Implementing Patient-Reported Outcome Measures in Clinical Practice: A Companion Guide to the ISOQOL User's Guide

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Introduction

Patient reported outcome (PRO) measures are increasingly being used in clinical practice to support patient care by helping providers monitor health outcomes and health-related quality of life (HRQOL), track patient progress, and enhance communication with their patients. However, evidence suggests that healthcare providers often experience significant practical challenges to successfully integrating PRO assessment into clinical practice workflows [1,2]. In response, the International Society for Quality of Life Research (ISOQOL) Quality of Life in Clinical Practice special interest group (CP-SIG) created a User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice (the "User's Guide").[3] The User's Guide is an evidence synthesis that outlines core considerations, with supporting citations, for implementing PRO assessment in clinics and hospitals. The User's Guide addresses the following nine questions:

1. What are the goals for collecting PRO data in clinical practice and what resources are available? Which key barriers require attention?
2. Which groups of patients will be assessed?
3. How will the PRO measures be selected?
4. How often will the PRO measures be administered?
5. How will the PRO measures be administered and scored?
6. What tools are available to aid in score interpretation and how will scores requiring clinical follow-up be determined?
7. When, where, how, and to whom will results be presented?
8. What will be done to respond to issues identified through the PRO assessment?
9. How will the value of PRO assessment be evaluated?

Impetus for the Companion Guide

During the 2013 ISOQOL CP-SIG meeting in Miami, members identified the need to better understand the realities, challenges and opportunities associated with using PRO measures in clinical practice. In response, the CP-SIG sought to create a Companion Guide to the User's Guide with information from real-world case studies of current PRO implementations in clinical practice to assist health care providers with the operational issues involved in implementing and using PRO measures in clinical care.

Methods

A core working group of CP-SIG volunteers (KH, LN, TE, EC, SPM) was established. The group initially developed a template based on the nine questions represented in the User's Guide, to inform the collection of real life case studies with which to illuminate pragmatic experience and guidance for PRO implementation and use. During 2014, the working group sent an open invitation to members of the CP-SIG to share their experiences of PROM use in clinical practice by participating in either a semi-structured survey or telephone interview.

Participants

Ten members of the CP-SIG agreed to participate in the initiative with six completing the survey and four participating in telephone interviews. Semi-structured telephone interviews were informed by the survey template. Participants worked largely in academic hospital settings and practiced in Canada (n=2), Denmark

(n=1), Holland (n=1), England (n=2), and the United States (n=4). The participants worked with a range of patient populations and specialties, including General Practice/Pediatrics, Occupational Medicine, Oncology, Lung/Heart Transplantation, Orthopedics, Rheumatology and Chronic Pain. Below is a list of the participating respondent sites.

Case Study #	Reference Identifier	Participant Name	Population	Country
#1	SA	Sarah Ahmed	Chronic lower back pain	Canada
#2	SB	Susan Bartlett	Rheumatoid arthritis	United States
#3	SG	Scott Gilbert	Prostate cancer	United States
#4	MH	Michele Halyard	Oncology	United States
#5	LH	Lotte Haverman	General pediatrics	Holland
#6	NHH	Niels Henrik Hjøllund	Occupational medicine	Denmark
#7	RJ	Rebecca Johnson	Orthopedics	United States
#8	AMR	Anne-Marie Russell	General practice, idiopathic pulmonary fibrosis	England
#9	MS	Maria Santana	Lung and heart transplant	Canada
#10	GV	Galina Velikova	Oncology	England

Data analysis

Members of the core working group (KH, LN, TE, EC, SPM) each analyzed up to three of the nine sub-sections of the template to identify key themes within each section. Each subsection was reviewed by at least two members to assure reliability. All reviewers met to discuss resultant themes and agree on a final overall thematic framework. This Companion Guide presents the results of the analysis, organized according to the nine questions of the User's Guide, to provide examples of issues and considerations related to the implementation of PROs in clinical practice.

Section 1: What are your goals for collecting PROs in your clinical practice and what resources are available? Which key barriers require attention?

All ten respondents reported their view that successful implementation of PRO assessment in clinical practice must start with careful, inclusive organizational planning. Prior to implementation, three key requirements were described: (1) goal setting for PRO collection, (2) identifying needed implementation resources, and (3) clearly communicating justifications for a PRO implementation to essential stakeholders.

1.1 Goals for PRO collection

A range of PRO collection goals were described, including:

1) Screening, monitoring, treatment evaluation and treatment planning were noted as being important by 8 respondents. One respondent recalled:

"*The goal is to monitor and screen children with various chronic illnesses to be able to detect problems that arise at an early stage and to provide tailored interventions before the problems increase. By providing members of the multidisciplinary team with patient responses, we facilitate multidisciplinary communication and communication between the team and the patient/parents. We also provide the response profile to patients themselves to encourage more patient-centered care." (LH)*

2) Treatment decision-making, including shared decision-making with patients and families (4 respondents).

3) Quality improvement (8 respondents). For some, PRO data collection was mandated by external agencies for quality assurance purposes:

   "Performance evaluation of a continuum of services for chronic pain to inform quality of care improvement initiatives was mandated by the Ministry of Health." (SA)

4) Enhanced patient and provider satisfaction through improved patient-provider communication and patient involvement in care (1 respondent).

5) Reimbursement, in cases where PRO data collection was mandated by payers (1 respondent). One site noted that this was the key driver:

   "*This was for standard of care which, of course, one of the reasons we do it is research, but then there's also reimbursement." (RJ)*

1.2 Defining resource needs

Resource availability varied greatly; whilst some described substantial support, for others, resources were limited. Limitations included a lack of direct financial support for materials and systems to integrate and utilize PRO data, and appropriate human resources, including available time to both initiate and maintain an implementation.

Six respondents highlighted the financial and other resources required for successful implementation. For some, a lack of up-front funding or reliance on inconsistent outside funding sources created significant challenges. Two respondents reported the benefit of using electronic PRO (ePRO) systems, but experienced difficulties with procuring appropriate funding for hardware, software, and technical resources. While integration of PRO assessment into a provider's electronic health record (EHR) could help to streamline PRO-related workflows, implementation may be difficult. Enhancing EHR systems to either accept PRO measures or link out to an external electronic system often required additional development funds and/or navigation through slow and/or complex EHR change control processes.

Moreover, creating new electronic systems was time-consuming in both the conceptualization and design stages, but the investment was essential to ensure an adequate fit with clinical workflows. One site noted that any switch to change EHR products had the potential to negatively affect implementation of PRO assessment. Two respondents reported using established electronic PRO collection ("e-PRO") systems such as the Patient Reported Outcomes Measurement Information System (PROMIS) Assessment Center (https://www.assessmentcenter.net/), which has built-in PRO capabilities such as the use of computer adaptive testing. One site discussed the implementation of a paper-based PRO collection system, but found that this was not without significant resource challenges as well. Since electronic systems can aid in the analysis and dissemination of PRO data, resources were spent transferring paper scores into an electronic data collection system.

Three respondents commented on the importance of not underestimating the amount of time and human resources required to establish and sustain PRO projects. Two respondents found that establishing the trust and buy-in from all stakeholders, including patients and providers, was an essential requirement. However, this can be a time-consuming endeavor. Six respondents reported the involvement of many different professionals on their healthcare teams, including medical doctors, nurses, medical assistants, physiotherapists, psychologists, and even front-desk administrative staff, in the administration and use of PRO measures and the presentation of PRO results. Presenting the case for PRO assessment often

requires multiple meetings and presentations over time that may be difficult to schedule, requiring more novel approaches such as early morning meetings to catch providers during rounds. One site noted a high turnover rate for clinical team members, which required sustained time and effort to ensure that new team members were up to speed. Several respondents described the importance of a local "champion" with the ability to marshal the human, technological, and other resources needed for successful implementation and adoption:

> "*Me, and then one other person that's been very supportive here…we teamed with our IT team, our enterprise data warehouse, technical all the behind the scenes coding, and architects, and analysts to build it all". (RJ)*

Four respondents discussed the importance of training both at the start and throughout the implementation process to ensure that PRO measures are being used effectively. Training is needed to ensure that stakeholders such as providers, patients, and other staff supporting PRO workflows, know how to use and implement the PRO system and interpret PRO data. One site noted a lack of existing training regimens as a barrier to adequately training stakeholders. Respondents reported training measures that ranged from short presentations and provision of reference materials to the development of a training program which adopted a behavioral change framework to formalize a knowledge transfer.

1.3 Communicating a clear justification for PRO data collection

Respondents noted that efforts must be made before initiating a PRO implementation to ensure that all concerned stakeholders – including clinicians, patients and administrative staff - will derive value from the initiative. Two respondents suggested that clinicians and staff were more likely to support PRO implementation if they understand the value of PRO data. Moreover, respondents said that clinicians should agree on the purpose of the PRO implementation, and that the chosen PRO measures should fill information gaps and meet the needs of all relevant stakeholders. It was recommended that practices achieve consensus prospectively on how best to respond to PRO results.

Nine respondents noted that it is important to consider how PRO assessments fit into clinical workflows. Six respondents noted that some clinicians reject the use of PRO measures due to the belief that their use would lengthen clinic visits. Two suggested that communicating the value of PRO data early in the implementation process, and how it can aid in clinical decision-making and the provision of services, was an important strategy to enhance buy-in. One respondent noted that patients tend to be invested in PRO assessment when their providers are invested. Unfortunately, another respondent highlighted the relative ambivalence of some clinicians; only some clinicians in their implementing clinic integrated PRO measures into a patient visits. Even when PRO data were available, some maintained a 'wait and see' attitude to issues uncovered with the PRO assessment.

Four respondents discussed how the policy implications of PRO implementation should not be overlooked. High-level leadership, information technology staff, and policymakers should be consulted to ensure that a PRO project fits all applicable security, system access, data reporting, and change control processes. Three respondents highlighted the importance of harmonizing plans for PRO data capture with organizational data security policies, stakeholder privacy concerns, and relevant laws.

Section 2: Which groups of patients will be assessed?

The characteristics of the patients involved with a PRO assessment must be carefully considered before implementation. After determining which patient populations to assess with PRO measures and the goals of assessment, attention to two key characteristics of the patient population were deemed essential by respondents to enhance PRO data collection: (1) language, physical, and mental abilities, and (2) age-based considerations. An awareness of the language abilities of the patient population - including speaking, reading, and writing – is essential to supporting the chosen patient population. Three respondents noted the importance of PRO data collection systems allowing patients to participate irrespective of their language abilities; an inability to speak a country's dominant language was reported as an exclusion criterion for using PRO assessments at two respondent sites. One respondent noted that arthritic patients found pen and paper completion of PRO measures to be problematic due to impaired manual dexterity, and these challenges were

addressed by the adoption of tablets with touch screen capabilities. In order to support the collection of PROs for children, one respondent detailed the availability of team members at clinics to support children in PRO completion. Another respondent noted the importance of using observer-reported assessments for children aged between 0 and 7 years. In addition to challenges related to the different mental and physical abilities of younger children and older adults, a patient's comfort with engaging with different technologies should be considered as well. For example, older adults may be less comfortable with electronic systems.

Section 3: How will PRO measures be selected?

Respondents described the importance of selecting the most appropriate PRO measure to collect desired information. Four major themes emerged: 1) use of existing guidelines and conceptual models; 2) consideration of measurement properties; 3) measurement ease of use; and 4) engaging clinicians, patients, and other stakeholders in reaching consensus.

3.1 Use of Existing Guidelines and Conceptual Models

Three respondents reported using existing care guidelines and conceptual models to help select the most appropriate PRO measures. These included the ISOQOL User's Guide to Implementing PROs [3], the US Food and Drug Administration (FDA) Industry Guidance document [4] and the European Medicines Agency (EMA) Reflections Paper [5], the International Classification of Functioning (ICF) [6], the Wilson and Cleary model [7], and the Triple Aim Framework [8]. Other respondents described use of the online PROMIS system (https://www.assessmentcenter.net/), because it provided a useful mode of assessment for their patient population.

3.2 Measurement Properties

To inform PRO selection, respondents described the importance of seeking evidence of key measurement properties generally, although no one discussed measurement properties as they relate specifically to individual-level rather than group-level assessment. Three respondents conducted literature reviews to aid PRO measurement selection. Respondents reported the following additional drivers:

- The PRO's face validity in the context of clinical practice
- Whether the PRO measure covers a specific medical domain or is a general quality of life indicator
- The recall period of measure items
- The availability of meaningful cut-off points to inform interpretation of results
- Clinician preferences for specific measures, including considerations of measure length and appropriateness to clinical practice
- Available language translations of the PRO measure and its cultural appropriateness

An important consideration noted by two respondents was how PRO measurement results can be used for clinical decision-making, for example, to provide information about treatment side effects, illness impact, or chronic symptoms. The experiences of one respondent lead them to state that evidence of PRO measurement validity and reliability is inadequate for judging if a measure will adequately support clinical decision-making. Three respondents described the difficulty of finding appropriate and relevant PRO measures; in response, consensus-driven lists of ad hoc questions derived from multiple measures were created.

3.3 Measurement Ease of Use

Multiple respondents felt that practical considerations such as ease of use of a measure are at least as important as the measurement properties of PRO measures. One respondent stated that in general practice, PRO measures were chosen mainly with regard to accessibility, length (i.e. number of items/time burden), response options, and ease of scoring. Three respondents noted that the length of assessments was an important consideration since having too many questions placed an undue time burden on patients. For example, an implementation in a pain clinic used a battery of measures to try to collect data on all possible outcomes for pain, which ended up being an overwhelming number of measures. Length is an important consideration for providers as well. One respondent commented that clinicians do not want to work with a lot

of unnecessary data during a clinic visit due to time constraints, and that clinicians prefer measures that are short and easy to use.

3.4 Involving Stakeholders and Patients in Reaching Consensus

Five respondent sites used meetings, focus groups, and measures involving various stakeholders and patients to reach consensus on PRO selection. Clinicians felt that it was consistent with their role to contribute to the selection and implementation of PRO measures. One respondent reported that it was vital that clinicians have full confidence in a PRO measure, down to the individual questions being asked. For this site, the content of the PRO measures at that site were negotiated based on an iterative process that involved literature reviews, interviews, and several rounds of surveys with patients and clinicians. One respondent stated that assessing patient needs was of prime importance, and that PRO implementation needed to facilitate discussion between patients and health care providers about the patient's HRQOL and psychosocial functioning. One respondent reported perceived inconsistencies between PRO results and how patients viewed their own health status, highlighting the importance of engaging with patients as 'partners' in determining which measures would be acceptable and relevant for the proposed application. During their implementation, the inclusion of measures of depression and anxiety was interpreted by a patient as suggesting that clinicians thought that their pain and disability were just 'in their head'. One respondent reviewed PRO selection with stakeholders and they collectively chose one measure to assess each domain of interest. This site noted challenges such as the time-consuming nature of gathering feedback from many stakeholders and the need to reconcile contradicting views, but they found that contributions from clinicians and government representatives were important in developing the final list of measures. These individuals provided input on policy planning, including cost of the program relative to individual and health system gains.

Section 4: How often will PRO measures be administered?

Four respondents discussed the frequency of PRO administration, and data collection was tied to clinical and/or research visits in all cases. The length of time for the collection of follow-up data varied by disease and/or treatment, the discretion of the care team, frequency of outpatient visits, and type of PRO measurement being used (e.g., whether measures were related to HRQOL, psychosocial factors, symptoms, or body functions). Data were commonly collected at the start of treatment and the most common follow-up periods were 3 months, 6 months, and 1 year. For monitoring, 1 to 2 weeks at a time was the shortest interval reported.

Section 5: How will PRO measures be administered and scored?

Three key themes emerged from respondents in terms of administering and scoring PRO measures: 1) mode and format of data capture, 2) measure scoring, and 3) engagement with providers and patients.

5.1 Mode and Format of Data Capture

Respondents reported multiple workflows for collecting PROs from patients. In five implementations, PRO data were collected via web-based systems that patients could access at home, with email prompts sent to patients and/or caregivers indicating when the measures were to be completed. This allowed PRO data collection to happen before the patient visited the clinic. Three respondents suggested that the electronic collection of PRO data could reduce errors in completion and scoring by automatically calculating complex scoring rubrics and potentially displaying warnings if patients accidentally skipped questions. Two respondents commented that patients were prompted by staff to complete measures electronically in the clinic, either through using a laptop that resides in the clinician's waiting room or a desktop in the patient room. In discussing electronic PRO administration, two respondents mentioned how important it is to consider data security measures, such as firewalls that are used to protect hospital computer systems, and decide how the PRO database will be managed in this regard. Another respondent noted that patients would not be able to access a survey if it was stored on their hospital system due to the technological firewall protecting the system, so they use an internet-based system which is linked to the patient's medical record to resolve this issue.

Three respondents also talked about paper-and-pencil administration of PRO measures with one respondent noting that response rates are often higher with this format, although patients were encouraged to use electronic modes whenever possible. Paper versions of measures were generally made available in the clinic for patients who were not able to complete them electronically, for example when hospital patients entered the clinic on a gurney and could not sit in front of a desktop computer. Multiple sites noted issues with implementing paper processes, including the "time to transfer the data into our system", paper forms being scanned into an electronic health record (EHR) and the scans being unreadable, and difficulties with providers not prioritizing the use of PRO measures if they exist outside of EHR workflows. One respondent that used a paper process considered giving patients paper forms to fill out at home, but was concerned about being able to give patients help with filling out the forms if needed, and also struggled with logistic problems around getting patients the right forms at the right time and ensuring that forms were fully completed. This respondent noted that when patients did not fill out PRO measures before coming to the clinic it caused delays in the clinic schedule, and that scanning paper forms into their EHR required significant time.

Four respondents discussed additional issues with having patients complete measures in the clinician's office/waiting room or outpatient clinic settings. One respondent noted that a significant drawback of patients completing PRO measures in front of the clinician is that the clinician has to anticipate this and have the appropriate measure ready for the patient to complete, saying:

> *You have to remember to print and have a copy before the patient walks in the clinic room. This is why screen prompts and having the questionnaire embedded in the EHR is valuable. (AMR)*

Respondents noted that busy clinicians sometimes guide patients on how to respond to PRO measure questions to hasten the PRO data collection process, which can impact the reliability and validity of results. Respondents detailed the involvement of multiple stakeholders to minimize the impact of PRO data collection on the clinician: one site had medical assistants administer PRO measures as patients checked-in and nurse practitioners access PRO data reports for follow-up visits, and another site involved front-desk staff in administering PRO measures. One respondent noted that measures were not always filled out by the patient as expected, instead being filled out by family members.

5.2 Scoring PRO Measures

In cases where PRO measures were collected electronically, the electronic software or platform used to administer the measure scored them automatically. Two respondents who administered paper-based measures had clinicians or researchers score them manually. One respondent viewed simplicity in scoring to be important, and commented on the challenge of relying on manual administration and scoring:

> *When done manually on paper, they [PRO measures] are often scanned into MR [medical record] and lost in the letters section and therefore not acted upon. (AMR)*

Respondents noted that that for validated measures, the scoring manual or guidance associated with that measure should be used. One also stated that for newly created measures that have not been thoroughly evaluated, scoring is based on evolving discussions with the clinicians using the measure.

5.3 Engagement with Providers and Patients

One respondent noted that PRO administration is most effective when the clinicians are 'on board'. They explained that completion was better in clinics where the providers were engaged in the process and initiative, noting that:

> *It depends on the clinic as well, and the provider, because if they really bought into it, I mean if a patient refuses – I've got some providers that go in there and sit down with them and say, this is really important, and finish with them. Whereas others were like 'I don't care less if they do it.' (RJ)*

Care must be taken when presenting new PRO measures to patients. One respondent reported cases where patients became upset when they were given certain measures, such as depression and anxiety

scales, when they did not feel that these scales were appropriate, and clinicians struggled to handle these types of situations. Patients also need to be engaged regularly regarding the collection of PRO data. One respondent felt that the value of PRO collection was not adequately communicated to patients by their clinical staff, which lead to patients ignoring communications about setting up an account for the online PRO collection system and subsequently not entering any data. The respondent noted that patients who were in long-term treatment needed to be reminded to answer PRO measures regularly. Two respondents found difficulties with relying on their patients' primary health care providers to refer patients to use the system as family doctors many times would not inform patients of the PRO system, or encourage them to use it.

Section 6: What tools are available to aid in score interpretation and how will scores requiring follow-up be determined?

Respondents noted several issues with the interpretation of PRO results. Some respondents noted that patients often have challenges interpreting PRO scores, subsequently finding that providers did not feel that they had time to review scores at every visit. This issue is compounded by providers and other involved stakeholders not having a background in measurement science, which can lead to issues such as over-interpretation of scores (i.e., investing them with more meaning than is warranted). Some providers at one site voiced disagreements between assessments based on their clinical experience and PROs, which could be a barrier to clinicians using them. Seven key themes related to supporting interpretation of PRO results emerged from our respondents: 1) using standardized data, 2) representing data graphically, 3) using comparison data, 4) education and training, and 5) stakeholder consensus.

6.1 Using Standardized Data

Multiple respondents noted that a meaningful change in score – a change that might warrant a change in treatment, indicates the relative severity of a problem, or alerts clinicians to a particular clinical issue – can be defined by empirically derived data describing the minimal clinically important difference (MCID) in the literature. Four respondents also reported that relating clinical variables, such as the start of different treatments, to PRO results can enhance the clinical utility of PRO scores. Two respondents noted the importance of providing written information linking PRO feedback to standard treatment guidelines to aid in data interpretation and clinical decision-making.

6.2 Graphical Representation of Data

Four respondents talked about the benefits of using graphical displays to help communicate results of PRO measures, with two specifically mentioning the utility of graphs to display longitudinal scores over time. Five respondents reported approaches to support the visual illustration of scores, making use of methods such as colour coding, 'traffic-light' systems, or bar charts, often in combination with text. Presentations showing detailed trends in scores over time highlighted how much scores had changed and when specific follow-up or attention was required. One respondent noted the importance of consistently displaying scores such that the magnitude of data should is displayed in one direction for all measures used. For example, if larger scores indicate worse functioning in one measure, all measures should be oriented so that larger scores indicate worse functioning. Three respondents commented that their electronic systems helped with the presentation of results by creating automated reports generated through templates embedded within the software.

6.3 Using Comparison Data

PRO score interpretation was also informed by reference to population-based scores or disease-specific values. One respondent described the use of a colour-coded temperature map that showed individual scores in relation to population scores. This respondent noted demands from both patients and clinicians that PRO scores be shown in comparison to others with the same disease, rather than the general population. Two respondents valued the presentation features in the PROMIS system and their provision of 'maps' or 'scripts' to highlight individual scores in comparison to expected values. One respondent reported the importance of capturing adequate patient baseline data, noting that comparisons to baseline scores were necessary for creating an effective care plan. One respondent initially compared patient scores to normative values, however, stopped the practice due to a concern that it could cause patients stress if their scores are poor relative to comparison data.

6.4 Education and Training

The provision of training on how to interpret PRO scores was reported to be of crucial importance at three respondent sites. However, it was suggested that the need for appropriate training and education to support clinicians and patients in PRO measure completion and data interpretation was often underestimated. One respondent noted:

"Most people believe they understand measurement far better than they actually do. The questions revealed that understanding what scores mean, the limits of testing, how to avoid over-interpretation, etc. are things we understand but most clinicians, stakeholders, and patients don't. People really take this very seriously, and literally". [SB]

In terms of specific training requirements, one respondent suggested that clinicians should be trained on how to interpret PRO scores and the visual displays (e.g. graphs and tabulated data) presented to them. One respondent developed a site-specific training module to support interpretation along with accompanying presentations and references to aid in the use of PRO data for decision-making.

6.5 Stakeholder Consensus

One respondent noted that many PRO measures do not have standardized cut-points like an MCID value defined in the literature, so they worked with their clinicians to come to a consensus on important score changes. Respondents also noted the importance of working together with different stakeholders to ensure that PRO concepts are relevant to both patients and clinicians, develop approaches to enhance the visual presentation of PRO data and its interpretation, and determine clinical utility.

Section 7: When, where, how, and to whom will results be presented?

After PRO data are collected and scored, care must be taken to adequately integrate this data into clinical workflows. Respondents stressed the importance of sharing and discussing PRO results with patients, suggesting that potential implementers need plans for (1) when and where, (2) how, (3) and to whom results are provided.

7.1 When and Where to Present Results

When to present PRO results to patients depended upon the respondent's framework for clinical management. Two respondents reported that results were presented in real time to meet their organization's standard of care. One respondent noted that optimizing a PRO implementation in a clinic setting required the provision of detailed PRO feedback in advance of a clinic consultation. This was echoed by another respondent who noted that the PRO scoring results collected by their electronic system were available to patients and providers several days prior to a clinical visit through a web-based portal. Other respondents noted that scores were accessible through the electronic systems they used to collect the PRO data, with one respondent reporting plans to integrate results into their patient portal for patient access. One respondent furthermore reported that scores were integrated into reports of combined patient data in quarterly team meetings to support quality assurance activities. One respondent site planned a 'research day' with their patients and relatives to present the results of PRO assessments, and reported that the session made patients feel valued, and demonstrated to providers in a patient-centered way the seriousness of their patients' conditions.

7.2 How Results are Presented

When asked how the results were presented, the majority of respondents reported graphs as the primary presentation method. Respondents noted that results were presented on electronic patient lists in a 'stop light' style to physicians and nurses to help them focus on patients with worse results, or listing results in tables with clinically significant scores highlighted to identify problem areas. Another respondent site presented both the answers to individual questions along with a graph of calculated scores over time along with normed values. Another respondent site reported having scores on electronic summary reports by patient and date so that it was easy for providers to look up past results. One respondent site noted that they give patients paper copies of their results in graphical form due to their patient population being more comfortable with paper forms, along with having the information in the EHR for providers to use.

7.3 Who Receives Score Reports

All respondents reported that PRO results were used by health providers to inform the clinical management of patients. In most cases this was one specific clinician, however two respondents talked about involving multidisciplinary teams or a wider group of stakeholders as part of this feedback process. When a multidisciplinary team was involved, efforts were made to only show each team member scores that were relevant to their area of clinical expertise. One respondent also qualified that involvement of wider stakeholders generally occurred on a 'request only' basis, meaning that the clinician automatically receives the PRO results but other clinicians had to request this information. Moreover, some respondents reported that group-level results were also shared with other stakeholders such as commissioners and local and regional managers to provide evidence of a health care program's efficacy. Two respondents also reported using PRO results in referrals to mental health services.

Four respondents reported that results were presented to patients or to patients' caregivers. One respondent noted that the report generated by their PRO system for patients is provided to the doctor who is expected to explain the findings to the patient. However, this respondent commented that additional training is required to support clinicians in communicating the report and its findings to patients more effectively. Another respondent raised an issue around feeding back scores to patients over time when scores reflect worsening of symptoms, asking:

"How do we present PRO data to patients themselves, especially if they see their scores getting worse? In the past we have not shown patients their data. But now we believe that even if they are getting worse, they are okay with that and know anyway. Ideally, we ask patients if they want to see it and also their clinician in case their clinician is against it. In the past we have shown normative data but we are no longer doing that." [GV]

Section 8: What will be done to respond to issues identified through the PRO assessment?

One respondent talked about the importance of linking a patient's measure results to clinical decision-making once the clinician has access to their PRO scores. Specifically, they explained that their system enables clinicians to answer two key questions to aid in care management: (1) does the patient require a visit or consultation?, and (2) which symptoms are a priority in terms of treatment and management?

Section 9: How will the value of PRO assessment be evaluated?

Respondents described both (1) formal and (2) informal evaluations of PRO application in clinical practice.

9.1 Formal Evaluations of Impact

One respondent site explored the potential impact of providing standardized PRO information in oncology care across many clinical variables, comparing clinicians who were provided with PRO data to those who were not. Although failing to find any statistically significant differences between groups in terms of patient quality of life, interpersonal provider relationships, or clinician global satisfaction, it was suggested that this could have been influenced by the high levels of patient satisfaction reported in both groups and therefore was possibly a ceiling effect. In contrast, a similar comparison in an oncology population highlighted statistically significant higher scores for both quality of life and satisfaction for patients who completed PRO measures and whose scores were presented to clinicians during clinic visits (unpublished results).
One respondent detailed a formal evaluation of the use of tele-completed PROs in patients within an occupational medicine clinic, resulting in positive results which informed a change to clinical practice. Clinicians reported improvement in the quality of clinic appointments and telephone conversations, valued the systematic overview provided with the PRO feedback, and reported a reduction in time spent on documentation, thus improving time availability for patients. Moreover, although not anticipated, patients with more severe symptoms were successfully transferred to the tele-PRO system. Although patients were still provided with the opportunity to ask for a face-to-face meeting, the results supported a change from routine

face-to-face consultations to tele-PRO consultation. Patients were generally positive about the use of PRO measures, and specifically about the impact on their level of understanding about their disease, enabling them to become a more active partner in disease management. They valued the time available to consider their responses, and the reduction in time spent on hospital visits, and reported a confidence in the system.

The developers of a pediatric PRO system described routine, annual evaluations of the PRO system itself by parents, children, and providers. Children and their parents are invited to complete web-based measures which seek their views and experiences of using the PRO website. Providers are invited to participate in focus groups during which an overview of the implementation process from the preceding year is presented, and their experiences and wishes for the future are explored. Future developments include the use of focus groups with patients and their parents and evaluation measures for clinicians.

Clinicians who were interviewed following the implementation of PRO assessment as part of a chronic pain management program found that PRO results were most beneficial at discharge and follow-up, providing them with tangible data of patient progress at both the individual and group level. Unexpectedly, providing PRO data had the positive effect of prompting stakeholders to begin requesting data to inform their decision-making:

> *Stakeholders began to specifically request this data (pull) whereas we had expected to send the data and require effort for stakeholders to consider PRO scores in decision-making (push) [SA].*

9.2 Informal Evaluations of Impact

Several respondents described more informal assessments, reporting positive responses from clinicians and patients to the use of PRO measures in clinical practice. The positive reviews from clinicians were underpinned by reports that PRO measures can: enhance decision-making; complement patient management; identify issues for discussion ahead of the clinical consultation, improving the efficiency of the clinical encounter; identify issues for discussion that would not normally be addressed. Although being able to access data retrospectively was viewed as helpful, clinicians needed to have access to real-time PRO data and feedback. One respondent reported for a clinician:

> *He loves being able to have these simple easy reports and watch the trends of his patients. [RJ]*

However, several respondents reported skepticism among some providers, particularly when new to the concept of PRO application. Providers called for ‘harder’, more clinically relevant data to supplement the use of PRO data. Two respondents reported on the benefit of inviting patients and clinicians to comment on the content of PRO measures, highlighting where changes may be important to improve PRO measure relevance and acceptability. These views were obtained via questionnaires, nominal groups, and informally. One respondent indicated that patients would be given their own copy of the feedback report and that this was well-received.

Some sites reported that patients praised the use of PRO measurement. Patients reported that they liked being more actively involved with their health management and found that PRO results helped them better understand their condition. Patients also reported that the PRO measures helped them think about different aspects of their health before they entered the doctor’s office.

9.3 Further Evaluation Research

One respondent highlighted the importance of future research to better understand how researchers and clinicians use PRO-related information to inform decision-making. Moreover, the impact of PRO application on referral patterns was suggested as an area of interest.

Section 10: Key Take-Home Points

The respondents discussed essential suggestions across five areas that are important for sites to take into account when considering a PRO implementation: (1) how to optimally integrate PRO assessment into

clinical work flows and treatment decision-making, (2) how to maximally engage all key stakeholders, (3) assessing what necessary institutional resources are required for successful implementation, (4) how to best leverage electronic PRO data collection for maximal efficiency, and (5) how to best time implementation of PRO assessments.

10.1 Integration of PROs into Clinical Practice

Respondents noted benefits to their clinical practice from implementing PRO assessments. One respondent explained that clinicians at their site noticed that PRO measures informed medical referrals that the provider would not have made otherwise, that they encourage discussions that might not have happened otherwise, and that they have been useful for research purposes. This respondent site's main takeaways are that a PRO implementation needs ease of use, ease of access, and a clinical determinant. Another respondent suggested that PRO measures need to be seen as at the center of care and not on the periphery, and that the effective use of PRO measures can help to identify patients who are in need of heightened attention. Another respondent noted that PRO measures must address gaps in information needs for all stakeholders. This respondent also stressed that PRO feedback needs to be actionable, and that it must trigger appropriate responses. Another respondent stressed that patients should not be overburdened with PRO data collection, and that implementers should be careful not to use more than one measure to assess one concept. This respondent noted that implementers need to simplify the interpretation of PRO results, and suggested the use of both visual features such as bar graphs along with textual descriptions. Clean integration into workflows, however, takes process-based work by key stakeholders over time.

10.2 Engage Stakeholders

Three respondents noted the importance of engaging stakeholders. Support is needed from all stakeholders involved including all levels of administrative support, clinicians, and patients. One respondent emphasized the importance of having of a clinician champion who will interact with both clinical and administrative stakeholders. Another respondent noted the importance of motivating the care team and involving them in the decision-making process. Another respondent noted that to keep stakeholders engaged, the team must be able to quickly demonstrate the practical clinical value of PRO results.

10.3 Institutional Resources

Three respondents noted the imperative of having adequate institutional resources to support PRO assessment. One respondent noted the need for adequate support and assistance for PRO workflows, and two stressed the importance of having enough training for all involved.

10.4 EHRs and Technology

Three respondents stressed the importance of considering how PROs will be integrated into the EHR and the organization's technical infrastructure. One respondent felt it important to integrate data into the EHR into clinician notes for use by the clinician. Another respondent noted the importance of data security and ensuring that important patient PRO data is safely stored and transmitted if using an electronic system.

10.5 Timeframe of Implementation

Three respondents commented on the amount of time it took to implement PRO measures in clinical practice. One respondent noted an estimated three months to get stakeholders to the table and implement a pilot. Another respondent, who used an implementation of the electronic AC Lite system from the PROMIS Assessment Center, estimated six months to get an initial system up and running. They noted that the entire process from conceptualization to implementation took about three years. Another site also reported that implementation took a number of years.

Summary

The purpose of this Companion Guide is to provide a platform for clinicians and researchers to share the realities and challenges associated with using PRO measures in clinical practice with the intention that others working in the field may gain insight and learn from the case studies presented. It was also designed to further contextualize the evidence synthesis presented in the User's Guide with 'real-world' examples. With contributions from the 10 case studies, the Companion Guide outlines some of the potential barriers and

opportunities when embarking on a PRO programme in clinical practice, covering a range of patient populations, specialties and countries. The respondents provide detailed insight into their experiences and emphasize that PRO initiatives are likely to be more successful if there is purposeful integration into clinical practice, meaningful engagement with all stakeholders, access to necessary resources, the ability to leverage technology to facilitate successful implementation and realistic, and consensus-driven expectations for planning and timing.

The aspiration is that this Companion Guide continues as a living repository for PRO researchers and practitioners. If you would like to ask any questions or share your experiences, please get in touch with the CP-SIG via the ISOQOL website: www.isoqol.com.

Following the development of the ISOQOL User's Guide, ISOQOL collaborated on a project to develop guidance on integrating PROs in EHRs. The PRO-EHR Users' Guide, along with the ISOQOL User's Guide and this Companion Guide, serves as a valuable resource for those seeking to implement PRO measures in clinical practice by integrating in the EHR. Snyder C, Wu AW [Eds.]. Users' Guide to Integrating Patient-Reported Outcomes in Electronic Health Records. Patient-Centered Outcomes Research Institute, 2017. Available at: http://www.pcori.org/document/users-guide-integrating-patient-reported-outcomes-electronic-health-records.

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