

Original Investigation

Evidence for a Standardized Preadmission Showering Regimen to Achieve Maximal Antiseptic Skin Surface Concentrations of Chlorhexidine Gluconate, 4%, in Surgical Patients

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← Invited Commentary

IMPORTANCE To reduce the amount of skin surface bacteria for patients undergoing elective surgery, selective health care facilities have instituted a preadmission antiseptic skin cleansing protocol using chlorhexidine gluconate. A Cochrane Collaborative review suggests that existing data do not justify preoperative skin cleansing as a strategy to reduce surgical site infection.

OBJECTIVES To develop and evaluate the efficacy of a standardized preadmission showering protocol that optimizes skin surface concentrations of chlorhexidine gluconate and to compare the findings with the design and methods of published studies on preoperative skin preparation.

DESIGN, SETTING, AND PARTICIPANTS A randomized prospective analysis in 120 healthy volunteers was conducted at an academic tertiary care medical center from June 1, 2014, to September, 30, 2014. Data analysis was performed from October 13, 2014, to October 27, 2014. A standardized process of dose, duration, and timing was used to maximize antiseptic skin surface concentrations of chlorhexidine gluconate applied during preoperative showering. The volunteers were randomized to 2 chlorhexidine gluconate, 4%, showering groups (2 vs 3 showers), containing 60 participants each, and 3 subgroups (no pause, 1-minute pause, or 2-minute pause before rinsing), containing 20 participants each. Volunteers used 118 mL of chlorhexidine gluconate, 4%, for each shower. Skin surface concentrations of chlorhexidine gluconate were analyzed using colorimetric assay at 5 separate anatomic sites. Individual groups were analyzed using paired *t* test and analysis of variance.

INTERVENTION Preadmission showers using chlorhexidine gluconate, 4%.

MAIN OUTCOMES AND MEASURES The primary outcome was to develop a standardized approach for administering the preadmission shower with chlorhexidine gluconate, 4%, resulting in maximal, persistent skin antiseptics by delineating a precise dose (volume) of chlorhexidine gluconate, 4%; duration (number of showers); and timing (pause) before rinsing.

RESULTS The mean (SD) composite chlorhexidine gluconate concentrations were significantly higher ($P < .001$) in the 1- and 2-minute pause groups compared with the no-pause group in participants taking 2 (978.8 [234.6], 1042.2 [219.9], and 265.6 [113.3] $\mu\text{g/mL}$, respectively) or 3 (1067.2 [205.6], 1017.9 [227.8], and 387.1 [217.5] $\mu\text{g/mL}$, respectively) showers. There was no significant difference in concentrations between 2 and 3 showers or between the 1- and 2-minute pauses.

CONCLUSIONS AND RELEVANCE A standardized preadmission shower regimen that includes 118 mL of aqueous chlorhexidine gluconate, 4%, per shower; a minimum of 2 sequential showers; and a 1-minute pause before rinsing results in maximal skin surface ($16.5 \mu\text{g}/\text{cm}^2$) concentrations of chlorhexidine gluconate that are sufficient to inhibit or kill gram-positive or gram-negative surgical wound pathogens. This showering regimen corrects deficiencies present in current nonstandardized preadmission shower protocols for patients undergoing elective surgery.

JAMA Surg. doi:10.1001/jamasurg.2015.2210
Published online August 26, 2015.

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The concept of the preadmission shower as a risk reduction strategy was addressed in the 1999 Centers for Disease Control and Prevention Hospital Infection Control Practices Advisory Committee document. “A preoperative antiseptic shower or bath decreases skin microbial colony counts. In a study of more than 700 patients who received 2 preoperative antiseptic showers, chlorhexidine reduced bacterial colony counts 9-fold, while povidone-iodine or triclocarban-medicated soap reduced colony counts by 1.3- and 1.9-fold, respectively.”^{1(p257)} This process was designated by the Centers for Disease Control and Prevention guidelines as a category 1B clinical practice and “strongly recommended.” Although there is universal agreement that a chlorhexidine gluconate, 2% or 4%, whole-body bath or shower will reduce bacterial colonization of the skin, there are no definitive data suggesting that this practice is an effective strategy for reducing postoperative surgical site infections.^{1,2} The most recent Cochrane Collaborative review³ reviewed 7 clinical trials: 6 were conducted over a 9-year period from 1983 to 1992 and 1 trial⁴ was published in 2009; the review suggested that existing evidence-based data did not justify continuation of this practice. A meta-analysis⁵ published in 2013 evaluated 16 clinical trials from 1979 to 2011 involving 9980 patients and reached a similar conclusion: whole-body showering or cleansing showed no benefit in preventing postoperative surgical site infection. However, a separate analysis⁶ found that many of the previous clinical studies were technically and scientifically flawed and that a rigorous standardization of the preadmission showering process was lacking. A clinical analysis⁷ found that a nonstandardized approach to the application of chlorhexidine gluconate during showering resulted in skin surface concentrations that were inadequate for inhibiting most anticipated gram-positive and gram-negative surgical pathogens. Although several evidence-based analyses appear not to support the routine use of a chlorhexidine gluconate, 4%, preadmission whole-body cleansing or showering, 2 pivotal factors should be considered when evaluating this low-risk, low-cost intervention^{2,8}:

1. Chlorhexidine gluconate skin surface concentrations accumulate with repetitive application; therefore, a single application may not approach concentrations sufficient to inhibit skin flora.
2. Chlorhexidine gluconate binding to skin protein is influenced by the amount of the antiseptic agent the skin is exposed to and the duration of exposure before rinsing.

Although the preadmission shower has been instituted by many health care institutions for patients undergoing elective surgery, 3 unresolved questions remain:

1. Is there a measureable difference in the skin surface concentrations of chlorhexidine gluconate in patients who shower 2 or 3 times before hospital admission?
2. Would a pause before rinsing enhance skin surface concentrations of chlorhexidine gluconate compared with immediately rinsing off the antiseptic agent following application?
3. Is a definite volume of chlorhexidine gluconate, 4% (118 mL) important for achieving maximal skin surface concentrations?

The objective of the present study was to address these 3 unresolved questions from a pharmacokinetic perspective in a randomized prospective study involving healthy volun-

teers who showered 2 or 3 times using aqueous chlorhexidine gluconate, 4%, in an effort to maximize the benefit of the preadmission shower as an effective risk reduction strategy.

Methods

Randomized Study Groups

The study protocol was reviewed and approved by the Medical College of Wisconsin institutional review board. The study was conducted from June 1, 2014, to September, 30, 2014. Data analysis was performed from October 13, 2014, to October 27, 2014.

After providing written informed consent, 120 healthy volunteers were randomized to either 2 showers (group A) or 3 showers (group B). The participants were further randomized into 3 subgroups:

Group A. Chlorhexidine gluconate, 4%, 2-shower arm (night/morning; 60 participants)

A1. No pause (n = 20)

A2. 1-minute pause (n = 20)

A3. 2-minute pause (n = 20)

Group B. Chlorhexidine gluconate, 4%, 3-shower arm (2 nights/1 morning; 60 participants)

B1. No pause (n = 20)

B2. 1-minute pause (n = 20)

B3. 2-minute pause (n = 20)

Chlorhexidine Gluconate, 4%, Showering Protocol

All participants received both oral and written instructions on applying chlorhexidine gluconate, 4%; the time until rinsing (0, 1 minute, or 2 minutes); and safety information. Study volunteers showering twice were given 2 bottles of chlorhexidine gluconate, 4% (each 118 mL), and individuals showering 3 times were given 3 bottles of the same size. The bottles were distributed 48 hours before the first shower. The participants were instructed to use the entire bottle of chlorhexidine gluconate, 4%, during each showering episode. The bottles were individually numbered (1, 2, or 3). All volunteers were required to return to the surgical microbiology research laboratory in the department of surgery within 3 to 4 hours after the morning (last) shower to assess chlorhexidine gluconate skin surface concentrations; they were instructed to bring the empty bottles. The volunteers applied chlorhexidine gluconate, 4%, using a clean washcloth that was supplied in each cleansing kit (Clorox Healthcare 4% CHG Skin Cleaning Kit; The Clorox Company). Aqueous chlorhexidine gluconate, 4%, was applied to the entire torso with the caveat not to apply the agent to the face or around the ears. Participants were instructed to immediately rinse and report any burning, tingling, or discomfort following application of chlorhexidine gluconate, 4%, to the principal investigator (C.E.E.) or study coordinator (C.J.K.).

Measurement of Chlorhexidine Gluconate Skin Surface Concentrations

The chlorhexidine gluconate skin surface concentration assay is based on an adaptation of a US official monograph

Table 1. Time Between Last Shower and Skin Surface Analysis of Aqueous Chlorhexidine Gluconate, 4%

Study Group ^a	No. of Participants	Time, Mean (SD), min
2 Showers		
A1	20	102.6 (49.3)
A2	20	102.1 (45.3)
A3	20	125.5 (70.3)
3 Showers		
B1	20	104.7 (52.2)
B2	20	139.8 (42.8)
B3	20	134.1 (51.5)

^a No pause before rinsing, groups A1 and B1; 1-minute pause before rinsing, groups A2 and B2; and 2-minute pause before rinsing, groups A3 and B3.

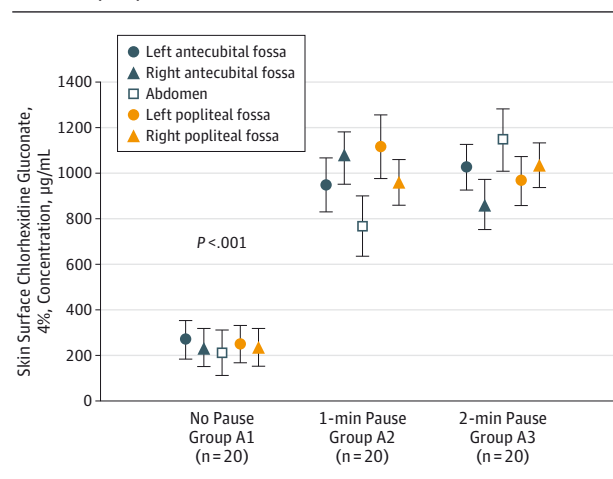
for the identification of chlorhexidine gluconate solution.⁹ The standard method was modified to allow portability and ease of use by clinicians for point-of-use testing. In brief, a swab (Bio-Swab; Arrowhead Forensics Inc) was used to obtain a sample from a defined skin surface area (2-cm² template) on the right and left antecubital fossae, right and left popliteal fossae, and abdomen by rolling the swab back and forth across the skin for 15 seconds. The swabs were then immediately placed in a screw-cap container to prevent desiccation before analysis. One hundred microliters of freshly prepared indicator solution (5 parts cetyltrimethylammonium bromide, 1% [Sigma-Aldrich Co]; 2 parts sodium hypobromite [Fisher Scientific]) was added to each swab. A light pink to intense red color indicates the presence of chlorhexidine gluconate, with intensity of the color reflective of the relative concentration of chlorhexidine gluconate on the surface of the skin. The color reaction on each swab was compared with a freshly prepared chlorhexidine gluconate standard, which ranged from 2.5 to 10 000 µg/mL. The assay was read by an independent blinded observer who compared test swabs with the chlorhexidine gluconate standard. A fresh standard solution was prepared daily before testing of volunteer sample swabs.

Statistical Analysis

The principal investigator was blinded to all randomization codes until the final volunteer was processed, at which point the codes were broken and individual groups were analyzed. Analysis of variance and 1-sided paired *t* test were used to analyze the difference between the relative mean concentrations of chlorhexidine gluconate skin surface concentrations in the no pause groups, A1 and B1 compared to pausing 1 or 2 minutes prior to rinsing in groups A2, B2 and A3, B3; level of significance was assessed at *P* ≤ .05. Statistical analysis was conducted using the MINITAB Statistical Program, release 12 (MINITAB Inc).

Results

Six participants did not return their empty bottles of chlorhexidine gluconate, 4%; although they verbally indicated adherence to the protocol, failure to return the bottles

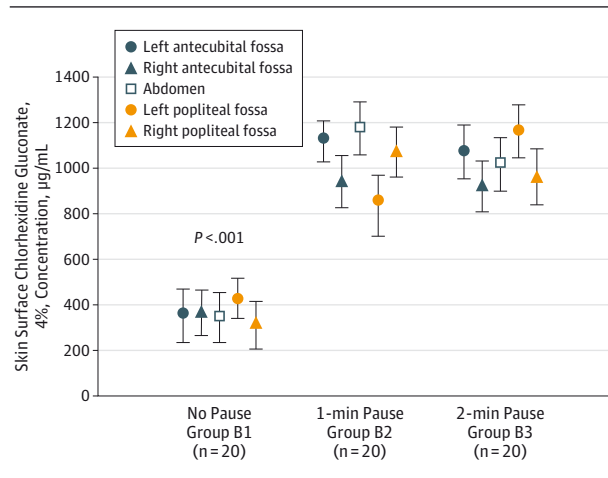
Figure 1. Mean Skin Surface Concentration of Aqueous Chlorhexidine Gluconate, 4%, after 2 Preadmission Showers

A significant increase in the skin surface concentrations of aqueous chlorhexidine gluconate, 4%, was observed in participants who paused for 1 or 2 minutes before rinsing compared with no pause. Limit lines indicate SD.

was viewed as a protocol violation and they were excluded from analysis. Six replacement volunteers (groups A1, 1; A3, 2; B1, 1; B2, 1; and B3, 1) were added at the end of the study to complete the requirement of 20 volunteers per group. Three participants (5.0%) in the 2-shower group and 2 volunteers (3.3%) in the 3-shower group reported slight tingling and irritation on the torso following application of aqueous chlorhexidine gluconate, 4%, but did not view this as a significant event requiring notification of the principal investigator or study coordinator.

Table 1 documents the mean time differential between the last shower and chlorhexidine gluconate, 4%, skin surface analysis for study participants. No significant difference was observed in the time differential between final shower and laboratory analysis of chlorhexidine gluconate skin surface concentrations between groups A1 to A3 or B1 to B3. Most volunteers returned to the laboratory within 2 hours after taking their last shower. **Figure 1** illustrates the mean skin surface concentrations of chlorhexidine gluconate in the left and right antecubital fossae, right and left popliteal fossae, and abdomen in participants who were instructed to shower twice. In participants who showered twice with no pause before rinsing (A1), the mean skin surface chlorhexidine gluconate concentrations were 285.6, 251.3, 292.6, 289.9, and 211.7 µg/mL in the left and right antecubital fossae, left and right popliteal fossae, and abdomen, respectively. In comparison, in volunteers who paused for 1 minute (A2), the mean skin surface concentrations in the left and right antecubital fossae, right and left popliteal fossae, and abdomen were 968.1, 1074.8, 1107.9, 939.6, and 816.6 µg/mL, respectively. The mean skin surface chlorhexidine gluconate concentrations in participants who paused for 2 minutes (A3) before rinsing were 1088.7, 889.3, 999.7, 1053.3, and 1181.9, µg/mL in the left and right antecubital fossae, right

Figure 2. Mean Skin Surface Concentration of Aqueous Chlorhexidine Gluconate, 4%, After 3 Preadmission Showers



A significant increase in the skin surface concentrations of aqueous chlorhexidine gluconate, 4%, was observed in participants who paused for 1 or 2 minutes before rinsing compared with no pause. Limit lines indicate SD.

and left popliteal fossae, and abdomen, respectively. A significant difference in skin surface concentrations was noted between volunteers showering twice with no pause before rinsing compared with those showering twice and pausing for 1 or 2 minutes before rinsing ($P < .001$).

Figure 2 presents the mean skin surface concentrations of chlorhexidine gluconate in the left and right antecubital fossae, left and right popliteal fossae, and abdomen in participants who were instructed to shower 3 times. In those who rinsed immediately after chlorhexidine gluconate, 4%, application (B1), the mean skin surface chlorhexidine gluconate concentrations were 393.3, 406.7, 449.6, 332.9, and 354.5 µg/mL in the left and right antecubital fossae, left and right popliteal fossae, and abdomen, respectively. In comparison, in those who paused for 1 minute (B2), the mean skin surface concentrations were 1157.6, 978.9, 893.1, 1098.8, and 1211.3 µg/mL, respectively. The mean skin surface chlorhexidine gluconate concentrations in participants who paused for 2 minutes (B3) before rinsing were 1101.6, 939.9, 1177.5, 979.1, and 1039.2 µg/mL, respectively. A significant difference in chlorhexidine gluconate skin surface concentrations was also noted in volunteers who showered 3 times with no pause before rinsing compared with those pausing for 1 or 2 minutes before rinsing ($P < .001$). **Table 2** reports the composite (antecubital, abdominal, and popliteal sites) mean skin surface concentrations of chlorhexidine gluconate in patients taking 2 or 3 showers. Pausing for 1 or 2 minutes before rinsing resulted in a significant increase in skin surface concentrations of chlorhexidine gluconate compared with concentrations in participants who rinsed immediately after application of chlorhexidine gluconate, 4% ($P < .001$). Subgroup analysis documented no statistically significant difference in skin surface concentrations of chlorhexidine gluconate in volunteers who showered 2 times vs those who showered 3 times.

Table 2. Composite Comparison of Aqueous Chlorhexidine Gluconate, 4%, Skin Surface Concentrations for Combined Anatomic Sites^a

Group ^b	No.	Chlorhexidine Gluconate, 4%, Concentrations, Mean (SD), µg/mL	P Value
2 Showers			
A1	20	265.6 (113.3)	
A2	20	978.8 (234.6)	<.001 ^c
A3	20	1042.2 (219.9)	
3 Showers			
B1	20	387.1 (217.5)	
B2	20	1067.2 (205.6)	<.001 ^d
B3	20	1017.9 (227.8)	

^a Anatomic sites included right and left antecubital fossae, abdomen, and right and left popliteal fossae.

^b No pause before rinsing, groups A1 and B1; 1-minute pause before rinsing, groups A2 and B2; and 2-minute pause before rinsing, groups A3 and B3.

^c Significant difference in groups A2 and A3 chlorhexidine gluconate, 4%, skin surface concentrations compared with group A1.

^d Significant difference in groups B2 and B3 chlorhexidine gluconate, 4%, skin surface concentrations compared with B1.

Discussion

Many health care facilities have incorporated an antiseptic skin cleansing protocol, often referred to as *preoperative bathing or cleansing*, to reduce the microbial burden on the skin of patients undergoing elective surgery with the aim of reducing the risk of surgical site infections. A survey of California hospitals reported that 91% of all facilities that perform coronary artery bypass surgery have instituted a standardized presurgery bathing and cleansing protocol.¹⁰ This practice has been endorsed by national and international organizations, including the Hospital Infection Control Practice Advisory Committee, Centers for Disease Control and Prevention,¹ Association for Professionals in Infection Control and Epidemiology,¹¹ Association of Perioperative Registered Nurses,¹² Institute for Healthcare Improvement,¹³ and the UK National Institute for Health and Care Excellence,¹⁴ who recommending bathing or cleansing with an antiseptic agent before surgery as a component of a broader strategy to reduce surgical site infections. However, the Cochrane Collaborative³ has reported that no benefit is derived from a series of preadmission showers with an antiseptic agent as a risk reduction strategy for preventing surgical site infections. A careful analysis of the 7 publications^{4,15-20} cited in the Cochrane Collaborative review reveals significant operational and methodologic flaws. As a collective group, the studies cited in the Cochrane Collaborative review expressed a high level of surgical heterogeneity with no documented standard of practice for the preadmission shower or cleansing process. Some patients showered once; other patients showered 2 or 3 times.^{4,15-20} There was no evidence in any of the cited studies that an effort was made to measure patient adherence.^{4,15-20} In 5 of the 7 studies, investigators failed to include a 30-day surveillance period for postoperative follow-up.¹⁶⁻²⁰ No written instructions or inadequate instructions were noted in 5

studies.^{4,16-18,20} One study²⁰ was conducted during a 6-year period (1978-1984), which may have influenced the continuity of patient selection and randomization. Although the 7 studies are reported as randomized clinical trials, they all exhibited significant methodologic flaws and cannot be viewed as robust examples of current evidence-based practice. Studies published since 2009 have controlled for many of the variables viewed as deficient in earlier investigations, including retrospective, sequential, and prospective cohort analyses; case-control studies; prospective observational and interventional clinical trials; and randomized clinical trials.²¹⁻³³ An analysis⁷ of chlorhexidine gluconate skin surface concentrations found that individuals who showered using chlorhexidine gluconate, 4%, without receiving any instructions or guidance had a mean (SD) skin surface concentration of 9.9 (7.1) $\mu\text{g/mL}$; this concentration is insufficient to inhibit most documented surgical pathogens.

The first aim of the present study was to assess the optimal number of applications of chlorhexidine gluconate, 4%, to ensure a maximum skin surface concentration of the antiseptic agent. Because the skin surface antimicrobial activity of chlorhexidine gluconate is enhanced following multiple applications, most protocols would recommend 2 to 5 separate applications before surgery. However, there are no clinical or pharmacologic data suggesting that more than 2 chlorhexidine gluconate showers results in a higher skin surface concentration. The second aim of this study was to ascertain whether pausing prior to rinsing off chlorhexidine gluconate, 4%, resulted in an enhanced skin surface concentration compared with rinsing immediately after application. As a topical antiseptic, chlorhexidine gluconate binds to proteins present in human skin and mucous membranes, and prolonged activity is associated with slow release from these tissues.^{2,34} The final component of the study involved determining whether a standard volume of chlorhexidine gluconate, 4% (118 mL), resulted in higher skin surface concentrations than reported in previous studies^{7,34} in which less than 50 mL per shower was used.

The study concluded that no significant difference in chlorhexidine gluconate skin surface concentrations were observed between participants taking 2 or 3 carefully standardized preadmission showers. However, a 1- or 2-minute pause before rinsing was associated with a significantly higher skin surface concentration of chlorhexidine gluconate at all 5 anatomic study sites compared with immediately rinsing after application of the antiseptic ($P < .001$). A 2-minute pause did not result in a significant increase in skin surface concentrations compared with a 1-minute pause before rinsing. Furthermore, a 118-mL volume of chlorhexidine gluconate, 4%, per shower in addition to a minimum 1-minute pause before rinsing resulted in saturated binding of chlorhexidine gluconate to the skin with significantly higher skin surface concentrations than reported in previous studies.^{7,34}

An important component of any quality improvement initiative is patient adherence. An institutional quality initiative conducted in January 2011 by the author (C.E.E.) documented that almost one-third of the patients failed to complete the preadmission shower protocol, therefore truncat-

ing the potential value of this intervention. In an effort to improve patient adherence, a study³⁴ assessed the benefit of sending a text message or email to remind individuals to complete their preadmission showering process. Those receiving an electronic alert had a significant increase in the skin surface concentration of chlorhexidine gluconate compared with individuals who were not prompted ($P < .007$). This simple addition to the showering protocol was highly effective in enhancing patient adherence to the preadmission shower protocol. Several clinical studies³⁵⁻³⁹ have instituted preadmission showering with chlorhexidine gluconate, 4%, as part of an evidence-based surgical care bundle, and poor adherence to any individual component of the care bundle can potentially reduce the value of the intervention. Based on our knowledge of what should be included in an effective preadmission showering protocol, the following standardized regimen is recommended:

1. All patients should take a minimum of 2 preadmission showers with chlorhexidine gluconate, 4%, operationally the night before and the morning before surgery.
2. Patients should be instructed to pause for 1 minute before rinsing off the chlorhexidine gluconate, 4%.
3. Patients should use a total volume of 118 mL of chlorhexidine gluconate, 4%, during each shower.
4. A text, email, or voicemail alert should be used to remind the patient to complete the shower protocol.

The present study was designed from a pharmacokinetic perspective in which dosage (volume of chlorhexidine gluconate, 4%, use), timing (0, 1-minute, or 2-minute pause), and duration of treatment (2 vs 3 showers) were assessed as part of an integrated attempt to maximize skin surface concentrations of chlorhexidine gluconate. The findings suggest an evidence-based metric for enhancing skin concentrations resulting in a mean composite skin surface concentration of approximately 970 $\mu\text{g/mL}$ or an actual skin surface area concentration of 16.5 $\mu\text{g/cm}^2$, which is above the 90% minimum inhibitory concentration for most gram-positive and gram-negative surgical wound pathogens.

Conclusions

The modern approach to skin antisepsis strives to reduce the microbial burden at the incisional site, protecting the wound from gross contamination. However, presence of a high microbial burden on selective skin surfaces sites, such as the groin, axilla, perineum, or antecubital and popliteal fossae, may increase the risk of postoperative infection. An analysis⁴⁰ of 100 consecutive lower extremity vascular procedures determined by multivariate analysis that high bacterial loads on the second postoperative day in combination with a diagnosis of diabetes mellitus independently increases the risk of surgical site infection. Although the present clinical study does not directly correlate the use of a chlorhexidine gluconate, 4%, preadmission shower with reduction in the incidence of surgical site infection, this standardized approach to the preadmission shower regimen

provides a cognizant pathway for achieving high, sustainable concentrations of chlorhexidine gluconate on the skin that are sufficient to inhibit or kill microbial pathogens harbored on the skin at the surgical site. The associated facility costs of providing 2 bottles of chlorhexidine gluconate, 4%, and supporting an electronic alert system (text, email, or

voicemail) reminding the patient to complete the preadmission shower process, thereby enhancing patient adherence, is less than \$9.³⁴ An economical initiative resulting in fewer microorganisms on the skin surface adjacent to the surgical incision should be a sentinel component of an effective surgical care bundle.

ARTICLE INFORMATION

Accepted for Publication: May 3, 2015.

Published Online: August 26, 2015.
doi:10.1001/jamasurg.2015.2210.

Author Contributions: Drs Edmiston and Seabrook had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Drafting of the manuscript: Edmiston, Lee, Leaper, Rossi.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Edmiston.

Obtained funding: Edmiston, Seabrook.

Administrative, technical, or material support: Lee, Krepel, Rossi, Seabrook.

Study supervision: Krepel, Seabrook.

Conflict of Interest Disclosures: Drs Edmiston and Seabrook report receiving grant support from Clorox Healthcare. No disclosures were reported.

Funding/Support: The study was supported in part by an unrestricted grant from Clorox Healthcare (Drs Edmiston and Seabrook).

Role of the Funder/Sponsor: The funding source had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: All comments and opinions in this article represent the composition, review, and sole deliberation of the cited authors.

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