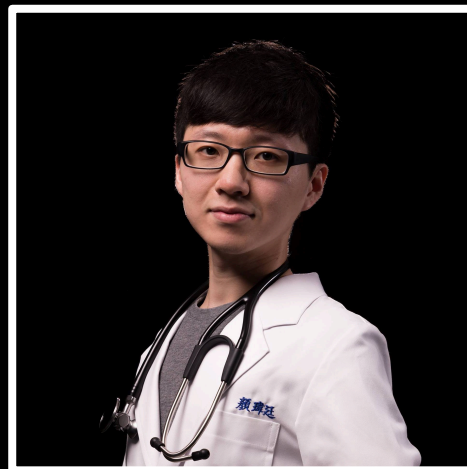




**李卓豪**  
一般醫學部  
PGY住院醫師



**張鈞智**  
臨床藥學部  
PGY住院藥局藥師



**顏瑋廷**  
大學部  
醫學系五年級生

# 國防醫學院三軍總醫院

參賽編號：17-C40012

## 院內實證醫學應用競賽-示範組



# 臨床情境

林媽媽有兩個小孩，大兒子常常感冒拉肚子，她很怕剛出生不久**2個多月**大的女兒也會出狀況。最近聽說有一種**輪狀病毒的疫苗**，可以增加免疫力。她想要知道**值不值得**打這個疫苗，又有點**擔心副作用**。



## 瞭解病人的主要問題

1. 2個多月大的女兒值不值得施打輪狀病毒疫苗？效果如何？
2. 擔心輪狀病毒疫苗的副作用

## 尊重病人的治療意願

1. 希望可以施打疫苗增加免疫力
2. 希望不要有嚴重的副作用

# 背景知識



## 輪狀病毒腸胃炎

### 特性

1. 在**4個月大**到**兩歲**的小孩最容易感染
2. 疫苗施打後，疾病的發生率已經下降

### 治療

1. 目前並無**抗病毒藥物**
2. 採用**支持性療法**

### 預防

1. 服用**口服減毒疫苗**(建議達**六週**的嬰兒開始服用)
2. 注意**接觸感染**



# 根據臨床問題形成第一個PICO

	P I C O / 關鍵字	MeSH同義詞	中文關鍵字
P	<ul style="list-style-type: none"> <li>• 2m/o <b>infant(girl)</b></li> <li>• Asian</li> </ul>	<ul style="list-style-type: none"> <li>• Child</li> <li>• Children</li> <li>• Preschool</li> </ul>	<ul style="list-style-type: none"> <li>• 女嬰</li> </ul>
I	<ul style="list-style-type: none"> <li>• <b>Rotavirus Vaccination</b></li> </ul>	<ul style="list-style-type: none"> <li>• Viral vaccines</li> <li>• Rotavirus vaccines</li> </ul>	<ul style="list-style-type: none"> <li>• 輪狀病毒疫苗</li> </ul>
C	<ul style="list-style-type: none"> <li>• <b>Placebo</b></li> </ul>	<ul style="list-style-type: none"> <li>• -/-</li> </ul>	<ul style="list-style-type: none"> <li>• 安慰劑</li> </ul>
O	<p>Major</p> <ul style="list-style-type: none"> <li>• <b>Severe rotavirus diarrhea incidence rate</b></li> </ul> <p>Minor</p> <ul style="list-style-type: none"> <li>• Hospitalizations rate</li> <li>• Diarrhea mortality rate</li> </ul>	<ul style="list-style-type: none"> <li>• Severe Infantile incidence rate</li> <li>• Digestive symptoms incidence rate</li> <li>• Survival rate</li> <li>• Fatal outcome</li> </ul>	<ul style="list-style-type: none"> <li>• 嚴重輪狀病毒腹瀉</li> <li>• 住院率</li> <li>• 死亡率</li> </ul>

治療/預防型問題  
  診斷型問題  
  預後型問題  
  傷害/病因型問題

# 根據臨床問題形成第二個PICO

	P I C O / 關鍵字	MeSH同義詞	中文關鍵字
P	<ul style="list-style-type: none"> <li>7y/o children(boy)</li> <li>Asian</li> </ul>	<ul style="list-style-type: none"> <li>Child</li> <li>Children</li> <li>Preschool</li> </ul>	<ul style="list-style-type: none"> <li>男童</li> </ul>
I	<ul style="list-style-type: none"> <li>Enterovirus 71 Vaccination</li> </ul>	<ul style="list-style-type: none"> <li>Viral vaccines</li> <li>EV71 vaccines</li> </ul>	<ul style="list-style-type: none"> <li>腸病毒71型疫苗</li> </ul>
C	<ul style="list-style-type: none"> <li>Placebo</li> </ul>	<ul style="list-style-type: none"> <li>-/-</li> </ul>	<ul style="list-style-type: none"> <li>安慰劑</li> </ul>
O	<p>Major</p> <ul style="list-style-type: none"> <li>Hand foot and mouth disease incidence rate</li> </ul> <p>Minor</p> <ul style="list-style-type: none"> <li>Herpangina incidence rate</li> <li>Viral encephalitis incidence</li> </ul>	<ul style="list-style-type: none"> <li>Coxsackievirus infectious rate</li> <li>Meningoencephalitis incidence rate</li> <li>Brain disease incidence rate</li> </ul>	<ul style="list-style-type: none"> <li>手足口病</li> <li>疱疹性咽峽炎</li> <li>病毒性腦炎</li> </ul>

治療/預防型問題  
  診斷型問題  
  預後型問題  
  傷害/病因型問題

# 檢索策略-提升檢索效率

首先以『P』、『I』做搜尋，再依據結果適當加入關鍵字及同義詞

P

AND

I

AND

C

AND

O

Children  
OR  
Child  
OR  
Children  
OR  
Preschool

Rotavirus vaccination  
OR  
Viral vaccine  
OR  
Rotavirus vaccines

Placebo

Severe rotavirus  
diarrhea  
OR  
Severe Infantile  
incidence rate  
OR  
Digestive symptoms  
incidence rate

限定搜尋範圍

Free full text、Within 5 years、Human species

限定研究類型

Systematic review、Meta-analysis、Randomized controlled trial

限定語言地區

English、中文[台灣本土文獻]

# 檢索策略-我們的主要目標



**Clinical** Queries

**Systematic Review** (Meta-Analysis)[Major]  
Randomized Controlled Trial/Cohort Study

Within **5** Years

Meet our 『**PICO**』

# 搜尋Cochrane Library-提升檢索效率

**Cochrane Library** Trusted evidence. Informed decisions. Better health. [Log in / Register](#)

Search Search Manager Medical Terms (MeSH) Browse

Search: Title, Abstract, Keywords

**Database**

- Cochrane Reviews
  - All
  - Review
  - Protocol
- Other Reviews
  - Trials
  - Methods Studies
  - Technology Assessments
  - Economic Evaluations
  - Cochrane Groups

**Dates**

Publication Year (available for all databases)  
Year (YYYY) the article was originally published  
\*\*For Cochrane Reviews, this is the year of the last update

All Years  
 Between  and

輸入**關鍵字**、適當使用**Truncation**  
『**Infant rotavirus vaccin\***』

使用**Limit功能**

限定『**Review**』之文章  
限定『**2012-2016**』文章

# 搜尋Pubmed-利用**限定**縮小檢索範圍

Builder

All Fields  [Show index list](#)

AND All Fields  [Show index list](#)

or [Add to history](#)

輸入**關鍵字**、適當使用**Truncation**

『 **rotavirus vaccin\*** 』

適當使用布林運算

『 **AND** 』、『 **OR** 』

限定適當**文章類型**

『 **Meta-Analysis** 』、『 **Systematic Reviews** 』

『 **Randomized Controlled Trial** 』

限定適當**搜尋範圍**

限定 『 **5年** 』內之文章

限定 『 **Full text** 』有全文可供評讀

限定 『 **Humans** 』 species

Article types

- ✓ Meta-Analysis
- ✓ Randomized Controlled Trial
- ✓ Systematic Reviews
- Customize ...

Text availability

- Abstract
- Free full text
- ✓ Full text

Publication dates

- ✓ 5 years
- 10 years
- Custom range...

Species

- ✓ Humans
- Other Animals

# 搜尋Pubmed-再利用My NCBI 篩選器提升效率

All (77)

Chinese (0)

[Clinical Trial \(41\)](#)

[Costs/Narrow \(5\)](#)

Diagnosis/Narrow (0)

[Economics/Narrow \(3\)](#)

[Etiology/Narrow \(12\)](#)

Japanese (0)

Korean (0)

[Meta-analysis \(9\)](#)

[Practice Guideline \(7\)](#)

[Prognosis/Narrow \(13\)](#)

[Published in the last 5 years \(77\)](#)

[Randomized Controlled Trial \(41\)](#)

[Systematic Reviews \(37\)](#)

[Therapy/Narrow \(43\)](#)

根據臨床問題類型篩選

『治療型問題』

『診斷型問題』

『預後型問題』

『病因型問題』

同時注意含有經濟效益分析之文章

『Costs/Narrow』

『Economics/Narrow』

找出可能含亞洲族群文章納入考慮

『Chinese』

Secondary Database

Primary Database



輸入『P』、『I』及適當同義詞，並搭配各資料庫限定或filter之功能

2 results

0 results

選擇『Systematic Review』之文章

2 results

6 results

0 results

選擇『5年內』之文章

1 results

4 results

7 results

0 results

選擇『符合臨床問題』之文章

1 results



2 results

1 results

0 results



# 各資料庫收納結果

來源	標題	年份
 Cochrane Library	Vaccines for preventing rotavirus diarrhoea: vaccines in use (Review) [2012]	2012
Embase <sup>®</sup>	Rotavirus vaccine effectiveness in Latin American and Caribbean countries: A systematic review and meta-analysis[2015]	2015
	A Systematic Review of the Effect of Rotavirus Vaccination on Diarrhea Outcomes Among Children Younger Than 5 Years[2016]	2016
 PubMed	2008 estimate of worldwide rotavirus-associated mortality in children younger than 5 years before the introduction of universal rotavirus vaccination programmes: a systematic review and meta-analysis[2012]	2012

# 比較收納文獻-選出最佳文獻，並提出我們的理由









## Vaccines for preventing rotavirus diarrhoea: vaccines in use (Review) [2012]

M	Systematic review	●
P	Children aged less than one year Children aged up to two years (without Asian)	●
I	Rotavirus vaccination	●
C	Placebo	●
O	Severe rotavirus diarrhea incidence rate Mortality rate	●
T	2month-2years	●

# 比較收納文獻-選出最佳文獻，並提出我們的理由

Embase<sup>®</sup>







## Rotavirus vaccine effectiveness in Latin American and Caribbean countries: A systematic review and meta-analysis[2015]

M	Systematic review and meta-analysis	
P	Latin American and Caribbean countries child (age > 6 months)	
I	Rotavirus vaccine (single or combined)	
C	Placebo	
O	Vesikari score	
T	Follow up at least 1 years	

# 比較收納文獻-選出最佳文獻，並提出我們的理由

Embase®

## A Systematic Review of the Effect of Rotavirus Vaccination on Diarrhea Outcomes Among Children Younger Than 5 Years[2016]

M	Systematic review	
P	Global children younger than 5 years (East Asia Group)	
I	Single or combined Rotavirus vaccine (RV1, RV5)	
C	Placebo	
O	Sever diarrhea, hospitalization, mortality Vesikari score of $\geq 11$ on a 20-point scale	
T	Follow up duration at least 2 years	

# 比較收納文獻-選出最佳文獻，並提出我們的理由



## 2008 estimate of worldwide rotavirus-associated mortality in children younger than 5 years before the introduction of universal rotavirus vaccination programmes: a systematic review and meta-analysis[2012]

M	Systematic review and meta-analysis	
P	Children younger than 5 years	
I	Vaccination	
C	Placebo	
O	Rotavirus-associated mortality	
T	1 year	

# 收納文獻比較總整理-選出最佳文獻

收 納 文 章	M	P	I	C	O	T
Vaccines for preventing rotavirus diarrhoea: vaccines in use (Review) [2012]	●	●	●	●	●	●
Rotavirus vaccine effectiveness in Latin American and Caribbean countries: A systematic review and meta-analysis[2015]	●	●	●	●	●	●
<del>A Systematic Review of the Effect of Rotavirus Vaccination on Diarrhea Outcomes Among Children Younger Than 5 Years[2016]</del>	●	●	●	●	●	●
2008 estimate of worldwide rotavirus-associated mortality in children younger than 5 years before the introduction of universal rotavirus vaccination programmes: a systematic review and meta-analysis[2012]	●	●	●	●	●	●

# 嚴格評讀之文章及評讀工具

VACCINE REPORTS

- ✓ 最佳的研究設計
- ✓ 較新的發表年份
- ✓ 含有『台灣』資料
- ✓ 最符合臨床情境

## A Systematic Review of the Effect of Rotavirus vaccination on Diarrhea Outcomes Among Children Younger Than 5 Years

*Laura M. Lamberti, PhD, MHS, Sania Ashraf, MPH, Christa L. Fischer Walker, PhD, MHS, and Robert E. Black, MD, MPH*

**Background:** Rotavirus is the leading cause of vaccine-preventable diarrhea among children under 5 globally. Rotavirus vaccination has been

World Health Organization recommends the inclusion of rotavirus vaccination in all national immunization programs.<sup>6</sup> There are 2 licensed oral live attenuated rotavirus vaccines currently avail-

**CASP** [31.05.13]

**Systematic Review Checklist**





# Validity

**1. Did the review address a clearly focused question ?  
此回顧是否問了一個清楚、明確的臨床問題？**



# 評讀結果

**Background:** Rotavirus is the leading cause of vaccine-preventable diarrhea among children under 5 globally. Rotavirus vaccination has been shown to prevent severe rotavirus infections with varying efficacy and effectiveness by region.

**Methods:** We sought to generate updated region-specific estimates of rotavirus vaccine efficacy and effectiveness. We systematically reviewed published vaccine efficacy and effectiveness studies to assess the region-specific effect of rotavirus vaccination on select diarrheal morbidity and mortality outcomes in children under 5 years of age. We employed meta-analytic methods to generate pooled effect sizes by Millennium Development Goal region.

**Results:** Rotavirus vaccination was both efficacious and effective in preventing rotavirus diarrhea, severe rotavirus diarrhea and rotavirus hospitalizations among children under 5 across all regions represented by the 48 included studies. Efficacy against severe rotavirus diarrhea ranged from 90.6% [95% confidence interval (CI): 82.3–95.0] in the developed region to 88.4% (95% CI: 67.1–95.9) in Eastern/Southeastern Asia, 79.6% (95% CI: 71.3–85.5) in Latin America and the Caribbean, 50.0% (95% CI: 34.4–61.9) in Southern Asia and 46.1% (95% CI: 29.1–59.1) in sub-Saharan Africa. Region-specific effectiveness followed a similar pattern. There was also evidence of vaccine efficacy against severe diarrhea and diarrheal hospitalizations.

**Conclusion:** Our findings confirm the protective efficacy and effectiveness of rotavirus vaccination against rotavirus diarrheal outcomes among children under 5 globally.

**Key Words:** rotavirus, vaccine, children, global

(*Pediatr Infect Dis J* 2016;35:992–998)

P

Children under 5 years of age  
(first dose at 6-14 weeks)

I

Rotavirus vaccination  
(RV1, RV5)

C

Placebo

O

Diarrhea  
Sever rotavirus diarrhea  
Rotavirus hospitalization

T

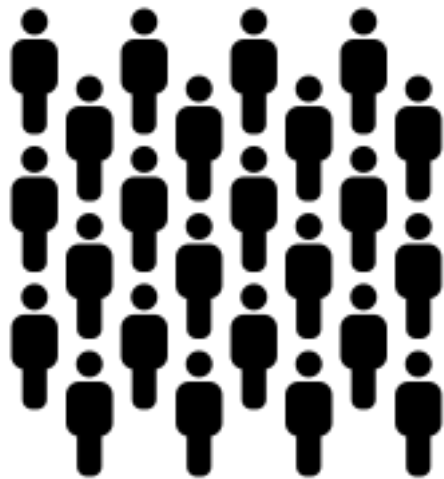
>2 years

作者清楚地說明了PICOT，因此評讀結果為Yes。

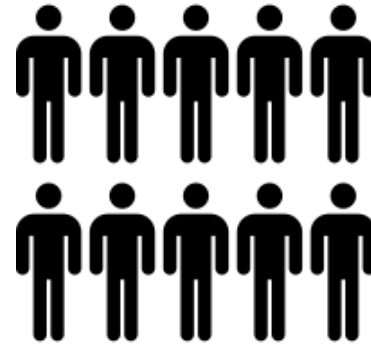
Yes

No

Unclear



RCT



Validity

2. Did the authors look for the right type of papers?  
作者是否收納適當的研究類型？

# 評讀結果

## Inclusion and Exclusion Criteria

Two independent reviewers screened titles and subsequently reviewed abstracts for inclusion and exclusion criteria. All randomized controlled trials (RCTs) and observational studies reporting outcomes related to rotavirus diarrhea or diarrhea of unspecified etiology in children <5 years of age were eligible for inclusion. Outcomes of interest included episodes of any severity, severe episodes as indicated by a Vesikari score of  $\geq 11$  on a 20-point scale or a Clark score of  $>16$  on a 24-point scale,<sup>23,24</sup> hospitalizations and deaths.

We excluded review articles, phase I and II trials, cost-effectiveness studies and editorials. We excluded efficacy trials that failed to report separate effect sizes for the intention-to-treat and per-protocol populations and observational studies only reporting the effectiveness of partial vaccine doses. We did not exclude studies on the basis of age at vaccination. Data from studies that solely focused on specific subpopulations, such as HIV-infected children, in which immune responses are likely to differ from those of the general population, were excluded to ensure the generalizability of the pooled estimates. For analytical purposes, we also excluded studies that did not report the inputs required for meta-analysis (eg, effect size and 95% CI) and did not provide sufficient raw data from which the required inputs could be calculated.

## Data Abstraction

We categorized the included studies by study design and MDG region<sup>25</sup>; we combined data from Southeastern Asia and Eastern Asia but excluded studies that pooled outcomes across other MDG regions. For each outcome, we abstracted published effect sizes and 95% CIs for vaccine efficacy, vaccine effective-

## 優點

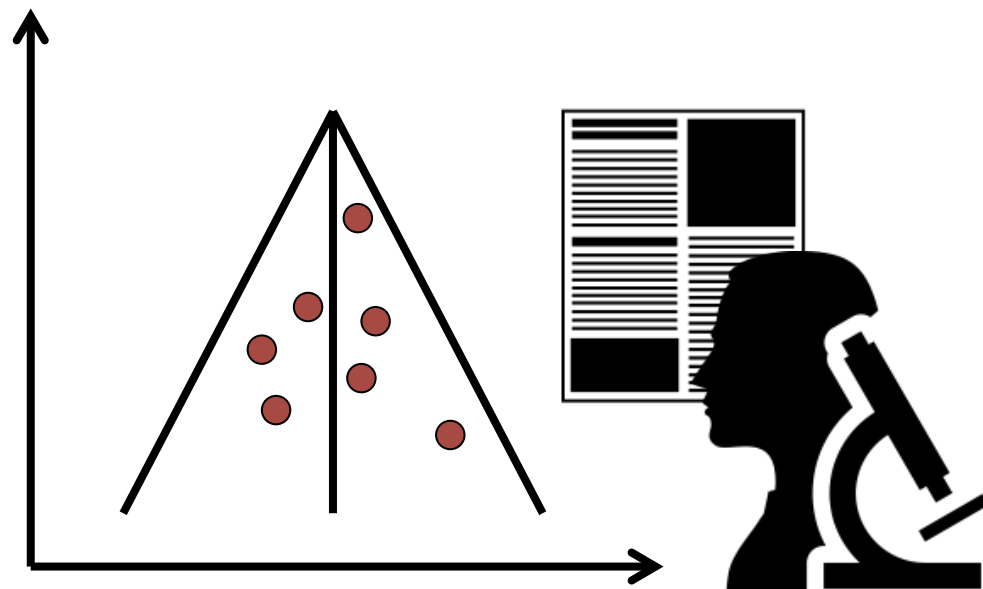
1. 收錄符合問題的**RCT與觀察性文章**
2. 清楚定義了**納入條件**
3. 清楚定義了**排除條件**
4. 納入的**RCT**，皆使用**雙盲及placebo capsule**
5. **RCT文章與觀察性文章分開統計**

## 缺點

Yes

No

Unclear

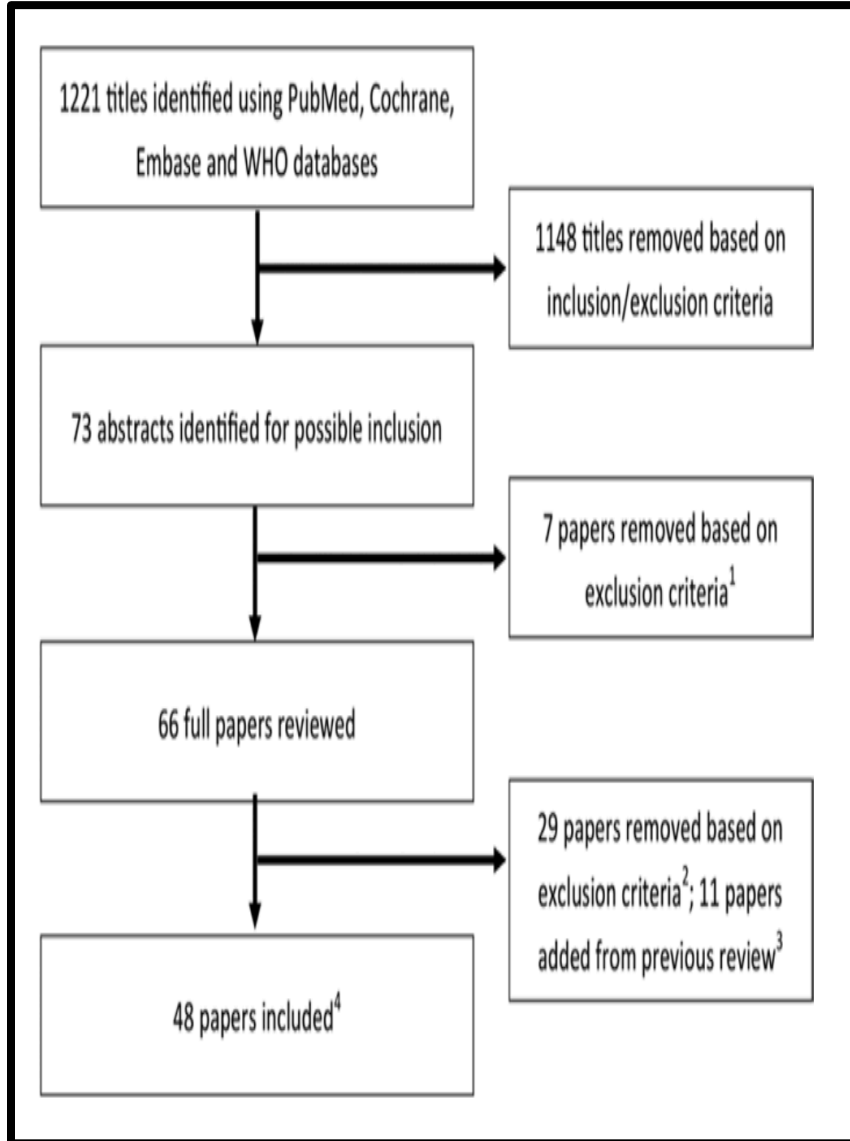


# Validity

3. Do you think the important, relevant studies were included?

**重要、相關的研究是否皆被納入？**

# 評讀結果



## 優點

1. 作者盡可能搜尋了各種一級和二級資料庫
2. 作者更進一步取得尚未發表的文章
3. 列出flow chart清楚說明納入、排除理由
4. 包含亞洲(台灣)資料

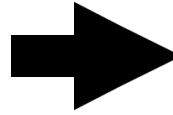
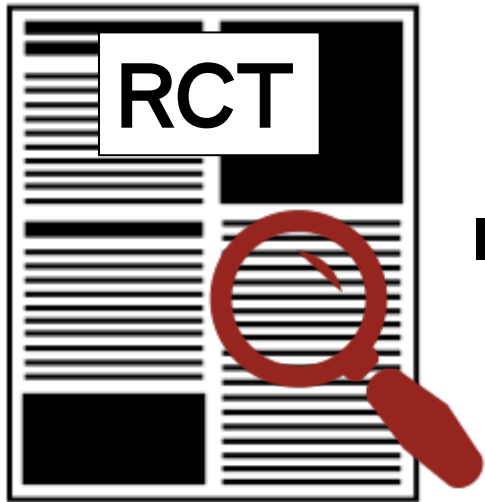
## 缺點

1. 語言限制與否並無說明
2. 沒有漏斗圖

Yes

No

Unclear



-	-	-	?	?
-	?	-	-	?
+	+	+	+	+
?	?	+	?	?
?	?	?	?	?
?	?	-	?	?
-	?	+	?	?

# Validity

4. Did the review's authors do enough to assess the quality of the included studies?

作者是否有評估收納研究的品質？

# 評讀結果

## Data Analysis

From the abstracted estimates of vaccine efficacy and effectiveness, we calculated relative risk (RR) and odds ratios (OR) and used random effects meta-analysis to generate inverse-variance-weighted pooled estimates across studies. We subsequently converted the pooled effect sizes into vaccine efficacy [ $100\% \times (1 - RR)$ ] and vaccine effectiveness [ $100\% \times (1 - OR)$ ]. For observational studies reporting percent reduction, we combined estimates across studies by fitting logistic regression models weighted by inverse variance. All statistical analyses were conducted using Stata 12.0 statistical software.<sup>26</sup> We conducted Q-tests to assess heterogeneity across studies.

We assessed the quality of evidence for each pooled outcome using the standards for *Child Health Epidemiology Reference Group* reviews of child survival interventions.<sup>28</sup> Applying these guidelines, we graded the evidence for each effect estimate on a 4-point scale (ie, high, moderate, low, very low) based on an evaluation of the design, limitations, consistency and generalizability of contributing studies. RCTs were automatically granted a score of “high” and downgraded for lack of consistency or major limitations, including failure to blind or conceal allocation. Observational studies were given a score of low and upgraded to moderate if effect sizes were consistent across all studies and regions.

## 優點

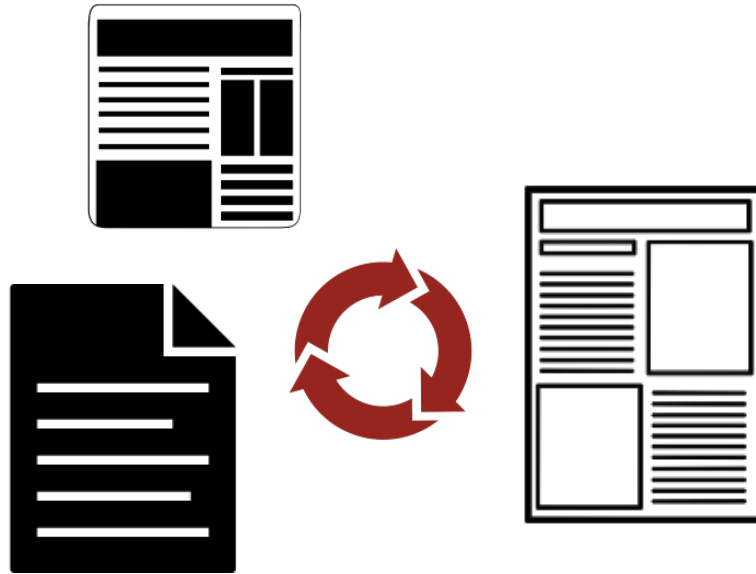
1. 由兩位作者獨立評讀
2. 使用standards for Child Health Epidemiology Reference Group reviews of child survival interventions作為guideline將文章評等
3. 評級依研究設計、限制、一致性判斷貢獻度

## 缺點

Yes

No

Unclear



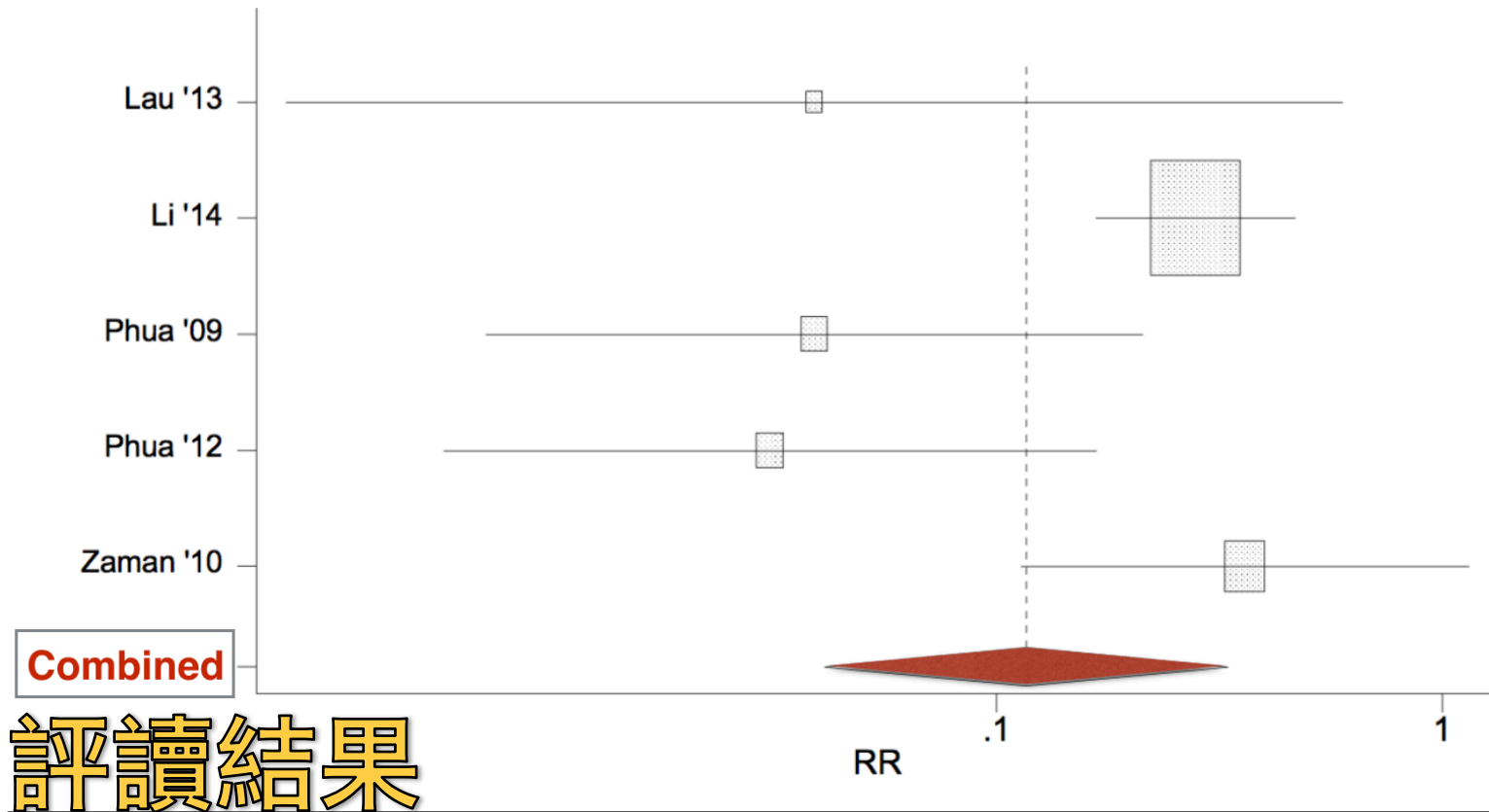
# Validity

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

作者是否有把各個研究的結果合併起來？  
這樣的合併是合理的嗎？



# 主要結果-嚴重腹瀉



## 評讀結果

異源性(Heterogeneity): 共五篇RCT. Random effect

Q=12.216 , P=0.016 , study variance: 0.843

高異質性

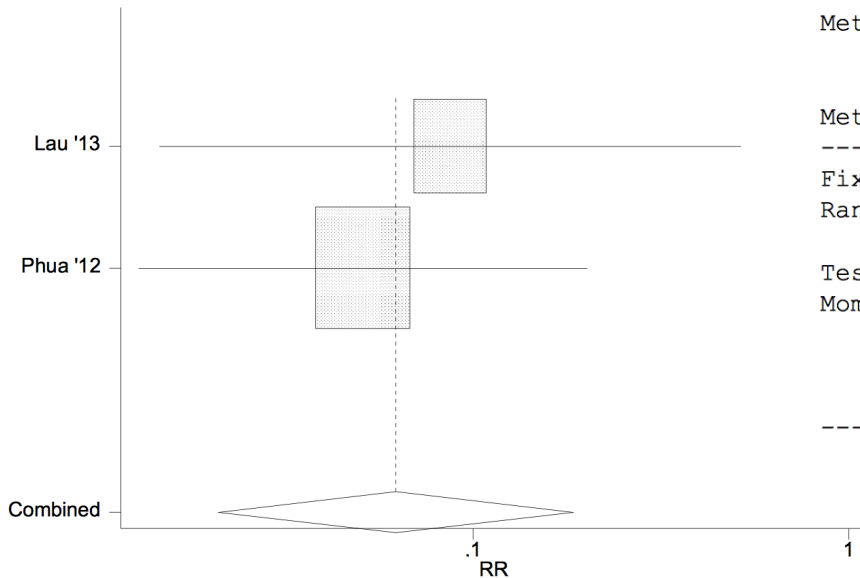
Yes

No

Unclear

# 次要結果-住院率

Supplemental Figure 11: Rotavirus Hospitalizations: Vaccine Efficacy, East Asia/ SE Asia



Meta-analysis (exponential form)

Method	Pooled Est	95% CI		Asymptotic		No. of studies
		Lower	Upper	z_value	p_value	
Fixed	0.062	0.021	0.185	-5.003	0.000	2
Random	0.062	0.021	0.185	-5.003	0.000	

Test for heterogeneity:  $Q = 0.216$  on 1 degrees of freedom ( $p = 0.642$ )  
 Moment-based estimate of between studies variance = 0.000

Study	Weights		Study Est	95% CI	
	Fixed	Random		Lower	Upper
Lau '13	1.21	1.21	0.09	0.01	0.52
Phua '12	2.04	2.04	0.05	0.01	0.20

## 評讀結果

異源性(Heterogeneity): 共二篇RCT，Bi-model

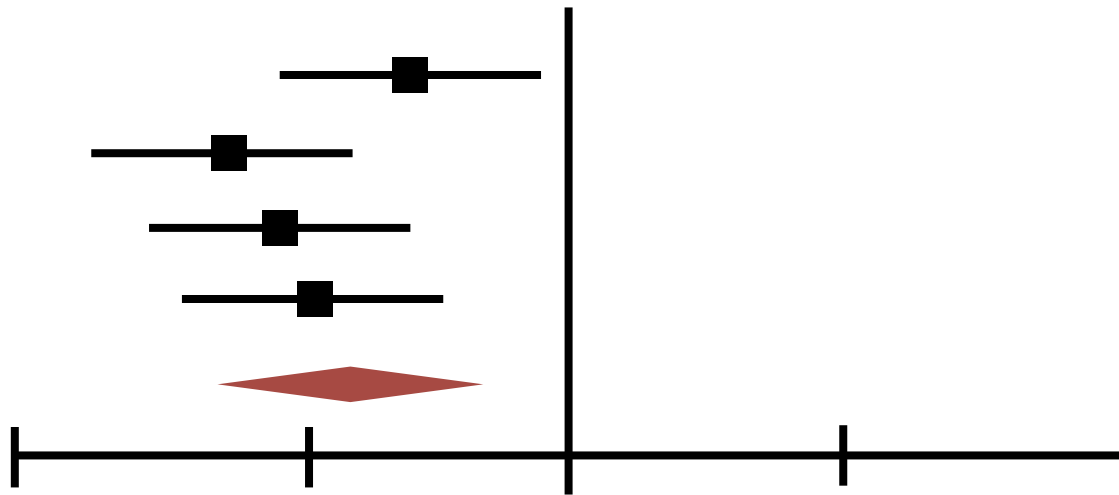
$Q = 0.216$ ， $P = 0.642$ ，studies variance: 0.000

**低異質性**

Yes

No

Unclear

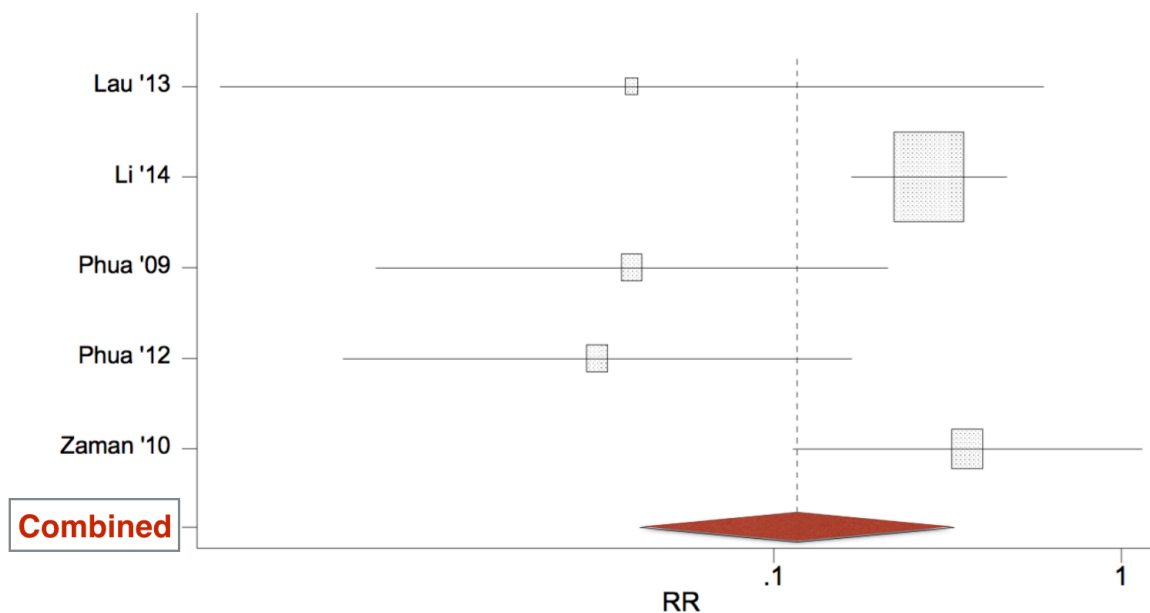


Importance

6. What are the overall results of the review?

這篇回顧呈現了什麼結果？

# 主要結果-嚴重腹瀉



## 評讀結果

Intervention

Rotavirus vaccine (RV1, RV5)

Comparison

Placebo

Time

>2 years

研究結果

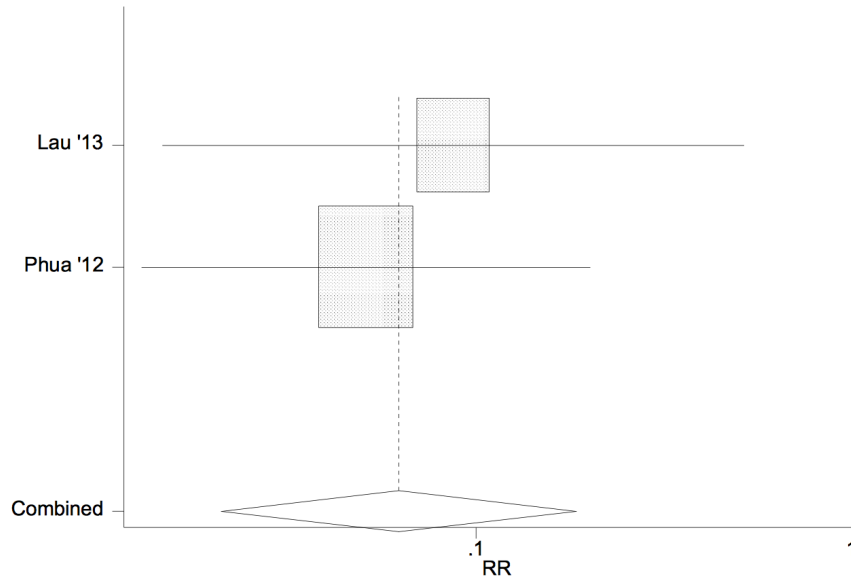
RR=0.116 [0.041, 0.329](95%CI)

結論

輪狀病毒的疫苗，確實能夠有效降低嚴重腹瀉的情況，且亞洲地區的研究呈現相同結果

# 次要結果-住院率

Supplemental Figure 11: Rotavirus Hospitalizations: Vaccine Efficacy, East Asia/ SE Asia



## 評讀結果

Intervention

Rotavirus vaccine (RV1, RV5)

Comparison

Placebo

Time

>2 years

研究結果

RR=0.062[0.021,0.185](95%CI)

結論

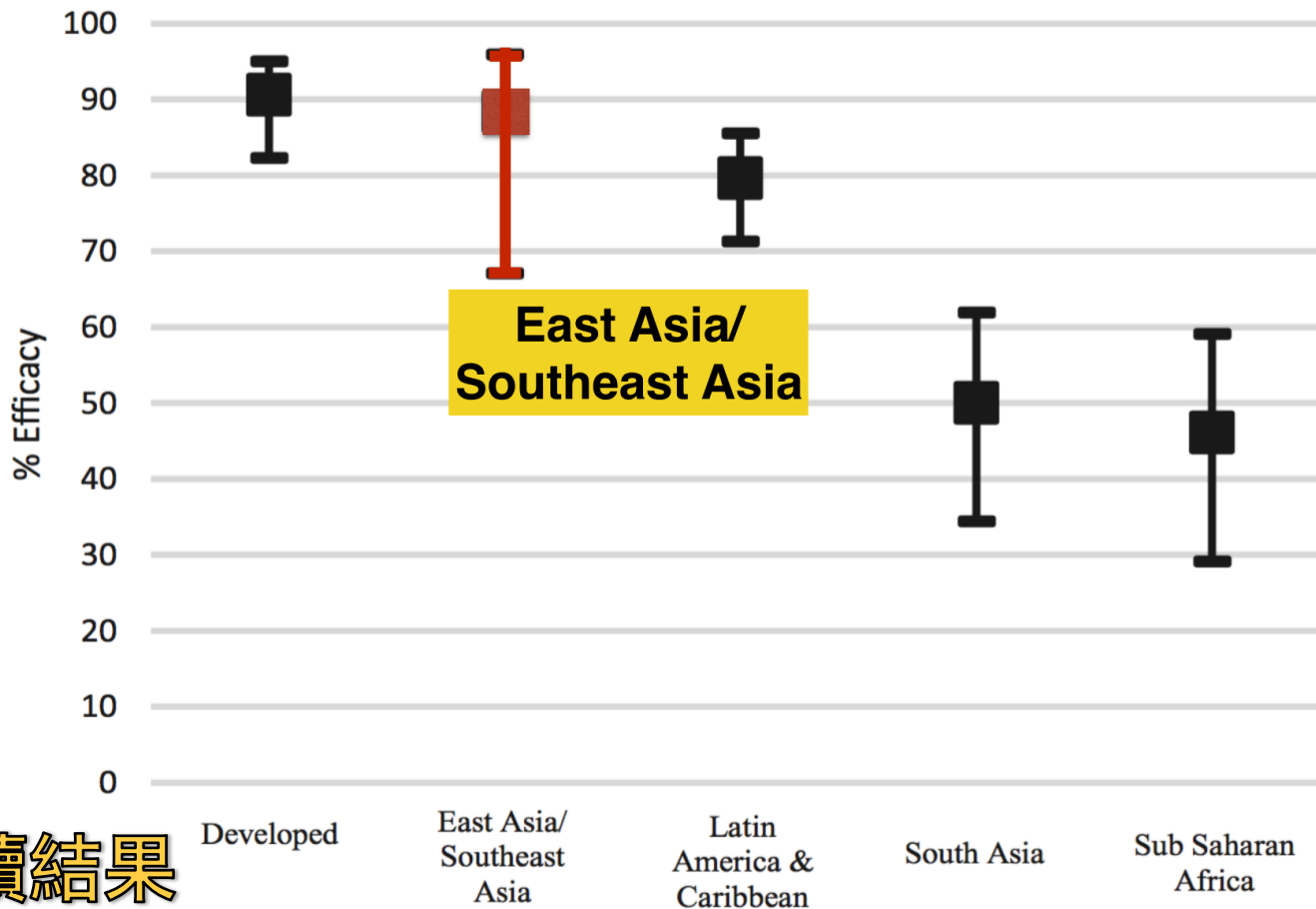
輪狀病毒疫苗確實能夠降低住院率，且成效卓著



# Importance

7. How precise are the results?

結果精準嗎？



## 評讀結果

1. 納入之病人有相似的年齡 < 5y/o (在 6-14 周接受第一劑)、亞洲種族等
2. 收錄之 RCT 有相似之研究結果
3. 結果之 95% 信賴區間窄 [61.7, 95.9] (95%)

Yes

No

Unclear

# 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)
<b>How common is the problem?</b>	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
<b>Is this diagnostic or monitoring test accurate?</b> (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
<b>What will happen if we do not add a therapy?</b> (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
<b>Does this intervention help?</b> (Treatment Benefits)	Systematic review of randomized trials or <i>n</i> -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
<b>What are the COMMON harms?</b> (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, <i>n</i> -of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided	Case-series, case-control, or historically controlled	Mechanism-based reasoning
<b>What are the RARE harms?</b> (Treatment Harms)	Systematic review of randomized trials or <i>n</i> -of-1 trial	Randomized trial or (exceptionally) observational study			
<b>Is this (early detection) test worthwhile?</b> (Screening)	Systematic review of randomized trials	Randomized trial			



**【預後型問題】**  
**RCT之系統性回顧文章**  
**證據等級為 Level 1**  
**※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
- 絕對效果小
- PICO和臨床情境不相符
- 證據間沒有一致性
- 研究不精確(95%CI過大)



## 臨床問題：輪狀病毒疫苗的效果如何？

輪狀病毒預防的效果		『主要』結果	『次要』結果
		嚴重輪狀病毒腹瀉	住院率
		RR:0.116(95%CI) [0.041,0.329]	RR:0.062(95%CI) [0.021,0.185]
研究設計		RCT	RCT
降 階	1. 存在誤差風險	●	●
	2. 結果不一致	●	●
	3. 證據不具直接性	●	●
	4. 結果不精準	●	●
	5. 存在發表誤差	●	●
升 階	1. 效果顯著		
	2. 降低干擾因素		
	3. 具劑量-反應效果		
<b>證據等級</b>		 HIGH	 LOW



# Practice

**8. Can the results be applied to the local population?  
此研究是否可應用到你的病患？**

# 評估適用性-比較評讀文獻及臨床情境

	評讀文獻	臨床情境
P	<5 y/o兒童(第一劑在6-14週施打) 東亞, 東南亞地區已開發國家	2m/o女嬰、台灣人
I	輪狀病毒疫苗(混合RV1, RV5)	輪狀病毒疫苗(混合RV1, RV5)
C	安慰劑	安慰劑
O	嚴重輪狀病毒腹瀉、住院率	嚴重輪狀病毒腹瀉、住院率

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

Yes

No

Unclear



# Practice

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

# 效益分析-病患能從此介入獲得之好處

## 次要結果: 請輸入次要結果

研究  
(人數)

RR

Efficacy

5項  
(20536人)

0.116  
[0.041, 0.329]

88.4%  
[67.1, 95.9]

此文獻提供了臨床問題的重要Outcome，並可進而推算NNT

Main outcome

1. 嚴重腹瀉

Minor outcome

1. 住院率

Yes

No

Unclear



# Practice

**10. 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？**

# 成本效益-藥價、藥效

藥物	優點	缺點(副作用)	健保單價
RotaTeq(輪達停)	<ul style="list-style-type: none"><li>• 3次</li><li>• 抗病毒假數較多(4個)</li></ul>	<ul style="list-style-type: none"><li>• 服用次數較多</li><li>• 費用較高</li></ul>	NT. 5325元 (3劑)
Rotarix(羅特律)	<ul style="list-style-type: none"><li>• 病毒保護力較多(G1-4, G9)</li></ul>	<ul style="list-style-type: none"><li>• 副作用相同</li></ul>	NT. 4250元 (2劑)

Reference:



衛生福利部中央健康保險署

NATIONAL HEALTH INSURANCE ADMINISTRATION, MINISTRY OF HEALTH AND WELFARE

# 成本效益-有形、無形支出

品項	有形支出	無形支出	次數	一年總數
母親請假	每月基本工資 20,008元 基本工時120元	減少休息時間	1/月	11,520元 (960*12)
來回醫院交通費	300	舟車勞頓	1/月	3600元
掛號費	450	感染風險	1/月	5400元

Reference:



衛生福利部中央健康保險署

NATIONAL HEALTH INSURANCE ADMINISTRATION, MINISTRY OF HEALTH AND WELFARE



# 其他選擇-對醫療品質的影響

選擇	好處	壞處	證據等級
個人衛生保健 勤洗手	<ul style="list-style-type: none"><li>• 同時預防多種傳染疾病</li><li>• 便宜簡便</li></ul>	<ul style="list-style-type: none"><li>• 缺乏專一性預防效果</li></ul>	LEVEL 3
腸道益生菌	<ul style="list-style-type: none"><li>• 預防部分腸胃道傳染疾病</li></ul>	<ul style="list-style-type: none"><li>• 需花費資金</li><li>• 無確定療效</li></ul>	LEVEL 3

# 共享決策-Share Decision Making

## 醫療現況(實證醫學)

- 證據等級:GRADE (High)  
CEBM (level 1)
- 建議等級:強烈建議輪狀病毒預防嚴重腹瀉及因病住院，效益卓著



## 病人治療的偏好

- 希望可以藉由輪狀病毒疫苗達到增強免疫力的效果，且花費不需要太大
- 希望不要讓小朋友產生副作用



## 利弊平衡

- 使用輪狀病毒疫苗預防嚴重腹瀉以及住院，效果非常顯著，可達到88.4%的有效性
- 除了局部注射位置紅腫、局部感染外，亦有案例報導腸套疊



## 費用資源

- 輪狀病毒疫苗的注射，總共需要注射兩劑到三劑，費用約4000-5000\$，但可顯著預防輪狀病毒的腹瀉及住院率，一旦發生嚴重腹瀉，耗費的人力照顧成本及醫療成本將遠大於預防



# 臨床應用-回覆病人問題

林媽媽您好，經過我們團隊縝密的實證搜尋後，目前現有最佳證據是由**系統性回顧文章**支持，輪狀病毒疫苗的使用可**有效降低腹瀉及住院率**，且總花費**\$4000-\$5000**，因您的小朋友屬於輪狀病毒感染的危險族群，**強烈建議**您的小孩接受兩劑或三劑的輪狀病毒疫苗。

另外平常仍需**注意個人衛生保健、勤洗手**，這樣才能達到有效預防的效果



**感謝各位評審聆聽！**