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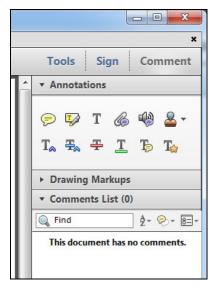
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Q1

Empowering the Surgical Patient: A Randomized, Prospective Analysis of an Innovative Strategy for Improving Patient Compliance with Preadmission **Showering Protocol**

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BACKGROUND:

Surgical site infections (SSIs) are responsible for significant morbidity, mortality, and excess use of health care resources. The preadmission antiseptic shower is accepted as an effective strategy for reducing the risk for SSIs. The study analyzes the benefit of an innovative electronic patient alert system (EAS) for enhancing compliance with a preadmission showering protocol with 4% chlorhexidine gluconate (CHG).

STUDY DESIGN: After providing informed consent, 80 volunteers were randomized to 4 CHG showering groups. Groups A1 and A2 showered twice. Group A1 was prompted to shower via EAS. Groups B1 and B2 showered 3 times. Group B1 was prompted via EAS. Subjects in groups A2 and B2 were not prompted (non-EAS groups). Skin-surface concentrations of CHG (μg/ mL) were analyzed using colorimetric assay at 5 separate anatomic sites. Study personnel were blinded to the randomization code; after final volunteer processing, the code was broken and individual groups were analyzed.

RESULTS:

Mean composite CHG skin-surface concentrations were significantly higher (p < 0.007) in EAS groups A1 (30.9 \pm 8.8 μ g/mL) and B1 (29.0 \pm 8.3 μ g/mL) compared with non-EAS groups A2 (10.5 \pm 3.9 μ g/mL) and B2 (9.5 \pm 3.1 μ g/mL). Overall, 66% and 67% reductions in CHG skin-surface concentrations were observed in non-EAS groups A2 and B2 compared with EAS study groups. Analysis of returned (unused) CHG (mL) suggests that a wide variation in volume of biocide was used per shower in all groups.

CONCLUSIONS:

The findings suggest that EAS was effective in enhancing patient compliance with a preadmission showering protocol, resulting in a significant (p < 0.007) increase in skin-surface concentrations of CHG compared with non-EAS controls. However, variation in amount of unused 4% CHG suggests that rigorous standardization is required to maximize the benefits of this patient-centric interventional strategy. (J Am Coll Surg 2014;∎:1−9. © 2014 by the American College of Surgeons)

In 2010, the CDC reported that a total of 51.4 million inpatient surgical procedures were performed in the United States. It is estimated that approximately 400,000 surgical site infections (SSIs) occur in the United States each year,

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Correspondence address: Charles E Edmiston Jr, PhD, Department of Surgery, Division of Vascular Surgery, Medical College of Wisconsin, 9200 West Wisconsin Ave, Milwaukee, WI 53225. email: edmiston@mcw.edu with an associated mortality rate approaching 25% (n = 100,000).²⁻⁵ These numbers have historically been extrapolated from inpatient procedures alone, therefore, the actual number of SSIs is likely to be much higher because recent CDC data suggest that >34 million surgical procedures are performed in outpatient US ambulatory surgical centers.⁶ Postoperative SSIs, in addition to having an adverse impact on patient outcomes, also contribute to increased use of hospital-based resources, which has a negative impact on the fiscal health of the institution. The evolution of the Center for Medicare and Medicaid Services' value-based purchasing initiative now requires health care providers to be held accountable for both the cost and quality of Electronic Alert as a Strategy for Improving Patient Compliance

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Abbreviations and Acronyms

CHG = chlorhexidine gluconate EAS = electronic alert system SMS = short message service = surgical site infection

the delivered care. In doing so, hospitals have a financial incentive to improve the quality of care that patients receive by eliminating or reducing adverse events, adopting evidence-based practices, and re-engineering the health care process to improve the patient-care experience.^{7,8}

The 1999 CDC Surgical Site Infection Prevention guidelines designated the preadmission antiseptic shower as a category 1B, "strongly recommended," clinical practice.9 A study published in 2011 found that many of the earlier clinical studies purporting no clinical benefit associated with preoperative antiseptic showering were technically and scientifically flawed, lacking rigorous standardization.¹⁰ Several authors have suggested that preadmission showering with chlorhexidine gluconate (CHG) as part of an evidence-based interventional strategy is beneficial in reducing the risk of postoperative SSIs. 11-15 A mitigating factor, which effectively reduces the benefit of any patient-centric intervention, is procedural compliance or patient adherence. Factors associated with patient noncompliance include failure to understand administrative instructions, use of unfamiliar medical terminology, social isolation, language barrier, low educational level, illiteracy, and socioeconomic status. 16 Reminder-based interventions (recurrent cues) have been shown to be beneficial in enhancing patient compliance (or adherence) with taking prescription medication.¹⁷ This investigation describes the impact of an electronic alert system (EAS), short message service (SMS) text messaging, email, or voicemail to remind study volunteers of the need to complete a 4% CHG showering protocol. Compliance was evaluated by measuring the skin-surface concentration of CHG at 5 separate anatomic sites. This investigation was reviewed and approved by the Institutional Human Subjects Review Board.

MATERIALS AND METHODS

Randomization study

After providing informed consent, 80 healthy volunteer were randomized into 1 of 4 skin-antiseptic showering groups (n = 20 per group):

Group A: 4% CHG, 2-shower arm (evening/morning) A1: EAS group (SMS text, email, or voicemail), n = 20A2: Non-EAS group, n = 20

Group B: 4% CHG, 3-shower arm (2 consecutive evenings/1 morning)

B1: EAS (SMS text, email, or voicemail), n = 20

B2: Non-EAS group, n = 20

The 4% chlorhexidine gluconate showering groups

Study volunteers were instructed to apply the 4% CHG soap (Scrub Care Exidine; CareFusion) to their body using a sponge applicator provided in the kit, covering all body surface areas, excluding the face and scalp. Subjects were instructed to dispose of the used applicator after each shower and, if they experienced any burning, tingling, or discomfort after CHG application, they should immediately rinse and report this event to the principal investigator or study coordinator. All subjects were instructed to report back to the investigator's laboratory according to a timing schedule for assessment of skin-surface CHG concentrations. The timing and return for determination of CHG skin-surface concentrations was staged to occur 10 to 14 days after informed consent, randomization, and receiving study supplies. The volunteers in groups A1 and B1 were asked their preference for receiving an electronic alert before each showering event (ie, SMS text message, email, or voicemail). The individualized reminders were entered into an internetbased menu system (StartClean Program; CareFusion) that sets the date, time of day, and the number of alerts that each volunteer would receive before showering. Subjects in group A1 received 2 alerts and subjects in group B1 received 3 alerts. Subjects in groups A2 and B2 did not receive any alerts before the designated showering times. To complete study eligibility, all volunteers were required to return the bottle of CHG with any unused portion of the biocide so that residual CHG (mL) could be measured and recorded.

Determination of chlorhexidine gluconate skinsurface concentration assay

The CHG skin-surface concentration assay is based on an adaptation of a US Official Monograph for the Identification of Chlorhexidine Gluconate Solution. 18 In brief, a Bio-Swab (Arrowhead Forensics Inc) was used to sample a defined skin-surface area (3 cm²) on the right and left antecubital fossae, abdomen, and right and left popliteal fossae by rotating the swab back and forth across the skin for 15 seconds. The swab was immediately placed in a screw-cap container to prevent desiccation before analysis. One hundred microliters of a freshly prepared indicator solution (5 parts 1% cetyltrimethylammonium bromide [Sigma-Aldrich Co.] and 2 parts sodium hypobromite [Fisher Scientific]) was added to each swab.

A light pink to intense red color indicated the presence of CHG, with intensity of the color reflective of the relative concentration of CHG on the surface of the skin. The color reaction on the swab was compared with a fresh daily-prepared CHG standard (dilution), which ranged from 2.5 μg/mL to 10,000 μg/mL. The assay was read by an independent and blinded observer who compared test swabs with the CHG standard before recording the relative CHG skin-surface concentration.

Statistical analysis

The principal investigator was blinded to all randomization codes until the final volunteer was processed, at which point the code was broken and individual groups were analyzed. Analysis of variance and paired *t*-test were used to analyze the differences among the relative mean CHG skin-surface concentrations in groups A1, A2, B1, and B2 at the 0.05 level of significance. Statistical analysis was conducted using the MINITAB Statistical Program (MINITAB Inc.).

RESULTS

All subjects verbally indicated compliance with either the 2- or 3-shower protocol. A total of 4 randomized subjects did not fulfill study criteria and were excluded and replaced by 4 additional volunteers; 2 subjects did not return with the CHG bottle and 2 subjects did not return at the assigned date and time for determination of CHG skin-surface concentration. One volunteer indicated a slight tingling sensation on application of the 4% CHG, but did not consider it sufficient to contact the principal investigator or study coordinator. No additional adverse events were noted in the study. Eighty percent (32 of 40) of study volunteers preferred to receive an SMS text message alert before showering, and 6 (15%) and 2 (5%) volunteers preferred to be prompted by email or voicemail, respectively. Table 1 documents the mean time differential between the last shower and CHG skin-surface analyses for men, women, or all study participants. No significant difference was observed in the time differential between final shower and laboratory analyses of CHG skin-surface concentrations between groups A1 and A2 or B1 and B2. The majority of subjects returned to the laboratory within 3 hours of taking their last shower. Figure 1 documents the mean skin-surface concentrations of CHG in subjects who showered twice (group A, evening/morning). Mean skin-surface concentrations on the left and right antecubital fossae, abdomen, and left and right popliteal fossae in subjects who were notified by the EAS (group A1) was 29.4, 21.6, 33.8, 44.5, and 25.6 μg/mL, respectively. In

Table 1. Subgroup Analysis: Mean Time between Last Shower and Skin-Surface Analysis of Chlorhexidine Gluconate

Study group*	n	Time, min [†]
Group A1		
Men	4	89.5 ± 25.2
Women	16	158.6 ± 60.7
All	20	144.8 ± 64.4
Group A2		
Men	7	150.9 ± 33.6
Women	13	138.2 ± 72.7
All	20	142.6 ± 61.1
Group B1		
Men	5	148.0 ± 66.2
Women	15	168.8 ± 53.0
All	20	163.6 ± 64.4
Group B2		
Men	6	170.5 ± 106.4
Women	14	172.5 ± 72.2
All	20	172.0 ± 80.9

*Volunteers in group A were instructed to take 2 showers; A1 volunteers received 2 electronic alerts and A2 volunteers did not receive an electronic alert reminder. Volunteers in group B were instructed to take 3 showers; B1 volunteers received 3 electronic alerts and B2 volunteers did not receive an electronic alert reminder.

[†]No significant difference in mean times amng all study groups.

comparison, the mean skin-surface concentrations on the left and right antecubital fossae, abdomen, and left and right popliteal fossae in subjects who did not receive an alert (group A2) were 11.2, 7.9, 8.0, 13.5 and 12.1 μ g/mL, respectively. Overall composite mean skin-surface concentrations (μ g/mL) observed in both subgroups was 30.9 \pm 8.8 (group A1) and 10.5 \pm 3.9 (group A2) (p < 0.007).

Figure 2 documents the mean skin-surface concentrations of CHG in those individuals who were instructed to shower 3 times (group B, 2 consecutive evenings/ morning). Mean skin-surface CHG concentrations on the left and right antecubital fossae, abdomen, and left and right popliteal fossae in subjects who were prompted by the EAS (group B1) was 32.1, 41.0, 29.6, 22.4, and 20.1 µg/mL, respectively. In comparison, the mean skin-surface CHG concentrations on the left and right antecubital fossae, abdomen, and left and right popliteal fossae in the group that did not receive an alert (group B2) before showering was 11.0, 9.1, 11.9, 7.8, and 7.1 ug/mL. Overall composite mean skin-surface concentrations observed in both groups were 29.0 \pm 8.3 $\mu g/mL$ (group B1) and 9.5 \pm 3.1 µg/mL (group B2) (p < 0.007).

Table 2 reports the summary of the mean composite skin-surface concentrations (μg/mL) of CHG and mean

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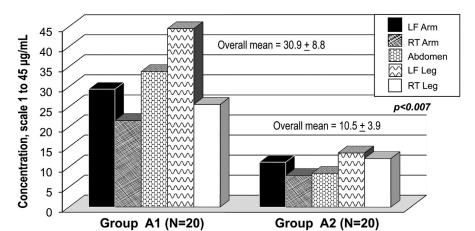


Figure 1. Mean skin-surface concentration (µg/mL) of 4% chlorhexidine gluconate after 2 preadmission showers. Group A1 subjects were alerted by short message service text, email, or voicemail. Group A2 subjects were not alerted before showering. The 90% minimum inhibitory concentration = 5 µg/mL for skin staphylococcal flora (including MRSA). LF, left; RT, right.

portion (unused, mL) of CHG remaining in the returned bottle at the time of skin-surface analysis. In a comparative analysis between groups A1 and A2, there was a 66% reduction in the composite mean concentration of CHG on the skin surface in volunteers who were not alerted to shower compared with those that received 2 electronic reminders. In comparison, there was a 67% reduction in the composite mean skin-surface concentration of CHG in those subjects who were not alerted before showering compared with subjects who received 3 separate electronic alerts (SMS text messaging, email, or voicemail). Mean unused volume of CHG returned at the time of skin-surface analysis was 30.5 mL (25.8%), 37.7 mL (31.9%), 24.4 mL

(20.7%), and 39.7 mL (33.6%), in groups A1, A2, B1, and B2, respectively.

Table 3 documents the subgroup analysis of the amount of unused CHG returned by men, women, and all volunteers in groups A1, A2, B1, and B2. Although no significant difference was noted in the mean portion of CHG returned by study participants in the 4 subgroups, it is interesting to note that the mean volume of CHG returned in groups A2 and B2 trended higher than in the groups receiving the electronic alert. Each bottle of 4% CHG contained 118 mL and the amount of unused CHG ranged from a low of <10 mL in selective subjects in groups A1 and B1 to >60 mL (>50%) in

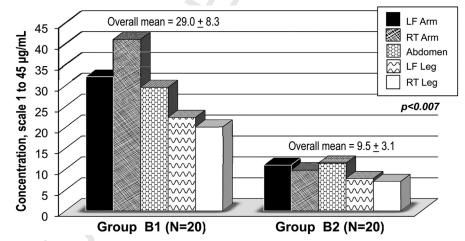


Figure 2. Mean skin-surface concentration (µg/mL) of 4% chlorhexidine gluconate after 3 preadmission showers. Group B1 subjects were alerted by short message service text, email, or voicemail. Group B2 subjects were not alerted before showering. The 90% minimum inhibitory concentration = 5 μg/mL for skin staphylococcal flora (including MRSA). LF, left; RT, right.

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Table 2. Mean Composition Skin-Surface Concentration of Chlorhexidine Gluconate and Mean Residual Aqueous 4% Chlorhexidine Gluconate

Study group*	n	Mean chlorhexidine gluconate, μg/mL [†]	Reduction, % (p Value)	Residual chlorhexidine gluconate, μg/mL (%)
A1	20	30.9 ± 8.8		30.5 (25.8)
A2	20	10.5 ± 4.9	66 (<0.007)	37.7 (31.9)
B1	20	29.0 ± 8.3		24.4 (20.7)
B2	20	9.5 ± 3.1	67.0 (<0.007)	39.7 (33.6)

Volunteers were required to return bottle containing unused portion of 4% chlorhexidine gluconate.

selective subjects in groups A2 and B2. Male volunteers were more likely to return a larger volume of unused CHG than female study subjects in groups A2 and B2.

DISCUSSION

The primary benefit of the preadmission antiseptic shower is to reduce the microbial log-burden on the surface of the skin before hospital admission, thereby functioning as an adjunctive strategy for reducing the risk of intraoperative wound contamination, which, in turn, can reduce postoperative risk of SSIs. In a recent Cochrane analysis, 7 trials involving a total of 10,157 participants who bathed before hospital admission with

Table 3. Subgroup Analysis, Residual Aqueous 4% Chlorhexidine Gluconate in Men, Women, and All Study Subjects

Charles duning t	_	Mean residual chlorhexidine
Study group*	n	gluconate, mL ^T
Group A1		
Men	4	37.9 ± 18.9
Women	16	25.4 ± 22.4
All	20	30.5 ± 21.9
Group A2		
Men	7	46.1 ± 28.6
Women	13	30.1 ± 20.4
All	20	37.7 ± 24.6
Group B1		
Men	5	29.0 ± 21.4
Women	15	22.5 ± 18.2
All	20	24.4 ± 20.5
Group B2		
Men	6	42.9 ± 29.1
Women	14	36.3 ± 27.5
All	20	39.7 ± 28.9

^{*}Volunteers in group A were instructed to take 2 showers; A1 volunteers received 2 electronic alerts and A2 volunteers did not receive an electronic alert reminder. Volunteers in group B were instructed to take 3 showers; B1 volunteers received 3 electronic alerts and B2 volunteers did not receive an electronic alert reminder.

4% CHG were analyzed to determine if this practice was effective in preventing SSIs. The conclusion of this analysis suggested that preoperative bathing or cleansing with CHG does not result in a substantial reduction in SSIs.¹⁹ The authors noted, however, multiple inconsistencies in both the interventions and the control procedures among the studies. For instance, timing of the shower was highly variable in some of the selected studies, and timing was not specified in 2 of the clinical trials. In some studies, CHG was used for total body cleansing, and in clinical trials, CHG was applied to a localized anatomic site. In several of the cited studies, there was no documentation of a uniform standard of practice (ie, some patients showered multiple times, other patients showered only once). There was no evidence that an attempt was made to standardize a timed duration of the antiseptic shower or cleansing process. The authors pointed out that the method of post-discharge followup was difficult to assess in several of the reviewed studies, which, from a surveillance perspective, makes it difficult if not impossible to accurately assess the benefit of any SSI interventional practice if the numerator or denominator component is lacking or inaccurate. Finally, there was no indication of whether an effort was made to assess patient compliance with the study protocols. It is apparent from this Cochrane analysis that, based on previous published clinical trials, failure to adhere to a prescribed standard of practice makes it extremely difficult to assess the benefits of the preadmission shower from an evidencebased perspective.

The benefit of the preadmission cleansing strategy is likely to be highly dependent on a patient's adherence to a standardized preadmission showering protocol. Evidence-based interventions that are designed to improve patient outcomes maximize the quality of the caregiving process. Noncompliance increases patient morbidity (and mortality in selective scenarios), leading to increased

517 financial burden to the health care system, which often in-518 cludes additional pharmacologic and diagnostic interven-519 tions.¹⁷ Studies conducted in emergency medicine have 520

^{*}Volunteers in group A were instructed to take 2 showers; A1 volunteers received 2 electronic alerts and A2 volunteers did not receive an electronic alert reminder. Volunteers in group B were instructed to take 3 showers; B1 volunteers received 3 electronic alerts and B2 volunteers did not receive an electronic alert reminder.

[†]Composite concentration of 5 separate anatomic sites (left and right antecubital fossae, left and right popliteal fossae, and abdomen).

[†]No significant difference in mean residual chlorhexidine gluconate among all study groups.

Electronic Alert as a Strategy for Improving Patient Compliance

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documented that patient noncompliance to discharge medication dosing often exceeds 25%. 16,20,21 The reasons for patient deviation from agreed-on treatment plans are highly complex and might be intentional or unintentional.²² Starting in 2011, patients undergoing elective surgical procedures at Froedtert Hospital, the teachinghospital affiliate of the Medical College of Wisconsin in Milwaukee, were provided with packets containing polyester cloths coated with 500 mg (2%) CHG and oral and written instructions documenting how the preadmission cleansing process should be carried out. The patients were instructed to cleanse twice (night/morning) before arriving at the hospital for their elective procedure. During a 12-month period, a quality-assurance (nonpublished) analysis was conducted with 100 randomly selected general surgical and orthopaedic patients, questioning their use of the CHG-coated cloths for preadmission cleansing. Seventy-one patients indicated that they had completed the total body cleansing as per instructions; 19 indicated that they had used the cloths once rather than twice, either the night before or morning before admission; and 10 patients indicated they had omitted both cleansings entirely. When queried as to why they had not complied with the physician instructions, the respondents indicated that they thought one cleansing would be sufficient, they had completely forgotten to use the antiseptic agent provided by the health care institution, or they did not think that total body cleansing with CHG was actually that important to their surgical outcomes. These 3 responses suggest that the factors contributing to noncompliance with preadmission antiseptic showering protocol most likely include failure of the health care provider to clearly document the potential benefits (ie, reduction in risk of SSI) of the preadmission shower regimen, failure of the patient to prioritize the preadmission shower as an important component of the entire extended care plan, or apathy on the part of the patient to "buy into" the showering process as to its overall importance or benefit.

This investigation suggests that use of an EAS was highly effective in elevating skin-surface skin concentrations of CHG in patients assigned to showering 2 or 3 times. It is important to note that the composite mean skin-surface concentration of CHG in those subjects who showered 3 times was essentially identical to the composite mean concentration measured in volunteers who showered twice. The CHG skin-surface concentrations measured in subjects who were not alerted by SMS text messaging, email, or voicemail were significantly less than in the EAS group (p < 0.007). It is notable that the skin-surface concentrations in the non-EAS groups (group A2: 10.5 mL and group B2: 9.6 mL) were remarkably similar to "pilot" levels of CHG reported in an earlier publication.¹¹ In that

study, published in 2008, a group of healthy volunteers were given a bottle of 4% CHG without any additional instructions, except to shower twice (evening/morning) and report back for analysis at a designated time and date. The mean composite skin-surface concentration measured in this group was 9.9 µg/mL.11 In the current analysis, in subjects who received an electronic alert, the composite mean CHG skin-surface concentrations were significantly (p < 0.007) higher (3 times) than in subjects who did not receive an electronic prompting. Although skin-surface concentrations in the electronic alert groups were well above (6 times) the 90% minimum inhibitory concentration (5.0 µg/mL) required to inhibit or kill Q3 skin staphylococci (Staphylococcus aureus, Staphylococcus epidermidis, and MRSA) at all sampled sites, the overall mean skin concentrations were lower than the values reported in our earlier 2008 study.

The differences between the 2008 study and the current study are worthy of discussion. In the experimental arm of the 2008 study, all participants received their supplies and were tested within a 5-day window. In the current analysis, after randomization, subjects were scheduled to return 10 to 14 days after receiving their supplies, mimicking the clinical scenario. In addition, as noted earlier, no significant difference was noted in skin-surface concentrations of CHG in patients who showered twice (group A1) vs those who showered 3 times (group B1). The composite mean skin-surface concentration in the group that showered 3 times (group B1) was statistically identical (29.0 µg/mL) to the mean concentration in those individuals (group A1) who showered twice (30.9 µg/mL). Intrinsically, one might have expected to see a higher skin-surface concentration after 3 vs 2 applications of 4% CHG. However, there are several possible reasons why this did not occur in the current study. First, in the 2008 study, subjects were given both written and oral instructions requiring the deposition of a predetermined amount (mL) of aqueous CHG onto the surface of a washcloth and application of the antiseptic soap to all body surfaces below the chin. Second, the subjects were then instructed (without rinsing) to reapply the 4% CHG soap again to all body surfaces using the same washcloth and then wait 2 minutes ("time out") before rinsing and towel drying. The subjects in the earlier study were provided with disposable timers. In the current analysis, subjects were instructed to apply the 4% CHG once using a disposable sponge to all body surfaces below the chin, and they were not required to take a time out before rinsing. The difference in the skin-surface concentrations between these 2 studies might well reflect that a more rigorous, standardized approach is warranted, maximizing the antimicrobial benefit and suppressing the skin-surface

microbial populations often associated with postoperative infection. During repeat topical application, chlorhexidine binds to the proteins present on the skin and mucous membranes with limited systemic absorption. The protein-bound release of CHG occurs slowly, leading to prolonged activity on the skin surface. In some cases, this antimicrobial activity has been measured to last at least 48 hours. ^{15,23,24} This process is likely enhanced by repeat applications and allowing the CHG to bind to the skin before rinsing (ie, time out).

Maximizing the preadmission interventional benefits of the 4% chlorhexidine gluconate showering protocol

Based on the findings of this study, use of an electronic alert system (SMS text messaging, email, or voicemail) to remind patients of the need to complete a 2- or 3-shower regimen was an effective strategy for enhancing patient compliance and empowering them to become effective partners in their own health care experience. However, part of this empowerment process requires that the health care providers clearly delineate the reasons for the antiseptic shower, emphasizing the importance of this intervention as part of an evidence-based component of the entire surgical experience. To maximize the effectiveness of the preadmission showering regimen, the following components should be included when developing a thoughtful interventional strategy:

- 1. Emphasize the overall benefits of the preadmission antiseptic shower;
- 2. Oral and written instructions should be given to the patient;
- 3. Define a precise amount of CHG (mL) used for each shower, double application is warranted;
- 4. A 60-second pause (time out) before rinsing is appropriate;
- Lotions, creams, emollients, or perfumes should not be applied after CHG application because they can mask or adversely (pharmacologically) affect antimicrobial activity or enhance skin sensitivity;
- 6. Patients should wear loose-fitting garments after application;
- 7. If significant burning or itching occurs patients should rinse immediately and report occurrence to health care provider;
- 8. Keep CHG from the eyes or ears, if exposed, rinse immediately;
- 9. The CHG must be provided to the patient by the health care institution (provider); and
- 10. A telephone contact should be provided if the patient has questions or concerns.

Recent efforts to improve patient compliance have focused on the use of electronic reminder systems, including SMS text messaging. Pragmatically, in today's society, SMS texting or other forms of electronic reminders are highly functional, individually focused, and associated with minimal cost. A recent systematic review of 13 studies has documented that electronic messaging or SMS texting was highly effective in increasing patient medication compliance.²⁵ Mobile phone messaging has been shown in some patient populations to have preventative health care benefits, improving health status and health behavior.²⁶ An example of this benefit was reported in a study published in 2012, where use of SMS text messaging to parents was associated with an increased rate of influenza vaccination within a lowincome pediatric and adolescent patient population compared with a telephone reminder control group (p $< 0.001).^{27}$

It is estimated that in 2013, approximately 91% of US adults have a cell phone, and that 56% of the public have some form of smartphone technology.²⁸ The density of cell phone users in the United States has growth exponentially during the past 10 years, suggesting that use of an EAS would be an appropriate strategy for enhancing patient compliance with complete preoperative orders before hospital admission. Although to date, most applications of SMS texting have occurred in emergency medicine, preventative health programs, or compliance strategies for prescription medication, some limited use of SMS texting has occurred in the surgical sciences. A report from Australia in 2005 suggested that SMS communication was a suitable strategy for improving patient attendance at scheduled surgical clinic appointments.²⁹ In addition, SMS texting has been use for assessing and monitoring postoperative pain in children undergoing tonsillectomy.30

CONCLUSIONS

Results of this study represent the first effort to use SMS texting, email, or voicemail alerts to enhance patient compliance with a preadmission showering protocol. The objective of a thoughtful and thorough preadmission shower strategy is to achieve a high sustainable level of skin antisepsis on the surface of the skin as an adjunctive intervention to reduce the risk of intraoperative wound contamination. Although mechanistically the process of preadmission showering would appear to be quite simplistic, operationally the process is ripe for error and omission. Although the current study focuses on an innovative compliance strategy for completing the preadmission shower, moving forward, embracing an EAS

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would likely enhance compliance with a myriad of preadmission surgical orders, reminding the patient to complete important patient-care practices before hospital admission for elective surgery. A cautionary comment is warranted, although conceptually a case can be made that SMS texting or some other form of EAS appears to enhance individual compliance with preadmission showering and result in higher skin-surface concentrations of CHG, the concept of higher skin-surface concentrations of CHG translating into a lower SSI rate awaits additional evidence-based validation.

Author Contributions

Study conception and design: CE Edmiston, Krepel, Spencer, Seabrook

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Analysis and interpretation of data: CE Edmiston, Krepel, SE Edmiston, Lee, Brown

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REFERENCES

- Centers for Disease Control and Prevention. National Hospital Discharge Survey: 2010 Table, Procedures by Selected Patient Characteristics—Number by Procedure Category and Age. Available at: http://www.cdc.gov/nchs/fastats/insurg.htm. Published 2010. Accessed August 27, 2013.
- Reed D, Kemmerly SA. Infection control and prevention: a review of hospital-acquired infections and the economic implications. Oscher J 2009;9:27–31.
- Shepard J, Ward W, Milstone A, et al. Financial impact of surgical site infections on hospital: the hospital management perspective. JAMA Surg 2013;148:907

 –914.
- 4. De Lissovoy G, Fraeman K, Hutchins V, et al. Surgical site infection: incidence and impact on hospital utilization and treatment costs. Am J Infect Control 2009;37:387–397.
- Herwaldt LA, Cullen JJ, Scholz D, et al. A prospective study of outcome, healthcare resource utilization, and cost associated with postoperative nosocomial infections. Infect Control Hosp Epidemiol 2006;27:1291–1298.
- Centers for Disease Control and Prevention. Ambulatory Surgery in the United States, 2006. http://www.cdc.gov/nchs/data/nhsr/nhsr011.pdf. Published September 4, 2009. Accessed August 27, 2013.
- Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services. Medicare program; hospital inpatient value-based purchasing program: final rule. Fed Regist 2011;76[88]:26490–26547.
- Centers for Medicare & Medicaid Services. FY 2014 achievement performance standards for clinical process of care measures. Fed Regist 2011;76[230]:74538

 –74539.
- 9. Mangram AJ, Horan TC, Pearson ML, et al. The Hospital Infection Control Practice Advisory Committee: guidelines

- for the prevention of surgical site infections. Am J Infect Control 1999;27:97–132.
- Jakobsson J, Perlkvist A, Wann-Hansson C. Searching for evidence regarding using preoperative disinfection showers to prevent surgical site infections: a systematic review. Worldviews Evid Based Nurs 2011;8:143–152.
- 11. Edmiston CE, Krepel CJ, Seabrook GR, et al. Preoperative shower revisited: can high topical antiseptic levels be achieved on the skin surface before surgical admission. J Am Coll Surg 2008;207:233–239.
- 12. Eiselt D. Presurgical skin preparation with a novel 2% chlorhexidine gluconate cloth reduces rates of surgical site infection in orthopaedic surgical patients, Orthop Nurs 2009;28:141–145.
- Lipke VL, Hyott AS. Reducing surgical site infections by bundling multiple risk reduction strategies and active surveillance. AORN J 2010;92:288–296.
- 14. Kim DH, Spencer M, Davidson SM, et al. Institutional prescreening for detection and eradication of methicillin-resistant *Staphylococcus aureus* in patients undergoing elective orthopedic surgery. J Bone Joint Surg 2010;92:1820–1826.
- 15. Edmiston CE, Bruden B, Rucinski M, et al. Reducing the risk of surgical site infections: does chlorhexidine gluconate provide a risk-reduction benefit? Am J Infect Control 2013;41[Suppl]: S49—S55.
- Gignon M, Ammirati C, Mercier R, Detave M. Compliance with emergency department discharge instructions. J Emerg Nurs 2014;40:51-55.
- Fenerty SD, West C, Davis SA, et al. The effect of reminder systems on patients' adherence to treatment. Patient Prefer Adherence 2012;6:127–135.
- 18. The USP Official Monograph for the Identification of Chlorhexidine Gluconate Solution. The United States Pharmacopeia (USP 29), The National Formulary (NF 24). Rockville, MD: US Pharmacopeial Convention; 2006:477–478.
- 19. Webster J, Osborne S. Preoperative bathing or showering with skin antiseptics to prevent surgical site infection. Cochrane Database Sys Rev 2012 Sept 12;9:CD004985. http://dx.doi.org/10.1002/14651858.CD004985.pub4.
- Hugtenburg JG, Timmers L, Elders PJM, et al. Definitions, variants, and causes of nonadherence with medication: a challenge for tailored interventions. Patient Prefer Adherence 2013;7:675–682.
- Van Dulmen S, Sluijs E, van Dijk L, et al. Patient adherence to medical treatment: a review of reviews. BMC Health Serv Res 2007;7:1–13.
- 22. Wroe AL. Intentional and unintentional nonadherence: a study of decision making. J Behav Med 2002;25:355–372.
- World Health Organization. WHO Guidelines on Hand Hygiene in Health Care. Available at: http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf. Accessed ■■■. Q4
- 24. Hibbard J. Analysis comparing the antimicrobial activity and safety of current antiseptics: a review. J Infus Nurs 2005;28: 194–207.
- 25. Vervloet M, Linn AJ, van Weert JC, et al. The effectiveness of interventions using electronic reminders to improve adherence to chronic medication: a systematic review of the literature. J Am Med Inform Assoc 2012;19:696–704.
- Vodopivec-Jamsek V, de Jongh T, Gurol-Urganci I, et al. Mobile phone messaging for preventive health care. Cochrane Database Syst Rev 2012;12:CD007457.
- 27. Stockwell MS, Karbanda EO, Martinez RA, et al. Effect of a text messaging intervention on influenza vaccination in an

- 837 Q5

- urban, low-income pediatric and adolescent population: a randomized controlled trial. JAMA 2012;307:1702-1708.
- 28. Pew Research Center. Cell phone ownership hits 91% of adults. June 6, 2013. Available at: http://www.pewresearch. org/fact-tank/2013/06/06/cell-phone-ownership-hits-91-ofadults/. Accessed ■■■.
- 29. Downer SR, Meara JG. Da Costa AC. Use of SMS text messaging to improve outpatient attendance. Med J Aust 2005;183:366-368.
- 30. Chen Y, Chin M, Greenberg S, et al. Post-tonsillectomy pain in 24 children—utilising short message service (SMS) to assess postoperative outcomes. Clin Otolaryngol 2012;37:412-414.

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937 938	Empowering the Surgical Patient: A Randomized, Prospective Analysis of an
	Innovative Strategy for Improving Patient Compliance with Preadmission Showering
939	Protocol
940	Charles E Edmiston Jr, PhD, Candace J Krepel, MS, Sarah E Edmiston, MEd, Maureen
941	Spencer, MEd, Cheong Lee, MD, Kellie R Brown, MD, FACS, Brian D Lewis, MD,

Charles E Edmiston Jr, PhD, Candace J Krepel, MS, Sarah E Edmiston, MEd, Maureen Spencer, MEd, Cheong Lee, MD, Kellie R Brown, MD, FACS, Brian D Lewis, MD, FACS, Peter J Rossi, MD, FACS, Michael Malinowski, MD, Gary Seabrook, MD, FACS This investigation represents the first effort to use an electronic alert system to enhance patient compliance with a preadmission showering protocol. The findings suggest that embracing an electronic alert system was an effective strategy (p < 0.007) for enhancing patient compliance with a preadmission showering protocol.

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