



Contents lists available at ScienceDirect

Trends in Anaesthesia and Critical Care

journal homepage: www.elsevier.com/locate/tacc

Opinion

Evidence-based medicine: A predictably flawed paradigm

Michael Keane ^{a, b, c, *}, Chris Berg ^{d, e}^a Swinburne University, Centre for Human Psychopharmacology, Mail H24, PO Box 218, Hawthorn, Victoria, 3122, Australia^b Monash University, Melbourne, Australia^c Casey Hospital, Berwick, Victoria, Australia^d Institute of Public Affairs, Level 2, 410 Collins Street, Melbourne, Victoria, 3000, Australia^e Royal Melbourne Institute of Technology, Melbourne, Australia

ARTICLE INFO

Article history:

Received 21 March 2016

Received in revised form

26 June 2016

Accepted 5 July 2016

1. Introduction

Is evidence based medicine (EBM) the most appropriate paradigm for advancing clinical knowledge? There is increasing discussion of how evidence and science guides clinical medicine [1] and the accumulating awareness that individualized medicine inevitably falls within a clinical gray-zone.

While there are legitimate arguments relating to the precise definition of EBM, by EBM we refer to the overarching paradigm which gives primacy to “the formal assessment of medical interventions using controlled trials” [2], in particular the randomized controlled trial (RCT). Here we argue that the basic proposition that an analysis of historical data from controlled trials can objectively and efficiently decipher what treatments are uniformly superior is fundamentally flawed. We also argue in particular that in such a complex system as acute medicine it is *predictable* that RCTs will frequently lack the fidelity to give definitive or even useful answers, especially around the margin of progress.

The goal of this Opinion article is not to provide a comprehensive review of the individual failings of EBM. Overall, we agree with the conclusion of a classic paper by Ioannidis which contends that most published research is unreliable anyway [3]. One overview found that 35% of published re-analyses of RCTs gave a result contrary to that originally published [4].

Rather, we observe that the authors of such critiques always propose the solution as being more and more rules in an attempt to

achieve purer EBM [5]. The solutions always involve an underlying assumption that the scientific method of controlled experimentation using RCTs must be the most sophisticated way to determine allocation of interventions and treatments. This belief is enshrined in the levels of evidence that underlie the EBM paradigm [2]. A generation of clinicians have accepted that while EBM has problems it still represents the most rational and objective method of advancing medicine; it just needs to be practiced in the right way [6].

Yet EBM misunderstands the interactions between the complex systems of biology, clinical medicine, the human condition and lessons learned in other fields of human inquiry. Basic science is appropriately carried out using the scientific method of controlled experiments. But clinical medicine is not necessarily the same as basic science. Bridging the gap will involve a fundamental paradigm shift.

In this Opinion article we argue that the scientific method of controlled experiments has been the wrong paradigm to optimize information gathering in such a dynamically changing and complex system as acute clinical medicine. Clinical medicine should, more appropriately, be conceptualized as a marketplace of ideas - a market of inordinate combinations of competing ways of caring for patients from which clinicians have to choose from. Each of these inordinate combinations of interventions have a difficult to predict and complex array of interacting benefits and long term and short term side effects occurring in an unfathomably complex, dynamically evolving system of biological interactions. A model which demands definitive “evidence” based on historical controlled scientific experiments would not be expected to have the fidelity to deal with individual patients, especially around the margin, nor have the flexibility to effect progress in the most efficient way in such a complex and changing system.

The problem of system complexity and legibility is not unique to medicine. Section 1 of this Opinion article considers a parallel field - economics - where such a paradigm shift has been accomplished. Section 2 uses this parallel to explore what we call the “evidence based paradox” - that clinically relevant evidence uncovered by RCTs is contestable at the margin and therefore less objective than understood. In Section 3 we propose an alternative paradigm and address its relevance for clinical practice.

* Corresponding author. Swinburne University, Centre for Human Psychopharmacology, Mail H24, PO Box 218, Hawthorn, Victoria, 3122, Australia.

E-mail addresses: mkeane@swin.edu.au (M. Keane), cberg@ipa.org.au (C. Berg).

Because what we are proposing as a response to the failings of EBM is so radically different it is important to clarify the following points up front. To reject the EBM paradigm does not mean we suggest that practice should not be based on rational inquiry or objectivity. Quite the opposite: we propose that the system must incorporate far more information and data. “Market signals” should be constantly generated and considered, including all effects, side effects and remedies to the side effects that occur. A more ‘market’ oriented approach would consider every conceivable piece of relevant information, practice would move forward and rigorous analysis would be undertaken to see what works and what doesn’t in the context of continuous open and intense competition; with individual clinicians, institutions and professional bodies all involved.

Nor are we rejecting science. The scientific method is important to get us to the starting point, as relates to the basic science of drugs and different operative interventions. Science leads us to a point where we can observe that a drug has a basic pharmacological effect that can be measured in reproducible experiments. However, clinical medicine involves the next step. It requires practitioners to consider how to best put together the inordinate combinations of different investigations, medicines, interventions, to anticipate the negative consequences of that combination and to adjust and additionally treat those effects. The static model of historical evidence represented by RCTs would *never* be expected to be the optimum way to deal with such a complex system.

2. An analogy to economics

One way to think about the epistemological problems of EBM is to consider the analogous situation of an economic system. Throughout the twentieth century many academics championed the principle that central authorities were best placed to allocate resources. Central planning had at its heart the premise that rational experts, armed with the best computational power available, could understand the complex economic system and outperform the market.

Two critiques of the rational planner model of economic allocation are relevant to the EBM discussion. Long ago, Hayek argued that planners face a fundamental knowledge problem [7]. The market system is a disaggregated communication network which harnesses local information and distributes it around the economy. Knowledge about efficient allocation depends on subtle on-the-ground factors, constantly changing economic, social and technological conditions, shifting individual preferences and so on; which is exactly what we face in clinical medicine. Central planners are unable to acquire that knowledge as it is both dispersed and contingent on the existence of an external process - a market - in order to arise [8].

A more recent contribution by Scott adds to our understanding about the effect of top-down approaches to knowledge in a complex system [9]. Scott describes the process whereby planners seek to make social phenomenon “legible” by deliberately reducing the variation natural in the system. Planners require aggregated information in order to rationally reshape the society they command. This involves the grouping together of distinct phenomenon into uniform categories. Yet the process of seeking legibility comes at the expense of fidelity. Natural variation is often fundamental to the operation of the system itself.

Here we emphasise the concept that an economic system is too complex to understand and centrally plan using backward looking data. By contrast, market allocation was more flexible and adaptable - information was constantly gained and most importantly adaptations were constantly being made to correct problems. Entrepreneurs make decisions based on their best reasoning of the

information available to them - including information about historical trends and technical analyses. Inefficiencies (lack of effect or side effects) are elucidated during the ongoing process of implementation and are most effectively corrected through the intense competition of alternative approaches.

No analogy is perfect and there are obvious differences between resource allocation in an economic system and medical practice. However, there are important parallels. In clinical medicine the research question being asked is always occurring in the context of a dynamic, complex, changing and individualized system. Information about the effect of interventions, especially in variable and changing combinations, will more efficiently be elucidated by open competition than by trying to isolate a variable through the experimental method. But such a free-floating, evolutionary vision of medical progress is strikingly counter to that which drives EBM.

3. The evidence base paradox

The “evidence” regarding the efficacy of a given treatment is not an objective, non-contingent phenomena. It is instructive to appreciate what could be called the evidence base paradox [10]. That is, the more something really needs an objective assessment of the evidence, the less it is possible to gain an objective answer free from ideological bias and other human frailties. If the margin of the clinical effect of an intervention is so wide, or the lack of effect so solid, that it can survive the most stringent debate related to transferability to the constantly changing, dynamic, complex system of clinical medicine, then the intervention is obviously not in the gray area of medicine and an RCT is not needed. It is on the other end of the spectrum, where the intervention is around the margin of practice, that the problems with the RCT experimental paradigm becomes apparent. At this margin, the smallest methodological quirks or intricacies of a study will potentially be magnified to render the result irrelevant. It is impossible to know. The closer to the margin, the more the effect of loss of fidelity from making the system legible will outweigh the real effect of the studied intervention. This is especially so as practice continually changes and practitioners negate the bad elements and enhance the good elements of an intervention and background community medication and treatment practices change. We ought to concede that evidence-based medicine is still, especially around the margin of practice, no more than opinion-based medicine.

This is compounded by the fact that in acute care medicine, only an approximate version of the scientific method is usually used anyway. Medicine is not about setting an experiment and letting it run to a conclusion regardless of the unique circumstances of patient. Practitioners have an ethical obligation to make sure all changeable elements are optimized to their contemporary understanding of best treatment. Thus, the experimental milieu is constantly changed during the course of the experiment. Furthermore, if the rigor demanded of scientific experimentation was demanded of EBM, especially as it relates to true blinding, then it is an unavoidable axiom of EBM that it seeks to find a clinically significant difference for an intervention that is at the same time, by definition, clinically indistinguishable to the clinician during the course of the “experiment” [11].

The evidence base paradox undermines the claim that RCTs represent a gold standard method for determining the effect of an intervention. In order to make the clinical scenario “legible” enough to study, this necessarily reduces fidelity. The RCT’s lack of fidelity is akin to slicing cheese with an ax. All new medical knowledge emerges in the context of a constantly evolving dynamic system. The difference that a given studied intervention will make must be small and contentious (if it is obvious it would already be taken up by clinicians). However the artificiality of having to have rigid

Download English Version:

<https://daneshyari.com/en/article/5584157>

Download Persian Version:

<https://daneshyari.com/article/5584157>

[Daneshyari.com](https://daneshyari.com)