



The National Institutes of Health's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The goals of the Agency are to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health; develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease; expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

One trans-National Institutes of Health example that is consistent with its mission and goals and advances the National Quality Strategy is the Patient-Reported Outcomes Measurement Information System (PROMIS®). The Patient Reported Outcomes Measurement Information System was among the first National Institutes of Health/Common Fund initiatives begun in 2005. The goals of the Patient-Reported Outcomes Measurement Information System were to utilize state-of-the-art item development and modern psychometrics (e.g., Item Response Theory) to develop item banks (a collection of questions and answers with their associated calibrations) measuring patient-reported clinical outcomes and to make these banks easily obtained and widely available for use in clinical research and practice. Because the Patient-Reported Outcomes Measurement Information System banks are not disease specific (e.g., physical function, not physical impairments due to arthritis), they allow comparisons across disease groups and are particularly useful to assessing outcomes in multi-morbidity patients. The use of Item Response Theory also allows these banks to be co-calibrated with existing measures of the same construct, thereby allowing researchers to more easily compare, merge, and integrate data across past, present, and future studies. The Patient-Reported Outcomes Measurement Information System item banks can be flexibly administered, including the use of computer adaptive testing in which administration of each item is dependent on the responses of the prior items. As a result, these banks can produce highly precise estimates of patient-reported outcomes with minimal respondent burden.

To date, the Patient-Reported Outcomes Measurement Information System network has produced more than 50 banks measuring a range of physical, mental, and social health constructs. There have been over 125 publications of the network, including validation studies in a variety of disease groups. The National Institutes of Health Common Fund efforts are limited to 10 years so. The funding for the network ends in August 2014. However, a number of National Institutes of Health institutes have collaborated to issue a funding announcement for a Patient-Centered Outcomes Research Resource that will serve as the resource for the Patient-Reported Outcomes Measurement

Information System and other National Institutes of Health-supported outcome instruments (e.g., National Institutes of Health Toolbox, Neuro-QOL) through 2018. This funding announcement includes the development of a sustainability plan in which National Institutes of Health funding is reduced each year as the Patient-Centered Outcomes Research Resource leverages private funding sources to sustain these resources for long-term availability to clinical researchers and clinical practice systems.

The National Institutes of Health had many quality-related achievements during the past year. The release and imminent funding of Patient-Centered Outcomes Research Resource is the primary activity taken by the National Institutes of Health this year to ensure continued use of Patient Reported Outcomes Measurement Information System. The Patient Reported Outcomes Measurement Information System Assessment Center (the system that automates the administration, scoring, and download of patient responses to Patient-Reported Outcomes Measurement Information System banks) also has been set up within the National Institutes of Health Clinical Center system this year, allowing National Institutes of Health intramural researchers access to this system and further insuring sustainability.

Over the previous year, the Patient-Reported Outcomes Measurement Information System network has developed a number of collaborations with other Federal Agencies to facilitate the use of the Patient-Reported Outcomes Measurement Information System banks for various outcome and quality assessments.

- **The U.S. Food and Drug Administration**—Patient-Reported Outcomes Measurement Information System has worked with the Food and Drug Administration from its inception, and it has been a regular topic of the Food and Drug Administration/National Institutes of Health Clinical Outcomes Assessment Working Group. The National Institutes of Health and the Food and Drug Administration continue to discuss how the Patient-Reported Outcomes Measurement Information System banks can be submitted for the Food and Drug Administration drug development tools qualification process.
- **Department of Defense**—In collaboration with Patient-Reported Outcomes Measurement Information System Technology Center, the Department of Defense has been developing an electronic clinical management system for chronic pain patients (Pain Assessment Screening Tool and Outcomes Registry). This effort has involved consulting on the use of selected Patient-Reported Outcomes Measurement Information System banks for measuring outcomes in clinical populations, and using the Assessment Center platform for the automated administration, scoring, and reporting of these banks in their system.
- **Substance Abuse and Mental Health Services Administration**—The Substance Abuse and Mental Health Services Administration’s Health Information Technology initiative is working to develop modular, open-source tools that can be integrated with electronic health record (EHR) systems to advance behavioral health care. One of the projects is focused on promoting integration of standardized patient assessment tools into electronic health records.

- **The Centers for Medicare & Medicaid Services**—The National Institute of Health Patient-Reported Outcomes Measurement Information System has been working with Centers for Medicare & Medicaid Services' Centers for Clinical Standards and Quality over the past year regarding the use of Patient-Reported Outcomes Measurement Information System instruments as quality performance measures. Yale's Center for Outcomes Research and Evaluation has a contract with the Centers for Medicare & Medicaid Services to recommend initial performance measurement projects, and the Patient Reported-Outcomes Measurement Information System has provided research and system information to the Centers for Medicare & Medicaid Services and the Yale group for consideration.
- **Centers for Disease Control and Prevention**—In 2010, the National Health Interview Survey included the Patient-Reported Outcomes Measurement Information System global items as a health-related quality-of-life measure in their survey of 35,000 households. One result of that inclusion was that the Healthy People 2020 Quality of Life and Well-Being Working Group recommended that one of the health-related quality-of-life goals be based on the Patient-Reported Outcomes Measurement Information System global items. An outgrowth of this Working Group was a collaboration between the Center for Disease Control and Prevention's National Center for Chronic Disease Prevention and Health Promotion and the National Cancer Institute's Outcomes Research Branch to fund data collection and analysis of the Patient-Reported Outcomes Measurement Information System global items and the Behavioral Risk Factor Surveillance System Healthy Days quality-of-life items.

The National Institutes of Health will continue to support the Patient-Reported Outcomes Measurement Information System via funding of the Patient-Centered Outcomes Research Resource initiative, and will play an active role in this cooperative agreement in the upcoming year. Existing collaborations will continue to be fostered, and new collaborations sought, to facilitate the use of the Patient-Reported Outcomes Measurement Information System banks in clinical research, clinical practice, and survey research. The current National Academies effort on behavioral and social measures in electronic health records includes interests in domains that are measured via Patient-Reported Outcomes Measurement Information System banks. The National Institutes of Health will continue to foster the use of Patient-Reported Outcomes Measurement Information System banks in electronic health records, including electronic health record vendors such as Epic. The National Institutes of Health will also continue to pursue the use of patient-reported outcomes for various quality metrics and continue discussions with various groups interested in developing quality metrics based on patient reported outcomes. For survey purposes, The National Institutes of Health will continue to work with the Centers for Disease Control and Prevention to evaluate data from the National Health Interview Survey, Behavioral Risk Factor Surveillance System, and other national and State surveys of health to further validate and refine the use of Patient-Reported Outcomes Measurement Information System measures in survey methodology.