



*Improving Oral Health Through Measurement*

# ENVIRONMENTAL SCAN OF PATIENT REPORTED ORAL HEALTHCARE MEASUREMENT

## **FINAL REPORT**

NOVEMBER 2020

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## Purpose

The purpose of this report is to summarize the findings of the environmental scan focused on patient-reported oral health measures pursuant to the following two resolutions of the Dental Quality Alliance (DQA) at its June 2019 meeting:

***Resolved**, that the Measure Development and Maintenance Committee conduct an environmental scan of measures derived from patient reported data including but not limited to: patient reported outcome measures, quality of life, patient experience with healthcare and patient satisfaction and submit a report to the Dental Quality Alliance by the June 2020 meeting.*

***Resolved**, that the MDMC explore the development of criteria that the DQA might use to endorse tools and/or measures derived from patient reported data.*

A draft report describing the methodology and results of the scan was released in July 2020 for stakeholder feedback. This report provides an overview of the scan conducted, methodology utilized, key findings, and public comments received.

**The DQA appreciates stakeholders' engagement and thoughtful feedback during this process.**

**DQA acknowledges the members of its [Measures Development & Maintenance Committee \(MDMC\)](#) that led this work.**

## Executive Summary

Oral healthcare measures are routinely being used in quality improvement and accountability initiatives. Most oral healthcare measures that have been tested for reliability and validity address utilization, access, or processes of care. Given the increasing emphasis on patient-centered care and the need to measure outcomes, the DQA conducted an environmental scan of patient reported oral health measures.

**Intent:** The *intent of the environmental scan* is to provide information related to the current state of oral healthcare measures that are reported by patients. *This report* summarizes the methodology and findings of the environmental scan, which was comprised of a search for measures that exist either in the literature or may be in use. In addition, the report summarizes criteria used by the National Quality Forum (NQF) to evaluate performance measures derived from patient-reported data.

**Scan Strategy:** An initial framework of four broad patient-reported measurement terms included in the DQA resolution were used in the search strategy: patient-reported outcomes (PROs), patient experience, patient satisfaction, and oral health-related quality of life (OH-QOL). The scan findings identified **several additional** categories of patient-reported measurement that were not specifically included as search terms. Some terms that were not used in the search strategy relate to domains of measures such as health behavior, health literacy/ oral health knowledge, culturally appropriate care, and health equity.

This report does not include any qualitative assessment of the identified measures. Evaluation of such factors as patient involvement in the measure design process, scientific acceptability, and testing for validity and reliability was not undertaken and is beyond the scope of this report. Evaluation of potential uses of the identified measures is also beyond the scope of the report and is not addressed.

**Findings:** Measures identified through the scan were categorized as follows: access and affordability, dental visit/ dental use, patient satisfaction, patient experience, disease & condition impact, disease & condition status, and patient attributes such as dental fear, anxiety, health behavior etc.

The DQA identified that many of these concepts formed a basis for defining what a “patient reported outcome” is. Through careful review of different definitions of patient-reported outcomes from various recognized authorities in this field, the DQA notes that for concepts to represent patient-reported outcomes, they must be the result of the patient’s interaction (or lack thereof) with the care system and supported by evidence that the health care system can influence the outcome.

The scan highlighted that there are a range of oral health focused survey instruments that are well-validated in research contexts, but lack validation for use in clinical quality applications. There are national- and state-level population-based surveys that capture patient-reported data and focus on questions related to access and use of oral health care. While PROs, are often highlighted as true indicators of patient-centeredness, it is also worth noting that patient reporting of access/affordability, dental use/visits, health behaviors and intrinsic attributes such as fear and anxiety are also important to overall quality improvement efforts. As systems of care seek to understand their patients’ perspectives on care and the factors that influence their oral health and care seeking behaviors, these concepts provide the foundation for that assessment. The scan also identified some efforts underway to establish reliable and valid use of dental PRO performance measures in quality improvement applications.

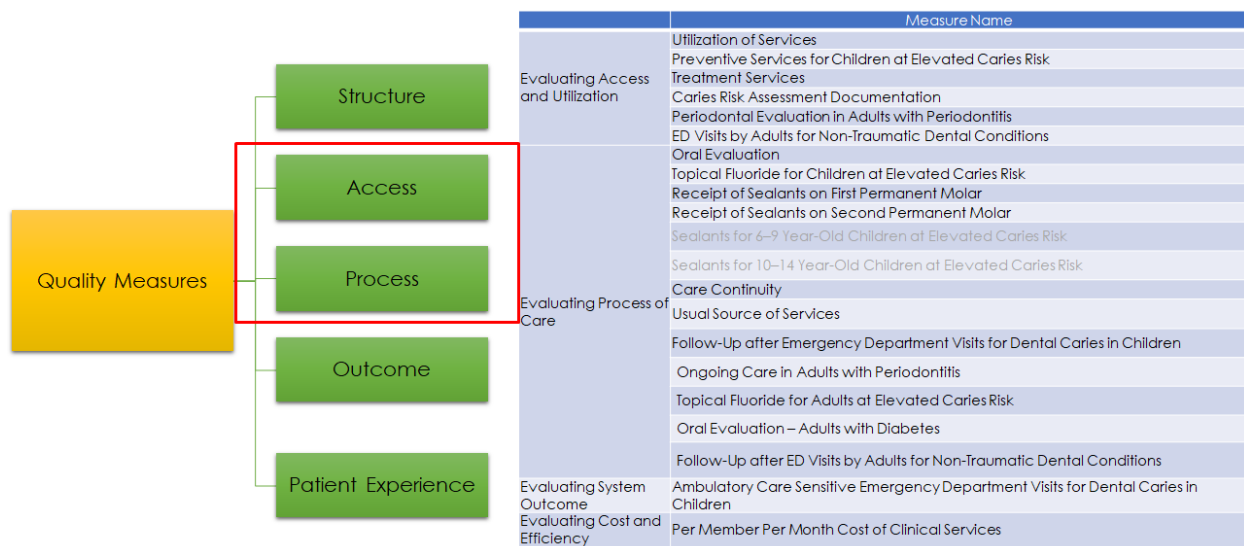
**Next steps:** The DQA identifies that this is not a complete environmental scan of all patient-reported oral healthcare measures but rather a start towards building a knowledgebase to inform on the availability and the use of such measures. As the next step, the DQA intends to build on this scan to assess patient-reported measures that may be used in the quality improvement context using assessment criteria already developed by the NQF.

## Current State of Oral Healthcare Measurement

Focused on utilization and processes of care

Since its inception in 2010, the DQA has led the development of nationally standardized and validated measures. Several measures have received NQF endorsement. DQA measures have been formally adopted by the Centers for Medicare and Medicaid Services (CMS), the Health Services and Resources Administration (HRSA), state Medicaid programs, and state Marketplaces.<sup>1-3</sup> Most DQA measures, as well as other dental measures, are focused on utilization and processes of care (Figure 1).<sup>4,5</sup>

Figure 1: DQA Measures



## Challenges in measuring oral healthcare outcomes

The DQA’s interest in exploring patient-reported measurement stemmed in large part from the lack of outcome measures and the difficulty in measuring oral healthcare outcomes using currently available clinical record or administrative claims data. The National Quality Measures Clearinghouse (NQMC) defines an outcome quality measure as “a health state of a patient resulting from health care.”<sup>6</sup>

There are several challenges in measuring clinically-assessed outcomes:

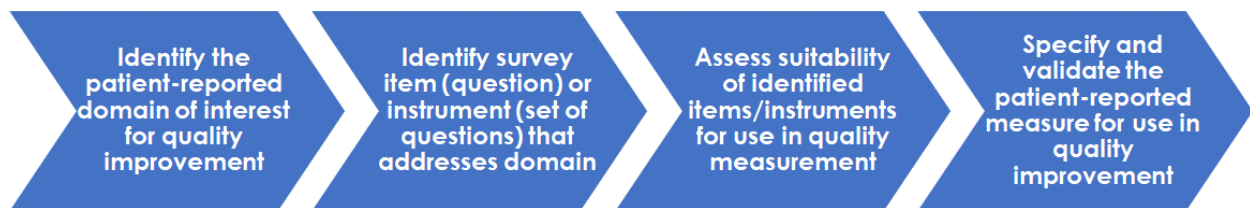
1. Most dental measures rely on administrative claims and encounter data. Diagnostic codes are essential for measuring clinically-assessed outcomes. However, diagnostic codes are not linked to billing. Unlike medical claims data, dental claims do not routinely capture diagnostic codes
2. Electronic dental records frequently have diagnostic information, but they lack standardization and the ability to integrate data across systems; consequently, reporting measures on aggregated populations is currently not feasible.
3. In addition, there are significant gaps in high-quality evidence needed to support linkages between oral healthcare interventions and patient outcomes.<sup>7-9</sup>

An increasing emphasis on patient-centered care has been accompanied by increasing interest in developing measures, particularly outcome measures, based on patient-reported data.<sup>10</sup> The NQF notes that patients are an important source of information not only for experience with care but also for other dimensions of care such as symptom and symptom burden, health-related quality of life, functional status, and health behaviors.<sup>10</sup> Patient-reported outcomes have been identified as important for measuring outcomes that are most meaningful to patients, engaging patients in their care, and promoting shared decision-making.<sup>10-12</sup> **Consequently, the DQA sought to better understand the current state of patient-reported measurements in oral health to inform their applications in quality improvement.**

### Using patient-reported data for quality measurement

There are numerous survey instruments that collect oral health and oral healthcare related information from patients. Using such information specifically for quality measurement purposes involves several steps, which are summarized in Figure 2 below.

Figure 2: Steps in Using Patient-Reported Data for Quality Measurement



This scan provides the foundation for the first two steps in this process: identifying measurement domains and the survey items/instruments that address those domains.

### Scan Objectives

The objective of the scan was to **identify existing patient-reported oral healthcare related performance and quality measure concepts**. The scan was **not limited to patient-reported outcomes specifically**, but rather focused on **patient-reported measures more broadly**.

### Methods

#### Databases

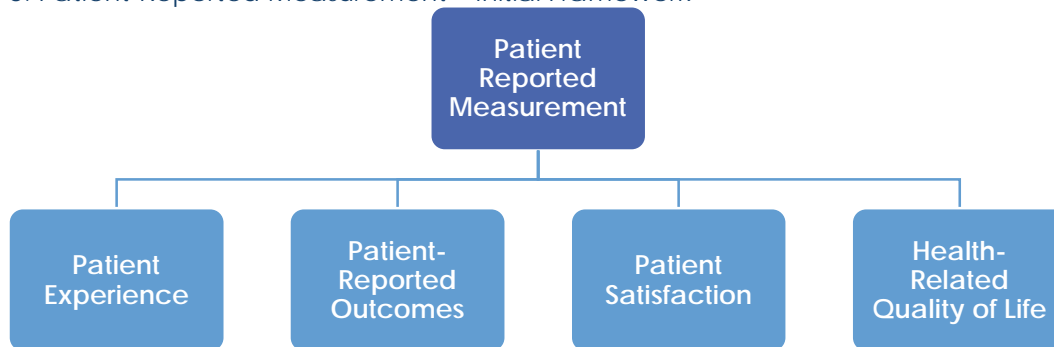
Searches were conducted within PubMed. Internet searches also were conducted, including searches within relevant organizations, such as the Patient-Reported Outcomes Measurement Information System (PROMIS), the International Consortium for Health Outcomes Measurement (ICHOM), the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), and RAND. Relevant instruments also were identified through recommendations from experts and instruments referenced during the literature reviews.

## Search strategy

The search strategy was developed in collaboration with the American Dental Association Library and Archives Department.

As an initial framework for considering patient-reported measurement, four broad terms were identified to focus the search strategy: patient-reported outcomes, patient experience, patient satisfaction, and health-related quality of life (Figure 3).

Figure 3: Patient-Reported Measurement – Initial Framework



The search strategy can be summarized as follows:

- terms related to patient-reported measurement, AND
- terms related to data collection and data collection instruments, AND
- terms related to dental/oral health.

The specific search strategy used in PubMed was:

((("Quality of Life"[Mesh] OR "Patient Satisfaction"[Mesh] OR "Patient Reported Outcome Measures"[Mesh] OR ("patient driven"[tiab] OR "patient reported"[tiab] OR "patient centered"[tiab]) AND (outcome[tiab] OR outcomes[tiab] OR data[tiab] OR measure[tiab] OR measures[tiab] OR measurement[tiab] OR measurements[tiab])) OR "patient experience"[tiab] OR "patient experiences"[tiab] OR "patient satisfaction"[tiab] OR "quality of life"[tiab])) AND (("Data Collection"[Mesh] OR "data collection"[tiab] OR assessment[tiab] OR assessments[tiab] OR measure[tiab] OR measures[tiab] OR measurement[tiab] OR measurements[tiab] OR "focus group"[tiab] OR "focus groups"[tiab] OR interview[tiab] OR interviews[tiab] OR survey[tiab] OR surveys[tiab] OR instrument[tiab] OR instruments[tiab] OR scale[tiab] OR scales[tiab] OR questionnaire[tiab] OR questionnaires[tiab] OR screening[tiab] OR screenings[tiab] OR tool[tiab] OR tools[tiab] OR "patient experience"[tiab] OR "patient experiences"[tiab] OR "patient satisfaction"[tiab] OR "quality of life"[tiab])) AND (("Oral Health"[Mesh] OR "Dentistry"[Mesh] OR "Dental Health Services"[Mesh] OR "oral health"[tiab] OR "oral surgery"[tiab] OR "oral surgeon"[tiab] OR "oral status"[tiab] OR "oral function"[tiab] OR dental[tiab] OR dentist[tiab] OR dentists[tiab] OR dentistry[tiab] OR orofacial[tiab] OR temporomandibular[tiab] OR craniomandibular[tiab] OR orthodontic\*[tiab] OR periodont\*[tiab] OR endodont\*[tiab] OR prosthodont\*[tiab]))

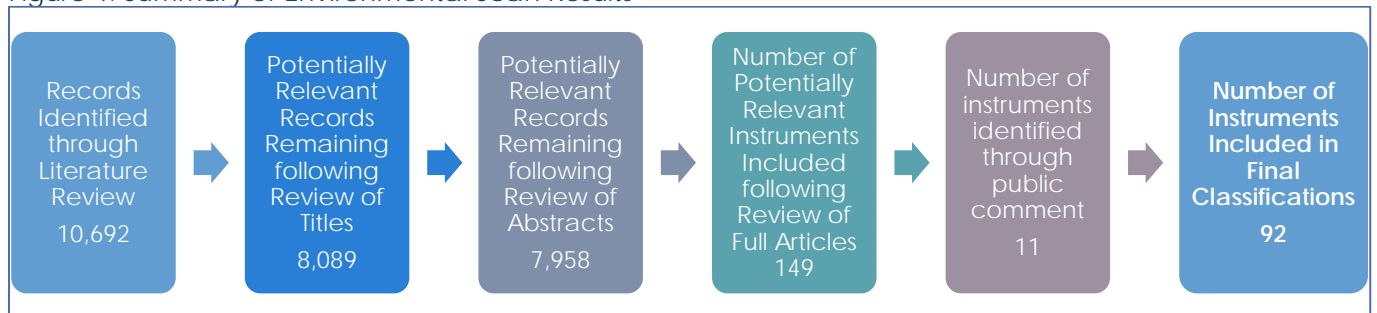
Some terms that were not used in the search strategy relate to the domains of measures such as health behavior, health literacy/ oral health knowledge, culturally appropriate care, and health equity. There were no qualitative assessments of the identified instruments. Evaluation of such factors as patient involvement in the instrument design process, scientific acceptability, and testing for validity and reliability was not undertaken and is beyond the scope of this scan. Evaluation of potential use of the identified instruments is also beyond the intent of the scan and is not addressed.

## Results

### Patient-reported oral health instruments identified through the scan

The term **measure** refers to an instrument, scale, or individual item (question) used to assess the patient-reported concepts. The goal of the search was to identify unique instruments containing patient-reported oral health measures. Consequently, search records were de-duplicated based on the instruments identified. Instruments with multiple versions based on different lengths and languages, were frequently de-duplicated (i.e., all lengths and languages were not included). A total of 92 unique oral health related instruments were identified and obtained.

Figure 4: Summary of Environmental Scan Results

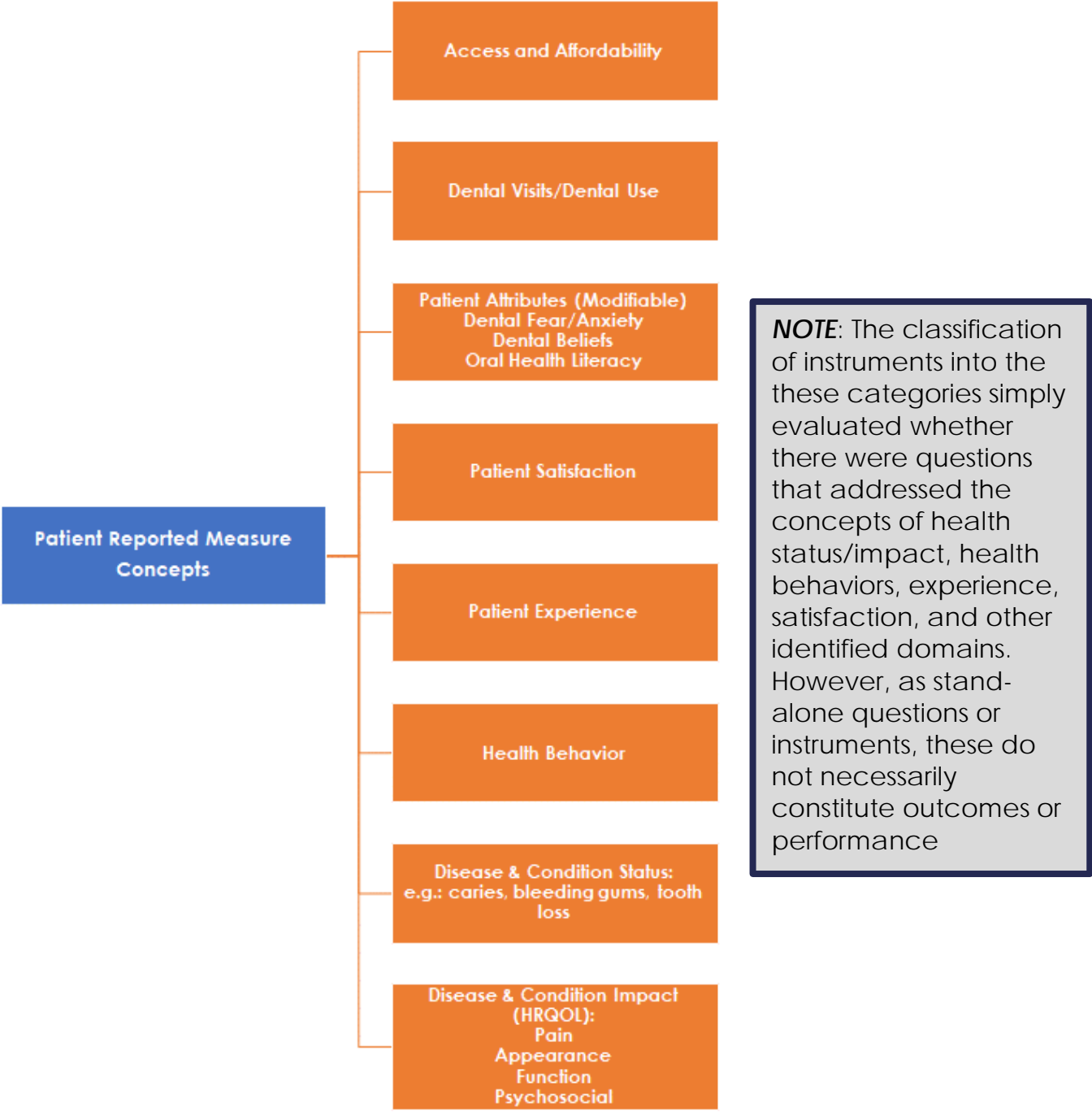


### Classification of instruments into patient-reported measure concepts

The DQA MDMC reviewed all of the oral health patient-reported instruments located through the scan and classified the identified measures into different measure concept categories. During its review, the MDMC identified additional categories beyond the initial four that are represented in Figure 3. MDMC reviewed all *items* (survey questions) within each instrument. During this process, MDMC reviewed a total of 1,293 items from 92 instruments. Items that were not reported by patients were excluded from review. Items that were also not related to oral health or oral healthcare were excluded from review. Review also found that the same instrument could have items addressing more than one measure concept and, therefore, could be reflected in more than one category. Figure 5 below summarizes the categories of measures identified through the scan. The complete set of classifications of the instruments is contained in [Appendix 2](#).



Figure 5: Patient-Reported Measure Concepts Identified through Scan



### Defining patient-reported measure *concepts*

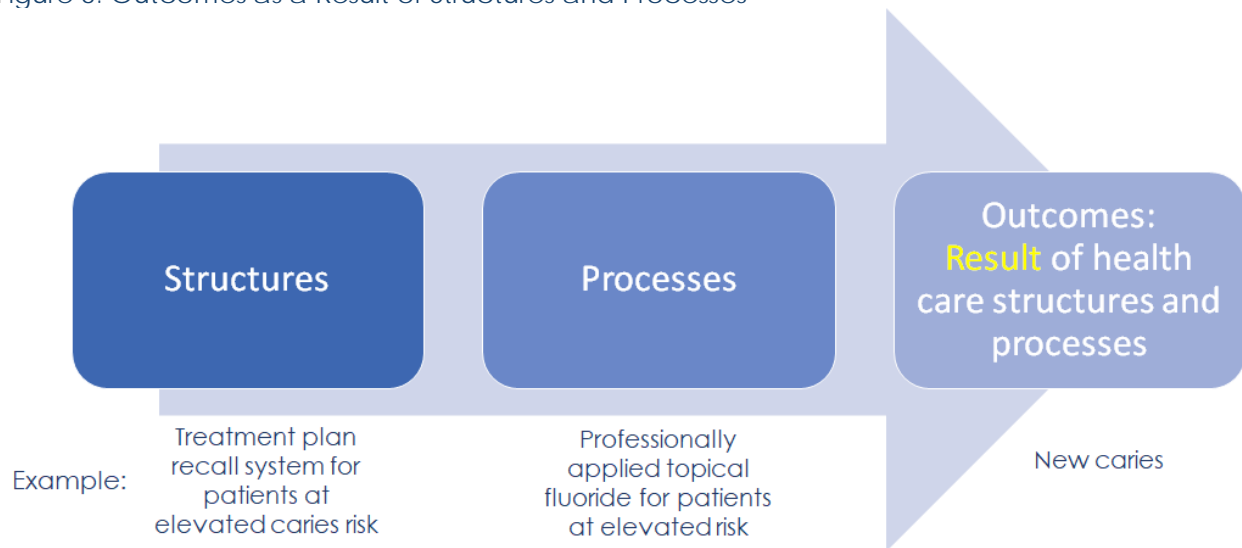
During the process of classifying the instruments into measure concepts, the MDMC reviewed reports and definitions from the following organizations that provide guidance related to patient-reported quality measurement: Agency for Healthcare Research and Quality (AHRQ), including the National Quality Measures Clearinghouse (NQMC); the National Quality Forum (NQF); and the Food and Drug Administration (FDA). A summary of the key definitions relied upon is provided in Appendix 1. Drawing from these definitions, the MDMC identified the following measure concepts.

- (1) Measure concepts that may form the basis for **patient-reported outcomes**

#### Defining patient-reported outcomes

Because the ultimate goal is to consider *quality measures derived from patient-reported data*, and particularly the potential for *outcome* measures, a particular focus was on clarifying what is a *patient-reported outcome*? The MDMC reviewed multiple definitions of outcome measures in general and patient-reported outcomes specifically ([Appendix 1](#)). The MDMC identified the attributes of a patient-reported measure that are required for the measure to be considered an *outcome* measure. The MDMC identified as a key attribute that the proposed outcome measure must be the result of the patient’s interaction (or lack thereof) with the care system. NQF advises that performance measures of health outcomes should be linked to evidence-based structures and processes (Figure 6).<sup>10</sup> With respect to selecting patient-reported outcome measures specifically, NQF identifies as a consideration whether there is “evidence that the outcome of interest is responsive to a specific healthcare or support service or intervention.”<sup>10</sup>

Figure 6: Outcomes as a Result of Structures and Processes



## Measure concepts underlying patient-reported outcomes

During the process of reviewing the different types of patient-reported measures, the MDMC identified the following measure concepts that could form the basis for patient-reported outcome measures (Figure 7):

### *Measures of health status and impact*

All definitions of *outcome* measures reviewed ([Appendix 1](#)) identified the patient's health status (also referred to as "health state" or "status of health condition") as a key PRO domain. As noted above, for health status to be an *outcome measure*, it must be the result of some interaction with the healthcare system. As NQMC observes, health status, by itself, may simply reflect condition prevalence and not be attributable to health care.<sup>6</sup>

To clarify what is meant by "health status," the MDMC adopted the **FDI's definition of oral health status**: "the ability to speak, smile, smell, taste, touch, chew, swallow and convey a range of emotions through facial expressions with confidence and without pain, discomfort and disease of the craniofacial complex."<sup>13</sup> The MDMC further distinguished disease and condition *status* from disease and condition *impact*.

**Measures of disease and condition status** address diseases of the craniofacial structures: e.g., caries status, tooth loss, and bleeding gums. Measures of condition and disease status often are more reliably assessed through clinical evaluations. But patient-reported indicators may be important when clinical assessments are not available or as a gauge of a patient's understanding and perception of his/her oral health status. Thirty-five instruments included items addressing disease and condition status.

**Measures of disease and condition impact** address the impact of disease and condition status on:<sup>14</sup>

1. Pain
2. Appearance (aesthetics)
3. Functional status
4. Psychosocial impacts

Disease and condition impact reflect health-related quality of life (HRQOL). The Oral Health Impact Profile is an example of an instrument that addresses disease and condition impact/HRQOL. Sixty-seven instruments included items addressing disease and condition impact.

### *Measures of health behavior*

The NQF defines health behaviors as "behaviors expressed by individuals to protect, maintain or promote their health status."<sup>10</sup> However, the MDMC observed that the NQF definition focuses on positive health behaviors, but noted that health risk behaviors such as tobacco use can adversely impact health. Consequently, it adopted the definition put forth by Short and Mollborn: "actions taken by individuals that affect health or mortality. These actions may be intentional or unintentional, and can promote or detract from the health of the actor or

## Key Concept

Survey items and instruments do not, by themselves, constitute patient-reported outcomes. Rather, they measure concepts that may represent a patient-reported outcome in a specific application.

others.”<sup>15</sup> Examples of health behaviors include diet, exercise, tobacco use, substance use, health care seeking behaviors, and adherence to prescribed treatments.

Twenty-two instruments included items addressing health behaviors. The oral health behaviors most commonly captured in the identified instruments were brushing, flossing, tobacco use, and alcohol use. The search strategy was designed to broadly capture oral health patient-reported measurement. As stated above, the term “behavior” was not explicitly included in the search. As a result, behaviors that influence disease risk, prevention, and management were not comprehensively captured. Oral health behaviors are critical to preventing and managing oral disease and improving oral health status. Clinical interventions are not restricted to technical processes of care; they also may target behaviors through such activities as counseling and motivational interviewing. Health behaviors supported by evidence that they can be influenced by healthcare structures and processes may also represent patient-reported outcomes.

### *Measures of experience*

The NQMC defines patient experience as the patient’s “report of observations of and participation in health care, or assessment of any resulting change in their health.”<sup>6</sup> AHRQ notes that “to assess patient experience, one must find out from patients whether something that should happen in a health care setting (such as clear communication with a provider) actually happened or how often it happened.”<sup>16</sup> AHRQ’s Consumer Assessment of Healthcare Providers and Systems (CAHPS) Dental Plan Survey is an example of an instrument that addresses patient experience with oral health care. A total of eight instruments that included items that assessed patient experience with care were identified by the scan.

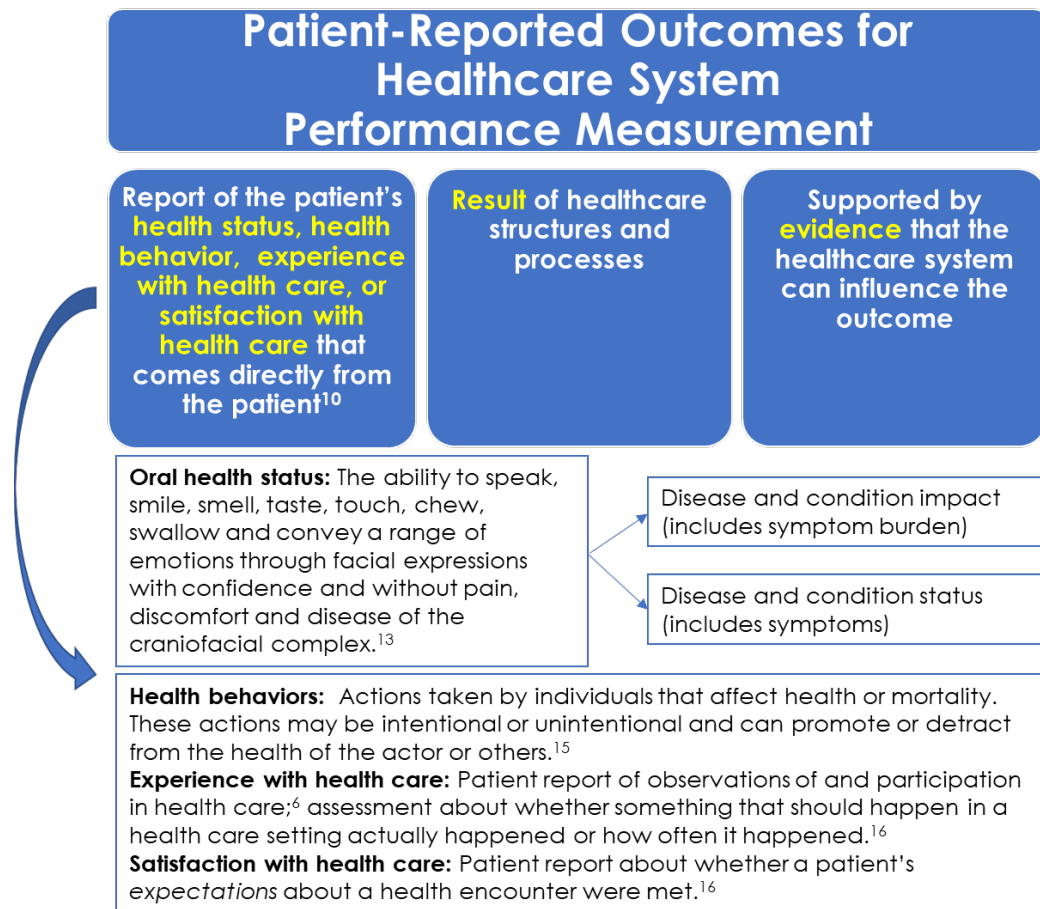
### *Measures of satisfaction*

AHRQ distinguishes patient satisfaction from patient experience as follows: “Satisfaction is about whether a patient’s *expectations* about a health encounter were met. Two people who receive the exact same care, but who have different expectations for how that care is supposed to be delivered, can give different satisfaction ratings because of their different *expectations*.”<sup>16</sup> Five instruments included items that address patient satisfaction of care. Examples include the Dental Satisfaction Questionnaire and the Dental Visit Satisfaction Survey.

The MDMC considered whether measures of patient satisfaction would be too subjective to form the basis for patient-reported outcomes. The MDMC noted that all PROs reflect patient perceptions and are subjective.<sup>12</sup> Moreover, the MDMC also noted that for a patient-reported concept (including concepts of patient satisfaction) to become a patient-reported outcome performance measure, it must meet reliability and validity criteria and address threats to reliability and validity including those stemming from patient-specific factors that influence the outcome.<sup>10,12</sup> Although it is not formally part of the NQF PRO definition, the NQF commented: “Among the concepts that PROMs would ideally capture are the following: health-related quality of life (including functional status); symptom and symptom burden; experience with care and **satisfaction** with the services; perceived utility of the services for achieving personal goals; or health behaviors”<sup>10</sup>.

To summarize, the DQA notes that many of the concepts identified through the scan formed a basis for defining what a “patient reported outcome” is. After careful review of different definitions of patient-reported outcomes from various recognized authorities in this field ([Appendix 1](#)), the DQA notes that for these concepts to represent patient-reported outcomes, they must be the result of the patient’s interaction (or lack thereof) with the care system and supported by evidence that the health care system can influence the outcome.

Figure 7: Defining Patient-Reported Outcomes for Performance Measurement



## (2) Other patient-reported data

Collectively the instruments identified also contained questions in the following areas:

- *Modifiable patient attributes*, such as dental fear and anxiety about dental visits and procedures, dental beliefs, and oral health literacy (13 instruments). These attributes may be heavily shaped by factors outside of the care system even though they may also be influenced by prior experiences with care.
- *Access and affordability*, such as whether the patient has dental insurance, out-of-pocket costs, and reasons for not having (or difficulties obtaining) a dental visit (11 instruments).
- *Dental visits and use of services*, such as whether and how recently the patient has seen a dentist or other dental provider (21 instruments).

These areas are important for a comprehensive understanding of care systems and factors affecting patients' access to care, use of dental services, experiences with care and health behaviors. They have not been a focus of patient-reported quality measure development. Literature shows that both clinical and non-clinical patient factors impact a PRO.<sup>12,13</sup> Instruments addressing these areas may be useful as part of overall quality improvement efforts as systems of care seek to understand their patients' perspectives on care and the factors that influence their oral health and care seeking behaviors.

## Application of Patient-Reported Measurement

### Current applications

Despite the increasing emphasis on patient-centered and outcomes-focused measurement, patient-reported measures are not widely used for routine quality assessment in clinical settings, including in medicine.<sup>10</sup>

With respect to oral health specifically, there are national and state-level population-based surveys that capture patient-reported data. However, the surveys largely focus on questions related to access and use of oral health care. Some of the surveys also capture self-reported disease and condition status while some capture significant information on the impacts of oral health disease. For example, the Pregnancy Risk Assessment Monitoring System (PRAMS) captures state-level information for pregnant women on receipt of certain dental services, such as teeth cleanings, difficulties in obtaining care, and some information on self-reported oral health disease and condition status. The impacts of oral disease are not addressed within PRAMS. Similarly, the Behavior Risk Factor Surveillance System is a state-level survey that includes questions pertaining to dental visits and tooth loss. Because these are broad population-based surveys, they can provide population-based insights into oral healthcare quality and may help to shape quality improvement at a broad systems level. For example, there are National Performance Measures related to oral health for use by state Title V Maternal and Child Health Programs, including patient-reported data from PRAMS, but the focus is on dental visits. However, current efforts are underway to develop a more robust set of quality indicators that includes outcomes-oriented measures.<sup>17</sup> But broad surveillance indicators are not particularly useful for practices, health centers, and other entities seeking to improve quality at the site of care.

One of the best-known patient experience instruments are those that comprise the suite of Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys.<sup>18</sup> There is a single dental plan survey targeting adult patients. Some Medicaid programs and dental plans have adapted questions from this survey for application to other populations and settings. In medicine, there are NQF-endorsed performance measures developed from CAHPS instruments.

At the level of point of care, practices and health centers may use more streamlined experience or satisfaction surveys to elicit patient feedback about their care. These instruments may be market-tested. Because these instruments are typically proprietary, there is little information on their reliability and validity. In addition, the instruments vary across sites. Consequently, such instruments are currently limited in their ability to drive meaningful widespread improvements in quality. However, this is an evolving field. The scan also identified some efforts underway to establish reliable and valid use of dental PRO performance measures in quality improvement applications. An AHRQ funded research activity has identified two PRO measures that have undergone validation testing.<sup>19</sup> Efforts are also underway by researchers at the University of California Los Angeles who are working on a NIH-funded project to develop measures for use with the Patient Reported Outcomes Measurement Information System (PROMIS) project.<sup>20</sup> They have developed a comprehensive framework for patient reported measurement. ICHOM recently published an article that summarizes the development of a set of adult oral health measures that includes questions on psychosocial status, physiological functioning, disease and condition status, as well as related health determinants, based on information from both the practitioner and the patient.<sup>21</sup>

Vision for the future: patient-reported outcome measures

Most survey instruments that address PRO concepts are not designed for quality improvement applications. The NQF lays out a framework for moving from a PRO concept to a PRO *performance measure* (PRO-PM) that can be used in quality improvement applications.<sup>10</sup> Table 1 below defines key terms with examples.

Table 1: Illustration of PROs, PROMS, and PRO-PMs

Concept <sup>10</sup>	Medical Example from NQF Report <sup>10</sup>	Potential Oral Health Example (not formally validated as a PROM and PRO-PM for use in QI applications)
<b>Patient-reported outcome (PRO):</b> “any report of the status of a patient’s (or person’s) health condition, health behavior, or experience with healthcare that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else”	Symptom: Depression	Symptom: Orofacial Pain
<b>PRO measure (PROM):</b> “Instrument, scale, or single-item measure used to assess the PRO concept as perceived by the patient, obtained by directly asking the patient to self-report”	PHQ-9 <sup>®</sup> , a standardized tool to assess depression (9 items to assess depression)	Oral Health Impact Profile (49) – Physical Pain Sub-Scale (8 items to assess orofacial pain)
<b>PRO-based performance measure (PRO-PM):</b> “A performance measure that is based on PROM data aggregated for an accountable healthcare entity”	Percentage of patients with diagnosis of major depression or dysthymia and initial PHQ-9 score >9 with a follow-up PHQ-9 score <5 at 6 months (NQF #0711)	% of patients within a responsible care system, with a statistically significant and clinically meaningful change in the physical pain sub-scale score from measurement period 1 to measurement period 2

Although there are numerous research studies that use variations of the OHIP and other concepts that may be suitable for developing patient-reported outcome measures, such measures are not widely adopted for quality improvement in clinical practice. Barriers to adoption include the burden of administering the instrument (e.g., questionnaire length); integrating into clinical workflows; capturing and storing patient-reported data; and analyzing the results. Consequently, in addition to capturing meaningful and actionable patient-reported measures, the instruments and processes used must be sufficiently streamlined to support adoption in a busy clinical care setting. In addition, although instruments may be well-validated for reliability and validity in a research context, reliability and validity may not transfer to quality improvement applications. Consequently, additional testing must be conducted for use of these measures in quality improvement applications specifically.



PRO-PMs: A Note on Risk Adjustment

Even when carefully selecting PROs that have an evidence-based linkage to healthcare structures and processes, it is important to recognize that there often are clinical and non-clinical patient factors that affect PROs.<sup>12,22</sup> Consequently, the use of a PRO for performance measurement should be preceded by an evaluation of the need for methodologies, such as risk adjustment or stratification, to take into account these other influences.<sup>23</sup>

**Criteria under Consideration for Evaluating Patient-Reported Measurement for Quality Improvement Applications**

The NQF has developed criteria for evaluating patient-reported measures for use in performance measurement applications. These criteria are summarized in Table 2. The NQF criteria can be used as a guide for developing a PROMs evaluation scorecard. Such a scorecard could be used: (1) to “endorse” existing patient-reported oral health instruments or measures or (2) to identify instruments that form a suitable foundation for developing new patient-reported oral healthcare performance measures.

Table 2: National Quality Forum Criteria for Evaluating Patient-Reported Measures<sup>10</sup>

Criteria	Additional criteria details	Consideration for Evaluation
Importance to Measure and Report		<ul style="list-style-type: none"> <li>• Is there evidence to support the measure</li> <li>• Was there patient input during measure development</li> <li>• Is the concept actionable in response to a healthcare intervention</li> </ul>
Conceptual/Measurement Model	Documentation of how the concepts are organized into a measurement model, including evidence for dimensionality of the measure.	<ul style="list-style-type: none"> <li>• Number and nature of items in a concept’s scale has been evaluated through factor analysis.</li> </ul>
Scientific Acceptability	Reliability	<ul style="list-style-type: none"> <li>• Internal consistency (multi-item scales)</li> <li>• Reproducibility (stability over time)</li> </ul>
	Validity	<ul style="list-style-type: none"> <li>• Content Validity</li> <li>• Construct and Criterion-related Validity</li> <li>• Responsiveness</li> </ul>
Feasibility		<ul style="list-style-type: none"> <li>• Burden of data collection</li> <li>• Mode of administration</li> <li>• Instrument length</li> </ul>
Use & Usability	Adequate demonstration of the criteria supports usability and ultimately the use of an instrument-based measure for accountability and performance improvement.	<ul style="list-style-type: none"> <li>• Interpretability of scores</li> <li>• Ability to identify clinically important changes</li> <li>• Ability to apply or translate scores for use in quality improvement</li> <li>• Availability in multiple languages</li> </ul>



## Appendix 1: Definitions of Patient-Reported Measurement Concepts

Concept	Definition	Contextual Notes
<b>Defining Outcomes</b>		
<b>Outcome (clinical quality measure)</b>	<b>AHRQ/NQMC:</b> An outcome of care is a health state of a patient resulting from health care. Outcome measures are supported by evidence that the measure has been used to detect the impact of one or more clinical interventions (or public health interventions for population outcomes). <sup>6</sup>	<ul style="list-style-type: none"> <li>• Definition emphasizes that health state as an outcome must result from health care.</li> <li>• NQMC distinguishes “health state” alone as a “related health care delivery measure” that by definition “is not known to be the result of antecedent health care.”<sup>6</sup></li> </ul>
<b>Patient-Reported Outcome</b>	<b>FDA:</b> A PRO is any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else. The outcome can be measured in absolute terms (e.g., severity of a symptom, sign, or state of a disease) or as a change from a previous measure. <sup>24</sup>	<ul style="list-style-type: none"> <li>• Definition itself does not incorporate the concept “as a result of health care.”</li> <li>• However, the definition is provided in the context of specific guidance for a clinical application: “to support claims in approved medical product labeling” in which PRO data are “used to measure treatment benefit or risk in medical product clinical trials.”<sup>24</sup></li> </ul>
	<b>NQF:</b> A patient-reported outcome (PRO) is any report of the status of a patient’s (or person’s) health condition, health behavior, or experience with healthcare that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else. Key PRO domains include health-related quality of life (including functional status); symptoms and symptom burden (e.g. pain, fatigue); experience with care; and health behaviors (e.g., smoking, diet, exercise). <sup>10,25</sup>	<ul style="list-style-type: none"> <li>• NQF expands the FDA definition to include reports not only of a patient’s <i>health condition</i>, but also <i>health behavior</i> and <i>experience with healthcare</i>.</li> <li>• Definition does not explicitly incorporate the concept “as a result of health care.”</li> <li>• However, the definition is part of broader guidance pertaining to the use of PROs in <i>performance measurement</i>. As part of the guidance, NQF notes that selection of a PRO measure should consider whether there is “evidence that the outcome of interest is responsive to a specific healthcare or support service or intervention.”<sup>7</sup> NQF notes that “outcome performance measures (including PRO-PMs) intended for both accountability and improvement should be supported by evidence that the providers being evaluated can influence the person’s short- or long-term outcomes.”<sup>7</sup></li> </ul>
<b>Components of “Outcomes” and Related Concepts</b>		
<b>Oral Health Status</b>	<b>FDI:</b> Oral health is defined as the ability to speak, smile, smell, taste, touch, chew, swallow and convey a range of emotions through facial expressions with confidence and without pain, discomfort and disease of the craniofacial complex. <sup>13</sup>	<ul style="list-style-type: none"> <li>• Health status (or “health state” or “status of health condition”) is a key component in all outcome definitions.</li> </ul>
<b>Health-Related Quality of Life</b>	<b>NQF:</b> A multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning. It goes beyond direct measures of population health, life expectancy and causes of death, and focuses on the	<ul style="list-style-type: none"> <li>• NQF includes health-related quality of life as a key PRO domain and identifies functional status as being included within this domain.</li> </ul>

ENVIRONMENTAL SCAN OF PATIENT REPORTED ORAL HEALTHCARE MEASUREMENT

Concept	Definition	Contextual Notes
	impact health status has on quality of life. <sup>10</sup>	
Health Behavior	<b>NQF:</b> Health behaviors are behaviors expressed by individuals to protect, maintain or promote their health status. <sup>10</sup>	<ul style="list-style-type: none"> <li>NQF includes health behaviors as PROs.</li> </ul>
	<b>Short and Mollborn:</b> Health behaviors are actions taken by individuals that affect health or mortality. These actions may be intentional or unintentional, and can promote or detract from the health of the actor or others. <sup>15</sup>	<ul style="list-style-type: none"> <li>Definition takes into account health risk behaviors.</li> </ul>
Patient Experience	<b>NQMC:</b> Experience of care is a patient's or enrollee's report of observations of and participation in health care, or assessment of any resulting change in their health. <sup>6</sup>	<ul style="list-style-type: none"> <li>NQF includes patient experiences with health care as PROs, but does not formally define the term "patient experience."</li> <li>NQMC defines patient experience with health care. The definition includes "assessment of any resulting change in their [the patients'] health." However, NQMC does not have "patient-reported outcomes" as a distinct concept in its framework.</li> </ul>
	<b>AHRQ:</b> Patient experience encompasses the range of interactions that patients have with the health care system, including their care from health plans, and from doctors, nurses, and staff in hospitals, physician practices, and other health care facilities. To assess patient experience, one must find out from patients whether something that should happen in a health care setting (such as clear communication with a provider) actually happened or how often it happened. <sup>16</sup>	<ul style="list-style-type: none"> <li>In contrast to NQF, AHRQ distinguishes patient <i>experience</i> as a separate category of quality measures from <i>clinical outcomes</i>. However, it does not explicitly address <i>patient-reported outcomes</i> at the same time.</li> </ul>
Patient Satisfaction	<b>AHRQ:</b> Distinguishes patient <i>satisfaction</i> from patient <i>experience</i> as follows: Satisfaction is about whether a patient's <i>expectations</i> about a health encounter were met. Two people who receive the exact same care, but who have different <i>expectations</i> for how that care is supposed to be delivered, can give different satisfaction ratings because of their different <i>expectations</i> . <sup>16</sup>	

Appendix 2: Patient Reported Measurement Identified through the Environmental Scan

INSTRUMENT	PATIENT REPORTED DISEASE & CONDITION IMPACT AND STATUS		PATIENT REPORTED EXPERIENCE WITH CARE	PATIENT REPORTED SATISFACTION	PATIENT REPORTED DENTAL VISITS/USE OF SERVICES	PATIENT REPORTED ACCESS/ AFFORDABILITY	PATIENT REPORTED DENTAL ANXIETY/ FEAR; DENTAL BELIEFS; ORAL HEALTH LITERACY	PATIENT REPORTED HEALTH BEHAVIORS
	Disease & condition impact (pain, function, aesthetic, psychosocial)	Disease & condition status (e.g., caries, bleeding gums, missing teeth)						
ADA Patient Satisfaction Survey			X	X				
Behavioral Risk Factor Surveillance System (BRFSS)		X			X			X
Brief Pain Inventory - Facial	X							
Burdens in Prosthetic Dentistry Questionnaire (BiPD-Q)			X					
Chewing Function Questionnaire (CFQ)	X							
Child and Parent Reported Pediatric Oral Health Related Distress Item Bank	X							
Child and Parent Reported Pediatric Oral Health Related Well Being Item Bank - Child Report	X							
Child and Parent Reported Pediatric Oral Health Related Well Being Item Bank - Parent Report	X							
Children's Oral Health Status Index	X	X					X	X
Children's Oral Health Status Index - SF	X	X					X	x

Child Pediatric Oral Health Pain/Inflammation Item Bank (POHPI)	X	X		
Child Perception Questionnaires 11-14	X	X		
Child Perceptions Questionnaire 8-10	X	X		
Children's Fear Survey - Dental Subscale				X
Craniofacial Pain and Disability Inventory	X			
Dental Anxiety Scale, Modified (DAS-M)				X
Modified Child Dental Anxiety Scale (MC-DAS)				X
Dental Anxiety Scale - Revised (R-DAS)				X
Dental Concerns Assessment				X
Dental Belief Survey				X
Dental CAHPS			X	
Dental Discomfort Questionnaire - Original	X			
Dental Discomfort Questionnaire - Modified	X			
Dental Fear Survey				X
Dental Impact on Daily Living (DIDL) questionnaire	X			
Dental Impact Profile (different than DIDL)	X			

ENVIRONMENTAL SCAN OF PATIENT REPORTED ORAL HEALTHCARE MEASUREMENT

Dental Satisfaction Questionnaire (DSQ) (14- and 19- item versions)	X		X					
Dental Visit Satisfaction Survey	X		X					
Dental/Dental Hygienist Belief Survey								X
Dentine Hypersensitivity Experience Questionnaire (DHEQ)	X							X
Early Childhood Oral Health Impact Scale	X							
Family Impact Scale (FIS)	X							
Fonseca's questionnaire	X							
Geriatric Oral Health Assessment Index	X							
Gothenburg Trismus Questionnaire (GTQ)	X							
Health and Retirement Survey 2018	X	X				X		X
ICHOM Oral Health Dataset	X	X			X			
ICHOM - Adult Oral Health Standard Set (AOHSS)	X	X				X	X	X
Illness Perception Questionnaire Revised for Dental Use in Older/Elder Adults (IPQ-RDE)	X						X	X
Jaw Disability Checklist	X							
Jaw Function Limitation Scale - 20	X							
Jaw Function Limitation Scale - 8	X							

Liverpool Oral Rehabilitation Questionnaire	X						
Malocclusion Impact Questionnaire (MIQ)	X						
Manchester Orofacial Pain Disability Scale	X						
Mandibular Function Impairment Questionnaire	X						
McGill denture satisfaction questionnaire	X			X			
Michigan Oral Health Quality of Life (MI OH QoL) Parent/ Guardian	X						
Michigan Oral Health Quality of Life (MI OH QoL) - Child	X						
National Dental Telephone Interview Survey - 2002	X	X			X	X	
National Health Interview Survey - 2003		X			X	X	X
National Health Interview Survey - 2004		X			X	X	X
National Health Interview Survey - 2005		X			X	X	X
National Health Interview Survey - 2006		X			X	X	X
National Health Interview Survey - 2008	X	X			X	X	X
National Health Interview Survey - 2010		X			X	X	X
National Health Interview Survey - 2017		X			X	X	X
National Health and Nutrition Examination Survey 2019- 2020	X	X	X		X		X

National Survey of Children's Health - 2019	X	X	X
National Longitudinal Survey of Youth, Children and Young Adults - 2016			X
OHIP-49 (from which various OHIP instruments have been derived including OHIP-14 and OHIP-5)	X		X
Oral Aesthetic Subjective Impact Scale	X		
Oral Health Impact Profile - 49	X	X	
Oral Health Impact Profile - 38	X	X	
Oral Health Impact Profile - Child	X	X	
Oral Health Impact Profile - Child - 34	X	X	
Oral Health Impact Profile - Child - G19	X	X	
Oral Health Impact Profile - Child - ortho	X	X	
Oral Health Impact Profile - Child - SF-19	X	X	
Oral Health Literacy Adult Questionnaire			X
Oral Health Quality of Life Inventory	X	X	
Oral Impacts on Daily Performance (OIDP) questionnaire	X	X	X
Orofacial Esthetic Scale	X		

ENVIRONMENTAL SCAN OF PATIENT REPORTED ORAL HEALTHCARE MEASUREMENT

Parent-Guardian Oral Health Quality of Life Item Bank - PGOHRQoL	X						
Parent Pediatric Oral Health Pain/Inflammation Item Bank (POHPI)	X	X					
Parental-Caregivers Perception Questionnaire (P-CPQ-16)	X	X					
Pregnancy Risk Assessment Monitoring System (PRAMS) - Core					X	X	X
Pregnancy Risk Assessment Monitoring System (PRAMS) - Standard	X	X					X
Promis - Adult - item bank 57 profile**	X						
Psychosocial Impact of Dental Aesthetics Questionnaire	X						
Schizophrenia Oral Health Profile (SOHP) questionnaire	X	X					
SF-36	X						
Symptom Severity Index (SSI)	X						
Subjective Oral Health Status Indicators	X	X					
UW QOL - University of Washington Quality of Life Survey	X						
RAND Dental Health Index	X						
RAND Measurement of Dental Health Status (Enrollment Medical History Questionnaire Non-Dayton, Ages 14 and older)	X	X	X		X		X



RAND Measurement of Dental Health Status (Enrollment Medical History Questionnaire Dayton, Ages 14 and older)	X	X	X		X		X
RAND Measurement of Dental Health Status (Enrollment Medical History Questionnaire Non-Dayton, Ages 5-13, Teeth and Gums)	X				X		X
RAND Measurement of Dental Health Status (Enrollment Medical History Questionnaire Dayton, Ages 5 to 13, Teeth or Gums)	X				X		X
RAND Measurement of Dental Health Status (Enrollment Medical History Questionnaire Non-Dayton, Ages 14 and Older, Eating Habits and Diet)							X
RAND Measurement of Dental Health Status (Enrollment Medical History Questionnaire Non-Dayton, Ages 5 to 13, Fluorides, Diet)					X		X

## Appendix 3: Comments Received

Comment Submitter	Comments
<b>George Salem</b> DQA - Public Member	<ul style="list-style-type: none"> <li>• Page 1 - DQA Measures – I like this very much and given that I am not clinical , I think it best to focus on the areas that I understand most and stay away from commenting on subjects that only someone trained in dentistry would understand. Regarding Patient experience – Do Emergency departments today actually staff for children dental care? I expect that you are referring to Children’s Hospitals primarily and most likely Medicaid patients. In other words, if this policy is going to be adopted then there has to be a means for delivering the care. Also, and along the same line, the concept of a PMPM makes sense, but depending on the payer, who is responsible for those payments and which payers will participate.</li> <li>• Patient reported outcomes – how are patient reported outcomes obtained? In other word, what are the requirements of providers to report on patient experiences and/or does it vary by provider type? I struggle with believing that dental providers will actually take the time and effort to provide meaningful reporting unless they are compensated for it. And, these measures and metrics associated with the measures and the most important means of truly documenting results.</li> <li>• Page 10 – Current applications – I believe that as time goes on the patient –reported measures will gradually be used and reported with greater frequency. As with all aspects of healthcare, we are in a state of evolution. And, the DQA has done an excellent job if including the right stakeholders in setting both qualitative and procedural standards. As these stakeholders begin to exercise their influence on setting standards of operation and altering reimbursement to include greater information reporting and matching that with results oriented compensation for services, I believe that this matter will resolve itself. Stay the course and keep the key players involved and these policies will continue to be meaningful and relevant. I realize that surveys are one of the best means for gathering intel, but in time there will be required reporting that will provide the industry even more data.</li> </ul>
<b>Mike John</b> University of Minnesota - CDPH Project dPRO Research Team	<ol style="list-style-type: none"> <li>1. The scan is broad, very broad. We wondered whether you want to give the reader more guidance on which group of dPROs you are particularly interested in.</li> <li>2. The broad nature of the scan led to the identification of many instruments. The instruments (N=81) are a very heterogeneous mix. It seems, some of the instruments should not be even in the list (e.g., the Pregnancy instrument). Some tools may not even be “instruments” in a strict sense but rather a collection of questionnaires/questions. One instrument that we identified in a systematic review of oral health-generic dPROMs was not in the list. (This is just some friendly feedback and not a critique – we understand all the pros and cons of broad electronic searches.) It seems not all identified instruments are equally good (whatever “good” is here.) We wondered whether some guidance should be given to the reader regarding which instruments meet certain criteria, e.g., have information about score reliability and validity.</li> </ol> <p>Regarding the minor comments, we wondered whether an interactive discussion would be an appropriate tool to move forward. Our comments certainly go into many directions. Your guidance on what is of interest to you would certainly be informative.</p>
<b>Julie Reynolds</b> University of Iowa	<p>A couple of comments on the PRO report, which was extremely thorough and well done overall. My only concern is where patient-reported measures of access fit into your working conceptual model of PROs. Based on the first paragraph on p. 10, it looks like the access measures are being excluded from PRO development activities moving forward – is that right? Seems like that could be appropriate if you’ll be focusing entirely at the practice level, but if you will also be working on system-level applications then it would be really important to include patient-reported access measures such as unmet need for care, care barriers, having a regular dentist, etc.</p>
<b>Joseph DiFazio</b> American college of Prosthodontics	<p>I believe it was a well thought out Draft report and have no additions or subtractions from the draft. Nicely done.</p>
<b>Stephen Canis</b> United Concordia Dental	<ol style="list-style-type: none"> <li>1. During the Search strategy, it might have been wise and insightful to directly poll/ask patients what they felt is important to measure. Including the perspective of the group to be measured in the reported measures seems rational.</li> <li>2. Maybe it would be best for all involved to wait for the adoption of dental diagnostic coding before having to change what has been approved in proxy.... yet again.</li> </ol>

<p>Jessica Lee John Rutkauskas AAPD</p>	<ol style="list-style-type: none"> <li>1. AAPD supports the engagement of parents in care of their children and recognizes the treatment triangle that is unique to our specialty. For this reason, further work needs to be done to insure that any measurement instrument addresses that relationship and reliably and validly portrays the experiences of both parent and child. Our composite literature often uses parental opinion as a surrogate measure of the child experience, but also often assumes that those data accurately represent effects and experiences of the child. The DQA's suggestion that the FDI definition of health be used, suggests a complexity that needs thorough study in terms of outcomes and the effect of treatment on a child's future oral health and health behaviors.</li> <li>2. Pediatric dentists almost universally care for children and adults with special health care needs (99% report treating special needs patients). For that reason, the FDI composite definition of oral health which is inclusive of numerous aspects of oral health outcomes may be overly ambitious in application to pediatric dental care. About 20 percent of US children are considered to have some special need, so achievement of oral health per the FDI definition may be difficult. Any measure needs to account for the complexity of care required for a significant number of children treated almost exclusively by pediatric dentists in the U.S. at this time.</li> <li>3. By its nature, pediatric dental care has a developmental and long-term component in many cases. A measure of patient satisfaction of pediatric dental care that is immediate and does not account for an intended long-term outcome would not be acceptable. For example, in the report, Figure 6 suggests future caries as an outcome. Considering the challenges of managing early childhood caries, as an example, achievement of that outcome may counter-intuitively be accompanied by initial or intermediate low patient satisfaction due to issues of cost, necessary behavior guidance, and access.</li> <li>4. Several of the reviewed measures address access. The AAPD has for several decades been a leader in dentistry related to improving access, whether through its support of Title VII programs to increase access to pediatric dentists, its leadership within dentistry as Medicaid providers, or a host of other actions. Applying an access or affordability patient satisfaction measure to pediatric dental care would be undesirable and likely yield inaccurate and potentially deleterious information.</li> <li>5. Pediatric dentistry, by its nature, is often interdisciplinary. The vast majority of pediatric dentists work in hospitals, maintain relationships with the orthodontic community, and because of our treatment of special needs patients, work with the medical community including surgeons and pediatric subspecialties. Any patient-reported measure needs to address these relationships and how multiple providers and systematic care would be sorted out. The same sort of combination care is not the standard in the general dental community.</li> <li>6. As the report addresses early, these types of measures are not based on claims and thus somewhat less objective. The AAPD would be concerned if a methodology for assessing these types of measures was not designed to assure accuracy. The relationship between patient-reported measures and health outcomes and actual care can be tenuous; any measure needs to be well-designed and be able to be tracked backward for quality using accepted CQI methods.</li> <li>7. Also related to the lack of a claims basis is how patient-reported measures will be obtained, retained, archived and accessible. Unlike claim-based quality measures, patient-reported measures do not have the same de-identification or security assurances. They also need to have clearly defined administration parameters and other safeguards for reporters and providers. Our assumption would be that any measure and its application system would have necessary privacy and accountability safeguards. Our members' experiences with on-line internet patient satisfaction and the difficulties with validity, truthfulness, accountability and other issues make this a concern.</li> <li>8. Finally, we strongly recommend and would greatly appreciate DQA's assurance that testing of any pediatric patient-reported measure involve private practice participation. Testing within institutions or educational care facilities would not, in our opinion, reflect the same relationships present in private practice which represents the overwhelming proportion of care delivery in the US.</li> </ol>
<p>Patrick Finnerty</p>	<p>***See Report***My comments include a few wording and layout suggestions. My main "content" suggestion is to include some discussion of the importance of "culturally appropriate" care as a key part of patient satisfaction and patient-reported outcomes. While this may be subsumed under other terms used in the report, I think it needs to be specifically named and at least some discussion of its importance should be included. If it's not included in some other measure, I think it should be and it should be noted as such. Many underserved populations face not only a "general" shortage of providers, but an even greater shortage of providers who understand various cultural aspects of the patient that are very important to the patient's care experience. The importance of "culturally appropriate" care impacts not only the patient care experience, but perhaps even more importantly, it is also a deciding factor in their "care-seeking behavior" that is mentioned in the report.</p>
<p>Jennifer Koberstein WI Collaborative for Healthcare Quality</p>	<p>We have presented the DQA environmental scan to our Oral Health Collaborative and received feedback on the importance and quality of this work. The work is reflective of the emphasis health care systems have placed on the patient experience as a measurement tool in assessing quality. The work is comprehensive, evaluation hundreds of patient-reported outcomes. The DQA focus on patient-reported oral health measures increases the emphasis on patient-centered care, patient quality of life, and functional status. The emphasis on these additional domains will provide a better picture of the quality of oral health services being provided to oral health patients and the impact the oral health system has on the outcome.</p> <p>As the report points out, although there is an emphasis on patient-centered measurement, the healthcare system has not widely embraced the consistent use of patient-reported measures. The dental community has focused efforts on questions of access. Few organizations have captured information on the impact of oral health disease and services on a person's life. DQA has placed an emphasis on patient-reported outcomes designed for quality improvement application, thereby positioning the oral health community to measure and impact the quality of oral health services being provided.</p>
<p>Honghu Liu James Crall  UCLA School of Dentistry</p>	<p>The report presents nicely the underlying structure, components, domains and sub-domains of patient reported measures, particularly patient reported outcome measures in the context of oral health. It sheds lights on the complex oral health measurement issue and provides clear guidelines on how define, classify and select oral health PROs.</p> <p>Although it is comprehensive and instrumental, the reports has been conceptualized and structured in a way that might have some limitation on inclusiveness and/or completeness. Although it is not explicitly</p>

stated, it seems that the report tends to imply oral health PROs are mainly those clinical outcomes (e.g., dental caries, tooth loss, bleeding gums, etc.) and classify mental health related oral health (e.g., emotional distress, dental phobia) and probably also social function related oral health (e.g., peer relationship, ability to participate) only as “disease and condition impact”. The report probably has also missed some other domains/sub-domains, such as oral health knowledge. Furthermore, it separates “patient satisfaction” from “patient reported outcomes”, but “patient satisfaction” is commonly a part of patient reported outcomes.

Given the importance of PROs, the National Institutes of Health (NIH) initiated a large-scale nation-wide roadmap project in 2004 titled “Patient-Reported Outcomes Measurement Information System (PROMIS®)” to create item banks that offer the potential for efficient (minimizes item number without compromising reliability), flexible (enables optional use of interchangeable items), and precise (minimal error in estimate) measurement of commonly studied PROs. PROMIS was established to assess patient outcomes that have a large impact on the daily life of individuals across many diseases and conditions. Members of our UCLA team have participated in the national PROMIS initiative, starting from its conceptualization and design, and have been involved through the 10-year span of both PROMIS I and PROMIS II. PROMIS item bank systems have become a significant driver of PRO measure development across a wide range of diseases and valued national resource as part of the NIH Roadmap.

With extensive knowledge of and experience in the overall PROMIS initiative, our team has expanded the coverage of PROMIS to the oral health arena. In 2013, the team was funded by the National Institute of Dental and Cranial Facial Research (NIDCR) to spearhead an effort to create the nation’s first patient-reported oral health item bank systems for children and adolescents 2 to 17 years of age who are receiving dental care (i.e., those who already have a dental home).

Our Oral Health PROMIS (OH PROMIS) project was based on the PROMIS® framework and used state-of-the-science qualitative and quantitative approaches to develop the first oral health item banks that can be used by oral health professionals, researchers and policy makers to effectively measure oral health outcomes among children and adolescents, including those who are particularly vulnerable to dental and oral health problems and diseases (Liu et al., 2016). Based on physical, dental and cognitive development. We have grouped the children into groups of 2- 7, 8-13 and 14-17 years. The oral health items can be used to create effective ad hoc short forms and/or computerized adaptive tests/toolkits targeting specific areas of oral health. One use of these tools is to survey large populations of children in a much less costly approach compared with traditional clinical oral health examinations/screenings. These tools also afford greater safety in light of the COVID-19 pandemic.

Our study design involves four phases. Phase 1 involved conducting a systematic review of the literature to identify instruments and survey items associated with oral health. Based on a systematic literature search and focus groups, we identified core (physical health, mental health, and social function domains) and peripheral (e.g., need and access) oral health domains. Phase 2 included focus groups, cognitive interviews, item selection, and drafting of oral health items. We then drafted and revised survey items based on cognitive interviews. Phase 3 consisted of conducting field tests of subject surveys and dental examinations with more than 700 children and adolescents ages 2-17 and their parents. Phase 4 applied psychometric analyses of oral health items to create oral health item banks and tools. To maintain alignment with the PROMIS framework and completely and effectively measure PROs related to children’s oral health, we have structured and classified oral health measures into different components: general oral health, oral health-related aspects of physical health, oral health-related aspects of mental health, and social functioning related oral health. Each of these major components has been further classified into sub-components. For the physical dimension, oral health is further classified into symptoms, functions, and oral health status. For mental health, oral health impacts are further clarified into affect, behaviors, and cognition. For social functioning, oral health impacts are further classified into relationships and function. Each of the sub-components within the major components are then further classified into domains. For example, the physical sub-component of symptoms is further classified into domains of pain, aesthetics, and other symptoms. Each of the domains is further classified into sub-domains. For example, the domain of pain is further classified into occurrence, behavior, severity, and interference. Finally, each sub-domain is measured by a certain number of items/survey questions (see Liu et al., 2018 for details of the domain structure of oral health conceptual model using the PROMIS framework approach for measurement structure).

With more than 5 years of NIH-funded team efforts, we have conducted a substantial amount of research, testing and development to accomplish our proposed aims. Moreover, we have successfully built the first set of PROMIS-based items bank systems with more than 120 items for measuring oral health of children and adolescents who access clinical dental care. We also have contributed extensively to the literature for PROs related to oral health with summaries of our results and findings (see bibliography below). Our approaches and process for conducting focus group interviews with children/adolescents, parents and oral health care professionals is summarized in Maida et al., 2015. Findings from cognitive interviews with 27 children/adolescents and parents from 39 families are summarized in Maida et al., 2017. Findings from use of the Children’s Oral Health Status Index (COHSI) survey items to examine child and parent reports about a child’s oral health and analyses to assess the associations of these reports with clinical assessments of oral health status by trained dental examiners are reported in a Marcus et al., 2018 publication. We have developed the OH PROMIS Short Form (SF) child survey for 8-17 year-olds for use in assessing oral health status of children and adolescents (Liu et al. 2018). These items were administered to 334 children and adolescents (8-17 years) along with concurrent dental examinations. An OH PROMIS long form consists of 28 items. The short-form includes 12 items (8 for COHSI and 7 for urgency of treatment need with 3 common items). We used cutting-edge dynamic individualized survey approaches to develop computerized adaptive testing (CAT) and short forms of self-reported oral health measures that are predictive of both a child’s oral health status index (COHSI) and child oral health referral recommendation (COHRR) scales for children and adolescents ages 8-17 (Shen et al. 2020). The attached publication list below includes 9 published articles based on our OH PROMIS project. The oral health item banks developed by our group have been submitted to the National PROMIS Coordinating Center at Northwestern University for evaluation of their validity and consistency with standard PROMIS item bank requirements (metric, scales and item response theory (IRT) parametrization). The evaluation process is in its final stages and, once completed, these OH PROMIS item banks will be available for access by oral health researchers, clinicians, professionals and the general public through the National PROMIS Assessment Center at Northwestern University.



<p><b>Kelli Smith</b> eClinical Works</p>	<p>How to collect the information: Collecting this data must be electronic to administer surveys, calculate scores, and trend results. This requires an electronic patient platform that syncs with a patient portal and is integrated into the E.D.R. Dentists at least in the FQHC sector just started using screening tools over the last few years. Caries risk assessment and screening for Respiratory illness and emergency visits for example. Dentists will need to take another giant step into patient engagement world to embrace in getting patients to report data. Dentists will need robust patient engagement tools to support these efforts which will drive accurate positive outcomes and not be burdensome to providers and patients. 3rd party apps over HL7 FHIR API come to mind in meeting this need but will need to work seamlessly for providers and patients to be fully adopted. However, there will be a large learning curve and financial investment for Dentists to embark on this journey. I imagine the private dental sector will need to weigh- out the ability to opt in due to cost. FQHCs already have robust patient engagement tools they can leverage, although development will be necessary from vendors. Today there is also a positive trend in patient driven healthcare. With COVID disrupting patient care this year, patients have been forced to begin embracing technology as we move to contactless check in on smart phones at the doctor and dentist office and adapting to telehealth visits. So it appears the time is ripe to further embark on this path to further engage patients in their dental care.</p> <p>Standard Data Collection: Patient reported data needs to be collected in a way that conforms to coded data elements and value sets. This way information can be aggregated the same way across the continuum of different EDR systems and in turn provide data that can be rolled up nationally. There has been a lot of work done on social determinants of health which screens for social barriers to care. When I saw the question on access and affordability, I just wonder if it would be worth looking at the standards they are working on at SIREN through The Gravity Project to achieve a National standard data collection. The Gravity Project seeks to identify coded data elements and associated value sets to represent social determinants of health (SDOH) data documented in electronic health records (EHRs), across four clinical activities: screening, diagnosis, goal setting, and interventions. The project focuses on three specific social risk domains: food insecurity, housing instability and quality, and transportation access. This project has representation by CDC, Insurance Payers and Health Systems etc.</p> <p>Future state: How will the dentist need to use this data? Once data is collected from the patient, what will dentists need to review and analyze to take this feedback into account for the daily dental care and make decisions regarding treatment? This is very important for the data to be actionable. It also speaks to the data being available in real time to the provider so they can review and analyze. What about Trending? Forecasting? Providing the ability to see patient feedback on a particular question over time..... These pieces will be important for dentists to adopt these new ideas and to use the information gathered from the patient. We look forward to many ideas and discussions on these topics to see how we could bring this to life for dentists!</p>
<p><b>Brewer Elizabeth</b> GSK Consumer Healthcare</p>	<p><b>RE: GlaxoSmithKline (GSK) Response to Dental Quality Alliance (DQA) Patient Reported Measurement Draft Report on the Environmental Scan To Whom It May Concern:</b></p> <p>GlaxoSmithKline (GSK) appreciates this opportunity to submit comments on the Dental Quality Alliance's (DQA) Draft Report on the Environmental Scan of Patient Reported Measurement. We enthusiastically support the DQA's efforts to endorse oral health measures derived from patient-reported data. The Draft Report is an insightful look into the current state of patient reported measurement in oral healthcare and suggests important areas for development within the field.</p> <p>GSK is a science-led global healthcare company. We have three world-leading businesses that research, develop and manufacture innovative pharmaceutical medicines, vaccines and consumer healthcare products. GSK supports policy solutions that transform our healthcare system to one that rewards innovation, improves patient outcomes and achieves higher-value care.</p> <p>GSK applauds the DQA's efforts to improve the quality of oral healthcare through the use of patient-reported data and measurement.</p> <p>Historically, dentistry and oral health promotion have been excluded from national conversations around quality measure development and measurement improvement. 1,2 We appreciate the DQA's long-standing commitment to develop measures that generate better oral health outcomes and we acknowledge the extensive work required to conduct an environmental scan of this scale. Due to the many challenges in measuring oral health outcomes, such as limited accessibility of claims data, it is imperative that the patient perspective be included in measure development. 1 Incorporation of patient-reported measurement (PRM) can lead to a more robust understanding of the patient experience and better evaluation of oral healthcare delivery based on indicators that are most meaningful to patients. The Report on the Environmental Scan of Patient Reported Measurement is a tremendous step in that direction.</p> <p>GSK encourages the DQA to develop and advocate for measures that are derived from patient-reported data on access and affordability of oral healthcare.</p> <p>In defining patient-reported measure concepts, the Report pulls a comprehensive list of the instruments used to collect oral health-related patient-reported data. The documented instruments include a variety of surveys and questionnaires that focus on patient attributes such as anxiety towards dental visits as well as instruments that gauge frequency of oral health visits and use of dental services. The Report also cites 10 instruments that assess access and affordability for patients. While this section mentions that such instruments may be an important part of quality improvement efforts, we urge the DQA to continue to prioritize the use of access and affordability data in measure development.</p> <p>More so than in any other form of healthcare, costs and financial barriers prevent individuals from receiving the dental care that they need.<sup>3</sup> This is the case across socioeconomic factors as cost is the leading barrier to dental care regardless of one's income, age, or source of dental benefits<sup>3</sup>; however, the effects are exacerbated for vulnerable and underserved individuals. In 2015, analysis of Medical Expenditure Panel 2 Survey data conducted by the Health Policy Institute (HPI) revealed that 48.5% of children, 43.7% of seniors, and 36.0% of adults in the U.S. visited a general dentist in the previous 12 months. However, these rates were drastically lower among those living below the poverty line: 38.5% of children, 22.5% of seniors, and 19.2% of adults.<sup>4</sup> Furthermore, low individual and household income is directly</p>

associated with higher rates of oral cancer, dental caries, tooth loss, traumatic dental injuries, and periodontal disease.<sup>5</sup>

GSK appreciates the DQA's efforts to identify patient-reported data instruments in oral health and we recommend further investigation into how measures related to affordability and accessibility can be implemented into oral healthcare evaluation. Understanding that large portions of the population face barriers to dental care in the form of cost and accessibility, it is crucial that future quality improvement efforts include the patient perspective on these factors, particularly among low-income populations. Further understanding of oral health PRMs and the impact of affordability and accessibility could drive higher quality oral healthcare delivery for all.

GSK urges the DQA to continue to develop adult oral health measures and the impact of periodontal disease among the aging population.

Similar to low-income individuals, older adults are disproportionately impacted by lack of access to dental care. Only 33.7% of adults age 65 and older have dental benefits and costs continue to be a barrier for older adults to receive oral healthcare services. While all other age groups are seeing a decline in cost barriers to dental care, seniors are experiencing increases.<sup>4,6</sup> These oral health disparities among seniors have the potential to create a significant economic burden on the U.S. healthcare system.

The effects of an aging population on the U.S. health care system are well-documented and it is clear that health care costs could increase at an unprecedented rate as Americans live longer.<sup>7,8,9</sup> However, there has been much less research around the impact of the aging population on oral healthcare. With older adults increasingly reaching later stages of life, the number of seniors requiring periodontal treatment will increase dramatically in the future.<sup>10</sup> Periodontal disease is also positively associated with higher risk for lung, pancreatic, and neck cancers, and higher prevalence of these diseases in senior populations would contribute to the economic burden created by oral healthcare disparities among older adults.

The Report highlights the stark contrast in resources directed to improving children's oral health outcomes compared to those directed towards adults. There are far more instruments used to collect patient-reported data from children than adults, particularly adults age 65 and older. While oral health improvement initiatives tend to be geared more towards children, data from the HPI and the American Dental Association showed that 1 in 3 adults in 2015 had no form of dental benefits coverage compared to just 10.3% of children.<sup>6</sup> There is a clear quality gap between older adults compared to children. There is much work to be done in closing the gap between child and adult oral health measurement and quality improvement, and GSK applauds the DQA's current efforts. We urge the DQA to continue to develop patient-reported oral health measures and advance the use of instruments that collect PRM data from adults, especially those over 65. In doing so, the DQA can promote better oral health for an often-overlooked portion of the population while also alleviating the cost burden to the US health care system from an aging population.

GSK recommends the DQA consider future development of patient-reported measures on teledentistry.

The DQA's Report identifies a variety of different patient-reported oral health instruments and PRM concepts, but none of these include teledentistry. While teledentistry is a relatively new practice that continues to develop as a form of care delivery, there is evidence to suggest that teledentistry can lead to 3 greater patient and provider satisfaction while also driving better outcomes at lower costs.<sup>11</sup> Additionally, models of comprehensive healthcare that include teledentistry are being evaluated as a means of improving access to care.<sup>12</sup> Teledentistry has the potential to reach marginalized sectors of the patient population including low-income individuals and older adults.

Both payers and providers have begun to adopt teledentistry guidelines at an increasing rate and this trend has gained momentum with changes to healthcare resulting from the spread of COVID-19.<sup>13,14,15</sup> As the use of teledentistry becomes more prevalent among patients and providers, it will be important to have measures and instruments in place to evaluate its effectiveness. Much of teledentistry's potential remains unknown and for this reason, it will also be critical to include the patient perspective when generating evidence for future use of digital technology in oral healthcare delivery. Again, GSK applauds the ongoing work of the DQA to identify and develop evidence-based oral healthcare performance measures and measurement resources, and we believe that this report makes valuable progress towards those goals. We urge the continued development of measures and instrumentation derived from patient-reported data on access and affordability as well as the development of adult oral health measures focused on the health of older adults. GSK also hopes to see future measure development related to teledentistry.

We thank you for this opportunity to comment on the Draft Report on the Environmental Scan of Patient Reported Measurement. If you have any questions or if GSK can provide additional insight, please do not hesitate to reach out to Liz Brewer at [elizabeth.8.brewer@gsk.com](mailto:elizabeth.8.brewer@gsk.com) and Tilithia McBride at [tilithia.x.mcbride@gsk.com](mailto:tilithia.x.mcbride@gsk.com).

Respectfully submitted,  
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## Appendix 4: Measures Development and Maintenance Committee

### Measures Development and Maintenance Committee:

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### DQA Leadership:

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Tom Meyers, Chair-Elect, Dental Quality Alliance

### The Committee was supported by:

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