

Principles of evidence based medicine

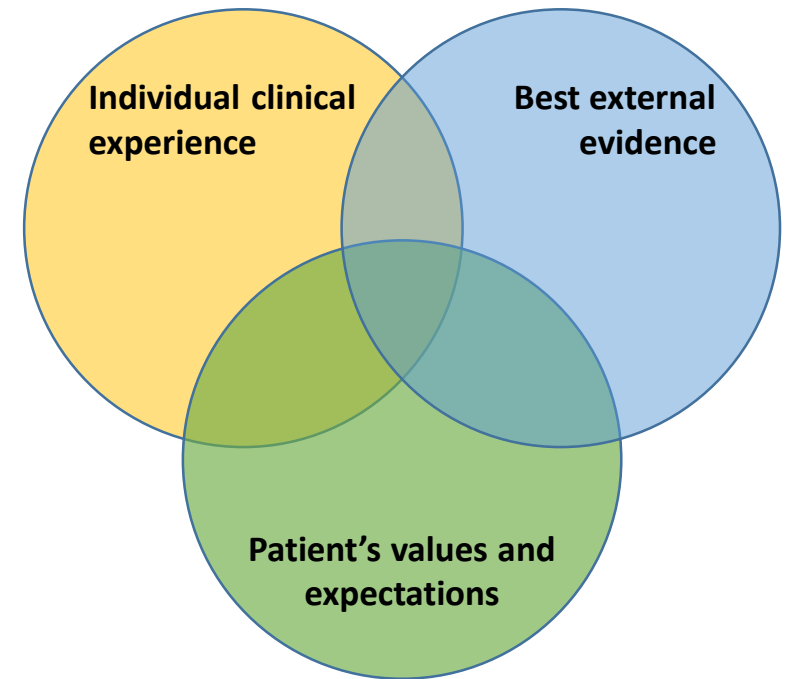
«Some doctors do the same mistakes for many years and call it clinical experience»

N. Fabricant

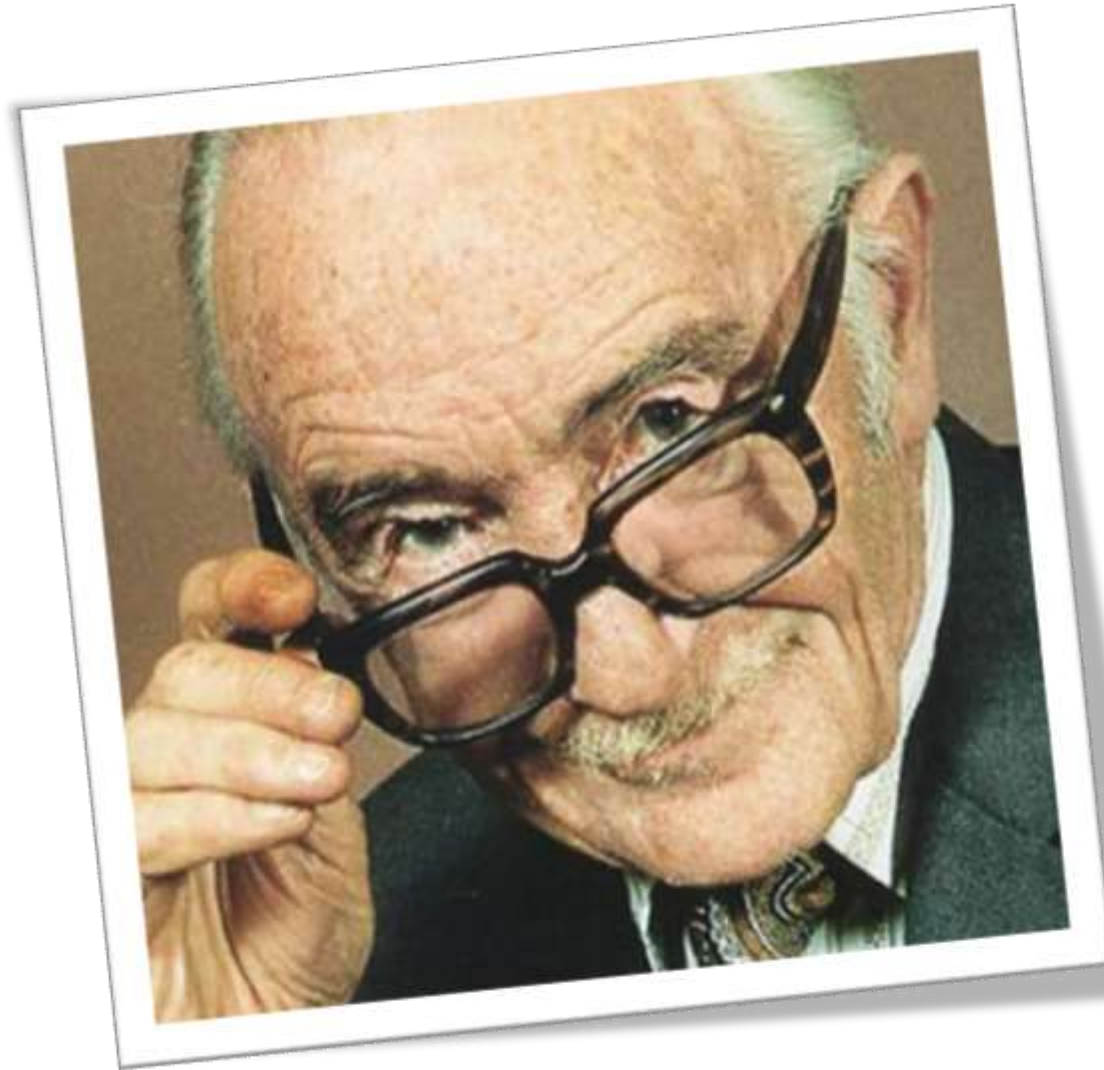


Evidence based medicine (EBM)

- the integration of the best research evidence with clinical expertise and patient values



(Archie Cochrane), the founder of EBM



History of EBM

- 1940 - the first randomized study
- 1960 - a tragedy associated with thalidomide
- 1962 - The US Committee for the control of medicines and food products introduced rules requiring controlled trials of new drugs
- 1971 - Cochran raised the issue of lack of scientific evidence
- 1980-90 - to draw attention to the need to include systematic reviews in clinical guidelines
- 1994 - the first Cochrane colloquium in Oxford
- 1994 - The term EBM
- 1996 - the majority of UK doctors know the term EBM
- 1996 - British Minister of Health said - its main task is to promote the concept of EBM
- 1996 - The term EBM Titles British newspapers
- 1999 - BMJ publishes a guide to EBM
- 2001 - German, Spanish, Russian, Japanese edition

Why do we need EBM? Lifelong Learning

- **Old method:** read a few journal articles per week
- **Reality:**
 - Primary care docs would need over **17 hrs/day** just to review reasonable and pertinent material
 - Even in one narrow specialty would need 6+hrs/wk
 - Practicing docs (all specialties) average 1-1.5 hrs/wk

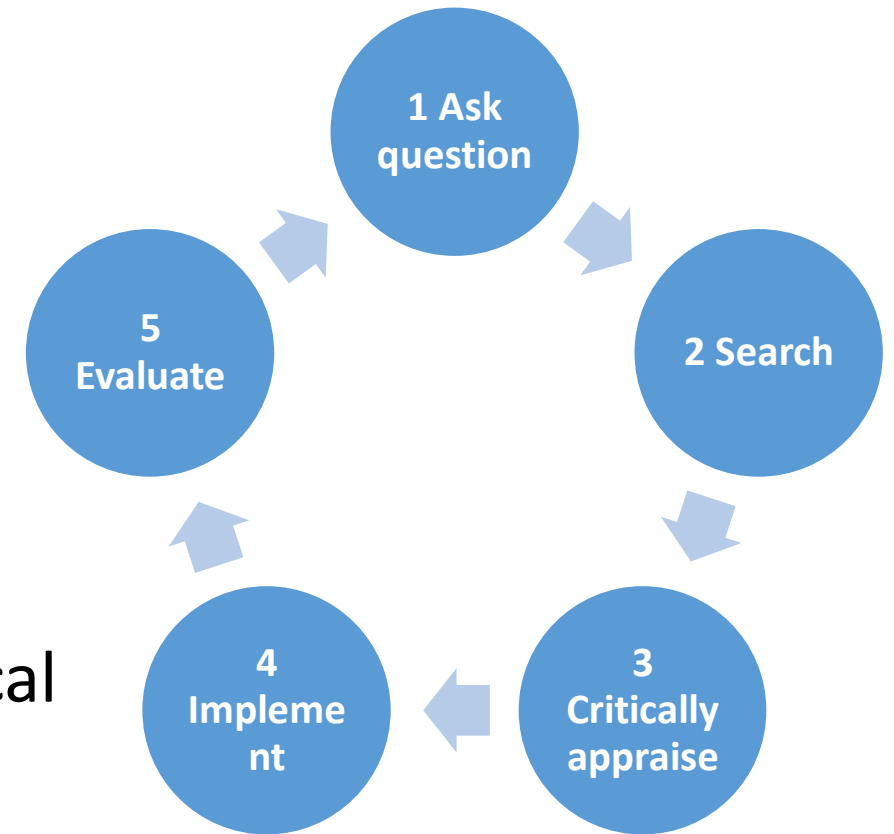


The aim of evidence based medicine

- give physicians the ability to find and use in clinical decision-making research evidence obtained in the course of properly conducted clinical research, improve the accuracy of prediction of outcomes of medical interventions
- The concept is based on two main ideas:
- Each physician clinical judgment should be made taking into account the scientific data
- The weight of each fact greater, the more severe methods of scientific research in which it was received

The Process of EBM use

- **ASK:** Formulate an answerable clinical question
- **ACCESS:** Track down the best Evidence
- **APPRAISE:** Appraise the evidence for its validity and usefulness
- **APPLY:** Integrate the results with your clinical expertise and your patient values/local conditions
- **ASSESS:** Evaluate the effectiveness of the process



Step 1: ASK an answerable clinical question

Ask
question

- Background questions (*What do I know about this?*)
- Foreground (Clinical) Questions

P patient, population, problem	I intervention	C comparison	O outcome
Who?	What?	Alternative Intervention?	Outcomes
"How would I describe a group of patients similar to this particular patient?"	"Which treatment, test or other intervention?"	"Compared to what other treatment, test, or perhaps compared to doing nothing"	What is the patient oriented outcome – better prognosis? Higher rate of cure? Etc.?"

Examples

P	I	C	O
Kids with acute otitis media -2-4 y/o	Antibiotics	No treatment except acetaminophen for pain/fever	No pain after two days?
Adult with microhematuria	IVP	CT scan	Diagnostic accuracy (Predictive value or likelihood ratio)
Adult patients <70	TIA	No TIA	Rates of CVA within 90 days
Healthy adolescents	Routine scoliosis screen	No screening – evaluate only if problems	Pain, disability, need for intervention

Example: Intervention Questions

- Identify background questions, create a PICO and a focused clinical question for this case:

54 year old male patient was diagnosed with intermediate grade prostate cancer and wants to know whether to get a radical prostatectomy or radiation treatment. He is concerned about death from prostate cancer and also risks of impotence and incontinence.

Example: Formulate the Clinical Question

- PICO

- **P** – 54 year old male with intermediate grade prostate cancer
- **I** – radical prostatectomy
- **C** – radiation treatment
- **O** – reduce risk of mortality, impotence, and incontinence

- Focused clinical question

In 54 year old male patients with intermediate grade prostate cancer is radical prostatectomy more effective compared to radiation treatment in reducing the risk of mortality, impotence, and incontinence?

Etiology and Risk Questions

- What causes a disease or health condition?
- The reverse of intervention questions-they deal with harmful outcomes of an activity or exposure (public health issues)
- Develop a clinical question for the case:

S. is a smoker and just found out that she is 3 months pregnant. She quit smoking immediately. But she is worried if her developing baby was harmed and if the baby is at risk for having developmental problems. She is asking you if smoking during the first trimester can harm her baby?

Etiology or Risk Questions

- **P** – babies of mothers who smoke
 - **I** – smoking in first trimester
 - **C** – nothing
 - **O** – increase risk of developmental problems
-
- Question:
Are babies of mothers who smoke during their first trimester at an increased risk of developmental disabilities?

Diagnosis Questions

- These questions are concerned with how accurate a diagnostic test is in various groups and in comparison to other tests or usually to a “gold standard test”.

As part of your clinic assessment of elderly patients, there is a hearing check. You think that a simple whispered voice test is very accurate compared to other methods. You want to do a literature search. What is your question? (1)

Glasziou P, Del Mar C, Salisbury J. EBP Workbook, 2nd. ed. BMJ Books, 2007.

Example

- **P** – elderly people
 - **I** – whispered voice test
 - **C** – no test (or other tests)
 - **O** – accurate diagnosis of hearing problems
-
- Question: In elderly people, does the whispered voice compared to other tests give an accurate diagnosis of hearing problems?

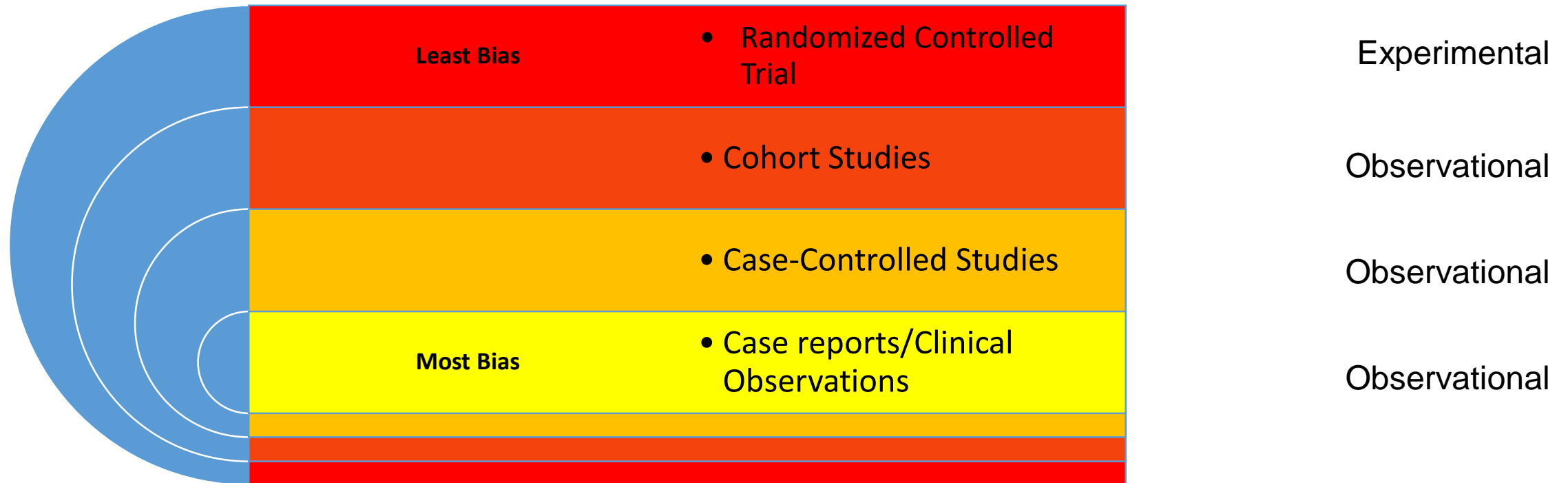
Choose the best type of study for question

A hierarchy of evidence for each type of question

Therapy/Prevention What should I do about this problem?	RCT -> cohort -> case control -> case series
Diagnosis Does this person have the problem?	cross-sectional study with blind comparison to a gold standard
Etiology/Harm What causes the problem?	RCT -> cohort -> case control -> case series
Prognosis/Prediction Who will get the problem?	RCT -> cohort study -> case control -> case series
Frequency and Rate How common is the problem?	cohort study -> cross-sectional study

NOTE: A well designed systematic review of RCTS (randomized controlled trials) is **best** as it is least biased therefore more valid.

Hierarchy of Study Designs for Intervention

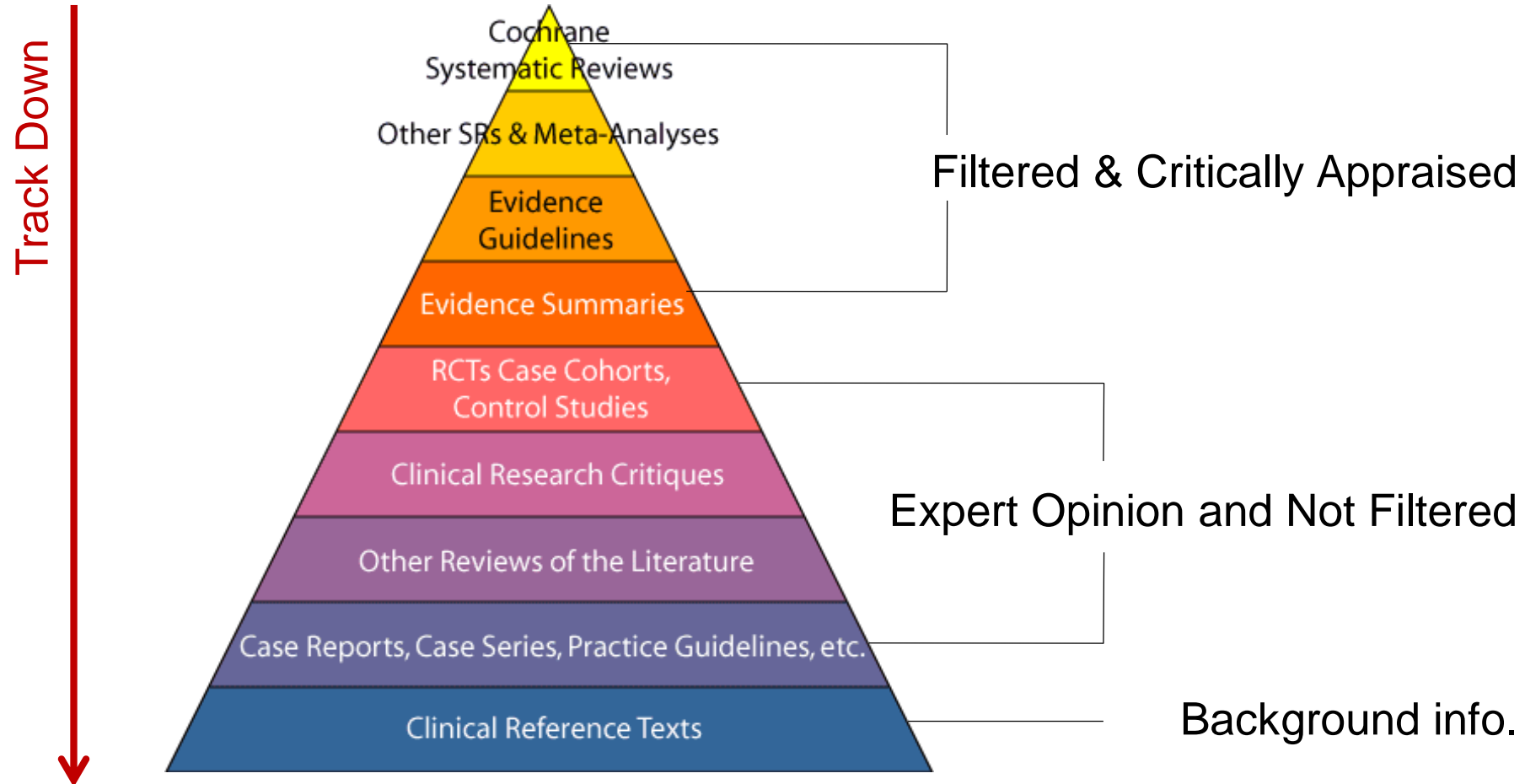


To recognize the type of study ask the questions:

1. Is intervention randomly assigned? Yes-RCT; No-Observational study
2. When were the outcomes determined?
 - After the exposure-cohort study (prospective study)
 - During the exposure-cross-sectional study
 - Before the exposure-case-control study (retrospective study based on recall)

Hierarchy of Evidence – Access evidence at the level that will give you the best evidence

Most clinically relevant (at the top) Least clinically relevant (at the bottom)



Levels of Evidence (LOE)

Centre for Evidence-Based Medicine, Oxford

- Level 1: Systematic Review (with meta-analysis) of Randomized Clinical Trials
- Level 2: Cohort Studies
- Level 3: Case-Control Studies
- Level 4: Case-series
- Level 5: Expert Opinion

Strength of Recommendation (SOR) Taxonomy

- A: There is good research-based evidence to support the recommendation.
- B: There is fair research-based evidence to support the recommendation.
- C: The recommendation is based on expert opinion and panel consensus.
- X: There is evidence of harm from this intervention.

Bottom Line on LOE or SOR

LOE	SOR	
Level 1	A	Highest level
Level 2		
Level 3	B	
Level 4		
Level 5	C	Lowest level, but still evidence

Filtered and Critically Appraised Evidence-Based Resources

- *The Cochrane Library* by The Cochrane Collaboration via Wiley
 - Independent non-for-profit international collaboration
 - Reviews are among the studies of highest scientific evidence
 - Minimum Bias: Evidence is included/excluded on the basis of explicit quality criteria
 - Reviews involve exhaustive searches for all RCT, both published and unpublished, on a particular topic
 - Abstracts searchable for free on the Internet; complete database is available via HINARI for most countries
 - 1995-

Clinical guidelines (recommendations)

statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options



The objectives of clinical guidelines

- **make** evidence-based **recommendations clear** and accessible;
- **simplify** and make more objective process of **clinical decision-making** at the bedside;
- serve as a **criterion** for the evaluation **of professional activity**;
- provide **segregation of duties** (for example, between a general practitioner and specialist);
- **educate patients and physicians** on the best currently processes of care;
- **improve the cost-effectiveness** of health care
- serve as an instrument of **external control**

Evidence value of recommendations

- **Class I.** Evidence and / or general agreement that these methods of diagnostic / treatment - **helpful and efficient**.
- **Class II.** Evidence is **controversial** and / or opposing views about the **usefulness / efficacy** of treatment.
- **II-a class.** **Most of the evidence** / opinion in favor **of usefulness / efficacy**
- **II-B class.** The **usefulness / efficacy are not sufficient** evidence / definite opinion.
- **Class III.** Evidence of, and / or general agreement indicates that the **treatment is not useful / effective** and in some cases may be harmful

Levels of evidence

- Level A. The proofs are based on data from many randomized clinical trials or meta-analyzes.
- Level B. The proofs are based on data from one randomized clinical trial or multiple non-randomized studies.
- Level C. Agreed expert opinions and / or a few studies, retrospective studies, registries.
- The highest level of recommendation - I, A.

Randomized controlled trials (RCTs)

- **answer** to the question of the **effectiveness** of clinical diagnostic and therapeutic measures
- distribution of patients is randomly into **2 groups (of intervention and control)**.
- aimed at **identification of** pre-identified outcomes "**hard end points**" (the development of stroke, myocardial infarction, and so on).
- reliable data on risk factors and safety of medical interventions can also be found in the RCT.

Features of RCT

- **Blind** (blind study) - one or more of the parties involved do not know how patients are distributed and / or agents for the treatment and control groups
- **Randomization** (randomized study / trial) - Patients allocated to treatment groups based on randomization procedure (equal probability to increase the preparation of each of the funds)
- **Stratification** (stratification) - improving the uniformity of the distribution of risk factors (age, sex, obesity, genetic marker, and others.) In the treatment groups
- **Criteria for inclusion** /exception - features that allow / not allow the patient to participate in the study.

A systematic review and meta-analysis

Systematic (systematic) review

- it is almost a scientific study, the material for which are the results of clinical trials
- the goal is balanced and impartial examination of the results of earlier studies
- the main requirement is the analysis of all quality original research, dedicated to a specific issue.
- Quantitative assessment of the total effect, established on the basis of the results of all investigated studies carried out using meta-analysis.

Meta-analysis

- A meta-analysis is a statistical method to combine the results of all trials devoted to the same subject.
- used to evaluate the clinical efficacy of therapeutic interventions (methods of examination and treatment)
- the results of the meta-analysis are usually presented in the form of a graph, and the odds ratio - the total index of the severity of the effect.
- The results of clinical trials and the conclusion of a meta-analysis made based on them, are commonly used in writing clinical guidelines (recommendations)



Sources of information on evidence-based medicine.

"Knowledge is of two types - we do know the subject or we know where to find information about it"

S. Johnson

Medical electronic databases, which include only materials that meet the criteria of methodological quality

- **Best Evidence**
- **Cochrane Library (Кокрановская библиотека)**
- **UpToDate**
- **MEDLINE**
- **PubMed**
- **Clinical Evidence**

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Клинические протоколы и рекомендации
Кардиология:

<i>Сердечно-сосудистые заболевания</i>	Клинический протокол оказания медицинской помощи по кардиологии (Приказ МОЗ Украины от 03.07.2006г. № 436). Сердечно-сосудистые заболевания. Классификация, стандарты диагностики и лечения. Под ред. проф. В. Н. Коваленко, проф. М. И. Лутая, проф. Ю. М. Сиренко.
<i>Сочетанная патология</i>	Рекомендации по диабету, предиабету и сердечно-сосудистым заболеваниям EASD/ESC, 2014 2014 ESC/ESA Guidelines on non-cardiac surgery: cardiovascular assessment and management, 2014
<i>Артериальная гипертензия</i>	2013 ESH/ESC Guidelines for the management of arterial hypertension. Рекомендации ESH/ESC по артериальной гипертензии 2013 Гипертензивные кризы: диагностика и лечение. Консенсус Ассоциации кардиологов Украины и Украинской ассоциации по борьбе с инсультом. Киев, 2013.

Поиск по сайту:

 **Міністерство охорони здоров'я України**

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Пульмонология:

[Клинический протокол оказания медицинской помощи по специальности "Пульмонология" \(наказ МОЗ 128 від 19.03.2007 р.\).](#)

[Рекомендации GOLD 2015, eng. - современные рекомендации по лечению ХОЗЛ.](#)

[Рекомендации GOLD 2014, рус.яз. - современные рекомендации по лечению ХОЗЛ.](#)

[Introduction and methods: British Thoracic Society pleural disease guideline 2010 - Руководство по лечению плевритов, Британия, 2010](#)

[Global strategy for asthma management and prevention 2015.](#)

[Pocket guide for asthma management and prevention \(for Adults and Children Older than 5 years\) / GINA poket 2015](#)

[Pocket guide to COPD diagnosos, management, and prevention / Global Initiative for Chronic Obstructive Lung Disease 2015](#)

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