

Shift Needed in Evidence-Based Medicine

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It was just 20 years ago that the term *evidence-based medicine* (EBM) first appeared in the medical literature of a major journal.¹ EBM's seemingly unstoppable march, which subsequently spawned disciplines such as evidence-based orthopedic surgery, and the rise of managed care organizations, has dramatically changed the medical landscape. This shift was probably felt more acutely here, in the US, than in other countries with national health systems.



When we treat patients, a sacrosanct bond exists between the patient and physician, one that has been in place for millennia. But in today's world, we cannot ignore that there are other agents, and factors, that influence the treatment rendered,² not the least of which is the payer (whether government or private), who has a vested interest in the treatment chosen, and especially cost.

Payers and other agents were previously kept out of the loop because of the specialized medical decision-making knowledge of the practitioner. EBM has caused a paradigm shift, shunting a great deal of influence away from physicians into the hands of the other agents. This has given rise to new stakeholders including the medical manager who, armed with the results of clinical studies and an eye on costs, may attempt to influence the standard of care.³

Whether your interest in EBM is to help make the best treatment choice or to lower costs, while achieving the same levels of effectiveness, the need for more and better evidence is clear. Similarly, the rationale for comparative effectiveness research in orthopedics is self-evident, given that we have so many implants and procedures at our disposal, which are all designed to treat the same problem.

But isn't there an inherent tension between the physician and payer given that the best sources of evidence (eg, large randomized double-blind trials) are not only the most expensive, but almost impossible to conduct in surgery,

especially orthopedic surgery. Payers looking for "Level I" evidence for many surgical options are mostly disappointed because "orthopaedics lags behind many fields in the 'raw material' for [EBM]."⁴ It should also be remembered that surgery was traditionally the preserve of surgical "eminences" who operated—in every sense of the word—with a great deal of autonomy.⁵ The poor situation for orthopedic surgery evidence is also not helped by methodological problems in conducting clinical investigations in any surgical specialty.^{6,7}

One essential element of EBM is the production of new evidence, generally achieved by conducting studies in a scientifically proven way. However, for most centers, this presents a real challenge due to a lack of experience, knowledge, and training, coupled with a lack of suitable facilities, including inadequate archive. There is no standardization of the evidence provider!

The AO Clinical Investigation and Documentation Division of the AO Foundation has worked with approximately 300 different clinics from around the world over the past decade, and has seen firsthand the wide variations in ability to conduct clinical studies. This experience served as the impetus to develop the AO Clinical Study Center program (AOCSC) to at least standardize the clinical investigations at orthopedic and trauma centers.

Standardization is achieved through a combination of implementing defined processes, training and quality assurance. The adoption of a full barrage of standard operating procedures (SOPs) relating to clinical research means that centers have the know-how to conduct clinical research. In addition, accredited training in good clinical practice is available, a legal requirement for investigators in a growing number of countries. On-site visits ensure that all the elements needed to conduct high quality clinical research are in place.

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Am J Orthop. 2012;41(9):396,412. Copyright Quadrant HealthCom Inc. 2012. All rights reserved.

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One result of having clinics qualified to conduct high-quality research is the creation of a scientific network that provides benefits to both the centers (ie, trained and motivated personnel, increased attractiveness to other sponsors, etc.) and the AO Foundation (ie, a readily accessible network of centers where clinical research can be conducted to a known level).

While the program is currently being prepared for a global rollout, the pilot phase conducted in 25 clinics on 3 continents received very good feedback. The concept could serve as a model for other programs, on either a national or international level. Indeed, just like the American College of Surgeons set standards for levels, and provides ongoing qualification for Trauma Centers in

the US, there should be no restraint to doing similarly for the evidence providers at orthopedics and/or trauma centers. Just like EBM, the idea is simple and malleable enough to be shaped for other purposes.

Although many factors may influence the results of a trial, we are duty-bound to strive to conduct these studies to the highest level possible. The creation of a strong network of EBM-trained sites which produce more and better evidence on the increasing number of different treatment options will definitely help orthopedic surgeons in the choices they make for their patients.

In the end it is the patient who will benefit most from initiatives like this one... just as it should be.

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