Why Disability and Rehabilitation Specialists Should Lead the Way in Patient-Reported Outcomes

Janna Friedly, MD, a,b Venu Akuthota, MD, c Dagmar Amtmann, PhD, a,d Donald Patrick, PhD, MSPHe

From the aDepartment of Rehabilitation Medicine and the bComparative Effectiveness, Cost and Outcomes Research Center, University of Washington, Seattle, WA; cDepartment of Physical Medicine and Rehabilitation, University of Colorado, Denver, CO; dUniversity of Washington Center on Outcomes Research in Rehabilitation, Seattle, WA; and eSeattle Quality of Life Group, University of Washington, Seattle, WA.

Patient-reported outcomes (PROs), or any report directly from patients about their health status, including functional status and feelings, are becoming increasingly recognized as important for many reasons. Not only do PROs represent the patients’ view of their health status, but they are more reflective of real life than many objective performance measures historically used in clinical research. PROs are also more predictive of distal outcomes such as mortality in cancer, as well as function and quality of life (QOL) in people with low back pain, than are “objective” measures of disease status (such as imaging findings).1,2

The recent push to include PROs in research and clinical care dovetails extremely well with the fundamental foundation of the field of medical rehabilitation—improving patient outcomes by partnering with patients to maximize function. So shouldn’t rehabilitation specialists be leading the way with incorporation of PROs into clinical care? Although rehabilitation specialists in many ways have been integrally involved in the advancement of functional outcomes research,4-8 we have not yet as a specialty, become leaders in the development of infrastructure and standardized methods for applying PROs to the clinical care of our patient populations. Since medical rehabilitation has a long history of leading the field of medicine in similar advances in clinical care that once seemed far-reaching, such as team-based interdisciplinary care, chronic disease/disability management, and a focus on function, we are well poised to lead the way with incorporation of PROs into clinical care and research.

Integration of PROs into clinical care

PROs have been incorporated into research for decades, but there is now a strong and growing impetus to incorporate PROs into both research and clinical settings in an integrated way.9 Increasingly, PROs are being recognized as important for assessing clinical outcomes, advancing quality improvement, and informing technology assessment and reimbursement decisions. Many national organizations have recognized the importance of PROs in clinical care, and the following significant activity has already occurred: (1) National Institutes of Health (NIH) funding for the Patient-Reported Outcomes Measurement Information System (PROMIS) and Neuro-QOL network; (2) legislation authorizing the Patient-Centered Outcomes Research Institute; (3) grants from the Agency for Healthcare Research and Quality; (4) activity at the Centers for Medicare and Medicaid Services; and (5) regulatory guidance from the Food and Drug Administration and other public and private organizations. Integration of PROs into electronic health records (EHRs) is also a key component of the Center for Medicare and Medicaid Services’ financial incentive program to demonstrate “meaningful use” of EHRs. In addition, with the health care reform movement toward the development of accountable care organizations, integration of PROs into EHRs is also becoming an important tool for measuring and demonstrating the success of care provided through accountable care organizations. Therefore, there are both financial and ethical rationales for incorporating PROs into routine clinical care.

Importance of PROs to patient-centered clinical care and rehabilitation

The key tenant of patient-centered care is putting the needs of patients and families first. It is well known that PROs and individualized goal setting are more meaningful to patients than non-PRO measures. In addition, many PROs are being integrated into systems that provide real-time or timely feedback to patients and clinicians for shared decision-making. Individualized goal setting and measuring improvement in function in relation to patient-defined goals have been a key component of rehabilitation...
medicine since the inception of this specialty. However, despite the importance of measuring improvement toward individualized goals (“goal attainment scaling”), we have yet to develop the methodology for how to incorporate these measurements into clinical research in a meaningful way. Measuring group change as the result of common, yet individualized treatment using individualized outcomes remains a methodological challenge. There is, however, emerging research to suggest that goal attainment scaling can be more responsive and patient-centered for at least some rehabilitation populations than legacy measures of function such as the FIM, which is widely used in rehabilitation settings. In addition, rehabilitation treatment involves many different, simultaneous, and complex components, and we have yet to develop methods for examining the comparative effectiveness of individual treatment components within the context of actual clinical practice.

There is also growing evidence that providing real-time feedback to providers can improve management of a variety of chronic diseases by encouraging active monitoring of outcomes and better medical management of the conditions. However, there are still many unanswered questions about how to provide the resources to incorporate this type of feedback to providers and patients in routine clinical care in a useful way, and to what extent this feedback improves outcomes.

**Importance of PROs in comparative effectiveness research**

The motivation for PROs in medical rehabilitation is not just for patient-centered clinical care but also as a comparative effectiveness research (CER) tool. In recent years, the United States has made a significant investment in CER with the goal of providing rigorous evidence on the relative effectiveness of alternative methods of preventing, diagnosing, treating, and managing medical conditions or improving the delivery of care. In an effort to discover what works best in real-world practice and not just for carefully selected patients in clinical trials done under tightly controlled conditions, CER often relies on observational studies that examine existing insurance claims, medical records, and clinical registries. Since a central goal of CER is to compare the benefits and risks of different ways to prevent, diagnose, and treat clinical conditions, it is important to include the patient perspective regarding outcomes in order for CER to assist with patient and provider decision-making. CER is an excellent vehicle for rehabilitation and its myriad treatments because it has the potential to identify underused effective rehabilitation treatments and, conversely, overused costly treatments.

It is widely recognized that health care costs are substantially higher in the United States than in other developed countries, but yet quality of care is not necessarily better. The rapid “learning health care system” is an important strategy described by the Institute of Medicine to quickly integrate pragmatic research findings into clinical practice and to develop research that is driven by clinical needs. The rapid learning health care system leverages advances in health data infrastructure with EHR systems and pragmatic CER trials to promote improvements in large health care systems. Given that both the underutilization of effective treatments and the overutilization of unnecessary treatments contribute to these soaring costs and lower quality of care, the Institute of Medicine has strongly recommended implementation of rapid learning health systems to address these issues. Integrated PROs are one essential feature of learning health care systems because they can provide real-time feedback from patients on health status and outcomes of importance to them.

**Moving toward national standardization of PROs**

To provide real-time outcomes, it is necessary to have infrastructure for collecting these data from patients, synthesizing the data in a meaningful way, presenting the data back to both patients and providers, and developing strategies for acting on the information to improve clinical care of patients. Many health care systems and organizations have been focusing on exactly this problem, and a myriad of potential solutions have been developed. For example, as part of the NIH Roadmap for Medical Research, the PROMIS initiative, funded in 2004, developed instruments that use modern psychometric theory to measure symptoms and QOL indicators, including pain, physical function, fatigue, depression, anxiety, and social role participation, across a variety of chronic diseases. In addition, the NIH National Institute of Neurological Disorders and Stroke funded the development of a sister project called Neuro-QOL that developed instruments for measuring health-related QOL of adults and children with neurologic disorders. The overarching goal of PROMIS is to improve the reporting and quantification of changes in PROs. PROMIS seeks to create precise but brief measures to make them more feasible for use in clinical practice and research. To date, substantial research funding, through the NIH as well as the Patient-Centered Outcomes Research Institute, has been devoted to the effort of bringing PROMIS to fruition for use broadly in research and clinical settings to accomplish the goal of developing a publicly available national system of valid, novel tools for the collection of PROs. PROMIS is suitable to be a national platform in that PROMIS scores are centered on the United States general population norm, and the scores can be cross-walked to many commonly used legacy measures, facilitating continuity of research and clinical data. The PROMIS initiative has conducted numerous research studies to validate its fixed-length short forms, item banks, and computerized adaptive testing methods in a variety of patient populations, but gaps still exist in terms of the methods for using PROMIS widely and the applicability of PROMIS clinically (eg, availability of clinically meaningful cutoffs, estimates of minimal clinically important differences) and for research purposes in a broad range of populations and clinical settings. These gaps have resulted in a reluctance to fully invest in PROMIS as a national standard for collecting PROs in the clinical setting, despite the enormous potential of this type of system. However, there is traction nationally for incorporation of PROMIS into EHRs, and one commonly used commercial EHR software, Epic, has now incorporated PROMIS short forms into EHR data capture. In addition, other national organizations, including the Department of Defense, are partnering with PROMIS to incorporate PROMIS into routine clinical care.

**List of abbreviations:**

- CER: comparative effectiveness research
- EHR: electronic health record
- NIH: National Institutes of Health
- PRO: patient-reported outcome
- PROMIS: Patient-Reported Outcomes Measurement Information System
- QOL: quality of life
The rehabilitation PROMIS: opportunities for medical rehabilitation leadership

There are tremendous opportunities for disability and rehabilitation researchers and clinicians to become actively involved in the process of validating the PROMIS measures in our patient populations, testing the feasibility of using PROMIS particularly for our complex patients with disabilities, and measuring the sensitivity to change in clinically important changes in function and health status over time. Because of the complexities of each health system’s EHR, clinical culture and practice, and patient populations, developing a national infrastructure and common platform for incorporation of PROs into EHRs is a daunting task. Developing a common national platform for PRO use and incorporation into EHRs will require substantial financial investment and interdisciplinary participation of a multitude of specialties and stakeholders.

Several related activities in medical rehabilitation have recently been initiated to develop a common language and platforms for the collection of PROs. The Rehabilitation Measures Database (www.rehabmeasures.org) was developed with the goal of helping clinicians and researchers identify reliable and valid instruments, including PROs, to assess patient outcomes during all phases of rehabilitation. The database provides evidence-based summaries that include concise descriptions of each instrument’s psychometric properties, instructions for administering and scoring each assessment, and a representative bibliography with citations linked to PubMed abstracts. The development of this database was guided by focus groups composed of physical, occupational, and speech therapists, as well as psychologists and nurses with experience in rehabilitation medicine. The Musculoskeletal Outcomes Research Collaborative is a recently formed, independent, non—industry-sponsored study group focused on increasing research collaboration through shared research infrastructure and common data elements to drive personalized, effective, nonoperative musculoskeletal treatments. As an extension of the Musculoskeletal Outcomes Research Collaborative activities, Allen Heinemann, PhD, ABPP, was recently awarded a Foundation for Physical Medicine and Rehabilitation research grant to develop outcomes data management and reporting capacity for musculoskeletal rehabilitation programs. Another ongoing effort is through a large Agency for Healthcare Research and Quality—funded study being conducted through the University of Washington to develop a large registry of older adults with back pain within several large integrated health systems (Back Pain Outcomes using Longitudinal Data registry).22

In addition, the American Academy of Physical Medicine and Rehabilitation has recently recognized the importance of a national registry to collect PRO data and has initiated a Registry Exploration Task Force consisting of rehabilitation clinicians and researchers to begin charting a course for developing a plan to address the complexities of rehabilitation populations and treatments.

Recommendations/Future directions

For us to succeed in becoming leaders in this complex task of incorporation of PROs into clinical care, we need to create, at a specialty level, a clear roadmap for short-term and long-term development of expertise, methods, and infrastructure for widespread PRO use in rehabilitation settings. We will first need to identify and promote key leaders and content experts within our field, identify ways to engage our patients in developing meaningful PROs and processes, outline priorities and gaps for both clinical and research arenas, and develop goals to achieve coordinated efforts across our national specialty organizations. Although much of this work has yet to be done and we among ourselves have not come to consensus about the specific PROs of importance to us and to our patients, we do already know quite a bit about what is important to us as a specialty in terms of PROs. PROMIS appears to be the system that provides the greatest hope of developing a standardized infrastructure for the collection of PROs that are broad in scope, meaningful to patients, and adaptable to a variety of clinical and research settings and needs. Increasingly, PROMIS is being incorporated into EHR and research initiatives nationally and likely will continue to be the dominating initiative in PROs. With this in mind, disability and rehabilitation researchers need to be actively involved in building on and extending PROMIS to be responsive to our patient populations and the needs of our specialty.

Medical rehabilitation priorities for PROs in clinical care

- Measures that address patient-identified concerns and goals
- Measures that are acceptable and meaningful to patients who consult rehabilitation specialists
- Measures that are accessible to rehabilitation patients including a variety of modes of administration that take into account physical, cognitive, and communication limitations
- Measures that can be used in real time in a variety of practice settings
- Measures that can assess individual improvement in function and feelings
- Analytic systems that can accommodate individualized outcome measures in clinical research
- Methods for incorporating computerized adaptive testing into clinical trials and clinical practice
- Methods for incorporating individualized goal attainment scaling into clinical trials
- Ability to interpret the score changes at both the individual level and group level

Supplier

a. Epic, 1979 Milky Way, Verona, WI 53593

Corresponding author

Janna Friedly, MD, Assistant Professor, University of Washington, Department of Rehabilitation Medicine, Comparative Effectiveness, Cost and Outcomes Research Center, Box 359859, Seattle, WA 98104. E-mail address: friedlyj@uw.edu.

References

16. Gray BH. With the inclusion of $1.1 billion for comparative effectiveness research in the 2009 fiscal stimulus bill in the United States, the experience of other countries with such research is of substantial interest in this country. Milbank Q 2009;87:335-4.