



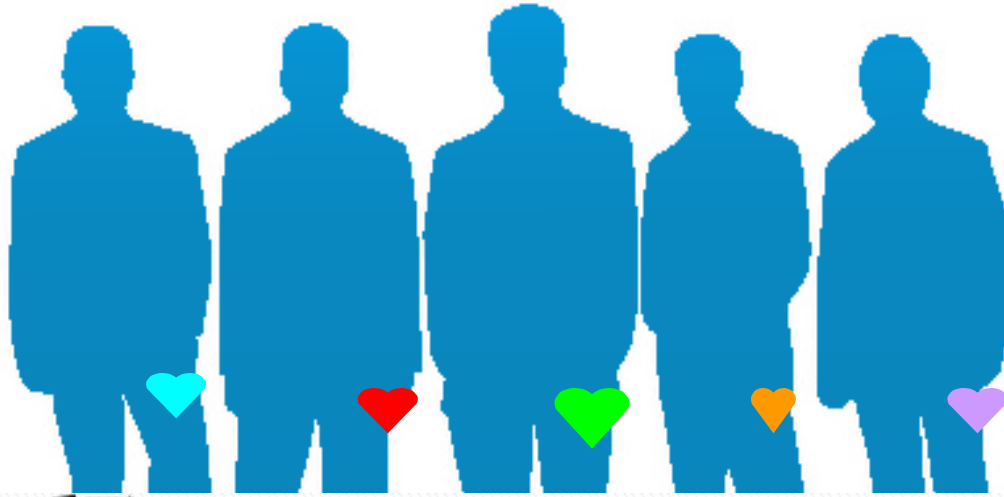
Evidence-Based Medicine

Date : 2016/09/26

Presented By : R1 張皓智

Supervisor : 唐守宏 醫師





實證是守護病患健康最好的工具





從問題到行動

▶ 從臨床問題 (clinical problem) 到行動 (action) 的六步驟

(Evid Based Med. 2003; 8: 165-6.)



內在證據 = 專業訓練與經驗知識

外在證據 = 教科書、期刊、資料庫、專家資訊

評讀 = 有根據的 (valid)、重要的 (important) 且適用的 (applicable)





臨床場景 *Clinical Scenario*

林媽媽有兩個小孩，大兒子將要上小學，常常感冒拉肚子，她很怕剛出生不久兩個多月大的女兒也會出狀況。最近聽說有一種輪狀病毒疫苗，可以增強免疫力。他想知道值不值得打這個疫苗，又有一點擔心副作用。另外大兒子趁著就讀小學前跟爸爸去大陸旅遊，最近的新聞報導指出今年大陸正在發生腸病毒71型的大流行。因此考慮是否到大陸當地立刻至醫院施打「腸病毒71型疫苗」？打了之後又可以提供甚麼樣的保護效果？





臨床問題1

Asking 提出可以回答的臨床問題



Key Word



Synonym 1



Synonym 2

P

Rotavirus diarrhea

Viral gastroenteritis

I

Rotavirus vaccine

Rotavirrus diarrhea prevention

C

Placebo

O

Efficacy

Effect



這是一個



預防型

診斷型

預後型

全傷害型總問題

全人照護

Wholehearted, Holistic Care



臨床問題2

Asking 提出可以回答的臨床問題



Key Word



Synonym 1



Synonym 2

P

Enterovirus infection

I

Enterovirus vaccine

C

Placebo

O

Efficacy

Effect



這是一個



預防型

診斷型

預後型

全傷害型問題

全人照護

Wholehearted, Holistic Care



背景資訊 *Background Knowledge*

- Rotaviruses were identified as important causes of viral gastroenteritis, particularly in children between the ages of **six months and two years**.
- Pathogenesis
 - loss of brush border enzymes
 - direct effect of the rotavirus enterotoxin NSP4
 - activation of the enteric nervous system





背景資訊 *Background Knowledge*

- Clinical manifestations
 - Vomiting
 - Nonbloody diarrhea
 - Fever
 - Dehydration
 - Seizures (2-3%)
 - Laboratory findings
 - Dehydration with elevated blood urea nitrogen
 - Hyperchloremic metabolic acidosis
 - Hypocalcemia
 - Mild elevations in the serum aspartase aminotransferase (AST)
 - One-third stool routine => Minimal to moderate numbers of fecal leukocytes





背景資訊 *Background Knowledge*

- Diagnosis
 - enzyme-linked immunosorbent assay (ELISA)
 - latex agglutination testing
 - polymerase chain reaction (PCR)
- Treatment
 - Fluid repletion and maintenance
 - Diet
 - Resumption of an age-appropriate diet as soon as rehydration
 - Breastfeeding can continue during diarrhea
 - Antidiarrheal agents
 - Not recommended
 - Antiemetic agents
 - Not to used





背景資訊 *Background Knowledge*

- Vaccine
 - Indication
 - Universal immunization of infants against rotavirus was recommended
 - Contraindication
 - Severe (anaphylactic) allergic reaction after a previous dose
 - RV1 => severe allergy(anaphylactic) to latex
 - Severe combined immunodeficiency (SCID)
 - With a history of intussusception
 - Planned or status-post hematopoietic stem cell transplant
 - Status-post solid organ transplant
 - Planned or current receipt of cancer chemotherapy
 - Adverse events
 - Intussusception (1/20,000~100,000)
 - Kawasaki disease (unclear)





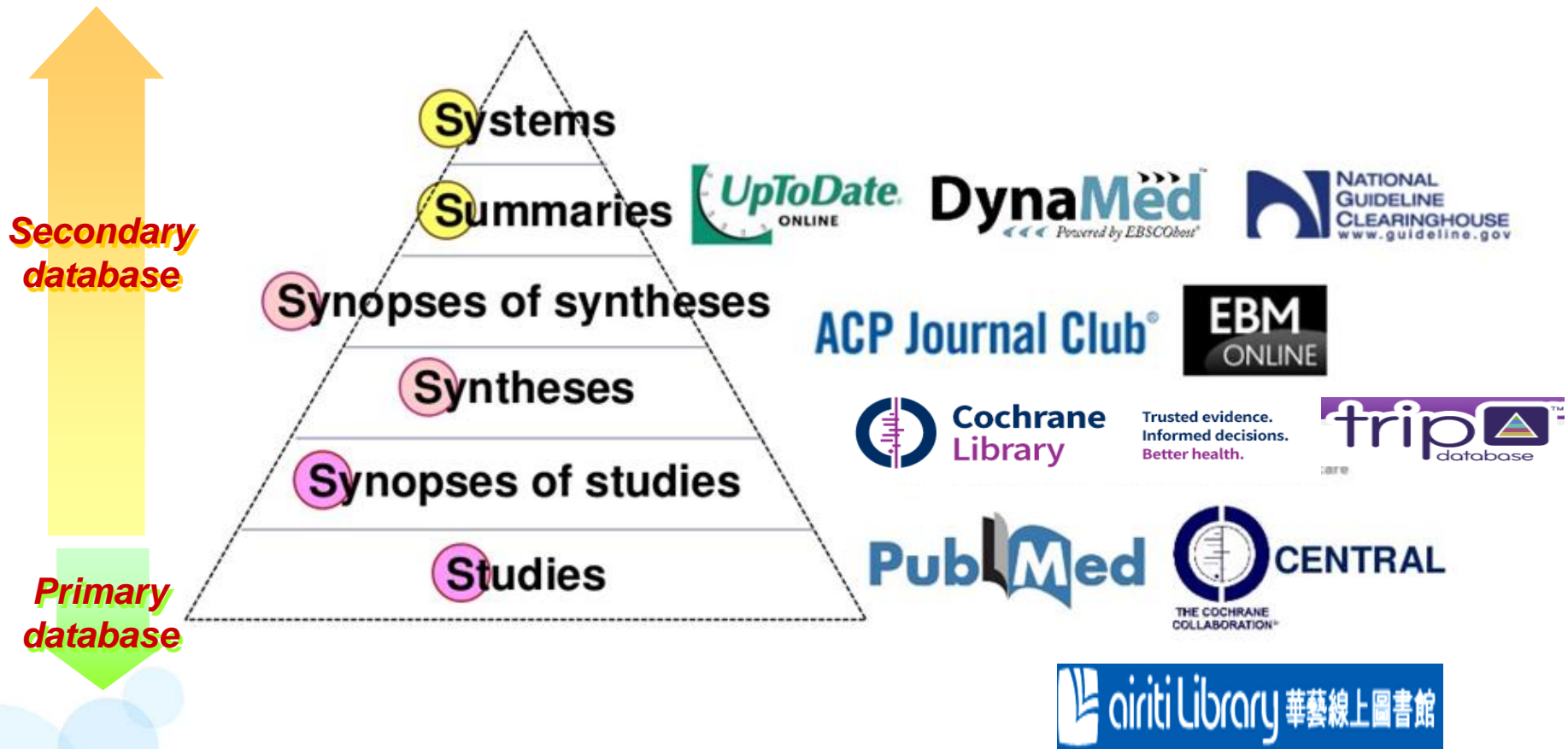
背景資訊 *Background Knowledge*

Comparison of rotavirus vaccines licensed in the United States

	Pentavalent human-bovine reassortant vaccine (PRV, RV5)	Attenuated human rotavirus vaccine (HRV, RV1)
Trade name	RotaTeq	Rotarix
Serotypes contained	G1, G2, G3, G4, P1[8]	G1P[8]
Dose	2 mL	1 mL
Administration	Ready-to-use	Requires reconstitution
Number of doses	3	2
Recommended schedule	2, 4, 6 months	2, 4 months
Minimum age first dose	6 weeks	6 weeks
Maximum age first dose		
United States	14 weeks, 6 days	14 weeks, 6 days
Europe	12 weeks	12 weeks
Minimal interval between doses	4 weeks	4 weeks
Maximum age last dose		
United States	8 months, 0 days	8 months, 0 days
Europe	24 weeks	24 weeks
Oral applicator	Latex-free	Contains latex*
Contains thimerosal	No	No



檢索策略 → 現今的最佳證據 (best available evidence)



⊕ Title, Abstract, Keywords

rotavirus vaccine, effect

Go

Save

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(Word variations have been searched)

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Clear

All Results (124)

Cochrane Reviews (2)

All

Review

Protocol

Other Reviews (2)

Trials (118)

Methods Studies (0)

Technology Assessments (0)

Economic Evaluations (2)

Cochrane Groups (0)

All

Current Issue

Me Methodology

Dx Diagnostic

Ov Overview

Pg Prognosis

Qu Qualitative

Cc Conclusions changed

Ns New search

Mc Major change

Up Update


Cochrane Database of Systematic Reviews : Issue 12 of 12, December 2016

Issue **updated daily** throughout month

There are **2** results from **9664** records for your search on 'rotavirus vaccine, effect in Title, Abstract, Keywords in Cochrane Reviews'

Sort by Relevance: high to low

[Select all](#) | [Export all](#) | [Export selected](#)

 **Vaccines for preventing rotavirus diarrhoea: vaccines in use**
 Karla Soares-Weiser , Harriet MacLehose , Hanna Bergman , Irit Ben-Aharon , Sukrti Nagpal , Elad Goldberg , Femi Pitan and Nigel Cunliffe
 Online Publication Date: November 2012

Ns **Review**

 **Rotavirus vaccine for preventing diarrhoea**
 Karla Soares-Weiser , Elad Goldberg , Ghandi Tamimi , Leonard Leibovici and Femi Pitan
 Online Publication Date: January 2004

Review

[Export selected](#)

Article types

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Review
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Text availability

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10 years
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Humans
Other Animals

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- [A Bayesian approach to estimating causal vaccine effects on binary post-infection outcomes.](#)
 1. Zhou J, Chu H, Hudgens MG, Halloran ME.
Stat Med. 2016 Jan 15;35(1):53-64. doi: 10.1002/sim.6573.
PMID: 26194767
[Similar articles](#)
 - [Association of serum anti-rotavirus immunoglobulin A antibody seropositivity and protection against severe rotavirus gastroenteritis: analysis of clinical trials of human rotavirus vaccine.](#)
 2. Cheuvar B, Neuzil KM, Steele AD, Cunliffe N, Madhi SA, Karkada N, Han HH, Vinals C.
Hum Vaccin Immunother. 2014;10(2):505-11. doi: 10.4161/hv.27097.
PMID: 24240068 **Free PMC Article**
[Similar articles](#)
 - [Lack of nonspecific protection against all-cause nonrotavirus gastroenteritis by vaccination with orally administered rotavirus vaccine.](#)
 3. Grant L, Watt J, Moulton L, Weatherholtz R, Reid R, Santosham M, O'Brien K.
J Pediatr Gastroenterol Nutr. 2013 Jun;56(6):635-40. doi: 10.1097/MPG.0b013e318287c5cc.
PMID: 23343932
[Similar articles](#)
 - [Vaccines for preventing rotavirus diarrhoea: vaccines in use.](#)
 4. Soares-Weiser K, Macle hose H, Bergman H, Ben-Aharon I, Nagpal S, Goldberg E, Pitan F, Cunliffe N.
Cochrane Database Syst Rev. 2012 Nov 14;11:CD008521. doi: 10.1002/14651858.CD008521.pub3. Review.
PMID: 23152260
[Similar articles](#)



5. [Malnutrition levels among vaccinated children between 2 and 3 years of age following enrollment in a randomized clinical trial with the pentavalent rotavirus vaccine \(PRV\) in Bangladesh.](#)

Feller AJ, Zaman K, Lewis KD, Hossain I, Yunus M, Sack DA.

Vaccine. 2012 Apr 27;30 Suppl 1:A101-5. doi: 10.1016/j.vaccine.2011.09.065.

PMID: 22520118

[Similar articles](#)

6. [Pentavalent rotavirus vaccine in developing countries: safety and health care resource utilization.](#)

- Christie CD, Duncan ND, Thame KA, Onorato MT, Smith HD, Malcolm LG, Itzler RF, Dinubile MJ, Heaton PM.

Pediatrics. 2010 Dec;126(6):e1499-506. doi: 10.1542/peds.2010-1240.

PMID: 21115586

[Similar articles](#)

7. [Effect of human rotavirus vaccine on severe diarrhea in African infants.](#)

- Madhi SA, Cunliffe NA, Steele D, Witte D, Kirsten M, Louw C, Ngwira B, Victor JC, Gillard PH, Cheuvart BB, Han HH, Neuzil KM.

N Engl J Med. 2010 Jan 28;362(4):289-98. doi: 10.1056/NEJMoa0904797.

PMID: 20107214 **Free Article**

[Similar articles](#)

8. [Live attenuated human rotavirus vaccine, RIX4414, provides clinical protection in infants against rotavirus strains with and without shared G and P genotypes: integrated analysis of randomized controlled trials.](#)

De Vos B, Han HH, Bouckenoghe A, Debrus S, Gillard P, Ward R, Cheuvart B.

Pediatr Infect Dis J. 2009 Apr;28(4):261-6. doi: 10.1097/INF.0b013e3181907177.

PMID: 19289978

[Similar articles](#)

9. [Efficacy of a pentavalent rotavirus vaccine in reducing rotavirus-associated health care utilization across three regions \(11 countries\).](#)

Vesikari T, Itzler R, Matson DO, Santosham M, Christie CD, Coia M, Cook JR, Koch G, Heaton P.

Int J Infect Dis. 2007 Nov;11 Suppl 2:S29-35. doi: 10.1016/S1201-9712(07)60019-8.

PMID: 18162243 **Free Article**

[Similar articles](#)



Hospital

[Rotavirus vaccine for preventing diarrhoea.](#)

12. Soares-Weiser K, Goldberg E, Tamimi G, Pitan OC, Leibovici L.
Cochrane Database Syst Rev. 2004;(1):CD002848. Review.
PMID: 14973994
[Similar articles](#)

[Efficacy of live, attenuated, human rotavirus vaccine 89-12 in infants: a randomised placebo-controlled trial.](#)

13. Bernstein DI, Sack DA, Rothstein E, Reisinger K, Smith VE, O'Sullivan D, Spriggs DR, Ward RL.
Lancet. 1999 Jul 24;354(9175):287-90.
PMID: 10440305
[Similar articles](#)

[Rotaviruses detected by reverse transcription polymerase chain reaction in acute gastroenteritis during a trial of rhesus-human reassortant rotavirus tetravalent vaccine: implications for vaccine efficacy analysis.](#)

14. Pang XL, Joensuu J, Hoshino Y, Kapikian AZ, Vesikari T.
J Clin Virol. 1999 Jun;13(1-2):9-16.
PMID: 10405887
[Similar articles](#)

[Concurrent oral poliovirus and rhesus-human reassortant rotavirus vaccination: effects on immune responses to both vaccines and on efficacy of rotavirus vaccines. The US Rotavirus Vaccine Efficacy Group.](#)

15. Rennels MB, Ward RL, Mack ME, Zito ET.
J Infect Dis. 1996 Feb;173(2):306-13. Erratum in: J Infect Dis 1996 Jun;173(6):1529.
PMID: 8568290 **Free Article**
[Similar articles](#)



期刊文章 11 會議論文 0 碩博士論文 25 電子書 0

中文文獻檢索關鍵字—輪狀病毒，疫苗，作用效果

依下方條件來精確結果

查詢 (輪狀病毒，疫苗，效果作用) 所有欄位

來源資料庫

CEPS中文電子期刊 (1)
CJTD中國大陸期刊 (10)

學科分類

醫學與生命科學 (11)

年代

2014年以後 (4)
2012年以後 (5)
2011 (1)

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出版品名稱

篇名.關鍵字.摘要 作者 刊名 起始年 結束年

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- 1 **輪狀病毒血清抗体与保护作用关系的研究进展**
刘悦越 ; 国泰 ; 祁自柏 ; 中国药品生物制品检定所疫苗二室 ;
中国生物制品学杂志 2008年 08期 (2008/07) , 732-734
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2 **轮状病毒血清抗体与保护作用关系的研究进展**
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中國生物制品學雜誌 21卷8期 (2008/08) , 732-734
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3 **轮状病毒疫苗在发展中国家面临的挑战**
马涛 ; 430060,武汉生物制品研究所有限责任公司**轮状病毒疫苗**课题组 ; MA Tao
国际生物制品学杂志 2013年 04期 (2013/07) , 190-194
轮状病毒疫苗 ; 佐剂,免疫 ; 接种 ; 母传抗体 ; 综述 ; Rotavirus vaccines ; Adjuvants,immunologic ; Vaccination ; Maternal antibody ; Reviews
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4 **口服轮状病毒疫苗及卫生宣教预防小儿秋季腹泻的效果分析**
王爱梅 ; 李敏 ; 赵淑娟 ; 浙江省桐乡市濮院镇中心卫生院,314500 ;
黑龙江医药 2011年 03期 (2011/07) , 473-474
轮状病毒疫苗 ; 卫生宣教 ; 小儿秋季腹泻效果 ;
預覽摘要 [加入追蹤](#) [全文下載](#)

5 **国产轮状病毒疫苗接种效果评价的病例对照研究**
刘娜 ; 中国疾病预防控制中心**病毒病**预防控制所 ; 刘娜 ; 段招军 ; 中国疾病预防控制中心**病毒病**预防控制所,北京,100052 ; Liu Na ; Duan Zhaojun
中华实验和临床病毒学杂志 2015年 03期 (2015/08) , 256-258
轮状病毒疫苗 ; **轮状病毒属** ; 接种 ; **病毒病**诊断与治疗 ; Rotavirus vaccines ; Rotavirus ; Vaccination ; Diagnosis and treatment of viral diseases
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6 **轮状病毒疫苗预防轮状病毒性肠炎效果观察**
李泸莎 ; 周静 ; 王俊芝 ; 谢晓娅 ; 成都铁路局中心医院儿科,成都,610081 ;
微生物学免疫学进展 2004年 02期 (2004/07) , 20-21
轮状病毒 ; **疫苗** ; 预防 ; 肠炎 ;
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7 **口服轮状病毒活疫苗预防轮状病毒肠炎的临床效果观察**

钟秋兰 ; 东莞市横沥医院 ; 东莞市横沥医院,广东 东莞,523460 ;

现代诊断与治疗 2015年 09期 (2015/08) , 2090-2091

口服 ; 轮状病毒 ; 活疫苗 ; 预防 ; 轮状病毒肠炎 ; 临床效果 ; 经验体会 ;

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8 **轮状病毒疫苗对小儿秋季腹泻的临床分析**

邵桂芝 ; 山东省临沂市河东区郑旺镇卫生院 ; 山东省临沂市河东区郑旺镇卫生院,山东临沂,276028 ;

临床医药文献电子杂志 2014年 06期 (2014/03) , 915-916

腹泻 ; 秋季 ; 疫苗 ; 轮状病毒 ; 肠炎 ; 临床交流 ;

預覽摘要

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9 **人轮状病毒抗原非复制型重组腺病毒黏膜免疫效果的研究**

何金生 ; 王健伟 ; 姜秀丽 ; 王大燕 ; 温乐英 ; 董京芳 ; 屈建国 ; 洪涛 ; 安徽医科大学免疫教研室,

合肥,230032 ; 中国疾病预防控制中心病毒病预防控制所,北京,100052 ;

中国免疫学杂志 2004年 12期 (2004/07) , 813-815

重组腺病毒 ; 轮状病毒 ; 黏膜免疫 ;

預覽摘要

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10 **用重组腺病毒表达A组轮状病毒主要中和抗原VP7可获得良好的免疫学效果**

何金生 ; 王健伟 ; 温乐英 ; 徐倏木 ; 屈建国 ; 姜慧英 ; 洪涛 ; 中国预防医学科学院病毒学研究所 ,
北京 100052 ;

病毒学报 2001年 02期 (2001/07) , 122-126

重组腺病毒 ; 基因工程疫苗 ; 轮状病毒 ; VP7基因 ;

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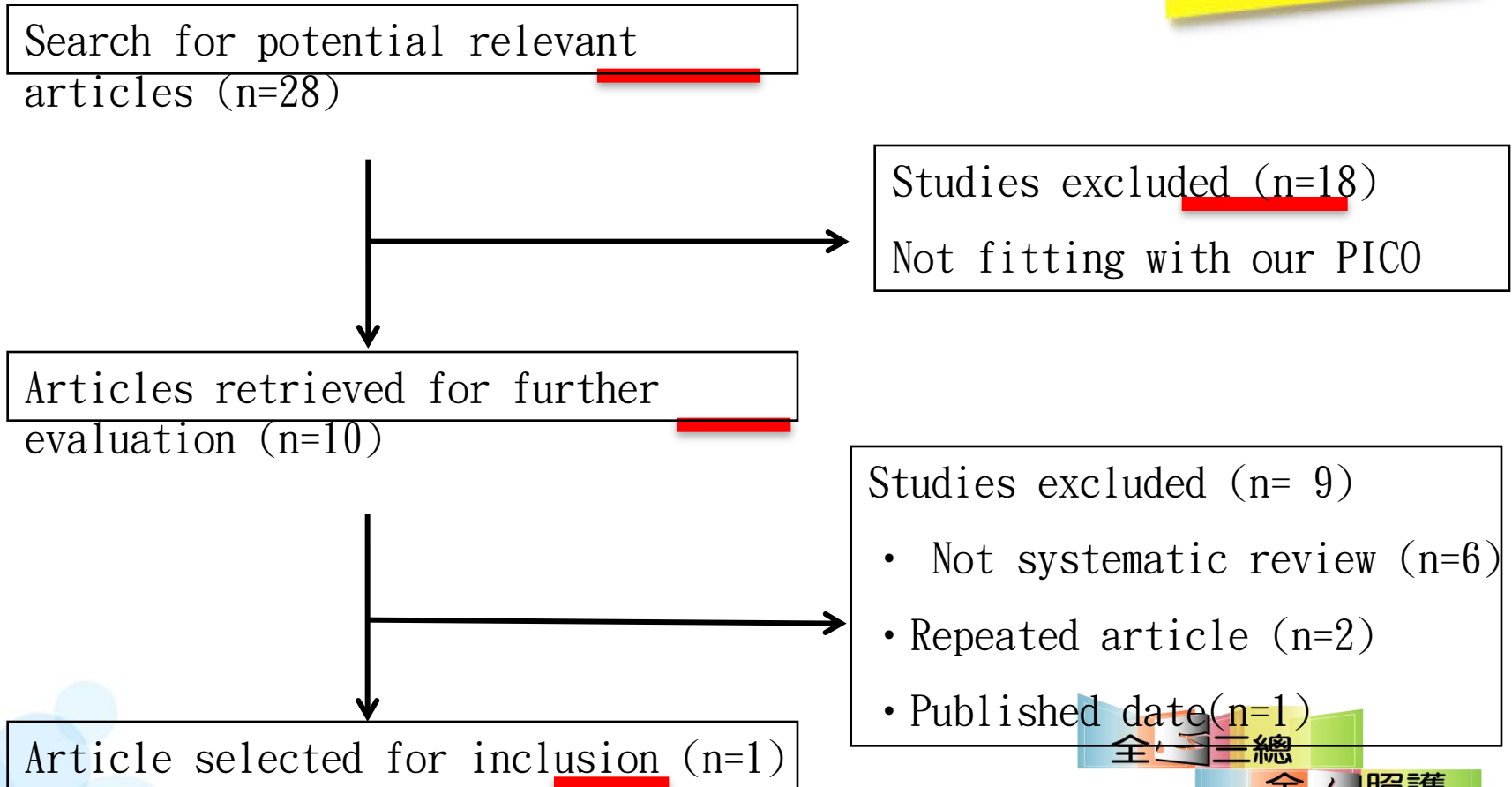
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Flowchart for selection of articles

Acquire



全三總

全人照護

Wholehearted,
Holistic Care



Go to old article view

Cochrane Database of Systematic Reviews

Vaccines for preventing rotavirus diarrhoea: vaccines in use

New search

Review

Intervention

Karla Soares-Weiser, Harriet MacLehose, Hanna Bergman, Irit Ben-Aharon, Sukrti Nagpal, Elad Goldberg, Femi Pitan, Nigel Cunliffe

First published: 14 November 2012

Editorial Group: Cochrane Infectious Diseases Group

DOI: 10.1002/14651858.CD008521.pub3 View/save citation

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**(A) Are the result of the review
valid**





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?

Objectives

Primary objectives were to evaluate the efficacy of rotavirus vaccines approved for use (RV1, RV5, and LLR) for preventing rotavirus diarrhoea, all-cause diarrhoea and death in children up to one and up to two years old for low- and high-mortality countries, and to evaluate serious adverse events including intussusception for the same age and mortality groups. Secondary objectives were to evaluate the efficacy of rotavirus vaccines on hospital admission, and reactogenicity and immunogenicity profiles.



Yes



Can't tell



No



評讀

Appraise



2. Did the authors look for the right type of papers ?

作者是否收納適當的研究類型？

Types of studies

RCTs.

Types of participants

Children (age as defined in the trials).

<6 M/O



Yes



Can't tell



No





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

作者有沒有可能遺漏掉重要.相關研究？

Dr Vittoria Lutje (Information Specialist, Cochrane Infectious Diseases Group) or KS-W searched the following databases using the search terms and strategy described in [Appendix 1: Cochrane Infectious Diseases Group Specialized Register](#) (10 May 2012); Cochrane Central Register of Controlled Trials (CENTRAL), published in *The Cochrane Library* (2012, Issue 5); MEDLINE (via PubMed; 1966 to May 2012); EMBASE (1974 to 10 May 2012); LILACS (1982 to 10 May 2012); and BIOSIS (1926 to 10 May 2012). The International Clinical Trials Registry Platform (ICTRP) was also searched on 10 May 2012, and HB searched Clinicaltrials.gov Clinical Study Register (www.clinicaltrials.gov) on 28 May 2012 using 'rotavirus' as the search term.

Consider:

- Health workers could be; clinicians, nurses etc
- Study personnel – especially outcome assessors

1. 此篇文章收錄41個RCT
2. 收錄中英文發表之文獻



Yes



Can't tell



No





4. Did the review's authors do enough to assess the quality of the included studies 作者是否評估收納研究的品質?

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
RV1 Anh 2011-PHL	+	+	+	+	+	?
RV1 Anh 2011-VNM	+	+	+	+	?	?
RV1 Bernstein 1998-USA	?	?	?	?	?	?
RV1 Bernstein 1999-USA	+	+	?	+	+	?
RV1 Dennehy 2005-NA	?	+	+	+	?	?
RV1 GSK[021] 2007-PAN	?	?	?	?	?	?



Yes



Can't tell

評讀

Appraise



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

作者是否把各個研究的結果合併起來？這樣的研究合理嗎？

The 41 trials enrolled about 186,263 participants (approximate number as some trials provided only the number evaluable), and each trial compared a rotavirus vaccine with a placebo. The vaccines tested were RV1 (29 trials reported in 130 publications or reports; 101,671 participants) and RV5 (12 trials reported in 47 publications or reports; 84,592 participants). None of the identified trials used LLR.



評讀
Appraise

6. What are the overall results of the review?

RV1, low mortality country

HINT: Consider

Outcomes	RR	95%CI	Prevent
Severe rotavirus diarrhoea 1y	0.14	0.07-0.26	86%
Diarrhea 1y	0.6	0.5-0.72	40%
Severe rotavirus diarrhoea 2y	0.15	0.12-0.20	85%
Diarrhea 2y	0.63	0.89-1.81	37%

對於,low mortality country,RV1有預防效果。



6. What are the overall results of the review?

RV1, high mortality country

HINT: Consider

Outcomes	RR	95%CI	Prevent
Severe rotavirus diarrhoea 1y	0.37	0.18-0.75	63%
Diarrhea 1y	0.66	0.44-0.98	34%
Severe rotavirus diarrhoea 2y	0.58	0.42-0.79	40%
Diarrhea 2y	0.82	0.71-0.95	18%

對於,high mortality country,RV1有預防效果。



6. What are the overall results of the review?

RV5, low mortality country

HINT: Consider

Outcomes	RR	95%CI	Prevent
Severe rotavirus diarrhoea 1y	0.13	0.04-.15	87
Diarrhea 1y	0.28	0.16-0.48	72
Severe rotavirus diarrhoea 2y	0.18	0.07-0.50	82
Diarrhea 2y	0.04	0.0-0.7	96

對於,low mortality country,RV5有預防效果。



6. What are the overall results of the review?

RV5, high mortality country

HINT: Consider

Outcomes	RR	95%CI	Prevent
Severe rotavirus diarrhoea 1y	0.43	0.29-0.62	57
Severe rotavirus diarrhoea 2y	0.59	0.43-0.82	41

對於,high mortality country,RV5有預防效果。



7. How precise are the results?



Yes



Can't tell



No

HINT: Look at the confidence intervals, if given

Outcomes	RR	95%CI	Prevent
Severe rotavirus diarrhoea 1y	0.43	0.29-0.62	57
Severe rotavirus diarrhoea 2y	0.59	0.43-0.82	41



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



Yes



Can't tell



No

HINT: Consider whether

Dr Vittoria Lutje (Information Specialist, Cochrane Infectious Diseases Group) of KS-W searched the following databases using the search terms and strategy described in [Appendix 1: Cochrane Infectious Diseases Group Specialized Register](#) (10 May 2012); Cochrane Central Register of Controlled Trials (CENTRAL), published in *The Cochrane Library* (2012, Issue 5); MEDLINE (via PubMed; 1966 to May 2012); EMBASE (1974 to 10 May 2012); LILACS (1982 to 10 May 2012); and BIOSIS (1926 to 10 May 2012). The International Clinical Trials Registry Platform (ICTRP) was also searched on 10 May 2012, and HB searched Clinicaltrials.gov Clinical Study Register (www.clinicaltrials.gov) on 28 May 2012 using 'rotavirus' as the search term.



Tri-Service General Hospital

9. Were all important outcomes considered?



Yes



Can't tell



No

Types of outcome measures

Primary*

- Rotavirus diarrhoea: severe (as defined in trial report).
- All-cause diarrhoea: severe.
- All-cause death.
- Serious adverse events (that are fatal, life-threatening, or result in hospitalization); eg Kawasaki disease.
- Intussusception.





Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

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 <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
What are the COMMON harms? (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 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 <i>n</i> -of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non-randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

* Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.





臨床回覆 *Clinical Answer*

- 林媽媽你好，根據實證醫學的結果，施打輪狀病毒疫苗可能的副作用有發生腸套疊或川崎氏症的可能，不過機率非常低，衡量疫苗所帶來的保護效果與副作用可能的發生機率，我們建議施打輪狀病毒疫苗。



Thank you for your attention

