National Quality Forum
Patient Reported Outcomes Workshop #1
July 30-31

1030 15th Street NW, 9th Floor Conference Center

Audience dial-in: (877) 303-9138; Passcode: 95535825

URL: http://nqf.commpartners.com, Type **408010 i**n the "Enter a Meeting" box
Wifi Network: guest; Password: NQFguest

Final 07/26/12

Meeting Objectives:

1. Identify best practices and lessons learned from initiatives that have implemented individual-level PROs in performance measurement;
2. Discuss the major methodological issues related to the selection, administration and use of individual-level PROs in performance measures;
3. Discuss key considerations for inclusion of PROs into EHRs and policy implications;
4. Identify the characteristics of individual-level PROs suitable for potential use in performance measures; and
5. Identify an initial set of PROs most suitable for development and testing of performance measures.

AGENDA

Day 1

8:30-9:00 Continental Breakfast (provided for Expert Panel/Authors)

9:00-9:30 Welcome & Setting the Stage

Patricia Brennan*, University of Wisconsin-Madison*
& Joyce Dubow*, AARP, Co-chairs*
Helen Burstin*, Senior Vice President, Performance Measures, National Quality Forum*

- Overview of project scope and acknowledgment of sponsor
  - How this project fits into the broader Quality Measurement Enterprise and NQF portfolio of performance metrics
  - Distinctions and connections between PROs and performance measures
- Value of PROs to patients and clinicians
  - Duplicity of uses of PROs: quality improvement and accountability (e.g., public reporting and payment)
- Defining PROs – parameters of what's in and what's out
  - Framing PROs within the NQF endorsed patient-focused episode of care measurement framework including health behaviors
  - End game: Objectives and desired outcomes of today's meeting

Audience engagement and feedback

9:35-10:45 Acknowledging the Patient as an Authoritative Data Source

Moderator: Joyce Dubow
David Cella, *Northwestern University Feinberg School of Medicine, Commissioned Paper Author tees-up key issues for discussion*

Reactor Panel: Stephan Fihn*, Veterans Health Administration;* Jennifer-Eames Huff, *Pacific Business Group on Health;* Charles Mosley, *National Association of State Directors of Developmental Disability Services*

- How do we best build the value proposition for clinicians and policy makers that patient input is credible? (e.g., evidence-base linking PROs to improved outcomes; PROs informing care processes)
- How do we ensure PRO data is useful to patients as well as other end users?
- What are best practices to minimize barriers to individuals being able to self-report outcomes (e.g., age, functional status, cognition, language/culture) and implications on performance measurement?

Audience engagement and feedback

10:45-11:00 **BREAK**

11:00-11:40 Promise of PROs in Improving Patient Outcomes: Lessons from the Field

Moderator: Greg Pawlson, *BlueCross BlueShield Association*

- Partners Healthcare (*Elizabeth Mort, Massachusetts General Hospital*)
- Dartmouth Spine Center (*Eugene Nelson, Dartmouth- Hitchcock Medical Center*)

Audience engagement and feedback

11:45-1:00 Methodological Issues: Method of Administration/Collection & Response
Moderator: Ethan Basch, *Memorial Sloan-Kettering Cancer Center*
David Cella *tees-up key issues for discussion*
Brief demo of CAT (e.g., PROMIS) by David Cella

Reactor Panel: Lewis Kazis, *Boston University School of Public Health*;
Richard Bankowitz, *Premier Healthcare Alliance*;
Lori Frank, *Patient Centered Outcomes Research Institute*

- What is the relationship between static and adaptive approaches to measurement? How do we bridge these approaches (e.g., hybrid approaches)?
- What are the implications of different types of administration (e.g., in-person, mail, web, CAT, IRT, tablet in the waiting room/exam room, provider vs. third party) on response rate, reliability, and validity/bias?
- What are the implications for reliability and validity of using a different method of administration than originally validated, or using multiple methods of administration?
- What are the implications of low response rates and potential bias in responders versus non-responders for usefulness in performance measurement?
- Are responses by proxies allowed, under what circumstances, and what are the implications for reliability and validity of the reported outcome?
- What are the implications of response shift (adaptation) in the measurement of PROs?

Audience engagement and feedback

1:00-1:45 **LUNCH BREAK** (lunch provided for Expert Panel/Authors)

1:50-3:00 Methodological Issues: Selecting Patient-level PROs
Moderator: Albert Wu, *Johns Hopkins Health System*
David Cella *tees-up key issues for discussion*
Reactor Panel: Jim Bellows, *Kaiser Permanente*; Eugene Nelson, *Dartmouth-Hitchcock Medical Center*; Kalahn Taylor-Clark, *National Partnership for Women & Families*; Kenneth Ottenbacher, *The University of Texas Medical Branch at Galveston*

- What characteristics identify PROs that are suitable for potential use in performance measures?
- What is the relevance of PROs used in controlled research conditions to use in real-life clinical practice? (e.g. , large clinical trial versus small clinic setting)
- When can general health status measures be utilized and when should condition-specific measures be utilized? Are there any setting-specific issues for selection of PROs?
- What conditions would be most sensitive to measuring changes in patient health status/outcomes? What is the variation in patient-level scores related to clinical interventions (e.g., hip replacement)?
- What are meaningful (clinically and to the patient), not just statistically significant changes (effect size) in patient-reported outcomes?
- What is the impact of patient baseline characteristics and baseline PRO scores on change in scores?
- Under what circumstances is stabilization (no change) a desired outcome?

Audience engagement and feedback

3:00-3:15 **BREAK**

3:20-4:30 Key Considerations for Incorporating PROs into Electronic Health Records
Moderator: Patricia Brennan
David Cella *tees-up key issues for discussion*
Reactor Panel: Kevin Larsen, *Office of the National Coordinator for Health Information Technology*; Ted Rooney, *Maine Quality Counts;* Uma Kotagal*, Cincinnati Children's Hospital Medical Center*

- How does the use of EHRs enable PROs to be used in performance measurement?
- To what extent should different types of patient-reported information be incorporated into EHRs (e.g., function, health status vs. health behaviors, experience with care)? How will patient privacy be safeguarded?
- How can existing programs/initiatives be leveraged (e.g., meaningful use)?
- What are the essential conditions (e.g., EHR structure, technology, data integration, data standards) to integrate PROs into the electronic health record?

Audience engagement and feedback

4:35-5:00 Closing Comments and Prep for Day 2 Activities
Patricia Brennan & Joyce Dubow, Co-chairs

Day 2

1030 15th Street NW, 9th Floor Conference Center

Audience dial-in: (877) 303-9138; Passcode: 95551282

URL: http://nqf.commpartners.com, Type **837858** in the "Enter a Meeting" box
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8:00-8:30 Continental Breakfast (provided for Expert Panel/Authors)

8:30-9:00 Recap of Key Themes from Day 1
Patricia Brennan*, University of Wisconsin-Madison &* Joyce Dubow*, AARP, Co-chairs*

Audience engagement and feedback

9:05-9:20 Break- out Session: Selecting Individual-level PROs for Performance Measures
Session Overview: Eugene Nelson*, Dartmouth-Hitchcock Medical Center*
& Karen Adams, *Vice President, National Priorities, National Quality Forum*

9:20-9:30 Travel to breakout groups

Logistics:

- *Participants will breakout into workgroups addressing the following 4 categories of PROs:*
  - *HRQoL/Functional Status:* Facilitator: Kathleen Lohr, *Research Triangle Institute*
  - *Health-Related Behaviors:* Facilitator: Eugene Nelson
  - *Symptoms & Symptom Burden:* Facilitator: Debra Saliba, *University of California- Los Angeles Borun Center*
  - *Patient Experience with healthcare:* Facilitator: Robert Weech-Maldonado, *University of Alabama at Birmingham*

- *Participants will be pre-assigned to a group before the meeting based on preference as feasible.*
- *Participants will be charged to apply the emerging characteristics from the meeting discussion (and informed by the background paper) to select PROs in their designated category to determine readiness to consider for performance measurement.*
- *A facilitator from the planning committee will be pre- assigned to each group*
- *The Expert Panel will be dispersed amongst the groups.*

- *NQF staff will be assigned to each break out group to help with transfer and note taking.*
- *Each group will self-identify a spokesperson to report back to the full group & a scribe who will assist the assigned NQF staff with populating the template.*

9:35-11:30 Breakout group work (not available through webinar or conference call)
Based on the background paper & workshop discussion thus far:

- What characteristics should be used to identify PROs for potential use in performance measures? Will these differ based on the needs of the end-user?
- What existing individual-level PROs have these identified characteristics and are candidates for potential development of performance measures?

11:30-12:15 **LUNCH BREAK** (lunch provided for Expert Panel/Authors)

12:20-1:30 Report Back & Iterative Discussion
Characteristics are captured real time by staff and projected on the screen for validation & additional feedback. List of potential PROs is compiled.
David Cella, *Northwestern University Feinberg School of Medicine, Commissioned paper author*

- Discussion of emerging characteristics and list of eligible PROs for potential development of performance measures

1:30-2:00 Recap & Next Steps for 2nd Workshop
Joyce Dubow & Patricia Brennan (virtually), Co-chairs

2:00 Adjourn

Methodological issues in the selection, administration and use of patient-reported outcomes in performance measurement in health care settings

Draft manuscript, July 17, 2012
Prepared for NQF PRO Workshop #1 – July 30-31, 2012

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I. Introduction

The increasing integration of health care delivery systems provides an opportunity to manage the entire patient-focused episode of care[3] and to assess the impact of care on patient outcomes, including patient-reported outcomes. This paper reviews issues to consider when evaluating patient-reported outcomes (PROs)[5] as candidate performance measures in health care settings.

PROs are defined here as "any report of the status of a patient's health condition, health behavior, or experience with health care that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else (See Figure 1)." In other words, PRO tools measure what patients are able to do and how they feel by direct, unfiltered inquiry. The use of PROs is supported by a large literature that provides cogent evidence suggesting that clinical providers are limited in accurately estimating outcomes for patients.[6-10] PRO tools enable assessment of patient–reported health status domains (e.g., health status; physical, mental, and social functioning; health behavior; experience with health care). A wide variety of patient-level instruments to measure PROs have been used for clinical research purposes and to guide clinical care; many have been evaluated and catalogued in the work conducted by the NIH Patient-Reported Outcomes Measurement Information System (PROMIS; www.nihpromis.org) cooperative group. The PROMIS system itself has not yet been used for performance measurement; however, components of it have been used in the past. There are two major challenges to using PROs for purposes of accountability and performance improvement: 1) they have not been widely adopted in clinical use, and are therefore not familiar to many providers and payers; and 2) little is known about the best set of responsive questions to aggregate for the purpose of measuring *performance* of the health care entity.

While there has been great interest in moving toward use of PROs, foundational work needs to be undertaken to address methodological and data challenges. Efforts are currently underway to develop and test mechanisms for collecting patient-reported data, so this is an opportune time to also consider methodological issues, including collection of PRO data in the clinical environment and the aggregation of the data to assess organization/provider-level performance.

The purpose of this white paper is to address the major methodological issues related to the selection, administration and use of PROs for individual patients in clinical practice settings. This will inform the selection of PROs for use in performance measures. This paper will also identify best practices in the context of identifying and using PROs in performance measures. A separate white paper will outline the path to developing reliable and valid performance

measures eligible for NQF endorsement that can be used for accountability and to inform quality improvement.

Figure 1. Definitions and key concepts that are central to the purpose of this paper

Patient-reported outcome (PRO): Any report of the status of a patient's health condition, health behavior, or experience with health care that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.

PRO measure/instrument: A standardized tool to assess health condition (e.g., health status; physical, mental, and social functioning), health behavior, or experience with health care).

Performance measure: Numeric quantification of health care quality for a designated accountable health care entity, such as hospital, health plan, nursing home, clinician, etc.

PRO-based performance measure: A performance measure that is based on patient-reported outcome data aggregated for an accountable health care entity (e.g., percentage of patients in an accountable care organization with an improved depression score as measured by a standardized tool).

e-health[1,2]**:** Health-related Internet applications that deliver a range of content, connectivity and clinical care. Examples include: online formularies, prescription refills, test results, physician-patient communication.

Patient-Centered E-Health (PCEH)[4]**:** Combination of three themes: (1) Patient-focus (developed primarily based on needs and perspectives of patients); (2) Patient-activity (application designs in which patients can participate meaningfully to provide and consume information about, and of interest to, them); and (3) Patient-empowerment (applications assume that patient want to, and are able to, control far-ranging aspects of their health care via a PCEH application).

Patient-Centered Outcomes Research (PCOR): PCOR is the integration of patient perspectives and experiences with clinical and biological data collected from the patient to evaluate the safety and efficacy of an intervention.

Reliability and Validity: A measure may be reliable (always yields the same score for the same state), but it may not be valid, in that it may be consistently measuring the wrong thing (not measuring what it is supposed to measure). Reliability and Validity are not static characteristics. Demonstrating reliability is essentially accumulating evidence about the stability of the measure, whereas demonstrating validity involves accumulating evidence of many different types which indicate the degree to which the measure denotes what it was intended to represent.

II. Types of PROs

PROs can be used to assess a wide variety of health-relevant concepts, including health-related quality of life, functional status, symptoms and symptom burden, health behaviors, and patient satisfaction. These concepts are neither mutually exclusive nor exhaustive. Table 1 summarizes the main characteristics of these types of PROs.

Health-Related Quality of Life

One type of PRO is health-related quality of life (HRQL). HRQL is a multi-dimensional[11] construct encompassing physical, social, and emotional well-being associated with illness and its treatment.[12] Different types of HRQL measures[13,14] are useful for different purposes.[15] There are a number of generic health status measures such as the SF-36 and Sickness Impact Profile.[16-19] This type of HRQL PRO is useful in assessing both individuals with and without a health condition. This allows for comparisons of groups with and without a specific condition as well as identifying population norms. A health utility or preference measure is also not disease-specific. It provides a score ranging from 0 (death) to 1 (perfect health) that represents the patient's value on his or her own health.[20] This score can be used to calculate quality adjusted life years or compared to population norms.

Many PROs are intended for use in populations with chronic illness.[21-23] Recently, the Patient-Reported Outcome Measurement Information System (PROMIS) has developed a number of PROs in physical, mental, and social health for adults and pediatric samples with chronic conditions.[24,25] Neuro-QOL is another measurement effort focused on capturing important areas of functioning and well-being in neurologic diseases.[26] Each of these measurement efforts do not reference a specific disease in the items and allows for comparisons across conditions. Other PROs are targeted to focus on a specific disease (e.g., spinal cord injury) or treatment (e.g., chemotherapy).[27,28] Often these instruments are developed to be able to demonstrate responsiveness to treatment in a clinical trial rather than compare to population norms or other conditions.[29] Disease-specific PROs often provide additional, complementary information about a patient's HRQL when compared with generic instruments.[22,30-32]

Functional Status

Another type of PRO is a functional status measure. Functional status refers to a patient's ability to perform both basic and more advanced (instrumental) activities of daily life.[33] Examples of functional status include physical function, cognitive function and sexual function. As with HRQL instruments, there are a large number of functional status measure that vary widely in quality.[34] Some may address a very specific type of function (e.g., Upper Limb Functional Index), be developed for use in a specific disease population (e.g., multiple sclerosis), or appropriate for use across chronic conditions.[35-41]

Symptoms and Symptom Burden

Symptoms such as fatigue and pain intensity are also best assessed by PRO measures. Symptoms are typically negative and best assessed through patient report.[42] Scales are focused on severity. The impact of symptoms such as the degree to which pain interferes with usual functioning, is also a common focus of PROs. Symptom burden captures the combination of both symptom severity and impact experienced with a specific disease or treatment.[42]

Common symptom and symptom burden measures include the Functional Assessment of Chronic Illness Therapy – Fatigue scale[43-46] and disease-focused symptom indices.[43-46] The PROMIS initiative developed the PROMIS Pain Interference measure that quantifies the impact of pain on functioning.[43-46]

Health behaviors

Another category of PROs assesses health behaviors. While health behaviors may be considered predictors of health outcomes, they are also health outcomes in their own right in the sense that they may be impacted by health care interventions. The information obtained from health behavior PROs serves several important clinical purposes. Health behavior PROs can be used to monitor risk behaviors with potentially deleterious health consequences. This information enables the identification of areas for risk reduction and health promotion intervention. Health behavior PROs can also be used to assess patients' response to health promotion intervention and for monitoring of health behaviors over time.

The increasing recognition of the impact of preventable unhealthy behaviors on the rising incidence of costly chronic health conditions strengthens the rationale for more widespread use of health behavior PROs. Health behavior PROs are increasingly viewed as important metrics of quality improvement and health outcomes in the clinical setting.[47] Moreover, with the introduction of legislation emphasizing the role of electronic health records (EHRs) in the promotion of patient-centered care, health behavior PROs will constitute an important aspect of future stages of "meaningful use" EHRs.[48,49] This increasing emphasis on health behavior PROs reflects initiatives to shift from a "response to disease" model to a "prevention of disease" model.[50]

As the emphasis on the importance of health behaviors has increased, so has the number of available PROs developed to assess health behaviors across multiple domains. Although many of the available health behavior PROs were originally developed for use in research, they are increasingly being implemented in the clinical setting. PROs measuring aspects of substance use constitute one important category of health behavior PRO tools. A number of substance use PROs have been identified as candidates for use in the clinical setting. Several examples include: the health risk survey, an interactive computer-based health risk survey assessing alcohol consumption and smoking;[51] the CAGE-Adapted to Include Drugs (CAGE-AID), a self-reported screening measure of substance use disorder among treatment-seeking adolescents;[52] the Methadone Treatment Index (MTI), a measure of recent substance abuse, social/behavioral functioning and physical and psychological health for use in methadone maintenance clinics;[47] the alcohol use screener;[53] and the tobacco use screener.[54] In addition to substance use PROs, several PROs have been created to assess other types of risky compulsive behaviors. For example, the Compulsive Internet Use Scale (CIUS)[55] and the Compulsive Sexual Behavior Inventory[56] measure problematic internet use and problematic sexual behavior, respectively. A subset of health behavior PROs also assesses health-promoting behaviors. "Starting the conversation," a brief measure of dietary intake,[57] "Exercise as the fifth vital sign," a brief measure of physical activity,[58] School Health Action, Planning and Evaluation System (SHAPES), a school-based self-report physical activity measure,[59] and the Morisky Medication Adherence Scale (8 item)[60] constitute several examples of PROs assessing health-promoting behaviors. Sleep quality has emerged as another clinically-relevant health behavior, with several PROs available, including the PROMIS sleep disturbance short form.[61]

Patient Experience of Care

Patient ratings of health care are an integral component of patient-centered care. In its definition of the essential dimensions of patient-centered care, the Institute of Medicine includes shared decision-making among clinicians, patients and families; self-efficacy and self-management skills for patients; and the patient's experience of care.[62,63] Conceptually, measurement of patient ratings is a complex concept that is related to perceived needs, expectations of care, and experience of care.[64-71] Patient ratings can cover the spectrum of patient engagement, from experience to shared decision-making to self-management to full activation. Recognition of patient preferences can help to tailor treatments based on informed decisions. In fact, improving decision quality is one of the most important things that the nation can do to improve quality and outcomes and value. Thus, patient ratings have policy implications and are also of great importance to patients and their families. Each safe practice in the updated NQF consensus report includes a section titled "Opportunities for Patient and Family Involvement."[72]

There are two major types of patient health care ratings: 1) patient satisfaction, and 2) patient reports of their actual experiences. Patient satisfaction is a multidimensional construct that includes patient concerns about the disease and its treatment, issues of treatment affordability and financial burden for the patient, communication with health care providers, access to services, satisfaction with treatment explanations, and confidence in the physician.[73] [74-79] Shikiar and Rentz[69] proposed a three-level hierarchy of satisfaction: 1) satisfaction with health care delivery, including issues of accessibility, clinician-patient communication, quality of facilities; 2) satisfaction with treatment, including medication and other aspects of treatment, e.g., dietary and exercise recommendations; and 3) satisfaction with the medication itself, rather than the broader treatment. Patient satisfaction has important implications for clinical decision-making and improvement in the delivery of health care services, and is increasingly the focus of research and evaluation of medical treatments, services and interventions.[80] It has been shown to be an important indicator of future adherence to treatment. [68,81-86] Satisfaction has a long history of measurement and there are numerous available instruments.[66,71,87-95]

There is a newer focus on measuring patient reports of their actual experiences with health care services.[96] Reports about care are often regarded as more specific, actionable, understandable, and objective than general ratings alone.[97,98] The Consumer Assessment of Healthcare Providers and Systems (CAHPS) program is a multi-year initiative of the Agency for Healthcare Research and Quality (AHRQ) to support and promote the assessment of consumers' experiences with health care (www.cahps.ahrq.gov/About-CAHPS/CAHPS-Program.aspx) The goals of the CAHPS program are: 1) to develop standardized patient questionnaires that can be used to compare results across sponsors and over time, and 2) to generate tools and resources that sponsors can use to produce understandable and usable comparative information for both consumers and health care providers. The CAHPS project has become a leading mechanism for the measurement of patient perspectives on health care access and quality.[96]

Table 1. Main Characteristics of PROs

PRO Category	Main Characteristics	Strengths	Limitations
HRQL	• Multi-dimensional • Can be generic or disease-specific	• Global summary of well-being	• May not be considered a sufficiently specific construct
Functional Status	• Ability to perform specific activities	• Provide patient-reported data that can be used in addition to performance-based measures of function	• Self-reported capability and actual performance of activities may vary
Symptoms and Symptom Burden	• Specific to type of symptom of interest • Capable of measuring symptoms not otherwise captured by medical work-up	• Best assessed through self-report	• May fail to capture general, global aspects of well-being considered important to patients
Health Behaviors	• Specific to type of behavior • Typically measures frequency of behavior • Available for health risk behaviors as well as health promoting behaviors	• Targeted	• Validity may be impacted by social desirability • Potential patient discomfort in reporting socially undesirable behaviors
Patient Experience	• Satisfaction with health care delivery, treatment recommendations, and medications • Actual experiences with health care services	• Essential component of patient-centered care • Valued by patients, families and policymakers • Related to treatment adherence	• Complex, multidimensional construct • Confidentiality required to ensure patient comfort in disclosing negative experiences

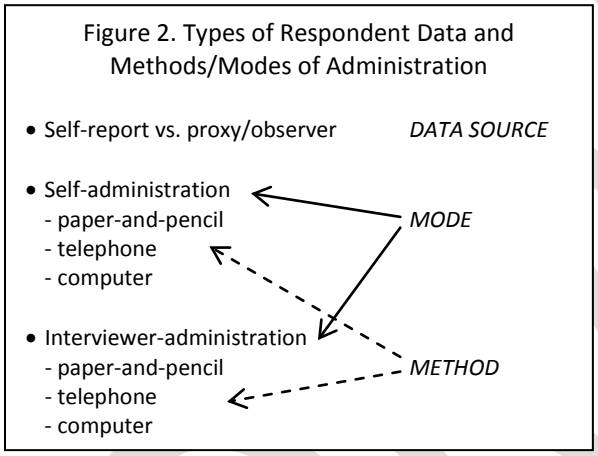
III. Method and mode of administration, data collection and analysis issues

In order to accommodate the needs of patients with diverse linguistic, cultural, educational and functional skills, clinicians and researchers require some flexibility in choosing appropriate methods and modes of questionnaire administration for PROs.[99] There are many issues involved in scoring and analysis of PRO response data. We first describe these methodological issues (see summary in Table 2) and then discuss barriers.

Methodological issues

Administration of PRO instruments requires decisions about three aspects of data collection: the source of the information, the recorder of the information (mode), and the method used to capture the information (see Figure 2). Each of these is described below. These three aspects can also be combined in various ways, e.g., a patient might use the telephone to self-administer a PRO instrument, or an interviewer might use a computer to read questions and record answers.

Figure 2. Types of Respondent Data and Methods/Modes of Administration



Source: Self versus Proxy

The patient's perspective is the focal point of PRO assessment. There are circumstances in which it may be difficult or impossible to directly obtain this perspective. In adults, cognitive and communications deficits and burden of disease, for example, can limit potential subjects' ability to complete PRO questionnaires.[100] This is especially likely to occur with the elderly, with people who suffer from neurological disorders and those with severe disease. Children's participation can be limited by these same factors plus issues specific to age and developmental level.[100-102] Yet, failing to include these populations can result in potentially misleading interpretations of results.

One way to ensure inclusion of the greatest number of patients is to use proxy respondents to obtain PRO information in conjunction with patient reports. Using either significant others (e.g., parents, spouses or other family members, friends) or formal caregivers (physicians, nurses, teachers) as proxies can provide many potential benefits. They not only allow inclusion of a broader and more representative range of patients, they can also help minimize missing data and increase the feasibility of longitudinal assessment. However, the usefulness of proxy

responses as substitutes for patient responses depends on the validity and reliability of proxy responses compared to patient responses. When evaluating the quality of proxy responses, proxy responses are usually compared to patient responses. This is a reasonable approach, when proxy responses are being used to replace patient responses. Agreement between proxies and patient pairs is typically assessed at the subscale level via the Intraclass Correlation Coefficient (ICC) or at the item level by the kappa statistic, although other types of analyses have been advocated.[103] Patient and proxy responses are also often compared at the group level by comparing mean scores. Group comparisons help detect the magnitude and direction of any systematic bias that might be present.

Both the adult and pediatric literature suggests that there is greater agreement between proxy and patient ratings when rating observable functioning or HRQL dimensions such as physical and instrumental activities of daily living, physical health and motor function and less for more subjective dimensions such as social functioning, pain, cognitive status/function and psychological or and emotional well-being.[102,104-108] Using continuous rather than dichotomous ratings improves agreement.[109] Extent of disagreement increases with increasing age of adolescents,[110] and as the severity of patient illness, cognitive impairment or disability increases[111-114] Type of proxy (e.g., parent versus caregiver), and proxy characteristics such as age, education, and level of stress may also affect agreement.[115,116] In terms of direction of disagreement, proxies for adults tend to rate them as having more symptoms, functional difficulties, emotional distress and negative quality of life with the exception of pain; where proxies tend to under-report.[104] There is no consistent pattern of disagreement for child versus proxy reported outcomes.[117] Even when there is disagreement for children or adults, differences tend to be small.[117,118]

Proxy assessment may substitute for patient assessment where needed, but may also complement it. Proxies can be asked to assess the patient as they think the patient would respond (i.e. proxy-patient perspective) or for the proxy to provide their own perspective on the patient's functioning or HRQL. This type of rating may be better described as either external- or other-ratings[119] for the sake of clarity. It is important that the measure makes clear which perspective is desired.[117] The external or other perspective may provide particularly relevant information when the person is unable to self-assess, but can be important even when they can. In such cases, patient-other agreement may not be necessarily desirable. This point can be illustrated in Alzheimer's disease when patients in the earlier stages of dementia fail to recognize the extent of their impaired well-being and physical role functioning compared to family members around them. In such cases, next-of-kin caregivers such as a spouse could provide a different ("external") assessment that indicates the patient has a lot of problems getting the groceries from A to B, or a lot of problems with being comfortable in a social setting, thereby introducing clinically important information.

Mode: Self-administration versus Interviewer-administration

Self-administration of PRO questionnaires is neither expensive nor influenced by interviewer effects, and therefore has traditionally been preferred. However, self-administration is not feasible for some patient populations, such as those who may be too ill to self-administer a questionnaire. In these cases, interviewer-administration is often required. Until recently, interviewer-administration was also required for those with low literacy; however, new multimedia methods are now available to overcome this issue (see below).

Advantages and disadvantages of different modes of administration were summarized by

Fowler[120] and Naughton[121] (see Table 2). Self-administered instruments are more cost-effective from a staffing perspective, and may yield more participant disclosure, especially when collecting sensitive information.[122] Disadvantages include the potential for more missing data, and the inability to clarify any misunderstandings. Interviewer-administered instruments allow for probes and clarification, and permit more complexity in survey design (e.g., the use of skip patterns). This mode is also useful for respondents with reading, writing or vision difficulties, and for culturally diverse populations. Disadvantages include the costs required to hire, train and supervise interviewers, and the potential pressure on respondents to answer quickly, without letting them proceed at their own pace. There is also a potential for interviewer bias, resulting in systematic differences from interviewer to interviewer, or, occasionally, systematic errors on the part of many or even all interviewers.[123] Other sources of bias for both administration modes include social desirability (the tendency to give a favorable picture of oneself) and acquiescent response sets (the tendency to agree/disagree with statements regardless of their content).[124,125]

There has been some concern about the potential biasing effects of mode of administration on data quality and interpretation.[126] Overall, there is evidence of high reliability for instruments administered with different modes, but response effects have varied and have not been consistently in the same direction.[121-124] For example, some studies found evidence of more favorable reports of well-being on self-administered questionnaires,[127] while others found the opposite effect.[128-130] Still other studies reported mixed results[131] or found no important differences due to mode of administration, after adjusting for other factors.[120,132,133] Fortunately, many types of error and bias can be overcome by appropriate selection and training of interviewers. Effects of different modes can also be evaluated with various psychometric and statistical techniques and models to determine the potential impact of response effects.[134-138]

Method of Administration

Advances in technology have changed the face of PRO assessment, increasing the number of administration options available. Multiple methods of self-report administration currently exist, and the different methods may have different effects on the quality of the data.[126] While the different administration methods provide more options for researchers and clinicians, the different methods of administration require different skills and resources of the participant and consequently may result in differing levels of participant burden.[126] A number of factors may account for differences in data quality across methods of administration, including the impersonality of the method, cognitive burden on the participant, ability to establish the legitimacy of the study, control over the questionnaires, and communication style.[126] Thus, these factors must be considered when deciding upon the appropriate method of administration for a given PRO.

Historically, paper-and-pencil administration served as the primary method of PRO assessment. As such, many PROs were originally developed with the intention of paper-based administration, but may be amenable to an electronic-based administration.[139] Paper-and-pencil remains a widely used PRO administration method, with its primary advantage being cost-effectiveness. However, the paper-and-pencil method is not without its disadvantages. For example, it typically requires that a participant's responses be manually entered into a database for scoring purposes, raising the possibility of data entry errors that threaten the integrity of the results. Similarly, the need for manual data entry and scoring can also be time-intensive. This may limit the acceptability of paper-and-pencil administration for purposes in which timely scoring and interpretation is of importance. Finally, paper-based PROs are less likely to provide

structured data in EHRs, limiting their usefulness in tracking patient progress over time or influencing change in care plans and, consequently, health outcomes.

Advances in technology and the increasingly widespread availability of electronic resources have provided a number of alternatives to the paper-and-pencil administration method. Advances in telephone technology have enabled the use of interactive voice response (IVR) to administer PROs. IVR involves a computer audio recording of PRO questions administered via telephone to which participants indicate their response by selecting the appropriate key.[126,139] In addition, a number of computer-based administration methods have emerged as feasible alternatives to paper-and-pencil, such as web-based platforms, touchscreen computers, and multimedia platforms that can accommodate people with a range of literacy and computer skills (e.g., Talking Touchscreen/Pantalla Parlanchina, audiovisual computer-assisted self-interviewing[126,139-141]). Newer mobile forms of technology such as tablet computers and smartphones also offer promise as newer generation methods of PRO administration. The electronic administration methods have a number of advantages that contribute to their increasingly widespread adoption. For example, because the participant enters the data themselves, there is minimal chance for data entry errors. These electronic methods also typically allow for immediate scoring and feedback, which lends well to purposes requiring timely results. Furthermore, electronic PRO administration is interactive and has been demonstrated to be practical, acceptable, and cost-effective.[51] Electronic methods may also provide participants with increased comfort when responding to questions about socially undesirable behaviors.[142] However, these advantages must be considered in light of several important disadvantages. First, while electronic PRO administration methods may be cost effective, the cost of purchasing technology-based platforms may exceed that of traditional paper-and-pencil methods. Additionally, some participants may experience discomfort with technology or lack the skills necessary to navigate electronic administration methods. Moreover, reliance upon methods such as web-based platforms or smartphones raises questions about participants' access to these technologies, if they are not provided to them as part of the study.

The availability of multiple methods of PRO administration highlights the importance of measurement equivalence across methods.[139] Measurement equivalence is determined by comparing the psychometric properties of the data obtained via paper-based administration and electronic-based administration.[139] It can be assessed via cognitive testing, usability testing, equivalence testing, or psychometric testing.[139] A growing body of research findings support the equivalence of electronic and paper-and-pencil administration of PROs.[143-145] These findings support the viability of electronic PRO administration as an alternative to paper-and-pencil methods.

In addition to measurement equivalence, patient privacy is another concern that cuts across both paper-and-pencil and electronic administration methods, albeit in differing ways. In the case of paper-based PROs, the physical transfer of the PRO measure from patient to provider, as well as the physical existence of the PRO confers threat to the privacy of patients' responses. Privacy also emerges as a concern with electronic-based methods, given the potential security concerns related to transfer of data or unauthorized access to patient-reported data. This underscores the need for reliable and secure electronic platforms in order to protect patients' privacy in the context of PRO assessment.

PROs in the Clinical Setting

The collection of PRO data as part of clinical care has become more common. Advocates for the use of PROs in clinical care propose that the results assist clinical providers management of patients' care,[146] enhance the efficiency of clinical practice,[145,147] improve patient-provider communication,[145,147-149] identify patient needs in a timely manner,[145,150] and facilitate patient-centered care.[145] However, as PROs are used more in clinical practice, a number of methodological issues pertaining to the settings in which they are administered merit consideration.

A growing number of studies have investigated the use of PROs in the clinic setting.[145,147,149-154] When selecting PROs for administration in the clinic setting, it is important to consider the efficiency of the PRO administration, scoring, and interpretation, given the time-sensitive nature of the clinic flow.[145,151] In addition, the acceptability of the PRO measures and data collection process for both patients and clinic staff is essential.[145,151,155] Historically, several barriers have impeded the widespread implementation of PRO data collection in clinics, many of which are inherent to the drawbacks associated with paper-and-pencil administration of PROs. One such barrier involves concerns about the potential disruption to clinic flow if patients are asked to complete PROs.[146] Conversely, concerns arise regarding the impact of clinic flow on the integrity of data collection, given the potential for patients to be interrupted while completing PROs, which could potentially result in missing data.[146] Another potential barrier involves the possibility that patients may experience anxiety in completing PRO measures in clinic prior to their appointments.[146] Similarly, the lack of privacy when completing PROs in-clinic poses another methodological barrier. Finally, in-clinic collection of PRO data may be impeded by staff burden and clinician disengagement.[146] Fortunately, technology advances, and the increased opportunities for methods of PRO administration that they afford, may help to overcome some barriers to in-clinic PRO data collection.[151] For example, findings support the feasibility of using tablet computers[145,150] and touchscreen computers for in-clinic PRO data collection.[140,141,149,151,152] The use of computers to administer PROs in-clinic may streamline and expedite the process, as well as minimize staff burden and impact on clinic flow.

Given some of the barriers to PRO data collection in-clinic, completion of PRO measures from home prior to or in between medical appointments has been proposed as one strategy to overcoming barriers to collecting PRO data in-clinic.[146,156,157] Both web-based PRO administration and interactive voice response constitute possible methods for at-home PRO data collection.[151,161,162] While the home may serve as a feasible alternative to the clinic for a number of reasons, there are several factors to consider when implementing home-based PRO data collection completed prior to clinic visit.[146,156] First, in order for patients to be able to complete PRO measures at home, they must have access to the type of technology by which the PRO is administered (e.g., internet). Second, the type of PRO data collected from home must be useful in informing clinical care. Third, the completion of PRO measures at home must be acceptable for patients. Finally, there must be a plan in place to address the reporting of critical or acute problems via home-based PROs. This may pose a logistical challenge in comparison to PROs completed in-clinic, where medical providers and access to intervention is readily available. Several additional barriers to home-based collection of PRO data exist. For example, health information privacy is paramount, and therefore one barrier to home-based PROs is availability of secure data collection platforms.[146 158] As noted, patient safety poses another potential barrier to collection of PRO data at home, given the challenges to addressing critical patient-reported health issues. An additional barrier involves clinician acceptability of home-based PRO data collection, given that questions arise regarding clinician reimbursement for clinician time using a website to address patient-reported outcomes, as opposed to meeting directly with patients to discuss the findings from PROs.[146,158]

Implementation of PRO data collection in other settings, such as rehabilitation or skilled nursing facilities, may also yield valuable clinical information and guide interventions. Less research has addressed the methodological issues involved in administering PROs in these settings. However, handheld technology has been proposed as a means to facilitate collection of PRO data in home health care and the rehabilitation setting following orthopedic surgery.[159] Given the varying level of patients' acuity status in these types of settings, potential factors to consider may include patients' cognitive capacity to complete PRO measures, and whether the use of proxy reports may be beneficial.

Scoring: Classical Test Theory versus Modern Test Theory

PROs are "latent (not directly observable) variables." The only way to estimate a person's level on a particular attribute is by asking questions that are representative of that attribute. Most PRO instruments are comprised of multiple items that are aggregated in some way to produce an overall score that best represents the latent attribute. Scoring is based on classical test theory (raw scores) or modern test theory (item response theory; IRT).[160-169] Multiple items are preferred because a response to a single item provides only limited information to distinguish between individuals.[170] In addition, measurement error (the difference between the "true" score and the "observed" score) tends to "average out" when responses to individual items are summed to obtain a total score.[170-172]

Classical test theory (CTT) estimates the level of an attribute as the sum, perhaps weighted, of responses to individual items, i.e., as a linear combination.[170,173-177] This approach requires all of the items on a particular PRO instrument to be used in every situation in order for it to be considered valid, i.e., the instrument is "test-dependent"[174,177-179] Item response theory (ITT) enables "test-free" measurement, i.e. the latent trait can be estimated using different items as long as their locations (difficulty levels) have been calibrated on the same scale as the patients' ability levels.[170,176-180] [170,181,182] IRT allows computer-adaptive testing (CAT), where questions are tailored to the individual patient. This has two advantages: 1) questionnaires can be shorter, and 2) the scale scores can be estimated more precisely for any given test length. This also means that patients do not need to complete the same set of items in every situation.[176]

There are some challenges to be overcome in order to use IRT. It can be difficult to understand the assumptions and the psychometric jargon, e.g., calibration, difficulty levels. The methodology and software are complex. IRT is also not appropriate for causal variables and complex latent traits.[176-178,183] Overall, though, IRT offers a very convenient and efficient framework for PRO measurement.

Linking/Cross-talk Between Different Measures of the Same Construct

A common problem when using an array of health-related outcomes for diverse patient populations and subgroups is establishing the comparability of scales or units on which the outcomes are reported.[184,185] The emphasis has typically been focused on the metric over the measure. "Equating" is a technique that involves the process of converting the system of units of one measure to that of another. This process of deriving equivalent scores has been used successfully in educational testing to compare test scores obtained from parallel or alternate forms that measure the same characteristic with or without having common anchor items. Theoretically (and in practice when certain conditions are met) different age-specific measures could be linked, thus placing child, adult, and geriatric estimates on a common metric. The many items that constitute a disease-specific (e.g., cancer) quality of life scale could be incorporated into a single shared bank and linked through a common-anchor design.[184] The

methods of establishing comparable scores (often called “linking”) vary substantially depending on the definition of comparability, and therefore, standardization is critical in facilitating comparing PROs across studies. Two measures may be considered linked if they produce scores that match the first two moments (i.e., mean and SD) of their distributions for a specific group of examinees or two randomly equivalent groups. Another definition may involve matching scores with equal percentile ranks based on a single sample of examinees or random samples drawn from the same population.

Table 2. Main characteristics of key PRO methodological issues

Methodological Issue	**Main Characteristics**	**Strengths**	**Limitations**
Source of report			
Self	• Person responds about him/herself	• Expert on own experience	• Not always possible to assess directly e.g., because of cognitive or communication deficits or age/developmental level
Proxy	• Person responds about someone else	• Useful when target of assessment unable to respond • Can provide complementary information	• May not accurately represent subjective or other experiences
Mode of administration			
Self	• Person self-administers PRO and records the responses	• Cost-effective • May yield more participant disclosure • Proceed at one’s own pace	• Potential for missing data • Simple survey design (e.g., minimal skip patterns)
Interviewer	• Interviewer reads questions out loud and records the responses	• More complex survey design (e.g., skip patterns) • Useful for respondents with reading, writing or vision difficulties	• Interviewer costs • Potential for bias (interviewer bias, social desirability bias, acquiescent response sets)

Methodological Issue	Main Characteristics	Strengths	Limitations
Method of administration			
Paper-and-pencil	• Patients self-administer PRO using a paper and writing utensil	• Cost-effective	• Prone to data entry errors • Data entry, scoring requires more time • Less amenable to incorporation within EHR
Electronic	• Patient self-administers PRO using computer- or telephone-based platform	• Interactive • Practical • Increased comfort for socially undesirable behaviors • Minimizes data entry errors • Immediate scoring, feedback • Amenable to incorporation within EHR	• Cost • Potential discomfort with technology • Accessibility • Measurement equivalence
Setting of administration			
Clinic	• Patients complete PROs when they arrive to clinic appointments	• Real-time assessment of outcomes • Feasibility with use of electronic methods of administration	• Impact on clinic flow • Interruptions resulting in missing data • Patient anxiety • Staff burden
Home	• Patients complete PROs at home prior to, or in between clinic visits	• Minimizes impact on clinic flow • Minimizes staff burden	• Accessibility • Health information privacy • Data security • Patient safety
Other	• Patients complete PROs at other types of settings (e.g., skilled nursing, rehabilitation)	• Feasibility with electronic methods of administration	• Cognitive capacity and potential need for proxy

Methodological Issue	Main Characteristics	Strengths	Limitations
Scoring			
Classical test theory	• Raw scores	• Easy to implement and understand	• All items must be administered
Modern test theory	• Probabilistic approach	• Enables CAT (tailored questions) • Shorter questionnaires with more precision	• Difficult to implement and understand

Addressing Barriers to PRO Measurement

Several barriers to PRO measurement exist, including administering PROs in vulnerable populations, literacy, language and cultural differences, differences in functional abilities, response shift, use of different methods and modes of administration, and the impact of non-responders. These will each be reviewed below, along with best practices and recommendations for addressing these barriers.

Vulnerable Populations

There is growing recognition that some population subgroups are particularly vulnerable to receiving suboptimal health care and achieving poorer health outcomes compared with the general population. [186-188] Vulnerability is multifaceted and may be because of financial circumstances or place of residence; health, functional, or developmental status; ability to communicate effectively; or age, race, ethnicity, or gender.[186] This definition encompasses populations who are vulnerable because of a chronic or terminal illness or disability and those with literacy or language difficulties.[140,187] It also includes people residing in areas with health professional shortages.[168]

Administration of PRO questionnaires is usually performed with paper-and-pencil instruments, and multilingual versions of questionnaires are often not available. Interviewer administration is labor intensive and cost prohibitive in most health care settings. Therefore, patients with low literacy, those with certain functional limitations, or those who do not speak English are typically excluded, either explicitly or implicitly, from any outcome evaluation in a clinical practice setting in which patient-reported data are collected on forms.

As PROs continue to play a greater role in medical decision making and evaluation of the quality of health care, sensitive and efficient methods of measuring those outcomes among underserved populations must be developed and validated. Minority status, language preference, and literacy level may be critical variables in differentiating those who receive and respond well to treatment from those who do not. These patients may experience different health outcomes because of disparities in care or barriers to care. Outcome measurement in these patients may provide new insight into disease or treatment problems that may have gone

undetected simply because many studies have not been able to accommodate the special needs of such patients.[187,189]

Literacy

Low literacy is a widespread but neglected problem in the U.S. The 1992 National Adult Literacy Survey (NALS)[190] and the 2003 National Assessment of Adult Literacy (NAAL)[191] measured three kinds of English language literacy tasks that adults encounter in daily life (prose literacy, document literacy, quantitative literacy). Almost half of the adult population experiences difficulty in using reading, speaking, writing, and computational skills in everyday life situations. An additional seven million adults in the U.S. population were estimated to be non-literate in English. "Health literacy," the constellation of skills required to function in the health care environment, may be significantly worse than functional literacy because of the unfamiliar context and vocabulary of the health care system.[192]

Contributing to poor understanding of the importance of literacy skills is the fact that low literacy is often underreported. The NALS reported that 66% to 75% of adults in the lowest reading level and 93% to 97% in the second-lowest reading level described themselves as being able to read or write English "well" or "very well."[190] In addition, many low literate individuals are ashamed of their reading difficulties and try to hide the problem, even from their family.[193,194] Lack of recognition and denial of reading problems creates a barrier to health care. Because they are ashamed of their reading difficulties, low literacy patients have acknowledged avoidance of medical care.[193,194] And because there are generally only moderate reading demands in everyday life, individuals may not be aware of their reading problems until a literacy-challenging event (e.g., reviewing treatment options, reading a consent document, completing health assessment forms).[193,194]

A reader's comprehension of text is dependent on the purpose for reading, the ability of the reader, and the text that is being read. Two important factors in the readability of text are word frequency (semantic difficulty) and sentence length (syntactic complexity).[195] Unfamiliar words are difficult when first encountered. Long sentences are likely to contain more clauses, which communicates more information and more ideas. Longer sentences may also require the reader to retain more information in short-term memory.[196-199]

Addressing health literacy is now recognized as critical to delivering person-centered health care.[200] It is an important component of providing quality health care to diverse populations, and will be incorporated into the National Standards for Culturally and Linguistically Appropriate Services.[201] Health literacy practices are also included in the National Quality Forum updated set of safe practices.[72] A recent discussion paper summarized 10 attributes that exemplify a "health literate health care organization."[200] These attributes cover practical strategies across all aspects of health care, from leadership planning and evaluation, to workforce training, to clear communication practices for patients.

Language and Culture

The availability of multiple language versions of PRO questionnaires has enabled them to be routinely measured in diverse research and practice settings. It is often desirable to perform analyses on data that have been pooled across all patients. Yet concern is often voiced regarding combining data from different cultures or languages.[5] In some research and practice-based initiatives, there is interest in evaluating cross-cultural differences in PROs. In all of these

applications, it is important to use unbiased questionnaires that can detect important differences between patients.[187,202,203]

Possible cultural differences in interpreting questions and in response styles may limit data pooling or may limit comparisons between members of different cultural groups.[204-206] Similarly, poor quality translations could result in non-comparable language versions of PRO questionnaires.[205,207 205,208] The extent to which items in a questionnaire perform similarly across different groups (e.g., the extent to which they are cross-culturally or cross-linguistically equivalent) is of critical interest when determining whether the questionnaire can be used as an unbiased measure of a PRO.[209-220 203] Without assurances that the PRO questionnaire is culturally and linguistically "fair," detected treatment differences caused by items that function differently across groups could incorrectly be interpreted to reflect real treatment differences. Similarly, true treatment differences may be masked by differences in questionnaire performance, especially if there is imbalance of language or cultural groups across treatment arms. These possible unwanted effects of cultural or linguistic differences on PRO measurement and outcomes are therefore important at the most basic level.

Functional Abilities

Ideally, PRO instruments that are intended to be used in performance measures are capable of being completed by all patients in the target population. Otherwise, if a significant proportion of the population is excluded, the sample may be unrepresentative and the validity of the performance measure can be compromised. Functional limitations associated with disability are one type of potential barrier to PRO assessment that could affect PRO use in performance measures. The prevalence of disability, defined as specific functional or sensory limitations, is estimated as 47.5 million Americans, or 22% of the U.S. population.[221] People with disability are more likely to develop health conditions and be consumers of health care. Thus, they are an important group to include when evaluating health care but one that is frequently excluded in health research.[222,223]

Common disabilities that can affect PRO assessment include vision (e.g., decreased visual acuity, color-blindness), hearing, motor (e.g. upper extremity limitations) and cognitive deficits (e.g., impaired comprehension, reading). Fortunately, many of these barriers can be addressed by choice of method and mode of data collection, by enabling the use of Assistive Devices/Technology, and by using principles of universal design when developing instruments [201-202]. Universal Design refers to designing products and environments in such a way as to be usable by all people, to the greatest extent possible, without adaptation or specialization.[224,225] A well-known example of universal design is the use of curb cuts. Initially intended to facilitate the use of wheelchairs, they have also benefited bicycle riders and children in strollers, amongst others. An exhaustive examination of how the principles of universal design can be applied to PRO assessment is beyond the scope of this paper, and those developing or modifying measures according to the principles of universal design are encouraged to consult with relevant experts. Also ,if developing an information-technology based instrument, using the standards included in Section 508 of the Rehabilitation Act Amendments of 1998 can maximize flexibility.[226] While we cannot list all potential ways to address functional limitations, in the next paragraph we identify some common ways to do so. Harniss and colleagues provide a description on how PROMIS is taking a systematic approach to enhancing accessibility.[227]

In general, it is important to provide multiple means of understanding and responding to measures including visual, voiced and tactile. The specific means may differ depending on the method and mode of administration. Thus, for people with impaired vision one might consider

using in-person or telephone interviews (advantages and disadvantages discussed in an earlier section), an Integrated Voice Response system, Braille responses for Braille users, or touchscreen with tactile or audio cues. Information technology-based systems should enable assistive devices such as screen readers and screen-enlargement software. For the hearing impaired, options include providing visual presentation of words or images, use of TTY or a Video Relay Service, and allowing the user to adjust the sound level. For those with motor limitations, response modes that are easier to manipulate (track ball) or non-motoric (e.g. using voice recognition software) can be helpful. For those with certain types of cognitive deficits (e.g., limited reading comprehension) the methods to address literacy described earlier should be considered. However, if cognitive deficits are severe it may be more appropriate to use a proxy respondent.

Concerns have been raised that allowing for multiple response modes or methods may lead to measurement error. In a later section, we discuss the potential impact of different methods and modes on response rate, reliability and validity. The risk of introducing measurement error seems outweighed by the risk of excluding a significant segment of the population.

Response Shift, Adaptation, and Other Challenges to Detecting True Change

The ability to detect true change over time in PROs poses another barrier to the integrity of PRO assessment. Often, the ability to detect true change is attributable to the phenomenon of response shift, which has been defined as, "A change in the meaning of one's self-evaluation of a target construct as a result of (a) a change in the respondent's internal standards of measurement (i.e., scale recalibration); (b) a change in the respondent's values (i.e., the importance of component domains constituting the target construct); or (c) a redefinition of the target construct (i.e., reconceptualization)."[228] A change in perspective over time may result in participants attending to PROs in a systematically different way from one time point to another.[229]

Response shift serves as a barrier to PRO assessment for several important reasons. For example, it threatens longitudinal PRO assessment validity, reliability, and responsiveness.[229-232] Response shift can complicate the interpretation of PRO outcomes, since a change in PRO outcome may occur due to a response shift, an effect of treatment, or both.[233]

Monitoring for response shift can aid in interpretation of longitudinal PRO data.[231] A number of strategies have been proposed to identify response shift, although each has limitations. The "then test" compares an actual pre-test rating and a retrospective pre-test rating to assess for shift, but is less robust than other methods of detecting response shift,[229] and is confounded with recall bias.[232] Structural equation modeling (SEM) has also been proposed as a method to identify response shift; however, it is sensitive only if most of the sample is likely to make response shifts.[234] Finally, growth modeling represents another potential strategy for identifying response shift. Growth modeling creates a predictive growth curve model to investigate patterns in discrepancies between expected and observed scores, thus assessing response shift at the individual level.[235] Although growth modeling enables detection of both the timing and shape of response shift,[231] it cannot differentiate between random error and response shift.[232]

Implications of the Different Methods and Modes on Response Rate, Reliability and Validity

Decisions About the Choice of Data Collection Methods

Decisions must be made related to the data collection method and the implications of those decisions on costs and errors in surveys.[122] Two basic issues underlie these decisions: (1) "What is the most appropriate method to choose for a particular question?" and (2) "What is the impact of a particular method on survey errors and costs?" Different methods differ along a variety of dimensions,[122] including the degree of interviewer involvement, the level of interaction with the respondent, the channels of communication used (sight, sound, touch; various combinations may yield different issues of comprehension, memory stimulation, social influence affecting judgment, and response hurdles), and the degree of technology use.

Implications of Using a Different Method/Mode than Originally Validated

It is also necessary to consider the implications of using a different method or mode than with which the PRO was originally validated. Many existing PROs were initially validated in paper-and-pencil form. However, potential differences exist between paper-and-pencil and electronic-based PRO administration,[143] ranging from differences in how items/responses presented (e.g., items presented one at a time, size of text) to differences in participant comfort level in responding (e.g., ability to interact with electronic –based platform).[143] As noted earlier, a growing body of research suggests measurement equivalence between paper- and computer-administered PROs.[143,236] However, the effect of a particular data collection method on a particular source of error may depend on the specific combination of methods used.[122] Thus, as new methods are developed, studies comparing them to the methods they may replace must be done. Theory is important to inform our expectations about the likely effect of a particular approach. Theory is informed by past mode-effects literature as well as by an understanding of the features or elements of a particular design.[122] Similarly, mode choices involve trade-offs and compromises. As such, the choice of a particular approach must be made within the context of the particular objectives of the survey and the resources available.[122]

Implications of Using Multiple Methods/Modes

The implications of using multiple methods and modes also warrant consideration. There are a number of reasons why one might choose to blend methods, such as cost reduction, faster data collection, and optimization of response rates.[122] When combining methods/modes, it is critical to ensure that any effects of the method/mode can be disentangled from other sample characteristics. This is especially true when respondents choose which method/mode they prefer, or when access issues determine the choice of method/mode.[122] As in the case of using a different method/mode than originally validated, instruments and procedures should be designed to ensure equivalence across methods/modes.[237]

Impact of Non-responders

Difficulties with data collection and compliance are major barriers to the successful implementation of PRO assessment. The principal problem is that bias may be introduced through data that are missing.[176] The choice of mode and method of questionnaire administration can affect nonresponse rates and nonresponse bias.[122] In addition, retrospective collection of PRO data is rarely possible, and often the timing of the assessment is important, e.g., prior to or just after surgery.

Missing data may be classified as either item non-response (one or more missing items within a questionnaire), or unit non-response (the whole questionnaire is missing for a patient). It is important to evaluate the amount, reasons and patterns of missing data.[238-241] Some common strategies to evaluate non-response bias are listed here:

- Conduct an abbreviated follow-up survey with initial non-respondents[122]
- Compare characteristics of respondents and non-respondents[242,243]
- Compare respondent data with comparable information from other sources[244]
- Compare early vs. late respondents[245]

When dealing with missing data, there are various statistical methods of adjustment. For item non-response in multi-item scales, several techniques are useful and tend to yield unbiased estimates of scores, e.g., simple mean imputation, regression imputation, and IRT models. For both item and unit non-response it is important to determine whether missing data are considered to be missing completely at random (MCAR), missing at random (MAR) or missing not at random (MNAR).[238,239] For unit non-response, there is a range of statistical techniques that could be implemented, depending on the reason for missing data.[246-250]

IV. Selection of patient-level PRO measures

Patient-Centered Outcomes Research

An essential aspect of patient-centered outcomes research (PCOR) is the integration of patient perspectives and experiences with clinical and biological data collected from the patient to evaluate the safety and efficacy of an intervention. Such integration recognizes that while traditional clinical endpoints such as laboratory values or survival are still very important, we also need to look at how patients' health-related quality of life (HRQL) is affected by the disease and treatment. For such HRQL endpoints, in most cases, the patient is the best source for reporting what they are experiencing. The challenge is how to best capture patient data in a way that maximizes our ability to inform decision making in the research, healthcare delivery, and policy settings.

Access to psychometrically sound and decision-relevant PRO will allow investigators to collect the empirical evidence on the differential benefits of a study intervention.[251-254] These data can then be disseminated to patients, providers and policy makers to provide a richer perspective on the impact of interventions on patients' lives using endpoints that are meaningful to the patients.[255] Increasingly, longitudinal observational and experimental studies have included PRO measures. In order to optimize decision making in clinical care, these PROs must be measured in a standardized way using questionnaires that demonstrate specific measurement properties.[251,254,256-259] Our group recently identified minimum standards for the design or selection of a PRO for use in patient-centered outcomes research.[260] Central to this work was an understanding of the critical attributes for which a PRO is judged to be appropriate or inappropriate for such purposes. We identified these standards through two complementary approaches. The first was an extensive review of the literature including both published and unpublished guidance documents. The second was to assemble a group of international experts in PRO and patient-centered outcomes research to seek consensus on the minimum standards.[260]

Common Themes and Lessons Learned

There exist many documents summarizing attributes of a good HRQL measure, including guidance documents from the FDA; [261-264] the 2002 Medical Outcomes Trust guidelines on attributes of a good HRQL measure;[265] the extensive, international expert-driven recommendations from COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments);[257,266-270] the European Organization for Research and Treatment of Cancer (EORTC) guidelines for developing questionnaires; [271] the Functional Assessment of

Chronic Illness Therapy (FACIT) approach;[28] the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) task force recommendation documents;[139,213,272,273] and several others.[217,256,274-276] There is also a standards documents just released by the NIH Patient-Reported Outcomes Measurement Information System® (PROMIS®) network, which we considered useful for informing the minimal and optimal standards for designing PRO measures. In addition, the ISOQOL recently completed two guidance documents on use of PROs in comparative effectiveness research and on integrating PROs in healthcare delivery settings that were relevant for this landscape review.

The selection of PROs for use in performance measurement raises the question of what are the key differences, if any, when selecting PROs for research purposes as opposed to performance measurement. Generally speaking, the factors to consider when selecting PROs for research versus performance measurement are more similar than different. One key difference to consider involves the length of the PRO. Although longer PROs with more items may be better tolerated in the context of research, the feasibility and acceptability of using PROs for performance measurement demands shorter instrument length to facilitate widespread adoption. The need for shortened PRO measure length for use in performance measurement may compromise other important measurement characteristics, such as measurement precision. Another key difference in factors to consider when selecting PROs for performance measurement versus research is the implication or consequence of the PRO data. Specifically, the use of PROs for performance measurement carries the expectation that there will be consequences in terms of public reporting and accountability for the clinical providers or clinical setting. Therefore, the stakes of PROs are higher in the performance measurement context, but there may be constraints to the quality of the measurement level due to factors unique to performance measurement, such as length. This highlights the importance of emphasizing responsiveness/sensitivity to change when considering PROs for use in performance measurement.

In selecting a PRO for performance measurement purposes, a logical first step involves a review of what measures have been used successfully previously. While the use of PROs in performance measurement remains an under-studied area, several examples of PROs used as indexes of performance measurement provide an initial foundation upon which the field can expand. This is most clearly illustrated by the Veterans Health Study, which was developed to assess patient-reported outcomes within the VA system.[277] In response to the Veterans Health Administration's incorporation of patient-reported functional status as a domain of interest in their performance measurement system, the Veterans RAND 36 Item Health Survey (VR-36) and the Veterans Rand 12 Item Health Survey (VR-12) have been administered within the VA system to evaluate veterans' needs as well as to assess outcomes of clinical care at the hospital, regional, and healthcare system levels.[277,278] These methods have also been applied for performance measurement in the Medicare Advantage Program[279] and the VR-12 has also been designated as the principal outcomes of the Medicare Health Outcomes Survey (HOS).[280]

While the research examining the VR-36 and SF-36 in patient-reported performance measures informs the selection of PROs for performance measurement, there are limitations to the use of these measures as indexes of performance and accountability. These limitations include their "static" nature which requires all items to be administered in order to receive a score, even if some items add little to the precision of measurement. In addition, content is fixed by the composition of the scale. As such, attention has turned to alternative PROs with the potential for use as patient-reported performance measures. The PROMIS measurement system constitutes one example of a future direction of PROs acceptable for use in performance measurement. Developed using IRT methodology, PROMIS offers a new generation of PRO

measures with improved reliability, validity, precision, and shortened length.[167] PROMIS PRO measures form a hybrid between static generic PROs and more flexible adaptive measures that are comprised of items specific to measure content, but applicable across the diverse spectrum of health status. Although a growing body of literature provides preliminary evidence supporting the psychometric adequacy of the PROMIS measures, future work is needed to explore the application of PROMIS measures as performance measure PROs. Nevertheless, the PROMIS system provides a model by which the use of PROs as performance measures can be expanded and elaborated upon, owing to its rigorous methodological characteristics.

(Please see Table 3 for characteristics and best practices to evaluate and select PROs for use in performance measurement.)

Documentation, in peer-reviewed literature and/or on publically accessible websites, of the evidence of a PRO to reflect these measurement properties will result in greater acceptance of the PRO for use as performance measures. To the extent the evidence was obtained from populations similar to the studies' target population, the more confidence the investigator will have in the PRO to capture patient's experiences and perspectives.

There are a number of considerations when applying any set of selection standards for PROs. The populations participating in research will likely be quite heterogeneous. This population heterogeneity should be reflected in the samples that participate in the evaluation of the measurement properties for the PRO. For example, both qualitative and quantitative studies may require quota sampling based on race/ethnicity that reflects the prevalence of the condition in the study target population.

Literacy demand is also an important consideration for use of PROs. Data collected from PRO measures is only valid if the participants in a study can understand what is asked of them and can provide a response that accurately reflects their experiences or perspectives. It is critical that developers of PRO measures be attentive to make sure the questions and response options are clear and easy to understand. Pre-testing of the instrument (e.g., cognitive testing) should include individuals with low literacy to evaluate the questions.[281]

Response burden must be considered when selecting a PRO measure and using it in a PCOR study. The instrument must not be overly burdensome for patients as they are often sick and cannot be subjected to long questionnaires or be asked repeatedly to provide repeated, longitudinal data that may significantly disrupt their lives.

Finally, researchers much carefully consider the strength of evidence for the measurement properties. There is no threshold for which an instrument is valid or not valid for any or all populations or applications. In addition, there can be no single study that confirms all the measurement properties for all contexts. Like any scientific discipline, measurement science relies on an iterative, accumulating body of evidence examining key properties in different contexts. Thus, it is the weight of the evidence that informs the evaluation of the appropriateness of a PRO. Older PROs will have the benefit of having more evidence than more recent PROs; yet the newer PROs tend to have improved basic measurement properties that warrant attention.

PRO Characteristics for Consideration

Global versus Condition-specific Measures

One of the primary factors to consider when selecting a patient-level PRO measure is whether to use a global versus a condition-specific PRO. Several elements inform the selection of global versus condition-specific measures.[282] The specific population of interest may guide whether one opts to use a global or condition specific PRO. For example, if the target population is largely comprised of healthy individuals, a global measure may be the preferred choice; conversely, if the goal is to examine a specific subset of patients with a particular health concern, then a condition-specific measure may be more appropriate. Similarly, the outcomes of interest may guide the selection process given that global measures may capture a different category of outcomes when compared to a condition-specific PRO. Additionally, the assessment purpose will likely influence the selection of global versus specific measures. An excellent example of this stems from guidance from the Food and Drug Administration guidance stating that pharmaceutical company claims of improved QOL must be specific to the QOL domain that was measured, with the recommended that the assessment of specific symptoms is an appropriate starting point for improved measurement of QOL domains.[283]

Global PRO measures have several important advantages. They allow for comparability across patients/populations,[282] although they are more suitable for comparison across groups than for individual clinical use.[284] Global PROs also allow for normative data which can be used to interpret scores.[282] This enables comparison to population norms or directly with other disease conditions. They can also be applied to individuals without specific health conditions, and can differentiate groups on indexes of overall health/well-being.[282] In spite of these advantages, global PROs also have several disadvantages. They have tended to be less sensitive to change and therefore may underestimate health changes in specific patient populations.[285] Additionally, they may fail to capture important condition-specific concerns[285] when applied in specific disease populations.

Condition-specific PROs serve as an alternative to global PROs. One advantage of condition-specific PROs is greater sensitivity to change, because they focus on the concerns pertinent to the given condition.[282] They also enable differentiation of groups at level of specific symptoms/concerns.[282] However, given their condition-specific focus, one notable limitation is the difficulty in making comparisons across patient/disease populations.[282]

Given their respective unique benefits and limitations, the use of a combination of global and condition-specific measures is recommended. Global and condition-specific PRO measures may measure different aspects of QOL when administered in combination,[286] resulting in more comprehensive assessment. Consequently, hybrid measurement systems have emerged to facilitate the combination of global and condition-specific PROs. For example, the FACIT system consists of a generic HRQL measure plus condition-specific subscales. The PROMIS measurement system, which was developed to create item banks that are appropriate for use across common chronic disease conditions,[287] represents another example of a hybrid system of PROs that combine both global and targeted approaches.

Measurement Precision

Another factor to consider when selecting a patient-level PRO measure is measurement precision. Measurement precision refers to the level of variation in multiple measurements of the same factor, such that measures with greater precision have less variation across measurement time points. PROs with greater measurement precision also demonstrate greater sensitivity to change.[288] Given that most PROs were originally developed as research outcome measures, they may lack the level of precision necessary for assessment of individuals.[289] Although

performance measures will aggregate to provider or organization, adequate measurement precision at the patient-level is still needed.

When considering measurement precision in the selection of PROs, measures based on IRT tend to have greater precision than measures based on classical test theory.[289] Specifically, computerized adaptive tests (CATs) offer greater precision than static short-forms derived from item banks; however, short forms are acceptable alternative when CAT is not feasible.[290,291] Although CATs include a greater number of items in an item bank, they allow tailored measurement, resulting in shorter instrument length and improved precision. Consequently, the use of PROs derived from IRT methodology is recommended in order to achieve the greatest measurement precision.

Sensitivity to Change/Responsiveness

Sensitivity to change constitutes another important factor to consider when selecting a PRO measure because the ability to detect a small, but important change is necessary when monitoring patients and implementing clinical interventions.[30] Sensitivity to change is a component of construct validity characterized by within subject changes over time on the PRO following an intervention.[292,293] There is great variation in how responsiveness is conceptualized, resulting in different findings and interpretations.[294] Definitions of sensitivity to change range from the ability to detect any kind of change, regardless of meaningfulness (e.g., a statistically significant change post-treatment), to the ability to detect a clinically important change. In order to be clinically useful, PROs must demonstrate sensitivity to change when individuals improve as well as when they deteriorate.[293]

Just as great variation exists in how responsiveness is defined, there is also great variation in the methods for assessing responsiveness. These methods primarily differ in terms of whether they are intended to demonstrate statistically significant changes versus quantify the magnitude of change.[294] The lack of equivalence across methods for detecting change can be problematic for interpretation, given that the different methods for detecting responsiveness produce different classifications of who is improved or not.[295] However, solely relying on statistical tests of responsiveness is not recommended, given that it may not accurately reflect what is meaningful to patient or clinician.[296]

There are a number of factors which may limit a PRO measure's sensitivity to change. First, the use of multi-trait scales containing items that are not relevant to the population being assessed may fail to capture change over time.[297] The responsiveness of a PRO measure may also be constrained by the use of scales that offer categorical or a limited range of response options.[297] PRO measures that utilize an extensive timeframe for reporting also will not be likely to demonstrate change if administered regularly over a brief period of time.[297] The responsiveness of a PRO measure is also limited by the inclusion of items that reflect stable characteristics which are unlikely to change as well as scales that contain items with floor or ceiling effects.[297] It is also important to note that a PRO measure's sensitivity to change may depend upon the direction of the change. For example, Eurich and colleagues found that PROs were more responsive to change when there was clinical improvement, relative to deterioration.[30]

In addition to those factors, a growing body of research suggests that condition-specific PROs are more sensitive to change than generic PROs.[30,32,298-300] This reflects the fact that responsiveness to change is likely impacted by the purpose for which the measure was originally developed.[300] For example, measures developed to emphasize specific content areas

would be expected to show greater change secondary to treatment in those content areas.[293] Thus, the greater sensitivity to change in condition-specific PROs is likely due to the strong content validity inherent in disease-specific measures. [30] As a result, the use of a combination of disease-specific and generic PRO measures may yield the most meaningful data.[30,32]

Minimally Important Differences and Changes

The difference between clinical versus statistical significance also merits consideration when selecting a PRO measure. Historically, research has relied upon tests of statistical significance to examine differences in PRO scores between patients or within patients over time. However, concerns arise regarding whether statistically significant differences truly reflect differences that would be perceived as important to the patient or the clinician. Consequently, attention has shifted to the concept of clinically significant differences in PRO scores. A variety of approaches to determining clinical significance have been proposed. For example, clinically significant change has been defined as "changes in patient functioning that are meaningful for individuals who undergo psychosocial or medical interventions."[301] Similarly, meaningful change is defined as ""one that results in a meaningful reduction in symptoms or improvement in function…" [from the patient perspective].[302] Minimally important differences (MIDs) represent a specific approach to clinical significance, and are defined as "…the smallest difference in score in the outcome of interest that informed patients or informed proxies perceive as important."[303] Finally, minimum clinically important differences (MCIDs) comprise an even more specific category of MID and are defined as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management."[304]

The examination of clinically significant differences carries a number of important implications.[303] First, investigating clinically significant (versus statistically significant) differences in scores aids in the interpretation of PROs. Second, the focus on clinically significant differences also emphasizes the importance of the patient perspective, which may not be adequately captured when strictly looking at statistically significant differences. Third, the ability to look at clinically significant differences in PRO scores informs the evaluation of the success of a clinical intervention. Finally, in the context of clinical research, clinically significant differences can assist with sample size estimation.

Currently, no methodological "gold standard" exists for estimating MIDs;[302,305] however, two primary methods are currently in-use: the anchor-based method and the distribution-based method. The anchor-based method of establishing MIDs assesses the relationship between scores on the PRO and some independent measure which is interpretable.[303] Several options exist for the type of anchor selected when using the anchor-based method. First, clinical anchors which are correlated with the PRO measure at the $r \geq 0.30$ level may serve as appropriate anchors. [276,306] Clinical trial experience can be used to inform the selection of these clinical anchors,[307] which also enables the use of multiple clinical anchors.[308] Transition ratings represent another potential source of anchors when establishing MIDs. Transition ratings are within-person global ratings of change made by a patient.[306,309] However, due to concerns about validity, it is recommended that researchers examine the correlation between pre-and post-test PRO scores and the transition rating.[310] Between-person differences made by patients can also be used as anchors when establishing MIDs for PRO measures.[314,317] Additional sources for anchors when establishing MIDs include HRQL-related functional measures used by clinicians [306,309] and objective standards (e.g., hospital admissions, time away from work.[310] Although the anchor-based method offers promise for establishing MIDs in PRO measures, several limitations should be considered. First, the transition rating approach to anchor selection is

subject to recall bias on the part of the patient. [302] Second, global ratings may only account for some variance in PRO scores.[302] Third, the anchor based method does not take into consideration measurement precision of instrument.[302]

The distribution-based method represents the second method of establishing MIDs in PRO measures. The distribution-based method uses the statistical characteristics of the PRO scores when establishing MIDs.[303] Specifically, the distribution-based approach evaluates change in scores in relation to the probability that the change occurred at random.[302] As in the case of the anchor-based method, there are several methods available when applying a distribution-based approach to MID establishment. First, the t-test statistic has been used to establish MID when examining change over time.[302] However, given that this relies solely on statistical significance, it may not reflect change that is clinically meaningful and it is also subject to variation due to sample size.[302] Distribution-based methods may also be grounded in measurement precision and the standard error of mean (SEM). [302] Specifically, it has been suggested that the 1 SEM criterion can be used as an alternative to MID when assessing the magnitude of PRO score changes.[311] Sample variation, such as effect size and standardized response mean, constitutes another method for establishing MIDs using the distribution-based method.[302] When using this method, it is recommended that the effect size by specific to the population being studied.[309] Evidence suggests that MID estimates using sample variation are approximately half of a standard deviation.[312] Finally, reliable change constitutes another method of using the distribution-based approach to establishing MIDs.[302] Reliable change is based on the standard error of measurement difference (SEMD) and indicates how much the observed change exceeds fluctuations in an imprecise measure that are random in nature.[302] While the distribution-based approach serves as a possible alternative to the anchor-based methods, there is little consensus on the benchmarks for establishing changes that are clinically significant.[302]

Given limitations of the anchor- and distribution-based approaches, it is recommended that multiple methods and triangulation should be used to determine the MID.[276,302,312] Moreover, the final selection of MID values should be based on systematic review and an evaluation process such as the Delphi method.[276] When considering MIDs for PRO measures, a single MID should not be applied to situation involving that particular PRO, given that MID varies by population/context.[276] Consequently, it is recommended that the distribution around the MID be provided rather than just a single MID value.[308] Finally, because the criteria for assessing clinically important change in individuals do not directly translate to evaluating clinically important group differences,[306] a useful strategy is to calculate the proportion of patients who experience a clinically significant change.[252,306]

Essential Conditions to Integrate PROs into the Electronic Health Record

Health information technology (HIT) has the potential to enable dramatic transformation in health care delivery, but the empirical research evidence base supporting its benefits is limited.[313]

E-health refers to health-related Internet applications that deliver a range of content, connectivity and clinical care.[1] This includes health information, online formularies, prescription refills, appointment scheduling, test results, advance care planning and health care proxy designation, and physician-patient communication.[314] Patient-Centered E-Health (PCEH) is an emerging discipline that is defined as the combination of three themes:[4]

- Patient-focus: PCEH applications are developed primarily based on needs and perspectives of patients.

- Patient-activity: PCEH application designs assume that patients can participate meaningfully in providing and consuming information about, and of interest to, them,
- Patient-empowerment: PCEH applications assume that patients want to, and are able to, control far-ranging aspects of their health care via a PCEH application.

Although e-health applications have become common, they tend to focus on the needs of health care providers and organizations. Patients desire a range of services to be brought online by their own health care provider.[315] However, there is little evidence about whether the services offered by providers are services that patients desire.[2] It is important that providers attend to patient acceptability factors.[2,316]

Measurement of PROs will constitute an important aspect of future stages of "meaningful use" of electronic health records (EHRs).[48,49] There is the potential for enhanced access by allowing entry directly from commonly used devices such as smart phones. Enabling clinical decision support by providing structured data directly into EHRs will permit PROs to (a) be used for tracking patient progress over time, or (b) use individual question responses to drive change in care plans or care processes concurrently thus improving outcomes over time. The use of a standardized instrument registered in an established code system (e.g., LOINC) enables EHRs to incorporate the instrument as an observation with a known set of responses using standard terminology (SNOMED-CT) or numerical responses. Each question in the standardized instrument can also be coded (structured) to drive changes based on those responses.

Unfortunately, in an updated systematic review of health information technology studies published during 2004-2007, PROs were not mentioned at all.[314]

The passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act creates a mix of incentives and penalties that will induce a large proportion of physicians and hospitals to move toward EHR systems by the end of this decade.[317] The discussion should now focus on whether HIT will support the models of care delivery that will help achieve broader policy goals: safer, more effective, and more efficient care.

Three features of EHRs are critical to enable accountable care organizations to succeed: interoperability and widespread health information exchange; automated, real-time quality and cost measurement; and smarter analytic capacities. Having a complete picture of the patient's care is a critical start, yet most EHRs are not interoperable and have limited data-sharing capabilities.[318] In summary, important issues include: a) the patient perspective (patients want to be involved "as a participant and partner in the flow of information" relating to their own health care[319]); b) clinical buy-in; c) compatibility with clinical flow; and d) meaningful use.

Examples. Health care centers are beginning to implement ways to use patient-reported information ("the voice of the patient") to provide higher quality care.[320] Three recent case studies (two in the U.S. and one in Sweden) are particularly informative to illustrate "lessons learned" about such initiatives.[320] The Dartmouth Spine Center collects health survey data from patients before each visit, either at home or in the clinic. The data are summarized in a report and are available for use by the patients and clinicians to develop or modify the care plan, and to monitor results over time to guide treatment decisions. Longitudinal changes are incorporated into the report with each new assessment. The Karolinska University hospital (Stockholm, Sweden) developed a Swedish Rheumatology Quality registry in 1995 to improve the quality and value of care for people suffering from arthritis and other rheumatic diseases. Paper forms have now been replaced with a web-based system that makes use of real-time data provided by patients, clinicians and diagnostic tests. Longitudinal summaries of PRO measures and other

health information are incorporated into graphical reports that are available to patients and providers. An electronic Health Risk Assessment has been integrated with an electronic health record at Group Health Cooperative in the State of Washington. Patients can complete PRO measures, make appointments, fill prescriptions, review health benefits, communicate with their providers, and get vetted health information. Customized reports are available to patients and providers.

Both patients and clinicians have generally favorable reactions to the patient-reported measurement systems implemented in these three very different health care settings. The information gathered helps to support patient-centered care by focusing attention on the health issues and outcomes that are important to patients. Although both patients and clinicians acknowledge that using PROs takes extra time for data collection, both groups report that it makes the care more effective and efficient. Key design principles to successful use of patient-reported measurement systems include fitting PRO measures into the flow of care, designing the systems with stakeholder engagement, merging PRO data with other types of data (clinician reports, medical records, claims), and engaging in continuous improvement of the systems based on users' experiences and new technology.

Other examples can be found in the use of PROs in the management of advanced cancer where the primary goals of care are to maximize symptom management and minimize treatment toxicity. Clinicians and patients often base treatment decisions on informal assessments of health-related quality of life (HRQL). Integrating formal HRQL assessment into treatment decision-making has the potential to improve patient-centered care for advanced cancer patients. Computer-based PRO assessment can reduce patient and administrative burden while enabling real-time scoring and presentation of HRQL data. Two pilot studies conducted with advanced lung cancer patients reported that the computer technology was acceptable and feasible for patients and physicians.[151,321] Patients felt that the HRQL questionnaire helped them focus on issues to discuss with their physicians, and physicians indicated that the HRQL report helped them to evaluate patient responses over time.

A new initiative in the Robert H. Lurie Comprehensive Cancer Center involves the development and implementation of patient-reported symptom assessment in Gynecologic Oncology clinics. Prior to clinic visits, outpatients complete instruments measuring fatigue, pain, physical function, depression and anxiety through the electronic health record (EHR) patient communication portal at home or in-clinic using an iPad. Results immediately populate the EHR. Severe symptoms trigger EHR notifications to providers. The EHR provides automated triage for psychosocial and nutritional care when indicated.

Selection of PROs that Meet the Recommended Characteristics for use in Performance Measures

A number of characteristics have been recommended when evaluating the appropriateness of a PRO for use in performance measures, as indicated in Table 3. Given that PROs are not yet in widespread use in clinical practice, little is known about how best to aggregate these patient-level outcomes for the purpose of measuring performance of the health care entity. In spite of this, in order to accommodate the needs of patients with diverse linguistic, cultural, educational and functional skills, evidence is needed regarding the equivalence of multiple methods and modes of questionnaire administration. Additionally, scoring, analysis and reporting of PRO response data needs to be user-friendly and understandable to clinicians for use in real-time in clinical settings. Moreover, the timing of measurement must include pre-intervention in order to allow for measurement of responsiveness to change, to allow for risk

adjustment, and to facilitate candidate screening for clinical intervention. In order to illustrate the application of these recommended characteristics when evaluating the appropriateness of a PRO for use as a performance measure, we provide the following example related to the evaluation of a PRO for use as a performance measure when evaluating the success of total hip arthroplasty.

Example of Applying Recommended Characteristics to Evaluate a Hip Osteoarthritis PRO for use in Performance Measurement

Total hip arthroplasty has emerged as an acceptable surgical treatment for individuals experiencing intractable pain and remarkable functional impairments for whom conservative treatment has yielded minimal improvement.[322,323 324,325] The most common indication for total hip arthroplasty is joint deterioration secondary to osteoarthritis.[326] Consequently, the aging of the population is likely to result in an increased demand for both primary, as well as revision total hip arthroplasty procedures.[327-329] Patient-reported outcomes have increasingly been included alongside more traditional indices of surgical outcome such as morbidity and mortality when evaluating the success of total hip arthroplasty as an intervention. With the increasing focus on patient-reported outcomes, such as functioning and quality of life, a widespread array of PROs have been developed and applied to the measurement of total hip arthroplasty outcomes.[326] Consequently, total hip arthroplasty provides a relevant context in which to review the use of recommended characteristics in the selection of PRO measures. Table 3 illustrates the application of important characteristics and best practices to evaluate and select a PRO for use as a performance measure for hip replacement outcomes. In this example, we illustrate the process of examining the characteristics of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a PRO measure developed to examine pain, stiffness, and physical function in individuals with osteoarthritis.[330]

Conclusion

Patient Reported Outcome (PRO) measures have reached a level of sophistication to enable their use in performance measures in the clinical setting. Attention to the many methodological considerations discussed in this paper will help produce meaningful, actionable results. Judicious use of a mixture of generic and disease-specific assessment, along with modern measurement methods such as item response theory, and the application of technology to enable standardized, equitable assessment across a range of patients, such as that applied in the development and validation of the PROMIS instruments, can effectively shorten assessment time without compromising accuracy, meeting the demands of clinical application of PROs for performance measurement.

Table 3[1]. Important characteristics and best practices to evaluate and select PROs for use in performance measures[260,265]

	Characteristic	Specific issues to address for performance measures	Example: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[330] for use in hip arthroplasty
1.	**Conceptual and Measurement Model**		
	A PRO measure should have documentation defining and describing the concept(s) included and the intended population(s) for use.	Target PRO concept should be a high priority for the health care system.	Factorial validity of the physical function and pain subscales has been inadequate.[331]
	There should be documentation of how the concept(s) are organized into a measurement model, including evidence for the dimensionality of the measure, how items relate to each measured concept, and the relationship among concepts.		
2.	**Reliability**		
	The degree to which an instrument is free from random error.		
2a.	***Internal consistency*** *(multi-item scales)*	▪ reliability estimate ≥ 0.70 for group-level purposes ▪ reliability estimate ≥ 0.90 for individual-level purposes	Cronbach alphas for the three subscales range from 0.86 to 0.98.[332-334]
2b.	***Reproducibility*** *(stability over time)* ▪ type of test-retest estimate depends on the response scale (dichotomous, nominal ordinal, interval, ratio)		Test-retest reliability has been adequate for the pain and physical function subscales, but less adequate for the stiffness subscale.[334]
3.	**Validity**		
	The degree to which the instrument reflects what it is supposed to measure.	There are a limited number of PRO instruments that have been validated for performance measurement.	
3a.	***Content Validity***		
	The extent to which a measure samples a representative range of the content.		
	A PRO measure should have evidence supporting its content validity, including evidence that patients and/or experts consider the content of the PRO measure relevant and comprehensive for the concept, population, and aim of the measurement application.		Development involved expert clinician input, and survey input from patients,[335] as well as a review of existing measures.

[1] This table is adapted from recommendations contained within a report from the Scientific Advisory Committee of the Medical Outcomes Trust and a report submitted to the PCORI Methodology Committee. The recommendations from these sources have been adapted to enhance relevance to PRO selection for performance measurement.

	Characteristic	Specific issues to address for performance measures	Example: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[330] for use in hip arthroplasty
	Documentation of qualitative and/or quantitative methods used to solicit and confirm attributes (i.e., concepts measured by the items) of the PRO relevant to the measurement application.		
	Documentation of the characteristics of participants included in the evaluation (e.g., race/ethnicity, culture, age, socio-economic status, literacy).		
	Documentation of sources from which items were derived, modified, and prioritized during the PRO measure development process.		
	Justification for the recall period for the measurement application.		
3b.	***Construct and Criterion-related Validity***		
	A PRO measure should have evidence supporting its construct validity, including: • documentation of empirical findings that support predefined hypotheses on the expected associations among measures similar or dissimilar to the measured PRO • documentation of empirical findings that support predefined hypotheses of the expected differences in scores between "known" groups		Patient ratings of satisfaction with arthroplasty were correlated with WOMAC scores in the expected direction.[22,336,337]
	A PRO measure should have evidence that shows the extent to which scores of the instrument are related to a criterion measure.		
3c.	***Responsiveness***		
	A PRO measure for use in longitudinal initiatives should have evidence of responsiveness, including empirical evidence of changes in scores consistent with predefined hypotheses regarding changes in the target population.	If a PRO measure has cross-sectional data that provides sufficient evidence in regard to the reliability (internal consistency), content validity, and construct validity but has no data yet on responsiveness over time (i.e., ability of a PRO measure to detect changes in the construct being measured over time), would you accept use of the PRO measure to provide valid data over time in a longitudinal study if no other PRO measure was available?	Demonstrates adequate responsiveness and ability to detect change in response to clinical intervention.[338]
		Important to emphasize responsiveness because there is an expectation of consequences. Need to be able to demonstrate responsiveness if action is to be taken.	
4.	**Interpretability of Scores**		

	Characteristic	Specific issues to address for performance measures	Example: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[330] for use in hip arthroplasty
	A PRO measure should have documentation to support interpretation of scores, including: • what low and high scores represent for the measured concept • representative mean(s) and standard deviation(s) in the reference population • guidance on the minimally important difference in scores between groups and/or over time that can be considered meaningful from the patient and/or clinical perspective	▪ If different PROs are used, it is important to establish a link or cross-walk between them. ▪ Because the criteria for assessing clinically important change in individuals does not directly translate to evaluating clinically important group differences, [306] a useful strategy is to calculate the proportion of patients who experience a clinically significant change[252,306]	Availability of population-based, age- and gender-normative values[339] Availability of minimal clinically important improvement values[340] Can be translated into a utility score for use in economic and accountability evaluations[341]
5.	**Burden**		
	The time, effort, and other demands on the respondent and the administrator.	In a busy clinic setting, PRO assessment should be as brief as possible, and reporting should be done in real-time.	Short form available[342] Average time to complete mobile phone WOMAC = 4.8 minutes[343]
6.	**Alternatives modes and methods of administration**	The use of multiple modes and methods can be useful for diverse populations. However, there should be evidence regarding their equivalence.	Validated mobile phone and touchscreen based platforms[344,345]
7.	**Cultural and language adaptations**	The mode, method and question wording must yield equivalent estimates of PRO measures.	Available in over 65 languages[346]
8.	**Electronic health records (EHR)**	Critical features: ▪ interoperability ▪ automated, real-time measurement and reporting ▪ sophisticated analytic capacities	Electronic data capture may allow for integration within EHR[343]

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Patient-Reported Outcomes

Workshop

July 30-31, 2012

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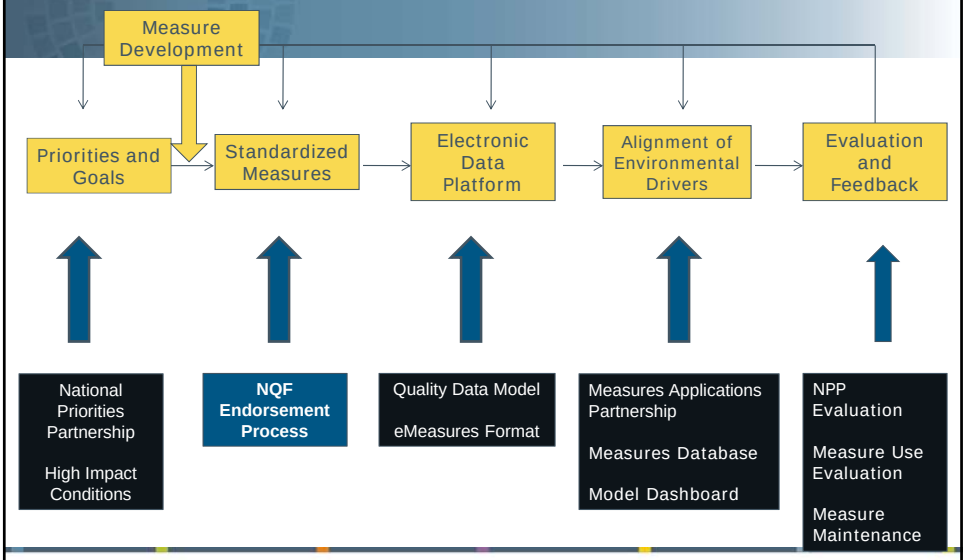
Project Scope and Activities

- Focused on methodological issues, not endorsement
- Under the guidance of an expert panel 2 workshops are planned to bring together the stakeholders necessary to facilitate the groundwork for the development, testing, endorsement, and implementation of PRO-based performance measures.
- Two commissioned papers will help inform next steps regarding: 1) selection of patient-level PROs for use in performance measures, and 2) the path to developing reliable and valid PRO-based performance measures eligible for NQF endorsement that can be used for accountability and to inform quality improvement
- Funded by HHS

Timeline

Call for nominations closed		4/2/12
Hold workshop #1		7/30-31/12
Expert Panel to discuss revision of first commissioned paper		8/21/12
Receive final version of first commissioned paper and prepare draft report of findings/recommendations		8/31/12
Hold workshop #2		9/11-12/12
Expert Panel review 2nd paper revisions & draft report for comment		10/11/12
Public/member comment period	open 10/23	11/21/12
Expert Panel to review comments received		12/3/12
CSAC and NQF Board review and approval		12/20/12

Quality Measurement Enterprise



Performance Measurement in Evolution

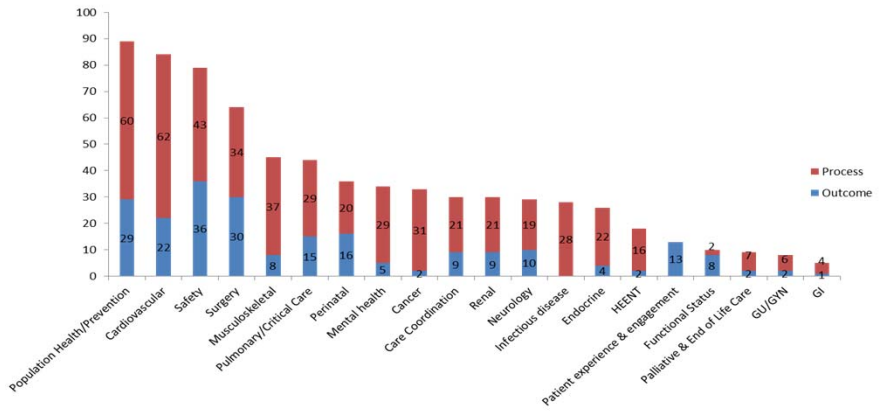
- Drive toward higher performance
- Measure disparities in all we do
- Shift toward composite measures
- Harmonize measures across sites and providers
- Measurement across longitudinal patient-focused episodes
  - Outcome measures (including PROs)
  - Process measures with direct evidence of impact on desired outcomes
  - Appropriateness measures
  - Cost/resource use measures coupled with quality measures, including overuse

Evidence for the Measure Focus

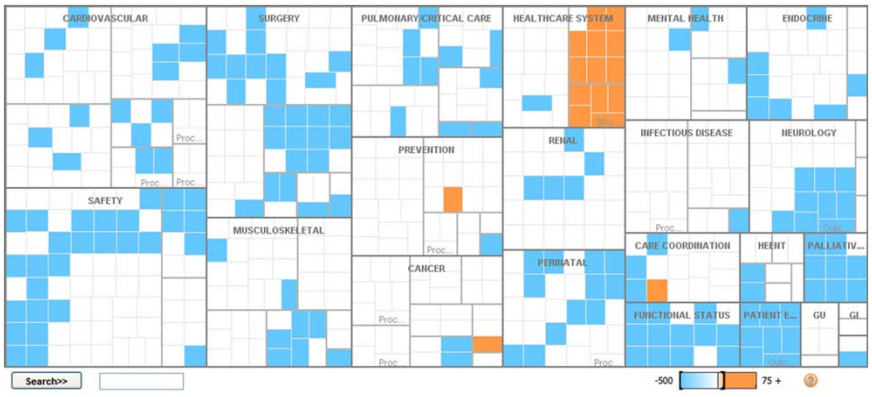
- Hierarchical preference for
  - Outcomes linked to evidence-based processes/structures
  - Outcomes of substantial importance with plausible process/structure relationships
  - Intermediate outcomes
  - Processes/structures

Most closely linked to outcomes

NQF Measure Portfolio: Process and Outcome Measures



NQF Measure Portfolio: Condition and Cross-Cutting Measures by Measure Types



Color legend: Process (white); Outcome (blue), Structure (orange)

Individual-Level PRO vs. Performance Measure

- **NQF does not endorse individual-level instruments or scales**
  - Although reliable and valid and useful in clinical practice or research, individual patient scores alone are not sufficient to determine performance and make conclusions about quality of a healthcare entity
  - Individual-level scores are the data that would be used in a performance measure
- **NQF endorses performance measures that result in a score for an accountable healthcare entity (and use data from all eligible patients)**
  - An endorsed performance measure must be standardized and precisely specified so specific instruments/scales and scoring must be identified

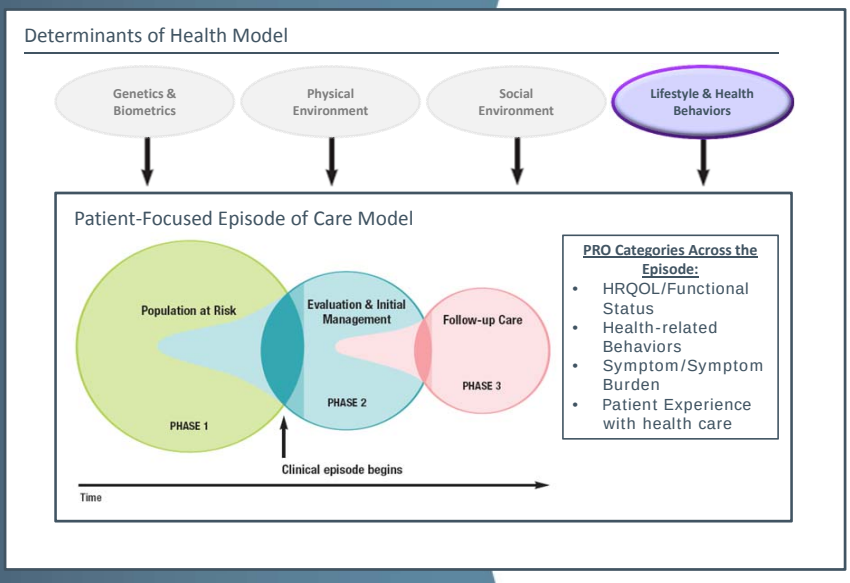
Examples: Endorsed PRO Performance Measures

- **Depression** (MN Community Measurement)
  - Depression Utilization of the Patient Health Questionnaire (PHQ-9) tool paired with:
    - Depression remission at six months
    - Depression remission at twelve months
- **Visual Function** (AAO)
  - Improvement in patient's visual function achieved within 90 days following cataract surgery
    - Improvement in visual function is defined by the quantitative scale used in the VF-14 survey instrument pre- and post-surgery.

Value Proposition

- Individual Level PRO
  - Inform care processes
  - Patient feedback and self monitoring
  - Shared decision-making
- Aggregate Level: Performance Measure
  - Quality improvement
  - Accountability (e.g., public reporting/transparency, payment)

Framing PROs Within Existing Conceptual Models



Today's Meeting Objectives

- Identify best practices and lessons learned from initiatives that have implemented individual-level PROs in performance measurement;
- Discuss the major methodological issues related to the selection, administration and use of individual-level PROs in performance measures;
- Discuss key considerations for inclusion of PROs into EHRs and policy implications;
- Identify the characteristics of individual-level PROs suitable for potential use in performance measures; and
- Identify an initial set of PROs most suitable for development and testing of performance measures.

Patient-reported outcomes in health care performance measurement: Issues related to selection and administration

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- Nan Rothrock

Acknowledging the Patient as an Authoritative Data Source

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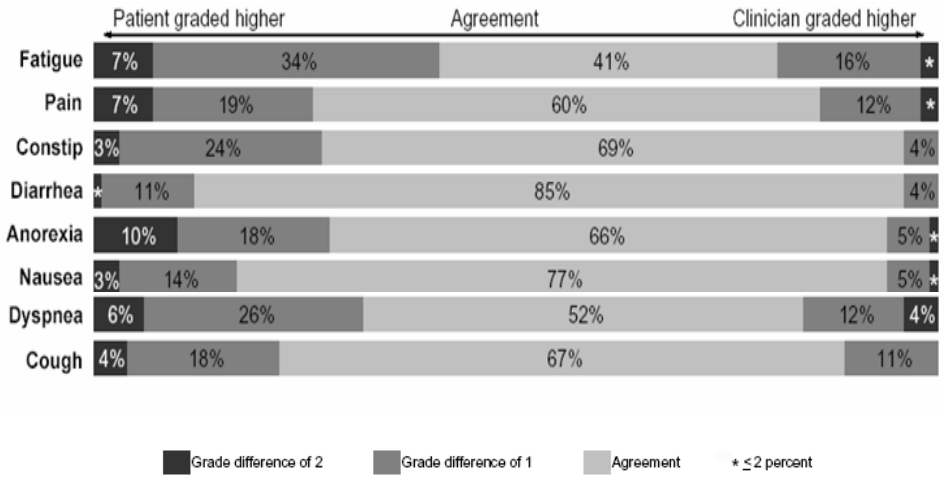
Why not just ask clinicians?

- Vast literature demonstrating that clinical providers do not accurately capture outcomes that are logically obtained by direct patient query

Comparison of Paired Observations



Basch, Lancet Oncol 2006

Correlations* Between Clinician AE and Patient Reports: Lung Cancer

- Uniscale
- Functional Assessment of Cancer Therapy Lung (FACT-L)
- Lung Cancer Symptom Scale (LCSS)
- Symptom Distress Scale (SDS)

Bruner et al, 2008

Potential for PRO use in clinical care

- Assist clinical providers in care management
- Enhance clinical efficiency
- Improve patient-provider communication
- Identify patient needs in a timely manner
- Facilitate patient-centered care

However…

- Routine PRO assessment is not common in clinical practice

Patient Experience of Care: an integral component of patient-centered care

- Patient satisfaction

(example from FACIT-TS; www.facit.org)

Did your doctor seem to understand what was important to you?	No, not at all	Yes, but not as much as I wanted	Yes, almost as much as I wanted	Yes, and as much as I wanted

- Patient reports of their actual experiences

(example from CAHPS; www.ahrq.gov.cahps)

In the last 12 months, when you phoned this provider's office during regular office hours, how often did you get an answer to your medical question that same day?	Never	Sometimes	Usually	Always

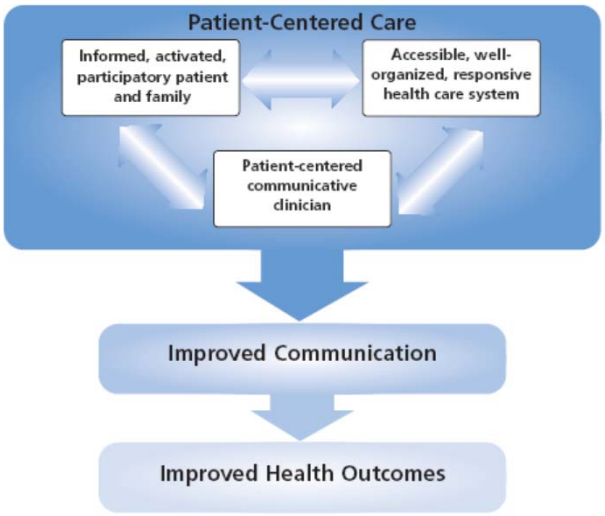
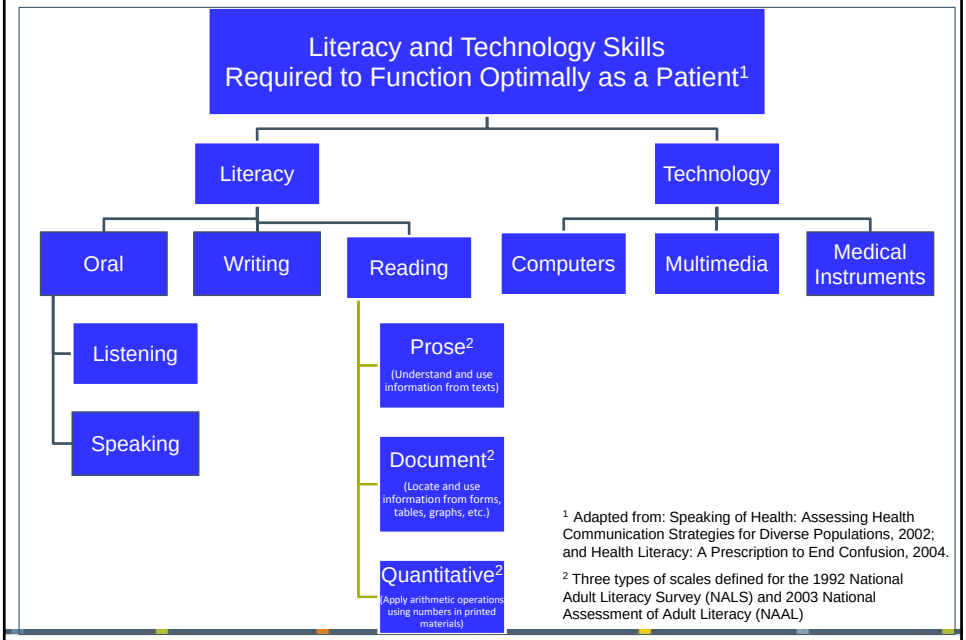


Figure 1.1 Based upon Epstein et al, Soc Sci Med, 2005, [from 2007 NCI/NIH Pub. #07-6225 "Patient-Centered Communication in Cancer Care"]

Best practices to minimize self-report barriers

- Select appropriate method and mode of administration
  - Consider age, functional status, cognition as they relate to use of proxies and assistive devices.
- Universal design principles, high-quality translations and cultural adaptations can provide comparable or equivalent versions
- Flexibility in location/setting (in-clinic, at home, at rehabilitation facilities)
  - requires access to the technology selected for the PRO
  - health information privacy must be protected
  - patient safety must be addressed
- Addressing *functional literacy* and *health literacy* are critical to delivering person-centered health care



[1] Adapted from: Speaking of Health: Assessing Health Communication Strategies for Diverse Populations, 2002; and Health Literacy: A Prescription to End Confusion, 2004.

[2] Three types of scales defined for the 1992 National Adult Literacy Survey (NALS) and 2003 National Assessment of Adult Literacy (NAAL)

Best practices to minimize barriers to self-reporting

- There are some circumstances in which it may be difficult or impossible to directly obtain PRO assessment by self-report.
- Proxy reporting is useful:
  - for people with cognitive or communications deficits or severe disease burden
  - for people in the early stages of dementia who may fail to recognize the extent of their impairment
  - for young children

Discussion

Methodological Issues: Method of Administration/Collection & Response

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Implications of Method/Mode of Administration and Response

- Decisions must be made related to data collection methods and the implications of those decisions on costs and errors in surveys (Groves, 2009)
  - What is the most appropriate method to choose for a particular question?
  - What is the impact of a particular method on survey errors and costs?
- Methods and modes differ along various dimensions:
  - Degree of interviewer involvement
  - Level of interaction with respondent
  - Channels of communication used
  - Degree of technology use

Source of Data and Methods/Modes of Survey Administration

- Self-report vs. proxy/observer ← ***DATA SOURCE***
- Self-administration
  - paper-and-pencil
  - telephone
  - computer
- Interviewer-administration
  - paper-and-pencil
  - telephone
  - computer

MODE

METHOD

Implications of Data Source: Self Versus Proxy

- Proxy reporting is useful when it may be difficult or impossible to directly obtain PROs:
  - Allows inclusion of a broader and more representative range of patients
  - Helps minimize missing data and increases the feasibility of longitudinal assessment
- Proxy reports may substitute for patient assessment or complement it
  - May involve proxies assessing the patient as they think the patient would respond
  - May involve proxies providing their own perspective on the patient's status
- Evaluating agreement between patients and proxies
  - Greater agreement when rating observable functioning, activities of daily living, physical health, motor functioning and less agreement when rating social functioning, pain, cognitive status, psychological, emotional well-being
  - Greater agreement when using continuous (vs dichotomous) ratings
  - Magnitude of disagreement can be minimized
    - Disagreement may provide useful information (e.g., MCI → early dementia)

Implications of Method/Mode of Administration

- Mode choices involve trade-offs and compromises
  - Consider the particular objectives of the assessment and the resources available
    - Self administration:
      - *Advantages:: Cost-effective, May yield more participant disclosure. Proceed at one's own pace*
      - *Disadvantages: Potential for missing data, Requires simple survey design*
    - Interviewer administration
      - *Advantages: Allows more complex survey design, Useful for patients with reading, writing, or vision difficulties*
      - *Disadvantages:: Less cost-effective, Potential for bias*
- Concern about the effects of mode on data quality and interpretation
  - High reliability for PROs administered using different modes
  - Response effects tend to vary and are not consistently in the same direction

Implications of Method/Mode of Administration

- Paper-and-pencil
  - Advantages: cost-effective
  - Disadvantages: prone to data entry errors, data entry and scoring require more time, less amenable to incorporation within EHR
- Electronic:
  - Advantages: interactive, practical, increased comfort for socially undesirable behaviors, minimizes data entry errors, immediate scoring/feedback, amenable to incorporation within EHR
  - Disadvantages: cost, potential discomfort with technology, accessibility, measurement equivalence
- Potential for differences between paper-and-pencil and electronic-based PROs:
  - Impersonality of the method
  - Cognitive burden on patient
  - Ability to establish the legitimacy of the study
  - Control over the questionnaires
  - Communication style
- There is increasing evidence of measurement equivalence between methods
  - As new methods are developed, it is critical to compare them to existing methods
- Across methods, patient privacy is always a concern

PROMIS Example: Mode of Administration

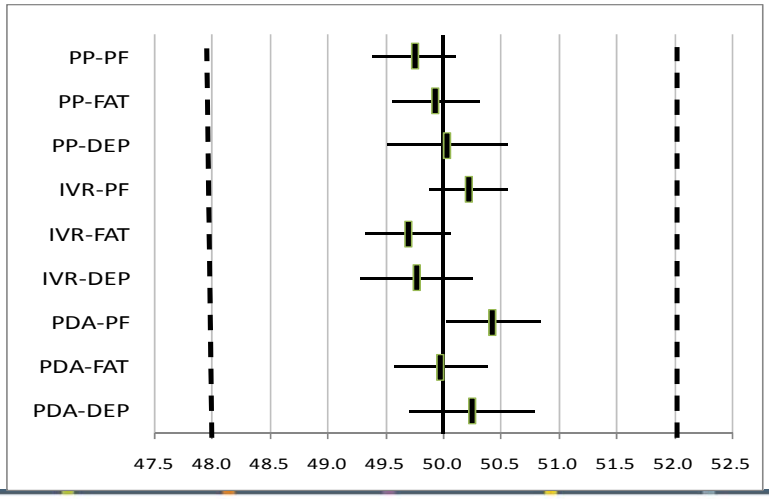



No meaningful differences found between modes of administration

< 1.5 points on 100-point scale

21

Comparisons to PC Administration
Assuming MID = 2 points (0.2 SD)



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People preferred the computer screen interface

23

Implications of Setting of Administration

- Clinic setting:
  - Strengths:
    - Real-time assessment of outcomes
    - Feasibility with use of electronic methods of administration
  - Limitations:
    - Impact on clinic flow
    - Interruptions resulting in missing data
    - Patient anxiety
    - Staff burden
- Home setting:
  - Strengths:
    - Minimizes impact on clinic flow
    - Minimizes staff burden
  - Limitations:
    - Accessibility
    - Health information privacy
    - Data security
    - Patient safety

Non-Response and Response Shift

- Bias may be introduced through data that are missing
  - Evaluate the amount, reasons and patterns of missing data
  - Apply statistical adjustments based on degree and pattern of missing data
  - Strategies to evaluate non-response bias:
    - Conduct an abbreviated follow-up survey with initial non-responders
    - Compare characteristics of respondents and non-respondents
    - Compare respondent data with comparable information from other sources
    - Compare early versus late respondents
- Patient adaptation and response shift over time can complicate the interpretation of PRO outcomes
  - Improvement may be unrelated to treatment effect
  - Consider monitoring for response shift or implementing control/comparator arms with longitudinal follow-up

Implications of Test Theory Type

- Classical Test Theory (CTT): estimates the level of an attribute as the sum of responses to individual items
  - "Test-dependent": validity dependent upon all items to be completed
- Item Response Theory (IRT): "test-free": enables estimation of the latent trait using different items as long as their locations have been calibrated on the same scale as the patients' ability levels
- IRT enables customized assessment, including computer-adaptive testing (CAT) in which the questions are tailored to the individual patient
  - Questionnaires can be shorter
  - The scale scores can be estimated more precisely for any given test length
  - Patients do not need to complete the same set of items in every situation

PROMIS Demo

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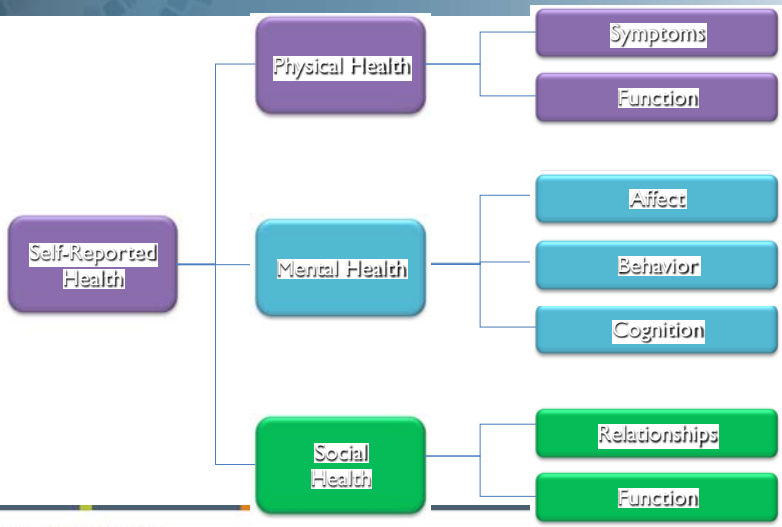
PROMIS Domain Framework



An item bank is a large collection of items measuring a single domain.

Any and all items can be used to provide a score for that domain.

The PROMIS Metric

T Score

Mean = 50

SD = 10

Referenced to the US General Population

PROMIS Basic Tools

Derived from Item Banks

Computerized Adaptive Testing (CAT)

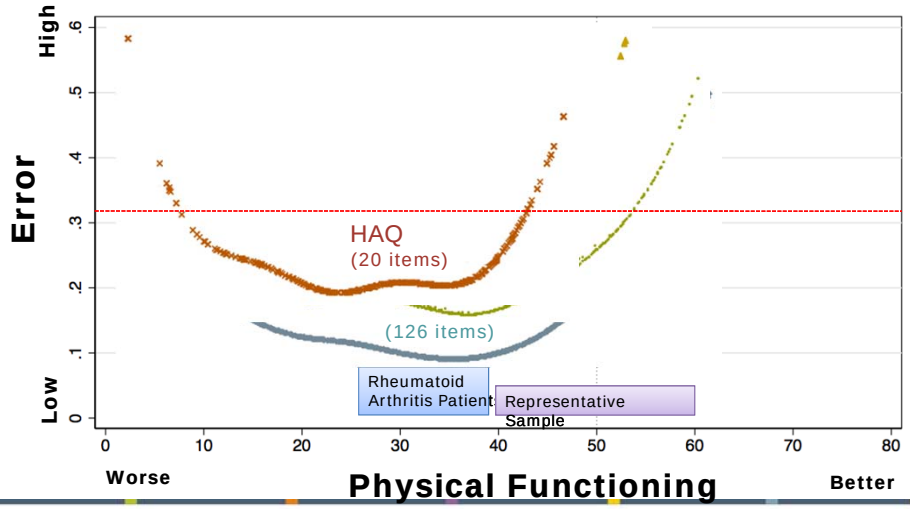
- Dynamic testing averaging 6 items per domain

Fixed Length Forms

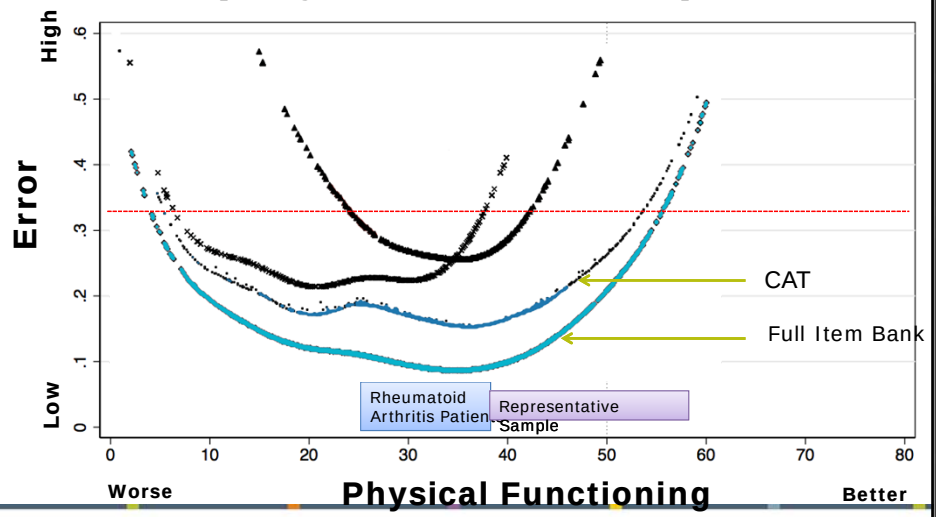
- By individual domain (8-10 items)
- By health profile (-29, -43, -57)

Global Health Index

Reliability/Precision of PROMIS (Physical Function)

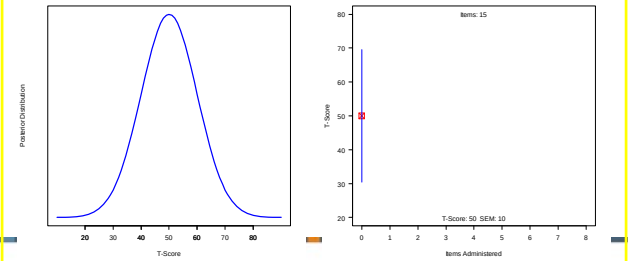


Relative Precision of PROs
(Physical Function)

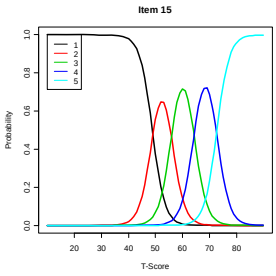


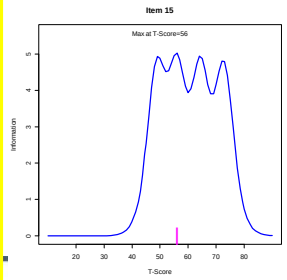
Beginning of CAT

T-Score = **50** SE = **10**



Best Item-I felt depressed

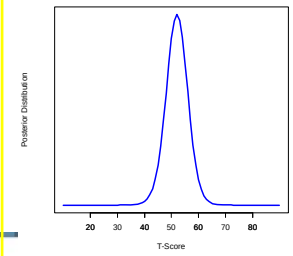


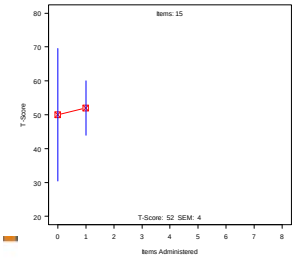


I felt depressed

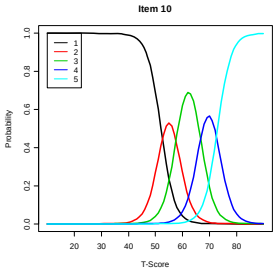
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

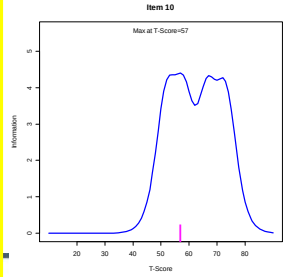
T-Score = **52** SE = **4**





Next Best Item-I felt like a failure

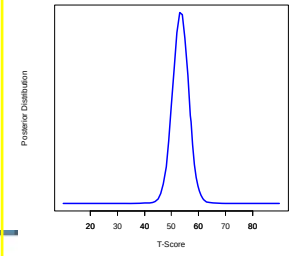


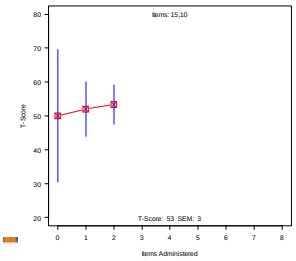


I felt like a failure

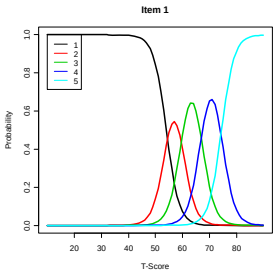
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

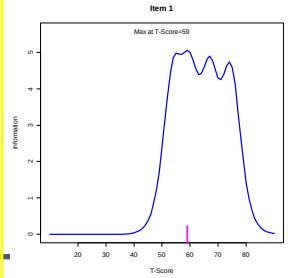
T-Score = **53** SE = **3**





Next Best Item-I felt worthless

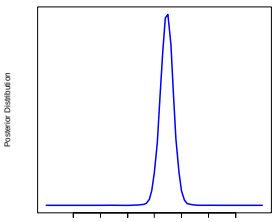


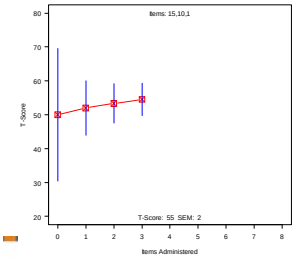


I felt worthless

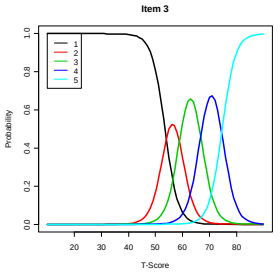
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

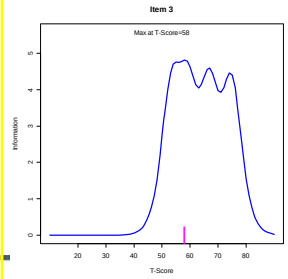
T-Score = **55** SE = **2**





Next Best Item-I felt helpless

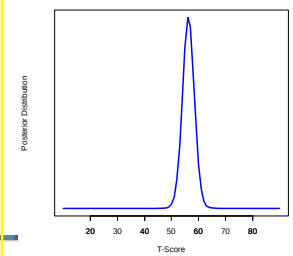


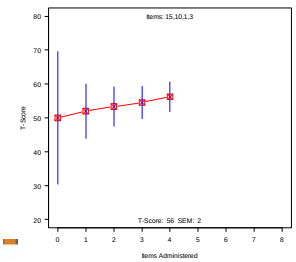


I felt helpless

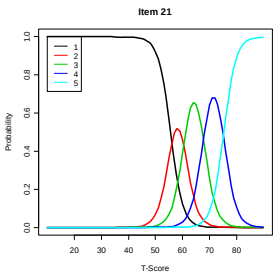
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

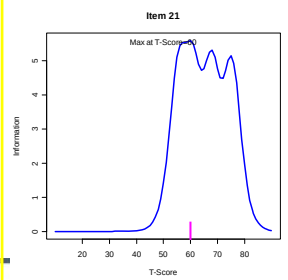
T-Score = **56** SE = **2**





Next Best Item-I felt hopeless

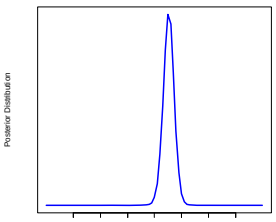


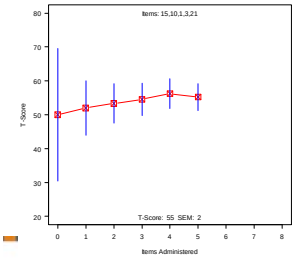


I felt hopeless

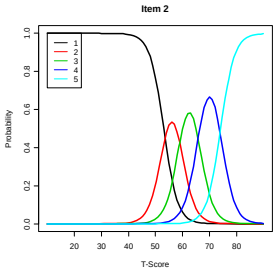
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

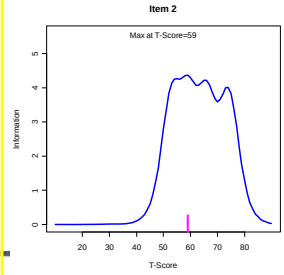
T-Score = **55** SE = **2**





Next Best Item-nothing to look forward to

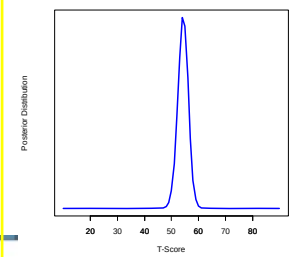


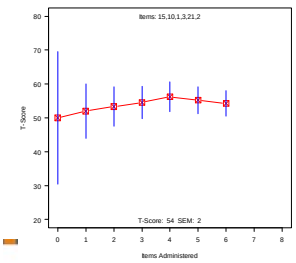


I felt that I had nothing to look forward to

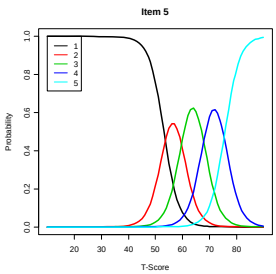
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

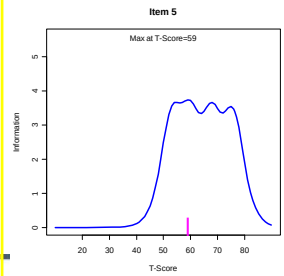
T-Score = **54** SE = **2**





Next Best Item-nothing cheer up

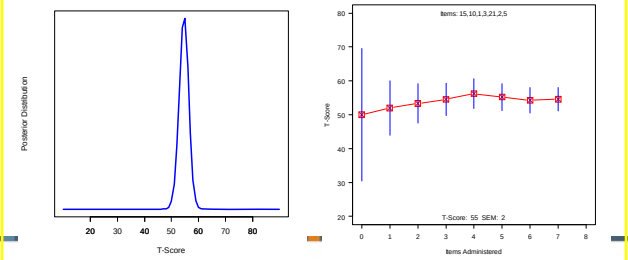




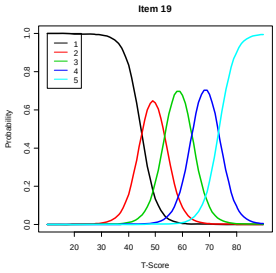
I felt that nothing could cheer me up

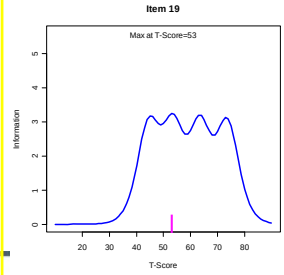
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

T-Score = **55** SE = **2**



Next Best Item-I felt unhappy

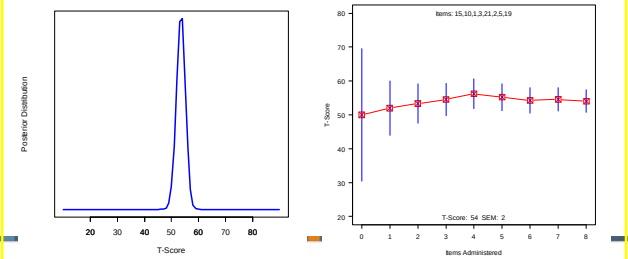




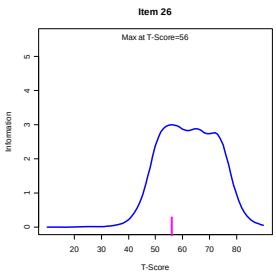
I felt unhappy

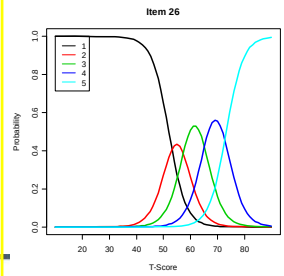
1. Never
2. Rarely
3. Sometimes
4. Often
5. Always

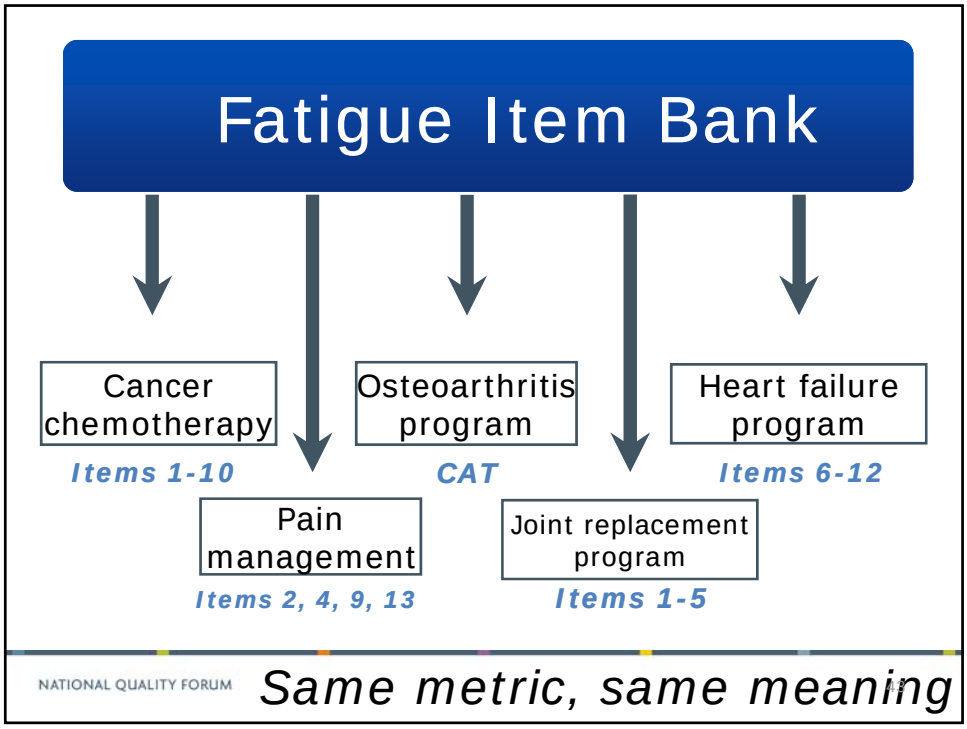
T-Score = **54** SE = **2**



Next Best Item-life was empty



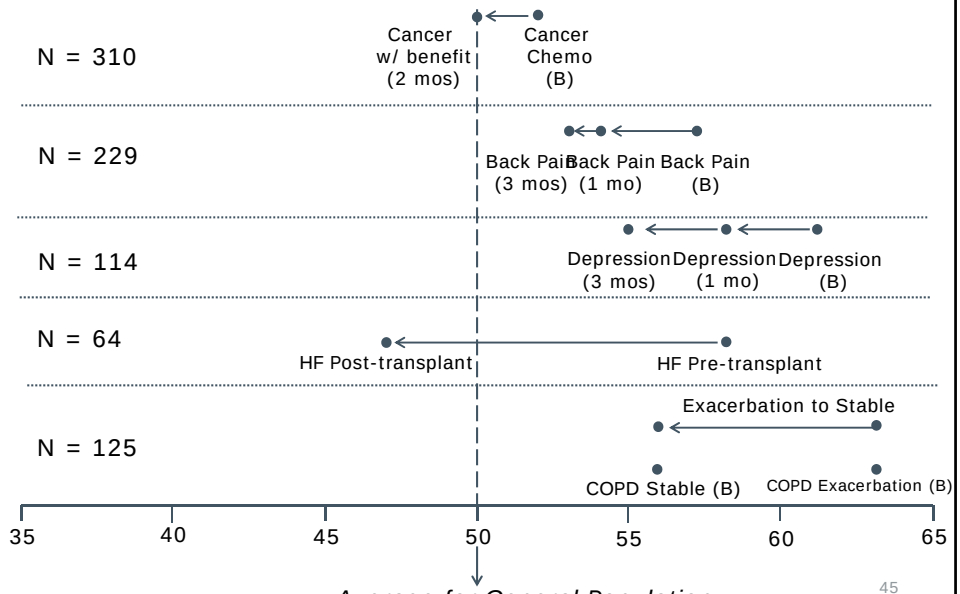




PROMIS Measures Tested in Six Conditions

Condition	Relevant Item Banks
COPD	Physical Function Fatigue Pain Social Role Satisfaction Emotional Distress (Depression, Anxiety, Anger)
Heart Failure	Physical Function Fatigue Social Role Satisfaction Depression
Low Back Pain	Pain (Interference and Behavior) Physical Function Depression Fatigue Sleep Disturbance
Depression	Emotional Distress (Depression, Anxiety, Anger) Sleep Disturbance Fatigue Physical Function Pain
Arthritis	Physical Function
Cancer	Pain Fatigue Emotional Distress (Depression, Anxiety) Physical Function

PROMIS Fatigue Across Five Clinical Conditions



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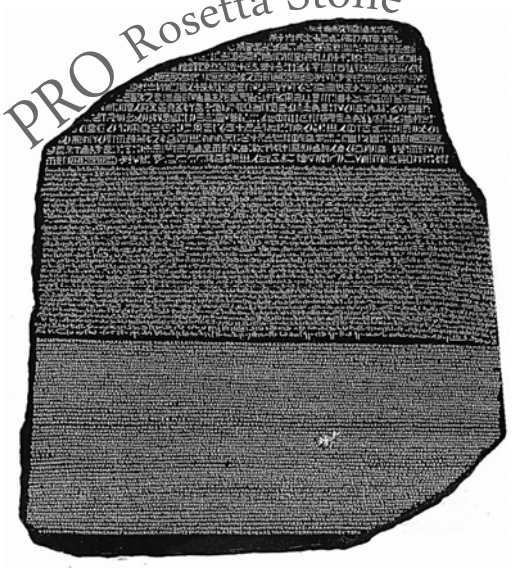
PRO Rosetta Stone



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PROsetta Stone Early Output

FACIT-F Score	PROMIS T-Score
52	27.8
51	32.8
50	35.9
49	38.4
48	40.3
47	42.0
46	43.4
45	44.8
44	45.8
43	46.9
42	47.9
41	48.8
40	49.8
39	50.5
38	51.3
37	52.1
36	52.8
35	53.6
34	54.3
33	55.0
32	55.7
31	56.3
30	57.0
29	57.6
28	58.3
27	58.9
26	59.5

FACIT-F Score	PROMIS T-Score
25	60.2
24	60.8
23	61.4
22	62.1
21	62.7
20	63.4
19	64.0
18	64.6
17	65.3
16	65.9
15	66.6
14	67.3
13	68.0
12	68.8
11	69.5
10	70.4
9	71.2
8	72.1
7	73.0
6	74.1
5	75.3
4	76.5
3	77.9
2	79.7
1	81.9
0	85.0

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Smith et al, PM&R 2010: 2: 359-363

Discussion

Methodological Issues:
Selecting Patient-level PROs

Selecting PROs for Use in Performance Measurement

- To optimize decision-making in clinical care, PROs must be measured in a standardized way using questionnaires with known properties
  - Many guidance documents address attributes for PROs used in research
  - Little guidance regarding attributes for PROs used as performance measures

Selecting PROs for Use in Performance Measurement

- Differences in selecting PROs as performance measures vs research
  - More similarities than differences
  - Importance of shorter instrument length
  - Higher stakes (consequences)
- Established PROs have more evidence than newer PROs…Newer PROs have better measurement properties
  - SF-36, SF-12, VR-36, VR-12 have been used most often
    - Limitation: Static measures
  - Future direction: IRT-based measures (e.g., PROMIS)

Characteristics of PROs Suitable for Use in Performance Measurement

- *Review of recommended characteristics for PROs for use in performance measures*
- *Example: applying recommended PRO characteristics to the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC; Bellamy, 2008)*
  - *PRO for use in individuals with knee and hip osteoarthritis*
  - *24 items covering 1-14 days*
  - *5-point Likert-type and 100mm visual analog formats available*
  - *3 subscales:*
    - Pain (5 items)
    - Disability/Physical Function (17 items)
    - Joint stiffness (2 items)

Characteristics of PROs Suitable for Use in Performance Measurement

1. Conceptual and measurement model

- Documentation should include description of:
  - Concept(s) included and the intended population(s)
  - Organization of concept(s) into a measurement model
- Target PRO should be a high priority for the health care system
- Example: WOMAC
  - Factorial validity of the physical function and pain subscales has been inadequate (Pua et al., 2009)

Characteristics of PROs Suitable for Use in Performance Measurement

2. Reliability

- Internal consistency reliability should be:
  - ≥ 0.70 for group-level purposes
  - ≥ 0.90 for individual-level purposes
- Stability/Reproducibility depends upon the time window
- Example: WOMAC
  - Cronbach's alpha for the three subscales range from 0.86 to 0.98
  - Stability has been adequate for the pain and physical function subscales, but less adequate for the stiffness subscale

Characteristics of PROs Suitable for Use in Performance Measurement

3. Validity

- Evidence supporting:
  - Content validity
  - Construct validity
  - Criterion validity
- Limited number of PRO instruments have been validated for use in performance measurement
- Example: WOMAC
  - Development involved expert clinician input, and survey input from patients, as well as a review of existing measures
  - Patient ratings of satisfaction with arthroplasty correlate positively with WOMAC scores

Characteristics of PROs Suitable for Use in Performance Measurement

4. Responsiveness

- Evidence of changes in scores consistent with predefined hypotheses regarding changes in the target population
- Important for performance measurement because there is an expectation of consequences
- Responsiveness is necessary if results are to be actionable
- Example: WOMAC
  - Demonstrates adequate responsiveness and ability to detect change in response to clinical intervention

Characteristics of PROs Suitable for Use in Performance Measurement

5. Interpretability of scores

- Documentation should include:
  - What low and high scores represent
  - Representative mean(s) and standard deviation(s) in the reference population
  - Guidance on estimating a minimally important difference between groups and/ change over time
- Performance measures:
  - If different PROs are used, it is important to establish a link or cross-walk between them.
  - Application of criteria to determine clinically meaningful change
- Example: WOMAC
  - Availability of population-based, age- and gender-normative values
  - Availability of minimal clinically important improvement values
  - Can be translated into a utility score for use in economic and accountability evaluations

Characteristics of PROs Suitable for Use in Performance Measurement

6. Burden

- Time, effort, and other demands on the respondent and the administrator
- Performance Measures:
  - PRO assessments should be as brief as possible
  - Reporting should be done in real-time
- Example: WOMAC
  - Short form available
  - Average time to complete mobile phone WOMAC = 4.8 minutes

Characteristics of PROs Suitable for Use in Performance Measurement

7. Alternative modes/methods of administration
   - The use of multiple modes and methods can be useful for diverse populations
   - Performance measures: Evidence of measurement equivalence necessary
   - Example: WOMAC
     - Validated mobile phone and touchscreen platforms

Characteristics of PROs Suitable for Use in Performance Measurement

8. Cultural and language adaptations
   - Performance measures: Mode, method and question wording must yield equivalent estimates of PRO measures
   - Example: WOMAC
     - Available in over 65 languages

Characteristics of PROs Suitable for Use in Performance Measurement

9. Electronic health records
   - Performance measures: Critical features:
     - Interoperability
     - Automated, real-time measurement and reporting
     - Sophisticated analytic capabilities
   - Example: WOMAC
     - Electronic data capture may allow for integration within EHR

Discussion

Incorporating PROs into Electronic Health Records & Personal Health Records

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E-health:
"health-related Internet applications that deliver a range of content, connectivity and clinical care"

- health information
- online formularies and prescription refills
- appointment scheduling and test results
- advance care planning and health care proxy designation

- e-health applications tend to focus on the needs of health care providers and organizations
- there is little evidence regarding whether the services offered are those that patients desire

Integrating PROs into EHRs & PHRs

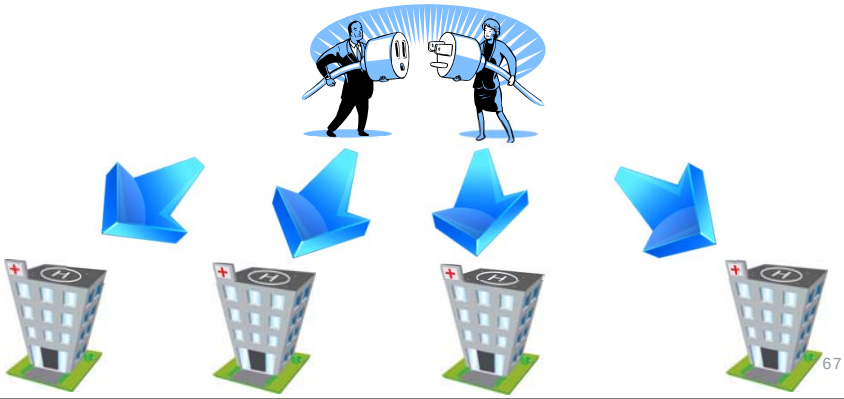
- PROs will likely constitute an important aspect of future stages of "meaningful use" of EHRs
- Critical features:
  - Interoperability and widespread health information exchange
  - Automated, real-time quality and cost measurement
  - Sophisticated analytic capacities

Integrating PROs into EHRs & PHRs

- Important issues:
  - Patient perspective:
    - Patients want to be involved as a partner in the flow of information
  - Clinical buy-in
  - Compatibility with clinical flow
  - Meaningful use
  - Patient privacy:
    - physical transfer of the paper-based PRO measure from patient to provider
    - electronic transfer of data or unauthorized access to patient-reported data
- Key design principles:
  - Fitting PRO measures into flow of care
  - Designing the system with stakeholder engagement
  - Merging PRO data with other types of data
  - Engaging in continuous improvement of the systems based on user experience and new technology

PROMIS Assessment Center℠

SNOMED and LOINC codes



Discussion

Patient-Reported Outcomes Workshop #1

Breakout Session

July 31, 2012

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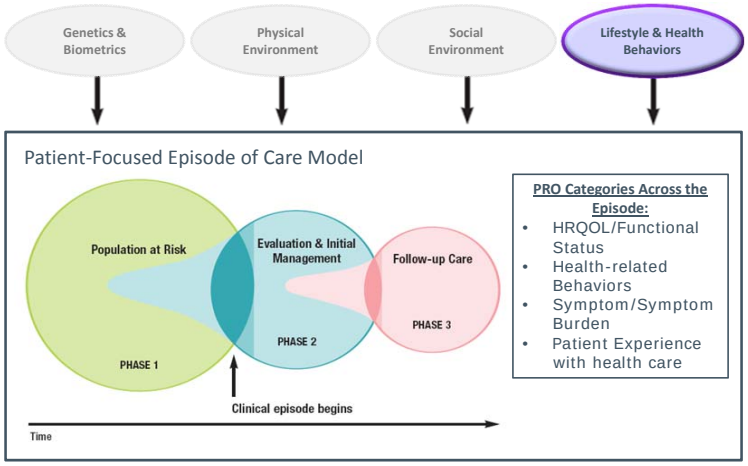
Framing PROs Within Existing Conceptual Models

Determinants of Health Model



AGENDA

- 9:35-9:45 Round Robin Introductions & identify spokesperson
- 9:45-10:30 Discussion of Question #1
  - What characteristics should be used to identify PROs for potential use in performance measures? Will these differ based on the needs of the end-user?
- 10:30-11:15 Discussion of Question #2
  - What existing individual-level PROs have these identified characteristics and are candidates for potential development of performance measures?
- 11:15-11:30 Synthesis and complete templates for report out

Patient-Reported Outcomes Expert Panel

***Patricia Brennan, RN, PhD, FAAN, FACMI (Co-Chair)**
University of Wisconsin-Madison, Madison, WI

***Joyce Dubow, MUP (Co-Chair)**
AARP, Washington, DC

Richard Bankowitz, MBA, MD, FACP
Premier Healthcare Alliance, Washington, DC

Ethan Basch, MD, MSc
Memorial Sloan-Kettering Cancer Center, Bronx, NY

Jim Bellows, PhD, MPH
Kaiser Permanente, Oakland, CA

Laurie Burke, RN
Food and Drug Administration, Silver Spring, MD

Jennifer Eames-Huff
Pacific Business Group on Health, San Francisco, CA

***Stephan Fihn, MD, MPH**
Veterans Health Administration, Seattle, Washington

Floyd Fowler, PhD
Foundation for Informed Medical Decision Making, Boston, MA

Lori Frank, PhD
Patient Centered Outcomes Research Institute, Washington, DC

Theodore Ganiats, MD
University of California San Diego Health System, La Jolla, CA

***Kate Goodrich, MD**
Centers for Medicare & Medicaid Services, Washington, DC

Judith Hibbard, DrPH
University of Oregon, Eugene, OR

Dennis Kaldenberg, PhD
Press Ganey Associates, South Bend, IN

Irene Katzan, MD, MS
Cleveland Clinic, Cleveland, OH

***Lewis Kazis, Sc.D**
Boston University School of Public Health, Boston, MA

Uma Kotagal, MSc
Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Kevin Larsen, MD, FACP
Office of the National Coordinator for Health Information Technology, Washington, DC

Kathleen Lohr, PhD
RTI International, Chapel Hill, NC

Elizabeth Mort, MD
Massachusetts General Hospital, Boston, MA

Charles Moseley, Ed.D.
National Association of State Directors of Developmental Disabilities Services, Alexandria, VA

***Eugene Nelson, DSc, MPH**
Dartmouth- Hitchcock Medical Center, Lebanon, NH

Kenneth Ottenbacher, PhD, OTR
The University of Texas Medical Branch at Galveston, Galveston, TX

***Greg Pawlson, MD, MPH**
BlueCross BlueShield Association, Washington, DC

Eleanor Perfetto, PhD
Pfizer, Washington, DC

Collette Pitzen, BSN, RN, CPHQ
Minnesota Community Measurement, Minneapolis, MN

Cheryl Powell
Centers for Medicaid & Medicare Services, Baltimore, MD

David Radley, PhD
Institute for Healthcare Improvement, Cambridge, MA

Ted Rooney, RN, MPH
Maine Quality Counts, Manchester, ME

Debra Saliba, MD, MPH
UCLA Borun Center, Los Angeles VA Medical Center, The RAND Corporation, Los Angeles, CA

Marcel Salive, MD, MPH
National Institutes of Health, Rockville, MD

Barbara Summers, PhD, RN, FAAN
University of Texas-MD Anderson Cancer Center, Houston, TX

Kalahn Taylor-Clark, PhD, MPH, BA
National Partnership for Women & Families, Washington, DC

Mary Tinetti, MD
Yale New Haven Health System, New Haven, CT

Phyllis Torda, MA
National Committee for Quality Assurance, Washington, DC

John Wasson, MD
Dartmouth Medical School, Lebanon, NH

Robert Weech-Maldonado, PhD
University of Alabama at Birmingham, Birmingham, AL

Linda Wilkinson, MBA
Dartmouth Hitchcock Medical Center, Lebanon, NH

Albert Wu, MD, MPH
Johns Hopkins Health System, Baltimore, MD

" * " Indications a member of the Planning Committee

Project Staff

Helen Burstin, MD, MPH
Karen Adams, PhD
Karen Pace, PhD, MSN
Gene Cunningham, MS
Jessica Weber, MPH

Patient-Reported Outcomes Expert Panel

EXPERT PANEL MEMBERS

Dr. Richard Bankowitz, MBA, MD, FACP
Chief Medical Officer, Premier, Inc.

Richard Bankowitz, MD, MBA, FACP is currently serving as Chief Medical Officer of Premier Inc. Dr. Bankowitz engages physicians, provides leadership and ensures that Premier continues to deliver value to its clinician constituency. Dr. Bankowitz previously served as VP and medical director for Premier Healthcare Informatics. A board-certified internist and a medical informaticist, Dr. Bankowitz has devoted his career to improving healthcare quality at the national level by promoting rigorous, data-driven approaches to quality improvement. He began his career at the University of Pittsburgh School of Medicine as an assistant professor of medicine and medical informatics and served as the architect of the University HealthSystem Consortium.

Dr. Ethan Basch, MD, MSc
Associate Attending Physician and Outcomes Research Scientist- Memorial Sloan-Kettering Cancer Center

Dr. Ethan Basch is an oncologist and outcomes researcher at Memorial Sloan-Kettering Cancer Center who directs a program on patient-reported outcomes, clinical informatics, comparative effectiveness and product safety evaluation. He leads the National Cancer Institute's PRO-CTCAE initiative to develop a standardized patient-centered approach to adverse event reporting in clinical trials. He is a member of the PCORI Methodology Committee and chairs the Patient-Centeredness Workgroup. He is immediate past Chair of the American Society of Clinical Oncology Clinical Practice Guidelines Committee, member of the Comparative Effectiveness Research Task Force and liaison to the Quality of Care Committee. Dr. Basch received his MD from Harvard.

Dr. Jim Bellows, PhD, MPH
Senior Director, Evaluation and Analytics- Kaiser Permanente Care Management Institute (CMI)

Jim Bellows is Senior Director, Evaluation and Analytics in Kaiser Permanente's Care Management Institute. Dr. Bellows leads an Evaluation and Analytics staff with expertise in metrics development, analytics, and quantitative and qualitative evaluation, and with accountability for developing and producing performance metrics, identifying specific population care practices that contribute to superior performance, and evaluating the impact of quality improvement initiatives as they mature. Dr. Bellows shares responsibility for building collaborations that apply the capabilities of KP's externally-funded research investigators to clinical and operational challenges of strategic importance within KP.

Dr. Patricia Flatley Brennan, RN, PhD
Professor, School of Nursing and College of Engineering, University of Wisconsin

Dr. Brennan is the Lillian L. Moehlman Bascom Professor at the School of Nursing and College of Engineering, University of Wisconsin-Madison. Dr. Brennan received a Masters of Science in Nursing from the University of Pennsylvania and a PhD in Industrial Engineering from the University of Wisconsin-Madison. Following seven years of clinical practice in critical care nursing and psychiatric nursing, Dr. Brennan held several academic positions. She developed the ComputerLink, an electronic network designed to reduce isolation and improve

self-care among home care patients and directed HeartCare, a WWW-based tailored information and communication service that helped home-dwelling cardiac patients recover faster, and with fewer symptoms.

Ms. Laurie Burke, RN
Associate Director for Study Endpoints and Labeling in the Center for Drug Evaluation and Research, Food and Drug Administration

Ms. Burke is an advocate for the development of good measurement practices and leads in the development of regulatory policy for outcome assessments to support claims in labeling. She has led many FDA-wide initiatives including the publication of FDA's Patient Reported Outcome guidance and has authored numerous white papers through her involvement in FDA working groups and professional associations. The Study Endpoints Team identifies best measurement practices and works with all FDA medical product reviewers to determine whether clinical outcome assessments are well-defined and reliable with respect to their context of use in the support of medical product development, labeling, and promotion.

Ms. Joyce Dubow, MUP
Senior Director, Health Care Reform- AARP

Ms. Dubow is a Senior Advisor in AARP's Office of Policy and Strategy where she has responsibility for a broad portfolio, including health care quality, measurement, public reporting, patient decision making, HIT, and related issues. Before joining this office, she was Associate Director in AARP's Public Policy Institute where I had responsibility for public policy research and analysis. In a "former life," she was executive vice-president of the Georgetown University Community Health Plan, a university-sponsored prepaid group practice plan. Ms. Dubow also served as the Director of Policy and Legislation in the federal Office of Health Maintenance Organizations.

Ms. Jennifer Eames-Huff, MPH
Director, Consumer-Purchaser Disclosure Project- Pacific Business Group on Health

Ms. Eames Huff is Director for the Consumer-Purchaser Disclosure Project, which is a group of leading employer, consumer, and labor organizations improving health care quality and affordability by advancing public reporting of provider performance information so it can be used for improvement, consumer choice, and payment. Ms. Huff brings over fifteen years experience working in the arena of health care performance measurement to the project. Prior to joining PBGH Ms. Huff was a Health Economist at Genentech. Before that, she was a Program Officer at the California HealthCare Foundation. Ms. Huff earned a BA with Honors from Wellesley College and an MPH in Health Policy and Management from University of California at Berkeley.

Dr. Stephan Fihn, MD, MPH
Director, Office of Analytics and Business Intelligence, Veterans Health Administration

Dr. Stephan Fihn is a general internist and health services researcher at VA Puget Sound Health Care System and the University of Washington in Seattle. Until recently, he served as Director of the Northwest VA Health Services Research & Development Center of Excellence at VAPSHCS. He now serves as Director, Office of Analytics and Business Intelligence for Veterans Health Administration. His office will provide comprehensive analytic and business intelligence support to all of VHA. He also serves as Head of the Division of General Internal Medicine at the University of Washington. His research interests relate to developing strategies for improving the efficiency and quality of primary medical care and understanding the epidemiology of common ambulatory problems.

Dr. Floyd Jackson Fowler, Jr., PhD
Senior Scientific Advisor and Past President- Foundation for Informed Medical Decision Making

Floyd J Fowler Jr. is a Senior Scientific Advisor to the Foundation for Informed Medical Decision Making. He served as President of the Foundation from 2002-2009. He has also been a Senior Research Fellow at the Center for Survey Research, UMass Boston since 1971, and he served as Director of the Center for 14 years. Dr. Fowler is a social scientist whose special expertise is survey methodology. He is the author (or co-author) of four widely used books on survey research methods. He also has been a major contributor to research on patient outcomes and on how patients are affected by the treatments they receive. Dr. Fowler received a BA degree in English from Wesleyan University and a Ph.D. is Social Psychology from the University of Michigan.

Dr. Lori Frank, PhD
Director, Engagement Research- Patient Centered Outcomes Research Institute

Lori Frank, PhD, has worked as a PRO researcher for over 15 years. At PCORI Dr. Frank's work focuses on the patient perspective on comparative effectiveness research. As Executive Director of the Center for Health Outcomes Research at United BioSource she led multiple PRO development and psychometric evaluation studies, and initiated and led the Cognition Initiative, now part of the Critical Path Institute PRO Consortium. Her published work includes both qualitative and quantitative studies of PROs. She serves on the Memory Screening Advisory Board of the Alzheimer's Foundation of America and has also served on the Center for Trauma and the Community of Georgetown University Department of Psychiatry.

Dr. Theodore Ganiats, MD
Professor- University of California San Diego

Theodore G. Ganiats, MD, is Professor of Family and Preventive Medicine at the University of California San Diego (UCSD) School of Medicine and the Executive Director of the UCSD Health Services Research Center. Dr. Ganiats' research interests involve outcomes research, focusing on both applied and theoretical aspects of quality of life assessment (an important patient-reported outcome) and cost-effectiveness analysis. He has co-chaired or been a member of over fifty national systemic reviews, clinical practice guidelines (often as a methodology consultant) and performance measurement panels, including NQF heart failure and diabetes panels. He remains clinically active, giving him the additional perspective of the practicing clinician.

Dr. Kate Goodrich, MD
Senior Technical Advisor to the Director of the Office of Clinical Standards and Quality and Chief Medical Officer, Centers for Medicare and Medicaid Services

Dr. Goodrich earned her M.D. from Louisiana State University Medical Center. She completed her residency in Internal Medicine at George Washington University Medical Center, followed by a year as Chief Medical Resident. She joined the faculty of GWUMC as a hospitalist in the Department of Medicine. A new Division of Hospital Medicine was created in 2005, and Dr. Goodrich was appointed Division Director. From 2003-2008 she served as Chair of the Institutional Review Board at GWUMC. She also took a position as Medical Officer at the Department of Health and Human Services in the office of the Assistant Secretary for Planning and Evaluation. Dr. Goodrich continues to practice clinical medicine as a hospitalist at George Washington University Hospital.

Dr. Judith Hibbard, DrPH
Professor Emerita and Senior Researcher, Institute for Policy Research and Innovation, University of Oregon

Dr. Hibbard has focused her research on 1) how the presentation of quality data affects consumers' use of

quality information in decision-making, 2) how health literacy affects choices, 3) measuring patient engagement and activation, and 4) whether public reporting stimulates quality improvement. She has led over a dozen studies using both qualitative and quantitative approaches. She has examined how to present quality data to highly vulnerable populations, such as Medicare beneficiaries, patients with chronic illnesses, and patients with low numeracy levels. One of the most important facets of her work is elaborating whether patients become more engaged in their own health in response to information.

Dr. Dennis Kaldenberg, PhD
Chief Scientist, Senior Vice President- Press Ganey Associates

As Chief Scientist, Dennis Kaldenberg provides leadership to the areas of research and analytics including such issues as data integration, information collection protocols and the accurate and useful dissemination of information. During his tenure he has been instrumental in the creation and revision of many tools to measure patient experience, patient satisfaction, and other patient reported outcomes. Dr. Kaldenberg has written on a variety of topics related to patient satisfaction, health care service delivery, health care professionals, and research methods. He has presented at the national meetings of numerous health care professional associations, Dr. Kaldenberg received his Ph.D. from Iowa State University with a specialization in research methods.

Dr. Irene L. Katzan, MD, MS
Director, Neurological Institute Center for Outcomes Research & Evaluation- Cleveland Clinic

Irene Katzan MD, MS is a board-certified vascular neurologist and health services researcher at Cleveland Clinic. She is Director of the Neurological Institute Center for Outcomes Research and Evaluation and the Knowledge Program, a technology initiative to harness electronic clinical information for research and patient care. Dr. Katzan is also a senior researcher at Case's Center for Health Care Research & Policy. She has a background in evaluating outcomes of care and modifying systems to optimize patient management in multiple settings. She is actively involved in regional stroke care initiatives and is the lead physician of the Ohio Coverdell Stroke Registry, a quality initiative of Centers for Disease Control & Prevention.

Dr. Lewis Kazis, Sc.D
Professor, Health Policy and Management- Boston University School of Public Health

Dr. Kazis is Professor of Health Policy and Management at Boston University School of Public Health. He has published well over 150 peer reviewed publications including those involving PROs. Dr. Kazis was the recipient of the Research Career Scientist Award from the VA for almost a decade. Dr. Kazis served as a special consultant to the Office of Quality and Performance in the VA and a consultant to the Centers for Medicare and Medicaid Services for the evaluation of the Medicare Advantage Program. Dr. Kazis is the principal developer of the Veterans RAND 36 and 12 Item Health Survey's (VR-36/12). The VR-12 has been adopted by the Veterans Administration historically and by the CMS Medicare Advantage Program.

Dr. Uma Kotagal, M.B.B.S, MSc
Senior Vice President for Safety, Quality and Transformation and Executive Director of the James M. Anderson Center for Health Systems Excellence, Cincinnati Children's Hospital Medical Center

Dr. Uma Kotagal is the Senior Vice President for Safety, Quality and Transformation and Executive Director of the James M. Anderson Center for Health Systems Excellence at Cincinnati Children's Hospital Medical Center. Dr. Kotagal is Chair of the Quality Steering Team of the Ohio Children's Hospital Association, member of the Advisory Committee of the Toronto Patient Safety Center, Associate Editor for the BMJ Quality and Safety, and is a member of the Institute of Medicine. Dr. Kotagal holds a MS in Epidemiology from Harvard

University-School of Public Health and a Bachelors of Medicine, Surgery from Grant Medical College, Mumbai, India.

Dr. Kevin Larsen, MD
Medical Director of Meaningful Use, Office of the National Coordinator

Kevin L. Larsen, MD is Medical Director of Meaningful Use at the Office of the National Coordinator for Health IT. In that role he is responsible for coordinating the clinical quality measures for Meaningful Use Certification and overseas the development of the Population Health Tool http://projectpophealth.org. Prior to working for the federal government he was Chief Medical Informatics Officer and Associate Medical Director at Hennepin County Medical Center in Minneapolis, Minnesota. He is also an Associate Professor of Medicine at the University of Minnesota. Dr. Larsen graduated from the University of Minnesota Medical School and was a resident and chief medical resident at Hennepin County Medical Center. He is a general internist and teacher in the medical school and residency programs. His research includes health care financing for people living in poverty, computer systems to support clinical decision making, and health literacy. In Minneapolis he was also the Medical Director for the Center for Urban Health, a hospital, community collaboration to eliminate health disparities. He served on a number of state and national committees in informatics, data standards and health IT.

Dr. Kathleen Lohr, PhD
Distinguished Fellow, RTI International

Kathleen N. Lohr, PhD, Distinguished Fellow at RTI International, was the founding director of the RTI–UNC Evidence-based Practice Center; recent projects involve systematic or comparative effectiveness reviews, “content” and “readability” guidance for AHRQ reviews, and EPC methods projects. Dr. Lohr was the founding Editor-in-Chief of RTI Press (www.rti.org/RTIPress); she was Associate Editor of Quality of Life Research and is on the editorial board of Comparative Effectiveness Research. She received (2005) the Avedis Donabedian Outcomes Research Lifetime Achievement Award from the International Society of Pharmacoeconomics & Outcomes Research. She was a member of AHRQ’s National Advisory Council (2008-2010).

Dr. Elizabeth Mort, MD
Associate Chief Medical Officer, Senior Vice President Quality and Safety, Massachusetts General Hospital

Dr. Mort oversees data collection and external reporting for public reporting for MGH. She sits on the hospital’s Quality Executive Committee and the Board Subcommittee on Quality which set the quality and safety agenda for the hospital and the physicians’ organization. She chairs MGH’s Quality and Safety Measurement Steering Committee, and one of the committee’s goals is to encourage clinical experts at the institution to participate in national measurement and reporting exercises, to comment actively and provide active feedback to organizations like NQF, CMS, and The Joint Commission. She has in-depth familiarity with key national data sets used at MGH such as NSQIP, Vermont Oxford, The Society for Thoracic Surgery data set, and the American College of Cardiology data set.

Dr. Charles Moseley, Ed.D.
Associate Executive Director- National Association of State Directors of Developmental Disabilities Services

Dr. Moseley became the Director of the Division of Developmental Services for the State of Vermont in 1988. He worked with the NASDDDS staff the directors of six other states and the Association's partners at the Human Services Research Institute to develop and operationalize the National Core Indicators (NCI) developmental disabilities performance assessment system to provide state developmental disabilities agencies with valid and reliable statistical tools to track service outcomes and performance trends, perform

state to state comparisons and improve service delivery over time. He is currently working with five states, including Connecticut, Michigan, Maryland, South Carolina and Virginia to assist them in developing the capacity to gather and report NCI outcome and performance data.

Dr. Eugene C. Nelson, DSc, MPH
Director, Population Health Measurement Program, The Dartmouth Institute; Director, Population Health and Measurement, Dartmouth-Hitchcock Medical Center; Professor, Community & Family Medicine and of The Dartmouth Institute for Health Policy and Clinical Practice
Dartmouth Medical School

Dr. Nelson is a national leader in health care improvement and the development and application of measures of quality, system performance, health outcomes, value, and patient and customer perceptions. In the early 1990s, Dr. Nelson and his colleagues at Dartmouth began developing clinical microsystem thinking. His work developing the "clinical value compass" and "whole system measures" to assess health care system performance has made him a well-recognized quality and value measurement expert. He is the recipient of The Joint Commission's Ernest A. Codman award for his work on outcomes measurement in health care. He received an AB from Dartmouth College, a MPH from Yale University and a DSc from Harvard University.

Dr. Kenneth Ottenbacher, PhD, OTR
Russell Shearn Moody Distinguished Chair in Rehabilitation, University of Texas Medical Branch at Galveston

Kenneth J. Ottenbacher holds the Russell Shearn Moody Distinguished Chair in Rehabilitation at the University of Texas Medical Branch in Galveston. He serves as Senior Associate Dean and Director of the Division of Rehabilitation Sciences in the School of Health Professions. He is also Associate Director for the Sealy Center on Aging. Dr. Ottenbacher received his PhD from the University of Missouri-Columbia and is a licensed occupational therapist. His research interests include rehabilitation outcomes with a focus on functional assessment, disability and frailty in older adults. Dr. Ottenbacher's research has been supported by continuous federal funding since 1986. He is a member of several editorial boards.

Dr. Greg Pawlson, MD, MPH
Executive Director, Quality Innovations- BlueCross BlueShield Association Office of Policy and Representation

Prior to BCBSA, Dr. Pawlson was Executive Vice President of the National Committee for Quality Assurance (NCQA), where he was responsible for oversight of all activities related to research and analysis, development of performance measurement measures related to most major diseases, and more recently measures related to overuse, resource use and cost. He also served as NCQA's primary liaison to physician specialty societies and medical boards including the American College of Physicians, the American Academy of Family Physicians and the American Board of Internal Medicine. Before NCQA, Dr. Pawlson served as Senior Associate VP for Health Affairs and Medical Director for Quality and Utilization Management for the faculty practice at The George Washington University Medical Center.

Dr. Eleanor M. Perfetto, PhD
Senior Director- Pfizer

Dr. Perfetto holds BS and MS degrees in pharmacy from the University of Rhode Island, and a PhD from the University of North Carolina School of Public Health. She currently serves as a board member of the Pharmacy Quality Alliance (PQA), and is co-chair of the PQA Research Coordinating Council. Prior to joining Pfizer, Dr. Perfetto provided research consulting services for over eight years to government agencies, the pharmaceutical industry, and professional organizations. Prior to consulting, she established a new division responsible for global health outcome and economic research at Wyeth-Ayerst. She also served in the U.S. Public Health Service as senior pharmacoepidemiologist within the Agency for Health Care Policy & Research

(now AHRQ).

Ms. Collette M. Pitzen, BSN, RN, CPHQ
Manager, Measure & Program Development- Minnesota Community Measurement

Collette Pitzen is the manager for Measure and Program Development at MN Community Measurement, a non-profit organization whose mission is to accelerate the improvement of health by publicly reporting health care information. She has 27 years' experience in a variety of health care settings including neurology, cardiovascular and dialysis with a significant portion devoted to quality improvement, measure design and reporting. Prior to her current position, Collette worked for Fairview Physician Associates and was responsible for implementing a Clinical Excellence and internal reward program for FPA's primary and specialty care clinics. Collette holds a BS degree from the University Of Minnesota School Of Nursing and is a Certified Professional in Healthcare Quality.

Ms. Cheryl Powell, MS
Deputy Director, Federal Coordinated Health Care Office- Centers for Medicare and Medicaid Services

Cheryl Powell is the Deputy Director of the Medicare-Medicaid Coordination Office (Federal Coordinated Health Care Office) at the Centers for Medicare & Medicaid Services. As the Deputy Director, she assists the Director in leading the work of this office charged with more effectively integrating benefits to create seamless care for individuals eligible for both Medicare and Medicaid and improving coordination between the federal government and states for such dual eligible beneficiaries. She has extensive experience in both Medicare and Medicaid policy development and operations. She is an expert on Medicaid reform activities and policy development. She earned a master's degree in public policy from the John F. Kennedy School of Government at Harvard.

Dr. David Radley, PhD, MPH
Senior Policy Analyst and Project Director, Institute for Healthcare Improvement

David C. Radley, Ph.D., M.P.H., is a Senior Policy Analyst and Project Director at the Institute for Healthcare Improvement. Through a grant from the Commonwealth Fund, Dr. Radley oversees development and production of the Commonwealth Fund's national, state and sub-state health system performance scorecard series. His methodological expertise is in health system performance measurement and in studies that use large administrative and survey-based datasets. Dr. Radley received his Ph.D. from the Dartmouth Institute for Health Policy and Clinical Practice in 2008.

Mr. Ted Rooney, RN, MPH
Project Leader, Maine Quality Counts

Ted is Project Leader for the Maine Health Management Coalition's Pathways to Excellence initiatives, which measure and report the value of health care, and work to change the reimbursement system to reward high value care. Ted is also Project Leader for Aligning Forces for Quality, a Robert Wood Johnson Foundation funded initiative led in Maine by Quality Counts in partnership with the Maine Quality Forum and Maine Health Management Coalition. Ted serves on various Boards and Committees: Maine Health Data Organization Board, AHRQ Healthcare Cost and Utilization Project Steering Committee, Quality Alliance Steering Committee National-Regional Implementation Workgroup, and Healthy Choices for ME advisory committee.

Dr. Debra Saliba, MD, MPH
Senior Natural Scientist, The RAND Corporation

Debra Saliba, MD, MPH is the UCLA Anna and Harry Borun Endowed Chair in Geriatrics and Gerontology and Director of the UCLA/JH Borun Center for Applied Gerontological Research. Dr. Saliba is a practicing physician with the VA GRECC and serves as the Strategic Program Lead for Aging and Long-term Care populations in the VA HSR&D Center of Excellence for the Study of Healthcare Provider Behavior. She is also a senior natural scientist at RAND. Her research in quality of care and vulnerable populations has received awards from the Journal of American Medical Directors Association, VA Health Services Research & Development, and the American Geriatrics Society.

Dr. Marcel Salive, MD, MPH
Health Scientist Administrator, Division of Geriatrics & Clinical Gerontology, National Institutes of Health

Marcel Salive, MD, MPH, joined the Division of Geriatrics and Gerontology, National Institute on Aging, in 2010 and oversees the research portfolio on multi-morbidity treatment and prevention, polypharmacy and comparative effectiveness. Marcel has held leadership positions in the Centers for Medicare & Medicaid Services (CMS), National Heart, Lung and Blood Institute, and Food and Drug Administration. From 2003-2010, he served as Director of the Division of Medical and Surgical Services within the Coverage and Analysis Group of CMS and was responsible for developing and maintaining national coverage decisions for Medicare beneficiaries using a rigorous and open evidence-based process.

Dr. Barbara L. Summers, PhD, RN, FAAN
VP, Nursing Practice and Chief Nursing Officer- University of Texas-MD Anderson Cancer Center

Dr. Barbara Summers is Vice President, Chief Nursing Officer and Head, Division of Nursing at MD Anderson Cancer Center. Dr. Summers has led the creation of new frameworks and models to build an organizational culture that promotes patient-centeredness, healthcare safety and quality, and inter-professional collaboration. Her passion for and commitment to excellence includes sustaining highly reliable, patient-focused systems of care. She serves on the Board of Directors of the Institute for Interactive Patient Care, an organization dedicated to empowering patients and improving health outcomes through direct patient engagement.

Dr. Kalahn A. Taylor-Clark, PhD, MPH
Director, Health Policy- The National Partnership for Women & Families

Dr. Kalahn Taylor-Clark currently serves as the Director of Health Policy at the National Partnership for Women and Families. Her primary responsibilities are in shaping and implementing the policy agenda for the National Partnership's major initiative, the Campaign for Better Care, as well as providing strategic policy support on a range of activities related to delivery system reform, including payment reform, quality measurement, reduction of health disparities, consumer engagement, and promotion of patient-centered care delivery and the effective use of health information technology. Prior to joining NP, she led the Patient-Centeredness and Health Equity Portfolio in the Engelberg Center for Health Care Reform at the Brookings Institution.

Dr. Mary Tinetti, MD
Professor of Medicine and Epidemiology, Yale School of Medicine

Dr. Tinetti is the Gladys Phillips Crofoot Professor of Medicine and Epidemiology at Yale School of Medicine and Chief of the Section of Geriatrics. She was the first investigator to identify that older adults at risk for falling and injury could be identified, that falls and injuries were associated with a range of serious adverse outcomes, and that multifactorial risk reduction strategies were effective and cost-effective. She is involved in efforts to

translate these research findings into clinical and public health practice. Her current research focus is on clinical decision-making for older adults in the face of multiple health conditions, particularly trade-offs among health conditions and the harms and benefits of commonly recommended treatments.

Ms. Phyllis Torda, MA
Vice President, Quality Solutions Group- National Committee for Quality Assurance

Phyllis Torda is the Vice President for Strategy and the Quality Solutions Group at NCQA. She leads strategic planning for the company and its consulting arm, which provides services to the federal and state governments. In her 15 years at NCQA, she has led a wide variety of activities related to performance measurement and reporting. She is the principal investigator for NCQA's contract with CMS to develop performance measures for the Medicare population and to evaluate Medicare Special Needs Plans. She also leads the development of measures of inpatient psychiatric care and cancer care for CMS. Ms. Torda has participated in development of the CAHPS surveys since the inception of that AHRQ initiative.

Dr. John Wasson, MD
Emeritus Professor, Dartmouth Medical School

Dr. John Wasson is Emeritus Professor of Community and Family Medicine and Medicine at Dartmouth Medical School. He is Associate Director for the Center for the Aging and is a member of The Dartmouth Institute Patient-reported Measure (and Information) Trust. He represents a research team working at The Dartmouth Institute's Patient-reported Measure (and Information) Trust. This team is committed to collaborative development and testing of patient-reported measures. This team also plans to make publically available the best patient-reported measures for health care. He has participated in the development and reliability testing of several patient-reported measures with a particular focus on functional status and patient experience reporting.

Dr. Robert Weech-Maldonado, PhD
Professor and Chair- University of Alabama at Birmingham

Robert Weech-Maldonado, PhD is Professor and L.R. Jordan Endowed Chair in the Department of Health Services Administration, University of Alabama at Birmingham. Dr. Weech-Maldonado is an organizational researcher who examines the impact of cultural competency strategies in reducing disparities in quality and access to care. He is currently the PI in the Patient Assessments of Cultural Competency (PACC) project, where he is developing and testing patient-centered measures of cultural competency. In another project, he developed and tested the Cultural Competency Assessment Tool for Hospitals (CCATH), an instrument that assesses hospital's adherence to the Cultural and Linguistic Appropriateness Services (CLAS) standards.

Ms. Linda Wilkinson, MBA
Coordinator of Patient and Family Centered Care, Dartmouth Hitchcock Medical Center

Ms. Wilkinson is Coordinator of Patient and Family Centered Care at Dartmouth-Hitchcock on D-H's Value Measurement, Quality and Patient Safety team. She helps design and implement strategies and initiatives to support institution-wide Patient/Family Centered Care practices. She builds liaisons with clinicians, staff, management and communities to assure direct engagement of volunteer patients and family members in policy and process design, from planning to co-production of care. Wilkinson manages the recruitment, training and supervision of Patient/Family Advisors (PFAs) who become working partners with professionals throughout the D-H system to assure the patient perspective of the health care experience is an integral part of D-H's planning process.

Dr. Albert Wu, MD, MPH
Professor- Johns Hopkins Bloomberg School of Public Health

Dr. Wu is a practicing general internist, Professor of Health Policy and Management, Director of the Center for Health Services and Outcomes Research (CHSOR) at the Johns Hopkins Bloomberg School of Public Health, and Director of the DEcIDE center for comparative effectiveness research. His research and teaching focus on patient reported outcomes and quality of care. He was the first to measure the quality of life impact of antiretroviral therapy in HIV clinical trials, and has developed and tested many widely-used PRO measures. He has applied PROs as performance measures for the care of asthma and other chronic conditions. He was President of the International Society for Quality of Life and has authored over 300 peer review publications.

NATIONAL QUALITY FORUM

Patient-Reported Outcomes Workshop
July 30-31, 2012
Workshop Participants (On-Site)

Baranowski, Rebecca
American Board of Internal Medicine

Bershadsky, Julie
Human Services Research Institute

Berzon, Rick
National Institutes of Health

Blum, Steven
Forest Research Institute

Chang, Victor
VA New Jersey Health Care System/ UMDNJ

Cotter, Frances
Substance Abuse and Mental Health Administration

Dailey, Maureen
American Nurses Association

DeSoto, Mia
AHRQ

Deutsch, Anne
RTI International

Diamond, Louis
QHC

Doermann Byrd, Katherine
American College of Cardiology

Faerberg, Jennifer,
AAMC

Gage, Barbara
The Brookings Institution

Garfinkel, Danielle
RTI International

Giovannetti, Erin
National Committee for Quality Assurance

Hinds, Pamela
Children's National Medical Center

Ireland, Andrea
NCQA

James, Tom
Humana

Kelleher, Cindy
RTI

Keller, San
American Institutes for Research

Kennedy, Cille
DHHS/ASPE

Lentz, Lisa
CMS

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Workshop Participants (On-Site)

Mabry-Hernandez, Iris
AHRQ

Makadia, Preyanka
Agency for Healthcare Research and Quality

Mastanduno, Melanie
The Dartmouth Institute for Health Policy & Clinical Practice

McGuinn, Kristyne
American College of Cardiology

McNiff, Kristen
American Society of Clinical Oncology

Mitchell, Sandra
National Cancer Institute

Moon, JeanHee
Children's Hospital of Philadelphia

Moore, Jennifer
Agency for Healthcare Research & Quality

Patawaran, Wally
The John A. Hartford Foundation

Petrillo, Jennifer
Novartis

Riley, William
National Cancer Institute

Ross, Clarke
American Association on Health and Disability

Rubin, Koryn
American Association of Neurological Surgeons

Servies, Tammy
Uniformed Services University of the Health Sciences

Suarez, Monica
George Washington Internal Medicine Residency

Teschendorf, Bonnie
Adelphi Values

Tonkins, Phil
NIH/NIAMS

Wright, Lacey
Agency for Healthcare Research and Quality

Yang, DerShung
BrightOutcome Inc.

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Workshop Participants (Off-Site)

Aravamudhan, Krishna
Dental Quality Alliance

Asher, Anthony
American Association of Neurological Surgeons

Bilimoria, Karl
Northwestern

Brill, Joel
American Gastroenterological Association

Chang, Chih-Hung
Northwestern University Feinberg School of Medicine

Charlifue, Susan
Craig Hospital

Chauhan, Cynthia
Mayo Clinic Breast SPORE

Chen, Christine
Pacific Business Group on Health

Chisolm, Deena
The Research Institute at Nationwide Children's Hospital

Chiu, Jensen
American College of Cardiology

DeMark Neumann, Holly
Rehabilitation Institute of Chicago

Destefano, Alicia
Merck

Edwards, Todd
University of Washington

Gruber-Baldini, Ann
University of Maryland School of Medicine

Haas, Niina
BrightOutcome, Inc

Hagan, Eileen
American College of Cardiology

Han, Jane
The Society of Thoracic Surgeons

Harder, Joel
SCAI

Heinemann, Allen
Rehabilitation Institute of Chicago

Jalundhwala, Yash
UIC

NATIONAL QUALITY FORUM

Patient-Reported Outcomes Workshop
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Workshop Participants (Off-Site)

Jensen, Sally
Northwestern University

Jewell, Kay
Tara Center LLC

Kidin, Lisa
UT MD Anderson

Ko, Clifford
American College of Surgeons

Lai, Jin-Shei
Northwestern University

Lepore, Michael
Planetree

Lewis, Barbara
Regeneron Pharmaceuticals, Inc

Maddux, Suzanne
ASCO

Matheson, James
EIP Consulting

McGonigal, Lisa
KCP

Miller, Lesley-Ann
GlaxoSmithKline

Myslinski, Rachel
American College of Rheumatology

Otte, Diane
Mayo Clinic Health System - Franciscan Healthcare

Shahriary, Melanie
American College of Cardiology

Spinks, Tracy
MD Anderson Cancer Center

Swain-Eng, Rebecca
American Academy of Neurology

Tavernier, Susan
University of Utah

Tobin, Judith
CMS

Whiteneck, Gale
Craig Hospital