

REVIEW

The philosophy of Evidence-based Medicine

Michael G. Samarkos

*5th Department of Internal Medicine,
Evangelismos Hospital, 45 Ipsilantou
Str., Athens 106 76, Greece*

LIST OF ABBREVIATIONS:

EBM: Evidence-based Medicine,
NHS: National Health System,
RCT: Randomised controlled trials

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medicine, clinical epidemiology,
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Address for correspondence:
Dr M. Samarkos, MSc, MD,
5th Dept of Internal Medicine,
Evangelismos Hospital
45 Ipsilantou Str., Athens 106 76,
Greece
Phone: +30 210 7201830
Fax: +30 210 7216408
e-mail: msamarkos@otenet.gr

ABSTRACT

Evidence-based Medicine is the application of the best evidence available in the care of individual patients, using mathematical estimates of probability and risk. Although elements of EBM have appeared centuries ago, the term Evidence-based Medicine has been used for 10 years only.

The spread of EBM followed studies which had shown that in contemporary medicine a significant proportion of interventions, although they are considered as the standard of care, have not proven efficacy.

The two principles of EBM are that evidence alone is not enough for clinical decision making and that there is a hierarchy of evidence. Evidence-based medicine can be practiced in up to five steps i.e. formulating answerable clinical questions, searching for the best available evidence, critically appraising the evidence, applying the evidence in clinical situations and evaluating one's effectiveness and efficiency. One does not have to go through all steps in practicing EBM, e.g. there now exist the so called secondary publications which are systematic reviews or meta-analyses of all available studies on a clinical problem or journals entirely devoted in appraisal of original studies.

Notwithstanding the "success" of EBM there is a strong current of criticism on subjects practical and philosophical alike. The strongest point against EBM however is that there is no evidence that practicing EBM improves patients' outcomes.

In our opinion, EBM is a very useful instrument with wide-ranging applications in the practice of medicine. However EBM is neither a new scientific field nor a paradigm shift in contemporary medicine. As an empirical approach to clinical problems, EBM does not produce scientific knowledge and therefore it should not be given more room than it deserves, neglecting basic or clinical research.

"...between man and angel there is this difference, that an angel perceives the truth by simple apprehension, whereas man becomes acquainted with a simple truth by a process from manifold data"

Thomas Aquinas, Summa Theologica.

INTRODUCTION

The term "Evidence-based Medicine" was coined in 1992 [1], but fragments of EBM philosophy can be tracked down centuries before that date. Arguably the

most important moment in the “pre-history” of EBM is the publication in 1835 of a study by PCA Louis, a Paris physician, who examined the effectiveness of blood-letting for the treatment of pneumonia. Blood-letting was then considered the standard of care in pneumonia but Louis collected a vast amount of relevant data and after systematically studying and analysing them he concluded that blood-letting was absolutely ineffective in the treatment of pneumonia [2]. PCA Louis’ contribution to Clinical Epidemiology lies in that he based his conclusions not on the individual but on the collective clinical experience. A year later Louis’ study was published in English with an Editorial introduction noting that “...it is one of the most important medical works of the present century, marking the start of a new era in science” and that “this study is the first formal exposition of the results of the only true method of investigation in regard to the therapeutic value of remedial agents” [3]. However the negative comments were as strongly worded: “The physician called to treat a sick man is not an actuary advising a company to accept or deny risks, but someone who must deal with a specific individual at a vulnerable moment”.

In 1847 James Lind, a Great Britain naval officer compared different treatments in 12 sailors suffering from scurvy and concluded that “The most sudden and visible good effects were perceived from the use of oranges and lemons” [4].

The establishment of the modern randomised clinical trial is attributed to Sir Austin Bradford Hill. The trials of the Medical Research Council on the use of streptomycin for pulmonary tuberculosis, under the guidance of Hill, have been regarded as the forefront of a new era in medical science [5].

Another important date in the “pre-history” of EBM is the publication of the book “Effectiveness and Efficiency”, by A.L. Cochrane in 1972. In this book Cochrane argues for the establishment of an international registry of randomised clinical trials and the use of strict quality criteria for the evaluation of clinical studies [6].

Historically EBM in its present form followed the spread of Clinical Epidemiology which was based on the use of epidemiological data in clinical decision making [7]. Despite its limitations Clinical Epidemiology introduced a new approach and motivated doctors so as to start to interpret epidemiological data themselves.

Evidence based medicine originated in McMaster University in Canada and in the University of Oxford. It was soon spread with workshops and the publication of an array of books, medical journals and the appearance of web pages [8,9].

David Sackett, defined Evidence-based Medicine (EBM) as “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients” [10]. However, because EBM employs widely numerical data, Greenhalgh and Donald defined it as the enhancement

of a clinician’s traditional skills in diagnosis, treatment, prevention and related areas through the systematic framing of relevant and answerable questions and the use of mathematical estimates of probability and risk [11].

At present EBM is a dominant movement in contemporary medicine, despite reactions and criticism.

IS TODAY’S MEDICINE EVIDENCE - BASED ?

When someone faces the term EBM for the first time, the natural reaction is to ask “does this mean that the practice of medicine so far was not evidence-based?” Physicians collect information before a medical decision and are among the professions studying the most. No drug is given to patients unless there is evidence on its efficacy. Using medications for unlabelled use might be considered illegal. It seems that medicine always was evidence-based. Why all the fuss?

The answer is that unfortunately medicine was not always evidence-based. We could go back to previous centuries when blood-letting, enemas, blistering ointments, hot or cold baths and cupping were generally accepted treatments. This has led many famous physicians to a “therapeutic nihilism”. William Osler thought that most of the treatments in his era were more likely to cause harm than benefit [12].

Although today the situation is completely different, there are many examples that support the argument that despite control mechanisms, medical interventions are at least potentially dangerous. Characteristic examples are the withdrawal from the market of widely prescribed drugs such as rofecoxib recently and of some statins a few years ago, because of adverse effects. Given the fact that all drugs have more or less frequent, mild or severe side effects we should be absolutely certain for the benefit we expect from their use [13]. However a significant number of physicians use drugs when the expected benefit is negligible. A good example is the frequent use of antibiotics for upper respiratory tract infections, at least in Greece, although the majority of these infections are viral.

There is a number of studies on the behaviour of physicians, nurses and other health care workers, most of which have concluded that clinical decisions are not always based on the existing evidence. It was estimated during the 1980’s that only 10%-20% of the medical interventions (drugs, surgical interventions, imaging studies, laboratory tests) were performed on the basis of sound evidence [14]. These studies however evaluated all existing interventions, irrespectively of the frequency of their use. When medical interventions were studied in patient series, when therefore the actual frequency of the use of each intervention was taken into account, it was found that, depending on the specialty, 60-90% of clinical decisions were evidence-based [15,16]. However these numbers refer to departments with experience in EBM, consequently

it is expected that the percentage would be much lower in the average department or unit. A recent study in a Pulmonary Clinic showed that only 50% of the tests for initial diagnosis and 20% of tests for re-evaluation or follow-up had been chosen on the basis of sound evidence [17].

It is therefore obvious that for a large part, the contemporary “conventional” (the term is used in contrast to the evidence-based) medicine is not evidence-based. How then clinical decisions are made in conventional medicine? Physicians make clinical decisions based on their clinical judgement, their individual experience, an article or a textbook, the pathophysiology of the disorder or, finally, on expert opinion.

Clinical judgement is indispensable and invaluable, whichever way one practices medicine. However, many times clinical experience does not help in decision making, for example in the use of a new medication, in which case it is important that the physician is familiar with the recent developments.

DECISION MAKING BASED ON INDIVIDUAL EXPERIENCE

Experienced physicians quite often make clinical decisions based on their individual experience. One antibiotic may be preferred over another because the second “in the physician’s experience” is not as effective. Although this decision might have been made by the physician on a background of many years of clinical practice, we should remember that the individual experience does not stand any comparison, either quantitative or qualitative, to the collective experience, as this is recorded in a clinical trial. A large study, such as ALLHAT on hypertension, can analyse tens of thousands of patients [19]. Who can claim that he has cared for a similar number of patients, even in the busiest Hypertension clinic? But even if somebody would, it is impossible that someone remembers the percentage of patients which have responded to each drug, the number of patients which have presented side effects or the number of patients with potentially confounding factors (eg diabetes), so that he can reach safe conclusions. Human memory is selective and subject to bias.

DECISION MAKING BASED ON A STUDY OR A TEXTBOOK

At the other end of the spectrum is decision making based on the results of a single study that the physician has recently read, without however questioning the design and the methods and not having searched the literature for other studies addressing the same question. The problem is that, as we will see, the quality of evidence of a single study depends on many factors which we should take into account. Classic textbooks are necessary because they contain the background information for decision making, however when a particular clinical problem is concerned, textbooks offer general directions rather than specific solutions.

DECISION MAKING BASED ON EXPERT OPINION

Expert opinion is expressed in publications, either reviews or consensus conferences, which more often than not, have not gone through the peer-review process. It is not unusual however that these publications have been financially supported, directly or indirectly, by pharmaceutical companies. Someone would argue that experts on a subject are more suitable to summarize the best evidence on a clinical problem. However experts, exactly because of their interest on a subject, they usually have an opinion biased by their research interests or even by their financial or other ties with the health care industry. For example in a therapeutic intervention where evidence is conflicting, i.e. some studies show benefit while other studies not, an expert who conducted a “positive” study would support the intervention, while an expert who conducted a “negative” trial would argue for the contrary. Who we are going to believe in this case? In fact it has been demonstrated that experts on a subject are less suitable to review it, in comparison with a non-expert, who has the advantage of an unbiased opinion [20].

DECISION MAKING BASED ON PATHOPHYSIOLOGY

Traditional medical education gave a central role in pathophysiology as a background upon which decisions were made. Medical students were taught mechanisms of disease and they were instructed to use the so called inferential reasoning to reach decisions, be it diagnostic or therapeutic. Indeed our ever increasing knowledge on the mechanisms underlying different disorders has led clinicians to make decisions based on the response expected after intervening on the mechanism of disease. Unfortunately as our knowledge on pathophysiology increases we realize how complicated this is. One of the best examples is the cytokine network. The more we learn on this, the more complicated become the actions and interactions of individual cytokines. This “incomplete” knowledge of pathophysiology can lead us to wrong decisions. Just a few years ago the established management of patients with myocardial infarction with premature ventricular beats included the use of prophylactic antiarrhythmic medication. The pathophysiological basis was that by suppressing extrasystoles we decrease the possibility of sudden death. Clinical studies however have shown that in fact prophylactic antiarrhythmic medication did not improve survival and in some instances it actually increased mortality [21].

DO WE REALLY NEED EVIDENCE-BASED MEDICINE?

Even if we accept that today’s medicine is evidence-based, the question is if we need EBM. For what reasons do we need EBM?

During the everyday practice of medicine questions arise and there is need for clinical information regarding diagnosis, treatment, prognosis, and prevention of various diseases and syndromes. A study in general physicians showed that for the management of outpatients new information is needed approximately twice every three patient visits, while for inpatients the number is five per patient [22]. This necessary information may regard the epidemiology, pathophysiology and pathology of a disease or syndrome ("background" questions), for example what is the prevalence of disease X in individuals over 50 years of age? There is however another class of clinical questions which refer to diagnosis, treatment, prognosis or prevention ("foreground" questions). In the aforementioned study physicians reported that they answered these questions consulting textbooks and journals, but they managed to answer only a fraction of these questions, approximately 30%. However, direct observation revealed that in fact physicians consulted their colleagues. It was estimated that a general physician would have changed 4 clinical decisions in a day, had he had available the appropriate information [22]. So why do clinicians not manage to answer the questions which arise during patient care?

One of the reasons is that physicians do not spend time to study for their patients. A study in Great Britain showed that the time spent for studying about specific patient problems ranged from 1-2 hours per week for medical students, to 15-60 minutes per week for trainee doctors [10].

The second reason is the insufficiency of the conventional sources of information for clinicians. Medical textbooks cover more the "background" questions and, additionally, the information they contain are relatively old, especially if one takes into account the rate medicine changes in our times. Textbooks are oriented in giving general directions eg on treating a disorder rather than answering specific treatment questions.

Finally, although medical literature contains the best information for someone to answer a clinical question, it is impossible for anyone to be absolutely up to date, because of the sheer volume of information. Approximately 20,000 medical journals are published around the world and the MEDLINE database contains bibliographic information for 4,600 of these journals. MEDLINE contains over 12,000,000 citations and over 450,000 new ones are added every year [23]. It has been estimated that an internist in order to be up to date, he has to read 17 journal articles every day for every single day of the year.

The inability of physicians to answer the questions which arise during patient care has the consequence that although certain abilities such as diagnostic acumen and clinical judgement increase over the years, the overall clinical performance declines, with negative influence on the quality of care the physician delivers. Indeed the degree of knowledge of the recent developments is reciprocal to the time from medical school graduation [24]. A study of clinical behaviour from

Canada has shown that the decision to start antihypertensive medication was more closely associated with the time from medical school graduation rather than the degree of target organ damage [25]. Continuous medical education tries to solve this problem but it does not seem to be effective [26]. Continuous medical education especially in didactic form (lectures and seminars) although increases the knowledge of physicians does not change their clinical behaviour neither improves patient outcomes [27]. Evidence-based medicine tries to solve the above problems suggesting a different approach in clinical training [3]. This approach includes the training of physicians in formulating their clinical questions, in searching for the best evidence, in evaluating the evidence and finally in applying it where appropriate. The practice of the above was so far from difficult to impossible. However the development of informatics gave the appropriate tools so that literature searching is now fast and can be performed from doctor's offices. At the same time databases were created which contain randomised clinical trials or systematic reviews (e.g. Cochrane Library), and several "secondary" journals were published (journals critically reviewing the literature). These developments made it possible to practice EBM in the restricted time available in clinical practice.

THE PRINCIPLES OF EVIDENCE-BASED MEDICINE

As it has already been mentioned the principles of EBM are two: the first is the acceptance of the insufficiency of the evidence from the literature alone to support clinical decisions and the second is the hierarchy of evidence.

Clinical decisions cannot be based solely only on evidence. Medicine is practiced in specific patients and in a particular social frame, not in an abstract environment. Therefore medicine has to respect the values of this social frame and the preferences of patients regarding their own health. Consequently for clinical decision making we have to take into account, except for the evidence from literature concerning the benefit and risk of an intervention, other variables such as personal preferences and societal cost. For example in the literature it is clear that colonoscopy is superior to barium enema for the diagnosis of colon neoplasm. However a patient may not wish to undergo colonoscopy because he values more the less distress associated with barium enema than the better performance of the colonoscopy. Another example is that of clopidogrel for ischemic stroke prevention. Clopidogrel is superior to aspirin in secondary stroke prevention but it is much more expensive. For this reason several health authorities recommend aspirin considering the marginal benefit of clopidogrel not worth the additional cost. Literature supports clopidogrel use but considering other factors, such as the distribution of the finite health expenditures, health authorities decide to recommend

aspirin. In other words a clinical judgement is made regarding the cost and benefit of the intervention.

The second principle of EBM is the hierarchy of evidence. Evidence-based medicine defines as potential evidence “every empirical observation about the apparent relation between events” [11]. Consequently the observations of an individual clinician, the results of a clinical trial, even the results of an *in vitro* experiment constitute potential evidence. However all pieces of evidence do not have the same power. Individual observations are unsystematic and subject to bias while their reliability is undermined by the small number of patients. The value of experimental data is restricted by the very fact that they are experimental, therefore they have been obtained under controlled conditions, which is not certain that they resemble the real ones. Finally even the best designed and conducted randomised double blind controlled trial for the evaluation of a therapeutic intervention can have low power or be conducted in a population of patients different from ours. For these reasons EBM suggests that evidence should be rated according to its origin. The rating of evidence differs according to whether question regards therapy, diagnosis, prognosis or prevention. For example randomised clinical trials are high quality evidence for therapeutic interventions while when we evaluate diagnostic tests cohort studies are sufficient.

When therapeutic interventions are evaluated the randomised controlled trials in one patient (N of 1 randomised controlled trial) are on the top of the hierarchy of evidence. In this case the patient is subjected in succession to the intervention under evaluation and an alternative intervention (which could be placebo drug), without neither the patient nor the physicians knowing to which intervention the patient is subjected [28]. During this trial the appropriate end points are recorded (e.g. signs, symptoms, laboratory findings) and after analysis of the results it is decided to which intervention the patient will be subjected from then on. This sort of study is not always possible but when they are feasible, they consist the best way of establishing the effectiveness of a therapeutic intervention. After the N of 1 studies in the hierarchy of evidence are the systematic reviews of randomised controlled trials, individual controlled trial, observational studies etc.

Here we have to stress two points. The first is that the hierarchy of evidence is not absolute but depends on different factors such as the number of patients and the design of the study [29]. If for example the therapeutic effect is large an observational study could give evidence as strong as or even stronger than that of a randomised controlled trial. Furthermore a badly designed and executed RCT could be inferior to a good observational study. The second point is that hierarchy of evidence means that we consider the relatively strongest evidence available, even when this evidence is weak. It could be that the only evidence available is a case series; consequently we have to base our decisions on this evidence. Evidence could be weak but it almost always exists.

STAGES OF EBM

As it has already been mentioned there are 5 stages which someone goes through when practicing EBM: formulating the clinical question, searching for the evidence, evaluating the evidence, applying the evidence and finally evaluating his performance. However it is not obligatory that each clinician wishing to practice EBM has to go through all 5 stages himself. Alternatively one can search in secondary literature, which has already been mentioned, for evaluated evidence, or he can follow protocols which have been developed and evaluated according to the principles of EBM [11].

FORMULATING AN ANSWERABLE QUESTION

The first step in practicing EBM is formulating an answerable question [30]. Clinical questions will arise anyway during the practice of medicine. However to be able to proceed to the next steps, we have to formulate our questions. Formulating a question we create a framework based on which we will search for evidence and we will appraise the value and relevance of the evidence to our patient.

The first part of a formulated question is the description of the patient. For example male 50 year old patient with hypertension, 80 year old patient with class IV NYHA heart failure or post-menopausal woman. The second part is the intervention under study (e.g. drug X or diagnostic test Y) and the third part, which is not always necessary, is the control or comparator intervention (e.g. another drug or placebo, diagnostic test Z). Finally the fourth part is the outcome or end-point (e.g. mortality, morbidity, establishing a diagnosis). It is noted that formulated questions can refer to clinical examination issues, differential diagnosis, etiology of a symptom or syndrome, diagnosis, treatment or prognosis.

Here are some examples of formulated clinical questions:

In patients with class IV heart failure (first part – description of the patient) does the addition of spironolactone (second part – intervention), in comparison to standard treatment (third part – comparator intervention), increase survival (fourth part – outcome)?

In outpatients with suspected pulmonary embolism (first part) does a low concentration of d-dimers as measured by rapid ELISA (second part) exclude pulmonary embolism (fourth part)?

In patients in the emergency department with possible pneumonia (first part) which is the diagnostic accuracy of clinical examination (second part) in comparison to chest X-ray (third part) for the diagnosis of pneumonia (fourth part)?

SEARCHING FOR THE EVIDENCE

In our time there are multiple sources of clinical evidence. These are the classic textbooks, drug companies' leaflets,

proceedings of medical conferences and seminars, medical journals and finally the internet. We have to point out that some of these sources do not provide reliable evidence e.g. the drug company leaflets for obvious reasons and a significant part of the websites because there is no control or peer review on the information they contain. Additionally some medical journals, particularly the ones freely distributed by mail, contain articles that have not gone through peer review. Sometimes these journals are financially dependent on drug companies, usually indirectly in the form of advertisement profits. In other instances the authors might have economic relationships with drug companies and present selective or biased evidence.

The most reliable source of evidence are the peer review medical journals, that is journals which publish papers that have been evaluated by two or three reviewers. The largest database of medical journals is MEDLINE which has already been mentioned [23]. In some cases it is relatively easy to search evidence from MEDLINE but in others the number of articles is so vast that it becomes impossible to evaluate them all. MEDLINE is so large that special expertise is needed for a productive search. This is the reason that the so called secondary literature has developed. Secondary literature is represented mainly by the Cochrane Library which is a database of systematic reviews written by the members of the Cochrane Collaboration as well as a large registry of clinical trials [31]. Another valuable secondary source of evidence is the half-yearly publication Clinical Evidence (BMJ Publishing Group) which contains appraised evidence on treatment and it has practically become an official publication of the British National Health Service (NHS). Finally there are many journals which appraise the evidence applying predefined criteria such as Evidence-based Medicine [32] and Journal Watch, while there are similar publications for medical specialties (e.g. Evidence-based Cardiology).

CRITICAL APPRAISAL OF THE EVIDENCE

It is arguably the more critical stage in practicing EBM. After evidence is evaluated on the basis of the hierarchy of evidence, it is appraised on the basis of the following questions:

Are the results of the study valid?

This question includes a series of secondary questions which examine whether the design and the conduct of the study were appropriate. The secondary questions depend on the kind of the clinical problem (e.g. therapeutic intervention or diagnostic test study). Consequently, if the study is a clinical trial of a therapeutic intervention the secondary questions are if there was randomization, if the study was blinded, how many patients completed follow up, how many dropped out etc. If the clinical problem is the evaluation of a diagnostic test then the secondary questions are if the diagnostic test under

study was compared with the reference diagnostic test (gold standard), if the patient cohort included a wide spectrum of patients etc.

Which are the results of the study?

This question refers to the quantitative evaluation of the results of the study. If we appraise a therapeutic study we should examine how large is the treatment effect, how accurate is the estimation of the treatment effect (checking the confidence intervals) and if it is clinically relevant.

APPLYING THE EVIDENCE

In the case of a therapeutic intervention the physician should check whether the characteristics of his/her patient are similar to that of the patients studied, whether the study examined all the important end points, the benefit of the intervention compensates possible harm and the intervention is cost-effective.

When diagnostic tests are concerned we have to examine if, taking into account the evidence from history, clinical examination, laboratory tests and imaging techniques, the results of this test will substantially modify (increase or decrease) the probability of a disease, so that this diagnosis is established or discarded respectively.

Finally before applying the evidence, one must ask whether doing this is in accordance with patient's preferences and values.

EVALUATING OUR PERFORMANCE

The last but not least important step in practicing EBM is the evaluation of our clinical performance. Evaluating our performance is essential because it offers us the potential to trace down our mistakes, omissions or even practices which are not wrong but they are not the best ones. In this context, apart from improving health services, EBM functions as an educational tool. It detects our knowledge gaps and effectively fills them. Clinicians are trained in a problem-manner rather than follow a predetermined curriculum [33]. In this way clinicians are always under training but they are defining their own objectives.

TOOLS FOR EVALUATION

CRITICISM FOR EBM

As it has already been noted there is strong criticism and negative reactions to EBM. These include challenging its effectiveness, reactions for its quick spread and dominance, questions regarding the ethics of EBM and queries for its philosophical foundations [34].

Criticism for EBM could be divided into three groups. The first group includes all criticism towards the rapid spread of EBM and its "dominant" position in today's medicine. In most

of these cases criticism focuses on the connections between EBM and health and medical authorities in defining health policy. This criticism is valid in the United Kingdom where EBM has spread widely, with the strong support of the NHS and the British Medical Journal, which is an official publication of the British Medical Association. Criticism focuses on the leading figures of EBM who are accused that they are self-proclaimed reformers, that they disregard every other way of practicing medicine, that they are detached from clinical practice or that they are not even physicians but epidemiologists, biostatisticians or health economists. Evidence-based medicine is criticized because it has been used by the NHS to impose preferred clinical pathways to physicians [35]. Finally critics point out that EBM has failed to respond to criticism and that there has not been a substantial discussion for the benefit of EBM, if there is one. However reading this kind of criticism the contempt against EBM is palpable and it is also apparent that this criticism does not point to the substance of EBM but to the way it is practiced. This criticism concerns more the individuals involved rather than the idea of EBM.

The second group includes criticism which focuses more on practical aspects of EBM [36]. Thus EBM is criticised because it denigrates clinical expertise, it ignores patient preferences and values, it promotes “cookbook” medicine, it is a cost-containment instrument, its practice is detached from the bedside, it restricts physicians’ autonomy, and that when strong evidence is lacking it leads to therapeutic nihilism [37]. Additionally critics point out that there is not strong evidence that practicing EBM improves patient care [38]. Most of the above criticism originated from an incomplete understanding of what EBM is. When one reads what EBM is, he/she understands that clinical expertise and the patient himself have a central role in decision making, since the physician must judge, based on his expertise, if the evidence from a clinical trial is applicable to a particular patient [1]. Following clinical protocols, without taking into account the problems and preferences of the patient is bad EBM or is not EBM at all. Evidence-based medicine does not force clinicians to apply what is found in the literature as long as they have a different opinion, which is based on specific evidence. Guidelines are issued but as Margaret Thatcher once said “...they are exactly what they say, guidelines, they are not the law...” [39]. The argument of therapeutic nihilism reveals ignorance of the basics of EBM, because as evidence we could use not only randomised clinical trial but much less systematic observation as well. Evidence-based medicine ranks the evidence and uses the strongest. As it has already been noted, evidence could be weak but it almost always exists. The criticism regarding the cost-containment use of EBM is also very weak, as EBM could either lower cost (when it shows that a cheap treatment is as good as or better than an expensive one) or increase the cost (when it shows that the more expensive treatment is the more effective one).

The strongest point against EBM is that there is not evidence that practicing it improves patient care, which is true. It has been shown that EBM keeps physicians more up to date in comparison with the conventional continuous medical education, but this does not translate to improved patient outcomes [37]. This is a weak point for EBM and well designed trials are needed to show its effectiveness.

Finally the third group of criticisms includes questions of the ethical and philosophical background of EBM. This group of criticisms concerns problems which are somehow detached from clinical practice, notwithstanding especially important. Critics of EBM suggest that supporters of EBM are convinced of its effectiveness despite the lack of evidence on this, while at the same time they demand evidence on the effectiveness of other interventions [38]. The major ethical fault of EBM supporters is that the stand on a primary, unstructured and instinctive feeling that their own opinion is “closest to truth”, which they attempt to accommodate into a system of knowledge [34].

Criticism from a philosophy of knowledge point of view concerns the fact that EBM ranks evidence from statistical calculations on top of the hierarchy of evidence, while it assigns to pathophysiology a minor role. Criticism points to the fact that statistics suggest an association between measures or events but they tell us nothing regarding a cause and effect relationship. However the objective of science is searching for this relationship, therefore EBM is not a scientific process but a practical procedure. Another criticism regard how innovative is EBM. In the philosophy of knowledge the term “paradigm shift” is used. This term was coined by Thomas Kuhn to describe the radical changes brought about in the framework of science, after a great scientific revolution [41]. Supporters of EBM argue that EBM is a “paradigm shift” in medicine. Critics of EBM on the contrary suggest that EBM does not change radically the way medicine is practiced, because medicine was always based on evidence, but what was lacking was a system of critically appraising and ranking evidence. Evidence-based medicine is an important advance but is not a “paradigm shift” in medicine [41]. One must admit that this group of criticisms is the hardest to confront. Indeed EBM is based on facts, which may have a practical value since they are the result of outcome studies, but for this very reason it does not offer explanations. Therefore EBM does not produce new scientific knowledge nor advances medicine; it offers a framework and the rules for a rational practice of medicine.

CONCLUSION

Evidence-based medicine is a movement for a different framework in the practice of medicine. It promotes the transfer of the results of clinical trials to the everyday practice, taking into account the problems and preferences of each individual

patients. Evidence-based medicine should not be looked at as an instrument with a limited range of applications. The philosophy of EBM, which is essentially the search and the critical appraisal of evidence, permeates many aspects of the practice of medicine such as medical education, health policy and evaluation of various interventions in health. On the other hand EBM should be seen in the context of its limits, which are put by the fact that EBM is not a scientific but an empirical management of clinical problems. Thus EBM does not produce scientific knowledge and therefore it should not be given more room than it deserves, neglecting basic or clinical research.

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