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## Evidence-based medicine: Fifteen years later. Golem the good, the bad, and the ugly in need of a review?

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### Summary

Despite its well-deserved strengths, Evidence-Based Medicine (EBM) 's shell still remains half-full. Its strong points are clouded in persisting philosophical gaps and mostly ideological advancements of its concepts and rules. Further clarification of its logic and critical use of evidence is required. In this non-systematic essay and review, several present and future necessary achievements are outlined: Solid methodological tools were developed under the umbrella of surprisingly less-operational definition(s) of EBM and 'evidence' itself, incomplete classifications of various evidences and limited scope of original critical appraisal of evidence. The integration of the best evidence with clinical expertise, setting and circumstances, as well as patient expectations, values, and preferences and the application of evidence to a specific patient have only been conceptually traced so far and usable rules remain in waiting. The question of whether the practice of EBM produces better results than its alternatives also remains unanswered. Uses of the best evidence as a basis for the fundamental elements of modern argumentation and critical thinking applied to medicine may be one of the promising paths, but this approach still must be more widely applied and evaluated on its own merit. In other words, we do have a point, but it needs to be improved.

**key words:**

**evidence-based medicine • critical appraisal and uses of evidence • logic and critical thinking in clinical practice • teaching and research**

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The Golem is a legendary clay creature artificially brought to life through the use of God's name. Created initially as an obedient servant in 16<sup>th</sup> century Prague (this author's birthplace), the Golem would at times employ its great strength malignantly. In fact, with its dangerous powers growing from day to day, the Golem needed to be restored to dust by removing or erasing the *alef* (the first letter of the Phoenician and Jewish alphabet as a sort of a guiding spirit) from its forehead in order to prevent it from overpowering members of the household. Isn't Evidence-Based Medicine (EBM) a sort of new Golem? [1]. Doesn't it need a better *alef*—guiding spirit—*shem* than the one we created so that it can take even better steps?

About fifteen years have elapsed since the first proposal of the term, domain, and content of EBM [2,3]. Since then, there has been an unprecedented expansion of its methodology, uses and applications. The original monograph on the subject in two editions was produced by a group of its original protagonists [4,5], followed by other introductory books on general EBM and an even more extensive number of works on its coverage in various clinical specialties in view of their specific practice be it community medicine and public health [6], nursing [7,8], and other health sciences (dentistry, veterinary medicine). Excellent series of papers authored by the Evidence-Based Medicine Working Group were intended as a guide to medical literature users and appeared later in a single volume [9]. There are currently about 435 textbooks on diverse aspects and domains of application of EBM in all major clinical specialties, family medicine and primary care [10]. Medical educators are being trained in EBM in increasing numbers and the teaching of EBM is being integrated to varying degrees within an increasing number of undergraduate and graduate curricula.

Perhaps one of the most important contributions of EBM has been to drive us from “*do this ... do that*” medicine to the justification of “*why to do this or that*”. This helps us balance the heart and brain in medicine, going from a ‘big heart/small brain’ version to care with Mother Teresa's heart and Albert Einstein's brain.

All these exceptional deeds necessarily developed strengths and some room for improvement. This ‘*stop, look, and listen*’ and hopefully useful exercise should tell us where we stand today and whether to continue the discussion about EBM's future directions. For numerous reasons, EBM is still a highly emotional topic. Our good will, sincerity and energy and the years we invested in this domain deserve to be channeled in the best direction possible for the full benefit of patients and the community. Many (the author of this paper included) have contributed so much of their time and efforts to this emotionally draining field to make medicine better. Does this mean, though, that everything is automatically right? Not necessarily.

The success of EBM was closely followed by healthy criticism and evaluation. For example, the Journal of Evaluation in Clinical Practice occasionally assesses the strengths and weaknesses of EBM, the most recent review occurring this year [11]. EBM's understanding of evidence is often perceived as positivist, i.e. recognizing only scientifically verifiable propositions. It is proposed as an empirically adequate

standard of reasonable practice and it is intended to be a means of increasing certainty at the expense of intuition, unsystematic clinical experience with patient and pathological-physiological rationale [12]. Our observations are, however, always laden with our background beliefs and assumptions [12]. The hierarchy of evidence is established based essentially on the methodological character of studies rather than on their quality. Goldenberg concludes that ‘... *while evidence-based approaches can improve de rigueur medical practice, “evidence-based” should not be understood to be synonymous with “best practice” in all relevant respects* [12]. And the EBM debate continues. At least four recent analyses of EBM dealing with philosophical aspects of the problem [12–15] may be a good starting point for discussion.

EBM today needs refinements leading to a better understanding and justification of its components. Nevertheless, on the basis of our current knowledge, experience and ways of thinking, we have the right to consider EBM as an appropriate pathway until EBM is either even better supported by evidence of its effectiveness, efficiency and efficacy or proven otherwise. EBM, is indeed, a belief, conviction or claim that still must be fully justified. Without proposing improvements and better alternatives, a pure philosophical “deconstruction” of EBM has its inherent limits.

EBM and its movement may be methodologically sound from an epidemiological, biostatistical, and economic or in many instances ethical standpoint, but it remains weak from a philosophical perspective and it remains in need of many fundamental and practical improvements as this discussion will attempt to show.

In this context, we will examine some aspects of evidence-based medicine for a clearer understanding of the general principles and ideas lying behind the views, comprehension, and decisions about health, disease, and care that relate to the branch of logic and critical thinking. We are all well aware that EBM was originally derived primarily from clinical epidemiology. Today, we try to see this domain in light of new contributions and experiences gathered over an increasing number of years. If both pictures do not fit, the EBM domain, its objectives and activities should perhaps be redefined taking into account accumulated experience.

Hence, what can we be proud of today (Golem the Good), what can be done better (Golem the Bad) and what wouldn't be missed if it no longer existed (Golem the Ugly)? This reflection should bring some considerations about the past and the present of EBM and the best possible directions for it in times to come as seen by a physician-epidemiologist involved in, concerned by, and trying to contribute to the EBM movement.

## WHAT CAN WE BE PROUD OF (GOLEM THE GOOD)

Most of the evidence-based domain is about cause-effect relationships whose current rules were established by philosophers, epidemiologists, biostatisticians and others: treatment as a cause of improvements in health and disease, environmental factors as a cause of cancer and other acute and chronic diseases, health programs as a cause of disease(s) prevented, etc. So far, EBM is mostly ‘causality-based medicine’. EBM shows us that this problem should

be our continuous challenge and primary consideration as well as the foundation of the clinical and community health decisions we make.

Many remarkable achievements within the EBM movement occurred in a relatively short period of time. In its original spirit, EBM succeeded in liberating us from authority as a crucial indicator of what to learn, believe and do. An appeal to the best evidence has taught us to seek and find independently of others the evidence that gives us our understanding of health problems and possibly best directions for decision making, i.e. what to decide and do about them. Experience and well-established rules for cause-effect relationships in the study of harm developed by classical epidemiology and experimental work were applied to the study of increased health benefits as produced by prevention, treatment and care. In some cases, this taught us that evidence-based problem solving is practical not only in research based on series of patients and clinical observations in view of general guidelines for particular health problems and their management, but that it can also be used at the bedside (or almost) while making recommendations and decisions for a specific patient. It has, in fact, been applied to decision making specific in a wide array of specialties thus showing its general usability and appeal.

Having said this, the best evidence possible is needed well beyond cause-effect interactions. As an example, McGee shows us the relevance of evidence-based assessment of physical examination and diagnosis in patients [16]. The diagnostic power across the literature in relation to specific pathologies of such clinical maneuvers as blood pressure measurement, analysis of fever patterns, cough in relation to pneumonia, relevance of physical findings in relation to chronic obstructive lung disease, bedside examination in cases of possible abdominal aortic aneurism or palpation and percussion of abdomen to assess ascites (bulging flanks, edema, flank and shifting dullness or fluid wave) produce evidence as to whether elements of such a classical component of clinical care as physical examination should be kept or deleted from our diagnostic armamentarium. The evidence-based approach travels well in domains other than therapeutic decision-making.

We have learned how to formulate appropriate questions and to clearly state problems to be solved as vital triggers of the entire EBM process. We know how to retrieve relevant information for medical decisions and understanding from the increasingly voluminous maze of information available through various electronic and printed sources.

EBM's major general contribution may be summarized in this way: It leads us to the best founded evidence and more explicitly answers our "why" questions about health and disease finding a justified emotionally detached and empathic "because" response. 'Because' is not simply followed by an authoritative statement, but by the best evidence available as seen independently by us, especially if the best evidence matches the 'why' question. Here is an example: **Why** should patients be treated by beta-blockers after myocardial infarction? **Because** the following original studies (... quoted and critically appraised in the context ...) and their integration (meta-analysis, systematic review) show that such treatment improves patient survival after heart

attacks and that such benefits outweigh their adverse (undesirable) effects.

In this spirit, invaluable contributions have developed within EBM or been adopted from other areas and put to good use. Today, we could not imagine medicine without them:

- Formulating more precise research and practice oriented questions to answer,
- Expanding the cause-effect reasoning and its statistical and epidemiological analysis from the domain of noxious factors (risk, harm) to the domain of health benefits and improvement of well-being due to clinical or community medicine intervention,
- Regrouping experiences from multiple sources tackling the same question in terms of meta-analysis and systematic reviews,
- Proposing new pragmatic and usable rules and hierarchies of evidence in medical research is a great achievement itself, however questionable or limited it still might be,
- Attention to the applicability of observations and findings to bedside decisions about an individual patient despite its ongoing and persisting challenge,
- Development and practice of n-of-one clinical trials,
- Assessment of the magnitude of effect of beneficial and noxious factors as those reflected in the numbers needed to treat (NNT) or harm (NNH),
- Structuring evidence search, finding, critical appraisal, and dissemination as steps in EBM practice,
- Popularizing, under its catchy name, clinical and fundamental epidemiology as a useful tool in everyday clinical and community care problem solving.
- Creating several periodicals devoted particularly to EBM.

It is less important to know whether all these contributions come from EBM itself or whether they arise from other combinations of domains that preceded EBM, like some aspects of decision analysis or clinical epidemiology.

But what questionable characteristics, content and still missing elements of EBM should we focus on?

The main problem of EBM today is perhaps that it is ideologically strong, while remaining philosophically weak. Consequently, it is subject to several potential reconsiderations. There is nothing wrong with good doctrine, ideology, belief, or rhetoric as the art of influencing the thought and conduct of the reader or the listener. This does not exclude us, however, from further improvements.

### WHAT CAN WE DO BETTER (GOLEM THE BAD)

Looking at health problems around us and questions about them has quite naturally led to still incomplete answers and room for improvement. In other words, even though 'it is not so bad, it could be better'. The following may at least partly specify for EBM users and more recent enthusiasts what the original EBM protagonists had or did not have in mind.

#### The definition of 'EBM'

After fifteen years of development and practice, EBM itself needs to be redefined to reflect its present orientation, di-

mension and scope. A well-formulated question requires an equally well-formulated answer. Do we have a clear answer as to what EBM is today?

Correct definitions of any subject of interest are crucial for our understanding and for a subsequent validity of the argumentation we use to solve health problems and to determine what is a part of the subject and what isn't. These definitions also help us establish how meaningful are our claims, recommendations and conclusions we draw from any argument as a way of reflective thinking. They represent a rather heterogeneous group of values determining their usefulness for a particular purpose [17,18]. Ambiguous and vague definitions hamper clear thinking [19] as we already know too well. Correctly defining clinical signs, symptoms, syndromes, disease or causal or other factors related to them is a crucial initial step in creating correct premises about our reasoning and ultimately our understanding and decision-making about a health problem. (Remember the story of toxic shock syndrome or AIDS?) The greater the number of definitions of a particular subject, the greater our persisting uncertainty regarding the subject.

How clear is the domain of EBM? The number of related definitions compiled [20] does not necessarily imply better clarity: Thirteen for Evidence-Based Medicine two for Evidence-Based Clinical Practice, five for Evidence-Based Healthcare, one for Evidence-Based Practice, (and two for Evidence-Based Public Health), and counting. Let us examine just four examples of the definition of EBM.

1. The most restrictive definition: *Evidence based medicine is the process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions* [21]. Only the process of evidence is at the core of this definition. Clinical decisions are derived from its uses.
2. The original and the most often cited definition proposed by a group of five authors: *Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients* [22,23]. (N.B. What about groups of patients and other sets of individuals?) This definition is excellent from a motivational standpoint with a mass appeal and mobilization, but useless for operational purposes given the vagueness and ambiguity of its adjectives. Who is then a practitioner of EBM and who isn't? Who is *conscientious, explicit* and *judicious* in his or her uses of the *best* (how do we know?) *current* evidence (of what?) and in which scope of care, and who isn't? What action or behavior is and what is not *conscientious, explicit, judicious, systematic* or *consistent* making one clinician an EBM practitioner and another not? It is not as difficult to define who is an obstetrician, epidemiologist or thoracic surgeon. If we do not like this 'preacher's' definition, can we improve it?
3. The latter as reworded in the International Epidemiological Association's (IEA) Dictionary of Epidemiology [22-24]: *The consistent use of current best evidence derived from published clinical and epidemiological research in management of patients, with attention to the balance of risks and benefits of diagnostic tests and alternative treatment regimens, taking account of each patient's unique circumstances, including baseline risk, comorbid conditions and personal preferences.* A much better definition indeed!

Once again, who pays attention to other elements of EBM clinical decision-making beyond the best evidence and who does not? Given the challenges associated with the definition of EBM, the third edition of the original EBM book does not offer any definition at all [5]. Could *consistent* be defined in more operational terms? Aren't we facing here an 'intention-based definition of evidence-based medicine'?

4. The more recent definition, more or less in line with that of its original proponents [25], is shorter (but not much better either) and it stresses only three essential components of clinical decision making: *Evidence-Based Medicine is a practice of medicine based on the integration of the best research evidence with clinical expertise and patient values* [26]. (N.B. Clinical setting and patient preferences and expectations may be added as a fourth and fifth component.) Again, isn't this mainly an 'intention-based definition of evidence-based medicine'?

In light of various types of definitions [18], most EBM definitions are motivational, persuasive and essentialist rather than reportive, stipulative and operational. Such originally motivational and persuasive definitions [19,17] were useful at the beginning of the EBM movement, but after fifteen years of experience, we deserve a better definition and rules, perhaps new, more recursive [17] ones. Suggestions anyone? Distinguishing between virtue and professional qualification remains difficult.

In retrospect, it is astonishing how EBM as loosely defined as it is above has caught on. It is perhaps precisely due to its loose meaning that a good number of adherents and followers have become comfortable, enthusiastic and often empowered in this domain. Such vagueness may be a mixed blessing since it has led to disparate domains of problem solving like qualitative research, health economics or management being included within EBM. On the other hand, it has produced a perverse effect of labeling at the discretion of the proponent any message as 'evidence-based' making it automatically more credible in the information consumer's mind. It also erroneously gives proponents that identify with the domain a not sufficiently substantiated feeling of righteousness and power.

The underlying uncertainty about EBM itself is felt in the third edition of *Evidence-Based Medicine. How to Practice and Teach EBM* whose Authors state 'what EBM requires' (p.1) as opposed to what it is by definition [5]. If Authors are not able to do so themselves, what do they (and us) expect from their first time readers and other users? The challenge is now to go beyond solemn declarations of intent.

#### The definition of 'Evidence' itself within EBM

Ultimately, we cannot blame anyone for a poor definition of EBM if 'evidence' itself has not been defined first. 'Evidence' is another philosophers' and lawyers' stone. For more than a decade, the definition of 'evidence' itself was ignored by EBM protagonists. Originally, we proposed its 1999 definition as '*a fact or body of facts on which a proof, belief or judgment is based. Evidence does not mean certainty. Rather, it represents an available proof with varying degrees of certainty*' [27]. More specifically, we later (in 2003) felt, beyond the context of clinical case reporting, that evidence is '*any data or information, whether*



*solid or weak, obtained through experience, observational research or experimental work (trials). This data or information must be relevant either to the understanding of the problem (case) or to the clinical decisions (diagnostic, therapeutic, or care-oriented) made about the case* [28]. This definition gives a whole new dimension to EBM itself by encompassing not only the best research evidence, but also clinical information provided by the physician, his or her patient and the setting of the practice. Would this accommodate some defenders and critics of EBM?

If EBM were limited in its scope to its main concern, a cause-effect relationship, in the context of a 'causality-based medicine', should we not simply define evidence as 'the demonstration of causality' and best evidence as 'the best available evaluation of such (i.e. cause-effect) relationship'?

The concept of EBM is only as valid as the definition and concept of evidence itself.

Let us not forget that within the general scope of evidence, as seen by philosophers/critical thinkers, falls not only a demonstration of causality, but also intuition, personal experience, testimonials, appeals to authorities, personal observations, case examples, research studies (beyond causality), and analogies [29]. Such an enlarged spectrum of evidence calls perhaps for a more refined view of evidence in medicine.

#### Definition of the 'best' (evidence)

Once we know what evidence in EBM (and EBM itself) is, do we know to a satisfactory extent what the 'best' evidence means? Yes, but only in a single situation: In the case of a cause-effect relationship where a well-controlled clinical trial is possible and a research synthesis (meta-analysis) is feasible: Synthesis of the best evidence research findings (if available) → well-designed clinical trials → observational analytical studies → multiple observational time series ('descriptive' studies) → consensus and expert opinions of groups as authorities or knowledgeable individuals → simple anecdotal experience. Summarized elsewhere [30], this hierarchy was adopted with various refinements and modifications by the Canadian [31] and US [32,33] Task Forces in their guides to better preventive medicine and other services. Furthermore, the hierarchy is built according to the type of study, thus providing equal quality for each type of study. In other cases, such as in studies of risk (ie. causal factors) of disease where trials are not possible for ethical or technical reasons, is evidence from some impeccable observational analytical research then only second best? What is the best in that instance?

And how should we approach the hierarchy of the best available evidence in the domain of diagnostic tests, tools and technologies? Some hierarchy of evidence can be established by relying on other criteria based, in this case, essentially on disease spectrum and gradient of disease being diagnosed, comorbidity, treatment for the main problem and for comorbidity, and the preselection or not of patients for a diagnostic process [34–36]. This is quite a different hierarchy from the classification of cause-effect relationship proof. In the domain of clinical trials, their phases also produce a different hierarchy of evidence pertaining to a cause-effect relationship based on different questions about it. In the hierarchy of the effectiveness of clinical in-

terventions, the question remains the same: Does it work? In the other domains, another question arises: In what circumstances does it work the best?

Nonetheless, even the diagnostic process is essentially an evaluation of another cause-effect relationship: A morphological or functional anomaly, physical or psychological 'causes', a positive test result. Traditionally in medicine, we ignore this basic function and proof of cause-effect relationships. We proceed instead directly to the evaluation of operational diagnostic or screening test criteria and virtues like sensitivity, specificity, predictive values, likelihood ratios, receiver-operating characteristic (ROC) curves and other characteristics. The hierarchy of evidence for a diagnostic test remains blurred.

Should studies of prognosis be subject to similar classification as studies of an immediate effect of treatment? We believe so.

Until this kind of question is solved, EBM cannot be an all-encompassing 'golden standard' for clinical practice and guidelines **throughout the entire field of medicine**. It is still too vague and incomplete in most of its methodological scope as a general tool usable and useful everywhere to the same degree.

#### Critical appraisal and hierarchy of evidence

The current hierarchy of evidence is based mainly on the theoretical nature of each study contributing to the demonstration of some cause-effect relationship wherever an experimental proof (clinical trial) is possible. It presumes implicitly that any clinical trial is automatically and by definition better than any other kind of cause-effect link demonstration like observational analytical studies.

Critical appraisal as originally developed for EBM means critical appraisal **of evidence**: Which evidence is the best, which evidence is acceptable, and which evidence should be discarded? Hence, some criteria of quality of research studies and their findings must be and already are established. Having said this, we may be right in thinking that conceptually, and only conceptually, clinical trials are better than observational analytical studies such as cohort or case control studies. On the other hand, a clinical trial may be bad, and a case control study of the same problem based on representative incident cases bearing characteristics that would make them eligible for a clinical trial and yielding ideally a good estimation of exposure rate in all groups compared might be as good or almost as an experimental study with comparable qualities and flaws. Any classification and hierarchy of evidence based solely on the nature of the study (observational, experimental, with or without control groups) stands only if all types of studies under consideration, with all their inherent strengths, weaknesses and limitations have been *a priori* critically appraised for their acceptable quality making them eligible for comparisons, assessment and synthesis if needed. A flawed clinical trial is not necessarily superior to an impeccable observational analytical study.

And what of the hierarchy of evidence about a cause-effect relationship where clinical trials are impossible, such as in the observational analytical research of the role of possibly noxious factors leading to disease? If we say that 'evidence ob-

tained from well designed observational cohort or case-control studies, preferably from more than one center or research group' is only level two, then it may be level one wherever experimental proof is impossible, regardless of the reason.

Critical appraisal of evidence remains essential also for weighing study results based on its quality if used in meta-analysis and systematic reviews of evidence.

A systematic review and research synthesis of evidence does not automatically mean the best evidence, especially given the challenge of the application of its findings to a specific patient. Meta-analysis or any kind of research synthesis should remain explicitly free from fallacies of generalization (composition) or hasty conclusion (division). In fact, greater attention should be paid to these types of fallacies in the interpretation and uses of research synthesis findings.

What is more important in research synthesis? Is it an overall impression based on all quantitative analysis refinements that methodological perfectionism (sometimes teasingly referred to as *PhD Syndrome*) might provide? Or is it a rational analysis and interpretation of the meaning and applicability of a mosaic of original studies as an 'epidemiology of their results' [37,38], however heterogeneous they might be?

What hierarchy of studies is the most appropriate in surgery, psychiatry, pediatrics or emergency medicine given the ethical limitations of causal research and other problem solving?

Having the evidence at hand, subjecting it to its critical appraisal and grading followed by its dissemination and the evaluation of its uptake is just the beginning of the road, not the end of medical decision-making. What about its uses?

#### **Critical appraisal of the argumentation process in which evidence is used**

If we now better understand how to critically appraise evidence, we should have an equally structured and organized method for how to use the best evidence in conjunction with physician clinical expertise (knowledge, attitudes, and skills), health care setting, patient expectations, values, preferences and choices. The challenge of such a process is determining how to go beyond a solemn declaration of intent.

Critical appraisal of uses of evidence relies on the modern methodology of argumentation, informal logic and critical thinking. It is at least as important as the critical appraisal of evidence itself. Its methodology, adapted to medicine is now available [26,39] and using it widely would be the best test of its intrinsic and extrinsic value and relevance for practice and research.

The best evidence is only meaningful if used in proper argumentation. Argumentation itself is only meaningful if based on the best evidence in its building blocks.

#### **Integrating the best evidence with clinical experience, setting (situation), and patients' expectations, values, preferences, and choices**

Once we have the most satisfactory evidence at hand ... *as the basis for clinical decisions* [21], what should we do with it

in our clinical decision-making? What kind of step-by-step procedure beyond an intention should we follow? Should we start with evidence first, then consider clinical experience and setting and ultimately add the patient's standpoint? Or should we follow some other sequence and interaction of EBM constituting elements in a clear structure of thought?

#### *Symbolic structuring of the integration*

After the first critiques pointed out that EBM was limited to the search for and use of the best evidence only, its integration with other aspects of clinical practice was proposed [25]. Various types of clinical practice to which EBM could be applied were also identified [36]. Figure 1 is an Euler diagram reflecting these different clinical practices including the desired integration.

#### *Developing a decision analysis that includes evidence, patient preferences and values, clinical setting and physician clinical expertise (experience)*

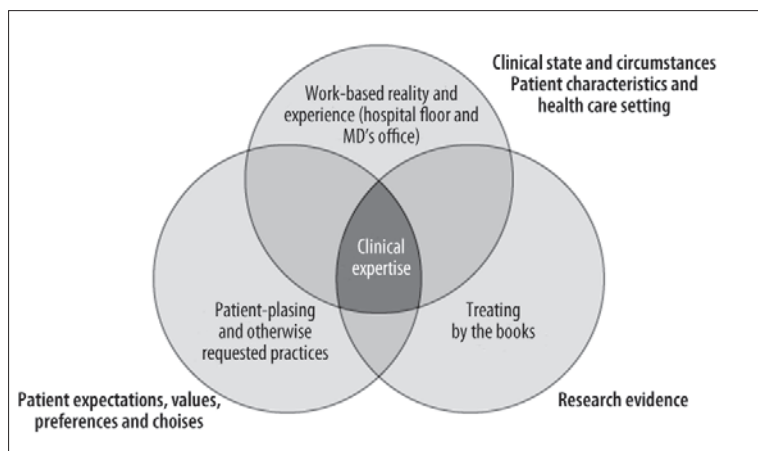
So far, we do not have a clear methodological guide to help us make such a desirable integration work. We need to go beyond simple rhetoric. For example, decision analysis remains one of the possible pathways [5], but its complexity excludes it from most bedside clinical decision-making and often relegates it as a possible technique for more general strategies beyond a single patient and case of disease.

Now, we just need someone to tell us how to do all this research/clinical work in clear operational terms, according to which criteria and in which explicit steps! How should we correctly weigh all components of an EBM integrated approach to clinical decision making? Will the patient and his or her ethicist always have the last word? What, more precisely, is the process of argumentation and the reasoning to follow from the best evidence to the final appropriate claim or conclusion (in critical thinking terms) or decision about the patient? Methods of modern critical thinking applied to medicine [26,39] may prove useful if not necessary for solving the problem.

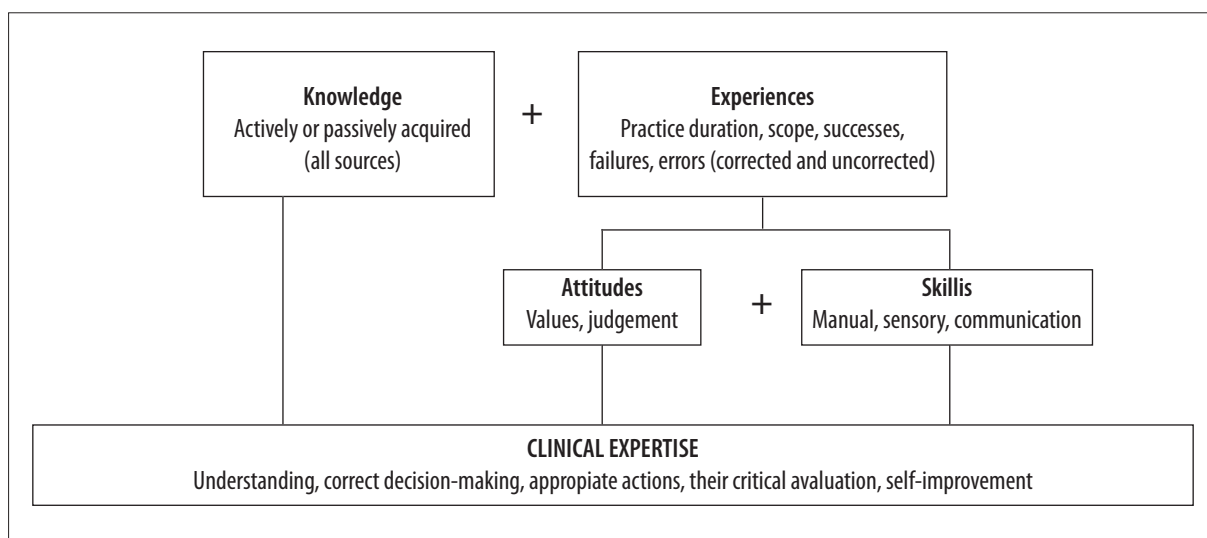
How to create this 'integration' remains unclear. Or does all this mean simply trying to find common ground with patients by explaining to them your rationale as a physician, listening to their views, making sense from both points of view and ultimately reaching a mutually acceptable agreement about what to do?

#### *How should we better define clinical expertise?*

When trying to define research evidence, shouldn't we also do so for the benefit of clinical expertise? Clinical experience often equals, but not always, compatibility with evidence. Does this mean years of experience, errors made, detected and corrected, diagnostic, therapeutic and prognostic successes and failures accounted for, impeccable bedside manners, respect of deontology or something else? The often mystical nature of clinical experience and its non-compatibility with evidence remain unexplained. This point may be even more important in decisions about treatment wherever clinical trials are not feasible for ethical and other reasons. Our decisions rely heavily on clinical expertise.



**Figure 1.** Evidence-based clinical decisions. Modified from Ref. 25 and 36.



**Figure 2.** Components of clinical expertise.

Figure 2 illustrates that in essence:

- **Clinical expertise** means the best possible understanding of and correct decision-making about a health problem (in a patient, patients, and the community),
- It relies on two critical elements, namely **knowledge** and **experience** in a given clinical and community setting,
- Experience relies on correct **attitudes** and **skills**.

The ideal integrated clinical expertise and ensuing medical decision-making should perhaps include more than the basic triad of research evidence, clinical state and circumstances, patient preferences and actions [25]. **Research evidence, clinical circumstances** (patient demographic and clinical characteristics, principal and other conditions, comorbidity, treatment for comorbidity), **clinical setting** (human and physical environment, current practices, rules, what can and what cannot be made), **patient values, patient preferences, patient expectations** (they may differ from patient values) and **ultimate patient choices**, as well as **intrinsic and extraneous ethical considerations** are all worthy of consideration, if not necessary, in medical understanding and decision-making. Either they all fit the setting of the research evidence or not, creating an additional challenge from the latter.

*Using evidence, values, preferences, clinical setting and experience of and by all in clinical argumentations*

All the above-mentioned elements are invaluable as components of the various building blocks of a modern argument like grounds, backing or rebuttals. This kind of argumentation still needs to be tested in real-life applications. **'Evidence-based argumentation'** (a bidirectional process between a proponent (physician) and the listener (other physicians, patients, other community stakeholders in health)) may be the way to go.

If EBM relies on the integration of research findings (ideally best evidence), patients' preferences and actions, as well as clinical state and circumstances [24], such an integration should be reflected in and be part of most argument building blocks, not only the best evidence. Elements of our argumentation such as backing, grounds, and rebuttals (if our claims, i.e. decisions, about the patient reflect such a tripartite philosophy) should also be made more operational by other manners of reasoning and decision-making that would include the components of clinical expertise and the broader spectrum of evidence as outlined above.

### Applicability of the best evidence to individual patients

Tonelli [13,14] was one of the most vocal supporters of a better link between what is seen in groups of patients and in an individual patient under physician's care. This link still needs to be better understood. Completing the late Alvan Feinstein's words (personal communication) that the first criterion may rely on the eligibility of the individual patient for enrolment in a study that evaluated evidence for a group of patients having similar demographic and clinical characteristics, we should look even closer to see whether the characteristics of our patient are those of the patients who benefited from the treatment in the trial. Finally, we need to look at the compatibility of the application and setting of research such as trials and other relevant endeavors.

But how should we apply findings from meta-analyses and systematic reviews to an individual patient? This challenge is even greater than the one related to original research. Findings from systematic reviews and meta-analyses may be a good guide to making decisions about an individual patient if the clinical and demographic characteristics of patients in original studies and across the meta-analysis are similar to those in our patient. If they are not, we may over- or underestimate the expected effect from meta-analysis when applying it to our patient.

And how should we evaluate whether the application of extraneous findings to the individual patient was correct? This question also waits for an answer.

### WHAT WOULDNT BE MISSED AND WHAT IS STILL MISSING (GOLEM THE UGLY)

Some current views and propositions concerning EBM require an even more thorough reworking.

#### More authors, more legitimacy

Some statements are derived from the reflection and experience of many highly qualified specialists in various fields of practice and specialties. Original research papers now specify how and in which way their authors contributed to the study. This should also apply to position papers and strategic statements for the development of new directions for medicine. Do we really need 'petitions', 'manifestos' or proposals of intention in which only a collective responsibility of 'working groups' is stated?

#### Is EBM a new paradigm of medicine?

A paradigm was defined by T. Kuhn as a set of scientific and metaphysical beliefs that make up a theoretical framework within which scientific theories can be tested, evaluated, and if necessary revised [39,40]. EBM was heralded as a **new paradigm of medicine**. Is it? If it is, it is being increasingly tested, but this is not enough. It has not been sufficiently evaluated and it is in need of revision.

As we have already stressed elsewhere [15], medicine has always been evidence-based, only evidence now has taken on a new meaning: From belief, authority, sincere impression based on personal experience etc, the best evidence today, at least for intervention as a cause-effect relationship, is symbolized by a well organized randomized controlled

trial and eventually a synthesis of multiple experiences of the latter kind (systematic review and meta-analysis of evidence). Hence, we are facing a **new paradigm of best evidence only**. Ultimately, any kind of evidence may be combined with clinical expertise, setting, circumstances, patient state, preferences, values and choices, as well as with ethical considerations. This was always done to a varying degree for all components of practice and decision-making. Any claim of a new paradigm must be substantiated.

Not explicitly mentioning EBM's roots in fundamental and clinical epidemiology methodology, experience and contributions is unjust and wrong wherever it occurs. EBM is an evolutionary process, not a revolutionary one. It is just a logical sequel to the former experience. We have tried to reflect this point in our own *Foundations of Evidence-Based Medicine* [36].

#### 'New' terms and entities

Absolute risk reduction or increase, relative risk reduction or increase are repeatedly proposed in newer EBM periodicals or textbooks as 'new' terms to be used in EBM without specifying that they are similar to the traditional terms used in epidemiology for decades such as risk difference, attributable risk, relative risk, attributable fraction, etiological fraction, attributable risk percent, etc. Bridging of both terminologies was not done beyond our own attempt [36] and many new adepts of EBM may remain confused or simply ignore that there is often nothing new behind those terms perhaps being more explicit for some clinicians with a less solid grasp of epidemiology in a clinical setting, trials, and decisions. It may hamper establishing links between the past and the present and various domains of health sciences research, experience and understanding of contributions in various complementary fields of health care and research. Such terminology artificially kept apart from the epidemiology mainstream may even be misleading and keep consultants in biostatistics and epidemiology busy enlightening EBM Boeotians.

#### The inexistent updated definition of EBM

Authors of the recent edition of the basic EBM textbook written by the original protagonists of EBM (DL Sackett retired from the EBM domain in the midst of the EBM debate) simply did not offer a definition of EBM [5]. Baltzan [41] did it for them perhaps by adding the adjective 'scientific', thus leading to '*scientific evidence-based medicine*' or '*best evidence-based medicine*'. In the simplest terms, aren't we tackling a sort of '*study substantiated or unsubstantiated medicine*'? '*Research enhanced health care*'? [25] '*Evidence-based critical-thinking medicine*'? [42] '*Reasoned medicine*'? [15] '*Evidence-grounded argument-based medicine*'? [15] or even '*critical thinking medicine*' (including tacit evidence)? And so on. The term EBM must not implicitly suggest that before rigorous cause-effect situations, such as a phase three (and beyond) randomized double blind controlled clinical trial, there was no evidence in medicine. Only the nature of evidence from research and practice have changed.

#### Does the practice of EBM bring better clinical results and benefits for the patient than any of its alternatives?

We still do not know. The current edition of the original EBM book considers EBM evaluation essentially as a process eval-



uation [5,23], i.e. how it is practiced. Authors call this 'performance'. Evaluating whether physicians practice EBM well and consistently still does not mean automatically that their performance yields better results. We also need an evaluation of EBM's impact in terms of successes in health care. Based on our perhaps imperfect literature search, no one has yet run a controlled trial comparing EBM performance with some other best possible intervention or model of care. If we just want to be consistent with EBM precepts we must sooner or later evaluate the effectiveness of EBM practice itself. Where is the evidence about the superiority of EBM practice? Until the evidence is found then, EBM will remain another more or less, however logical it might be, new unsubstantiated belief even if its rationale is the best it can be [15]. We may be accused of committing an *ad populum* fallacy by stressing its spread, wide acceptance and practice by many as the justification for EBM [43-45]. The rest of our *ad hoc* paper (its critics in their current uproar [43-45]) focuses on the following statement (out of the context): "*The EBM challenge is important because it is unquestionably the right approach to follow in medicine whenever and wherever possible. ... In its present state, EBM is a great step forward but not the only step. ...*" [15]. We may 'logically' be right, but is this enough? Our sincere belief (confidence in the truth or existence of EBM's superiority not immediately susceptible to rigorous proof) or conviction as a fixed or firm belief in the soundness of EBM is still not enough to advance EBM farther. We need evidence of EBM's effectiveness. Otherwise, following EBM's philosophy, EBM remains just another new belief, regardless of how intellectually justified it might be. Critics of the present lack of proof (evidence) that EBM works better than its alternatives certainly realize, so far, that the **proof of the contrary, i.e. that EBM does not work better or at all, can be as challenged as proof that it does.** If EBM 'does not make sense' what else does?

#### **Presentation of the constituting elements, method and techniques of EBM**

Many authors suggest that EBM's handling of risk in the patient, causes of harm or of benefits, prognosis and other pieces of the whole EBM mosaic is appropriate. What message is meant to be convincing? What is good or bad ideology and what is good or bad doctrine? We still do not know.

Straightforward presentations very often lack discussion of weaknesses and limitations of the method proposed with its alternatives whenever they are available and relevant. Instead, an authoritative message is signed by multiple authors with individual contributions remaining unknown to the reader. Hence, evidence of evidence is replaced by views of a group of experts, however qualified they are, who probably do not work always as an organized and structured team behind modern clinical recommendations and guidelines.

As already mentioned, most of EBM's methodological elements originate from fundamental and clinical epidemiology and biostatistics and elements adapted from neighboring fields like decision analysis, qualitative research methodology or economics just to name a few. The authority of the message is enhanced by an impressive number of experts of remarkable quality and experience. Some of them play the role of a synod or curia advancing major lines in ideology and doctrine to follow rather than the role of carriers

of new factual and methodological findings and scientific proof itself. The era of petition-like papers seems over.

#### **EBM's mantra**

In the minds of many, a laudatory mantra chanting of EBM immediately gives legitimacy to whatever falls under its umbrella. Advice to aspiring authors of medical articles or monographs might be: '*Label it 'Evidence-Based' and you have a greater chance of getting published and getting away with it.*' Even our own book on logic and critical thinking in medicine was (rightly) presented by the Publisher in the larger framework of evidence-based practice [39]. This is all due to the correct stressing of the uses of scientific evidence in our medical decision-making. It is not always necessarily so in your own handling of evidence for a special purpose.

A publishing trend may be noticeable. Is it enough to write a book by specifying the quality of evidence behind any diagnostic or therapeutic recommendation? "Can this or that be considered satisfactory evidence as a basis for decision-making because there was a good quality controlled clinical trial published tackling the problem"? That may often be a fairly narrow answer, but it is not necessarily enough to cover all EBM considerations regarding the clinical activity under evaluation. So far, 'evidence-based' books sell well. Because of their title, they automatically appear more credible, scientific and better than their 'evidence unspecified' competitors. But is this always really so?

#### **CONCLUSIONS. WHAT IS A BETTER ALEF TO WRITE ON THE GOLEM'S FOREHEAD OR HOW CAN WE IMPROVE EBM**

Many readers of this paper may be disappointed that it does not bring answers to all the questions it raises. This is due to the fact that there are still too many other questions to be considered for which we do not have satisfactory answers. EBM remains an unfinished story. So far, foundations of and current contributions to EBM are remarkable and they will remain so. However, as essential as they might be, they are still not sufficient to advance EBM beyond its ideological character. As long as the Golem or giant on clay feet does not receive a better prosthetic replacement of its clay pieces, EBM needs to be put on more solid philosophical foundations. EBM may still be less of a scientific procedure and more of an ideological movement and doctrine for many of us and for some time to come.

Too broadly defined in noble but less precise terms, EBM remains prone and open to multiple interpretations, applications and uses. Many books of faith are written this way. Everybody finds in them something to his or her liking, hence their wide popularity. EBM is an open gate to change rather than a straightjacket of reasoning by applying and following its rules (without evaluation) in any and all domains for which it was proposed.

As a way of critical thinking, EBM should and already is helping us create an affective and rational distance between the EBM user and ideas of interest whether his or hers or others', for the better understanding of their truth, relevance, validity, and rationality. EBM as an expression of critical thinking should offer us tools and virtues of skepticism over gullibility or dogmatism, reason over faith, sci-

ence or pseudoscience, or rationality over wishful thinking [46]. From a philosophical point of view, we remain at the beginning of the road.

Finding the solution to a health problem is an exercise in argumentation in which evidence for grounds or backing as well as the whole reasoning process into which it enters are present, well-linked and directed to the solution of the problem (claim, conclusions, and recommendations). It is an exercise in informal logic and critical thinking [26,39]. Appraising the quality of evidence and appraising the quality of argumentation based on its components are two different, but complementary and necessary endeavors. Currently, only more time and experience will enrich the symbiosis between these two paths leading towards the best clinical decisions.

Being persuasive and convincing is more difficult than being doctrinarian and/or dogmatic in a prescriptive way. The authority of an individual is replaced by the new authority of evidence, but is it enough? Replacing the 'because I am telling you so' medicine, regardless of how qualified the 'telling' might be, by an independent critical appraisal performed by an EBM trained clinical decision maker is just part of the solution. Neither an EBMers' sometimes authoritarian directions nor a blind Ludite bashing by his or her opponents will be very beneficial. The deconstruction of ongoing argumentations must be followed by further construction of the EBM domain.

It is up to the reader to judge how persuasive and convincing this reflection about the EBM Golem has been. Implementing and evaluating EBM goes well beyond the school of faith or the tele-evangelical spread of the word.

Being critical of EBM does not mean its denial, but rather a will to see it improve. We can always ask any EBM rejectionist: So, what else would you do? What is an equally clear alternative? We can also ask the EBM adherent: What can you do now to make it better? What do you suggest?

EBM is here to stay. After all, it is 'evidence' in its modern meaning (mainly a well demonstrated cause-effect relationship) that distinguishes medicine from faith and religion. Without evidence, i.e. the best available demonstration of the cause-effect relationship in medicine, comforting a patient sadly enough might be done in many instances better by clergy than by many health professionals. Without continuous improvements of the EBM domain, wide acceptance of EBM should not lead us to creating a new religion of EBM itself.

If philosophy in medicine (based on Webster's general definition [47]) is the *rational investigation* (but also practice!) *of the truths* (evidences) *and principles of being* (a patient or his health care provider), *knowledge* (basic, clinical, community) *or conduct* (prevention and clinical and community care), it requires many serious commitments from all of us. We often forget that philosophy is not simply a critical study of basic principles and concepts of a particular branch of knowledge to improve our understanding (EBM in this case, our practice, etc.). It also represents a system of principles and guidance in practical affairs [47]. In addition, it is supposed to lead us to composure and calm in the presence of troubles and annoyances [46] and to the achievements and rewards

that innovation and progress generate. Each of us needs to be a philosopher in and of medicine in this sense.

In order to achieve a balance, a complex set of priorities in modern medicine stemming from individual patient and community care must be established. '*EBM must expand to include new methods and study design and knowledge integration, and must adapt to the needs of both patients and healthcare professionals in order to provide the best care at the lowest possible cost*' [48].

EBM has reached its adolescence and it should be wished all the best in its further development. As in our own lives, a 'new look' is often desirable at this age. Even though we are on the right track with EBM, it is clear that we still have some work to do.

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