

Virtual Mentor

American Medical Association Journal of Ethics
January 2011, Volume 13, Number 1: 26-30.

JOURNAL DISCUSSION

The Limitations of Evidence-Based Medicine—Applying Population-Based Recommendations to Individual Patients

Joshua J. Goldman and Tiffany L. Shih

Tonelli MR. The philosophical limits of evidence-based medicine. *Acad Med.* 1998;73(12):1234-1240.

In the last three decades, evidence-based medicine (EBM) has become the gold standard for clinical practice. In fact, physicians who forgo evidence-based recommendations in favor of treatments supported by personal experience or undocumented recommendations make themselves more vulnerable to liability and subsequent indictment and may even appear arbitrary or unscientific.

Nevertheless, EBM's rise to prominence in clinical practice has stirred up some physician opposition, particularly from older health care professionals, who perhaps better recognize the growing divide in perceived value between the art of medicine and the science (a subtlety younger generations of physicians born into a system focused on EBM may not be able to appreciate as acutely). Some physicians view EBM measures as a form of "cookbook medicine" that discounts and interferes with individual physicians' medical judgment [1, 2]. Physician resistance also stems from the concern that some EBM measures rely on inadequate and occasionally contradictory information [3]. In "The Philosophical Limits of Evidence-Based Medicine," published in *Academic Medicine* in 1998, Mark R. Tonelli, MD, MA, argues that EBM fails to account for intangible factors in the individual case, in addition to being innately limited in philosophical scope. In other words, EBM cannot replace clinical judgment or account sufficiently for the complexity of individual cases. The limitations of EBM must be acknowledged and addressed so that it can be used effectively and without compromising patient care.

Defining EBM

Tonelli defines evidence-based medicine as a twofold concept. First, EBM is an optimal method for developing and describing population-based medical evidence—what he calls "a school of medical epistemology" [4]. Secondly, EBM "attempts to describe a clinical practice centered on evidence derived from clinical studies" [4]. Tonelli argues that the shortcomings of EBM arise from presupposing the validity of the epistemological framework. As he sees it, EBM does not satisfactorily integrate clinical experience, patient and professional values, pathophysiologic rationale, and expert opinion into treatment; the solution is a shift from minimizing "nonevidentiary knowledge" (individual clinical experience, physiologic principles, expert opinion, understanding of professional and patient values—that is, what is

often referred to as the art of medicine) to a system that integrates nonevidentiary knowledge into clinical decision making.

Two years after the publication of Tonelli's paper, Buetow et al. [5] expanded this argument, agreeing that strictly equating EBM's "evidence" with "scientific evidence" and sidelining such factors as clinical expertise denigrated an important aspect of the practice of medicine. They suggest that EBM should recognize multiple dimensions and modalities of knowledge, including basic science, physiological theory, practical expertise, and ethical standards. This multidimensional definition of evidence better characterizes the contemporary view of EBM and may be a first step toward rectifying the devaluation of these factors. That said, simply acknowledging the validity of these dimensions of clinical judgment may ameliorate the semantic problem of what constitutes "evidence" or appease those who oppose devaluing the art of medical practice, but it does not resolve the limitations of EBM (both practical and philosophical).

Practical Limitations

To expand the definition of EBM too broadly, Tonelli explains, would erode the meaning of the term "evidence-based"—which is to say, it would just be a new label for the mix of strategies and judgment calls known as clinical medicine. Tonelli points out that the concept of "evidence-based" (as opposed to, for example, experience-based or physiology-based medicine) is predicated on giving "general priority" to "knowledge derived from clinical research" [4]. A host of questions remain about how other types of knowledge might be usefully, rather than haphazardly, integrated into EBM. How would one go about standardizing nonevidentiary knowledge so that its incorporation into clinical practice was not wildly variable or arbitrary? How would one decide in what situations value-based or opinion-based alternatives would better serve the individual case than the evidence-based recommendation? Does *standardization* of care—assuring a high quality of care for all patients—inherently entail a shift away from *individualization*, or can we achieve both?

Despite increasing access to well-designed clinical trials and systematic reviews, Tonelli argues, EBM cannot overcome the gap between clinical research and practice. The practical limitations of EBM include "obstacles to the development, dissemination, and incorporation of medical evidence" [4]. For one thing, data sources are often called into question because the companies that stand to gain the most from an intervention's success fund the studies that investigate them. For another, rare diseases that affect small patient populations have little clinical data to rely upon. And no matter how many studies are done or how strong the evidence is, every variable in the circumstances of each patient cannot be accounted for. What is a physician to do when the validity of evidence is called into question, clinical trials on a particular subject simply do not exist, or there are nonempirical matters to be considered?

Philosophical Limitations

Tonelli asserts that “to the extent that [there are] *relevant differences* between individuals [that] cannot be made explicit and quantified, an epistemologic gap between research and practice must remain” [6]. He offers the example of two patients experiencing abdominal pain who have identical history, examination, and laboratory data. Patient A proves to have appendicitis and Patient B does not. Tonelli claims that “there may be non-quantifiable differences between patients, perhaps detectable by an experienced surgeon, that provide additional clues to the diagnosis” before surgery [6].

If we think that improvements in imaging technology in the last 12 years can substitute for the experienced surgeon’s judgment, consider this example. Again, imagine two patients with identical histories of present illness, examination, and laboratory data. The only difference between the two patients is that Patient A has a loving wife who drives him to and from his appointments, while Patient B lives alone and takes the bus to his appointments. Patients A and B have identical tumors treatable with radiation applied daily for 4–6 weeks or chemotherapy taken by mouth at home. Let’s suppose that the radiation treatment has a higher 5-year survival rate than the at-home treatment.

Though clinical trials cannot quantifiably assess the effect on outcome of either a patient’s attitude and motivation in obtaining treatments or assistance and support from family, it is easy to see that these variables may affect the patient. A strictly evidence-based recommendation would be that both patients undergo radiotherapy, because it provides the best outcome by survival rate. Experience and logic-based knowledge might suggest that Patient B would be better served, given his transport situation, with the less inconvenient chemotherapy. After all, if the patient misses radiotherapy sessions because he misses the bus, the trial data no longer applies, and who knows what the survival rate would be.

Furthermore, not all nonquantifiable variables are as clear-cut as those in this example. Happiness and other emotional attributes have been scientifically linked to hormonal changes that affect the immune system [7]. If the only difference between patients A and B were outlook on life, reasons to live, pain, or happiness, how would their treatment options be affected? How should the patient be individually assessed to account for these differences if they are not addressed by the original prospective clinical trials? If, in a physician’s experience, these aspects have an effect on the success of a particular treatment or the prognosis of a particular disease, then are these cases in which experience-based judgment should take precedence over empirical data? As Tonelli puts it, “a good clinician cannot ignore these individual differences, at least if clinical medicine is to remain a discipline aimed at the treatment of individuals” [8].

Tonelli argues that EBM has greatly changed the way clinical judgment in medicine is understood. Deviating from EBM guidelines is immediately considered suspect until proper justification is provided. With this in mind, physicians often act to avoid liability (a practice known as “defensive medicine”), recognizing that citing their

personal experience with similar patients, however expansive, will not be nearly as helpful in court as citing a study from a reputable journal, whether the data supports the best decision for this individual patient or not.

Tonelli warns against misunderstanding the nature of EBM and its limitations, which can result in the undesirable consequence of “devaluation of the individual, a shift in the focus of medical practice from the individual to society at large, and the failure to appreciate and cultivate the complex nature of sound clinical judgment” [8]. In an attempt to form a universally relied-upon bank of clinical knowledge, the EBM movement has encouraged more “objective” decisions that neglect nonquantifiable individual variations. While practicing EBM may maximize the likelihood of positive outcomes over a large population, it does not promise “the best decision in a particular situation” [8].

Ethical Limitations

Another pertinent aspect of the gap between research and practice is that “no amount of empiric data can ever tell us what we ought to do in any particular situation, as conclusions regarding what ought to be done are value-based” [8]. If you look again at our prior example, the data clearly shows that the *survival* of Patient A will be maximized by radiotherapy. The data, however, cannot tell us whether that is the outcome that is most important to the patient, most in line with his values. Parsing possible interventions to offer the patient requires some understanding of these values. Patient values are again nonquantifiable variables best uncovered by simply discussing them with the patient and offering options that best comply with the answers given. If patients value quality over quantity of life, if they wish to be able to be home for the remainder of their treatments, if they prefer not to have surgery, if their religion or values dictate any of these decisions, the physician will need to adapt, engage in joint decision making, and offer options that suit patient needs.

Conclusion

As EBM evolves, it is easy to imagine a world where population statistics dictate medical decision making. Further *integrating* knowledge modalities into or with EBM (as opposed to replacing either one) and continuing to incorporate joint decision making into clinical practice (to safeguard the importance of individual patient values) may lessen the dangers of that paradigm.

Adding other bases of knowledge into the category of clinically relevant evidence may alleviate the burden of practical limitations in EBM, but EBM must grant priority to research-derived recommendations in order to retain its meaning as a label. Furthermore, the standardization of use of other knowledge modalities presents its own difficulties, and the proper situations in which these modalities should take precedence over EBM or be used at all remains nebulous at best. As Tonelli says, “evidence can never directly dictate care; the evidence cannot tell us when it is best to ignore the evidence” [9]. As long as these questions remain unanswered, keeping the focus of clinical practice on the individual will remain the duty of the physician.

References

1. Hasnain-Wynia R. Is evidence-based medicine patient-centered and is patient-centered care evidence-based? *Health Serv Res.* 2006;41(1):1-8.
2. Scalise D. Evidence-based medicine: pressured by payers and regulators, hospitals and physicians must transform yesterday's abstract concept into a nuts-and-bolts blueprint from how they deliver care. *Hospitalconnect.com.* Dec. 15, 2004. http://www.hhnmag.com/hhnmag_app/hospitalconnect/search/article.jsp?dcrpath=HHNMAG/PubsNewsArticle/data/0412HHN_FE_A_Cover_Story&domain=HHNMAG. Accessed December 17, 2010.
3. Wyer PC, Silver SA. Where is the wisdom? I—a conceptual history of evidence-based medicine. *J Eval Clin Pract.* 2009;15(6):891-898.
4. Tonelli MR. The philosophical limits of evidence-based medicine. *Acad Med.* 1998;73(12):1235.
5. Buetow S, Kenealy T. Evidence-based medicine: the need for a new definition. *J Eval Clin Pract.* 2000;6(2):85-92.
6. Tonelli, 1236.
7. Barak Y. The immune system and happiness. *Autoimmun Rev.* 2006;5(8):523-527.
8. Tonelli, 1237.
9. Tonelli, 1239.

Joshua J. Goldman is a third-year medical student at the Texas Tech University Health Sciences Center School of Medicine in Midland and the vice chair of the American Medical Association Medical Student Section (AMA-MSS) Committee on Bioethics and Humanities. His interest in the ethics of research and medicine was sparked at Stanford University, where he graduated with a BS in biological sciences and a minor in philosophy. He plans to pursue residency training in plastic and reconstructive surgery with a special interest in postcancer reconstruction.

Tiffany L. Shih is a third-year medical student at Texas Tech University Health Sciences Center School of Medicine in Midland. She graduated from the University of Virginia with a BS in biomedical engineering. Her major career interests are in new cancer therapeutics, and she is currently conducting studies in the racial disparities in breast cancer prevention and treatment. She plans to pursue a career in hematology/oncology.

Related in VM

[When the Evidence Isn't There—Seeking Informed Consent for New Procedures](#), January 2011

[Is There Room for Art in Evidence-Based Medicine?](#) January 2011

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.

Copyright 2011 American Medical Association. All rights reserved.