

CONTROVERSY AND DEBATE

Evidence-based medicine was bound to fail: a report to Alvan Feinstein

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Accepted 31 January 2017

Abstract

John Ioannidis has provided a lucid account, in the form of a report to David Sackett, of how evidence-based medicine (EBM) was hijacked to serve vested interests: major randomized controlled trials are largely done by and for the benefit of the industry; meta-analyses and guidelines are flooded with conflicts of interest; national and federal research funds are unable to address basic clinical questions. Nonetheless, EBM would remain a worthwhile goal. In this paper, in the form of a report to Alvan Feinstein, it is argued that current developments were largely predictable. EBM certainly gave an important contribution to questioning unsubstantiated therapeutic claims. Time has come, however, to become aware of its considerable limitations, including overall reductionism and insufficient consideration of problems related to financial conflicts of interest. EBM does not represent the scientific approach to medicine: it is only a restrictive interpretation of the scientific approach to clinical practice. EBM drives the prescribing clinician to an overestimated consideration of potential benefits, paying little attention to the likelihood of responsiveness and to potential vulnerabilities in relations to the adverse effects of treatment. It is time to substitute the fashionable popularity of a strategy developed outside of clinical medicine with models and research based on the insights of clinical judgment and patient–doctor interaction, as Feinstein had outlined. © 2017 Elsevier Inc. All rights reserved.

*Keywords:* Evidence-based medicine; Clinimetrics; Conflict of interest

John Ioannidis, building on a conversation he had with David Sackett in 2004, provided a lucid account of the long-term outcome of evidence-based medicine (EBM). His considerations identify with exceptional clarity current major problems of medical research: major randomized controlled trials (RCTs) are largely done by and for the benefit of the industry; meta-analyses and guidelines are flooded with conflicts of interest; national and federal research funds are unable to address basic clinical questions [1]. EBM was hijacked to serve vested interests. Ioannidis remarkably shares his personal pathway to EBM, and the sense of personal failure and disappointment at not being able to accomplish its goals. Yet, he still believes that EBM remains a worthwhile goal, that should still be possible [1].

In reading his personal account, I thought of when, in the mid-70s, I was an Italian medical student spending a summer elective in a clinical unit of St. Joseph's Hospital in Hamilton, Ontario. My supervisor, an accomplished

clinician, suggested me to come back the following summer and spend an elective in the Department of Clinical Epidemiology and Biostatistics of McMaster University. "Since you are interested in research, you can learn a lot there. They have no idea of what is going on in the real world, but in the future you will be able to combine the two worlds." The problem was that, as other young people of my generation, I wanted to change the world and a place so far apart from real life could not suit my needs. I was looking for revolutionary approaches and my choice for the following summer fell on Rochester, NY. I had read papers by George Engel, and psychosomatic medicine appeared to be off the beaten path. He criticized the traditional concept of disease and elaborated a unified concept of health and disease: there is no health and no disease, only a dynamic balance between them [2]. The biopsychosocial model allows illness to be viewed as a result of interacting mechanisms at the cellular, tissue, organismic, interpersonal, and environmental levels. Accordingly, the study of every disease must include the individual, his/her body, and his/her surrounding environment as essential components of the total system in what was defined as an ecological perspective, long before ecology became fashionable. Engel was able to foresee the

Conflict of interest: None.

Funding: None.

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growing dangers of conflicts of interest in medicine [2]. He pointed to the alliance between commercial interests in medicine and biomedical reductionism leading to practices such as unnecessary hospitalization, overuse of drugs, excessive surgery, and inappropriate utilization of diagnostic tests. How could Engel identify the dangers of special interest groups, as they are sadly known these days [3], in the 70s is simply astonishing.

I spent the summer in his medical—psychiatric unit and the experience was for me an endless source of knowledge and inspiration. George Engel [4] differentiated between “scientific physicians” (clinicians who fully apply the scientific method in their care of patients and in their understanding of the disease) and “physician scientists” (physicians whose primary commitment is to scientific research pertaining to medicine and who have little or no familiarity with the clinical process). Clinical practice is the source of fundamental scientific challenges for scientific physicians, whereas the application of basic (including pharmaceutical) research is the preferred focus of physician scientists. At the end of the summer, I knew I wanted to become a scientific physician and not a physician scientist. I also intended to become like George Engel and to be knowledgeable of both internal medicine and psychiatry. In due course, I realized that one specialty was already more than I could handle and I chose psychiatry, the field where most of the psychosomatic researchers came from.

### 1. Feinstein and evidence-based medicine

Engel [2] criticized the attitude that tends to restrict what is categorized as disease to what the physician does understand and recognize, and he/she believes can be helped by his/her intervention. The fact that physicians arbitrarily exclude certain categories of complaints or signs as not pertinent reflects their social and institutional roles that may vary with time and circumstances. Yet it was another supporter of the psychosomatic movement, the father of clinical epidemiology, and the founding editor of this journal, Alvan Feinstein, who provided a viable research and clinical alternative to the outdated concept of disease. According to Feinstein [5], in clinical medicine, there is the tendency to rely exclusively on “hard data,” preferably expressed in the dimensional numbers of laboratory measurements, excluding “soft information” such as impairment, distress, and well-being. This soft information, however, could be assessed by reliable methods. He introduced the term “clinimetrics” to indicate a domain concerned with indexes, rating scales, and other expressions that are used to describe or measure symptoms, physical signs, and other clinical phenomena [6,7]. I got in touch with Feinstein and, even though I was not formally trained by him, I did benefit from his mentorship throughout the years. His advice was particularly important when I became editor-in-chief of a medical journal.

Feinstein and Horwitz [8] were among the first to warn about excessive reliance on RCTs and meta-analyses in EBM that were not intended to answer questions about the treatment of individual patients. The results of RCTs may show comparative efficacy of treatments for the average randomized patient but not for those whose characteristics such as severity of symptoms, comorbidity, and other clinical features depart from standard presentations [8]. Feinstein [9] compared meta-analyses to the alchemy that existed before modern scientific chemistry. The analogy was the hope to convert existing things into something better (changing base metals into gold) and the work with material that was heterogeneous and poorly identified. Indeed, meta-analyses often include highly heterogeneous studies and ascribe conflicting results to random variability, whereas different outcomes may reflect different patient populations, enrollment, and protocol characteristics [10].

As Engel anticipated the growing influence of commercial interests on medical research and practice [2], Feinstein and Horwitz [8] predicted the dangerous outcomes of EBM that Ioannidis so well described but interpreted as faulty applications of a worthwhile method [1]:

The laudable goal of making clinical decision based on evidence can be impaired by the restricted quality and scope of what is collected as “best available evidence.” The authoritative aura given to the collection, however, may lead to major abuses that produce inappropriate guidelines or doctrinaire dogmas for clinical practice ([8], p.529).

Each therapeutic act may be seen as a result of multiple ingredients, that may be specific or nonspecific. Expectations, preferences, motivation, patient—doctor interactions are examples of variables that may affect treatment outcome [11]. The changed spectrum of medical disorders (shifted toward aging, chronicity, and comorbidity) and the interindividual differences in health priorities make the focus on single diseases as potentially misleading, whereas there is growing awareness that the aim of treatment should refer to personal goals (from attainment of cure to prevention of recurrence, from removal of functional impairment to alleviation of symptoms) [12]. EBM does not do justice to the importance of these interactions and provides an oversimplified view of treatment, which is particularly dangerous in medical education. This is exactly what Engel warned about reductionism and its liability to commercial influences [2]. Indeed, the presence of investigators with substantial financial conflicts of interest in panels concerned with clinical guidelines and the excessive reliance of meta-analyses on industry-funded studies constitute two major sources of bias in literature interpretation [3]. It is thus not surprising that there is currently little evidence that EBM has actually improved patient care [1,11].

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