NIH Collaboratory Rethinking Clinical Trials™
Health Care Systems Research Collaboratory

Challenges and Opportunities for the Use of NIH-supported PRO Tools in Comparative Effectiveness Research

Proceedings from the NIH Health Care Systems Research Collaboratory Patient-Reported Outcomes Core Workshop

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Executive Summary

Although standardized, validated tools exist to gather data on patient-reported outcomes (PROs) for both clinical care and research, significant barriers persist in the incorporation of these measures into routine clinical care, making them unavailable for later comparative effectiveness research or pragmatic clinical trials. To address these barriers and improve the availability of research-ready PRO data in electronic medical record systems, representatives from the National Institutes of Health (NIH) Health Care Systems Research Collaboratory PRO Core gathered a group of clinician-scientists, PRO methodologists, psychometricians, representatives from NIH and FDA, and a patient representative (Appendix A) for a workshop in Baltimore, MD on January 8–9, 2015. During the workshop, participants described case studies and lessons learned from their home institutions for implementing PRO measures into care, and working groups considered barriers to incorporating PROs into routine care and how the barriers might be addressed.

Case Studies

Investigators presented case studies from the Patient Centered Outcomes Research Network Initiative (PCORnet), including 1) Vanderbilt University's use of PROs in the Mid-South Clinical Data Research Network (CDRN) and 2) the patient-powered research network (PPRN), Crohn's and Colitis Foundation of America (CCFA). Other case studies included 3) the Cincinnati Children's Hospital Medical Center, and 4) the NIH Healthcare Systems Collaboratory demonstration project, Collaborative Care for Pain in Primary Care (PPACT). Some components of successful PRO implementation included: buy-in from stakeholders, a quality improvement framework, a multidisciplinary governance team, and adequate training. Innovation is needed to enhance multimodal support, account for confounders, and enhance clinical utility. Examples of innovative approaches to the collection of PROs include the creation of apps to determine patient eligibility and direct users to surveys, where patients can choose to consent to participate, and patient portals that allow patients to upload and sync data from devices.

Barriers and Solutions

The meeting participants agreed upon a framework for categorizing barriers and solutions to the integration of PROs within the healthcare system. Workshop participants broke into three groups to consider these barriers and their potential solutions. Regarding the decision of healthcare systems, clinics, or individual clinicians to collect PROs, barriers include lack of leadership and financial support, inadequate IT resources, lack of clinician support and uptake, and insufficient messaging. Some corresponding solutions include demonstrating return on investment, tying PROs to performance indicators and/or reimbursement, and use of provider and patient champions (Appendix B).

With respect to barriers associated with domain and instrument selection, there are differences across therapeutic areas regarding which domains are considered important, uncertainty of how to incorporate PRO scores into clinical decision-making, and overall too many different measures being used in the field, including some poor quality instruments. Other issues included cultural/linguistic challenges, and adaptability of measures to support both clinical care and high-quality research endpoints. Solutions to these problems

included stakeholder engagement in adopting a universal set of domains, creation of measurement approaches that use brief screening items that can trigger more precise multi-item assessments where appropriate, use of PROMIS measures or others from item banks, and use of PROsetta Stone (a tool that provides equivalent scores for different scales that measure the same health outcome) and funding for additional cross-walk studies.

The barriers to PRO implementation and data collection include a lack of buy-in and value proposition from multiple stakeholders, gaps in IT infrastructure, workflow coordination issues, regulatory and ethical issues, as well as limiting patient factors, such as low literacy. Social and economic incentives from payers and others could boost buy-in from stakeholders. To address infrastructure issues, institutions like the NIH, or the Office of the National Coordinator for Health Information Technology (ONC) could push for a common language for data recording. Regulatory and ethical issues could potentially be resolved by developing guidance documents and protocols for clinic integration, as well as for Institutional Review Boards and informed consent, depending on the use case.

Stakeholders

Stakeholders will be critical to addressing these challenges (Appendix C). Administrators, clinicians, NIH, patient advocates, and even companies that have been successful at creating marketing tools (e.g. Starbucks) are partners who may help obviate some of the barriers. For example, the hospital administrator is a key decision maker for whether a healthcare system will collect PROs and may be more inclined to use PROs if they contribute to the financial health of the institution, are in line with the institution's mission, and do not incur legal liability. Clinicians will support PRO data collection if it saves time, doesn't interfere with clinic workflow, and improves quality of care. Patients will agree to complete PROs if they understand that the data will be used for their care, will enable them to track their progress, and will inform on how they compare to others with similar conditions.

Next Steps

Next steps for the NIH Collaboratory PRO Core include disseminating the results from this workshop in the form of a white paper (the present document) that will be available on the NIH Collaboratory website at https://www.nihcollaboratory.org/Pages/Knowledge-Repository.aspx. The PRO Core is also discussing opportunities to engage stakeholders in future workshops, Collaboratory Demonstration Projects, and future publications.

Introduction

Patient-reported outcomes (PROs) are outcomes that are reported by the patient and are typically referred to as "outcomes that matter to patients," such as health-related quality of life. Standardized, validated tools for collecting PROs are freely available (Table 1), but these research-ready measures have not yet been widely incorporated into electronic medical records (EMR). The National Patient Centered Resource (PCAR) was recently developed to support and enhance the use of four NIH-sponsored measurement systems (Table 1) and to provide an integrated platform for automated use of these systems.

However, significant barriers to incorporating PROMIS and other measurement systems exist in real-world clinical scenarios. To address these barriers and improve the availability of research-ready PRO data in EMR systems, representatives from the National Institutes of Health (NIH) Health Care Systems Research Collaboratory PRO Core gathered a group of clinician-scientists, PRO methodologists, psychometricians, federal representatives from NIH and FDA, and a patient representative (Appendix A), for a workshop at the Marriott Waterfront Hotel in Baltimore, MD on January 8-9, 2015. During the workshop, participants with experience incorporating PRO data collection into planned clinical research and/or patient care were invited to describe case studies of their processes and lessons learned. Speakers presented on patient perspectives and crosscutting themes, including measuring PRO domains, selecting PRO measures, and informatics issues with PRO collection. Working groups were assembled to consider the following questions: where in the process are the barriers; what is the nature of the barrier; how can this barrier best be addressed; and who is best positioned to address it?

This white paper will briefly summarize the case studies, patient perspective, and cross-cutting issues, as well as to delve into the barriers and strategies for addressing barriers

Table 1. Standardized, Validated Tools for Collecting PROs

Name	Acronym	Domain	Funding Source
Patient Reported Outcome Measurement Information System	PROMIS	Health-related adult and pediatric measures	NIH Common Fund
NIH Toolbox for the assessment of neurological and behavioral function	NIH Toolbox	Cognitive, emotional, motor, and sensory function	NIH Blueprint for Neuroscience Research
Neuro-QOL: Quality of life in neurological disorders	Neuro-QOL	Health-related quality of life (HRQOL) of adults and children with neurological disorders such as stroke, multiple sclerosis, amyotrophic lateral sclerosis, Parkinson disease, epilepsy, and muscular dystrophy	National Institute of Neurological Disorders and Stroke
Adult Sickle Cell Quality of Life Measurement Information System	ASCQ-ME	HRQOL instrument for adults with sickle cell disease	NIH/National Heart, Lung, and Blood Institute (NHLBI) initiative

Case Studies

During the first day, investigators who conduct research studies and collect PRO data within healthcare systems were invited to share their experience with integrating PROs into clinical practice and the EMR.

Implementation of Patient-Reported Outcomes in a Pediatric Health System

Dr. Esi DeWitt discussed the process of PRO implementation at Cincinnati Children's Hospital Medical Center (CCHMC). Along with the processes for selecting domains and measures, workflow, and data collection, she outlined some of the technical aspects of data collection and offered some lessons learned.

Briefly, CCHMC uses PROs as a measure of quality of care in three areas: medical and quality of life outcomes, patient and family experiences, and value. When clinics decide to collect patient reported outcomes at CCHMC, a PRO specialist meets with the team to assess their readiness, identify the outcomes they want to measure, and determine their experience with PROs. The specialist helps the team select the most appropriate measures, which are specifically tailored to the needs and mission of the clinic. These proposed measures are then sent a multidisciplinary Patient Reported Outcomes Governance Committee, consisting of psychometricians, clinician researchers, and experts in IT and Quality Improvement (QI) for final approval.

As a not-for-profit hospital, CCHMC oversees clinical divisions that have implemented PROs in order to monitor whether the system is operating with high reliability and can be used to measure performance. A quality improvement framework underpins the program, and there are several metrics for quality improvement in place. Clinics using PROs employ QI tools to guide improvements, for example, key driver diagrams are used to document specific and measurable aims, factors related to achieving the aims ("key drivers"), and planned interventions. A 90% completion rate is desired to report data that can be considered representative.

Lessons Learned

The following were key components of successful PRO implementation:

- Institutional buy-in on PRO use
- A quality improvement framework that underpins the program
- A multidisciplinary PRO Governance team in place
- PRO instrument appraisal with periodic monitoring of performance metrics and process for intervening
- Training providers and patients in PRO use and interpretation is a recognized gap

Patient-generated Health Data Case Study: Vanderbilt University, PCORnet Mid-South CDRN

Dr. Sunil Kripalani presented data on Vanderbilt's use of PROs for research through the Mid-South Clinical Data Research Network (CDRN), which is part of the Patient Centered Outcomes Research Network Initiative (PCORnet), and the challenges of using an in-house

EHR system. Mid-South is using the EMR to identify patients with coronary heart disease via billing and procedure codes. Eligible patients are recruited to participate in a 57-item healthy weight survey. The survey covers over 23 domains, ranging from symptoms to health literacy.

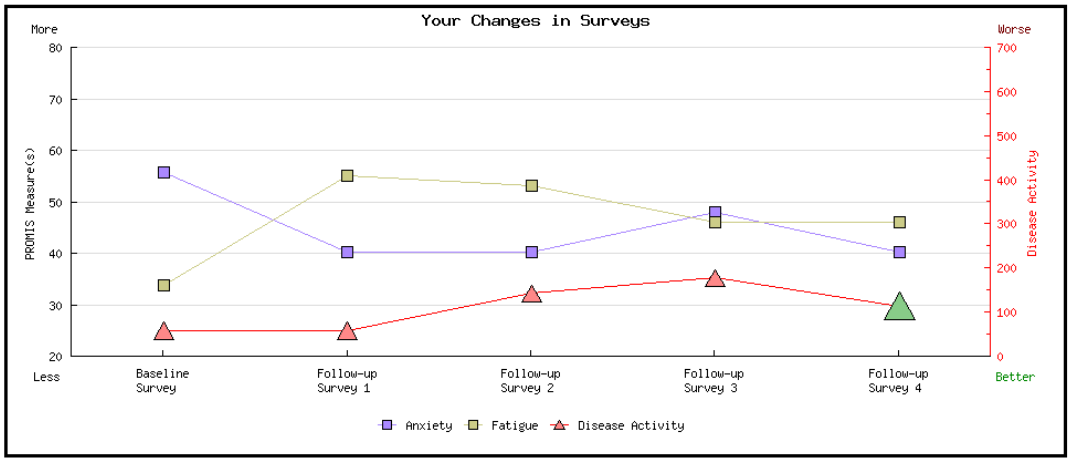
Having a number of different modes of data collection available (paper, tablet, phone, etc.) has helped minimize missing data, especially among individuals with low literacy and older populations. Impediments to data collection include disruptions to workflow and a high dependence on clinic staff to assist patients with assessments, although having clinic staff briefly introduce the survey has helped with recruitment. An app was developed to determine patient eligibility and automatically direct users to a REDCap survey, where patients can choose to consent to participate.

Selection and Use of Patient-Reported Outcomes in a Patient-Powered Research Network

Dr. Michael Kappelman presented PRO activities being conducted as part of the Crohn's and Colitis Foundation of America (CCFA) Partners PCORnet Patient Powered Research Network (PPRN).

CCFA Partners is an Internet-based cohort of patients with inflammatory bowel disease (IBD). Participants complete web-based surveys on exposures (e.g., medications, smoking), health behavior (e.g., diet, medication adherence), and outcomes (e.g., pain, gastrointestinal symptoms). CCFA Partners uses a combination disease-specific and generic instruments for these assessments. PROs are selected by clinician researchers with input from methodologists, then reviewed and modified by a Patient Governing Committee and harmonized to PCORNet Common Data Models where appropriate. Research findings are returned to patients in the form of lay summaries and infographics. Additionally, individual-level PRO data are returned to participants in a variety of graphics (e.g. charts and dashboards) that display fatigue and other outcomes scores with trends over time and show comparisons to similar patients (Figure 1).

Figure 1: Patient Trends over Time.



Dr. Kappelman's team is currently testing a new patient portal that will allow patients to upload and sync data from devices (e.g., fitbit, fuelband). Linked with data in EMR, these PRO data could be used for future observational studies as well. The group is also conducting qualitative interviews with patients to determine which PROs they think would best contribute to self-tracking and patient-provider communication tools.

Use of PROs in the Primary Care Setting to Support Care for Patients with Chronic Pain on Long Term Opioid Therapy.

Dr. Lynn Debar is the Principal Investigator for the Collaborative Care for Pain in Primary Care (PPACT), a National Institutes of Health's Healthcare Systems Collaboratory demonstration project. She discussed the routine use of PROs in primary care. She highlighted the dangers of opioid overmedication, and touted the importance of PROs in the management of chronic pain. Kaiser Permanente has an initiative to improve safety in pain management that includes using PROs to assess pain.

PRO adoption at Kaiser Permanente, in particular, is often driven by regulatory and safety concerns ("stick") rather than clinical utility ("carrot"). Kaiser Permanente has historically used the Brief Pain Inventory (BPI) to track patients' pain and assess opioid treatment program "risk" level. When designing the chronic pain study, the team used the legacy BPI rather than adopting a new PRO because the BPI was short, easy to deploy, and familiar to both patients and clinicians. Establishing the BPI as part of routine clinical care was a multi-step process that involved planning, selecting measure length (4 vs. 12 items), obtaining approvals from gatekeepers and other stakeholders; then developing and identifying care gap criteria, implementing the BPI, communicating about issues and results, and monitoring data collection.

Assessing the effectiveness of collecting BPI data online via the personal health record portal and having a process for contacting/reminding patients to fill out the BPI was also important. Unfortunately, the EHR system at Kaiser Permanente is not ideally configured for rendering PRO data accessible to clinicians. Once collected, the PRO data are integrated into the EHR but are entered in a separate charting area, not in the clinic notes. Thus, reviewing BPI data requires an extra step for clinicians.

Lessons Learned

Dr. Debar offered these lessons learned:

- Current PRO adoption is more often driven by "sticks" (e.g., regulatory concerns) than "carrots" (e.g., clinical utility)
- PRO data in EHR (frequency and amount) is often confounded by patient's clinical severity
- Pushing PROs into the EHR to enhance clinical utility is a good goal, but multimodal support may be needed, and current displays limit clinical utility for patients with complex conditions. There is technology available to enhance PRO data displays, but using a system untethered to EMR may not be feasible.

Crosscutting Themes

Three invited speakers, Drs. Albert Wu, Irene Katzan, and James Willig, were asked to present on crosscutting themes on selecting PROs, measuring PRO domains, and informatics issues in PRO measurement, respectively. Additionally, a patient representative, Michelle Carras, was asked to discuss patients' perspectives on PRO collection.

Measuring PRO Domains in Clinical Settings: Needs and Opportunities

Dr. Wu, MD, MPH, is a Professor and Director at the Center for Health Services and Outcomes Research at the Johns Hopkins Bloomberg School of Public Health. In his presentation, he emphasized the role of patient engagement in healthcare, stating that patients and clinicians have the same needs (e.g., staying healthy, getting better, etc.), but that patients have additional needs that need to be met by clinicians, including access to information, communication, engagement in their own healthcare, and autonomy. Patients are interested in their own data and in how they compare to others like themselves. In terms of PROs, patients want to see that the time spent answering the measures will be relevant to them, and they want more control over the questions that they're answering, as well as questions that capture their goals and aspirations. More efficient data collection is more respectful and also gets greater patient engagement. This includes meeting patients' needs by providing different modes of collection (e.g., paper, interview, tablet, etc.), as well as offering PROs in patients' native languages and incorporating family feedback. Clinicians can be resistant to adding activities that require more time, but they want improved patient outcomes. They are most interested in actionable thresholds, panic values, and meaningful changes in scores. While it is currently not standard practice, having PRO data available in the EHR would add great value. However, this availability will require a lot of institutional resources to make the data user-friendly.

Selecting PRO Measures: PROMIS versus Other Alternatives

Dr. Irene Katzan, MD, is the Director of the Center for Outcomes Research and Evaluation at the Neurological Institute at the Cleveland Clinic. In her presentation, she discussed the importance of selecting measures that fit the context of use and of ensuring that collecting a PRO is the most appropriate approach. How the data will be used—clinical care, quality improvement, outcomes analysis or research—will dictate the most appropriate measure. For example, PROMIS measures may be appropriate for outcomes assessment, but another tool might be more appropriate for use in clinical care or screening. In addition, disease-specific domains may have been developed for use in specific populations and may not be appropriate for making comparisons with other populations. Clinician researchers should consider a combination of disease-specific and general domains to maximize the comparative ability of the data. Other important factors to consider when selecting a measure include reliability, validity, and responsiveness; feasibility of collection and patient burden; interoperability and comparability; and comfort level. Dr. Katzan noted that in their experience, PROMIS measures outperformed other measures in terms of psychometrics, ease of collection, interpretability, comparability, and comfort level.

PROs: Informatics and Other Issues

Dr. James Willig, MD, is an Associate Professor at the University of Alabama-Birmingham (UAB) School of Medicine, and he presented on the role of PROs in institutional innovation. At the University of Alabama-Birmingham, routine assessment of PROs has aided both clinical decision-making and research. They have found that a 3:1 ratio of clinically relevant questions to research questions is most effective, and that PROs can help clinicians better identify medication adherence and substance abuse issues.

Some critical aspects to the successful implementation of PROs at UAB include multimodal collection tools, having a person committed to monitoring completion in real time, and having a protocol for addressing areas of concern. The UAB Infectious Disease Clinic uses PROs to trigger interventions. For example, if a PRO reveals suicidal ideation, an established suicide protocol kicks in, and a psychiatrist or other relevant health care provider is paged by the system with little interruption to clinic workflow. Often, the research coordinator and response team has already talked to the patient before the clinician walks in the room. This has led to exploration of evidence-based social work.

Dr. Willig also discussed informatics tools (e.g., apps and tools that provide game-like structures and incentives) that are being developed to enhance participant participation in research and add value to patient care and research. 'SureScripts' is an application in development that helps patients keep track of and share medication lists and that also alerts patients when they have not picked up their prescriptions. Patient and community involvement (e.g., focus groups, etc.) have been useful in helping develop and fine tune these technologies.

Regarding EHR integration, Dr. Willig concluded that the EHR barriers could be overcome by linking the data back into the EHR, and by using a master patient index for the health system.

Patient Perspectives

Michelle Carras (a patient representative) presented an overview of patient perspectives on the value and use of PROs. Patients care about safety, compassionate human interactions, continuity in care, access to meaningful information, patient/clinician partnering, and shared decision-making. Patients want ownership of their data, not just access, and special efforts may need to be made to accomplish this, especially in populations with different cultural backgrounds, socioeconomic status, and literacy levels. Although it will be challenging because of knowledge gaps between patients and researchers, she suggested that patients should be actively involved in the design of clinical research.

Barriers to PRO implementation

The workshop attendees broke into small groups to discuss barriers and possible solutions to PRO implementation. Three working groups were formed to discuss barriers to incorporating PROs into healthcare with regards to the following: 1) the decision to collect PROs; 2) domain/ instrument selection; and 3) PRO implementation and data collection. Each group was again asked to consider the four primary questions that the workshop sought to address, specifically: (1) where in the process are the barriers; (2) what is the nature of the barrier; (3) how can this barrier best be addressed; and (4) who is best positioned to address it for each area in the PRO incorporation process.

All three groups identified several barriers and solutions to integration of PROs with the healthcare system (see Appendix B), as well as stakeholders who would be critical in finding solutions around these challenges (Appendix C).

Group 1 was assigned to discuss barriers to the decision of healthcare systems or clinicians to collect PROs. The group identified several common barriers, including lack of leadership and financial support, the need for additional IT resources, promoting the value of PROs to stakeholders, and engaging patients in the team to facilitate implementation and compliance. The group felt that these barriers could be lifted with appropriate marketing, performance indicators tied to reimbursement, and other motivators (Appendix B).

Group 2 focused on barriers associated with domain and instrument selection. The group felt that the current tendency is to "create your own" instrument, which has led to too many measures in field, bias towards instrument selection and investment in certain instruments, and some poor quality instruments. Other issues included cultural/linguistic challenges, and adaptability of one measurement to support both clinical care and high quality research endpoints. Solutions to these problems included using PROsetta Stone, a tool that provides equivalent scores for different scales that measure the same health outcome. Other solutions involved increased integration of PROMIS measures, providing funding for additional cross-walk studies to put commonly used measures on a standard metric (e.g., t-score), and the development of hybrid measures using brief screening items to trigger more precise multi-item assessments. The group stated that additional funding would be needed to address these issues, as well as greater involvement of patients to help with content validity and feasibility. They also felt that more effort to disseminate the message about PROs was needed, and working with subspecialty societies was a possible solution (Appendix B).

Group 3 listed several barriers to PRO implementation and data collection, including: lack of buy-in and value proposition for multiple stakeholders, gaps in IT infrastructure, workflow coordination issues, regulatory and ethical issues, as well as other patient factors (Appendix B). The group suggested that social and economic incentives from payers (e.g., the Centers for Medicare and Medicaid Services [CMS], professional societies, regulators (e.g., FDA), and others could boost buy-in from stakeholders. To address infrastructure issues, institutions like the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), the Office of the National Coordinator for Health Information Technology (ONC) and others could push for the creation of a common language to record data or ask EMR vendors to accept a common data format. Also, these groups could lead the effort in creating systems that allow for data collection in and out of the clinic, giving patients more options to choose methods that best fit their needs. Regulatory and ethical issues could potentially be resolved by developing guidance documents and protocols for clinic integration, as well as for Institutional Review Boards (IRBs) and informed consent, depending on use case. Workflow issues could be addressed by creating protocols that direct clinic integration; providing consultancy and training to staff; and developing algorithms for how the data are collected to avoid duplication. These algorithms should describe who is in charge of responding to specific issues, conditional on the context, and help determine primary responsibility for providing or designating responsibility. To address patient factors (e.g., literacy, data ownership, etc.), assessing the needs of the patient population and including patients in the design of the study would help overcome some of the barriers.

Depending on the barrier, different stakeholders (Appendix C) are best equipped to address challenges. Congress, the military, and even companies like Starbucks, who have been successful at creating marketing tools, are possible partners who can help remove some of the barriers. The hospital administrator will usually decide whether or not to collect PROs and will be more positive if PROs contribute the financial health of the institution, are in line with the mission, and if legal liability can be avoided. The clinician can make recommendations to leadership and use PROs with their own patients. Clinicians will support PRO data collection as long as it saves time, doesn't conflict with personal interests, improves quality of care, and is able to address patient problems efficiently and effectively. IT groups have a role in encouraging or discouraging recommendations to leadership. Lastly, the patient has a role in deciding whether or not to complete assessments, which will depend heavily on clinician and staff encouragement. Patients will most likely choose to complete PROs if they feel it is a good use of their time, understand that the data will be used for their care, will enable them to track their progress, and will inform on how they compare to others with similar condition

Next Steps

The workshop was very successful in identifying a variety of areas of concern for the integration of PROs into routine clinical care and the EHR [Appendix B]. Stakeholders who could contribute to moving this initiative forward were also identified, including funding institutions like CMS and PCORI, federal organizations (e.g., NIH), as well patients, patient advocacy groups, consumer-based companies (e.g., pharmaceutical) and others in the support for adoption of PROs into the electronic medical record [Appendix C].

Next steps for the NIH Collaboratory PRO Core include disseminating the results from this workshop in the form of a white paper (this document) that will be available on the NIH Collaboratory website at https://www.nihcollaboratory.org/Pages/Knowledge-Repository.aspx. Additional publications are also being discussed. The PRO Core is also discussing opportunities to engage stakeholders in future workshops, Collaboratory Demonstration Projects, and future publications.

Appendix A: Workshop Participants

Name	Affiliation
Susan Bartlett, PhD	Associate Professor of Medicine, Divisions of Clinical Epidemiology, Rheumatology and Respiratory Epidemiology and Clinical Trials Unit McGill University / Royal Victoria Hospital
Leslie Blackhall, MD	Associate Professor of Medicine, General Medicine, University of Virginia
Antonia Bennett, PhD	Research Assistant Professor, Health Policy and Management, University of North Carolina-Chapel Hill
Clifton Bingham, MD	Associate Professor of Medicine; Director, Johns Hopkins Arthritis Center, Johns Hopkins University
Dave Cella, PhD	Director, Center for Patient-Centered Outcomes - Institute for Public Health and Medicine
Susan Czajkowski, PhD	Program Director, Clinical Applications and Prevention Branch, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute (NHLBI)
Michelle Colder Carras, PhD Candidate	Patient representative; PhD Candidate & NIDA Drug Dependence Epidemiology Training Fellow, Johns Hopkins Bloomberg School of Public Health
Lynn Debar, PhD	Senior Investigator, Center for Health Research Kaiser Permanente, NIH Collaboratory Demonstration Project PI (PPACT)
Carrie Dombeck	Project Planner, Duke Clinical Research Institute
Kathryn Flynn, PhD	Associate Professor of Medicine, Medical College of Wisconsin
Richard Gershon, PhD	Associate Professor in Medical Social Sciences and Preventive Medicine-Health and Biomedical Informatics
Carol Greco, MD	Assistant Professor of Psychiatry, University of Pittsburgh
Kimberly Gregory, MD	Vice Chair of Women's Healthcare Quality and Performance Improvement and the Director of the Division of Maternal-Fetal Medicine at Cedars-Sinai.
Roxanne Jensen, PhD	Instructor, Population Sciences, Georgetown University
Laura Lee Johnson, PhD	Food and Drug Administration
Michael Kappelman, MD	Pediatric gastroenterologist, Assistant Professor at University of North Carolina at Chapel Hill School of Medicine
Irene Katzan, MD, MS	Director, Center for Outcomes Research and Evaluation, Cleveland Clinic
Dinesh Khanna, MD	Associate Professor, Department of Internal Medicine; Marvin and Betty Danto Research Professor; Director, Scleroderma Program, University of Michigan
Gregory Kotzbauer	Manager Director, Strategic Technology Initiatives, Dartmouth Institute
Sunil Kripalani, MD, MS	Associate Professor and Chief of the Section of Hospital Medicine in the Division of General Internal Medicine and Public Health, Vanderbilt
Tracie Locklear, PhD	Patient Reported Outcomes Core Project Manager, Duke University
Esi Morgan Dewitt, MD, MSCE	Associate Professor of Pediatrics, Cincinnati Childrens

Name	Affiliation
Bryce Reeve, PhD	Associate Professor, Health Policy and Management, University of North Carolina-Chapel Hill
William Riley, PhD	Acting Director, NIH Office of Behavioral and Social Sciences Research (OBSSR) Chief, Science of Research and Technology Branch Division of Cancer Control and Population Sciences, National Cancer Institute
Claire Snyder, PhD	Associate Professor, Division of General Internal Medicine, Johns Hopkins University
Kevin Weinfurt, PhD	Patient Reported Outcomes Core Leader; Professor in Psychiatry and Behavioral Sciences, Duke University
Ashley Wilder-Smith. PhD, MPH	Program Director in the Outcomes Research Branch of the Applied Research Program, NCI
William Tonkins, Jr, Dr.PH	Division of Skin and Rheumatic Diseases Health Scientist Administrator
James Willig, MD	Associate Professor, Division of Infectious Disease, University of Alabama-Birmingham; PCORnet PRO TF member (AR-PoWER PPRN)
Albert Wu, MD	Director, Center for Health Services and Outcomes Research, Johns Hopkins University

Appendix B: Final List of Barriers to Integrating PROs into Routine Healthcare and Opportunities for Reform

Decision to collect PROs: Barriers*	Solutions

Lack of healthcare leadership and financial support	• Demonstrate return on investment both financially and by improvements in care
	• Tie PROs to reimbursements, performance measures, and the institution's strategic plan, and use PROs to evaluate performance internally.
	• Create/identify champions/advocates within leadership
	• Market successful case studies, present info on needs from patients and from patient advocacy groups
	  o Use corporate models (e.g., Starbucks, Walmart, etc.)
	  o Use pharmaceutical corporate models and examples of doing this
	• Use PROs to prioritize activities and share patient satisfaction ratings
	• Motivate larger systems/companies to develop innovative financial incentives for PRO adoption
	  o Funders and third party payers (e.g., CMS, PCORI)

Lack of clinician support and uptake	• Make PROs part of required performance measures (e.g., quality improvement) and tie to receipt of resources
	• Evaluate and demonstrate how PROs will save clinician time and help direct care. Demonstrate that clinicians will be able to address the problems that they are comfortable with, and other departments will be notified to provide support and care for other concerns.
	• Evaluate and demonstrate how PROs improve patient-physician communication and patient outcomes
	• Educate about value/demonstrate how PROs can assist with pre-visit team planning and trigger additional services (e.g., social work)
	• Provide data on what patients/clinicians want
	• Ensure adequate infrastructure to reduce burden
	• Research data mining, new data generation
	• Collaborate with partners to take next steps
	  o Graduate medical organizations (e.g., the Association of American Medical Colleges [AAMC])
	  o Patient advocacy groups
	  o Funders
	  o Continuing professional education and professional organizations

Insufficient budget for IT support of high quality PRO integration/Identifying and providing appropriate IT/Informatics resources; IT bottleneck due to lack of professionals	• Create process for disseminating lessons learned
	• Share budgets, protocols, security and other documents
	• Recruit high level technical assistance when developing system
	• Collaborate with partners to take next steps
	  ○ Incorporate funders and vendors into discussions
	  ○ American Medical Informatics Association (AMIA)
	  ○ Bring IT/Informatics community to the table
	  ○ Incorporate public health informaticists

Insufficient messaging ("spreading the word")	• Better, faster dissemination of message (e.g., YouTube, social media, etc.)
	  ○ Use resources like PatientsLikeMe as outlets for messaging
	• Academic detailing
	  ○ Use models developed by pharmaceutical companies
	• Engaging patients in PRO collection and use
	  ○ Use social media to engage patients, but pay attention to framing

Selecting Domains: Barriers	**Solutions**
Reconciling differences among domains that are (1) important for evaluating benefit/harm in research, (2) providing care, (3) respecting what patients feel are important to report	• Have major stakeholders participate in design/selection of domains
Perception from clinicians that domains are only important if federal partners (e.g., FDA) or other stakeholders think they are important	

Gaining acceptance of a universal set of domains	• Up-front stakeholder engagement in adopting a universal set recommended by the Collaboratory
	  ○ Role for PCORI and Collaboratory leadership, the Office of the National Coordinator for Health Information Technology (ONC), Agency for Healthcare Research and Quality (AHRQ),
	  ○ CMS can require PROs for Medicare Current Beneficiary Survey (MCBS)
	  ○ Society of Behavioral Medicine (SBM)/ National Cancer Institute (NCI) can make recommendations for general practice
	• Communicate that local PROs are not the future
	  ○ Hold stakeholder summits to promote need for a universal set of domains (ex. Pulmonary summit with NIH/National Heart Lung Blood Institute [NHLBI])

Getting agreement required for disease-specific (add-ons)	• Solicit feedback from societies, foundations, etc.
Pushback on choice	• Target messaging that explains why some domains are better for certain settings and how to use disease-specific domains • Demonstrate value and return on investment (ROI) versus burden on patients and provider
Selecting Instruments: Barriers	**Solutions**
Clinicians don't want to compare patients to general population	• Generate disease-specific reference values and use in display of scores
Finding single measurement approach that simultaneously supports both analysis of high-quality research questions and clinical care (e.g., monitoring patient status and screening for follow-up)	• Create hybrid measurement approach using brief, single-item screening items that can trigger more precise multi-item assessments
Lack of resources (e.g., staff, etc.) to adopt or incorporate new or different instruments	• Show data that support superiority of new measures [REFERENCE IRENE's criteria]
Clinician's comfort level with preferred instruments over alternative ones	• Incorporate co-calibration or other linking methodologies to permit translation to common metrics
Availability of instruments in multiple languages	• PROMIS integration ○ Adoption of PROMIS international measures
Uncertainty of how to incorporate PRO scores into clinical decision-making/feeling that scores are not clinically actionable	• Research is needed to derive estimates of meaningful changes (e.g., "panic values" etc.) • Research is needed to demonstrate effect of integrating PRO-based decision-making algorithms into care
Proprietary measures are not in public domain, have associated extra costs, and introduce an extra legal step	• Use existing public-domain measures • Develop new public-domain measures
Response categories are not meaningful/friendly to patients	
Different measures of same domain in use across different clinics and across time	

Too many choices for instruments	• PROsetta Stone, cross-walk studies to common metric (t-score), empower people to keep their instrument of choice
Packaging	• Design dashboards and create thresholds for clinical utility ○ Funding Opportunity Announcement (FOA) needed

Bad/inappropriate instruments	• Use instrument recommendations provided by Medical Outcomes Trust on 8 attributes on quality measures/ COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN)/International Society for Quality of Life Research (ISOQOL)
	  ○ Messaging and collaborating with subspecialty societies
	  ○ Patients can help ensure content validity and feasibility

Criterion values	
Implementation, Collection and Maintenance of PROs: Barriers	**Solutions**
Low response rate	• Offer various modes of data collection • Offer solutions depending on purpose of data collection (e.g., integration into care)
Insufficient resources available to integrate into care	
Workflow disruption	• Tailor collection to specific group • Integrate collection into EHR • Develop guidance for how to integrate into clinic • Provide consultancy function/train the trainer • Develop algorithms for how the data are collected to avoid duplication • Develop algorithms for who is in charge of responding, conditional on the context. Identify a primary responder
Redundancy of questions	
Unhelpful data display (clinicians and patients)	

Lack of buy-in/value proposition	• Create incentives by providing evidence of value and demonstrating meaningful use
	  ○ This can be led by professional societies with payers and regulatory bodies to create incentives
	• Automate to create efficiencies and decrease impact on workflow
	  ○ This can be led by IT companies and private industry

Infrastructure limitations	• Create common language to record data
	• Ask EMR vendors to accept data format
	  ○ Vendors and Office of National Coordinator are best suited to do this
	• Create systems that allow for collection in and out of clinic
	• Give patients capability to choose the option that is helpful for them
	• Consider efficiencies of centralized resources
	  ○ Creating centralized resources could be job of vendors.
	  ○ Agency for Healthcare Research and Quality (AHRQ) can lead in development of decision-making and research tools
	• Apply best-practice information for data presentation

Regulatory/Ethics Issues	• Develop guidance for Institutional Review Boards (IRBs) and informed consent, depending on use case
Patient factors (e.g., low literacy)	• Determine and address population needs ○ These issues are best addressed by patient champions/patient advocate groups and the IT community

Appendix C: Stakeholder Best Equipped to Address Challenges

Stakeholder	Rationale
Hospital administrator	The hospital administrator ultimately makes the decision to collect PROs and will do so if PROs contribute the financial health of the institution, are in line with the mission, and if legal liability can be avoided.
Clinician	The clinician can make recommendations to leadership and use PROs with their own patients. Clinicians will support PRO data collection as long as it saves time, doesn't conflict with personal interests, improves quality of care, and helps address patient problems efficiently and effectively.
IT	IT groups have a role in encouraging/discouraging recommendation to leadership. Example: Researchers from the American Medical Informatics Association and public health informaticists can be brought together to discuss needs and opportunities for addressing IT limitations
Patient	The patient has a role in deciding whether or not to complete assessments, and participation will depend heavily on clinician and staff encouragement. Patients will most likely choose to complete PROs if they feel it is a good use of their time. They need to understand that the data will be used for their care, give them ability to track their progress, and help them learn how they compare to others with similar conditions
Financial partners/Funders and third party payers (e.g., CMS, PCORI)	Providing financial incentive for adoption of PROs, promotion of EMR integration
Corporate models (e.g., Safeway, Starbucks, Walmart, Aetna)	Can serve as examples of best methods of marketing products to consumers
International regulatory groups	
Military/VA system	
Vendors	Provide leadership in EMR integration
Patient advocacy groups and patient champions	• Reduce barriers in HCS and clinician leadership support • Assist with publicity and engagement of patients via social media. Example: PatientsLikeMe

Stakeholder	Rationale
Congress/Lobbyists	
State-sponsored organizations (e.g., public health)	
Graduate medical organizations (e.g., AAMC)/Professional organizations/Continuing education	
Organizations/Continuing education	Assist with clinician leadership support
Big Pharma/Medical product industry	Use as models for disseminating information about PROs