PCORI Patient-Reported Outcomes (PRO) Infrastructure Workshop
"Integrating PROs into EHRs" Atlanta, November 19-20, 2013

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Executive Summary

The Patient Centered Outcomes Research Institute (PCORI) and the PCORI Methodology Committee hosted a Patient Reported Outcomes (PRO) Infrastructure Workshop on Integrating PROs into Electronic Health Records (EHR) on November 19-20, 2013. The workshop focused on developing an action plan for enhancing the use of PROs for clinical care, research and performance measurement. Meeting participants included patients, clinicians, researchers, health system leaders, IT experts, policy makers, and other key stakeholders. The meeting format was panel presentations, focused on the integration of PROs into EHRs each with a question and answer period, breakout sessions on cross cutting issues including take away messages, barriers, facilitators and opportunities/challenges.

The opening presentation by Dr. Albert Wu and a team from the Johns Hopkins Bloomberg School of Public Health summarized a landscape review developed in preparation for the meeting, entitled "Advances in PRO Measurement in the Electronic Health Record." (Landscape Review). The review featured leading applications from Dartmouth, the Cleveland Clinic, Kaiser Permanante and Epic Systems Corporation. It enumerated barriers to inclusion of PROs in EHR at the patient, clinician and institutional level, and proposed elements of PRO measures and EHR systems that would benefit from high-level harmonization. Seven panels followed.

Panel #1 was on the value of using PROs in EHRs. Important take away points included that patients are interested in their own data and how they compare to other "patients like me" and that PRO data should include outcomes that patients experience as meaningful. They need help with interpreting the results and appreciate tracking them over time. Currently there are some structural and policy barriers to real-time patient access to their own records. Consumer standards for data output could be helpful.

Panel #2 was on regulatory and quality drivers of PRO use. Federal policies are already in place, such as Meaningful Use, the National Quality Strategy and the FDA's PRO Guidance that can help provide a strategy for PRO based measure development. There are notable gaps in the availability of PRO measures and PRO performance measures, as well as gaps in evidence and experience for using PROs to support quality measures. There is substantial variability in strategies for measure development and selection. The problem of missing data is important with PROs, particularly to follow up on patient outcomes.

Panel #3 was on clinician and patient use of PRO data through EHRs. More thorough EHR integration allows greater usefulness. Attention is needed to incorporate PRO data collection and use into the clinical workflow. It is important for both patients and clinicians to see clear and immediate clinical relevance of PROs. The optimal ways of presenting data to patients and clinicians still need to be determined.

Panel #4 was on integration of research, clinical care and quality. In the best cases, PRO data collection can simultaneously help drive research, improve practice, and increase the population health focus in clinical practice. Patients need to be involved in developing best practices for PRO data collection and use. Although PRO measures may be used in clinical care, research and quality improvement, there may at times be different requirements for the different purposes.

Panel #5 was on research use of PRO data from EHRs. Selecting the right questions and instruments to use benefits from broad consensus that involves multiple providers and patients and actual testing of alternatives. Since primary care patients have multiple areas of need, capturing multiple domains is important. Obtaining acceptable response rates is likely to require providing multiple options for responding to PRO measures, and systematic follow up efforts. Both technical and sociocultural elements are required to integrate PROs into EHRs.

Panel # 6 was on current practice and future possibilities. It was noted that we cannot deliver outcome-based therapy if we do not systematically assess our outcomes. This will also require measurement of positive aspects of health including strength and asset measures. Senior leaders need to understand and support the underlying conceptual frameworks for routine measurement. There are efforts by existing taskforces and groups, such as PCORNet, that can help to accelerate progress.

Panel #7 was on successful models of "scaling up" PROs. There are examples of successful efforts in both integrated and non-integrated health care delivery systems. Physician engagement is important to scaling up. There is also the potential to spread PRO data collection into community based settings. Standardization is needed to facilitate consolidation of data from multiple locations.

Major breakout sessions covered issues related to Patients and PRO data, Clinical Use of PRO data, and Research and Quality Measurement uses for PRO data. Final recommendations fell into areas for Infrastructure/Shared Resources, Methods, and Health Systems.

A. Recommendations for Infrastructure/Shared Resources

A.1. Establish a PRO-specific library, providing detailed information on a core set of measurement considerations geared to both clinical and research applications for commonly-used PRO measures.

A.2. Develop educational materials to guide PRO measure selection, with specific attention to considerations facilitating electronic health record (EHR) integration (e.g., electronic format currently available).

A.3. Identify opportunities to develop recommendations guiding PRO implementation in EHR systems in collaboration with stakeholder groups (patients, NQF, FDA, CMS, etc.).

A.4. Develop and evaluate training of clinicians, patients and stakeholders on the implementation, use and interpretation of PROs in multiple clinical and research settings.

A.5. Develop interoperable open data platforms and web tools that can interface with EHRs, to encourage standardized large-scale PRO assessment and evaluation across many health care systems (including non-integrated health care delivery systems).

A.6. Establish minimum standards for PRO measure development, use and interpretation.

A.7. Develop PRO measurement sets that serve multiple needs in multiple settings.

A.8. Identify and establish processes for the qualification of measures important in regulatory review of new treatments or diagnostics.

A.9. Address human subjects protection and privacy needs for patients and all PRO users.

B. Recommendations for Methods

B.1. Conduct clinical trials and observational studies to establish the value of PRO data to support clinical care actions, quality measurement and comparative effectiveness research.

B.2. Determine patients' and clinicians' awareness of PRO data and expectations for its use in clinical decision-making.

B.3. Develop PRO calibration methods that allow cross-walking and score interpretation across different PRO measures.

B.4. Promote research to determine best practices in establishing clinically meaningful differences, to aid PRO reporting and interpretation.

B.5. Compare and evaluate current methods to elicit individual patient preferences and goals regarding the elicitation, trajectory and identification of clinically-relevant, goal oriented actions.

B.6. Develop and implement standards for collection, storage, reporting and transmitting PRO data. Standards should include guidelines for optimizing response rates and handling missing data.

B.7. Identify methods to match PRO measures to identified needs (e.g., for management of multiple conditions).

B.8. Develop PRO data collection options that include patient caregivers and their social network.

B.9. Identify and evaluate potential data validity concerns due to electronic web-based administration (e.g. response bias, multiple log-ins per assessment, use of N/A or Missing fields).

B.10. Design methods to integrate PRO data, other patient-reported information and structured clinical data to facilitate health care decision-making.

B.11. Demonstrate the measurement equivalence of PROs in multiple languages and modes of administration.

C. Recommendations for Health Systems

C.1. Identify needs for PRO data by target audience (patients, clinicians, health systems, purchasers, payers).

C.2. Demonstrate the value of database linkages (e.g., EHR, claims data) incorporating PROs in the evaluation of clinical care, comparative effectiveness research, and research applications.

C.3. Evaluate payment models for PRO data collection and use in collaboration with payer organizations.

C.4. Demonstrate usefulness of combining and reconciling PRO and clinical EHR data to conduct quality of care assessment and promote quality improvement activities.

C.5. Develop and evaluate training materials to educate patients and clinicians on the value of PROs and the patient-perspective for clinical care and research.

C.6. Evaluate approaches to provide patients access to and use of their own self reported PRO data.

C.7. Design optimal clinical workflow and procedures that incorporate PRO data for patient management, including those with multiple comorbidities.

C.8. Develop and evaluate the effectiveness of PRO score automation (response mapping) in clinical settings, including who acts on specific data elements.

C.9. Establish standard actionable thresholds for clinical meaningfulness and related actions for commonly assessed PRO domains.

C.10. Demonstrate the role of PRO in a learning health system.

In the final session of the meeting, a synthesis of recommendations was presented under three rubrics: recommendations for infrastructure and shared resources, recommendations for methods and recommendations for health systems. These recommendations were subjected to a prioritization survey that was sent to meeting attendees after the face-to-face meeting. The most highly ranked recommendations were to identify the needs for PRO data by target audience (patients, clinicians, health systems, purchasers and payers) and to conduct clinical trials and observational studies to establish the value of PRO data to support clinical care actions, quality measurement and comparative effectiveness research. For Infrastructure, the top recommendation was to develop interoperable data platforms. For methods, the top recommendation was to develop and implement standards for collecting, storing, reporting and transmitting PRO data, with guidelines for optimizing response rates and handling missing data. For Health Systems, the top recommendation was the aforementioned identifying needs for PRO data based on target audience.

Overall, these top-identified priorities suggest that respondents:

- Feel general guidelines are needed to ensure data quality, accurate reporting and use.
- Consider interoperability to be a key requirement for large-scale PRO collection.
- Recognize the wide range of uses PRO information can have when integrated into an EHR system-- and the current lack of knowledge as to PRO content needs for a wide range of stakeholders.
- Are looking for tools and resources for large-scale, sustainable use of PROs within health care through EHR platforms.

The final section of the report summarizes the overall findings, with themes highlighted for future consideration. The recommendations and discussion can form the nucleus of future efforts for standardization, integration and future research.

Introduction

On November 19th and 20th, 2013, the Patient Centered Outcomes Research Institute (PCORI) along with the PCORI Methodology Committee hosted a Patient Reported Outcomes (PRO) Infrastructure Workshop on Integrating PROs into Electronic Health Records (EHR) in Atlanta, Georgia. The plan for the meeting was to discuss strategies for increasing the use of PROs in EHRs. The workshop was focused on developing an action plan for enhancing use of PROs for clinical care, research, and performance monitoring.

The Planning Committee for the meeting included Todd Anderson from Epic, Leo Morales of the Group Health Research Institute, Ethan Basch and Mary Tinetti from the PCORI Methodology Committee, and Lori Frank from PCORI. As a starting point for the discussion, a landscape review of the topic area was prepared by Albert Wu from Johns Hopkins and a team of experts. Meeting participants included patients, clinicians, researchers, healthcare system leaders, IT experts, policy makers, and other key stakeholders.

The format of the meeting was panel presentations by leaders and experts in the application of PROs in research, practice and quality improvement, with a focus on integration with electronic health records.

For each panel, the individual presentations are summarized and then cross-cutting issues related to take-away messages, barriers, facilitators, and opportunities/challenges are highlighted. Time was provided for questions and discussion at the end of each panel.

During the workshop breakout groups were held that allowed all attendees to participate in separate, focused discussion of three topics: patients and use of PRO data, clinical use of PRO data, and research and quality measurement.

In the final session of the meeting, a synthesis of recommendations gleaned from the topic groups was presented under the rubrics of three categories: infrastructure and shared resources, methods, and health systems. Discussion with the workshop participants led to further refinements of these lists. Many of these recommendations comprise the basis for future efforts for standardization, integration and future research studies.

Immediately following the meeting, a prioritization survey was sent to meeting attendees, asking them to rank order the numbered recommendations that emerged from the meeting, grouped by the three topic areas. These results were tabulated and are presented in Table 1.

In the final section of this report, a summary of the overall findings is presented, and themes are identified for future consideration in the integration of PROs into EHRs for use in clinical practice, patient centered research and quality improvement efforts.

The agenda for the meeting is provided in the Appendix.

"Setting the Stage: PRO Landscape Review"– Albert Wu (Johns Hopkins Bloomberg School of Public Health)

"PRO data come solely from the individual, which is important because in general we are not sufficiently patient centered"

This opening presentation was based in part on the landscape review prepared for the meeting, entitled "Advances in PRO Measurement in the Electronic Health Record," with co-authors Roxanne Jensen, Claudia Salzberg and Claire Snyder (Landscape Review). There has been a fortuitous convergence of trends, including the recent increase in comparative effectiveness research, intensifying attention to patient reported outcome (PRO) measurement and the use of PROs in research, and expanding use of electronic health records (EHR). All of these make the topic of this workshop especially timely. It is strategic to turn the traditional adage "measure twice, cut once" on its head -- namely, to capture PRO data once in the EHR, then use it for multiple purposes related to clinical care, research, quality improvement and accountability (Wu). In general, the integration of PROs in the EHR is in its early stages, but there are leading applications, such as those at Dartmouth, the Cleveland Clinic, UCLA/University of Michigan, and the Epic Systems Corporation MyChart patient portal, the latter of which is fully integrated with the EahapicCare clinical record. Each of these is described in more detail in the Landscape Review (Landscape Review). The perceived benefits of clinical use of PROs to a few visionary and dedicated individuals provided the impetus for the first in-clinic PRO data collection efforts. Integration of PRO measures into the EHR. Patient portals also tended to develop independently. Migration of PROs to EHRs and portals followed thereafter as EHR adoption increased.

There are a number of questions being considered by individual organizations that are common across systems and which would benefit from harmonization. Key questions include: Can the same PRO measures be used for different purposes? And, if different PRO measures are used, can they be calibrated together? What standards are needed for data collection and metadata? What is a meaningful change in score? Is there equivalence across different language versions and in different clinical contexts? When should PRO data be available, and to whom? What are the special concerns for privacy? And how can PRO use in the EHR be coordinated and governed?

There are barriers to inclusion and use of PROs in EHRs at the patient, clinician and institutional level. For example, at the patient level, barriers include lack of internet access and time constraints; at the clinician level, lack of familiarity with PRO measures and time limitations; at the system level, competing demands for the time of IT staff needed to support the work. There are also factors that could speed PRO integration. At the patient level, enablers include the availability of computerized adaptive tests, improved communication to patients about the uses and value of PROs, including readily available explanations about the tools; at the clinician

level, the provision of just-in-time support and local champions; at the system level, standardization of procedures and methods.

To investigate these questions and overcome these barriers, support will be needed from funders and government in collaboration with professional bodies to conduct research, improve methods, develop infrastructure, and provide education. This meeting represented the beginning of these efforts, with a focus on the following questions:

- Patients and data use
  - How can patients be engaged in PRO data collection?
  - What are ethical barriers to use of PROs for clinical care and research?
- Clinical use of PRO data
  - How can PRO measures be integrated in the clinical workflow?
  - What are current barriers to collection and integration and how can we learn from successful models?
  - How can PRO data be presented to clinicians to facilitate usefulness?
- Research and quality measurement
  - How can PRO data collected for clinical practice be made useful for research and quality performance measurement?
  - How can needs be addressed at the measure selection stage?

Panel # 1: "**What is the value of using PROs in EHRs?"** was moderated by Dr. Carolyn Kerrigan (Dartmouth)

"The next phase of meaningful use is making it useful to patients"
Presentation 1: Leslie Kelly Hall (Healthwise, Senior Vice President for Policy)

Leslie Kelly Hall identified that a key effect of the Office of the National Coordinator for Health IT (ONC) Meaningful Use program is to help activate patients to become involved in their care. There is a growing group of patients who consider themselves experts about health care, and think of themselves as an integral part of their care teams. In their own words, these patients want their care to include "nothing about me without me," want medical information to be understandable, in "plain language and my language," want "communication based upon my preferences," and want providers to "CC: me…some or all of my records." These sentiments represent key tenets for facilitating patient engagement: incorporating the patient perspective and input, ensuring medical information is clear and understood by the patient, and that communication preferences are understood and respected.

A key challenge for health care organizations is adapting the current workflow to both support patient engagement and be directed and facilitated by the patient. She presented an example showing how a data flow might be directed by patients, orders to be directed to them, data reconciliation to include them, and transmission of data to be accompanied by educational materials.

Two key questions central to ensuring sustained patient engagement were presented: (1) "how do I compare to other patients like me?" (2) "What has research suggested about treatments that have been effective for people like me?"

Presentation 2: Patient Reported Outcomes - Peter Yu (Palo Alto Medical Foundation)

Dr. Yu spoke as President-Elect of the American Society of Clinical Oncology (ASCO). He noted that PROs can capture important, detailed information about beneficial outcomes and toxicity in a value-based framework in clinical oncology (Outcomes, Toxicity, Cost). To this end, ASCO's Quality of Care Committee and PRO Workgroup are currently considering how to measure post chemotherapy nausea and pain in cancer practices. ASCO's Quality Oncology Practice Initiative (QOPI) and CancerLinQ learning health system project are both amenable to using PRO measures. He also mentioned the Palo Alto Medical Foundation (PAM), a thousand physician integrated multidisciplinary medical group that adopted the Epic EHR in 1999. A league-leading 75% of their patients are active users of MyChart, which can be used to deliver PROs such as the Expanded Prostate Cancer Index Composite-26 questionnaire for prostate cancer. In the future, mobile phones are likely to be a common mode of PRO administration. It would be desirable to be able to compare different hospitals based on their patients' outcomes.

Presentation 3: What's the value of using PROs in EHRs: a triple play or a grand slam? - Carolyn Kerrigan (Dartmouth)

Dr. Kerrigan began by describing pioneering work done by Dr. James Weinstein who began using PROs in the Dartmouth Spine Center. Dr. Weinstein was quoted as saying "I can't be a good doctor without this" information. PRO data were initially introduced into the EHR with the goal of improving decisions made during care. Today, PRO data are "fed forward" to help match the care that is delivered to the patient's needs and preferences. Patients receive a personalized risk assessment generated from their own PRO data, which can help them make treatment decisions. The system also provides comparative data to improve clinical programs and for research. The co-production of work based in part on the "quantified self" and collection of PRO data was viewed as essential to improving care and outcomes. A similar system is being used for the Swedish Rheumatology Quality Registry, which collects PRO data on 90% of rheumatoid arthritis patients in Sweden. The registry has changed the role of patients in both providing and sharing data. The presentation concluded with four benefits of integrating PROs into EHRs: 1) better care for individuals based on needs and preferences, 2) better data on outcomes for practice improvement, 3) better research data, and 4) links between clinical and population registries.

Question and Answer:

The question and answer session addressed a broad range of topics regarding the integration of PROs into the patient care experience. There was a discussion about the range of patients' engagement in their own care and the implications in the collection and use of PROs. One participant made the point that patient access to his or her own health information, while changing, is often the patient's responsibility. Another questioner commented on the

developing role of PRO monitoring paired with medical devices and other tracking tools, how social media outlets can be used to gain further information about the patient experience, and how data are shared.

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Cross-cutting themes from this session:

Take away points:

- To help achieve really meaningful use, a simple principle is "For every EHR action there should be a patient-facing system reaction."
- Data collection for patient outcomes should include outcomes that patients experience and can report on.
- To answer the patient question "how do I compare?" (to other patients like me) we need patient specific dashboards, the patient's expected health trajectory, and recommendations for what care should the patient be getting.
- Some patients feel slowed by the presence of clinician intermediaries for PRO data – they feel it should be available to them immediately.
- To define value in oncology we need to know what is a clinically meaningful gain in survival and in PROs.
- To be able to interpret the importance of PRO results, information is needed on personal goals for patient outcomes. These data are also crucial for the management of individual patients.
- To be useful to patients, PRO information is needed over the course of illness and treatment, including management of disease and long term symptoms even after treatment is completed.
- The data patients generate should have interoperability, ideally enabling comparison of PROs across organizations.

Barriers:

- IT systems become outdated quickly, including systems to collect and present PRO data.
- PRO information is not always available at informative points in time, and may lack clinically-meaningful interpretation.
- Patient medical information restrictions can prevent/delay access. For example, in some states (e.g., California), it is illegal for patients to be given direct access to a laboratory diagnosis of HIV or cancer.
- Most clinicians are not ready for patients to read/review all of their records.
- Traditional communication between physicians and patients does not include the review of structured PRO information.

Facilitators:

- There are several existing efforts and innovations that should be encouraged.

- In oncology, QOPI and CancerLinQ have a natural affinity for incorporating PRO data into measures of care quality.
- A recent initiative, OpenNotes (Delbanco), demonstrates the feasibility of allowing patients full access to their medical records

Opportunities for the Field and for PCORI:

- Only a few EHRs have functionality that includes the ability to remind patients to complete PROs, alert for problematic scores, and plot and compare PROs to clinical outcomes.
- There is still limited information communication across care networks.
- The patient can serve as "a health data exchange of 1" and help to increase information transfer.
- Incorporating the patient voice/perspective into the EHR requires accepting that the patient is a credible source of information.
- Orders can be directed to the patient.
- Patient may be the best source of adherence data.
- Data reconciliation and curating should include the patient.
- Metadata can enhance usability of PRO data.
- There should be consumer standards for EHR PRO data output, and provider standards for EHR data PRO input.
- Consumer and health vocabulary should be harmonized with respect to PRO assessments.
- Social media, such as email and text communications, and personal medical records are not currently integrated with EHRs.

Panel Presentation #2: **Regulatory and Quality Drivers of PRO Use** was moderated by Phyllis Torda (National Committee on Quality Assurance [NCQA])

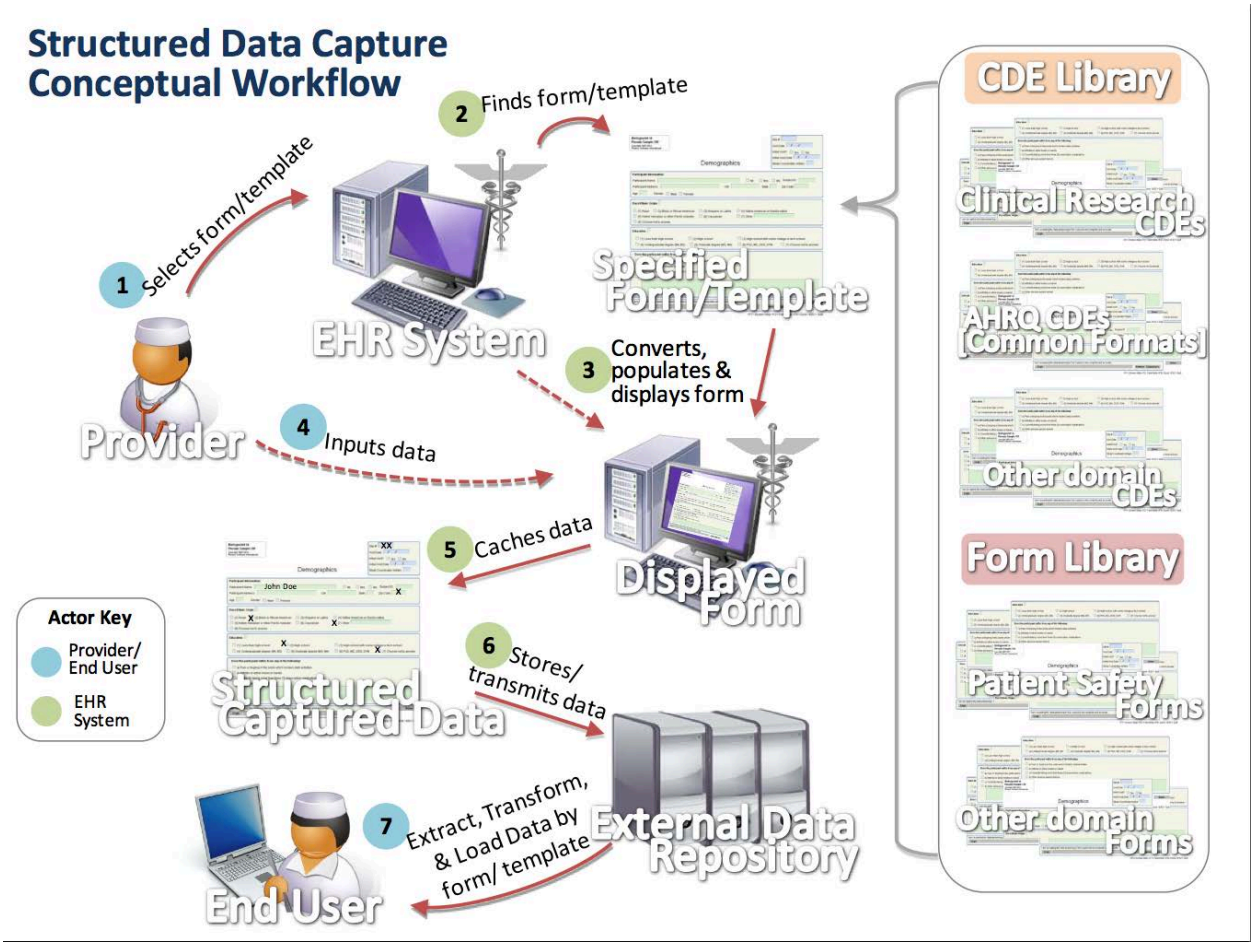
"I am the expert about me" "Small data is our short term focus"

Presentation 1: Patient centered outcomes research and EHRs - Kevin Larsen (Office of the National Coordinator [ONC] of Health IT)

Dr. Larsen, the Medical Director for Meaningful Use, began by explaining that PROs are an important data element of the current stage (Stage 2 - advanced clinical processes), and upcoming Meaningful Use Stage 3 (MU3) will focus on improved patient outcomes. Both MU2 and MU3 include PROs, for example the collection of data on functional status pre- and post-hip surgery, and depression remission. These data collection efforts involve a short-term focus on small data, rather than the long-term goal of big data. He described that a National Quality

Forum (NQF) project on developing PRO Performance Measures include three characteristics: 1) they are meaningful to consumers, 2) measure bundles of care through patient experience, and 3) assess PROs. ONC's vision takes multiple current measures and unites them via EHR reporting. This will be made possible in part through the development of new standards to enable EHRs to capture and store structured data. He explained these standard using a conceptual workflow for structured data capture (Figure).

Figure: used with permission
http://wiki.siframework.org/Structured+Data+Capture+Initiative)



Presentation 2: Patient reported outcome measures in CMS programs - Kate Goodrich (Centers for Medicare and Medicaid Services [CMS]

Kate Goodrich, director of the Quality Measurement & Health Assessment Group, reviewed the triple aim of better care, healthy people and communities and affordable care, priorities of the National Quality Strategy and the CMS framework for measurement. The CMS vision for quality measurement includes implementing measures of patient experience and PROs, with the aim of showing individual as well as population level improvement over time. Three-quarters of

Medicare Beneficiaries have multiple chronic conditions, and for these individuals the most important outcome is to maintain function or relieve symptoms, rather than prolong longevity. This argues for replacing disease focused quality metrics with patient centered metrics including goal ascertainment, and PROs. Among PROs, the current focus is on patient experience of care measures, i.e., the CAHPS family of measures. However in 2012, CMS funded NQF to develop guidance on development of additional PRO measures that can be incorporated into quality reporting programs. CMS now includes patients in all measure development work.

Presentation 3: Measures Using Patient Reported Outcomes - Phyllis Torda (NCQA)

Phyllis Torda, Vice President of the Quality Solutions Group at NCQA reviewed PRO-based performance measures (PRO-PM) to assess functional status in hip and knee replacement, congestive heart failure, asthma, rheumatoid arthritis and pain. An example of a PRO-PM might be improvement in functional status from baseline to 6 months for adult patients undergoing elective total hip replacement. For heart failure, a variety of different generic and condition-specific PRO measures are in use in a few centers. Currently, standardized functional status measures are not generally used systematically in clinical practice. Most of these measures were designed for individual patient assessment in research studies. This could potentially limit their applicability to evaluate clinical practice. In addition, risk adjustment will be needed to allow fair comparisons in PROs among groups. There is support at NCQA for pairing process measures with goal setting/goal attainment around functional status. Aggregated outcome scores are difficult from some clinicians to use. This finding, among others, suggests the need for additional work on how to construct PRO measures that are useful in clinical practice.

Presentation 4: Patient reported outcomes: examples of measure in MN for depression remission, asthma control and orthopedic functional status - Collette Pitzen (MN Community Measurement)

Collette Pitzen, Clinical Measure Developer, provided examples from MN Community Measurement, which supports broad use of PRO performance measures across Minnesota and neighboring states. The PHQ-9, an NQF-endorsed depression measure, has been publically reported since 2009 in primary care and behavioral health practices, and is completed by >80,000 patients annually via direct data submission. It has been implemented in EMR systems that incorporate pop-up recommendations based on the severity of depression. Depression remission at 6 months is tracked and publically reported by each clinic online (www.mnhealthscores.org). A current problem is the high loss to follow-up (72%), which reduces the utility of the results for clinic level and population level assessment. For asthma, they have three PRO performance measures to choose among – the Asthma Control Test, the Asthma Control Questionnaire, and the Asthma Therapy Assessment Questionnaire. An impressive 76% of the eligible population is completing them, the majority of whom are reporting low rates of asthma symptom control. Currently there is a pilot for total knee replacement and lumbar spine surgery quality measures, which report change between pre-

and post-operative PRO scores, adjusting for obesity, tobacco use, and pre-operative functional status. An interesting issue is that the desired follow-up time point may be a long time post procedure, which may make it difficult to obtain an acceptable response rate.

Presentation 5: PROs in EHR: regulatory considerations for use in clinical trials - Ann Marie Trentacosti (Food and Drug Administration [FDA])

Ann Marie Trentacosti described instrument selection and special considerations for electronic data collection. The 2009 FDA PRO Guidance document (FDA PRO Guidance) defines how the FDA interprets "well defined and reliable" PRO measures intended to provide evidence of treatment benefit to support labeling claims. From the FDA perspective, the PRO instrument includes the questionnaire itself and all information and documentation that supports its use. It is crucial that PRO instrument selection be fit to the purpose of capturing a specified treatment benefit. There are four desired steps: 1) define the disease population, 2) define other aspects of the context of use, 3) define the concepts that will define treatment benefit, and 4) select or develop well defined and reliable PRO measures and data collection methods. Several considerations inform selection of the appropriate mode of administration, which might be on paper, electronic or handheld device, web or browser based, or interactive voice response system. She also reviewed issues related to translation, and migration of an existing paper PRO to electronic versions. The FDA is interested in quality control for data collection methods, including the electronic collection of PROs, which can complicate fulfillment of FDA requirements for access to source data.

Presentation 6: What is the potential for using PROs in performance measurement? - Karen Beckman Pace (National Quality Forum)

Karen Beckman Pace, Senior Director of Performance Measures, concluded the session with a review of the NQF project to develop PRO-based Performance Measures. For the sake of precision, NQF draws a distinction among PRO (the concept), PROM (a measure), and PRO-PMs (a performance measure based on aggregated PROM data). As part of their project, they identified a pathway from PRO to NQF endorsed PRO-PM using their established endorsement process. She identified a sample of the methodologic questions that need attention, including determining the approach to aggregating PROM data for a performance measure, and considerations for risk adjustment of a PRO-PM. Despite the availability of hundreds of PRO measures, new PRO-PMs are needed to measure domains not addressed by current measures – for example, person and family centered care.

Question and Answer:

The question and answer session identified some considerations for PRO use in clinical practice. What does PRO use mean in a small practice, and what is the value outside of an academic medical center or integrated delivery system? What individual patient-level considerations (i.e., cultural, intellectual disability) should be applied when administering PROs? Questions were raised about risk adjustment variables for scores and practical clinical care uses of PRO information. The session ended with a discussion about considering how PRO measures should

be evaluated when moving from a clinical trial to clinical care context. Should psychometric properties still be considered the gold standard in PRO development? Or, should feasibility, potential to do harm, and clinical actionability be more important properties in these settings?

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Cross-cutting themes from this session:

Take away points:

- Federal policies and guidance are already in place, such as Meaningful Use, the National Quality Strategy and the FDA PRO Guidance documents that can help to provide a strategy for PRO-based measure development.
- There are standards in place to support those policies, and efforts to support, develop and implement PRO measures and PRO performance measures.
- It is worth drawing the distinction between PRO (the concept), PROM (a measure), and PRO-PMs (a performance measure based on aggregated PROM data), since each is accompanied by different levels of specificity.
- There have been a few notable early successes implementing PRO-PMs, encouraged by payment incentives and public reporting.
- There are notable gaps in the armamentarium of existing PROM and especially PRO-PMs.
- There are also gaps in experience and evidence to support the use of PROMs and PRO-PMs for specific applications, such as to support labeling claims for new drugs.
- There are many legacy paper instruments with demonstrated reliability and validity that are now migrating to electronic format that lack evidence for comparability.
- New PROMs and better ways to analyze and present the data are needed.
- Measurement and data systems are evolving rapidly.
- There should be a system with excellent interoperability to facilitate data sharing.

Barriers:

- Although there should be a future focus on big data, the current focus is on small data, and local organizations are unsure how to use it.
- Until very recently, there have been no accepted standards or strategies for measure development or selection.
- Current practice is very disease focused, and most PROMs are designed accordingly. However, the majority of older patients have multiple chronic conditions, and PRO measurement is not yet aligned to this reality.
- Benchmarking is challenging under this situation and risk adjustment methods are needed to interpret comparisons among groups of patients.
- There is relatively little experience in incorporating patients into the clinical use of PROMs.
- There is insufficient guidance on how PROMs should be used clinically and for quality improvement.

- A large proportion of patients are lost to follow-up and do not provide post-op PRO scores.

Facilitators:

- There is an increasing amount of publicly available information on PROMs.
- The near universal adoption of EHRs by health care organizations will facilitate PRO data collection.
- The Meaningful Use Program has been demonstrated to be able to change provider behavior.
- Efforts by ONC, CMS and NQF have the potential to help standardize practice in PRO adoption in EHRs.

Opportunities for the Field and for PCORI:

- Consumer e-Health data could provide a new and as yet untapped source of health information.
- The Meaningful Use Program will also provide data for local providers to use for quality improvement efforts.
- The use of PROMs provides the opportunity to transition from a narrow clinically centered focus on single instances of care to broader bundles of care viewed from the perspective of the patient, facility or population.
- There is a need to develop PRO-PMs for patients with multiple chronic conditions.
- Use PROMs to engage patients in goal setting and measurement of goal attainment.
- Replace disease focused quality metrics with patient centered metrics.
- Determine appropriate PROMs to use for specific regulatory purposes and provide guidance for electronic use.
- Identify methods to collect and review electronic data trails to fulfill FDA and sponsor access to source data.
- Establish new standards at FDA and other regulators to match the new reality of electronic PRO data.

Panel Presentation #3: **Clinician and Patient Use of PRO Data through EHRs** was moderated by Todd Anderson (Epic Systems)

"Moving from paper to electronic format is perhaps more efficient, not a 'magic bullet' "

Presentation 1: Functionality of Electronic PROs in Clinical Care - Roxanne Jensen (Georgetown University)

The first presentation provided an overview of electronic PRO collection and integration in clinical oncology. This presentation addressed how electronic data are collected, how commonly PRO collection is integrated with EHRs and how electronically captured PRO information is currently being used in clinical care settings. Currently, EHR integration is

limited, but is being used increasingly in clinically focused systems. This allows for broader evaluations of care quality, moving from patient-focused symptom reporting for use in the clinical encounter to automated score alerts (referrals) and clinic-level quality improvement efforts.

While a small number of systems in clinical oncology have been developed specifically to track and provide patients with information about their symptom severity, these are in the minority. Most systems focus on presenting information to the clinician, and many do not allow independent patient review of their scores.

Presentation 2: "Use of PRO data through the EHR for outcomes improvement: an example from pediatric rheumatology" - Esi Morgan DeWitt (Cincinnati Children's Hospital)

The second presentation provided a detailed example of how electronic PRO collection has been integrated into clinical care in a pediatric specialty clinic. This example highlights the benefits of certain electronic PRO collection features (e.g., use of tablets, real-time scoring for same day use during the clinician visit) and EHR integration (automatic selection of content-relevant PRO surveys using demographic and visit history information pulled at registration from a patient's record).

This project was started as an effort to improve patient outcomes in chronic illness care, with strong institutional support and oversight from a quality improvement committee with expertise in PRO measurement. Quality improvement evaluations focus specifically on how successfully PRO measurement and reporting has been integrated into the clinic workflow. A key focus of this example has been a strong focus on automating the collection process as much as possible.

This presentation also looked to the future of clinical use: how PROs can be used other than at the point of care. By implementing features such as automatic referrals triggered by high symptom scores, the use of PRO scores to identify "at-risk" patients in need of a care coordinator, decision support tools and better integration with EHRs and registries, the utility of PROs in clinical care can be enhanced. In order to effectively implement such changes, however, it will be important to promote the use of patient-facing reporting to enhance shared decision-making, while improving our understanding of the optimal way to present data to patients and providers.

Question and Answer:
Points mentioned in the question and answer session included a discussion of patient response rates (in-clinic vs. at-home, which tend to be lower), in light of the experience that even in-clinic response rates are lower than might be expected (Cincinnati reported 80%); a discussion of potential patient discomfort in reporting PRO information in a clinical, non-research, situation; and the privacy and protection of PRO responses. Should patients have full access to their own scores, and what are the barriers that hinder patients' involvement in selecting PRO content? Cost considerations and sustainability were also discussed.

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Cross-cutting themes from this session:

Take away points:

- EHR integration allows broader evaluations of quality of care, PRO triggered alerts and referrals, clinic level quality improvement.
- Adoption is facilitated by automated selection of relevant PRO surveys triggered by patient characteristics (e.g., demographics, visit history).
- PRO integration can be accelerated by quality improvement evaluations that focus specifically on successful integration of data collection into the clinical workflow.

Barriers:

- Limited standardization of electronic PRO collection.
- Response burden, in terms of both (1) how a patient interacts with the collection system and (2) the number and frequency of questions administered.
- Technical difficulty: the staff needed to create and manage this type of data collection in light of clinical needs and workflow.
- Issues related to data quality: Are responses accurate? Which patients are missed? Is the information used correctly?

Facilitators:

- Leadership buy-in to the project.
- Clear provider-level performance metrics tied to PRO reporting.
- Designing and periodically evaluating the design specifically to reduce clinic disruption.
- Clear and immediate clinical relevance seen by both patients and clinicians.

Opportunities for the Field and for PCORI:

- How can PROs be used at other than the point of care (e.g., between visits)?
- How can PROs be integrated into EHR based patient registries?
- How can PROs be used to enhance shared decision making?
- What is the optimal way to present data to patients and providers?

Panel Presentation #4: **Integration of Research, Clinical Care and Quality** was moderated by Leo Morales (Group Health Research Institute)

"Our goal is to place systematic measurement at the center of health care quality. Research is just a side effect."

Presentation 1: Challenges and opportunities to create a PRO infrastructure for purposes of informing clinical care, research and quality improvement - Bryce Reeve (University of North Carolina at Chapel Hill)

This presentation highlighted the key challenges in moving forward to develop a PRO collection infrastructure for use in both research and practice. It explored three content areas: clinical requirements, research standards (e.g., validity, reliability, and missing data), and methodological considerations.

Clinical requirements included: the premium on clinical relevance, identification of useful patient-reported content, the role of patient's preferences and values, and PRO assessment brevity. Methodological considerations examined how current methods can be used to establish a common measurement scale for different PRO surveys (cross-calibration and linking), provide interpretation across the lifespan, and reduce unnecessary, redundant content (computer adaptive testing). Research standards addressed the role of proxy reporting, validity and reliability standards (in particular individual vs. group-level benchmarks), and missing data.

The presentation examined where research and clinical priorities may not be aligned: use of proxy information, actionable vs. non-actionable content, data presentation and clarity. The context of clinical use (patient-level use vs. clinic-level quality evaluation) can also lead to a meaningfully different patient experience ranging from tailored assessments based on patient-preferences to, on the other end, collecting PRO information from people who identify few problems and would perceive very little individual-level value.

Presentation 2: Using systematic outcome assessment for patient care, quality improvement and research - Greg Simon (Group Health Research Institute)

This presentation illustrated how a learning health care system can use PRO data to continuously drive both research and practice. After implementation in a standards assessment program in 2011, compliance with a depression screen (PHQ-9) use and documentation has increased to over 80% (all visits for patients $\geq$12 years of age) across the Group Health system. A high compliance rate has allowed the system to explore suicide risk (identified on the PHQ-9), in further depth. Research has examined if the PHQ-9 suicidal ideation item can identify which patients are at high risk of a suicide attempt, and when this will occur. These population-based findings have driven changes in practice support and quality improvement. This provides a new paradigm in suicide risk prevention that incorporates practice support (tools for risk assessment and follow-up care) and allows for quality improvement (monitoring adherence). It has also led to new ways of thinking about risk prevention, and to grant funded research programs.

This presentation emphasized two limitations: data quality and privacy protection. Missing data still a data concern for research. It can indicate that clinical assessments are not performed or recorded, reasons for treatment choices are not documented, or patient non-response representing loss to follow-up. All of these data quality issues impact the quality of research and practice. Privacy protections for patients, using EHR-based clinical data is limited. Patients may not know who is looking at their data, how it is informing their care, and how this information has helped others.

Hugo Campos (Patient) enumerated several current issues and the importance of patient access to their own PRO data. Sharing PRO data with patients and caregivers is important and considered fundamental to his relationship with his doctor, and it also provides a way for him to monitor and empower himself between doctor visits. He identified barriers to accessing his own health data: 1) a device manufacturer that has stated their business model does not include allowing access to raw data to the patient or provider; 2) the assumption that information is too complex for patients to understand; and 3) the perception by some physicians that this will "cut them out of the circle" and that they may lose payments and visits. Ultimately, he wants the ability to access his data but often it is locked behind patient portals or devices.

Mr. Campos also discussed the patient perspective on engagement. He noted that when a patient is collecting information for his or her own use, there is not a problem with response or burden. However, if information gathering is burdensome, what does that mean for whether the information being collected is correct? PROs must be relevant and it must be clear what value they provide, if they are to support patient engagement. However, from his perspective patient engagement is not an end but a means to an end. Ultimately, many patients would love to be less engaged with their health care, and "get along with their life". PROs may provide a platform for a new dialog between patients and their doctors.

Question and Answer:

The question and answer session focused on the idea of patient and content relevance. There was a discussion about the strengths and weaknesses of using validated vs. non-validated PRO measures. There was also discussion about the need to clarify and identify the full range of patient-reported constructs and validated measure in clinical care (e.g., goals, patient preferences and shared decision-making). Another topic discussed was the idea of PROs and transparency. Who controls patient PRO data? Should patients be able to take PRO information from a medical record to a non –medical environment (e.g., non-profit, advocacy group)? PRO data are often restricted, and not designed to be easily portable; both of these properties may be structural barriers to exporting and transferring data to the patient. The last topic of discussion was a consideration of PRO reporting and use for underserved communities. It is possible that individuals in these groups may have both different needs and degrees of understanding. A lack of health literacy, or limited access to care do not mean that a patient does not want to know and understand the information they are reporting. However, little is known about perceptions of PRO collection and reporting in underserved groups.

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Cross-cutting themes from this session:

Take away points:

- The context of clinical use of PROs can add or detract from the patient's experience.
- PRO data collection can help to drive both research and improve practice.
- PRO data can help introduce a population health focus to clinical practice.

- Sharing PROs with patients and caregivers is necessary to partnering with providers.
- Patients must see value of PRO measurement in order to provide accurate data.

Barriers:

- Data quality issues – missing data is a key threat to validity.
- Patient privacy protections.
- Heterogeneity of PRO measures.
- Conflicting priorities between research and clinical practice.
- Conflicting priorities within clinical care.

Facilitators:

- Focusing on research that can directly inform practice.
- Involving the patient, understanding and incorporating their priorities.
- Applying methods that allow for wide-scale standardization and comparisons.

Opportunities for the Field and for PCORI:

- Research is needed to address the potentially different requirements for PRO measures for use in clinical care, research and quality improvement.
- Research is needed on optimal strategies to reduce missing data, and to handle it when it occurs.
- Research is needed on patient preferences for privacy and for the sharing of the PRO data.

Panel presentation #5: **Research use of PRO data from EHRs** was moderated by Mary Tinetti (Yale)

"Selecting the right questions requires broad consensus from providers and patients"

Presentation 1: Research use of PRO data from EHRs - Carolyn L. Kerrigan (Dartmouth) Dr. Kerrigan, a Professor of Surgery, related how the vision for PRO that originated in 1998 at the Spine Center at Dartmouth-Hitchcock has led to subsequent developments over the ensuing 15 years. Today, a dozen departments and programs use PROMs on a routine basis for specific conditions and requirements. She emphasized the importance of obtaining buy-in from multiple providers and patients to select the right questions and optimizing respondent burden. Patients can also be engaged in co-designing and testing to improve usability. The ultimate vision is seamless integration of PROs in the medical practice alongside other data sources. To achieve high completion rates there need to be multiple options so that patients can use the one that suits them best. Incorporating options for multimedia can help patients make informed decisions about, for example, colon cancer screening. Frontline teams also need training to be able to use PRO data.

Presentation 2: My Own Health Report (MOHR) project - Russell Glasgow (University of Colorado School of Medicine)

This talk presented experience with MOHR, a system to assess and provide feedback on 10 key health behavior, mental health risk and substance abuse factors in primary care settings. A problem inherent to primary care practice is the need to address many different things. Therefore, items for their system were selected to be brief, actionable and to provide immediate summary feedback. The MOHR measures included 17 screening items and 9 demographic questions collected via a web-based system. Their project was a cluster randomized trial of 9 pairs of clinics with an early-late adoption design. Their main outcome was having a personalized action plan, and the study is ongoing.

Presentation 3: PRO, EMR and research: the Cleveland Clinic experience – Ajit Krishnaney (Cleveland Clinic)

This talk described work from the Center for Spine Health in the Department of Neurosurgery. Their PRO data collection is part of the Knowledge Program originated in 2007 by the Neurological Institute and IT partners at the Cleveland Clinic. They began with a goal of capturing PROs with efficient data entry and work flow. Although they began with longer standard measures, poor completion rates led them to change to very brief tools. Today, these are completed primarily using tablet devices and are integrated into patient records that can be viewed by clinicians. Although there are still challenges related to inconsistent long-term follow-up, this initiative has enabled incorporation of PROMs into multiple research studies and publications.

Presentation 4: Research and clinical uses of EMRs and PROs - Marc Berger (Pfizer Real World Data and Analytics)

This presentation described an explosion of data volume, technology for data storage, advanced analytic techniques and applications. He defined "real world data" as a variety of big healthcare data used for decision-making that are collected outside of conventional randomized clinical trials. This includes patient reported measurement. He also highlighted the issue of "heterogeneity of treatment effects" which may be related to specific patient characteristics. PRO data assist in assessing patient heterogeneity, and also have an important role to play in assuring that patients achieve the best outcomes. He identified several challenges, including the fact that current EHRs are not well designed to support research, and the potential use of Natural Language Processing to extract PRO data from unstructured notes. He challenged designers that successfully embedding PROMs into clinical practice requires making the clinician's job easier. He concluded with an interesting assertion that patients should perhaps be the ultimate owners of their data.

Question and Answer:

The question and answer session for this set of presentations addressed big data, current barriers to use, and system sustainability considerations. The first discussion question elaborated on the idea that EHR integration is facilitating a movement from traditional

hypothesis-based research questions to the data driven (inductive world). While the speed of analyses is increasing at a fast rate in learning health care systems, there is a resistance to the use of inductive "data driven" research methods. The ability to link to incredibly rich socioeconomic information (GIS, FICO scores) that integrates with heath care information provides an important resource to investigate and understand health disparities. This session ended with a brief discussion about sustainability of systems in community-based settings. Recommendations included adapting systems to fit into patient work flow, thinking ahead to future reporting and accreditation needs, and clarity on system costs.

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Cross-cutting themes from this session:

Take away points:

- A "build it and they will come" approach to incorporating PROs into the clinical encounter is likely to fail.
- A shorter form that is completed is better than a long one that is not.
- Selecting the right questions requires a broad consensus that includes multiple providers and patients, and actual testing of alternatives.
- Primary care patients are likely to have multiple areas of need, so capturing multiple domains is important, as is incorporating ways to prioritize among needs.
- Even if longer standardized PROMs may be prescribed, shorter measures are sometimes better.
- Obtaining acceptable response rates may require providing patients multiple options for responding to PROMs and more systematic efforts to follow up.
- New and expanding sources of real world data provide more options for filling in gaps in the data.

Barriers:

- The current focus tends to be on the technical side of PRO measurement, but we often ignore the social and cultural elements required to capture the patient perspective.
- Systematic follow-up is not currently routine for much of clinical care, but missing data can limit research use of the data.
- Current EHRs are not designed to support research in general, and PRO based research in particular. Additional steps may be needed, such as embedding standardized data elements into clinical practice.
- Patients feel that they share in the ownership of their own data in the EHR.

Facilitators:

- Buy in and support from top leaders.
- Buy in from multiple clinicians and patients.
- The presence of clinical champions for each clinical condition or unit.
- When possible, the use of rigorous designs to demonstrate value of PRO measurement.

- Partnering between clinical, measurement and health IT experts.
- Adoption of innovation in health IT such as Natural Language Processing.

Opportunities for the Field and for PCORI:

- Current forms of patient information, such as the American Heart Association website, recommend tests for use in for example heart failure, but do not yet include PROs.
- Adoption of a vision for the administration of PRO measures seamlessly into practice could lead to achievement of other important goals such as higher completion rates and tracking of measures.
- Patients can be engaged in helping to design PRO measures including the displays of the results that are presented to a patients.

Panel Presentation #6: **Current practice and future possibilities** was moderated by Albert Wu (Johns Hopkins Bloomberg School of Public Health)

"…achieving the sweet spot between research, quality improvement and clinical decision support…must systematically address implementation issues (it's not about the technology)"

Presentation 1: Patient reported outcomes for mental health services: current practice and future possibilities - Arne Beck (Kaiser Permanente Colorado)

Dr. Beck described the successful efforts of a behavioral health quality measurement task force to systematically assess patient outcomes. Senior leaders support the conceptual basis for measurement of symptoms, functioning, substance abuse and therapeutic alliance. Data are collected from tablets at all intake and follow-up visits, and are available in real-time for clinicians, quality improvement and research. There is not yet full integration as summary scores are input into the EHR by staff. Data can be used to recruit patients into research studies or to identify comparison groups.

Presentation 2: Patient reported outcomes for the program of excellence for low back pain: current practice and future possibilities - Kevin Bowman (Anthem BlueCross BlueShield)

Dr. Bowman described the goals and guiding principles behind their program which aims to improve clinical outcomes, member satisfaction and appropriate utilization of services. Multidisciplinary teams are formed that agree to follow specified evidence-based protocols that include assessment of comorbidities and behavioral health status, use of shared decision-making tools, and measuring pain and functional status at certain time points. Physicians are rewarded by payment of a case management fee, as well as education and support. Future efforts aim to align treatment choices with patient preferences and optimize pre and postoperative management.

Presentation 3: Patient reported outcomes in the national patient-centered clinical research network - Rachael Fleurence (PCORI)

Rachel Fleurence gave an overview of PCORI's newly christened National Patient-Centered Clinical Research Network. The goal is to improve the nation's capacity to conduct comparative effectiveness research efficiently by creating a large, highly representative network that can support a learning US healthcare system. Patient reported outcomes are a key area of focus. The member organizations are Clinical Data Research Networks (CDRNs), each of which will describe how they will incorporate routine collection of PRO information into the EHR. Activated patients in the parallel Patient Powered Research Networks (PPRNs) will explore ways to collect these data, aiming for at least 80% of members. A national coordinating PRO Task Force will support selection, implementation, technology solutions and best practice guidelines.

Question and Answer:

The question and answer for this session focused on a wide range of future possibilities in measurement, implementation and sustainability. Measurement-related topics included considering how PRO collection can be improved to better address the heterogeneity of individual patients. For example, ceiling effects for measures currently limit how well we can measure patient improvement for higher-functioning patients. Financial incentives to promote physician use and long-term sustainability of PRO measurement in clinical care were discussed. Current barriers to PRO use in quality improvement were discussed: the measurement of physician-level quality and methodical issues due to the known variability in patient outcomes. Long-term future directions in this area highlighted the importance of aligning patient preferences and knowledge with the skills and abilities of the physician, along with system-level monitoring. This session closed with a discussion of how PRO measurement can move forward and be inclusive of diverse and underserved communities. Moving forward, translation and cultural adaptation of PRO instruments built into systems is necessary. Geo-coding and census block information will be important tools to integrate with EHR data to evaluate the diverse populations that are entering the health care system due to Medicaid expansion.

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Cross-cutting themes from this session:

Take away points:

- We cannot deliver outcomes-informed therapy if we do not systematically assess our outcomes.
- Support by senior leaders of health care organization of the underlying conceptual frameworks can increase the chances of success.

Barriers:

- We need to find ways to successfully include PRO collection into the health care delivery work flow, in a way that is acceptable to patients.
- Evidence is still lacking regarding key questions related to acceptability to clinicians and usefulness to researchers.

- It is not yet clear how well suited generic vs. disease-specific PRO measures are to specific applications.

Facilitators:

- Efforts by existing task forces and groups can be used to accelerate progress.
- Financial rewards can be structured to encourage adoption by clinicians.

Opportunities for the Field and for PCORI:

- In the future, it should be possible to use PROs to assess physician and practice performance.
- Mental health and low back pain provide concrete examples for other clinical areas.
- Emergent areas include development of strength and asset based measures rather than tools that focus on limitations, measurement of patient goals and preferences and patient generated data.
- There will be a constant tension in efforts to achieve "the sweet spot between research, quality improvement and clinical decision support."
- Although finding technological solutions will be important, the socio-technical solutions may well be more difficult to attain.
- Research and development are needed to answer the many unanswered scientific and practical questions about integrating PROs into EHRs and health care delivery.
- The creation of PCORNet with its component CDRN, PPRN and NCRN, represents the largest initiative to build national infrastructure for PCOR to date. Work pledged by the component networks should accelerate the adoption of PROs within EHRs.

Panel Presentation 7: **"Scaling up" PROs: successful models** was moderated by David Flum (University of Washington)

"By including key stakeholders and demonstrating the benefits to them, when scaling up they are your fans not your barriers"

Presentation 1: Implementing patient reported outcomes in routine clinical care: HIV as an example to improve clinical care and facilitate research - Heidi Crane (University of Washington)

This presentation discussed lessons from an electronic PRO collection and reporting system developed at the University of Washington HIV outpatient clinic, used as a template by the CFAR Network of Integrated Clinical Systems (CNICS) to regularly collect PRO information for 27,000 HIV-infected individuals across the US.

Key themes identified were the necessity of flexible implementation methods, and tailoring of design based on each clinic's flow pattern and EHR system. The PRO software platform is open-source, non-proprietary, encrypted, free and web-based, selected to work with any clinic

configuration. It has been tested and found to be well-accepted and feasible among HIV-infected patients in routine clinical care. Assessments consider patient burden by incorporating tailored skip patterns based on PRO results, clinical and demographic data and time since last completed instrument. Clinic-level customization is encouraged, with variations in the assessment design, and whether paper or electronic PRO reports are generated for clinicians.

A key supporting factor identified was establishing provider buy-in. This model has done that by demonstrating specific and immediate improvements to patient care. Specifically, evaluations demonstrated that PRO reports identify symptoms that were underreported, serve as a communication tool and have been minimally disruptive to clinic workflow. Ultimately, this project has demonstrated the feasibility of reporting PROs across very different HIV-clinics, with their own EHRs, workflow, priorities and interest.

Presentation 2: Use of PROs in the primary care setting to support care for patients with chronic pain on long term opioid therapy - Lynn L. DeBar (Kaiser Permanente Center for Health Research)

This presentation described how a patient-reported pain measure has been incorporated into a multi-site chronic pain management and decision support program in an integrated health care system. It highlighted key barriers to implementation this effort has overcome. There is a large, diverse number of stakeholders in their system (e.g., medical group, health plan, IT development and IT integration). Each is required to develop and launch these efforts. Technology and data reporting are not standardized across sites. Embedding PRO summaries into the EHR is a "work in progress," currently relying often on scanned documents that require the involvement of staff members and work-arounds to ensure quick load times. Flexibility of data collection is also important, and multiple methods to collect information from patients (web-portal, IVR, phone call by a medical assistant) are being applied.

Presentation 3: "Scaling up" a successful geriatrics model of care - Michael Malone (Aurora Health Care)

This presentation focused on how PRO and other clinical assessments have been incorporated into a team-centered model of elderly care, Acute Care for Elders (ACE). This successful care model has been adapted and integrated across the Aurora Health Care organization. The following guidelines were presented based on efforts to expand this program. Tools must be simple and easy to use and resulting care should be easily understood. The tool should be designed around patient needs, and must work across a system and be usable by any team member in any type of clinic. Communication and guidance is also important, so electronic trainings are held regularly.

Question and Answer:

The question and answer session discussed topics surrounding how to develop and promote PRO measure use across different, non-integrated health care systems. A key way to expand use is to show value, or how PRO information can support the clinical care experience. For clinicians, this can mean showing impact and usefulness, and how PRO measures can help

integrate across a wide range of clinical cultures. For patients, it can be through addressing needs and considering how PRO information can be used to support them in the clinic, but also help their caregivers and family.

The question was also raised about how to implement PRO measures in very different settings. Potential facilitators of implementation include the promotion of telemedicine and other tools, lowering the burden of developmental costs and ultimately focusing on simple clinically-relevant assessment tools, like checklists, that can be easily translated and integrated in different health care settings. The session wrapped up with a discussion about the important and necessary role of professional medical societies as a "force for change" to promote and encourage PRO use across systems. A key path to promote buy-in from these groups is to show specific and meaningful value to their members.

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Cross-cutting themes from this session were:

Take away points:

- PRO assessment can be successful in non-integrated health care delivery systems.
- Doctors and other clinician users are important to promote PRO collection and use -- how can they be empowered to be forces of change?
- Physician readiness and cultural barriers can limit use. However, these examples show that a clear goal of improving clinical care can help.
- Can PRO collection scale beyond the health care setting to a broader community-based setting?

Barriers:

- Consolidating data from multiple locations can be difficult.
- Standardizing data and reporting systems across clinics is difficult.

Facilitators:

- Keep things simple and clear.
- Allow for a wide range of technological capabilities and EHR integration.
- A common goal can help align efforts across institutions.
- Keep content relevant to the patient and promote clinical usefulness.
- While often clinician driven, other personnel can facilitate these efforts.

Opportunities for the Field and for PCORI:

- Partner with existing research consortia to conduct PRO research.
- Establish standards for PRO measurement and data collection.

Breakout Sessions: Summary and major points discussed

Interspersed with the more didactic sessions, discussions were held that focused on three breakout topics: patients and PRO data, clinical use of PRO data, and research and quality measurement use of PRO data. Meeting participants rotated from topic to topic, so that all had the opportunity to contribute to each of them.

Breakout 1 – Patients and PRO data

This break-out topic initially focused on two issues: 1) engaging patients in PRO data collection and 2) ethical issues in the use of PROs for clinical and research purposes. However, discussion ranged into additional areas including 3) ensuring content relevance and 4) integrating PROs into the patient's clinical care experience.

Engaging patients in PRO data collection

This discussion focused in part on the patient's experience in providing PRO information.

There was disagreement among workshop participants about the degree of patient interest in filling out PRO measures, irrespective of clinical relevance. Key issues identified in engaging patients to complete PROs was that they could be seen as "boring" and "time consuming." Some participants suggested that patient burden due to the number of questions asked was a key concern and expressed general skepticism that patients would participate on a regular basis. Patient representatives, however, said that there is strong interest in this information, especially in situations where it informs care.

Several barriers limit patient engagement in PRO assessment, including clinicians appearing not to see or use PRO data, PROs not collected in the patient's native language, and standardized PRO measures missing concerns that are important to individual patients. Technological and system barriers were also discussed as features that limit patient engagement. The complexity and number of steps necessary for patients to independently interact with the system to complete assessments was identified as a potential limitation on self-initiated PRO assessments (e.g., at-home administration). Examples of technological features that should be evaluated included patient system log-in and password entry, required entry fields, and the ability to optimize for current technology (i.e., touch screens and smartphones).

There was general consensus that patients are willing to complete PRO measures if clinicians use that data and coordinate follow-up to address issues across departments. Different patients may prefer to provide PRO data in different ways. Potential ways to improve engagement include flexibility in options for ways to complete PRO measures; considering physical handicaps of participants (e.g., limited fine motor skills); optimizing the data entry experience to take full advantage of current technology (e.g., touch screens); customizing questions to fit individual patient needs such as goal setting and patient-selected PRO content; providing immediate feedback about PRO scores and their significance; demonstrating the importance of PROs and that they are seen and used by clinicians, explaining the meaning of PRO scores including comparison to reference groups, and linking PRO scores to action plans. At a different level, patients should be engaged to participate in PRO development and should be provided with feedback about their impact on the process. PRO measures can include both

positive as well as negative aspects of health. This is particularly relevant to patients interested in health maintenance and promotion, and to capture improvements in health. The workflow for data collection can be designed to ask the right questions from the right sources without redundancy, and to routinely share the data with patients.

Ethical issues to use of PROs for clinical care and research

Ethical issues relate to potential harms from PRO data collection, respect for persons, and privacy. PRO data collection can have some negative impacts for patients. Data collection can disrupt the patient's "life flow" and can also add time and hassle to the clinical workflow. Negative and disease focused questions can be demoralizing to some patients. It is a problem that PRO information collected often does not follow patients (get transmitted through the health care sites the patient contacts). Questions that are asked repeatedly by clinicians at different points in the health system are annoying and seem disrespectful of a patient's time. Lack of immediate feedback about PRO scores in many situations, or lack of access to PRO data in general, are also seen to violate patient rights. There are also small risks related to patient privacy, such as the risk of information leaking that the patient has depression, or a provider learning that an individual patient was dissatisfied with the care received. The consenting process itself can be a barrier to PRO data collection. Blanket consent is used by many organizations, in which patients who agree to be treated at a facility give consent for all of their data, both clinical and self-reported, to be used for multiple purposes.

Evaluating and communicating content relevance

A commonly mentioned barrier was that the PROs collected may not be relevant to the care of the individual patient. There was also a discussion about the perception that PRO instruments are focused on goals too far removed from the individual patient; as a result, PRO measures validated in the research context may not be appropriate or useful in clinical care situations. In addition, the benefits of PRO reporting are not clearly stated to patients. For example, patients are asked to provide information about their symptoms but receive little information about what is being collected and how it is being used. This confusion can impact the clinical care encounter if patients assume that their provider will see and evaluate the responses they have given, without understanding that the information is being collected solely for research purposes.

Possible solutions in this area vary by target audience. At the individual-patient level, communication of clinical relevance is important. More broadly, guidance is needed about how to select and use PRO measures that effectively ensure content relevance; clear, clinically-relevant interpretation will help communicate PRO relevance.

Implementing PROs in the clinical care experience

While not a directed discussion point, this issue was discussed from the patient perspective. There was concern that clinician-specific barriers exist that could impact patient use by discouraging clinician use, such as perceptions of disruption and inconvenience in the clinical

workflow. There were also concerns that PROs could focus clinicians on data and scores rather than the patient. Opportunities identified include targeted education for staff and clinicians, as well as financial incentives to review and discuss PRO scores with patients.

Final recommendations from this breakout included:

- Collect consent in a way to encourage collection of PRO measures, and assure that consent documents are worded in simple language.
- The Department of Health and Human Services should establish guidelines for uniform use of PRO data.
- Provide guidance to Institutional Review Boards for consent and data use.
- Streamline data collection to fit the clinical workflow.
- Confirm preferred PRO data collection channels with patients.
- Focus on consistent display of PRO results.
- Give patient control of data and how they are displayed to them.
- Involve patients in PRO development.
- Collect information on the relevance and importance of specific questions for individual patients.
- Provide multiple modes of data collection.
- Use open data platforms and interoperable webtools.
- Provide ways to collect individualized data where needed.
- Develop standards that allow data to be transmitted across different vendors.

Breakout 2 – Clinical use of PRO data

These sessions were initially focused on 5 questions: 1) How can PROs be integrated into the workflow? 2) What are current barriers to collection and integration; what are some examples of successes? 3) How can PRO data be presented to clinicians? 4) What are facilitators of clinician use? 5) What stakeholders are involved in enhancing clinician use? Discussion ranged into additional areas as well.

How can PROs be integrated into the workflow?

PRO measurement must be integrated into clinical care across the continuum of care, beginning with the patient, moving on to the clinical team, and continuing on to the health care organization. It was noted that the clinical team comprises far more than physicians, and both receipt of PRO data and acting upon them might in many cases be delegated to other members of the provider team. It was hoped that examination of workflow integration might be the basis for a series of research questions aimed at providing solutions.

What are current barriers to collection and integration; what are some examples of successes?
Several barriers were noted to collection of PRO data and integration with the EHR. Time poses a barrier for multiple stakeholders. These included patients who face time and hassles in completing PRO questionnaires; providers, for whom PROs are not integrated into their EHRs or

workflow; health systems and their IT departments, which require time for planning and programming. Current technology may also make it difficult to deliver PRO measures in a timely manner to patients who would benefit most from completing them. The resources required for PRO measure implementation and integration pose a second barrier. There are additional challenges for implementing PRO measurement in non-integrated health care systems as opposed to large academic medical centers where many of the current examples are generated. A third barrier was a lack of vision by many health systems regarding the goals for PRO data collection and how these data will help organizations achieve specific objectives. A fourth barrier is the current lack of sophistication and familiarity by patients and clinicians about PRO measurement. A final and related barrier is the lack of evidence for the application of many PRO measures in the clinical sphere. Many current measures were not designed for clinical practice, and all may not be equally useful.

How can PRO data be presented to clinicians?

This question was not addressed by specific suggestions or examples in the breakout session. Education was also mentioned as a foundational need that can prepare providers to receive PRO data. For example, education and training in medical school and residency would help physicians to understand and use PRO data.

What are facilitators of clinician use?

Some facilitators of clinician use can be provided from the top down. Policies, formulated at the level of individual organizations, or higher, such as at the level of large EHR systems, states, regional Health Information Exchanges, payers or the ONC, can provide rationales and incentives for use. PRO data collection may help to identify patients in need for specific services. In the future, it may also be reasonable for clinicians or health care organizations to bill for the use of PRO "tests" that are demonstrated to provide valuable information. It will be very helpful to obtain evidence demonstrating the value of PRO measures to patient outcomes.

Continued advances in technology can facilitate the use of PRO measures by patients. It was noted that 64% of pay-per-use phones are now smartphones, increasing opportunities for data entry even in disadvantaged populations. In the future bring-your-own-device (BYOD) technology will be increasingly prevalent and will reduce barriers to data completion and use.

What stakeholders are involved in enhancing clinician use?

This question was not addressed directly in the breakout session. However, various stakeholders were alluded to in the discussion, including patients and their caregivers, health care providers including the entire clinical team rather than simply physicians, trainees such as medical residents and their training programs, EHR managers and manufacturers, quality improvement professionals, researchers including measurement experts, data analysts, clinical and health care researchers, and health systems and payers.

Final recommendations from this breakout included:

- Measure other patient reported information in addition to outcomes, such as patient experiences with care, goals and preferences.
- Move away from a measurement model that assumes care is centered on the health system. It will be valuable to assess PROs in other settings, including at home or at work.
- Determine which measures are most appropriate for specific patients and settings.
- Make patients part of the PRO development process in order to, among other things, present questions in plain and acceptable language.
- Provide immediate information and create immediate benefits for patients in order to demonstrate and advance their interest in PROs. There was mixed enthusiasm for compensating patients for providing PRO data.
- Use PROs to inform shared decision-making and promote individualized care plans.
- Expand options to maximize accessibility of data collection to the greatest number and variety of patients.
- Conduct research to identify PRO measures and best practices in different contexts– for whom, when, and what.
- Form a working group to establish standards for the development of interoperable PRO tools.

Breakout 3 – Research and Quality Measurement Uses for the Data

Discussions in this breakout focused on 1) PRO standardization and measurement equivalence, 2) PRO infrastructure and software needs, and 3) promoting and supporting use.

PRO standardization and measurement equivalence

A key discussion point was the necessity of better understanding the methodological requirements and differences between research and clinical use of PRO information. This session identified the need for reliable, comparable measures that work across clinical care settings and populations. This group discussed how this can be achieved through the use of methodologic applications (i.e., IRT-derived crosswalks), setting methodologic standards or recommending a common set of PRO measures across all PCORI-funded work.

PRO infrastructure and software needs

Current EHR systems lack data collection specificity geared towards PRO data. In order to move forward with large-scale PRO collection necessary for both research and quality improvement projects, standards are necessary. Recommendations included the development of a clear, stable, open source platform and standards for the collection, storage and use of data. A better understanding of metadata collected along with PRO scores and how it can be used to support adoption in quality improvement efforts is also required.

Promoting and supporting use

How PROs can be used in large-scale quality improvement is still a developing area. Stakeholder involvement in the development process should be a key priority. Ideas include (1) leveraging large research networks (CDRN/PPRN), which have an infrastructure to support the development of PRO-based measures and (2) working with the NQF on quality performance measures. This group also recognized the necessity of prioritizing research and PRO measurement in areas that are relevant to patients to promote adoption and use, especially for self-management.

Refining Final Recommendations Moderators: Lori Frank (PCORI) and Robin Newhouse

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In this final session, recommendations were presented and categorized into infrastructure, methods and health systems.

A. Recommendations for Infrastructure/Shared Resources

A.1. Establish a PRO-specific library, providing detailed information on a core set of measurement considerations geared to both clinical and research applications for commonly-used PRO measures.

A.2. Develop educational materials to guide PRO measure selection, with specific attention to considerations facilitating electronic health record (EHR) integration (e.g., electronic format currently available).

A.3. Identify opportunities to develop recommendations guiding PRO implementation in EHR systems in collaboration with stakeholder groups (patients, NQF, FDA, CMS, etc.).

A.4. Develop and evaluate training of clinicians, patients and stakeholders on the implementation, use and interpretation of PROs in multiple clinical and research settings.

A.5. Develop interoperable open data platforms and web tools that can interface with EHRs, to encourage standardized large-scale PRO assessment and evaluation across many health care systems (including non-integrated health care delivery systems).

A.6. Establish minimum standards for PRO measure development, use and interpretation.

A.7. Develop PRO measurement sets that serve multiple needs in multiple settings.

A.8. Identify and establish processes for the qualification of measures important in regulatory review of new treatments or diagnostics.

A.9. Address human subjects protection and privacy needs for patients and all PRO users.

B. Recommendations for Methods

B.1. Conduct clinical trials and observational studies to establish the value of PRO data to support clinical care actions, quality measurement and comparative effectiveness research.

B.2. Determine patients' and clinicians' awareness of PRO data and expectations for its use in clinical decision-making.

B.3. Develop PRO calibration methods that allow cross-walking and score interpretation across different PRO measures.

B.4. Promote research to determine best practices in establishing clinically meaningful differences, to aid PRO reporting and interpretation.

B.5. Compare and evaluate current methods to elicit individual patient preferences and goals regarding the elicitation, trajectory and identification of clinically-relevant, goal oriented actions.

B.6. Develop and implement standards for collection, storage, reporting and transmitting PRO data. Standards should include guidelines for optimizing response rates and handling missing data.

B.7. Identify methods to match PRO measures to identified needs (e.g., for management of multiple conditions).

B.8. Develop PRO data collection options that include patient caregivers and their social network.

B.9. Identify and evaluate potential data validity concerns due to electronic web-based administration (e.g. response bias, multiple log-ins per assessment, use of N/A or Missing fields).

B.10. Design methods to integrate PRO data, other patient-reported information and structured clinical data to facilitate health care decision-making.

B.11. Demonstrate the measurement equivalence of PROs in multiple languages and modes of administration.

C. Recommendations for Health Systems

C.1. Identify needs for PRO data by target audience (patients, clinicians, health systems, purchasers, payers).

C.2. Demonstrate the value of database linkages (e.g., EHR, claims data) incorporating PROs in the evaluation of clinical care, comparative effectiveness research and research applications.

C.3. Evaluate payment models for PRO data collection and use in collaboration with payer organizations.

C.4. Demonstrate usefulness of combining and reconciling PRO and clinical EHR data to conduct quality of care assessment and promote quality improvement activities.

C.5. Develop and evaluate training materials to educate patients and clinicians on the value of PROs and the patient-perspective for clinical care and research.

C.6. Evaluate approaches to provide patients access to and use of their own self reported PRO data.

C.7. Design optimal clinical workflow and procedures that incorporate PRO data for patient management, including those with multiple comorbidities.

C.8. Develop and evaluate the effectiveness of PRO score automation (response mapping) in clinical settings, including who acts on specific data elements.

C.9. Establish standard actionable thresholds for clinical meaningfulness and related actions for commonly assessed PRO domains.

C.10. Demonstrate the role of PRO in a learning health system.

Prioritization Exercise

Post-Workshop Survey

After the meeting, workshop participants were directed via email to complete a recommendation prioritization survey, based on the summary workshop recommendations. Respondents were asked to rank (from highest to lowest) numbered recommendations within the three topic areas: (A) Infrastructure/Shared Resources, (B) Methodologic and (C) Enhancing Use of PROs in Health Systems — and to identify their top three research priorities.

Nineteen workshop participants responded. Half of survey participants listed their primary affiliation as academic, 16% as clinician, and 5% as patient, policymaker, or payer (16% did not identify any affiliation).

Overall Recommendations: The top recommendation was a tie between A3 Identify needs for PRO data by target audience (patients, clinicians, health systems, purchasers, payers) and B1 Conduct clinical trials and observational studies to establish the value of PRO data to support clinical care actions, quality measurement and comparative effectiveness research. The top recommendations grouped by topic area are: Methodologic (14 times), Enhancing Use of PROs in Health Systems (8 times), and Infrastructure/Shared Resources (5 times). Two survey participants also volunteered a write-in suggestion of testing PRO reporting formats for both patients and providers.

Within each category (when ranked highest to lowest), the top recommendations were: develop interoperable data platforms (A5); develop and implement standards for collecting, storing, reporting and transmitting PRO data with guidelines for optimizing response rates and handling missing data (B6); and identify needs for PRO data by target audience (patients, clinicians, health systems, purchasers, payers) (C1).

These top-identified priorities suggest that respondents:

- Feel general guidelines are needed to ensure data quality, accurate reporting and use.
- Consider interoperability to be a key requirement for large-scale PRO collection.
- Recognize the wide range of uses PRO information can have when integrated into an EHR system-- and the current lack of knowledge as to PRO content needs for a wide range of stakeholders.
- Are looking for tools and resources needed for large-scale, sustainable use of PROs within health care through EHR platforms.

Overall Summary and Synthesis

A brief summary of important take away points from the meeting can be organized around the questions posed at the beginning of the meeting related to patients and PRO data use, clinical use of PRO data, and research and quality measurement:

Patients and data use

How can patients be engaged in PRO data collection?

The quote "The next phase of meaningful use is making it useful to patients" captures the goal that directs a variety of strategies to engage patients in PRO data collection. A good starting point is providing information that answers patients' questions, such as "how do I compare to other patients like me?" with regard to outcomes that are important to them. Patients generally have few objections to providing information about themselves so long as they get appropriate feedback that the information is used to inform their care. Education and demonstrations about the usefulness of PROs can be motivating to some patients. Offering patients more control over which PRO measures they complete, and when they complete them, may allow for a more active role for patients. Questions that speak to goals and aspirations of patients in a way they can identify with can improve engagement. Patients and caregivers represent a wide range of ages and illness experiences, and have varying degrees of internet access. Tailoring PRO collection to the individual patient preferences, while limiting burden is important to achieve acceptable response rates. Ultimately, while clinic PRO collection can improve response rates, work is necessary to best integrate collection within a clinic's workflow to eliminate redundancy and respect a patient's time.

What are ethical barriers to use of PROs for clinical care and research?

Medical ethics hinges on the principles of the relative benefits and harms from PRO data collection, on respect for persons, and privacy. For PRO use to be considered acceptable to patients, they must understand and value the benefits. There are some potential harms associated with PRO data collection and the use of those data. Data collection can take time, can require responses to questions patients may not want to answer, and can ask questions about symptoms and function that have the potential to be upsetting, or make the patient uncomfortable (i.e., a sensitive topic on sexual function, drug or alcohol use, or mental health) . Additionally, administering questionnaires over the internet brings with it the risk of data security and unauthorized access. Questions that do not seem germane, do not seem to be used, or that are asked repeatedly would be considered disrespectful if not adequately explained to the patient.

Patients have the right to review medical information about themselves. Initiatives such as Blue Button (Blue Button) and OpenNotes (Delbanco) that give patients access to their health information suggest this movement is gaining momentum in health care. However patients only have limited, if any, access to their PRO scores, reports, or raw item-level data. They have very limited control over who has access to collected PRO data, even for sensitive topics for which they may want access restricted. The design of instruments, data collection and data displays should keep these ethical issues in consideration.

It is possible to envision a continuum of patient engagement in the production of PRO data. At the most basic level, the patient is a passive provider of data with no knowledge of where the data go and no access to the results or other clinical data. The next level is patient as data provider who is informed about the uses of the data. The third level would be patient data

provider with access to their own results and consolidated data about their health. The final level would be the patient as active partner in health data provision, with a role in deciding what PRO data to provide, when they are provided, and to whom.

Clinical use of PRO data

How can PRO measures be integrated in the clinical workflow?

Integrating PRO measures into the clinical workflow and the electronic health record requires a detailed understanding of what that workflow is in the first place. The clinical team includes multiple staff members, and should not be designed with only physicians in mind. On the other hand, the involvement of physicians is needed at multiple points in the lifecycle of PRO development, selection and implementation. Following both the patient through the course of care and the clinicians in their work can promote successful integration. Automating data processing so that PROs collected once can be used to actually save time, and direct appropriate clinical actions can both promote adoption and improve care.

What are current barriers to collection and integration and how can we learn from successful models?

Important barriers include time pressures, IT bottlenecks, inadequate available hardware and software, lack of interoperability (particularly in smaller health systems and practices), lack of familiarity among patients and clinicians about PROs, and lack of sufficient evidence to support best practices and clinical usefulness of PRO measures. There are a few examples of successful models and best practices around the US, which have taken different approaches to governance, design and implementation. It is possible to learn from and replicate some of those approaches, particularly in ways that promote common data models and interoperability.

How can PRO data be presented to clinicians to facilitate usefulness?

The optimal methods of data display for clinicians have yet to be identified. Both top down and bottom up approaches have been successful in fostering use. Policies, models and technology formulated and promoted by large systems or locations, can provide economies of scale in training and incentives for use. Clinician need to be convinced of the utility of PROs to their practice. Mechanisms that use PRO data to trigger evidence based treatment recommendations can help. The availability of physician or other clinical champions can accelerate the use of PRO measures in specific clinical areas. Training of clinicians, particularly hands on experience with PRO data, accompanied by guidelines for action can also promote learning.

In general, we need to gain a better understanding of the patient perspective and incorporate this into PRO measures. The value proposition requires obtaining information from the patient perspective to define benefits obtained from a specific treatment or approach. More needs to be done to assure patient buy-in on what and how PROs are measured. Measuring PROs efficiently may be facilitated by computer adaptive tests. It may include capturing patient goals

and preferences, and selecting PROs accordingly. More also needs to be known about how PROs apply in different contexts, such as different environments, regions and patient populations. This will require addressing culture issues and disparities in factors that affect PROs. At the same time PRO measures need to be accepted and valued by clinicians.

A general principle is to translate PROs into actions, for both patients and the clinician. For clinicians, this may include recommendations for what do to in response to PRO scores. For patients, it may include recommendations for self-management. This will require partnership among stakeholders, and research to define the actions that are most effective. PCORI can play an important role in establishing this evidence base. Value-based payment is likely to involve reimbursement by payers based on PRO scores that patients achieve. Policies need to be designed to do this in a way that creates positive incentives for access as well as high quality care.

Research and quality measurement

How can PRO data collected for clinical practice be made useful for research and quality performance measurement?

It is not certain that PRO data collected for one purpose, such a clinical practice, will necessarily be equally useful for additional purposes. For all purposes, measures must have relevance to the clinical population and demonstrated reliability and validity in those populations. This requires deliberate processes for measure selection. Strategies must be deployed to reduce missing data and handle it analytically when it occurs. Multiple modes of administration may be needed to accommodate individual preferences and circumstances. In some cases, providing incentives for data collection should be considered. For research, if data are to be aggregated across groups of patients, standardization of measures, data collection and data models are needed. This applies equally to quality measurement and improvement, and is particularly true if the goal is comparison of different groups of providers for accountability. All of these suggest that collaborative governance and cooperation across different components of the health system are desirable for research and quality measurement. The strategy of engaging patients has the fringe benefit of improving the quality of PRO data for all purposes, by improving reliability and validity and by reducing missing data.

How can needs be addressed at the measure selection stage?

For all purposes, measures must have relevance to the clinical population and demonstrated reliability and validity in those populations. This means that design or selection of measures should be done by groups including multiple stakeholders including people with the condition of interest, clinicians experienced in treating that condition, and measurement experts. For research, it may be ideal for measures to be selected by collaborative groups above the level of individual institutions.

A Challenge to the Field: Can PRO scores become as ubiquitous as blood pressure and other clinical care measures?

This meeting presented a wide-range of examples of PRO use in clinical care and population-based measurement, as well as the methods and practical considerations necessary to capture, report and use PRO information within an EHR system. Ultimately EHR integration is a game changer that allows for the integration of standardized, structured PRO information captured directly from the patient into the clinical record. It broadens the number PRO reporting options available at the individual patient-level and also allows evaluation at the clinic- and population-level.

Meaningful barriers stand in the way of commonplace, every day use of PROs, many highlighted in this workshop. In contrast to blood pressure recordings and other clinical care measures, PRO collection requires a high degree of patient engagement in the process. Ultimately, if this is not a task that is judged to be useful, it may be skipped over by patients and/or downplayed by clinicians. To be used routinely, PRO measures need to achieve a degree of familiarity and to be accompanied by clinically-relevant interpretation and advice.

To date, the majority of efforts to collect and integrate PRO information in the EHR have been driven by demonstrating clinical relevance at the individual-level. This focus on clinical relevance was a consistent theme throughout the conference as a key focus point for patient engagement, clinical practice, sustainability and large-scale research and quality improvement evaluations.

However, there was also a tension identified in this workshop between PRO use at the individual patient-level of care delivery vs. broader clinic and population-based evaluation and use. As the scope of PRO use widens, additional issues will arise regarding the usefulness of PROs to measure and monitor care. Vision, clear guidance and definitions for both patient and population-level PRO use will be important to successful PRO integration across all levels of care.

In conclusion, the PCORI Patient Reported Outcomes (PRO) Infrastructure Workshop joined patients, clinicians, researchers, healthcare system leaders, policy makers and other key stakeholders to discuss the integration of PRO measures into electronic health records. The meeting achieved its goals of developing action items for enhancing use of PROs for clinical care, research, and performance monitoring. Next steps will be to disseminate these findings widely, and to incorporate the recommended items into an action plan for infrastructure, methods and systems to accelerate the successful addition of PRO measures to the clinical database. Engagement of both patients and clinicians will be essential to assure the collection and quality of PRO data. Researchers and IT professionals will need to work together closely. Interoperability will be a key requirement if the data are to be useful for research and quality improvement. High level standardization of measures, procedures and data models and data sharing agreements will be needed. Existing networks and research collaborations should be enlisted as contributors. New methodologic research will be required to address current gaps

in conceptualization, measurement and implementation. Adoption and support by professional, private and government organizations will be required to attain sustainable use.

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Appendix

Participants

1. Panelists and Biographies
2. Planning Committee
3. Participants

Panelists Biographies

Todd Anderson
Mr. Anderson is a Software Developer for EPIC. He holds a BS in computer science engineering from Washington University in St. Louis

Elissa Bantug
Ms. Bantug is a Program Coordinator with the Breast Cancer Survivorship Program at Johns Hopkins School of Medicine. She is a breast cancer survivor with an extensive history of breast cancer advocacy and outreach work with multiple cancer organizations.

Ethan Basch
Dr. Ethan Basch is a medical oncologist and health services researcher at the Lineberger Comprehensive Cancer Center at the University of North Carolina School of Medicine. His clinical expertise is prostate cancer, and his research expertise includes patient-reported outcomes, drug regulatory policy, and comparative effectiveness research

Arne Beck
Arne L. Beck, PhD, is the Director of Quality Improvement and Strategic Research of the Institute for Health Research. His areas of research include mental health services, geriatrics, and advancements in health care innovation.

Marc Berger
Marc L. Berger, M.D. is Vice President, Real World Data and Analytics at Pfizer. His professional activities have included serving on the Medicare Evidence Development & Coverage Advisory Committee (MedCAC), the board of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), and the steering committee for the Agency for Health Care Research and Quality (AHRQ) Centers for Research and Education on Therapeutics (CERTs). He also co-chaired the ISPOR Taskforce on Prospective Observational Studies for Comparative Effectiveness Research and currently chairs the AMCP-ISPOR-NPC Collaborative Initiative Taskforce for the Interpreting Prospective Observational Studies for Health Care Decisions

Kevin Bowman
Kevin Bowman is the Medical Director at Well Point.

Hugo Campos
Hugo Campos is the founder of the ICD User Group. He advocates for the rights of patients with pacemakers and implantable defibrillators to gain electronic access to the data collected by their devices. Campos has been interviewed by numerous U.S. and international publications, including the San Francisco Chronicle, the San Jose Mercury News, NPR, Technology Review, Slate, 0 Estade de S. Paulo and MedGadget Espanol.

Heidi Crane
Dr. Crane is Associate Professor of Medicine in the Division of Allergy and Infectious Diseases. She is the associate director of the UW Centers for AIDS Research (CFAR) Clinical Epidemiology and Health Services Research (CE&HSR) Core, which promotes research comparing the effectiveness of management strategies for HIV-infected patients in routine clinical practice. Her research interests include chronic complications of HIV, including metabolic issues and cardiovascular disease; adherence; and other patient-reported outcomes. Dr. Crane is co-chair of the Centers for AIDS Research Network of Integrated Clinical Systems (CNICS) Sociobehavioral working group, and leads the CNICS Patient Reported Outcomes Committee.

Lynn DeBar
Lynn DeBar, PhD, is a behavioral health researcher; her work focuses on health issues that have both emotional and physical causes and manifestations, such as eating disorders, pain syndromes, and obeSity-related health problems. She is particularly interested in exploring how these health issues can be addressed and treated in primary-care settings and general medical practices. Dr. DeBar is a Clinical Assistant Professor of Public Health & Preventive Medicine at Oregon Health & Sciences University. She received a National Research Service Award postdoctoral fellowship from the Agency for Healthcare Policy and Research and previously served as a staff psychologist at the Portland VA Medical Center.

Rachael Fleurence
Rachael Fleurence, Ph.D., is Program Director of the CER Methods and Infrastructure Program at the Patient-Centered Outcomes Research Institute (PCORIL where she leads the research prioritization initiative to help identify important patient and stakeholder generated questions and establish a rigorous research prioritization process to rank these questions. methodologist with experience in systematic reviews and evidence synthesis, health technology assessment, and research prioritization methods, Dr. Fleurence has 15 years of experience in the field of health outcomes research.

David Flum
Dr. David Flum is a board-certified general surgeon whose areas of particular expertise include surgical management of gastrointestinal disorders; advanced laparoscopy; biliary tract disorders; complex abdominal wall hernias; and bariatric surgery for the treatment of diabetes. He is also an Associate Chair of Research and the Director of the Surgical Outcomes Research Center (SORCE).

Lori Frank
Dr. Lori Frank is Program Director of the Research Integration and Evaluation program at the Patient-Centered Outcomes Research Institute (PCORI). Her current research focus is on bringing the patient perspective to comparative effectiveness research to enhance the meaningfulness of outcomes and to improve decision making by health care consumers and providers. Her research on patient-based health outcomes assessment centers on psychiatric

disorders. She initiated and served as Principal Investigator of the Cognition Initiative, a multi-sponsor patient-reported outcome (PRO) development consortium and has continued in an advisory role for that work, now part of the Critical Path Institute PRO Consortium. Her other work addresses psychological, ethical, and legal aspects of memory screening and medical treatment decision making by older adult patients. Dr. Frank serves on the Memory Screening Advisory Board of the Alzheimer's Foundation of America, bringing the patient perspective to this work to maximize patient autonomy and optimize patient and caregiver care decision making.

Russell Glasgow
Russell Glasgow, PhD, joined the School of Medicine in September as associate director of the School's Colorado Health Outcomes (COHO) research program and as visiting professor in the Department of Family Medicine. Glasgow is a nationally known expert in studying ways to improve the translation of research into the health care delivery system and is a driving force behind a planning and evaluation model called RE-AIM. Glasgow was deputy director for implementation science at the U.S. National Cancer Institute from 2010 to 2013. His extensive experience includes working for the AMC Cancer Research Center from 1998 through 2002 and Kaiser Permanente Colorado's Institute for Health Research from 2002 through 2010.

Kate Goodrich
Kate Goodrich is the Director of the Quality Measurement and Health Assessment Group at the Centers for Medicare & Medicaid Services. Prior to coming to CMS, Dr. Goodrich served as a Medical Officer in the office of the Assistant Secretary for Planning and Evaluation (ASPE). She managed the portfolio of ASPE Comparative Effectiveness Research (CER) projects, including the creation of a multi-payer claims database for CER. She was also the project manager for the HHS contract with the National Quality Forum.

Leslie Kelly Hall
Leslie Kelly Hall is the Senior Vice President of Policy at Healthwise. She combines experience as a former hospital administrator and vision as a consumer/patient advocate to fuel patient engagement in health care. In addition to her patient engagement efforts, her HHS committee work gives her in-depth knowledge of Meaningful Use requirements. Hall is a frequent presenter at federal and industry summits, including the 2012 White House Patient Access to Health Data Summit, the Post-Acute Health IT Summit, and the HL7 Plenary Session on Patient Engagement.

Roxanne Jensen
Roxanne Jensen is an Instructor on the Research Track in Population Sciences at Georgetown University.

Carolyn Kerrigan
Carolyn Kerrigan is a professor of surgery at the Dartmouth Geisel School of Medicine. She is board certified in plastic surgery and surgery of the hand. She completed her medical education and residencies at the McGill University in Montreal.

Ajit Krishnaney
Ajit Krishnaney, MD, is a Staff Physician in the Center for Spine Health, an Associate Staff Physician in Neurological Surgery and an Associate Staff Physician in the Cerebrovascular Center at Cleveland Clinic. He was appointed in 2005. Dr. Krishnaney's specialty interests include cervical spondylosis, degenerative spine disease, complex spine instrumentation, spine tumors, spinal cord tumors, syringomyelia, spinal vascular malformations, cerebrovascular disease including AVMs and intracranial aneurysms, general neurosurgery.

Kevin Larsen
Kevin L. Larsen, MD is Medical Director of Meaningful Use at the Office of the National Coordinator for Health IT. 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.

Michael Malone

Leo Morales
An accomplished physician scientist known for his research on Latino and immigrant health, Dr. Morales is jumpstarting the Institute's investigations into regional health disparities and cross-cultural survey methodology. Before joining the Institute, Dr. Morales was a tenured associate professor in general internal medicine and health services research at the David Geffen School of Medicine at University of California, Los Angeles (UCLA).

Esi Morgan DeWitt
Esi Morgan DeWitt, MD, MSCE is a pediatric rheumatologist and researcher. Dr. Morgan DeWitt leads a research project to develop new measures to assess pain in children and youth, as well as to validate measures of health related quality of life in children with juvenile idiopathic arthritis or chronic pain as part of a national network of investigators. Dr. Morgan DeWitt is a leader in a multi-center quality improvement network to improve the outcome of care in children with JIA, the Pediatric-Rheumatology Care and Outcomes Improvement Network. Additionally, she has served on expert panels in development of JIA treatment recommendations and measures of quality of care in treatment of JIA."

Eugene Nelson
Eugene Nelson is a Professor of Community and Family Medicine, and a Professor of The Dartmouth Institute. Dr. Nelson's research interests involve quality improvement and measurement of system performance, health outcomes, customer satisfaction, and the development of patient-centered healthcare systems.

Karen Pace
Karen Pace is the Senior Director of Performance Improvement for the National Quality Forum.

Collette Pitzen
Collette Pitzen, RN, BSN, CPHQ supports the development and testing of new clinical measures for MNCM. Measure development work at MNCM has included measures in the following areas: depression, spine surgery, total knee replacement, hospital readmission and pediatric prevention. She has 27 years of experience in a variety of health care settings, with a significant portion of time devoted to quality improvement, measure design and reporting.

Bryce Reeve
Dr. Reeve is a psychometrician and outcomes researcher. His work focuses on enhancing the application of patient-reported outcomes (PROs) in clinical research and practice to improve the quality of care for pediatric and adult cancer patients. This includes the development of PRO measures using qualitative and quantitative methodologies and integration of PRO data in research and healthcare delivery to inform decision-making. He is the Principal Investigator of the Coordinating Center for the NCI-funded network to develop the pediatric version of the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE).

Gregory Simon
Greg Simon is a Senior Investigator and Pshychiatrist with Group Health. r. Simon has led several studies showing that simple, relatively inexpensive care management programs can significantly improve the lives of people with mood disorders-both at Group Health and in clinics serving low-income urban patients in developing countries. Dr. Simon is especially interested in developing and studying programs that empower patients to become more active partners in their care and to achieve a fult rewarding life-not just a decrease in symptoms and side effects. He frequently partners with the Depression and Bipolar Support Alliance (DBSA), the nation's largest patient-run organization for people living with mental health conditions. He also chairs their scientific advisory board.

Mary Tinetti
Mary Tinetti is an American physician, and Gladys Phillips Crofoot Professor of Medicine and Epidemiology and Public Health at Yale University, and Director of the Yale Program on Aging. She pioneered the study of morbidity due to falls by elderly people, and investigated risk reduction strategies that were both effective and cost-effective. Dr. Tinetti has been a member

of the Board of Directors for the American Geriatrics Society and served on several national advisory committees including the Advisory Council of the National Institute on Aging, the Beeson Faculty Scholars, the Robert Wood Johnson Generalist Physician Faculty Award, the Brookdale fellowship, and the Food and Drug Administration Nonprescription Drug Advisory Committee which she chaired. She is a member of the Institute of Medicine and was recently named a MacArthur Foundation fellow and is currently an Atlantic Philanthropies Health and Aging Policy fellow at Centers for Medicare & Medicaid Services.

Phyllis Torda
Phyllis Torda is Vice President of the Quality Solutions Group at NCQA, which leverages NCQA's expertise to meet the needs of agencies and organizations in both the public and private sectors. Current initiatives include promoting the use of electronic health records for performance measurement, strategies and methodologies for physician measurement and evaluating Medicare Special Needs Plans. Prior to coming to NCQA, Ms. Torda was Director of Health and Social Policy at Families USA, a consumer advocacy group focusing on health reform issues. Ms. Torda has worked for over 25 years on health policy issues, particularly those relating to vulnerable populations. She has completed all requirements except the dissertation for a Ph.D. in History from the University of Wisconsin (Madison).

Ann Marie Trentacosti
Ann Marie Trentacosti, M.D. is a senior medical reviewer with the Office of New Drugs (ONDL) Center for Drug Evaluation and Research, FDA. Her current position is acting Labeling Team Leader in Study Endpoints and Labeling Development (SEALD). She advises OND review divisions in matters of regulatory policy pertaining to the development and validation of study endpoints and the adequacy of clinical study protocol design and analysis plans to support the interpretation of study endpoints intended for use in labeling and promotion. Much of her endpoint activities have focused on measures of treatment benefit to determine the impact of medical products to treat gastrointestinal disorders

Albert Wu
Albert Wu is a professor at the the Johns Hopkins Bloomberg School of Public Health and the Director of the Center for HEalth Services and Outcomes Research. His research and teaching focus on patient outcomes and quality of care. He was among the first to measure quality of life outcomes in people with HIV. He was one of the founders ofthe Outcomes Committe of the AIDS Clinical Trials Group of the NIH ACTG. He developed the MOS-HIV Health Survey, a leading measure of health related quality of life for people with HIV that is used widely in international trials and research studies. He is director of the AHRQ-funded Hopkins DEcIDE center for comparative effectiveness research. He is co-developer of PatientViewpoint, a web portal to link patient reported outcomes to the Electronic Health Record. He is a practicing general internist.

Peter Yu

Peter P. Yu, MD, a renowned medical oncologist and hematologist and a pioneer in advancing health information technology to improve quality of care, has been elected President of the American Society of Clinical Oncology (ASCO) for a one-year term beginning in June 2014. Dr. Yu is currently the Director of Cancer Research at Palo Alto Medical Foundation. He received his medical degree from Brown University, and performed his internship and residency in Internal Medicine at St. Luke's-Roosevelt Hospital and a fellowship in Neoplastic Diseases at Mount Sinai Hospital. Dr. Yu was also a Research Fellow and Associate at Memorial Sloan-Kettering Cancer Center. Dr. Yu is well-known for his knowledge and understanding of how health information technology can advance the prevention, diagnosis and treatment of cancer care.

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