# Adopting Patient-Reported Outcomes in Clinical Care: Challenges and Opportunities

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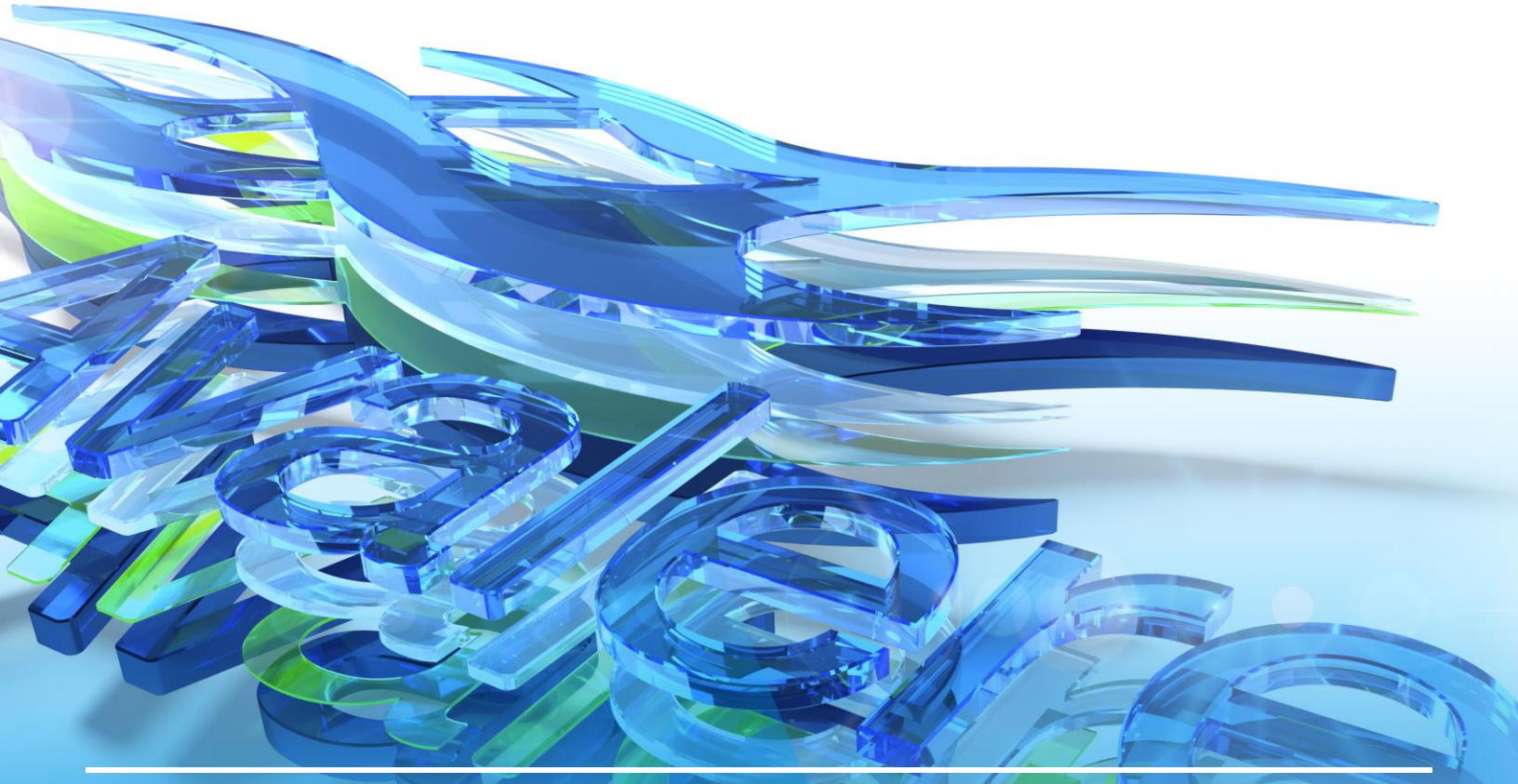

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# Introduction

Patient-reported outcomes (PROs) have been used for several decades in clinical research to assess health-related quality of life (HRQoL) and functional status as reported directly by patients. PROs are now also being used by forward-thinking providers and payers in ongoing clinical care to track patients' health status and responses to treatment. Less frequently, PRO-based performance measures (PRO-PMs) are being used to assess quality and to determine payments for care. These routine uses of PROs in clinical practice are critical to the movement to value-based payment from volume and to patient-centric care. Yet, to date, their use has been limited without payment incentives and legislative mandates to spur the development and implementation of PRO-PMs. Despite some progress by early adopters, there are still considerable challenges to the broad adoption of PROs in clinical care.

To better understand key motivations and barriers to using PROs in clinical care, Avalere conducted a literature review, identified existing PRO-PMs in use by payers through our proprietary quality measures database, and conducted interviews with early adopters of PROs. In this paper, we provide our findings and recommendations for next steps.

# Background

The case for broad use of PROs in care delivery is strong. Building PROs into clinical care offers a means of responding to calls by policymakers, providers, and payers for more patient-centric care. PROs can be used to provide clinicians direct patient feedback about their response to medications, experience of symptoms, barriers to treatment adherence, and health status. PROs can also be used to help stakeholders understand which interventions achieve the best clinical outcomes in which patient groups. The National Qualify Forum, in its 2011 National Voluntary Consensus Standards for Patient Outcomes: A Consensus Report, stated that PROs collected in care delivery are important because they "reflect the reason consumers seek healthcare".[1] One researcher noted that "patient reported outcome measures are precisely the missing link in defining a good outcome."[2] Patient groups, clinicians, manufacturers, and professional societies have elevated the need for more PROs in hopes of using the right tools to answer questions such as:

- What treatments work for patients and when should they be administered?
- What opportunities exist for customizing treatment approaches?
- How can patient progress toward a clinical goal be systematically tracked?
- Does the patient believe treatment has improved his/her HRQoL?
- Where should systems of care invest resources to improve performance and optimize potential gains associated with the use of PRO-PMs?

Despite the potential value of broad PRO use in clinical care, their adoption in the US is largely limited to select patient groups and conditions – such as patient responses to chemotherapy regimens or to interventions for mood disorders or joint replacements.[3-5] Instead, public and private payers largely rely on measures of hospital performance such as avoidable readmissions, hospital-acquired infections, rates of "never events," and untimely deaths. For ambulatory care, they use process measures such as rates of annual eye exams for diabetics, prenatal monitoring, and changes in clinical values such as blood pressure A1C levels. While PRO collection could supplement these measures with valuable information from patients about how their disease and treatments are affecting their health and well-being, use across broad groups of patient types and treatments is in early stages of implementation by only a handful of early adopters.

# Methods

As part of this research, Avalere conducted a literature search, reviewed existing performance measures, and conducted interviews with clinicians/administrators of provider organizations.

- Literature search was conducted using Clinicaltrials.gov for studies published between 01/2011-11/2017. Search terms included "patient-reported outcome," "PROM," and "patient-reported outcome measure". Available literature published on PubMed between 01/2011 – 10/2016 was reviewed for 9 disease states (Inflammatory Bowel Disease, Rheumatoid Arthritis, Psoriasis, Prostate Cancer, Non-Small Cell Lung Cancer, Mantle Cell Lymphoma, Chronic Lymphocytic Leukemia, Multiple Myeloma, Depression), which were selected because they are high-burden, high-cost conditions. Articles were limited to English and research from the US or Europe (Search Strategy: Appendix 1).
- Using Avalere's proprietary database of 6,000+ quality measures in use by US payers and providers, Quality Measures Navigator® (QMN), we identified existing PRO-PMs (Exclusions: measures of patient satisfaction and experience). See Appendix 2 for additional information about the QMN.
- Interviews were conducted with 4 clinicians and administrators based on providers using PROs in care delivery. Organizations were located in Massachusetts, Michigan, Connecticut, and Utah. Telephone interviews were 45 minutes in length and guided by a structured interview guide (Interview Guide: Appendix 3).

# Key Findings

## Current PRO Tools Are Limited in Their Applicability to Clinical Practice

Most tools to collect PROs in existence today are not directly applicable to routine use in clinical practice. Patient surveys have been shown to be an effective way to capture PROs.[6] They can help assess health status and response to disease treatment; however, many surveys lack customization to either the disease and/or measurement of care. The development of health-related patient surveys has primarily been research focused with specific objectives. In the US, the RAND Health Insurance Experiment advanced methods for developing and validating patient surveys assessing health-related function and well-being in the late 1970s and early 1980s.[7] As pharmaceutical manufacturers included PROs in clinical trials throughout the 1980s, debate regarding whether PROs sufficiently measure change in disease as a response to treatment grew. The trend in development of PROs for use in clinical trials has been one of rigorous methodological requirements for documenting layers of general health status change in addition to disease- and treatment-specific outcomes.[8]

As a result, PRO survey development has been tailored to the conditions of clinical trials, defined study periods, clinical trial providers, and clinical trial patients. These are distinct from the requirements for PRO surveys to be used in ongoing clinical care, outside of research settings. While there are many PRO surveys available, careful selection and adaptation to the requirements of clinical practice is needed.

## Barriers to Adoption of PROs in Clinical Care Are Prevalent

The literature review revealed extensive discussions of barriers to adoption of PROs in clinical care. A key barrier is a lack of clearly established practices for implementing and managing a PRO program. Issues include which surveys to use for which patient types, how to manage data collection, how to ensure adequate patient response rates, and how to best report data to clinicians.[9-11] In addition, variation in clinician perceptions of the value of PRO reports, insufficient training for survey use, and lack of payment for time spent interpreting outcomes discourages clinicians from collecting and using PROs.[10,11-14]

Another theme identified in the literature is skepticism concerning the value of PROs due to a lack of consistency between data collected and clinical measures. For example, in a review of the literature linking improvement in pain to patient satisfaction following spine surgery, more than 50% of patients reported satisfaction with surgery despite no clinically documented improvements.[15] Another study reported that 6 weeks following joint replacement surgery, patients reported pain reduction and increased walking distances, even though daily steps tracked did not actually increase.[16] For many providers, findings such as these call into question the reliability of PRO data linked to clinical outcomes; however, discordance between patient-reported and provider-observed outcomes may be appropriate as only the patient may notice certain treatment effects.

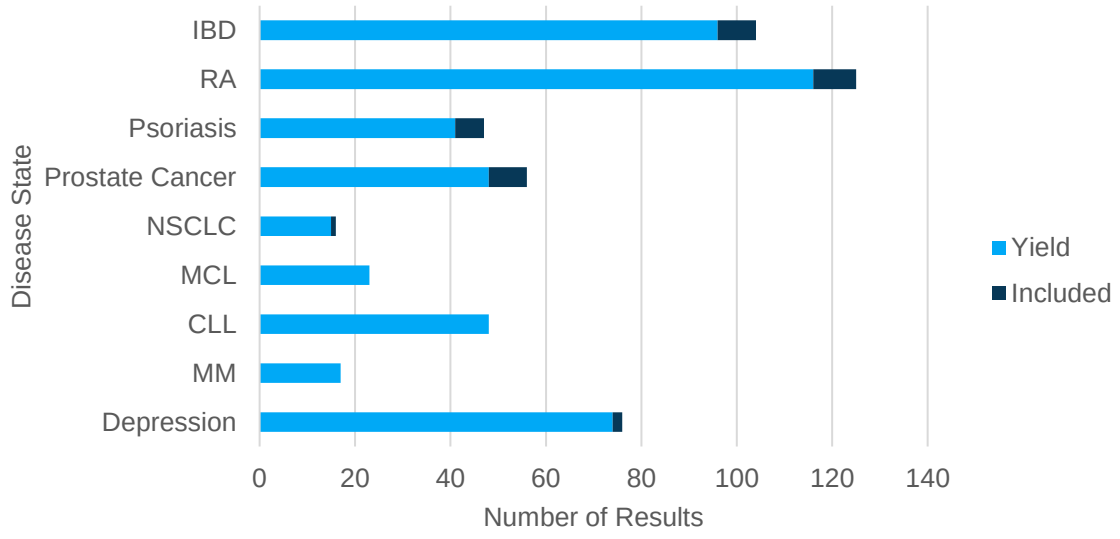
The literature also addresses the burden of collecting PROs given a lack of infrastructure, as few electronic medical records (EMRs) have integrated PROs into practice.[9,11,14] While studies have demonstrated the potential to successfully integrate PROs into electronic formats,[17] this is not routinely done in clinical practice, highlighting a need for standardization.

## Range of Use of PROs Is Narrow

There are limited indications of PRO use in clinical care in both numbers of providers using them and PRO surveys being used. In 2016, Health Catalyst conducted a national survey of 100 hospital executives, which found that 18% of respondents reported they consistently used PROs to inform care decisions.[18] The survey asked respondents to indicate barriers to PRO collection. The most common responses were lack of incentives for survey completion and time to review the PROs, followed by difficulty fitting PRO collection and reporting into established work flows.[18] However, a majority (72%) of respondents who are not currently collecting PROs, predicted they would start using PROs within 3 years.[18]

Our PubMed search found 478 articles discussing integration of PROs across the 9 disease states reviewed, such as survey development, testing, data collection requirements and challenges, etc., but only 34 articles discussed the use of PROs in clinical care. Of the 9 disease states, only 4 (IBD, RA, psoriasis and NSCLC) had studies that discussed PRO use in clinical care (Figure 1).

**Figure 1: PubMed Search Results by Disease State**




IBD: Inflammatory Bowel Disease; RA: Rheumatoid Arthritis; NSCLC: Non-Small Cell Lung Cancer; MCL: Mantle Cell Lymphoma; CLL: Chronic Lymphocytic Leukemia; MM: Multiple Myeloma

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Using the QMN, we found limited use of PROs. Of the 6,000+ measures in the database, only 13 were based on PROs. These measures are all used in Medicare programs in 2017 (Figure 2). They apply to a limited number of patient diseases/conditions: cataracts; pain management; depression; varicose veins; headaches; and care transitions.

**Figure 2: 2017 PRO-PMs Used in Medicare Performance Programs**

- Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
- Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery
- Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment
- Depression Remission at Six Months
- Depression Remission at Twelve Months
- Improvement in Pain Interfering with Activity
- Percent of Patients Who Self-Report Moderate to Severe Pain (Long-Stay)
- Percent of Patients Who Self-Report Moderate to Severe Pain (Short-Stay)
- Percent of Patients Who Have Depressive Symptoms (Long-Stay)
- Percentage of Patients Treated for Varicose Veins Who Are Treated with Saphenous Ablation and Receive an Outcomes Survey Before and After Treatment to track change over time
- 3-Item Care Transition Measure (CTM-3)
- Quality of Life Assessment for Patients with Primary Headache Disorders
- SF-36 (Health Outcomes Survey) - intended for patients in outpatient care

## Experience with PROs in Clinical Care Is Mixed

In interviews with early-adopter clinicians and administrators in practices using PROs, respondents indicated elements of successful implementation. A medical director in a New England health system reported their PRO program was possible due to efficient electronic collection of PROs and automatic reporting into the EMR, demonstrating benefit for the health system. They also reported that support from payers, both in requiring PRO collection for selected conditions and in counting PRO collection as part of a quality performance metric, was important (Figure 3).

**Figure 3: Case Study – Implementation of PROs**

| Case Study | |
|---|---|
| This Massachusetts-based organization is an integrated delivery system (IDS) providing care to 700,000+ covered lives in 20 ambulatory practices. In 2017, with the strong support of its largest payer, Blue Cross Blue Shield of Massachusetts (BCBSMA), this IDS began collecting PROs for its hip and knee pain patients as a part of its quality improvement activities. The IDS now plans to collect PROs from patients with the following conditions: depression; COPD; prostate cancer; coronary disease; back pain; and chemotherapy/radiation patients. As a long-term goal, the IDS would like to collect measures addressing social determinants of health. | |
| **Key elements of the PRO program include:** | **Use focuses on two key issues:** |
| • Electronic PRO collection<br>• Display of patient reports in medical record<br>• Support from payer | • To report back to clinicians to judge effectiveness of treatment and patient needs.<br>• To assess (on a population basis) what interventions are working best for which patients. |

An interviewee from an academic medical center located in the Southwest, indicated their medical system requires patients to complete a brief PRO survey prior to each visit. Patients can view their PRO scores in their EMR portal and enter free text comments. Patient willingness to complete surveys is attributed to this patient access to PRO records.

In another case, a medical director at a Northwest health system cited barriers to PRO use including cost of collecting and reporting data and a lack of plans for how clinicians or administrators would use outputs. The interviewee noted the use of both a depression and an anxiety symptoms severity PRO (PHQ-9 and GAD-7) for patients being treated with computer-aided cognitive behavioral therapy (CCBT). For patients in this program, depression and anxiety symptoms became less severe during and after CCBT. Evidence allowed this program to spread and scale.

A medical director and Emergency Department physician in a New England academic medical center found PROs to be useful in improving doctor-patient communications, in detecting unrecognized problems, and in "simply letting patients have more control over their care." He also observed problems for clinicians in using PROs: difficulty interpreting PROs, translating data into meaningful action, and concerns patients may be biased in what they report for their clinicians' viewing. Limited clinical utility, difficulty with interpretation, concern about bias, and delayed reporting are just a few of the issues that we have seen with PRO data collection.[19] He

also noted PROs are more valuable to clinicians involved in ongoing management of patients and less valuable in episodic care settings, such as the Emergency Department.[19]

# Conclusions

We found evidence in both the health policy literature and in interviews with providers that despite strong interest in broadening the use of PROs in clinical care, there are barriers to adoption. Our research finds that while PROs are a valuable patient-centric tool, funding for collecting, reporting, and interpreting PROs is not generally available.

On a practical level, one of the first steps to increasing clinicians' effective use of PROs is to report survey responses to help guide treatment decisions. When there is an appreciation for PRO value, early adopters can begin to use aggregate survey responses to assess how well specific interventions are working, to support protocols, and to assess general patterns of care. Other practical efforts to decrease barriers to PRO use would be to provide training in implementation and interpretation of PROs, and to reimburse providers for time spent reading and discussing reports with patients. In addition, the development of easy-to-use digital tools for PRO collection that give patients choices of how and where they enter responses would support timely patient responses and better data.

At the policy level, both federal and non-governmental agencies are taking actions to address impediments to wider PRO collection and use in clinical care (Appendix 4). Steps such as these appear both well-aimed and well-timed to support quality improvement through the wider collection and use of PROs to support both treatment decisions for individual patients and selection of key performance measures for patient populations. Concerted stakeholder focus on the development of PRO-PMs will not only help stakeholders to address key treatment and resource investment questions, but also better prepare clinicians as payment incentives and value-based contracting linked to such outcomes continues to evolve.

We have reached a stage in PRO use in clinical care where there is a meaningful core of early adopter providers and payers eager to exchange their experiences, challenges, and solutions for broader collection and use of PRO-PMs. A consortium of these early adopters combined with initiatives by both governmental and non-governmental agencies could speed the adoption of PROs. We have an opportunity to convene more collaborative efforts across interested providers, payers, governmental and non-governmental agencies to exchange knowledge and identify the most valuable and innovative implementations.

# Appendices

## Appendix 1: PubMed Therapeutic Area Specific Search Terms

| Disease | Search Criteria |
|---|---|
| **IBD** | (inflammatory bowel diseases [MeSH Terms] OR Crohn's disease [MeSH Terms] OR colitis, ulcerative [MeSH Terms]) AND ("patient-reported outcome" OR "patient-reported outcomes" OR "PRO" OR "PROM") Article type: Review, Publication dates: 5 years |
| **RA** | (arthritis, rheumatoid [MeSH Terms]) AND ("patient-reported outcome" OR "patient-reported outcomes" OR "PRO" OR "PROM") Article type: Review, Publication dates: 5 years |
| **Psoriasis** | (psoriasis [MeSH Terms] OR arthritis, psoriatic [MeSH Terms]) AND ("patient-reported outcome" OR "patient-reported outcomes" OR "PRO" OR "PROM") ") Article type: Review, Publication dates: 5 years |
| **Prostate cancer** | (prostatic neoplasms [MeSH Terms]) AND ("patient-reported outcome" OR "patient-reported outcomes" OR "PRO" OR "PROM") Article type: Review, Publication dates: 5 years |
| **NSCLC** | (carcinoma, non small cell lung [MeSH Terms]) AND ("patient-reported outcome" OR "patient-reported outcomes" OR "PRO" OR "PROM") Article type: Review, Publication dates: 5 years |
| **MCL** | (lymphoma, mantle cell [MeSH Terms]) AND ("patient-reported outcome" OR "patient-reported outcomes" OR "PRO" OR "PROM") Article type: Review, Publication dates: 5 years<br><br>(lymphoma [MeSH Terms]) AND ("patient-reported outcome" OR "patient-reported outcomes" OR "PRO" OR "PROM") Article type: Review, Publication dates: 5 years |
| **CLL** | (leukemia [MeSH Terms] OR leukemia, lymphocytic, chronic [MeSH Terms]) AND ("patient-reported outcome" OR "patient-reported outcomes" OR "PRO" OR "PROM") Article type: Review, Publication dates: 5 years |
| **MM** | (multiple myeloma [MeSH Terms]) AND ("patient-reported outcome" OR "patient-reported outcomes" OR "PRO" OR "PROM") Article type: Review, Publication dates: 5 years |
| **Depression** | (depression [MeSH Terms]) AND ("patient-reported outcome" OR "patient-reported outcomes" OR "PRO" OR "PROM") Article type: Review, Publication dates: 5 years |

## Appendix 2: Description of the Quality Measures Navigator

Quality Measures Navigator® (QMN) is Avalere's first-in-class quality measure database. The QMN is a regularly updated, dynamic repository of quality measures obtained from publicly available sources, including: Quality measure databases such as the National Quality Forum (NQF) Quality Positioning System; U.S. professional societies, and PCPI®; quality programs including those sponsored by the Centers for Medicare & Medicaid Services (CMS); and quality recognition and accreditation programs sponsored by organizations such as URAC, the Joint Commission and the National Committee for Quality Assurance (NCQA). Measures are regularly updated within the database at differing intervals depending on the source (e.g., NQF bi-monthly, NCQA annually).

## Appendix 3: Interview Guide

| Goal | Question |
|---|---|
| Understand the stakeholder | • Could you please confirm which department you sit in at Atrius? How does that relate to the overall organizational structure?<br>• Can you talk about the link between your role and Patient-Reported Outcomes (PROs)? Specifically, how you involved in the selection of PROMs or the decision-making related to PROMs?<br>• How are PROMs and PRO data viewed at your institution? A high priority? Still hasn't caught on yet? |
| Assess current PROM data collection efforts | • We know that Atrius is affiliated with the Blues, was it the larger organization of Blue Cross Blue Shield that urged Atrius to start collecting PROMs, or someone at Atrius? If it was from the Blues, what department specifically and if it was at Atrius, where did this drive come from?<br>• In addition to the 3 PROMs in depression, oswestry, and total joint pain that BCBS requires you to collect, do you as an organization collect any other PROMs?<br>• If yes, what PROMs do you include, and for what disease/therapeutic areas (probe: oncology, depression, psoriasis, IBD, Crohns)?<br>  o How were these PROMs identified? Are the tools used in these PROMs one that are established or were they developed by Atrius?<br>• What barriers have you experienced in collecting PRO data? What efforts or modifications have you made to overcome them? |

| | |
|---|---|
| | ○ Examples of challenges: resistance of providers, administrative costs, and lack of efficient means to collect, analyze and apply to care (i.e. claims data).<br>• What is the data collection method for those PROMs you assess? What is the scoring method?<br>• How are clinicians trained to collect this data? |
| Determine how PROM outcomes are used | • How do you use data collected from PROMs for internal decision-making? (i.e. to make decisions about what drugs to use, to determine what types of disease interventions to apply, how to better manage patients etc.)<br>• Are there interventions applied to patients based on the outcomes of PRO data?<br>• Are there any incentives tied to clinicians reporting on PROMs? If so, what are they? |
| Future of PROM/PRO-PM use (US-Based Questions) | • Do you anticipate any changes in the use of PRO data for decision-making? In which ways?<br>• Are there plans to collect additional PROMs in the future? If yes, has your organization identified in what therapeutic areas you would ideally collect PROMs? Is the plan to use existing PROMs or are you looking at creating your own?<br>• Do you see opportunities for more PROM collection in expanding availability of mobile devices, web-based tools, patient portals, etc. (if yes, can you provide some examples of what you currently doing)?<br>• What tools/modes of data collection for PROs do you see as supporting data collection for measures?<br>• What are the biggest obstacles to routine and widespread use of PROM measures to drive quality in the health care system? |

## Appendix 4: Federal & Non-governmental Agency Efforts to Advance PRO Collection & Use

| | |
|---|---|
| At the federal level, in 2016 and 2017 CMS announced work on quality measures, including PROs for patient groups as diverse as hospice, post-acute care, and end-stage renal patients.[20] Further, the Agency for Healthcare Research and Quality (AHRQ) will host a competition in 2018 to encourage integration of patient-friendly PRO collection tools into EMRs.[21] | **2018**<br><br>AHRQ will host a competition to encourage integration of PRO tools into EMRs |
| Non-governmental organizations (NGOs) are also taking meaningful steps to support PROs in clinical care. For example, PatientsLikeMe, seeks to advance patient-centered research by providing a repository of PRO data that can be used in research and measure development and/or validation.[22] In 2012, the Patient Centered Outcomes Research Institute (PCORI), issued a $735,234 grant to Johns Hopkins University to develop presentations of PRO data that are meaningful and useful for patients and clinicians. Their research identified the best visual displays to help patients track their illness symptoms and compare treatment options, and to help clinicians compare treatment options.[23] | **$735,234**<br><br>Grant to Johns Hopkins University to develop presentations of PRO data |

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