CSIRO PUBLISHING
Healthcare Infection, 2013, **18**, 121–129
http://dx.doi.org/10.1071/HI13002

Review

Shelf life of sterilized packaged items stored in acute care hospital settings: factors for consideration

Prabha Lakhan[1,3] BN, MN, PhD

Joan Faoagali[2] MBChB, MPH, FRCPA

Rosemary Steinhardt[1] BHSc, GradCertMngt, GradDipInfection Control

Dolly Olesen[1] Grad Dip(Clinical Nursing Studies), MHSc(Infection Control)

[1]Centre for Healthcare Related Infection Surveillance and Prevention, Communicable Diseases Unit, Chief Health Officer Branch, Health Service and Clinical Innovation Division, Queensland Health.
[2]Princess Alexandra Hospital, Ipswich Road, Woolloongabba, Qld 4102, Australia.
[3]Corresponding author. Email: Prabha_Lakhan@health.qld.gov.au

Abstract. ***Introduction*:** Reusable medical devices are sterilized and stored before their use in hospital settings. The length of time the sterilized item can be stored (shelf life) to maintain sterility has been discussed in the literature over the last four decades, with a shift to an event rather than time-related determination of shelf life. This paper reviews the evidence and provides a summary of some key issues for consideration when adopting event-related or time-based shelf life recommendations for packaged sterile items in Australian hospitals.

***Discussion*:** Australian and international standards provide guidelines for procedures to be used for sterilization of reusable medical devices and storage conditions following sterilization. Reusable medical devices are sterilized by commercial manufacturers or sterilizing departments located in hospitals. Commercial manufacturers allocate expiry dates on sterilized items which should be respected, unless sterility is compromised by an event. The shelf life of items sterilized in hospital is debated, with growing support for event- rather than time-related sterility. Many factors determine whether event- or time-related shelf life should be followed. Well designed experimental studies into shelf life of sterilized items are lacking, with some small studies indicating that items can remain sterile for 12 to 24 months. Factors for consideration by hospitals are outlined and an algorithm to assist in implementation of event-related or time-based shelf life for reprocessed reusable medical devices is provided.

***Conclusion*:** The method of determining shelf life in hospitals is dependent on adequacy of processes for sterilization, monitoring of sterility over time and storage conditions.

Received 3 January 2013, accepted 24 March 2013, published online 7 May 2013

Introduction

In Australian acute hospital settings, medical devices used for invasive procedures can either be sterilized and supplied by commercial manufacturers, using various methods of terminal sterilization under strict conditions stipulated in national standards (e.g. ethylene oxide and gamma irradiation) or reprocessed in a Central Sterilizing Supply Department (CSSD). Prior to their use, sterilized packages are stored in a variety of areas within wards and units, operating theatres, and emergency and outpatient departments. It is essential that adequate quality management systems and processes exist in organisations to ensure patient safety and quality.[1] Processes which ensure that reusable medical devices are sterilized, packaged, stored appropriately and remain sterile at the time of their use, and provide certainty that any breeches in sterility are identified before the item is used will ensure patient safety and quality care. The Australian and New Zealand Standard (AS/NS 4187 : 2003) and the International Standard Organisation (ISO 11607-1; ISO 11607-2:2006) outline strict criteria and processes to be followed for sterilization of packaging systems, storage conditions (including optimal temperature and humidity), and monitoring of reprocessed reusable medical devices in Australia.[2–4] In general, nurses are primarily responsible for appropriate storage and monitoring integrity of sterilized packages, and maintaining an inventory control method to ensure items do not stay on shelves for lengthy periods of time, especially items with an expiry date.

The length of time that an item can remain sterile (shelf life) has been discussed and reviewed in the literature over the past four decades.[5–8] The type of packaging material, storage

Implications

- Shelf life of reprocessed reusable medical devices may be time-based or event-related.
- Conducting a risk assessment and developing an implementation plan or time-based or event-related shelf life is essential.
- Regular monitoring for compliance and review of any reprocessing or storage-related breaches should be conducted post-implementation for time-based and event-related methods of determining shelf life.

conditions and environment, as well as care with and frequency of handling are important determinants of shelf life.[9] For example, in the 1970s shelf life of items was time-related (known as time-related shelf life), with reprocessed reusable medical devices (RMDs) having to be reprocessed after the expiry date. Advances in packaging material and recognition of the need to control dust, temperature, humidity and vermin have resulted in better storage conditions that have enabled a shift from time-related to event-related shelf life. Event-related shelf life is a cost-effective and widely recommended method for shorter and longer term storage of reprocessed RMDs. The reprocessed packaged items are considered sterile indefinitely until a package is opened, or microorganisms gain entry through events such as the packaging getting wet, torn or punctured or the seal breaking.[7,10,11]

Although event-related sterility is being recommended in the literature for determining shelf life of reprocessed packages, this method of determining shelf life of RMDs is not applied in all hospitals. Some hospitals continue to use a time-related shelf life for RMDs.[9,11] This method can also be used as an inventory-control strategy by hospitals to ensure that items do not stay on shelves for long periods of time and items with shorter expiry times are used before those with longer shelf lives.

In situations where time-related shelf life is practiced, if the packaging material is exposed to an event, it will be rejected irrespective of the expiry date. It is important to identify instances where an adverse handling or environmental event may reduce or negate the routine time-related shelf life. Some Australian nurses have voiced concerns regarding the risk of loss of sterility of rarely used items stored for greater than 12 months. This paper reviews the available evidence regarding application of event-related sterility for RMDs and the factors for consideration when implementing either an event- or time-related shelf life policy for storage of reprocessed packaged RMDs in Australian hospitals.

Evidence on shelf life of sterile reprocessed medical devices in hospital settings

Search of the literature revealed eight studies that investigated microbiological contamination of sterilized items stored over varying time periods (see Table 1).[6,10,12–17] The items were routinely sterilized in hospital-based Central Sterilizing Supply Departments for seven studies. Details of location of sterilization were not provided in the eighth study.

A limited variety of reusable instruments and wrapping materials was examined in each study. Test packages in all the studies were stored in usual hospital settings and handled in the same manner as other sterile items. Control packs were included in most studies. These packs contained the same instruments or materials as the test packs, but were not exposed to the sterilization process.

Studies that examined sterility of reprocessed instruments over time reported that some remained sterile from 6 months[10] to 2 years,[17] with some items remaining sterile for up to 10 years.[6] Studies finding small numbers of positive cultures either reported a lack of any trend in increased contamination over time;[6,15] or believed that the 3 out of 240 items with a positive growth were most likely due to contamination during the culturing processing.[16] Webster *et al.*[17] also reported that nine items in their study had maintained their sterility despite experiencing an 'event' (six were dropped, two had torn wrapping, and one had blood on the outer wrapping).

There were several weaknesses in the published studies that examined the shelf life of sterile reprocessed RMDs. These included: a lack of detailed information on study methods, lack of similarity in criteria (packaging materials, instruments, and time intervals) used for examining contamination across studies, lack of recent studies examining current packaging materials, limited number of instruments examined in existing studies and a lack of studies on long-term sterility of stored sterile packages. Although a larger number of total items were tested in some studies, allocating a small number of items for testing each month meant only a small number were tested for longer lengths of time. For example, a study that examined sterility of 60 items only tested 5 items that had been stored for 12 months.[16] The limited numbers and types of instruments tested in existing studies were not representative of the wide variety of commonly used instruments that are regularly reprocessed and packaged in healthcare settings. This limits the application of findings to all clinical settings although the similar findings reported in all the studies could suggest that these findings may be able to be extrapolated to alternative items prepared and packaged in a manner similar to the study items.

Shelf life of commercially sterilized items

Manufacturers supplying sterile medical devices follow strict sterilization procedures to ensure that the sterilized items and packaging system can withstand various storage and handling conditions. No studies were found that examined the sterility of packages containing items that were commercially sterilized and had been allocated an expiry date. The International Standards Organisation (ISO11607-1 and ISO11607-2)[2,3] has described the standards and requirements for sterilization of healthcare products, including wrapping materials, sterile barrier and packaging systems, and the