

# 第11屆醫療品質獎 實證醫學文獻查證類競賽

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# Clinical Scenario



- 林小姐是一位大學生，騎摩托車發生了一個小車禍，她跌倒膝蓋著地造成一個直徑五公分真皮層的擦傷。朋友將她送入急診後，醫師用大量生理食鹽水沖洗傷口，打破傷風疫苗，用抗生素藥膏，再用紗布包紮，給三天口服抗生素後，就讓她離院了，母親說要保持傷口乾燥讓傷口早點結疤早點好，是真的嗎？需要吃那麼多天藥嗎？有什麼方法比較不會留疤？

# Four steps of EBM

## Step 1

- Asking questions

## Step 2

- Searching for evidence

## Step 3

- Appraising evidences

## Step 4

- Applying to patients

# PICO 1

Patient/Problem	Young age woman with abrasion wound
Intervention	Prophylactic antibiotics
Comparison	No Antibiotics
Outcome	Wound infection rate Adverse effect

# PICO 2

Patient/Problem

Young age woman with abrasion wound

Intervention

Moist dressing

Comparison

Dry dressing

Outcome

Wound healing time  
Scar formation  
Pain

我們選擇了PICO 1  
口服抗生素究竟能不能夠預防  
傷口感染?

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# Keyword

**P** ( Wound and Injuries [MeSH] OR abras\* wound ) AND

**I** ( Anti-Bacterial agent[MeSH] OR antibiotic\* OR Prophyla\* ) AND

**C** ( Placebo) AND

**O** ( Wound Infection [MeSH]OR infect\* rate OR Adverse effect)  
AND



# Our Database

- **Prefiltered**
  - Cochrane library
  - Clin-eguide (ACP journal club, Cochrane, DARE database)
- **Unfiltered**
  - Pubmed
  - Medline

# PubMed

關鍵字	篇數
(1) Wounds AND Injuryies [MeSH]	465928
(2) Abras* wound	1321
(3) Anti-Bacterial Agents[MeSH] OR antibiotic*	135456
(4) Wound infection [MeSH]	32022
(5) #1 OR #2	466312
(6) #5 AND #3	2234
(7) #6 AND #4	1211

Limitation: Meta analysis, RCT, Human

# Literature Selection Process

Cochrane

PubMed

Clin-guide

55 publication type is systematic review or RCT

32 publication type is systematic review or RCT

49 publication type is systematic review or RCT

Cochrane: 2

PubMed: 8

Clin-guide: 4

Excluded  
#fracture  
#burn  
#DM foot

Full- text articles: 3

## 以下是我們搜尋到的文獻

- **Stamou 1999**, Wound infection after minor limb laceration: risk factors and the role of antimicrobial agent
- **Whittaker 2005**, The role of antibiotic prophylaxis in clean incised hand injuries: a prospective randomized placebo controlled double blind trial
- **Cummings 1995**, Antibiotics to prevent infection of simple wounds: a meta-analysis of randomized studies

# **Antibiotics to Prevent Infection of Simple Wounds: A Meta-Analysis of Randomized Studies**

PETER CUMMINGS, MD, MPH,\* MARK A. DEL BECCARO, MD†

From Am J Emer Med 1995;13:396-400  
收錄在 DARE database, CRD group: well-conducted meta-analysis

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**CRITICAL APPRAISAL SKILLS  
PROGRAMME**

**CASP For Systematic Review**

# 評讀的三個重要問題

1. 證據可信嗎？效度 validity
2. 結果重要嗎？效益 Impact
3. 可以應用在我們的病人身上嗎？  
運用 Practice



# 1. Did the review ask a clearly-focused question?

– *the population studied*

Pt with **simple non-bite wounds**, who are treated in emergency departments

– *the intervention given or exposure*

**Prophylactic, systemic antibiotics** given orally or by an IM route

– *the outcomes considered*

**Wound infection rate**



YES

## 2. Did the review include the right type of study?

*Consider if the included studies:*



*– address the review's question*

Including: **uninfected wounds** to an **antibiotic** treatment group or a control group and then followed pts for the **occurrence of infection**

*– have an appropriate study design*

Including: RCT

**TABLE 1. Randomized Studies Included in Meta-Analysis of Antibiotics for Prophylaxis of Infection in Simple Lacerations**

Trial (year)	Antibiotic	Inclusion	Exclusions
Beesley et al (1975) <sup>7</sup>	Flucloxacillin plus ampicillin	Hand wounds only	Age ≤5 years Tendon, bone, or joint involvement "Obviously contaminated"
Day (1975) <sup>8</sup>	Triplopen*	Sutured wounds only	Wound ≥4 hours old Contaminated, deep, or contused wounds No tetanus booster within 5 years Allergy to antibiotics On antibiotics
Roberts and Teddy (1977) <sup>10†</sup>	Triplopen* or flucloxacillin	Sutured hand wounds only	Nerve or tendon involved Fracture requiring fixation Allergy to penicillin Wound not suitable for primary closure Patient lived outside local area
Hutton et al (1978) <sup>11</sup>	Triplopen*	Sutured hand wounds only	Wound not suitable for primary closure Allergy to penicillin On antibiotic Antibiotic in last 2 weeks No history of any tetanus immunization Admitted patients Wound >4 hours old
Worlock et al (1980) <sup>12</sup>	Cephalexin‡	Hand wounds only	Established infection Allergy to cephalosporins Renal failure Age <13 years
Grossman et al (1981) <sup>14</sup>	Oral cephalexin or cefazolin	Sutured hand wounds only	Wound to nerve or tendon Fracture Patient had diabetes Patient steroid-dependent Penicillin allergy
Thirlby et al (1983) <sup>15</sup>	Cephalexin	Sutured wounds only	Bite wounds Wound >8 hours old Patient has diabetes or is on steroids or chemotherapy Allergy to cephalosporins Mouth wounds

### 3. Did the reviewers try to identify all relevant studies?

– *which bibliographic databases were used*

Computer MEDLINE, Key words: “wound infection” and “antibiotics” for nonbite wounds managed in EDs. The bibliographies of clinical trials and reviews were examined to find further trials

– *if there was follow-up from reference lists*

Not mentioned

– *if there was personal contact with experts*

Not mentioned

– *if the reviewers searched for unpublished studies*

Not mentioned

– *if the reviewers searched for non-English-language studies*

The search was not limited to articles in English



Can't  
tell

## 4. Did the reviewers assess the quality of the included studies?

YES

– more than one assessor: PS: the other one is blinded to result

The reviewers assessed each article with **randomisation, blindness, or intention-to-treat analysis (9→7)**

TABLE 2. Further Details of Randomized Studies Included in Meta-Analysis of Antibiotics for Prophylaxis of Infection in Simple Lacerations

Trial	Blinded	Number of Patients Entered	Number With Reported Results (%)
Beesley et al <sup>7</sup>	Double	145	130 (89.7%)
Day <sup>8</sup>	Single	?	112 (?)
Roberts and Teddy <sup>10</sup>	No	338	305 (90.2)
Hutton et al <sup>11</sup>	No	301	285 (94.7)
Worlock et al <sup>12</sup>	Double	118	105 (90.0)
Grossman et al <sup>14</sup>	Double	280	265 (94.6)
Thirlby et al <sup>15</sup>	No	?	499 (?)

5. If the results of the studies have been combined, was it reasonable to do so?

– *the results of each study are clearly displayed*



YES

**For each trial, a 2\*2 table was created** to summarize the number of patients reported as infected or uninfected in each treatment arm

– *the results were similar from study to study (look for tests of heterogeneity)*

**A test for heterogeneity was not significant (p=0.5)**

**TABLE 3.** Results of Randomized Studies of Antibiotics for Nonbite Wounds

Trial	Antibiotic		Controls		Odds Ratio <sup>†</sup>	95% CI
	Total	Infected (%)	Total	Infected (%)		
Beelsey et al <sup>7</sup>	64	1 (1.6)	66	1 (1.5)	1.03	0.01 to 82.22
Day <sup>8</sup>	56	12 (21.4)	56	4 (7.1)	3.55	0.97 to 16.00
Roberts et al <sup>10</sup>	205 <sup>‡</sup>	18 (8.8)	100	12 (12.0)	0.71	0.31 to 1.68
Hutton et al <sup>11</sup>	142	10 (7.0)	143	9 (6.3)	1.13	0.40 to 3.25
Worlock et al <sup>12</sup>	71 <sup>‡</sup>	5 (7.0)	34	2 (5.9)	1.21	0.19 to 13.36
Grossman et al <sup>14</sup>	174 <sup>§</sup>	2 (1.1)	91	1 (1.1)	1.05	0.05 to 62.42
Thirby et al <sup>15</sup>	227	16 (7.0)	272	17 (6.3)	1.14	0.52 to 2.46
SUMMARY	939		762		1.16	0.77 to 1.78

2\*2 table in each study

效度是可信的, 那麼結果重要嗎?

效益 Impact



## 6. How are the results presented and what is the main result?

- *The total sample size: 1,734 patients*
- *Results: Summary odds ratio (Mantel-Haenszel method)*  
*Antibiotics versus placebo, for incidence of infection:*  
*odds ratio 1.16 (95% CI 0.77 to 1.78)*

預防性抗生素在Nonbite wound病人身上並不能預防感染

## 7. How precise are these results?

本結果以Odds ratio表現，並附上95%信賴區間

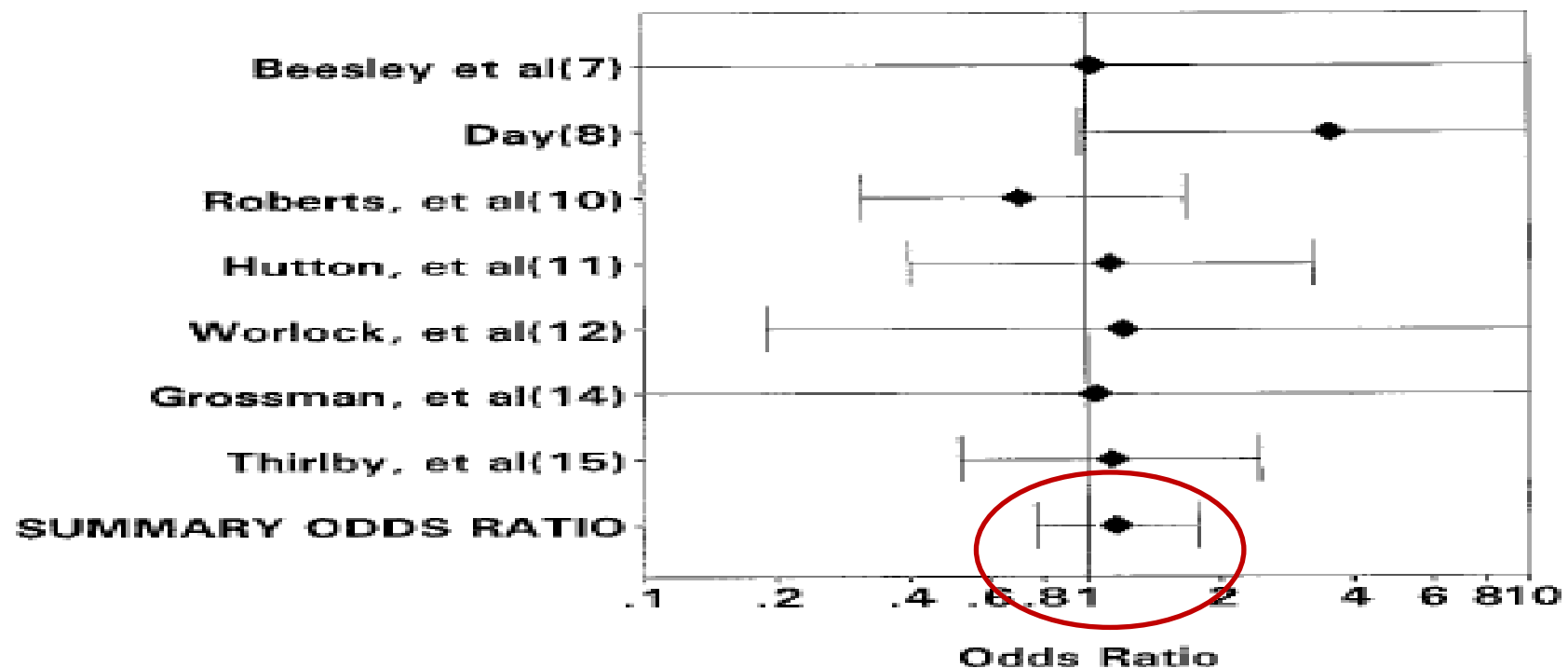


FIGURE 1. Odds ratio estimates and 95% CIs for individual studies and the summary odds ratio for all studies. The odds ratio closely approximates the relative risk of infection among patients administered antibiotics compared with controls. An odds ratio estimate less than 1.0 indicates that antibiotic treatment reduces the risk of infection, whereas an estimate greater than 1.0 favors the control group. The reference number is given for individual studies.

# 證據等級

Grade of Recommendation	Level of Evidence	Prevention
[A]	1a	Systemic review of RCTs
	1b	Single RCT
	1c	'All-or-none'
[B]	2a	Systemic review of cohort studies
	2b	Cohort study or poor RCT
	2c	'Outcomes' research
	3a	Systemic review of case-control studies
[C]	3b	Case-control study
	4	Case series
[D]	5	Expert opinion, physiology, bench research

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這篇 1A 的 evidence, 可以應用在  
林小姐身上嗎？

## 8. Can the results be applied to the population?



YES

1. 實驗族群: 在急診室治療的**Simple non-bite wound**病患，與林小姐相同

2. 執業地點: 雖然是**家醫科門診**，但也可採納此證據作為醫療決策

3. 風土民情: 有些**台灣**的病人看病很喜歡拿藥，沒給藥好像沒治療，需要提出證據耐心教育

## 9. Were all important outcomes considered?

*Consider outcomes from the point of view of the:*

- *individual* : 可以不用吃那麼多天的藥, 不必承擔抗生素副作用
- *policy makers and professionals*: 節省醫療成本

## 10. Should policy or practice change as a result of the evidence contained in this review?

透過**EBM**介入方式與傳統介入方式對醫療照顧的差異：

**醫療現況：**仍有許多醫師會對**Non-bite wound**開立  
抗生素

**EBM 介入：**對於無特殊**Underlying disease**病患的  
簡單傷口，在處理時不應給予口服或肌注抗生素，因  
為並不能預防傷口感染，病患還可能會承擔副作用！  
且增加不必要的健保花費

**改變帶來的醫療品質提升：**較少花費，沒有副作用，且  
並不會增加傷口感染率



# 成本效益

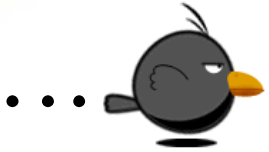
藥物	劑量	療程	單價	總費用
<b>AUGMENTIN</b>	<b>375 MG TID</b>	<b>3天</b>	<b>8.4</b>	<b>75.6</b>
<b>CLOXACILLIN</b>	<b>250 MG TID</b>	<b>3天</b>	<b>1.5</b>	<b>13.5</b>
<b>CEPHALEXIN</b>	<b>250 MG TID</b>	<b>3天</b>	<b>1.2</b>	<b>10.8</b>



[http://www.nhi.gov.tw/inquire/query1.asp?menu=1&menu\\_id=8&WD\\_ID=42](http://www.nhi.gov.tw/inquire/query1.asp?menu=1&menu_id=8&WD_ID=42)

# Scenario II

- 林小姐吃完藥三天後回家醫科門診，對醫師提出了疑問



所以我是  
那我不吃  
白麼多了  
藥了...  
個醫生  
傷  
率



# 心得

- 雖是一篇老文章，但此文章之後就沒有類似的RCT，可見其證據之強，且存在已久，但爲什麼醫師們還是會開立抗生素？
  - 開立抗生素不痛不癢，而且很便宜
  - 認知到行爲改變需要一段時間
- 我們要不斷的Update自己的knowledge
- EBM skill 是一個重要的Tool，能幫助我們Update