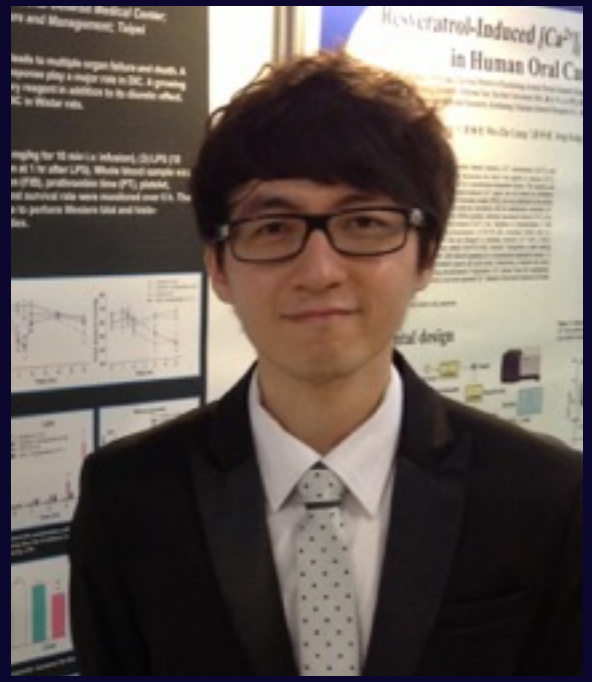


丁肇壯

小兒部
總醫師

洪浩淵

臨床藥學部
藥師

陳虹儒

大學部
實習醫學生

國防醫學院三軍總醫院

實證醫學—小兒部

臨床情境

- 一對姐妹因為54歲母親這個月初因子宮頸癌過世，來到婦產科門診詢問子宮頸抹片檢查，姐姐已婚25歲有6歲及4歲子女，妹妹未婚16歲尚無性經驗。因目前健保有給付30歲以上婦女每年免費進行一次抹片檢查，另外可打疫苗來預防。國內目前有三種子宮頸癌疫苗，分別是兩價、四價及最近才上市的九價疫苗。
- 蘇小姐的問題是

1. 如果要自費做抹片檢查，是否有其他自費檢查更準確?
2. 如果要自費打疫苗，是不是多價的愈有效?

了解 病人 主要問題

- 除了抹片檢查是否有其他檢查對於子宮頸癌發現會更準確。
- 不同價子宮頸疫苗對於預防子宮頸癌的效果

尊重 病人 治療意願

可接受自費檢查或疫苗，重視預防效果

Ask
問問題

背景知識 -

DynaMed Powered by EBSCOhost

特性

Cervical cancer is the most common cancer experienced by women worldwide; however, screening techniques are very effective for reducing the risk of death. The national cervical cancer screening program was implemented in Taiwan in 1995.

預防

1. screening:Screening is performed using cervical cytology (Pap test) or a human papillomavirus (HPV) test, or a combination of the two tests.
2. Vaccine: Each of the three HPV vaccines is a noninfectious, virus-like particle (VLP) vaccine. 2vHPV, 4vHPV and 9vHPV all target HPV 16 and 18, types that cause approximately 66% of cervical cancers and the majority of other HPV-associated cancers in both women and men in the United States.8 Both 4vHPV and 9vHPV also protect against HPV 6 and 11, types that cause anogenital warts. In addition, 9vHPV also targets five additional cancer causing types (HPV 31, 33, 45, 52, and 58) which cause about 15% of cervical cancers. 4vHPV and 9vHPV are licensed and recommended for use in females and males; 2vHPV is licensed and recommended for use in females.

Ask 問問題

根據臨床問題形成第一個 P I C O

	中文關鍵字	英文關鍵字	同義字/MeSH
P	25歲已婚女性	25y/o married female patient	
I	9價子宮頸癌疫苗	9-varient HPV vaccine (9vHPV)	
C	4價子宮頸癌疫苗	4-varient HPV vaccine (9vHPV)	
O	預防效果	Immunogenicity	

Ask
問問題

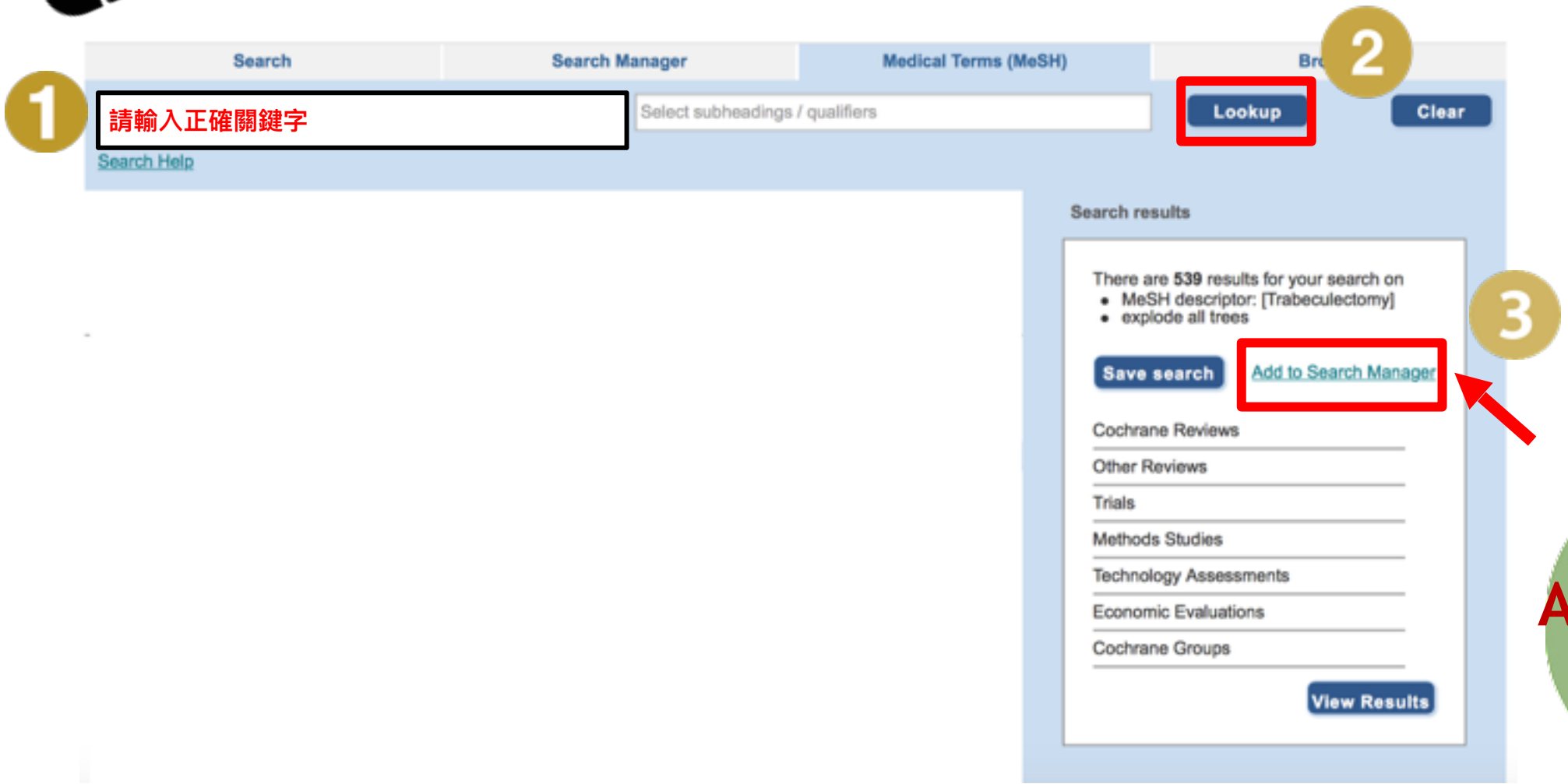
根據臨床問題形成第二個 PICO

	中文關鍵字	英文關鍵字	同義字/MeSH
P	25歲已婚女性	25y/o married female patient	
I	固定抹片檢查	high-risk human papillomavirus (HPV) DNA testing	
C	其他自費檢查	Pap tests	"papanicolaou test"[MeSH Terms]
O	準確度	efficacy of detection	

Ask
問問題

策略 - 先搜尋secondary database

輸入『P』、『I』作為關鍵字,搜尋同義詞 MeSH,並加到 Search Manager

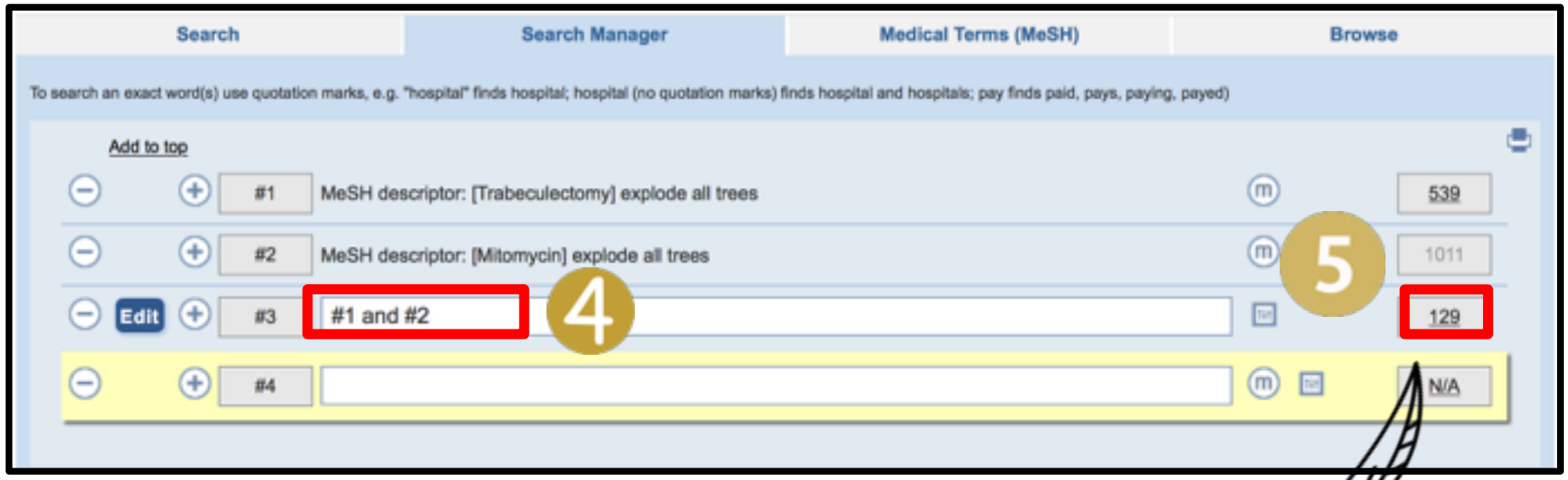


Acquire
找資料

策略 - 先搜尋secondary database

Cochrane Library

使用search Manager 搜尋, 加入布林邏輯 『 AND 』作為搜尋連結

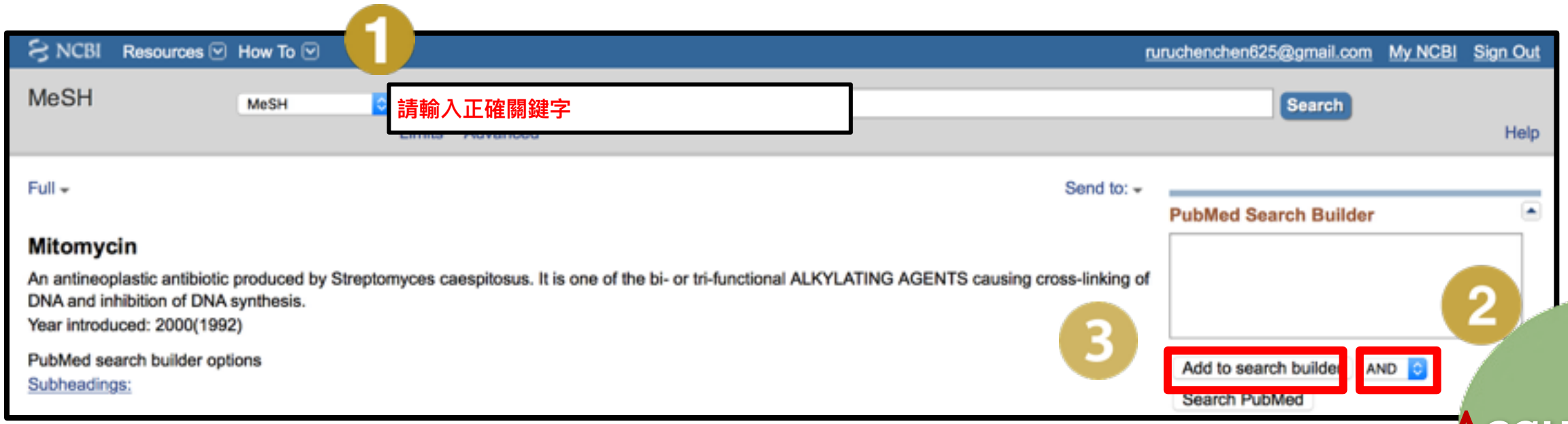


共搜尋到 X篇 Cochrane review

Acquire
找資料

檢索策略 - 再搜尋primary database

首先在MeSH database,以『P』、『I』搜尋同義詞MeSH,
選擇布林邏輯 『 AND 』再加入 search builder,最後再按下
Search PubMed



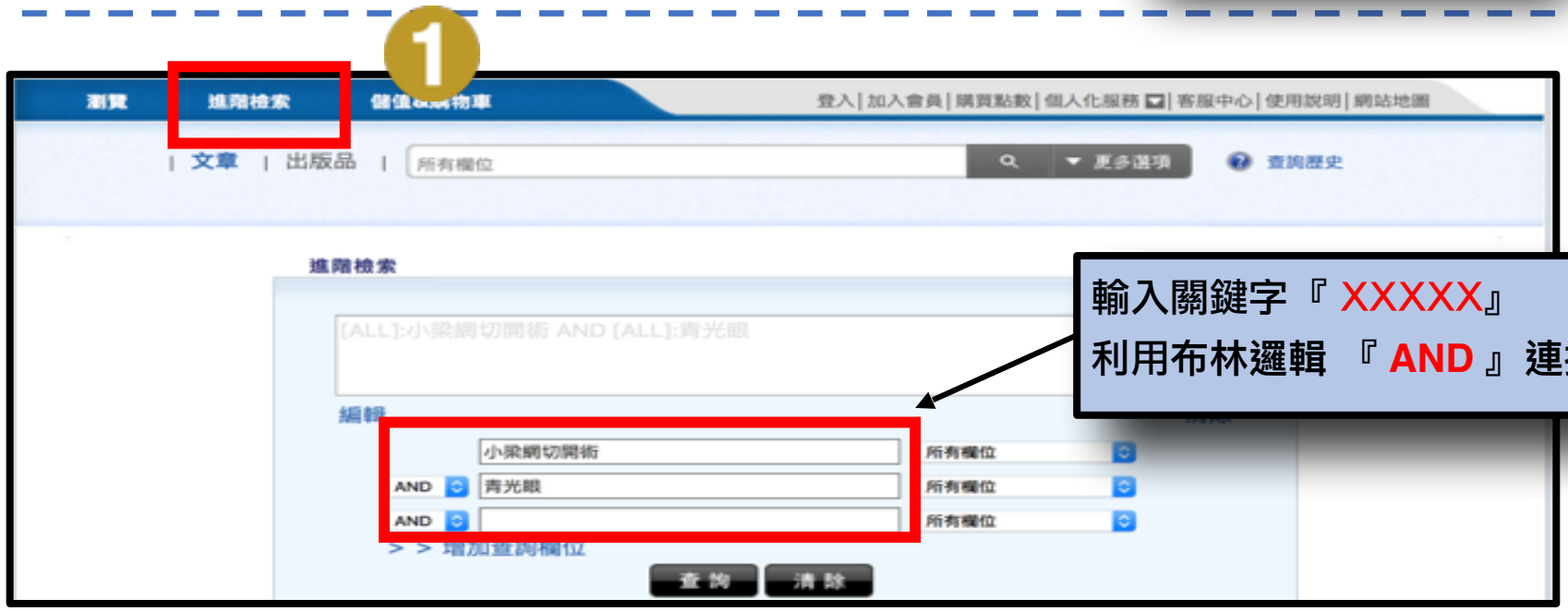
Acquire
找資料

檢索策略 - 再搜尋primary database

Acquire
找資料

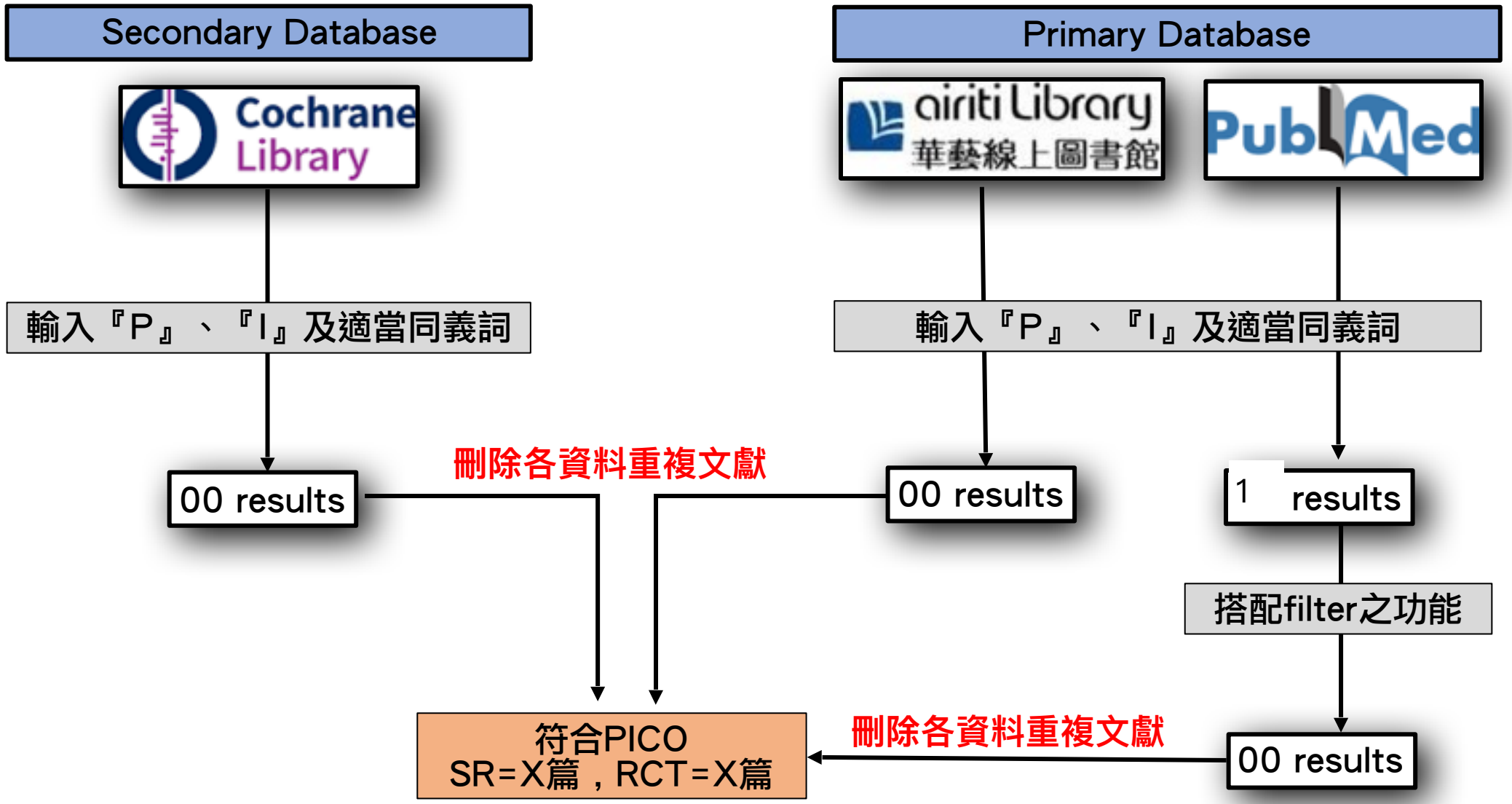
檢索策略 - 再搜尋primary database

airiti Library 華藝線上圖書館



輸入關鍵字『 XXXXX』
利用布林邏輯 『 AND 』連接

Acquire
找資料


Secondary Database
Primary Database
Cochrane Library
airiti Library 華藝線上圖書館
PubMed
輸入『P』、『I』及適當同義詞
輸入『P』、『I』及適當同義詞
00 results
刪除各資料重複文獻
00 results
1 results
搭配filter之功能
符合PICO
SR=X篇，RCT=X篇
刪除各資料重複文獻
00 results

Acquire
找資料

各資料庫收納結果

來源	標題
Cochrane Library	[文末標年份]
PubMed	[文末標年份]
PubMed	[文末標年份]

Acquire
找資料

文獻篩選 1/4

題目

S

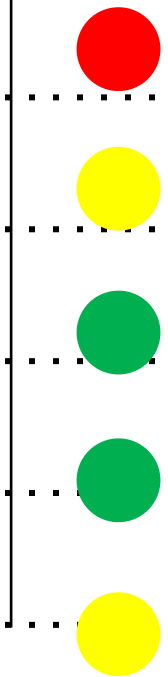
P

I

C

O

年份



Acquire
找資料

文獻篩選 2/4

題目

S

P

I

C

O

年份

Acquire
找資料

文獻篩選 3/4

題目

S

P

I

C

O

年份

Acquire
找資料

文獻篩選 4/4

題目

S

P

I

C

O

年份

Acquire
找資料

篩選出最佳文獻，並提出我們的理由

文章題目	S	P	I	C	O
	🟢	🔴	🟢	🔴	🟢
	🟢	🟢	🟢	🟡	🟡
	🟢	🟢	🟢	🟢	🟢
	🟢	🟡	🟢	🟢	🟢

Acquire
找資料

嚴格評讀

- □最佳的研究設計
- □較新的發表年份
- □含有亞洲人種資料
- □最符合臨床情境

CAS
P

[13.03.17]

domised Controlled Trials Cl

(A) Are the results of the trial valid?

Screening Questions

Validity
效度

Screening Questions

1. Did the trial address a clearly focused issue?
   此研究是否問了一個清楚明確的問題？

HINT: An issue can be “focused” In terms of

1. The population studied
2. The intervention given
3. The comparator given
4. The outcome considered

評讀結果

Validity
效度

BACKGROUND

The investigational 9-valent viruslike particle vaccine against human papillomavirus (HPV) includes the HPV types in the quadrivalent HPV (qHPV) vaccine (6, 11, 16, and 18) and five additional oncogenic types (31, 33, 45, 52, and 58). Here we present the results of a study of the efficacy and immunogenicity of the 9vHPV vaccine in women 16 to 26 years of age.

METHODS

We performed a randomized, international, double-blind, phase 2b–3 study of the 9vHPV vaccine in 14,215 women. Participants received the 9vHPV vaccine or the qHPV vaccine in a series of three intramuscular injections on day 1 and at months 2 and 6. Serum was collected for analysis of antibody responses. Swabs of labial, vulvar, perineal, perianal, endocervical, and ectocervical tissue were obtained and used for HPV DNA testing, and liquid-based cytologic testing (Papanicolaou testing) was performed regularly. Tissue obtained by means of biopsy or as part of definitive therapy (including a loop electrosurgical excision procedure and conization) was tested for HPV.

RESULTS

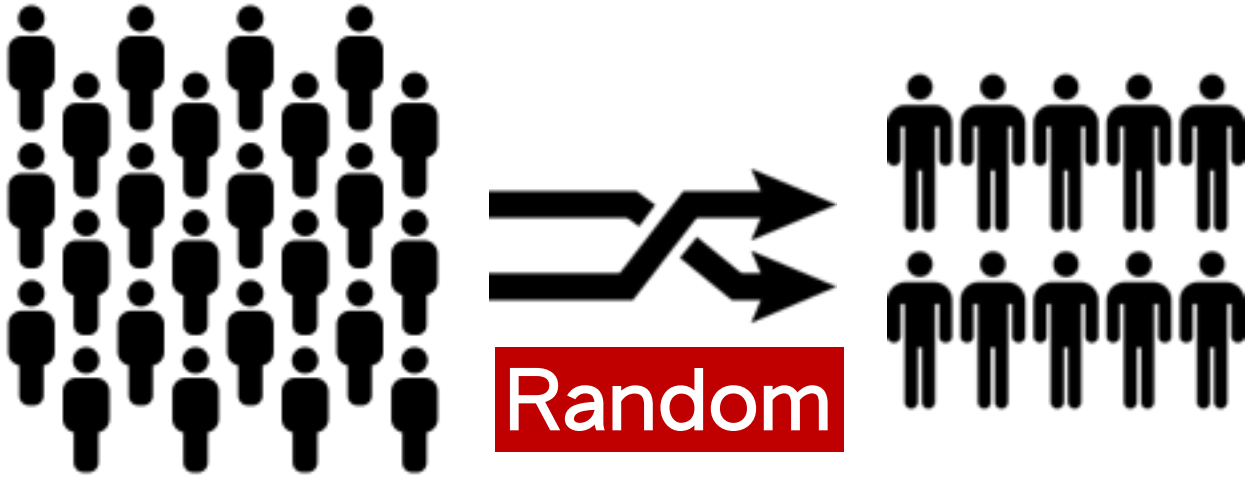
The rate of high-grade cervical, vulvar, or vaginal disease irrespective of HPV type (i.e., disease caused by HPV types included in the 9vHPV vaccine and those not included) in the modified intention-to-treat population (which included participants with and those without prevalent infection or disease) was 14.0 per 1000 person-years in both vaccine groups. The rate of high-grade cervical, vulvar, or vaginal disease related to HPV-31, 33, 45, 52, and 58 in a prespecified per-protocol efficacy population (susceptible population) was 0.1 per 1000 person-years in the 9vHPV group and 1.6 per 1000 person-years in the qHPV group (efficacy of the 9vHPV vaccine, 96.7%; 95% confidence interval, 80.9 to 99.8). Antibody responses to HPV-6, 11, 16, and 18 were noninferior to those generated by the qHPV vaccine. Adverse events related to injection site were more common in the 9vHPV group than in the qHPV group.

P	Females aged 16-26 y/o
I	9-valent cervical vaccine
C	Quadrivalent cervical vaccine
O	Prevention cervical cancer
T	54 m/o

作者清楚地說明了PICOT，因此評讀結果為Yes。

☑ Yes ☐ No ☐ Unclear

Validity
效度



2. Was the assignment of patients to treatments randomised?
此研究是否適當的隨機分派病患？

HINT: Consider

1. How was this carried out?
2. Was the allocation sequence concealed from
3. researchers and patients?

BACKGROUND

The investigational 9-valent viruslike particle vaccine against human papillomavirus (HPV) includes the HPV types in the quadrivalent HPV (qHPV) vaccine (6, 11, 16, and 18) and five additional oncogenic types (31, 33, 45, 52, and 58). Here we present the results of a study of the efficacy and immunogenicity of the 9vHPV vaccine in women 16 to 26 years of age.

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評讀結果

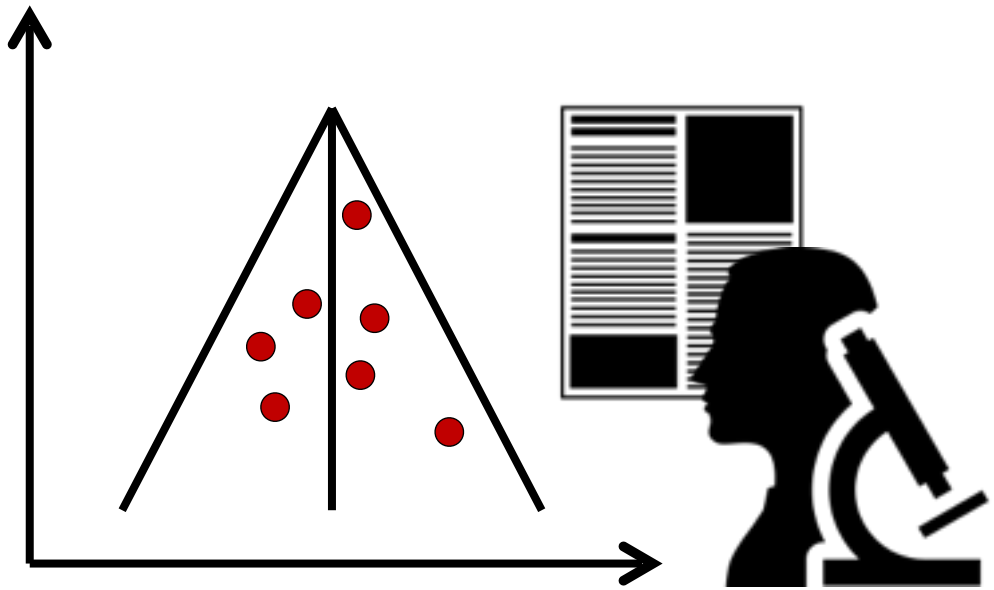
Validity
效度

優點

1. 清楚定義了納入條件
2. RCT使用雙盲

☑ Yes ☐ No ☐ Unclear

Validity
效度



3. Were all of the patients who entered the trial properly accounted for at its conclusion?

是否所有的病患都有納入結果中去分析？

HINT: Consider

1. Was the trial stopped early?
2. Were patients analysed in the groups to which they were randomised?

評讀結果

Validity
效度

RESULTS

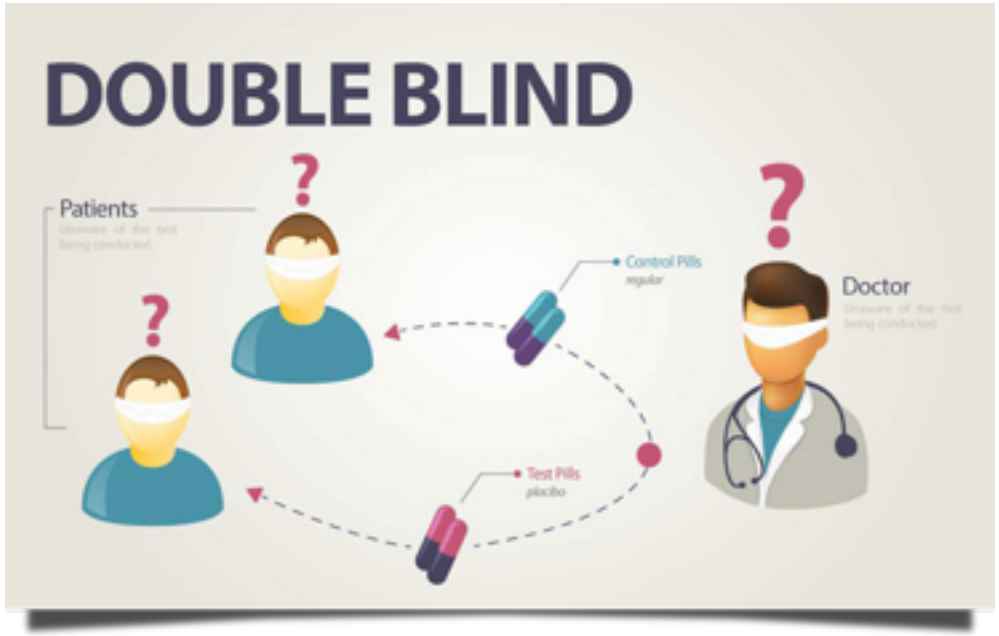
The rate of high-grade cervical, vulvar, or vaginal disease irrespective of HPV type (i.e., disease caused by HPV types included in the 9vHPV vaccine and those not included) in the modified intention-to-treat population (which included participants with and those without prevalent infection or disease) was 14.0 per 1000 person-years in both vaccine groups. The rate of high-grade cervical, vulvar, or vaginal disease related to HPV-31, 33, 45, 52, and 58 in a prespecified per-protocol efficacy population (susceptible population) was 0.1 per 1000 person-years in the 9vHPV group and 1.6 per 1000 person-years in the qHPV group (efficacy of the 9vHPV vaccine, 96.7%; 95% confidence interval, 80.9 to 99.8). Antibody responses to HPV-6, 11, 16, and 18 were noninferior to those generated by the qHPV vaccine. Adverse events related to injection site were more common in the 9vHPV group than in the qHPV group.

1. 使用 Intention-To-Treat (ITT) analysis
2. loss follow-up< 1%

☑ Yes ☐ No ☐ Unclear

Is it worth continuing? 

Validity
效度



Detailed questions

4. Were patients, health workers and study personnel ‘blind’ to treatment?

病患、(給藥、測量結果的)醫療照護者、分析數據人員是否都是「盲性的」？

HINT: Think about

1. Patients?
2. Health workers?
3. Study personnel?

評讀結果

Validity
效度

METHODS

STUDY DESIGN

We conducted a randomized, international, multicenter, double-blind study of the immunogenicity, efficacy, and side-effect profile of the 9vHPV vaccine in women 16 to 26 years of age. The study was based on a phase 2–3 adaptive design (see the Supplementary Appendix, available with the full text of this article at NEJM.org). An initial group of 1242 women were randomly assigned to receive one of three doses of the 9vHPV vaccine or a qHPV vaccine control. A larger group of 13,598 women were then randomly assigned to receive either the 9vHPV vaccine at the dose selected on the basis of results in the initial group or the qHPV vaccine control. The efficacy study included these 13,598 women together with the 307 women in the initial group assigned to receive the 9vHPV vaccine at the dose selected and the 310 women in the initial group assigned to the qHPV vaccine, representing a total of 14,215 women (Fig. S1 and S2 in the Supplementary Appendix).

優點

1. 作者利用「double-blind」來避免“觀察者偏差observer bias”
2. 受試者:「blind」
3. 研究者:「blind」

☑ Yes ☐ No ☐ Unclear

5. Were the groups similar at the start of the trial?
隨機分派後的兩組病患是否具有可比性？

HINT: Look at

- Other factors that might affect the outcome such as age, sex, social class

評讀結果

Validity
效度

RESULTS

STUDY POPULATION

A total of 14,215 participants underwent randomization for the efficacy portion of this study (Fig. S1 in the Supplementary Appendix). The makeup of the populations for the efficacy and immunogenicity analyses is shown in Table S1 in the Supplementary Appendix. The baseline characteristics were similar in the two vaccination groups (Table 1).

優點

1. 作者描述病患的基本特質,並沒有統計上的差異

☑ Yes ☐ No ☐ Unclear

Validity
效度

6. Aside from the experimental intervention, were the groups treated equally?
除了研究介入 (intervention)的差別，兩組間其他的治療是否相等？

225 μg of the adjuvant amorphous aluminum hydroxyphosphate sulfate (AAHS).[14] A 0.5-ml dose of 9vHPV vaccine contains 30 μg of HPV-6, 40 μg of HPV-11, 60 μg of HPV-16, 40 μg of HPV-18, 20 μg of HPV-31, 20 μg of HPV-33, 20 μg of HPV-45, 20 μg of HPV-52, and 20 μg of HPV-58 viruslike particles, and 500 μg of AAHS. Vaccines were administered as a 0.5-ml intramuscular injection in three doses, on day 1 and at month 2 and month 6. Information on randomization to a vaccine group is available in the Supplementary Appendix. At study vaccination visits, all participants received a vaccination report card on which they recorded oral temperatures on each of the 5 days after vaccination and adverse events related to the injection site as well as systemic adverse events on each of the 15 days after vaccination.

(B) What are the results?

Importance
重要性

7. How large was the treatment effect?
介入的治療效果有多大？

HINT: Consider

1. **What outcomes were measured?**
2. **Is the primary outcome clearly specified?**
3. **What results were found for each outcome?**

主要結果-High-grade cervical, vulvar, and vaginal disease

Importance
重要性

Table 2. Effect of 9vHPV Vaccine on the Incidence of Cervical, Vulvar, and Vaginal Disease and of Persistent HPV-Related Infection.*

End Point	9vHPV Vaccine (N=7099)		qHPV Vaccine (N=7105)		Risk Reduction (95% CI)
	no./total no.	cases/1000 person-yr	no./total no.	cases/1000 person-yr	
Modified intention-to-treat population					
High-grade cervical, vulvar, and vaginal disease†					
All participants	340/7027	14.0	344/7027	14.0	0.7 (−15.7 to 14.8)
HPV-uninfected on day 1	26/3032	2.4	46/3077	4.2	42.5 (7.9 to 65.9)
Not related to 9 vaccine HPV types‡	26/3032	2.4	33/3077	3.0	19.7 (−34.5 to 52.5)
Related to 9 vaccine HPV types‡	0/3032	0.0	13/3076	1.2	100 (70.4 to 100)
HPV-infected on day 1	314/3995	23.1	298/3950	22.1	−4.8 (−23.3 to 10.8)
Not related to 9 vaccine HPV types‡	141/3995	10.0	137/3950	9.8	−2.0 (−30.0 to 19.9)
Related to 9 vaccine HPV types‡	173/3992	12.4	161/3946	11.6	−6.8 (−33.2 to 14.3)
Average risk reduction§	—	—	—	—	19.0 (−1.6 to 35.3)
High-grade cervical epithelial neoplasia, adenocarcinoma in situ, and cervical cancer					
All participants	325/6882	14.1	326/6871	14.1	−0.3 (−17.3 to 14.3)
HPV-uninfected on day 1	26/2976	2.5	44/3009	4.2	39.7 (1.8 to 64.3)
Not related to 9 vaccine HPV types‡	26/2976	2.5	31/3009	3.0	14.3 (−49.1 to 49.1)
Related to 9 vaccine HPV types‡	0/2976	0.0	13/3009	1.2	100 (70.3 to 100)
HPV-infected on day 1	299/3906	23.3	282/3862	22.2	−5.3 (−24.1 to 10.8)
Not related to 9 vaccine HPV types‡	131/3906	10.1	132/3862	10.3	1.8 (−26.0 to 23.5)
Related to 9 vaccine HPV types‡	168/3906	13.0	150/3862	11.7	−11.3 (−39.6 to 11.0)
Average risk reduction§	—	—	—	—	17.1 (−4.2 to 34.0)

評讀結果

Intervention	9-valent cervical vaccine
Comparison	Quadrivalent cervical vaccine
Time	54 m/o
研究結果	RR=0.7[-15.7,14.8](95%CI)
結論	九價疫苗與四價疫苗在預防 High-grade cervical, vulvar, and vaginal disease 並無顯著差異

Importance
重要性

8. How precise was the estimate of the treatment effect?治療效果的估計值有多精確？

HINT: Consider

- **What are the confidence limits?**

主要結果-High-grade cervical, vulvar, and vaginal disease

Importance
重要性

結果精確嗎？

Table 2. Effect of 9vHPV Vaccine on the Incidence of Cervical, Vulvar, and Vaginal Disease and of Persistent HPV-Related Infection.*

End Point	9vHPV Vaccine (N=7099)		qHPV Vaccine (N=7105)		Risk Reduction (95% CI)
	no./total no.	cases/1000 person-yr	no./total no.	cases/1000 person-yr	
Modified intention-to-treat population					
High-grade cervical, vulvar, and vaginal disease†					
All participants	340/7027	14.0	344/7027	14.0	0.7 (−15.7 to 14.8)
HPV-uninfected on day 1	26/3032	2.4	46/3077	4.2	42.5 (7.9 to 65.9)
Not related to 9 vaccine HPV types‡	26/3032	2.4	33/3077	3.0	19.7 (−34.5 to 52.5)
Related to 9 vaccine HPV types‡	0/3032	0.0	13/3076	1.2	100 (70.4 to 100)
HPV-infected on day 1	314/3995	23.1	298/3950	22.1	−4.8 (−23.3 to 10.8)
Not related to 9 vaccine HPV types‡	141/3995	10.0	137/3950	9.8	−2.0 (−30.0 to 19.9)
Related to 9 vaccine HPV types‡	173/3992	12.4	161/3946	11.6	−6.8 (−33.2 to 14.3)
Average risk reduction§	—	—	—	—	19.0 (−1.6 to 35.3)
High-grade cervical epithelial neoplasia, adenocarcinoma in situ, and cervical cancer					
All participants	325/6882	14.1	326/6871	14.1	−0.3 (−17.3 to 14.3)
HPV-uninfected on day 1	26/2976	2.5	44/3009	4.2	39.7 (1.8 to 64.3)
Not related to 9 vaccine HPV types‡	26/2976	2.5	31/3009	3.0	14.3 (−49.1 to 49.1)
Related to 9 vaccine HPV types‡	0/2976	0.0	13/3009	1.2	100 (70.3 to 100)
HPV-infected on day 1	299/3906	23.3	282/3862	22.2	−5.3 (−24.1 to 10.8)
Not related to 9 vaccine HPV types‡	131/3906	10.1	132/3862	10.3	1.8 (−26.0 to 23.5)
Related to 9 vaccine HPV types‡	168/3906	13.0	150/3862	11.7	−11.3 (−39.6 to 11.0)
Average risk reduction§	—	—	—	—	17.1 (−4.2 to 34.0)

Intervention	9-valent cervical vaccine
Comparison	Quadrivalent cervical vaccine
Time	54 m/o
研究結果	RR=-0.3[-17.3,14.3](95%CI)
結論	九價疫苗的RR 95%信賴區間上界減下界為28.6% 信賴區間窄

評定證據等級-OCEBM Level of Evidence, 2011

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or *n*-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, *n*-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptional) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or *n*-of-1 trial	Randomized trial or (exceptional) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial			

【治療型問題】
RCT 證據等級為 **Level 2**
※經嚴格評讀，無其他需要考慮降階理由

考慮降階之理由

- □研究品質差
- □證據間沒有一致性
- □絕對效果小
- □研究不精確(95%CI過大)
- □PICO和臨床情境不相符

(c) Will the results help locally?

9. Can the results be applied in your context? (or to the local population?)
此研究是否可應用到你的病患？

HINT: Consider whether

- Do you think that the patients covered by the trial are similar enough to the patients to whom you will apply this?, if not how to they differ?

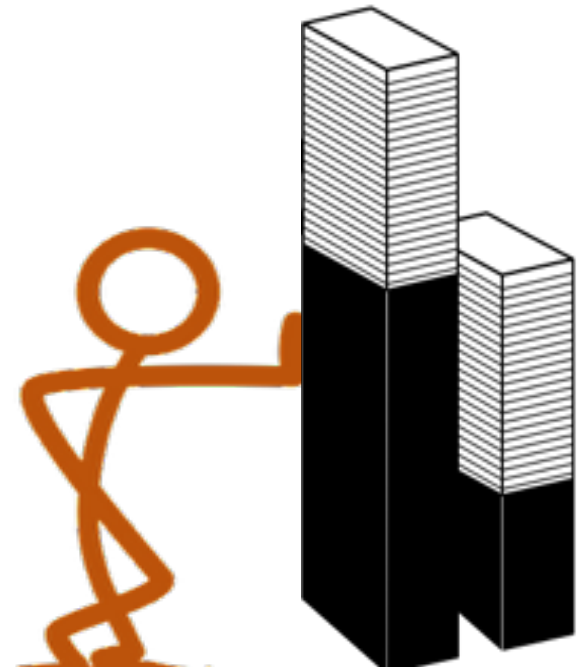
評估適用性-比較評讀文獻與臨床情境

Practic
e 應用

	評讀文獻	臨床情境
P	Females aged 16-26 y/o	25y/o married female patient
I	9-valent cervical vaccine	9-varient HPV vaccine (9vHPV)
C	Quadrivalent cervical vaccine	4-varient HPV vaccine (9vHPV)
O	Prevention cervical cancer	Immunogenicity

1. 我們的病患與文獻研究是否相似？ ☑年齡 ☑性別 ☑種族 ☑共病 ☑同時服用其他治療藥物 ☑疾病嚴重度	是
2. 這項治療在台灣是否可行？	可

☑Yes ☐No ☐Unclear



10. Were all important outcomes considered?
是否所有重要的臨床結果都被考量到？

HINT: Consider whether

1. Is there other information you would like to have seen
2. If not, does this affect the decision?

效益分析-病患能從此介入獲得之好處

Practic
e 應用

主要結果: 請輸入
RR
-0.3[-17.3,14.3]

此文獻提供了臨床問題的重要Outcome，並可進而推算NNT

Main outcome

High-grade cervical epithelial neoplasia, adenocarcino- ma in situ, and cervical cancer

Minor outcome

~~High-grade cervical,~~ vulvar, and vaginal disease

☑ Yes ☑ No ☑ Unclear

11. Are the benefits worth the harms and costs?
這些好處隨之而來的傷害和花費是否值得？

HINT: Consider

- Even if this is not addressed by the review, what do you think?

成本分析-個人負擔

交通費/月		治療花費/月		掛號費/月		其他費用/月		總花費
100	+	4300	+	400	+	700	=	5400

	請假損失			
其他費用	700			

Reference:

衛生福利部中央健康保險署
NATIONAL HEALTH INSURANCE ADMINISTRATION,MINISTRY OF HEALTH AND WELF

臨床應用-回覆病人問題

蘇小姐，經過我們文獻查詢的結果，目前有一個大型的臨床隨機試驗比較九價與四價疫苗在子宮頸癌預防的效果。結果無論在婦科疾病及婦科惡性腫瘤上的預防效果都沒有顯著的差異。如果蘇小姐有價格上的考量，那麼相對於九價疫苗(NT4300/劑)，四價疫苗有相當的效果並且價格相對便宜。(NT3400/劑)