Introduction in Evidence-Based Medicine

Thunyarat Anothaisintawee, M.D., Ph.D. (Clin. Epid.)

- The science of making decisions about individual patients by using strong scientific methods of studies to ensure that predictions are accurate.
- Goal: clinical observation have valid conclusion by avoiding bias and random error.

Clinical Epidemiology

"helping smart doctors stop prescribing dumb treatments."

Dr. David Sackett since 1960s

- Sackett is the founder of the first clinical epidemiology department in Canada and led the move toward "evidence-based medicine," which he said has three components:
  1. Being a good doctor with clinical skills to diagnose patients well.
  2. Using evidence generated from proper research, such as randomized clinical trials and are then carefully followed up to see whether they fare better.
  3. Incorporating a patient's expectations and values of health care.

Types of health care professional

Evidence Users

Evidence generator

Evidence Finders

Evidence Ignorer

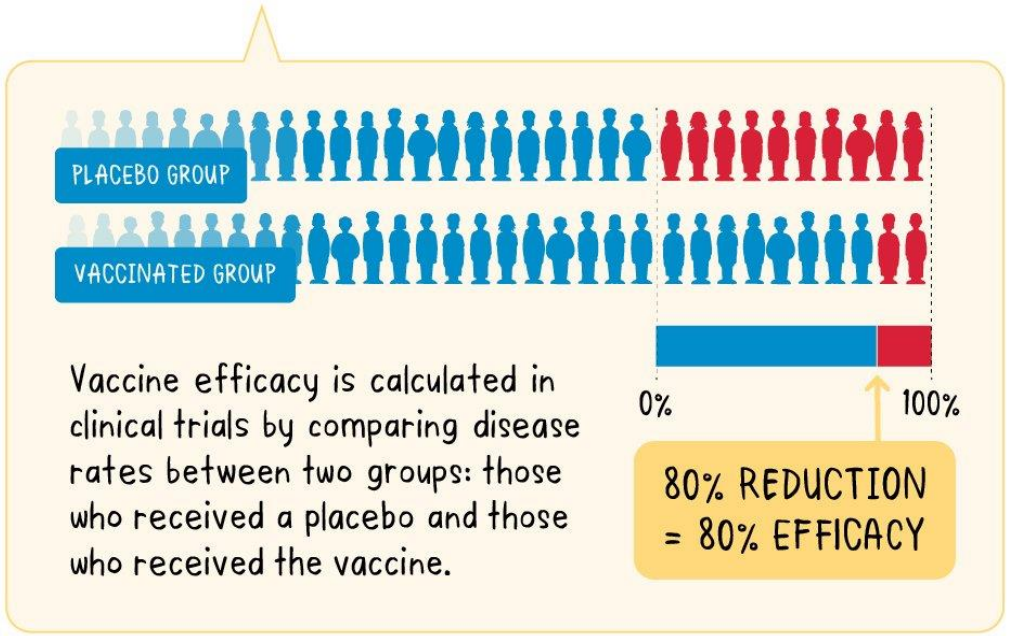
What EBM?

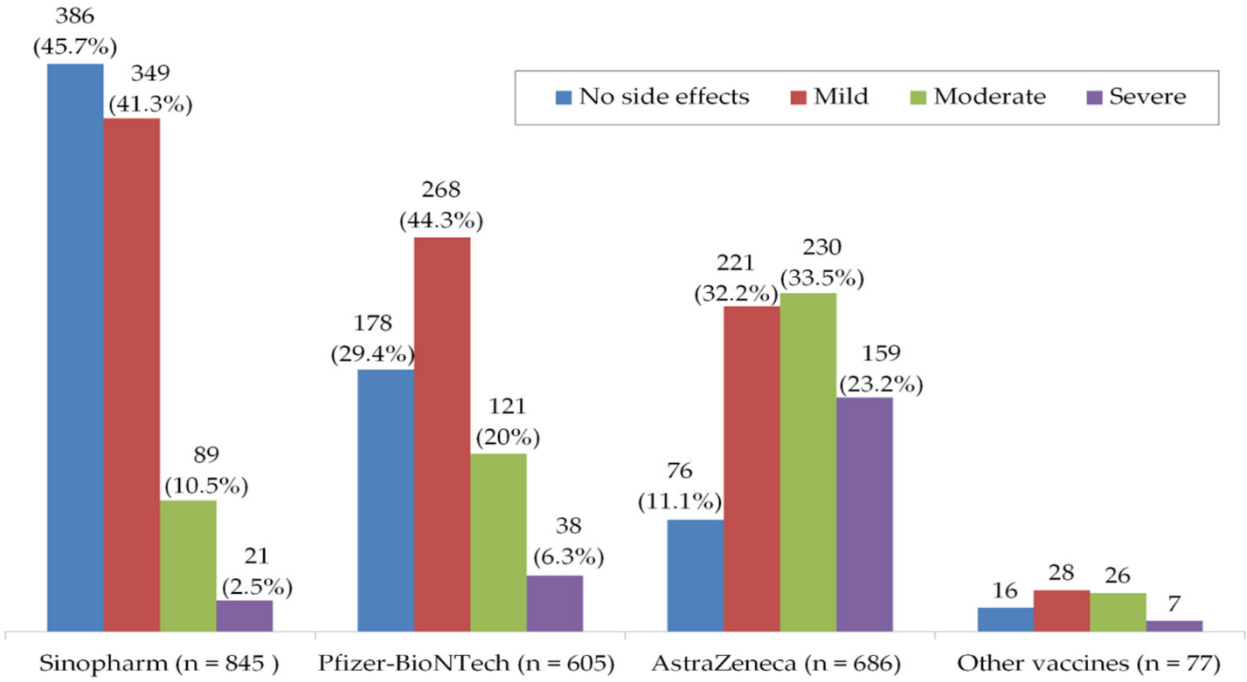
Expertise in integrating

1. Best research evidence
2. Clinical Circumstance
3. Patient values in clinical decisions”

Evidence alone is never sufficient to make a clinical decision

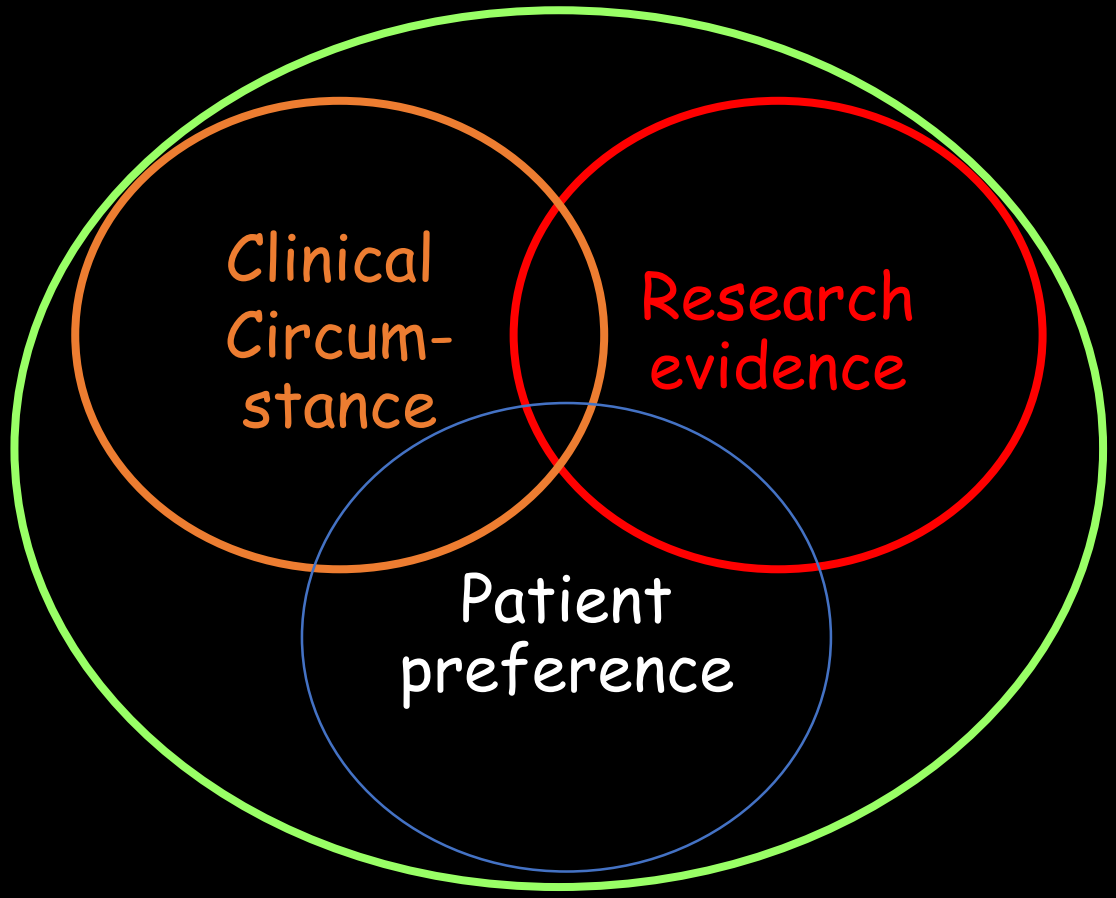
- Tread-off among
  - Benefit
  - Risk
  - Cost
  - Practicality
  - Patients' value





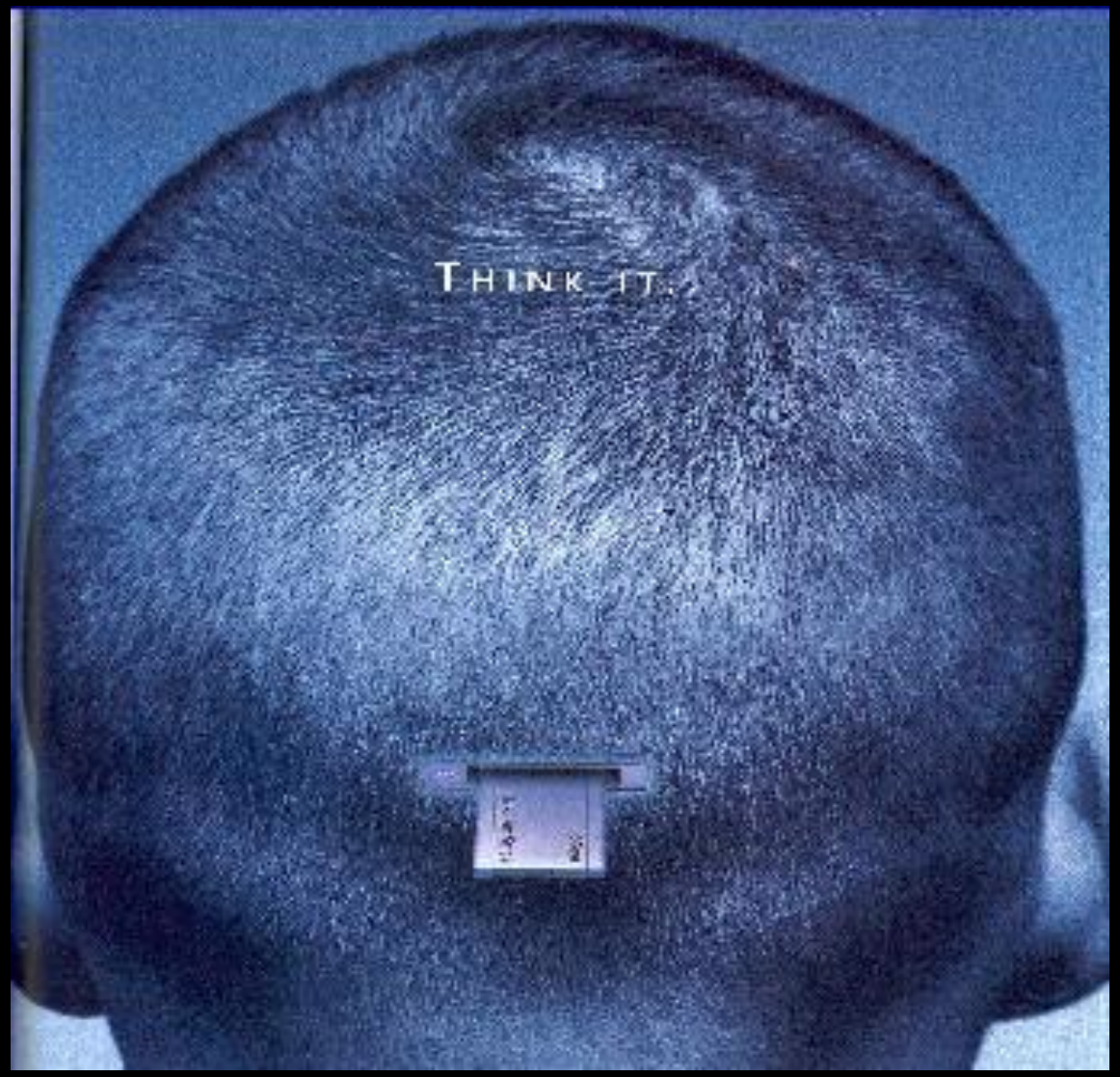
COVID-19 vaccine

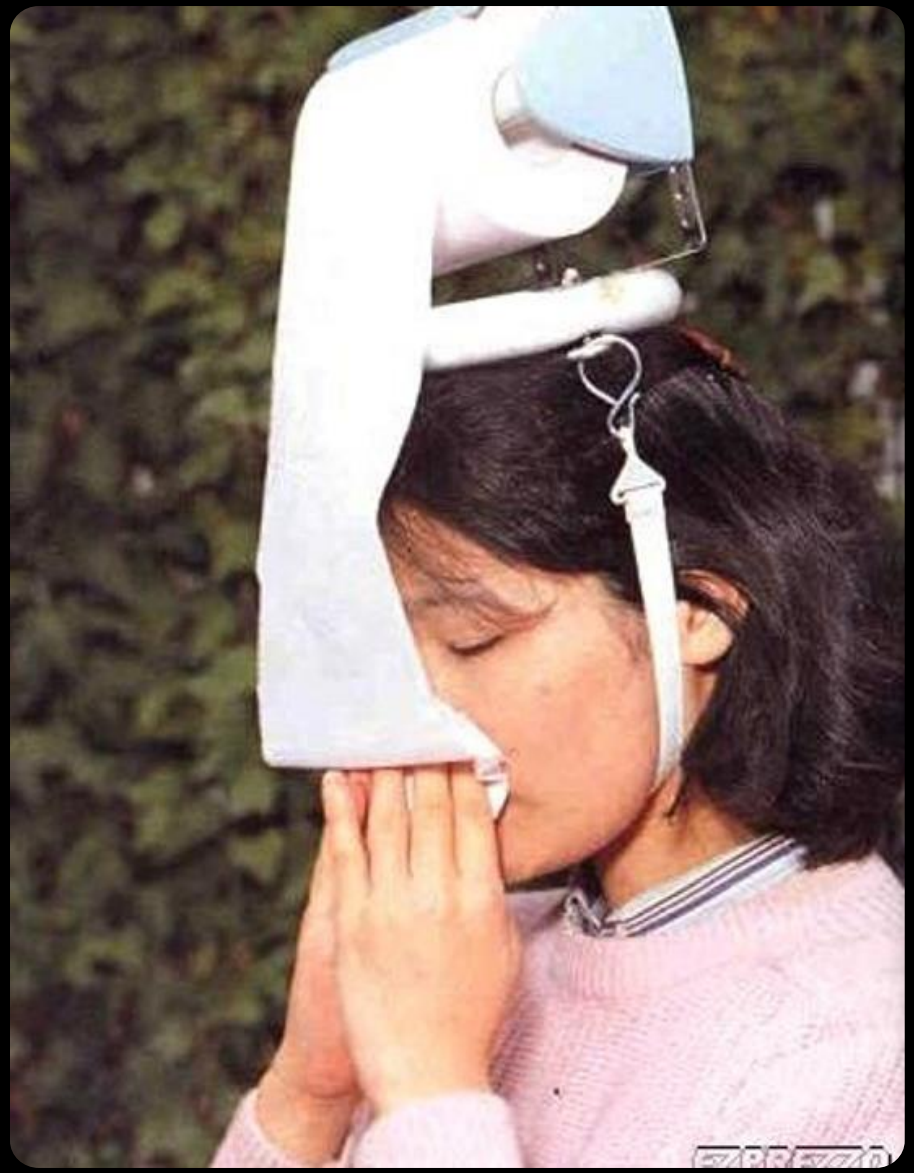
Evidence-Based Medicine



What EBM is not:

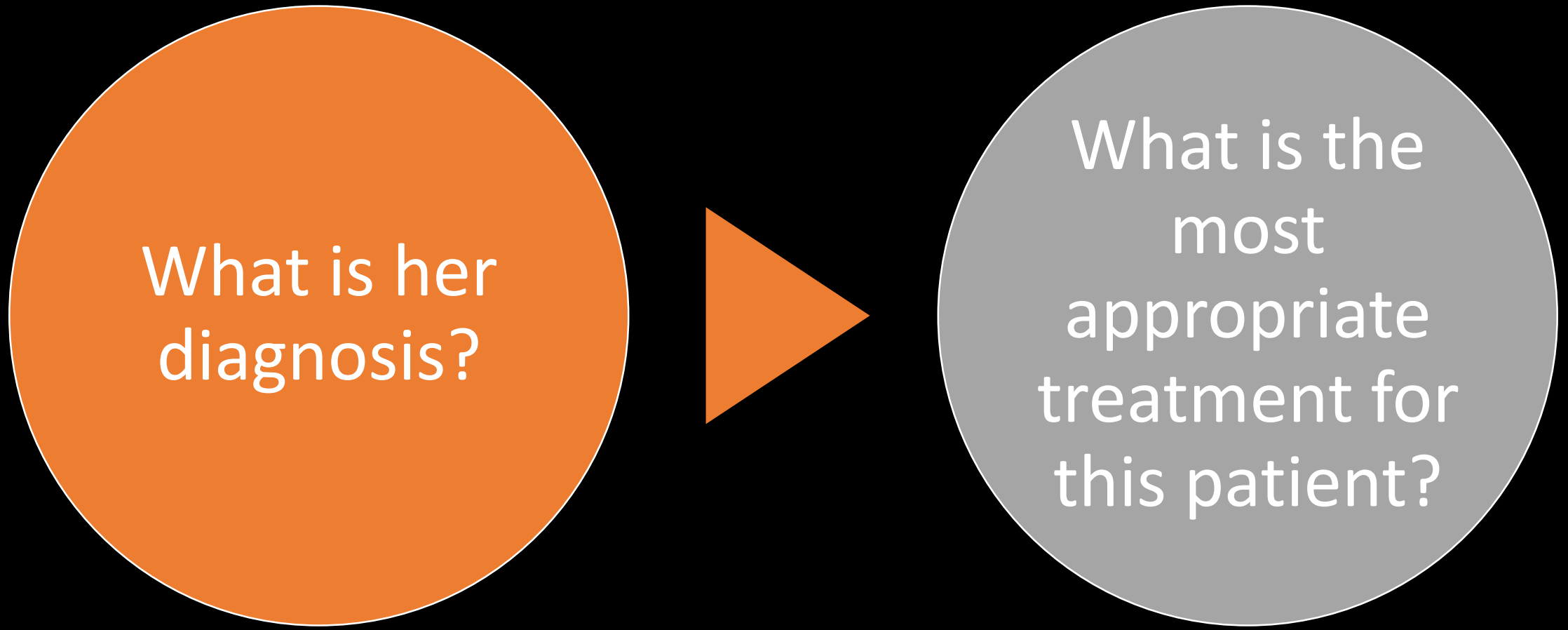
- Cookbook medicine
- Overrules experience/expertise
- Always about RCT's
- Always cost-minimizing





Case study

- A Thai female patient aged 25 years
- Came with low grade fever, pain at both cheeks, and nasal congestion with discharge for 2 days
- BT = 38 c, tender at maxilla sinus, posterior nasal dripping


What is her diagnosis?
What is the most appropriate treatment for this patient?

- Her diagnosis is acute rhinosinusitis
- You will prescribe antibiotics for her?
- Or just only symptomatic treatment?

Your decision based on?

Your own experiences

Past observation from your teachers

Advice from your colleagues

Clinical practice guideline

Results from systematic review

- No treatment effect of antibiotics, even in patients whose symptoms had persisted for more than 10 days.

- *Antibiotics for adults with clinically diagnosed acute rhinosinusitis: a meta-analysis of individual patient data. Lancet. Mar 15 2008;371(9616):908-14*

Case scenario

- Doctor gave her antibiotic and her symptoms relieved in the next three days.

Why patients get better?

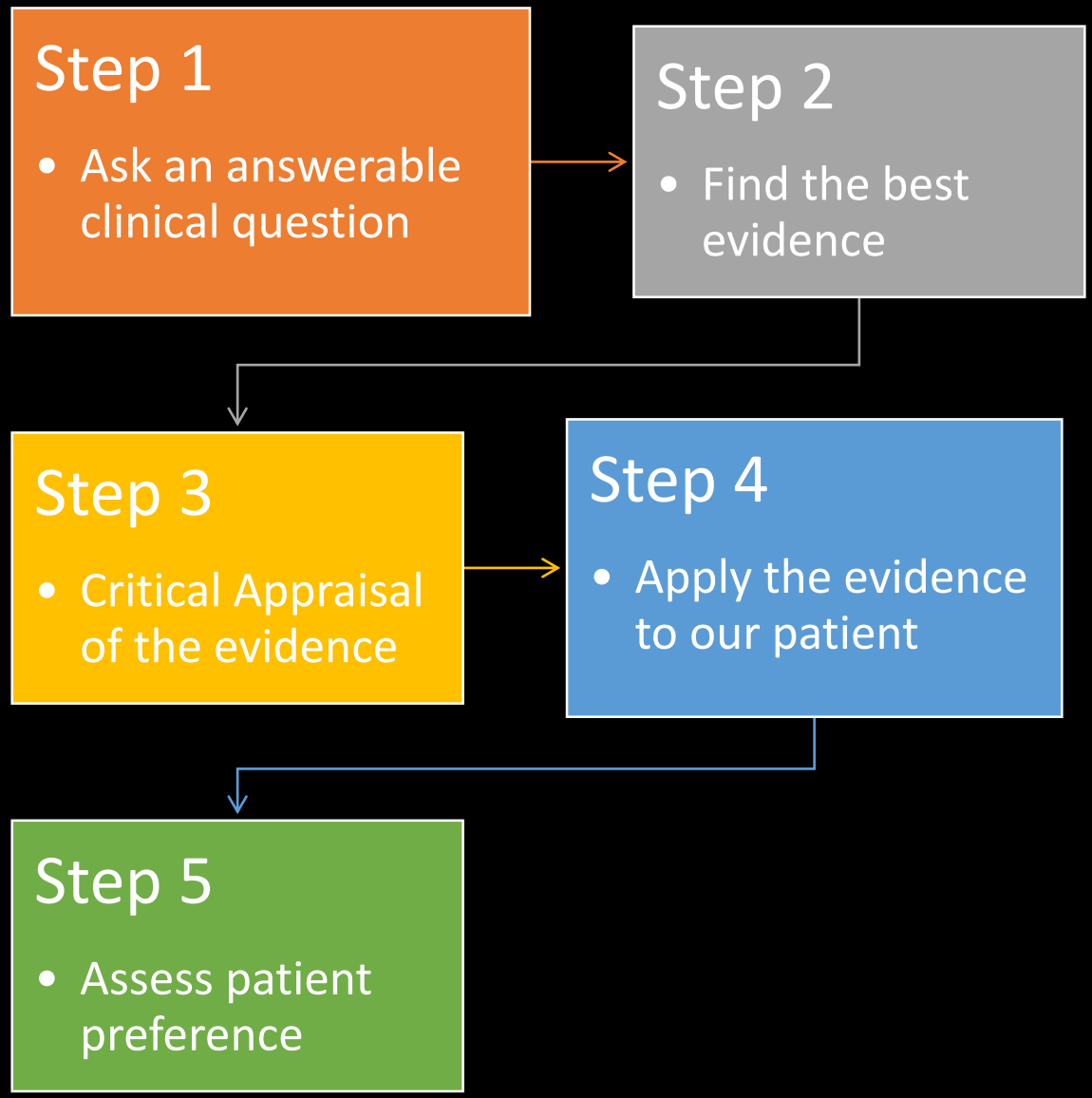
Even though there is no evidence that antibiotic is effective for treatment of acute rhinosinusitis.

Most of acute rhinosinusitis are caused from viral infection.

Thus, giving antibiotic to every patients with acute rhinosinusitis has more risk than benefit.

How to practice Evidence-Based Medicine?

5 A's of EBM


Step 1
• Ask an answerable clinical question
Step 2
• Find the best evidence
Step 3
• Critical Appraisal of the evidence
Step 4
• Apply the evidence to our patient
Step 5
• Assess patient preference

4 parts of clinical question

- Patient or Problem P
- Intervention or exposure I
- Comparison C
- Outcome O

PICO

Patient or Problem

Intervention

Comparison

Outcome

"Patient" refers to the person presenting with the problem, or more simply, to the problem itself. Both concepts are important in searching.

PICO

Patient or Problem

Intervention

Comparison

Outcome

"Intervention" refers to the action taken in response to the problem. This is often a drug or surgical procedure, but it can take many forms.

PICO

Patient or Problem

Intervention

Comparison

Outcome

"Comparison" refers to the benchmark against which the intervention is measured. Often it refers to another treatment, no treatment, or a placebo.

PICO

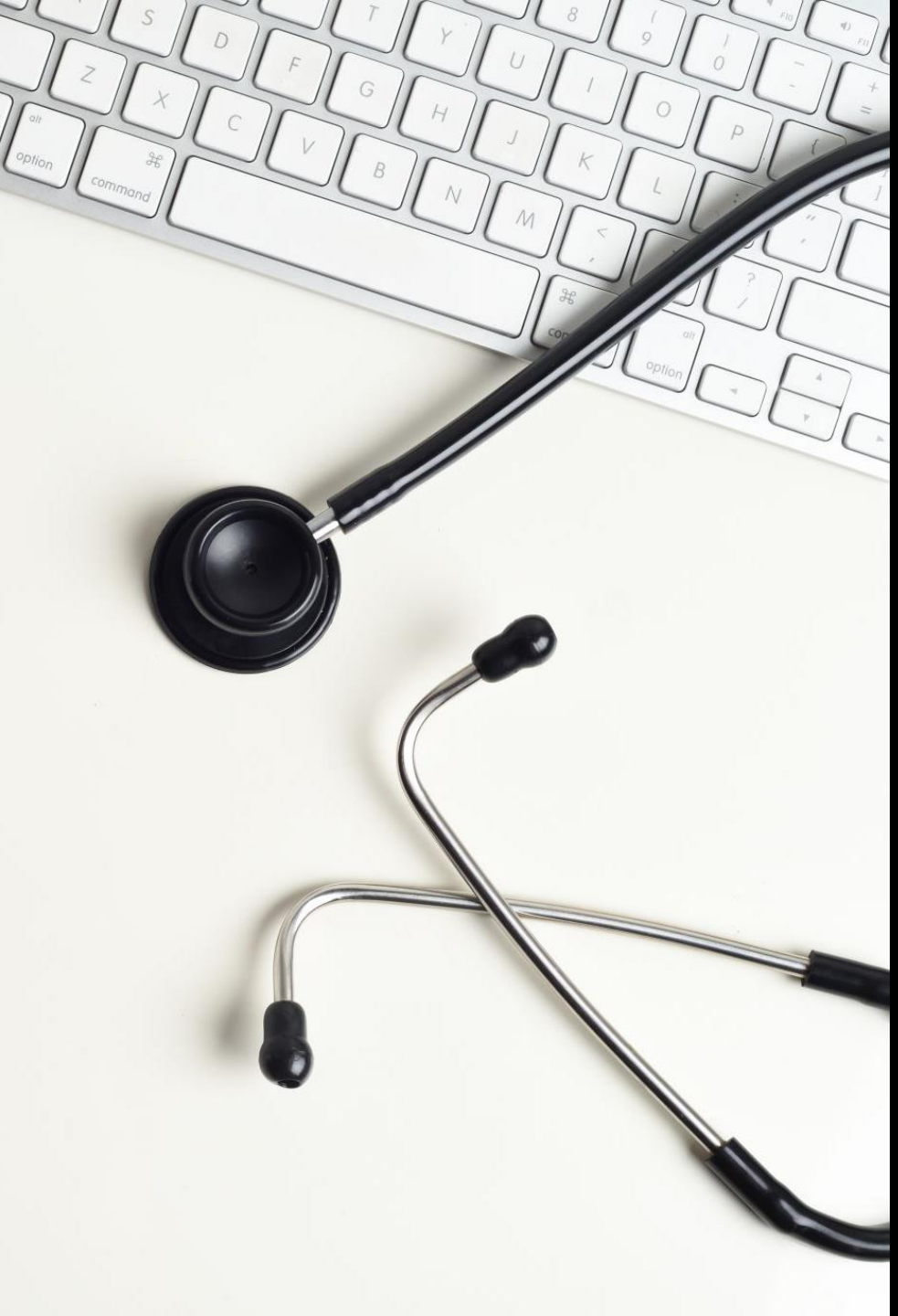
Patient or Problem

Intervention

Comparison

Outcome

"Outcome" refers to the anticipated result of the intervention.



Scenario 2

- You are a physician supervising a senior resident in a tertiary care hospital in Bangkok.
- Your 60-year-old uncle was admitted at your hospital due to congestive heart failure. His underlying diseases were DM, HT and HLP and he has treated with ASA already.
- After recovery from CHF, his EF was 25% with sinus rhythm so his son concerned about thromboembolic risk and ask you whether you will prescribe anti-coagulant for him or not.

Step 1 Converting a clinical problem into a clinical question

P: In 60-year-old man with heart failure, sinus rhythm

I: Warfarin

C: ASA

O: Stroke, Mortality

How can you recognize and formulate clinical questions as they occur?

- Pay careful attention to the questions that spontaneously occur to you.
- Listen for the question behind the question
    - Should he be prescribed for anti-coagulant?

    Might become

    - Is anti-coagulant like wafarin more effective than aspirin for prevention of death and stroke in patients with heart failure?

What if too many questions arise?

- Patients may have several active problems
  - possible questions about diagnosis, prognosis, therapy for each problem
- What is the most important issue for this patient now?
- Which question, when answered, will help me most?
- Then selecting from the many the few questions that are most important to answer right away.

Step 2: Searching the evidence

How?

1. Formulate your PICO question

2. Try secondary sources

3. Choose primary database(s)

4. Combine textwords

5. Filter for the right type of study

Information Sources

SYSTEMS

SYNOPSES

SUMMARIES

STUDIES

Synopses

- Pre-appraised journals and databases
- To identify the most important and valid research articles
- **Benefit of synopses:** save time
- To get the relevant information that would be contained in 1 Evidence-Based Medicine article.

Synopses

ACP Journal club: **http://annals.org/journalclub.aspx**

InfoPOEMs: **http://www.infopoems.com**

EBM Journal (by BMJ): **http://ebm.bmj.com/**

ACP Journal Club

The Best New Evidence for Patient Care

ACP Journal Club summarizes the best new evidence for internal medicine from over 130 clinical journals. Once a bimonthly stand-alone journal, ACP Journal Club is now a monthly feature of Annals of Internal Medicine. Research staff and clinical editors rigorously assess the scientific merit of the medical literature as it is published and a worldwide panel of over 6000 physicians assesses the clinical relevance and newsworthiness of rigorous studies.

2015 ACP Journal Club Articles

17 March 2015

Review: Perioperative β-blockers have variable effects on outcomes in cardiac and noncardiac surgery

17 March 2015

Review: β-blockers do not reduce mortality in myocardial infarction in the reperfusion era

For preventing exacerbations of COPD, withdrawal of inhaled glucocorticoids was noninferior to continuation

Magnussen H, Disse B, Rodriguez-Roisin R, et al; WISDOM Investigators. ***Withdrawal of inhaled glucocorticoids and exacerbations of COPD.*** *N Engl J Med. 2014;371:1285-94.*

Clinical impact ratings: GM ★★★★★★☆ PM ★★★★★★★

Question

In adults with chronic obstructive pulmonary disease (COPD) who use long-acting muscarinic antagonists (LAMAs), long-acting β-agonists, and inhaled corticosteroids (ICSs), is withdrawal of ICSs noninferior to continuing ICSs for preventing exacerbations?

Methods

Design: Randomized controlled noninferiority trial (Withdrawal of Inhaled Steroids during Optimized Bronchodilator Management [WISDOM] study). ClinicalTrials.com NCT00975195.

Allocation: {Concealed}*.†

Blinding: Blinded† {patients, clinicians, data collectors, statisticians, and manuscript writers}*.

Follow-up period: 1 year.

Setting: 200 clinical centers in 23 countries.

Patients: 2488 adults ≥ 40 years of age (mean age 64 y, 83% men, mean FEV_1 after bronchodilation 0.93 L) who had severe or very severe COPD and ≥ 1 exacerbation in the past year; were current or past smokers; and successfully completed a 6-week run-in period with tiotropium, salmeterol xinafoate, and fluticasone propionate. Exclusion criteria included significant illnesses other than COPD, including asthma; oxygen dependence; cancer requiring treatment; hypersensitivity to study therapies; recent pulmonary rehabilitation or steroid use; previous lung resection; or unstable cardiac conditions.

Intervention: ICS withdrawal (n = 1244) or ICS continuation (n = 1244). The withdrawal group received tiotropium and salmeterol as per run-in, but fluticasone was reduced from 1000

Patient follow-up: 81% (modified intention-to-treat analysis of patients who had ≥ 1 dose of study drug).

Main results

ICS withdrawal was noninferior to ICS continuation for moderate or severe COPD exacerbation (Table). Groups did not differ for severe exacerbations (hazard ratio 1.20, 95% CI 0.98 to 1.48) or for change in dyspnea or health status (Table). ICS withdrawal had a 43-mL greater reduction in trough FEV_1 than did ICS continuation (P = 0.001).

Conclusions

In adults with chronic obstructive pulmonary disease who receive both long-acting muscarinic antagonists, long-acting β-agonists, and inhaled corticosteroids (ICSs), withdrawal of ICSs was noninferior to continuing ICSs for preventing exacerbations. ICS withdrawal reduced FEV_1 by a small amount compared with ICS continuation.

**Information provided by author.*

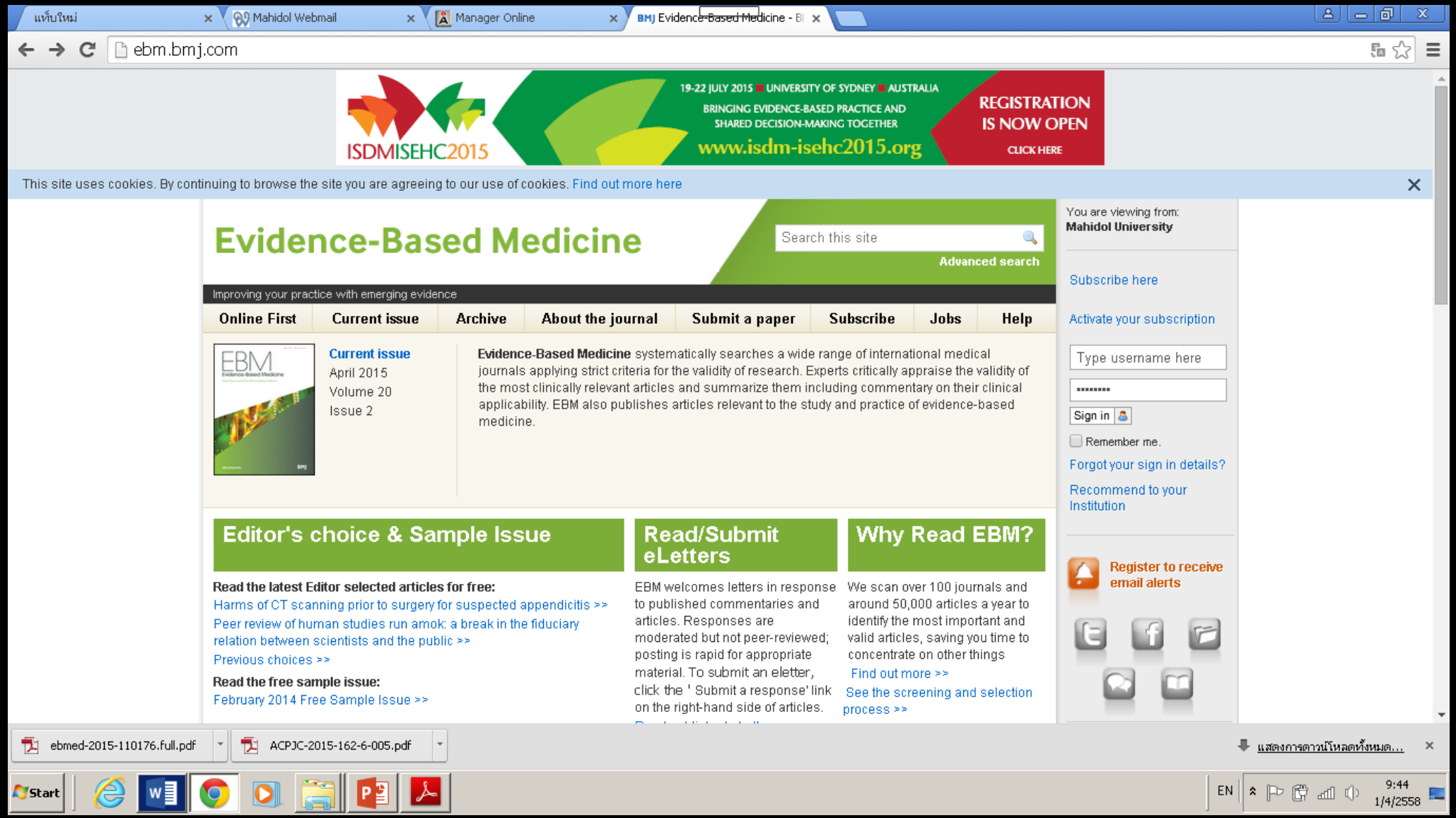
†See Glossary.

Source of funding: Boehringer Ingelheim Pharma.

For correspondence: Dr. H. Magnussen, Pulmonary Research Institute at Lung Clinic Grosshansdorf, Grosshansdorf, Germany. E-mail magnussen@pulmoresearch.de. ■

Commentary

In an earlier era when ICSs were used alone in COPD and before LAMAs became available, withdrawal of ICSs in COPD caused exacerbations and worsened quality of life (1). The contrasting find-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Issue 2
Evidence-Based Medicine systematically searches a wide range of international medical journals applying strict criteria for the validity of research. Experts critically appraise the validity of the most clinically relevant articles and summarize them including commentary on their clinical applicability. EBM also publishes articles relevant to the study and practice of evidence-based medicine.
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Randomised controlled trial

Invasive revascularisation in patients with moderate intermittent claudication provides a significant improvement in quality of life compared with conservative treatment

10.1136/ebmed-2015-110176

Andrew K Kurklinsky

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Correspondence to: Dr Andrew K Kurklinsky, Division of Cardiovascular Medicine, Mayo Clinic, 4500 San Pablo Rd, Jacksonville, FL 32224, USA; kurklinsky.andrew@mayo.edu

Commentary on: Nordanstig J, Taft C, Hensäter M, *et al*. Improved quality of life after 1 year with an invasive versus a noninvasive treatment strategy in claudicants: one-year results of the Invasive Revascularization or Not in Intermittent Claudication (IRONIC) Trial. *Circulation* 2014;130:939–47.

Context

Compared to the age-matched and sex-matched reference group, SF-36 scores were similar in the invasive group, while in the non-invasive group they were significantly lower on all but one subscale.

Increase of ICD in the invasive group (+124 m) was greater than in the non-invasive group (+50 m) (p=0.003), while MWD change in the invasive group (+59 m) compared to non-invasive group (+30 m) trended towards significance (p=0.170).

There was no difference in mortality, amputation rates, or changes in laboratory values between the two groups. In the invasive group 19% of the patients underwent reinterventions to maintain patency.

Commentary

The study results imply a significantly greater positive effect of revascularisation on QoL among patients with moderate IC than with non-invasive treatments. Invasive strategies also seem to provide a greater increase in the walking distances after 1 year. The crossover rate between the groups was low; only 8% of the non-invasive group patients crossed over into the invasive group.

Supervised exercise programmes deliver greater results than non-supervised exercises as in this trial.[1] Nonetheless, in the absence of reimbursement, non-supervised exercises represent the real life reality. It was previously demonstrated that while the walking distance gains may be greater with structured walking exercises than with revascularisation, the greatest improvement in QoL was seen with revascularisation.[2] However, the recommendation for walking exercises three times a week provided in this trial is hardly sufficient and falls short of what is considered to be effective.[1]

Revascularisation provides relief relatively quickly, while non-invasive therapies require time to confer full benefit. As it was previously demonstrated, the cost-effectiveness of exercise training to improve IC symptoms

Information Sources

SYSTEMS

SYNOPSES

SUMMARIES

STUDIES

System

- Regularly updated evidence
- Sometimes with guidance/recommendations
- PIER: http://pier.acponline.org/index.html
- UpToDate: http://www.uptodate.com/
- BMJ Clinical Evidence: http://www.clinicalevidence.com

prediabetes

Wolters Kluwer Health | UpToDate

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Prediction and prevention of type 2 diabetes mellitus

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David K McCulloch, MD
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Topic Outline

INTRODUCTION

Type 2 diabetes mellitus (DM) is characterized by hyperglycemia, insulin resistance, and relative impairment in insulin secretion. Although the lifetime risk of type 2 diabetes is high, our ability to predict and prevent type 2 diabetes in the general population is limited. However, subjects at high-risk, including those with impaired fasting glucose (IFG), impaired glucose tolerance (IGT), obesity, close relatives with type 2 diabetes, or who are members of certain ethnic groups (Asian, Hispanic, black), are appropriate candidates for preventive interventions [1]. (See "Risk factors for type 2 diabetes mellitus".)

The goals of diabetes prevention are delaying the onset of diabetes, preserving beta cell function, and preventing or delaying microvascular and perhaps cardiovascular complications. Of these, preservation of beta cell function may be more important, as beta cell failure largely underlies the transition from pre-diabetic states to diabetes (as well as worsening of glycemic control once diabetes has developed). The individuals demonstrably at highest risk for development of diabetes include those with IFG, IGT, and especially those with combined IFG and IGT [2].

GLUCOSE TOLERANCE STATES AS PREDICTORS OF DM

Abnormal glucose metabolism can be documented years before the onset of overt diabetes. In some groups, insulin resistance appears to be the best predictor of future type 2 diabetes [3], but tests for insulin resistance are not practical in routine clinical practice. Other studies suggest that abnormalities of insulin secretion may precede the development of insulin resistance [4-6].

Information Sources

SYSTEMS

SYNOPSES

SUMMARIES

STUDIES

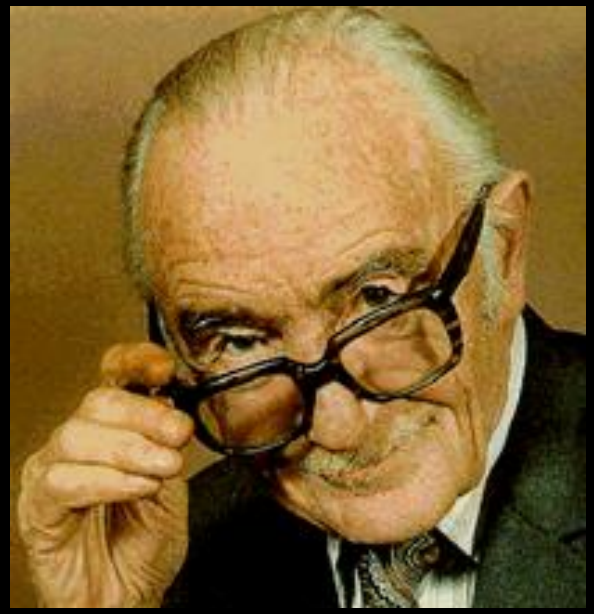
Summaries

Systematic reviews that are well conducted

The Cochrane Library: http://www.cochrane.org

Medical database: Medline, EMBASE, Scopus

Cochrane Library



- http://www.thecochranelibrary.com
- The Cochrane Collaboration founded with respected to Archie Cochrane (1909-1988)

Cochrane library

- Cochrane Database of Systematic Reviews (CDSR)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Cochrane Methodology Register (CMR)
- Database of Abstracts of Reviews of Effects (DARE)
- Health Technology Assessment Database (HTA)
- NHS Economic Evaluation Database

Home - The Cochrane Lib ×

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COCHRANE DATABASE OF SYSTEMATIC REVIEWS

Issue 12 of 12, Dec 2012 | Contents

BROWSE BY TOPICS

- Anaesthesia & pain control (208)
- Blood disorders (127)
- Cancer (416)
- Child health (1502)
- Complementary & alternative medicine (551)
- Consumer & communication strategies (59)
- Dentistry & oral health (142)

SPECIAL COLLECTIONS


World AIDS Day 2012

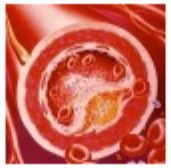

Avoiding unnecessary blood transfusion


Cochrane Evidence Aid: resources for flooding and poor water sanitation

View all

EDITORIAL

Convincing evidence from controlled and uncontrolled studies on the lipid-lowering effect of a statin


Lipitor (atorvastatin) is one of the best-selling pharmaceutical drugs of all time. This month's issue of the Cochrane Database of Systematic Reviews includes a new review by Wright, Adams, and Tsang concerning the effects of this statin. The review is big, and it is not like most of the others in the database...

Read more | View archive

COCHRANE METHODS

www.thecochranelibrary.com/view/0/index.html

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Try secondary sources

Uptodate:
http://www.**uptodate**.com

Cochrane library:
http://www.**thecochranelibrary.**com

TRIP database:
http://www.**tripdatabase**.com

Trip

CT angiography AND MRA AND "renal artery stenosis

Search

Advanced search

PICO search

How to use Trip

PICO Search

PICO is a novel approach of allowing users to conduct a focussed search based on a structured clinical question Learn more at cebm.net

There are 4 elements and not all are compulsory, but the more you use the more focussed the results. We use a contingency search to reduce information overload, click here for further details.

Population: Hypertension

Intervention: CTA

Comparison: MRA

Outcome: renal artery stenosis

Search

Information Sources

SYSTEMS

SYNOPSES

SUMMARIES

STUDIES

Studies

- Original primary studies
  - Randomized/Nonrandomized Controlled Trials
  - Cohort studies
  - Case-control studies
  - Cross sectional studies
  - Case reports

Primary sources

Choosing the right bibliographic database(s)

Database	Coverage
MEDLINE	US database covering all aspects of clinical medicine, biological sciences, education and technology
EMBASE	European equivalent of MEDLINE, with emphasis on drugs and pharmacology
CINAHL	Nursing and allied heath, health education, occupational and physiotherapy, social services

Medical databases

Database	Time	Search engine	Field
MEDLINE	1946 to date	PubMed	American journals
EMBASE	1974 to date	Ovid	European journals
CINAHL	1937 to date	EBSCO	Nursing, allied health
PsycInfo	1887 to date	Ovid	behavioral sciences and mental health

PubMed

- 22 million citations for biomedical literature from MEDLINE, life science journals, and online books
- Is developed and maintained by the National Center for Biotechnology Information (NCBI)
- Free of charge

Scopus

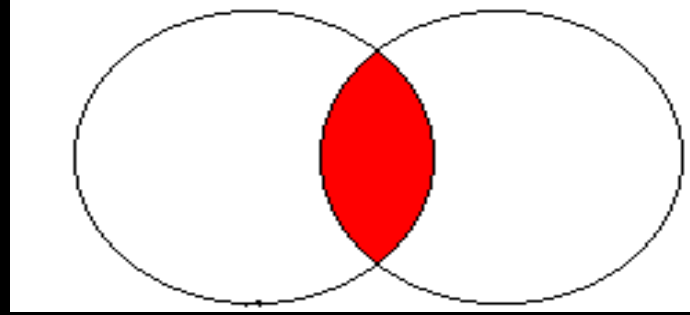
- Original articles from 20,000 peer-reviewed journals
- "Articles-in-Press" from more than 3,850 journals and publishers
- 29 million records, including references, going back to 1995
- 21 million pre-1996 records going back as far as 1823

Search Engine and Database

Search Engine	Database(s)
PubMed	MEDLINE
Ovid	MEDLINE, EMBASE, …
Scopus	SCOPUS

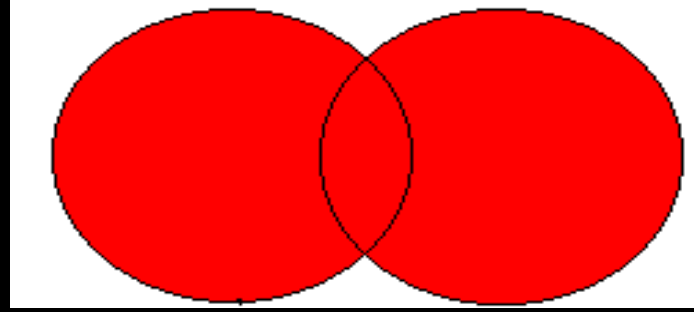
Combine text words Boolean Operators

- Intersection (AND)
  - only those citations that contain selected terms.
- Union (OR)
  - citations that contain at least one of the selected terms.
- Difference (NOT)
  - exclude citations with the selected term



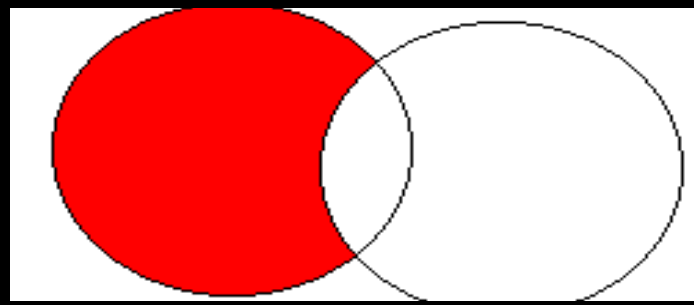
AND

AMD Bevacizumab



OR

AMD DME



NOT

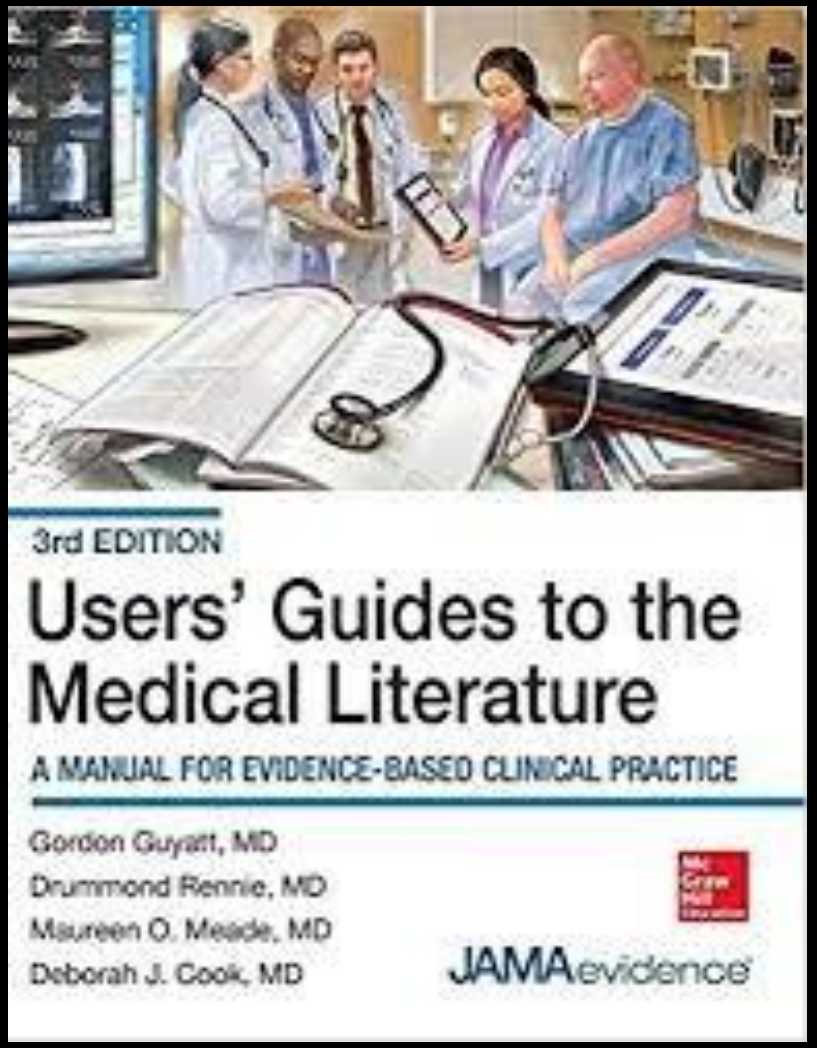
AMD RVO

MEDLINE searching skills

- Searched with keywords
- Applied “Limits’’
- Used “Clinical Queries”
- Used Medical Subject Headings (MeSH)

Step 3 Critical Appraisal of the evidence

Users' Guide for an Article



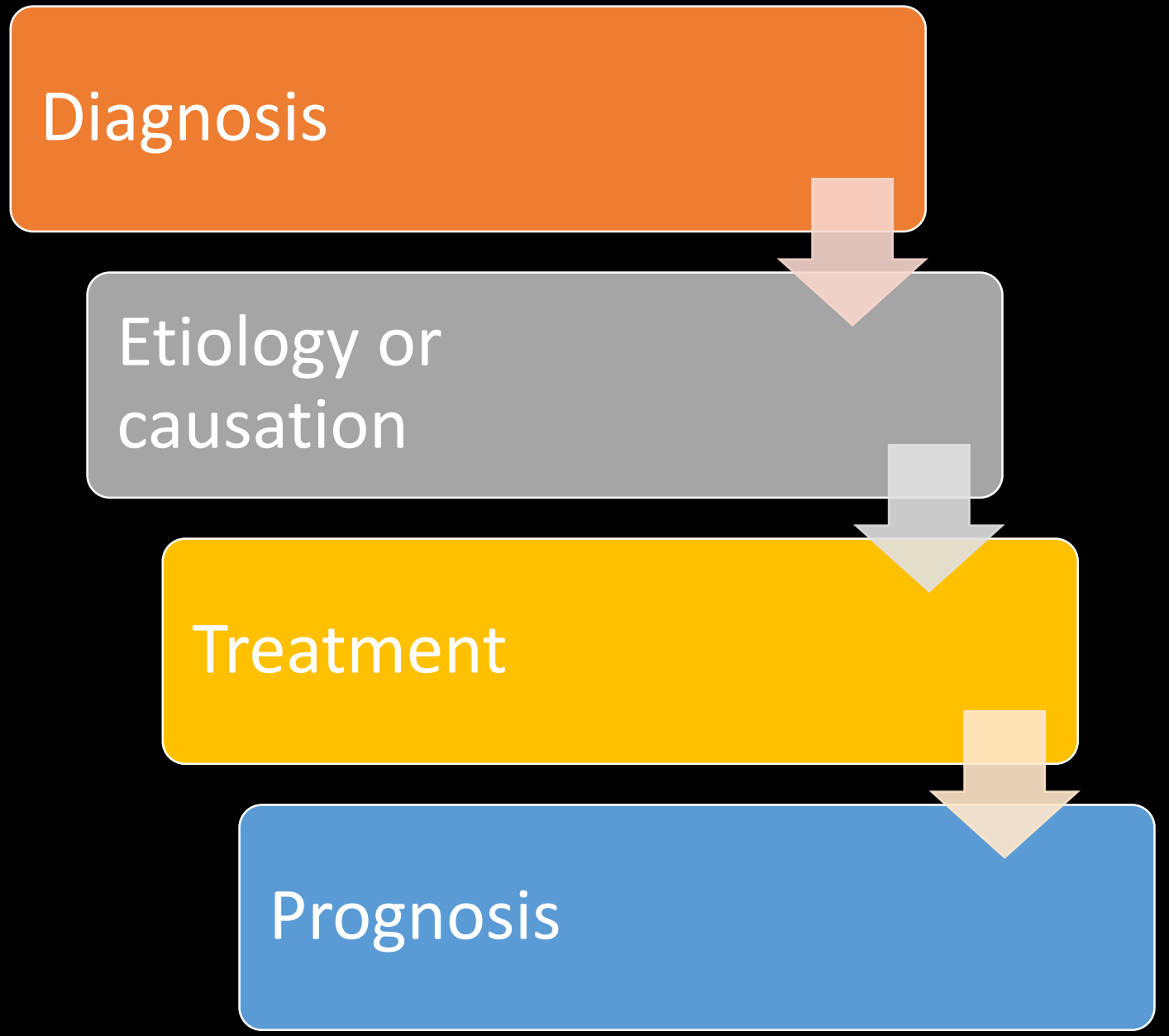
Critical appraisal

Are the results of the study valid?

What are the results?

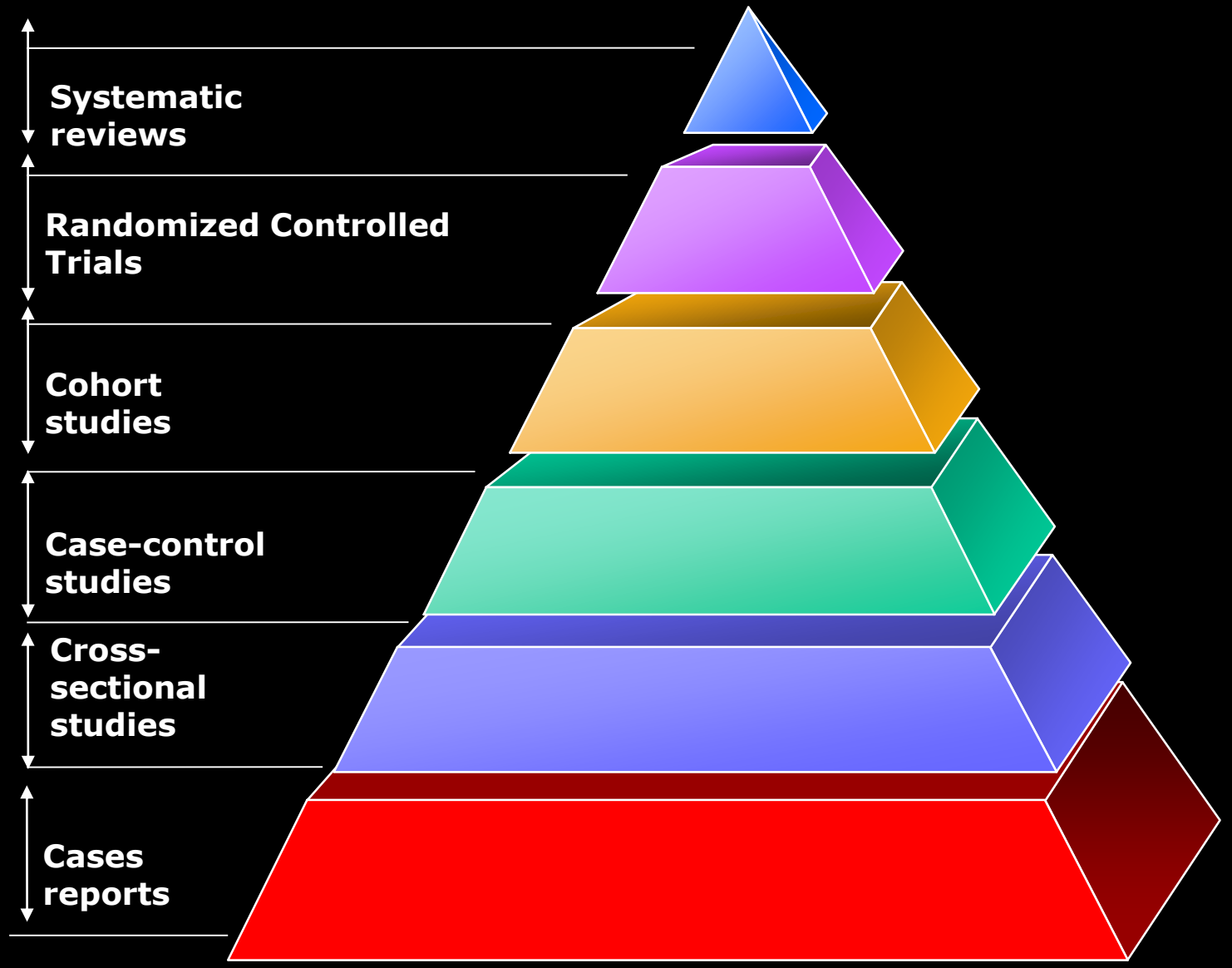
How can you apply the results to patient care?

Type of question in clinical practice

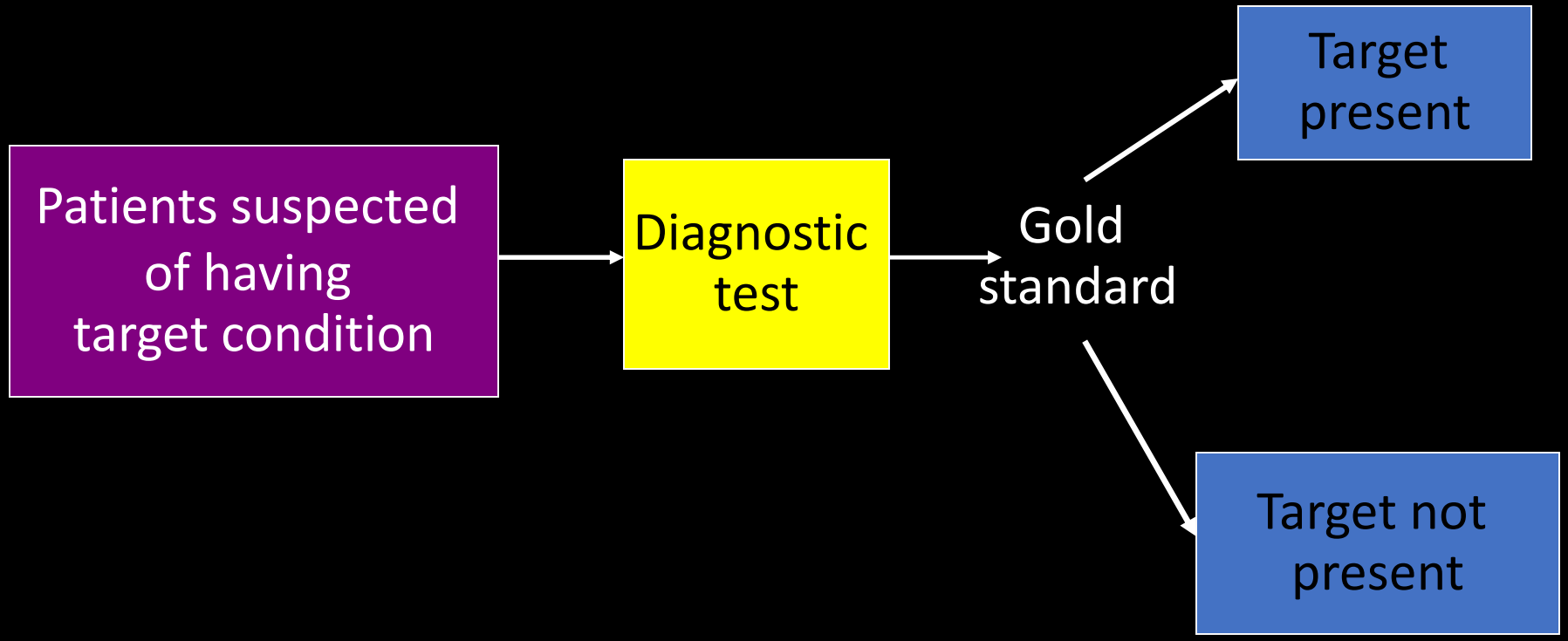


What is the best study design for each types of clinical question?

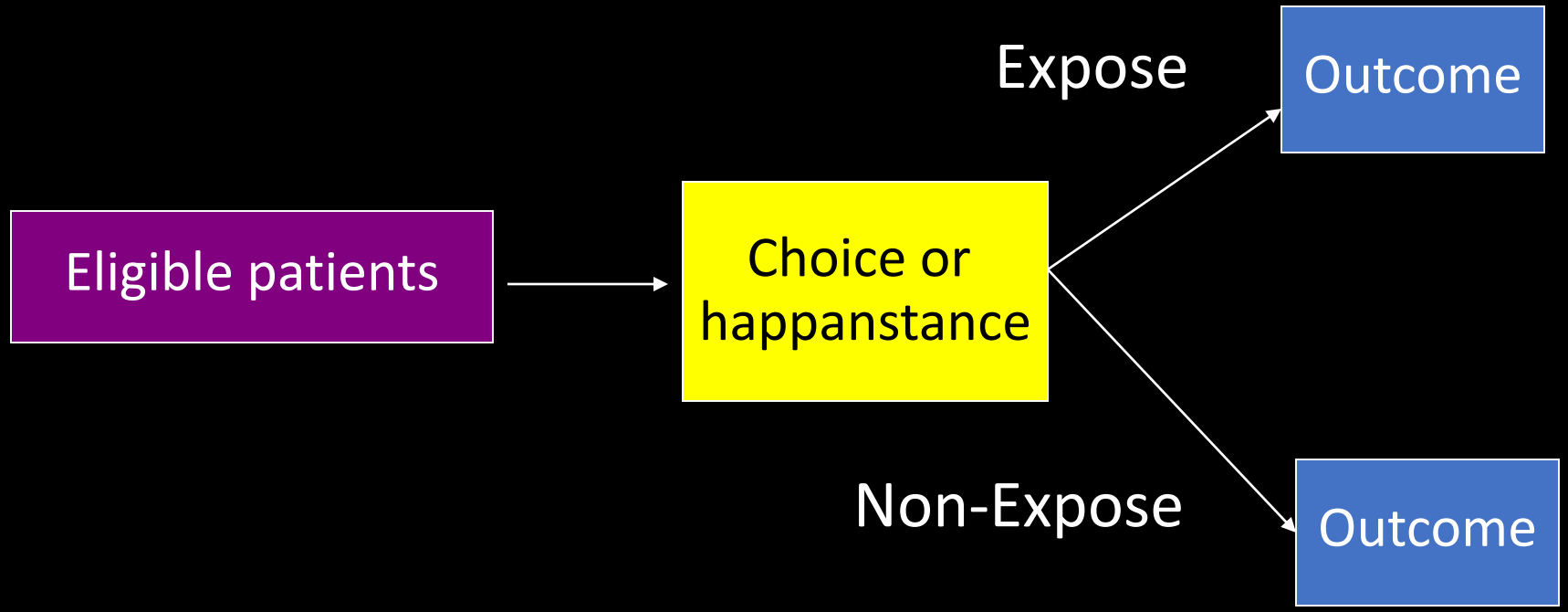
Hierarchy of Evidence



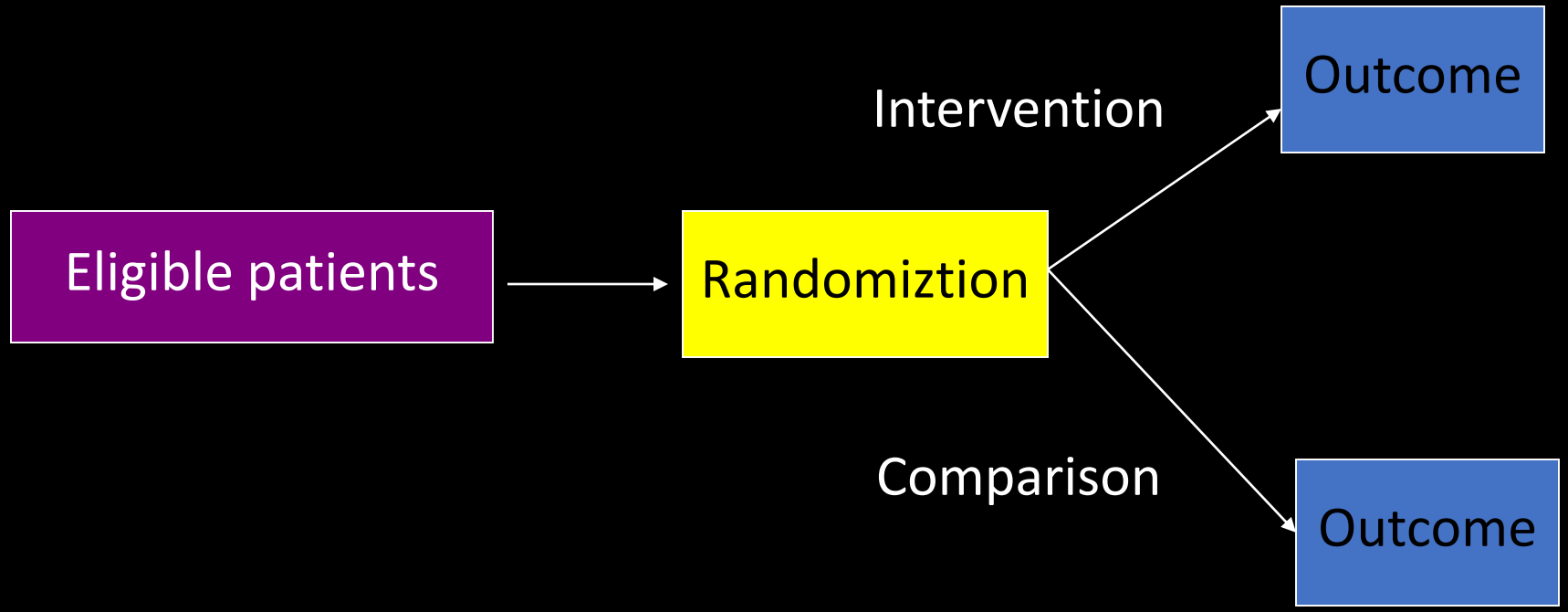
Diagnostic study



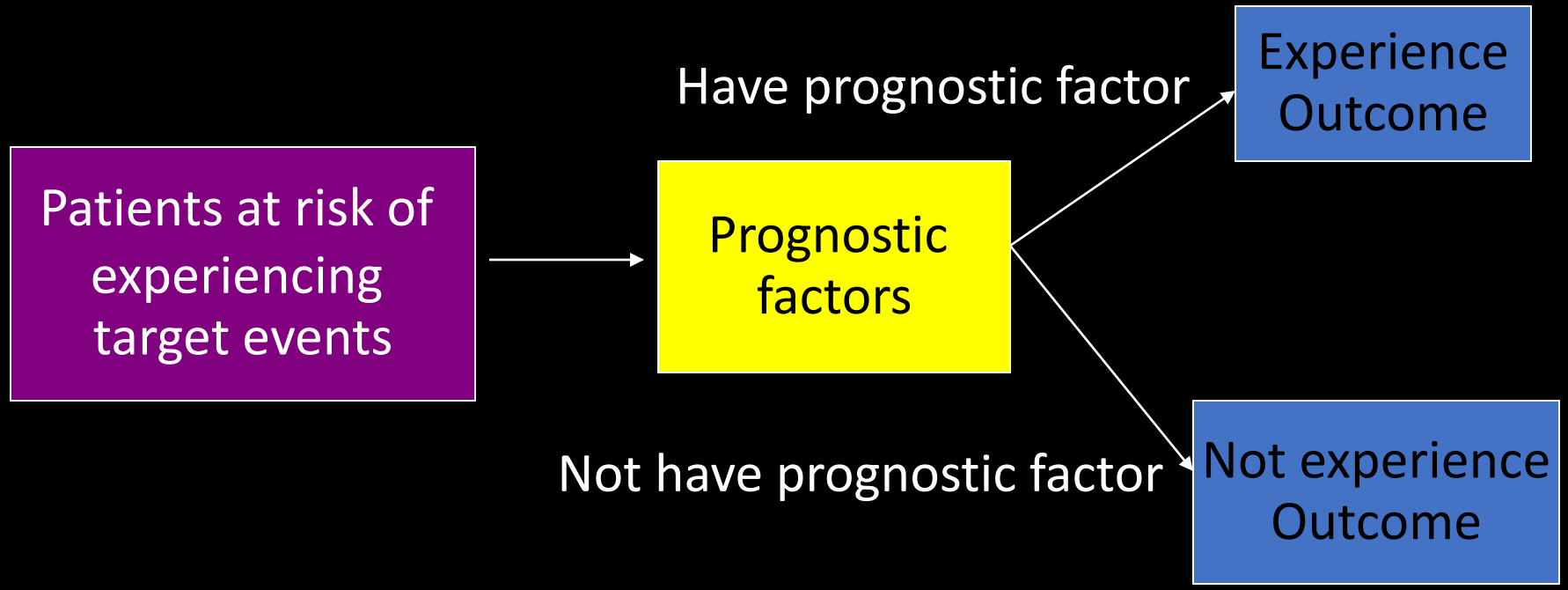
Harm study

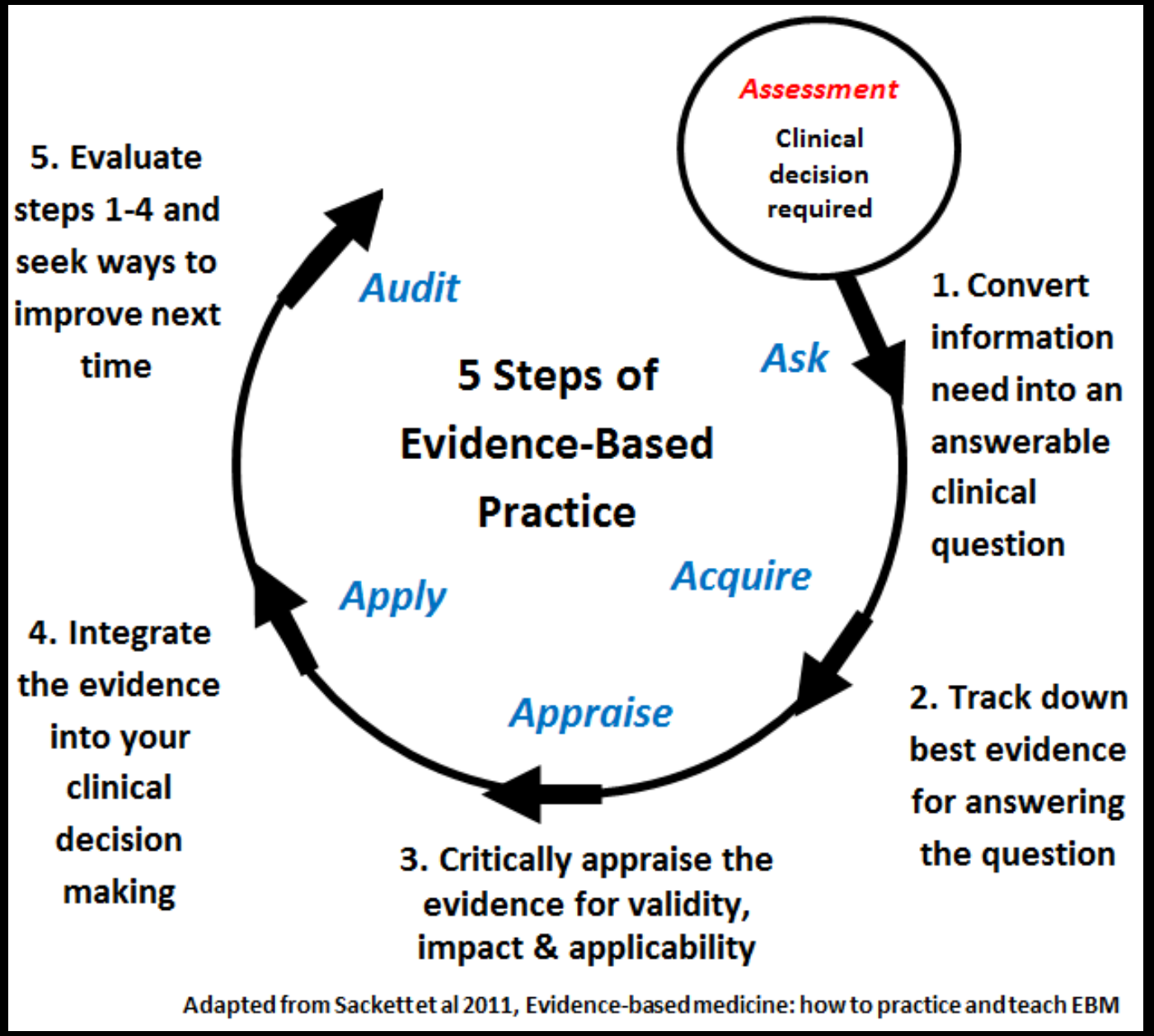

Expose
Outcome
Eligible patients
Choice or happanstance
Non-Expose
Outcome

Therapy study



Prognosis study




Assessment
Clinical decision required
1. Convert information need into an answerable clinical question
2. Track down best evidence for answering the question
3. Critically appraise the evidence for validity, impact & applicability
4. Integrate the evidence into your clinical decision making
5. Evaluate steps 1-4 and seek ways to improve next time
Ask
Acquire
Appraise
Apply
Audit
5 Steps of Evidence-Based Practice
Adapted from Sackett et al 2011, Evidence-based medicine: how to practice and teach EBM

EBM is a lifelong learning process that includes:

- Evaluating the performance of the information in clinical practice.
- Discovering areas where more research is needed.
- Applying the information in clinical practice with physicians.

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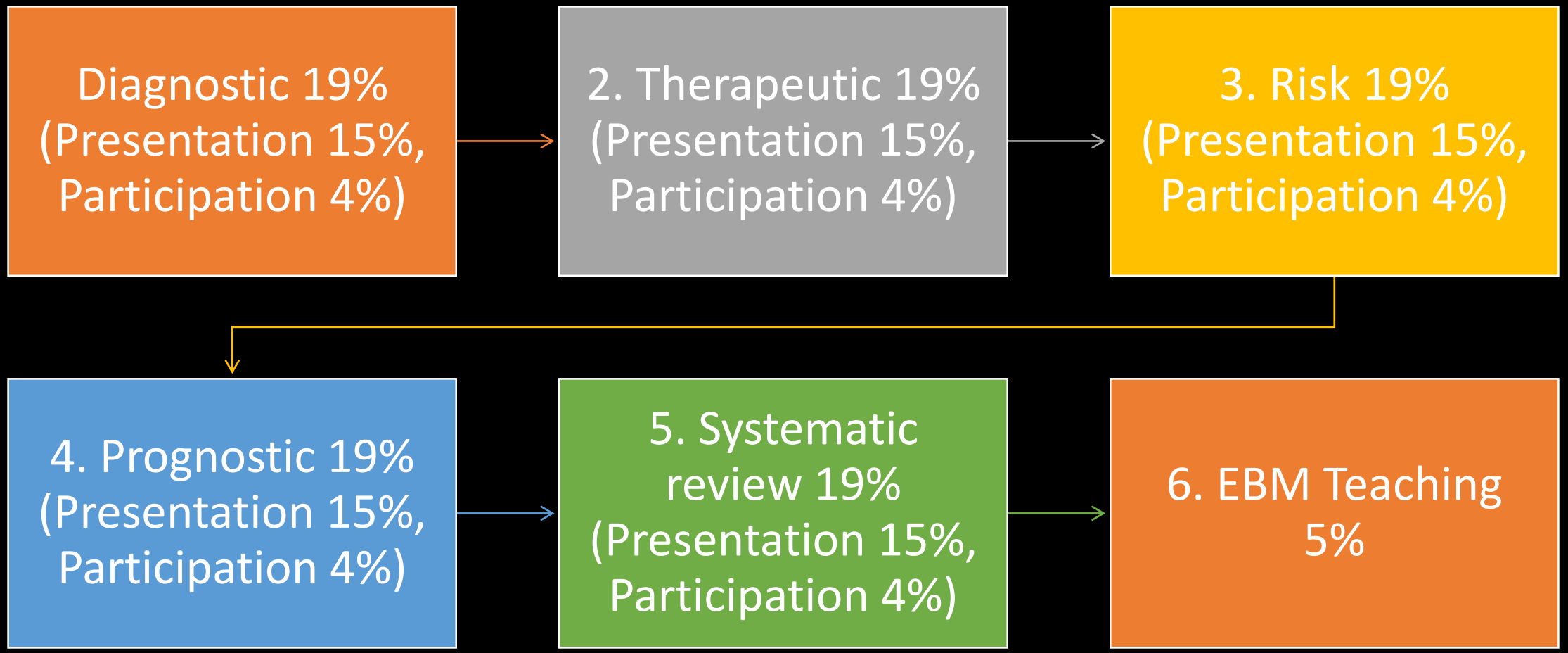
- Diagnostic study
- Therapeutic study
- Risk/harm study
- Prognostic study
- Systematic review
- Guideline

LECTURE

SMALL GROUP DISCUSSION

PRESENTATION OF CRITICAL APPRAISAL

Assignment


Diagnostic 19% (Presentation 15%, Participation 4%)
2. Therapeutic 19% (Presentation 15%, Participation 4%)
3. Risk 19% (Presentation 15%, Participation 4%)
4. Prognostic 19% (Presentation 15%, Participation 4%)
5. Systematic review 19% (Presentation 15%, Participation 4%)
6. EBM Teaching 5%