Model Text on PROMIS for Grant Applications

Background

The Patient-Reported Outcomes Measurement Information System (PROMIS®) is a product of a multi-year cooperative agreement between the NIH and several research institutions and academic medical centers. PROMIS® is part of the National Institutes of Health (NIH) Common Fund effort to develop a technological infrastructure that supports the conduct of NIH-funded clinical investigators across Institutes, disciplines, diseases, and subpopulations. PROMIS® is a health *domain*-focused, rather than a *disease*-focused measurement system. To ensure comparable data and the accumulation of knowledge across patient subgroups and therapies, PROMIS® refers to aspects of functioning and well-being that are relevant across most chronic conditions (e.g., cognitive functioning or fatigue). Thus, PROMIS® is designed to provide a valid assessment of this broad definition of health (historically referred to as "health-related quality of life").

PROMIS® measures of health domains use "banks" of questions to address different domains of health (e.g. sleep quality, pain, social functioning) wherein each response category to each question is calibrated to have a precise value on the continuum of health for that particular topic. These item banks were developed following rigorous protocols that involved extensive formative research and statistical analysis. [1,2] PROMIS uses Item Response Theory (IRT) to identify health domains and to calibrate PROMIS question responses in relationship to those domains. These item calibrations are used to produce scores for individuals on a particular health domain based on the questions they respond to and the responses they provide. IRT enables each item to produce a score on that health domain which is why it is possible to adapt the PROMIS assessments to the individual respondent. Even though different individuals receive different sets of questions, their question responses are calibrated to a common health domain and so the scores they receive for that health domain are comparable. Computer Adaptive Testing (CAT) software is used to implement the adaptive feature of PROMIS. PROMIS measures also include short, fixed forms which are a sets of questions calibrated to the health domain. When fixed forms are administered everyone answers the same set of questions. The fixed forms can be completed without the aid of computer software. PROMIS® measures were developed following a conceptual framework that includes physical, mental and social health and includes assessments for both adult and pediatric patients. Adult health domains include physical function, pain, fatigue, sleep, sexual functioning, gastro-intestinal symptoms, dyspnea, depression, anxiety, anger, cognitive function, alcohol use/expectancies/consequences psychosocial illness impact, self-efficacy, satisfaction with social roles and activities, ability to participate in social roles and activities, social support, social isolation, companionship, and global health. Pediatric assessments include physical function, pain, fatigue, subjective wellbeing, depressive symptoms, anxiety, anger, stress, peer-relationships and family belongingness. PROMIS® investigators developed these item banks by collecting data via Web-enabled questionnaires administered to thousands of people spanning the U.S. general population as well a number of chronic diseases. [3,4] Finally, for the statistical analysis of these data, PROMIS® investigators followed a standard protocol including identifying dimensions, calibrating item responses, and evaluating bias in measurement across gender, education level, and self-identified chronic conditions. [5]

Innovation

PROs

Patient-Reported Outcomes (PROs) have a number of advantages over many traditional clinical indicators. These advantages include additional clinical information that can only be supplied by the patient, high standards for the data reliability and validity, greater discrimination within levels of impairment, and, often, fewer burdens for patients and administrators. PRO metrics increase the available health outcome information by deriving data from the patient.. Traditional indicators of health care outcome (e.g., blood counts, radiographs, resting temperature and pulse, and body mass index) do not require the patients' conscious participation.

PRO assessments have logistical advantages, including relatively low respondent and administrative burden, compared to alternative health measures. Unlike laboratory analysis, PRO assessments do not require the use of physically invasive medical procedures. Unlike radiographic imaging or physical performance tests, they do not require the purchase of expensive machinery and software.

PROMIS®

The PROMIS® tools were developed using sophisticated measurement techniques, including item response theory (IRT), to create psychometrically robust fixed-length short forms and computerized adaptive tests (CATs).[6,7] While IRT scoring and CAT has been used for years in high-stakes, national testing applications (e.g., the Armed Services Vocational Aptitude Battery or Graduate Record Exam), adaptation of this technology to be appropriate for health measurement represents an innovation. [8]

The IRT-based CAT measurement approach enables comparability across PRO measures while reducing respondent and administrative data collection burden. IRT is used to develop scores which are sample-independent[9], meaning that they are equally valid across groups of patients who differ in demographic characteristics. This enables CAT to administer a different set of questions to different groups of respondents and yet obtain comparable data.[10,11] For example, chronically ill patients with limited functioning are asked, "are you able to get in and out of bed?" while healthy patients are asked "are you able to jog for 1 mile?" Because all items are from the same item bank, scores from different PROMIS® measures that contain different items can be compared or combined. For each health domain, PROMIS® measures have been evaluated in comparison to well-tested and widely-adopted legacy PRO measures (e.g. the SF-36, Brief Pain Inventory, CES-D, HAQ).[12]

Electronic Data Capture

PROMIS® health assessment data can be collected with minimal respondent burden and without error introduced by data entry through the use of electronic systems[13] including electronic medical record software (e.g. Epic). The Assessment Center™ (AC) is a Web-based administrative platform that enables the investigator to create a data collection Web site including any PROMIS® item banks and short forms, free of charge.[14] In addition, investigators may upload or create their own questions to be administered in addition to the PROMIS® measures including additional PRO measures, study-specific participant background questions and informed consent forms. AC supports data collection designs that include multiple time points and multiple treatment arms and enables investigators to monitor enrollment of

participants and completeness of data collection during the course of their research in real time. Web-enabled data collection such as AC facilitates multi-site research in two ways: 1) participants can access the assessments at a study-specific URL from any location, eliminating the need to coordinate participants' schedules with those of the personnel and equipment at the study location; and 2) data from these multiple locations are stored centrally in a single database that can be downloaded from the study Web site, eliminating the need to merge data bases contributed by each of multiple sites. A final advantage of AC is rigorous development and testing within clinical research applications.[15]

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