聯新國際醫院

實證醫學(EBM)種子教師培育課程-

第一階段課程

聯新國際醫院
影像檢查科
教師培育中心
蘇逸欣

2020.09.26

測試題

IRS練習題

請問你有用**牙膏**或**醬油**處理過**燙傷的傷口**嗎？

1. 有
2. 沒有
3. 沒有，但是我覺得是可以的
4. 沒有，而且我覺得是錯誤的

請問你覺得吃**葡萄糖胺**對於預防膝蓋**退化性關節炎**有效嗎？

1.有
2.沒有
3.沒有，但是我覺得是可以的
4.沒有，而且我覺得是錯誤的

請問你有被用**線綁在門上**或者用**鉗子**拔過**牙齒**嗎？

1.有
2.沒有
3.沒有，但是我覺得是可以的
4.沒有，而且我覺得是錯誤的

請問你認為**癲癇**發作時需要使患者嘴巴**咬住物品**嗎？

1. 需要

2.不需要

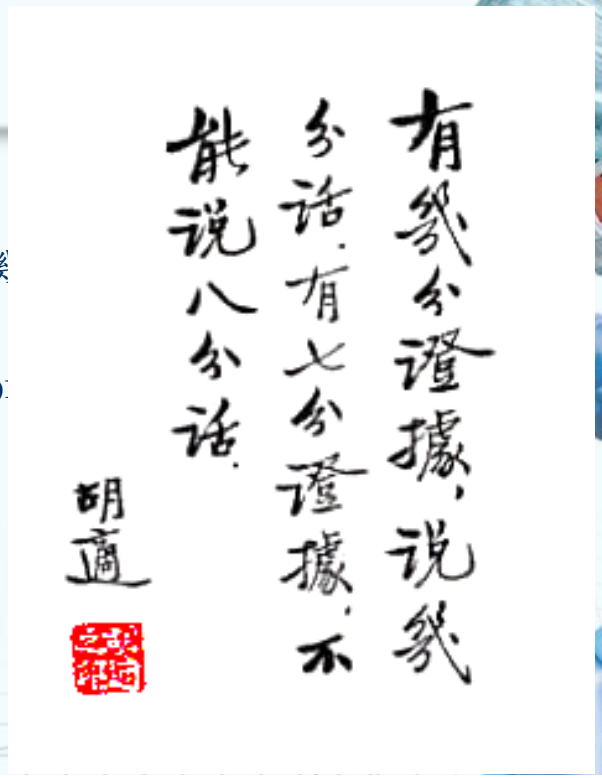
請問你認為做完**腰椎穿刺後**，需要**平躺6小時**休息以**避免頭痛**嗎嗎？

1.需要

2.不需要

- 有幾分證據，說幾

---引自胡適先生(19



Outline

- 什麼是EBM?
- 流行病學簡介
- EBM五步驟

什麼是EBM?

- 請問什麼是EBM的縮寫？

Evidence-

Based-

Medicine

什麼是EBM?

- EBM：

實證醫學 (EBM, Evidence-based medicine) 是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。

Fieldm & Lohrm研究報告發現醫師每天所作的決策：

- **4%是有強而有力的臨床研究證據所支持**
- **45%是有謹慎的臨床研究證據，且醫師間有一定程度的共識**
- **51%不但缺乏有力的證據支持，在醫師間亦無共識，屬灰色地帶**

什麼是EBM?

- EBM：

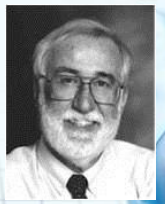
西元1972年，英國臨床流行病學者Archie Cochrane提出「謹慎地、明確地、小心地採用目前最佳的證據，作為照顧病人臨床決策的參考」。

〔Conscientious, explicit, and judicious use of current best evidence in making decisions about individual patients. ~ Archie Cochrane 1972〕

什麼是EBM?

- EBM：

實證醫學”此一名詞自1992年加拿大McMaster大學Gordon Guyatt教授所領導的小組正式命名後，1992英國國家衛生部成立實證醫學中心，以Archie Cochrane之名命名，並由David L. Sackett擔任實證醫學中心主任，進而促成1993年Cochrane Collaboration的設立。



Dave Sackett

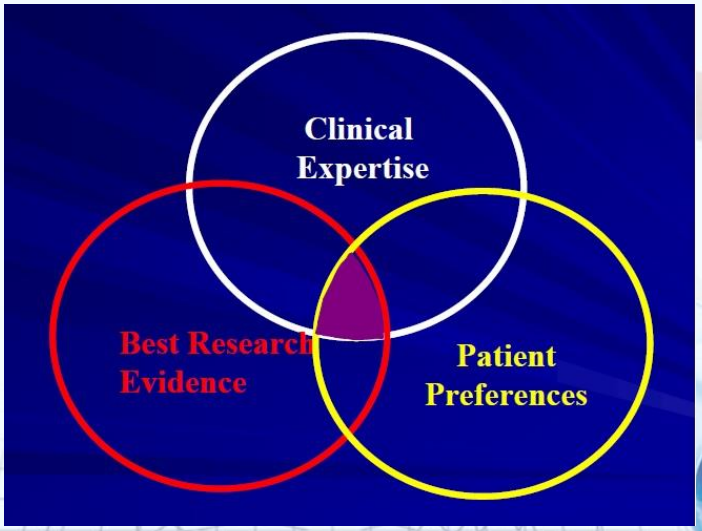
什麼是EBM?

- EBM：

- 目前世界各地有13個國家、15個實證醫學中心〔Cochrane Center〕在積極推動這個工作，其目標是從龐大的醫學資料庫中嚴格過濾、評讀這些文獻，並做系統性文獻回顧及綜合分析，以方便應用於臨床工作中，作為照護病患的依據。

什麼是EBM?

- EBM：



什麼是EBM?

- EBM：

56歲男性病人突然急性腹痛及背痛至急診就醫，做了KUB攝影發現左腎隱約有結石，因為影像不清楚因此又開立了IVP檢查，病人至影像醫學科檢查時問了問題：我從報導中得知低劑量電腦斷層也可以健查出泌尿道結石，請問低劑量電腦斷層與IVP檢查有什麼差異以及他們的準確度為何?

什麼是

- 請

什麼是EBM?

- EBM：

A systematic review comparing the appropriateness of the intravenous urogram and the Computed Tomography Urogram in terms of diagnostic accuracy and risk of radiation dose for patients with urolithiasis.

Conclusions:

Non-enhanced spiral CT provided **greater diagnostic utility** in this **systematic review**.

Crompton G, Cosson P. Radiography 2011; 17(4): 304-310

什麼是EBM?

	Sensitivity	Specificity
NCCT	95~98%	96~98%
low dose CT	97%	95%
IVU	85.20%	90.40%

NCCT	7.3~10	mSv
low dose CT	1.4~1.97	mSv
KUB	0.67~1.1	mSv

- 近年來多家醫院使用**預充式導管沖洗器沖洗IV SET**，據說可以降低感染率，但是不曉得到底**可以降低多少感染率**?

引用自BD公司資料

使用預沖式導管沖洗器後 CRBSI Rate從6.3降為2.7 (per 1000 catheter days)

Journal of Hospital Infection xxx (2013) 1–4

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journal homepage: www.elsevierhealth.com/journals/jhin

Short report

Pre-filled normal saline syringes to reduce totally implantable venous access device-associated bloodstream infection: a single institution pilot study

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SUMMARY

Flushing totally implantable venous access devices (TIVADs) with manually filled saline syringes may increase contamination and catheter-related bloodstream infection (CRBSI). We used a retrospective cohort study to assess the impact of changing from manually filled syringes to manufactured pre-filled syringes on the frequency of CRBSI in 718 TIVADs. Manually filled syringes were used in 269 patients and pre-filled syringes in 449. The CRBSI rate was 2.7% in the pre-filled syringe group and 6.3% in the manually filled syringe group ($P = 0.016$). Sex, tumour type and stage, access site and access body side were not independent risk factors for CRBSI.

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引用自BD公司資料

BD預充式導管沖洗器文獻證實降低CRBSI 60%

- 2013 Journal of Hospital Infection
- Title: Pre-filled normal saline syringes to reduce totally implantable venous access device-associated bloodstream infection: a single institution pilot study
- Flushing totally implantable venous access devices (TIVADs) with manually filled saline syringes may increase contamination and catheter-related bloodstream infection (CRBSI).
  以手工配置食鹽水沖管會增加汙染及導管相關血流導管感染發生率
- **此研究顯示：使用預充式導管沖洗器可降低60%導管相關 血流感染率(CRBSI%)，從6.3(手工配置)降至2.7%(預充式)**

S. [illegible] a, P. Vassallo d, S. Beltramini e, A. DeMaria f,g Reference: 2013 The Healthcare Infection Society. Published by Elsevier Ltd.
Keywords: Central venous system Equipment contamination Infusion Microbiology

Outline

- 什麼是EBM?
- 流行病學簡介
- EBM五步驟

流行病學簡介

- **流行病學**（epidemiology）是研究特定人群中疾病、健康狀況的分布及其決定因素，並研究防治疾病及促進健康的策略和措施的科學。 搜尋證據 (Evidence search)
- 流行病學的定義和特徵。描述分布的常用測量指標(發病率、罹患率、患病率、死亡率、病死率)的意義、用途與計算方法。描述疾病流行強度的常用語：爆發、流行和大流行；疾病的分布的概念及主要內容。

請問**霍亂**病毒主要感染途徑為？

1.眼神接觸以及四目交接

2.主要由飲水所傳染, 污染來自嘔吐物或糞便, 食物傳染但較少見

3. 血液

4.接吻

流行病學簡介

FIGURE 1–12. Photograph of John Snow. (From the Wellcome Historical Medical Museum and Library, London.)

John Snow與霍亂的大事記

- 流行病學發展的中心人物當屬John Snow（1813－1858）這個人。他是一位臨床麻醉科醫師，但也是早期少數清楚瞭解到一個醫生的工作應該要超乎治療疾病的人之一。
- 透過一系列的觀察與研究，Snow發現1854年倫敦地區的霍亂流行是由飲用水受到人類糞便污染而引發的。

流行病學簡介

John Snow與霍亂的大事記

- 這項發現比微生物學家發現霍亂弧菌（Vibrio cholerae）的時間早32年；也比Pasteur於1865年證明微生物會造成疾病流行的觀察早了10年。
- 1854年英倫敦地區爆發霍亂流行，當時倫敦的飲水是由數家私人水公司經營。

流行病學簡介

John Snow與霍亂的大事記

- Snow分析了所有霍亂死亡個案的飲水來源後發現飲用Southwark & Vauxhall這家公司供水的人有較高的死亡率。
- 當數據顯示Southwark & Vauxhall公司所供應的家戶其霍亂死亡率是其他公司的5至10倍後，他開始懷疑霍亂流行是與Southwark & Vauxhall公司所供應的水有關。

流行病學簡介

John Snow與霍亂的大事記

- Snow正確的使用「比率」描述疾病在族群中分佈的情形是他能夠始終在正確方向上的重要因素。他接著仔細觀察Southwark & Vauxhall公司供水的來源，它發現Southwark & Vauxhall公司的水源位於河川的下游，河川上游並有人類糞便的排泄。

流行病學簡介

John Snow與霍亂的大事記

- 當Snow有了這些觀察後，他接續進行了幾個流行病學研究過程中很重要的步驟。
- 當他將霍亂病例按居住地區繪於地圖上時，他發現個案有「聚集」於Broadway Street上取水站的現象，而這也更另他相信霍亂的發生與水有關。
- 透過人時地的描述嘗試發現**聚集（clustering）**現象是描述性流行病學研究的核心工作。

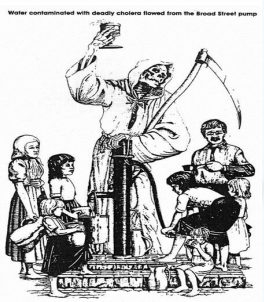
流行病學簡介

John Snow與霍亂的大事記

- Snow的這項觀察實際上是融入了現代科學研究中**對照組（control group）**的概念，也使用了現代流行病學研究中經常使用的**假說演繹**的推論（hypothetico-deductive reasoning）。

流行病學簡介

John Snow與霍亂的大事記



- 雖然當時的生物學知識與技術並無法提供進一步的驗證支持Snow的發現，但當倫敦衛生當局於1854年9月8日將Broadway Street取水站的壓水手把移除後，霍亂死亡個案數隨即**急速減少**，到9月20日以後每日報告的死亡數便與9月1日暴發流行之前一樣。

流行病學簡介

John Snow與霍亂的大事記

流行病學簡介

近代流行病學

- 社區**飲水加氟**的試驗提供了能夠**預防齲齒**的氟濃度。
- **沙克疫苗**的臨床試驗證據提供了人類消滅**小兒麻痺**的利器。
- Framingham Heart Study讓人類更加瞭解**心血管疾病**的病因與預防之道。
- **吸菸**與**肺癌**及其他健康效應的研究。
- **長崎廣島原子彈**爆炸**存活者的追縱研究**都讓人類更加瞭解環境與健康的互動。

Outline

- 什麼是EBM?
- 流行病學簡介
- EBM五步驟

什麼是EBM?

- EBM五步驟：
  - 提出問題 (Question formulation)
  - 搜尋證據 (Evidence search)
  - 嚴格判讀 (Critical appraisal)
  - 恰當運用 (Evidence application)
  - 評估結果 (Outcome evaluation)

EBM五步驟

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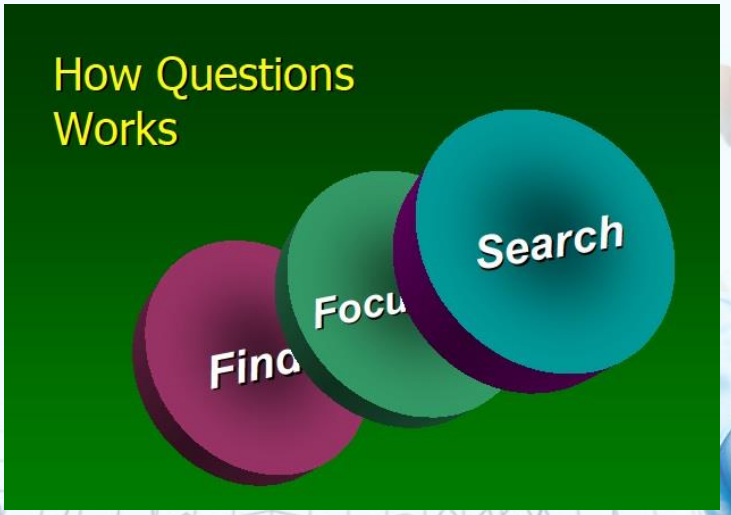
- 提出問題 (Question formulation)



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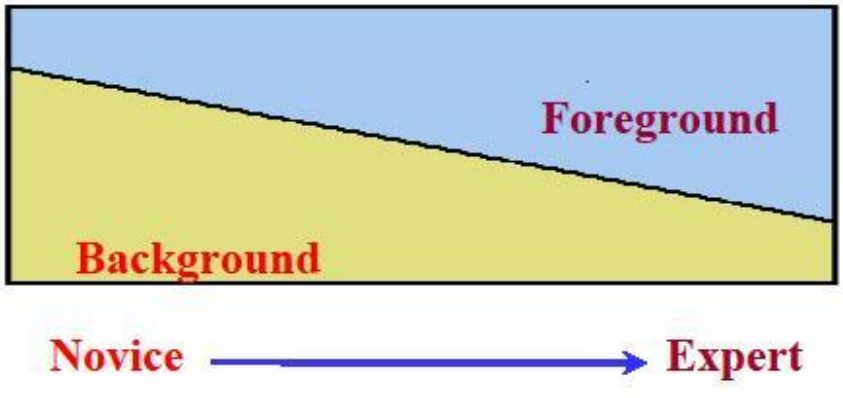

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提出問題 (Question formulation)

背景問題 (Background questions)：5W1H

意指與疾病相關的知識性問題，問題的結構通常包括 (who、what、where、when、how、why) 。

Who：病患特性、危險因子等

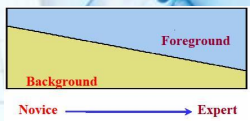
What：自然病程、症狀學等

Where：影響的器官與系統、疾病分佈的區域等

When：疾病好發的年齡、時間、季節等

How：病理生理學

Why：病因



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- 評估結果 (Outcome evaluation)

提出問題 (Question formulation)

背景問題 (Background questions)：

案例:**急性心肌梗塞**

Who：老年人、男性、家族史

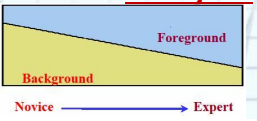
What：胸口悶痛、流冷汗等等

Where：心臟冠狀動脈阻塞的位置、程度等等

When：氣溫變化劇烈、氣溫低.....等

How：動脈硬化斑塊破裂、血栓形成

Why：動脈硬化危險因子、糖尿病、高血壓、高血脂 症、抽菸, 肥胖, 少運動



EBM五步驟

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- 評估結果 (Outcome evaluation)

提出問題 (Question formulation)

前景問題 (Foreground questions)：

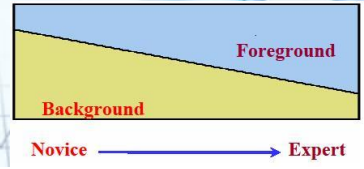
指與治療病患相關的特殊性問題，通常包括有 6 個項目：

Therapy/Prevention：評估不同治療方式...

Harm/Etiology：評估會造成的傷害...

Diagnosis (tests)：不同診斷工具的準確度...

Prognosis：評估疾病癒後...



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- 評估結果 (Outcome evaluation)

提出問題 (Question formulation)

- **Therapy/Prevention**：
  研究治療或預防方法的有效性
  例如：服用“阿斯匹林”是否可以預防中風？

- **Harm/Etiology**：
  研究暴露的危害或疾病的原因
  例如：停經婦女使用荷爾蒙治療是否會增加乳癌的機會？

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

提出問題 (Question formulation)

- **Diagnosis (tests)**：
  研究檢查方法或臨床表徵對疾病診斷的有效性
  例如：Low dose CT 診斷肺癌的敏感度及特異度為何？

- **Prognosis**：
  建立疾病預後的預測模式，例如：利用 Ranson's criteria 預測急性胰臟炎死亡率為何？

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
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- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

- 提出問題 (Question formulation)

Patient	Intervention	Comparison	Outcome

- P：patient and/or problem(病患)
- I ：intervention(處理)
- C：comparison of intervention(對照)
- O：clinical outcome(臨床結果)

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
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- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

- 提出問題 (Question formulation)

Patient or Problem	Intervention	Comparison intervention	Outcome
Description of the patient or the target disorder of interest	Could include: •Exposure •Diagnostic test •Prognostic factor •Therapy •Patient perception etc.	Relevant most often when looking at therapy questions	Clinical outcome of interest to you and your patient

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

提出問題 (Question formulation)

Patient or Problem	Intervention	Comparison intervention	Outcome
65 year old man with stroke and moderate carotid stenosis	Carotid endarterectomy	Medical therapy	Functional Class

- In a 65 year old man with stroke and moderate carotid stenosis, can carotid endarterectomy improve functional class after stroke compared with medical therapy?

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
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- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

提出問題 (Question formulation)

張先生今年55歲，至影像醫學部做骨質密度檢查，詢問放射師說，有聽媒體報導說**喝咖啡會導致增加骨質流失之風險**，且增加，那像他很喜歡喝咖啡的人很多，難道**真的會**增加骨質流失之**風險嗎**?

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

提出問題 (Question formulation)

Patient	**I**ntervention	**C**omparison	**O**utcome
55歲男性	咖啡	沒有喝咖啡	骨質流失

- P：patient and/or problem(病患)
- I ：intervention(處理)
- C：comparison of intervention(對照)
- O：clinical outcome(臨床結果)

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

搜尋證據 (Evidence search)

- 關鍵字設定
- 資料庫選擇
- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

EBM五步驟

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- 提出問題 (Question formulation)
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- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

搜尋證據 (Evidence search)

	Primary Term	Synonym 1	Synonym 2	
P	(	OR	OR	) AND
I	(	OR	OR	) AND
C	(	OR	OR	) AND
O	(	OR	OR	

- 關鍵字設定
- 資料庫選擇
- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

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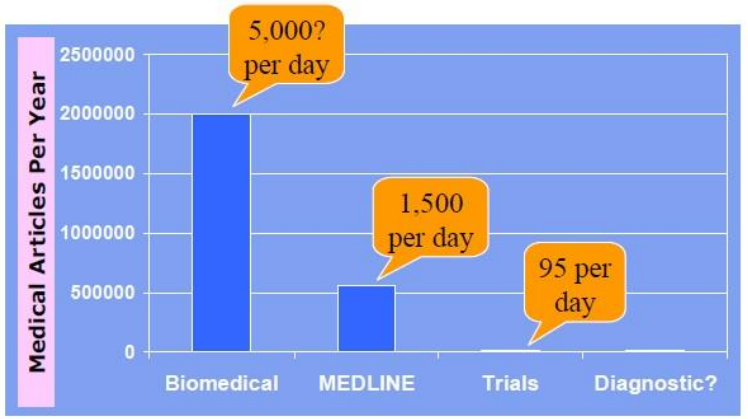
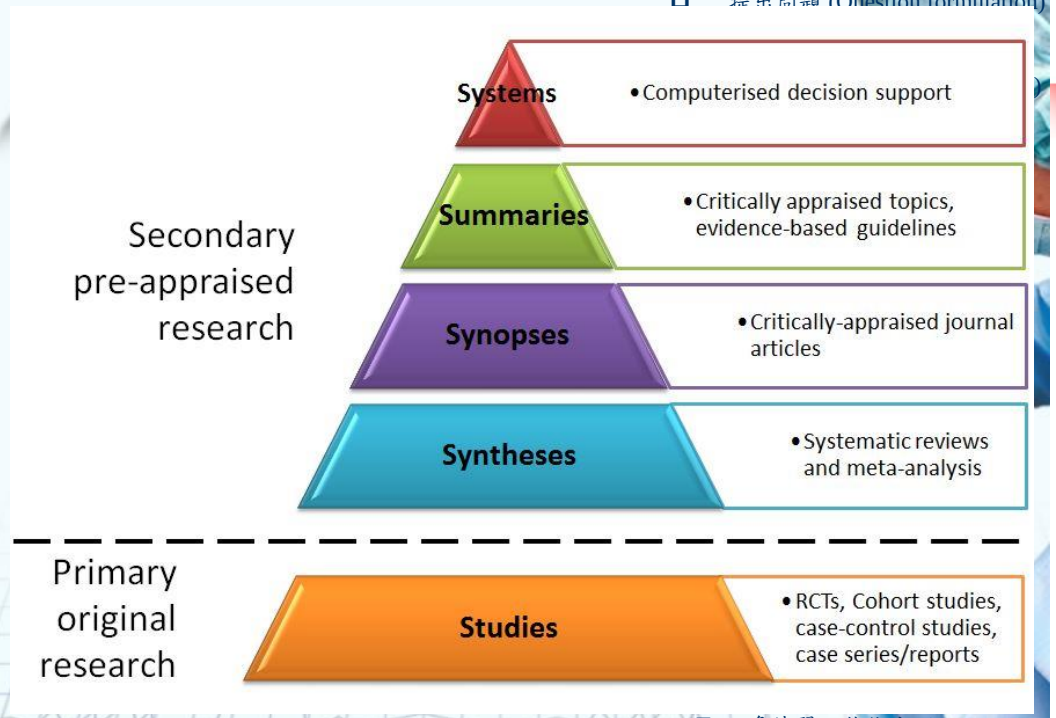
搜尋證據 (Evidence search)



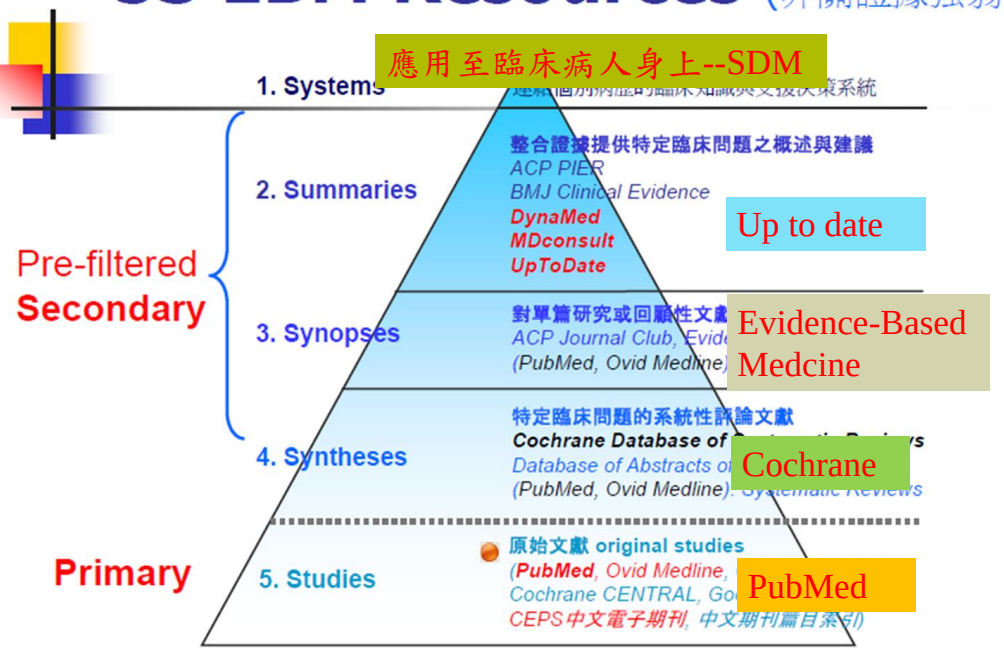
- 關鍵字設定
- 資料庫選擇
- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

EBM五步驟：
- 提出問題 (Question formulation)



- 多練習，熟能生巧

5S EBM Resources (非關證據強弱!)



Model from: Haynes, R. B. (2006). Of studies, syntheses, synopses, summaries, and systems: the "5S" evolution of information services for evidence-based health care decisions. ACP Journal Club, 145(3), A8.

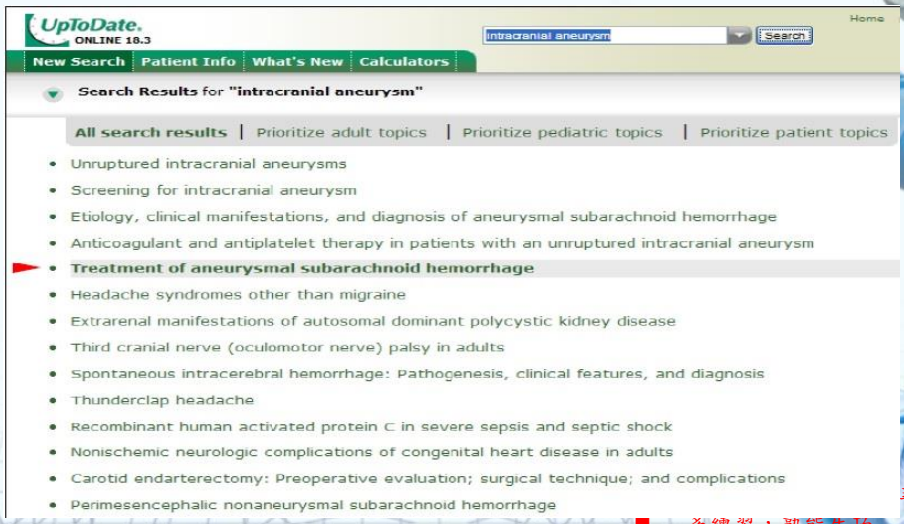
請問你會從哪一個層級開始搜尋？

1. Studies
2. Syntheses
3. Synopses
4. Summaries

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

搜尋證據 (Evidence search)



尋方法

多練習，熟能生巧

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
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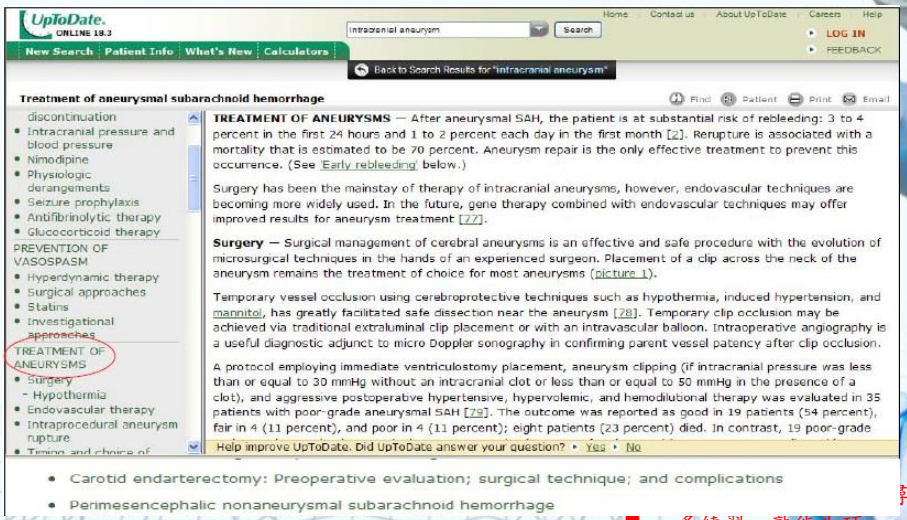
搜尋證據 (Evidence search)



尋方法

多練習，熟能生巧

EBM五步驟

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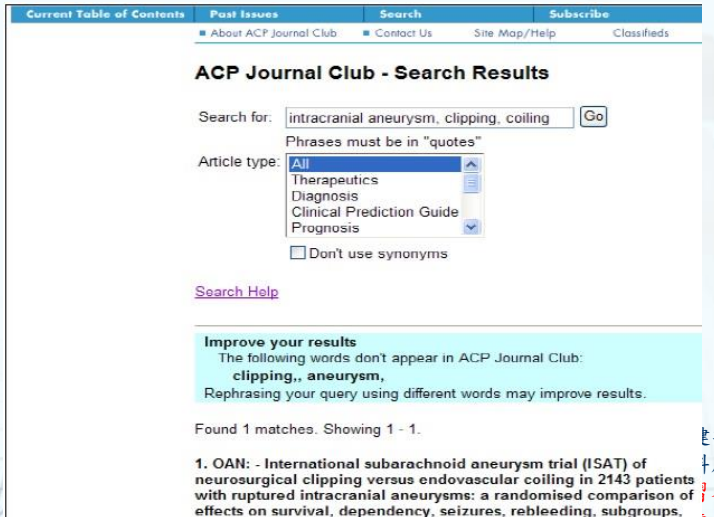
搜尋證據 (Evidence search)



字設定
庫選擇
各種資料庫的搜尋方法

習，熟能生巧

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
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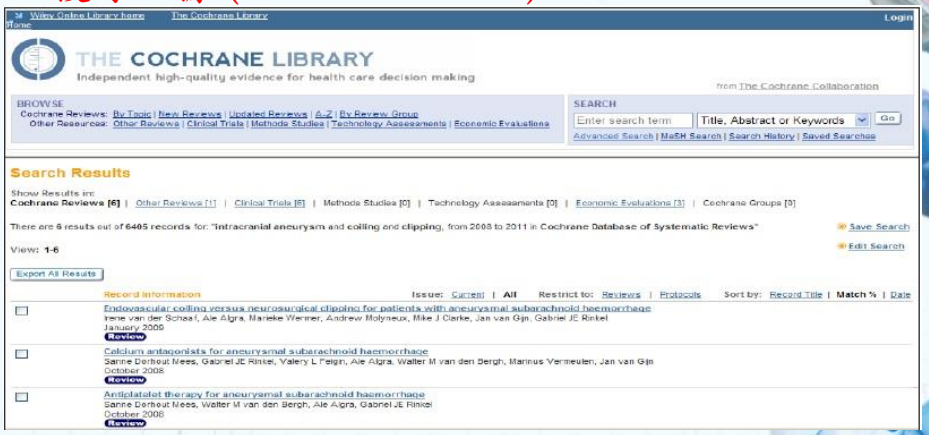
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

搜尋證據 (Evidence search)



- 關鍵字設定
- 資料庫選擇
- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

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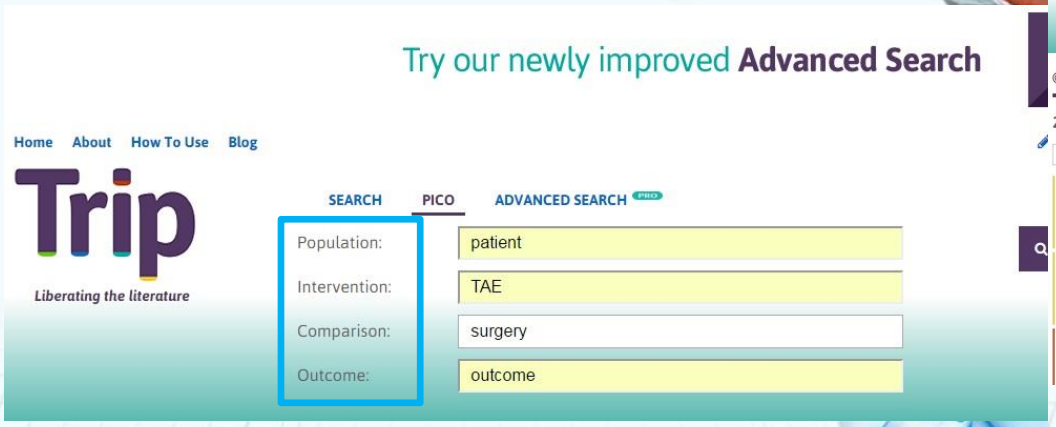

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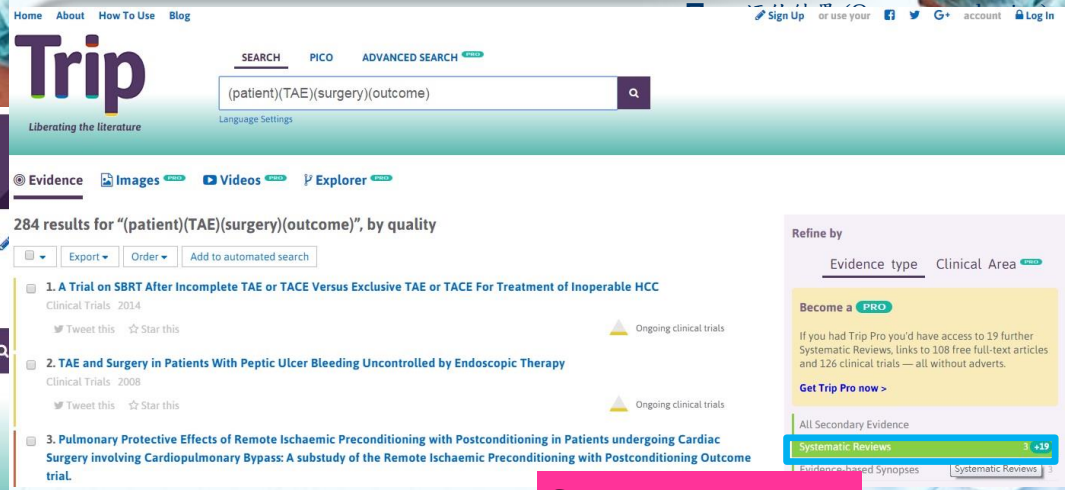

Systematic review

- 關鍵字設定
- 資料庫選擇
- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

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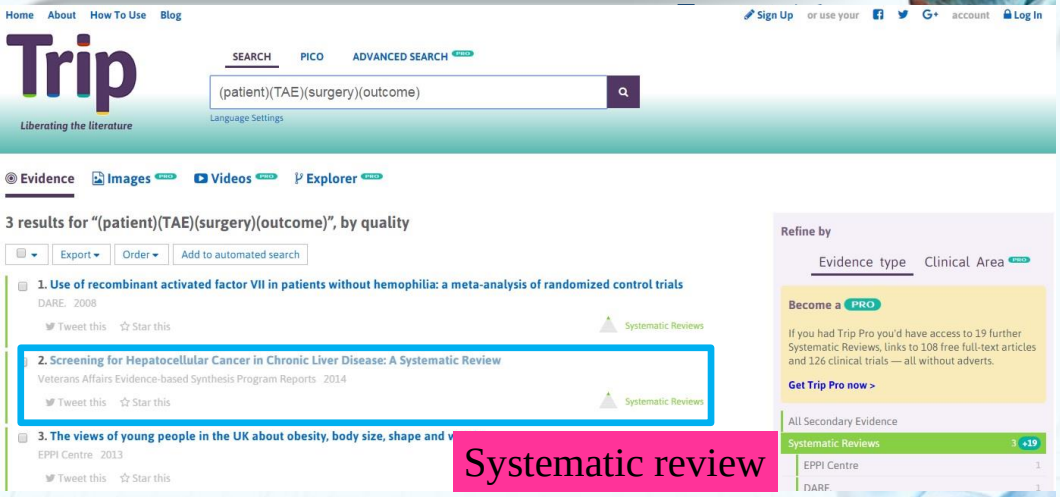

Systematic review

- 關鍵字設定
- 資料庫選擇
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- 多練習，熟能生巧

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搜尋證據 (Evidence search)

QUERI

Screening for Hepatocellular Cancer in Chronic Liver Disease: A Systematic Review

- 關鍵字設定
- 資料庫選擇
- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

EBM五步驟

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- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

搜尋證據 (Evidence search)

METHODS

Data sources: Medline, PsycInfo, Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews to March 2013; clinical trial registries; reference lists; and technical advisors.

Study Selection: We examined controlled clinical trials and observational studies comparing screening to no screening, and controlled clinical trials comparing different screening intervals. We also examined controlled clinical trials and observational studies comparing one of the following active treatments to conservative treatment in patients with early-stage HCC: transarterial chemoembolization (TACE), partial hepatic resection, orthotopic liver transplant (OLT), radiofrequency ablation (RFA), and sorafenib. Because of the dearth of studies for all treatments other than TACE comparing active to conservative treatments, we evaluated noncomparative observational studies for evidence on harms and long-term survival. The population of interest was patients with chronic liver disease with or without cirrhosis.

- 關鍵字設定
- 資料庫選擇
- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

EBM五步驟：
- 提出問題 (Question formulation)

Effects of screening on mortality: RCTs

Two trials, both conducted in China, compared the effects of screening to no screening on mortality among participants mainly with hepatitis B. One trial used a cluster-randomized design to assign factories, business, and schools to screening or no screening groups. Screening group participants (n = 9,757) were offered serum AFP testing and ultrasonography every 6 months. The primary outcome of HCC mortality occurred less frequently in the screening group (83.2/100,000 person-years vs 131.5/100,000 person-years; rate ratio 0.63, 95% CI 0.41 – 0.98). However, this trial, carried a high-risk of bias because of several serious methodological limitations that threaten the validity of the results. The second trial used patient-level randomization stratified by township to assign hepatitis B patients to the screening intervention (n = 3,712), which consisted of serial AFP tests followed by ultrasound for high AFP values, or the usual care group (n = 1,869). HCC mortality was similar in both groups (1,138/100,000 person-years vs 1114/100,000 person-years, p = 0.86), as was all-cause mortality (1,843/100,000 person-years vs 1,788/100,000 person-years, p = NS). This trial carried an unclear risk of bias because of poor reporting of randomization and allocation concealment techniques.

Two additional trials compared different ultrasound screening intervals. One unclear risk of bias trial found no survival advantage comparing 4-month to 12-month ultrasound screening intervals in patients with serologic evidence of hepatitis B or C. A trial with low risk-of-bias compared 3-month to 6-month ultrasound screening intervals in 1,278 patients with cirrhosis from alcohol use and/or viral hepatitis and found similar all-cause mortality rates in both groups.

- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
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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 *n*-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, *n*-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (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 *n*-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

- 關鍵字設定
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Expert

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

搜尋證據 (Evidence search)

Systematic review

Cohort studies

Treatment Benefits

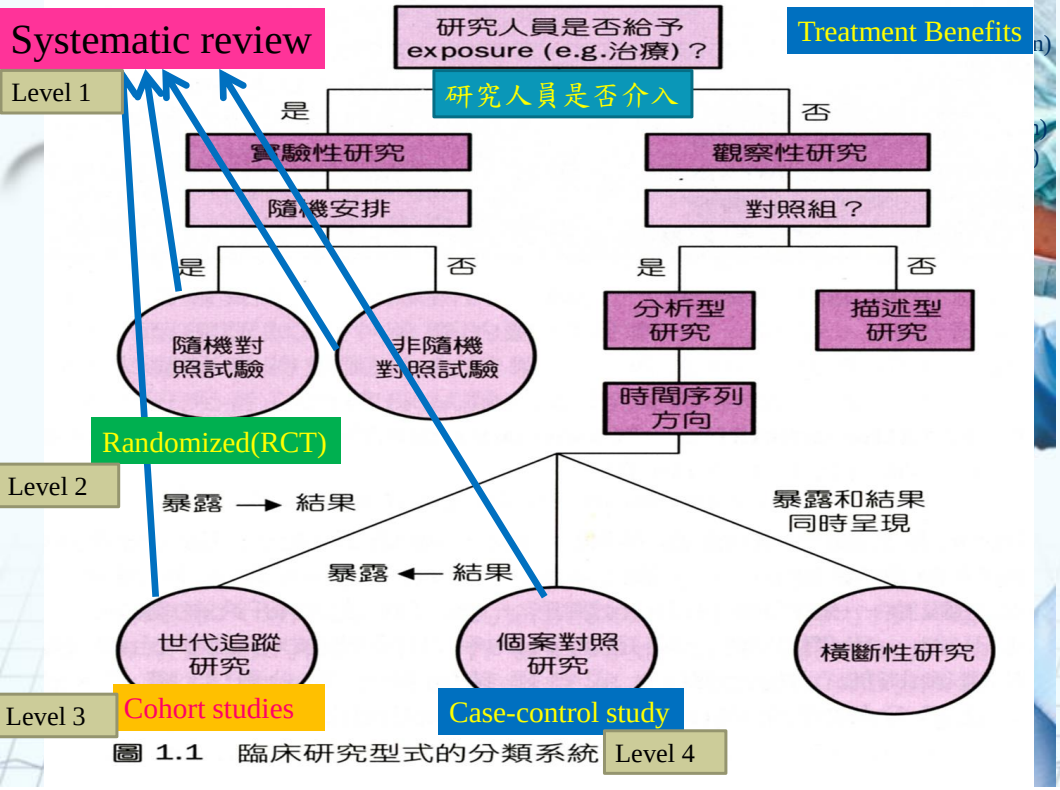
Randomized(RCT)

Case-control study

- 關鍵字設定
- 資料庫選擇
- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

Systematic review

Treatment Benefits



Level 1

Randomized(RCT)

Level 2

Level 3

Cohort studies

Case-control study

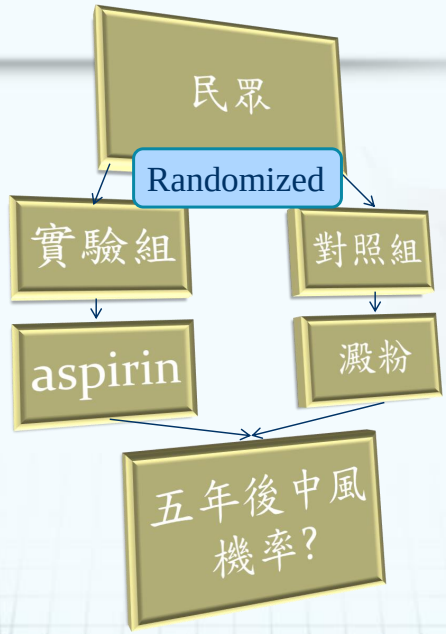
Level 4

圖 1.1 臨床研究型式的分類系統

- 搜尋證據 (Evidence search)

原始研究（Original Study）

- **隨機對照實驗**（Randomized Control Trial, **RCT**）給**實驗組**及**對照組**不同的治療，觀察其後果。例如：實驗組吃**aspirin**，對照組吃**澱粉**，比較兩組**五年後中風的機率**。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）。在此設計中，如果能夠採行**雙盲**對照（double blinded, placebo-controlled）則干擾因素的影響可以進一步減少



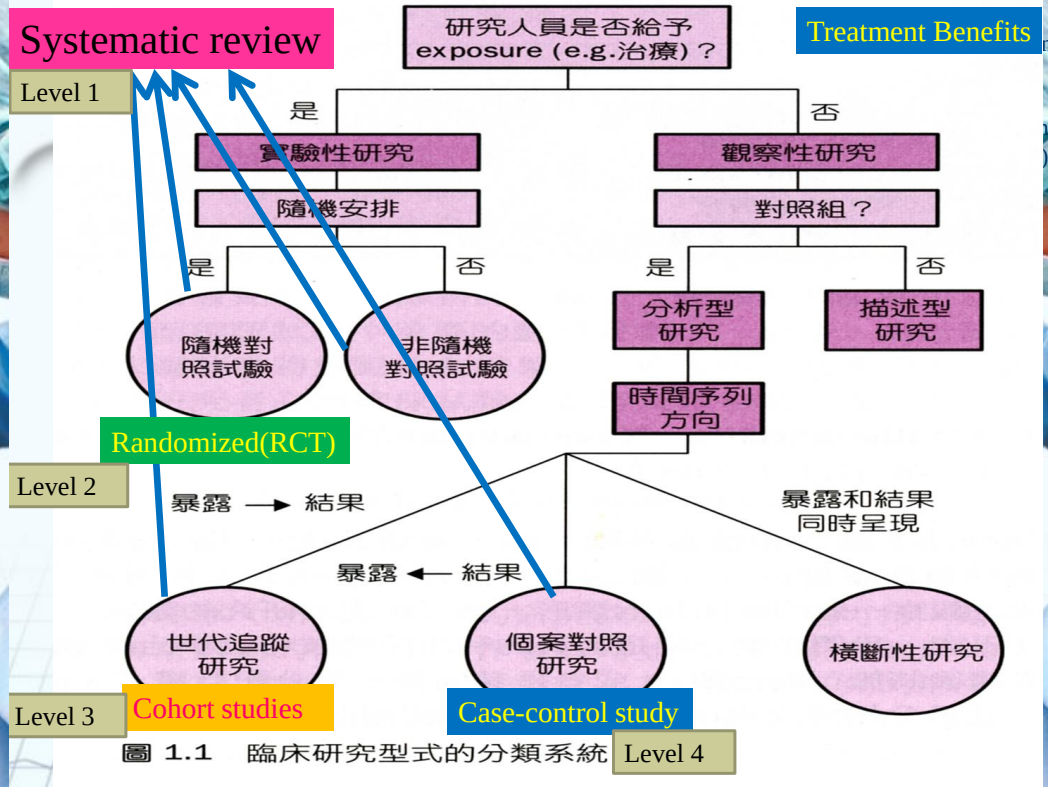


圖 1.1 臨床研究型式的分類系統

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

longitudinal studies - ***Cohort studies***

Prospective

Retrospective

2,000	2,001	2,002	2,003	2,004	2,005	2,006	2,007

Patient → **Random**

→ **Not Random**

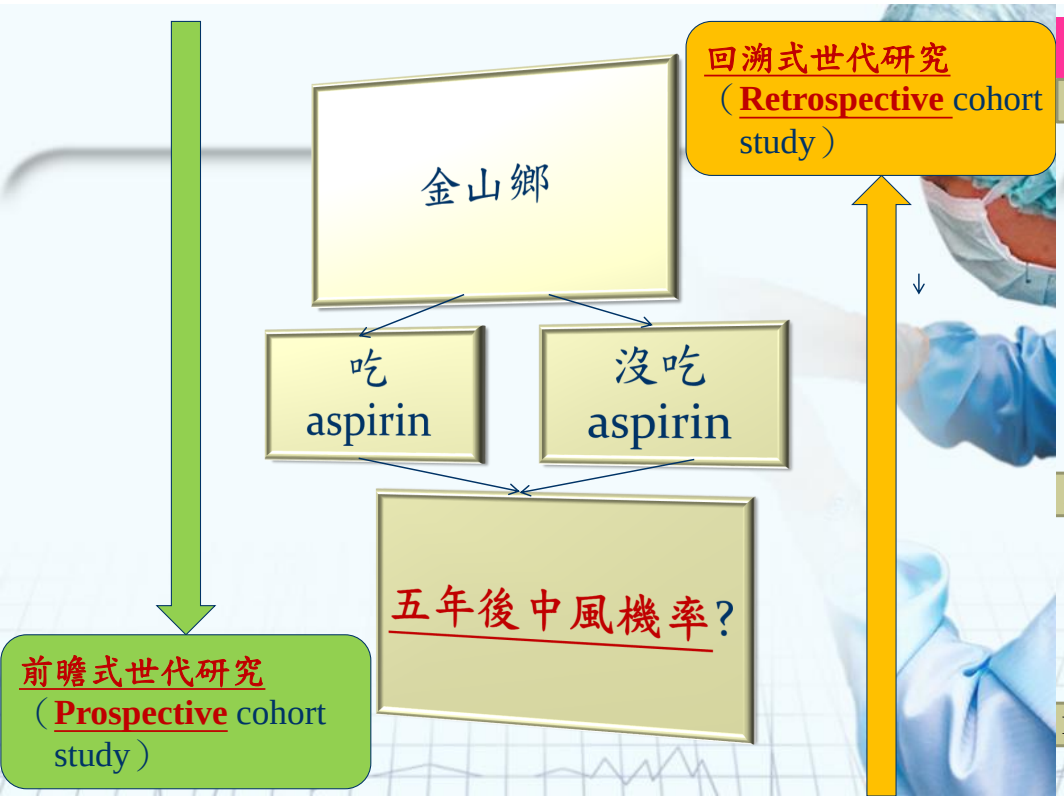
- 關鍵字設定
- 資料庫選擇
- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

- 搜尋證據 (Evidence search)

原始研究（Original Study）

- **世代研究**（**Cohort** Study）

觀察自然暴露/治療方式的影響，長期追蹤其結果。例如：比較金山鄉有吃**aspirin** 及沒有吃aspirin 的人，五年後新發中風的機率。提供**比隨機對照試驗**證據力較**次一級**之研究證據，是屬於臨床流行病學中之觀察性研究。針對幾個子群，**由接受暴露因子開始，一直追蹤到結果**。



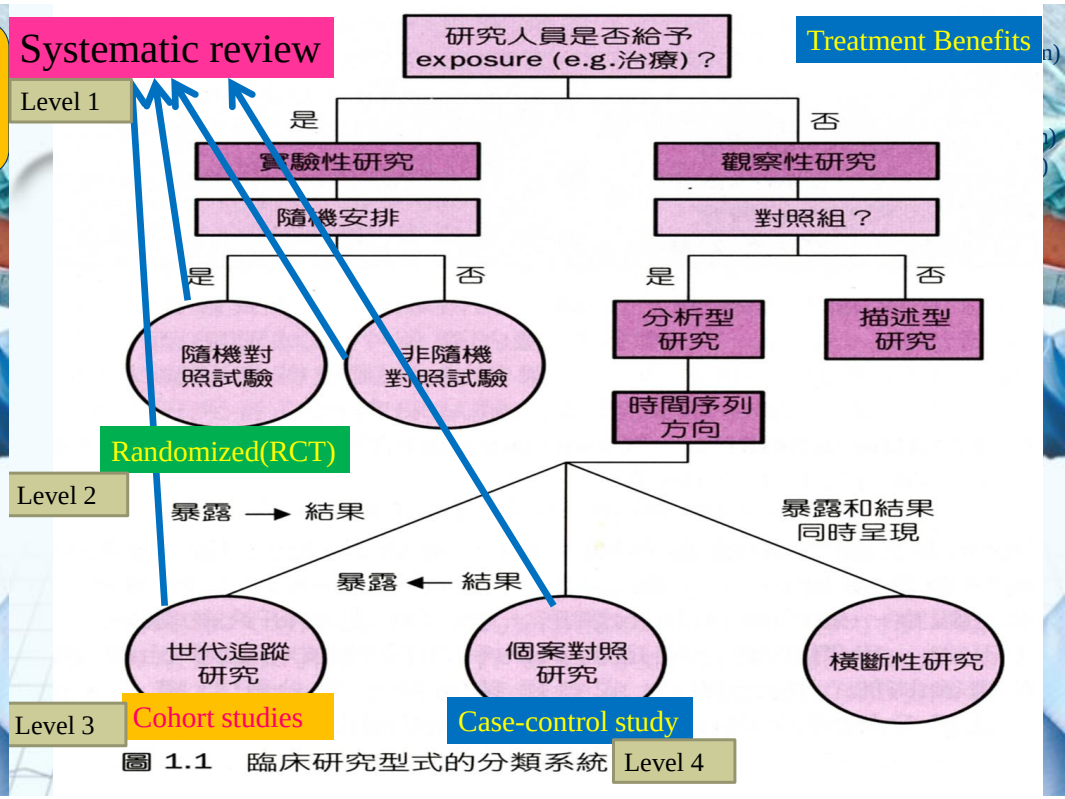


圖 1.1 臨床研究型式的分類系統

- 搜尋證據 (Evidence search)

原始研究（Original Study）

- **個案對照研究**（**Case Control Study**）

選擇病人組及對照組，研究其暴露/治療的影響。

例如：比較500 個有 中風的個案及500 個沒有中風的個案，他們吃 aspirin的比例。這是**流行病學中極重要的研究方式**，雖然它的臨床**證據力**較世代研究為**低**，但可以在**短時間內**以**少許資金與努力**，就能得到重要的科學發現，是最有效率的研究設計，但也容易受到偏見的影響。

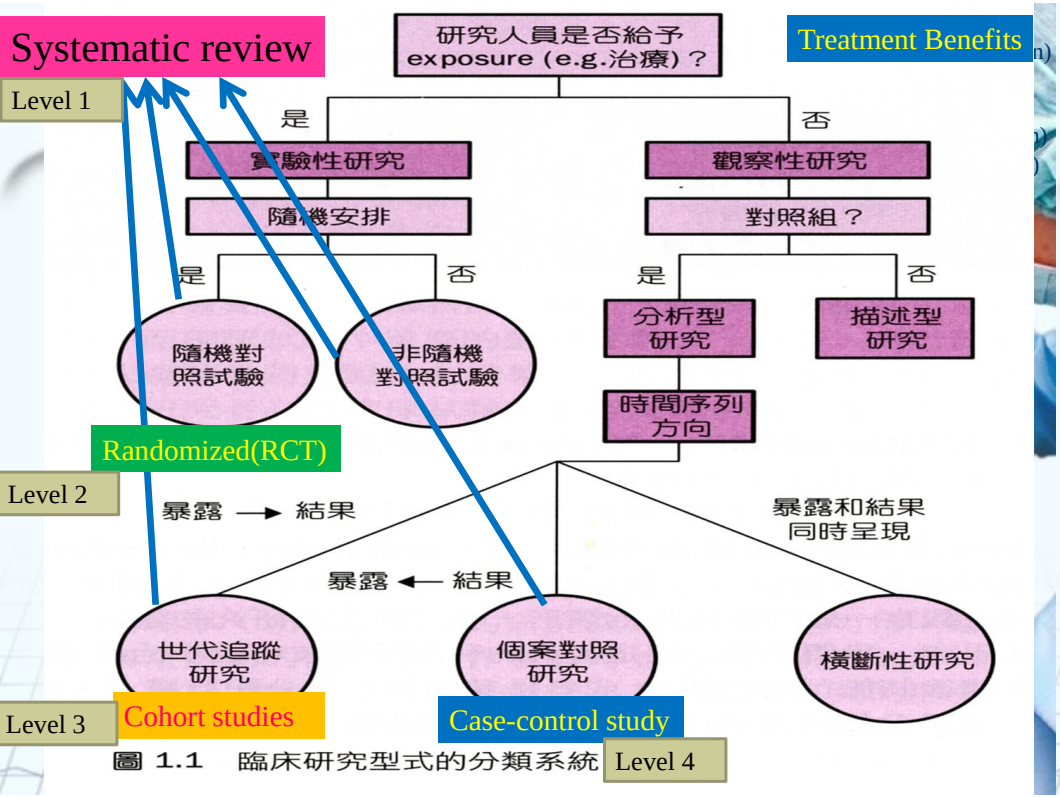


圖 1.1 臨床研究型式的分類系統

- 搜尋證據 (Evidence search)

文獻回顧（Review of Literature）

- **系統性回顧（systemic review）**

系統性的文獻回顧，將個人好惡及偏差減至最低。**需引用各種文獻資料庫**，並說明查詢的關鍵字，**有引用文獻的明確標準**，不能依作者喜好選取文獻，通常會使用統計方法（**Meta-Analysis 統合分析**），以解決臨床爭議為目的。

EBM五步驟

EBM五步驟：

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Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

Systematic review

信度較差之研究

Diagnosis

Cross sectional

Case-control study

Question					
How common is the problem?		surveys o local		Step 5 (Level 5)	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	Systematic review on cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*		
intervention help? (Treatment Benefits)	Systematic review of randomized trials or *n-of-1* trials	or observational study with dramatic effect	controlled cohort/follow-up study**		
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, *n-of-1* trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (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.)**	or historically controlled studies**	reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or *n-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

- 關鍵字設定
- 資料庫選擇
- 學習各種資料庫的搜尋方法
- 多練習，熟能生巧

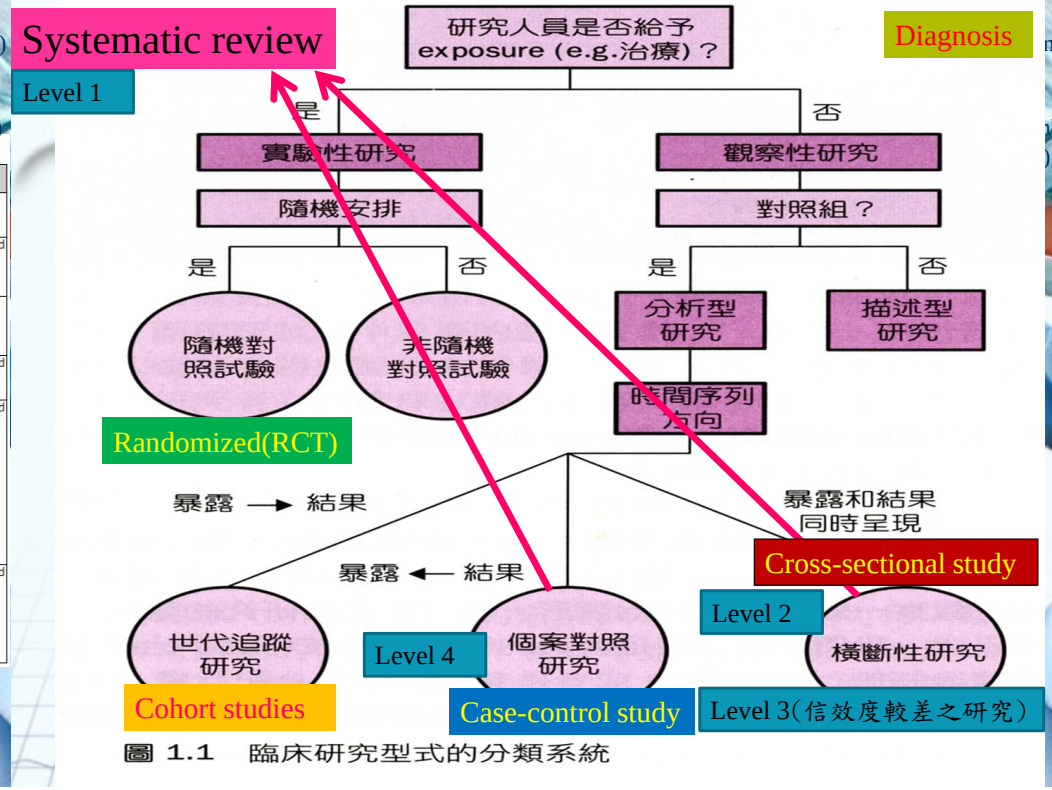

圖 1.1 臨床研究型式的分類系統

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
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longitudinal studies - ***Cohort studies***

Prospective

Retrospective

2,000	2,001	2,002	2,003	2,004	2,005	2,006	2,007

cross-sectional studies

Patient → **Random**

→ **Not Random**

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research design

PubMed.gov
U.S. National Library of Medicine
National Institutes of Health

Search: PubMed | Limits | Advanced search | Help

Display Settings: Abstract | Send to:

Early Hum Dev. 2011 Mar 10. [Epub ahead of print]

Longitudinal study of smoking cessation before pregnancy and children's cognitive abilities at 56months of age.

Heinonen K, Räikkönen K, Pesonen AK, Andersson S, Kajantie E, Eriksson JG, Wolke D, Lano A.

Institute of Behavioral Science, P.O. Box 9, FI-00014, University of Helsinki, Finland.

Abstract

BACKGROUND: An inverse relationship exists between the rates of maternal smoking during pregnancy and children's cognitive abilities. The effect of maternal cessation of smoking before pregnancy on child's cognitive development is less clear.

AIMS: To study whether maternal cessation of smoking before pregnancy is associated with children's cognitive abilities.

STUDY DESIGN AND SUBJECTS: The original cohort included all 1535 live-born infants admitted to the neonatal wards during 1year and 658 randomly recruited non-admitted infants. The present study sample comprised 1019 (68.2%) children of the original sample born at term and free of any major impairment followed up to 56months.

OUTCOME MEASURES: Child's general reasoning, visual-motor integration, verbal competence, and language comprehension

- 學習各種資料庫的搜尋方法
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Search: PubMed | Limits | Advanced search | Help

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Eur J Cardiovasc Nurs. 2011 Mar 11. [Epub ahead of print]

The impact of the metabolic syndrome on health-related quality of life: A cross-sectional study in Greece.

Tziallas D, Kastanioti C, Kostapanos MS, Skapinakis P, Elisaf MS, Mavreas V.

Department of Internal Medicine, University of Ioannina, Ioannina, Greece.

Abstract

BACKGROUND: Metabolic syndrome [MetS] is a chronic, progressive and multi-complex health problem that can trigger physical, emotional and psychosocial problems. The aim of this study is to investigate the association between MetS and health-related quality of life (HRQoL) as well as depressive and anxiety disorders.

METHODS: New consecutive patients who attended an outpatient lipid clinic for evaluation for MetS were eligible for inclusion in the study. The MetS was defined according to the new definition of International Diabetes Federation (IDF). The Medical Outcomes Study, Short Form-36 (SF-36) was used to assess HRQoL. Anxiety and depressive symptoms were assessed by a validated Greek version of the Hospital Anxiety and Depression Scale (HADS).

- 多練習，熟能生巧

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research design

PubMed.gov
U.S. National Library of Medicine
National Institutes of Health

Search: PubMed | Limits | Advanced search | Help

Display Settings: Abstract | Send to:

Osteoarthritis Cartilage. 2011 Mar 8. [Epub ahead of print]

Systematic review of the concurrent and predictive validity of MRI biomarkers in OA.

Hunter DJ, Zhang W, Conaghan PG, Hirko K, Menashe L, Li L, Reichmann WM, Losina E.

Rheumatology Department, Royal North Shore Hospital and Northern Clinical School, University of Sydney, Sydney, NSW Australia; Division of Research, New England Baptist Hospital, Boston MA USA.

Abstract

OBJECTIVE: To summarize literature on the concurrent and predictive validity of MRI-based measures of osteoarthritis (OA) structural change.

METHODS: An online literature search was conducted of the OVID, EMBASE, CINAHL, PsychInfo and Cochrane databases of articles published up to the time of the search, April 2009. 1,338 abstracts obtained with this search were preliminarily screened for relevance by two reviewers. Of these, 243 were selected for data extraction for this analysis on validity as well as separate reviews on discriminate validity and diagnostic performance. Of these 142 manuscripts included data pertinent to concurrent validity and 61 manuscripts for the predictive validity review. For this analysis we extracted data on criterion (concurrent and predictive) validity from both longitudinal and cross-sectional studies for all synovial joint tissues as it relates to MRI

- 多練習，熟能生巧

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搜尋證據 (Evidence search)

- 關鍵字設定
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■ 請問你個人比較喜歡的可樂是？

1.可口可樂

2.百事可樂

3.他牌可樂

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Coffee and Cancer of the Pancreas

每天喝三杯咖啡者得胰臟癌的風險為不喝咖啡者的 ~~2.7倍~~ (1.6 to 4.7).

But it's has occur ➡ **Select bias**

被選擇參與研究者皆為腸胃科病人

Brian MacMahon, M.D., Stella Yen, M.D., Dimitrios Trichopoulos, M.D., Kenneth Warren, M.D., and George Nardi, M.D. N Engl J Med 1981; 304:630-633March 12, 1981.

- 資料庫選擇
- 關鍵字設定
- 學習各種資料庫的搜尋方法
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- 嚴格判讀 (Critical appraisal)-簡單判讀
- **Oxford** Evidence-Based Medicine Levels-**Level 1-5**

最主要有三個主要步驟，即為**VIP**：

- **V**（Validity/Reliability）效度/信度：文獻研究收集個案方式是否嚴謹，是否具有效度(Validity)?
- **I**（Importance/Impact）重要性、文獻統計方法是否正確，結果是否具有重要性)?
- **P**（Practice/Applicability）臨床適用性。

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- 嚴格判讀 (Critical appraisal)

V

- 文獻個案收集方式是否隨機取樣(Randomization)?

  Randomization、case-control study、case-series
- 個案追蹤成功率是否高?
- 是否進行單盲(Single-blind)或雙盲(Double-blind)測試?
- 研究進行中個案是否經由嚴謹管制?
- 個案是否追蹤遺失?

- 文獻研究收集個案方式是否嚴謹，是否具有效度(Vali
- 文獻統計方法是否正確，結果是否具有重要性(Impor
- 文獻是否適合應用在您病人身上?

EBM五步驟

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- 提出問題 (Question formulation)
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I

不同的問題利用不同的統計量

Therapy/Prevention	Diagnosis
RRR	Sensitivity
ARR	Specificity
NNT	PPV
Relative risk	NPV
Odds ratio(Case-control study)	LR

- 文獻研究收集個案方式是否嚴謹，是否具有效度(Validity)?
- 文獻統計方法是否正確，結果是否具有重要性(Importance)?
- 文獻是否適合應用在您病人身上?

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- 提出問題 (Question formulation)
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I

Diagnostic test	Disease			
	Present(有病)		Absent(沒病)	
Positive	731	a	270	b
Negative	78	c	1500	d

Sensitivity (敏感度)	為有病者診斷結果為陽性的比率=真陽性率=真陽性 / 生病 = a / a+c= 731/809 = 90%
Specificity (特異性)	為沒病者診斷結果為陰性的比率 d/b+d = 真陰性率=真陰性 / 健康 = d / b+d=1500/1770 = 85%

- 文獻統計方法是否正確，結果是否具有重要性(Importance)?
- 文獻是否適合應用在您病人身上?

I EBM五步驟

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Diagnostic test	Disease	
	Present(有病)	Absent(沒病)
Positive	731 a	270 b
Negative	78 c	1500 d

Positive Predictive Value, PPV (陽性預測值)	**診斷試驗結果呈現陽性且確實有病者的比率=真陽性 / 陽性試驗結果 = a / a+b= 731/1001 = 73%**
Negative Predictive Value, NPV (陰性預測值)	診斷試驗結果呈陰性且確實無患病者的比率=真陰性 / 陰性試驗結果 = d / c+d = 1500/1578 = 95%

- 文獻研究收集個案方式是否嚴謹，是否具有效度(Validity)?
- 文獻統計方法是否正確，結果是否具有重要性(Importance)?
- 文獻是否適合應用在您病人身上?

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Diagnostic test	Disease	
	Present(有病)	Absent(沒病)
Positive	731 a	270 b
Negative	78 c	1500 d

prevalence	**a+c/a+b+c+d= 31%**
Likelihood Ratios (相似比)	分子：疾病中診斷試驗(陽性或陰性)比率 分母：無疾病中診斷試驗(陽性或陰性)比率
LR(+)	**真陽性率 / 假陽性率=Sensitivity / (1-Specificity) = (a/a+c) / (b/b+d) = 90%/15% = 6**
LR(-)	**假陰性率 / 真陰性率= (1-Sensitivity) / Specificity = (c/a+c) / (d/b+d) = 10%/85% = 0.12**

- 文獻是否適合應用在您病人身上?

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Likelihood Ratios (相似比) 數值所代表的臨床意義

Likelihood Ratio	Interpretation
>10	Strong evidence to rule in disease
5–10	Moderate evidence to rule in disease
2–5	Weak evidence to rule in disease
0.5–2.0	No significant change in the likelihood
0.2–0.5	Weak evidence to rule out disease
0.1–0.2	Moderate evidence to rule out disease
<0.1	Strong evidence to rule out disease

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- 嚴格判讀 (Critical appraisal)

Treatment(Treatment Benefits)	Event	
	Positive	Negative
experimental-(RCT 或 Cohort studies)	A = 1	B = 29
control-(RCT 或 Cohort studies)	C = 9	D = 21

實驗組事件發生率 (EER, Experimental Event Rrate)	**a/a+b = 0.033**
對照組事件發生率 (CER, Control Event Rrate)	c/c+d = 0.30
相對風險比率差 (RRR, Relative Risk Reduction)	**|EER – CER| / CER，實驗組和對照組間產生的風險比率所降低的相對百分比 |0.033 – 0.3| / 0.3=0.267/0.3=0.89=89%**

I

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Treatment(Treatment Benefits)	Event	
	Positive	Negative
experimental-(RCT 或 Cohort studies)	A = 1	B = 29
control-(RCT 或 Cohort studies)	C = 9	D = 21

絕對風險比率差 (ARR, Absolute Risk Reduction)	|EER – CER| = |0.033– 0.3|=0.267 實驗組與對照組間不良結果機率差的絕對值, 伴隨95%信賴區間(CI)
需要被治療的病人數目 (NNT, Number Needed to Treat)	1/ARR = 1/0.267 =3.75 ，為減少一個不良結果所需治療4病人, 伴隨95%信賴區間(CI)

- 文獻研究收集個案方式是否嚴謹，是否具有效度(Validity)?
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Treatment(Treatment Harms)	Event	
	Positive	Negative
experimental-(RCT 或 Cohort studies)	A = 1	B = 29
control-(RCT 或 Cohort studies)	C = 9	D = 21

Relative risk(RR) -相對危險比	EER/CER = (a/a+b)/(c/c+d) = 0.11，接受治療病患相對未接受治療病患的不良事件風險

- 文獻研究收集個案方式是否嚴謹，是否具有效度(Validity)?
- 文獻統計方法是否正確，結果是否具有重要性(Importance)?
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Treatment(Treatment Harms)	Event	
	Positive	Negative
Exposed(Case-control study)	A = 1	B = 29
Not exposed (Case-control study)	C = 9	D = 21

Experimental event Odds	a/b = 0.034
Control event Odds	c/d = 0.43
Odds ratio-勝算比	(a/b)/(c/d) = ad/bc = 0.080 ，通常被使用於個案對照研究之中。為試驗組中發生結果的勝算（Odds）與對照組中發生結果的勝算，此兩者間的比值就稱為勝算比（OR）

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	Positive	Negative
Exposed(Case-control study)	A = 9	B = 21
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Experimental event Odds	a/b = 0.43
Control event Odds	c/d = 0.034
Odds ratio-勝算比	(a/b)/(c/d) = ad/bc = 12.65 ，通常被使用於個案對照研究之中。為試驗組中發生結果的勝算（Odds）與對照組中發生結果的勝算，此兩者間的比值就稱為勝算比（OR）

以肺癌者有無抽菸為例

- 文獻研究收集個案方式是否嚴謹，是否具有效度(Validity)?
- 文獻統計方法是否正確，結果是否具有重要性(Importance)?
- 文獻是否適合應用在您病人身上?

I

EBM五步驟

EBM五步驟：
- 提出問題 (Question formulation)
- 搜尋證據 (Evidence search)
- 嚴格判讀 (Critical appraisal)
- 恰當運用 (Evidence application)
- 評估結果 (Outcome evaluation)

- 嚴格判讀 (Critical appraisal)-有深度判讀-**CASP**
- Systematic reviews之評讀

Q1. Did the review ask a clearly-focused question?

Q2. Did the review include the right type of study?

Q3. Did the reviewers try to identify all relevant studies?

- 文獻研究收集個案方式是否嚴謹，是否具有效度(Validity)?
- 文獻統計方法是否正確，結果是否具有重要性(Importance)?
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- 嚴格判讀 (Critical appraisal)-有深度判讀
- Systematic reviews之評讀

Q4. Did the reviewers assess the quality of the included studies?

Q5. If the results of the studies have been combined, was it reasonable to do so?

Q6. How are the results presented and what is the main result?

Q7. How precise are these results?

- 文獻研究收集個案方式是否嚴謹，是否具有效度(Validity)?
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- Systematic reviews之評讀

Q8. Can the results be applied to the local population?

Q9. Were all important outcomes considered?

Q10. Should policy or practice change as a result of the evidence contained in this review?

- 文獻研究收集個案方式是否嚴謹，是否具有效度(Validity)?
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P

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- 評估結果 (Outcome evaluation)

- 嚴格判讀 (Critical appraisal)
- P（Practice/Applicability）**臨床適用性**。如果我們相信這個研究，它的結果**是否可以應用**在我們的**病患身上**？”其中要考量的是病患的差異、可運用的資源以及病患的偏好。在這個部份我們可以考量病患的生物因素（biologic issues）即是”同樣的治療應用在**不同的病患族群**是否有不同的反應？”

- 文獻研究收集個案方式是否嚴謹，是否具有效度(Validity)?
- 文獻統計方法是否正確，結果是否具有重要性(Importance)?
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恰當運用 (Evidence application

- ***Evidence is never enough***
  證據，永遠是不足的
- Can the results be applied to my patient?
  –有效且重要的證據能實際應用到我照顧的病人身上嗎？
- ***Evidence Applicability*** –證據適用性

- 實際應用到你的病人
- 將證據“外推”，應用於個案？
- 個案自己的價值觀與喜好？

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恰當運用 (Evidence application

- 病人與研究文獻所收錄的病人，有無明顯差異？
  – 研究族群為60-70歲有效，但是你的病人為40歲
- 評估病人接受與研究文獻所施行相同的治療（或處置），所得益處（及害處）將有多大？
  –應用到您的個案前，需先藉此修正文獻結果
  –單位或是你自己是否有能力（資源）施行相同的治療（或處置）？執行品質為何？

- 實際應用到你的病人
- 將證據“外推”，應用於個案？
- 個案自己的價值觀與喜好？

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恰當運用 (Evidence application

- 是否清楚與個案（及家屬）說明溝通？
- 個案對治療（或處置）的遵從性？
- 實際追蹤你的個案的成果（**outcome**）

- 實際應用到你的病人
- 將證據“外推”，應用於個案？
- 個案自己的價值觀與喜好？

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評估結果 (Outcome evaluation)

- Self – Evaluation （自我評估）
  – 所遇到的臨床問題是可以回答的嗎？
  – 搜尋文獻及評讀證據的速度夠快嗎？
  – 這些證據應用在適當的臨床病人嗎
- Evaluation (Audit) by Expert or peer
  –專家監督或同儕彼此評估

EBM五步驟

- 實例分享
  - 一位65歲婦人，因胸悶胸痛,懷疑是CAD ，但在做CATH 診斷之前醫師經常會開**Treadmill ECG**但患者虛弱關節痛，無法運動，**是否可以用Tl 201來取代檢查運動心電圖**(Tredmill ECG)，並提供足夠的診斷精確性與可信賴度且可運用於臨床。

EBM五步驟

- 提出問題 (Question formulation)

Patient	Intervention	Comparison	Outcome

- P：65歲婦女, 懷疑 CAD.
- I ：Myocardial perfusion ,Thallium
- C：Treadmill ECG
- O：CAD Diagnostic accuracy

EBM五步驟

- 案例分享
  - PubMed
  - **Noninvasive Diagnostic Techniques for Coronary Disease in Women. (2012)**

EBM五步驟

- 實例分享
  - **Exercise MPI** ：**Sensitivity** (**78% to 88%**)
    Specificity (**64% to 91%**)
  - **Vasodilator** ：**Sensitivity** (**91%**)
    Specificity (**86%**)

EBM五步驟

- 實例分享
  - –Tl 201檢查的診斷敏度與特異性與運動心電圖(Tredmill ECG)，因此**可用Tl 201檢查來替代運動心電圖**，並提供足夠的診斷精確性與可信賴度。

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Thank’s for your attention
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