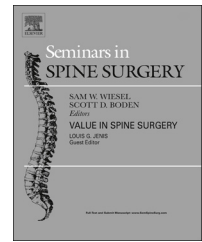


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Patient reported outcome measures for spinal disorders



Kenneth Nwosu, MD, and Joseph Schwab, MD

Massachusetts General Hospital, Department of Orthopaedic Surgery, 55 Fruit St, Boston, MA 02114

ABSTRACT

The systematic collection of patient-based outcomes in spine care will inform the debate regarding the efficacy of various treatment and allow them to be comparable to other spine disease-specific and non-diseases-specific outcomes, and to other non-musculoskeletal diseases regarding effect on patient's global health states. Patient-based outcome measures are usually classified as generic, including global ratings of health status, as well as multidimensional measures of health-related quality of life (HRQOL) or disease-specific measures that are attributable to symptoms and functional limitations caused by a specific condition. In this article, we discuss the recommended core results that should be measured in patients with spinal disorders, instruments used to measure them, and the emergence of PROMIS (Patient-Reported Outcome Measure Information System).

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Per capita health care cost in the United States surpasses those of other developed countries but continues to rise at comparable rates.¹ Yet, U.S. consumers report higher dissatisfaction with their health care system compared to their counterparts in other developed nations.² In addition, high expenditure on U.S. health care do not result in longer life expectancy, or more good years of health compared to citizens of other nations.³

This discord between health care expenditure and patient outcomes is troubling. While investigating the cause of this discrepancy, the Institute of Medicine (IOM) found that overtreatment, undertreatment, and medical errors are disturbingly common in American medicine.⁴ Also, there is a wide variety of medical practices and healthcare costs between different regions in the U.S. Other contributing factors they found includes: increasing malpractice lawsuit rates, rising malpractice insurance premiums, increasing administrative costs, and as a result, a declining ability for U.S. businesses to adequately insure their employees.⁴ Explaining this paradoxical conundrum has become a critical step towards reforming the American healthcare system.

Value, as defined by Porter et al. is outcomes relative to costs.⁵ Only by measuring and holding each system accountable for

results will value be consistently demonstrated in the U.S. healthcare system. Hence, mandatory measurement and reporting of results is perhaps the most important step in reforming the U.S. healthcare system. Historically, this notion was resisted by many providers, who were fearful of biases and comparisons, and ignored by health plans, employers, suppliers, and government. As a result, "value" in health care was largely unmeasured and many clinicians; especially those that cared for patients with spinal disorders, came under increased scrutiny due their inability to demonstrate value in expensive treatments for common conditions.⁶ However, efforts are now being made, and resources diverted, towards demonstrating the value of spinal surgery. For example, Weinstein et al. elegantly demonstrated, utilizing SPORT's data that: (1) Surgical treatment for lumbar disc herniation, degenerative spondylolisthesis, and spinal stenosis is associated with improved health outcomes and satisfaction, but at a higher cost. (2) Cost per QALY at 2 years are \$34,355 and \$115,600 for disc herniation and degenerative spondylolisthesis respectively. (3) Cost per QALY at 4 years decreased to \$20,600 and \$64,300, respectively. Hence, these condition-specific treatments can be considered cost effective or "valuable" if we adopt the convention that a cost of \$100,000 per QALY per year is reasonable.⁷

E-mail address: jschwab@partners.org (J. Schwab).

In this review, we will discuss the recommended core results that should be measured in patients with spinal disorders, instruments used to measure them, and the emergence of PROMIS (Patient-Reported Outcome Measure Information System).

1. Core measures

Recently, there has been an exponential increase in PROIs (Patient Reported Outcome Instruments) construction and utility for spinal conditions. This was reflected in a systematic review that reported on over a thousand different PROIs utilized to measure outcomes in patients with spinal disorders.⁸ Chapman et al.⁹ identified 75 PROIs used to evaluate chronic low back pain alone.

The proliferation of new PROIs to assess spinal disorders, rather than adding value, have become exhaustive, confusing, and impractical. As a result, determining specific important results to be measured became necessary to further compartmentalize and standardize the process. Important properties of any health status measure have been reported to include: practicality, precision, validity, and responsiveness.^{10–12} Also, Chapman et al.⁹ recommended considering domains that best measure what are most important to patients when selecting the appropriate PROIs to use in a given scenario. To assess the utilization of the above recommendations, Guzman et al.⁸ reported on the most utilized PROIs for spine disorders including: (1) visual analog scale, (2) Oswestry disability index, (3) Short Form-36, (4) Japanese Orthopaedic Association Outcome Questionnaire, (5) neck disability index, and (6) Scoliosis research society-22. Hence, it is likely that most studies are utilizing PROIs that meet the above criteria, however, they are not consistently assessing all the domains that are likely important to patients.

Patient-based outcome measures are usually classified as generic or disease specific.¹³ Generic measures include global ratings of health status, as well as multidimensional measures of health-related quality of life (HRQOL). These are applicable to patients across different types of conditions. Whereas, the hallmark of disease-specific measures is their attributability to symptoms and functional limitations caused by a specific condition. Five core subdomains were developed by an expert panel to more consistently measure, report and compare outcomes that are most important to patients with spinal disorders including; generic health status, back specific function, pain, work disability, and patient satisfaction.¹⁴

2. Generic health status

Although generic health status measures are less responsive to condition-specific changes, they add significant value in their ability to make broad comparisons of the relative effect of different conditions or treatments on the health of the population, accelerating the accumulation of interpretation guidelines that are essential to determining the clinical, economic, and social relevance of differences in health states and outcomes. Lurie¹⁵ evaluated reasonably well studied generic health PROIs including: the Sickness Impact Profile

(SIP), the Nottingham Health Profile (NHP), the Duke Health Profile (DUKE), and the COOP/WONCA charts; a revised and shortened version of the original charts developed by the Dartmouth Primary Care Cooperative Information Project (COOP), which was modified by the World Organization of National Colleges, Academies and Academic Associations of General Practitioners and Family Physicians (WONCA). They compared these instruments to the short-form instruments developed from the Medical Outcomes Study (MOS); the MOS SF-36 and SF-12, within the context of practicality, precision, validity, and responsiveness.

The SIP is most extensively tested for reliability, validity, and responsiveness, but has significant practical limitations as a result of its length. However, because it includes measures that assess profound disability, it may be more useful in severely ill populations. The NHP is practical and precise, however it is severely limited in its capacity to assess the psychometric domain of a population, relative to the SF-36. The DUKE is practical, and valid; however, its poor test-retest reliability makes it less attractive. Lastly, the COOP/WONCA charts have the advantage of being brief, and widely available in several languages, however, it lacks rigorous testing compared to the other Instruments. Lurie et al. concluded that the SF-36 has several advantages over the aforementioned instruments and should probably be used in most settings, unless a particular scenario lends itself to another instrument.

The SF-36 is a multipurpose short-form health survey with only 36 questions that yields an eight-scale profile of scores as well as physical and mental health summary measures. It has been useful in comparisons within and between general and specific populations; comparing the relative burden of diseases; differentiating benefits produced from wide range of treatments; and screening individual patients.¹⁶ Although it meets the four criteria for evaluating measures, it is unique and has been widely adopted, as predicted when first published, because of its brevity and comprehensiveness.¹⁷ Population and large-group descriptive studies and clinical trials to date demonstrate that the SF-36 is very useful for descriptive purposes such as documenting differences between sick and well patients, and for estimating the relative burden of different medical conditions. In addition, experience from more than 250 longitudinal studies suggests that the SF-36 is also useful for evaluating the benefits of alternative treatments.¹⁶

3. Pain

Measures of pain severity and pain affect are distinct. Pain severity is the magnitude of a person's pain, whereas pain affect is more reflective of a mental state triggered by pain. Hence, the measurement of pain severity is relatively straightforward, however many unresolved questions about the construct of pain affect remains.

4. Pain intensity

The three most commonly used PROIs to measure pain intensity are the verbal rating scale (VRS), visual analog scale

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