

The Shifting Sands of EBM

Anthony Rosner, PhD, LLD [Hon.], LLC

Evidence-based medicine (EBM) - that darling catchment for all things good and rock-solid in making things scientific in medicine - has undergone an assault and transformation in the past decade that rivals the speed at which the polar ice cap is crumbling under the onslaught of global warming.

Cracks in the foundation of the conventional wisdom of randomized clinical trials (RCTs) began to appear in the 1980s when the quality of observational (cohort, case series) studies was found to improve such that their predictive value in clinical situations could now be compared to that seen in the more rigorous RCTs.^{1,2} At the same time, RCTs began to be seriously challenged due to their limited applicability in clinical situations.^{3,4} Among other problems, RCTs were found to lack insight into lifestyles, nutritional interventions and long-latency deficiency diseases.⁵ Quirks have even surfaced which demonstrate how the exalted meta-analysis is subject to human error and bias.⁶

The result seemed to be a breakaway from painting by numbers, realizing that such realities as patient subgroups and comorbidities played a major role in therapeutic decisions, such that clinical judgment became recognized as important. This sentiment could not have been better expressed than by the epidemiologist, David Sackett, who wrote:⁷

[EBM] means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise, we mean the proficiency and judgment that we individual clinicians acquire through clinical experience and clinical practice. By best available external clinical evidence, we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient-centered clinical research into the accuracy and precision of diagnostic tests [including clinical examination], the power of prognostic markers and the efficacy and safety of therapeutic, rehabilitative and preventive regimens. Good doctors use both individual clinical expertise and the best available external evidence and neither alone is enough [emphasis added].

Without clinical expertise, practice risks becoming tyrannized by external evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best external evidence, practice risks becoming rapidly out-of-date, to the detriment of patients.

Then we add another ball to the EBM juggler's manifest - the patient. In their recent introduction to what they consider to be the techniques of evidence-based medicine, Fisher and Wood make it clear that the use of such patient-based outcome measures as the Health-Related Quality of Life Index and cost-effectiveness will continue to grow as integral parts of EBM. They argue that the most compelling and growing component of EBM is the empowerment of the patient in the decision-making process.⁸ It reminds you of how quickly and extensively the patient factor must be

considered a part of the EBM edifice, just as cellular telephones have gained prominence in telecommunications.

With patients being the best judge of values, clinical decisions necessarily need to be shared between patient and clinician.⁹ Such can be demonstrated by the proliferation of such preference-based outcome measures as the EQ-5D,¹⁰ the Health Utilities Index¹¹ and the SF-36D.¹² This shifting of the EBM sands simply echoes what a few years earlier appeared to be a revolutionary upheaval suggested by Wayne Jonas. He presented what appeared to be, for all intents and purposes, a virtual inversion of the classical evidence pyramid. In Jonas' presentation of the "evidence house," such entities as use testing, public health and audience preferences gained ascendancy.¹³

None of this is intended to discredit EBM, per se, but to make us aware that it must never be divorced from human values or be used inappropriately. In a brilliant essay, Erich Loewy argues that EBM actually becomes an anti-intellectual tool when it is applied in the interest of efficiency for profit. Using EBM to simply hold down costs represents its most egregious abuse, such that there could be instances in which patients - sometimes with few alternatives - are discouraged from following certain highly promising leads in experimentation, such as stem-cell therapy. Pigeonholing patients into untested groups and excluding alternative choices which have been shown to be safe, inexpensive and -with some supporting data - could be argued to be at odds with the tenets of truly informed consent in experimental science. These have all been painstakingly laid down over the years by the Nuremburg Code, the Helsinki Declaration and the Belmont Report. To disregard these could therefore be argued to be morally repugnant.¹⁴

In other words, if our concepts of EBM become ossified, they risk becoming more of an algorithm, a paint-by-numbers exercise that excludes intuitions which might in certain instances actually be of benefit to a particular patient in a given situation. What are these intuitions? Some might call them hunches which, in more cases than not, draw from a network of information that Stewart

Hampshire has termed a compost heap,¹⁵ no longer capable of being separated into component parts. Our collective informational storehouse must also include the outstanding case studies which formed our basic understanding and acceptance of everything from heart transplants to Paget's disease to Freudian psychology, yet never went on to become RCTs in their own right. Not to be ignored are several outstanding examples in the chiropractic literature as well, to which further additions must continue to be made by the field practitioner.

For these reasons, it is a sorry day indeed when the physician is reduced to therapeutic choices simply because it is what a managed care organization might have mandated - often using EBM as a justification without seriously asking whether it is truly in the patient's best interest. This warning needs to be especially heeded when we realize that the current model of medical diagnosis and treatment fails to adequately address the chronic disease burden affecting over a third of the American population.¹⁶ This then becomes precisely the area in which chiropractic has the best opportunity to excel - and must.

References

1. Benson K, Hartz AJ. A comparison of observational studies and randomized, controlled trials. *New England Journal of Medicine*, 2000;342(25):1878-86.
2. Concato J, Nirav-Shah, Horwitz RI. Randomized, controlled trials, observational studies and the hierarchy of research designs. *New England Journal of Medicine*, 2000;342(25):1887-92.
3. Walach H, Jonas WB, Lewith GT. The role of outcomes research in evaluating complementary and alternative medicine. *Alternative Therapies in Health and Medicine*, 2002;8(3):88-95.

4. Tonelli MR. The philosophical limits of evidence-based medicine. *Academic Medicine*, 1998;73(12):1234-40.
5. Heany R. Long-latency deficiency disease: insights from calcium and vitamin D. *American Journal of Clinical Nutrition*, 2003;78:912-9.
6. Rosner A. Fables of foibles: inherent problems with RCTs. *Journal of Manipulative and Physiological Therapeutics*, 2003;26(7):460-7.
7. Sackett DL. Evidence-based medicine. *Seminars in Perinatology*, 1997;21:3-5.
8. Fisher CG, Wood KB. Introduction to and techniques of evidence-based medicine. *Spine*, 2007;32(19S):S66-72.
9. O'Connor A. Using patient decision aids to promote evidence-based decision-making. *EMB Notebook*, 2001;6:100-2.
10. Brooks R. EuroQuol: The current state of play. *Health Policy*, 1996;37:53-72.
11. Torrance GW, Furlong W, Feeny D, Boyle M. Multi-attribute preference functions: Health Utilities Index. *Pharmacoeconomics*, 1995;7(6):503-20.
12. Brazier J, Roberts J, Deverill M. The estimation of a preference-based measure of health from the SF-36. *Journal of Health Economics*, 2002;21:271-92.
13. Jonas W. The evidence house: How to build an inclusive base for complementary medicine. *Western Journal of Medicine*, 2001;175:79-80.
14. Loewy EH. Ethics and evidence-based medicine. Is there a conflict? Available at: www.medscape.com/viewarticle/559977_1.
15. Hampshire S. *Innocence and Experience*. Cambridge, Mass.: Harvard University Press, 1989:121.
16. The Integrator Blog. Available at: www.theintegratorblog.com/sites/index.php?option=com_content&task=view&id=94&Itemid=144.

FEBRUARY 2008