

March 11, 2010

Janet Corrigan, PhD, MBA President and CEO National Quality Forum 601 Thirteenth St, NW Suite 500 North Washington, DC 20005

Request to Remove Recommendation of a Specific Preoperative Skin Preparation

Dear Dr Corrigan,

As background, 3M is committed to patient safety by providing commercial solutions that help reduce risk of surgical site infection (SSI). Additionally, we are committed to continued innovations to further improve patient safety through ongoing discovery, research and development activities. We collaborate with professional associations and experts globally in an effort to bring these solutions to healthcare settings where patients receive care.

In follow-up to previous communications with members of the Safe Practices Committee regarding Safe Practice #22 and its recommendation of a specific surgical skin antiseptic preparation, we are formally requesting an NQF Ad Hoc Review of the recommendation under Criteria #1 and #2.

Criterion #1: "The evidence supporting the focus of the measure, practice, or event has changed and it no longer reflects updated evidence". The Draft Safe Practices notes in the Comments section for Safe Practice 22, "Based on the results of a randomized, controlled trial showing that chlorhexidine gluconate 2% and isopropyl alcohol significantly reduced SSI compared to povidone iodine for preoperative skin antisepsis, the committee recommended this as an additional specification." As we discuss in more detail below, this study did not assess DuraPrep, an iodine povacrylex and alcohol surgical prep, and it cannot be concluded that Chloraprep would perform better than DuraPrep based on this study. Furthermore, the performance of ChloraPrep and DuraPrep was assessed in a recent publication that was not reviewed by the committee, and as we discuss below, DuraPrep performed better than ChloraPrep in this study. 3M believes that these studies suggest the need for additional clinical study before the NQF Safe Practices can recommend one prep over another.

Criterion #2. "There is evidence that the implementation of the measure or practice may result in unintended consequences", Section A. "Use of the measure or practice may result in inappropriate or harmful care." Safe Practice #22 recommends a surgical prep that is contraindicated in meninges, and accordingly it is not appropriate to include it in a general recommendation.

We respectfully request the committee's review of the enclosed reference materials.

The specification of a single surgical skin antiseptic preparation is not supported with an adequate body of evidence published in peer reviewed journals and may compromise patient safety.

Rationale:

- <u>Clinical Evidence</u>. The majority of skin preparation clinical studies conducted over the
 past decades measured only non-validated surrogate endpoints such as skin flora
 reduction. Recently two large clinical studies, comparing the effect of different surgical
 skin preparations on SSI rates in general surgical procedures, have been published.
 - 1. Swenson et al (1)
 - Quasi-experimental design comparing SSI outcomes by sequential 6 month periods and by prep
 - Compared three commercially available skin preparations:
 - CHG/alcohol (chlorhexidine gluconate 2% and 70% isopropyl alcohol)
 - iodine-povacrylex/alcohol (iodine povacrylex and isopropyl alcohol 74% w/w)
 - PVP-I (povidone iodine) with alcohol paint
 - The use of both iodophor-based preparations resulted in significantly lower SSI rates than the use of CHG/alcohol, concluding that the iodophor preps may be better than CHG/alcohol
 - Limitations: study design is less robust than a randomized trial

2. Darouiche et al (2)

- Randomized clinical trial
- Compared two commercially available skin preparations CHG/alcohol versus aqueous PVP-I (no alcohol)
- The use of CHG/alcohol preparation resulted in significantly lower SSI rates than the use of PVP-I, concluding that CHG/alcohol is better than PVP-I
- Limitations:
 - compared CHG/alcohol with a prep containing only PVP-I (two active ingredients versus one)
 - did not include iodine povacrylex/alcohol
 - did not include the use of PVP-I with alcohol

Each of these studies has its limitations and the body of evidence is incomplete. Therefore further studies are required to determine which preps are appropriate in a broader surgical population.

- Additional Limitations/Contradictions. Surgical skin antiseptics containing alcohol are limited in application due to contra-indications for use in open wounds and mucosal tissue. CHG antiseptics are further contra-indicated for use in procedures involving potential exposure to meninges (spine, epidurals, craniotomy procedures), for prepping the head or face and the genital area (Attachment 1). Consequently, this limits the use of CHG and alcohol combination products to ~40% of all surgeries (3).
- Available Surgical Skin Preparations. There are currently many surgical site antiseptics
 that meet FDA standards on microbial log reduction (ie effective kill of skin flora studies
 done according to ASTM-1173 methodology). These include but are not limited to:
 - o CHG 4% solution
 - PVP-I solution
 - o iodine povacrylex/alcohol
 - CHG/alcohol

This portfolio of surgical skin preparations enables surgeons to safely meet patient needs broadly.

3M respectfully requests that NQF remove the proposed recommendation in Safe Practice Number 22 to use a single preoperative skin preparation. Clearly, the body of clinical evidence supporting the recommendation of any single surgical skin preparation is incomplete at this time and standardization to a single surgical skin antiseptic may compromise patient safety.

Sincerely,

Gregg Bennett, Ph.D

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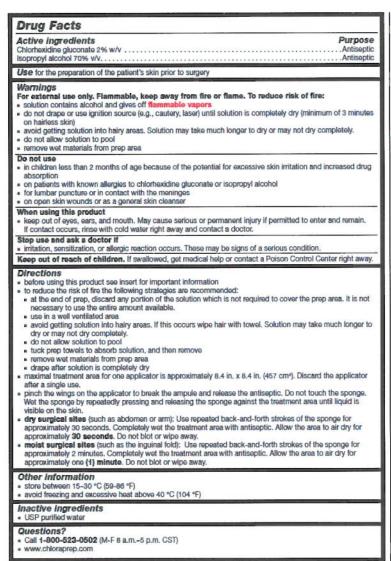
651-733-1980

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References:

- Swenson BR, Hedrick TL, Metzger R, Bonatti H, Pruett TL, Sawyet RG. Infect Control Hosp Epidemiol 2009; 30:964-971
- Darouiche RO, Wall MJ, Itani KMF, Oterson MF, Webb AL, Carrick MM, Miller HJ, Awad SS, Crosby CT, Mosier MC, AlSharif A, Berger DH. N Engl J Med 2010; 362:18-26
- 3. National Health Statistics Reports, Number 5, July 30, 2008. Tables 8, 9, 10.

Attachment 1



ChloraPrep^e One-Step 10.5 mL Applicator

Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v

Patient Preoperative Skin Preparation WARNING, FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

10.5 mL Applicator

Cat No: 260700

Applicator is sterile if package is intact

Single Use

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