Event Related Outdating

A Fairy Tale Comes True

By Sandy Chadwick, R.N.

O.R. Legend tells us that once upon a time, in a hospital basement far, far, away, an O.R. 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 O.R. nurse grabbed the package eagerly and took 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 O.R. 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Hospitals have traditionally outdated or reprocessed unused sterile goods based on expiry dates established many years ago by the wrapper manufacturers.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 practised 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 labour 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 utilised as a method to rotate materials and reduce the time packages and items are exposed to factors that may result in contamination."[1]

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." [3] 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. labelling 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.

vii) Current Policies and Procedures reflecting professional standards of sterilization practice.

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.
-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 utilised first.

1. ORNAC, 1993 Recommended Professional & Clinical Standards (Canada: ORNAC, 1993), p. 39.
2. AORN, 1993 Standards & Recommended Practices (Denver: AORN, 1993), p.211.
3. CSA, Effective Sterilization in Hospitals by the Steam Process (Toronto: CSA, 1991), p.26.

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4. Review of Handling of Sterile Goods

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."[4] The amount of handling a sterile item undergoes should be minimised.

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.[5]

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 labour 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 labour 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 labour to monitor event related outdating.

At York Central Hospital, we have decided to use two systems to monitor the event related outdating system:

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.

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.

4. AORN, 1993 Standards and Recommended Practices, (Denver: AORN,1993), p.101.

5. Arlene Donovan, David W. Turner and Arthur Smith, "Successful, documented studies favouring indefinite shelf life", *Journal of Healthcare Materiel Management*. March (1991), 37-40.

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.

6. AORN,p.211.

7. William E. Butt and others, "Evaluation of the Shelf life of Sterile Instrument Packs," Journal of Oral Surgery. Medicine&Pathology, 72(1991), pp.650-654.

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 labour 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 Outdatng System

A) Reprocessing Labour Costs

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

B) Restocking Labour Costs

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

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