The definition of sterility is the absence of all living microorganisms. In the practice of labeling commercially sterilized, single-use medical products, sterile has been defined as a probability of sterility based on an arbitrary standard of 10^-6. This means that if a manufacturer can validate statistically that there is a probability of not more than one surviving microorganism in a million, they can legally label the contents sterile. In other words, there is a very high probability that the contents are sterile. This is called a sterility assurance level (SAL) of 10^-6.

Similarly, minimum performance requirements for manufacturers of sterilizers require data demonstrating their recommended cycle has a SAL of at least 10^-6. It is generally accepted that a SAL of 10^-6 is appropriate for items intended to come into contact with tissue that has lost the integrity of the natural body barriers (compromised tissue) and that a SAL of 10^-3 is considered acceptable for items not intended to come into contact with compromised tissue.

Because of the damage that dust can cause in computer chip manufacture, companies like Intel manufacture in a class 1 clean room environment. Class 1 means no more than one dust particle per cubic foot. Pharmaceutical sterile fill operations are typically done in class 100 environments, sterile device packaging in class 100,000 rooms. While 100,000 particles per cubic foot seem like a lot, this is a very clean environment, far cleaner than a typical OR suite aseptic environment.

Not every dust particle is contaminated by infectious bacteria but it is normally assumed that dust particles contain bacteria. Therefore, the probability of contamination (loss of sterility) in any environment depends on the level of dust (contamination) in the environment, the number of people, the amount of air movement (activity), and time passage.

I have constructed a theoretical chart that shows the probability of contamination along the vertical axis and time along the horizontal. The lines represent Class 1, Class 100, Class 100,000 and a typical OR suite. This is truly an exercise in mathematical theory. What is shown is that any sterile item exposed to a typical OR environment may very quickly become non-sterile. An instrument tray in a flash sterilizer will be sterile, hot, and wet at the end of the cycle, but will probably become contaminated very soon after the sterilizer door is opened. Sterile gloves are sterile for probably only minutes after they are donned. The horizontal portion of a sterile field is probably sterile for a far less time than the vertical portion. The fronts of gowns are probably no more sterile than the backs.

Once we accept the reality of sterile probability and stop thinking about sterile fields as though they were really sterile the sooner we will challenge procedures that assume sterility when it doesn't really exist, the sooner we will change unsafe practices and improve environmental controls. Think probably sterile field, with its sterility decreasing rapidly depending on how dirty the environment, how many people, the amount of activity and the passage of time. There are not degrees of sterility (it is either sterile or it is not) but there certainly are degrees of probable sterility.

What is the probability that there are no living organisms on what you now call sterile?

Dan Mayworm
Publisher

INFECTION CONTROL & STERILIZATION TECHNOLOGY — MARCH 1995
Event Related Outdating

A Fairy Tale Comes True
By Sandy Chadwick, PN.

Legend tells us that once upon a rime, in a hospital basement far, far, away, an OR. nurse found a package wrapped in newspaper and tied with a string beneath a pile of obsolete total hip instruments. The package bore an inscription which read, "Sterile bandages" and was dated twenty years previously. The OR. nurse grabbed the package eagerly and rook it to the Chief Wizard of the Lab, who submitted the mysterious package to all manner of tests.

Lo and behold, the package was declared to be sterile!

There was much rejoicing throughout the OR. Kingdom. There was amazement that past hospital dwellers were able to create and maintain sterility under such conditions, for this was contrary to all that the OR and CSR kingdoms held to be true. There was rejoicing, and there was wonder, but unfortunately little else, for both the OR and the CSR continued to outdate based on time related criteria. And so it has remained in most ORs and CSRs to this very day.

This is where the fairy tale ends and event related outdating begins.

Event Related Outdating

Event related outdating is based on the knowledge that items that have been properly cleaned, wrapped, sterilized, stored and handled will remain sterile indefinitely, until some event occurs that leads to actual or potential contamination of the sterile item. Event related outdating is easy and inexpensive to implement and monitor. It saves thousands of dollars in both staffing and supply costs. It decreases waste caused by the disposal or reprocessing of wrappers for sterile goods and decreases steam and Ethylene Oxide sterilization requirements. Event related outdating does not compromise patient care or increase intra-operative risks because it does not change the existing quality assurance practices regarding sterilization and the handling of sterile goods.

Hospitals have traditionally outdated or reprocessed unused sterile goods based on expiry dates established many years ago by the wrapper manufacturers. For example, items wrapped in reusable muslin/linen wrappers outdate in one month according to the linen manufacturers, regardless of the conditions of handling and storage. It is interesting to note that the one-month timeframe has been interpreted as 28, 30 or 31 days by various hospitals. Interpretations of shelf life have been known to vary between different departments in the same institution.

Professional Standards and Recommended Practice

Although not widely practiced in Canadian operating rooms and central supply departments, event related outdating is supported by several organizations.

Abstract

Traditionally ORs and CSRs have outdated reusable sterile goods at predetermined times. Professional standards (ORNAC, AORN, CSA) support event related outdating meaning that sterile goods remain sterile indefinitely unless package integrity is compromised. Significant savings in supply and labor costs can be realized without compromising patient care. The article outlines a model for the implementation of event related outdating.

The ORNAC 1993 Recommended Standards of Professional & Clinical Practice, Standard 2: Item 5.14 state "Shelf life is event related rather than time related. Dates shall be utilized as a method to rotate materials and reduce the time packages and items are exposed to factors that may result in contamination."

AORN Recommended Practice XI for Steam and EO Sterilization states that: "Shelf life of a packaged sterile item is event related." 2 and The Canadian Standards Association Standard 8.2.2 states "Shelf life
is event related." In industry, it is common practice for vendors to print, "Contents sterile, unless damaged or opened." on sterile goods.

**Implementing an Event Related Outdating System**
Despite such support, and the obvious benefits of event related outdating, most ORs and CSRs continue to outdate based on date related criteria.
In order to be able to implement a system of event related outdating, the following steps should be implemented:

1. **Literature Review**
   Conduct a literature review to become familiar with the entire topic of event related outdating.

2. **Review of Decontamination and Sterilization Processes**
   A review of the decontamination and sterilization processes occurring in both the OR and CSR is required to determine compliance with the applicable professional standards for decontamination, packaging and sterilization. Sterility assurance mechanisms should also be in place including:
   i) Process Indicators to ensure that parameters of the processing are sufficient to cause sterilization.
      - chemical indicators i.e. Labeling tapes and internal chemical indicators for all sterile packs.
      - biological indicators i.e. commercially available ampoules containing live spores for routine testing and to be included with all implants.
      - mechanical indicators i.e. sterilizer graphs and printouts.
   ii) Load numbers on the contents of each sterilizer load for potential recall situations.
   iii) Tamper Proof Locks for container systems.
   iv) Bowie Dick Test - to monitor the effectiveness of air removal from the sterilizer chamber.
   v) Routine Preventative Maintenance to sterilizers
   vi) Regular cleaning of sterilizers according to manufacturer's recommendations.
   viii) Education - on-going training conducted for OR and CSR personnel to ensure understanding and compliance with reprocessing policies.

3. **Review of Transportation and Storage Protocols**
   A review of the transportation, storage and handling processes for sterile goods is required. AORN Recommended Practices for Steam and Ethylene Oxide Sterilization IX and X and CSA Standard CAN/CSA-Z23 14.3-M91 detail the elements of effective transportation and storage. Some key components of these standards include:
   - items are covered, enclosed and protected from contamination and physical damage or loss during transportation.
   - items are stored in controlled temperature, humidity and ventilation.
   - there is limited access and minimal traffic through the storage area and no street clothes allowed.
   - products are stored off the floor on sectioned shelving.
   - items must be kept dry, vermin and dust free.

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Author
Sandy Chadwick is Team Leader OR/PACU at York Central Hospital in Richmond Hill, Ontario. The author wishes to acknowledge the assistance of Sheila Arnston R. N. ID in the development of this project.
-items are adequately spaced to prevent crushing, bending, tearing or puncturing and are easily visible and retrievable to prevent damage to the wrapper or label.
-inventory control measures are implemented to ensure that stock is rotated such that oldest stock is utilized first.

Nursing and technical personnel should adhere to the AORN Recommended Practices for Aseptic Technique III: "All items presented to the sterile field should be checked for proper packaging, processing, moisture, seal integrity, package integrity and the appearance of the sterilization indicator.”

Steps three (3) and four(4) identify the events that may lead to contamination of sterile goods. Attempts should be made to prevent the problems identified in compliance with the standards.

5. Culture & Sensitivity Testing of Outdated Items
Case studies reported in the literature regarding the culturing of expired items, have demonstrated that items that have exceeded their expiry date for as long as seven years, have remained sterile. If expired items in intact packages can be located (and most OR have at least a few), conduct C&S testing on the items. Sterility maintained beyond the expiry date supports the implementation of event related outdating.

6. Cost Benefit Analysis
i) Determine the current costs of supplies and labor to complete date based outdating. Chart 1 provides a sample worksheet which can be used to estimate the annual costs.
York Central Hospital operates five to six ORs, performing 8,200 surgical cases annually. Based on this formula, our expected savings in labor and supply costs due to the implementation of event related outdating in the OR alone will be $5,800. The savings reported in the literature have been $20,000+.

ii) Determine the cost in supplies and labor to monitor event related outdating.
At York Central Hospital, we have decided to use
a) a random audit of ten items monthly to ensure proper stock rotation and conditions of storage
b) C&S testing of five items per month randomly selected throughout the O.R, packaged in:
   - ready-made paper envelopes heat sealed in OR
   - paper wrappers
   - linen wrapped in the two most frequently used sizes
   - container

iii) Determine the cost of any training or education required to implement event related outdating.
We estimate that these activities will require less than one-half hour of technical aide time monthly, or less than $100 annually. The Lab has estimated that the costs arising from the C&S testing are negligible and can be easily assumed by Lab personnel without an increase in the supply or staffing budgets.
New labels will be required to be placed on sterile goods declaring that the item is sterile indefinitely, unless package integrity is damaged. Contact a representative from the company providing your chemical indicators and other sterility process supplies to determine the availability and costs of these labels.
We have obtained labels from 3M Canada Ltd. at the same cost as the current load indicator labels, so we will not incur any incremental costs.

6. AORN,p.211.
7. Seek Support from Key Users
Armed with the professional standards, results of your literature review and the C&S testing combined with your Cost Benefit Analysis, seek support from key individuals/departments throughout the institution:
- Infection Control Practitioner and Infection Control Committee
- Manager of CSR/SPD
- OR Nursing and Technical personnel
- OR Committee, Chief of Surgery, Program Directors
Submit a formal proposal to the Senior Management Committee. Be prepared for this information to be shared with the Medical Advisory Committee and the Board of Trustees, as required by your institution's policies.

A Point of Discussion: Sterility Maintenance Covers
The AORN states: "The length of time an item is considered sterile depends on factors that include the:
- type and configuration of packaging materials
- number of times a package is handled before use
- storage on open or closed shelves
- conditions of the storage area (e.g. cleanliness, temperature, humidity)
- use of dust covers and method of seal."6
There are no specific guidelines regarding what items should be placed in dust covers, how the dust covers should be sealed or their duration of use. The manufacturer of the dust cover states that sterility will be maintained indefinitely providing the dust cover's integrity is intact. For properly prepared, handled and stored sterile goods, a dust cover is redundant and not cost-effective.
This has been clearly demonstrated by the studies that have already proven that properly handled items are sterile indefinitely providing package integrity is intact, without dust covers. At least one other study of fifty weeks duration, has shown that sterility was not impacted by the use of dust covers. 7
Dust covers will not be routinely utilized in the O.R at YCH. The number and type of items that remain unused for one year will be monitored. These items will be evaluated to determine if they should remain sterile, need to remain in stock unsterile or should be deleted from inventory. This action will improve inventory control and may result in space savings, a benefit to any Operating Room Suite.

Summary
The legend has a happy ending. Event related outdating does not need to remain a fairy tale. It is easy to implement and monitor. It does not compromise patient care and is supported by professional standards. It can save the OR and CSR thousands of dollars in supply and staffing costs, money and labor that can be redirect to providing optimal patient care. It is this type of reengineering of traditional systems that can provide the savings necessary to remain fiscally viable in the current cost cutting climate. Event related outdating can become reality in any O.R.
Chart 1

York Central Hospital
Annual Cost of
Existing Outdating System

A) Reprocessing Labour Costs

# hours/year x average annual cost
to reprocess x hourly rate = reprocessing

B) Restocking Labour Costs

# hours/year x average annual cost
to restock x hourly rate = restocking

C) Reprocessing Supply Costs

1. Determine the number of items outdated annually.
2. Calculate the percentage wrapped in linen, peel pack and paper wrappers.
   (i) Linen
   % of total items reprocessed annually x cost of wrappers
   (ii) Peel Pack
   % of total items reprocessed annually x cost of peel pack
   (iii) Paper wrappers
   % of total items reprocessed annually x cost of wrappers
3. Include the cost of external and internal chemical indicators.

* May need to be calculated for each size of wrapper under (i), (ii) and (iii) based on individual OR’s style of wrapping. Include additional wrapping supplies such as towels, instrument tip protectors.

D. Costs of Sterilization

# loads/year x cost/load

Total Reprocessing Costs = A + B + C + D
= Potential Annual Savings of Event Related Outdating
Indefinite Shelf Life . . . Amen!

The author describes her personal journey towards implementing an Indefinite Shelf Life standard in her CS department.

by Dorothy Jevitt

Over the years, I would become gleefully overjoyed when I found a package that had been buried "somewhere" in the hospital for many years. I would march right over to the Lab with my treasure, never understanding why they weren't just as ecstatic about my find. In fact, I got into hot water when a lab technician questioned why I insisted on culturing these "things." It took every ounce of self-control not to take offense with such questions.

I don't think I ever convinced that lab technician of Central Service's need to prove that once an item is properly packaged and sterilized, it will remain sterile indefinitely unless the package becomes wet, torn, has a broken seal, or is damaged in some other way. The "proof of the pudding" is culturing a small part of the outdated package's contents to verify its sterility regardless of the item's age.

This trip to the lab more than 10 years ago was the first step in my efforts to institute an indefinite shelf life system of hospital sterilized packages. My efforts included cultures on outdated packages, plus a study on the different types of packaging materials, open/closed shelving systems, and clean/dirty environments. I used small safety pins which are easy to culture. We made enough test packages to test after two weeks, and then every month for 18 months. We tested packages that were:

- Stored in open, closed, clean and dirty areas; and
- Muslin wrapped, disposable non-woven wrapped (both with and without plastic "dust" covers), and paper/plastic peel pouches.

All cultures were negative—which proved to me that our packaging and handling techniques were ensuring the sterility of items processed in CS.

It takes time to change the ingrained perceptions of people. We were all taught that on a given day, at a given time, a sterile package will no longer be sterile, cannot be used as a sterile item, and must be resterilized. And, as we all know, this has cost hospitals many dollars in labor, supplies and inconvenience. What a waste! Dates still have their place and should be used, but for inventory control purposes only! Dates should also be used to alert personnel to medications or materials within a package, such as balloons on catheters, which deteriorate with the passage of time.

Two years ago, I made preparations toward my goal of an indefinite shelf life. I went as far as ordering "Sterile Unless Damaged or Opened" labels. Then I chickened out. I ten' the timing wasn't right, for many internal reasons. I patiently bided my time while still seeking additional support from others in our field for the "sterility is event-oriented, not time-oriented" theory. In the meantime, whenever teaching new RNs and technicians, I never missed an opportunity to state and restate that a properly packaged and sterilized item will remain sterile until the package becomes torn, wet or unsealed.

Lo and behold, the day came when our Chief Anesthesiologist raised the question: "Why are we putting an expiration date on CS packages when commercially packaged items say 'sterile unless damaged or opened'?" That was my cue! I discussed my plans with my vice president, confessing that I had lacked the courage to pursue the new shelf life procedures before this. She said, "Be courageous. Do it!"
Our new system
We immediately discontinued our color-coded 12 month system (which had worked beautifully, by the way) and began our new shelf life procedure. All items sterilized in our CS department using paper/plastic packaging (or muslin wrapped items in plastic covers) are considered to have an indefinite shelf life unless the integrity of the package has been compromised. A label stating "Sterility is guaranteed until the package is damaged or opened" is affixed to all packages and trays. Muslin wrapped packages without plastic dust covers are given one month expiration dates.

We monitor the labels with Julian dates: the last digit of the year the item is sterilized, the sterilizer number and the cycle number. (For example, "1764 1 6" is read as follows: 176 is the Julian date; 4 is the last digit of 1984; 1 is the sterilizer number; and 6 is the cycle number.) These labels, are necessary for recall and inventory control purposes.

Instruction for users
Instruction on our new system was given to all personnel within the hospital who use sterile products. Head nurses and other department heads were approached individually to explain the "new" theory of shelf life. All users were informed that it is their responsibility to inspect the package prior to use. It the package is torn, wet or damaged, the item cannot be considered sterile.

A memo describing the new procedure was circulated to all nursing units, the emergency room, OR, physical therapy, X-ray, the Lab, ambulatory care center, continuing education department and satellite clinics. The memo explained that expiration dates do not guarantee sterility, but instead act as a "control" for rotation of sterile items, and promote the use of older items first. Rotation of supplies is important to ensure that "old" supplies are used prior to "new" supplies.

1. from left to right: Old supplies are removed from the left of the shelf; new supplies are added to the right side, moving older supplies to the left. (IAHCSM calls for right to left rotation, however, our hospital has been rotating supplies left to right for more than 20 years.)
2. from top to bottom: Old supplies are removed from top of stock; new supplies are added to the bottom.
3. from front to back: Old supplies are removed from front of shelf; new supplies are added to the back of the shelf.

Proper handling of sterile supplies helps to maintain sterility. They should be handled gently. Do not bend, crush or compress items which could break the seal or puncture the package. Storage areas must be maintained clean, dry, dust and lint tree, and protected from insects and vermin.

Of course, we inserviced our own central service and surgery personnel. They were happy to see an end to the countless hours of checking, repackaging and resterilization of outdated supplies. In an era when we are trying to control and limit the cost of operations, this new procedure has been a relief to all of us.

The author
Dorothy Jevitt, RN, has been Director of Central Services at Wuesthoff Memorial Hospital in Rockledge, Florida for 13 years. A graduate of the Indiana University Medical Center School of Nursing in Indianapolis, Indiana, Jevitt is also corresponding secretary for the Central Florida Chapter of IAHCSM.
Shelf Life

Shelf life is defined as the duration of sterility of a packaged sterile item. Shelf life is designated as either time related or event related. AORN believes that loss of sterility of a packaged sterile item is event related. That is, the length of time the item remains sterile depends on the occurrence of a contaminating event. Naturally, the opportunity for a contaminating event increases over time. However, studies have shown the shelf life of some packaged items to extend up to and beyond 50 weeks with no contaminating event. Factors that affect the shelf life of an item include:

1) the type of materials used for packaging and the methods of wrapping,
2) whether dust covers are used and the methods for sealing the dust covers,
3) the number of times the package is handled and the number of different people handling the package, and
4) storage conditions, such as open or closed shelves, cleanliness of the storage area, and the temperature and humidity of the storage area.

The Joint Commission on Accreditation on Healthcare Organizations requires facilities to have policies and procedures designating either time-related or event-related shelf life for hospital sterilized items and for commercially prepared sterile items that do not contain an expiration date. The Joint Commission further requires that the policies established be consistent in intent and application throughout the facility.

Many facilities have adopted an event-related, shelf life policy. When such a policy is adopted, it is advisable to develop a protocol to ensure that the oldest items are used first. Sterilized items should be marked with the date of sterilization. At regular, periodical intervals, stock should be rotated so that items with the oldest sterilization dates are at the front of the shelf or bin. These items should be used first to avoid prolonged opportunity for a contaminating event to occur.

Sterile items that remain on shelves and are unused for a period of over one year should be evaluated as to the continued need for maintaining the item in a sterile state. Items remaining on shelves for extended periods represent poorly managed inventory dollars. Slow inventory turnover should be carefully evaluated to determine the necessity of stocking such items.

The following sources provide additional information related to shelf life:


The Materials Management Department of the Regina Health District (RHD) adopted an event related sterility system in March 1996 (1,2). Previously, all muslin wrapped sterilized hospital products were dated with an expiry date (30 days from the date of sterilization). Health care personnel would verify that a product was sterile by checking the expiration date. Outdated packages were considered contaminated. The assumption was that, with the progression of time, articles would become contaminated. Outdated muslin packages were reprocessed before they could be used. Reprocessing outdated products was expensive in terms of staffing and supplies. An event-related sterility system was considered because of the "potential savings in money, time and effort." (1).

Three packages that had been sterilized over 40 years ago were found stored in an open box in the sub-basement of the Regina General Hospital. The packages were double wrapped in brown paper: one was dated May 1953, and two were dated October 1955. The items in the packages were cultured in March, 1996.

Method

Each of the packages contained a safety pin, gauze, and a large abdominal pad. These were cultured in order to determine the presence of bacteria. The safety pins were placed into test tubes containing Bacto D/E Neutralizing Broth (FA; Difco Laboratories, Detroit, Mich.). The gauze and the abdominal pads were cut into pieces approximately 5 cm. by 5 cm. using sterile scissors and placed in the broth in a sterile container. Broths were incubated aerobically for 48 hours at 35°C. All broths showing turbidity were subcultured. Broths that were not turbid were incubated for an additional 48 hours at 22°C. All broths were subcultured to blood agar plates which were incubated aerobically at 35°C for 48 hours. The plates were examined for bacterial growth. Plates showing no growth were reincubated for an additional 48 hours at 22°C. All isolates were identified to species level using standard bacteriology procedures.

Results

The large pad in package I grew Staphylococcus coagulase negative after 48 hours incubation; the other two items in this package were sterile. This was the first package that was tested and may have been contaminated during the testing procedure as the pad was awkward to handle. All three items from package II were sterile. The paper wrapping of package III was disintegrating on the corners, therefore, it was not securely sealed. The safety pin in package III was sterile. Bacillus species was isolated from the gauze. Staphylococcus coagulase negative and agrobacterium radiobacter were isolated from the pad. Testing results are summarized in the table below.

Discussion

In an event related sterility system, the emphasis is on events that occur to damage the integrity of the package and not on the date the item was processed. Packages that are torn or unsealed are considered contaminated. If we assume that a 30-day time period means contamination, then package II would have been considered to be contaminated 40 years ago. It is intriguing that a package, kept in sub-optimal conditions, could maintain sterility for a period of 40 years.

Acknowledgements

The authors thank Mickey Gessell, Coordinator of Materials Management Processing, Regina General Hospital for supplying the sterile packages.

References

Significant Savings Achieved By Implementing Event Related Outdating
By J. Lamb, S. Foster, E. Henderson, & W. Krulicki

Introduction
The event related outdating (ERO) theory is based on the assumption that items that have been properly cleaned, wrapped, sterilized, stored and handled will remain sterile indefinitely unless the integrity of the package becomes compromised. Hospitals have traditionally outdated or reprocessed re-usable sterile products (RSP) based on unscientific dates that were established years ago. These predetermined expiration dates vary among institutions. An ERO policy does not jeopardize patient care or increase interoperative risks. Although not widely practiced in Canadian hospitals, ERO is supported by research and practice standards.

Abstract
The event related outdating (ERO) theory is based on the assumption that items that are properly cleaned, wrapped, sterilized, stored and handled will remain sterile indefinitely unless the integrity of the package becomes compromised. The authors describe how one Surgical Suite (performing approximately 600 cases/month) implemented an ERO program with estimated annual savings of almost $10,000/year.

Literature Search
As long ago as 1984, Mayworm suggested that the practice of outdating sterile goods was archaic. Instead, he postulated that properly packaged material would remain sterile indefinitely. A literature search revealed there have been several studies supporting this theory. A study by Klapes et al in 1987 showed that storage periods of up to fifty weeks did not increase the probability of contamination, regardless of the wrapping material. More recently, Donovan, Turner and Smith (1991) presented two case studies where hospitals converted their central sterile storage policy and procedure from "time related" to "event related". This eliminated the need of expiration dates on their in-house sterilized products. Chadwick (1994) describes successfully implementing an ERO system at the York Central Hospital. Current standards and recommended practices of the Association for the Advancement of Medical Instrumentation (AAMI), the Association of Operating Room Nurses (AORN), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Center for Disease Control (CDC) support ERO (AORN, 1994, Schroeder, 1994). The Canadian Standards Association states that "shelf life is event related" (Canadian Standards Association, 1991). In addition, the Operating Room Nurses Association of Canada (ORNAC) Recommended Standards of Professional & Clinical Practice state that "shelf life is event related rather than time related. Dates shall be utilized as a method to rotate materials and reduce the time packages and items are exposed to factors that may result in contamination" (ORNAC, 1993).

Implementation
Following the literature review, it was determined by OR management and Infection Control that there was enough evidence to support ERO. In January 1995 a

<table>
<thead>
<tr>
<th>Method of Sterilization</th>
<th>Items Tested N (%)</th>
<th>Types of Packaging N (%)</th>
<th>Items Tested N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>122 (66.7)</td>
<td>PeelPack</td>
<td>79 (64.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ClothWrap</td>
<td>24 (19.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other</td>
<td>19 (15.5)</td>
</tr>
<tr>
<td>ETO</td>
<td>61 (33.3)</td>
<td>Peel/Stripack</td>
<td>48 (78.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other</td>
<td>13 (21.3)</td>
</tr>
</tbody>
</table>
search of the OR produced twelve items with expiry dates from January 1991 to November 1994. Most of these reusable items were articles that did not require sterility to be maintained (e.g., oral suction). Eleven of these items were in peel packs, and one was in a cloth wrapper. Mean time from expiry date was 809 (+/-155 days). The range was 81 -1496 days. These items had originally been either steam or ethylene oxide sterilized (ETO). The items were aseptically cultured in a HEPA-filtered hood. All surfaces were sampled using two swabs. One swab was placed on a SABOURAUD AGAR plate (for fungi) and the other in Mueller-Hinton broth (for bacteria). Cultures were incubated at 37 degrees C and checked daily. No growth was detected after seven days observation. A draft policy and procedure was developed and presented for approval to the Infection Control Committee. This policy included:

1. discontinuation of expiration dates;
2. labeling of each RSP with sterilization date and sterilization load indicator for recall purposes;
3. inspection of all packaging prior to use for external or internal indications of damage; and
4. emphasis on the importance of proper storage and rotation of inventory.

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**Table 2
Estimated Cost Savings**

<table>
<thead>
<tr>
<th>Weekly Savings ($)</th>
<th>Annual Savings ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials *</td>
<td>35</td>
</tr>
<tr>
<td>Sterilization</td>
<td>157</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>192</strong></td>
</tr>
</tbody>
</table>

*Wrappers, filters, tape, cart covers, etc.*
**Staff were assigned other duties

---

**Results**

The policy and procedure was implemented in February of 1995. A continuous quality monitoring process, whereby ten items per month were randomly selected for culturing was also implemented at this time. (Table 1). After eight months of quality assurance monitoring, there was no growth on the sterile items. It was decided at that time to reduce the quality monitoring to ten items every six months.

Our OR does approximately 600 general surgery, major orthopedic, neurosurgery, plastic, urological and peripheral cardiovascular procedures per month. The estimated savings for materials and sterilization costs is $9984 annually (Table 2). The time saved by the staff in gathering, re-wrapping, reprocessing and re-shelving the items was not included in the estimates. The ERO policy has been implemented in Labour and Delivery as well as another Surgical Suite in the city. Hospital-wide implementation throughout the Calgary Regional Health Authority is recommended. Use of this policy can achieve significant savings.

**References**


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**Authors**

The authors are employees of the Calgary Regional Health Authority, Bow Valley Site. At the time this project was undertaken, Jeanne Lamb, RN, BN, was Assistant Nursing Unit Manager of the Surgical Suite. Sheila Foster is the working leader, Surgical Reprocessing. Dr. E. Henderson, Ph.D., Epidemiology, Associate Professor, University of Calgary, is an Epidemiologist, Infection Control. Wally Krulicki is a research technologist, Infection Control.