

Offsite theatre sterile surgical units – a clinical risk?

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Abstract

Introduction

Effective decontamination of surgical instruments is critical in the management of healthcare associated infection and patient safety. The objective of this study was to identify clinical risk issues relating to both on-site and off-site Theatre Sterile Surgical Units (TSSU).

Materials and Methods

A questionnaire based survey of 500 Fellows of the British Orthopaedic Association identifying their current use of TSSU. The location of their hospitals TSSU department, current practice of checking instrument sets prior to surgery and various clinical risk scenarios were identified in the questionnaire.

Results

309 Fellows responded (62%). 81% of surgeons operated with onsite TSSU facilities. Only 42% checked the instrument sets prior to induction of anaesthesia with 10% employing no routine checks. If there was evidence of contamination or a missing/broken key instrument; 60% were prepared to accept as reasonable the above risks providing a back-up instrument set was immediately available. With no back-up set, 90% would not accept the risk. 45% of surgeons were prepared to start a case with no back-up set immediately available but being processed in an on-site TSSU.

Discussion

This study highlights the use of sterilisation services amongst trauma and orthopaedic surgeons. The responses to our questions highlight areas of clinical risk. The additional comments identified a general concern with the move to centralised TSSU with almost 60% of surgeons currently using off-site TSSU's having problems. Twenty percent reported

cancelling the operation or changing the pre-planned procedure intra-operatively. We anticipate that similar difficulties would be encountered by other surgical specialities.

Conclusion

Whilst implementing the national guidelines with a policy to centralise the sterilisation units may lead to a reduced risk of disease transmission, consideration has to be given to the day-to-day difficulties encountered by the surgical specialities and the potential for increased clinical risk.

Key Words:

Theatre sterile surgical units(TSSU)

sterilisation

clinical risk

INTRODUCTION

Effective decontamination of surgical instruments is critical in the management of healthcare associated infection and patient safety. It is essential that practices and processes applied to the reprocessing of surgical instruments are of the highest quality, reflecting modern day standards.¹

The Department of Health (DOH) has launched an initiative to resolve problems with substandard theatre sterile surgical services units (TSSU) by moving to commercially run off-site sterile service super-centres serving multiple hospitals. By 2007, over 100 NHS trusts are expected to be dependent on this model. The NHS Estates (NE) responsible for the reprocessing service have sought advice from a variety of organisations including the medical Royal Colleges and the Association of British Healthcare Industry with the aim of promoting an exchange of information on all aspects of the decontamination process. Concern has been raised by surgical groups relating to the loss of local control and influence of the process and the need for increased instrumentation to deal with the longer turnaround times and inability to decontaminate and re-sterilise on site. Delivery of decontamination services of such volume have not previously been undertaken in the UK, although there have been limited local ventures. The balance sought, is to achieve high standard modern decontamination of instruments and implants but without creating new risks in the logistics and practical clinical care problems for the surgeons and operating department personnel at surgery. Efficiency of surgical departments is key to a hospital's performance and it's aspiration to achieve waiting list targets. Delays in surgical set availability or delays between cases resulting from concern over the checking of the required sets are common perceptions.

Surgeons and operating theatre staff practise currently within a “comfort zone” of knowledge of their previous TSSU performance. The loss of this, even transiently, creates anxiety. Liability for aborting surgery, depending on the consequences, is borne by the hospital and professional, by members of the surgical team.

The primary objective of this study was to assess current clinical practice and determine the perceived acceptable clinical risks with the use of supplied sterile surgical sets. The survey was undertaken amongst trauma and orthopaedic surgeons in the England and Wales. It is recognised that there is the highest degree of surgical set complexity and multiplicity in this specialty.

Materials and Methods

A short questionnaire was designed by the authors and approved by the Professional Practice Committee of the British Orthopaedic Association (BOA). Piloting of the questionnaire by orthopaedic surgeons in our unit ensured clarity. Five hundred fellows of the BOA in current practice were identified at random, stratified to select two from each secondary care centre, from the current handbook (2005) of the BOA. The questionnaire (Appendix 1) was sent with a covering letter and a reply-paid envelope. The Fellows were asked to complete a tick-box questionnaire covering one A4 sheet containing two main sections, A and B.

Section A questions (Figure 1) were designed to assess their current NHS hospital's practice of opening surgical sets and checking instruments. In Section B, the surgeons were asked about their 'willingness' to accept as 'reasonable' the difficulties created, if on opening the primary set, there was evidence of contamination or a key instrument was found absent or a broken. The surgeon was asked for their opinion about the acceptability of the clinical risk of this whether or not a back-up set (second set) was immediately available.

Finally, they were asked whether they would consider it an appropriate risk to start an operation if a back up set (second set) was being processed at an on-site TSSU but was not immediately available if required.

Results

From 500 questionnaires sent, 309 (61.8%) fellows of the BOA responded.

The results are as illustrated in Table 1:

Clinical issues relating to off-site TSSU provided by the surgeons in the additional comments section are as in Table 2.

Discussion

In September 1999, following concerns surrounding the theoretical transmission of vCJD, the DOH commissioned a survey of the decontamination of surgical instruments in a range of NHS hospitals, private and voluntary organisations and general medical and dental practices in England. The remit of the survey was to investigate the application of decontamination standards and it found instances where decontamination processes fell short of current standards. The report identified that substantial improvements could be achieved by ensuring effective management of decontamination services, and improvements to staff training and development. In October 2000, a National Decontamination Programme (NDP) was launched and a national review was carried out ending in November 2001. The report highlighted the need for major financial investment and in January 2001, the DOH allocated £200 million to improve the standard of decontamination in the NHS in England. A national strategy was developed to rationalise and centralize sterilization services.

Decontamination describes a combination of processes including cleaning, disinfection and/or sterilization which renders a re-usable item safe for further use. The life cycle of decontamination is as Figure 1.² All elements of this cycle need to be controlled and managed if decontamination is to be effective.

Potential risks were identified for each stage of the life-cycle. A risk was perceived to be any aspect of the process which could have a detrimental effect on the attainment and maintenance of sterility. The most significant risks were identified to be the cleaning, disinfection, inspection and sterilization processes.

The advantages of centralising the sterilization process are uniformity of standards within accredited centres using automated processes and the more efficient use of clinical staff time within hospitals. Disadvantages include the finance needed to build and maintain accredited centres, transport of instruments, the cost and need of additional instrument sets with the resultant transfer of clinical risks. The benefits of having an on-site TSSU are local control of the sterilization process, reduced 'turnover time', the reduced number of surgical instrument sets required and maintaining individualized set reflecting surgeon's preference. Disadvantages include the cost to the hospital of managing the on-site TSSU, employing staff and the reduction in clinical activity space.

Concerns have been raised within the surgical community about increasing outsourcing of TSSU to centralized sites particular for acute and emergency services. The purpose of this study was therefore to review current views and practices amongst trauma and orthopaedic surgeons with regard to sterilization of surgical sets. The questionnaire was prepared to highlight practice issues and identify areas of concern.

Our results (Table 1) show that 253 of the 309 (81.8%) respondents worked in a hospital where the TSSU was on-site. Two surgeons were not aware where their TSSU was located. Historically, sterile service units have been on-site; the fact that almost 20% of surgeons

practiced surgery with off-site facilities would seem to indicate that shared or centralized services are on the increase.

According to our results:

Less than half the (42.4%) surgeons worked in theatres that had a practice of opening the surgical sets and checking the instruments before induction of anaesthesia. For 173 (55.9%) surgeons the first check occurred after induction of anaesthesia. Five surgeons (1.6%) were not aware of their procedure. 268 (86.7%) of surgeons recognised formal checks performed routinely, 12 (3.6%) gave no reply.

Section B (Appendix 1) gave certain potential clinical risk scenarios which may occur in clinical practice. In the event of a 'back up' instrument set being immediately available, almost two-thirds were prepared to accept the risk as reasonable if there was evidence of contamination to the first set opened. In this situation, the 'back up' set would be used for the procedure. In the presence of a broken or missing key instrument, 60% would accept as reasonable that difficulty created. 33 – 38% of respondents would not be willing to accept any of the above scenarios despite the 'back up' set.

More than 90% of surgeons were not prepared to accept any of the given clinical scenarios when no 'back up' set was immediately available. This policy minimises the clinical risk to the patient and highlights the need to always have a 'back up' set immediately available. Were there to be a problem with transfer of sets from an off-site TSSU, operations may be delayed or cancelled. Of interest, were the 'back up' set not available but undergoing the sterilisation process on-site, 45% of surgeons were prepared to start the surgical procedure.

This policy may be a clinical risk issue if the primary surgical set is sub-standard and there are delays processing the 'back up' set, but may reflect **historical confidence** in the local on-site TSSU performance. **Delays during the procedure whilst awaiting for a 'back-up' set may lead to an increased risk of infection resultant from the surgical wound being left open for a prolonged period.**

A space was provided at the end of the questionnaire for any additional comments. Twenty-four of the 53 (45%) surgeons currently working with off-site TSSU and 103 of the 253 (40.7%) working with on-site TSSU made comments on current or anticipated problems of centralising the instrument sterilisation services (Table 2). No surgeon made a positive comment. The move to an off-site TSSU was opposed by 53% (currently on-site) and 58% (currently off-site) of the surgeons.

Surgeons currently working with an off-site TSSU expressed concerns with the overall quality of the service provided (frequent torn packaging of sets) with one surgeon suggesting that the back up sets purchased were of inferior quality to the primary set to reduce costs. Sub-standard sterilisation of an essential instrument for a specific procedure had resulted in the planned surgical procedure having to be altered or cancelled. **Abandoning the procedure leads to the patient having an unnecessary anaesthetic.**

The above responses highlighted areas of clinical risk, which led to an increase in clinical incident forms. In addition, contacting staff at the off-site centres to express difficulties and attempt to improve the service was often difficult and unproductive for both surgeons and

theatre managers. The turnover time for surgical sets and the increased number of back-up sets required (which often led to storage problems) were also difficulties encountered. The increased financial burden to the NHS Trust of a centralised service was emphasised. This was primarily related to the transport of equipment and increased set requirements. Interestingly, surgeons who had not worked with off-site TSSU anticipated and were concerned with similar problems.

Of significant concern and a real area of clinical risk, were reports of instances where the off-site manager had taken a decision not to sterilise certain instruments, examples included: flexible depth gauge, drill bits and reamers.

This study highlights the use of sterilisation services amongst a group of surgeons. Whilst this survey is only of orthopaedic surgeons, it is clear that the vast array of instrumentation required for trauma and orthopaedic procedures would make this one of the specialities particularly susceptible to problems with the sterilisation practice. Similar difficulties would be encountered by other surgical specialities. The variable responses to our questions do highlight areas of clinical risk. Most problems occur with off-site sterilisation. Whilst implementing the national guidelines with a policy to centralise the sterilisation units may lead to a reduced risk of disease transmission, consideration has to be given to the day-to-day difficulties encountered by the surgical specialities and the potential for increased clinical risk.

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Questions (See Appendix 1 for Full Question)	Response		
	Yes	No	Do not know
<i>Is your current TSSU on-site?</i>	253 (81.8%)	53 (17.15 %)	2 (0.05%)
Section A			
<i>When are the sets opened and instruments checked?</i>			
(i) before induction of anaesthesia	131 (42.3%)		5 (1.6%)
(ii) before the operation is commenced	173 (55.9%)		
<i>Are formal checks regularly undertaken?</i>	268 (86.73%)	29 (9.6%)	12 (3.6%)
Section B			
Would you accept as reasonable the following scenarios?			
<i>(a) if a back up set was immediately available</i>			
(i) evidence of contamination	205 (66.34%)	102 (33%)	2 (0.6%)
(ii) absence of a key instrument	188 (60.84%)	119 (38.51%)	2 (0.6%)
(iii) a broken key instrument	188 (60.84%)	119 (38.51%)	2 (0.6%)
<i>(b) if there was no back up set immediately available?</i>			
(i) Contamination	22 (7.11%)	283 (91.58%)	4 (1.3%)
(ii) Absent instrument	25 (8%)	280 (90.61%)	4(1.3%)
(iii) Broken key instrument	25 (8%)	280 (90.61%)	4 (1.3%)
Would you start an operation knowing that the back-up set is not immediately available but is being processed on-site?	139 (45.15%)	156 (50.16%)	14 (4.6%)

Table 1: Response to the questionnaire (number of surgeons with %).

Location of TSSU	On site (n = 253) n = 103 Problems anticipated	Off site (n =53) n = 24 Current problems
General concern with off-site TSSU(cancellation of cases)	55(53%)	14 (58%)
Change of procedure during the operation	18 (17.4%)	5 (20.83%)
Staff training issues	15 (14.56%)	5 (20.83%)
Quality (sterilisation/broken instruments)	38 (36.89%)	12 (50%)
Sterilisation of an essential instrument during the operation	14(13.59%)	5 (20.83%)
Communication	8 (7.76%)	5 (20.83%)
Logistic issues (turnover time/transport)	26(25.24%)	7 (29.16%)
Shelf number of sets Storage problems	40 (38.83%) 14 (13.59%)	10 (41.66%) 3 (12.5%)
Costs (transport, extra equipment)	20 (19.41%)	6 (25%)

Table 2. The important issues raised by the Fellows with regards to off-site TSSU.

Figure legends

Table 1: Response to the questionnaire (number of surgeons with %).

Table 2. The important issues raised by the Fellows with regards to off-site TSSU.

Figure 1. Life cycle of re-usable surgical instruments.