

Using Patient-Reported Outcomes to Assess Healthcare Quality: Toward Better Measurement of Patient-Centered Care in Cardiovascular Disease

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ABSTRACT: Patient-reported outcomes (PROs) are elicited directly from patients so they can describe their overall health status, including their symptoms, function, and quality of life. While commonly used as end points in clinical trials, PROs can play an important role in routine clinical care, population health management, and as a means for quantifying the quality of patient care. In this review, we propose that PROs be used to improve patient-centered care in the treatment of cardiovascular diseases given their importance to patients and society and their ability to improve doctor-provider communication. Furthermore, given the current variability in patients' health status across different clinics and the fact that PROs can be improved by titrating therapy, we contend that PROs have a key opportunity to serve as measures of healthcare quality.

INTRODUCTION

Improving the quality of care is a foundational goal for the medical profession. To that end, the National Academy of Medicine (formerly known as the Institute of Medicine) defined key pillars of high-quality health care, one of which is that care should be patient centered.¹ Patient-centered care requires that treatments be tailored to each patient's specific needs, with the aim of improving their symptoms, function, quality of life, and survival. While survival is straightforward to measure, quantifying patients' symptoms, function, and quality of life (together referred to as "health status") requires eliciting this information directly from patients through questionnaires. This is referred to as patient-reported outcomes (PROs).

The design of robust PROs has evolved over the past several decades. Specifically, PROs need to be valid, reliable, sensitive to clinical change, and interpretable.² Once a psychometrically sound PRO is available, it can be used in multiple applications where it is relevant to understand a patient's health status—for example, clinical trial outcomes, population health management, tools for providing clinical care, and quantifying a provider's success in optimizing patients' health status to assess quality of care. To date, PROs are commonly used as end points in clinical trials to determine the impact of an intervention on patients' health status. In fact, the US Food and Drug Administration recently clarified its position on the importance of improving patient health status, stating that even in the absence of a favorable impact on survival or hospitalization risk, improvement in patient symptoms and function (key components of health status) could be sufficient for regulatory approval.^{2,3}

While the roles of PROs in clinical trials have been well established, their use in routine clinical and cardiovascular care, population health, and quantifying the quality of patient care are still being developed. This article discusses the rationale for using PROs to measure healthcare quality with the goal of elevating the patient-centeredness of current quality assessments to further improve healthcare value. This perspective is built on the conceptual arguments of Berwick, and more recently Porter, that value is defined by the triple aim of improved patient experience and outcome divided by cost.^{4,5}

$$\text{Value} = \frac{\text{Patient Experience} + \text{Outcomes}}{\text{Cost}}$$

The numerator of this equation can be quantified by PROs because they capture both the experiences of patients living with a disease and highly relevant outcomes. Moreover, a growing body of literature demonstrates that patient health status and outcomes vary between providers.⁶ Thus, increasing the focus on patient health status can incentivize new efforts to further improve patient symptoms, function, and quality of life. A natural extension of using PROs in quality assessment is that they will need to be routinely collected in clinical practice. Accordingly, this article justifies the recent calls to use PROs as quality metrics and describes why their routine use may also enhance the patient-centeredness of care.⁷

IMPORTANCE OF HEALTH STATUS AND OUTCOMES TO PATIENTS

Quality of care is frequently evaluated and optimized by healthcare providers; however, these efforts need to

emphasize the outcomes (or the processes of care that lead to these outcomes) that are most important to patients.^{8,9} Health measures, which quantify a patient's health status at a specific point in time, are an outcome that is important to patients and often their primary reason for seeking care. While the term "quality of life" is often used synonymously with health status, the Wilson-Cleary model considers quality of life to be only one domain of the broader concept of patient health status.¹⁰ Therefore, we use the term "health status" to include all domains in which disease impacts a patient's life.

It seems almost obvious that patients assign great importance to their health status. One prospective study evaluated whether patients preferred to maintain their current state of health or choose a shorter but healthier life. More than two-thirds of the respondents were willing to sacrifice some duration of survival in exchange for better health status.⁸ In another study of outpatients with heart failure (HF), over a quarter of patients were willing to give up half or more of their remaining life for perfect health.⁹ Such studies provide empirical support for the importance of optimizing patient health status and highlight how quality assessments that focus only on clinical events, such as mortality, fail to capture outcomes that are equally important, or even more so, to many patients.

QUANTIFYING PATIENT HEALTH STATUS

Types of Patient-Reported Outcomes

When promoting patient-centered care, it is necessary to measure health from the patient perspective. PROs are any reports of a patient's health status that come directly from the patient, without interpretation by a clinician or other healthcare providers.¹¹ Although digital technologies are introducing new measures of patient health status, PROs are traditionally questionnaires that ask the patient to describe their health status over a certain (recall) period of time.¹¹ Broadly, there are three categories of PRO measures: generic measures, disease-specific measures, and health-state utilities.

Generic PROs (eg, the Short Form [SF]-12 or SF-36, or the Patient-Reported Outcomes Measurement Information System [PROMIS])¹²⁻¹⁴ are designed to quantify the total impact of a patient's multiple health conditions on their overall physical and emotional function. The advantages of generic PROs are that they assess patients' overall health and can therefore be used to compare the health status of patients with different diseases. Since it can be difficult for patients to attribute which of several comorbidities limits their ability to walk or causes depressive feelings, there is a strong argument for measuring overall health status. For

clinical practice and quality assessment, however, there is often a desire to treat a specific condition; thus, more focused measures of how that disease impacts a patient's health status are needed.

Disease-specific PRO measures (eg, the Seattle Angina Questionnaire [SAQ] or Kansas City Cardiomyopathy Questionnaire [KCCQ])¹⁵⁻¹⁸ quantify the impact of a specific disease on a patient's health.¹⁹ Accordingly, they can measure a symptom of that disease (eg, angina for patients with coronary disease) that cannot be captured by a generic measure but may be a key treatment focus. Moreover, cardiologists and other specialists are often primarily responsible for managing one of a patient's diseases and would want their degree of quality to be judged by how well they manage diseases within their specialty. By measuring the manifestations of a specific disease, disease-specific PROs^{15-18,20-32} are often more sensitive to clinical changes and more interpretable, useful, and actionable in clinical practice.

Finally, the escalating costs of care require explicit efforts to define the value of each new intervention through cost-utility analyses. Thus, the third PRO type, health-state utilities (eg, the EQ-5D), is used to distill health status into a single number between 0 and 1 to support cost-utility analyses.³³⁻³⁶ Generic measures, such as the EQ-5D, have been developed to help apply societal-based utility weights to patient health outcomes to support economic assessments.³⁷ However, while the importance of incorporating patient health into cost-effectiveness analyses is unquestioned, these tools are not designed to support clinical care and are limited in measuring quality of care (which is why, to our knowledge, they have not been proposed as quality measures).

Psychometric Properties of Patient-Reported Outcomes

For a given PRO to accurately capture patient health status, certain psychometric properties need to be explicitly demonstrated. For instance, they must validly measure the concepts they are intended to measure, do so in a reliable fashion, and be sensitive to clinical change. Additionally, one of the most important features of a PRO is that it be clinically interpretable to clinicians and patients. This feature increases the PRO's usefulness in delivering care so that it can be used as a foundation for initiating and monitoring responses to treatment. Tables 1 and 2 provide an overview of the key psychometric properties needed for a PRO to be useful in delivering or measuring quality of care.³⁸

WHY PATIENT-REPORTED OUTCOMES ARE IDEAL QUALITY METRICS

There are several clinical and scientific arguments that can be made to support the use of PROs as tools for measuring

PSYCHOMETRIC PROPERTY	DESCRIPTION	EXAMPLES
Validity	When the designated measure clearly quantifies the concept it seeks to represent. There are different types of validity, including: content validity (the PRO measures all relevant concepts that are important to patients); face validity (the questions make sense and are capturing what is intended); criterion validity (the measure is associated with other measures, external to the questionnaire, that quantify the same concept); and predictive validity (the measure is associated with subsequent clinical events as would be expected by clinical logic).	<p>Example of content validity: Qualitative interviews with patients reveal that the concepts captured by the PRO align with the most common symptoms and impacts of the disease from patients' perspectives.</p> <p>Example of criterion validity: When assessing the physical limitations of a patient through a PRO, the score of the PRO appropriately matches with the limitations found within a 6-minute walk test.</p> <p>Example of predictive validity: When assessing the symptoms or physical limitations of a patient through a PRO, the score of the PRO appropriately matches logical subsequent clinical events.</p>
Reliability	Test-retest reliability demonstrates very comparable results in the PRO in patients whose condition has not changed. This is usually described by comparing mean scores using paired t-tests or intra-class correlation coefficients. Internal reliability or consistency describes the similarity of different items in measuring a conceptual domain, as quantified by Chronbach's alpha.	When a PRO has good test-retest reliability, the measure's scores are very similar when serially administered to patients who are stable between administrations (ie, the status/severity of their disease does not change).
Responsiveness/sensitivity	The opposite of reliability, a responsive PRO measure is one that changes directionally and proportionately to the magnitude of clinical change that a patient experiences.	A PRO for coronary artery disease should change substantially when a patient with Class III angina is rendered asymptomatic by coronary revascularization.
Interpretability	The ability to translate either cross-sectional or longitudinal scores on an instrument into a clinically interpretable construct that is meaningful to patients and providers.	<p>PROs are built on a scale that often ranges between 0 and 100 but is not intuitively familiar to patients, providers, or regulators. Defining the clinical importance of changes (or scores) is among the most difficult and important features of a PRO so that the impact of novel therapies or the quality of a patient's health status can be appreciated. For example, after an extensive series of studies examining the mean changes in KCCQ scores for patients (or their providers) who felt a small, moderate, or large clinical change had occurred, changes of 5, 10, and 20 points are considered to be small but clinically important, moderate to large, and large to very large clinical changes, respectively.</p> <p>As an example of the clinical interpretability of cross-sectional PRO assessments, SAQ Angina Frequency scores of 0-30, 31-60, 61-99, and 100 reflect daily, weekly, monthly, and no angina, respectively.³⁷</p>

Table 1.

Core psychometric properties of patient-reported outcomes. EQ-5D assessment: Europe Quality of Life 5-Dimensional assessment; KCCQ: Kansas City Cardiomyopathy Questionnaire; NYHA: New York Heart Association; SAQ: Seattle Angina Questionnaire; SF: short form

PSYCHOMETRIC PROPERTY	DESCRIPTION	EXAMPLES
Actionability	When information from the designated measure is useful in informing how to modify treatment.	While largely a consequence of the interpretability of a PRO, a key advantage of disease-specific PROs is that by directly measuring the severity of symptoms or limitations from a particular disease, there are often treatments that can be offered (or care escalated) for either severe symptoms/limitations or acute worsening. For example, worsening symptoms in heart failure might trigger better blood pressure control or more diuresis, whereas worsening angina might support more aggressive antianginal therapy or coronary revascularization.
Feasibility	To be practical to use in clinical care, it is essential that the PROs be as brief as possible while still maintaining the requisite psychometric properties outlined above.	Example(s): Efforts to reduce PROs—such as the SF-36 to 12 items, the SAQ from 19 to 7 items, or the KCCQ from 23 to 12 items—are intended to capture as much psychometrically sound information as possible in as few items as are necessary.

Table 2.

Additional psychometric properties of patient-reported outcomes supporting their use in routine clinical care. KCCQ: Kansas City Cardiomyopathy Questionnaire; SAQ: Seattle Angina Questionnaire; SF: short form

CARDIOVASCULAR DISEASE	EXAMPLES OF PATIENT-REPORTED OUTCOME
Atrial fibrillation	Atrial Fibrillation Effect on Quality-of-life (AFEQT), Atrial Fibrillation Quality of Life (AF-QoL) ²⁰⁻²²
Coronary artery disease	Seattle Angina Questionnaire (SAQ) ^{14,15}
Heart failure, cardiomyopathy	Kansas City Cardiomyopathy Questionnaire (KCCQ), ^{16,17} Minnesota Living with Heart Failure Questionnaire (MLWHFQ) ^{24,25}
Peripheral arterial disease	Peripheral Artery Questionnaire (PAQ), Vascular Quality of Life Questionnaire (VASCUQOL) ²⁶⁻²⁸
Stroke	Stroke Impact Scale, ³⁰ Stroke Specific Quality of Life Scale ²⁹⁻³¹

Table 3.

Examples of disease-specific patient-reported outcomes in cardiovascular disease.

healthcare quality. For example, PROs exist for a number of common cardiovascular diseases (CVDs), there is significant variation in patient health status between providers, better care can improve patients' health status, and PROs can be used not only to measure the quality of care but also to potentially help deliver (and improve) that care.

Psychometrically Sound PROs Exist for Several Cardiovascular Diseases

Table 3 provides an incomplete summary of psychometrically sound disease-specific PROs for a range of cardiovascular conditions.^{15-19,21-28,35,36} Although physicians' unfamiliarity with the scales and their interpretation presents a challenge to the widespread use of PROs,³⁹ greater experience in how to use them, particularly in clinical trials and practice, will overcome these obstacles.^{40,41}

Variability in Clinical Care and Consistency of PROs

Among the few reported assessments of disease-specific health status of patients in routine clinical practice, marked variability across providers has been documented. In the Coronary Artery Disease in General Practice (CADENCE) study of > 200 primary care practices in Australia, patients with known ischemic heart disease were asked to complete the SAQ at a regularly scheduled office visit, and the number of patients reporting daily/weekly angina (SAQ Angina Frequency score \geq 60) was compared across clinics. Although about 10% of clinics had no patients reporting such frequent angina, a similar proportion had over half of their patients report daily/weekly angina; furthermore, in eight practices, all patients reported daily/weekly angina. Importantly, physicians in the study thought that their patients' angina was much better controlled than what their patients reported in the PROs. Among the patients reporting weekly angina, approximately a quarter of their physicians graded their angina as Canadian Cardiovascular Society (CCS) Grade I, and half thought that the angina

was "optimally controlled."⁴² Although unproven, we believe that if physicians were held accountable for control of their patients' angina, they would be more diligent in taking patient histories and thereby intensify treatment to optimize their patients' health status.

A more recent study of outpatients with HF found similar variability in health status across providers. The Change the Management of Patients With Heart Failure (CHAMP-HF) registry assessed the health status of 3,494 HF patients across 140 US practices using the KCCQ. Using the highest range of scores (75-100) for either the KCCQ Symptom Frequency domain (arguably the most modifiable) and the KCCQ Overall Summary score, the proportion of patients with excellent health status varied greatly, with ranges of 8% to 82% and 0% to 77%, respectively. Even after adjusting for patient characteristics, the median odds ratio for good to excellent KCCQ Overall Summary scores was 1.70, suggesting an average 70% higher odds of a patient having excellent health status if treated at one random clinic compared with another.⁸ Both of these examples highlight the marked variability in the control of patients' health status—partly because PROs are not explicitly used to measure healthcare quality.

Of course, this variability can also exist across sociodemographic characteristics. The CHAMP-HF registry also noted differences in the health status of women versus men, Black versus White patients, and socioeconomically disadvantaged versus wealthier patients, even after adjusting for patient characteristics and the site of care.⁴³ Given the medical and cardiovascular profession's goal to eradicate such disparities,⁴⁴ routinely collecting PROs and using them as a foundation to quantify quality of care could potentially improve healthcare equity.

It is important to note that in both of these examples, the argument that the routine collection of PRO data will lead to improvements in patient health status is speculative

because PROs have not been used in quality assessment, and changes in care and patient health status have not been documented. Taking HF as an example, however, we believe that creating provider-level accountability for patient health status through a performance measure will provide a strong incentive to improve care. There are a number of treatments that can improve patient health status, including angiotensin receptor-neprilysin inhibitors,⁴⁵ sodium-glucose cotransporter-2 inhibitors,^{46,47} intravenous iron supplementation,⁴⁸ ivabradine,⁴⁹ and cardiac resynchronization.⁵⁰ However, these therapies with known health status benefits remain underused.⁵¹⁻⁵³ There appears to be a substantial opportunity to improve patient health status by increasing providers accountability for optimizing the health status of their patients.

Capability to Modify Health Status with Treatment

Although it is important to document variability, it is only useful as a quality measure if there are actions a provider can pursue to improve the health status of their patients. Then, and only then, would it be reasonable for providers to be accountable for their patients' health status. In another analysis from CHAMP-HF, Thomas et al. examined whether changes in patient medications were associated with improvements in their health status. In more than 3,300 outpatients with HF with reduced ejection fraction, the authors found that a significantly greater proportion of patients whose medications were adjusted had large improvements in their health status compared with those whose medications were not changed (26% vs 14%).⁵⁴ This study provides empirical evidence that physicians can improve their patients' health status by titrating medications and further supports the use of PROs as measures of healthcare quality.

Potential Advantages of Using PROs as Quality Measures—The Potential to Directly Improve Clinical Care

If PROs were used as quality measures and integrated into routine clinical practice, there are a number of potential, albeit unproven, advantages that could justify their use.⁵⁵ In fact, in 2014 we wrote about this potential and the requirements for PROs to become an integral component of clinical practice: PROs must be actionable, efficient, interpretable, obligatory, and user friendly.⁵⁶ Since that article, many of these requirements have been met for HF and coronary disease PROs, and efforts are underway in other disease-specific PROs for CVD.

One potential benefit of the routine use of PROs in practice is their ability to decrease interoperator variability and support population health management. In the Angina

Prevalence and Provider Evaluation of Angina Relief (APPEAR) study, 1,257 outpatients with coronary artery disease were screened across 25 cardiology practices using the SAQ.⁵⁷ A series of analyses demonstrated that there was marked discordance between doctors' and patients' assessments of the frequency of their angina,⁵⁸ that a substantial proportion of patients had their angina under recognized by their physician (and this was primarily associated with the doctor who saw the patient rather than any individual patient characteristics),⁵⁹ and that under-recognized angina was the strongest risk factor for not intensifying treatment.⁶⁰ These data suggest that the routine use of PROs in clinical care might avoid under-recognition of CVD symptoms and improve the treatment of patients to optimize their health status.

It is also possible that PROs could become the foundation for shared medical decision making. In fact, given the importance of health status outcomes to patients, it can be argued that PROs should serve as the foundation for selecting many invasive therapies. In the International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) trial, a population of 5,179 patients with stable coronary disease and moderate or severe reversible ischemia across 37 countries were randomized to either an invasive strategy of angiography and revascularization or a conservative strategy of medical and lifestyle interventions alone.⁶¹ The primary benefit of an invasive strategy was an improvement in patient health status, with a much greater probability of becoming angina-free.^{62,63} These benefits, however, were most strongly associated with patients' baseline health status as assessed by the SAQ.⁶¹ Quality of life outcomes from the ISCHEMIA trial demonstrate the probability of being angina free, or having good-to-excellent disease-specific health status, as a function of baseline SAQ Angina Frequency score.³⁸ Using the SAQ in clinical practice can help clinicians easily use these findings to provide patients with an evidence-based expectation of the benefits (eg, the probability of being angina free) of a particular management strategy.

In addition, PROs can be advantageous in telehealth triage and care. For example, one study on telemedicine demonstrated how a patient's health status can be improved when PROs are integrated into telehealth care.⁶⁴ In the era of the COVID-19 pandemic and its dramatic shift to virtual visits, deciding which patients could be treated remotely and which need an in-person evaluation can be difficult. Health systems need to develop new workflows and strategies to determine which type of visit is more appropriate. An untested strategy might be to have patients complete a PRO before their scheduled visit and use the results to triage patients. Patients with stable or improving health

status would be directed to telehealth visits and those with worsening health status would receive a clinic visit. Other triage strategies may be considered, but a PRO-based approach would be more consistent and potentially less time-consuming than directly calling patients to assess their status. Although such approaches warrant rigorous prospective evaluation, the urgency of responding to the pandemic warrants novel strategies for tailoring treatment to risk and exploring the use of PROs.

THE POTENTIAL FUTURE OF PATIENT-REPORTED OUTCOMES

The Future of Risk-Based Contracts in Healthcare Financing

Given the increasing pressures to transition from volume-based to value-based reimbursement, it is important to create methods to quantify the value of health care. To this end, the International Consortium for Health Outcomes Measurement (ICHOM) has developed value-based measurement sets for a broad range of diseases,⁶⁵ and the use of PROs is a core tenet of their vision for measuring value. As such, its cardiovascular measurement sets prominently include disease-specific PROs.¹⁵⁻¹⁸ Tools such as these create the platform for payers to use PROs in at-risk contracting, although the evolution of this process has been slow.³⁹ In risk-sharing contracts, the incentive to lower cost could create a financial incentive to avoid prescribing expensive therapies, such as coronary revascularization or biventricular pacemakers, as long as patient health status is good. Conversely, measuring the health status of patients covered by such a contract would create a strong incentive for using these treatments in appropriate patients.

Next Steps

Despite the potential for PROs to improve care, there are still barriers to using them as quality performance measures. For example, the 2020 American College of Cardiology/American Heart Association Clinical Performance and Quality Measures for Adults with Heart Failure proposed using PROs as quality measures rather than performance measures.⁶⁶ The critical reason for this was the lack of appropriate patient-level risk-adjustment models, which makes the development of such methodologies a key research priority to avoid incentivizing providers to minimize caring for the sickest patients.

Another barrier in the clinical use of PROs is the failure of electronic health records systems (including EPIC, Cerner, or AllScripts) to support PRO collection, scoring, and presentation of results in a clinically interpretable format. Addressing this problem would support PRO clinical use and data extraction for quality assessment or performance-based

contracting programs. Overcoming the barriers and supporting facilitators of PRO adoption could lead to more successful implementation of PROs in cardiovascular practices.

CONCLUSION

Patient-centered care requires tailoring treatments to each patient's specific needs. In addition to survival, one of the most important patient-centered goals is to improve a patient's health status: their symptoms, function, and quality of life. To improve patient-centered care and accurately measure patient health status, we propose increasing the use of PROs because they explicitly ask patients to describe their perspective of their own health status. In addition to serving as end points in clinical trials, PROs can play an important role in routine clinical care, population health management, and as a means for quantifying the quality of patient care. Given the wide variability in clinical care, PROs are a way to assess whether the chosen strategies have successfully optimized patients' health status. They have the potential to improve quality of care, reduce interoperator variability and health disparities, strengthen shared decision making, and be effectively implemented in the emerging era of telemedicine. Specifically, using PROs to enhance patient-centered care may provide a consistent means to measure and monitor health and wellbeing in patients with CVD.

KEY POINTS

- A primary treatment goal is to improve patients' health status, including their symptoms, function, and quality of life.
- Patient-reported outcomes (PROs), once demonstrated to be psychometrically sound, can quantify patients' health status from their perspectives.
- Psychometrically sound PROs exist for several cardiovascular diseases but are currently used primarily as outcomes in clinical trials.
- Numerous research studies have suggested the potential of PROs to improve the process of care, but this has rarely been tested prospectively.
- Because PROs can quantify an important outcome for patients, potentially improve the processes of care, and be modified by better treatment, they will likely become important quality measures to insure and reward higher-quality health care.

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Keywords:

patient-centered care; health status; patient-reported outcomes; psychometric properties; performance measures; quality measures

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