

Review Article

Evidence Based Medicine: Key Aspects in Clinical Decision Making

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Abstract: It is an overview involving the key aspect of evidence based medicine that is important in solving the clinical problem arising nowadays. It also describes the components or principles involved in evidence based medicine and its evolution. Besides, the five steps involved in practicing evidence based medicine are discussed here. This article also reveals the advantages and highlights the limitation of practicing evidence based medicine. The applications of evidence based medicine are also being explained in brief followed by a case report.

Keywords: Description, Evolution, Steps, Importance, Limitation, Application.

INTRODUCTION

Evidence-based medicine (EBM) has become an integral part of the medical training and has caused a great interest among the various healthcare professionals. Its emergence speeded exceedingly with medicine for past decades that speaks of the attraction and fundamental soundness of the main idea that patient therapeutic response should be based on evidences [1]. EBM is a lifelong learning process, where the clinician exercises him or herself reading the abstracts of the related articles and appraises the relevant literatures and uses them in a way that benefits the patient. This simultaneously helps the clinician to expand his knowledge as well. It begins with an individual patient and an individual clinician who works together to make a decision regarding the patient's care. Thus, it is very important for the clinician to ensure that he or she has adequate knowledge on the particular condition or issue related to the patient. The clinician then formulates relevant questions, searches for the answer and then evaluates the answer he or she has got to ensure its validity and importance. Finally, the clinician together with the individual patient, attempt to apply the knowledge gained to the patient's problem [2].

DESCRIPTION OF EBM

Evidence-based medicine rooted in the words of Archie Cochrane (1909–1988), a British epidemiologist, who understood the importance of synthesizing high-quality evidence to inform clinical decisions, can be defined as the *conscientious, explicit, and judicious use of current best evidence in making decisions about the care of the individuals* [3]. EBM broadly describes of two related entities. Firstly, EBM

deals with the issue of knowledge in medicine followed by the second entity that is describing a clinical practice centered on evidence derived from clinical studies.

In the first entity, EBM defines the optimal ways to develop knowledge, seeks to define at least one aspect of medical knowledge, that which derived from the results of the clinical research. Besides, “non-evidentiary” knowledge is also acknowledged by EBM which includes individual clinical experience, physiologic principles and understanding of professional and patient values. Secondly, EBM focuses on the practical world of providing health care through incorporation of the evidence into clinical practice. This requires a specific kind of clinical reasoning (scientific), as it attempts to objectively and deductively apply empirical knowledge to specific cases [4].

In early days, EBM focused mainly on determining the best research evidence relevant to a clinical problem or decision and applying that evidence to resolve the issue. However, a new and more advanced prescriptive model has been developed to describe EBM (Figure 1), that defines EBM as the integration of best research evidence with clinical expertise and patient values [5]. It simply means relating individual clinical signs, individual clinical experience with the best scientific evidences obtained by the clinical research. This model acknowledges that patient' preferences rather than clinicians' preferences should be considered first whenever it is possible to do so because many clinical practitioners may handle a critically ill patient with same circumstances in different ways, according to their preferences [1].

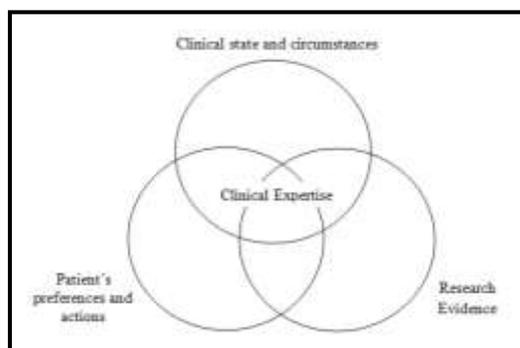


Fig-1: Prescriptive model of EBM

EVOLUTION OF EBM

EBM was first practiced in the year 1716–1794 by James Lind for the treatment of scurvy which was an ailment that often plagued sailors during the 18th century. He describes of his experience as ship's surgeon where he designed a study to compare six remedies for the treatment of scurvy. In his study involving 12 men with similar cases of illness, six different group of two were treated with six different kind of treatment. Among the six treatment, it was found that citrus serves as the better option for the treatment of scurvy despite of the those recommended by the Royal College of Physicians and the Admiralty which were sulfuric acid and vinegar respectively. This was a example of a fair test that refuted the expert's opinion [6, 7].

Also in 18th century, a new method of lithotomy was introduced by a British surgeon named William Cheselden. Lithotomy is a surgical procedure that is used to remove bladder stones and was credited with another important feature of valid evidence. In his research, he included the ages and dates of operation for all patient undergoing lithotomy, and he found out that even the most aged and most miserable cases expected to be saved by the surgical procedure. Based on Cheselden's realization that differences in treatment outcome may be due to dissimilarities in patient's age, another British physician by the name John Yelloly highlighted that, gender and size of bladder stones should also be considered and documented as they may interfere with the mortality rates associated with lithotomy [6].

Apart from that, consequences of using unproven practices had also contributed to the evolution of EBM. It was when an expert's opinion gone wrong that had taken the life of many little ones. Dr. Benjamin Spock, an American childcare specialist recommended that infants sleep in prone position and not in supine position to avoid choking and vomiting. However, there wasn't any conclusive evidence to prove that sleeping in prone position is safer than in supine position. Many healthcare workers and families listen to this expert's advice and this had cause the dead of thousands of children due to sudden infant death syndrome [8].

In the 19th century, radical mastectomy was developed by William Halsted and it was the most common method for treating breast cancer. This commonly used invasive treatment was later found to provide no better outcome than less invasive treatments has also lead to development of EBM. During that time, it was believed by the cancer specialist that extensive removal of the affected area should cure the cancer. Radical mastectomy involves complete removal of the affected breast area and pectoralis muscle, and in more severe cases, splitting of the breast bone and removal of ribs to access the lymph nodes. However, survival rates did not improve prior to the widespread use of this invasive procedure. Later, the cancer specialists revised their original theory and prompt the use of a less invasive procedure called lumpectomy followed by chemotherapy and radiation. An American surgeon, Bernard Fisher and his colleagues conducted a randomized controlled trial to compare the effectiveness between radical mastectomy and lumpectomy followed by chemotherapy and radiation. Prior to 20 years of follow up, result showed that lumpectomy followed by chemotherapy and radiation has equal effectiveness to that of radical mastectomy. This has prevented many women from undergoing the unnecessary treatment without added benefit [9].

5 STEPS IN EBM

Incorporating best evidence into clinical care requires a systematic approach in order to be manageable. A clear series of five steps in essential in practice of EBM which includes first, converting information needs into answerable questions; second, finding the best evidence with which to answer the questions; third, critically appraising the evidence for its validity and usefulness; fourth, applying the results of the appraisal into clinical practice; and fifth, evaluating performance. This stepwise approach is also known as Evidence Cycle (Figure 2).

Step 1: Formulating answerable clinical question

Here, translation of a clinical problem into an answerable question takes place which may be a difficult step while practicing EBM. When dealing with patients with particular problem, we often wonders of various questions for which answers are needed to solve them. However, sometimes these question may be unstructured and complex and may not be clear in our minds. Thus, it is very essential to start practicing EBM with well formulated clinical questions where answers can be obtained. A good clinical question simply means a question that is clear, direct to the point or the problem faced, and most importantly answerable via searching the medical literature [10].

There are generally two types of questions which are "background" question and "foreground" question [11]. Background question is nothing but question on general knowledge of the particular disease or disorder

or problem. Foreground question on the other side refers to question that are more specific to the disorder as in how to manage the particular disease or disorder. A useful framework of formulating an answerable clinical question was suggested and it is called as PICO format that comprises of four important components which are:

1. **P**atient involved or **P**roblem
2. **I**ntervention considered and that would be appropriate

3. **C**omparisons of intervention, and
4. **O**utcomes of interest/ intervention

It is important to understand that PICO format is not only used to formulate questions on how to treat a disease (intervention), but it can also be used to find out the risk factors, causes, diagnosis, or prognosis of a disease [12]. Two examples of clinical questions that are formulated according to the PICO format are as follow:

Category	Scenario	PICO Format		Clinical question
Interventions	A 28-year-old male presents with recurrent Furunculosis (skin boils) for past 8 months. He has been treated with drainage and several courses of antibiotics but keep recurring. Now, he asks if recurrences can be prevented.	P	Patient with recurrent Furunculosis	Does prophylactic antibiotic reduces the rate of recurrence of Furunculosis in patient with recurrent Furunculosis?
		I	Prophylactic antibiotics	
		C	No treatment	
		O	Reduction in recurrence rate of Furunculosis	
Risk factors	A 46-year-old woman has a 7-year history of extensive ulcerative colitis. Recently, he seeks his family physician and want to know if he can get bowel cancer	P	Elderly woman	In a 46-year-old woman with a 7-year history of extensive ulcerative colitis, what is the risk for developing bowel cancer?
		I	History of extensive ulcerative colitis	
		C	No history of extensive ulcerative colitis	
		O	Bowel cancer	

Step 2: Finding the evidence

The next step is to look for relevant evidence that will help in answering the clinical question formulated earlier. Many sources of information are available that can provide useful and reliable information. In early days, traditional sources of information were used such as using textbooks and journal that may be disorganized and outdated. Not only that, expert’s opinions may also be considered in making any clinical decision even though it may be based on one-man view and not based on randomized controlled trials or population based [13].

However, in this new era, there emerge many sources of information where one can seek for information on electronic databases that provide not only quick evidences but also updated information. Such secondary sources include:

- Archimedes (<http://adc.bmjournals.com/cgi/collection/archimedes>),
- BestBets (<http://www.bestbets.org/index.html>),
- Clinical Evidence (<http://www.clinicalevidence.com/cweb/conditions/index.jsp>), and
- MEDLINE, through PubMed (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>).

The ability to search on the online electronic bibliographic databases effectively is an important aspect of EBM. This maximizes the potential of extracting relevant articles or journals within a short period of time. Here are some basic principles of

searching for information needed pertaining to clinical question formulated according to the PICO format [14]:

1. **Generating appropriate or suitable keywords:**
Based on the clinical question formulated, a list of words can be generated. For example, based on the above clinical question formulated (category: intervention), the keyword that can be created are *recurrent Furunculosis*, *prophylactic antibiotics*, and *reduction in rate of recurrence*.
2. **Choosing a bibliographic database:**
Although there are numerous online databases available, yet being familiar and retrieving information from minimum two or three databases would be sufficient. This is simply to avoid confusion in making clinical decision based on evidence. One of the search engines that allows search with a focus on the clinical topics is the SUMsearch (<http://sumsearch.uthscsa.edu>).
3. **Conducting the search:**
Once the keywords have been generated and databases identifies, the last step is to conduct the search. Search can be effective when done by using the word “AND” and/or “OR” to combine two keywords. Often more than what is required, number of article will appear. However, online database like PubMed allow the user to limit their search based on type of search, date of publication and others.

Step 3: Appraising the evidence

Next step involve appraising the evidence for its validity and clinical usefulness which involves carefully reading and analyzing the article with respect to how study was conducted, what were the result of the study and was it reasonable. This is important so as to prevent form incorporating unreliable evidence into practice that could bring harm to patient's life. Critical appraisal provides a simple and structured method for accessing the research evidence in three basic areas which are validity, importance, and applicability to the patient.

Various tools has been developed such as tools for appraising randomized controlled trials, cohort-studies, case-control studies as well as systematic reviews. To critically appraise research evidence, one needs to learn how to ask question about the validity of the evidence and its relevance to particular group of people which can be done easily [15]. Self directed learning materials like JAMA series of user's guide to the medical literature have been developed to help researcher apply different critical appraisal question to different scenarios. Some of those questions are as follow:

1. What were the results?
2. Are the results valid?
3. Were all patients who entered the trial properly accounted for and attributed at its conclusion?
4. Can the results be applied to my patient care?
5. Do the benefits of the result outweigh the risk of the same?

Step 4: Applying the evidence

Having the valid and important as well as reliable clinical evidence in hand, the fourth step is to determine the suitability of applying that evidence to the current patient care. While deciding, certain factors need to be considered which includes patient's own personal values and circumstances together with the physician's clinical experience. Efficacy and the risk of the intervention should be fully discussed with the patient or caregiver, so that it coincides with the principle of EBM that is integration of good evidence with clinical expertise and patient values [16]. Pharmacoeconomics also plays a crucial role here while deciding whether to implement the intervention or not.

Step 5: Evaluating the performance

Finally, after incorporating clinical evidence in routine clinical practice, it is essential to evaluate the particular approach frequently. This helps to decide whether there is any need for improvement on any previous four steps. A feedback loop in which the effectiveness and efficiency of the process is determined should be carried out [11].

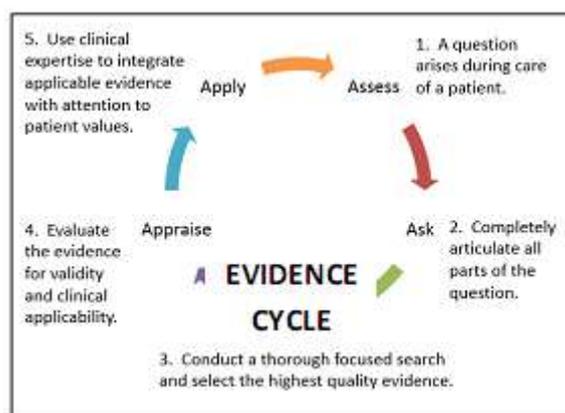


Fig-2: 5 A's of the Evidence Cycle

IMPORTANCE/ ADVANTAGES OF EBM

EBM that uses scientific, clinical, reliable and valid evidence obtained rigorously has been very important to healthcare workers in their routine clinical practice when decision making is needed. An immediate attraction of EBM is the integration of medical education with clinical practice. Many physicians and also medical student begin to learn about EBM and start applying them to answer formulated clinical questions. By using various sources of information like the online databases mentioned above, they are able to provide quick response to the questions being addressed to them. Students who carry out critical appraisals not only learn about EBM but also do contribute them to the society [15].

In addition to that, the main advantage of EBM is its use in the development of evidence-based treatment guidelines. It is potential in improving the continuity and uniformity of the care provided by the physicians by using the common guidelines developed. This helps physicians especially during prescribing medicine to patient since these guidelines promotes cost-effective formulary decisions. Not only that, it also serves as a common framework for problem solving and prevents miscommunication and misunderstanding between people of different background which includes physicians, patients and caregivers [17].

If older paradigm of medical practice gives practitioners a variety of options for treatment, now EBM provides concise evidence based on which treatment can be initiated. Physicians neither need to search in textbooks nor refer cases to local experts in particular field, but just carry out treatment based on compiled clinical evidence in the guideline developed. EBM has overtaken the traditional paradigm as it makes certain assumptions that do not reflect the older ways of clinical thinking [18].

Besides, using EBM in clinical practices helps maintain the regional consistency that further helps in sustaining the national standards of treatments. Through this, excellency of medical practice can be measured based on performance and high chance for awarding

physicians with enhanced reimbursement or high capitation. This is one way to reflect the values of using EBM in clinical practice [19].

EBM also helps physician in providing rational care with better outcomes based on guideline developed. Guidelines are generally developed based on evidence obtained from conducting large, randomized controlled trials, and they are flexible. However, individualization-based therapy or treatment is required especially in treating patient with serious illness and also when treatments for specific issues are not covered in the guidelines. This is when, physicians clinical judgment and experience play a role in providing patient care [19].

Overall, EBM provides the best physicians with best medication of low cost that improves patient quality of life

LIMITATIONS OF EBM

Even though, EBM may benefit the healthcare system, yet there are few drawbacks associated with it. Firstly, the prolong time period taken to learn and to practice EBM. For instance, it roughly takes about two hours to carry out the EBM process, from the formulating the clinical question to evaluating the outcome of the intervention. Being a team leader has always been a tough job as he or she needs to be of high responsibility, ensuring all the team members benefits from a discussion [15]. Thus, it is the duty of the leader to ensure the discussion is well-organized where each team member will be given a task to be completed. By this way, time taken can be minimized and stressful working environment can be avoided.

Next drawback, the high cost in establishing the infrastructure to practice EBM. Since EBM is based on online or electronic databases, thus high storage capacities of the hardware available in hospitals are required which may be of high cost [15]. Not only software and hardware, but also certain online databases impose subscription fee which may be burdensome for clinical practitioners. This may lead to lack of appropriate evidence gathered for the initiation of EBM.

Inexorably, EBM exposes gaps in the evidences which may be frustrating particularly for inexperienced physicians [20]. This occurs especially when they are not familiar with specific treatment where evidence is needed. Even if evidence is available, it may not be reliable or valid evidence. Thus, it is again the responsibility of the senior physician to actually overcome this problem by setting questions for which there is likely to be good evidence.

Another drawback associated with electronic databases is that they are not comprehensive and are not always well indexed. There are certain times where a lengthy search of literature seems to be unfruitful.

Although computer literacy and keyboard skills are minimally required, yet some olden days physician are facing some difficult in conducting the search. This may even delay the literature search and results in ineffective drug therapy.

APPLICATIONS OF EBM

Nowadays, not only the healthcare system adopts EBM, but also by policy makers, legislators and payers. EBM often serves as the key component of pay for performance program that reward the physicians for having achieving the predetermined outcomes. While designing a health plan benefit also, EBM plays an important role in which they are used to determine which therapies and drugs will be covered. Comparative effectiveness research (CER) is done to compare between available treatment option that would be appropriate for specific condition of the patient. Parameters like medical benefits, risk and cost associated with therapies are considered or analyzed in the CER [21].

Furthermore, EBM also plays a role in developing the Continuing Medical Education (CME) content. It is required by the Accreditation Council for Continuing Medical Education guideline, that educational activities should address gaps in practice, physician and patient education as well as patient care. This is to change the competency and performance of the physician and also patient outcome. To strengthen the effectiveness of CME activities, educational objectives and patient care recommendations are poised to it, thus providing practical tools for the physicians to improve their practice [21].

Besides, EBM also integrates nicely with core gals of the internal medicine clerkship. There are nine basic general list of competencies associated with internal medicine clerkship, of which three of them can be enhanced by the addition of EBM. These three competencies are nothing but self-directed learning, diagnostic decision making and therapeutic decision making. However, there is a danger when incorporating EBM into the internal medicine clerkship, where students will be tempted to practice it too early and too often. This is because most of the knowledge, skills and attitudes that remain the central agenda of the clerkship are still best obtained at the bedside of their patient. Moreover, clerkship student are expected to spent more time in the early stages of gaining more knowledge and experience, since finding a solution for clinical question may require more time in seeking evidence and appraising those evidence before applying them to the patient [2].

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