations are provided by the manufacturer. The Food and Drug Administration in the U.S. places the onus on the institution or practitioner to demonstrate that the device can be adequately reprocessed, that its integrity is maintained, and that it remains safe and effective. The Centers for Disease Control, U.S., recommends against reusing devices which will be compromised by reprocessing. The U.S. Joint Commission for Accreditation of Health Care Organizations requires that guidelines for selection, storage, handling, use and disposal of re-usables be in writing.

Canadian manufacturers (through MEDEC) do not sanction reuse of single-use medical devices under any circumstances. In the U.S., manufacturers do not approve of reuse.

According to the Quebec Hospital Association, hospitals and hospital staff are protected; as of 1991, no lawsuit related to reuse had been filed. The Canadian Medical Protective Association will continue coverage of its members even if re-use is the practice in their institution.
The position of Quebec's Ministry of Health and Social Services is that reuse can, under certain conditions, be justifiable and even desirable; it is an institutional decision. However, it must be done when there is proof that patients' safety is not placed at risk, when it is established by the health professionals in each institution, and when it is carried out according to guidelines openly and formally approved by the Board of the institution.

There is, of course, the patients’ perspective as well. Some predict reuse will come under greater scrutiny by consumer organizations. One opinion is that a patient should have an inviolate right to accept or decline a used device, without jeopardizing his/her subsequent care. Standards for quality of care must not be subordinated to, or compromised by, financial interests of the provider.

The role of management

Hospitals intending to develop policies on reuse of single-use devices must take the above considerations into account. Hospital administrators must fulfil their managerial responsibility within constraints. They must abide by Canadian law, and if in Quebec, they must satisfy the civil code regarding acting with prudence, avoiding undue risks and taking reasonable measures. Managers must also ensure that patients are fully informed.

Management must also cope with risk, which may be defined as "the combination of the probability of occurrence of an undesired event and the possible extent of that event’s consequences". Judgement must be exercised in determining what is achievable and reasonable.

Managers also have the responsibility of reducing pollution; this involves reducing consumption, reusing and recycling. It also involves the use of steam as much as possible, and other less-polluting sterilization techniques. They also need to consider the types of materials that devices are made of.

Recommendations
In light of the above, hospital administrators should take advantage of manufacturers' experience (where available), scientific literature, unpublished experience of other institutions and the expertise of specialists in the hospitals. Within each hospital, a permanent multidisciplinary re-use committee should be established. It should include the head of the sterilization department, a microbiologist, an infection control nurse, an engineer or physician. This committee should define the terminology and concepts of reuse and establish a library of scientific literature on safety, efficacy and efficiency of reuse. For each device, the committee should decide on reuse (or not), keep track of devices to be reused, decide upon the specific cleaning method and sterilization, and determine the responsibilities of all involved. It should develop and maintain guidelines for reuse, device-specific procedures and quality control measures. It should ensure that all reuse policies are approved at the highest level. The Committee should also analyze reuse incident reports, make appropriate recommendations, and ensure the personnel are appropriately trained.
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