Ethics and EBM: acknowledging bias, accepting difference and embracing politics

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Abstract

Evidence-based medicine (EBM) has been effective because it confers both epistemic and moral authority, promising that both individual patient care and public health interventions are effective, safe and efficient, that these decisions and standards can be determined (and therefore judged) in a transparent manner and that this form of decision making is reliable, objective and value-free. The problem is that EBM refers to particular, ideologically and philosophically specific concepts of evidence, medicine and the relationship between them. The analysis of the ‘ethics’ of EBM, therefore, requires not only a critique of its philosophical naïveté and its attachment to modernism and positivism, but a critique of its social, cultural and political implications.

Over the past decade and a half since the inception of evidence-based medicine (EBM), evidence-based principles and practices have come to have a profound influence on the setting of biomedical research priorities, the generation of public health and clinical practice guidelines and the implementation of these guidelines in practice. At present, all funders and publishers of biomedical research and all policy makers and practitioners of clinical and public health medicine are expected to understand and implement the principles of EBM.

Evidence-based medicine (which has variously been described as a paradigm, a methodology, a practice, a system of regulation or audit and a political movement) has been so effective because it has and confers both epistemic and moral authority. It promises that both individual patient care and public health interventions are effective, safe and efficient, that these decisions and standards can be determined (and therefore judged) in a transparent manner and that this form of decision making is reliable, objective and value-free.

There is not and cannot be anything inherently wrong with medicine that incorporates or is based on evidence. On the contrary, that is what we should all be striving for all the time. The problem is that ‘evidence-based medicine’ is different from ‘evidence-based medicine’, in that the term refers to particular, ideologically and philosophically specific concepts of evidence, medicine and the relationship between them. The analysis of the ‘ethics’ of EBM, therefore, requires not only a critique of its philosophical naïveté and its attachment to modernism and positivism, but a critique of its social, cultural and political implications.
What is EBM?

One of the difficulties of examining EBM in any substantive way is that it takes many forms and is emergent, like many concepts promulgated through different discourse communities [1].

Evidence-based medicine first emerged from the work of a group of professors of epidemiology, biostatistics and medical informatics at McMaster University in Canada [2]. The initial formulation of EBM was very clear: it was that medicine should be based upon the ‘conscientious, explicit and judicious use of current best evidence’[3] and that ‘best evidence’ should be identified using ‘epidemiological and biostatistical ways of thinking.’[4] Through the methods it privileged, EBM distinguished itself from traditional medicine, which relied on unsystematic observations, medical intuition, pathological principles and clinical experience [3].

Evidence-based medicine has since been further qualified as ‘. . . the integration of best research evidence with clinical expertise and patient values’; [5, p. 1] and ‘the integration of best research evidence with our clinical expertise and our patient’s unique values and circumstances’[6]. While what constitutes the ‘best research evidence’ is generally not defined in texts of EBM, the best evidence is specified, to some extent, by the ‘evidence hierarchy’, an a priori ranking of study designs that are generally based on ideological or consensus judgements about which studies are most likely to provide estimates of ‘truth’ through reliable and valid data. Over 60 such evidence hierarchies exist [7], although the vast majority place randomized controlled trials (RCTs) and meta-analyses near the top [8]. Guyatt and Rennie [9], for example, lay out a ranking of methods that practitioners should use in order to evaluate published evidence for a new therapy (where evidence generated by higher ranked methods supplants data generated by lower ranked methods).

- N of one RCT;
- systematic review of randomized trials;
- single randomized trial;
- systematic review of observational studies addressing patient-important outcomes;
- single observational study addressing patient-important outcomes;
- physiological studies, and
- unsystematic clinical observations ([9, p. 7]).

Criticisms of EBM

Since its first conceptualization, EBM has gained and retained considerable power, becoming incorporated into medical curricula worldwide, colonizing other fields of practice, such as nursing, complementary medicine and public health, and spawning journals, research centres, web sites and the like [10,11]. There are a number of reasons why this may be the case. EBM provides epistemic power/authority and legitimacy; it provides a means of managing complex and extensive datasets; it provides a means of using data and controlling both uncertainty and disease; it promises access to knowledge about the best and least harmful therapy and it carries normative power – to practice any other form of medicine is to abrogate one’s moral responsibility [12].

In recent years, however, a large body of clinical, philosophical, bioethical, sociological and anthropological literature has emerged challenging every aspect of EBM – its theoretical structure/foundations/assumptions, its method and its practice/translation into policy [13–18].

The criticisms of EBM are well known and may be summarized as follows:

- That it may displace clinical judgement and patient values and narratives from decision making, even where it does take account of these.
• That EBM (or at least the authority it confers) may be used to justify restriction of expenditure and patient choice.

• That it is based on a self-sustaining circularity as it gives priority to those things for which there are good data – in a world where not everything is amenable to measurement, or at least measurement according to the types of epidemiological or biomedical methods preferred by EBM – the RCT, systematic review and meta-analysis.

• That it may create an imperative to conduct research (notably RCTs) where there already exists sufficient evidence to support the rejection or adoption of a therapy or practice.

• That it promises, but is unable to apply epidemiological data to the care of individuals.

• That it is systematically bias towards individualized interventions.

• That it has been unsuccessful in dissemination and implementing evidence into practice.

• That there is no evidence that EBM has produced better patient outcomes than ‘traditional medicine’[19].

• That it may restrict patient choice and limit the options available to clinicians and patients (thereby limiting the autonomy of each).

Advocates of EBM have often responded to these criticisms by pointing out that they arise from a misunderstanding of EBM, result from the enthusiastic but misguided application of ‘crude’ EBM or are irrelevant as they simply point to the limitations inherent in all research/practice [20–22]. These defences are both true – as many of these concerns relate to the definition, generation and use of evidence in medicine, by whatever means, and untrue – as they fail to accept that EBM is also an ideology and epistemology that valorizes particular forms of evidence and particular processes of reasoning. And certainly it is true that EBM may both threaten doctors’ authority (general practitioners lost power while academic doctors and epidemiologists gained some power and status) and perpetuate it (over complementary and alternative medicine and other professions), may be used to provide resources, or at least to create an argument that a resource should be provided, and also create an argument for restriction of services and for therapeutic or policy nihilism, and may be used to make an argument that a service or intervention is both without evidence (and therefore without value) and evidence-based (and thus, value-able). In other words, EBM may be operationalized differently by different people, different stakeholders and within different health systems – something for which EBM may not be held entirely responsible for but equally something that is also facilitated by the promise and actuality of EBM [20].

What is most striking about the critiques of EBM, however, is the fact that many have not been rejected or contested, but accepted and incorporated. Hierarchies of evidence have been modified to take account of methodological critiques of RCTs and the entire notion of EBM has been modified to place EBM within the clinical context. Most notably, in the paper by Sackett et al. published in the British Medical Journal in 1996 [3], they described a Venn diagram with three interlocking circles termed research evidence, clinical expertise and patient preferences. This diagram was, of course, subsequently further modified to place evidence within interpretive art and clinical experience [23]. Likewise, development of models of ‘evidence-based patient choice’, which combine EBM and patient-centred care, has emerged in response to criticisms of EBM that it excluded the patient and was concerned more with the clinicians and the passive transfer of information [24]. In other words, criticism has been assimilated through corrections to the original formulation of EBM.

The evolution of EBM

Since its inception, EBM has been the subject of considerable professional and political debate and its principles and practice have evolved over time. There is, for example, an increasing recognition of the importance of integrating clinical expertise and patient values into evidence-based practice, of the need to avoid ‘cookbook’ and ‘defensive’ EBM practice and of the need to challenge the
traditional hierarchy that privileges randomized trials over all other study designs. Whether these concerns have been addressed adequately is open to debate.

Initial formulations of EBM, regardless of one’s views of them, were clear. It is now, however, increasingly difficult to define what EBM is and is not (to paraphrase Sackett [3]). The initial ideas about hierarchies of evidence, about the promise of EBM and about its translation into practice have all become increasingly fragmented as EBM has tried to accommodate many of the challenges about the nature, biases and value of evidence. Brody, for example, in a defence of EBM, describes how ‘sophisticated EBM’ . . . accepts the best available evidence may be studies of different methodology, may be pathobiological data or may even be clinical experience and fully accepts uncertainty.’[20] Strauss et al. likewise, suggest that EBM no longer prioritizes the RCT or meta-analysis, and accepts that at times the best available evidence may be ‘clinical anecdote’[25].

While this degree of intellectual dynamism is, on the one hand, to be admired, it creates substantial problems for the utility and (apparent) simplicity of EBM. It is also impossible not to be reminded of Popper’s description of problems that may emerge from theoretical accommodation. As he notes in Conjectures and Refutations:

“Some genuinely testable theories, when found to be false, are still held by their admirers – for example by introducing ad hoc some auxiliary assumption, or by re-interpreting the theory ad hoc in such a way that it escapes refutation. Such a procedure is always possible, but it rescues the theory from refutation only at the price of destroying, or at least lowering, its scientific status.” [26, p. 37]

But if EBM has lost some of its original (apparent) coherence, what it has retained is its rhetorical force and its moral status. Thus, while it may be increasingly hard to recognize or describe EBM, it remains even harder to speak against it.

Ethics and EBM

Evidence-based medicine, like health care itself, carries considerable moral force. For if health care is something that we value, and EBM promises the most effective means for identifying and implementing the safest, most effective and most efficient health care interventions, then we are morally obliged to practise EBM [12]. But even if we accept the goals of EBM, there is good reason to question the assumptions and practices of EBM and to ask whether unreflective application of EBM can actually create harm.¹

In general terms there are eight major ethical critiques of EBM. They are: that the research methods that form the basis of EBM are themselves ethically problematic and raise difficult issues related to placebo controls, randomization, stopping rules and therapeutic equipoise; that the implicit and explicit requirement for RCTs may lead to unnecessary research being done where sufficient evidence already exists; that methods privileged by EBM, most notably the RCT, are methodologically unable to answer questions related to individual patients; that EBM allows, or demands, consideration of data regardless of the ethics of its generation; that evidence hierarchies are inadequate and misleading; that the dataset that EBM draws from is systematically biased; that evidence is not value-neutral and cannot be easily translated into practice and that the translation of evidence into practice through clinical practice guidelines and decision aids is both ethically and epistemologically problematic. In this paper I will concern myself primarily with the adequacy of the EBM evidence base, the hierarchies of evidence and the translation of evidence into practice and then consider how EBM may respond to questions about the adequacy and application of evidence in medicine.

¹ In attempting to understand the ethics of EBM I must acknowledge the work of Kenneth Goodman [27], Miles Little [1], Mona Gupta [12], Michael Loughlin [28], Ross Upshur [29], Michael Lowe [30] and Maya Goldenberg [11]—among others.
Ethics and the (in)adequacy of the ‘evidence base’ of EBM

Evidence-based medicine places great store in data derived from empirical studies and assumes that these data provide access to ‘truths about the world’. But even if one accepts that this positivist assumption is correct, there is good reason to doubt the integrity of these data and to question whether they adequately represents the experiences and interventions that they seeks to clarify. Gupta [12], Goldenberg [11] and others have described the sorts of biases that determine the evidence upon which decisions in medicine turn.

Technical (methodological) bias

Any system is fundamentally consequentialist if it demands that everything is measurable and comparable. The problem for EBM, which claims to provide a process for reasoning and decision making based on data (or evidence), is that some outcomes of medicine are not adequately measurable or comparable (such as pain), some may not be measurable at all (such as justice or cultural integrity) and some (such as quality of life) may not even be adequately definable [30]. This requires either that these outcomes are somehow excluded from any calculation of efficacy or benefit, that some value (which may represent the meaning and ontological significance) is attached to that outcome or that outcome is placed outside the realm of evidence but within another domain relevant to decision making, such as patient preferences or context, which in turn still requires some means for balancing it against empirical evidence. The other consequence of this difficulty in defining and measuring all the relevant outcomes of health care is that it is more likely that we will conduct research into those things we can test and we are more likely to publish the results of studies we can easily understand and incorporate into our decision making.

Consider, for example, how we investigate death and dying. Despite the fact that in many ways the concept of health is determined by the way that we understand death, we understand relatively little about the experiences of pain and suffering and even less about the experience of dying. In part this is because we have no ready-made language to describe the meaning of these experiences. In part it is because dying is the most extreme possibility that we can comprehend – the recognition of the certainty of our own extinction towering over every other statement of certainty in life and the biosciences [31]. And in part it is because what is special about dying is its singularity, its uniqueness, its ‘unsayability’ and aloneness – while we may empathize with someone who is dying we cannot really know what kind of suffering they are going through [32]. While some narrative or qualitative accounts of dying may give some insights into this suffering, the idea that we will obtain some measure of understanding or generalizability through measurement or quantitation and that we should prima facie prefer such measures, is nonsensical. Rather, those things that give us genuine insights into the meaning of suffering and dying (rather than instrumental concerns of dying, such as analgesic requirements or attitudes to cardiopulmonary resuscitation) are literature, music, poetry and philosophy. The music of Mozart, the poetry of Larkin and Auden, the language of Dostoyevsky (who described the sense that ‘a house is collapsing on you’), the philosophical insights of Kierkegaard (who described the anxious dread of death that lies within happiness) and Heidegger (who described the imminence of death and the loss of a future and past that occurs as one dies) – these are the things that allow us even a glimpse of the experience of dying [33–35]. And if we accept that these types of insights, these types of ‘non-medical forms of knowing’ do allow us to understand dying – where would we place them in our hierarchies of evidence, how would we make them commensurable with other ways of knowing? Even if we were to say that we have no way of incorporating them within our hierarchies of evidence but that they fall within some of the other sectors of our Venn diagram of medical decision making – perhaps in the sectors of context or clinical experience or patient preferences (although of course these also fit poorly in to these domains), how are we to describe exactly how these insights fit with the others and with empirical evidence?
Cultural and gender bias

Evidence-based medicine not only draws from existing evidence, it demands its generation, publication and, following assessment of its quality, its application. In doing so it holds out the promise of transparency, objectivity and universalizability. But data reflect the context in which they were produced and the social, cultural and political context clearly influences the framing of what counts as evidence, the determination of the research agenda, the production of research evidence itself and the selective utilization of that evidence in policy and practice. Obesity is a major health issue in some contexts but not others, dialysis in the elderly can be justified in some contexts but not in others, and even something as ‘real’ and non-socially constructed as leukaemia is treated one way in the USA, another in France and yet another in Australia and the UK – all on evidentiary grounds.

Evidence, therefore, is socio-culturally constructed. This seems uncontroversial. But evidence is also expensive and technologically grounded and the standards and processes of evidence and EBM are not accessible to all cultures and all people. This means not only that the data we have, the evidence we construct, is relative, but that it is systematically biased and discriminatory. It also means that it can change the very understanding of disease, diagnosis, treatment and prognosis and so create its own taxonomy of disease and illness. A disease in the West, for which there is evidence, becomes different to that same disease in the developing world. This creates the possibility for increasing harm to large numbers of people through the misapplication of evidence.

Publication bias

Evidence-based medicine relies on the existence and availability of data. One of the early challenges for advocates of EBM was to ensure that data adequately represented ‘reality’. The problem is that data may not be easily accessible, because they are hidden for commercial interests or are in the grey literature or may not represent experience, because of publication bias in the scientific and medical literature. Publication bias (whereby journals are more likely to publish positive and/or statistically significant results and also more likely to publish particular study types, e.g. RCTs, than others, such as qualitative studies) serve both to narrow the dataset available to guide decisions and to misrepresent the experience or intervention in question [36]. While clinical trial registries, grey literature databases and guidelines for conduct of systematic reviews have, to some extent, ameliorated these biases, it is unlikely that they can ever account for the epistemic bias in medicine and the paradigms of peer review.

Commercial biases

It is now widely recognized that commercial interests have distorted and restricted the data that we draw from – the ‘evidence base’ of EBM [37]. Indeed it is my view that the major risk of industry engagement with medicine is not its influence on prescribing but the impact on the epistemology of medicine and on the construction of disease, for example, the emergence of the bio-bio model of psychiatric disease. We know, for example, that:

- 60–80% of all clinical research in USA and 20–60% of clinical research in Australia is sponsored by the pharmaceutical industry.
- The conduct and governance of clinical research is increasingly moving out of hospitals and academic centres and to Contract Research Organisations who may have close ties to industry.
- >80% of professional organizations and journals are sponsored by, or receive advertising revenue from, the pharmaceutical industry.
- An increasing amount of clinical research is conducted in BRIC (Brazil, Russia, India and China) and that, in general, the methodological and ethical standards of this research are less than research conducted in the West. And at the same time, the relative contribution of Europe, the USA, Canada and Australia to research is decreasing.
There are a number of implications of this for medicine, and for EBM in particular. There is evidence of a distortion of the research agenda (90/10 divide), distortion of evidence, with positive results more likely to be reported and pharma-sponsored studies more likely to generate findings favourable to the sponsored product [38–41], distortion of research methodologies (from superiority to inferiority studies), distortion of research questions (limited head-to-head studies) and delay or non-publication of key findings for commercial reasons (e.g. Cox-2 inhibitors and SSRIs in children). The adverse impact of these distortions is significant, including the loss of researcher integrity and independence, creation of multiple ties and conflict of interest, loss of transparency in science and, perhaps most importantly, the erosion and distortion of the evidence according to which patients are treated and health policy developed.

The impact of commercial interests on the very institutions that create and monitor quality in research cannot be overstated. At the current time, 65–75% of all clinical trials published in major medical journals – Annals of Internal Medicine, JAMA, NEJM and the Lancet – are industry-sponsored [42]. This clearly benefits both parties. Journals want RCTs because they and their readers have come to regard them as the highest form of evidence and because they need both advertising revenue and revenue derived from selling supplements and reprints (sales of reprints of large RCTs brings in approximately $US1 million and has an enormous profit margin). Industry, in turn, relies on journals to publish RCTs and meta-analyses as they provide epistemic authority, media coverage, distribution and the sort of medical status that no form of advertising can provide. This has led those involved in medical publishing to question the manner in which they have been co-opted by industry. To quote just a few figures who are or have been prominently engaged in medical publishing in the last decade:

- Journals have devolved into laundering operations for the pharmaceutical industry (Richard Horton – Lancet) [43].
- The pharmaceutical industry has co-opted every institution that might stand in its way (Marcia Angell – NEJM) [44].
- Medical journals are an extension of the marketing arm of pharmaceutical companies (Richard Smith – BMJ) [42].
- There is a cycle of dependency between journals and the pharmaceutical industry (PLoS Editors) [45].

None of these people are ‘industry ascetics’ and all express the same concern – the mechanisms that provide epistemic authority in medicine, research, publishing and peer review, are each diminished or altered by industry such that their adequacy and validity is called into question. These issues are, of course, a concern for all those engaged in health and biomedicine. But they do present particular changes to systems of thought, like EBM, that emphasize published research, empirical data and that ascribe particular authority to study types (RCTs and meta-analyses) that are largely ‘supplied’ by pharma [46,47]. The impact of this bias is difficult to quantify and is likely to have far higher impact in some areas of medicine than in others. The impact of this evidentiary distortion is also incremental and so less likely to be seen. As Brody has, rather dramatically, noted ‘... it will probably take years before we can determine the extent to which the evidentiary water supply has systematically become polluted in the last few decades as a result of commercial bias.’[20]

**Evidence, context, subjectivity and decision making**

Evidence-based medicine requires not only the generation and assessment of evidence but its integration with patient values and preferences and its translation into clinical practice. While this seems straightforward, it is, of course, anything but. In large measure this is because EBM is naïve about evidence (and research) [28] and because it fails to take adequate account of subjectivity – both in the identification and weighting of evidence and in the contribution of evidence to decision making.
Evidence-based medicine generally assumes that (research) data are the same as evidence, whereas in fact evidence is a status conferred upon a piece of data [27,28] and what counts as evidence is highly subjective [12,48]. A clinician may be interested in the recanalization of coronary arteries with thrombolysis, whereas I will be interested only in the number of medications I need to take and the adverse effects of each of these medications. The US Food and Drug Administration may be concerned that an anti-arrhythmic agent increases the risk of sudden death, whereas I will be interested only in the fact that it improves my (limited) quality of life. In other words, what counts as meaningful evidence is contested, contextual, embodied and ultimately, negotiated.

While EBM has long recognized that clinical decision making does not rely on evidence alone, and has facilitated the development of decision aids to assist individualized treatment decisions and facilitate the incorporation of patient’s unique values and preferences into the decision-making process [6], it inadequately theorizes how one may weigh evidence against values, particularly when the two conflict, and implicitly gives greater weight to evidence. This may be enormously misleading as even the ‘best evidence’ may be of no value. Parents making decisions about the use of an adrenalin syringe for a child with possible peanut anaphylaxis may decide not on the basis of extensive epidemiological and immunological data regarding risk but on the basis of ‘future regret’, while patients considering whether to go ahead with a bone marrow transplant may choose not on the basis of a careful consideration of the risks and benefits of transplant in their situation, but on the basis that as they confront death there is, in reality, no choice.

At a policy level, also, the priority given to evidence and the assumption that it is value-free and not determined by the theoretical frame of the inquisitor, may lead to blindness of the fact that decisions are based not simply on evidence but on a wide range of inputs and that the criteria for evaluating the efficacy of public health interventions may differ from clinical practice. This is particularly evident in transfusion medicine, where policy decisions are often based on considerations other than the best research evidence, including public expectations about transfusion/blood safety and proposals for applying the precautionary principle to transfusion medicine [49]. EBM may also compel action on the basis of existing evidence, even where that evidence is incomplete or inadequate, because it is ‘the best available evidence’, and this may ultimately problematize complex social issues simplistically. In Australia this has been a feature of recent policy making in Aboriginal and Torres Strait Islander Health Care, where evidence of disease (such as ear disease in children) or social problems (notably child sexual abuse) has provoked massive but profoundly inadequate policy responses. For evidence, even if it is acknowledged to be only part of the picture, creates a moral imperative to act and provides epistemic authority in ways that ethical principles often do not.

While these challenges, of identifying what counts as evidence, attaching weight to it and integrating these assessments of evidence with patients or groups values or preferences, are an issue for all of medicine, by privileging evidence, and empirical evidence in particular, I would suggest that they are more of a threat to EBM.

Evidence . . . of what? The problem of evidence hierarchies

Evidence-based medicine arose, in part, as a response to the practical need to manage the massive amounts of data relevant to medical care. It provided a simple approach to complex medical problem, a way to mediate between competing data, interests or claims and a promise of objectivity, impartiality, consistency, rationality, truth and certainty. The reality, of course, is that EBM could provide none of these things as evidence is not value-free, self-apparent, disinterested or atheoretical [50] but is socially and culturally constructed, relational, gendered, embodied, intersubjective and communal [51–53].

The mistake that EBM makes, as Maya Goldenberg and others have pointed out, is that it relies upon a largely discredited positivist view of science and evidence [11,16,28,54,55]. The assumptions that EBM makes about the authority and objectivity of scientific evidence, assumptions that have been
the subject of extensive philosophical and feminist critiques, are ethically problematic for four reasons. First, they serve to obscure the socio-political and moral determinants of health care decisions at the clinical and policy levels. Second, they do not account for the fact that what counts as evidence may be determined by those in power and with authority, most notable those in medicine and in government [56,57]. Third, by valorizing the objectivity of evidence and certain methods for establishing evidence, EBM and evidence-based policy making accentuate the biases of biomedicine and the gaps in the evidence base of medicine [11]. Thus, the evidentiary exclusion of women, vulnerable groups and those in the developing world are not rebutted by EBM but incorporated into guidelines and promulgated through practice [51]. And fourth, they guide and reinforce the type of evidence that ‘counts’.

It is difficult to be critical of the methodologies of EBM as there are so many descriptions of EBM and it has, as I have described, increasingly attempted to incorporate different forms of evidence. But I think it remains true that for the most part EBM has had remained true to quantitative measure of evidence, the meta-analysis and the RCT, and had some difficulty including evidence that is narrative, phenomenological and qualitative. This has meant that EBM has largely turned away from questions and experiences that are difficult to define or measure or categorize, such as quality of life concerns, issues related to death and dying and questions of sexuality and mothering. It has also meant that EBM has been slow to recognize that hierarchies of evidence have been based largely upon ideology, that different research methods have different strengths, that measures of quality are more important within categories of method than between and that the evidentiary hierarchy is largely dependent upon the question being asked than any a priori judgement of evidentiary power [11].

**Flexibility or unrecognized incommensurability? Beyond hierarchies of evidence**

The central claim of EBM is that medicine should be based upon the ‘conscientious, explicit and judicious use of current best evidence.’ While this seems a reasonable aim, EBM, as both a method and a social movement [58] has had difficulty achieving this because its’ (original) epistemic basis was rigid and did not take account of different forms of ‘evidence’, because the philosophical and methodological assumptions upon which EBM is based are highly questionable, because it (EBM) did not provide an adequate model of decision making and because it could not account for the difficulty in applying research data to individuals [16,19,59–62].

Advocates and critics of EBM have responded to concerns regarding the privileging of RCTs and meta-analyses within EBM by proposing that EBM should recognize that the academic traditions and methods of the humanities, social sciences and applied sciences provide very different notions of what counts as ‘evidence’ and that less quantitative or less ‘tangible’ forms of evidence, such as that offered by qualitative research and narrative, should be incorporated into EBM [29,63–65]. Similar concerns have also led to calls for EBM to incorporate pathophysiological data, clinical expertise, and the values and goals of patients (often after quantitation into ‘patient utilities’ amenable to analysis and inclusion into decision tools) [66]. This represents a radical departure for EBM as its original formulation made it very clear that research data were different from, and more important than, other ways of knowing, such as clinical experience, patient narratives and pathophysiological data.

While it would seem highly desirable to integrate different kinds of knowledge into EBM, the recognition of qualitative or non-empirical kinds of knowledge presents a major challenge for EBM. First, it is not at all clear how one can meaningfully integrate different types of knowledge, knowledge that is epistemologically, ontologically and methodologically distinct, into EBM under a broader umbrella of evidence or how one can decide where these different types of knowledge fit in any evidence hierarchy [62]. Hierarchies of evidence, which claim simply to provide a ranking of quality and/or validity, are based upon philosophical assumptions about the status and meaning of knowledge and it may be that ways of knowing are so distinct that they are both incommensurable and irreducible and cannot be incorporated within a single ‘theory’ of decision making. Second, even
if one were able to incorporate different ways of knowing into EBM, EBM remains largely silent about how a practitioner could balance all the (possibly) conflicting types of knowledge and then understand these in light of the patient’s values and goals [29,62]. And in the face of such uncertainty, EBM and practitioners of EBM, will retain an implicit or explicit preference for empirical research data [48]. While the continued preference for certain types of evidence, particularly RCTs, may infuriate critics of EBM, it is probably important for EBM that it prefers the results of empirical research data as to do anything else simply erodes its integrity, utility and authority (just as Popper would have predicted).

There are, however, alternatives to persisting with this model of EBM. One alternative is to base medical decision making not around evidence, but around values. ‘Values-based medicine’ has been posited as an alternative to EBM on the grounds that health care is primarily a moral enterprise based upon universal values, such as caring and compassion and that these values are pervasive and are the major determinants of decisions about health, clinical practice and research [67]. A second is to train doctors in what Berkowitz has called ‘a social model of criticism’ that would encourage them to recognize the social and cultural forces that shape research activity, the selection of evidence and the development of policy [68].

A third alternative is to clearly separate the different ways of knowing such that EBM is used only as a tool to evaluate outcome derived from quantitative research, and kept distinct from other types of knowing and from other influences on decision making, such as narrative, qualitative data, sociological and anthropological research data, pathophysiological data and patients’ goals and values. Mark Tonelli has made a case for this type of process, arguing that a casuistic approach (which bases consideration of ‘evidence’ around the particularities of a clinical case) more closely mimics the ‘real world’ of clinical care, allows for the integration of different forms of evidence and still enables assessment of the quality of evidence, within each category of evidence. In a landmark paper [62] he outlined the five topics relevant to medical decision making:

- empirical evidence – derived from clinical research;
- experiential evidence – derived from clinical experience and from expert knowledge (of others);
- pathophysiological rationale – based on underlying theories of physiology, disease and healing;
- patient values and preferences – derived from interaction with individual patients, and
- system features – including resource availability, societal and professional values, legal and cultural concerns.

Tonelli argues that none of these topics take priority over the other and any may prove determinative in a particular clinical decision. While EBM gives priority to empirical evidence, Tonelli’s approach genuinely does require ‘conscientious and judicious’ use of empirical evidence. For Tonelli the task for clinicians is to weigh up the various warrants for action by employing both practical and theoretical reasoning skills (phronesis) and by comparing their patient with paradigm cases from the literature. This approach is appealing because it acknowledges complexity and because it requires close attention to context and to a patient’s situation and judgement by the clinician as to whether the ‘average patient’ from empirical research resembles the actual patient sitting in front of them (although arguably so do late constructions of EBM, as these also place empirical evidence in the context of values and clinical expertise). The other benefits of this approach are that it demands acknowledgement of the difficulties in negotiating between evidentiary and non-evidentiary forms of knowledge, does not see practice variation as a weakness and demands rigour and transparency in decision making. While Tonelli’s model is attractive, it remains relatively under-theorized and it is unclear how this approach would work at the level of policy making.
Evidence-based medicine promised certainty, simplicity and better decision making and arguably has delivered none of those things. But I would suggest that this is both because of the philosophical and methodological inadequacies of EBM and because of the very nature of medicine. Medicine is complex, messy, difficult and constantly requires normative judgment. And the space that medicine inhabits, furthermore, is richly contextual and filled with different sorts of data that may not be comparable in any meaningful sense and may be valued differently by different people. As such, it may be that in seeking to modify or improve EBM, or to come up with an alternative meta-theory of medicine or even to provide a monolithic model of clinical decision making, that we are seeking a false certainty and asking too much of EBM and of evidence.

This is not to say that clinical research, including the results of RCTs, is irrelevant to health care — indeed such a claim would be impossible to sustain. Nor is it to say that EBM is completely unhelpful, or even that the EBM movement has been counterproductive, for it has certainly encouraged a critique of medical authority, has facilitated development of quality criteria in research and tools for managing massive datasets and brought out into the open debates about evidence and justification in medicine. And the hierarchies of EBM may still have (more restricted) utility in the analysis of epidemiological data.

Rather than propose an alternative model for decision making, I would suggest that what is (still) required is further reflection on the definition and function of evidence in medicine and the goals of medicine (both in general and for each individual patient). At both the clinical and macro levels we need to continuously ask ourselves:

- What is evidence being used for?
- What counts as evidence and what evidence counts?
- What is the evidence we have, or seek, evidence of?
- What weight are we giving to each type of evidence?
- How are we to incorporate these different types/pieces of evidence into our decisions?

These questions are important for any system of medical decision making as they determine both the nature of our discourse with others (who may answer them differently because they may have a different epistemology of evidence or risk) and the way that we will identify ‘best evidence’, as this may depend largely upon the question asked and the theory used. If, for example, I seek information about causation, then I may well rank the results of an RCT above other types of studies. If, on the other hand, I seek insights into the experience of dying I may turn to qualitative research, narrative accounts or poetry and if I am interested in population determinants of risk or outcome, then I will likely attend more to the results of molecular epidemiological studies of biobanked tissue specimens.

But while clinicians and their patients should be able to identify, discuss and critically appraise the medical and non-medical ‘evidence’ in light of their specific situation, evidence cannot provide the certainty and security that each require, particularly for patients, who seek not only expertise but also care and respect at a time of great vulnerability. Clinical decision making draws upon a range of different ways of facts, reasons and ‘knowledges’ and it is the manner in which these are considered and balanced in the light of a particular patient’s needs, perspectives, values and beliefs that gives health care its essential character. Thus, what may be required is a recognition that assessments of evidence must be made in the context of uncertainty and a commitment to presence, discourse and to ongoing critical appraisal of the evidence as it emerges during the illness trajectory. Clinicians may therefore assess the available evidence in terms of internally valid measures of quality, consider this evidence in light of the patient’s specific situation, and, in discussion with the patient, weigh this up against the patient’s goals and preferences and alongside other forms of evidence. This process of
judgement will inform clinical management and shape the dyadic relationship. It may turn out for the best, and it may not. And where it does not the clinician will need to sceptically re-examine the judgements made.

While this formulation will discourage those who wish to have a simple guide for decision making in medicine, I would argue that it simply acknowledges what practitioners and policy makers already know, that medicine is discursive and political and unavoidably normative and while we expect evidence to play a role in decision making, what we ultimately require is judgement.

References