EDITORIAL INTRODUCTION

Models in the balance: evidence-based medicine versus evidence-informed individualized care

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Introduction

Medicine today is not what it used to be. Exponential increases in technological and biomedical advance over the last 100 years or so have radically transformed the scope, possibility and power of clinical practice, driving enormous shifts in individual and population health. Yet despite such staggering progress, there is a growing and pervasive sense of unease within international medicine, indeed a frank recognition perhaps, that all is not entirely well, leading an increasing number of authors and commentators from a wide variety of clinical, academic and patient backgrounds, to claim that medicine has entered a time of significant crisis, urgently needing to re-learn what it has progressively forgotten in over a century of empiricism [1]. The aetiology of the crisis in medicine is complex in nature, but is characterized principally by the evolution of a scientific reductionism and executive technocracy in health care, the former deriving from movements within medicine itself and the latter arising from the colonization of health care decision making by non-clinical administrators remote from clinical practice, a new elite that has emerged from the rise of managerialism within global health services [2].

In this Editorial Introduction to the 13th Thematic Edition of the Journal of Evaluation in Clinical Practice on the nature of knowledge and action in clinical practice, we reflect briefly on Paul Tournier’s thinking, comment on the current status of the Evidence-Based Medicine (EBM) Movement and note how growing interest in the personalization of health care services in response to system failures in modern health services and the ascendance of patient empowerment initiatives is beginning to transform the health care landscape across the globe.

Paul Tournier, EBM and the rise of person-centred medicine

Of many authors writing during the 20th Century who warned against the negative aspects of scientific medicine, while firmly acknowledging the positive results of biomedical and technological progress, we find a particularly resonant voice in Paul Tournier (1898–1986). Tournier, a Swiss general practitioner who practised medicine in Geneva for most of his professional life, encouraged the study of the value of an integrated approach in medicine, where clinical intervention occurs within a century of empiricism [1]. The aetiology of the crisis in medicine is complex in nature, but is characterized principally by the evolution of a scientific reductionism and executive technocracy in health care, the former deriving from movements within medicine itself and the latter arising from the colonization of health care decision making by non-clinical administrators remote from clinical practice, a new elite that has emerged from the rise of managerialism within global health services [2].

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reveal only one side of man’s nature – that of his mechanisms. He emphasized that there would remain a need to augment such knowledge in clinical practice with ‘a personal knowledge, which is of a different order, the order of the person, not that of things’, knowledge that was ‘within the reach of every doctor, whether he be an ordinary general practitioner or a learned specialist’ [5].

Should we interpret this as some form of anti-science stance on Tournier’s part? Was the exposition of his philosophies of clinical medicine a coded plea to reverse the scientific progress being made in medicine and thus to denude it of the powers for the cure and attenuation of disease it had then only so very recently developed? We think not. Tournier had, in fact, become alarmed at the stripping out from medicine of much of its humanity, with a preferential concentration being given to the development of the science base of medicine at the expense of medicine’s essential humanism. Here, ‘curing’ was gradually substituting for ‘caring’, so that rather than holding these two foundational components of medicine firmly together, they were, in fact, being ripped apart. This process of the de-coupling of medicine’s science from its ‘soul’ [6,7] has continued from Tournier’s times to our own, with the substitution of scientific medicine for *scientistic* medicine and an accompanying collapse of humanistic values and practice in medicine, a phenomenon reaching its culmination in the emergence of the EBM movement [8]. But 20 years of intensive philosophical and clinical argumentation as part of the international EBM debate [9–23] and a recognition and embrace of the inescapable complexity of clinical practice [24], have modified the vision for a ‘modern’ model of clinical practice. Despite its serial reconstitutions, the EBM construct is now essentially defunct, being increasingly abandoned as part of an active search for a more clinically coherent and economically sustainable alternative.

### The rise and fall of EBM

If we have seen, then, a rise and now a fall of EBM [25,26], then what (with the history of the former well documented) can explain the latter? Certainly, EBM proved of considerable initial interest to executive technocrats and government policy makers, given its potential to identify therapies and interventions lacking scientific evidence of treatment efficacy – the sole criterion of interest to the ‘active, evidence-based practitioners’ [27]. When so identified, these ‘non evidence-based’ treatments and procedures could be prioritized for excision from routine practice, thus representing a highly convenient cost-cutting tool: the ‘evidence’, not managers, taking the responsibility for subsequent service rationalization and treatment decommissioning. Such a tool, however, was always a two-edged sword. If EBM’s philosophy was that the removal of ‘ineffective’ or ‘dangerous’ treatments from clinical practice was necessary, then it was also and equally necessary that ‘effective’ and ‘safer’ treatments, based on the ‘best evidence’ identified by EBM methodologies, should replace them. And ‘best evidence’ costs money, with the E of EBM far more likely to increase health care costs overall in our times of rapid biomedical and technological advance, than to contain them.

Given the political impossibility of using EBM selectively to de-select some treatments while blocking the uptake of new, more expensive ones [28], it became clear over time that the increases in costs generated by the relentless incorporation of expensive new modalities into clinical practice based on the latest biomedical and technological advances lauded by EBM would no longer prove acceptable to funders. Furthermore, from a humanistic perspective, EBM has now been shown incapable of incorporating patients’ values and preferences into clinical decision making when these are in conflict with EBM’s ‘evidence’. A recent Encyclopedic from the EBM Community admitted as much [29], with extensive scholarly commentary confirming the same [26,30–35]. Even the latest Apologia from the EBM Community fails, on analysis, to resolve this philosophical and clinical conundrum, indicating a profound irreconcilability between EBM and patient-centred care [36].

To lucid investigators, this result comes as little surprise. Indeed, the idea that data derived from the results of intrinsically methodologically limited epidemiological study designs, such as RCTs and meta-analyses, would be routinely applicable to individuals in clinic or that the recommendations from EBM-style systematic reviews of the literature could ever have formed the base of clinical practice, was always an intellectual and clinical absurdity [33,35]. One of the great questions of our time is how such a notion could ever have captured (a significant part of) the medical and public imagination for so long. Arguably, this was a triumph not of academic argument or evidence (as even the movement’s defenders accepted its fundamental ideas were not and could not be supported by evidence [20]), but of opinion management [2,20]. Defenders of EBM successfully claimed ‘ownership’ of the term ‘evidence’ and traded on its rhetorical properties to discredit critics as ‘anti-evidence’. As substantive definitions of the term became increasingly vacuous in EBM literature, the persuasive power of the prefix ‘evidence-based’ remained [31–33] and indeed this prefix was exported to a range of non-medical contexts whose methodologies bore no substantive resemblance to those of EBM [20,32]. The prefix functioned as a ‘brand name’ to market the approach [32,35] and the success of such non-rational rhetorical strategies for so long should function as something of a cautionary tale. We predict that, as the debates about personalisation and scientific reductionism (or scientism!) intensify, similar tactics are highly likely to be employed. Those rejecting scientism for a more humanistic approach to clinical practice will find themselves increasingly being labelled ‘anti-science’ by the vanguard of scientism. It will be increasingly important to distinguish ‘science’ (a crucial component of good practice) from ‘scientism’ (a dogma about the role of science as the exclusive basis for practice) and to resist the efforts of those who will aim to dismiss all opposition to scientism as based on an irrational opposition to, or ignorance of, science.

In this context, it is interesting to note how the schools of thought which previously would have employed the term ‘evidence-based’ (and did so incontinently) have now commenced a preferential employment of the term ‘evidence-informed’ (italicization ours) [37], indicating that they have finally assimilated much of the argumentation documented within the JECP and elsewhere and, in accordance with the proper precepts and processes of science, have modified their

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1 There are legitimate debates about the appropriateness of reductionism in many areas of science and we have no desire to pronounce dogmatically on matters beyond our remit – our target here is not any area of science, but a thesis about the relationship between science and medicine whose problematic nature has been already outlined [1].
intellectual position accordingly. This is to be welcomed as confirmation that the persistent insistence upon clarity in thought and language can lead to real intellectual progress. While it was undoubtedly naively optimistic to suggest that someone with the stature of Gordon Guyatt might ever ‘retract’ rather than simply ‘clarify’ previous assertions [32], we believe the ground has now been prepared for what we might (again at the risk of sounding overly enthusiastic) characterise as a ‘Hegelian’ moment in the debate. That is simply to say, we are at a point in the history of medicine where insights from approaches which have, historically, been set up in opposition to each other (the focus on improving the science of medicine and the focus on medicine as a caring, human occupation, whose practitioners and patients are persons, with all this entails) might be fully reconciled. Rather, than subordinating one approach to the other, rather than privileging one side of the picture and then puzzling over how to re-integrate the other, we look forward to the proper synthesis of these approaches. The challenge of medical humanities is as intellectually serious and practically urgent as medical science, and we look forward to the development of accounts of medicine that do full justice to its human and social complexity, drawing on the full range of sources that form our intellectual heritage – in science, ethics, philosophy and applied humanities.

A momentum for change

There is little doubt in our minds that health services are beginning to undergo a fundamental exercise in reflection, a reflection on the need for re-personalization. Certainly, the increasing ability to personalize scientific medical intervention based on advances in genomic and translational medicine has led to increasing interest in the need to individualize health care more generally. In our attempts to describe this occurrence, we refrain from a premature employment of the term ‘paradigm shift’, given its strident misuse as part of the EBM agendum and movement [26,30–35]. Rather, we prefer to talk in terms of the observation of a momentum for change, based on a recognition within health systems and Society more generally, that current models of health care are not fit for the future, that they are in fact unsustainable in both humanistic and economic terms and that there is an urgent need – articulated increasingly loudly by patients themselves – to move away from impersonal, fragmented and decontextualized systems of health care towards personalized, integrated and contextualized models of clinical practice. As a direct result, the challenge now is to debate and develop methodologies that will enable affordable biomedical and technological advance to be delivered to patients within a humanistic framework of care that recognizes the importance of applying science in a manner which respects the patient as a person and takes full account of his values, preferences, stories, cultural context, fears, worries, hopes and anxieties and which thus recognizes and responds to his emotional and spiritual necessities in addition to his physical needs.

While the philosophy that underpins such reasoning is applicable to all the specialties and subspecialties of medicine and the health care professions, it is of very particular applicability and value in the management of chronic disease and thus to current and evolving health care contexts, where a dramatic rise in the incidence and prevalence of chronic diseases worldwide has become apparent [38] and which poses very serious challenges indeed for the funding and delivery of health services globally. In the context of these long-term conditions, the old formula of ‘diagnose, treat, cure, discharge’ has become defunct in large measure and newer, more ‘fit for purpose’ models of care are urgently in need of development for use.

Person-centred clinical medicine

If EBM, by its nature and directly for the reasons we have discussed above, cannot function as the basis of such models of care, then what can? It is here that the discourse of person-centred medicine (PCM) becomes of immediate relevance. Mezzich has articulated a useful definition of PCM that provides a template for ongoing methodological development in the field, describing PCM as a medicine of the person (of the totality of the person’s health, including its ill and positive aspects), for the person (promoting the fulfillment of the person’s life project), by the person (with clinicians extending themselves as full human beings, well grounded in science and with high ethical aspirations) and with the person (working respectfully, in collaboration and in an empowering manner through a partnership of patient, family and clinicians) [39,40].

These are fine words and noble aims, but how is such an undeniably optimal vision of clinical practice to be achieved operationally and afforded within economically constrained health services where the developers of health services have long argued if not directly against optimal care, then certainly tacitly so in speaking preferentially of reasonable population health? And what of the workforce that has become disillusioned, even ‘burnt out’ by the effects of the manifold pressures of working within modern health services? Will the additional time required by personalized approaches to care and the building and maintenance of meaningful clinical relationships with patients not add to such economic and human resources dilemmas? Currently accumulating evidence suggests the contrary to be true, especially in the management of long-term conditions, where PCM approaches in the primary health care setting have been observed to increase adherence to medication regimens, reduce episodes of exacerbation and increase self-care, leading to a stabilization of disease progression, reduced hospital admission and re-admission rates and a lowering of the costs of drug prescription for the management of the condition itself and for the control of uncontrolled disease. Moreover, increases in both patient and clinician satisfaction with the process and outcome of such care have also been reported. Far from representing a poison chalice, PCM may therefore come to represent a golden one – for patients, clinicians, executives and policy makers alike [41].

Poison or golden chalice apart, it is unfortunate that the use of the nomenclature ‘person-centred medicine’ risks the accusation that such a term represents a further rhetorical addition to the already rhetorically over-burdened nature of health services. It is certainly true (as was and is the case for EBM) that the prefix ‘person-centred’ possesses a degree of rhetorical force, having an emotive component as well as a descriptive one. For the leaders of the PCM movement, however, the use of the prefix ‘person-centred’ has become necessary not for reasons of sensationalism or hubris (as characterized the inception and promotion of EBM) [9,10], but rather as a simple mechanism to remind
medicine of its epicentre – the person who is the patient. When the arguments are won for a medicine informed by rather than one based on the E of EBM and where the person of the patient returns to the very centre of the clinical encounter, the detachment of all such prefixes from medicine will become possible, their usefulness and necessity by that point having become mercifully defunct.

Conclusion

While the EBM movement attempted to force clinical practice in the direction of a codification of an impersonal medicine based on statistical averages and the effect sizes of meta-analyses, the foundational philosophy of medicine has remained ‘to cure sometimes, to relieve often and to comfort always’. Although we must now preface this ancient maxim with ‘to prevent illness where possible’ and although we might come at some point to conclude it with ‘to assist death where and when necessary’, the mission and purpose of medicine remains absolutely the same. Medicine has the unalterable imperative to care, comfort and console as well to as to attenuate, ameliorate and cure. A preferential concentration on either care or cure, rather than on a search for a means of integrating both, risks the creation of an ethical and moral chaos in the profession of medicine and a grave outcome for patients. We have noted elsewhere [42] that it seems incontrovertibly clear from raised voices worldwide, that patients are no longer prepared to be ‘dealt with’ or ‘processed’ by technicians in applied bioscience, but wish rather to be attended by scientifically trained advocates who recognize their problems not only at an organic, but also at an emotional and spiritual level and who, in addition, then proceed through shared decision making to tailor treatment for the patient through a medicine of, for, by and with the patient [39,40]. This is the core of medicine. It is, put simply, what medicine is for.

The argumentation of this Editorial Introduction and the 41 papers of this issue [43–83] together constitute the 13th thematic edition of the Journal of Evaluation in Clinical Practice, building upon the work of the previous 12 [12–23]. We have entitled this year’s edition ‘Models in the Balance: Evidence-informed Individualised Care’, because we believe that the time is now right to institute a debate on the need to progress towards the formulation of personalized models of care informed, but not based, on the E of EBM, representing a Hegelian shift in understanding following some 20 years of intensive philosophical and clinical argumentation on the nature of knowledge and action in clinical practice. Without progress of this type, we fear that we will see the standards of health care proceed inexorably downwards towards the lowest common denominator. Such could hardly be considered a professional or moral ideal. If through such debate and development, we are able to achieve this renewed vision of medical practice, then there is a real possibility that the personalization of health services can contribute importantly to causal increases in the quality of care and to patient and professional satisfaction with health processes and outcomes both in the clinic and at the bedside. Unlike many ‘priorities’ in modern health services, we argue that this one in particular is altogether worthy of sustained attention and developmental effort.

References


