



ELSEVIER

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

An evaluation of immediate-use steam sterilization practices in adult knee and hip arthroplasty procedures

Scott L. Zuckerman BS^a, Ravi Parikh BS^a, David C. Moore BA^a, Thomas R. Talbot MD, MPH^{b,*}^a Vanderbilt University School of Medicine, Nashville, TN^b Departments of Medicine and Preventive Medicine, Vanderbilt University School of Medicine, Nashville, TN

Key Words:

Flash sterilization
Quality assurance
Surgical site infection
Perioperative
Operating room
Patient safety
Checklist

Background: Immediate-use steam sterilization (IUSS) is a safe method to sterilize emergently contaminated instruments, but inappropriate use may lead to an increased risk for surgical site infection. This study aimed to identify risk factors, rationale, and variability in procedural adherence in cases of IUSS.

Methods: This retrospective, case-control study compared adult patients undergoing hip and knee arthroplasty in which IUSS was (n = 104) and was not (n = 81) performed.

Results: Multivariate analysis revealed 4 predictive risk factors for IUSS: history of malignancy (odds ratio [OR], 3.2 [95% confidence interval (CI) 1.1-9.3]), obesity (OR, 2.3 [95% CI: 1.02-5.2]), procedure performed in operating room 13 (OR, 2.5 [95% CI: 1.2-5.4]), and Monday procedure (OR, 3.6 [95% CI: 1.4-9.1]). The only factor that protected against IUSS was performing the procedure in the morning (OR, 0.4 [95% CI: 0.2-0.96]). Only 9.5% of cases of IUSS involved an acceptable indication. Documented adherence to core practices was also variable.

Conclusion: Several patient- and case-specific factors can help predict the incidence of IUSS. Furthermore, practices should be hardwired to ensure IUSS is utilized for the correct indication. Documentation must be improved to allow institutions to accurately track IUSS.

Copyright © 2012 by the Association for Professionals in Infection Control and Epidemiology, Inc. Published by Elsevier Inc. All rights reserved.

Over 40 million surgical procedures are performed in US hospitals each year,¹ resulting in nearly 300,000 surgical site infections (SSI).² Identifying perioperative practices that may increase a patient's risk for such morbidity is an important step in reducing SSIs. One practice that, if not performed correctly, has potential to increase risk of infection is flash sterilization, recently termed *immediate-use steam sterilization* (IUSS).

The Association for the Advancement of Medical Instrumentation defines IUSS as, "the process designated for the steam sterilization of patient care items for immediate use."³ This is performed on an as-needed basis when instruments designated for a procedure become contaminated or sterile instruments are not immediately available.⁴ When performed correctly, immediate-use, or flash, sterilization is a safe means to sterilize contaminated instruments for urgent use, only to be used in carefully selected

clinical situations.⁵ The Centers for Disease Control and Prevention (CDC),⁶ the Joint Commission,⁷ and the Association of periOperative Registered Nurses (AORN)⁸ all concur that IUSS should be reserved for emergent situations and never utilized for implantable hardware or devices. Additionally, detailed procedures for safe IUSS practices have been published.^{6,9-11}

A major concern regarding IUSS is that its convenience may lead to nonemergent, inappropriate use. This abuse of IUSS has the potential to increase risk for development of SSI, increased health care costs, and even direct thermal injury to the patient.^{5,12,13} Even if utilized appropriately, the stresses associated with an urgent need for the instrument may lead to skipped steps in the sterilization process and wide variability in practices.⁸ Minimizing the use of IUSS has been integral in efforts to reduce infection rates following both cardiothoracic¹⁴ and orthopedic procedures.¹⁵ Some institutions have even discontinued IUSS almost entirely.¹⁶ Despite the growing literature outlining the risks of IUSS, there is limited published information about the variability of IUSS practices in an operative setting.

It is important to determine what patient and procedural factors are associated with increased rates of IUSS to allow for targeted

* Address correspondence to Thomas R. Talbot, MD, MPH, Associate Professor of Medicine & Preventive Medicine, Vanderbilt University School of Medicine, A2200 Medical Center North, 1161 21st Avenue South, Nashville, TN 37232.

E-mail address: tom.talbot@vanderbilt.edu (T.R. Talbot).

S.L.Z. and R.P. contributed equally to this work.

Conflicts of interest: None to report.

interventions to prevent excessive use of this risk-inherent procedure. Furthermore, identifying lapses in IUSS practices will provide insight into improving the natural practice of this important perioperative measure. Rather than determining the correct criteria for IUSS and/or what items should be sterilized, our aim was to study IUSS practices in a real-world, hospital setting. The current retrospective, case-control study aimed to accomplish 3 objectives: (1) identify risk factors for performing IUSS during elective adult orthopedic arthroplasty procedures, (2) examine the stated rationale for IUSS in these cases to assess appropriate utilization, and (3) assess the variability in documented adherence to core components of the IUSS process.

METHODS

Institutional Review Board approval was obtained prior to conducting this retrospective, case-control study. Adult patients ≥ 18 years of age who underwent an elective hip or knee arthroplasty operation in Vanderbilt University Hospital's main operating room suites 12 and 13 were eligible for inclusion into the study. Suites 12 and 13 were selected because they serve as the primary operating areas for orthopedic arthroplasty procedures and utilize a set cohort of operating room personnel. Excluding those rare procedures performed in alternative operating rooms with different operating room personnel less familiar with orthopedic surgery was done to eliminate potential confounders related to the behaviors of different surgical teams less familiar with orthopedic procedures. Patients undergoing nonelective or emergent procedures were excluded because these procedures may have increased risk for performing IUSS because of acuity of illness, and we desired to remove any potential confounders from our analysis. In addition, patients undergoing surgery during a period when IUSS records were not available or incomplete were also excluded. The study time period was defined as January through May, August, and October of the 2008 calendar year. Because IUSS records were paper based and stored in archives at a remote location, complete records were available only for those 7 months of the year.

A record of all adult, elective orthopedic procedures during the 2008 calendar year was obtained from the perioperative informatics database. Hip and knee arthroplasty procedures, as defined by Current Procedural Terminology codes (27125, 27130, 27132, 27134, 27442, 27447, 27486, 27487) were selected. Cases were defined as patients who underwent hip or knee arthroplasty procedures in which IUSS occurred, as determined by review of IUSS records. Each incident of IUSS was recorded on a paper sterilization log (Fig 1). Based on the medical record number noted on the sterilization log, the electronic medical record was retrieved. Each medical record number was cross-checked with the list of arthroplasty procedures performed during the study period. Case subjects were defined as patients who underwent hip or knee arthroplasty procedures in which IUSS was not performed. Controls were obtained by cross-checking the comprehensive arthroplasty list and selecting for those procedures that occurred during the study period without a record of IUSS.

Electronic medical records were used to confirm the specific procedure performed as well as to capture the following patient and procedure-associated variables for all cases and controls: patient age, weight, and height; patient comorbidities defined as cardiovascular (ie, history of coronary artery disease, congestive heart failure, prior acute coronary syndrome or myocardial infarction, congenital heart defect, cardiomyopathy, atrial fibrillation, peripheral vascular disease, or carotid stenosis); diabetes mellitus (either insulin or non-insulin-dependent); history of malignancy; obesity (defined as body mass index greater than 30); American Society of Anesthesiologists score; joint involved (ie, hip or knee);

operating room suite in which procedure was performed (ie, room 12 or 13); day of week of procedure; whether procedure was a primary or revision arthroplasty; attending surgeon; time under anesthesia; total time in the operating room; and total number of operating room personnel.

For each incident of IUSS, adherence to key components of the sterilization process as documented in the IUSS log was assessed. These components, recommended by national organizations, included the rationale for IUSS, cycle time, peak pressure, peak temperature, use of a biological indicator (BI), use of a chemical indicator, and adequate description of the sterilized instruments (Table 1). Per institutional policy, BIs are used in every case of IUSS to monitor sterilization efficacy. The description of sterilized instruments had to be legible enough to allow clear identification of individual instruments by 2 independent observers. Illegible documentation of instruments, determined independently by 2 medical students, was noted as improperly documented.

Baseline characteristics between the 2 groups were compared using Student *t* test and Wilcoxon rank-sum test for continuous variables and χ^2 and Fisher exact test for categorical variables. Multivariate relationships between predictor variables and use of IUSS were analyzed using logistic regression. Variables included in the model were the following: age, American Society of Anesthesiologists score, cardiovascular disease, diabetes mellitus, malignancy, obesity, performance of procedure in operating room 13, morning procedure started before 12:00 PM (vs afternoon), Monday procedure (vs other day), revision procedure, bilateral procedure, total anesthesia time, total operating room time, and total number of operating room personnel. Because surgeon 1 performed a majority of procedures, performance of surgery by surgeon 1 was also included in the model. A stratified analysis by type of joint (ie, knee vs hip) was also performed. In the knee arthroplasty analysis, use of a tourniquet was also included in the model. All analyses were conducted using STATA version 9.0 (Stata Corporation, College Station, TX). Nonadherence to key components of the sterilization process was described as the proportion of case procedures with inadequate documentation of each core practice.

RESULTS

In 2008, 1,576 adult elective orthopedic procedures were performed. Of these, 482 were hip or knee arthroplasties. During the defined study period, 185 hip or knee arthroplasties took place in operating room 12 or 13. There were 104 procedures in which IUSS occurred (49 hip arthroplasty procedures and 55 knee arthroplasty procedures). There were 81 control procedures in which IUSS did not occur (28 hip arthroplasty procedures and 53 knee arthroplasty procedures). In the case group, the 104 surgical procedures were performed with 168 IUSS events, with a mean of 1.6 events per procedure (range, 1-4).

Risk factor analysis

On univariate analysis (Table 2), patient history of malignancy was positively associated with IUSS ($P = .02$) and use of tourniquet was negatively associated with IUSS ($P = .02$). On multivariate analysis of the entire cohort (Table 3), 4 factors predicted IUSS: history of malignancy (odds ratio [OR], 3.2 [95% confidence interval (CI): 1.1-9.3]), obesity (OR, 2.3 [95% CI: 1.0-5.2]), procedure performed in operating room 13 (OR, 2.5 [95% CI: 1.2-5.4]), and Monday procedure (OR, 3.6 [95% CI: 1.4-9.1]). When stratified by hip arthroplasty, procedure performed in operating room 13 (OR, 26.1 [95% CI: 3.6-191.3]) predicted the use of IUSS. When stratified by knee arthroplasty, obesity (OR, 4.3 [95% CI: 1.2-15.1]) and Monday procedure (OR, 4.5 [95% CI: 1.3-15.7]) predicted the use of

Vanderbilt University Medical Center
Operative Services
UNIT BASED STERILIZATION LOG

Department: _____ Sterilizer #: _____ Date: ____/____/____

Load #	Reason	Cycle Type	OR #	In Sterilizer	Exposure	Chemical Indicator	BI Included	Patient Sticker	LOAD ITEMS
				Time	Time	Maximum Temp	Pressure 27-32	Circle One	Circle One
Loading Operator	1. Contaminated in OR	Gravity		Time				ACCEPT	Pass
	2. Received Unsterile			A.M. P.M.					
	3. Turnover	Prevac		Out of Sterilizer				REJECT	N/A
	4. One of a Kind Item			Time					
	5. Terminal	Prevac		Unloading Operator Signature				REJECT	Fail
	6. Hole In Wrapper			Time					
	7. Implant			A.M. P.M.					
	8.								
Load #	Reason	Cycle Type	OR #	In Sterilizer	Exposure	Chemical Indicator	BI Included	Patient Sticker	LOAD ITEMS
Loading Operator	1. Contaminated in OR	Gravity		Time				ACCEPT	Pass
	2. Received Unsterile			A.M. P.M.					
	3. Turnover	Prevac		Out of Sterilizer				REJECT	N/A
	4. One of a Kind Item			Time					
	5. Terminal	Prevac		Unloading Operator Signature				REJECT	Fail
	6. Hole In Wrapper			Time					
	7. Implant			A.M. P.M.					
	8.								
Load #	Reason	Cycle Type	OR #	In Sterilizer	Exposure	Chemical Indicator	BI Included	Patient Sticker	LOAD ITEMS
Loading Operator	1. Contaminated in OR	Gravity		Time				ACCEPT	Pass
	2. Received Unsterile			A.M. P.M.					
	3. Turnover	Prevac		Out of Sterilizer				REJECT	N/A
	4. One of a Kind Item			Time					
	5. Terminal	Prevac		Unloading Operator Signature				REJECT	Fail
	6. Hole In Wrapper			Time					
	7. Implant			A.M. P.M.					
	8.								

mydocuments/forms/office/vanderbilt daily sterilizer log

MC 0715 (1/2006)

Fig 1. Blank IUSS log.

IUSS, whereas performing the procedure in the morning (OR, 0.4 [95% CI: 0.2-0.96]) negatively predicted the use of IUSS.

Assessment of rationale for IUSS

In review of all cases, the most commonly documented reasons for use of IUSS (Table 4) were operating room turnover (noted in 63 of 168 IUSS events [37.5%]), instrument was received unsterile (noted in 76 of 168 [45.2%]), instrument was contaminated intraoperatively (noted in 16 of 168 [9.5%]), and instrument was one-of-a-kind (noted in 5 of 168 [3.0%]). The rationale for sterilization was incomplete in 8 of 168 (4.8%) events. Of the total 54.7% of cases in which instruments that were considered contaminated underwent IUSS (ie, breach in wrapping, contamination during procedure, received unsterile), in only 9.5% were the instruments contaminated intraoperatively, whereas 8.9% involved instrument contamination because of breaches in packaging.

Adherence to core components of IUSS

The documentation review of core components of IUSS process revealed frequent potential lapses in practice (Table 5). IUSS logs had missing or incomplete documentation of the following variables: use of a chemical indicator (missing or incomplete documentation in 6.0% of cases), use of a BI (4.8%), peak pressure at which instruments were sterilized (4.2%), peak temperature at which the instruments were sterilized (0.6%), and cycle time in the sterilizer (0.6%). A description of the specific instruments sterilized was not documented in 6.0% of IUSS episodes (10/168), and the written description was illegible in 8.9% (15/168), resulting in a total of 14.9% of IUSS episodes (25/168) in which this key information was not documented.

Table 1 Key components of the IUSS process

Component	Definition/appropriate use
Cycle time	Cycle time is recommended to range from 3-10 minutes depending on type of sterilizer, ie, gravity displacement, prevacuum, pulsing gravity, or abbreviated prevacuum.
Temperature	Temperatures should be set to 270-272°F.
Peak pressure	Mechanical control monitors should be used to verify pressure.
Biological indicator	According to the Centers for Disease Control and Prevention, use of a BI is the most accepted means of monitoring lethality of the sterilization process because of its detection of resistant microorganisms. All BIs should be interpreted by qualified personnel and included in the sterilization records.
Chemical indicator	According to the Centers for Disease Control and Prevention, a CI assesses achievement of proper temperature and pressure for sterilization. All CI test results should be interpreted by qualified personnel and included in the sterilization records.
Description of load item	Full, complete description of instrument placed in sterilizer is recommended.

BI, biological indicator; CI, chemical indicator.

DISCUSSION

In our quality assessment of IUSS practices in elective adult hip and knee arthroplasty procedures at a large, academic medical center, several significant risk factors were identified that predicted the occurrence of IUSS. In addition, we identified a high percentage of IUSS that was performed for indications incongruent with current recommendations,⁶⁻⁸ and, last, documented compliance with core components of the IUSS process was missing in a substantial number of episodes.

Investigations into patient and procedural factors that lead to a greater propensity for IUSS are lacking. Four risk factors were

Table 2
Baseline characteristics between adult patients undergoing elective knee and hip arthroplasty in which IUSS was and was not utilized

	Procedures with IUSS (n = 104)	Procedures without IUSS (n = 81)	P value
Mean age (range), yr	60.8 (17-93)	58.9 (19-93)	.37
Mean ASA score (range)	2.5 (2-4)	2.6 (1-4)	.35
Comorbid conditions, n (%)			
Cardiovascular disease	44/104 (42.3)	30/81 (37.0)	.47
Diabetes mellitus	20/104 (19.2)	13/81 (16.1)	.58
History of malignancy	22/104 (21.2)	7/81 (8.6)	.02
Obesity	79/104 (76.0)	58/81 (71.6)	.50
Joint involved, n (%)			
Hip	49/104 (47.1)	28/81 (34.6)	.09
Knee	55/104 (52.9)	53/81 (65.4)	Reference
Procedure performed in operating room 13, n (%)	72/104 (69.2)	46/81 (56.8)	.09
Monday procedure, n (%)	46/104 (44.2)	27/81 (33.3)	.13
Morning procedure, n (%)	48/104 (46.2)	45/81 (55.6)	.13
Revision procedure, n (%)	9/104 (8.7)	9/81 (11.1)	.62
Bilateral procedure, n (%)	7/104 (6.7)	8/81 (9.9)	.59
Performed by attending surgeon 1, n (%)	67/104 (64.4)	53/81 (65.4)	.89
Mean total anesthesia time (range), min	216.3 (138-487)	228.7 (37-998)	.35
Mean total operating room time, min	198.9 (126-456)	215.2 (95-968)	.35
Use of tourniquet, n (%)	27/104 (26.0)	34/81 (42)	.02
Mean total tourniquet time (range), min*	86.8 (23-152)	83.6 (7-140)	.86
Mean total operating room personnel (range)	9.2 people (6-13)	9.3 people (6-21)	.78

ASA, American Society of Anesthesiologists.

*Mean tourniquet time is for the 61 knee arthroplasty procedures only.

found to positively predict the usage of IUSS: procedure performed in operating room 13, Monday procedure, obesity, and history of malignancy. One risk factor, morning procedure, was found to protect against IUSS.

Adding context to these findings, many aspects of the physical operating room can contribute to an increase or decrease in the amount of IUSS. For example, a smaller room may increase the likelihood of instruments being mishandled or dropped and subsequently contaminated. Comparatively, a room that is closer to the sterilization autoclave may have higher incidences of IUSS because of proximity. Moreover, a specific operating room may have a surgeon or nurse who is more likely to inappropriately send an instrument for IUSS. In addition to the room itself, Monday procedure also predicted IUSS. This was somewhat unexpected, as one would predict ample instrument availability at the week's outset rather than its conclusion, after several days of procedures and associated instrument utilization. However, it may reflect poor planning at the week's outset to prepare for a busy week of surgery ahead.

The association of obesity and history of malignancy with use of IUSS raises some concern. Obese patients make any surgical operation more complex, especially hip or knee arthroplasties, where a heavy limb must be propped up for hours. In addition, patients with a malignancy history have most likely undergone intensive medical treatments such as chemotherapy, radiation, or prior invasive surgery. Perhaps heightened preoperative morbidity may increase case complexity, leading to higher propensity of contaminating previously sterilized instruments.

When stratified by joint, morning procedures were protective for IUSS in knee arthroplasty. This finding highlights an important concept: as case volume increases throughout the day, with multiple procedures occurring at once, IUSS is more likely to occur. Instruments may be readily available for the first case of the morning, but, as the day progresses, resources are stretched thin. Operating rooms must have enough instruments to meet the demands of a full operating room schedule, a well-known phenomenon in the literature.⁶⁻⁹

Overall, the current study identified several important predictive and protective risk factors for IUSS that can be of use to hospital personnel. With the knowledge of patient characteristics, such as obesity and history of malignancy, and time-specific data for each

Table 3
Multivariate analysis of risk factors for IUSS in adults undergoing elective hip or knee arthroplasty, entire cohort, and stratified by joint

	Multivariate OR (95% CI)
Whole cohort	
History of malignancy	3.2 (1.1-9.3)
Obesity	2.3 (1.0-5.2)
Procedure performed in operating room 13	2.5 (1.2-5.4)
Monday procedure	3.6 (1.4-9.1)
Hip arthroplasty only	
Procedure performed in operating room 13	26.1 (3.6-191.3)
Knee arthroplasty only	
Obesity	4.3 (1.2-15.1)
Monday procedure	4.5 (1.3-15.7)
Morning procedure	0.4 (0.2-0.96)

CI, confidence interval; OR, odds ratio.

case, hospitals may be better equipped to handle IUSS practices and know when to have increased vigilance. Last, we must be cautious of generalizing these IUSS predictors to other surgical populations.

Our results also confirm one of the major issues regarding IUSS: inappropriate usage.^{4,6,10,15} The AORN, Joint Commission, and CDC recommend that IUSS be restricted to emergent situations only, such as inadvertently dropping an instrument.¹⁴ Moreover, although the Association for the Advancement of Medical Instrumentation defines IUSS for "immediate-use," it does not restrict its use to emergent situations. However, all 4 of the aforementioned professional organizations discourage the use of IUSS because of inadequate inventory or as an alternative to purchasing additional instruments.⁶⁻⁹ Results from the current study noted that only 9.5% of IUSS events were completed for an acceptable indication: intraoperative contamination. Therefore, 85.7% of IUSS events occurred for reasons incongruent with recommended guidelines, with 4.8% of cases missing indications.

The current study's experience is not unique in terms of inappropriate IUSS usage.¹¹ Leonard et al linked IUSS with infection rates and reported that 77.7% of IUSS events were because of an instrument from a previous procedure being needed but not available, 8.3% because of a dropped item, 3.3% because of a torn rapper, and 0.8% because of chemical indicator failure.⁴ Although indications for IUSS were not discussed, their findings corroborate

Table 4

Documented rationale for IUSS in cases of adult elective hip or knee arthroplasty procedures

Rationale	Proportion of cases in which specific rationale noted, n (%)
Operating room turnover	63/168 (37.5)
Received unsterile	76/168 (45.2)
Contaminated intraoperatively	16/168 (9.5)
One of a kind	5/168 (3.0)
Not documented	8/168 (4.8)

Table 5

Frequency of incomplete documentation of core components of IUSS process among adult elective hip and knee arthroplasty procedures

Core component	Frequency of incomplete documentation of component, n (%)
Rationale for IUSS not documented	15/168 (8.93)
Cycle time not documented	1/168 (<1)
Temperature not documented	1/168 (<1)
Pressure not documented	7/168 (4.2)
Use of biological indicator not documented	8/168 (4.8)
Use of chemical indicator not documented	10/168 (6.0)
Load items	
Illegible	15/168 (8.9)
Not documented	10/168 (6.0)

the current study's results of low rates of appropriate IUSS. Intraoperative contamination is the only acceptable reason to immediately sterilize instruments, and both studies found that <10% of the time this was the case. Similarly, in their investigation of SSI with arthroscopic procedures, Babcock et al¹⁵ noted that IUSS occurred at inappropriately high rates because of instrument shortage. At the conclusion of both studies, the facilities studied by Leonard et al⁴ and Babcock et al¹⁵ purchased additional instruments to correct inappropriate practice. Many institutions have purchased more instruments to curb inappropriate usage.¹⁴

From an economic standpoint, some have noted that it may be less expensive to diagnose and treat the postoperative infections than to purchase additional instruments for inventory of the immediate-use items.⁴ However, from a clinical perspective, protecting patient outcomes and preventing SSI remains the utmost priority. A safer and more cost-effective approach may be to increase education on standard indications and procedures for IUSS for operating room personnel, including physicians, nurses, surgical technologists, and sterilization staff members.¹⁵

The value of recording the rationale for IUSS is that the appropriate use of IUSS is an indicator of quality assurance. Much like antibiotic timing, appropriate use must be documented, and changes in practice must occur if the practice of IUSS is occurring inappropriately according to the current guidelines. Furthermore, surgical safety checklists are becoming increasingly common to ensure safe operative practices. Based on our experience, we have devised a safety checklist to ensure that the appropriate and correct indications for IUSS have been met (Table 6). It is our hope that this checklist can improve correct usage of IUSS, with the ultimate goal of minimizing risk to patients.

Similarly, completeness of documentation and adherence to core sterilization practices are crucial. Our results noted common lapses in documentation, most notably with regards to the rationale for IUSS, use of a BI, use of a chemical indicator, and contents. Lapses in documentation not only pose a risk to the patient and raise questions about the quality of the sterilization process, but they prevent institutions from tracking performance. Records allow for traceability of load instruments, and, if more instruments need

Table 6

Safety checklist to ensure proper indications for IUSS usage

Completed	Surgical parameter
<input type="checkbox"/>	Surgical instrument made unsterile and/or unusable (ie, dropped to contaminated area)
<input type="checkbox"/>	Surgical case cannot be completed safely without contaminated surgical instrument
<input type="checkbox"/>	There are no remaining surgical instruments available that can accomplish identical goal of contaminated surgical instrument
<input type="checkbox"/>	There is no available surgical instrument on the scrub technician's tray
<input type="checkbox"/>	There is no available surgical instrument in the operating room
<input type="checkbox"/>	There is no surgical instrument available in the operative suite or supply room

NOTE. The checklist should be completed in order. If all boxes are checked, it is appropriate to immediately steam sterilize surgical instrument.

to be purchased, detailed documentation is necessary to develop an accurate financial plan. Furthermore, if there is a recall of an item or IUSS records are subpoenaed for a lawsuit, complete documentation is vital.⁵

Our study identified a high rate of improper biological and chemical indicator documentation, 4.8% and 6.0%, respectively. BIs provide a direct measure of the lethality of the sterilization process.⁵ They are used to determine sterilizer efficacy, sterilizer qualification, and necessity for major repairs. In the event of a positive BI, all items that were sterilized from the time of last negative BI must be recalled.¹² Chemical indicators are placed inside each tray being sterilized and indicate whether the conditions for sterilization were met for each cycle. In the 8 cases of missing BI, there is no record of a negative test indicating lethality. Equally, for the 10 cases of missing chemical indicators, there is no documented confirmation that the indications for sterilization were met. We have no evidence the indicators were positive, only that documentation was missing.

The limitations inherent in the current study have implications for its interpretation. First, all information gathered was from paper IUSS logs, which are not as standardized as electronic records. Paper records have higher chance of being inaccurate and missing. Furthermore, we were not able to examine the risk of SSI related to the occurrence of IUSS because infection rates in this population were very low, and the study was not powered to examine this relationship. In addition, the generalizability of the findings to other institutions and other surgical procedures is unclear. Last, because of the possible underreporting with paper-based records, counting false-negatives in our control group is a possibility we cannot exclude for certain. Despite these limitations, the current study demonstrates importance in documentation of this important perioperative sterilization procedure.

CONCLUSION

Our study suggests that IUSS is associated with several factors predicting its usage. Furthermore, we encourage institutions to strictly assess the rationale for IUSS and documentation of core IUSS components. Only through sound documentation can practices be monitored and quality improved.

References

- Hall MJ, DeFrances CJ, Williams SN, Golosinskiy A, Schwartzman A. National hospital discharge survey: 2007 summary. *Natl Health Stat Rep* 2010;29:1-24.
- Klevens RM, Edwards JR, Richards CL, Horan TC, Gaynes RP, Pollock DA, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. *Public Health Rep* 2007;122:160-6.

3. Association for the Advancement of Medical Instrumentation. Flash sterilization: steam sterilization of patient care items for immediate use. Arlington [VA]: Association for the Advancement of Medical Instrumentation; 1996.
4. Leonard Y, Speroni KG, Atherton M, Corriher J. Evaluating use of flash sterilization in the OR with regard to postoperative infections. *AORN J* 2006;83:672-80.
5. Carlo A. The new era of flash sterilization. *AORN J* 2007;86:58-68.
6. CDC. Guideline for the prevention of surgical site infection, 1999. Centers for Disease Control and Prevention. Available from: <http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/ssi.pdf>. Accessed February 19, 2011.
7. Scott D. JCAHO's new patient safety focus: tips for survey preparedness. Today's Surgicenter. Available from: <http://www.surgistrategies.com/articles/2003/09/today-s-surgicenter-jcaho-s-new-patient-safety-fo.aspx>. Accessed February 22, 2011.
8. Association of periOperative Registered Nurses. Recommended practices for sterilization in the perioperative setting. In: Standards, Recommended Practices, and Guidelines. Denver [CO]: AORN, Inc.; 2007. p. 647-87.
9. Huggins KA, Mood R, Koch F. A process for improving flash sterilization. *AORN J* 2002;75:127-33.
10. Springer R. Flash sterilization. *Plast Surg Nurs* 2009;29:263-5.
11. Department of Veteran Affairs. Office of Inspector General. Healthcare inspection; supply, processing and distribution issues and quality of care concerns. Columbia [SC]: William Jennings Bryan Dorn VA Medical Center; February 20, 2008. Report number 07-02902-78.
12. Spry C. Understanding current steam sterilization recommendations and guidelines. *AORN J* 2008;88:537-50.
13. Rutala WA, Weber DJ, Chappell KJ. Patient injury from flash -sterilized instruments. *Infect Control Hosp Epidemiol* 1999;20:458.
14. McConkey SJ, L'Ecuyer PB, Murphy DM, et al. Results of a comprehensive infection control program for reducing surgical-site infections in coronary artery bypass surgery. *Infect Control Hosp Epidemiol* 1999;20:533-8.
15. Babcock HM, Carroll C, Matava M, L'ecuyer P, Fraser V. Surgical site infections after arthroscopy: outbreak investigation and case control study. *Arthroscopy* 2003;19:172-81.
16. Nimmo L. Meeting standards, following guidelines: hospital eliminates routine flash sterilization, reduces infection risk. Interview by Alan Joch. *Mater Manag Health Care* 2009;18:9-11.