Methodology Report

Median Time to Pain Medication for Patients
With a Diagnosis of Sickle Cell Disease (SCD)
With Vaso-Occlusive Episode (VOE)

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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. Additionally, the TEP agreed with the prioritization, for further development and testing, of 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):

> **Measure Title:** Median Time to Pain Medication for Patients with a Diagnosis of Sickle Cell Disease (SCD) with Vaso-Occlusive Episode (VOE)
>
> **Measure Description:** Median time (in minutes) from Emergency Department (ED) arrival to initial administration of pain medication for all patients, regardless of age, with a principal encounter diagnosis of sickle cell disease (SCD) with vaso-occlusive episode (VOE)

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, 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. A sensitivity analysis examined the differences in time to pain medication between pediatric and adult populations, and measure performance across the combined and adult only populations, and the potential impact of pediatric inclusion on validity and reliability. 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 median time of pain medication administration for patients with a diagnosis of SCD with VOE. 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.[1]
  - The National Academies of Sciences, Engineering, and Medicine,[2] the U.S Department of Health and Human Services (HHS),[3,4] and the Centers for Medicare & Medicaid Services (CMS)[5,6] 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.[7]
  - Approximately 80% of patients with SCD report avoiding the healthcare system and live with chronic pain that is undermanaged.[8] 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.[9]
  - 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 patient-centered measure concept.
  - The mean measure score for patients with SCD with VOE across 25 facilities was 87.7 minutes (SD = 45.8) with wide variation in performance observed between 42 and 268 minutes (lower scores are better).
  - The measure is supported by the ASH 2020 Guidelines for SCD Management of Acute and Chronic Pain[10] and the National Heart, Lung and Blood Institute: Evidence-Based Management of SCD Expert Panel Report, published in 2014.[11] 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,[12] and access to guideline-recommended treatments.[13] Admission rates[14] and hospital length of stays may also be reduced.[14-16]

- **Scientific Acceptability**
  - The measure performance score was highly reliable, which indicates that the measure can differentiate performance between facilities. Reliability estimates (corrected Pearson

correlation coefficients) from the 3,000 simulated split-half replicates ranged from 0.70 to 1.0 with a mean of 0.96 and an estimated 95% confidence interval of 0.89 to 0.99.

- 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 for discrepant records 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.
- Including pediatric data in the sample, which accounted for 6% of total cases, resulted in a minimal 1-minute reduction in overall median time to pain medication.
- The TEP reviewed the final measure specifications and testing results, and 100% (7/7) agreed that the measure, specified for all ages, reflects its intended focus of assessing the timely administration of pain medication for patients with SCD, 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.[17-19]
  - In socioeconomically deprived areas, patients with SCD have higher rates of SCD complications, leading to increased health system utilization and higher readmission rates.[20,21]
  - 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.[22]
  - 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.[23]
- **Harmonization**
  - There are currently no consensus-based entity (CBE)-endorsed measures that specifically evaluate the timing of administration of pain medications for patients, regardless of age, with a diagnosis of SCD with VOE.

- 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.[24]

Conclusion

In summary, the *Median Time to Pain Medication for Patients with a Diagnosis of SCD with VOE* 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, regardless of age, 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):

> **Measure Title:** Median Time to Pain Medication for Patients with a Diagnosis of Sickle Cell Disease (SCD) with Vaso-Occlusive Episode (VOE)
>
> **Measure Description:** Median time (in minutes) from Emergency Department (ED) arrival to initial administration of pain medication for all patients, regardless of age, with a principal encounter diagnosis of sickle cell disease (SCD) with vaso-occlusive episode (VOE)

1.1 Development of the Measure Concepts

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 developed 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: readmissions for VOE, patients who develop acute chest syndrome, pain management, and 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.

1.2 Importance

SCD is the most common inherited blood disorder and estimated to affect approximately 100,000 individuals in the United States.[1] 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.[25] 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.[26]

The National Academies of Sciences, Engineering, and Medicine,[2] HHS,[3,4] and CMS[5,6] 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.[2] 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.[8] 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,[9,27] and an another study across seven EDs found that half of all pediatric visits had a time to first opioid over one hour.[28]

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.[29] 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.[7] Compared with prior estimates (1999 to 2007), the overall volume of ED visits has increased by nearly 13%.[7] Individuals with SCD face health inequities stemming from socioeconomic factors, including disease stigma, racial prejudice, and lack of access to specialized care.[17-19,30] In socioeconomically deprived areas, patients with SCD have higher rates of SCD complications, leading to increased health system utilization and higher readmission rates.[20,21] 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.[22] 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%).[31] 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.[32] These patients are particularly at risk for poor outcomes, including early death, during the transition period between pediatric and adult care.[33-36] 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.[23] 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.[37]

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,[16,27,38] 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.[12,14,39,40]

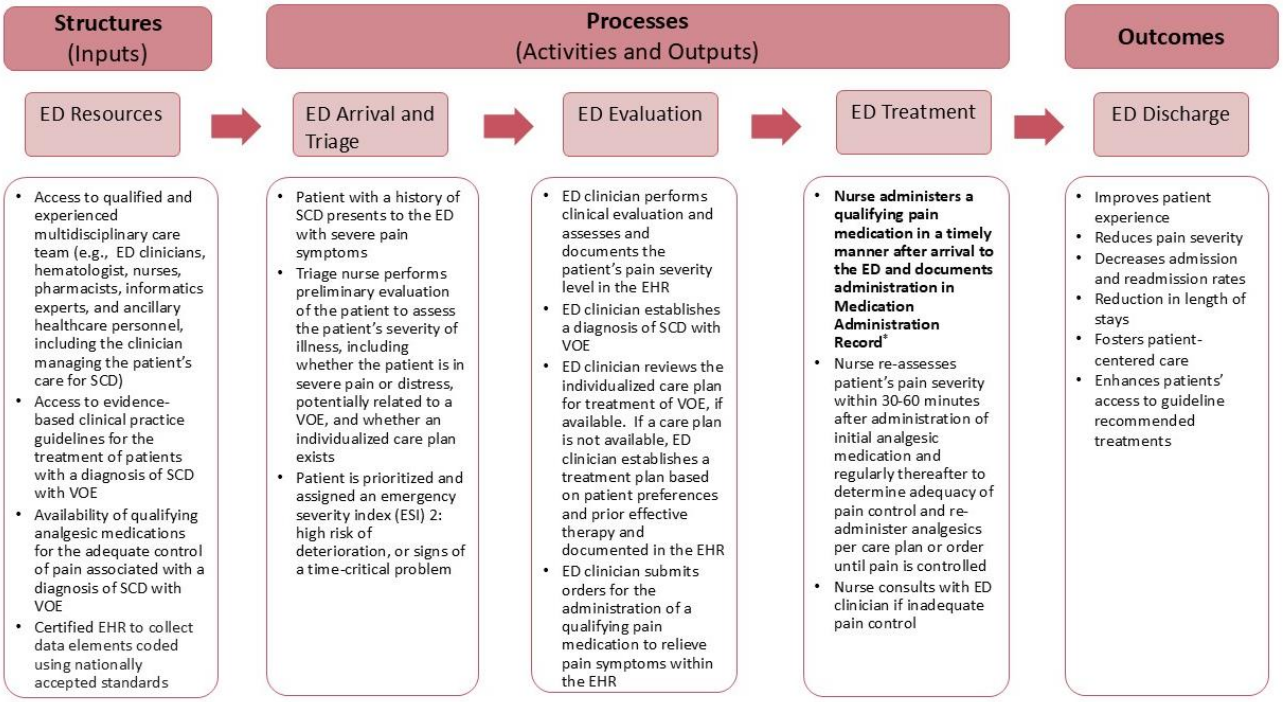
This measure may also enhance patients’ access to care by increasing the number of patients with SCD receiving guideline-recommended treatment. In a 2022 study, establishing a quality measure based on guideline-recommended pain management increased the percentage of patients with SCD receiving analgesia within 60 minutes of triage from 17 to 72 percent.[13] 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.[12,41,42]

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[43] 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,[44] shorter ED and hospital length of stay[45,46] and more rapid reduction in pain scores,[47] when compared with weight-based dosing.

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



*Represents the focus of the measure

1.3 Clinical Practice Guidelines

The measure is supported by two clinical practice guidelines: (1) the ASH 2020 Guidelines for SCD Management of Acute and Chronic Pain and (2) the National Heart, Lung and Blood Institute: Evidence-Based Management of SCD Expert Panel Report, published in 2014. 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. Information in Table 1 provides the specific practice guideline title, citation, recommendation, strength of the recommendation, and grade of evidence for each recommendation.

Table 1. Clinical Guideline Recommendations

Clinical Practice Guideline Developer	Recommendation	Strength of Recommendation	Grade of Evidence
American Society of Hematology 2020 Guidelines[10]	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 Institute[43]	In adults and children with SCD and a VOC associated with severe pain, rapidly initiate treatment with parenteral opioids.	Strong recommendation	High quality evidence
	Rapidly initiate analgesic therapy within 30 minutes of triage or 60 minutes of registration.	Expert opinion	No grade

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. It includes descriptions of the stratification strategies employed and the method used to conduct a sensitivity analysis comparing the administration of non-parenteral opioids versus non-opioids. Additionally, this section describes the methods used to evaluate the measure's reliability and validity, assess disparities in care across patient subpopulations, 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, regardless of age, 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, 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 based on the ASH 2020 guidelines for sickle cell disease: management of acute and chronic pain.[10] The broad list of generic pain medications was then organized into four distinct categories that were further stratified by parenteral and non-parenteral routes of administration.

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 and Appendix C. Generic List of Qualifying Pain Medications by Parenteral and Non-Parenteral Route.

2.2 Measure Performance Scoring Methodology

This section describes the methodology used to assess measure performance for the adult population, which was the original target population for the measure. A sensitivity analysis was also conducted to evaluate the potential impact of including the pediatric population.

2.2.1 Adult Population

The measure was originally specified for the adult population (patients aged 18 years and older) presenting to the ED with a principal diagnosis of SCD with VOE. As a continuous variable measure, performance was calculated as the median time (in minutes) from ED arrival to initial administration of pain medication. Opportunity for improvement was assessed by examining descriptive statistics (e.g., mean, standard deviation, and percentiles) for the distribution of measure scores across EDs. 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 the median and the highest-performing ED of the sample.

2.2.2 Sensitivity Analysis: Inclusion of the Pediatric Population

In response to public comment feedback (Appendix D) recommending the inclusion of pediatric populations, a sensitivity analysis was conducted to evaluate the potential impact of expanding the measure to include patients under 18 years of age. This analysis was based on data from a subset of ED sites that contributed data on both adult and pediatric patients. The objectives of the analysis was to examine the distribution of time to pain medication for the adult-only population and the combined adult and pediatric populations and assess measure performance across sites for the combined and separate populations.

2.3 Stratification Methodology

This section provides the methodologies used to stratify measure scores by medication administration route (parenteral vs. non-parenteral), evaluate differences by ED site, and assess the frequency of administration of non-parenteral opioid versus non-opioid medications.

2.3.1 Stratification by Medication Route Across All Encounters

To evaluate differences in time to pain medication based on administration route, each qualifying ED encounter was categorized into one of two groups based on the route of administration for the first pain medication administered during the ED visit:

- Parenteral routes: Includes medications administered by injection, including intravenous (IV), intramuscular (IM), or subcutaneous routes of administration.
- Non-parenteral routes: Includes medications administered by oral, buccal, sublingual, rectal, nasal, or mucosal routes.

Topical medications and medications administered via implantable devices were excluded from the analysis. For each stratum, descriptive statistics (e.g., median and mean time from ED arrival to pain medication administration) were calculated using all qualifying encounters. This stratification approach was used to assess concerns raised during public comment (Appendix D) that facilities might favor non-parenteral medications to shorten administration time, potentially at the expense of appropriate clinical evaluation. This analysis was conducted to inform whether the measure should be stratified by parenteral versus non-parenteral medication administration route.

2.3.2 Stratification by Medication Route and by ED Site

To further assess differences in measure performance and variation in prescribing practices across sites, a stratified measure performance score analysis by medication administration route was conducted at the ED site level. Each site's encounters were divided into two strata based on the route of administration for the first administered pain medication (parenteral vs. non-parenteral), consistent with the stratification route definitions described in Section 2.3.1.

For each stratum within each ED site, the median time to first pain medication was calculated. Sites that administered medications exclusively via one route were assigned a single stratified score. Sites that administered both parenteral and non-parenteral medications received stratified scores for each group.

The goal of this stratified site-level analysis was to detect systematic differences in performance based on route selection and to identify whether any ED sites relied disproportionately on non-parenteral medications. Results were used to assess whether such reliance correlated with higher or lower measure scores, and to inform guidance regarding potential unintended consequences of the measure.

2.3.3 Sensitivity Analysis: Frequency of Non-Parenteral Medications (Opioid vs. Non-Opioid)

To further assess concerns raised by CMS and public commenters (Appendix D) about the inclusion of non-opioid oral medications in the measure, a sensitivity analysis was conducted on the subset of encounters in which the first administered pain medication was delivered via a non-parenteral route. The objective of this analysis was to evaluate the frequency of administered non-parenteral opioid versus non-opioid medications and to identify whether inclusion of non-opioids introduced any measurable performance differences.

Using all qualifying ED encounters, the subset with non-parenteral first-administered medications was further stratified into two groups:

1. Non-parenteral opioid group: Included oral formulations of oxycodone, hydromorphone, morphine, acetaminophen-opioid combinations, and other oral opioids.
2. Non-parenteral non-opioid group: Included acetaminophen, ibuprofen, naproxen, oral ketorolac, and combination products without opioid components.

Descriptive statistics were used to assess and compare the frequency of medication types and the distribution of time from ED arrival to first pain medication. This analysis was designed to inform whether future stratification or measure refinement may be warranted. Clinical appropriateness could not be assessed due to limitations in the available data, such as lack of access to individualized care plans, allergy history, or prior opioid use.

2.4 Reliability Testing Methodology

2.4.1 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.

2.4.2 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. Median time (in minutes) from ED arrival to initial administration of pain medication 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.

2.5 Validity Testing Methodology

2.5.1 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 CBE thresholds, which establishes a 70% agreement as an acceptable standard.[48]

2.5.2 Systematic Assessment of Face Validity

To systematically assess face validity, we surveyed a group of experts, which was 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, specified for all ages, reflects its intended focus to assess the timely administration of pain medication for patients with SCD, based on your experience?
    a. Yes, I agree.
    b. No, I do not agree.

2.6 Disparity Testing Methodology

The project team evaluated the feasibility of analysis stratified by sociodemographic data elements: race (White, American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, other race), ethnicity (Hispanic or Latino, not Hispanic or Latino, sex (male, female), and payer (Medicaid, Medicare, other). This assessment was performed by evaluating whether statistically significant differences in measure performance for patients with various sociodemographic characteristics were present. All eligible encounters over the two-year period were pooled, and quantile regression was used to estimate the effect of each sociodemographic variable separately on the overall median time to administration of pain medication. Statistically significant coefficients of the model ($p < 0.05$) were considered evidence of disparities in the median time to first analgesic medication associated with each group relative to the reference. Due to the highly skewed race and ethnicity distribution of encounters—the sample consisted primarily of encounters with Black or African American and not Hispanic or Latino patients, as expected for this patient population—only sex and payer comparisons were included in the final analysis.

2.7 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, and findings related to whether disparities in care exist among subpopulations.

3.1 Sample Characteristics

3.1.1 Characteristics of the Adult Sample for Scientific Acceptability Testing

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	MO	EPIC	Urban	Academic	No	No designation

ED Site	State	EHR System Type	Urban/Rural Designation	Academic Designation	ED Type Free-Standing	ED Trauma Level
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	MO	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 and disparities testing included 7,707 unique encounters satisfying 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).

Table 3. Qualifying ED Encounters by ED Site

ED Site	Number of Qualifying Encounters with SCD with VOE
25	1,421
2	1,278
1	814
3	537
24	495
7	351
4	294
21	276
22	265
5	263
9	232
6	179
8	176
10	157
12	134
14	129
23	122
17	115
15	97
13	92
16	74
20	62

ED Site	Number of Qualifying Encounters with SCD with VOE
18	50
11	47
19	47
Total	**7,707**

The average patient age across the 4,680 unique patients was 32.5 (SD = 8.9) years at ED arrival, and the majority of patients were female (58.6%), Black or African American (97.6%), and not Hispanic or Latino (94.0%) and had Medicaid (40.8%) or Medicare (33.3%) as their primary insurance (Table 4).

Table 4. Demographics for Patients with Qualifying ED Encounters

Demographic	SCD with VOE
Qualifying Encounters, N	7,707
Total Unique Patients, N	4,680
Age, years	
Mean ± Std Dev	32.5 (8.9)
Median (Range)	31 (57)
Sex, N (% of total)	
Female	2,744 (58.6%)
Male	1,936 (41.4%)
Race, N (% of total)	
Black or African American	4,566 (97.6%)
White	38 (0.8%)
American Indian or Alaska Native	3 (0.1%)
Asian	2 (0.0%)
Other	32 (0.7%)
Unknown or Missing	39 (0.8%)
Ethnicity, N (% of total)	
Not Hispanic or Latino	4,400 (94.0%)
Hispanic or Latino	74 (1.6%)
Unknown or Missing	206 (4.4%)
Payer, N (% of total)	
Medicaid	1,902 (40.6%)
Medicare	1,562 (33.4%)
Private	359 (7.7%)
Other	671 (14.3%)
Missing	186 (4.0%)

3.1.2 Characteristics of the Pediatric Sensitivity Analysis Sample

The sensitivity analysis included three urban, academic ED sites representing three different electronic health record (EHR) systems. Pediatric encounters accounted for 6% of the total sensitivity analysis sample, with distributions summarized in

Table 5. Characteristics of Pediatric and Adult Populations Across ED Sites.

Table 5. Characteristics of Pediatric and Adult Populations Across ED Sites

ED Site	State	EHR System Type	Urban/Rural Designation	Academic Designation	ED Trauma Level	Population	Number of Qualifying Encounters, N (%)
A	DE	Cerner	Urban	Academic	1	Pediatric	0 (0%)
						Adult	265 (100%)
						Total	**265**
B	NY	Epic	Urban	Academic	2	Pediatric	22 (2%)
						Adult	1,420 (98%)
						Total	**1,442**
C	NY	Allscripts	Urban	Academic	2	Pediatric	119 (19%)
						Adult	495 (81%)
						Total	**614**
					Overall	Pediatric	141 (6%)
						Adult	2,180 (94%)
						Total	**2,321**

3.2 Measure Performance Score Results

This section presents results from the sensitivity analyses on the pediatric inclusion, as well as performance analysis of the measure, including stratification by medication administration route across all encounters and by ED site.

3.2.1 Adult Population

The mean measure score for adult patients with SCD with VOE across sites was 87.7 minutes (SD = 45.8, N = 25), and the median of measure scores across sites was 73.0 minutes, while the mean time from ED arrival to pain medication across all encounters was 90.7 minutes (SD = 73.2, N = 7,707). 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 42 to 268 minutes. The difference between the median and the 10th percentile of the distribution of scores, where lower scores indicate better performance, was 22 minutes—a 30% difference. In addition, the bottom-performing 10% of the EDs (i.e., the 90th percentile) had a measure score of 142 minutes or more, which indicates that patients with SCD and VOE are typically waiting almost two and a half hours from the time they arrive at these EDs until they receive their first dose of pain medication. Considering that the overall median measure score was 73.0 minutes, well above the 60-minute benchmark set by the clinical guidelines, these results highlight a clear opportunity for improvement.

Table 6. Measure Scores and Distribution of Measure Scores

	Mean of Median Times Across EDs	N	Standard Deviation	Min	Percentiles					Max
					10th	25th	50th	75th	90th	
SCD with VOE	87.7	25	45.8	42.0	51.0	63.5	73.0	93.0	142.0	268.0

Table 7. Individual ED Site Measure Scores

ED Site	Measure Score
7	42
16	46.5
6	51
2	58
3	60
5	60
9	63.5
10	66
17	67
25	70
4	70
12	70
22	73
14	75
21	82.2
15	88
8	90.2
18	91
20	93
24	101.3
1	105.7
11	113
23	142
13	145.5
19	268

3.2.2 Sensitivity Analysis: Inclusion of Pediatric Population

The data in

Table 8 display the distributions of time to pain medication from ED arrival (in minutes) for the adult-only population and the combined adult and pediatric populations. Across the three sites, there were 2,180 qualifying encounters for adults with SCD and VOE, with an average time to pain medication of 92.5 minutes (SD 70.6 minutes) and a median (50th percentile) time of 77 minutes. The revised distribution, which added the 141 pediatric cases for a total of 2,321 qualifying encounters, was very similar to the original distribution, with an average time to pain medication of 90.9 minutes (SD 70.3 minutes) and a median (50th percentile) time of 76 minutes.

Table 8. Distribution of Time to Pain Medication Across Encounters for Adult-Only Population versus Adult + Pediatric Population for All Three Sites Combined

Population	Number of Qualifying Encounters, N	Time (in minutes) from ED Arrival to Initial Administration of Pain Medication								
		Mean	Standard Deviation	Min	Percentiles					Max
					10th	25th	50th	75th	90th	
Adult-Only	2,180	92.5	70.6	9	36	52	77	114	162	1,720
Adult + Pediatric	2,321	90.9	70.3	6	34	50	76	112	160	1,720

The data in

Table 9 show the proportion of pediatric and adult encounters and measure performance score by these populations across the three sites. Site A had no eligible pediatric encounters for patients with a diagnosis of SCD with VOE, thus there were no differences in median time from ED arrival to initial administration of pain medication between the total and adult-only populations. At Site B, there were 22 pediatric encounters, representing 2% of the overall number of encounters. The pediatric population had a measure performance score of 92 minutes, which was 22 minutes greater than the adult-only population measure performance score of 70 minutes. However, the measure performance score for the total population, which included both the pediatric and adult populations, was 70 minutes, which was equal to the adult-only population. At Site C, there were 119 pediatric encounters, representing 19% of the overall number of encounters. The pediatric population had a measure performance score of 44 minutes, which was almost an hour less than the adult-only population measure performance score of 101 minutes. The measure performance score for the total population, which included both the pediatric and adult populations, was 92 minutes, which was 9 minutes less than the adult-only population. When data from all sites were combined, the measure score for the total population (adult and pediatric) differed from the adult-only population by only 1 minute.

Table 9. Proportion of Encounters and Measure Performance Scores by Population

ED Site	Population	Number of Qualifying Encounters, N (%)	Median Time from ED Arrival to Initial Administration of Pain Medication	Difference Between Total and Adult-Only Populations
A	Pediatric	0 (0%)	N/A	0 min
	Adult	265 (100%)	73 min	
	Total (Adult + Pediatric)	**265**	**73 min**	
B	Pediatric	22 (2%)	92 min	0 min
	Adult	1,420 (98%)	70 min	
	Total (Adult + Pediatric)	**1,442**	**70 min**	
C	Pediatric	119 (19%)	44 min	-9 min
	Adult	495 (81%)	101 min	
	Total (Adult + Pediatric)	**614**	**92 min**	
Overall	Pediatric	141 (6%)	51 min	-1 min
	Adult	2,180 (94%)	77 min	
	Total (Adult + Pediatric)	**2,321**	**76 min**	

3.3 Stratification Results

3.3.1 Stratification by Medication Route Across All Encounters

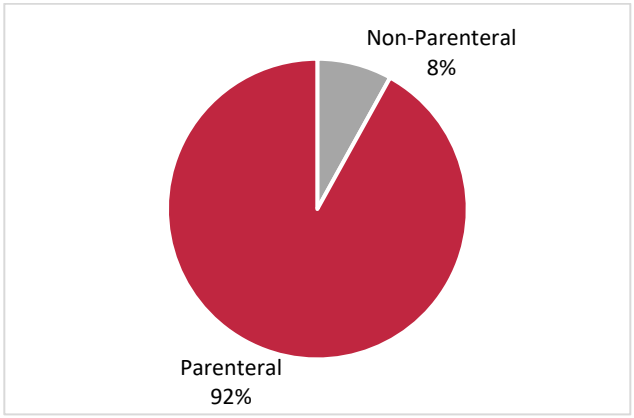
The following analyses were conducted at the encounter level (i.e., no aggregation by facility). The data in Table 10 display the number of eligible encounters, the median, and the mean time to pain medication from ED arrival (in minutes) for each medication route stratum. Across all 25 sites, there were 7,701 encounters for adults with SCD and VOE with qualifying medications to be used in the stratification analyses. Six encounters from one of the sites were excluded from the analyses because the associated medication codes were not included in the measure value sets.

Table 10. Time from ED Arrival to Pain Medication Stratified by Pain Medication Route

Stratification	Number of Qualifying Encounters, N	Percent	Time from ED Arrival to Pain Medication	
			Median	Mean
Parenteral	7,081	91.9%	70	89.3
Non-Parenteral	620	8.1%	67	105.5

Figure 2 illustrates the proportion of eligible encounters in each medication route stratum: parenteral and non-parenteral. For most cases, the first pain medication was administered parenterally (N=7,081, 91.9%), and for about one in twelve cases, the first pain medication was administered non-parenterally (N=620, 8.1%).

Figure 2. Proportion of Sample in Each Stratum



As illustrated in Figure 3, the mean time to pain medication was about 15 minutes quicker for patients given parenteral medications than for patients given non-parenteral medications (89.3 minutes for parenteral vs. 105.5 minutes for non-parenteral). However, the *median times* from ED arrival to pain medication were generally shorter and more similar between the strata (67 minutes for non-parenteral vs. 70 minutes for parenteral). This finding is indicative of the long "tails" of the underlying data – most patients' time from ED arrival to pain medication is clustered around this 70-minute mark, but because there are some patients that have very long wait times, the value of the mean measure score is stretched further away from this cluster.

Figure 3. Time to Pain Medication (in minutes), by Stratum

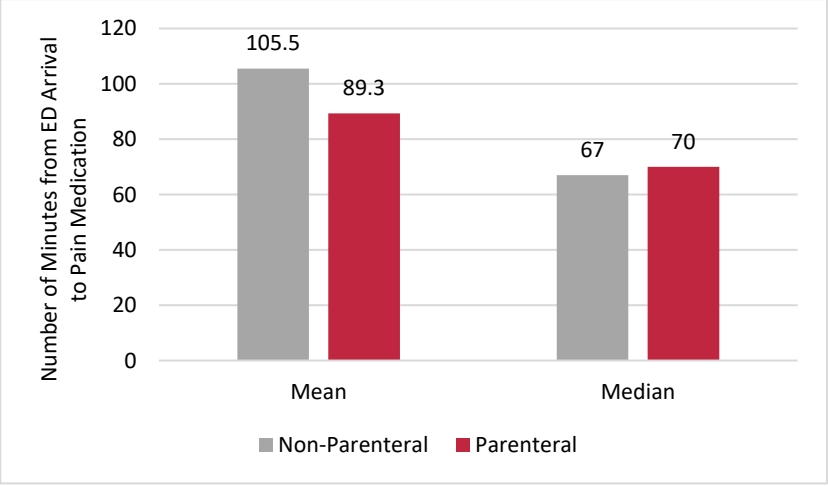
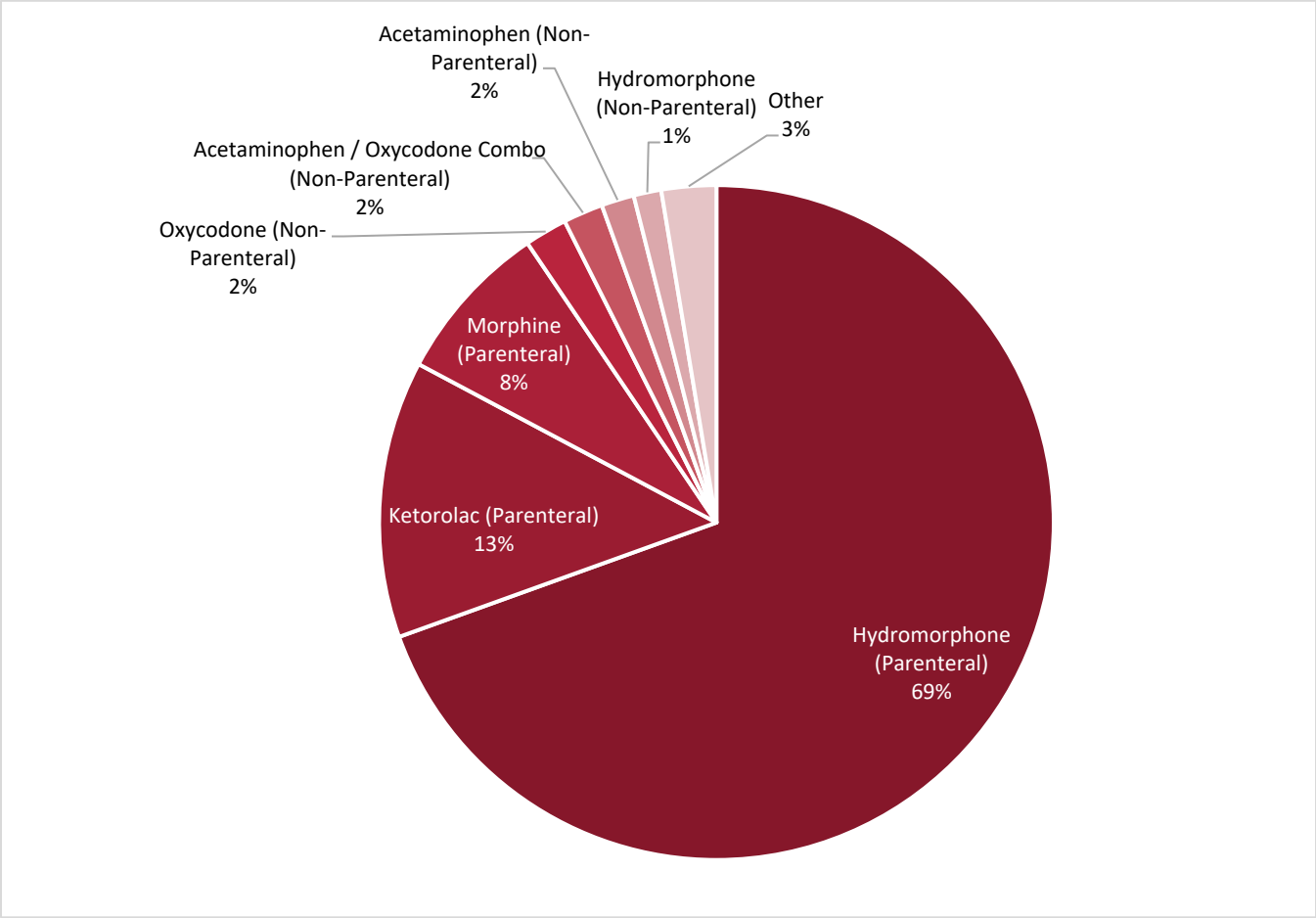


Table 11 displays the frequencies of the first-administered pain medication, while Figure 4 illustrates the proportions of each pain medication. The most common pain medication used for the treatment of acute VOE in patients with SCD across the 25 sites was parenteral hydromorphone (69.5%), followed by parenterally administered ketorolac (13.3%) and morphine (7.8%). Together, these three parenteral medications were associated with just over 90% of the cases in the sample population. The next most common medications were all orally administered oxycodone (2.0%), acetaminophen/oxycodone (1.9%), acetaminophen (1.6%), and hydromorphone (1.3%). The remaining pain medications represented less than one percent of the total number of qualifying encounters.

Table 11. Frequencies of First-Administered Pain Medication

Pain Medication	Stratum	Number of Qualifying Encounters, N	Percent	Cumulative Percent
Hydromorphone	Parenteral	5352	69.5%	69.5%
Ketorolac	Parenteral	1023	13.3%	82.8%
Morphine	Parenteral	597	7.8%	90.5%
Oxycodone	Non-Parenteral	157	2.0%	92.6%
Acetaminophen / Oxycodone Combo	Non-Parenteral	147	1.9%	94.5%
Acetaminophen	Non-Parenteral	121	1.6%	96.1%
Hydromorphone	Non-Parenteral	102	1.3%	97.4%
Fentanyl	Parenteral	63	0.8%	98.2%
Morphine	Non-Parenteral	30	0.4%	98.6%
Ibuprofen	Non-Parenteral	28	0.4%	99.0%
Acetaminophen	Parenteral	26	0.3%	99.3%
Acetaminophen / Hydrocodone Combo	Non-Parenteral	23	0.3%	99.6%
Meperidine	Parenteral	16	0.2%	99.8%
Nalbuphine	Parenteral	3	0.0%	99.8%
Acetaminophen / Codeine Combo	Non-Parenteral	3	0.0%	99.9%
Ketorolac	Non-Parenteral	3	0.0%	99.9%
Acetaminophen / Butalbital / Caffeine Combo	Non-Parenteral	2	0.0%	99.9%
Buprenorphine	Parenteral	1	0.0%	99.9%
Buprenorphine	Non-Parenteral	1	0.0%	100.0%
Hydrocodone Polistirex	Non-Parenteral	1	0.0%	100.0%
Naproxen	Non-Parenteral	1	0.0%	100.0%
Tramadol	Non-Parenteral	1	0.0%	100.0%

Figure 4. First-Administered Pain Medication



3.2.2 Stratification by Medication Route and by ED Site

The data in Table 12 display the stratified measure scores and number of qualifying encounters for each of the sites, along with the non-stratified measure score, for comparison. The frequency with which a non-parenteral medication was used for the treatment of acute VOE in patients with SCD varied across ED sites. All but one ED site (ED Site 20) administered more pain medications via a parenteral route than non-parenteral routes. This ED site administered 95.7% of its pain medications via a non-parenteral route and had a significantly larger measure score compared to the rest of the ED sites (268 minutes, compared to the overall average measure score of 87.7 minutes). Two ED sites in the testing sample administered pain medications exclusively via a parenteral route (ED Sites 16 and 21) and had relatively average measure scores (88.0 minutes and 93.0 minutes, respectively, compared to the overall average measure score of 87.7 minutes).

The mean measure scores were very similar between the strata (92.8 minutes for non-parenteral vs. 90.3 minutes for parenteral). The median non-parenteral measure score was nearly 10 minutes longer than the parenteral median measure score (84.0 minutes for non-parenteral vs. 74.9 minutes for parenteral).

Table 12. Stratified Measure Scores by ED Site

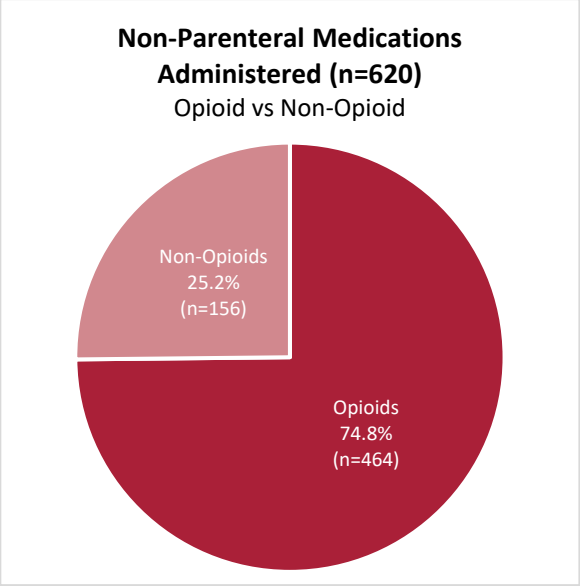
ED Site	Medication Route	Number of Qualifying Encounters, N	Percent	Stratified Measure Score	Non-Stratified Measure Score
1	Non-Parenteral	19	2.3%	110.8	105.7
	Parenteral	795	97.7%	105.3	
2	Non-Parenteral	108	8.5%	63.0	58.0
	Parenteral	1170	91.5%	57.0	
3	Non-Parenteral	98	18.2%	59.0	60.0
	Parenteral	439	81.8%	61.0	
4	Non-Parenteral	32	10.9%	84.0	70.0
	Parenteral	262	89.1%	70.0	
5	Non-Parenteral	12	4.6%	57.0	60.0
	Parenteral	251	95.4%	60.0	
6	Non-Parenteral	33	18.4%	39.0	51.0
	Parenteral	146	81.6%	55.5	
7	Non-Parenteral	30	8.5%	41.5	42.0
	Parenteral	321	91.5%	42.0	
8	Non-Parenteral	1	0.6%	63.7	90.2
	Parenteral	175	99.4%	91.1	
9	Non-Parenteral	14	6.0%	102.5	63.5
	Parenteral	218	94.0%	63.0	
10	Non-Parenteral	11	7.0%	41.0	66.0
	Parenteral	146	93.0%	66.0	
11	Non-Parenteral	15	31.9%	125.0	113.0
	Parenteral	32	68.1%	106.5	
12	Non-Parenteral	20	14.9%	60.5	70.0
	Parenteral	114	85.1%	74.0	
13	Non-Parenteral	9	9.8%	216.0	145.5
	Parenteral	83	90.2%	143.0	
14	Non-Parenteral	1	0.8%	108.2	75.0
	Parenteral	128	99.2%	74.9	
15	Non-Parenteral	0	0.0%	N/A	88.0
	Parenteral	97	100.0%	88.0	
16	Non-Parenteral	7	9.5%	112.0	46.5
	Parenteral	67	90.5%	44.0	
17	Non-Parenteral	7	6.1%	44.0	67.0
	Parenteral	108	93.9%	70.5	
18	Non-Parenteral	5	10.0%	105.0	91.0
	Parenteral	45	90.0%	91.0	
19	Non-Parenteral	45	95.7%	257.0	268.0
	Parenteral	2	4.3%	318.0	
20	Non-Parenteral	0	0.0%	N/A	93.0

ED Site	Medication Route	Number of Qualifying Encounters, N	Percent	Stratified Measure Score	Non-Stratified Measure Score
	Parenteral	62	100.0%	93.0	
21	Non-Parenteral	14	5.1%	52.1	82.2
	Parenteral	262	94.9%	85.9	
22	Non-Parenteral	59	22.8%	38.0	73.0
	Parenteral	200	77.2%	84.0	
23	Non-Parenteral	23	18.9%	138.0	142.0
	Parenteral	99	81.1%	144.0	
24	Non-Parenteral	30	6.1%	95.0	101.3
	Parenteral	465	93.9%	101.5	
25	Non-Parenteral	27	1.9%	123.0	70.0
	Parenteral	1394	98.1%	69.0	

3.2.3 Sensitivity Analysis: Frequency of Non-Parenteral Medications (Opioid vs. Non-Opioid)

An analysis of the measure data using 7,701 encounters from 25 EDs indicates that parenteral medications are used in the vast majority of cases (91.9%, n=7,081). Among the 8.1% (n=620) of qualifying encounters that involved non-parenteral medications as the first-administered pain medication, the majority were opioids (74.7%, n=463), as displayed in Figure 5.

Figure 5. Administered Non-Parenteral Opioid Vs. Non-Opioid Medications



Non-parenteral opioid medications accounted for 74.8% (n=464) of ED encounters, compared to non-opioids, which accounted for 25.2% (n=156). Among non-parenteral medications, the most commonly administered non-opioid medications included acetaminophen alone (77.6%, n=121) and ibuprofen alone (16.0%, n=28). The frequencies of all non-parenteral medications administered are displayed in Table 13.

Table 13. Types of Non-Parenteral Medications Administered

Opioid vs Non-Opioid	Pain Medication	Frequency, n	Percent, %
Opioid	Oxycodone	157	25.3
	Acetaminophen / Oxycodone Combo	147	23.7
	Hydromorphone	102	16.5
	Morphine	30	4.8
	Acetaminophen / Hydrocodone Combo	23	3.7
	Acetaminophen / Codeine Combo	3	0.5
	Hydrocodone Polistirex	1	0.2
	Tramadol	1	0.2
	Subtotal: Opioids	**464**	**74.8**
Non-Opioid	Acetaminophen	121	19.5
	Ibuprofen	28	4.5
	Ketorolac	3	0.5
	Acetaminophen / Butalbital / Caffeine Combo	2	0.3
	Buprenorphine	1	0.2
	Naproxen	1	0.2
	Subtotal: Non-Opioids	**156**	**25.2**
	Total	**620**	**100.0**

It was not feasible to assess the clinical appropriateness of the administration of non-opioid non-parenteral pain medications, without having additional information related to patient allergies, preference, and adherence to individualized care plans.

The testing data demonstrate that a minority of ED encounters had a non-parenteral medication as the first administered pain medication (8.1%, n=620). While it was expected that the majority of patients received their first dose of pain medication parenterally, it is reasonable for some patients to receive non-parenteral medications first, as part of an individualized care plan or alternative treatment protocol. Continued tracking of the first administered pain medications by medication route and type of medication will be needed to assess whether anecdotal concerns raised during measure development are warranted.

3.4 Reliability Testing Results

3.4.1 Measure Performance Score Reliability Results of the Primary Sample

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 ranged from 0.70 to 1.0, with a mean of 0.96 and an estimated 95% confidence interval of 0.89 to 0.99. This indicates very high reliability of the measure score.

3.5 Validity Testing Results

3.5.1 Data Element Validity Results of the Primary Sample

The overall percent agreement for all critical data elements exceeded the 70% threshold, indicating acceptable agreement (Table 14). 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:

1. 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.[48] 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 14. Data Element Testing Results for Critical Data Elements

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

3.5.2 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, specified for all ages, reflects its intended focus of assessing the timely administration of pain medication for patients with SCD, an indication that the measure has good face validity.

3.6 Disparity Testing Results

Disparities analysis indicated strong evidence that median time to pain medication administration was 6 minutes longer for female patients than for males (Table 15). There was also evidence that pain medication administration was 6 minutes longer for Medicaid patients relative to other insurance coverage, although a greater percentage of values for this variable (3.8%) were missing. These results suggest there are disparities between male and female patients and possibly based on insurance payer.

Table 15. Median Time to Pain Medication by Sociodemographic Variable

Variable/Stratum	Number of Qualifying Encounters, N	Median	Difference-in-Medians (comparison – reference)	*p*-value
Sex				
Female	3,387	70.0	6.0	<0.001
Male	2,430	64.0	(ref)	(ref)
Payer (N = 222 missing values removed)				
Medicaid Only	2,607	70.0	6.0	0.003
Medicare Only	1,946	64.8	0.8	0.727
Other	1,042	64.0	(ref)	(ref)

3.7 Feasibility Testing Results

Feasibility testing results across the three ED sites used to perform feasibility testing are shown in Table 16. 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 16. Feasibility Scorecards Across Three ED Sites

No.	Data Element	EHR #1: Meditech				EHR #2: EPIC-A				EHR #3: EPIC-B			
		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	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
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%

* *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[49] 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 timing of administration of pain medication for all patients, regardless of age, with a diagnosis of SCD with VOE.

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.

ASH submitted the measure to CMS during the 2024 Annual Call for Measures, and it was subsequently reviewed by the Pre-Rulemaking Measure Review (PRMR) Committee in January 2025. The PRMR Committee issued a "Recommended with Conditions" rating, specifying that future implementation of the measure should include a defined minimum case volume and stratification by both facility volume and urban versus rural status.[50] Although CMS ultimately did not propose the *Median Time to Pain Medication for Patients with a Diagnosis of Sickle Cell Disease (SCD) with Vaso-Occlusive Episode (VOE)* measure for inclusion in the Hospital Outpatient Quality Reporting Program in the Calendar Year (CY) 2026 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (90 FR 33476),[51] the recommendations from the PRMR Committee remain valid beyond the current rulemaking cycle, as confirmed by Battelle, the PRMR contractor. ASH is committed to continued collaboration with CMS to identify a path for implementation in CMS programs in subsequent years.

ASH remains committed to advancing the measure's implementation. ASH has publicly posted the measure specifications and will offer technical resources to support implementation by interested stakeholders, including EDs and health IT vendors. ASH will also engage with organizations interested in adopting the measure within their existing quality improvement programs or digital platforms, promoting broader dissemination and use.

To ensure transparency and mitigate potential unintended consequences, such as preferential use of non-parenteral medications to achieve faster treatment times, as raised during the public comment period (Appendix D), the measure incorporates a stratified reporting approach. Specifically, providers using the measure should report the following measure results:

- The overall median time to first pain medication administration,
- Stratified median times for parenteral and non-parenteral medication administration, and
- The proportion of encounters in which a parenteral medication was administered first, compared to non-parenteral.

This stratification strategy is intended to monitor variation in clinical practice and support equitable and appropriate pain management across settings.

5. Conclusion

The measure addresses an important measurement gap for the timing of administration of pain medications in adult and pediatric patients with a diagnosis of SCD with VOE who present to the ED. The TEP, patients, and caregivers who were consulted found the measure to be both important and meaningful. Measure score results indicate 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 CBE endorsement thresholds for reliability and data element validity. It is harmonized with other measures and is specified as an eCQM, using only clinical digital data sources. Data elements are accurate, routinely captured during the clinical course of care and use standardized vocabularies, adding minimal burden for providers. The data elements used in the measure are also consistent with the standard set of data elements as defined by the USCDI, Version 5.[24]

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

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Appendix A. Measure Information Form / Algorithm

eCQM Title	Median Time to Pain Medication for Patients with a Diagnosis of Sickle Cell Disease (SCD) with Vaso-Occlusive Episode (VOE)
Version	1.1.000
Measure Description	Median time (in minutes) from Emergency Department (ED) arrival to initial administration of pain medication for all patients, regardless of age, with a principal encounter diagnosis of sickle cell disease (SCD) with vaso-occlusive episode (VOE)
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. (R) or [R] represents Registered Trademark, and (c) represents Copyright.
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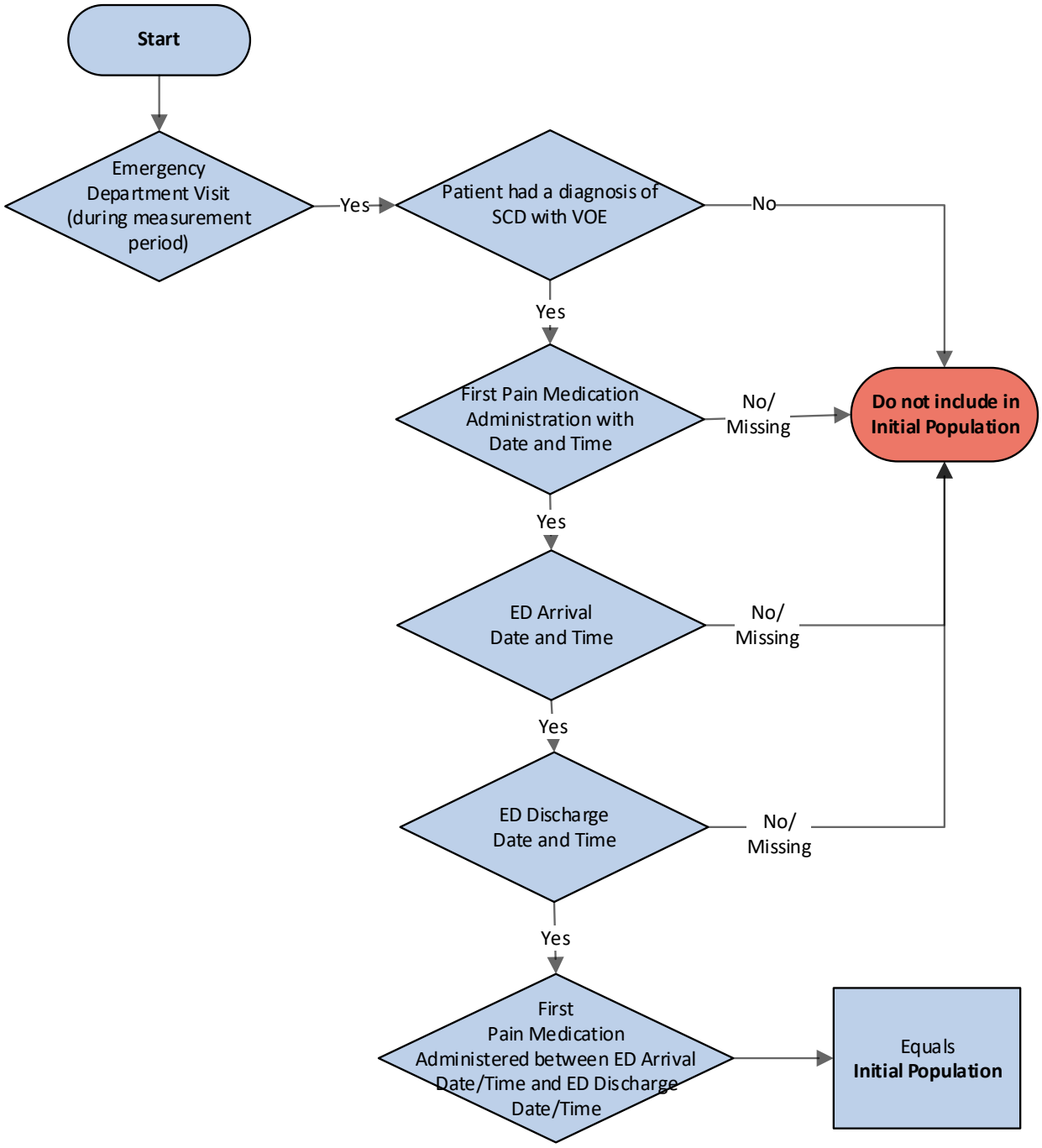
Initial Population	ED encounters with a discharge time during the two-year measurement period for all patients, regardless of age, who have a principal encounter diagnosis of SCD with VOE and who have at least one qualifying pain medication administered during the ED encounter
Observation Description	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	This measure is supported by two evidence-based clinical practice guidelines. The clinical recommendation statements from the supporting guidelines are noted below and specifically recommend the rapid initiation of analgesic medications for patients presenting to the ED with acute pain associated with a diagnosis of SCD with VOE, which demonstrates a direct relationship to this measure: 1) The American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain (Brandow et al., 2020) **Statement:** 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).
Rationale	Sickle Cell Disease (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).	
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 a patient, regardless of age, 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, 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	☐ Outcome ☐ Patient Engagement/Experience ☐ Patient Reported Outcome Performance Measure ☐ Structure
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



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

Stratification 1: Median time (in minutes) from ED arrival to initial administration of parenteral pain medication

Stratification 2: Median time (in minutes) from ED arrival to initial administration of non-parenteral pain medication

Encounter Level Time To Pain Medication Calculation =

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

Measure Score Calculation of Median Time to Pain Medication =

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

Appendix B. Generic List of Qualifying Pain Medications*

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

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

Appendix C. Generic List of Qualifying Pain Medications by Parenteral and Non-Parenteral Route

Pain Medication Categories	Qualifying Generic Pain Medications		
	Parenteral	**Non-Parenteral**	
Opioids	• Alfentanil • Buprenorphine • Butorphanol • Fentanyl • Hydromorphone • Meperidine • Methadone • Morphine • Nalbuphine • Oliceridine • Pentazocine • Remifentanil • Sufentanil	• Buprenorphine • Butorphanol • Codeine • Fentanyl • Hydrocodone • Hydromorphone • Levorphanol • Meperidine • Methadone • Morphine	• Oxycodone • Oxymorphone • Pentazocine/naloxone • Sufentanil • Tapentadol • Tramadol
Opioid Combinations	• None	• Benzhydrocodone/Acetaminophen • Buprenorphine/Naloxone • Codeine combinations • Codeine/Acetaminophen • Codeine/Acetaminophen combinations • Dihydrocodeine/Acetaminophen	• Hydrocodone combinations • Hydrocodone/Acetaminophen • Hydrocodone/Aspirin • Hydrocodone/Ibuprofen • Morphine/Naltrexone • Oxycodone/Acetaminophen • Oxycodone/Aspirin • Oxycodone/Ibuprofen • Tramadol /Acetaminophen • Tramadol/Celecoxib
NSAIDs	• Bupivacaine/Meloxicam • Ibuprofen • Indomethacin • Ketorolac • Meloxicam	• Acetaminophen/NSAID combinations • Celecoxib • Diclofenac • Diclofenac/Misoprostol • Diflunisal • Etodolac • Fenoprofen • Flurbiprofen • Ibuprofen • Ibuprofen combinations • Indomethacin • Ketoprofen • Ketorolac	• Magnesium Salicylate • Magnesium Salicylate combinations • Meclofenamate • Mefenamic Acid • Meloxicam • Nabumetone • Naproxen • Naproxen combinations • Oxaprozin • Piroxicam • Salsalate • Sulindac • Tolmetin
Other Analgesics	• Acetaminophen • Ketamine • Ziconotide	• Acetaminophen • Acetaminophen combinations Gabapentin	

Appendix D. Public Comment Summary

Public Comment Summary

Median Time to Pain Medication for Patients
With a Diagnosis of Sickle Cell Disease (SCD)
With Vaso-Occlusive Episode (VOE)

May 17, 2024

This document was prepared by the Health Services Advisory Group, Inc. (HSAG), under contract with the American Society of Hematology (ASH). The contents presented do not necessarily reflect ASH policy.

Project Overview

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 (the team) convened a Technical Expert Panel (TEP) composed of clinical experts in hematology and emergency medicine, as well as a patient representative, 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 also agreed with the prioritization of this concept for further development and testing. The team developed the following patient-centered and equity-focused facility-level eCQM draft measure 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):

> **Measure Title:** Median Time to Pain Medication for Patients with a Diagnosis of Sickle Cell Disease (SCD) with Vaso-Occlusive Episode (VOE)
>
> **Measure Description:** Median time (in minutes) from ED arrival to initial administration of pain medication for adult patients with a principal diagnosis of SCD with VOE

Purpose of this Report

This report serves to describe the methodology used to solicit feedback from interested parties on the above-referenced quality measure, provide a summary of the public comments received, and provide a list of the verbatim comments obtained. The project team uses input obtained by interested parties to further refine the measure specifications.

Public Comment Solicitation

The project team facilitated a 15-day public comment period between April 15 and April 29, 2024. ASH invited all of its members, including members of various committees, the American College of Emergency Physician (ACEP) staff members, the Emergency Department Sickle Cell Care Coalition leaders, and various federal partners to provide comments on the importance/relevance, reliability, and/or feasibility aspects of the quality measure. Additionally, all members of the TEP were encouraged to share the call for public comment with interested colleagues. Please refer to Appendix D.1 for a complete list of organizations/groups contacted. The announcement for the Call for Public Comment was posted on the ASH website. The Methodology Report, including the testing results and value sets used in the measure specifications were made available to the commenters to review.

A total of 48 participants submitted comments on the measure, of which 81% represented comments from an individual perspective and 19% represented comments from an organizational perspective. Of the 48 participants who provided comments, 54% represented adult and pediatric hematology and hematology/oncology specialties, followed by 10% emergency medicine, and 2% psychiatry. The team also received feedback from three commenters (6%) who identified as a patient or caregiver. International comments were

received from five countries outside the U.S. (i.e., Azerbaijan, India, Nigeria, Oman, and Uganda).

Summary of Stakeholder Comments—Specific Categories and General Comments

Stakeholders were requested to provide feedback on the measure concerning any of the following measure evaluation criteria:

1. Importance/Relevance that the measure addresses a high-impact or meaningful aspect of healthcare
2. Feasibility, which assesses the extent to which the required data are available, retrievable without undue burden, and the extent to which they can be implemented for performance measurement
3. Reliability, such that the measure produces reliable results about the intended areas of measurement. Comments regarding data element validity were not specifically solicited as data element testing was not completed at the time of the public comment solicitation.

In addition, the team solicited General Comments on the measure. The comments were summarized by HSAG and categorized below. Although the team did not specifically solicit comments related to the Equity/Disparities topic, we received multiple comments on this topic and have summarized those comments in a separate topic below. Appendix D.2 contains the verbatim comments received with individual responses.

Importance/Relevance

- 85% expressed overwhelming support for the measure and emphasized the importance of timely analgesic medication administration in this population. For example, one commenter said: "*This is the one best specific, measurable, achievable and feasible QI in SCD right now.*" There was consensus that information provided by this measure would improve care for patients with SCD and VOE treated in EDs and help to reduce length of stay.

Feasibility

- 19% indicated the measure should be fully operationalized within the electronic medial record (EMR) and would be highly feasible, if implemented. For example, one commenter said: "*Brilliant—should be fully operationalized within EMR and brings welcome attention to the SCD pain Clinical Practice Guidelines (CPG). Congratulations to the quality measures team!*"

Equity/Disparities:

- 15% indicated the measure has the potential to reduce disparities for this vulnerable patient population and encouraged the measure steward to continue to evaluate the measure for equity gaps. For example, one commenter said: "*Introducing a quality measure for expectation of timely analgesia can reduce the disparities in care.*"

Reliability

- 6% indicated the measure had good reliability. For example, one commenter said: "*This measure appears to have reliability given studied across different states and settings...*"

General Comments

Twenty-nine percent (14/48) of commenters provided general comments unrelated to importance, feasibility or reliability as part of their response. These comments, their related responses, and whether changes were made to the measure specifications based on feedback from public comments are summarized in Table D.1.

Table D.1. Other Topics from Public Comments

General Comments	Response	Specification Changes
• Low median times may not always be feasible depending on competing demands and resources available. • Reluctant to use such a metric to incentivize/penalize performance given the difficulty controlling all the variables: - High acuity of patient mix - Number of staff / types of staff - ED volume at time of patient's presentation - Geographic location of ED - Familiarity of ED staff with management of SCD - EMR.	• The measure encourages that standard procedures are established to reduce variation. • The planned use for the measure is pay-for-reporting and quality improvement—not pay-for-performance. • Depending on CMS use, hospitals may be compared only to those facilities with similar volume. • Process measures are not currently risk adjusted.	No changes recommended at this time.
• Consider including pediatric population.	• The measure's population was originally restricted to adults because there was already an existing pediatric measure, which assessed patients younger than 18 years of age who had a parenteral analgesic within 60 minutes following initial contact. However, given the public comment feedback and the fact that the clinical practice guidelines that support this measure include the pediatric population, we will expand the measure's population to include all patients, regardless of age.	The measure population will be expanded to include all patients, regardless of age; additional testing will be completed to include the pediatric population.

General Comments	Response	Specification Changes
• Clarify starting point from which "time" is measured.	• To reduce provider burden associated with reporting data on quality measures, the measure was harmonized and aligned, to the extent possible, with four existing measures* implemented in the hospital Outpatient Quality Reporting (OQR) program that use *ED Arrival Date* and *ED Arrival Time.* These measures define ED arrival as earliest documented time the patient arrived in the ED. See list of measure at the bottom of this table.	No changes recommended at this time.
• Use NHLBI [National Heart, Lung, and Blood Institute] expert opinion recommendation requiring analgesic administration within 30 min. of ED triage or 60 min. of registration.	• The TEP cautioned against using time thresholds as a metric since the evidence is mostly based on expert opinion and there could be unintended consequences with specifying the measure with an explicit time threshold. • Differences in facility characteristics (e.g., volume, patient acuity) also factored into the decision to not require a specified threshold.	No changes recommended at this time.
• Question received about whether measure accounts for the type of ED (e.g., trauma center, rural, urban).	• Testing included diverse types of EDs, but depending on the CMS use of the measure, scores may be reported stratified by facility volume.	No changes recommended at this time.
• Giving everyone acetaminophen orally at check in or in the waiting room will meet the measure. • A single dose of ibuprofen or gabapentin at triage would produce a stellar metric but would do little to change care. • Suggest re-evaluating analgesic list: Evidence for	• The TEP re-evaluated the list of analgesic medications following public comment and agreed to remove implausible pain medications. • The TEP favored retaining a broad list of pain medications to allow for individualized patient-centered treatment plans (e.g., opioid vs non-	• Updated the pain medication value set to remove a limited number of medications implausible to be administered in the ED for patients presenting with pain symptoms related to SCD and VOE. • Stratify the measure by route upon implementation.

General Comments	Response	Specification Changes
NSAIDs for adults in crisis is thin, some included medications are nonexistent or implausible.	opioid). However, the measure is recommended for stratification by route of administration to monitor for potential unintended consequences resulting from the implementation of the measure.	
Additional or different metrics were proposed: • Rate of opioid usage as a balancing measure to avoid overprescribing to improve on the measure. • Time to pain control OR effectiveness of pain management OR re-evaluation and re-dosing. • Time from medication ordered to medication administration. • Time from registration to first dose OR entrance to first dose. • Proportion receiving an opioid first or time to first opioid in those receiving opioids. • Time to second dose in those receiving a second dose. • Treatment with disease modifying therapies to prevent need for time to pain medication measures.	• ASH appreciates hearing about additional metrics of interest from commenters. ASH will evaluate whether supplemental or alternative metrics could be developed as *de novo* measures in the future.	No changes recommended at this time.

* OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival, OP18: Median Time from ED Arrival to ED Departure for Discharged ED Patients, OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival, and OP-40: Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED). Of note, in 2025, OP-40 will replace OP-2.

Summary of Actions Taken

We appreciate the feedback from all commenters. The following clarifications to the measure specifications have been made:

- The measure population will be expanded to include all patients, regardless of age; additional testing will be completed to include the pediatric population.
- The TEP re-evaluated the list of qualifying pain medications and agreed to remove a limited number of medications implausible to be administered in the ED for patients presenting with pain symptoms related to SCD and VOE.
- The TEP favored retaining a broad list of pain medications to allow for individualized treatment plans and clinical autonomy.
- Measure scores will be stratified by route of medication administration to monitor for potential unintended consequences resulting from the implementation of the measure.

ASH has submitted the measure to the CMS Annual Call for Measures for consideration in the hospital Outpatient Quality Reporting (OQR) and Rural Emergency Hospital (REH) programs, both of which are pay-for-reporting programs. Hospitals providing emergency services that participate in the OQR and REH programs collect and report data on a set of select quality measures for potential public reporting on the CMS Hospital Care Compare website. The level of accountability for the measure is specified at the ED level for use in the outpatient setting in either freestanding ED facilities or EDs affiliated with an acute care hospital or within a rural emergency hospital, using a two-year measurement period. This measure is specified and is intended to be implemented as an eCQM.

Appendix D.1. List of Organizations/Groups Contacted

1. All members of the ASH SCD Technical Expert Panel
2. All members of the American Society of Hematology
3. ASH - Committee on Quality
4. ASH - Quality Measure Oversight Subcommittee
5. ASH - Guideline Oversight Subcommittee
6. ASH - Subcommittee on Dissemination and Implementation Science
7. ASH - Subcommittee on Quality Improvement Education and Training
8. ASH - Subcommittee on Stewardship and Systems-based Hematology
9. ASH - Committee on Government Affairs
10. ASH - Committee on Practice
11. ASH Clinicians in Practice (ACIP)
12. ASH Research Collaborative (ASHRC) Data Hub participants
13. American College of Emergency Physician (ACEP) staff contacts
14. Emergency Department Sickle Cell Care Coalition (EDSC3) leaders
15. Community Groups:
    - Sick Cells
    - Sickle Cell Disease Association of America
    - Sickle Cell Community Consortium
16. Federal Partners at HHS, CDC, HRSA, FDA, CMS and NIH
17. Sickle Cell Disease Coalition (SCDC) (100+ organizational members) via the weekly Flash Friday e-mail message and the Monthly SCDC Update (e-mail newsletter that goes to many people beyond the Coalition). ASH also mentioned the public comment period on recent calls with SCDC members.

Appendix D.2. Public Comment Verbatim Report

Verbatim comments received during the public comment period are provided below Table D.2 shows comments from individual perspectives and Appendix D.3 shows comments received from the organizational perspective in order they were received. If the responder chose to remain anonymous, *Anonymous* is entered in the table; other missing information is entered as *Not indicated*. All comments in the tables appear as they were received and have not been edited for spelling, punctuation, grammar, or any other reasons.

Table D.2. Verbatim Public Comments – Individual Perspective

No.	Date Received	Name, Credentials, and Title	Organization of Commenter	Specialty or Perspective	Text of Comments	ASH and HSAG Response
1.	4/15/2024	Zora R. Rogers, MD Professor of Pediatrics Emerita	University of Texas Southwestern Medical Center, Dallas, TX	Pediatric Hematologist and Sickle Cell Specialist	What is critical is that there is standardization of the starting point from which "time" is measured..... first registration in ED, being placed in room, time first seen by provider (sic). However, this is the best measure of how an ED responds to the most basic needs of sickle cell patients.	We appreciate your comments and support of the measure. To reduce provider burden associated with reporting data on quality measures, the measure was harmonized and aligned, to the extent possible, with four existing measures* implemented in the hospital Outpatient Quality Reporting (OQR) program that use *ED Arrival Date* and *ED Arrival Time.* These measures define ED arrival as earliest documented time the patient arrived in the ED. See list of measure at the bottom of this table.
2.	4/15/2024	Neil Zakai, MD Professor of Medicine / Attending Physician	University of Vermont	Hematology	The time to administration of pain medication is not the real metric. Most people would agree that giving everyone acetaminophen orally when they check in isn't appropriate but would meet this metric. The real importance is time to pain control not time to administering pain medication.	Thank you for your comment. We agree that the ultimate treatment goal for patients with SCD presenting to the ED with severe pain is appropriate pain control. However, even across the 23 sites we tested, the mean measure score across facilities was 87.9 minutes with scores ranging between 42 and 268 minutes. When compared to the benchmark of 60.0 minutes per the ASH 2020 guidelines for sickle cell disease, these results indicate the measure shows ample room for improvement.
3.	4/15/2024	Hauwau Aminu Inuwa, MBBS, Physician	Aminu Kano Teaching Hospital, Nigeria	Clinical Hematology	It is relevant as it will help is hasten administration of analgesia to alleviate pain in patients with moderate to severe VOC.	We appreciate your comments and support of the measure.
4.	4/15/2024	Roger Berkow, MD Professor of Pediatrics	Morehouse School of Medicine	Hematology	Very important and feasible.	We appreciate your comments and support of the measure.

No.	Date Received	Name, Credentials, and Title	Organization of Commenter	Specialty or Perspective	Text of Comments	ASH and HSAG Response
5.	4/15/2024	Matthew Cheung, MD	Not indicated	Not indicated	Brilliant- should be fully operationalized within EMR and brings welcome attention to the SCD pain CPG. Congratulations to the quality measures team!	We appreciate your comments and support of the measure.
6.	4/15/2024	Keith Quirolo, MD Medical consultant for sc101	Sickle Cell 101 (SC101)	Pediatric Sickle Cell Disease	This metric has been used frequently. Hopefully takes into account the type of ED (trauma center, rural, urban, etc.)	Thank you for your comment. Testing of the measure included a variety of different EDs, from urban and rural sites, trauma levels, and whether they were freestanding or not. Depending on CMS decision, hospitals may be compared based on volume categories.
7.	4/15/2024	Philipe Fleurimond,	Not indicated	Caregiver	Good	We appreciate your comments and support of the measure.
8.	4/15/2024	Heather Male, MD Associate Professor	Not indicated	Hematologist, physician advisor	Recognition and intervention of vaso-occlusive events and analgesia delivered timely and equitably are essential for treatment of sickle cell disease. Individualized care plans with consistency and equity for analgesia is essential for these patients, who often face stigma and labels while suffering from a debilitating disease. Introducing a quality measure for expectation of timely analgesia can reduce the disparities in care. Opioid dependence and abuse remain a challenge in all chronic pain diseases, and sickle cell disease is not excluded from this concern. Introduction of a measure that could perpetuate this problem is not the intent and I support the inclusion of use of non-opioid analgesics that qualify.	We appreciate your comments and support of the measure.
9.	4/15/2024	Rebecca McFall, MD	Advocate Children's	Pediatric Hematology Oncology	Reasonable metric. That's what I was taught 20 years ago. Would you target registration to first dose? Or entrance to first dose?	We appreciate your comments and support of the measure. To minimize provider burden associated with reporting data for the measure and ensure harmonization, we aligned the specifications with existing measures* that use similar data elements and definitions that are currently implemented in in the hospital Outpatient Quality Reporting (OQR) program (e.g., *Arrival Time*). OQR defines *Arrival Time* as the earliest documented time (military time) the patient arrived at the outpatient or emergency department.

No.	Date Received	Name, Credentials, and Title	Organization of Commenter	Specialty or Perspective	Text of Comments	ASH and HSAG Response
10.	4/15/2024	Tulika Seth, MD, Physician	AIIMS, New Delhi, India	Hematology	Variables in culture, some marginalized communities may be unwilling to express dissatisfaction with pain control or describe pain severity.	We appreciate your comments and support of the measure.
11.	4/15/2024	Ofelia Alvarez, MD Professor of Pediatrics	University of Miami	Pediatric hematology	Extremely important. I am actually this is QI project in the hospital I work at.	We appreciate your comments and support of the measure.
12.	4/16/2024	Ted Wun, MD Professor of Medicine	UC Davis Health	Hematology	An important metric for most patients.	We appreciate your comments and support of the measure.
13.	4/16/2024	Anonymous	Not indicated	Hematology	The focus of this as a quality measure is misguided. Why are you not focused on why so few patients are treated with disease modifying therapy to prevent the need for time to pain medication measures?	Thank you for your comment. We prioritized the development of this measure based on input from patients who were surveyed who indicated that pain management was the most important measure concept that would help inform their care decisions.
14.	4/16/2024	Caterina Minniti, MD Professor of Medicine and Pediatric	Albert Einstein college of medicine	Hematology-Oncology	Very important and relevant.	We appreciate your comments and support of the measure.
15.	4/16/2024	Anna Sitthi-amorn, MD, MHQS	Not indicated	Not indicated	Great and very important measure. Long overdue. If not already planned, please consider tracking the rate of opioids usage with implementation as a balancing measure. This is to ensure no overprescribing in an effort to get the quality score up.	We appreciate your comments and support of the measure. We also appreciate the suggestion for developing a balancing measure to avoid overprescribing opioids. ASH will evaluate whether supplemental or alternative metrics could be developed as *de novo* measures in the future.
16.	4/16/2024	Erin Werner, PA	UW Health	Emergency Medicine	This quality measure is a metric that is of utmost importance for the SCD population, similar to other quality measures that are tracked (time to EKG, ABX, etc.) for the purposes of patient outcomes and satisfaction. Knowing our own department, it will vary based on the day and providers/staff working, and low median times may not always be feasible depending on resources available, and competing demands (high acuity, MCI, etc.). Staff	We appreciate your comments and support of the measure. The measure will encourage providers to establish standard procedures to help reduce variation.

No.	Date Received	Name, Credentials, and Title	Organization of Commenter	Specialty or Perspective	Text of Comments	ASH and HSAG Response
					education is one easy-to-implement aspect that can have high impact.	
17.	4/16/2024	Esteban Gomez, MD Hematologist	The Center for Inherited Blood Disorders	Hematology	Extremely important.	We appreciate your comments and support of the measure.
18.	4/16/2024	Henry, MD, PhD, Physician	le Mémorial Medical, Uganda	Hematology	Extremely important, relevant and feasible.	We appreciate your comments and support of the measure.
19.	4/16/2024	Wally R Smith, MD, Physician, Florence Neal Cooper Smith Professor of Sickle Cell Disease, VCU	Virginia Commomwealth University	Hematology, Quality Improvement	This is the one best specific, measurable, achievable and feasible QI in SCD right now.	We appreciate your comments and support of the measure.
20.	4/16/2024	Oladipo Cole, MD	Not indicated	Hematology	This is highly important. There are several studies that report positive outcomes when time to pain medication, specifically parental opioids reduce hospitalization, and even total stays. It also improves patient suffering and quality of care. This is something that can be easily monitored. If healthcare organizations abide by this quality measure, it will increase patient satisfaction, healthcare costs and reduce complications. This will also help with equity in healthcare.	We appreciate your comments and support of the measure. We have recommended that the measure be stratified by route of administration to monitor potential unintended consequences resulting from the implementation of the measure.
21.	4/17/2024	Fatima Mohamed Ahmed Mukhtar Ahmed, MD Doctor	Purelab	Hematology	To provide long life free from pain for patient with SCD with VOE.	
22.	4/17/2024	C. Patrick Carroll, MD Director of Psychiatric Services, Sickle Cell Center for Adults	Johns Hopkins School of Medicine	SCD psychiatrist and chronic pain clinician	I applaud the work to develop this measure. It's an important effort. I take the state of evidence to be that rapid, individualized analgesia with equally rapid re-evaluation and re-dosing for patients presenting with a crisis works best. I think therefore that the "Grail metric" would measure rapid initiation and fidelity to an individualized treatment plan. This of course presupposes that patients universally have an individualized plan, and that is far from true right now. This metric attempt to measure rapidity in a straightforward, reliable way - which is likely useful, but as a single measure divorced from	Thank you for your comment. The TEP re-evaluated the list of pain medications and agreed to remove implausible pain medications (i.e., opium tincture and belladonna opium). However, the medication list has been left intentionally broad to allow for individualized patient-centered treatment plans (e.g., opioid vs non-opioid). Additionally, we have recommended that the measure be stratified by route of administration to

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					individualized analgesia has serious weaknesses on the side of validity, since the incentive structure of quality metric reporting is very different from the research protocols in which we found that time to first dose was important. In the real world, I think time to first dose is strikingly easy to "game," meaning to intentionally divorce the metric from the assumed metric-to-process-quality relationship and adjust the former without substantive change to the latter. As a simple example, a policy to provide everyone with SCD with a single dose of ibuprofen or gabapentin at triage would produce a stellar-looking metric but would probably do little to change care. This can very easily backfire in the real world and penalize those operating in good faith when true improvement can be so easily and cheaply mimicked. I agree in principle with the decision to "cast the net wide" on what counts as a qualifying analgesic *if* we do not have individualized treatment plans available. However, it's also true that the evidence for NSAIDs in adults for crisis is thin, for some medicines that are included in the list it is nonexistent and a little implausible, and we don't have any good way of telling if this represents an intensification of treatment over the patient's at-home regimen. I would suggest taking a hard look at the analgesic list, and perhaps considering producing more than one metric - proportion receiving an opioid first, time to first analgesic AND time to first opioid in those receiving opioids, and to capture re-evaluation and re-dosing (also probably a critical process measure) consider adding time to SECOND dose of analgesic/opioid in those receiving a second dose. I also note that this metric is divorced from effectiveness. We have some reasonable benchmarks for pain improvement during SCD crises, and it seems this would be a very useful measure to include. -Pat	monitor potential unintended consequences resulting from the implementation of the measure.
23.	4/17/2024	Charleen Jacobs-McFarlane, PhD,	Mount Sinai Hospital	Sickle cell Provider	Agree with the findings.	We appreciate your comments and support of the measure.

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		RN, ANP-BC, Nurse Practitioner				
24.	4/18/2024	Abimbola Aboluwarin, MD, Physician	Sicklelive foundation, Nigeria	Patient	The quality measure is extremely important and feasible. It will be of benefit to care of patients with SCD.	We appreciate your comments and support of the measure.
25.	4/18/2024	Jackie Powers, MD Associate Professor	Baylor College of Medicine / Texas Children's	Pediatric Hematology	The measure is excellent. I believe it is important and relevant to the affected patient population in terms of appropriate clinical care. It gives an objective target to a population that is affected tremendously by discrimination and bias. My only question is why the measure description is limited to adult patients and not also inclusive of pediatric patients with SCD. These patients, especially adolescent SCD patients are subject to similar biases and would also benefit from timely pain medication administration. Thank you.	We appreciate your comments and support of the measure. The measure's population was originally restricted to adults because there was already a pediatric measure that existed, which assessed patients younger than 18 years of age who had a parenteral analgesic within 60 minutes following initial contact. However, given the public comment feedback and the fact that the clinical practice guidelines that support this measure include the pediatric population, we will expand the measure's population to include all patients, regardless of age.
26.	4/18/2024	Regina D. Crawford, MD SCD Adult Clinic Medical Director	The Ohio State University	Hematology	Importance is for timely care of pain in patients with sickle cell disease. This measure appears to have reliability given studied across different states and settings, although noted no west coast centers were included.	We appreciate your comments and support of the measure. Since SCD is a rare disease, we prioritized the selection of test sites that were located in states with the highest population of patients with SCD.
27.	4/19/2024	Nkonge Ronald, MD Immunologist	Integrated Biorepository of H3Africa, Uganda	Research and Caregiver	Quality always predicts the outcome of the product.	We appreciate your comments and support of the measure.
28.	4/19/2024	Gail Sealy, mother of patient with SCD	Not indicated	Caregiver	This is highly needed. There is unbelievable suffering due to ignorance in the E R for patients with SCD. Also, if they have a fever, potential for sepsis is not recognized. Guidelines are needed for all ER to escalate patients with pain and/or fever to be given priority attention. Ability to refer to a rapid response team would also be beneficial. thanks for the initiative.	We appreciate your comments and support of the measure.
29.	4/20/2024	Ify Osunkwo, MD Chief patient Officer	Novo Nordisk rare disease	Hematology	I like that the measurement is for any/all pain med rather than parental accommodating broad ED practices. Also, it's not just limited to opioid meds reducing potential stigma	We appreciate your comments and support of the measure.

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					bias This makes for high feasibility and uptake by centers including those with strong bias against giving opioids to persons with SCD. Highly relevant measure as it shows degree to which addressing. VOE is prioritized over squabbles on which or how much opioid to administer.	
30.	4/20/2024	John Burke, MD Physician	Rocky Mountain Cancer Centers	Hematologist	I support using this important measure. It should be reliable, feasible, and reproducible.	We appreciate your comments and support of the measure.
31.	4/20/2024	Jerome Seid, MD, FACP Physician	Great Lakes Cancer Management Specialists	Hematology, Oncology	The median time to pain medication administration is a reasonable and worthwhile quality metric. Patients and providers need to know what level of care is to be expected in an ED. However, the variability of resource availability makes this somewhat unreliable, especially as a stand-alone measure. For example, staffing types and numbers (physician, pharmacy, nursing), EMR, ED volume at the time of a patient's presentation, geographic location and the familiarity of the ED staff with the management of SCD patients could introduce wide variability even within one experienced ED. I would be reluctant to use such a metric as a way to incentivize or penalize performance outside the margin of error given the difficulty controlling all the variables. But I am cautiously optimistic that such a quality measure will help to establish a benchmark for further improvement efforts and will result in improved and more uniform care for SCD patients with VOE.	We appreciate your comments and support of the measure. The measure will encourage providers to establish standard procedures to help reduce variation. Please consider that the planned use for the measure is a pay-for-reporting incentive and not pay-for-performance.
32.	4/21/2024	Claire Honl, RN Registered nurse	Not indicated	Hematology/ Blood and Marrow Transplant	This is a highly important measure, and I would encourage continually assessing it from a lens of equity. It will be important to consider not just length of time for medication administration but also length of time for when the medication was actually ordered. Often times delays occur that delay the time to order placement, which may be the overall root delay of the administration.	We appreciate your comments and support of the measure. The measure encourages that standard procedures are established to reduce variation.
33.	4/23/2024	Erin Jou, MD Attending Physician		Hematology	Given ASH's strong recommendation for early intervention, this is a very important project that addresses an important measurement gap. It shows an area of opportunity for	We appreciate your comments and support of the measure.

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					improvement which will hopefully lead to improvement in quality of care for our patients with SCD.	
34.	4/25/2024	Judith Paice, PhD, RN Director, Cancer Pain Program	Northwestern University	Hematology/ Oncology	As an advanced practice provider who provides care for people with sickle cell disease and severe pain, I strongly support the electronic clinical quality measure that will incorporate median time to pain medication in the emergency department. Those with sickle cell disease and vaso-occlusive episodes often face protracted wait times when seeking care in the emergency department for severe pain. This measure has the potential to advance pain care for this vulnerable population.	We appreciate your comments and support of the measure.
35.	4/25/2024	Paula Tanabe, RN, PhD Distinguished Professor of Nursing	Duke University	Emergency nursing and researcher in improving treatment of SCD in the ED	Thank you for the opportunity to comment on this incredibly important measure. I have dedicated my career to improving the treatment of VOE in the ED. I am an emergency nurse scientist. I spent 25 years at the bedside providing care to patients with SCD in the ED and witnessed the bias, stigma, and poor treatment of pain to individuals with SCD. I have collaborated closely with SCD experts and hematologists. I also led the chapter on Acute Complications of the 2014 NHLBI recommendations. As a nurse scientist I spent the last 24 years of my career conducting research to demonstrate the problem and develop interventions to improve ED care for individuals with SCD. I was funded by NHLBI and NINR and the results of these trials have been published in peer reviewed journals. I have included these as additional references that are relevant to this measure and were not included and should be. These trials compare the difference in reduction of pain for patients with SCD randomized to individualized vs. weight-based pain plans in the ED, as recommended in both the NHLBI and ASH guidelines. I strongly endorse this measure. It will lend credibility to the importance of improving ED care for those suffering with SCD. Adoption of this as an eCQM would be so important. Release of this measure which recommends rapid time to first opioid comes at a time of record ED overcrowding and an opioid epidemic. In order to provide rapid pain relief to individuals with SCD a team approach between hematologists, ED providers and informatics specialists is needed. It will be	We appreciate your comments and support of the measure. Thank you for sharing these studies, which demonstrate the importance of reducing time to pain relief and use of individualized treatment plans for patients with SCD. To align with our measure, our literature review targeted studies that assessed time to pain medication administration in the emergency department for patients with SCD. As ASH develops implementation materials, these studies will serve as additional resources to emergency departments that are reporting on this measure and are looking to identify ways to improve the quality of care overall for patients with SCD (beyond the timing of initial analgesia). We will also consider where we can incorporate these studies and your recommended changes into a finalized version of our methodology report.

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					necessary to provide initial pain management in the waiting room. I have made several suggestions to the logic model which I believe are very important to actually allow EDs to successfully meet the intent of this measure. I want to thank all of those involved in the development of this measure; this is incredible work. I hope you find my suggestions helpful. I am also available for any questions. Paula Tanabe, Laurel Chadwick Distinguished Professor of Nursing, Duke University. paula.tanabe@duke.edu Executive Summary Key Findings Importance There are many other references that support reduction in admission and re-admission rates and other patient outcomes that are not included. Evidence base Bullet 1 – NHLBI also recommends treatment of pain within 60 minutes of arrival. As written, it appears as only ASH recommends within 60 minutes of arrival. Bullet 2 – There are many other references that support reduction in admission and re-admission rates and other patient outcomes that are not included. The following papers are from my team's work and I respectfully request that they are incorporated as supporting references either in the Executive summary, Section 1.2 - Importance and Impact, or Section 1.3 - Evidence Base Supporting the Measure. 1. Tanabe, P, Silva, S, Bosworth, HB, Crawford, R, Paice JA, Richardson, LD, Miller, CN, Glassberg J. (2018). A Randomized Controlled trial comparing two vaso-occlusive episodes (VOE) protocols in sickle cell disease. Am. J. Hematology,93(2), 153-168. PMID: 29047145 doi: 10.1002/ajh.24948. 2. Knight, L. M. J., Onsomu, E. O., Bosworth, H., Crawford, R., DeMartino, T., Glassberg, J., … Tanabe, P. (2018). Exploring emergency department provider experiences with and perceptions of weight-based and individualized vaso-occlusive treatment protocols in sickle cell disease. Advanced Journal of Emergency Nursing, 41(1):86-97. Doi: 10.1097/TME.0000000000000232. PMID: 30702538 3. Luo L, King AA, Carroll Y, Baumann A, Brambilla D, Carpenter C, Colla J, Gibson R, Hall G, Klesges L, Lyon M, Melvin CL, Norell S, Mueller M, Potter MB, Richesson R, Richardson LD, Ryan G, Siewny L, Treadwell M, Zun L, Cox L, Armstrong-Brown J, Tanabe P, on behalf of the	

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					Sickle Cell Disease Implementation Research Consortium. (2020). Implementing an individualized pain plan with patient and provider Electronic Health Record access for emergency department treatment of vaso-occlusive episodes in adults with sickle cell disease: Protocol for a pre-post study. JMIR: Res Protoc (accepted December 18, 2020). doi: 10.2196/24818. 4. Tanabe, Bosworth, Crawford, Glassberg, Miller, Paice, Richardson, Silva. (2023) Time to pain relief: A randomized controlled trial in the emergency department to reduce pain during vaso-occlusive episodes among patients with sickle cell disease. European Journal of Haematology, 110(5);518-526. doi: 10.1111/ejh.13924. 5. Tanabe, P., Ibemere, S., Pierce, A.E., Freiermuth, C.E., Bosworth, H.B., Yang, H., Osunkwo, I., Paxton, J.H., Strouse, J.J., Miller, J., Paice, J.A., Veeramreddy, P., Kavanagh, P.L., Wilkerson, R.G., Hughes, R., and Barnhart, H. X. (2023). A Comparison of the effect of patient-specific vs. weight-based protocols to treat vaso-occlusive episodes (VOE) in the emergency department. Academic Emergency Medicine, 30(12): 1210-1222. doi: 10.1111/acem.14805. PMID: 37731093 Logic Model ED Resources – Include informatics team members in the multi-disciplinary team. They are essential to allow for easy accessibility of individualized care plans. Specify SCD and ED providers including nurses, vs. clinicians. Very important: A bullet should be added that states the following: "The SCD provider should develop an individualized pain plan for treatment of VOE. The plan should be based on patient preferences and prior effective therapy. This plan should be uploaded in the EMR for use by the ED providers and in the patient portal for easy patient access." It is the SCD team that is able to write the plan, the ED provider cannot do this as they do not know the patient and do not have the time in a busy ED. Bullet 2 – Suggest "Access to evidence based" vs. clinical practice guidelines. This will encourage use of NHLBI and ASH guidelines, vs. random guidelines that exist and are not evidence based. ED Arrival and Triage – Consider re-naming to "ED Arrival, Triage and Treatment Initiation" - Suggest adding a bullet to allow nurses to administer	

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					opioids per the patients individualized pain plan, when available in the EMR, in the waiting room. Many ED's already use individualized pain plan that are available in the electronic health record and triage nurses can access these plans and use administer opioids in the waiting room. Most ED's do NOT allow this, but, if included in the CMS logic model it will provide rationale for additional ED's to allow nurses to administer opioids in the waiting room. This is necessary to truly improve times to administration of 1st pain med. ED overcrowding is at an all time high and much care is now administered in the waiting room. ED's must adapt and be creative in "where" they are providing care. With monitoring, it is safe. ED Evaluation – The ED clinician should be referring to the individualized pain plan that was developed by the SCD providers (see comment in ED resources). The ED clinician CANNOT establish an individualized plan. The ED clinician does not know the patient, nor have the time. Consider adding another bullet – If an individualized plan is not available, order a weight based opioid dose. (additional references to support listed in the reference section of comments). ED Treatment – Consider revising the first bullet to read: "Nurse administers a qualifying pain medication within 60 minutes of arrival to the ED". This is supported by the NHLBI and ASH guidelines. Consider revising the 2nd bullet to read: "Re-assess pain severity 30-60 minutes after administration of the initial analgesic and re-administer analgesics per plan or order until pain controlled". This language is more in align with the NHLBI and ASH guidelines. 1.3 Evidence Base supporting the measure The NHLBI recommendations in the table are incorrect. The top row in "Recommendation" column does not exist. The recommendation "Rapidly initiate analgesic therapy within 30 minutes of triage or 60 minutes of registration" is correct. There is no "OR" recommendati+AB7on as presented in the table. There is other evidence that has demonstrated positive outcomes from rapid dosing. Consider adding to the table.	

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36.	4/25/2024	Lauren Siewny, MD Assistant Professor	Duke University Hospital	Emergency Medicine	As an NIH-funded researcher in SCD and Medical Director of an ED I can attest that the evidence behind faster arrival to pain medication dosing is an important metric to pursue. Studies have shown that patients with SCD wait longer to both be seen and for pain medications than patients arriving for other complaints of similar acuity due to inequalities related to race. Having a goal median time would enhance their care greatly as currently hospitals are experiencing prolonged wait times, impacting in particular this population.	We appreciate your comments and support of the measure.
37.	4/27/2024	Marsha Treadwell, PhD Professor In Residence	University of California San Francisco	Quality Improvement, Research	I am in enthusiastic support of the adoption of this important measure. ASH and ACEP have collaborated to submit the measure for ED SCD care. However, it is critical that this becomes a measure endorsed by CMS. Individuals with SCD are in need of measures to improve quality of care given the pervasive and longstanding disparities in health resources that they have faced.	We appreciate your comments and support of the measure. ASH has submitted the measure to the CMS Annual Call for Measures for consideration in the hospital OQR and REH programs, both of which are pay-for-reporting programs.
38.	4/28/2024	Emine Tunc, MD Assistant Professor	University of Texas Southwestern (UTSW) Medical Center	Peds EM	What type of pain medications to be included?	Thank you for your comment. For a final list of qualifying pain medications, please refer to the *Analgesics for Pain Acute Pain* Value Set (OID: 2.16.840.1.113762.1.4.1160.43), which is available for reference in the National Library of Medicine Value Set Authority Center at: https://vsac.nlm.nih.gov/welcome
39.	4/29/2024	Dominique Bulgin, PhD, RN Assistant Professor	University of TN, Knoxville	Research	Sickle Cell Disease (SCD) is a chronic, debilitating condition that affects millions worldwide, with profound impacts on quality of life and healthcare resources. Vaso-Occlusive Episodes (VOEs) are the hallmark of SCD and manifest as acute, severe pain crises requiring prompt medical attention. Despite this, patients often encounter significant delays in receiving analgesia. The implementation of a Median Time to Pain Medication measurement tool would mark a transformative step in addressing these critical issues by 1) establishing benchmarks for timely pain management that align with best practices, 2) motivating healthcare facilities to prioritize rapid assessment and	We appreciate your comments and support of the measure.

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					administration of analgesics, and 3) identifying disparities in care delivery, facilitating targeted interventions.	

* OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival, OP18: Median Time from ED Arrival to ED Departure for Discharged ED Patients, OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival, and OP-40: Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED). Of note, in 2025, OP-40 will replace OP-2.

Appendix D.3. Verbatim Public Comments – Organizational Perspective

No.	Date Received	Name, Credentials, and Title	Organization of Commenter	Specialty or Perspective	Text of Comments	ASH and HSAG Response
1.	4/15/2024	Konul Bagirova, MD, Physician	Azerbaijan Hematology and Transfusiology Center	Pediatric Hematology	Assessing the importance, relevance, reliability, and feasibility of the measure regarding median time to pain medication for sickle cell patients is essential for understanding its impact on patient care.	We appreciate your comments and support of the measure.
2.	4/15/2024	Hani Kuttab, MD, Assistant Professor and Medical Director, East Madison Hospital. Madison, WI.	University of Wisconsin-Madison	Emergency Medicine. ED Sickle Cell Disease 'Champion'	Highly important; numerous research has shown that timely administration of narcotics in this population reduces ED length of stay, hospitalization, and in-hospital length of stay. Our group has also researched this area.	We appreciate your comments and support of the measure.
3.	4/15/2024	Lewis Hsu, MD, PhD, Chief Medical Officer	Sickle Cell Disease Association of America	Community-based organization, Sickle Cell Disease Association of America	Reliability - This could be difficult to compare without concrete details - is "arrival" the registration time or triage time? is qualifying pain medicine (section 2.1.2) appropriate -- parenteral vs oral - a miniscule oral dose of acetaminophen in the waiting room should not count as pain medication for sickle cell VOE but seems to meet the categorization of Methodology section 2 .1.2.	Thank you for your comment. To reduce provider burden associated with reporting data on quality measures, the measure was harmonized and aligned, to the extent possible, with four existing measures* implemented in the hospital Outpatient Quality Reporting (OQR) program that use *ED Arrival Date* and *ED Arrival Time*. These measures define ED arrival as earliest documented time the patient arrived in the ED. See list of measure at the bottom of this table. Additionally, we recommend that the measure be stratified by route of administration to monitor

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						potential unintended consequences resulting from the implementation of the measure.
4.	4/16/2024	Dr. Elghamry Islam, MD, Pediatric Hematologist Consultant	Sultan Qaboos University Hospital (SQUH), Oman	Pediatric Hematologist	Very important.	We appreciate your comments and support of the measure.
5.	4/18/2024	Pauline Z. Bryant, MSN-Ed, RN, Community Outreach Nurse	Ohio Sickle Cell & Health Association	Not indicated	1. Recommend concise language for future research in reference to 2.1.1 Qualifying ED Encounters on Page 11. Add to Bullet #3 •Instead of stating "The encounter requires at least one qualifying pain medication administered in the ED between the arrival and discharge date and time". Use the Expert's Opinion Recommendation Statement from Page 25: "The encounter requires at least one qualifying pain medication administered in the ED rapidly within 30 minutes of triage or 60 minutes of registration and discharge date and time" 2. Recommend consideration for patient's perspective in reference to 2.1.2 Qualifying Pain Medications in Paragraph #2. 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. Comment: This is one reason this population rate clinicians low for patient satisfaction. Recommend the most appropriate pain management treatment plan be patient-centered based on the most effective medication for each individual- not on the clinician's flexibility in establishing what a clinician assume will best manage pain for patients experiencing a sickle cell pain crisis.	Thank you for your comment. We will consider where we can incorporate your recommended changes into a finalized version of our methodology report.
6.	4/18/2024	Todd L. Savitt, PhD, Chair	Not indicated	North Carolina Governor's Appointed Council on Sickle Cell Syndrome	Reducing wait time in Emergency Departments for administration of pain medication to sickle cell patients in pain crisis would go a long way in restoring confidence among these patients in the American health care system generally and Emergency Departments in particular. The NC Governor's Council	We appreciate your comments and support of the measure.

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					on Sickle Cell Syndrome strongly encourages CMS to adopt this measure to help relieve patient suffering. What a great day it will be when patients in sickle cell pain crisis can enter an ED confident that they will receive relief within an hour and with a minimum of hassle.	
7.	4/25/2024	Anjulika Chawla, MD Senior Medical Director, Clinical Research	bluebird bio	Sickle cell therapy	We support incorporation of this measure as it is important and relevant. Rapid pain control and a trustful encounter allows for earlier and more comprehensive management of pain, leading to more effective patient/provider engagement and access to care.	We appreciate your comments and support of the measure.
8.	4/25/2024	Kathleen Jarrett, MD, FACP Internal Medicine Hospitalist/Sickle Cell Medical Director	Corewell Health	Internal Medicine/ Quality Improvement	I think that the importance of timely administration of narcotics is essential in a pain crisis. Fast administration of gentle fluids and IV narcotics via PCA or IV push is essential to breaking the pain crisis fast. What we do in the first 48 hours determines the trajectory of the hospitalization and LOS in my opinion.	We appreciate your comments and support of the measure.
9.	5/1/2024**	Stephanie Ibemere, PhD, RN Assistant Professor, Duke University School of Nursing	International Association of Sickle Cell Nurses and Professional Associates	Nursing	Please see the statement below sent on behalf of the International Association of Sickle Cell Nurses and Professional Associates: Sickle cell disease (SCD) is a life-threatening chronic hemoglobinopathy with complications that worsen with age which include vasculopathy. The hallmark presenting symptom, pain, is associated with acute (and chronic) vaso-occlusive episodes (VOE). It is important to note that pain in SCD is not only pain, but a signal of tissue and end organ ischemia. The underlying cause should be quickly identified and treated effectively with patient-centered approaches. Rapid, effective treatment of pain resulting from VOE is paramount as **time is tissue** just as is the case with other vascular conditions. As the technical group has described, unfortunately, rapid and effective treatment of VOE in the emergency department (ED) has been plagued by stigma placed on individuals with SCD suggesting this incredibly resilient group of people are	We appreciate your comments and support of the measure. ASH has submitted the measure to the CMS Annual Call for Measures for consideration in the hospital OQR and REH programs, both of which are pay-for-reporting programs.

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					drug seeking, “non-compliant,” or possibly not in as much as pain as they describe if they do not present to the ED exhibiting the clinician’s definition of pain experience. These implicit and explicit biases translate to negative patient experiences thus leading to delayed presentation to the ED for treatment of acute VOE. In some cases, we lose sickle cell warriors prematurely or they experience catastrophic complications such as acute chest syndrome or stroke. The National Heart, Lung, and Blood Institute as well as the American Society of Hematology have published very clear recommendations on the treatment of VOE in the ED which highlight the need to treat pain within 30 minutes of triage or 60 minutes of registration using individualized or standardized protocols. The most recent evidence of the feasibility of implementing such protocols was just recently published in the Academic Emergency Medicine journal (Tanabe et al., 2023). Therefore, as an organization, we are supportive of a new quality measure which would legitimize the aforementioned guidelines and research conducted to date. A quality indicator which captures time to first dose would be a game changing achievement for the SCD community of patients, families, providers, and researchers. Having such a quality indicator as the standard of care would assist in addressing the aforementioned biases which lead to unnecessary repeat ED visits, readmissions, decreases in quality of life, and the unfortunate loss of life. Our hope as an organization is that this quality indicator would eventually be adopted by CMS as an objective measure for holding health systems accountable to the established guidelines for the care of individuals with SCD. This step forward could significantly impact acute care utilization in this population, aiming to reduce expenditures for both the patient and the health system. This is especially crucial in given the challenges of ED overcrowding and workforce capacity constraints. As an organization of healthcare professionals with the goal to treat and advocate for people with sickle cell	

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					disease, the International Association of Sickle Cell Disease Nurses and Professional Associates (IASCNAPA), supports the development and implementation of the Median Time to Pain Medication for Patients with a Diagnosis of Sickle Cell Disease (SCD) with Vaso-Occlusive Episode (VOE) quality indicator.	

[*] OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival, OP18: Median Time from ED Arrival to ED Departure for Discharged ED Patients, OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation Within 45 minutes of Arrival, and OP-40: Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED). Of note, in 2025, OP-40 will replace OP-2.

[**] *Commenter requested and received permission to submit a comment after the close of the public comment period.*