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EDITORIAL INTRODUCTION AND COMMENTARY

Evidence-based healthcare, clinical knowledge and the rise of personalised medicine

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Introduction

In the 10th Thematic Edition within Volume 13 of the *Journal of Evaluation in Clinical Practice* published in August 2007 [1], we made reference to the decade-long period over which the *Journal* had systematically contributed to the international discussions on the theoretical foundations and practical applications of evidence-based medicine (EBM) and indicated our determination to progress the debate in the direction of an eventual intellectual resolution. In accordance with that statement of scholarly intent, we are gratified to commit in this 11th thematic edition of the JECP, some 53 papers which either reflect upon or directly illustrate current thinking on EBM and we structure the Edition into three delineated parts: Part One (Philosophy and Concepts – 24 articles); Part Two (Clinical Attitudes to and Understanding of EBM & Guidelines Use/Implementation – 19 articles) & Part Three (Progress in Methodology & Statistics – 9 articles). We therefore advance the current Edition as a major stimulus to epistemological, ethical, methodological and clinical debate on the nature of evidence for clinical practice and commit this Thematic Issue to the international literature on knowledge in Medicine.

To those colleagues who suggest that the EBM debate is 'over' or that 'the argument is won', we say: 'no, it is not' and 'no, it has not been'. Indeed, at the time of writing, no author has been able convincingly to show the superiority of the EBM 'approach', 'paradigm', 'methodology', 'philosophy', 'system' or 'process' and neither has it been demonstrated that EBM is 'unquestionably the right approach to follow in Medicine, wherever and whenever possible' or that it is the 'only way to view Medicine in the near future', such that assertions that 'anyone in Medicine today who does not believe it is in the wrong business', remain what they originally were – expressions of bald rhetoric and intellectually bankrupt hyperbole [1–6].

We view with no small dismay and profound disappointment the continued refusal of the protagonists of EBM to engage in formal intellectual exchange, a position which represents nothing more than the long maintenance of an unscientific and antiscientific posture [7] which we have come to interpret as a pragmatic mechanism designed to protect the cherished ideological convictions of the EBM community (see Loughlin [8]). If these colleagues view their settled positions as intellectually defensible and morally justifiable, then why are they so utterly opposed to confronting their critics? Why do they recoil from entering the intellectual forum of the JECP, the 'lions' den', as it were, in order to justify the generalities and specifics of their thesis, if they believe them to be so eminently justifiable? We advance that the reason they desist from doing so is multifaceted. Certainly, they continue to show the magisterial disdain of criticism that we have noted on multiple occasions previously and which more accurately characterises the modern politician than the intellectual [7,9,10]. But there are, surely, other reasons in addition. Amongst these is, we believe, a fundamental inability to mount a sustainable intellectual response to the JECP's arguments against EBM in terms of the nature of science, medicine, knowledge and authority and the need to conceal that inability in the interests of dogma and political progress.

Such a position is shocking in intellectual terms and reflects badly on the scholarship and personalities of EBM's leading

protagonists. In sequential thematic editions of the JECP we have called again and again upon a range of scientists to engage in proper discussions on the theoretical basis of EBM, with reference to the ethos, spirit and imperatives of their scientific training and medical professionalism. The luminaries of EBM have consistently declined to respond. We anticipate that these colleagues' scale and extent of journal reading and literature searching – a central tenet of their 'method' – cannot possibly have led them accidentally to overlook ten volumes of the JECP's contribution to the debate that they themselves originated. But the single most important reason of all for this continued silence is, perhaps, the fact that EBM has been effectively sidelined and marginalised by significant developments in patient-centredness and its methods and by recent progress in genomics and translational science that are leading to what is increasingly described as *personalised medicine*. Attempts to associate EBM with these developments in conventional Medicine – as if they have always been somehow integral to EBM and a perfectly natural part of the evolution of the 'new paradigm' so that we now have 'new EBM' – are extraordinarily lacking in intellectual credibility, are profoundly revisionist and demonstrate that little has changed in terms of EBM's ideology or hubris with the exception of an increase in self-delusion and a refusal to accept that EBM is 'finished' in scientific, philosophical and clinical terms. We hold this observation up to the international medical community with the invitation that it draws its own conclusions accordingly in this context. We will reflect further, and in some detail, on such matters in the General Discussion, but first let us now move to a consideration and review of the individual papers that collectively constitute the current Opus.

Part I: Ongoing philosophical and conceptual arguments within the international EBM debate

EBM and the Tree of Knowledge

In the opening article of the Edition, Saad begins by re-iterating that most fundamentally relevant of questions: 'Do we have any evidence that EBM indeed improves clinical outcomes?' [11]. As he notes, the question was initially posed by the Evidence-based Medicine Working Group itself some 16 years ago [12] and has been asked by a muliplicity of authors ever since with the answer grudgingly given, but on rare occasions, in the negative. What, then, is the significance of this observation? It is that an idea has been recommended for wholesale implementation into health services in the absence of any firm theoretical foundation such that, as Saad points out, 'no one really knows how many people owe their lives to EBM, just as no one really knows how many have died because of it'. In order to commence the exposition of his thinking, Saad introduces the reader to his sceptic who asks: 'Aren't you all chasing your tail? What is this "evidence" that you're looking for?' Saad's response is simple: '. . . (the) results of a specific randomised controlled trial in which two groups of doctors are studied: one is trained by the methods of the traditional paradigm, and the other, by evidence based education'.

We agree with Saad's sceptic that interpreting the results of such a trial is likely to be more difficult than carrying it out. That is no reason in itself to avoid working towards some sort of trial design. As Saad points out, the definition of EBM advanced by its protagonists involves the integration of 'individual clinical expertise with the best external evidence from systematic research' [13]. It has always been clear that the EBMers have held quite different conceptions of expertise from non-EBMers and that the definition of what constitutes evidence for direct application in clinical practice has also differed substantially. So there is a basis for characterizing two quite specifically different interventions as part of a head to head trial. Saad also suggests mortality and morbidity and the costs of treatment as important clinical outcomes for use in such a trial, but while such quantitative measures of treatment outcome are undoubtedly pivotal, the more qualitative assessment of outcomes from the so called 'art' of Medicine are equally of considerable importance in the determination of the superior efficacy of the one intervention over the other. Among these we include the application and use of listening, compassion, re-assurance and consolation and understanding of patients' hopes, fears and anxieties [14–16], many of which are neglected in clinical practice by the EBMers whose continuing biomedical reductionism leaves little room for their exercise, but all of which are utterly characteristic of 'traditional' and what we would unashamedly refer to as 'good' Medicine [1,14–16]. While we are enthusiastic to progress the thinking on how such a trial design may be perfected, applied and its results interpreted and call for papers on this matter for consideration of publication in the 12th Thematic Edition of the JECP, we appreciate that this is not the principal concern of Saad's paper. To consider the 'evidence-based paradox' he advances and whether his use of the terms 'paradigm' and 'scepticism' are philosophically sustainable, we turn to his commentator in the article which follows.

Loughlin [17] takes immediate issue with Saad's use of the term 'the EBM paradigm', noting that most EBM authors who appropriate this term make only a perfunctory reference to Kuhn's usage within *The Structure of Scientific Revolutions* [18]. To qualify as a 'paradigm' in the sense determined by Kuhn, EBM would need to have developed a detailed theoretical structure with explanatory power and substantial empirical corroboration – which it has not [1,3,19,20]. But Loughlin's main target is Saad's 'Sceptical argument' which 'risks letting EBMers off the hook more gratuitously than the uncritical adoption of their affected use of Kühn's terminology' [17].

Saad's posited sceptic constructs a dilemma for those of us 'who advocate putting EBM to the test' in terms of the criteria EBMers regard as the 'gold standard' [17]. Depending on its outcome, the proposed clinical trial to determine whether EBM improves clinical outcomes either undermines itself (by undermining its own epistemic basis) or it proves nothing (due to being part of a circular argument). On the one hand, if the results obtained from the EBM arm of the trial were inferior to the 'Traditional Medicine' arm, Saad's sceptic would declare this result 'difficult to interpret', reasoning that 'if it is incorrect to use evidence from systematic research, then it is incorrect to use the evidence from *this* trial' [11]. On the other hand, if the results showed superior efficacy of the EBM approach over 'Traditional Medicine', Saad's sceptic would point out that the significance of this outcome depended on the prior assumption 'that you should use the results of *this trial* in clinical decision-making', rendering the argument 'circular' [11]. But Loughlin notes that both 'horns' of this dilemma 'are blunt' [17]. Considering the first possibility (inferior outcomes for EBM)

he notes that in this case EBM would have failed in terms of its own criteria of evidence, rendering the claim 'that we should use EBM in clinical decision making' a directly self-defeating proposition. In declaring such an outcome 'difficult to interpret', Saad's sceptic seems strangely unfamiliar with centuries of reasoning espoused by sceptical philosophers [21,22] who relied on the fundamental point of logic, that 'if a proposition implies its own falsehood then we have grounds to think it false' [17]. Considering the second possibility, (superior outcomes for EBM) in dismissing its significance Saad's sceptic again appears ignorant of the history of ideas. Reminding us of Hume's demonstration [21] that basic inductive reasoning (predicated on the belief in universal causality) could not be 'proved' in a non-circular manner (because it is so fundamental in nature that any evidence in its favour only counts as evidence on the assumption of its truth), Loughlin notes the profound effect of this demonstration on subsequent debates in epistemology and the philosophy of science. If by 'proof' we mean the demonstration that a claim is 'a logical consequence of irrefutable evidence' then very little can be 'proved', but according to all plausible positions in the philosophy of science, a positive outcome for EBM in such a trial would greatly enhance its scientific status. On Popper's account of the logic of scientific discovery [23], a major exercise in falsification would, in this instance, have been applied and resisted, substantially enhancing EBM's status as a scientific theory, while refusal to subject it to such tests negates its scientific status. However, Loughlin believes Saad's use of the 'sceptical argument' to be much more subtle and philosophically significant than the argument itself. In the section of his paper that is devoted to the essence of clinical trials and how their results influence and modify clinical practice, Saad neatly articulates the fact that the value of the results of any clinical trial in routine clinical practice depends on the interpretations and intuitions of the doctor considering the use of them within his individual patient. In this sense, Loughlin believes the comparison with Adam and Eve to be more than appropriate, reminding us of the general and ancient epistemic problem that Saad elegantly highlights: that it would be futile for Eve to search for a meta-tree to direct her decision as to whether she should eat of the Tree of Knowledge or not. Indeed, all humans face essentially the same 'generic dilemmas': which sources of knowledge to trust and to what extent to make use of them in the specific circumstances we encounter. As Loughlin says, no formal guidelines can obviate the need for intuition (a subject to which we turn a little later in this article) because any single criterion, set of guidelines or protocol presented and available to us must be evaluated by each of us as to its suitability for informing our decisions in satisfaction of our need(s) within the contexts of given scenarios. It is here, perhaps, that intuitive responses are regarded as increasingly relevant if not completely indispensable; certainly for us, and to quote Saad directly, 'it is intuition the whole way down' [11]. Once we have appreciated the points about intervention and the role of intuition, we are in an altogether better position to understand the challenge that Saad's sceptical position presents. Indeed, for Loughlin, it is futile to contribute to the EBM debate unless one frames that debate with reference to the commonsensical and overwhelmingly plausible points of epistemology that Saad's 'Tree of Knowledge' analogy encapsulates. However, he is equally clear that if Saad's argument succeeds, then it has implications for both critics and advocates of EBM.

Indeed, the lack of evidence for EBM is certainly a highly significant deficiency in arguments which (continue to) advocate its implementation into health services, but for Loughlin a more significant deficiency is, perhaps, not so much the empirical problems of EBM, but the conceptual – the entire manner in which the exponents of the 'EBM paradigm' construe the processes of knowledge, the relationship between research evidence, understanding and practice, such that the profound, indeed terminal, problem for EBM is philosophical [1,24]. It is its lack of a firm position in medical epistemology and the failure of EBM's advocates to concede the intellectual necessity to explore the processes of medical knowledge as they relate, for example, to such vital and under-researched factors as the role of tacit knowledge in medical education and clinical practice that are representative of fatal deficiencies. To remain focussed *solely* on the lack of trial evidence for EBM's superior or inferior efficacy is thus, as Loughlin says, to view clinical practice *solely* through the lens of trial results and thus to enter into or remain within the epistemic 'cage' of EBM. So what, then, of the 'consequences' of Saad's argument for defending EBM? For Loughlin, these are 'far more ominous'. If, for example, the EBM arm of the hypothetical trial had demonstrated a superiority of the EBM approach over the Traditional Medicine approach, EBM would still fail in its own terms, given Saad's argument about the need for intuition 'all the way down' [11], especially at the point where theoretical medicine meets the individual, ill or desperate patient. It is indeed difficult here to predict or understand how anyone working within the 'cage' of EBM to which Loughlin refers, could deliver credible answers to the three salient questions which Saad advances in the conclusion of his article. It is precisely because Loughlin finds it intellectually impossible to work within the positivistic straightjacket that EBM protagonists either directly prescribe or implicitly refer to when challenged to justify their position [25,26], that he is able to escape the second 'horn' of the sceptical argument identified above and thus to defend EBM against the claim that a positive outcome from the EBM arm of the hypothetical trial would be insignificant. Ultimately, Loughlin does not believe that Saad's sceptic establishes his point, but he remains clear that the sceptic's position is worthy of careful consideration – not least because in order to address the sceptical argument, it is necessary to reject the assumptions about science and rationality which the EBM approach embodies.

EBM, the Academy and clinical practice: notions of hierarchy, dominance and resistance

We move next to the article by Isaac and Franceschi [27] and the two associated commentaries [28,29] and one Essay [30] which reflect on all or part of it. For Isaac and Franceschi, the overemphasis of EBM on the use of quantitative research findings in clinical practice of its nature stimulates debate between researchers and clinicians on the role of expertise and patient values in making decisions about the care of patients. The authors note that the protagonists of EBM are convinced mistrusters and suppressers, as it were, of qualitative knowledge [1,24] and view EBM within Foucault's description of power/knowledge practices, as an attempt to normalise and regulate knowledge/power production, but one which, at the time of writing at least, is liable to usurpation by the resistance of individuals who reject the empirical, modernist practice of EBM. Constructing a framework based on postmod-

ern theoretical concepts, the authors proceed to examine patterns of discourse, subjectivity, resistance and power/knowledge within the specific context of the physical therapy profession. Isaac and Franceschi seek to illustrate the 'revolving relationship of power', arguing for the displacement of an oppressive hierarchy in favour of contextual interaction between individuals and organisations. For them, the blurring of modernist and postmodern practices 'does not sustain an emancipatory movement' and the objective is to open and sustain dialogue within epistemological boundaries. Thus, their vision is to redefine EBM as a 'circular integration of best research evidence, clinical expertise and patient values', concluding that 'resistance to the hierarchical discourse broadens medical knowledge and produces mixture and collaboration rather than opposition between researcher, clinician and patient'.

Meta-theory, change and EBM

Opening his Commentary on Isaac and Franceschi, Stephen Buetow [28] recalls Berwick's view of EBM as having created 'a wall that excludes too much of the knowledge that can be harvested from experience' [31] and sees the authors' article as implying a breaking down of the fortified wall of EBM in its description of an 'epistemological duel between the modern and postmodern discourse in medical practice'. In response, Buetow's questions are simple: '. . . is EBM today still a walled construction?' 'Does . . . (EBM) . . . perpetuate a hierarchical discourse of medical knowledge . . . that produces opposition rather than collaboration between researcher, clinician and patient?' and '. . . when is it possible to blur epistemologies?'. Pertinently, Buetow asks that – even if this last question commences a step late by focussing on epistemology rather than ontology – is it really legitimate to blur the metatheoretical positions within which modern and postmodern epistemologies operate? And it is on each of these questions that Buetow meditates in his analysis of Isaac and Franceschi's paper. Having done so in a short but penetrating treatise, Buetow concludes that – although at first reading Isaac and Franceschi appear to have advocated a middle way, as it were, between modernist and postmodernist practice – this appearance is, essentially, illusory. He is convinced that the authors are in all respects postmodernists whose undeveloped 'solution' is postmodern and extreme, not least in its apparent faith that modernist and postmodernist boundaries are breaking down [32] and he advocates a radical suspicion of such a position of 'faith', given its capacity to blur fundamentally different metatheories for the purpose of eschewing an ostensibly unhelpful opposition between researchers, clinicians and patients. Moreover, Buetow is convinced that Isaac and Franceschi's argument has exposed an internal contradiction within postmodernism, specifically that to blur boundaries is to *remove* rather than *retain* respect for the difference that postmodernism endorses. Finally, the relativistic claim within Isaac and Franceschi's paper, for the broadening of medical knowledge, also, for Buetow, lacks authority in that it views all truths merely as perspectives, so that by its own definition, it cannot be 'more right' than a modernist perspective.

Misunderstanding epistemic incommensurability?

In the second Commentary on Isaac and Franceschi's article, Holmes and Gagnon [29] conclude at the outset that the authors have not only failed to deliver a systematic critique of EBM, but that they have at the same time oversimplified the complexity of Foucault's thought, so that while a contested introduction to Foucault's thinking has been attempted, his fundamental concepts have been employed in a most un-Foucauldian manner. There is also, for Holmes and Gagnon, the omission by the authors of a proper discussion of the hidden politics of EBM/EBHS, despite the accumulated literature on the political complexion of the 'evidence-based' movements [1,33–37] not only in Medicine and Nursing, but very recently within Isaac and Franceschi's own specialism of physical therapy itself [38,39]. They proceed to engage with Isaac and Franceschi, focussing particularly on the latter's argument that there is a 'need to alleviate perceptions of dominance and create connections in order to produce cohesion within medical communities'. Holmes and Gangnon find this argument surprisingly naive, demonstrating a lack of epistemological understanding. Readers will best understand Holmes and Gagnon's conclusion in this context by reflecting directly upon the content of recently published works from this research group. Indeed, the authors have previously argued, successfully in our view [1], that the evidence-based movement colonizes health sciences by an all-encompassing research paradigm – that of postpositivism – thus producing a dominant ideology that excludes alternative forms of knowledge [33]. The contribution of this contention to the epistemological debate remains foundational and brings with it a definitive position on the existing frontiers and dynamics between research paradigms.

Thus, the core philosophy of Holmes and of Murray and their co-workers is one which continues to emphasise the co-existence of research paradigms and to explain how they must exist concomitantly to produce opposing discourses and to compete with one another [33–36,40]. This reasoning has enabled these commentators to argue that EBM (and its paradigm postpositivism) is 'both self-serving and dangerously exclusionary in its epistemological methodologies' [35,36]. Their over-riding concern is one ardently shared by the *Journal*, that it is imperative that health scientists continue to acknowledge the importance of maintaining different forms of knowledge as a means of preserving the necessary tensions between paradigms and, as a consequence, between epistemologies. It is for this reason that Holmes and Gagnon take such exception to Isaac and Franceschi's thesis. Indeed, the idea that 'connecting' forms of knowledge – while alleviating domination – fails to consider the epistemic incommensurability inherent within this position has been noted previously by the authors which Holmes and Gagnon cite [41]. These commentators conclude, therefore, that Isaac and Franceschi have 'romanticised' the idea of connections, while ignoring the implications of producing cohesion (as opposed to fragmentation and the necessary co-existence of opposing epistemologies) within health sciences. On the matter of the need to alleviate the perception of dominance within health science, Isaac and Franceschi's commentators are similarly unconvinced. Indeed, if by this the authors are implying that dominance *can* be eliminated and that resistance as a symptom of oppositions and tensions is unproductive (which appears to be part of their argument), then Holmes and Gagnon explicitly reject such a thesis, believing, on the contrary, that dominance and tensions in the production of alternative forms of knowledge is, especially in the current 'evidence-based' era, absolutely essential [33–36,42].

Reason, reality and objectivity: characteristics of the current 'scientistic' and 'postmodern' EBM debate

In contrast to Buetow [28] and to Holmes and Gagnon [29], Loughlin [30] finds a greater merit in Isaac and Franceschi's work, seeing its value in its defence of a conclusion that appears so clear and reasonable that any objective reader ought to regard it as sheer common sense. He notes the authors' rejection of the 'oppressive hierarchy' (which priviliges research evidence and insists that the knowledge of practitioners be subordinated to, and shaped by, such evidence), in favour of a 'contextual interaction' and a 'circular integration' of 'best research evidence, clinical expertise and patient values' and interprets their comments as indicating the authors' beliefs that all of these perspectives are valuable and that each can helpfully inform the other. For Loughlin, to adopt a unidirectional model (in opposition to Isaac and Franceschi's 'multidirectional' picture) is to assume that practitioner knowledge can and should be systematically 'led' by research, yet it is not at all clear that the diverse and unique situations that clinical practitioners routinely face could be adequately understood or dealt with in such a way. For this reason alone it remains impossible to recommend such an approach to clinical practice as an ideal to which practitioners should aspire.

What troubles Loughlin is not the authors' conclusions (as summarised above) but the premises in terms of which they see fit to defend those conclusions. He notes that Isaac & Franceschi, as well as a number of the postmodernist commentators they cite with approval, make philosophical claims that seem unnecessary to establish their points about EBM and would require substantial argumentation to be rendered plausible. Both defenders and certain critics of EBM share philosophical commitments – assumptions about the meaning of, and relationship between, such fundamental concepts as 'objectivity', 'subjectivity' and 'rationality' – that frame the debate between them. Loughlin [30] points out that critics of EBM need to exercise caution when analysing their own philosophical commitments, because failure to do so has led some to ground their rejection of EBM in philosophical theses that are less clear and/or more contentious than the reasonable conclusions that they wished to defend. Loughlin is clear that there is no need to label 'objectivity' a 'myth' or 'scientific method' an 'illusion' in order to identify what is wrong in EBM. Indeed, such strategies play into the hands of EBM dogmatists by allowing them to continue to position themselves as the defenders of 'science' and 'reason'.

Referring to the history of ideas, Loughlin notes the intellectual heritage of EBM discourse in a conceptual framework variously referred to as 'positivism', 'postpositivism', 'scientism', 'modernism' or (sometimes) 'objectivism', though he comments that authors are by no means consistently clear in their uses of these terms. Such scientism embodies much more than a defence of science. It embodies a philosophical framework, a way of viewing the world and our place within it, including a specific *and contentious* account of the nature of science, evidence, value and the role of judgement in rational decision making. It depicts 'objectivity' and 'rationality' as *alternatives* to thinking that is 'subjective' and 'personal': these categories are treated as oppositions, mutually exclusive, on either side of an absolute dividing line. Yet this is bizarre, because surely reasoning, scientific investigation and experimentation are human practices, the activities of persons – whatever their context, all thoughts have subjects. The dominance of this way of thinking has led to a 'devaluing of the personal' and the desire to develop (apparently) 'impersonal' mechanisms for making all serious decisions. Describing the impact of this conceptual shift on our thinking about the running of organisations and policy formation, the alleged 'relativity' of 'value judgements' and some of the most contentious aspects of EBM (in particular the belief in a 'hierarchy of evidence' and the lowly status typically ascribed to personal experience, intuition and judgement or 'opinion'), Loughlin demonstrates that it is a practically unsustainable philosophy, rendering rational judgement and most real science impossible. To explain the initial appeal of this philosophy, Loughlin reminds us of the conditions that led to the rise of the logical positivist school in philosophy, identifying as key factors confusions about the nature of 'bias', as well as the need to find responses to sceptical problems in the philosophy of science and general epistemology.

What is needed, for Loughlin, is a 'reframing' of the debate which 'calls scientistic authors to account for their theft of the language of science and reason', rather than allowing their attempts to secure 'ownership' of this language to succeed by attacking these concepts and the human practices and activities they represent. Critics who fall into this trap show that they have not freed themselves from the underlying assumptions about the meanings of these terms that their opponents promote. Loughlin calls for a 'robust defence' of the role of value judgements, intuition and 'the personal and the contextual' in science and practical reasoning, and a return to insights from ancient (in particular Aristotelian) philosophy, developed before the false dichotomies (between epistemology and ethics, between the theoretical and the practical) that characterise the 'modern / postmodern debate' had been established.

EBM, information, experts and evidence

In his article on 'Evidence-based medicine and limits to the literature search', Robin Nunn [43] is clear that searching the literature – a core requirement of the initial and continuing EBM methodology – has been impossibly oversold in an attempt, he feels, to circumvent individual expert authority. But for Nunn, as for us, the more information there is, the more expert authority is needed – a contention that is not simple 'philosophical musing', but rather based on a proper understanding of the fundamental nature of information itself. In order to illustrate the same, Nunn begins by examining the paradox that evidence on which to base Medicine is supposed to be at the same time authoritative and not authoritative, illustrating the shift that has taken place within the EBM movement from an emphasis on individual practitioner literature searching to individual practitioner reliance on so-called pre-prepared authoritative digests of 'evidence' constructed and disseminated by the EBM community. He then proceeds to discuss the general limitations of literature searching in the particular contexts of content and informed decision making.

In his Commentary, Miles [44] joins with Nunn in noting how the initial and fairly absolute denigration of clinical expertise by the protagonists of EBM – a position born of scientism and its corollary reductionism [45], has fairly quickly given way to the acknowledgement that the possession of clinical expertise, as an indispensable part of clinical responsibility, is so necessary in the

ability 'to integrate research evidence and patients' circumstances and preferences to help patients arrive at optimal decisions' [46]. Miles notes that this concession from the original posturing [12] has been a major one, but that it continues to represent nothing more than a further example of the serial reconstitutions (rather than slow, thoughtful, evolutionary development in thinking) that have characterised the short history of EBM and which are sure to be documented with comment by the History of Medicine. Notwithstanding these concessions, there appears for the protagonists of EBM to be 'an odd distinction between "evidence" from an expert and "evidence" from a literature search, as if they are somehow different species of authority, incapable of interbreeding' [43]. For Miles [44], the observations made by some that EBM is not against expertise *per se*, but rather that it values different types of expertise differently, therefore appears unsupportable. Indeed, he views EBM not so much as valuing expertise *differently*, but sees EBM as valuing it *less*, while 'digests' of 'evidence' derived from EBM approaches to knowledge generation are valued *more*.

Towards an ethics of authentic practice

In the 10th Thematic Edition of the *Journal*, Miles and associates [1], advance the suggestion that far from there being a moral requirement to 'bend a knee' at the altar of EBM, to do so would in reality violate one's primary duty as an autonomous being. Indeed, those authors insist that there may well be an alternative position to that of the emerging 'evidence-based ethics', such that we are able to advocate the replacement of an 'ethics of compliance' with an *ethics of authentic practice*, the essential difference between the two resting in the fact that, at the time of writing, there was (and remains) no valid argument for the former, while there is a lengthy philosophical history to defences of the latter [1,8,25,26]. In their article within the current Edition, Murray and Holmes and colleagues [47], building and developing upon former works [33–36] set out, under the title of their paper 'Towards an ethics of authentic practice', to clarify their former arguments in response to their commentators [1,37,48–50]. The authors' immediate concern is to define their use of the word 'authenticity' and what sort of ethics relate to it, re-iterating their defence of the role of theory in the applied sciences, arguing that without theory, practice is blind and demonstrating that, without critical theoretical insight into the epistemological and political assumptions that underpin the logic of EBM, EBM amounts to an unethical and dangerous practice [47]. The authors engage directly with Miettinen and Miettinen [49] in terms of the latter authors' central arguments and advance three counter-arguments to Miettinen and Miettinen's thinking on the nature of evidence, authority and professional integrity, before proceeding to examine the nature of the relationship between an 'ethics of authentic practice' and 'authority', by drawing on a range of philosophical sources such as Derrida, Arendt and Foucault [47]. They are clear that rapid advances in modern Medicine threaten to outstrip our intellectual and ethical capacities to make sense of them from an existential position, increasing, perhaps, the urgency with which an ethics beyond good and evil, beyond authoritarianism and anti-authoritarianism needs to be developed and they call for the immediate dismantling of the power and moral authority of EBM in the name of an ethics of authentic practice.

Medicine and intuition: concepts, understanding and practical application

Intuition. How exactly do we describe it? Does it have any relevance for the making of clinical decisions in 2008 and beyond? To initiate a contemplation of such questions, we turn now to two reviews by Loughlin [51] and Upshur [52] of *Inside Intuition* by Eugene Sadler-Smith [53].

For Sadler-Smith, intuition is a 'phenomenon' that occurs 'across languages, cultures, continents and history and throughout human endeavour from business to Buddhism', a phenomenon that is not necessarily magical, but certainly amenable to study by science.

While applauding Sadler-Smith's attempt to make sense of this crucial component of human thinking and decision making, Loughlin [51] finds the author's account somewhat superficial, packed with diverting diagrams and the sorts of visual tricks and games that are the hallmark of popular science, but guiding the reader safely around, rather than into, any difficult theoretical territory. The claim that the book will help the reader to develop better intuitive responses is, Loughlin claims, spurious. The book's 'action points' rarely amount to more than sheer common sense and the blindingly obvious, and Sadler-Smith repeatedly claims that successful intuitive thinkers do not 'know how' they know. Intuition, for Sadler-Smith, is an unconscious process wholly distinct from explicit, rational and analytical thought, from which point Loughlin infers that reading a book like this one cannot, on its author's own account, in any way contribute to making its readers more likely to understand how better to develop their own intuitive responses. Good 'intuitives' neither need, nor can make use of, the sort of theoretical account of intuition the book presents, if the author's own claims about the nature of intuition are to be believed [51].

Loughlin questions the author's attempts to classify so many different applications of the same term, 'intuition', as signifying instances of the same 'phenomenon', as though the commitment of Plato and Aristotle to the idea of 'intuition' as a rational disposition represents the same idea as a management theorist's entreaty to 'lead from the gut'; as though Einstein's thought experiments concerning the speed of light are obviously instances of 'the same' phenomenon as Howard Schultz's 'vision' to flood America with over-priced coffee; as though 'intuition' as a term signifies 'the same' process in clinical practice, music, Buddhism and Lockean epistemology [51]. Yet it is only via this unexplained subsuming of so many potentially distinct ideas and activities under the same term that Sadler-Smith can attempt to provide 'it' with the same sort of general 'explanation' – in terms of the language of cognitive neuroscience. So the author fails to justify his fundamental conceptual assumptions, about the nature of intuition and its logical relationship to reasoning and justification. But, Loughlin argues, it is at this level that arguments are needed, if the book is not to beg all of the interesting questions about the role of intuition in rational decision making and judgement. The book's dogmatic reductionism is further revealed in its uncritical commitment to a computational model of the mind, and the author's numerous misleading assertions designed to convince readers unfamiliar with the philosophy of the mind that such a model is universally accepted by all serious contributors to this field – when, in fact, nothing could be further from the truth.

In the paired review of Sadler-Smith's volume, Upshur [52] records his initial reaction to the book as being highly negative, based on a deeply held suspicion of 'psychologism' when applied to matters of inference and reason. Indeed, he sees the volume as bearing all of the hallmarks of having been conceived by an author who has enthusiastically embraced the neuroscience revolution, but with no philosophical qualms about neurophysiological reduction. Upshur's view is that the book will have limited appeal to clinicians. As he points out, while medical examples can be found throughout the volume, they are hardly characterised by any particular insight. We are told, for example, that: 'The clinical judgement exercised by healthcare professionals is another example of an area of practice in which it is difficult to account for effective performance in purely technical and rational terms'. 'Yes', Upshur says, 'of course', but, he asks, 'But does invoking intuition bring us closer to the sort of account we desire of clinical judgement?' 'Does it make it capable of being expressed explicitly and, more importantly, taught?' The volume does not consider such questions and although, for Upshur, quite readable in small aliquots, with engaging and diverting diagrams and photographs of famous intuitives, the book ultimately fails to provide an in-depth study of intuition in a manner which would stimulate the interest of practising clinicians.

EBM, the individual patient and psychological Medicine

'Medicine of the Person', mind, body and health

In the Essay 'Towards an evidence-based Medicine of the Person', Cox [54] is concerned to outline how the conceptual and clinical approaches of psychiatry contribute to an increased understanding about the nature of evidence and the 'art and science' of Medicine. His Essay is based on his own personal search for a more integrative medicine, which has been highly influenced by Paul Tournier's 'Medicine de la Personne' and the International Programme on Psychiatry for the Person led by the World Psychiatric Association, but it refers also to relatively recent evidence from Palliative Care, General Practice and to new educational and research initiatives from major international institutions such as the World Medical Association, the World Federation for Medical Education, the World Association of Family Practice and the medical Royal Colleges [55–63].

Cox argues for the rediscovery of empathy as an essential component of optimal care [16,64] along with the need to understand patients' explanatory models for their illness in advance of decisions being made in relation to therapy. He views Kleinman's work as clearly instructive in this context [65], particularly in terms of its cogent challenge to the preoccupation of modern Medicine with the dominant paradigm of biomedicine, the technology of decontextualised patient care and the neglect of compassion. As Cox points out, psychiatrists have generally had a questioning attitude to reliance on research-based evidence alone when deciding on the management of patients [66] and have traditionally regarded different management strategies for individual patients not necessarily as a disadvantage or as an indication that some doctors are better than others, but rather as a recognition that each patient is a distinct individual [16,54]. As part of this wholly sound approach to clinical care, clinicians must necessarily consider the 'wholeness of persons' and not merely tinker with symptoms, taking care to deal with questions of interpersonal responsibility and not being afraid to confront any spiritual malaise that patients may communicate. Cox is clear that what is now required is more robust evaluations of health service interventions that embrace a person-centred approach and to ascertain whether or not medicine of the person, person-centred care or an attitude to caring can be taught – and whether these approaches as part of care can improve clinical outcomes.

EBM, mental health and clinical policies

Continuing on the theme of mental health, Tanenbaum [67] contributes her article examining the perspectives on evidence-based practice from consumers in the US public mental health system. As she points out, evidence-based practice (EBP) is a matter of mental health policy in the USA [68–71], despite the controversies associated with its use [66,70]. Tanenbaum notes the two-fold usefulness of EBP in mental health advocated by its proponents and discusses these in insightful detail. Firstly, individual mental health practices are considered 'evidence-based' if statistical data on their effectiveness have been judged sufficiently robust, such that the list of these 'evidence-based' practices (which can vary across list-making authorities) subsequently functions as the basis for decision making in relation to which services are funded within the given setting. Here, patients receiving clinical services may or may not be informed that these are evidence-based and may, in fact, have little or no choice in receiving them. As Tanenbaum notes, the assumption is that consumers will benefit from receiving what has been shown to 'work' [67,70]. Secondly, supporters of EBM attend closely to the role of consumers in decisions about their care.

Evidence-based shared decision making (EBSDM) defines EBP here and evidence informs, but does not determine, practitioners' or consumers' decisions about treatment or services. The putative benefits to consumers are thus advanced as two-fold: access to the 'best' information and some measure of self-determination in the process of care. Given that consumer perspectives play an important role in the second form of EBP, Tanenbaum researched the range and logic of these perspectives and of related views about the role of information in decision making and reports her results within the body of her article. Interestingly, she finds that EBP *per se* has mostly by-passed consumers in the American public mental health system and finds that their misgivings about evidence are reasonable, showing that these individuals bring to EBP the complexity of decision making, the centrality of relationships and the stark limitations of their life circumstances.

Harnessing experience and the gap between EBM and clinical practice

In the paper 'Harnessing experience: exploring the gap between evidence-based medicine and clinical practice', Hay and colleagues [72] bring an interesting perspective to the international debate. Noting the mounting evidence of a gap between the recommendations of EBM and clinical practice and explaining this at least partially in terms of the recognition by clinicians that EBM is based on 'averaged global evidence gathered from exogenous populations which may not be relevant to local circumstances'

[73], the authors describe a new approach to decision making in clinical care – that of 'evidence farming' (EF). They hypothesize that EF could usefully complement EBM, encouraging clinicians to be front line researchers working in accordance with EBM principles, but harnessing their own clinical experience to provide optimal care for particular patients or population groups of patients with the subsequent dissemination of that evidence as 'on the ground, best medical practice' within communities.

As part of their research the authors found, unsurprisingly perhaps, that physicians tend to favour experience (either their own or that of trusted colleagues) in making clinical decisions, referring to the EBM literature either for general information about a condition or to double check, as it were, that a given therapy does not have a published negative outcome. Thus, decisions are made with some reference to EBM, but it is experience that can be seen to weigh more heavily in clinical decision making about therapeutics. Interestingly, Hay and colleagues were able to observe that while experience is certainly built up with reference to EBM, the learning of traditions of practice through apprenticeships and learning from the personal experience of particular cases, remains pivotal and that the general view held by clinicians is that the EBM literature is not wholly translatable into the realities of particular patients, contexts or histories. Many physicians, it seems, argue that they are integrating EBM into their practice through the use of electronic clinical resources and balancing this process through the exercise of clinical judgement. Hay and colleagues [72] ask: 'When local evidence is uncollected, weak and unanalysed, what choice do physicians have for justifying medical decisions other than stated reference to EBM?' They answer that if local evidence were collected, strong and analysable, it could provide alternative, scientifically valid and clinically useful knowledge. Thus, they argue, when both local and global evidence are available, but where neither is stronger than the other, the potential exists for them to be combined in some systematic manner. Their conclusion, then, is simple: improvements in patient outcomes may be gained by balancing the global data of EBM with locally relevant data through scientifically harnessing clinical experience via processes such as EF [72].

Reasoning in Medicine

Medical decision making based on values and probability

It is axiomatic that diagnostic reasoning and treatment decisions are key competencies of doctors, with EBM having focussed preeminently on the latter processes. In the article which follows, Ortendahl [74] contends that doctors' reasoning skills are imperfect in many clinical situations, with errors in diagnosis made more frequently as a result of a failure properly to integrate clinical data into clinical conclusions than as a function of the availability of inaccurate data [75,76]. She notes that diagnostic experts use relatively few clinical data, for example, with modes of reasoning sometimes oversimplified [7] and views these limitations as connected to several aspects of clinical decision making, not least, perhaps, a failure to acknowledge the various components of knowledge that are of use within routine clinical practice. To illustrate and address this point, Ortendahl [74] discusses a model of decision making based on values and probability in order to provide a conceptual framework for clinical judgements and decisions and to facilitate the integration of clinical and biomedical knowledge (see [77]). As she acknowledges, EBM is often viewed as a scientific tool for quality improvement, even though those who would apply it in practice comment on the need to combine scientific facts with value judgements along with a consideration of the costs of treatment [78,79]. Yet some studies also indicate that clinical experts experience difficulties in differentiating between 'relevant' and 'irrelevant' clinical features, often giving equal consideration to all available information in a given case [80]. For Ortendahl, then, clinical judgements and decisions are inherently complicated and while they have no simple solutions, decision counselling can assist the clarification of the patient's personal preferences and thus facilitate the attainment of the ideal of informed and shared decision making [81,82].

Learning through experience and case-based reasoning

We continue the discussion of reasoning, values and knowledge in the article by Dussart and his associates [83]. As these authors point out, learning through experience is an important approach that humans employ in order to comprehend new problems. Medical practice in this context relies on sustained learning and study, with successfully solved problems retained for use in the solution of future problems. Conversely, with unsuccessfully solved problems, the reason for failure is identified and the experience gained retained and employed in the avoidance of deficiency or error in the future. In this sense, the knowledge of experts does not consist simply of rules, but rather of a mixture of academically acquired knowledge plus direct experience, so that expertise is associated not with a single basic representation, but with multiple coordinated representations in memory, from causal mechanisms to prior examples [83,84]. As Dussart *et al.* note, this process is not without its biases and the most common and typical of these were reviewed within the *Journal* some seven years ago by Bornstein and Emler [85].

The exercise of modern medical practice is, as Dussart and colleagues note, facing a major challenge of knowledge discovery as a direct function of a rapidly expanding literature and they are right to describe this corpus of knowledge and experience 'a priceless asset'. Clinicians will utilise this extraordinary modern resource in various ways, of which the EBM approach has been advanced as one. Another, and distinct, approach, Dussart and colleagues maintain, is the use of case-based reasoning (CBR), a method generally ascribed to the seminal work of Schank and his co-workers in cognitive science [86–89] investigating the process by which humans remember information and are in turn reminded of information [83,90]. In their review of the method of CBR and in providing examples of a selection of CBR systems [83,91], Dussart and colleagues remain aware of the limitations of CBR and the scepticism which has been directed at it [92], especially its potential within the medical informatics domain, to result in a dehumanisation of the health care system, a key concern of the *Journal*, and they defend CBR as an effective reasoning strategy for the optimization of clinical practice.

EBM, clinical circumstances and patient values

The *Journal* has commented on numerous occasions on the serial reconstitutions of image, definition and method that have charac-

terised the evolution of EBM since its inception, although we have found the nature, scale and frequency of such changes unsurprising, given the status of EBM as a practice bereft of a theoretical foundation [1,8,35,93–95]. In his article on 'Evidence-based medicine beyond the bedside: keeping an eye on context', Tilburt [96] notes some of the essentials of our own observations in this context, in particular the reconstitutions of EBM in the face of sustained critcism which led to the grudging acknowledgement that patient values and clinical circumstances are essential for evidence-based decision making and were therefore henceforth to be held as part of EBM's *Depositum fidei* [46,97–99]. This was a major concession by the EBM camp that greatly undermined earlier conceptions of their method [1]. Tilburt [96] argues for an extension of this concession to contexts 'beyond the bedside', that is, to evidence-based decision making in any context, but in particular public health and health policy contexts, although Tilbert's enthusiasm for this development is far from universally shared and many authors continue to insist either explicitly or implicitly that decision making on the basis of available research evidence alone is sufficient [100–104]. From this observation it is easy to understand the frustrations of some authors with such reductionism [105–107]. Nevertheless, Tilbert contributes usefully to the discussion of what factors might constitute core elements of an evidence-based decision, initially with reference to a key publication from the EBM camp [97] and then by exploring how those authors' thinking could be applied in decision making contexts in healthcare, beyond the bedside.

Randomised controlled trials to personalised Medicine

Under this immediately stimulating title (which the author of the next paper modifies and explains), Shahar [108] presents his *Essay Review* of the recently published *Lancet* text 'Treating Individuals: From Randomised Trials to Personalised Medicine' [109]. As he notes, the book presents itself as the volume for which practising clinicians have long searched: 'words of scientific wisdom that will teach you how to weigh the evidence from randomised trials and how to apply the evidence to Mrs. Smith in the corner bed in room 376, or to Mr. Jones who is about to enter your clinic'. But on closer examination, Shahar is able to conclude that the *Lancet* has produced nothing more than an expanded version of a thematic journal edition, most of which appears to have catered to the rhetoric of the so-called evidence-based medicine movement [1,110]. Shahar notes the claim of the collection of essays of varying quality and relevance (which is the book) to teach the reader a great deal within the domain of cause-and-effect, one of the most challenging topics in epidemiology, statistics and the philosophy of science [108], but where detailed discussions of epistemology, probability, models of causation, causal parameters, estimators and their desired properties, 'fallible estimates', effect measure modification, sources of random variation, clashing schools of statistical thought, etc., are essentially missing, such that the text appears to have avoided the real challenges of causal inquiry and causal inference. For Shahar, however, one chapter within the volume is immediately conspicuous by its title: 'Applying results to treatment decisions in complex clinical situations' ([109] p. 111). As he notes, no fan of the rhetoric of 'evidence-based medicine', 'best evidence', 'best practice', 'managed care', 'systematic reviews' and 'practice guidelines' would *ever* choose such a title. Following his consideration of the particular clinical case histories and their treatment as described within this particular chapter, Shahar asks: 'Did he . . . (the doctor) . . . use any algorithm, prescribed rules or dogmatic thinking to decide on "external validity"?' And his answer is 'No!' 'Would you want him to be your doctor?' And his answer is: 'I would!'

Towards the conclusion of his *Essay Review*, Shahar [108] compares and contrasts the position of that doctor with that of a statistician whose work is published within the same volume ([108] p. 191): 'When we do not have evidence about treatment effects in specific subgroups of patients, these decisions have to be based on evidence about overall effectiveness. We should only make different decisions for specific patient groups when strong evidence supporting this becomes available'. Shahar's immediate reaction to such a thesis is definitive. Indeed, he asks of that author: 'Has he never seen an human being who was harmed when that rule was followed?' Comparing and contrasting these apparently diametrically opposed perspectives, Shahar [108] reflects on the mind of the doctor quoted and the mind of the statistician quoted – the first is concerned to make a decision in the interests of the individual patient, whereas the second appears preoccupied with the concept of 'patient groups'. Indeed, the first is worried about the fallibility of scientific knowledge and possible heterogeneity by personal identity, whereas the second denies any heterogeneity until 'proven' otherwise – as Shahar wonders, by 'a small *P*-value', perhaps? So, for Shahar [108], we have an interesting dichotomy: the doctor who is not sure about his treatment decision for a single patient and the statistician who has no doubt about how all patients should be treated. Faced with this dichotomy, Shahar asks: 'Which school of thought do you prefer in medical practice?'

EBM *versus* NBM *versus* NEBM

In their article on 'A local habitation and a name: how narrative evidence-based medicine (NEBM) transforms the translational research paradigm', Goyal and colleagues [111] propose NEBM as a necessary elaboration of the US National Institutes of Health translational research roadmap. That roadmap defined two complex, major obstacles – T1 and T2 – to the progress of research from the findings of laboratory science to the application of new knowledge to the patient (the so-called 'bench to bedside' gulf), the traversal of which requires the emergence of complex transformative relationships between the parties and stakeholders, although for Goyal and associates it fails to encompass patient interactions, hesitancies and alliances with medical care. Instead, the authors suggest a third transformative step, T3, that begins at the point that practitioners have themselves elected to adopt and recommends strategies and interventions based on high level evidence and guidelines. Here, T3 encompasses all aspects of care that converge on the practitioner-patient relationship and which ultimately determine what therapies and choices patients actually make regarding their care. The authors recognise the rhetoric of EBM when it talks of integrating the best research evidence with clinical expertise and patient values, but emphasise the value of narrative medicine in promoting and valuing the detail of the doctor-patient encounter, so like shared decision-making

[112,113], patient centredness [114–119], relationship-centred care and the biopsychosocial model [120], narrative medicine insists on the fundamentally human quality of the medical encounter [121–124]. For Goyal and colleagues [111], then, the combination of the EBM approach and the narrative medicine approach superimposes the specific onto the general, representing a potentially novel and effective means of improving the quality and outcome of patient care.

User-driven health care, multidimensional information needs and post-EBM approaches in clinical care

We move next to two articles from Biswas and colleagues which are similarly concerned with patient-centredness in health care [114–116], specifically in terms of the information that is required to provide it. Separating their work into the ruminations of a conceptual model [125] before proceeding to describe an operational model [126], Biswas *et al.* begin by defining user-driven health care as: 'Improved health care achieved with concerted collaborative learning between multiple users and stakeholders, primarily patients, health professionals and other actors in the care giving collaborative network across a web interface'. User-driven health care is thus to be distinguished from *consumer*-driven health care which is, as Biswas *et al.* point out, descriptive of a strategy for users/consumers to decide how thay may pay for their own health care through multiple stakeholders like employers who provide the money and insurance companies who receive the premiums [127]. The authors' principal hypothesis is that, despite a relatively massive expansion in medical information in recent years, physicians still do not have access to the types of information required to allow them to tailor optimal care for a given individual patient and that an information system that can seamlessly integrate different types of information to meet diverse user group needs is therefore urgently required. Biswas and associates recognise that one of the original intentions of the advocates of EBM was to address this concern, but are equally clear that one of the biggest challenges for EBM has been to keep care patient-centred and they usefully illustrate this dilemma by reflecting upon Armstrong's discussions [128]. In their accompanying paper, Biswas and co-workers [126] present an operationalisation, as it were, of the concepts discussed in their preceding work [125], as an experimental prelude to a systematic evaluation of the validity of their technique within more extensive studies. The JECP wishes the authors well in taking the developed model described here to the Malaysian Government in order to secure the necessary funding and collaboration that must now constitute the next stage of their important project.

Individualised population care

The *Journal* has previously described 'public health' as 'impersonal medicine' [129] and we will shortly look again at recent developments in the field from a detailed philosophical perspective [107]. In the interim, we publish Buetow and colleagues' thinking on how population models of care can be delivered within a modern policy framework in a way which acts to guarantee patient-centred, personal care [130] in response to fears that an expanded role for general practice in delivering population care [131] may undermine the commitment and moral responsibility of personal doctoring to individual patients and their personal interests [130,132]. In order to address these concerns, Buetow *et al.* [130] pose two central questions: 'What is the nature of these types of care?' (that is, population and personal care) and 'Can individualised population care provide a conduit between them in general practice?'. Overall, Buetow and associates advocate a constructive but critical attitude towards the idea of population-based interventions in everyday general practice, but conclude that the concept of individualised population care can, actually, integrate traditional personal care and whole population care. But they are clear that the process of individualising population care presupposes high levels of clinical-epidemiological expertise and moral awareness in clinicians and that external stakeholders need to acknowledge that even though an intervention may have a documented benefit on a population level, it can be an inadequate priority in the context of a particular clinical encounter [130].

EBM, knowledge, knowledge in general and knowledge in particular

In 'Knowing – in Medicine', the penultimate article within Part One of this Edition, Sturmberg and Martin [133], taking inspiration from a recent *Lancet* paper [124], are concerned to emphasise that knowledge is a complex entity that can be explored from several perspectives and ask: 'So what constitutes knowledge – knowledge in general and in Medicine in particular?' Recognising that – according to many thinkers – knowledge must be 'justified, true and believed', they also acknowledge the understanding of knowledge in pragmatic terms as 'information we are aware of' and which can be divided into *knowing what* (facts and relationships) and *knowing how* (explaining procedures), as well as being amenable to description as *explicit* (codifiable and communicable) and *tacit* (non-codifiable and communicable with difficulty).

Moving through a discussion of 'knowledge – shifting from a static to a dynamic state' [134], to a discussion of knowledge generation and knowledge management as a sense-making process [135], Sturmberg and Martin [133] conclude their article by emphasising that the preoccupation of defining the 'right kind of knowledge' to determine 'best practice' is misguided in that, seeing only part of the whole picture, proponents residing in a particular domain assert that their 'static picture' of knowledge is the 'right one' for all the others [133]. Thus, the authors contend, two flaws become readily evident: the one being the decontextualisation of knowledge and the other the loss of necessary flexibility when a particular knowledge model is not sufficient to achieve the desired outcome. They are convinced that the time has come to acknowledge that medical knowledge is inherently uncertain and to enact a context-driven, flexible approach to 'medical care models' congruent with the limitations and the emergence of knowing, avoiding the lure of over-simplified approaches to care such as EBM and NBM [136–139]. For the authors, it is the development and use of systems and transdisciplinary approaches incorporating multi-method methodologies and dynamic synthesis that is more likely to create the required knowledge to develop care models that integrate 'all we know' to address population needs, the needs of vulnerable groups and patients with specific needs and

which therefore enable the building of bridges to overcome patient mistrust, disease and illness dichotomies as well as social and economic inequalities [133].

Towards scientific medicine – an information outlook

The question of what exactly constitutes knowledge for practice continues in the closing paper of Part One of this Edition. Here, Miettinen and colleagues [140] reflect upon the understandings of the term *scientific medicine* by perhaps the two most influential examinations of medical education that have taken place within the last one hundred years – the 'Flexner Report' published in 1910 [141] and the advent of the EBM movement in 1992 [12]. We agree with Miettinen *et al.* [140] that in neither of these initial conceptions, nor in EBM as it stands today [1,46,142], is 'scientific medicine' characterised by the bringing to bear of scientific knowledge on the problems of the individual patient or on any other type of knowledge and that the challenge facing the advancement of Medicine today is the need to move away from the Flexnerian and EBM conceptions of scientific medicine towards an outlook that is more realistic. For Miettinen and associates [140], this is represented by knowledge-based medicine (KBM), a system of knowing and acting that adopts a tenable conception of the requisite knowledge base of Medicine in our information age, practical and rational in form, typical of experts in content and codified in cyberspace for as-needed retrieval for practice.

Part II: Clinical attitudes to and understanding of EBM and the implementation and use of clinical practice guidelines

Knowledge and attitudes of junior physicians to EBM

How does an understanding of EBM practices affect clinicians' attitudes to, and enthusiasm for, EBM? What factors continue to mediate the implementation and use of clinical practice guidelines and care protocols? It is to these questions that we now turn in this second Part of the Edition, which contributes 19 articles to the associated medical and HSR literature.

Ahmadi-Abhari and colleagues [143] are clear enthusiasts for the EBM approach. We certainly take issue with their claim that 'EBM has . . . gained *widespread* acceptance among health professionals', with their understanding of medical epistemology when they declare a simple belief that 'high quality health care implies clinical practice that is consistent with the current *best evidence'*, with their statement that '. . . EBM represents a *vital approach to lifelong, self-directed learning*', with the premises that underlie their reference to clinicans' needs 'to retrieve, appraise and apply current *best evidence'* (all italicisations ours)[12,142,144–146] and with their suggestion that 'EBM education may be one of the ways to bridge its implementation into clinical practice', which we see as nothing more than the ideological review and selection of methods designed to facilitate indoctrination, compliance and subordination of clinicians [1,8] to current academic fashions and to current political expedients.

Despite these major reservations on their overall thesis, we are happy to publish the methods and results of their questionnaire survey evaluating knowledge of EBM precepts and method among trainee physicians at a Tehran university hospital. Interestingly, this simple survey demonstrated that the majority of these junior doctors lacked 'adequate' knowledge of the basic concepts of EBM and that they continue to refer to what the authors describe as 'traditional sources of knowledge', rather than so-called 'evidence-based sources' [143]. The authors, were, however, able to show that the same cohort of doctors had demonstrated an 'overall positive attitude towards EBM' and that they had shown a 'positive tendency to take part in EBM training courses'. We note with some interest the authors' description of the 'incompetency' of the senior medical faculty of Tehran University (the 'best' university in Tehran which enrols only the 'top' students [143]), which appears to be singularly blamed by the authors for refusing to genuflect to EBM and who therefore act to obstruct, by example, the Iranian EBM implementation programme. Are these colleagues representative of the 'gerontocratic, dyspeptic and politically right-leaning conservative elite' to which Miles refers? [44]. Perhaps, Ahmadi-Abhari and colleagues might extend their next questionnaire survey to these colleagues in order to find out?

Resident-Preceptor interactions and adherence to EBM

In the paper which follows, Tilburt and colleagues [147] pose the question: 'Do we practise what we preach?' in the context of their qualitative assessment of resident-preceptor interactions for aderence to evidence-based practice. Reflecting the position of the authors of the preceding paper, Tilburt *et al.* take as read the need to teach '. . . the process of EBM . . . (as) . . . an important objective of residency training so that it is eventually integrated into patient care' [147,148] and they set out to examine the extent to which EBM principles are implemented into the processes of routine clinical care using a qualitative, observational approach. The results and conclusions of their study were able to show that EBM was not optimally implemented in the clinics studied. However, rather than posing the academically necessary questions as to what factors underlie the resistance to EBM approaches in an effort to understand clinical objections to what remains an alien approach to the humanistic care of ill people, the authors elect preferentially to advocate the research of methods through which EBM might be more systematically implemented into their ambulatory care complex. Such a position provides yet a further example (if one were needed) of ideology and pragmatism.

Knowledge: a barrier to implementing LBP guidelines?

Is knowledge a barrier to implementing guidelines? This is the question to which Dahan *et al.* [149] turn. These investigators' major concern has been to measure the knowledge of Israeli doctors' familiarity with the low back pain (LBP) clinical practice guidelines prior to designing an intervention programme aimed at enhancing guideline adherence in practice. The results of their study demonstrate that despite a majority of doctors having been exposed to the LBP guidelines, only a minority reported having used them, findings in agreement with the results of similar studies

[150]. Dahan *et al.* explain the differences between doctors' adherence to guidelines recommendations in terms of the striking variations in their knowledge base. In their study, qualified family doctors were found to have a better knowledge of the LBP guidelines than other doctor subgroups and they reflect on the association between individual doctor characteristics and overall guideline adherence [149,151]. For the authors, their findings indicate the necessity for the development of interventions to increase guideline adherence that are specifically targetted at the specifically differing doctor subgroups identified by their study. We wonder whether the authors' conclusions, though interesting, are nevertheless simplistic. While the extent of familiarity with the existence of a set of guidelines can be expected to have a clear influence on the extent of their use, a missing dimension in Dahan and colleagues' study is surely the investigation of doctors' views on the nature and validity of the so-called evidence base of the LBP guidelines in question and how such evidence matched or differed from their own individual or collective experience over long years in everyday clinical practice. Such a question is pivotal to interpreting observed variations in guidelines use and should surely be explored well in advance of the design of coercive measures aimed at forcing guideline implementation and use? The current paper is Dahan *et al.'* s second contribution to the *Journal*, following on from their first [152]. A third contribution should, in our view, be constituted by an in-depth examination of the specific factor we have discussed immediately above.

EBM and 'complementary' and 'alternative' Medicine

Do practitioners of so-called 'complementary' and 'alternative' Medicine reason differently from practitioners of conventional Medicine about EBM? This is the question posed by Leach and Gillham [153]. Certainly, the term complementary and alternative medicine (CAM) encompasses a diverse range of theoretical and philosophical views of health and illness as well as a wide variety of approaches to treatment [153], the majority of which remain greatly disputed and highly controversial within mainstream clinical medical practice. Noting the enthusiasm of Australians for the ministrations of CAM practitioners [154] and given the controversies surrounding the effectiveness of CAM, the authors undertook the development of a tool to assess the extent to which CAM practitioners employ the 'best evidence' at their disposal and thus the attitude of these practitioners to the concept of 'evidence-based' care. The methodology reported appears to support the validity and reliability of the Evidence-Based practice Attitude and utilization Survey (EBASE) technique and, with the authors, we look forward to studying the results of the application of the method within defined practitioner populations in order to enable a meaningful assessment of its accuracy and reproducibility in larger studies.

Adherence to clinical practice guidelines

UBT referrals and primary care practice

Dyspepsia is commonly encountered by doctors working within primary care, where between 30% to 40% of the general population report symptoms [155–157]. Noting the recommendations of international guidelines for the investigation of suspected *Helicobacter pylori* infection [158], Noya and associates [159] report their study doctors' adherence to available recommendations for urea breath test (UBT) referrals in Israel. Despite its established diagnostic potential, the authors' suspicion had been that the use of the UBT was significantly inappropriate with the potential to lead to the administration of potentially unnecessary treatments, a suspicion confirmed by their study which observed nearly 45% of UBT referrals in primary care practice to be inappropriate with a failure to refer a significant number of dyspeptic patients to endoscopic evaluation. Noya and colleagues consider the factors that may mediate the substantial non-compliance with internationally agreed guidelines and recommend strategies aimed at increasing guidelines implementation and use.

Psoriasis guidelines in general practice

The development of clinical guidelines is a costly exercise and the justification of investment is rarely achieve unless the developed guidelines are translated into clinical practice with measurable benefits for patients. In the paper which follows, Nast and associates [160] examine the extent to which nationally agreed guidelines for the management of psoriasis vulgaris were translated into German dermatological practice following their development, publication and dissemination and discuss the role of educational interventions in encouraging guideline adherence. Nast *et al.*'s paper is timely, since there is a paucity of studies which has examined the effect of practice guidelines on the management of psoriasis. As the authors note, two of the most prominent studies have shown discrepant results [161,162], an outcome due possibly to suboptimal guideline dissemination and/or a lack of supporting educational interventions designed to encourage guideline use [160]. In analysing the results of their study, Nast *et al.* were able to identify several major factors mediating guideline use, including the inadequacy of single as opposed to multiple systems of guidelines dissemination to practising dermatologists, the inability of busy clinicians to find the necessary time to study the guidelines, the lack of confidence in the use of modern approaches to therapy and incompleteness of knowledge on the safety and efficacy of new treatments. Interestingly, the authors identified the use of an educational workshop designed to explain guideline structure, content and use, etc., to be judged as either 'useful' or 'very useful' by responding dermatologists. Thus, Nast and colleagues conclude that in addition to multifaceted dissemination strategies, intensive educational interventions of this type should play a pivotal role in guidelines projects.

UI guidelines in primary care

Variations in the extent to which doctors adhere to professional guidelines remains the subject of our next paper. Here, Albers-Heitner and colleagues [163] report the results of their assessment of the extent to which Dutch general practitioners adhere to the Guideline on Urinary Incontinence of the Dutch College of General Practitioners, reviewing the reasons for non-compliance. Urinary incontinence (UI) is a common presentation in general medical practice with a significant impact on quality of life and with high annual costs of care [164–166]. Many commentators have pointed out that little data exist to measure the extent of

adherence to guidelines in attempts to improve the quality of care and contain its costs [167]. In order to generate some insights into the characteristics of UI management in primary care in the Netherlands, Albers-Heitner and her colleagues conducted a cross-sectional study (postal survey) to assess the level of adherence to national UI guidelines and to understand the factors which mediate compliance or non-compliance. Their results demonstrate only a partial adherence to the UI guidelines which may be lower in actuality than the study results indicate and for the reasons given. In comparing their results with an earlier Dutch study which demonstrated a higher guidelines adherence [168,169], the authors reflect on the potential of training in improving guideline use [169] and on the role of specialised nurses [170,171] and integrated continence care services in maximising guideline implementation [167,172].

Practice guidelines for the management of venous leg ulcers

As with dyspepsia [159], psoriasis [160] and urinary incontinence [163], leg ulceration is commonly encountered in routine clinical practice [173], with the majority of ulcers being venous in origin and having significant psychological as well as physical effects in the patient [174,175]. In the paper which follows, Van Hecke and colleagues [176], writing from Belgium, review the history of guideline development for the management of limb ulceration and investigate the clinical evidence on which guidelines have been based, advocating the selection of particular sets of guidelines over others. Interestingly, the authors were able to observe that while most of the venous leg ulcer guidelines included in their review described scope and purpose clearly, they varied significantly in stakeholder involvement, in the methods of weighing evidence, in the disclosure of conflicts of interest and the coverage of content issues. Additionally, the authors found little emphasis on pain management and the provision of lifestyle advice and on compliance and compliance-enhancing strategies [176]. In common with many guidelines projects, Van Hecke *et al.* were able to note a general failure to consider the development of dissemination and implementation strategies and the need to state policies for subsequent guidelines revisions. Consequently, they advance recommendations aimed at addressing these deficiencies and, importantly, they emphasise the need to consider non-RCT derived information as well as trial data as sources of evidence for practice [177–179] in order to ensure the inclusion of data on safety, cost-effectiveness, patient preference and quality of life, etc., into guideline development.

CHF, evidence and guidelines implementation and use

Chronic systolic heart failure (CHF) is associated with high morbidity, mortality and overall burden of illness in the patient [180,181], with a definitive body of evidence indicating the nature of optimal treatment that has now become codified within national and international guidelines [182,183]. Against the backdrop of these advances in cardiological practice, studies continue to show divergence from guideline recommendations in both primary and secondary care settings [184,185], despite the fact that adherence to the guidelines has been shown to be tightly correlated to improvements in clinical outcome [186,187]. Following their review of these advances and the barriers to guidelines implementation and use, Peters-Klimm and associates [188] describe their 'train-the-trainer' trial (TTT) conducted in Germany and which aimed at optimising the care of patients with CHF via an innovative, multifaceted training course for general practitioners, compared with a standard lecture, measuring differences between the two groups in terms of quality of care as assessed by performance of guideline-orientated pharmacotherapy, including class adherence, up-titration and use of target doses. The results of the authors' study demonstrate the superiority of the more complex TTT intervention above the standard intervention, providing further insight into the relative effectiveness of varying implementation strategies. Indeed, performance feedback, repetitive, interactive and interdisciplinary meetings (including educational, communication training, peer group meetings, audit and organisational components) are concluded to represent the factors precipitating the superiority of the TTT approach, although the design of the authors' study means that the relative effectiveness of the multiple interventions utilised as part of the TTT approach cannot yet be measured.

Hypertension, evidence, guidelines and the use of knowledge

What effect do evidence-based guidelines on the management of hypertension have on the clinical practices of primary care nurses? And does their availability create a new division of labour between doctors and nurses? It is to these questions that Seija and colleagues turn in their study of hypertension guidelines implementation in Finland [189]. As they point out, clinical practice guidelines for the management of hypertension have been developed in many countries in an effort to improve the quality of care [190,191] and while initial investigation and treatment remains medically led, the modern management of hypertension has become a multidisciplinary task with nurses often made responsible for patient follow-up and lifestyle counselling, important functions in optimising clinical outcomes [191–193]. A particular characteristic of Seija *et al.*'s study is its innovative nature in being among the first to evaluate nurses' perceptions of the implementation of evidence-based Current Care Guidelines in Finland, demonstrating that the hypertension guideline had been widely adopted in primary care nursing in Finland, resulting in observable changes in clinical practice and noting the importance of multifaceted strategies in enhancing guideline use. In accordance with one of their objectives, the authors were also able to study and comment upon the modifications in the division of labour that appeared to result from guideline implementation, changes which have been directly related to improvements in the quality and effectiveness of clinical care [194–196]. Finally, and importantly, advising patients of the availability of the guidelines and educatiung them in their contents may also facilitate guideline implementation [197], a factor observed in the authors' study and having the effect, perhaps, of 'putting pressure' on professionals to adopt guideline recommendations [189].

UI, audit and primary care

That guideline implementation requires a multifaceted, rather than a singular approach, is now well recognised, as we have seen from the observations of the preceding papers, from the bibliography to

which they refer and as we shall discuss when reviewing the final article in Part II of this Edition. Of the very many different interventions that may be of use when implementing practice guidelines, audit retains an important place. In the next paper, Gerrits and associates [198] evaluate guideline adherence with feedback in general practice in order to improve the routine management of UI in the United Kingdom. Noting, along with Albers-Heitner *et al.* in the previous paper on UI [163] that guidelines availability does not guarantee their use [199,200], the authors pose the following questions: 'Do GPs adhere to the guidelines on UI management?' and 'Is (audit) feedback on adherence to the guidelines on UI a tool for improving UI management in general practice?' Although their study was essentially small scale with several limitations, the authors' results show that, in general terms, GPs do not adhere to current UK national guidelines – citing lack of time as a principal barrier to guideline use, while audit feedback appeared effective in illustrating to GPs the extent of their non-adherence, thus demonstrating its potential as an educational tool of value in improving care processes.

Implementation strategies, a test-retest study

The factors mediating the implementation of practice guidelines remain the subject of the next paper. Here, Christel and associates focus on the development of an instrument for the evaluation of clinical practice guidelines in Sweden, specifically investigating the test-retest reliability of a questionnaire approach to the collection of data about guidelines that have been implemented as well as information about factors which influence the success of implementation [201]. The questionnaire was specifically concerned with whether practice guidelines were used, the most recently implemented guidelines, the basis and authority of employed guidelines, the implementation strategies employed, whether the implementation was judged successful, perceptions of 'circumstances' in clinical practice and if and how the use of guidelines was evaluated. The authors present interesting data under each of these domains and conclude that the test-retest scores were acceptable for most items, indicating a reasonable stability of their instrument, although the authors acknowledge some limitations of this tool and recommend approaches to the development of their method for future studies.

Protocols, audit and guidelines implementation

The evaluation of methods to facilitate the implementation of clinical protocols is the subject of the paper which follows. Here, Charrier and associates [202] reflect upon the difficulties commonly experienced in precipitating necessary changes in clinical practice within institutions and some of the reasons underlying these difficulties. The aim of the authors' study was to evaluate the efficacy of an implementation strategy (for the prevention of pressure lesions and the management of peripheral and central venous catheters in an Italian hospital) characterised by clinical-organisational integrated audits followed by feedback and by the presence of facilitators in departments, using cluster randomised controlled and open trial methods. The results of the study, though interesting overall in demonstrating changes in practice deemed important by the authors, were variable and a notable obstacle to the institution and sustaining of change was identified as 'time'.

Evidence-based prescribing, educational outreach and EBM

While audit continues to be employed as an important tool in facilitating guidelines implementation, a variety of other methods have been tested for their effectiveness in this context, including, for example, direct and indirect interventions aimed at modifyng medical prescribing behaviour. Here, strategies have involved formulary restrictions, computerised alerts, collaborative care, broad educational efforts and so-called 'academic detailing' [203–209]. The last intervention, that of 'academic detailing', typically recruits peer clinicians of distinguished reputation [210] who employ social marketing approaches in combination wth core principles drawn from motivational interviewing approaches within the context of face-to-face interactions with target clinical groups in an attempt to cause a change in clinical behaviour or drug prescribing patterns. A multiplicity of studies has demonstrated the efficacy of 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors (statins) in improving the clinical outcomes in individuals at risk of significant cardiac events, the accumulated evidence having been codified into clinical practice guidelines [211].

Nevertheless, and as Zillich *et al.* describe, the translation of these guidelines into routine clinical practice has been far from optimal despite general acceptance of the evidence [212], thus raising the possibility that dissemination and implementation strategies for the guidelines have been inadequate with calls for research on the best methods of enhancing distribution and use being made [197,203]. In the paper which follows, Zillich and his associates [213] report their evaluation of an academic detailing programme designed to increase new statin prescriptions in individuals at high risk of cardiovascular complications, incorporating their programme within a state-wide chronic disease management programme for Medicaid members and additionally using administrative claims from medical and pharmacy data to target both prescribers and patients for educational interventions. Interestingly, the authors were unable to identify a significant effect of their programme on statin prescription despite having anticipated being able to do so on the basis of the results of separate studies [214] and they go on to discuss in detail the four principal factors they suspect may singly, or in combination, explain their results in an effort to inform the development of more effective academic detailing programmes within cardiovascular medicine and other specialties, for the future.

Guideline adherence and clinical reminders

We continue our study of implementation interventions in cardiovascular medicine in the paper which follows. Here, Hung and colleagues [215], writing from Taiwan, reflect on the well recognised mortality and morbidity from coronary heart disease (CHD) that can be significantly reduced by lifestyle change and risk factor modification, with lipid management being among the most important risk-reducing strategies in both the primary and secondary prevention of cardiovascular disease [215,216]. However, despite the availability of internationally disseminated, professionally produced practice guidelines on lipid management, there is considerable evidence of inadequate management of at-risk patients within the context of routine clinical practice [215,217,218]. Following

their review of the various interventions that have been employed in efforts to increase physician adherence to practice guidelines, including informatics-based reminders [219], the authors advance their hypothesis that a paper chart-based reminder that provided lipid guidelines as well as local insurance reimbursement policy could affect the prescribing behaviour of doctors, increasing adherence to current standards in lipid management. The results of their study certainly indicate an effectiveness of their method as a simple, inexpensive and informatics-independent approach to the stimulation of a more thorough clinical review of patients. However, its ultimate usefulness within the practice setting in which it was tested, was limited, if not precluded, by the discrepancy observed between the local reimbursement policy and the recommendations of the internationally accepted guideline and the reluctance of doctors to become involved in the dilemma represented by a compromise in quality of care and a punitive action by the reimbursement system. As the authors conclude, the successful transformation of accepted guidelines into clinical practice requires the cooperation and support of health policy makers and insurance reimbursement systems (which take, of course, different forms in different countries).

Protocols, care and service delivery

Clinical practice guidelines, long described and disputed as promoting 'cookbook medicine' [220,221], continue to be viewed with suspicion by the majority of practising clinicians. Yes, they have value in summarising available knowledge as an aid to decision making in the face of the individual but, yes, they also represent mechanisms through which a population health-based standardisation of care could be achieved in the longer term. So what of 'protocols' which imply imperatives, rather than discretions and judgements [222,223] and which are designed to have definitive impacts on roles and service delivery? It is to the subject of protocol-based care that Rycroft-Malone and her associates turn in the paper which follows [224]. For the authors, the integration of protocol-based care into care delivery has been illustrated, for example, within the development of National Service Frameworks in the UK which explicitly identify the role of service protocols as tools for implementing clinical and service standards. Here, and more generally, protocols have been viewed as tools for promoting autonomous nurse practice, including nurse-led clinics and nurse prescribing [224] and for the legitimation of nursing knowledge [225,226].

Typically, medical staff view protocol-based care with little regard [227–229] and questions remain in terms of how standardised approaches to care can work in practice and what, precisely, their impact is on nurses' and health professonals' working. In order to address these questions, Rycroft-Malone *et al.* employ the technique of 'realistic evaluation' to study the relevant issues within the clinical setting [230]. Their results are significant and interesting. Perhaps, unsurprisingly, their findings showed that the use and impact of standardized care approaches varies and was context and professionally specific, such that it appears clear that the standardized care approach will not be used in practice in the manner in which it was initially intended to be, thus challenging the political ambitions at its inception [224]. However, the authors did observe definitive effects on the extension of nurses' roles leading to the development of new service initiatives that precluded the need to refer to, or follow up with, medical staff. The authors conclude that there is an utility in the use of standardized care approaches in particular circumstances. However, since their use is varied and influenced by individual, professional and contextual factors, the ambition to 'perfect' standardization through the use of tool such as guidelines and protocols is unlikely to be fully realised [224].

Clinical practice guidelines: local, regional and global perspectives

Why are guidelines in Medicine so important today? What role do they have? Why and how did the World Gastroenterology Organisation (WGO) choose a global focus? What does this mean for guidelines? It is to these very particular questions that Fried and Krabshuis turn in their paper: 'Can "Cascades" make guidelines global?' [231]. The fourteen 'grand' challenges in global health identified by the World Health Organisation (WHO) [232] were augmented, as it were, by Pang and associates [233] who called in addition for concerted action in applying already existing knowledge into practice, via guidelines, to seek to bridge the gap between knowing and doing. Against this call for action, Fried and Krabshuis advance the concept of adding 'Cascades' to guidelines in order to increase their impact in large parts of the World and, in doing so, these authors add a new and important dimension to the 'knowledge into action' and practice guidelines debate. The authors are refreshingly clear on a very central point: we live in a networked society where medical advances are generating rising expectations that are increasingly falling short of what is often available locally; rich, developed countries continue to synthesise 'gold standard' guidelines of interest to everybody, but translatable into the routine clinical practice of just a few. Indeed, there is no realistic chance of the clinicians outside of the developed World being able to apply the high standards of care prescribed by these guidelines because of lack of funding, education and training. What, then, the authors ask, are their options? Fried and Krabshuis argue convincingly that the time has come to review the whole field of guideline development. As part of their study, they sought the views of various professionals on the limits of Western-made gold standard guidelines and the results of their consultation are, indeed, striking. The authors make clear that they embrace the ideals of applying existing knowledge to the best of our ability and fully acknowledge the potential of practice guidelines within that context. But they argue that this is not enough and that we must go further in an effort to develop resource-sensitive solutions – these they refer to as 'Cascades' and they go on to explain their thinking in considerable detail, providing examples of Cascades and also Cascade-related initiatives.

Guidelines and clinical pathways in gastrointestinal surgery: effectiveness and efficiency

In the article which follows, Lemmens and colleagues report the result of their systematic review on the effectiveness of clinical pathways in gastrointestinal surgery [234]. Clinical pathways are also known as 'care pathways' and 'critical pathways' and remain popular as tools through which reductions in hospital stay and costs might be achieved and reductions in variations in care rea-

lised [235–240]. Definitions vary, but the European Pathway Association defines a clinical or care pathway as: '. . . a methodology for the mutual decision making and organisation of care for a well-defined group of patients during a well-defined period', adding that a care pathway requires: '. . . an explicit statement of the goals and key elments of care based on evidence, best practice and patient expectations; the facilitation of the communication, coordination of roles, and sequencing the activities of the multidisciplinary care team, patients and their relatives; the documentation, monitoring and evaluation of variances and outcomes; and the identification of the appropriate resources'. Finally, it is emphasised that the aim of a care pathway is to 'enhance the quality of care by improving patient outcomes, promoting patient safety, increasing patient satisfaction and optimising the use of resources' [241]. Hardly a succinct definition and one open to much philosophical enquiry, but on the basis of it, Lemmens *et al.* present the results of their evaluation based on a simplified set of indices: the 'clinical', 'service', 'team', 'process' and 'financial' domains [242].

Implementing practice guidelines: a systematic review

After having commented on multiple articles within the current Section of the Edition which have investigated guideline adherence and strategies to facilitate the same, we now move to the closing paper of this Part, a synthesis of systematic review findings on the effectiveness of clinical guideline implementation contributed from Australia by Prior and co-workers [243]. The authors' work is certainly exhaustive, their methodology having identified 144 potential papers from which 33 systematic reviews were included. These reflected 714 primary studies involving 22 512 clinicians within a range of health care settings. Their analysis is impressive, confirming the results gained from previously published reviews and generating new insights.

Part III. Knowledge and evidence in clinical practice: progress in methodology and statistics

Knowledge, education and the role and value of journal clubs

Journal clubs are long-established fora designed to enable the critique of published articles and to keep clinicians up-to-date with the latest research developments in their field [244–246], so that shared knowledge may prove of direct use in informing modern clinical practice. Despite their growing popularity, little formal evidence appears to exist describing the 'ideal' structures and processes that might constitute an effective journal club, nor, it seems, are there many published suggestions as to how journal club attendance and participation might be evaluated in terms of its potential to translate into research-based care. Noting the same, Deenadayalan and associates conducted a systematic review of journal club operation in order to identify the key characteristics of a club that mediate its success [247]. Using their methodology, the authors identified 101 articles, 21 of which constituted the body of evidence and where over 80% of the selected papers identified the journal club intervention as an effective tool in improving knowledge and critical appraisal skills. Interestingly, few articles included reports on the psychometric properties of their outcome indicators and none reported on the translation of evidence from the journal club into clinical practice [247]. Nevertheless, Deenadayalan *et al.* were able to harvest significant data from their study, specifically in terms of the characteristics which define an effective journal club, these including regular and anticipated meetings, mandatory attendance, clear long and short term purpose, appropriate meeting timing and incentives, a trained journal club leader to choose papers and lead discussion, circulating papers prior to the meeting, using the Internet for wider dissemination and data storage, using established critical appraisal processes and summarizing journal club findings.

Rigour in qualitative research

It is the exception, perhaps, rather than the rule, for journal clubs (indeed systematic reviews) to review the potential of qualitative research for application in clinical practice, yet much can be learned from well conducted studies of this type. Indeed, qualitative research is a multifaceted field with its own methodology, journals, disciplines, and philosophy [248] and it is to the assessment of the rigour of qualitative enquiry that Sale turns in the paper which follows [249]. For Sale, two problems exist with the critical appraisal criteria that can be employed for assessing rigour – many of these criteria imply that qualitative researchers are positioned within a positivist/post-positivist paradigm, acknowledging the methodological differences between a qualitative and a quantitative study, but not acknowledging the philosophical differences between them. Moreover, critical appraisal criteria for the assessment of qualitative research typically fail to address the differences *between* qualitative traditions and to the variants *within* each of those traditions. Sale's view is that there is an urgent need to develop within-tradition critical appraisal criteria that directly acknowledge the philosophical positions and that, in the interim, qualitative researchers and reviewers should be selective in adhering to criteria that fit with their tradition of inquiry and philosophical stance [249].

Disease management, propensity score stratification and the evaluation of clinical practice

The randomised controlled trial remains beloved of EBM and the most popular of techniques designed to evaluate treatment effects, although it is hardly the only source of knowledge in this context (as the *Journal* has vigorously maintained) and when RCTs are judged either unfeasible or inappropriate in answering particular research questions, investigators turn to powerful quasi-experimental techniques, especially when only observational studies can be conducted. In the paper which follows, Linden and Adams [250], building on prevous work [251–259], review the the utility of these designs with specific reference to propensity score matching, one of the most popular approaches in disease management (DM) programme evaluations. The propensity score (where the probability of assignment to the treatment group is conditional on covariates, that is, independent variables) controls for pre-intervention differences between enrolled and non-enrolled

groups. Here, the rationale for employing the propensity score in evaluations of disease management programmes rests on the assumption that enrollment into the programme is associated with observable pre-programme variables.

The scores themselves are derived from a logistic regression equation that reduces each subject's set of covariates to a single score where, conditional on this score, all observed pre-treatment covariates can be considered independent of group assignment – in large samples, covariates will be distributed equally in both groups and will not confound estimated treatment effects [250]. Following the estimation of the propensity score, modelling of treatment effects is made possible using matching, stratification, weighting and/or regression adjustment. Linden and Adams, using the propensity scoring methodology, illustrate the power of this technique in providing important insights relating to the entire population from which programme participants are drawn, estimating the change in hospital admission rates between participants and non-participants in a disease management programme for congestive heart failure, assessing these results relative to the distribution of hospitalization rate changes by quintile.

Interaction effects and subgroup analyses in clinical trials

A significant corpus of medical knowledge about the efficacy of a treatment typically derives from pre-test/post-test studies and from randomised controlled trials, data from the latter type of study being typically reported initially in terms of aggregate effects and which in statistical terms are referred to as *main effects*. In addition to these 'primary results', researchers are also concerned with other types of observed effects – *interaction effects*, which are commonly investigated by *subgroup analyses* in the biomedical literature and as *analyses of simple effects* in the behavioural and social science literature. It is to the challenges that subgroup analyses pose that Sevdalis and Jacklin turn in the paper which follows [260]. As these authors point out, the first challenge is that the performance of multiple subgroup analyses increases the likelihood of obtaining spuriously significant results. The second challenge rests on the fact that the effects that are observed at the level of subgroup are composite, a factor that has not yet received the degree of acknowledgement and discussion that is desirable and it is here that Sevdalis and Jacklin have aimed to make their specific contribution by using a simple additive model based on the findings of the recent CHARISMA trial on the efficacy of clopidogrel plus aspirin in the treatment of patients at risk of atherothrombotic events in order quantitatively to demonstrate the composition of effects at the level of subgroups. For Sevdalis and Jackson, the value of the approach they describe is vested in its generalisability to any research design, irrespective of its complexity and that it is likely to persuade clinicians to consider the multiple causality underlying medical research findings [260].

Combined bias suppression in single-arm therapy studies

In therapy evaluation studies, control groups are sometimes not feasible and in single arm studies multiple factors distinct from the test therapy can contribute to the outcome, such as natural recovery, adjunctive therapies and observational bias. It is in order to address – and minimize – the potential biases that are inherent in single arm studies that Hamre and colleagues [261] devote their study. The authors present a procedure for combined suppression of several bias factors using two methods: sample restriction to patients unaffected by bias, and score adjustment. The authors employed their procedure in a secondary analysis of disease score in a cohort of patients receiving anthroposophic therapies for chronic diseases. Their approach involved the suppression of four biases: attrition bias (by replacing missing values with the baseline value carried forward), bias from natural recovery (by sample restriction to patients with disease duration of >12 months), regression to the mean due to symptom-driven, self-selection (by replacing baseline scores with scores three months before enrollment) and and bias from adjunctive therapies (by sample restriction to patients not using adjunctive therapies). Their procedure, for the combined suppression of these four biases that may affect outcomes in single-arm studies, contributes a new area of discussion to the methodological literature.

Sensitivity, specificity and kappa: relationships between statistical measures of agreement

The concepts of sensitivity, specificity and Cohen's (unweighted) kappa are typically employed by clinicians when comparing a diagnostic test with a gold standard. When a sufficiently high kappa is not achieved in such studies the question may be posed as to what caused the low value of kappa. Low sensitivity? Low specificity? Or both? Additionally, what are the minimum values of sensitivity and specificity that will ncessarily achieve a certain fixed kappa? What is the maximum achievable value of kappa for a given sensitivity and specificity? Are these last two questions related in some way? For Feuerman and Miller [262], it is evident that in order to address these issues we need an analytic formula that displays the relationship between sensitivity, specificity and kappa and in their contribution to the *Journal* they present, by building on previous complex mathematical research [263,264], a discussion tailored to the needs of clinicians in everyday practice, especially in light of the ongoing controversies in the literature with reference to the application and interpretation of the kappa statistic [265,266]. Thus, they provide a graph of the curves representing minimal pairs of sensitivity and specificity for selected values of kappa that range from good to excellent, of use to clinicians and biostatisticians in better interpreting the outcomes of an alternative diagnostic test wherever the measures of sensitivity, specificity and kappa are employed together.

Intuitive estimation of likelihood ratios on an ordinal scale: does it outperform estimation of sensitivities and specificities? Bayesian clinical reasoning

Few clinicians would disagree with the opinion that the bedside use of Bayes' theorem for estimating the probability of a disease, with its complex and time-consuming mathematics, would be a cumbersome exercise and it is certainly not a procedure to which clinicians are enthusiastically and naturally inclined. Based on this observation, and with reference to the growing advocacy in

recent years of Bayesian reasoning as an essential component of clinical logic [267], several educational tools have been developed in order to encourage its formal rather than intuitive use [268], but with limited success to date [269]. In the paper which follows, Moreira and associates [270] propose an alternative approach, based on five categories of powers of tests, ranging from 'useless' to 'very powerful' and assess the performance of clinicians in using it. The authors were able to observe that the study participants demonstrated greater accuracy in estimating powers using a categorical approach than with sensitivities and specificities, with post-test probabilities over-estimated using both approaches. Knowledge of the disease did not appear to influence the estimation of post-test probabilities and the authors conclude that the use of a categorical approach might represent an interesting instructional tool, the potential benefits of which deserve more formal evaluation.

Meta-analysis

Repeated measures study designs

The final two papers in this Edition are concerned with the technique of meta-analysis, its problems and potential. Meta-analyses generate, on average, more citations within the health sciences literature than any other study design [271], although the technique itself – a cornerstone of the methodological principles of EBM [12,142] – continues to excite controversy and is the subject of an ever-expanding literature on its advantages and disadvantages.

In the penultimate article, Peters and Mengersen [272] present their paper on the meta-analysis of repeated measures study designs. As the author explains, repeated measures studies are designed to record measurements or observations of a unit, such as an individual or site, at a number of time points in order to assess follow-up, trend or change over time. This type of study has been employed within a diverse range of disciplines, but the associated analyses are far from straightforward given that the unit of analysis is not the observation *per se*, but the unit on which the observations are made. Thus, the temporal, non-independence between measurements must be considered, as the same individuals, or sites, are being measured at each time point [272]. The authors review the approaches to the primary analysis of these types of data and note that while standard techniques are available for the meta-analysis of most types of studies, there has, to date, been little guidance available to researchers to inform the meta-analysis of repeated measures in order to ensure that the structural dependence of data is appropriately accommodated and the findings therefore meaningful. Using a published meta-analysis on the impact of dietary advice on weight reduction in obese or overweight individuals, Peters and Mengersen demonstrate possible approaches for repeated measures meta-analysis in this context, their methods being generalisable to other modelling scenarios such as fixed effects rather than random effects meta-analysis and more complex hierarchical meta-analysis models.

Heterogeneity and bias

The ultimate paper which closes the 2008 Thematic Edition on EBM has been contributed by John Ioannidis and is concerned with the interpretation of tests of heterogeneity and bias in meta-analysis [273]. The main goal of meta-analysis has been to combine data across many studies or datasets to arrive at summary estimates of effects, but as Ioannidis points out, several issues arise as part of the process of integrating evidence, the principal concerns being heterogeneity [274] and bias [275]. These long recognised complications of the technique which can give rise (and indeed have given rise) to serious flaws in published meta-analyses and erroneous treatment effect size estimates, have led in latter years to the development of methodological approaches and statistical tests to evaluate the presence of between-study heterogeneity in meta-analysis and which have been collectively described as 'diagnostics of bias'. In his article, Ioannidis discusses how these tests should be used and interpreted, why they can often be misleading and how misleading influences can be avoided, concluding his paper with nine suggestions to those who are engaged in the quantitative synthesis of data for direct application in the care of patents.

General Discussion

In reflecting on the content of the last 11 annual thematic editions on EBM of the *Journal* [1,7,129,276–283], it seems clear to us that EBM has changed little in terms of its core precepts and beliefs, but rather in terms of its manner of presentation and in the methodological approaches it now recommends. Thus, the outbursts of rhetoric and triumphalism that characterised the inception of EBM have essentially (though not completely) ceased and few EBM enthusiasts now recommend the initial 5-step [284] or 6-step [285] technique. Instead, EBMers go more quietly about the business of promoting their creed [332] and have substituted the ideal of the individual clinician as searcher, appraiser and applier of literature-based clinical data, for the figure of the individual *follower* of evidence digests prepared by EBM groups strictly in accordance with EBM's reductionist understanding of clinical science and medical practice [43,44]. No attempts have been made to address the lack of a theoretical base for EBM, despite their urgent necessity [1], nor to address the complete lack of evidence that EBM is superior in terms of its outcomes to so-called conventional Medicine [1] – a factor which invalidates the EBM thesis in accordance with its own rules. Rather, repeated invitations to engage in intellectual exchange remain resisted and attention continues to be given, in a 'business as usual' fashion, to the synthesis of systematic reviews and clinical practice guidelines based on 'best evidence', with an increasing emphasis on the implementation of such tools, without debate, into routine clinical practice [1,332]. It is entirely possible to conclude from these observations that EBM *remains* a dogmatic phenomenon, displaying all of the cardinal characteristics of an ideology [8]. That EBM continues to represent a *dangerous* ideology is clear to us from its potential to interfere in the working lives and professional judgements of practising clinicians and to shift clinical practice away from an humanitarian and Hippocratic ideal to a set of simple technical, quasi-assembly line procedures.

Until relatively recently, it appeared as if this process of mindless implementation of a novel method of clinical practice, bereft of a theoretical foundation and utterly lacking in an evidentiary basis, would achieve implementation, inexorably, into clinical practice through a simple pragmatic determination of its protago-

nists in combination with the assistance of regulation-obsessed, cost containing and rationing governments [1]. However, the advent of 'patient-centredness' (and the acceptance of the methods thereof, including shared decision making) as a fundamental ethic of good care and, most recently perhaps, the continuing advances in genomics and translational science that are leading to what has conveniently, and aptly been entitled, *personalised medicine*, are destabilising the EBM ideology and are beginning radically to interrupt its codification into practice. It is not yet possible to predict the outcome of such developments. However, there is no doubt that all of this has come as a very significant shock to EBM and it is hardly surprising that it has had to consider its response to such developments with urgency. What is interesting in this context is the significant amount of revisionism that appears now to be occurring, as some elements of the EBM camp seek to 'clarify' their prior statements and thinking, as if to give the impression that their concept had always anticipated a series of conceptional, methodological and rhetorical metamorphoses in response to such facets of political and scientific progress. Thus, we have the familiar hubristic attitude still in evidence [9,10] which, collectively, now says: "Now that EBM has embraced patient-centred care and personalised medicine, it is more relevant than ever and we must therefore continue to use it in driving forward the development and modernisation of health services". In reality, these recent developments have, effectively, devastated the original EBM concepts and since these continue to be held in their original form, the EBM project lies in ruins. Indeed, we contend that EBM has become embarrassingly sidelined and marginalised by the developments we cite (which have occurred quite independently from EBM, although certainly in some reaction to it).

The idea, however, muted by some strategists within the EBM community, that 'old EBM' can now somehow become 'new EBM' (rather in the manner of 'old Labour' to 'new Labour' in UK politics) through absorbing such developments, while still remaining EBM and retaining the famous (or notorious) title, beggars belief and appears to us to be nothing more than an attempt to retain the old ideology – and seductive nomenclature – at all costs and which strategic 'spin' cannot be allowed to escape unchallenged. Thus, we open the General Discussion with a teaching summary of the history of EBM from inception to date in order to remind readers of what the initial conception of EBM looked like and actively to demonstrate what little change in conceptual thinking has taken place, methodological strategy only, in our view, having changed. We will later discuss how EBM is, in fact, being essentially abandoned (incrementally certainly, but surely) by Western Medicine as technological, philosophical, bioethical and sociopolitical developments in conventional Medicine are rendering EBM's fundamental concepts redundant. In a previous thematic edition, some 11 years ago now, we wondered if the 'screaming baby of EBM' would eventually be consigned to what we referred to as the 'formaldehyde of Medical History' [45] and it now appears to us that this immersion is at least half complete. We seem to think that the next few years may see a completion of this process, with the result that proper consideration can then return to being given to the historic mission of Medicine without the 'distraction of quantitative models' and the malign influence of 'scientific fetishism and fashion' at the expense of good and personalised Medicine.

We shall therefore aim to be as comprehensive as necessary in our treatment of the relevant issues here, but as concise as possible, given the limitations of space in this, the largest of our thematic editions to date. Readers are thus encouraged to consult the primary literature we discuss wherever possible, as it is cited across the 333 references we set out within the Bibliography which follows.

EBM: A brief history of its time

Distinguished in history?

Following the formulation of the neologism 'evidence-based medicine' in 1991 [9,10,286] and its codification in 1992 [12], EBM became, almost immediately, a new and dominant ideology in medical discourse [7,8]. Was it something new? Had it evolved naturally from previous movements? Certainly, medical historians had documented that, as far back as Frederick II (Emperor of the Romans and King of Sicily and Jerusalem 1192–1250) physicians were studying treatment effects, with an interest in the method of trial and observation that re-emerged centuries subsequently in the 17th Century in the studies of the physician-philosopher Jan Baptista van Helmont and the French physician Pierre Charles Alexandre Louis [287]. The principles of EBM were associated by its protagonists with such early philosophical thought [13] and although some parallels could certainly be drawn between the emerging EBM ideas and the so-called 'numerical method' espoused by Louis [287] (which was later found wanting and discarded [288]), the intellectual lineages could easily be seen to be quite distinct. Indeed, the manner of advocacy of EBM, its system of thought and its dogmaticism made it essentially novel in nature and its appeals to Tradition were made in a *post hoc* fashion and in a fairly transparent attempt to gain the legitimacy and credibility that an historical aspect can sometimes afford.

A novel concept: platitudinous and impracticable

Several prominent commentators disputed and dismissed such tendentious chronology and concluded that EBM was, in reality, an entirely novel concept which had "grown over the past 25 years or so from a subversive whisper to a strident insistence that it is improper to practise medicine of any other kind" [289]. Around the same time, in 1996, Charlton subjected EBM to the platitude test (where the converse of a statement is so absurd and implausible as to show the statement itself to be platitudinous), showing that EBM's bold principles failed that test, and in spectacular fashion [290]. This was immediately clear when applied to Step 1 of the sequential methodological steps of EBM as described by Rosenberg and Donald [291]('unclear clinical questions should be formulated on the basis of something other than the patient's problem' (!)), but Steps 2–4 were also quickly seized upon and dissected with some vigour by a variety of authors.

Rosenberg and Donald had advanced the new EBM method as applicable wherever doubt existed in relation to diagnosis, prognosis or management, advocating the determination of keywords and search strategies, electronic literature searching, identification of potentially relevant papers from the search, application of critical appraisal criteria to the recovered papers, identification of a

remaining pool of 'useful' papers and then the formulation of a judgement on how the data within the papers could be employed in the formulation of a clinical decision for the patient – all, ideally, at the bedside. Busy health services physicians (as opposed to some academic clinicians) dismissed the method as inherently limited by impracticability in routine practice, representing nothing more than an utopian ideal, dislocated from the necessities of, for example, communication skills, contextual scientific knowledge, experience and judgement [292–295], but these early calls for wisdom and measure failed to preclude the repeated registrations, from a growing EBM chorus, of exaggerated claims for the primacy of EBM as the one and only acceptable form of clinical medical practice.

Salvific power in medical practice?

The founding fathers and acolytes of EBM had claimed that graduates from traditional medical curricula "progressively decline in their knowledge of appropriate clinical practice" [291] and often "fail to identify or address (their) daily needs for clinically important knowledge (which) may lead to a progressive decline in (their) clinical competency" [296] because the evidence doctors use in their work often "represents extrapolations of pathophysiological principles and logic rather than established facts based on data derived from patients" [296]. Clinicians were advised that only "EBM seems able to halt (this) progressive deterioriation in clinical performance that is otherwise routine and which continuing medical education cannot stop" [297] because it is based on an "increasing realisation of the power of probabilistic reasoning (which) has shifted us from an older anecdotal to a new epidemiological standard" [298] so that "authoritarian medicine may be gradually yielding ground to authoritative medicine" [298] in parallel with an increasing "democratization of medical decision making power" [299]. Moreover, it was anticipated by them that EBM "will cause authoritarian clinicians to lose face by sometimes exposing their current practice as obsolete or occasionally even dangerous . . . at times it will alter the dynamics of the team, removing hierarchical distinctions based on seniority; some will rue the day when a junior member of the team, by conducting a search and critical appraisal (of the literature), has as much authority and respect as the team's most senior member" so that doctors might be transmogrified "from passive, opinion-based spectators of clinical practice to active, evidence-based clinicians" [291]. This, then, was typical of the initial hubris and rhetoric of EBM that had "lacked finesse and balance" [289] in attempting to foist its ideas onto the medical profession, the articulation of which produced wide-ranging, visceral and sustained anti-EBM sentiment within the international medical press [45,300] in response to the whole idea that real, good and competent medicine had only just been discovered.

Occupational use of the term 'best evidence'

A key characteristic of the EBM concept was its ability to identify evidence suitable for immediate implementation into clinical practice. The occupational use of the term 'best evidence' by the protagonists of EBM remains notable. For the protagonists of EBM, the 'best evidence' for clinical practice continues to derive from the 'best studies' – typically large published databases formulated in accordance with positivist precepts aimed at establishing the probability with which a given intervention will result in a given outcome (rather than studying the relationship between the two). Thus, for EBM, the 'truth' is derivable from statistical analyses of the available data and so probabilistic studies are viewed as providing what evidence there is for clinical medicine and are therefore seen as the preferred basis for medical practice. Thus, the EBM protagonists continue to glorify probabilism based on statistical data [301], synthesizing a certainty based on what the analysis of epidemiological data suggests is statistically probable which, in the clinical setting, does not represent certainty at all. This type of 'certainty' remains a 'false certainty', a fact to which the international body of practising and experienced clinicians continues vigorously to attest.

The imposition of simplistic decision-making processes upon complex clinical situations in an attempt to manufacture clear answers to unclear problems was always doomed to failure, but it remains a very clear and central tenet of EBM as we write. It was explicitly stated and remains a held dogma that EBM has the ability to 'incorporate the best evidence' into clinical policies which 'state what should be done in clinical practice' [302] and that the Cochrane library produces 'absolutely the best evidence ever' [303]. Sackett and Haynes, in reviewing their methods for the production of abstracts for publication in the journal *Evidence-based Medicine* explicitly claimed the ability of their approach to identify findings that are 'highly likely to be true' [333] and that they therefore represent a suitable and immediate source of information for treatment decisions. We were told that such methods distinguish '. . . true evidence-based services from a burgeoning host of pretenders' [304].

EBM in 2008

If, then, we compare EBM's core precepts today with how they were originally articulated (ignoring the style of presentation) then we see that they remain *essentially the same*. The core difficulty (as we have emphasised earlier) remains EBM's refusal to abandon or at least re-interpret its so-called 'hierarchy of evidence', which represents the fundamental epistemological stumbling block of the whole EBM thesis. It is this foundational dogma of EBM that remains fully unaltered, with the EBM community continuing to maintain the status of the RCT as the 'gold standard' of evidence, the *criterion reference* of validity by which all other forms of information are judged. Thus, EBM continues to insist that RCTs provide the 'best' evidence of clinical effectiveness with RCTs occupying a position of primacy at the top of the hierarchy of evidence followed, in descending order by cohort studies, case control studies, surveys, case series and single case studies and opinion [284]. This 'hierarchy of evidence' rapidly attained (and retains) the status of an unquestioned dogma among the biostatistically inclined, although it has absolutely no status as a principle of scientific method whatsoever. The 'gold standard' status accorded to the RCT is, in reality, wholly arbitrary, with the founding fathers of EBM merely deciding that this kind of epidemiological information was both necessary and sufficient to define best practice. This is, in reality, akin to a biologist asserting that evidence from microscopy is always the best evidence, without regard to the system being studied or the question being asked [290]. Despite a wide range of challenges to the notion of the

hierarchy (see, e.g. [305–312]) and impressive and illuminating attempts to foster different ways of looking at the 'problem of evidence' within the *Journal of Evaluation in Clinical Practice* (see, e.g. [313–328]), the EBM community remain resolutely committed to an immutable understanding of their evidentiary ranking. Will this matter for the future? Probably not and for the reasons we discuss as we conclude below.

Conclusion

Interpretations of medical evidence advanced from positions of study and learning are always useful, but none necessarily deserves a special place of honour. The clinical interpretations of medical evidence advanced by the protagonists of EBM and their subjective abstraction into academic journals and guidelines and reviews are therefore valuable activities in their own right, but only in the context of their *contribution* to the general scientific debate. Thus, clinical interpretations of medical evidence will differ and attempts to select one interpretation over another or to synthesize a third, subsequently declaring it as 'truth' are irresponsible and cannot be recognised as belonging to the scientific ability or methodological competency of any one group of clinical academics or practising clinicians. Yet this is what the the EBM community has aimed to do, and what the Cochrane Collaboration continues to do, despite Chalmers' cynical employment of a celebrated quote of Xenophanes for association with the Library to function as a hollow disclaimer: 'through seeking we may learn and know things better. But as for certain truth, no man hath known it, for all is but a woven web of guesses' [329].

Given all of the above, it seems extraordinary that some authors continue to refer to the 'genius of EBM' and to celebrate 'the return of empiricism as embodied in evidence-based medicine and its slow ascendance over eminence-based medicine', referring within the same article to the 'mandatory retirement of experts' and to how conventional Medicine has branched 'away from science to the boggy marsh of intuition, opinion and reason revered as clinical experience' (!) [330].

There is no need to omit the word 'evidence' from continuing discourse but those who wish to understand the current status of EBM should be aware of the dangers in the use of this word [331]. A word ('evidence'), like a name ('Cochrane') or any other symbol, is easily appropriated by a cause and the intellectual and rhetorical struggles that have defined the international EBM debate to date cannot be understood independently from a wider consideration of misguided vision, arrogance and careerism.

What, then, do we do instead of EBM? How do we channel laudable reforming zeal in a more productive and useful direction, away from methodologically limited studies towards experimental rigour, representative sampling and a heightened appreciation of the compassion and intimacy of the clinical encounter? The common understanding of a positive vision of 'traditional' medical practice remains imprecise and 'more of the same' does not meet the urgent demands for improvement and change in modern Medicine. One major reason for the early 'success' of EBM is that it linked a negative critique to a positive vision. Rather than looking for a single substitute for EBM, we should accept that a plurality of information is in every way preferable to a monopolistic concept of epidemiological evidence as the basis of modern medical practice. As we have argued extensively over the last decade in the *Journal*, clinical science is of unquestionable importance to the development of modern clinical medical practice, but it simply cannot be equated to its essence. The essence of clinical practice is the provision of personal medical services through the mechanism of the consultation. The place of EBM, and science more broadly, is utterly subordinate to this. The advent of patient-centredness and shared clinical decision making and the rise in importance of genomics and translational sciences is rapidly marginalising EBM, so that the concept of EBM is losing influence as the promises and potential of *personalised medicine* are increasingly recognised. EBM was initially known as 'clinical epidemiology', the application of epidemiological data to clinical practice. That is what it was, what it always has been and that is what it remains.

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