

What is the Best Way to Assess Functional Health? The History of the Development and Application of the Patient Reported Outcome Measurement Information System (PROMIS)

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Abstract

For more than seven decades, the World Health Organization has defined health as a “state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” Among researchers and clinicians, translation of this definition into outcomes measurements has proven challenging. The Patient-Reported Outcomes Measurement Information System (PROMIS) is an initiative connected to the National Institutes of Health Roadmap for Medical

Research. Recently, this tool was successfully applied in a comparative evaluation of intervention models (the Functional Medicine model versus the standard-of-care model for primary medicine) in patients with chronic health complaints. This study demonstrated that information derived from validated patient-reported outcomes surveys can be used to design clinical research approaches focused on improving health and well-being.

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The historical significance of the year 1945 is profound. World War II had finally—*finally*—been brought to a close, the business of rebuilding lives and communities commenced, and at the same time a cautious optimism about the future began to emerge. Famously, diplomats from 50 countries gathered in San Francisco in June 1945 to discuss the formation of the United Nations, which would be an institution dedicated to international peace and security. During that meeting, the need to establish a separate humanitarian organization focused on global health was identified. One year later—in June 1946—the International Health Conference was convened in New York City and the Constitution of the World Health Organization (WHO) was adopted. In the preamble of this epic declaration, the first principle is the following statement: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” On April 7, 1948, the WHO became an officially recognized entity and this statement became the official definition of the word *health*. This description has stood the test of time; there has been no modification to the wording in more than seven decades.¹

Far from existing in a time capsule, the WHO has done tremendous work around the world since its formation, especially among vulnerable populations with limited resources. As time has marched forward, *health* has steadfastly remained the core mission of the organization, even as different administrators have come and gone, even as political ideologies and physical borders have shifted. In developed countries, extraordinary progress in scientific research has taken place, but at the same time we’ve seen large medical systems and powerful reimbursement providers—in the name of efficiency—destabilize the ability of independent practitioners to thrive, leaving patients who seek a relationship-based style of care with limited choices and virtually no autonomy. This modern model, in essence, is one in which the *absence of disease* has become a primary defining principle.

It seems as if for a brief moment in time back in the late 1940s there was unity and consensus. How, then, has it come to pass that disease consumes attention and resources, while health has become embedded—and sometimes lost—inside of a disease-focused model? Certainly, those early leaders could not have anticipated the marketplace trends that were to come: diagnostic thinking rather than prognostic thinking, an ICD-10 containing more than 68 000 codes, and billions of dollars spent every year in the name of conditions that people have come to fear and worry about in their daily lives. Disease, it turns out, is easy to quantify using well-established pathognomonic criteria. Health, on the other hand, when described as “a state of complete physical, mental and social well-being,” may capture the sense of higher purpose that the medical profession is meant to embody, but it is also more subjective and therefore more complicated to standardize and document. This

combination of factors has led modern-day medicine to contextualize health as a by-product of the treatment of the signs and symptoms of disease-related phenotypes or “disease risk factors.” It is an etiopathological approach that is convenient because the “absence of disease” is a scalable and financially viable model, but it is decidedly problematic in other ways. The practice of medicine has always been looked upon as a higher calling—one that is meant to be focused on helping individuals live their lives feeling well and functioning optimally. In our present era, we find ourselves living in a world where the term “health care” encompasses all factors that relate the treatment or prevention of disease, not the achievement of personal health aspirations by way of a successful therapeutic relationship between provider and patient.

Quantifying Function: The PROMIS Initiative

In 1980, James Fries, MD, an immunologist and rheumatologist at Stanford University, published a landmark paper in the *New England Journal of Medicine* titled “Aging, Natural Death, and the Compression of Morbidity.”² Dr Fries suggested that a person could experience a delay in the age of first infirmity through the implementation of a patient-focused lifestyle intervention program that would reduce the rate of loss of organ reserve and thereby improve function longer into the lifespan. The ideal and very possible result of the successful implementation of such a program would be to compress disease into a much shorter period of an individual’s life, allowing for a natural death—one that did not include a long period of medical treatment—to take place.

Dr Fries was (and still is) a respected researcher affiliated with one of the leading medical schools in the United States. Even so, his “compression of morbidity” concept was considered controversial and not achievable when he published his article in 1980. Ironically, given that the WHO definition of health had been in place for 32 years at that time, some argued that the objective of the medical system was to treat people with disease, not to prevent or delay the onset of illness. The philosophical divide was clearly evident. For myself, I was at the start of a lecture career that would eventually take me all over the globe and introduce me to thousands of practitioners. I began referring to this entrenched stance that the medical establishment had adopted as the “tyranny of the diagnosis.” My position was then, and still is now, that the system had become so focused on disease, little room was left for the valid point of view that function in an individual can be measured and used as a method for quantitating health.

As an early pioneer in the field of health metrics, Dr Fries had been exploring ways of evaluating function in individuals through the use of patient-reported outcomes information since the 1970s. While doing clinical work as a rheumatologist, he had observed that patients with the same diagnosis and who were following the same course

of treatment had significantly different outcomes, and these variances seemed to be tied to lifestyle, environmental, and social factors. His research led Dr Fries and his colleagues to develop the Stanford Health Appraisal Questionnaire (HAQ), which was the first validated instrument for evaluating functional health.³ The HAQ tracked patient-reported functional health determinants, including disability, pain, costs related to care, medication effects, and quality of life.⁴

Over the decades, Dr Fries has expanded his areas of interest and he is now known for his work in the field of healthy aging.⁵ In 2011, Dr Fries and two colleagues at Stanford—Bonnie Bruce, DrPH, MPH, RD, and Eliza Chakravarty, MD—jointly published an article in which they reviewed the progress that has been made since 1980 in utilizing the patient-reported health outcomes survey to demonstrate the importance of lifestyle, environment, and behavioral impacts on the “compression of morbidity” and functional health.⁶

John E. Ware, Jr, PhD, is another researcher who has become internationally recognized for his work on outcomes measures. As a research psychologist, Dr Ware spent 15 years at the RAND Corporation studying methods for evaluating physical and mental health in relation to quality of life.⁷ Dr Ware is now affiliated with the University of Massachusetts Medical School and the Harvard T.H. Chan School of Public Health. He is the developer of the Medical Outcomes Survey (MOS), a validated tool that has been shown to successfully assess personal health outcomes using functional criteria consistent with the original WHO definition of health.^{8,9,10}

In 2004, the National Institutes of Health (NIH) began funding the Patient-Reported Outcomes Measurement Information System (PROMIS) as one of the initiatives connected to the NIH Roadmap for Medical Research. James Fries and John Ware, Jr, along with many others, were members of the network this initiative brought together to work collaboratively on the development of a consensus-based framework for self-reported health through the systematic evaluation of instruments and datasets that address functional health domains that have been demonstrated to have a major impact on quality of life.¹¹ These functional health domains include pain, fatigue, physical function, emotional distress, and social/behavioral function. Work on PROMIS is now complete, and the tools that were developed are publicly available. The NIH website currently features the following description of the project: “Clinical measures of health outcomes, such as X-rays and lab tests, may have minimal relevance to the day-to-day functioning of patients with chronic diseases. Often, the best way patients can judge the effectiveness of treatments is by changes in symptoms. The goal of PROMIS was to improve the reporting and quantification of changes in PROs [patient-reported outcomes].” Another statement is this one: “PROMIS created new paradigms for how clinical research

information is collected, used, and reported. The PROMIS initiative addressed a need in the clinical research community for a rigorously tested PRO measurement tool that utilized recent advances in information technology, psychometrics, and qualitative, cognitive, and health survey research.¹² Numerous studies have now been published using PROMIS as a tool for successfully quantifying health outcomes such as improvement in physical, mental, and behavioral health after various therapies.^{13,14,15} Looking ahead, PROMIS is a potential instrument for the quantification of functional health outcomes in people undergoing personalized lifestyle medicine interventions, such as those described by Deanna Minich, PhD, and me in our 2013 article, “Personalized Lifestyle Medicine: Relevance for Nutrition and Lifestyle Recommendations.”¹⁶

Functional Medicine and the Application of PROMIS in the Evaluation of Functional Health Outcomes

The Functional Medicine model of care is built upon the principle of assessing function in four quadrants that align with PROMIS global health measures: physical, metabolic, cognitive, and behavioral/psychological health. In the October 25, 2019 issue of *JAMA Network Open*, a study was published demonstrating the value of PROMIS as an instrument to evaluate the comparative outcomes of patients experiencing a variety of chronic symptoms related to functional health disturbances; the title of this open-access article is “Association of the Functional Medicine Model of Care With Patient-Reported Health-Related Quality-of-Life Outcomes.”¹⁷ This large-scale retrospective study followed 7252 patients with chronic health issues who were patients at either the Cleveland Clinic’s Center for Functional Medicine (CFM) or one of the Cleveland Clinic’s family health centers (FHC). Health status was evaluated using PROMIS questionnaires for Global Physical Health (GPH) and Global Mental Health (GMH). The patients were matched for their presenting symptoms, and an evaluation of outcomes was done at 6 months and 12 months. Data showed that participants receiving Functional Medicine treatment demonstrated significantly greater improvements in GPH and GMH than those receiving standard treatment. In the words of the authors: “In this study, the functional medicine model of care demonstrated beneficial and sustainable associations with patient-reported HRQoL [health-related quality-of-life].”

This important study marked a milestone for Functional Medicine by confirming the effectiveness of the model that many people have been working to build over the last 40 years, but it is equally significant for the door that has now been opened for further research. PROMIS is a valuable tool that can be used to assess health outcomes across the four functional domains in comparative intervention trials involving patients with various chronic health issues. Additional studies are now on the horizon, some of which

may focus on assessing and quantifying function in healthy populations. As the model continues to evolve, I predict that a true healthcare system—one that reflects the intent and spirit of the WHO’s 1948 definition of health—may finally emerge to stand next to, but apart from, the disease-care system that is efficient for crises but suboptimal for addressing the personal health needs of a significant portion of the population.

What is the Best Way to Assess Functional Health? The Data Tells a Story

Dr Fries, developer of the HAQ, has spent most of his long and remarkable career at Stanford University, as I have already noted. In the mid-1970s, that era during which cutting-edge technology took the form of punch cards and room-sized computers, Dr Fries and his colleagues developed the world’s first chronic disease data bank system. It was called ARAMIS, which was an acronym for the Arthritis, Rheumatism and Aging Medical Information System. The ARAMIS project was not hailed as revolutionary, nor did it even generate much excitement when it made its initial debut. At that time in history, the usefulness and validity of patient-reported outcomes data was in dispute and this perception persisted from many years. But data, as we all know, is hard to argue with, and this is especially true when big numbers are involved. Significantly, more than 900 peer-reviewed studies have been published about the ARAMIS database since its inception.¹⁸ Over time, as information technology improved and collaboration among research groups became more common, the ARAMIS system grew to include data from more than 16 centers, which encompassed 22 000 patients, 140 000 patient encounters, and 80 000 000 observations.¹⁹ Back in 1984, Dr Fries forecasted that the most pressing medical problems in the future would be tied to the rising prevalence of chronic illness; the data he collected has chronicled that unfolding story for the past four decades.²⁰

Cell phones, smart devices, and cloud-based networks now connect billions of people worldwide. Consumers are not only comfortable with technology, they demand it. Wearable devices and digital health engagement tools are very popular and they represent an opportunity for both the implementation of personalized lifestyle medicine interventions and the continuous collection of patient-reported outcomes data. I have recently launched an ambitious data project of my own. I am building a database of responses to the question: “What does health mean to you?” Over the past year, hundreds of people have been invited to add their personal definition of health to this unique collection and it is growing every day. One theme has already emerged: Health is a deeply personal concept that means different things to different people. In the 21st century health economy, data will tell the story of each individual through the quantification of function and the achievement of personal health aspirations.

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