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The evidence-based medicine model of clinical practice: scientific teaching or belief-based preaching?

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Abstract

Rationale Evidence-based medicine (EBM) is commonly advocated as a ‘gold standard’ of clinical practice. A prominent definition of EBM is: the integration of best research evidence with clinical expertise and patient values. Over time, various versions of a conceptual model or framework for implementing EBM (i.e. how to practice EBM) have been developed.
Aims and objectives This paper (i) traces the evolution of the different versions of the conceptual model; (ii) tries to make explicit the underlying goals, assumptions and logic of the various versions by exploring the definitions and meaning of the components identified in each model, and the methods suggested for integrating these into clinical practice; and (iii) offers an analytic critique of the various model iterations.
Methods A literature review was undertaken to identify, summarize, and compare the content of articles and books discussing EBM as a conceptual model to guide physicians in clinical practice.
Results Our findings suggest that the EBM model of clinical practice, as it has evolved over time, is largely belief-based, because it is lacking in empirical evidence and theoretical support. The model is not well developed and articulated in terms of defining model components, justifying their inclusion and suggesting ways to integrate these in clinical practice.
Conclusion These findings are significant because without a model that clearly defines what constitutes an EBM approach to clinical practice we cannot (i) consistently teach clinicians how to do it and (ii) evaluate whether it is being done.

Introduction

David Eddy has observed that the term ‘evidence-based medicine’ (EBM) has spread through medicine with amazing speed during the past 15 years (p. 9) [1]. Evidence-based approaches are increasingly advocated not only in guiding clinical practice but also in ‘shaping research agendas, formulating policy, and allocating financial resources’ (p. 2613) [2]. In the clinical context, the term EBM has two different but related meanings. The first focuses on EBM as a method to generate and assess research evidence on the clinical effectiveness of various treatments. This focus emphasizes the importance of incorporating science into medicine by developing a hierarchy of research evidence, and using critical appraisal tools to evaluate clinical research on treatment outcomes. There is a large body of literature on the generation and application of such tools.

This paper addresses **only** the second meaning of EBM: as a model of clinical practice in the medical encounter. While initially, the EBM movement focused on the importance of incorporating science into medicine and how to do this, over time it was recognized that physicians needed guidance not only on how to generate and assess research evidence but also on how to implement an evidence-based model of practice. EBM is now equated with ‘best practice’ and, as Lambert and colleagues noted, holds a position of symbolic authority in clinical decision making [2]. Hence, what constitutes an EBM model of clinical practice and how this should be implemented is of great importance to clinicians, teachers and policy makers. Without a model that clearly defines what constitutes EBM practice we cannot (i) consistently teach clinicians how to do it and (ii) evaluate whether it is being done.

Evidence-based medicine as a model of clinical practice has been developed and modified over time. While originally focusing on using research evidence as a basis for decision making, the model has been revised several times to recognize that: (i) there were other components (in addition to clinical research evidence) of an EBM model of practice that had been de-emphasized or ignored in the first description of this approach; (ii) each of these components played an important role in defining EBM practice; and (iii) the task of the EBM physician was to integrate these various components (once identified) in order to derive the best treatment decision for each patient.

Evidence-based medicine advocates emphasize the importance of assessing the scientific rigor of clinical research evidence used to inform clinical decision making. Suggesting a conceptual model of how to practise EBM requires, from a scientific perspective, a similar attempt to promote rigor in the development process. This means that the developers should (i) clearly define and operationalize each component of the model; (ii) justify the inclusion of each component; and (iii) clarify the method recommended for integrating (e.g. weighting) each component in order to implement evidence-based practice. Also, when revising the model (or suggesting a new model) it is important to justify the changes made {e.g. why certain components are added, deleted or modified and how the revised model works [points (i) to (iii) above]}. In this paper we explore the extent to which the above steps have been undertaken and the extent to which the various versions of the EBM model of clinical practice that have been developed provide a sufficient basis to differentiate an evidence-based decision and practice from one that is not evidence-based.

We argue that the various versions of the EBM model (and the accompanying diagrams depicting these over time) reflect a vague, often inconsistent and incomplete description of an EBM model of clinical practice and how it should be implemented. Conceptually, this ambiguity leaves the reader to fill in the gaps and interpret the meaning of evidence-based clinical practice in potentially different ways. Normatively, this ambiguity leaves physicians with a confusing message about how to implement EBM. One of the problems that may contribute to this ambiguity is the lack of underlying theory and/or empirical evidence to support the framework's development. This results in a predominantly belief-based rationale for the inclusion and advocacy of various model components, and the absence of any clear description of or rationale for how these should be integrated in practice.

Methods

A literature review was undertaken, using a computerized search strategy to identify relevant articles for review. Articles were included if they: (i) focused on EBM in the context of individual level clinical decision making; (ii) focused on a discussion of EBM as a conceptual model to guide physicians in clinical practice; (iii) were published in medical journals from 1992 to 2008; and iv) were written in English. Our search was focused on identifying conceptual articles/chapters that described defining components of an EBM model of clinical practice and their integration in clinical decision making.

Titles of articles, and where available, abstracts, were read to assess the relevance of the articles for this analysis. Several medical and two nursing textbooks containing discussions of conceptual models/frameworks for describing an EBM approach to clinical practice were also reviewed. Atlas*ti™, version 5, a qualitative software program, was used to enter the documents, and assist in data management, coding and analysis [3].

We used sensitizing concepts such as: definitions of EBM, EBM model/framework components, and integration of components as guides to identify relevant data segments to retrieve from the documents [4] and an editing approach to inductively identify key themes from the data (papers and book chapters) to be included for analysis [5]. To undertake the document analysis [6], first, the defining components of each version of the EBM model/framework identified in the literature were described as they evolved over time, beginning with the earliest version (1992) and ending with the most recent version identified in 2008. The components of each model (including diagrams) were then compared and contrasted to document (i) how they changed over time; (ii) explanations provided for such changes; and (iii) suggestions made for how to integrate these components for use in clinical practice. To simplify the presentation of our findings we have somewhat arbitrarily identified four versions of the EBM model based on the time periods within which they were discussed and new versions evolved (the first three versions that we identified are similar to those identified by Buetow [7] but were independently derived inductively from our own data analysis). When we talk in this paper about the evolution of the EBM model of practice, we will cite specific published papers to illustrate each version, but we do not claim to have included all papers written on this topic. In using the term 'model' we are using the language which authors use to describe their own work.

Results: conceptual models describing an EBM approach to clinical practice

Version 1

The first commonly cited version of EBM as a 'new' approach to clinical practice was published in 1992 by the Evidence-Based Working Group. The development of this 'new' approach was motivated by several factors: for example, the information overload faced by physicians due to advances in medical knowledge and the increase in medical research reported in clinical journals [8,9], the need for physicians to have readier access to clinically important research evidence to inform practice, and the development of strategies or tools within the emergent field of clinical epidemiology to generate and assess clinical research evidence. In the original 1992 paper, EBM was described as a move towards a 'new paradigm' (in the Kuhnian sense) for medical practice and medical teaching and a move away from using traditional sources of knowledge such as 'intuition, unsystematic clinical experience, and pathophysiological rationale as sufficient grounds for clinical decision making . . .' (p. 2420) [10].

The 'new' EBM framework (version 1) was described as using the medical literature (and specifically clinical research evidence) more effectively in guiding medical practice. The authors claimed that physicians who do this will 'provide superior patient care' (p. 2421) [10]. Physicians were advised to rely much more on the results of clinical research evidence to guide their practice and much less on traditional skills and authority. The issue of how to integrate research evidence with other identified but downplayed and undefined components was not addressed at this time. The authors did note that implementing this type of practice (EBM) would require new methodological skills from practitioners, such as literature searching and the application of formal rules of evidence for evaluating clinical research so that physicians could differentiate between high and low quality studies, using only the former as a guide to clinical action. Version 1 was described in words only; no diagram was developed to schematically portray the components of this 'new paradigm' for medical practice.

The authors' claim that their ideas constituted a paradigm shift as described by Kuhn [11] has been vigorously debated in the medical and philosophy of science literature [12–15]. Until recently, EBM leaders seemed immune to these criticisms and continued to assert the legitimacy of this claim, rather than arguing the merits of their case. However, in a 2009 article written by Djulbegovic *et al*. [16], the authors, including one of the originators of the EBM movement, acknowledged that 'EBM should not be construed as a new scientific or philosophical theory that changes the nature of medicine or our understanding thereof' (p. 158). This article has stimulated several commentaries and renewed debate on the epistemological underpinnings of EBM [17–23].

The claims made by the Working Group for the superiority of an EBM approach to clinical practice in the early 1990s generated criticism because the authors were perceived as disparaging traditional ways of making clinical decisions, and by implication, physicians who practiced these methods. Opponents of EBM argued that the use of research evidence was not new [24,25], that research evidence offered little help in the many grey zones of practice [26], that the definition of what counted as 'evidence' was overly narrow and restrictive [27], that EBM did not represent a paradigm shift [13,14,25] and that use of an EBM model to guide clinical practice would result in 'cook book' medicine [28]. EBM was also criticized as de-contextualizing medical practice, making the unwarranted inferential leap of assuming that average outcomes from randomized controlled trials (RCTs) could be used to determine what is best for an individual patient, and ignoring patient input into the decision-making process [29–36].

Version 2

Version 2 of the EBM model appeared in the mid 1990s and is most explicitly described in the following papers and books: Haynes, Sackett, Gray *et al*. [37,38]; Sackett, Rosenberg, Gray *et al*. [39]; Sackett & Wennberg [40]; Sackett, Richardson, Rosenberg *et al*. [9]; Haynes, Devereaux & Guyatt [41,42].

In version 2, several new features were introduced. First, the model was formalized and labelled explicitly as a 'model' for clinical decision making. Second, the model included three separate components, labelled patient preferences, clinical expertise and research evidence, depicted as three overlapping circles (Fig. 1). Third, the authors stated that a key challenge of the framework was how to integrate individual clinical expertise with current best evidence from systematic research in order to apply the framework in clinical decision making.

In this version of the model, most clearly articulated by Haynes, Sackett, Grey *et al*. [37] the concept of patent preferences, while added as a new component, was not defined and little empirical evidence or theoretical justification was provided for its inclusion. Papers written during this time used several different terms to signify the types of patient information that physicians should consider in making evidence-based decisions: for example patient rights, patient choice and patient predicaments [39] as well as patient preferences. None of these terms was defined so it was not clear whether they were intended to be interpreted as synonymous or to hold different meanings. The overall definition of EBM commonly cited during this time: 'the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients' (p. 71) [39] did not mention patient information at all. Hence, there was some disconnect between the definition of EBM and the various components of the model as defined in the diagram and discussed in accompanying texts. Clinical expertise was defined in this version as 'the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice' (p. 2) [9]. Although depicted in the diagram as one component of an EBM approach, it too was not included in the predominant definition of EBM at this time.

The scope of what was to be included in the concept of clinical expertise varied in different texts. In their 1997 book on EBM, Sackett, Richardson, Rosenberg and Haynes [9] wrote that increased clinical expertise is reflected in many ways, but 'especially . . . in the compassionate use of individual patients' predicaments, rights and preferences in making clinical decisions about their care' (p. 2). Here, the authors suggested that the physician's ability to use patients' preferences, predicaments and rights was an indicator of increased clinical expertise, i.e. part of the clinical expertise/judgment component of the model. However, in the 1996 diagram, 'patient preferences' were identified as an independent component (circle) to be integrated with the other components, such as clinical expertise. Physicians were considered to be responsible for making treatment decisions. They were encouraged to elicit and use patient preferences (even though these were not defined) in making treatment decisions, rather than providing patients with the opportunity to participate in the decision-making process as much as they wished. This reflected a paternalistic model of treatment decision making [43,44].

The visual diagram (Fig. 1) depicting version 2 of the model [37,38] resembled a Venn diagram in which the size of the circles

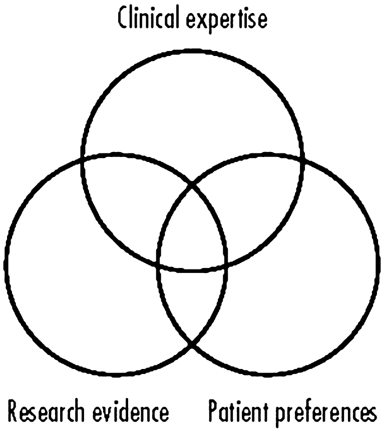

Figure 1 Version 2 of the EBM model of clinical practice. Source: Reproduced with permission from the American College of Physicians from Haynes, Devereaux & Guyatt [42].

and overlapping areas have meaning, and which illustrates the relationship between and among sets that share something in common. However, no explanation was given as to why the circles in the EBM diagram were drawn to be: (i) of equal size; (ii) partially overlapping; and (iii) placed such that clinical expertise was at the top, research evidence on the lower left and patient preferences on the lower right of the diagram. The authors did note that 'clinical expertise and patient preferences may override the other components of the model for a given decision' (p. A-15) [37] and provided one example of each of these possible scenarios. Otherwise, no guidance was provided on the 'complex' problem of how to integrate the model components in order to practice EBM.

In a paper written in 2002 on the historical development of various versions of the EBM model of practice, version 2 was retrospectively defined as descriptive, suggesting that this framework depicted how physicians actually behaved at the time [42]. But elsewhere, one of the same authors argued that there are 'striking variations in . . . the integration of patient values into our clinical behavior' (p. 3) [9] suggesting considerable heterogeneity in physician treatment decision-making styles. In fact, version 2 seems more normative than descriptive because the authors do not provide evidence to show that physicians actually practised evidence-based decision making as described in their model, i.e. that physicians actually used the three components to the same extent and in the same ways to arrive at a clinical decision.

Version 3

The third iteration of the EBM model evolved in the early 2000s. Key papers discussing this iteration include: Sackett, Straus, Richardson, Rosenberg, & Haynes [45]; Guyatt & Rennie [46]; Haynes, Devereaux, & Guyatt [42]; Montori & Guyatt [47]; Haynes, Devereaux, & Guyatt [41]; Straus, Richardson, Glasziou, & Haynes [48]. EBM was now defined as the 'integration of best research evidence with clinical expertise and patient values' [41,45].

In version 3 (Fig. 2), several changes were made to the model. First, the research evidence circle and the patient preferences circle changed places. Second, the top circle, labelled as clinical expertise in version 2, was now labelled 'clinical state and circumstances'. Third, clinical expertise was redrawn with a dotted line as an oval which partially overlapped all three overlapping circles. Fourth, the patient preferences circle was relabelled 'patient preferences and actions'. Fifth, the framework as a whole shifted in status from being described as descriptive to prescriptive; i.e. it became in this version 'a guide for thinking about how decisions should be made rather than a schema for how they are made' (p. A-11) [42]. This version was described as 'a more advanced model for evidence-based decisions' (p. A-11) [42].

In identifying the need for a prescriptive 'model', the authors stated that 'at present, clinicians' individual preferences (as distinct from clinical expertise) often play a large role in their actions, leading to large practice variations in managing similar cases' (p. A-11). This trend was seen as a concern from a quality of care perspective [42]. The concept of physician preferences introduced here was not defined; nor were physician preferences included as a component in this or any other of the model diagrams. The authors noted that 'our model acknowledges that patients' preferences rather than clinicians' preferences should be considered first whenever it is possible to do so' (p. A-11) [42] but did not comment on the conditions under which it would be possible or not to do so. Hence, it was not clear whether the authors thought that physician preferences should or should not be a legitimate influence in evidence-based practice.

The reversal in the placement of the patient preferences and research evidence circles in version 3 (Fig. 2) was undertaken to signify the 'frequent precedence' (p. A-11) of the former over the latter [42]. No explanation was given as to why the authors now felt that patient preferences should have frequent precedence over research evidence.

The term 'action' was added to the patient preferences component in this new version of the model because 'patients' actions may differ from both their preferences and their clinician's advice' (p. A-12) [42]. This narrow definition seemed to equate patient action with either inconsistency in the patient's behaviour with respect to previously stated preferences for treatment, for example a patient who states a preference to lose weight but whose 'actions fall short of achieving' (p. A-12) this goal [42], or a discrepancy between the patient's behaviour and the physician's advice. No guidance was provided on how a given physician should respond in situations where there was conflict between the patient and physician perspectives.

Patient preferences were depicted in one article (p. A-12) [42] as depending, in part, on patient values. Here, values were identified as one determinant of preferences, rather than synonymous with it. However, another 2002 publication treated these two concepts as synonymous: 'By *values* and preferences we mean the underlying processes we bring to bear in weighting what our patients and our society will gain – or lose – when we make a management decision' (p. 6) [46]. In yet another article, patient preferences and actions were defined in terms of 'what interventions she or he (the patient) is ready and able to accept' (p. 1350) [41]. Patient preferences also included 'the patient's desired level of involvement in decision making' (p. 525) [47]. Hence, the meaning attributed to

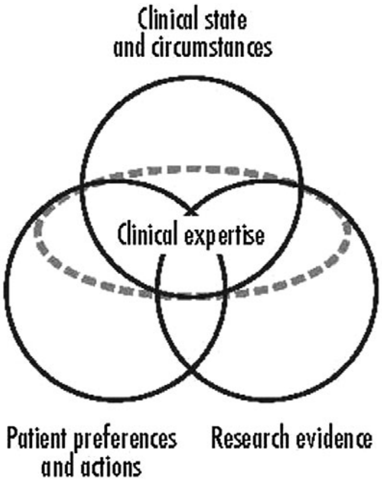

Figure 2 Version 3 of the EBM model of clinical practice. Source: Reproduced with permission from the American College of Physicians from Haynes, Devereaux & Guyatt [42].

the concept of patient preferences was not consistent from one paper to another; nor for the most part, were attempts made to operationalize these concepts.

The concept of societal values was identified during this period as important to the practice of EBM [46]. No definition was provided or explanation given as to how to elicit these values or integrate them into clinical decision making. The concept of societal values was not included in any iteration of the diagrams depicting the components of an EBM model of clinical practice. Perhaps the authors assumed that patient and 'societal' values were synonymous and, hence, only one circle was needed. If so, this assumption ignored a potentially crucial distinction between what is the 'best' decision for a population in the aggregate (which includes patients and healthy individuals) and one that is best for a given patient.

Ways of eliciting individual patient preferences were either not discussed at all or discussed only briefly. Several different strategies were offered to elicit patient preferences. First, physicians could communicate to patients the risks and benefits of relevant treatment options, 'thus permitting them to incorporate their own values and preferences in the decision'. This option was seen to have the advantage of avoiding the 'vexing' problem of measuring patients' values [49]. The other general method suggested was quantitative, asking patients to place a relative value on the key outcomes associated with the management options. The authors noted that 'communicating the nature of the outcomes and their probabilities in a way the patient will understand, or accurately ascertaining the patient's values regarding outcomes, remains problematic' (p. 579–580) [49]. Published patient surveys establishing median values for patient preferences for specific outcomes was another suggestion made for establishing patient preferences. Giving one example of such a survey, the authors stated: 'You conclude that these values are sufficiently close to those of the presenting patient that you can use the decision analysis to guide your approach to this patient' (p. 578) [49] but no direction was provided as to how to make this assessment or define the meaning of the phrase 'sufficiently close'.

In general, physicians were strongly urged to quantify patient values as a way to lend more rigor to the decision-making process [50]. Physicians were advised that: 'A vague sense of the patient's preferences cannot fully satisfy the rigor of the optimal evidence-based medicine approach' (p. 572) [49]. The rationale for this belief that numbers would yield more accurate representations of patients' preferences than their own words was not made clear. Moreover, while physicians were urged to assume that the clinical effectiveness results from RCTs could be applied to their own patients, unless there was a good reason not to make this default assumption (p. 132) [48], the authors did not comment on whether this same assumption should be made about other model components such as patient preferences. Assuming homogeneity in patient preferences both within and across RCTs for a given disease is in itself problematic, let alone assuming that such preferences will be similar for RCT patients and patients in a given medical practice. In fact, in many RCTs, patient preferences for treatment are unknown because they are deliberately suppressed as part of the process of randomization to different treatments.

Little recognition was given at this time to the idea that eliciting patient preferences might be better conceptualized within the context of (i) the physician/patient relationship and (ii) different potential approaches to treatment decision making within the medical encounter, rather than being viewed primarily as a technical problem requiring more advanced measurement procedures. For example, patient preferences will play different roles in the treatment decision-making process in the medical encounter depending on whether the approach selected to make such decisions reflects a paternalistic, shared or informed model. In a 'pure' paternalistic approach, the physician makes the treatment decision without eliciting patient preferences. In a 'pure' shared approach, both patient and physician preferences are important to consider in making the treatment decision. In the 'pure' informed approach, the patient makes the treatment decision based on her values, with the physician's role being limited to providing the patient with the necessary clinical research evidence to create an informed patient [43,44]. The latter more patient-oriented approaches to treatment decision making, while increasingly described and/or advocated in the social science literature during this time, were largely ignored in discussions of both an EBM approach to clinical practice and how the EBM approach could or could not accommodate alternatives to more physician-centred models [51,52].

The final component of version 3 was clinical expertise, depicted, not as a circle but as an oval shape overlapping the three circles and drawn with a dotted line. Clinical expertise was described as having an expanded and central role for determining the appropriate integration of the model components [42]. The authors admitted that 'achieving the right balance among the factors that can affect a decision is not necessarily easy' [41]. No advice was offered on how to integrate (i.e. weight) the various model components, but it was stated that 'accomplishing this goal often involves sorting through tradeoffs' and that 'the model can accommodate different weights for each component of the decision' (p. A-13) [42]. This statement suggested that any combination (weighting) of the different components would constitute an EBM model of practice, in which case, how to distinguish between an EBM and non-EBM model of practice becomes problematic.

In describing the potential influence of this version of the model, the authors stated that: 'It is also impossible to implement the model as prescribed. For example, at present, it is not possible to make an accurate prediction of the patient's likelihood of following a treatment program . . . Thus, our model is conceptual rather than practical and remains under development' (p. A-13) [42]. Given this statement, it is unclear why this version of the model was offered as a normative guide to clinical practice. Those who advocate normative models typically do so in the hopes that physicians and patients will buy into this approach and will change their behaviour accordingly. The above quote seemed to confuse the process of treatment decision making with the process of following a treatment regimen. Also, if the 'model' was truly normative, as stated earlier by the authors, then its purpose was not to predict how physicians or their patients would behave, but rather how they should behave.

Version 4

In version 4, the EBM model and accompanying diagram (Fig. 3) were generalized beyond medicine to apply also to nursing and other health care practitioners. Version 4 is described in the following book chapters: DiCenso, Ciliska & Guyatt [53]; Guyatt, Haynes, Jaeschke, Meade, Wilson, Montori *et al.* [54] and

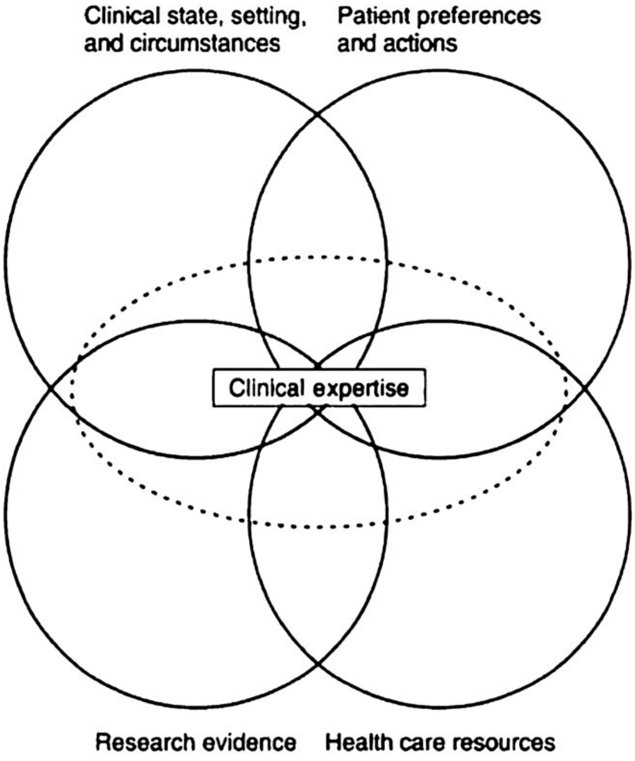

Figure 3 Version 4 of the EBM model of clinical practice. Source: Reproduced with permission from Elsevier from DiCenso, Ciliska & Guyatt [53], p. 5.

DiCenso, Cullum & Ciliska [55]. This fourth version of the EBM framework is derived from version 3, and is acknowledged as such by the various authors.

In version 4, a new component is added labelled 'health care resources'. The position of the patient preferences and actions circle, and research evidence circle are again reversed in the accompanying diagram. A new definition of patient preferences and values is provided. The complexity and difficulties of measuring and integrating patient values with other components of the EBM model for clinical practice are more strongly articulated.

The addition of the new component labelled health care resources is somewhat puzzling [53,55]. It is not clear whether the authors view health care resources as part of the clinical context or as a potential structural constraint at the public policy level that defines the broader economic context within which physicians practise. If it is seen as part of the clinical context, it should logically be included in this circle instead of being depicted as a new component (circle) in the framework. In describing the rationale for including this component the authors stated: 'We know that most decisions in health care have resources implications . . . Occasions arise when decision makers may conclude that the potential benefits of an intervention are not worth the costs. Decision makers must always weight the benefits and risks, inconvenience, and costs associated with alternative management strategies and, in doing so, consider the patient's-values' (p. 5) [53].

If the above statements are arguing that health care providers might conclude that the costs of a given treatment are not worth the benefits, then presumably the authors see the provider's role as going beyond being an agent for the patient, i.e. providing the best care possible for that patient. For an effective intervention, whether the benefits are greater than the costs has to do with affordability constraints [56]. This is a system level decision (i.e. whether to pay for a given treatment or not). A health care provider (e.g. nurse or physician) typically does not have the information required to make this decision. Further, as noted earlier, a provider role as societal agent is in potential conflict with his/her role as an agent for any given patient (a tension now explicitly recognized) (p. 7) [53] because doing all that one can for one patient may reduce the resources available for other patients. Hence, the meaning of and rationale for including health care resources as a new component and circle in this iteration of the EBM model is unclear.

No explanation is provided as to why the position of the patient preferences and actions circle, and the research evidence circle has been reversed again in this version of the diagram. The clinical expertise component is now depicted as a rectangular box, overlapping the now four overlapping circles [53,55].

In the updated version of the *Users' Guides to the Medical Literature*, values and preferences are given a new definition: 'the collection of goals, expectations, predispositions and beliefs that individuals have for certain decisions and their potential outcomes' (p. 12) [54]. Later in this same book values and preferences are defined as 'an overarching term that includes patients' perspectives, beliefs, expectations, and goals for health and life' (p. 644) [57]. Patient values and preferences are defined in the 2005 Evidence-Based Nursing book as: '. . . the underlying assumptions and beliefs that are involved when clinicians, along with patients weight what they will gain – or lose – when making a management decision' (p. 8) [53]. Clearly, the concepts of patient values and preferences in version 4 are still elusive, inconsistent in scope, and not amenable to easy operationalization or measurement.

Limitations of decision analysis as a tool for measuring patient preferences are more explicitly acknowledged in the new Users' Guide. The authors note, for example that studies show that patients do not consistently follow the underlying assumptions of decision analyses, there is limited empirical support for these assumptions, and decisions from these analyses may not be the ones that rational patients would make (p. 645) [57]. In fact, the authors now downplay the use of decision analysis by saying: 'Given the limitations of valuation tools and decision analytic models, in the context of individual decision making, the true value of tools that elicit values and preferences may not be to enable the clinician to capture patients' values and preferences to incorporate in a formal decision analysis' (p. 654) [57]. The authors suggest that 'many unanswered questions remain concerning how to elicit preferences and how to incorporate them in clinical encounters . . .' (p. 13) [54].

In the new Users' Guide, the authors spend more time trying to contextualize the treatment decision-making process within the medical encounter. They describe different models of treatment decision-making (e.g. paternalistic, shared, physician as perfect agent), noting that all models except for parental (i.e. paternalistic) are consistent with EBM principles, but they do not discuss further which principles they are referring to or the definition and measurement of compatibility (p. 648) [57]. The key issue of how to integrate all the different components of the model to arrive at a clinical decision is left unanswered.

Discussion

Evidence-based medicine has been described as 'an attitude of enlightened skepticism toward the application of diagnostic, therapeutic and prognostic technologies in their day-to-day management of patients' [58], a philosophy of teaching [59], an approach to clinical practice [10], a medical epistemology [15], a methodology for evaluating the validity of research in clinical medicine [60], and a regulatory mechanism that uses research evidence for the production of clinical guidelines, meant to not only rationalize clinical practice but also to control medical expenditures [61]. In this paper we have focused on the development and evolution of various versions of the EBM model of clinical practice.

We explored the underlying goals, logic and assumptions of the various model iterations, the different components (circles in the diagrams) of the framework and how these changed over time, the definition and meaning of key terms, and methods offered for integrating the various components of the model for application in clinical practice. A number of issues can be raised as a result of this review:

First, many terms, essential to understanding the meaning of various aspects of the EBM model as a guide to clinical practice were either not defined, defined vaguely, or defined inconsistently over time. The various discussions of the meaning of patient preferences and values illustrate this theme.

Second, the rationale for including and adding (or modifying) various components of the model are not made explicit. They are deemed to be important because the authors say so. This means that the components of the EBM practice model, as they evolve and change over time, seem to be based more on personal beliefs (a belief-based approach) rather than scientific evidence. Nor do these components appear to derive from theory which is testable through empirical research. Rather specific components are added based on the opinions of the authors without discussion of the extent to which these components are overlapping, internally consistent, and collectively exhaustive. Moreover, almost everything that was suggested should be de-emphasized in version 1 of the model has been brought back in, with seemingly equal status. While this may be seen as a positive evolution, it begs the question of why these components were de-emphasized in the first place.

Third, in the various iterations of the diagrams depicting the EBM framework, the position of the circles changes over time with little explanation as to why. In version 3, the authors identify as deliberate the change in position of the patient preferences circle to the bottom left hand corner, symbolizing a real change in perspective about the importance of this component in the overall framework. But in the next version of the framework diagram, the patient preferences circle is moved back to its old position, with no explanation. Hence, it is difficult to know whether the positioning of the specific circles (and the overlap among them) is meaningful or not, and if so, meaningful in what way.

Fourth, an EBM approach to clinical practice was originally advocated because it would lead to better patient outcomes. If this is the case, it follows that each new version of the model, and added components, were believed to be significant new contributions to achieving the overall goal of better patient outcomes. What is missing is an explanation of why the authors believe this to be the case and a description of the mechanisms by which these new components are expected to operate to achieve better patient outcomes, as well as which specific outcomes will be affected. In fact, it could be argued that if the goal of EBM practice is only to achieve better treatment outcomes, and we know through clinical research what the 'good' outcomes are and how to achieve them, then there is no need to consider any component of the framework other than research evidence. But because EBM advocates insist that evidence alone is never sufficient to make a clinical decision, the issue of how to weight and integrate all of the EBM components is crucial for translating this model into practice [62].

Fifth, the patient preferences component of the various versions of the framework seems conceptually weak in terms of the clarity of this concept and its importance in the overall model. The definition of this term is sometimes depicted as narrow (preferences for outcomes), sometimes broad (patients' goals for health and life) and shifts in meaning from one version of the model to another, without a clear rationale as to why. Not only patient but also societal preferences are now identified as important to consider in an evidence-based model of clinical decision making but little analytic thought is given to what this means, potential conflicts between individual and societal preferences, how they might be resolved, or the conditions under which one set of preferences should take precedence over the other. In addition, the issue of eliciting, weighting and integrating patient preferences in evidence-based practice remains problematic.

Sixth, it is not clear whether EBM advocates think that physicians should have a decision-making role in determining which treatments should be funded at a societal level, or whether physicians should predominantly act as gatekeepers determining which treatments are clinically necessary for which patients at the practice level (i.e. determining whether patients qualify for given treatments), or both. The role proposed for physician values, if any, in EBM practice is also unclear.

Seventh, while described as a normative model of evidence-based medical practice, little guidance is offered as to how the model should be implemented. While EBM advocates do say that different components may take precedence in a given clinical circumstance and provide some specific examples, these are not at the level of general conditions which could act as a template when considering specific situations. The critical issue of applying clinical judgment to determine the right amount of each component when making a clinical decision remains a black box. In fact, it appears that any combination of the model components counts as evidence-based practice so it is difficult to differentiate between an evidence-based practice (or treatment decision) and one that is not.

Conclusion

Encouraging the use of scientific evidence (or science) in clinical decision making has been a major contribution of the EBM movement. Developing a model of how to implement an EBM practice also requires scientific rigor in terms of (i) clearly defining and operationalizing each component of the model; (ii) justifying the inclusion of each component; and (iii) clarifying the method recommended for weighting and integrating each component in order to implement evidence-based practice. Also, when revising the model it is important that the developers justify the changes {e.g.

why certain components are added, deleted or modified, and how the revised model works [points (i) to (iii) above]}.

Our review suggests that these conditions have not yet been met and that the overall approach to development has been more belief-based rather than evidence or theory-based. The EBM model of practice is not well developed and articulated in terms of defining components, justifying their inclusion and suggesting ways to integrate these in clinical practice. These findings are significant because without a model that clearly defines what constitutes an EBM approach to practice we cannot (i) consistently teach clinicians how to do it and (ii) evaluate whether it is being done.

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