Methodology Report

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

April 12, 2024

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HSAG HEALTH SERVICES ADVISORY GROUP

Acknowledgments

HSAG Project Team

Kyle Campbell, PharmD
VP, Healthcare Policy and Quality Measurement

Hayley Dykhoff, MSPH
Senior Analyst

Marie C. Hall, RN
Senior Nurse Informaticist

Kendra Hanley, MS, BA
Executive Director

Susan Hemmingway, BS
Technical Writer

Alan Mai, MPH
Analyst I

Valerie Mayorga, PharmD, BCPS
Clinician Pharmacist Researcher

Robert Ziemba, PhD
Statistician

ASH Project Team

Emily Cahill, MPH, BS
Deputy Director, Clinical Quality Improvement

Sarah Paliani, MPH
Manager, Clinical Quality Improvement

Technical Expert Panel

HSAG would like to thank the following members of the SCD Measure Development Project Technical Expert Panel (TEP), who provided important insight and feedback during measure development and testing.

Maureen Achebe, MD, MPH
Hematologist and Clinical Director for Hematology
Brigham and Women's Hospital

Rae Blaylark
Patient Panelist

Payal Desai, MD
Director of the Adult Sickle Cell Enterprise
Atrium Health

Titilope Fasipe, MD, PhD (TEP Chair)
Co-Director, Sickle Cell Program
Texas Children's Hospital

Jeffrey Glassberg, MD, FACEP
Director of Sickle Cell Program
Icahn School of Medicine at Mount Sinai

Richard D. Shih, MD, FACEP
Professor of Emergency Medicine
Florida Atlantic University

Amy Sobota, MD, MPH
Pediatric Hematologist
Boston Medical Center and
Boston University School of Medicine

Teonna Woolford
Patient Panelist

Table of Contents

List of Tables

List of Figures

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 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. Additionally, the TEP agreed with the prioritization, for further development and testing, of the following patient-centered and equity-focused 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 ED arrival to initial administration of pain medication for adult patients with a principal diagnosis of SCD with VOE

Methods

Measure development and beta testing were conducted using data extracted from 23 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 = 15), and Meditech (N = 7). Beta testing 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 5,817 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 an adult patient who was at least 18 years old at the time of arrival to the ED 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. The reliability of the measure score was evaluated using a split-half correlation analysis. The TEP will review the final measure specifications and testing result during a May 2024 TEP meeting to assess face validity of the measure as an indicator of differences in facility-level quality. The feasibility of implementing the measure was assessed by confirming that all scoring data elements are accurate, use standardized terminologies, are collected as part of the provider's workflow, and can be extracted electronically from EHRs. Harmonization of scoring data elements was achieved to the extent possible by examining whether they can be operationalized in the same way as similar scoring data elements used in other quality measures.

Key Findings

- **Importance**
  - The National Academies of Sciences, Engineering, and Medicine,[1] the U.S Department of Health and Human Services,[2,3] and the Centers for Medicare & Medicaid Services (CMS)[4,5] all support improving acute pain management for patients with SCD.
  - SCD is the most common inherited blood disorder and estimated to affect approximately 100,000 individuals in the United States.[6]
  - Three-fourths of the 222,612 estimated yearly average number of ED visits by patients with any diagnosis of SCD were due to a complaint of pain. Compared with prior estimates, the overall volume of ED visits has increased by nearly 13%.[7]
  - Approximately 80% of patients with SCD avoid 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, 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 concept.
  - The mean measure score for patients with SCD with VOE across 23 facilities was 87.7 minutes (SD = 47.4, N = 23) with wide variation in performance observed between 42 and 268 minutes (lower scores are better).
- **Evidence Base**
  - 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.
  - There is a direct relationship between the structures, processes, and outcomes related to this measure (Figure 1). Reducing the administration time of pain medications 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, access to guideline-recommended treatments, and reduction of pain severity. Admission and readmission rates and hospital length of stays may also be reduced.
- **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 1.0.
  - The project team is conducting patient/encounter level (data element) reliability testing for critical data elements, which will be completed in May 2024.
  - The TEP will vote on the face validity of the measure at the TEP meeting scheduled on May 2, 2024, to assess whether the measure scores represent a valid assessment of facility-level quality.
- **Feasibility**
  - A standardized scorecard was used to assess feasibility of the measure. All critical data elements required to calculate the measure score obtained 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.[12-14]
  - In socioeconomically deprived areas, patients with SCD have higher rates of SCD complications, leading to increased health system utilization and higher readmission rates.[15,16]
  - 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.[17]
  - 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.[18]
- **Harmonization**
  - There are currently no consensus-based entity (CBE)-endorsed measures that specifically evaluate the timing of administration of pain medications for adult patients 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 4.[19]

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 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. The project team is finalizing validity testing and currently seeking public comment on this important measure.

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 a patient representative to contribute input into the development of the measure. In addition, 70.0% (14/20) of patients and caregivers affected by SCD who were consulted about the measure agreed with the prioritization of the measure and indicated that pain management for acute severe pain episodes was an aspect of health care that was most meaningful to them. The TEP prioritized the testing 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 ED arrival to initial administration of pain medication for adult patients with a principal diagnosis of SCD with 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 concept topics 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 and Impact

SCD is the most common inherited blood disorder and estimated to affect approximately 100,000 individuals in the United States.[6] 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.[20] Therefore, although SCD is a low prevalent condition, it is important, as its impact on affected patients, their families, and the community is profound.

The National Academies of Sciences, Engineering, and Medicine,[1] HHS,[2,3] and CMS[4,5] 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.[1] Evidence suggests that up to 80% of patients with SCD avoid 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, patients have been shown to wait an average of 90 minutes before analgesics are given.[9]

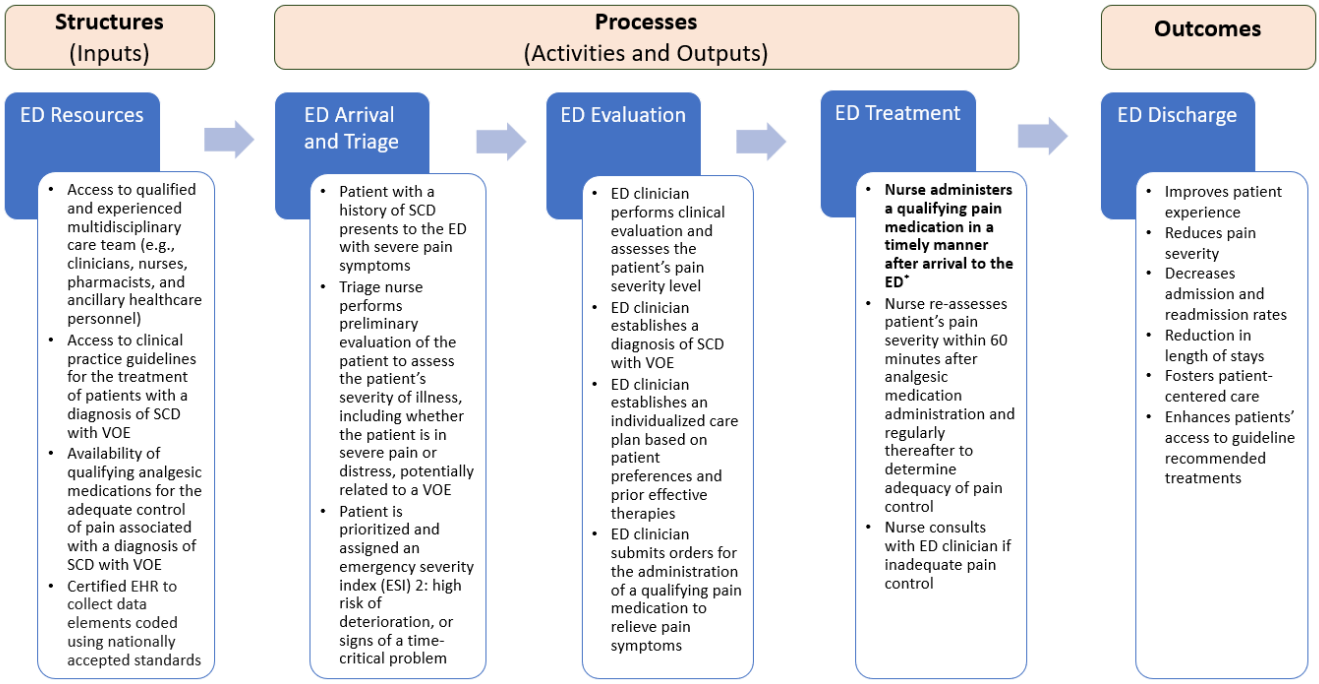
ED visits are common among patients with SCD. Based on data from California and Georgia from the Centers for Diseases Control and Prevention (CDC), roughly 40% of patients with SCD had at least one ED visit or hospital admission for a pain crisis or VOE crisis in 2015.[21] In addition, updated data from the National 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, the overall volume of ED visits have 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.[12-14] In socioeconomically deprived areas, patients with SCD have higher rates of SCD complications, leading to increased health system utilization and higher readmission rates.[15,16] 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.[17] 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%).[22] 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. [23] These patients are particularly at risk for poor outcomes, including early death, during the transition period between pediatric and adult care, highlighting the importance of implementing a measure directed at improving care for adults with SCD.[24-27] 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.[18] 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.[28]

The implementation of an eCQM targeting timing to administration of pain medication for patients with SCD presenting to the ED may significantly impact pain management and other outcomes, including admission rates,[29] hospital length of stay,[29] and patient satisfaction.[30] 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.[30] 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.[29-32]

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.[33] 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.[30,34,35]

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 Evidence Base Supporting the Measure

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 Title	Citation	Recommendation	Strength of Recommendation	Grade of Evidence
American Society of Hematology 2020 Guidelines	Brandow AM, Carroll CP, Creary S, et al; American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Adv 2020; 4 (12): 2656–2701. doi: https://doi.org/10.1182/bloodadvances.2020001851	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

Clinical Practice Guideline Title	Citation	Recommendation	Strength of Recommendation	Grade of Evidence
National Heart, Lung and Blood Institute (NHLBI) 2014	US Department of Health and Human Services. National Heart, Lung and Blood Institute (NHLBI); Evidence-Based Management of Sickle Cell Disease Expert Panel Report, 2014. https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease	In adults and children with SCD and a VOC associated with severe pain, rapidly initiate treatment with parenteral opioids if VOE with severe pain. OR	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 of the report describes the approach used to develop and operationalize the measure specifications and scoring methodology. This section also describes the approach used to assess the reliability and validity of the measure as well as the approach used to determine whether disparities in care exist between different subpopulations of patients.

2.1 Measure Specification Development

Please refer to the Appendix A for the Measure Information/Algorithm.

For the value sets used in the development of the measure, please download the Zip file available at: https://www.hematology.org/education/clinicians/guidelines-and-quality-care/hematology-quality-metrics.

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 an adult patient who was at least 18 years old at the time of arrival to the ED 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.

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] Only pain medications that were available in the United States or agents that were systemic acting were included. The broad list of generic pain medications was then organized into four distinct categories:

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

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. 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 by category is provided in Appendix B.

2.2 Measure Performance Scoring Methodology

The measure is a continuous variable measure calculated as median time (in minutes) from ED arrival to initial administration of pain medication for adult patients with a principal diagnosis of SCD with VOE. Please refer to Appendix A for more information about the measure. Room for improvement in measure scores was assessed by examining descriptive statistics (e.g., mean, standard deviation, and percentiles) for the distribution of measure

scores across the sampled EDs. In particular, comparing the median with the 10th percentile (where lower scores are better) was used to determine the minimum improvement in measure scores that can be expected between a middle-ranked and a top-performing ED.

2.3 Reliability Testing Methodology

2.3.1 Data Extracts from Measure Testing Sites

To test the measure, data were obtained from 23 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 = 15), and Meditech (N = 7). Each ED provided a data extract containing clinical information for a two-year period from January 1, 2020, through December 31, 2021. The data extract included de-identified metadata about each ED, such as the type of EHR, state, urban-rural designation, academic/non-academic designation, trauma level and type of ED (i.e., freestanding or non-freestanding). The data extract also included de-identified patient-level and de-identified ED encounter-level information such as the arrival date and time; discharge date and time; discharge disposition; principal diagnosis; first pain medication administered, including the medication name and administration date and time; and pain medication code system. Finally, the data extract included patient characteristics such as age, sex, race, ethnicity, and payer.

2.3.2 Measure Performance Score Reliability

Measure performance score reliability was conducted using a split-half design where eligible encounters in each ED observed over the two-year period were randomly divided into two subsamples. 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 identical sample size as the original measure cohort. Each replicate dataset (3,000 replicates) was split into two halves, and the correlation between measure scores across EDs was calculated from the two halves as above. The mean of this distribution of correlation coefficients was taken as the overall reliability of the measure score, and a confidence interval for the correlation coefficient was estimated using the 2.5th and 97.5th percentiles.

2.4 Validity Testing Methodology

2.4.1 Systematic Assessment of Face Validity

A face validity assessment of the measure score will be obtained by a TEP vote at the conclusion of measure refinement. The TEP will receive the final measure specifications and the results of field testing and feedback from public comment about the measure.

2.5 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—only sex and payer comparisons were included in the final analysis.

2.6 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. This section also provides the results of the assessments of the reliability of the measure, as well as the feasibility assessment results, and any findings related to whether disparities in care exist among subpopulations. The project team is conducting patient-/encounter-level (data element) reliability testing for critical data elements, which will be completed in May 2024.

3.1 Sample Characteristics

The data sample used to test the measure included 23 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
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

The sample used for measure score reliability and disparities testing included 5,817 unique encounters satisfying the inclusion criteria across 23 EDs. The number of encounters was similar for ED arrival dates in 2020 (2,888) and 2021 (2,929). The number of qualifying encounters across ED test sites ranged from 47 to 1,278 over the two-year period (Table 3). Mean patient age for 4,313 unique patients across encounters was 32.8 (SD = 9.1) years at ED arrival, and the majority of patients were female (58.2%), Black or African American (99.1%), and not Hispanic or Latino (99.1%) and had Medicaid (44.8.%) or Medicare (33.5%) as their primary insurance (Table 4).

Table 3. Qualifying ED Encounters by ED Site

ED Site	Number of Qualifying Encounters with SCD with VOE
2	1,278
1	814
3	537
7	351
4	294
21	276
22	265
5	263
9	232
6	179
8	176
10	157
23	148
12	134
14	129
17	115
15	97
13	92
16	74
20	62
18	50
11	47
19	47
Total	**5,817**

Table 4. Demographics for Patients with Qualifying ED Encounters

Demographic	SCD with VOE
Qualifying Encounters, N	5,817
Total Unique Patients, N	4,313
Age, years	
Mean ± Std Dev	32.8 (9.1)
Median (Range)	31 (57)
Sex, N (% of total)	
Female	3,387 (58.2%)
Male	2,430 (41.8%)
Race, N (% of total)	
Black or African American	5,765 (99.1%)
White	34 (0.58%)
American Indian or Alaska Native	3 (0.05%)
Other	15 (0.26%)
Ethnicity, N (% of total)	
Not Hispanic or Latino	5,764 (99.1%)
Hispanic or Latino	52 (0.89%)
Missing	1 (0.02%)
Payer, N (% of total)	
Medicaid	2,607 (44.8%)
Medicare	1,946 (33.5%)
Other	1,042 (17.91%)
Missing	222 (3.8%)

3.4 Measure Performance Score Results

The mean measure score for patients with SCD with VOE across facilities was 87.7 minutes (SD = 47.4, N = 23), and the median of measure scores across facilities was (73.0 minutes), while the mean time to analgesic across all encounters was 91.0 minutes (SD = 76.5, N = 5817). The distribution of the measure scores is presented in Table 5; individual ED scores are presented in Table 6. 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, 10% of the EDs had a measure score of 138.5 minutes or more—more than two hours from arrival to medication administration. Taken together with the fact that the median score was 73.0 minutes compared with the benchmark of 60.0 minutes, based on clinical guidelines, these results indicate the measure shows room for improvement.

Table 5. 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	23	47.4	42.0	51.0	60.0	73.0	93.0	138.5	268.0

Table 6. Individual ED Site Measure Scores

ED Site	Measure Score
7	42.0
16	46.5
6	51.0
2	58.0
3	60.0
5	60.0
9	63.5
10	66.0
17	67.0
4	70.0
12	70.0
22	73.0
14	75.0
21	82.2
15	88.0
8	90.2
18	91.0
20	93.0
1	105.7
11	113.0
23	138.5
13	145.5
19	268.0

3.5 Reliability Testing Results

3.5.1 Measure Performance Score Reliability Results

Reliability estimates (corrected Pearson correlation coefficients) from the 3,000 bootstrap replicates ranged from 0.72 to 1.0 with a mean of 0.96 and an estimated 95% confidence interval of 0.89 to 1.0. This indicates very high reliability of the measure score.

3.6 Validity Testing Results

3.6.1 Systematic Assessment of Face Validity Results

HSAG will obtain a face validity vote during the May 2024 TEP meeting.

3.7 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 8). 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 7. Median Time to Pain Medication by Sociodemographic Variable

Variable/Stratum	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)

3.8 Feasibility Testing Results

Feasibility testing results across the three ED sites used to perform feasibility testing are shown in Table 9. The measure includes six critical data elements and four supplemental patient characteristic data elements. All six critical data elements required for automated calculation of the measure were available and accessible within the EHR in a structured field. All seven critical data elements have a high likelihood of being accurate because they are entered by a provider or healthcare staff into the EHR at the time of care delivery or entered for the purpose of billing (i.e., ICD-10-CM codes). All critical data elements were also codified using nationally accepted vocabularies per data terminology standards (e.g., ICD-10-CM, SNOMED-CT, RxNorm). Additionally, feasibility testing showed that generating and collecting the data elements had no impact on provider workflow at the three ED sites since all data elements were generated during the ordinary course of care. Patient characteristic data elements were similarly available and accurate and used standard terminology; however, some race and payer categories had to be manually mapped from the site's EHR system to the associated codes within the specified value set.

Table 8. Feasibility Scorecards Across Three ED Sites

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

ASH is considering submitting the measure to the CMS Annual Call for Measures for the Hospital Outpatient Quality Reporting (OQR) Program, a pay-for-reporting program. Hospitals with outpatient services that participate in the Hospital OQR Program collect and report data on 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 EDs or EDs affiliated with an acute care hospital, using a two-year measurement period. This measure is intended to be implemented as an eCQM.

4.2 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. 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 the *Arrival Date*, *Arrival Time*, and *Age* (as a proxy for *Birthdate*) data elements that are used in other measures implemented in the hospital OQR Program.

The project team also used existing value sets published through the National Library of Medicine's Value Set Authority Center to construct the measure. For example, the project team used, without modification, 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 six data elements used in the measure align with similar data elements found in the USCDI, Version 4.

Finally, the project team conducted a review of the current landscape of quality measures to determine whether the measure would compete with 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 adult patients with a diagnosis of SCD with VOE.

5. Conclusion

The measure addresses an important measurement gap for the timing of administration of pain medications in adult patients with a diagnosis of SCD with VOE who present to the ED. The TEP, patients, and caregivers who were consulted found the measure to be both important and meaningful. As demonstrated by the analysis results, the measure score indicates considerable opportunities for EDs to improve the timeliness of pain medication administration for these patients. Improvement in measure scores could lead to improved outcomes and patient experience. Timeliness of analgesia administration is a patient-centered issue in need of improvement. The measure meets the scientific acceptability thresholds for reliability as established by the CBE for measure endorsement. The measure is harmonized with other measures that use similar data elements and is specified as an eCQM, using only clinical digital data sources. The data elements used in the measure were found to be available and accurate and were captured using standardized vocabularies while adding no to minimal burden for providers to collect because data are routinely captured during the clinical course of care. The data elements used in the measure are also consistent with the standard set of data elements as defined by the USCDI, Version 4.[19] Finally, the measure addresses the primary CMS Meaningful Measure 2.0 priority[36,37] of *Person-Centered Care* and addresses both *Equity* and *Chronic Conditions* as secondary priorities. 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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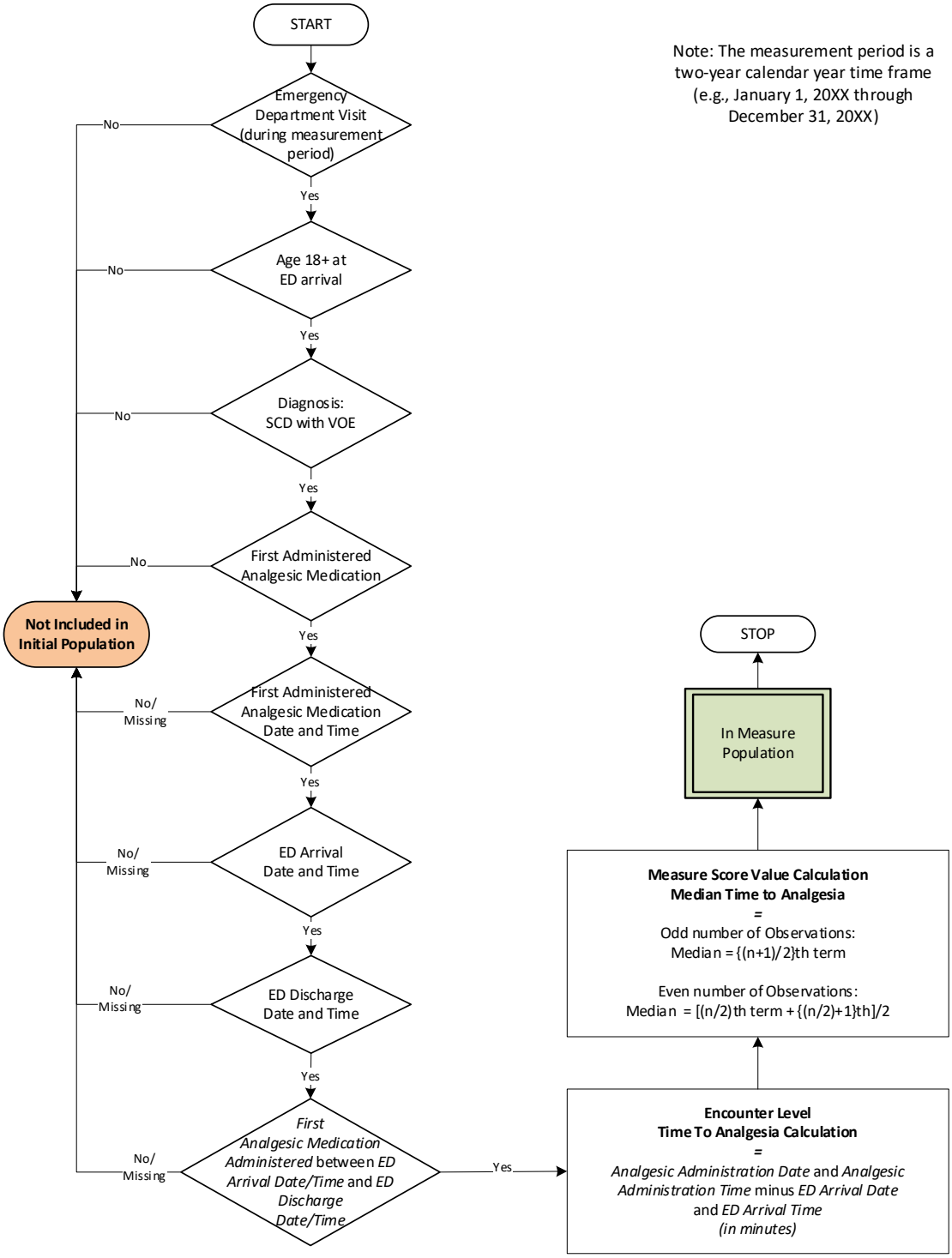
Appendix A. Measure Information Form / Algorithm

eCQM Title	Median Time to Pain Medication for Patients with a Diagnosis of Sickle Cell Disease (SCD) with Vaso-Occlusive Episode (VOE)
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.
Copyright	Measure specifications are in the Public Domain. Users of proprietary code sets should obtain all necessary licenses from the owners of the code sets. The American Society of Hematology (ASH) disclaims all liability for use or accuracy of any third-party codes contained in the specifications. The measure contains proprietary codes such as the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), Current Procedural Terminology (CPT[R]), and standardized nomenclature for clinical drugs, produced by the National Library of Medicine (RxNorm).
Disclaimer	The measure is not a clinical guideline, does not establish a standard of medical care, and has not been tested for all potential applications. THE MEASURE AND SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. Due to technical limitations, registered trademarks are indicated by (R) or [R] and unregistered trademarks are indicated by (TM) or [TM].
Initial Population	Encounters of patients who are 18 years of age or older at the time of arrival to the Emergency Department (ED) who have a principal diagnosis of Sickle Cell Disease (SCD) with Vaso-Occlusive Episode (VOE) and who have at least one documented qualifying analgesic agent administered in the ED. A qualifying ED encounter is defined as: • An ED visit for an adult patient who was at least 18 years old at the time of arrival to the ED 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 (see Analgesic Medication for Acute Pain value set) administered in the ED between the arrival and discharge date and time.
Measure Population	Equals Initial Population
Measurement Period	The measure uses a two-year measurement period.
Measure Exclusions	None
Evidence Base	The measure is supported by the following two clinical practice guidelines and clinical recommendation statements: 1) The American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Recommendation Statement: Provide rapid (within 1 hour of ED arrival) assessment and administration of analgesia [Strong recommendation; low certainty of evidence] Citation: Brandow, A. M., Carroll, C. P., Creary, S., Edwards-Elliott, R., Glassberg, J., Hurley, R. W., Kutlar, A., Seisa, M., Stinson, J., Strouse, J. J., Yusuf, F., Zempsky, W., & Lang, E. (2020).

	American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Advances, 4(12), 2656–2701. https://doi.org/10.1182/bloodadvances.2020001851 2) The 2014 National Heart, Lung and Blood Institute (NHLBI); Evidence-Based Management of Sickle Cell Disease Expert Panel Report. Recommendation Statement: Rapidly initiate treatment with parenteral opioids if VOE with severe pain [Strong recommendation; high quality evidence] OR rapidly initiate analgesic therapy within 30 minutes of triage or 60 minutes of registration [Expert Opinion] Citation: National Institutes of Health, National Heart, Lung, and Blood Institute. (2014). Evidence-based management of sickle cell disease: expert panel report, 2014. Retrieved from https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease.	
Rationale	Refer to section 1.2 Importance and Impact of this report.	
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 (Outpatient Emergency Departments)	
Type of Score	Continuous variable	
Improvement Notation	Lower score indicates better quality	
Primary Meaningful Measure 2.0 Priority	☒ Person-Centered Care ☐ Equity ☐ Safety ☐ Affordability and Efficiency	☐ Chronic Conditions ☐ Wellness and Prevention ☐ Seamless Care Coordination ☐ Behavioral Health
Secondary Meaningful Measure 2.0 Priority	☐ Person-Centered Care ☒ Equity ☐ Safety ☐ Affordability and Efficiency	☒ Chronic Conditions ☐ Wellness and Prevention ☐ Seamless Care Coordination ☐ Behavioral Health

Median Time to Pain Medication for Patients with a Diagnosis of SCD with VOE

Disclaimer: Refer to the corresponding value sets for specific codes included in the measure.



Appendix B. Generic List of Qualifying Pain Medications

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