

Evidence Was Sufficient Yesterday, Added Value Is Needed Today

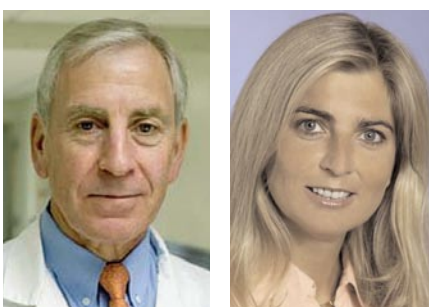
David L. Helfet, MD, MBChB,
and Beate Hanson, MD, MPH

Don't be misled by the title of this editorial; there is still, of course, a need for evidence-based medicine today. Surgeons have turned from being independent decision makers into valuable cogs in an evidence-gathering machine over the past 20 years or so.

The Need for Value, Shrinking Budgets

However, what is currently of significant importance to surgeons is the need to add value to the healthcare system. This is a result of a changing, and mostly contracting, funding environment.

Conducting any kind of high-quality medical research is not cheap—usually for very good reasons. Companies that try to cut corners or scrimp on budgets necessary for adequate studies of new products or techniques usually find that such moves come back to haunt them. Consider the controversial use in German hospitals of total hip arthroplasty done using computer-assisted surgery. Mass surgery was conducted without scientific proof of effectiveness. The results of a randomized controlled trial eventually showed high revision rates, muscle damage, and limping. All of which led to a slew of expensive lawsuits.^{1,2}



“...many national healthcare budgets are shrinking. Who is going to step into the funding breach if not industry? Will industry’s input be enough?”

Perversely, at a time when there is an ever-growing demand from society for innovation in healthcare, many national healthcare budgets are shrinking. Who is going to step into the funding breach if not industry? And, given the current economic problems facing most of the world, will industry’s input be enough?

It is projected that the American healthcare market will consume 20% of US gross domestic product (GDP) by 2017. By 2006, the average American already spent almost twice as much of their personal expenditure on healthcare as they did on food.³ One Australian study⁴ envisions a threefold increase in healthcare expenditure there in the 20-year period beginning in 2013.

Constraining Factors

As surgeons we should be patient-oriented. However, demographic changes are certain to have an influence on our workload in the future—people are living longer and engaging in activities that will lead to even greater numbers presenting for treatment. For example, the World Health Organization⁵ believes road traffic crashes will be ranked number 4 among all causes of disability-adjusted life years by the year 2030—up from its current position of eighth and the highest predicted jump within the top 15 causes.

Further constraints are caused by legal regulations. Some jurisdictions such as Germany and the United Kingdom are top-heavy with national legislation, not to mention other European Union laws that also have to be applied. Even in the United States, since 2004 the number of medical devices to receive FDA approval has fallen from over 50% to under 30%. At the same time, in any one year the number of recalls lies somewhere between 10% and 30%. The indications are that regulations will be tightened in the future, leading to an increased level of paperwork and more attention to proving the efficacy of devices.

Dr. Helfet, this journal’s Associate Editor for Trauma, is Professor, Department of Orthopedic Surgery, Cornell University Medical College, and Director of the Orthopaedic Trauma Service at the Hospital for Special Surgery and New York–Presbyterian Hospital, New York, New York.

Dr. Hanson is Director, AO Clinical Investigation and Documentation, Dübendorf, Switzerland.

Am J Orthop. 2009;38(9):438-439. Copyright, Quadrant HealthCom Inc. 2009. All rights reserved.

Successfully Adding Value

Are these changing conditions and difficulties in bringing new devices to market insurmountable challenges? The answer, of course, is no, but careful planning and top-quality research are required if these hurdles are to be cleared.

A good example of adding value can be seen in the 2003 to 2005 study⁶ on the efficiency and safety of balloon kyphoplasty compared with nonsurgical care for vertebral compression fractures. A randomized controlled trial was conducted using 300 patients. The results demonstrated an improvement in patients' quality of life, function, and mobility in the first 12 months after surgery. In the modern world, people are prepared to pay top dollar for increased benefits, especially if this means they can resume their normal lives more quickly. For many, viewing this from a purely financial angle, the extra cost of treatment is offset by the expedited return to work, not to mention the resumption of "normal" life.

While the patient can clearly see the value in a treatment like balloon kyphoplasty, others in the healthcare value chain also profit from scientifically validated innovations. For example, hospitals benefit from faster patient throughput and consequently can reduce patient waiting lists, improve bed occupancy planning, etc. Naturally, health insurance companies welcome shorter patient stays and the reduced

payouts these bring. In theory, they can then pass on some of the savings to consumers in the form of reduced premiums, thereby increasing the numbers of patients with proper health coverage while expanding their own customer base.

Who Will Control Future Studies?

The medical system is under constant scrutiny, not only from politicians and regulatory groups, but also from patients who are increasingly better informed about diseases and the available treatment methods. There are now so many stakeholders in clinical studies that one could almost be forgiven for forgetting that it was in fact the surgeons who went to medical school! However, in modern society, where the customer is king, everyone understands (or at least claims to understand) the costs and benefits of transactions. Clearly, if we want to maintain our ability to continue doing what is right and beneficial, as well as being the primary decision makers, we must show...VALUE! VALUE to the patient, VALUE to the hospital, and VALUE to the payor, private or public.

We hope, in addition to alerting you to a possible future funding crunch, that this editorial serves as a timely reminder that we need to retain as much control as possible of what is, after all, our area of expertise.

Authors' Disclosure Statement

Dr. Helfet wishes to note that he is a member of the Board of Directors for Synthes. Dr. Hanson reports no actual or potential conflict of interest in relation to this article.

References

1. McAllister J. Crippled German patients sue cyber-surgeon. *The Scotsman*. October 5, 2003. <http://news.scotsman.com/latest-news/Crippled-German-patients-sue-cyber-surgeon.2467428.jp>. Accessed August 21, 2009.
2. Schröder P. *Roboterunterstützte Fräsverfahren am coxalen Femur bei Hüftgelenktotalendopr othesenimplantation Methodenbewertung am Beispiel „Robodoc®“*. Medizinischer Dienst der Spitzenverbände der Krankenkassen e.V. (MDS). Available at: http://www.mds-ev.org/media/pdf/G_Robodoc.pdf. Published April 2004. Accessed August 21, 2009.
3. Angier C. Health care to consume 20% of GDP by 2017. Nolan Chart Web site. <http://www.nolanchart.com/article2922.html>. Published February 26, 2008. Accessed August 21, 2009.
4. Vos T, Goss J, Begg S, Mann N. Projection of health care expenditure by disease: a case study from Australia. A background paper used in the preparation of: *World Economic and Social Survey 2007: Development in an Ageing World*. New York: United Nations; 2007. Available at: <http://www.un.org/esa/policy/wess/wess2007files/background-papers/australia.pdf>. Accessed August 21, 2009.
5. World Health Organization. Projections of mortality and burden of disease, 2002-2030. http://www.who.int/healthinfo/global_burden_disease/projections/en/index.html. Accessed August 21, 2009.
6. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet*. 2009;373(9668):1016-1024.