

Evidence Based Medicine

Steps and Qualification of Evidence

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What Is Evidence-Based Medicine (EBM)

It is the type of medicine which utilize the best available evidence in literature and incorporates the physician's clinical judgment together with the patient's values and principles in order to create the best management plan for this particular patient with a specific health problem.

In other words, it is a systematic approach to applying state-of-the-art medical knowledge to improve outcomes.

The Rapid Spread of EBM-The Reasons

- 1-The daily need for valid information about diagnosis, prognosis, therapy & prevention.
- 2-Inadequacy of traditional sources of information: textbooks are out-of-date, experts opinions are frequently wrong, ineffective CME programs and medical journals are variable in validity for clinical use.

The Rapid Spread of EBM-The Reasons

- 3-The disparity between our diagnostic skills and clinical judgement, which increase with experience, and our up-to-date knowledge and clinical performance which decline.
- 4-The inability to set aside adequate time per patient for finding the evidence, or to set time per week for general reading and study.

Steps of Evidence Based Medicine

- A-Formulate a clinical searchable question: Converting the need for information (about prevention, diagnosis, prognosis, therapy, etc.) into an answerable question.
- B-Conduct a literature search to find the best evidence to answer that question.
- C-Evaluating the validity of available sources. Critically appraising that evidence for its validity, size of the effect and applicability.

Steps of Evidence Based Medicine (Cont.)

D-Integrating the critical appraisal with your clinical expertise and with your patient's values.

E-Evaluating your effectiveness and efficiency in executing Steps 1-4 and seek methods to improve them for future patients.

Steps in The EBM Process (Cont.)

Patient	Identify clinical problem.
Question	Construct a well defined question (PICO).
Resource	Conduct a search from appropriate resource.
Evaluation	Critically appraise the evidence (randomization, blindness, completeness of follow up...).
Patient	Integrate the evidence with clinical expertise and patient preference.
Self-evaluation	Evaluate your performance with this patient.

Clinical Scenario I

A 30-year-old lady with severe preeclampsia who had several doses of magnesium sulphate through few hours. She developed oliguria, respiratory depression and her reflexes were found to be hypoactive.

-You are concerned whether these manifestations are due to magnesium sulphate toxicity.

-Is calcium gluconate 10% effective in ameliorating these manifestations?

Practice

- 1-Patient population: Oliguria/respiratory depression and hypoactive reflexes are associated with Mgso₄.
 - 2-Intervention: Calcium gluconate 10%.
 - 3-Comparison: To placebo.
 - 4-Outcome: amelioration of toxic manifestations.
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Formulate a clinical question that can be answered using evidence-based principles:

Is calcium gluconate 10% compared to placebo, effective in ameliorating signs of Mgso₄ toxicity.

Constructing A Strategy

Clinical question	Clinical scenario	Search strategy
Patient population	Lady on Mgso4 who developed signs of toxicity	Mgso4, oliguria, respiratory depression, hypoactive reflexes
Intervention	Calcium gluconate 10%	Calcium gluconate 10%
Comparison	Placebo	RCT
Outcome	Ameliorating signs of toxicity	?

Clinical Scenario II

A female 32 years old diagnosed with extensive endometriosis was advised to use GnRH agonists for 1 year.

At a follow up visit, she was concerned about possible decreased bone mass after 6 months of GnRH agonists use.

Add back therapy in the form of oestrogen and progesterone was described.

Practice

- 1-Patient population: A female 32 years old diagnosed with extensive endometriosis was advised to use GnRH agonists for 1 year.
- 2-Intervention: Oestrogen and progesterone add back therapy.
- 3-Comparison: To placebo.
- 4-Outcome: maintains bone mass.

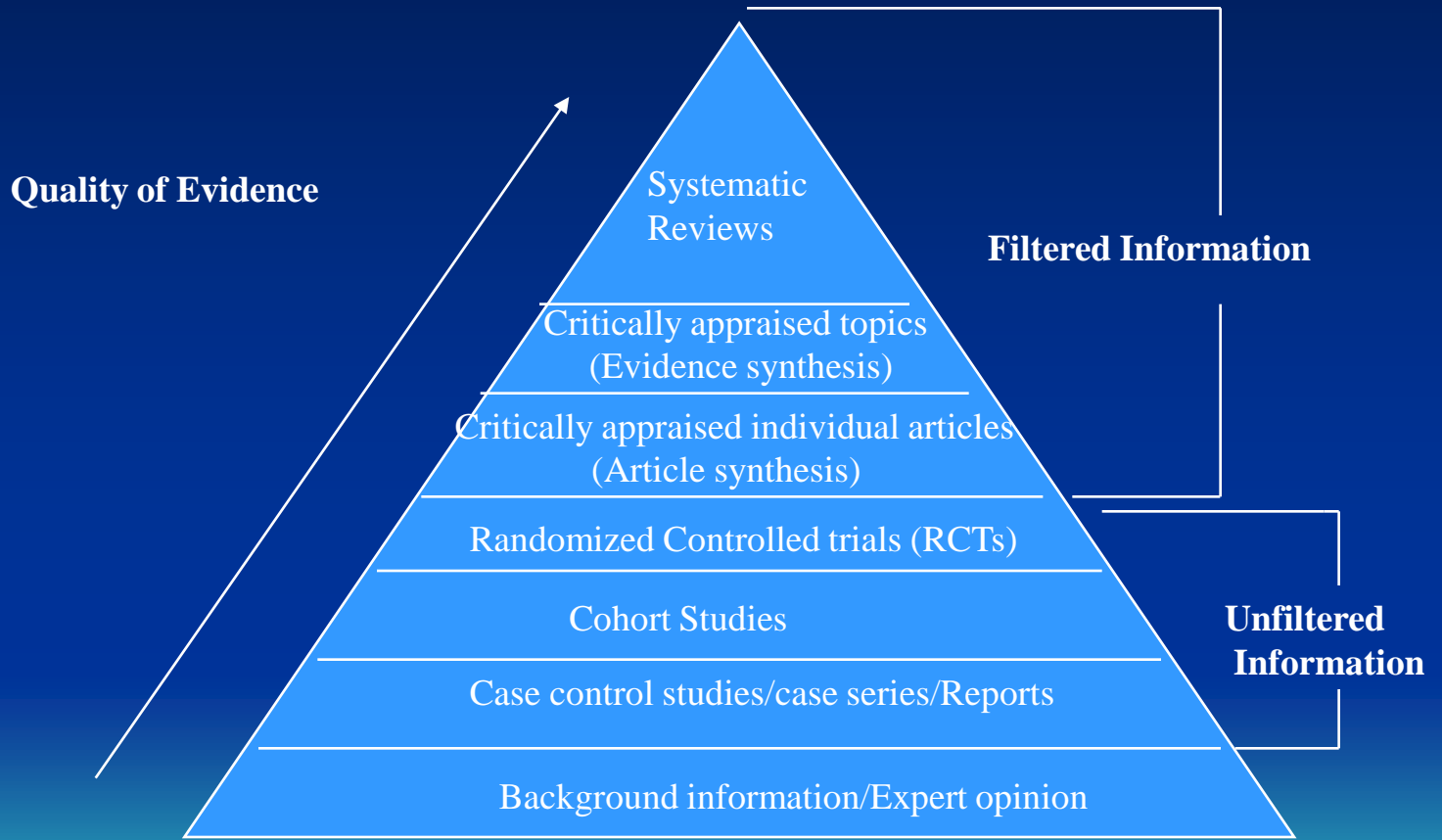
Formulate a clinical question that can be answered using evidence-based principles:

Is E+P add back therapy, compared to placebo, helps to maintain bone mass after 1 year of continuous use of GnRH α .

Constructing A Strategy

Clinical question	Clinical scenario	Search strategy
Patient population	A female on GnRH agonists for endometriosis	Bone mass
Intervention	Estrogen & Progesterone add back therapy	Estrogen & Progesterone add back therapy
Comparison	Placebo	RCT
Outcome	Maintains bone mass	?

Hierarchy of Evidence



Sackett DL, et al.
BMJ 1996;312:71-72.

Systematic Reviews and Meta-Analysis

- Systematic reviews provide a rational basis for comparing similar studies.
- They use uniform criteria to choose studies & decide which to include.
- They may include a meta-analysis, a quantitative method for comparing results across multiple studies.

Qualification of Evidence

Evidence-based medicine categorizes and ranks different types of clinical evidence according to the strength and freedom from the various biases. For example, the strongest evidence for therapeutic interventions is provided by systematic review of randomized, double-blind, placebo-controlled trials involving a homogeneous patient population and medical condition. In contrast, patient testimonials, case reports, and even expert opinion have little value because of the biases inherent in observation & reporting of cases, difficulties in defining who is an expert & other causes.

Qualification of Evidence (Cont.)

The U.S. Preventive Services Task Force have ranked evidence about the effectiveness of treatments or screening as follows:

- Level I: Evidence obtained from at least one properly designed RCT.
- Level II-1: Evidence obtained from well-designed controlled trials without randomization.
- Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- Level II-3: Evidence obtained from multiple time series with/without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.
- Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Qualification of Evidence (Cont.)

The UK National Health Service uses a similar system with categories labeled A, B, C, and D. The above Levels are only appropriate for treatment or interventions.

- Level A: Consistent RCT, cohort study, validated in different populations.
- Level B: Consistent Retrospective Cohort, exploratory Cohort, ecological Study, outcomes research, case-control study or extrapolations from level A studies.
- Level C: Case-series study or extrapolations from level B studies.
- Level D: Expert opinion without explicit critical appraisal, or based on physiology, bench research or first principles.

Qualification of Evidence (Cont.)

A newer system is by the Grade Working Group and takes in account more dimensions that just the quality of medical evidence. Extrapolations are where data is used in a situation which has potentially clinically important differences than the original study situation. Thus, the quality of evidence to support a clinical decision is a combination of the quality of research data and the clinical 'directness' of the data.

Categories of Recommendations

- Level A: Good scientific evidence suggests that the benefits of the clinical service substantially outweighs the potential risks.
- Level B: At least fair scientific evidence suggests that the benefits of the clinical service outweighs the potential risks.
In levels A & B, clinicians should discuss the service with eligible patients.
- Level C: At least fair scientific evidence suggests that there are benefits provided by the clinical service, but the balance between benefits and risks are too close for making general recommendations. Clinicians need not offer it unless there are individual considerations.

Categories of Recommendations (Cont.)

- Level D: At least fair scientific evidence suggests that the risks of the clinical service outweighs potential benefits. Clinicians should not routinely offer the service to asymptomatic patients.
- Level I: Scientific evidence is lacking, of poor quality, or conflicting, such that the risk versus benefit balance cannot be assessed. Clinicians should help patients understand the uncertainty surrounding the clinical service.

Thank you

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