Evidence Based Medicine - Principles & Practice

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Abstract

Evidence–based medicine (EBM), is the integration of best research evidence with clinical expertise and patient values. It aims to apply the best available evidence gained from the scientific method to medical decision making and it seek to assess the quality of evidence of the risks and benefits of treatments. Evidence–based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

Two types of evidence based practice have been proposed. 1. Evidence-Based guidelines, 2. Evidence-based individual decision making. Five steps in EBM practice, i.e.

1. Asking focused clinical questions that arise in caring for patients
2. Acquiring the best available evidence through electronic searching
3. Appraising the quality of the evidence acquired against explicit methodological criteria
4. Applying the evidence appropriately to the clinical management of individuals
5. Assessing performance in relation to the previous four steps

are discussed. Systems to stratify evidence by quality have been developed. KDIGO Clinical practice guidelines for glomerulonephritis is discussed as example of application of EBM Practice Guidelines.

New concept of, “Test of Time” for evolving evidence, over the period of time is being introduced. Limitations of Evidence-Based Medicine, (EBM), with reference to, ethics, cost, generalizability, political criticism, publication bias, ghost writers, etc. are deliberated

Keywords

Evidence Based Medicine(EBM), Evidence Based Guidelines, Medical Decision Making & Analysis, Critical Appraisal Methods, KDIGO Practice guidelines, Test of Time, Generalizability, Publication Bias

What is, “Evidence Based Medicine” EBM:

Evidence based medicine has thus been defined as the optimal integration of the best research evidence with clinical expertise and patient values. Best research evidence is generally derived from the basic sciences of medicine regarding the accuracy and precision of diagnostic tests, the power of prognostic markers, the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. Clinical
expertise would include ability to use clinical skills and past experience to evaluate the unique health state of the patient, assess the risks and benefits of potential interventions, and incorporate the personal values and expectations into clinical decision making. The unique preferences, concerns and expectations brought into the clinical encounter by an individual patient represent the third component to be integrated into the decision making process. Triangulation of these three elements results in the forging of an alliance between clinicians and patients for optimizing clinical outcomes and quality of life.

At least four major factors are facilitating the adoption of EBM by clinicians. The type of literature being made available to the medical fraternity has undergone substantive qualitative change. The unstructured review articles based on personal opinions of experts in the field have been replaced by peer reviewed reports of research studies designed and executed with scientific rigor. Systemic reviews of multiple research studies and publication of a number of evidence based journals provide validated information to the reader. The second major advance has been in the area of evolution of electronic information systems. Information dissemination systems have come long way from the days of storing information in large mainframe computers at few privileged academic centers to the making information available on the desktop users all across the globe through World Wide Web. Simultaneously the librarians (Information Science specialists in modern day parlance) have evolved faster and far more efficient strategies for sifting through tons of literature and locating the evidence of interest to address the issues raised during a clinical encounter.

Two types of evidence based practice have been proposed.3

Evidence- Based guidelines

Evidence-based guidelines (EBG) is the practice of evidence-based medicine at the organizational or institutional level. This includes the production of guidelines, policy, and regulations. This approach has been called as evidence based healthcare.4

Evidence-based individual decision making

Evidence-based individual decision (EBID) making is evidence based medicine as practiced by the individual health care provider. There is concern that current evidence-based medicine focuses excessively on EBID3. The American Academy of Family Physicians says that DynaMED may be of assistance to family physicians in answering clinical questions with high quality evidence.5

The requirements for the practice of evidence-based medicine includes a process called, “Critical Appraisal Exercise”(Evidence-Based Medicine Group, 1992) which consists of following steps: 1) defining a patient problem and the information that is required to resolve the patient’s problem, 2) conducting an efficient literature search, 3) selection of the best of the relevant studies, and application of the rules of evidence to determine their validity, 4) should be able to present to colleagues regarding the strengths and weaknesses of the article in an effective manner, 5) extracting the message and applying it to the patient problem.7 Another requirement for the practice of evidence-based medicine is the physician’s sensitivity towards the patient’s emotional needs, i.e. understanding the patient’s suffering and how that suffering can be ameliorated by caring and compassionate physician are the fundamental requirements for medical practice. These required skills can be acquired through careful observation of patients and of physicians of role models.9 In this regard, the randomized clinical trials using different strategies for interacting with patients will be helpful.6,10

Steps in EBM practice:

It consists of five related steps:11
Step 1: Asking focused clinical questions that arise in caring for patients

Step 2: Acquiring the best available evidence through electronic searching

Step 3: Appraising the quality of the evidence acquired against explicit methodological criteria

Step 4: Applying the evidence appropriately to the clinical management of individuals

Step 5: Assessing performance in relation to the previous four steps.

Figure 1.1 Steps in practice of Evidence-based Medicine (EBM)

Need For Information

About Prevention, Diagnosis, Prognosis, Therapy, Causation etc.

Step 1
Converting into an Answerable Question

Step 2
Tracking down the best evidence

With which to answer the question evolved after step 1

Step 3
Critically Appraising that Evidence

For its validity, (closeness to the truth), impact (size of the effect), and applicability (usefulness in our clinical practice)

Step 4
Integrating the critical appraisal with our clinical expertise

With our patient’s unique biology, values, and circumstances
Step 5

Evaluating our effectiveness & efficiency in executing steps 1-4

*Seeking ways to improve them both for next time*

Figure 1.2  Stepwise approach in practice of EBM

Application of the evidence based model on other public policy matters:

There has been discussion of applying what has been learned from EBM to public policy. In his 1996 inaugural speech as President of the Royal Statistical Society, Adrian Smith held out evidence-based medicine as an exemplar for all public policy. He proposed that “evidence-based policy” should be established for education, prisons and policing policy and all areas of government. 12

Public Policy Matters

*Health Policy Related Issues, Questions, Other Policy Matters*

Evolved Best Evidence

*Using Step, 1-4, as mentioned in Fig. 1.2*

Medical Decision Making & Analysis

Health Economics Scrutiny

Cost-Benefit Analysis CB

Cost-Effective Analysis CE

As Applicable

Customized, Tailored, Best Evolved Evidence

*Applying Clinical Experience, Expertise, & need based Judgement*
Evaluation of Steps & Appropriate Application

Ranking the quality of evidence:

**US Preventive Services Task Force**

Systems to stratify evidence by quality have been developed, such as this one by the U.S. Preventive Services Task Force for ranking evidence about the effectiveness of treatments or screening.  

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

**National Health Service**

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; different types of research are required for assessing diagnostic accuracy or natural history and prognosis, and hence different levels are required. For example, the Oxford Centre for Evidence-based Medicine suggests levels of evidence (LOE) according to the study designs and critical appraisal of prevention, diagnosis, prognosis, therapy and harm studies.

- Level A: Consistent Randomized Controlled Clinical Trial, cohort study, all or none.(see note below) Clinical decision rule 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.

**Example of application; Evidence-based Practice Guidelines:**

**KDIGO Clinical Practice Guideline**

for Glomerulonephritis

**Evolution of Evidence, “Test of Time”:**

**Strong Evidence**

*Sound, Biological, Lab. or therapeutic rationale*
Limitations of Evidence-Based Medicine, (EBM)

Although evidence-based medicine is becoming regarded as the “gold standard” for clinical practice there are a number of limitations and criticisms of it’s use.

Ethics

In some cases, such as in open-heart surgery, conducting randomized, placebo-controlled trials is commonly considered to be unethical, although observational studies may address these problems to some degree.

Cost

The types of trials considered “gold standard”(i.e. large randomized double-blind placebo-controlled trials) are expensive, so that funding sources play a role in what gets investigated. For example, public authorities may tend to fund preventive medicine studies to improve public health, while pharmaceutical companies fund studies intended to demonstrate the efficacy and safety of particular drug.
Generalizability

Furthermore, evidence-based guidelines do not remove the problem of extrapolation to different populations or longer timeframes. Even if several top-quality studies are available, questions always remain about how far, and to which populations, their results are “generalizable”.

The quality of studies performed varies, making it difficult to compare them and generalize about the result.

Certain groups have been historically under-researched (racial minorities and people with many co-morbid diseases), and thus the literature is sparse in areas that do not allow for generalizing.

Political criticism

There is a good deal of criticism of evidence-based medicine, which is suspected of being—as against what the phrase suggests—in essence a tool not so much for medical science as for health managers, who want to introduce managerialist techniques into medical administration. Thus Dr Michael Fitzpatrick writes: “To some of its critics, in its disparagement of theory and its crude number-crunching, EBM marks a return to ‘empiricist quackery’ in medical practice.”

Its main appeal, as Singh and Ernst suggests, is to health economists, policymakers and managers, to whom it appears useful for measuring performance and rationing resources.

Publication bias

It is recognized that not all evidence is made available, that can limit the effectiveness of any approach, and that efforts to reduce publication bias and retrieval bias is required.

Failure to publish negative trials is the most obvious gap, and moves to register all trials at the outset, and then to pursue their results are underway. Changes in publication methods, particularly related to Web, should reduce the difficulty of obtaining publication for a paper on trial that concludes it did not prove anything new, including its starting hypothesis.

Treatment effectiveness reported from clinical studies may be higher than that achieved in later routine clinical practice due to closer patient monitoring during trials that leads to much higher compliance rates.

The studies that are published in medical journals may not be representative of all studies that are completed on given topic (published and unpublished) or may be misleading due to conflicts of interest (i.e. publication bias). Thus the array of evidence available on particular therapies may not be well-represented in the literature. A 2004 statement by the International Committee of Medical Journal Editors (that they will refuse to publish clinical trial results if the trial was not recorded at its outset) may help with this, although this has not yet been implemented.

Ghost writers

Main article: Medical ghostwriters

Populations, clinical experience, and dubious diagnosis
EBM applies to groups of people but this does not preclude clinicians from using their personal experience in deciding how to treat the person in front of them. In The limits of evidence-based medicine, Tonelli advises that, “the knowledge gained from clinical research does not directly answer the primary clinical question of what is best for the patient at hand” and suggests that evidence-based medicine should not discount the value of clinical experience.

David Sackett writes that, “the practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic search.”

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BIOGRAPHY

DR.V.L.GUPTA, MD, PhD, BA, MNAMS, FICP, FICE, FISN, is consultant nephrologist at Ashwini Kidney Dialysis Center, and Avanti Institute of Cardiology, Nagpur. He is Ex-Professor & Head dept. of nephrology, Super Speciality hospital & PG Institute of Medical Sciences. He has also been, Director, Clinical Epidemiology Unit, GMC, Nagpur. He has UG, & PG teaching experience of over thirty two years in medicine and nephrology. He has been UG & PG examiner across universities in India. He was postgraduate guide for MD, DNB, and PhD for RSTM university Nagpur.

Winner of research awards & medals, He is recipient of several oration and lecturer ship awards at National level, including, “Searle Oration” API 2004. He was awarded, “INCLEN, USAID, fellowship in Clinical Epidemiology, in 1987-88, during which he was part of Master’s program and was trained in Clinical Epidemiology, Research Methodology, at UNC, NC, USA, 87-88, beside he has received several other fellowships at national & international level. Being member over dozen professional bodies, and scientific societies. He has been heading several of them. His name has been included in “Asia’s Who’s Who” of Medicine, 2014. He has authored and published three books, beside contributing to other published monograms & Books, has published over 90 research papers.

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