Forum HH : « Evidence-based medicine/nursing et PCi »
Mardi 7 novembre 2023

Comment sont élaborées les recommandations ?

Dr Bruno Grandbastien
Centre Hospitalier Universitaire Vaudois
et Université de Lausanne

UNIL | Université de Lausanne

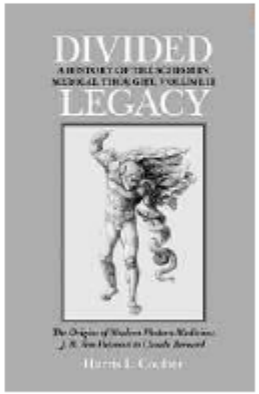
Les recommandations de bonne pratique en PCi

- Synthèse des recommandations
  ± commentaires
- Argumentaire scientifique
- Liste des références
- Méthode de recherche bibliographique
- Éléments complémentaires :
  - métaanalyses
  - …

Historique des essais randomisés

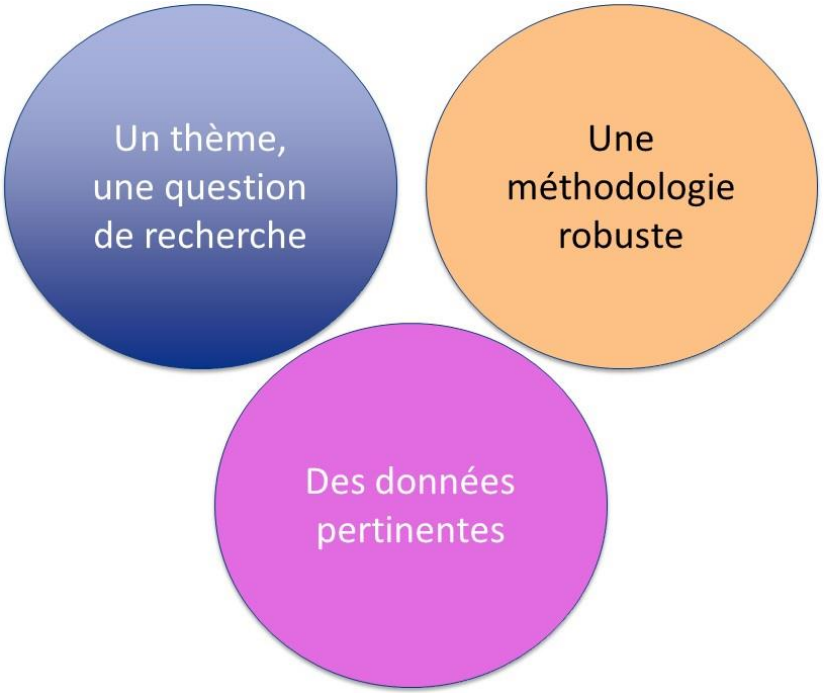
- « Laissez-moi prendre dans un hôpital ou dans un camp ou ailleurs, 200 ou 500 pauvres atteints de fièvre ou de pleurésie etc. laissez-moi les diviser en deux et tirer au sort ceux que je soignerai et ceux que vous soignerez... Nous verrons ensuite combien chacun de nous observera de décès : mais laissons la récompense du pari, disons 300 florins répartie des deux côtés »
  - Jean-Baptiste Van Helmont (1662)

- Harris Coulter
- The Origins of Modern Western Medicine: J.B. Van Helmont to Claude Bernard
- North Atlantic Books. 2001. 816 p



Pyramide des niveaux de preuve

Triptyque caractérisant une bonne étude



Comment sont présentées les recommandations ?

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

Perform hand hygiene § in the following clinical situations:

IV.A.3.a. Before having direct contact with patients [664, 979]. *Category IB*

IV.A.3.b. After contact with blood, body fluids or excretions, mucous membranes, nonintact skin, or wound dressings [664]. *Category IA*

IV.A.3.c. After contact with a patient's intact skin (e.g., when taking a pulse or blood pressure or lifting a patient) [167, 976, 979, 980]. *Category IB*

IV.A.3.d. If hands will be moving from a contaminated-body site to a clean-body site during patient care. *Category II*

IV.A.3.e. After contact with inanimate objects (including medical equipment) in the immediate vicinity of the patient [72, 73, 88, 800, 981 982]. *Category II*

IV.A.3.f. After removing gloves [728, 741, 742]. *Category IB*

Antisepsie cutanée avant geste chirurgical sur peau saine

R4 Avant geste chirurgical sur peau saine, il est fortement recommandé de pratiquer une désinfection large du site opératoire. **(A-3)**

R5 Avant geste chirurgical sur peau saine, il est fortement recommandé de veiller à l'absence de collection (« coulure ») d'antiseptique alcoolique afin de prévenir un risque de brûlure lors de l'utilisation du bistouri électrique. **(A-2)**

R6 Avant geste chirurgical sur peau saine, il est recommandé d'utiliser une solution alcoolique d'antiseptique plutôt qu'une solution aqueuse. **(B-3)**

R7 Avant geste chirurgical sur peau saine, il est possible d'utiliser une solution alcoolique de chlorhexidine ou de povidone iodée. **(C-2)**

COMMENTAIRES

- Pour la préparation cutanée de l'opéré, les recommandations 2013 de la SF2H concernant la douche préopératoire doivent être appliquées.

Gradation des recommandations

- Multitudes de systèmes :
  - Haute Autorité de santé - France (2013)
  - New Zealand Guidelines Group (2001)
  - American academy of pediatrics (2004)
  - The Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group (2008)
  - Scottish Intercollegiate Guidelines Network (2008)
  - US Preventive Services Task Force (2008)
  - National Health and Medical Research Council (2009)
  - National Institute for Health and Clinical Excellence (2009)
  - American College of Physicians' system (2010)
  - Infectious Diseases Society of America (2010)
  - ....

Gradation des recommandations

- Multitudes de systèmes :
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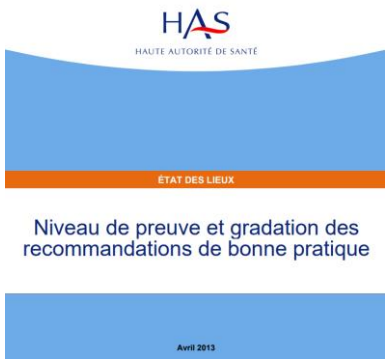
  - American College of Physicians' system (2010)
  - Infectious Diseases Society of America (2010)
  - ....

Gradation des niveaux de preuve

- Haute Autorité de Santé (France)



Grade des recommandations	Niveau de preuve scientifique fourni par la littérature
A Preuve scientifique établie	Niveau 1 - essais comparatifs randomisés de forte puissance ; - méta-analyse d'essais comparatifs randomisés ; - analyse de décision fondée sur des études bien menées.
B Présomption scientifique	Niveau 2 - essais comparatifs randomisés de faible puissance ; - études comparatives non randomisées bien menées ; - études de cohortes.
C Faible niveau de preuve scientifique	Niveau 3 - études cas-témoins.
	Niveau 4 - études comparatives comportant des biais importants ; - études rétrospectives ; - séries de cas ; - études épidémiologiques descriptives (transversale, longitudinale).

Gradation de la force de la recommandation

- D'après la Haute Autorité de Santé (France) : mise à jour 2020

« consensus formalisé d'experts » :

- Accord fort
- Accord relatif

« recommandation pour la pratique clinique» :

- 1 : « il est fortement recommandé de … »
- 2 : « il est recommandé de … »
- 3 : « il est possible de … »

Gradation : en synthèse

- Haute Autorité de Santé (France)

		Force de la recommandation		
		1 : « Il est fortement recommandé de … »	**2** : « il est recommandé de … »	**3** : « il est possible de … »
Niveau de preuve	**A** : établi	A1	A2	A3
	B : présomption	B1	B2	B3
	C: faible	C1	C2	C3

Gradation des niveaux de preuve

- IDSA

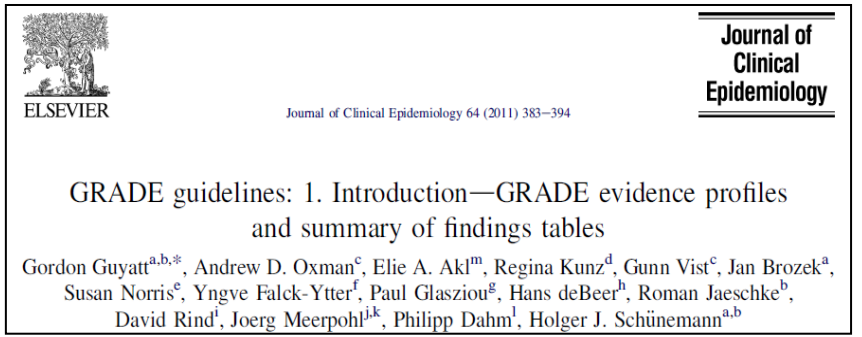
Table 2. Infectious Diseases Society of America–United States Public Health Service Grading System for ranking recommendations in clinical guidelines.

Category, grade	Definition
Strength of recommendation	
A	Good evidence to support a recommendation for use
B	Moderate evidence to support a recommendation for use
C	Poor evidence to support a recommendation
D	Moderate evidence to support a recommendation against use
E	Good evidence to support a recommendation against use
Quality of evidence	
I	Evidence from ⩾1 properly randomized, controlled trial
II	Evidence from ⩾1 well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from >1 center); from multiple time-series; or from dramatic results from uncontrolled experiments
III	Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Kish MA, Clin Infect Dis 2001

Grading of Recommendations Assessment, Development and Evaluation (GRADE)

- Qualité des données scientifiques
  = fondée sur une revue systématique de la recherche clinique pertinente
- Prise en compte de la qualité des études, l'homogénéité des résultats, le caractère direct des données
  - –études randomisées : qualité élevée
  - –études observationnelles : qualité faible
- Prise en compte des biais



ELSEVIER

Journal of Clinical Epidemiology 64 (2011) 383–394

Journal of Clinical Epidemiology

GRADE guidelines: 1. Introduction—GRADE evidence profiles and summary of findings tables

Gordon Guyatt[a,b,*], Andrew D. Oxman[c], Elie A. Akl[m], Regina Kunz[d], Gunn Vist[c], Jan Brozek[a], Susan Norris[e], Yngve Falck-Ytter[f], Paul Glasziou[g], Hans deBeer[h], Roman Jaeschke[b], David Rind[i], Joerg Meerpohl[j,k], Philipp Dahm[l], Holger J. Schünemann[a,b]

Guyatt G, J Clin Epidemiol 2011

GRADE : présentation de l'analyse

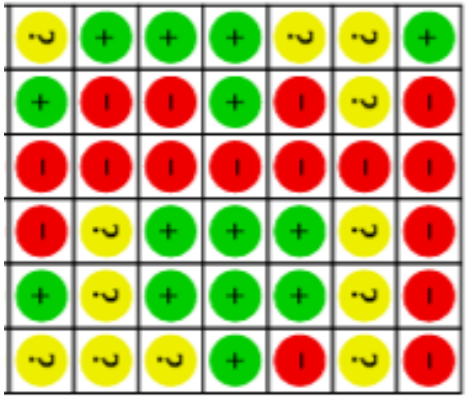
Tableau VIII – Choix de la molécule antiseptique avant chirurgie ; restriction aux études comparant des antiseptiques en solutions alcooliques.

Auteur, Année	Méthode	Population	Intervention	Critère de jugement	Résultats	Commentaires
Berry *et al.* 1982 [134]	• Essai randomisé	• Royaume-Uni • 866 patients de chirurgie réglée (voies biliaires : 167, colon : 61, laparotomies d'indications autres : 96, autres : 542)	• (1) Antisepsie à 0,5 % CHX + alcool • (2) Antisepsie à 10 % PVI + IPA	• ISO	• (1) 44/453 : 9,7 % • (2) 61/413 : 14,8 % • RR = 0,66 ; IC95 [0,46-0,95], p = 0.03	• Hétérogénéité des interventions incluses • Taux d'ISO élevés
Ostrander *et al.* 2005 [135]	• Essai randomisé	• États-Unis • 125 patients avec chirurgie du pied et de la cheville	• (1) Antisepsie à 2 % CHX + 70 % IPA (2) Antisepsie à 0,7 % PVI + 70 % IPA • (3) Antisepsie au chloroxylénol 3 %	• Cultures cutanées (hallux, doigt de pied) • ISO	• Cultures cutanées - (1) : 30 %, (2) : 65 % et (3) : 95 % - p < 0,001 • ISO - (1) : 1/40, (2) : 0/45 et (3) : 2/40 - p = 0,32	• Effectifs faibles • Pas de renseignements sur la méthode d'identification des ISO
Saltzman *et al.* 2009 [72]	• Essai randomisé	• États-Unis • 150 patients avec chirurgie de l'épaule	• (1) Antisepsie à 2 % CHX + 70 % IPA • (2) Antisepsie à 0,7 % PVI + 74 % IPA	• Cultures cutanées • ISO	• Cultures cutanées - (1) : 7 % et (2) : 19 % - p < 0,01 • ISO : aucune	• Effectifs faibles • Part importante de chirurgie par arthroscopie (137/150) • Pas de renseignements sur la méthode d'identification des ISO
Veiga *et al.* 2008 [136]	• Essai randomisé	• États-Unis • 250 patients avec chirurgie plastique propre réglée	• (1) Antisepsie à 0,5 % CHX + alcool • (2) Antisepsie à 10 % PVI à 10 % + alcool	• Cultures cutanées • ISO	• Cultures cutanées en fin de chirurgie - (1) : 7,9 UFC et (2) : 2,7 UFC - p < 0,006 • ISO - (1) : 0 et (2) : 4/125 (3,2 %) - p = 0,12	• Effectifs faibles • Interprétation erronée du test statistique dans la publication (test exact de Fisher unilatéral) ; la valeur réelle est reprise dans ce tableau
Tuuli *et al.* 2016 [7]	• Essai randomisé	• États-Unis • 1 147 patientes césarisées	• (1) Antisepsie à 2 % CHX + 70 % IPA • (2) Antisepsie à 8,3 % PVI + 72,5 % IPA	• ISO	• (1) : 23/572 (4 %) • (2) : 42/575 (7,3 %) • RR : 0,55 ; IC95 [0,34 – 0,90], p = 0,02	• Étude monocentrique • Période d'inclusion longue (3,7 ans)
Ngail *et al.* 2015 [8]	• Essai randomisé	• États-Unis • 1 404 patientes césarisées	• (1) Antisepsie à 2 % CHX + 70 % IPA • (2) Antisepsie à la PVI alcoolique • (3) PVI alcoolique, puis 2 % CHX alcoolique	• ISO	• (1) : 21/463 (4,6 %) • (2) : 21/474 (4,5 %) • (3) : 18/467 (3,9 %) • p = 0,85	• Étude monocentrique • Pas de précision sur la concentration en PVI

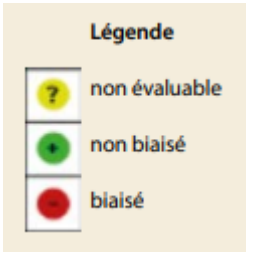
CHX : gluconate de chlorhexidine, IPA : alcool isopropylique, ISO : infection du site opératoire, PVI : povidone iodée.

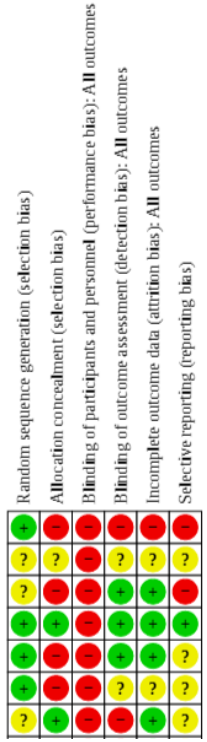
SF2H. Antisepsie de la peau saine avant un geste invasif chez l'adulte, HygièneS 2016

Méthode GRADE : présentation des biais



- Randomisation explicitée
- Attribution à l'aveugle
- Participants et investigateurs aveugles
- Evaluation de l'impact aveugle
- Données incomplètes quant au critère de jugement
- Publications sélectionnés





GRADE : impact sur le niveau de preuve

- **Niveau de preuve diminue si:**
  - 1. Biais (serious: -1 / very serious : -2)
  - 2. Imprécision (serious: -1 / very serious : -2)
  - 3. Hétérogénéité des résultats (serious: -1 / very serious : -2)
  - 4. Mesure indirecte (serious: -1 / very serious : -2)
  - 5. Probable biais de publication (non détecté / fortement suspecté : -1)

GRADE : impact sur le niveau de preuve

- **Niveau de preuve augmente si:**
  - 1. Effets importants (importants: +1; très importants: +2)
  - 2. Gradient dose-réponse (+1)
  - 3. Facteurs confondants diminuant probablement l'effet observé (+1)

GRADE : illustration

Qualité de l'étude

Type d'étude	Grade initial	Critères entrainant une décote	Critères entrainant une surcote	Grade final
Essai randomisé	Haut	Limitation (-1) ou limitation importante (-2) dans la qualité de l'étude		Haut Modéré
Etude observationnelle	Bas		Association forte (+1) ou très forte (+2)	Bas Modéré

GRADE : illustration

Cohérence

Type d'étude	Grade initial	Critères entrainant une décote	Critères entrainant une surcote	Grade final
Etude observa-tionnelle	Bas	Défaut de cohérence (-1)		Bas
			Identification d'une relation dose-effet (+1)	Modéré
ou autres	Très bas			Bas

GRADE : illustration

Biais

Type d'étude	Grade initial	Critères entrainant une décote	Critères entrainant une surcote	Grade final
Etude observa-tionnelle	Bas	Quelques biais (-1) ou très nombreux biais (-2)	Prise en compte des biais dans l'analyse (+1)	Bas
ou autres	Très bas			Modéré / Bas

Lecture critique des recommandations : quelques exemples

Quelle antisepsie avant un geste chirurgical ?

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Chlorhexidine–Alcohol versus Povidone–Iodine for Surgical-Site Antisepsis

Rabih O. Darouiche, M.D., Matthew J. Wall, Jr., M.D., Kamal M.F. Itani, M.D., Mary F. Otterson, M.D., Alexandra L. Webb, M.D., Matthew M. Carrick, M.D., Harold J. Miller, M.D., Samir S. Awad, M.D., Cynthia T. Crosby, B.S., Michael C. Mosier, Ph.D., Atef AlSharif, M.D., and David H. Berger, M.D.

Darouiche R, NEJM 2010

- But : choix de la molécule antiseptique
- Étude randomisée contrôlée
- Multicentrique, 849 patients
- 2 bras :
  - chlorhexidine 2% en solution alcoolique (isopropanol 70%)
  - povidone iodée 10% en solution aqueuse
- Analyse en intention de traiter

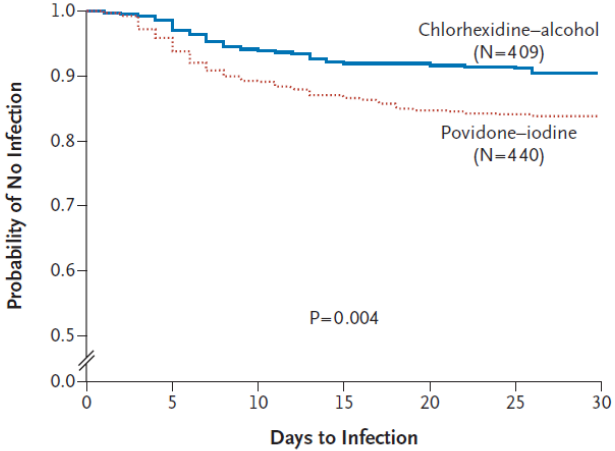


Figure 2. Kaplan–Meier Curves for Freedom from Surgical-Site Infection (Intention-to-Treat Population).

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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Darouiche R, NEJM 2010

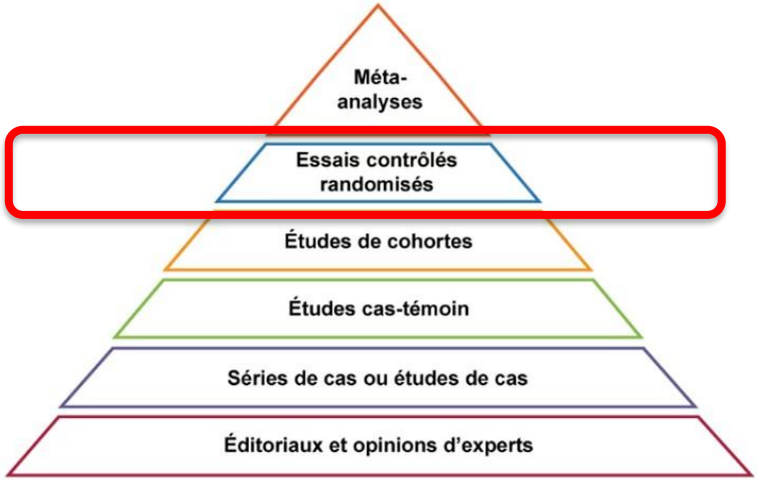
Table 2. Proportion of Patients with Surgical-Site Infection, According to Type of Infection (Intention-to-Treat Population).

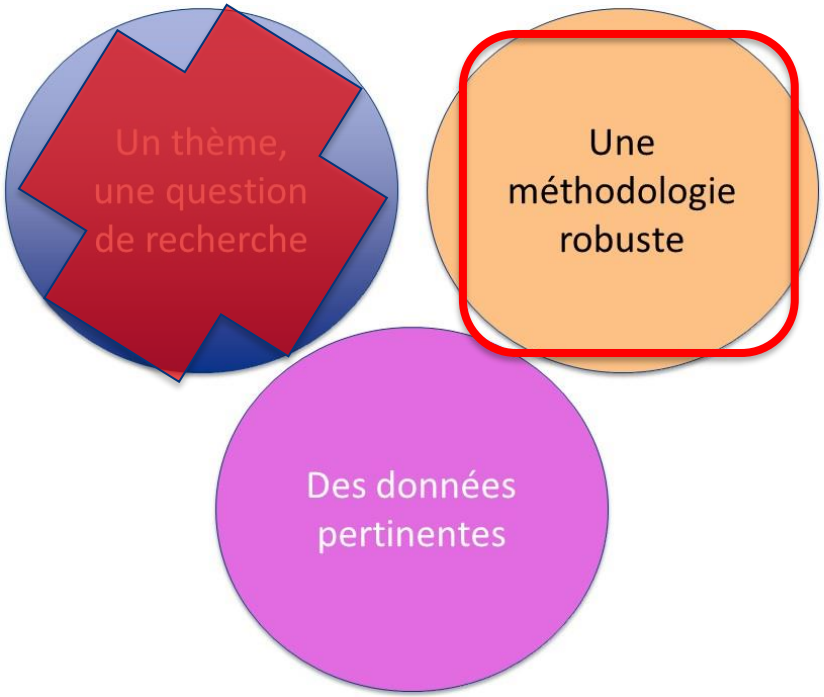
Type of Infection	Chlorhexidine–Alcohol (N=409)	Povidone–Iodine (N=440)	Relative Risk (95% CI)*	P Value†
	no. (%)			
Any surgical-site infection	39 (9.5)	71 (16.1)	0.59 (0.41–0.85)	0.004
Superficial incisional infection	17 (4.2)	38 (8.6)	0.48 (0.28–0.84)	0.008
Deep incisional infection	4 (1.0)	13 (3.0)	0.33 (0.11–1.01)	0.05

Interprétation ?

- Conclusion des auteurs :
  - antisepsie pré-op : **CHX-alcoolique >>> PVPi**
  - effets secondaires identiques dans les 2 groupes

- Mais quelle était la question ?
  - choix d'une molécule ATS ?


Méta-analyses
Essais contrôlés randomisés
Études de cohortes
Études cas-témoin
Séries de cas ou études de cas
Éditoriaux et opinions d'experts


Un thème, une question de recherche
Une méthodologie robuste
Des données pertinentes

Series

Surgical site infections 1

New WHO recommendations on preoperative measures for surgical site infection prevention: an evidence-based global perspective

*Benedetta Allegranzi, Peter Bischoff, Stijn de Jonge, N Zeynep Kubilay, Bassim Zayed, Stacey M Gomes, Mohamed Abbas, Jasper J Atema, Sarah Gans, Miranda van Rijen, Marja A Boermeester, Matthias Egger, Jan Kluytmans, Didier Pittet, Joseph S Solomkin, and the WHO Guidelines Development Group**

Series

Surgical site infections 2

New WHO recommendations on intraoperative and postoperative measures for surgical site infection prevention: an evidence-based global perspective

Benedetta Allegranzi, Bassim Zayed, Peter Bischoff, N Zeynep Kubilay, Stijn de Jonge, Fleur de Vries, Stacey M Gomes, Sarah Gans, Elon D Wallert, Xiuwen Wu, Mohamed Abbas, Marja A Boermeester, E Patchen Dellinger, Matthias Egger, Petra Gastmeier, Xavier Guirao, Jianan Ren, Didier Pittet, Joseph S Solomkin, and the WHO Guidelines Development Group

Lancet ID 2016

Guide OMS, update 2018

GLOBAL GUIDELINES
FOR THE PREVENTION OF
SURGICAL SITE INFECTION

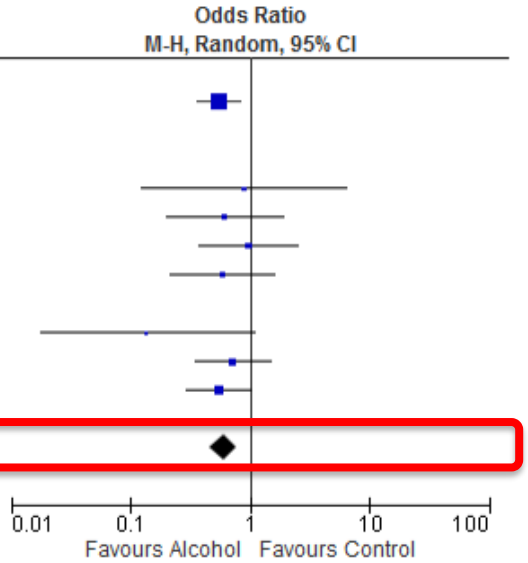
World Health Organization

Choix d'une solution alcoolique ?

Comparison 1: Alcohol-based solutions vs. aqueous solutions - overall RCTs, outcome SSI

Study or Subgroup	Alcohol Events	Alcohol Total	Control Events	Control Total	Weight	Odds Ratio M-H, Random, 95% CI
Bibbo, 2005	0	60	0	67		Not estimable
Darouiche, 2010	39	409	71	440	42.3%	0.55 [0.36, 0.83]
Gilliam, 1990	0	30	0	30		Not estimable
Hort, 2002	0	23	0	26		Not estimable
Howard, 1991	2	84	2	75	1.9%	0.89 [0.12, 6.48]
Paocharoen, 2009	5	250	8	250	5.7%	0.62 [0.20, 1.91]
Roberts, 1995	9	96	10	104	8.2%	0.97 [0.38, 2.51]
Rodrigues, 2013	7	95	11	92	7.4%	0.59 [0.22, 1.58]
Saltzman, 2009	0	100	0	50		Not estimable
Segal, 2002	1	50	14	108	1.7%	0.14 [0.02, 1.07]
Sistla, 2010	14	200	19	200	14.2%	0.72 [0.35, 1.47]
Srinivas, 2014	17	158	33	184	18.6%	0.55 [0.29, 1.03]
Total (95% CI)		**1555**		**1626**	**100.0%**	**0.60 [0.45, 0.78]**
Total events	94		168			

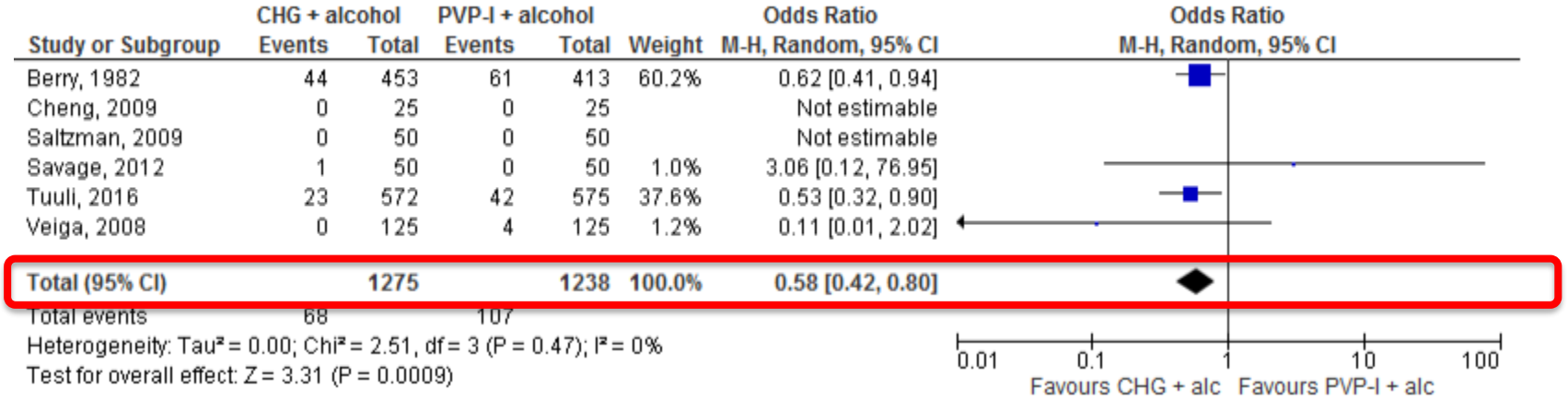
Heterogeneity: Tau² = 0.00; Chi² = 3.65, df = 7 (P = 0.82); I² = 0%
Test for overall effect: Z = 3.75 (P = 0.0002)



Guide OMS ; V2 de 2018 ; données supplémentaires (appendix #8)

https://cdn.who.int/media/docs/default-source/integrated-health-services-(ihs)/ssi/evidence/appendix8.pdf?sfvrsn=eaf9f849_2

Choix de la molécule antiseptique ?



Study or Subgroup	CHG + alcohol Events	Total	PVP-I + alcohol Events	Total	Weight	Odds Ratio M-H, Random, 95% CI
Berry, 1982	44	453	61	413	60.2%	0.62 [0.41, 0.94]
Cheng, 2009	0	25	0	25		Not estimable
Saltzman, 2009	0	50	0	50		Not estimable
Savage, 2012	1	50	0	50	1.0%	3.06 [0.12, 76.95]
Tuuli, 2016	23	572	42	575	37.6%	0.53 [0.32, 0.90]
Veiga, 2008	0	125	4	125	1.2%	0.11 [0.01, 2.02]
Total (95% CI)		**1275**		**1238**	**100.0%**	**0.58 [0.42, 0.80]**
Total events	68		107			

Heterogeneity: Tau² = 0.00; Chi² = 2.51, df = 3 (P = 0.47); I² = 0%
Test for overall effect: Z = 3.31 (P = 0.0009)

Guide OMS ; V2 de 2018 ; données supplémentaires (appendix #8)

https://cdn.who.int/media/docs/default-source/integrated-health-services-(ihs)/ssi/evidence/appendix8.pdf?sfvrsn=eaf9f849_2

Surgical site infections 1

New WHO recommendations on preoperative measures for surgical site infection prevention: an evidence-based global perspective

Benedetta Allegranzi, Peter Bischoff, Stijn de Jonge, N Zeynep Kubilay, Bassim Zayed, Stacey M Gomes, Mohamed Abbas, Jasper J Atema, Sarah Gans, Miranda van Rijen, Marja A Boermeester, Matthias Egger, Jan Kluytmans, Didier Pittet, Joseph S Solomkin, and the WHO Guidelines Development Group*

Allegranzi B, Lancet ID 2016

	Key research question	Recommendations for prevention of SSIs	Strength of recommendation (quality of evidence retrieved†)	Notes for implementation in low-income and middle-income countries
(12) Surgical site preparation	In surgical patients, should alcohol-based antiseptic or aqueous solutions be used for skin preparation and, more specifically, should CHG or povidone-iodine solutions be used?	Alcohol-based antiseptic solutions based on CHG for surgical site skin preparation should be used in patients undergoing surgical procedures	Strong recommendation (low to moderate)	Availability of alcohol-based antiseptic solutions based on CHG is low and their use can be an additional cost for the health-care facility; local production should be encouraged

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized Trial Comparing Skin Antiseptic Agents at Cesarean Delivery

Methodius G. Tuuli, M.D., M.P.H., Jingxia Liu, Ph.D., Molly J. Stout, M.D., M.S.C.I., Shannon Martin, R.N., Alison G. Cahill, M.D., M.S.C.I., Anthony O. Odibo, M.D., M.S.C.E., Graham A. Colditz, M.D., Dr.P.H., and George A. Macones, M.D., M.S.C.E.

Tuuli MG, NEJM 2016

- Étude randomisée contrôlée
- 1 147 césariennes
- CHX 2% dans isopropanol 70%
  vs PVPi 8,3% dans 70% isopropanol
- analyse en intention de traiter

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Tuuli MG, NEJM 2016

Outcome	Chlorhexidine–Alcohol (N=572)	Iodine–Alcohol (N=575)	Relative Risk (95% CI)	P Value*
Primary outcome				
Surgical-site infection — no. (%)	23 (4.0)	42 (7.3)	0.55 (0.34–0.90)	0.02
Superficial incisional	17 (3.0)	28 (4.9)	0.61 (0.34–1.10)	0.10
Deep incisional	6 (1.0)	14 (2.4)	0.43 (0.17–1.11)	0.07

Mais …

Original Research

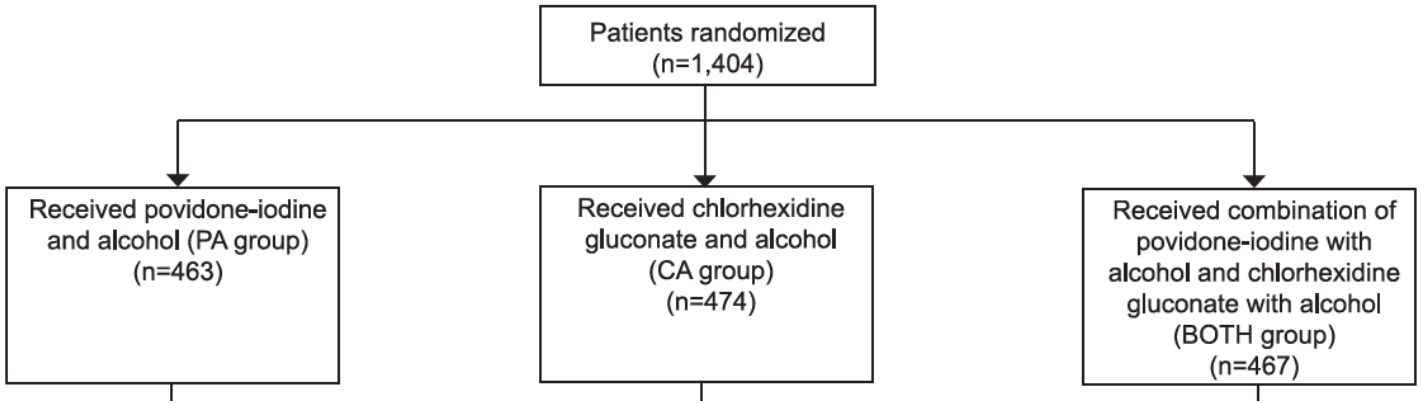
Skin Preparation for Prevention of Surgical Site Infection After Cesarean Delivery

A Randomized Controlled Trial

Ivan M. Ngai, MD, Anne Van Arsdale, MD, MSc, Shravya Govindappagari, MD, Nancy E. Judge, MD, Nicole K. Neto, MD, Jeffrey Bernstein, MD, Peter S. Bernstein, MD, MPH, and David J. Garry, DO

Ngai IM, Obst & Gynecol 2015

- Étude randomisée contrôlée



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Skin Preparation for Prevention of Surgical Site Infection After Cesarean Delivery

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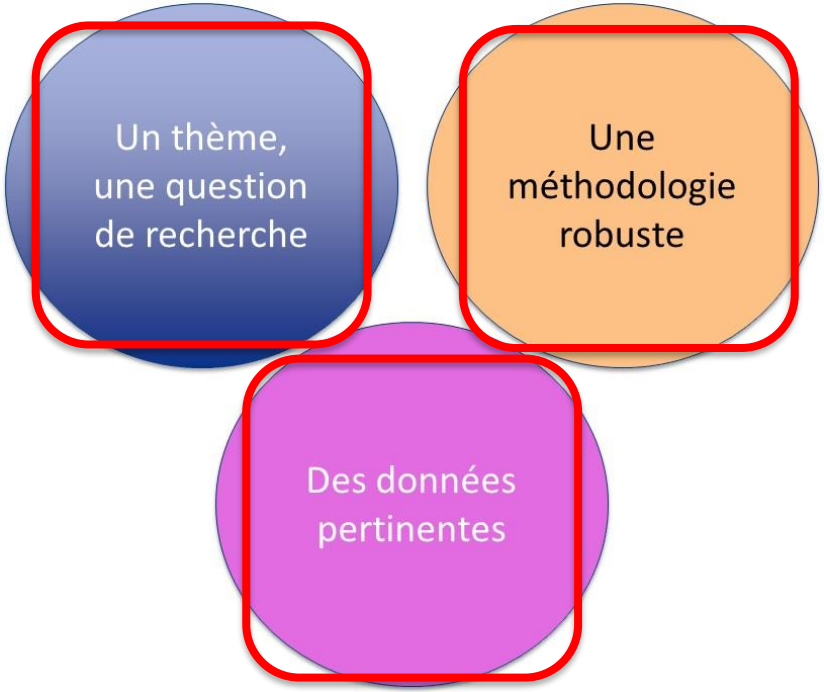
Ngai IM, Obst & Gynecol 2015

Table 2. Surgical Site Infection Rate

Characteristic	Iodine (n=463)	Chlorhexidine (n=474)	Both (n=467)	*P*
Any SSI	21 (4.6)	21 (4.5)	18 (3.9)	.85
SSI type				.96
Superficial	16 (3.5)	15 (3.2)	15 (3.2)	
Deep	3 (0.7)	3 (0.6)	1 (0.2)	
Organ	2 (0.4)	3 (0.6)	2 (0.4)	

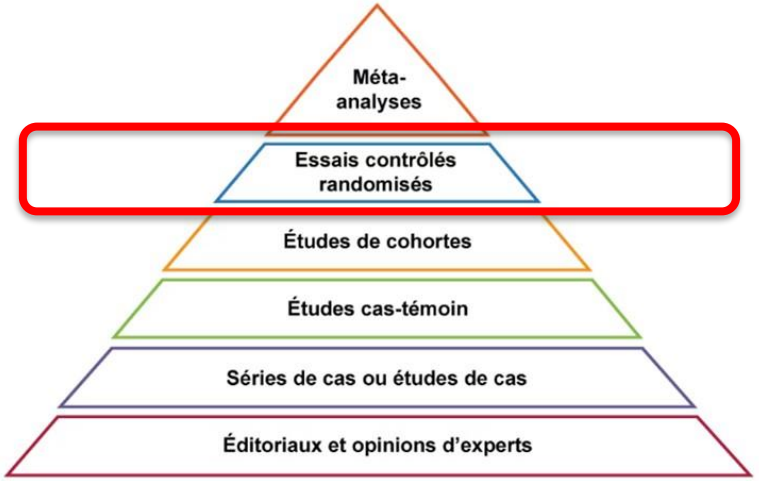
SSI, surgical site infection.
Data are n (%) unless otherwise specified.

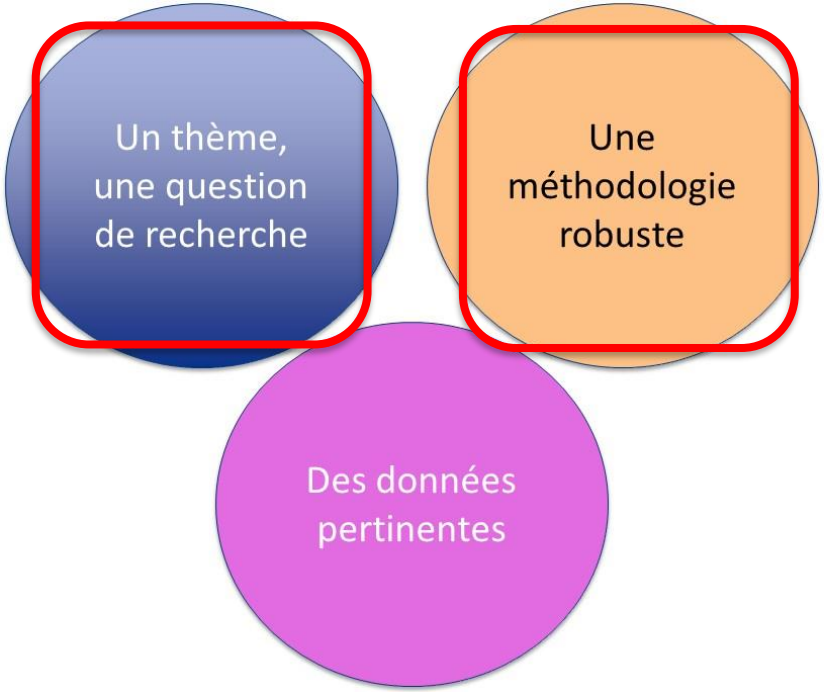
Guide OMS



En faveur d'une antisepsie par chlorhexidine alcoolique

Tuuli et Ngai …





Une étude : ++ CHX alcoolique, l'autre : pas de choix

- Protocole proposé
- Étude randomisée contrôlée
- 4 100 patients de chirurgie cardiaque
- CHX 2% dans 70% isopropanol vs PVPi 5% dans 69% éthanol
- Analyse en intention de traiter
- Recrutement terminé le 25 mai 2022


Open access Protocol

BMJ Open

Multicentre, open-label, randomised, controlled clinical trial comparing 2% chlorhexidine–70% isopropanol and 5% povidone iodine–69% ethanol for skin antisepsis in reducing surgical-site infection after cardiac surgery: the CLEAN 2 study protocol

Matthieu Boisson,[1,2] Pierre Corbi,[3] Thomas Kerforne,[1] Lionel Camilleri,[4] Mathieu Debauchez,[5] Pierre Demondion,[6] Vedat Eljezi,[7] Erwan Flecher,[8] Didier Lepelletier,[9] Pascal Leprince,[6] Nicolas Nesseler,[10] Jacques Yves Nizou,[11] Jean Christian Roussel,[12] Bertrand Rozec,[13] Stéphane Ruckly,[14] Jean-Christophe Lucet,[15,16] Jean-François Timsit,[14,17] Olivier Mimoz[2,18]

Boisson M, BMJOpen 2019

Place du flux unidirectionnel au bloc opératoire en prévention des infections du site opératoire en chirurgie orthopédique prothétique ?

Etude princeps …

Effect of ultraclean air in operating rooms on deep sepsis in the joint after total hip or knee replacement: a randomised study

O M LIDWELL, E J L LOWBURY, W WHYTE, R BLOWERS, S J STANLEY, D LOWE

Lidwell O, Br Med J 1982

- Etude ± randomisée ; prothèses de hanche et de genou
- Multicentrique
- 8 055 interventions (6 781 hanches et 1 274 genoux)
- Critères de jugement :
  - aérobiocontamination salle
  - contamination de la plaie
  - incidence des ISO

Effect of ultraclean air in operating rooms on deep sepsis in the joint after total hip or knee replacement: a randomised study

O M LIDWELL, E J L LOWBURY, W WHYTE, R BLOWERS, S J STANLEY, D LOWE

Lidwell O, Br Med J 1982

… deep sepsis after 63 out of 4 133 operations in the control group (1.5%) and after 23 out of 3 922 operations in the ultraclean-air groups (0.6%)
(ratio 2.6, 95% confidence limits 1.6-4.2; p <0 001)

Mais …

- Métanalyse

Journal of Hospital Infection 81 (2012) 73–78

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Review

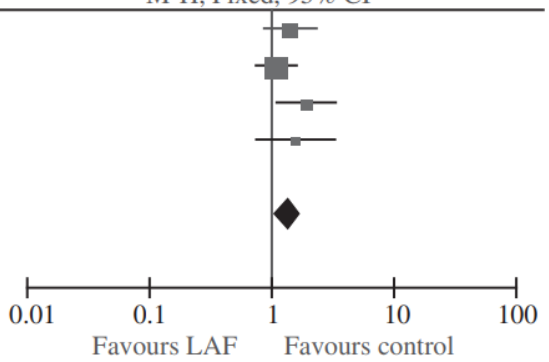
Influence of laminar airflow on prosthetic joint infections: a systematic review

P. Gastmeier [a,*], A.-C. Breier [a], C. Brandt [b]

[a] Institute of Hygiene and Environmental Medicine, Charité-Universitätsmedizin Berlin, Germany
[b] Institute of Medical Microbiology and Infection Control, Goethe-University Frankfurt, Germany

Gastmeier P, J Hosp Infect 2012

Study or Subgroup	Risk Ratio M-H, Fixed, 95% CI
Brandt et al.[13]	1.42 [0.87, 2.32]
Breier et al.[3]	1.09 [0.74, 1.60]
Hooper et al.[2]	1.92 [1.10, 3.34]
Miner et al.[12]	1.57 [0.75, 3.29]
Total (95% CI)	1.36 [1.06, 1.74]
Total events	
Heterogeneity: Chi² = 2.91, df = 3 (P = 0.41); I² = 0%	
Test for overall effect: Z = 2.42 (P = 0.02)	



Mais …

Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff, N Zeynep Kubilay, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier

- Métanalyses

Bischoff P, Lancet ID 2017

	Laminar airflow		Conventional ventilation		Weight	Odds ratio (95% CI)
	Events	Total	Events	Total		
Kakwani et al (2007)[39]	0	212	9	223	0·9%	0·05 (0·00–0·92)
Brandt et al (2008)[30]	242	17 657	99	10 966	16·1%	1·53 (1·21–1·93)
Dale et al (2009)[31]	324	45 620	260	48 338	17·1%	1·32 (1·12–1·56)
Pedersen et al (2010)[35]	517	72 423	80	8333	16·0%	0·74 (0·59–0·94)
Breier et al (2011)[37]	356	29 530	77	11 682	15·9%	1·84 (1·44–2·36)
Hooper et al (2011)[38]	25	16 990	21	34 495	10·1%	2·42 (1·35–4·32)
Namba et al (2012)[33]	46	8478	109	22 013	14·2%	1·10 (0·78–1·55)
Song et al (2012)[36]	34	2037	16	1149	9·8%	1·20 (0·66–2·19)
Total	1544	192 947	671	137 199	100·0%	1·29 (0·98–1·71)

Prothèse de hanche

	Laminar airflow		Conventional ventilation		Weight	Odds ratio (95% CI)
	Events	Total	Events	Total		
Miner et al (2007)[40]	15	3513	13	4775	11·4%	1·57 (0·75–3·31)
Brandt et al (2008)[30]	55	5993	22	3403	16·5%	1·42 (0·87–2·34)
Breier et al (2011)[37]	93	14 456	36	6098	19·1%	1·09 (0·74–1·60)
Hooper et al (2011)[38]	27	13 994	23	22 832	15·1%	1·92 (1·10–3·34)
Song et al (2012)[36]	27	2151	23	937	15·0%	0·51 (0·29–0·89)
Namba et al (2013)[34]	105	16 693	299	39 523	22·9%	0·83 (0·66–1·04)
Total	322	56 800	416	77 568	100·0%	1·08 (0·77–1·52)

Prothèse de genou

Pas de bénéfice à un flux unidirectionnel

CONTENTS

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The literature search did not identify any studies that reported on SSI-attributable mortality.

Additional factors considered when formulating the recommendation

Values and preferences

No study was found on patient values and preferences with regards to this intervention. The GDG is confident that the typical values and preferences of the target population regarding the outcome would not favour the intervention and therefore would agree with the recommendation. The GDG believes also that patients would not have an opinion about a hospital ventilation system, as long as other aspects are being taken into account to prevent infections.

Resource use

Cost-effectiveness analyses found laminar airflow to be more expensive compared to a conventional ventilation system. An Italian study *(18)* evaluated an increase of 24% in building costs and an increase of 36% in annual operating costs. A model calculation study from Australia *(19)* evaluated additional costs of AUD$ 4.59 million per 30 000 THAs performed. Additional costs of € 3.24 procedure (1000 procedures per year for 15 years) were calculated by a German study group *(20)*. The GDG highlighted that the implementation of laminar airflow is difficult in low-income settings due to the lack of resources, technical expertise and infrastructure.

Research gaps

The GDG highlighted the very low quality evidence available on the topic and the need for further research on the effects of laminar flow in reducing the SSI rate, particularly well-designed clinical trials in the field of endoprosthetic surgery. The GDG acknowledged that RCTs may not be reasonable as they would require a massive investment with a high sample size to have enough power to see a difference. In addition, cluster trials could be problematic as it would be almost impossible to control for confounding factors, such as different surgeons operating in the same operating room. Nationwide databases may provide the best affordable information, but adherence to international definitions and more information about confounders need to be obtained from country surveillance systems and registries. The lack of evidence on the impact of fans/cooling devices and natural ventilation on the SSI rate compared to conventional ventilation emphasizes the need for further research in this field in order to evaluate whether these systems might be an alternative in resource-limited countries when properly designed and maintained.

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Mais …

- Recommandations de l'OMS :

Guide OMS, update 2018

Topic	Research questions	Recommendations	Strength	Quality o evidence
		Preoperative measures		
Laminar flow ventilation systems in the context of OR ventilation	1. Is the use of laminar air flow in the OR associated with the reduction of overall or deep SSI?	The panel suggests that laminar airflow ventilation systems should **not** be used to reduce the risk of SSI for patients undergoing total arthroplasty surgery.	Conditional	Low to very low

nations. Some MENA countries have experienced political unrest for several years on end, which disrupts the deliverance of even basic medical care and long-term commitment to preventive medical policies becomes a very low priority.[4] So, although we do agree with Gültekin and Akgül, we also strongly believe that, to control HPV and cervical cancer effectively, it is of utmost importance to tailor the control methods to the individual cultural, political, and economic standards of the countries.

We declare no competing interests.

*Hossein Bannazadeh Baghi, Mohammad Aghazadeh

hbannazadeh@tbzmed.ac.ir

Infectious and Tropical Diseases Research Center, Tabriz University of Medical Sciences, PO Box 5165665931, Tabriz, Iran (HBB); Immunology Research Center, Tabriz University of Medical Sciences, Tabriz, Iran (HBB, MA); and Department of Microbiology, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran (HBB, MA)

1 Gültekin M, Akgül B. HPV screening in Islamic countries. *Lancet Infect Dis* 2017; **17**: 368.
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4 Seoud M. Extended Middle East and north Africa: cervical cancer and human papillomavirus: can we make the case for prevention in this "relatively" low prevalence region? *Vaccine* 2013; **31** (suppl 6): 7–8.

Laminar flow: the better choice in orthopaedic implants

Peter Bisschof and colleagues published a systematic review and meta-analysis in *The Lancet Infectious Diseases* regarding the effect of laminar airflow ventilation on surgical site infection (SSI).[1] This study was done in the context of guidelines on SSI by WHO[2,3] and was also in line with publications of the same institution.[4] We disagree with the conclusion that laminar airflow ventilation should not be used, especially in case of biomaterial implantation, for various reasons.

The studies of the Charité-group and some other studies included in the meta-analysis[4–6] were based on large surveillance or registry databases combined with a questionnaire about the used airflow system. These questionnaires were not validated, so the reliability of the answers is questionable. Surgeons and medical professionals in general are unaware of the type of airflow system present in an operating theatre. Furthermore, data derived from arthroplasty registry studies underestimate the percentage of periprosthetic joint infection by up to 40%.[7]

Another important fundamental weakness of these studies is that the mere presence of laminar airflow ventilation does not guarantee its proper function—for example, during commissioning and classification measurements it often appears that systems do not permit air to flow as intended, thus not protecting patient and sterile instruments sufficiently.

The authors use high cost as decisive argument not to use laminar airflow ventilation. However, they do not cite the complete literature and select only the articles that support their case. Cacciari and colleagues[8] found that the building of facilities with suitable airflow increased costs by 24% compared with non-specialised facilities, including a much better air filtration system to provide an ultra-clean system (increasing the total surgical facility cost by 5·5%). Another publication[9] showed no additional costs per patient for laminar airflow ventilation (2·8–6·7 D-Mark in an operating theatre with a laminar airflow system *vs* 4·5–6·7 D-Mark if conventional air is present), and we have found the costs to be similarly low at present in the Netherlands. The investment and operational cost of a ventilation or air handling system are mostly defined by the amount of air to be conditioned (cooled, heated, humidified, or dehumidified).

The use and combination of big data that are not designed to assess the effectiveness of laminar airflow ventilation is not justifiable and not the solution for the scarcity of randomised trials. The next level of evidence must then be used: observational and experimental studies. In the Netherlands, an evidence based guideline for air handling systems in operating theatres has been established by a multidisciplinary group that includes microbiologists.[10] We have found clear evidence that laminar airflow reduces the number of bacteria in the air at the level of the incision and instrument table at rest as well as during surgery. Therefore, Dutch orthopaedic surgeons persist on the use of a well functioning and properly used laminar airflow ventilation system.

We declare no competing interests.

*Paul C Jutte, Roberto AAL Traversari, Geert HIM Walenkamp

p.c.jutte@umcg.nl

Department of Orthopedic Surgery, University Medical Center Groningen, University of Groningen, Groningen, PO-Box 30 001, 9700RB, Netherlands (PCJ); Dutch Organization for Applied Scientific Research, Innovation Centre Building, Delft, Netherlands (RAALT), and Department of Orthopedic Surgery, Maastricht University Medical Centre, Maastricht, Netherlands (GHIMW)

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Authors' reply

We appreciate Paul Jutte and colleagues' comments on our systematic review of studies of the effect of laminar airflow ventilation on surgical site infections (SSI).[1] One of their main concerns is the use of data obtained from national surveillance systems and registries, since these databases were not designed specifically to address whether laminar airflow systems decrease the risk of SSIs. In their comment, Weinstein and Bonten[2] also highlighted the high amount of clinical and statistical heterogeneity of the studies included in our review. Of note, despite all the heterogeneity, none of the relevant observational studies published within the past 35 years found a robust protective effect of laminar airflow on the reduction of SSI after orthopaedic joint replacement surgery. Neither do the meta-analyses point to a direction that could support the argument of laminar airflow having the presumed preventive effect on SSI. The included studies actually had serious limitations and overall were graded as of very low quality, but they represent the best available evidence. Moreover, the studies done before 1990 that we excluded from our review, among them two randomised trials that took surgical antibiotic prophylaxis into account, did not find that laminar airflow systems decreased the risk of SSIs.[3]

Jutte and colleagues argue that a fundamental weakness of the studies is, although facilities might have installed the correct equipment, the possibly improper functioning of the laminar airflow. We rather think that this might be a fundamental weakness of the systems itself. We agree that operating rooms might be misclassified because, especially during surgical procedures, the intended airflow is often not achieved.[3] Concerning the costs of the different ventilation systems, we believe that our discussion of the relevant literature was comprehensive and up to date, whereas the study mentioned by Jutte and colleagues was from 1994 and no longer relevant.[3]

We acknowledge that the Dutch guideline mentioned by Jutte and colleagues was based on a comprehensive review of the literature. Indeed, many experimental studies have shown that laminar airflow reduces bacterial and particulate contamination of the air. However, the causal link between microbial air contamination and SSIs has not been shown in any study so far. Apparently, in the routine situation reflected by the studies included in our systematic review, the higher microbial air contamination within a conventionally ventilated operating room does not have a negative effect on the risk of developing a SSI.

We declare no competing interests.

*Peter Bischoff, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier

peter.bischoff@charite.de

Institute of Hygiene and Environmental Health, Charité—University Medicine Berlin, 12203 Berlin, Germany (PB, PG); World Health Organization Patient Safety Program, World Health Organization, Geneva, Switzerland (BA); and Institute of Social and Preventive Medicine (ISPM), University of Bern, Bern, Switzerland (ME)

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National Institute for Health and Care Excellence

Draft for Consultation

Joint replacement (primary): hip, knee and shoulder

[I] Evidence review for ultra clean-air

NICE guideline

Intervention evidence review

October 2019

Table 1: PICO characteristics of revi

Population	Adults having primary e metallic implants.
Intervention	Ultra clean-air theatres (including laminar flow and ex flow
Comparison	Conventional airflow theatres
Outcomes	**Critical** • Mortality: 30 day (dichotomous) • Quality of life (continuous) • Deep surgical site infection (dichotomous) • Superficial surgical site infection (dichotomous) **Important** • Return to theatre (dichotomous) • Hospital readmission (dichotomous) • Length of stay (continuous)
Study design	Randomised controlled trials If no well-conducted RCTs are available, observational stu analysis will be investigated.

Table 2: Summary of studies included in the evidence review

Study	Intervention and comparison	Population	Outcomes	Comments
Randomised controlled trials				
Fitzgerald Jr 1992[20]	Horizontal ultra clean-air operating theatre versus Conventional ventilated operating theatre with turbulent airflow	People having primary total hip or knee replacement surgery N=6,050 USA	Deep surgical site infection Follow-up was varied: 1 to 8 years.	Prophylactic antibiotic therapy utilised. Traffic in theatre controlled. Personnel isolator systems (body suits) not used.
Lidwell 1982[33, 35]	Ultra-clean air ve versus Conventionally v operating room pressure air sup 4 hospitals utilis exhaust suits or clothing in ultra surgeries. 15 ho one or the other Additional result presented for thi The decision wh prophylactic anti made by the sur Additional result presented for thi			

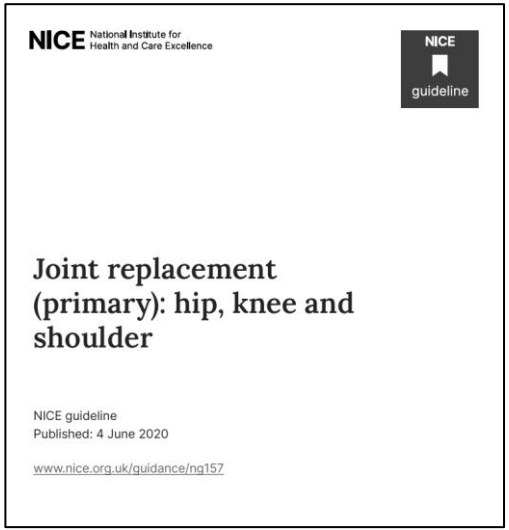
Evidence statements

Clinical evidence statements

Evidence from 2 randomised controlled trials and 7 observational studies reported on infection prevention in joint replacement surgery through the use of ultra clean-air ventilation compared to conventional ventilation. 1 RCT (very low quality, n=6050) found no difference in deep surgical site infection. The second RCT was analysed using the original randomised groups and found a benefit of ultra clean-air in confirmed sepsis (very low quality, n=8055). This same evidence was also sub-grouped in 2 ways. The first where all people were given prophylactic antibiotics and ultra clean-air operating teams either wore body exhaust suits or conventional clothing and that found a benefit of ultra clean-air in confirmed sepsis (very low quality, n=5831). The second where all people given prophylactic antibiotics and ultra clean-air operating teams wore conventional clothing found no clinically important difference between interventions in confirmed sepsis (very low quality, n=4247). Evidence from observational studies was not meta-analysed due to control of different confounding factors and variation in data gathering of the outcome of interest. 2 studies reported revision due to infection and one found no clinical difference and the other found a benefit for conventional ventilation (very low quality, n=80,756-97,344). 5 studies reported on surgical site infection across 8 outcomes and 4 indicated no clinical difference and 4 indicated a clinically important benefit of conventional ventilation (low to very low quality, n=6,848-85,609). No evidence was available for 30-day mortality or quality of life.

Health economic evidence statements

One comparative cost utility analysis found that use of laminar airflow in theatres was: dominant (less costly and more effective) compared to not using any other infection prevention strategy; not cost effective when used as an adjunct to systemic antibiotics; dominated when used as an adjunct to systemic antibiotics and antibiotic impregnated cement; and dominated (cost more and less effective) when used as an adjunct to systemic antibiotics, antibiotic impregnated cement and body exhaust suits. This analysis was assessed as partially applicable with potentially serious limitations.



1.5 Preventing infections

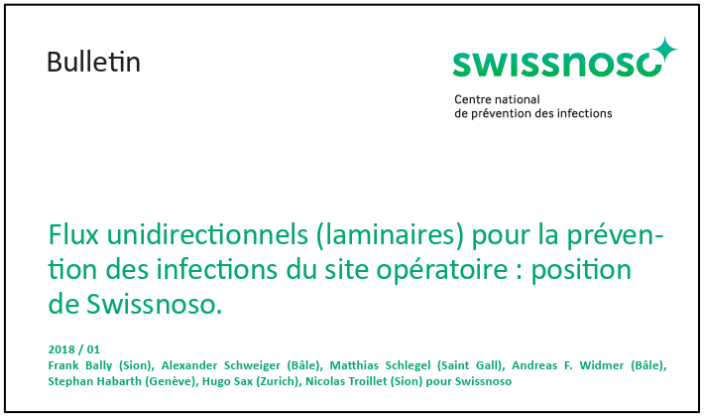
Antibiotic or antiseptic agents in wound wash-out solutions

1.5.1 Follow the recommendations on antibiotic prophylaxis, wound irrigation and intracavity lavage, and antiseptics and antibiotics before wound closure in the NICE guideline on surgical site infections, for people having primary elective hip, knee or shoulder replacement.

Ultra-clean air ventilation in operating theatres

1.5.2 Use ultra-clean air ventilation in operating theatres for primary hip, knee or shoulder elective joint replacement.

There was little good evidence on the use of ultra-clean air ventilation in operating theatres. Evidence from randomised controlled trials supported ultra-clean air ventilation, but these trials may not fully reflect current practice. Evidence from observational studies supported conventional air ventilation systems, [...].
Although the committee noted the limitations in the evidence, they agreed that ultra-clean air ventilation is likely to be more effective at reducing surgical site infections than conventional turbulent air ventilation [...].


Bulletin

swissnoso
Centre national
de prévention des infections

Flux unidirectionnels (laminaires) pour la prévention des infections du site opératoire : position de Swissnoso.

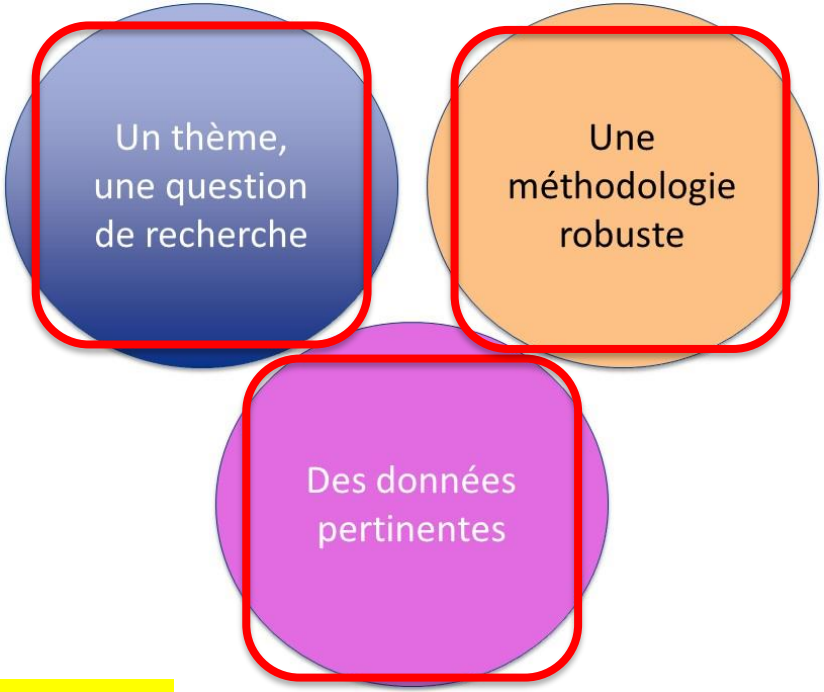
2018 / 01
Frank Bally (Sion), Alexander Schweiger (Bâle), Matthias Schlegel (Saint Gall), Andreas F. Widmer (Bâle), Stephan Habarth (Genève), Hugo Sax (Zurich), Nicolas Troillet (Sion) pour Swissnoso

https://www.swissnoso.ch/

Conclusion

Il est douteux, en l'état actuel des connaissances, que le flux unidirectionnel diminue le risque infectieux lors d'opérations à haute exigence d'asepsie, telles que des arthroplasties ou l'implantation de valves cardiaques. Certaines données récentes indiqueraient même une tendance du flux unidirectionnel à augmenter ce risque.

Swissnoso recommande d'investir plutôt dans la réalisation de mesures préventives dont l'effet sur la diminution du risque d'infection est bien documenté, mais dont l'application peut être améliorée. En effet, l'application effective de ces mesures remplacerait avec certitude, et probablement avantageusement, l'effet incertain du flux unidirectionnel.



… mais réponses très contrastées

Au total …

- De plus en plus de questions en PCi donnent lieu à des études solides
- Les recommandations s'appuient de plus en plus sur des données probantes
- Nécessité de garder un regard critique sur les études
  - chapitre « méthodes » ; argumentaire des recommandations
  - recherche des biais

  Intérêt +++ de la méthode GRADE