Transcranial Doppler Ultrasonography Screening Among Children with Sickle Cell Anemia

Section 1. Basic Measure Information

1.A. Measure Name

Transcranial Doppler Ultrasonography Screening Among Children with Sickle Cell Anemia

1.B. Measure Number

0139

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 15 years with sickle cell anemia (hemoglobin [Hb] SS) who received at least one transcranial Doppler (TCD) screening within a year. TCD ultrasonography measures the blood flow velocity in cerebral arteries, specifically, the distal internal carotid artery and the proximal middle cerebral artery. High blood velocities are indicative of an upcoming stroke and the need to begin stroke prevention efforts among children with sickle cell anemia. Stroke prevention efforts result in a substantial reduction in the incidence of stroke among children with sickle cell anemia.

1.D. Measure Owner

The Quality Measurement, Evaluation, Testing, Review, and Implementation Consortium (QMETRIC).

1.E. National Quality Forum (NQF) ID (if applicable)

2797

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 QMETRIC Sickle Cell Disease 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.

This measure is part of the QMETRIC Sickle Cell Disease Administrative Claims set.

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 numerator is the number of children ages 2 through 15 years with sickle cell anemia who received at least one TCD screening within the measurement year.

Details

- Each measurement year extends from January 1 to December 31 (12 months).
- Cases from the target population with target process (receipt of TCD screening): Receipt of TCD screening is identified as the presence of at least one CPT code for any of five acceptable ultrasonography tests within the measurement year among children in the target population.
- Acceptable CPT codes are: 93886 (complete study); 93888 (limited study); 93890 (vasoreactivity study); 93892 (emboli detection without intravenous microbubble injection); and 93893 (emboli detection with intravenous microbubble injection).

1.H. Numerator Exclusions

None

1.I. Denominator Statement

The denominator is the number of children ages 2 through 15 years with sickle cell anemia within the measurement year.

Details

- Children with sickle cell anemia are identified through the presence of at least three separate health care encounters related to sickle cell anemia (defined as Hb SS) within the measurement year.
- Sickle cell anemia-related health care encounters are identified through ICD codes. The ICD-9-CM codes to identify Hb SS-related health care encounters are as follows: 282.61 (Hb-SS disease w/o crisis) and 282.62 (Hb-SS disease with crisis). The ICD-10-CM codes for Hb SS-related health care encounters are as follows: D57.00 (Hb-SS disease with crisis, unspecified); D57.01 (Hb-SS disease with acute chest syndrome); and D57.02 (Hb-SS disease with splenic sequestration).
- Children ages 2 through 15 years are included within the target population (i.e., must not have a 2nd or 16th birthday within the measurement year).

It is important to note that accurate calculation of this measure requires that the target population be selected from among children who have all of their health services for the measurement year included in the administrative claims data set. For children who have dual enrollment in other health plans, their claims may not be complete since some of their health services may have been paid for by another health plan. Inclusion of children with other health insurance would potentially cause this measure to be understated. As a consequence, this measure requires that children must not only be continuously enrolled within the health plan from which claims are available, the enrollment files must also be assessed to determine whether other forms of health insurance existed during the measurement year. Children with evidence of other insurance during the measurement year (i.e., coordination of benefits) are excluded from the target population.

1.J. Denominator Exclusions

None.

1.K. Data Sources

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

Administrative claims

If other, please list all other data sources in the field below.

Not applicable.

Section 2: Detailed Measure Specifications

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

Please see the Appendix, Transcranial Doppler Ultrasonography Screening Among Children with Sickle Cell Anemia, which appears at the end of this document to review the specifications, a flow chart for the measure, and SAS code.

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).

Children with sickle cell anemia (Hb SS) have over 300 times the stroke risk compared with children with normal hemoglobin (Verduzco, Nathan, 2009). Without intervention, approximately 11 percent of children with sickle cell anemia will have a stroke by age 20 (Verduzco, Nathan, 2009; Ohene-Frempong, Weiner, Sleeper, et al., 1998). Transcranial Doppler (TCD) ultrasonography measures the blood velocities within the cerebral vessels (Adams, McKie, Carl, et al., 1997; Adams, McVie, Nichols, et al., 1992). Children over the age of 2 with a timeaverage mean maximum blood flow velocity of 200cm/sec or greater as measured by TCD ultrasonography have been shown to have 27 times the risk of stroke compared with children with velocities less than 200cm/sec. This corresponds to a 40 percent risk of stroke within 3 years among those with high velocities (Adams, et al., 1997). Initiation of chronic blood transfusions reduces the risk of stroke by 92 percent among children at highest risk of stroke as identified through TCD screening (Adams, et al., 1997; Adams, et al., 1992). TCD screening is a reasonable method to assess stroke risk among children with sickle cell anemia, as it is safe, noninvasive, and low cost (Markus, 2000). Although other predictors of stroke have been examined, such as hematocrit levels and white blood cell count, TCD velocities have been shown to be the only independent predictor of stroke (Adams, et al., 1992). Given the importance of TCD screening to stroke prevention among children with sickle cell anemia, the National Heart, Lung, and Blood Institute (NHLBI) recommends that each child with sickle cell anemia receive one TCD screen per year from ages 2 to 16 years (NHLBI, 2014).

Although the benefits of TCD screening among children with sickle cell anemia have been known since the late 1990s, prior studies indicate that TCD screening rates are low. These reports are limited in their generalizability, however, as they often are focused on a single health care provider or registry. This measure establishes a claims-based method for identifying receipt of TCD screening among larger and broader populations of children with sickle cell anemia. The measure specifications are reflective of the guidelines from the NHLBI. The performance scores calculated through this measure will identify areas in need of improvement in receipt of TCD screening among children with sickle cell anemia.

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).

Not applicable

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 quality measure does not overlap with any existing sickle cell anemia pediatric quality measures.

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: Yes.
- e. Service care for acute conditions: No.
- 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: No.
- k. Measure Topic family experience with care: No
- **I.** 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 2-5 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; ages 11-15 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.

The basis for the measure is the National Heart, Lung, and Blood Institute's Evidence-Based Management of Sickle Cell Disease: Expert Report (NHLBI, 2014).

The body of evidence is from the NHLBI Evidence-Based Clinical Guidelines for the Management of Sickle Cell Disease (evidence tables: Table 9. Transcranial Doppler Results) (Nabhan, Hazem, Elraiyah, et al, 2012). The specific service addressed in this evidence review was TCD screening.

RECOMMENDATIONS

1. In children with SCA, screen annually with TCD according to methods employed in the STOP studies, beginning at age 2 and continuing until at least age 16. *(Strong Recommendation, Moderate-Quality Evidence)*

2. In children with conditional (170-199 cm/sec) or elevated (>200 cm/sec) TCD results, refer to a specialist with expertise in chronic transfusion therapy aimed at preventing stroke. (*Strong Recommendation, High-Quality Evidence*)

3. In children with genotypes other than SCA (e.g., HbSB⁺-thalassemia or HbSC), do not perform screening with TCD.

(Strong Recommendation, Los-Quality Evidence)

4. In asymptomatic children with SCD, do not perform screening with MRI or CT. *(Moderate Recommendation, Low-Quality Evidence)*

5. In asymptomatic adults with SCD, do not perform screening with neuroimaging (TCD, MRI, or CT).

(Moderate Recommendation, Very Low-Quality Evidence)

Strong Recommendation, Moderate-Quality Evidence						
Strong recommendation Moderate-quality evidence	Benefits clearly outweigh harms and burdens, or vice versa	Evidence from RCTS with important limitations (inconsistent results, methodological flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies	Recommendation can apply to most patients in most circumstances. Further research (if performed) is likely to have an impact on our confidence in the estimate of effect and may change the estimate.			

Receipt of TCD screening does not directly impact the risk of stroke among children with sickle cell anemia; however, the indication of high risk of stroke identified from TCD screening (blood flow velocity>200cm/sec) prompts the initiation of primary stroke prevention efforts in the form of blood transfusions. For brevity, we have included estimates of benefit and consistency among studies within the body of evidence directly related to the process of TCD screening and the health-related outcome of primary stroke prevention among children with sickle cell anemia. The majority of the studies used a standard definition of an abnormal TCD screening result (blood flow velocity>200cm/sec). A handful of studies used a looser definition, classifying velocities of over 170cm/sec as abnormal; however, these children would have been included in the definition of conditional TCD screening result in the other studies. Studies reported between 2 percent and

33 percent abnormal TCD screening results within their study populations; this large range may be attributable to differing study population inclusion criteria.

All studies investigating the relationship between blood flow velocity as detected by TCD screening and stroke risk show that children with high blood flow velocities in the cerebral vessels are at a significantly increased risk of stroke. Adams et al. (1992) reported in a prospective observational study that among seven children who had a stroke within the study period (overall n=190), six children had an abnormal TCD screening result (Fisher's exact pvalue<0.00001). Adams, Brambilla, Granger, et al. (2004) also reported that among 2,342 children with SCD who received a TCD screen, risk of stroke with abnormal TCD was much higher than with normal results (p-value<.001), conditional findings (p-value<.001), or inadequate TCD results (p value=.002). All studies that assessed stroke rates pre- and post-TCD screening recommendations found a significantly decreased rate of first stroke among children with sickle cell anemia post-TCD recommendations when compared with the pre-TCD recommendation time period. Armstrong-Wells, Grimes, Sidney, et al. (2008) reported a stroke rate of 0.44 per 100 pre-TCD recommendations and a stroke rate of 0.19 per 100 person-years post-TCD recommendations; Enninful-Eghan, Moore, Ichord, et al. (2010) reported a stroke rate of 0.67 per 100 person-years pre-TCD recommendations and a post-TCD stroke rate of 0.06 per 100 person-years (p-value<0.0001). In addition, McCarville (2008) showed significantly decreasing stroke rates with increasing TCD use (p-value=0.045).

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.

See discussion above.

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.

Data

This measure is based on administrative claims data. The following datasets were used for testing:

Existing Datasets:

- Michigan Medicaid administrative claims data provided by the Michigan Department of Health and Human Services (MDHHS).
- Medicaid Analytic eXtract (MAX) administrative claims data for six State Medicaid programs provided by the Centers for Medicare & Medicaid Services (CMS). Note, CMS develops and maintains standardized MAX data for public use using administrative claims submitted by each State Medicaid program. The MAX data are the only national, person-level administrative claims dataset available for the Medicaid program.

Other data used for testing (not existing datasets):

- Medical record data from Children's Hospital of Michigan (CHM), Detroit, MI; Hurley Medical Center (HMC), Flint, MI; and University of Michigan Health Services (UMHS), Ann Arbor, MI.
- Michigan Newborn Screening (NBS) results.

Dates include Michigan Medicaid data 2007-2011; MAX data: 2005-2010; CHM, HMC, and UMHS medical record data: 2012; and Michigan NBS data: 1987-2010.

The measure was specified and tested at the health plan level.

- The Michigan Medicaid data consisted of all Medicaid claims for Medicaid enrollees within the State of Michigan (2007-2011).
- The MAX data consisted of all Medicaid claims reported to CMS for Medicaid enrollees within six State Medicaid programs with moderate to high prevalence of sickle cell anemia: Florida, Illinois, Louisiana, Michigan, South Carolina, and Texas (2005-2010).
- The medical record data were obtained from three hospitals: CHM, HMC, and UMHS (2012). These three large medical centers are located in urban areas in Michigan that are reflective of the residence of the vast majority of children with sickle cell anemia living in Michigan:
 - CHM is a tertiary medical center located in Detroit, Michigan.
 - HMC is a tertiary medical center located in Flint, Michigan.
 - UMHS is an academic medical center located in Ann Arbor, Michigan.
- The Michigan NBS data consisted of all births within the State of Michigan (1987-2010).

Michigan Medicaid data from 2007 to 2009 represented a complete census of all children ages 2-16 years with sickle cell anemia who met eligibility criteria within each year (Table 1). The population was equally divided between sexes; approximately 98 percent were black.

Table 1: Number of children ages 2 to 16 years with sickle cell anemia enrolled in MichiganMedicaid, 2007-2009

2007	2008	2009
359	334	359

- The Michigan Medicaid data from 2010 and 2011 provided a complete census of all children ages 1-18 years with at least one SCD-related administrative claim, continuously enrolled annually within Michigan Medicaid in 2010 and/or 2011, with a newborn screening result available. This included 938 children in 2010 and 924 children in 2011. The population was equally divided between sexes; approximately 75 percent were black, and the average age was approximately 10 years.
- The MAX data included all children ages 2-16 years with sickle cell anemia that met eligibility criteria within each year for Medicaid claims reported by selected States (Table 2). The population was equally divided between sexes; approximately 98 percent were black.

State	2005	2006	2007	2008	2009	2010
Florida	526	489	449	502	697	734
Illinois	250	276	278	291	338	302
Louisiana	364	321	322	334	356	361
Michigan	240	219	243	228	259	240
South Carolina	214	189	173	124	102	134
Texas	258	292	343	352	370	370

Table 2: Number of children enrolled in Medicaid with sickle cell anemia, MAX data by State,2005-2010

• A sample of abstracted medical records from 91 children with sickle cell anemia ages 2-16 years who were enrolled in Michigan Medicaid was drawn at three sickle cell centers in Michigan (CHM, HMC, UMHS) for children meeting the transcranial Doppler (TCD) screening measure specification criteria during 2012.

• The Michigan NBS data included all children born in the State of Michigan from 1987- 2010 with a positive and confirmed screening result who had at least one SCD-related claim and were continuously enrolled in Michigan Medicaid in either 2010 or 2011.

Reliability

The reliability of MAX data to evaluate TCD screening is of high importance, since this is the only national source of State Medicaid data available upon which State-to-State comparisons may be conducted. The reliability of this measure was calculated using a signal-to-noise analysis. The signal-to-noise analysis was focused on assessing the reliability to confidently distinguish the performance of one State's Medicaid program from that of another State. For this approach, reliability was estimated with a beta-binomial model (RAND Corporation, TR-653-NCQA, 2009). State-specific reliability results for receipt of TCD screening among children with sickle cell anemia are detailed in Table 3. These results show that the reliability based on signal-to-noise analysis ranged from 0.96 to 0.99, with a median of 0.98.

State	Numerator	Denominator	Reliability Statistic
Florida	1141	3397	0.99
Illinois	474	1735	0.98
Louisiana	954	2058	0.98
Michigan	334	1429	0.98
South Carolina	273	936	0.96
Texas	464	1985	0.98
Median (range)			0.98 (0.96-0.99)

Note: Between State Variance: 0.0056

State-specific reliability is very good; observed reliability was consistently greater than 0.95. In general, reliability scores can range from 0.0 (all variation is attributable to measurement error) to 1.0 (all variation is caused by real differences). While there is not a clear cut off for minimum reliability level, values above 0.7 are considered sufficient to distinguish differences between some States and the mean; reliability values above 0.9 are considered sufficient to see differences between States (RAND Corporation, TR-653-NCQA, 2009). The median reliability observed across States was 0.98 (range: 0.96-0.99), which is consistent with a high degree of reliability.

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).

The validity of this measure was assessed through the validity of coded data, empirical testing of the measures, and face validity.

Validity of Coded Data

Numerator

The accuracy of administrative claims in identifying receipt of TCD screening was assessed through comparison with the gold standard of medical charts. An audit was conducted by trained medical record abstractors to compare administrative claims data with corresponding medical records data. Medical records were abstracted for all children meeting the TCD screening measure specification criteria; agreement between the medical records and the administrative claims was assessed using kappa. In addition, the reliability of the data element abstracted from the medical chart was assessed by identifying a subset of the charts to be re-abstracted by another trained medical record abstractor; the results of the two abstractors were compared using percent agreement and kappa.

Furthermore, the sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV) of administrative claims for receipt of TCD screening were calculated; the medical charts were the gold standard for comparison.

Denominator

The accuracy of the case definition (at least three claims for sickle cell anemia [Hb SS] within the measurement year) to identify children with sickle cell anemia was assessed through comparison with the gold standard of newborn screening results for the State of Michigan for children enrolled in Michigan Medicaid in 2010 and 2011 with at least one SCD-related health care claim within their enrollment year(s). The area under the receiver operating characteristic (ROC) curve, sensitivity, specificity, PPV, and NPV were calculated for the case definition. As a comparison, these values were also calculated for those with a minimum of at least one or two Hb SS claims within each year.

Results

Numerator

For this comparison, 91 children with sickle cell anemia who were enrolled within Michigan Medicaid were successfully matched with their Michigan Medicaid administrative claims data. Among these children, TCD screening was identified in both the administrative claims data and the medical record review for 47 (51.6 percent) cases (Table 4). Similarly, 41 (45.1 percent)

cases were classified as not having a TCD in both data sources, yielding an overall agreement of 96.7 percent (kappa = 0.93, 95 percent confidence interval [CI]: 0.86, 1). Using administrative claims to identify receipt of TCD screening resulted in a sensitivity of 94 percent (95 percent CI: 83 percent-99 percent), a specificity of 100 percent (95 percent CI: 91 percent-100 percent), a NPV of 93 percent (95 percent CI: 81 percent-99 percent), and a PPV of 93 percent (95 percent CI: 92 percent-100 percent) compared with the gold standard of medical records. Ten charts were also chosen for exploration of inter-rater reliability; the two trained abstractors had 100 percent agreement with each other for abstracting receipt of TCD screening from the medical records, resulting in a kappa of 1.00.

Table 4: Michigan validation testing (administra	tive claims vs. medical records) for transcranial			
Doppler screening among children with sickle cell anemia				

Transcranial Doppler Screening in Medicaid Claims Data	Transcranial Doppler Screening in Medical Record (n=91)			
	Yes	No	Total	
Yes	51.6 percent (47)	0	51.6 percent (47)	
No	3.3 percent (3)	45.1 percent (41)	48.4 percent (44)	
Total	54.9 percent (50)	45.1 percent (41)	100 percent (91)	

Denominator

For this comparison, 865 children met eligibility criteria in 2010 (at least one SCD-related claim ages 1-18, continuous enrollment in Michigan Medicaid in 2010, a newborn screening result available); 836 children met eligibility criteria in 2011. In 2010, a case definition of three Hb SS claims within the year was 91.4 percent sensitive and 80 percent specific in identifying children with sickle cell anemia (Hb SS) (PPV: 80.4 percent; NPV: 91.3 percent). These results were replicated with nearly identical precision among the study population in 2011 (Table 5). In comparison, using a case definition of at least one Hb SS claim or at least two Hb SS claims to identify the study population resulted in substantially less specificity.

Table 5. Accuracy of case definition of at least 1, 2 and 3 Hb SS claims within a year to identify children with sickle cell anemia as compared to the gold standard of newborn screening 2010 Results

Algorithm	Area under the ROC Curve	# True Positives	# False Positives	# True Negatives	# False Negatives	Sensitivity	Specificity	PPV	NPV
>1 Hb SS Claim	0.50	409	456	0	0	100.0 percent	0.0 percent	47.3 percent	NA
>2 Hb SS Claims	0.82	391	144	312	18	95.6 percent	68.4 percent	73.1 percent	94.5 percent
>3 Hb SS Claims	0.86	374	91	365	35	91.4 percent	80.0 percent	80.4 percent	91.3 percent

2011 Results

Algorithm	Area under the ROC Curve	# True Positives	# False Positives	# True Negatives	# False Negatives	Sensitivity	Specificity	PPV	NPV
>1 Hb SS Claim	0.50	397	439	0	0	100.0 percent	0.0 percent	47.5 percent	NA
>2 Hb SS Claims	0.79	377	163	276	20	95.0 percent	62.9 percent	69.8 percent	93.2 percent
>3 Hb SS Claims	0.87	363	97	342	34	91.4 percent	77.9 percent	78.9 percent	91.0 percent

Numerator

A kappa of greater than .81 is considered almost perfect agreement (Landis, Koch, 1997). In addition, the sensitivity, specificity, NPV and PPV are high. Given this evidence, we believe the validity of administrative claims in assessing receipt of TCD screening is very high.

Denominator

A sensitivity of over 90 percent and a specificity of approximately 80 percent, as well as the reliability across years, allow us to conclude that the denominator is valid for accurately identifying children with sickle cell anemia within administrative claims. These results indicate that the case definition used has a very high ability to correctly identify true cases and a somewhat lower ability to distinguish false positives. However, other less stringent case definitions resulted in substantially more misclassification than the chosen definition of at least three Hb SS claims within the measurement year.

Empirical Validity Testing of the Performance Measure

Although a State would typically have direct access to its own Medicaid data, it is unlikely that a State would have similar access to other States' data for comparison. Because MAX data are the only national, person-level administrative claims dataset available for the Medicaid program, these data are likely to be used to perform cross-State comparisons of TCD screening among children with sickle cell anemia, rather than data acquired directly from individual Medicaid

programs. Since States submit their Medicaid data to CMS for conversion into the MAX datasets, a State's own Medicaid data can be considered the authoritative source for administrative claims.

Our empirical validity testing of this performance measure compared the MAX data for the State of Michigan (obtained from CMS) with the gold standard of Michigan Medicaid data (obtained directly from Michigan's claims data warehouse) for the same time period (2007-2009). Note that the testing time period was constrained to align with the most recent MAX data available from CMS at the time of this analysis. Rates of TCD screening using each source of data were calculated and compared using z-tests for two proportions; for these tests, the null hypothesis was that the rate in each year would be the same in both Michigan Medicaid data and MAX data. Additionally, the correlation coefficient and squared correlation coefficient were calculated to identify the extent of the linear relationship between the two data sources.

Results

The comparison of rates of TCD screening from the gold standard of Michigan Medicaid data as compared with MAX data can be seen in Table 6. This illustrates that the number of TCD cases among children with sickle cell anemia ranged from 45 to 114 screenings in the claims acquired directly from the Medicaid data warehouse, versus a range of 26 to 93 screenings from MAX data for the same time period.

Source	Rate Components	2007	2008	2009
MAX data	Numerator	26	49	93
	Denominator	243	228	259
	Percentage	10.7 percent	21.5 percent	35.9 percent
Michigan Medicaid data	Numerator	45	58	114
	Denominator	359	334	359
	Percentage	12.5 percent	17.4 percent	31.8 percent

 Table 6: Comparison of transcranial Doppler screening by source of Medicaid claims data for the

 State of Michigan, 2007-2009

Figure 1 illustrates the TCD screening rates observed between the Michigan Medicaid data from the State warehouse and MAX data from CMS for each overlapping year noted, respectively: 12.5 percent versus 10.7 percent (2007); 17.4 percent versus 21.5 percent (2008); and 31.8 percent versus 35.9 percent (2009).

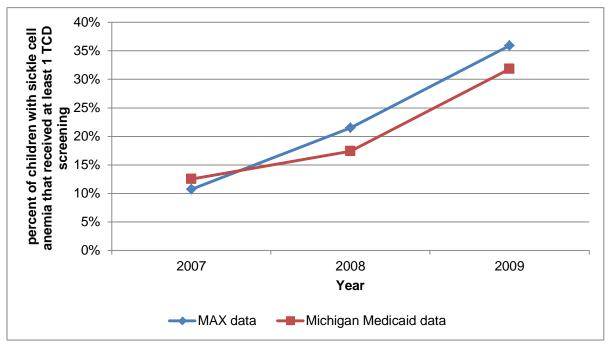


Figure 1: Comparison of transcranial Doppler screening by source of Medicaid claims data, Michigan

Table 7 reports the z-scores and p-values from the two-sample z-tests comparing the proportion of children that received screening each year between Michigan Medicaid and MAX data.

Table 7: Comparison of transcranial Doppler screening by source of Medicaid claims
data, Michigan

	2007	2008	2009
z-score	-0.685	1.223	1.079
p-score	0.4965	0.2225	0.2801

Additionally, the data comparison revealed a Pearson correlation coefficient of 0.98, corresponding to a squared correlation coefficient of 0.96.

Our results suggest that, compared with the gold standard of Michigan Medicaid data, MAX data have a very high degree of validity. When TCD screening was assessed for the same State (Michigan) from these two data sources for the same time period (2007-2009), no differences in rates were observed (all p-values >0.20). Additionally, the high values of the correlation coefficient and the squared correlation coefficient indicate a high level of reliability. Correlation coefficients of greater than 0.70 indicate a strong positive linear relationship; therefore, our results suggest that compared with Michigan Medicaid data, MAX data are highly valid. The squared correlation coefficient value of 0.96 indicates that nearly 96 percent of the variability in the MAX data from CMS for the State of Michigan can be explained by variation in the data

received directly from the Michigan Medicaid program. This finding indicates that the strength of the relationship between the two data sources is extremely strong.

Face Validity

The face validity of this measure was established by a panel of national experts and advocates for families of children with SCD convened by the Quality Measurement, Evaluation, Testing, Review, and Implementation Consortium (QMETRIC). The QMETRIC expert panel included nationally recognized experts in SCD, representing hematology, pediatrics, and SCD family advocacy. In addition, measure validity was considered by experts in State Medicaid program operations, health plan quality measurement, health informatics, and health care quality measurement. In total, the QMETRIC SCD panel included 14 experts, providing a comprehensive perspective on SCD management and the measurement of quality metrics for States and health plans. The expert panel assessed whether the performance of the measure would result in improved quality of care for children with sickle cell disease. Specifically, in respect to TCD screening, the panel weighed evidence to determine if the performance of TCD as outlined in the measure would improve the quality of care provided to patients. The voting process to prioritize the measure was based on the ability of the measure to distinguish good from poor quality.

Results

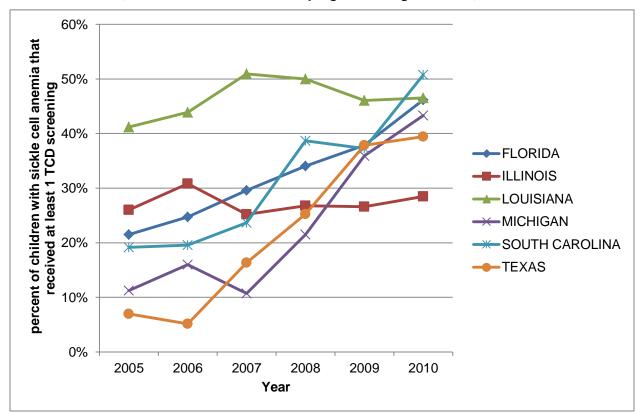
The QMETRIC expert panel concluded that this measure has a very high degree of face validity through a detailed review of concepts and metrics considered to be essential to effective SCD management and treatment. Concepts and draft measures were rated by this group for their relative importance. This measure was among the most highly rated, receiving an average score of 8.5 (with 9 as the highest possible score). In addition, the expert panel concluded that the performance of TCD as outlined in this measure would improve the quality of care provided to patients, and the measure would be able to distinguish good from poor quality.

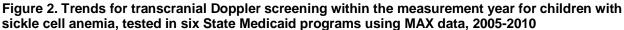
Given the high rating of the QMETRIC expert panel, we feel this measure has a very high degree of face validity.

Performance Scores

Using the MAX data, the proportion of children receiving annual TCD screening was calculated for each year in the study period (2005 - 2010). We examined differences in performance across the 6 years included within this dataset. Logistic regression was used to estimate the associations between each year and receipt of TCD screening, with 2005 used as the reference category. Generalized estimating equation (GEE) models with robust standard errors were used to account for the correlation among children. Odds ratios with 95 percent confidence intervals were used to assess the final associations. The presence of trends in TCD screening rates were also assessed over time using linear regression. For all models, regression diagnostics were performed to assess normality of error variances.

The proportion of children receiving TCD screening ranged from 7 percent to 51 percent (Figure 2).





Source: Reeves SL, Madden B, Freed GL, et al. Transcranial Doppler screening among children and adolescents with sickle cell anemia. JAMA Pediatr 2016; 170(6):550-6. Used with permission.

Compared with 2005, children had higher odds of receiving TCD screening; these odds were statistically significant starting in 2007 (Table 8). Results from the linear regression model indicated that these rates did increase over time (p=0.0001).

Year	Odds Ratio	95 percent Confidence Interval	p-value
2005	Reference	Reference	N/A
2006	1.09	0.96, 1.25	0.17
2007	1.26	1.10, 1.44	0.0008
2008	1.60	1.40, 1.83	<0.0001
2009	1.94	1.69, 2.22	<0.0001
2010	2.36	2.10, 2.70	<0.0001

Table 8. Odds of receipt of TCD screening among children with sickle cell anemiaenrolled in six State Medicaid programs by year using MAX data, 2005-2010

This measure successfully distinguished differences in performance across years; the measure was also able to detect changes over time. As children in all years after 2005 had increased odds of receipt of TCD screening compared with children in 2005, these results demonstrate that the likelihood of receiving a TCD screening did increase significantly over time.

Conversion of ICD-9-CM to ICD-10-CM

The goal of ICD-9-CM to ICD-10-CM conversion was to convert this measure to a new code set, fully consistent with the intent of the original measure. All ICD-9-CM diagnosis codes were converted to the corresponding ICD-10-CM codes using the CMS 2015 diagnosis code General Equivalence Mappings (GEMs) and diagnosis code description files (accessed on August 26, 2015); these mapping files were created by CMS. The target ICD-9-CM codes were converted to ICD-10-CM using the GEM file and manually reviewed for consistency using the diagnosis code descriptions for the source ICD-9-CM and converted ICD-10-CM codes. In addition, the resultant ICD-10-CM codes were back-translated to ICD-9-CM to verify the accuracy of the coding. Source files from CMS were acquired from these files:

1. ICD-9-CM to ICD-10-CM diagnosis GEM -2015_19gem.txt

https://www.cms.gov/Medicare/Coding/ICD10/2015-ICD-10-CM-and-GEMs.html

2. ICD-10-CM to ICD-9-CM diagnosis GEM - 2015_10gem.txt

https://www.cms.gov/Medicare/Coding/ICD10/2015-ICD-10-CM-and-GEMs.html

3. ICD-9-CM description file CMS32_DESC_SHORT_DX.txt

https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html

4. ICD-10-CM description file - *icd10cm_order_2015.txt*

https://www.cms.gov/Medicare/Coding/ICD10/2015-ICD-10-CM-and-GEMs.html

The ICD-9-CM code 282.61 (Hb-SS disease without crisis) mapped to the ICD-10-CM code of D57.1 (sickle-cell disease without crisis). This ICD-10-CM code was not included in the measure specification, as it is not specific to sickle cell anemia (Hb SS). The ICD-9-CM code 282.62 (Hb-SS disease with crisis) mapped to ICD-10-CM D57.00 (Hb-SS disease with crisis, unspecified) and was included in the specification. Subsequent verification using the GEMs indicated that ICD-10-CM codes D57.01 (Hb-SS disease with acute chest syndrome) and D57.02 (Hb-SS disease with splenic sequestration) were also appropriate to include in the measure specification to identify the study population (denominator).

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.

There are no gender disparities in TCD screening among children with sickle cell anemia (chisquare=1.2, p-value=0.28). The data used for performance scores are from State Medicaid programs; therefore, there are no disparities identified by insurance or socioeconomic status. Younger children (ages 2-6) were more likely to receive TCD screening than older children (chisquare=99.01, p-value<0.0001). For those 2 to 6 years old, 36 percent received a TCD screen; for those ages 7 to 11 years, 31 percent received a TCD screen; and for those ages 12-15 years, 25 percent were screened.

7.A. Race/Ethnicity

As sickle cell anemia predominately affects minority populations in the United States, the sample sizes were not available to stratify by race/ethnicity.

7.B. Special Health Care Needs

The MAX Medicaid administrative claims data do not include indicators of special care needs.

7.C. Socioeconomic Status

The MAX Medicaid administrative claims data do not include indicators of socioeconomic status.

7.D. Rurality/Urbanicity

The MAX Medicaid administrative claims data do not include indicators of urban/rural residence.

7.E. Limited English Proficiency (LEP) Populations

The MAX Medicaid administrative claims data do not include indicators of 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?

Data Collection Strategy

This measure was tested using Medicaid administrative claims data. The primary information needed for this measure includes a unique member identifier, health plan enrollment information, date of birth, dates of service, diagnosis codes, and procedure codes. These data are widely available, although obtaining them may require a restricted-use data agreement. For multiple-State comparisons, Medicaid Analytic eXtract (MAX) data are available from CMS. When the measure is used at the single-State level, State health departments can use their own Medicaid data.

QMETRIC testing determined that this measure is feasible using existing data from administrative claims systems. While QMETRIC testing efforts support the feasibility of implementing this measure, the testing process demonstrated the technical challenges that may exist when identifying sickle cell anemia cases from very large administrative claims files, such as MAX data.

This measure was also tested using Medicaid administrative claims data acquired directly from the State of Michigan. Acquisition of data directly from State Medicaid programs requires the cooperation of those jurisdictions, as well as modification of the statistical programming code developed for use with MAX files. Such modifications are necessary given the unique structure of the data files obtained directly from State Medicaid programs.

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?

Not applicable.

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.

Planned Use

Program Name: New York State Health Department

Name: New York State Health Department; Sponsor: Dr. David Anders

URL: https://www.health.ny.gov/

Purpose

The purpose is to assess rates of TCD screening among children with sickle cell anemia in the State of New York.

Geographic Area

Children with sickle cell anemia born from 2006-2014 enrolled in Medicaid in the State of New York.

2. If the measure has been used or is in use, what methods, if any, have already been used to collect data for this measure?

Not applicable.

3. What lessons are available from the current or prior use of the measure?

Not applicable.

Section 9. Levels of Aggregation

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

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

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

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

State level* Can compare States

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

Yes.

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

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?

In each State, the sample size would consist of all children ages 2 through 15 years identified in at least three health care encounters as having SCD, according to designated ICD-9 codes.

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?

None identified; this is the level at which Medicaid administrative claims data for SCD are collected and maintained in the United States.

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? No.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

Not applicable.

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? 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? No.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

Not applicable.

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? 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? Yes.

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?

In each health plan, the sample size would consist of all children ages 2 through 15 years identified in at least three health care encounters as having SCD, according to designated ICD-9 codes.

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? None identified.

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? No.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

Not applicable.

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? Not applicable.

Provider Level

Hospital: Can compare hospitals 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? No.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

Not applicable.

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? Not applicable.

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? No.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

Not applicable.

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? 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 families with a straightforward measure for assessing how well stroke risk is being managed in children with sickle cell anemia. Low rates of TCD screening are easily understood to be unsatisfactory. The simplicity of the measure likewise makes it a straightforward guide for providers and purchasers to assess how well stroke risk is managed in children with sickle cell anemia. This measure has not been assessed for comprehension. The primary information needed for this measure comes from 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.

Information technology, such as computerized provider order entry (CPOE), may improve the use of this measure. CPOE will provide an actual order for TCD screening, the date ordered, and the prescribers' signature; this information will serve as an accurate marker for the timeliness and duration of TCD screenings. However, these data will not furnish information regarding whether the child ever received the TCD screening; the subsequent results reported to the EHR will furnish an indicator of TCD screenings being completed. Technologies that support the capture and query of structured data fields from EHRs, such as chronic disease indicators, CPOE, and imaging study results, will facilitate future enhancements to this measure.

Importantly, the accuracy of this measure hinges on the completeness of TCD screenings among sickle cell anemia patients in a given jurisdiction. The measure was tested at the State level and assumes a complete, centralized source of administrative claims data for children with sickle cell anemia. Although increasingly, individual providers will have access to information within their respective EHR systems for children with sickle cell anemia, the completeness of information about TCD screenings and other imaging studies within their respective EHRs may be limited by interoperability with other providers' EHRs that also may capture imaging events for these patients. This interoperability will be influenced by health information exchange (HIE)

technologies that are rapidly becoming operational throughout the United States. HIEs will enable the comprehensive reporting of imaging information among children with SCD to appropriate State public health departments. In States where this reporting already exists through other methods, the HIE reporting will enable improvements to the timeliness and completeness of these events being reported from physician practices.

11.B. Health IT Testing

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

Yes.

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

This measure was tested using administrative claims data and EHR review conducted at three major sickle cell anemia treatment facilities in Michigan.

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.

The key data needed for this measure (date of birth, diagnosis codes, and procedure codes and dates) are captured by existing EHR systems for children ages 2 through 15 years. Indicators of chronic conditions are frequently tracked in EHRs, providing an alternative mechanism to the use of administrative claims to identify children with sickle cell anemia. Where not available from EHR data, TCD screening information can be queried from administrative claims systems for those with the requisite sickle cell anemia-related ICD-9-CM codes on three or more separate health care encounters during the measurement year. Sickle cell anemia screening is both documented by providers and ordered using electronic ordering systems, depending on the EHR. Results can be stored in the EHR and available for review.

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 Office of the National Coordinator for Health Information Technology's (ONC's) Health IT Standards explicitly address the receipt of laboratory results and other diagnostic tests, including radiology/imaging into EHRs. In addition, these standards indicate the requirement to track specific patient conditions, such as sickle cell anemia. The ONC standards include the following specific requirements in the Certification criteria (ONC, 2010).

Stage 2 Meaningful Use requirements include:

Stage 2 (beginning in 2013): CMS has proposed that its goals for the Stage 2 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, expand upon the Stage 1 criteria to encourage the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible, such as the electronic transmission of orders entered using CPOE and the electronic transmission of diagnostic test results (such as blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, pulmonary function tests, and other such data needed to diagnose and treat disease). Additionally, we may consider applying the criteria more broadly to both the inpatient and outpatient hospital settings.

Incorporate clinical laboratory test results into the EHR as structured data:

- 1. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.
- 2. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC[®] codes.
- Electronically display all the information for a test report specified at 42 CFR 493.1291(c) (1) through (7). Generate lists of patients by specific conditions to use for quality improvement reduction of disparities outreach.
- 4. Enable a user to electronically update a patient's record based upon received laboratory test results. Enable a user to electronically select, sort, retrieve, and output a list of patients and patients' clinical information, based on user-defined demographic data, medication list, and specific conditions.

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 codes selected to indicate sickle cell anemia/SCD.
- 3. Date of TCD.
- 4. Type of TCD test.

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?

Implementation of an order entry system will allow easy access to date of ordering. This measure is based on the completion of TCD screening; knowing when the test was ordered will be important if the measure is low. Implementation of a reporting system for results or a secure messaging platform should greatly affect the ability to communicate results to patients or providers, thereby improving this measure.

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 assesses the percentage of children ages 2 through 15 years with sickle cell anemia who undergo TCD screening during the measurement year. TCD measures blood flow through brain blood vessels and is used in sickle cell anemia patients to assess the risk of stroke. This measure is implemented with Medicaid administrative claims data. The primary information needed for this measure includes basic demographics, diagnosis codes, and procedure codes and dates. These data are widely available, although obtaining them often requires a restricted use data agreement. For multi-State comparisons, MAX data are available from CMS. When the measure is used at the single-State level, State health departments can use their own Medicaid data.

QMETRIC testing determined that this measure, which is intended to be used with Medicaid administrative claims data systems, works well in that environment. The measure was also tested for reliability and validity using medical chart data from both paper and EHR sources. Continuing advances in the development and implementation of EHRs may establish the feasibility of regularly implementing this measure with data supplied by EHRs.

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 15 years with sickle cell anemia (Hb SS) who received at least one transcranial Doppler (TCD) screening within a year. TCD ultrasonography measures the blood flow velocity in cerebral arteries; high blood velocities are indicative of an upcoming stroke and the need to begin stroke prevention efforts among children with sickle cell anemia. Stroke prevention efforts result in a substantial reduction in the incidence of stroke among children with sickle cell anemia. Our results indicate that significant opportunity for improvement exists in the receipt of TCD screening among children with sickle cell anemia. In addition, this measure is reliable and valid, with high feasibility and usability.

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Section 14: Identifying Information for the Measure Submitter

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 [AHRO] 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, AHRO 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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Appendix. Transcranial Doppler Ultrasonography Screening Among Children with Sickle Cell Anemia

Description

The percentage of children ages 2 through 15 years with sickle cell anemia (SCA, hemoglobin [Hb] SS) who received at least one transcranial Doppler ultrasonography screening within the measurement year. A higher proportion indicates better performance as reflected by appropriate testing.

Calculation

This measure requires administrative data and is calculated as follows:

The percentage of eligible children who received transcranial Doppler ultrasonography screening.

Definitions	
Intake period	January 1 of the measurement year through December 31 of the measurement year.
Transcranial	A test measuring blood flow through intracranial arteries. Receipt of TCD
Doppler	screening is identified as the presence of at least one CPT code for any of five
ultrasonography	acceptable ultrasonography tests within the measurement year among children in
screening	the target population (see Table 1).

Table 1: Acceptable transcranial Doppler ultrasonography screening tests

TCD Description	CPT code
Complete study	93886
Limited study	93888
Vasoreactivity study	93890
Emboli detection without intravenous microbubble injection	93892
Emboli detection with intravenous microbubble injection	93893

Eligible Population		
Ages	Children 24 months or older on January 1 of the measurement year but younger than 16 years on December 31 of the measurement year.	
Enrollment	Continuous enrollment during the measurement year, with no other form of health insurance for the entire measurement year.	
Event/Diagnosis	Identify members as having sickle cell anemia (Table 2) who had appropriate sickle cell anemia-related ICD-9 or ICD-10 codes on three or more separate health care encounters during the measurement year.	

Table 2: Codes to identify sickle cell anemia

Condition Name	Hemoglobin Screening Result	ICD Code(s)
Hb SS-disease (sickle cell anemia)	Hb F,S	ICD-9-CM
		282.61, 282.62
		ICD-10-CM
		D57.00 (Hb-SS disease with crisis, unspecified); D57.01 (Hb-SS disease with acute chest syndrome); and D57.02 (Hb-SS disease with splenic sequestration)

Specification	
Denominator	The denominator is the number of children ages 2 through 15 years with SCA (Hb SS) within the measurement year.
Numerator	The numerator is the number of children ages 2 through 15 years with SCA (Hb SS) who received at least one TCD screening within the measurement year.