

Massimo Sartelli

U.O. Chirurgia Generale
Ospedale di Macerata

SIMPIOS

In base al **Regolamento (UE) 528/2012** (Biocidal Product Regulation, BPR) — che ha sostituito il precedente Regolamento UE 582/2012,— il Ministero della Salute, con il **Decreto Direttoriale del 29 marzo 2023**, ha stabilito quanto segue:

Principali disposizioni del Decreto Direttoriale 29 marzo 2023

1. Revoca delle autorizzazioni come PMC

Le autorizzazioni per l'immissione in commercio in qualità di presidi medico-chirurgici (PMC), con riferimento ai prodotti destinati alla disinfezione *della cute integra prima di un trattamento medico* (ad esempio preparazione preoperatoria della pelle), saranno revocate a partire dal 1° gennaio 2025.

2. Periodo transitorio per i lotti già immessi sul mercato

I lotti dei prodotti PMC già immessi in commercio antecedentemente al 1° gennaio 2025 potranno essere messi a disposizione, venduti e utilizzati fino al 30 giugno 2025. Dopo questa data non sarà più consentito l'uso di quei prodotti.

3. Dopo la revoca, per l'antisepsi cutanea in occasione di trattamenti medici (es. preparazione preoperatoria), sarà necessario utilizzare specialità medicinali (rigorosamente autorizzate con AIC) per l'antisepsi di cute integra.

Rischio di limitata scelta di antisettici autorizzati come medicinali, specialmente per le soluzioni alcoliche a base di clorexidina (fortemente usate come standard clinico).

Le infezioni del sito chirurgico

a cura di
Massimo Sartelli, Francesco Scaglione,
Nicola Petrosillo, Antonio Silvestri

edra



SIMPIOS



Società Italiana Multidisciplinare per la Prevenzione delle Infezioni
nelle Organizzazioni Sanitarie

L'antisepsi preoperatoria della cute

DOCUMENTO DI POSIZIONE

L'antisepsi preoperatoria della cute è uno dei punti cardine della prevenzione delle infezioni del sito chirurgico. I batteri residenti possono essere, infatti, notevolmente ridotti, riducendo il rischio di infezione del sito chirurgico, mediante un'appropriata disinfezione della cute.

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Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017

Sanford L. Bernstein, MD; Craig A. Umetsu, MD, MSc; Dale W. Bratzler, DO, MPH; Brian Leier, MA, MS; Greg C. Stone, MA; Rachel R. Katz, MD, MSc; Carolyn E. Reinke, MD, MScAP; Sherry Morgan, RN, MLS, IND; Jennifer S. Schuchat, MD; John T. Marshall, MD, PhD; Michael D. Lohr, MD; Karen M. Lohr, PhD; Mark A. Miller, MD; David A. Berenholtz, MD; Michael J. Lohr, MD; Jean Banchereau, MD, PhD; Michael C. Lohr, PhD; George Alter, PhD, CIC; CNSR; Jan A. J. W. Kuylenstierna, MD; Rodger Conran, PhD; William P. Schutte, MD; for the Healthcare Infection Control Practices Advisory Committee

IMPORTANCE The human and financial costs of treating surgical site infections (SSIs) are increasing. The number of surgical procedures performed in the United States continues to rise, and surgical patients are initially seen with increasingly complex comorbidities. It is estimated that approximately half of SSIs are deemed preventable using evidence-based strategies.

OBJECTIVE To provide new and updated evidence-based recommendations for the prevention of SSI.

EVIDENCE REVIEW A targeted systematic review of the literature was conducted in MEDLINE, EMBASE, CINAHL, and the Cochrane Library from 1998 through April 2014. A modified Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach was used to assess the quality of evidence and the strength of the resulting recommendations and to provide explicit links between them. Of 5487 points by relevant studies identified in literature searches, 5750 titles and abstracts were screened, and 896 underwent full-text review by 2 independent reviewers. After exclusions, 170 studies were extracted into evidence, evaluated, and categorized.

PRINCIPLES Before surgery, patients should shower or bathe (full body) with soap and antimicrobial or nonantimicrobial or an antiseptic agent at least the night before the operative day. Antiemetic prophylaxis should be administered only when indicated based on published clinical practice guidelines and limited such that a bacterial load concentration of the agents is established in the serum and tissues when the incision is made. In cesarean section procedures, antimicrobial prophylaxis should be administered before skin incision. Skin preparation of the operating room should be performed using an alcohol-based agent prophylactically or preoperatively. For clean and clean-contaminated procedures, additional prophylactic antimicrobial agents should not be administered after the surgical incision is closed in the operating room, even in the presence of a drain. Topical antimicrobial agents should not be applied to the surgical incision. During surgery, glycemic control should be implemented using blood glucose target levels less than 100 mg/dL, and normothermia should be maintained in all patients. Increased fraction of inspired oxygen should be administered during surgery and her excretion in the immediate postoperative period for patients with normal pulmonary function undergoing general anesthesia is an endotracheal intubation. Transfusion of blood products should not be withheld from surgical patients as a means to prevent SSI.

CONCLUSIONS AND RELEVANCE This guideline is intended to provide new and updated evidence-based recommendations for the prevention of SSI and should be incorporated into comprehensive surgical quality improvement programs to improve patient safety.

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Initiated Commentary
Supplemental content

NICE National Institute for
Health and Care Excellence



Surgical site infections: prevention and treatment

Author Affiliations Author affiliations are listed at the end of the article.
Correspondence: The Healthcare Infection Control Practices Advisory Committee members are listed at the end of the article.
Correspondence to: Michael S. Calderwood, MD, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, 1600 Clifton Rd, NC, Mailstop A-2029, Atlanta, GA 30333 (mcalderwood@cdc.gov).

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GLOBAL GUIDELINES FOR THE PREVENTION OF SURGICAL SITE INFECTION



Strategies to prevent surgical site infections in acute-care hospitals: 2022 Update

Michael S. Calderwood MD, MPH^{1,2}, Deverick J. Anderson MD, MPH^{2,3}, Dale W. Bratzler DO, MPH², E. Patchen Dellinger MD⁴, Sylvia Garcia-Houchins RN, MBA, CIC⁵, Lisa L. Maragakis MD, MPH⁶, Ann-Christine Nyquist MD, MSPH⁷, Kiran M. Perkins MD, MPH⁸, Michael Anne Preas RN, MS, CIC⁹, Lisa Saiman MD, MPH¹⁰, Joshua K. Schaffzin MD, PhD¹¹, Marin Schweizer PhD¹², Deborah S. Yokoe MD, MPH¹³ and Keith S. Kaye MD, MPH¹⁴

¹Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire, United States; ²Duke Center for Antimicrobial Stewardship and Infection Prevention, Duke University School of Medicine, Durham, North Carolina, United States; ³University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, United States; ⁴University of Washington Medical Center, Seattle, Washington, United States; ⁵The Joint Commission, Oakbrook Terrace, Illinois, United States; ⁶Johns Hopkins School of Medicine, Baltimore, Maryland, United States; ⁷Children's Hospital Colorado, University of Colorado School of Medicine, Aurora, Colorado, United States; ⁸Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Atlanta, Georgia, United States; ⁹University of Maryland Medical System, Baltimore, Maryland, United States; ¹⁰Columbia University Irving Medical Center and NewYork-Presbyterian Hospital, New York, New York, United States; ¹¹Children's Hospital of Philadelphia, University of Pennsylvania, Philadelphia, Pennsylvania, United States; ¹²University of California-San Francisco, San Francisco, California, United States; ¹³Rutgers Robert Wood Johnson Medical School, New Brunswick, New Jersey, United States

Abstract and purpose

The intent of this document is to highlight practical recommendations in a concise format designed to assist acute-care hospitals in implementing and prioritizing their surgical site infection (SSI) prevention efforts. This document updates the *Strategies to Prevent Surgical Site Infections in Acute Care Hospitals* published in 2014. This expert guidance document is sponsored by the Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), the Association for Professionals in Infection Control and Epidemiology (APIC), the American Hospital Association (AHA), and The Joint Commission, with major contributions from representatives of a number of organizations and societies with content expertise.

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Summary of major changes

This section lists major changes from the *Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update*, including recommendations that have been added, removed, or altered. The recommendations are organized into 3 main practices that should be adopted by all acute-care hospitals (in 2014, these were "basic practices" renamed to highlight their importance as a foundation for hospitals' healthcare-associated infection (HAI) prevention programs) or additional approaches that can be considered for use in locations and/or populations within hospitals when SSIs are not controlled after implementation of essential practices (in 2014 these were called "special approaches"). See Table 1 for

a complete summary of recommendations contained in this document.

Essential practices

- Modified recommendation to administer prophylaxis according to evidence-based standards and guidelines to emphasize that antimicrobial prophylaxis should be discontinued at the time of surgical closure in the operating room.
- The use of parenteral and oral antibiotics prior to elective colorectal surgery is now considered an essential practice. This recommendation was included in the 2014 document but was a sub-optional recommendation. The 2014 recommendation was elevated to its own recommendation for increased emphasis.
- Reclassified decolonization of surgical patients with an anti-staphylococcal agent for cardiothoracic and orthopedic procedures from an Additional Approach to an Essential Practice.
- The use of vaginal preparation with an antiseptic solution prior to cesarean delivery and hysterectomy was added as an essential practice.

Author for correspondence: Michael S. Calderwood, MD, MPH, mcalderwood@cdc.gov.

*Authors of equal contribution.

†Senior author.

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L'evidenza di letteratura suggerisce la superiorità degli antisettici in soluzione alcolica.

La clorexidina in soluzione alcolica dovrebbe essere preferita all'iodio in soluzione alcolica. La clorexidina al 2% in soluzione alcolica, in base alle evidenze attualmente disponibili, è il disinettante di prima scelta per la preparazione preoperatoria del sito chirurgico. Le altre concentrazioni di clorexidina a base alcolica dovrebbero essere usate in casi di indisponibilità di clorexidina al 2% in soluzione alcolica.

Lo iodopovidone in soluzione alcolica nella meta-analisi complessiva degli studi appare meno attivo della clorexidina in soluzione alcolica, anche se due recenti studi randomizzati controllati pubblicati nel 2024 da Widmer et al. e di Boisson et al. non hanno dimostrato la superiorità di clorexidina in soluzione alcolica

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<https://doi.org/10.1007/s00134-024-07693-0>

ORIGINAL

Chlorhexidine-alcohol compared with povidone-iodine-alcohol skin antisepsis protocols in major cardiac surgery: a randomized clinical trial



Matthieu Boisson^{1*} Géraldine Allain², Jean-Christian Roussel³, Nicolas d' Ostrevy⁴, Silvia Burbassi⁵, Pierre Demondion⁶, Paul-Michel Mertes⁷, François Labaste⁸, Thomas Kerforne⁹, Bertrand Rozec¹⁰, Vedat Eljezi¹¹, Konstantinos Zannis¹², Pascal Leprince⁶, Walid Oulehri¹³, Vincent Minville⁸, Sabrina Seguin¹⁴, Ambre Loiodice¹⁵, Stéphane Ruckly¹⁶, Jean-Christophe Lucet¹⁷, Jean-François Timsit^{18,19} and Olivier Mimoz²⁰ on behalf of the CLEAN 2 Study Group

Research

JAMA | Original Investigation

Povidone Iodine vs Chlorhexidine Gluconate in Alcohol for Preoperative Skin Antisepsis A Randomized Clinical Trial

Andreas F. Widmer, MD, MS; Andrew Atkinson, PhD; Stefan P. Kuster, MD; Aline Wolfensberger, MD; Steffi Klimke, RN; Rami Sommerstein, MD; Friedrich S. Eckstein, MD; Florian Schoenhoff, MD; Guido Beldi, MD; Christian A. Gutschow, MD; Jonas Marschall, MD; Alexander Schweiger, MD; Philipp Jent, MD

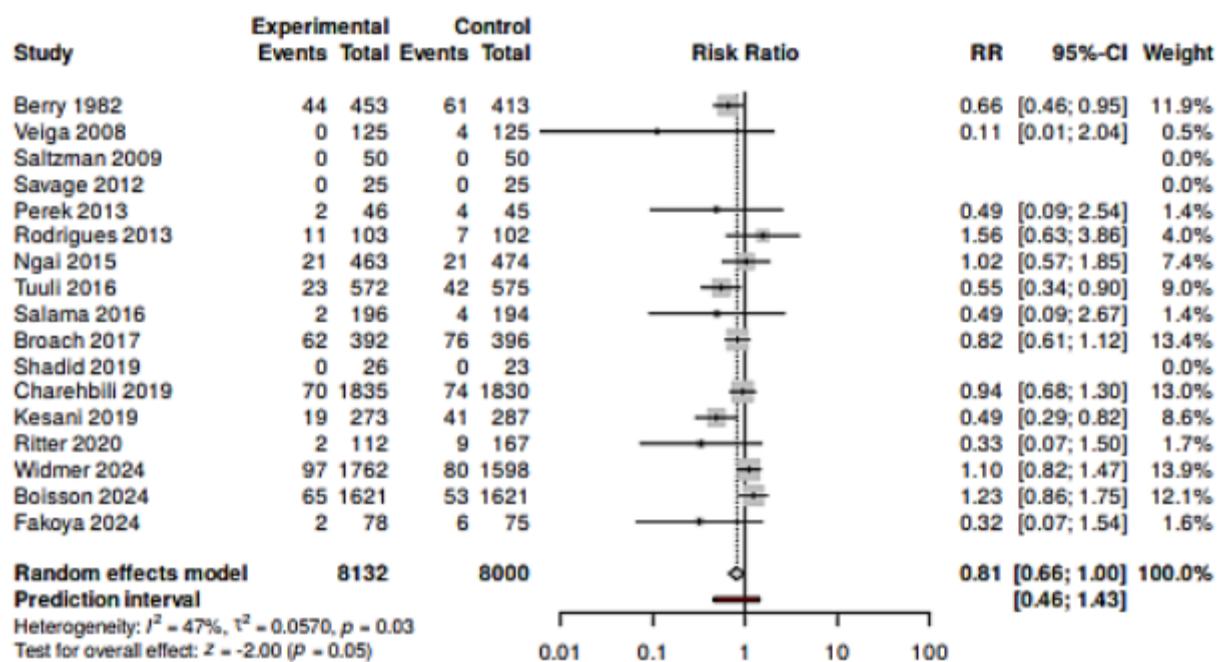


Figura 1. Clorexidina in soluzione alcolica Vs. Iodio in soluzione alcolica



Major article

A comparison of the efficacy of 70% v/v isopropyl alcohol with either 0.5% w/v or 2% w/v chlorhexidine gluconate for skin preparation before harvest of the long saphenous vein used in coronary artery bypass grafting

This work was presented in part as a poster at the 18th European Congress of Clinical Microbiology and Infectious Diseases, Barcelona, Spain, April 19-22, 2008.

Anna Casey PhD^a, Abdul Itraky FRCS^b, Chrissie Birkett PgDip^b, Alan Clethro PgDip^b, Robert Bonser FRCS^b, Tim Graham FRCS^b, Jorge Mascaro FRCS^b, Domenico Pagano MD^b, Stephen Rooney FRCS^b, Ian Wilson FRCS^b, Peter Nightingale PhD^c, Cynthia Crosby PhD^d, Thomas Elliott DSc^c  

^a

Results

The total numbers of microorganisms on the skin 2 minutes after skin antisepsis and after wound closure was lower with 2% CHG/70% IPA compared with 0.5% CHG/70% IPA ($P=.033$ and $P=.016$, respectively). Six of 41 patients in the 0.5% CHG/70%IPA group developed a superficial surgical site infection compared with 2 of 44 patients in the 2% CHG/70% IPA group (relative risk, 3.22; 95% confidence interval, 0.63-22.75; $P=.147$).

Conclusions

Isopropyl alcohol (70%) containing 2% CHG compared with 0.5% CHG reduces the number of microorganisms detectable on a surgical patient's skin perioperatively.



Efficacy of different preoperative skin antiseptics on the incidence of surgical site infections: a systematic review, GRADE assessment, and network meta-analysis

Hasti Jalalzadeh*, Hannah Groenen*, Dennis R Buis, Yasmine EM Dreissen, Jon HM Goosen, Frank FA Ijppma, Maarten J van der Laan, Roald R Schaad, Patrique Segers, Wil C van der Zwet, Mitchel Griekspoor, Wouter J Harmsen, Niels Wolfhagen, Marja A Boermeester



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*Contributed equally
Amsterdam University Medical Center, Department of Surgery, University of Amsterdam, Amsterdam, Netherlands (H.Jalalzadeh MD, H.Groenen MD, N.Wolfhagen MD, Prof M.A.Boermeester MD); Amsterdam Gastroenterology Endocrinology and Metabolism, Amsterdam, Netherlands (H.Jalalzadeh, H.Groenen, N.Wolfhagen, Prof M.A.Boermeester); Dutch National Guideline Group for Prevention of Postoperative Surgical Site Infections, Utrecht, Netherlands (H.Jalalzadeh, H.Groenen, D.R.Buis MD, Y.E.M.Dreissen MD, J.H.M.Goosen MD, F.F.A.Ijppma MD, M.J.van der Laan MD, R.R.Schaad MD, P.Segers MD, W.C.van der Zwet MD, M.Griekspoor MSc, W.J.Harmsen PhD, N.Wolfhagen, Prof M.A.Boermeester)

Correspondence to:
Prof Marja A Boermeester,
Amsterdam University Medical Center Department of Surgery

Summary

Background Surgical site infection (SSI) is the most common postoperative complication and substantially increases health-care costs. Published meta-analyses and international guidelines differ with regard to which preoperative skin antiseptic solution and concentration has the highest efficacy. We aimed to compare the efficacy of different skin preparation solutions and concentrations for the prevention of SSIs, and to provide an overview of current guidelines.

Methods This systematic review and network meta-analysis compared different preoperative skin antiseptics in the prevention of SSIs in adult patients undergoing surgery of any wound classification. We searched for randomised controlled trials (RCTs) in MEDLINE, Embase, and Cochrane CENTRAL, published up to Nov 23, 2021, that directly compared two or more antiseptic agents (ie, chlorhexidine, iodine, or olnexidine) or concentrations in aqueous and alcohol-based solutions. We excluded paediatric, animal, and non-randomised studies, and studies not providing standard preoperative intravenous antibiotic prophylaxis. Studies with no SSIs in both groups were excluded from the quantitative analysis. Two reviewers screened and reviewed eligible full texts and extracted data. The primary outcome was the occurrence of SSI (ie, superficial, deep, and organ space). We conducted a frequentist random effects network meta-analysis to estimate the network effects of the skin preparation solutions on the prevention of SSIs. A risk-of-bias and Grading of Recommendations, Assessment, Development, and Evaluation assessment were done to determine the certainty of the evidence. This study is registered with PROSPERO, CRD42021293554.

Findings Overall, 2326 articles were identified, 33 studies were eligible for the systematic review, and 27 studies with 17735 patients reporting 2144 SSIs (overall incidence of 12.1%) were included in the quantitative analysis. Only 2.0–2.5% chlorhexidine in alcohol (relative risk 0.75, 95% CI 0.61–0.92) and 1.5% olnexidine (0.49, 0.26–0.92) significantly reduced the rate of SSIs compared with aqueous iodine. For clean surgery, we found no difference in efficacy between different concentrations of chlorhexidine in alcohol. Seven RCTs were at high risk of bias, 24 had some concerns, and two had low risk of bias. Heterogeneity across the studies was moderate ($P=27.5\%$), and netsplitting did not show inconsistencies between direct and indirect comparisons. Five of ten studies that mentioned adverse events related to the skin preparation solutions reported no adverse events, and five reported a total of 56 mild events (mainly erythema, pruritus, dermatitis, skin irritation, or mild allergic symptoms); none reported a substantial difference in adverse events between groups.

Interpretation For adult patients undergoing a surgical procedure of any wound classification, skin preparation using either 2.0–2.5% chlorhexidine in alcohol or 1.5% olnexidine is most effective in the prevention of SSIs. For clean surgery, no specific concentration of chlorhexidine in alcohol can be recommended. The efficacy of olnexidine was established by a single randomised trial and further investigation is needed.

Funding Dutch Association for Quality Funds Medical Specialists.

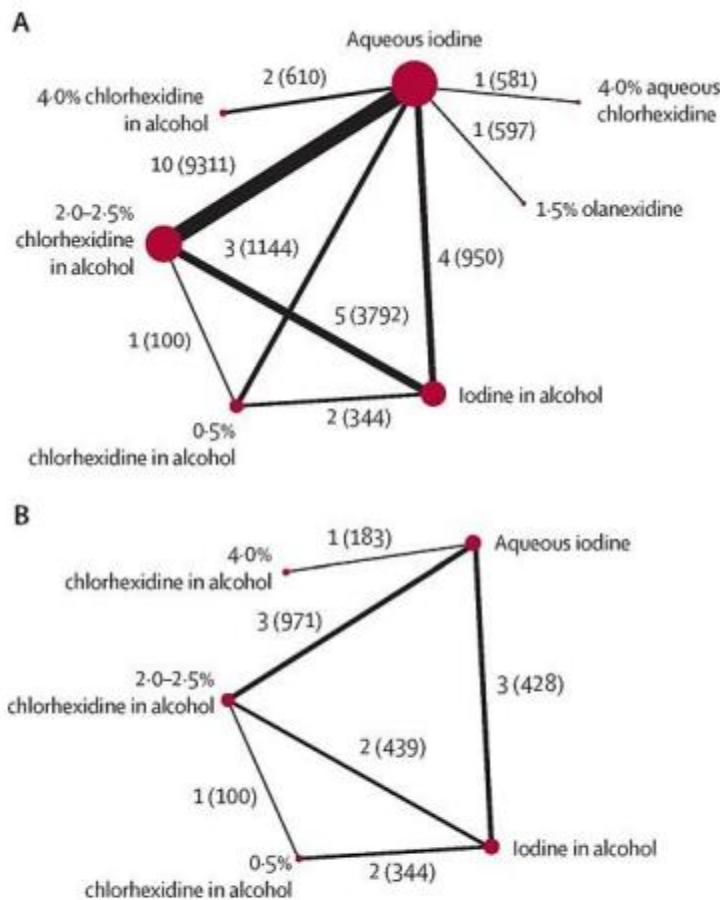


Figura 2. A: Numero di studi e pazienti che indagano l'efficacia dei diversi metodi di preparazione della cute per la prevenzione delle ISC. **B:** Numero di studi e pazienti che indagano l'efficacia dei diversi metodi di preparazione della cute per la prevenzione delle ISC nella chirurgia pulita [30]. (Figura inclusa con il permesso degli autori).

		Analysis	Recommendation
Any type of surgery			
Berrios-Torres (2017) ⁴	Multiple meta-analyses	"Perform intraoperative skin preparation with an alcohol-based antiseptic agent unless contraindicated."	
WHO (2018) ⁵	Multiple meta-analyses	"The panel recommends alcohol-based antiseptic solutions based on chlorhexidine for surgical site skin preparation in patients undergoing surgical procedures."	
NICE (2019) ⁶	Network meta-analysis	First choice of skin preparation is alcohol-based solution of chlorhexidine, alternative is aqueous solution of chlorhexidine if surgical site is next to a mucous membrane. If chlorhexidine is contraindicated, alcohol-based solution of povidone-iodine can be used as an alternative. If both an alcohol-based solution and chlorhexidine are unsuitable, aqueous solution of povidone-iodine can be used.	
Our study	Network meta-analysis	Use chlorhexidine in alcohol in a concentration of 2.0–2.5% for skin preparation before any surgical procedures; if this concentration is not available, 0.5% or 4.0% chlorhexidine in alcohol can be used.	
Clean surgery only			
Wade et al (2021) ¹⁵	Network meta-analysis	"Alcoholic formulations of 4%–5% chlorhexidine seem to be safe and twice as effective as povidone iodine (alcoholic or aqueous solutions) in preventing infection after clean surgery in adults. These findings concur with the literature on contaminated and clean-contaminated surgery, and endorse guidelines worldwide which advocate the use of alcoholic chlorhexidine for preoperative skin antisepsis."	
Dumville et al (2015) ⁴⁴	Multiple meta-analyses	"A comprehensive review of current evidence found some evidence that preoperative skin preparation with 0.5% chlorhexidine in methylated spirits was associated with lower rates of SSIs following clean surgery than alcohol-based povidone iodine paint. However this single study was poorly reported. Practitioners may therefore elect to consider other characteristics such as costs and potential side effects when choosing between alternatives."	
Our study	Network meta-analysis	Use chlorhexidine in alcohol for skin preparation before clean surgical procedure (no specific concentration of chlorhexidine plus alcohol).	
NICE=National Institute for Health and Care Excellence. SSIs=surgical site infections.			
Table 3: Comparison of current recommendations of different network meta-analyses			



**L'antisepsi della cute integra prima di un
trattamento medico alla luce della nuova
normativa.**

Indicazioni di SIMPIOS

Gruppo di lavoro SIMPIOS

Massimo Sartelli, Beatrice Casini, Alessandra De Palma, Elisa Fabbri, Enrica Martini, Maria Luisa Moro, Matteo Moro, Angelo Pan, Daniela Pasero, Giancarlo Ripabelli, Lucia Rossi.

Cateterismo
venoso
periferico

Cateterismo
venoso
centrale

Intervento
chirurgico

Cateterismo venoso periferico: suggerita clorexidina in soluzione alcolica con concentrazione 2%; possibili altre soluzioni medicinali, purché accompagnate da rigorosa asepsi.

Cateterismo venoso centrale: clorexidina alcolica con concentrazione 2% resta lo standard; altre opzioni ammesse solo in caso di intolleranza documentata.

Preparazione preoperatoria della cute: clorexidina alcolica al 2% è la prima scelta per chirurgia maggiore e ad alto rischio di infezione; concentrazioni più basse possono essere utilizzate solo per interventi minori o a basso rischio.

In tutti i casi, l'uso di soluzioni acquose è limitato a situazioni specifiche (prossimità a mucose, controindicazioni all'alcol).



* 5. Skin Preparation

Recommendations for catheter skin preparation by ID number and category.

#	Recommendation	Category
1.	Prepare clean skin with an antiseptic (70% alcohol, tincture of iodine, or alcoholic chlorhexidine gluconate solution) before peripheral venous catheter insertion.	IB
2.	Prepare clean skin with a >0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives.	IA
3.	No comparison has been made between using chlorhexidine preparations with alcohol and povidone-iodine in alcohol to prepare clean skin.	Unresolved issue
4.	No recommendation can be made for the safety or efficacy of chlorhexidine in infants aged <2 months.	Unresolved issue
5.	Antiseptics should be allowed to dry according to the manufacturer's recommendation prior to placing the catheter.	IB

Surgical site infections: prevention and treatment

NICE guideline
Published: 11 April 2019
Last updated: 19 August 2020

www.nice.org.uk/guidance/ng125

When	Choice of antiseptic skin preparation
First choice unless contraindicated or the surgical site is next to a mucous membrane	<p>Alcohol-based solution of chlorhexidine</p> <p>At the time of publication (April 2019), 0.5% chlorhexidine in 70% alcohol solution (Hydrex; Prevase) was licensed for 'preoperative skin disinfection prior to minor surgical procedures' and 2.0% chlorhexidine in 70% alcohol applicators (ChloraPrep) was licensed for 'disinfection of the skin prior to invasive medical procedures'. Some formulations of chlorhexidine in alcohol were off label for this use. See NICE's information on prescribing medicines.</p>
Alternative if the surgical site is next to a mucous membrane	<p>Aqueous solution of chlorhexidine</p> <p>At the time of publication (April 2019), 4.0% aqueous chlorhexidine (Hibiscrub) was licensed for 'preoperative and postoperative skin antisepsis for patients undergoing elective surgery'; however, relevant instructions were limited to use as a body wash to be used before the person enters the operating theatre. Other formulations of aqueous chlorhexidine were off label for this use. See NICE's information on prescribing medicines.</p>
Alternative if chlorhexidine is contraindicated	<p>Alcohol-based solution of povidone-iodine</p> <p>At the time of publication (April 2019), 10% povidone-iodine alcoholic solution (Videne alcoholic tincture) was licensed for 'topical application'. 10% povidone-iodine (Betadine Alcoholic solution) was licensed for 'antiseptic skin cleanser for major and minor surgical procedures'. Other formulations of povidone-iodine alcoholic solution were off label for this use. See NICE's information on prescribing medicines.</p>

Articles ■

Efficacy of different preoperative skin antiseptics on the incidence of surgical site infections: a systematic review, GRADE assessment, and network meta-analysis

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*Contributed equally
Amsterdam University Medical Center, Department of Surgery, University of Amsterdam, Amsterdam, Netherlands (H Jalalzadeh MD, H Groenen MD, N Wolfhagen MD, Prof M A Boermeester MD); Amsterdam Gastroenterology Endocrinology and Metabolism, Amsterdam, Netherlands (H Jalalzadeh, H Groenen, N Wolfhagen, Prof M A Boermeester); Dutch National Guideline Group for Prevention of Postoperative Surgical Site Infections, Utrecht, Netherlands (H Jalalzadeh, H Groenen, D R Buis MD, Y E M Dreissen MD, J H M Goosen MD, F F A Ijzma MD, M J van der Loos MD, R R Schaadt MD, P Segers MD, W C van der Zwart MD, M Griekspoor MSC, W J Harmsen PhD, N Wolfhagen, Prof M A Boermeester)

Correspondence to
Prof Marja A Boermeester,
Amsterdam University Medical Center Department of Surgery

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Berrios-Torres (2017) ⁴	Multiple meta-analyses	“Perform intraoperative skin preparation with an alcohol-based antiseptic agent unless contraindicated.”
WHO (2018) ⁵	Multiple meta-analyses	“The panel recommends alcohol-based antiseptic solutions based on chlorhexidine for surgical site skin preparation in patients undergoing surgical procedures.”
NICE (2019) ³	Network meta-analysis	First choice of skin preparation is alcohol-based solution of chlorhexidine, alternative is aqueous solution of chlorhexidine if surgical site is next to a mucous membrane. If chlorhexidine is contraindicated, alcohol-based solution of povidone-iodine can be used as an alternative. If both an alcohol-based solution and chlorhexidine are unsuitable, aqueous solution of povidone-iodine can be used.
Our study	Network meta-analysis	Use chlorhexidine in alcohol in a concentration of 2.0–2.5% for skin preparation before any surgical procedures; if this concentration is not available, 0.5% or 4.0% chlorhexidine in alcohol can be used.
Clean surgery only		
Wade et al (2021) ⁶	Network meta-analysis	“Alcoholic formulations of 4%–5% chlorhexidine seem to be safe and twice as effective as povidone iodine (alcoholic or aqueous solutions) in preventing infection after clean surgery in adults. These findings concur with the literature on contaminated and clean-contaminated surgery, and endorse guidelines worldwide which advocate the use of alcoholic chlorhexidine for preoperative skin antisepsis.”
Dumville et al (2015) ⁴⁴	Multiple meta-analyses	“A comprehensive review of current evidence found some evidence that preoperative skin preparation with 0.5% chlorhexidine in methylated spirits was associated with lower rates of SSIs following clean surgery than alcohol-based povidone iodine paint. However this single study was poorly reported. Practitioners may therefore elect to consider other characteristics such as costs and potential side effects when choosing between alternatives.”
Our study	Network meta-analysis	Use chlorhexidine in alcohol for skin preparation before clean surgical procedure (no specific concentration of chlorhexidine plus alcohol).
NICE=National Institute for Health and Care Excellence. SSIs=surgical site infections.		

Table 3: Comparison of current recommendations of different network meta-analyses

Disinfettanti: solo specialità medicinali per l'antisepsi ma c'è scarsa disponibilità

Dal 31 agosto non è più consentito utilizzare presidi medico-chirurgici per la disinfezione della cute integra prima di un intervento in sala operatoria

di Massimo Sartelli*

18 settembre 2025



Rischio immediato

Mancata applicazione
della normativa

Importazione di
prodotti da Paesi
extraeuropei

Preparati galenici
realizzati con scarsa
rigorosità

La vera sfida oggi è garantire una transizione sostenibile per il sistema sanitario, senza mai perdere di vista l'obiettivo primario: **ridurre le infezioni e proteggere i pazienti.**

Rispettare le nuove regole significa non solo adeguarsi alla legge, ma rafforzare la cultura della prevenzione e la sicurezza delle cure. Nel frattempo, le decisioni basate sulle evidenze rimangono strumenti imprescindibili per trasformare un passaggio complesso in un'occasione preziosa per consolidare un approccio più rigoroso alla lotta contro le infezioni ospedaliere.

La multidisciplinarietà può fare la differenza



Società Italiana Multidisciplinare per la Prevenzione
delle Infezioni nelle Organizzazioni Sanitarie

SIMPIOS da più di 20 anni
promuove la ricerca, la
formazione e l'informazione
sul tema delle infezioni nelle
organizzazioni sanitarie,
integrando le varie
professionalità
coinvolte nella prevenzione
e nel controllo delle infezioni

Grazie per l'attenzione

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