Title: *Guidelines for Integrating Electronic Patient-Reported Outcomes Into Health Systems*

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STRUCTURED ABSTRACT

Purpose: As health systems advance their capacity to drive patient-centered care, many are expanding their capture of electronic patient data, particularly using electronic patient-reported outcome (ePRO) measures. However, ePROs are complex to incorporate; they entail unique considerations regarding workflow, measurement, and technology that health systems may not initially be positioned to navigate.

Scope: We report on our effort to develop generalizable learnings that can support the integration of ePROs into clinical practice across healthcare systems.

Methods: Guided by action research methodology, we engaged in iterative cycles of planning, acting, observing, and reflecting regarding ePRO use, with two primary goals: 1) mobilize an ePRO community of practice to facilitate knowledge-sharing, and 2) establish guidelines for ePRO use in the context of practice. Multiple emergent data collection activities generated generalizable *guidelines* that document tangible best practices for ePRO use in clinical care. We organized guidelines around thematic areas that reflect the structures and stakeholders within healthcare systems.

Results: Three core *thematic areas* (and 24 guidelines) emerged. *Governance* reflects the importance of leadership, knowledge management, and facilitation of organizational learning around best practice models for ePRO use. *Integration* considers the intersection of workflow, technology, and human factors for ePROs across areas of care delivery. Lastly, *reporting* reflects critical considerations for curating data and information, designing system functions and interactions, and presentation of ePRO data to support the translation of knowledge to action. Final guidelines and supporting tools and resources are available on a public web-based toolkit (epros.becertain.org), which has been widely disseminated.

Key Words: patient-reported outcomes (PROs), stakeholder engagement, learning health system, patient-facing technologies

PURPOSE

Capturing data from patients through patient-reported outcomes (PROs) is an emerging aspect of healthcare delivery.[1-3] PROs are a type of patient-generated health data that provide clinically meaningful insight into screening, diagnosis, treatment response, and population health.[4] PRO data, when integrated into care, provide standardized assessments of how patients experience health and healthcare. Such data support health system initiatives by providing a mechanism to bring the patient voice into real-time clinical documentation and decision-making.[5-7] Traditional approaches to PRO data collection focus on paper-based workflows, yet healthcare policy[8,9] has prompted advancements in health information technology (HIT) to promote patient engagement and interoperability across electronic health record (EHR) systems. In response to changing healthcare and policy environments, many health systems have prioritized the electronic capture and presentation of PROs (ePROs), leveraging HIT (e.g., EHRs, patient portals, third-party applications, SMART on FHIR) to enhance patient-centered, personalized care. Despite the role ePROs can play in advancing patient-centered care, there is limited evidence on how healthcare organizations should approach the implementation and evaluation of ePRO use in practice.[10] Establishing such guidelines is especially important as efforts grow to scale and spread use of ePROs across clinical contexts and health systems at large. There is, therefore, an imperative to better understand a systems approach for integrating ePROs throughout the organization in ways that enhance learning and advancement.[4]

The objective of this study was to develop guidelines for the integration and use of PROs in clinical practice. This report summarizes learnings from a 6-year AHRQ-funded project guided by action research that aimed to develop generalizable recommendations to support systemwide ePRO integration. Specifically, we approached this work intent on a research *process* (i.e., action research) that is rooted in learning, flexible enough to accommodate the complexity of real-world practice, and would result in an *output* (i.e., *guidelines*) that reflects the process by which health systems can harness patient data to advance the goals of patient-centered care. The full results of this project are publicly available at our project website (http://epros.becertain.org/).[11]

SCOPE

Background

Patient-reported outcome measures (PROMs) are questionnaires that allow patients to report their experience with disease symptoms or well-being, without modification by a healthcare team member.[12] PRO data can provide clinically meaningful and patient-centered insight into screening, diagnosis, and response to treatment. Such outcomes are particularly relevant when assessing health issues for which the patient is the best source of information—for example, understanding patient symptoms during the course of cancer treatment.[3] PROMs are standardized assessments of patient experience with symptoms, often measured repeatedly over time, to evaluate the impact of treatments or progression of disease. They are often developed through iterative psychometric and clinical content review and validated among target patient populations to evaluate their psychometric properties before use.[11]

Originally developed to support clinical research, PROMs provide healthcare teams with three primary advantages.[2,4,13] Such measures make possible better standardized assessments of patient symptom experiences; they allow for the possibility of remote monitoring and tracking of patient health status, minimizing the burden for in-person clinical evaluation; and they promote assessment of patient-centered outcomes and health-related quality of life.

As the evidence for PROs in clinical practice continues to expand, a variety of stakeholders—including patients, providers, healthcare administrators, population health teams, and payers—are increasingly interested in using PROMs as part of routine clinical data gathered to inform care delivery. Beyond point-of-care use, federal and local policies are also incentivizing the use of PROMs to support value-based models of care delivery and quality monitoring (Figure 1).[6,12,14-16]

Figure 1: Drivers of ePRO use for clinical care by stakeholder group

From: ePROs Toolkit/Overview (ePRO = electronic patient-reported outcome)[11]

As the use of ePROs in clinical practice has evolved, so has the technology available to support ePRO data collection and review. A variety of third-party apps, web-based platforms, and EHR functionality have emerged, promoting new modalities for engaging users in ePRO data collection and review while identifying significant challenges related to workflow and interoperability. One example includes efforts by EPIC and Cerner, the two largest US-based EHR vendors, to work with the Patient-Reported Outcome Measurement Information System ([PROMIS]), which supports ePRO measurement across a range of important health domains.[17] PROMIS measures are available in existing EHR questionnaire sets to support the expanded use of these measures in clinical care, yet work is needed to support workflow integration and data use to support clinical care.[17,18]

Context

Data are increasingly harnessed in ways that empower and engage patients and care teams to optimize care quality and outcomes.[19] For example, learning health systems are advancing care through the alignment of data, technology, and care delivery in the continuous generation and application of evidence to practice.[19,20] In this context, PRO data, when integrated into care via HIT, provide standardized assessments of how patients experience health and healthcare and serve as the means to bring the patient voice into real-time clinical documentation and decision-making.[1,13,15,21] In general, ePROs generate new or expanded data sources that can support learning and care improvement across an organization;[22] specifically, such data provide a means to pivot from cumbersome analog approaches (i.e., paper-based) to the integration of electronic capture into care, which allows for real-time collection and reporting.

The ability to administer PRO surveys electronically resolves some challenges (e.g., auto-reminders and distribution to patients to complete ePROs ahead of visits) and creates new opportunities for improving care delivery (e.g., clinical and quality dashboards that present ePROs and clinical data collectively).[23] Yet, ePROs can also amplify existing HIT barriers (e.g.,

low patient portal enrollment and limited functionalities of EHR systems) and introduce others, in particular, information overload for clinical teams.[4,24-26] Although there is demonstrated value and increasing pressure to incorporate ePROs into clinical care, many health systems have met challenges when trying to bring ePROs to scale and balance the needs of individual users with the system at large.[1] This is due in part to the complex interplay of technology, workflow, and human factors that influence the success of ePRO adoption, as well as the leadership and governance that ensures the sustainability of ePRO implementations. Establishing guidance for health systems is important as efforts to scale and spread use of ePROs across clinical contexts and health systems at large increase.[4]

Understanding of the sociotechnical, interpersonal, and organizational factors that characterize how providers and learning health systems can effectively use ePROs in clinical care addresses a gap in knowledge for advancing the capture and use of PRO data. Experimental designs may not be well suited to evaluate the functionality of ePRO tools in complex, adaptive settings that are marked by dynamic interactions between the individual, team, and system-level behaviors. Therefore, we opted to use action research methods, which allow for the emergence of learnings, or *guidelines*, that are rooted in real-world experiences and can provide a foundation for continuous learning, iteration, and application across learning health systems looking to implement ePROs.[27,28]

<u>Settings and Participants</u>

The setting and participants involved throughout this study drew from local initiatives for integrating ePROs in practice as well as from a wider community of practice representing experiences and perspectives from different settings. The local community of practice drew from the University of Washington (UW) Medicine, a four-hospital health system in the Seattle metropolitan area. In 2016, UW Medicine launched a systemwide practice transformation initiative to promote evidence-based, patient-centered care. The objectives of this initiative included the use of standard care pathways, increased engagement with patients outside the care setting, and greater inclusion of patient voice in clinical documentation and decision-making. The present study sought to work alongside this initiative to support system-level change.[10] We first worked locally within our health system to develop our community of practice. By canvassing existing committees and organizational units involved in patient engagement work or the use of patient-facing technologies in practice we identified a core group of local stakeholders that reflected a breadth of experiences related to ePRO use, HIT, workflow, and health system leadership; they comprised our governance committee. We collaborated with UW Medicine stakeholders to describe how PROs are currently used across the health system and to identify common use cases to serve as the blueprint for the design of systemwide PRO implementation strategies.

We then expanded nationally via professional groups associated with PRO measurement and practice, medical informatics, and health services research. We subsequently expanded our community of practice beyond our initial setting at UW Medicine to engage national and international audiences through professional groups associated with PRO measurement, medical informatics, and health services research (e.g., American Medical Informatics Association, International Society for Quality of Life Research, and Academy Health). The experiences and perspectives across the broader community of practice regarding the use of ePROs in clinical care played a pivotal role in facilitating insights and reflexivity during all phases of the action research process.

METHODS

<u>Study Design</u>

We took an action research approach to generate knowledge that informs change, marked by multiple, iterative cycles of planning, action, observation, and reflection, and continuous stakeholder participation.[28,29] Participatory action research systematically elicits action and change; the process involves and is informed by the collective participation of stakeholders affected by the problem of interest.[30] Such methods are a way of approaching scientific inquiry that draw from the perspectives of stakeholders.

Over the course of the project, our iterative cycles of action research[29] centered on two areas of focus: 1) mobilize an ePRO community of practice to facilitate knowledge sharing, and 2) establish guidelines for ePRO use in the context of real-world practice (Figure 2).

Figure 2: ePRO guideline development process
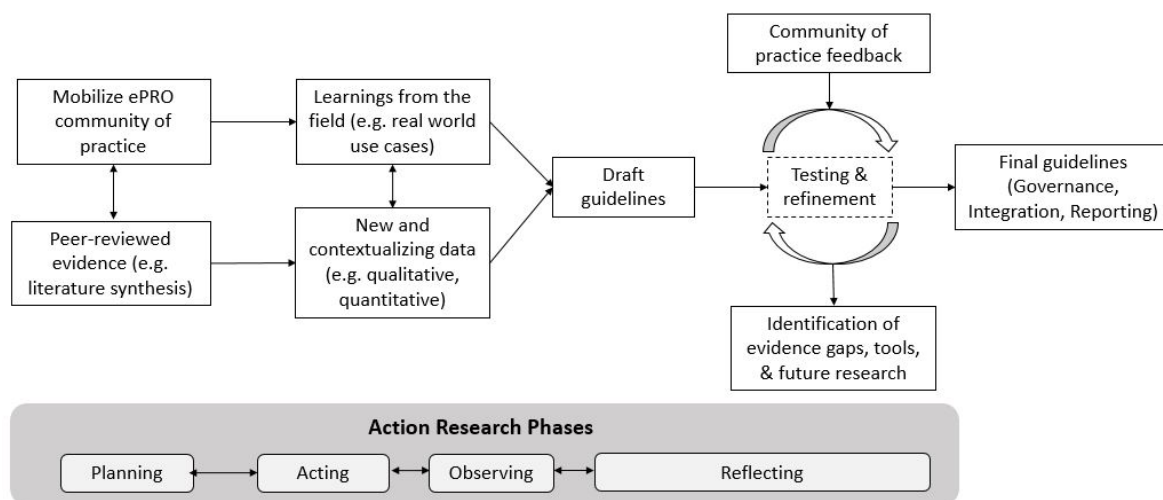
From: Austin EJ, et al. A learning health system approach to integrating electronic patient-reported outcomes across the health care organization. Learning Health Systems. epub March 1, 2021; ePRO = electronic patient-reported outcome.

Throughout the project, the processes of stakeholder engagement, co-production of knowledge, and reflexivity guided and informed continuous feedback loops.[26] By engaging in multiple, iterative action research cycles, we were able to enhance learning and better capture the continuous evolution of practice. All activities were reviewed and approved by the UW Institutional Review Board, and informed consent was obtained as appropriate for study activities. We shared learnings across the community of practice to augment community knowledge and engagement and distill experiences into generalizable learnings and recommendations. Lastly, we presented learnings back to the practice community for review, feedback, and identification of future research and practice topics.[31]

<u>Data Sources/Collection</u>

Mobilizing an ePRO community of practice, that is, a learning community composed of stakeholders who bring broad experiences and perspectives on the use of ePROs in practice, served as our primary data source for collecting practice-based insights across all phases of the action research process. Table 1 details the community of practice activities and outputs that

occurred throughout our action research phases and informed activities related to our second area of focus, developing *guidelines* for ePRO use.

Table 1: Description of data-generating activities that contributed to guideline development

Data-Generating Activity	Associated Research Approach	Alignment with Action Research Phase
Evidence review and qualitative synthesis	Systematic search and qualitative synthesis[32] of peer-reviewed literature (n=82) describing ePRO use. Details and results of the qualitative synthesis are provided as a supplemental material (A).	A synthesis of the current evidence around ePRO use supported the *planning* phase of action research activities.
Semi-structured interviews	Qualitative interviews with clinical providers (n=20) engaged in ePRO use across a variety of specialties.[33] Interview questions were guided by the Sittig & Zhang sociotechnical models of HIT implementation.[34,35]	Thematic analysis of interview data provided insights into the challenges associated with ePRO use, and informed the *planning* phase.
Local ePRO use cases catalog	Catalog existing ePRO implementations across health system (n=14 use cases) via structured survey to identify and report on sociotechnical characteristics of ePRO tools, workflows, and ePRO measures used (details reported elsewhere).[10]	Cataloging of local implementations supported the *planning* phase by characterizing the breadth of ePRO uses across the health system.
Implementation monitoring data	Monitor ePRO assessment tools (n=9) within the EHR, spanning preventive (e.g., annual health risk assessment), chronic (e.g., depression and anxiety management), and interventional (e.g., total joint replacement, spine fusion) care contexts, over the course of 4 years (2016-2020). Monitor implementation process, which included bi-weekly data review of EHR-generated metrics (e.g., ePRO deployment and completion rates), brief interviews with patients (n=15), and informal discussions with ePRO clinical sites (n=4 sites, inclusive of providers and administrative staff) that evaluated usability and satisfaction with ePRO tools.[36] Triangulate quantitative and qualitative data to inform needed modifications and implementation support.	Involvement in the design of ePRO tools, workflows, and training materials enabled the *action* phase. Monitoring ePRO use over time, and across multiple settings of care, supported the *observation* phase. Additionally, data across implementations were compared and triangulated to support systemwide learnings and *reflection*.
Field notes and observation	Document analysis of field notes from implementation team meetings for individual ePRO implementations, clinic and staff trainings, and periodic observations of clinic workflow and ePRO use in practice. Document review and analysis performed on an iterative (e.g., monthly/quarterly) basis with implementation teams and broader community of practice for feedback and reflection.	Data from field notes and participant observation supported the *observation* and *reflection* phases.
Guideline development	Learnings across data collection efforts aggregated and organized into thematic areas. Guidelines drafted and iteratively reviewed with local and national ePRO practice communities for feedback and validation via workshops and networking events, and further tested against data gathered from ePRO implementations, as described above.	*Reflection* across implementation experiences contributed to development of generalizable guidelines.

From: [37] *Austin EJ, et al. A learning health system approach to integrating electronic patient-reported outcomes across the health care organization. ePRO = electronic patient-reported outcome, HIT = health information technology; EHR = electronic health record.*

Limitations

There are a few limitations that are important to acknowledge in this work. First, our focus was on generating learnings that could inform health systems looking to be responsive to external pressures and policy changes related to patient data, considering the perspectives of providers, administrators, and other stakeholders working to provide clinical care. While we consulted with patients as part of both the local and national community of practice (including members of the UW Medicine Patient and Family Advisory Council Steering Committee, and patient advisors who served on operational committees within the health system), we did not directly involve patients on the research team. During the conduct of this work, we recognized this gap and involved patients in our local planning and development efforts for ePROs and, more broadly, patient-generated health data.[38] As the use of technology for involving and engaging patients in healthcare delivery advances, more work is needed to focus on methods, processes, and results of involving patients in the co-design of systemwide approaches. Second, it is essential to acknowledge that technology, such as the tools used to facilitate ePRO capture and reporting, are continually evolving, and, in parallel, so are stakeholder interests and uses of those tools in practice. The learnings presented from this work reflect the experiences of our community of practice at one point in time where evidence on the use of patient-reported and generated health data via different technology enabled approaches is evolving, but it is subject to continued change and evolution. Finally, the learnings presented reflect our experiences within a U.S.-based healthcare system; while the guidelines produced from this work are intended to be agnostic to healthcare setting, there are likely important differences related to policy, regulatory requirements, and data use to acknowledge in other contexts outside the United States.

RESULTS

Principle Findings

The core results of our work consist of 24 *guidelines* that emerged across three thematic areas: Governance, Integration, and Reporting.[37] The development of the guidelines was informed through the identification of common use cases.[10] We engaged stakeholders using a combination of electronic questionnaires and in-person interviews to inventory current PRO implementations across UW Medicine, characterized common use cases for PROs, and developed recommendations for a systemwide implementation strategy. The use of action research methods enabled the study of healthcare settings where clinical stakeholders have deep contextual knowledge about their environments and where researchers benefit from actively participating in the topic of study.[28,39,40] Through cycles of planning (identifying issues, research questions, and inquiry methods), acting (gathering data), observing (health system project activities and meetings), and reflecting (analyzing data and communicating),[29] the research team informed UW Medicine clinical practice transformation as well as a broader PRO stakeholder community interested in systemwide PRO implementations.

The guidelines are agnostic to any specific HIT platform or PRO measurement approach. This is intentional, recognizing that health systems have different sociotechnical resources available.[4] As a result, the guidelines provide a tangible framework to support considerations and decision-making around ePRO use that can be adapted to the local context. Below, we provide an overview of the *guidelines* (indicated by italics) that emerged (Table 2), a full listing of guidelines, additional guideline details, and recommendations to support future use in practice. The full ePRO toolkit produced from this work is available at http://epros.becertain.org/.[11]

Table 2. Comprehensive Guideline List.

Guideline No.	Full Guideline Statement
Guideline Theme 1: Governance	
1	Align ePROs with health system goals
2	Align goals for ePRO use with IT infrastructure
3	Establish an ePRO governance structure
4	Identify governance activities that guide practice
5	Disseminate best practices for use and management
Guideline Theme 2: Integration	
6	Clarify how data will be accessed and support care
7	Design workflows for easy data capture
8	Leverage HIT to facilitate ePRO use
9	Engage users in ePRO adoption and use
10	Encourage continuous learning throughout implementation
Guideline Theme 3: Reporting	
11	Display most useful statistical presentation
12	Provide longitudinal PRO information
13	Provide comparative PRO information
14	Augment PRO data with contextual information
15	Automate to improve ePRO workflow
16	Customize to enhance usability
17	Include drill-down or -up capacity
18	Provide means to filter PRO data
19	Integrate PRO and clinical data platforms
20	Accommodate multiple platforms
21	Visually enhance key information
22	Provide simple and familiar graphs
23	Organize display of multiple visualizations
24	Model clinical use of ePRO reports

ePRO = electronic patient-reported outcome; PRO = patient-reported outcome

Guideline Theme 1: Governance

We define governance as the strategic process and structure whereby responsibilities of ePRO implementations are conceptualized and carried out. Governance activities are commonly overseen by a management committee, with the involvement of multi-disciplinary workgroups that participate in the development and pilot of new ePRO resources as needed.[11] Our experience working with the local community of practice, including leading workshops, needs assessments, and governance activities, provided insights that helped clarify the need for scope and the role of governance for ePRO data within systems. For example, in the case of

measuring depression, we identified multiple needs for ePRO capture, reporting, point-of-care and system-level decision-making.[10]The most critical role of governance focuses on the work of boundary setting that fosters health system behavior in ways that balance health system goals while avoiding overextension of roles, responsibilities, or resources.

We identified five guidelines that encompass the governance practices needed to support organizational readiness for ePRO use across the health system. These guidelines consider both the technical and clinical ramifications of scaling ePRO implementation across a healthcare delivery system and echo the importance of multidisciplinary stakeholder engagement and continuous learning around best practices. First, health systems must define objectives for ePRO use and *align ePRO objectives with broader health system goals*, to create pathways for organizational support and incentive alignment and clear leadership for ePRO objectives. Next, health systems should *develop an IT strategy* for ePRO use that considers the desired technical capabilities for ePROs, existing IT architecture, and needed modifications to the IT environment to support the development of ePRO tools. Third, health systems should *establish formal structures for ePRO governance* that define membership, systemwide roles and responsibilities, decision-making capacity, and relationships to other governing structures within the organization. ePRO governance teams can then develop the tools, resources, and practices needed to *operationalize governance objectives*. For example, ePRO governance teams may need to develop processes to manage the intake and prioritization of new ePRO project requests. Lastly, ePRO governance will need to actively *disseminate best practice models* for ePRO use by facilitating organizational learning across stakeholder networks and engaging in knowledge management of ePRO learnings over time.

Guideline Theme 2: Integration

The theme of integration encapsulates the work of moving ePRO use from conceptual to practical, considering the interactions between workflow, technology, and human factors that influence how ePROs are used at the point of care. In this, it is crucial to take a systems approach that acknowledges the dynamic nature of how ePRO data facilitates goals across the micro, meso, and macro layers of the organization.[41] While many evidence-based models to guide the implementation process exist, our goal was to identify the core considerations for ePRO implementation that augment the goal of harnessing the power of data.

We identified five guidelines that reflect the unique considerations for supporting ePRO integration at the point of care, including preventive, chronic, and interventional care delivery settings.[10] An important starting point is *clarifying how ePRO data will support care delivery*. Project teams looking to implement ePROs should explore questions around how care teams will need to receive ePRO results, what the appropriate clinical response is for ePRO data, and whether clinical teams have the capacity to facilitate that response. Next, teams should *design workflows and tools that enable easy ePRO data capture* for patients and care teams, considering alignment with existing workflows for clinical visits. Once workflows have been developed, teams should *leverage health IT to facilitate efficiencies and improved user experience in ePRO use*. As teams prepare to launch ePRO use, they should identify and implement strategies that actively *engage users (e.g., clinical team, patient) in ePRO adoption and use*. Lastly, teams should *encourage continuous learning throughout ePRO implementation* to facilitate ongoing process improvement and share learnings throughout broader organizational networks that support the identification of best practice models.

Guideline Theme 3: Reporting

The role of reporting ePRO data is perhaps the lynchpin to translating ePRO data into action supporting healthcare transformation. While ePROs have a long history of use in research, their application in point-of-care decision-making still warrants the need for strategies that can support the data-to-knowledge-to-action pathways, considering the user needs of patients, providers, and other key stakeholder groups. Consequently, our focus of reporting centered on the needs and desires for how ePRO data could inform shared decision-making, recognizing that underlying IT abilities will continually evolve. Through in-depth interviews with current ePRO users and documentation of experiences supporting the design and use of ePRO reports for our implementation practice sites, our experience highlights the challenge of aligning health system and technology functional capabilities with user needs and preferences. In order to align and support the goals of a health system, the ePRO reports and options selected in practice should leverage feedback loops that facilitate continuous learning about the use of ePRO reports and their application across diverse areas of practice.

We identified 14 guidelines that address considerations for curating *data and information*, designing *system functions and interactions*, and appropriate *presentation* of ePRO data to end users. These guidelines reflect a breadth of ePRO reporting for supporting providers and other stakeholders across clinical and organizational use cases, including point of care, quality improvement, population health, and contractual reporting. The theme of reporting also considers that the activity of reporting involves the interaction between reporting tools themselves and the *use* of those tools by patients and care teams. When determining what data and information are included in ePRO reporting options, teams need to consider what information will most appropriately facilitate the interpretation of ePRO data. As part of this process, project teams should identify whether to *provide longitudinal* or *comparative ePRO information* to clinical users, determine *the most useful statistical presentation to display*, and consider how to *augment PRO data with contextual information*, such as clinical variables that support decision-making. As teams look to design the ePRO reporting tool functions and interactive elements, they should identify functions that facilitate ease of use and reduce barriers to ePRO data access and review. Teams may face decisions around the use of *automation to improve ePRO reporting workflows*, allowing *customization to enhance usability*, *including drill-down or drill-up capacities*, or *providing means to filter PRO data* for different review needs.

Additionally, teams should consider the need to *integrate ePRO reporting tools with clinical data platforms* (including those that are internal or external to the EHR) and *accommodate reporting across multiple platforms* where clinical users may interact. Lastly, as teams consider approaches for presenting ePRO data to clinical users, they should identify design strategies that enhance ePRO data review, especially quick review at the point of care. Strategies could include *visually enhancing key information*, *providing simple and familiar graph* formats, *organizing displays of multiple ePRO visualizations* together, and *modeling clinical use of ePRO reports* via simulation and training.

<u>Future Directions</u>

Over the course of this project, the landscape for capturing and using ePRO data has continued to evolve. Notably, the increased interest in capturing ePROs within different clinical settings has spurred discussions for how health systems can better coordinate efforts within and across the organization. We anticipate continued efforts among health systems to leverage technology-driven strategies for patient engagement. As a result, this will remain a fluid space for learning. Experience with ePROs, as well as with other forms of patient-generated health data, will produce new evidence for the advancement of patient-centered care. To support future

directions, we present in Table 3 areas where practice-based learnings are needed to advance the use of ePROs and patient-centered technologies in clinical care.[11]

Table 3: Challenges and Recommendations for Future ePRO work

Area	Challenges Facing ePRO Implementations	Future Directions
Governance and leadership	ePROs require multiple levels of health system governance. Supporting ePRO implementation through structured initiatives guided by multidisciplinary teams is important, but governance models are not well understood.	• Identify which governance models are most effective for different settings/systems • Evaluate the effect of systemwide ePRO implementation on care quality metrics • Evaluate how ePRO implementation supports contractual/quality reporting initiatives
Workflow and human factors	Expanding the ability to collect data from patients outside of the clinical visit requires redesign of workflows to ensure patient care is safe, efficient, and high quality. Attention to how new workflows contribute to the efficiency of healthcare teams is also important.	• Identify workflow design standards that can support ePRO use across the health system • Create guidance for involving patients and care partners in ePRO workflow co-design and implementation • Explore how heterogeneity of user goals (diagnosis, severity, treatment plan, cadence of PROs) may impact design of workflows and tools • Understand how the capture of data outside of clinical care impacts the workforce with regard to burnout and workload
Technology evolution	A "best of breed" ePRO technology does not exist. Challenges facing interoperability persist, further stifling advancement in ePRO and PGHD capture and use.	• Expand use cases for how APIs and other tools can bridge gaps in EHR functionality for ePRO implementation • Design ePRO reporting tools to encompass implementation monitoring and evaluation needs at the clinic level • Design ePRO reporting tools to encompass implementation monitoring and evaluation needs at the health system level
Data-driven care and data science	Clinicians and patients must know how to apply ePRO data to clinical practice and decision-making. Evidence on how PGHD improves care continues to evolve.	• Create training resources for providers and patients to support score and visualization interpretation across clinical use cases • Generate real world evidence on how PROMs and PGHD may be used to inform decision-making • Consider the use of ePROs in leveraging predictive analytics to support population health, quality improvement, and process improvement
Citizen science and engagement	Achieving patient-centered care through ePROs will require meaningful patient engagement. Health systems are not well poised to support patients acting in a partnership role.	• Advance capacity for health systems to involve patient and community members in co-design of ePRO systems • Learn from citizen science culture and methodology to recognize innovative ways people leverage PGHD for healthcare

ePRO = electronic patient-reported outcome; PRO = patient-reported outcome; EHR = electronic health record; PGHD = patient-generated health data; API = application programming interface

Discussion and Implications

This work and the resulting guidelines address a gap in the resources available for health systems working to integrate ePROs across their organization and provide more patient-centered care. We leveraged action research methodology and a robust community of practice to develop guidelines for the integration of ePROs into real-world contexts. Three thematic areas (i.e., Governance, Integration, and Reporting) reflect the application of ePRO use to health system goals and reinforce the need for organizational learning processes to translate across multiple layers of the organization to support continuous learning and practice change.

In addition to the tangible guidelines and recommendations that emerged from this work, several cross-cutting learnings can continue to inform how health systems integrate ePROs and other forms of patient-generated health data. ePROs are complex interventions whereby the implementation will impact multiple layers of healthcare organizations. From a technical standpoint, ePROs represent much more than the addition of a few clinical variables to EHR; ePROs require dynamic technical capabilities for data flow and data representation. Workflows for ePRO data capture can involve complex and often hybrid combinations of EHR-integrated and external ePRO platforms, as well as electronic and paper-based tools.[4] Approaches to visualizing ePRO data may need to consider the visual requirements of diverse users, the nuanced parameters for ePRO score interpretation, and the potential need for normative or population health displays of ePRO data in context with other clinical variables. From a social perspective, effective ePRO data collection and use rely on the engagement of multiple user groups, including patients, clinical staff, providers, and administrators or health system leadership. In order for health systems to advance the data-knowledge-practice continuum, health systems may need to expand their focus on the complex relationship between implementation strategies, processes, and outcomes that influence the quality and adoption of ePRO data in practice.[37,41,42]

Though the use of action research methods was a strength, it also presented some challenges; in particular, the challenge of recognizing when learnings had reached a point of saturation, such that they could be summarized and shared. In our experience, engaging a community of practice that involved stakeholders beyond our practice site (e.g., stakeholders involved in ePRO use at other healthcare settings) played a pivotal role in informing decisions around how inquiry activities were designed, conducted, and concluded. When we were able to achieve consensus between our local and national ePRO stakeholders, this confirmed that saturation had been reached; however, when community of practice stakeholders continued to bring up experiential examples that did not align with our learnings, this signified the need to continue inquiry and the action research process to reconcile learnings.

Conclusion

It is expected that the use and expansion of technology to drive improvements in the quality and efficiency of care will persist. This includes advancements in how patient-reported and patient-generated health data are captured and used to advanced collaborative and patient-centered care. The guidelines produced from this work can inform how a health system governs, integrates, and reports ePRO data to facilitate patient-centered care. This work showcases the critical need to involve multidisciplinary stakeholders throughout the complex design, implementation, and evaluation of health innovations such as ePROs, and it highlights the value of action research approaches to enable rapid, iterative learning that leverages the experience of communities of practice. Future endeavors will benefit from building a community of practice, inclusive of patients and community members, to advance research and knowledge translation. In this manner, as healthcare transforms, the patient voice will remain central to the journey.

LIST OF PUBLICATIONS and PRODUCTS (Bibliography of Outputs from the study. Follow the AHRQ Citation Style Format at: http://www.ahrq.gov/funding/grants/tips-tools/refstyle.html

Peer-reviewed Manuscripts:
1. Austin E, LeRouge C, Hartzler AL, Segal C, Lavallee DC. Capturing the patient voice: implementing patient-reported outcomes across the health system. Qual Life Res. 2020 Feb;29(2):347-355. doi: 10.1007/s11136-019-02320-8. Epub 2019 Oct 12.
2. Austin E, LeRouge C, Hartzler AL, Chung AE, Segal C, Lavallee DC. Opportunities and challenges to advance the use of electronic patient-reported outcomes in clinical care: a report from AMIA workshop proceedings. JAMIA Open. 2019 Aug 20;2(4):407-410. doi: 10.1093/jamiaopen/ooz042.
3. Lavallee DC, Austin E, Franklin PD. (2018). How can health systems advance patient-reported outcome measurement? Jt Comm J Qual Patient Saf. 2018 Aug; 44(8):439-440. doi: 10.1016/j.jcjq.2018.05.005.
4. LeRouge C, Hasselquist MB, Kellogg L, Austin E, Fey B, Hartzler A, Flum DR, Lavallee DC. Using Heuristic Evaluation to Enhance the Visual Display of a Provider Dashboard for Patient-Reported Outcomes. EGEMS (Wash DC). 2017 Apr 20;5(2):6. doi: 10.13063/2327-9214.1283.
5. Austin EJ, LeRouge C, Lee JR, Segal C, Sangameswarn S, Heim J, Lober WB, Hartzler AL, Lavallee DC. A learning health systems approach to integrating electronic patient-reported outcomes across the health care organization. Learning Health Systems. epub March 1, 2021; https://doi.org/10.1002/lrh2.10263.

Products:
1. **ePROs in Clinical Care Toolkit** (epros.becertain.org)
   Print and web-based toolkit that provides evidence-based guidelines and tools to help healthcare systems successfully use ePROs in clinical care, considering activities of governance, design, integration, and ongoing evaluation.
   Citation: LeRouge C, Austin E, Lee J, Segal C, Sangameswaran S, Hartzler A, Lober B, Heim J, Lavallee DC. ePROs in Clinical Care: Guidelines and Tools for Health Systems. Seattle, WA: CERTAIN, University of Washington. May 2020.

Published Abstracts and Conference Materials:

1. Austin E, Sangameswaran S, Heim J, Lavallee D. Understanding workflows for integrating ePROs across clinical settings: A systems approach to implementation. Poster presented at 2020 Academy Health Annual Conference on the science of Dissemination & Implementation in Health, virtual.

2. Austin E, LeRouge C, Hartzer A, Heim J, Lober W, Segal C, Sangameswaran S, Lavallee D. A learning health systems approach to integrating electronic patient-reported outcomes across the healthcare organization. Poster presented at 2020 Academy Health Annual Conference on the science of Dissemination & Implementation in Health, virtual.

3. Segal C, Austin E, Chang D, Sutton E, Lavallee DC. Optimizing workflows in the patient portal to incorporate patient-reported outcomes in clinical practice. Presentation at: American Medical Informatics Association Annual Symposium; 2019 Nov 16-21, Washington, DC.

4. Austin E, Segal C, Heim J, Sangameswaran S, Lavallee DC. A checklist to support effective and scalable design of ePRO tools in electronic health records. Poster at: American Medical Informatics Association Annual Symposium; 2019 Nov 16-21, Washington, DC.

5. Segal C, Austin E, Lavallee DC, Chang D. Optimizing workflows in the patient portal to collect the Patient Health Questionnaire Across a health system. Presentation at: International Society for Quality of Life Research Annual Meeting; 2019 Oct 23-26, San Diego, CA.

6. Austin E, Segal C, Lavallee DC. Leveraging digital engagement to enhance efficiency and patient-centered care: A case study with the Medicare Annual Wellness visit. Poster at: International Society for Quality of Life Research Annual Meeting; 2019 Oct 23-26, San Diego, CA.

7. Segal C, Austin E, Chang D, Lavallee DC. Optimizing real-time data collection and reporting of an electronic PHQ for depression care. Poster at: Academy Health Annual Research Meeting; 2019 Jun 1-3, Washington DC.

8. Segal C, LeRouge C, Austin E, Lavallee DC. Provider perspectives on integrating electronic patient-reported outcomes into clinical practice workflow. Poster at: American Medical Informatics Association Annual Symposium; 2018 Nov 3-7, San Francisco, CA.

9. Austin E, LeRouge C, Hartzler A, Lober B, Segal C, Lavallee DC. An enterprise approach to assessing the fit of technical solutions for patient-reported outcomes (PROs) systems. Poster at: Academy Health Annual Research Meeting; 2018 Jun 23-26, Seattle WA.

10. Segal C, LeRouge C, Austin E, Lavallee D. Providers as end-users of patient-reported outcomes integrated into electronic health records. Presentation at: Academy Health Annual Research Meeting; 2018 Jun 23-26, Seattle WA.

11. Austin E, LeRouge C, Crane H, Voelzke B, Murinova N, Mauritz-Miller K, Flum D, Lavallee D. Cataloging the diversity of patient reported outcomes implementations across a large hospital system. Poster presented at Academy Health Annual Research meeting, 2017 June 25-27; New Orleans, LA.

12. Hasselquist MB, Austin E, Fey B, Kellogg L, LeRouge C, Hartzler A, Flum D, Lavallee D. Visual Optimization of a Provider Dashboard for Patient-Reported Outcomes in Surgical Spine Patients. Poster presented at 40th American Medical Informatics Association meeting, 2016 Nov 12-16; IL.

Professional Presentations:

1. Austin EJ, Sangameswaran S, Segal C, Drake L, Chang D, Lavallee DC. Leveraging technology to enhance depression screening and management: Lessons to support the

scale and spread of the electronic capture of the PHQ9. Presentation at 2020 Academy Health Annual Conference on the science of Dissemination & Implementation in Health, virtual.

2. Austin EJ, Hanmer J, Hess R, Lavallee DC. From single site to scale: What does it take to implement PROs across health systems? Symposium presentation at the 2020 International Society for Quality of Life Research (ISOQOL) Annual Conference, virtual.

3. Lavallee DC, Austin EJ. Navigating PRO implementation from a systems lens. Panel presentation in *Clinical Implementation of PROMs* Plenary Session, at the 2020 PROMIS Health Organization Annual Conference, virtual.

4. Rudin RS, LeRouge C, Lavallee DC, Reddy MC, Dalal AK. Implementing e-PROs into Clinical Practice. AMIA 2019. Presentation at AMIA November 2019, virtual.

5. Austin EJ, LeRouge C, Hartzler AL, Lavallee DC, Chung A. Incorporating the patient's voice into clinical care to advance learning health systems. Workshop at: American Medical Informatics Association Annual Symposium; 2019 Nov 16-21, Washington, DC.

6. Austin EJ, LeRouge C, Hartzler AL, Lavallee DC, Chung A. How Health Systems Should be Thinking About Clinical Integration of Electronic Patient Reported Outcomes. Workshop at: American Medical Informatics Association Annual Symposium; 2018 Nov 3-7, San Francisco, CA.

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8. Austin EJ, LeRouge C, Hartzler AL, Lober B, Lavallee DC. An enterprise approach to designing patient-reported outcomes (PROs) systems: Diverse perspectives across a large healthcare organization. Presentation at: Workshop on Interactive Systems in Health Care; 2017 Nov 3, Washington, DC.

9. Austin EJ, Crane H, Murinova N, Cizik A, Lavallee DC. Leveraging the diversity of patient reported outcomes (PROs) implementations across a large hospital system to inform an enterprise approach to PROs data use. Symposium presentation at: Society for Medical Decision-Making conference; 2017 Oct 22-25, Pittsburgh, PA.

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