SECTION I.
BASIC MEASURE INFORMATION

I.A. Measure Name

Appropriate Emergency Department Blood Testing for Children with Sickle Cell Disease

I.B. Measure Citation Information

Dombkowski KJ, Madden B, Shevrin CA, McCormick J, Freed GL for the Quality Measurement, Evaluation, Testing, Review, and Implementation Consortium. Appropriate Emergency Department Blood Testing for Children with Sickle Cell Disease. National Quality Measures Clearinghouse (NQMC). Rockville (MD): Agency for Healthcare Research and Quality (AHRQ). Published March 23, 2015.

I.C. Measure Description

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

This measure assesses the percentage of children younger than 18 years of age identified as having sickle cell disease (SCD) presenting to an emergency department (ED) with fever during the measurement year, who had a pulse oximetry reading, complete blood count, reticulocyte count, and blood culture within 60 minutes following initial contact. A higher proportion indicates better performance as reflected by appropriate testing.

Approximately 2,000 infants are born with 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. Because children with SCD are susceptible to spleen damage, a condition that compromises their ability to deal with infection, they are at high risk for developing septicemia and meningitis from *S. pneumococci* and other encapsulated bacteria. These illnesses can rapidly become life-threatening. Any temperature greater the 38 degrees Celsius (100.4 degrees Fahrenheit) should be immediately evaluated; this often requires a visit to the ED for timely treatment. Assessment for fever in children with SCD should include a pulse oximetry reading, complete blood count, reticulocyte count, and a blood culture. Ideally, the values collected in the ED can be compared with baseline values that should be available as part an established database profile. There are no existing quality measures for appropriate blood testing in children with SCD.

This measure uses medical record data to calculate four rates; each specified action must occur within 60 minutes following initial contact in the ED:

1. The percentage of children who had a pulse oximetry performed.
2. The percentage of children who had a complete blood count performed.
3. The percentage of children who had a reticulocyte count performed.

4. The percentage of children who had a blood culture performed.

An overall rate is calculated as the percentage of children who had a pulse oximetry reading, complete blood count, reticulocyte count, and blood culture within the same 60 minute period following initial contact in the ED.

I.D. Measure Owner

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

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

Not applicable

I.F. Measure Hierarchy

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

I.F.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.

I.F.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.

I.F.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

I.F.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

I.G. Numerator Statement

The eligible population for the numerator is the number of children younger than 18 years of age identified as having SCD presenting to an ED with fever (defined 38 degrees C [100.4 degrees F] or

above) during the measurement year (January 1-December 31), who had 1) a pulse oximetry reading, 2) a complete blood count, 3) a reticulocyte count, and 4) a blood culture within 60 minutes following initial contact. Eligible children are restricted to those with SCD variants identified in Table 1, 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. Four individual numerators and one overall composite of the four numerators are calculated:

1. Pulse oximetry – The number of eligible children who had a pulse oximetry reading performed within 60 minutes following initial contact in the ED.
2. Complete blood count – The number of eligible children who had a complete blood count performed within 60 minutes following initial contact in the ED.
3. Reticulocyte count – The number of eligible children who had a reticulocyte count performed within 60 minutes following initial contact in the ED.
4. Blood culture – The number of children who had a blood culture performed within 60 minutes following initial contact in the ED.
5. Overall – The number of eligible children who had pulse oximetry, a complete blood count, a reticulocyte count, and a blood culture performed within the same 60-minute period.

Evidence of a pulse oximetry reading, blood count, reticulocyte count, and blood culture is determined through medical record review of emergency department visits. Documentation in the medical record must include, at minimum, a note containing the time(s) at which pulse oximetry, a complete blood count, a reticulocyte count, and a blood culture were performed.

Table 1: Codes to Identify Sickle Cell Disease

Condition Name	Hemoglobin Screening Result	ICD-9 Code(s)
Hb beta zero-thalassemia	Hb F only	282.49
Hb S beta-thalassemia	Hb F,S,A	282.41, 282.42
Hb SC-disease	Hb F,S,C	282.63, 282.64
Hb SD-disease	Hb F,S,D	282.68, 282.69
Hb SS-disease (sickle cell anemia)	Hb F,S	282.6, 282.61, 282.62

Table 2: Blood Tests for the Emergency Department Management of Sickle Cell Disease

Definitions	Procedure Code	Short Description	Long Description
Pulse oximetry reading	0Y4306	Pulse oximetry	Pulse oximetry
Complete blood count	85025	Complete CBC w/auto diff WBC	Blood count; complete (cbc), automated (hgb, hct, rbc, wbc and platelet count) and automated differential wbc count
Complete blood count	85027	Complete CBC automated	Blood count; complete (CBC), automated (HGB, HCT, RBC, WBC and platelet count)
Complete blood count	85014	Hematocrit	Blood count; hematocrit (HCT)
Complete blood count	85018	Hemoglobin	Blood count; hemoglobin (HGB)
Reticulocyte count	85044	Manual reticulocyte count	Blood count; reticulocyte, manual
Reticulocyte count	85045	Automated reticulocyte count	Blood count; reticulocyte, automated
Reticulocyte count	85046	Reticyte/HgB concentrate	Blood count; reticulocytes, automated, including one or more cellular parameters (EG, reticulocyte hemoglobin content (CHR), immature reticulocyte fraction (IRF), reticulocyte volume (MRV), RNA content), direct measurement
Blood culture	87040	Blood culture	Isolation and identification of microorganisms and susceptibility testing, when appropriate. Other isolated organisms, i.e., anaerobes, yeast, etc.) may be referred for identification and/or susceptibility testing if medically indicated AND a separate culture procedure has NOT yielded the same organism(s).

I.H. Numerator Exclusions (as appropriate)

1. Inpatient stays, outpatient visits, urgent care visits, and acute care (evaluation and management) visits with a primary care physician are excluded from the calculation.
2. Children with a diagnosis in the sampled medical record indicating one of the SCD variants listed in Table 3 should not be included in the eligible population *unless* there is also a diagnosis for a sickle cell variant listed in Table 1.

Table 3: Excluded Sickle Cell Disease Diagnosis Codes

Condition Name	Hemoglobin Screening Result	ICD-9 Code(s)
Hb C beta-thalassemia	Hb F,C,A	282.49
Hb D beta-thalassemia	Hb F,D,A	282.49
Hb E beta-thalassemia	Hb F,E,A	282.49
Hb C-disease	Hb F,C	282.7
Hb E-disease	Hb F,E	282.7
Hb H-disease	Hb F,H	282.49
Hb SE-disease	Hb F,S,E	282.68, 282.69
Hb C-carrier	Hb F,A,C	282.7
Hb D-carrier	Hb F,A,D	282.7
Hb E-carrier	Hb F,A,E	282.7
Hb S (sickle)-carrier	Hb F,A,S	282.5

I.I. Denominator Statement

The eligible population for the denominator is the number of children younger than 18 years of age identified as having SCD who presented to an ED with fever (defined 38 degrees C [100.4 degrees F] or above)during the measurement year, (January 1-December 31) as documented in the medical record. Eligible children are restricted to those with SCD variants identified in Table 1, based on appropriate ICD-9 codes as documented in the medical record.

I.J. Denominator Exclusions (as appropriate)

1. Inpatient stays, outpatient visits, urgent care visits, and acute care (evaluation and management) visits with primary care physician are excluded from the calculation.
2. Children with a diagnosis in the sampled medical record indicating one of the SCD variants listed in Table 3 should not be included in the eligible population *unless* there is also a diagnosis for a sickle cell variant listed in Table 1.

I.K. Data Sources

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

Data Source	
1. Administrative Data (e.g., claims data)	
2. Paper Medical Record	
3. Survey – Health care professional report	
4. Survey – Parent/caregiver report	
5. Survey – Child report	
6. Electronic Medical Record	**X**
7. Other (If other, please list all other data sources in the field below.)	

SECTION II.
DETAILED MEASURE SPECIFICATIONS

Provide sufficient detail to describe how a measure would be calculated from the recommended data sources, either by uploading a separate document or by providing a link to a URL in the field below. 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.[1] 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 specification, *Q-METRIC Sickle Cell Disease Measure 14, Appropriate Emergency Department Blood Testing for Children with Sickle Cell Disease,* at the end of this document. This SCD codebook used for medical record data abstraction is also included as a separate file.

[1] Initial Core Set of Children's Health Care Quality Measures: Technical Specifications and Resource Manual for Federal Fiscal Year 2011 Reporting. Available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Downloads/InitialCoreSetResourceManual.pdf and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/CHIPRA-Initial-Core-Set-of-Childrens-Health-Care-Quality-Measures.html.

SECTION III.
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).

III.A. Evidence for General Importance of the Measure

Provide evidence for all applicable aspects of general importance, including but not limited to the following:

- Addresses a known or suspected quality gap or disparity in quality (e.g., addresses a socioeconomic disparity, a racial/ethnic disparity, a disparity for Children with Special Health Care Needs (CSHCN) and/or a disparity for limited English proficiency (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 et al., 2011). The National Heart, Lung and Blood Institute 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 African and Hispanic descent (Hassell et al., 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 SCD (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 (Lemanek et al., 2009; Alvim et al., 2005). Although medical management of SCD continues to improve over time, 196 US children died from SCD-related causes between 1999 and 2002 (Yanni et al., 2009).

Sickle Cell Disease Cost

In a study of health care utilization among low income children with SCD between 2004 and 2007, 27% of these children required inpatient hospitalization and 39% used emergency care during a year. Of these children, 63% averaged one well-child visit per year and 10% had at least one outpatient visit with a specialist (Raphael et al., 2009). Patients with SCD use many parts of the health care 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 (AHRQ, 2012). Kauf et al. estimate the lifetime cost of health care per patient with SCD to be approximately $460,000 (Kauf et al., 2009).

Outcomes of Appropriate Emergency Department Blood Testing for Children with Sickle Cell Disease

Because the spleen is often compromised at an early age in children with SCD, infection is a frequent and serious complication; the respiratory tract, in particular, serves as a common port of entry for infectious agents. Septicemia and meningitis caused by *Streptococcus pneumonia* are major cause of mortality in children with SCD under the age of 2 years, as this patient population experiences a 400-fold incidence of *S. pneumonia* compared with children without SCD (NHLBI, 2002; Taylor et al., 2001). Other serious illnesses in children with SCD such as acute chest syndrome also involve fever and the presence of bacteria. Therefore, the presence of fever in children with SCD should be approached with high suspicion for systemic infection, and any febrile illness should be evaluated immediately. It is crucial that families and clinicians understand that in children with SCD, a temperature over 38.5 degrees Celsius is an emergency (NHLBI, 2002; AAP, 2002; Pack-Mabien et al., 2009). (Note that for testing purposes, the Q-METRIC quality measure drops the fever threshold to 38.0 C from the 38.5 C standard used in many of the clinical guidelines.)

Among the essential tests for children with SCD being evaluated for fever in the ED are a pulse oximetry reading, complete blood count, reticulocyte count, and a blood culture (NHLBI, 2002). Pulse oximetry is used to monitor arterial saturation and indicates presence of hypoxemia (Fitzgerald et al., 2001). Observed changes in values obtained from a complete blood count (which includes

hemoglobin concentration, white blood cell count, and hematocrit) may support the suspicion of infection. A reticulocyte count documents the efficiency of the marrow response and is used in determining risk of transient red cell aplasia, acute hepatic sequestration, and acute splenic sequestration complication. A blood culture probes for the presence of bacteria in the blood (NHLBI, 2002).

All children with SCD should have a set of baseline values for these test results on file so these values can be used for comparison during times of acute illness. It is important that health care providers in the ED are able to access this information quickly. Also, children with SCD should be followed at a practice or center with 24-hour access to medical consultants, hematology and microbiology laboratories, and a blood bank, among other services (NHLBI, 2002). Beyond having access to information and extended services, ED staff treating children with SCD must be skilled in providing complex care and interventions, including assessment, infection control, pain management, and appropriate understanding of complex hematological and immunological issues. This care is often delivered in the psychosocially complicated context of chronic illness for the patient and family (Taylor et al., 2001)

A snapshot view of ED use by pediatric SCD patients at a major urban children's hospital found that in 97% of visits for fever, a complete blood count with differential and reticulocyte count were performed; 90% of fever visits had a blood culture sent; and hospital admissions occurred in 92% of patient visits for fever (Kunkel et al., 1994). Further 53% of ED visits occurred at night and 36% were on the weekend. In this same study, a query of families involved in the visits (40% contact rate) found that the mean duration of symptoms before the ED visit for fever was 0.4 days. Failure to respond to home treatment was the most common reason provided for visiting the ED (46.3%); worsening symptoms was cited as a reason 22.2% of the time. All families reported that they brought their children to the ED after initial home treatment and consultation with a hematology nurse or physician. In a study of the Healthcare Cost and Utilization Project inpatient and ED databases, Brousseau and colleagues found that for acute care encounters per year in children with SCD ages 1 to 9 years old, 57.4% had one to two visits per year and 8.6% had three to 10 encounters. For children with SCD ages 10 to 17, those numbers were 51.0% and 12.6%, respectively (Brousseau et al., 2010).

This measure assesses whether children younger than 18 years of age with SCD presenting to an ED with a fever received appropriate blood testing within 60 minutes of initial contact: a pulse oximetry reading and orders for a complete blood count, reticulocyte count, and a blood culture. The measure does not change across developmental stages.

Performance Gap

A common complaint among patients with SCD and their families is that of receiving inappropriate care in the ED. The issue is not so much a lack of knowledge about the disease on the part of ED staff, but rather that staff are unfamiliar with the individual presenting. Given the fast pace of most EDs and the needs of the young patient with SCD for rapid and efficient evaluation, quick access to individual care plans and patient records (including values for baseline blood work) as described above is essential. Electronic medical records, patient information cards, and phone calls to patient providers are all means to transmit information quickly during an emergency (NHLBI, 2002).

Underdeveloped quality standards for treating children with SCD presenting to the ED is another identified gap (Tanabe et al., 2013). Caring for children in the ED is complex from both a medical and behavioral perspective. Children vary developmentally; their ability to communicate and degree of independence may vary widely. For children with SCD, physical challenges and neurocognitive deficits can make ED visits even more complicated. The quality measures developed by Q-METRIC are one approach to rectifying this problem, as are quality of care indicators recently proposed (Wang et al., 2011).

III.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).[2]
- Any other specific relevance to Medicaid/CHIP (please specify).

Sickle Cell Disease and Medicaid/CHIP

This majority of children with SCD are enrolled in Medicaid. In 2009, 67% of pediatric SCD patients discharged from the hospital were enrolled in Medicaid; only 25% had private insurance (AHRQ, 2012). In a study of the Healthcare Cost and Utilization Project inpatient and ED databases, Brousseau and colleagues found that for acute care encounters (ED and hospitalization) for patients with SCD, children ages 1-9 years with pubic insurance had 1.6 visits per year compared with 1.39 for those with private insurance and 1.10 for the uninsured (Brousseau et al., 2010).

A study of patients, including children, with SCD enrolled in TennCare, Tennessee's Medicaid managed health care program, from January 1995 to December 2002 showed much higher rates of ED use compared with black patients in TennCare without SCD. For children younger than 5 years of age the rate ratio (RR) of ED visits per 1,000 person years was 1.8 for boys (95% confidence interval [CI] = 1.7 to 1.9) and 2.0 for girls (1.9 -2.2). For those ages 5 to 9 years, the RR for boys was 2.7 (2.5-2.9) and for girls was 3.0 (2.8-3.2). For those ages 10 to 19 years, the RR for boys was 3.7 (3.5-3.9) and for girls was 3.7 (3.4-3.7) (Shankar et al., 2005).

Medicaid enrollment often serves as a marker of poverty. The large number of children with SCD on Medicaid suggests some of these patients may be receiving suboptimum treatment because of

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2 The EPSDT is a comprehensive set of benefits available to children and youth under age 21 who are enrolled in Medicaid. For more information, see http://www.healthlaw.org/images/stories/epsdt/3-ESDPT08.pdf.

unstable living situations. They may not be receiving prophylactic antibiotics to help prevent bacterial infections, and they may experience delays in being taken for medical care if family situations are such that work responsibilities, school commitments for siblings, or lack of transportation make seeking prompt medical attention difficult (Tanabe et al., 2013). Having consistent standards of care to treat these children quickly and effectively when they present in the ED is an important measure to help rectify disadvantages they face because of socioeconomic status.

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

References for Section III

Agency for Healthcare Research and Quality. Welcome to HCUPnet: Healthcare Cost and Utilization Project (HCUP). 2012; http://hcupnet.ahrq.gov/.

American Academy of Pediatrics Section on Hematology/Oncology and Committee on Genetics. Health supervision for children with sickle cell disease. *Pediatrics* 2002; 109(3):526-535.

Alvim RC, Viana MB, Pires MA, et al. Inefficacy of piracetam in the prevention of painful crises in children and adolescents with sickle cell disease. *Acta Haematol* 2005; 113(4):228-233.

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Taylor S, Moore KJ. Emergency nursing care of pediatric sickle cell patients: meeting the challenge. *Pediatr Emerg Care* 2001. 17(3):220-225.

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Yanni E, Grosse SD, Yang Q, Olney RS. Trends in pediatric sickle cell disease-related mortality in the United States, 1983-2002. *J Pediatr* 2009; 154(4):541-545.

SECTION IV.
MEASURE CATEGORIES

CHIPRA legislation[3] 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,[4] 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.

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3 Children's Health Insurance Program Reauthorization Act of 2009. Public Law No. 111-3, 123 Stat. 8 (2009). Available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ003.111.

4 Under Section 214 of CHIPRA, States may elect to cover the following groups under Medicaid only or under both Medicaid and CHIP: pregnant women and children up to age 19 for CHIP or up to age 21 for Medicaid.

	Does the measure address this category [Yes/No drop-down]	
a. Care Setting – ambulatory	**Yes**	
b. Care Setting – inpatient	**No**	
c. Care Setting – other—please specify	**No**	**[Add the following choices: home, school, other community and public health settings, long-term care, other---drop-down or radio buttons]**
d. Service – preventive health	**No**	
e. Service – care for acute conditions	**Yes**	
f. Service - care for children with special health care needs/chronic conditions	**Yes**	
g. Service – health promotion and services to promote healthy birth	**No**	
h. Service-other (please specify)	**No**	
i. Measure Topic -duration of enrollment	**No**	
j. Measure Topic – clinical quality	**Yes**	
k. Measure Topic – patient safety	**No**	
l. Measure Topic – family experience with care	**No**	
m. Measure Topic – care in the most integrated setting	**No**	
n. Measure Topic – other (please specify)		n/a
o. Population – pregnant women		n/a
p. Population – neonates (28 days after birth) (specify age range)	**Yes**	Birth – 28 days
q. Population – infants (29 days to 1 year) (specify age range)	**Yes**	Children ages 29 days to 1 year
r. Population – pre-school age children (1 year through 5 years) (specify age range)	**Yes**	All ages in this range
s. Population – school-age children (6 years through 10 years) (specify age range)	**Yes**	All ages in this range
t. Population – adolescents (11 years through 20 years) (specify age range)	**Yes**	Adolescents 11 through 17years

SECTION V.
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.

V.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 emergency department blood testing for children with SCD), that, if followed, results in a desirable clinical outcome (timely discovery and treatment of infection in children with SCD). The measure highlights where providers or hospitals are falling short in offering quality health care in the ED for children with SCD.

In the ED, fever in children with SCD is a very high-triage priority because the risk of sepsis is life threatening. Early identification and management of infection are critical (Tanabe et al., 2013). To that end, performing standard-of-care blood tests quickly in the ED is essential to establish a diagnosis and initiate treatment. Overall, clinical guidelines indicate that providers should perform pulse oximetry, a complete blood count, reticulocyte count, and blood culture soon after presenting at the ED. Table 4 summarizes several key sources of evidence for this measure, using the US Preventive Services Task Force (USPSTF) rankings (criteria denoted in Table 4).

Table 4: Evidence Supporting Appropriate Emergency Department Blood Testing in Children with Sickle Cell Disease

Type of evidence	Key findings	Level of evidence (USPSTF ranking*)	Citation(s)
Clinical guidelines	All children with SCD who have fever (greater than 38.5 degrees Celsius or 101 degrees Fahrenheit and other signs of infection should be evaluated promptly. The younger the child, the higher the index of suspicion. In a child with no obvious sources of infection, a minimum evaluation should include blood culture, complete blood count, reticulocyte count, and chest x-rays for children under 3 years of age. Immediately after the blood is taken, the child should be given broad-spectrum antibiotics, preferably intravenously (p. 28). Ideally, children with SCD are followed at a practice or center that allows for comprehensive management of their disease. These facilities should have 24-hour access to medical consultants, hematology and microbiology laboratories, and a blood bank, among other services (p. 29).	III	National Heart Lung and Blood Institute. The Management of Sickle Cell Disease. National Institutes of Health. Bethesda, MD, 2002.
Clinical guidelines	A child with fever or pallor and listlessness should always be initially evaluated, if possible, at a site where complete blood cell (CBC) and reticulocyte counts, blood cultures, intravenous antibiotics, and red blood cell transfusions are readily available. Because patients with SCD develop splenic dysfunction at as early as 3 months of age, they are at high risk for septicemia and meningitis with pneumococci and other encapsulated bacteria. Thus, all patients with temperature greater than 38.5 degrees C require rapid triage and physical assessment, urgent CBC and reticulocyte counts, blood culture (plus cerebrospinal fluid analysis and other cultures as indicated), and prompt administration of a broad-spectrum parenteral antibiotic, such as ceftriaxone sodium, cefuroxime, or cefotaxime sodium (p. 529).	III	American Academy of Pediatrics Section on Hematology/Oncology and Committee on Genetics. Health supervision for children with sickle cell disease. Pediatrics. Mar 2002;109(3):526-535.
Clinical guidelines	Infectious processes are a serious cause of morbidity in the child with SCD, as these patients have decreased immunologic function due to chronic microinfarcts within the spleen. Functional asplenia is found in more than 90% of SCD patients by age 5; therefore, greater	III	Taylor S et al. Emergency nursing care of pediatric sickle cell patients: Meeting the challenge. *Pediatr Emerg Care* 2001; 17(3):220-225.

Type of evidence	Key findings	Level of evidence (USPSTF ranking*)	Citation(s)
	vigilance for occult bacteremia, meningitis, and sepsis must be practiced … the presence of fever in patients with SCD should be treated with a higher index of suspicion for systemic infection than in the non-SCD patient (p.222) Assessment in the ED of pediatric patients with SCD complications should start a pulse oximetry reading (compared, if possible, to the patient's normal pulse ox reading, if known) … Laboratory tests for should include a complete blood count to assess the level of anemia, reticulocyte count to assess the body's response to anemia, and a blood culture for febrile patients (pp. 221-222)		
Clinical guidelines	For children with SCD who present with fever or history of fever (greater than or equal to 38.5 degrees Celsius) a complete blood count, reticulocyte count, and blood culture should be obtained. Children with SCD with a fever greater than or equal to 38.5 degrees Celsius should be given parenteral broad spectrum antibiotic treatment within 60 minutes of triage	III	Wang CJ et al. Quality-of-care indicators for children with sickle cell disease. Pediatrics 2011; 128:484-493.

Note: USPSTF criteria for assessing evidence at the individual study level are as follows: I) Properly powered and conducted randomized controlled trial (RCT); well-conducted systematic review or meta-analysis of homogeneous RCTs. II) Well-designed cohort or case-control analytic study. III) Opinions of respected authorities, based on clinical experience; descriptive studies or case reports; reports of expert committees.

V.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.

Children with SCD are at high risk of developing bacterial infections because of the loss of splenic function by the age of 2 to 3 months. Prophylactic use of antibiotics in children until age 5 (Gaston et al., 1986) has decreased the incidence of sepsis and meningitis; routine flu vaccinations and the introduction of the 7-valent pneumococcal conjugate vaccine may also contributed to a reduced incidence of bacteremia, though the connection is still debated (Adamkiewicz et al., 2003). Still, given the susceptibility of these children to infection, a high degree of suspicion should be maintained for children with SCD who present with fever. A study by Bansil et al. reported that during a 10-year period, 16% of febrile children with SCD discharged from the pediatric ED of a major medical center had a serious bacterial infection: pneumonia was diagnosed most often at 13.8%, followed by bacteremia and urinary tract infections, both at 1.1%. The authors suggested that because children with SCD have lower immunity, they may be susceptible to *S. pneumonia* serotypes not covered by the PCV (Bansil et al., 2013).

Fever is also associated with other serious SCD complications, such as acute chest syndrome, a common and life-threatening condition in children with SCD that can also be caused by bacterial infections. Acute chest syndrome is difficult to distinguish from pneumonia because both illnesses present with fever and cough. In children with SCD younger than 2 years of age, 97% of those with acute chest syndrome are febrile; 17.4 % of febrile children with SCD have acute chest syndrome (Chang et al., 2013).

SCD is a chronic hematologic disorder, characterized by the presence of hemoglobin S. Oxygenated HbS functions normally but in decreased oxygen states (hypoxemia), HbS becomes distorted to the 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). Blood testing provides important information about a patient's status regarding many SCD-related conditions, including anemia, infection and fever, stroke, acute chest syndrome, and pain. Expert consensus indicates that the four tests blood tests listed below should be conducted immediately when febrile children with SCD present in the ED:

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 health care providers to assess the amount of oxygen in the blood (Johns Hopkins Medicine).

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; mean platelet volume (MPV) (WebMD, 2012).

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

A blood culture tests for infection in the blood by detecting the presence of bacteria or fungi. A bacterial infection in the blood can be serious because the blood can spread bacteria to any part of the body. To test for infection, blood is collected and placed in a cup with substances that allow bacteria or fungus to grow. If this occurs, the bacteria or fungus are checked visually by a microscope and chemically. Further sensitivity testing is conducted to determine the best antibiotic to use to kill the bacteria. Two or three samples may be taken from different veins to make sure infection is not missed. If nothing grows, the blood culture is called negative (WebMD, 2012).

A prospective study at the Children's Hospital of Philadelphia looked at the use of blood cultures in

determining the presence of bacteremia in children with SCD. Because management varies for evaluating febrile illness in this population, establishing an average time to a positive culture in a continuously monitored blood culture instrument will allow for guidelines to be developed to stratify the length of time a child should be observed, based on clinical, laboratory, and social features (Norris et al., 2003).

References for Section V

Adamkiewicz TV, Sarnaik S, Buchanan GR, et al. Invasive pneumococcal infections in children with sickle cell disease in the era of penicillin prophylaxis, antibiotic resistance, and 23-valent pneumococcal polysaccharide vaccination. *J Pediatr* 2003; 143(4):438-444.

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Norris CF, Smith-Whitley K, McGowan KL. Positive blood cultures in sickle cell disease: time to positivity and clinical outcome. *J Pediatr Hematol Oncol* 2003; 25(5):390-395.

Tanabe P, Dias N, Gorman L. Care of children with sickle cell disease in the emergency department: Parent and provider perspectives inform quality improvement efforts. *J Pediatri Oncol Nurs* 2013; 30(4):205-217.

Information and resources: Complete blood count (CBC), WebMD. http://www.webmd.com/a-to-z-guides/complete-blood-count-cbc. Updated August 6, 2012; accessed April 21, 2014.

Information and resources: Reticulocyte count. WebMD. http://www.webmd.com/a-to-z-guides/reticulocyte-count. Updated May 29, 2012; accessed April 21, 2014.

Information and resources: Blood culture. WebMD. http://www.webmd.com/a-to-z-guides/blood-culture; Updated August 6, 2012; accessed April 21, 2014.

SECTION VI.
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.

VI.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 below.

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 measure, 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% 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 each of the measure numerators, 14 of 435 unique patient records (3%) from Phase 1 of the abstraction process were assessed for IRR across the three testing sites. Additionally, in order for a record to be abstracted for this measure, patients must meet a specific medical criterion (fever). Therefore, IRR was also assessed for this eligibility criterion. For fever, 29 of 435 unique patient records (7%) from Phase 1 of the abstraction process were assessed for IRR across the three testing sites.

Table 5 shows the percent agreement and Kappa statistic for each numerator and the fever eligibility criterion of this measure for each site and across all sites. The overall agreement for three of the numerators (complete blood count, reticulocyte, and blood culture) was 100% and the Kappa was 1.00, indicating a perfect IRR level was achieved. The overall agreement for the pulse oximetry numerator was 64% with a Kappa statistic of 0.10.The overall agreement for fever, an eligibility criterion, was 90% and the Kappa was 0.79.

Discrepancies

When discrepancies between abstractors were found, the abstractors and a study team member reopened the electronic medical record to review each abstractor's response and determine the correct answer. After discussion, a consensus result was obtained and inconsistent records were corrected for the final dataset. When consistent differences were noted between the abstractors, clarification was provided and the abstraction tool modified, where appropriate.

For the fever eligibility criterion, 26 of 29 records agreed, resulting in a 90% agreement and a Kappa score of 0.79. In two of the three records where there was disagreement, it was because the first temperature taken in the ED was below the fever threshold. Therefore, one of the abstractors recorded that there was not a fever. The second abstractor used a temperature reading taken later in the visit that was above the threshold to indicate that there was a fever. During the review meeting, it was clarified that the patient had to present to the ED with a fever, therefore the first temperature recorded should be used to determine eligibility. This text was also added to the abstraction tool.

The numerator that assesses pulse oximetry had a percent agreement of 64% and a Kappa statistic of 0.10 due to five of 14 records in disagreement. All five of the disagreements occurred in records at one hospital. While reviewing the medical records, it was discovered that pulse oximetry readings were not always listed with other vital signs. It was not initially known that the abstractor may have to navigate to another section of the record to find this information. Following review, the abstractors verified that they knew where to find pulse oximetry information, thus resolving this issue.

Table 5: Agreement and Kappa Statistics for Sickle Cell Disease for Inter-Rater Reliability at Three Sites

Site	Eligibility Criteria/ Measure Numerators	Number of Records Reviewed	N Agreed (%)	Kappa Statistic
Hospital #1	Fever Criterion	3	100%	1.00
	Pulse Oximetry	0	-	-
	Complete Blood Count	0	-	-
	Reticulocyte	0	-	-
	Blood Culture	0	-	-
Hospital #2	Fever Criterion	7	100%	1.00
	Pulse Oximetry	4	100%	1.00
	Complete Blood Count	4	100%	1.00
	Reticulocyte	4	100%	1.00
	Blood Culture	4	100%	1.00
Hospital #3	Fever Criterion	19	84%	0.68
	Pulse Oximetry	10	50%	0.00
	Complete Blood Count	10	100%	1.00
	Reticulocyte	10	100%	1.00
	Blood Culture	10	100%	1.00
All Sites	Fever Criterion	29	90%	0.79
	Pulse Oximetry	14	64%	0.10
	Complete Blood Count	14	100%	1.00
	Reticulocyte	14	100%	1.00
	Blood Culture	14	100%	1.00

Note: Measure 14 includes a numerator that assesses whether the patient received all four required tests within 60 minutes of initial contact in the ED. IRR calculations are not included for the overall numerator since it would be redundant with the IRRs calculated for the individual numerators.

VI.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., R^2 for concurrent validity). Provide appropriate citations to justify methods.

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 health care quality measurement. In total, the Q-METRIC SCD panel included 14 experts, providing a comprehensive perspective on SCD management and the measurement of quality metrics 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 8.1 (with 9 as the highest possible score).

Validity of Abstracted Data

This measure was tested using medical record data. This source is considered the gold standard for clinical information; our findings indicate that these data have a high degree of face validity. This measure was tested among a total of 123 children younger than 18 years of age with sickle cell disease (Table 6). Overall, appropriate blood testing was conducted within 60 minutes of initial contact in the ED for 10% of children with SCD (range among the three hospitals: 7%-10%). Pulse oximetry was conducted within 60 minutes of initial contact in the ED on 51% of children (range: 39%-100%). Similarly, a complete blood count was conducted within 60 minutes of initial contact in the ED for 25% of children (range: 20%-26%); a reticulocyte count was conducted within 60 minutes of initial contact in the ED for 24% of children (range: 20-25%); a blood culture was conducted within 60 minutes of initial contact in the ED for 39% of children (range: 7%-44%).

Table 6: Appropriate Outpatient Blood Testing for Children with Sickle Cell Disease

Site	Pulse Oximetry Numerator		Complete Blood Count Numerator		Reticulocyte Numerator		Blood Culture Numerator		Overall Numerator		Denominator
	Rate	N	Rate	N	Rate	N	Rate	N	Rate	N	
Hospital #1	100%	10	20%	2	20%	2	30%	3	10%	1	10
Hospital #2	100%	14	21%	3	21%	3	7%	1	7%	1	14
Hospital #3	39%	39	26%	26	25%	25	44%	44	10%	10	99
All Sites	51%	63	25%	31	24%	30	39%	48	10%	12	123

SECTION VII.
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.

VII.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 7 summarizes the distribution across race and ethnicity groups for all SCD births in Michigan during that time period.

Table 7: Race/Ethnicity for Newborns with SCD in Michigan, 2004-2008 (n=294)

White			Black			Asian or Pacific Islander			Other	
Non-Hispanic	Hispanic	Total	Non-Hispanic	Hispanic	Total	Non-Hispanic	Hispanic	Total	Unknown	Total
2%	1%	3%	81%	1%	82%	1%	0%	1%	15%	100%

VII.B. Special Health Care Needs

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

VII.C. Socioeconomic Status

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

VII.D. Rurality/Urbanicity

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

VII.E. Limited English Proficiency (LEP) Populations

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

SECTION VIII.
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.[5] Using the following sections, explain the methods used to determine the feasibility of implementing the measure.

VIII.A. Data Availability

VIII.A.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 EHRs at all three sites.

Medical records for 100% 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; 123 records (18%) met denominator criteria for this measure.

Based on the abstracted chart data, rates were calculated for each of the five numerators (see Table 6 in the Validity section above) as follows:

1. Pulse Oximetry: The percentage of children with SCD who had a pulse oximetry reading within 60 minutes following initial contact in the ED (51%). Pulse oximetry numerator (63) divided by denominator (123).

2. Complete Blood Count: The percentage of children with SCD who had a complete blood count within 60 minutes following initial contact in the ED (25%). Complete blood count numerator (31) divided by denominator (123).

3. Reticulocyte: The percentage of children with SCD who had a reticulocyte count within 60 minutes following initial contact in the ED (24%). Reticulocyte numerator (30) divided by denominator 123).

4. Blood Culture: The percentage of children with SCD who had a blood culture count within 60 minutes following initial contact in the ED (39%). Blood culture numerator (48) divided by denominator (123).

5. Overall: The overall rate is the percentage of children with SCD who had a pulse oximetry,

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[5] The definition is adapted from: Centers for Medicare & Medicaid Services Quality Measurement and Health Assessment Group glossary, as part of the Measures Management System Measure Development Overview. Available at: http://www.cms.gov/MMS/19_MeasuresManagementSystemBlueprint.asp#TopOfPage. Accessed February 6, 2012.

complete blood count, reticulocyte count, and blood culture performed within 60 minutes following initial contact in the ED (10%). Overall numerator (12) divided by denominator (123).

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 technical 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. Abstractors participated in onsite training during which the measure was discussed in 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 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 12 minutes per eligible SCD case abstracting the data for this measure, with times ranging from 5-45 minutes.

VIII.A.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?

The proposed measure was determined to be feasible by Q-METRIC using electronic medical record data from the three largest centers serving SCD patients in Michigan during 2012.

VIII.B. Lessons from Use of the Measure

VIII.B.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.

VIII.B.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

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

Not applicable

SECTION IX.
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 Section XVI. 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. Table IX-1 shows the questions (in columns) about the measure's use at different levels of aggregation for quality reporting (in rows) included in the CHIPRA PQMP Candidate Measure Submission Form (CPCF).

Table IX-1. Questions about the measure's use at different levels of aggregation for quality reporting

Level of aggregation (Unit) for reporting on the quality of care for children covered by Medicaid/CHIP†	**Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)**	**Data Sources: Are data sources available to support reporting at this level?**	**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 Use: Have measure results been reported at this level previously?**	**Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**	**Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?**
State level*: Can compare States	☐Yes ☒No	No	Not applicable	No	No	Not applicable
Other geographic level: Can compare other geographic regions (e.g., MSA, HRR)	☐Yes ☒No	No	Not applicable	No	No	Not applicable
Medicaid or CHIP Payment model: Can compare payment models (e.g., managed care, primary care case management, FFS, and other models)	☐Yes ☒No	No	Not applicable	No	No	Not applicable
Health plan*: Can compare quality of care among health plans.	☐Yes ☒No	No	Not applicable	No	No	Not applicable
Provider-level* Individual practitioner: Can compare individual health care professionals	☐Yes ☒No	No	Not applicable	No	No	Not applicable
Hospital: Can compare hospitals that serve SCD patients.	☒Yes ☐No	Yes.	The sample would be comprised of all children with clinical documentation of sickle cell disease [see Table 1] presenting to the ED	No.	No.	Not applicable
Practice, group, or facility:** Can compare: (i) practice sites; (ii) medical or other professional groups; or (iii) integrated or other delivery networks	☐Yes ☒No	No	Not applicable	No	No	Not applicable

† There could be other levels of reporting that could be of interest to Medicaid agencies such as markets and referral regions.

* Required in CHIPRA legislation. ** There is no implication that measures that are applicable at one level are automatically applicable at all three of the levels listed in this row.

SECTION X.
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 to assess how well basic levels of comprehensive care are being provided for children with SCD. Low rates for the provision of care in the emergency department 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 comprehensive care, including treatment in the ED, is managed in children with SCD.

This measure has not been assessed for comprehension. The primary information needed for this measure comes from medical records data and includes basic demographics, 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 XI.
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 calculation of the measure.

XI.A. Health IT Enhancement

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

Health IT may enhance the use of this measure by providing the vehicle for ensuring timely completion of these activities, and by providing queues for these activities that are aligned with roles. For example, when a patient arrives to an ED that has performed poorly on these measures, the source of poor performance may be related to waiting times. Health IT in the triage area could trigger different decision-making that allows these patients to be seen more quickly. Another source might be documentation of completed tasks, which can be either automated by health IT or augmented by tools such as mobile entry tools for nursing staff.

XI.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 three major SCD treatment facilities in Michigan.

XI.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.

This information is most typically captured in orders or results within the EHR or computerized physician order entry (CPOE) system. It will be captured by nurses, technicians, or physicians, depending on the workflow of the clinic. Because relative time is a stated part of the measure, although visit documentation may be helpful to ascertain IF any of these activities were completed, it is unlikely that documentation will be a useful source for these specific measures.

XI.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: http://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 (Federal Register 2010) pertaining to Stage 2 Meaningful Use requirements include:

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 include 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.

XI.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 sickle cell anemia/SCD

3. Date and time of treatment
4. Type of tests administered
5. Date of tests performed
6. Care setting

XI.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 on the measure?

Being able to show these measure results in health IT, especially to patients, might be transformative. Imagine, for example, an electronic white board in the room that describes "Our goals for your care" and has green, yellow, and red lights next to each of these measures. This system would be hypothesized to improve delivery of this care. Another approach that has been demonstrated to significantly improve quality is through the use of a process control system that health care administrators or leaders could monitor to ensure 100% compliance with these measures, employing the same types of warnings to incentive action before the time window has expired.

References for Section XI

Health information technology: Initial set of standards, implementation specifications, and certification criteria for electronic health record technology." Fed Regist **75**(8): 2013-2047.

SECTION XII.
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) presenting to an emergency department (ED) with fever during the measurement year, who 1) received a pulse oximetry reading and 2) had a complete blood count, 3) reticulocyte count and 4) blood culture within 60 minutes following initial contact.

This measure is implemented with medical record data, and was tested with electronic 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 several considerations that may further strengthen this measure and potentially ease the burden of data collection. Specific feedback from our medical record abstractors suggested that either the time the test was ordered or the time the result was recorded in lieu of the time the test was performed would be easier to find in the medical record. The abstractors also suggested that future versions of the specification note whether any temperature above the threshold (38°C / 100.4° F) can be used to indicate fever or if abstractors should use only the first temperature recorded to determine presence or absence of a fever in the ED. If any fever is acceptable, state whether or not time of presentation should be used as the base time (as opposed to time of fever). Finally, abstractors suggested that it be noted whether a statement by the patient or caregiver indicating a fever (temperature greater than 38° C / 100.4° F) obtained prior to arriving at the ED qualifies as fever in the ED. Although our testing results for this measure do not include these changes, they should be considered prior to subsequent implementation of this measure.

SECTION XIII.
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 Emergency Department Blood Testing for Children with Sickle Cell Disease*, assesses the percentage of children younger than 18 years of age identified as having SCD presenting to an ED with fever during the measurement year, who 1) received a pulse oximetry reading and 2) had a complete blood count, 3) reticulocyte count, and 4) blood culture performed within 60 minutes following initial contact. This measure uses medical record data to calculate individual rates for the four tests, as well as an overall rate that is a composite of the four individual rates. A higher proportion indicates better performance, as reflected by appropriate testing. There are no existing quality measures for appropriate blood testing in the ED for children with SCD.

Clinical guidelines indicate that all children with SCD who present to the ED with a fever and other signs of infection should be evaluated promptly. Tests should include a pulse oximetry reading, complete blood count, reticulocyte count, and a blood culture. Because the spleen is often compromised at an early age in children with SCD, infection is a frequent and serious complication. Septicemia and meningitis caused by *Streptococcus pneumonia* are major cause of mortality in children with SCD under the age of 2 years. The presence of fever in children with SCD should be approached with high suspicion for systemic infection. It is crucial that families and clinicians understand that in children with SCD, a temperature of 38 degrees C is an emergency. However, caring for children in the ED is complex from both a medical and behavioral perspective. Children vary developmentally; their ability to communicate and degree of independence may vary widely. For children with SCD, physical challenges and neurocognitive deficits can make ED visits even more complicated. Also, families of children with SCD have reported receiving inappropriate care in the ED stemming from both a lack of familiarity with the children presenting and underdeveloped quality standards for treating children with SCD in the ED.

This measure was tested among a total of 123 children younger than 18 years of age with sickle cell disease. Overall, appropriate blood testing was conducted on 10% of children with SCD (range: 7%-10%). Pulse oximetry was conducted within 60 minutes of initial contact in the ED for 51% of children (range among the three hospitals was: 39%-100%). Similarly, a complete blood count was conducted within 60 minutes of initial contact in the ED for 25% of children (range: 20%-26%); a reticulocyte count was conducted within 60 minutes of initial contact in the ED for 24% of children (range: 20-25%); a blood culture was conducted within 60 minutes of initial contact in the ED for 39% of children (range: 7%-44%).

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, including in the ED. 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 information technology may establish the feasibility of regularly implementing this measure with data supplied by electronic medical records.

SECTION XIV.
IDENTIFYING INFORMATION FOR THE MEASURE SUBMITTER

Complete information about the person submitting the material, including the following:

a. Gary L. Freed, MD, MPH

b. Percy and Mary Murphy Professor of Pediatrics, School of Medicine; Professor of Health Management and Policy, School of Public Health

c. University of Michigan

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g. Signed written statement guaranteeing that all aspects of the measure will be publicly available, as defined in the Public Disclosure Requirements.

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 (Section XIV: Identifying Information for the Measure Submitter).

This work was funded by the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) under the CHIPRA Pediatric Quality Measures Program Centers of Excellence grant number U18 HS020516. AHRQ, in accordance to CHIPRA 42 U.S.C. Section 1139A(b), and consistent with AHRQ's mandate to disseminate research results, 42 U.S.C. Section 299c-3, has a worldwide irrevocable license to use and permit others to use products and materials from the grant for government purposes, which may include making the materials available for verification or replication by other researchers and making them available to the health care community and the public, if such distribution would significantly increase access to a product and thereby produce substantial or valuable public health benefits.

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Sickle Cell Disease

Measure 14: Appropriate Emergency Department Blood Testing for Children with Sickle Cell Disease

Description

The percentage of children identified as having Sickle Cell Disease presenting to an emergency department with fever during the measurement year, who had a pulse oximetry reading, complete blood count, reticulocyte count, and blood culture within 60 minutes following initial contact. A higher proportion indicates better performance as reflected by appropriate testing.

Calculation

This measure requires medical record data and is calculated as four rates as well as an overall rate that is a composite of the four individual rates. The four individual rates are:

1. The percentage of children who had a pulse oximetry within 60 minutes following initial contact (pulse oximetry numerator divided by denominator).

2. The percentage of children who had a complete blood count within 60 minutes following initial contact (blood count numerator divided by denominator).

3. The percentage of children who had a reticulocyte count within 60 minutes following initial contact (reticulocyte numerator divided by denominator).

4. The percentage of children who had a blood culture within 60 minutes following initial contact (blood culture numerator divided by denominator).

The overall rate is the percentage of children who have received each of the four tests within the same 60 minute period (overall numerator divided by denominator).

Definitions

Intake period	January 1 to December 31 of the measurement year
Pulse oximetry reading	Pulse oximetry was performed within 60 minutes following initial contact (see Table 14-A).
Complete blood count	A complete blood count was performed within 60 minutes following initial contact (see Table 14-A).
Reticulocyte count	A reticulocyte count was performed within 60 minutes following initial contact (see Table 14-A).
Blood culture	A blood culture was performed within 60 minutes following initial contact (see Table 14-A).
Fever	Body temperature ≥ 38 degrees C (100.4 degrees F).

Initial contact Child's first presentation to emergency department staff. Use the earliest time stamp in the medical record.

Table 14-A: Blood tests for the emergency department management of sickle cell disease

Definitions	Procedure Code	Short Description	Long Description
Pulse oximetry reading	0Y4306	Pulse oximetry	PULSE OXIMETRY
Complete blood count	85025	Complete CBC w/auto diff WBC	BLOOD COUNT; COMPLETE (CBC), AUTOMATED (HGB, HCT, RBC, WBC AND PLATELET COUNT) AND AUTOMATED DIFFERENTIAL WBC COUNT
Complete blood count	85027	Complete CBC automated	BLOOD COUNT; COMPLETE (CBC), AUTOMATED (HGB, HCT, RBC, WBC AND PLATELET COUNT)
Complete blood count	85014	Hematocrit	BLOOD COUNT; HEMATOCRIT (HCT)
Complete blood count	85018	Hemoglobin	BLOOD COUNT; HEMOGLOBIN (HGB)
Reticulocyte count	85044	Manual reticulocyte count	BLOOD COUNT; RETICULOCYTE, MANUAL
Reticulocyte count	85045	Automated reticulocyte count	BLOOD COUNT; RETICULOCYTE, AUTOMATED
Reticulocyte count	85046	Reticyte/HgB concentrate	BLOOD COUNT; RETICULOCYTES, AUTOMATED, INCLUDING ONE OR MORE CELLULAR PARAMETERS (EG, RETICULOCYTE HEMOGLOBIN CONTENT (CHR), IMMATURE RETICULOCYTE FRACTION (IRF), RETICULOCYTE VOLUME (MRV), RNA CONTENT), DIRECT MEASUREMENT

Eligible Population

The determination of eligible population for this measure requires medical record data.

Ages Younger than eighteen years of age during the measurement year.

Event/Diagnosis Diagnosed with sickle cell disease and presented to an emergency department with fever as documented in the medical record (see Table 14-B). All emergency department visits for fever during the measurement year qualify.

NOTE: See exclusions noted below; there are several sickle cell variants that may be recorded under the 282.49 ICD-9 code that do not qualify for inclusion (see Table 4-D). Medical records for cases with ICD-9 code 282.49 should not be reviewed unless a diagnosis of Hb beta zero-thalassemia can be confirmed.

Table 14-B: Codes to Identify Sickle Cell Disease

Condition Name	Hemoglobin Screening Result	ICD-9 Code(s)
Hb beta zero-thalassemia	Hb F only	282.49
Hb S beta-thalassemia	Hb F,S,A	282.41, 282.42
Hb SC-disease	Hb F,S,C	282.63, 282.64
Hb SD-disease	Hb F,S,D	282.68, 282.69
Hb SS-disease (sickle cell anemia)	Hb F,S	282.6, 282.61, 282.62

Specification

Denominator The eligible population for the denominator is the number of children younger than 18 years of age identified as having SCD who presented to an ED with fever (defined 38 degrees C [100.4 degrees F] or above) during the measurement year.

Numerators

Pulse oximetry The eligible population for the numerator is the number of children younger than 18 years of age identified as having SCD presenting to an ED with fever (defined 38 degrees C [100.4 degrees F] or above) during the measurement year, who had a pulse oximetry reading within 60 minutes following initial contact.

Blood count The eligible population for the numerator is the number of children younger than 18 years of age identified as having SCD presenting to an ED with fever (defined 38 degrees C [100.4 degrees F] or above) during the measurement year, who had a complete blood count within 60 minutes following initial contact.

Reticulocyte The eligible population for the numerator is the number of children younger than 18 years of age identified as having SCD presenting to an ED with fever (defined 38 degrees C [100.4 degrees F] or above) during the measurement year, who had a reticulocyte count within 60 minutes following initial contact.

Blood culture The eligible population for the numerator is the number of children younger than 18 years of age identified as having SCD presenting to an ED with fever (defined 38 degrees C [100.4 degrees F] or above) during the measurement year, who had a blood culture within 60 minutes following initial contact.

Overall The eligible population for the numerator is the number of children younger than 18 years of age identified as having SCD presenting to an ED with fever (defined 38 degrees C [100.4 degrees F] or above) during the measurement year, who had 1) a pulse oximetry reading, 2) a complete blood count, 3) a reticulocyte count, and 4) a blood culture within 60 minutes following initial contact.

Documentation in medical record must include, at a minimum, a note containing the time at which the test was performed.

Exclusions

- Inpatient stays, outpatient visits, urgent care visits, acute care (evaluation and management) visits with primary care physician
- Children with diagnosis in the sampled medical record indicating one of the sickle cell disease variants listed in Table 14-C should not be included in the eligible population *unless* there is also a diagnosis for a sickle cell variant listed in Table 14-B.

Table 14-C: Excluded Sickle Cell Disease Diagnosis Codes

Condition Name	Hemoglobin Screening Result	ICD-9 Code(s)
Hb C beta-thalassemia	Hb F,C,A	282.49
Hb D beta-thalassemia	Hb F,D,A	282.49
Hb E beta-thalassemia	Hb F,E,A	282.49
Hb C-disease	Hb F,C	282.7
Hb E-disease	Hb F,E	282.7
Hb H-disease	Hb F,H	282.49
Hb SE-disease	Hb F,S,E	282.68, 282.69
Hb C-carrier	Hb F,A,C	282.7
Hb D-carrier	Hb F,A,D	282.7
Hb E-carrier	Hb F,A,E	282.7
Hb S (sickle)-carrier	Hb F,A,S	282.5