NATIONAL QUALITY FORUM

TO: NQF Members

FR: NQF staff

RE: Ad Hoc Review of Safe Practice 22, Surgical-site Infection Prevention

DA: Tuesday, July 6, 2010

The National Quality Forum (NQF) received a request for an ad hoc review of Safe Practice 22: Surgical-site Infection Prevention, from 3M Healthcare Business (3M). The request for ad hoc review followed maintenance review and endorsement of the Safe Practices 2010 update. Within a letter submitted to NQF (Attachment – Justification for Review), concerns were expressed about the new specification referencing the use of a specific surgical skin preparation in NQF Safe Practice 22. The letter cites that studies "suggest the need for additional clinical study before the NQF Safe Practices can recommend one prep over another."

The NQF Consensus Development Process (CDP) enables ad hoc reviews of measures at any time when adequate justification is provided to substantiate the review. This request falls under the first two criteria justifying a review: the evidence supporting the measure focus has changed and the measure does not reflect updated evidence and there is evidence that implementation of the measure or practice may result in unintended consequences: use of the measure or practice may result in inappropriate or harmful care.

TECHNICAL REVIEW
Experts who participated in this ad hoc review were:

Dale Bratzler, DO, MPH
Oklahoma Foundation for Medical Quality

Darrell A. Campbell, Jr., MD
University of Michigan Hospitals and Health Centers

Bruce L. Hall, MD
Washington University St. Louis

BACKGROUND

The NQF-endorsed Safe Practices (SPs) were first published in 2003 and have undergone two revisions (2006 and 2009) to ensure the currency of the underlying evidence base. SP 22 focuses on prevention strategies for surgical site infection. The Statement for SP 22 is found in lines 77-79 and the Additional Specifications are found in lines 81-122 of the text included in Attachment – Specifications and Summary of Evidence. The bullet in lines 120-122 is a new specification for this SP that was endorsed, without challenge, through the NQF CDP, which included a public comment period, CSAC and NQF Board approvals, and an appeals process.

Based upon the concern raised by 3M subsequent to the completion of CDP processes, an ad hoc review was justified due to concerns with the evolving evidence base underlying the new specifications in lines 120-122.

The technical experts were asked to address whether the evidence supports this new specification. After completing a review of the evidence provided, two of the three technical experts concluded that the evidence was insufficient to determine whether one solution was superior to the other. One expert noted that the specification of the single acceptable skin preparation agent was based on research that is not universally applicable. Additional well designed, randomized trials comparing CHG-alcohol to iodine-alcohol solutions are needed. At this time, no one single acceptable skin preparation can be recommended over another and it was recommended that this specification should be removed from SP22. However, one expert upon review of the evidence determined that recent studies supported the use of CHG-alcohol as preferable to povidone-iodine in the context of general surgical cases, primarily abdominal, and studies that examined other povidone-iodine and alcohol regimens were not randomized nor controlled and thus did not provide the level of evidence desired.

The rationales provided for the recommendations from each of the technical experts are included on the next page.

At this time, NQF is seeking additional input during the member and public comment period on this specification within Safe Practice 22.

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Ad Hoc Review of Safe Practice #22 Surgical-site Infection Prevention

Responses by Technical Experts on the Questions Posed

Technical Expert	Rationale for Recommendation on whether the evidence supports this specification within Safe Practice 22
#1	There are simply insufficient studies directly comparing the outcome of interest (surgical site infections) between patients whose preoperative skin preparation included CHG-alcohol with patients whose skin prep included iodine-alcohol. The majority of the published studies showing superiority of CHG-alcohol used as a comparator group, iodine-alone skin prep. While not directly related to surgical site infections, at the recent CDC 5th Decennial meeting on healthcare-associated infections, there were a group of studies looking at skin prep for intravenous line placement showing no difference in infection rates (CHG-alcohol versus iodine-alcohol) or trends towards superiority of the iodine-alcohol preps. There is a need for additional well designed randomized trials comparing CHG-alcohol with iodine-alcohol.
#2	The evidence that exists is not of highest quality or does not address all relevant issues for each potential situation, surgical procedure type, or body location. The specification of a single acceptable skin prep agent is based on research result(s) that is not universally applicable. The specification of a single acceptable skin preparation approach is inappropriate and should be broadened to allow multiple prep agent options.
#3	There is concern that NQF SP #22 is too prescriptive in recommending only one type of pre operative skin disinfectant, CHG 2% - isopropyl alcohol for the prevention of SSI. This concern has been raised by the 3M corporation, the makers of a competing product. Recent excellent evidence, in the form of a randomized controlled clinical trial, has supported the use of CHG-alcohol as preferable to povone-iodine in the context of general surgical cases, primarily abdominal. (Darouiche) Different evidence, in the form of a randomized controlled clinical trial in foot and ankle surgery also supported the use of CHG-alcohol as opposed to povidone-iodine, at least to the degree that the former reduced skin flora more effectively than the latter.(Bibbio) The concerned party points to a 3M supported study indicating that other povidone-iodine and alcohol regimens were more effective in reducing the incidence of SSI than CHG-alcohol, underscoring the possible importance of alcohol in the disinfectant regimen, which was not a part of the povidone-iodine control group in the previous studies (Swenson). However the latter study had a more empiric, and, in my mind, a weaker experimental design.

	This study was neither randomized nor controlled, but was instead a chronologically designed study, in which 3 sequential time periods were examined, each using a different skin disinfectant regimen. Many other unmeasured factors associated with the different time periods could have influenced results. The 3M group suggests that future studies may show the comparability of CHG alcohol to povidone iodine alcohol, however I am unmoved by this argument, since such a study, equal in quality to the Darouiche NEJM paper, has not been done. Since the SP is being analyzed at present, it seems logical to base the NQF recommendation on the current, good evidence available at present. If at some future date solid evidence becomes available supporting the 3M concern, the SP #22 could be revised at that time. I would leave SP22 as it is.