# **Methodology Report**

Difference in Median Times to Pain Medication Between Adult Patients With a Diagnosis of Sickle Cell Disease (SCD) With Vaso-Occlusive Episode (VOE) and Renal Colic

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## **Executive Summary**

## **Background**

The American Society of Hematology (ASH) contracted with Health Services Advisory Group, Inc. (HSAG) to develop an electronic clinical quality measure (eCQM) that drives quality improvement for patients with sickle cell disease (SCD). As part of the measure development process, HSAG and ASH convened a technical expert panel (TEP) composed of clinical experts in hematology and emergency medicine, as well as patient representatives, to contribute input into the development of the measure. The project team developed four measure concepts related to SCD and presented these concepts to patients and caregivers affected by SCD to assess which concept was most meaningful to them for making health care decisions. Seventy percent (14/20) of the respondents indicated that management of acute severe pain episodes was the most meaningful concept.

The TEP prioritized a measure for further development and testing that compared the timing of initial pain medication to a clinically similar patient population to facilitate within-ED comparisons. The TEP selected renal colic as an appropriate comparison group to SCD based on similarities in pain intensity, pain management approaches, Emergency Severity Index (ESI) classification, and treatment urgency, upon presentation to the ED. The following patient-centered facility-level eCQM to assess the timing of pain management for patients who present to the emergency department (ED) with a diagnosis of SCD with vaso-occlusive episode (VOE) compared to patients who present to the ED with renal colic:

**Measure Title:** Difference in median times to pain medication between adult patients with a diagnosis of sickle cell disease (SCD) with vaso-occlusive episode (VOE) and renal colic

**Measure Description:** Difference in median times in minutes from ED arrival to initial administration of pain medication between adult patients with a principal diagnosis of SCD with VOE and adult patients with a principal diagnosis of renal colic

ASH recommends this measure be used for internal quality improvement and plans to collaborate and offer technical resources to EDs and other organizations interested in implementing the measure in quality improvement programs and software platforms.

#### Methods

Measure score reliability testing was conducted using data extracted from 25 EDs across nine states (DE, GA, IL, MD, MO, NC, NY, SC, WI). A variety of electronic health record (EHR) systems were tested: Cerner (N = 1), Epic (N = 16), Meditech (N = 7), and Allscripts (N=1). Data across these ED sites included a mix of trauma levels and academic medical centers in urban and rural areas. The final data set for analysis of the measure included 7,707 qualifying encounters for patients with a principal diagnosis of SCD with VOE occurring between January 1, 2020, and December 31, 2021.

A qualifying encounter is defined as:

- An ED visit for which the arrival time occurred during the two-year measurement period (i.e., between January 1, 2020, and December 31, 2021), and
- The encounter requires a principal diagnosis of SCD with VOE or renal colic, and
- The encounter requires at least one qualifying pain medication administered in the ED between the arrival and discharge date and time.



Room for improvement was assessed by analyzing the distribution of measure scores across the sampled EDs. Measure score reliability was evaluated using a split-half correlation analysis. Data element validity was assessed by comparing electronically extracted data with manually abstracted records for key data fields, including ED Arrival Date/Time, Medication Name, Medication Administration Date/Time, and Principal Diagnosis. Standardized rules were applied to resolve discrepancies and assess agreement. Face validity was systematically evaluated by surveying experts, including hematologists, ED physicians, and a patient/caregiver representative, who were asked whether they agreed that the measure reflects its intended focus of assessing the comparison of the median time of pain medication administration between patients with a diagnosis of SCD with VOE and patients with renal colic. Feasibility was assessed by ensuring that scoring data elements were accurate, standardized, integrated in provider workflows, and extractable from EHRs. Harmonization was achieved by aligning data element definitions with similar elements in other quality measures where possible.

### **Key Findings**

#### Importance

- SCD is the most common inherited blood disorder and estimated to affect approximately 100,000 individuals in the United States.<sup>1</sup>
- The National Academies of Sciences, Engineering, and Medicine,<sup>2</sup> the U.S Department of Health and Human Services,<sup>3,4</sup> and the Centers for Medicare & Medicaid Services (CMS)<sup>5,6</sup> all support improving acute pain management for patients with SCD.
- From 1999 to 2020, pain accounted for three-fourths of the estimated 222,612 annual ED visits by patients with SCD, which represents a 13% increase from the 197,333 visits estimated for 1999 to 2007.<sup>7</sup>
- Approximately 80% of patients with SCD report avoiding the healthcare system and live with chronic pain that is undermanaged.<sup>8</sup> When they do seek emergency care due to an acute severe pain crisis, patients have been shown to wait an average of 90 minutes before analgesics are given.<sup>9</sup>
- Seventy percent (14/20) of patients and caregivers affected by SCD indicated that pain management for acute severe pain episodes was the most meaningful and patientcentered measure concept.
- The mean measure score was 18.2 minutes, indicating that, on average, patients with SCD and VOE waited 18.2 minutes longer for pain medication than those with renal colic. Scores ranged from -13.0 to 73.0 minutes, with a median of 15.3 minutes. These findings demonstrate a clear opportunity to improve equitable pain management for patients with SCD. The measure is supported by the ASH 2020 Guidelines for SCD Management of Acute and Chronic Pain<sup>10</sup> and the National Heart, Lung and Blood Institute: Evidence-Based Management of SCD Expert Panel Report, published in 2014.<sup>11</sup> Both guidelines recommend rapid initiation of treatment with analgesia, with the ASH guideline additionally specifying rapid treatment to be within one hour (60 minutes) of ED arrival.



Reducing the administration time of pain medication for patients who present to the ED with a diagnosis of SCD with VOE improves several patient outcomes, including improved patient experience and patient-centered care,<sup>12</sup> and access to guideline-recommended treatments.<sup>13</sup> Admission rates<sup>14</sup> and hospital length of stays may also be reduced.<sup>14-16</sup>

#### Scientific Acceptability

- The measure performance score was highly reliable, which indicates that the measure can differentiate performance between facilities. Reliability estimates (Pearson correlation coefficients corrected with the Spearman-Brown prophecy formula to account for the split-half design) from the 3,000 bootstrap replicates had a mean of 0.73 and an estimated 95% confidence interval of 0.67 to 0.95. This indicates high reliability of the measure score.
- Patient/encounter level (data element) validity testing of all critical data elements demonstrated acceptable reliability, ranging from 85.4% to 95.8%. Medication Administration Date/Time was the data element with the lowest agreement. Discrepancies were due to initial data extraction errors and ambiguities in mapping chart data to discrete fields, which were resolved through specific mismatch rules. Time differences between manual and electronic records were minimal, averaging 4.6 minutes for ED Arrival and 7.3 minutes for Medication Administration earlier than extracted data. These findings affirm the validity of the data elements.
- The TEP reviewed the final measure specifications and testing results, and 100% (7/7) agreed that the measure, specified for adult patients, reflects its intended focus of assessing the comparison of the median times of pain medication administration between patients with SCD and patients with renal colic, an indication that the measure has good face validity.

#### Feasibility

A standardized scorecard was used to assess the feasibility of the measure. All critical
data elements required to calculate the measure score from EHRs were found to be
available, accurate, and codified using nationally accepted vocabularies. All data
elements were generated during the ordinary course of care, thereby having no or
minimal impact on provider workflow.

#### Equity

- Individuals with SCD face health inequities stemming from socioeconomic factors, including disease stigma, racial prejudice, and lack of access to specialized care.<sup>17-19</sup>
- In socioeconomically deprived areas, patients with SCD have higher rates of SCD complications, leading to increased health system utilization and higher readmission rates.<sup>20,21</sup>
- Individuals with SCD, a majority of whom are African Americans, often face discrimination because of repeated acute care visits and are often characterized as having "drug-seeking" behavior.<sup>22</sup>



 A study demonstrated health inequities for adult patients with SCD, who, despite higher arrival pain scores and triage acuity levels, experienced longer time to initial analgesia when compared with patients with renal colic.<sup>23</sup>

#### Harmonization

- There are currently no consensus-based entity (CBE)-endorsed measures that specifically evaluate the timing of administration of pain medications for patients with a diagnosis of SCD with VOE or compare the timing of initial pain administration to other patient populations.
- The measure specifications align with existing measures implemented in the ED setting for the Hospital Outpatient Quality Reporting (OQR) Program that contain data elements related to arrival to the ED.
- The critical data elements used in the measure are consistent with the standard set of data elements as defined by the United States Core Data for Interoperability (USCDI), version 5.<sup>24</sup>

#### **Conclusion**

In summary, the *Difference in Median Times to Pain Medication Between Adult Patients With a Diagnosis of Sickle Cell Disease (SCD) With Vaso-Occlusive Episode (VOE) and Renal Colic is a feasible and highly reliable eCQM that could be implemented with minimal burden in EDs nationally.* The measure addresses a critical quality gap identified by patients with SCD and has been prioritized by a multidisciplinary TEP. Reducing the time to analgesia for patients with SCD with VOE has been shown to improve patient outcomes, including reduction in pain severity, admission rates, and hospital length of stays, as well as improved patient experience.



## 1. Introduction

The American Society of Hematology (ASH) contracted with Health Services Advisory Group, Inc. (HSAG) to develop an electronic clinical quality measure (eCQM) that drives quality improvement for patients with sickle cell disease (SCD). SCD is a condition where red blood cells, which are normally biconcave in shape, take on an irregular morphology known as sickled. The sickling of red blood cells increases the risk of clumping, causing blockage and impeding blood supply to the organs leading to ischemia, and is often associated with significant pain. As part of the measure development process, HSAG and ASH convened a Technical Expert Panel (TEP) comprised of clinical experts in hematology and emergency medicine as well as patient representatives to contribute input into the development of the measure. The TEP prioritized development of the following facility-level eCQM focused on timely administration of pain medication for patients who present to the emergency department (ED) with SCD and Vaso-Occlusive Episode (VOE) compared to patients who present to the ED with renal colic:

**Measure Title:** Difference in median times to pain medication between adult patients with a diagnosis of sickle cell disease (SCD) with vaso-occlusive episode (VOE) and renal colic

**Measure Description:** Difference in median times in minutes from ED arrival to initial administration of pain medication between adult patients with a principal diagnosis of SCD with VOE and adult patients with a principal diagnosis of renal colic

## 1.1 Development of the Measure Concept

Prior to developing the measure, the project team conducted an environmental scan to identify quality measurement gaps related to SCD for the development of different measure concepts for prioritization. To ensure the selected measure concepts were evidence-based, clinical practice guidelines focused on SCD treatment were reviewed if the guidelines were U.S.-based, were published within the past 10 years, and used a systematic method of grading evidence and developing clinical recommendations. The following four measure concepts emerged from this work: (1) readmissions for VOE; (2) patients who develop acute chest syndrome; (3) pain management; and (4) patients who develop a stroke.

Next, the project team conducted a survey of 14 patients and six caregivers affected by SCD and asked these individuals to indicate which of the four measure concepts were most meaningful to them to improve care for patients with SCD. Of the 20 respondents, 70.0% (10 patients and 4 caregivers) indicated that pain management for acute severe pain episodes was the concept that was most meaningful. The project team then presented the four measure concepts to the TEP along with findings from the patient and caregiver survey for prioritization. The TEP favored the pain management measure concept for further development and emphasized the importance of developing a pain management measure that incorporates a comparator group to highlight differences in treatment timeliness between patients with a diagnosis of SCD and VOE and other similarly presenting patients. This recommendation aligned with the goal of developing an equity-oriented outcome measure that could identify treatment delays experienced by patients with a diagnosis of SCD and VOE in the ED. Based on this input, the project team began evaluating potential comparator groups to determine which patient populations would provide the most appropriate and interpretable comparison.

To develop a measure concept focused on a comparable patient population, the project team evaluated the pain management literature for patients with a principal diagnosis of cancer, migraine, and renal colic. These conditions were selected based on their similarities to SCD in terms of pain intensity, pain management approaches, Emergency Severity Index (ESI) classifications, and treatment urgency. Based on preliminary testing results, the TEP recommended using renal colic as the comparator cohort,



as its analgesic treatment most closely aligned with that for patients with SCD, and cancer and migraine were eliminated as comparator groups. The cancer cohort was excluded due to a low number of ED encounters with a principal diagnosis of cancer in the test sample, and the migraine cohort was excluded because migraine pain is often treated with medications other than analgesics, such as selective serotonin receptor agonists.

Although this measure was not posted for public comment during the measure development process, ASH received comments on the *Median Time to Pain Medication for Patients with a Diagnosis of Sickle Cell Disease (SCD) with Vaso-Occlusive Episode (VOE)* quality measure, and those comments are included in that measure's methodology report, available at: <a href="https://www.hematology.org/education/clinicians/guidelines-and-quality-care/hematology-quality-metrics">https://www.hematology.org/education/clinicians/guidelines-and-quality-care/hematology-quality-metrics</a>.

## 1.2 Importance

#### 1.2.1 Sickle Cell Disease

SCD is the most common inherited blood disorder and estimated to affect approximately 100,000 individuals in the United States. SCD is most prominent among Black or African American patients—affecting 1 out of 365 Black or African American births—and the average life expectancy of publicly insured individuals with SCD is reported to be approximately 52.6 years of age. Therefore, although SCD is a low prevalence condition, it is important, as its impact on affected patients, their families, and the community is profound. The medical and non-medical costs of SCD have a large economic toll. Based on a 2022 systematic review and landscape analysis, costs were higher for SCD patients when compared with non-SCD individuals, with the total annual costs per patient within the general SCD population ranging from \$14,012 to \$80,842 per patient per year.

The National Academies of Sciences, Engineering, and Medicine,<sup>2</sup> HHS,<sup>3,4</sup> and CMS<sup>5,6</sup> all support improving acute pain management for patients with SCD. In 2020, the National Academy of Medicine (NAM) published a strategic plan and blueprint for action to address SCD with a special emphasis on enhancing the quality of care provided to patients presenting with pain.<sup>2</sup> Evidence suggests that up to 80% of patients with SCD report avoiding the healthcare system whenever possible and live with chronic pain that is undermanaged.<sup>8</sup> When they do seek emergency care due to an acute severe pain crisis, studies have shown patients wait an average of 90 minutes before analgesics are given.<sup>9,27</sup>

ED visits are common among patients with SCD. Based on data from California and Georgia from the Centers for Diseases Control and Prevention (CDC), roughly 40% of patients with SCD had at least one ED visit or hospital admission for a pain crisis or VOE crisis in 2015.<sup>28</sup> In addition, updated data from the National Hospital Ambulatory Medical Care Survey (NHAMCS) show that from 1999 to 2020, of the 222,612 estimated yearly average number of ED visits by patients with a diagnosis of SCD, three-fourths were due to a complaint of pain.<sup>7</sup> Compared with prior estimates (1999 to 2007), the overall volume of ED visits has increased by nearly 13%.<sup>7</sup> Individuals with SCD face health inequities stemming from socioeconomic factors, including disease stigma, racial prejudice, and lack of access to specialized care.<sup>17-19,29</sup> In socioeconomically deprived areas, patients with SCD have higher rates of SCD complications, leading to increased health system utilization and higher readmission rates.<sup>20,21</sup> Individuals with SCD, a majority of whom are African Americans, often face discrimination because of repeated acute care visits and are often characterized as having "drug-seeking" behavior.<sup>22</sup> A survey of providers delivering clinical care for individuals with SCD reported that the most common barriers to prescribing opioids to patients with SCD were drug dependence (63%), tolerance (60%), and addiction (54%).<sup>30</sup> This negative perception from healthcare providers contributes to the fact that 77% of young



adults with SCD avoid the healthcare system whenever possible and suboptimally manage pain at home.<sup>31</sup> These patients are particularly at risk for poor outcomes, including early death, during the transition period between pediatric and adult care.<sup>32-35</sup> These inequities were also demonstrated in a study of adult patients with acute pain from SCD and renal colic in an ED. This study showed that despite higher arrival pain scores and triage acuity levels, patients with SCD experienced longer time to initial analgesia when compared to patients with renal colic.<sup>23</sup> In a different study of patients with SCD, opioids were not given within 60 minutes for more than 40% of ED visits for pain, and females and individuals on public insurance were shown to have a significantly longer time to receipt of opioid treatment.<sup>36</sup>

The implementation of an eCQM targeting timing to administration of pain medication for adult and pediatric patients with SCD presenting to the ED may significantly impact pain management and other outcomes, including admission rates, 14 hospital length of stay, 14-16 length of ED stay, 16,27,37 and patient satisfaction. 12 A study published in 2017 by Kim, et al., found that implementing guideline recommendations regarding time to administration of analgesia for treatment of SCD pain crisis reduced the time to first pain medication by approximately 33% in addition to significantly improving patient satisfaction scores. 12 Other factors that have been found to aid in achieving a decreased time to analgesia for SCD patients presenting to the ED include the use of standardized SCD order sets, intranasal fentanyl, and individualized pain plans. 12,14,38,39

This measure may also enhance patients' access to care by increasing the number of patients with SCD receiving guideline-recommended treatment. In a 2022 study, establishing a quality measure based on guideline-recommended pain management increased the percentage of patients with SCD receiving analgesia within 60 minutes of triage from 17 to 72 percent.<sup>13</sup> The health inequities faced by patients with SCD may also be addressed by this measure, as by adopting evidence-based care for SCD, healthcare institutions can address and mitigate the effects of implicit biases that may contribute to disparities in pain management. <sup>12,40,41</sup>

To promote rapid, effective, and safe analgesic management and resolution of VOE, the 2014 National Heart, Lung and Blood Institute (NHLBI) Evidence-Based Management of Sickle Cell Disease Expert Panel Report<sup>42</sup> recommends the use of an individualized prescribing and monitoring protocol or an SCD-specific protocol whenever possible. Individualized care plans, developed by the patient's SCD clinician, are based on the patient's home opioid consumption and effective dosing from previous ED visits. The plan is made available to ED clinicians via the electronic health record and provide direction on pain management. Individualized prescribing and monitoring protocols in patients with SCD have demonstrated decreased time to first opioid,<sup>43</sup> shorter ED and hospital length of stay<sup>44,45</sup> and more rapid reduction in pain scores,<sup>46</sup> when compared with weight-based dosing.

#### 1.2.2 Renal Colic

Renal colic serves as a clinically relevant comparator cohort for patients with SCD and VOE because both conditions are characterized by sudden onset of severe pain requiring urgent intervention. Both groups frequently report pain scores of 8 out of 10 or higher at triage, making this comparison valuable for assessing timeliness and equity in emergency pain management.<sup>47</sup>

Additionally, renal colic patients have a similarly urgent need for treatment. The Emergency Severity Index (ESI) Handbook recommends assigning these patients the same triage level, stating, "Patients experiencing severe pain or distress as a result of a systemic disruption, for example, renal colic, cancer, or sickle cell crisis, should be triaged as ESI level 2, and placement should be facilitated as quickly as possible." Typically caused by ureteral obstruction from kidney stones, renal colic presents abruptly with severe flank or abdominal pain that is often described as among the most intense types of acute pain encountered in clinical settings. Given the severity of renal colic, prompt and effective pain



relief is a primary goal in the ED to alleviate patient suffering while awaiting definitive diagnosis or further treatment, reduce the risk of return ED visits, and avoid prolonged hospital stays.<sup>49,50</sup>

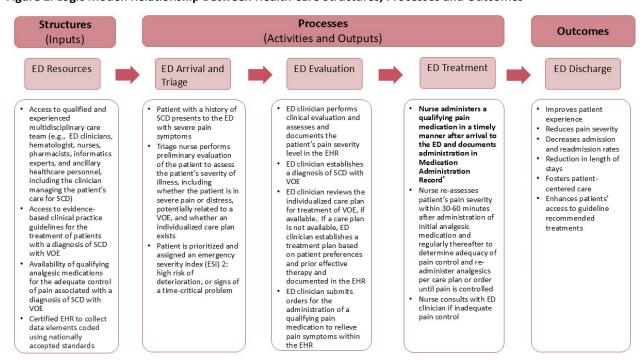
In the United States, renal colic accounts for an estimated 1 to 2 million ED visits annually, based on national data from 2011 and extrapolated estimates published through 2019. These visits are associated with significant healthcare expenditures, exceeding \$10 billion annually.<sup>51</sup> In the United States, the lifetime prevalence of kidney stones among adults has remained relatively stable over the past decade at around 9–10%, with a significant rise observed among women.<sup>52</sup>

Timely and effective pain control is a central objective in the emergency management of renal colic.<sup>49</sup> Several meta-analyses and systematic reviews, including evidence-based clinical resource information on "acute pain control for renal colic," recommend nonsteroidal anti-inflammatory drugs (NSAIDs) as a preferred initial treatment due to their demonstrated efficacy in reducing pain severity, lowering the need for rescue analgesia, and minimizing side effects such as nausea when compared to opioids.<sup>49,53-55</sup> When NSAIDs are contraindicated or insufficient, opioids remain an appropriate and effective option for achieving rapid pain control, particularly when tailored to the patient's clinical presentation. This treatment framework parallels that used in the treatment of severe acute pain, such as in patients with SCD and VOE, where both NSAIDs and opioids can be effective treatment options based on the patient's individualized care plan. While no universal benchmark for analgesic timing exists for patients who present to the ED with symptoms of renal colic, expert recommendations support pain medication administration within 30 to 60 minutes of ED arrival to improve outcomes and patient experience.<sup>47,56</sup>

## 1.3 Logic Model

The following diagram is a logic model that depicts the inputs, activities and outputs, and outcomes to describe the associations between the healthcare structures and processes, and the desired health outcomes related to the implementation of this process measure.

Figure 1. Logic Model: Relationship Between Health Care Structures, Processes and Outcomes



<sup>\*</sup>Represents the focus of the measure



#### 1.4 Clinical Practice Guidelines

The measure is supported by several clinical practice guidelines recommending rapid initiation of treatment with analgesia for patients with SCD and renal colic. Table 1 outlines key recommendations for pain management from relevant guidelines for both SCD and renal colic, including the strength of recommendations and the certainty or quality of the evidence, where available.

**Table 1. Clinical Guideline Recommendations** 

Clinical Practice Guideline Developer	Recommendation	Strength of Recommendation	Grade of Evidence
American Society of Hematology 2020 Guidelines <sup>10</sup>	For adults and children with SCD presenting to an acute care setting with acute pain related to SCD, the ASH guideline panel recommends rapid (within 1 hour of ED arrival) assessment and administration of analgesia with frequent reassessments (every 30–60 minutes) to optimize pain control.	Strong recommendation	Low certainty of evidence
National Heart, Lung and Blood	In adults and children with SCD and a VOC associated with severe pain, rapidly initiate treatment with parenteral opioids.	Strong recommendation	High quality evidence
Institute <sup>42</sup>	Rapidly initiate analgesic therapy within 30 minutes of triage or 60 minutes of registration.	Expert opinion	No grade
European Association of Urology: 2025	Offer a non-steroidal anti-inflammatory as the first drug of choice; depending on cardiovascular risk factors and side effects.	Strong	1b – Individual RCT with narrow confidence interval
Guidelines on Urolithiasis <sup>57</sup>	Offer opiates (hydromorphine, pentazocine or tramadol) as a second choice.	Weak	1b - Individual RCT with narrow confidence interval

## 2. Methods

This section outlines the approach used to develop and operationalize the measure specifications (Appendix A) and details the methodology for assessing measure performance. Additionally, this section describes the methods used to evaluate the measure's reliability and validity and conduct feasibility testing.

## 2.1 Measure Specification Development

The following information defines qualifying ED encounters and pain medications.

## 2.1.1 Qualifying ED Encounters

To perform the analysis of overall measure performance, the project team defined a qualifying encounter as:

- An ED visit for all patients, aged 18 years or older, for which the arrival time occurred during the two-year measurement period (i.e., between January 1, 2020, and December 31, 2021), and
- A principal encounter diagnosis of SCD with VOE or renal colic, and
- At least one qualifying pain medication administered during the ED encounter between the arrival and discharge date and time.



#### 2.1.2 Qualifying Pain Medications

To perform the testing of the qualifying pain medications, the project team's pharmacist compiled a broad list of drugs not only based on the ASH 2020 guidelines for sickle cell disease: management of acute and chronic pain, 10 but also informed by medications commonly used in EDs to treat other severe acute pain conditions, such as renal colic. The broad list of generic pain medications was then organized into four distinct categories.

- 1. Opioids
- 2. Opioid combinations
- 3. Nonsteroidal anti-inflammatory drugs (NSAIDs)
- 4. Other analgesic agents

Notably, for testing we collected data for only the first qualifying pain medication administered in the ED; therefore, if multiple medications were administered with the same time stamp, the testing dataset only contains information for one of these medications, selected at random.

The TEP favored creating a broad list of pain medications because this allows for greater clinician flexibility in establishing the most appropriate pain management treatment plan for each individual and would capture any pain medications administered. From medications within these categories, several that were not considered clinically appropriate (e.g., acetaminophen-based cough and cold medications, phenazopyridine) were excluded. The final list of included generic pain medications is provided in Appendix B. Generic List of Qualifying Pain Medications.

## 2.2 Measure Performance Scoring Methodology

This section describes the methodology used to assess measure performance. The measure is a continuous variable measure calculated as the difference in median time (in minutes) from ED arrival to initial administration of pain medication for adult patients with a principal diagnosis of SCD with VOE minus the median time for adult patients with renal colic.

Opportunity for improvement in measure scores was assessed by examining descriptive statistics (e.g., mean, standard deviation, and percentiles) for the distribution of measure scores across the sampled EDs for each population group. In particular, comparing the median with the 10th percentile (where lower scores are better) was used to determine the minimum improvement in measure scores that can be expected between a middle-ranked and a top-performing ED.

## 2.3 Reliability Testing Methodology

#### 2.3.1 Data Extracts from Measure Testing Sites

To test the measure, data were obtained from 25 EDs across nine states (DE, GA, IL, MD, MO, NC, NY, SC, WI). A variety of EHR systems were tested: Cerner (N = 1), Epic (N = 16), Meditech (N = 7), and Allscripts (N = 1). Each ED provided a data extract containing clinical information for a two-year period from January 1, 2020, through December 31, 2021. The data extract included de-identified metadata about each ED, such as the type of EHR, state, urban-rural designation, academic/non-academic designation, trauma level and type of ED (i.e., freestanding or non-freestanding). The data extract also included de-identified patient-level and de-identified ED encounter-level information such as the arrival date and time; discharge date and time; discharge disposition; principal diagnosis; first pain medication administered, including the medication name and administration date and time; and pain medication



code system. Finally, the data extract included patient characteristics such as age, sex, race, ethnicity, and payer.

#### 2.3.2 Measure Performance Score Reliability

Measure performance score reliability was conducted using a split-half design where eligible encounters in each ED observed over the two-year period were randomly divided into two subsamples, for each clinical population (SCD with VOE and renal colic). Median time (in minutes) from ED arrival to initial administration of pain medication for patients with a diagnosis of SCD with VOE minus the median time for patients with renal colic was calculated for each split half in each ED, and the correlation between the two split halves across all EDs was calculated using the Pearson correlation coefficient, corrected for the split-half design using the Spearman-Brown prophecy formula. Values of the correlation coefficient that are closer to 1.0 indicate greater measure score reliability. Since each random split can produce different reliability estimates by chance, we evaluated variation in reliability using bootstrap analysis. The distribution of reliability statistics was estimated by resampling the original data with replacement (stratified by ED), resulting in a new dataset with an identical sample size as the original measure cohort. Each replicate dataset (3,000 replicates) was split into two halves, and the correlation between measure scores across EDs was calculated from the two halves as above. The mean of this distribution of correlation coefficients was taken as the overall reliability of the measure score, and a confidence interval for the correlation coefficient was estimated using the 2.5th and 97.5th percentiles.

## 2.4 Validity Testing Methodology

### 2.4.1 Data Element Validity

Data element validity testing was conducted to evaluate the agreement between manually abstracted data and electronically extracted data from EHRs for critical data elements used in eCQM calculation. Data were collected from two ED sites using different EHR systems (Cerner and Epic). Each site provided a data extract of all qualifying encounters, and a random sample of 48 encounters was selected for manual abstraction. One physician per site manually abstracted data for these encounters. Key data elements assessed for validity testing included ED Arrival Date/Time, Medication Name, Medication Administration Date/Time, and Principal Diagnosis. Percent agreement was calculated for each data element to assess reliability.

Ambiguities in mapping chart data to discrete EHR fields were resolved using standardized rules. Medication Name mismatches were reconciled if the abstractor noted, or medical record reviews confirmed both medications were administered. Errors resulting from manual abstraction of incorrect fields were corrected upon re-review of medical records. Principal Diagnosis mismatches were resolved if codes were in the same diagnostic family. Additionally, time differences between manually abstracted and electronically extracted data were measured for ED Arrival Date/Time and Medication Administration Date/Time. Testing adhered to the Consensus Based Entity (CBE) thresholds, which establishes a 70% agreement as an acceptable threshold.<sup>58</sup>

## 2.4.2 Systematic Assessment of Face Validity

To systematically assess face validity, we surveyed a group of experts, which were comprised of pediatric and adult hematologists and emergency medicine physicians, as well as a patient/caregiver representative. We asked each individual to indicate whether they agree or do not agree with the following question:



- 1. Do you agree that the measure reflects its intended focus of assessing the comparison of the median time of pain medication administration between patients with a diagnosis of SCD and VOE and patients with renal colic, based on your experience?
  - a. Yes, I agree.
  - b. No, I do not agree.

## 2.5 Feasibility Testing Methodology

Feasibility testing consisted of an assessment of the extent to which the data elements required to construct and calculate the measure scores are available in discrete fields within the EHR system, are accurate, are coded using nationally accepted terminology standards, and are routinely collected as part of current clinical workflow, thereby requiring minimal to no added burden for providers to collect. Feasibility testing was performed using two different EHR systems (i.e., Meditech and Epic) in three different ED sites.

To evaluate the feasibility of data elements, each of the three ED sites completed eCQM feasibility scorecards. The six critical data elements used in the measure was evaluated for data availability, data accuracy, data standardization, and impact on clinical workflow:

- 1. Age (proxy for Birthdate)
- 2. Diagnosis: Sickle Cell Disease with Vaso Occlusive Episode
- 3. Medication Administered: Analgesic
- 4. Medication, Administered: Analgesic Date Time
- 5. ED Arrival Date Time
- 6. ED Discharge Date Time

A feasibility assessment informs whether the measure could be tested using data derived from discrete fields from the ED's EHR and whether changes to clinical workflows would be needed to collect the necessary data elements if the measure were implemented for accountability or internal quality improvement purposes.

## 3. Results

This section provides the results of analyses that informed the specifications of the measure, including patient-encounter-level (data element) validity testing for critical data elements. This section also provides the results of the assessments of the reliability of the measure scores, as well as the feasibility assessment results.

## 3.1 Sample Characteristics

The data sample used to test the measure included 25 ED sites from nine states (DE, GA, IL, MD, MO, NC, NY, SC, WI). Facilities varied in characteristics such as EHR system type, urban/rural, and academic designation. Three were rural and two were free-standing ED sites. Table 2 shows the characteristics of the ED sites included in testing the measure.



Table 2. Characteristics of ED Sites

ED Site	State	EHR System Type	Urban/Rural Designation	Academic Designation	ED Type Free-Standing	ED Trauma Level
1	GA	Meditech	Urban	Academic	No	Obtaining Level 1
2	SC	EPIC	Urban	Academic	No	1
3	IL	EPIC	Urban	Academic	No	1
4	GA	EPIC	Urban	Academic	No	2
5	GA	EPIC	Urban	Academic	No	2
6	SC	EPIC	Urban	Academic	No	No designation
7	МО	EPIC	Urban	Academic	No	No designation
8	GA	Meditech	Urban	Academic	No	Obtaining Level 1
9	GA	EPIC	Rural	Academic	No	4
10	SC	EPIC	Urban	Academic	Yes	3
11	GA	EPIC	Urban	Academic	No	1
12	МО	EPIC	Urban	Academic	No	No designation
13	GA	EPIC	Rural	Non-academic	No	2
14	NY	Meditech	Urban	Academic	No	2
15	SC	EPIC	Urban	Academic	No	No designation
16	GA	EPIC	Rural	Academic	No	4
17	SC	EPIC	Urban	Academic	Yes	No designation
18	NY	Meditech	Urban	Academic	No	1
19	MD	Meditech	Urban	Academic	No	No designation
20	NC	Meditech	Urban	Non-academic	No	3
21	SC	Meditech	Urban	Academic	No	No designation
22	DE	Cerner	Urban	Academic	No	1
23	WI	Epic	Urban	Academic	No	1
24	NY	Allscripts	Urban	Academic	No	2
25	NY	Epic	Urban	Academic	No	2

The sample used for measure score reliability included 7,707 unique encounters for patients with a diagnosis of SCD and VOE who satisfied the inclusion criteria across 25 ED sites. There were slightly more ED encounters with arrival dates in 2021 (N=4,217, 54.7%) than in 2020 (N=3,490, 45.3%). The number of qualifying encounters across ED test sites ranged from 47 to 1,421 over the two-year period (Table 3).

For the renal colic population, 8,220 unique encounters met the inclusion criteria for the measure across 25 ED sites. Of note, disparities testing was not performed for this population.



Table 3. Qualifying ED Encounters by ED Site

ED Site	Number of Qualifying Encounters with SCD with VOE	Number of Qualifying Encounters with Renal Colic
25	1,421	885
2	1,278	180
1	814	471
3	537	210
24	495	1009
7	351	141
4	294	478
21	276	347
22	265	745
5	263	324
9	232	492
6	179	112
8	176	156
10	157	234
12	134	146
14	129	85
23	122	195
17	115	248
15	97	113
13	92	728
16	74	303
20	62	370
18	50	111
11	47	74
19	47	63
Total	7,707	8,220

The 7,707 qualifying encounters for SCD with VOE represented 4,680 unique patients. The average patient age for this group was 32.5 years (SD = 8.9) at ED arrival. In contrast, the 8,220 qualifying encounters for renal colic represented 7,899 unique patients. The patients treated for renal colic were generally older, with a mean age of 45.6 years (SD = 15.1). While the majority of patients in the SCD and VOE group were female (58.6%), the renal colic population group had a higher proportion of males (56.9%). The racial and ethnic compositions also differed significantly between the two population groups. Nearly all patients with SCD and VOE were Black or African American (97.6%), whereas the renal colic group was predominantly White (61.3%), with Black or African American patients comprising just 21.5%. Additionally, the SCD with VOE population was overwhelmingly not Hispanic or Latino (94.0%), compared to 81.9% in the renal colic group, which included a larger proportion of Hispanic or Latino patients (9.7% vs. 1.6%).

Insurance coverage also varied notably between the two population groups. Patients with SCD and VOE were more likely to be insured through Medicaid (40.8%) or Medicare (33.3%). In contrast, the renal colic population had a more diverse payer mix, with the most common primary payer listed as "Other" (43.7%), followed by private insurance (27.4%), Medicaid (14.3%) and Medicare (12.3%), (Table 4).



**Table 4. Demographics for Patients with Qualifying ED Encounters** 

Demographic	SCD with VOE	Renal Colic
Qualifying Encounters, N	7,707	8,220
Total Unique Patients, N	4,680	7,899
Age, years		
Mean ± Std Dev	32.5 (8.9)	45.6 (15.1)
Median (Range)	31 (57)	45 (79)
Sex, N (% of total)		
Female	2,744 (58.6%)	3,400 (43.0%)
Male	1,936 (41.4%)	4,497 (56.9%)
Unknown or Missing	0 (0.0%)	2 (0.0%)
Race, N (% of total)		
Black or African American	4,566 (97.6%)	1701 (21.5%)
White	38 (0.8%)	4846 (61.3%)
American Indian or Alaska Native	3 (0.1%)	19 (0.2%)
Asian	2 (0.0%)	395 (5.0%)
Native Hawaiian or Other Pacific Islander	0 (0.0%)	6 (0.1%)
Other	32 (0.7%)	641 (8.1%)
Unknown or Missing	39 (0.8%)	291 (3.7%)
Ethnicity, N (% of total)		
Not Hispanic or Latino	4,400 (94.0%)	6467 (81.9%)
Hispanic or Latino	74 (1.6%)	770 (9.7%)
Unknown or Missing	206 (4.4%)	662 (8.4%)
Payer, N (% of total)		
Medicaid	1.902 (40.6%)	1,133 (14.3%)
Medicare	1.562 (33.4%)	974 (12.3%)
Private	359 (7.7%)	2,161 (27.4%)
Other	671 (14.3%)	3,451 (43.7%)
Missing	186 (4.0%)	180 (2.3%)

#### **3.2 Measure Performance Score Results**

The mean difference in time to pain medication between patients with SCD with VOE and those with renal colic across sites was 18.2 minutes (SD = 20.0, N = 25), and the median of measure scores across sites was 15.3 minutes. The distribution of the measure scores is presented in Table 6 and individual measure scores by site are presented in Table 7. The measure scores ranged from -13.0 to 73.0 minutes. The difference between the median and the 10th percentile of the distribution of scores, where lower scores indicate better performance, was 18.3 minutes—a 120% difference. In addition, the bottom-performing 10% of the EDs (i.e., the 90<sup>th</sup> percentile) had a measure score of 47.0 minutes or more which indicates that patients with SCD and VOE are typically waiting 47 minutes longer from the time they arrive at these EDs until they receive their first dose of pain medication, compared to patients with a renal colic diagnosis. Considering that the overall median measure score was 15.3 minutes, these results highlight a clear opportunity for improvement.



**Table 5. Measure Scores and Distribution of Measure Scores** 

	Manu		Standard				Percentiles	;		Man
	Mean	N	Deviation	Min	10 <sup>th</sup>	25 <sup>th</sup>	50 <sup>th</sup>	75 <sup>th</sup>	90 <sup>th</sup>	Max
Time Difference (SCD – RC)	18.2	25	20.0	-13.0	-3.0	6.5	15.3	25.0	47.0	73.0

#### **Table 6. Individual ED Site Measure Scores**

ED Site	Measure Score (minutes)
18	-13.0
14	-11.4
7	-3.0
25	2.0
6	4.0
3	5.0
2	6.5
4	7.0
5	7.0
16	8.5
9	11.5
12	12.0
24	15.3
21	16.2
10	16.5
17	17.5
8	22.6
1	24.4
22	25.0
20	32.8
15	36.0
11	41.5
13	47.0
23	51.0
19	73.0



## 3.3 Reliability Testing Results

#### 3.3.1 Measure Performance Score Reliability Results

Reliability estimates (Pearson correlation coefficients corrected with the Spearman-Brown prophecy formula to account for the split-half design) from the 3,000 bootstrap replicates had a mean of 0.73 and an estimated 95% confidence interval of 0.67 to 0.95. This indicates high reliability of the measure score.

## 3.4 Validity Testing Results

#### 3.4.1 Data Element Validity Results

The overall percent agreement for all critical data elements exceeded the 70% threshold, indicating acceptable agreement (Table 13). The data element with the lowest agreement in our overall sample was the *Medication Administration Date/Time* at 85.4%. This is above the 70% threshold established by the CBE.

Initial testing indicated errors in the original electronically exported data extract and these errors were corrected before assessing percent agreement. In addition, there was ambiguity mapping chart data to the discrete data fields in the electronically exported data extract, resulting in multiple possible valid data elements. To resolve these ambiguities the following rules for counting mismatches were applied, none of which are expected to affect the validity of the measure in practice:

- In cases where multiple analgesic medications were administered at the same time, resulting in two different medications recorded from the electronic extract and manual abstraction, the Medication Name data fields were considered matching if the abstractor notes indicated that both medications were administered, or the abstractor could later confirm this was the case by reviewing the medical record.
- 2. In cases where the manual abstractor recorded a date/time or diagnosis from an incorrect field in the medical record, these fields were considered matching if the manual abstractor could locate and confirm the element in the medical record upon re-review.
- 3. In cases where the manual abstractor recorded a diagnosis code that was not an exact match to that found by the electronic extract, but it was in the same family of codes (e.g., D57.00 Hb-SS disease with crisis, unspecified and D57.219 Sickle-cell/Hb-C disease with crisis, unspecified), the Principal Diagnosis data fields were considered a match.

Where there was a mismatch between the manually abstracted data and the data extract for medication administration date/time, we calculated the difference in minutes between the two sources. Results show that, on average, the abstracted data were 4.6 minutes earlier than the extracted data for ED Arrival Date/Time and 7.3 minutes earlier than the extracted data for Medication Administration Date/Time.

Overall, the percent agreement for all data elements was well above the 70% threshold generally considered acceptable.<sup>58</sup> Additionally, the data elements are included in the eCQI Resource Center Data Element Repository (DERep) and used in existing measures, and the time differences observed were minimal. Therefore, we conclude that the relevant data elements for this measure would be reliable and valid when implemented. It is also plausible that appropriate mapping and accuracy would improve with implementation.



**Table 7. Data Element Testing Results for Critical Data Element** 

Data Element Name	ED Site 1 % Agreement	ED Site 2 % Agreement	Overall % Agreement
ED Arrival Date/Time	79.2	100.0	89.6
Medication Name	95.8	95.8	95.8
Medication Administration Date/Time	70.8	100.0	85.4
Principal Diagnosis	95.8	87.5	91.7

#### 3.4.2 Systematic Assessment of Face Validity Results

HSAG obtained a face validity vote through a survey of TEP members. 100% (7/7) of individuals who voted, agreed that the measure reflects its intended focus of assessing the difference of the median time of pain medication administration between patients with a diagnosis of SCD with VOE and patients with renal colic.

## 3.5 Feasibility Testing Results

Feasibility testing results across the three ED sites used to perform feasibility testing are shown in Table 15. The measure includes five critical data elements and four supplemental patient characteristic data elements. All five critical data elements required for automated calculation of the measure were available and accessible within the EHR in a structured field. All five critical data elements have a high likelihood of being accurate because they are entered by a provider or healthcare staff into the EHR at the time of care delivery or entered for the purpose of billing (i.e., ICD-10-CM codes). All critical data elements were also codified using nationally accepted vocabularies per data terminology standards (e.g., ICD-10-CM, SNOMED-CT, RxNorm). Additionally, feasibility testing showed that generating and collecting the data elements had no impact on provider workflow at the three ED sites since all data elements were generated during the ordinary course of care. Patient characteristic data elements were similarly available and accurate and used standard terminology; however, some race and payer categories had to be manually mapped from the site's EHR system to the associated codes within the specified value set.

**Table 8. Feasibility Scorecards Across Three ED Sites** 

		EHF	R #1:	Medit	ech	El	HR #2	: EPIC	-A	El	IR #3	EPIC-	В
No.	Data Element	Availability	Accuracy	Standards	Workflow	Availability	Accuracy	Standards	Workflow	Availability	Accuracy	Standards	Workflow
1.	Encounter, Performed: Emergency Department Visit	1	1	1	1	1	1	1	1	1	1	1	1
2.	Age (proxy for Birthdate)*	1	1	1	1	1	1	1	1	1	1	1	1
3.	Diagnosis: Sickle Cell Disease with Vaso Occlusive Episode*		1	1	1	1	1	1	1	1	1	1	1
4.	Medication Administered: Analgesic*	1	1	1	1	1	1	1	1	1	1	1	1
5.	Medication, Administered: Analgesic Date_Time*	1	1	1	1	1	1	1	1	1	1	1	1
6.	ED Arrival Date_Time*	1	1	1	1	1	1	1	1	1	1	1	1
7.	Patient Characteristic, Race: Race	1	1	1	1	1	1	1	1	1	1	1	1
8.	Patient Characteristic, Ethnicity: Ethnicity	1	1	1	1	1	1	1	1	1	1	1	1
9.	Patient Characteristic, Payer: Payer	1	1	1	1	1	1	1	1	1	1	1	1



			R #1:	Medit	ech	El	IR #2:	: EPIC-	-A	EHR #3: EPIC-B			
No.	Data Element	Availability	Accuracy	Standards	Workflow	Availability	Accuracy	Standards	Workflow	Availability	Accuracy	Standards	Workflow
10.	Patient Characteristic, Sex: ONC Administrative Sex	1	1	1	1	1	1	1	1	1	1	1	1
	Summary												
Data Elements Scoring 0 within Domain		0	0	0	0	0	0	0	0	0	0	0	0
Total data elements		11	11	11	11	11	11	11	11	11	11	11	11
% of data elements requiring review within domain		0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%

<sup>\*</sup> Critical data element used to calculate the measure score.

## 4. Discussion

#### 4.1 Measure Harmonization

Throughout the measure development process, the project team aligned the specifications of the measure, to the extent possible, with existing measures that contain similar data elements that are used in the hospital OQR program. Measures with the same focus or target population that have disparate specifications can create confusion among healthcare consumers and providers about not only the interpretation of the measure results across settings or patient populations, but also about how the measure scores are calculated. To ensure harmonization, the project team used the same data definitions for similar data elements that are used in other measures implemented in the hospital OQR Program. Specifically, the measure is harmonized and aligned with certain data elements included in the Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED) (CBE-3613e).

The project team also leveraged existing value sets published through the National Library of Medicine's Value Set Authority Center<sup>59</sup> to construct the measure. For example, the project team used, without modification, the "Emergency Department Visit" value set developed by The Joint Commission and the "Emergency Department Evaluation and Management Visit" value set developed by the National Committee for Quality Assurance to identify ED encounters. The project team also ensured that the five critical data elements used in the measure align with similar data elements found in the USCDI, Version 5.

Finally, the project team conducted a review of the current landscape of quality measures to determine whether the measure would be duplicative of an existing measure. As of the date of this report, there were no current CBE-endorsed measures that specifically evaluate the difference in timing of pain medication administration between patients with a diagnosis of SCD and VOE and those with renal colic.

## **4.2 Measure Implementation**

This measure is specified at the ED/facility level of analysis and is intended for use in hospital outpatient settings, including both freestanding EDs and those affiliated with acute care hospitals, using a two-year measurement period. The measure is designed for implementation as an eCQM for internal quality improvement. To support adoption, ASH will collaborate with and offer technical resources to



EDs, and other organizations interested in implementing the measure in quality improvement programs, and software platforms.

## 5. Conclusion

The measure addresses an important measurement gap for the timing of administration of pain medications in adult patients with a diagnosis of SCD with VOE compared to those who present to the ED with a diagnosis of renal colic. The TEP, patients, and caregivers who were consulted found the measure to be both important and meaningful. As demonstrated by the analysis results, the measure score indicates considerable opportunities for EDs to improve the timeliness of pain medication administration for these patients.

Improvement in measure scores could lead to improved outcomes and patient experience. Timeliness of analgesia administration is a patient-centered issue in need of improvement. The measure meets the scientific acceptability thresholds for reliability and data element validity as established by the CBE for measure endorsement.

The measure is harmonized with other measures that use similar data elements and is specified as an eCQM, using only clinical digital data sources. The data elements used in the measure were found to be available and accurate and were captured using standardized vocabularies while adding no to minimal burden for providers to collect because data are routinely captured during the clinical course of care. The data elements used in the measure are also consistent with the standard set of data elements as defined by the USCDI, Version 5.<sup>24</sup>

In summary, implementation of this measure will be informative to providers and patients, and it is anticipated to lead to improvements in the quality and equity of care provided to patients with a diagnosis of SCD with VOE compared to those who present to the ED with a diagnosis of renal colic.



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# **Appendix A. Measure Information Form / Algorithm**

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eCQM Title	Difference in Median Time to Pain Medication Between Adult Patients With a Diagnosis of Sickle Cell Disease (SCD) With Vaso-Occlusive Episode (VOE) and Adult Patients with a Diagnosis of Renal Colic
Version	1.0.000
Measure Description	Difference in median time (in minutes) from Emergency Department (ED) arrival to initial administration of pain medication between adult patients with a principal diagnosis of sickle cell disease (SCD) with vaso-occlusive episode (VOE) and those with a principal diagnosis of renal colic
Copyright	This measure is Copyright (c) 2025 American Society of Hematology. All Rights Reserved.
	LOINC (R) copyright 2004-2024, Regenstrief Institute, Inc. SNOMED Clinical Terms (R) (SNOMED CT [R]) copyright 2004-2024, The International Health Terminology Standards Development Organisation (IHTSDO). ICD-10 is copyright 2024 World Health Organization. All Rights Reserved.
	The copyrights in the Current Procedural Terminology ("CPT") codes are owned by the American Medical Association ("AMA"). Copyright 2024 American Medical Association. All rights are reserved by the AMA. You cannot, without express written permission from the AMA, copy, modify, distribute, display, or use CPT for any commercial purpose, including for productive use in a clinical setting. Any such use requires a separate license from the AMA.
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Disclaimer	This measure, including specifications ("Measure"), is not a clinical guideline, does not establish a standard of medical care, and has not been tested for all potential applications. The Measure is not intended to diagnose or treat disease or other conditions. The Measure is not a medical device and has not been evaluated by the Food and Drug Administration. Information provided through the Measure is not intended to direct or substitute for the independent assessment or judgment of a qualified healthcare professional. The American Society of Hematology ("ASH") assumes no liability for use of the Measure, or data contained or not contained in the Measure.
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	To request permission to make a commercial use of the Measure, please email: quality@hematology.org. Any commercial use of the Measure requires a separate license from ASH.
	Any use, publication, or other dissemination of this Measure shall include the following attribution:
	"This [publication, etc.] was prepared using clinical quality measures developed by the American Society of Hematology. The content reflects the views of [name of author(s)]."
	You agree that you shall not remove, obscure, or alter any proprietary rights notices (including copyright and trademark notices) which may be affixed to or contained within the Measure.
	Information contained in the Measure may include information protected by intellectual property rights of third parties which are not owned by ASH. ASH disclaims all liability for the use or accuracy of any such



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	USE OF THE MEASURE (INCLUDING ANY CPT CODES) IS AT YOUR SOLE RISK. THE MEASURE IS PROVIDED "AS IS" WITHOUT EXPRESS OR IMPLIED WARRANTIES OF ANY KIND, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT. ASH EXPRESSLY DISCLAIMS ANY AND ALL RESPONSIBILITY OR LIABILITY FOR DAMAGES OF ANY KIND ARISING OUT OF USE, REFERENCE TO, OR RELIANCE ON THE MEASURE.			
Initial Population	ED encounters with a discharge time during the two-year measurement period for all patients aged 18 years or older at the start of the ED encounter, that meet criteria for one of the following:			
	Population 1: ED encounters that have a principal encounter diagnosis of SCD with VOE AND at least one qualifying pain medication administered during the ED encounter.			
	Population 2: ED encounters that have a principal encounter diagnosis of Renal Colic AND at least one qualifying pain medication administered during the ED encounter.			
Observation Description	Time (in minutes) from ED arrival to initial administration of pain medication			
Measure Population	Equals Initial Population			
Measurement Period	The measure uses a two-year measurement period			
Measure Exclusions	None			
Clinical Recommendations	The measure is supported by several clinical practice guidelines recommending rapid initiation of treatment with analgesia for patients with SCD and renal colic. The clinical recommendation statements from the supporting guidelines are noted below:			
	1) The American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain (Brandow et al., 2020)			
	<b>Statement:</b> Recommendation 1A - For adults and children with SCD presenting to an acute care setting with acute pain related to SCD, the ASH guideline panel recommends rapid (within 1 hour of emergency department [ED] arrival) assessment and administration of analgesia with frequent reassessments (every 30-60 minutes) to optimize pain control (strong recommendation based on low certainty in the evidence about effects).			
	2) The 2014 National Heart, Lung, and Blood Institute (NHLBI): Evidence-Based Management of Sickle Cell Disease Expert Panel Report (NIH & NHLBI, 2014)			
Statement: In adults and children with SCD and a vaso-occlusive crisis (VOC):				
	a) Rapidly initiate treatment with parenteral opioids associated with severe pain (Strong Recommendation, High-Quality Evidence)			
	OR			
	b) Rapidly initiate analgesic therapy within 30 minutes of triage or within 60 minutes of registration. (Consensus–Panel Expertise – Expert Opinion).			
	3) European Association of Urology: 2025 Guidelines on Urolithiasis (Skolarikos et al., 2025)			



Statement: Relevant evidence and recommendations for the management of renal colic:

a) Offer a non-steroidal anti-inflammatory as the first drug of choice; depending on cardiovascular risk factors and side effects (Strong Recommendation, Grade 1b – Individual RCT with narrow confidence interval)

OR

b) Offer opiates (hydromorphine, pentazocine or tramadol) as a second choice (Weak Recommendation, Grade 1b – Individual RCT with narrow confidence interval)

#### Rationale

#### Sickle Cell Disease (SCD)

SCD is the most common inherited blood disorder and is estimated to affect approximately 100,000 individuals in the United States (National Center on Birth Defects and Developmental Disabilities & Centers for Disease Control and Prevention, 2023). SCD is also most prominent among Black or African American patients—affecting 1 out of 365 Black or African American births—and the average life expectancy of publicly insured individuals with SCD is reported to be approximately 52.6 years of age (Jiao et al., 2023). Based on a 2022 systematic review, total annual costs (medical and non-medical) were estimated to range from \$14,012 to \$80,842 per patient per year (Baldwin et al., 2022).

Evidence suggests that up to 80% of patients with SCD avoid the healthcare system whenever possible and live with chronic pain that is undermanaged (Ely, Dampier, Gilday, O'Neal, & Brodecki, 2002). When they do seek emergency care due to an acute severe pain crisis, single-site studies have shown patients wait an average of 90 minutes before analgesics are given (Tanabe, 2007; Lin, Strouse, Whiteman, Anders, & Stewart, 2016), and a multi-site study across seven EDs found that half of all pediatric visits had a time to first opioid over one hour (Brousseau et al., 2020). Updated data from the National Hospital Ambulatory Medical Care Survey (NHAMCS) show that from 1999 to 2020, of the 222,612 estimated yearly average number of ED visits by patients with a diagnosis of SCD, three-fourths were due to a complaint of pain (Attell et al., 2024). Compared with prior estimates (1999-2007), the overall volume of ED visits has increased by nearly 13% (Attell et al., 2024). Individuals with SCD face health inequities stemming from socioeconomic factors, including disease stigma, racial prejudice, and lack of access to specialized care (Haywood et al., 2014; Pokhrel, Olayemi, Ogbonda, Nair, & Wang, 2023; Telfair, Haque, Etienne, Tang, & Strasser, 2003; Wahab et al., 2024). These inequities were demonstrated in a study of adult patients with acute pain from SCD and renal colic in an ED. This study showed that despite higher arrival pain scores and triage acuity levels in patients with SCD, SCD patients experienced longer time to initial analgesia when compared with renal colic patients (Lazio et al., 2010).

To promote rapid, effective, and safe analgesic management and resolution of VOE, the 2014 National Heart, Lung, and Blood Institute (NHLBI) Evidence-Based Management of Sickle Cell Disease Expert Panel Report recommends the use of an individualized prescribing and monitoring protocol or an SCD-specific protocol whenever possible (National Institutes of Health [NIH] & NHLBI, 2014). Individualized care plans, developed by the patient's SCD clinician, are based on the patient's home opioid consumption and effective dosing from previous ED visits. The plan is made available to ED clinicians via the electronic health record and provides direction on pain management. Individualized prescribing and monitoring protocols in patients with SCD have demonstrated decreased time to first opioid, shorter ED and hospital length of stay, and more rapid reduction in pain scores, when compared with weight-based dosing (Della-Moretta et al., 2020; Tanabe et al., 2023a; Tanabe et al., 2023b; Welch-Coltrane et al., 2021).

The implementation of this eCQM targeting timing to administration of pain medication for adult and pediatric patients with SCD presenting to the ED may significantly improve pain management and other outcomes, including admission rates (Wachnik et al., 2022), hospital length of stay (Wachnik et al., 2022; Brandow et al., 2016; King, Albright, & Murry, 2023), length of ED stay (Lin et al., 2016; King et al., 2023; Mathias & McCavit, 2015), and patient satisfaction (Kim, Brathwaite, & Kim, 2017).

#### **Renal Colic**

Renal colic serves as a clinically relevant comparator cohort for patients with SCD and VOE because both conditions are characterized by sudden onset of severe pain requiring urgent intervention. Both groups frequently report pain scores of 8 out of 10 or higher at triage, making this comparison valuable for assessing timeliness and equity in emergency pain management (Patrick, Rosenthal, Iezzi, & Brand, 2015).



Additionally, renal colic patients have a similarly urgent need for treatment. The Emergency Severity Index (ESI) Handbook recommends assigning these patients the same triage level, stating, "Patients experiencing severe pain or distress as a result of a systemic disruption, for example, renal colic, cancer, or sickle cell crisis, should be triaged as ESI level 2, and placement should be facilitated as quickly as possible" (Emergency Nurses Association, 2023). Typically caused by ureteral obstruction from kidney stones, renal colic presents abruptly with severe flank or abdominal pain that is often described as among the most intense types of acute pain encountered in clinical settings. Given the severity of renal colic, prompt and effective pain relief is a primary goal in the ED to alleviate patient suffering while awaiting definitive diagnosis or further treatment, reduce the risk of return ED visits, and avoid prolonged hospital stays (Bultitude & Rees, 2012; O'Connor, Schug, & Cardwell, 2000). In the United States, renal colic accounts for an estimated 1 to 2 million ED visits annually, based on national data from 2011 and extrapolated estimates published through 2019. These visits are associated with significant healthcare expenditures, exceeding \$10 billion annually (Schoenfeld et al., 2019). In the United States, the lifetime prevalence of kidney stones among adults has remained relatively stable over the past decade at around 9–10%, with a significant rise observed among women (Chen et al., 2025). Timely and effective pain control is a central objective in the emergency management of renal colic (Bultitude & Rees, 2012). Several meta-analyses and systematic reviews, including evidence-based clinical resource information on "acute pain control for renal colic," recommend nonsteroidal anti-inflammatory drugs (NSAIDs) as a preferred initial treatment due to their demonstrated efficacy in reducing pain severity, lowering the need for rescue analgesia, and minimizing side effects such as nausea when compared to opioids (Afshar K, 2015; Bultitude & Rees, 2012; Holdgate & Pollock, 2004; Pathan, Mitra, & Cameron, 2018). When NSAIDs are contraindicated or insufficient, opioids remain an appropriate and effective option for achieving rapid pain control, particularly when tailored to the patient's clinical presentation. This treatment framework parallels that used in the treatment of severe acute pain, such as in patients with SCD and VOE, where both NSAIDs and opioids can be effective treatment options based on the patient's individualized care plan. While no universal benchmark for analgesic timing exists for patients who present to the ED with symptoms of renal colic, expert recommendations support pain medication administration within 30 to 60 minutes of ED arrival to improve outcomes and patient experience (Fontenelle & Sarti, 2019; Patrick et al., 2015). Guidance This eCQM is an episode-based measure. An episode is defined as a qualifying emergency department encounter that ends during the measurement period. The measure uses a two-year measurement period from January 1, XXXX through December 31, XXXX. This version of the eCQM uses QDM version 5.6. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Definition** A qualifying encounter is defined as an ED visit for adult patients for which the discharge time occurred during the two-year measurement period and the following criteria are met: - The ED visit requires a principal diagnosis of SCD with VOE or renal colic, and - The ED visit requires at least one qualifying pain medication administered during the ED encounter **Measure Type** ☑ Process ☐ Appropriate Use Process ☐ Cost/Resource Use ☐ Efficiency ☐ Intermediate Clinical Outcome **Level of Measurement** Facility (Emergency Departments) Type of Score Continuous variable **Improvement Notation** Lower score indicates better quality

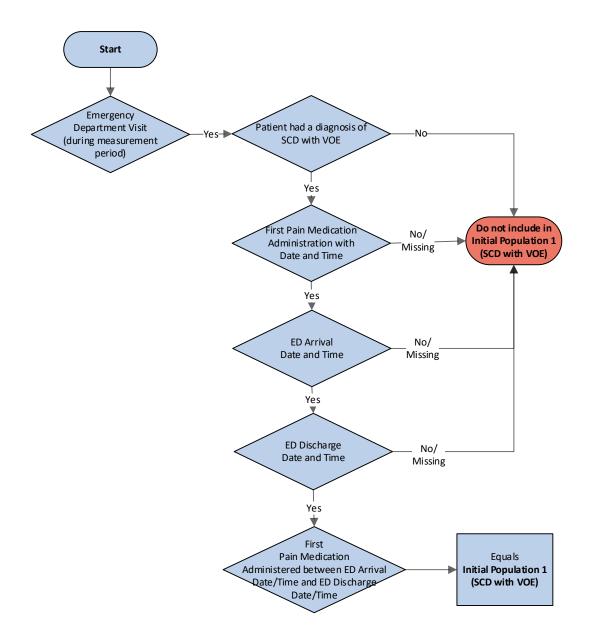


**Disclaimer:** Please refer to the full eCQM specifications available at:

https://www.hematology.org/education/clinicians/guidelines-and-quality-care/hematology-quality-metrics.

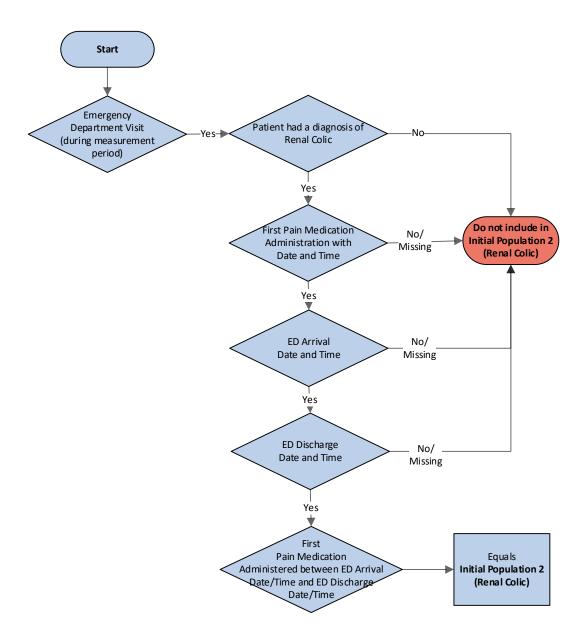
For the complete list of value set codes used in the eCQM, please visit the Value Set Authority Center (VSAC) at: https://vsac.nlm.nih.gov. (Login required)

**Initial Population 1:** ED encounters that have a principal encounter diagnosis of SCD with VOE AND at least one qualifying pain medication administered during the ED encounter.





**Initial Population 2:** ED encounters that have a principal encounter diagnosis of Renal Colic AND at least one qualifying pain medication administered during the ED encounter.





**Population 1:** ED encounters that have a principal encounter diagnosis of SCD with VOE AND at least one qualifying pain medication administered during the ED encounter.

Measure Observation: Time (in minutes) from ED arrival to initial administration of pain medication

#### **Encounter Level Time To Pain Medication Calculation =**

Pain Medication Administration Date and Time minus [ - ] ED Arrival Date and Time (in minutes)

#### Calculation of Median Time to Pain Medication (Population 1) =

a) Odd number of Observations: Median =  $\{(n+1)/2\}$ th term

OR

b) Even number of Observations: Median =  $[(n/2)th term + {(n/2)+1}th]/2$ 

**Population 2:** ED encounters that have a principal encounter diagnosis of Renal Colic AND at least one qualifying pain medication administered during the ED encounter.

Measure Observation: Time (in minutes) from ED arrival to initial administration of pain medication

#### **Encounter Level Time To Pain Medication Calculation =**

Pain Medication Administration Date and Time minus [ - ] ED Arrival Date and Time (in minutes)

#### Calculation of Median Time to Pain Medication (Population 2) =

a) Odd number of Observations: Median =  $\{(n+1)/2\}$ th term

OR

b) Even number of Observations: Median =  $[(n/2)th term + {(n/2)+1}th]/2$ 

#### Measure Score Calculation

#### Performance Rate =

Median (Population 2) – Median (Population 1)



# **Appendix B. Generic List of Qualifying Pain Medications**\*

Pain Medication Categories	Qualifying Generic Pain Medications			
Opioids	<ul> <li>Alfentanil</li> <li>Buprenorphine</li> <li>Butorphanol</li> <li>Codeine</li> <li>Fentanyl</li> <li>Hydrocodone</li> <li>Hydromorphone</li> <li>Levorphanol</li> </ul>	<ul> <li>Meperidine</li> <li>Methadone</li> <li>Morphine</li> <li>Nalbuphine</li> <li>Oliceridine</li> <li>Oxycodone</li> <li>Oxymorphone</li> </ul>	<ul> <li>Pentazocine</li> <li>Pentazocine/naloxone</li> <li>Remifentanil</li> <li>Sufentanil</li> <li>Tapentadol</li> <li>Tramadol</li> </ul>	
Opioid Combinations	<ul> <li>Benzhydrocodone/Acetaminophen</li> <li>Bupivacaine/Meloxicam</li> <li>Buprenorphine/Naloxone</li> <li>Codeine combinations</li> <li>Codeine/Acetaminophen</li> <li>Codeine/Acetaminophen combinations</li> </ul>	<ul> <li>Dihydrocodeine/Acetaminophen</li> <li>Hydrocodone combinations</li> <li>Hydrocodone/Acetaminophen</li> <li>Hydrocodone/Aspirin</li> <li>Hydrocodone/Ibuprofen</li> <li>Morphine/Naltrexone</li> </ul>	<ul> <li>Oxycodone/Acetaminophen</li> <li>Oxycodone/Aspirin</li> <li>Oxycodone/Ibuprofen</li> <li>Tramadol /Acetaminophen</li> <li>Tramadol/Celecoxib</li> </ul>	
NSAIDs	<ul> <li>Acetaminophen/NSAID combinations</li> <li>Celecoxib</li> <li>Diclofenac</li> <li>Diclofenac/Misoprostol</li> <li>Diflunisal</li> <li>Etodolac</li> <li>Fenoprofen</li> <li>Flurbiprofen</li> </ul>	<ul> <li>Ibuprofen</li> <li>Ibuprofen combinations</li> <li>Indomethacin</li> <li>Ketoprofen</li> <li>Ketorolac</li> <li>Magnesium Salicylate</li> <li>Magnesium Salicylate combinations</li> <li>Meclofenamate</li> <li>Mefenamic Acid</li> <li>Meloxicam</li> </ul>	<ul> <li>Nabumetone</li> <li>Naproxen</li> <li>Naproxen combinations</li> <li>Oxaprozin</li> <li>Piroxicam</li> <li>Salsalate</li> <li>Sulindac</li> <li>Tolmetin</li> </ul>	
Other Analgesics	<ul><li>Acetaminophen</li><li>Acetaminophen combinations</li></ul>	Gabapentin     Ketamine	Ziconotide	

<sup>\*</sup> This measure does not replace clinical judgment. The medication list is intentionally broad to support clinician-patient decision-making.