

Evidence Based Medicine: A Paradigm for Clinical Practice

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ABSTRACT

Evidence based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values. In the practice of EBM it is the physician's duty to find the best and most current information and apply it judiciously for the benefit of the patient.

The practice of EBM involves formulating a clear clinical question from a patient's problem, searching the literature to acquire the evidence, then critically appraising the evidence for its validity and usefulness, and applying the results by implementing useful findings into clinical practice, and finally evaluating this application of evidence on patient. An important rule in EBM is that it starts with the patient and ends with the patient.

Evidence based medicine requires new skills of the physician, including efficient literature searching and the application of formal rules of evidence evaluation from the clinical literature.

Incorporation of EBM into one's practice will not only make one a better clinician, it also allows one to provide the best possible quality of medical care to his or her patients. Thus EBM can be incorporated as an integral part of the medical curriculum.

INTRODUCTION

The idea of EBM appeared at the McMaster University in Canada in 1988, but during the 1990s became known throughout the world. The term "evidence based" was first used in 1990 by David Eddy. The term "Evidence based medicine" first appeared in the medical literature in 1992 in a research article by Guyatt *et al*¹. The explicit methodologies used to determine "best evidence" was established by the McMaster University research group in Ontario, Canada, led by **Dr David Sackett**² and Gordon Guyatt.

Though Dr David Sackett² (An American Canadian Medical Doctor) and his colleagues proposed evidence based medicine (EBM) as a new way of teaching, learning and practicing medicine, the founder of EBM is considered to be an English epidemiologist, **Professor Archie Cochrane**.

Cochrane's work was honored through the naming of centers of evidence based medical research as Cochrane Centers, and an international organization, the Cochrane collaboration³.

Evidence based medicine is a form of medicine that aims to develop decision-making by emphasizing the use of evidence from well designed and conducted research. It is an interdisciplinary approach to clinical practice to make decisions about how to promote health or provide care by integrating the best available evidence with practitioner expertise and other resources.

Evidence based medicine is the most intellectual advance in the process of clinical decision making⁴. It is a movement which aims to increase the use of high quality clinical research in clinical decision making. EBM application means relating patient's clinical signs and doctor's clinical

experience with the best scientific evidences obtained by clinical research. Its good application brings cost-effective and better healthcare³. Taking an evidence based approach to the care of patients is an intellectually exciting style of practice, which leads you down a path of exploration and life-long learning⁵.

The principles of EBM are not only applicable to medicine, but also to nursing, physiotherapy, occupational therapy and all other fields of healthcare. Hence the term **Evidence based health care (EBHC)** emerged⁴.

EBM is now formally taught in many centers of higher education, such as McMasters University, Oxford University, The University of North Carolina, and Duke University⁶.

DEFINITION

Evidence based medicine is defined as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients².

In other words, EBM is a systematic approach to clinical problem solving which allows the integration of the best available research evidence with clinical expertise and patient values³.

Thus, evidence based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values (Fig 1).

Fig 1: Three dimensions of evidence based medicine



By **best research evidence** we mean clinically relevant research, often from the basic sciences of medicine, but

especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. New evidence from clinical research both invalidates, previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer.

By **clinical expertise** we mean the ability to use our clinical skills and past experience to rapidly identify each patient's unique health status and diagnosis, their individual risks and benefits of potential interventions, and their personal values and expectations.

By **patient values** we mean the unique preferences, concerns and expectations each patient brings to a clinical encounter and which must be integrated into clinical decisions if they are to serve the patient.

When these three elements are integrated (Fig 2), clinicians and patients form a diagnostic and therapeutic alliance which optimizes clinical outcome and quality of life.

Fig 2: Evidence based medicine triad (Source:meduottawa.ca)



You do not have to become a researcher or epidemiologist to practice EBM. Focus on how to use research reports. However, you must have a solid understanding of basic research principles and study designs in order to understand and interpret the evidence.

Instead of routinely reviewing the contents of dozens of journals for interesting articles, EBM suggests us to target our reading to issues related to specific patient problems. Developing clinical questions and then searching current databases may be a more productive way of keeping current with the literature.

THE PRACTICE OF EVIDENCE BASED MEDICINE (THE PROCESS OF EBM)

The practice of EBM is a process of life-long, self-directed, problem based learning and requires the judicious integration of **individual clinical expertise** with the **best available external clinical evidence** from systematic research, and **patient understanding and values** (Fig 3, 4, 5). In the practice of EBM it is the physician's duty to find the best and most current information and apply it judiciously for the benefit of the patient.

Fig 3: Three major components of evidence based medicine

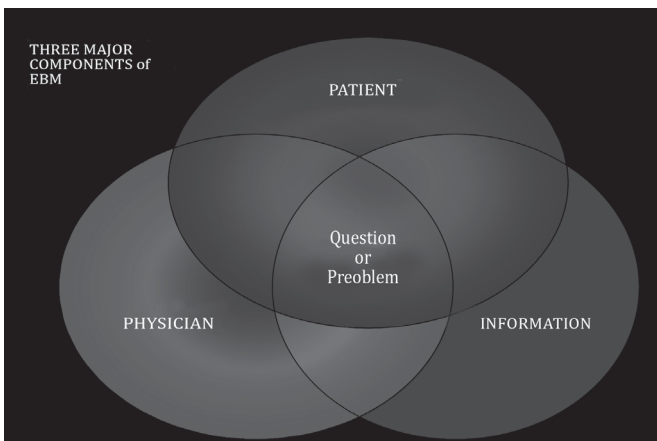


Fig 4: Added details to the three major components of evidence based medicine

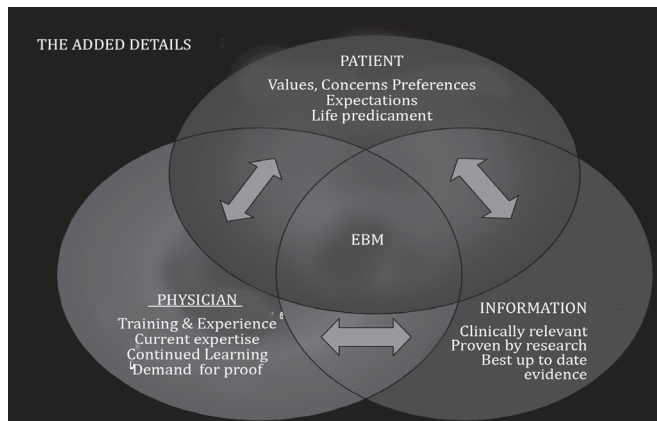
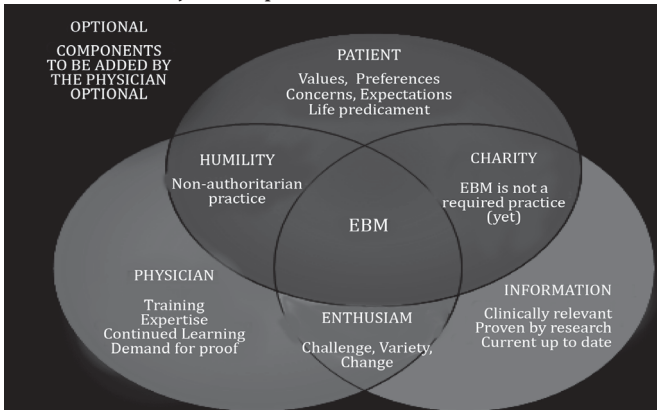


Fig 5: Optional components to be added by the physician to the three major components of evidence based medicine



Incorporating best evidence into clinical practice requires a systematic approach in order to be manageable. A clear series of five basic steps must be followed by each individual physician in the application of this EBM process⁷.

Table 1: Steps to practice EBM

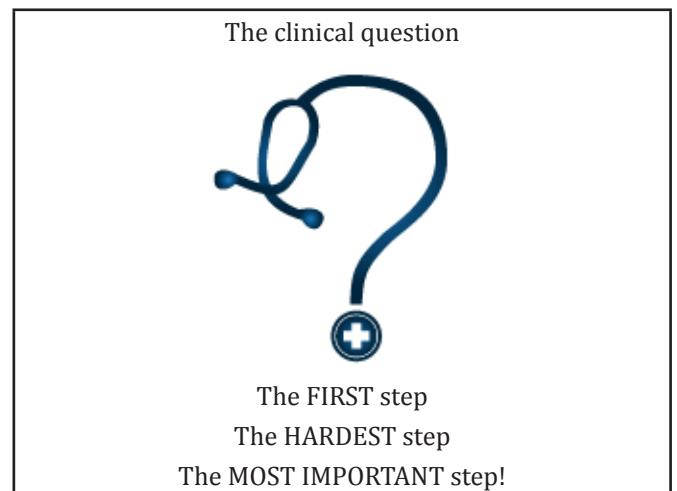
| |
|--|
| 1. Formulating a well-built clinical question |
| 2. Searching the best evidence from literature by identifying articles and other evidence based resources that answer the question |
| 3. Critically appraising the evidence to assess its validity |
| 4. Applying the evidence into decision making |
| 5. Efficacy evaluation of this application of evidence on a patient and areas for improvement |

Fig 6: EBM process (Source: slideshare.net)



1. Formulating the clinical question (Clinical question development)

The first critical step is to clarify one or two key issues that come up in the course of caring for your patient and to develop a focused clinical question. However, without this critical first step, the rest of the steps are immaterial.



Ask a clear, patient-oriented, relevant, answerable question about the health status and context of patients or populations. A good clinical question is focused and

relevant, provides clear communication, clarifies your goal or need and should be specific and answerable and should contain multiple aspects structured in the **PICO** format.

P Patient – Describe the most important characteristics of the patient or population (E.g. age, disease/condition, gender)

I Intervention – Describe the main clinical intervention (E.g. medication, procedure, diagnostic/screening test, surgery, radiation, drug, vaccine) or **Exposure** - Environmental, personal, biological (E.g. tobacco, drug, diet, pregnancy or menopause, MRSA, allergy)

C Comparison – Describe the main alternative treatment being considered (E.g. placebo, standard therapy, no treatment, the gold standard)

O Outcome (Clinical outcome of interest) – Describe what you are trying to accomplish, measure, improve, affect. (E.g. reduced mortality or morbidity, improved memory, accurate and timely diagnosis, decreased infections, fewer hospitalizations)

Quantitative questions provide solid evidence of measurable answer or response necessary for scientific study and necessary for the practice of EBM.

Qualitative questions provide fuzzy data such as impact on daily life, work, family (Quality of life) etc. These qualitative questions may be very important and influential to decisions - especially for the patient and may create added challenge or twist to the practice of EBM.

The patient’s questions must be considered, often qualitative (Feelings, ideas, experiences, preferences, concerns, fears, beliefs, ethnicity) and usually based on limited background (perception of problem, self-diagnosis, treatment wanted or needed, alternatives (read, heard, considered, tried), what patient is hoping to avoid, what benefits does the patient want or need most etc.).

2. Searching the best evidence from literature

Armed with well-built clinical question, our attention next turns to efficiently **acquire** the best evidence in the medical literature that will provide the answer to the question. Many resources are currently available (Table 2). Potential literary sources include text books, journals, review articles (summaries, abstracts), systematic reviews (prepared in systematic, rigorous manner E.g. Cochrane collection), meta-analyses, clinical practice guidelines, electronic resources, data bases, internet (E.g. Medline,

PubMed, Medscape, HDCN etc.).

Identify primary and secondary sources of data. A **primary source** is first hand testimony or direct evidence concerning a topic under investigation. Primary sources are generally articles that appear in peer-reviewed journals and are found primarily by searching MedLine and PubMed. **Secondary sources** describe, discuss, appraise, interpret, comment upon, analyze, evaluate, summarize, and process pri sources. Secondary source materials can be articles in newspapers or popular magazines, book or movie reviews, or articles found in scholarly journals that discuss or evaluate someone else’s original research⁸.

Brian Haines^{9,13} has proposed the **4S Resources**, namely Systems, Synopses, Syntheses, and Studies, which redefine the earlier primary and secondary sources.

Table 2: Some of the leading EBM resources

| |
|--|
| Journals |
| <ul style="list-style-type: none"> • ACP Journal Club • American Family Physician • Bandolier • The Journal of Family Practice |
| Evidence summaries |
| <ul style="list-style-type: none"> • Clinical Evidence • The Cochrane Database of Systematic reviews • Dynamed • FIRSTconsult • InfoRetriever • SUMsearch • TRIP database (Turning Research Into Practice) • The York Database of Abstracts of Reviews of Effects (DARE) |
| Clinical guidelines |
| <ul style="list-style-type: none"> • Institute for Clinical Systems Improvement (ICSI) • National Guideline Clearinghouse • U.S. Preventive Services Task Force (USPSTF) |
| Other |
| <ul style="list-style-type: none"> • DailyPOEMs |

The ideal information source must be valid (contains high quality data), relevant (clinically applicable, comprehensive (has data on all benefits and harms of all possible interventions), and is user-friendly (is quick and easy to access and use).

The best evidence is i) External from outside resources (Researchers, experts), ii) Current (most recent, not out of date), iii) High quality (accurate, precise, effective, safe), and iv) Patient focused (applicable and appropriate for

individual patient).

Search and retrieve the best evidence and learn and practice various search strategies to find useful information quickly and to eliminate irrelevant, inappropriate or weak information. One of the greatest achievements of EBM has been the development of systematic reviews and meta-analyses, methods by which researchers identify multiple studies on a topic, separate the best ones and then critically analyze them to come up with a summary of the best available evidence⁵.

There are several study designs as shown in Table 3

Table 3: Study designs

| | |
|--|--|
| I. Observational/ non-experimental | |
| Descriptive Studies | Case studies Case series Ecological studies |
| Analytical Studies | Cross-sectional studies Case-control Cohort |
| II. Experimental (Interventional) Studies | |
| | Randomized control trial Quasi-experimental studies/ Non-randomized control trial Community trial Pretest-posttest study design |

Classify the clinical question in to various domains such as diagnosis, therapy, prognosis and harm or casualty and find out which study design fits it best⁸.

Table 4: What type of evidence best addresses the question, problem or issue?

| Type of question | Ideal type of study* |
|------------------|---|
| Therapy | Randomized control clinical trials (RCT) |
| Prevention | RCT > Cohort study > Case control |
| Diagnosis | Prospective, blind controlled trial comparison to gold standard |
| Prognosis | Cohort study > Case control > Case series/ Case report |
| Etiology/Harm | RCT > Cohort study > Case control |
| Miscellaneous | Basic science, Genetics, Immunology |
| Cost analysis | economic analysis |

*Meta-analyses and systematic reviews provide the best answers to clinical questions

3. Critical appraisal of the evidence

With a potential literary source in hand, the clinician must appraise the evidence to further examine its worth and reliability. Evaluate the evidence for quality and usefulness by assessing validity, reliability, relevance and

clinical importance.

Table 5: Evaluation of evidence by assessing validity, reliability, relevance, clinical importance

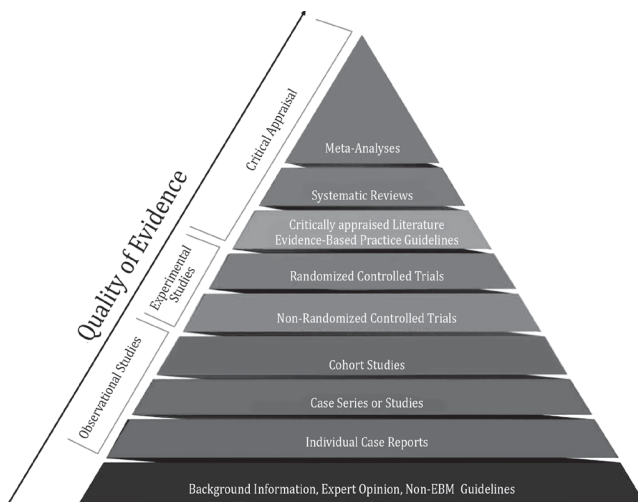
| | |
|----------------------------|---|
| Validity | <ul style="list-style-type: none"> What was the original purpose of the study? When was it prepared? By whom it was prepared? (Credentials, affiliations) <p>Sample Population</p> <ul style="list-style-type: none"> Did the subjects represent appropriate test group? How were they selected? Were controls used? How was the information gathered and processed? Was the study completed? Did the study account for all test subjects? <p>Information</p> <ul style="list-style-type: none"> Does the information accurately represented Does it represent truth? Does the paper support its claims <p>Results</p> <ul style="list-style-type: none"> Are the results believable? To what degree of confidence? <p>Comprehensiveness</p> <ul style="list-style-type: none"> Size: Was it large enough to yield credible results? Thoroughness: Was it complete enough? Duration: Was it long enough? |
| Reliability | <ul style="list-style-type: none"> Was the type of study design used proper for the question? Are the measurements and results reproducible? Is there consistency among researchers in measurement methods and interpretation of results? Is there any evidence of bias (Patient bias or researcher bias)? |
| Relevance | <ul style="list-style-type: none"> Does the problem address the questions raised? Are the study patients are comparable to your patient? Are the study professionals comparable to you? |
| Clinical importance | <ul style="list-style-type: none"> Is the information clinically relevant? |

Evidence based medicine pyramid

Evidence based medicine pyramid is simply a diagram created to understand how to weigh different levels of evidence in order to make health related decisions. It helps us to put the results of each study design into perspective, based on the relative strengths and weaknesses of each study design⁸.

Evidence based medicine pyramid is divided into levels. Each ascending level represents a different type of study design and corresponds to increasing rigor, quality, and reliability of the evidence. In other words, as we ascend through these different study designs, we become more confident that their results are accurate, have less chance of statistical error, and minimize bias from confounding variables that could have influenced the results⁸.

Fig 7: Evidence based medicine pyramid (Source: sciencebasedmedicine.org)



4. Applying evidence to the patient

The clinician has to decide whether it is appropriate to apply the evidence to the particular patient and their unique values and circumstances. Evidence alone is never sufficient to direct decision making. Rather, it must be put into context with a patient's values.

Each piece of evidence that we review adds something to our understanding of our patient's situation. However, we need to consider how to generalize the results from clinical trials to our individual patient. We must consider whether the patient populations and treatments or interventions are comparable to our setting. The final challenge is to combine the evidence and clinical expertise with compassion and patient values¹⁰.

The personal priorities of a patient may conflict with physician. Recognize the needs, choices, preferences, values, socio-economic concerns of the patient. Respect the personal priorities of the patient. Help the patient to understand and interpret available information and negotiate a decision on intervention, treatment¹⁰.

An important rule in EBM is that it starts with the patient

and ends with the patient. Patient's preferences must be considered.

5. Efficacy evaluation of EBM application on a patient

The final step is the evaluation of evidence based approach and efficiency of its application to a specific patient. During this process it is important to assess whether certain evidence which is applied to the patient, caused changes to better and that to the extent that is confirmed by research. If the data differ significantly, it would be necessary to investigate why some patients did not respond to the changes introduced in the expected way and what can be done to change it.

DISCUSSION

Evidence based medicine is conscious, specific, reasonable use of modern, best evidences in making decisions about treatment of individual patients⁷. Its real purpose is that by the use of the best possible evidence doctor chooses for his/her patient the best possible solution, wanting to provide optimum healthcare to patient. Good doctors apply their clinical observation and experience, together with the best scientific evidence from medical literature. EBM requires new knowledge from physicians, primarily knowledge of English language and work on the computer, which provides access to medical databases, the ability to search medical literature and basic skills in the interpretation of epidemiological and statistical results¹¹. The physicians should master the search technique and the use of EBM. The proper use of EBM saves doctors time and raises his/her level as well as the quality of provided medical services, and increases satisfaction of health professionals¹². The shift from traditional clinical practice to EBM is not easy and requires a personal attitude and an internal commitment to change¹¹.

Advantages of EBM¹⁴

- Clinicians update knowledge base routinely
- Improved understanding of research methods
- Physician becomes more critical in use of data
- Increased confidence in management decisions
- Increased computer literacy, data search technology
- Better reading habits
- Provides framework for group problem solving, team generated practice
- Transforms weakness or paucity of knowledge into positive change

- Integrates medical education, research and clinical expertise
- Can be learned by non-clinicians and other health care workers

Disadvantages of EBM¹⁴

- Time consuming
- Information overload
- Time to learn and practice
- Time may be needed for team conferencing, planning and review
- Requires financial sources to establish resource infrastructure – library, office, computers, peripherals etc.
- Internet costs
- Programs, software information, CD-ROMS
- Subscription costs – online and paper resources
- May increase cost of care
- Online references made to unavailable journals or references
- Exposes gaps in the evidence (but provides ideas for researchers!)
- Requires computer skills (but can be done with minimal computer literacy and skill)
- May expose your current practice as obsolete or dangerous (loss of authority and respect)

Limitations of EBM¹⁴

- Lack of evidence (shortage of studies)
- Difficulty in applying evidence to care of a particular patient
- Barriers to the practice of high quality medicine
- Lack of skills (search, appraise, etc.) (Foster development of new skills!)
- Lack of time to learn and practice EBM (Promotes lifelong learning through better focus)
- Lack of physician resources for instant access to evidence (EBM has worldwide applicability)
- Language barriers – available evidence may be unreadable
- Physician attitude can be the greatest limitation

CONCLUSION

EBM is a set of principles, tools and methods intended to ensure that to the greatest extent possible medical decisions, guidelines, and policies are based on and consistent with good evidence of effectiveness, and serve

to provide better patient care.

EBM emphasizes on practicing medicine based on evidence derived from well designed and well conducted research. It not only helps in treating an individual patient more effectively but also in forming policies related to health care which influences an entire community. The influence of evidence based medicine on clinical practice and medical education is increasing. EBM has made a clear and probable permanent mark on the face of medicine.

Incorporation of EBM into one's practice will not only make one a better clinician, it also allows one to provide the best possible quality of medical care to his or her patients. Thus EBM can be incorporated as an integral part of the medical curriculum. It also helps in creating effective teaching programs for medical students and continued medical education (CME) programs for medical professionals.

EBM reduces variations in medical practice among clinicians, errors in clinical reasoning, lacunae in evidence, weaknesses in decision making and unnecessary procedures.

Recommendations

To promote the understanding and practice of EBM, yearly workshops can be conducted. The medical schools must develop an infrastructure that allows problem-based, self directed learning methods to develop within the didactic, lecture-based curriculum.

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