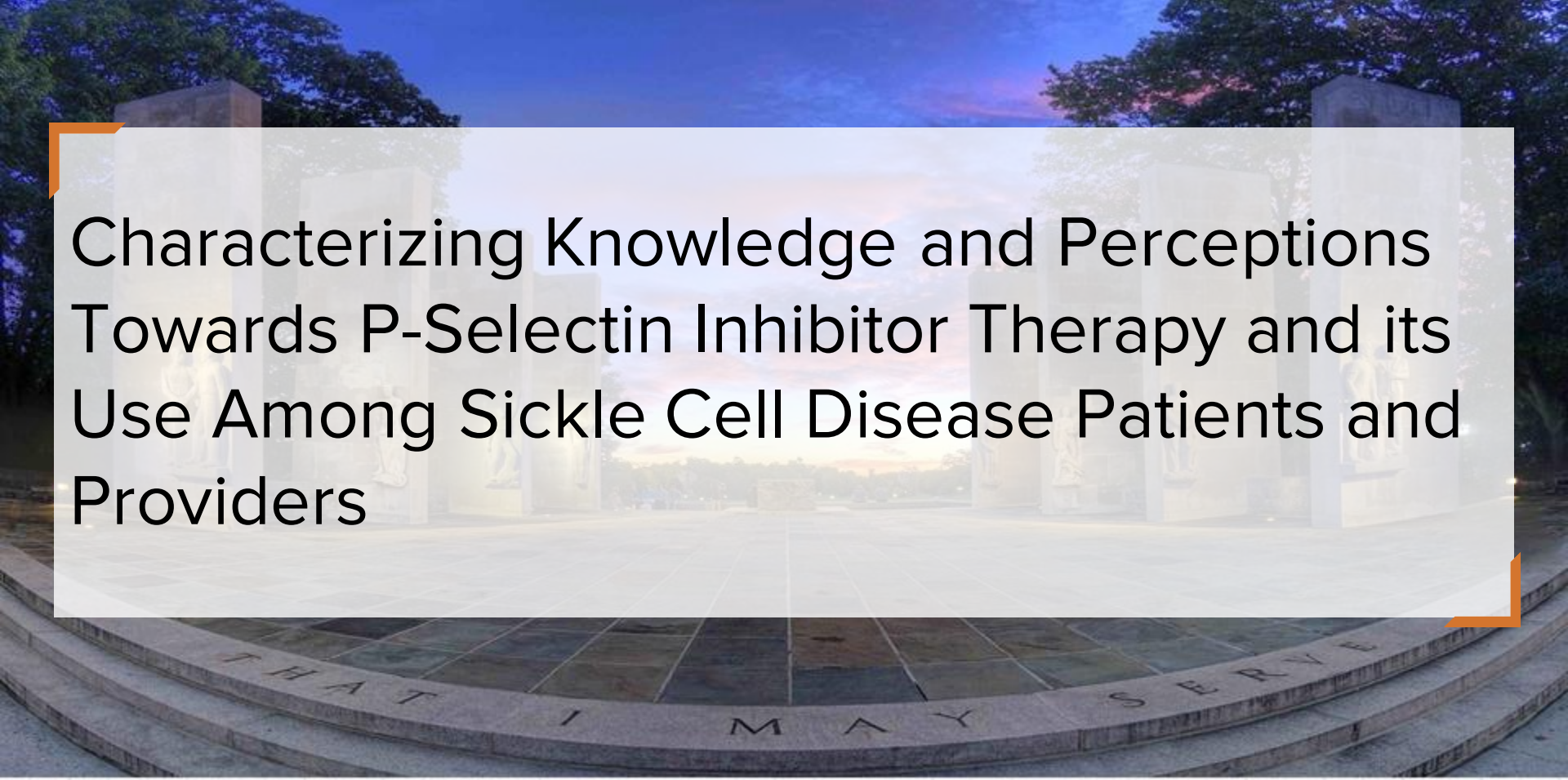

Characterizing Knowledge and Perceptions Towards P-Selectin Inhibitor Therapy and its Use Among Sickle Cell Disease Patients and Providers

November 6, 2022 - APHA

Presented by: Miles Thomas, MS-3 VTCSOM

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Inclusive Introduction

Presenter Disclosures

Characterizing Knowledge and Perceptions Towards P-Selectin Inhibitor Therapy and its Use in Sickle Cell Disease Patients and Providers

The following personal financial relationships with commercial interests relevant to this presentation existed during the past 24 months:

No relationships to disclose

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Background and Knowledge Gap

- Crizanlizumab was approved in 2019 for the reduction of vaso-occlusive crises (VOCs) in sickle cell disease (SCD).[1,2]
- Crizanlizumab appeared to be sparsely used as of 2022, per TriNetX data review.
- How is crizanlizumab deployed in the community? What considerations dictate its use?
- Knowing the barriers and perceptions in using crizanlizumab would help us understand the uptake of newly approved medications in this patient population.

[1] Food and Drug Administration (11/2019). Crizanlizumab Drug Label. Retrieved 3/28/2021 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761128s000lbl.pdf

[2] Lee, B. Y. (2019). FDA Approves Crizanlizumab, A New Drug For Sickle Cell Disease. Forbes. Retrieved 4/28/22 from https://www.forbes.com/sites/brucelee/2019/11/17/fda-approves-crizanlizumab-here-is-a-new-drug-for-sickle-cell-disease/?sh=1a1a2e162b78

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Study Objectives

1. Establish frequency of crizanlizumab use.
2. Identify clinical and demographic characteristics of patients taking this medication.

Hypothesis:

- There will be a low rate of crizanlizumab use among patients potentially eligible.

TriNetX Data Analysis

Methods

- **Retrospective descriptive analysis**
- Patients with a **diagnosis of SCD with and without crisis** (ICD-10 codes D57.0, D57.1, D57.2, D57.4. D57.8), excluding those with sickle cell trait (D57.3) were retrospectively identified through the TriNetX research network, comprising **EHR data from 58 HCOs**.
- De-identified EHR data for **46,340 patients** meeting the above mentioned criteria was transferred to the study team.

Data Cleaning

Diagnosis or Procedure	Code Types	Codes	TriNetX Data Set	Columns returned
SCD with Crisis	ICD10 and ICD9	D57.0, D57.21, D57.41, D57.43, D57.45, D57.81, 282.62, 282.69, 282.64	Diagnosis	ICD10 - 730,882 ICD9 - 363,044
Hydroxyurea	NDC and RxNORM	0003-6335-17, 0003-6336-17, 0003-6337-17, 0003-0830-50, 0904-6939-61, 70518-0916-0, 0555-0882-02, 10135-702-01, 49884-724-01, 42291-321-01, 68084-284-01, 69315-164-01, 55154-7143-0, 60429-265-01, 71770-105-60, 71770-120-30, 216755, 151871, 5552,1999309,200342, 200343, 200344,105602, 197797,1999308, 1999314, 1999316	Medication Ingredients and Drugs	Med_Ingred - 592908 Med_Drug - 262,264
Crizanlizumab	NDC and RxNORM	2262279, 2262430, 78088361	Medication Ingredients and Drugs	Med_Ingred - 4,468 Med_Drug - 117
Voxelotor	NDC and RxNORM	2265683, 2265689, 2265678, 72786010101	Medication Ingredients and Drugs	Med_Ingred - 5,401 Med_Drug - 1,426
Blood Transfusions	ICD-10-PCS, ICD-9-CM, CPT, SNOMED, HCPCS	30233N0, 30233N1 ,30233H, 30243H, 30243N, 99.0, 99.00,99.01, 99.02, 99.03, 99.04, 36430, 36455, P9010, P9011, P9016, P9021, P9022, P9038, P9039, P3040, P9051, P9054, P9057, P9058	Procedure	161,831
HgA	LOINC	4546-8, 20572-4, 42244-4, 10346-5	Lab_Result	128,990
Pregnancy	ICD10 and ICD9	O00-O9A, Z33, Z33.1, Z34, O00-O08, V22, V22.0, V22.1, V22.2	Diagnosis	59,880

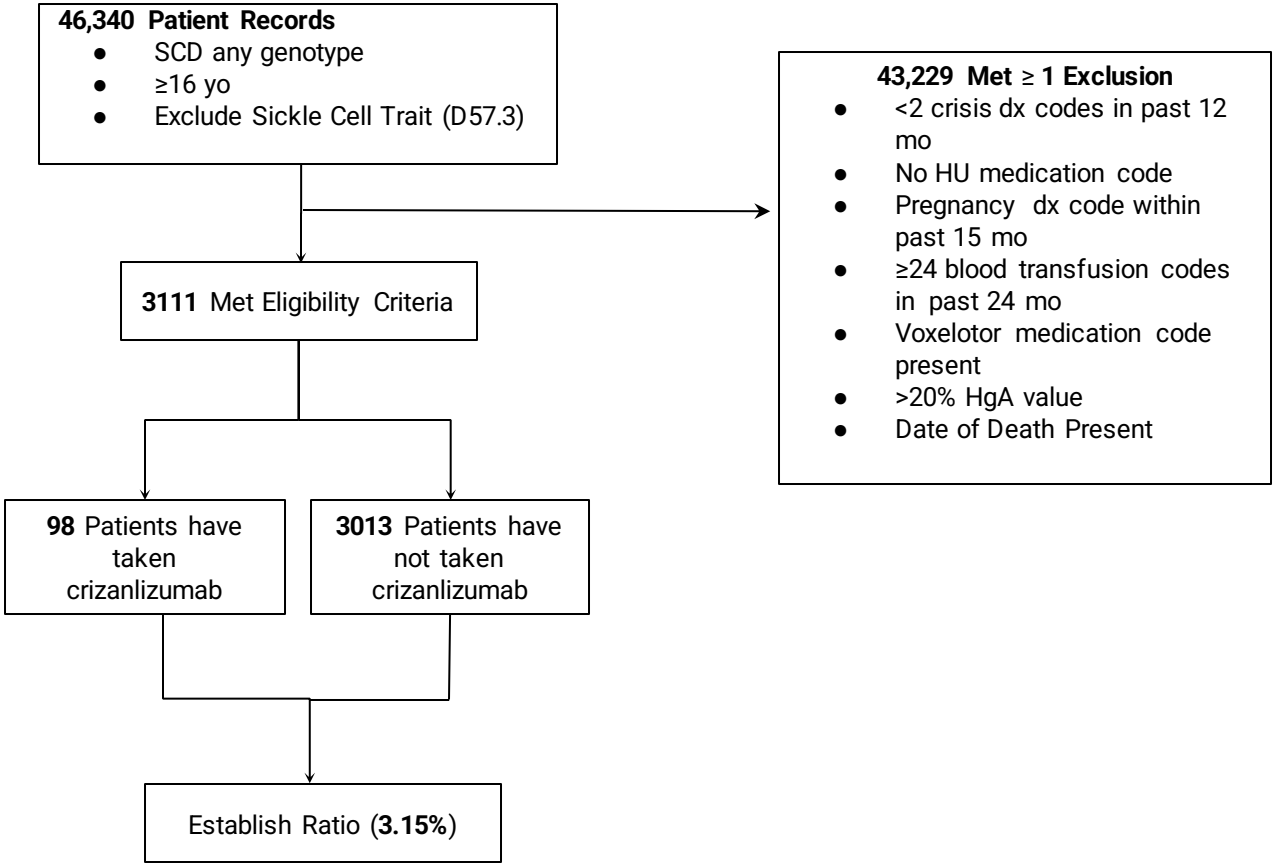
Crizanlizumab Eligibility Criteria

- ≥ 2 crisis diagnosis codes in past 12 months
- ≥ 1 hydroxyurea medication code
- Not pregnant within past 462.5 days (280 days (40 wks) pregnancy + 182.5 days (6 mo) average for breastfeeding)
- Less than 24 blood transfusion procedure codes in past 24 months
- No history of voxelotor medication codes
- Hemoglobin A ≤ 20%
- No date of death in EHR

Statistical Methodology

Descriptive Analysis:

- Measures of central tendency reported as mean for continuous data, compared with 2 sample t-test.
- Categorical data reported as counts (%), compared via chi-square test.
- P value of 0.05 considered statistically significant.



***Percentage of patients taking crizanlizumab is small among those "eligible".**

***But much larger than the percentage among all patients (0.7%)**

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Next Step

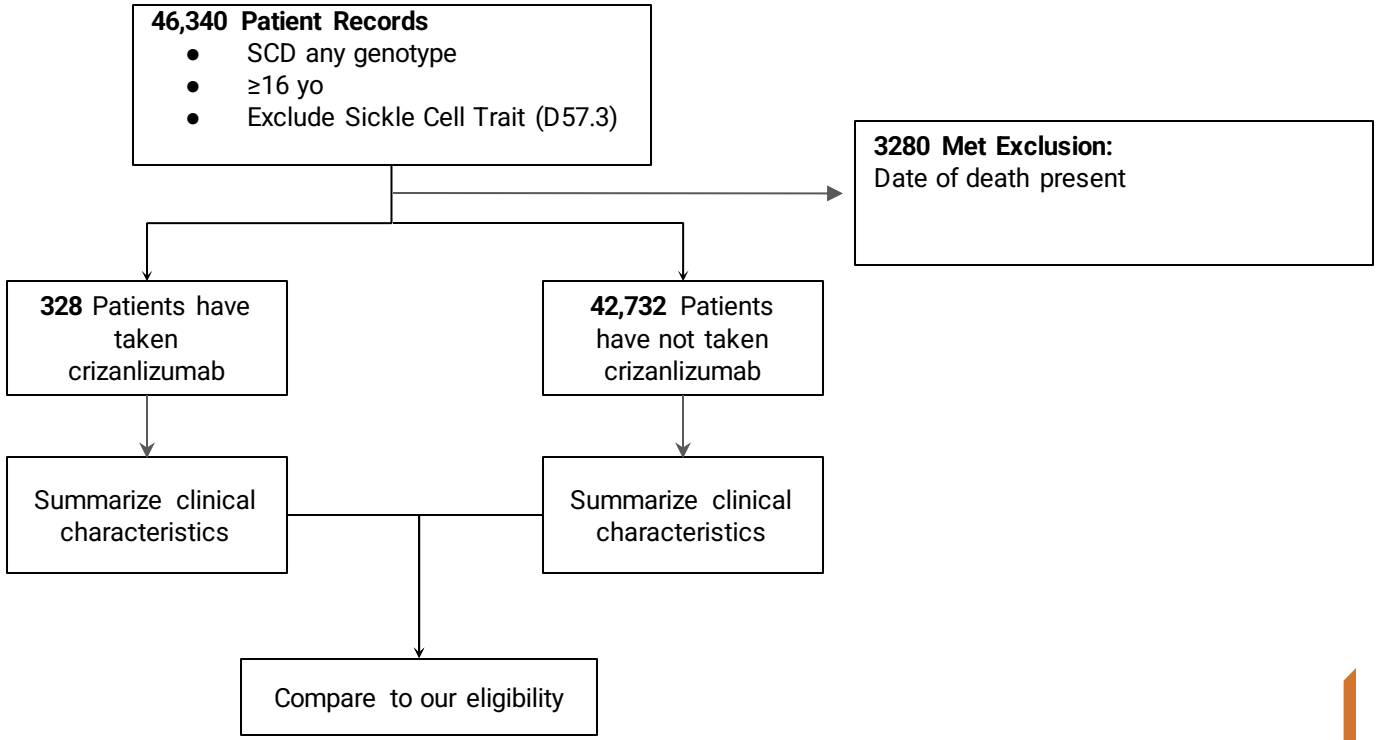

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Table 1. Characteristics of crizanlizumab vs. non crizanlizumab			
Variable	**Crizanlizumab (N = 328)**	**Non-Crizanlizumab (N = 42,732)**	**P-value or Total**
Mean Age (range) - yr	**33.9 (17-75)**	**41.5 (16-90)**	**<0.01**
Sex - no. (%) Male Female	 115 (35%) 213 (65%)	 16629 (37%) 28145 (63%)	 0.43
Meet Study Inclusion Criteria (%)	98 (29.9%)	3013 (7.1%)	3111
Geographic Region - no. (%) - **Midwest** - **Northeast** - **South** - **West** - **Ex-US**	 **72 (22.0%)** **13 (4%)** **225 (68.6%)** **8 (5.5%)** **0 (0.0%)**	 **4997 (12.3%)** **10334 (25.5%)** **23448 (57.8%)** **1578 (3.9%)** **245 (0.6%)**	**<0.01**
Number Crisis Codes - no of patients. - **0** - **1-2** - **3-4** - **5+**	 **43 (13.1.%)** **17 (5.2%)** **8 (2.4%)** **260 (79.3%)**	 **33538 (78.5%)** **3018 (7.1%)** **1310 (3.1%)** **4866 (11.4%)**	**<0.01**

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Table 1 continued. Characteristics of crizanlizumab vs. non crizanlizumab			
Characteristic	**Crizanlizumab (N = 328)**	**Non-Crizanlizumab (N = 42,732)**	**P-value or Total**
Other Complications - Mean (SD)* - Acute chest syndrome - Splenic sequestration - Cerebral Vascular Involvement	 2.01 (6.08) 0.018 (0.23) 0.03 (0.26)	 0.1 (1.17) 0.008 (0.5) 0.013 (0.39)	- **<0.01** - 0.73 - 0.36
Mean number of emergency encounters (SD)	**39.9 (107.6)**	**32.2 (7.8)**	**<0.01**
HU Status - no (%) - **Hx of HU** - **None**	 **295 (89.9%)** **33 (10.1%)**	 **10703 (25.0%)** **32029 (75%)**	**<0.01**
**Not including ICD-9-CM diagnoses before 10/1/2015 (Not well enough defined in the data)*			

Limitations and Areas for Further Exploration

- Eligibility criteria is not consistent across private payers and state Medicaid programs. Our eligibility criteria may have been too restrictive.
- Diagnosis codes give us a rough proxy for healthcare encounters associated with a disease, but they do not substitute a detailed chart review.
- Our data may not have captured prescriptions given in the context of a clinical trial.

Next Steps

Patient and Provider Surveys

Survey Aims:

- *Identify rationale and considerations used by providers for prescribing crizanlizumab.*
- *Assess awareness and perceptions towards crizanlizumab.*
- *Identify barriers to access and which barriers most strongly prevent treatment with this medication.*

Thank You!

Feel free to reach out
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