

How Outcomes Can Affect Cost: The Importance of Defining Patient-Relevant and Proxy Outcome Measurements

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It may be a well-worn idea, but it is still a very true one: the world has changed dramatically and quickly over the past 100 or so years. What once was hailed as revolutionary is now commonplace. This phenomenon is especially true in the world of medicine.

Take x-rays for example; they were discovered over a century ago by Wilhelm Röntgen, who won the Nobel Prize in 1901 for this advance in medicine. Nowadays, x-ray machines can be found in hospitals of every size all over the world and we cannot imagine a time without them.

Changing expectations as a result of medical breakthroughs also can be seen in patient demands. Patients presenting for treatment with a broken bone now take it for granted that it can be fixed. They cannot comprehend how their great-grandparents would have viewed a broken leg as a life-altering, potentially crippling injury. Today's patients with broken legs are more interested in knowing how quickly they can regain full function and return to work.



“...critically examine your outcome measurements; it may save you a lot of work and money.”

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This challenges surgeons in a positive way, as it helps us to keep our feet on the ground and to recognize how each patient views the criteria for an operation's success. Other forces, such as patient advocacy groups, are at work to help remind us that, above all else, we are here to improve patient care.

Outcome Measurements in Orthopedics

Outcome measurement instruments in orthopedics have been developed to allow for more scientific methods of describing outcomes—rather than simply judging them as “good” or “excellent.” These outcome measurements can play an important role in the development of new procedures, techniques, protocols, and evidence-based medicine.

Selecting the correct instrument to measure outcomes can be a daunting task, however. For example, for the shoulder joint alone there are over 30 different outcome measurement instruments available, and this list is growing.

PROXY OUTCOMES

Proxies are used in medicine for a variety of reasons. Parents, instead of children, may provide information to a pediatric study. Other trials have used proxy information from relatives in cases where participants have died during the course of a longitudinal study.¹

Proxy Outcome Measurements in Orthopedics

An additional impediment is that, at times, it is simply impossible to measure the exact outcome we would like to know. In place of an easily measurable outcome, a proxy outcome measurement may be employed as a next-best solution.

For example, since there is no accurate measure of overall bone strength, proxy outcome measurements, such as bone mineral density and *t* scores, are commonly used.

A further illustration comes from a study of blunt trauma and possible cervical spine injury. Patients who did not have C-spine radiography as part of their standard care underwent a structured and validated 14-day proxy outcome measure by telephone instead.²

CASE STUDY

We are currently involved in a randomized, controlled trial for an implant known as ASLS (Angular Stable Locking System). This system was developed to improve fracture stability in patients undergoing intramedullary fixation for long bone fractures who present with fractures close to a joint or with osteoporotic bone. Angle stable fixation between the nail and screws is achieved via

resorbable sleeves, which act as dowels in the locking holes.

Our outcome-related problem was that measuring fracture stability is only possible in a laboratory set-up, thus a proxy outcome measurement had to be determined. As a result of experience gained during the pretrial, the ability to bear full weight with minimum pain was chosen to serve as a proxy outcome measurement for a stable fracture.

A final thought is that making outcomes patient relevant also may lead to cost-saving changes in the study design. Had we defined our outcome as the nonunion rate after 6 months, we would have needed over 1000 patients to have achieved a sufficiently powered study. By choosing full weight bearing

with minimum pain at 5 specified time points from the time of discharge to 12 months after the operation, only 130 patients were needed for a study with the same amount of power.

So don't forget to critically examine your outcome measurements; it may save you a lot of work and money, and your patients will thank you!

References

1. Mulrooney DA, Yeazel MW, Kawashima T, et al. Cardiac outcomes in a cohort of adult survivors of childhood and adolescent cancer: retrospective analysis of the Childhood Cancer Survivor Study cohort. *BMJ*. 2009;339:b4606.
2. Stiell IG, Wells GA, Vandemheen KL, et al. The Canadian C-spine rule for radiography in alert and stable trauma patients. *JAMA*. 2001;286(15):1841-1848.

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The 2010 Resident Writer's Award competition is sponsored through a restricted grant provided by DePuy. Orthopedic residents are invited to submit technique papers, tips of the trade, original studies, review papers, or case reports for publication. Papers published in 2010 will be judged by *The American Journal of Orthopedics* Editorial Board. Honoraria will be presented to the winners at the 2011 AAOS annual meeting.

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