Technology Assessment Program

Office of Patient Care Services

BRIEF OVERVIEW

SHELF-LIFE OF STORED STERILIZED MATERIALS: SHOULD VHA ADOPT EXPIRATION DATING OR EVENT-RELATED OUTDATING?

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A SUMMARY FOR HTA REPORTS
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This summary form is intended as an aid for those who want to record the extent to which a HTA report meets the 17 questions presented in the checklist. It is NOT intended as a scorecard to rate the standard of HTA reports – reports may be valid and useful without meeting all of the criteria that have been listed.

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SHELF-LIFE OF STORED STERILIZED MATERIALS:
SHOULD VHA ADOPT EXPIRATION DATING
OR EVENT-RELATED OUTDATING?
(AUGUST 2003)

Item	Yes	Partly	No
Preliminary			
1. Appropriate contact details for further information?	√		
2. Authors identified?	√		
3. Statement regarding conflict of interest?			√
4. Statement on whether report externally reviewed?	√		
5. Short summary in non-technical language?	√		
Why?			
6. Reference to the question that is addressed and context of the assessment?	√		
7. Scope of the assessment specified?	√		
8. Description of the health technology?	√		
How?			
9. Details on sources of information?	√		
10. Information on selection of material for assessment?	√		
11. Information on basis for interpretation of selected data?	√		
What?			
12. Results of assessment clearly presented?	√		
13. Interpretation of the assessment results included?	√		
What Then?			
14. Findings of the assessment discussed?	√		
15. Medico-legal implications considered?		√	
16. Conclusions from assessment clearly stated?	√		
17. Suggestions for further actions?	√		

TECHNOLOGY ASSESSMENT PROGRAM

An Effective Resource for Evidence-based Managers

VA's Technology Assessment Program (VATAP) is a national program within the Office of Patient Care Services dedicated to advancing evidence-based decision making in VA. VATAP responds to the information needs of senior VHA policy makers by carrying out systematic reviews of the medical literature on health care technologies to determine "what works" in health care. "Technologies" may be devices, drugs, procedures, and organizational and supportive systems used in health care. VATAP reports can be used to support better resource management.

VATAP has two categories of products directed toward meeting the urgent information needs of its VA clients. VATAP assigns a category to each new request based largely on the availability of studies from results of initial searches of peer-reviewed literature databases:

- The ***Short report*** is a self-contained, rapidly-produced qualitative systematic review of 5 to 20 pages in length. It provides sufficient background information and clinical context to its subject technology to be accessible to a wide audience, including non-clinician managers.

- The ***Brief overview*** originated as an internal memo to VA clients with both well-defined and urgent information needs. It usually comprises 2 to 10 pages and assumes sufficient existing knowledge regarding clinical context and technology issues by its readers to omit these components of other VATAP products. It often requires some additional reading of documents (provided to the client with the overview) to obtain a full and comprehensive picture of the state of knowledge on the topic.

All VATAP products are reviewed by VATAP's physician advisor and/or key experts in VHA. Additional comments and information on this report can be sent to:

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BRIEF OVERVIEW

SHELF-LIFE FOR STORED STERILIZED MATERIALS: SHOULD VHA ADOPT EXPIRATION DATING OR EVENT-RELATED OUTDATING?

BACKGROUND

The Veterans Health Administration (VHA) Assistant Deputy Under Secretary for Health charged the VHA working group on sterilization (convened in 2003) with making recommendations for change to the VHA policy that limits the shelf life of VHA-sterilized stored materials to one year or 30 days, depending on the type of packaging (VHA white paper; June, 2003); after expiration of packaging-dependent dating, the materials must be re-packaged and re-sterilized.

The working group requested a review of the literature from the VA Technology Assessment Program (VATAP) as support for evidence-based policy recommendations. Particular issues to be addressed by the review were cost or patient safety benefits (or risks) that had been demonstrated to be associated with either policy option:

Event-related outdating

"The event related outdating (ERO) theory is based on the assumption that items that have been properly cleaned, 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 based on unscientific dates that were established years ago. These predetermined expiration dates vary among institutions..." (Lamb, 1996)

"To adopt event-related dating would mean that sterilized items would be considered indefinitely sterile unless their packaging became damaged (i.e. had holes, were wet or had a broken seal). We felt we could save the hospital thousands of dollars a year if shelf-life was based on the condition of the item versus the time it sat unused." (Donovan, 1991)

Expiration dates

"…Recommendations regarding specific storage times of various sterile packs were published by the Centers for Disease Control in 1983. Subsequent recommendations by the Centers for Disease Control, the Association for the Advancement of Medical Instrumentation, the Association of Operating Room Nurses, the Association for Practitioners in Infection Control, and in the 1990 Accreditation Manual for Hospitals published by the Joint Commission on Accreditation of Healthcare Organizations do not indicate specific shelf-lives for sterile items. Rather, current recommendations place the burden of shelf life determination on each medical facility by considering "package sterility to be event-related depending on the quality of the wrapping material, the storage conditions, and the amount of handling…The CDC currently makes no shelf-life recommendations for sterile packs…

Many hospitals and clinics still follow the old CDC guidelines. Several authors have suggested that these times may be too short, resulting in wasted time, materials, and manpower to unnecessarily reprocess sterile packs. " (Butt, 1991)

> *"Despite continued research in the last twenty years, the optimal expiration date of hospital supplies after sterilization remains controversial. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) in the USA requires that there be written policies addressing the shelf life of all stored sterile items. The expiration date generally accepted for US hospitals, as for The University of Iowa Hospitals and Clinics (UIHC), is approximately one month. However, no studies have unambiguously demonstrated the safe time to use. The UIHC spends at least $24,000 yearly for repacking and resterilization of approximately 1920 expired autoclaved surgical packs..."*
>
> *"Hospitals still rely on the shelf-life policy based on data by Standard and colleagues from the Centers for Disease Control (CDC) in 1973. In these studies, contamination occurred as early as three days after sterilization..."* (Widmer, 1992)

Schwartz (1992) encapsulates the issues and questions underlying the VHA working group request:

> *"The use of packaged, sterile instruments is a basic process in health care facilities. Most facilities have a policy which dictates a specific shelf-life for sterile instrument packs. There is some confusion, however, about how long that should be. How long do packaged sterile instruments remain sterile? When do they need to be repackaged and resterilized?"*

METHODS

Search strategy

VATAP performed extensive MEDLINE searches covering 1985 to the present using the MeSH descriptor sterilization as a major descriptor in addition to specific subheadings for the economics or utilization of sterilization. These were combined with free text words and MeSH terms for shelf life, time factors, infection control, asepsis, storage time, re-circulation, quality assurance, safety, contamination, equipment failure and safety practices. This resulted in a large retrieval set that was then combined with free text words and MeSH terms for efficacy, effectiveness, evidence, technology assessment, guidelines, outcome and process, clinical studies, controlled studies, feasibility studies, and other terms implying randomized or controlled study protocols. Finally, VATAP used PubMed for several searches using the related articles button on key citations that emerged from the initial searches.

Further, VATAP searched the health technology assessment (HTA) database maintained by The International Network of Agencies for Health Technology Assessment (INAHTA) using search terms for sterilization in completed reports or projects in progress.

Search results

These searches retrieved 675 citations from MEDLINE covering the years 1986 to 2003. After removal of duplicate or non peer-reviewed citations, and multiple reports on the same research project from the same authors, the search strategies yielded 187 references, categorized in Table 1 below:

Table 1. Frequency of categories of articles in citations retrieved by VATAP searches

Study type	Details	Number of articles
Descriptive	Sterilization 101*	35
	Hand disinfection	4
	Re-use of single use materials	20
	Miscellaneous (other descriptive, opinion, survey or case study)	77
	Purchasing equipment	12
	Hospital cleaning	4
	Behavior of materials with sterilization	21
	Baseline contamination after cleaning	9
Systematic review of any sterilization issue	1 (not relevant to this report)	
Analytic	Comparison of cleaning, disinfection, or sterilization products or methods	94
	Agri-food industry	4
	Shelf life of sterile packs	3
	Handling of sterilized surgical packs	2

* Rudimentary description of sterilization principles and/or practices in a non-peer-reviewed journal.

Selection criteria

VATAP required that articles included in this overview report primary data collection on any association between policy options and patient safety outcomes (i.e., nosocomial infections) or costs of operation for hospital surgical or sterile supply services, or that material sterility status, time, and package integrity be reported. Since the most recent Centers for Disease Control (CDC) guidelines specifying storage times for certain types of wrappers were dated 1983 (Klapes, 1987; Butt, 1991), VATAP restricted its attention to research reports published after that date.

RESULTS/DISCUSSION

The three empirical analytic studies that addressed shelf life of sterile packs are abstracted in Table 2; two use dental instruments and one uses general surgical packs. Two additional studies (also listed in Table 2) analyzed effects of handling or inter-hospital transportation on pack sterility. While none of these five studies fully meets the inclusion criteria, they do represent the only published research to date that directly addresses VHA policy concerns. For this reason, they were deemed by VATAP to be worthy of close attention for this overview. From these post-1983 studies, one sees that:

- Recently published studies (first section, “effect of time on sterility of pack, Table 2) do not provide evidence of spontaneous contamination of properly wrapped and

intact sterile materials and packages over observation periods of up to one year with careful periodic aerobic and anaerobic culture.

- Handling of sterile packages, including moving on shelves within a central sterilization department, does appear to predispose the contents to risk of contamination, even when visibly damaged packs are removed from the analyses (Widmer, 1992). However, a second handling study (Greene, 1987) reported that careful inter-hospital transport of sterilized surgical packs did not inherently predispose to contamination.

Any discussion of event-related versus expiration outdating should recognize that no published studies directly associate patient safety outcomes with either policy. Rather, the published research relies on the intermediate outcomes supplied by bacteriologic culture as evidence of contamination. Bacteriologic culture studies may be one instance in which surrogate or intermediate outcomes are acceptable and clinically meaningful, but even the culture studies do not identify the specific pathogens or pathogenic potential of any microbial contaminants that they identified.

The CDC has reviewed the same literature, barring the handling and transportation studies, and arrived at the same conclusions (CDC 2002):

> *"Sterilized instruments should be stored in a manner that preserves the integrity of the package. The following are recommendations for storage:*
>
> 1. *Sterilized items should remain wrapped until they are needed for use. They should be opened in the treatment area in a manner that will allow the inside of the wrapping to serve as a sterile field.*
> 2. *Unwrapped instruments are susceptible to contamination. Storing instruments loose in drawers or cabinets is not recommended as they cannot be kept sterile. Instruments stored in this manner are subject to contamination from dust, aerosols generated during treatment, and handling with contaminated hands.*
> 3. *Sterile items should be stored in enclosed cabinets or drawers free from moisture and dust. The storage area should be cleaned and disinfected weekly.*
> 4. *Sterile items should not be stored on the floor, under sinks, on window sills, or adjacent to air vents. These conditions lead to contamination that compromises the sterility of the packages and instruments.*
> 5. *A rotational policy should be developed (e.g., the "oldest" packs should be used first). This policy is also referred to as the "first in—first out" system of stock rotation."…*

COST IMPLICATIONS

VATAP literature database searches did not identify published documentation of relative or absolute costs associated with either policy option.

SUMMARY OF FINDINGS FROM PUBLISHED ANALYTIC STUDIES

The five studies abstracted in Table 2 indirectly support event-related outdating by providing bacteriologic culture evidence that the contents of intact sterile packaging do not spontaneously become contaminated with time. However, handling of sterile packages does appear to predispose their contents to risk of contamination, even when

visibly damaged packs are removed from the analyses. The CDC (2002) reports that other organizations concur with these conclusions.

The limited research evidence available suggests that VHA would be well-advised to change its policy and adopt event-related outdating of stored, sterilized materials, while following CDC guidelines for their careful storage and handling.

Table 2. Published research addressing shelf life of stored sterilized materials

Reference	Purpose of research	Material types	Study design/methods	Results/Conclusions	Comments
Effect of time on sterility of pack contents					
Butt (1991)	To examine the effect of time on sterile integrity for paper envelopes, peel pouches, nylon sleeves	Glass rods contaminated with human saliva to represent dental instruments	7200 (3600 controls) sample packs with 3 glass rods each Controls: opened immediately after steam sterilization and examined for bacterial contamination Test packs: randomly sorted after sterilization and stored in dental operatories (AU: Check previous word), then opened and sampled for culture at monthly intervals for 12 months	• Differences between control and test packs were insignificant for paper envelopes and peel pouches; • Nylon sleeves did show significant differences, but they were not time-related, and were attributed to difficulties in maintaining sterility while removing glass rods from test packages; • No trend toward increased rate of contamination over time for any package type tested.	A 12-month storage period does not adversely impact sterility of materials stored in covered containers in dental operatories.
Schwartz (1990)	To evaluate potential shelf life of sterile packaging materials used in dentistry	Dental instruments; one per pack	• Random selection of non-sterile instruments (300) for packaging type (paper, nylon, paper-plastic peel pouch all stored in frequently-opened drawers also containing non-sterile materials); • Aerobic or anaerobic culture (after inspection of pack integrity) at monthly intervals for 1 year after chemical vapor sterilization; • 60 unsterilized controls	• Group 1 aerobic cultured before sterilization: 59/60 packs positive; • Group 2 aerobic cultured 1 hour after sterilization: 1/60 packs positive; • Group 3 aerobic cultured 15 packs per month for one year: 2/180 packs positive; • Group 4 anaerobic cultured 16 packs/quarter for 1 year: 0/60 packs positive. Overall: • No time-related trends in positive cultures; • Contamination levels were within the range reported to result from unwrapping and transfer of sterile instruments, so culturing process itself may have been the source of contaminants.	• "Random selection" process not defined; • Cultures read only as "growth" or "no growth"; dichotomatous options may obscure true results; • Cultures did not address presence or absence of viruses, nor identification of specific organisms.
Klapes (1987)	To investigate the effects of 4 wrapping materials, dust covers, 2 storage locations, and times from 2 to 50 weeks on sterile integrity of surgical packs	Stainless steel coupons simulating surgical instruments, wrapped in packs with towels or surgical gowns	• 263 packs with stainless steel coupons were prepared, wrapped (2-ply reusable non-barrier woven, disposable barrier non-woven, polypropylene peel pouches), sterilized, and stored; • Reusable woven wraps were randomly selected from those routinely used, multiply laundered supply available in Central Sterilization Department; • 50% of packs dust-covered prior to storage; • Monthly intervals for 1 year: packs of each type were opened in laminar flow hood and coupons used to inoculate culture medium; • Cultures read as "growth" or "sterile".	Contamination probabilities: • Reusable woven wraps: 0.019; • Disposable non-woven packs: 0.017; • Peel pouches: 0.016; • Probability of finding a contaminated coupon after 50 weeks: 0.018. Differences not significant; no trend for increased contamination over time observed for any pack types studied.	Cultures read only as "growth" or "no growth"; dichotomous options may obscure true results.
Effects of handling or transporting packs on sterility					
Widmer (1992)	To develop a standardized protocol for sterility testing of autoclaved surgical trays that included potential injuries (events) as they might occur under clinical conditions	General surgical trays including test specimens of gauze, plastic, and stainless steel	• Protocol for "events" developed from observations of Central Sterilization staff (frequent events occurring to surgical packs after sterilization until use in the operating room); • Event protocol involved moving sterilized trays via cart or on shelves in storage area; • 600 samples in 100 surgical trays were tested.	• 8.3% (odds ratio, 3.5; p = 0.07) of surgical trays that had been moved (60 test trays) were contaminated versus 40 controls; • Test trays with visible evidence of problems with package integrity were removed from study at two points; • Double layer of cloth did not adequately protect surgical instruments from movement-associated contamination.	Strictly anaerobic cultures were not performed

Reference	Purpose of research	Material types	Study design/methods	Results/Conclusions	Comments
Greene (1987)	To test if surgical packs remain sterile when moved in specially equipped trucks	Stainless steel strips, surgical instruments & sponges; packs sterilized in Hospital A (moved on carts between floors, then transported to Hospital B)	• All test (steam sterilized and control {sterile and contaminated}) packs sterilized at Hospital A; • Packs to be used at Hospital A were transported on carts between floors; • Packs to be used at Hospital B were transported to trucks on carts, then loaded into trucks designed to maintain same atmospheric conditions as within Hospital A.	• Sterility and media controls indicated that autoclave was functioning properly; • Contamination controls: contamination could be detected 98% of the time; • Aseptic handling controls: sporadic contamination occurs despite lack of perceptible breaks in aseptic technique; • No significant difference in sterility between packs available at Hospitals A and B. • Inter-hospital transport of surgical packs, using a specially designed transfer system, can be accomplished without compromising the sterile status to a significantly greater degree than that associated with transport within a hospital.	

REFERENCES

Butt WE, Bradley DV, Jr., Mayhew RB, Schwartz RS. Evaluation of the shelf life of sterile instrument packs. *Oral Surgery, Oral Medicine, and Oral Pathology,* 1991; 72: 650-654.

Donovan A, Turner DW, Smith A. Successful, documented studies favoring indefinite shelf life. *Journal of Healthcare Material Management,* 1991; 9: 34, 36, 38 passim.

Greene VW, Klapes NA, Langholz AC, Reier D. Interhospital transportation: Monitoring sterility of instrument packs. *AORN Journal.* 1987;45(6):1420-24.

Klapes NA, Greene VW, Langholz AC, Hunstiger C. Effect of long-term storage on sterile status of devices in surgical packs. *Infection Control,* 1987; 8: 289-293.

Lamb J, Foster S, Henderson E, Krulicki W. Significant savings achieved by implementing event related outdating. *Canadian Operating Room Nursing Journal,* 1996; 14: 12-14.

National Center for Chronic Disease Prevention and Health Promotion. CDC. Accessed: July 23, 2003. Frequently Asked Questions on Infection Control: Sterilization – Packaging and Storage. [Web Site]. Available: August 2002. http://www.cdc.gov/oralhealth/infection_control/faq/sterilization.htm.

Schwartz R, Davis R. Safe storage times for sterile dental packs. *Oral Surgery, Oral Medicine, and Oral Pathology,* 1990; 70: 297-300.

Schwartz RS, Butt WE, Bradley DV, Mayhew RB. Safe storage times for sterile instrument packs. *Military Medicine,* 1992; 157: 406-409.

Widmer AF, Houston A, Bollinger E, Wenzel RP. A new standard for sterility testing for autoclaved surgical trays. *Journal of Hospital Infection,* 1992; 21: 253-260.

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TECHNOLOGY ASSESSMENT PROGRAM

Mission Statement

To enhance the health of veterans and the nation by providing and fostering technology assessment for evidence-based health care

Values

Integrity and pride in the work that we do

Quality products that are clinically valid and methodologically transparent

Objectivity in evaluating and presenting research evidence

Commitment to continuous quality improvement and to the guiding principles of evidence based practices

Flexibility in responding to changes in VA and the larger healthcare environment

Innovation in designing products and their dissemination to best meet VA's needs

Accessibility of products and services