

## **Outcomes Research and Spine Surgery**

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During the past decade, there has been an explosion of interest in measuring the outcomes of medical care. In the past, clinical research in spine surgery focused on physiological outcomes such as range of motion, muscle strength, or neurological deficits. In recent years, however, there has been increasing attention given to the rigorous measurement of symptoms, functional status, satisfaction with treatment, and health care costs associated with spinal interventions. There is an emerging understanding for the need to improve the quality and comprehensiveness of the assessment of the outcomes of neurosurgical spinal interventions. There is also a growing recognition that patient perspectives are essential, both in making medical decisions and in judging the results of treatment.

Outcomes research evolved from studies that demonstrated the presence of wide geographic variations in the practice of medicine and surgery. Such differences in utilization were unaccompanied by any discernible difference in patient outcomes. With escalating health care costs, there has been a growing interest in measuring the outcomes of medical intervention to determine the quality and appropriateness of medical care, especially expensive surgical interventions.

Outcomes research refers to a genre of clinical investigation that emphasizes the measurement of patient health outcomes, including the patient's symptoms, functional status, quality of life, satisfaction with treatment, and health care costs. In the narrowest sense, "outcomes" refers to what patients experience as a result of a disease and its treatment. The emphasis of this study technique is on an array of outcomes beyond simple restoration of normal anatomic relationships and particularly on end points emphasizing the patient's assessment of pain, function, quality of life (QOL), and satisfaction with the results of the intervention. General considerations in outcomes evaluations include the following: 1) the end points should measure impairment or disability; 2) the determination of the outcome should include both the benefits and the risks of the procedure; 3) the outcome and complications should be documented

according to a defined protocol; and 4) the outcomes instruments used should have been tested for their reliability, validity, and sensitivity.

Health-related QOL may be defined as the extent to which one's usual or expected physical, emotional, and social well-being are affected by a medical condition or treatment. Such outcomes are being much more closely scrutinized in patients undergoing treatment for spinal disorders. The goal of all health care is to maximize QOL. Quality of life measurement tools can be dichotomously classified as either "health status" or "preference-based" instruments. Health status instruments decompose quality of QOL into several domains based on a conceptual model, and provide a score in each of the domains. The instruments are typically multiple-choice questionnaires asking about current symptoms and functioning, and responses are used to calculate scores. The most widely used generic (i.e., applicable to subjects with various diseases) health status QOL instrument is the Medical Outcomes Study Short Form-36 (SF-36).

Preference-based QOL instruments elicit patient's valuations for their current health state. The instruments generate a single QOL value expressed on a zero to one ratio scale, where zero represents the value of death and one represents the value of perfect health. This valuation of a health state is also known as "utility," a concept developed by economists to indicate the strength of an individual's preference. The "gold standard" in utility measurement is the "standard gamble" (SG). The "time trade-off" (TTO) was designed as an alternative utility measurement technique that may be easier to administer than the SG. Both the SG and TTO generate utilities that can be combined with economic data to perform cost-effectiveness analyses. Preference-based QOL measurements are increasingly common in the medical literature, and are arguably superior to health status or functional measures, since preference-based measures incorporate individual attitudes towards functional status, pain, or disability, and integrate these attitudes proportionate to their importance to each patient. Despite this advantage, to date preference-based QOL instruments have received little attention in studies of spine disease.

The table below lists several of the most commonly applied outcomes instruments for the evaluation of spinal interventions. Such instruments are uniformly used by clinical trials funded by the National Institutes of Health. There are several excellent

resources available to those interested in using outcomes instruments in their clinic research. Selected references are listed below.

The true value of our spinal interventions can be determined only by a systematic examination of patient outcomes. To accomplish this goal, methods are required that are relatively unfamiliar to many clinical researchers. As an organization, our clinical research should routinely include patient-oriented outcomes measures that previously would otherwise focus solely on physiologic or anatomic outcomes such as rates of fusion or effects on ambulation. Such outcomes data will become essential to determine which surgical spine treatment strategies should be abandoned and which should gain acceptance by spine surgeons. Our patients deserve, and in the future may demand, such information.

### **Selected Instruments Useful for Measuring Spinal Intervention Outcomes**

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Oswestry Low Back Pain Disability Questionnaire

Beck Depression Inventory (BDI)

Medical Outcomes Survey 36-Item Short-Form Health Survey (SF-36)

McGill Pain Questionnaire

Roland and Morris Disability Questionnaire

### **Selected References**

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