

Overuse of Imaging for the Evaluation of Children with Post-Traumatic Headache

Section 1. Basic Measure Information

1.A. Measure Name

Overuse of Imaging for the Evaluation of Children with Post-Traumatic Headache

1.B. Measure Number

0195

1.C. Measure Description

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

This measure assesses the percentage of children, ages 2 through 17 years, with post-traumatic headache who were evaluated in the emergency department (ED) within 24 hours after an injury, and imaging of the head (computed tomography [CT] or magnetic resonance imaging [MRI]) was obtained in the absence of documented neurologic signs or symptoms that suggest intracranial hemorrhage or basilar skull fracture. A lower percentage indicates better performance, as reflected by avoidance of CT imaging when it is not indicated.

Post-traumatic headaches in children are a common clinical presentation in the setting of concussion and mild traumatic brain injury. In the United States, it has been estimated that more than 500,000 children younger than 15 years of age were evaluated in an ED following mild traumatic brain injury each year from 1998 to 2000 (Bazarian, McClung, Shah, et al., 2005). Over the past decade, ED visits for traumatic brain injuries have increased substantially (Coronado, Haileyesus, Cheng et al., 2015).

Well-established evidence shows that neuroimaging to evaluate children with post-traumatic headache in the absence of documented neurologic signs or symptoms that suggest intracranial hemorrhage or skull fracture is rarely clinically indicated and is potentially harmful (ACR Expert Panel on Imaging, Ryan, et al., 2014; Kuppermann, Holmes, Dayan, et al., 2009; Lateef, Grewal, McClintock, et al., 2009; Lateef, Kriss, Carpenter, et al., 2012). The American Academy of Pediatrics (AAP) Choosing Wisely initiative includes guidance to discourage the unnecessary use of CT scans for the immediate evaluation of minor head injuries and encourage reliance on clinical observation and criteria established by the Pediatric Emergency Care Applied Research Network (PECARN) to determine whether imaging is indicated (AAP, 2013; Kuppermann, et al., 2009).

CT use has increased in the past 20 years. In a cross-sectional analysis of data from the National Hospital Ambulatory Medical Care Survey, Blackwell and colleagues found the use of CT scans for the evaluation of children with head injury nearly doubled from 1995 to 2003 (13 percent to 22 percent) (Blackwell, Gorelick Holmes, et al., 2007). Zonfrillo and colleagues found evidence to suggest continued increases in CT use for ED patients with concussion from 2006 to 2011 (Zonfrillo, Kim, Arbogast, 2015). Some research suggests that rates of imaging following head injury appear to have declined in free-standing children's hospitals (Mannix, Meehan, Monuteaux, et al., 2012; Menoch, Hirsh, Khan, et al., 2012; Parker, Shah, Hall, et al., 2015) and general EDs (Marin, Weaver, Barnato, et al., 2014). Also, CT rates for children with mild head trauma vary widely between hospitals. Between 2004 and 2006, CT rates ranged from 19 to 69 percent across 25 EDs (Stanley, Hoyle, Dayan, et al., 2014). Similarly, CT rates ranged from 19 to 58 percent for patients with minor head injury in a retrospective analysis of 5 years (2005-2009) of hospital administrative data from 40 free-standing children's hospitals (Mannix, et al., 2012).

Overuse has been defined as use in any patient who undergoes a procedure or test for an inappropriate indication (Lawson, Gibbons, Ko, et al., 2012). Imaging overuse for the evaluation of children with post-traumatic headaches without signs or symptoms of intracranial injury subjects children to a number of risks (Malviya, Voepel-Lewis, Eldevik, et al., 2000; Mathews, Forsythe, Brady, et al., 2013; Pearce, Salotti, Little, 2012; Wachtel, Dexter, Dow, 2009). Individuals who undergo CT scans in early childhood tend to be at greater risk for developing leukemia, primary brain tumors, and other malignancies later in life (Mathews, et al., 2013; Pearce, et al., 2012). Children are also at risk for complications from sedation or anesthesia, which are often required for longer CT imaging sequences and for MRI, and from intravenous contrast media (Zo'o, Hoermann, Balassy, et al., 2011). Cost is also an issue (Callaghan, Kerber, Pace, et al., 2014) that burdens patients, as well as payers.

This measure uses administrative claims data to identify the eligible population for medical record review; it assesses the percentage of children, ages 2 through 17 years old, with post-traumatic headache who were evaluated in the ED within 24 hours after an injury, and imaging of the head (CT or MRI) was obtained in the absence of documented neurologic signs or symptoms that suggest intracranial hemorrhage or basilar skull fracture.

1.D. Measure Owner

The Quality Measurement, Evaluation, Testing, Review, and Implementation Consortium (Q-METRIC).

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:

- 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.**

This measure is part of the Q-METRIC Overuse of Imaging for the Evaluation of Children with Headache or Seizures measures collection.

- 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

The number of children, ages 2 through 17 years, with post-traumatic headache who were evaluated in the ED within 24 hours after an injury, and imaging of the head (CT or MRI) was obtained in the absence of documented neurologic signs or symptoms that suggest intracranial hemorrhage or basilar skull fracture. The time period for data includes the measurement year (January 1 through December 31) (for imaging of the head for the evaluation of a post-traumatic headache) and the year (365 days) prior to the imaging event (for the purpose of identifying a claims-based denominator exclusion).

1.H. Numerator Exclusions

Numerator exclusions are based on chart review; they are briefly summarized here and identified in the measure specifications (see Supporting Documents).

- Severe mechanism of injury (e.g., penetrating trauma, fall from more than 5 feet, struck by vehicle).
- History of seizure or convulsions associated with trauma.
- History of loss of consciousness associated with trauma.
- Repeated vomiting.
- Documented basilar skull fracture or signs of suspected basilar skull fracture, including “Raccoon eyes,” Battle’s sign, and hemotympanum.
- Abnormal neurologic examination or signs or symptoms of intracranial hemorrhage or increased intracranial pressure (e.g., decreased alertness, altered mental status, Glasgow Coma Scale (GCS) score <14, diplopia, abnormal face or eye movements, gait disturbance).

1.I. Denominator Statement

The number of children, ages 2 through 17 years, with post-traumatic headache who were evaluated in the ED within 24 hours after an injury, and imaging of the head (CT or MRI) was obtained in the absence of suspected child abuse and neglect or a history of a medical condition that would otherwise warrant neuroimaging. Eligible children must be ages 2 through 17 years during the measurement year for which imaging of the head is obtained and must be continuously enrolled in their insurance plan during both the measurement year and the year prior. Eligible children must also receive head imaging in association with an ED visit for post-traumatic headache within 24 hours of the time of injury.

1.J. Denominator Exclusions

Children under evaluation for child abuse and neglect and children with a history of a medical condition that could otherwise warrant neuroimaging (e.g., bleeding disorder, intracranial tumor, hydrocephalus) for the evaluation of a post-traumatic headache were excluded from this overuse measure. Children with a diagnosis of headache without a documented history of trauma and children with a diagnosis of concussion without documentation of headache as a symptom were excluded because post-traumatic headache is the focus of this measure. Denominator exclusions are identified in the measure specifications (see Supporting Documents).

1.K. Data Sources

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

Administrative claims data; paper and electronic clinical data; paper and electronic health record (EHR).

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.

See Supporting Documents for detailed measure specifications.

Calculation Algorithm/Measure Logic

1. Identify children in the denominator:
 - a. Using administrative claims, identify the population eligible for the denominator. The eligible population consists of all individuals who satisfy specified criteria, including age, enrollment, diagnosis, and imaging requirements within the measurement year.
 - b. Using administrative claims, exclude individuals with ICD-9-CM codes associated with child abuse and neglect or a history of a medical condition that could otherwise warrant neuroimaging for the evaluation of a post-traumatic headache.
 - c. Select a random sample of those still eligible for the denominator for chart abstraction.
 - d. Among those who have a chart abstracted, exclude individuals with no documented time of injury or a time of injury greater than 24 hours prior to the ED visit, a diagnosis of headache without documentation of trauma, a diagnosis of concussion without documentation of headache as a symptom, concern for child abuse, or a history of a medical condition that could otherwise warrant neuroimaging to obtain the population included within the final denominator.
2. Identify children in the numerator:
 - a. Among children included within the final denominator, exclude from the numerator individuals who have documented within the medical chart the following: severe mechanism of injury, seizure associated with trauma, loss of consciousness associated with trauma, repeated vomiting, documented or suspected basilar skull fracture, or abnormal neurologic examination including altered mental status, Glasgow Coma Scale score <14, abnormal face or extremity movements, or gait disturbance.

3. Calculate the percentage overuse (numerator / denominator times 100 percent).

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).**

Post-Traumatic Headache Prevalence and Incidence

Post-traumatic headaches in children are a common clinical presentation in the setting of concussion and mild traumatic brain injury. In the United States, it has been estimated that more than 500,000 children younger than 15 years of age were evaluated in an ED following mild traumatic brain injury each year from 1998 to 2000 (Bazarian ,et al., 2005). During the period 2001-2012, ED visits for traumatic brain injuries increased substantially (Coronado, et al., 2015).

In a cross-sectional analysis of data from the National Hospital Ambulatory Medical Care Survey, Blackwell and colleagues found the use of CT scans for the evaluation of children with head injury nearly doubled from 1995 to 2003 (13 percent to 22 percent) (Blackwell, et al., 2007). Zonfrillo and colleagues found evidence to suggest continued increases in CT use for ED patients with concussion from 2006 to 2011 (Zonfrillo, et al., 2015). Some research suggests that rates of imaging following head injury appear to have declined in free-standing children's hospitals (Mannix, et al., 2012; Menoch, Hirsh, Khan, et al., 2012; Parker, et al., 2015) and general EDs (Marin, et al., 2014). In addition, CT rates for children with mild head trauma vary widely between hospitals. Between 2004 and 2006, CT rates ranged from 19 to 69 percent across 25 EDs (Stanley et al., 2014). Similarly, CT rates ranged from 19 to 58 percent for patients with minor head injury in a retrospective analysis of 5 years of hospital administrative data from 40 free-standing children's hospitals (Mannix, et al., 2012).

Burden of Overuse of Imaging for Post-Traumatic Headache

The literature offers many examples of the potential risks associated with imaging. Chief among these are risks related to radiation (Mathews, et al., 2013; Pearce, et al., 2012), sedation and/or anesthesia (Malviya, et al., 2000; Wachtel, et al., 2009), and intravenous contrast media (Zo'o, et al., 2011). Cost is also an issue (Callaghan, et al., 2014).

Radiation-Related Burden and Risk

Radiation exposure associated with CT-imaging introduces the possibility of chronic health risks related to malignancies arising from radiation effects (Berrington de González, Mahesh, Kim, et al., 2009; Mathews, et al., 2013; Pearce, et al., 2012). Children have developing cellular structures and tissues that are significantly more radio-sensitive than those of adults; children, therefore, will be at substantially elevated risk for malignancy following radiation exposure from CT imaging (ACR Expert Panel on Pediatric Imaging, et al., 2012). Radio-sensitive organs—including the brain, bone marrow, lens of the eye, and thyroid gland—can be exposed to radiation during CT of the head (Papadakis, Perisinakis, Oikonomou, et al., 2011). In children younger than 5 years of age, about 20 percent of the active bone marrow is in the cranium, compared with 8 percent in adults (Christy, 1981).

To conduct imaging studies with radiation dosing that is appropriate for children, many facilities follow policies and protocols using the concept of ALARA (As Low As Reasonably Achievable). ALARA principles deem any additional radiation beyond the minimum needed for interpretable images both detrimental and non-efficacious (ACR, 2009). Professional practice and patient advocacy groups—including the American College of Radiology (ACR), the American Academy of Neurology (AAN), and the American Academy of Pediatrics (AAP)—have developed and promoted ALARA protocols and policies; these guidelines support the use of CT imaging in children only when clinically indicated, decreasing the risk of harm from radiation.

Sedation- and Anesthesia-Related Burden and Risk

Use of sedation may be necessary to avoid motion artifacts, which invariably occur if the child moves during the image acquisition, thus interfering with image quality. Motion artifacts sometimes undermine imaging quality to the point of rendering images unreadable. In the case of CT imaging, this may result in additional radiation exposure to obtain images sufficient for interpretation.

Although the sedation used for pediatric imaging has been identified as low risk, it does have potential attendant complications (Cravero, Bilke, Beach, et al., 2006; Malviya, et al., 2000). Levels of sedation are on a continuum from minimal anxiolysis (administration of an anxiety reduction agent) to deep sedation, in which the patient can be roused only via vigorous stimuli (Arthurs, Sury, 2013). Compared with minimal sedation, moderate and deep sedation carry a greater risk of airway compromise, hypoxia resulting in central nervous system injury, and death (Cravero, et al., 2006).

In certain instances, sedation may not be sufficient, and anesthesia will be required to complete imaging. Anesthesia includes administration of medication that results in some degree of respiratory suppression and potential for cardiac depression; the patient cannot be roused by external stimuli or commands (Arthurs, Sury, 2013). Administration of anesthesia raises risks related to the process of intubation for respiratory support. These risks include dental trauma; airway edema (swelling of the windpipe); vocal cord spasm or injury; regurgitation of stomach contents with subsequent aspiration (inhalation) pneumonia; injury to arteries, veins, or nerves; alterations in blood pressure; and/or irregular heart rhythms (Society for Pediatric Anesthesia, 2014). The most severe, though rare, risks include brain damage and death (Society for Pediatric Anesthesia, 2014).

Intravenous Contrast-Related Burden and Risk

During the course of CT and MRI studies, intravenous (IV) contrast media may be used to enhance visualization of vascular structures and provide important information about neurologic anatomy. It is possible a child may experience an allergic reaction to IV contrast or subcutaneous fluid leakage (extravasation) during administration of IV contrast. IV contrast administration also includes the risk of contrast-induced nephrotoxicity (CIN) (Basu, 2014; Zo'o, et al., 2011). Children with poor kidney function are at greater risk for developing CIN and, in rare cases, will develop renal failure requiring dialysis.

Cost-Related Burden

Overuse of imaging is costly and places additional strain on an already heavily burdened health care system (Callaghan, et al., 2014). As an example, charges for a CT of the brain can be as much as \$2,000 and can vary substantially by region of the country. In addition, the likelihood that neuroimaging will result in the identification of clinically important structural abnormalities in this patient population is low. Incidental findings, however, may require follow-up testing with associated charges and potential complications (Lumbreras, Donat, Hernandez-Aquado, 2010; Rogers, Mayer, Schunk, et al., 2013).

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).**

Virtually any alteration in resource utilization or expenditure substantially affects children covered by Medicaid or CHIP; in 2011 alone, 30.6 million or 40 percent of children through the age of 18 years were Medicaid recipients (Tang, 2011). Although there is no study on the number of children with post-traumatic headache who are enrolled in Medicaid or CHIP, curtailing the overuse of imaging will reduce radiation exposure, poor anesthesia or sedation outcomes, and costs.

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).

This pediatric measure is aligned with NQF Measure #0668: Appropriate Head CT Imaging in Adults with Mild Traumatic Brain Injury. The measures are harmonized in terms of the basic clinical criteria (imaging obtained in the ED within 24 hours of a head injury among patients with a GCS score of greater than or equal to 14) used to identify the population eligible for inclusion in the denominator.

The pediatric measure differs in several ways, including consideration of current trends in neuroimaging, the ability to use administrative claims to narrow the population considered eligible for the more labor-intensive chart review process, and the available evidence on the need for neuroimaging of children with post-traumatic headache. The endorsed adult measure is focused on CT imaging alone; this pediatric measure was tested to assess the overuse of neuroimaging more broadly, including both CT and MRI, for children who are evaluated for post-traumatic headache. The inclusion of MRI is important with recent shifts toward imaging modalities that avoid radiation exposure but still subject patients to risks from sedation/anesthesia, incidental findings, and costs associated with overuse of imaging studies. The pediatric measure was tested in a two-stage approach that first used administrative claims to identify the potentially eligible population and then used chart review to account for exclusions that could be documented in the provider notes but not captured with a relevant ICD-9-CM code. We used an extensive list of ICD-9-CM codes indicative of conditions in which neuroimaging

for post-traumatic headache could be warranted (for example, coagulopathy or cerebral cyst) in order to focus this measure on clear cases of overuse of neuroimaging. Finally, we applied the specific factors that were identified by Kuppermann and colleagues as relevant to the risk of clinically important brain injury in children with minor trauma based on results of the largest prospective cohort study of pediatric traumatic brain injury (Kuppermann, et al., 2009).

There is overlap between the NQF Measure #0668: Appropriate Head CT Imaging in Adults with Mild Traumatic Brain Injury and the pediatric measure. The adult measure includes children 16 to 18 years old, while the pediatric measure is more narrowly focused on children 2 through 17 years of age. Because of the unique nature of child illness and injury, a pediatric-focused measure is needed.

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: No.**
- d. Service – preventive health, including services to promote healthy birth: No.**
- e. Service – care for acute conditions: Yes.**
- f. Service – care for children with acute conditions: Yes.**
- g. Service – other (please specify): No.**
- h. Measure Topic – duration of enrollment: No.**
- i. Measure Topic – clinical quality: Yes.**
- j. Measure Topic – patient safety: 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): No.**
- n. Population – pregnant women: No.**
- o. Population – neonates (28 days after birth) (specify age range): No.**
- p. Population – infants (29 days to 1 year) (specify age range): No.**
- q. Population – pre-school age children (1 year through 5 years) (specify age range):
Yes - Ages 2 through 5 years.**

- 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 – Adolescents 11 through 17 years.
- t. **Population – other (specify age range):** No.
- 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.

This is a process measure. The focus of the measure is the imaging (CT or MRI) of children with post-traumatic headache who are evaluated in the ED within 24 hours after an injury, in the absence of documented neurologic signs or symptoms that suggest intracranial hemorrhage or skull fracture.

The steps between the measure focus and health outcome are illustrated in Figure 1 (see Supporting Documents).

CT and MRI of the brain are the neuroimaging modalities at the center of this overuse measure. Both are radiologic modalities used to create images of internal structures in a slice-by-slice manner. CT uses X-ray radiation (hereafter simply called radiation), and MRI uses magnetic fields and radio waves.

Currently, professional guidelines do not support neuroimaging in children 2 years and older with minor head injury in the absence of neurologic signs or high-risk factors indicative of

intracranial injury (ACR Expert Panel on Pediatric Imaging, Ryan et al., 2014). Potential consequences of imaging overuse include complications of sedation or anesthesia, incidental findings, and radiation exposure. Therefore, measurement of overuse of neuroimaging with CT and MRI is an important quality indicator among children with post-traumatic headache following minor head injury.

The Pediatric Emergency Care Applied Research Network (PECARN) conducted the largest prospective study of children presenting to the ED within 24 hours of head injury and confirmed numerous prior lower quality studies that had documented low yield of neuroimaging of children with head injuries in the absence of signs or symptoms to suggest intracranial injury, as summarized in the Evidence Table published by the ACR Expert Panel on Pediatric Imaging, Head Trauma - Child (Ryan et al., 2014). The PECARN head imaging clinical decision rule for children with mild traumatic brain injury has 99.9 percent negative predictive value and 96.8 percent sensitivity for predicting clinically important injury. The PECARN study provides evidence that imaging was overused in approximately 20 percent of the study population age 2 years and older who demonstrated none of the six predictors that make up the decision rule.

Estimates of Benefit and Consistency across Studies in the Body of Evidence

The main benefit of reducing neuroimaging among children with post-traumatic headache relates to the avoidance of harms. Schachar and colleagues tested the sensitivity and specificity of three clinical decision rules (New Orleans Criteria, Canadian CT Head Rule, and NEXUS II) in a population of 2,101 children with head injuries. They found sensitivities ranging from 65.2 percent (95 percent CI 69.9-86.7) for the Canadian CT Head Rule to 96.7 percent (95 percent CI: 93.1-100) for the New Orleans Criteria and negative predictive values above 97 percent. Specificity ranged from 11.2 percent (95 percent CI: 9.8-12.6) for the New Orleans Criteria to 64.2 percent for the Canadian CT Head Rule (Schachar, Zampolin, Miller, et al., 2011).

The evidence related to the need for neuroimaging in the evaluation of children within 24 hours of mild traumatic brain injury was greatly strengthened by research conducted by PECARN investigators. Their research found that CT scans were obtained for 14,969 (35 percent) of 42,412 children evaluated in participating EDs within 24 hours of head injury; however, clinically important traumatic brain injuries were present in just 376 (<1 percent) (Kuppermann, et al., 2009). This study generated a clinical decision rule that can guide the decision to order CT imaging for children with mild head trauma and no findings that suggest clinically important traumatic brain injury.

Harms Studied and their Effects on Net Benefit

CT use has increased in the past 20 years without an increase in the yield of imaging studies. CT rates for children with mild head trauma vary widely between hospitals. CT rates ranged from 19 to 58 percent for patients with minor head injury in a retrospective analysis of 5 years of hospital administrative data from 40 free-standing children's hospitals (Mannix, et al., 2012). This research also suggests that rates of imaging following head injury may be declining in free-standing children's hospitals in recent years.

The harms of neuroimaging among children with post-traumatic headache have not been directly studied but can be implied from the literature that describes the potential harm associated with radiation exposure (Pearce, et al., 2012). The absolute incidence of induced lethal malignancy is estimated at 1/1000-1/5000 per cranial CT (Brenner, Hall, 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.

The American College of Radiology (ACR) Appropriateness Criteria® (AC) are evidence-based guidelines to assist referring physicians and other providers in making the most appropriate imaging or treatment decision for a specific clinical condition. The AC assess the benefits and harms of recommended medical care or advanced diagnostic imaging options, using scientific evidence to the extent possible, and clinical judgment and expert consensus, as necessary. The guidelines are developed by a panel of experts in diagnostic imaging, interventional radiology, and radiation oncology with participation from over 20 medical societies. The ACR, in addition to evidence-based guidelines, has also published specific "Appropriateness Criteria" for pediatric mild head injury (Figures 2 and 3; see Supporting Documents).

CT scans and MRI of the head in children older than 2 years with minor head injury and without neurologic signs or high risk factors has been rated Category 3 or lower for appropriateness. Categories 1, 2 and 3 are considered "usually not appropriate," where the harms of the procedure outweigh the benefits.

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.

Abstracted Medical Record Data

Medical record data were obtained from HealthCore, Inc., an independent subsidiary of Anthem, Inc., which is the largest health benefits company/insurer in the United States. HealthCore owns and operates the HealthCore Integrated Research Database (HIRD), a longitudinal database of medical and pharmacy claims and enrollment information for members from 14 geographically diverse Blue Cross Blue Shield (BCBS) health plans in the Northeast, South, West, and Central regions of the United States, with members living in all 50 States. The HIRD includes automated computerized claims data and enrollment information for approximately 60 million individuals with medical enrollment, over 37 million individuals with combined medical and pharmacy enrollment, and 16 million individuals with outpatient laboratory data from the BCBS licensed plans.

This measure belongs to the Q-METRIC Overuse of Imaging for the Evaluation of Children with Headache or Seizures measures collection. As part of the initial sampling strategy for testing multiple measures in this collection, approximately 2.1 million children, ages 6 months through 17 years, were identified in the HIRD for the study's 2012 measurement year. Of these, a cohort of children with diagnosis codes for headaches and seizures was identified (57,748 children). Members who did not have continuous eligibility during the 2011 and 2012 calendar years were excluded, narrowing the group to 36,985 children (64.0 percent).

Specifically for this measure, administrative claims were used to identify children, ages 2 through 17 years, who had ICD-9-CM codes that indicated a post-traumatic headache, concussion, or general symptoms of headache evaluated in the ED, 5,912 children (16.0 percent). From this group, 2,967 children (50.2 percent) were identified as having either CT or MR imaging. After applying claims-based exclusions (suspected abuse and neglect, history of a medical condition that could warrant neuroimaging, loss of consciousness, skull fracture, and intracranial hemorrhage), 2,419 children (81.5 percent) were eligible to sample for chart review.

Once the population eligible for chart review was determined using administrative claims, providers associated with visits were identified. The final sampling population for chart review comprised 1,714 children (70.9 percent) who could be linked to a provider having complete contact information. Once subjects were identified, patient medical records were requested from provider offices and health care facilities; records were sent to a centralized location for data abstraction. To ensure an adequate number of cases to test the feasibility of this measure, we set a target sample of 200 abstracted charts. The first 204 charts received were abstracted for measure testing; 86 children (42.2 percent) were female, and the average age was 12.0 (SD = 3.9).

Of the 204 abstracted charts, one (0.5 percent) was excluded based on clinical documentation of suspected child abuse or neglect, and five (2.5 percent) were excluded due to documentation of a medical condition that could otherwise warrant neuroimaging. There were 65 charts (31.9 percent) with clinical documentation of trauma occurring within 24 hours of the ED visit; among those, eight were excluded, as they had concussion as a diagnosis without evidence of a headache as a symptom, leaving 57 charts (27.9 percent) in the eligible study population.

Among the eligible study population, 15 children (26.3 percent) were imaged in the absence of documented neurologic signs or symptoms that suggest intracranial hemorrhage or skull fracture. Overall, our results indicate there is an opportunity to reduce the overuse of neuroimaging among children with post-traumatic headache.

We were unable to assess plan, hospital ED, and provider-level variations based on the limited number of eligible medical records that were available for calculation of this measure following chart review. However, this measure was able to successfully distinguish statistically significant differences ($p < 0.05$) in overuse of imaging from the theoretical target percentage of 5 percent. The overuse percentage in this sample was significantly higher than a target percentage of 5 percent, which indicates less than optimal performance. Sample size calculations for both 95 percent confidence interval (CI) half-widths and two-sample proportion tests are provided to guide appropriate sample size targets for use of this measure in quality improvement and quality performance reporting. A minimum of 196 charts included in the denominator after chart review would be recommended to obtain a 95 percent CI with a 5 percent half-width around an expected overuse percentage of 15 percent. A per group minimum of 335 charts included in the denominator after chart review would be recommended for a two-sample proportion test to detect a 10 percent difference from a control proportion of 15 percent with power of 0.90 and alpha of 0.05.

Inter-Rater Reliability

Testing this measure using medical record data required the development of an abstraction tool and the use of qualified nurse abstractors. Reliability of medical record data was determined through re-abstraction of patient record data to calculate the inter-rater reliability (IRR) between abstractors. Broadly, IRR is the extent to which the abstracted information is collected in a consistent manner. Low IRR may be a sign of poorly executed abstraction procedures, such as ambiguous wording in the data collection tool, inadequate abstractor training, or abstractor fatigue. For this measure, the medical record data collected by three abstractors were individually compared with the data obtained by a senior abstractor. Any differences were remedied by review of the chart. IRR was determined by calculating both percent agreement and Cohen's kappa statistic. Sensitivity, specificity, and negative and positive predictive values were also calculated.

Of the 204 abstracted medical records, 30 (15 percent) were reviewed for IRR; percent agreement and kappa were calculated. IRR was assessed by comparing individual abstractor agreement with a senior abstractor as the gold standard on the 16 data elements abstracted from charts for this measure (corresponding to 441 eligible items after accounting for skip patterns). Disagreement was identified for two of the 16 data elements:

1. Was there documentation of increased intracranial pressure? (Indications include: swelling of the optic disc (papilledema), double vision (diplopia), abnormal face or eye movements, dizziness (vertigo), abnormal gait (ataxia), abnormal coordination (dysmetria), confusion); percent agreement was 96.7 percent (kappa 0.84).

2. Was there documentation of altered mental status including comments such as “not acting like himself” per parent report?—percent agreement was 96.7 percent (kappa 0.90).

Overall, abstractor agreement was 99.3 percent (kappa 0.98). The sensitivity of the abstractors to identify chart-based exclusions compared with the senior abstractor was 100 percent (95 percent CI; 94.6, 100); specificity was 99.5 percent (95 percent CI; 98.1, 99.9); positive predictive value was 97.1 percent (95 percent CI; 89.9, 99.7), and negative predictive value was 100 percent (95 percent CI; 99.0, 100.0). The related contingency table is shown in Table 1 (see Supporting Documents).

A kappa greater than 0.81 is considered almost perfect agreement (Landis, Koch, 1977). A percent agreement of 99.3 percent and kappa statistic of 0.98 indicate that a very high level of agreement was achieved. Given this evidence, the data elements needed for calculation of the measure can be abstracted with a high degree of accuracy.

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).

Level of Validity Testing

Critical data elements used in the measure; systematic assessment of face validity of performance measure score as an indicator of quality or resource use.

Face Validity

Face validity is the degree to which the measure construct characterizes the concept being assessed. The face validity of this measure was established by a national panel of experts and parent representatives for families of children with headaches and seizures convened by Q-METRIC. The Q-METRIC Representative Panel included nationally recognized experts in the area of imaging children, representing general pediatrics, pediatric radiology, pediatric neurology, pediatric neurosurgery, pediatric emergency medicine, general emergency medicine, and family medicine. The Q-METRIC Feasibility Panel included experts in State Medicaid program operations, health plan quality measurement, health informatics, and health care quality measurement. In total, the Q-METRIC imaging panel included 15 experts, providing a comprehensive perspective on imaging children and the measurement of quality metrics for States, health plans, and EDs. The expert panel assessed whether the performance of this measure would result in improved quality of care for children with headache and/or seizures in relation to neuroimaging. Specifically, the panel weighed the evidence to determine if this measure of overuse could reduce unnecessary imaging among children with post-traumatic

headache. The voting process to prioritize the measure was based on the ability of the measure to distinguish good from poor quality.

The Q-METRIC expert panels concluded that this measure has a high degree of face validity through a detailed review of concepts and metrics considered to be essential to appropriately imaging children. Concepts and draft measures were rated by this group for their relative importance. This measure was highly rated, receiving an average score of 7.0 (with 9 as the highest possible score).

Given the high rating assigned by the Q-METRIC expert panel, we feel this measure has a very high degree of face validity.

Validity of Exclusion Criteria

Denominator: We tested the validity of administrative claims to exclude cases from the denominator based on two ICD-9-CM code-based criteria: (1) suspected child abuse and neglect and (2) history of a medical condition that could otherwise warrant neuroimaging. Claims data were tested against medical records, which are considered the gold standard of clinical documentation. Children with ICD-9-CM codes associated with these claims-based exclusions were not included in the chart review sample. In other words, none of the charts sampled for medical record review contained ICD-9-CM codes associated with these claims-based exclusions. We tested the accuracy of the assumption that the absence of these ICD-9-CM codes in administrative claims would mean the absence of clinical documentation indicative of these exclusionary conditions in the medical record.

Of the 204 charts reviewed, one (0.5 percent) had clinical documentation of suspected child abuse or neglect, and five (2.5 percent) contained clinical documentation of a medical condition that could otherwise warrant neuroimaging in the absence of ICD-9-CM codes associated with these two claims-based denominator exclusions. Therefore, 97 percent (198 of 204) of the charts reviewed were in agreement with the administrative claims regarding the absence of these denominator exclusions.

Our results demonstrate that we were able to exclude nearly all children with clinical evidence of child abuse or neglect or a medical condition that could otherwise warrant neuroimaging through exclusions based on associated ICD-9-CM codes present in administrative claims. Therefore, the use of administrative claims is an appropriate and valid method to narrow the population of charts sampled within this measure specification. However, the presence of these exclusionary conditions in the medical record indicates that medical record abstraction is necessary to accurately identify these two denominator exclusions. The abstraction of this information should be conducted in conjunction with the chart review necessary to identify children with post-traumatic headache, an ED visit within 24 hours of trauma, and the numerator exclusions required for calculation of this measure.

Numerator: We tested administrative claims against chart review data to determine the potential to exclude cases from the numerator using administrative claims for two numerator criteria: (1)

seizure or convulsion and (2) indicators of increased intracranial pressure. Data for these two numerator criteria were abstracted from charts, and ICD-9-CM codes were identified in administrative claims. The medical chart was considered the gold standard. Sensitivity, specificity, and negative and positive predictive values were calculated.

Among children eligible for the denominator after chart review (n=57), the sensitivity of claims for identification of seizure was 0 percent (95 percent CI; 0.0, 97.5) because there were no true positives in the sample (i.e., no seizures were identified using both claims and charts), and the specificity was 100 percent (95 percent CI; 93.6, 100). Positive predictive value could not be calculated because there were no true or false positives, and negative predictive value was 98.3 percent (95 percent CI; 90.6, 99.9). The sensitivity of claims for identification of indicators of increased intracranial pressure was 8.1 percent (95 percent CI; 1.7, 21.9), and the specificity was 90.0 percent (95 percent CI; 68.3, 98.8); positive predictive value was 60.0 percent (95 percent CI; 14.7, 94.7), and negative predictive value was 34.6 percent (95 percent CI; 22.0, 49.1). Contingency tables for both variables are shown in Tables 2 and 3 (see Supporting Documents).

The low sensitivity of administrative claims compared with the gold standard of the medical record for the two variables tested indicates that chart review is required for the accurate and complete collection of numerator exclusion criteria.

This measure relies on chart review for the identification of inclusion criteria for which there are no ICD-9-CM codes (e.g., documentation of trauma within 24 hours of the ED visit). Chart review also provides a secondary opportunity to identify exclusion criteria that may not be fully captured in ICD-9-CM codes contained in administrative data. Therefore, we conclude that administrative claims alone are insufficient for calculating neuroimaging overuse percentages at this time.

Exclusions Analysis

Several exclusion criteria can be applied to administrative claims to narrow the population eligible for chart review. The degree to which these exclusion criteria affect overuse percentage calculations is unknown. Therefore, we performed a sensitivity analysis of exclusion criteria, as follows.

Among 2,967 children that visited the ED with a post-traumatic headache, concussion, or general headache and underwent CT or MRI, 450 children (15.2 percent) had the presence of at least one ICD-9-CM code indicative of child abuse and neglect, loss of consciousness, skull fracture, or intracranial hemorrhage. This group of ICD-9-CM codes was flagged as present or absent in the administrative data available to the Q-METRIC team. Claims-based exclusions for medical conditions that could otherwise warrant neuroimaging (n=98) were applied to the denominator with a unique flag. Claims-based exclusions for indicators of increased intracranial pressure (n=343) and seizure/convulsions (n=67) were applied to the numerator with unique flags.

To perform the sensitivity analysis of exclusion criteria, we varied the number of children among the 450 (originally classified as having abuse/neglect or loss of consciousness, skull fracture, or

intracranial hemorrhage) with the denominator exclusion of child abuse and neglect by 25 percent, 50 percent, 90 percent, and 100 percent. In each scenario, children who were not excluded for abuse/neglect were counted as having numerator exclusions for loss of consciousness, skull fracture, or intracranial hemorrhage. We held constant the claims-based exclusions for medical conditions that could otherwise warrant neuroimaging (increased intracranial pressure, seizure/convulsions). In each scenario, we calculated the overuse percentage based solely on administrative claims data.

In the sample of abstracted charts (n=204), we determined the overuse percentage using exclusions that were identified in administrative claims before chart review. We subsequently calculated the overuse percentage using criteria abstracted during medical record review. Results are presented in Tables 4 and 5 (see Supporting Documents).

The results of the exclusion analysis demonstrate that without the use of chart review, the overuse percentage would be substantially over-estimated by 56 to 80 percentage points. Although the initial application of ICD-9-CM code-based exclusions decreases the burden of reviewing charts unlikely to meet final inclusion criteria for calculation of this measure as specified, the application of exclusions obtained exclusively from chart review substantially changes the neuroimaging overuse percentage as compared to claims alone. Therefore, identification of exclusions in both administrative claims and chart review are necessary for calculation of this measure. Lastly, it is important to note that there are key elements for this measure that cannot be captured in any form using administrative claims. For example, there are currently no ICD-9-CM or ICD-10-CM codes for the major inclusion criteria of having an injury within 24 hours of the ED visit. The vast differences between overuse percentages calculated using data available in administrative claims alone and through chart review justify the burden of chart review for the calculation of this measure.

Identification of Statistically Significant/Meaningful Differences in Performance

We calculated a single neuroimaging overuse percentage for the evaluation of children with post-traumatic headache within a sample of charts obtained by HealthCore after cases were narrowed using administrative claims from the HIRD. Due to the small sample size of charts eligible for inclusion in the numerator and denominator after chart review, we were unable to perform comparisons between health plans or hospital EDs.

A two-sided two-proportion z-test was conducted to determine if the observed overuse percentage in our sample was statistically different than the observed rate of overuse within the 2009 PECARN study of children with traumatic brain injury to develop a clinical decision rule for CT imaging (Kuppermann, et al., 2009). In addition, we conducted a one-sided one-proportion z-test to determine if the observed overuse percentage in our sample was greater than a theoretical target overuse percentage of 5 percent.

In order to inform future applications of this measure, we calculated the sample size needed to achieve 95 percent CIs with half widths of 2.5 percent, 5 percent, and 8 percent for anticipated overuse percentages ranging from 5 percent to 25 percent. We also calculated the per group

sample size needed to detect 5 percent to 20 percent differences in two proportions with power of 80, 90, and 95. We used a control overuse percentage of 15 percent for this calculation

The overuse percentage in our chart review sample was 14.0 percent. The sample sizes needed to achieve 95 percent CIs with half widths of 2.5 percent, 5 percent, and 8 percent for anticipated overuse percentages ranging from 5 percent to 25 percent are presented in Table 6 (see Supporting Documents).

When comparing our overuse percentage (14.0 percent) with the rate of imaging in children lacking all of the six predictors of clinically important traumatic brain injury in the PECARN derivation sample (25.4 percent), a z-score of -2.0704 was obtained, corresponding to a two-sided p-value of 0.038. When comparing our overuse percentage (14.0 percent) with the rate of imaging in children lacking all of the six predictors of clinically important traumatic brain injury in the PECARN validation sample (24.1 percent), a z-score of -1.8339 was obtained, corresponding to a two-sided p-value of 0.067. When comparing our observed overuse percentage with the theoretical target overuse percentage of 5 percent, a z-score of 3.017 was obtained, corresponding to a one-sided p-value of 0.0013. The results of our sample size calculation to guide future testing of this measure are presented in Table 7 (see Supporting Documents).

Despite the small number of charts eligible for our overuse percentage calculations, this measure was able to successfully distinguish statistically significant differences ($p < 0.05$) in overuse of imaging from the historical PECARN rates around 25 percent and the theoretical target percentage of 5 percent. Sample size calculations for both 95 percent CI half-widths and two-sample proportion tests are provided to guide appropriate sample size targets for use of this measure in quality improvement and quality performance reporting. A minimum of 196 charts included in the denominator after chart review would be recommended to obtain a 95 percent CI with a 5 percent half-width around an expected overuse percentage of 15 percent. A per-group minimum of 335 charts included in the denominator after chart review would be recommended for a two-sample proportion test to detect a 10 percent difference from a control proportion of 15 percent with power of 0.90 and alpha of 0.05.

The neuroimaging overuse percentage in this sample is significantly lower, both statistically and clinically, than unnecessary imaging rates reported for the derivation sample in the PECARN study (Kuppermann, et al., 2009). A reduction in the overuse of neuroimaging by more than 10 percentage points is clinically significant when considering the large number of children who undergo neuroimaging for evaluation of post-traumatic headache. However, overuse percentages in this sample remain significantly higher than a target percentage of 5 percent, which indicates less than optimal performance.

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.

Summary of Disparities Data from the Literature

In a cross-sectional study of 50,835 pediatric ED visits for head injury captured in the National Hospital Ambulatory Medical Care Survey 2002-2006, white race was associated with higher odds of neuroimaging (OR 1.5, 95 percent CI: 1.02-2.1) (Mannix, Bourgeois, Schutzman, et al., 2010). Natale and colleagues conducted a secondary analysis of data prospectively collected for PECARN head imaging decision rule (Kuppermann, et al., 2009) to test for associations between race/ethnicity and the ordering of CT among children with blunt head injury. They found that children of black non-Hispanic or Hispanic race/ethnicity had lower odds of undergoing head CT than white non-Hispanic children (Natale, Joseph, Rogers, et al., 2012). Parental anxiety and parental request were cited as reasons for ordering head CT in children of white, non-Hispanic race/ethnicity. Their findings suggest that overuse of CT imaging may disproportionately affect white, non-Hispanic children. Similarly, Morrison and colleagues found that minority race was associated with less radiologic testing in the children of parents with low health literacy in a cross-sectional study of 504 caregivers accompanying their child to a pediatric ED (Morrison, Brousseau, Brazauskas, et al., 2015). When associated with race/ethnicity, overuse of health care, in general, is greater among white patients (Kressin, Groeneveld, 2015).

Summary of Disparities Data from Measure Testing

Patient-level demographic and socioeconomic characteristics were generally unavailable from the medial records reviewed for measure testing. Therefore, we used ZIP-code level race and ethnicity, median household income, and urbanicity, collected for the 2010 United States Census and the 2011 American Community Survey (ACS), as proxy variables to characterize the population. The small numbers of eligible numerator and denominator cases (n=15 and n=57, respectively) do not allow for meaningful comparisons of overuse of neuroimaging among children with post-traumatic headache evaluated in EDs across different socio-demographic groups (U.S. Census Bureau, 2010, 2011).

7.A. Race/Ethnicity

On average, children with post-traumatic headache who obtained neuroimaging resided in ZIP codes reporting primarily white race (80.2 percent) and modest levels of Hispanic ethnicity (9.8 percent). The children included in the denominator group resided in ZIP codes reporting a higher proportion of white residents (81.8 percent) and a similar proportion of Hispanic ethnicity (10.0

percent). The children included in the numerator group resided in ZIP codes reporting a still higher proportion of white residents (83.3 percent) and a slightly lower proportion of residents of Hispanic ethnicity (6.5 percent). These demographic characteristics differ from the population of the United States as a whole, as the 2010 U.S. Census data indicate that approximately 72.4 percent of the population was white, 13.2 percent of the population was black, and 16.3 percent of the population was of Hispanic ethnicity in 2010. The summary statistics for race and ethnicity within ZIP code across the sampled subgroups of children with valid ZIP codes are reported in Tables 8 and 9 (see Supporting Documents).

7.B. Special Health Care Needs

The medical records data abstracted for this study did not include indicators of special health care needs.

7.C. Socioeconomic Status

On average, the ZIP code-level median household income for children with post-traumatic headache who obtained neuroimaging was \$69,540. The children in the denominator group resided in ZIP codes with higher median household incomes (mean \$81,430), and those included in the numerator group resided in ZIP codes with lower median household incomes (mean \$65,263). The median household income for the ZIP-codes in which these children resided was substantially higher than the median household income of the population of the entire United States as reported in the ACS in 2011, which was \$50,502. The summary statistics for distribution of the ZIP-code level median household income for sampled groups of children with valid ZIP codes and complete census data are reported in Table 10 (see Supporting Documents).

7.D. Rurality/Urbanicity

Children with post-traumatic headache who obtained neuroimaging primarily reside in urban ZIP codes (75.4 percent). The subset of children meeting denominator criteria resided in ZIP codes that were slightly more urban (77.9 percent), and those children meeting numerator criteria resided in less urban ZIP codes (66.6 percent). The proportion of children in this sample who resided in urban ZIP codes is similar to the rest of the United States, where approximately 79 percent of the population resides in an urban area. The summary statistics for urbanicity within ZIP code for sampled groups of children with valid ZIP codes are reported in Table 11 (see Supporting Documents).

7.E. Limited English Proficiency (LEP) Populations

The medical records data abstracted for this study did not include indicators of LEP.

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?

Our results indicate that the data elements required for the calculation of this measure are typically recorded in electronic health record (EHR) systems. However, important information required for numerator or denominator exclusion criteria may be recorded in an unstructured format in problem lists, as well as in nursing and physician notes.

Availability of medical records meeting inclusion criteria will vary by the entity using this measure. This measure was tested using a target sample of 200 abstracted charts for eligible children during the measurement year. Of the 204 charts abstracted for testing, 75 children had a headache diagnosis code, and 67 of those charts were excluded because there was no clinical documentation of trauma occurring within 24 hours of the ED visit. Overall, we found 57 charts (27.9 percent of the sample obtained for chart review) met denominator criteria and were eligible for evaluation of measure numerator exclusions. A sample of 55 charts included in the denominator would yield a 95 percent CI with a half-width of 8 percent for an expected overuse percentage of 10 percent. A sample size of 554 would be needed to achieve a 95 percent CI with a half-width of 2.5 percent for an expected overuse percentage of 10 percent. Larger numbers of abstracted charts will be required to ensure sufficient sample size; this will allow greater confidence in overuse percentage estimates and enable testing for differences between providers, hospital EDs, or health plans.

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?

Order entry systems can provide structured information about orders placed for neuroimaging studies, providing key information necessary for future applications of the measure. Importantly, for this measure to be accurate, it may be necessary to combine data from multiple EHR systems. The use of Health Information Exchange (HIE), especially using the DIRECT protocol for exchange across individual electronic medical records (EMRs), would be an important tactical step to enable this measure.

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.

To our knowledge, this measure is not currently in use anywhere in the United States.

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)

No.

Data Sources: Are data sources available to support reporting at this level?

Not applicable.

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 applicable.

In Use: Have measure results been reported at this level previously?

Not applicable.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

Not applicable.

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

Not applicable.

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)

No.

Data Sources: Are data sources available to support reporting at this level?

Not applicable.

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 applicable.

In Use: Have measure results been reported at this level previously?

Not applicable.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

Not applicable.

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

Not applicable.

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)

No.

Data Sources: Are data sources available to support reporting at this level?

Not applicable.

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 applicable.

***In Use:* Have measure results been reported at this level previously?**

Not applicable.

***Reliability & Validity:* Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**

Not applicable.

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

Not applicable.

***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?**

This measure requires medical record abstraction; medical records are maintained by all health services providers. Target population for sampling requires administrative claims data to identify subgroups of potentially eligible cases for medical record review.

***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?**

This measure was tested using a target sample of 200 abstracted charts for eligible children during the measurement year. The yield of charts eligible after the application of denominator exclusions was lower than expected; 27.9 percent of the 204 charts abstracted for testing were eligible for the denominator. In addition, 67 of the 75 children had a ‘general symptoms of headache’ diagnosis code and had no clinical documentation of trauma occurring within 24 hours of the ED visit. The inclusion of this non-specific code contributed substantially to the attrition of eligible cases. Larger samples of charts would be required for abstraction in order to ensure adequate sample size remains in the denominator after application of exclusion criteria. To detect differences between two health plans, hospital EDs, or providers with overuse percentages of 20 percent and 10 percent, would require a sample size of at least 199 denominator-eligible cases per group, with a p-value of 0.05 and 80 percent power.

***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?

No unintended negative consequences to individuals or populations were identified during testing. The primary potential unintended consequence of a quality measure to assess the extent to which imaging is overused would be reduction of imaging for children who do have an indication. In other words, the measurement of overuse could result in underuse. By measuring overuse (imaging without the appropriate indications) and not use (imaging for any indication), we have specified the situations where reduction in imaging would be of greatest benefit.

Provider Level

Individual practitioner: Can compare individual health care professionals

Intended use: Is measure intended to support meaningful comparisons at this level?

(Yes/No)

No.

Data Sources: Are data sources available to support reporting at this level?

Not applicable.

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 applicable.

In Use: Have measure results been reported at this level previously?

Not applicable.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

Not applicable.

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

Not applicable.

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?

This measure requires medical record abstraction; medical records are maintained by all health services providers.

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?

This measure has not been tested at the hospital level; consequently, the minimum number of patients required per hospital has not been 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?

Again, the primary potential unintended consequence of a quality measure to assess the extent to which imaging is overused would be reduction of imaging for children who do have an indication. In other words, the measurement of overuse could result in underuse. By measuring overuse (imaging without the appropriate indications) and not use (imaging for any indication), we have specified the situations where reduction in imaging would be of greatest benefit.

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)

No.

Data Sources: Are data sources available to support reporting at this level?

Not applicable.

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 applicable.

In Use: Have measure results been reported at this level previously?

Not applicable.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

Not applicable.

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

Not applicable.

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).

This measure provides a straightforward means to assess the extent to which neuroimaging studies (CT and MRI) are being overused for the evaluation of children with post-traumatic headache. High percentages of overuse are easily understood to be unsatisfactory. The primary information needed for this measure is sourced from medical records and administrative claims data and includes basic demographics, diagnostic codes, and procedure codes, all of which are widely available.

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.

Health information technology (IT) provides a platform that could support various new uses of the measure. First, health IT can show feedback at the time of imaging order entry. Health IT can also provide education about alternatives to imaging. Alerts and reminders, given to patients as well as to providers, might also enhance use of the measure.

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.

Our results indicate that these data are already recorded in EHR systems. Order entry systems can provide structured information about orders placed for neuroimaging studies; this furnishes key information necessary for the measure. However, important information required for numerator or denominator exclusion criteria may be recorded in an unstructured format in problem lists, as well as in nursing and physician notes. Importantly, for this measure to be accurate, it may be necessary to combine data from multiple EHR systems. The use of HIE, especially using the DIRECT protocol for exchange across individual EMRs, would be an important tactical step to enable this measure.

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 criteria (see healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_standards_ifr/1195)?

Yes.

If yes, please describe.

The ONC's Health IT Standards explicitly address the receipt of CT and MRI results and other diagnostic tests into EHRs, which may be relevant in hospitals providing imaging services to children. The ONC standards include the following specific requirements in the Certification criteria (ONC, 2010) pertaining to Stage 2 Meaningful Use requirements:

Stage 2 (beginning in 2013): CMS has proposed that its goals for the Stage 2 meaningful use criteria expand upon the Stage 1 criteria to encourage the use of health IT for continuous quality improvement at the point of care. In addition, the exchange of information in the most structured format possible is encouraged. This can be accomplished through mechanisms such as the electronic transmission of orders entered using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results, which provides evidence that ordered imaging studies were completed. Electronic transmission of diagnostic test results includes a broad array of data important to quality measurement and, for this measure, specifically includes radiology studies such as CT and MR imaging.

11.E. Health IT Calculation

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

Missing or ambiguous information in the following areas could lead to missing cases or calculation errors:

1. Child's date of birth.
2. ICD-9-CM/CPT codes.
3. Date and time of treatment.
4. Type of tests administered.
5. Date of tests performed.
6. Care setting.
7. Lack of a consistent radiation dose moderation strategy.
8. Possibly a scanned or electronic clinical document in the medical record

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?

One function that may enhance performance might be the use of clinical decision support to understand when CT/MRI is not indicated. Information buttons could link to educational resources at the point of care to discourage unnecessary ordering as well.

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).

This measure was tested using medical record data after administrative claims were used to identify the population to sample for chart review. Administrative data needed for this measure include date of birth, diagnosis codes, and procedure codes and dates. These data are generally available, although obtaining them may require a restricted-use data agreement and Institutional Review Board (IRB) approval.

Testing this measure using medical record data required the development of an abstraction tool and the use of qualified nurse abstractors. Review of clinical documentation was required to ensure that exclusions were appropriately captured for the determination of overuse of neuroimaging (i.e., imaging obtained in the absence of indicators of intracranial hemorrhage or basilar skull fracture).

Our review of medical charts indicated that 72.1 percent (147/204) of the children who were included in the chart review sampling population after the application of administrative claims

exclusions were subsequently excluded from the denominator based on information in the medical chart. Importantly, the majority of numerator exclusions (i.e., symptoms of intracranial injury that represent a clinical indication for neuroimaging) were not adequately captured in administrative claims. As a consequence, using administrative data alone would result in a substantial overestimation of the degree to which neuroimaging is overused in the evaluation of children with post-traumatic headache. This finding is not unexpected, as there are several exclusions that can only be accurately captured through review of clinical documentation contained within the medical record. As an example, one denominator exclusion criterion, time of injury greater than 24 hours, cannot be identified through the use of administrative claims.

Chart review also may be beneficial to confirm that individuals with claims-based denominator exclusions have been appropriately identified and removed from the final eligible population, although we found high validity between data elements available within administrative claims compared with data elements documented within the medical chart (see Testing section in this report, Section 6). Additionally, chart review is necessary to determine that cases meet measure inclusion criteria for post-traumatic headache. Some of the ICD-9-CM codes used to identify cases for chart review were intentionally non-specific, such as ‘general symptoms of headache’ (ICD-9-CM code 784.0), as they reflect codes that are used in clinical practice to bill for care delivered to children with post-traumatic headache but require determination of a trauma history within 24 hours of the ED visit based on chart review.

This measure was tested using a target sample of 200 abstracted charts for eligible children during the measurement year. The yield of charts eligible after the application of denominator exclusions was lower than expected; 27.9 percent of the 204 charts abstracted for testing were eligible for the denominator. In addition, 67 of the 75 children had a ‘general symptoms of headache’ diagnosis code and had no clinical documentation of trauma occurring within 24 hours of the ED visit. The inclusion of this non-specific code contributed substantially to the attrition of eligible cases. Larger samples of charts would be required for abstraction in order to ensure adequate sample size remains in the denominator after application of exclusion criteria. To detect differences between two health plans, hospital EDs, or providers with overuse percentages of 20 percent and 10 percent, would require a sample size of at least 199 denominator-eligible cases per group, with a p-value of 0.05 and 80 percent power.

Continuing advances in the development and implementation of EHRs may prompt providers to document key elements needed for application of inclusion and exclusion criteria necessary for this measure. Advances would further allow for electronic capture of structured clinical information needed to determine if and when neuroimaging has been overused in the evaluation of children experiencing a post-traumatic headache.

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.

This measure assesses the percentage of children, ages 2 through 17 years, with post-traumatic headache who were evaluated in the ED within 24 hours after an injury, and imaging of the head (CT or MRI) was obtained in the absence of documented neurologic signs or symptoms that suggest intracranial hemorrhage or basilar skull fracture. A lower percentage indicates better performance, as reflected by avoidance of CT imaging when it is not indicated. This measure was tested using administrative claims data to identify the eligible population for medical record review.

Post-traumatic headaches in children are a common clinical presentation in the setting of concussion and mild traumatic brain injury. Over the past decade, ED visits for traumatic brain injuries have increased substantially. Neuroimaging is increasingly used to evaluate children with post-traumatic headache, but the benefit of these studies in the absence of documented neurologic signs or symptoms that suggest intracranial hemorrhage or skull fracture is rarely clinically indicated and is potentially harmful. One of the most worrisome prospects for overuse of neuroimaging relates to the radiation exposure associated with CT scans and the resultant increased risk for malignancy later in life.

Q-METRIC testing results indicate that this measure is feasible using existing data sources. The measure was tested with data abstracted from medical records after administrative claims were used to identify the eligible population. In total, 204 charts were reviewed; 57 (27.9 percent) met denominator criteria for this measure. Among these children, 15 (26.3 percent) were imaged in the absence of documented neurologic signs or symptoms that suggest intracranial hemorrhage or skull fracture. This measure was also tested to determine the feasibility of using administrative claims data exclusively. Many denominator and numerator exclusions were not adequately captured in administrative claims. As a consequence, using administrative data alone would result in a substantial overestimation of the degree to which neuroimaging is overused in the evaluation of children with post-traumatic headache.

This measure provides a means to assess the extent to which neuroimaging studies (CT and MRI) are being overused for the evaluation of children with post-traumatic headache by providers within a health plan or Medicaid program. High percentages of overuse are easily understood to be unsatisfactory. The primary information needed for this measure is sourced from medical records and administrative claims data and includes basic demographics, diagnostic codes, and procedure codes, all of which are available, though access may require a restricted-use data agreement and IRB approval. Certain limitations were observed during measure testing. Most importantly, data contained in administrative claims are insufficient to capture all of the specified exclusions. Continuing advances in the development and implementation of EHRs may prompt providers to document key elements needed for application of inclusion and exclusion criteria necessary for this measure. This would allow for electronic capture of clinical information needed to determine if and when neuroimaging has been overused in the evaluation of children experiencing a post-traumatic headache.

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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 Medicare & 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.

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