

Evidence-Based Medicine

Samuel N. Forjuoh, MB, ChB, DrPH

Associate Professor

Department of Family & Community Medicine

Texas A&M University System Health Science Center

College of Medicine, Scott & White Hospital

Temple, Texas



Outline of Presentation

- * EBM: definition, concept, rationale
- * **EBM: process, application, methods**
- * EBM: role of medical informatics
- * **Critical reading & appraisal of the medical literature**



EBM - Definition, **Concepts & Rationale**

Definition: What is EBM?

* EBM involves the *integration* of the following parameters in **making decisions** about **patient care**:

- Clinical expertise
- **Patho-physiological knowledge**
- Patient preferences
- **The current best evidence**

EBM means . . .

- * A conscientious, explicit, and judicious use of *the current best evidence (proof, support or testimony)* to make a decision about the care of patients

EBM also means ...

- * Integrating individual **clinical expertise** learned in medical school with the best available clinical evidence from **systematic research**



EBM is simply

- * The long awaited **bridge** between medical research and medical practice
- * The translation of relevant research findings into clinical practice

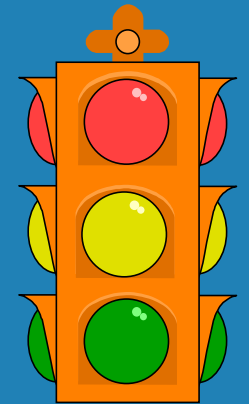


Practicing EBM ...

- * Requires a **significant shift** from the clinical thought processes that most physicians were trained to use

Practicing EBM also ...

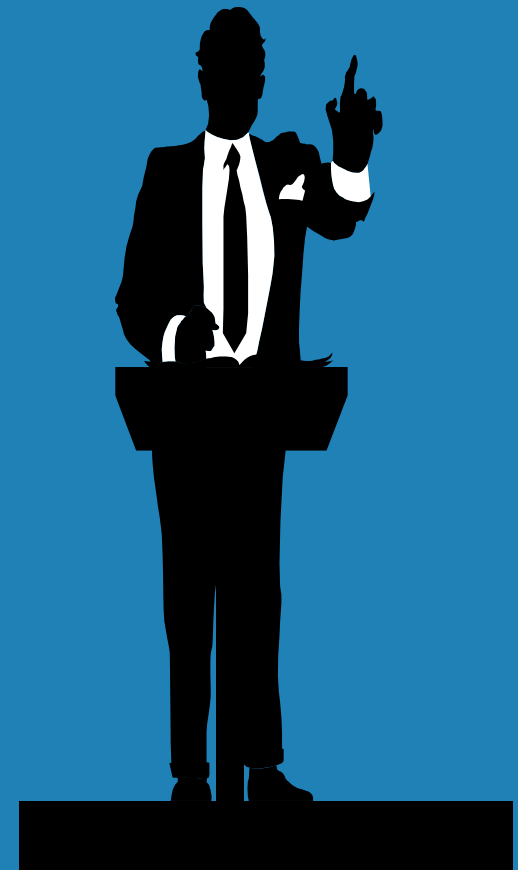
* Requires a **significant attitude shift** from:



- **Authority** ==> **Evidence**
- **Anecdotes** ==> **Outcomes**

Clinical Decisions In the Past

- * **Clinical experience**
- * Expert opinions
- * **Collegial relationships**
- * Patho-physiology
- * **Common sense**
- * Community standards
- * **Published materials**



EBM Clinical Decisions

- *Clinical experience*
- *Expert opinions*
- *Collegial relationships*
- *Patho-physiology*
- *Common sense*
- *Community standards*
- *Published materials*

* **Filtering questions**

- What is the evidence?
- On what evidence is this advice based?



Practicing EMB implies

- * We should not do things because that is the way everybody does it
- * **Practice guidelines should be based on evidence that has passed through the filtering questions**
- * Practice should be based on specific clinical issues in an explicit & accountable manner

Why Support EBM? ...

- ✧ **Cost-containment for efficacious therapies**
 - Government directives
 - Insurance industry directives
- ✧ **Improved quality of care**
- ✧ **Improved patient satisfaction**
- ✧ **Computer age**

Why Support EBM?

- ✧ **Intellectual reward for clinician**
- ✧ **Increased knowledge:**
 - **what works?**
 - **what does not work?**
- ✧ **Organizational educational mission**
- ✧ **Service to the community**

Current Advocacy for EBM

* Enhance physicians'

- Information needs
- Information retrieval skills
- Knowledge base after training
- Practice *via* removing variation for intervention with established efficacy

* Make clinicians **intelligent & informed consumers** of research



Reasons for Resistance to EBM

- * **Tradition**
- * Competition with clinical judgment
- * **Lack of time**
- * Cookbook medicine



EBM - Process,

Application & Methods



Process/Steps of EBM

- * Define the question
- * Find the evidence
- * Analyze the evidence
- * Summarize the evidence
- * Use evidence for practice

Application of EBM

*Disease management

- Diabetes
- Congestive heart failure

*Clinical teaching

- Attending rounds
- Resident reports

Methods of EBM ...

- ✧ **Posing relevant focused questions**
- ✧ Critical appraisal of the literature
- ✧ **Searching for the best evidence electronically**
- ✧ Application of the evidence in clinical decision-making

Methods of EBM

*Requires knowledge of:

- Clinical epidemiology
- **Biostatistics**
- Medical informatics
- **Critical appraisal skills**

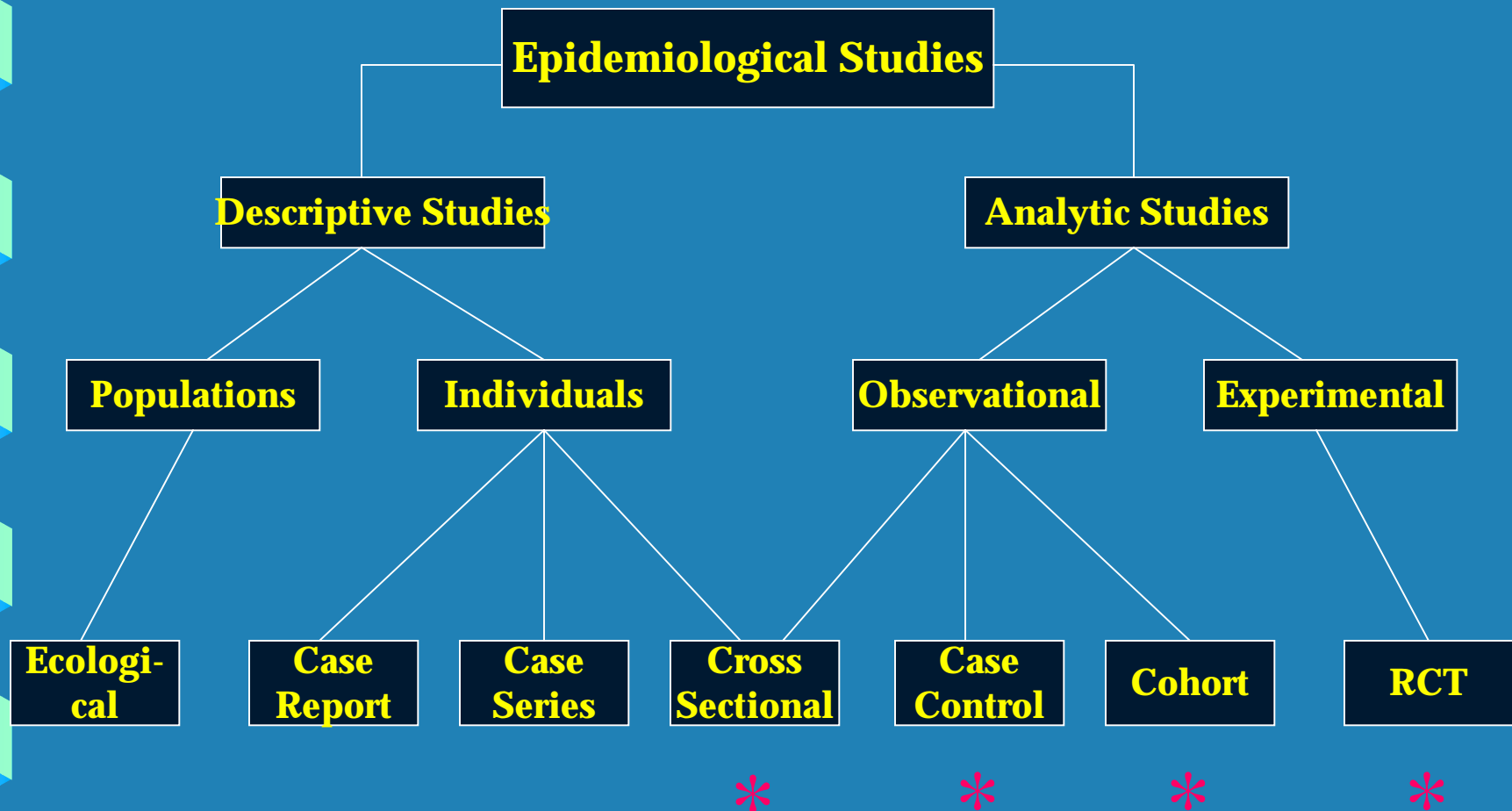
Review: Elements of EBM

- * **Clinical expertise**
- * **Patho-physiological knowledge**
- * **Patient preferences**
- * **The current best evidence**
– from systematic research

Systematic Research in EBM

- ✦ **Clinico-epidemiological studies**
 - Case-control studies
 - Cohort studies
- ✦ **Randomized controlled trials**
- ✦ **Meta-analysis**
- ✦ **Cost-effectiveness analysis**
- ✦ **Decision analysis**

Review: Epidemiological Design Strategies



Meta-Analysis

- * A systematic process of combining the results of different research studies using statistical methods to obtain a numerical estimate of an overall effect
 - Primary aim: to enhance the statistical power of research findings when numbers in the available studies are too small
 - Involves a 7-step process
 - Has some pitfalls, e.g., publication bias

Cost-Effectiveness Analysis

- * An economic process of evaluating decision alternatives by making all effects commensurable in terms of money *or* a natural unit (e.g., lives saved, cases of diseases averted) and comparing these dimensions of impact
 - Result expressed as cost per unit of clinical effect

Decision Analysis

- * An explicit process of considering medical choices, medical outcomes, and the uncertainty in the clinical and test data used to make decisions
- * Elements in a formal DeA
 - Decision diagram *or* tree
 - Probabilities for uncertain events
 - Incorporation of test results
 - Medical outcomes of alternative choices

Summary: Research in EBM

- * CES => Practice guidelines
- * RCT => Performance measures
- * MeA => Pathways of care
- * CEA => *Process-based data*
- * DeA => *Outcome-based data*

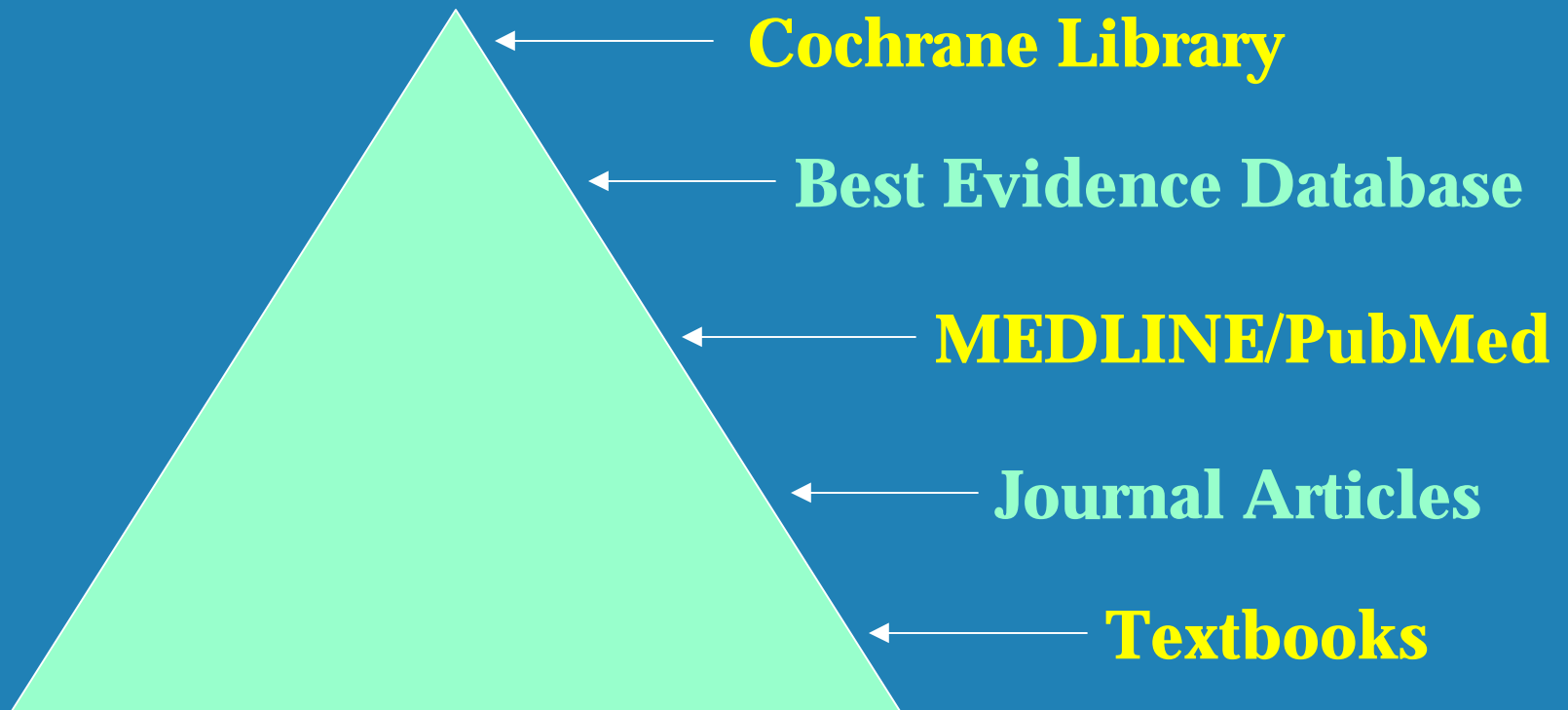


EBM - Role of Medical Informatics

Medical Information System

- * **Journal articles**
- * Monographs
- * **Newsletters**
- * News media
- * **Computers**
- * Textbooks
 - **etc, etc, etc.**
- * Practice guidelines
- * **CME courses**
- * Colleagues
- * **Clinical experience**
- * Journal clubs
- * **Patients**
 - **etc, etc, etc.**

Hierarchical Search for Evidence





Cochrane Library

- ✧ Electronic publication designed to supply high quality evidence for healthcare decision making
- ✧ Parts of the Cochrane Library
 - Cochrane Database of Systematic Reviews
 - Database of Abstracts of Reviews of Effectiveness (D.A.R.E.)
 - Cochrane Controlled Trials Register

Best Evidence Database

* **Electronic database of the summaries of articles from the major medical journals, along with commentaries from experts**

- JAMA, BMJ, NEJM, e.t.c.

MEDLINE & PubMed Search

*PubMed - National Library of Medicine's version of the MEDLINE database

- Related articles

Netting the Evidence

- * <http://www.shef.ac.uk/~scharr/ir/email.html>
 - E-mail discussion lists on evidence-based healthcare
- * <http://www.cochrane.org>
 - The Cochrane Collaboration home page
- * <http://www.familypractice.msu.edu/InfoMastery>
 - “Information Mastery: An Introduction” which is a web-based course from Michigan State U
- * <http://www.infomedica.org/ebm>
 - Evidence-Based Medicine - in the Italian language



Lecture Series

Goal & Summary

To make you all intelligent & informed consumers of medical research

- Principles of Epidemiology
- Methods of Epidemiology/Biostatistics
- Evidence-Based Medicine

Medical Information Process

Analogy to the Steps in the
Production of Petrol for
Consumers

Step 1
Production
Original research
Clinical experience

Step 2
Refinery
Meta-analyses
Decision analyses

Step 3
Delivery
Informatics
process

Step 4
Sales/Market
Intelligent
consumption

The 4 Steps of the Medical Information Process

Adapted from: Shaughnessy & Slawson (1999)



Critical Reading & Appraisal of Literature

Appraising Clinical Trials ...

- ✧ **What was the null hypothesis?**
- ✧ Which group was being tested
- ✧ **How many subjects were entered into the trial and how were they selected?**
- ✧ How adequate was the description of the treatment(s)?



Appraising Clinical Trials

- ✧ How was blinding achieved?
- ✧ **What were the results**
- ✧ How biologically plausible are the results?
- ✧ **How consistent are the results with previous literature?**

The Null Hypothesis

- ✧ **What was the outcome of interest?**
- ✧ What was thought to be a meaningful difference in outcome between the current and new treatment?

Groups Being Tested

- ✧ How was the study population for the trial selected?
 - Exclusion criteria
 - **Random selection vs volunteerism**
- ✧ What were demographic and health characteristics of the group?



Sample Size & Subject Selection

- ✧ Was the sample size determined a-priori?
- ✧ Was it based on an acceptable sample size estimation procedure?
- ✧ Were subjects selected in a way to ensure equal distribution of known risks?



Treatment In the Trial

- ✧ If appropriate, was there a non-treated group?
- ✧ If the control was “standard therapy”, was the treatment reasonable?



Blinding Subjects/Investigators

- ✧ Did the patients know which treatment they received?
- ✧ Did the investigators know which treatments patients received?
- ✧ Did the person measuring the outcome know if patients were in the experimental or control group?

Results

- ✧ **Were groups similar w.r.t. known prognostic factors?**
- ✧ Were side effects recorded and reported?
- ✧ **Who were included in the final analysis?**
- ✧ Was loss to follow-up addressed?
- ✧ **Were confidence intervals reported?**
- ✧ If results were negative, was statistical power addressed?



Biological Plausibility of Results

- ✧ **Were results biologically plausible?**
- ✧ If not, was this addressed adequately?
- ✧ **During analysis, were patients kept in their originally assigned groups?**

Consistency of Results

- * Were results consistent with previous literature?
- * If not, was this addressed adequately?
- * Were enough of the data presented to permit justification of conclusions?

Appraising Observational Studies

- * **Clarity of stated hypotheses, if any**
- * Use of the appropriate design for question to be addressed
- * **Source of study subjects => same source**
- * Clarity of definition of exposures and outcomes of interest
- * **Objective measures or markers to validate subjective measures**



Appraising Observational Studies

- * Adequacy of follow-up for outcome development
- * Discussion of losses to follow-up
- * Examination of dose-response relations
- * Appropriateness of analytical methods
- * Statistical significance of the results with confidence intervals or p-values
- * Clinical meaning of the results