



**Centre for Clinical Effectiveness**

Enhancing patient outcomes through clinical application of the best available evidence

**EVIDENCE CENTRE**  
**CRITICAL APPRAISAL**  
Series 2001: Therapy

# **Disposable or reusable gowns and drapes and surgical site infections**

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## **SUMMARY STATEMENT**

**Disclaimer** - please refer to Appendix 1 for information.

**Copyright** – please refer to Appendix 1 for information.

**Publication of materials** – please use the following format when citing this article:

Bernath VF (2001). Disposable versus reusable gowns and drapes – effect on surgical wound infection rates. [Online]. Available from <http://www.med.monash.edu.au/healthservices/cce/> [Access Date...]

**Form Version** – B.2001.01.04.1

## **REQUEST**

Is the use of disposable gowns and drapes associated with a reduction in surgical site infection rates when compared with the use of reusable gowns and drapes?

## **REQUESTED BY**

**Douglas Mill**, Operations Manager, Perioperative Services, Operating Suites, Monash Medical Centre, Clayton.

## **METHODOLOGY**

### **Search Strategy**

The Centre for Clinical Effectiveness defines the 'best available evidence' as that research we can identify that is least susceptible to bias. We determine this according to pre-defined National Health and Medical Research Council (NHMRC, 2000) criteria (see Appendix 1).

First, we search for systematic reviews, evidence based clinical practice guidelines, health technology assessments and randomised controlled trials. If we identify sound, relevant material of this type, the search stops. Otherwise, our search strategy broadens to include studies that are more prone to bias, less generalisable or have other methodological difficulties. We include case-control and longitudinal cohort studies in our critical appraisal reports. While we cite observational and case series studies, and narrative reviews and consensus statements, in our reports we do not critically appraise them. Such studies can produce accurate results but they are generally too prone to bias to allow determination of their validity beyond their immediate setting.

### **Details of Evidence Request**

Patients (Subjects): Any surgical procedure  
Intervention: Use of disposable gowns and drapes  
Comparisons: Use of reusable gowns and drapes  
Outcomes: Surgical site infection rates

### **Search terms**

(see Appendix 2 for exact search strategy)

Patient (Subject): surg/ery/ical, operat/ion/ing  
Intervention: clothing, protective clothing, drape/s, gown/s  
Outcome: surgical wound infection

## Resources Searched

We searched the following databases and Internet websites:

The Cochrane Library (CD-ROM)	2001 Issue 4
Medline (OVID)	Mid 1998 to October Week 5 2001
PREMEDLINE (OVID)	November 14, 2001
CINAHL (OVID)	1982 to October Week 4 2001
Current Contents (OVID)	1993 Week 26 to 2001 Week 47
Australasian Medical Index (INFORMIT)	September 2001
National Guideline Clearinghouse	16 November 2001

## Refinements, Searching & Reporting Constraints

As this question has been addressed in the "Guideline for prevention of surgical site infection" (Mangram et al 1999) we restricted our search to material published since the Guideline was developed, in 1999 or later. We also restricted retrieval to clinical studies, excluding laboratory investigations of fabrics.

## RESULTS

From our sources we identified 5 potentially relevant articles. We obtained the full text of these articles to determine their relevance.

After examination of the 5 articles, the following were excluded as follows:

Reason for exclusion	Number
<b>Narrative review</b>	<b>2</b>
<b>Level IV Evidence</b>	<b>1</b>
<b>Not investigating disposable fabrics</b>	<b>1</b>
<b>Total</b>	<b>4</b>

1 article then remained for appraisal. This study is classified as follows:

Study Design	Number included
Systematic reviews or meta-analyses	0
Evidence-based clinical practice guidelines	0
<b>Randomised controlled trials</b>	<b>1</b>
<b>Total</b>	<b>1</b>

Based on our refinements, searching and reporting constraints we are reasonably confident these articles represent the most relevant findings published to date.

The one randomised controlled trial found that the use of disposable drapes and gowns conferred no benefit over reusable fabric in terms of postoperative wound infection. It is unclear whether the reusable fabric had been laundered and reused in the trial.

## EVIDENCE SUMMARIES

### Format

Evidence summaries are presented as spreadsheets attached to this report. Each spreadsheet contains the article citation, details of the study design, patient description, scientific validity of the article, results, and pertinent remarks from the authors and Centre for Clinical Effectiveness reviewer.

## REFERENCES

### ARTICLES CRITICALLY APPRAISED FOR THIS REPORT

Bellchambers J, Harris JM, Cullinan P *et al.* (1999). A prospective study of wound infection in coronary artery surgery. *European Journal of Cardio-thoracic Surgery* 15:45-50.

### ARTICLES NOT CRITICALLY APPRAISED

#### Level IV Evidence

Ross GL, Taams KO (2000). The versatile use of fenestrated adhesive disposable drapes. *European Journal of Plastic Surgery* 23:361-365.

#### Narrative Reviews

Laufman H, Belkin NL, Meyer KK (2000). A critical review of a century's progress in surgical apparel: how far have we come? *Journal of the American College of Surgeons* 191:554-568.

Rutala WA, Weber DJ (2001). A review of single-use and reusable gowns and drapes in health care. *Infection Control & Hospital Epidemiology* 22:248-57.

#### Not investigating disposable fabrics

Tammelin A, Hambraeus A and Stahle E (2001). Routes and sources of *Staphylococcus aureus* transmitted to the surgical wound during cardiothoracic surgery: Possibility of preventing wound contamination by use of special scrub suits. *Infection control and Hospital Epidemiology* 22:338-346.

### ADDITIONAL REFERENCE

Mangram AJ, Horan TC, Pearson ML *et al* (1999). Guideline for prevention of surgical site infection, 1999. *Infection Control and Hospital Epidemiology* 20:247-278.

## APPENDIX 1

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### Levels Of Evidence

Based on "How to use the evidence: assessment and application of scientific evidence" (National Health & Medical Research Council, Canberra, 2000):

Level I		Evidence obtained from a systematic review (or meta-analysis) of all relevant randomised controlled trials.
Level II		Evidence obtained from at least one randomised controlled trial.
Level III	-1	Evidence obtained from pseudorandomised controlled trials (alternate allocation or some other method).
	-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies or interrupted time series with a control group.
	-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group.
Level IV		Evidence obtained from case series, either post-test or pretest/post-test.

## APPENDIX 2

### Search strategy

	<b>Search terms for MEDLINE</b>
1	clothing/ or protective clothing/
2	drape\$.tw
3	gown\$.tw
4	or/1-3
5	surgical wound infection/
6	surg\$.tw
7	operat\$.tw
8	or/5-7
9	4 and 8
10	limit 9 to yr=1999-2002

<p style="text-align: center;"><b>Evidence Summary Therapy/Intervention</b></p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <p>Disposable or reusable gowns and drapes and surgical site infection</p> </div>	<p style="text-align: center;"><b>Study 1</b></p> <p>Bellchambers J, Harris JM, Cullinan P <i>et al.</i> (1999). A prospective study of wound infection in coronary artery surgery. <i>European Journal of Cardio-thoracic Surgery</i> 15:45-50.</p>
<p><b>STUDY DESIGN &amp; NHMRC LEVELS OF EVIDENCE</b></p>	<p><b>Level II – Randomised Controlled Trial</b></p>
<p><b>DESCRIPTION:</b> Patients (subjects), Intervention, Comparisons, Outcomes, Inclusion &amp; Exclusion Criteria</p>	<p><b>Patients (subjects):</b> 505 patients undergoing isolated coronary artery surgery  <b>Intervention:</b> disposable drapes and gowns  <b>Comparisons:</b> reusable fabric drapes and gowns  <b>Outcomes:</b> postoperative surgical site infections  <b>Incl &amp; Excl Criteria:</b> Not stated</p>
<p><b>VALIDITY:</b> Methodology, rigour, selection</p>	<p><b>Randomisation:</b> Computer-generated random numbers in sealed envelopes  <b>Blinding:</b> Assessment of wounds initially by nurse unaware of allocation, followed by telephone data collection  <b>All patients accounted for:</b> Yes  <b>Patients treated equally:</b> Yes  <b>Similar groups:</b> Similar in most aspects, except for higher prevalence of diabetes mellitus in group with disposable drapes and gowns, and longer ventilation of patients with reusable drapes.</p>
<p><b>RESULTS:</b> Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p>	<p>There was no evidence of any difference in rates of infection between the two drape groups.</p>
<p><b>AUTHOR(S) CONCLUSIONS:</b> Limitations, implications for practice and research</p>	<p>“In a randomised controlled study of patients undergoing coronary artery surgery we found that the use of paper drapes and gowns conferred no benefit over a reusable fabric in terms of post-operative wound infection. Although females and diabetics are more likely to experience this complication, an important additional risk factor is an extended operating time.”  The authors state that a significant difference between the two groups is unlikely to emerge with less than 5000 patients.</p>
<p><b>OUR COMMENTS:</b> Opportunity for bias, weakness and strength</p>	<p><b>Potential for bias:</b> This report does not state whether the reusable fabric drapes and gowns were new or had undergone some method of laundering, that is, whether those items were being used for the first time or were being reused. It is, in fact, reuse that should be tested rather than just fabric-type.  <b>Weakness:</b> See authors’ comment on sample size required for significant effect to be measurable  <b>Strength:</b> This is a well-designed trial using rigorous methods to limit random bias effects.</p>

## **EXPLANATION OF TERMINOLOGY USED IN SPREADSHEET**

**Level of evidence:** A hierarchy of study evidence that indicates the degree to which bias has been eliminated in the study design.

**Intervention:** A therapeutic procedure such as treatment with a pharmaceutical agent, surgery, a dietary supplement, a dietary change or psychotherapy.

**Randomisation:** A process of allocating participants to treatment or control group within a controlled trial by using a random mechanism, such as coin toss, random number table or computer-generated random numbers. Study subjects have an equal chance of being allocated to an intervention or control group; thus, the two groups are comparable. Randomisation ensures that the results are not biased by the selection of particular types of patients to receive a specific therapy.

**Blinding:** Blinding or masking is a process used in epidemiological studies and clinical trials in which the observers and the subjects have no knowledge as to which treatment groups subjects are assigned. It is undertaken in order to minimise bias occurring in patient response and outcome measurement.

**All patients accounted for:** Once patients are randomly allocated to a specific group and withdraw before study conclusion, they have to be accounted for in order to ensure that patients withdrawing from the study are not significantly different from those continuing in the study. The final analysis should be conducted on an intention-to-treat basis, which includes the results of withdrawn patients in the analysis.

**Patients treated equally:** To be able to attribute any difference in the observed outcome to the intervention, study patients need to be treated equally in every way except for the intervention being evaluated.

**Similar groups:** Baseline characteristics of patients that are also likely to affect results should be evenly distributed between the intervention and control groups. Following proper randomisation, patients' attributes would be expected to be equally distributed between groups.

### **Validity:**

Of measurement: an expression of the degree to which a measurement measures what it purports to measure; it includes construct and content validity.

Of study: the degree to which the inferences drawn from the study are warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn (internal and external validity, applicability, generalisability).

**Potential for bias:** Bias is a systematic deviation of a measurement from the 'true' value leading to either an over (or under) estimation of the treatment effect. Bias can originate from many different sources (including allocation of patients, measurement, interpretation, publication and review of data).