Patient-Reported Outcomes: Best Practices on Selection and Data Collection

DRAFT TECHNICAL REPORT FOR COMMENT

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Executive Summary

Foundational work by the National Quality Forum (NQF) created structured recommendations around Patient-Reported Outcomes (PROs), Patient-Reported Outcome Measures (PROMs), and Patient-Reported Outcome Performance Measures (PRO-PMs). Unfortunately, the widespread use and adoption of PROs and PROMs have faced barriers, as has the development, endorsement, and implementation of PRO-PMs. This report offers guidance to clinicians and organizations about how to address some of the barriers that affect the selection and implementation of PROs and PROMs.

The selection of PROs is the first step for clinics or health systems that want to utilize feedback directly from the patient. The report reviews the five domains of PROs, then presents four best practices for the selection of PROs. Patient involvement is a critical component of this first step, and the report identifies several ways to engage patients as part of a multistakeholder process to select PROs that are important and meaningful.

Once the multistakeholder selection team has identified PROs that are important and meaningful, the next step is to select PROMs to collect data and generate scores for the PROs. Again, patient involvement is critical to this step, as patients bring a unique perspective that no other stakeholder can fully provide. The report reviews and expands upon the attributes of PROMs that were discussed in past literature and that should be considered during the selection process. An Attribute Grid is presented as a tool to aid in comparing and selecting PROMs, and four best practices for PROM selection are introduced.

After the selection team has identified PROMs, implementation can begin. The report explores best and promising practices related to implementation of PROMs. Buy-in from critical stakeholders, including leadership, is arguably the most critical aspect of implementation, and the report offers guidance on securing buy-in. The burden of data collection impacts both clinical staff and patients, and recommendations are provided to minimize this burden. Workflow implementation is addressed, including the opportunities to delegate tasks in order to reduce clinician burden. Clinicians must be able to accurately interpret scores and communicate effectively with patients about the scores’ meaning, and recommendations are included to improve interpretation and communication. Promising practices around the integration of PROMs with electronic health records (EHRs) are explored, as are the implications of attaching return on investment to PROMs.

Using three clinical scenarios as a basis (burns and trauma, heart failure, and joint replacement), the report tests best practices and recommendations around PRO and PROM selection by looking at key elements of PROMs and developing use cases for different people involved in the selection process. The report concludes with a brief look at future opportunities related to PROs and PROMs.
Introduction

Patient-reported outcomes (PROs) are increasingly being used for a variety of healthcare-related activities, including care provision, performance measurement, and clinical, health services, and comparative effectiveness research.1,2 PROs provide important information about a patient’s health that may not otherwise be available through clinician-reported or third-party data sources (e.g., claims, health records). Using data reported directly by patients and/or their caregivers promotes a patient-centered approach to care management and helps drive quality measurement towards assessing outcomes and improvement in areas most meaningful to patients.

However, the literature identifies multiple barriers related to the use of PROs, including challenges identifying PROs that are meaningful and important to a clinic or organization, differentiating between the multitude of patient-reported outcome measures (PROMs) that are used to collect and measure data, and a lack of guidance on how organizations can implement PROMs in ways that are person-centered and strategic. Foundational work from 20131 and 20153 established clear terminology and provided a pathway from PROs to NQF-endorsed Patient-Reported Outcome Performance Measures (PRO-PMs). In this project, a Technical Expert Panel (TEP) built upon the previous work by establishing best practices for the selection of PROs and selection and implementation of PROMs, primarily in the context of care management and planning.

Purpose and Objectives

In 2019, the Department of Health and Human Services (HHS) contracted with the National Quality Forum (NQF) to convene a TEP to recommend best practices that address challenges in the selection of PROs and the selection and implementation of PROMs, including data collection and EHR use. The TEP also developed use cases related to burns and trauma, heart failure, and joint replacement. These use cases represent both acute and chronic conditions that often necessitate provision of care across settings and providers. While the best practices were applied to select use cases and often discussed in these contexts, they are intended to be generally applicable to other conditions with some expansion (e.g., determining the most important PROs for a specific condition).

PROs are defined as any report of the status of a patient’s health condition, health behavior, or experience with healthcare that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.1 The term “patient” is intended to be inclusive of all persons, including patients, families, caregivers, and consumers more broadly; as well as all persons receiving support services, such as those with disabilities.

In addition to defining PROs, it is also important to clearly differentiate between PROMs and PRO-PMs. A PROM is any standardized or structured questionnaire regarding the status of a patient’s health condition, health behavior, or experience with health care that comes directly from the patient (i.e., a PRO).3 A PRO-PM is defined as a performance measure that is based on PROM data that are aggregated for an accountable healthcare entity.

It is important to note that this report includes both the selection of PROs (the concept of the outcome) and the selection of PROMs (the instruments), as well as the implementation of PROMs. Though this project does not specifically focus on PRO-PMs, the challenges and best practices presented likely have implications related to PRO-PMs.
The TEP’s deliberations and recommendations were informed by an environmental scan of current practices in selecting PROs and collecting PRO data. The TEP focused the scope of this work primarily on care planning and monitoring, as it agreed that PROs and PROMs should ideally inform routine decision-making and care delivery. The TEP’s feedback and guidance was collected over several meetings and created the foundation for this report. In addition, key informants were selected from the TEP members, based on their diverse perspectives and expertise. These key informants were interviewed to help provide a nuanced perspective on PRO and PROM selection and PROM implementation. For an overview to these key informant interviews, please refer to Appendix B: Key Informant Interview Guide. This final technical report presents expert recommendations for best practices to address key challenges in selecting PROs and selecting and implementing PROMs. Within the report, unless a fact or recommendation is explicitly attributed to a specific source, information has been gathered from the TEP and synthesized by NQF.

Background and Context

In 2012, HHS provided funding to NQF to convene a multistakeholder Expert Panel to create the groundwork for developing, testing, endorsing, and implementing PRO-PMs. The resulting report articulated guiding principles and a detailed pathway of taking a PRO to a PRO-PM, with the intention of steering work in the field towards a more person-centered approach. The 2013 final report was updated by Cella, et al. in 2015 and remains an essential resource for the field’s understanding of PROs.

Despite five years passing since the Cella report, there are a limited number of PRO-PMs that meet NQF endorsement criteria. This suggests several improvement opportunities for the healthcare quality field, such as providing guidance to help encourage the development of PRO-PMs based on PROMs and implementing policy that incentivizes the use of PRO-PMs in accountability programs. Measure developers may need more direction in PRO-PM development, as well as a motivation to strive for NQF-endorsement. However, there are data quality and collection issues that affect these opportunities. These issues highlight an upstream gap in clinician knowledge of the value of collecting PROs and PROMs, and of how to best select, implement, and use PROs and PROMs in ways that ensure high data quality while being mindful of burden and clinical workflow.

Given the opportunity to build upon the foundational work from 2013 and 2015, NQF seated and facilitated a TEP and conducted an environmental scan to identify current approaches to PRO and PROM selection and implementation in care planning and monitoring. The environmental scan included the identification of challenges associated with the selection and implementation of PROs; documentation of how various approaches to selection and implementation affect the quality of PRO data; analysis of PROs and PROMs relevant to burns/trauma, heart failure, and joint replacement; and identification of performance measures and measure concepts relevant to burns/trauma, heart failure, and joint replacement.

The environmental scan highlighted the following key challenges pertaining to selection and implementation of PROs and PROMs:

- Differences in the perceived importance of PROs between patients and clinicians
- Lack of PROMs that focus on the PROs that are considered most important to patients
- Difficulty achieving stakeholder buy-in
- Burden of data collection
• Barriers to incorporating PROs and PROMs into the clinician workflow
• Lack of clear interpretation of scores, for both patients and clinicians
• Difficulties incorporating the data into electronic health records (EHRs)

Although the challenges emerged during investigations of PROs and PROMs in care planning and monitoring, they extend to healthcare performance measurement and associated quality improvement and accountability applications.

This report builds on the 2013 and 2015 reports and includes recommendations to address the challenges of selecting PROs and implementing PROMs, while ensuring the collection of high-quality data. By addressing these upstream concerns, the report paves the way for improvement opportunities related to PRO-PMs.

**Best Practice Recommendations for Selecting PROs**

The first step to begin using PROs is to select the outcomes that are most pertinent to a clinical setting. There is no single “correct” way to select these PROs, nor is there a definitive set of PROs that are “right” for a given setting. There are, however, best practices that can guide the selection process and help ensure the PROs are relevant to patients, clinicians, and other key stakeholders. This report focuses on best practices for care planning and monitoring, but clinicians with different goals (e.g., performance measurement, research) should still find value in these concepts.

**Five Domains of PROs**

It is critical that everyone involved in the selection process understand five domains of PROs: Health-related quality of life (HRQoL), functional status, symptoms and symptom burden, health behaviors, and experience with care. HRQoL includes an individual’s perception of their physical and mental health, such as energy and mood. Functional status was included within the HRQoL domain in the 2013 NQF report, but subsequent research moved it into a separate domain focused on activities of daily living. Symptoms and symptom burden focus on factors like pain, fatigue, and shortness of breath that are often (but not always) related to a disease or condition. Health behaviors consider individual behaviors that can influence health status, such as tobacco use, diet, and exercise.

The fifth domain, experience with care, raises unique concerns. Patients can mistake experiences of care for HRQoL, so clear distinctions must be made between the two domains. Patient experience of care is typically measured by Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys and accounts for different types of methodology in both sampling and healthcare system integration. It is typically more removed from the care experience to preserve patient anonymity, and it often measures clinician performance in areas like communication or access to appointments. While these experiences are important to measure and assess, they are typically less relevant to health outcomes than the other four domains.

When considering the PRO domains, clinicians and other people responsible for selecting PROs should look beyond basic measures of HRQoL and functional status (such as those listed above) and consider patient outcomes that include psychosocial adaptations, emotional and mental health, social support/social isolation, role functioning (e.g., the ability to return to work, family, and social roles), self-efficacy, and goal setting/goal concordance.
Best Practices for PRO Selection

Knowledge of the five PRO domains will help the people who are leading the selection process understand the different types of outcomes that are available to be measured. Once this understanding is in place, there are four best practices to selecting PROs in the clinical setting: patient engagement, expert opinion, goal setting, and clinician consensus.

The first and most important practice for selecting PROs is to engage patients in determining what outcomes should be measured. This step is critical in building alignment between patients and clinicians, and it helps to ensure that the PROs provide value to both patients and clinicians. One potential area of alignment can be talking with patients to understand which outcomes are meaningful and important to them. As an example, when PROs were discussed during clinical encounters with heart failure patients, the patients left the visit with a better understanding of the importance of medication adherence. Because the team selecting the PROs knew which outcomes were important to patients, the clinical encounter became more valuable to both the physician and the patient. Another potential area of alignment is understanding key concerns that patients might have about that PRO. If patients are considering a PRO and wonder, “Why is this applicable to me?” or “Why am I being asked about something this personal?”, then there is a risk they will disengage from PRO efforts.

Several effective approaches exist to engage patients in selecting PROs. Focus groups can elicit perspectives from many different patients in a relatively short period of time, particularly when decision-makers address relevant social determinants of health—such as access to transportation or computers—when selecting and questioning the participants. One-on-one interviews allow for a deeper exploration of individual perspectives but are more time consuming than focus groups. Patient and Family Advisory Councils (PFACs) can provide rich information related to PROs from committed patient partners who are already engaged with a clinic or health system and who understand how healthcare organizations function. In all of the above scenarios, open-ended questions and appropriate interview techniques (e.g., cognitive interviewing) should be utilized, and dialogue should be continued until no new ideas emerge. Social media also presents opportunities to gather information from a large and diverse cross-section of patients, and clinics or health systems with active social media presences can ask pointed questions to followers that will help shape the selection of PROs. Any or all of the above approaches can be effective in eliciting patient feedback that assists with selecting PROs.

It is important to note that there is not a universal answer for which PROs are meaningful and important to patients. Different patients will have different perspectives and priorities. One patient cannot represent an entire patient population, so the people leading the selection of PROs should assemble a diverse selection of patient partners who represent varied socioeconomic status, educational levels, age groups, genders and gender identities, disease states, functional abilities, and/or other characteristics that are relevant to the clinical population. Additionally, the leaders of the PRO initiative should consider engaging patients who have expressed frustration with current practices and are interested in helping the clinic or health system improve. By engaging with multiple patients who bring a diversity of perspectives, clarity will emerge on what outcomes are generally meaningful and important to the unique patient population that the clinic serves.

The second practice for selecting PROs is to review the opinions of experts in the field (e.g., clinicians experienced with using PROs, researchers, measure developers, performance measurement experts). While patient input is widely viewed as the most important step in selecting PROs, reviewing expert
opinions can occur before patient input is gathered, and can create a foundation that benefits patient engagement activities and helps the overall selection process progress more fluidly. Literature reviews are an important way to gather expert opinions, but feedback from professional associations, peers, and colleagues—particularly those within the same area of practice—can also provide valuable information.

The third practice for selecting PROs is goal setting, or explicitly identifying the goals that the clinic aims to achieve by implementing PROs and PROMs. Goal setting helps the people selecting the PROs assess how well specific outcomes align with the clinic’s goals. For example, if a clinical goal is to increase screenings that are typically performed via a one-time PRO assessment, then outcomes that are assessed by monitoring progress over time would be a lower priority during the selection process. This step is particularly important, as it creates the foundation of the PROM Attribute Grid that is discussed in the next section of this report.

The fourth practice for selecting PROs is to build clinician consensus around PROs that are actionable. Actionability is the ability for the PRO to be responsive to healthcare interventions. If a PRO is overly broad or cannot be impacted by the actions of the care team that is tracking the outcomes, then it might not be the ideal selection. As an example, while some heart failure patients suffer from arthritis, cardiologists will likely find PROs related to symptoms and symptom burden of arthritis less actionable than a PRO that is directly related to the therapeutic interventions offered within the heart failure clinic. Different PROs across the five domains may have different levels of actionability, however, and it is important not to dismiss an outcome simply because it appears less actionable—or less immediately actionable—than PROs in other domains. PROs related to health behaviors may seem less actionable than those related to symptoms and symptom burden because of inherent challenges related to changing patient behavior, but these outcomes are still important and actionable, and they should not be excluded from the selection process. Similarly, PROs that are not disease specific (such as HRQoL and functional status outcomes) might seem less actionable to a specialist, but these are actionable outcomes that help to provide a holistic view of the patient, and they should be equally considered during the selection process.

Consensus around approaches to PROs can occur in a number of ways. In some cases, consensus is reached among organizational leaders, who take a top-down approach to implementing PROs throughout the organization. In these cases, best practices include identifying and clarifying organizational goals that align with PROs, identifying champion stakeholders throughout the organization who understand the value of PROs and are receptive to using them, identifying PROs that support the aforementioned goals, and rolling the PROs out across the organization. A more common approach to consensus, however, is a bottom-up approach that organically grows from clinicians who want to use PROs. In these cases, clinicians realize the importance of gathering and measuring PROs to use as part of care planning and monitoring. This realization is often rooted in some combination of achieving a quality goal, demonstrating the effectiveness of therapy, spotting potential trends in the patient population, or responding to patient requests for more information or engagement.

There are other important criteria—such as interpretability, reliability, and validity—that are discussed in the next section, Best Practice Recommendations for Selection PROMs. PROM selection should only begin once careful consideration has been given to selecting PROs.
Best Practice Recommendations for Selecting PROMs

Once clinicians, patients, and any other key stakeholders have selected PROs, the next step is to select the PROMs that will be used to directly capture and measure input from patients. While this report is focused on care planning and monitoring, the processes described have relevance to stakeholders with other goals, such as performance measurement and/or research.

Like PROs, PROMs should be selected based on importance and/or meaningfulness to patients. However, PROMs also must be selected with the clinician in mind to ensure that PROMs can be used effectively in a clinical setting. PROMs must be sensitive enough to capture changes in patients across time and should promote discussions between clinicians and patients.

There are often various PROMs to consider when providers or facilities seek to select an instrument. The environmental scan revealed 81 disease- or condition-specific PROMs relevant to burns, trauma, joint replacement, or heart failure; additionally, there are many more PROMs—such as those related to HRQoL or functional status—that are disease- or condition-agnostic and can be used across a broad population of patients. Given the large number of PROMs available to clinicians, the first step in the selection process is to understand key attributes of PROMs. All stakeholders—including patients and clinicians—who are involved in the selection of PROMs should familiarize themselves with these key attributes and prioritize the most important attributes before beginning the selection process.

Patient Involvement

Patients often have concerns and perspectives that differ from clinicians. Patient perspectives can span the continuum of care and highlight the outcomes that the patients value most. (For example, a knee replacement patient’s perspective can span the primary care setting, the orthopedic surgical process, and physical therapy.) As such, patients need to be involved in all aspects of PROM selection and implementation. Involving patients in the selection of PROMs helps to ensure the instruments chosen are meaningful and important. Even PROMs that have been validated may have off-putting or confusing questions, or may not address what patients consider to be the most important outcomes.

One way patients can be engaged in PROM selection and implementation is through PFACs; however, such councils may not be optimal since they often include highly-engaged patients who may not represent the general patient population. While PFACs can and should be involved in the selection process, patient engagement needs to include a variety of patients, including those who are currently undergoing treatment as well as those who have progressed in their treatment or condition trajectories. Diverse people who represent the patient population should be involved, and engagement should use similar methods as described in the Best Practice Recommendations for Selecting PROs section.

Specific to PROM selection, patients should look at different instruments’ attributes to determine which questions resonate most with their experience or are very important to them.

PROM Attributes

Numerous attributes of PROMs can be considered during the selection process. The 2013 NQF report identified five guiding principles to PROM selection in the context of performance measurement, and each of these principles are relevant to care planning and monitoring. Each of these principles—Psychometric Soundness, Person-Centeredness, Meaningfulness, Actionability (i.e., Amenability to Change), and Implementability—remain important today. Additional attributes have emerged since
the publication of the 2013 report, and these also can impact the ability of PROMs to be used successfully as part of the care process. These attributes should be considered when selecting PROMs.

**Table 1. PROM Attributes**

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covers Desired PROs</td>
<td>Based on the PRO selection process, the PROM(s) effectively measure the desired outcomes</td>
</tr>
<tr>
<td>Psychometric Soundness</td>
<td>Consistent with eight consensus-based criteria for selecting PROM(s) to be used in performance measurement, including: documentation of conceptual and measurement models; reliability; validity, including validity for longitudinal use; how scores are interpreted; burden, including time and effort to fill out the PROM(s); alternate modes and methods of administration; cultural and language adaptations, including evaluation of equivalence across languages; and ability to be integrated into EHRs</td>
</tr>
<tr>
<td>Person-Centered</td>
<td>PROM(s) are person-centered; patients are involved in development and/or selection of PROM(s), not only as advisors but as co-designers; can be used to foster shared-decision making for patients who choose to engage in this process</td>
</tr>
<tr>
<td>Meaningful</td>
<td>The relevance and importance of PROM(s), as perceived by patients, families, caregivers, and clinicians, and as assessed on three aspects: conceptual, or what matters most to patients; contextual, or how the information is used; and consequential, determining what happens when PRO-PM information is used for accountability</td>
</tr>
<tr>
<td>Actionable (i.e., Amenable to Change)</td>
<td>The PROM(s) are responsive to healthcare interventions; for example, a PROM that assesses angina in patients with coronary artery disease is actionable because the score is responsive to therapeutic interventions (e.g., adding or changing doses of a beta-blocker)</td>
</tr>
<tr>
<td>Implementable</td>
<td>The practical factors and potential barriers that can hinder implementation, particularly related to collecting data and reporting results</td>
</tr>
<tr>
<td>Feasible</td>
<td>The PROM(s) are feasible to use as part of a standard clinical workflow once they are implemented</td>
</tr>
<tr>
<td>Patient Burden</td>
<td>Although addressed under Psychometric Soundness, patient burden has emerged as an increasingly important selection criterion with multiple considerations, including frequency of PROM use (e.g., every clinic visit, every 6 months, overly frequent/redundant administration of PROMs); number of questions; types of questions (e.g., multiple-choice, open-ended); and appropriate time to measure the outcome</td>
</tr>
<tr>
<td>Multiple Languages Available</td>
<td>Although partially addressed under Psychometric Soundness, this criterion explicitly asks if reliable and valid PROM(s) are available in all languages relevant to the patient population; evidence should demonstrate that PROMs perform similarly across languages</td>
</tr>
<tr>
<td>Attribute</td>
<td>Description</td>
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<tr>
<td>Cost</td>
<td>The PROM(s) either have no licensing fees or have fees that are within the budget of the organization, particularly if the PROM(s) are part of a large-scale implementation across a health system; the capital costs related to collecting, storing, and analyzing data are within the organizational budget, e.g., tablets, paper, data warehouse.</td>
</tr>
<tr>
<td>Current Practices</td>
<td>The PROM(s) are aligned with current best practices and standards of care; guidance exists to map data from older PROMs to newer PROMs (e.g., crosswalks between Oxford Hip Score and the Hip disability and Osteoarthritis Outcome Score, Joint Replacement)8,11.</td>
</tr>
<tr>
<td>Data Management</td>
<td>Where appropriate, the PROM(s) are aligned with prevalent instruments in use at other clinics or organizations, to allow for data sharing and comparisons; literature reviews and consultations with colleagues and professional societies are performed to guide strategic decisions about data collection, storage, and sharing8,12.</td>
</tr>
<tr>
<td>Goal-Attainment</td>
<td>The PROM(s) measure to what extent did the patient obtain the outcomes that led them to seek treatment; PROM(s) align with documentation of patient outcome goals.</td>
</tr>
</tbody>
</table>

Actionability and psychometric soundness (specifically reliability, validity, and correct score interpretation) are particularly important when prioritizing PROM attributes. It is equally important to select measurement tools that have meaningful interpretations to different stakeholders in healthcare (i.e., having instruments that are inherently interpretable, clinically actionable and understandable, and can inform and aid in a discussion with patients). Finally, it is important that evidence supports the PROM and that clinicians will integrate the PROM into patient care.

Not all PROM attributes will be priorities in all clinical settings; this is why “Covers Desired PROs” is the first PROM attribute, so that individual needs and goals of a clinic can drive attribute prioritization. As an example, a clinic that serves a high percentage of patients who are discharged to post-acute care may prioritize actionability or goal-attainment differently than a clinic where patients are typically discharged home. While actionability and goal-attainment are always important attributes, flexibility should exist for clinics and patients to identify PROs and PROMs that are important and meaningful to the patient population. Goal-attainment should align with reasonable clinical expectations.

**Attribute Grid for PROM Selection**

An Attribute Grid can be an effective tool during the PROM selection process by detailing different criteria relevant to a clinical setting. The grid provides a systematic method to perform a side-by-side comparison of important PROM attributes. This grid is meant to guide the selection process and is intended to be used by those in the field seeking to select and use PROMs. While many of the steps for using the Attribute Grid should be performed by a staff member with knowledge and expertise of PROMs and other measurement tools, patients should be engaged whenever possible.

Using the Attribute Grid for PROM Selection:
• Review the literature and consult peers to identify candidate PROMs
• Obtain a copy of each PROM, along with pertinent educational / reference information (e.g., scoring methodology, estimated time to complete)
• Use the sample Attribute Grid in Appendix D, and add/remove rows based on organizational goals and priorities
• Complete one column of the Attribute Grid for each PROM, adding additional columns as needed; actual PROMs must be available for reference during the selection process
• If multiple clinics are participating in the selection of PROMs, each clinic can assign weights to attributes based on their individual needs
• Expect that it may be necessary to use multiple PROMs to complement one another; in many cases, no single PROM will address every required attribute

A sample Attribute Grid was created to aid in PROM selection (Appendix D). The first and most important attribute on the grid highlights whether a chosen PROM covers the desired PROs deemed most important and meaningful. The sample grid then includes both “must have” criteria and “nice to have” criteria, because these different criteria may influence the final selection in valuable ways. While each attribute is important, each organization has its own goals (e.g. comparing clinician or medical group performance, informing care of individual patients) and may prioritize the attributes differently. When completing an Attribution Grid, organizations should engage staff with expertise and knowledge of both measurement and specialty clinical care.

The Attribute Grid includes options for “good, better, or best” related to the attribute of interest. These options reflect a comparative process that considers a specific organization’s priorities and intent to narrow PROM selection, as opposed to a universal Attribute Grid that attempts to assist all clinics and health systems in an identical way. As such, there are limitations to the sample grid, and organizations are invited to customize the Attribution Grid with weights, goals, and other unique needs.

In addition to the sample Attribute Grid in Appendix D, an example of a completed grid for a heart failure clinic is included in Appendix E.

**Best Practices for PROM Selection**

Once an understanding of PROM attributes is in place, there are four best practices for organizations to use when selecting PROMs.

1. Identify PROMs used by others for similar patients, topics, and conditions. This can be done by conducting literature reviews, reviewing communications from specialty societies, and conferring with peers and colleagues.
2. Select PROMs that closely align with or best capture outcomes that are most valuable to both patients and clinicians.
   • Think broadly about how they can assist patients with outcomes.
   • Consider a PROM even if there is a perception that clinicians cannot control the related outcome. For example, clinicians can still help patients better cope with an illness or disability, even if they cannot cure it.
   • Explore using more than one PROM if no single instrument fully captures all desired patient-reported outcomes, being mindful of both staff and patient burden.
3. Evaluate various PROM selection criteria systematically and pragmatically. This can be accomplished by utilizing a PROM attribute grid like the one in Appendix D.
   - A robust method to select PROMs is highly encouraged, as selection decisions have long-term impacts on the implementation of the PROM.
   - To the extent possible, use of the same PROM across clinics is encouraged to promote alignment and to better track patient outcomes and other trends over time.

4. Document the selection process. Selecting a PROM is an iterative exercise, and documenting the process is critical to establishing rationale for the final decision.

A robust selection process for PROMs will support the collection of data that measure the organizational PROs. Once the PROMs are identified, they must be effectively implemented.

**Implementing PROMs**

The same kinds of thoughtful and pragmatic methods that are used to select PROs and PROMs must be applied throughout implementation. This can be challenging because every clinical setting has unique variables that influence how PROMs are implemented. A systematic approach to implementation can minimize these differences and contribute to successful implementations across diverse clinical environments.

One variable that affects implementation is whether a clinic is a high-resource or low-resource environment. Resources include time, staff, finances, and physical materials (particularly IT resources and professionals). For example, a high-resource environment is a health system that uses the same EHR vendor across hospitals and clinician practices, has available IT professionals, provides financial support, and has staff members with sufficient time to dedicate to a PROMs implementation. A low resource environment could be a small clinician practice with no dedicated IT or quality team to assist with implementation. Availability of finances, time, and people (particularly IT resources and professionals) must be considered.

Another consideration is how various sociodemographic factors (e.g., literacy, cognitive function) can affect implementation. For example, proxy respondents may be needed to assist in gathering accurate PROM data. There may also be additional considerations for PROM implementation by clinical setting. For example, using PROMs in an outpatient clinic may have different workflow considerations than using PROMs to follow-up on acute care visits or in an emergency care setting.

In light of these differences across clinical settings, the following steps are applicable to the implementation of PROMs across diverse environments:

1. Garner the support and commitment of executive and clinical leadership
2. Determine and finalize the implementation location and team
3. Select desired PRO(s) and applicable PROM(s), considering all aspects presented in previous sections
4. Address essential steps to successful data collection
5. Interpret scores and report results (includes “feedback of data” in both the direct clinical care setting and in the larger sense to understand and improve care in the aggregate); this is where work may take place to integrate the records into the EHR
6. Act upon the findings in clinical practice (e.g., modifying treatment; knowing whether a patient should or should not have recovered by a certain point; changing workflows to address overarching care issues); this also includes engaging the patient and explaining the importance of their survey responses.

The recommended best practice topic areas are categorized based on which implementation challenges they primarily address (e.g., data collection burden, workflow implications). It is important to note that, although listed separately, many of these barriers are interconnected.

Achieving Stakeholder Buy-In

Stakeholder and leadership buy-in is an integral piece of a successful PROM implementation. Without leadership support, implementation is likely to be limited or prove unsuccessful. Multiple stakeholders play a role in PROM implementation including patients, clinicians, clinic staff, administration, payers, and IT staff and vendors, and best practices encourage support across stakeholders to advance the use of PROMs. Clinics implementing PROMs should identify and engage a key set of stakeholder champions and utilize their support for PROMs to increase opportunities for success.

To be successful, a PROM implementation must have the backing of a clinical champion. A clinician champion—often, but not always a physician—leads the clinical adoption of PROMs among physicians and staff and helps to ensure that PROMs are used to improve care, promote patient buy-in, and support cross-department collaboration. The clinical champion facilitates the restructuring of clinic workflow to accommodate outcomes-oriented activities. Without a clinical champion, clinic staff who are essential to PROM implementation will be reluctant to take on the new responsibilities associated with collecting outcomes data. Clinician champions promote acceptance and understanding of why PROMs are beneficial and may have both knowledge of the PROM and the specific clinical topic area. Finally, because clinician burden may be more prevalent when decisions about PROM implementation are coming from organizational leadership, the clinical champion can offset the natural resistance to top-down change and help to foster an organic, bottom-up support for PROMs at the grassroots level.

Patient champions are also essential stakeholders. Patient champions not only provide input on workflow but also advise clinicians and staff on how to communicate the value of PROMs to other patients. This advice is important because patients will be less likely to complete the PROM if there is no perceived relevance or benefit and if the information is not used to inform their care or the care of other patients. Working with organizational PFACs is one option to connect with patients but should not be the only method of soliciting feedback.5 The patient engagement techniques described previously in this report can also be used for PROM implementation.

Buy-in from clinic staff is critical, as these team members are often the gatekeepers to a successful PROM implementation. Scheduling staff are often the first opportunity to tell patients about PROMs and state the importance of completing the questionnaires. Front-desk workers may ask patients to complete PROMs at point-of-care. Nurses and medical assistants typically interact with patients before physicians and can reiterate the importance and meaningfulness of PROMs. It is beneficial to identify champions within the staff who will, along with the clinician and patient champions, ensure staff understand the importance of PROMs and adhere to workflows. If any member of the clinic staff does not buy in, data collection suffers. Clinic staff are often key spokespersons for PROM completion, and their buy-in can affect implementation and data collection.5

Because buy-in from both clinicians and support staff often follows an adoption curve (i.e., early adopters immediately support the use of PROMs while laggards are the slowest to buy-in), clinical and administrative leaders should provide education and mentoring, and should be aware of behaviors that
downplay the importance of PROMs (e.g., body language, verbal criticism). Even in clinics where bottom-up support led to the decision to use PROMs, late adopters might intentionally or unconsciously derail efforts. Formal or informal accountability programs—such as giving physicians a report of how many patients completed questionnaires, or making questionnaire completion a mandatory part of front-desk competencies—can help clinics navigate different stages of buy-in along the adoption curve.

There is an opportunity to learn from how others are implementing PROMs and use the information as a “starting point” for adapting workflow and achieving buy-in. For example, one could “map out” or otherwise illustrate how the process works in another hospital or clinic and invite input on how to modify as needed. This increases the likelihood that clinicians will know how to intervene when PROMs begin to reveal new information that historically was not available to discuss during a clinic visit. For example, if PROM data indicate that a patient’s social functioning is impaired, a process map can help a clinician understand when a direct intervention is appropriate and when a referral for additional medical or social support might be most effective.

Finally, opportunities to increase cross-stakeholder buy-in should be explored whenever possible, particularly when perspectives are included that go beyond clinicians, clinic staff, and patients. An example of cross-stakeholder buy-in occurred in Michigan, where the largest payer in the state partially supported the collection of PRO-PMs related to oncology using a centralized vendor for data collection. About 90% of medical oncology practices in Michigan were represented and the vendor was supported by the payer. The Patient-Reported Outcome Measures for Oncology Care (PROMOnc) project focuses on patients with earlier stage cancers receiving curative intent chemotherapy to address current gap areas. The program collects data from PRO-PMs that target symptom outcomes of cancer diagnosis and treatment that persist and impact patient re-entry into cancer survivorship.\textsuperscript{13,14}

A similar effort is underway in California, with a vendor partnering with a multistakeholder healthcare improvement collaborative (including large health plans and provider organizations) to endorse a common set of measures, with PROs as a general category. These include areas such as screening and remission of depression, alcohol and drug dependence treatment, and opioids.\textsuperscript{14,15} The effort has prioritized the implementation of the Patient Health Questionnaire-9 (PHQ-9), a PROM designed to assess and monitor depression,\textsuperscript{16} with the expectation to scale the work and collect PROMs for other conditions, with a potential transition into a pay-for-performance program.\textsuperscript{14,15}

**Data Collection Burden**

The real and perceived burden of data collection is relevant for both clinicians and patients.

Clinician burden may be exacerbated by workflow or technology, and can lead to care disruptions, PROM information that is not immediately useful in clinical decision making, and clinicians who are working below their licensure. EHR integration challenges can add to these areas of burden.

Patient burden can occur in multiple circumstances. Burden arises when patients do not understand the importance of PROM completion. It also occurs when patients view the process as too time consuming, a problem that can be exacerbated by long questionnaires or multiple PROMs. Patients may feel that certain PROM questions are intrusive or irrelevant, a problem that underscores the importance of engaging a diverse population of patients in the selection of PROs and PROMs. Patients may also have the perception that filling out the PROM (if conducted in the office setting) may delay care. Some data collection methods (e.g., patient portals) could potentially result in selection bias that leads to low participation from certain vulnerable populations, such as those in low income communities who may have access to fewer resources.
The use and impact of patient incentives could be a method to improve PROM data collection. There is debate whether financial incentives would be an ethical option to increase participation, or would offend patients or bias results. Although some research has shown benefit in paying patients to adhere to medication regimens, there has been little discussion or research on potential benefits or risks of paying patients to complete PROMs. There is also a perspective that compares PROMs to diagnostic tests, which patients or their insurance companies typically pay to have completed.

Incentives must also be considered with regards to clinician burden. There are currently few financial incentives for physicians to utilize PROMs in care planning and monitoring. Research on how incentives impact physicians’ willingness to complete surveys might offer useful insights on how physicians could be incentivized to engage with patients to complete PROMs. While some organizations create incentives to using PROMs (e.g., clinics that attach physician bonuses to PROM utilization or payers who negotiate increased rates for practices that use PROMs to demonstrate long-term quality), there is no overarching incentive program that motivates clinicians to adopt PROMs. As a comparison, the Medicare and Medicaid Electronic Health Records (EHR) Incentive Programs incentivized organizations and providers to overcome burdens attached to EHR implementation and use. A similar approach could be beneficial in increasing the adoption and utilization of PROMs.

**Recommended Best Practices**

There are ample best practices related to patient and clinician burden, which include using multiple modes and methods to increase patient participation, minimizing the number of PROMs, ensuring the questions within each PROM do not add to burden, administering PROMs at time intervals that are not overly frequent, helping stakeholders to perceive the value of PROMs, and utilizing workflows and technology that minimize clinician burden.

The first practice is to use multiple modes (e.g., whether a PROM is self-administered or completed via interview) and methods (e.g., paper, email, patient portal) to encourage patient participation, especially focusing on vulnerable populations. Multiple methods facilitate maximum participation, as different people have diverse preferences and needs. Using various forms of technology to administer PROMs (e.g., use of tablets and patient portals, making the response choices as “tap answers” rather than free response text boxes) can reduce burden. Patients without access to the internet or technology, or those who prefer not to use it, should have other ways to take the survey, such as bi-directional text messaging or paper-based versions upon arrival to the clinic. All modes and methods must have a corresponding workflow to ensure data are properly collected and stored (e.g., if paper forms are used at the front-desk, a workflow must be in place to ensure the patient responses are entered into the database). Options should exist for patients to complete questionnaires at home, not only to encourage collection but also to better serve those who need adaptive technology or assistive devices. Clinics can consider implementing the PROM via interview to enable those with low literacy levels or discomfort with technology to participate. Additionally, different systems should be put into place to record information regarding PROM administration (i.e., pertinent metadata such as whether the patient has had help in responding). It is essential that all patients can engage, including those with functional limitations that preclude their ability to fill out a survey on their own.

The second practice is to minimize the number of PROMs used within a system, while still ensuring adequate data are available for clinical decision making. For example, if use of the PROM Attribute Grid leads to two overlapping, disease-specific PROMs, the organization should work with patient and clinical...
stakeholders to determine if both PROMs are essential to care planning and monitoring, or if a single PROM is sufficient. Clinics should consider building appointment rules within EHRs that assign PROMs to patients based on their current needs at an appropriate frequency (e.g., visiting a heart failure clinic will prompt a heart failure PROM, while an annual physical prompts a depression screening PROM).

While reducing the number of PROMs is important, the third practice centers on the number of questions within a PROM, their structure, and their relevance to patients. Questionnaire length contributes to burden, therefore it should be a consideration when selecting PROMs. A cited threshold for survey length is that patient perceived burden begins at 24 questions, and patients start to miss questions or abandon questionnaires at 45 items. Methods to reduce burden also include favoring PROMs with yes or no questions and multiple choice questions over those that contain open-ended questions. Questions that patients perceive as less relevant to their disease or treatment can increase the perception of burden, and lead patients to disengage from the PROMs process. Additionally, investing in technologies such as Computer Adaptive Testing (CAT) in electronic PROM implementation can reduce patient burden. CAT represents an advanced method of assessing PROs by tailoring the questions to the health status of the individual patient. The CAT algorithm is initiated when a patient responds to the first item in a PROM, and based on the response, selects the next item whose difficulty matches the patient’s response pathway. This technology can help streamline both the quantity and quality of the measures asked of each patient, helping improve overall accuracy and decrease patient burden.

Another best practice involves reducing frequency of use and redundancies in PROM data collection. This can be particularly challenging for organizations that collect data both at point-of-care and prior to clinic visits, and it underscores the need to have well-designed workflows that identify patients who completed PROMs in advance. Similar redundancies exist for hospitalized patients who are questioned about health behaviors (e.g., smoking) on a daily basis. It is also important to consider perceived redundancies that are due to limitations in technological workflows. For example, if a clinic is administering a HRQoL PROM on the annual anniversary of all joint replacement surgeries, a patient who had a hip replacement in January of 2015 and a knee replacement in February of 2016 will receive an identical HRQoL questionnaire one month apart every year, unless well-designed technologies and workflows are in place. Overall, organizations should strive to make the data collection process as seamless, effortless, and feasible as possible, in order to reduce data collection burden and increase the precision and participation of PROMs.

Maximizing the perceived value of a PROM is a best practice that can reduce data collection burden. Both clinicians and patients balance perceived burden with the perceived value of PROMs. Ultimately, what matters to patients is the perceived worth received from the effort expended to complete a PROM. A clinic can help to maximize perceived value of a PROM by informing patients how the data from the PROM will be used and using the data as soon as possible (e.g., during the clinical appointment). This allows for the effort to be recognized by the patient, while gathering useful information that the clinician recognizes as valuable.

The final practice looks specifically at steps to reduce clinician burden. With well-designed workflows and technology, clinician burden with PROMs should be minimal. The day-to-day work related to educating patients, collecting data, and reminding patients to complete questionnaires should be distributed among support staff. With strong workflows in place, clinician burden is largely limited to
discussing PROM scores with patients during the clinic visit. While clinicians must navigate an initial learning curve, discussing PROM scores with patients soon becomes as natural as discussing lab values. The impact of both workflows and technology on clinician burden are discussed in upcoming sections of the report.

Workflow

Workflow describes the critical processes around when, where, and how patient-reported data are collected, as well as how scores are presented to clinicians and back to patients. Workflow considers how a care process can integrate PROMs and what steps are needed to ensure a smooth transition to using PROMs as part of care delivery.

A major challenge to workflow requires changing clinicians’ long-held patterns of providing care and sharing information with patients (i.e., attitudinal shifts as well as behavioral shifts). In one orthopedics department, a joint replacement PROM was readily available as part of the workflow since it was built into the EHR, yet PROM results were opened only during 2-3% of patient encounters. The surgeons had long-standing routines of how they approach information and patient encounters. There are also challenges associated with balancing use of standardized instruments in clinical care with providing individualized care.

Generally, patients are amenable to participating in PROMs that are utilized and discussed by the clinician during the clinical encounter. Reducing barriers to the use of PROMs during patient care (e.g., making scores easy to find by placing them on the EHR’s vital signs screen) is key. For example, “Ms. Smith, today your Kansas City Cardiomyopathy Questionnaire (KCCQ) score is 54, I am going to prescribe a new medicine and we will see how your KCCQ score changes when I see you again in 2 months; that will help us know if the new medicine is helping.” Having physicians integrate PROMs into their evaluations and conversations with patients can be transformational.

There are numerous best practices that are applicable to implementing PROMs in the care planning and monitoring process. Therefore, the recommended best practices related to workflow are categorized by two key stakeholder perspectives: the leadership team that guides the design and implementation of workflows, and the clinicians and staff who execute the workflow on a daily basis. Both perspectives should actively consider patient feedback in the design, monitoring, and improvement of workflows.

Recommended Best Practices, Leadership:

Workflow should be designed with input from multiple stakeholders, including patients, clinic staff, leadership, IT staff, quality staff, and clinicians. Key stakeholders should be identified and engaged early in the design process, as the ideas and experience of diverse stakeholders helps identify and address potential problems prior to implementation. Furthermore, a multistakeholder team is typically well-prepared to address unintended consequences and realities of workflow changes when and if they arise.

The stakeholder team—with strong leadership from clinicians who were involved in the selection of PROMs—should identify and implement “triggers” for when patients are asked to fill out a specific PROM. For example, based on the best practices related to a given PROM, a joint replacement practice might identify the triggers as the initial appointment, 1 week pre-op, then 1, 3, 6, 12 and 24 months post-op. Workflow related to this step could include sending an e-mail to patients at trigger points, then providing the patient with a tablet at the time of visit if questionnaires were not
completed via patient portal. Technological workflows include automating the triggers within the EHR or other systems, so that certain appointment types prompt a specific PROM to be sent to the patient (e.g., sending an abbreviated depression screening for an annual physical appointment).

It is important for leadership to promote buy-in from clinicians and staff, and to convey the importance of completing a PROM to the patient. Accountability measures should be built into the implementation plan, so leaders, clinicians, and staff have visibility into their own performance related to supporting and using PROMs. Additionally, clinic leaders (e.g., practice manager, office manager) should be empowered to educate staff on the importance of PROMs and hold staff accountable for complying with workflows.

Instead of attempting to launch PROMs widely throughout an organization, leadership should start with a focused pilot program in a small clinic or patient population. This can help offset the risk and complications inherent in workflow changes that accompany new initiatives. Considering a specific clinic or patient population and creating a dedicated and supported implementation team can focus efforts and improves chances of success for a widespread PROM implementation. Leadership and clinical champions should lead these efforts, and should model their pilot plan on successful examples identified through the literature or a peer network. Once the pilot program is successful, quality professionals can help advise leadership on how to spread PROMs to other clinics and/or patients.

Workflows should be monitored for opportunities to improve efficiency. Short-term monitoring during the pilot period is critical, as leaders should not assume that what was put into practice is working as expected. Leaders should use the time during the pilot implementation to find and address barriers to full implementation. After the pilot period is complete and widespread implementation has occurred, practices should continue to monitor and adjust workflow using established quality improvement cycles (e.g., PDSA). A structured plan should be developed for leadership to evaluate workflows at least once per year, as both workflows and stakeholder needs can change. Workflows can be monitored by designing and developing structured reports early in the implementation process that monitor measurable goals, such as percentage of patients completing PROMs at home, in-clinic, or not at all.

Once the implementation is stable, leaders should ensure that stakeholders and key staff members engage in a structured “lessons learned” activity that highlights what went well during implementation and what improvement opportunities exist.

**Recommended Best Practices, Clinicians and Staff:**

The clinic manager should be empowered to ensure PROMs fit into the clinical workflow. This can include the ability to make decisions regarding essential technology (e.g., tablets used for PROMs at the front desk), to identify and implement improvement opportunities, and to hold staff accountable for following workflows related to PROMs.

Trained clinic staff should educate patients on the importance and value of completing PROMs. Staff should be able to describe how the information will be used and how it will benefit not only individual patients but also the entire patient population. The combination of personal benefit and altruistic service can help to improve patients’ perception of the importance and meaningfulness of PROMs.

At key points throughout the appointment lifecycle (e.g., scheduling, reminder, clinic visit), staff should remind patients about the importance of completing PROMs. The communication can be as simple as a
verbal reminder at checkout or a note on the visit summary. Some clinics take creative approaches to reminders, such as using a pad of paper similar to a prescription pad that includes a “prescription” for PROMs, such as what an email or link would look like upon receipt. When developing reminder workflows, patients should be engaged in identifying and designing compelling patient-facing materials.

Staff should encourage completion of PROMs in a way that resonates with the patient. For example, staff in a joint replacement clinic could explain that consistently completing questionnaires pre- and post-operatively will help patients see their progress and could provide early indications if problems arise. This level of data collection would create an ample database to aid with predictive modeling and help mitigate complications in other patients.

Clinicians should consider multiple possible workflows for incorporating results in the clinical encounter. For example, the medical office assistant could print the PROM results (scored in real time) when rooming patients so a paper copy is readily available for discussion. While physicians generally should not directly administer the PROM, they should refer to the results as part of care. There is positive patient feedback when a provider refers to the results of their PROM and asks the patient to expand on their responses. Patients should know how the information is being used and the benefits to remaining actively engaged in completing PROMs. A fully embedded PROM workflow and system can result in lower perceived clinician burden, as PROM implementation is an integrated part of the visit.

Clinicians and staff can also help to design workflows that engage other clinicians in the utilization of PROMs data and scores. Members of integrated care teams (e.g., social workers, physical therapists) might benefit from multidisciplinary communication that can arise from PROMs. An example includes how a cognitive function screen in primary care can trigger a neurology consult, which encourages a more coordinated downstream workflow.

Interpretability of Scores
A major challenge with implementing PROMs is interpretability of scores for both clinicians and patients. When clinicians see scores on a scale of 0 to 100, they may intuitively be able to interpret them. What is less clear, however, is what a score of 7 means on a PROM that uses a 12-point scale. Additionally, comparing average scores of physicians or clinics is challenging—and potentially misleading—when there is no intuitive understanding of score differences. The interpretation of a PROM result must be understood in the same way that clinicians today immediately understand a high blood pressure reading or a low-density lipoprotein (LDL) result. PROM scores and results must be integrated and viewed as actionable values upon a quick glance to successfully be incorporated into the clinical treatment plan.

The use of PROM scores in clinical care is ideal; clear interpretability thresholds and context for score interpretation enables clinicians to render the information actionable and deliver more informed, holistic care to patients. There is still a learning curve, however, between the current state and the ideal state. For example, while patients would like to see and understand their results in real-time, it is not always feasible for clinicians to interpret and act upon them promptly, particularly for clinicians who are not yet intimately familiar with interpreting the scores of specific PROMs and taking clinical action based on those interpretations.

There is still concern regarding some of the softer results of PROMs, e.g., quality of life or psychosocial scores. For example, even if a cardiologist fully understands how to interpret scores from specific
PROMs, that provider might not know how to respond if a patient stated they were lonely or depressed. As part of the implementation process, educational materials should be created to guide patients on how to understand PROM results both generally and specifically. Possible results should be aligned with healthcare decision making, knowing that an interdisciplinary approach will be needed to address PROM results in ways that foster better communication and care coordination.

There are additional parallels to PROM results being flagged electronically within an EHR, similarly to the flagging of a critical value as the result of an ordered lab test. Though PROM results are not as straightforward as lab values, the parallels help clinicians form working theories of action and implementation. While there are not yet models to help instruct this effort, the consistent comparison of PROM scores to lab results helps rationalize future efforts.

**Recommended Best Practices**

Although more research is needed to inform the best ways to present PROM results to patients, there are best practice recommendations to address interpretability challenges. Leadership needs to provide educational resources to clinicians, so that providers understand PROM results clearly and thoroughly and can act upon them quickly and accurately. Such education can be acquired in a number of ways, including via formal courses, online modules, or internal training by relevant clinical departments.

PROMs should be developed in a way that is useful in caring for individual patients and in providing comparative feedback and direction for quality improvement. The lack of an information base to inform action based on the results, especially at the local level (e.g., how to address reduced social function using community resources) may be a barrier.

Real-time information and interpretation must be available to accompany PROM scores. This information should explain patient results in a person-centered manner that is clear, uses plain language, and guides a conversation with providers in ways that facilitate necessary clinical actions. There should be a direct correlation between the score or outcome, and what the patient or provider can do as a result.

**Integration into EHRs**

There is ongoing acknowledgement that data standards need to be finalized before PROMs can be fully integrated into EHRs, with a continued need for standards on how the data will be stored and visualized. There is progress with organizations that are fully integrating PROMs into their EHR systems, and in most cases, data are being collected in discrete fields. PROM data collection in EHRs can also be used for population level analysis and testing for potential confounders.

Some PROM implementation teams opt for full integration of PROMs and results into their EHRs, while others have limited or no integration, either by choice or due to limitations (e.g., technological, financial). Decisions may be influenced by EHR capabilities, which can vary between practices and EHR vendors (e.g., small primary care practices often do not use the more sophisticated systems, some practices do not have the opportunity to change EHR systems). There is foundational work funded by the Patient-Centered Outcomes Research Institute (PCORI) on this topic.

EHR-based PROM implementations are not feasible for every clinic due to various constraints (e.g., cost). Furthermore, even for clinics that do use EHRs, the systems are not always consistent across clinics or
organizations that would like to share and compare data. Some organizations that could integrate
PROMs with the EHR opt instead to use a standalone web-based system for data collection.
Interpretability would improve if the presentation of data and results were integrated into EHRs.

**Promising Practices**

EHR vendors should build and implement PROMs within their systems. While barriers do exist that could
prevent EHRs from including PROMs “out of the box” (e.g., licensing fees), the systems should have the
 technological capability for clients to request PROMs that are already available or build PROMs into the
system. Even when organizations think their EHRs do not support PROMs, fact-finding with vendors and
peer organizations may lead to the discovery of PROM capabilities that already exist within the EHR.

Available technologies, such as single-sign-on EHR access, should be used as much as possible. This not
only helps to reduce barriers to information, but also reduces clinician burden and increases the
likelihood of a clinician discussing PROMs during the patient encounter. More sophisticated tools to
enhance PROM data presentation should become best practices as technology advances. Advantages of
full EHR integration would be improved workflow and ability to visualize results alongside other clinical
data.

There is encouragement of EHR vendors to improve the data presentation tools that are available as
part of their systems. Steps are being taken for EHRs to have PROMs built into their systems, as opposed
to integrated from external platforms. If EHR companies build in the capacity to receive PROMs data,
score the data accurately, and represent data in a clinically interpretable framework, the data could
serve as a resource for performance measurement and a tool to inform clinician decision making, shared
decision making, patient selection, and appropriate use criteria.

Data should be stored in a meaningful and thoughtful way to best align with the goals of the PROM.
Electronic data collection and submission leads to a vast database of administrative data. These data can
also be used to measure involvement or inform quality improvement efforts, including response or
denial rates by provider, clinic, or clinical staff member to ensure active participation and benchmarking
against peers. Storing information thoughtfully, while using validated and prevalent PROMs can increase
the potential to be able to compare data across different systems, locations, and patient populations.
As an example, this can enable two surgeons who use different approaches or medical devices to
compare outcomes and propagate promising practices within their clinic.

EHRs should present scores in an interpretable and actionable way. Examples include a simple line chart
of scores over time with labels on the y-axis (PROMs scores) to indicate what the scores mean (e.g.,
daily, weekly, monthly or no symptoms; New York Heart Association [NYHA] class; improvement or
decline in status).

There are different opportunities to maximize technology. Some examples include an IT service that
offers multiple customizable presentation options depending on condition. A registry could provide
patients with access to a portal where they can self-initiate a PRO anytime they think their symptoms
have worsened. Patients could learn along with the clinician about how to interpret their scores so they
can monitor themselves over time (similar to blood pressure readings or LDL results). Their data also
help inform appropriate appointment timing or clinician intervention. Another option could be a
program for congestive heart failure patients, in which patients answer a limited number of questions

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related to their condition and nurses review the data and monitor potential concerning changes at a population level. By weighing needs and customizing approaches specific to clinical opportunities, EHR integration of PROMs is an ongoing opportunity waiting for final determination of best practice guidelines for implementation.

Return on Investment

A largely unconfirmed area of PRO and PROM implementation research is a demonstrated return on investment (ROI). There are areas of exploration in the correlation between PROM implementation and different realized downstream cost savings or positive impact for the system. One area of consideration is improved patient experience scores due to improved communication with providers. A health system could see a decrease in preventable emergency or urgent care visits, as well as the ability to pick up on challenging issues sooner and actively reach out to and gather information from patients. There could even be an improved mortality rate, related to a prescriptive and specific systematic symptom tracking system.

Depending on organization size and implementation strategies, outlay can be relatively low and should be considered an enterprise investment. For example, executive leadership that is bought-in to the importance of PROM implementation view related costs as operational and necessary. Organizations that may not have implemented programs or may be new to the PRO journey may view these costs as unnecessary expenditures, uncertain of the returned value.

Currently PROs and PROMs are an interesting option for health systems to implement, but the incentive is intangible with a difficult direct connection to cost savings. While a financial ROI cannot be clearly and consistently demonstrated at this point, PROs are an important and novel route to gather important clinical outcomes information.

Additional Considerations

Other aspects of implementation that must be considered include governance (i.e., oversight of implementation activities); training and engaging clinicians, IT staff, administrative staff, and patients on measure selection and reporting; ethical and legal considerations, including security, privacy, and other related issues. Legal considerations are generally unknown currently. This could range from licensing or copyright issues, to the potential implications of asking electronically about sensitive topic areas, to a positive screening to depression, suicidal, or homicidal ideation with the potential lack of reporting or action from the healthcare organization.

There are additional factors to consider, such as the potential administrative and financial challenges such as the cost of training staff, licensing PROMs, and purchasing devices to administer PROMs (e.g., tablets and maintenance).

Use Cases for Selection of PROs and PROMs

To begin testing the best practices for PRO selection, the TEP provided feedback on PRO selection for three specific scenarios: burns and trauma, heart failure, and joint replacement. Patients from the TEP shared their perspectives and then clinicians weighed in about the actionability of the PROs identified by the patients. The PROs noted for each condition represent the TEP’s consensus recommendations for priority PROs in each respective area.
There is growing support for the inclusion of goal attainment as a PROM attribution. Goal attainment is important to include but is also aspirational, as there may not be any existing validated instruments to identify and monitor this information. This concept allows different patients to have different goals or expectations. Measuring goal attainment would be flexible and assess whether an individual’s goal is being met or is being addressed satisfactorily. To do so, an entity would ask a question about each patient’s most important outcome as well as a goal attainment follow-up question to assess the degree to which that goal has been achieved. There is a need to identify and monitor each patient’s particular goal, but there is not a current validated process to reproducibly do so.

Three Use Cases were developed related to burns and trauma, based on how different stakeholders (or “actors”) would engage with the selection process for PROs and PROMs. The first takes a systemic approach to selection of PROs and PROMs from the perspective of a patient (Table 2). The Use Case identified questions and themes that patients should ask when they are part of the team that is selecting PROs that are important and meaningful to an organization and the people it serves. The second and third Use Cases take a similar approach but focus on providers (Table 3) and quality improvement experts (Table 4) who are involved in the selection and implementation process. Use Cases were then developed from the patient and provider perspective for heart failure (Table 5 and Table 6) and joint replacement (Table 7 and Table 8).

All Use Cases are intended for the actor to not simply ask questions and raise themes from his or her individual perspective, but to think as a global representative for all stakeholders in this role who will interact with the PROs and PROMs. As such, the actor should approach the questions and themes with a sense of what is best for all stakeholders in this role.

Each clinical area Use Case is presented as a standalone table. While there is significant overlap across the Use Cases, it is important to recognize that many steps that different actors face during the selection process are agnostic to a disease or condition. The Use Cases are also presented with overlapping information so readers interested in one specific scenario can see a complete set of interactions between the actor and the selection process.

Use Cases, Burns and Trauma

The availability of best practices for selecting and collecting PROs for long-term outcome quality of patients surviving burn or traumatic injury events is critical for informing clinical decision making, improving long-term quality of care, and fostering the communication between patients and providers. The use of burn and trauma care outcomes as testing cases for applying PRO selection and data collection best practices aims at moving the field forward.

In the area of burns and trauma, certain condition-specific factors must be factored in and recognized by both patients and providers in the areas of selecting PROs and PROMs.

- Long-term quality of life measurement
- Changes in physical symptoms (e.g., itching, pain)
- Changes in physical limitations (e.g., range of motion, sleep disturbances, heat or cold intolerance)
- Psychosocial or social components (e.g., romantic/sexual relationships, adjusting to a new physical appearance, returning to work)
- Ability to perform activities of daily living
- Emotional coping
- Wound and/or scar self-care knowledge
- Social participation (e.g., PTSD, social avoidance, depression)
- Incorporation of an interdisciplinary approach to care coordination
- Financial burdens
- Potential stigmas

Table 2. Patient Use Case for Burns and Trauma

<table>
<thead>
<tr>
<th>Title</th>
<th>Burns and Trauma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scenario</td>
<td>Selection of PROs and PROMs for Burns and Trauma</td>
</tr>
</tbody>
</table>
| Assumptions | • Multistakeholder team will participate in selecting PROs and PROMs related to Burns and Trauma  
• Patients provide a critical perspective to the selection of PROs and PROMs. Patients can identify what outcomes are meaningful and important from a patient perspective, as well as questions and concerns that might make patients disengage from PRO processes. |
| Actor | Patients |
| Use Cases (i.e., Actor Interactions with PROs and PROMs) and Key Areas of Exploration for Each Use Case | • Patient-Reported Outcomes  
  o How is the outcome meaningful for the patient population?  
  o How is the outcome important for the patient population?  
  o How does the outcome reflect patient goals?  
  o How does the outcome reflect the recovery process?  
  o What attributes from the Attribute Grid (Appendix D) are most important to patients?  
• Data Collection using PROMs  
  o Is completing the questionnaire burdensome?  
  o How well can patients recovering from burn/trauma complete the questionnaire?  
  o How comfortable would the patient population be sharing this information?  
  o How comfortable would the patient population be with caregivers or other proxies completing the questionnaire?  
  o How ready is the patient population to share PRO information digitally?  
  o What barriers would prevent patients from completing the questionnaire (for example, are there language or cognitive barriers)?  
• Discussing Outcomes in Clinical Setting:  
  o How well will the patient population understand the score?  
  o How could the visualization of the score over time be more meaningful for the patient population?  
  o What meaningful conversations will this outcome generate between patients and the clinical team?  
  o Does the outcome foster a clear, goal-focused discussion with the physician?  
  o If the patient is interested in Shared Decision Making, how does the score contribute to that process? |
**Decision-making Points:**
- If PROs are being tracked over time, what baseline score is most meaningful to patients (e.g., pre-incident baseline, post-incident baseline)?
- Does the baseline score support realistic goal setting?

### Table 3. Provider Use Case for Burns and Trauma

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>Burns and Trauma</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scenario</strong></td>
<td>Selection of PROs and PROMs for Burns and Trauma</td>
</tr>
<tr>
<td><strong>Assumptions</strong></td>
<td>Multistakeholder team will participate in selecting PROs and PROMs related to Burns and Trauma</td>
</tr>
<tr>
<td></td>
<td>Providers offer a critical perspective to the selection of PROs and PROMs. Providers can identify what outcomes are meaningful and important from a clinical perspective, while keeping a holistic approach to patient care. Using their experience and medical training, providers can help prioritize which PROs are important to helping predict or navigate future medical issues.</td>
</tr>
</tbody>
</table>

**Actor**

**Providers**

*Use Cases (i.e., Actor Interactions with PROs and PROMs) and Key Areas of Exploration for Each Use Case*

- **Patient-Reported Outcomes**
  - How is the outcome useful from a provider perspective?  
  - How is the outcome important from a provider perspective?  
  - How is the outcome actionable by the provider?  
  - How does the outcome reflect the recovery process?  
  - What attributes from the Attribute Grid *(Appendix D)* are most important to providers?  
  - How does the outcome lend itself to PROM selection?  
  - Does a provider need multiple PROMs to gather necessary information?  

- **PROs in a Clinic Setting**
  - What clinical resources will support this PRO?  
  - What clinical resources are missing and will be needed to support this PRO?  
  - How does this PRO align with the clinic’s overarching strategic goals?  

- **Data Collection using PROMs**
  - Is completing the questionnaire burdensome to patients?  
  - What aspects of the PRO or PROM might create clinician burden? How can that burden be reduced?  
  - Can patients recovering from burn/trauma reasonably complete the questionnaire?  
  - How could the questionnaire be automatically prompted to be completed by the correct patients?  
  - How can we ensure the collection is HIPAA compliant?  
  - Will having caregivers or proxies complete this questionnaire invalidate results in any way?  
  - How can we facilitate collection from all patients, including those who face barriers to completing questionnaires?  
  - How can the clinic support a digital PROM implementation?
• Discussing Outcomes in Clinical Setting
  o How well does the provider understand the results?
  o Can the provider explain the results in a way the patient population can understand?
  o How well can the provider explain changes to the score over time?
  o What meaningful conversations will this outcome generate between patients and the clinical team?
  o Does the outcome foster a clear, goal-focused discussion with the patient?
  o What useful information does the score provide for Shared Decision Making?

• Decision-making Points
  o If PROs are being tracked over time, what baseline score is most meaningful (e.g., pre-incident baseline, post-incident baseline)?
  o Does the baseline score support realistic goal setting?
  o Which endpoints are clinically meaningful?
    - Static timeline (i.e., 30, 60, 90 days)?
    - Clinical progress with recovery (i.e., stages of healing)?
    - Functionality?
    - Quality of life?

Table 4. Quality Improvement Use Case for Burns and Trauma

<table>
<thead>
<tr>
<th>Title</th>
<th>Burns and Trauma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scenario</td>
<td>Selection of PROs and PROMs for Burns and Trauma</td>
</tr>
<tr>
<td>Assumptions</td>
<td>• Multistakeholder team will participate in selecting PROs and PROMs related to Burns and Trauma</td>
</tr>
<tr>
<td></td>
<td>• Measurement experts will be an integral piece of a PRO and PROM implementation. Providing an administrative and measurement perspective to ensure valid and accurate data are collected in a meaningful way.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Actor</th>
<th>Quality Improvement Expert/Implementation Team</th>
</tr>
</thead>
</table>
| Use Cases (i.e., Actor Interactions with PROs and PROMs) and Key Areas of Exploration for Each Use Case | • Patient-Reported Outcomes
  o Is the outcome useful from both a patient and provider perspective?
  o Is the outcome important from both a patient and provider perspective?
  o Are there opportunities to allow for instruction or guidance depending on outcome results, for both providers and patients?
  o Are all questionnaire options standardized and validated?
  o Does a provider need multiple PROMs to gather necessary information?

• PROs in a Clinic Setting
  o Does the clinic have sufficient resources to support this PRO?
Does this PRO align with the clinic’s overarching strategic goals?
What method of PROM implementation is right for the organization?
Can our clinic support a digital PROM implementation?

- **Data Collection using PROMs**
  - Can this data be reliably collected for all applicable patients?
  - Where is this data being stored once completed?
  - Is there an audit trail or administrative data able to be referenced?
  - Is the data able to be validated and compared to like patient populations?
  - Is the data available in a way to measure the improvements of the organization’s patient population as an aggregate?
  - How could the process be streamlined or automated to reduce any variation in data collection?
  - How can we ensure the collection is HIPAA compliant?
  - Will having caregivers or proxies complete this questionnaire invalidate results in any way?
  - How can we ensure collection from all patients? Allowing for those who are not comfortable with the digital aspect, or have language barriers, or are cognitively unable?

- **Discussing Outcomes in Clinical Setting:**
  - Are the results stored over time and able to be referenced when applicable, for both the provider and patient?
  - Is the data visualized in an easy, understandable way for end-users?
  - Are there reference materials available for additional information?
  - Is the conversation documented within the same system?

- **Decision-making Points:**
  - What specific results would prompt action to a provider? For example, if a specific range of results prompts a referral to plastic surgery for a scar PROM, or a social work consult for a depression PROM, whereas some results do not prompt any follow-up actions
  - Are there timeframes that can be automated for follow-up or the collection of an additional PROM? For example, automatically 30 days after an appointment

---

**Use Cases, Heart Failure**

A number of condition-specific factors are important for patients and caregivers to consider when selecting Heart Failure PROs and PROMs for care planning and monitoring. These factors may be less relevant in other settings (e.g., performance measurement).

- Symptoms burden (difficulty lying flat in bed to sleep)
- Functional status / impact on daily activities (physical and social)
- Impact on mental health (e.g., depression, anxiety)
• Symptoms (e.g., fatigue, shortness of breath, edema)
• Overall quality of life (long-term impact)
• Heart failure specific quality of life
• Goal attainment
• Patients’ understanding of the disease
• Patients’ understanding of prognosis
• Patients’ assessment of self-efficacy in managing the condition
• Medication adherence

As with all selection processes, it is important to balance data collection with patient and clinician burden. It is also important to note that while many of these PROs are actionable, they may require care coordination with an interdisciplinary team.

Table 5: Patient Use Case for Heart Failure

<table>
<thead>
<tr>
<th>Title</th>
<th>Heart Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scenario</td>
<td>Selection of PROs and PROMs for Heart Failure</td>
</tr>
</tbody>
</table>
| Assumptions | • Multistakeholder team will participate in selecting PROs and PROMs related to Heart Failure  
• Patients provide a critical perspective to the selection of PROs and PROMs. Patients can identify what outcomes are meaningful and important from a patient perspective, as well as questions and concerns that might make patients disengage from PRO processes. |
| Actor | Patients |
| Use Cases (i.e., Actor Interactions with PROs and PROMs) and Key Areas of Exploration for Each Use Case | • Patient-Reported Outcomes  
  o How is the outcome meaningful for the patient population?  
  o How is the outcome important for the patient population?  
  o How does the outcome reflect patient goals?  
  o How does the outcome reflect the recovery process?  
  o What attributes from the Attribute Grid (Appendix D) are most important to patients?  
• Data Collection using PROMs  
  o Is completing the questionnaire burdensome?  
  o Would heart failure patients be able to complete this questionnaire independently?  
  o How comfortable would the patient population be sharing this information?  
  o How comfortable would the patient population be with caregivers or other proxies completing the questionnaire?  
  o How ready is the patient population to share PRO information digitally?  
  o What barriers would prevent patients from completing the questionnaire (for example, are there language or cognitive barriers)?  
• Discussing Outcomes in Clinical Setting:  
  o How well will the patient population understand the score?  
  o How could the visualization of the score over time be more meaningful for the patient population? |
Is a new or continued medication regimen an element in the discussion?
How will the outcome improve the patient population’s understanding of heart failure?
How will the patient population’s understanding of the prognosis change?
What meaningful conversations will this outcome generate between patients and the clinical team?
Does the outcome foster a clear, goal-focused discussion with the physician?
If the patient is interested in Shared Decision Making, how does the score contribute to that process?
How effectively does the outcome assess burden of care, for the patient and/or the caregiver?

**Decision-making Points:**
What specific results would prompt a patient to contact a provider? For example, if a specific recovery goal is met (e.g., going up stairs without trouble breathing, laying down flat without having trouble breathing)?

### Table 6: Provider Use Case for Heart Failure

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>Heart Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scenario</strong></td>
<td>Selection of PROs and PROMs for Heart Failure</td>
</tr>
<tr>
<td><strong>Assumptions</strong></td>
<td></td>
</tr>
</tbody>
</table>
  - Multistakeholder team will participate in selecting PROs and PROMs related to Heart Failure
  - Providers offer a critical perspective to the selection of PROs and PROMs. Providers can identify what outcomes are meaningful and important from a clinical perspective, while keeping a holistic approach to patient care. Using their experience and medical training, providers can help prioritize which PROs are important to helping predict or navigate future medical issues. |

<table>
<thead>
<tr>
<th><strong>Actor</strong></th>
<th>Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use Cases (i.e., Actor Interactions with PROs and PROMs) and Key Areas of Exploration for Each Use Case</strong></td>
<td></td>
</tr>
</tbody>
</table>
  - **Patient-Reported Outcomes**
    - How is the outcome useful from a provider perspective?
    - How is the outcome important from a provider perspective?
    - How is the outcome actionable by the provider?
    - How does the outcome reflect the recovery process?
    - What attributes from the Attribute Grid (Appendix D) are most important to providers?
    - How does the outcome lend itself to PROM selection?
    - Does a provider need multiple PROMs to gather necessary information?
  - **PROs in a Clinic Setting**
    - What clinical resources will support this PRO?
    - What clinical resources are missing and will be needed to support this PRO?
    - How does this PRO align with the clinic’s overarching strategic goals? |
• Data Collection using PROMs
  o Is completing the questionnaire burdensome to patients?
  o What aspects of the PRO or PROM might create clinician burden? How can that burden be reduced?
  o How could the questionnaire be automatically prompted to be completed by the correct patients?
  o How can we ensure the collection is HIPAA compliant?
  o Will having caregivers or proxies complete this questionnaire invalidate results in any way?
  o How can we facilitate collection from all patients, including those who face barriers to completing questionnaires?
  o How can the clinic support a digital PROM implementation?

• Discussing Outcomes in Clinical Setting
  o How well does the provider understand the results?
  o Can the provider explain the results in a way the patient population can understand?
  o How well can the provider explain changes to the score over time?
  o What meaningful conversations will this outcome generate between patients and the clinical team?
  o Does the outcome foster a clear, goal-focused discussion with the patient?
  o What useful information does the score provide for Shared Decision Making?

• Decision-making Points
  o Does the baseline score support realistic goal setting?
  o Which endpoints are clinically meaningful?
    ▪ Static timeline (i.e., 30, 60, 90 days)?
    ▪ Functionality?
    ▪ Quality of life?

Use Cases, Joint Replacement
For joint replacement patients, important and meaningful outcomes to patients largely relates to whether a patient is on or off the expected trajectory of proper recovery, and return to baseline functionality or mobility.

  • Abilities post-replacement that were not possible prior to surgery
  • Pain
  • Ability to function as desired
  • Goal attainment
  • Joint-specific pain
  • Physical function
  • Quality of life
  • Mobility

Walking a specified distance without pain is an example of goal-attainment that can be assessed with a PROM. Increased awareness of adverse events in joint replacement and additional monitoring of these
events, similar to the tracking of adverse events for cancer care\textsuperscript{24} would be meaningful and inform patient-centered care.

Table 7: Patient Use Case for Joint Replacement

<table>
<thead>
<tr>
<th>Title</th>
<th>Joint Replacement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scenario</td>
<td>Selection of PROs and PROMs for Joint Replacement</td>
</tr>
</tbody>
</table>
| Assumptions                                | • Multistakeholder team will participate in selecting PROs and PROMs related to Joint Replacement  
• Patients provide a critical perspective to the selection of PROs and PROMs. Patients can identify what outcomes are meaningful and important from a patient perspective, as well as questions and concerns that might make patients disengage from PRO processes. |
| Actor                                      | Patients                                                                          |
| Use Cases (i.e., Actor Interactions with PROs and PROMs) and Key Areas of Exploration for Each Use Case | • **Patient-Reported Outcomes**  
  o How is the outcome meaningful for the patient population?  
  o How is the outcome important for the patient population?  
  o How does the outcome reflect patient goals?  
  o How does the outcome reflect the recovery process?  
  o What attributes from the Attribute Grid (Appendix D) are most important to patients?  
• **Data Collection using PROMs**  
  o Is completing the questionnaire burdensome?  
  o How comfortable would the patient population be sharing this information?  
  o How comfortable would the patient population be with caregivers or other proxies completing the questionnaire?  
  o How ready is the patient population to share PRO information digitally?  
  o What barriers would prevent patients from completing the questionnaire (for example, are there language or cognitive barriers)?  
• **Discussing Outcomes in Clinical Setting:**  
  o How well will the patient population understand the score?  
  o How could the visualization of the score over time be more meaningful for the patient population?  
  o What meaningful conversations will this outcome generate between patients and the clinical team?  
  o Does the outcome foster a clear, goal-focused discussion with the physician?  
  o How will the patient population identify and measure abilities that emerge post-replacement?  
  o If the patient is interested in Shared Decision Making, how does the score contribute to that process?  
• **Decision-making Points:**  
  o What specific results would prompt a patient to contact a provider? For example, if a specific recovery goal is met (e.g., certain number of steps without pain)? |
Table 8: Provider Use Case for Joint Replacement

<table>
<thead>
<tr>
<th>Title</th>
<th>Joint Replacement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scenario</td>
<td>Selection of PROs and PROMs for Joint Replacement</td>
</tr>
</tbody>
</table>

**Assumptions**
- Multistakeholder team will participate in selecting PROs and PROMs related to Joint Replacement
- Providers offer a critical perspective to the selection of PROs and PROMs. Providers can identify what outcomes are meaningful and important from a clinical perspective, while keeping a holistic approach to patient care. Using their experience and medical training, providers can help prioritize which PROs are important to helping predict or navigate future medical issues.

<table>
<thead>
<tr>
<th>Actor</th>
<th>Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use Cases (i.e., Actor Interactions with PROs and PROMs) and Key Areas of Exploration for Each Use Case</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Patient-Reported Outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>o How is the outcome useful from a provider perspective?</td>
<td></td>
</tr>
<tr>
<td>o How is the outcome important from a provider perspective?</td>
<td></td>
</tr>
<tr>
<td>o How is the outcome actionable by the provider?</td>
<td></td>
</tr>
<tr>
<td>o How does the outcome reflect the recovery process?</td>
<td></td>
</tr>
<tr>
<td>o What attributes from the Attribute Grid (Appendix D) are most important to providers?</td>
<td></td>
</tr>
<tr>
<td>o How does the outcome lend itself to PROM selection?</td>
<td></td>
</tr>
<tr>
<td>o Does a provider need multiple PROMs to gather necessary information?</td>
<td></td>
</tr>
<tr>
<td><strong>PROs in a Clinic Setting</strong></td>
<td></td>
</tr>
<tr>
<td>o What clinical resources will support this PRO?</td>
<td></td>
</tr>
<tr>
<td>o What clinical resources are missing and will be needed to support this PRO?</td>
<td></td>
</tr>
<tr>
<td>o How does this PRO align with the clinic’s overarching strategic goals?</td>
<td></td>
</tr>
<tr>
<td><strong>Data Collection using PROMs</strong></td>
<td></td>
</tr>
<tr>
<td>o Is completing the questionnaire burdensome to patients?</td>
<td></td>
</tr>
<tr>
<td>o What aspects of the PRO or PROM might create clinician burden? How can that burden be reduced?</td>
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<tr>
<td>o How could the questionnaire be automatically prompted to be completed by the correct patients?</td>
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<tr>
<td>o How can we ensure the collection is HIPAA compliant?</td>
<td></td>
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<tr>
<td>o Will having caregivers or proxies complete this questionnaire invalidate results in any way?</td>
<td></td>
</tr>
<tr>
<td>o How can we facilitate collection from all patients, including those who face barriers to completing questionnaires?</td>
<td></td>
</tr>
<tr>
<td>o How can the clinic support a digital PROM implementation?</td>
<td></td>
</tr>
<tr>
<td>o How will we collect data when a single patient has multiple clinical events (e.g., separate surgeries on left and right knees, outcomes related to physical therapy vs. injections vs. surgery)?</td>
<td></td>
</tr>
<tr>
<td><strong>Discussing Outcomes in Clinical Setting</strong></td>
<td></td>
</tr>
<tr>
<td>o How well does the provider understand the results?</td>
<td></td>
</tr>
<tr>
<td>o Can the provider explain the results in a way the patient population can understand?</td>
<td></td>
</tr>
</tbody>
</table>
• Decision-making Points:
  o What specific results would prompt action to a provider? For example, a certain number of steps without pain? If a patient is not making benchmarks, when would a physical therapy referral be prompted?
  o Are there timeframes that can be automated for follow-up or the collection of an additional PROM? For example, automatically 3, 7, or 30 days after surgery?

Future Goals and Considerations

The healthcare field is in need of a movement to gather valuable information directly from patients. While there are key best practices to advance the selection and implementation of PROs and PROMs, some key issues require further examination. Patients want to understand their results in real time and clinicians should be able to use results to inform care delivery. Fully integrating PROM data into decision-making requires more timely calculation of PROM results and ability to interpret results.

Timely understanding of results may also improve if more PROMs are integrated into EHRs. Additional research and dialogue is needed in order to identify specific mechanisms and steps for the integration of PROMs into EHRs.

Three use case scenarios to inform the creation of best practices, but other potential scenarios (e.g., PROMs deployed outside of the outpatient setting, PROMs for the pediatric population) may pose unique challenges and opportunities for additional guidance.

More research is needed on approaches to measure individual-level change using PROM data and to determine meaningful change over time for individual patients.

There is a need for specific recommendations of PROMs best-suited for widespread use, emphasizing that not making specific selection recommendations runs the risk that every practice will use a different measure for the same construct. Lack of alignment may render interpretability across practices challenging, introduce performance measurement issues, and make the attempt to apply clinical research evidence into practice more difficult. Similarly, to promote alignment and enhanced comparability there was support for development of disease-agnostic PROMs.

Finally, ROI continues to be a barrier that hinders the implementation of PROMs. Additional work needs to investigate how PROs and PROMs benefit both patients and healthcare organizations, and clarify the financial incentives that could motivate clinics and health systems to adopt PROMs. Payers also need to
continue to explore ways to incentivize the adoption of PROMs through accountability and quality programs.

**Next Steps**

The draft of this report will be released for a 30-day NQF member and public comment period. This commenting period will open on June 1, 2020 and will close on June 30, 2020. Once the commenting period closes, NQF staff will review and synthesize themes from the comments. On July 13, 2020, the TEP will reconvene for its final webinar to discuss the comments and offer feedback to aid in revising the report. The report will be finalized in August 2020.
References


7 John Spertus, MD, MPH. Key Informant Interview. April 2020.

8 Carolyn Kerrigan, MD, MHCDS. Key Informant Interview. April 2020.

9 Albert Wu, MD, MPH. Key Informant Interview. April 2020.


12 Kathleen Fear, PhD, MSI. Key Informant Interview. April 2020.


14 Rachel Brodie. Email Correspondence. May 2020.


Appendix A: Technical Expert Panel Members and NQF Staff

TECHNICAL EXPERT PANEL

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Denver, Colorado

**Jana Malinowski**
Cerner Corporation
Kansas City, Missouri

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Seattle, Washington

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Assistant Director of Emergency Medicine, Massachusetts General Hospital
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**Jeffrey Schneider, MD**
Medical Director, Spaulding Rehabilitation Hospital
Charleston, Massachusetts

**Paul Shekelle, MD, PhD, MPH**
Director, Southern California Evidence-Based Practice Center, RAND Corporation
Santa Monica, California

**Leif Solberg, MD**
Senior Advisor and Senior Investigator, HealthPartners
Minneapolis, Minnesota
*John Spertus, MD, MPH
Professor, University of Missouri, Kansas City
Kansas City, Missouri

* Indicates a Key Informant Interview

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Director

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Director

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Kathryn Berryman, MPAP
Project Manager

Teresa Brown, MHA, MA, CPHQ, CPPS
Senior Manager

Hannah Bui, MPH
Manager
Appendix B: Key Informant Interview Guide

NQF is convening Key Informant Interviews to identify and recommend practical methods to address gaps in our report and further improve the quality of the report’s content. Stakeholders have a significant need for information on how PROs can be successfully implemented. This includes how to select a PRO, how to determine which Patient-Reported Outcome Measure (PROM) will best collect the desired information, and how to identify opportunities and challenges related to workflow, clinician buy-in, data collection burden, interpretation of data, and action upon results. Your feedback will ultimately help inform the public on how to best capture and measure the voice of the patient.

All Key Informant Interviews were conducted from April 22 – April 29th, 2020.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Questions/Discussion Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introductions/Welcome</td>
<td>• NQF staff introductions&lt;br&gt;• Interviewee introductions&lt;br&gt;• Recording consent&lt;br&gt;• Brief description of your role and responsibilities in your current position(s)</td>
</tr>
</tbody>
</table>
| Purpose and overview of interview    | • Brief NQF Overview<br>• Brief Project Description<br>• Purpose of interview /What we hope to learn<br>• Interview Overview<br>Defining PROs/PROMs/PROMs-PMs<br>The Key Informants will identify and recommend innovative, efficient, and effective approaches to determine appropriate Patient-Reported Outcomes for organizations and provide context and examples on the measuring and implementation of Patient-Reported Outcome tools. There is a significant stakeholder need for information on how to implement Patient-Reported Outcome tools, and possible issues or challenges associated with measure implementation. This information would help inform stakeholders on a successful Patient-Reported Outcome measurement implementation, to capture and measure the patient voice.
| North Star Statement: The purpose of this Task Order (TO) is to identify best practices that will help clinicians and administrators understand how to select the patient-reported outcomes that are most pertinent to a care setting, choose the PROMs that will capture these outcomes accurately, and implement the PROMs by incorporating them in clinician workflows in a way that balance clinician, patient, and measurement needs. |
| Experience with implementation        | • How should a high quality/high impact Patient-Reported Outcome be selected?<br>• Once the PRO is selected, what factors should users take into consideration during the process of PROM selection?<br>• Disease specific or non-disease specific tools and reasons for why? |
| **EHR Implications** | • Have you received feedback concerning the clinician burden of measure implementation?  
• How have PROs informed your quality improvement efforts?  
• What are some workflow considerations during selection of PROs/PROMs?  
• How to determine which endpoints (e.g., 30, 60, 90 days) are clinically meaningful?  
• How to tell whether a PRO is interpretable or actionable?  
• Do you have decision points or flags where a patient response triggers a response or action from the clinic?  

| **Return on Investment** | • Are you collecting your PROMs in your EHR, or what role does your EHR play?  
• What is your average patient response rate?  
• What are the challenges in navigating the patient portal?  
• Are there implications in PRO collection as part of the legal medical record?  
• What data elements used in performance measures are most burdensome for you to note in the EHR?  
• What are some of the major data presentation problems in current EHR design?  
• What is the resource investment to implement an EHR PROM?  

| **Data Collection** | • How is the ROI measured in your PRO/PROM implementation?  

| **Challenges & Strategies** | • What platforms or tools are you using to collect data/feedback, and from whom does the data/feedback originate?  
• What are the characteristics of the data/feedback you are collecting, e.g. qualitative, quantitative?  
• How often are you collecting data/feedback, and what is the approximate volume of feedback collected?  
• How is this data/feedback compiled, and presented to internal and external stakeholders?  

| **Wrap-up** | • How to determine which PRO is most valuable and meaningful to both patients and providers?  
• How can a solo practitioner be able to select the best PROs for her patients quickly and reliability, if she does not have other experts to defer to?  
• How to convince the physician lead the importance and value of a PRO for her practice and patients?  
• What are unintended consequences affected PRO measure design and revision process?  
• How have PROs changed/informed patient care?  
• Recap follow up items  
• Next steps  
• Close |
Appendix C: PROMs Related to Use Cases

PROMs for Heart Failure:
- Minnesota Living with Heart Failure Questionnaire
- Kansas City Cardiomyopathy Questionnaire (KCCQ)
- KCCQ-12
- Chronic Heart Failure Assessment Tool (CHAT)
- 9-Item European Heart Failure Self-Care (EHFScB-9)
- Patient-Reported Outcomes Measurement Information System (PROMIS)-29

PROMS for Burns:
- Adult Burn Outcome Questionnaire (ABOQ)
- Coping with Burns Questionnaire (CBQ)
- Young Adult Burn Outcome Questionnaire
- Satisfaction with Appearance scale (SWAP)
- Brisbane Burn Scar Impact Profile
- Life Impact Burn Recovery Evaluation Profile (LIBRE)
- Burns Anxiety Inventory
- Rosenberg Self-Esteem Scale (RSES)
- PROMIS-29
- Death Anxiety Questionnaire

PROMs for Joint Replacement:
- Oxford Hip Score
- Oxford Knee Score
- Hip disability and Osteoarthritis Outcome Score-12
- Knee injury and Osteoarthritis Outcome Score-12
- HOOS-JR
- HOOS
- KOOS
- Surgical Patient Education Interview
- Forgotten Joint Score
- Stanford Health Assessment Questionnaire
- Assessment of Quality of Life-4D (AQoL-4D)
- Western Ontario and McMaster (WOMAC) Universities Arthritis Index
## Appendix D: PROM Attribute Grid Example

<table>
<thead>
<tr>
<th>PROM</th>
<th>PROM 1</th>
<th>PROM 2</th>
<th>PROM 3</th>
<th>PROM 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covers desired PROs:</td>
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<tr>
<td>Covers desired PROs:</td>
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<td>Covers desired PROs:</td>
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<tr>
<td>Covers desired PROs:</td>
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<tr>
<td>Contains goal attainment and goal attainment follow-up questions</td>
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<tr>
<td>Symptoms</td>
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<tr>
<td>Impacts</td>
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<tr>
<td>Costs/fees</td>
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<tr>
<td>Languages/translations available</td>
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<tr>
<td>Length (number of items)</td>
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<tr>
<td>Psychometric soundness: Burden, including time and effort</td>
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<tr>
<td>Concepts included:</td>
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<td>Concepts included:</td>
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<td>Concepts included:</td>
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<tr>
<td>Psychometric soundness: Clear conceptual and measurement models</td>
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<td>Intended population:</td>
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<td>Intended population:</td>
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<td>Intended population:</td>
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<tr>
<td>Clinical applicability to desired population</td>
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<tr>
<td>Psychometric soundness: reliability (include sample size, various estimates if provided, and applicable population(s))</td>
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<tr>
<td>Test-retest reliability:</td>
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<td>Test-retest reliability:</td>
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<tr>
<td>Test-retest reliability:</td>
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<tr>
<td>Internal Consistency (Cronbach’s a):</td>
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<td>Internal Consistency (Cronbach’s a):</td>
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<td>Internal Consistency (Cronbach’s a):</td>
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<tr>
<td>Internal Consistency (Cronbach’s a):</td>
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<tr>
<td>Good, better, or best reliability</td>
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<tr>
<td>PROM</td>
<td>PROM 1</td>
<td>PROM 2</td>
<td>PROM 3</td>
<td>PROM 4</td>
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<tr>
<td>Psychometric soundness: validity (include various estimates if provided and notes applicable population(s))</td>
<td>Construct Validity (Population):</td>
<td>Construct Validity (Population):</td>
<td>Construct Validity (Population):</td>
<td>Construct Validity (Population):</td>
</tr>
<tr>
<td>Psychometric soundness: Responsiveness—ability to detect change</td>
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<tr>
<td>Good, better, or best actionability</td>
<td></td>
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</tr>
<tr>
<td>Psychometric soundness: Clear documentation on how to interpret scores</td>
<td>Minimal clinically important difference: Summary or total score change</td>
<td>Minimal clinically important difference: Summary or total score change</td>
<td>Minimal clinically important difference: Summary or total score change</td>
<td>Minimal clinically important difference: Summary or total score change</td>
</tr>
<tr>
<td>Good, better, or best interpretability</td>
<td></td>
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</tbody>
</table>
Appendix E: PROM Attribute Grid – Example for Heart Failure

To provide a more tangible example of how the Attribute Grid should be completed to inform PROM selection, NQF staff and the TEP completed the attribute grid for four heart failure PROMs. To best utilize the Attribute Grid, staff member(s) with knowledge of both measurement and disease- or condition-specific requirements should review the literature and secure copies of each PROM being assessed. The robustness of the literature and available study data will have an impact on decision-making. When analyzing the Attribute Grid information to select a PROM, clinics also need to consider factors that are not explicitly addressed by the grid, such as resources and methods for implementation, particularly for data collection and scoring.

Ultimately, there will be trade-offs when choosing one PROM over another. Depending on the scenario, using multiple complementary PROMs may be necessary, as it is unlikely a single PROM covers every essential attribute. For example, if mental health is an important aspect of a patient with heart failure’s treatment, but the available heart failure-specific PROMs do not cover this outcome, an additional depression screening instrument may be appropriate. Multiple PROMs might be needed for specific conditions (e.g., trauma and burns, heart failure, and joint replacement), especially since different PROMs focus on different areas such as self-care behaviors and experience of care.

“Goal attainment” is an aspirational attribute and is not yet considered by any currently available instruments, but should remain a priority in PROM development.

While the grid allows for a more standardized comparison of the key PROM attributes, the TEP acknowledged that filling out the grid takes time and may not be a simple task. In the real-world setting, a quality measurement professional would assist with completing the grid.

<table>
<thead>
<tr>
<th>PROM</th>
<th>Minnesota Living with Heart Failure Questionnaire</th>
<th>KCCQ-23 (Kansas City Cardiomyopathy Questionnaire)</th>
<th>KCCQ-12 (Kansas City Cardiomyopathy Questionnaire)</th>
<th>CHAT (Chronic Heart Failure Assessment Tool)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covers desired PROs: Symptoms such as fatigue, SoB, difficulty lying flat to sleep, edema</td>
<td>Mostly</td>
<td>Yes (items 3, 5, 7, and 9)</td>
<td>Yes</td>
<td>Some</td>
</tr>
<tr>
<td>Covers desired PROs: Impact on daily activities, physical and social</td>
<td>Mostly</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Covers desired PROs: Impact on mental health (e.g., depression)</td>
<td>Yes</td>
<td>Yes (item 14 addresses depression)</td>
<td>No</td>
<td>Mostly</td>
</tr>
<tr>
<td>Covers desired PROs: Understanding of condition</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>PROM</td>
<td>Minnesota Living with Heart Failure Questionnaire</td>
<td>KCCQ-23 (Kansas City Cardiomyopathy Questionnaire)</td>
<td>KCCQ-12 (Kansas City Cardiomyopathy Questionnaire)</td>
<td>CHAT (Chronic Heart Failure Assessment Tool)</td>
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</tr>
<tr>
<td>Covers desired PROs: Patient acceptability of questions in the instruments</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contains a goal attainment and a goal attainment follow-up question</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Ankle/leg swelling, shortness of breath, fatigue, poor memory, or concentration, depression</td>
<td>Shortness of breath, fatigue, ankle swelling, sleeping upright/orthopnea</td>
<td>Swelling, fatigue, dyspnea, sleeping upright</td>
<td>Shortness of breath with and without activity, fatigue, fear</td>
</tr>
<tr>
<td>Impacts</td>
<td>Physical activity, sleep, sexual activity, financial difficulty, leisure activity, eating</td>
<td>Physical limitation, self-efficacy, social interference, QoL, sexual activity</td>
<td>Physical limitation, social interference, QoL</td>
<td>Physical activities, family activities, social activities, sleep, sexual relationships, anger, fear, tension, concern</td>
</tr>
<tr>
<td>Costs/fees</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>Languages/translations available</td>
<td>At least 34 languages available</td>
<td>Approximately 100 available</td>
<td>Approximately 100 available</td>
<td>Information not available</td>
</tr>
<tr>
<td>Length</td>
<td>21 items</td>
<td>23 items</td>
<td>12 items</td>
<td>46 items</td>
</tr>
<tr>
<td>Psychometric soundness: Burden, including time and effort</td>
<td>Not reported</td>
<td>5-8 minutes</td>
<td>Half that of the KCCQ-23</td>
<td>Not reported</td>
</tr>
<tr>
<td>Psychometric soundness: Clear conceptual and measurement models</td>
<td>Concepts included: physical, emotional <strong>Intended population</strong>: Heart failure New York Heart Association functional class I-III, reduced LVEF</td>
<td>Concepts included: Physical, Symptoms, Change, Self-efficacy, Social, QoL <strong>Intended population</strong>: Acute or chronic HF, including reduced and preserved LVEF and valve disease</td>
<td>Concepts included: physical limitation, symptom frequency, quality of life, and social limitation <strong>Intended population</strong>: stable HF, outpatient HF clinic visits, and acute HF recovery (1 week after hospitalization for decompensated HF).</td>
<td>Concepts included: Symptoms, activity levels, psychosocial aspects, emotions <strong>Intended population</strong>: Heart failure</td>
</tr>
<tr>
<td>Clinical applicability to desired population</td>
<td></td>
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</tr>
<tr>
<td>PROM</td>
<td>Minnesota Living with Heart Failure Questionnaire</td>
<td>KCCQ-23 (Kansas City Cardiomyopathy Questionnaire)</td>
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<tr>
<td>Psychometric soundness: reliability (include sample size, various estimates if provided, and applicable population, e.g., R=0.7 in community-dwelling adults ages 65+)</td>
<td>Test-retest reliability: 1–3 weeks: (n=83), Mean change: –1 (–11 to 5), weighted k = 0.84 4 weeks: Total r = 0.79, Physical r = 0.74, Emotional r = 0.75 Internal Consistency (Cronbach's a) Physical (0.94), Emotional (0.88–0.90), Total (0.94–0.95)</td>
<td>Test-retest reliability: 3 months: (n=39) Summary score range =0.8–4 (p &gt; 0.05) 6 weeks: (n=79) Physical ri = 0.85, Symptoms ri = 0.83, QoL ri = 0.76, Social ri = 0.86, Summary ri = 0.91 Internal Consistency (Cronbach's a) Physical (0.87–0.90), Symptoms (0.88–0.89), QoL (0.78–0.82), Social (0.86–0.88), Self-efficacy (0.62–0.64), Functional status (0.92–0.93), Summary (0.94–0.95) For HFpEF all domains (&gt;0.69) Summary (0.96)</td>
<td>Test-retest reliability: Among 79 clinically stable patients assessed 6 weeks after a HF clinic visit, the KCCQ-12 revealed minimal changes in scores between assessments and showed high intraclass correlations of ≥0.76 for all domains. The overall summary score had the highest reproducibility with an intraclass correlation of 0.92. Internal Consistency (Cronbach's a) Comparable to KCCQ-23.</td>
<td>Test-retest reliability: Not reported Internal Consistency (Cronbach's a) Symptoms (0.93) Activity levels (0.92) Psychosocial (0.86) Emotions (0.84)</td>
</tr>
<tr>
<td>PROM</td>
<td>Minnesota Living with Heart Failure Questionnaire</td>
<td>KCCQ-23 (Kansas City Cardiomyopathy Questionnaire)</td>
<td>KCCQ-12 (Kansas City Cardiomyopathy Questionnaire)</td>
<td>CHAT (Chronic Heart Failure Assessment Tool)</td>
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</tr>
<tr>
<td>Psychometric soundness: validity (include various estimates if provided and notes applicable population, e.g., R=0.7 in community-dwelling adults ages 65+)</td>
<td><strong>Construct Validity (Population)</strong></td>
<td><strong>Construct Validity (Population)</strong></td>
<td>Agreement between the KCCQ-12 and full KCCQ scores was excellent in all clinical settings, with concordances of 0.97 for physical limitation scores, 0.93 to 0.96 for quality of life scores, 0.98 for social limitation scores, and 0.98 to 0.99 for summary scores</td>
<td></td>
</tr>
<tr>
<td>Good, better, or best validity</td>
<td><strong>Outpatient pulmonary hypertension</strong>: (n = 83)</td>
<td><strong>Decompensated HFrEF</strong> (n = 129)</td>
<td><strong>Outpatient HFpEF</strong> (n = 68)</td>
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<tr>
<td></td>
<td>Total score: 6MWT (r = –0.54, p = 0.01)</td>
<td>Physical score: NYHA functional class (r = –0.65, p &lt; 0.001), Physical score: 6MWT (r = 0.48, p &lt; 0.001), QoL score: MLHFQ, Emotional (r = 0.62, p &lt; 0.001), Summary score: NYHA functional class (F = 41.9, p &lt; 0.001)</td>
<td>Total score: SF36 total (r = 0.79, CI: 0.68–0.87) Total score: MLHFQ total (r = 0.57, CI:0.39–0.71)</td>
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<tr>
<td></td>
<td>Total score: NYHA functional class (r = 0.54, p = 0.01)</td>
<td><strong>Outpatient HF</strong> (n = 211)</td>
<td><strong>Outpatient HFrEF</strong> (n = 505)</td>
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<tr>
<td></td>
<td>Physical score: 6MWT (r = –0.58, p = 0.01)</td>
<td>Total score: NYHA functional class (r = 0.60, p &lt; 0.01)</td>
<td>Summary score &lt;25: 1-year Mortality or HF Hospitalization (HR: 2.77, p = 0.02)</td>
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<tr>
<td></td>
<td>Physical score: NYHA functional class (r = 0.63, p =0.01)</td>
<td><strong>Outpatient HF</strong> (n = 211)</td>
<td><strong>Outpatient HFpEF</strong> (n = 200)</td>
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<tr>
<td></td>
<td><strong>Inpatient and outpatient HF</strong> (n = 83)</td>
<td>Total score: NYHA functional class (ANOVA p = 0.0001)</td>
<td>Summary score: NYHA functional class (r = –0.62, p &lt; 0.001), Summary score: death or hospitalization (log rank p &lt; 0.001)</td>
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<tr>
<td></td>
<td>Total score: NYHA functional class (r = 0.60, p &lt; 0.01)</td>
<td><strong>Outpatient HF</strong> (n = 1,151)</td>
<td><strong>HF after MI</strong> (n = 1,358)</td>
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<tr>
<td></td>
<td><strong>Outpatient HF</strong> (n = 211)</td>
<td>Total score: 1-, 3-, 5-year mortality (HR: 1.012, p &lt; 0.001)</td>
<td>5-point decrease summary score: 2-yr mortality (HR: 1.11)</td>
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<td><strong>Outpatient HFrEF</strong> (n = 5,025)</td>
<td><strong>Outpatient HF</strong> (n = 198)</td>
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<td></td>
<td>Total score: 1.5-year mortality (RR: 1.205, p &lt; 0.001)</td>
<td>Total score: Naughton treadmill (r = 0.33, p &lt; 0.01)</td>
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<td></td>
<td>Total score: 1.5-year hospitalization (RR: 1.188, p &lt; 0.001)</td>
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<tr>
<td>PROM</td>
<td>Minnesota Living with Heart Failure Questionnaire</td>
<td>KCCQ-23 (Kansas City Cardiomyopathy Questionnaire)</td>
<td>KCCQ-12 (Kansas City Cardiomyopathy Questionnaire)</td>
<td>CHAT (Chronic Heart Failure Assessment Tool)</td>
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<td>---------------------------------------------</td>
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<tr>
<td>Psychometric soundness: Responsiveness—ability to detect change</td>
<td>(n = 173) Mean change of total score 3 months after hospitalization: 13.3 with further total score change from 3–6 months: 2.2 (p &lt; 0.001)</td>
<td>6 weeks: (n = 298) Summary scores outperformed EQ-5D and RAND12; c-statistic: 0.77 (small change) 0.90 (large change) 3 months: (n = 39) Mean change of summary score on hospital admission 24.3 (p &lt; 0.001), outperformed MLHFQ and SF36</td>
<td>The KCCQ-12 showed substantial responsiveness to clinical change. One week after hospitalization for acute HF, mean KCCQ-12 scores increased by &gt;16 points for all domains, with the greatest increase in the symptom frequency score (31.0 points; Table 6). Standardized response means were good to excellent, ranging from 0.65 for physical limitation to 1.12 for the summary score.</td>
<td>Not reported</td>
</tr>
<tr>
<td>Minimal clinically important difference: Total score change: 4.84; Physical: 2.56; Emotional: 0.98</td>
<td>Minimal clinically important difference: Summary score change: 5 = mild 10 = medium 15 = large (Summary score change &gt;=5)</td>
<td>Minimal clinically important difference: Among patients at 6 weeks after a HF clinic visit, change in the KCCQ-12 summary score was strongly associated with physicians’ assessment of clinically significant improvement (c-index = 0.67) and deterioration (c-index = 0.77), mirroring that of the full KCCQ (c-indices of 0.68 and 0.77, respectively). The optimal cut point based on</td>
<td>Minimal clinically important difference: Not reported</td>
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<tr>
<td>PROM</td>
<td>Minnesota Living with Heart Failure Questionnaire</td>
<td>KCCQ-23 (Kansas City Cardiomyopathy Questionnaire)</td>
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<td>Youden’s index was 4.7 points for predicting improvement and −3.1 points for predicting deterioration, both agreeing favorably with analogous cut points for the full KCCQ (Table 7). A 5-point improvement or deterioration in scores for individual patients was associated with a 58% and 67% sensitivity and a 70% and 75% specificity, respectively, that a physician would have assessed the patient to have a clinically important improvement or deterioration in their HF status. These results were comparable to the full KCCQ and support a minimal clinically important difference of ≈3 to 5 points for the KCCQ-12 summary score.</td>
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