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Special Section on Patient-Reported Outcomes and Informatics: Collection of Patient-Reported Outcome Measures in Rural and Underserved Populations

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Abstract:
The NIH Pragmatic Trials Collaboratory supports the design and conduct of 31 embedded pragmatic clinical trials, and many of these trials use patient-reported outcome measures (PROMs) to provide valuable information about their patients' health and wellness. Often these trials enroll medically underserved patients, including people with incomes below the federal poverty threshold, racial or ethnically minoritized groups, or rural or frontier communities. In this series of trial case reports, we provide lessons learned about collecting PROMs in these populations. The unbiased collection of PROM data is critical to increase the generalizability of trial outcomes and to address health inequities. Use of electronic health records (EHRs) and other digital modes of PROM administration have gained traction. However, engagement with these modes is often low among disparities prone populations due to lessened digital proficiency, device access, and uptake of EHR portals and web interfaces. To maximize the completeness and representativeness of their trial outcome data, study teams tested a range of strategies to improve PROM response rates with emphasis on disparities prone and underserved patient groups. This manuscript describes the approaches, their implementation, and the targeted populations. Optimized PROM collection required hybrid approaches with multiple outreach modes, high-touch methods, creativity in promoting digital uptake, multi-modal participant engagement, and text messaging.

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Special Section on Patient-Reported Outcomes and Informatics: Collection of Patient-Reported Outcome Measures in Rural and Underserved Populations

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Abstract

Background: The NIH Pragmatic Trials Collaboratory supports the design and conduct of 31 embedded pragmatic clinical trials, and many of these trials use patient-reported outcome measures (PROMs) to provide valuable information about their patients' health and wellness. Often these trials enroll medically underserved patients, including people with incomes below the federal poverty threshold, racial or ethnically minoritized groups, or rural or frontier communities.

Objectives: In this series of trial case reports, we provide lessons learned about collecting PROMs in these populations. The unbiased collection of PROM data is critical to increase the generalizability of

trial outcomes and to address health inequities. Use of electronic health records (EHRs) and other digital modes of PROM administration have gained traction. However, engagement with these modes is often low among disparities prone populations due to lessened digital proficiency, device access, and uptake of EHR portals and web interfaces.

Methods: To maximize the completeness and representativeness of their trial outcome data, study teams tested a range of strategies to improve PROM response rates with emphasis on disparities prone and underserved patient groups. This manuscript describes the approaches, their implementation, and the targeted populations.

Conclusions: Optimized PROM collection required hybrid approaches with multiple outreach modes, high-touch methods, creativity in promoting digital uptake, multi-modal participant engagement, and text messaging.

Keywords: patient-reported outcome measures, patient-reported outcomes, pain, pragmatic clinical trials

INTRODUCTION

Patient-reported outcome measures (PROMs) assess patients' experiences and provide valuable information about defining aspects of their health including pain, health-related quality of life, depression, and physical functioning. When integrated into electronic health record (EHR) systems, PROMs can be used to significantly enhance and individualize care.[1] When PROMs are included in embedded pragmatic clinical trials (ePCTs) – trials that evaluate interventions as part of routine care – PROMs can also help investigators elucidate the effectiveness of treatments, characterize study cohorts and outcomes, and track symptom changes over time among sub-groups that may benefit most or least from these interventions.

There are persistent challenges with collecting and integrating PROMs into the EHR and other digital systems that may inadvertently exacerbate health inequities. Competing health system priorities and low rates of portal adoption, among other factors, drive inconsistent and low PROM response rates among patient subgroups. These issues are salient among rural, low-income, and historically marginalized populations, particularly if they receive care in under-resourced environments. Inclusivity needs to be prioritized and intentional in the collection of PROM data to ensure that healthcare outcomes are equitable and representative of diverse patient needs and preferences.

Given the growing reliance on EHR-derived data in ePCTs, researchers should acknowledge and mitigate biases arising from inconsistent PROM data collection from specific subsets of the population.[2,3] If these biases are left unaddressed, pragmatic trialists could unwittingly exacerbate existing health inequities by propagating findings that are not valid for patients who do not use technology.

Complete outcome reporting across trial participants is vital to reduce bias and optimize the external validity of trial results. Therefore, pragmatic trialists monitor PROM response rates and often use strategies to engage participants who do not, or infrequently, use electronic reporting tools. To illustrate the challenges and provide case examples of solutions, we draw on experiences from five of the NIH Pragmatic Trials Collaboratory trials that gather information from people who are medically underserved due to low socioeconomic status (SES), being from racial or ethnic minoritized groups, or who live in rural or frontier settings (Table 1).

METHODS

The NIH Pragmatic Trials Collaboratory supports the design and conduct of 31 ePCTs, and many of these trials use PROMs to provide valuable information about their participants' health and wellness. On a series of calls with the Patient-Centered Outcomes Core Working Group of the NIH Pragmatic Trials

Collaboratory, the Principal Investigators and project teams noted challenges when collecting PROM data from people who are medically underserved and described solutions for overcoming these challenges. Interested members of the Working Group provided case examples and iterated the manuscript with the salient lessons learned.

RESULTS

Below we summarize key findings from projects that enrolled people from low income households, racial or ethnic minoritized groups, or who live in rural or frontier settings. These findings illustrate the variety of approaches to PROM administration that may be useful when collecting data in these communities.

Multiple modes of outreach: NOHARM[4]

Using three Epic EHR modes of electronic PROM administration (portal, tablet at encounter check in, and provider flowsheet entry) response rates were low among rural participants, 30%-40% at some sites. Completion via tablet and provider entry were most common, with portals being least used. As a population-level study with a projected sample exceeding 70,000 participants, NOHARM strategies to increase PROM response rates had to be automated and scalable. Investigators 1) identified participants' preferred mode and language for PROM administration and made this their default, and 2) adapted EHR-directed modes of PROM administration. The latter approach placed NOHARM PROMs first on tablet questionnaire queues at all clinical encounters. Additionally, an EHR-directed (automatic) mailed print option was added by generating daily EHR reports that identified patients whose PROMs were due and who were either portal non-users or preferred print administration. The report triggered the printing and mailing of NOHARM PROMs. The study team additionally prompted desk staff and providers to acknowledge and laud participants' PROM completion efforts during clinical encounters. The EHR-based approaches were relatively easy to implement and went live within 6 weeks, approximately 7-8 months

after the trial started. Provider- and desk-staff-directed strategies were integrated into established implementation efforts and, though straightforward, were more gradual to roll out across all sites.

High touch methods: OPTIMUM[5] All PROMs were implemented in the Research Electronic Data Capture (REDCap) system. Participants were sent links to the PROM surveys electronically to their email or cell phone. One-on-one training between a research team member and participant was the most effective way to impart technology knowledge. The training included how to open a linkto the PROM survey, how to complete the survey, and how to submit the survey. Participants often expressed feeling "dumb" that they could not figure out technology when in reality they had never been instructed in its use. The REDCap survey tool that enabled participants to have the items read aloud was implemented to mitigate difficulty with vision or reading. If participants continued to have difficulty with the technology, they could request that the research assistants collect the PROMs via telephone.

Trialists also trained participants over an electronic videoconferencing platform to ensure they could engage with the telehealth intervention. Despite its widespread use during the pandemic, many participants were unfamiliar with the platforms and required extensive assistance even after an initial group training session. Again, individual training was required in many cases. The training included how to log in to the system, mute/unmute, turn the camera on and off, change their display name, and raise their had to ask a question. OPTIMUM provided a phone/tablet stand to facilitate participation in the telehealth intervention and provided tablets, phones, or funds to cover data costs as needed. Most who participated in the study used a smart phone, but it became clear that not all potential participants in rural areas were able to enroll. For example, a collaborating clinic serving older adults noted that their clients would need hands-on help signing in both due to their unfamiliarity with the platforms and due to limited cell phone coverage at their homes. As we could not remediate the limited cell phone coverage, we could not address this limitation to participation.

Overcoming lack of internet access and high frequency contact: FM-TIPS[6]

In FM-TIPS, all PROM responses are entered electronically by the participant into REDCap and thus Internet access is required. However, some individuals who would like to participate do not have internet access or a computer device. To combat this, teams provided iPads to the clinics for individuals complete their PROMs (we call this homework) at the clinic. The study team has also worked with individuals to use their local libraries, or to obtain help and access through family members or friends in their community, to complete their PROMs.

Many participants were more comfortable with the research process if they had contact with the study team and the clinicians who interacted with them in the physical therapy clinic. For this reason, all participants were contacted after they passed screening so that study personnel could answer questions, describe the study, and encourage enrolling in the study. Following enrollment, participants were again contacted by phone, email, and/or text to offer assistance with completion of baseline PROMs in their first homework assignment. Once participants gained familiarity with the REDCap platform, participants reliably completed all the PROMs. High frequency contact around homework time points enhanced overall retention and completion of PROMs. The study initially implemented contacts after enrollment and after Day 60. With additional resources, we added contacts at all data collection time points and were able to see an increase in PROM completion rates at other time periods.

Multiple mechanisms to keep participants engaged: GRACE[7]

For the GRACE trial, retention strategies are adapted to meet the needs of the participants and clinic workflows at each of the three study sites and to facilitate the completion of PROMs. Strategies include sending automatic emails and/or text messages 1 week before the survey due date with three total auto-reminders sent if not completed on Days 1, 4, and 7. (Upon enrolling, participants indicate their

preferred method of contact.) One site assigns one research staff person to each participant to build rapport and trust. One site sends holiday cards to all participants. Strategies used to ensure all PROMs are collected include: 1) face-to-face engagement aligning with clinic appointments to offer assistance with completion of measures on a study tablet; 2) confirmation of contact information so participants can be reached at a later time; and 3) emailing, calling and/or text outreach offering to assist with completion of PROMs, especially for those who start, but do not complete all surveys. One year into recruitment, we implemented regular texting contact with participants to improve survey completion rates, as they were lower than anticipated at two of the three sites (see Table 1).

Bi-directional text messages are used to communicate with patients and link to REDCap distribution of PROMs: BeatPain Utah[8]

Text-messaging. Cellphone ownership is near universal, even among people with low income (over 97% have at least a text and voice cellphone), whereas use of patient portals is low.[9] In addition, community health centers already communicate with their patients via text for activities such as appointment reminders, and this was a primary reason for delivering research activities such as recruitment and access to surveys via cellphone. Text-messaging offers a unique opportunity to maximize reach to populations experiencing health disparities. In BeatPain, eligible patients who are not referred to the study during their clinic visit receive an automated bidirectional text message (i.e., text messages with a fixed set of single-touch response options for patients to reply) offering a connection to the telehealth service. Patients could reply “YES” to connect to the service, “NO” if they were not interested, or “STOP” to opt-out from receiving further messages. Patients who enroll in the trial and receive BeatPain interventions self-report PROMs through REDCap surveys (launched via a hyperlink sent by text messaging and/or e-mail) or verbally via phone by patient preference.

Discussion

In these case reports, we demonstrate how trialists increased PROM response rates among participants with low income, belonging to racial or ethnic minoritized groups, and living in rural settings. The case reports describe strategies that increased the representation of these groups in clinical research. Although these approaches derive from trials, the insights gained may serve to advance equity through improved PROM capture in both clinical and research contexts.

Patient characteristics associated with healthcare inequities are prevalent and include low income, lesser educational achievement, rural residence, ethnic or racial minority status, and limited English fluency, among others.[3] Measuring PROMs in these populations facilitates recognition of health equity issues. However, our ability to measure PROMs is hampered by patients' limited digital proficiency, difficulty understanding PROMS as written, and access to portals and the Internet.[3] Increasing use of these interfaces in health care may improve outcomes,[7] but with low uptake among disparities prone populations,[8,10,11] reliance on portals may inadvertently exacerbate health inequities.[2,3,12] Strategies that could ameliorate the problem include multimodal efforts, including text messaging and phone calls;[13] mHealth apps,[14] and efforts to improve comprehension.[15]

PROMs are additionally important because they assess subjective dimensions of a patient's health experience and have been increasingly integrated into clinical decision making. Providers' consideration of PROMs is associated with improved patient care experiences and outcomes.[12] Our experiences capturing PROM data for ePCTs highlight the potential need for high-touch methods that involve human resources and creativity. The comprehensive capture of PROM data as part of clinical care to mitigate health inequities may require similar resources and innovation. To this end, in collaboration with the Health Equity Core, The PCO Core developed a toolkit to help investigators incorporate health equity considerations into the process of selecting and implementing PRO measures, and to leverage existing resources available to facilitate appropriate adaptation.[16]

As researchers, we aim to achieve a representative sample to optimize the external validity and generalizability of our results. Variations in outcome collection between subgroups can introduce bias, distort results, and undermine valid inference. Bias may differ by subgroup. For example, people living in rural settings may have a different set of challenges than those in urban settings, even though both are of low SES. Therefore, we must monitor response rates and differences across subgroups and take steps, like those described in the case studies above, to enable inclusion and downstream generalizability of results.

Note that most EHRs reliably identify patients who do not interact with the patient portal and solicit their preferred modes of outreach (as seen in the NOHARM and BeatPain Utah examples). These patients can be contacted via their language and mode of choice. PROMs are a widely available means of quantifying the frequency, type, and success of patients' portal and electronic interface use. The granularity of PROM usage data permit efficient, real-time evaluation of strategies to improve uptake of digital healthcare. In this sense, ePCTs provide a means to characterize the extent of these inequities by using PROMs responses as a proxy for uptake of EHR and digital technology in general. PROMs provide a discrete marker of EHR utilization and can identify where other modes of outreach for research and clinical care may be used to improve outcomes.

This collection of case studies initiates a roadmap for future research that integrates lessons learned and continues to test strategies to improve PROM data collection. Interface with multiple stakeholder groups, especially community partners, will be vital to ensure that engagement and communication methods are appropriately nuanced and robust. Capture of complete PROM data from all eligible patients will enhance understanding of intervention effectiveness in diverse healthcare systems, under-served subgroups. Moreover, representative PROM data will mitigate bias and exacerbation of health inequities, enhance the generalizability of ePCTs, and promote health equity.

Limitations

Our findings include lessons learned from the NIH Pragmatic Trials Collaboratory Trials and may not be generalizable across all trials.

CONCLUSIONS

Based on these examples from the 5 ePCTs, we found that multiple modes of outreach are needed, along with high-touch methods, creativity in overcoming barriers to Internet access, and multiple mechanisms to keep participants engaged.

Clinical Relevance Statement

Complete collection of patient-reported outcome data in people with low socioeconomic status, from racial or ethnic minoritized populations, or from rural and frontier communities can help reduce bias in research results, increase generalizability, and potentially help address the health equity gap. Collection of this information cannot yet be collected by technology alone, and hybrid methods are often needed.

Multiple Choice Questions

1. To reduce bias in the reporting of patient-reported outcome measures (PROMs), researchers should
    a. Determine which PROMs are collected in the electronic health record and use these, especially in pragmatic clinical trials.
    b. Monitor PROM response rates and use strategies to engage participants who do not, or

infrequently, use electronic reporting tools.

c. Use the same method for collecting PROMs across all participants.

d. Use RedCap to collect all PROMs

2. Why is it especially important to use various methods to collect PROMs in rural and underserved populations?

    a. Complete collection of these data could reduce bias, increase generalizability of trial results, and reduce health equity inequities.

    b. The data are already collected in the electronic health record.

    c. Only one method should be used to decrease bias in research results.

    d. Patient-reported outcomes are not as clinically relevant as more objective, clinically measurable outcomes, such as blood pressure.

Conflict of Interest

All authors declare that they have no conflicts of interest in the research.

Disclosures

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Human subjects protections

This paper summarizes lessons learned from ongoing trials, and human subjects were not directly involved in the project. All studies included here were performed in compliance with the WorldMedical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects and were reviewed by Institutional Review Boards on a study-by-study basis.

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Table 1 Case Reports from the NIH Pragmatic Trials Collaboratory

GOAL	Overview	Population	Challenges and Solutions	Effect of Solution (Change in response rates)

NOHARM (NCT04570371) Evaluate a bundled EHR-embedded intervention that includes patient- and clinician-facing decision support to advance use of non-pharmacologic pain care for perioperative pain management.[4]	The intervention seeks to improve PROs and reduce opioid use during the 3 months after qualifying surgeries across 6 trial sites that share a common Epic EHR. 4-6 item PROMS for pain, physical function, anxiety, and sleep are collected via EHR modes.	Approximately 82,000 surgeries among ~72,000 patients in 22 practice clusters in 4 large integrated healthcare systems. The trial cohort is from the Upper Midwest with high representation of rural- and frontier-dwelling patients of low SES.	Just one third of patients from community sites use the portal. Starting month 7, of the 41-month trial, we adapted EHR PROM admini-stration by matching mode and lan-guage with patient preference, placing NOHARM PROMs first on tablet questionnaire queues, adding a print option, and encouraging providers and support staff to acknowledge and thank patients for completing PROMs.	Increases in response rates with these changes varied across sites and patient subgroups. Within 7 months rates increased > 70% among elderly, frontier-dwellers, and > 50% among those lacking broadband access.
OPTIMUM (NCT04129450) Evaluate a group-	OPTIMUM is a pragmatic clinical trial	Approximately 450 patients with chronic	PROMS are collected at baseline, following the 8-week program, and at	After technology training

based mindfulness program (mindfulness-based stress reduction) for patients with chronic low back pain within primary care. [5]	delivered via telemedicine. It is being conducted in three health care systems: the largest safety net hospital in New England, federally qualified health centers and academic health centers in central North Carolina and Pittsburgh, Pennsylvania.	low back pain in primary care clinics in 3 large healthcare systems The population is made up of people who are of low SES and/or people who are racial and ethnic minorities. Many participants at the North Carolina site lived in small towns or rural areas.	6 and 12-months online or via telephone. The three sites did not consistently collect PROMS and as a result the EHR could not be used to collect PROMs. However, the EHR is being used to collect interaction with the health care system such as emergency department visits. Participants needed to be trained how to use a smart phone as well as videoconferencing platform.	participants logged in and engaged more easily and fully with the telemedicine session. This strategy was an adaptation after the team realized participants were having difficulty using technology.
FM-TIPS (NCT04683042) Test the feasibility and effectiveness	FM-TIPS = is being conducted in 27 clinics across six	Approximately 6000 patients with fibromyalgia in	PROMS are collected on day 1, 30, 60, 90, 180. In these small mostly private PT clinics, use of	Before implementation of additional outreach via

of adding transcutaneous electrical nerve stimulation (TENS) nonpharmacologic treatment for pain and fatigue in patients with fibromyalgia (FM) [6]	physical therapy, health care systems, 5 systems (25 clinics) are private outpatient physical therapy practices.	24 routine physical therapy clinics in 6 healthcare systems, across the Midwest and include rural and low SES communities.	the EHR to collect PROMs was not feasible. Screening is performed electronically by the clinic on an I-Pad provided. PROMs are collected electronically by the participant at home through an individualized link sent by e-mail and text then entered directly into REDCap.	telephone, completion of the PROMs for the 6 month time period ranged between 62-68%, while after implementation of additional calls 6 month completion rates averaged 79-82%.
GRACE (NCT04906447) Determine the effectiveness of guided relaxation and acupuncture compared with usual care in decreasing pain and opioid use for	**GRACE**) is a hybrid effectiveness-implementation trial that prioritizes effectiveness while documenting facilitators and	Adults with sickle cell disease from 3 large healthcare systems, including people from racial or ethnic minority groups, with lower SES,	PROMs were collected at baseline, and week 6,12, and 24. The GRACE Trial was originally designed to collect all PROMs in EPIC via MyChart. However, the study had to pay for integration of each PROM into EPIC, and	Six months after initiating regular text exchanges with participants, rates of completion at two of the sites for all survey timepoints

patients with sickle cell disease.[7]	barriers to offering these complementary and integrative health interventions. It is conducted at 3 sites: University of Illinois Chicago, Duke University, and University of Florida.	who are uninsured or underinsured, and who have disabilities	these integrations were not prioritized by the health systems, as clinical care needs were prioritized over research. For all 3 sickle cell clinics, MyChart-activated accounts range from 50% to 81% and no-show rates are up to 40%. Both factors ultimately impact MyChart completion rates. Therefore, GRACE decided to complete all PROMs on REDCap.[10,11] To improve response rates for PROMs in REDCap, we implemented regular engagement via text with each participant starting in late November 2022, with	increased. At the 12-week survey, one site increased by 19.4% and the other by 27.4%. The third site had already achieved a high level of engagement (94%) and did not show improvement after initiating regular text communication.

			additional communication via phone or email to participants who started but did not finish surveys.	
BeatPain Utah (NCT04923334) Improve pain management and reduce reliance on opioids for patients with chronic back pain in federally qualified health centers in Utah	BeatPain Utah is a hybrid type I effectiveness-implementation trial comparing telehealth-based interventions for the treatment of chronic low back pain to patients receiving care at safety net community health centers (CHCs).[8] The	Adults with chronic low back pain in federally qualified health centers in Utah. From the centers in which we are recruiting: 49% identify as Hispanic/Latinx, 37% communicate in a language other than English, and 66% have a	PROMS are collected at baseline and at 12, 26, and 52 weeks. Beat pain is recruiting participants from 14 health centers. The low use of patient portals, limited PROMS within these EHR systems, and recommendations from community partners drove our strategy to collect PROMS via REDCap, with participant reminders to complete the survey sent via text messaging. Participants are also given the option	As of August 2024, 7,041 text messages have been sent offering a connection to BeatPain. 46.7% of the 793 patients in the trial so far were recruited via text messaging. Response rates to PROMS surveys were 89.7% (12 weeks), 89.4% (26 weeks), and

	telehealth service is provided by physical therapists at the University of Utah who are members of the BeatPain team.	household income at or below the federal poverty level.	to complete the PROM via phone with a research assistant.	85.7% (52 weeks).