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OP-ED

A Call to Integrate Ethics and Evidence-Based Medicine

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It is generally accepted that medicine, and indeed all health care, should be based on or informed by evidence. Yet this truism belies the complexities and nuances involved in understanding what we mean by evidence and how it serves as a base to medicine. How evidence and ethics interrelate is an often neglected and overlooked dimension of evidence-based approaches to health care. While the laudable aim of evidence-based medicine (EBM) is to avoid biased and arbitrary decisions in medical care, the more important task is to manage the inherent uncertainty that is constitutive of the practice of medicine—a task that calls for considering how ethics should be integrated with evidence.

What Is Evidence-Based Medicine?

It seems obvious to expect that medicine be based on evidence; otherwise it would rely on caprice, whim, or arbitrary authority. Yet EBM established itself as the dominant approach to clinical medicine only in the late twentieth century. It has been rapidly taken up in all clinical fields and has been regarded as revolutionary by some and, by others, as the unrivaled standard by which medicine is to be practiced [1]. The descriptor “evidence-based” is now ubiquitous, but there are multiple claims to approaches being evidence-based, and these show considerable heterogeneity [2].

EBM emerged in the early 1990s as an approach to clinical medicine that sought to orient clinician decision making away from reliance on experience, authority, or pathophysiological inference to reliance on rigorously designed, clinically based, research [3]. The practice of EBM consists of five sequential steps [4].

1. Asking a focused question,
2. Finding the research evidence relevant to that question through a systematic search of the literature,
3. Critically appraising the results of the search for its validity and applicability to the question,
4. Applying the results of this search in practice and integrating it with patient preferences and values, and
5. Evaluating the impact of this decision in the care of the patient and in terms of performance.

Supporting this process is a graded hierarchy of evidence that is supposed to link to the strength of clinical recommendations. This hierarchy gives preference to systematic reviews, meta-analysis and randomized controlled trials for most therapeutic decisions.

What Is “Evidence”?

Proponents of EBM seldom define what they mean by “evidence.” The closest approximation to a definition is provided by Brian Haynes. He writes:

...it is hardly surprising that the term evidence-based medicine is confusing to many, who do not appreciate that its evidence is narrowly defined as having to do with systematic observations from certain types of research. The very name has been an impediment to getting across its main objective, namely, that healthcare research is nowadays producing important results that, if applied, can benefit patients more than the treatments that clinicians are experienced in recommending. Using the technical definition of EBM, evidence from healthcare research is a modern, never-before-available complement to traditional medicine. Perhaps a better name would be "certain-types-of-high-quality-and-clinically-relevant-evidence-from-health-care-research-in-support-of-health-care-decision-making"...an accurate but mind-numbing descriptor [5].

It is important to be clear on just what emerges from “systematic observations from certain types of research” and what it means to base treatment decisions on this type of evidence. Most research studies provide estimates of measures of effect expressed in statistical terms with ranges of uncertainty associated with these estimates. They are claims to truth, but not necessarily true, nor inevitably applicable in any individual case. Evidence has probative status, but can be overturned, displaced, or superseded in light of new findings. The probabilistic demonstration of an effect does not translate into the necessity of this effect occurring in any particular case at hand.

In essence, evidence—narrowly defined or not—is a provisional departure point in the consideration of whether or not a particular course of action is to be taken in any clinical context.

There are other properties of evidence worth considering. Access to evidence is not equally available to all specialties in medicine and health care. Ethical considerations dictate that certain types of evidence never be available (an idea most famously captured by R.A. Fisher’s assertion that no randomized controlled trial could be performed to assess the harm due to cigarettes) [6]. There will always necessarily be significant swaths of uncertainty and large “grey zones” in practice [7, 8].

Integrating Evidence and Ethics

In my interpretation, evidence-based approaches are one manner by which to manage uncertainty. Uncertainty has various dimensions. One dimension stems from lack of knowledge when knowledge is available, and EBM seeks to inculcate lifelong learning strategies to reduce this. The more significant sense of uncertainty relates to incomplete knowledge. Research attempts to fill or reduce this incompleteness—however, this is an eternal undertaking.

At the time when clinical decisions are required, appropriate evidence may not be available or there may not be agreement on the interpretation of existing evidence. These points illustrate why integrating ethics and evidence-based approaches is essential.

That EBM has significant ethical implications has been well described in the literature. I direct readers to two particularly insightful accounts, one by Ian Kerridge and colleagues and another by Mona Gupta [9, 10]. Kerridge et al. point out that, in the practice of EBM, certain outcomes that are poorly measured or cannot be measured are either neglected or lessened in significance. Measurement may crowd out meaning. They also note that EBM is poorly adapted to explicating and mediating conflicting values and interests in the creation and dissemination of evidence. Gupta carefully examines the ethical assumptions of EBM and notes that EBM assumes following the five steps outlined above is the optimal method to securing the best course of action for a particular decision. It presumes that there exists a moral imperative to practice these five steps. However, as Gupta demonstrates, there are good reasons to question this moral imperative.

EBM may give the false impression of its own value neutrality, an interpretation reinforced by a critical reading of the steps of EBM. The values of those posing a clinical question and the manner in which these values can influence the interpretation of the evidence are not considered. In a value-neutral view of EBM, the research literature is regarded as a set of accumulated “facts.” This is very likely a naive conceptualization, particularly in light of a wide range of influences on the published literature, some of which (e.g., ghostwriting) can easily escape the most sophisticated critical appraisal tools. In much discussion of EBM, values appear as something only relevant to patients (alongside “preferences”) to be integrated with a seemingly value-free clinical judgment informed by evidence. That the facts themselves contain claims about desired human states of affairs seems to have escaped notice. Indeed, the distinction between facts and values is often “collapsed” in clinical research [11].

Thus, the relationship between ethics and EBM is by no means straightforward or unproblematic. It deserves attention for the educators who have avidly introduced EBM in medical curricula at the undergraduate and postgraduate level, but seldom include discussions of its ethical dimensions. In my view, there is much to be gained by countering this divorce and taking steps for greater integration. This would entail a more explicit focus on the implications of uncertainty for clinical practice and time spent exploring reflexivity with respect to the values of the clinician in the steps of EBM. A promising direction that may resonate with practitioners is emerging from virtue theory, in which virtues such as curiosity, courage, honesty, and humility leading to prudence and practical wisdom are seen as promoting excellence in practice [12]. Within this framework, attention to evidence, however conceived, is linked to commitment to care. Rather than being seen as distinct spheres, ethics and evidence become part of an integrated whole.

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