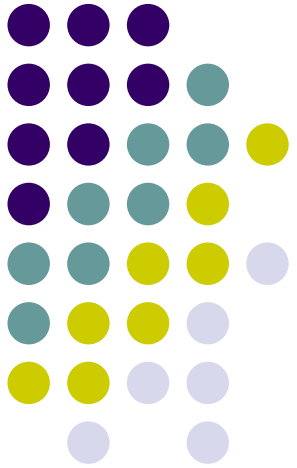
Evidence Based Medicine
ENT

報告日期：99/5/24

報告人：R1王興良

指導老師：VS簡禎佑



臨床情境（Clinical Scenario）

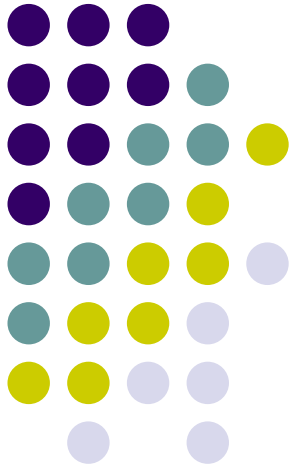
- 陳小妹今年5歲，因高燒3日合併支氣管炎住進小兒科病房，病患有常見之呼吸道感染症狀，如cough, sputum, nasal obstruction, running nose…等。
- 剛住院時，值班醫師依據抽血結果(WBC,CRP均正常)及臨床症狀初步判定為病毒性感染，故給予發燒控制及一些症狀緩解之藥物，如**Cypromin, Methylephedrine**, prophyllin, mubroxol…等。

臨床情境（Clinical Scenario）

- 然而陳小妹的媽媽提及，為什麼陳小妹吃了藥以後，整天都**無精打采且一直在睡覺**，咳嗽都一直沒好，且**痰好像都咳不太出來**了，是不是跟藥物有關，而且**鼻塞也沒什麼改善**，這些藥物一定要吃嗎?吃這些藥對身體會不會有什麼副作用呀?

Asking Clinical Questions

Are antihistamine and / or decongestants effective for respiratory infection symptoms control in children?



EBM五大步驟

- Asking
  - 將病人的問題寫成PICO
- Acquire
  - 找資料來回答問題
- Appraisal
  - 嚴格評讀文獻
- Apply
  - 是否可應用到病人身上
- Audit
  - 自我評估

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PICO

P Patient/Problem	Children with respiratory infection symptoms
I Intervention	Antihistamine ± Decongestants
C comparison	Placebo
O Outcome	Symtomatic therapy outcome, side effects

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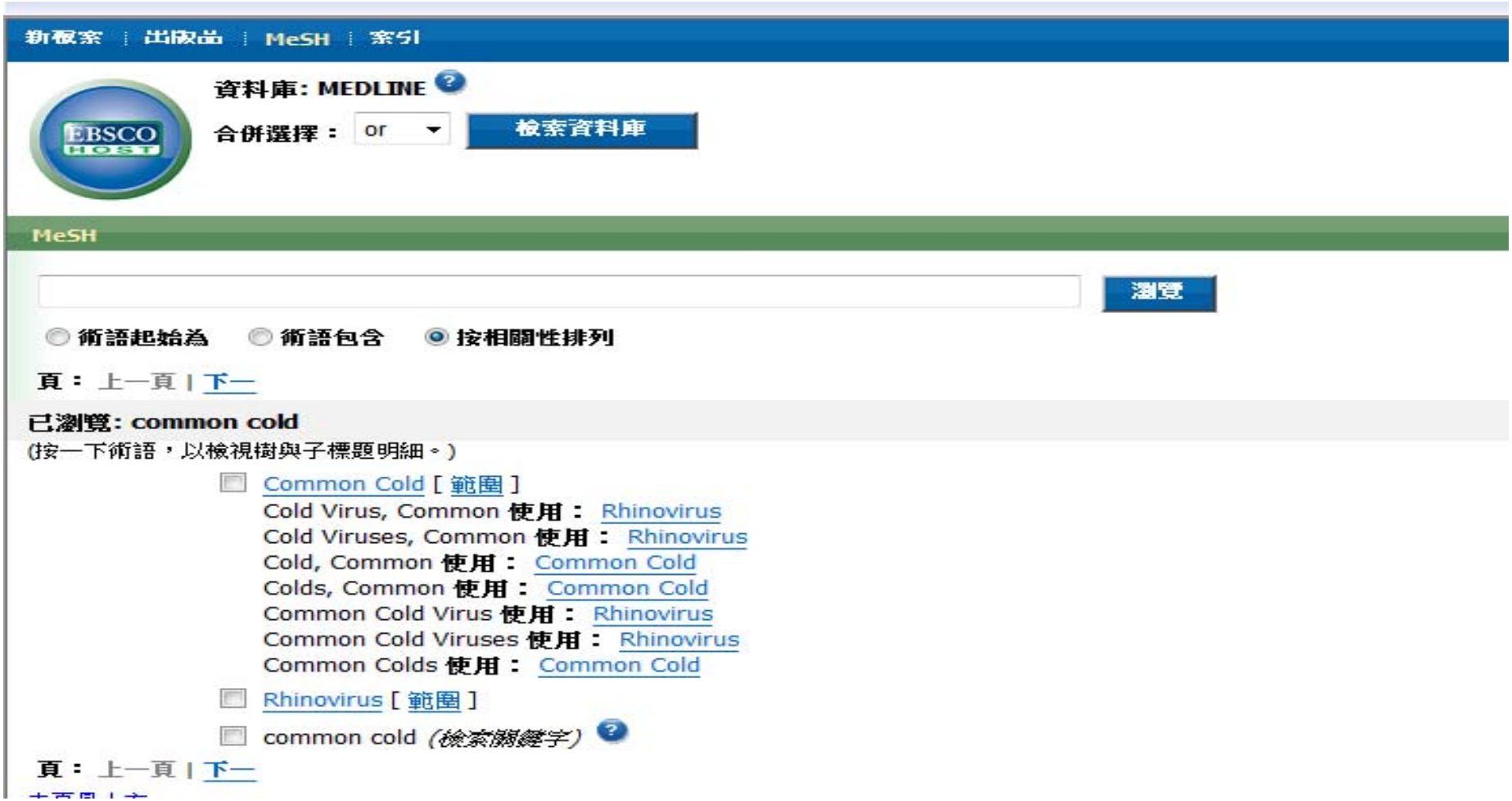
Searching Strategy 1：Finding out The Correct Keywords

- Use MeSH to help identify terms



Search Strategy 2 : ”The 5S” Levels

The "5S" levels of organisation of evidence from healthcare research

Brian Haynes, R Evid Based Med 2006;11:162-164

EBM ONLINE

UpToDate

DynaMed

ACP PIER

BMJ Clinical Evidence

ACP journal club

Evidence based medicine.com

Cochrane Library

BMJ Evidence Updates

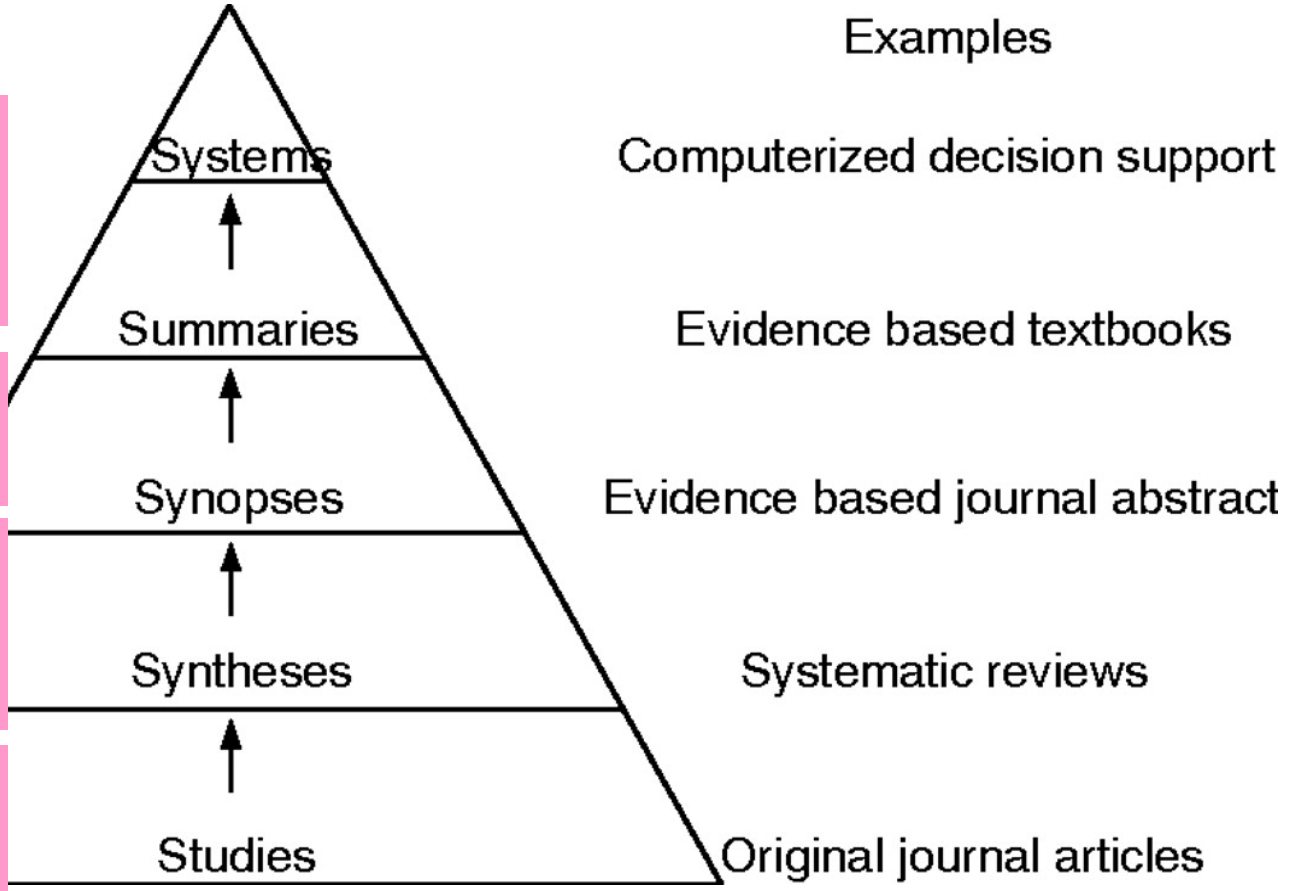
Other Systemic reviews eg. PubMed systemic reivew

PubMed

SUMsearch

TRIP

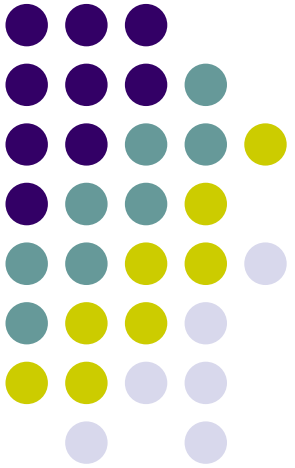
Google



Keywords from PICO item

MeSH terms :

Children , Respiratory infection,
Common cold, treatment,
Antihistamine , Decongestants



Search for Answers

Summary

搜尋：

Key word: Children , Respiratory infection, Common cold, treatment, Antihistamine , Decongestants

Results from Searching: Summaries

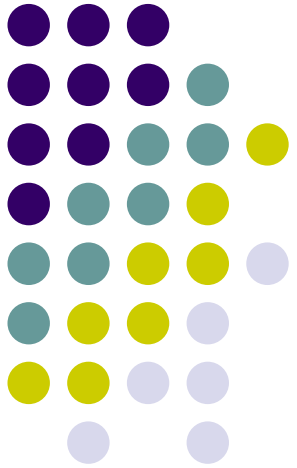
Database	UpToDate
Title of article	The common cold in children, 2010
Content	**Antihistamines** — The anticholinergic effects of the first generation antihistamines (eg, diphenhydramine) may help to reduce the secretions associated with the common cold. However, in controlled trials, antihistamines have been ineffective in relieving the symptoms of children with URI, whether administered in combination with decongestants or as monotherapy .

Results from Searching: Summaries

Content	In addition to sedation, side effects of antihistamines may include paradoxic excitability, respiratory depression, and hallucinations. Because of the potential toxicity and the lack of proven efficacy, antihistamines should only be used in children over 12 months of age and with the knowledge that sedation may be the only beneficial effect of treatment

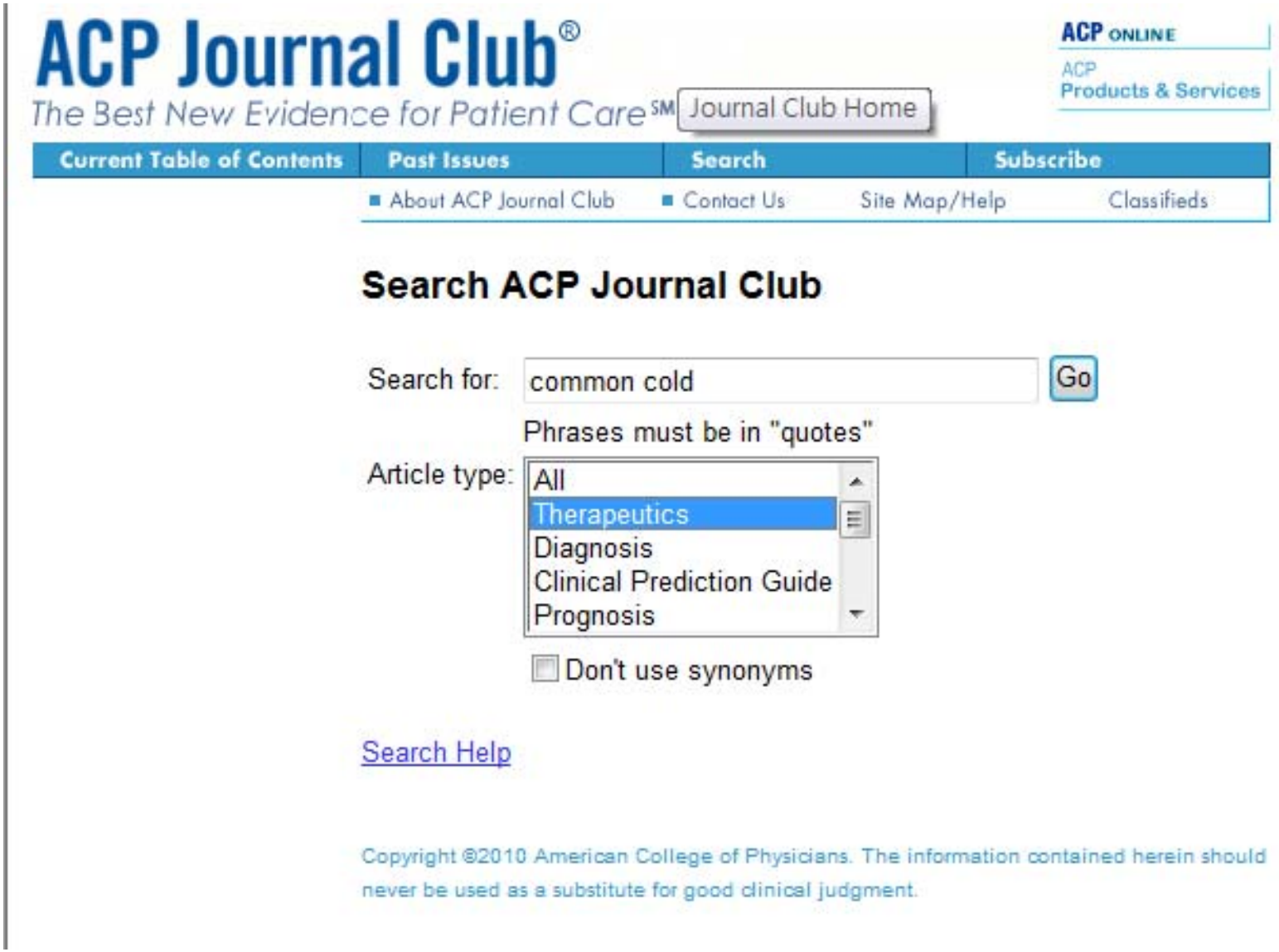
Synopses

搜尋：ACP Journal Club℠
The Best New Evidence for Patient Care



Key word: Children , Respiratory infection, Common cold, treatment, Antihistamine , Decongestants

Search ACP Journal Club



Syntheses

搜尋：

Key word: Children , Respiratory infection, Common cold, treatment, Antihistamine , Decongestants

July 2005
Review

Vitamin C for preventing and treating the common cold
Harri Hemilä, Elizabeth Chalker, Bob Douglas
March 2010
Review

Garlic for the common cold
Elizabeth Lissiman, Alice L Bhasale, Marc Cohen
October 2009
Review

Nasal decongestants for the common cold
David Taverner, G. Jenny Latte
April 2009
Review

Non-steroidal anti-inflammatory drugs for the common cold
Soo young Kim, Yoon-Jung Chang, Hye Min Cho, Ye-won Hwang, Yoo Sun Moon
July 2009
Review

Antihistamines for the common cold
An IM De Sutter, Marc Lemiengre, Harry Campbell
October 2009
Review

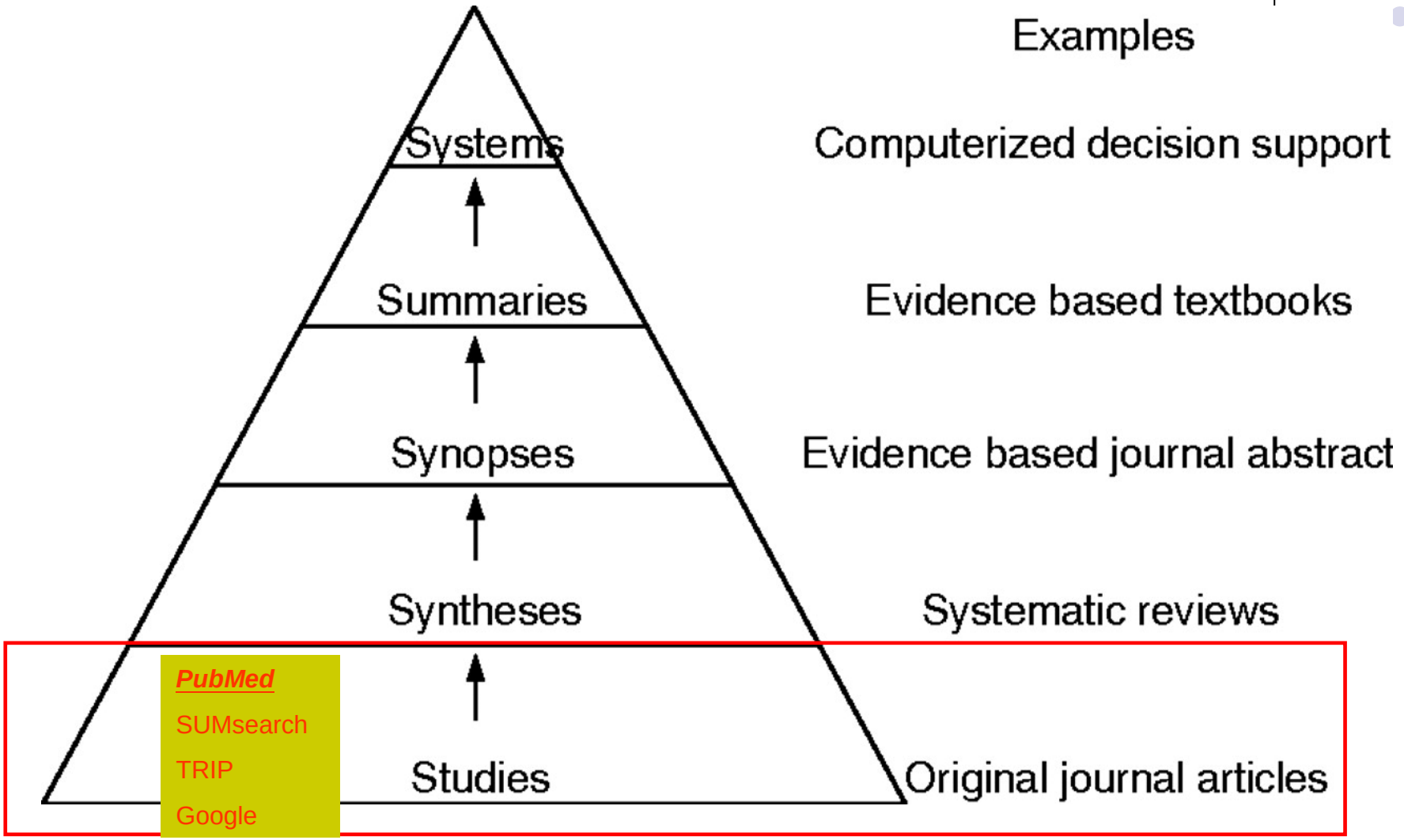
Echinacea for preventing and treating the common cold
Klaus Linde, Bruce Barrett, Rudolf Bauer, Dieter Melchart, Karin Woelkart
October 2009
Review

Zinc for the common cold
Ian IR Marshall
July 2006
Review

Heated, humidified air for the common cold
Meenu Singh
July 2009
Review

Chinese medicinal herbs for the common cold

Primary database

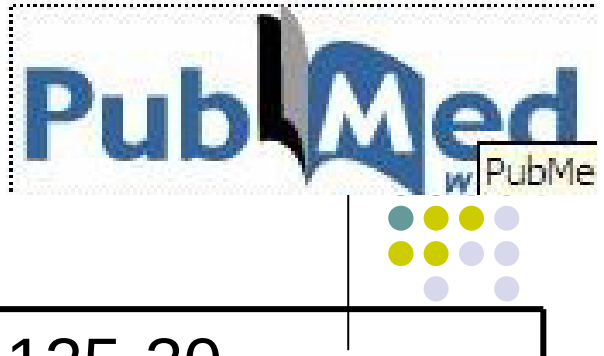


Studies

搜尋：

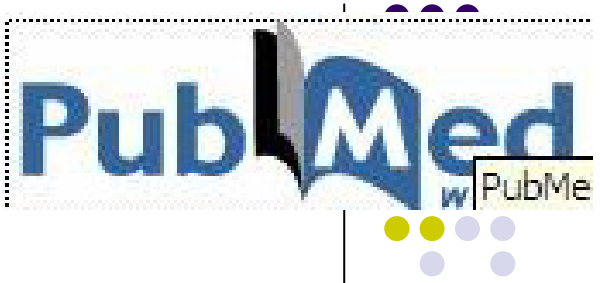
Key word: Children , Respiratory infection, Common cold, treatment, Antihistamine , Decongestants

Results from Searching: Summaries



Database	J Pediatr 1991 Jan;118(1):125-30.
Title of article	Effectiveness of an antihistamine-decongestant combination for young children with the common cold: a randomized, controlled clinical trial
Content	We tested the hypothesis that antihistamine-decongestant combinations cause no clinically significant relief of the symptoms of upper respiratory tract infections in young children by randomly assigning 96 children to one of three treatment groups: antihistamine-decongestant, placebo, and no treatment. There were no differences among the three study groups in the proportion of children considered "better" overall by the parent 48 hours after the initial assessment (drug, 67%; placebo, 71%; no treatment, 57%; p = 0.53).

Results from Searching: Summaries

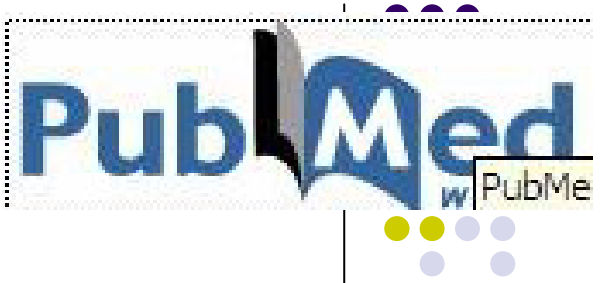


Content	Parents who wanted medicine at the initial visit reported more improvement at follow-up, regardless of whether the child received drug, placebo, or no treatment. We conclude that there is no clinically significant improvement in symptoms of upper respiratory tract infection, including no significant placebo effect, in young children for whom an antihistamine-decongestant is prescribed.

Results from Searching: Summaries

Database	J Pediatr 1997 Mar;130(3):463-6.
Title of article	Is an antihistamine-decongestant combination effective in temporarily relieving symptoms of the common cold in preschool children?
Content	DESIGN: Randomized, double-blind, placebo-controlled trial. SETTING: Four pediatric offices in the Seattle, Wash, area. PARTICIPANTS: Children 6 months through 5 years of age with a URI of less than 7 days' duration. METHODS: Children were randomly assigned to receive an ADC (brompheniramine maleate-phenylpropanolamine hydrochloride) or placebo as needed for URI symptoms

Results from Searching: Summaries



Content	RESULTS: A total of 175 responses were recorded for 59 patients. There were no statistically significant differences in symptom improvement between the ADC and the placebo group (runny nose, p = 0.48; nasal congestion, p = 0.94; cough, p = 0.66) . However, the proportion of children asleep 2 hours after receiving the ADC was significantly higher than the proportion receiving placebo (46.6% vs 26.5%; p = 0.01). CONCLUSIONS: The ADC was equivalent to placebo in providing temporary relief of URI symptoms in preschool children. However, the ADC did have significantly greater sedative effects than did placebo.

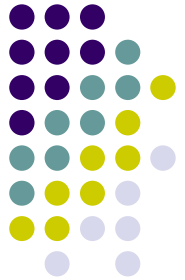
Level of evidence

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	D p
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	S p
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with ≥ 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre	R f
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	A
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	S b
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only	Exploratory** cohort study with good†††reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases	R f
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		E
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	S b
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	N v
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	C r
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	E a b

Title 1

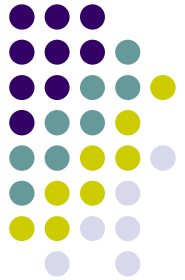
- The common cold in children
- uptodate. 2010.一月. Review
- Level of evidence: Ia

搜尋到的文章標題及文獻等級



- Title 2：Effectiveness of an antihistamine-decongestant combination for young children with the common cold: a randomized, controlled clinical trial
- J Pediatr 1991 Jan;118(1):125-30
- Level of evidence：Ib

搜尋到的文章標題及文獻等級



- Title 3： Is an antihistamine-decongestant combination effective in temporarily relieving symptoms of the common cold in preschool children?
- J Pediatr 1997 Mar;130(3):463-6
- Level of evidence： Ib

EBM五大步驟

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Appraisal (嚴格評讀）
AAMPICO

用AAM初步排除文不對題或文獻等級較低者
之後使用GATE frame融合worksheet內容進行
嚴格評讀

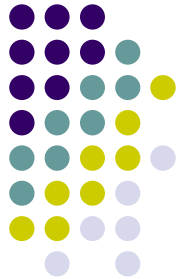
參考資料：
1. The GATE frame: critical appraisal with pictures
   ACP Journal Club March/April 2006 | Volume 144
2. JAMA,1994;271:1615-1619
3. Sackett Corrected 2 Dec 1996

What question did the systematic review addressed (PICO) 想要回答什麼問題？

■ 是	□ 否	□ 不清楚
Are antihistamine and / or decongestants effective for respiratory infection symptoms control in children?		

Systematic review worksheet

Were the criteria used to select articles for inclusion appropriate 選擇文獻的準則適當?



■ 是	□ 否	□ 不清楚

All trials identified on the research topic were evaluated by two reviewers to determine relevant articles for full text retrieval. The retrieved studies were assessed for eligibility by the two reviewers according to the inclusion criteria specified. For each trial fulfilling the inclusion requirements, an assessment of methodological quality was done by the two reviewers independently. Data extraction was also done independently by the two investigators. The information collected from each trial included study design, patient characteristics, interventions compared and outcomes measured. Authors of studies were contacted when the need for additional information arose. A third reviewer did an independent review to settle any difference of opinion between the two primary reviewers.

Included studies were assessed for validity using the Philippine Cardiovascular Research Group Meta-analysis Quality Scale (Alejandria 2003). This instrument determined the presence of selection, performance, exclusion and detection biases, qualitatively. Specific terms evaluated in this instrument were allocation concealment, balance in baseline characteristics, blinding, drop-out rates and analysis by intention-to-treat (ITT).

Were the included studies sufficiently valid for the type of question asked

選擇的文獻有效回答所問的問題?

■是	□ 否	□ 不清楚

Antihistamines: in controlled trials, antihistamines have been ineffective in relieving the symptoms of children with URI, whether administered in combination with decongestants or as monotherapy . In addition to sedation, side effects of antihistamines may include paradoxic excitability, respiratory depression, and hallucinations. Because of the potential toxicity and the lack of proven efficacy, antihistamines should only be used in children over 12 months of age and with the knowledge that sedation may be the only beneficial effect of treatment.

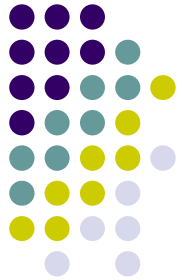
Were the included studies sufficiently valid for the type of question asked

選擇的文獻有效回答所問的問題?

■ 是	□ 否	□ 不清楚

Decongestants: there are no studies demonstrating the effectiveness of these medications in children. Side effects of decongestants may include tachycardia, elevated diastolic blood pressure, and palpitations. Because of the substantial risks of these products without proven benefit, decongestants are not recommended for pediatric use.

EBM五大步驟



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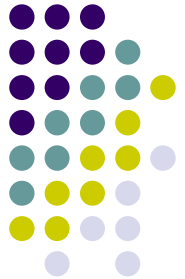
Apply The Result to Our Patient



P Patient/Problem	Children with respiratory infection symptoms
I Intervention	Antihistamine ± Decongestants
C comparison	Placebo
O Outcome	Symtomatic therapy outcome, side effects

Apply：

一、結合實證醫學的結果、臨床專業經驗給予病人建議

二、結合病人價值，幫助病人做出最後的決定

- 實證醫學的結果:
  - Antihistamine ± Decongestants were lack of proven efficacy in children with respiratory infection
- 臨床專業經驗:
  - Uncertain due to limited patient numbers
- 以去學術化的語言給予病人建議：
  - 流鼻水及鼻塞藥物(Antihistamine 及 Decongestants)對症狀緩解之效果有限，但副作用反讓病人而更不舒服，故不建議使用。

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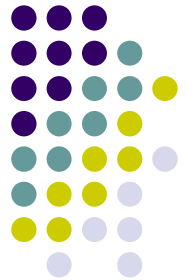
在「提出臨床問題」方面的自我評估



- 我提出的問題是否具有臨床重要性？有
- 我是否明確的陳述了我的問題？是
- 我是否清楚的知道自己問題的定位？（亦即可以定位自己的問題是屬於診斷上的、治療上的、預後上的或流行病學上的），並據以提出問題？知道，屬於治療範疇
- 對於無法立刻回答的問題，我是否有任何方式將問題紀錄起來以備將來有空時再找答案？有

在「搜尋最佳證據」方面的自我評估

- 我是否已盡全力搜尋？是
- 我是否知道我的問題的最佳證據來源？是
- 我是否從大量的資料庫來搜尋答案？是
- 我工作環境的軟硬體設備是否能支援我在遇到問題時進行立即的搜尋？部分
- 我是否在搜尋上愈來愈熟練了？是
- 我會使用「斷字」、布林邏輯、同義詞、MeSH term，限制（limiters)等方法來搜尋？會
- 我的搜尋比起圖書館人員或其他對於提供病人最新最好醫療有熱情的同事如何？普通

關於「嚴格評讀文獻」方面的自我評估

- 我是否盡全力做評讀了？是
- 我是否了解worksheet每一項的意義？是
- 評讀後，我是否做出了結論？是

關於「應用到病人身上」的自我評估

- 我是否將搜尋到的最佳證據應用到我的臨床工作中？
  是
- 當搜尋到的最佳證據與實際臨床作為不同時，我如何解釋？每個人對藥物的反應及代謝情形不同若藥物使用之副作用大於效益則不一定要使用該藥物。

改變「醫療行為」的自我評估

- 當最佳證據顯示目前臨床策略需改變時，我是否遭遇任何阻止改變的阻力？否
- 我是否因此搜尋結果而改變了原來的治療策略？有
- 做了那些改變？有，取消Antihistamine 及Decongestants的使用，病人整天昏睡情形改善，食慾恢復，且痰咳得出來了，過兩天即出院。

效率評估

- 這篇報告，我總共花了多少時間？兩個晚上
- 我是否覺得這個進行實證醫學的過程是值得的？值得，疑問得到解答，也更熟悉EBM的操作
- 我還有那些問題或建議？評讀paper的方法不甚熟練

結語

以上簡報完畢
謝謝各位聆聽
敬請指教