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A categorization and analysis of the criticisms of Evidence-Based Medicine

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Summary The major criticisms and limitations of Evidence-Based Medicine (EBM) appearing in the literature over the past decade can be summarized and categorized into five recurring themes. The themes include: reliance on empiricism, narrow definition of evidence, lack of evidence of efficacy, limited usefulness for individual patients, and threats to the autonomy of the doctor/patient relationship. Analysis of EBM according to these themes leads to the conclusion that EBM can be a useful tool, but has severe drawbacks when used in isolation in the practice of individual patient care. Modern medicine must strive to balance an extremely complex set of priorities. To be an effective aid in achieving this balance, the theory and practice of EBM must expand to include new methods of study design and integration, and must adapt to the needs of both patients and the health care system in order to provide patients with the best care at the lowest cost.

1. Introduction

Evidence-Based Medicine (EBM) is a tool used to evaluate health care information and is promoted by its adherents as the preferred means to select and incorporate health care research into the practice of patient care [1]. Medical informatics and EBM are closely associated [2,3]. EBM is an increasingly popular usage model for information within medical informatics [4], and like any usage model, places substantial requirements and limitations on any information system designed to support it. Therefore, it is essential that medical informaticians are familiar with the principles, major issues, criticisms, and limitations associated with the theory and practice of EBM in order to achieve their goal of effectively using and managing health care information.

The initial conception for what would later become known as Evidence-Based Medicine, was originated by clinical epidemiologists at McMaster University in Canada [1]. The core concepts of EBM are rooted in work done by these epidemiologists during the 1970s and 1980s applying the principles of epidemiology to the practice of patient care. This work was motivated, in part, as a response to the accusations made by Archibald Cochrane in his book, *Effectiveness and Efficiency*, which Hill describes as a ''a biting scientific critique of medical practice''. In it, Cochrane accuses that many of the treatments, interventions, tests, and procedures used in medicine had no evidence to demonstrate their effectiveness, and may in fact be doing more harm than good [5].

Cochrane promoted the use of randomized controlled trials (RCTs) as the best means of

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demonstrating the efficacy of a therapy or an intervention, as well as the concept of ''efficient health care'', that is, using the available healthcare resources to ''maximize the delivery of effective interventions [5].'' Cochrane's ideas were adopted and expanded upon by David Sackett and others at McMaster University in the 1970s, which led to two major developments that form the core of EBM as it exists today: first was the establishment of the Cochrane Collaboration as an international group to ''prepare, maintain, and disseminate up-to-date reviews of RCTs of health care [5]''; second was the idea that epidemiological principles should be used to incorporate the latest results of these reviews into the fundamentals of physician training and the practice of patient care. This second development later was given the name ''Evidence-Based Medicine''.

The application of epidemiologic principles to the practice of patient care was first widely disseminated in the textbook *Clinical Epidemiology*, written by the McMaster epidemiologists Sackett, Haynes, and Tugwell and published in 1985 [6,7]. This book discussed methods for applying epidemiological information as an aid in guiding clinical practice. But it did not coin or use the term ''Evidence-Based Medicine [7,8].''

The beginnings of EBM as a named movement (or ''new paradigm'' as some have called it) began in the early 1990s in Canada, the United Kingdom, and slightly later, in the United States [1]. The earliest recorded use of the term in an English medical journal appears to be in a 1991 editorial by Guyatt in the *American College of Physicians Journal Club* [9]. One of the first articles to popularize the concepts of EBM in the United States was published in *JAMA* in 1992 by the Evidence-Based Medicine Working Group [7]. Almost since its introduction, EBM has been an issue of polarized debate among physicians and other people involved in health care. In 1995 a new journal was founded, *Evidence-Based Medicine*, to further develop and disseminate the ideas of EBM and to aid doctors in putting its ideas into practice [10]. Davidoff, Haynes, Sackett, and Smith launched the journal with an announcement published as an editorial in the 29 April 1995 edition of the *British Medical Journal* (BMJ). The next several issues of the *BMJ* contain letters responding to the announcement and focusing on the failings of Evidence-Based Medicine [11—13].

Since then, over a hundred books and thousands of articles have been published applying, evaluating, debating, criticizing, and supporting EBM. Proponents continue to state that the goal of EBM is to save the practice of medicine from many of its major ills, including wide variations in clinical practice, use of unproven interventions, and failure to apply consistent practice guidelines. Opponents deny either the severity of these issues, or that EBM can adequately address them, and dismiss EBM on the grounds of many philosophical and practical flaws.

One recent essay by Straus and McAlister surveying the literature and categorizing criticisms on EBM grouped common criticisms into three categories: (1) limitations universal to the practice of medicine, (2) limitations unique to evidence-based medicine, and (3) misperceptions of Evidence-Based Medicine [14]. No categories specifically addressed flaws or omissions in the philosophical basis of EBM, and many practical issues, such as EBM requiring the expenditure of limited health care resources that may be needed elsewhere, were ignored or glossed over.

The Straus and McAlister paper placed as many issues into the ''misperceptions of EBM'' category as into the ''limitations'' categories, the implication being that an overwhelming number of the EBM critics simply do not understand EBM. Given that the pros and cons of EBM have been debated for over a decade, it is unlikely that the EBM critics have basic misunderstandings of the fundamental principles of EBM. It is more likely that Straus and McAlister's choice of categories shows a strong pro-EBM bias and fails to elucidate the true nature of the issues.

With the discussion of EBM being dominated by strong supporters and opponents, it seems worthwhile to take a step back and attempt to evaluate EBM dispassionately and objectively. The goal of this paper is to categorize and evaluate the criticisms and limitations of EBM to gain a better understanding of the role EBM can most appropriately play in medical science and modern health care.

2. Operational definition of Evidence-Based Medicine

In order to evaluate the limitations and criticisms EBM it will be useful to provide a specific definition on which to base the analysis. The previously mentioned 1995 editorial in the British Medical Journal announcing the creation of the journal *Evidence-Based Medicine* gave this definition of EBM:

> ...evidence based medicine is rooted in five linked ideas: firstly, clinical decisions should be based on the best available scientific evidence; secondly, the clinical problem - rather than habits or protocols - should determine the type of evidence to be sought; thirdly, identifying the best evidence means using epidemiological and

biostatistical ways of thinking; fourthly, conclusions derived from identifying and critically appraising evidence are useful only if put into action in managing patients or making health care decisions; and, finally, performance should be constantly evaluated [10].

Supporters of EBM have suggested alternative definitions over the last seven years. In a 1996 editorial, Sackett, Rosenberg, Gray, Haynes, and Richardson define EBM as ''the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients [15].'' In 2002, Haynes gives a pragmatic definition of EBM as ''a set of tools and resources for finding and applying current best evidence from research for the care of individual patients [1].''

The definition given in the 1995 Davidoff editorial is the most appropriate one on which to base an analysis of the criticisms and limitations of EBM. This was the definition presented to the medical profession by the EBM community when the journal *Evidence-Based Medicine* was launched, and therefore defines the practice of EBM that is at the origin of much of the debate. While none of the later definitions are in disagreement with the 1995 Davidoff definition, none of them are as complete. Most importantly, this definition contains the core set of issues historically and currently surrounding Evidence-Based Medicine.

3. Criticisms and limitations of Evidence-Based Medicine

More than 10 years of debate and discussion about EBM have uncovered many areas of disagreement between EBM supporters and detractors, as well as many unanswered questions about the use and role of EBM in modern health care. Nevertheless, the debate tends to revolve around a small number of themes that will serve as useful foci for discussion.

Current criticisms and limitations of EBM can be grouped into five main themes:

1. EBM is based on empiricism, misunderstands or misrepresents the philosophy of science, and is a poor philosophic basis for medicine [8,16].
2. The EBM definition of evidence is narrow and excludes information important to clinicians [17,18].
3. EBM is not evidence-based, that is, it does not meet its own empirical tests for efficacy [1,19,20].
4. The usefulness of applying EBM to individual patients is limited [12,18,21].
5. EBM threatens the autonomy of the doctor/patient relationship [5,8,18,22].

Each of these themes will be discussed in terms of the definition and goals of EBM and the effect of what these themes represent on the practice of medicine.

3.1. EBM is a poor philosophic basis for medicine

Part of the criticism surrounding EBM is based on its philosophical underpinnings, rather than on practical issues or the current state of knowledge and understanding about the effects of EBM in practice. Originally, supporters of EBM declared it ''a new paradigm, in which evidence from health care research is the best basis for decisions for individual patients and health systems [1].'' Thomas Kuhn describes a paradigm as ''a conceptual box into which scientists try to fit nature [23].'' Applied to medicine, this amounts to declaring that EBM was a new way of thinking about medical knowledge and healthcare, replacing what came before with a new, better view of the world of patient care.

The Davidoff definition of EBM alludes to the original proponent's thinking about EBM as a new paradigm. The definition states, ''clinical decisions should be based on the best available scientific evidence''. EBM elevates experimental evidence to primary importance over other forms of evidence and this is intended to serve as the new basis for clinical thinking. In a historical review, Haynes, one of the founders of EBM, states that EBM was initially ''pitted against'' [1] traditional medical teaching where the ''understanding of basic pathophysiologic mechanisms of disease coupled with clinical experience'' is of primary importance [16].

Several articles have been published discussing the philosophical problems with treating EBM as a new paradigm and a new basis for medical and healthcare thought [8,16,20]. The primary criticism is rooted in the idea that EBM is an approach founded on evidence provided by experimental studies designed to minimize bias, rather than on physiologic theory [16]. The belief that scientific observations can be made independent of the biases of the observer is one of the aspects of the philosophy of science known as empiricism; the empirical view holds that medical observations can be made independent of pathophysiological theory. In contrast, one of the basic principles of qualitative research assumes that all observers are biased and therefore requires that the viewpoint and biases of the observer be made explicit [24]. EBM as a paradigm ''suffers'' from empiricism in

that ''evidence'' is deemed both more reliable and more important to clinical decision making than other kinds of knowledge, thus relegating to lesser importance the theory and the understanding of physiology and disease processes. Interestingly, EBM was originally declared to be ''rational, objective and altruistic [8]'', when in fact it has been understood by philosophers and scientists since the late 19th century that making theory-free, objective observation is impossible [16].

Since observations cannot be made by a naive, completely objective observer, the biases, and therefore the world-view, of the observer must be identified and taken into account. That world-view defines and limits what questions can be asked, as well as which information is deemed important and which is deemed noise. Clearer observations allow for theory to be challenged and eventually replaced by better theory. Better theory allows for more specific, more detailed, and ultimately more useful observations. EBM ignores this essential interplay between observation and theory. In part the assumption that the observer is objective is inherited from the quantitative research methods on which EBM is based, which attempt to limit the introduction of bias as much as possible. However, by relying primarily on the truthfulness of empiric data as a philosophical basis, EBM goes too far by postulating this as a fact rather than as a goal.

For these reasons, some critics have called EBM both unscientific and anti-scientific [8,25]. To have observation, rather than understanding, as the basis of medical knowledge and thought is to remove medicine from its scientific underpinnings. Declaring that medicine is ''evidence-based'' implies subservience to empiricism.

Some medical practitioners who consider themselves applied scientists have found this an unappealing theoretical basis for medicine and the practice of health care, since it places them in the position of focusing on evaluating the statistical purity of studies instead of understanding physiological processes and the mechanisms of disease [8]. In fact, the preferable situation is for clinical trials to provide evidence that supports theory. Kiwan, Chaput, and Joyce state that, ''the impact of a randomized clinical trial is greatest when it can establish a broad therapeutic principle [26].''

The original proponents of EBM may have mistakenly touted EBM as a revolutionary new paradigm, disregarding the philosophy of science [1]. In their eagerness to bring the tool of clinical epidemiology to health practitioners, they oversold the very nature of what EBM could be. Recently, some EBM proponents have backed off of this position, and are now promoting EBM as a new tool available to ''augment'' the capabilities of the practicing clinician [1].

3.2. The EBM definition of evidence is narrow and excludes important information

EBM grades evidence; evidence gathered by specific preferred methods is deemed better than evidence from other sources. In particular, for evaluation of an intervention, EBM gives the randomized controlled trial (RCT) the highest grade of evidence. EBM also defines ''highest quality'' forms of evidence for other areas of medicine such as diagnosis (comparison with a known gold standard), harm (an RCT if feasible, or a cohort study if not), and prognosis (follow up of a well-defined representative group). These ratings on the quality of evidence are derived from the principles of clinical epidemiology, which deems higher quality studies as those least likely to be biased, and postulates that certain types of studies are less vulnerable to bias [1,15]. The Davidoff definition of EBM makes this explicit: ''identifying the best evidence means using epidemiological and biostatistical ways of thinking''. These forms of evidence are given precedence over information that is gathered by other methods, such as observational and ethnographic studies, as well as clinical experience, and are also deemed as better than information analyzed using other means, such as qualitative methods [1].

Many authors have raised issues with this manner of evaluating evidence as it applies to clinical medicine. These criticisms center on three main points: (1) RCTs and meta-analysis have not been shown to be more reliable than other research methods, (2) the questions that EBM can answer are limited, and (3) EBM has failed to provide a means to integrate other, non-statistical, forms of medical information, such as professional experience and patient specific factors.

Studies have failed to show that RCTs and meta-analysis are consistently better than good quality research using other methods for determining clinical effectiveness. This has been demonstrated in several ways. For example, similarly designed RCTs researching the same question frequently disagree with each other [1] (the recent conflicting mammogram screening studies published in the *Annals of Internal Medicine* serve as a notable example [27]). Furthermore, good quality cohort studies more often than not agree with the findings of RCT studies, demonstrating that high confidence can be placed in study designs besides the RCT [1,28]. Additionally, RCTs and meta-analysis are themselves subject to certain kinds of bias, and meta-analysis

itself is subject to publication bias and weaknesses in the 'weighted-average' approach [25].

The second criticism is that ''evidence'', as currently defined by, EBM, can only answer those questions for which is it suited [12]. Questions specific to small patient populations, or those that require subjective evaluation (such as improvement in the quality of life), qualitative methods, or natural observations cannot be studied by the methods that EBM deems ''best''. Furthermore, since the methods of EBM are epidemiological and statistical, clinically important details may be hidden, overlooked, or simply ''averaged out'' by the methods of the study.

There are other sources and types of important and clinically useful evidence, besides that defined by EBM [25]. Upshur describes a taxonomy that includes four types of evidence: qualitative-personal, qualitative-general, quantitative-personal, and quantitative-general [17]. Upshur's categorization conceptualizes the essential qualities of evidence as being the context of its use and its means of production, and does not rank one combination as inherently better than another. Of these four categories, EBM only specifically deals with the quantitative-general form of evidence. Charlton and Miles believe that these other forms of evidence include a vast body of valuable information that some proponents of EBM have attempted to deprecate [8], some of which may be undetectable with current EBM methods and may amenable to study only by using other methods, such as ethnography [29].

In recent years some proponents of EBM have expanded their definition to include other high quality forms of evidence and information relevant to the care of a patient [1,28,30,31]. However, EBM advocates have not outlined any specific process for integrating and weighting evidence from widely varying sources and methodologies [1], other than continuing to state that the methods of EBM identify the highest quality evidence. This belief is problematic in itself since ''context modifies the relevance of evidence [17].'' EBM advocates state that clinicians must rely on their professional experience and clinical expertise, which highlights the weakness of EBM in clinical practice and lends credence to the opinion that there is nothing new in EBM, rather that it is just a new marketing name for a small part of how medicine has always been practiced [8,13].

All of these criticisms refute the EBM postulate that some kinds of evidence are inherently better than others, and therefore should take precedence during patient care. A multi-dimensional manner of looking at evidence determined from a variety of approaches would address many of these shortcomings [25]. Currently, meta-analysis attempts to combine data from many essentially similar studies into a single ''meta'' result. The issues raised here emphasize a need for a multi-dimensional analysis technique that will combine the results of studies that use a variety of different methods. Metaphorically, this technique is much like the principle of triangulation, which is observing an object from several points of view in order to precisely determine its location [24].

3.3. EBM is not evidence-based

EBM assumes that it will improve the quality of health care [1]. Certainly, while this assumption is a necessary start to explore the effects of EBM, it is ''not self-evident'' as some would like it to be [8]. Like any theory, the assumptions have to be validated continuously.

Considering that EBM focuses on basing patient care on statistically valid clinical trials, it is somewhat surprising and ironic to find there is no evidence (as defined by EBM) to back up this underlying assumption. In fact, as of the time of this writing, there is no convincing evidence that doctors practicing EBM provide better health care than those who do not [1]. The decision to apply EBM is itself not based on evidence. This situation is even more ironic since the Davidoff definition of EBM declares that, ''performance should be constantly evaluated.'' More than ten years after the inception of the practice of EBM, there is no evidence of its effectiveness in providing higher quality healthcare.

EBM advocates might argue that since EBM is not a test, a therapy, or an intervention, it does not require the same level of evidence for support. This argument is misleading in that the tremendous resources required to support and practice EBM are ignored [8]. EBM requires clinician time to be spent training in EBM methods and keeping up with the latest research. EBM is claimed to guide the expenditure of medical resources to those interventions that work. In that sense, EBM itself is an intervention for the way that medicine is practiced, and consumes a great deal of health care resources. Therefore, according to the principles of EBM, compelling evidence should be provided before the expenditure of these resources. Instead, EBM demands and consumes health care resources with no evidence to support the expenditure [8].

Another defense offered by EBM advocates is that the appropriate studies cannot be conducted, either that it is impossible to do appropriate double-blind studies, or that the studies would be unethical [1]. This defense conveniently dismisses

other study designs, such as ethnographic methods and qualitative analysis, as not helpful in determining the efficacy or the effectiveness of EBM. Charlton and Miles accuse EBM of declaring itself ''above criticism'', and that avoiding the requirement for EBM prove its own worth has taken EBM ''directly from being a 'bright idea', to the implementation of this idea—leaving out the usual period of critique, evaluation, and testing [8].''

Defending EBM supporters contend that EBM, while not proven effective, has been proven teachable. While this in itself may be true [1], it really does not address the central issue of evidence of the efficacy of EBM. More troubling is that studies showing EBM is teachable have been offered as the evidence that EBM is effective [10]. Whether intentional or not, these statements are misleading and their ambiguity is difficult for the reader to detect unless the cited references are examined.

There is little defense for a movement that does not hold to its own principles. EBM expends medical resources without any of the proof it requires of other interventions or changes in clinical practice. EBM must evolve to include a broader definition of high quality evidence that will allow for studies that can demonstrate the efficacy or effectiveness of EBM, or the lack thereof. Until then, EBM will continue to be an interesting, but unproven theoretical approach to the practice of medicine.

3.4. The usefulness of applying EBM to individual patients is limited

EBM is based on applying principles of epidemiology to individual patient care and therefore, as already noted, carries with it many of the assumptions of epidemiology, and other tenets core to the field of statistics. The information that EBM provides the clinician is statistically-based; clinical studies and randomized trials uncover trends and average behaviors of a group (sometimes a very large group) of ''acceptably similar'' patients.

There are two problems in trying to apply these statistical trends to individual patients. First, there is often a lack of studies relevant to the specific patient and intervention under consideration. Second patients are individuals and not groups. There is no ''mean tendency'' for a single patient. A therapy is beneficial for a person, or it is not.

Fortunately, the practice of clinical medicine deals with each patient individually, meaning that evidence applied in the management of a patient must be based on studies that reflect the situation and needs of that patient. Unfortunately, individual circumstances and values can be so varied [18,21], and there are so many uncommon diseases and variants that, as Jones and Sagar state, for ''an increasing number of subgroups of patients we will never have higher levels of evidence [12].''

Medical research tends to be practiced on common clinical situations. Uncommon diseases get less attention, even though there are many rare diseases and total number of patients with rare diseases may be large. The National Organization for Rare Disorders (NORD) maintains a catalog of over 1100 rare disorders (the total number of affected patients for all of these diseases appears to be unknown.) Due to small patient populations, uncommon diseases are hard to study with EBM methods. Highest quality evidence can only be gathered for diseases that affect enough people to be grouped into statistically significant populations. For many subgroups of patients, medical decisions need to be made based on information that EBM deems as low in quality.

Individual patients will respond, to some extent, in their own unique way to a therapy. An individual's response often cannot be adequately predicted from the results of a clinical trial [18]. Jones and Sagar state, ''When one treatment is shown to be better than another on a population basis this does not mean that it is the best treatment for the patient [12].'' In fact, science (including epidemiology) and clinical practice work from different directions. Science moves from specific observations to general rules. Clinical medicine must resolve disagreements between general rules, empirical data, theory, principles, and patient values and apply them to an individual patient [1,18].

Therefore, the application of any generalized theory or data to an individual patient needs a large amount of clinical judgment. Many EBM supporters recognize this situation, while at the same time admitting that it is unclear exactly how clinical expertise should be integrated in with EBM evidence [1]. The lack of a well-articulated approach to integrating individual circumstances, clinician expertise, and high-quality evidence is a long-standing limitation of EBM. Perhaps as EBM continues to develop and evolve, more specific directions on how to combine evidence with a patient's individual circumstances and a physician's clinical expertise will emerge.

3.5. EBM reduces the autonomy of the doctor/patient relationship

EBM has been criticized for reducing the autonomy of the doctor/patient relationship. Critics say that EBM brings the weight of numbers down on decisions made by the patient with the doctor's

assistance. This may result in limiting the patient's right to choose what is best in his or her individual circumstances.

Since the beginning of EBM, advocates have declared that it is not ''cookbook medicine [1]'', and that the application of EBM in order to restrict patient or doctor options would be a ''misuse of Evidence-Based Medicine [15].'' Sackett addresses the ''fear that Evidence-Based Medicine will be hijacked by purchasers and managers to cut the costs of health care'' by simply by stating that this fear is a fundamental misunderstanding of the financial consequences of EBM, and that doctors practicing EBM ''may raise rather than lower the cost'' of their patient care [15]. While it is certainly possible that EBM will lead to increased health expenditures, this response is more a philosophic belief than an analysis of the overall effect on clinical medicine.

The originators of EBM have no control over how EBM is used or deployed, and EBM advocates do not have the power to decide how society will apply EBM to healthcare delivery. Understandably, opponents of EBM feel that, through the creation of enforced guidelines, EBM may be used to prevent physicians from acting, holding them hostage and unable to use a treatment on a willing patient, while waiting for appropriate statistical evidence. The strongest EBM opponents think that EBM is particularly susceptible to hijacking by organizational cost containers [22]. Charlton and Miles state that ''EBM involves a takeover of the clinical consultation by an alliance of managers and their statistical technocrats...easily regulated by politicians, bureaucrats and their statistical technicians [8].''

As the amount of money and resources that healthcare consumes continues to grow, there is a greater and greater incentive to cut down on costs. Logically, EBM *could* be used to limit the application of health care resources to those situations in which there is ''high quality evidence'' of efficacy. As has already been shown, there are many patients and many situations for which this evidence will not be available anytime in the foreseeable future. The lack of evidence may be used as a cost-cutting tool to deny patients treatment for conditions where there is nothing ''proven'' effective, even though accepting an unproven treatment may be what the patient decides is the most attractive option.

As of this writing, there is no strong indication that EBM will, or will not, result in reducing the autonomy of the doctor/patient relationship. All the criticism of this type, as well as the defense, is based on conjecture, and the analysis of hypothetical situations. Time will tell whether EBM has led to a reduction in the autonomy of the patient/doctor relationship or an increase in spending on evidence supported interventions. Interestingly, the very nature of this question seems to be one that the methods of EBM cannot address, as it may require observational or other qualitative research methods to determine the overall effect of EBM on the autonomy of the patient/doctor relationship.

4. Conclusions

To some extent, the root of all of the issues with EBM, reflected in all of the themes, stems from the name ''Evidence-Based Medicine'' [1]. By declaring that medicine itself should be ''evidence-based'', EBM advocates branded a specific clinical tool as superior and in opposition to the traditional, patient-optimized approach to the practice of clinical medicine.

This was unfortunate, because it started a decade-long debate about whether medicine should be ruled by ''evidence'' and what this would really mean. Clinicians and patients would have been better served if the decade of discussion had instead focused on the best ways to incorporate evidence into the multi-faceted clinical decision making process. Current techniques to handle this complex issue are weak, limited, and cumbersome [32]. Perhaps EBM should be renamed ''methods of incorporating epidemiologic evidence into clinical practice'', but, as Haynes concludes after making a similar proposal, this is quite a cumbersome moniker [1].

One specific area in which EBM may be especially useful is in the area of prevention. David Sackett accuses preventive medicine of three elements of arrogance: aggressive assertiveness, such as pursuing healthy asymptomatic individuals for intervention; presumption, defined as confidence that the preventive interventions will on average do more harm than good; and finally, overbearingly attacking those who question the value of the preventive recommendations. He goes on to argue that subjecting healthy people to screening requires the highest level of evidence-based on randomized trials and systematic reviews. He gives several examples of negative outcomes where this policy was not followed [33].

Unlike usual clinical practice where the patient comes to the doctor with a chief-complaint, preventative medicine requires clinicians to suggest interventions in the absence of disease. In such cases, proven benefit, or at least proven absence of harm, is paramount. While it is probably impossible to be certain that a preventative intervention will result in a benefit for an individual patient, EBM techniques at least allow one to gain confidence that

a large population as a whole will benefit. For example, modern medicine is expecting a tidal wave of patient-specific genomic information sometime soon. EBM techniques may be especially useful for evaluation of preventative measures based on genetic predispositions.

None of the critics of EBM suggest that high-quality evidence obtained by clinical epidemiological methods should be ignored in the context of patient care. But it is only one factor of many, in a very complex context. Quite often, epidemiological evidence is not one of the most important factors.

This paper has analyzed the major limitations and criticisms of EBM according to a categorization consisting of five major themes. Identifying and analyzing EBM according to these themes helps to make clear the role of EBM in the future of health care and the directions in which EBM must grow. EBM is not a new philosophy of medicine, but is instead a useful, imperfect tool available as an aid in making individual and group health care decisions, and in discussing care with patients [32]. EBM as a method must continue to develop in order to incorporate high quality studies from various methodologies, and to integrate studies using multiple methodologies into a single, triangulated, ''best current answer''. The use of EBM itself must be studied by appropriate methods, and modified or reduced when those studies show a lack of cost effectiveness. Finally, individual patient values and circumstances must always be considered. The limitations of EBM must be carefully considered before current evidence is used to restrict patient access to health care, and outcomes must be watched closely for cases where the healthcare system has failed a patient because they were too unlike the average.

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