Appropriate Emergency Department Pain Assessment for Children with Sickle Cell Disease

Section 1. Basic Measure Information

1.A. Measure Name
Appropriate Emergency Department Pain Assessment for Children with Sickle Cell Disease

1.B. Measure Number
0217

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

This measure assesses the percentage of children younger than 18 years of age identified as having sickle cell disease (SCD) presenting to an emergency department (ED) with an acute pain episode during the measurement year who had a pain assessment within 30 minutes following initial contact. A higher proportion indicates better performance, as reflected by appropriate treatment.

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, including the hallmark clinical manifestation of SCD, the acute vaso-occlusive event or pain crisis. This unique type of pain can start as early as 6 months of age, recur unpredictably over a lifetime, and require treatment with opioids. Painful events are the most common cause of ED visits and hospitalizations for children. A majority of patients with SCD have at least one episode of pain per year, and a small minority will have almost constant pain. The severity and unpredictability of pain, the lack of objective markers, and conflicting perceptions about intensity and treatment make pain management a particularly challenging aspect of SCD. Accurate, prompt, and insightful assessment of pain is therefore essential for developing an effective plan for treatment. There are no existing quality measures for appropriate ED assessment of pain in children with SCD.

This measure uses medical record data to calculate the percentage of eligible children who received an appropriate assessment of pain in the ED.

1.D. Measure Owner
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's National Quality Measures Clearinghouse and are available at http://www.qualitymeasures.ahrq.gov/about/hierarchy.aspx:

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 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
The eligible population for the numerator is the number of children younger than 18 years of age with SCD presenting to the ED with an acute pain episode during the measurement year (January 1 - December 31) who had a pain assessment within 30 minutes following initial contact, as determined by a medical record review. 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. ICD-9 codes used to identify pain assessments are listed in Table 2 (see Supporting Documents).

Documentation in the medical record must include, at a minimum, a note containing the time at which the pain assessment was performed.
1.H. Numerator Exclusions
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. Ineligible pain assessment procedure codes are listed in Table 3 (see Supporting Documents).
3. 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 presenting to the ED with an acute pain episode 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.

1.J. Denominator Exclusions
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. Ineligible pain assessment procedure codes are listed in Table 3 (see Supporting Documents).
3. Children with diagnosis in the sampled medical record indicating one of the sickle cell disease 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.
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. See Supporting Documents for the detailed measure specifications and the SCD codebook used for medical record data abstraction.

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 African 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 health care 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 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 (Agency for Healthcare Research and Quality [AHRQ], 2012). Kauf and colleagues estimate the lifetime cost of health care per patient with SCD to be approximately $460,000 (Kauf, Coates, Huazhi, et al., 2009).

Outcomes of Appropriate ED Pain Assessment for Children with Sickle Cell Disease

Treating pain associated with SCD is one of the most daunting challenges of managing the disease. Pain episodes, which are caused when blood flow is impeded to various parts of the body, tend to be unpredictable in onset and duration and can range in intensity from mild to excruciating (Claster, Vichinsky, 2003). SCD pain has been described as being worse than post-operative pain and as intense as pain associated with terminal cancer (Stinson, Naser, 2003). How effectively pain is managed in children can affect their ability to cope physically, emotionally, socially, and academically as adolescents and adults (Brandow, Brousseau, Pajewski, et al., 2010).

The goals of pain assessment are to quantify and observe the patient’s pain status and related experiences over time and to document the efficacy of interventions. Approaches to pain management recommend the use of standard pain measures and regular, documented assessment (Franck, Treadwell, Jacob, et al., 2002). Because past, present, and anticipated experiences affect pain management, pain must be assessed and treated in a developmental and psychosocial context (NHLBI, 2002). Developing a comprehensive assessment strategy is a critical first step in providing effective clinical interventions. A thorough approach to eliciting reports of pain in children with SCD requires a developmental and bio-psychosocial framework that considers all
pain experiences, not just the current event. An evaluation of sensory, affective, behavioral, and sociocultural aspects of pain should be included as well (Stinson, et al., 2003).

Without prompt assessment and treatment, painful episodes that are of mild to moderate severity may progress to severe pain because of associated fear, panic, and stress (Jacob, 2001). The frequency of vaso-occlusive events has been identified as an indicator of clinical severity and is associated with premature death in patients over the age of 20 years with SCD; patients with the higher pain rates (episodes/year) have an increased risk of death compared to those with the lowest (Ellison, Shaw, 2007; Pack-Mabien, Haynes Jr, 2009).

Ideally, all 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 and have an 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, Moore, 2001).

This measure assesses whether children younger than 18 years of age identified as having SCD and presenting to an ED with an acute pain episode during the measurement year had a pain assessment within 30 minutes following initial contact. The measure does not change across developmental stages.

**Performance Gap**

Pain assessment poses many challenges in infants and preverbal children with SCD, given the subjective and complex nature of vaso-occlusive pain, as well as the development and language limitations that preclude comprehension and self-report (Stinson, et al., 2003). Relying on a parent’s judgment can sometimes be problematic. Research shows that parents tend to rate their children’s health-related quality of life higher than do the children during SCD pain episodes; the disagreement worsens as the severity of the pain increases (Brandow, et al., 2010). Further, the general pain literature suggests that parents can be reluctant to medicate their children for pain; when they do, the analgesics provided are inadequate in terms of dose and/or frequency. These conflicting reports of pain and attitudes about medications can negatively influence instructions from health care providers about pain management, prescriptions of analgesics, and quality of care (Dampier, Ely, Brodecki, et al., 2001).

Clinicians, too, are sometimes suspicious about the truth or validity of the pain scores reported by children with SCD. These providers often believe that children who are watching TV, playing, or sleeping are not in as much pain as they report. But children may often use these strategies as ways of coping with pain. The disparity between the patient’s self-report and their affect and behavior leads to distrust on the part of health care providers. Further, unfamiliarity with the effective use of analgesics and fear of adverse effects, such as respiratory depression and addiction, may affect the clinician’s use of analgesics, resulting in a cycle of under-treatment of pain. This, in turn, may lead to seemingly aberrant behaviors in children and adolescents with SCD (e.g., clock-watching, requesting specific medications and doses), which are misunderstood
by clinicians as drug-seeking, when in fact they are pain relief-seeking behaviors that disappear with adequate pain control and weaning (Stinson, et al., 2003).

Lack of understanding about the characteristics of SCD pain may contribute to mistrust, stigmatization, and excessive control by health professionals of patients’ pain management, leading to both over- and under-treatment of pain (Franck, et al., 2002). Health care providers should be trained to assess and manage SCD pain so as to not unwittingly dismiss a patient’s pain or cause an exacerbation of pain-related behaviors. Education is important because inconsistent or adversarial care given in these settings can cause mistrust or other problems that affect patients’ relationships with other health care professionals (NHLBI, 2002).

It is also important that providers take the time to listen to concerns voiced by the families of children with SCD so that guidance is provided in a manner that is sensitive to medical and psychosocial needs and that families have assistance in assessing available resources. Failure to consider and appreciate ethnic and cultural differences between providers, patients, and families often contributes to misunderstanding and lack of trust. Education should be provided in an open, non-judgmental, mutually respectful environment. Providers should recognize that personal and cultural beliefs about illness, stress, and support systems affect the way that families respond to the challenge of raising a child with this chronic illness (Lane, Buchanan, Hunter, et al., 2001).

Underdeveloped quality standards for treating children with SCD presenting to the ED is one identified gap (Tanabe, Dias, Gorman, 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 providing consistent standards of care, as are quality of care indicators proposed by Wang and colleagues (Wang, Kavanagh, Little, et al., 2011).

Another 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 is essential. All children with SCD should have a set of baseline laboratory 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. Electronic medical records, patient information cards, and phone calls to patient providers are all means to transmit information quickly during an emergency (NHLBI, 2002).

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).

**Sickle Cell Disease and Medicaid/CHIP**

The majority of children with SCD are enrolled in Medicaid. In 2009, 67 percent of pediatric SCD patients discharged from the hospital were enrolled in Medicaid; only 25 percent had private insurance (AHRQ, 2012). In a study of the Healthcare Cost and Utilization Project (HCUP) 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 public insurance had 1.6 visits per year compared with 1.39 for those with private insurance and 1.10 for the uninsured (Brousseau, Owens, Mosso, et al, 2010).

A study comprising primarily black 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 percent 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 it 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 it was 3.7 (3.4-3.7) (Shankar, Arbogast, Mitchel, 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 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.

**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: No.
e. Service – care for acute conditions: Yes.
g. Service – other (please specify): No.
h. Measure Topic – duration of enrollment: No.
i. Measure Topic – clinical quality: Yes.
k. Measure Topic – family experience with care: No.
l. Measure Topic – care in the most integrated setting: No.
m. Measure Topic other (please specify): 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 11 through 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 (pain assessment within 30 minutes following initial contact in the ED for children with SCD who are experiencing an acute pain episode), that, if followed, results in a desirable clinical outcome (timely and effective treatment of pain). Appropriate management of pain in SCD begins with a prompt and accurate assessment that will inform a feasible treatment plan. The measure highlights where providers or health systems are falling short in providing health care maintenance for children with SCD. Few if any useful measures of pain have been identified for patients with SCD beyond self-reporting. However, the varying abilities of young patients to describe pain, compounded by subjective interpretations by family members and health care providers, make pain assessment a challenging aspect of treatment. Table 5 summarizes several key sources of evidence for this measure, using the US 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.

The painful episodes that are considered characteristic of SCD are believed to result from tissue ischemia caused by occlusion of the vascular beds, which results from the sickling and adhesion of the red blood cells (Pack-Mabien, Haynes Jr, 2009). Most pain episodes have no identifiable cause; known contributors include temperature extremes, dehydration, physical and emotional stress, hypoxemia, and infection (Ellison, Shaw, 2007; Steinberg, 1999). To help prevent the onset of sickle cell pain, patients are advised to stay hydrated; avoid being too hot or too cold; avoid high altitudes (flying, climbing, high cities); avoid exposure to low oxygen levels (exertion); and consider hydroxyurea treatment (Centers for Disease Control and Prevention [CDC], 2014).

Pain rates are inversely proportional to the concentration of fetal hemoglobin (Hb F), which prevents sickling. Pain symptoms begin to occur around 6 months of age when, as expected, Hb F levels begin to decline (Claster, Vichinsky, 2003, Ellison, Shaw, 2007). Young infants and toddlers develop dactylitis (pain in the hands and feet from restricted blood flow) and may be irritable, refuse to walk, or cry when their hands or feet are touched. Typically, after the first few
years of life, interruption of blood flow occurs in the larger bones of the extremities, vertebrae, rib cage, and periarticular structure (tissue around joints), producing painful crises of the bones and joints. In adolescents, common painful sites are the abdomen, chest, and lower back. On average, pain crises persist for 4 to 5 days, though protracted episodes may last for 2 to 3 weeks. Patients may describe pain as throbbing, achy, sharp, or dull (Pack-Mabien, Haynes Jr, 2009). Pain associated with vaso-occlusive episodes usually involves two to three sites and may be migratory. Other commonly affected areas include the lower back, hips, abdomen, and head (Ellison, Shaw, 2007).

Observational approaches to assessing pain in children with SCD include evaluating motor ability and asking family members to note differences from usual behavior patterns. One scale for children 1 to 7 years of age is the Facial expression, Leg movement, Activity, Cry, Consolability (FLACC) pain scale. School-aged children with SCD may be observed for the following behaviors: guarding, bracing, rubbing, grimacing, and sighing. By the time children are 3 to 4 years old, they should be able to use a self-report tool to rate the intensity of pain. Analog, verbal, numerical, and facial scales for assessing pain exist, as do multidimensional tools for adolescents. Whatever approach is used, it is important to choose one tool and use it routinely so that the child and health care provider become familiar with its significance to the individual patient (Stinson, Naser, 2003). Pain management guidelines emphasize the importance of assessing pain using multiple methods to ensure adequate and reliable pain ratings. Multimodal assessment is important when working with children with SCD when parents function as proxy reporters of their child’s pain if the child is too young or otherwise unable to describe the sensation (McClellan, et al., 2009).

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 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 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 the measure numerator, 17 of 435 unique patient records (4 percent) 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 (pain). Therefore, IRR was also assessed for this eligibility criterion. For pain, 25 of 435 unique patient records (6 percent) from Phase 1 of the abstraction process were assessed for IRR across the three testing sites.

Table 6 shows the percent agreement and Kappa statistic for the numerator and the pain eligibility criterion of this measure for each site and across all sites. The overall agreement for the numerator was 100 percent, and the Kappa was 1.00, indicating a perfect IRR level was achieved. The overall agreement for the pain eligibility criterion was 84 percent, and the Kappa was 0.57.
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 measure numerator, there was perfect agreement among the sample of records selected for IRR, and no discrepancies were noted.

For the pain eligibility criterion, 21 of 25 records agreed, resulting in 84 percent agreement and a Kappa score of 0.57. In the case of all four disagreements, one abstractor indicated that there was an acute pain episode when there was documentation of “no pain” without indication of a numeric pain scale used. The other abstractor did not consider documentation of “no pain” as an acute pain episode. It was clarified that to qualify as an acute pain episode, pain had to be assessed on a numeric scale. The abstraction tool was modified to explicitly state this.

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 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).
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 measure do not include indicators of special health care needs.

7.C. Socioeconomic Status

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

7.D. Rurality/Urbanicity

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

7.E. Limited English Proficiency (LEP) Populations

The medical records data abstracted for this measure 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 EHRs at all three sites.

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; 293 records (44 percent) met denominator criteria for this measure.

Based on the abstracted chart data, the rate was calculated as the percentage of children younger than 18 years of age identified as having SCD presenting to an ED with an acute pain episode during the measurement year who had a pain assessment within 30 minutes following initial contact: measure numerator (265) divided by denominator (293). See Table 7 in the Supporting Documents.

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 specifications 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 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 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 13 minutes per eligible SCD case abstracting the data for this measure, with times ranging from 3 to 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?

The 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.
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 presenting to the ED.

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 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 ED 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 for 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 11. Health Information Technology

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

11.A. Health IT Enhancement

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

Health 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 would allow 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.

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 three major SCD treatment facilities in Michigan.

11.C. Health IT Workflow

Please describe how the information needed to calculate the measure may be captured as part of routine clinical or administrative workflow.

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

11.D. Health IT Standards

Are the data elements in this measure supported explicitly by the Office of the National Coordinator for Health IT Standards and Certification (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 results of blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, and pulmonary function tests.

Incorporate clinical lab-test results into the EHR as structured data:

1. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.
2. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes.
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, the 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 sickle cell anemia/SCD.
3. Date and time of treatment.
4. Type of tests administered.
5. Date 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?

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” that 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 percent compliance with these measures, employing the same types of warnings to incentivize action before the time window has expired.

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 with SCD presenting to an ED with an acute pain episode during the measurement year who had a pain assessment within 30 minutes following initial contact. A higher proportion indicates better performance as reflected by appropriate guidance.

This measure is implemented with medical record data from EHR sources. The primary information needed for this measure includes basic date of birth, diagnosis codes, and procedure codes and dates. These data are available, although obtaining them often requires a restricted-use data agreement and Institutional Review Board approval. Analysis of the data also required the development of an abstraction tool and the use of qualified nurse abstractors. Continuing advances in the development and implementation of EHRs may establish the feasibility of regularly implementing this measure with data supplied by EHRs.

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 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. The abstractors also suggested that it may be helpful to explicitly state in the measure specification that a pain assessment of “no pain” qualifies, since it appears in Table 16-A

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(see the technical specifications in the Supporting Documents) as a valid value. 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 Emergency Department Pain Assessment for Children with Sickle Cell Disease, assesses the percentage of children younger than 18 years of age with SCD who present to an ED with an acute pain episode during the measurement year and have a pain assessment within 30 minutes following initial contact. A higher proportion indicates better performance, as reflected by appropriate treatment. This measure was tested using medical record data. There are no existing quality measures for pain assessment in the ED for children with SCD presenting with an acute pain episode.

Pain is the hallmark clinical manifestation of SCD. The acute vaso-occlusive event is a unique type of pain that can start as early as 6 months of age, recur unpredictably over a lifetime, and require treatment with opioids. Treating pain in children with SCD is one of the most daunting challenges of managing the disease. Patients must be reassured that when they do experience pain it will be taken seriously and managed optimally. Accurate and prompt assessment of pain is essential for developing an effective plan for treatment. Clinical guidelines suggest that clinicians should ask about pain and use patients’ reports as the primary source for assessment, except in infants where behavioral observations are the main basis for evaluation. However, pain assessment poses many challenges in infants and preverbal children with SCD, given the subjective and complex nature of vaso-occlusive pain, as well as the development and language limitations that preclude comprehension and self-report. Also, parents may underestimate their child’s pain, and clinicians are sometimes suspicious about the validity of pain scores reported by children. As a result, patients with SCD may be undertreated for pain out of concerns about addiction or other adverse effects like respiratory depression.

Q-METRIC tested this measure among a total of 293 children younger than 18 years of age with SCD. Overall, a pain assessment was conducted within 30 minutes of initial contact in the ED for 90 percent of children with SCD (range among the three hospitals: 75 percent-96 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, 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.

References


Lane PA, Buchanan GR, Hutter JJ, et al. Sickle cell disease in children and adolescents: Diagnosis, guidelines for comprehensive care, and care paths and protocols for management of acute and chronic complications. Revised at the Annual Meeting of the Sickle Cell Disease Care


Section 14: Identifying Information for the Measure Submitter

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The CHIPRA Pediatric Quality Measures Program (PQMP) Candidate Measure Submission Form (CPCF) was approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act.

The OMB Control Number is 0935-0205 and the Expiration Date is December 31, 2015.

Public Disclosure Requirements

Each submission must include a written statement agreeing that, should U.S. Department of Health and Human Services accept the measure for the 2014 and/or 2015 Improved Core Measure Sets, full measure specifications for the accepted measure will be subject to public disclosure (e.g., on the Agency for Healthcare Research and Quality [AHRQ] and/or Centers for Medicare & Medicaid Services [CMS] websites), except that potential measure users will not be permitted to use the measure for commercial use. In addition, AHRQ expects that measures and full measure specifications will be made reasonably available to all interested parties. "Full measure specifications" is defined as all information that any potential measure implementer will need to use and analyze the measure, including use and analysis within an electronic health record or other health information technology. As used herein, "commercial use" refers to any sale, license or distribution of a measure for commercial gain, or incorporation of a measure into any product or service that is sold, licensed or distributed for commercial gain, even if there is no actual charge for inclusion of the measure. This statement must be signed by an individual authorized to act for any holder of copyright on each submitted measure or instrument. The authority of the signatory to provide such authorization should be described in the letter.

AHRQ Publication No. 14(18)-P007-10-EF
April 2018