

## EDITORIAL INTRODUCTION AND COMMENTARY

### The evidence-based health care debate – 2006. Where are we now?

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#### Introduction

When an academic in the History of Medicine comes to write a comprehensive account of the nature, characteristics and scale of contribution to human progress of the evidence-based health care movement, there will indeed be a great deal of considerable interest to read. Rarely before, it seems, has there been such fierce and greatly protracted polarization of both scientific and clinical positions as in the last 16 years since the coining of that now severely tired, and almost defunct neologism, 'evidence-based medicine' (EBM) (Evidence-Based Medicine Working Group 1992; Polychronis *et al.* 1996a,b). The *Journal of Evaluation in Clinical Practice*, over this time, has achieved a pre-eminent reputation in directly ensuring that the necessary debates on the nature of 'evidence' took place and,

indeed, that they *continue to take place*. If one accepts, as is now essentially universally accepted, that clinical medicine and health care more broadly, are to be developed and evaluated according to the extent to which they are in alignment with widely accepted concepts and norms of practice, themselves continually evolving through highly reasoned debate and careful observation, then it is the duty and ambition of any scholarly periodical with a definitive interest in the evaluation and development of that most human of activities, the care of the sick, to place itself at the centre of such debate. While disliking the term 'mission', given its inane and intellectually bankrupt modern usage, and preferring the classical understanding of the term, this is precisely the 'mission' we, at the *Journal of Evaluation in Clinical Practice* have adopted and, on the basis of which mission, we will continue to operate, within the environ-

ment of complete editorial independence that Blackwell Publishing have always rightly afforded to their Editors.

We had thought that the practice of publishing an annual Thematic Edition charting the progress of the EBM debate had 'worn thin', as it were, and that an alternative form of presenting the many papers we receive on EBM was warranted – a recurring section, perhaps, in successive issues of the *Journal*. But the reaction to the Editor's announcement that the annual Thematic Edition was to cease, met with no small protest and so the decision to continue the publication of the annual Thematic Edition has been taken. We are therefore gratified to commit to the international medical literature the present Part One of the 9th Thematic Edition (Volume 12, Number 3) on the progress of the EBM movement, which augments the previous eight (Miles *et al.* 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004) and, at the time of writing, we are completing the editing of Part Two of the present Thematic Edition, to be published as the next issue (Volume 12, Number 4). This very large *opus* having been achieved, we invite contributions to the 10th Thematic Edition for publication in 2007.

### **Evidence-based health care: progressing scholarly debate through 2006 into 2007**

#### Concepts, epistemology and the nature of clinical knowledge

Starting with an analysis of concepts, we have made the centrepiece of this edition Tonelli's article: 'Integrating evidence into clinical practice: an alternative to evidence-based approaches' (Tonelli 2006). Tonelli (2006) notes that despite the lack of good evidence that teaching EBM improves the quality of medical education or the subsequent care of patients, the vast majority of internal medicine programmes in the USA now incorporate some aspect of EBM into residency training and a third have a free standing curriculum in EBM. The author additionally notes that while such a widespread adoption of EBM into graduate medical education promises to alter the way that the next generation of doctors practise clinical medicine, it remains quite unclear as to whether such a change will ultimately benefit patients. An extraor-

dinary observation indeed. The *Journal of Evaluation in Clinical Practice* has documented the same such observation on countless occasions previously and continues to share Tonelli's elegantly expressed concern that, although the bulk of the literature on EBM focuses on the practical issues related to the development, acquisition, interpretation and incorporation of the results of clinical research into clinical practice, EBM continues to rest on certain philosophical assumptions and arguments about the nature of medical knowledge that have *still not adequately been elucidated* (see, for example, and noting the substantial bibliography within: Miles *et al.* 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2006; Norman 1999, 2003). Indeed, and as Tonelli (2006) points out, although now at last acknowledging the need to integrate various kinds of what they continue to regard as medical knowledge with what they continue to regard as 'non-medical knowledge' in the making of clinical decisions, the protagonists of EBM have said little about how such integration should actually take place and it is precisely this process whereby 'evidence' is applied to decision making that is most under-described by EBM-influenced educational curricula. Thus, Tonelli (2006) argues that it remains unclear by what process clinicians are to balance what may be described as conflicting 'warrants for action', deriving not only from published clinical research, but also from personal clinical experience, pathophysiological understanding of disease, the preferences of individual patients and other such sources which have typically been regarded by the protagonists of EBM as being 'non-evidentiary' in nature.

Tonelli (2006) proceeds to argue that the very few attempts by the protagonists of EBM to describe a method for integrating various kinds of medical knowledge and reasoning into clinical decision making have all, without real exception, proved unsatisfactory. The failure of the EBM approach centres, this author feels, on its attempts to treat different potential warrants for medical decision making, such as empiric evidence, clinical experience and pathophysiological rationale, as *different in degree*, rather than *different in kind*. Tonelli (2006) argues that, under such a rationale, one form of medical knowledge, specifically that derived from clinical research, is judged (wrongly in our view and in his) as superior

to the others and he argues that this approach is philosophically untenable and that various potential warrants for medical decision making differ *in kind* from one another. It is this understanding of the nature of medical knowledge, Tonelli (2006), contends, that requires an alternative method for integrating various warrants into a particular medical decision, a method that for him closely resembles the casuistic or case-based approach to medical ethics advanced by Jonsen *et al.* (1992). For Tonelli (2006), this understanding of medical epistemology can provide for an explicit defence of a more 'common sense' practice of medicine that has been called for time and time again (Porta 2004).

We regarded Tonelli's thesis to be of such importance that we took the unusual step of commissioning not one, but rather 11 commentaries on this author's reasoning, from a wide range of scholarly sources, spanning a large range of disciplines, both within, and applied to, Medicine, and it is this most important set of articles which follows Tonelli's piece. The commentaries by Djulbegovic (2006), Miettinen (2006), Porta (2006), Lipman (2006), Tanenbaum (2006), Couto (2006), Upshur (2006), Loughlin (2006a), Malterud (2006), Gupta (2006) and Geanellos & Wilson (2006), make fascinating reading and to exercise editorial comment here on these editorially commissioned commentaries would be superfluous. Instead, we are content to advance these articles as essential reading in conjunction with Tonelli's work (Tonelli 2006) and we remain excited by the way in which they have substantially developed the primary insights which Tonelli records, each commentary providing considerable scholarship in its own right.

In previous Thematic Editions on EBM, the *Journal of Evaluation in Clinical Practice* has studied contentions relating to the so-called 'ethics of EBM', publishing papers by colleagues who have argued for the existence of an ethical imperative to implement the tenets and methodologies of EBM into routine patient care. Most notable among these have been the articles contributed by Gupta (2003, 2004) learned commentaries on the same (see Couto 2003; Miettinen 2003; Norman 2003; Shahar 2003) and an incisive Essay Review by the distinguished health philosopher Michael Loughlin (Loughlin 2003). We turn now to the article in the present issue by Borry

*et al.* (2006) and its related commentary 'A platitude too far'. (Loughlin 2006b). The central arguments advanced by Borry *et al.* (2006) relate to the 'need' to base clinical decision making on the latest and 'best available' medical research findings, with the clear implication that should such clinical decision making not be based on such data, it would, *ipso facto*, be less than ethical, if not directly unethical. For Borry *et al.*, the use of the latest research will *automatically* result in decision making that is more ethical, because it will therefore be 'better informed' and 'better justified'. For his part, Loughlin (2006b) is able to agree with the authors that one should not fully support the call for a misleading extension of the term 'evidence based' to the 'field' of 'ethics'. In fact, he is clear that *one should not support it at all* and he shows the authors' overall thesis to be fundamentally defective because it fails (or refuses) to acknowledge the fundamental fallacy embodied by the use of the terms 'evidence', 'evidence-based' and 'evidence-based medicine' in the context of medical epistemology. In the analysis which follows, Loughlin (2006b) goes on to study, in no small depth, both of the two central assumptions of 'evidence-based ethics' put forward by the authors. We find ourselves in agreement with this commentator when he argues that the last thing we currently need is the creation of a new 'field' of so-called 'evidence-based ethics', 'with training days to explain to us why we are all unethical because we fail to conduct our practices in terms of whatever meaning the powers that be care to attribute to the term "evidence-based" on the day'. Indeed, as Loughlin (2006b) points out, such developments can harm proper professional practice 'as competent professionals (are) labelled immoral for refusing to "genuflect" to a variety of academic altars in the absence of any demonstration of the true nature of whatever academic deities – be they labelled "quality", "evidence" or even "ethics" – these altars supposedly represent' (see Loughlin 2002, 2003).

### **Exposing the limitations of EBM in public health medicine, in psychological medicine and in cardiovascular medicine**

Following on, we move to four articles that focus specifically on the limitations of 'evidence-based public

health', 'evidence-based psychiatry' and 'evidence-based cardiovascular medicine'. In the first of these articles, Kemm (2006) examines how the concept of the 'evidence-based' approach has transferred from clinical medicine to public health and has been applied to health promotion and policy making. He notes that in policy making, evidence has always been interpreted broadly in order to cover all types of reasoned enquiry and after some debate the same is true, he observes, for health promotion. For Kemm (2006), taking communities rather than individuals as the unit of intervention, and given the importance of context, means that randomized controlled trials are frequently inappropriate for the study of public health interventions. This author goes on to suggest that the notion of a 'best solution' ignores the complexity of the decision-making process. Interestingly, and as we agree, Kemm (2006) is clear that the availability of evidence 'enlightens' policy makers in confronting their policy problems but does not in any way provide a direct answer to the given problem(s). He concludes, persuasively, that there are lessons from the way that evidence-based policy is being applied in public health that could usefully be taken back into clinical medicine.

Kemm's analysis of the limitations of the EBM approach in public health medicine leads us to Maier's discussion of the incompleteness of the concept and practice of EBM in psychiatry (Maier 2006). While Maier is clear that 'evidence-based psychiatry' is an important concept and might prove with time and development to be an useful method, he is equally clear that its application currently covers only a limited range of the clinical problems that psychiatrists and indeed psychotherapists encounter within their daily work. By way of specific example, the author describes the limited validity of psychiatric diagnoses and notes how EBM, which is fundamentally based on correctness of diagnosis (a limitation we have discussed previously), has an almost automatically doubtful applicability in psychological medicine. Moreover, there is the issue of 'complexity', the effects of which are more obvious in psychiatric and psychotherapeutic cases than perhaps in other branches of Medicine. In this particular context, Maier (2006) argues that, owing to its conceptual bases, EBM cannot sufficiently consider such effects and is therefore of limited usefulness when

clinicians address particular problems in fluctuating or symptomatically shifting diseases. Additionally, the predominant focus of EBM on decision making simply does not reflect the clinical reality of psychological medicine where diagnostic and therapeutic procedures are in fact more iterative, with decisions being constantly re-evaluated. This highly individual approach to therapy means that, *ipso facto*, EBM cannot assist clinicians in achieving anything which could be described as optimal psychiatric clinical care. This brief focus on EBM and psychiatry continues in Dewhurst's short account of its limitations, but from the particular perspective of personal experience of illness – valuable insight indeed for any clinician who may treat the disease or condition from which he himself has suffered (Dewhurst 2006).

The fourth and final paper of this section is concerned to examine the relationship between evidence-based treatment of heart failure and the resulting quality of life of the patient. Here, Dobre *et al.* (2006) report the results of their study which explored whether prescription of evidence-based drug therapy is associated with better quality of life in patients with heart failure. The authors were able to observe that quality of life measurements did not, in fact, differ significantly between evidence-based and under-treated patients, unadjusted or after adjustment for significant patient imbalances. On this basis they conclude that conventional step-up medication approaches in heart failure may well have a positive impact on survival and morbidity but do not necessarily translate into improvements in the patient's quality of life – a noteworthy observation indeed.

### **Implementing 'evidence-based' approaches to clinical care**

#### **Knowledge management and practice guidelines**

Wherever there is a consensus on the definition of what exactly constitutes evidence for a given clinical practice – and such a consensus is usually, and entirely properly, reached only after sufficient time has elapsed to enable adequate debate by experts in the given field and for adequate experience of the operational use of an intervention in 'hands on' clin-

ical practice to have accumulated – then there is a clear imperative to move to systems of implementation. Indeed, that is the quintessential basis on which clinical practice evaluation and development properly and wisely takes place. In the opening part of this section of the thematic issue, Sandars & Heller (2006) describe how experience of knowledge management initiatives in non-health care organizations can offer useful insights, and strategies, to implement evidence-based practice in clinical situations. Knowledge management, as they describe, offers a structured process for the generation, storage, distribution and application of knowledge in organizations, including both tacit knowledge (which the authors define as ‘personal experience’) and explicit knowledge (which the authors describe as ‘evidence’) which they see as becoming integrated within ‘communities of practice’. The benefit of the approach that these authors recommend is that it takes fundamental account of ‘context’ and they argue for more in-depth study of how such methodologies can be implemented into modern health care systems and the benefits of doing so measured.

Clinical practice guidelines remain, when certain conditions are met and their limitations fully understood, useful vehicles for implementing agreed changes to clinical practice and service provision. Certainly, the process of deriving and implementing clinical practice guidelines has developed into a science in its own right, so extensive and complex has this field of study become. The *Journal of Evaluation in Clinical Practice* has published much on this subject over the last 11 years, insisting that the proper place of practice guidelines is one of simple reference as part of an holistic assessment of clinical need, evaluated and assessed within the context of the immediate experience of the individual patient in the forum of the consultation (Miles *et al.* 2000). The reductionism of the dominant methodologies for practice guidelines development, in one sense understandable in the face of complexity, renders much of the library of current practice guidelines of highly limited value in everyday clinical practice and in many ways the limitations of practice guidelines are their defining characteristics. The second paper in this section, in describing the process of ‘upgrading’ the strength of recommendations for guidelines development in situations where the conduct of trials

would be either impractical or unethical (Roddy *et al.* 2006), adds interestingly and indeed usefully to methodological thinking on guideline development and use.

### **Evidence-based health care and clinical education**

In the opening article of this final section of the Thematic Edition, Leung & Johnston (2006) are concerned to chart the direction of ‘evidence-based’ medical education. For these authors, the evidence base for most educational initiatives has been essentially composed of low level evidence with four major barriers to its progress. The authors advocate the adoption of a ‘balanced scorecard’ approach in the evaluation of educational interventions that brings together a comprehensive panel of outcomes under one framework. They list and discuss the range of applied methods of use in generating these outcomes which derive from the quantitative and qualitative disciplines of epidemiology, psychology and economics, recommending that the research community discusses and agrees upon a standardized set of common metrics or benchmarks and they describe the use of hand-held computer clinical decision support tools in improving the clerkship learning of EBM. In the paper which follows, Stevenson *et al.* (2006) report the results of their study of the effects of an educational programme in physiotherapy on the management of low back pain and we conclude the issue with a contribution from Upton & Upton (2006), comparing the views, knowledge and practice of ‘evidence-based medicine’ between hospital doctors with their general practitioner counterparts.

### **Conclusion**

We have previously noted that in articulating their creed so extensively and with such passion, the protagonists of EBM have fulfilled a most important function in demonstrating quite clearly what good clinical medicine is *not* about (Miles *et al.* 2004). In direct consequence, it is surely now ostentatiously clear that evidence-based clinical practice as defined by Sackettism (Miettinen 2003), and good clinical

medicine, cannot possibly be equated and remain in our view fundamentally irreconcilable. Thus, EBM is currently to be seen as a 'form' or 'mode' of clinical practice, theoretical and experimental in nature, with no evidence whatsoever for a superior clinical effectiveness or patient satisfaction profile. With these quite central and fundamental observations documented, and supported by an extensive literature, it seems extraordinary that so much argument continues to take place, that so many medical education curricula continue to change with reference to EBM criteria and that so much clinical practice has been altered – all on the basis of a concept underpinned by an absolute lack of evidentiary basis. The initial EBM doctrines, so set in stone as absolutes at the time, are now in ruins, such that it is currently difficult to define quite what those colleagues who still describe themselves as 'evidence-based practitioners' actually now believe in. Certainly, the initial concepts and methodological approaches have fragmented into many pieces in the face of sustained intellectual and clinical challenge and as the understanding of the true nature of what constitutes evidence for clinical practice has become clearer. It is dramatically ironic indeed that in insisting so vigorously on a narrow definition of evidence, the reductionism of the 'EBMers' directly fuelled a more expansionist view, generating fascinating new insights into a very old question. In that sense, they have made an exceptional contribution, even though the process that they initiated resulted in the devastation of their creed. It is, perhaps, the arrogance that defines the 'EBM personality' (Polychronis *et al.* 1996b) that prevents their taking well deserved credit for having developed medicine in a way that they did not quite anticipate or intend.

Adherence to the EBM philosophy was never universal, indeed far from it, and where EBM continues to be preached, its continuing attraction appears to remain based on some clinicians' need for certainty in the inherently uncertain World of clinical practice. This, as has been argued extensively in the *Journal of Evaluation in Clinical Practice* and elsewhere, is not to deal with the problem of uncertainty at all, but on the contrary risks synthesizing a 'false certainty', far more liable to result in suboptimal care at the least and error and injury at the worst, than the exercise of what has often been pejoratively

described as 'traditional' clinical medicine with its well-established emphasis on caution, experience and consensus. Not that one has ceased to experience the use of the prefix 'evidence-based' in day to day health services and, indeed, even in the (general) academic literature. On the contrary, a large number of (and it has to be said) non-medical colleagues continue to use the prefix with incontinence, lacking a critical understanding of the proper use of that prefix; an observation all too readily made when they are confronted with an altogether reasonable request to define terms. Perhaps the latest abuse is the appearance of 'evidence-based research' (!). What can explain such a phenomenon? Certainly, the almost 'magic' words 'evidence-based' continue to possess highly persuasive rhetorical force, but it is surely depressing that some colleagues seemingly lack the critical faculties necessary to recognize nonsense in order to expose it for what it is? (Loughlin 2002). So, it appears, EBM continues to survive for these two very different reasons: the almost lustful (though ultimately futile) search for clinical certainty and the almost sexual excitement some colleagues appear to experience when hearing or articulating the words 'evidence-based'. If these observations are held, then there is a clear need to continue the debate. Tonelli's article in the present edition (Tonelli 2006), and the associated set of 11 learned commentaries, contribute directly to this debate. The wide range of observations made and questions raised within these 12 articles deserve further, individual study if the debate on EBM is to move forward from its current position. We fully expect the remaining protagonists of EBM to maintain their magisterial disdain for proper academic exchange and thus to remain hilariously mute in the face of the further deposit of considerable scholarship on the limitations of EBM contributed to the literature of academic medicine by the present issue. If we are proved wrong, then we would indeed be delighted and the Editor exhorts them here, yet again, to answer their critics.

The sheer volume of scholarly writing on the various facets of the EBM debate submitted to the *Journal of Evaluation in Clinical Practice* in the last year has meant that we have been unable to publish in the present issue all articles of relevance to the debate that we would have wished. Thus, the remaining

articles will be published together in the next issue (Volume 12, Number 4) which will in effect thus constitute Part II of the 2006 Thematic Edition. Space and necessity argue against our detailing here the content of that issue. However, the reader may be interested to note that in the edition which follows, we explore the possibility of both: (a) ideological and also (b) financial conflicts of interest, that may separately or together directly result in biases which act to promote the concept and practice of EBM by learned (and in the instance we describe, established and notable) journals, while at the same time suppressing dissent and debate. (Buetow *et al.* 2006; Upshur 2006) Such biases act to remove science from the forum of democratic argument into the realm of the spin doctor and thus out of the intellectual forum into a quasi-political milieu. Such phenomena call for urgent explanation, a process on which we embark in the next issue.

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