NIH Collaboratory Rethinking Clinical Trials™
Health Care Systems Research Collaboratory

Strategies for Overcoming Barriers to the Implementation of Patient-Reported Outcomes Measures

An NIH Health Care Systems Research Collaboratory Patient Reported Outcomes Core White Paper

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This work is funded by the Office Of The Director, National Institutes Of Health and supported by the NIH Common Fund through a cooperative agreement (U54 AT007748) with the NIH Health Care Systems Research Collaboratory. The views presented here are solely the responsibility of the authors and do not necessarily represent the official views of the National Institutes of Health.

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Introduction

As health systems shift toward clinical practice that is more patient-centered, the voice of the patient is increasingly heard through patient-reported outcomes (PROs) measures, which are defined as outcomes reported directly by patients without interpretation by clinicians.[1] PROs typically include information about health-related quality of life (HRQOL), symptoms, function, satisfaction with care or symptoms, adherence to prescribed medicine or therapy, and perceived value of treatment.[2,3] The evidence in favor of self-reporting by patients is robust: PRO use increases patient satisfaction with care, patient-provider communication, overall quality of life; is considered valuable to clinicians; is well accepted and feasible; and improves symptom management and health quality.[4–12] PRO data have also been used to inform clinical decisions, such beginning supportive therapy, triaging for additional medical services, or evaluating a complaint, and to compare alternative treatment options, professionals, institutions, and changes in performance over time.[4–7] The benefits and clinical utility of PRO measures have prompted supporters to call for routine PRO collection in clinical care, yet significant barriers to initiating and implementing this still remain. Despite an ever-growing body of literature demonstrating an association between PRO utilization and an improvement in outcomes across a variety of disease states,[13–18] along with evidence that PROs are valid outcomes (e.g., quality of life, pain, breathlessness, physical functioning),[19,20–27] widespread physician acceptance has been lacking.

PATIENT REPORTED OUTCOMES (PROs): The Food and Drug Administration (FDA) defines PROs as: "outcomes reported directly by patients without interpretation by clinicians."[1]

Major barriers to incorporating PRO data capture into clinical practice involve engaging clinicians amid concerns about overburdening the work staff or costs of hiring additional personnel to orchestrate PRO collection, analysis, and reporting.[28,29] Many clinicians are unsure how to use and interpret patient-reported outcomes assessments and do not see the value-added for introducing such measures into an already hectic workflow.[15] Other implementation barriers from the patient, clinician and administrative perspective include cost, burden, feasibility, usability, and benefit in a target population.[28,30]

Practical strategies for overcoming these barriers are currently missing from the literature. In this manuscript, we examine barriers from clinician, patient, and administrative perspectives and provide real-world examples and strategies for overcoming these obstacles. In addition, members of the PRO Core of the NIH Health Care Systems Research Collaboratory will be conducting interviews with sites that routinely collect PRO data as part of a landscape summary. The Core will publish these summaries in the Living Textbook blog: Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials. Upcoming posts include summaries from the University of Alabama at Birmingham, the University of Virginia, Duke University's Center for Learning Health Care (CLHC), and Dartmouth.

Clinician Barriers and Strategies

In most published examples of routine PRO collection, clinician barriers to using PROs include: a) the concern that the PRO instrument will uncover issues that clinicians feel incapable of handling, or that they will become liable for if inadequately addressed;[31,32] b) that the collection and utilization of PROs will disturb work flows and decrease efficiency;[32–35] c) that the benefit to patient care will be only theoretical and unsubstantiated;[31,32,35,36] and d) that managing responses will be just another responsibility for already overburdened clinicians.[34] On a more basic level, some clinicians may be hesitant to incorporate PROs into routine care because they are unsure how to make use of the data and might require support (personnel or information technology) to help navigate the information provided by the patient. Currently, one of the biggest barriers to PRO implementation is reluctance to change.

FIVE PRACTICAL APPROACHES: We present five practical approaches to help overcome the hesitations of caregivers and realize the potential of PROs: a) collaborate to define the goals and expectations for PRO endeavors up front, b) establish standard operating procedures around the collection of PROs, c) integrate the data generated from PROs into the clinical workflow, d) define clinical triggers and specific interventions that will improve outcomes, and e) engage senior physician champions.

Define Goals and Expectations

Clearly defining the goals and expectations surrounding the collection and use of ePROs, with input from all representative stakeholders is crucial to buy-in and will help alleviate concerns about potential issues raised by PROs.[6,30,37] By collaborating with stakeholders to define the purposes for collecting PROs, the needs of end-users can be met, and misperceptions can be avoided. Collaboration between patients, nurses, clinicians and researchers sets the foundation for the rest of the project and can help shape the perception of the PRO data.[30] This type of collaboration was employed by the developers of PatientViewpoint,[38] who conducted literature reviews and solicited suggestions from experts from various disciplines, such as cancer outcomes research, palliative care, clergy, and patient advocacy. A panel of experts vetted initial recommendations. The final guidelines incorporated several perspectives that offered clinicians a myriad of choices for addressing issues brought to light by PROs ranging from treatment modification to life-style changes.[38] The end result is clinicians can click on the “What can I do? “ link to review suggestions.

Establish Standard Operating Procedures

Another core principle for successful PRO data collection is striking the right balance between standardization of procedures and providing flexibility where needed. Generating standard operating procedures that delineate how patients, researchers, and clinicians implement data collection systems ensures that consistency of approach, professionalism, privacy and security standards are met, that survey data is consistently handled, and that the new approach becomes the norm.[30] Part of establishing standard operating procedures includes training that is tailored to specific team members (e.g., front-end staff and physicians interact with the system differently and training should reflect this). This standardization must be balanced with the need for flexibility in integrating the collection procedures into the clinical workflow, so as to avoid confusion and limit burden on clinical and staff team members. Further, the standard operating procedures cannot be so rigid as to preclude adjustments and iterative improvements driven by feedback from end-users.

Integrate Data Generated into Clinical Workflow

Integrating PRO data into clinical workflow depends on the clinical scenario. For clinicians and their patients, introducing a new process into the clinical workflow is often resisted, and in the case of PROs, this is exacerbated by the fact that not all providers use PROs similarly, so the perceived value varies. In order for routine ePRO collection to be embraced, a cultural change is often necessary. Effecting this change is best done by demonstrating the value of the PRO to all the relevant stakeholders.

Embedding PRO collection into routine care dilutes many of the concerns surrounding respondent burden. If PRO data are viewed as integral to the patient care process and completing the instrument yields tangible benefits to patients, completing PROs will not be viewed as burdensome, but as part of the culture of clinical care. An example of a tangible benefit is a summary document of PRO data that the clinician can use to promote discussion with the patient, like the example report shown in Figure 1.

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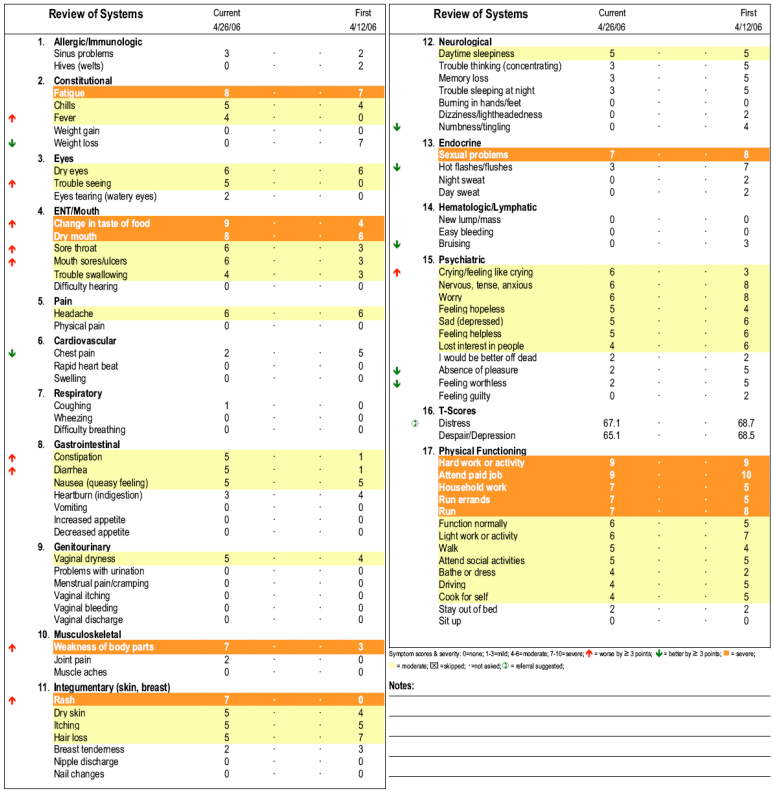
Figure 1. Sample report from the Patient Care Monitor generated after the patient has submitted responses. The report summarizes all responses, and highlights, via colors, areas of higher scores, as well as trends in scores over time, using colored arrows to the left of categories.



	Review of Systems	Current 4/26/06	First 4/12/06
	1. **Allergic/Immunologic**		
	Sinus problems	3	2
	Hives (welts)	0	2
	2. **Constitutional**		
	Fatigue	8	7
	Chills	5	4
↑	Fever	4	0
	Weight gain	0	0
↓	Weight loss	0	7
	3. **Eyes**		
	Dry eyes	6	6
↑	Trouble seeing	5	0
	Eyes tearing (watery eyes)	2	0
	4. **ENT/Mouth**		
↑	Change in taste of food	9	4
	Dry mouth	8	6
↑	Sore throat	6	3
↑	Mouth sores/ulcers	6	3
	Trouble swallowing	4	3
	Difficulty hearing	0	0
	5. **Pain**		
	Headache	6	6
	Physical pain	0	0
	6. **Cardiovascular**		
↓	Chest pain	2	5
	Rapid heart beat	0	0
	Swelling	0	0
	7. **Respiratory**		
	Coughing	1	0
	Wheezing	0	0
	Difficulty breathing	0	0
	8. **Gastrointestinal**		
↑	Constipation	5	1
↑	Diarrhea	5	1
	Nausea (queasy feeling)	5	5
	Heartburn (indigestion)	3	4
	Vomiting	0	0
	Increased appetite	0	0
	Decreased appetite	0	0
	9. **Genitourinary**		
	Vaginal dryness	5	4
	Problems with urination	0	0
	Menstrual pain/cramping	0	0
	Vaginal itching	0	0
	Vaginal bleeding	0	0
	Vaginal discharge	0	0
	10. **Musculoskeletal**		
↑	Weakness of body parts	7	3
	Joint pain	2	0
	Muscle aches	0	0
	11. **Integumentary (skin, breast)**		
↑	Rash	7	0
	Dry skin	5	4
	Itching	5	5
	Hair loss	5	7
	Breast tenderness	2	3
	Nipple discharge	0	0
	Nail changes	0	0

	Review of Systems	Current 4/26/06	First 4/12/06
	12. **Neurological**		
	Daytime sleepiness	5	5
	Trouble thinking (concentrating)	3	5
	Memory loss	3	5
	Trouble sleeping at night	3	5
	Burning in hands/feet	0	0
	Dizziness/lightheadedness	0	2
↓	Numbness/tingling	0	4
	13. **Endocrine**		
	Sexual problems	7	8
↓	Hot flashes/flushes	3	7
	Night sweat	0	2
	Day sweat	0	2
	14. **Hematologic/Lymphatic**		
	New lump/mass	0	0
	Easy bleeding	0	0
↓	Bruising	0	3
	15. **Psychiatric**		
↑	Crying/feeling like crying	6	3
	Nervous, tense, anxious	6	8
	Worry	6	8
	Feeling hopeless	5	4
	Sad (depressed)	5	6
	Feeling helpless	5	6
	Lost interest in people	4	6
	I would be better off dead	2	2
↓	Absence of pleasure	2	5
↓	Feeling worthless	2	5
	Feeling guilty	0	2
	16. **T-Scores**		
②	Distress	67.1	68.7
	Despair/Depression	65.1	68.5
	17. **Physical Functioning**		
	Hard work or activity	9	9
	Attend paid job	9	10
	Household work	7	5
	Run errands	7	5
	Run	7	8
	Function normally	6	5
	Light work or activity	6	7
	Walk	5	4
	Attend social activities	5	5
	Bathe or dress	4	2
	Driving	4	5
	Cook for self	4	5
	Stay out of bed	2	2
	Sit up	0	0

Symptom scores & severity: 0=none; 1-3=mild; 4-6=moderate; 7-10=severe; ↑ = worse by ≥ 3 points; ↓ = better by ≥ 3 points; ■ = severe; ■ = moderate; ☒ =skipped; - =not asked; ② = referral suggested;

Notes:

The developers of the Integrating Mental and Physical Healthcare: Research, Training and Services (IMPARTS) web-based systems provide clinicians guidance on how to address issues identified by PRO questionnaires.[39] The IMPARTS informatics team worked with physical healthcare providers to develop a referral algorithm to provide clinicians advice on care and referral for patients who screen positive for a mental health issue.[39] The referral algorithm was tailored to the specific clinical setting and relied on data captured in the informatics system (e.g., type and rate of mental disorder) to determine the referral pathway.

Data analysis and automatic reporting in real-time is feasible with electronic PRO measurement systems. Many software programs exist that allow access to graphs of patient self-reports from the electronic health record (EHR) in real-time or enable a printed report that can be added to the patient's chart or given to the clinician or the patient. Domains with scores that represent potential problem areas are highlighted or presented in an easy-to read summary format (See Figure 1 an example). The summary report can be used to promote discussion, trigger interventions, and to compare changes over time, improving

patient-provider communication without extending clinic visits. For example, researchers at the University of Washington found that when clinicians were provided with patient self-reports, they were 29% more likely to discuss threshold symptom and quality of life events than with patients in the control group where no report was provided.[9] Significantly, there was no significant increase in the length of clinic visits.[9] Examples of existing software programs and platforms include The Knowledge Program,[40] Patient ViewPoint,[41] the IMPARTS platform,[39] the Patient Assessment Care and Education (PACE) e/Tablet system,[11] and the electronic self-report assessment-Cancer (ESRA-C) tool.[42] Most systems offer a flexible user interface where a menu of validated PROs are available to clinicians. There are a number of national, validated PRO instruments that can be used on some of these platforms, such as The Patient-Reported Outcome Measurement Information System (PROMIS®),[43] which provides adult- and child-reported measures of health and well-being across a wide range of conditions and diseases, the National Institutes of Health (NIH) Toolbox for the assessment of neurological and behavioral function,[44] and Neuro-QOL,[45] a set of PRO measures that assesses the quality of life of adults and children with neurological disorders such as stroke, multiple sclerosis, amyotrophic lateral sclerosis, Parkinson disease, epilepsy, and muscular dystrophy.

Define Clinical Triggers for Specific Interventions

Specific items that change dramatically over the trajectory of a disease or exceed some threshold can be highlighted on a report for the physician who would then offer referrals, treatments, support group contacts, patient education, counseling, etc. depending on the domain that troubles the patient.[29,38,46,47] To prevent clinicians from being overwhelmed and to demonstrate value of the system, it is important to define clinical triggers and interventions that can be automated within the systems, offloading duties traditionally required of clinicians. For example, at the University of Alabama, a high distress score may prompt a visit by the psychosocial care team.[48] The interventions may also include patient education—whether provided by the electronic collection tool (e.g., tablet computer) or the nursing staff. In addition to helping the clinical team, these triggers benefit patients and mitigate legal concerns from PROs being overlooked or unaddressed.

The alert capabilities of software platforms can send an email or pager notification to clinic staff for follow-up. For example, post-operative symptom severity was significantly reduced in cancer patients when clinicians were sent email alerts regarding patient's symptoms.[8] The monitoring feature tracked changes in patient's self-reports over time and flagged significant changes based on a pre-determined threshold, allowing the clinician to intervene when needed.

Another example is the mobile phone-based advanced symptom monitoring system (ASyMS) developed in the United Kingdom. The ASyMS monitors treatment-related symptoms in cancer patients receiving chemotherapy.[49,50] With the ASyMS service, patients complete a symptom assessment on their phones twice a day and anytime they feel unwell. Data are sent to the study server and reports of severe symptoms are immediately sent to clinicians.

Engage Senior Physician Champions

Physician champions who value the data and insist on its presence and completeness are often the missing link in the incorporation of PROs into clinical practice. Physician champions understand that including the patient perspective helps clinicians get a more complete picture of a patient's health, which ultimately leads to improved patient care. Physician leaders can provide not only evidence of PRO utility, but also implementation methods, such as demonstrating ease of use, patient satisfaction scores, and key opinion leader input.

Patient Barriers and Strategies

From a patient's point of view, the primary barrier is the perception of burden.[30,32,41] The definition of *burden* varies by clinical context, but in general, the instrument should not be too long, it should be easy for the intended population to use, and it should have a clinical impact. If PRO reports automatically trigger events that mitigate the problem (e.g. communication with the doctor, patient education, triage to the emergency department), then the perception of burden is mitigated, and patients are more accepting of the time and effort required to answer questions.

Limiting the number of questions that a patient needs to answer will reduce the time it takes to complete the PRO measure and the burden on the patient. When researchers in a recent trial used too many PRO instruments in an effort to get a thorough understanding of the effectiveness of a drug, the patients found the questionnaires exhausting and overwhelming and indicated that the PRO measures were the leading cause for dissatisfaction with the trial.[51] The recommended amount of time for a given PRO is 10–15 minutes.[52] Many instruments, such as PROMIS, use a computerized adaptive test (CAT), in which subsequent questions are based on answers to preliminary questions. For example, if a clinician wants to know about physical ability, the patient will be given a question with a range of skills, from "Are you able to get out of bed unassisted?" to "Are you able to run five kilometers?" The next question will be geared toward the range of physical ability indicated in the first question. Short (4-5 item) measures given with CAT have been shown to be as effective as longer measures.[53]

Several studies have demonstrated patient preference for electronic administration of PROs, even among patients with low computer literacy.[54,55] Patient preference for electronic forms may be due to convenience and a sense of confidentiality,[56–58] and patients using tablets have been shown to be more likely to answer highly personal questions than on paper forms.[58] Some strategies for making the interface user friendly include asking only one question per screen, increasing the font size, adapting language for patients, limiting pop-up windows, and automatic advancement to the next screen.[55,56,58] As an example of adjusting the language, in the patient version of a PRO for patients undergoing chemotherapy, a grade 4 toxicity description was changed from "life-threatening" in the source description to "disabling" in the patient language adaptation.[55]

There is also a pervasive belief that ill patients struggle to complete PRO surveys; this belief frequently proliferates in a clinical environment without input from patients and caregivers regarding what might be reasonable. As a case in point, research has shown it feasible to collect (e)PRO data in palliative settings,[39–42] though physicians, and the paternalistic perception that patients are "too ill" to participate, may hinder such efforts more than patients themselves.[61,62]

Additionally, patients have concerns that clinicians will not review the survey results so the patients will have wasted time in responding, that responses may not be secure, and that they will not have access to their own responses.[32,34] However, an evolving literature suggests willingness for patients to share their data consistently with little attrition.[63,64] When PRO collection is aligned with clinical care and the uses of the information are transparent (i.e., triage, quality monitoring, triggering interventions and education, and research), then patients can engage in their own health care while informing and improving it. For example, the PatientViewpoint system provides patients with access to their data online. Once logged in, patients are able to see their scores over time represented graphically with accompanying explanations.[41] Other systems, such as the ASyMS system and IMPART, send patients self-care advice tailored to their responses.[39,49,50]

One of the most important ways to ensure that the patient does not find the instrument too burdensome is to engage them in the process. Before selecting an instrument, ask patients about the information that is meaningful to them. Engage them in the implementation process and ask for input at each stage of the process.

Administrative Barriers and Strategies

There are a number of important considerations from an administrative standpoint, and first are resource-related concerns. What capital investment is needed to initiate the project? What are the ongoing needs for data warehousing and management? What are the workflow implications? Privacy and security are also of concern. Who, beyond those directly involved in the patient's care, will have access to the data? How will that access be controlled and protected? Finally, there are legal considerations: Who is responsible for responding to "critical" PROs (e.g., suicidality, new-onset chest pain)? What happens if these "critical" issues are not addressed in a timely manner?

Even if the PRO data uncover unexpected results, this information can lead to improvements in care. For example, the ePRO system used at Duke uncovered a high prevalence of sexual distress among oncology patients, independent of cancer type.[58,65] Because questions about sexual distress are routinely asked only in specific settings, such as among prostate cancer patients after prostatectomy or radiation, the prevalence was underestimated. The new insights led to the identification of the problem and the design of a clinical trial at Duke to better understand how to address sexual distress, hopefully improving the quality of life of cancer patients.

Addressing issues of data security, access to data, and patient confidentiality are a high priority as next generation technology integrates mobile apps designed specifically for clinicians that rely on cloud-based storage. While technological advances will make delivering healthcare more efficacious, efficient and cost-effective, care must be taken to ensure patient privacy. Data security concerns have been addressed by encrypting data on tablet computers before transmission to the cloud server and subsequent decrypting by the research institution,[66] and by ensuring that patient-identifiable information is stored behind firewalls and all data flows are encrypted.[56]

PRO data is most useful to clinicians when linked to and analyzed with individual patient diagnostic and treatment information from their EHR. Many informatics systems have the capacity to link PRO reports to the EHR,[11,67] and some can link from the EHR to a data warehouse for subsequent research[40] wherein PRO data can inform comparative effectiveness research (CER), improve post-market surveillance, and compliment quality improvement initiatives.[68,69] Electronic systems have also been developed to regularly capture PRO data for linking and storing within registries and data networks.[56,57,70]

Missing Data

If the PRO data are to be used for research, missing data can be an important issue because it effects the quality of the data and the subsequent statistical analysis. Sometimes issues with missing data can be addressed by small changes in clinic workflow, such as asking patients to come in 15 minutes early for an appointment. Where this is not feasible, electronic systems with reminder alerts can prompt patients and staff to complete due assessments. Several institutions have employed this method to improve patient self-reporting. Memorial Sloan-Kettering's Symptom Tracking and Reporting (STAR) system automatically sends reminder emails two weeks before a patient's scheduled appointment and again to patients who have missed scheduled surveys.[67] The system also notifies clinical staff to call and follow up with patients. A key patient adherence to self-reporting has been to remind patients that their responses go directly to their clinical record so their doctors can see how they are doing.[67]

Many other programs use a reminder function to either send an email or a letter directly to the patient or to a nurse who follows up with a call, including the Knowledge Program (KP),[40] PatientViewpoint,[41,71] the Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship registry (PROFILE),[57,72] and the Electronic Patient-reported Outcomes from Cancer Survivors (ePOCS) system.[56]

Discussion

Clinicians need to recognize that PROs represent important predictors of the patient experience; for many patients, quality of life, pain, and symptom burden drive decision-making. PROs can help clinicians systematically measure critical patient attributes, and they can be leveraged to streamline and focus the care being delivered. Researchers who are helping to develop the elements of these systems must keep in mind that the instruments should be clinically feasible and relevant, fit into clinic workflows, and improve care for

patients. These factors need not compromise the quality of data collected, so long as researchers and instrument developers are mindful of the requirements for learning health systems. We cannot sacrifice the utility and potential of PRO instruments due to an over-reliance on issues such as comprehensiveness.

Longitudinal collection of ePRO data has the capacity to transform clinical practice—improving efficiency and streamlining care, enhancing patient education, and supporting clinical decision-making. It can also serve as an important pillar for research within learning health care models, as the patient experience is critical to truly developing the ideal care model. The ultimate key to overcoming barriers to PRO collection is to collaborate with all the relevant stakeholders and make the data collected be relevant to the patient, the clinician and the researcher.

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