NATIONAL QUALITY FORUM
Driving measurable health improvements together

Request for Proposal

Omnibus Anxiety and Depression Patient-Reported Outcome Performance Measure

Introduction

The National Quality Forum (NQF) Aligned Innovation Initiative has identified depression and anxiety outcomes as major gaps in our nation's portfolio of quality measures, particularly for children and adolescents, and aims to advance the quality of care for these conditions by using Patient-Reported Outcome Measures (PROMs) to build Patient-Reported Outcome Performance Measures (PRO-PMs). The resulting PROM and PRO-PM measures are intended to evaluate the effectiveness of treatment and progress in managing depression and anxiety for children, adolescents, and adults, and should be structured to support patients' self-reporting of their symptoms and functional status over time to inform clinical care and quality measurement.

Anxiety and depression are highly prevalent, often coexisting conditions, that can have long-lasting effects on one's physical and mental well-being if left untreated.[1] In 2021, it was estimated that one in five U.S. adults live with a mental illness with varying degrees of severity.[2] Generalized anxiety disorder (GAD) affects 6.8 million adults in the U.S. while 21 million adults had at least one episode of major depression in 2019.[3,4] In addition, approximately 5.8 million children were diagnosed with anxiety and 2.7 million children were diagnosed with depression in 2016-2019, and rates of these conditions have increased over time.[5] The COVID-19 pandemic had a further impact on mental health, with anxiety and depression rates four times higher among U.S. adults between April 2020 and August 2021 than in 2019.[6] As a result of the COVID-19 pandemic, activities such as school closures and lockdown produced higher levels of anxiety and regressive behaviors in children while adolescents experienced more isolation and depressive symptoms.[7]

The **Aligned Innovation Initiative** is driven by a multistakeholder Innovator Coalition ("Coalition") of private and public sector payers, purchasers, and providers committed to meaningful progress toward a next generation of healthcare performance measures that fill high priority gaps and represent outcomes that matter to patients and the clinicians who care for them. The initiative is different from traditional measure development in the following ways:

- **Genesis of the Measure Concepts:**
  - Public and private sector payers, providers, and purchasers ("Coalition") align on the highest priority gaps in our nation's portfolio of measures, particularly for value-based payment, population health and advancing health equity.
  - With the priority gap areas defined, patients with experiences relevant to these priority gaps and clinicians who care for these patient populations identify outcomes that are most important to them. These become the **outcome measure concepts** for measure development.
- **Measure Development, Testing & Validation:**
  - A broad and diverse set of provider partners affiliated with Coalition members engage with the measure developer to create a measure that is both clinically acceptable and operationally feasible.

    - Provider partners then implement the measure to generate broader, more diverse data on use of the measure in practice and for statistical/psychometric testing.
- **Multistakeholder Engagement:**
    - NQF engages a Multistakeholder Advisory Council (MAC) – comprised of public and private sector stakeholders representing end-users and enablers of the proposed measure – throughout the process to ensure that the measure is informed by their perspectives, supported by them, and positioned for broad adoption and use.
- **Timeline:**
    - The end-to-end process of Aligned innovation is 24-months, which is significantly shorter than traditional measure development timelines.

The Coalition identified depression and anxiety as among its top priority areas for new outcome measure development during this cycle. NQF conducted focus groups with a wide range of patients (and parents of patients) with depression and anxiety and clinicians who care for patients with these conditions to elicit the outcomes that matter most to them. Both clinicians and patients noted that symptom mitigation and improved functioning are their priorities for care for these conditions. Clinicians further noted that available measures focus only on symptoms and do not include assessment and monitoring of the many dimensions of functioning relevant to depression and anxiety (e.g., emotional functioning, social functioning, role functioning). The Coalition coalesced around creating 1) an omnibus survey tool (a PROM) that assesses both symptoms and relevant domains of function related to anxiety and depression and 2) a measure of changes in symptoms and functioning over time (a PRO-PM) based on longitudinal assessment of patients in each of three age groups: children, adolescents, adults.

Project Overview

NQF is soliciting proposals from quality measure development teams to develop, test, and support the implementation of one or more PRO-PMs that address patient-reported outcomes for depression and anxiety, including symptoms and function, using a new omnibus tool built from existing validated PROMs and previously validated survey items. Proposals should include development of at least one omnibus tool to assess symptoms and multiple relevant domains of functional status in patients with depression and/or anxiety during childhood, adolescence, and adulthood. Teams can combine age groups if clinically and empirically supported. Proposals may include the development of more than one PRO-PM to accommodate the required age populations.

This request for proposals (RFP) describes the outcome measure concept for development and testing, its desired measure characteristics, and the project structure and expectations related to testing and development within the Aligned Innovation infrastructure. **NQF encourages innovative approaches to measure development and testing that promote efficiencies in the processes and associated budget.**

NQF has a robust set of resources in place to support the measure developer's success and reduce development costs. These include:

- Diverse clinical testing sites and partners for implementation, testing, and data collection
- A cloud-based data solution to collect PROM data and centralize it for analysis
- Behavioral health subject matter experts
- A starting list of existing depression and anxiety PROMs and questions from the public domain

NQF expects the developer to select from a robust library of existing psychometrically sound PROMs and survey items that assess depression and anxiety symptoms and combine those tools with existing functional assessment PROMs, psychometrically validated functional domains, or validated standalone

questions into an omnibus tool. Functional domains of interest may include social, emotional, cognitive, sleep, work/school, and other activities. This omnibus assessment could be accomplished, for example, by using tools that screen for depression and anxiety such as the PHQ-9 and GAD-7 and combining those with select domains of function from RAND-36 or WHODAS 2.0 associated with improvements in function related to mood. The underlying PROMs used to build this measure must have high statistical reliability and validity and show responsiveness in detecting changes over time.

We encourage, but do not require, the use of computer-assisted technology (CAT) or Item Response Theory (IRT) to minimize patient burden and increase patient engagement. Likewise, we recognize the difficulties CAT and IRT present in building and implementing a PRO-PM, including possible licensing fees. As such, we urge creativity and novel approaches to designing the PRO-PM. We also encourage evaluation and use of PROMIS for its substantial, validated question repository, flexibility in delivery, and easy integration into common Electronic Health Records (EHRs).

Due to the ubiquity of PHQ-9 and GAD-7 as screening and symptom assessments, the new omnibus tool and resulting PRO-PMs must either incorporate these tools or be calibrated to them. The goal is not to disrupt the use of existing screening or symptom assessments; rather, to complement them with an assessment of functioning. NQF will support this effort by providing a list of candidate PROMs, providing stakeholder introductions, and facilitating and convening conversations to expedite successful development. Experts and stakeholders include specialty society leaders, academic researchers in the field of patient reported outcomes, and leaders in the field of PROM implementation.

As noted above, NQF is engaging a healthcare information technology (HIT) vendor that will support PROM implementation and data collection for the PROMs selected by the developer. The Coalition will select the sites to purposefully represent a full range of care settings and patient populations. The developer will work with the HIT vendor and clinician partners to deploy the surveys, determine time frames for data collection, and specify enrollment triggers. The HIT vendor will support bi-directional EHR integration which will allow data elements outside of the PROM to be accessible for the developers use in risk-adjustment or stratification. Throughout the data collection and analysis period, as defined by the developer, the data will be available in a secure cloud environment for the developer's use.

The PRO-PM should be constructed to provide an interpretable and usable performance score for clinician groups while meaningfully supporting clinical care. We prefer development of a composite score for the purpose of the PRO-PM, with patient level score and domain changes visible to the clinician on the patient level, if supported by empirical evidence. This will allow the measure to both be used in a quality/accountability program and serve as a tool for clinicians to interpret where the patient is or is not improving. However, if a single composite score is not valid, the developer should propose composite scores for each symptom or functional domain. The PRO-PM should be built as an electronic clinical quality measure (eCQM) and specified using the most up-to-date Health Quality Measure Format (HQMF). The measure should be specified using both Quality Data Model (QDM) and Fast Healthcare Interoperability Resources (FHIR) standards, to ensure the measure's immediate applicability and continued use as part of the broader transition to digital measures. Should non-standardized data elements prohibit eCQM completion, the developer should submit any necessary data elements to the appropriate organizations (e.g., LOINC).

Patient Population

We are seeking proposals for measures that include children, adolescents, and adults with a diagnosis of depression and/or anxiety who are being treated in an ambulatory setting. The developer should propose specific depression and/or anxiety population criteria (e.g., whether measure should include

acute conditions, chronic conditions, or both) and other evidence driven diagnostic criteria. Recognizing that different PROMs target different age groups, we are soliciting proposals for PRO-PMs that span childhood through adulthood. It may or may not be necessary to have differentiated content for children, adolescents, and adults. We welcome and encourage proposals that build out multiple (two to three) PRO-PMs. We defer to the developer's expertise and creativity in leveraging similar content across age groups to the extent clinically appropriate and useful for efficiencies in measurement.

Throughout the development process, the measure developer is expected to continuously consider health equity and integrate equity concerns in data collection, testing, implementation, measure development, population definitions, risk-adjustment, and protocol for implementation.

Level of Measurement

The PRO-PM(s) should be constructed in a way that shows a demonstrable change in score with clinically significant patient-level change over a period of treatment time or can indicate that the patient has achieved an acceptable threshold. It should be tested and validated at the clinician practice level and span various care settings including outpatient behavioral health clinics and primary care physician practices. Variation in performance scores between practices should be due to the quality of care received and minimize the influence of external factors.

Scope of Work

Tasks

The measure developer teams will conduct the following tasks:

- Task 1: Review existing PROMs and select PROMs, validated survey items and/or functional domains to build an omnibus tool(s).
    - Identify specific items that will be administered in the omnibus tool as part of testing, based on the developer's expertise as well as input from expert partners.
        - The measure developer will have access to experts from the Coalition, their provider partners, and the Aligned Innovation Multistakeholder Advisory Council (including experts in healthcare IT and specialty society leaders). NQF will facilitate the identification of additional experts, as needed.
    - Content for children, adolescents, and adults
    - Note: Developer must address PROM permissions and any necessary preemptive work to ensure its use in a PRO-PM eCQM (e.g., submission to LOINC)
- Task 2: Define preliminary measure specifications
    - The measure developer will describe the following:
        - Measure cohort – inclusion/exclusion criteria, including patients with acute and chronic diagnoses of depression and/or anxiety
        - Outcome definition – PROMs /survey items selected for use; minimal clinically important difference and/or threshold
        - Threats to validity, including the need for risk-adjustment, approach to non-response bias, and sample size requirements
        - Proposed protocol for data collection
        - Consideration of health equity – stratification for social risk factors. At a minimum, developers should consider factors including age, gender, race, ethnicity, urbanicity/rurality, poverty, social vulnerability, and frailty/disability as described in NQF's Risk Adjustment Technical Guidance Final Report.

    - Identify remaining specification decisions which will be informed by testing
    - Prepare a briefing for the Coalition on the preliminary measure specifications. **(*Deliverable 1*)**
        - Pre-brief NQF staff and revise the briefing as needed.
- Task 3: Gain Coalition feedback on preliminary measure specification for the PRO-PM(s)
    - Present and discuss the initial approach with the Coalition for their feedback and support.
        - NQF to preview content and provide feedback prior to Coalition presentation.
    - Adjust preliminary measure specifications to reflect input from coalition with NQF's support.
    - Document preliminary specifications and rationale in a methods report **(*Deliverable 2*)**
- Task 4: Develop a test plan describing how you plan to test and evaluate the preliminary measure specifications
    - Describe how you will test and evaluate the remaining specification decisions and the draft measure performance characteristics, including reliability (data element and measure score level-reliability), validity, feasibility/burden, and usability. **(*Deliverable 3*)**
- Task 5: Partner with the HIT vendor to develop implementation and testing guidance for the testing sites:
    - Enter a data use agreement with the HIT vendor providing the data solution.
    - Work with NQF and HIT vendor to set up and implement the PROM(s). The HIT vendor will coordinate directly with testing sites to integrate PROMs with their EHR systems and processes. HIT vendor will train sites on using the PROMs.
    - Note: In addition to PROM data, the HIT vendor can pull supplemental information from the EHR to support your risk adjustment and stratification analyses (e.g., diagnostic codes, demographics.)
- Task 6: Partner with clinical test sites and HIT vendor to collect sufficient PROM and supplementary data
    - Work with the Coalition and between 10-30 provider partner sites (provided by NQF/Coalition) who will serve as test beds.
    - Use the NQF-provided cloud-based HIT vendor to facilitate and support PROM administration, data collection, management, aggregation, clinician feedback on scores to clinicians, and lower administrative burden.
    - Discuss and determine workflow requirements for the clinical testing sites including PROM triggers and cadence for longitudinal data collection.
    - Meet bi-monthly with testing sites throughout the data collection period to gain experiential insights.
- Task 7: Implement testing plan and test and refine measure specification.
- Task 8: Draft final measure specifications and testing results. ***(Deliverable 4)***
    - Build packaged measure specifications with feedback from clinical test sites
    - Describe psychometric testing to include validity, reliability, feasibility, and a stratified equity analysis.
- Task 9: Present draft final measure specifications and testing results to the Coalition. **(*Deliverable 5*)**
    - NQF to preview content and provide feedback prior to Coalition presentation.
- Task 10: Incorporate Coalition feedback to build preliminary PRO-PM eCQM measure specifications, including risk adjustment and stratification(s) as appropriate. **(*Deliverable 6*)**
    - The developer will build the data model, expression logic, and the structure for the eCQM.

        - Construct QDM data elements in (e.g., using CMS Measure Authoring Tool (MAT))
            - CQL/QDM for current standards
            - CQL/FHIR for future standard requirements
    - Include reliability and validity testing.
    - Use Bonnie to test and verify behavior of the eCQM logic.
    - Use Value Set Authority Center (nih.gov) for value sets used.
- Task 11: Test eCQM specifications
    - Test eCQM in at least 2 different test sites and in two different EHRs
- Task 12: Summarize measure development and testing results, including final measure specifications, equity assessment or risk stratification methodology, in a final methodology report. ***(Deliverable 7)***
    - Provide packaged final measure specifications, including a psychometric testing summary, a written stratified equity analysis, and recommendations for implementation and further refinement.
        - Packaged final measure specifications (a human-readable document that can be viewed in a web browser; HQMF XML containing metadata, terminology, data elements, and specific population definitions respective to the measure; a CQL file which contains the terminology and expression logic used by the measure; an ELM XML export that is a computer-readable version of the CQL file, and a JSON export which is a serialized format of the ELM file).
    - Include feedback provided by the Coalition during the meeting described in Task 8
- Task 13: Provide NQF with monthly project status updates, including work completed and in progress, problems and proposed solution(s), and upcoming activities. ***(Deliverable 8)***

Deliverables:

- **Deliverable 1:** Coalition briefing: Preliminary approach and definitions
- **Deliverable 2:** Methods report and preliminary specifications
- **Deliverable 3:** Testing plan
- **Deliverable 4:** Draft final measure specifications and testing results
- **Deliverable 5:** Coalition briefing: Draft final measure specifications and testing results
- **Deliverable 6:** Preliminary PRO-PM eCQM measure specifications
- **Deliverable 7:** Final measure development and testing results report
- **Deliverable 8:** Monthly project status updates

Timeline:

The end-to-end process is intended to take no more than 18 months and NQF encourages innovative approaches that promote process and timeline efficiencies. However, we prioritize the need to collect enough data to accumulate an adequate sample size in each age group and over the timeframe needed from initial assessment to discern measurable clinical differences in response to quality-of-care differences. The developer should identify key assumptions in their proposal that will allow them to complete the work in 18 months.

Key Stakeholders and Roles

- **Aligned Innovation Coalition:** A group of public and private sector organizations that are the drivers and key customers for this measure. They are the final decision makers and are interested in building these PRO-PMs for use in accountability or quality programs at the national level.
- **Provider Partners:** The Coalition will bring provider partners at clinical sites across the country to collaborate with the measure developer and HIT vendor in testing and implementing the PROMs to provide data for the PRO-PMs.
- **NQF Staff:** NQF will facilitate all convenings and communication with the developer and all engaged stakeholders. NQF will also provide suggestions and identify opportunities for efficiencies.
- **HIT Vendor:** The HIT Vendor will provide a cloud-based data solution that will integrate directly with EHRs at clinical sites, facilitating the centralized collection of PROM data and easing development burden, and will collaborate with and support the developer.
- **Multistakeholder Advisory Council (MAC):** The MAC is a broad and diverse set of organizations that represent important end-users and enablers of measures who provide input and advice throughout the Aligned Innovation process. The MAC will review the measure specifications, stratification approach(es), and testing plan. Subject matter expert members of the MAC will be available throughout the development process to provide input and advice to the measure developers.
- **Specialty Societies:** Relevant Specialty Societies are engaged for expertise and participation of clinical experts.

Proposal Requirements

Responses to the RFP **must not exceed 10 single spaced pages** in length (excluding resumes, appendices, estimated budget, and references).

Applicants should submit a **technical proposal** including the following information:

- **High-level Work Plan:** This should outline your proposed approach for each task, including selection of PROMs, development, and testing activities. Testing activities include feasibility, reliability, and validity testing and risk stratification (or risk adjustment) and equity methodology, as appropriate. The work plan should address the methods, processes, procedures, and protocols necessary for effective and efficient completion of all measure development and testing activities and associated tasks and deliverables. There should be sufficient description so that NQF staff can evaluate the appropriateness and sufficiency of the proposed approach.
- **Project Timeline:** This should outline the key project milestones and dates for each task, with the intent to take no more than 18 months. Include your rationale for a timeline extending beyond 18 months. Note: NQF prioritizes the need to collect enough data to accumulate an adequate sample size in each age group and over the timeframe needed from initial assessment to discern measurable clinical differences in response to quality-of-care differences.
- **Project Management**: This should describe how you will manage the work throughout the project period, including how you will monitor the quality of the work and stay within the timeline and budget. You should also include how you will communicate your progress, risks, and any additional needs.
- **Project Staff:** Proposed team members should include at least one methodologist or statistician, data analyst, behavioral health expert, and project manager. Staff should have an established

history of successful development of quality outcome measures and considerable experience with PRO-PMs. Please include resumes for proposed staff (limit to four pages).
- **Experience:** Include examples of previous measure development activities, with an emphasis on PRO-PMs.

Applicants should submit a **business proposal** including an **estimated budget** for each task with justification, including estimated hours by labor category and fees for each task.

Note: NQF **recommends** that the developer use NQF's Patient-Reported Outcome Measures to Patient Reported Outcome Performance Measure Technical Guidance Final Report as a guide in crafting proposal responses and work plans.

Evaluation of Responses

Responses will be evaluated based on the following criteria:

- **Overall Suitability:** Proposed development, implementation, and testing approach must meet the scope and needs outlined above and be presented in a clear and organized manner.
- **Value and Cost:** Respondents will be evaluated on the quality, timeline, and cost of their approach based on the work to be performed in accordance with the scope of this project.
- **Experience/Qualifications:** Respondents will be evaluated based on their experience as it pertains to the scope of this project. Respondents should provide descriptions and documentation of assigned key personnel's technical expertise and experience.
- **Novelty and Efficiency:** Proposed development and testing approaches will be evaluated for their novelty, ability to provide efficient and cost-effective development and testing of PRO-PMs, and ability to effectively partner with experts, provider test sites, HIT vendor and other diverse stakeholders involved in the Aligned Innovation model of engagement.

Terms and Conditions

- **Work for Hire**: All deliverables will be owned by NQF, its successors and assigns.
- **Costs of Preparing Responses**: NQF will not pay any applicant costs associated with preparing responses to this RFP.
- **Responses Property of NQF**: Materials submitted in response to this RFP will not be returned.
- **RFP Amendments/Cancellation/Reissue/Reopen**: NQF reserves the right to change the RFP Schedule or issue amendments to this RFP at any time. NQF also reserves the right to cancel or reissue the RFP.
- **Type of Contract**: NQF intends to contract with the selected applicant(s) via a Time and Materials agreement, Not To Exceed (NTE).
- **No Obligation to Enter a Contract**:
    - The release of this RFP does not compel NQF to enter any contract.
    - NQF reserves the right to refrain from contracting with any vendor that has responded to this RFP, whether or not the applicant's response has been evaluated and whether or not the applicant has been determined to be qualified. Exercise of this reserved right does not affect NQF's right to contract with any other applicant.
    - NQF reserves the right to request an interview with any applicant prior to entering into a contract with that applicant. If an applicant declines the request for an interview or demonstration for any reason, the applicant may be eliminated from further consideration.
- **Multiple Contracts**: NQF reserves the right to enter into contracts with more than one applicant

as a result of this RFP.

- **Non-Endorsement**: The selection of an applicant pursuant to this RFP does not constitute an endorsement of the applicant's services. The applicant agrees to make no reference to NQF or the Coalition in any literature, promotional material, brochures, sales presentations, or the like without the express written consent of NQF and the Coalition.

Submission Instructions

Responses should be submitted via email to alignedinnovation@qualityforum.org by 5:00 PM ET on **October 5, 2023**, and decisions will be made by November 30, 2023.

Please submit any questions related to the RFP to alignedinnovation@qualityforum.org by 5:00 PM ET on **August 30, 2023**. We will post questions and answers to the Aligned Innovation webpage.

Although not required, applicants are strongly encouraged to submit a non-binding e-mail letter of intent to apply for this funding opportunity. This letter of intent will assist NQF in planning for the application review process. The letter of intent is requested by **August 30, 2023**. Interested organizations can send the letter of intent to alignedinnovation@qualityforum.org. Please identify the name of the applicant organization, the city and state in which the applicant organization is located, and the title of the RFP you intend to apply for.

References

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2. National Institute of Mental Health. Mental Illness. Published May 18, 2023. Accessed May 18, 2023. https://www.nimh.nih.gov/health/statistics/mental-illness
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4. National Institute of Mental Health. Major Depression. Published May 18, 2023. Accessed May 18, 2023. https://www.nimh.nih.gov/health/statistics/major-depression
5. Centers for Disease Control and Prevention. Anxiety and depression in children: Get the facts | CDC. Published May 18, 2023. Accessed May 18, 2023. https://www.cdc.gov/childrensmentalhealth/features/anxiety-depression-children.html
6. https://www.apa.org. Depression and anxiety escalate during COVID. Published May 18, 2023. Accessed May 18, 2023. https://www.apa.org/monitor/2021/11/numbers-depression-anxiety
7. Del Sol Calderon P, Izquierdo A, Moreno MG. Effects of the pandemic on the mental health of children and adolescents. review and current scientific evidence of the SARS-COV2 pandemic. *Eur Psychiatr*. 2021;64(S1):S223-S224. doi:10.1192/j.eurpsy.2021.597