

# Success in Spine Care: The Proof Is in the Measurements, Part II

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## Introduction

In the previous Science in Spine article, we covered the ABCs of spine measurements. These include (A) baseline factors, (B) treatment factors, and (C) perioperative/immediate post-treatment events. Without these, it is difficult to make much sense of the outcomes we measure. Once these are finalized, outcomes measure selection becomes a critical step in planning your data collection project whether it is for clinical quality improvement or comparative effectiveness and safety in research. Because ultimately study results may lead to recommending a course of treatment for spine care, it is important that they be chosen judiciously. This task, however, can be challenging. In the balance, one treatment protocol or intervention may be deemed better than another based on a specific outcome measure (e.g., pain), but not as good based on another measure (e.g., quality of life.). A well-designed report that clearly delineates superiority of one treatment over another may provide insufficient evidence or even be harmful if it fails to measure a clinically important outcome.

Critical to any clinical or research setting with respect to measuring treatment effectiveness is identifying and measuring clinically “important” outcomes. Selecting “clinically important” outcomes is a challenging task; however, much thought should go into this decision, and it should be tied directly to project objectives and desired claims.

The health status of a population has traditionally been measured in terms of mortality and morbidity. Yet, with the epidemiologic transition from infectious disease to chronic diseases (which many spine conditions are), quantifying health in terms of death and disease rates is seen to be increasingly inadequate.<sup>1</sup> In spine care, there are a myriad of potential physiologic (e.g., bony union) and clinician-based outcomes (e.g., range of motion, walking tests, and so on) available for use in clinical studies.<sup>2</sup> Depending on the study objective, such measurements may be important but they are also time intensive and may not represent real function or reflect factors that are important to patients.

One exception, complications, should always be reported as a measure of safety.<sup>3</sup> However, other measurements from the clinician's perspective should be justified. A mismatch between the patient's perception and the clinician's assessment is not uncommon<sup>4</sup>; therefore, it is increasingly recognized that traditional clinician-based outcome measures need to be complemented or replaced by measures that focus on the patient's concerns to evaluate interventions and identify whether one treatment is better than another.<sup>5</sup> The remainder of this article will focus on patient-reported outcomes (PROs).

## Patient-Reported Outcomes

The increasing complexity of treatment allocation, acceptability, and utility makes the views of consumers more critical in intervention development, evaluation, and health service planning.<sup>6</sup> Emerging PRO measures are doing a better job of measuring aspects of patients' lives that patients consider important. Furthermore, they are generally more carefully developed and tested. Generally, PROs are questionnaires or instruments that patients complete by themselves or, when necessary, others complete on their behalf to obtain information in relation to functional ability, symptoms, health status, health-related quality of life, and results on specific treatment strategies. Interest in PROs has been fueled by an increased importance of chronic conditions, where the objectives of treatment are to restore or improve function while preventing future functional decline.<sup>7</sup> PROs extend beyond traditional clinical efficacy and adverse effects and represent the patient's perspective on the impact of disease and its treatment on daily functioning and well-being.<sup>5</sup>

The U.S. Food and Drug Administration has released “Draft Guidance” encouraging the use of PROs in clinical trials for new medical products because: “(1) some treatment effects are known only to the patient; (2) there is a desire to know the patient perspective about the effectiveness of a treatment; or (3) systematic assessment of the patient's perspective may provide valuable information that can be lost when that

perspective is filtered through a clinician's evaluation of the patient's response to clinical interview questions." Similar recommendations are being made for health policy decisions. Some have argued that effective policy and planning of health care services depends on the impact on individuals and their families, underscoring the importance of assessing PROs.<sup>7</sup>

PROs are classified as either general (generic), condition-specific, or patient-preference measures of health-related quality of life. General measures are designed to be used across different diseases and across different demographic and cultural subgroups.<sup>8</sup> They are usually multidimensional and are designed to give a comprehensive and general overview of health-related quality of life. Spine condition-specific measures of health-related quality of life, on the other hand, focus on the aspects of health that are specific to an injury (e.g., fracture), disease (e.g., spinal stenosis), anatomic area (e.g., cervical spine), or population of interest (e.g., elderly).

### Preference-based Outcomes

Due to increased demands and costs for health care services, health authorities and policy makers have become interested in the effectiveness and cost-effectiveness of health care interventions. Patient-perceived health status is an important health care outcome, relevant to patients, surgeons, and policy makers. A full discussion of these and how they are used in formal economic analyses is beyond the scope of this article. The most common preference-based outcomes measures are the EuroQol Five Dimensions (EQ-5D) and the Short Form Six Dimensions (SF-6D). Neither outcome measure has yet been tested for validity, reliability, or responsiveness in spine populations; however, the SF-6D was found to be sensitive to changes in health status of patients with rheumatoid arthritis treated with infliximab.<sup>9</sup> The SF-6D was derived from the Short Form 36 (SF-36) by Brazier et al as a preference-based single index.<sup>10,11</sup> The main approach in health economics has been to value health status in a single unit of measurement known as "quality-adjusted life years" (QALY), or "well years." The index or "utility" scale is anchored on 0 (death) and 1 (full health) and is integrated with survival, so that not merely are the number of years of life expectancy considered but also the quality of those years. The SF-6D was developed to bridge the gap between the SF-36 and the QALY approach, which has resulted in a six-dimensional health classification. A health state is composed of statements from each of six dimensions, starting with physical functioning and ending with vitality. A total of 18,000 possible health states are defined this way.

Given the increasing costs of health care, health care purchasers, payers, and hospital systems are adopting the concept of value-based purchasing, which is having a significant impact on low-quality providers and hospitals. Quality rankings are now being publicly reported. True measures of quality, such as surgical complications and validated PROs of effectiveness, may be burdensome and costly to collect. Therefore, the selection of the appropriate measures should be done judiciously with an understanding what makes a quality measure while considering the burden and the yield of such selection. In the final article of this series, we will discuss the selection of outcomes, the anatomy of a quality outcome measure, and the importance of understanding why you are collecting the measures you are.

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