Surgical Skin Antisepsis Preparation Intervention Guidelines

SSII Surgical Site Infection Improvement Programme

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Version
0.7

Date Created
22 October 2013

Date Updated
10 February 2014

Health Quality & Safety Commission New Zealand
Kupu Taurangi Hauora o Aotearoa

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Change Record

Date	Version	Modified By	Description
22/10/2013	0.1	Jane Barnett	First draft for approval
24/10/2013	0.2	Angelica Harry	Updated following feedback from Sally Roberts
19/11/2013	0.3	Angelica Harry	Updated following feedback from Margaret Drury
21/11/2013	0.4	Angelica Harry	Updated following feedback from the Clinical Leadership Group
20/01/2014	0.5	Hayley Callard	Updated with preface, new front cover and general formatting.
30/01/2014	0.6	Hayley Callard	Updated preface following feedback from Arthur Morris.
10/02/2014	0.7	Hayley Callard	Amendment to wording about drying time of alcohol solution.

CONTENTS

PREFACE

The Surgical Site Infection Improvement (SSII) Programme is one component of the Health Quality & Safety Commission's (the Commission) Infection Prevention and Control Programme.The Commission's programmes aim to reduce healthcare associated infections, including surgical site infections.

SSIs can cause emotional and financial stress, serious illness, longer hospital stays, long-term disability, and can result in loss of life. The consequences for patients, as well as health services, mean that the prevention of SSIs is extremely important.

To address this, in 2012 the Commission entered into a partnership with Auckland and Canterbury District Health Boards to deliver the SSII Programme nationally.

Drawing upon the 2010 report to the Ministry of Health *Recommendations for a National Surgical and Procedural Site Infection Surveillance Program*, the SSII Programme in collaboration with district health boards throughout the country, has refined these recommendations and has implemented a consistent, evidence-based approach for collecting and reporting high quality data about hip and knee arthroplasty procedures.

Through its consultative process the SSII Programme promotes culture change and practice improvements that focus on the prevention of SSIs. This encourages performance improvement by highlighting practice that may require attention. The Programme also provides intervention guidance on how to drive improvements that result in safer patient care.

Over the next one to two years the SSII Programme will focus on SSIs following selected cardiac procedures and caesarean sections. The SSII Programme has been intentionally spread over three to five years to ensure that improvement can be achieved in a sustainable way.

EXECUTIVE SUMMARY

Alcohol, chlorhexidine and povidone-iodine (iodine tinctures or iodophors) are the most commonly used antiseptic agents. An optimal surgical skin antisepsis preparation regimen that helps to reduce the risk of SSI ensures that patients receive:

An alcohol based antiseptic solution (at least 70%) containing one of the following antiseptics:

1. Chlorhexidine gluconate
   OR
2. Povidone-iodine.

DOCUMENT PURPOSE

This document has been produced to encourage healthcare professionals to use skin antisepsis preparation more effectively to improve the safety and quality of care that patients receive. The appropriate use of skin antisepsis preparation is the second in a series of SSI Improvement Programme intervention guidelines.

Antiseptics can be defined as biocidal products that destroy or inhibit growth of microorganisms in, or on, living tissue, for example, the skin. Antiseptics can include a wide variety of formulations and preparations including hand washes, surgical scrubs, preoperative skin preparations, ointments, creams, tinctures, mouthwashes and toothpaste. Overall, they should have the following characteristics:

- A wide spectrum of activity against bacteria, fungi and viruses
- Rapid biocidal activity
- Little or no damage, irritation or toxicity to the tissue
- Little or no absorption into the body
- If possible, some persistent biocidal activity.

Preoperative skin antisepsis is a simple and effective measure to reduce the risk of surgical site infections (Maiwald, 2012). The primary source of organisms contributing to infection following surgery is the bacteria on a patient's skin. The aim of skin antisepsis is to eliminate and rapidly kill skin flora at the site of a planned surgical incision (Safer Healthcare Now, 2011).

Preoperative skin preparation of the operative site involves use of an antiseptic agent with both rapid and long-acting antimicrobial activity. Two types of preoperative skin preparations that combine alcohol (which has an immediate and dramatic effect on

skin bacteria) with long-acting antimicrobial agents appear to be more effective at preventing SSI (IHI, 2012):

- Chlorhexidine gluconate plus alcohol (at least 70%)
- Povidone-iodine plus alcohol (at least 70%)

APPROPRIATE USE OF SKIN ANTISEPSIS PREPARATION

Alcohol, chlorhexidine and povidone-iodine (iodine tinctures or iodophors) are the most commonly used antiseptic agents. An optimal surgical skin antisepsis preparation regimen that helps to reduce the risk of SSI ensures that patients receive:

An alcohol based antiseptic solution (at least 70%) containing one of the following antiseptics:

1. Chlorhexidine gluconate
   OR
2. Povidone-iodine.

Evidence supports the use of surgical skin antisepsis preparation for:

- Clean surgery involving the placement of a prosthesis or implant
- Clean-contaminated surgery
- Contaminated surgery.

Alcohol based chlorhexidine and povidone-iodine antiseptic solutions significantly reduce the likelihood of surgical site colonisation and maximise the rapidity, potency and duration of bactericidal activity when compared to other solutions.

Skin antisepsis preparation:
Either alcohol and chlorhexidine or alcohol and povidone-iodine is used

Rationale	This measure assesses whether DHBs are complying with evidence based practice.
Improvement	An increase in the rate of compliance i.e. xx% of patients receiving skin antisepsis with alcohol (at least 70%) containing either chlorhexidine or povidone-iodine.
Numerator statement	Number of procedures where a skin antisepsis with alcohol (at least 70%) containing either chlorhexidine or povidone-iodine was used.
Denominator statement	Number of procedures.

Chlorhexidine gluconate

The properties that make chlorhexidine highly effective are a strong affinity for binding to the skin, high antibacterial activity and prolonged residual effects on rebound bacterial growth. Chlorhexidine exhibits excellent activity against gram-positive and good activity against gram-negative vegetative organisms and fungi (APIC 2010).

Chlorhexidine is typically used in concentrations of 2% to 4% for hospital scrubs and hand washes, however, when the formulation includes alcohol, the concentration of chlorhexidine is usually 0.5% to 2%.

Patients that are allergic to chlorhexidine gluconate should receive povidone-iodine with alcohol (at least 70%) as an alternative.

Povidone-iodine

Iodine has been widely used as an antiseptic. Traditional solutions in water or alcohol include tincture of iodine or Lugol's solutions. Iodophors are preparations containing iodine complexed with a solubilising agent such as a surfactant or povidone (povidone iodine (PVP)). Iodophors have allowed for greater flexibility in the use of iodine in antiseptics. Depending on the concentration of free-iodine iodophors can be used for routine and high risk applications such as surgical scrubs and preoperative skin antisepsis. They are generally associated with low toxicity and little irritation.

The concentration of iodine varies depends on the formulation used. For example, one formulation contains iodine poyacrylex (0.7% available iodine) and 74% weight to weight (w/w) isopropyl alcohol.

IMPLEMENTING SURGICAL SKIN ANTISEPSIS PREPARATION

While fires in the operative theatre are extremely rare, alcohol based antiseptics are flammable and therefore the Programme recommends the following precautions be taken when using alcohol based antiseptic skin preparation solutions:

- Staff need to be educated before using a chlorhexidine gluconate-alcohol or povidone-iodine-alcohol solution on how to be safe and effective in their application of a flammable skin preparation agent
- Avoid dripping or pooling of alcohol based antiseptic solutions on sheets, padding, positioning equipment, adhesive tape and on or under the patient
- Ensure that the liquid has completely dried by evaporation – three minutes is usually sufficient. Areas with excess hair may take longer to dry. **Note** that drying is equally important for the biocidal activities of alcohol
- Develop protocols that ensure and document that the applied solution is completely dry before draping the patient
- Single-use applicators should ideally be used to apply flammable antiseptic agents
- Cleanse the incision area for 30 seconds and then paint the rest of the extremity
- Consider use of a tinted chlorhexidine gluconate-alcohol prep (orange, red or teal) for greater visibility.

Implementing the interventions to prevent SSI for hip and knee arthroplasty presents an important opportunity to build collaboration within the hospital setting, including the following:

- Enlisting the support of senior leadership in the hospital and surgical and anaesthesia departments
- Identifying one or two surgeons and anaesthetists to further champion the case and influence peers to enhance the adoption of, implementation of and adherence to the above interventions
- Exploring how to best communicate these interventions through strategies such as face-to-face communication at staff meetings, outreach to surgeons office, or telephone calls from leaders to their peers
- Building collaborative relationships between the hospital operating room management team (OR nurses, anaesthetists and anaesthetic technicians) and surgeons to establish reliable processes and hand-overs for pre-operative assessment, planning and follow up.

APPENDIX ONE: REVIEW OF THE EVIDENCE FOR CHOICE OF SURGICAL SKIN ANTISEPSIS AGENT

Authors/ Journal	Title of Publication	Date	Description	Findings	Conclusions	Comment
Carroll K, Dowsey M, Choong P, Peel T Clin Microbiol Infect. 2013; doi: 10.1111/1469-0691.12209.	Risk factors for superficial wound complications in hip and knee arthroplasty	2013	Retrospective cohort study of 964 patients undergoing primary or revision hip/knee procedures over an 18 month period. Multiple risk factors examined including skin antisepsis Outcome measure: incidence and severity of superficial SSI.	Multivariable logistic regression analysis. Patients who received skin prep with 0.5% chlorhexidine and alcohol were at higher risk of superficial infection than those who received 1% iodine and alcohol, p=0.012.	Authors acknowledge findings may reflect surgeon preference and experience and that skin prep requires more evaluation/RCT.	Limitations- single centre, retrospective, superficial SSI with 30 day follow up only.
Tschudin-Sutter et al Ann Surg 2012 ; 255 (3):565-569	No risk of surgical site infections from residual bacteria after disinfection with povidone-iodine-alcohol in 1014 cases: a prospective observational study.	2012	Prospective study looking at skin microbial counts taken after skin disinfection with povidone-iodine-alcohol in 1005 patients. Counts compared with SSI rates.	3.6% of skin cultures revealed significant colonization and 41 (4%) SSI were detected. Residual bacteria before incision was unrelated to SSI even after adjusting for confounding variables.	Povidone-iodine-alcohol is an effective skin antisepsis agent.	Supports findings of Swenson et al, ICHE 2009.
Darouiche R et al NEJM 2010 ; 362 : 18-26	Chlorhexidine-alcohol versus povidone-iodine for surgical site antisepsis	2010	Prospective RCT involving 849 subjects over 4 year period in 6 hospitals in US. Clean-contaminated surgery.	Overall rate of SSI was significantly lower in the chlorhexidine-alcohol group than in the povidone-iodine group.	Authors recommend use of 2% chlorhexidine gluconate with alcohol over aqueous povidone-iodine.	Comparison of chlorhexidine gluconate and alcohol versus aqueous povidone-iodine. Needed additional comparator

Authors/ Journal	Title of Publication	Date	Description	Findings	Conclusions	Comment
						arm with povidone-iodine and alcohol.
Ostrander R et al J Bone Joint Surg Am. 2005; 87: 980-985	Efficacy of surgical preparation solutions in foot and ankle surgery	2005	Prospective study comparing elimination of bacteria from sites disinfected using 3 different products. Cultures were undertaken on 125 consecutive patients undergoing surgery on the foot/ankle. 3 randomly selected preps were used: 0.7% iodine/alcohol; 3% chloroxylenol and 2% chlorhexidine/70% alcohol.	Limited study by numbers. Too small a study to link to fully evaluate SSI rates. Did not measure levels of microorganisms on the foot prior to skin preparation.	Suggestion that chloroprep (chlorhexidine and alcohol) was more effective at reducing counts of skin organisms pre-operatively.	Under powered as sample size too small.
Swenson et al Infect Control Hosp Epidemiol 2009: 30: 964-71	Effects of preoperative skin preparation on post operative wound infection rates: a prospective study of 3 skin preparation protocols	2009	18 month study comparing 3 different skin preparations on SSI rates. Povidone iodine/alcohol; chlorhexidine/alcohol and iodine povacrylex in alcohol.	Use of each agent for 6 months each on all general surgery cases. SSI tracked for 30 days post operatively.	No difference in primary outcomes between traditional povidone/iodine/alcohol and iodine povacrlex in alcohol. SSI 3% higher with 2% chlorhexidine gluconate and alcohol.	Study involved general surgery patients so a mix of clean/clean-contaminated and contaminated cases. Study not randomised.
Adams et al	Evaluation of a 2% chlorhexidine gluconate in 70% isopropyl alcohol skin disinfectant	2005	In vitro study comparing 6 commonly used skin disinfectants against *S. epidermidis* The disinfectants tested were: 1. 2%chlorhexidine/70% alcohol;	All disinfectants achieved a log $_{10}$ reduction factor of 5 in suspension ± protein. However, when challenged with biofilm, effectiveness was reduced reflecting inhibition of in the presence	Suggests that 2% chlorhexidine gluconate in 70% alcohol may offer advantages over other chlorhexidine gluconate products.	Need in vivo studies to assess effectiveness of this product in the clinical situation.

Authors/ Journal	Title of Publication	Date	Description	Findings	Conclusions	Comment
J Hosp Infect 2005: 61: 287-90.			2. 70% alcohol 3. aqueous 10% povidone iodine 4. 0.5% aqueous chlorhexidine gluconate 5. 2% aqueous chlorhexidine gluconate 6. 0.5% chlorhexidine gluconate in 70% alcohol	of organic matter. Most effective agent tested against *S. epidermidis* were 2% chlorhexidine gluconate in 70% alcohol and 10% aqueous povidone iodine.	No alcohol and povidone iodine comparator.	

APPENDIX TWO: SYTEMATIC REVIEWS AND GUIDELINES

Authors/ Journal	Title of Publication	Date	Description	Findings	Conclusion	Comment
Dumville JC, McFarlane E, Edwards P, Lipp A, Holmes A Cochrane Database of Systematic Reviews 2013; 3	Pre-operative skin antiseptics for preventing surgical wound infections after clean surgery.	2013	Review of RCTs on preoperative skin preparation. Multiple different formulations used.	13 studies included Only clean surgery included.	Majority under powered to show a difference A single study from 1982 showed 0.5% chlorhexidine in methylated spirits reduced SSI compared to alcohol containing iodine paint.	Limited information provided. More research is required.
Maiwald M and Chan E PLOS ONE	The forgotten role of alcohol: a systematic review and meta analysis of the clinical efficacy and	2012	Systematic literature review of clinical trials and systematic reviews investigating compounds for blood culture collection, vascular access and surgical skin preparation.	Perceived efficacy of chlorhexidine gluconate often based on the efficacy of chlorhexidine gluconate and alcohol. Rapid effect of alcohol effect skin antisepsis is often	Alcohol is a key component of any skin preparation. Surgery requires both immediate skin activity (alcohol) plus persistent activity (chlorhexidine	Skin antiseptics should contain alcohol of at least 70% for rapid action and another skin antiseptic e.g. chlorhexidine or povidone iodine for

Authors/ Journal	Title of Publication	Date	Description	Findings	Conclusion	Comment
2012; 7: e44277 doi:10.1371/journal.pone.0044277	perceived role of chlorhexidine gluconate in skin antisepsis.			overlooked and comparative studies compare alcohol containing preparations with non-alcohol containing.	gluconate or povidone iodine) hence the combination of both.	more persistent effect.
Alexander J et al Annals of Surgery 2011; 253: 1082-1093	Updated recommendations for control of surgical site infections.	2011	Updated guidelines for the prevention of surgical wound infections based on review and interpretation of current and past literature.	Findings from literature review inconclusive. Suggest alcohol chlorhexidine gluconate skin count is lower than iodophor/alcohol. Both better than acqueous povidone iodine.	Use an alcohol containing skin preparation containing chlorhexidine gluconate although alcohol/iodophors are also acceptable.	Use alcohol containing skin preparation with an additional antiseptic property i.e. chlorhexidine or iodophor.
Lee et al Infect Control Hosp Epidemiol 2010; 31: 1219-1229	Systematic review and cost analysis comparing use of chlorhexidine with use of iodine for preoperative skin antisepsis to prevent surgical site infection.	2010	Literature review and meta analysis. 18 articles underwent review of full text. Included 9 RCTs.	Moderate quality of evidence to use chlorhexidine over iodine for skin antisepsis to prevent SSI. Moderate quality evidence that use of chlorhexidine is associated with fewer skin cultures after application.	5 of the trials included compared chlorhexidine/alcohol with povidone iodine aqueous (hence not comparable) see Darouche et al.	

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