Q&A

Using a Standardized Regimen for Pre-Admission Patient Skin Cleansing: A Q&A with Charles Edmiston, PhD

Charles Edmiston

In this Q&A, Charles Edmiston, PhD, professor of surgery and hospital epidemiologist in the Department of Surgery at the Medical College of Wisconsin, discusses the evolution of his team's CHG research and the importance of using a standardized regimen for pre-admission skin cleansing using chlorhexidine gluconate (CHG). Edmiston has documented through his various research studies components of an effective, risk-reduction showering regimen, which suggests that the CHG shower/cleansing should be a component of every surgical care bundle and used for all elective surgeries, not just orthopedic or cardiothoracic procedures.

Q: Forthcoming guidelines from the Association of periOperative Registered Nurses (AORN) and the Centers for Disease Control and Prevention (CDC)/HICPAC are evolving to indicate just one shower with a soap or antiseptic is indicated, and they do not recommend the use of CHG. Yet you believe that the preponderance of evidence indicates otherwise. Can you speak to this issue?

A: The revised AORN guideline is very much in line with the HICPAC/CDC surgical site infection prevention guideline -- they recommend just one shower. The CDC consulted the University of Pennsylvania Evidence Based Medicine Institute for its review and vetting of the evidence-based literature. A much lower emphasis was placed on retrospective, observational trials and prospective interventional cohort trials. While these studies are not considered as randomized controlled trials (RCT), they were however conducted in a thoughtful and organized manner by many well-respected investigators. I feel that they represent valid contributions to the preadmission shower/cleansing literature. The issue I have with the CDC guideline is that the document provides insufficient guidance. So infection preventionists are asking, 'what should we do?' Institutions will look at these guidelines and say, 'They are not recommending CHG so why should we invest in it?' I am hoping that those of us who disagree with this guidance can -- through our various publications and presentations -- counteract some of the negative influence those future guidelines will have on our risk-reduction efforts. As an example, I recently received an email from an infection preventionist who wants our institution's evidence-based guidelines and justification for the use of CHG showers for patients under-going elective surgery, not just orthopedic procedures, but for every inpatient. I think IPs get it -- it's the other ancillary healthcare professionals who don't have experience with CHG or exposure to the breath of medical/surgical literature supporting this endeavor. We must be diligent in emphasizing why hospitals should have a standardized patient skin-cleansing protocol and why two showers should be considered the gold standard for preadmission cleansing.

Q: Can you share with us some of your research on exogenous skin flora levels and CHG bathing?

A: We published a study in the Journal of the American College of Surgeons in 2008 in which we looked at the skin-surface concentrations of CHG. We conducted that study because my group had published a paper in 2007 which was part of the FDA analysis of the 2 percent CHG cloth versus the 4 percent CHG soap. We wanted to see if there is any real difference in skin-surface CHG concentrations between 4 percent aqueous products and the 2 percent cloth. We discovered during the study that if you simply gave an individual a bottle of 4% CHG and told them to shower without any instructions at all, the concentrations on the skin were barely sufficient to address the minimal concentration required to inhibit or kill staphylococci, including MRSA. However, if you provided instructions that included taking two showers and a one-minute time-out prior to rinsing then we saw much higher skin-surface concentrations of CHG, approaching 120 ppm.

Abstract: Subjects were randomized to one of three shower (4% soap)/skin cleansing (2% cloth) groups (n = 20 per group): (group 1 A/B) evening, (group 2 A/B) morning, or (group 3 A/B) evening and morning. After showering or skin cleansing, volunteers returned to the investiga-tor's laboratory where CHG skin surface concentrations were determined at five separate skin sites. CHG concentrations were compared with CHG minimal inhibitory concentration that inhibits 90% (MIC90) of staphylococcal skin isolates. CHG MIC90 for 61 skin isolates was 4.8 parts per million (ppm). In group 1A, 4% CHG skin concentrations ranged from 17.2 to 31.6 ppm, and CHG concentrations were 361.5 to 589.5 ppm ($p < 0.0001$) in group 1B (2%). In group 2A (4%), CHG levels ranged from 51.6 to 119.6 ppm and 848.1 to 1,049.6 ppm in group 2B (2%), respectively ($p < 0.0001$). CHG levels ranged from 101.4 to 149.4 ppm in the 4% CHG group (group 3A) compared with 1,484.6 to 2,031.3 ppm in 2% CHG cloth (group 3B) group ($p < 0.0001$). Effective CHG levels were not detected in the 4% CHG group in selected sites in seven (35%) subjects in group 1A, three (15%) in group 2A, and five (25%) in group 3A.

Conclusion: Effective CHG levels were achieved on most skin sites after using 4% CHG; gaps in antiseptic coverage were noted at selective sites even after repeated application. Use of the 2% CHG polyester cloth resulted in considerably higher skin concentrations with no gaps in antiseptic coverage. Effective decolonization of the skin before hospital admission can play an important role in reducing risk of surgical site infections.

Reference: Edmiston CE, Krepel CJ, Seabrook GR, Lewis BD, Brown KR and Towne JB. Preoperative Shower Revisited: Can High Topical Antiseptic Levels Be Achieved on the Skin Surface Before Surgical Admission? Journal of the American College of Surgeons. Vol. 207, No. 2, Pages 233–239. August 2008.

Q: You then became interested in compliance-related issues?

A: I discovered that not all of our elective-surgery patients were using the 2 percent cloth, which is what we used in our institution. We found about 29 percent of the patients were not using it, and the reasons were varied -- they didn't realize how important CHG cleansing was, while others said they simply forgot. Some patients said they thought one cleansing was sufficient. We realized that we had to think about some kind of technology through which we could use to remind the patients to take their showers. Again, we decided to measure compliance by looking at surface concentrations. We published our results this past year in the Journal of the American College of Surgeons, showing there was a significant difference (increase in skin-surface

concentrations of CHG) between those individuals who were texted or recevied emails or voicemails as opposed to individuals who did not receive that kind of promoting. I came to the conclusion that reminders and prompting do work. Other studies have shown in the field of medicine that SMS-texting or emails can significantly increase a patient's medication compliance. There was however one flaw to that study though -- we didn't recommend a time-out for those individuals who were showering -- we just presented directions for showering and we prompted the individuals at a specific time to shower. What we discovered was that even though there was a significantly higher concentration of CHG on the skin of those who were texted compared to those who were not texted, we did not achieve the concentrations we saw in the 2008 paper, simply because we didn't have a time-out.

Abstract: 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. Mean composite CHG skin-surface concentrations were significantly higher ($p < 0.007$) in EAS groups A1 (30.9 ± 8.8 μg/mL) and B1 (29.0 ± 8.3 μg/mL) compared with non-EAS groups A2 (10.5 ± 3.9 μg/mL) and B2 (9.5 ± 3.1 μg/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.

Conclusion: 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.

Reference: Edmiston CE, Krepel CJ, Edmiston SE, Spencer M, Lee C, Brown KR, Lewis BD, Rossi PJ, Malinowski M and Seabrook G. Empowering the Surgical Patient: A Randomized, Prospective Analysis of an Innovative Strategy for Improving Patient Compliance with Preadmission Showering Protocol. Journal of the American College of Surgeons. Vol. 219, No. 2, Pages 256-264. August 2014.

Q: You then started thinking about preoperative bathing in a new way?

A: One day I was in my office, talking to a surgical colleague about antibiotic prophylaxis, and the importance of the right dose at the right time, and especially a weight-based dose for some of our heavier patients. It hit me that we have always thought about the preadmission showering as a kind of a mundane activity -- we really don't think about it as a medicinal process -- so I decided that we needed to think about showering from a pharmacokinetic prospective. In essence we needed to think of the preadmission shower in the same manner in which we viewed delivery of an anti-infective for treatment or prophylaxis, to achieve maximal blood or tissue concentrations appropriate for any anticipated pathogen. We decided that for our next study that we would have three groups; one group where no timeout was taken, a one-minute timeout, and a two-minute timeout. We also wanted to determine if there is a difference between two or three showers, and we wanted to see if by using a whole bottle of 4 percent CHG as opposed to a half or some portion thereof, could we achieve a maximal skin-surface concentration. So now we are

controlling for dose (the amount of CHG), controlling for time (the timeout) and also controlling for repetition (looking at the difference in skin-surface concentrations of CHG between two or three showers). The reason I included that third shower is that I was curious about the IHI Joint Project study which really didn't provide substantial documentation for why you need to take three versus two showers. We completed our study and we discovered that if you don't take a timeout, the concentrations you find on the skin are substantially lower compared to a 1 or 2 minute time out (p value equal to 0.001). We also discovered there was actually no difference in skin-surface concentrations of CHG between a one-minute timeout and a two-minute timeout. By using a whole bottle of CHG, you essentially saturated the skin, so you maximize the skin surface concentrations; taking that third shower did not provide any benefit whatsoever. So we have answered a few basic questions; one, that the timeout is extremely important for achieving maximal concentrations on the skin; that two or three showers are equivalent; and you need to use all four ounces of CHG, again to effect a maximal skin-surface concentration.

For a more in-depth discussion of this issue, please see the forthcoming special report from ICT on preoperative skin cleansing and SSI prevention, to be available for download in late January 2015.

Editor's note: Edmiston currently consults with Clorox Healthcare surrounding the proper use of skin antiseptics.