NATIONAL QUALITY FORUM

TO: CSAC

FR: Heidi Bossley, MSN, MBA

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

DA: Thursday, October 7, 2010

The CSAC will be reviewing the technical expert recommendation and comments received on the ad hoc review of Safe Practice 22, Surgical-site Infection Prevention. This memo includes background information on the request, the review by the technical experts and the comments received.

CSAC ACTION REQUIRED
Pursuant to the CDP, the CSAC may consider approval of the ad hoc request to remove the specification referencing the use of a specific surgical skin preparation in NQF Safe Practice 22.

BACKGROUND
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

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 below.

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.

Comments Received

Seventy-nine comments from the member and the public were received.
Comments both in support and against the specification were submitted and

shared with the technical experts. Comments addressed 1) current experience with one skin preparation over another and 2) the lack of clear evidence and randomized control trials to support CHG-alcohol over iodine-alcohol preparations.

Current Experience with One Skin Preparation over Another

Many of the comments that supported the use of CHG-alcohol based on personal experience and observations within the individual's hospital. These comments were noted by the experts to be informative but anecdotal.

Lack of Clear Evidence and Randomized Control Trials

Other individuals and organizations who commented cited concerns that the evidence does not yet support the use of one preparation versus another. These comments were consistent with the initial review provided by two of the technical experts.

All of the experts agreed that the comments did not provide any new evidence or information for the inclusion of the specification for recommending one skin preparation over another at this time.

RECOMMENDATION:

Given the lack of clear evidence in support of one skin preparation over another and the experts agreement, it is recommended that this specification be deleted from Safe Practice 22:

> **Preoperatively, use chlorhexidine gluconate 2% and isopropyl alcohol solution as skin antiseptic preparation, and allow appropriate drying time per product guidelines.** [Darouiche, 2008; Darouiche, 2010]

National Quality Forum

Comments on Ad Hoc Review of Safe Practice #22 Specification

#	Organization Contact	Topic	Comment
7	Nancy Moureau, PICC Excellence	Justification	Adams D, Quayum M, Worthington T, Lambert P, Elliot T. Evaluation of a 2% chlorhexidine gluconate in 70% isopropyl alcohol skin disinfectant. J Hosp Infect. 2005;61:287–290. Atherton SL, Tjoelker RC. Evidence based fact sheet: an effective method for implementing change. Am J Infect Control . 2006;34:E51. Presented at: 33rd Annual Educational Conference and International Meeting of the Association for Professionals in Infection Control and Epidemiology: June 11-15, 2006; Tampa, Florida. Abstract 7-53. Render ML, Brungs S, et al. Evidence-based practice to reduce central line infections. Jt Comm J Qual Patient Saf. 2006 May;32(5):253-60. Carpenter D. Prevent nosocomial infections at the start. Mater Manag Health Care. 2006;15:46–48. Darouiche R, Wall M Jr, Itani M, et al. Chlorhexidine-Alcohol versus Povidone-Iodine for Surgical-Site Antisepsis. N Engl J Med. 2010;362:18-26. Fletcher N, Sofianos D, Brantling Berkes M, Obremskey WT. Prevention of Perioperative Infection. J Bone Joint Surg Am . 2007;89:1601-1618. Florman S. Nichols RL. Tulane Abdominal Transplant Institute, Tulane University School of Medicine, New Orleans, Louisiana Department of Surgery. Tulane University School of Medicine, New Orleans, Louisiana. Current Approaches for the Prevention of Surgical Site Infections. Am J Infect Dis . 2007;3(1): 51-61. Garcia R, Hibbard JS. Antimicrobial activity of a recently approved chlorhexidine-isopropyl alcohol antiseptic And Many more...

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9	Nancy Moureau, PICC Excellence	Justification	Because of its effectiveness and the increasing evidence of its superior performance compared to other antiseptics, chlorhexidine should be considered as the default skin prep. Since 2002, the Centers for Disease Control has recommended 2% chlorhexidine with 70% isopropyl alcohol as the skin antiseptic of choice prior to the insertion of vascular catheters. It has yet to release a statement for pre-surgical skin preparation. More recently, the National Quality Forum, in its Safe Practices 22: Surgical Site Infection Prevention, calls for the use of a chlorhexidine and isopropyl alcohol solution as a skin prep prior to surgical procedures. Chlorhexidine and alcohol are now considered the most recommended prepping agent for the United States and around the world. These recommendations were recently bolstered by a study published in the January 7 issue of the New England Journal of Medicine. In a multi-center study with 849 surgical patients, Darouiche and colleagues found that patients who were prepped with chlorhexidine and alcohol had nearly half as many surgical site infections (9.5%) compared to those prepped with povidone-iodine (16.1%). This study follows a related study from 2005 in which researchers at the University of California, San Diego analyzed culture specimens gathered from foot and ankle surgery patients who were prepped with chlorhexidine, iodine-alcohol or chloroxylenol.
10	Kathy Lemmon, DuBois Regional Medical Center	Justification	After implementation of ChloraPrep (CHG/Alcohol), we have seen a dramatic decline in SSIs. We have had zero adverse effects from use of ChloraPrep. CHG is a superior disinfecting agent and we will continue to use it for most surgical preps.
12	Linda Cheshier, Ottawa Regional Hospital and Healthcare Center	Justification	Duraprep is marketed as a 1 step skin prep device that eliminates the need for a separate paint with alcohol. The studies conducted comparing Chloraprep to Duraprep were valid. Chloraprep is a combination solution of prep agents that is effective in lowering SSI rates. The one step prep by Chloraprep vs Duraprep were compared equally and fairly. I recommend that if a one step prep is supported and endorsed under Safe Practice 22, it would be for chlorhexidine and alcohol in a one step application method.

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13	nikolaus gravenstein, university of florida college of medicine	Justification	There is no perfect universal skin prep solution; but given that disinfection is imperfect and that therefore the remaining microbes lie in wait to muliply it is difficult to not favor a chlorhexidine containing solution with a much more enduring effect and one that is not interfered with by proteins in blood as is encountered during surgical procedures as compared to an iodine based prep. no doubt in both cases the alcoholic component is relevant. re the studies neither the 3m cited ones nor the chg advocating ones are perfectly comparable but on balance it is very difficult to compellingly argue against chg-ipa as the preferred skin prep solution for eligible operative sites. Other solutions should certainly be allowed and accomodated. The many specialty societies and organizations that have looked at the preferred preferred preprocedure disinfecting skin prep have i think overwhelmingly and independently also concluded that chlorhexidine/ alcohol is preferred- even when it comes for example to neuraxial access (American Society of Regional Anesthesia)
15	Debby Ohayon, kaleidahealth	Justification	Based on the evidence and my experience 2%CHG and alcohol is a superior patient prep solution compared to iodine based solutions. It provides facilities with a quick bacterial kill as well as prolonged persistence which has shown to be an integral part in lowering SSI rates.
18	Kevin Bussiere, Sentara Leigh Hospital	Justification	I believe that the NQF is justified in making recommendations based upon the existing research that is cureently available. The current research shows that the combination of CHG and alcohol has an effective antisepsis superior to any antisepsis that has= been tested in a similar clinical trial. It is the mechanism of the CHG/Alcohol which is superior. Iodopurs have too narrow a function range with limited residual effect. PCMX is a mediocre antiseptic with mod residual according to the FDA research So the highest kill claims are CHG & Alcohol and the hughest residual is CHG & alcohol. If furture reserach identifies a beter product or comination, let's embrace that one THEN, but for now let's embrace what we know works.
21	Sandra Neri, SMCS	Justification	Both DuraPrep and ChloraPrep in our facility are the most utilized prep products. At our facility it is still an MD choice for the chosen product. Most of our surgeons who were using DuraPrep have switched to ChloraPrep, they like the 48 hour kill factor for bacterial growth. Some groups have made the decision to swith solely to ChloraPrep - OBGYN, Ortho, and for all Central Line Placements by Infection Control.
25	Brenda Helms, BHCS	Justification	There are numerous studies stating that 2% CHG and 70% alcohol are the most effective in preventing infections. The recent study was not a randomized control study and so I don't feel that it is a study that can truly be compared with a study that is.

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27	Susan Tolentino, Holy Cross Hospital	Justification	We have chosen to convert to 2% chlorhexdine and 70%IPA because of the evidence out there right now. The SSI study done in the New Englad Journal proved a 41% reduction in SSI's compared to betadine. The problem with products that have betdine is that iodine can be neutralized in the presence of blood and organic matter. It is also not as broad spectrum as chlorhexidine. Our facility has had great success with Chloraprep.
28	Janee Macklin, McLaren Health Care	Justification	Dear NQF Reviewers, While I can appreciate 3M's concern due to potential market share & financial loss to their company I encourage you to not be confused by their half truths and misleading information that is presented in their request. If you do choose to entertain their comments please ask them to provide clinical studies that document the safety of PVP-I solutions related to meninges. No such studies exist for any skin prep. There are however sufficient studies published that demonstrate the superiority of CHG/IPA solutions over PVP-I solutions in a variety of patient settings. Please consider the many documented successes and potential lives saved from the implementation of CHG/IPA solutions. Do not allow yourselves to become side tracked with deceptive illusions portrayed by for-profit companies who are attempting to manipulate you in order to minimize their own financial loss that they may experience by you doing the right thing to protect the patients in this country.

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31	Kathleen Kohut, Independent Consultant	Justification	Surgical preps have not been well studied and the recent evidence cited is insufficient to allow for such a prescriptive perspective by the NQF. All of the three most recent studies are flawed in some manner: Example #1- Saltzman, MD, et al. Efficacy of Surgical Preparation Solutions in Shoulder Surgery. J Bone Joint Surg AM 2009;91:1949053 is a microbial count study with a sample size of 150 patients. The comparison between the prep solutions determined that microbial counts were less when the CHG product was used. However, the SSI outcomes for these patients was of no statistical significance. The correlation between microbial counts and SSI outcomes has not been established and therefore a poor proxy for analysis. Example #2 -Swenson, et al. Preoperative skin preparation on postoperative wound infection: a prospective study of three skin preparation protocols. Infect Control Hosp Epidemiol 2009; 30:964-971. This study was not randomized but did compare three preps solutions and utilized SSI outcomes as the endpoint. The results demonstrated that of the 3200 patients, the iodophor based skin preps had lower SSI rates than the CHG product in certain categories. The researchers concluded that more research is warranted prior to making any strong conclusions regarding surgical skin preps.

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32	Kathleen Kohut, Independent Consultant	Justification	The most recent study of surgical preps was published in 2010. Darouiche, RO, et al. Chlorhexidine-Alcohol versus Povidone-Iodine for Surgical-Site Antisepsis. N Engl J Med 2010; 362(1):18-26 is a comparison between iodophor scrub and paint and a CHG/alcohol product. The CHG/alcohol product demonstrated significant SSI reductions in some categories. However, it is common knowledge that surgical skin preps that contain alcohol outperform preps without alcohol due to the superior kill factor of alcohol. This study should be repeated comparing iodophor/alcohol products to CHG/alcohol products to really understand the efficacy of each. In addition to the efficacy of the prepping solutions the ease of application may be a significant factor between surgical skin preps. Surgical preps that must be scrubbed onto the skin are much more difficult to apply as compared to painted products. In my own observations of product usage, the products requiring scrubbing techniques are rarely applied according to manufacturer's directions and therefore, pose a safety risk to patients who are not benefiting from the proper application and efficacy of the product. Body surfaces must also be taken into consideration as certain surgical sites are contraindicated with CHG based products. There is not "one size fits all" evidence to warrant the advocacy of CHG skin prepping solutions over other FDA approved surgical skin prep solutions.
34	Ed Septimus, HCA	Justification	I agrre with the concerns discussed in letter by 3M The literature currently does not clealry favor one alcohol prep over another further trials will need to be done
36	Richard Raffule, Kaleida Health	Justification	I am writing this as a member of a core team that has been tasked with decreasing the post-op infection rate for our organization, which is made up of 5 hospitals. Our doctors, nurses, and infection control team has weighed the evidence of past studies and the most recent studies concerning CHG and alcohol compared to iodine and alcohol. Based on the evidence, and results we have achieved already with CHG and alcohol products, we have found that CHG and alcohol provides our patients with the best protection in preventing surgical site infections. Our clinical team has been impressed with the results that CHG and alcohol products have provided for our patients.
50	Troy Thurmond, St. Vincent's Medical Center	Justification	I would like to see a true study of Chloraprep vs DuraPrep

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52	Amy Whisnant, CVMC	Justification	Our postoperative infections dropped considerably after implementing Chlora Prep.
54	Paul Durgan, St. Vincent Hospital	Justification	This is clearly a company (3M) defending it's product. There are multiple studies available that have compared CHG based preps versus Iodine based preps and the evidence is out there - CHG based preps have a much better track record of reducing SSI as well as IV site infections. It's amazing that 3M promotes Duraprep for skin prep but Avagard for a Surgical Hand scrub. Avagard is CHG and alcohol! It has the longest residual effect which is why we use it! You can not change the evidence based on one study that was not done on a randomized basis. The overwhelming evidence that CHG based preps have better outcomes speaks for itself.
56	Margaret Mulcrone, Henry Ford West Bloomfield Hospital	Justification	Chloraprep is a good product. My hospital converted over to chloraprep based on Safe Practice 22 statement. The only problem we had initially is teaching the staff to apply the chloraprep as recommended. SSI rate is low to none. If we had problems with post-op infections relating to surgery it was usually caused by incorrect application of product. However, I have to agree with the justification for review. More studies needs to done on Chloraprep vs. Duraprep. I think you are going to find both provide superior skin aseptic qualities. Also, it is very difficult to recommend one skin antiseptic product when the skin antiseptic product has limitations to where it can be applied. Another issue is cost. Chloraprep is at least double the cost of Duraprep. It would be great to be have choices.
59	Laura Larson, Tanner Health System	Justification	I feel that NQF SP22 should remain as it is. Good evidence supports CHG over PI at this time. In the future, if studies support Duraprep as well, then the SP22 could be amended to include Duraprep. We need to go with what evidence-based practice dictates to do at this time.
60	Claudine DeFreytas, Huntington Hospital	Justification	I believe that the MQS safe practice Number 22 should stay the way it is written in favor of the 2% chlorhexadine in 70% alcohol for a surgical site prep. There is evidence that the 2% chlorhexadine in 70% alcohol is superior and we use it as our prep of choice.
62	Paul Kearney, UKHealthcare	Justification	Not a bad argument but must there must be balance realizing that 3M has a proprietary interest in the success of their product in the Market.

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64	javad Parvizi, Rothman Institute	Justification	As a joint surgeon with special interest in periprosthetic joint infection, I endorse the notion that there is insufficient evidence to support the use of a single skin preparation. It would therefore be prudent for the NQF, as recommended by the expert panel, to avoid being prescriptive in their recommendations. Iodine combined with alcohol has been used at my instituion as the skin preparation of choice for over 30 years leading to SSI rate that is well below the national average, even in high risk patients. I agree with the concern raised by 3M in that some of the studies evaluating SSI that have demonstrated superiority of one prep over another had major methodological flaw and should not for the basis for recommending a single prep. I believe efforts to minimize SSI in our patients should intensify as th eburden presented by this dreaded complication is on the rise. Conducting well designed and unbiased studies are the steps in right direction.
68	Molly McBrayer, Roper St. Francis Healthcare	Justification	3M is requesting the removal of a product-specific item being listed in the recommendation because it is not their product. Rather than accepting that the CHG-alcohol product is a superior product with a focus on quality patient care in the reduction of surgical site infections, 3M is focused on revenue. I strongly recommend that the CHG-alcohol product remain the recommendation for those surgical procedures in which it may safely be used for skin preparation.
81	Stephen Lewis, CareFusion	Justification	We agree that recent evidence regarding use of 2% chlorhexidine gluconate and isopropyl alcohol (CHG) did need to be reviewed given that published work that followed the original proposed text in SP22 is relevant. Two studies are critical. One by Swenson et al (October 2009 ICHE) was a weakly-controlled study that found lower surgical site infection (SSI) rates in the combined povidone-iodine & iodine-povacrylex group than CHG. The other was a multicenter randomized prospective trial published by Darouiche (January 2010 NEJM) that clearly favors the use of CHG over povidone-iodine. This is not the first time where a properly controlled randomized trial has found results different from earlier non-randomized and weakly controlled studies. The NEJM editorial by Wenzel accompanying the Darouiche paper stated "the weight of evidence suggests that chlorhexidine–alcohol should replace povidone-iodine as the standard for preoperative surgical scrubs." We submit that SP22 in its original form overstated recommended practice and that it should be amended to reflect current best evidence to read: In clean-contaminated surgical cases, use chlorhexidine gluconate 2% and isopropyl alcohol solution preoperatively as the skin antiseptic preparation when not contraindicated. (See submitted supportive document CareFusion_SP22_Response)

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82	Stephen Lewis, CareFusion	Justification	At least some factions within 3M may not have shared the view that review was necessary. In the expert comments, reviewer #3 commented that the concerns regarding Safe Practice 22 were raised by 3M as "makers of a competing product." However, 3M also makes the same product, chlorhexidine gluconate 2% and isopropyl alcohol but the 3M product is only licensed in Canada and has not received FDA approval in the U.S. Their own advertising in Canada (see figure 1 in the attached supporting document CareFusion_SP22_Response) that presents 3M as "CHG Experts" directly quotes the Darouiche paper stating that "preoperative skin cleaning with chlorhexidine-alcohol better protects against infection than povidone-iodine."
88	Rebecca Zimmermann, AHIP	Justification	AHIP appreciates the opportunity to provide comments on the Ad Hoc review of Safe Practice #22, Surgical Site Infection. Given the currently available evidence, the inclusion of chlorhexidine gluconate 2% and isopropyl alcohol solution in the Safe Practice appears to be overly prescriptive. We support a revision to Safe Practice #22 to recommend appropriate perioperative skin preparation and removal of language supporting one specific technique of skin preparation.
6	Nancy Moureau, PICC Excellence	Assessment	39 different studies/reports support the Chlorhexidine gluconate as a highly effective skin disinfectant with residual qualities that promote safety in reduction of infection. As quoted by the Agency for Healthcare Quality and Research "Strict adherence to infection control methods, such as engaging in proper handwashing, using maximum barrier precautions, and using chlorhexidine gluconate antiseptic instead of betadine during catheter placement can reduce central line infection rates significantly.3 The Centers for Disease Control have long recommended Chlorhexidine as the preferred agent for skin preparation with the statement: Cutaneous antisepsis: Disinfect clean skin with an appropriate antiseptic before catheter insertion and during dressing changes. Although a 2% chlorhexidine-based preparation is preferred, tincture of iodine, an iodophor, or 70% alcohol can be used. (CDC/MMWR, 2002). With the drafted form of the 2010 recommendations the preference for Chlorhexidine will be upgraded. While other disinfecting agents reduce bacterial load on the skin, only chlorhexidine provides a long lasting residual action against bacteria, lasting 48 hours or more. Chlorhexidine is considered the preferred agent for skin disinfection by CDC, Infectious Disease Society of America (IDSA) and The Society for Healthcare Epidemiology of America. I would hope that you would consider listing Chlorhexidine Gluconate with alcohol as the preferred agent for surgical site skin disinfection.

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8	Nancy Moureau, PICC Excellence	Assessment	One Stop Guide to Surgical Preps: www.outpatientsurgery.net April/May 2010 Choose chlorhexidine as your default skin prep. Chlorhexidine gluconate, or CHG, is known for its relatively fast microbial kill, but it has another characteristic that is not as widely known. Its killing action against micro-organisms remains active much longer than with alcohol, povidone-iodine, or parachlorometaxylenol (PCMX). Chlorhexidine works by disrupting the cell membrane of bacteria. The CDC rates chlorhexidine as excellent against gram-negative bacteria such as Escherichia coli and salmonella, and good against gram-positive bacteria such as Clostridium difficile, Enterococcus and Staphylococcus aureus, which are the cause of 20% to 30% of surgical site infections, according to the Centers for Disease Control. Chlorhexidine has limited effectiveness against viruses, tuberculosis and fungi, but when combined with 70% alcohol the speed and effectiveness of action increases. Additionally, chlorhexidine is not deactivated when it comes into contact with blood making it an effective killing agent during surgical procedures. In addition to rating how well a skin prep kills bacteria initially, its residual effective kill time should also be considered in terms of as important or even of greater importance depending on the application. Ideally, residual activity of a prepping agent should continue for 48 hours or more as is the case with chlorhexidine.
11	Kathy Lemmon, DuBois Regional Medical Center	Assessment	As Director of Infection Control, I know without doubt, that use of CHG products have a significant positive impact on infection reduction. We currently daily bathe our ICU patients with a CHG product. Since implementation of this practice, we have had zero VAPs (ventilator-associated pneumonias), and zero catheter-associated urinary tract infections.
14	nikolaus gravenstein, university of florida college of medicine	Assessment	Clearly more studies are desirable as concluded by the panel. There is no compelling panel opinion to not still conclude that chlorhexidine alcohol is the preferred skin antiseptic. If future data show otherwise or demonstrate equivalent or better efficacy than chlorhexidine alcohol then the Safe Practice 22 language should of course be modified accordingly as information accumulates, but current best evidence and practice favors chlorhexidine alcohol as still being at least the preferred solution.
16	Karen Dominguez, St. Vincent's Medical Center	Assessment	Our facility has been using CHG products increasingly over the past few years to reduce bloodstream infections, surgical site infections, and contaminants when drawing blood cultures. We have seen a decrease in central line-associated bloodstream infections since we added ChloraPrep to our insertion bundles. As an Infection Preventionist, I advocate for our surgeons to use ChloraPrep as the standard for preventing SSI and have recently witnessed a decrease in SSI after several surgeons switched to using ChloraPrep. I agree with Expert #3's response; while there could always be more evidence to use CHG-alcohol for all sites, I have witnessed the success and support the use of ChloraPrep.

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17	Marti Phelps, St. Vincent's Medical Center	Assessment	CHG products have been integral to our facility's reduction of Central Line, Blood Stream, UTI, and Surgical Site Infections in the last several years. In particular, the use of ChloraPrep has made a great impact on the reduction of the SSI rates. As an Infection Preventionist, and based on our facility's results, I advocate the use of this product as a surgical prep.
19	Teresa Smith, Methodist Hospitals of Memphis	Assessment	I can only speak personally (not to represent system position); however, NQF's Technical Expert #3 got it right (IMHO), i.e.,"if it isn't broken, don't fix it". Until convincing evidence from randomized controlled clinical trials in sizeable samples changes my mind, I will continue to support CHG for surgical skin preps (w/no involvement of meninges/mucous membranes).
20	gail rudder, sentara careplex hospital	Assessment	I agree that there needs to be supportive not suggestive documentation to show that there is comparability between the CHG/isopropyl alcohol skin prep and an iodine/alcohol prep. CHG as a skin prep prior to surgical and invasive procedures has been proven and supported by the CDC, SHEA and IDSA. 3M has a vested interest in posing these requests for consideration, however, I disagree that there should be a revision of any recommendation which supports evidenced based research.
22	Sandra Neri, SMCS	Assessment	The effectiveness of ChloraPrep seems to have great results if application is done according to manufacturer directions. I will be interested in reading further research done to support the use of ChloraPrep over other prep methods. Truly with Infection Control "strongly" enforcing the use of a 2% Chlorhexidine with alcohol, to be used as the prep of choice on all Central Line Placement procedures and with strict adherence to sterile technique, the results have been strong.

#	Organization Contact	Topic	Comment
23	Robbie Singer, Sutter Medical Center, Sacramento	Assessment	We recently switched from utilizing DuraPrep solution to ChloraPrep solution for all of our cesarean section surgery preps based on recent studies that have been published. We have found the ChloraPrep solution to be advantageous for a number of reasons including that the CHG solution does not require any removal other than soap & water post surgery. DuraPrep required the application of a special lotion to remove the dried prep solution from the patient's skin post-op. This extra lotion (and associated costs) had been routinely requested by our physicians and patients prepped with DuraPrep due to the discomfort of the dried, extremely sticky solution post-operatively. Another factor we were interested in is the duration of the sustained antimicrobial activity which we believe to be longer with ChloraPrep, especially since we do not remove the solution as we had with the DuraPrep. We have not had any incidence of surgical site infections since we have made the switch to ChloraPrep in our department. Whereas, last year we had 7 reported cases total with DuraPrep. Of course, there could be many other variables other than the surgical prep solution at work here. For example, when we switched over to utilizing ChloraPrep, we reinserviced all staff to the principles of surgical skin prep and required return demonstrations. Our procedure was totally rewritten and updated to current AORN standards.

#	Organization Contact	Topic	Comment
24	Michelle Stevens, 3M Healthcare Business	Assessment	Response to reviewer 3 on other factors that could have influenced the SSI results from univariate analysis of the non-randomized Swenson study In addition to the univariate SSI analyses by study period (Table 2) and by actual prep used (Table 4), a multivariate analysis (logistic regression) was also performed, which included all the variables with a significant association with SSI (Table 3).This multivariate analysis (Table 5) resulted in a SSI odds ratio for the CHG/alcohol prep of 1.35, (95% CI of 0.97-1.87, p=0.073).Although not significant at the 5% level, there was a strong trend towards higher SSI with CHG/alcohol prep since the odds of a SSI in this case were 35% higher than with iodophor/alcohol preps. In other words, in 95% of patients the chance of having a SSI with CHG/alcohol ranged from 3% less to 87% higher than with iodophor/alcohol.These statistics imply that CHG/alcohol prepped patients would have a higher chance for a SSI than iodophor/alcohol prepped patients. Unfortunately, the randomized study (Darouiche) did not use an iodophor/alcohol prep control but rather aqueous PVP-I and thereby prevents any comparison to iodophor/alcohol preps.In contrast, the compelling data from the multivariate analysis favoring iodophor/alcohol in the Swenson study is the only clinical outcome study comparing iodophor/alcohol to CHG/alcohol preps.Consequently, 3M does not agree with reviewer #3 on recommending the endorsement of SP22 at this time due to insufficient data.
26	Brenda Helms, BHCS	Assessment	I agree with Expert #3. The study cited by 3M was not a randomized control study and was not independent of the manufacturer of Duraprep. At my facility (Cardiovascular Surgical Hospital) we use only 2%CHG and 70% alcohol as a surgical skin prep. By log reduction of microbes on the skin the chance of the patient developing an infection are decreased. Our infection rates are minimal and we intend to stick with our prep.

#	Organization Contact	Topic	Comment
29	Janee Macklin, McLaren Health Care	Assessment	Dear NQF Reviewers, Regarding the recommendations of your ad hoc committee on Safe Practice 22, I see no reason for further delay in implementing your recommendation to endorse a CHG/IPA solution as the preferred & recommended pre-operative surgical skin prep. While further studies are always comforting they are also time consuming to complete. Upon reviewing the published data again I have confidence that you will not find them insufficient. We are at a time in our history where national healthcare reform and evidence based medicine is in the forefront due to the lives at stake. Timely decisions regarding best practice need to made with the information we have at present. I understand national guidelines & recommendations for best practice are not made lightly. However, please understand that healthcare institutions often will not act on their own without these national guidelines & set standards of care. With more government involvement and taxpayer dollars invested in healthcare there is a significant cost savings associated with infection prevention. There is no reason to believe that the same success that we have enjoyed in preventing blood stream infections will not also be experienced when you take a pro-active stand on behalf of vulnerable patients by affording them the same level of infection prevention when you make CHG/IPA solutions the prefered pre-operative skin prep. Thank you.

#	Organization Contact	Topic	Comment
30	Gregg Bennett, 3M	Assessment	Response to reviewer 3 regarding 3M's support of a clinical study: Industry support was provided for all three clinical studies cited by reviewer 3 to varying degrees and by different manufacturers. The Darouiche study cited by reviewer 3 includes an industry author. As is well known, support of such clinical studies is common industry practice and helps advance patient safety and clinical science. 3M is supportive of such collaborations and believes in their value. Specific to the Swenson study, 3M's support in the form of an unrestricted educational grant was modest, and equivalent to less than $10/patient studied. Additionally, 3M is not biased against CHG/alchohol preps and offers CHG/alcohol preps as part of our global product portfolio. It is our belief that clinicians are in the best position to choose the appropriate patient prepping protocol to meet the needs of their patients based on their interpretation of the available clinical evidence. Because CHG/alcohol preps are contraindicated for certain surgeries it is 3M's position that multiple effective preps should be recommended in any industry guideline. Consequently, 3M does not agree with reviewer #3 on recommending the endorsement of SP22.
33	Ed Septimus, HCA	Assessment	from available studies the best curent conclusion would be that an alcohol based prep is better than a non-alcohol based prep. Current literature is not conclusive whether alcohol/CHG is better than alcohol/iodophor therefore NQF should favor an alcohol based prep with either CHG or iodophor

#	Organization Contact	Topic	Comment
37	Donna Jones, MADRI	Assessment	In conjunction with the recent annual conference of the Multidisciplinary Alliance Against Device-Related Infections (MADRI), an advisory panel comprising surgeons and infectious disease physicians held a meeting in Boston on June 3, 2010 to discuss the NQF Safe Practice Guideline #22 on prevention of surgical-site infections. Members of the advisory panel were selected and invited by MADRI which organized the meeting. The 10-member advisory panel included (in alphabetical order) Drs. David Berger, Rabih Darouiche, Donald Fry, Kamal Itani, John Mazuski, Robert Moellering, Lena Napolitano Joseph Solomkin, Robert Sherertz, and Sandra Torres. CareFusion provided educational funds to MADRI and had representatives present at the meeting. It was the opinion of this advisory panel that scientific evidence from published peer-reviewed studies that are listed below supports the role of chlorhexidine-alcohol as a superior agent for cleansing the skin before select types of surgery. A number of clinical studies over the past decade evaluated the efficacy of different antiseptic skin preparations in reducing skin flora. These studies support the efficacy of chlorhexidine. While reducing resident skin flora is important, two recent prospective randomized studies assessed the clinical outcome of surgical-site infection supported the notion that chlorhexidine-alcohol based preparations are more protective against infection than iodophor-based products without alcohol.
38	Donna Jones, MADRI	Assessment	Concerns were expressed regarding the generalizability of these two pivotal chlorhexidine-alcohol clinical outcome studies. (A) Published surgical studies that address the microbiologic impact of chlorhexidine-based vs. iodophors-based products include: (1) Bibbo, et al. Clin Orthop. 2005;438:204-8. A prospective randomized study of patients undergoing foot and ankle surgery reported significantly lower rates of culture-positive specimens in the chlorhexidine group than the iodophor group (38% vs. 79%; p=0.001). (2) Ostrander, et al. J Bone Joint Surg Am. 2005;87:980-985. A prospective randomized study of patients undergoing hallux and toe surgery indicated that the highest percentage of positive cultures occurred in the chloroxylenol group and the lowest percentage of positive cultures occurred in the chlorhexidine-alcohol group. It also demonstrated that the chlorhexidine-alcohol group had significantly lower percentage of positive cultures than the iodophor-alcohol group ($p<0.0001$). (3) Saltzman, et al, J Bone Joint Surg Am. 2009;91:1949-53. A prospective single-institution study of patients undergoing shoulder surgery evaluated the efficacy of povidone iodine, povidone iodine-alcohol, and chlorhexidine-alcohol. Overall, the chlorhexidine-alcohol group had the lowest positive cultures (7%) as compared with iodophor group (31%; $p<0.0001$) and even the iodophor-alcohol group (19%; p=0.01).

#	Organization Contact	Topic	Comment
39	Donna Jones, MADRI	Assessment	When considering only coagulase-negative staphylococci (most common isolate), both chlorhexidine-alcohol and iodophor-alcohol preparations were more effective than iodophor alone, but there was no significant difference between the two alcohol-based preparations. (B) Published prospective, randomized, clinical studies that support the superior protection afforded by chlorhexidine-alcohol based vs. iodophor-based antiseptic preparations in preventing surgical-site infection: (1) Paochareon, et al. J Med Assoc Thai. 2009;92:898-902. This prospective, randomized trial of patients undergoing general surgery showed that bacterial colonization at the incision site was significantly lower in the chlorhexidine-alcohol arm than in the iodophor arm (14.4% vs. 31.2%; 95% CI: 2.15-3.35). More importantly, the incidence of surgical-site infection at one month after surgery was significantly lower in the chlorhexidine arm than in the iodophor arm (2% vs. 3.2%; 95% CI = 1.40-1.81). (2) Darouiche, et al. N England J Med. 2010;362:18-26. This prospective, randomized, multi-center trial of patients undergoing clean-contaminated surgery demonstrated that the overall rate of surgical-site infection was significantly lower in patients whose skin was preoperatively cleansed with chlorhexidine-alcohol vs. povidone-iodine (9.5% vs. 16.1%; P=0.004).
40	Donna Jones, MADRI	Assessment	Not only did this large study yield a degree of reduction (41%) in the rate of surgical site infection in the chlorhexidine group that was comparable to that reported in the above study by Paochareon (38%), but it also expanded the applicability of this finding to both abdominal (colorectal, biliary, small intestinal, and gastroesophageal) and non-abdominal (thoracic, gynaecologic, urologic) clean-contaminated surgeries. The advisory panel also discussed the trial by Swenson, et al. Infect Control Hospital Epidemiology. 2009;30:964-71. This 3-group, cross-over, quasi-experimental, single-institution study was affected by a number of factors including differences in risk factors for infection between study groups, incomplete protocol application in each study period, unclear time as to when after surgery was surgical site infection assessed, and statistical grouping of iodophor and iodophor-alcohol groups for comparison with the chlorhexidine-alcohol group. These problems raise important concerns as to the reliability of the data and derived conclusions. The advisory panel believes that the body of scientific evidence supports a recommendation stating that chlorhexidine-alcohol preparation is preferable to povidone-iodine scrub and paint for preoperative cleansing of the skin in patients undergoing select clean-contaminated surgeries (level 1A evidence).

#	Organization Contact	Topic	Comment
41	Donna Jones, MADRI	Assessment	As is the case with other types of antiseptic skin preparations, the use of chlorhexidine-alcohol preparation should adhere to the FDA-approved instructions of use in order to avoid toxicity and optimize efficacy. Because of the relatively low rate of surgical-site infection after clean surgery, it is unlikely that a sufficiently-powered, randomized, controlled trial would be performed to compare the efficacy of antiseptic preparations in patients undergoing clean surgery. The issue of whether the addition of alcohol to iodophor increases the efficacy of iodophor-based preoperative skin preparations was also considered. (C) Published studies that compared the efficacy of iodophor vs. iodophor-alcohol preparations: 1. Birnbach, et al. Anesthesiology. 2003;98:164-9. This prospective single-institution study compared the efficacy of povidone-iodine vs. an iodophor- alcohol solution for skin disinfection prior to epidural catheter insertion in parturient patient population. The proportion of subjects with positive skin cultures immediately after skin disinfection was significantly higher in the povidone-iodine group vs. iodophor- alcohol group (30 vs. 3%, respectively, P = 0.01).
42	Donna Jones, MADRI	Assessment	The number of subjects with any positive skin cultures at the time of catheter removal was also greater in the povidone-iodine group than the iodophor- alcohol group (97 vs. 50%, respectively; P =0.0001), as was the number of colonies cultured from the skin (log CFU, 1.93 +/- 0.40 vs. 0.90 +/- 0.23, respectively; P = 0.03). 2. Boston, et al. Infect Control Hospital Epidemiology. 2009;30:884-889. This case-control study examined patient- and hospital-associated risk factors for surgical-site infection by using existing data on patients who underwent spinal operations. Multivariable analysis using logistic regression analysis showed that preoperative skin antisepsis with only povidone iodine, instead of iodine and iodophor-alcohol, was more protective against surgical-site infection (OR, 0.16; 95% CI, 0.06-0.45). 3. Segal, et al. AORNJ. 2002;76:821–8. This randomized study evaluated the effect of four different preoperative skin preparations on wound infection rates in patients undergoing open heart surgery. Patients received one of the four following skin preparations: povidone-iodine paint, povidone-iodine 5-minute scrub with paint, one-step Iodophor-alcohol water insoluble film, and one-step Iodophor-alcohol water insoluble film with iodine-impregnated incise drape. Although fewer infections occurred in the one-step Iodophor-alcohol water insoluble film group, the study was underpowered to detect real differences.

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43	Donna Jones, MADRI	Assessment	4. Alexander, et al. Arch Surg. 1985;120:1357–61. This study compared three different preoperative scrubs: a 1-minute scrub using 70% alcohol, a 1-minute scrub using 2% iodine in 90% alcohol, and a 10-minute iodine soap scrub followed by iodine paint. Similar rates of surgical-site infection were reported in the three groups. 5. Lorenz, et al. J Reprod Med. 1988;33:202–4. This study compared a 5-minute Iodophor scrub with a 1-minute isopropyl alcohol scrub and an Iodophor antimicrobial drape. The two study groups had similar rates of surgical-site infection. 6. Kothuis et al. Neth J Surg. 1981;33186–9. This study evaluated the effect of povidone-iodine vs. alcohol plus iodine tincture in patients undergoing elective laparotomy. The wound sepsis rate was 16% in the povidone-iodine group vs. 13% in the alcohol-iodine group. The investigators concluded that the two studied antiseptic preparations were comparable. 7. Gilliam, et al. Clin Orthop. 1990;250:258–60. This randomized study compared the efficacy of an iodophor 5-minute scrub-and-paint vs. a single application of a water insoluble Iodophor-alcohol solution in patients undergoing clean total joint surgery. The skin of each patient was cultured before applying the antiseptic preparation and before wound closure. The two studied preparations were equally effective in reducing the number of bacteria on the skin.
44	Donna Jones, MADRI	Assessment	. 8. Hort, et al. Foot Ankle Int. 2002;23(10): 946–8. This randomized study investigated the effects of a standard povidone-iodine skin preparation with and without alcohol. Patients received either a 10-minute scrub with povidone-iodine followed by skin painting with povidone- iodine or the same procedure with the addition of a 3-minute preoperative preparation with 70% alcohol. Culture swabs were obtained immediately after skin preparation. Cultures were positive in 35% of patients receiving the standard preparation and in 57% of patients receiving the standard preparation plus alcohol. No patients had clinical evidence of infection or wound problems. The investigators concluded that the inclusion of alcohol provided no additional benefit in the prevention of surgical-site contamination. Although the trial by Birnbach and colleagues (study #1) showed that iodophor-alcohol is superior to iodophor alone in reducing contamination of the skin and the epidural catheter, this study did not assess the clinical outcome of infection and was not a surgical study. The seven listed surgical studies collectively indicated that iodophor-alcohol is not superior to iodophor alone in preventing surgical-site infection (studies #2, 3, 4, 5 and 6) or reducing microbiologic contamination (studies #7 and 8).
45	Donna Jones, MADRI	Assessment	Taking into consideration that some of these studies were underpowered and had important methodological limitations, we found no clear evidence that iodophor-alcohol is superior to iodophor alone for preoperative cleansing of the skin. The advisory panel believes that this issue cannot be fully resolved without a well-designed comparative clinical outcome trial.

#	Organization Contact	Topic	Comment
46	Inmaculada Soria, 3M	Assessment	SwensonBR,SawyerRG.Importance of Alcohol in Skin Preparation Protocols.Infect Control Hosp Epidem 2010;31(9) http://www.ncbi.nlm.nih.gov/pubmed/20636130 Main points from this correspondence: •Darouiche study showed that patients prepared with CHG/alcohol have lower SSI rates than with aqueous iodophor (no alcohol) •Swenson study showed that patients prepared with iodophor/alcohol have lower SSI rates than with CHG/alcohol •SSI rate for CHG/alcohol prepared patients undergoing clean-contaminated surgeries was similar in both studies (Darouiche 39/409-9.5% and Swenson 46/454-10.1%) •Alcohol,with its rapid bactericidal activity,may be a critical component of the iodophor preps •Darouiche study is limited by the exclusion of alcohol in the iodophor group •There is agreement that,based on the Darouiche results,the use of iodophor (no alcohol) should be abandoned •There is a clear need for additional experimental data comparing SSI rates between CHG/alcohol and iodophor/alcohol preps, before the question of whether one or the other is superior can be answered Randomized,controlled studies (RCT) and well designed observational studies are important tools in clinical research.The results of a single RCT or observational study should be interpreted with caution1 since further investigation is needed before recommending application of the findings.At this time there is not enough clinical evidence to support a single skin prep 1Concato J et al.N Eng J Med 2000,342:1887-1892
49	Laura Haskins, Memphis Midsouth OB-GYN Alliance	Assessment	Over the last several years I have used 2% chlorhexidine with 70% isopropyl alcohol on my surgical patients with outstanding clinical outcomes. It is the best surgical prep available. I highly recommend adopting safe practice 22 as written.
51	Troy Thurmond, St. Vincent's Medical Center	Assessment	I agree that I would support liquid CHG over liquid betadine for a surgical prep. The prime reason is CHG does not have to wait to dry to begin killing action. Also the presence of blood, breaks down betadine liquid.
53	Lyn Tipton, Huntsville Hospital	Assessment	Infection Prevention @ our Organization beieves the 2% CHG with 70% IPA is the best and has the best literature that shows this.
55	Paul Durgan, St. Vincent Hospital	Assessment	I agree that the statement should remain as is. If there new evidence that becomes available, the statement can be revised as indicated. For now, the evidence supports the use of CHG.

#	Organization Contact	Topic	Comment
57	Margaret Mulcrone, Henry Ford West Bloomfield Hospital	Assessment	I do not agree with the final assessment. I think recommending one skin antiseptic product is very limited and does not meet every aspect/area of skin prepping. SP 22 should not recommend one product but instead all products and where they best serve. I think that all skin prep products possess acceptable qualities when used correctly.
58	Michelle Flood, APIC-GD	Assessment	I support the recommendation of using a skin prep with CHG and alcohol. Currently there are more well done studies that support the use of this skin prep over the alternatives.
61	Claudine DeFreytas, Huntington Hospital	Assessment	As an Infection Control Professional ,I agree with the # 3 expert that states there is overwhelming evidence of the superior effectiveness of 2% CHG and 70% alcohol
63	Paul Kearney, UKHealthcare	Assessment	There is absolutely no question that Chlorhexidine/alcolol is superior to povidone-iodine preps. The real question is whether glue based povidone-iodine-alcohol are equivalent to CHG-alcohol. The latter is a better antiseptic, it has dermal absorption. As a consequence antisepsis continues even when the surface layer is washed off.
65	Marc Chavez, Kootenai Medical Center	Assessment	I agree with technical expert #3. The overwhelming amount of evidence suggests that 2% CHG/70% IPA should replace Povidone-Iodine as the new standard for surgical-site antisepsis for appropriate surgical procedures. I have yet to find a well designed study that proves DuraPrep to be more protective than PVP. Since PVP is still the most widely used surgical skin prep, it only makes sense to create a new standard of care if a product has been proven significantly superior through well controlled, multicenter, randomized studies. Data generated from non-randomized studies, i.e. the Swenson study, should not be assessed as evidence and the author himself states, "The current study has limitations that will prevent widespread application of its findings." This study did not control multiple risk factors that affect infection. Also, compliance in regards to the assigned skin prep was only 70% at best, yet all infections were attributed to the period groups assigned. We need to take the prevention of surgical site infections seriously and let the weight of high quality evidence rule our decision in making new recommendations.

#	Organization Contact	Topic	Comment
66	Bernard Rosenfeld, Women's Hospital of Texas	Assessment	As a surgeon, I agree completely the evidence based medicine risk benefit ratio should demand the CHG-alcohol should replace povidone-iodine preoperative routine skin antisepsis. As a surgeon we depend on our colleagues in the Infection disease Department to recommend best preoperative practices to prevent surgical site infections. I agree completely with Dr. Dickema wrote in Journal Watch Infectious diseases. That CHG- alcohol which is about preferred for skin preparation before I.V. Catheter placement should now replace povidone-iodine for preoperative skin asepsis. CHG-alcohol should now be standard of care. A future 4 year prospective study to compare CHG- alcohol to povidone-iodine would be unethical as the povidone-iodine group would need to be informed that there is only and 4 in 1000 chance (p0.004) that CHG-ALCOHOL does not prevent surgical site infections better than povidone-iodine. All of the hospitals in the Texas Medical Center have now replaced povidone-iodine with CHG-alcohol as the standard preoperative scrub when appropriate. My nursing staff has conducted a phone survey to 65 of the largest United States hospitals Infectious Disease Departments and found over 20 % have recently switched to CHG-alcohol since the New England Journal article was published. It is obvious that they would not have switched to this new costly skin preparation if they reviewed the evidence and felt this was the correct action.
67	Donna Seidel, Orlando Health	Assessment	GYN OR changed to CHG/alcohol prep as part of a care "bundle" with a resulting surgical site infection rate of <1%
69	Molly McBrayer, Roper St. Francis Healthcare	Assessment	CHG-alcohol skin preparation is a superior product with proven efficacy in reducing surgical site infections. With a log reduction of 48+ hours, the CHG-alcohol product outpreforms the iodine-alcohol product in persisence for resident bacteria. I personally have requested CHG-alcohol skin preparation for myself and my family as well as my patients. If able to use an acohol-based product for a specific surgical procedure, I recommend CHG-alcohol tincture product. In those procedures in which CHG should not be used, such as with any potential contact with meninges, the iodine-alcohol product is superior rather than iodine-based without the tincture alcohol.
70	Ary Habig, Gulf Breeze Hospital	Assessment	CHG is persistent activity after application, iodine based products do not.
71	Ary Habig, Gulf Breeze Hospital	Assessment	CHG is effective in the prescence of blood, iodine based products are not.
72	Ary Habig, Gulf Breeze Hospital	Assessment	CHG is persistent activity after application, iodine based products do not.

#	Organization Contact	Topic	Comment
74	Bernard Rosenfeld, Women's Hospital of Texas	Assessment	The major concern about CHG-alcohol is that it is significantly more expensive that povidone-iodine. This is not true in July 2010. While the wholesale price of generic CGH-alcohol is $54.99 the generic price of providone is $55.79. This should not be a contest between representatives of 3M and Cardinal Health, but a broad scientific inquiry of the evidence. CHG-alcohol should replace povidone-iodine as the routine surgical scrub.
75	Tricia Kassab, City of Hope	Assessment	What is being challenged is a previous decision to use chlorhexidine gluconate 2% and isopropyl alcohol solution as the preferred preoperative skin preparation as part of Saafe Practice #22. What I understand we as NQF members are being asked to comment on is whether there is sufficient evidence to sustain the original decision. A majority of the technical experts concluded that the evidence was insufficient to determine whether one solution was superior to the other. Based on my review of the submitted evidence, I would agree with the majority opinion of the technical experts. I have no constructive comments to offer that were not already part of the technical experts review. From a data collection perspective, preoperative skin preparations are documented in our Nursing Intraoperative record under prep solutions. I believe that this document is printed from our SIS or surgery documentation system. There does not appear to be any documentation of the drying time.
76	Sherrie Mannarino, RoperSt.Francis Healthcare	Assessment	From my clinical perspective, the use of Chloraprep for prepping the surgical incision is valid and warranted. Although I do not have data at my fingertips, the incidence of surgical site infections among cardiac patients has dramatically been reduced since the inception of Chloraprep use. Additionally, the majority of orthopedic surgeons have converted from betadine to Chloraprep. This practice change has resulted in improved patient outcomes.
77	Neil Zaboy, ranciscan Health System	Assessment	Currently the best available evidence supports the use of CHG in many cases. Since CHG is a comparaelatively new product and has had to demonstrate safety, efficacy and effectiveness more recently, whereas iodine-alcohol and other formulations were grandfathered as an accepted practice, it would be prudent to put Iodine- alcohol and other products through a comparative accelerated new product or orphan drug type review. NPSG 22 should stand as written until additional comparable supporting evidence for other products is accepted and reviewed.

#	Organization Contact	Topic	Comment
78	Rita Munley Gallagher, PhD, RN, American Nurses Association	Assessment	The American Nurses Association (ANA) concurs with the need for additional clinical study before the NQF Safe Practices can recommend one prep over another. It is ANA's understanding that both CHG-alcohol and iodine-based + alcohol solutions used for skin antisepsis have very similar properties. Therefore, ANA would support the recommendation that NQF not specify a particular agent, but instead emphasize the requirements for broad spectrum activity, rapid action, persistent/residual activity and safety both in patient application and environmental use. Given the dynamic nature of the Safe Practices, ANA respectfully suggests that NQF qualify the statement with the understanding that when new data are presented that show one product to be superior to all others a revised practice statement will be issued.
79	Stephen Lewis, CareFusion	Assessment	A justification for review is that "there is evidence that implementation of the measure in practice may result in inappropriate or harmful care. The evidence obtained from a randomized multicenter trial (Darouiche, NEJM Jan 2010) showed a 40% reduction in surgical site infection rates in clean-contaminated surgery with use of 2% chlorhexidine gluconate and isopropyl alcohol (CHG). Using the definitions for clean-contaminated surgery from the Darouiche study, we estimated the number of such cases in the nationwide sample contained in the 2007 AHRQ Healthcare Cost and Utilization Project data to be 2,085,981 such cases. The Darouiche study showed a 6.6% absolute SSI rate reduction favoring use of CHG. This translates into 137,675 preventable SSIs and 1,377 preventable deaths annually. An estimate of $12,197 (Kilgore, Medical Care Jan 2008) for the incremental cost per HAI, suggests an annual potential cost saving to the healthcare system of $1,679,218,877. A decision to strike mention of CHG in Safe Practice 22 while awaiting further prospective trials would expose clean-contaminated surgery patients in the U.S to needless risk. Hence, we propose amending it to read: In clean-contaminated surgical cases, use chlorhexidine gluconate 2% and isopropyl alcohol solution preoperatively as the skin antiseptic preparation when not contraindicated. (See submitted supportive document CareFusion_SP22_Response)

#	Organization Contact	Topic	Comment
80	Stephen Lewis, CareFusion	Assessment	As part of the expert review, reviewer #3 commented that "recent excellent evidence, in the form of a randomized controlled clinical trial, has supported the use of CHG-alcohol as preferable to povidone-iodine in the context of general surgical cases, primarily abdominal." Reviewer 3 went on to comment on the methodological issues surrounding the Swenson study (Swenson ICHE October 2009) and concluded "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." This is strongly supportive of the original recommendation. Thus, we are surprised that in the face of a split decision and with evidence from a prospective trial, a decision to strike comment regarding CHG in SP 22 was made. We strongly suggest that rather than striking CHG in Safe Practice 22 it be amended to read: In clean-contaminated surgical cases, use chlorhexidine gluconate 2% and isopropyl alcohol solution preoperatively as the skin antiseptic preparation when not contraindicated. (See submitted supportive document CareFusion_SP22_Response
83	Arely Rego, Doctors Hospital, Baptist Health South Florida	Assessment	There is substantial evidence that supports the use of 2% chlorhexidine gluconate + 70% isopropyl alcohol as skin prep as opposed to iodine-based preps to prevent catheter-related blood stream infections. The Darouiche study is further evidence supporting the use of this combination in the OR. By implementing the 2% CHG + 70% IPA combination as the skin prep of choice in my facility, the incidence of catheter related blood stream infections has been reduced significantly. It is my belief that the same combination would also reduce surgical site infections in the OR, and should therefore be recommended in the NQF Safe Practices.
84	Rebecca Zimmermann, AHIP	Assessment	AHIP appreciates the opportunity to provide comments on the Ad Hoc review of Safe Practice #22, Surgical Site Infection. Given the currently available evidence, the inclusion of chlorhexidine gluconate 2% and isopropyl alcohol solution in the Safe Practice appears to be overly prescriptive. We support a revision to Safe Practice #22 to recommend appropriate perioperative skin preparation and removal of language supporting one specific technique of skin preparation.

#	Organization Contact	Topic	Comment
85	Ron Walters, The University of Texas MD Anderson Cancer Center	Assessment	Based on the information presented, we agree that the recommended single approach (CHG 2% with isopropyl alcohol solution) for preoperative SSI prevention is inappropriate. First, the recommendation is to use isopropyl alcohol, which is flammable and has a warning label, instead of something that might be safer. The danger of flammability, while low, is real and profound and accordingly must be given due consideration. Additionally, CHG and alcohol are not appropriate for all surgical sites and applications. For example, CHG is contraindicated for use in or around the eyes, ears, mucous membranes or dura. Reports of blindness and deafness after contact in the eyes or ears have been reported. The head and neck is an area of high vascularity, and for clean cases the risk of an SSI is 1% or less. For clean-contaminated cases the risk is higher, but the source of wound contamination during surgery is from mucosally-based flora. Prophylactic antibiotics are used to target these organisms. Intuitively, skin flora are not a significant source of pathogens in these cases.
86	Ron Walters, The University of Texas MD Anderson Cancer Center	Assessment	The literature concerning surgical skin preparation is quite extensive comparing different combination of preps to different outcomes in various populations. The majority of studies compare "single" agents (chlorhexidine or povidone-iodine) against one of the alcohol combination preparations; of note, the studies show evidence which support the combination preparations. Rather than endorsing a single approach, NQF guidelines should support the evidence and state that skin preparations combined with alcohol have been shown to be more effective than single agent preparations in preventing surgical site infections. At this time, there are no controlled-randomized studies that compare the combination preparations of chlorhexidine-alcohol and iodine-alcohol. The Darouiche paper, being level-one evidence, only shows that CHG/alcohol is better than povidone-iodine. No data supports the non-use of other alcohol-containing preps. Therefore, there is insufficient evidence to support one combination skin preparation over another preparation. Prior to sweeping implementation as a general recommendation, the findings of the Darouiche study should be verified by follow-up studies since the data are not entirely clear for all surgical sites/applications of overwhelming superiority of one agent.

#	Organization Contact	Topic	Comment
87	Nancy H. Nielsen, MD, PhD, American Medical Association	Assessment	The American Medical Association (AMA) is pleased to have the opportunity to comment on the National Quality Forum's (NQF) Ad Hoc Review of Safe Practice 22, Surgical-site Infection Prevention. The AMA appreciates that NQF has put an ad hoc review process in place, and believes it is important to reassess safe practices, performance measures, and other recommendations that emerge from the work of NQF when new evidence becomes available. With respect to Safe Practice 22, the AMA also agrees with a less prescriptive safe practice approach allowing multiple antiseptic preparation agent options. It appears that the evidence-base is inconclusive and a more inclusive approach is appropriate at this point. However, we believe it is imperative that as new evidence becomes available this safe practice is reviewed once again. We appreciate the opportunity to comment on this report.

CareFusion

AUG 0 3 2010

July 13, 2010

Janet M. Corrigan, PhD, MBA
National Quality Forum
601 Thirteenth St, NW
Suite 500 North
Washington, DC 20005

RE: Open member comment on the Ad Hoc Review of Safe Practice 22, Surgical-site Infection Prevention

Dear Dr. Corrigan,

As a member of the NQF Supplier Council, CareFusion would like to comment on the Ad Hoc Review of Safe Practice No. 22. This review was conducted according to NQF procedures in response to a challenge. The challenge argued that both criteria for review were met.

Criterion 1: The evidence supporting the measure focus has changed and the measure does not reflect updated evidence.

Criterion 2: There is evidence that implementation of the measure or practice may result in unintended consequences:

The external review by three experts was not unanimous and differed in important ways that we will address. The NQF is now seeking additional input prior to making a formal decision. We would concur that the original text for Safe Practice 22 was too broadly worded. In this vein, we would agree with the comments of reviewer #2 who suggested that recommending a single skin preparation across the board is not appropriate. However, striking this recommendation entirely is equally inappropriate. Our recommendation would be to draft a more specific recommendation in the spirit of comments by reviewer #3 by amending the text to read:

In clean-contaminated surgical cases, use chlorhexidine gluconate 2% and isopropyl alcohol solution preoperatively as the skin antiseptic preparation when not contraindicated.

To support this position, it is useful to examine the underlying clinical evidence and the expert review surrounding the issues for both Criteria 1 and Criteria 2. In taking this approach, we will strive to make the points that the evidence does exist for a more limited recommendation for use in clean-contaminated surgery (Criteria 1) and that failure to make such a recommendation may result in unintended consequences (Criteria 2).

All three reviewers commented on the current evidence and 3M in their challenge also commented on the key clinical studies. Prior to examining those studies, it is valuable to point out the underlying biological mechanisms that created the rationale for examining differences among various skin preparations. Chlorhexidine has been studied extensively regarding its ability to reduce colony counts on skin surfaces.[1,2,3] A prospective study conducted at the University of California, San Diego[4] examined colonization rates in foot and ankle surgery, a site that has been shown to have high post-operative infection rates. Quantitative cultures were obtained from the heel, toe and a control site on the leg following random selection of one of three skin preparations, Techni-Care (3.0% chloroxylenol), DuraPrep™ (iodine-povacrylex) and ChloraPrep® (2% chlorhexidine/70% isopropyl alcohol). The colonization rates for the hallux and toe and control sites were 95%, 98% and 35% for the Techni-Care group, 65%, 45% and 23% for the DuraPrep™ group and 30%, 23% and 10% for the ChloraPrep® group, respectively. These colonization data as well as the classic 1991Maki[5] trial support the clinical practice of including the chlorhexidine molecule in the bundles used for insertion and management of blood stream infections associated with the use of central venous catheters.[6,7] Furthermore, they contributed to the rationale for the study by Darouiche[8] et al. to test chlorhexidine and 70% alcohol in surgical site infections (SSI). We are in concert with the reviewer #3 who commented that "*recent excellent evidence, in the form of a randomized controlled clinical trial, has supported the use of CHG-alcohol as preferable to povidone-iodine in the context of general surgical cases, primarily abdominal.*" This study was a multicenter prospective randomized clinical trial including 849 patients and was the lead article in the January 7, 2010 issue of the New England Journal of Medicine. The study tested povidone-iodine against 2% chlorhexidine in 70% alcohol undergoing clean-contaminated surgery, using any form of surgical site infection thirty days post-operatively as the primary outcome. The results were striking. The surgical site infection rate in the chlorhexidine group was 9.5% compared with 16.1% in the povidone-iodine group. This equates to a relative risk of 0.59 (0.41-0.85 95%CI) in favor of the chlorhexidine group. The number-to-treat estimate, that is, the number of patients that required treatment to prevent an SSI, was only 17.[9] Of note, the Kaplan-Meier curves begin to diverge on post-operative day 4 and the difference continued to widen over the remainder of the thirty days of follow-up.

The counterpoint comes from a study by Swenson et al.[10] published in the October 2009 issue of Infection Control and Hospital Epidemiology, prior to the NEJM publication[9]. This single center study was neither randomized nor controlled but examined rates in three sequential periods using three different skin disinfectant regimens. They reported higher SSI rates, 4.8% (68 of 827) versus 8.2% (110 of 2308) in the chlorhexidine group than in the combined povidone-iodine/povacrylex group (p = 0.001). This study suffers from design issues. For example, the cross-over among the 3 regimens was substantial as shown in Table 1 of the paper and reproduced in the table below:

Preparation Used	Period 1 (n = 987)	Period 2 (n = 994)	Period 3 (n = 1,228)
Povidone-Iodine	970 (98.3%)	261 (26.3%)	283 (23.0%)
Chlorhexidine	2 (0.2%)	699 (70.3%)	126 (10.3%)
Iodine povacrylex	0 (0%)	0 (0%)	794 (64.7%)
Other	15 (1.5%)	34 (3.4%)	25 (2.0%)

This degree of cross-over may contribute to considerable selection bias. The baseline rates between the Swenson and Darouiche studies are also different. Except for the first period between one fourth and one third of cases fell into a treatment group that was not intended for

that interval. Furthermore, the data were not analyzed by intention to treat and all cases in all intervals were reported in the summary tables. The closest direct comparison between similar patients in both studies can be found in the data in table 4 of the Swenson study where the rates found in clean-contaminated cases can compared in the povidone-iodine group versus the chlorhexidine group. The rate in the povidone-iodine group was 44 infections in 541 procedures (8.1%) versus 46 infections in 454 (10.1%) procedures in the chlorhexidine group ($p = 0.274$ Chi-square), essentially no difference. This is the explicit comparison where Darouiche found a relative risk of 0.59 with a controlled randomized study. This raises immediate concerns. There are always issues with poorly controlled studies where unmeasured differences contribute to the measured outcome other than the intended intervention. For example, the period with the highest rates also happens to be a six month period beginning with July 1 whereas the other two periods run from January 1 to June 30. It is possible that house staff changes in a large teaching hospital are contributing to the observed rate differences across the three periods instead of the antiseptic agents used.

Table 2 in the Swenson study also allows some insights into flaws in the study's design. For instance, the 1,459 clean contaminated cases are not broken down by period. There were 970 povidone-iodine cases in period one, 261 cases in period two and 283 cases in period three. Unfortunately, despite the rather large number of cases in each of the three time periods, there are no data to show rate changes for this single disinfectant across the three periods. There were no real attempts to discuss or deal with confounding by indication in the design and analysis of this study.

The overall pair-wise comparison by combining the povidone-iodine and iodine-polyacrylex cases into one group raises two issues. First of all, it seems to contradict the biological premise from the introduction that iodine-povacrylex is different in action from povidone-iodine. Also, by combining the two groups, it could be argued that iodine-povacrylex and povidone iodine are members of the same class of agent. This logic would then imply that a direct comparison with DuraPrep™ may be unnecessary as the Darouiche study compared directly against one member of this class, povidone-iodine. By combining these two groups the argument that there is a missing direct comparison in the Darouiche study of chlorhexidine and iodine-povacrylex is weakened considerably.

Both studies received industry support, Darouiche from Cardinal Health and Swenson from 3M. The Darouiche study compared two products both produced by the same sponsor to assess potential superiority while the Swenson study examined products across competitors, one of which was a sponsor.

This is not the first instance where a properly controlled randomized trial has found results different from that of earlier non-randomized and weakly controlled studies. However, one of reviewers and the NQF summarization both alluded to further well designed randomized trials. This is not an area where one could expect multiple trials to be done. A search of the "clinicaltrials.gov" website using "chlorhexidine surgical site infection" reveals only 6 studies. Only one includes a iodine-povacrylex arm and the primary outcome is skin culture positivity not surgical site infection. This study is in recruitment at Northwestern University. In the description and justification for this study the investigators cited the work of Saltzman[11] who that showed the expected rates of skin colonization to be 7% for chlorhexidine, 31% for povidone-iodine and 19% for iodine-povacrylex.

None of the 6 listed studies directly compare surgical site infection rates in clean-contaminated surgical cases using a variety skin disinfectants. The Darouiche study took 4 years to recruit

and 2 more years to complete. To ask for another randomized trial at this point is to ask for a 6 year delay which brings us to our concerns regarding Criteria #2. What might the negative unintended consequences be if a more effective agent failed to be used for appropriate cases (clean-contaminated surgery) for the next five years?

The Agency for Healthcare Research and Quality supports a large aggregated data set known as the Healthcare Cost and Utilization Project (HCUP). HCUP is a sample of 1044 U.S. hospitals that represents 90% of all hospital admissions. Using the open access website to HCUP, HCUPnet,[2] we determined the number of clean-contaminated cases in the 2007 Nationwide Inpatient Sample. We applied the Darouiche definitions of colorectal, small intestinal, gastroesophageal, biliary, thoracic, gynecologic or urologic surgery to identify the number of clean-contaminated cases in this nationwide sample. There were 2,085,981 such cases. The Darouiche study showed a 6.6% absolute rate reduction in HAI rates favoring use of 2% chlorhexidine in isopropyl alcohol. This translates into **137,675 preventable HAIs and 1,377 preventable deaths annually**. Using the Kilgore[13] estimate of $12,197 for the incremental cost per HAI case, this suggests an **annual potential cost saving to the healthcare system of $1,679,218,877** that is possible by continuing to support the recommendation of the use of chlorhexidine gluconate 2% and isopropyl alcohol in clean-contaminated surgery. If a recommendation by the NQF only led to achieving 20% of this effect then a failure to make such a recommendation and a six year delay waiting for further studies leads right back to at least the 137,675 preventable SSIs, 1,377 preventable deaths and a preventable loss of $1,679,218,877 to the U.S. healthcare system.

The safe practices are just that, those practices that are judged to promote safety based on evidence. The evidential standard for safe practices is different from that required for public reporting or cross-hospital comparisons. Evidence Based Medicine upon which the NQF Safe Practices are built "aims to apply the best available evidence gained from the scientific method to medical decision making".[14] It seeks to assess the strength of evidence of the risks and benefits of treatments (including lack of treatment) and diagnostic tests.[15] The NQF 2010 Safe Practices Consensus Report is 396 pages in length and contains 34 safe practices divided into 9 chapter headings. Many of these practices such as Safe Practice 13 that relates to use of abbreviations have considerably less hard evidence behind them than a recommendation to amend Safe Practice 22 to support use of chlorhexidine gluconate 2% and isopropyl alcohol for skin preparation in clean contaminated surgery. The original writing regarding a recommendation for chlorhexidine was too extreme, but a complete striking of the recommendation is also too extreme as the evidence is strong in clean-contaminated surgery. Amending Safe Practice 22 making it more specific rather than striking any reference to chlorhexidine would be consistent with other recommendations contained in Safe Practice 22 such as maintenance of normothermia in colorectal surgery. An NQF decision to completely strike mention of chlorhexidine for use in clean-contaminated surgery opens the door to potentially large unintended negative consequences.

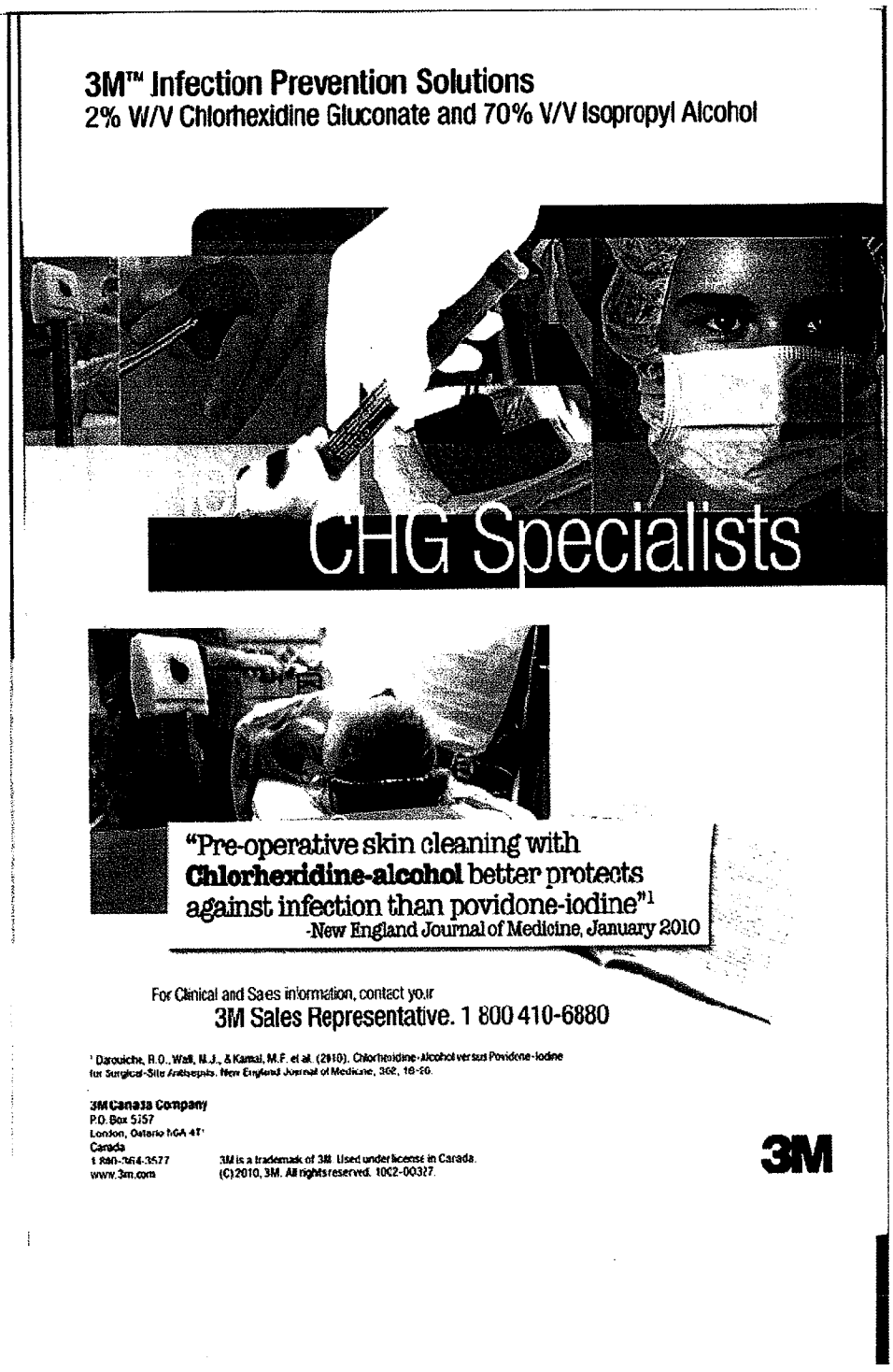
Finally, it would appear that some factions within 3M itself feel similarly. In the expert comments, reviewer #3 commented that the concerns regarding Safe Practice 22 were raised by 3M, "makers of a competing product." 3M also makes the same product, chlorhexidine gluconate 2% and isopropyl alcohol but it is only licensed in Canada and has not received FDA approval in the U.S. Their advertising in Canada (see figure 1 on the following page) that presents 3M as "CHG Experts" directly quotes the Darouiche paper stating that "preoperative skin cleaning with chlorhexidine-alcohol better protects against infection than povidone-iodine." We agree.

In conclusion, we respectfully submit that a decision to strike mention of chlorhexidine from Safe Practice 22 and the original text that prompted the review are both equally poor as final decisions . We strongly recommend that the NQF not strike the text referable to chlorhexidine but rather amend Safe Practice 22 to read: **In clean-contaminated surgical cases, use chlorhexidine gluconate 2% and isopropyl alcohol solution preoperatively as the skin antiseptic preparation when not contraindicated.**

Best Regards,

Stephen R. Lewis, M.D.
Chief Medical Officer
Senior Vice President
858-617-2105
Steve.lewis@carefusion.com

Figure 1


3M™ Infection Prevention Solutions
2% W/V Chlorhexidine Gluconate and 70% V/V Isopropyl Alcohol
CHG Specialists
"Pre-operative skin cleaning with Chlorhexidine-alcohol better protects against infection than povidone-iodine"1
-New England Journal of Medicine, January 2010
For Clinical and Sales information, contact your
3M Sales Representative. 1 800 410-6880
1 Darouiche, R.O., Wall, M.J., & Kamal, M.F. et al. (2010). Chlorhexidine-Alcohol versus Povidone-Iodine for Surgical-Site Antisepsis. New England Journal of Medicine, 362, 18-26.
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3M Health Care Business
3M Center
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March 11, 2010

Janet Corrigan, PhD, MBA
President and CEO
National Quality Forum
601 Thirteenth St, NW
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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:

- Clinical Evidence. 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.

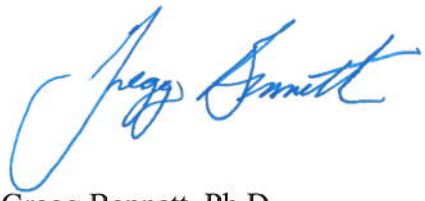
- Additional Limitations/Contradictions. Surgical skin antiseptics containing alcohol are limited in application due to contra-indications for use in open wounds and mucosal tissue. CHG antiseptics are further contra-indicated for use in procedures involving potential exposure to meninges (spine, epidurals, 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:
  - CHG 4% solution
  - PVP-I solution
  - 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,



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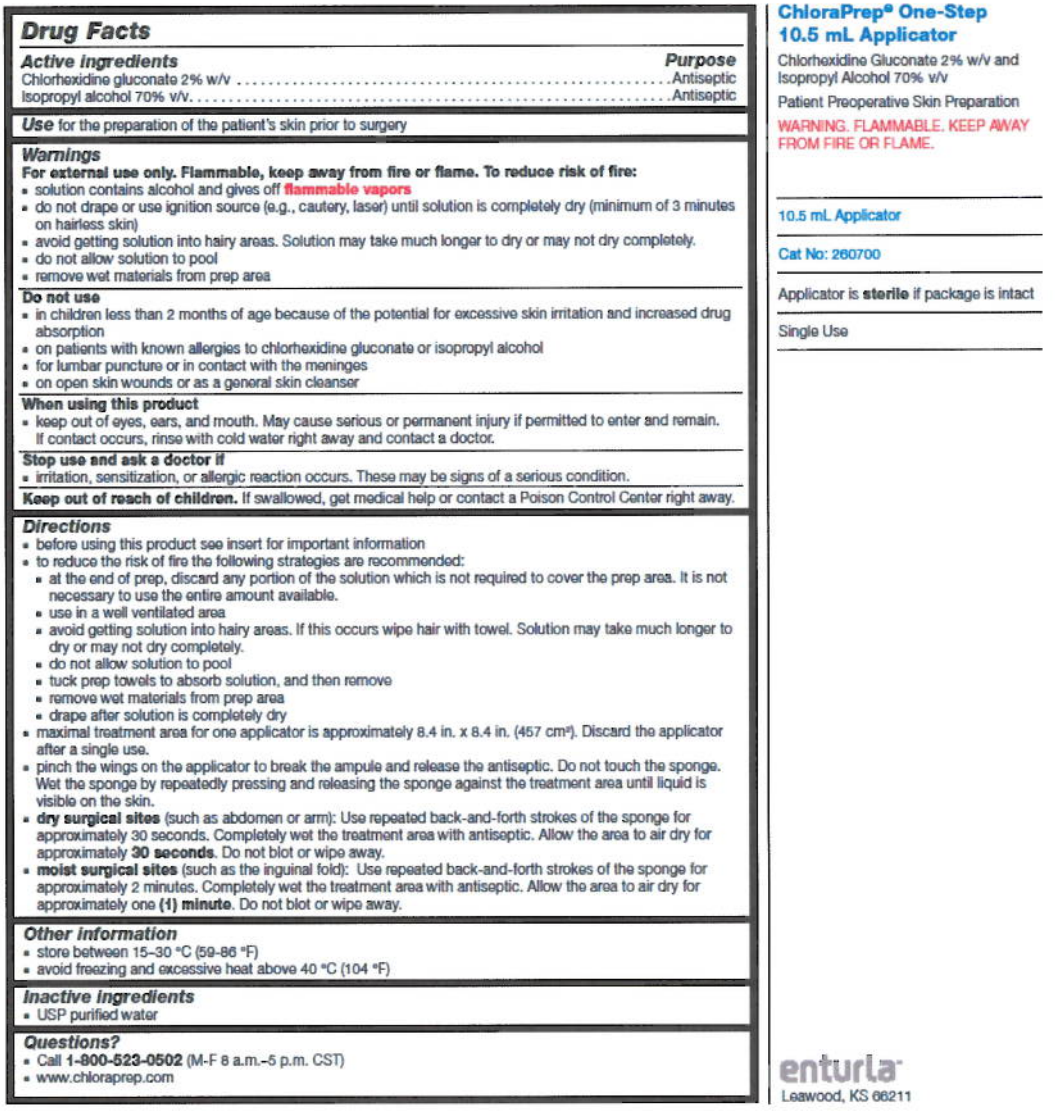
3. National Health Statistics Reports, Number 5, July 30, 2008. Tables 8, 9, 10.

Attachment 1



Drug Facts

Active ingredients	Purpose
Chlorhexidine gluconate 2% w/v	Antiseptic
Isopropyl alcohol 70% v/v	Antiseptic

Use for the preparation of the patient's skin prior to surgery

Warnings

For external use only. Flammable, keep away from fire or flame. To reduce risk of fire:

- solution contains alcohol and gives off **flammable vapors**
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin)
- avoid getting solution into hairy areas. Solution may take much longer to dry or may not dry completely.
- do not allow solution to pool
- remove wet materials from prep area

Do not use

- in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption
- on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol
- for lumbar puncture or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product

- keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

Stop use and ask a doctor if

- irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- before using this product see insert for important information
- to reduce the risk of fire the following strategies are recommended:
  - at the end of prep, discard any portion of the solution which is not required to cover the prep area. It is not necessary to use the entire amount available.
  - use in a well ventilated area
  - avoid getting solution into hairy areas. If this occurs wipe hair with towel. Solution may take much longer to dry or may not dry completely.
  - do not allow solution to pool
  - tuck prep towels to absorb solution, and then remove
  - remove wet materials from prep area
  - drape after solution is completely dry
- maximal treatment area for one applicator is approximately 8.4 in. x 8.4 in. (457 cm^2). Discard the applicator after a single use.
- pinch the wings on the applicator to break the ampule and release the antiseptic. Do not touch the sponge. Wet the sponge by repeatedly pressing and releasing the sponge against the treatment area until liquid is visible on the skin.
- **dry surgical sites** (such as abdomen or arm): Use repeated back-and-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately **30 seconds**. Do not blot or wipe away.
- **moist surgical sites** (such as the inguinal fold): Use repeated back-and-forth strokes of the sponge for approximately 2 minutes. Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately one **(1) minute**. Do not blot or wipe away.

Other information

- store between 15–30 °C (59–86 °F)
- avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients

- USP purified water

Questions?

- Call **1-800-523-0502** (M-F 8 a.m.–5 p.m. CST)
- www.chloraprep.com

ChloraPrep® 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

enturia

Leawood, KS 66211

The Objective

Prevent healthcare-associated surgical-site infections (SSIs).

The Problem

Traditional infection control programs are directionally correct, but insufficient to enable organizations to "chase zero" and reduce the harm of preventable healthcare-associated infections (HAIs). [Denham, 2009a; Denham, 2009b] Certifying, purchasing, and quality organizations agree that such departments need to be restructured and integrated into performance improvement programs. [Denham, 2009c] It is estimated that nearly 2 million patients experience a healthcare-associated infection each year; of these infections, 22 percent are SSIs. [Klevens, 2007] SSIs are infections that occur within 30 days after an operation and can involve the skin, subcutaneous tissue of incision, fascia, muscular layer, or the organ or surrounding space.

SSIs have the second highest frequency of any adverse event occurring in hospitalized patients and are the third most common health-care-associated infection (HAI). Approximately 500,000 SSIs occur each year in 2 to 5 percent of patients undergoing inpatient surgeries. [Anderson, 2008] Estimated rates for operative wound classifications are as follows: clean contaminated cases 3.3 percent, contaminated cases 6 percent, and dirty cases 7.1 percent. The national rate of SSI averages between 2 and 3 percent for clean cases, and an estimated 40 to 60 percent of these infections are preventable. [Kirkland, 1999; de Lissovoy, 2009]

The severity of SSI harm to patients is significant, resulting in increased mortality, readmission rate, length of hospital stay, and cost for patients who incur them. [Levinson, 2008] Each SSI is associated with an average of 9.7 additional postoperative hospital days. [Cruse, 1980; Cruse, 1981; de Lissovoy, 2009] According to the American Heart Association, approximately 700,000 open-heart procedures are performed each year in the United States; more than 67 percent of those are coronary artery bypass grafts (CABG). Mediastinitis can occur after an open-heart surgical procedure with rates of between 0.5 and 5.0 percent, with a mortality rate as high as 40 percent. In 2006, 2.7 percent of Medicare patients acquired postoperative pneumonia or a thromboembolic event. [AHRQ, 2009b] Patients with SSI have a 2 to 11 times higher risk of death

compared to operative patients without SSI. [Kirkland, 1999; Engemann, 2003] Approximately 8,205 patients die from an SSI each year. [Klevens, 2007] Seventy-seven percent of deaths in patients with an SSI are directly attributable to the infection. [Mangram, 1999]

The preventability of SSIs has been studied, and guidelines and recommendations for their prevention have been published by multiple professional organizations; the key recommended practices are consistent among them. [Anderson, 2008; WHO, 2008; WHO, 2009] These include: 1) proper selection and administration of antimicrobial prophylaxis, as well as timely discontinuation postoperatively; [Mangram, 1999; Bratzler, 2004; Bratzler, 2006; Kirby, 2009; Pan, 2009; Quinn, 2009] 2) avoidance of hair removal at the operative site, unless the presence of hair will interfere with the operation; [Mangram, 1999] and 3) maintaining blood glucose level at less than 200 mg/dL in patients undergoing cardiac surgeries. [Bratzler, 2006] The use of specific skin preparation solutions has been shown to reduce SSI by 40 percent. [Darouiche, 2008; Darouiche, 2010] Surveillance for SSI should be performed, and ongoing findings and feedback should be communicated to surgical personnel and organizational leadership. [Anderson, 2008]

Costs of SSIs vary depending on the type of operative procedure and the type of infecting pathogen; published estimates range from $3,000 to $29,000. [Coello, 1993; Vegas, 1993; Kirkland, 1999; Hollenbeak, 2000] However, the recent Pennsylvania Health Care Cost Containment Council found that the median cost of an SSI was $153,132, compared to a hospital stay with no infection of $33,260, resulting in an increased cost per patient of $119,872. [PHC4, 2008] Using the consumer price index for inpatient hospital services, the aggregate attributable hospital costs due to SSI range from $11,874 to $34,670 in 2007 dollars. [Scott, 2009] Using the 2005 Healthcare Cost and Utilization Project National Inpatient Sample (HCUP NIS) database, 6,891 cases of SSI were identified. On average, SSI extended the length of stay by 9.7 days, with an increase in cost of $20,842 per admission. Nationally, these SSI cases contributed to an additional 406,730 hospital days and hospital costs exceeding $900 million. Readmissions of 91,613 patients for treatment of SSI accounted for 521,933 days at a cost of nearly $700 million. [de Lissovoy, 2009] Sub-classifying analysis of SSIs into superficial incisional, deep

incisional, and organ/space categories will provide better precision in cost forecasting and a reality check to performance improvement cost-benefit assessments. [Anderson, 2008]

Beginning October 1, 2008, the Centers for Medicare & Medicaid Services (CMS) has selected SSIs, including mediastinitis after CABG; certain orthopedic procedures (spine, neck, shoulder, elbow); and bariatric surgery for obesity (laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery); as hospital-acquired conditions that will no longer receive a higher reimbursement when not present on admission. [CMS/HAC, 2008]

There is intense research of HAIs, and it will take time to understand the absolute magnitude of preventability and the value of risk assessment methods; however, there is full consensus that actions need to be taken now to reduce SSIs with what is currently known. [Denham, 2005; Denham, 2009d]

Safe Practice Statement

Take actions to prevent surgical-site infections by implementing evidence-based intervention practices. [Mangram, 1999; WHO, 2008; IHI, 2009b; JCR, 2010]

Additional Specifications

- Document the education of healthcare professionals, including nurses and physicians, involved in surgical procedures about healthcare-acquired infections, surgical-site infections (SSIs), and the importance of prevention. Education occurs upon hire and annually thereafter, and when involvement in surgical procedures is added to an individual's job responsibilities. [Bratzler, 2004; Bratzler, 2006; TMIT, 2008; Chatzizacharias, 2009; Rosenthal, 2009]
- Prior to all surgical procedures, educate the patient and his or her family as appropriate about SSI prevention. [Torpy, 2005; Schweon, 2006]
- Implement policies and practices that are aimed at reducing the risk of SSI that meet regulatory requirements, and that are aligned with evidence-based standards (e.g., CDC and/or professional organization guidelines). [Mangram, 1999; Dellinger, 2005; Bratzler, 2006; Anderson, 2008; WHO, 2009]

- Conduct periodic risk assessments for SSI, select SSI measures using best practices or evidence-based guidelines, monitor compliance with best practices or evidence-based guidelines, and evaluate the effectiveness of prevention efforts. [Bratzler, 2006]
- Ensure that measurement strategies follow evidence-based guidelines, and that SSI rates are measured for the first 30 days following procedures that do not involve the insertion of implantable devices, and for the first year following procedures that involve the insertion of implantable devices. [Horan, 1992; Biscione, 2009]
- Provide SSI rate data and prevention outcome measures to key stakeholders, including senior leadership, licensed independent practitioners, nursing staff, and other clinicians. [Mangram, 1999]
- Administer antimicrobial agents for prophylaxis with a particular procedure or disease according to evidence-based standards and guidelines for best practices. [ASHP, 1999; Mangram, 1999; Antimicrobial, 2001; IHI, 2009a]
  - Administer intravenous antimicrobial prophylaxis within one hour before incision to maximize tissue concentration (two hours are allowed for the administration of vancomycin and fluoroquinolones). [Bratzler, 2004; Bratzler, 2006]
  - Discontinue the prophylactic antimicrobial agent within 24 hours after surgery (within 48 hours is allowable for cardiothoracic procedures). [Bratzler, 2004; Bratzler, 2006]
- When hair removal is necessary, use clippers or depilatories. Note: Shaving is an inappropriate hair removal method. [Mangram, 1999]
- Maintain normothermia (temperature >36.0°C) immediately following colorectal surgery. [Kurz, 1996]
- Control blood glucose during the immediate postoperative period for cardiac surgery patients. [Bratzler, 2006; Dronge, 2006; Kao, 2009]
- **Preoperatively, use chlorhexidine gluconate 2% and isopropyl alcohol solution as skin antiseptic preparation, and allow appropriate drying time per product guidelines.** [Darouiche, 2008; Darouiche, 2010]

Applicable Clinical Care Settings

This practice is applicable to Centers for Medicare & Medicaid Services (CMS) care settings, to include ambulatory surgical center and inpatient service/hospital.

Example Implementation Approaches

- Perform expanded SSI surveillance to determine the source and extent of high SSI rates despite implementation of basic SSI prevention strategies. Consider expanding surveillance to include additional procedures, and possibly all National Healthcare Safety Network (NHSN) procedures. [Mangram, 1999]
- Implementation of the WHO 19-item surgical safety checklist has been estimated to save the lives of 1 in 144 surgical patients. [Haynes, 2009]
- Hospitals that have been successful in reducing SSIs have incorporated some, if not all, of the following elements as part of their prevention strategies and approaches: [Graf, 2009]
  - Appropriate and timely use of prophylactic antibiotics. [AHRQ, 2009a; AHRQ, 2009b; Pan, 2009; Ryckman, 2009]
  - Identify and treat all infections remote to the surgical site before elective surgery, and postpone elective surgeries until the infection has resolved.
  - Utilize mechanical and intraluminal antibiotic bowel preparation for patients undergoing elective colorectal surgery, as appropriate per patient clinical case. The literature is evolving and patients should be treated according to the latest evidence based practices. [Wille-Jørgensen, 2005; Guenaga, 2009; Howard, 2009; Slim, 2009]
  - Administer a prophylactic antimicrobial agent to patients, based on published guidelines and recommendations targeting the most common pathogens for the planned procedure.
  - Give appropriate weight-based guideline antibiotic dosing.
  - Ensure optimal antibiotic concentration by redosing based on antimicrobial agent half-life and length of procedure.
  - Utilize an intravenous route to administer prophylactic antimicrobial agents and antibiotics so that a bactericidal concentration is established in serum and tissues

when the incision is made (except for cesarean delivery, when antibiotics should be administered after cord clamp).

1. Give an intraoperative dose of antibiotic as indicated based on pharmacokinetics of the antibiotic and length of the surgical procedure.
2. If a cuff or tourniquet is used, fully infuse the antibiotic prior to inflation.
3. Use preprinted or computerized standing orders that specify antibiotic, timing, dose, and discontinuation.
4. Change operating room drug stocks to include only standard doses and standard drugs that reflect national guidelines.
5. Assign antibiotic dosing responsibilities to the anesthesia or holding area nurse to improve timeliness.
6. Use visible reminders, checklists, and stickers.
7. Involve pharmacy, infection control, and infectious disease staff to ensure appropriate selection, timing, and duration.

- Appropriate hair removal:
  - Remove hair from the incision site only if the hair interferes with the operation.
  - Educate patients not to shave themselves preoperatively. [Pan, 2009]
- Appropriate skin preparation:
  - Chlorhexidine gluconate 2% skin solutions have been shown to be more effective than iodine in reducing SSI. [Darouiche, 2008; Eiselt, 2009; Darouiche, 2010]
- Maintenance of postoperative glucose control:
  - Implement a glucose control protocol.
  - Regularly check preoperative blood glucose levels on all patients.
  - Assign responsibility and accountability for blood glucose monitoring and control.
- Establish postoperative normothermia, and maintain perioperative euthermia, based on the constellation of benefits beyond SSI for colorectal surgery patients.
  - Use warmed forced-air blankets preoperatively, during surgery, and in the post-anesthesia care unit (PACU).

- Increase the ambient temperature in the operating room.
- Use warming blankets under patients on the operating table.
- Use hats and booties on patients perioperatively.

Strategies of Progressive Organizations

- Some organizations advocate maintaining perioperative glucose at specific target levels for patients with Type 1 Diabetes and for those who have Type 2 Diabetes with insulin deficiency.
- Establish implementation of perioperative supplemental oxygen therapy. [Casey, 2009; Qadan, 2009]

Opportunities for Patient and Family Involvement [Denham, 2008; SHEA, N.D.]

- Consider including patients or families of patients who have experienced an SSI to serve on appropriate patient safety or performance improvement committees.
- Teach patients and families the proper care of the surgical site, as well as precautions for preventing infection.
- Teach patients and families to recognize the signs and symptoms of infection.
- Encourage patients to report changes in their surgical site or any new discomfort.
- Encourage patients and family members to make sure that doctors and nurses check the site every day for signs of infection.
- Invite patients to ask staff if they have washed their hands prior to treatment.
- Encourage patients and family members to ask questions before a surgical procedure is performed.

Outcome, Process, Structure, and Patient-Centered Measures

These performance measures are suggested for consideration to support internal healthcare organization quality improvement efforts, and may not necessarily all address external reporting needs.

- **Outcome Measures** include trending the rate of SSIs per procedure over time and reporting SSIs as part of a multicenter registry, for example, NHSN. [NHSN, N.D.]

Also consider trending operational and financial outcomes associated with reduction in SSI patient complications. Use NHSN definitions where appropriate. [NHSN, N.D.]

- National Quality Forum (NQF)-endorsed® outcome measures:
  1. #0130: Deep Sternal Wound Infection Rate [Hospital]: Percent of patients undergoing isolated CABG who developed deep sternal wound infection within 30 days post-operatively.
  2. #0299: Surgical-site infection rate [Hospital]: Percentage of surgical site infections occurring within thirty days after the operative procedure if no implant is left in place or with one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure.
  3. #0450: Postoperative DVT or PE: Percent of adult surgical discharges with a secondary diagnosis code of deep vein thrombosis or pulmonary embolism.

- **Process Measures** include periodic assessment of compliance with all components of the prevention bundle, with actions to mitigate performance gaps.
  - NQF-endorsed® process measures:
    1. #0125: Timing of Antibiotic Prophylaxis for Cardiac Surgery Patients [Hospital]: Percent of patients undergoing cardiac surgery who received prophylactic antibiotics within one hour prior to of surgical incision (two hours if receiving vancomycin).
    2. #0126: Selection of Antibiotic Prophylaxis for Cardiac Surgery Patients [Hospital]: Percent of patients undergoing cardiac surgery who received prophylactic antibiotics recommended for the operation.
    3. #0128: Duration of Prophylaxis for Cardiac Surgery Patients [Hospital]: Percent of patients undergoing cardiac surgery whose prophylactic antibiotics were discontinued within 24 hours after surgery end time.
    4. #0264: Prophylactic Intravenous (IV) Antibiotic Timing [Hospital, Ambulatory Surgical Centers]: Percentage of ASC patients who received IV antibiotics ordered for surgical site infection prophylaxis on time.

5. #0269: Timing of Prophylactic Antibiotics - Administering Physician [Hospital, Ambulatory Surgical Centers]: Percentage of surgical patients aged > 18 years with indications for prophylactic parenteral antibiotics for whom administration of the antibiotic has been initiated within one hour (if vancomycin, two hours) prior to the surgical incision or start of procedure when no incision is required.
6. #0270: Timing of Antibiotic Prophylaxis: Ordering Physician [Hospital, Ambulatory Surgical Centers]: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required).
7. #0271: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures) [Hospital, Ambulatory Surgical Centers]: Percentage of non- cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic antibiotics AND who received a prophylactic antibiotic, who have an order for discontinuation of prophylactic antibiotics within 24 hours of surgical end time.
8. #0472: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision or at the Time of Delivery – Cesarean section [Hospital]: Percentage of patients undergoing cesarean section who receive prophylactic antibiotics within one hour prior to surgical incision or at the time of delivery.
9. #0527: Prophylactic antibiotic received within 1 hour prior to surgical incision SCIP-Inf-2.
10. #0528: Prophylactic antibiotic selection for surgical patients.
11. #0529: Prophylactic antibiotics discontinued within 24 hours after surgery end time.
12. #0301: Surgery patients with appropriate hair removal [Hospital]: Percentage of surgery patients with surgical hair site removal with clippers or depilatory or no surgical site hair removal.

13. #0515: Ambulatory surgery patients with appropriate method of hair removal [Ambulatory Care (office/clinic)]: Percentage of ASC admissions with appropriate surgical site hair removal.
14. #0300: Cardiac surgery patients with controlled 6 A.M. postoperative serum glucose: Percentage of cardiac surgery patients with controlled 6 A.M. serum glucose (</=200 mg/dl) on postoperative day (POD) 1 and POD 2.
15. #0452: Surgery patients with perioperative temperature management: Surgery patients for whom either active warming was used intraoperatively for the purpose of maintaining normothermia, or who had at least one body temperature equal to or greater than 96.8° F/36° C recorded within the 30 minutes immediately prior to or the 15 minutes immediately after anesthesia end time.
16. #0218: Surgery patients who received appropriate VTE prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time: Percentage of surgery patients who received appropriate Venous Thromboembolism (VTE) Prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time.
17. #0239: Venous Thromboembolism (VTE) Prophylaxis [Hospital]: Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.
18. #0371: Venous Thromboembolism (VTE) Prophylaxis [Hospital]: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission.
19. #0372: Intensive Care Unit (ICU) VTE Prophylaxis [Hospital]: This measure assesses the number of patients who received VTE prophylaxis or have

documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).

20. #0376: Incidence of Potentially Preventable VTE [Hospital]: This measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present on arrival) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date.

- **Structure Measures** include verification that monitoring documentation incorporates the identification, stratification, and trending of specific risk factors of patients who have developed a SSI to determine the success of mitigation strategies.
- **Patient-Centered Measures** include evidence of education about the patient's role in perioperative infection risk reduction.

Settings of Care Considerations

- **Rural Healthcare Settings:** All requirements of the practice are applicable to rural settings where invasive procedures are performed.
- **Children's Healthcare Settings:** All requirements of the practice are applicable to children's healthcare settings where invasive procedures are performed.
- **Specialty Healthcare Settings:** All requirements of the practice are applicable to specialty settings where invasive procedures are performed.

New Horizons and Areas for Research

Further research is required to discern the optimal timing and use of antibiotics for specific patient profiles; the effectiveness of preoperative bathing with chlorhexidine-containing products; [Miller, 1996; Perl, 2002; Wilcox, 2003; Kallen, 2005; Nicholson, 2005] the effectiveness of routine screening for MRSA [Gould, 2009; Yano, 2009] and routine attempts to decolonize surgical patients with an antistaphylococcal agent in the preoperative setting; best strategies and evidence for maintaining oxygenation with supplemental oxygen during and following colorectal procedures; [Al-Niaimi, 2009;

Casey, 2009; Qadan, 2009] and the validity of preoperative intranasal and pharyngeal chlorhexidine treatment for patients undergoing cardiothoracic procedures. [Segers, 2006] Some organizations have learned from other industries, such as the food industry, and explored increasing the vigilance of environmental cleaning of high-contact surfaces in patient rooms, such as television remote control devices, and operating room equipment and devices, such as pulse oximeters that are shared or used across multiple patients. Other environmental design issues may have real importance to reducing preventable infections in the future. National harmonization efforts are being undertaken to optimize safety during the pre-operative, intra-operative, and post-operative periods, broadening the scope of a systematic approach to safe care of the surgical patient. [NPP, 2009]

Other Relevant Safe Practices

Refer to Safe Practice 1: Leadership Structures and Systems; Safe Practice 2: Culture Measurement, Feedback, and Intervention; Safe Practice 3: Teamwork Training and Skill Building; and Safe Practice 4: Identification and Mitigation of Risks and Hazards. Safe Practice 19: Hand Hygiene, is the cornerstone of an organization's infection control program. Implementing Safe Practice 24: Multidrug-Resistant Organism Prevention, will also reduce infections by using standard evidence-based practice prevention.

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SP 22 Text Cite	SP 22 SSI Prevention Full Citation
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KEYWORDS for PubMed search	**"surgical-site infection"; "surgical site infection"; 2009**

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Summary of Evidence:

CDC Guidelines. The 1999 CDC Guideline for Prevention of Surgical Site Infection speaks to chlorhexidine and povidone-iodine preparations for both preoperative antiseptic showering and for patient skin preparation in the operating room, referencing a number of citations. The relevant text follows:

Preoperative antiseptic showering. A preoperative antiseptic shower or bath decreases skin microbial colony counts. In a study of >700 patients who received two preoperative antiseptic showers, chlorhexidine reduced bacterial colony counts ninefold ($2.8x10^2$ to 0.3), while povidone-iodine or triclocarbanmedicated soap reduced colony counts by 1.3- and 1.9-fold, respectively. Other studies corroborate these findings. Chlorhexidine gluconate-containing products require several applications to attain maximum antimicrobial benefit, so repeated antiseptic showers are usually indicated. Even though preoperative showers reduce the skin's microbial colony counts, they have not definitively been shown to reduce SSI rates.

Patient skin preparation in the operating room. Several antiseptic agents are available for preoperative preparation of skin at the incision site. The iodophors (e.g., povidone-iodine), alcohol-containing products, and chlorhexidine gluconate are the most commonly used agents. No studies have adequately assessed the comparative effects of these preoperative skin antiseptics on SSI risk in well-controlled, operation-specific studies. …

Both chlorhexidine gluconate and iodophors have broad spectra of antimicrobial activity. In somecomparisons of the two antiseptics when used as preoperative hand scrubs, chlorhexidine gluconate achieved greaterreductions in skin microflora than did povidone-iodine and also had greater residual activity after a single application. Further, chlorhexidine gluconate is not inactivated by blood or serum proteins, but exert a bacteriostatic effect as long as they are present on the skin.

Source (citation)	Study Objective	Population and Methods	Findings	Notes
Swenson BR, Hedrick TL, Metzger R, et al. Effects of Preoperative Skin Preparation on Postoperative Wound Infection Rates: A Prospective Study of 3 Skin Preparation Protocols. Infect Control Hosp Epidemiol 2009; 30:964-971.	To compare effects of different skin preparation solutions on surgical site infection rates.	Single-center, unblinded, non-randomized protocol implementation comparison in context of overall risk reduction program. From 1/1/2006 – 6/30/2007 compared SSI rates in adults (18 and up) undergoing general surgery (GI, colorectal, breast, oncologic, hepatobiliary, transplant, or endocrine) in a single large academic medical center who received one of 3 skin preparations. Cases included elective & emergent; inpatients, outpatients, & those admitted following procedure. Pts who did not receive assigned prep were also followed.	Lowest infection rate in period 3 (3.9% compared with 6.4% (1) & 7.1% (2). P=.002. Use of iodophor-based preparation associated with lower, but not statistically significant different, incidence of SSI	Compliance with use of 2% chlorhexidine - 70%isopropyl alcohol as well as iodine povacrylex in isopropyl alcohol preps was in 70% range.

		Over 18 months and 3,209 operations, compared 3 skin preparations sequentially, each for 6 month period: 1. Betadine scrub-pain w/isopropyl alcohol between; 2. ChloraPrep; 3. DuraPrep) – each was identified as the preferred modality. Tracked for SSIs for 30 days. Prep methods varied; no information whether due to mfg. recommendations. Prep method outcomes analysis dichotomized two groups to a single iodophor-based group and compared to chlorhexidine-based group after finding no significant difference in the two separate iodophor-based prepped groups		
Darouiche RO, Wall MJ, Itani KMF, et al. Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. N Engl J Med 2010 Jan 7;362(1):18-26.	To compare effectiveness of chlorhexidine-alcohol (ChloraPrep) to povidone-iodine (Scrub Care Skin Prep Tray) as preoperative skin cleansing agent	Prospective, randomized (by hospital), six-center IRB approved clinical trial conducted between April 2004 and May 2008. Rates of SSI were conducted in 849 adults (age 18 and older) undergoing clean-contaminated surgery (colorectal, small intestinal, gastroesophageal, biliary, thoracic, gynecologic, urologic) in six university-affiliated hospitals who had skin prep using either chlorhexidine-alcohol (409) or povidone-iodine (440) was completed. All received prophylactic antibiotics within 1 hour before initial incision. Exclusions: Patients with history of allergy to chlorhexidine, alcohol, iodophor; evidence of infection at or adjacent to op site; perceived inability to follow patient's course for 30 days post surgery. Patients & site investigators who diagnosed SSI were unaware of group to which assigned	Relative risk of infection was significantly lower in the chlorhexidine-alcohol "intention to treat" population Any SSI (0.59, p=0.004)) Superficial (0.48, p=0.008) Deep (0.33, p=0.05) Lower for each of the 7 types of surgeries studied	

Bibbo C, Patel DV, Gehrmann RM, et al. Chlorhexidine provides superior skin decontamination in foot and ankle surgery: a prospective randomized study. Clinical Orthopaedics and Related Research 2005 Sept 438:204-208.	To compare effectiveness of two skin preparation methods in skin decontamination in foot and ankle surgery.	Prospective, randomized study in one facility. Study group included 127 patients ranging in age from 16 – 85 with intact, uninfected skin having clean elective foot and ankle surgery. Patients were randomly assigned to skin preparation with povidone-iodine (n=67) or with chlorhexidine scrub and isopropyl paint (n=60).	79% of patients in povidone-iodine group developed positive cultures vs 38% of those in chlorhexidine group.	
Miller J, Agarwal R, Umscheid CA, et al. Chlorhexidine versus povidone-iodine in skin antisepsis: a systematic review and cost analysis to inform initiatives to reduce hospital acquired infections. Poster session, University of Pennsylvania 2008.	To inform medical center purchasing decisions, efficacy and cost of chlorhexidine versus povidone-iodine in skin antisepsis was compared	Systenatic review of 9 rospective, randomized controlled clinical trial involving adults receiving topical antisepsis prior to surgery, blood cultures, and vascular or epidural catheter insertion. Compared chlorhexidine gluconate with and without alcohol with povidone iodine with and without alcohol 2 studies related to skin preparation prior to surgery (Berry, 1982 & Bibbo, 2005) were reviewed.	Reported efficacy of chlorhexidine vs. betadine in lowering infection or contamination rate of RR (random) 0.26 for the Berry study and 0.48 RR (random) for the Bibbo study with an overall of 0.38.	Included to represent additional evidence not found in review of scholarly articles.