A SHELF-LIFE TRIAL: EXAMINING THE EFFICACY OF EVENT RELATED STERILITY PRINCIPLES AND ITS IMPLICATIONS FOR NURSING PRACTICE

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ABSTRACT

This study set out to test the hypotheses that: 1) stock sterilised in a central sterilizing supply department using the guidelines from the Australian Standards (AS4187) will not become contaminated over two years unless it is exposed to an event; and, 2) a variety of packaging types can be used successfully in maintaining a sterile barrier over the two year trial period. A random controlled, time series, repeated measures design was used to test the hypotheses. Four hundred items were sterilised, wrapped in three different pack types, stored and regularly handled by nurses over a two-year period. Forty items were randomly selected for sterility testing each three months over the two years. The results showed that there was no contamination of stock over two years related either to time or the pack type used. Given that many nurses work in and manage CSSDs and many nurses use sterile stock in their work there are significant implications for nursing practice emanating from the findings. It was also calculated that the costs of meeting the Australian Standard AS4187 were reduced over the two year trial by up to 2400% by using event related sterility principles and an evidence based approach to the choice of packaging materials used in management of sterile stock.

INTRODUCTION

The stand alone central sterilising supply departments (CSSDs) of most hospitals in Australia have evolved historically from nurses' work in operating theatres to include maintaining and improving the management of sterile stock (Taylor 1993). The gradual introduction of new standards and evidence based principles for the management of sterile stock since the early 1990s has major implications for nurses who work in CSSDs and those who use sterile stock in their practice.

Current research supports the theory that contamination of sterilised stock is event related (Polzella and Holbeche 2002; Belkin 1996; Morall 1995; Taylor 1993; Butt et al 1991; Donovan et al 1991) and not, as it has been historically related, to time (Taylor 1993). The principle of event related sterility (ERS) is now considered as the Australian Standard (AS4187:55) for CSSDs. The standards suggest that contamination is related to features of the CSSD environment and/or the sterile storage area, wrapping materials, storage, handling and opening behaviours rather than just over time alone as has been the established principle.

A review of published material by Taylor (1993) indicated there was little evidence to show the veracity of time related sterilisation (TRS) principles yet as Taylor (1993) notes hospitals have historically expended considerable resources in complying with this principle. According to Polzella and Holbeche (2002) and Taylor (1993) most Australian hospitals have applied a policy of 30-day stock rotation. That means every item is considered contaminated every 30 days even if sterility barriers are still intact. The calculation of costs associated with sterilisation must consider: stock management; stock depreciation resulting from wear and tear through the regular sterilisation process; labour;

materials; and, damage to the environment from unnecessary use of cleaning products and wrapping materials. Every time an item is sterilised these costs are incurred. Though the time related sterility management process has appeared to be effective in controlling patient infections it is likely to have been a significant contribution to the high cost of managing CSSDs.

The two main potential benefits of ERS management strategies to the CSSD therefore are: 1) direct costs savings from reduced material, labour, stock depreciation arising from sterilisation; and, 2) the quality improvement and evidence based process that is implicit in the event related sterility principles.

Continuous improvement is more systematically applied to the processes of sterilisation, storage, handling, transport and opening of stock using ERS principles.

It would appear that ERS provides a principle for nurses and CSSD technicians to use in developing a more flexible evidence based approach to issues like choice of sterilising processes, packaging and shelf-life use by dates. To date, however, there are too few studies reported in the literature to provide the evidence required for CSSDs to be confidently informed to make decisions about changing practice. For the moment at least CSSDs have to validate their own practices by undertaking their own studies into their adoption of ERS principles. Only one clinical study (Polzella and Holbeche 2002) has been found that rigorously examines ERS and the more flexible use of packaging to maintain the AS4187 standards.

Polzella and Holbeche (2002) found there was no greater contamination when stock sterilized under AS4187 guidelines was stored for six months compared to stock that was reprocessed every 30 days. The authors also undertook a time and motion study examining the time taken to wrap sterile safety pins in three different pack types. The results showed a 90% difference in the time taken to wrap sterile safety pins in the most complicated packaging used in their study, double linen and double paper, compared to their simplest packaging, single paper and single linen. The findings also showed no contamination over the six-month trial indicating there was no difference between pack types for rates of contamination.

This study aimed to test over a two-year period the efficacy and material costs associated with shelf-life sterility and different combinations of packaging using the principles of event related sterility. The hypotheses for this study are that: 1) stock sterilised in CSSD using the guidelines from the Australian Standards (AS4187) will not become contaminated over two years unless they are exposed to an event; and, 2) costs can be reduced in the CSSD by using event related sterility principles compared to processes using the principle of time related sterility and a 30-day shelf life expiry date system of stock management.

METHOD

This study used a quasi-experimental, time series, repeated measures design. At the start of this trial no literature was available to benchmark the procedures or to assist in determining sample size. Anecdotal evidence from CSSD networks, however, suggested that 20 items was the minimum number of measurements required if auditing the reliability of the sterilization machines and other processes.

Our design allowed for 40 items to be selected randomly from a pool of 400 and be tested for contamination every three months for two years. In addition, 80 items of the overall sample would be randomly selected for testing immediately after sterilizing and packing; known as time zero. It was determined therefore that 400 would make up the sample required.

The test item chosen for sterilization was the 50mm steel paper clip wrapped in one of three different types of packaging: 1) Double linen and double paper; 2) Single linen and single paper; and 3) Laminate.

The paper clip is similar in mass and shape to screws, plates and other small items that are commonly processed in CSSDs. In addition, the paper clip was chosen as this was unfunded research. The relatively small cost of paper clips and packaging materials to wrap them would keep the resources required for the study to a minimum. We also found in a pilot test of the trial that larger items greatly increased the resources required by the microbiology laboratory in the processes of sterility testing.

Preparing the sample

In order for the study to have practical relevance, the processes by which the packs were prepared, stored, handled and transported mimicked as closely as possible the normal day-to-day processes of the department. All CSSD staff were included in the sterilising, wrapping and storing of the 400 paper clips as they would be under normal daily conditions of work on any stock item. Each pack carried a chemical indicator and was wrapped according to the AS4187 protocols for linen, paper and laminate wrapping.

1) Double linen double paper (n=100): The wraps were double linen inner pre laundered by the local linen service and a double outer Steri-sheet. These packs were wrapped using a horizontal inner wrap and an envelope outer wrap. Autoclave tape was used to secure the packs.

2) Single linen and single paper (n=200): The wraps were a single linen inner and a single outer Steri-sheet. The packs were wrapped using a horizontal inner wrap and an envelope outer wrap. Autoclave tape was used to secure the packs.

3) Laminate (n=100): These packs were prepared using rolls of laminate and securing a seal with a Zen-seal heat sealer.

Thermocouple tests were run and biological indicators were incubated on site as per standard protocol for tests of reliability.

Following the wrapping of all the items each item was numbered and then sterilized. Eighty packs were chosen by random number generation - numbered tickets were drawn from a sealed container by a blindfolded staff member and thus the equivalent numbered item was selected - and sent to the microbiology laboratory for sterility testing. The remainder were placed in a variety of locations on the department's shelves.

Sterile packs in this facility are stored in the CSSD in a designated sterile storage area which complies with the requirements of AS4187:55. Some sterile items are also stored in designated specialty trolleys. The packs for the research were randomly selected and stored among the sterile stock and also on the specialty trolleys by CSSD staff. Theatre staff regularly take extra items into the set-up rooms ('just in case') and if not used, these items are returned to CSSD. The theatre staff were blind to the purpose of the research items and routinely handled the items to move them around the stock trolleys and returned them unused to the sterile stock shelves. Each research item had an equal chance of being placed on the shelves or speciality trolleys by CSSD staff and treated in the manner described above by theatre staff.

Sterility testing of packs

Every three months 40 packs were selected by lottery method for sterilization testing at the microbiology laboratory. Each pack was identified by a code which was unknown to pathology staff. All packs were processed within 24 hours of arriving at the laboratory. All packs were processed inside a 'Class 2 Email safety cabinet' to reduce the risk of external contamination.

Thioglycollate broth was used as the growth medium as it supports the growth of the expected organism such as bacillus, staphylococcus, corynebacteria and streptococcus species.

Paper clips were removed from the packs using sterile forceps and placed into a sterile thioglycollate broth tube. The tubes were incubated for seven days at room temperature and seven days at 35°C (+/-2°C). The tubes were examined each day for turbidity. All broths were subcultured onto blood/MacConkey agar plates at the end of the 14-day incubation or when broth became turbid under aerobic conditions at 35°C. If broths were found to be turbid and no growth occurred on the initial subculture the broths were then subcultured onto full blood agar plates and incubated anaerobically at 35°C (+/-2°C).

RESULTS

Contamination

The initial random selection of 80 packs for testing at time zero showed that the paper clips were sterile and that the biomarkers and onsite incubation tests were reliable.

In a measure of 80 items at time zero and a further eight repeated measures of 40 items per measure over two years, no contamination occurred on any of the 400 items that was related to the sterilisation process, wrapping, storage, pack handling or transport over the two year period.

The pathology laboratory sterility tests were vicariously validated by the detection of five cultures growing organisms. On examination it was revealed that the contamination was directly related to failures in the seals of the broth tubes at the incubation phase of the laboratory tests. No contamination was found that directly related to the sterilization process or failure of the sterile barriers. Therefore, there was no difference between groups for contamination related to time or the type of packaging used.

Cost of materials

Table 1 shows the cost comparison of the actual cost of materials used in sterilising and wrapping the 400 paper clips under management practices guided by ERS compared to hypothetical costs using TRS and 30 day stock rotations over two years. The materials cost are based on prices as of July 2002.

The costs of materials as shown in table 1 is calculated by the formula PxNxR=C.

where: P=the cost of packaging used in the sterilization process for example linen, paper, laminate, cleaning solutions and bio tests; N=the number of similar items; R=the number of shelf life rotations and re-sterilisation; and C=the cost of materials.

Table 1 shows that material costs would have been 24 times greater for TRS management than the actual cost of materials used under ERS management principles. It also shows the difference in costs between the different pack types. Laminate was the cheapest at 57.8% less than the cost of the most expensive wrapping, double linen and double paper and 45.8% cheaper than single linen and single paper wraps. The single linen and single paper wraps were 22.3% cheaper than double linen and double paper.

DISCUSSION

These findings would appear to provide CSSD managers and nurses utilising sterile stock in their practice with an evidence base to support the introduction of event related sterility (ERS) principles. Despite the simulation of 'normal' handling and storage by nurses

Table 1: Cost comparison of sterile barrier materials using event related sterility principles versus time related sterility principles for 400 items and three different packing types over two years.

Wrap type	Event related sterility materials cost calculation				Time related sterility materials cost calculation			
	P x N x R = C				P x N x R = C			
Double linen + double paper	0.90	100	1	$ 90	0.90	100	24	$2,160
Single linen + single paper	0.70	200	1	$140	0.70	200	24	$3,360
Laminate	0.38	100	1	$ 38	0.38	100	24	$ 912

P x N x R= C P = price of packaging N = number of items R = number of sterilisations C = total cost of packaging materials over two years

over the two year trial, no contamination occurred to any of the 400 sterilised items.

These findings, like those of Polzella and Holbeche (2002), also show that there was no difference in the contamination rate between packing types. All packs containing sterile stock items were provided an equal random opportunity of a contamination event occurring as the trial procedure included a program of regular handling and transportation to and from CSSD stores by nurses and CSSD technicians.

Table 1 shows a 2,400% difference in cost of sterile barrier materials between event related sterility management strategies and time related sterility strategies. This calculation does not consider the additional costs associated with the process such as labour, stock depreciation through wear and tear related to the sterilisation process or other work process factors. It is likely the difference in the cost of these factors would also differ by a factor of 24 over two years as well.

Table 1 also shows the difference in cost of materials between each pack type. The material cost alone differed by 57.8% between the most expensive and the cheapest wrap. If the results of the time and motion study undertaken by Polzella and Holbeche (2002) can be extrapolated between CSSDs then labour costs associated with using these packaging types for small items could vary by up to 90%.

The evidence that there was no difference in contamination rates over time or related to pack types, for paper clips at least, suggests there are financial, human and environmental resource efficiencies to be gained by CSSD nurses and technicians in using an evidence based approach to the choice of wrapping.

This flexibility in practice does not appear to compromise standard AS4178. The evidence from these data does not support the traditionally held CSSD practice as discussed by Taylor (1993) which assumed that more packaging/wraps provides more protection from contamination, in the case of small items like paper clips at least. Whether this theory is sustained with more complicated and heavier items such as full instrument trays is yet to be tested.

While we have attempted to emulate the normal CSSD treatment of the test items in this study, in reality it is unlikely that 400 stock items would ever remain unused in a well managed department over two years. The example serves to show, however, that implementing ERS management strategies has the potential to generate large savings of resources without creating any greater risk of infection to the patients or staff than did TRS practices.

This research project has had a number of direct effects on CSSD and nursing practices. As a result of this study:

- Event related sterility has been established as the strategy of choice for most stock items;
- There has been a measurable reduction in backdating which affects consumable costs, staff hours and wear and tear on the equipment;
- The adoption of an evidence based approach by the nurse manager to the choice of packaging materials has reduced the costs of materials and labour;
- Processes have been developed to educate and maintain the skills of nursing staff in the storage and handling of the sterile packs in theatres and on the wards;
- The CSSD has developed an effective, valid and reliable method of investigation that has now become a significant part of the continuous quality improvement program. The department is now repeating the above study for large items such as full instrument trays.

CONCLUSION

This study set out to test the hypotheses that: 1) using the guidelines from the Australian Standards (AS4187) stock sterilised in CSSD will not become contaminated over two years unless exposed to an event; and, 2) costs are reduced in the CSSD by implementing event related sterility principles compared to time related sterility and a shelf life expiry date every 30 days.

The results showed that there was no contamination of stock related to time over two years and that considerable resource savings are associated with management that

uses event related sterility strategies. The cost of packaging materials alone was calculated to be 24 times cheaper for event related sterility management strategies than time related sterility with a 30 day stock rotation management strategy.

The results also showed that packaging materials in the sterilisation process could be chosen on an evidence based approach; that is, the packaging suitability can be determined by outcomes related to its ability to maintain an effective barrier as prescribed in the standard AS4187.

The findings of this study showed that there was no difference between the three packaging types under trial for contamination rates after two years despite regular handling and storing by nurses. The cost of the packaging, however, varied by 57.8% between the most expensive wraps; (double linen double paper), and the least expensive wrap (laminate). These findings have implications for hospital budgets and also provide evidence to support the use of ERS principles in the practice of nurses working in and managing CSSDs and those using and managing sterile stock in their work. What remains to be done is a series of replication studies examining the sterilisation of larger and more complex stock items.

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