

EBM簡介及臨床應用

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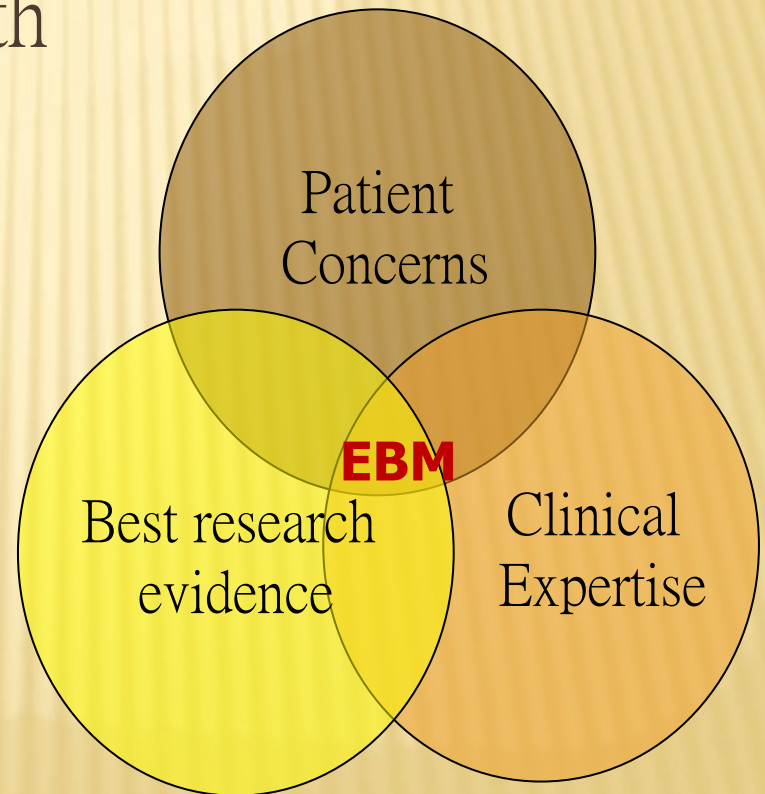
什麼是實證醫學

✦ 實證醫學 (EBM, Evidence-Based Medicine)

以**流行病學**和**統計學**的方法，從龐大的**醫學資料庫**中嚴格評讀、綜合分析找出值得信賴的部分，並將所能獲得的**最佳文獻證據**，應用於臨床工作中，使病人獲得最佳的照顧。

實證醫學的三大要素

- × “Evidence-based medicine is the integration of **best research evidence** with **clinical expertise** and **patient values**” .
- David L. Sackett



實證醫學的緣起

- ✘ 西元1992年Evidence-based Medicine一詞由加拿大McMaster大學Gordon Guyatt所領導的學術組織正式命名，引起世界對「實證醫學」的關注。

The Rational Clinical Examination

Evidence-Based Medicine

A New Approach to Teaching the Practice of Medicine

Evidence-Based Medicine Working Group

A NEW paradigm for medical practice is emerging. Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. Evidence-based medicine requires new skills of the physician, including efficient literature searching and the application of formal rules of evidence evaluating the clinical literature.

An important goal of our medical residency program is to educate physicians

dose of phenytoin intravenously and the drug is continued orally. A computed tomographic head scan is completely normal, and an electroencephalogram shows only nonspecific findings. The patient is very concerned about his risk of seizure recurrence. How might the resident proceed?

The Way of the Past

Faced with this situation as a clinical clerk, the resident was told by her senior resident (who was supported in his view by the attending physician) that

year is between 43% and 51%, and at 3 years the risk is between 51% and 60%. After a seizure-free period of 18 months his risk of recurrence would likely be less than 20%. She conveys this information to the patient, along with a recommendation that he take his medication, see his family doctor regularly, and have a review of his need for medication if he remains seizure-free for 18 months. The patient leaves with a clear idea of his likely prognosis.

A PARADIGM SHIFT

JAMA 1992;268:2420-5.

為何需要實證醫學

- ✘ 臨床工作者在處置病人所面臨的問題時有許多不確定性，此時可以借助客觀可信的臨床研究結果，作為照顧病人的主要依據。
- ✘ 實證醫學是具有科學方法，以及人文特質的診療模式，並且**以病人為中心**，以問題為導向的臨床行動，正確的應用可以**提昇整體的醫療品質**，**減少不必要的醫療浪費**。

為何需要實證醫學

- ✘ **電腦網路**在實證醫學的應用扮演重要的角色，文獻資料及最新的醫學進展可經由網路快速的查詢，比傳統幾年才出版一次的教科書更update。
- ✘ 集合學者回顧所有嚴謹發表或未發表的醫學文獻，做成**最接近正確的結論**，不須花很多時間便能了解其要旨，利用這些資源可以節省閱讀大量文獻的時間。

高雄長庚推廣實證醫學的情形

- ✘ 醫學教育委員會下設實證醫學訓練小組。
- ✘ 設置一名組長及十二位委員。
- ✘ 成員包括：醫師、藥師、護理師、醫檢師、圖書館員..等。
- ✘ 小組定期開會討論及規劃實證醫學相關課程。
- ✘ 定期公告實證醫學相關課程、活動訊息。
- ✘ 院內行政部門設置專責人員。



高雄長庚推廣實證醫學的情形

- ✘ 針對新進實習、住院醫師安排實證醫學核心課程。
- ✘ 每月辦理「EBM journal club」由院內及院外專家參與指導。
- ✘ 每年辦理院內實證醫學種子教師研習營教學，EBM核心課程workshop，全院性EBM比賽。
- ✘ 鼓勵人員公假公費參加參加院外實證醫學相關課程。



施行實證醫學的五大步驟 (5A)

- × **1 Ask**: 將臨床情境形成一個可回答的臨床問題
- × **2 Acquire**: 尋找最佳的文獻證據
- × **3 Appraise**: 嚴格評讀文獻
- × **4 Apply**: 應用於病人身上
- × **5 Audit**: 對過程進行稽核

施行實證醫學的五大步驟

× Ask: 將臨床情境形成一個可回答的臨床問題

PICO

× Acquire: 尋找最佳的文獻證據

× Appraise: 嚴格評讀文獻

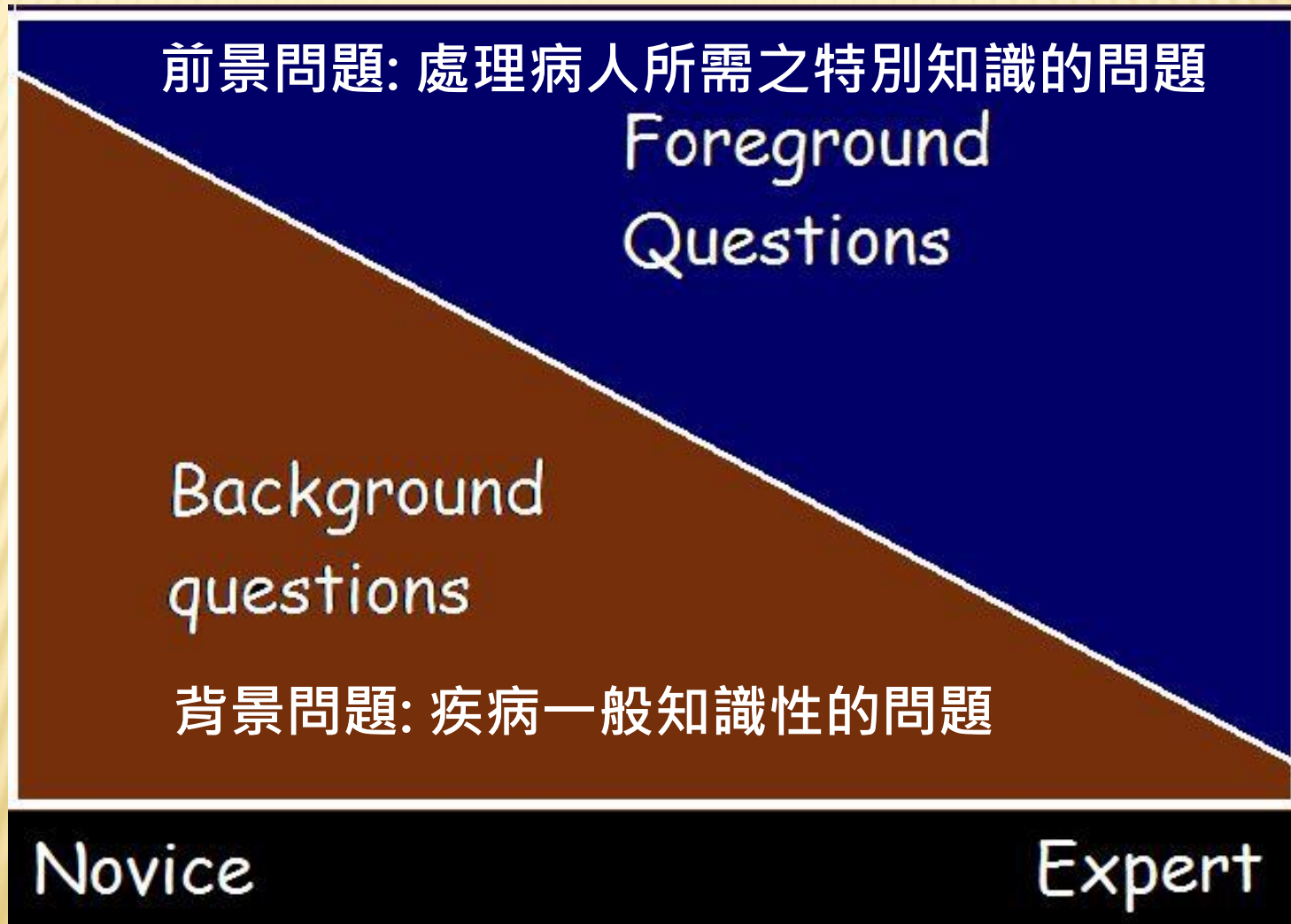
× Apply: 應用於病人身上

× Audit: 對過程進行稽核

設PICO

- × **P: Patient /Problem** 病人或問題
- × **I: Intervention** 介入或指標
 - 某種治療、檢查、危險因子
- × **C: Comparison** 比較
 - 該治療和甚麼相比？
- × **O: Outcome** 結果
 - 您想要達成或避免甚麼？
- × **Question**

臨床問題分類



前景問題 (Foreground Questions)

- ✘ 實證醫學主要處理的是**前景問題**。
- ✘ 養成提問的習慣，是改善醫療品質的第一步。
- ✘ 問題的提出，決定後續該問題相關實證醫學的實際操作步驟。

實證醫學的四大問題

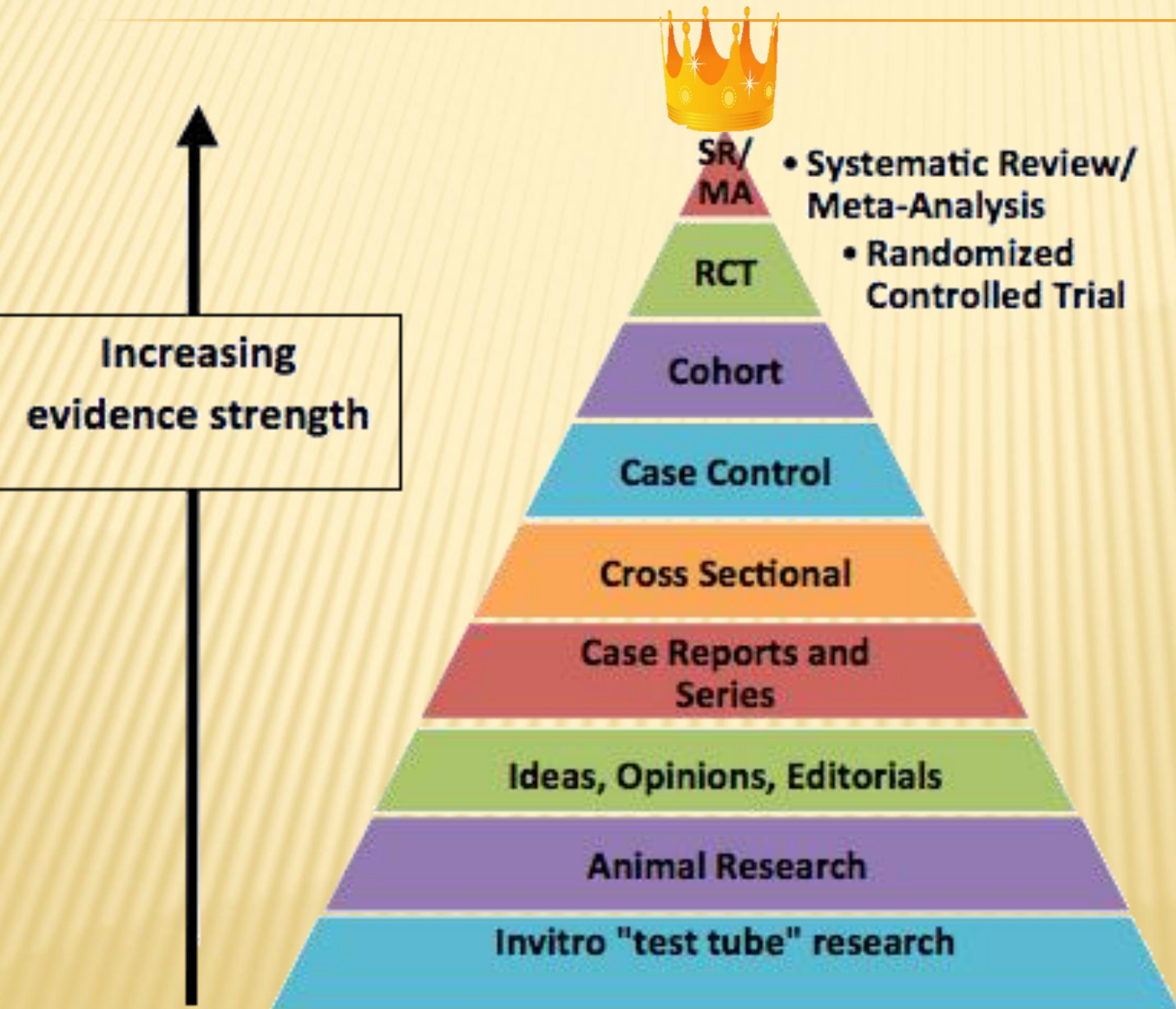
- × 治療 (Therapy)
- × 診斷 (Diagnosis)
- × 預後 (Prognosis)
- × 病因/傷害 (Etiology/Harm)



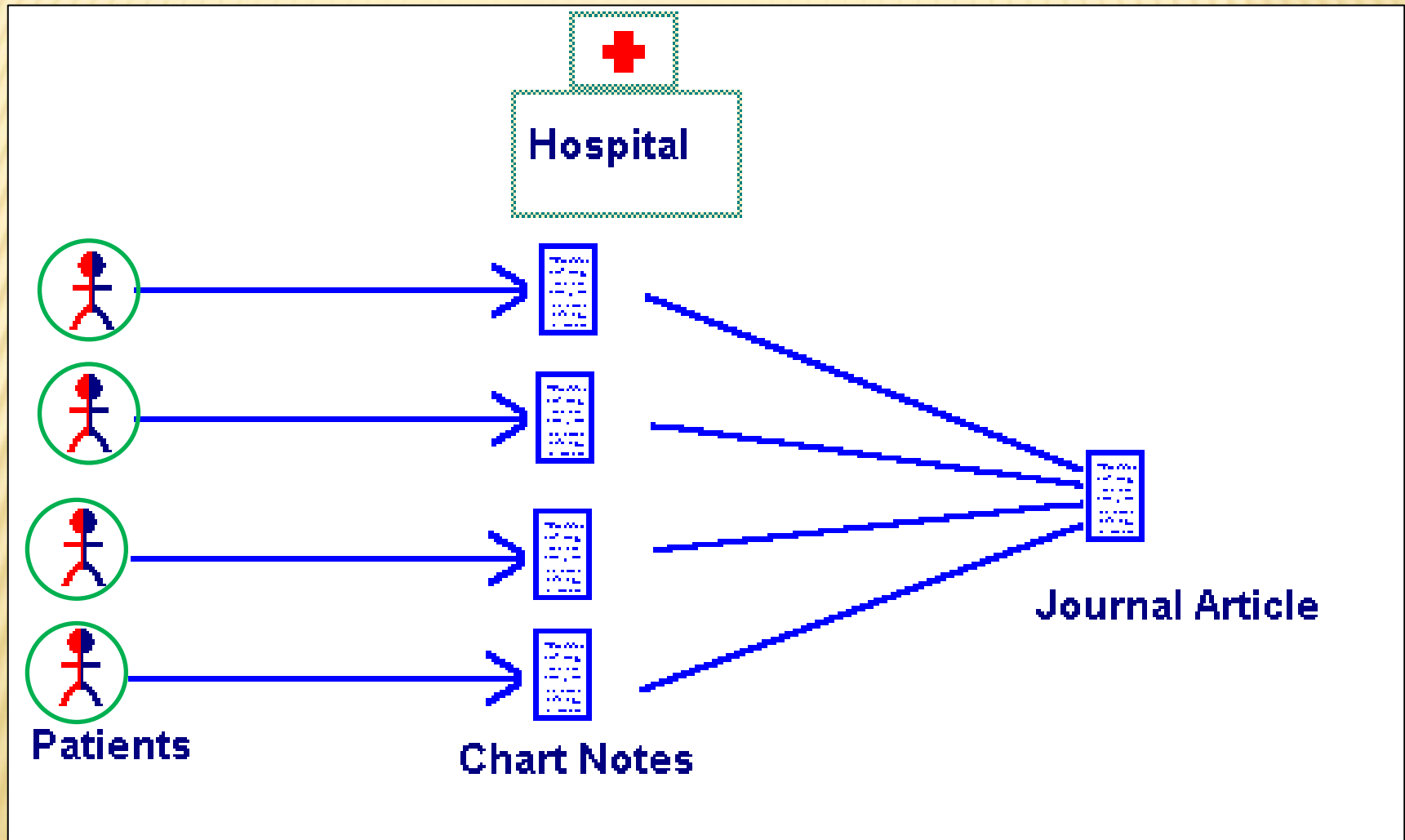
施行實證醫學的五大步驟

- × Ask: 將臨床情境形成一個可回答的臨床問題
- × **Acquire: 尋找最佳的文獻證據** **6S**
- × Appraise: 嚴格評讀文獻
- × Apply: 應用於病人身上
- × Audit: 對過程進行稽核

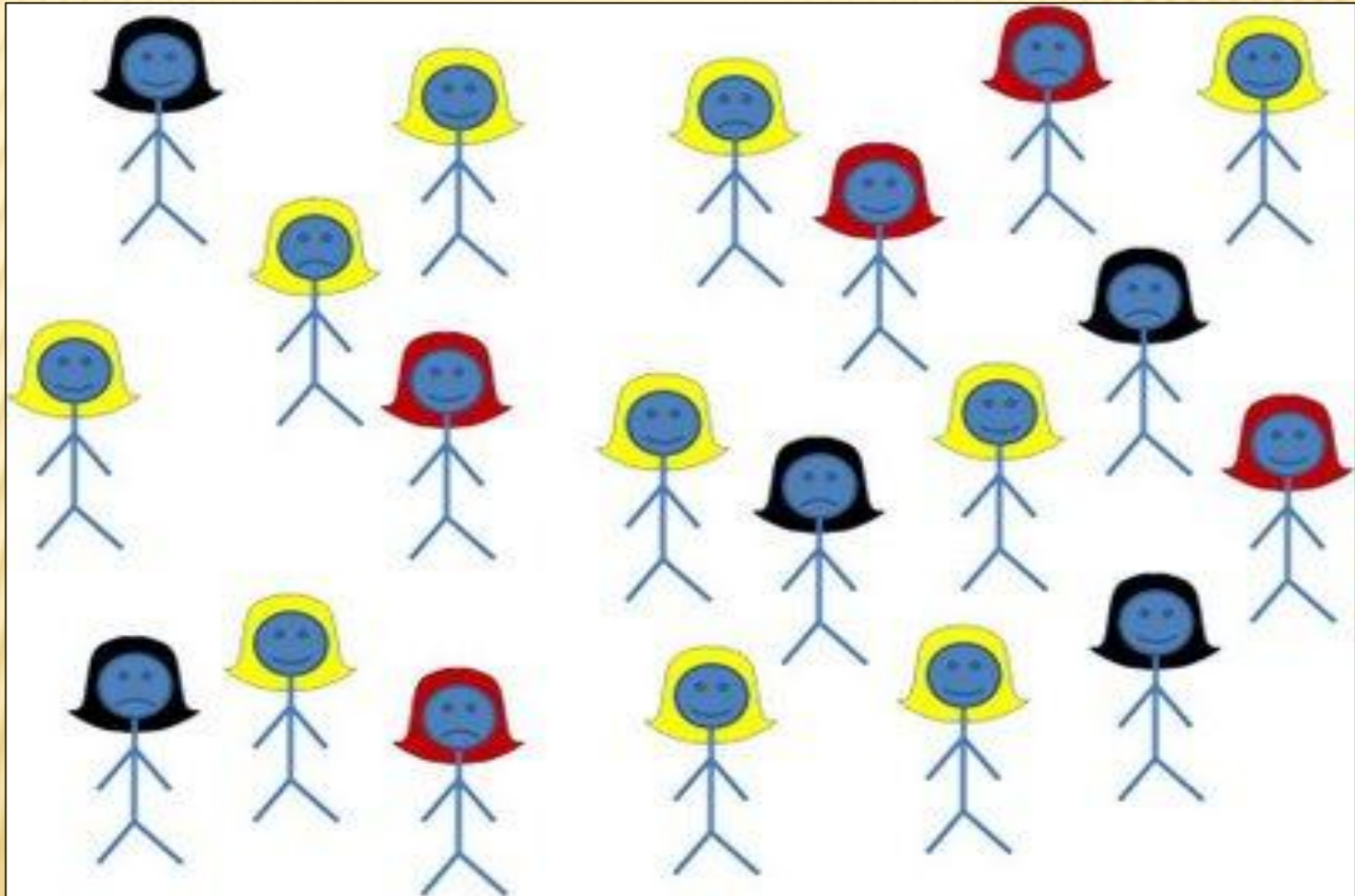
證據金字塔



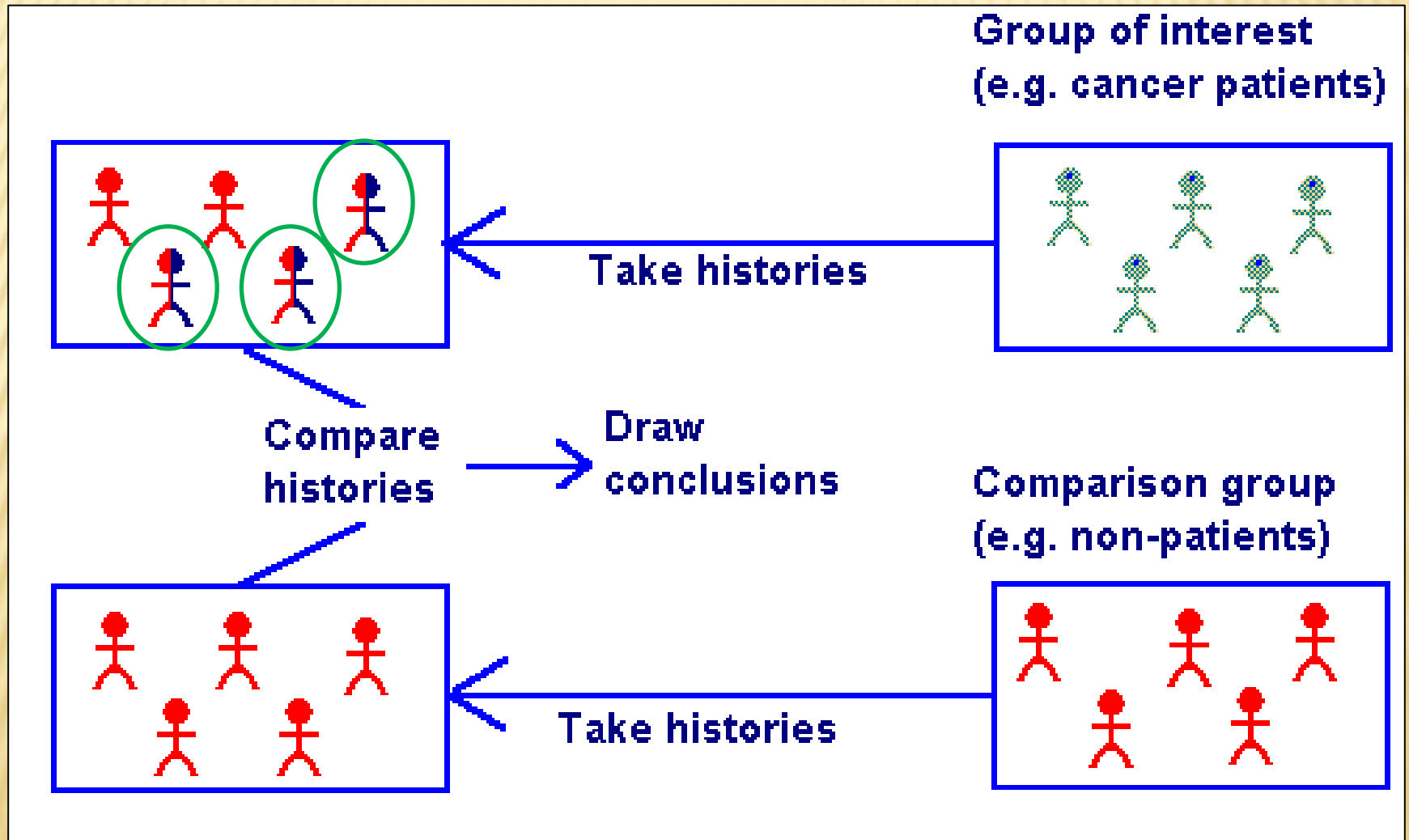
個案報告及個案系列報告 (Case Reports and Case-Series)



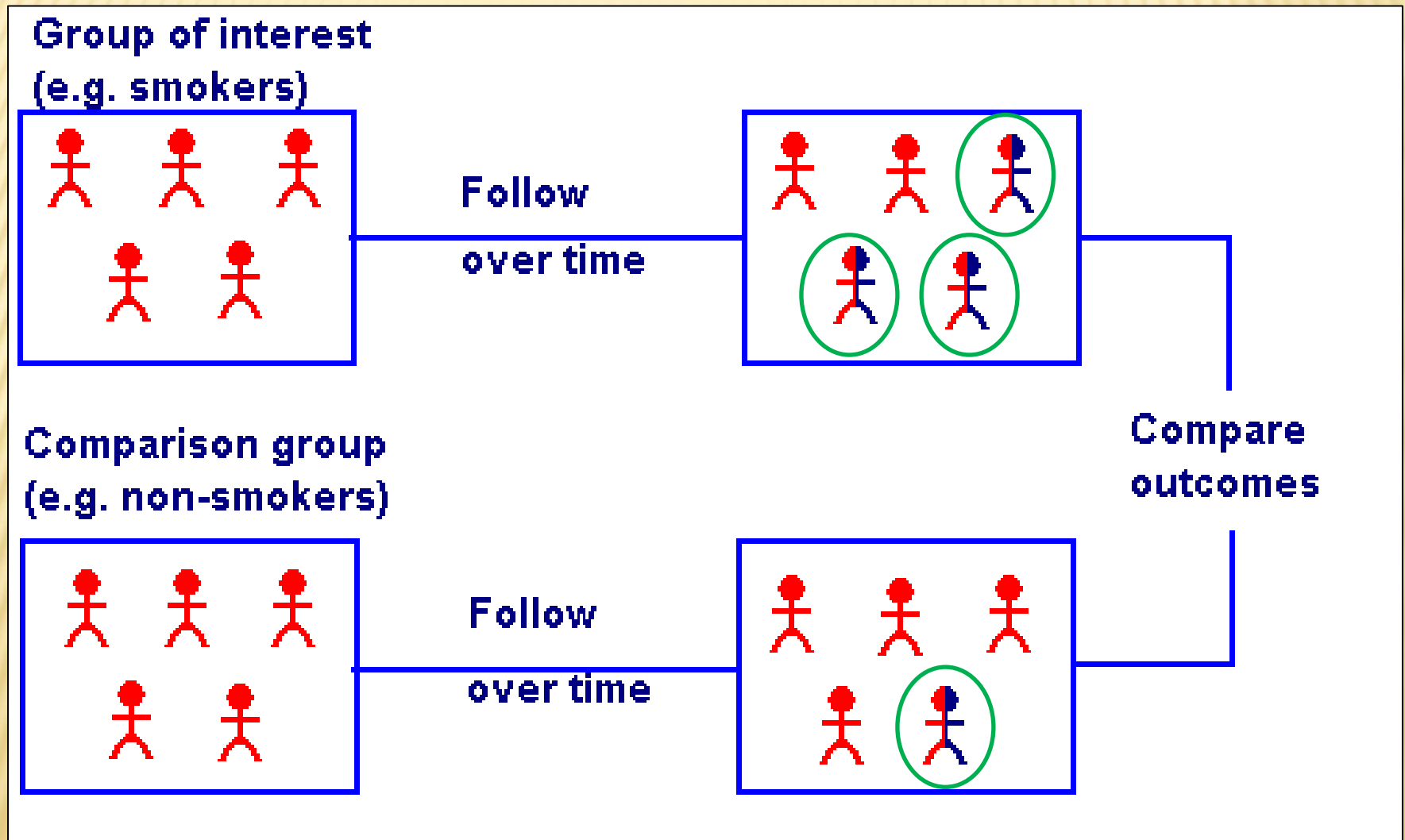
橫切研究 (Cross-Sectional Survey)



個案對照研究 (Case-Control Studies)



世代研究 (Cohort Studies)



隨機對照試驗

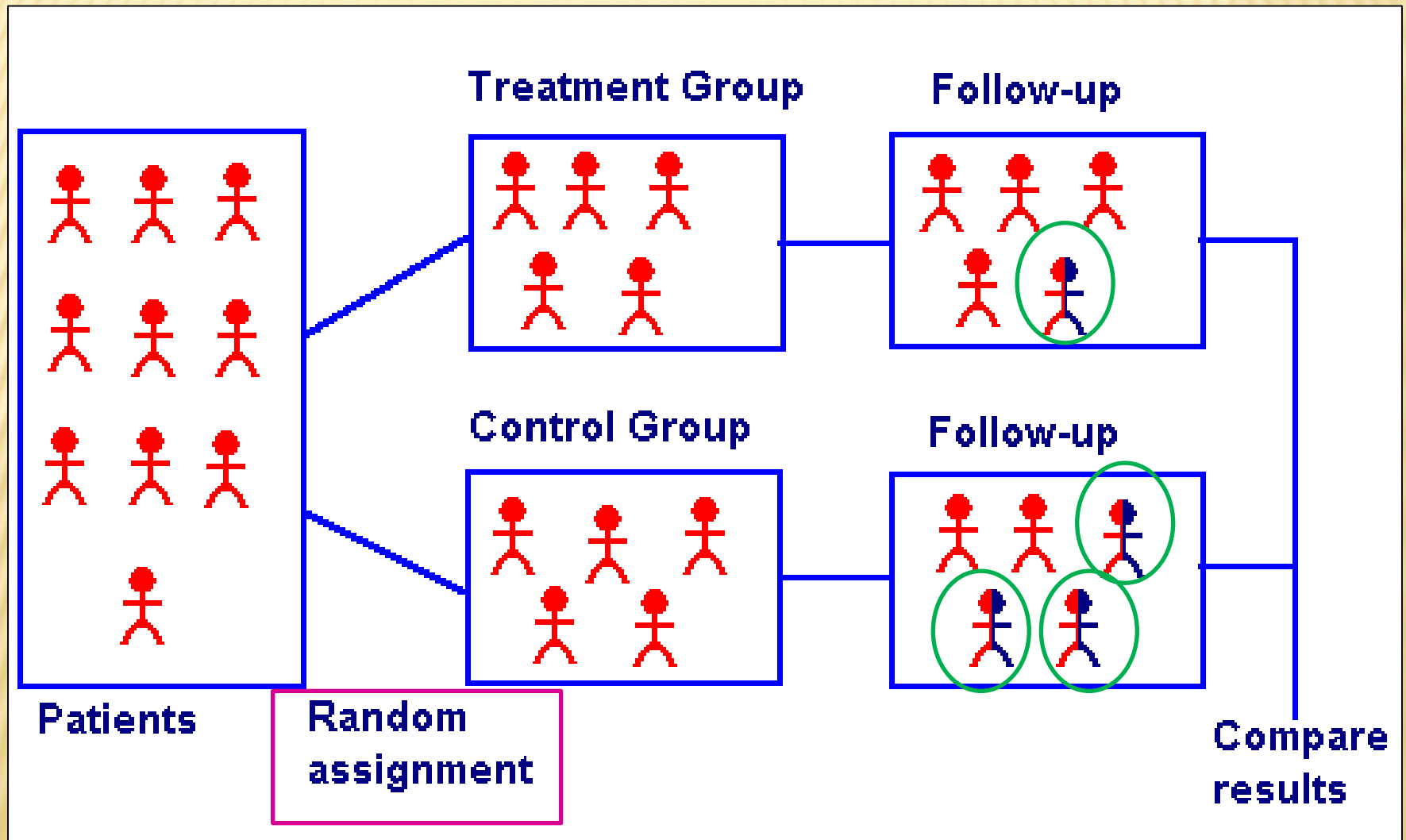
(Randomized Controlled Studies)

✘ 研究方法：

1. 屬於實驗性(experimental)研究。
2. 以隨機方式將受試者分為**治療組**及**控制組**，比較兩組的狀況以了解試驗**藥物的療效及安全性**，或某種處置之效益。
3. 為目前**臨床流行病學中公認證據力最強之原始介入性研究設計**（ primary interventional study ）。

隨機對照試驗

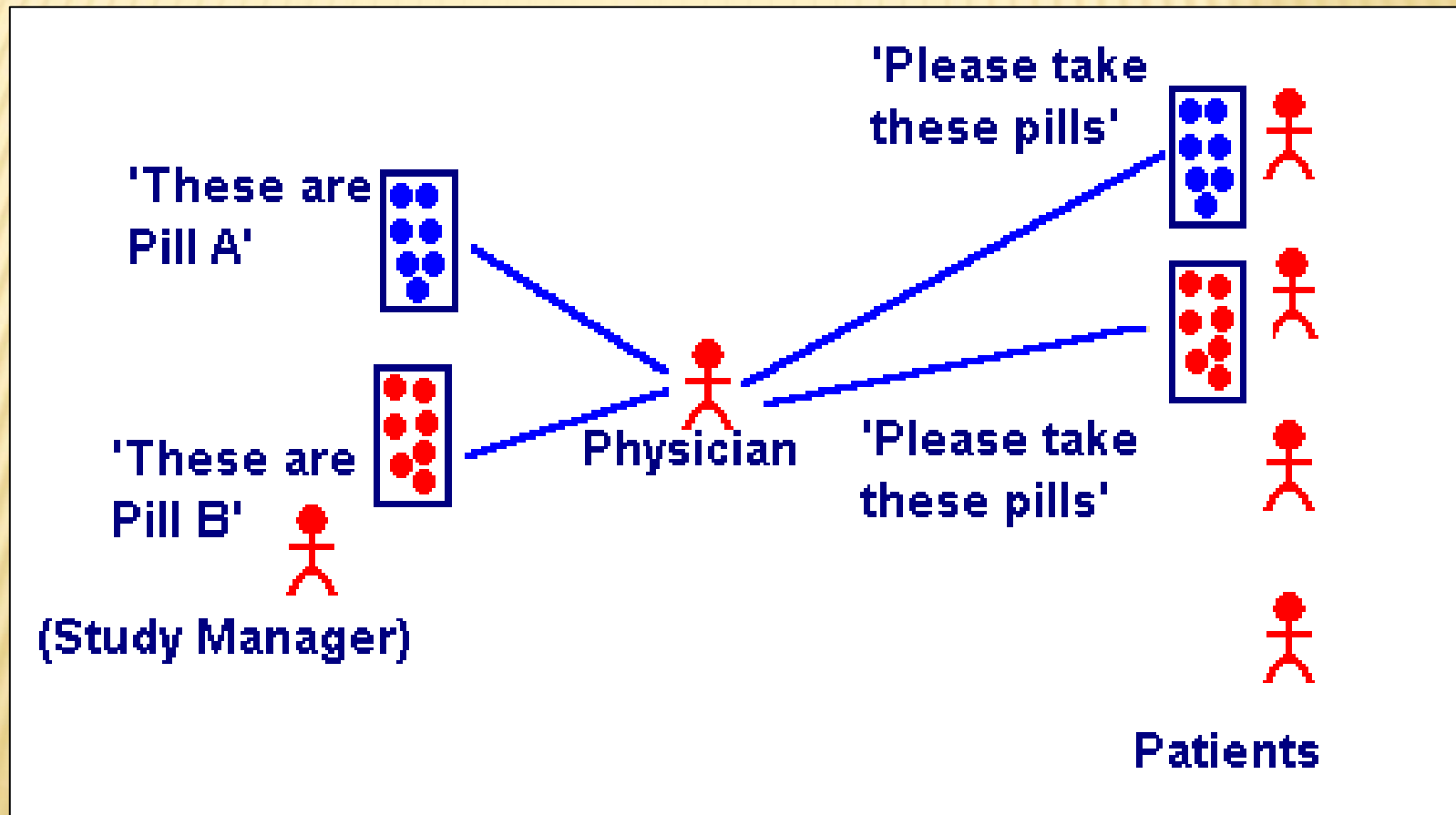
(Randomized Controlled Studies)



隨機對照試驗

(Randomized Controlled Studies)

- × 雙盲(The double blind method):

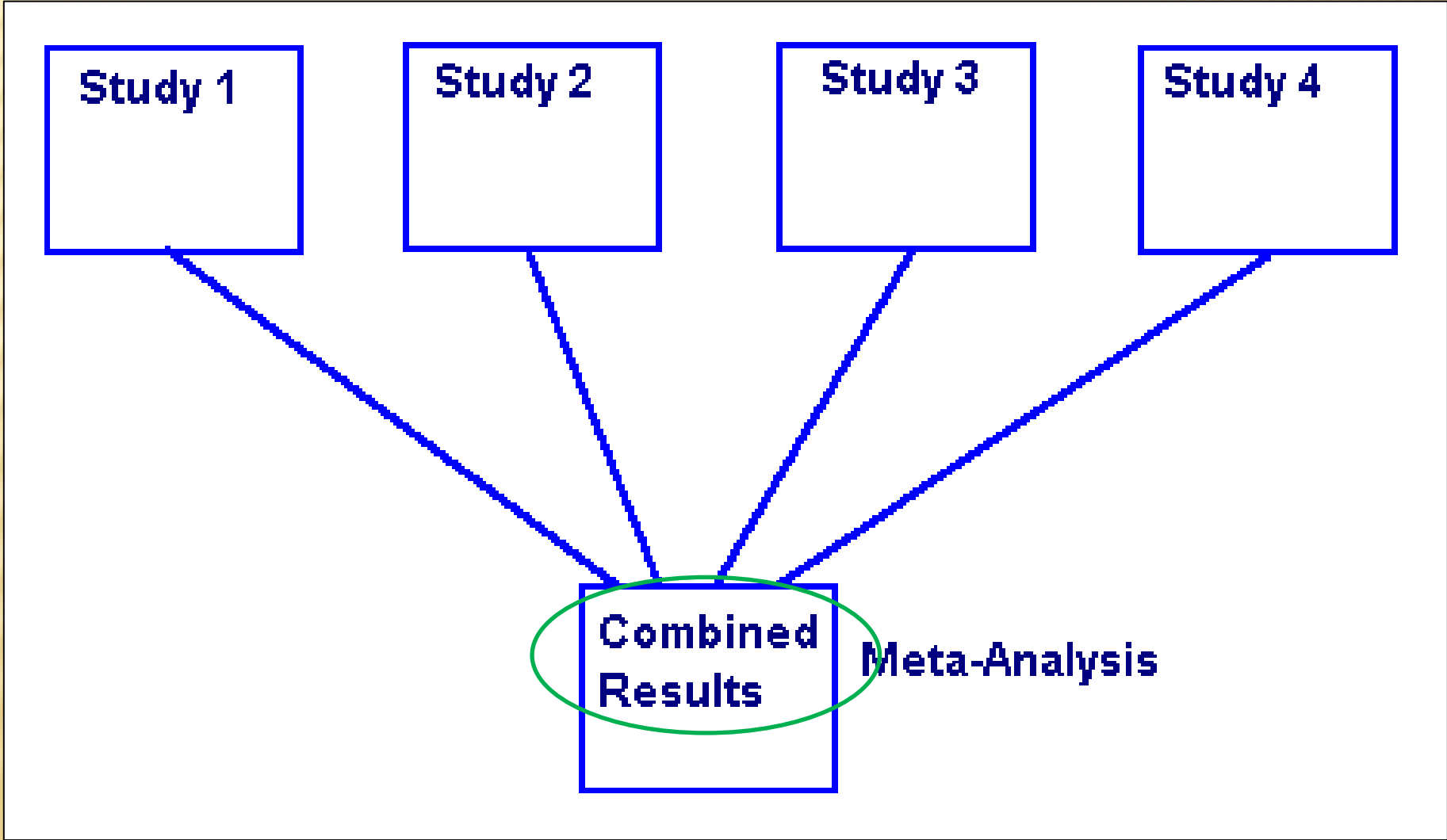


系統性回顧 (Systematic Reviews)

✦ 研究方法:

1. 集合多個**目的和方法相近**的研究整合在一起進行分析。
2. 若有將各研究的結果**合併進行統計**則稱為**統合分析 (meta-analysis)**。

系統性回顧 (Systematic Reviews)



系統性回顧 (Systematic reviews)

- ✘ Traditional review 與 systematic review 不同之處:

Systematic	Traditional
全文只探討一個明確的問題	文章探討不只一個問題
詳細列出文獻搜尋方法	沒有列出文獻搜尋方法
詳細列出納入文獻的條件	沒有列出納入文獻的條件
將納入文獻整合起來，若將其結果以統計之方法分析稱統合分析(meta-analysis)	沒有將納入文獻整合起來

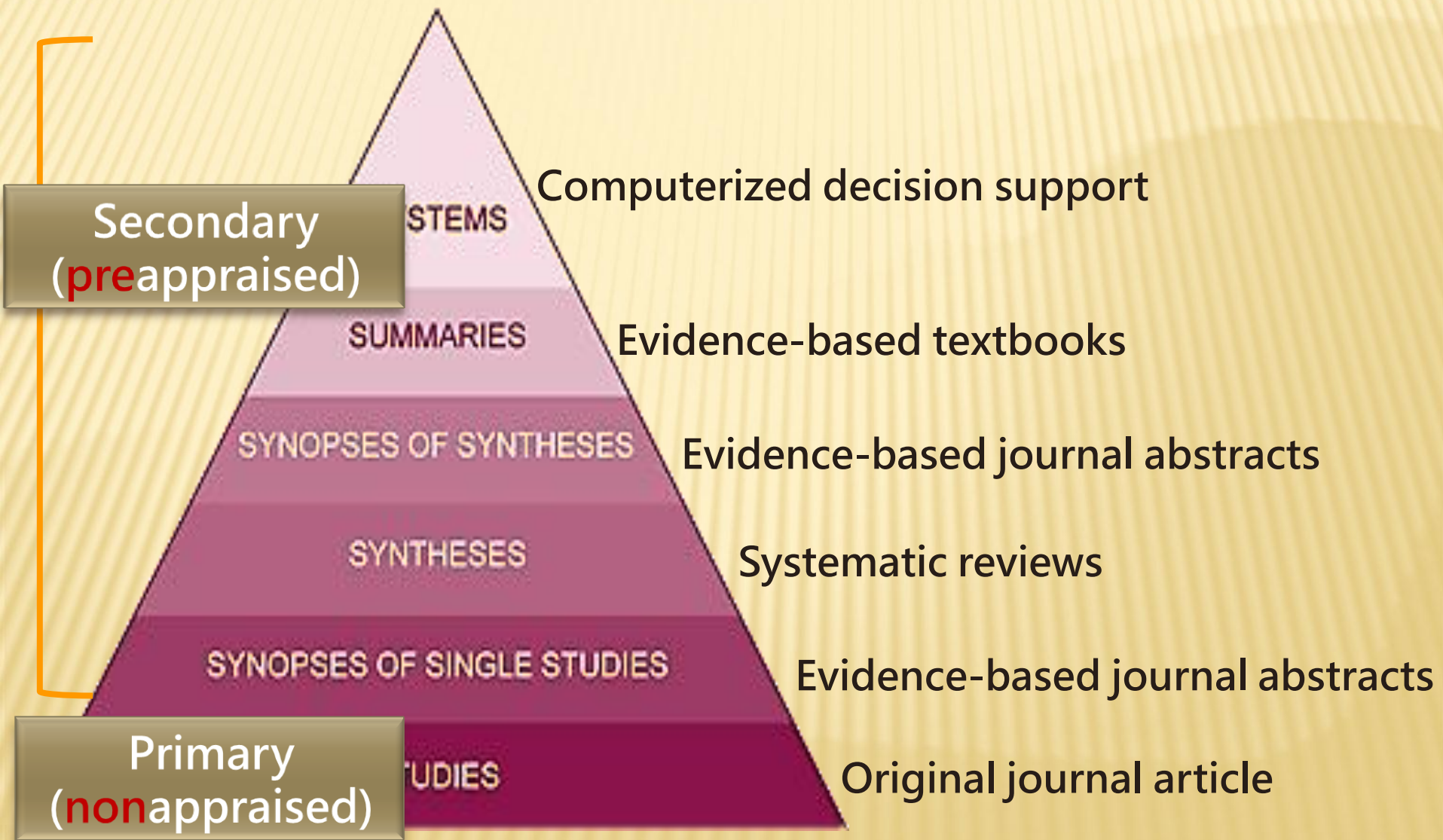
依據臨床問題尋找最佳文獻證據



Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

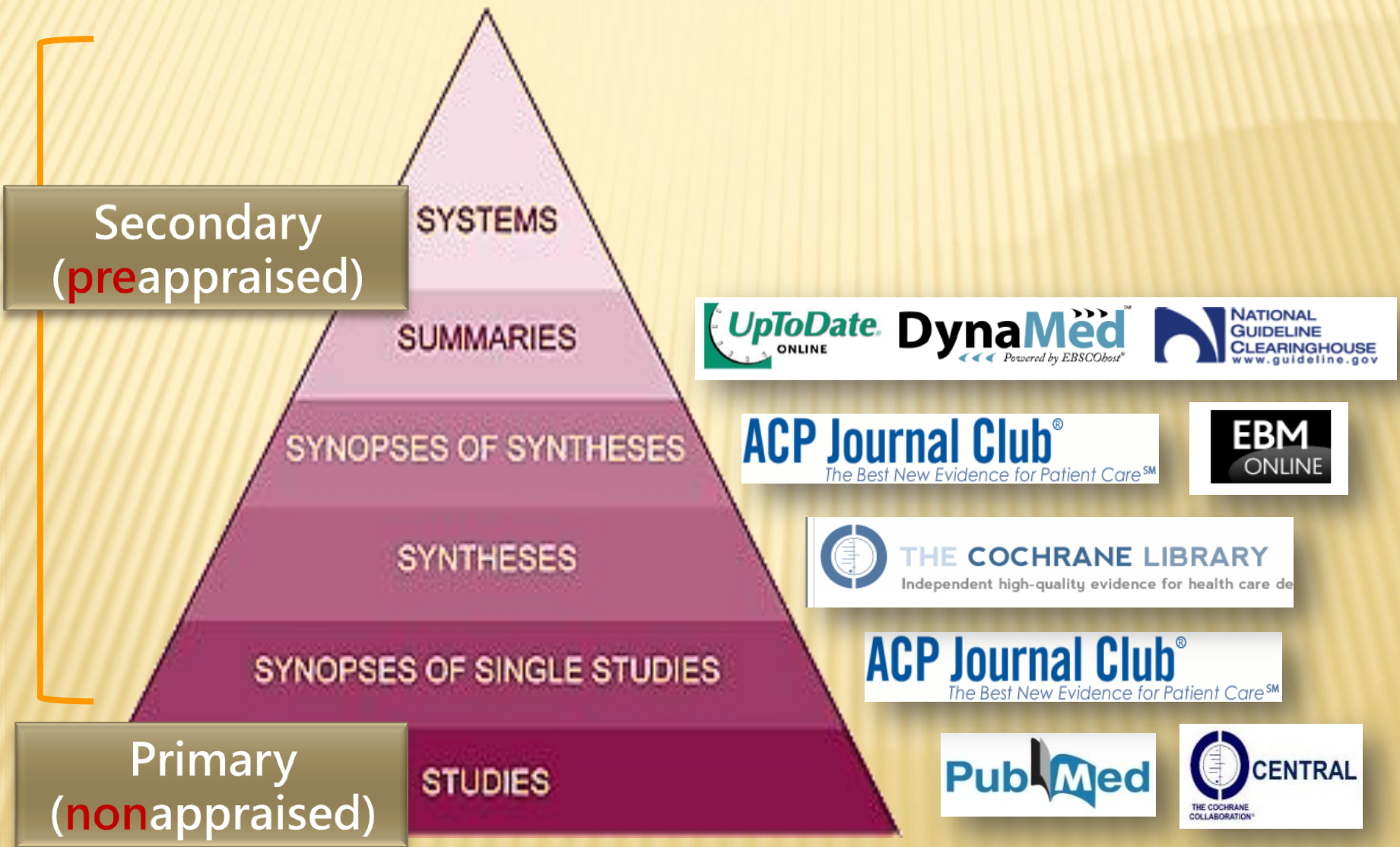
Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this 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 or randomized trials	Randomized trial	Non-randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

實證資源：6S



Modified from Ann Intern Med. 2009 Sep 15;151(6):JC3-2, JC3-3.

實證資源：6S



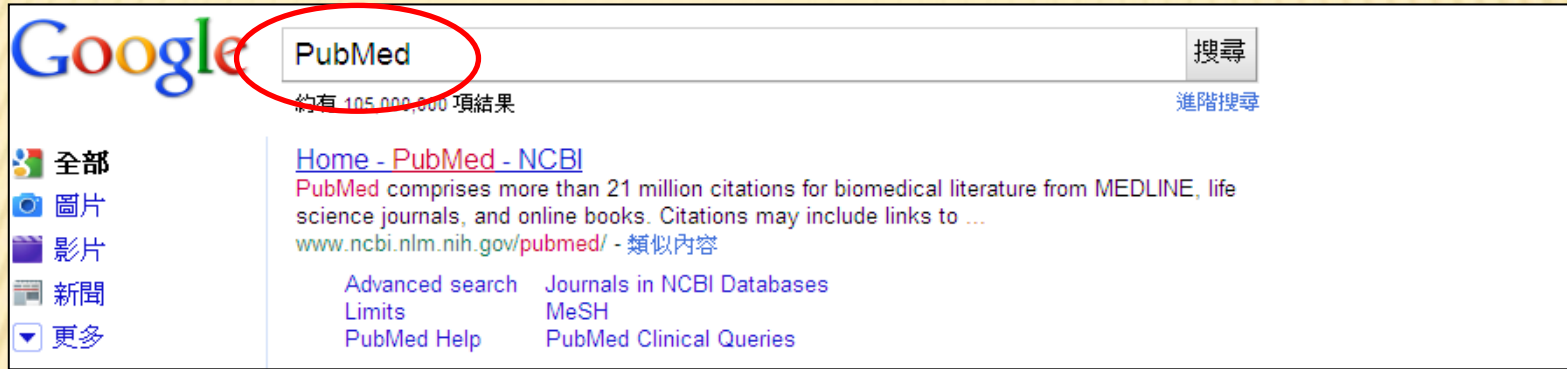
Modified from Ann Intern Med. 2009 Sep 15;151(6):JC3-2, JC3-3.

同義字的設定

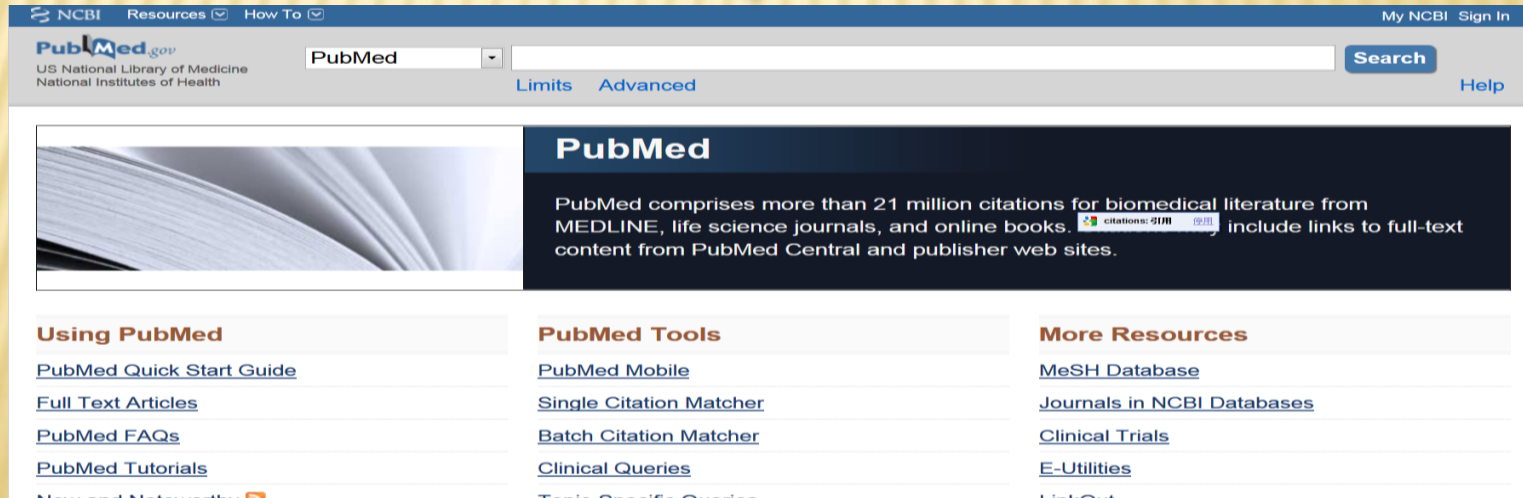
× 增加搜尋的敏感度:

原始單字	同義字1	同義字2
P (OR	OR) AND
I (OR	OR) AND
C (OR	OR) AND
O (OR	OR) AND

PubMed檢索



A screenshot of a Google search interface. The search bar contains the text "PubMed", which is circled in red. To the right of the search bar is a button labeled "搜尋" (Search). Below the search bar, it shows "約有 105,000,000 項結果" (About 105,000,000 results) and a link for "進階搜尋" (Advanced Search). On the left side, there are navigation links: "全部" (All), "圖片" (Images), "影片" (Videos), "新聞" (News), and "更多" (More). The main search results area shows a link for "Home - PubMed - NCBI" with a description: "PubMed comprises more than 21 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to ...". Below this, there are several links: "Advanced search Limits PubMed Help", "Journals in NCBI Databases MeSH PubMed Clinical Queries", and "www.ncbi.nlm.nih.gov/pubmed/ - 類似內容" (Similar content).



A screenshot of the PubMed website. The top navigation bar includes "NCBI Resources How To" and "My NCBI Sign In". The main header features the "PubMed.gov" logo, "US National Library of Medicine National Institutes of Health", a search bar with "PubMed" entered, and a "Search" button. Below the search bar are links for "Limits" and "Advanced". The main content area has a large image of a book and a heading "PubMed" with a description: "PubMed comprises more than 21 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full-text content from PubMed Central and publisher web sites." Below this, there are three columns of links: "Using PubMed" (PubMed Quick Start Guide, Full Text Articles, PubMed FAQs, PubMed Tutorials, New and Noteworthy), "PubMed Tools" (PubMed Mobile, Single Citation Matcher, Batch Citation Matcher, Clinical Queries, Topic Specific Queries), and "More Resources" (MeSH Database, Journals in NCBI Databases, Clinical Trials, E-Utilities, LinkOut).

PubMed檢索

✘ 檢索技巧:

◆ 布林邏輯(Boolean)：

AND、**OR**、**NOT** 需大寫，二個以上加「()」由左算到右、加括弧的先運算。

如：antiplatelet **AND** (aspirin **OR** clopidogrel)

◆ 切截(Truncate)：將 * 放在字尾進行模糊查詢。

例：obes*：obese, obesity...

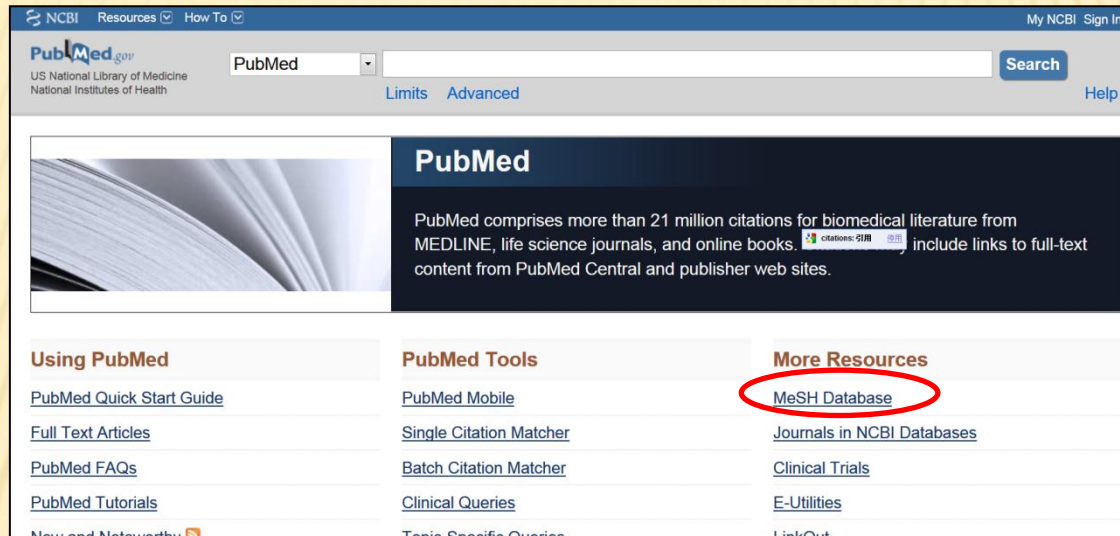
如結果超過六百個變化字，系統將出現警示語。

◆ 單字與片語：

用雙引號” ” 讓系統將多個關鍵字視為片語

lung cancer與” lung cancer”

PubMed - Mesh Database 檢索



✘ Medical Subject Headings :

- ◆ 醫學標題表之簡稱。是美國國家醫學圖書館(NLM)針對生物醫學資料所整理出的主題詞彙。
- ◆ 對同一概念採用固定的詞彙表達方式，以達到控制詞彙目的，方便生物醫學領域的學者或從業人員彼此間的溝通。

PubMed - Mesh Database 檢索

NCBI Resources ▾ How To ▾

MeSH MeSH ▾ cancer

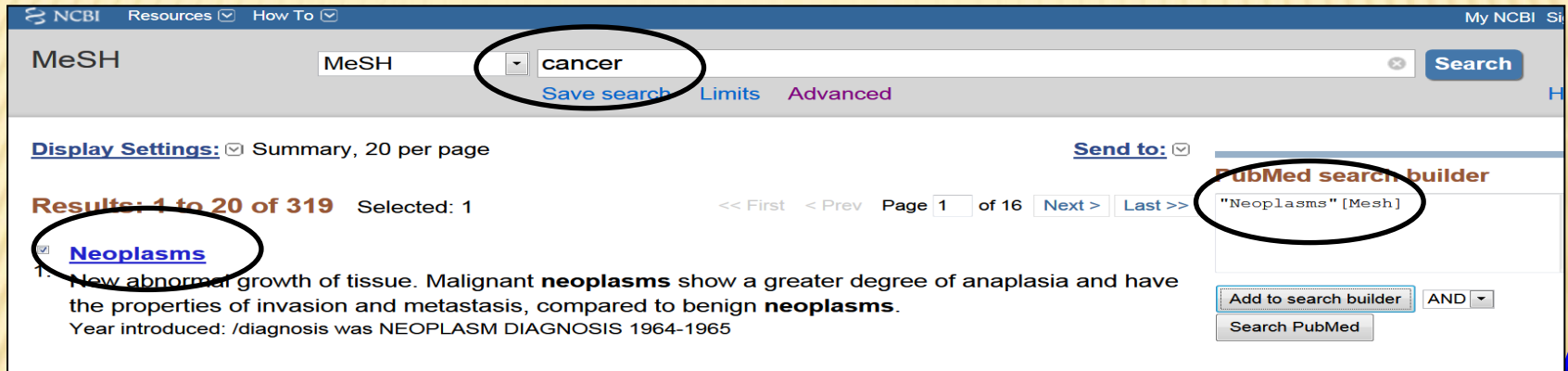
[Save search](#) [Limits](#) [Advanced](#)

[Display Settings:](#) Summary, 20 per page [Send to:](#)

Results: 1 to 20 of 319 << First < Prev Page 1 of 16 Next > Last >>

- [Neoplasms](#)
 1. New abnormal growth of tissue. Malignant **neoplasms** show a greater degree of anaplasia and have the properties of invasion and metastasis, compared to benign **neoplasms**.
Year introduced: /diagnosis was NEOPLASM DIAGNOSIS 1964-1965
- [Early Detection of Cancer](#)
 2. Methods to identify and characterize **cancer** in the early stages of disease and predict tumor behavior.
Year introduced: 2009
- [Cancer Care Facilities](#)
 3. Institutions specializing in the care of **cancer** patients.

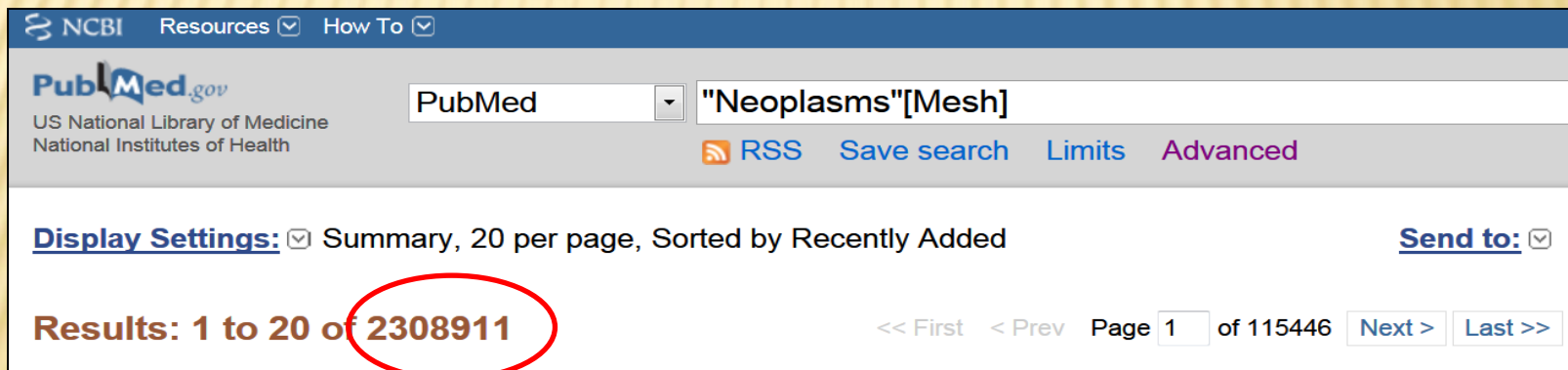
使用MeSH連接PubMed搜尋之文獻篇數



MeSH search interface showing the search term "cancer" selected in the MeSH dropdown menu. The search results display "Neoplasms" as the first result. A "PubMed search builder" sidebar is visible on the right, showing the selected term "Neoplasms" [Mesh] and options to "Add to search builder" and "Search PubMed".

MeSH search results for "cancer":

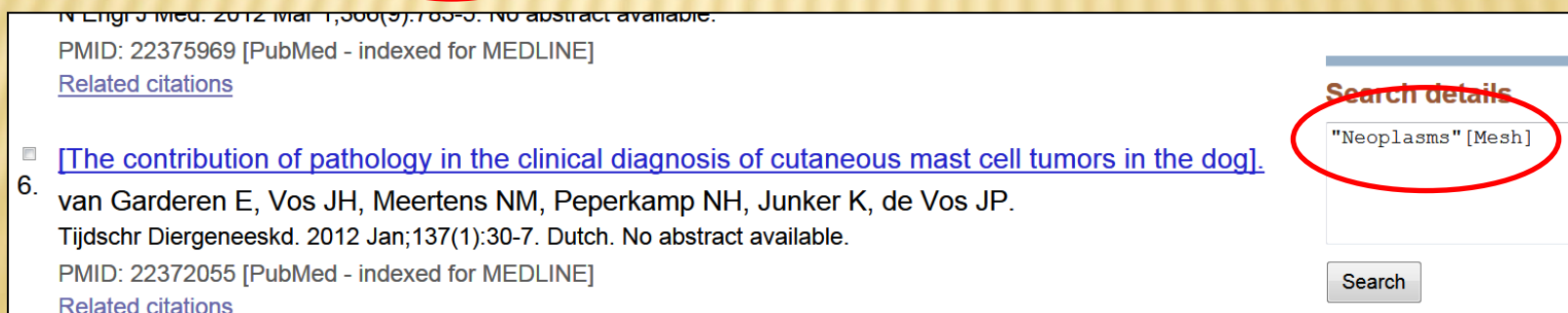
- 1. [Neoplasms](#)
New abnormal growth of tissue. Malignant **neoplasms** show a greater degree of anaplasia and have the properties of invasion and metastasis, compared to benign **neoplasms**.
Year introduced: /diagnosis was NEOPLASM DIAGNOSIS 1964-1965



PubMed search interface showing the search term "Neoplasms"[Mesh] entered in the search box. The search results display "Results: 1 to 20 of 2308911".

PubMed search results for "Neoplasms"[Mesh]:

Results: 1 to 20 of **2308911**



PubMed search results for "Neoplasms"[Mesh] showing a list of articles. The first article is "The contribution of pathology in the clinical diagnosis of cutaneous mast cell tumors in the dog".

Search results for "Neoplasms" [Mesh]:

- 1. [The contribution of pathology in the clinical diagnosis of cutaneous mast cell tumors in the dog.](#)
van Garderen E, Vos JH, Meertens NM, Peperkamp NH, Junker K, de Vos JP.
Tijdschr Diergeneeskd. 2012 Jan;137(1):30-7. Dutch. No abstract available.
PMID: 22372055 [PubMed - indexed for MEDLINE]
[Related citations](#)

直接使用PubMed搜尋之文獻篇數

NCBI Resources How To

PubMed.gov
US National Library of Medicine
National Institutes of Health

PubMed

RSS Save search Limits Advanced

Display Settings: Summary, 20 per page, Sorted by Recently Added **Send to:**

Results: 1 to 20 of 2612419 << First < Prev Page 1 of 130621 Next > Last >>

[Persian Gulf states outline regional approach to tackle cancer.](#)

[Current research trends](#)

Madaras B, Horváth Z, Láng I, Kásler M, Borbély K.
Magy Onkol. 2012 Mar;56(1):23-9. Epub 2011 Sep 28. Hungarian.
PMID: 22403759 [PubMed - in process]
[Related citations](#)

[Bilateral adrenal pheochromocytoma with a germline L790F mutation in the RET oncogene.](#)

8. Min JW, Park YJ, Kim HJ, Chang MC.
J Korean Surg Soc. 2012 Mar;82(3):185-9. Epub 2012 Feb 27.
PMID: 22403753 [PubMed - in process]

Search details

"neoplasms" [MeSH Terms]
OR "neoplasms" [All Fields]
OR "cancer" [All Fields]

Search See more

直接使用PubMed搜尋之文獻篇數

- ✘ 若不需要搜尋MeSH term，用 " " 雙引號括號起來即可：

The screenshot shows the PubMed search interface. At the top, the search bar contains the term "cancer" in quotes, which is circled in red. Below the search bar, the results are displayed. The text "Results: 1 to 20 of 1124677" is circled in red. The first result is "UH Cancer Center Hotline: Thyroid Cancer: Rising Incidence and Ethnic Disparities." with a sub-entry "1. Vogel CW. Hernandez BY. Morita SY. Wilkens LR.".

The screenshot shows the search details for the term "cancer". The search term "cancer" [All Fields] is circled in red. Below the search bar, the search results are displayed. The first result is "Harbouring HCV Replicon and in Replicon-Cured Cells." with authors "Okoli AS, Raftery MJ, Mendz GL." and publication information "Int J Hepatol. 2012;2012:501671. Epub 2012 Jul 30." The PMID is 22900193 and it is marked as a "Free Article". The second result is "Emerging Putative Biomarkers: The Role of Alpha 2 and 6 Integrins in Susceptibility, Treatment, and Prognosis." with authors "Marthick JR, Dickinson JL." and publication information "Prostate Cancer. 2012;2012:298732. Epub 2012 Jul 31." The PMID is 22900191 and it is marked as a "Free Article".

PubMed檢索

[Show additional filters](#)

Display Settings: Summary, 20 per page, Sorted by Recently Added

Send to: [Filters: Manage Filters](#)

Text availability

Abstract available

Free full text available

Full text available

Publication dates

5 years

10 years

Custom range..

Species

Humans

Other Animals

Article types

Clinical Trial

Meta-Analysis

Practice Guideline

Randomized Controlled Trial

Trial

Review

Systematic Reviews

Results: 1 to 20 of 2670352

<< First < Prev Page 1 of 133518 Next > Last >>

[Three cases of melorheostosis with foot and ankle involvement.](#)

1. Pino AE, Temple HT.
Am J Orthop (Belle Mead NJ). 2012 Aug;41(8):E115-9.
PMID: 22900256 [PubMed - in process]

[Ethnic Disparities.](#)

2. [Unifocal Thyroid Cancer Metastasis to the Urinary Bladder: Report of a Case and Review of the Literature.](#)
Grivas N, Housianitis Z, Doukas M, Stavropoulos NE.
Case Rep Urol. 2012;2012:178915. Epub 2012 Aug 1.
PMID: 22900222 [PubMed - as supplied by publisher] **Free Article**

3. [A Rare Case of Retroperitoneal Leiomyoma.](#)

4. Mahendru R, Gaba G, Yadav S, Gaba G, Gupta C.
Case Rep Surg. 2012;2012:425280. Epub 2012 Jul 31.

[A Rare Case of Retroperitoneal Leiomyoma.](#)

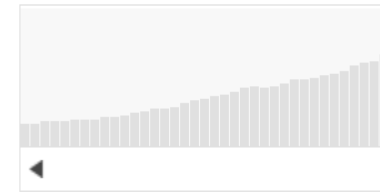
4. Mahendru R, Gaba G, Yadav S, Gaba G, Gupta C.
Case Rep Surg. 2012;2012:425280. Epub 2012 Jul 31.

Specify Custom Date Range

YYYY MM DD to YYYY MM DD

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Results by year



Related searches

breast cancer

lung cancer

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cancer stem

colorectal cancer

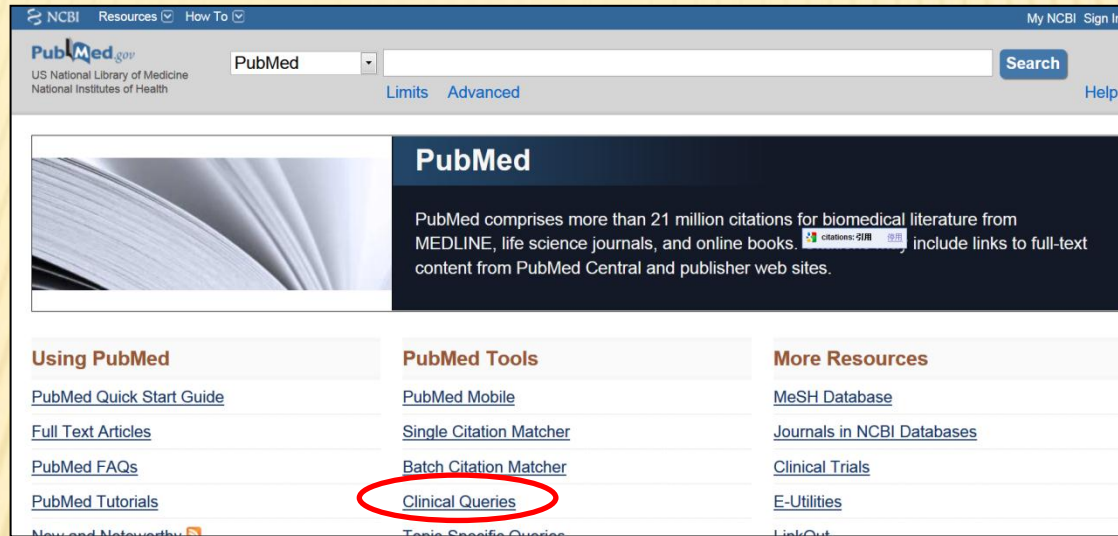
Titles with your search terms

Hallmarks of cancer: the next ge

Cancer statistics, 2012.

[CA Cancer J C

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Clinical Study Categories	Systematic Reviews	Medical Genetics
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Enter a term below and click Search to continue.

Search For:

In:

To search using field labels (e.g. heart:ti) use the [Search History](#) page.

Enter search term 1

Search All Text

AND

Enter search term 2

Record Title

AND

Enter search term 3

Author

AND

Enter search term 4

Abstract

AND

Enter search term 5

Keywords

Search

Go directly to Search History

Restrict Search by Product

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SEARCH TIPS

Tip No. 1:

Boolean operators AND, OR, and NOT can be selected from the pulldown selection boxes or entered directly within the search text boxes. Use parentheses to separate components when entering complex search directly in text box with mixed Boolean operators.

Example: *(colchicine AND liver) AND (fibrosis OR cirrhosis)*

Tip No. 2:

The AND operator is used by default between search terms. The string *brain stem* will match records where both words are included in any order or proximity.

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[Search by qualifier alone](#)

Search for a MeSH descriptor

Enter MeSH term: [Go To MeSH Trees](#)

[Thesaurus](#)

[Definition](#)

SEARCH TIPS

Using the MeSH Search

Find records using the MeSH thesaurus search through the following methods.

Thesaurus Search Options

Use the thesaurus to find a term for a MeSH Tree Search. Enter word in text box and click on Thesaurus to display the complete index of all MeSH descriptors that include the word. Click on an index term to select it for a MeSH Tree Search (see below).

MeSH Tree Search Options

Enter a term in the text box

實證醫學資料庫

✘ 考科藍實證醫學資料庫:

為推廣實證醫學於臨床上之應用，國衛院在全國醫學中心與醫學會的支持下，正持續進行**CDSR摘要**中文翻譯，成果已同步公布於國衛院考科藍實證醫學資料庫網站

<http://clc.nhri.org.tw/admin/clcmain1.aspx>，

也可由國衛院-實證臨床指引平台連結。

施行實證醫學的五大步驟

- × Ask: 將臨床情境形成一個可回答的臨床問題
- × Acquire: 尋找最佳的文獻證據
- × **Appraise: 嚴格評讀文獻** 
- × Apply: 應用於病人身上
- × Audit: 對過程進行稽核

文獻評讀三部曲

- × **V**: Validity/Reliability 效度/信度
我們能相信這篇文獻嗎?
- × **I**: Importance/Impact 重要性
我們相信了，但文獻的結論重要嗎?
- × **P**: Practice/Applicability 臨床適用性
這個結論可以應用在我們所有的病患嗎?

評讀工具

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[EBM Calculators](#)

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Critical Appraisal

This section contains useful tools and downloads for the critical appraisal of medical evidence. Example appraisal sheets are provided together with several helpful examples. Below, you can download our calculators, as well as our PC-based software tool **CATmaker**.



Critical Appraisal Sheets

- [Systematic Review Critical Appraisal Sheet](#)
- [Diagnostic Critical Appraisal Sheet](#)
- [Prognosis Critical Appraisal Sheet](#)
- [RCT Critical Appraisal Sheet](#)
- [PICO Critical Appraisal Sheet \(PDF\)](#)
- [PICO Critical Appraisal Sheet \(MS-Word\)](#)
- [Educational Prescription Critical Appraisal Sheet \(PDF\)](#)

Calculators

All-purpose 2x2 Table

The "CATmakers Scratching Post"
[Download](#) (Adobe Flash format)

Interactive Nomogram

Generates post-test probabilities from

Explanations & Examples

- [Pre-test probability](#)
- [SpPin and SnNout](#)
- [Likelihood Ratios](#)
- [NNTs](#)

CATmaker

CATmaker is a computer-assisted critical appraisal tool, which helps you create Critically



Over **1000** healthcare professionals from all over the world have trained at the CEBM in Oxford.

Latest courses and workshops

Teaching Evidence-based Practice
(5 days) *3rd-7th September 2012*
[More Information](#)

Workshop on Evidence-Based Practice
(1 day) *30th November 2012*

評讀工具



Critical Appraisal Skills Programme

Making sense of evidence

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Workshops

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News

Welcome to the **CASP** UK Website

The Critical Appraisal Skills Programme helps people to find and interpret the best available evidence from health research.

It is part of an international network that shares a commitment to self-directed learning and promoting better understanding of science.

On this website you can find out about the CASP approach, download the CASP checklists, and find out what sort of workshops we offer to help improve your appraisal skills.

You can even commission one that is custom designed for your needs.

Introduction by Amanda Burls:



➔ **Checklists**

Download the CASP critical appraisal checklists for:

- [Randomised Controlled Trials](#)
- [Systematic Reviews](#)
- [Cohort Studies](#)
- [Case-Control Studies](#)
- [Qualitative Studies](#)

➔ **Workshops**

The 2012 CASP International Training Week was held at Kellogg College from 16th-20th April. We are in the process of arranging the next training week, which is to be held from **18th-22nd March 2013**. If you would like to be notified when booking is open, please let us know via the 'contact us'

➔ **Network News**

CASP example used in this training and support resource for INVOLVE. [Click here](#) for more details.

24th May 2012: Webinar – Critical Appraisal Skills Programme's (CASP) Suite of Critical Appraisal Tools with the National Collaborating Centre for Methodology and Tools (NCCMT) is

統計名詞解釋

× P 值：

- (1) p 值是**機率**，以檢定統計量(test statistic)計算而得，用以衡量樣本資料支持 (或不支持) 虛無假設的程度。其值介於 0 與 1 之間。
- (2) 我們常應用的 P 值，是比較兩組是否有顯著的差異，但 P 值深受樣本數(sample size)影響，只要樣本數夠大，就算只有些微差異也變得顯著，**統計學上的顯著不一定代表臨床上有重大顯著意義**。

統計名詞解釋

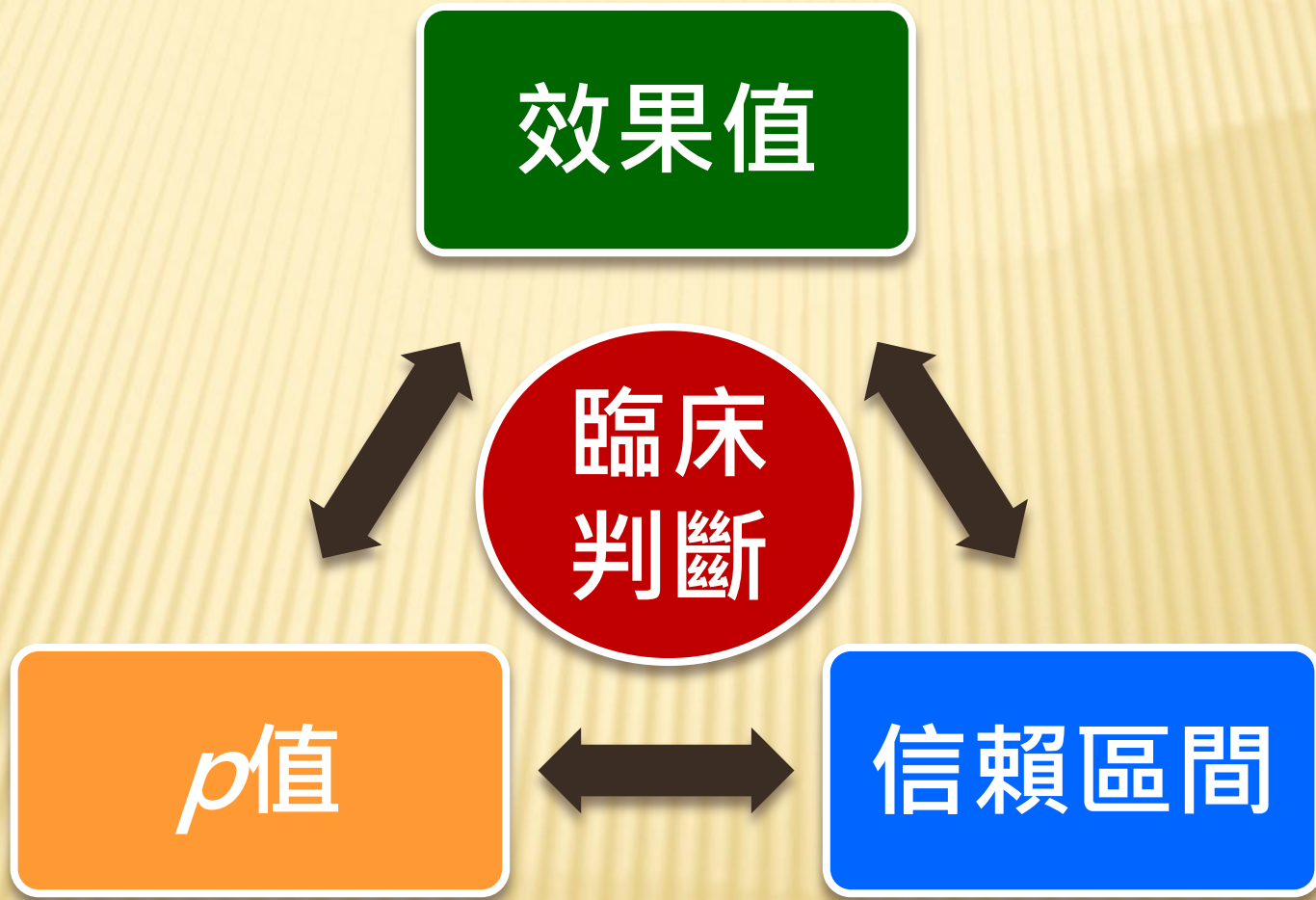
✦ 效果值 (effect size):

- (1) 是一種標準化的效果數據呈現，可讓論文讀者客觀的評估治療效果。
- (2) 讓讀者用以評估RCT結果的臨床意義。
- (3) 可用於設計/ 執行RCT時power的計算。
- (4) 可用於meta-analysis of RCTs的結果呈現。

統計名詞解釋

- ✘ 95%信賴區間 (95% Confidence interval (CI)):
指在某一信賴程度內，由樣本統計量所求出預期可以包括母群體的範圍，用以評估不確定性的指標。通常設為95%，代表我們有95%的信心確定母群體的真正數值會落在這個範圍內。

統計名詞解釋



隨機對照試驗評讀簡介

× Validity (信度/效度):

1. 這些病人的分組是隨機分派的嗎？(randomized?)
2. 分派的方法是否保密？(allocation concealment?)
3. 分派的兩組在治療開始時的baseline是否相似？若不相似，是否用統計的方法來修正，或增加被研究者的數目？
4. 除了研究治療項目以外，其他的治療在各組間是否相同？

隨機對照試驗評讀簡介

✘ Validity (信度/效度):

5. 治療方法對病患、醫護人員、研究者是否保持盲性 (non-blinded, single blinded, double blinded, or triple blinded) ?
6. 追蹤是否完整 ? (follow-up duration) (失聯者少 20% 為佳)
7. 分析時是否利用intention-to-treat analysis分析 ? (vs. per protocol analysis)

隨機對照試驗評讀簡介

- ✘ 治療意向分析法 (intention to treat analysis, **ITT**)：
是指研究結果分析應包含原先列入研究之所有對象之結果，不論其最後是否背離原始之分組治療模式，雖然這些背離的個案可能會影響各組之結果，但**此種方式保留了隨機取樣之精神**，且其結果較可能代表在原始設計情況下病人接受某種治療之真正的效度。
楊培銘 何謂實證醫學? 台灣內科醫學會八十九年會員大會學術演講論文
- ✘ 依計畫書分析法 (per-protocol analysis, **PP**)：
排除未遵守試驗計劃書、中途退出之受試者，僅納入符合試驗計劃書執行方式的受試者進行資料分析。

隨機對照試驗評讀簡介

	死亡人數	存活人數	總計
治療組	10	90	100
對照組	15	85	100
總計	25	175	200

- ✘ 治療組死亡率 (EER) : $10/100=0.1=10\%$
- ✘ 對照組死亡率 (CER) : $15/100=0.15=15\%$
- ✘ 相對風險比 (RR) : $EER/CER=0.1 / 0.15=0.67$
- ✘ 絕對風險下降率 (ARR) : $|CER-EER| = |15\%-10\%| = 5\%$
- ✘ 相對風險下降率 (RRR) : $ARR/CER=5\%/15%=0.33=33\%$
- ✘ 益一治療數 (NNT) : $1/ARR=1/5\%=20$

隨機對照試驗評讀簡介

- ✘ **NNT (number needed to treat) 益一治療**
:=1/ARR

使一位病人達到實驗組治療之有益結果（或預防產生一個不良結果）所需治療的病人數目。

- ✘ **NNH (number needed to harm) 害一治療**
:=1/ARI

對多少病人數目進行實驗組療法，與對照組做比較後，會有多一個病人產生不良副作用。

RRR v.s. ARR v.s. NNT

- × 相對風險下降率 (RRR)
- × 絕對風險下降率 (ARR)
- × 益一治療數 (NNT)

	CER	EER	RRR	ARR	NNT
治療 1	50%	30%	40% <small>= (50-30) / 50</small>	20%	5 人
治療 2	5.0%	3.0%	40%	2.0%	50 人
治療 3	0.5%	0.3%	40%	0.2%	500 人

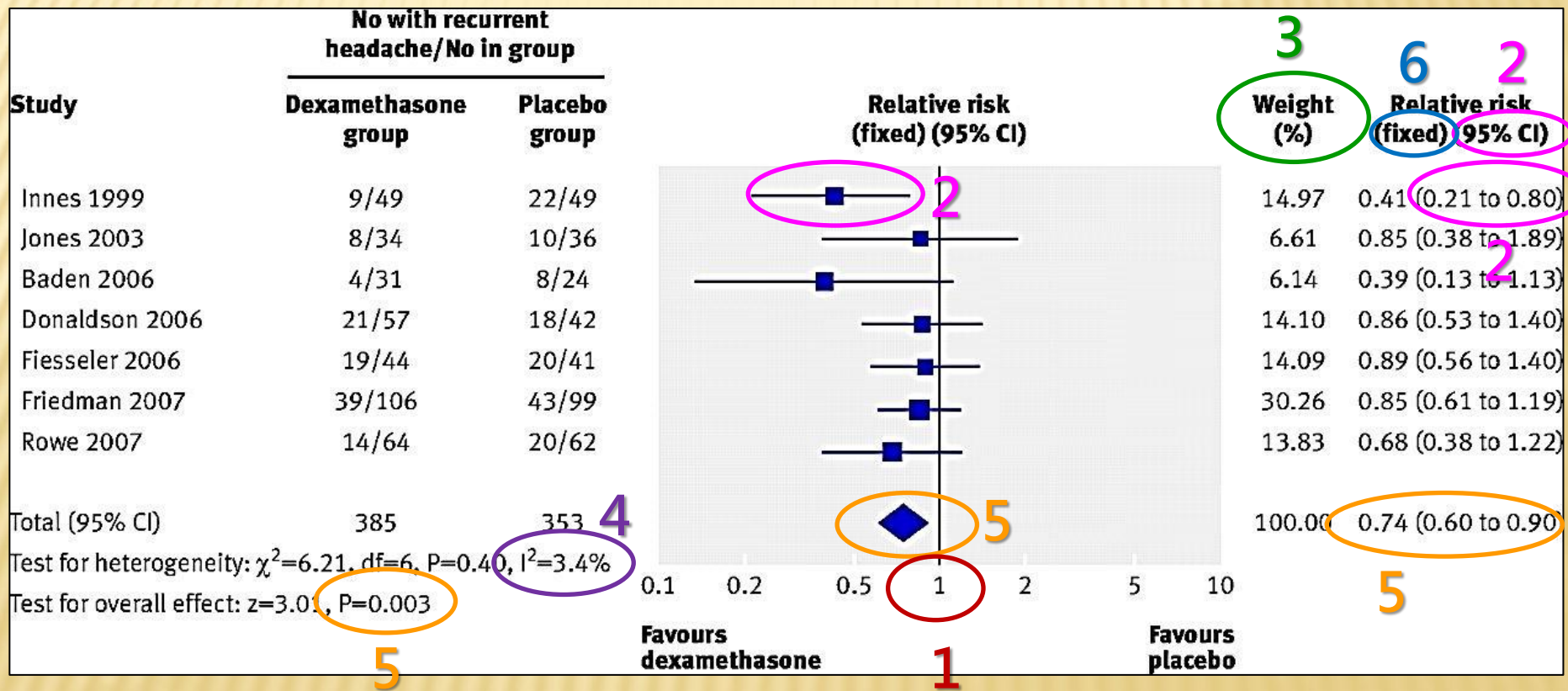
統合分析評讀簡介

× Validity (信度/效度):

1. 這篇文獻探討的問題為何?
2. 沒有遺漏重要的文獻?
3. 選擇文獻的準則適當?
4. 選擇的文獻有足夠的效度而能回答所問的問題?
5. 各研究的結果相似?

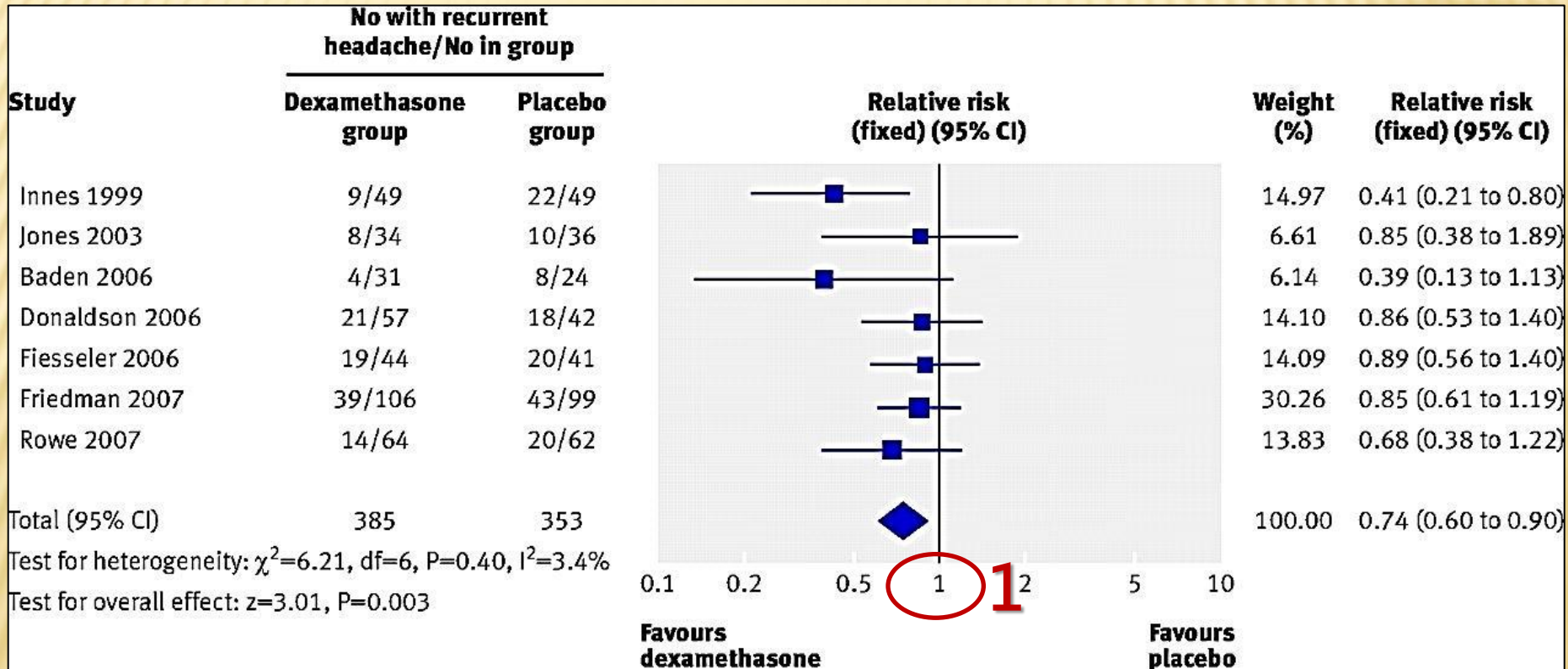
統合分析評讀簡介

✦ 數狀圖 (Forest plot)判讀:



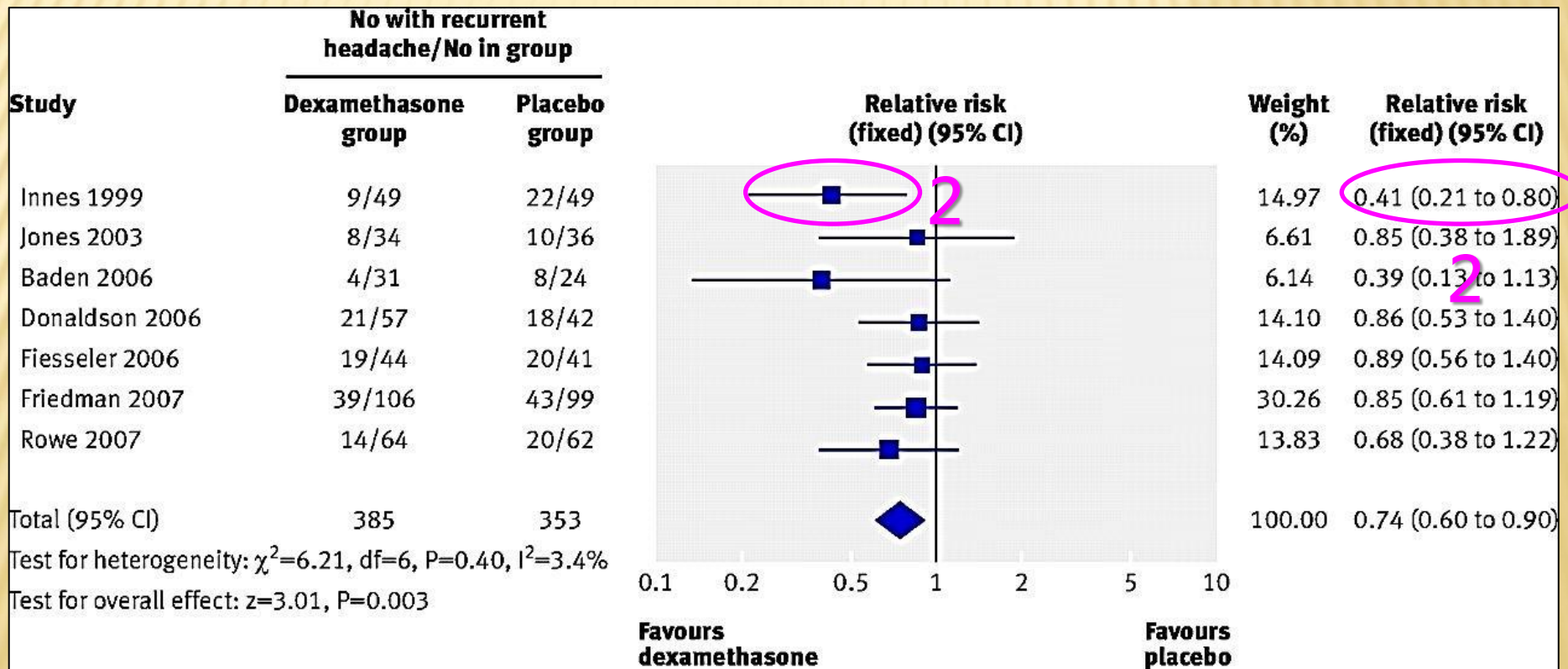
統合分析評讀簡介

1. Line of no effect



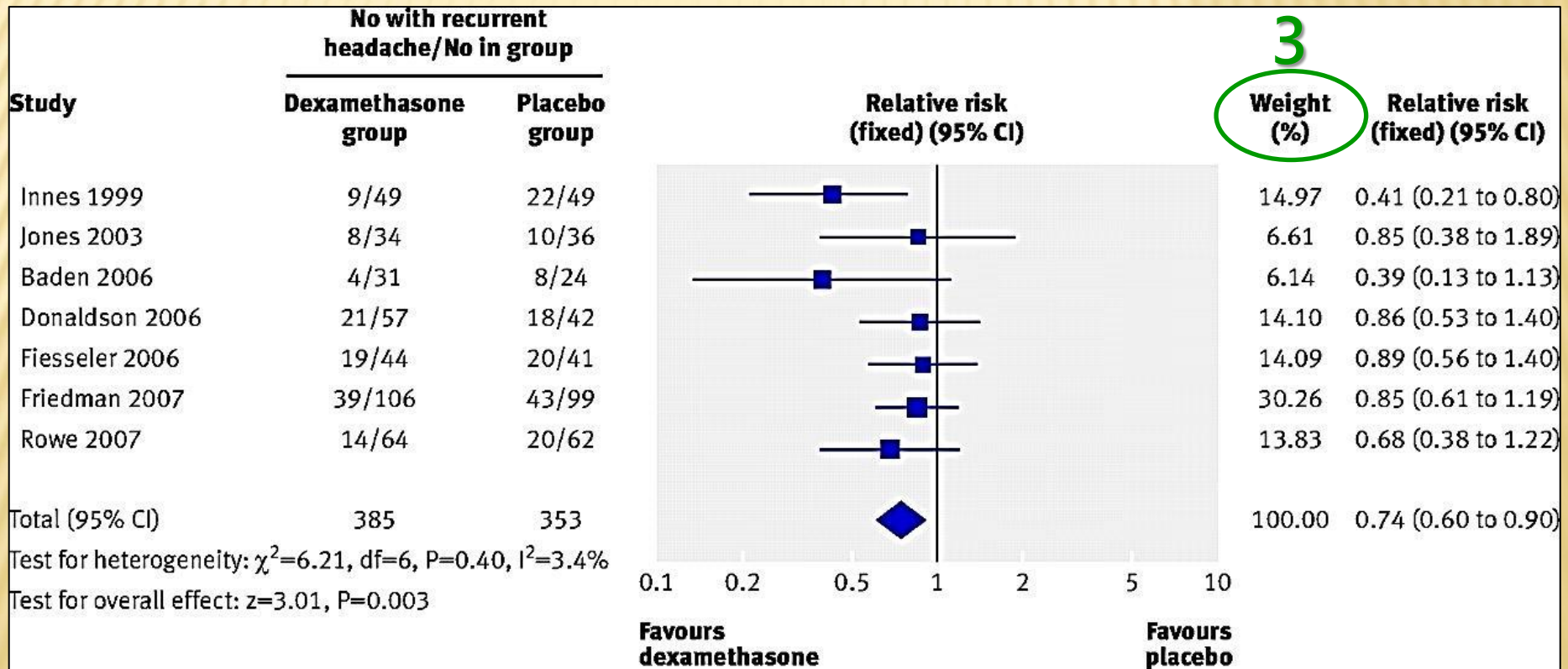
統合分析評讀簡介

2. Point estimate and 95% CI



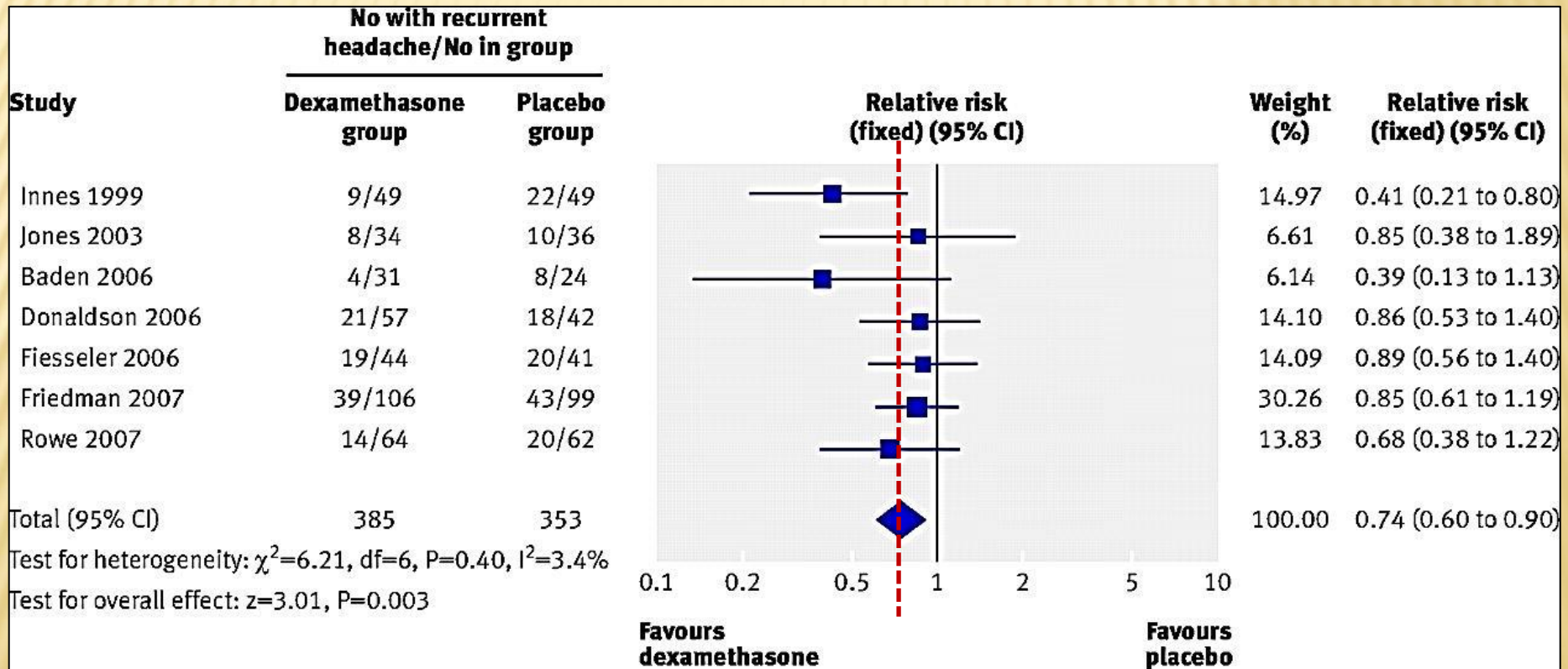
統合分析評讀簡介

3. Influence of studies on overall meta-analysis



統合分析評讀簡介

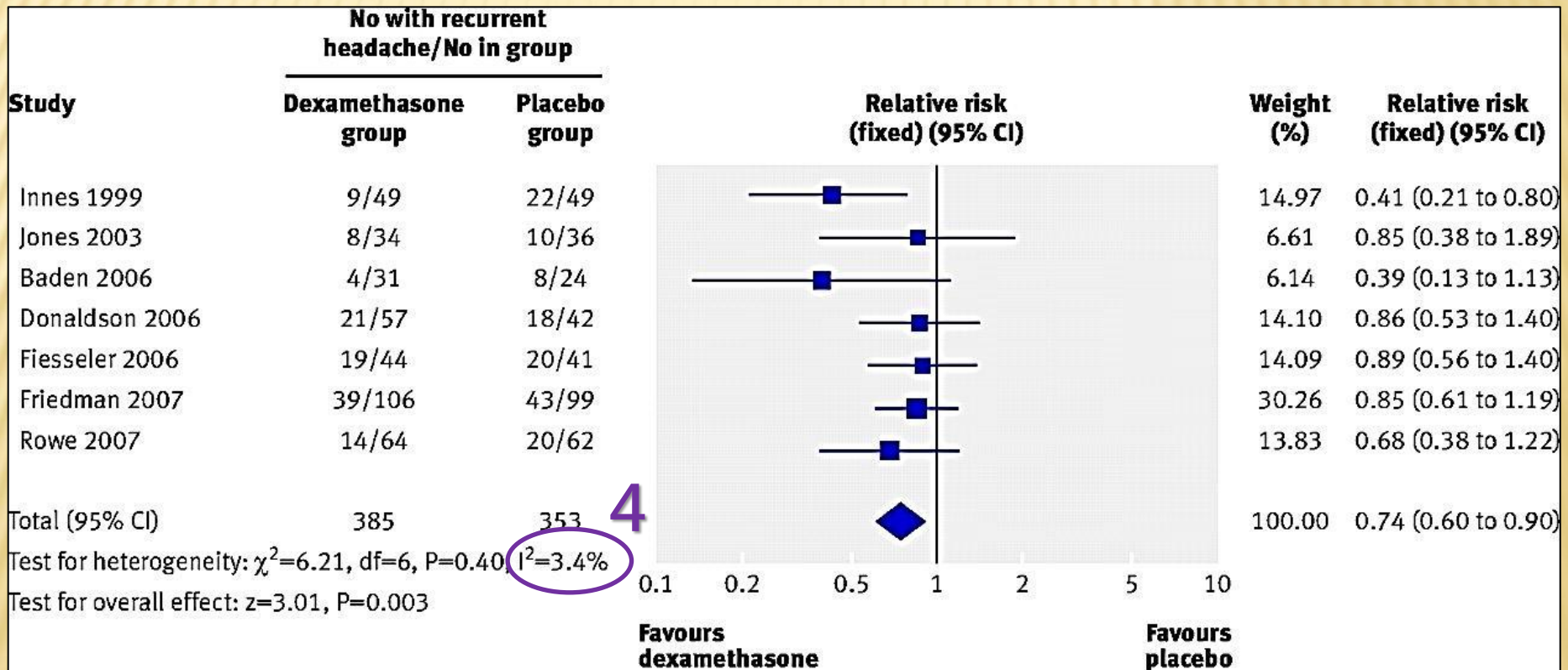
✘ Eyeball test



統合分析評讀簡介

4. Heterogeneity (I^2) = diversity between studies

25%: low; 25%-50%: medium; > 50%: high



統合分析評讀簡介

- × 0%~40%: might **not** be important
- × 30%~60%: may represent **moderate** heterogeneity
- × 50%~90%: may represent **substantial** heterogeneity
- × 75%~100%: **considerable** heterogeneity

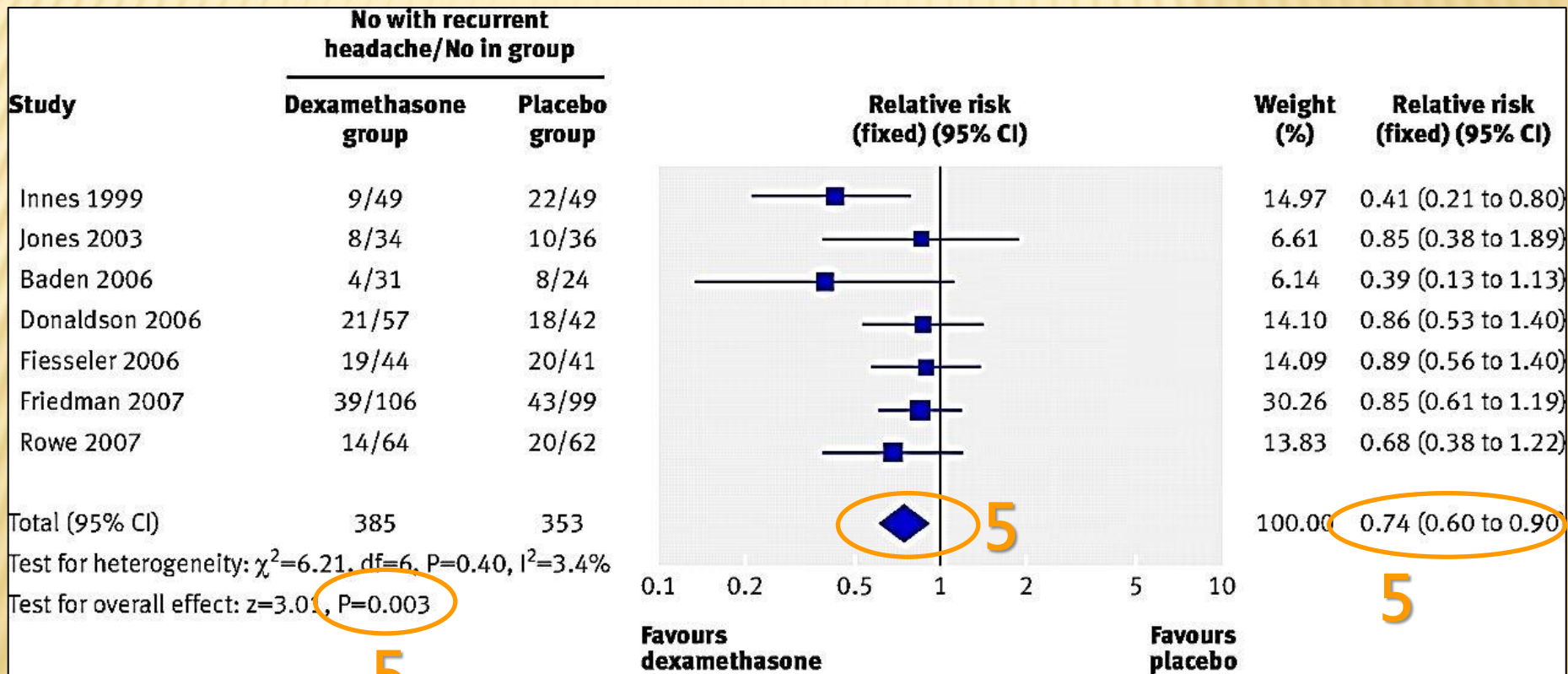
Deeks JJ, Higgins JPT, Altman DG (editors). Chapter 9: Analysing data and undertaking meta-analyses. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

統合分析評讀簡介

- ✘ Cochran chi-square (Cochran Q)
 - **確定有差異** (Definite heterogeneity)
Cochran Q ($P < 0.1$)
 - **可能有差異** (Possible heterogeneity)
Cochran Q is not statistically significant
Cochran Q / degrees of freedom (Q/df) > 1
 - **有差異機會不大** (Heterogeneity unlikely)
Cochran Q is not statistically significant
Q/df < 1

統合分析評讀簡介

5. Overall effect and the *p* value



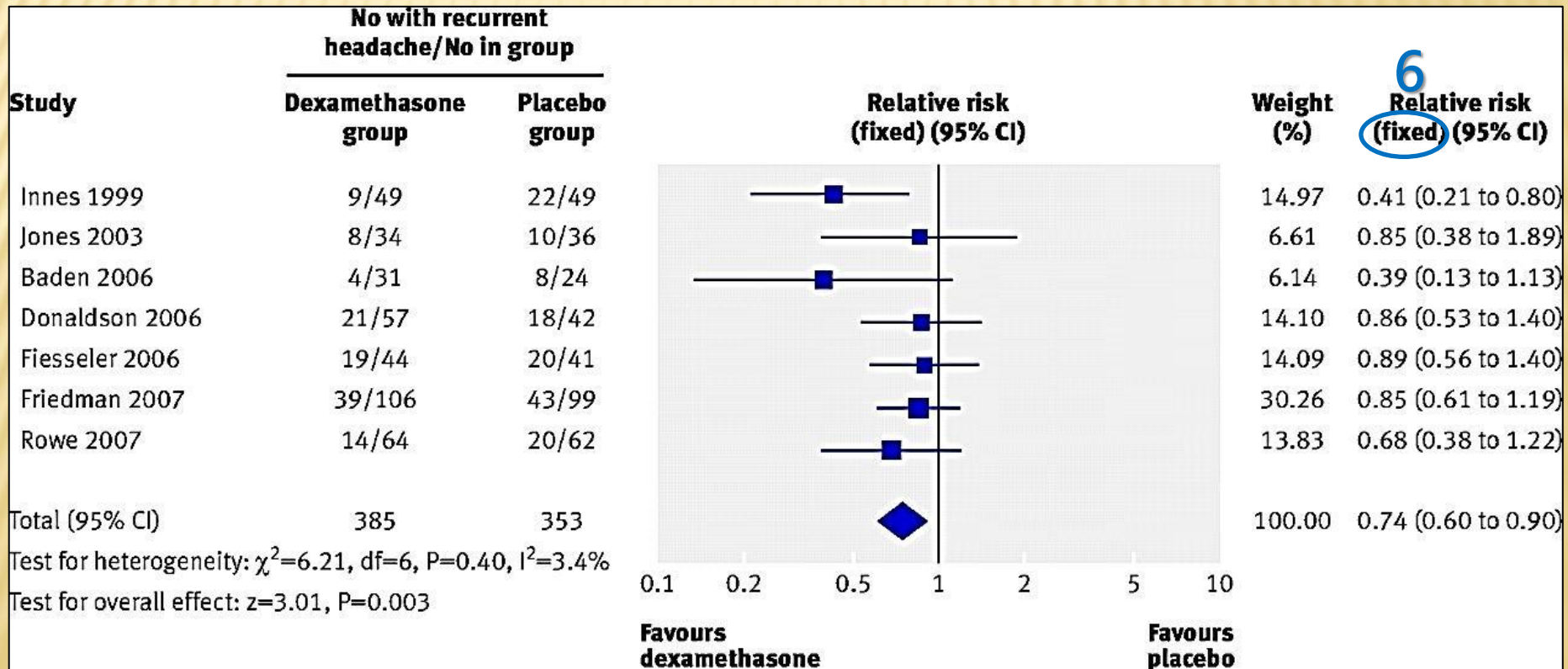
5

5

統合分析評讀簡介

6. Fix-effects model v.s. random-effects model

- ✘ 文獻間的異質性低，使用fix-effects model。
- ✘ 文獻間的異質性高，使用random-effects model。



證據等級評定



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 or randomized trials	Randomized trial	Non-randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

證據等級評定

× 等級 **Graded down** 的原因:

1. 試驗品質 (quality)
2. 結果不精確 (imprecision)
3. 間接結果 (indirectness ; study PICO與問題PICO不符合)
符合)
4. 文獻間的結果不一致 (inconsistency between studies)
5. 試驗結果之效果值 (effect size) 非常小

× 等級 **Graded up** 的原因:

試驗結果之效果值 (effect size) 大或非常大。

施行實證醫學的五大步驟

- × Ask: 將臨床情境形成一個可回答的臨床問題
- × Acquire: 尋找最佳的文獻證據
- × Appraise: 嚴格評讀文獻
- × **Apply: 應用於病人身上** **3E**
- × Audit: 對過程進行稽核

將證據應用在病患身上

- ✘ 決定要將研究結果應用到病患身上前，應該要先問：
 1. 我的病患和研究中的病患是不是相差很大，導致試驗結果無法應用在他們身上？
 2. 我們是否也有此項治療？
 3. 對我的病患而言，治療的潛在**效益**會**超過**治療的潛在**傷害**嗎？
 4. 成本效益分析。

施行實證醫學的五大步驟

× **A**sk: 將臨床情境形成一個可回答的臨床問題

PICO

× **A**cquire: 尋找最佳的文獻證據

6S

× **A**ppraise: 嚴格評讀文獻

VIP

× **A**pply: 應用於病人身上

3E

× **A**udit: 對過程進行稽核

Audit

- × **Ask:** 我有提出任何結構完整的臨床問題嗎?
- × **Acquire:** 我知道如何搜尋現有臨床領域中最佳的證據來源，且在搜尋方面變得更有效率?
- × **Appraise:** 對我而言，應用此研究證據之評讀指引變得更簡單，而我亦盡全力做評讀了?
- × **Apply:** 我是否將搜尋到之最佳證據的結果盡力審慎評估並應用到臨床工作中?



Thank you for your attention!