

# Evidence-Based Guidelines: Not Recommended

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On its face, evidence-based medicine is just what the doctor ordered. What rational person would argue that medical decisions should not be based on evidence?

Upon closer examination, however, the term is deceptive. Evidence-based guidelines (EBGs) in fact only use evidence from controlled trials, and deny other types of evidence or clinical judgment, thereby distorting the decision process. For example, according to evidence-based medicine, one could not recommend vitamin B-12 supplementation to treat pernicious anemia, penicillin for streptococcal pharyngitis, or biopsy to diagnose vasculitis, as these were not proven through controlled trials, although other types of evidence exist. EBGs are irresponsible, and should not be recommended.

## Understanding EBGs

According to EBGs, the only evidence that can be considered in recommending a test, procedure, or treatment is that from blinded controlled trials. All other types of evidence, including peer-reviewed publication of uncontrolled trials, case reports, or case series—which represent our collective experience—are considered “anecdotal,” and thus are barred. Personal observations, experience, judgment, or expert opinion are presumed biased, and are disallowed.

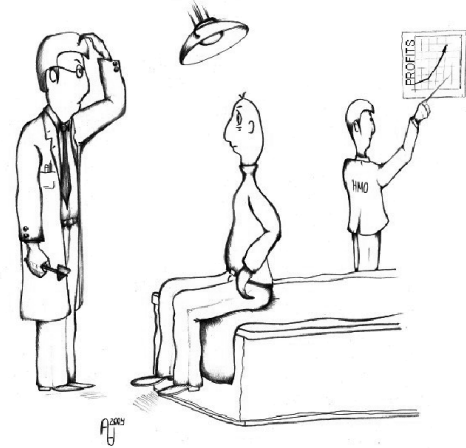
The same applies to evidence from biological experimentation. The writings of the founders of modern medicine, including William Harvey, Louis Pasteur, or William Osler, among others, would also not be considered because their contributions were not based on controlled trials.

Under EBGs, therapies can only be definitively recommended if they are based on evidence from rigorous, blinded, prospective controlled trials. Less rigorous trials can be used to justify a score of “may be considered,” or “should be considered,” but not “recommended.”

Finally, no recommendations can be made on the basis of uncontrolled trials, case series, case studies, or expert opinion, as these would be considered to be “unproven” or “unscientific,” even in situations in which there are no controlled trials to help make a decision.<sup>1</sup>

## EBGs vs. Clinical Practice

In clinical practice, physicians need to make specific recommendations, based on the best available evidence, and their



**“I know the medication makes you better, but according to evidence-based medicine, I can’t trust my own opinion.”**

own clinical experience and judgment. EBGs, however, cannot provide proper guidance on what to do in situations for which there are no controlled trials, or in which recommended treatments are ineffective or contraindicated.

At the bedside, an EBG that makes no recommendation, or scores recommendations only as “may be” or “should be considered,” is not particularly helpful. EBGs appear to be an academic exercise, mainly designed for evaluating the quality of clinical trials, with little thought given to what follows. Ironically, they have never been shown to improve care in any types of clinical trials, and are more likely to impair care, as they unreasonably limit the physician’s options.

Controlled trials are designed only to compare one treatment option to another. Yet medical decision-making is complex, and requires consideration of many variables, including clinical presentation, severity, progression, coexisting conditions, genetic or biologic variations, susceptibility to complications, and allergies to medications. It would be impossible to design trials that compare all the options.<sup>2</sup> We need expertise and clinical judgment.

## EBGs vs. Best Available Evidence

Controlled trials are useful, particularly where bias is suspected, or the benefits are delayed or too small to be obvious. But there are other ways of knowing. No one would argue, for example, that controlled trials are needed to know that the sun will rise tomorrow, that a bicycle rides better on round rather than square wheels, or that joining the ends of a broken bone help it heal. Sometimes controlled trials are needed, and sometimes common sense, “connecting the dots,” or outcome studies will do.

Traditionally, medical practices were proven through reproducibility and predictability, rather than by controlled trials, which are relatively new to medicine, complex, and costly. A physician would report a new observation and, if it was reproduced and confirmed by others, it would become general practice. This allowed rapid progress; even physicians with limited resources, working alone or in small groups, could make important contributions.

Such “anecdotal” evidence is responsible for most human scientific progress, including the discovery of the wheel, fire, rotation of the planets, gravity, the medical examination, anesthesia, penicillin, aseptic technique, and just about everything else. If controlled trials were required in every instance, it would have slowed progress to a trickle. It would be particularly foolish to require that all current procedures or treatments, even if their benefits are obvious, be subjected to controlled trials. We would waste valuable resources merely to justify EBGs, and probably get no new or important information.

Controlled trials would also be unethical in situations in which they would deny patients available care. Requiring that such trials be conducted for rare diseases or generic drugs is also unrealistic, as there is no one to pay for them.

For practice guidelines to be useful, they need to consider the best available evidence, including that from controlled trials, case series, and case reports. They must also allow for clinical experience and judgment, and the opinions of others, to help the physician decide the best care for the individual patient.<sup>3</sup>

### **EBGs Restrict Care and Distort the Medical Decision Making Process**

As EBGs are based on controlled trials, they are more restrictive than is practical in routine clinical practice. In making a diagnosis, for example, controlled trials require strict inclusion criteria, with few confounding variables. In clinical practice, however, patients have varied presentations, and the physician has to decide the most likely diagnosis, even if research criteria are not met.

With respect to treatment, a physician considers all the available therapeutic options, based on information from controlled and uncontrolled studies, as well as experience and clinical judgement. EBGs, however, offer too few options; they may be suitable for clinical research, but not for clinical practice.

A good example of how EBGs distort the decision process is the recently issued practice parameters for the Guillain-Barré syndrome.<sup>1</sup> The guidelines recommend treatment with intravenous immunoglobulin (IVIg) for nonambulatory patients, but do not recommend earlier intervention in progressive cases to prevent loss of ambulation, even though the treatment can limit the disease and prevent permanent damage. This is akin to withholding antibiotics from patients with worsening infection until they become septic. Other recommendations could not be supported, as the trial only included nonambulatory patients, and although timing of treatment was not examined, strict EBGs allow neither common sense nor clinical judgment.

Lacking adherence to the evidence-based rules, the process of developing practice guidelines becomes haphazard, with some therapies recommended, and others rejected, based on political correctness or sheer frustration, rather than agreed-upon criteria.

### **The Impetus for EBGs**

This drive toward evidence-based medicine probably represents a convergence of influences, including Managed Care Organizations (MCOs), which need to develop practice guidelines to control costs; the growing emphasis on clinical trials in academia; and the diminishing role of practicing physicians in shaping medical policy. More than ever, it's important for national physician organizations to represent the needs of practicing physicians, as well as those in academics.

Proponents of EBGs argue that the guidelines are meant to be educational: that they do not restrict physicians' options, that many reputable organizations have adopted them, and that expert opinion depends on who is asked. However, it is foolish to think that the guidelines don't restrict options, even as MCOs use them to decide coverage.<sup>4</sup>

If EBGs are only meant to be educational, why promote their adoption? Unquestioning adoption of EBGs by many professional organizations proves that we must be more vigilant in monitoring their policy decisions. The zealotry of EBG advocates—with their apparent willingness to abandon our hard-won knowledge and heritage in favor of a dysfunctional methodology that defies reason—is particularly troublesome.

### **Conclusions**

EBGs are a divisive force, creating uncertainty and mistrust, and undermining confidence in physicians and our medical system. EBGs can be used either to accuse physicians of withholding therapy, or of prescribing unnecessary or unproven treatments. Behind the façade of EBGs, MCOs can determine medical policy with impunity.

Our professional organizations need to lead the way in asserting the need for physicians to exercise independent judgment on the basis of the best available evidence in real clinical situations. Managers must not be permitted to define what constitutes evidence, or to brand any method other than a controlled trial as “unscientific.”

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**Conflict of Interest Statement:** Dr. Latov accepts payment from his patients in return for helping them get better.

### **REFERENCES**

- <sup>1</sup> Hughes PA, Wijdicks EF, Barohn R, et al. Report of the Quality Standards Subcommittee of the American Academy of Neurology. Practice parameters: immunotherapy for Guillain-Barré syndrome. *Neurology* 2003;61:736-40.
- <sup>2</sup> Caplan LR. Editorial. Evidence based medicine: concerns of a clinical neurologist. *J Neurol Neurosurg Psychiatr* 2001;71:569-576.
- <sup>3</sup> Kahn DA, Docherty JP, Carpenter D, Frances A. Consensus methods in practice guideline development: a review and description of a new method. *Psychopharmacol Bull* 1997;33:631-638.
- <sup>4</sup> News in Brief: Mich. Blues introduce bonus program. *American Medical News* 2004; (Dec): 18.