

**RCT**  
**Potential PURL Review Form**  
**PURL Jam Version**  
Version #11 October 29, 2009

**PURLs Surveillance System**  
**Family Physicians Inquiries Network**

**SECTION 1: Identifying Information for Nominated Potential PURL**  
**[to be completed by PURLs Project Manager]**

- 1. Citation** Heal C, Sriharan S, Buttner PG, Kimber D. Comparing non-sterile to sterile gloves for minor surgery: a prospective randomised controlled non-inferiority trial. Med J Aust. 2015 Jan 19;202(1):27-31. PubMed PMID: 25588441.
- 2. Hypertext link to PDF of full article** <http://www.ncbi.nlm.nih.gov/pubmed/?term=Comparing+non-sterile+with+sterile+gloves+for+minor+surgery>
- 3. First date published study available to readers** 01/19/15
- 4. PubMed ID** 25588441
- 5. Nominated By** Jim Stevermer Other:
- 6. Institutional Affiliation of Nominator** University of Missouri Other:
- 7. Date Nominated** 02/11/15
- 8. Identified Through** Other Other: POEMs
- 9. PURLS Editor Reviewing Nominated Potential PURL** Kate Rowland Other:
- 10. Nomination Decision Date** 3/9/15
- 11. Potential PURL Review Form (PPRF) Type** RCT
- 12. Other comments, materials or discussion**
- 13. Assigned Potential PURL Reviewer** Kohar Jones, MD
- 14. Reviewer Affiliation** University of Chicago Other:
- 15. Date Review Due** 03/26/15
- 16. Abstract** To compare the incidence of infection after minor surgery conducted using non-sterile clean boxed gloves with surgery conducted using sterile gloves.  
DESIGN:  
Prospective randomised controlled single-centre trial testing for non-inferiority in infection rates.  
SETTING:  
Primary care regional centre, Queensland, Australia.  
PARTICIPANTS:  
Consecutive patients presenting to participating general practitioners for a minor skin excision,

between 30 June 2012 and 28 March 2013, were eligible to participate.

**INTERVENTION:**

The use of non-sterile clean boxed gloves was compared with normal treatment using sterile gloves in the control group.

**MAIN OUTCOME MEASURES:**

Wound infection, assessed at the time of removal of sutures, and other adverse events.

**RESULTS:**

Four hundred and ninety-three consecutive patients presenting for minor skin excisions were randomly allocated to the two treatment groups: non-sterile clean boxed gloves (n = 250) or sterile gloves (n = 243). Four hundred and seventy-eight patients contributed data for analysis (241 non-sterile, 237 sterile gloves). The incidence of infection in the non-sterile gloves group (8.7%; 95% CI, 4.9%-12.6%) was significantly non-inferior compared with the incidence in the control group (9.3%; 95% CI, 7.4%-11.1%). The two-sided 95% CI for the difference in infection rate (- 0.6%) was - 4.0% to 2.9%, and did not reach the predetermined margin of 7% which had been assumed as the non-inferiority limit. RESULTS of the intention-to-treat analysis were confirmed by per-protocol and sensitivity analyses. There were no important adverse effects.

**CONCLUSION:**

Our study suggests that in regard to wound infection, non-sterile clean boxed gloves are not inferior to sterile gloves for minor skin excisions in general practice.

17. Pending  
PURL Review  
Date

**SECTION 2: Critical Appraisal of Validity**  
**[to be completed by the Potential PURL Reviewer]**  
**[to be revised by the Pending PURL Reviewer if needed]**

- |   |   |
|---|---|
| 1. Number of patients starting each arm of the study?   | Non-sterile gloves = 250, sterile gloves = 243  |
| 2. Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.)?           | Australian patients presenting outpatient to a private general practice needing a "minor skin excision" anywhere on the body, including two layer procedures. Exclusion: antibiotics or immune suppressants, skin flaps, excision of sebaceous cyst, history of latex allergy.  |
| 3. Intervention(s) being investigated?  | Use of non-sterile gloves   |
| 4. Comparison treatment(s), placebo, or nothing?  | Sterile gloves  |
| 5. Length of follow up? Note specified end points e.g. death, cure, etc.                                    | 30 days--no wound infection or wound infection  |
| 6. What outcome measures are used? List all that assess effectiveness.                                      | Primary Outcome: Incidence of surgical site infection (appearance within 30 days of one of the following: purulent discharge, pain or tenderness, localised swelling, redness or heat at site, diagnosis of SSI by general practitioner). Stitch abscess not counted as wound infection. Secondary Outcome: incidence of other adverse effects. |
| 7. What is the effect of the intervention(s)? Include absolute risk, relative risk, NNT, CI, p-values, etc. | Total infection rate 9%. Non sterile group 8.7% (95% CI 4.9%-12.6%); sterile group 9.3% (95% CI 7.4% - 11.1%). Two sided CI for difference in infection rate (0.6%) was -4% to 2.9%.  |
| 8. What are the adverse effects of intervention compared with no intervention?                              | None  |
| 9. Study addresses an appropriate and clearly focused question -  | <input checked="" type="checkbox"/> Well covered<br><input type="checkbox"/> Adequately addressed<br><input type="checkbox"/> Poorly addressed  |

**select one**

Not applicable

Comments:

**10.** Random allocation to comparison groups

- Well covered  
 Adequately addressed  
 Poorly addressed  
 Not applicable

Comments: computer generated

**11.** Concealed allocation to comparison groups

- Well covered  
 Adequately addressed  
 Poorly addressed  
 Not applicable

Comments: Concealed from SSI assessors

**12.** Subjects and investigators kept "blind" to comparison group allocation

- Well covered  
 Adequately addressed  
 Poorly addressed  
 Not applicable

Comments:

**12.** Comparison groups are similar at the start of the trial

- Well covered  
 Adequately addressed  
 Poorly addressed  
 Not applicable

Comments:

**14.** Were there any differences between the groups/arms of the study other than the intervention under investigation? If yes, please indicate whether the differences are a potential source of bias.

- Well covered  
 Adequately addressed  
 Poorly addressed  
 Not applicable

Comments:

**15.** Were all relevant outcomes measured in a standardized, valid, and reliable way?

- Well covered  
 Adequately addressed  
 Poorly addressed  
 Not applicable

Comments:

**16.** Are patient oriented outcomes included? If yes, what are they?

SSI

**17.** What percent dropped out, and were lost to follow up? Could this bias the results? How?

15/493 = 3%

**18.** Was there an intention-to-treat analysis? If not, could this bias the results? How?

Yes. Assuming all infected still reached non-inferiority.

19. If a multi-site study, are results comparable for all sites? N/A
20. Is the funding for the trial a potential source of bias? If yes, what measures were taken to insure scientific integrity? No
21. To which patients might the findings apply? Include patients in the study and other patients to whom the findings may be generalized. Patients in hot/humid climates
22. In what care settings might the findings apply, or not apply? Outpatient FM/derm
23. To which clinicians or policy makers might the findings be relevant? Those who provide minor skin excisions

**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 UpTo Date citations, use style modified from [http://www.uptodate.com/home/help/faq/using\\_UTD/index.html#cite](http://www.uptodate.com/home/help/faq/using_UTD/index.html#cite) & AMA style. Always use Basow DS as 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 dated modified if given.} Accessed February 12, 2009. {whatever date PPRF reviewer did their search.}

For DynaMed, use the following style:

Depression: treatment {insert search terms or title}. In: DynaMed [database online]. Available at: <http://www.DynamicMedical.com>. Last updated February 4, 2009. {Insert dated modified if given.} Accessed June 5, 2009. {search date}

1. DynaMed excerpts

No mention--difficult to find articles on how to approach minor skin excisions. The surgical site infection prevention article was dealing with major surgeries--their discussion was on alcohol vs aqueous scrub, when wound could get wet afterwards, etc.

2. DynaMed citation/access date

Title. Surgical site infection-prevention Author. In: DynaMed [database online]. Available at: [www.DynamicMedical.com](http://www.DynamicMedical.com) Last updated: December 2014. Accessed Feb 26, 2015

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

not clear.

4. UpToDate excerpts

Mask, gown, and sterile gloves are indicated for excisions and are reasonable for any patient at increased risk of infection [7]. (author's note: citation from 1984)

5. UpToDate citation/access date

**Always use Basow DS as editor & current year as publication year.**  
 Title. Skin Biopsy Techniques Author. Patrick Alguire and Barbara Mathes In: UpToDate [database online]. Available at: <http://www.uptodate.com>. Last updated: April 19 2014; last lit review Feb 2015. Accessed Feb 26 2015

6. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences)

Use sterile gloves for minor skin excisions.

7. PEPID PCP excerpts [www.pepidonline.com](http://www.pepidonline.com) username: fpinauthor pw: pepidpcp

Unable to find any mention of sterile vs non-sterile gloves (search terms: skin biopsy, surgical site infections, minor skin excisions, sterile technique, outpatient surgery)--discussions of wound care afterward, and surgical techniques did come up. No clear guidance.

8. PEPID citation/access data

Author. Title. In: PEPID [database online]. Available at: <http://www.pepidonline.com>. Last updated: . Accessed

9. PEPID content updating

1. Do you recommend that PEPID get updated on this topic?  
 Yes, there is important evidence or recommendations that are missing  
 No, this topic is current, accurate and up to date.

If yes, which PEPID Topic, Title(s):

Skin biopsy: Procedures and other images: excisional biopsy

2. Is there an EBM Inquiry (HelpDesk Answers and Clinical Inquiries) as indicated by the EB icon (EB) that should be updated on the basis of the review?

Yes, there is important evidence or recommendations that are missing  
 No, this topic is current, accurate and up to date.

If yes, which Evidence Based Inquiry(HelpDesk Answer or Clinical Inquiry), Title(s):

10. Other excerpts (USPSTF; other guidelines; etc.)

American Academy of Dermatology clinical guidelines office-based procedures upcoming "office based surgeries" in summer 2015--will be a discussion of anesthesia; "non-melanoma skin cancer" also to be released summer 2015, to discuss: "Guidelines of Care for Management and Treatment of Non-Melanoma Skin Cancer"

11. Citations for other excerpts

12. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences)

#### SECTION 4: Conclusions

[to be completed by the Potential PURL Reviewer]  
[to be revised by the Pending PURL Reviewer as needed]

1. **Validity:** How well does the study minimize sources of internal bias and maximize internal validity?

Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly)  
1 2 3 4 5 6 7

2. If 4.1 was coded as 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?

Authors report that the baseline characteristics of the patients were poorly tracked, with no tracking of suture size or occupation, and poor tracking of prevalence of diabetes and other chronic medical conditions. Also of concern, sterile gloves were powdered; non-sterile gloves were non-powdered, adding an additional confounding variable.

3. **Relevance:** Are the results of this study generalizable to and relevant to the health care needs of patients cared for by "full scope" family physicians?

Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly)  
1 2 3 4 5 6 7

4. If 4.3 was coded as 4, 5, 6, or 7, please provide an explanation.

### 5. Practice changing

**potential:** If the findings of the study are both valid and relevant, does the practice that would be based on these findings represent a change from current practice?

6. If 4.5 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.

### 7. 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, educating or counseling a patient; or creating a system for implementing an intervention?

8. If you coded 4.7 as a 4, 5, 6 or 7, please explain.

### 9. 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?

10. If you coded 4.9 as 4, 5, 6, or 7, please explain why.

### 11. Clinical meaningful outcomes or patient oriented outcomes:

Are the outcomes measured in the study clinically meaningful or patient oriented?

12. If you coded 4.11 as a 4, 5, 6, or 7 please explain why.

Give one number on a scale of 1 to 7

(1=definitely a change from current practice; 4=uncertain; 7=definitely not a change from current practice)

1 2 3 4 5 6 7

Use of non-sterile non-powdered gloves for minor skin excisions

Give one number on a scale of 1 to 7

(1=definitely could be done in a medical care setting; 4=uncertain; 7=definitely could not be done in a medical care setting)

1 2 3 4 5 6 7

Give one number on a scale of 1 to 7

(1=definitely could be immediately applied; 4=uncertain; 7=definitely could not be immediately applied)

1 2 3 4 5 6 7

Give one number on a scale of 1 to 7

(1=definitely clinically meaningful or patient oriented; 4=uncertain; 7=definitely not clinically meaningful or patient oriented)

1 2 3 4 5 6 7

**13.** In your opinion, is this a Pending PURL?

Criteria for a Pending PURL:

- Valid: Strong internal scientific validity; the findings appears to be true.
- Relevant: Relevant to the practice of family medicine
- 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.
- Applicability in medical setting:
- Immediacy of implementation

**14.** Comments on your response in 4.13

Give one number on a scale of 1 to 7

(1=definitely a Pending PURL; 4=uncertain; 7=definitely not a Pending PURL)

1 2 3 4 5 6 7

This applies to a practice site in a hot, humid environment with a baseline incidence of infection 350% higher than priorly studied practice sites. Does this apply to practice sites in other climates? Also, the sterile gloves were powdered. The non-sterile gloves were non-powdered. Is powder, rather than sterility, the variable factor impacting the infection rates? Do other practitioners with lower rates of infection habitually use non-powdered sterile gloves? Finally, the authors note a larger