

## **Patient-reported outcomes: more promise than practice?**

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By all accounts, patient-reported outcomes (PROs) are finally positioned to become an integral part of ongoing medical care. It has always been necessary for clinicians to ask patients for self-observations about their health. However, individualized outcomes-based care had been considered impractical and cost-prohibitive, mostly due to lack of scientific methods for tracking and analyzing personal perceptions of treatment results. With the right technology, clinicians and researchers are now able to collect, analyze, and respond to data provided by the most subjective link in the clinical data chain - the patients themselves.

The response has been overwhelmingly positive - and somewhat cautious. Patients with long-term illnesses seem to benefit the most, as they need to be observed over a longer period of time. Many clinicians realize that reactions to medication or therapy vary by individual body chemistry and factors such as trauma, pain, or depression. Their patients generally perceive the quality of their care as higher when their doctor evaluates their personal experiences along with clinical test results. The structured questionnaires, or PRO instruments, that make this possible are giving new hope to those who see the value of holistic long-term treatment. Meanwhile, the research projects still outnumber the implementation in clinical practice.

### **Researching Subjectivity**

The medical research community has reason to be both optimistic and concerned about PROs. They are answering valuable questions, but they have a challenging task ahead of them. Those in the field know that something is missing in the evaluation of a patient's progress toward health-related quality of life (HRQOL). They know that critical questions remain about which quality issues to measure, which survey instruments and methods are best, how to evaluate data with extensive variables, how to make sure results are scientifically valid, and how to ensure security for personal health information (PHI). The ultimate goal must be to quantify patient emotions and perceptions, and effectively use psychometrics in the form of PROs to improve quality of life for all patients. That's a tall order, even for the most educated people in the world.

Fortunately, the motivation to reach that goal is universally strong, for a number of reasons. Most patients need to have their own observations taken seriously by clinicians who cannot personally observe daily progress or regression. Most clinicians strive for patient satisfaction, for both altruistic and economic reasons. Government agencies are continually reevaluating how to spend their money more effectively, insisting on accountability. Toward that end, several research projects have been funded in recent years with the vision of integrating PRO tools into everyday healthcare management.

Still in development, PRO instruments are found in many forms. Some projects may only use one PRO survey instrument; most use a combination of multiple survey instruments. One clinician reports in a 2004 online [article](#) that the North American Spine Society has published reviews on over 100 different PRO survey instruments that could be used by spinal clinicians. Some PRO tools have been created specifically for a particular physical condition. The Oswestry Disability Questionnaire, the Quebec Back Pain Disability Scale, and the Dallas Pain Questionnaire were cited as having been used to evaluate spinal patients. Other PRO survey instruments can be used across conditions. For instance, the Minnesota Multiphasic Personality Inventory (MMPI) was mentioned in the same article as a viable research tool to evaluate post-surgical patients. Validity is apparently in the eye of the researcher.

## Discovery and Disparity

Several projects have been proposed to investigate the application of patient-reported outcomes to various areas of clinical treatment. Of those which have already reached conclusions, the results have been eye-opening.

One of the most prominent research collaborations is the Patient-Reported Outcomes Measurement Information System ([PROMIS](#)), funded by the National Institute of Health (NIH) and managed by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). This initiative is actually comprised of six research facilities and a statistical recording center, all of which are studying different aspects of the practical use of PRO instruments. Research topics include examining the relationship between psychological and physical symptoms, data measurement theory, and assessment issues in multicenter trials. Due to its success, a second four-year funding phase has been added.

The Spine Patients Outcomes Research Trial ([SPORT](#)), conducted by spinal specialists at several institutions, including Dartmouth-Hitchcock Medical Center (DHMC) in New Hampshire, recently used various PRO tools to conclude, among other things, that patients with certain common spine disorders with predominant leg pain reported better post-surgical results than similar patients with predominant back pain.

Supportive Oncology Services, Inc., a research-based health information company, describes PRO assessments as a “revolutionary” improvement in cancer treatment. [Medical News Today](#) says that this company helped pioneer the use of PROs with the development of PACE (Patient Assessment, Care, and Education System), used by over 100 cancer clinics since 2001.

The American Cancer Society, in a recent policy and research review [article](#), acknowledged the valuable use of PRO and HRQOL measures in researching the effectiveness of treatments for some types of cancer, but expressed discouragement about the imperfections in those measurements and lack of research being conducted in other areas of oncology. They are proposing a goal of 2015 for universal implementation of PROs in cancer treatment.

The Outcomes Research Branch of the National Cancer Institute is sponsoring a Small Business Innovation Research (SBIR) Initiative on [Integrating Patient-Reported Outcomes in Hospice and Palliative Care Practices](#). Their focus is on the development of innovative information technology for PRO management, geared toward maximizing HRQOL for the terminally ill patient.

Funding for these types of research may not always be easily accessible. A recent [study](#) of funding options sponsored by the American Society of Clinical Oncology found that PRO research has often been considered as part of other trials and not as a separate field of study. Funds from sources other than those specifically involved in cancer research have been needed to study specific PRO issues relating to cancer treatment.

## From Research to Practice

Responding to past research, some clinicians and government agencies are already using PROs and other quality controls to improve health care. The gateway of approval by the US Food and Drug Administration (FDA) provides a critical link between research and clinical practice. Its [advocacy](#) of scientifically reliable PRO survey instruments in the process of approving new drugs has begun to validate HRQOL issues and set standards for assessment methods. The FDA’s 2006 [draft guidance](#) for researchers outlines criteria for acceptable PRO survey instruments and provides information on preparing research results for FDA labels.

Several departments at the Dartmouth-Hitchcock Medical Center not only use the [SF-36](#) (named for its 36-question short form survey) for evaluation but also for prediction of surgical outcomes.

The Medicare Health Outcomes Survey ([HOS](#)), has been used by the US Centers for Medicare and Medicaid Services (CMS) in some form since 1998, but only on a limited basis. Since Congress asked CMS and the US Department of Health and Human Services (HHS) to develop a plan for value-based purchasing of all Medicare hospital services, they are evaluating new methods of measuring value and validating data, with appropriate changes in public reporting.

New incentive structures are also being built into the system to inspire Medicare hospitals to improve the quality of their patient care. These hospitals have been reporting data on program improvements for years, but the source of the incentive will soon begin to shift from the *act* of reporting to the *results* being reported. The [proposal](#) is that, in 2009, hospitals reporting successful quality measures will get the full 3% increase in payments as a pay-for-performance (P4P) incentive. Hospitals who do not report success will be penalized 2%, for a net increase of 1%. For the most part, the quality reporting still focuses more on improved lab results and promotion of preventive services than on patient input, but this new initiative is a step in the right direction for the patients.

In a related move, a new patient-based survey, the Hospital Consumer Assessment of Healthcare Providers and Systems ([HCAHPS](#)) has been developed by CMS and HHS. The [results](#) are formatted so that prospective patients can compare hospitals in their area, focusing on either general patient satisfaction or condition-specific statistics.

Using CMS criteria, hospitals seem to have improved services since implementing quality reporting programs. Medicare's success has been inspiring to other insurance providers. For instance, Anthem Blue Cross and Blue Shield in New Hampshire implemented a P4P program called the [Quality Hospital Incentive Program](#), partnering with several hospitals in the state, including the Dartmouth-Hitchcock Medical Center. In 2005, Anthem had launched its Primary Care Incentive Program, and had reached agreements with over 700 primary care physicians during the program's first year.

### **The Critical Importance of Collaboration**

It is evident from public literature that there are many similar projects being conducted at once. Achieving common standards of practice and universal use of patient-reported outcomes will require communication, collaboration, and consensus by all involved. Publication of the PROMIS initiative findings – a huge collaborative effort – should be influential in setting standards, as should the results of several pilot programs designed to test the waters.

CMS' [Premier Hospital Quality Incentive Demonstration](#) is interesting because it builds upon an existing system. Premier, Inc. is a nationwide group of non-profit hospitals which already had a 30-point QA system in place, so it was easier for CMS to use them in a P4P initiative with regular quality evaluations. Major improvements would be difficult without the collaboration between CMS, HHS, the AHRQ, and other government agencies on this type of project.

The development of condition-specific PRO instruments is another task which would be difficult without partnerships and information-sharing between non-profit advocacy groups, clinics, researchers, and patients. Treatment of long-term illness is complicated enough without various sources of stress along the way, including lack of communication. Without specific information on how a certain type of diabetes has affected different patients with the condition, or how external factors have influenced the course of any given treatment, many necessary adjustments in medication, therapy, or lifestyle might never be made.

Ancillary ventures are also becoming more prevalent as PRO research results become available. One international organization has formed a focus group specifically to analyze research results. The Cochrane Collaboration's [PRO Methods Group](#) has members from all over the world, each interested in sharing information about the latest studies and promoting awareness of new technologies in this area. Other private companies, such as RTI Health Solutions, are beginning to present themselves as PRO advocates, consultants, and research providers, aiming to give clinicians the tools to save time and increase value.

### **The Internet Connection**

Web-based PRO systems enable instant data collection and real-time decision-making for clinicians providing patient care. With the advent of the Internet and Web-based systems, universal reliance on patient-reported outcomes is within reach. The information can be accessed and analyzed, by patients and clinicians alike, from anywhere in the world at any time. In addition, real-time, digital patient-reported information is far more reliable than periodic hand-written surveys relying on memory recall.

Objections can arise from people unfamiliar or uncomfortable with technology. The first complaint often heard is by those unable to use a computer, whether they are functionally illiterate, occupationally disabled, computer illiterate, or without Internet access. This is perhaps the easiest problem to address. Clinicians wishing to ensure universal compliance with PRO data collection can provide a touch-screen computer with an Internet connection right in their facility. Properly designed, even technology-illiterate users can navigate the program well enough to digitally communicate their experiences with the clinician.

Security of personal information is a more complicated issue. With stories of identity theft and credit card fraud running rampant, it is no wonder that there is more suspicion than confidence when it comes to allowing one's personal information to be posted online. Fortunately for consumers, healthcare providers are bound by [ISO 22857](#), an industry-specific standard devoted exclusively to protect personal healthcare data, even across international boundaries.

Patient-reported outcomes are the link between feelings and facts. Once we understand the best way to navigate that link, the potential for truly personalized healthcare will be as vast as our physiological and psychological differences. That may be the best value-added service a clinician could provide.

*Note: All hyperlinks were retrieved on October 23, 2008.*