COMMENTARY


Suzana A. Silva MD MSc1 and Peter C. Wyer MD2

1Coordinator of Clinical Research, The Teaching and Research Center of Pro-Cardiaco/PROcep, Rio de Janeiro, Brazil
2Associate Clinical Professor of Medicine, College of Physicians and Surgeons, Columbia University Medical Center, New York, NY, USA

doi:10.1111/j.1365-2753.2009.01324.x

Introduction

Evidence-based medicine (EBM) burst on the scene in 1992 [1] as a challenging, innovative and ultimately enigmatic newcomer to the stage of clinical medicine. Its challenge to blind obeisance to authority and its systematic approach to the problems posed by the rapidly expanding terrain of medical knowledge ranked high on the list of EBM’s compelling features. A critical historical review, and companion piece to this exposition and commentary [2], concluded that EBM contributed tools and resources of unprecedented importance to the practice of clinical medicine in the Age of Information, but fell short of its initially bold claims to define a comprehensive and revolutionary practice model, despite several published attempts to elaborate it.

Challenges to EBM on epistemological and philosophical grounds have constituted a prominent aspect of criticisms of EBM since the 1992 proclamation. However, with few exceptions [3], responses to criticisms from the EBM camp have been confined to methodological issues pertaining to clinical research designs and to general goals and objectives [4]. Djulbegovic et al.’s [5] recent contribution constitutes the first attempt from within EBM to respond systematically to the published epistemological and philosophical challenges and, for this reason alone, deserves attention. However, our commentary is motivated not only by the historical importance of their submission. Rather we perceive clinical medicine to be in the midst of an epistemological crisis and the issues to which Djulbegovic et al. appear to be responding to be centrally related to this crisis.

The stated objective of EBM has been to close the gap between research and clinical practice [6]. However, such an endeavour begs the question of what constitutes the nature of that gap, that is, the proper role of research in determining or informing clinical action. As pointed out by Tonelli [6], this in turn constitutes an epistemological question insofar as it implies, following Djulbegovic, a ‘propose(d) specific relationship between theory, evidence, and knowledge’. It defines the need for a more rigorous delineation and understanding of the scientific foundations of clinical practice.

As stated by Tonelli, EBM represents a school of medical epistemology [6]. Epistemology deals with the theory of knowledge and is concerned not just with the nature but also with the limitations of knowledge. Hence, to discuss EBM within an epistemological framework we must address not only its accomplishments but also its main limitations. Epistemology deals with questions such as ‘What is knowledge?’, ‘How do we know what we know?’, ‘How is knowledge acquired?’ and ‘How does knowledge lead to wise and just action?’ Among these, the latter, corresponding to the realm of ‘practical wisdom’ or ‘phronesis’ in classical Aristotelian terms, appears most salient to the issue at hand. Thus, the need to address these matters in the framework of relevant concepts of science and scientific knowledge defines the need for a ‘clinical epistemology.’ [7] We find the paper by Djulbegovic to be a convenient and timely pretext for clarifying these issues in some depth.

Commentary

Djulbegovic et al. have composed a review of epistemological and philosophical issues related to the EBM movement in the form of an apologia and advocacy piece supporting that tendency. With respect to the issues it addresses, it is avowedly a ‘response to EBM critics’. In their survey of the epistemological issues and inquiries pertinent to EBM, the authors touch upon themes including the definitions and roles of evidence, the relationships between knowledge, truth and belief, models of scientific inference, and the relationship between EBM and various philosophical currents and tendencies of the last century.

Most pertinent to the epistemological issues that they set out to address are those that they largely ignore. We are surprised by these omissions in that they comprise the sentinel epistemological and philosophical concepts and challenges that have been discussed and debated in the relevant literature since EBM’s 1992 christening. Much of our commentary upon Djulbegovic et al.’s review will necessarily be directed at identifying and putting into perspective these neglected issues.

As a prelude to our detailed discussion, and echoing our preliminary comments we assert that, contrary to Djulbegovic et al. the issue posed by EBM is not the ‘relationship between theory, evidence and knowledge’ but rather the relationship between theory and practice, which means the relationship between ‘what
we know’ (knowledge) and ‘what we do with what we know’ (wisdom). We see this challenge as encapsulating the entirety of our commentary and exposition.

From the outset of Djulbegovic et al.’s discussion, there is ambiguity of intended focus. Their explicit point of departure is the 1992 proclamation of EBM as a new paradigm for clinical practice [1]. This article, which triggered the debate and discussion that followed, was explicitly and exclusively directed at the context of clinical care of individual patients, and the teaching of relevant skills and criteria to clinical learners. Surprisingly, Djulbegovic et al. adopt a definition of EBM that embraces all areas of health care:

- a set of principles and methods to ensure that, to the greatest extent possible, population-based policies and individual decisions are consistent with evidence of effectiveness and benefits.

Evidence, in turn, is defined as ‘that which justifies belief’.

This broad definition, encompassing as it does all evidence in relationship to all domains and venues of health care, including public health policy, is at variance with the definition implied in the above-cited 1992 epistle, the stated focus of their discourse and with the more explicit definitions that followed [8]. It also is, to our knowledge, entirely original. Specifically, it serves to blur the boundaries between two dimensions of EBM that are distinct and have remained so in the literature, namely evidence-based guidelines and evidence-based individualized care [9]. The former predates the 1992 article and pertains to the use of evidence from clinical research to inform health care recommendations for populations. The latter, initiated with the 1992 proclamation [1], asserts that these same classes of research be used as the basis of health care decisions for individual patients in the setting of traditional clinical practice. It was this assertion, and the bill of particulars that accompanied it, that was received as a provocation in many quarters and which triggered the epistemological debates that Djulbegovic et al. purport to address.

Djulbegovic et al.’s uniquely general definition of EBM, which they assign without comment to a glossary of terms at the end of the article, is in keeping with the over-generalized and abstract tenor of their discussion. It provides them license to avoid immersion in the heart and substance of the epistemological and philosophical issues that have emerged since the 1992 article, even as they allude to and cite some of the salient literature. To help remedy these omissions and to explore what we perceive to be a healthy and critically important debate, we will pick up some of the threads and pieces left behind by Djulbegovic et al. in the reconstruction that follows.

**The radical restructuring**

The most important thread mentioned but not followed to its ends and branches by Djulbegovic et al. is stated near the beginning:

- Critics of EBM commonly attack its epistemological credentials . . . (by) alleging that EBM is (or presents itself as) a radical restructuring of medical knowledge that discredits more traditional ways of knowing in medicine . . .

Djulbegovic et al. do not directly elaborate or address this ‘restructuring’, nor do they systematically discuss its implications. The 1992 article proclaimed at its very outset:

A NEW paradigm for medical practice is emerging. Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiological rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. [1]

Although a specific ordering among these three potential criteria for electing clinical actions and decisions for individual patients was not explicitly proposed in the 1992 article, it soon appeared in the form of hierarchical tables of evidence pertaining to decisions, sometimes in connection with practice guidelines [10], and at other times in connection with evidence-based individualized care [11,12]. A conceptual representation of this hierarchical ‘restructuring’ is included in Fig. 1a. Clinical evidence now resides at the top of a pyramidal representation, followed by pathophysiological reasoning and an ambiguously worded category at the very bottom, variously labelled ‘expert opinion’ [9], ‘clinical experience’ [1] or ‘unsystematic observations’ [11,12]. These categories were relatively undefined and elaborated in the pilot article, and readers, including academics and clinicians, were left to their own devices to interpret the implications of the proposed new model.

Responses came fast and furious. Clinicians and their academic advocates interpreted the pronouncement as a frontal assault on the central framework of individualized care, the expertise of the experienced clinician [13]. Sensing that the pilot article had
What is the ‘evidence’ in ‘evidence-based medicine’ evidence of?

Djulbegovic et al. discuss the term ‘evidence’ from a variety of perspectives relative to matters of scientific knowledge and inference. We again find this surprising in that, if there is one aspect of EBM and the literature of debate surrounding it that is clear and unambiguous, it is that the ‘evidence’ in ‘evidence-based medicine’ refers, centrally and primarily, to the results of clinical research, filtered for relevance to a clinical problem and assessed for susceptibility to bias and potential clinical importance for practice. It is unequivocally the interjection of clinical research evidence and an assertion of its role in routine care and decision making that has caused the conceptual ripples and resulting controversy.

And what is that evidence, evidence ‘of’? It is evidence of average effects of both medical treatments and harmful exposures as well as of the average frequency of diagnostic and clinical outcomes in defined populations of study subjects. Such evidence uniformly takes the form of a point estimate, i.e. the actually observed value of a population mean, and a confidence interval around that value. Djulbegovic et al. identify such data as generated through ‘deduction’ or ‘theory driven approach’ anchored in post-positivism. They also suggest that meta-analyses are ‘inferences to best explanation’ of reality (‘explanationism’ or ‘holism’), that is, a higher level of inference akin to pragmaticism and therefore closer to application of knowledge to practice. We find this suggestion unconvincing. Systematic reviews of sufficiently similar studies only allow their cumulative results to be represented in a similar, and generally more precise, form and thus do not change their inherent nature. The relevant direct inferences regarding such results pertain to the believability of those estimates as reflective of the ‘true’ population means, that is, the results that would be observed were it possible to enrol all eligible patients in the world in a study of identical design and execution, in a context of potential susceptibility to both systematic and random error.

The EBM literature proposes a hierarchy of possible study designs that reflects greater and lesser degrees of susceptibility to systematic error as well as reasonable criteria for assessing such susceptibility within a single study or review as reported [11,12,15]. Within this limited framework of inquiry, i.e. observations of estimates of population means, there would appear to be little basis for debate regarding the appropriate model of inference and, indeed, the ‘falsificationist’ model of Popper implicitly prevails within the context of clinical research reports, not only by virtue of hypothesis testing and the perennial ‘P-value’, but also the framework of estimation and interpretation of confidence intervals [16]. This applies equally and in the same way to the use of statistical methods to pool similar observations stemming from multiple individual studies, that is, meta-analysis, for purposes of gaining greater precision in the process of estimating the ‘true’ population mean for specific effects and outcomes.

What is the utility of the processed estimates of population effects and outcomes achieved by EBM? Such estimates allow us to determine whether a particular intervention does more harm than good, on average, with respect to a particular clinical outcome. Such information is of clear, and relatively non-controversial, interest to the makers of health policy and practice guidelines for populations. Although controversy and dissent have occasionally emerged regarding the positioning of randomized trials at the top of the hierarchy of evidence for recommendations [17], this aspect of EBM has generated neither the stage nor the actors that characterize the unfolding drama of epistemological debate that Djulbegovic et al. purport to address.

Rather the first epistemological challenge, forced by the 1992 proposal, is how inferences regarding the likely ranges of true average effects and frequencies across study populations can and should impact upon the process of delivering health care to individuals. Average results across populations, under the constrained conditions of clinical research, do not and cannot directly predict the response to an intervention or exposure on the part of an individual patient, nor whether that patient will or will not experience a clinical or diagnostic outcome [6,18]. Nor are such predictions likely to be possible in the foreseeable future [19]. Hence the ‘evidence’ stemming from clinical research, although direct with respect to the task of predicting population effects and outcomes, and perhaps with respect to evaluation of practice patterns of individual or groups of clinicians, is necessarily indirect evidence with respect to the decisions, actions and general clinical care of an individual patient.

For example, the evidence from clinical trials might be brought directly to bear on the process of testing a hypothesis such as ‘does aspirin relieve headaches on average, in a population of migraineurs’? However, it can only be brought indirectly to bear, in the form of probability estimates of the likelihood of benefit, on a hypothesis regarding an individual such as ‘will this medicine cure my headache’ [20]? The issue regarding the role of population-derived evidence in individual care and the epistemological and philosophical issues that arise from it, although discussed abundantly in literature they cite [6], is neither acknowledged nor explored by Djulbegovic et al.

Is evidence from clinical research knowledge and, if so, what is it knowledge of?

Proceeding down the revised hierarchy of medical knowledge proposed by EBM in 1992, we are led to the second tier, labelled ‘pathophysiological reasoning’. The authors of the pilot EBM article conceded that pathophysiological knowledge is necessarily brought to bear on the interpretation of clinical trials, and particularly issues such as the important similarities and differences between study and practice populations. They also stressed that their ‘deemphasis’ upon pathophysiological reasoning was directed at the use of such criteria as surrogates for empirical
demonstration of effectiveness of therapeutic and diagnostic interventions, an assertion supported by both recent trends in medical thinking and empirical evidence [21]. Finally, and usefully, they stated that their intent was to ‘deemphasize’ dogmatism and authority within the framework of medical education and to inject healthy scepticism and critical thinking among medical learners, values to which most subsequent critics and commentators clearly subscribe.

Despite these qualifications, the effect of this aspect of the 1992 hierarchical assertion was to posit a linear relationship between clinical evidence and pathophysiological understanding of disease and disease process. Later attempts to revise the implied model of EBM by placing other sources of criteria on an equal plane with evidence from clinical research with respect to generating clinical decisions for individual patients, and to call for ‘integrating’ such sources [22], did not remedy this implication. Indeed, pathophysiological knowledge in particular and foundational medical knowledge in general [23] no longer played an explicit role in these revised elaborations, even though continuing to appear in the standard hierarchies of ‘evidence’ [12].

The issue raised by the role of pathophysiological knowledge in clinical practice and the understanding of evidence from clinical research is of central importance in an epistemological discussion of EBM. Tonelli provocatively forces this issue in a discussion of the application of orthodox clinical research methods to the evaluation of alternative medical therapies, many of which are based on underlying theories of disease that are irreconcilable with the tenets of orthodox medical science [24]. He points out that the very design of such trials constitutes an epistemic error, necessarily yielding results that, on the one hand are incompatible with any underlying theory of disease and on the other hand fail to constitute adequate and appropriate tests of the alternative therapies themselves.

Tonelli’s argument is framed within a concept of medical knowledge that goes beyond the realm of self-evident observation, that is, beyond the framework of logical positivism. (Strictly speaking, the Vienna circle and the philosophers Alfred Ayer, Ludwig Wittgenstein should be considered ‘neo positivist’, the school of Auguste Comte constituting the original positivist movement of the 18th Century.) Reciprocally, placing observations drawn from clinical research categorically above the domain of underlying theory of disease defines EBM itself as primarily philosophically aligned with positivism. Djulbegovic et al. confirm this alignment, as do other commentators to relevant philosophical discussion [25].

Within the positivist worldview, knowledge and truth reside only in the directly observable and testable, as does any and all theory that would test and inform perceptions of truth. Within such a framework, the truth of any observations stemming from clinical research could only be tested by other direct observations. The hierarchy of study designs might contribute to the process of weighting the influence of specific observations on conclusions regarding knowledge and truth. However, from a positivist perspective, deeper and more complex theoretical constructs, such as those enjoyed by orthodox medical science with respect to disease process in general and to specific diseases such as heart failure in particular, would not be allowed to enter the knowledge equation because they cannot be directly tested through a simple observation.

Tonelli points out that one consequence of adherence to a positivist perspective is that EBM winds up being stranded on a barren beach in which alternative medicine, based on entirely unobservable and unverifiable theories of disease such as Qi, holds equal footing with medical practice based upon theoretical underpinnings such as the discovery of bacterial and viral pathogens, DNA, cell biology and our understanding of the genome and of the pathophysiology of both normal and diseased individuals [24]. He also suggests that failure to recognize coherence between unexpected results of clinical research and underlying theory contributes to the delay in acceptance of recommendations originating from such research on the part of individualized practitioners [24].

To the extent that today’s clinicians and their advocates require ultimate coherence between the empirical findings of clinical research and their understanding of pathophysiology, then, first, a higher level of knowledge than that which can be derived from the population-based observations of clinical research must exist and, second, the information stemming from clinical research can become ‘medical knowledge’ in the unrestricted sense only insofar as it is compatible and integrated with a larger body of theory.

To be sure, theory-relevant observations from clinical research may challenge the premises of such theory and lead to new and revised pathophysiological theories of disease. This very process would be regarded by post-positivists, such as Thomas Kuhn and Imre Lakatos [26], as central to both the definition and development of medicine as a potential science. Relevance and necessity of a theory of disease above and beyond the realm of simple observation constitutes an alternative perspective from that of positivism and might be considered to be a form of scientific fallibilism [27], in which underlying theory of disease is itself subject to revision on the basis of empirical observation.

Perhaps ironically, the 1992 EBM manifesto aligned itself not with positivism, its closest philosophical bedfellow, but with Kuhn, a post-positivist whose theories of scientific revolution are based on the premise of an underlying foundation theory, subject to being overturned by critical shifts in both empirical discoveries and theoretical formulations. The post-positivist philosophical perspective is based on acceptance of the inevitability of values attached to knowledge and to the research that advances it. From such a perspective, the ‘knowledge’ relevant to EBM is not merely the likely truth and precision of estimates of average effect and outcome in study populations of greater or lesser similarity to a clinician’s practice population. Rather such estimates constitute information, and become part of the fabric of knowledge only as they are considered in the light of other relevant empirical observations and filtered through the larger framework of prevailing pathophysiological theory. The resulting knowledge is embroiled by awareness of prognostic implications and by published and experienced ranges of variability of individual patients with respect to issues of therapy, diagnosis, prognosis and harm. This brings us to the threshold of a third tier of interpretation and integration, the primary arena within which the issues forced by the advent of EBM and the epistemological crisis in clinical medicine reside.

What is the knowledge that is enhanced by information from clinical research knowledge for?

If evidence-informed practical and theoretical knowledge of disease is conceded to constitute a higher level of synthesis than
the level of hypothesis verification and empirical observations of averages within artificially defined research populations, it is nonetheless only a stepping stone on the ladder that leads to the domain of clinical knowledge and truth within which decisions are made, actions are taken and individual healing takes place, that is, the context of individualized health care. It is at the threshold of the latter domain that the true nature of the crisis facing clinical practice in our time is revealed, the very concept of knowledge is transformed and the need for a higher order epistemological framework is defined. To understand the nature of this framework, we need to consider not only ‘what is the nature of that which is known?’, but also ‘who is the knower?’

As acknowledged by Djulbegovic et al. and summarized above, the 1992 EBM formulation, in which the overt form of the radical restructuring of medical knowledge was advanced, was later supplanted by published models in which the results of clinical research on populations, consideration of clinical circumstances, and patient values and preferences were placed on an equal plane as sources of information to be drawn on and integrated for the purposes of informing health care decisions for individual patients [28]. Although apparently aimed at soothing the flames of controversy that were triggered by the original proclamation, these models stop short of defining how the needed ‘integration’ is to take place, or how the result is to inform actions and decisions [2,6,21]. Furthermore, despite the concern for ‘incorporating patient values and preferences’ into the formula for clinical decision on the part of the EB M core group [22], the perspective of their prescription remains exclusively that of the practitioner.

We have already identified the dichotomy between population-based estimates of average effects and outcomes and the likely responses and destines of individual patients. Evidence from clinical research in support of the reliability of such estimates, raw or filtered through integration within the fabric of orthodox medical knowledge, can at best reduce uncertainty with respect to such responses and destines. It can never predict them for an individual [6]. Hence, knowledge from this domain, no matter how valid from the perspective of medical science, is indirect and incomplete. Use of such knowledge to ‘prescribe’ decisions and courses of actions to individual patients would effectively render the destiny of an individual subordinate to that of the population around them and would therefore likely fail to escape the now-antiquated paternalistic worldview of Parsons [29].

Tonelli, recognizing this dilemma [30], proposes a casuistic model to achieve the goals of EBM [21]. However, such a model remains confined to the perspective of the practitioner and falls into some of the same conceptual traps as the EBM models he is criticizing [31]. Goldenberg confronts the issue from a different, feminist, perspective and, after recapitulating the arguments regarding the gap between population-based and individually centred decisions and recommendations from this perspective, evokes the potential importance of instruments such as personal illness scripts as alternative sources of evidence bearing on the individualized setting [25].

Malterud, following a train of inquiry that began with personal experiences at the dawn of her career as a family practitioner, articulates the fundamental incompatibility between the existing framework of quantitative medical knowledge and the domain of individualized care and calls for the development of a new discipline to be christened ‘clinical epistemology’ [7]. Such an epistemology would necessarily define criteria relevant to knowledge generated from the patient–practitioner encounter, incorporate the narrative content of patients’ stories and would relate to the classical concepts of phronesis, that is, the wise and ethical use of knowledge for good. Her perspective incorporates the post-modern ideal of objectivity without the value neutrality of the positivists.

Malterud’s argument leads in a direction that advances beyond the encapsulated perspective of the practitioner and towards an epistemological domain characterized by the clinical interaction as the primary unit of knowledge, purposeful action and decision. Are there epistemological and philosophical currents that conform to such a construct? The primacy of the ‘other’ within the writings of the French philosopher and ethicist Emmanuel Levinas address such a concept on the level of metaphysics [32]. The theories of other constructivists such as Humberto Maturana are also relevant. On an empirically based level, we are particularly drawn to the educational theories of Paolo Freire [33,34]. According to Freire,

Knowledge is not extended from those who consider that they know to those who consider that they do not know. Knowledge is built up in the relations between human beings and the world, relations of transformation, and perfects itself in the critical problematization of these relations [35]. Freire’s ‘problematization’, by which he means actively and mutually constructed knowledge for ethical action, comes very close to the notion of knowledge appropriate to address actual clinical practice in medicine. Indeed, the concept of ‘constructed preferences’ has begun to creep into discussions of the patient–practitioner relationship [36]. Within this framework, the values, preferences and tacit knowledge [37] of at least two parties, one of whom is a health care professional, come into play, and to different degrees of dominance and awareness depending on the governing relational mode at any particular moment.

For the clinician, such tacit knowledge encompasses the latent backdrop of medical scientific knowledge through which all information from clinical research is necessarily filtered [38], together with her accumulated digested experience of relationships and inter-relationships with patients, their families and with other members of the health care environment. For the patient, it includes previous experiences of disease, both on the part of self and others, including relations with physicians and other health care providers. It is within this framework that knowledge based on information from clinical research is interpreted and lent meaning, not just by a practitioner ‘translating’ it to her patient, but mutually, based on the patient’s tacit knowledge, active concerns and the constructed values and priorities that emerge from the relationship [39].

Is the relational domain, within which medical knowledge informed by the results of clinical research becomes transformed into the scientific warrants for clinical action and decision, observable, and can it become a proper subject for scientific study? Exponents of narrative medicine describe techniques that allow an individual practitioner to study their own experiences of interaction and interpretation with individual patients through the use of independent witnesses [39]. An elaborate model and protocol for observation and measurement of clinical shared decision making has recently been published [40]. These and other efforts demonstrate a widening recognition that this domain of clinical medicine

© 2009 The Authors. Journal compilation © 2009 Blackwell Publishing Ltd
calls for scientific and objective inquiry, its own framework of epistemology [7] and a combination of quantitative and qualitative research methods [25].

Returning to Djulbegovic et al., although they allude to the limitations of inferences drawn from group observations and cite some of the literature that challenges the notion that such inferences are directly relevant to individualized care, they again stop short of acknowledging or discussing those epistemological challenges. After conceding that ‘the biggest challenge to EBM continues to be ensuring that decisions are consistent with patient values and preferences’ they propose that ‘the theoretical development that should inform further development of EBM should come from the field of decision sciences’, citing references that pertain to the use of statistical modelling techniques to incorporate patient values in the form of utilities. In asserting this, they overlook that such analyses take place ‘downstream’ of the process of defining, that is, ‘constructing’ clinical problems on an individualized level [25].

Djulbegovic et al. end with the statement that ‘(EBM) has become a coherent . . . theory of practice’, implying that they consider the relationship of group inferences to individual care to be self-evident. This assertion not only ignores the content of most of the published epistemological debate on EBM but also flies in the face of their above-cited definition of EBM, insofar as it relates to individualized care. Patient values and preferences, as well as the tacit and constructed dimensions of individualized care, may frequently overpower indirectly relevant inferences drawn from estimates of average effect and outcome in populations. Hence any individual decision may be ‘consistent with evidence of effectiveness and benefits (in groups of people)’, rendering meaningless Djulbegovic et al.’s stated criterion for ‘EBM’!

Exposition: bringing coherence to the hierarchy of epistemologies

Djulbegovic et al. address a multiplicity of philosophical currents, epistemological outlooks and theories of science in the course of their discussion. In the absence of a clear delineation of the actual epistemological issues raised by clinical practice in the Information Age [2], and particularly by the ‘radical restructuring of medical knowledge’ proposed by EBM in 1992 [1], their discussion is ultimately abstract. Indeed at one point they imply that the follower of EBM can simply choose the philosophical current or model of scientific inference that suits the moment, and not be troubled by deeper longings for coherence and consistency in the relevant framework of knowledge!

Ultimately, Djulbegovic et al.’s eclecticism constitutes an abandonment of their originally stated mission, which was to elaborate how, ‘because EBM proposes a specific relationship between theory, evidence and knowledge, the theoretical basis of EBM can be understood as an epistemological system’.

Is there a way of coherently representing the relationship of the different philosophical currents relevant to the various epistemological issues raised by EBM? We have seen that the contradictions and inconsistencies within the model of EBM proposed in 1992 arose from the implications of the ‘radical restructuring of medical knowledge’. This restructuring is qualitatively represented in the upper triangle, Fig. 1a. It asserted the domain of evidence from clinical research as dominant over evidence from basic science and clinical expertise respectively. We take the middle level to represent the equivalent of pathophysiological knowledge and foundational medical science and the lower level to reflect the domain we now refer to as the relational, interpretive, ‘constructivist’ domain within which individualized care unfolds. This construction does not necessarily reflect the actual intent of the authors of the 1992 announcement of EBM but rather its implications given the implied content of the component categories as well as the interpretation that would understandably ensue, given the avowedly radical nature of the 1992 pronouncement.

The lower portion, Fig. 1b, reflects the epistemological hierarchy that we perceive to have emerged from the combination of an historical review of the origins of EBM [2] and our reconstruction of the relevant epistemological issues. Within this framework, the upper level corresponds to the domain within which constructed clinical actions, decisions and healing take place. It constitutes the dominant realm of ‘wisdom’ and subsumes the two lower levels. The latter correspond, respectively, to biomedical ‘knowledge’ and theory, and to ‘information’ drawn from clinical research on groups. The proper epistemology of clinical practice in the era of clinical research therefore encompasses an interpretive interface between two independent domains of knowledge, that generated by the biomedical model and that defined by a constructivist, interpretive framework. Because the interpretive framework subsumes clinical action and decision, it necessarily dominates the entire hierarchical framework and subsumes a range of philosophical and epistemological paradigms. Relevant philosophical movements have been noted within the levels of the lower, inverted, pyramid of Fig. 1b.

Figure 2 supplements Fig. 1b by representing in a general form the philosophical trends that correspond to the hierarchical levels as an historical chronology. The 18th and 19th century empiricism, based on observation alone with minimal criteria for method, yielded to the more rigorous, method-driven orientation known as ‘verificationism’, within which observations at the expense of concern for deeper theory (neo-positivism) were succeeded by a resurgent concern for theory in the post-positivist movement. The latter was followed in turn by ‘pragmatist’ concerns for integration of knowledge with action, and finally by tendencies in the direction of socially centred and mutualized models of knowledge for practice, or ‘constructivism’. If we understand the three hierarchical levels of medical knowledge represented in Fig. 1b as ascending levels of integration from an epistemological standpoint, then the succession of philosophical trends portrayed in Fig. 2 can be understood as broadly representing the same hierarchy as an historical development.

Conclusion

We have attempted to elucidate the epistemological issues relevant to EBM and the debates regarding it that ensued following the pilot 1992 EBM announcement [1]. Drawing on the results of our historical review of the origins of EBM within the information literacy movement of the 1970s and 1980s [2], we conclude that the content of the debates reflects an emerging epistemological crisis facing individualized health care in the Information Age and, more specifically, the age of clinical research. We perceive the EBM movement to have usefully unmasked the content of this crisis but
not to have created it. Facilitated by EBM, the information explosion has interjected awareness and rules for prioritization of emerging information from clinical research. At the same time, as a result of the even broader expansion of medical knowledge on the level of basic science and the recognition of new diseases and new criteria for defining disease, still only a fraction of practical issues pertaining to clinical care are addressed through clinical research. The resulting collision of expanding universes of information has generated unprecedented complexity within clinical research. The resulting collision of expanding universes of information has generated unprecedented complexity within clinical practice, both in its nature and in its inter-relationships [41]. The practice of medicine today has therefore itself become an epistemological challenge, and one from which there can be no turning back.

Substantiating the thesis that EBM is properly seen as an accelerant, but not a cause, of the evolving crisis is the fact that one of the most sophisticated advocates for a new, ‘clinical’, epistemology, framed her call from a standpoint entirely independent of the EBM movement [6]. The task of such an undertaking will be to define reproducible and teachable criteria for integration of hierarchies of knowledge and information into effective clinical action. Most importantly, these criteria should help practitioners not only to harness the information obtained from population-based investigations for purposes of enhancing decision making for individual patients, but also to deliver the highest quality of individualized care in the absence of such information.

References