Appropriate Outpatient Blood Testing for Children with Sickle Cell Disease

Section 1. Basic Measure Information

1.A. Measure Name

Appropriate Outpatient Blood Testing for Children with Sickle Cell Disease

1.B. Measure Number

0222

1.C. Measure Description

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

Approximately 2,000 infants are born with sickle cell disease (SCD) in the United States each year, a condition that occurs predominantly in people of African and Hispanic descent. SCD is a chronic hematologic disorder, characterized by the presence of hemoglobin S. From infancy onward, the presence of this hemoglobin variant can lead to an array of serious medical conditions. Appropriate blood testing in children is crucial to establish baseline values to use as comparisons during acute illness and to detect abnormalities that presage possible illness. Clinical guidelines for SCD pediatric health maintenance recommend that blood tests should be obtained regularly throughout childhood. However, there are no existing quality measures for appropriate blood testing in children with SCD.

This measure uses medical record data to calculate individual rates for three blood tests, as well as an overall rate that is a composite of the three individual rates. The three individual rates are:

1. The percentage of children who had a pulse oximetry reading performed during the outpatient visit.
2. The percentage of children who had a complete blood count performed within 7 days of the outpatient visit.
3. The percentage of children who had a reticulocyte count performed within 7 days of the outpatient visit.

The overall rate is the percentage of children who, during outpatient care, had a pulse oximetry reading, a complete blood count, and a reticulocyte count performed within the same 7-day period.

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 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 Q-METRIC Sickle Cell Disease Medical Record Data 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

This measure assesses the percentage of children younger than 18 years of age identified as having SCD who had: (1) a pulse oximetry reading, (2) a complete blood count, and (3) a reticulocyte count performed within the same 7-day period as part of outpatient care during the measurement year. A higher proportion indicates better performance, as reflected by appropriate testing.

The eligible population for the numerator is the number of children younger than 18 years of age with SCD who had a pulse oximetry reading, a complete blood count, and a reticulocyte count performed within the same 7-day period as part of outpatient care during the measurement year

(January 1-December 31). Eligible children are restricted to those with SCD variants identified in Table 1 (see Supporting documents), based on appropriate ICD-9 codes as documented in the medical record. The outpatient blood tests for the management of SCD are identified in Table 2 (see Supporting Documents). Three individual numerators and one overall composite of the three numerators are calculated:

1. Pulse oximetry - The number of eligible children who had a pulse oximetry reading performed during the outpatient visit.

2. Complete blood count – The number of eligible children who had a complete blood count performed within 7 days of the outpatient visit.

3. Reticulocyte count – The number of eligible children who had a reticulocyte count performed within 7 days of the outpatient visit.

4. Overall – The number of eligible children, who during outpatient care, had a pulse oximetry, a complete blood count, and a reticulocyte count performed, all within the same 7-day period.

Evidence of a pulse oximetry reading, a complete blood count, and a reticulocyte count is determined through medical record review of outpatient visits (Table 3; see Supporting Documents). Documentation in the medical record must include, at minimum, a note containing the date(s) on which a pulse oximetry, a complete blood count, and a reticulocyte count were performed.

1.H. Numerator Exclusions

1. Inpatient stays, emergency department visits, and urgent care visits are excluded from the calculation.

2. Children with a diagnosis in the sampled medical record indicating one of the SCD variants listed in Table 4 (see Supporting Documents) should not be included in the eligible population unless there is also a diagnosis for a sickle cell variant listed in Table 1 (see Supporting Documents).

1.I. Denominator Statement

The eligible population for the denominator is the number of children younger than 18 years of age with SCD who received outpatient care during the measurement year (January 1 – December 31). Eligible children are restricted to those with SCD variants identified in Table 1 (see Supporting Documents), based on appropriate ICD-9 codes as documented in the medical record. Codes to identify outpatient care are presented in Table 3 (see Supporting Documents).

1.J. Denominator Exclusions

1. Tests that were conducted during inpatient stays, emergency department visits, and urgent care visits are excluded from the calculation.

2. Children with a diagnosis in the sampled medical record indicating one of the SCD variants listed in Table 4 (see Supporting Documents) should not be included in the eligible

population unless there is also a diagnosis for a sickle cell variant listed in Table 1 (see Supporting Documents).

1.K. Data Sources

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

Paper medical record; electronic medical record.

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.

Detailed measure specifications are provided (see the Supporting Documents).

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).**

Sickle Cell Disease Prevalence and Incidence

SCD is one of the most common genetic disorders in the United States (Kavanagh, Sprinz, Vinci, et al., 2011). The National Heart, Lung, and Blood Institute (NHLBI) estimates that 2,000 infants are born with SCD in the United States each year (NHLBI, 2002). SCD affects 70,000-100,000 children and adults in the United States, predominantly those of Africa and Hispanic descent (Hassell, 2010).

Sickle Cell Disease Pathology and Severity

Vaso-occlusion (the sudden blockage of a blood vessel caused by the sickle shape of abnormal blood cells) is responsible for most complications of SCD, including pain episodes, sepsis, stroke, acute chest syndrome, priapism, leg ulcers, osteonecrosis, and renal insufficiency (Steinberg, 1999). In addition, SCD can have hemolytic and infectious complications that result in morbidity and mortality in children with the condition (Kavanagh, et al., 2011).

Sickle Cell Disease Burden in Daily Life

The effect of SCD on children and families is significant; severe pain episodes and hospitalizations restrict daily activities and reflect negatively on school attendance and performance, as well as on sleep and social activities (Alvim, Viana, Pires, et al., 2005; Lemanek, Ranalli, Lukens, 2009). Although medical management of SCD continues to improve over time, 196 children in the United States died from SCD-related causes between 1999 and 2002 (Yanni, Grosse, Yang, et al., 2009).

Sickle Cell Disease Cost

In a study of healthcare utilization among low income children with SCD between 2004 and 2007, 27 percent of these children required inpatient hospitalization, and 39 percent used emergency care during a year. Of these children, 63 percent averaged one well-child visit per year, and 10 percent had at least one outpatient visit with a specialist (Raphael, Dietrich, Whitmire, et al., 2009). Patients with SCD use many parts of the healthcare system, incurring significant costs. In 2009, mean hospital charges for children with SCD and a hospital stay were

$23,000 for children with private insurance and $18,200 for children enrolled in Medicaid (Agency for Healthcare Research and Quality [AHRQ], 2012). Kauf and colleagues estimate the lifetime cost of healthcare per patient with SCD to be approximately $460,000 (Kauf, Coates, Huazhi, et al., 2009).

Outcomes of Appropriate Outpatient Blood Testing for Children with Sickle Cell Disease

Healthcare maintenance for children with SCD includes several routine clinical laboratory evaluations. It is important to establish baseline values for patients with SCD to be used for comparison during times of acute illness, as well as for use as detectors of possible illness or complications of disease. A pulse oximetry reading, complete blood count, and reticulocyte count are three important laboratory values that are a recommended part of routine clinical laboratory evaluations (NHLBI, 2002). Pulse oximetry is used to monitor arterial saturation and indicates presence of hypoxemia (Fitzgerald, Johnson, 2001). Observed increases and decreases in values obtained from a complete blood count (which includes hemoglobin concentration, white blood cell count, and hematocrit) are risk factors associated with osteonecrosis, infarctive stroke, hemorrhagic stroke, silent infarct, acute chest syndrome, and sickle cardiomyopathy in people with SCD (NHLBI, 2002). A reticulocyte count helps determine the need for transfusion and is used in determining risk of transient red cell aplasia, acute hepatic sequestration, and acute splenic sequestration complication (NHLBI, 2002).

This measure assesses annual performance of pulse oximetry, complete blood count, and reticulocyte count in children younger than 18 years of age with SCD. Pulse oximetry is assessed as readings taken during an outpatient encounter; the complete blood count and reticulocyte count are assessed as tests conducted within 7 days of the outpatient encounter. The measure does not change across developmental stages.

Performance Gap

Appropriate blood testing in children with SCD is crucial to establish baseline values to use as comparisons during acute illness and to detect abnormalities that presage impending illness. Clinical guidelines for SCD pediatric health maintenance recommend that blood tests be obtained regularly throughout childhood (NHLBI, 2002). Routine clinical laboratory evaluations should be a standard part of comprehensive care for children with SCD. Given how essential these simple test results are to support optimal health in pediatric patients with SCD, it is important that all affected children receive these assessments regularly.

To characterize healthcare utilization in children with SCD, Raphael et al. (2009) studied administrative claims data from a managed care plan serving children with Medicaid and the State Children's Health Insurance Plan (SCHIP) for 2007-2009. The researchers found that a substantial proportion of children with SCD did not meet minimum guidelines for outpatient primary care and hematology comprehensive care, the type of visits at which these essential baseline measures are obtained. During the study period, only 63 percent of patients had one routine outpatient visit with a primary care provider, and only 10 percent had a minimum of one outpatient visit per year with a hematologist. These findings are concerning, given that NHLBI guidelines recommend that pediatric patients with SCD maintain a regular schedule of well-child

visits. In the first 2 years of life, children should be seen every 2 to 3 months; after age 2, visits should occur at least every 6 months (NHLBI, 2002). In cases where pediatricians provide general healthcare for children with SCD, hematologists usually serve as consultants. An inadequate number of well-child visits could lead to gaps in the patient's baseline profile (including blood test results), undermining care during times of acute illness.

Earlier research by Kuhlthau and colleagues provided somewhat better results: 86 percent of children with SCD enrolled in Medicaid visited a generalist during the study year, and at least 27 percent visited a relevant pediatric subspecialist (Kuhlthau, Ferris, Beal, et al., 2001). But even those numbers reflect insufficient care and suggest that children may use primary care for most healthcare needs, including those that arise from their chronic condition. These types of visits may not include the routine blood testing essential for comparison during acute illness. Further, children enrolled in Medicaid may have a hard time accessing subspecialty services because of limitations such as scarce resources, lack of transportation, language barriers, and potential unwillingness of some providers to accept patients on Medicaid.

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).**

The majority of children with SCD are enrolled in Medicaid. In 2009, 67 percent of the pediatric patients discharged from the hospital were enrolled in Medicaid; only 25 percent had private insurance (AHRQ, 2012). Children with chronic conditions need high quality care—both primary care and specialty care. As described in the Performance Gap section above, research suggests that children with SCD who are enrolled in Medicaid may be receiving less than adequate general and specialized care. This, in turn, suggests that routine lab work, such as regular blood testing, may be missing from their baseline profiles (Kuhlthau, et al., 2001; Raphael, et al., 2009).

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).

There currently are no quality measures for the diagnosis, assessment, or treatment of pediatric SCD.

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:** No.
   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 special health care needs/chronic 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.
   l. **Measure Topic – care in the most integrated setting:** No.
   m. **Measure Topic other (please specify):** Not applicable.
   n. **Population – pregnant women:** Not applicable.
   o. **Population – neonates (28 days after birth) (specify age range):** Yes; birth to 28 days.
   p. **Population – infants (29 days to 1 year) (specify age range):** Yes; all ages in this range.
   q. **Population – pre-school age children (1 year through 5 years) (specify age range):** Yes; all ages in this range.
   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 ages 11-17 years.
   t. **Population – other (specify age range):** Not applicable.
   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 measure focuses on a clinical process (appropriate outpatient pulse oximetry, complete blood count, and reticulocyte count testing in children with SCD), that, if followed, results in a desirable clinical outcome (early detection of risk of complications for children with SCD). The measure highlights where providers or health systems are falling short in providing healthcare maintenance for children with SCD.

Overall, clinical guidelines indicate that children with SCD should receive a pulse oximetry reading, a complete blood count, and a reticulocyte count at least yearly. The body of evidence presents recommendations for the appropriate types of outpatient blood testing in children with SCD from birth through childhood and adolescence. Clinical guidelines further indicate that from birth, children with SCD should be should be scheduled regularly, depending on age, for routine medical evaluations to maintain a database of current baseline values for many useful tests, including pulse oximetry, complete blood count, and reticulocyte count. These values can be used as comparisons during acute illness and to detect abnormalities that presage possible illness. Table 5 (see Supporting Documents) summarizes several key sources of evidence for this measure, using the U.S. Preventive Services Task Force (USPSTF) rankings (criteria denoted in Table 5).

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.

SCD is a chronic hematologic disorder, characterized by the presence of hemoglobin S (Hgb S). Oxygenated Hgb S functions normally, but in decreased oxygen states (hypoxemia), Hgb S becomes distorted to a sickle shape, which leads to vaso-occlusion and ischemia. A cycle of hypoxemia and sickling is set up, which leads to SCD complications (Fitzgerald, et al., 2001). Routine blood testing provides important baseline information about a patient's status regarding many SCD-related conditions, including anemia, infection and fever, stroke, acute chest syndrome, and pain. The three blood tests identified here should be a regular part of comprehensive care for children with SCD:

Pulse oximetry is a simple, accurate, noninvasive technique to monitor the amount of oxygen in the blood (oxygen saturation). The test is administered using a small probe that's placed on a thin part of a patient's body, such as a finger or ear lobe. The probe transmits two wavelengths of light through the vascular tissue and measures the differential absorption of the light by oxyhemoglobin and deoxyhemoglobin, allowing healthcare providers to assess the amount of oxygen in the blood (Johns Hopkins Health Library).

A complete blood count (CBC) provides information about the kinds and numbers of cells in the blood, especially red blood cells, white blood cells, and platelets. The test helps to check symptoms and diagnose conditions. A CBC usually includes white blood cell (WBC, leukocyte) count; white blood cell types (WBC differential); red blood cell (RBC) count; hematocrit (HCT, packed cell volume, PVC); hemoglobin (Hgb); red blood cell indices; platelet (thrombocyte) count; and mean platelet volume (MPV) (WebMD, 2012).

A reticulocyte count measures the number of immature red blood cells (reticulocytes) released into the blood by the bone marrow. Usually reticulocytes are in the blood for about 2 days before developing into mature red blood cells; normally about 1 percent to 2 percent of red blood cells are reticulocytes. Reticulocyte counts rise when red blood cells are destroyed prematurely (WebMD, 2012).

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.

This measure is based on medical record data; reliability testing is described here.

Data and Methods

Our testing data consisted of an audit of medical records from the three largest centers serving SCD patients in Michigan during 2012: Children's Hospital of Michigan (CHM, Detroit), Hurley Medical Center (Hurley, Flint), and the University of Michigan Health System (UMHS, Ann Arbor). Combined, these sites treat the majority of children with SCD in Michigan. Medical records for all children with SCD meeting the measure specification criteria during the measurement year were abstracted at each site. Abstracting was conducted in two phases; during Phase 1, 435 records were abstracted among the three sites. In Phase 2, an additional 237 cases were abstracted at one site. In total, 672 unique records were reviewed for children with SCD to test this measure.

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 project, the medical record data collected by two nurse abstractors were compared.

Measuring IRR at the beginning of the abstraction is imperative to identify any misinterpretations early on. It is also important to assess IRR throughout the abstraction process to ensure that the collected data maintain high reliability standards. Therefore, the IRR was evaluated during Phase 1 at each site to address any reliability issues before beginning data abstraction at the next site.

IRR was determined by calculating both percent agreement and Kappa statistics. While abstraction was still being conducted at each site, IRR assessments were conducted for 5 percent of the total set of unique patient records that were abstracted during Phase 1 of data collection. Two abstractors reviewed the same medical records; findings from these abstractions were then compared, and a list of discrepancies was created.

Three separate IRR meetings were conducted, all of which included a review of multiple SCD measures that were being evaluated. Because of eligibility criteria, not all patients were eligible for all measures. Therefore, records for IRR were not chosen completely at random; rather, records were selected to maximize the number of measures assessed for IRR at each site.

Results

For this measure, 22 of 435 unique patient records (5 percent) from Phase 1 of the abstraction process were assessed for IRR across the three testing sites. Table 6 (see Supporting Documents) shows the percent agreement and Kapa statistic for each numerator of this measure for each site and across all sites. The agreement for each numerator is 100 percent, and the Kappa is 1.00, indicating a perfect IRR level was achieved.

Discrepancies

There was perfect agreement among the sample records selected for IRR, and no discrepancies were noted.

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 determined from two perspectives: face validity and validity of medical record data.

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 advocates for families of children with SCD convened by Q-METRIC. The Q-METRIC 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 healthcare quality measurement. In total, the Q-METRIC SCD panel included 14 experts, providing a comprehensive perspective on SCD management and the measurement of quality for States and health plans.

The Q-METRIC expert panel concluded that this measure has a 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 highly rated, receiving an average score of 8.0 (with 9 as the highest possible score).

Validity of Abstracted Data

This measure was tested using medical record data, which is considered the gold standard for clinical information; our findings indicate that these data have a high degree of face validity and reliability.

This measure was tested among a total of 500 children younger than 18 years of age with sickle cell disease (Table 7; see Supporting Documents). Overall, appropriate blood testing was conducted on 89 percent of children with SCD (range: 52 percent-97 percent). Pulse oximetry was conducted on 93 percent of children with sickle cell disease seen in outpatient clinics (range among the three hospitals was: 65 percent-99 percent). Similarly, a complete blood count was conducted within 7 days of the outpatient visit for 90 percent of children (range: 55 percent-98 percent); a reticulocyte count was conducted within 7 days of the outpatient visit for 89 percent of children (range: 55 percent-97 percent).

Section 7. Identification of Disparities

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

7.A. Race/Ethnicity

The measure was tested using medical records from the three largest centers serving SCD patients in Michigan during 2012: Children's Hospital of Michigan, Hurley Medical Center, and the University of Michigan Health System. Combined, these centers serve the vast majority of SCD patients in Michigan. While race and ethnicity data were not abstracted as part of the medical record review process, information is available from the State of Michigan for its entire population of births with an initial newborn screening result indicating SCD from 2004 to 2008. Table 8 (see Supporting Documents) summarizes the distribution across race and ethnicity groups for all SCD births in Michigan during that time period.

7.B. Special Health Care Needs

The medical records data abstracted for this study do not include indicators of special healthcare needs.

7.C. Socioeconomic Status

The medical records data abstracted for this study do not include indicators of socioeconomic status.

7.D. Rurality/Urbanicity

The medical records data abstracted for this study do not include indicators of rural/urban residence.

7.E. Limited English Proficiency (LEP) Populations

The medical records data abstracted for this study do 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?

This measure is based on review of medical record data. The medical chart audit included records from the three largest centers serving SCD patients in Michigan during 2012: Children's Hospital of Michigan, Hurley Medical Center, and the University of Michigan Health System. Data were abstracted from medical record systems at two sites that use EHRs (both Epic systems) and from one site using paper charts.

Medical records for 100 percent of children with SCD meeting the measure specification criteria during the measurement year were abstracted from each hospital. In total, 672 unique records were reviewed; 500 records (74 percent) met denominator criteria for this measure.

Based on the abstracted chart data, rates were calculated for each of the four numerators (see Table 7 in the Supporting Documents) as follows:

1. Pulse Oximetry: The percentage of children with SCD who had a pulse oximetry reading performed during the outpatient visit (93 percent). Pulse oximetry numerator (465) divided by denominator (500).

2. Complete Blood Count: The percentage of children with SCD who had a complete blood count performed within 7 days of the outpatient visit (90 percent). Complete blood count numerator (450) divided by denominator (500).

3. Reticulocyte: The percentage of children with SCD who had a reticulocyte count performed within 7 days of the outpatient visit (89 percent). Reticulocyte numerator (447) divided by denominator (500).

4. Overall: The overall rate is the percentage of children with SCD who, during outpatient care, had a pulse oximetry, complete blood count, and reticulocyte count performed within the same 7-day period (89 percent). Overall numerator (445) divided by denominator (500).

Medical record abstraction for this measure was accomplished with a data-collection tool developed using LimeSurvey software (version 1.92, formerly PHPSurveyor). LimeSurvey is an open-source online application based in MySQL that enables users to develop and publish surveys, as well as collect responses. The tool was piloted to determine its usability and revised as necessary. The measure specification for this measure also underwent revisions following pilot testing.

Data abstraction was completed by experienced nurse abstractors who had undergone training for each medical record system used, electronic and paper. Abstractors participated in onsite training during which the measure was discussed at length to include the description, calculation, definitions, eligible population specification, and exclusions. Following training, abstractors were provided with a coded list of potentially eligible cases from each of the sites. To abstract all pertinent data, two nurse abstractors reviewed the electronic and paper medical records. In addition to the specific data values required for this measure, key patient characteristics, such as date of birth and hemoglobin variant type, were also collected.

Abstraction Times

In addition to calculating IRR, the study team assessed how burdensome it was to locate and record the information used to test this measure by having abstractors note the time it took to complete each record. During Phase 1, on average, the abstractors spent 14 minutes per eligible SCD case abstracting the data for this measure, with times ranging from 3-45 minutes.

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?

This measure was determined to be feasible by Q-METRIC using medical record data from the three largest centers serving SCD patients in Michigan during 2012. Although paper charts were utilized at one of the three sites, this was not found to be a barrier. In fact, the average time spent abstracting records from paper charts (12 minutes) was less than the average time spent abstracting data from electronic medical records at the other two sites (14 minutes and 22 minutes).

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?**
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.

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)**
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
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)**
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?**
The sample would include all children with clinical documentation of sickle cell disease (Table 1; see Supporting Documents) presenting in an outpatient setting.

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
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 a straightforward means of assessing how well basic levels of comprehensive care are being provided for children with SCD. Low rates of outpatient blood testing are easily understood to be unsatisfactory.

This measure has not been assessed for comprehension. The primary information needed for this measure comes from medical records data and includes basic demographics, dates, diagnostic codes, and procedure codes, all of which are widely available. The nurse abstractors testing the measure provided feedback to refine the abstraction tool and thus the specifications. These changes are reflected in the final documentation.

Section 11. Health Information Technology

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

11.A. Health IT Enhancement

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

The feasibility of these measures could be further enhanced by advances in health IT. The activities that are the focus of these measures are a part of SCD care protocols. Inconsistent performance of these activities indicates poor implementation of care protocols. Health IT and process control dashboards may foster better compliance with these measures and thus with SCD care protocols. Decision support tools could be created to focus on the checkout process, and computerized order entry (CPOE) could include order sets to enable easy ordering of these tests.

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 electronic medical record review conducted at two major SCD treatment facilities in Michigan using the Epic electronic health record (EHR) system. The third facility used paper medical records for outpatient visits.

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 findings indicate that these data are already recorded in the EHR in unstructured data. Pulse oximetry readings are a part of nurses' notes and physician vital sign summaries for this population during acute care, though this information may not be routinely collected during preventive visits. In future implementations of this measure, all of these lab test orders or results should be easily recovered from the EHR with a data stamp matching that of the visit.

11.D. Health IT Standards

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

Yes.

If yes, please describe.

The ONC's Health IT Standards explicitly address the receipt of laboratory results and other diagnostic tests into EHRs, which are directly relevant to this measure. In addition, these standards indicate the requirement for EHRs to track specific patient conditions, such as SCD. 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. Electronic transmission of diagnostic test results includes a broad array of data important to quality measurement, such as blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, and pulmonary function tests.

Incorporate clinical lab-test results into 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.

3. 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 codes selected to indicate SCD/sickle cell anemia.

3. Date and time of treatment.

4. Type of tests administered.

5. Date of tests performed.

6. Care setting.

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?

Displaying real-time updates of these indicators for patients and providers to see would be transformative for care and would be one of the best ways to enhance performance. Alternatively, integrating these measures into views that might be seen by healthcare administrators will motivate changes in workflow or in operating models that can hardwire these orders into the provision of care for these patients.

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 younger than 18 years of age identified as having sickle cell disease (SCD) who had: (1) a pulse oximetry reading, (2) a complete blood count, and (3) a reticulocyte count performed within the same 7-day period as part of outpatient care during the measurement year.

This measure is implemented with medical record data; it was tested with electronic and paper medical records. The primary information needed for this measure includes date of birth, diagnosis codes, and procedure codes and dates. These data are available, although obtaining them may require a restricted-use data agreement. It also required the development of an abstraction tool and the use of qualified nurse abstractors. Continuing advances in the development and implementation of electronic medical records may establish the feasibility of regularly implementing this measure with data supplied by electronic medical records.

In future implementations, there are considerations that may further strengthen this measure and potentially ease the burden of data collection. Specific feedback from our medical record abstractors suggested that it may be helpful that when discrepancies are found regarding the timing for an event, a specific hierarchy be developed *a priori* regarding the most reliable source of time or the earliest time specified as the time to be collected, with this information being included in the measure specification. Although our testing results for this measure do not include these changes, they should be considered prior to subsequent implementation of this measure.

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, Appropriate Outpatient Blood Testing for Children with Sickle Cell Disease, assesses the percentage of children younger than 18 years of age identified as having SCD who had a pulse oximetry reading, complete blood count, and reticulocyte count performed within the same 7-day period as part of outpatient care during the measurement year. This measure uses medical record data to calculate individual rates for three blood tests, as well as an overall rate that is a composite of the three individual rates. A higher proportion indicates better performance, as reflected by appropriate testing. There are no existing quality measures for appropriate blood testing in children with SCD.

Clinical guidelines for SCD pediatric health maintenance recommend that blood tests be obtained regularly throughout childhood. It is important to establish baseline values for patients with SCD to be used for comparison during times of acute illness, as well as for use as detectors of possible illness or complications of disease. However, research suggests that children with SCD who are enrolled in Medicaid may be receiving less than adequate general and specialized care. This, in turn, suggests that routine lab work, such as regular blood testing, may be missing from their baseline profiles.

Q-METRIC tested this measure among a total of 500 eligible children. Results showed that appropriate blood testing was conducted on 89 percent of children with SCD (range: 52 percent-97 percent). Pulse oximetry was conducted on 93 percent of children with SCD seen in outpatient clinics (range among the three hospitals was: 65 percent-99 percent). Similarly, a complete blood count was conducted within 7 days of the outpatient visit for 90 percent of children (range: 55 percent-98 percent); a reticulocyte count was conducted within 7 days of the outpatient visit for 89 percent of children (range: 55 percent-97 percent).

This measure provides families, providers, and purchasers with a straightforward means of assessing how well basic levels of comprehensive care are being provided for children with SCD. The primary information needed for this measure includes basic demographics, dates, diagnostic codes, and procedure codes, all of which are widely available. Continuing advances in the development and implementation of health IT may establish the feasibility of regularly implementing this measure with data supplied by electronic medical records.

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Section 14: Identifying Information for the Measure Submitter

First Name: Gary L.

Last Name: Freed, MD, MPH

Title: Percy and Mary Murphy Professor of Pediatrics, School of Medicine

Professor of Health Management and Policy, School of Public Health

Organization: University of Michigan

Mailing Address: 300 North Ingalls, Room 6E08

City: Ann Arbor

State: MI

Postal Code: 48109

Telephone: 734-615-0616

Email: gfreed@med.umich.edu

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.