

EDITORIAL INTRODUCTION AND COMMENTARY

Continuing the evidence-based health care debate in 2006. The progress and price of EBM

Andrew Miles MSc MPhil PhD¹ and Michael Loughlin PhD²

¹Professor of Public Health Sciences & Editor-in-Chief, Journal of Evaluation in Clinical Practice/National Director, UK Key Advances in Clinical Practice Series, Bart's and The London, Queen Mary's School of Medicine and Dentistry, University of London, London, UK

²Reader in Philosophy, Manchester Metropolitan University, Crewe & Member of the Editorial Board, Journal of Evaluation in Clinical Practice, London, UK

Correspondence

Professor Andrew Miles
Bart's and The London
Queen Mary's School of Medicine and
Dentistry
University of London
c/o PO Box LB48
Mount Pleasant Royal Mail Centre
Farringdon Road
London EC1A 1LB
UK
E-mail:
andrew.miles@keyadvances.org.uk

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Introduction

In Volume 12, Part 3 of the *Journal of Evaluation in Clinical Practice*, we committed to the international medical literature a deposit of considerable scholarship on the evolution of the evidence-based medicine (EBM) debate and on the nature of evidence for clinical practice (Borry *et al.* 2006; Couto 2006; Dewhurst 2006; Djulbegovic 2006; Dobre *et al.* 2006; Geanellos & Wilson 2006; Gupta 2006; Leung & Johnston 2006; Lipman 2006; Loughlin 2006a,b; Kemm 2006; Maier 2006; Malterud 2006; Miettinen 2006; Miles *et al.* 2006; Porta 2006; Roddy *et al.* 2006; Sandars & Heller 2006; Stevenson *et al.* 2006; Tanenbaum 2006; Tonelli 2006; Upshur 2006a; Upton & Upton 2006). In the current issue, Volume 12, Part 4, we publish those articles that for practical reasons of space could not be included in Volume 12, Part 3, but where editorially judged urgency of publication precludes their being delayed until the 10th thematic edition on

EBM in early 2007. This Part II of the ninth thematic edition on the progress of the EBM movement therefore augments Part I (Miles *et al.* 2006) and the previous eight (see Miles *et al.* 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004). This *opus* having now been achieved, we again invite contributions to the 10th thematic edition for publication in 2007.

Scholarly clinical journals: do they always facilitate medical progress or can they sometimes suppress it? The example of the EBM debate

Recurrent themes in the contributions to this and previous thematic editions concern the apparent failure on the part of many advocates of EBM to explain and justify their most fundamental assumptions – about the nature of science, rationality and evidence itself, and how these key concepts may be put to work in the formulation of any defensible

view about proper medical practice. We believe that it is necessary for any intellectually serious analysis of the phenomena associated with EBM to explore and, if possible, attempt an explanation of this surprising omission on the part of defenders of so influential and pervasive a doctrine. Even the attempt to characterize EBM as a 'doctrine' may be challenged (Lipman 2006), but this difficulty in finding any consensus about what EBM *is* can itself be seen as one of the more puzzling of the phenomena crying out for explanation (Loughlin 2006c). Any author attempting such an analysis must be driven to consider not only contributions to the EBM literature, but also the processes that produce that literature – he must effectively take the debate itself as the object of his study and ask causal questions about how it comes to take the form it does. What forces drive the debate about EBM? What assumptions or interests give rise to or frame that debate? Why are some questions regarded as apparently unworthy of serious consideration and banished to the margins of debate by organs that (by general consensus) may be regarded as defining the 'mainstream' in medical discourse?

To address these questions, it will be necessary to consider the processes which affect publication practices in certain influential medical journals. In this context, it is therefore appropriate for us to discuss openly the processes which led to the publication of the first two papers in the current issue.

One of these (Upshur *et al.* 2006) poses in our view a necessary and, it would certainly seem, overdue question: 'Can scholarly journals be in financial conflict of interest situations?' Readers might imagine such a question to be purely theoretical, even somewhat ludicrous, given the level of trust built up over long years by periodicals of international stature. Recent events at the *Journal of the American Medical Association*, at the *Canadian Medical Association Journal* and elsewhere begin, however, to make questions relating to conflicts of interest in general, more than topical and essential to pose. In order to explain the Editor's rationale in commissioning and publishing such a paper, we would invite the reader to study, firstly, the juxtaposed paper contributed by Buetow *et al.* (2006).

It is now possible to document here that the substance of that particular article (Buetow *et al.* 2006)

was written, initially and relatively speedily, for publication in the *British Medical Journal* (BMJ), following that journal's decision to take, intentionally or inadvertently, the same position as the *Journal of Evaluation in Clinical Practice* (JECPC) in publishing a thematic edition on EBM (Straus 2004). **But while the JECPC has been noted for its impartiality and objectivity in publishing both so-called 'pro-EBM' as well as 'anti-EBM' articles, thus following the classical intellectual tradition, the thematic edition of the BMJ was characterized principally by its dramatically 'pro-EBM' stance.** Not believing that the BMJ could possibly simply be paying 'lip service' in inviting responses to its thematic edition, the authors (Buetow *et al.* 2006) submitted their article only to see it very swiftly rejected, despite the fact that it had directly addressed – and contested in lucid intellectual terms – many of the precepts and approbations of EBM that the BMJ had appeared selectively to favour for publication in its thematic edition. Indeed, the thematic edition of the BMJ had published an extensive number of so-called 'pro-EBM' views, while the only article expressing 'concerns' about the whole conceptual and practical basis of EBM had been relegated to the back of the BMJ and branded under the extraordinary heading *Personal View*. Buetow *et al.* (2006) subsequently contested the rejection of their article by the BMJ, understandably requiring, in these days of 'transparency' and 'accountability' (concepts, it must be noted, that the BMJ itself has seen fit to pioneer), a proper and fully rational account of the basis on which their article had been rejected. 'Lack of originality' was the reason given, yet the article had raised a considerable number of objections to the concept and practice of EBM that had not been considered by any of the articles selected for publication in the thematic edition of the BMJ on EBM. The reason for rejection given was therefore not accepted by Buetow *et al.*, who found it unsustainable for the reasons we have outlined. Thus, suspecting that the rejection of their article may have been the product of editorial bias (the potential nature of which we shall turn to below), Buetow *et al.* (2006) referred their objections to the Ombudsman of the BMJ who, by virtue of such high office, is able to exercise a final decision on such matters. The authors did not find surprising the decision of the BMJ Ombudsman that the initial editorial judge-

ment should stand. The Ombudsman is not an expert in the EBM debate, and therefore is not able to make a judgement on the intellectual content of EBM papers, but effectively an employee of the BMJ with a remit essentially confined to investigating whether proper editorial processes, including the processes of peer review as they are currently defined and understood, have taken place.

Peer review and the EBM debate

Now let us draw here a distinction between the processes of what is currently accepted as definitive and 'established' peer review and the actual effectiveness of such systems of peer review.

Anyone who believes in the possibility of intellectual progress agrees that a prerequisite for such progress is frank and open debate. This implies the possibility of genuine disagreements being aired – different and even contradictory viewpoints being brought to bear upon a controversy in the search for a resolution. Whether one puts the point in Hegelian terms (the necessity of consideration of both thesis and antithesis if a synthesis is to be achieved) or in terms of Mill's defence of free and open dialogue as 'the only unfailing and permanent source of improvement' in any human endeavour (Mill 1991), we take our basic point to be generally understood and accepted. Indeed, if any contributors to the EBM debate think that in this case open dialogue is *unnecessary*, and that the debate has already been settled, then we invite them to contact us explaining in clear and precise terms the time and manner of its intellectual resolution, since we find no evidence in the literature of any such resolution as having taken place at the time of writing.

Certainly, there is ample evidence that scientific progress is stifled where open dialogue is curtailed (Charlton 2000). We therefore regard it as absolutely essential that academic journals do not become *partisan* in their publishing policies. While it strikes us as wholly acceptable for an editor to have and express a position on a controversial matter (editors have viewpoints like anyone else and we see no virtue in their pretending otherwise), viewpoints contrary to the editorial line of the journal *must* be given full expression within its pages. Academic journals are the territory in which such debate takes place, and

this is why it is so important that they do not become the exclusive property of any given academic 'club'. They are the intellectual common ground which *must not* be circumscribed by any specific interests – be they financial, professional or ideological. This is the fundamental conviction underlying the above-mentioned policy of impartial publishing and it is our reason for commissioning commentaries on significant papers published in these pages and inviting the authors of original papers to respond to commentaries where appropriate. Were authors to get the impression that they needed to be 'on message' to appear in a 'credible' publication, this would, in our view, be immediately indicative of a climate of intellectual repression (Loughlin 2002).

To maintain such impartiality, it is necessary to be vigilant against possible abuses (witting or unwitting) of the peer review system. It is well-known that certain journal editors will preferentially select peers who are known to, or can be predicted to hold, given views of a paper or thesis, and if those peers understand they are at liberty to bring those views to bear in the synthesis of their judgement on the paper or thesis, then peer review can actually function to inhibit rather than promote scientific progress.

We, at the *Journal of Evaluation in Clinical Practice*, were greatly troubled by the observation of the rejection by the BMJ of Buetow *et al.*'s initial paper and have been concerned to examine the circumstances in the necessary detail. Accordingly, we commissioned, and contributed to, an article which set out to reflect on the matter. This brings us to the second paper in this Part II issue of the thematic edition on EBM 2006, the article by Upshur *et al.* (2006). In that paper, the hypothesis is advanced that some academic medical journals may find themselves in a financial conflict of interest position. In order to advance what might be termed 'proof of principle', on which more systematic study might be based, **the authors show the sheer extent of financial income that BMJ books, owned for many years until very recently by the British Medical Association (as is the BMJ itself) enjoyed through the commercial sale of a very extensive range of unashamedly 'pro-EBM' books and journals.** Indeed, the BMJ continues to lend its imprint to the promotion of the recently sold business and thus, we assume, continues to enjoy financial income from the sale of 'pro-EBM' books.

The authors hypothesize that scholarly journals can find themselves in conflict of interest positions when they operate business strategies which for commercial reasons may militate against the publication of articles which question the usefulness of the products being sold. Moreover, the authors advance the reasoning that the more extensive the merchandizing and the greater the commercial profits, the greater is the potential for conflict of interest.

EBM, ideology and ideologues

What, then, is the nature of the hypothesis advanced by Upshur *et al.* and considered in this Editorial? Are we insinuating wilful corruption on the part of individuals or a crude 'conspiracy theory'? However carefully we explain our position, some will choose to read us this way and dismiss our argument by knocking down its 'straw-man' facsimile. Lipman (2006) argues that EBM cannot be an 'ideology' for reasons which include the fact that it was not 'purposely designed by a sinister group of power-hungry conspirators'. We agree with Lipman that EBM was not the product of any such conspiracy. With regard to such phenomena as apparent biases in publication policies and the general climate of the debate about EBM, we prefer a type of 'invisible hand' explanation, owing more in its inspiration to the work of Adam Smith than that of Dan Brown. This does not show that EBM cannot be understood as a sort of 'ideology', nor does it imply that such a characterization of EBM can play no useful explanatory role in accounting for the development of the EBM debate.

With reference to the extensive literature on how an ideological 'consensus' can be 'manufactured' without any parties 'conspiring' to this effect, Upshur *et al.* (i) provide the theoretical basis for what we will term an 'ideological conflict of interest'; (ii) show how ideology can be linked to financial and other interests (again, without any crude forms of corruption or conspiracy necessarily coming into play); and (iii) raise the possibility that the current dominance of EBM is an illustrative case of a manufactured consent giving rise to ideological and financial conflicts of interest. Indeed, the authors argue that it would be 'naïve' in the extreme to assume that academic journals are axiomatically immune to processes and commercial

influences that are known to affect other published media.

There are many uses of the terms 'ideology' and 'ideological' in philosophical and social scientific literature, and it would be absurd for us to declare any one of them the correct usage, labelling all others incorrect. One use of the term 'ideological' in the context of the current debate is as follows. To say that a debate has ideological dimensions is to say that the parties bring to it assumptions of a fundamental nature which affect the way that they conceptualize the subject matter under discussion (Loughlin 2002). To say that someone is 'in the grip of' an ideology or is in fact an 'ideologue' is to say that he is either unable or unwilling to subject his fundamental assumptions to critical attention:

The ideologue treats his own basic assumptions as too obvious to need any clear explanation or defence. To such a person, the very fact that someone disagrees with (or even simply questions) his view is evidence that the dissenter has not understood. (Loughlin 2002)

This analysis has been applied in the explanation of the 'quality revolution' in management theory – a social phenomenon with profound effects upon the working lives of professionals in many areas, including health professionals (Loughlin 2002). Theories were developed that simplistically equated 'organizational quality' with the control of professional practice by a managerial class. The initial appeal of these theories no doubt had much to do with the fact that they served the career and political interests of certain groups, and the success of the 'quality movement' also owed much to the rhetorical properties of its defining term – for as defenders are never tired of pointing out, no one can be 'opposed to quality'. For this reason, the 'drive for quality' was able to win the vocal support of figures in government, irrespective of any coherent analysis of the real needs of organizations, let alone any sound argument or evidence that the 'quality movement' adequately addressed those needs. It serves the interests of politicians to be perceived as allied to ideas that are at once 'radical' and unquestionably good. As the movement developed, the assertions that formed its alleged 'theoretical base' changed with a rapidity that ought to have shocked anyone in the grip of the idea that this 'movement' represented any sort of 'scientific'

insight into the nature of good organization, as many of its exponents claimed.

Yet the more frequently such claims were repeated, and the more people became employed in the design and implementation of 'quality mechanisms' based in this purported 'management science', the more it seemed to many that the quality movement represented an unquestionable set of truths, such that the *questioning* of its unproven assumptions started to seem 'revolutionary' to some. In some management circles, the 'quality revolution' has become so 'mainstream' that the attempt to question it strikes its defenders as either frivolous or absurd, such that to do so is to be deemed 'out of touch' with the basic realities of life (Loughlin 2002). In this sense, 'quality management' has become an ideology: a set of dogmas, lacking in sound evidential or argumentative support, which encourage us to view the world in a certain way, and to practise accordingly – cooperating with every monitoring exercise and implementing whatever is the latest 'quality mechanism', without even pausing to question its rationale, because it is presented as an assurance of 'quality'. This ideology functions to serve the interests of many people: from the authors of the many 'quality' guides and handbooks, to politicians, senior managers and the growing army of non-productive employees whose work largely or entirely concerns the development and implementation of such mechanisms.

So, we can see how a network or family of interests can develop around a core idea, as the interests involved become increasingly interdependent: the more regulatory and monitoring mechanisms there are, the greater the demand for literature explaining how to negotiate such mechanisms in professional life, and the more employees will be needed to facilitate training days and other staff development events to acquaint staff with these 'new realities'.

Few, if any of these beneficiaries of 'quality culture' will regard themselves as parties to a conspiracy, but rather will see the need for quality as just too obvious to require a serious defence. The losers are, of course, the front line workforce and the users or clients of the organizations themselves, since the former, driven by the constant imperative to conform to the requirements of the dominant ideology, lack the autonomy, the time and frequently, the intellectual energy to think seriously about how best to meet the

needs of the latter, rendering organizations less, not more, responsive to those whose needs they putatively exist to serve.

We believe that a very similar process has facilitated the extraordinary success (in medico-political terms) of EBM. No one is opposed to evidence. Initial versions of EBM simplistically, and without argument, equated clinical evidence with evidence obtained from certain sources, primarily randomized controlled trials (RCTs). As the movement developed the assertions that formed its alleged 'theoretical base' changed with a rapidity that ought to have worried adherents (Tonelli 2006), yet many remained unperturbed by the shifting nature of the movement's fundamental 'insights'. Porta describes succinctly the complex network of interests that has developed around what seems to be an idea so simple as to be beyond question – that medicine should be 'based' on 'evidence':

Nowadays... it is mostly the pharmaceutical industry that can afford to run RCTs. As a result, the industry owns data which are fed, via epidemiologists and statisticians, to administrators and politicians in a circuit that tends to cut off the end-users: doctors and patients... EBM forms the basis for resource allocation, leading to a vicious circle... New treatments and procedures are tested, rigorously but very expensively, through RCTs whose costs are transferred to the final products. As new drugs, devices and equipment get increasingly expensive, rationing becomes more compelling. But the criteria to decide on reimbursement will remain based on empirical evidence. Hence, more trials will have to be run, resulting in more expenditure and so on. Layers of bureaucracy have been built on top of this. Involve yourself in an RCT and see how much paperwork goes into protocols, patient forms, registrations, approvals, amendments, notifications, monitoring, reporting, inspecting... a world has emerged in which EBM and its following of regulators and clinical research organisations have made themselves central to a circular mechanism, and thriving in it. (Porta 2006)

Despite the startling admission on the part of its defenders that EBM's fundamental claims 'lack evidential support' (Goodman 2003), EBM has easily

won the support of politicians, keen to be associated with an idea that seems (prior to a critical examination) at once simple, radical and unquestionably good. Along with 'quality management', EBM has been cited as a 'central plank' of government health policy (Halligan & Donaldson 2001). As with the 'quality theorists', we have seen that protagonists of EBM are not prepared even to consider the possibility that scepticism about their favoured theories might be justified. Indeed, we have noted their 'magisterial disdain of criticism' and their refusal to participate in learned debate, and have felt justified in describing such a position as both *unscientific* and *antiscientific*. The refusal of the protagonists of EBM to engage in scholarly debate takes two principal forms: (i) they typically refuse to reply to published articles which call loudly and with fundamental justification for them to answer their critics and; (ii) they typically never cite the published criticisms of their approach in their own articles. Take one of the earliest and most notable critics of EBM, Alvan Feinstein, for example. As an extraordinary intellect and undoubtedly a great leader in the field of clinical epidemiology, he is rarely, if ever, cited by the protagonists of EBM, an odd observation when one considers that one of the alleged 'central tenets' of EBM is to search for and utilize all available, relevant research (N. Goodman, personal communication). It is the ideological nature of the protagonists of EBM that would see the work of Feinstein, and that of many other leading scientists published in the *Journal of Evaluation in Clinical Practice*, as 'not relevant'. EBM acolytes are preferentially content to cite each others' opinions and *never* seek to refute those of their critics (Polychronis *et al.* 1996a,b). Instead, such criticisms are marginalized, appearing, if at all, as 'addenda' to the really 'relevant' debate, labelled 'personal' (to suggest, without argument, that they are somehow unscientific or subjective) or otherwise treated as too eccentric to merit an answer.

We have arrived at a moment in intellectual history when criticisms of dominant ideas can be dismissed, not because they have ever been demonstrated false, but because those with the power to shape and control debates (either because they own, or work for organizations that own, the media in which ideas are circulated, or in some cases they own the 'evidence' itself) regard these criticisms as simply

'not to our purpose' (Loughlin 2002). We ought to be a lot more worried about this than many current commentators appear to be.

'For Profit' or 'Not for Profit': can the truth be 'privatized'?

The truth cannot be defined with reference to the economic interests of any person, group or organization. If a debate or process of inquiry should prove to be circumscribed by such interests, this severely affects its credibility as a method for arriving at the truth.

In a world where the sources of evidence and the media are privately owned, we must be especially vigilant in maintaining the distinction between an impartial quest for the truth and a marketing strategy. Yet the current enthusiasm for EBM has led us to witness *product placement* in the pages of learned journals (Upshur *et al.* 2006), the unedifying spectacle of some doctors lusting for the false certainty of EBM (although not quite appreciating its falseness), other colleagues labelling everything they do in practice as 'evidence-based' and others unashamedly publishing books which in the title and in the content robotically repeat and recycle the prefix 'evidence-based'. There is no question, indeed it is incontrovertible, that such activities have dramatically escalated commercial profits. We ask: are some scholarly journals so heavily implicated in the activities of the EBM marketplace as to compromise their status as impartial sites for open debate? Have commercial forces begun to privatize the intellectual common ground? Such questions cannot be answered immediately here, and certainly not in the forum of an editorial introduction and commentary; indeed, such questions can be only *raised* at this juncture. At the time of writing, all we have are the observations that it has been possible to make, the preliminary interpretations that may be based on them and the justification to call for more systematic study of the hypotheses that are advanced both here and in some of the constituent papers of this issue. Nevertheless, the reader may wish to reflect carefully on what has been hypothesized and discussed here in relation to the ideological and financial basis of the EBM phenomenon. The reader is referred to the Editor's Note on p. 395.

The hard art of soft science: evidence-based medicine, reasoned medicine or both?

In the third paper of this Part II 2006 thematic edition on EBM, we move to a contribution from that spiritual home of EBM, McMaster University, Canada, the birthplace of Sackettism (Miettinen 2003). In his contribution entitled 'The Hard Art of Soft Science – Evidence-based Medicine, Reasoned Medicine, or Both'. Jenicek (2006) argues that in the last 14 years, EBM has enjoyed unprecedented development and gained widespread acceptance among health professionals. While we agree that EBM has enjoyed unprecedented publicity and has had strangely hypnotic effects, we do not agree that it has achieved widespread acceptance among professionals and it has most certainly not received universal consent, despite its very clever marketing strategies. Nevertheless, Jenicek questions whether we should 'continue pushing forward along this promising path or (whether we) should . . . further diversify the content and scope of EBM'. He wonders whether EBM is 'the only way to view medicine in the near future' and wonders whether 'more intensive and extensive EBM combined with "other features"-based medicine', may be the preferred strategy to follow, in order 'to determine (the) development, uses and evaluation of EBM'. With these questions and reflections in mind, Jenicek (2006) advances the concept of 'argument-based medicine', which he seems to equate with 'reasoned medicine', as an option that might be integrated into the mainstream of medical reasoning and decision making. Specifically in order to examine Jenicek's more original points, we commissioned two editorial commentaries on his article and publish these immediately following Jenicek's work.

In the first of these, Upshur (2006b) draws on the concept of biblical hermeneutics, which this author considers of relevance to his commentary, given the disturbing similarities between the EBM movement and the so-called faith-based movements. Indeed, he notes the growing volume of literature describing the ascendancy, triumphs and positive benefits of EBM, despite the fact that EBM has shown itself repeatedly and thus typically incapable of meeting its own standards of proof. Additionally, he notes its continuing refusal, or inability, to address the litany of serious

intellectual and clinical criticisms that have been levied against it. While finding much of interest in Jenicek's article, Upshur (2006b) views this work as symptomatic of the ongoing confusion within the EBM literature. Indeed, the author rightly observes that there is now no shortage of colleagues arguing for a preferred view of what EBM is or is not and, as a consequence, we have a proliferation of many perspectives of what EBM may be. As Upshur (2006b) notes, these are by no means identical visions. Who, then, are the 'true' proponents of EBM? This, for Upshur (2006b), constitutes the hermeneutic difficulty as it relates to standards of determination, although he is tempted to conclude that 'EBM' has no core meaning.

The second commentary (Loughlin 2006c) picks up on Jenicek's lack of clarity and consistency in the use of his own key terms and in the nature of the thesis being defended. The commentary brings out the striking similarities (alluded to above) between work on EBM and work on 'quality' in management theory. Jenicek repeatedly asserts that EBM is 'unquestionably the right approach to follow in medicine wherever and whenever possible' and that its 'growing acceptance . . . is more than justified'. But having advanced these opinions, the author follows almost immediately by posing questions as to what EBM really is and what the protagonists of EBM mean by 'evidence'. How can Jenicek assert: 'now that we have adopted EBM as one of the best available ways to practise medicine, we should evaluate if it works and how it works'? How is it that he can then go on to ask – having asserted that EBM is one of the best available ways to practise medicine – : 'Do our patients benefit more from the EBM approach than from its alternatives?' and 'Are our EBM approached patients better than those under any alternative care?' The central thesis appears to be that while EBM is 'correct', it is by no means certain what EBM is – a somewhat puzzling conclusion!

Jenicek's work may be seen to provide an illustration of the processes considered in the first part of this editorial. His stated intention is to raise serious questions about EBM. Yet, perhaps to appear reasonable, or balanced, and to avoid being labelled absurd or extremist in his criticism, he seems compelled to preface all attempted questions about the validity of EBM with an acknowledgement of its

undoubted superiority. He has worked in environments where anything short of absolute enthusiasm for EBM is enough to mark out a commentator as 'out of touch', and in any intellectual environment so effectively warped by ideological constraints, one must begin by paying homage to the dominant ideas as the price of entry to the debate, even when one wishes to go on to question these ideas in some respect. Yet to anyone not steeped in the intellectual culture surrounding EBM, this makes the paper a perplexing read, full of apparent tensions or even contradictions. So the commentary (Loughlin 2006c) concludes that it is 'astonishing' that an academic 'movement' can 'be declared unquestionably right' even by those purporting to raise questions about it, and invites Jenicek to take a clearer stance on the fundamental questions his paper hopes to raise.

There is a similar confusion, albeit much reduced in extent, in the short article by Lake (2006). This author, writing from the perspective of 'a clinician previously unaware of the degree of controversy ... (over EBM)', sets out much that might be termed 'clinical commonsense'. He reflects on the nature of the doctor-patient relationship, the obligations due to the patient and the profession under the Hippocratic Oath, the management of clinical uncertainty in the face of the individual patient (now a 'health care consumer') and on the nature of evidence for clinical practice. He is clear that medicine is not now, and never has been, an exact science, meaning that medicine cannot therefore rely on pure reasoning based on clinical studies. Indeed, he asks of those who would disagree: 'Why pretend?' Inexplicably, with reference to his earlier writing, Lake (2006) concludes by advancing the view that 'joined-up thinking is necessary to ensure that EBM continues to be properly implemented through wise and extensive application whilst avoiding an insistence upon slavish and unquestioning adherence to its precepts'. He believes that this 'process' can be realized through ensuring that 'the practice of EBM is firmed up without necessarily hamstringing the doctor, to deliver the right balance, ensure safe and effective care and embrace in conjunction other approaches to the same end ... (becoming) ... transmogrified and ... all encompassing to a composite EBM ... (to) ... deliver benefit to all patients' (Lake 2006). It is for this reason that we juxtapose this paper with that of

Jenicek (2006), in order to illustrate the nature of a confused type of thinking on the EBM debate to date, which can sometimes seem characterized by a lucid appreciation of the inconsistencies and errors of the ongoing EBM philosophies, while feeling the necessity to say: 'it would be great if EBM were different and therefore it should change a lot so we can implement it'. At some level, authors have internalized the idea that one cannot, simply, be opposed to EBM (any more than one could be against 'quality'). An ideology is deeply pervasive when it is seen to be in influence even in the writing of those attempting to question or critique it. This illustrates the extent to which many commentators are 'in the grip of' EBM ideology and the struggle that lies ahead if we are simply to achieve clarity on these issues. Much of what Upshur (2006b) and Loughlin (2006c) criticize in the article by Jenicek (2006) can therefore be applied to the concluding section of the paper by Lake (2006).

We move next to two contributions from De Simone (2006a, b). In these most interesting pieces, the author believes that the debate on EBM is actually the 'tip of an iceberg'. He notes that reductionist and postmodernist mindsets competitively coexist in science and society. For De Simone (2006), from a postmodern stance, EBM is observed to have crucial flaws, specifically with reference to its inability to appreciate and tolerate contrasting ideas and therefore in its ability to 'see a bigger picture', and he goes on to illustrate how certain characteristics of such a 'bigger picture' may be described.

External validity, expiration dates for systematic reviews and 'real world' versus trial-setting evaluations

We move in the second section of this issue to three papers which are concerned, essentially, with methodological aspects of synthesizing and interpreting evidence for clinical practice. In the first paper, Persaud & Mamdani (2006) are concerned to discuss the external validity of studies which they believe to be a neglected dimension in evidence ranking. They conceptualize the asking of typical questions by clinicians such as 'what treatment plan will best help my patient?' with the subsequent review of available options and where the options, which may be

described as ‘interventions’, have been graded according to ‘levels of evidence’ which typically place RCTs at the top of the list (‘Level 1’) with cohort studies then following (‘Level 2’) and case control studies ranked lowest (‘Level 3’). As Persaud & Mamdani (2006) point out, such ranking systems define the so-called “strength” of evidence primarily on the basis of internal validity, with external validity being generally viewed as a ‘second order’ concern which is best considered when applying the evidence and therefore best left to the individual clinician to consider rather than being incorporated into wider considerations in relation to the applicability of the intervention to specific patients. Following an informative review of the nature of internal and external validity and the indispensable nature of both when considering the effectiveness and appropriateness of interventions for direct clinical application, they advance their view that current evidence-ranking systems would be improved if they considered evidence in these two dimensions, leading to the position where only interventions supported by evidence with high internal validity *and* evidence with high external validity were selected as appropriate for clinical practice. Importantly, they point out that these latter studies would usefully address, for example, baseline prognosis in subgroups traditionally under-represented in RCTs and in the general population of patients outside of the specialized centres where trials are most frequently conducted. Moreover, these authors are clear that contextual issues (and they give the important example of operator skill) can be addressed with non-experimental designs. In this context, they remind us that observational studies have the very real advantage of enabling the study of ‘real’ clinical scenarios with the potential to provide immediately applicable findings.

Moving on from this consideration of internal and external validity of studies and its importance for clinical practice, we turn to Barroso *et al.*’s article on ‘time and timeliness’ as key issues in appraising and ensuring the clinical relevance of systematic reviews (Barroso *et al.* 2006). The authors note the growing reliance on systematic reviews as being evident not only in the volume of such studies being published in the literature, but also in what they rightly describe as the ‘burgeoning instructional and advice literature’, which includes, but is by no means restricted

to, the products of the Cochrane Collaboration and publications such as *Clinical Evidence*, and so on. With this observation in mind, Barosso *et al.* (2006) importantly point out the importance of the consideration of ‘time’. Indeed, they note that reports of systematic reviews usually include information relating to the dates of retrieval and publication of the reports selected for review but that, typically, it is not at all routine for such studies to provide information on, for example, the interpretation of review results and discussions on the overall relevance of the review to current clinical practice. It is these, and other observations, that the authors consider in their paper, enabling them to conclude that time is a key element that is not always but should inevitably be managed throughout the trajectory of the systematic review process as a means of ensuring clinically relevant research syntheses. Their description of time considerations as being integral to: (i) the formulation of the research question; (ii) the setting of parameters for search and retrieval of studies; (iii) the determination of inclusion and exclusion criteria; (iv) the appraisal of the clinical relevance of resulting findings; (v) the selection of the findings that will be synthesized; and (vi) the interpretation of the results of the synthesis, are timely and relevant. We agree with Barosso *et al.* when they emphasize the need for authors of systematic reviews to agree rapid publication of such reviews as a means of reducing the interval between submission of a completed review and its publication as a means of ensuring timeliness. This consideration is of no small relevance when one considers that most systematic reviews (and often the practice guidelines that derive from them) are frequently out-of-date, and therefore of questionable relevance, by the time they appear in the literature.

The final paper of this section presents a comparison between integrating clinical practice setting and RCT setting into economic evaluation models of therapeutics. For Farahani *et al.* (2006), the results of cost-effectiveness analyses generated from RCTs obtained under ‘ideal experimental conditions’ (efficacy) and the applicability of those data to ‘real world’ settings (effectiveness) may be problematic. As these authors remind us, there are fundamental differences between the design and conduct of RCTs and the evaluations in the ‘real world’ that will fol-

low. Indeed, in RCTs, the efficacy of the given drug is evaluated in an idealized clinical environment, applying narrow eligibility criteria and with the exclusion of patients with co-morbidities, the elderly and children. Moreover, the experimental treatment strategy is fixed (by design, by drug dose, etc.) and therefore in great contrast to community-based studies where 'real life' situations prevail through the potential involvement of a wide spectrum of patients, broad inclusion criteria and limited exclusion criteria. In order to explore the effects of these factors on the results of economic evaluation, Farahani *et al.* (2006) compared cost-effectiveness results derived from a RCT setting with the results obtained from community-based clinical practice, using data generated by a community-based cohort study and from a RCT. Two cost-effectiveness analyses were conducted with incremental cost-effectiveness ratios calculated for the use of etanercept in the treatment of patients with rheumatoid arthritis. Perhaps unsurprisingly, clinical setting was observed to be a pivotal determinant of the result obtained, directly assisting the explanation of the difference in cost-effectiveness reported in previous modelling studies, some of which were based on RCT assumptions and some of which were based on an effectiveness setting.

Conclusion

We are thus able to conclude Part I and Part II of the 2006 Thematic Issue on EBM of the *Journal of Evaluation in Clinical Practice*, by noting that 'evidence-based medicine', or 'evidence-based health care' or 'evidence-based decision making', or 'evidence-based ethics', or 'evidence-based practice', or 'evidence-based research' or 'evidence-based teaching' are all, *ad nauseam*, founded on 'a basic conceptual and epistemological error, so-called disciplines and approaches to practice which combine bogus science with manufactured evangelical zeal, hiding their own massive confusion behind spectacular flourishes of gobbledegook'. Indeed, they bear all of the cardinal features of intellectual bankruptcy exhibited by the so-called 'quality' theorists (see Loughlin 2002). That a range of educated colleagues can be excited by such neologistic and inflationary linguistics is both astonishing and highly depressing and directly illustrative of how hypnotic and seduc-

tive the rhetorical force of the prefix 'evidence-based' remains. Indeed, subsequent to the identification in Part I of this thematic edition (Miles *et al.* 2006) of the latest abuse of the prefix 'evidence-based' within the construction 'evidence-based research', the reader may be excited (although we hope otherwise) to note that the BMJ has advanced the concept of 'evidence-based knowledge' (Anonymous 2006). Indeed, while this observation adds further and substantially to our argument on the vacuous use of the phrase, the reader may be simultaneously entertained by noting that the BMJ identifies the power and utility of this novel concept and practice with reference to a study on nipple stimulation and its association with sexual arousal in men and women. Indeed, the new 'evidence-based knowledge' reveals to us that in a questionnaire administered to 301 sexually experienced undergraduates, 82% of women and 52% of men found the manipulation of their nipples sexually arousing, while 7% in both sexes reported that this particular activity decreased their libido. An interesting new concept and practice, then, and one most usefully applied following its definition? So much for 'evidence-based knowledge', although we look forward greatly to the documentation of further examples of its nature and application.

We agree with Ofri (2006) that medicine is not a science in the same way as physics, for example, where there exist absolute laws from which deviation is not possible. Indeed, as she points out, medicine is almost the living antithesis of this, where the biological variability of disease, and the human condition more broadly, make such an assured and idealized rationality almost laughable. She provides the useful example of diabetes where 'there has been enough written ... to sink a galleon, but (where) there is no invariant law that will predict exactly what will transpire in (the) patient with his unique constellation of glucose control, pulmonary pathology, drug absorption, cultural expectations, financial constraints and personality quirks' (Ofri 2006). She is clear that EBM 'will continue to scour the murky corners of medicine like an NIH-anointed Hoover vacuum cleaner', but that 'despite what doctors and patients wish to believe, medical science will always be an asymptote ... never fill(ing) the infinite space created by the variety of human health and pathology'.

Montgomery (2006), on whom Ofri commentates, is clear that 'science is the tool, rather than the soul of medicine', and that it is 'neither a science nor an art (but) a distinctive, practical endeavour whose particular way of knowing . . . qualifies it to be that impossible thing, a science of individuals'. Given this, the description of medicine as science is a fundamental *misdescription*. Since such misdescription continues to be perpetuated by the EBM camp as part of their ideology, it is worth reiterating that fundamental truth which we have previously advanced; that few questions in clinical medicine are 'scientific' in the sense intended by EBM enthusiasts and therefore cannot be answered by science as they understand it (Miles *et al.* 2002). Medicine, even in the face of its massive technological, pharmacological and biological progress, remains, as always, a human activity which is not a science but rather an activity which employs science (Battista *et al.* 1995; Jacobson *et al.* 1997; Kenny 1997; Helman 2006; Szczeklik 2006). With the complex nature of clinical practice being thus conveniently described as both science and art, it becomes indispensable to evaluate and develop medicine with proper reference to both 'components' and not simply to one or the other. The portrayal of doctors as scientists is therefore an inaccuracy which threatens to obscure the defining character of what it is to be a 'good doctor'. We have previously advanced our view, and do so again, that to proceed to define and develop medicine with reference to a reductionist, biomedical, scientific paradigm, represents nothing more than a 'science fetish', that exalts probability values and denigrates clinical expertise and which reaches its orgasm in the cumulative meta-analysis of quantitative studies. Practising clinicians continue to be wise in rejecting such narrow scientism – and the pseudoauthorities that promote it – and do well to continue to consider a wide variety of sources of clinical knowledge in the compassionate care of their individual patients.

We reiterate our view that the way forward is not 'evidence-based medicine' as described as part of Sackettism (Miettinen 2003), but rather knowledge-based medicine (see Malterud 1995, 2001, 2002, 2006; Miettinen 2004a,b,c,d) and we look forward to the construction of the 10th thematic edition on EBM which will have as its basis a detailed exposition and analysis of this direction.

Editor's Note

In concluding the editorial to Part I of this thematic edition on EBM (Miles *et al.* 2006), we promised that, in Part II, we would explore the possibility of financial and ideological conflicts of interest acting to promote the concept and practice of EBM and announced that two of the articles to appear in the forthcoming and now present Part II issue of the JECIP (Buetow *et al.* 2006, Upshur *et al.* 2006) would raise questions about the interests that may give rise to biases in publication practices in learned and particularly prominent medical journals. As we go to press, we note that the most recent issue of the BMJ contains an article (Lexchin & Light 2006) and an editorial (Godlee 2006) on the issues of conflicts of interest and commercial bias in medical journals, published subsequent to our announcement. We note similar moves to discuss conflict of interest positions subsequent to our announcement by leading protagonists of EBM outside of the UK. Whether or not our announcement was causal or has been coincidental in this context we are unable to determine at the time of going to press. Having studied this material, we feel no need to make any changes to the current Part II thematic issue of the JECIP, since we find that the analysis presented here, and the associated substantive argumentation, is unaffected by the observations made in the articles in the BMJ. Indeed, we are delighted that our declared intention to pursue this subject matter rigorously has been followed so swiftly by the publication of these articles and conflict of interest statements and we look forward to the full and frank exchange of ideas that we hope this development will precipitate.

Apology

The Editor apologises unreservedly to Dr. Stephen Buetow for the accidental omission of his Commentary on Tonelli (2006) from Volume 12 (3). Dr. Buetow's article is included in the current part (Buetow 2006, pp. 427–432).

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