NATIONAL QUALITY FORUM
Driving measurable health improvements together

Building a Roadmap From Patient-Reported Outcome Measures to Patient-Reported Outcome Performance Measures

Developer Feedback Report – Draft 2

May 12, 2022

This report is funded by the Centers for Medicare & Medicaid Services under contract HHSM-500-2017-00060I – 75FCMC20F0003.

Contents

Executive Summary

For more than 10 years, the National Quality Forum (NQF) and the Centers for Medicare & Medicaid Services (CMS) have partnered to elevate patient voices in outcome measurement. The decade-long collaboration to advance patient-reported outcomes (PROs) has increased the presence of the patient voice in quality measurement. However, patient-reported outcome performance measures (PRO-PMs) make up less than 7 percent of all NQF-endorsed quality measures, and few NQF-endorsed PRO-PMs are used in national reporting programs. Opportunities exist to increase the number of PRO-PMs that can be used in CMS value-based purchasing (VBP) programs or alternative payment models (APMs).

CMS works closely with experts to prioritize the development of measures that address measurement gaps.[1] In recent years, measure developers have expressed concerns to CMS about the lack of detailed technical guidance on developing PRO-PMs. Because of its goals to reduce measurement burden and commit to interoperable digital data, CMS is committed to providing guidance on the development of "digital" PRO-PMs (i.e., PRO-PMs that can be captured and transmitted electronically via interoperable systems).[2,3] CMS funded NQF to develop this guidance through the two-year initiative titled Building a Roadmap From Patient-Reported Outcome Measures to Patient-Reported Outcome Performance Measures (henceforth referred to as *Building a Roadmap*). This project seeks to provide guidance on developing PRO-PMs that utilize data from high quality patient-reported outcome measures (PROMs), are suitable for use in CMS' VBP programs and APMs, and can be calculated and transmitted electronically.

The purpose of this Developer Feedback Report is to capture and synthesize critical feedback from measure developers and other measurement experts on how to improve the Building a Roadmap Technical Guidance.

The Building a Roadmap initiative includes four reports:

- **The Environmental Scan Report** identifies and summarizes existing information relevant to the use of PROMs as the basis for high quality digital PRO-PMs in accountability programs. It provides background for the other Building a Roadmap documents.
- **The Interim Report** guides measure developers on identifying and selecting PROMs that are suitable data collection instruments for high quality digital PRO-PMs.
- **The Technical Guidance Report (henceforth referred to as *the Roadmap*)** describes a series of stages and tasks that measure developers can follow when developing and testing digital PRO-PMs; the Roadmap was published in November 2021 and will be updated in November 2022.
- **The Developer Feedback Report** identifies recommendations from measure developers and other key audience members on improving the Roadmap.

Developer feedback is critical to improving the Roadmap. NQF performed a series of structured key informant interviews (KIIs) with experts in the field of measure development and health information technology (IT) who read the November 2021 version of the Roadmap and shared ideas on how it can be improved (Appendix B). NQF staff interviewed each expert, then synthesized the feedback into recommendations that will inform the updated Roadmap. NQF staff grouped the recommendations into three categories based on how many interviewees raised each recommendation (i.e., five or more, two to four, or only one):

Recommendations raised by five or more interviewees:

- Strengthen the Overall Structure of the Roadmap: Interviewees identified opportunities to improve the structure of the Roadmap, as well as aspects of the report that should *not* change.
- Provide Improved Guidance on Digital Measurement: The experts offered suggestions on how the Roadmap can provide meaningful guidance on digital quality measures (dQMs) (i.e., software that processes digital data to produce a measure score or measure scores)[4], including PRO-PMs.
- Discuss Issues Related to Burden and Workflow: KIIs highlighted the need to include information about the patient burden of completing PROMs, clinician burden of PROM-related workflows, and the challenges of finding test sites to implement workflows for unproven measures.
- Explain Trade-offs in Data Collection Strategies for a PRO-PM: Interviewees offered recommendations to improve how the Roadmap presents trade-offs of using a single PROM to collect data for PRO-PMs versus using many different PROMs.

Recommendations identified by two to four interviewees:

- Describe Opportunities to Engage Patients: Several interviewees emphasized that the Roadmap should describe ways for measure developers to engage patient members of the stakeholder advisory group at every stage of the development process.
- Identify and Address Health Equity Issues: KIIs included discussions on how the Roadmap might provide guidance on proactively identifying and addressing equity issues related to PRO-PMs.
- Address Low Response Rates and Response Bias: Interviewees observed that the Roadmap could include more detail on how response rates and response bias can affect PRO-PM development.
- Discuss the Timing of PROM Data Collection: Experts suggested that the Roadmap should explicitly address the impact of PROM data collection intervals on PRO-PM development.

Additionally, this report includes five notable recommendations that warrant consideration from the Building a Roadmap initiative Technical Expert Panel (TEP), even though only one interviewee raised each recommendation.

Although the Developer Feedback Report will be made available to the public, its purpose is to provide end-user input to the TEP, federal liaisons, CMS, and NQF staff who will participate in the completion of final PRO-PM Roadmap Technical Guidance. This audience includes members of the TEP who will guide the improvements to the Roadmap and the federal liaisons who ensure the perspectives of diverse federal agencies are accurately represented (Appendix C). Core audience members also include CMS employees and NQF staff who aim to ensure the Building a Roadmap initiative achieves its intended purpose.

The Building a Roadmap initiative is relevant to the development of both traditional and digital PRO-PMs. At the recommendation of NQF, CMS, and the TEP, the Building a Roadmap initiative focuses on PROs (specifically health-related quality of life [HRQoL], functional status, and symptoms and symptom burden) as distinct from the experience of care measures. Most interviewees who participated in the KIIs supported this focus.

Additional materials related to this initiative, including reports and summaries of TEP meetings, are available on the Building a Roadmap project page.

Introduction

Effective healthcare quality measurement must include the patient voice. PRO-PMs facilitate the measurement of what matters to patients, using data that patients provide. NQF and CMS share a commitment to increasing the use of PRO-PMs for both quality improvement and accountability. However, PRO-PMs are challenging to develop and test, and PRO-PM developers do not have extensive guidance resources. The complexity of PRO-PMs is exacerbated by the shift to digital quality measurement, a field that is rapidly changing as technology and standards evolve.[5] These challenges are reflected in the fact that only 7 percent of all NQF measures are PRO-PMs.[6]

The purpose of this Developer Feedback Report is to capture and synthesize critical feedback on the successes and shortcomings of the November 2021 version of the Roadmap to inform a revised edition of the document.

Methodology

NQF prepared the Developer Feedback Report by performing KIIs with measure developers who possess varying amounts of development experience and represent a diverse mix of organizations. The intent of the KIIs is to obtain feedback on the strengths and limitations of the November 2021 version of the Roadmap, along with recommendations for updating it.

To identify candidate interviewees, NQF sought recommendations from CMS staff, NQF staff involved with the Consensus Development Process (CDP) and measure maintenance, and the co-chairs of the Building a Roadmap TEP. In addition to measure developers, NQF included health IT experts and patients as candidates for the interviews. NQF also included TEP members and federal liaisons with specialized knowledge or experience.

NQF selected nine individuals who work for private or not-for-profit organizations to participate in structured interviews using a standardized questionnaire (Appendix D). All the individuals who were invited to be interviewed agreed to participate. The selection criteria included the following:

- Years of experience as a measure developer
- Organizational affiliation
- Experience with digital measurement and/or digital PRO-PM development
- Experience with PRO-PM development
- Area of specialization (e.g., informaticist or psychometrician)
- Recent participation in the NQF CDP (endorsement results were not considered)
- Ability to represent a patient and/or health IT perspective

NQF identified three federal employees with specific knowledge of issues related to federal agencies' work with PROMs, PRO-PMs, and digital measurement, including the Patient-Reported Outcomes Measurement Information System (PROMIS), the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE), the United States Core Data for Interoperability

(USCDI), Fast Healthcare Interoperability Resources (FHIR), and other tools and technologies that have been developed and/or championed by the federal government. NQF used a separate, tailored questionnaire for this group (Appendix E). In addition, NQF took steps to ensure the federal employees could be interviewed without violating either the original CMS contract or the Paperwork Reduction Act of 1980 and worked closely with CMS staff to comply with all appropriate rules and regulations.

The two interview guides (Appendix D and Appendix E) include a statement of purpose for the Building a Roadmap initiative, a description of the KIIs and how interviewees are identified, an introduction to the interview process, an example of a script that NQF will follow while conducting the interviews, and a set of potential discussion questions for interviewees to consider (e.g., questions about the structure of the Roadmap as well as guidance on PROM selection, digital measurement, and PRO-PM development). NQF staff asked each interviewee to review the Roadmap before the interview and explained that the interview would include time to discuss improvement opportunities or other observations. (Because the guidance within the Interim Report is a detailed description of the work that occurs during stage 2 of the Roadmap, NQF also gave interviewees the opportunity to share feedback on the Interim Report.)

The interviews occurred between Wednesday, February 16 and Tuesday, April 5, 2022. Each interview was scheduled for a one-hour time slot, but one interview ended after 30 minutes due to an unplanned conflict within the interviewee's schedule. All interviews were performed using a web-based video meeting platform. NQF talked with one expert per interview, with a single exception in which NQF interviewed two federal liaisons from the same organization together. As a result, a total of 11 interviews were conducted with 12 experts. Every interview was recorded, and NQF analyzed each recording to identify the priority themes that are presented in this Developer Feedback Report.

Developer Feedback

The information from the KIIs reflected both enthusiasm for the guidance offered in the Roadmap and a robust set of improvement opportunities. Interviewees supported both the purpose and the structure of the document. The experts found the use of stages and tasks (described below) to be clear, effective, and intuitive. Improvement opportunities for the Roadmap focused on providing concrete advice that better assists developers with addressing barriers to PRO-PM development.

Federal employees and those experts who work for private or not-for-profit organizations did not present any notable differences in perspective.

The feedback from the KIIs is grouped into three categories based on how frequently the topic arose during the interviews:

- **Recommendations raised by five or more interviewees**
- **Recommendations identified by two to four interviewees**
- **Notable recommendations raised by only one interviewee**

Recommendations Raised by Five or More Interviewees

The first category contains four recommendations that emerged in at least five of the 11 KIIs, indicating that the TEP and NQF should strongly consider how to improve the guidance in the corresponding areas of the Roadmap:

- Strengthen the overall structure of the Roadmap
- Provide improved guidance on digital measurement
- Discuss issues with burden and workflow
- Explain trade-offs in data collection strategies for a PRO-PM

Strengthen the Overall Structure of the Roadmap

Both groups of KIIs addressed the structure of the Roadmap. Interviewees' responses included components of the Roadmap that should *not* be changed or removed in future versions of the document (i.e., Roadmap Strengths), a proposal for adding one new task to the Roadmap (i.e., Suggested New Task), and suggestions for modifications to improve the Roadmap (i.e., Updates to Existing Tasks).

Roadmap Strengths

Interviewees favored the report's use of stages and tasks to communicate the development process for a PRO-PM. Interviewees supported the report's articulation of four specific stages in the Roadmap (represented as columns in Figure 1). Interviewees understood that tasks (represented as the dark-colored boxes in Figure 1) could occur at multiple stages. The interviewees also understood that the Roadmap does not attempt to offer a prescriptive approach to measure development and said it succeeds in presenting the steps of PRO-PM development in a flexible way. The graphical representation of the structure received positive comments, and no interviewers suggested comprehensive changes to how the Roadmap is visualized.

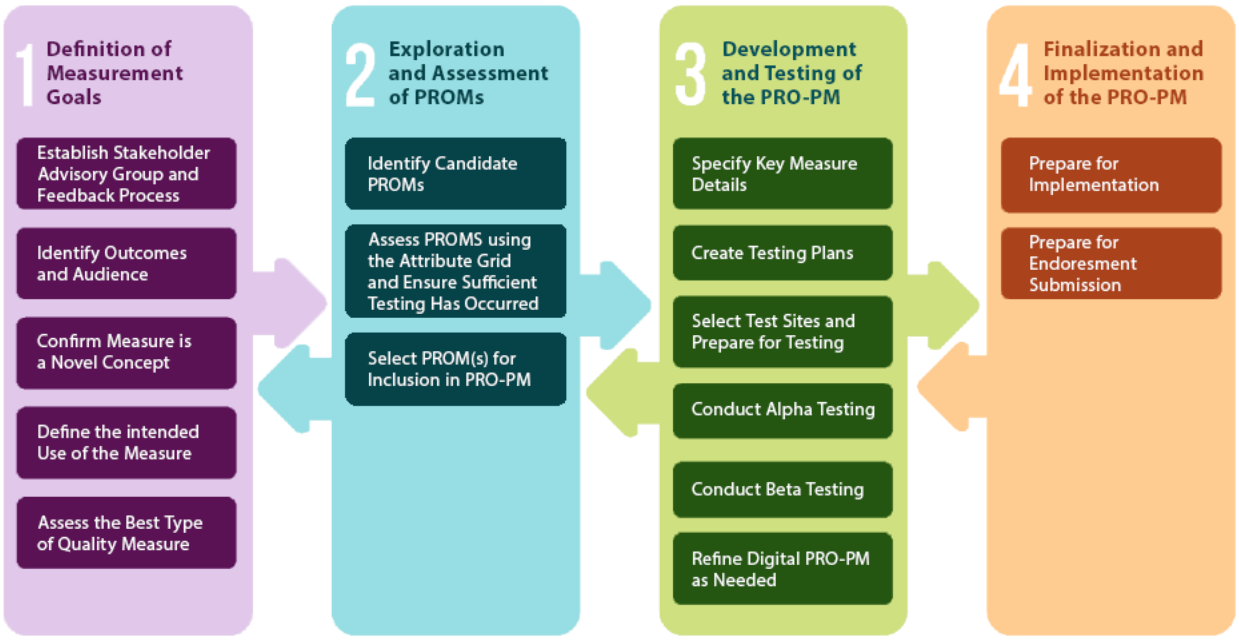

Figure 1. The visualization of the stages and tasks published in the November 2021 Roadmap. Each column contains one stage, and the bidirectional arrows indicate that tasks can move freely and be iterated across stages based on the needs, preferences, and protocols of measure developers and organizations.

Foundational literature identified five categories of PROs: HRQoL, functional status, symptoms and symptom burden, health behaviors, and patient experience.[7] Most interviewees agreed with the decision made by NQF, CMS, and the TEP to focus only on HRQoL, functional status, and symptoms and symptom burden. While one interviewee emphasized that patient experience should be included in the

report, others expressed that the different methodologies for collecting and analyzing patient experience data justified the Roadmap's focus.

Improvement opportunities related to the structure of the report revolved around two overarching themes: one suggested new task and the addition of supplemental details within existing tasks. A description of each follows below.

Suggested New Task

The experts identified one new task that NQF and the TEP should consider adding to the Roadmap.

Proposed New Task (Stage 1): Resources and Related Reading. Most of the interviewees favored providing additional content on complex technical topics in the Roadmap by adding links to "source of truth" documents (i.e., documents that are developed and maintained by organizations with expertise on specific aspects of measure development, such as the CMS Measures Management System Blueprint [henceforth referred to as the *CMS Blueprint*] and the NQF Measure Evaluation Criteria). NQF and the TEP can add these resources as a new stage 1 task focused on resources and related reading, as links scattered at relevant points throughout the document, or as a combination of the two. Interviewees identified three advantages of linking to these resources rather than incorporating the content in the text:

1. Ensuring the Roadmap is "evergreen" and that its recommendations remain relevant as technologies evolve and processes change
2. Deferring to official documentation from expert sources
3. Presenting information in the Roadmap in a way that does not overwhelm measure developers, particularly those who are new to the field or are working on their first PRO-PM

Interviewees said the Roadmap's level of detail on technical topics (particularly those addressed within stage 3) is appropriate for a guidance document and that adding detail on these topics could create a barrier to learning about PRO-PM development. Interviewees advised that, where possible, the Roadmap should link to organizational websites or publication webpages rather than specific versions of a report (e.g., link to the webpage for the CMS Blueprint instead of to the PDF for version 17 of the Blueprint). A partial list of primary resources that interviewees recommend during the KIIs includes the following:

- NQF publications related to PROs and PRO-PM development, along with the 2015 update by David Cella et al titled Patient-Reported Outcomes in Performance Measurement
- NQF information about the CDP, including the CDP homepage, the Measure Evaluation Criteria webpage, the Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement, and the Measure Developer Guidebook for Submitting Measures to NQF.
- NQF reports on pertinent areas of measure development, such as the Best Practices for Developing and Testing Risk Adjustment Models and Attribution reports from 2016 and 2021, respectively.
- The CMS Blueprint and pertinent supplements, including the Supplement on Patient-Reported Outcome Measures and the Supplement on Risk Adjustment in Quality Measures; although the Contractual Edition of the CMS Blueprint is not available to the public, the Roadmap should mention it as well

- CMS documents on digital quality measurement, if available
- CMS explanations of Qualified Clinical Data Registries (QCDR)
- The eCQI Resource Center website, including direct links to pages on electronic clinical quality measures (eCQMs), digital quality measures (dQMs), and Clinical Quality Language (CQL).
- The FHIR website, the Implementation Guide Registry, and the FHIR Confluence site
- Health Level Seven International (HL7) implementation guides
- The Office of the National Coordinator for Health Information Technology (ONC) USCDI website, which contains information about and links to current and previous versions of USCDI standards
- The ONC USCDI+ website, which describes the initiative and provides links to additional resources

Updates to Existing Tasks

The interviewees supported the report's presentation of existing tasks and did not flag any of the 16 tasks in the November 2021 version of the Roadmap for removal or deletion. However, the interviewees did share several opportunities for improving the write-up of the 16 tasks.

All Stages and Tasks: Add Time Frame Expectations. Several experts mentioned their surprise at how much longer certain tasks take for PRO-PMs than for other types of quality measures. One example that was raised during several KIIs was the long and sometimes unpredictable timeline regarding alpha and beta testing, which can take six to 12 months or even longer for a PRO-PM. A second example highlighted the NQF Intent to Submit process as an activity that took more time than developers expected. Because of the inherent complexity of PRO-PM development, interviewees suggested that the TEP identify and add time frames to each task so that measure developers can better understand the expected level of effort before embarking on a project.

All Stages and Tasks: Add Meaningful Examples. Several interviewees suggested that NQF and the TEP provide examples of how certain tasks in the Roadmap could be executed. Common examples in the interviews include providing samples that compare human-readable specifications to digital specifications and giving specific examples of how to meaningfully engage patient members of the stakeholder advisory group throughout the PRO-PM development cycle.

Stage 1: Add Specific PRO-PM Considerations. While the interviewees supported the tasks in stage 1, much of the information in the early tasks of the Roadmap is relevant but not specific to PRO-PMs. Interviewees commented that the Roadmap misses an opportunity to prepare measure developers for unique challenges related to PRO-PMs and possible mitigation strategies. One example that emerged during interviews is the importance of developing plans to ensure an adequate number of patients complete PROMs and preparing contingency plans in case of low response rates during testing. Unlike traditional outcome measures, which depend on data that are captured during routine clinical care (e.g., lab values and test results), PRO-PMs are dependent on the active participation of patients in voluntarily completing questionnaires. Insufficient response rates can delay or derail the testing process, which can put an entire PRO-PM development cycle at risk. Another example of early work that is unique to PRO-PMs is identifying hospitals with existing operational and electronic health record (EHR) workflows related to the desired PRO.

Stage 1: Include Rural Perspectives in the Stakeholder Advisory Group. Healthcare facilities in rural locations face quality measurement barriers that do not typically affect urban, suburban, or exurban

facilities. Challenges include low volumes of patients that lead to small measure denominators, inadequate technological infrastructure that limits access to digital services, and resource constraints that affect the organizational impact in health IT systems and trained quality improvement professionals. The TEP should consider highlighting the importance of including rural perspectives on the stakeholder advisory group and should explicitly mention any other critical perspectives.

Stage 1: Clarify Measure Concept Expectations. Stage 1 should explicitly state the importance of creating the measure concept and the expectations that accompany this work. This likely fits within the stage 1 task titled Identify Outcomes and Audience, but the TEP should consider where this work occurs, what is involved, and whether it warrants the creation of a separate task.

Stage 1 and/or Stage 2: Engage PROM Developers. The Roadmap does not adequately emphasize the importance of facilitating active engagement and collaboration between PROM developers and PRO-PM developers. The KIIs highlighted the importance of engaging the PROM developer in the work related to developing the PRO-PM, including the possibility of including PROM developers on the stakeholder advisory group. Interviewees highlighted examples of collaborative opportunities, such as educating PROM developers on the importance of Logical Observation Identifiers, Names, and Codes (LOINC) codes, identifying situations in which licensing fees might be waived, testing PROMs in different care settings, and identifying language barriers and validated translations of PROMs. One interviewee noted an historic divide between PROM developers and measure developers and recognized the Roadmap's opportunity to bridge this gap.

Stage 2: Add Examples and Guidance for Assessing, Requesting, and Using LOINC Codes in PROMs and PRO-PMs: The interviewees noted the need for specific guidance on how to assess the presence of LOINC codes in PROMs; determine whether multiple competing codes exist for an instrument, its questions, and/or its scores; apply for codes; and use the codes in the specification of the PRO-PM. To remain aligned with the suggested new task in stage 1, the TEP should consider whether this level of detail exists in an external "source of truth" document to which the Roadmap can link.

Stage 3: Add Side-by-Side Comparison of Traditional and Digital PRO-PM Specifications. As discussed previously, the interviewees identified several areas of the Roadmap in which examples would be beneficial. One recurrent theme in this discussion was that many measure developers do not understand the difference between traditional and digital specifications and would benefit from side-by-side examples that show how the same information is presented in human- and machine-readable specifications. The interviewees recognized that this might not be feasible due to the complexity and length of digital specifications; even so, several experts asked the TEP to consider this recommendation and explore how side-by-side examples might be featured in the Roadmap. One interviewee suggested that the TEP and/or NQF compare small but meaningful portions of specifications.

Stage 3: Include PRO-PM Specific Information on Alpha and Beta Testing. The KIIs emphasized that testing PRO-PMs is very different than testing other types of quality measures, but the guidance in stage 3 does not explicitly describe these differences or offer guidance on how to overcome them. Interviewees provided examples that include building PROMs in the test sites' EHRs, implementing PROM-specific workflows and training staff on how to accomplish them, educating patients on PROMs (particularly important if a test site has not previously used PROMs), and addressing contingency plans to minimize nonresponse. Several expert interviewees also noted the challenges related to identifying

sites that are willing to test PRO-PMs that have not received NQF endorsement or approval for use in federal programs; they requested specific guidance on overcoming this barrier.

Stage 3 and Stage 4: Reduce Redundancies With Source-of-Truth CDP Documentation. The Suggested New Task subsection summarizes the interviewees' recommendation that NQF should rely on links to external source-of-truth documents. This improvement opportunity is particularly evident in stage 3 and stage 4 of the Roadmap, which offer detailed summaries of NQF's CDP documentation. The expert interviewees requested that specific PRO-PM information about the CDP be included in these stages.

Stage 4: Include Guidance on Preparing for Measure Maintenance. The Roadmap currently offers only one sentence about preparing for measure maintenance. Expert interviewees recommended offering either more detail about preparing for maintenance (with a specific focus on maintenance of PRO-PMs) or links to relevant NQF documentation.

Stage 4: Include Information on the Purpose and Importance of NQF Endorsement. In the final task of stage 4, "Prepare for Endorsement Submission," the interviewees recommended adding a brief explanation of why NQF endorsement is important. Although the Roadmap highlights scientific acceptability in stage 3, the TEP might consider repeating a brief summary of its importance here, along with any other considerations and benefits of NQF endorsement.

Stage 4: Add Guidance on the NQF Intent to Submit. The Roadmap does not currently address the NQF Intent to Submit process. Given the time involved in this step of the endorsement process, interviewees suggested that the TEP include this in the task titled "Prepare for Endorsement Submission," along with any guidance specific to PRO-PMs.

Provide Improved Guidance on Digital Measurement

When the first version of the Roadmap was published in November 2021, NQF, CMS, and the TEP agreed on the need for improved guidance on digital measurement. The KIIs confirmed this stance and outlined several improvement opportunities:

- **Define and differentiate dQMs and eCQMs:** The TEP prioritized this improvement for the updated Environmental Scan Report, and updated information from the scan should be referenced or included in the Roadmap, as is appropriate. Interviewees asked for clearer discussion on the fact that eCQMs are a subset of dQMs that represent the current state of electronic measurement but are not the future state, along with a corresponding explanation that the future state of dQMs will entail a richer source of data from multiple inputs (e.g., claims data). A few interviews highlighted the importance of addressing novel forms of data, such as wearable devices and instruments.
- **Emphasize digital technology earlier and more consistently:** Although this feedback only emerged in a few interviews, it reflects comments made by TEP members that digital measurement should be established as a theme early in the Roadmap and maintained throughout. Interviewees suggested ideas that included callouts or examples offering side-by-side comparisons of traditional and digital PRO-PM elements and content within each task that explicitly addresses the steps taken for digital measures; however, some developers noted during their interviews that most steps within each task do not significantly differ between

traditional and digital measures and that the latter approach is less practical than it theoretically seems.

- **Explain and describe the use of digital technologies:** The Roadmap should include improved explanations of dQMs, FHIR, USCDI, and USCDI+, along with links to corresponding "sources of truth." Interviewees suggested that information on applying these technologies to digital PRO-PMs is more important than definitions.
- **Discuss interoperability standards:** While overlapping with the previous point on digital technologies, interviewees emphasized the importance of using data in a standardized way that is compliant with ONC's Health IT Certification Program and CMS' reporting program requirements and supports data sharing across the ecosystem.[8]
- **Offer guidance on translating measures to digital:** NQF should consider including guidance on how to convert existing measures to digital, but interviewees acknowledged that this is so novel that NQF and the TEP might not be able to provide accurate and timely evidence on the topic. However, even conceptual guidance could be beneficial, including the practice of seeking data sources beyond the EHR and the importance of not simply digitizing a paper specification but fully reconsidering how a digital version of a paper measure can improve its reliability, address care gaps, reduce burden, and incorporate more effective risk adjustment models or stratification by clinical or social risk.
- **Give specific examples of digital measure specifications:** Multiple developers said the Roadmap's description of digital measure specifications is at too high of a level and misses an opportunity to "connect the dots" for its audience. In addition to side-by-side comparisons of traditional and digital specs described elsewhere in this report, one interviewee suggested a use case on how to answer specific measurement questions using a digital spec.
- **Address trade-offs with digital modes of PROM administration and methods of data collection:** The existing Roadmap only discusses modes and methods as they refer to the development and testing of PRO-PMs in stage 3. Several interviewees pointed out the opportunities and barriers related to administering and collecting PROMs digitally and felt this should be addressed during stage 1 and/or stage 2 tasks or in the early sections that summarize environmental scan findings and recommendations from the Interim Report.
- **Discuss privacy and security:** The Roadmap should offer information and guidance on privacy and security implications of digital measurement, including sharing Health Insurance Portability and Accountability Act (HIPAA)-protected Protected Health Information (PHI) across health IT systems and incorporating privacy and security into measure specifications.
- **Represent diverse health technology systems, not just EHRs:** Several interviewees flagged the focus on EHRs throughout the Roadmap as both a limitation and an inaccuracy. Developers who are referencing the Roadmap as a guidance tool need an overview of key data sources beyond the EHR (e.g., health information exchanges [HIEs], qualified clinical data registries [QCDRs], patient portals, wearable devices, remote monitoring devices, patient symptom trackers and other apps, and claims data). Additionally, the developers recommended exploring novel ways in which diverse data sources (e.g., HIEs) could help to reduce challenges related to testing and identifying test sites.
- **Remove discussion of outdated standards:** Interviewees recommended that either discussions of Quality Data Model (QDM) and Bonnie should be removed or that wording regarding these discussions be "softer" (e.g., "a tool like Bonnie" or "a synthetic data tool").

- **Consider inclusion of case studies/promising practices:** Interviewees flagged examples of excellence that could benefit readers of the Roadmap. Examples include National Committee for Quality Assurance's (NCQA) work on digital PRO-PMs and/or Minnesota's use of a statewide data warehouse in which quality measure specifications will be centrally applied (thus reducing measurement burden).

Discuss Issues Related to Burden and Workflow

Nearly every interviewee commented on how the Roadmap presents information related to measurement burden (from both the clinician and patient perspectives) and clinical workflows related to PROM administration and data use. These comments span two major areas of the Roadmap: stage 2 (Exploration and Assessment of PROMs) and stage 3 (Development and Testing of the PRO-PM).

- **Stage 2 Recommendations:** In light of CMS' commitment to using PROs to elevate patients' voices, interviewees suggested that the Roadmap should acknowledge both clinician and patient burden related to data collection while presenting them as both novel and positive. One approach is to expand the Roadmap's guidance on PROMs that minimize patient burden (e.g., short forms or computerized adaptive testing [CAT]). Another recommendation is to discuss the opportunity to reduce clinical burden by weighing the benefits of licensed versus unlicensed PROMs (i.e., PROMs that clinicians or health systems must pay to use, as opposed to those that are available for no cost), PROMs that include LOINC codes, and PROMs that are already built into EHR systems. While many of these topics are addressed in the Environmental Scan Report and the Interim Report, as well as NQF's 2020 report on Best Practices on Selection and Data Collection, they are not explicitly discussed in the Roadmap; at minimum, links to the above reports might be beneficial.
- **Stage 3 Recommendations:** Several interviewees discussed challenges with identifying and securing test sites that are willing to address the workflow redesign and the patient/staff burden of PROM administration for a measure that is not endorsed by NQF or used by CMS in federal quality programs. NQF and the TEP should consider adding guidance to the Roadmap that helps measure developers overcome this barrier, although no specific examples emerged during the interviews.

Explain Trade-offs in Data Collection Strategies for a PRO-PM

The Roadmap contains a summary of pertinent environmental scan findings, including a discussion on the trade-offs of using one PROM or multiple different PROMs to collect data for a single PRO-PM. Nearly every interviewee had an opinion on this topic, although there was no consensus among this group of experts. While the viewpoints they expressed are consistent with what is already written in the report, a few people did recommend moving this from the *Environmental Scan Findings* section so that it is discussed within stage 1 or 2. These individuals felt that the discussion on this decision is critical to the early stages of developing a PRO-PM and that the topic warrants more visibility in the report. It could be added as a discrete task or folded into another task. Interviewees recommended explicitly addressing pertinent issues in the Roadmap (e.g., identifying crosswalks, aligning scores and cut points of different tools, and ensuring different tools comparably capture the same PROs).

Recommendations Identified by Two to Four Interviewees

The second category of recommendations are those that emerged during two to four KIIs. While these recommendations do not have the ubiquity of the previous category, they were raised by multiple experts and highlight important issues that are not always at the forefront of conversations regarding PRO-PM development. The TEP and NQF should carefully consider how to better address and integrate the following recommendations within the Roadmap:

- Describe opportunities to engage patients
- Identify and address health equity issues
- Address low response rates and response bias
- Discuss the timing of PROM data collection

Describe Opportunities to Engage Patients

A few interviewees noted the lack of clear guidance in the Roadmap on how to engage patients throughout the PRO-PM development process. These experts offered solutions that include expanding the role of the patient advisors in stage 2 activities regarding PROM selection and timing of data collection, actively engaging patients in designing workflows at test sites in stage 3 and during the stage 4 implementation guidance, and creating patient-specific workgroups that meet separately from the larger stakeholder advisory group and report back to the larger advisory body. The Roadmap should encourage measure developers not to approach patients with the bias or assumption that the material is too complex for them to understand but rather to present information and decision points in a nontechnical manner so that patients can offer meaningful input.

Identify and Address Health Equity Issues

Only a small number of interviewees directly raised issues of health equity, but it is an issue that NQF and the TEP should consider as they prioritize improvements to the Roadmap. The suggestions from the KIIs included expanding language in the measure design portion of stage 1 to explain inequitable differences in care and how to identify them; looking beyond race and ethnicity to also consider how factors such as gender, weight, and comorbidities are reflected in PROs; challenges of capturing and addressing social risk factors due to limitations in coded data (e.g., LOINC, International Classification of Diseases, 10th Revision [ICD-10]); and the impact of the digital divide (i.e., when promising health IT solutions adopted, are available to, or used by vulnerable populations) on data collection.[9] The Roadmap should discuss both novel and historically rejected approaches (e.g., interactive voice response systems [IVRS]) to data collection as ways to ensure the inclusion of patients who are affected by the digital divide. The Roadmap should also consider addressing equity issues related to older adults and those with cognitive disabilities.

Address Low Response Rates and Response Bias

Interviewees raised the Roadmap's discussion of response rates as the topic pertains to specific stages:

- Stage 1: the need for an initial understanding of why response rates are uniquely important to PRO-PMs
- Stage 3: the implications of poor response rates on testing
- Stage 4: the implications of poor response rates on implementation and accountability (e.g., low response can be an indicator of poor physician performance and poor outcomes, or it can be an

indication of high performance and outcomes because patients are thriving and do not feel the need to follow up)

One potential approach to addressing these recommendations is to add to stage 1 how response rates and response bias are unique to PRO-PMs. Unlike other quality measures, PRO-PMs are not based on clinical data and cannot be completed with existing data. This addition should address the importance of creating both strategies to ensure adequate patient response rate during testing and risk mitigation plans if those strategies are not successful. By addressing response rates in stage 1, developers will be more prepared for stage 3 testing.

Discuss the Timing of PROM Data Collection

This topic addresses how the intervals at which PROM data are collected can impact patient burden, clinical workflows, response rate, and overall measure success. The timing of PROM data collection affects early-stage activities, such as building relationships with PROM developers, engaging patient members of the stakeholder advisory group, and planning for response rate. By addressing this topic in stage 1, developers will be better positioned to consider PROM data collection during the definition of the measure specification and preparation for testing.

Notable Recommendations Raised by Only One Interviewee

Several notable recommendations to improve the Roadmap emerged during only one interview. Although each recommendation was only raised once, the TEP should consider whether and how to address each topic in the Roadmap. Notable recommendations included the following:

- Establish new terminology to reframe PROMs as instruments, not measures
- Address proxies
- Rewrite language with unintended interpretation
- Further differentiate between experience and outcomes
- Promote the benefits of PRO-PMs

Establish New Terminology to Reframe PROMs as Instruments, Not Measures

Stakeholders across the healthcare industry use confusing language to describe PROs, PROMs, and PRO-PMs. One interviewee specifically stated that PROMs are not measures and should be referred to as questionnaires, tools, or instruments. The interviewee expressed concern that confusing and inaccurate terminology could be a contributing factor to the slow adoption of PROMs and PRO-PMs and suggested that NQF use the Roadmap as an opportunity to propose a new and more accurate acronym, such as patient-reported outcome instruments (PROIs).

Address Proxies

One interviewee noted challenges related to proxies (i.e., one person completing a PROM on behalf of another person), such as when a parent completes PROMs on behalf of an adolescent, or a caregiver submits a questionnaire for a cognitively impaired patient. This interviewee suggested that the TEP should consider adding information about proxies in the Roadmap and determine whether this information fits best within an existing task or requires the creation of a new task.

Rewrite Language With Unintended Interpretation

One measure development expert highlighted a sentence in the Roadmap that could be interpreted in a manner that encourages stakeholders to collect patient-reported data in unorthodox ways when validated questionnaires, modes, and/or methods are difficult to administer. The interviewee encouraged NQF to rewrite this sentence, which begins at the bottom of page 19 and reads, "The current state of PROM data collection can create feasibility challenges, but the measure developer can mitigate these risks by using the Attribute Grid to identify high quality PROMs with LOINC codes and an evidence base that supports successful data collection in the relevant setting from the specified patient population." The TEP and NQF should review the Roadmap for other instances of unclear language.

Further Differentiate Between Experience and Outcomes

An interviewee acknowledged that the Roadmap provides an opportunity for NQF and the TEP to break from past literature and completely separate patient experience from PRO categories that address clinical outcomes. The recommendation applies to not only the Roadmap, but also the other reports in the Building a Roadmap initiative, including those that present lists of existing PRO-PMs. Public comments from both the Building a Roadmap initiative and NQF's 2020 report titled *Best Practices in Selection and Data Collection* made similar recommendations.

Promote the Benefits of PRO-PMs

The Roadmap should further identify and promote the many benefits of PRO-PMs, thereby focusing on what a PRO-PM can do rather than what a PRO-PM is. While this might be out of scope for the report, NQF and the TEP should consider adding brief content to the introductory section of the report that highlights these benefits. Alternately, NQF could include a brief list of benefits in a stage 1 task regarding the selection of measure types.

Limitations

NQF identified two minor methodological limitations to the Developer Feedback Report. First, the report might have benefitted from interviewing more than nine experts at private and nonprofit organizations. Additional KIIs would have offered a more diverse range of perspectives from organizations and individuals who develop or work closely with PRO-PMs. Additional interviews also would have allowed NQF to speak with multiple people within each organization, which might have been beneficial in understanding how both junior and senior staff perceive the Roadmap. Second, the one-hour time limit on interviews resulted in a few situations in which the interview ended before the interviewee had shared all of their feedback. With these limitations noted, NQF does not feel that the Developer Feedback Report significantly suffered from these constraints.

Next Steps

The TEP will review and discuss the recommendations in the Developer Feedback Report during its web meetings in the spring and summer of 2022, determine which recommendations should be incorporated into the updated Roadmap, and guide the development of content related to those recommendations. As the TEP considers these recommendations, its members will reassess the 16 tasks within the Roadmap to determine what (if any) new tasks should be added, which tasks would benefit from clear

and explicit examples, and how the guidance within each task can be improved and made specific to PRO-PMs.

Conclusion

The Building a Roadmap initiative aims to provide meaningful guidance to measure developers on selecting PROMs and developing digital PRO-PMs that can be used in CMS' VBP programs and APMs. This Developer Feedback Report offers NQF and the TEP critical guidance on how the first version of this guidance can be improved to better meet the needs of its audience. The expert interviewees shared meaningful suggestions with NQF and the TEP on how every stage and task in the Roadmap might be improved, from the preliminary work that occurs before measure development begins to the final steps before seeking NQF endorsement for a measure.

References

1. Centers for Medicare & Medicaid Services (CMS). Quality Payment Program Measure Development. Published April 2022. Accessed April 21, 2022. https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development

2. Centers for Medicare & Medicaid Services (CMS). Meaningful Measures 2.0: Moving from measure reduction to modernization. CMS. Published March 31, 2021. Accessed March 1, 2022. https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization

3. Centers for Medicare & Medicaid Services (CMS). What is CMS National Quality Strategy. Published April 2022. Accessed April 20, 2022. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy

4. Centers for Medicare & Medicaid Services (CMS). *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Changes to Medicaid Provider Enrollment; and Changes to the Medicare Shared Savings Program*.; 2021:45344. Accessed March 28, 2022. https://www.govinfo.gov/content/pkg/FR-2021-08-13/pdf/2021-16519.pdf

5. National Quality Forum. *Building a Roadmap From Patient-Reported Outcome Measures to Patient-Reported Outcome Performance Measures Environmental Scan - Final Report*.; 2021. Accessed April 21, 2022. https://www.qualityforum.org/Publications/2021/05/Building_a_Roadmap_From_Patient-Reported_Outcome_Measures_to_Patient-Reported_Outcome_Performance_Measures_Environmental_Scan_-_Final_Report.aspx

6. National Quality Forum (NQF). NQF: Quality Positioning System ™. Accessed March 1, 2022. https://www.qualityforum.org/QPS

7. Cella DF, Hahn EA, Jensen SE, et al. *Patient-Reported Outcomes in Performance Measurement*. Vol 97. RTI Press Research Triangle Park, NC; 2015.

8. The Office of the National Coordinator for Health Information Technology (ONC). The Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program. HealthIT.gov. Published April 2022. Accessed April 21, 2022. https://www.healthit.gov/topic/certification-ehrs/about-onc-health-it-certification-program

9. Sarkar U, Lisker S, Lyles CR. How to Narrow the Digital Divide in U.S. Health Care. *Harvard Business Review*. Published online May 6, 2021. Accessed April 21, 2022. https://hbr.org/2021/05/how-to-narrow-the-digital-divide-in-u-s-health-care

10. Centers for Medicare & Medicaid Services (CMS. Alternative Payment Models (APMs) Overview - QPP. Published April 2022. Accessed April 21, 2022. https://qpp.cms.gov/apms/overview

11. McGlothlin AE, Lewis RJ. Minimal clinically important difference: Defining what really matters to patients. *JAMA*. 2014;312(13):1342-1343. doi:10.1001/jama.2014.13128

12. National Quality Forum (NQF). Patient reported outcomes (PROs) in performance measurement. Published online January 10, 2013. https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72537

13. National Quality Forum (NQF). *Patient-Reported Outcomes: Best Practices on Selection and Data Collection - Final Technical Report*.; 2020. Accessed December 21, 2020. http://www.qualityforum.org/Publications/2020/09/Patient-Reported_Outcomes__Best_Practices_on_Selection_and_Data_Collection_-_Final_Technical_Report.aspx

14. National Quality Forum (NQF). *NQF: Attribution - Principles and Approaches*.; 2016. https://www.qualityforum.org/Publications/2016/12/Attribution_-_Principles_and_Approaches.aspx.

15. Deutsch A, Smith L, Gage B, Kelleher C, Garfinkel D. Patient-reported outcomes in performance measurement commissioned paper on PRO-based performance measures for healthcare accountable entities. Published online October 22, 2012. http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72157

16. Polascik BA, Hidaka C, Thompson MC, et al. Crosswalks between knee and hip arthroplasty short forms: HOOS/KOOS JR and Oxford. *JBJS*. 2020;102(11):983-990. doi:10.2106/JBJS.19.00916

17. Centers for Medicare & Medicaid Services (CMS). *CMS Measures Management System Blueprint*.; 2021:111. Accessed March 1, 2022. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf

18. National Quality Forum (NQF). NQF health information technology glossary: A guide to HIT jargon. https://www.qualityforum.org/Measuring_Performance/HIT_Glossary.aspx..

19. Office of the National Coordinator for Health Information Technology (ONC). What is FHIR? Published April 2022. https://www.healthit.gov/sites/default/files/2019-08/ONCFHIRFSWhatIsFHIR.pdf

20. Centers for Medicare & Medicaid Services (CMS). *Supplemental Materials to MMS Blueprint: Patient Reported Outcome Measures.; 2021:6.*; 2022. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint

21. National Quality Forum (NQF). Measuring performance. Accessed March 3, 2022. https://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx

22. Borsboom D, Molenaar D. Psychometrics. In: Wright JD, ed. *International Encyclopedia of the Social & Behavioral Sciences (Second Edition)*. Elsevier; 2015:418-422. doi:10.1016/B978-0-08-097086-8.43079-5

23. Office of the National Coordinator for Health Information Technology (ONC). USCDI+. HealthIT.gov. Published October 28, 2021. Accessed March 22, 2022. https://www.healthit.gov/topic/interoperability/uscdi-plus

24. Centers for Medicare & Medicaid Services (CMS). Hospital value-based purchasing | CMS. Accessed December 29, 2020. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing

Appendices

Appendix A. Glossary

Alternative Payment Models (APMs)

A payment approach that gives added incentive payments to provide high quality and cost-efficient care. APMs can apply to a specific clinical condition, care episode, or population.[10]

Anchors

Anchor-based methods are one of three types of methods used to determine minimal clinically important difference (MCID). A numerical scale for an outcome is "anchored" to a subjective and independent assessment of improvement. For example, a response of "a little better" to a question about how the patient feels post-treatment can be anchored to a numeric outcome.[11]

Attribute

A characteristic or trait of a PROM. Past National Quality Forum (NQF) reports have used *attribute* and *characteristic* synonymously.[12,13] Throughout the Building a Roadmap initiative, *attributes* primarily refer to the characteristics that make a PROM suitable for use in a PRO-PM.

Attribute Grid

A table designed to provide a systematic method to perform a side-by-side comparison of PROMs on the basis of meaningful PROM attributes.[13]

Attribution

A process used in quality measurement that aims to assign accountability for a patient's outcomes to a clinician, groups of clinicians, or a facility.[14]

Burden

Burden refers to the time, effort, or other demands placed on respondents or those administering the PROM. This can include the number and complexity of items and the literacy level needed to understand and complete the measure.[15]

Crosswalk

A concordance table to convert scores from one scale to the other and vice versa.[16] Crosswalks can allow harmonization of PROMs that measure similar outcomes (e.g., HRQoL after a knee replacement surgery), which may facilitate multicenter collaboration or allow sites to switch PROMs without loss of historic comparison data.[16]

Cut Points

Clinically meaningful thresholds of a score change within a PROM that is often associated with either improvement in patient outcome or indication of need for treatment.[11]

Digital Quality Measures (dQMs)

Software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient

portals or applications (for example, for collection of patient-generated health data), HIEs or registries, and other sources. We also note that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs.[4]

Electronic Clinical Quality Measures (eCQMs)

eCQMs are expressed and formatted to use data from EHRs and/or health IT systems to measure healthcare quality, ideally data captured in structured form during the process of patient care.[17] They are the most common type of digital quality measures and are specified for use in the Medicare and Medicaid EHR Incentive Programs. Eligible professionals, eligible hospitals, and critical access hospitals are required to submit eCQM data from certified EHR technology to help measure and track the quality of healthcare services provided within the healthcare system.[18]

Fast Healthcare Interoperability Resources (FHIR)

A Health Level Seven International (HL7) standard that defines how healthcare information can be exchanged between different computer systems regardless of how it is stored in those systems.[19]

Interpretability

The degree to which the meaning of the scores can be easily understood by any group requiring use of the scores. A PRO measure should have documentation to support interpretation of scores, including the meaning of low and high scores and guidance on the minimally important difference in scores between groups and/or over time.[12]

Logical Observation Identifiers, Names, and Codes (LOINC)

LOINC is a database and universal standard for identifying medical laboratory observations. It was developed in 1994 and is maintained by the Regenstrief Institute, a U.S. nonprofit medical research organization. LOINC was created in response to the demand for an electronic database for clinical care and management and is publicly available at no cost.[18]

Method

How PROM data are collected, such as via a paper form or a patient portal.

Minimal Clinically Important Difference (MCID)

MCID is the smallest improvement needed after treatment that would be considered worthwhile from the patient's perspective.[11] MCID can be calculated using three different methods: consensus or delphi method, which depends on consensus of an expert panel; anchors (described above); and a distribution-based method, which relies on the statistical analysis of the distribution of outcome scores.[11]

Mode

How a PROM is administered, such as self-administration or verbal administration by a clinician.

Patient-Reported Outcome (PRO)

Any report of the status of a patient's health condition or health behavior that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.[20]

Patient-Reported Outcome Measure (PROM)

Tools used to collect patient-reported outcomes.[20]

Patient-Reported Outcome Performance Measure (PRO-PM)

A way to aggregate the information from patients into a reliable, valid measure of performance at the measured entity, level, e.g., clinician.[20]

Performance Measures (PMs)

These are standards that can be used to measure and quantify healthcare processes, outcomes, patient perceptions, organizational structure, and/or systems that are associated with the ability to provide high quality care.[21]

Psychometric Soundness

How consistently and accurately an assessment measures what it purports to measure.[15] Validity and reliability are key aspects to attaining psychometric soundness. Psychometrics is a scientific discipline concerned with the construction of measurement models for psychological data.[22]

United States Core Data for Interoperability (USCDI)

A standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.[8]

USCDI+

An ONC initiative that supports the identification and establishment of domain or program-specific datasets that will operate as extensions to the existing USCDI. It is a service for federal agencies who have a need to establish, harmonize, and advance the use of interoperable datasets that extend beyond the core data in the USCDI in order to meet agency-specific programmatic requirements. The three pillars of USCDI+ are collaboration, harmonization, and specification.[23]

Value-Based Purchasing (VBP) Program[24]

Value-based programs reward healthcare providers with incentive payments or penalties for the quality of care they give to people with Medicare. These programs are part of CMS' larger quality strategy to reform how healthcare is delivered and paid for.

Appendix B. Key Informants

Lisa Anderson, MSN, RN-BC
Clinical Informatics Lead, Mathematica

David Clayman, DPM, MBA
Clinical Program Lead, Mathematica

Kyle Cobb, MS
U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONC)

Collette Cole, BSN, RN, CPHQ
Clinical Measurement Developer, Minnesota Community Measurement

Rebecca Etz, PhD
Cultural Anthropologist, Professor of Family Medicine and Population Health at Virginia Commonwealth

Grace Glennon, MS, RD, CHES
Health Outcomes Researcher, Yale/YNHH Center for Outcomes Research and Evaluation (CORE)

Ben Hamlin, DrPH, MPH
Senior Research Informacist, National Committee of Quality Assurance

Laura Jantos, LFHIMSS
Patient Advocate, Healthcare Technology/Digital Health

Samantha Tierney
Senior Scientist, Clinical Policy, American College of Physicians

Sandra Mitchell, PhD, CRNP, FAAN
National Institutes of Health, National Cancer Institute

Ashley Wilder Smith, PhD, MPH
National Institutes of Health, National Cancer Institute

Appendix C. TEP Members, Federal Liaisons, NQF Staff, and CMS Staff

Technical Expert Panel Members

* TEP members marked with an asterisk served in 2021; all others served 2021-2022.

Catherine MacLean, MD, PhD *(Co-Chair)*
Chief Value Medical Officer, Rheumatologist, Hospital for Special Surgery
New York, New York

Sam Simon, PhD *(Co-Chair)*
Director, Health Program Improvement, Mathematica
Cambridge, Massachusetts

David Andrews, PhD*
Patient Advisor
Aiken, South Carolina

Katherine Ast, MSW, LCSW
Director, Quality & Research, American Academy of Hospice and Palliative Medicine
Glenview, Illinois

Rachel Brodie, BA
Senior Director, Measurement & Accountability, Pacific Business Group on Health
San Francisco, California

Zahid Butt, MD, FACG
President and Chief Executive Officer (CEO), Medisolv, Inc.
Columbia, Maryland

Collette Cole, BSN, RN, CPHQ
Clinical Measurement Developer, Minnesota Community Measurement
Minneapolis, Minnesota

Paula Farrell, BSN, RN, CPHQ, LSSGB*
Associate Project Director, Clinical Quality Measurement, Department of Quality Measurement, The Joint Commission
Oakbrook Terrace, Illinois

Mark Friedberg, MD, MPP
Senior Vice President, Performance Measurement & Improvement, Blue Cross Blue Shield of Massachusetts
Boston, Massachusetts

Debbie Gipson, MD, MS
Professor of Pediatrics, University of Michigan
Ann Arbor, Michigan

Ben Hamlin, DrPH
Senior Research Informaticist, Research & Performance Measurement, National Committee for Quality Assurance

Washington, District of Columbia

Janel Hanmer, MD, PhD
Medical Director of Patient Reported Outcomes, University of Pittsburgh Medical Center
Pittsburgh, Pennsylvania

Helen Haskell, MA
Founder and President, Mothers Against Medical Error
Columbia, South Carolina

Brian Hurley, MD, MBA, DFASAM
Director of Addiction Medicine, Los Angeles County Department of Health Services
Los Angeles, California

Christine Izui, MS
Health Policy Principle, Center for Transforming Health, MITRE Corporation
McLean, Virginia

Laura Jantos, LFHIMSS
Patient Advocate, Healthcare Technology/Digital Health
Mercer Island, Washington

Kirk Munsch
Patient Advocate, Rare Patient Voice
Colorado Springs, Colorado

Deborah Paone, DrPH, MHA
Performance Evaluation Lead and Policy Consultant, SNP Alliance
Washington, District of Columbia

Brenna Rabel, MPH
Lead Health Research Scientist, Battelle Memorial Institute
Arlington, Virginia

Nan Rothrock, PhD, MA
Clinical Psychologist, Feinberg School of Medicine, Northwestern University
Chicago, Illinois

Mike Sacca, AS
Vice President, Healthcare Quality and Data Analytics, RELI Group
Douglassville, Pennsylvania

Rachel Sisodia, MD*
Senior Medical Director for Specialty Care and Patient Reported Outcomes, Massachusetts General Brigham Health
Boston, Massachusetts

John Spertus, MD, MPH, FACC, FAHA
Clinical Director of Cardiovascular Education and Outcomes Research, Mid America Heart Institute
Kansas City, Missouri

Ruth Wetta, PhD, MSN, MPH, RN
Lead Clinical Researcher, Population Health, Cerner Corporation
Kansas City, Missouri

Albert Wu, MD, MPH, FACP
Professor, Department of Health Policy and Management and Medicine, Johns Hopkins Bloomberg School of Public Health
Baltimore, Maryland

Federal Liaisons

Joel Andress, PhD
CMS, Center for Clinical Standards and Quality

Kyle Cobb, MS
U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONC)

Janis Grady, RHIT, FAC-COR III
CMS, Center for Clinical Standards and Quality

Sandra Mitchell, PhD, CRNP, FAAN
National Institutes of Health, National Cancer Institute

Ashley Wilder Smith, PhD, MPH
National Institutes of Health, National Cancer Institute

Rhona Limcango, PhD
Agency for Healthcare Research and Quality

Meghan McHugh, PhD, MPH
Substance Abuse and Mental Health Services Administration

Clifford A. Smith, PhD, ABPP-Cn
US Department of Veterans Affairs, Office of Mental Health and Suicide Prevention

David Au, MD, MS
US Department of Veterans Affairs, Center of Innovation for Veteran-Centered and Value-Driven Care

Girma Alemu, MD, MPH
Health Resources and Services Administration, Office of Planning, Analysis, and Evaluation

NQF Staff

Kathleen Giblin, RN
Senior Vice President

Elizabeth Drye, MD, SM
Chief Scientific Officer

Maha Taylor, MHA
Managing Director

Chuck Amos, MBA
Senior Director

Teresa Brown, MHA, MA
Director

Deidra Smith, MBA, PMP
Senior Project Manager

Evelyn Thomas, MPH, CHES
Senior Analyst

Zoe Waller, BA
Coordinator

CMS Staff

LaWanda Burwell, ScD
Task Order COR

Gequincia Polk
IDIQ COR

Helen Dollar-Maples
Director, DPMS/QMVIG/CCSQ

Marsha Smith, MD, MPH, FAAP
Medical Officer, DPMS/QMVIG/CCSQ

Appendix D. Interview Guide for Members of the Public

Purpose

This document details the National Quality Forum (NQF) team's approach to conducting the KIIs for the Building a Roadmap project. The purpose of these KIIs is to obtain feedback from measure developers on the strengths, limitations, and recommendations for updating the Technical Guidance Report. NQF will collect feedback on how the existing Technical Guidance Report can be improved to guide the development of digital PRO-PMs that can meet NQF's measure endorsement criteria. Additionally, the KIIs present an opportunity to gather information that could be relevant for the updated Environmental Scan Report.

Approach

NQF will conduct up to nine (9) KIIs with measure developers to supplement the Technical Guidance Report. NQF will seek measure developers from multiple organizations who are at different stages in their careers. While the interviews will aim to capture experts with experience developing digital PRO-PMs, NQF recognizes that this is a very small population and will aim to interview developers with experience in at least one of the following areas: dQM development, eCQM development, or PRO-PM development. Key informants may include co-chairs and members from the TEP, federal liaisons supporting the TEP, or other individuals with expertise not on the Committee.

The interviews are intended to collect feedback on any limitations of the Technical Guidance for digital PRO-PM development and recommendations on how to address these limitations to increase the value of the guidance to measure developers. Key informants will also be encouraged to provide suggestions for improving the Technical Guidance.

Brief Introduction to Be Sent to Key Informants in Advance of the Interview

Building a Roadmap builds upon a long history of collaborative work between Centers for Medicare & Medicaid Services (CMS) and NQF. This CMS-funded initiative aims to provide guidance to healthcare stakeholders, particularly measure developers, who are working to create and maintain digital PRO-PMs that can be used in CMS' VBP programs, APMs, and other accountability programs. The work began in 2020 and will culminate in late 2022. It is guided by a TEP composed of multistakeholder leaders in measure development, health IT, research, clinical care, patient advocacy, and other healthcare fields.

CMS is committed to elevating the voices of patients through the use of PROs. While hundreds of PROMs exist to capture data on patients' perspectives, only a few dozen NQF-endorsed PRO-PMs offer opportunities to use those data for performance measurement and accountability. Additionally, there is a lack of detailed technical guidance to help measure developers select high quality PROMs and create new digital PRO-PMs that can potentially be used in CMS' VBP programs or APMs. The Building a Roadmap initiative aims to address this barrier by identifying attributes of PROMs for use in high quality PRO-PMs and creating a roadmap to guide the development of digital PRO-PMs.

During 2021, NQF published two reports designed to address these barriers. The Interim Report focuses on selecting high quality PROMs for use in performance measures, and the Technical Guidance Report (i.e., the Roadmap) provides guidance to measure developers on how to develop a digital PRO-PM that can be used in accountability programs.

As part of this project, NQF is conducting interviews with measure developers who have different levels of experience in digital PRO-PM development. Our team has identified you as an expert who would provide a diverse and varied perspective to the project. We are inviting you to review both the Interim Report and the Roadmap, and then speak with us during a 60-minute interview. The focus of the interview will be to elicit your feedback on both reports, which ultimately will help NQF improve future drafts to make them more useful and meaningful. To help you prepare, we have attached both the Interim Report and the Roadmap, along with a list of potential questions. We will, however, target our questions to your specific experience. We look forward to speaking with you and getting your valuable insight.

Interview Script

The following is a potential script that will be used by NQF staff during the KIIs:

"Thank you for participating in this key informant interview for the *National Quality Forum's Building a Roadmap From Patient-Reported Outcome Measures to Patient-Reported Outcome Performance Measures* project. *[Introduce NQF staff participating in the call].* We would like to record this conversation as we plan on using your comments to share with our Technical Expert Panel (TEP), and to inform staff updates to the Interim Report and the Technical Guidance Report related to this project. Do we have your consent to record this conversation? Please also let us know if there is anyone joining you. We would ask if they would identify themselves. We would also like to acknowledge your contribution

to this work by listing your name in the final report of the project. Kindly let us know if you would prefer to opt out of being acknowledged. *[If consent is not given, stop recording]*

We sent you a brief outline of the project in advance that lists our goals for the project and this conversation. Do you have any questions? *[If yes, clarify questions]* As we mentioned, our goal today is for you to help us understand whether the Interim Report and the Technical Guidance Report are helpful for developing digital PRO-PMs that can meet NQF's measure endorsement criteria and be included in CMS' VBP programs and APMs. We aim to obtain feedback on the strengths, limitations, and recommendations for updating the report. We also welcome any additional feedback and suggestions. *[Pending the timing of the interview]*

We sent you a preview of the questions, so we will jump right in and have you address them as thoroughly as you can over the next hour. Before we start, are there any specific questions on the list that you want to make sure we address today? [*Interviewer to note any questions.*] Let's begin: [*Interviewer will ask questions from the discussion questions section of this document*]"

Discussion Questions

In advance of each interview, NQF will identify the goal of the interview based on the individual's knowledge area and expertise. The following questions will be used across interviews to ensure essential information is elicited from each interviewee in an objective manner, allowing staff to compare responses across interviewees. However, not every question will be appropriate for every interviewee and may be omitted as needed.

Discussion Topic	Discussion Questions
Introductory Questions	• How long have you worked as a measure developer? • What are your experiences with developing digital PRO-PMs? • What are your experiences with developing other types of measures? • Which, if any, NQF-endorsed measures have you helped develop?
General Questions	• If a new measure developer asked you for one piece of advice, what would you offer?
Structure of the Report	• Because there is not one "correct" linear process to measure development, the report refers to a series of stages and tasks. How clear is this structure, and how can it be improved? • Were the stages and tasks presented in a clear and understandable way? • What additional tasks should be considered when developing a digital PRO-PM? If so, please provide a rationale for each additional task that is suggested.

Discussion Topic	Discussion Questions
PROM Selection	• The Interim Report focuses on selecting PROMs for use in high quality digital PRO-PMs. What did you find most useful about this report? • What did you find least useful? • What information about selecting PROMs do you wish had been included in this report? • Were the attributes of PROMs complete and accurate? Were any attributes missing? • Was the information on digital PROMs (e.g., inclusion of LOINC codes in the attribute grid) sufficient, or was key guidance missing?
Digital Measure Guidance	• How can the guidance on digital measurement be improved in the report? • What resources for developing dQMs or eCQMs have you used in the past? • What guidance on developing digital measures is most difficult for you to locate or do you wish you had? • Specifically, what information on digital measures should be added to the report?
PRO-PM Guidance	• When you consider the development of PRO-PMs, what stands out to you as a critical step(s)? Were these steps appropriately addressed in the Roadmap? • How does development of digital PRO-PMs differ from other dQMs?
Accessibility for Measure Developers	• What improvements would make the report more useful to new measure developers? • What improvements would make the report more useful to experienced measure developers?
Terminology	• Which additional terms should be included in the glossary?
Recommendations	• What general recommendations, comments, or feedback do you have for the report?

Appendix E. Interview Guide for Federal Employees

Purpose

This document details the National Quality Forum (NQF) team's approach to conducting the federal liaison KIIs for the Building a Roadmap project. The purpose of these KIIs is to obtain feedback from federal employees who are experienced in measure development and/or digital quality measurement. This feedback will focus on the strengths, limitations, and recommendations for updating the Technical Guidance Report. NQF will collect feedback on how the existing Technical Guidance Report can be improved to better serve employees at federal agencies who develop or interact with digital PRO-PMs. Additionally, the KIIs present an opportunity to gather information that could be relevant for the updated Environmental Scan Report.

Approach

NQF will conduct KIIs with federal employees to supplement the Technical Guidance Report. NQF will seek to interview measure developers and health IT experts, primarily within the U.S. Department of Health & Human Services (HHS). These interviews will be intended to complement up to nine (9) KIIs of

measure developers from the private sector. While the interviews will aim to capture federal employees with experience developing digital PRO-PMs, NQF recognizes that this is a very small population and will aim to interview people with experience in at least one of the following areas: dQM development, eCQM development, or PRO-PM development. The KIIs will focus on federal liaisons who participate in the Building a Roadmap initiative.

The interviews are intended to collect feedback on any limitations of the Technical Guidance from the perspective of federal employees and recommendations on how to address these limitations to increase the value of the guidance. Key informants will also be encouraged to provide suggestions for improving the Technical Guidance.

Brief Introduction to Be Sent to Key Informants in Advance of the Interview

Building a Roadmap builds upon a long history of collaborative work between Centers for Medicare & Medicaid Services (CMS) and NQF. This CMS-funded initiative aims to provide guidance to healthcare stakeholders, particularly measure developers, who are working to create and maintain digital PRO-PMs that can be used in CMS' VBP programs, APMs, and other accountability programs. The work began in 2020 and will culminate in late 2022. It is guided by a TEP composed of multistakeholder leaders in measure development, health IT, research, clinical care, patient advocacy, and other healthcare fields. A team of federal liaisons, who are all employees of federal government agencies, act as advisors to the work.

CMS is committed to elevating the voices of patients through the use of PROs. While hundreds of PROMs exist to capture data on patients' perspectives, only a few dozen NQF-endorsed PRO-PMs offer opportunities to use those data for performance measurement and accountability. Additionally, there is a lack of detailed technical guidance to help measure developers select high quality PROMs and create new digital PRO-PMs that can potentially be used in CMS' VBP programs or APMs. The Building a Roadmap initiative aims to address this barrier by identifying attributes of PROMs for use in high quality PRO-PMs and creating a roadmap to guide the development of digital PRO-PMs.

During 2021, NQF published two reports designed to address these barriers. The Interim Report focuses on selecting high quality PROMs for use in performance measures, and the Technical Guidance Report (i.e., the Roadmap) provides guidance to measure developers on how to develop a digital PRO-PM that can be used in accountability programs.

As part of this project, NQF is conducting interviews with measure developers who have different levels of experience in digital PRO-PM development. Our team has identified you as an expert who would provide a diverse and varied perspective to the project. We are inviting you to review both the Interim Report and the Roadmap, and then speak with us during a 60-minute interview. The focus of the interview will be to elicit your feedback on both reports, which ultimately will help NQF improve future drafts to make them more useful and meaningful. To help you prepare, we have attached both the Interim Report and the Roadmap, along with a list of potential questions. We will, however, target our questions to your specific experience. We look forward to speaking with you and getting your valuable insight.

Interview Script

The following is a potential script that will be used by NQF staff during the KIIs:

"Thank you for participating in this key informant interview for Federal Liaisons from the *National Quality Forum's Building a Roadmap From Patient-Reported Outcome Measures to Patient-Reported Outcome Performance Measures* project. *[Introduce NQF staff participating in the call].* We would like to record this conversation as we plan on using your comments to share with our Technical Expert Panel (TEP), and to inform staff updates to the Interim Report and the Technical Guidance Report related to this project. Do we have your consent to record this conversation? Please also let us know if there is anyone joining you. We would ask if they would identify themselves. We would also like to acknowledge your contribution to this work by listing your name in the final report of the project. Kindly let us know if you would prefer to opt out of being acknowledged. *[If consent is not given, stop recording]*

We sent you a brief outline of the project in advance that lists our goals for the project and this conversation. Do you have any questions? *[If yes, clarify questions]* As we mentioned, our goal today is for you to help us understand improvement opportunities in the Interim Report and the Technical Guidance Report from the perspective of federal agencies and whether these reports are helpful for developing digital PRO-PMs that can meet NQF's measure endorsement criteria and be included in CMS' VBP programs and APMs. We aim to obtain feedback on the strengths, limitations, and recommendations for updating the report. We also welcome any additional feedback and suggestions. *[Pending the timing of the interview]*

We sent you a preview of the questions, so we will jump right in and have you address them as thoroughly as you can over the next hour. Before we start, are there any specific questions on the list that you want to make sure we address today? [*Interviewer to note any questions.*] Let's begin: [*Interviewer will ask questions from the discussion questions section of this document*]"

Discussion Questions

In advance of each interview, NQF will identify the goal of the interview based on the individual's knowledge area and expertise. The following questions will be used across interviews to ensure essential information is elicited from each interviewee in an objective manner, allowing staff to compare responses across interviewees. However, not every question will be appropriate for every interviewee and may be omitted as needed.

Discussion Topic	Discussion Questions
Introductory Questions	• Which federal agency employs you and in what role? • How long have you worked in a field related to measure development? • How would you describe your experiences with developing dQMs, including PRO-PMs? • Which, if any, NQF-endorsed measures have you helped develop?
Advice From the Federal Perspective	• From the perspective of a federal employee, what one piece of advice would you offer to measure developers working on PRO-PMs? • When considering a value-based program, what specific aspects of measurement and measure development are important to your federal agency? • As a federal employee, how do you engage patients and caregivers in the PRO-PM development process?

Discussion Topic	Discussion Questions
Structure of the Report	• Because there is not one "correct" linear process to measure development, the report refers to a series of stages and tasks. How clear is this structure, and how can it be improved? • Were the stages and tasks presented in a clear and understandable way? • What additional tasks should be considered when developing a digital PRO-PM? If so, please provide a rationale for each additional task that is suggested. • The report identifies the importance of a stakeholder advisory group (including patients and/or caregivers) as a critical piece of PRO-PM development. How can this guidance be improved?
PROM Selection	• The Interim Report focuses on selecting PROMs for use in high quality digital PRO-PMs. What did you find most useful about this report? • What did you find least useful or inaccurate?
Digital Measurement From the Federal Perspective	• Are there aspects of digital measurement that are particularly important from the federal perspective? Are these appropriately represented in the report? • Are you aware of publicly available resources within your agency that could help developers who are working on digital PRO-PMs? • What information on digital measures should be added to the report?
PRO-PM Guidance	• When you consider the development of PRO-PMs, what stands out to you as a critical step(s)? Were these steps appropriately addressed in the Roadmap? • How does the development of digital PRO-PMs differ from other dQMs or eCQMs?
Accessibility for Measure Developers	• What improvements would make the report more useful to new measure developers? • What improvements would make the report more useful to experienced measure developers?

Terminology and Definitions	• Which additional terms should be included in the glossary?
	• How would you differentiate a dQM from an eCQM?
	• NQF is planning to revise the definitions in the report to align with the CMS Blueprint. What, if any, concerns does this raise for you?
	  ◦ **PRO:** Any report of the status of a patient's health condition or health behavior that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else
	  ◦ **PROM:** Tools used to collect PROs
	  ◦ **PRO-PM:** A way to aggregate the information from patients into a reliable, valid measure of performance at the measured entity and/or level (e.g., clinician)

Recommendations	• What general recommendations, comments, or feedback do you have for the report?

Appendix F: Background on NQF's Role in Patient-Reported Outcomes

NQF and CMS have collaborated to advance PROs for more than 10 years, and the results of this work include several seminal reports on PROMs and PRO-PMs. These and other publications are described in additional detail in the Environmental Scan Report.

- Two white papers from 2012:
  - Methodological Issues in the Selection, Administration and Use of Patient-Reported Outcomes in Performance Measurement in Health Care Settings
  - PRO-Based Performance Measures for Healthcare Accountable Entities
- The final report from a 2013 Expert Panel: Patient-Reported Outcomes in Performance Measurement
- The final report from a 2020 TEP on implementing PROMs in clinical settings: Patient-Reported Outcomes: Best Practices on Selection and Data Collection (henceforth referred to as *PRO Best Practices*)

Appendix G: Public Comments

The Draft Developer Feedback Report was posted on the project webpage for public and National Quality Forum (NQF) member comment from **TBD** through **TBD**. **TBD** prompts were offered to guide public commenters on key areas of interest. The comments below are grouped by prompt, and the TEP's response is listed immediately beneath each comment. During the commenting period, NQF received **TBD** total comments from **TBD** organizations. Comments were elicited through various avenues, including the public commenting tool and additional organizational outreach. Unless otherwise noted, public comments are presented as they were received by NQF and have not been edited, with the exception of correcting minor spelling and punctuation issues.

To be updated after the public commenting period.