C. First date published study available to readers: 9/1/2016
D. PubMed ID: 27487033
E. Nominated By: Jim Stevermer
F. Institutional Affiliation of Nominator: University of Missouri
G. Date Nominated: 12/16/2016
H. Identified Through: JAMA Dermatol
I. PURLs Editor Reviewing Nominated Potential PURL: Corey Lyon
J. Nomination Decision Date: 12/21/2016
K. Potential PURL Review Form (PPRF) Type: Systematic Review
L. Assigned Potential PURL Reviewer: Greg Castelli
M. Reviewer Affiliation: UPMC St. Margarets
A. Abstract: IMPORTANCE:
Whether the use of sterile vs nonsterile gloves in outpatient cutaneous procedures affects the rate of postoperative wound infection is unknown.
OBJECTIVE:
To explore rates of surgical site infection (SSI) with the use of sterile vs nonsterile gloves in outpatient cutaneous surgical procedures.
DATA SOURCES:
This systematic review and meta-analysis identified studies from Ovid MEDLINE (1946 to present), Ovid Cochrane Central Register of Controlled Trials (1991 to present), Ovid EMBASE (1988 to present), EBSCO Cumulative Index to Nursing and Allied Health Literature (1980 to present), Scopus (1996 to present), and Web of Science (1975 to present).
STUDY SELECTION:
Studies with information on sterile vs nonsterile gloves in outpatient surgical procedures were retrieved. Only randomized clinical trials and comparative studies were included for final analysis.
DATA EXTRACTION:
Data of trial design, surgery characteristics, and outcomes from published manuscripts and unpublished data were independently extracted.
MAIN OUTCOMES AND MEASURES:
Randomized clinical trials were considered high quality if randomization, allocation concealment, blinding, and follow-up completeness were appropriate. Relative risk and 95% CIs were derived for postoperative wound infections.
RESULTS:
Fourteen articles met eligibility and inclusion criteria for systematic review; they included 12,275 unique patients who had undergone 12,275 unique outpatient procedures with sterile or nonsterile gloves and had follow-up regarding SSI. With the exclusion of 1 single-arm observational study of 1204 patients, 11,071 patients from 13 studies remained in the meta-analysis. Of these, 228 patients were documented as having postoperative SSI (2.1%), including 107 of 5031 patients in the nonsterile glove group (2.1%) and 121 of 6040 patients in the sterile glove group (2.0%). Overall relative risk for SSI with nonsterile glove use was 1.06 (95% CI, 0.81-1.39).

CONCLUSIONS AND RELEVANCE:
No difference was found in the rate of postoperative SSI between outpatient surgical procedures performed with sterile vs nonsterile gloves.

SECTION 2: Critical Appraisal of Validity
[to be completed by the Potential PURL Reviewer]

A. What types of studies are included in this review?
Both randomized and observational cohort trials.

B. What is the key question addressed by this review? Summarize the main conclusions and any strengths or weaknesses.
To explore rates of surgical site infection (SSI) with the use of sterile vs nonsterile gloves in outpatient cutaneous surgical procedures.

C. Study addresses an appropriate and clearly focused question. Well covered
Comments: Results may lead to a lower cost nonsurgical gloves with similar rates of infections.

D. A description of the methodology used is included. Well covered
Comments: Discuss MeSH terms, types of studies included, roles or authors.

E. The literature is sufficiently rigorous to identify all the relevant studies. Well covered
Comments: initially identified 512 publications. Ultimately included 11,071 unique patients.

F. Study quality is assessed and taken into account. Well covered
Comments: All of the included trials and observational studies were reviewed in detail for methodologic features most pertinent to potential bias. The 2 independent reviewers (J.D.B. and A.B.G.J.) assessed features according to the Cochrane collaboration guidelines for the randomized clinical trials, which included randomization, intention-to-treat analysis, completeness of follow-up, and outcome assessment and attrition rates. Allocation of concealment, blinding, and masking of allocation were not evaluated as part of the assessment of quality given that, by the nature of these studies, all parties could tell whether the gloves used for the procedure were sterile or nonsterile. The Newcastle-Ottawa Scale was used to assess the quality of observational studies. All discrepancies in quality assessment were resolved by consensus-forming discussions between the 2 investigators.

G. There are enough similarities between selected studies to make combining them reasonable. Well covered
Comments: Heterogeneity analysis of $I^2$ was 0% for all included studies which means they were very similar.
H. Are patient oriented outcomes included? If yes, what are they? 
   The primary outcome variable in this study was postoperative wound SSI. Yes

I. Are adverse effects addressed? If so, how would they affect recommendations? 
   None were discussed.

J. Is funding a potential source of bias? If yes, what measures (if any) were taken to ensure scientific integrity? 
   Funding is not discussed. Authors state they have no conflict of interests.

K. To which patients might the findings apply? Include patients in the metaanalysis and other patients to whom the findings may be generalized. 
   Any patients receiving routine procedures in family medicine offices.

L. In what care settings might the findings apply, or not apply? 
   Primary care offices.

M. To which clinicians or policy makers might the findings be relevant? 
   It has implications of cost savings, so hospital financial departments and administrators as well as clinicians who perform procedures.

SECTION 3: Review of Secondary Literature 
[to be completed by the Potential PURL Reviewer] 
[to be revised by the Pending PURL Reviewer as needed]

Citation Instructions: 
For up-to-date citations, use style modified from http://www.uptodate.com/home/help/faq/using_UTD/index.html#cite & AMA style. Always use Basow DS on editor & current year as publication year.

Example: Auth I. Title of article. {insert author name if given, & search terms or title.} In: Basow DS, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2009. Available at: http://www.uptodate.com. {Insert date modified if given.} Accesses February 12, 2009. [whatever date PPRF reviewer did their search.]

For DynaMed, use the following style: 

A. DynaMed excerpts
   None available.

C. Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences)

D. UpToDate excerpts
General principles of infection control include issues related to standard precautions (hand hygiene, use of gloves and masks) and isolation precautions. The principles of hand hygiene advocated in hospitals are applicable to outpatient settings (table 1). Personal protective equipment should be readily available for use (gowns, masks, respirators, gloves).

E. UpToDate citation

F. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences)
Does not address sterile vs nonsterile gloves. Points out wearing gloves is very important.

G. Other excerpts (USPSTF; other guidelines; etc.)
none.

H. Citations for other excerpts
none.

I. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences)
none.

SECTION 4: Conclusions
[to be completed by the Potential PURL Reviewer]
[to be revised by the Pending PURL Reviewer as needed]

A. Validity: Are the findings scientifically valid? 2

B. If A was coded 4, 5, 6, or 7, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?

C. Relevance: Is the topic relevant to the practice of family medicine and primary care practice, including outpatient, inpatient, obstetrics, emergency and long-term care? Are the patients being studied sufficiently similar to patients cared for in family medicine and primary care in the US such that results can be generalized? 1 (extremely well)

D. If C was coded 4, 5, 6, or 7, please provide an explanation.
**E. Practice changing potential:** If the findings of the study are both valid and relevant, are they not a currently widely accepted recommendation among family physicians and primary care clinicians for whom the recommendation is relevant to their patient care? Or are the findings likely to be a meaningful variation regarding awareness and acceptance of the recommendation?

2

**F.** If E was coded as 1, 2, 3, or 4, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit.

Coded a 2. For our faculty, it represents a change in practice. However current practice ranges widely. It may be different for each physician, each procedure, and in each institution.

**G. Applicability to a Family Medical Care Setting:**

Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc.), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, education or counseling a patient; or creating a system for implementing an intervention? 1 (definitely could be done in a medical care setting)

**H.** If G was coded as a 4, 5, 6, or 7, please explain.

**I. Immediacy of Implementation:**

Are there major barriers to immediate implementation? Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug, or other essentials available on the market? 2

**J.** If I was coded 4, 5, 6, or 7, please explain why.

**K. Clinically meaningful outcomes or patient oriented outcomes:**

Do the expected benefits outweigh the expected harms? Are the outcomes patient oriented (as opposed to disease oriented)? Are the measured outcomes, if true, clinically meaningful from a patient perspective? 3

**L.** If K was coded 4, 5, 6, or 7 please explain why.

**M. In your opinion, is this a pending PURL?**

2

1. Valid: Strong internal scientific validity; the findings appear to be true.

2. Relevant: Relevant to the practice of family medicine.
3. Practice Changing: There is a specific identifiable new practice recommendation that is applicable to what family physicians do in medical care settings and seems different than current practice.

4. Applicability in medical setting.

5. Immediacy of implementation

N. Comments on your response for question M.
   Our faculty would like to start teaching this to our residents and have one message.