Evidence-based medicine: requiescat in pace?

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Introduction

Over the last 15 academic volumes of publication of the Journal of Evaluation in Clinical Practice (JECP), the Editor, with an extensive number of colleagues internationally, has called continuously for the advocates of evidence-based medicine (EBM) to answer their critics in an open, intellectually rigorous and collegiate manner [1–14]. Now, some of the leading protagonists of EBM – Benjamin Djulbegovic, Gordon Guyatt and Richard Ashcroft – have risen, finally, to that challenge [15]. Or have they? In recalling one phrase: ‘all comes to ye who waits’, I am reminded immediately of another: ‘half a loaf is better than none’. Why? Because in finally addressing many of the substantive criticisms of the theoretical foundations and practical applicability of EBM, the authors present at best an incomplete thesis and in the process miss a valuable opportunity to contribute to the intellectual resolution of the ongoing arguments, something which is their duty to engage in as scholars [16].

The JECP has long considered EBM and its advocates to be both unscientific and antiscientific. Unscientific because they have based their thesis on assumptions rather than on a proven hypothesis that EBM can improve both the process and outcome of clinical intervention, relying preferentially on seductive rhetoric and misleading nomenclature in the advancement of their attempts to secure for EBM a position of absolute reference for competency in medical practice [17,18]. Antiscientific because EBM has promoted its own top-down approach to the identification of knowledge for practice based on aberrant methodological premises known as ‘rules of evidence’ and has consistently and determinedly avoided an active participation in the democratic, consensus building, ‘bottom-up’ processes of science. Within these contexts, EBM has typically demonstrated one of the most hubristic and authoritarian stances seen in Medicine in recent centuries and one of the most magisterial disdains of criticism that have even been seen in clinical science [18,19]. The immediately controversial nature of the EBM thesis, with its talk of the ‘radical restructuring of medical knowledge’, ‘paradigm shifts’ [20] and its attempts to distinguish ‘active, evidence-based clinicians’ from ‘passive, opinion-based spectators of clinical practice’ [21] (see Miles and Loughlin [13] and Wyer and da Silva [22] for a useful recent overview and review, respectively), resulted in a visceral reaction of the international medical community that has, over time, forced one concession from EBM after another, so that the serial reconstitutions of EBM have left the foundational claims of EBM in conceptual and methodological ruins.

During the last few years, there have been a number of insipid and sporadic attempts by the EBM community to concede the presence of defects in the concept and methods of their thesis. These have ranged from the difficulties even EBM advocates have experienced in implementing EBM practices [23] and the difficulties EBM has had in integrating patients’ values and preferences with ‘the evidence’ [24], factors which resulted in the inevitable acknowledgement by EBM leaders that ‘EBM has limitations and further innovation is required to resolve some of these’ (italicization mine) [23,25–27]. Add to these observations, the vacuity of theses such as those advanced by Jenicek [28–30] and we see a shocking picture of how, following the synthesis of the brand name ‘EBM’, a systematic attempt was made to revolutionize the whole nature of medical practice in the absence of a soundly worked out theoretical base and without any form of general acceptance of EBM principles by the international medical community. There are two words that can be added together to describe such actions in the Academy and they are: ‘highly’ and ‘irresponsible’.

But let us give Djulbegovic et al. their due since, until now, no one within the EBM community has come remotely close to conceding the need to conduct a detailed examination of the fundamental objections to EBM that have been consistently documented within the global medical literature. Indeed, the paper by Djulbegovic et al. clearly represents the first substantive response of EBM to its critics, as many of the core criticisms that the authors address are precisely those that have been levied against EBM in a sustained manner since its inception. Substantive, most certainly. And definitive, too, as Djulbegovic et al.’s paper is not a simple viewpoint piece outlining the personal opinions of three isolated academics. On the contrary, we may safely assume that the paper accords with the views of an extensive number of EBM enthusiasts internationally, as at its conclusion the authors confirm that ‘the content of the paper has been shaped by the ideas of people around the world who have freely exchanged their thoughts in contribution to the EBM debate’. Having canvassed and assimilated such views, the paper was then approved by the core leadership of EBM – Gordon Guyatt’s co-authorship certainly confirms that much. We may therefore regard the paper by Djulbegovic et al. as having been written and presented in the manner of a ‘position paper’, strategically conceived and delivered for publication not in the JECP (which has led the international EBM debate for the last 15 years and which could therefore have been objectively considered the most appropriate forum for publication), but, curiously, within the pages of Cancer Control, a learned journal certainly, but one with only a tangential historical interest in medical epistemology,
an observation made even more interesting by the absence within the paper of any really substantive reference to oncology. What motivated the choice of this particular periodical for a paper of this type? These things apart, let us turn, now, to the content and characteristics of the paper itself and to an analysis of the significance of this work to the international EBM debate.

Not an inquiry, but an apologia
Djulbegovic et al. frame their paper as an inquiry. It is, in fact, nothing of the sort. It is an apologia, although substantially more sophisticated than previous attempts by major figures within the EBM leadership to vindicate their creation at the particular times of writing [31]. Indeed, rather than set out a full list of the claims of EBM as have been made historically and as exist in the latest EBM model, the authors are preferentially content to reassert the basic premises of EBM, having found in their view a number of positions in the philosophy of science which could usefully be employed to defend them. While seeking for an intellectual justification to defend a position that has already been articulated many years previously without one is an approach not unknown within intellectual history [32] (Michael Loughlin, personal communication), in the case of the present paper by Djulbegovic et al. such a strategy appears immediately cynical and in the manner of an attempt at the retrospective validation of EBM in order to provide a mechanism to allow a continued advocacy of the central EBM dogmas.

Are the criticisms of the theoretical foundations of EBM (or lack of them) unjust?
Djulbegovic et al. view as unfair the criticisms of EBM that have been levied at its theoretical foundation (or lack, thereof), complaining that these observations have been misplaced, given that they could be levied at any scientific theory or methodology. On first reading, this objection in their paper appears compelling, but certainly not so on reflection when it is remembered that the epistemic assumptions of EBM have been highly specific in their nature and where refutations advanced over almost two decades have been met, until now, with essential silence from the EBM community. The criticisms of EBM have therefore not been unfair – what has been more than unfair, indeed, extraordinary, is the willful refusal by the EBM community to engage in the associated debates in order to answer their critics. Why have they taken 17 years to complain that rejections of their primary and ongoing theses are unfair? Would not ‘fairness’ in this context have been properly evaluated, justified or rejected through continuous scholarly exchange? Of course, it would have been. Any ‘unfairness’ has been on the part of the ‘EBMers’ and not on the part of their critics. To complain in retrospect, when they are directly responsible for the retrospection now necessary, is disingenuous in the extreme.

Did a general dissatisfaction with medicine necessitate and lead to the emergence of the EBM movement?
Djulbegovic et al. claim that EBM evolved out of ‘an increasing dissatisfaction with the practice of medicine’. But whose dissatisfaction? Certainly, a body of academic clinicians, remote from routine clinical practice with scientific proclivities and originating in McMaster University Canada widely advertised their increasing dissatisfaction, yes. But to generalize their own dissatisfaction and personal anxieties into an ‘increasing dissatisfaction with the practice of medicine’, as if this had been in any way incrementally evolving globally and as if it had been consistently expressed at the level of national and international medical conferences and to claim that, prior to EBM, the practice of medicine had been based ‘almost exclusively on the subjective opinion of experts’ is little short of a gross misrepresentation and an explicit revisionism of recent medical history. How is it that the authors thought they could ‘get away with’ such a claim? Do they imagine that if they repeat it frequently enough it will become, magically, true?

Paradigm
Djulbegovic et al. do not make clear in any unequivocal sense whether they believe that the advent of EBM represents a paradigm shift or not. The conclusion of their Abstract appears to indicate that they do not believe that the advent of EBM has represented a paradigm shift at all: ‘. . . EBM should not be construed as a new scientific or philosophical system that changes the nature of medicine or our understanding thereof’. But later, in the section of their paper on ‘EBM as a socially constructed phenomenon’ which follows, they tentatively argue that the advent of EBM nevertheless might represent a paradigm shift, but not in the sense understood and described by Kuhn. This is notable, and extraordinary, because EBM originally claimed to represent a paradigm shift with explicit reference to Kuhn’s The Structure of Scientific Revolutions [33] and has continued to maintain that reference ever since. Djulbegovic et al. attempt to rationalize this position through an appeal to post-Kuhnian arguments in the sociology of science and in order to achieve the necessary flexibility to describe EBM as indeed representing a paradigm shift probably, if EBM is viewed as: ‘a socially constructed phenomenon in terms of Kuhn’s (new) scientific paradigm . . .’. But their attempt is unsuccessful. Note here, the authors’ interruption of ‘Kuhn’s scientific paradigm’ with the parenthetically enclosed ‘new’. So the authors’ arguments in this section are almost semantic rather than intellectual and also transparently tactical in the sense that they have elected to be sufficiently non-committal to be able to claim subsequently that they actually meant ‘A’ or ‘B’ rather than ‘C’, when the whole notion of any form of paradigm shift as having occurred eventually collapses – and that collapse will occur definitively very shortly as the detailed epistemological inquiry that they themselves have failed to conduct progresses at the hands of others.

The relationship between theory, evidence and knowledge versus knowledge and action in clinical practice
Djulbegovic et al. needlessly complicate matters by mistakenly setting out to consider ‘the relationship between theory, evidence and knowledge’. They would far more usefully have confined themselves to an issue entirely more pertinent to the EBM debate: the specific relationship between knowledge and action in clinical practice [12]. But quite what do Djulbegovic et al. understand by
medical knowledge? And how do they understand it specifically in relation to ‘evidence’ as held by EBM? To answer this question, let us turn now, firstly, to their entirely new definition of EBM. This definition of EBM, set out in the authors’ paper for the first time, describes EBM as: ‘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’. This revised definition, the latest of many [20,34] and one eminently preferable in the interests of clarity and analysis to the definition of EBM as ‘Certain Types of High Quality and Clinically Relevant Evidence from Health Care Research in Support of Health Care Decision Making-based Medicine’ (CTHQCREHCRSHCDM-BM) (!) suggested by Brian Haynes [27], appears to be designed specifically to unify two previously separate areas of study within the EBM movement. I refer here to the evidence-based clinical practice guidelines development activities of EBM [35] and to the more recent concept of evidence-based individualized care [36]. Its enormously vague character, coupled with the authors’ neglect to attend to the full explanation that should always accompany the promulgation of a definition de novo as a matter of good scholarly practice, begs several questions, not least what the authors mean by ‘evidence’ in the way in which they use it within this startlingly new and significant definition.

‘Evidence’

The E in EBM has always been equated by the advocates of EBM with the results of empirical clinical research or, to be more specific, the results of that percentage of empirical clinical research that has been conducted and interpreted specifically in accordance with the methodological criteria developed by the EBM movement. In affording absolute primacy to the place of estimates of average treatment effects derived from methodologically limited epidemiological study designs in the care of patients, EBM concurrently de-emphasized ‘clinical authority’ based on often extensive experience and the expert opinion that derives from it and set out systematically to foster a scepticism in junior doctors and students of such knowledge for decision making. The irony, noted by a plethora of commentators, was that EBM merely substituted one form of clinical authority for another – its own. Personally, I do not accept and never have accepted models of medical care that seek explicitly to eject the medical expert from medical discourse and decision making and I have explained precisely why at length [14], Indeed, in commenting on Nunn [37] and adding to his thesis, I made clear my view that data deriving from epidemiological and other studies are data only – such information requires prima facie and particularly contextual interpretation by experts and integration into a larger theoretical base for it to become a contribution to knowledge that may or may not be applicable to the care of the individual patient who seeks, and submits to, the person of the doctor [14].

It is striking that in a paper written in direct response to EBM’s critics, the authors avoid a detailed discussion of what they regard to be the nature of evidence for clinical practice, yet the whole definition of evidence, the ‘E’ in EBM, has dominated the epistemological criticisms of EBM since its inception. A great deal of literature could be cited here in illustration of the manner in which EBM’s definition of ‘evidence’ has been shifting continuously, but for the purpose and brevity of the current Commentary, the reader is referred to two recent and excellent expositions on the subject by Tonelli [38,39]. So in preference to setting out a detailed explanation of their terms, Djulbegovic et al. preferentially advance their understanding of ‘evidence’ as primarily a guide to the truth, an impartial position, almost, which aids the reader in navigating between competing opinions on ‘what counts’. So for them, ‘evidence’ is ‘grounds for belief’ and something ‘which justifies belief’. But nowhere do the authors actually attempt a settled definition of the E of EBM that they believe is relevant to clinical medicine and how it can be employed in the making of clinical decisions in the context of the individual patient. To be sure, this is a clear and major intellectual deficit in any ‘epistemological inquiry’. And doubly so, since while the E in EBM was always for them directly equivalent to the results of randomized controlled trials and the effect sizes derived from meta-analyses within the EBM thesis, it has now, suddenly, become a far less tightly defined term within the EBM lexicon. Why?

Djulbegovic et al. have historically rejected ‘unsystematic clinical experience’ and the goals and values of patients as not constituting ‘evidence’ in any sense at all. Not surprisingly, because the identification of values and preferences does not derive from empirical clinical research studies. Suddenly, however, they now concede that such factors, including, remarkably clinical intuition, can be admitted into EBM thinking, because as sources of knowledge of relevance to clinical decision making, they therefore warrant the description of ‘evidence’ (!). Such a dramatic volte face is indeed extraordinary.

Michael Loughlin and I commented on the inevitability of such a revision in the 11th thematic edition of the JECP [13], arguing that sociopolitical developments and advances in patient-centred care and personalized medicine would force this change of position on EBM and that the preparedness of EBM to modify the EBM thesis in the face of such developments was a classical example of cynicism. Why did EBM not argue for the immutability of its core ‘philosophy’ in the face of such changes? It has muddled until now against traditional medicine in this way and in the manner of ‘vandals at the gates’ since 1992. Why could it not sustain its position in the manner of King Canute, even as patient-centred care and personalized medicine and the primacy of the patient’s perspective in decision-making advance like the tide? The answer lies, perhaps, somewhere between the epistemological instability of the whole EBM thesis from the beginning on the one hand and the tenacious ‘survivor mentality’ of the ‘EBMers’ on the other. Indeed, better to change the thesis in some way, perhaps, even in a major way, than to lose the ‘precious’, ‘magic’ and ‘historical’ words: ‘evidence-based’? And to lose, in addition, the reputation for progressiveness and radicality in medicine on which many careers and promotions in health services research have been built over the last two decades.

The reaction of EBM, by radically changing its conceptual understanding of what is and what is not ‘evidence’ is completely disingenuous, such that if any source of information can be considered of use in making clinical decisions it can now, suddenly, be described as ‘evidence’ and thus part of the ‘E’ in EBM! It need hardly be said that such major departures from the original epistemological thesis have grave difficulty in achieving intellectually credible ongoing positions in medical epistemology. Let us be clear – EBM had previously paid ‘lip service’ only to the need to integrate ‘evidence’ with patient values and preferences [40,41]
but had been criticized for remaining silent (unsurprisingly) on how such an integration could be achieved without a dereliction of the original EBM thesis [42]. Indeed, in having presided over a ‘radical restructuring of medical knowledge’, de-emphasizing and dis-integrating clinical authority and expertise from decision making, the advocates of EBM now see the urgent need to re-emphasize and re-integrate them. What a spectacle. One is reminded of the Grand Old Duke of York ‘who marched his 10 000 men up the hill, only to lead them back down again’. Could it be that the protagonists of EBM, who once criticized traditional medical practice so severely, now see its merits? Have the mists finally cleared? Has lucidity finally returned to them?

**EBM: does it rely in an integral way on logical positivism? Yes or no?**

Interestingly, Djulbegovic et al. actively attempt to dissociate themselves from the positivistic foundations of EBM by placing EBM a ‘safe distance’ away from the wholly discredited school of thought represented by positivism. But EBM’s original privileging of the results of empirical clinical research above pathophysiological reasoning directly associated EBM with positivist thought. Much of Djulbegovic et al.’s discourse seems to me to confirm this continuing association rather than refute it, an observation of current models of EBM noted by other commentators [43]. They insist, for example, that EBM does not take the classical positivist position of devaluing all non-empirical claims. How, then, can EBM incorporate non-empirical knowledge into clinical decision making in a way which avoids a devastation of EBM’s epistemological origins? Their attempt to make EBM do so is singularly unconvincing in epistemological terms.

Why do I say this? Well note, for example, the authors’ expressed determination to ‘limit ourselves to empiricism and...not consider rationalism’, which insists that reason alone, rather than empirical observation can be a source of knowledge’ (italicizations theirs). Fine. But they, nevertheless, find it impossible to avoid a discussion of various theoretical constructs in the practice of Medicine such that they are bound to conclude – and do so – that theoretical argumentation based on such constructs can lead to the exclusion from consideration of the results of methodologically rigorous studies which have not been based upon biologically plausible hypotheses. In my own view, this observation represents a notable concession by the leaders of EBM. They withdraw, however, from an entirely necessary explication of the implications of this concession, so that they effectively begin a discussion which they *terminate* almost immediately after having commenced it. This is highly disappointing, because such a discussion has the potential to provide insight (and justification) into the decisions of practising clinicians to deviate from the recommendations of medical practice algorithms and clinical protocols on the basis of rationalism rather than empiricism as part of the treatment of the individual patient and much could be learned here about the nature of, and necessity for, the exercise of clinical judgement in this context [14,44,45]. Indeed, such studies are of quite foundational importance in modern health care where practice guidelines are becoming increasingly imbedded into routine care, with managers increasingly mandating their technical application within health services and with deviations from guideline recommendations viewed as examples of clinical error rather than medical excellence. Djulbegovic et al.’s refusal to consider the role of pathophysiological rationale in their discussion of the epistemological foundations of EBM therefore represents a major omission, indeed a further intellectual deficit.

**Does and can a ‘hierarchy of evidence’ exist in clinical practice?**

EBM has, from the start, rested on the notion of a definitive hierarchy of evidence, the construction of which represented part of the radical restructuring of medical knowledge that they announced [20]. The *JECP* has consistently maintained that such a hierarchy has no validity whatsoever as a principle of scientific method [1–13]. As late as 2008, the protagonists of EBM defended their hierarchy as a foundational scientific principle of EBM, asserting categorically that an effective use and interpretation of the medical literature required a ‘sophisticated hierarchy of evidence’ [46]. Now, only a year or so later, Djulbegovic et al. in their ‘inquiry’, appear, albeit implicitly, to move away from that categorical assertion by recognizing the ‘tyranny of method’ represented by the 106 systems of hierarchical rules described in the literature and commenting on how none of these can be seen to demonstrate a complete and logical coherence. Of considerable significance in this very context, then, is the authors’ recognition that the rigid interpretation of ‘evidence’ by EBM has, in collision with the realities of clinical practice, illustrated that ‘(a) universal set of rules that govern medical evidence may not be possible to develop’ and that, furthermore, ‘there are always exceptions to the general rules described in EBM systems’. This further and again radical departure from the violently reductionist and scientific underpinning of EBM may well complete the next major shift in the whole EBM thesis. In fact, such an admission by the protagonists of EBM, although shrouded in circumlocution, is extremely welcome as it recognises that ‘looking for rules in a world of exceptions’ is doomed to the failure with which EBM has now come face to face [47]. Not that Djulbegovic et al. concede anywhere in their ‘inquiry’ that the results of empirical clinical research are of no relevance to clinical practice. They would, of course, be wrong to do so – science informs medicine, it does not in any sense equate to it [44]. But with the notion of a hierarchy of knowledge providing a single most authoritative and trustworthy source of ‘evidence’ for practice now effectively dismissed, their former definition of ‘evidence’ – the results of EBM-approved empirical clinical research [20] – is seen to occupy ‘a limited source of knowledge and authority in the care of patients’ [44] and with this demonstrated, they have no option but to turn to a detailed consideration of what other forms of knowledge are of relevance, indeed necessity, to clinical decision making in the context of the individual patient. They have done, grudgingly, as we have discussed above, finding it ‘vexing’.

**Reductionism**

Djulbegovic et al. admit that the description of EBM as reductionist ‘has some legitimacy’, but move immediately to diminish the significance of this observation by arguing that this particular characteristic of EBM has led to a ‘pragmatic approach to clinical problem solving’. Are we to understand, then, that the authors believe that attempts to apply incomplete sources of medical
knowledge in clinical practice are pragmatic and therefore by this definition practically useful? Surely, strategies which aim to make population-based estimates of statistical probability applicable to individual patients in order to satisfy the central dogmas of clinical epidemiology are anything but practically useful? They are, in fact, clinically irresponsible and that is why the reductionism and scientism of EBM have always been held to be the key components of its cardinal error. Do they not appreciate that navigating the huge inferential gap between the general and the singular has always been part of the exercise of judgement in medicine, which judgement necessarily appeals to sources of knowledge other than the results of empirical clinical research? Little wonder, then, that the concept, let alone the method of integrating patient values and preferences into clinical decisions should be described by them as a ‘vexing issue’. If it is ‘vexing’ for them, then are they incapable of effecting such integration in their own practice and teaching, or do they merely refuse to effect and teach the methods of such integration? If the former, then they have much to learn from clinically experienced colleagues. If the latter, then they should make this known to their patients in advance of any consultation and suffer the professional and reputational isolation that would inevitably follow. Patients are now very informed people. They appreciate the meaning of autonomy. How paternalistic EBM is shown still to be, through the use of such utterances as ‘vexing’ in this context.

Conclusion

What, then, is necessary to move forward? How can the international EBM debate progress in the direction of an eventual intellectual resolution? In my own view, the protagonists of EBM, in coming as far as they have within Djulbegovic et al.’s ‘inquiry’, must now go further. They must define what they mean by evidence in absolutely unambiguous terms. If evidence for practice is constituted not just by the results of EBM-approved empirical clinical research, then what exactly is it? Can one form of knowledge always be regarded as ‘superior’ in nature to all others in the care of patients and if so in what specific clinical circumstances? If the answer to the previous question is in the negative, then they must now explicitly reject the notion of a hierarchy of evidence and concede that they have engaged in the long maintenance of an erroneous position in the philosophy of clinical science that has contributed to a significant maleducation and indoctrination of almost two generations of doctors and medical students through an arrogant refusal to engage with their critics in the pursuit of knowledge through reason. If the advocates of EBM are, through addressing such questions without obfuscation, prepared to complete their ‘inquiry’ then we will be able to take more seriously their assurance that they are ‘open minded . . . and respectful of opposing views’ [15], for one cannot be open minded and respectful by cynically ignoring one’s colleagues’ responses (as in the current edition of the JECP) to an address one has written with them specifically in mind. If they flee from that scholarly obligation and imperative [16] now, the international scientific community will interpret their lack of action and the motives thereof and judge them accordingly.

Noteworthy is the authors’ admission that ‘EBM has yet to present a fully developed framework for accomplishing effective problem solving’ so that, unsurprisingly, no empirical proof for superiority of EBM approaches over so-called ‘traditional’ approaches exists. Is this tantamount to admitting that there is no ‘evidence’ for EBM? Of course it is. And as the JECP has consistently pointed out.

In summary, Djulbegovic et al. in their ‘inquiry’, preferentially discuss what they regard to be the continuing and ‘evolving’ strengths of EBM, but they do not inform such a discussion with a sufficiently frank account of its limitations, forgetting that epistemology is an area of study which requires a consideration of both. Overall, then, their achievement is to present yet another reconstitution of the original thesis and one which is almost certainly the last possible without a frank descent into intellectual, epistemological and strategic absurdity. What a disappointment. What an opportunity largely lost. I re-iterate, then, that EBM remains, simply, the application of epidemiological data to clinical practice, nothing less and certainly nothing more. Nothing within Djulbegovic et al.’s inflated philosophical treatise can or does alter this basic fact. Another fact is this: medicine has entered a period of enormous and increasing complexity [48]. And another fact is this: the continuing reductionism of EBM has, ipso facto, no place there.

References
