

Questions and Answers

From the Advances in Person-Centered Outcome Measurement: An Overview of PROMIS, Neuro-QOL, and NIH Toolbox June 10, 2014 Webinar

PROMIS, Neuro-QOL, NIH Toolbox

Q: How can I access PROMIS, Neuro-QOL, and NIH Toolbox instruments?

A: Go to the respective websites. Sample PROMIS instruments are available for download on www.assessmentcenter.net. All instruments can be downloaded as PDFs from within Assessment Center as well (login to Assessment Center in upper right corner, then click PDFs). Neuro-QOL instruments are available on its website (www.neuroqol.org). Some NIH Toolbox instruments are also available as PDFs on www.nihtoolbox.org.

Q: When are “coming soon” PROMIS instruments going to be available?

A: This varies depending on the instrument, but is expected in 2014. Check out the instrument library page on www.assessmentcenter.net for updates.

Q: You mentioned extending the measurement ceiling of the PROMIS physical function item bank. Will there be a similar update for floor effects?

A: We plan on also extending the floor of PROMIS physical function.

Q: Do you recommend using PROMIS as a whole or using subscales only?

A: You do NOT want to use all PROMIS measures. Select the domains of interest for your population. Then, for that domain, select a short form or CAT.

Q: Is the T-score the sum of item responses to x number of questions?

A: No, the T-score is a deviation scale where the mean is 50 (SD=10) in the general population.

Q: Is it possible to get an advanced release of the instruments not yet available?

A: Email help@assessmentcenter.net with this question and your question will be directed to the scientist leading development for that instrument.

Q: Are measures of caregiver reported cognition being developed?

A: There are measures of cognitive function self-report in PROMIS and Neuro-QOL and objective tests of cognitive function in NIH Toolbox. None of these instruments specifically mention one's role as a caregiver, but could be administered to a sample of caregivers.

Q: Please speak to the validity of PROMIS pediatric measures for use with adolescents.

A: The PROMIS pediatric self-report instruments were developed and tested in a sample of children aged 8 – 17. Currently, PROMIS is conducting a study that evaluates the pediatric and adult instruments among adolescents and young adults. This study will help to identify the relationship between scores on the child self-report and adult self-report items among adolescents and young adults. Preliminary results show that several measures are very highly correlated ($r=0.8$ to 0.9) between most pediatric and adult scales including anxiety, depression, and anger.

Q: Has the FDA endorsed PROMIS, Neuro-QOL, or NIH Toolbox instruments?

A: The FDA is committed to working with NIH to advance the use of patient-reported outcomes in clinical research. PROMIS, Neuro-QoL and the NIH Toolbox were developed using methods consistent with the *FDA Guidance for Industry, Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims* (found at www.fda.gov/RegulatoryInformation/Guidances/default.htm), and the FDA has provided constructive input toward the development of PROMIS. Full FDA endorsement, better-known as "qualification," occurs after prescribed submission of a measure as a Drug Development Tool (DDT). Currently, PROMIS investigators are working on submissions to the FDA to qualify the fatigue item bank in a number of chronic conditions. Any component of PROMIS, Neuro-QoL or NIH Toolbox can also be submitted to the FDA by an individual sponsor seeking a specific label claim with a new drug or device in a defined clinical area.

Q: Is PROsetta Stone the only way to have cutscores (e.g., mild, moderate, severe) on PROMIS instruments?

A: PROMIS instruments use the T-score metric where the mean is 50 within the US General Population. Knowing a patient's score provides information about how that patient compares with the population mean. The PROsetta Stone linking tables also offers an interpretation aid in that you can translate a score from another depression instrument (e.g., CES-D) to the PROMIS metric. Cut scores from that instrument can be converted to the PROMIS metric. Additional research is ongoing to establish specific cutscores for a specific population and purpose. It is expected that the thresholds for mild/moderate/severe, for example, may vary between populations. What may be considered moderate impairment in physical function in one condition, for example, may be considered mild impairment in another condition.

Q: Will PROsetta Stone have linking tables for pediatric instruments?

A: Yes! Watch the PROsetta Stone website for the addition of new linking tables (www.prosettastone.org).

Q: How do PROMIS measures map on to classic measures of basic and instrumental activities of daily living?

A: There are items about basic activities of daily living (e.g., feeding, dressing, toileting) in the PROMIS Physical Function item bank. Instrumental activities of daily living can include assessment of the ability to fulfill one's role. You will see items about this construct in different domains including physical function (e.g., ability to shop, take care of one's home), cognitive function (e.g., manage finances), and ability to participate in social roles and activities (e.g., fill role in family).

Q: How does PROMIS depression compare with other measures like the SCID, MINI, or Hamilton?

A: PROMIS depression is a self-report measure of depressive symptoms. It is appropriate to use alone to establish a depression diagnosis as it does not assess all criteria for a depressive disorder. The SCID, MINI, and Hamilton are typically utilized as diagnostic interviews. As such, they focus on the diagnostic criteria for depressive disorders and require trained interviewers. Check the PROMIS list of publications by domain to identify if researchers have compared these measures (<http://www.nihpromis.org/science/PubsDomain/pubsdomain>).

Q: Do you have any sense of the NIH perspective on using PROMIS CAT measures for NIH-sponsored intervention studies?

A: The NIH made a significant investment in PROMIS in an effort to improve measurement utilized in clinical research. A working group within the NIH is actively engaged in in-reach and outreach to educate science officers and researchers about these measurement initiatives. It may be helpful to speak directly with the science officer about acceptability of CAT as an outcome tool in intervention studies.

Q: Are you aware of instruments that measure irritability or agitation related to physical condition? Can these items be used individually with good reliability/validity?

A: The PROMIS Anger item bank has content that capture irritability. Neuro-QOL includes an item bank on emotional dysregulation. Both of these instruments don't make assumptions about the etiology of the symptom (e.g., related to physical condition). You can review the items from either item bank and construct a custom short form from PROMIS or Neuro-QOL items.

Q: Would you share your thoughts on using patient-report versus therapist-report for outcomes in developing payment reform.

A: We are encouraged by the increased interest in utilizing patient-reported instruments in evaluating quality of healthcare. Having the patient's voice included in his/her care is important for many reasons. Of course, therapist or clinician report also remains critical in evaluating health care quality. We feel this is not an "use either/or" decision, but a "use both" decision.

Q: Has instrument ___ been used in population ___?

A: The PROMIS, Neuro-QOL, and NIH Toolbox instruments have been widely adopted in many types of clinical research and clinical practice. A literature search for the domain of interest and population of interest is a good place to start to find out more information about a particular use. Additionally, on the PROMIS website is a list of publications by domain (<http://www.nihpromis.org/science/PubsDomain/pubsdomain>). Neuro-QOL and Toolbox also have lists of publications on their websites.

Q: What is the oldest age range of patients for PROMIS instruments?

A: PROMIS adult instruments were developed with input from older adults. Calibration testing included 20% of the sample over age 75. Validation studies have varied in age range tested, primarily because participants have been specific clinical groups whose age ranges vary.

Q: How do you measure outcomes if PROs are being used as the intervention with the aim of improving patient-centeredness of care?

A: Your measure should quantify the outcome you expect to change from your intervention (e.g., satisfaction with care, levels of symptoms). If you think the level of a symptom (e.g., fatigue) will change, you may want to utilize a different fatigue measure in your intervention than the measure you will use as the primary outcome for comparing intervention versus control groups.

Q: Can I use individual NIH Toolbox domains in isolation?

A: Yes! You are not required to use the entire battery.

Q: You mentioned these instruments are royalty-free. Are there other requirements for using them?

A: We ask that you not alter the items and continue to refer to the instrument as PROMIS, Neuro-QOL, or NIH Toolbox. We ask that if you are interested in translation, you work with our group to ensure you are utilizing our translation methodology.

Q: How do these instruments relate to visual analog scales?

A: Visual analog scales present two issues. First, as shown in Dr. Gershon's presentation, there are psychometric issues with common visual analog items (e.g., rating pain intensity). Second, when one uses a visual analog scale in which a respondent marks on a line which is then measured (e.g., 15 mm), this is more difficult to translate to electronic data collection tools. There are variations in browsers, screen resolution, mouse dexterity, etc that may introduce error when these items are collected across computers and mobile devices. All three measurement initiatives avoid or have minimal use of a visual analog scale.

Q: Should I do a feasibility study to show PROs can be captured in clinical care?

A: This depends upon your aims and study population. We suggest reading Broderick et al from 2013 in eGEMs found at <http://repository.academyhealth.org/egems/vol1/iss1/12/>

Q: Is conditional navigation used in a CAT?

A: No. Computer adaptive tests use underlying psychometric properties of items and responses to calculate an estimated score following each response. Then, the item bank is searched to find the best item remaining whose responses do the best job at distinguishing between scores at that point.

Q: Most CATs have a cross-sectional precision cut-point for between person comparisons. Individual person monitoring over time (within person change) requires more stringent criterion for stopping the assessment. Do you agree?

A: I would ensure that the standard error is sufficiently small to be able to detect individual change.

Data Collection Options

Q: When using Assessment Center, do you think respondents should select their own passwords? Can I use date of birth as the participant's login?

A: Determining if you should allow respondents to select a password, have a researcher set a password, or have Assessment Center automatically generate a password should be based on your study workflow (e.g., are participants recruited in person versus remotely). We strongly discourage utilizing date of birth as the login. This is protected health information. One's login or PIN is used in all data export files to identify that individual. This would mean that you are sharing protected health information unnecessarily with anyone who views the raw dataset. We would instead suggest capturing date of birth, or even better, age, as one of the registration variables.

Q: Can I use these instruments on our institution's technology?

A: Yes! Short forms are easily integrated. Scoring manuals should be utilized to guide how to score. If you want to use CAT instruments, you will need to work with us on enabling access to the CAT administration and scoring algorithm. Send queries to help@assessmentcenter.net. The proctor-administered NIH Toolbox objective tests have unique administration demands and will require more effort than a self-report instrument to enable in your institution's technology.

Q: Should I use REDCap or Epic?

A: There are pros and cons to all data collection systems. We suggest starting with a system that is used and supported at your institution. If you want to combine data from the electronic medical record, you may want to start by investigating Epic. If your institution has a data warehouse that makes data from the electronic medical record available, you could use another data collection system for your research data and merge datasets. REDCap was developed for research and has a lot of desirable research-oriented features. For that reason, it may be more likely to meet your study needs.

Q: Are there live Assessment Center training sessions planned anytime soon?

A: There are no live training sessions scheduled. We suggest you watch the training videos for Assessment Center at <https://www.assessmentcenter.net/Tutorials.aspx>.

Q: Can you touch on the process for extracting data and reporting from PROMIS?

A: Within Assessment Center, data is available in real time through a csv export file. This file type can be opened in Excel or a statistical analysis software package. Only study team members with the rights to export data would be able to extract this file.

Q: Can I view the webinar at a later date?

A: Yes, a recording of the webinar will be available for viewing at a later date on the www.assessmentcenter.net homepage under Presentations.

Q: Where can I get a copy of the slides from today's webinar?

A: This will be posted on the Assessment Center homepage under Presentations.