



## “Event Related Sterility” By Paul A. Hess, BSN, RN, CRCST, ACSP

“Time, time, time, see what’s become of me.”  
(A Hazy Shade Of Winter. Simon and Garfunkle, 1966) food for thought from one of my favorite duo’s. What

does happen to an item while it sits on the shelf? What magically happens after an arbitrary expenditure of time? That is what we are going to look at for the purpose of this in-service.

Upon completion of this in-service the reader (1) will be able to identify the factors that impact shelf life. (2) List sterility assurance measures to prolong shelf life, and (3) describe steps necessary to implement an event related sterility program.

The definition of Event Related Sterility is simply stated, “A package is considered sterile until some event makes it unsterile”, in other words, contaminated.

Packaging materials played an important role in the consideration for how long a sterilized package would remain sterile sitting on a shelf. Muslin wrappers were at the center of a Centers for Disease Control study regarding shelf life in the early 1970’s<sup>i,ii</sup>. The results of these studies showed that items wrapped in double layers of muslin had a shelf life of three weeks, while items placed into a dust cover were sterile up to nine months. Improvements in packaging materials and knowledge of what impacts shelf life have greatly improved our acceptance of event related sterility.

The factors that effect shelf life as we have stated are obviously the packaging materials and it’s susceptibility to tearing, puncture, crushing, compromised closures or seals and ability to shed moisture. Third generation fabrics with cotton / poly blends have replaced muslin as a reusable wrapper of choice. Rigid container systems provide greater protection than wrappers but still must allow the sterilant into and out of the container. That is the weak point of the containers design. The filter and / or seal are the openings to allow sterilant penetration, but if compromised also allow contamination.

The storage conditions that a sterile package is kept, plays a role in prolonging or maintaining sterility. These storage conditions include the environmental hygiene of the area, the number of air exchanges, the temperature and humidity, movement of personnel within the storage space and open or

closed shelving all play a role in keeping our products sterile. Never use aerosols around sterilized packages.

You can enhance the package shelf life by rotating stock using the FIFO (First In, First Out) principal. This will help minimize the number of times that a package may be handled while being stored on a shelf.

Why spend all of our time and energy and resources to make a package sterile then mishandle the package right out of the sterilizer. The handling of a package is another factor that plays a role in shelf life. Under the best-case circumstances a package is handled first when it is removed from the sterilizer cart. Second, when being placed on the case cart or supply cart and third when it is handled and opened for use. We all can identify many more times when a package is handled. Just give it some thought. How many times have you picked up a package then decided it was not what you wanted? Had an item being returned to your shelf after being “pulled” for a case? What happened to that package while it was away from your control?

Wrapped packages need to be picked up off a shelf. Dragging a package over the edge of the shelf will damage the wrapper. Dropping a wrapped package, stacking packages one on top of another causes compression of the lower packages. Carrying a package against one’s body allows body soils to be introduced to the packaging materials.

AAMI and AORN<sup>iii</sup> both have statements related to the sterility of a package being event related. The current JCAHO manual (Comprehensive Accreditation Manual for Hospitals, Update 4, November 2004) has no reference to shelf life or expiration dating but previous versions stated that hospitals should establish shelf life to be time or event related.

For control purposes we continue to label our packages with a load and lot number. This unique number identifies for the reader, the date in the form of a Julian date, sterilizer and load that the package was sterilized. This unique identifier allows for the rotation of stock, and for the recall in the event of a sterilization failure.

Using event related sterility minimizes the necessity to reprocess the outdates on the first of the month. The packages still need to be examined for integrity and signs of soil or water damage every time the package is handled. Savings are achieved in labor costs and packaging materials.

Event Related Sterility is a concept that a sterile package is more a victim of its environment than the clock.

Commercially sterilized products have a label that either lists an expiration date or has a statement similar to “the contents of this package are sterile until opened or damaged”. If a package bears both an expiration date and the aforementioned statement, the expiration date has nothing to do with sterility maintenance, it is the product's viability. In other words, something in the product will begin to break down and may fail during use.

To implement an event related sterility shelf-life program we must first establish our policies for acceptable storage conditions and enforce their adherence. The objective of any storage area is to preserve the integrity of the package contents until time of use.

Ideal conditions will help prolong the shelf life of our products. The ideal conditions are a temperature of 64°F (18°C) to 72° (22°C) to a high end of 75° F (26° C), minimum of four air exchanges per hour, controlled relative humidity of 35 to 75 percent. Fire codes usually dictate that the item should not be stored any closer to the sprinkler heads than 18” (45.72cm). The distance from the floor should be 8 (20.32cm) to 10”(25.4cm) and 2” (5.08cm) from the walls. The area should have limited access and general traffic flow should be at a minimum. This storage area should have a positive airflow relative to adjacent public and decontamination areas. General housekeeping and area hygiene should include at least daily cleaning of floors and horizontal work surfaces. Other surfaces, such as walls and storage shelves, should be cleaned on a regularly scheduled basis and more often if needed.

The general attire of the staff working in the storage area should be clean surgical attire. Attire should be changed daily or more often as needed (i.e., when wet, grossly soiled, or contaminated) and, if reusable, should be laundered by the laundry facilities used by the health care institution for other surgical textiles. Clean shoes, to be worn only in the hospital and a head cover to cover the hair completely should be worn while in the storage area.

The second step would be to establish acceptable packaging materials and their relationship to prolonging shelf life. The use of rigid containers and dust covers will enhance shelf life. Written policies need to be established to include statements regarding the suitability of the packaging material for the cycle and method (is the material compatible with the sterilization

process?, does it allow the sterilant to enter the package then be removed?); strength of the package (will it resist tears, puncture, temperature and humidity changes without changing the integrity of the material?); type of packaging (e.g., reusable woven or single-use non-woven textile wrapper, paper /plastic pouch, rigid container); package integrity properties and the ability to present to a sterile field.

Present the information to your Infection Control Committee. You always want to have the approval of this committee whenever you are making a process change. Your Infection Control Practitioner is your best ally to bring about change.

Identified obstacles to implementing event-related

sterilization. One author<sup>iv</sup> lists the following 10 challenges:

1. Overcoming resistance to change.
2. It takes too much time and effort to change.
3. How to work with state or local laws that still require expiration dates on hospital packages.
4. The hospital isn't comfortable with its storage practices.
5. Gaining control over transportation and handling procedures.
6. Uncertainty about whether packaging material will hold up in event-related sterility environments.
7. Fear of problems with the Joint Commission.
8. Writing a policy takes time and knowledge about the new system.
9. Establishing an effective labeling system.
10. Uncertainty about how long it will take to convert to an event- related sterility maintenance program

Hospitals that have implemented a successful event related sterility program began with:

- “a written event-related sterility assurance policy that clearly outlines the subject, objective, policy statement, and procedures.
- Consider all labor and materials involved and conduct a cost/benefit study to help educate those involved about the immediate payback if they incorporate this change.
- Present the written policy and cost/benefit analysis to your Infection Control committee for approval. Some monitoring suggestions to include are “first in/first out” stock rotation,



