The Evidence-Based Medicine Condition: A Report on Uses and Abuses*

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ABSTRACT
This article is not questioning the validity or even the usefulness of evidence-based medicine (EBM) technical developments. Rather, the author is engaging with the conceptual framework within which EBM has been developed, interpreted and presented. Thus, this article explores the sociopolitical conditions that underlie characterizing EBM as paradigm and the implications of this label on practicing it in the developed as well as developing world. As medicine does not belong to pure sciences, it is believed here that the claim of paradigmatic characteristic is implanted to fulfill authoritative symbolic function rather than expressing a presumed revolutionary and radical change. This authoritative function, which enables EBM to transcend the clinical epidemiology it established on, could articulate three axes: the demise of welfare state, the postmodernist assault on the classical notions of truth and certainty, and the crisis of the medical professions. One prominent evidence that supports our proposal is the dynamism of the movement and its capacity to "engulf" everything in its way including pseudoscience. It is noted that a major consequence of assigning EBM as paradigm is to give it a legitimized and rationalized potentiality for abuse by the profit-oriented medical-pharmaceutical complex. Another major impact is on the developing countries, which because they follow the educational and practical systems of medicine in the West, are in more positive attitude to both the drug companies and to new fashions. Beyond these issues, it is argued in the current paper that the claim of paradigm attains efficiently the control and power functions of EBM via achieving “totalizing” discourse creating norms for the consciousness and moral identity of the clinician. In short, it is via the paradigmatic characterization EBM engages in reasserting its hegemony in the face of a variety of challenges, and at the same time, assimilates as much as possible the sources of such challenges. It is assumed that the susceptibility of EBM for corruption will continue unless the disguising power of EBM is dismantled via humanist and medical critiques.

Key words: Abuse; Assimilation; Colonization; Developing world; Authority; Evidence-based medicine/practice; Knowledge/power; Paradigm; Pharmaceutical industry; Randomized control trials.

In 1992, the Evidence-Based Medicine Working Group produced a remarkable report in which evidence-based medicine (EBM) is characterized as emergent “new paradigm” for medical practice. This characterization seems, at first glance, innocent as it might represent a mere borrowing from the vocabularies of philosophy and history of science. Nevertheless, it is well to note that the word paradigm has become quite popular to a degree it is often used in meanings lacking a philosophical or theoretical framework. However, critical analysis of the historical contexts in which EBM has developed and its procedural logic reveals another story that is of major implications related to the “nature” of EBM or to the traditional medical discourses. Moreover, despite the fact that EBM uses techniques governed by rigorous methodologies, such as randomized control trials (RCT), meta-analyses, and guidelines, it is involved in description of flaws in traditional modes of knowledge dissemination, and makes claims about the nature of good evidence, we find that these facts are per se insufficient to consider EBM as new paradigm. Noticeably, it is Thomas Kuhn in his The Structure of Scientific
Revolutions, who conceptualized the word paradigm, and its sisters such like “paradigmatic shift” and, the more raucous one “scientific revolution”. Kuhn’s work was intended to historicize the pure or hard sciences such like physics, chemistry and astronomy. Paradoxically, while the Kuhnian use of the concept is limited to hard sciences, assigning it to EBM signifies that medicine is a discipline that belongs to the hard sciences. Framing medicine as a hard science is epistemically problematic because the statistical inference on which EBM is founded implies that health phenomena can be only grasped indirectly rather than by direct clinical inference. Moreover, the proponents of EBM themselves incorporate patient values as integrated component of the evidence-based practice (EBP); an additional characteristic that distances EBM from the belonging to hard sciences. Yet incongruously, while EBM calls and teaches critical practices instead of intuition and unsystematic clinical experience (or following Sackett et al.’s assault on the medical students and junior doctors who have “to carry out the orders of their consultants”), paradigm requires unquestionable acceptance of what is canonical or central doctrine in the scientific practices of “revolutionary” science. Thus, while an excellent empiricist study concludes that guidelines actually enforce professional autonomy rather than embodying a potential constant threat to it, it remains problematic how these conditions of creativity are maintained with paradigmatic enterprise conceived as constraining the space of judgment and decision-making as well as limiting the development of alternative hypotheses. Moreover, the paradigm trait has caused confusion among the critics and proponents of EBM. For example, Silva and Wyer believed that the 1992 EBM manifesto belongs to Kuhn’s post-positivism rather than to the positivism that Kuhn has subjected it to stark criticism. The spectrum of EBM stories tells involves an extreme case that is incomprehensible to occur in disciplines characterized to be paradigmatic. It is the tolerant appreciation of harsh attacks, which were published in journals that are enthusiastic about EBM literature e.g. the British Medical Journal (July 1996 issues). The case of Holmes et al. indicates to what extent EBM community is tolerant to and measurable by other discourses that can be fairly considered metamedical.

Although many authors raised the question whether it is correct to construe EBM “as a new scientific or philosophical theory that changes the nature of medicine or our understanding thereof”, it remains to wonder why the report, its advocates, e.g., and opponents, e.g., have hailed EBM as a paradigm or even “revolution”, in the sense put forward by Thomas Kuhn.

We would argue here that despite the description is not based on internal characteristic of EBM, it is yet not accidental, but has essential impact on the development of this movement and its external logic. We propose that this conceptual identification functions well in articulation of three intersected axes. The first is to assure dissemination of methodologies and epistemology of the movement among the majority of governmental and private sectors of health services. This would require, as any immature movement to consolidate its legitimacy and authority. Secondly, following the demise of welfare state system and the neoliberal restructuring of health sectors in the 1980s, the medical enterprise in the developed world entered a state of “crisis” (epistemologically as much as social). This will also have major impact on the developing countries, which because they follow the educational and practical systems of medicine in the West, are in chaotic sensitivity to both the crisis and its solutions. It is under these conditions that EBM provided a tentative solution, partly valid, to redistribute the intellectual resources via promising efficient, though questionably effective, epidemiological outcomes. This again, could not be realized without an established claim of superior methodologies. It does not mean, though that EBM has been able to escape the constraints of the crisis nor that its methodology is unproblematic, as we will argue below. And, lastly, as the crisis usually reveals multitude of interpretations and practices, EBM show dynamic characteristics that parallels the dynamicity of the post-industrial capitalist societies.

Knowledge/power of EBM complex

However, others still refuse the idea that EBM constitutes a new medical paradigm and consider it to be a discourse, or a “way of knowing”, which lacks philosophical foundation. Mykhalovsky and Weir, at their discretion consider the announcement of EMB as a new paradigm to represent nothing more than “rhetorical enthusiasm”.

* Consider also that both the incorporation of personal clinical expertise and inclusion of qualitative studies by EBM escalate the paradigmatic trait to its paradoxical state.
Perceiving clinical medicine to be in the midst of an epistemological crisis as highlighted in depth by Djulbegovic et al.,† the un-critical borrowing from Kuhn a concept that holds, indeed, a “dismantling”, i.e. negative, implication is but a sign of a new movement that understandably tends to asserts epistemic authoritative position that carries normative power regardless of nature of its promises and manners. ¶ There is however, something interesting in this pattern of development, which is compatible with age of “information” or more definitely, the age of “data”. EBM arose, in part, as a response to practical need for managing the massive amounts of data relevant to medical care. Its approaches of systematic review, guidelines and meta-analysis provide a simple access to complex medical problem, a way to mediate between competing data, interests or claims and a promise of objectivity.

Beside the authoritative position, the dynamic “engulfing” capacity, based on its encompassing mathematical and biostatistical worldview renders EBM a continuously evolving heuristic structure for optimizing clinical practice. This may explain, at least partly, how EBM rapidly gained and retained considerable power to become incorporated into medical curricula worldwide, “colonizing” other fields of practice, such as nursing and public health, and spawning journals, research centers, websites and the like.‡§

The third aspect characterizes EBM condition, is that while EBM calls for critical evaluation of the medical repertoire, it shows, at the same time, the capacity to tolerate its critics from all fronts, whether modern or postmodern, positivist or post-positivist, epistemological or ontological, or traditional or alternative. The most vulgar attack comes from sociologies, epistemologists and ethicists whose skepticism of notions such as truth, certainty, consistency, etc., involves the EBM notion of evidence, as being socially and culturally constructed, relational, gendered, embodied, intersubjective and communal. The most hostile assault on EBM, as mentioned above, is the one introduced by Holmes et al. who assert in provocative polemic that the modern evidence-based healthcare (EBHC) exemplifies fascist characteristics as it ‘... serves to (re)produce the exclusion of certain forms of research’. The ascribed function of ‘(re)production’ the “fascist” EBHC, which fruitlessly resonates Habermas’ conception of “colonization of lifeworld by the instrumental rationality”, is presumed to assure permanent stereotyped mode of functioning (see below). However, the authors fail to consider the essentially pluralistic approach of the EBHC movement. By pluralism it is not meant a mere lazy amalgamation of clichés but an effortful and intelligent mobilization within the whole epistemico-statistical, and hermeneutic strategies legitimized by, though inappropriately, authoritative position aiming, according to Djulbegovic et al. for optimizing clinical practice. Empirical studies by Berg et al. and Timmermans and Angelí move in this direction by suggesting the multiple forms of rationality inherent in guidelines and detail a capacity for flexibility and modification of their parameters.

Dynamicity of assimilation

The development of EBM is characterized by historical uniqueness. Its adaptive capacity to, and efficient “imbibition” of various antagonistic challenges reminds us of the capitalist system, whether in its Fordist, post-Fordist, and/or financial mode. Jürgen Habermas has conceded in his The Theory of Communicative Action that as the advanced capitalist societies have developed, the core integrative function of communication has been increasingly disabled (or “colonized”). In his theory he attempts to describe the conditions that would be adequate to the “ideal speech situation” that might restore the lost legitimacy in the system. In his suggestion that the capitalism is an “unfinished project”, Habermas distances himself from his predecessors of Frankfurt school as much as from the Marxist and neo-Marxist discourses. Several

† Denny also describes some aspects of the crisis in this form: “In an age in which there seem to be few certain signs of advance in the treatment of cancers, arthritis, and AIDS; in which tuberculosis in epidemic proportions is returning to North America; in which antibiotics are losing their potency, and in which iatrogenic suffering and inappropriate medicating are coming under intensifying scrutiny...”.

‡ In a similar vein, Denny argues that EBM should be seen as an ideological resource that the medical profession uses to buttress its authority, primarily by reinforcing the scientific character of medical practice. Of note, such proposed authoritative position/knowledge is realized via several textual techniques, the most prominent of them are guidelines and protocols.

§ This should not be confused with Holmes et al.’s “colonization” which is presumed to be resulting from the all-encompassing post-positivist paradigm that constitutes the philosophical framework of EBM.

* This is not orthogonal to the regulative functions of EBM that underlies its apparent openness to other disciplines and discourses but these functions would be effective under the banner of paradigm.
aspects of Habermas’ theorization might help to disclose what share the two systems, i.e. the capitalist system and EBM project. It is not accidental that emergence of EBM was associated with the escalation of welfare state crisis following a phase of oil prices explosion in the mid of 1970s. There is likely no causative correlation as some suppose, whether between the capitalism and EBM or between the capitalist crisis and medical crisis. However, EBM, as any other professional movement is not, as myths of technocracy admit, isolated from the sociopolitical conditions. Rather, these movements usually simulate the epistemic architecture and social stratum of their environments. What is essential in both the capitalism and EBM is the tremendous capacity to integrate everything they face in their way. It is in this regard that EBM tolerates all kinds of criticism, simply, because one of its strategies is to assimilate (Habermas would like to choose the word ‘colonize’) what is conflictual, contradictory and debatable.†

Addressing the question whether EBM is “unfinished project” a la Habermas’ capitalism or modernity, Or it is a “never finishing” project of medical practices could be relevant to our present discussion. The available signs would prefer the latter suggestion. The world that was predicted 50 years ago to be a global village is now amazed by plentiful of peer-reviewed biomedical journals, which according to recent estimation published 208 articles per hour [source: PubMed]. For a clinician to find an answer or several answers to her/his question, searching through Medline/PubMed would reveal infinite fragmented answers. It is in this “postmodern” world that EBM emerged as a reaction to ameliorate the chaotic flow of data. In consequence, “it would be difficult to envisage how a discourse which seeks to reframe medical authority in late twentieth century capitalist economies could do so successfully without incorporating discourses about the range of potentialities offered by information technologies”. This does not entail that EBM has no problems of its own. Rather, in such all-encompassing capitalism, there is no much free space in which EBM transcends the technocratic myth, or following Max Weber and Jürgen Habermas, the colonizing instrumental rationality.§

In this context, Mykhalovskiy and Weir describe an argument based on political economy that views EBM as part of the rationalization of health services. They acknowledge how “this way of making sense of EBM is informed by a longstanding concern about the growing penetration of health care by market relations”. If this critique was valid, the assimilation techniques of EBM are compatible with socio-political conditions and that its authoritative position is suitable for a style of charismatic’s testimony. Moreover, it can be argued that under conditions of rationalization, disguisedly mediated via textual dualist hermeneutics, EBM has a potentiality for abuse, as will be discussed below.

Potentiality for abuse

Many who support EBM in principle have argued that the movement is now facing a serious crisis. A major problem could be that “the evidence based “quality mark” has been misappropriated and distorted by vested interests”. In particular, the drug and medical devices industries increasingly set the research agenda. However, some internal conditions contribute to the susceptibility of EBM to abuse such as by having the potentiality for bias or, contrary to the claim of “hierarchical” evidence and omnipotent rationality, EBM methodologies remain an approximation. Another argument goes even further: there is no guarantee in EBM to avoid misapplication of statistics, leading to incorrect interpretation of findings.

On the side of pharmaceutical industry, it is obvious that the clinical trials sponsored by it are designed more to find small advantages that

† This would seem incompatible with the rigorous methodologies of EBM. However, the short history of EBM confirms that it is, in fact, more flexible than one may imagine. It has incorporated, and it is still doing, whatever scientific, valuable, ethical, and even pseudo-scientific data. In this regard, Guyatt et al. and Cipriani are just in their statement that EBM model continues to intentionally develop its structure and meaning on an almost monthly basis. We argue that although there might be internal conditions, i.e. from within the discourse of EBM and intra-professional domain, that establish the capacity for incorporativity of different themes, interests and topics, it is in the social construction of the movement that necessitates the conditions of harmonization of the multitude resulting from the isolated proliferation of institutes and their practices (see the main text; cf.).

§ Although the main concern in this article is of international capitalism and globalization, it can never be denied the presence of local historical conditions of the, for example, the Canadian capitalism (see Ref 18).

‡ In this regard, Traynor points to parallelism between the EBM textual discourses and the charismatic style being characteristic of the “capitalism’s appropriation for various commercial projects”. Thus, EBM communicative function, i.e. informative, does not target only the experts and professionals but also the individual patient as consumer “who simply need to be provided with the latest medical and nonmedical information if they are to make the best decisions in the health market.”
can be highlighted in promotional campaigns than to find clinically meaningful effects. As Freedman points out, a researcher in a team noted the fact that drug-company research wasn’t measuring critically important “hard” outcomes for patients, such as survival versus death, and instead tended to measure “softer” outcomes, such as self-reported symptoms (“my chest doesn’t hurt as much today”). Another noted that when drug-company data seemed to show patients’ health improving, the data often failed to show that the drug was responsible, or that the improvement was more than marginal. In a narrative style, writes Ioannidis that influential randomized trials are largely done by and for the benefit of the industry. Meta-analyses and guidelines have become a factory, mostly also serving vested interests and under market pressure the clinical medicine has been transformed to finance-based medicine. Ioannidis suggests that an obsession with winning funding has gone a long way toward weakening the reliability of medical research. So far, it is hard to escape the conclusion that many other new drugs add little to the therapeutic armamentarium except expense and confusion and that many industry-sponsored clinical trials are designed more to find small advantages than to find clinically meaningful effects.

Additional empirical findings revealed an association between for-profit sponsorship and the reporting of positive results in RCTs. Moreover, industry trials are often characterized by the wrong questions with the wrong short-term surrogate outcomes, the wrong analyses, the wrong criteria for success, and the wrong inferences. By this, it is not meant that industry-sponsored research should automatically be placed into the category of questionable or suspect science, but this commercial incentive automatically orient the evidence in a particular direction. The aforementioned positivity is represented by more favorable conclusions as compared to nonindustry-related trials. The possibility of a substandard comparison was highlighted in studies with fluconazole, where for-profit sponsored studies frequently compared this agent given intravenously against the oral, poorly absorbed drug nystatin, thus creating a bias in favor of fluconazole, where for-profit sponsored studies were associated with success rates that are 45–50% higher, relative to publicly sponsored RCTs. In RCTs conducted for evaluating treatments for multiple myeloma, Djulbegovic et al found that 47% of the studies funded by non-profit organizations favored the experimental arm. In contrast, 74% of RCTs supported by industry favored the experimental treatment. On the other hand, there are reports indicating that meta-analyses included authors who were employees of the manufacturer of the assessed drug were 22-fold [2% vs. 44%; P < 0.001] less likely to have negative statements about

Whether having the potentiality for bias and other caveats what allows pharmaceutical industry complex to abuse effectively EBM or there is something outside the EBM, i.e. in the nature of the developed countries economy (financial as well as professional capitals), that preconditions abusability of EBM methodologies, is an urgent issue. This is an important question as postmodernists wonder how “paradigm shift” occurs when the motivation for research is biased, not towards “best evidence”, but rather to that which would guarantee high-profile publication or sufficient pharmaceutical sales.

However, comparative studies reveal that the abusers apply the same EBM methodology that is used by the users. For instance, research based on analyses of publicly sponsored RCTs indicate that about 25–50% of all new cancer treatments tested in RCTs are successful. In comparison, industry-sponsored trials were associated with success rates that are 45–50% higher, relative to publicly sponsored RCTs. In RCTs conducted for evaluating treatments for multiple myeloma, Djulbegovic et al found that 47% of the studies funded by non-profit organizations favored the experimental arm. In contrast, 74% of RCTs supported by industry favored the experimental treatment. On the other hand, there are reports indicating that meta-analyses included authors who were employees of the manufacturer of the assessed drug were 22-fold [2% vs. 44%; P < 0.001] less likely to have negative statements about
Commentary notes on EBM and the developing countries

As the individual is impossibly represented in the averaged data, the major critique against EBM is extrapolating the research results, derived from collective population, to individual level. The problem becomes more difficult when it is conceived that the trials tend to reflect the priorities of developed countries rather than the global disease burden. Swingler et al., for example, analyzed nearly 3000 reviews from the Cochrane database of systematic reviews and the Database of Abstracts of Reviews of Effects (DARE) and assessed the correlation between the number of reviews and burden of disease. They found that only few systematic reviews focus on diseases and on aspects of health care affecting large numbers of the world’s population. These findings reveal a difficulty of generalizing applicability on developing-world patients who “may have patho-physiological differences in response to treatment, often present late, have co-morbidities (i.e. malnourishment, anemia, malaria), may be unable or unwilling to adhere with treatment, have cultural, behavioral and attitudinal differences, and poor facilities and resources influence treatment effectiveness”.

Besides the applicability problem, the developing countries lack the resources required for practicing EBM. Dans and Dans discuss in details the case in Philippines as an example of a developing country. They state that in many developing countries, the bulk of healthcare expenditures continue to be shouldered by individual patients or their families. Thus, nothing could be more appalling than a physician orders unnecessary tests or prescribing inappropriate treatments for indigent patients. For example, throughout the Philippines, resting electrocardiograms (ECGs) are routinely done in asymptomatic patients to screen for coronary artery disease (CAD). The test costs approximately US$5, enough to provide three full meals for a family of five. A careful appraisal of the evidence would have revealed to practitioners that resting ECGs are virtually useless as a screening instrument for CAD. Furthermore, because of limited resources, departments of health often falter in their role as regulators of the pharmaceutical industry. Approval of a drug for marketing becomes so easy that drugstores are flooded with myriad products, often listed for questionable indications. In the Philippines and in many other developing countries, drug companies invest heavily in continuing medical education (CME). Many medical societies and academic institutions are so poor that “scientific meetings” would not be possible without the support of industry. On the surface, this relation may seem innocent. In reality, however, this situation has given the pharmaceutical industry nearly total control of the direction and content of the scientific sessions and has dulled the distinction between CME and drug promotion.

Conclusion

We attempted a critical sociopolitical analysis of the historical context for emergence of EBM under the banner of paradigm. In this limited review of the literature, we find neither those celebrating EBM nor those who criticize it from within or from sociological, cultural, epistemological or historical perspective mention to the implications of attributing the movement a paradigmatic characteristic. In consequence, the underlying mechanisms for EBM abuse by pharmaceutical industry has been explained to be due to the tendency of the industry to increase their profits under the banner of EBM, armed with rigorous methodologies, but accounts also to a necessary legitimizing arc that would function well under the banner of paradigm. Even beyond the abuse issues, critics who targeted the control and power functions of EBM via achieving “totalizing” discourse, through penetrating attempts to create norms for the consciousness and moral identity (conscience) of the clinician, and through the providing of an explicit identity for the medical profession (or groups within it) in the face of ‘threats’ from without.” miss what is central for these practices and what guarantees their realization. It is argued in the current paper that the claim of paradigm serves efficiently such functions.

†† Giannakakis and Ioannidis describe how pharmaceutical companies, via conferences, cater to the material needs of doctors from the developing world. The main short-term outcome measures are travel, pleasure, amusement, and gifts to subvert, divert, and influence medical practice whereas the long-term outcomes are the market share of specific companies. The authors conclude: “Eat, drink, be merry, and boost prescriptions” [italic added].
 Although this paper meets many proposals provided by Denny, there are several divergent notions. For example, it is hard to agree with Denny’s suggestion that what protects EBM against any counter argumentation lies in the “ring of obviousness” of evidence as formulized by EBM. This insinuates that evidence as formulated by EBM provides protective capacity against its critics. However, critiques of evidence expose the vulnerability of evidence and the real practical EBM as a whole, confirming how the movement born fragile to the degree it inhabits its counter arguments as a best way for survival. Neither assimilation nor evidentiality nor methodological rigor can provide legitimized power if the project were not armed with a paradigmatic form of discursiveness. Denny believes also that the construction of a universalized medical authority is derived from a situated medical epistemology. However, it is described above that neither the methodology nor epistemology of the project are sufficient to attain authoritative position. It is in this regard that Denny acts, though implicitly to decode the implication of paradigm on the procedural logic of EBM by stating that “the authority of the (fallible) individual physician is bolstered through the reassertion of science as a regulating regime”. He goes further with an excellent insight affirming that EBM in fact establishes systematic authoritative position (implicitly, via its paradigmatic position). He thinks, “although the discourse of EBM appears to question the individual authority of medical doctors, it actually reinforces such authority by regulating the conditions under which a physician may speak authoritatively about health and illness.”. On the other hand, it is via the paradigmatic characterization EBM engages in reasserting its hegemony in the face of a variety of challenges, and at the same time, assimilates as much as possible the sources of such challenges. Rehearsing Berg in this regard, the project is not against the professional authority per se but it acts to replace the old one that is compatible with the emerging methodologies and biostatistics. We assert that characterization of EBM as paradigm does not reflect a canonical nature of the movement but gives it legitimized professional and extraprofessional (e.g. patient) power. Whether abuse in medical and biomedical disciplines is intentional or not, it is a widespread phenomenon, and it has major impact on society and individual when EBM is implicated. It can be argued here that the articulation of EBM as paradigm (which has never happened before in medical discourses) provides rich environment for abuse beyond, according to Booth et al., the P value associated with the result. And, as described above, it is the convergence of the presumed paradigmatic “nature” of EBM and external societal factors (e.g. financial power) that renders EBM susceptible for corruption and this state will continue, even more severely in the developing world (simply because it is “good” marked for importing any new commodity), unless the disguising power of EBM is dismantled via humanist and medical critiques.

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**Abbreviation list:** Evidence-based medicine (EBM), Evidence-based practice (EBP), Randomized control trials (RCT)

**Conflict of interest:** Author has nothing to declare.

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