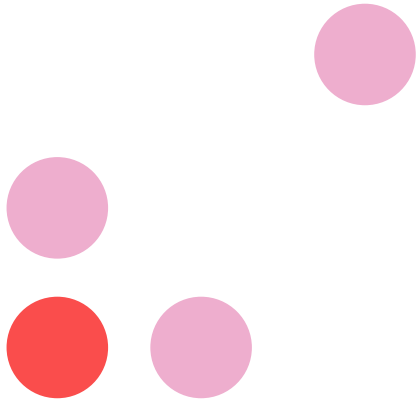


Where Medicine is a Mirror to Racial Inequities: Going Beyond the Sickled Cell

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Disclosures

The authors of this presentation have no relevant financial or nonfinancial relationships in the products or services described, reviewed, evaluated, or compared in this presentation to disclose.



Abbreviations

ATC = around-the-clock

CAP = community acquired pneumonia

CT = computerized tomography

ED = emergency department

EMR = electronic medical record

HGB = hemoglobin

IQR = interquartile range

MRA = magnetic resonance angiography

MRI = magnetic resonance imaging

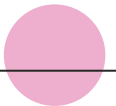
PCA = patient-controlled analgesia

PRBC = packed red blood cell

SCD = sickle cell disease

SCT = sickle cell trait

VOC = vaso-occlusive crisis



Objectives



01


Describe the epidemiology and pathophysiology of sickle cell disease, including the hemoglobin variants and vaso-occlusive crises

02

Review treatment strategies in management of acute sickle cell related complications

03

Recognize health care disparities in access to specialized care, poor disease outcomes, barriers to obtain pain treatment, and insufficient treatment options in patients with sickle cell disease



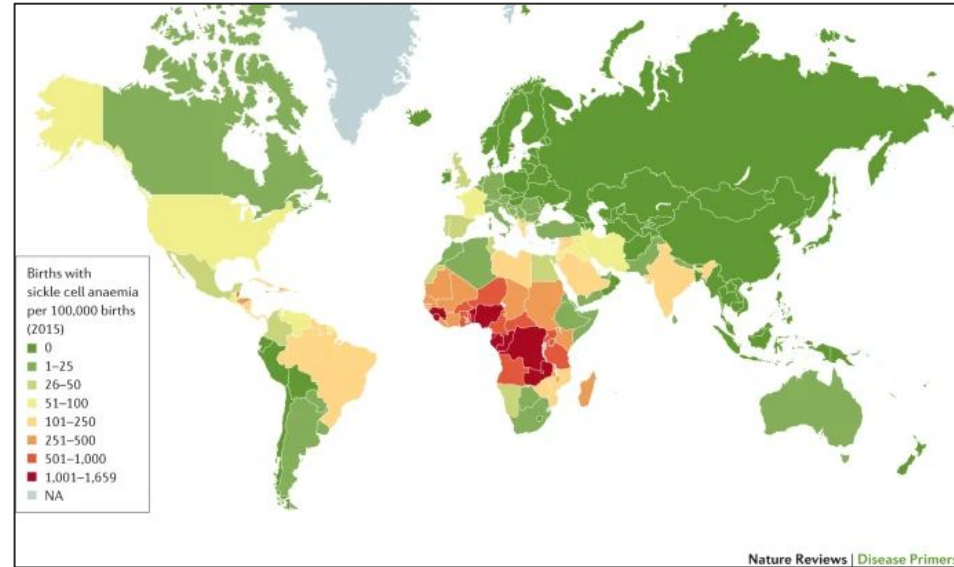
Epidemiology

- Sickle cell disease (SCD) is the most common blood disorder in the United States (~100,000 Americans)
- 1 in 365 13 Black/African-American babies is born with SCD
- 1 in 13 Black/African-American babies is born with SCT
- Most severe form of SCD can shorten the lives of people with SCD by 20 to 30 years

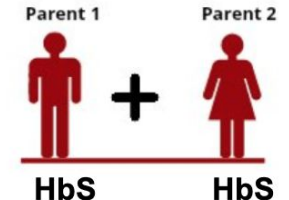
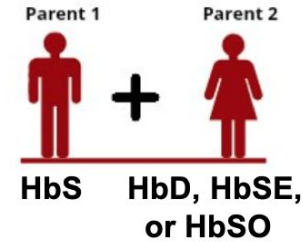
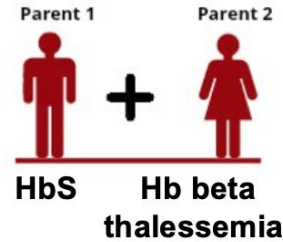
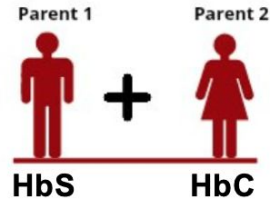
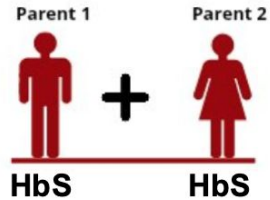


Epidemiology

- 3% of newborns in Africa have SCD
- 50% - 90% of children born with SCD in resource-poor regions die before age 5
- SCD is often not diagnosed and rarely listed as cause of death among children



Types of SCD



HbSS

Commonly called
"sickle cell anemia"

Most severe form of
SCD

HbSC

Milder form of SCD

HbS beta thalassemia

HbS beta⁰-
thalassemia have
severe form of SCD

HbS beta⁺-
thalassemia have
milder form of SCD.

HbSD, HbSE, and HbSO (rare)

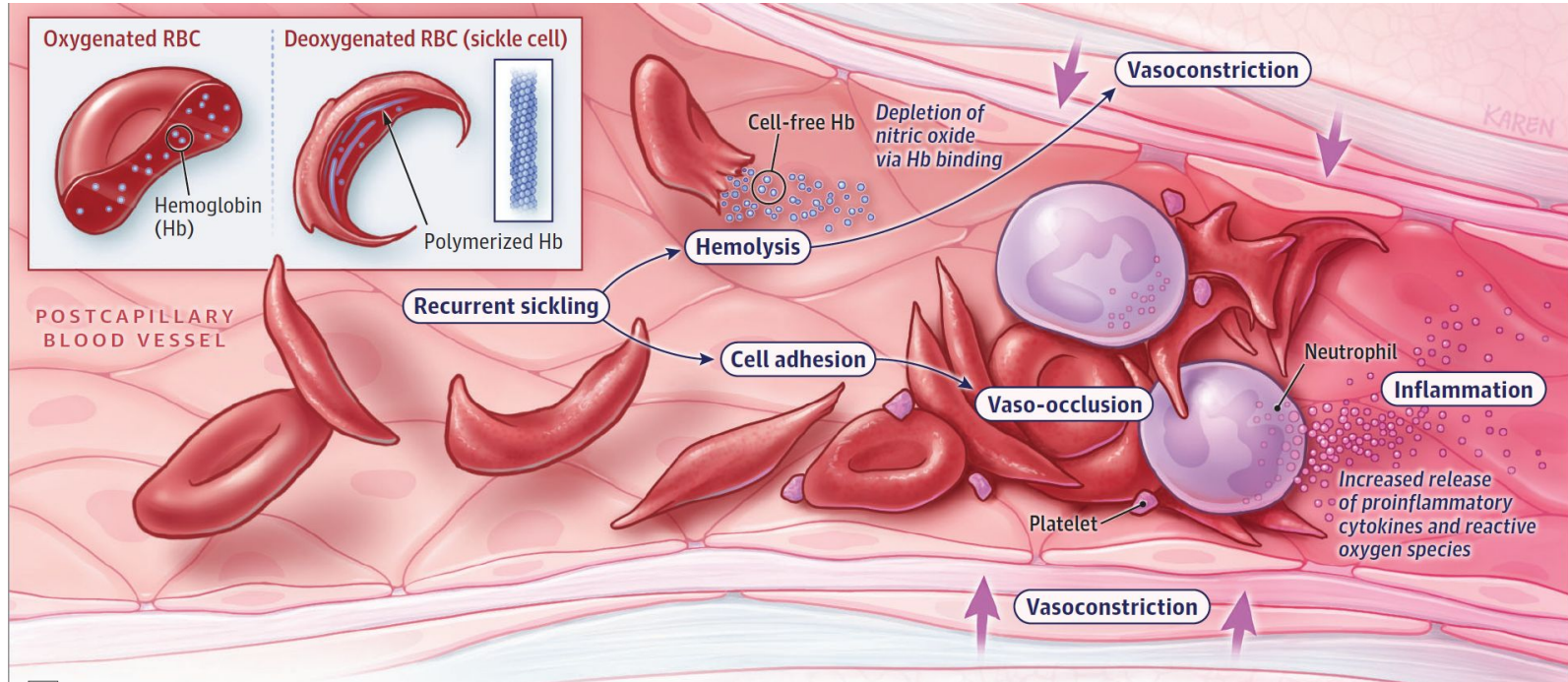
Severity varies

SCT (HbAS)

SCT usually do not
have any of the signs
of the disease.

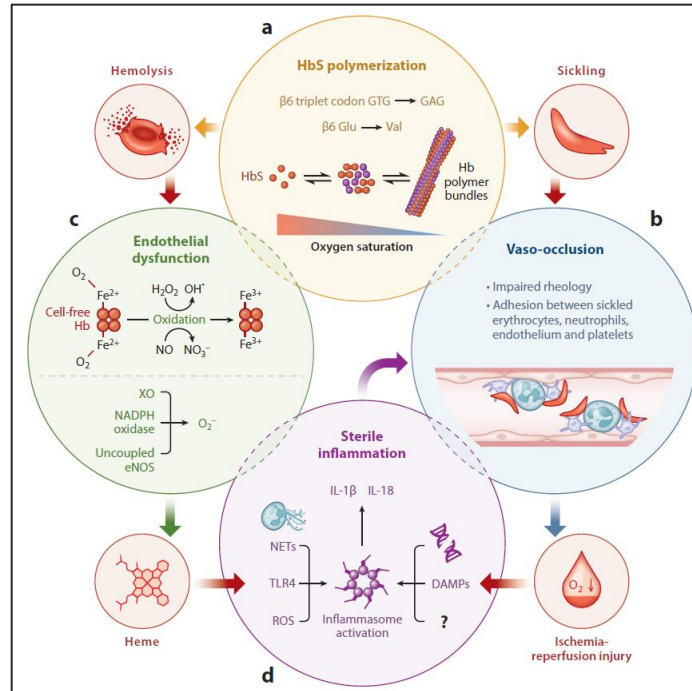
May develop health
problems when there
are other stresses on
the boy

Pathophysiology

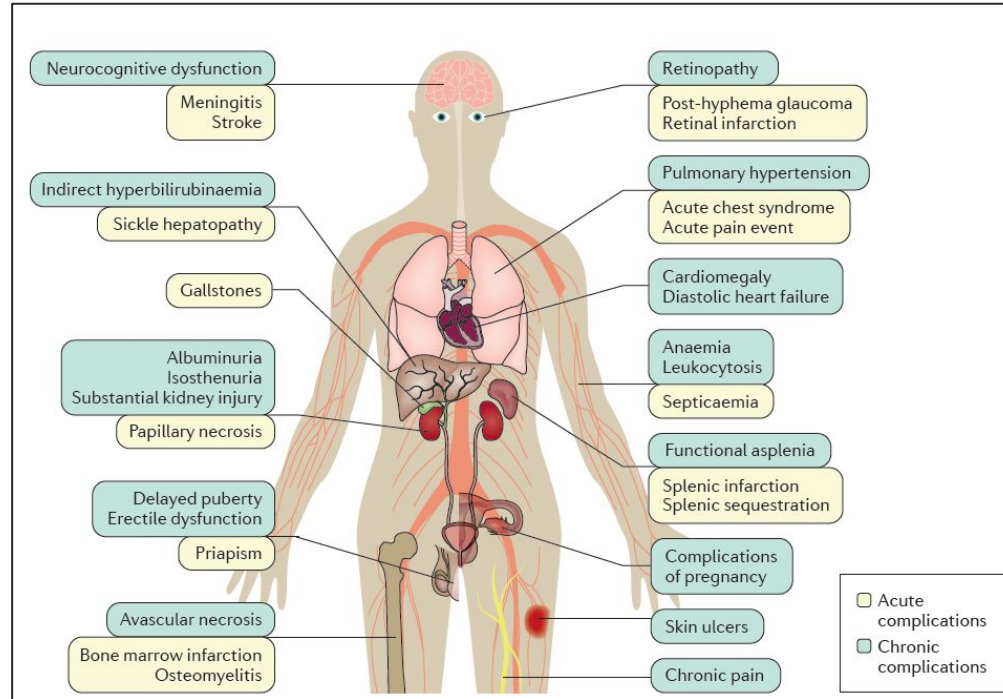


KAREN

Molecular Pathophysiology



SCD - Clinical Complications



Timeline of SCD Complications



Infancy and Childhood	Adolescence	Adulthood	
Delayed growth	Delayed puberty	Hemorrhagic stroke Leg ulcers	Pulmonary hypertension Reproductive complications
Aplastic crisis Osteomyelitis Splenic sequestration	Splenic infarction Sepsis	Avascular necrosis Cognitive dysfunction Chronic pain Gallstones	Priapism Sickle nephropathy Sickle retinopathy Venous thromboembolism
Acute pain		Acute chest syndrome	Ischemic stroke

Acute Complications





Acute Pain Episode

Pain Crises

- Most common cause of hospitalization
- Significant morbidity of patients with SCD with profound negative health-related quality of life (HRQOL)
- Complex and poorly understood pathophysiology
 - Local nociceptive pain from ischemia-perfusion injury and inflammation
 - Increased red-blood cell adhesion
 - Neuropathic pain
 - Central pain pathways





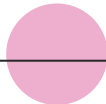


Acute Pain Episode

- No objective signs/acute laboratory findings
- Pain episodes preceded by 1-2 day prodromal phase (fatigue, diffuse body aches)
- Peak intensity day 3-7
- Majority of acute pain events managed at home with NSAIDs or oral opioid analgesics



Patient Evaluation

- Initiate diagnostic evaluation of causes of pain other than vaso-occlusive crises (VOC)
 - Typical VOC pain locations: extremities, chest, and back
 - Other acute complications:
 - Head - stroke
 - Flank - papillary necrosis
 - Abdomen - hepatic or splenic sequestration, constipation from opioid toxicity, or another hepatobiliary complication
- 
- 
- 



Assessment and Treatment



- Rapid assessment (within 1 hour of arrival at ED)
- Rapid administration of analgesia (within 30 minutes of triage/60 minutes of registration)
- Reassess pain and re-administer opioids if necessary until pain is under control (every 15-30 min)

SCD Patient Care Plans

- Individualized care plans
 - Developed by acute care and SCD providers
 - Patient specific effective treatments for medications + doses
 - Embed into EMR
- Acute pain management should incorporate patient preferences into shared decision-making process



Analgesia for Severe Pain

- Continue treatment with NSAIDs
- Calculate parenteral (IV/SC) opioid dose based on total daily short-acting opioid dose currently taken at home to manage VOC
- Maintain or consider escalation of the dose by 25% q15-30min until pain controlled
- ATC opioids via PCA vs. PRN
- Subanesthetic ketamine infusions
 - 0.1-0.3 mg/kg per hour (max 1 mg/kg per hour)
- Do not administer corticosteroids for acute pain management



Pediatric Dosing

Common Pediatric Doses of Drugs Used in SCD	
Agent	Typical Pediatric Dosing (≤ 50 kg)
Morphine	<u>IV</u> : 0.1-0.2 mg/kg q2-4h prn <u>PCA</u> : basal: 0.01-0.04 mg/kg/hr; bolus: 0.02 mg/kg
Hydromorphone	<u>IV</u> : 0.015 mg/kg q3-6h prn <u>PCA</u> : basal: 0.003-0.005 mg/kg/hr; bolus: 0.003-0.005 mg/kg
Fentanyl	<u>IV</u> : 1-2 mcg/kg q2-4h prn <u>PCA</u> : basal: 1 mcg/kg/hr; bolus: 0.5-1 mcg/kg
Ketorolac	<u>IV</u> : 0.5 mg/kg q6h prn (NTE 5 days of treatment and 30 mg/dose)
Ibuprofen	4-10 mg/kg/dose q6-8h prn (NTE 40 mg/kg/day or 800 mg/dose)
Acetaminophen	10-15 mg/kg q4-6h prn (NTE 75 mg/kg/day or 4g/day)
Ketamine	Limited data for pediatric use in acute VOC; used as opioid adjuvant in refractory pain patients
Hydroxyurea	Initial: 15 mg/kg/day; Max: 35 mg/kg/day

Monitoring

- Reassess pain q15-30min until pain controlled
- Monitor for side effects
- Pruritus: oral antihistamine Q4-6H PRN
- Oxygen, intravenous fluids, and red blood cell transfusions are not typically prescribed unless clinically indicated

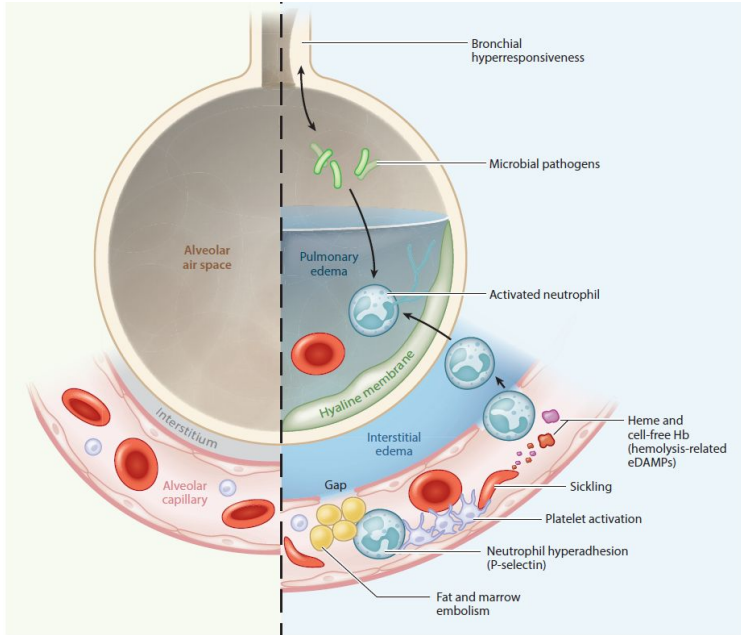


Acute Chest Syndrome (ACS)

- ACS the most common and serious complication of SCD
- Most common cause of death (>10% fatal)
- **ACS definition**- new infiltrate on chest imaging plus 2 of the following:
 - Pleuritic chest pain
 - Hypoxemia
 - Tachypnea
 - Fever



Normal Lung vs. ACS



- ACS may develop during first 3-4 days of **acute pain episode** due to:
 - Fat embolism
 - In situ sickling
 - Thromboembolism
- Triggers:
 - Pulmonary embolism
 - Fluid overload
 - Opioid narcosis
 - Hypoventilation
- Children may present with ACS due to infection (pneumonia)

ACS Treatment

Treatment:

- Supplemental oxygen/mechanical ventilation (goal SpO₂ >95%)
- Intravenous crystalloid infusion
- Pain relief (AVOID HYPOVENTILATION)
- Bronchodilators for acute bronchospasm or hx of asthma

Insufficient evidence:

- Inhaled nitric oxide
- Corticosteroids

ACS Treatment

- Antibiotics - CAP coverage

	Adults	Children
<u>Recommended Antibiotics</u>	<p>Amoxicillin/Clavulanic acid 1-2g IV TID + Clarithromycin 500 mg IV/PO TID</p> <p><u>Alternative regimen:</u> Ceftriaxone 2g IV once daily + Clarithromycin 500 mg IV/PO BID</p> <p><u>Penicillin allergy:</u> Vancomycin 1g IV BID + Clarithromycin</p>	<p>Amoxicillin/Clavulanic acid + Clarithromycin</p> <p>OR</p> <p>Ceftriaxone + Clarithromycin (May substitute Azithromycin for Clarithromycin)</p> <p><u>Penicillin allergy:</u> Seek microbiology advice</p>



ACS – Blood Transfusion

- Blood transfusions can produce rapid and dramatic improvements in clinical, radiological, and oxygenation parameters
- Decision to transfuse should be made by SCD expert

	Simple (“top up”) blood transfusion	Exchange transfusion
Procedure	Infusion of PRBC	Removal of RBC via erythrocytapheresis or manual phlebotomy plus concurrent infusion of PRBC
Indication	Symptomatic ACS whose hgb is >1.0 g/dL below baseline. May not be required for baseline hgb >9 g/dL	Rapid progression of ACS as manifested by O ₂ saturation <90% despite supplemental O ₂ , increasing respiratory distress, progressive pulmonary infiltrates, and/or decline in hgb concentration despite simple transfusion

Acute Stroke

- In the absence of primary stroke prevention:
 - ~10% of children with HbSS and HbS α^0 thalassemia will have overt strokes
 - Recurrence rate 46-90%
 - 20-35% of children with HbSS will have silent cerebral infarcts, which cause cognitive decline



Acute Stroke Recommendations

- Perform urgent head CT scan followed by MRI and MRA for patients who present with:
 - Severe headache
 - Altered level of consciousness
 - Seizures
 - Speech problems
 - Paralysis



Acute Stroke Treatment

- Emergency RBC exchange transfusion
 - Goal: HbS reduced to <30% or HbA >70% for HbSC
- Adult patients: receive standard therapy for acute stroke +/- thrombolytic therapy and thrombectomy if indicated, followed by RBC exchange transfusion
- Initiate monthly simple or exchange transfusion for adults and/or children who have had a stroke
 - If not possible to implement transfusion program, initiate hydroxyurea

Acute Anemia

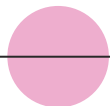
Acute Anemia Causes	Notes
Splenic sequestration crisis	<ul style="list-style-type: none">• Rapid swelling of spleen• Thrombocytopenia (<150,000/μL)• Increase in reticulocyte count 25% above baseline• Hypovolemia
Aplastic crisis	<ul style="list-style-type: none">• May be caused by parvovirus B19 infection or an acute inflammatory illness• Significant decrease in reticulocyte count from baseline• Assess for delayed hemolytic transfusion reaction up to 28 days after last RBC transfusion

Acute Anemia Treatment

- Acute Anemia: decline of >2.0 g/dL below patient's baseline Hgb

Hgb genotype	Baseline Hgb
SCA	6-8 g/dL
HbS β - thalassemia	9-12 g/dL
HbSC	10-15 g/dL

- Treatment: Transfusion
 - Consider splenectomy due to high recurrence rate





Other Acute Complications

- Fever
- Hepatobiliary
 - Cholelithiasis
 - Cholecystitis
 - Choledocholithiasis
 - Acute hepatic sequestration
 - Acute intrahepatic cholestasis
- Multiorgan failure
- Priapism
- Acute ocular conditions
- Venous Thromboembolism





Chronic Complications



- Chronic pain
- Avascular necrosis
- Leg ulcers
- Ophthalmologic complications
- Sickle retinopathy
- Sickle nephropathy
- Pulmonary hypertension
- Stuttering/recurrent priapism

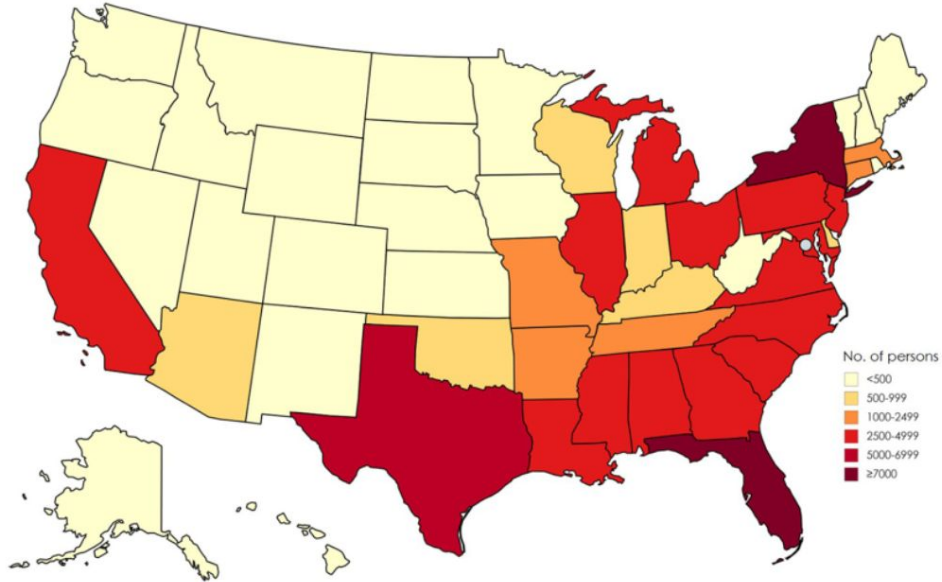
Disease-Modifying Therapies

Therapy	Hydroxyurea (1998) (Siklos, Hydrea)	L-glutamine (2017) (Endari)	Voxelotor (2019) (Oxbryta)	Crizanlizumab (2019) (Adakveo)
Age (years)	All	≥5	≥12	≥16
Route	Oral pill or liquid	Oral powder	Oral tablet	IV
Frequency	Once daily	Twice daily	Once daily	Once every 4 weeks (initial dose week 0, 2, and 4)
Monitoring	Frequent monitoring of CBC and dose titration	None	None	None
Benefits	<ul style="list-style-type: none"> Improved life expectancy Reduced vaso-occlusive complications (acute chest syndrome & stroke) 		<ul style="list-style-type: none"> Increased Hgb and decreased hemolysis 	<ul style="list-style-type: none"> Good choice for severe and frequent pain episodes
Annualized rate of acute pain episodes vs. placebo	2.5 vs. 4.5	3 vs. 4	2.8 vs. 3.2 (Non-statistically significant)	1.6 vs. 3
Caveats	<ul style="list-style-type: none"> Hair loss GI symptoms Avoid prior to conception (males and females) and during first trimester of pregnancy 	<ul style="list-style-type: none"> Mild GI symptoms 	<ul style="list-style-type: none"> Dose adjustments for CYP3A4 interactions GI symptoms Monitor Hgb in individuals with higher baseline Hgb (eg, HbSC disease) 	<ul style="list-style-type: none"> Infusion reactions Arthralgias/back pain Nausea Platelet clumping in samples collected in EDTA

Barriers to Care

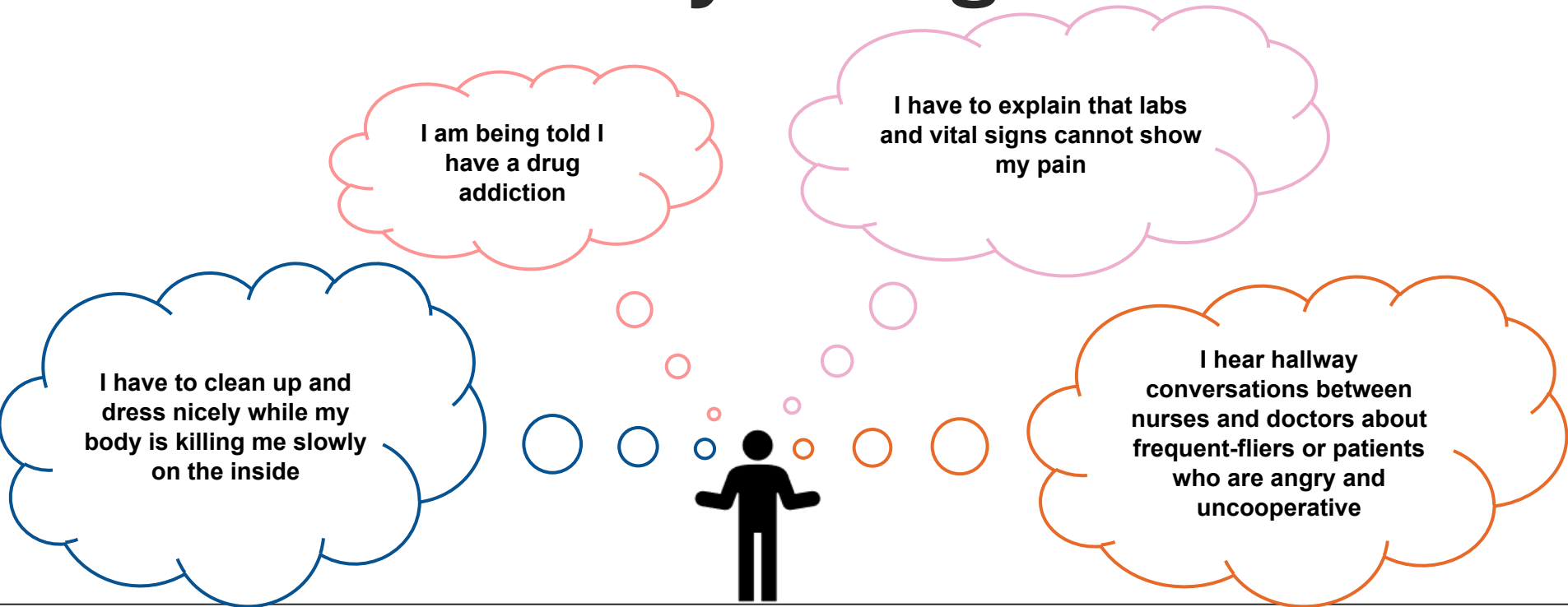


Number of Persons with SCD



- Orphan Disease: rare disease or condition that affects <200,000 persons nationwide

Mental and Psychological Pain



Emergency Room Studies

	Tanabe P, et al. 2017	Arnold T, et al. 2022	Evensen CT, et al. 2016
Study Design	Multicenter retrospective study of 159 unique patients with 612 patient visits related to SCD	Multidisciplinary quality improvement project involving notification of a patient with VOC, rapid evaluation, electronic order set	Survey responses from 556 adults with SCD on quality of care questions about access communications, ER care, and ER pain treatment
Primary Objective	Identify factors associated with a delay in receiving an initial analgesic	Have 75% of pediatric patients with VOCs receive initial analgesia within 60 minutes of being registered	Create a patient-reported outcomes measures of quality care
Findings	Mean time to administration of initial analgesic was 90 minutes (IQR: 54-159)	Average time to initial analgesia decrease from 61 minutes to 42 minutes ($p = 0.001$)	<ul style="list-style-type: none"> • Waits of >1 hour before treatment was reported by 62% • 81% chose to manage pain at home rather than the ER • 84% cited negative ER experiences

Arnold T, et al. Cureus. 2022 Sep 25;14(9):e29569.

Evensen CT, et al. Medicine (Baltimore). 2016 Aug;95(35):e4528.

Tanabe P, et al. Acad Emerg Med. 2007 May;14(5):419-25.

The Association of Clinician Characteristics with their Attitudes Toward Patients with Sickle Cell Disease: Secondary Analyses of a Randomized Controlled Trial

- **Objectives:** to explore the extent to which clinical characteristics such as race, sex, professional discipline, and amount of exposure to SCD patients in pain may be associated with attitudes toward SCD patients
- **Methods:** A scaled survey instrument assessing 276 clinicians' general attitudes towards patients with SCD

Negative Attitudes	Positive Attitudes	Suspicion Over Concern-Raising Behaviors
<ol style="list-style-type: none">1. Over report (exaggerate) pain2. Fail to comply with medical advice3. Abuse drugs and alcohol4. Attempt to manipulate clinicians5. Are drug-seeking when they come to the hospital6. Frustrating to care for	<ol style="list-style-type: none">1. Make the clinicians glad they went into medicine2. Are the kind of person the clinician could see themselves friends with3. Satisfying to take care of4. Are easy to empathize with	<ol style="list-style-type: none">1. Patient requests specific narcotic drugs and dose2. Patient appears comfortable while complaining of severe pain3. Patient has history of disputes with staff4. Patient rings bell for nurse and constantly asks for medication before the next dose is due



Author's Findings

- Asian clinicians reported more negative attitudes about SCD patients, including signs of inappropriate drug-seeking behaviors, when compared to White (mean difference 16.5, $p=0.003$)
- Nurses endorsed a greater level of negative attitudes about SCD patients when compared to clinicians (mean difference 11.5, 95% CL [3.3, 19.7]), and believe that patients are inappropriately drug-seeking (mean difference = 10.9 points, 95% CL [2.5, 19.4]) ‘
- Clinicians were reported caring for 11 or more SCD patients in the preceding 3 months endorsed greater levels of negative attitudes than those caring for none (mean difference 20.2, $p=0.001$) and belief that their behaviors are signs of inappropriate drug-seeking (mean difference 19.1, $p=0.004$)

FDA Approved Medication Use

	Hydroxyurea	L-Glutamine	Voxelotor	Crizanlizumab	Hydroxyurea + L-glutamine	Hydroxyurea + Voxelotor	Hydroxyurea + crizanlizumab	Crizanlizumab+ L-glutamine	Hydroxyurea + L-glutamine + Crizanlizumab
All Individuals with SCD	24.6% (1957/7957)	2.0% (49/7345)	1.9% (101/5304)	1.4% (72/5304)	1.2% (86/7345)	1.0% (55/5304)	0.6% (34/5304)	0.1% (5/5304)	<0.1% (3/5304)
Individuals with SCD and ≥ 2 episodes of pain a year	31.5% (1428/4531)	3.2% (135/4191)	2.9% (85/2888)	2.3% (65/2888)	1.8% (76/4191)	1.6% (46/2888)	1.1% (5/2888)	0.2 (5/2888)	0.1% (3/2888)

- Denominators are based on eligible participants when medications were FDA-approved
- Underutilization is seen for the medications

TCD Screening

Percent of children with sickle cell anemia who had transcranial doppler ultrasound screening

2014 30% ● ● 43%

2019 38% ● ● 47%

Hydroxyurea Use

Percent of children with sickle cell anemia who used hydroxyurea

2014 30% ● ● 43%

2019 38% ● ● 53%

● 2-9 years of age

● 10-16 years of age



Vital^{CDC}signs™


Source: September 2022 Vital Signs



CS332903

Comparison of US Federal and Foundation Funding of Research for Sickle Cell Disease and Cystic Fibrosis and Factors Associated With Research Productivity

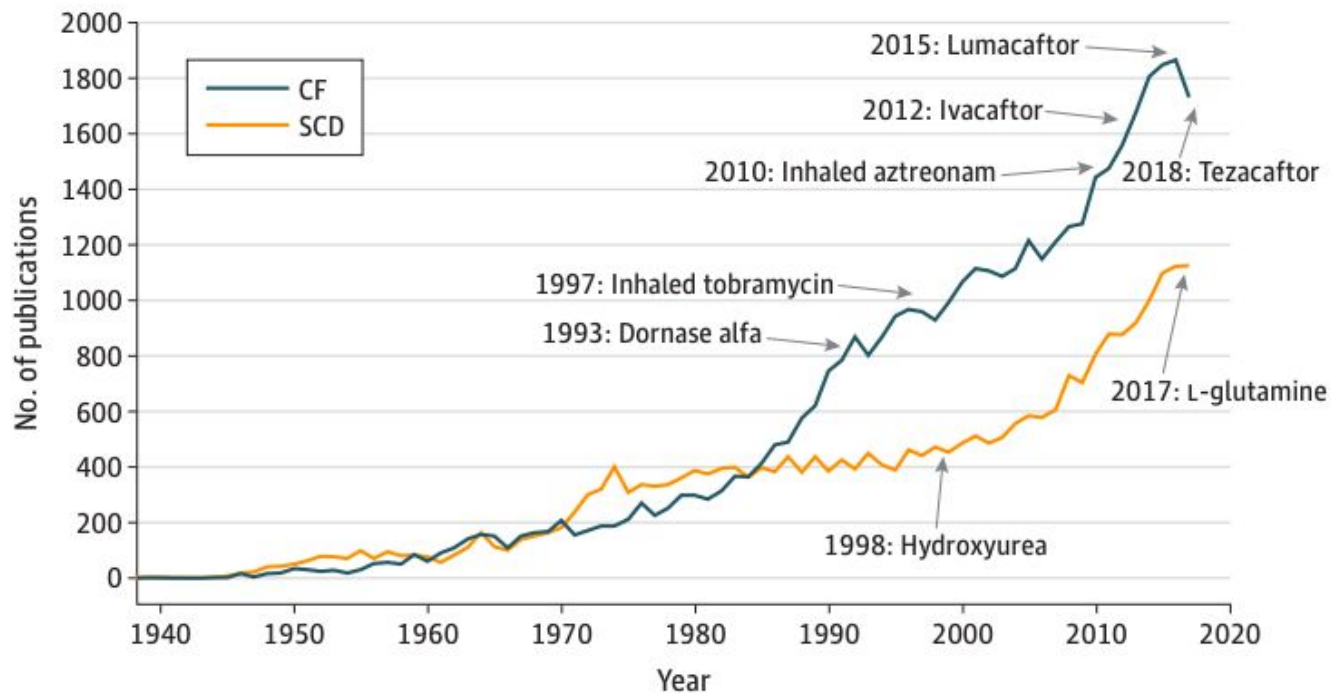
- **Objective:** Compare disease-specific funding between SCD and CF and the association between funding and research productivity
- **Methods:** Cross-sectional study of reported metrics of disease funding and indicators of research productivity between
 - National Institute of Health (2008-2017)
 - Publications (1940-2018)
 - Foundations or Universities (2008 and 2018)
 - Industry sponsored through ClinicalTrials.gov (2008 and 2018)
- **Results:** “Significantly more research articles and drug approvals were found for cystic fibrosis compared with sickle cell disease, but the total numbers of clinical trials were similar.”



	SCD	CF	P Value
Annual Funding (2008-2017)			
NIH funding (in millions), mean (SD), \$	76.3 (13)	84.2 (5.2)	0.05
NIH funding per person affected, mean (SD), \$	812 (147)	2807 (175)	<0.001
Foundation expenditures (in millions), mean (SD), \$	9.14 (1.2)	231 (119)	<0.001
Foundation expenditures per person affected, mean (SD), \$	102 (13.7)	7690 (3974)	<0.001
Total funding per person affected, mean (SD), \$	943 (148)	10592 (3841)	<0.001
Research output (2008-2018)			
Annual PubMed publications, mean (SD), #	926 (157)	1594 (225)	<0.001
Annual clinical trials, mean (SD), #	24 (6.3)	27 (6.9)	0.23
New FDA drug approvals, #	1	4	–
Novel FDA drug indications, #	2	11	–

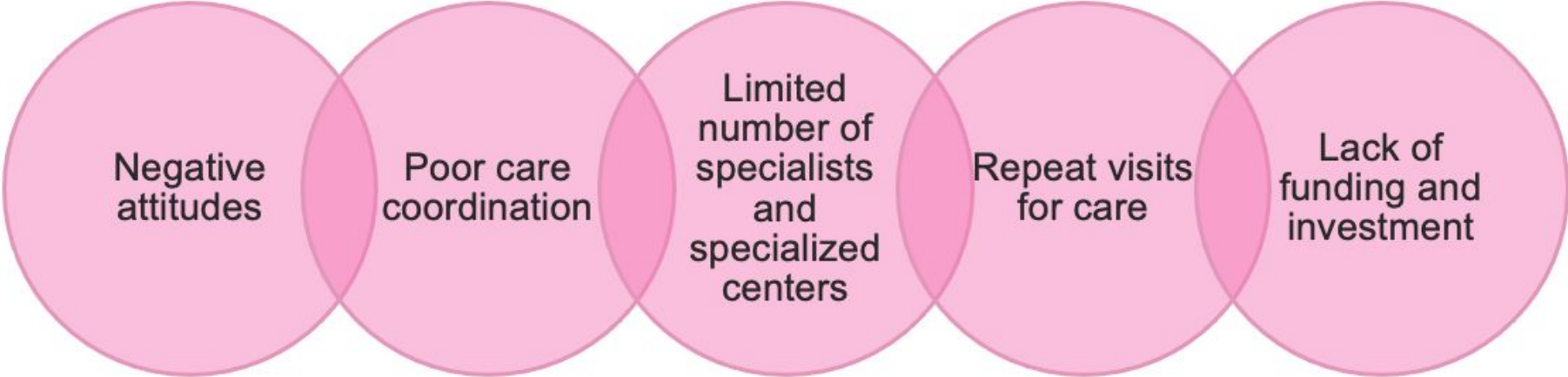


Figure 1. Number of Disease-Specific PubMed Listings and US Food and Drug Administration Drug Approvals Over Time





Summary of Barriers




Negative attitudes

Poor care coordination

Limited number of specialists and specialized centers

Repeat visits for care

Lack of funding and investment



How to Address Disparities




Reduce the Impact of Structural Racism on Patients with SCD

- Implement universal screening for social determinants of health
- Reintroduce federal funding for comprehensive sickle cell disease centers
- Analyze the effect of race and racism on federal funding disease research
- Psychosocial support for patients with SCD, including social workers, patient navigators, and psychologists

Dismantle Institutional Racism

- Develop formal, hospital-based reporting systems for safety events and quality improvements to document and respond to racist behavior
- Include patients and their advocates on anti-racism task forces
- Institute SCD specific pain management protocols to reduce the time to opiate administration
- Empower patients to safely report concerns about racism or inequity

Address Interpersonal Racism with Patients and Colleagues

- 
- Speak explicitly about race within and across medical teams, with a focus on experiences of patients with SCD
 - Develop partnerships with patients and recognize their ability to educate providers
 - Implement mandatory annual racial implicit bias training in a supportive environment
 - Practice mindfulness and self-reflection in care
 - Stop using the word “sickler”
 - Create safe spaces for all healthcare workers to discuss race and racism, and to report events when they happen

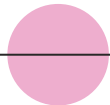


Develop a Curriculum



- Expose internal medicine residents to SCD patients
- Created a didactic lecture series for residents
 - Bias and its effect on healthcare
 - Compare and contrast session between SCD and cystic fibrosis
 - Mock root-causes analysis reviewing the death of a patient
 - Lecture on health-care disparities and racism
- “...resident comfort level managing patients with sickle cell disease slightly increased after the completion of our curriculum.”

“Change begins with a conversation, but words are not sufficient; we must take action to make enduring improvements in the care of patients with SCD.”





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