

Reuse of Disposables: Is It Worth The Risk?

By Gloria Spanton, RN, CPN(C)

The economic pressure on healthcare institutions has driven the current trend to reusing single use medical devices. The increasing number of expensive disposables has created a climate in which the financial lure of reuse may overshadow the risks involved. However, the protection of the patient's safety demands that institutions adopt a cautious and well planned approach to reuse. The prospect of significant savings merits skepticism and thorough analysis to prove that real savings are worth the risk to patient safety. Hospitals must evaluate the costs directly involved in reuse by utilizing five cost categories according to the guidelines published by the Canadian Hospital Association in 1996.

1. Direct labour: Wages and benefits for employees who prepare, deliver, clean, package and process

Abstract

The main reason institutions reuse single use medical devices is to save money. Most hospitals are reusing disposables in varying degrees, but few have thoroughly investigated the issues surrounding reuse. Are there true savings to be realized? What are the risks to patients and coworkers? What are the legal and liability hazards to our employers and to ourselves?

Professional nurses have a responsibility as patient advocates and employees to question the validity of the reuse of medical devices which are manufactured to be used only once. By reusing disposables are we really cutting costs, or are we cutting corners?

the device. Also include the time spent gathering information, attending meetings, developing policies and processing procedure protocols, testing the product and developing quality assurance programs for reuse.

2. Testing: Costs involved in validating the efficiency of the cleaning and sterilizing process. Include in this area devices for testing integrity of the devices to be sure that they are still functional and safe to use.

3. Expendable or consumer products: Cleaning agents, brushes, protective apparel, packaging, labels, monitors, and sterilants.

4. Education: Wages and benefits for the time spent creating, presenting and participating in training programs and in verifying worker competence.

5. Other: Indirect costs, i.e. overhead, maintenance, amortization of capital equipment and disposal costs (financial and environmental).

We must also remember that savings are dependent on the number of times a disposable can be reused. In-house or independent lab tests can help estimate

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the maximum number of uses. Most savings are achieved in the first recycle with diminishing subsequent savings. Reports on reuse suggest that reuse of disposables is economical only if the device is costly and is used in high volumes. Even high ticket items may not be worth reprocessing in low volumes, because efficiency and quality control would be difficult to achieve. Cost justification is a never-ending process

A thorough review of the other issues surrounding reuse must also be evaluated before commencing a reuse program.

Ethical

How much risk should an individual patient have to assume in order to benefit the larger society through an optimized use of health care finance resources? Which patient should receive a new device and which a reused device? Should the patient give informed consent? The health care professional has an obligation to avoid harm to patients. Is the health care provider fulfilling that obligation?

Integrity of Function

The physical and chemical effects of cleaning and sterilization on disposable materials is poorly documented. Various changes that can occur include weak spots, increasing brittleness, reduced performance and accumulation of biological debris. Sterilization processes vary among hospitals and make it impossible for manufacturer's guidelines to be duplicated exactly. Chemical treatments and detergents may remove some of the plastic's non-polymer components and may alter polymer. The cumulative stress effects of reuse will vary with clinical scenarios which may have implications when determining the optimal number of reuses of a device.

Patient Risk of Infection

Both patient to patient and environmental contamination in reused products have been documented as leading to outbreaks of infection. A preliminary FDA study in the United States has reported dozens of infections, chemical injuries and mechanical failures from reusing devices designed to be used only once. Difficulty with cleaning may leave a biofilm which can interfere with the effectiveness of disinfection or sterilization.

Endotoxic Reaction and Other Non-Infectious Risks

Certain types of bacteria contain endotoxins. They survive sterilization by both steam and EtO, needing dry heat to be deactivated. Endotoxins can come from growth of bacteria in residual moisture after the cleaning process and before the instrument is dried and sterilized. They can cause symptoms of fever, chills and hypotension in a patient. Toxicity is also thought to accrue from residues of detergents, disinfectants, and EtO accumulation during the cleaning and sterilizing process. EtO can combine with aqueous residues to produce ethylene glycol or react with saline solution to form ethylene chlorhydrin, both toxic substances.

Safety of Health Care Workers

Reuse of medical devices creates additional opportunities for health care workers to be exposed to body fluids, although universal precautions have been established to minimize risks of acquisition of patient-originated infections. It also creates exposure to toxic chemicals. Glutaraldehyde vapours may cause pulmonary edema, pneumonia, and even death at high concentrations, and irritation of mucous membranes and skin as well as long term hypersensitivity at low concentrations. EtO exposure can cause eye and respiratory tract irritation, headaches, nausea and vomiting, dermal irritation and burns from direct contact. It is suspected to be a human carcinogen.

Federal Regulations of Medical Devices

Canada's Food and Drug Act regulates medical devices but hasn't any regulatory authority over hospitals reusing disposables.

Legal and Liability Issues

The federal government regulates manufacturers of medical devices. However, manufacturers contend that reprocessing a device is creating a new product and thereby the reprocessor becomes the manufacturer, thereby responsible for the product. The law is not clear as to who is responsible for the reused device. It could even be the end user.

Conclusion

Reuse of single use medical devices is a very controversial subject with sound reasoning from both sides. There is evidence to support and arguments that caution against reuse. Facilities that decide to reuse should not do so on a casual basis. If cost effectiveness can be demonstrated, reuse must be used in association with clear guidelines, an institution-specific policy, stringent procedures and evaluation of quality assurance, after thorough examination of all the issues. If cost effectiveness cannot be demonstrated, then the other issues are irrelevant. ■

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Nutrition, not drugs key to better and longer lives

If health care practitioners were more concerned about nutritional therapy than about drugs, many patients would live better and longer.

That was the message of Dr. George Blackburn, head of Harvard University's Center for the Study of Nutrition.

The doctor, speaking at a media brief-ing at a recent American Medical Association meeting in New York, proceeded to compare medical data in 1994 from three countries. Although one of the countries was the United States, Canada's numbers in this case are not that dissimilar to our neighbours.

- *coronary heart disease (men)*
 - United States: 189 per 100,000
 - Greece: 33 per 100,000
 - Japan: 34 per 100,000
- *female breast cancer rates*
 - United States: 22 per 100,000

- Greece: 8 per 100,000
- Japan: 4 per 100,000

So, what's the common denominator in Greece and Japan that accounts for the marked discrepancy? According to Blackburn, "these two countries enjoy a basic low-cholesterol, high-fibre diet that is both delicious and healthful."

Garlic: Could it become the antibiotic of the future?

Researchers in Israel have found additional evidence for what folklore and our forebearers have probably known all along, namely, that eating plenty of garlic wards off infections.

Scientists at the Weizman Institute of Science isolated large quantities of allicin, garlic's main biologically active ingredient, and found it contains the ability to disable infection-causing amoebas in test tubes.

If allicin is found to kill infections, researchers say, garlic may become the "antibiotic of the future."

Conference Calendar

Canadian Nurses Association Perioperative Nursing Certification

Next Exam Date: **April 4, 1998.**

Deadline for application: **November 21, 1997.**
To obtain candidate information for the next exam date Phone 1-800-450-5206

April 23 - 25, 1998

16th Biennial Conference - B.C. Operating Room Nurses Group. Harrison Hot Springs, Harrison, B.C.
Theme: "Towards 2000"

October 22 - 24, 1998

Operating Room Nurses of Alberta Association - 18th Provincial Conference - Red Deer, Alberta. Theme - "Stepping Out of the '90s"

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Operating Room Nurses Association of Ontario - 5th Provincial Conference. Sheraton Fallsview, Niagara Falls, Ont. "Images & Influence '98" Increase your Confidence & Credibility. Prepare for the 21st Century. For more information contact: Publicity Chairperson - Audrey Macdonald (905) 878-2383 Ext. 2310, or Exhibitor Chairperson - Alaine Young (905) 521 - 2100 Ext. 3030.

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