Pediatric Oral Health Pain/Inflammation

Section 1. Basic Measure Information

1.A. Measure Name
Pediatric Oral Health Pain/Inflammation

1.B. Measure Number
0210

1.C. Measure Description
Please provide a non-technical description of the measure that conveys what it measures to a broad audience.

The Pediatric Oral Health Pain/Inflammation (POHPI) is an evidence-based, patient reported outcome quality measure for pediatric oral healthcare. The oral health pain/inflammation item bank comprises 38 questions regarding children’s perceptions of pain quality, pain location, bleeding/swelling, and pain impact. The measure will be available as a short form. The questions can be answered by children ages 8-17 years or parents of children ages 5-17 years. The measures use a 7-day report period.

The domain of pain/inflammation was selected based on an extensive literature review of oral health measures and prioritization by experts and children/parents. The item pools were developed using a rigorous mixed-methods approach in accordance with Patient Reported Outcome Measurement Information System® (PROMIS) standards. PROMIS is a federally funded initiative to develop patient-reported outcomes measures; it includes over 60 measures of patient-reported health. Methods included a systematic literature review of existing oral health measures; semi-structured interviews with pediatric dentists, parents, and youth; cognitive interviews with parents and youth; readability assessments; and classical and modern psychometric testing.

Development of the POHPI was conducted with 1,265 children and youth (ages 8-17 years) and 1,735 parents (of children ages 5-17 years). Participants resided in all 50 States. The measure has excellent reliability, which indicates that it yields very precise measurements of a child’s oral health pain/inflammation. Likewise, the validity is excellent, which suggests that indeed it evaluates a child’s oral health pain/inflammation. The POHPI has also been validated with other measures of children’s oral health, including the Child Oral Health Impact Profile-SF 19 (COHIP-SF 19).

The POHPI measure focuses on children’s pain experiences, including pain quality, pain location, bleeding/swelling, and pain impact. The POHPI is an outcome measure that will be useful in a wide variety of applications and across pediatric populations. Patient-reported outcome measures such as the POHPI provide information about health and the impact of
healthcare that is unique and complementary to information derived from measures of clinical outcomes and healthcare processes. Such measures have the potential to improve pediatric healthcare quality assessment at the point of care and through system-level performance evaluations.

1.D. Measure Owner
Children’s Hospital of Philadelphia

1.E. National Quality Forum (NQF) ID (if applicable)
Not applicable.

1.F. Measure Hierarchy
Please note here if the measure is part of a measure hierarchy or is part of a measure group or composite measure. The following definitions are used by AHRQ's National Quality Measures Clearinghouse and are available at http://www.qualitymeasures.ahrq.gov/about/hierarchy.aspx:

1. Please identify the name of the collection of measures to which the measure belongs (if applicable). A collection is the highest possible level of the measure hierarchy. A collection may contain one or more sets, subsets, composites, and/or individual measures.

The Pediatric Oral Health Pain/Inflammation measure will be incorporated into the PROMIS measure collection. The domain framework, which is hierarchically structured is shown in Figure 1 (see Supporting Documents). Note that the overall concept that PROMIS measures assess is self-reported health, and the highest level dimensions are physical, mental, and social health. This structure is reflective of the WHO tripartite conceptualization of health. The oral health measure is an evaluation of pain/inflammation, which integrates views of one’s physical, mental, and social health. The POHPI therefore evaluates all three dimensions of health.

2. Please identify the name of the measure set to which the measure belongs (if applicable). A set is the second level of the hierarchy. A set may include one or more subsets, composites, and/or individual measures.

Not applicable.

3. Please identify the name of the subset to which the measure belongs (if applicable). A subset is the third level of the hierarchy. A subset may include one or more composites, and/or individual measures.

Not applicable.

4. Please identify the name of the composite measure to which the measure belongs (if applicable). A composite is a measure with a score that is an aggregate of scores
from other measures. A composite may include one or more other composites and/or individual measures. Composites may comprise component measures that can or cannot be used on their own.

Not applicable.

1.G. Numerator Statement

We used an item response theory (IRT)-based approach for scoring. The raw summed score is ordinal, which means that a difference of one unit does not have the same meaning across the full scale. With interval scaling, a difference of one unit has the same meaning across the latent trait.

The score is computed by finding the raw summed score and converting that to an IRT-based (two-parameter graded response model) score, called Theta, which has a mean of 0. The theta score is then converted to a T-score, which has a mean of 50.

1.H. Numerator Exclusions

The child report measure is applicable to children ages 8-17 years. We recommend the exclusion of children with cognitive limitations or developmental delays that affect a child’s ability to self-report. The parent proxy report measure is applicable to children ages 5-17 years. Both of these age ranges are consistent with PROMIS standards.

1.I. Denominator Statement

The denominator is the total number of individuals within the population.

1.J. Denominator Exclusions

The denominator has the same exclusions as the numerator.

The child report measure is applicable to children ages 8-17 years. We recommend the exclusion of children with cognitive limitations or developmental delays that affect a child’s ability to self-report. The parent proxy report measure is applicable to children ages 5-17 years. Both of these age ranges are consistent with PROMIS standards.

1.K. Data Sources

Check all the data sources for which the measure is specified and tested.

Survey: parent/caregiver report, child report; Electronic medical record; Patient registry; Personal health record.

The POHPI is designed for questioning of children or their parents/guardians. The survey can be completed using paper and pencil, web-based forms in the electronic health record (e.g., EHRs
via patient portal), independent web-based data collection systems, patient-reported registries, and personal health records.

**If other, please list all other data sources in the field below.**
Not applicable.

### Section 2: Detailed Measure Specifications

Provide sufficient detail to describe how a measure would be calculated from the recommended data sources, uploading a separate document (+ Upload attachment) or a link to a URL. Examples of detailed measure specifications can be found in the CHIPRA Initial Core Set Technical Specifications Manual 2011 published by the Centers for Medicare & Medicaid Services. Although submission of formal programming code or algorithms that demonstrate how a measure would be calculated from a query of an appropriate electronic data source are not requested at this time, the availability of these resources may be a factor in determining whether a measure can be recommended for use.

Please see Supporting Documents for detailed measure specifications.

### Section 3. Importance of the Measure

In the following sections, provide brief descriptions of how the measure meets one or more of the following criteria for measure importance (general importance, importance to Medicaid and/or CHIP, complements or enhances an existing measure). Include references related to specific points made in your narrative (not a free-form listing of citations).

#### 3.A. Evidence for General Importance of the Measure

Provide evidence for all applicable aspects of general importance:

- Addresses a known or suspected quality gap and/or disparity in quality (e.g., addresses a socioeconomic disparity, a racial/ethnic disparity, a disparity for Children with Special Health Care Needs (CSHCN), a disparity for limited English proficient (LEP) populations).
- Potential for quality improvement (i.e., there are effective approaches to reducing the quality gap or disparity in quality).
- Prevalence of condition among children under age 21 and/or among pregnant women.
- Severity of condition and burden of condition on children, family, and society (unrelated to cost).
• Fiscal burden of measure focus (e.g., clinical condition) on patients, families, public and private payers, or society more generally, currently and over the life span of the child.

• Association of measure topic with children’s future health – for example, a measure addressing childhood obesity may have implications for the subsequent development of cardiovascular diseases.

• The extent to which the measure is applicable to changes across developmental stages (e.g., infancy, early childhood, middle childhood, adolescence, young adulthood).

Known Quality Gap or Disparity in Quality
The POHPI is an outcome measure designed to evaluate oral health pain/inflammation in the pediatric population and across socioeconomic and racial/ethnic groups. The measure may be useful for clinical, quality improvement, and research applications. The importance of measuring oral health was highlighted in the landmark, inaugural Surgeon General’s Report on Oral Health, underscoring the integral nature of oral health to general health and well-being (U.S. Department of Health and Human Services [HHS], 2000). Poor oral health has significant implications for children’s overall health, growth and development, and learning (HHS, 2000; Jackson, Vann, Kotch, et al., 2011).

Dental caries is the most common chronic disease of children in the United States, far exceeding even asthma, which is one of the most common pediatric conditions (American Dental Association [ADA], 2012). According to the National Health and Nutrition Examination Survey (NHANES), the prevalence of caries in primary teeth (untreated or filled, excluding missing teeth) in 2- to 5-year-olds increased from approximately 24 to 28 percent between the periods 1988 to 1994 and 1999 to 2004, with the majority of these children not having received appropriate treatment. Among 6-15 year-olds, one in two children are affected by dental caries (Dye, Tan, Smith, et al, 2007).

Importantly, untreated dental caries commonly lead to dental pain and inflammation. Pain, a sensory experience viewed as a consequence of disease or injury, is important as a person-reported outcome in oral health because it serves as one indicator for clinical endpoints, such as dental caries or gingivitis (Institute of Medicine [IOM], 2011). Furthermore, dental pain may have a significant negative impact on aspects of physical, mental, and social functioning.

The profound disparities that exist in dental caries, disproportionately affect minority and economically disadvantaged children (HHS, 2010). NHANES found that over 50 percent of children ages 2 to 11 years in families below the Federal poverty threshold experienced primary tooth dental caries, compared with one-third of children in families with incomes above 200 percent of the poverty threshold (Dye, et al, 2007).

The POHPI is a validated tool for researchers to better measure these gaps in quality.

Potential for Quality Improvement
An essential component of patient-centric quality improvement (QI) initiatives is to measure the impact of the intervention on patient outcomes. Studies have shown that young children are capable of answering their own questions related to oral health, and that questions answered via parent-proxy closely reflect their child’s oral health (Filstrup, Briskie, da Fonseca, et al., 2003).

The goal of most quality improvement (QI) activities is to improve the reliability of processes of care that have likely or established associations with patient outcomes. Typically QI initiatives do not measure the impact of the intervention on health. QI activity that reduces symptom burden or improves children's functional status will have a positive effect on their global health (see Figure 3 in the Supporting Documents for our adaptation of the Wilson and Cleary (1995) model of health-related quality of life).

In the case of oral health, there are bio-physiological processes related to the development of dental caries or other oral health conditions like gingivitis. These conditions may then lead to oral health symptoms like pain, which in turn may lead to a variety of oral health impacts, whether related to physical, mental, or social functioning. The POHPI measure can therefore support the evaluation of QI interventions, which are needed to bridge gaps in quality.

This measure is domain-specific rather than disease-specific. The domain of oral health pain/inflammation is applicable to all children and pregnant women. The POHPI is designed to measure the oral health pain/inflammation of children, with or without a specific oral health issue.

**Fiscal Burden of the Condition on Patients, Families, and Payers**

In 2010, dental services accounted for approximately 5 percent of national healthcare spending (CMS, 2015). Between 1990 and 2009, Medicaid dental expenditures grew from $756.1 million to $7.1 billion, or from 2.4 percent to 7.0 percent of total dental expenditures. Concurrently, dental costs continue to rise: Medicaid spending on dental services in 2012 was $7.3 billion – 60 percent higher than 5 years prior (CMS, 2015). Oral health disorders in children, if left untreated, commonly extend to adulthood, affecting an individual’s well-being and driving up financial costs that could have been avoided with proper childhood dental care (Mouradian, Wehr, Crall, 2000).

Not only is there a shortage of dental providers to the Medicaid population, children are three times as likely as adults to not have dental insurance and then medical insurance. Both these factors disproportionately affect low income and minority families (HHS, 2000) and pose significant fiscal barriers to care that inhibit children from receiving preventive services and treatment for dental care.

The consequences of poor oral care for children are numerous and have long-term impacts. These include: the development of progressive dental disease and greater risk of costly dental, infectious, and systemic disease in adulthood (HHS, 2000; Mouradian, et al., 2000).

Importantly, in psychometric testing of the POHPI, we found no age-related differential item functioning. This means that for a given score, younger and older children are equally likely to
endorse a response option for any given item. That is, younger and older children are using the measure similarly to describe their health.

3.B. Evidence for Importance of the Measure to Medicaid and/or CHIP

Comment on any specific features of this measure important to Medicaid and/or CHIP that are in addition to the evidence of importance described above, including the following:

- The extent to which the measure is understood to be sensitive to changes in Medicaid or CHIP (e.g., policy changes, quality improvement strategies).
- Relevance to the Early and Periodic Screening, Diagnostic and Treatment benefit in Medicaid (EPSDT).
- Any other specific relevance to Medicaid/CHIP (please specify).

CMS is the single largest payer of health services for children in the United States, and yet less than half of the nation’s 32 million children enrolled in Medicaid receive any dental service in a given year, and even fewer receive a preventive dental service (CMS, 2014). These low rates persist despite the inclusion of oral healthcare in Medicaid’s Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit for children. While low oral healthcare provider participation in Medicaid is an ongoing barrier to access – due in part to issues such as low reimbursement rates, administrative requirements – an additional 3.2 million children were expected to gain dental benefits via Medicaid expansion by 2018, taxing Medicaid programs with an already inadequate supply of providers (CMS, 2014; Health Management Associates [HMA], 2009). Concurrently, dental costs continue to rise: Medicaid spending on dental services in 2012 was $7.3 billion – 60 percent higher than 5 years prior (CMS, 2015). Medicaid agencies have an obligation to improve access to lower cost preventive and oral healthcare.

3.C. Relationship to Other Measures (if any)

Describe, if known, how this measure complements or improves on an existing measure in this topic area for the child or adult population, or if it is intended to fill a specific gap in an existing measure category or topic. For example, the proposed measure may enhance an existing measure in the initial core set, it may lower the age range for an existing adult-focused measure, or it may fill a gap in measurement (e.g., for asthma care quality, inpatient care measures).

Not applicable.

Section 4. Measure Categories

CHIPRA legislation requires that measures in the initial and improved core set, taken together, cover all settings, services, and topics of health care relevant to children. Moreover, the legislation requires the core set to address the needs of children across all ages, including services to promote healthy birth. Regardless of the eventual use of the measure, we are interested in knowing all settings, services, measure topics, and
populations that this measure addresses. These categories are not exclusive of one another, so please indicate "Yes" to all that apply.

Does the measure address this category?

a. Care Setting – ambulatory: Yes
b. Care Setting – inpatient: Yes.
c. Care Setting – other – please specify: Yes; home, school, long-term care. The POHPI is applicable across all settings where oral health evaluations are useful.
d. Service – preventive health, including services to promote healthy birth: Yes for preventive health.
e. Service – care for acute conditions: Yes.
g. Service – other (please specify): Health promotion; behavioral health; oral health.
h. Measure Topic – duration of enrollment: No.
i. Measure Topic – clinical quality: Yes.
k. Measure Topic – family experience with care: No.
l. Measure Topic – care in the most integrated setting: No.
m. Measure Topic other (please specify): Outcomes; patient-centered care.
q. Population – pre-school age children (1 year through 5 years) (specify age range): For age 5 only; the parent report version extends to children age 5.
r. Population – school-aged children (6 years through 10 years) (specify age range): Yes; all ages in this range.
s. Population – adolescents (11 years through 20 years) (specify age range): Yes; all ages in this range.
u. Other category (please specify): Not applicable.

Section 5. Evidence or Other Justification for the Focus of the Measure

The evidence base for the focus of the measures will be made explicit and transparent as part of the public release of CHIPRA deliberations; thus, it is critical for submitters to specify the scientific evidence or other basis for the focus of the measure in the following sections.

5.A. Research Evidence

Research evidence should include a brief description of the evidence base for valid relationship(s) among the structure, process, and/or outcome of health care that is the focus
of the measure. For example, evidence exists for the relationship between immunizing a child or adolescent (process of care) and improved outcomes for the child and the public. If sufficient evidence existed for the use of immunization registries in practice or at the State level and the provision of immunizations to children and adolescents, such evidence would support the focus of a measure on immunization registries (a structural measure).

Describe the nature of the evidence, including study design, and provide relevant citations for statements made. Evidence may include rigorous systematic reviews of research literature and high-quality research studies.

We conducted a systematic review of the published literature based on procedures outlined by Klem and colleagues to build a pediatric oral health conceptual framework (Klem, Saghafi, Abromitis, et al., 2009). Biomedical librarians at the University of Pennsylvania worked with our team to develop sets of terms related to dental/oral health, quality of life, measurement, and self/proxy report (Table 5; see Supporting Documents). The terms were applied to the Medline databases to identify articles that described or applied PRO instruments to assess children’s oral health.

Studies were eligible for inclusion if they were (1) written in the English language, (2) published in peer-reviewed journals or government reports in 1985 or later, (3) included specific measure(s) of child oral health outcomes (as indicated by presence of Dental/Oral Health, Quality of Life, Measurement, and Self/Proxy Report Terms), and (4) enrolled children and youth to 21 years of age. Two study investigators reviewed all article titles and abstracts to identify those that met the above criteria for potential eligibility. The full text of each potentially eligible paper was reviewed independently by two investigators. Differences between investigators were settled by consensus.

Characteristics of the PRO measures used in the eligible papers were abstracted using a standardized electronic abstraction form. The information abstracted included measure name, adult/child respondent, reporter, language, specific population, and reason. The top 25 most frequently found measures were identified and compiled (Table 6). Individual items from the top 25 measures were binned to construct the domain framework.

Constructing the domain framework involved classifying the concept text of each measure item into domains (12 identified) and sub-domains (55 identified). There were 11 key concepts derived from this analysis, with social-emotional well-being as the most common (Table 7). After this analysis was complete, the domain framework was reviewed and revised by six dental faculty members at the University of Pennsylvania. Additionally, framework development was supplemented by interviews with 13 content experts, 28 children (ages 8-17 years), and 25 parents of children ages 5-17 years. A qualitative analysis of these interviews was performed using a saturation mapping technique.

Once the domain framework was finalized, the items for the measure were created. Sets of items called “item banks” were developed and then calibrated using item response theory (IRT) methods. IRT modeling informs the selection of items that reliably measure the full range of a health experience (e.g., from very poor to excellent family relationships) with minimal gaps in
coverage and item redundancies. The models also provide a framework for investigating measurement bias as indicated by differential item functioning (DIF) and for developing computerized adaptive test (CAT) algorithms (Teresi, Fleishman, 2007). In CAT, items are presented to respondents based on their prior responses, tailoring the questions so that only a few items (typically five) are needed to reliably assess a full latent trait (Bjorner, Chang, Thissen, et al., 2007).

5.B. Clinical or Other Rationale Supporting the Focus of the Measure (optional)

Provide documentation of the clinical or other rationale for the focus of this measure, including citations as appropriate and available.

- Response to stakeholders: In stakeholder discussions that helped to identify the measure priorities for PQMP, several State leaders advocated for greater attention to child outcomes.

- Patient-centeredness: With the emergence of the Patient-Centered Outcomes Research Institute and a renewed emphasis in AHRQ and across the public sector on patient-centered care, new measures of outcomes from the patient’s perspective are needed.

POHPI is responsive to stakeholders, deals with a high-prevalence issue from a patient-centered perspective, and contributes to narrowing the existing gap in outcome measures for children.

Section 6. Scientific Soundness of the Measure

Explain the methods used to determine the scientific soundness of the measure itself. Include results of all tests of validity and reliability, including description(s) of the study sample(s) and methods used to arrive at the results. Note how characteristics of other data systems, data sources, or eligible populations may affect reliability and validity.

6.A. Reliability

Reliability of the measure is the extent to which the measure results are reproducible when conditions remain the same. The method for establishing the reliability of a measure will depend on the type of measure, data source, and other factors.

Explain your rationale for selecting the methods you have chosen, show how you used the methods chosen, and provide information on the results (e.g., the Kappa statistic). Provide appropriate citations to justify methods.

Internal Consistency Reliability

We calculated Cronbach’s alpha, a measure of internal consistency that assesses how closely related a set of items are as a group. A “high” value of alpha is often used as evidence that the items measure a latent construct, in this case pain/inflammation (Table 8, see Supporting
Documents).

**Precision Across the Full Range of the Latent Trait**

Reliability estimates are summaries of the precision of a measure computed from a sample. It is possible, and indeed likely, that the precision of a measure will differ by level of a latent trait.

To address this attribute of reliability, we have examined the test in formation function from a two-parameter graded response IRT model. The test information function (TIF) represents the reciprocal of the plot of the standard error of the measure, by the level of the latent trait, called “theta.” A theta of zero is the average level of pain/inflammation (Figures 4 and 5; see Supporting Documents).

**6.B. Validity**

Validity of the measure is the extent to which the measure meaningfully represents the concept being evaluated. The method for establishing the validity of a measure will depend on the type of measure, data source, and other factors.

Explain your rationale for selecting the methods you have chosen, show how you used the methods chosen, and provide information on the results (e.g., R2 for concurrent validity).

**Structural Validity**

This type of validity asks the question “how many different things, or dimensions, does this measure assess?” A unidimensional structure is a requirement for IRT modeling. It is desirable for the measure to be unidimensional for all ages, a phenomenon termed factor invariance. For the pain item pool, there was only evidence for a single factor (Tables 9 and 10; see Supporting Documents).

The ratio of eigenvalues supports the extraction of two factors for children and adolescents ages 8-17 years.

The well-being and distress banks were shown to be unidimensional using confirmatory factor analysis (CFA) to assess model fit for each distinct bank. The comparative fit index (CFI) was used to assess model fit. A CFI value of 0.95 or above is considered excellent fit. Table 11 (see Supporting Documents) shows the CFA model fit for each pediatric report bank.

**Concurrent Validity**

We have conducted a set of analyses that correlated the POHPI with other measures that we expected to be strongly related. To examine convergent and discriminant validity of the POHPI, we evaluated associations with two PROMIS pediatric measures of pain and global health. We also evaluated correlations with the Child Oral Impact Profile-Reduced and the Project Healthy Pathways Positive Body Image scale (Table 12; see Supporting Documents).

**Differential Item Functioning (DIF)**
In the context of IRT, DIF is observed when the probability of item response differs across comparison groups such as gender, age, and race, after conditioning on (controlling for) level of the underlying state or trait measured. Uniform DIF occurs if the probability of response is consistently higher (or lower) for one of the comparison groups across all levels of the state or trait. Non-uniform DIF is observed when the probability of response is in a different direction for the groups compared at different levels of the state or trait.

We used the R package, lordif, to fit ordinal logistic regression analyses (regressing the item responses on overall oral health well-being, distress or pain level (theta), and a putative DIF characteristic (e.g., gender). We tested the following characteristics for DIF across each of the questions in each bank: age, gender, and race/ethnicity. Results indicate no significant DIF by any of these characteristics.

These findings support the validity of the items, suggesting that there is no ‘built-in’ bias of the items that would add error to estimates of differences by groups defined by these characteristics. Lack of DIF is an important pre-condition for conducting disparity analyses.

Section 7. Identification of Disparities

CHIPRA requires that quality measures be able to identify disparities by race, ethnicity, socioeconomic status, and special health care needs. Thus, we strongly encourage nominators to have tested measures in diverse populations. Such testing provides evidence for assessing measure’s performance for disparities identification. In the sections below, describe the results of efforts to demonstrate the capacity of this measure to produce results that can be stratified by the characteristics noted and retain the scientific soundness (reliability and validity) within and across the relevant subgroups.

7.A. Race/Ethnicity
Known group comparisons for race and ethnicity were pending at the time this report was prepared.

7.B. Special Health Care Needs
Known group comparisons for special healthcare need status were pending at the time this report was written.

7.C. Socioeconomic Status
Socioeconomic status information was not available for analysis.

7.D. Rurality/Urbanicity
Known group comparisons for geographic area were pending at the time this report was pending.
7.E. Limited English Proficiency (LEP) Populations
LEP information was not available for analysis.

Section 8. Feasibility

Feasibility is the extent to which the data required for the measure are readily available, retrievable without undue burden, and can be implemented for performance measurement. Using the following sections, explain the methods used to determine the feasibility of implementing the measure.

8.A. Data Availability

1. What is the availability of data in existing data systems? How readily are the data available?

This is a new measure, and it has not been used. Data for the POHPI are not available in any existing data collection system. POHPI data are acquired through self-report and parent-proxy report. Person-reported outcome (PRO) measures can be conducted via self-administration or interviewer administration. Data can be captured through many of the typical administration methods including: face-to-face, telephone (interview or interactive voice response), mail, and internet.

2. If data are not available in existing data systems or would be better collected from future data systems, what is the potential for modifying current data systems or creating new data systems to enhance the feasibility of the measure and facilitate implementation?

With the imminent development of a short form, the brevity of the POHPI measure will make a variety of administration methods feasible. However, within the context of performance measurement activities at the State, health plan, or other level of the healthcare delivery system, implementation of these methods must be considered in terms of their sustainability over time.

We previously engaged Medicaid and CHIP leaders from the States of New Jersey, Pennsylvania, and Massachusetts to gather feedback on alternative approaches for implementing PRO performance measures. State leaders acknowledged that scarcity in resources poses barriers to any data collection effort that is not already systematically in use.

The following represent potential PRO administration contexts suggested by State leaders:

1. Inclusion in an existing survey

Many Medicaid and CHIP programs and health plans have a long history of fielding periodic surveys as part of their QI activities. As an example, many States utilize surveys from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) to obtain performance feedback regarding Medicaid clients’ satisfaction with healthcare and to provide feedback at the health plan, provider group, and individual provider levels. The family of CAHPS surveys
comprises widely disseminated tools that are used throughout the healthcare industry. Person-reported measures could be added to an existing survey, like the CAHPS.

2. Independent population-based survey

An alternative to integrating questions directly into another survey is to administer the POHPI measure, potentially even parallel and based on the same sampling procedures. As an independent survey, the tool could be internet-based or administered via the telephone or using a paper-and-pencil instrument. Health plans could integrate PRO measures as part of the new beneficiary on-boarding process, whereby new members may participate in health assessment surveys. States or plans could also focus on high-risk populations, administering the tool via case management systems that are already in place.

3. Patient portal integrated with an EHR

The use of patient portals as a mechanism for engaging patients and collecting important information continues to increase. The support of pilot studies and implementation efforts integrating PROs into EHRs have received major Federal support from the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), Patient Centered Outcomes Research Institute (PCORI), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), and the Office of the National Coordinator for Health Information Technology (ONC) (Wu, 2013). The integration of PROs into Epic Systems Corporation’s suite of EHR products also facilitates movement toward automated integration of PRO data into the EHR environment. As States and health plans continue to evolve in terms of their health information technology (IT) capacity and interconnectedness among different systems, the potential for administering PROs via patient portals will become increasingly viable. Input provided by health plans also raised the possibility of administering the survey at the point of care.

The second option was identified by States as the most opportunistic strategy, given the existence of and familiarity with administering surveys for a variety of QI and performance measurement activities.

CHOP’s extensive experience and success in administering PRO measures to thousands of children through multiple platforms and contexts (clinics, schools, etc.) provides insight into developing a strategy for implementing PROs in Medicaid and CHIP. In our work, we have observed important features of PRO administration that include low rates of non-completion, short completion duration, and reasonable time and resources to collect, process, and analyze data. These reflect important characteristics that are extremely relevant to publicly financed insurance programs where resources, including personnel time, energy, and funding, are very limited.

As States move progressively toward greater use and integration of health information systems, we believe that the opportunity for collecting and extracting PRO data via EHRs will be great. Software applications aimed at harnessing both clinical information and person-reported
outcomes have been developed and are in early stages of adoption. The key will be the identification of PRO measures that reflect the need and interests of relevant stakeholders.

8.B. Lessons from Use of the Measure

1. Describe the extent to which the measure has been used or is in use, including the types of settings in which it has been used, and purposes for which it has been used.
   Not applicable.

2. If the measure has been used or is in use, what methods, if any, have already been used to collect data for this measure?
   Not applicable.

3. What lessons are available from the current or prior use of the measure?
   Not applicable.

Section 9. Levels of Aggregation

CHIPRA states that data used in quality measures must be collected and reported in a standard format that permits comparison (at minimum) at State, health plan, and provider levels. Use the following table to provide information about this measure’s use for reporting at the levels of aggregation in the table.

For the purpose of this section, please refer to the definitions for provider, practice site, medical group, and network in the Glossary of Terms.

If there is no information about whether the measure could be meaningfully reported at a specific level of aggregation, please write "Not available" in the text field before progressing to the next section.

Level of aggregation (Unit) for reporting on the quality of care for children covered by Medicaid/CHIP†:

State level* Can compare States

Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)
Yes.

Data Sources: Are data sources available to support reporting at this level?
No.
**Sample Size:** What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?
Not determined.

**In Use:** Have measure results been reported at this level previously?
No.

**Reliability & Validity:** Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?
No.

**Unintended consequences:** What are the potential unintended consequences of reporting at this level of aggregation?
Unknown.

**Other geographic level:** Can compare other geographic regions (e.g., MSA, HRR)

**Intended use:** Is measure intended to support meaningful comparisons at this level? (Yes/No)
Yes.

**Data Sources:** Are data sources available to support reporting at this level?
Yes; all 50 States by race, ethnicity, private/public coverage, SES, chronic disease status, geography.

**Sample Size:** What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?
Not determined.

**In Use:** Have measure results been reported at this level previously?
No.

**Reliability & Validity:** Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?
No.

**Unintended consequences:** What are the potential unintended consequences of reporting at this level of aggregation?
Unknown.

**Medicaid or CHIP Payment model:** Can compare payment models (e.g., managed care, primary care case management, FFS, and other models)

**Intended use:** Is measure intended to support meaningful comparisons at this level? (Yes/No)
Yes.

**Data Sources:** Are data sources available to support reporting at this level? Yes, public vs. private.

**Sample Size:** What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size? Not determined.

**In Use:** Have measure results been reported at this level previously? No.

**Reliability & Validity:** Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation? No.

**Unintended consequences:** What are the potential unintended consequences of reporting at this level of aggregation? Unknown.

**Health plan***: Can compare quality of care among health plans.

**Intended use:** Is measure intended to support meaningful comparisons at this level? (Yes/No) Yes.

Data Sources: Are data sources available to support reporting at this level? No.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size? Not determined.

In Use: Have measure results been reported at this level previously? No.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation? No.

Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation? Unknown.
Provider Level

Individual practitioner: Can compare individual health care professionals

Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)
Yes.

Data Sources: Are data sources available to support reporting at this level? No.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?
Not determined.

In Use: Have measure results been reported at this level previously? No.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?
No.

Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?
Unknown.

Provider Level

Hospital: Can compare hospitals

Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)
Yes.

Data Sources: Are data sources available to support reporting at this level? No.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?
Not determined.

In Use: Have measure results been reported at this level previously? No.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?
No.
**Unintended consequences:** What are the potential unintended consequences of reporting at this level of aggregation?
Unknown.

**Provider Level**
*Practice, group, or facility:* **Can compare:** (i) practice sites; (ii) medical or other professional groups; or (iii) integrated or other delivery networks

**Intended use:** Is measure intended to support meaningful comparisons at this level? (Yes/No)
Yes.

**Data Sources:** Are data sources available to support reporting at this level?
No.

**Sample Size:** What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?
Not determined.

**In Use:** Have measure results been reported at this level previously?
No.

**Reliability & Validity:** Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?
No.

**Unintended consequences:** What are the potential unintended consequences of reporting at this level of aggregation?
Unknown.

**Section 10. Understandability**

CHIPRA states that the core set should allow purchasers, families, and health care providers to understand the quality of care for children. Please describe the usefulness of this measure toward achieving this goal. Describe efforts to assess the understandability of this measure (e.g., focus group testing with stakeholders).

State Medicaid programs, CHIP programs, and other key stakeholders have identified child health outcomes as an unmet need in pediatric health and healthcare quality measurement and expressed significant interest in identifying meaningful outcome measures that assess children's well-being and functioning. In addition to being validated as an important and meaningful measure concept throughout a large body of literature, the significance of oral health pain as a PRO concept was confirmed by dental clinicians and children through in-depth interviews. Assessment of pain by clinicians is already an integral and standard part of the dental clinical
examination and provides important clues around a child's oral health. These include characteristics of pain regarding the location, quality, nature, and impact. Among patient reportable outcomes, clinicians highlighted pain as a key concept to target. Furthermore, during the conduct of children and parent concept elicitation interviews, the pain/inflammation concept was clearly mapped to the extensive oral health experiences described from the perspectives of the intended PROM respondents, highlighting both the measure’s relevance and understandability.

Section 11. Health Information Technology

Please respond to the following questions in terms of any health information technology (health IT) that has been or could be incorporated into the measure calculation.

11.A. Health IT Enhancement

Please describe how health IT may enhance the use of this measure.

The utility and availability of the POHPI will be greatly enhanced when EHRs widely incorporate patient-reported outcomes in their patient portals. Epic has developed PRO applications in which PROMIS measures are part of the module and freely available to any user. The EHR module enables patients to complete the instrument at home, on a hand held device, or in the office waiting area. Data are stored in the EHR, which permits linkage with other clinical variables. Registries are another health IT application that will increase the availability of PROs. The pending development of the short form will further increase the likelihood of adoption as an evaluation of children’s health.

11.B. Health IT Testing

Has the measure been tested as part of an electronic health record (EHR) or other health IT system?

No.

If so, in what health IT system was it tested and what were the results of testing?

Not applicable.

11.C. Health IT Workflow

Please describe how the information needed to calculate the measure may be captured as part of routine clinical or administrative workflow.

See Section 11.A, above. In general, the information cannot be captured as part of current routine workflow.
11.D. Health IT Standards

Are the data elements in this measure supported explicitly by the Office of the National Coordinator for Health IT Standards and Certification (ONC) criteria (see healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_ifr/1195)?

No.

If yes, please describe.

Not applicable.

11.E. Health IT Calculation

Please assess the likelihood that missing or ambiguous information will lead to calculation errors.

Not applicable.

11.F. Health IT Other Functions

If the measure is implemented in an EHR or other health IT system, how might implementation of other health IT functions (e.g., computerized decision support systems in an EHR) enhance performance characteristics on the measure?

Not applicable.

Section 12. Limitations of the Measure

Describe any limitations of the measure related to the attributes included in this CPCF (i.e., availability of measure specifications, importance of the measure, evidence for the focus of the measure, scientific soundness of the measure, identification of disparities, feasibility, levels of aggregation, understandability, health information technology).

Age limitations: This measure does not address the health of children ages 0-4 years.

More work required to assess responsiveness: This measure requires longitudinal evaluation to assess its responsiveness to change.

Implementation: Activities to encourage PRO adoption are necessary in order to generate data that can be repurposed for performance measurement and other applications.
Section 13. Summary Statement

Provide a summary rationale for why the measure should be selected for use, taking into account a balance among desirable attributes and limitations of the measure. Highlight specific advantages that this measure has over alternative measures on the same topic that were considered by the measure developer or specific advantages that this measure has over existing measures. If there is any information about this measure that is important for the review process but has not been addressed above, include it here.

The Pediatric Oral Health Pain/Inflammation measure is an evidence-based, patient reported outcome measure of pediatric oral health that assesses a child’s report of oral pain/inflammation and includes perceptions of pain quality, pain location, bleeding/swelling, and pain impact. The full item bank comprises 38 items. The questions can be answered by children ages 8-17 years or by the parents of children ages 5-17 years.

The POHPI was developed according to the scientific standards of the Patient Reported Outcome Measurement Information System (PROMIS—www.nihpromis.org). PROMIS has developed over 60 measures of patient-reported health. The measure has excellent reliability, which indicates that it yields very precise measurements of a child’s oral health pain/inflammation. Likewise, the validity is excellent, which suggests that indeed it evaluates a child’s direct report of pain/inflammation. The comprehensive and rigorous PROM-development process ensures that the tool will be useful for clinical, population health, and research applications that require a precise and valid measure of children’s oral pain/inflammation experiences.

PRO measures may be integrated into existing data collection platforms, such as EHRs, ongoing surveys, and registries or be included in a new survey module. The instrument may be administered in a patient/ provider friendly manner (i.e., as an intake form or at the point of healthcare program initiation or as part of existing consumer survey administration) and subsequently coded into an EHR.

The POHPI measure is responsive to the voice of State leaders who advocated for greater attention to child outcomes; it represents an opportunity to address a topic of great public health and clinical significance. The tool summarizes children’s oral pain/inflammation experiences and the impact of these experiences. Patient-reported outcome measures such as the POHPI provide information about health and the impact of healthcare that is unique and complementary to information derived from measures of clinical outcomes and healthcare processes. Such measures have the potential to improve pediatric healthcare quality assessment at the point of care and through system-level performance evaluations.

References


Section 14: Identifying Information for the Measure Submitter

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The CHIPRA Pediatric Quality Measures Program (PQMP) Candidate Measure Submission Form (CPCF) was approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act.

The OMB Control Number is 0935-0205 and the Expiration Date is December 31, 2015.

Public Disclosure Requirements

Each submission must include a written statement agreeing that, should U.S. Department of Health and Human Services accept the measure for the 2014 and/or 2015 Improved Core Measure Sets, full measure specifications for the accepted measure will be subject to public disclosure (e.g., on the Agency for Healthcare Research and Quality [AHRQ] and/or Centers for Medicaid Services [CMS] websites), except that potential measure users will not be permitted to use the measure for commercial use. In addition, AHRQ expects that measures and full measure specifications will be made reasonably available to all interested parties. "Full measure specifications" is defined as all information that any potential measure implementer will need to use and analyze the measure, including use and analysis within an electronic health record or other health information technology. As used
herein, "commercial use" refers to any sale, license or distribution of a measure for commercial gain, or incorporation of a measure into any product or service that is sold, licensed or distributed for commercial gain, even if there is no actual charge for inclusion of the measure. This statement must be signed by an individual authorized to act for any holder of copyright on each submitted measure or instrument. The authority of the signatory to provide such authorization should be described in the letter.

AHRQ Publication No. 19-0050
July 2019