Research Article

Assessment of standardization in surgical skin preparation: does a compliance-culture exist?

Mouhanad M. El-Othmani¹, Bilal M. Mahmood¹, Lena Pearson², Hugo Xi²,
Kristin Delfino³, Khaled J. Saleh^{1*}

¹Division of Orthopaedics and Rehabilitation, Department of Surgery, Southern Illinois University School of Medicine, Springfield, IL 62794-9679, USA

²Division of Infection Prevention, Carefusion, Vernon Hills, IL 60061, USA

³Center for Clinical Research, Southern Illinois University School of Medicine, Springfield, IL 62794-9679, USA

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***Correspondence:**

Dr. Khaled J. Saleh,

E-mail: kjsaleh@gmail.com

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ABSTRACT

Background: Proper and adequate surgical site preparation is a vital part of reducing postoperative morbidity, mortality, and overall health care costs. A major key to improve quality-of-care is the compliance with standardized procedures that reduce variations.

Methods: We conducted a prospective, observational study in 257 hospitals across the US to assess standardization-rates of surgical-site skin-preparation. The adequacy of surgical skin-prepping duration and the drying-time as defined by the directions-for-use of each product were assessed.

Results: Our results showed a 24.6% compliance rate with both application and dry times, while 38.8% of hospitals were noncompliant with either application-time or dry-time. The use of a single-step applicator, a central-to-peripheral application, chlorhexidine-alcohol, and performing a single prep were correlated with higher compliance rates. The use of a 2-step application, aqueous-chlorhexidine, iodine, iodine-alcohol, and performing two or more total preps all showed a higher correlation with overall non-compliance. The compliance with adequate prep-time or dry-time was significantly correlated with higher compliance with both variables.

Conclusions: Among hospitals included in this study, the compliance rates with standardized recommendations were low and might be an indicator to drawbacks that extend beyond the act of skin preparation. The adequacy of skin preparation might be an indicator of the status of a compliance-culture and of the delivered-care quality.

Keywords: Standardization, Skin-preparation, Compliance, Compliance-culture, Quality

INTRODUCTION

In the United States, health care expenditure is continuously rising and is projected to reach up to \$2.5 trillion by the year 2023, consuming around 19.3% of the Gross Domestic Product.¹ With the current trends of unsustainable growth and increasing cost, healthcare facilities are faced with a crucial need to improve quality and decrease expenses while continuing to deliver patient-centered care.² Each year, 1.7 million patients

develop a healthcare-associated infection (HAI),³ leading to \$40 billion in added annual costs.⁴ The most common types of HAI were pneumonia (21.8%), surgical-site infections (21.8%), and gastrointestinal infections (17.1%).^{5,6} In addition to the increase in healthcare costs, it also contribute to an overall increase in postoperative morbidity and mortality rates while decreasing surgical outcomes.⁴ Thus, it is very important to improve the quality of care in surgery.

Techniques that are effective in improving quality of care have been extensively described in the literature, and include pre-operative, intraoperative as well as postoperative processes and practices.^{1,2,7-9} A major key to improve quality of care is the establishment of standardized procedures and protocols that reduce variations and increase effectiveness when implemented correctly. Many intervention-initiatives such as Surgical Check List and Surgical Care Improvement Project (SCIP) have demonstrated that standardized processes can substantially and successfully reduce the incidence of HAIs and mortality.^{10,11} With cumulative evidence reported in the literature, clinicians increasingly recognize that process steps with a specific goal of reducing variation between surgeons, result in more positive outcomes.^{12,13} One such process step that hasn't been studied in detail is the pre-operative skin preparation at the surgical site.

The purpose of this study was to assess the compliance and standardization rates of surgical site skin preparation procedures across a convenient sample of hospitals in the US. We hypothesize that regardless of the surgical skin preparation recommended guidelines and product directions, operating room staff are not standardized in practice, and that variations exist in compliance between hospitals across the US.

The secondary objectives were to determine whether the compliance rates correlated to: (1) product used for skin prepping (2) hospital characteristics.

METHODS

Institutional review board (IRB)

The Springfield Committee for Research Involving Human Subjects (SCRIHS) reviewed this project and determined that it does not meet criteria for research involving human subjects and hence IRB approval was not required.

Setting

These study reports aggregate findings from observations of surgical skin prepping procedures in a sample of U.S. healthcare facilities. The 257 facilities participating in the program are a convenience sample from hospitals across the US that has participated in monitoring the compliance to the appropriate pre-operative practice as recommended by guidelines. We were unable to randomize the centers and institutions where the observations were conducted.

Study design and surveillance

We conducted a prospective observational study to assess the compliance rates of the standardized perioperative skin preparation process. The data collection was conducted from December 2013 to December 2014. An

external audit team comprised of clinicians and quality care consultants assessed surgical skin prepping procedures through operating room (OR) monitoring techniques. The observers used a program on an automated tablet-based operating room observation tool (Figure 1), which helped ensure consistency in data collection between observers across different facilities. All observers have clinical background and have gone through training on the appropriate usage of tablet-based observation tool as well as the appropriate application of skin antiseptics. Observations are made at the OR, during regular work-hours (7 AM- 4 PM), by qualified observers directly. Questionnaires (Yes/No or choice list) are answered and recorded in the tablet while the observations are made. The date and time of operation room (OR) auditing was randomly conveniently assigned. All included procedures were elective cases, whereas emergency or urgent operations were excluded from our study. The OR team may be aware of the observation but was not informed about the details and contents of what was observed, in an attempt to minimize the risk of bias and behavioural changes associated with the awareness of being monitored.

Figure 1: Program used for observations.

Study variables and definition

We collected data prospectively on a standardized form for each monitored procedure. Studied variables included the following: surgery type, type of skin-prep used, number of total skin-preps utilized, prepping-steps, skin prepping-duration following label directions-for-use (DFU), prep drying-duration following label DFU, observation time, the use of gloves, surgical site moisture status (based on anatomic location), prepping done from site of incision to periphery. A detailed definition of the variables is provided in Table 1.

The collected hospital-characteristic information was: teaching status, number of beds, number of ORs, admissions per year, number of inpatient and outpatient

surgeries per year. The hospital characteristics and data are obtained from IMS Hospital Market Profile Database, 2015.

Table 1: List and definition of the collected variables.

Variable	Categories	Definition
Prep Type	CHG	Chlorhexidine
	CHG_Alcohol	Chlorhexidine with alcohol
	PVP	Iodine
	PVP Alcohol	Iodine with alcohol
Prep Used	Application of 1 prep	Total number of prep types used
	Application of 2+ preps	
Prep Step	1 Step Applicator	ChloraPrep, DuraPrep, Prevail and Prevail-Fx
	2 Step Application	Iodine Scrub & Paint
	Single Agent	1-Step Single Agent Prep Total (Aqueous CHG / Exidine, 10% PVP Paint)
Proper Dry-Time	Yes	Assessed based on time left to dry after application of prep, based on label's directions for each product
	No	
Proper Prep-Time	Yes	Assessed based on duration of prepping based on label's directions for each product
	No	
Procedure Type	Cardiovascular surgery	
	Ears, Eyes or Mouth	
	General Surgery	
	Orthopedics Lower Extremity	
	Orthopedics Upper Extremity	
	Neurosurgery	
	Plastic surgery	
	Reproductive (Female and male)	
	Other	
Procedure Time	AM	Before 12 PM
	PM	After 12 PM
Gloves	None	Gloves used during skin prepping
	Non-Sterile	
	Sterile	
Teaching Status	Academic	
	Non-Academic	
Surgical Site	Dry	Example: extremities, abdomen
	Moist	Example: inguinal folds, axillary area

The outcome of the study, the compliance rate, was assessed based on the variables skin prepping-duration and prep dry-time according to the label's DFU (Table 2 and 3).

Definition of primary outcome and compliance models

The primary outcome in our study was the rate of compliance with the DFU as described by each product's label. To cover the entire spectrum, we define compliance following 2 different models, the loose and strict compliance models. In the loose-compliance model, we

considered a procedure to be compliant if either the prepping-time or the dry-time (or both) were adequate as per DFU (Figure 2). In the strict-compliance model, a procedure is considered as adequate if both the prepping duration and the dry time are compliant with DFU (Figure 3). This definition allowed us to quantify and cover the complete spectrum of compliance, where non-compliance based on the loose-model is used to assess absolute non-compliance rates, while compliance based on the strict-model evaluates the overall compliance rate (Figure 4).

Table 2: Adequate prep drying-time for various products.

Product type	Adequate drying time described in approved product label directions
Alcohol-containing preps Iodine and alcohol, chlorhexidine and alcohol	≥3 min
Non-alcohol-containing preps 2-Step PVP-I Scrub & Paint, 10% PVP Paint	2-3 min

Table 3: Adequate prep application-time for various products.

Surgical Skin Prep Products	Adequate prep application time described in approved product label directions
Iodine-Containing Preps 1. 7.5% PVP Scrub (Single Step or 2-Step PVP-I Scrub & Paint)	5 min
Chlorhexidine-Containing Preps 1. Aqueous CHG 2% or 4% 2. Chlorhexidine and Alcohol	Varies (see below) • 4 min • 0.5-2 min

Figure 2: Loose-model for compliance definition. **Figure 3: Strict-model for compliance definition.** **Figure 4: Compliance scale.**

Statistical analysis

To avoid any under-expression or inflation of the results instigated by various numbers of observations examined at different hospitals, the collected data at each institution was collapsed and expressed as percentages for each hospital, a value representative of the variable at a specific hospital. For example, if seven out of a total of 10 observations at a specific hospital were noted to be compliant, the compliance rate at that specific institution would be expressed as 70%. The translation of observations into percentages minimizes bias and skewing of the results towards healthcare centers at which more procedures have been observed.

Data across observation sites was aggregated and analysed. The Statistical Package for the Social Sciences version 22 software program (SPSS, Chicago, Illinois, USA) was utilized to calculate the descriptive and frequency statistics as well as Pearson's correlation coefficients. A P value of 0.05 or less was considered statistically significant.

RESULTS

Between December 2013 and December 2014, a total of 5,439 observations were made across the 257 healthcare centers.

Hospitals characteristics

The healthcare centers participating in our study varied in a number of characteristics. The hospitals bed-size ranged from 6 to 1,246 inpatient beds (n=257, average=313.6), while the number of operating rooms ranged from 2 to 95 operating rooms per hospital (average=16.8). The average number of admissions at the participating healthcare centers was 16,441.7 admissions per year (range 80 to 115,081 admissions). The mean number of surgeries per hospital was 14,204.6 surgeries annually (range 1,440 to 133,137 procedures) with a breakdown average of 5,729 inpatient surgeries (n=235, range: 749-128,910) and 8,560 outpatient surgeries (n=236, range: 80-33,997).

Table 4: Characteristics of hospitals included in this study.

Variable	Minimum	Maximum	Mean
Staffed Beds	6	1,246	313.61
ORs	2	95	16.82
Admissions	80	115,081	16,441.74
Inpatient Surgeries	80	33,997	5,728.96
Outpatient Surgeries	749	128,910	8,560.06
Total Surgeries	1,440	133,137	14,204.56

The size of hospitals included in the study was stratified based on number of beds, and ranged from <99 beds (14.8%) to >500 beds (15.2%), with the majority of

hospitals falling within the 100-500 beds tier (Table 5). When stratified based on the academic status of the hospitals, 71.8% of the included hospitals were teaching institutions.

Table 5: Hospitals size based on number of beds.

Number of beds	Frequency	Percent
< 99 beds	38	14.8
100-199 beds	57	22.2
200-299 beds	48	18.7
300-399 beds	41	16.0
400-499 beds	34	13.2
500+ beds	39	15.2
Total	257	100.0

Table 6: Observational results across the 257 institutions.

Variable	Percentage
Gloves	Non-Sterile
	16.09%
	None
Procedure Time	AM
	PM
Prep Type	Aqueous CHG
	CHG with Alcohol
	Iodine
	Iodine with Alcohol
Prep Step	1-Step Applicator
	2-Step Applicator
	Single Agent
	Other Steps
Procedure Type	Cardiothoracic Surgery
	Eyes/Ears/Mouth
	General Surgery
	Lower extremity Orthopedics
	Neurosurgery
	Other
	Plastic
	Reproductive
	Upper extremity Orthopedics
	1 Prep
Prep Used	2+ Preps
	Yes
Prepping from incision to periphery	No
	Yes
Moist Surgical Site	No
	Yes
Compliance based on strict model	No
	Yes
Compliance based on loose model	No
	Yes

Table 7: Correlations and level of significance of compliance based on the loose and strict models.

Variables	Loose-compliance model				Strict-compliance model			
	No compliance		Compliant		No compliance		Compliant	
	Pearson Correlation	P value	Pearson Correlation	P value	Pearson Correlation	P value	Pearson Correlation	p value
Staffed Beds	0.034	0.589	-0.034	0.589	-0.075	0.231	0.075	0.231
Bed Tier	0.075	0.233	-0.075	0.233	-0.047	0.454	0.047	0.454
Non-Teaching Hospital	0.131	0.046	-0.131	0.046	0.001	0.993	-0.001	0.993
Number of Operation rooms	0.04	0.532	-0.04	0.532	-0.104	0.107	0.104	0.107
Number of Admissions	-0.02	0.759	0.02	0.759	-0.126	0.047	0.126	0.047
Number of Inpatient Surgeries	0.095	0.145	-0.095	0.145	-0.057	0.385	0.057	0.385
Number of Outpatient Surgeries	-0.058	0.376	0.058	0.376	-0.053	0.421	0.053	0.421
Total Number of Surgeries	-0.005	0.939	0.005	0.939	-0.058	0.373	0.058	0.373
Gloves Use								
Non-Sterile	-0.071	0.253	0.071	0.253	-0.106	0.089	0.106	0.089
None	-0.026	0.676	0.026	0.676	-0.065	0.297	0.065	0.297
Sterile	0.071	0.256	-0.071	0.256	0.121	0.053	-0.121	0.053
Application type								
Center-to-Periphery: No	0.125	0.045	-0.125	0.045	0.167	0.007	-0.167	0.007
Center-to-Periphery: Yes	-0.125	0.045	0.125	0.045	-0.167	0.007	0.167	0.007
Surgical site moisture								
Dry Surgical Site	-0.125	0.044	0.125	0.044	-0.129	0.039	0.129	0.039
Moist Surgical Site	0.125	0.044	-0.125	0.044	0.129	0.039	-0.129	0.039
Procedure Time								
AM	0.146	0.019	-0.146	0.019	0.02	0.75	-0.02	0.75
PM	-0.146	0.019	0.146	0.019	-0.02	0.75	0.02	0.75
Prep type								
Aqueous CHG	0.245	0	-0.245	0	0.202	0.001	-0.202	0.001
CHG with Alcohol	-0.487	0	0.487	0	-0.464	0	0.464	0
Iodine	0.178	0.004	-0.178	0.004	0.227	0	-0.227	0
Iodine with Alcohol	0.266	0	-0.266	0	0.269	0	-0.269	0
Prep step								
1 Step Application	-0.385	0	0.385	0	-0.357	0	0.357	0
2 Step Application	0.068	0.275	-0.068	0.275	0.14	0.025	-0.14	0.025
Single Agent	0.303	0	-0.303	0	0.264	0	-0.264	0
Other steps	0.296	0	-0.296	0	0.191	0.002	-0.191	0.002
Procedure type								
Cardiothoracic Surgery	0.029	0.648	-0.029	0.648	-0.022	0.723	0.022	0.723
Eyes/Ears/Mouth	0.111	0.076	-0.111	0.076	0.054	0.389	-0.054	0.389
General Surgery	-0.123	0.049	0.123	0.049	-0.144	0.021	0.144	0.021
Lower extremity Orthopedics	-0.011	0.862	0.011	0.862	-0.009	0.88	0.009	0.88
Neurosurgery	0.062	0.323	-0.062	0.323	0.088	0.16	-0.088	0.16
Other	-0.031	0.624	0.031	0.624	0.013	0.84	-0.013	0.84
Plastic Surgery	0.085	0.175	-0.085	0.175	0.113	0.07	-0.113	0.07
Reproductive Surgery	0.009	0.883	-0.009	0.883	0.004	0.946	-0.004	0.946
Upper extremity Orthopedics	0.071	0.256	-0.071	0.256	0.129	0.039	-0.129	0.039
Prep Used								
1 Prep	-0.271	0	0.271	0	-0.133	0.033	0.133	0.033
2+ Preps	0.271	0	-0.271	0	0.133	0.033	-0.133	0.033

Of the 5439 procedures observed, 60.05% were during morning (AM) hours, while 39.95% were observed during afternoon (PM) hours. The most common procedure types observed were general surgery (31.09%), lower limb orthopedic surgery (23.53%), reproductive surgery (14.6%), and upper limb orthopedic surgery (10.34%). The surgical site was considered as dry in 87.35% of the observations, while 12.65% of the procedures were performed on a moist surgical site. The type of prep used in the majority of the cases was CHG with alcohol (62.20%), followed by iodine (17.26%), iodine with alcohol (9.97%) and aqueous CHG (4.57%). In 72.61% of cases, 1-step application was used, while 2-step application was only used in 10.90% of cases, single agent prep was used in 10.86% of the time, and other combinations were used in the rest of the cases. A single preparation only was performed in the majority of cases (90.58%), while two or more preps were performed 9.42% of the time.

When analysing glove use during surgical site preparation, we observed that sterile gloves and non-sterile gloves were used 74.07% and 16.01% of the time, respectively, while gloves were not used at all in 9.84% of the procedures. With regard to performing the prep, application of prep starting at the center of the incision site and moving outward was observed 89.90% of the time.

Based on the loose-compliance model, the non-compliance rate was 38.9%, while compliance with DFU was reported in 61.1% of the cases. According to the strict-compliance model, compliance with DFU was noted in 24.6% of the cases, while the non-compliance rate reached up to 75.4% of the skin prepping product applications.

Correlation analysis

Loose-compliance model

When measuring compliance according to the loose model, nearly all hospital characteristics and glove use did not show a statistically significant correlation with prep-time or dry-time compliance. The only hospital-related variable to show a significant correlation according to the loose-compliance model was the academic status, where teaching hospitals were associated with higher non-compliance rate that was statistically significant compared to non-teaching hospitals ($r=0.131$, $p=0.046$). When considering personnel-related variables, the use of a central-to-peripheral prep application technique ($r=0.125$, $p=0.045$) and procedures taking place during afternoon hours ($r=0.146$, $p=0.019$) showed a positive correlation with compliance to either adequate prep-time or dry-time. When considering specific variables regarding the inherent nature of the surgical site, a dry surgical site ($r=0.125$, $p=0.044$) showed a positive correlation with being compliant to either adequate prep-time or dry-time.

The analysis of variables related to prep type, showed the use of CHG with alcohol prep ($r=0.487$, $p<0.01$), the use of a one-step application ($r=0.385$, $p<0.01$), and performing only one prep ($r=0.271$, $p<0.01$) all showed a positive correlation with being compliant to either prep-time or dry-time as per DFU. Furthermore, compliance with at least one of the two variables, adequate prep time and adequate dry time, shows a positive correlation with being compliant with both variables ($r=0.7$, $p<0.01$).

In contrast, when considering personnel-specific variables, the absence of a central-to-peripheral application technique ($r=0.125$, $p=0.045$) and procedures taking place during the AM hours ($r=0.146$, $p=0.019$) showed a positive correlation with non-compliance with both prep-time and dry-time. When considering specific variables regarding the inherent nature of the surgical site, a moist surgical site ($r=0.125$, $p=0.044$) showed a significant correlation with inadequacy of both prep-time and dry-time. When analysing variables related to prep type, the use aqueous CHG ($r=0.245$, $p<0.01$), iodine ($r=0.178$, $p=0.004$), iodine with alcohol ($r=0.266$, $p<0.01$), single agent prep ($r=0.303$, $p<0.01$), and performing two or more preps ($r=0.271$, $p<0.01$) all showed a statistically significant correlation with non-compliance with both adequate prep-time and dry-time.

Strict-compliance model

The evaluation of the strict-compliance model showed no statistically significant correlation between compliance and the time of the procedure, the use of gloves, and nearly all hospital-related variables. The only hospital characteristic to show a significant correlation with compliance was the number of admissions ($r=0.126$, $p=0.047$). When considering personnel-associated variables, the use of a central-to-peripheral prep application technique ($r=0.167$, $p<0.01$) showed a statistically significant correlation with compliance rates. A non-moist surgical site ($r=0.129$, $p=0.039$) also showed a statistically significant correlation with compliance to both adequate prep-time and dry-time as per DFU. When analysing variables related to prep type, the use of CHG with alcohol ($r=0.464$, $p<0.01$), the use of a one-step application ($r=0.357$, $p<0.01$), and performing only one prep ($r=0.133$, $p=0.033$) all showed a statistically significant correlation with compliance to both adequate prep time and adequate dry time.

In contrast, the absence of a central-to-peripheral application technique ($r=0.167$, $p=0.007$), a moist surgical site ($r=0.129$, $p=0.039$), the use of CHG prep ($r=0.202$, $p=0.001$), iodine prep ($r=0.227$, $p<0.01$), iodine with alcohol ($r=0.269$, $p<0.01$), the use of two-step application ($r=0.140$, $p=0.025$), and performing 2 or more preps ($r=0.133$, $p=0.033$) were all significantly associated with non-compliance to at least one of the two variables, adequate prep-time and adequate dry-time.

DISCUSSION

In the context of national implication of reimbursements based on performance-measures and changes proposed by the Affordable Care Act and other initiatives of healthcare reforms, the delivery of the highest quality in healthcare is a priority. HAI is a substantial complication among surgical patients, leading to considerable financial burden and decrease in postoperative outcomes. The Institute for Healthcare Improvement (IHI) launched the 5-Million Lives Campaign in an attempt to improve the quality of healthcare, and identified HAI, as one of the factors to reach this target.¹⁴ The appropriate skin antisepsis is among the recommendations suggested by the IHI.

The purpose of this study was to assess the rates of compliance with the recommendations for appropriate surgical skin preparation practices as highlighted by each product's DFU. Our results showed a 24.6% compliance rate according to the strict model, while 38.8% of hospitals were noted to be noncompliant according to the loose model. With 63.4% of the total data being distributed at the two extremes of the compliance spectrum, our results show relatively low compliance rates and major variability in standardized processes at the level of 257 hospitals. When assessing for correlation between compliance and the characteristics of the skin-prep product used, CHG with alcohol was the only product with a statistically significant higher correlation with compliance according to the strict model criteria ($r=0.464$, $p<0.01$). The compliance with the recommended prepping-time might be explained by the shorter duration required for CHG with alcohol (less than 2 minutes) when compared to other products. However, although CHG with alcohol requires a longer drying duration (≥ 3 minutes), a positive correlation with compliance to dry time was still observed. Furthermore, the use of aqueous CHG ($r=0.245$, $p<0.01$), iodine ($r=0.178$, $p=0.004$), and iodine with alcohol ($r=0.266$, $p<0.01$) all showed a significant higher correlation with overall non-compliance according to the loose model criteria. This correlation may be explained by the fact that iodine-containing preps and aqueous CHG only prep require longer prep application times, 5 minutes and 4 minutes, respectively, compared to the shorter application time of CHG with alcohol. The longer duration and the harder-to-fulfil criteria might be a pertinent explanation also for the observation that a dry surgical site ($r=0.129$, $p=0.039$) correlated to compliance according to the strict model criteria, while a moist surgical site was significantly correlated ($r=0.125$, $p=0.044$) with higher non-compliance rates following the loose model definition, since a longer prepping-time is required for moist surgical sites compared to dry sites, leading to less adherence to product's DFU.

Interestingly, using single-step application ($r=0.357$, $p<0.01$) was associated with compliance according to the strict model, while the use of two-step application

($r=0.140$, $p=0.025$) was correlated with non-compliance according to strict model. A potential explanation to this observation might be lying within the complexity of the process. The Lean Six Sigma (LSS) methodology is the concurrent application of strategies to reduce waste while improving workflow (Lean) and decreasing error rates by reducing variations (Six Sigma) through a stepwise process.¹⁵ LSS identifies complex-steps as a high risk for potential failures; non-compliance rates are expected to be higher when more criteria and requirements should be met for the process to be labelled as adherent to directions.

Based on the system engineering initiative for patient safety (SEIPS),¹⁶ there are multiple factors contributing to the success and failure of a complex healthcare process such as HAI prevention. Traditional infection prevention interventions limited to a single intervention (e.g., improving physician hand hygiene) will be inadequate to address HAI. Many of the more effective contemporary interventions to improve infection prevention compliance have been multidimensional including the choice of evidence based technology and tools to the personnel training and organizations streamline. Simplifying the processes, including skin antiseptics, may be helpful to improve quality and achieve better outcomes. Furthermore, our results showed that performing only one total prep ($r=0.133$, $p<0.033$) significantly correlated with compliance according to the strict model criteria, while performing two or more total preps was significantly associated with higher correlation to non-compliance according to the loose model criteria. This observation may be additionally related to the perception of the single prep as a crucial step in the appropriate antisepsis and hence it is imperative that it is done properly with strict adherence to prep-time and dry-time as per DFU. However, when multiple preps are to be performed then compliance with prep and dry durations at each application may be perceived as less important, and more confidence would be shifted towards the quantity of preps, rather than quality, to ensure effective antisepsis. Additionally, the use of a central-to-peripheral application technique showed a statistically significant higher correlation ($r=0.167$, $p=0.007$) with compliance according to the strict model criteria, whereas the absence of a central-to-peripheral technique ($r=0.125$, $p=0.045$) was significantly associated with noncompliance according to the loose model criteria. Such a finding brings to the forefront a potentially alarming concept of a "culture of compliance" rather than a product of convenience or random association, since the adherence to proper application technique correlates with compliance with both prep and dry time, while non-adherence to proper application technique correlates with non-compliance with both dry time and prep time. Reinforcing this statement is the observation that compliance with at least one of the two variables, adequate prep time and adequate dry time, was significantly correlated with higher compliance with both variables ($r=0.7$, $p<0.01$). These associations potentially

uncover an underlying problem that may extend beyond the basic concept of skin preparation. The lack of adherence to guidelines, at multiple levels, in elementary steps of the surgical process might be a pointer to the absence of compliance-culture at some institutions and healthcare centers.

The procedures that were done in the morning showed a significant higher correlation ($r=0.146$, $p=0.019$) with noncompliance according to the loose model criteria. A potential explanation might be the tighter monitoring and assessment of surgery start-time and procedure duration in the morning hours, at which point the surgical team might sacrifice the potential gain in safety, associated with compliance with adequate prep and dry time, at the expense of improving the monitored intraoperative efficiency, recorded as surgery start-time and length of the procedure.

The compliance rates in our study were not associated with hospital-specific characteristics (bed-tier, number of ORs, number of inpatient and outpatient procedures per year). The only two exceptions are the number of yearly admissions and the academic status of the hospital. The higher number of admissions showed a significantly higher correlation ($r=0.126$, $p=0.047$) with compliance according to the strict model criteria. In the literature search to evaluate the association between HAI rates and hospitals size, a bigger hospital size and a high surgical procedures volume, and a potentially more extensive experience, to lower SSI and ventilator associated pneumonia rates.^{17,18} They noted that the experience gained through the larger number of cases, may also lower risks of SSI by improving preventive approaches.

Interestingly, in our sample, teaching hospitals had a statistically significant higher correlation with non-compliance compared to non-teaching hospitals ($r=0.131$, $p=0.046$) according to the loose-model definition. This might be explained by the presence of learners in the OR, where more time would be allocated to teach students or residents the appropriate surgical skin preparation techniques. Another explanation might be related to the team-member preparing the skin, since learners are more likely to be non-compliant with the exact guidelines. Further research is required to identify the main factors that impact compliance rates at academic institutions.

Limitations

An integral facet of this study is to acknowledge its limitations. First, the healthcare centers enrolment process was not randomized. In addition surgical procedures selection, within each center, followed non-random and rather practical considerations, as the OR schedule and the day of the week. This might have implicated a selection-type bias. However, the large number of procedures and institutions included in our study minimized this bias.

Second, the behavior of the OR staff may have been affected by the awareness of the presence of an observer. The blinded direct observation of surgical cases aimed to prevent this potential observer bias, since the exact objective of the observations was not known to the OR team. This approach enabled the assessment of compliance rates and the reflection of true practices with adequate delineation of the studied problem.

Although this study provides a non-previously documented evaluation of the adherence to standardized processes across a large number of institutions, we couldn't provide evidence to associate the compliance rates with clinical postoperative outcomes. Continuous patient monitoring and follow up for assessment of outcomes such as wound infection and rates of HAI in correlation with compliance to standardized skin preparation techniques, although not feasible at this large scale and the available resources, would have been optimal.

CONCLUSION

The benefits of standardization and adherence to recommendations have been shown to improve patient outcomes and decrease preventable adverse events of surgery.¹⁸⁻²¹ However, these benefits cannot be achieved without adherence to existing guidelines and directions. The low compliance rates reported in our study might be an indicator to pitfalls that are not limited to the simple act of skin preparation before surgery, but rather extend potentially to countless stages of the surgical process. The simple act of surgical skin preparation might be a useful indicator of the quality of the delivered care. A compliance-culture will not be achieved by solely changing product type or target specific variables, and a more general educational and awareness-improvement measures might be needed as an approach to increase compliance rates.

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