

HAE

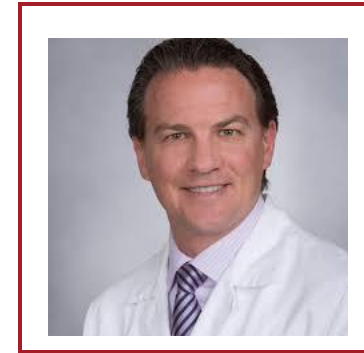
Inequalities of Care



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Disclosures

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Speaker Presentations

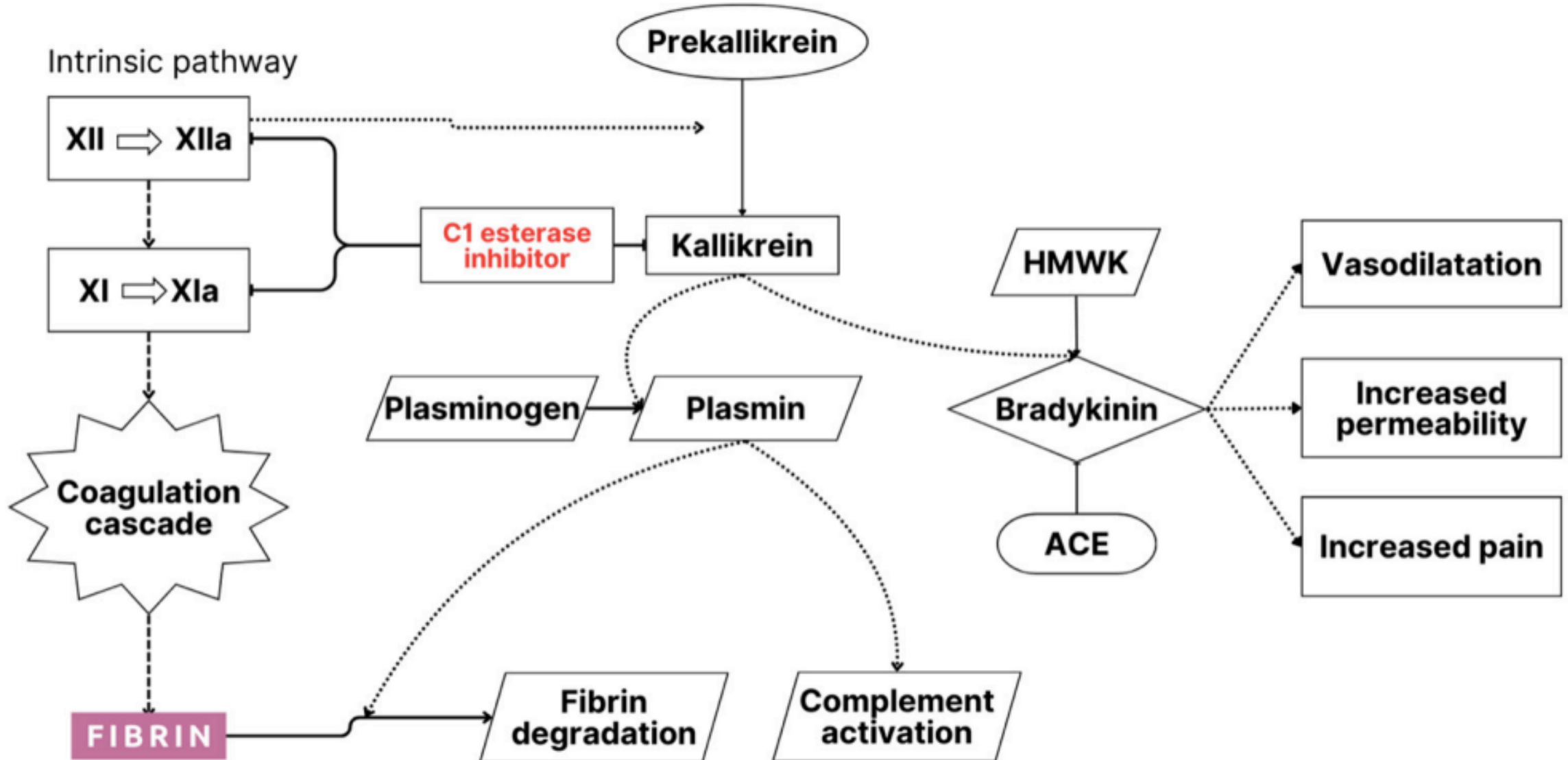
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HAE

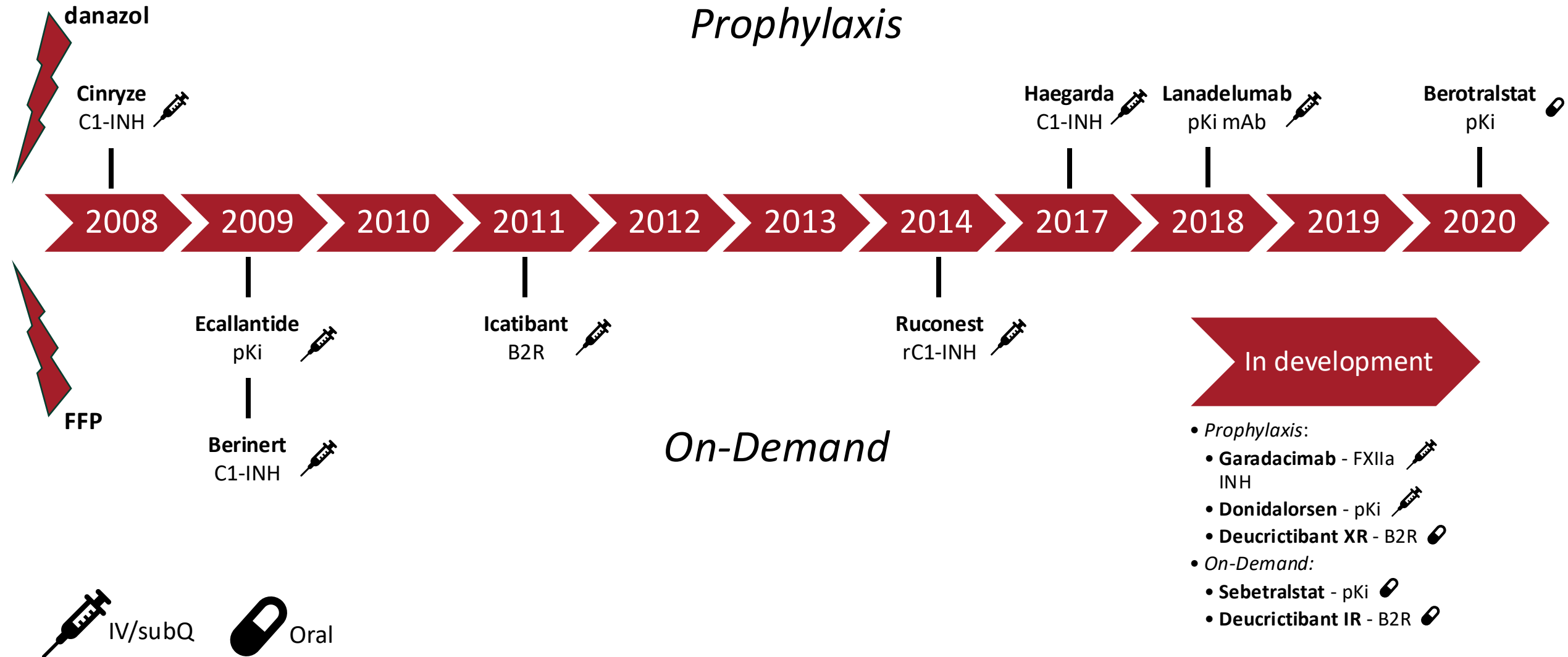


- A rare genetic disorder that leads to recurrent and unpredictable episodes of angioedema
- Airway swelling can be life threatening
- Significant impact on quality of life
- Significant improvement over the past 15 years for treating both attacks and prophylaxis

HAE Pathophysiology



HAE Prophylaxis and On-Demand Treatment



Disparities in the Diagnosis and Management of HAE

Years to diagnose properly

- Is that impacted by race, income, geography?

Patient access to specialized care

- Is that impacted by race, income, geography?

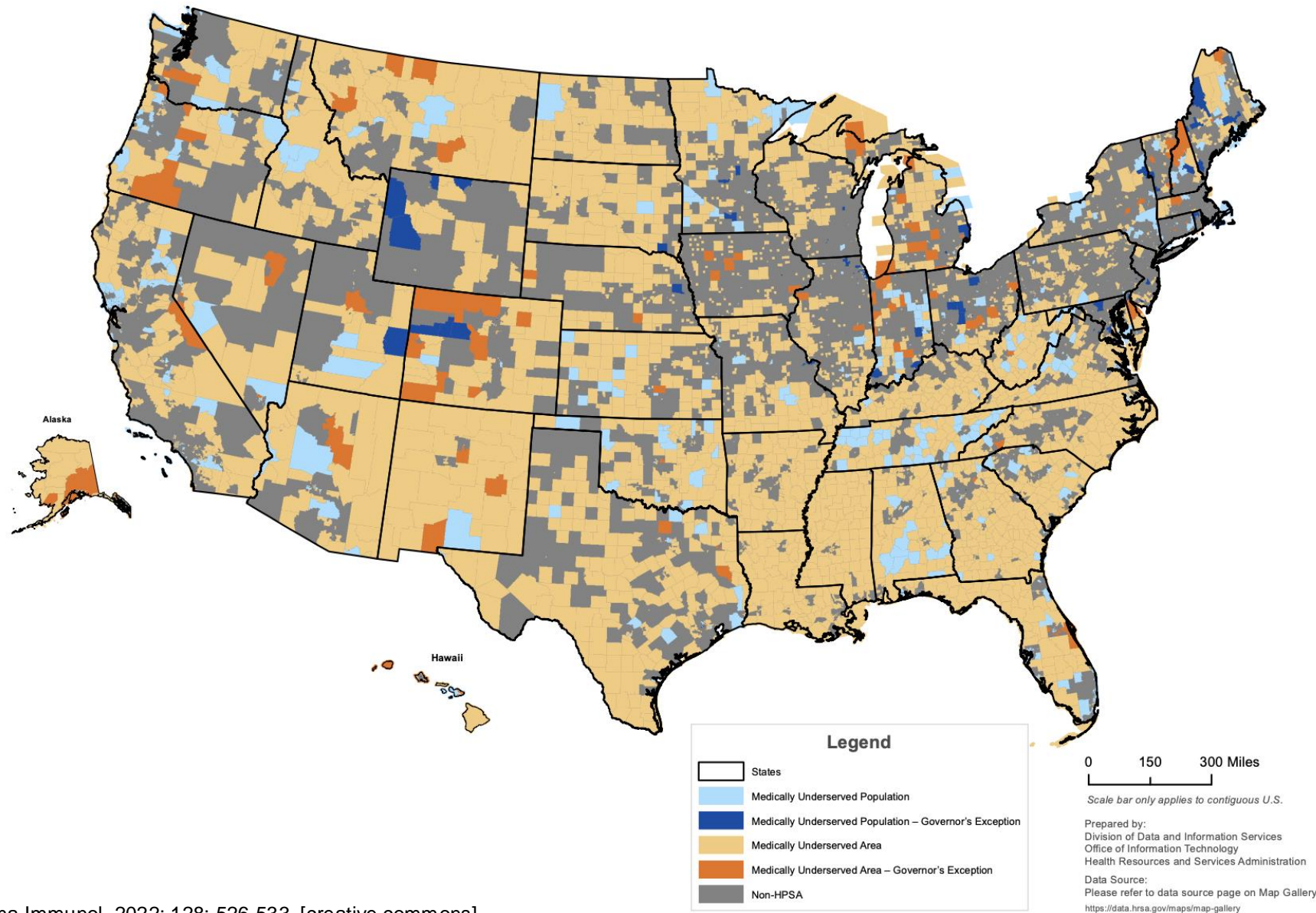
Access to targeted therapies (both on-demand and prophylactic medications)

- Is that impacted by race, income, geography?
- Is the clinical data representative of real-world demographics?
- How can we improve outcomes for all HAE patients?

HAE and Rural Settings



One-Fifth of HAE Patients Live in Rural Areas



HAE in Rural Communities: Challenges

- Individualized management plans
- Expanding role of telemedicine in rural areas
- Care for HAE from the primary care provider
- Care for HAE from the Emergency Department
- Access to medication
- Patient support and advocacy

HAE in Rural Communities: Strategies to Improve

- Barriers to diagnosis
- Access to specialist care
- Local health care
- Patient education
- On-demand and prophylactic medication
- Availability of telemedicine
- Health economic disparities

HAE Sample Letter for ED in Rural Community

RE: (NAME) (DOB)

To Whom It May Concern,

(NAME) carries the diagnosis of C1 esterase inhibitor deficiency, also known as hereditary angioedema (HAE) and is under my medical care to treat this condition.

This genetic condition is characterized by sporadic episodes of cutaneous, intestinal, and/or laryngeal angioedema. These episodes may cause severe pain, nausea, vomiting, and airway compromise, including fatal asphyxia.

(NAME) is currently prescribed (drug/dose/route) as prophylaxis. For treatment of acute attacks, (NAME) uses (drug/dose/route), which is U.S. Food and Drug Administration approved to treat HAE. A second dose of medication may be necessary in the event of a partial response or recurring angioedema symptoms. In the event of any laryngeal symptoms, administer HAE medication immediately.

In addition to this medication, management of acute attacks may include supportive care, including airway monitoring, analgesic and antiemetic medications, and intravenous fluids as appropriate.

Efficacy of epinephrine, steroids, and antihistamines is doubtful when treating HAE, a bradykinin-mediated form of angioedema.

It is medically necessary that the patient carry the listed HAE medications and related treatment supplies while traveling. In addition (NAME) has been instructed to bring their rescue medication to the emergency facility in the event they are needed.

If there are any questions, please contact (Care team 24-hour contact info)

Sincerely,

Letters for planned procedures should also include plans for preprocedure prophylaxis and extended monitoring, sample below.

Procedure and Date:

Before the procedure, (NAME) should receive prophylactic (drug/dose/route) and have additional doses of prophylactic medication available in the event of a hospital stay longer than 3–4 days.

In the event of postoperative swelling, (NAME) is to have access to U.S. Food and Drug Administration approved on-demand treatment, as above. If (NAME) is to have endotracheal anesthesia, it is recommended to have rescue medication immediately available and that the patient be monitored for a minimum of 24 hours after surgery.

Claims Data

Social Determinants of Health in Hereditary Angioedema and Their Impact on Patient Outcomes

Alan P. Baptist,¹ J. Allen Meadows,² Marc A. Riedl,³ Tigwa Davis,⁴ Scott B. Robinson,⁴ Yecheng Huang,⁴ Krystal Sing,⁵ Bob G. Schultz⁵

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INTRODUCTION

- Hereditary angioedema (HAE) is a rare genetic disorder that is characterized by unpredictable, episodic attacks of cutaneous/submucosal swelling.^{1,2}
- Clinical management of HAE requires several approaches, including on-demand treatment for acute HAE attacks, short-term prophylaxis where a trigger is anticipated, and long-term prophylaxis (LTP) to prevent attacks.²
- Although healthcare providers and patients with HAE have access to an increased range of treatment options, social determinants of health (SDOH) may impact patients' health and treatment outcomes.³
 - SDOH include characteristics such as neighborhood, culture, race/ethnicity, socioeconomic status, education/employment status, and access to healthcare.
- Few studies have investigated the effects of SDOH on outcomes (treatment patterns, emergency department (ED) visits, and hospitalization) in patients with HAE.

OBJECTIVE

- The aim this study is to evaluate outcomes by sociodemographic characteristics in patients with HAE.

METHODS

- In this observational, retrospective cohort analysis of claims among individuals assumed to have HAE, data were derived from the Inovalon Closed Claims database, which includes Medicare Advantage, Commercial, and Managed Medicaid patients.
- SDOH data were derived from Axiom's Market Indices database (an aggregation of the American Community Survey and Axiom's InfoBase® Geo file), which were linked to the Inovalon Closed Claims database.
- Inclusion criteria were:
 - ≥2 medical claims for HAE (D84.1), or angioedema (T783XXX) and ≥1 prescription for an HAE-specific medication (Table 1), during the case-finding period from January 1, 2017 to September 30, 2021.

- Index date was the first claim for HAE/angioedema or HAE pharmacologic treatment during the case-finding period.
- Patients were required to have ≥12 months and ≥24 months of continuous enrollment prior to and after their index date, respectively, to capture baseline comorbidities and monitor outcomes for 2 years.
- Race/Ethnicity, income, and rurality (Figure 1) were investigated as factors potentially impacting outcomes, including the percentage of patients receiving LTP, or on-demand therapy with fresh frozen plasma (FFP), and those who visited the ED or required hospitalization.
- A multivariable model, adjusting for age and sex, was developed to analyze differences in ED visits between groups.

FIGURE 1: SDOH INVESTIGATED IN PATIENTS WITH HAE



RESULTS

Patient population

- A total of 1209 individuals with HAE from the claims database met the criteria for inclusion; 960 patients had information about their race/ethnicity, 1102 had information about income, and 1101 had information about their rurality.
- Baseline demographics and clinical characteristics are shown in Table 2.
- Median patient age was highest among African American individuals and lowest among Hispanic individuals, with no notable differences by income and rurality.
- The proportion of patients on Medicaid was highest among Hispanic individuals and lowest among White individuals, and higher among individuals in the lower income group (Figure 2). There was no notable difference by rurality.

FIGURE 2: PROPORTION OF PATIENTS ON MEDICAID

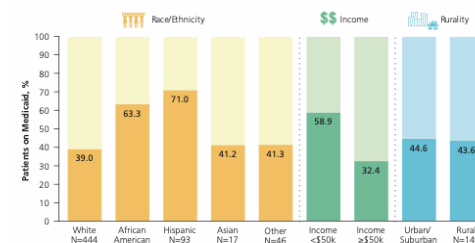


TABLE 1: HAE MEDICATIONS

Acute/STP therapies	LTP therapies
C1 esterase inhibitors (Berinert, Cinryze,* Haegarda,* Ruconest), ecallantide, FFP, icatibant	C1 esterase inhibitor (Cinryze), C1 esterase inhibitor (Haegarda), lanadelumab, antifibrinolytics, [†] androgens [†] (methyltestosterone, danazol, or oxandrolone)

*Cinryze and Haegarda were considered short-term prophylaxis (STP) if ≤14 days of continuous days' supply was dispensed. [†]Antifibrinolytics/androgens were not considered HAE-specific medications for patient inclusion criteria.

TABLE 2: BASELINE DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

	All patients N=1209	All patients N=1209
Female, n (%)	742 (61.4)	
Race/Ethnicity, %		
White	46.3	45.2
African American	37.5	40.0
Hispanic	9.7	14.9
Asian	1.8	
Other	4.8	
Median age	49.0	
Median age by race/ethnicity, years		
White	52.0	23.2
African American	55.0	24.6
Hispanic	34.0	21.1
Asian	36.0	17.8
Other	44.0	13.3
Median age by income, %		
<\$50K / ≥\$50K	53.0 / 47.0	
Median age by rurality, %		
Urban/Suburban	48.0	
Rural	53.0	2.3
Insurance type, %		
Managed Medicaid		45.2
Commercial		40.0
Medicare Advantage		14.9
Index year, %		
2017		23.2
2018		24.6
2019		21.1
2020		17.8
2021		13.3
US geographic region, %		
South		38.0
Midwest		25.7
West		18.5
Northeast		15.4
Unknown		2.3

Patients treated with LTP therapy

- LTP was used by 26.0% of patients overall, of whom 17.4% had an allergist/immunologist as their dedicated treatment specialist. African Americans, those on lower incomes, and those in rural areas had the lowest relative proportions of LTP therapy use, which correlated with having a lower proportion of allergist/immunologists as their specialist (Figure 3).

Patients treated with FFP

- FFP treatment was used by 51.3% of patients overall. African Americans, those on lower incomes, and those in rural areas were the groups with the highest proportions of FFP use (Figure 4).

ED visits and hospitalizations

- The proportions of individuals who had an ED visit are shown in Figure 5. Among the highest proportions were for African Americans, those on lower incomes, and those in rural areas.
- Asians had the highest proportion of hospitalizations, with no notable differences in the proportions of patients with hospitalizations by income or rurality (Table 3).

FIGURE 3: PROPORTION OF PATIENTS WITH A CLAIM FOR LTP TREATMENT

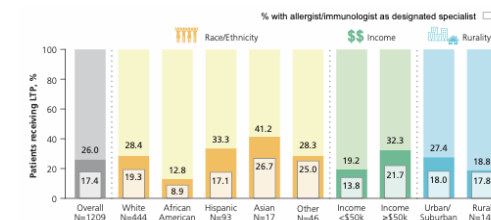


FIGURE 4: PROPORTION OF PATIENTS WITH A CLAIM FOR FFP TREATMENT

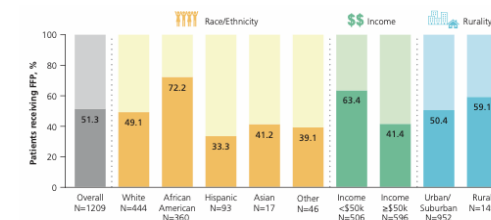
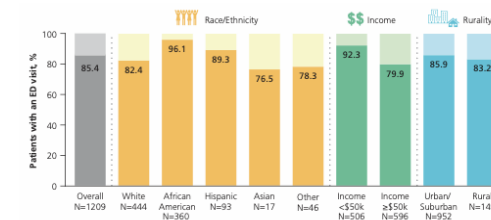


FIGURE 5: PROPORTION OF PATIENTS WITH AN ED VISIT



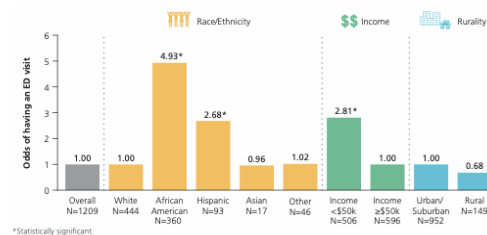
CONCLUSIONS

- Findings from this study indicate variability in healthcare utilization for patients with HAE in the United States, according to race/ethnicity, income, and rurality determinants.
- Traditionally underserved communities, such as African American and Hispanic populations, those on lower incomes, and those who resided in rural areas had lower LTP therapy use and more ED visits relative to other groups.
- These results warrant further evaluation, with strategies needed to reduce healthcare disparities among individuals with HAE in the United States.
- In multivariable models, African American patients and Hispanic patients had significantly higher odds of having an ED visit compared with White patients (odds ratio [OR], 4.93; 95% CI, 2.72–8.93 and OR, 2.68; 95% CI, 1.29–5.54, respectively, Figure 6).
- In addition, individuals with lower incomes had significantly higher odds of an ED visit (OR, 2.81; 95% CI, 1.90–4.15) compared with patients on higher incomes.

TABLE 3: PROPORTION OF PATIENTS REQUIRING HOSPITALIZATION

Race/Ethnicity	Hospitalization, %
White	33.6
African American	33.3
Hispanic	31.2
Asian	58.8
Other	28.3
Income	
<\$50K	29.4
≥\$50K	27.2
Rurality	
Urban/Suburban	30.7
Rural	36.3

FIGURE 6: ODDS OF HAVING AN ED VISIT



*Statistically significant.

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- Bernstein JA. *Am J Manag Care* 2018;24(Suppl 14):S292–S298.
- Busse PJ, et al. *J Allergy Clin Immunol Pract* 2021;9(1):132–150.e3.
- NEIM Catalyst. Social determinants of health (SDOH). 2019. <https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0312>. Accessed September 2024.

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DISCLOSURES

A.P. Baptist has research relationships with BioCryst, Ionis Pharmaceuticals, Pharvaris, and Takeda, and works as a consultant for BioCryst and Takeda. J.A. Meadows has been a speaker for Amgen, AstraZeneca, Pfizer, Regeneron, Sanofi, and Teva Pharmaceuticals; advisory board member for Bryn Pharma, Merck Sharp & Dohme, and Teva Pharmaceuticals; and consultant for Adhion, Takeda, and Teva Pharmaceuticals. M.A. Riedl has received research support from BioCryst, BioMarin, CSL Behring, Ionis Pharmaceuticals, Kalvista Pharmaceuticals, Pharvaris, and Takeda, has served as a consultant for Astra Therapeutics, BioCryst, BioMarin, CSL Behring, Cylex Pharma, Intellia Therapeutics, Kalvista Pharmaceuticals, Ono Pharmaceutical, Pfizer, Pharvaris, and Takeda, and provided speaker presentations for CSL Behring, Pharming, and Takeda. K. Sing and B.G. Schultz are employees of Takeda Pharmaceuticals USA, Inc., and hold stock options in Takeda Pharmaceutical Company Limited. T. Davis, S.B. Robinson, and Y. Huang are employees of Inovalon Insights, which was contracted by Takeda Pharmaceuticals USA, Inc. to perform this analysis.

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DISCLAIMER

This poster is intended for healthcare professionals only.

Claims Data

FIGURE 3: PROPORTION OF PATIENTS WITH A CLAIM FOR LTP TREATMENT

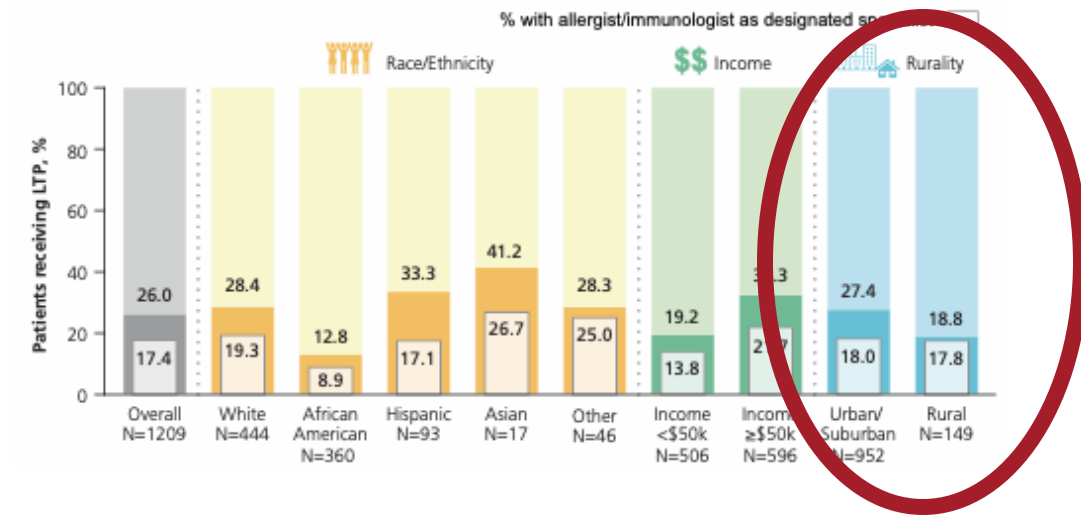


FIGURE 4: PROPORTION OF PATIENTS WITH A CLAIM FOR FFP TREATMENT

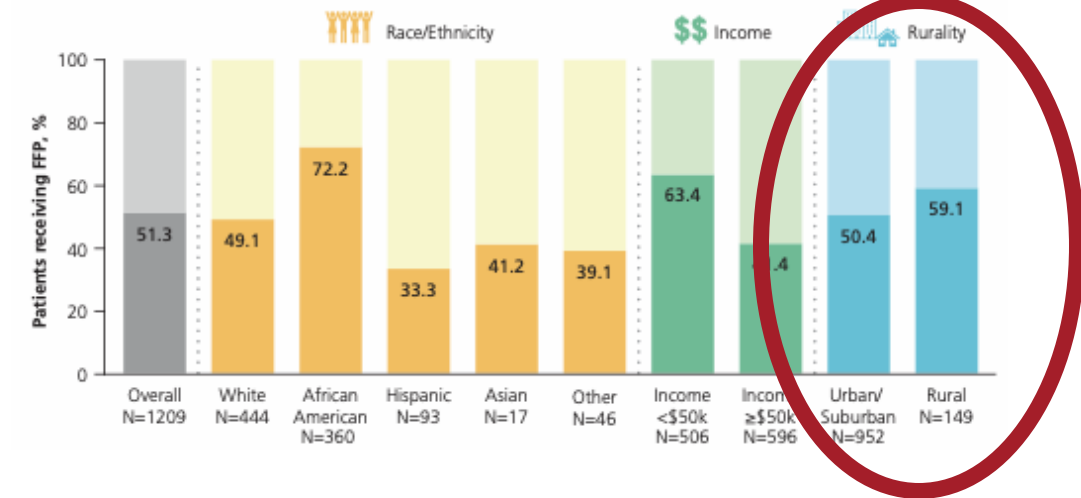


FIGURE 5: PROPORTION OF PATIENTS WITH AN ED VISIT

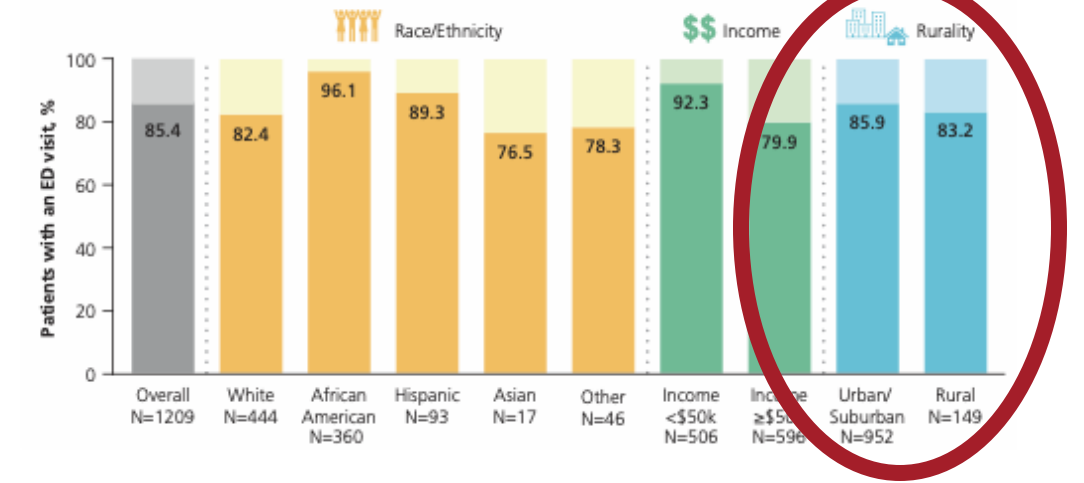
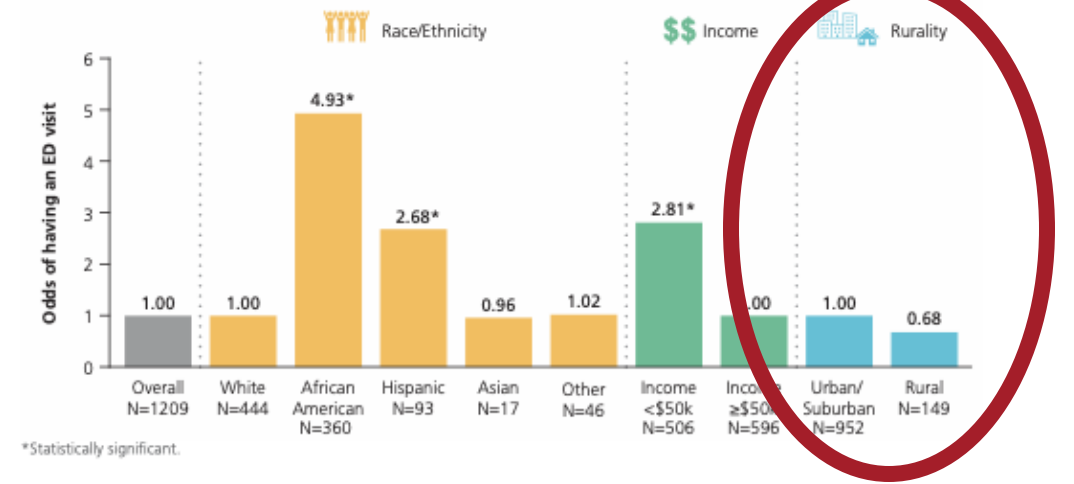
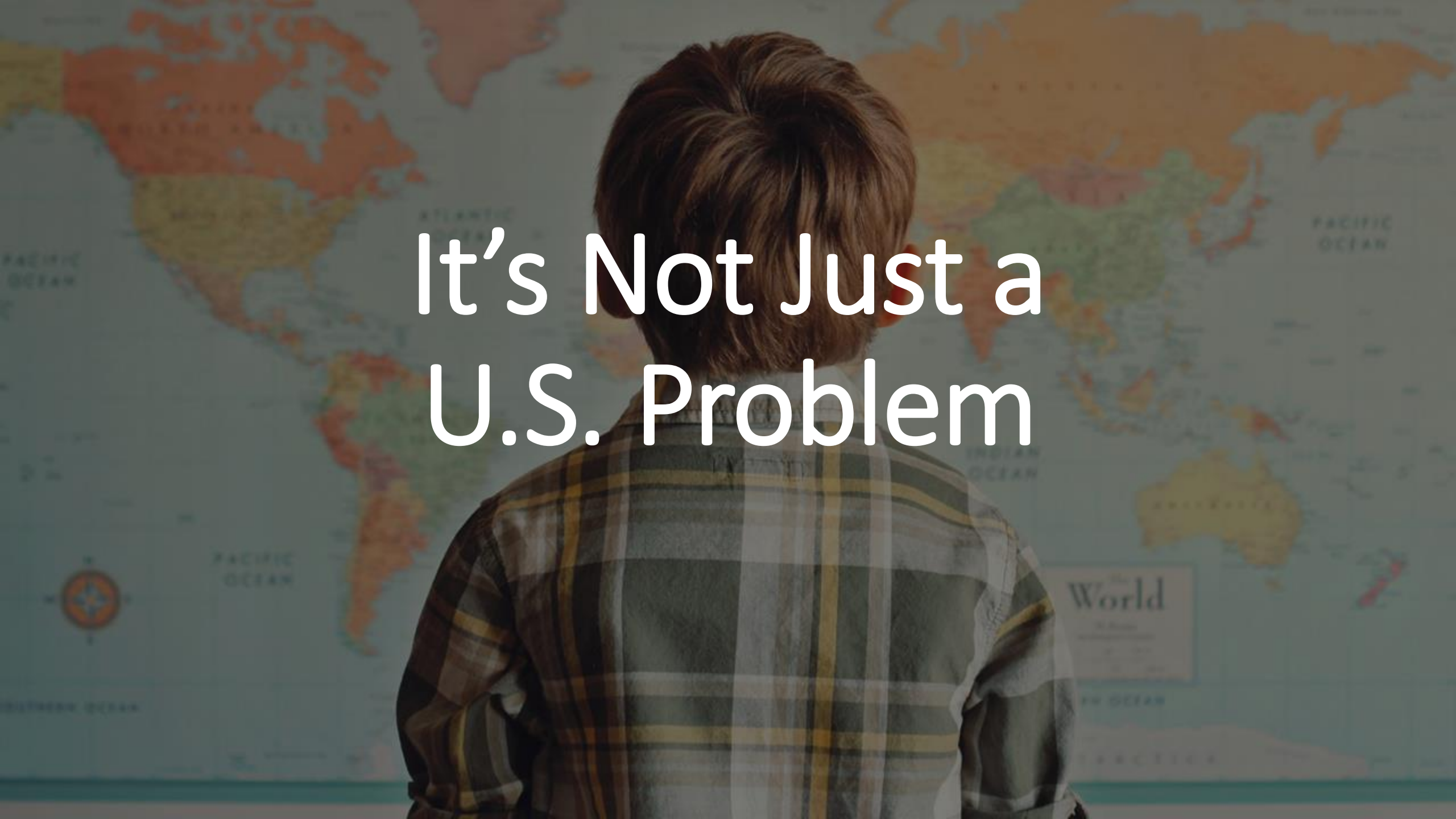


FIGURE 6: ODDS OF HAVING AN ED VISIT



*Statistically significant.

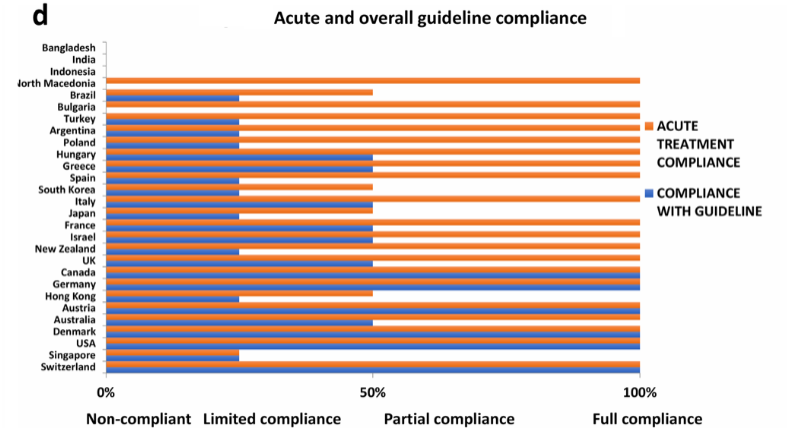
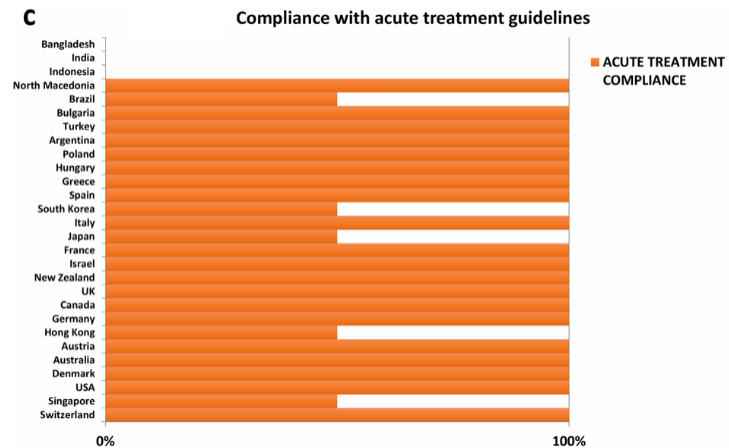
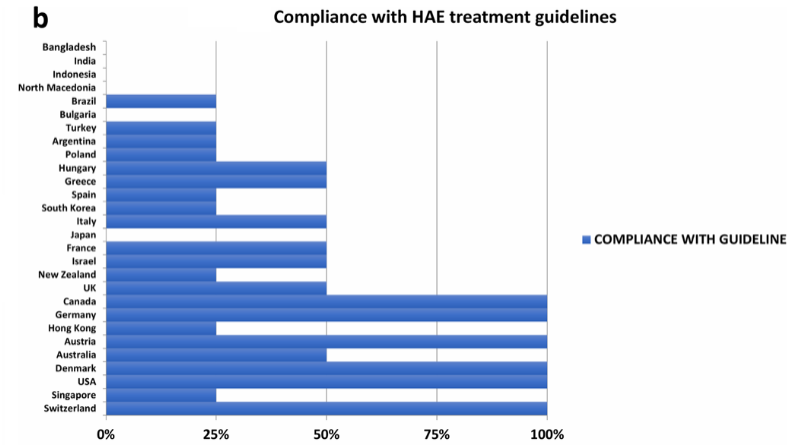
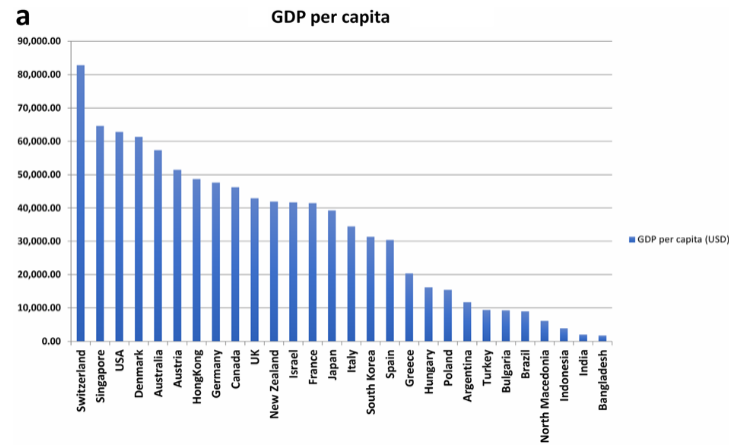


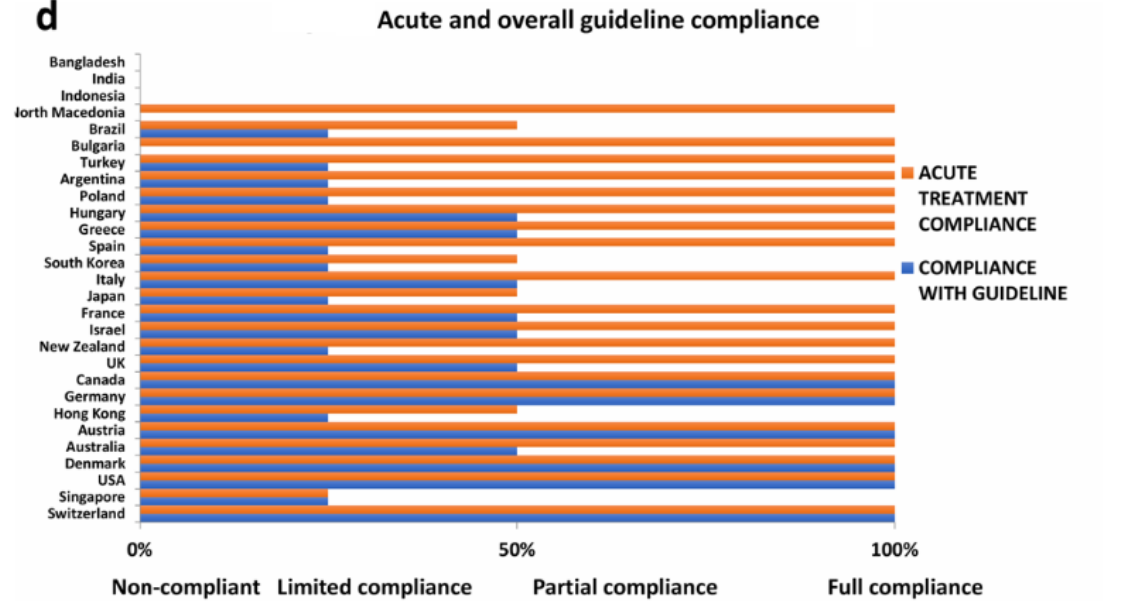
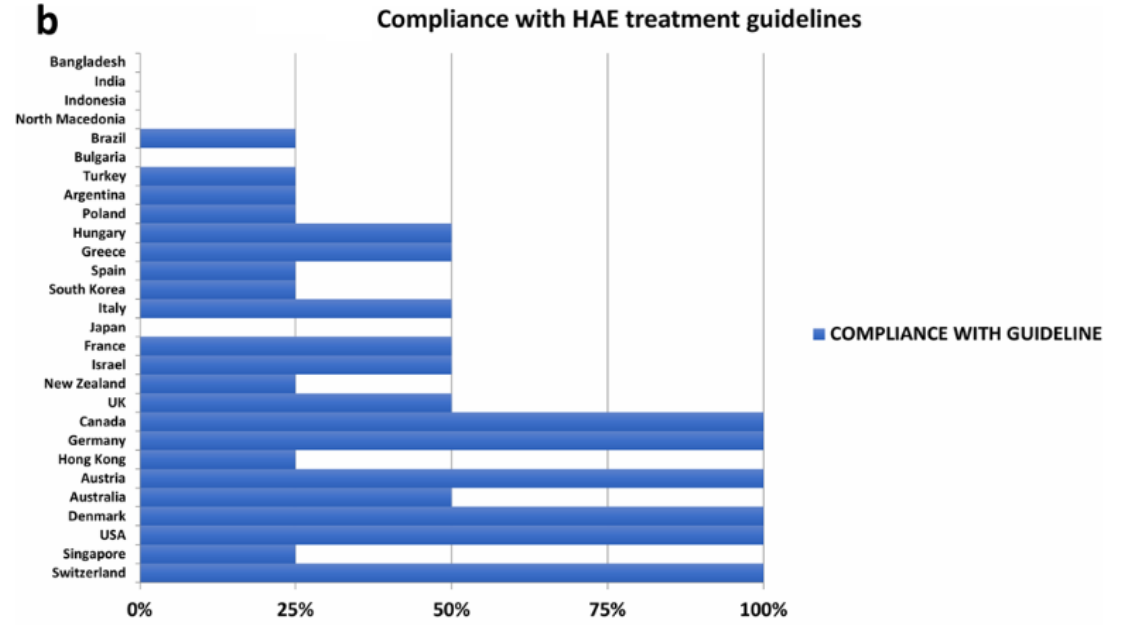
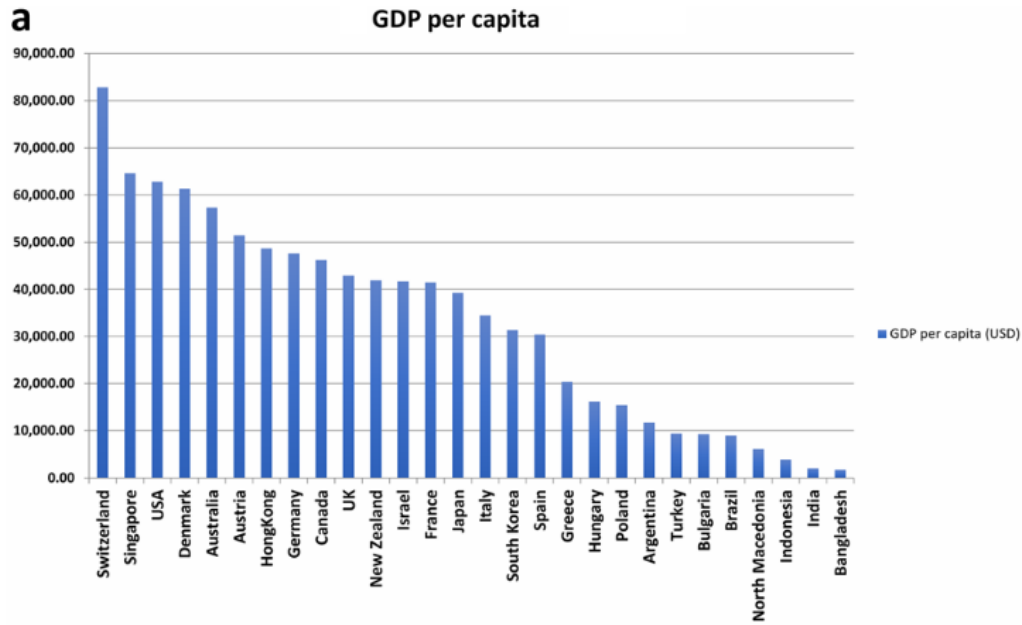
It's Not Just a U.S. Problem

HAE Management in Low- and Middle-Income Countries

Findings

1. Low- and middle-income countries rarely have adequate care for HAE.
2. Functional C1-inhibitor assays are rarely available in low- and middle-income countries.
3. Often the only therapies are androgens, tranexamic acid, and FFP.
4. Modern therapies are rarely available in most countries in the world.





Addressing the Problems

- Understand the barriers
- Telemedicine
- Education
- Team approach to care
- Other solutions



HAE and Race/Ethnicity

HAE Real-World vs. Clinical Trial

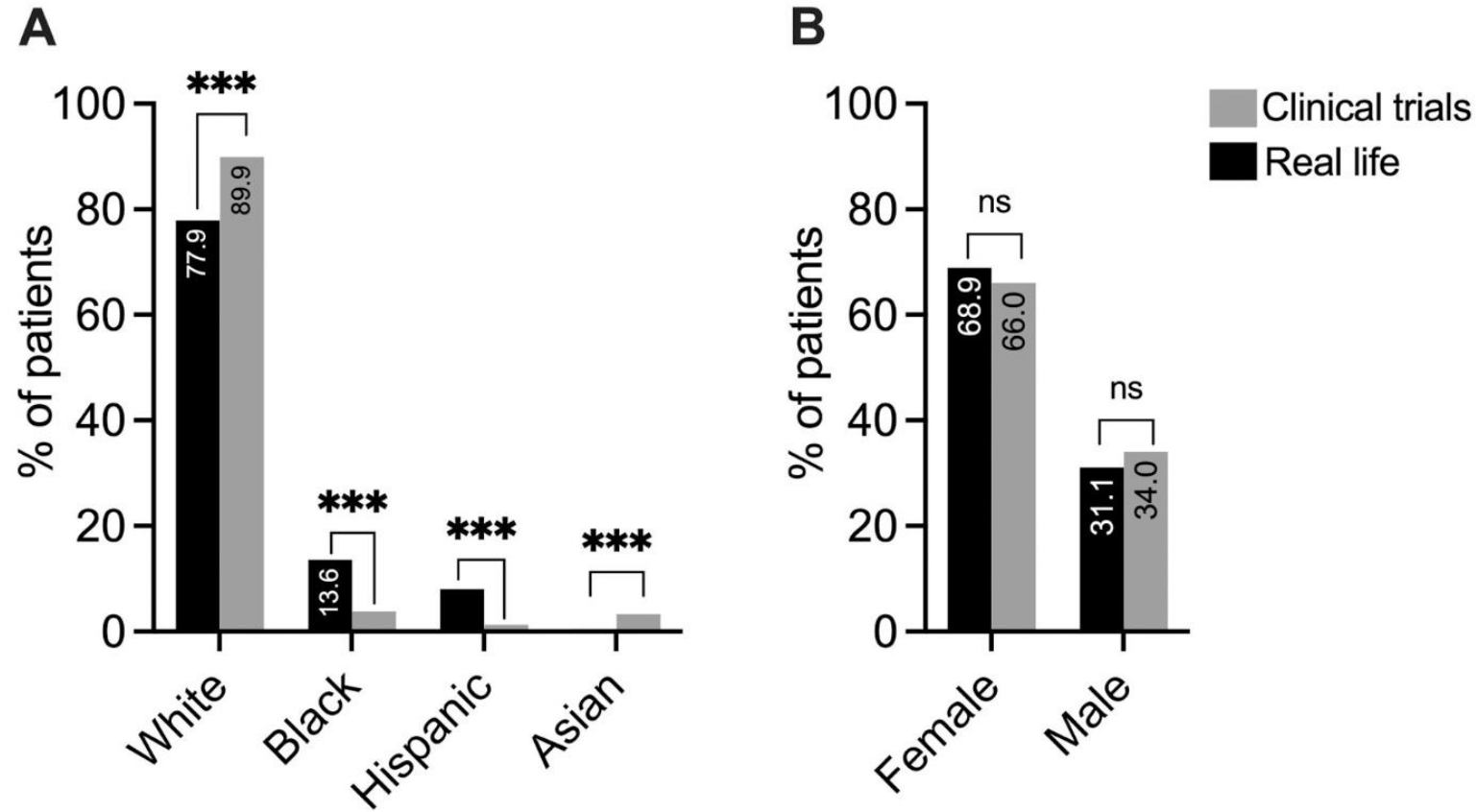


Figure 1. Race/Ethnic distribution of patients included in the clinical trials versus real life data.

(A) There is overrepresentation of White and Asian patients and underrepresentation of Black patients and Hispanic patients in clinical trials. (B) The sex distribution of patients was not different between real life data and clinical trial data. ns $P > 0.05$, * $P \leq .05$, ** $P \leq .01$, *** $P \leq .001$.

HAE Depression and Anxiety

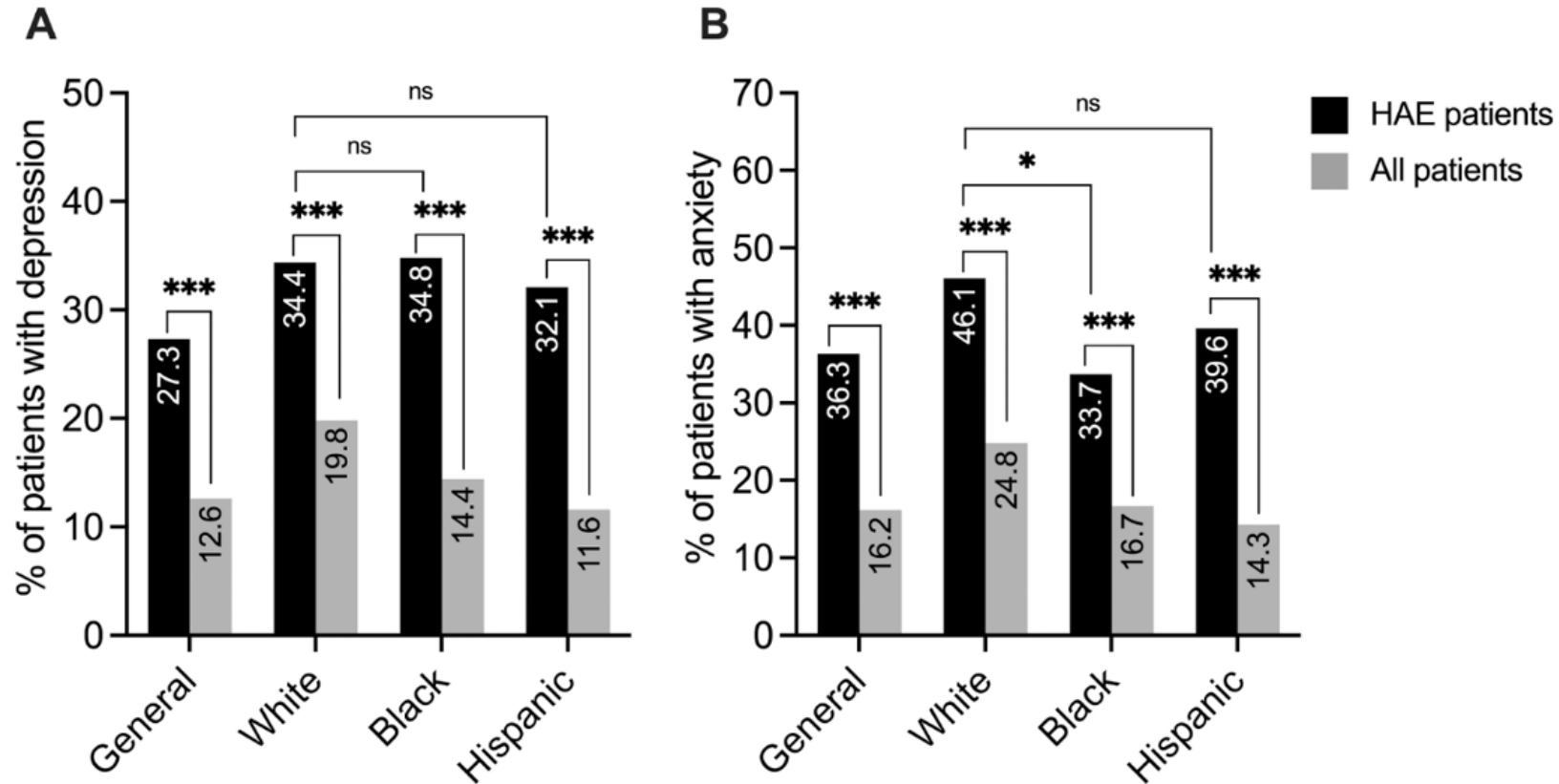
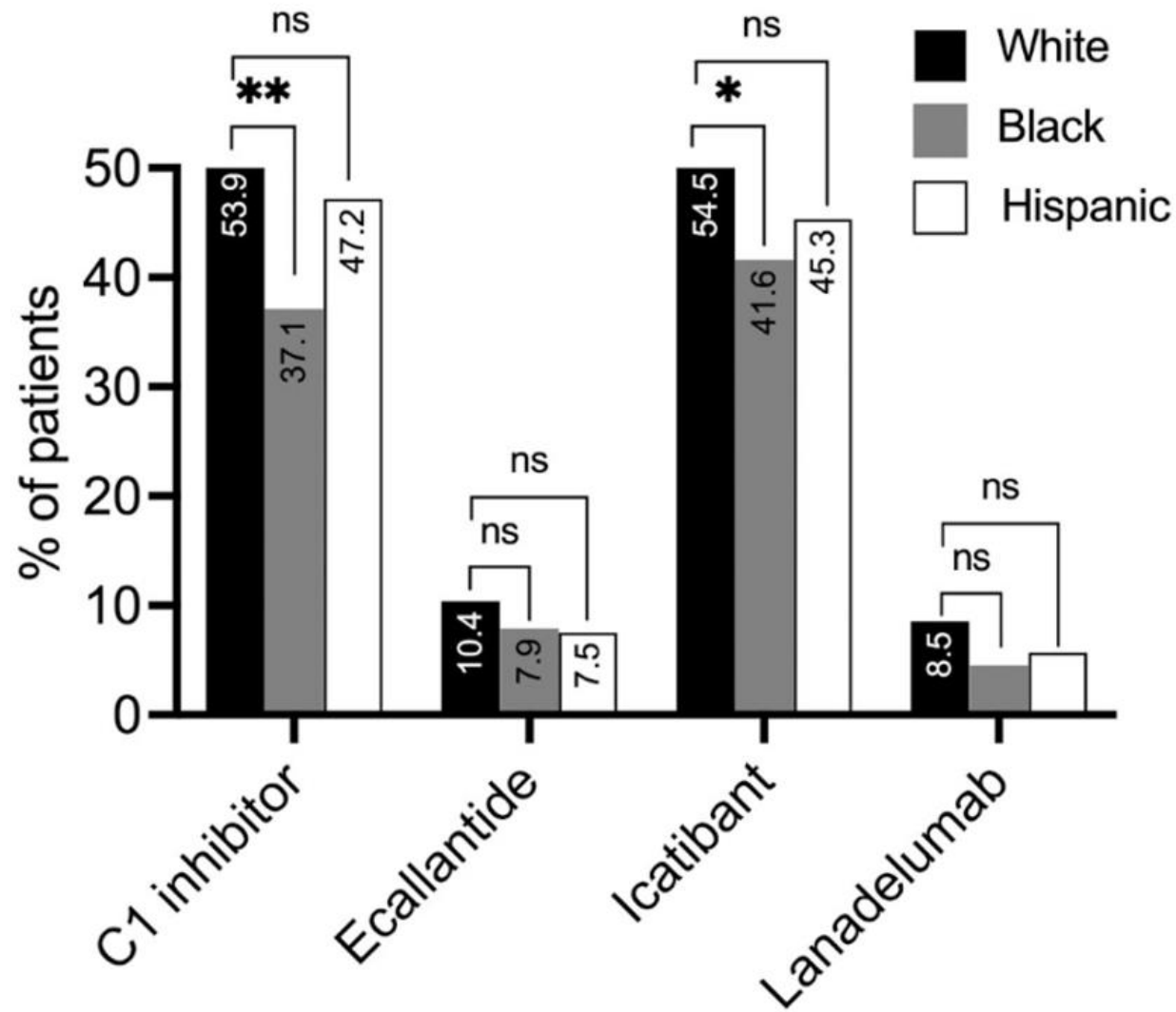


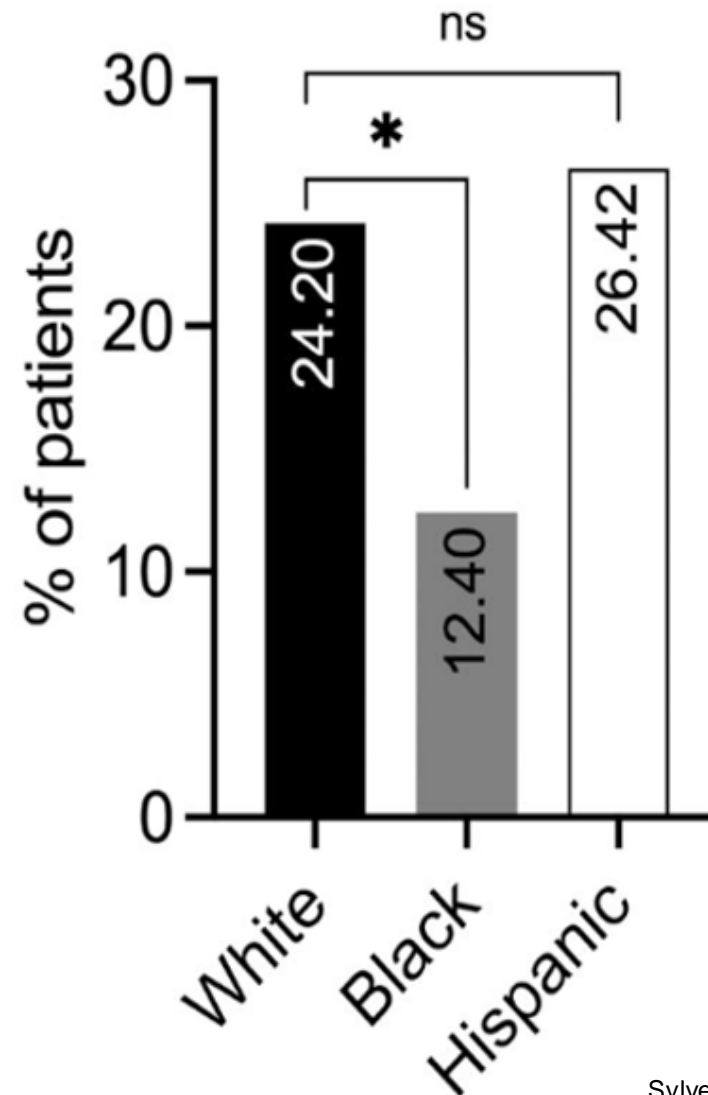
Figure 3. The prevalence of anxiety and depressive disorders across the different ethnic and racial groups in the population-based database.

(A) The prevalence of depressive disorders across the different ethnic/racial groups. (B) The prevalence of anxiety disorders across the different ethnic/racial groups. ns $P > 0.05$, * $P \leq .05$, ** $P \leq .01$, *** $P \leq .001$.

HAE Ethnic/Racial Concerns: Receiving Different Treatments

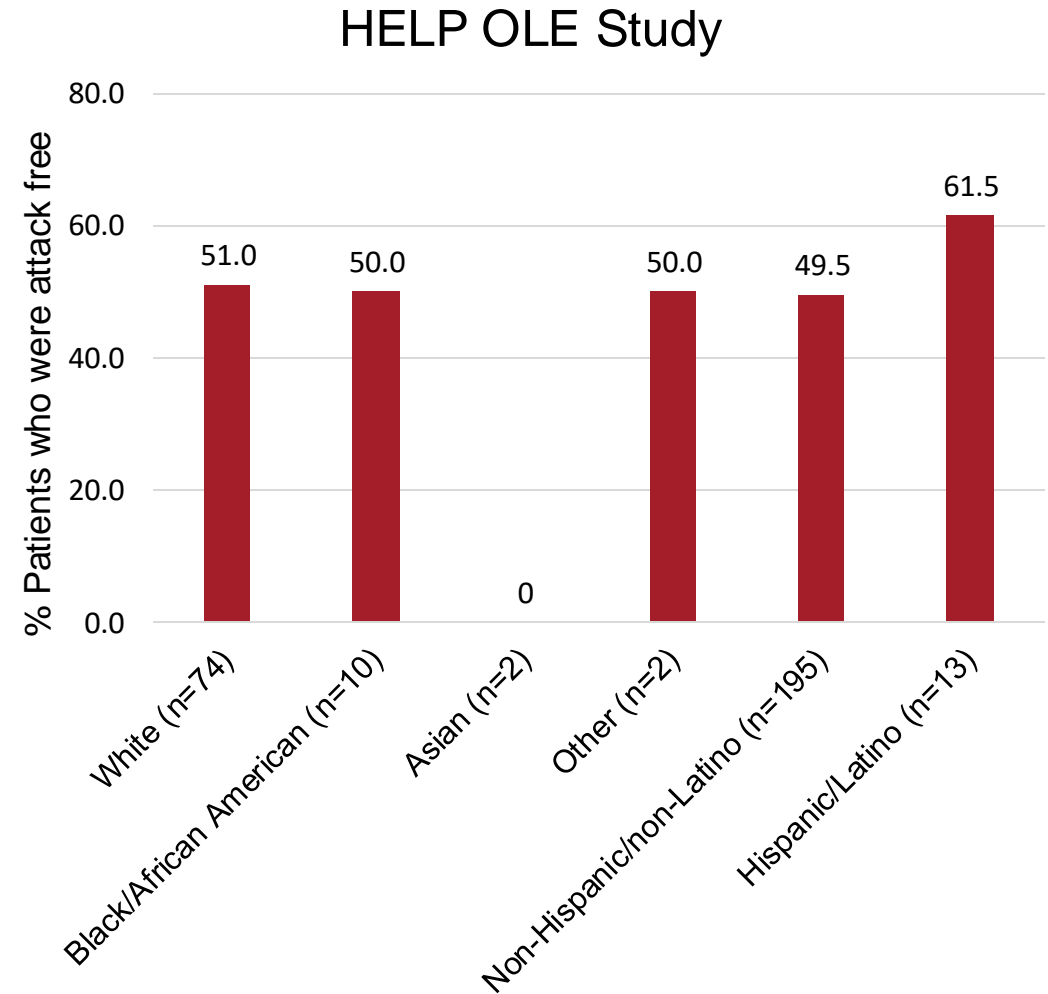
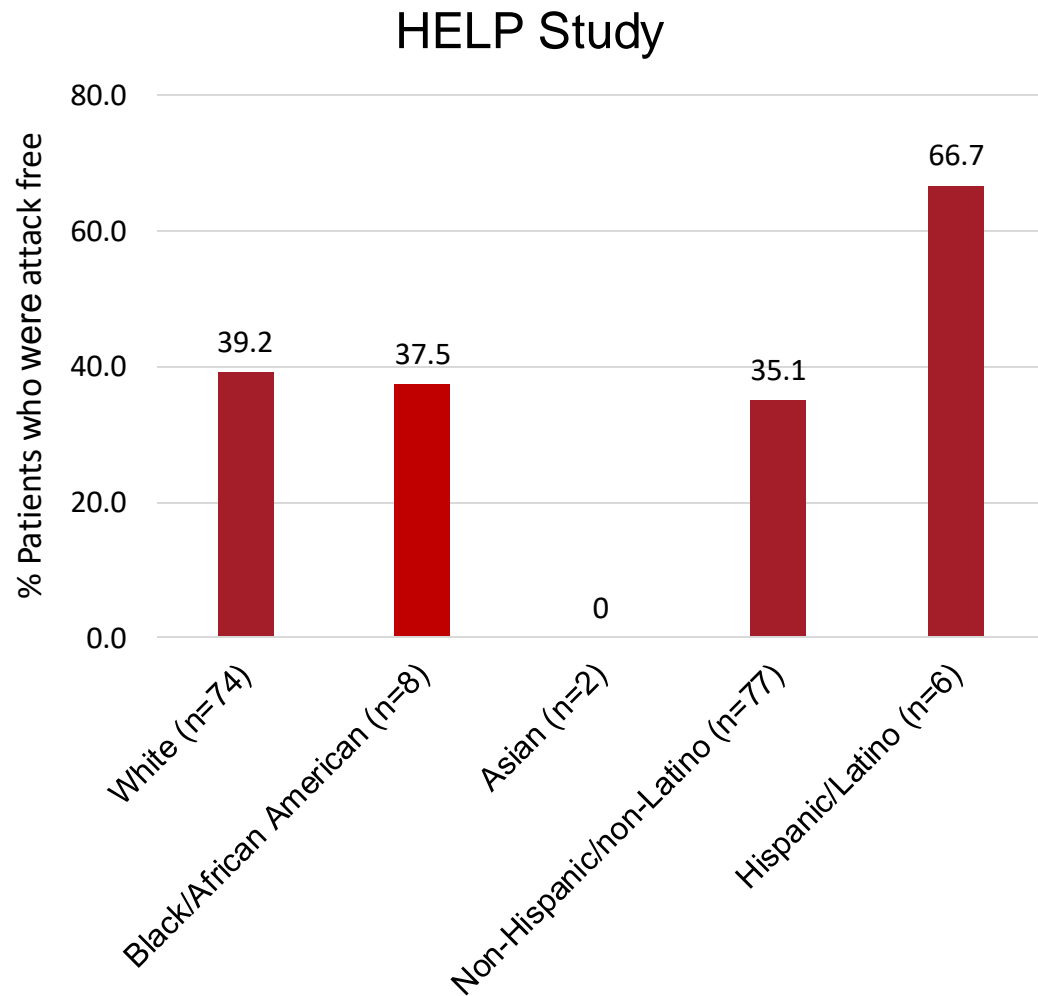


HAE Ethnic/Racial Concerns: Percentage Required Inpatient Management (over 5 yrs)



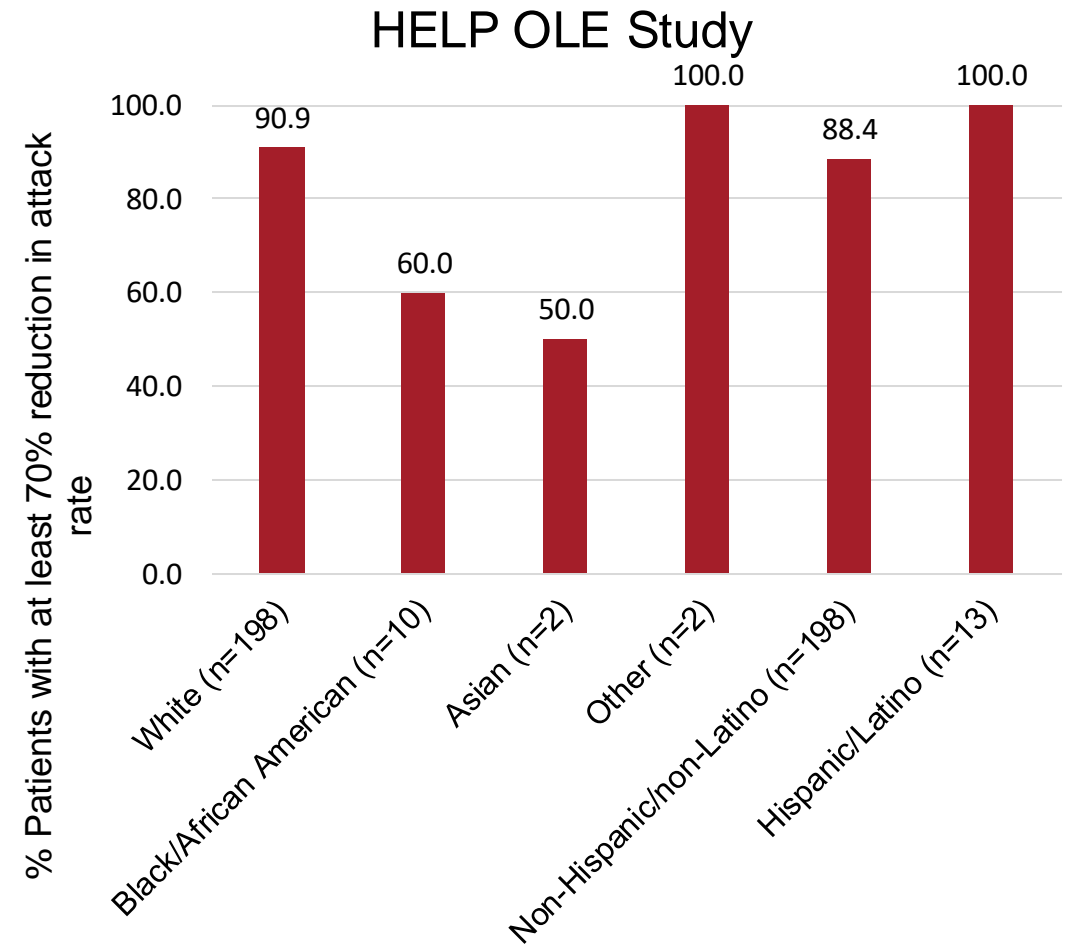
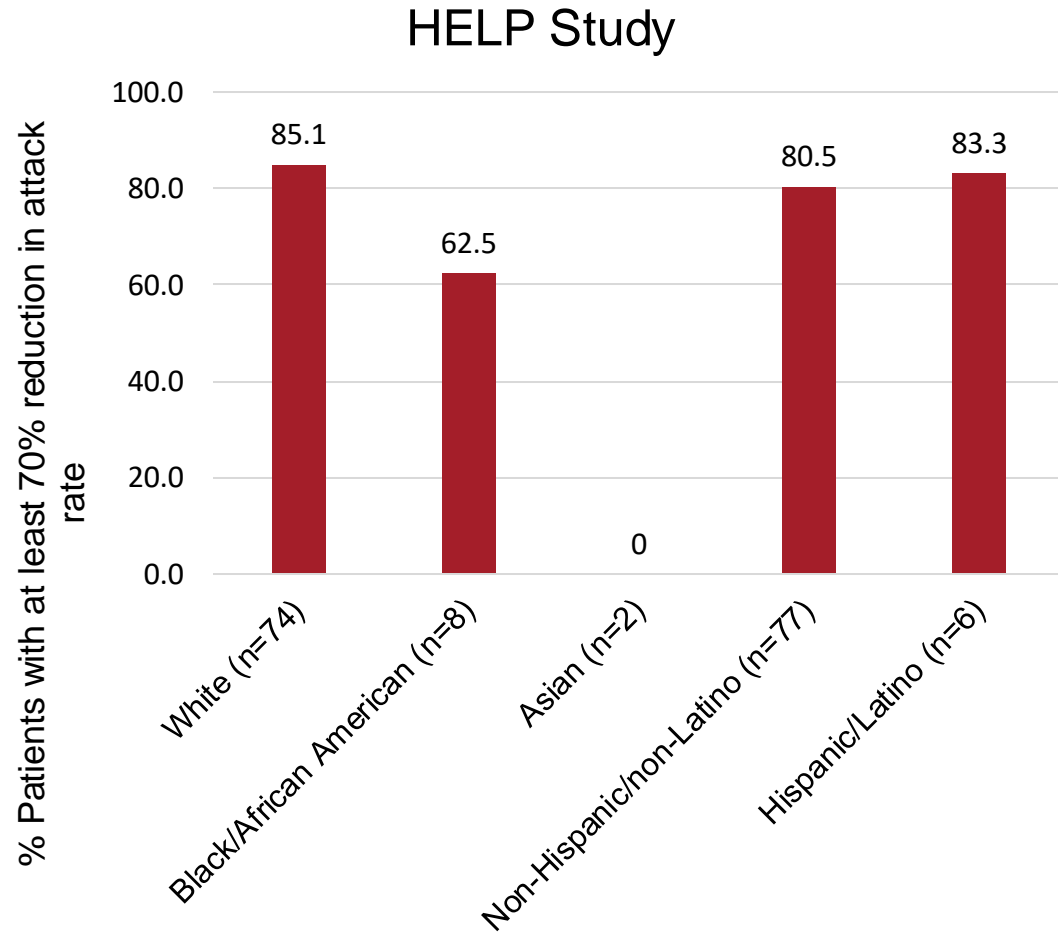
HAE Ethnic/Racial Concerns: Different Treatment Efficacies

Attack free 0 - 6 months after starting treatment



HAE Ethnic/Racial Concerns: Different Treatment Efficacies

Patients with > 70% reduction in attack rate during treatment



Patient Survey

Survey of 139 adults with HAE with underrepresented populations (i.e., 30% African American; 30% Hispanic, Latin American; 47% with annual household income < \$50,000)

Results:

- *Before Diagnosis*
 - 6.8 ± 10.9 HCPs seen before properly diagnosed.
 - 5.3 ± ED/UC visits
 - 2.7 ± 7.7 hospitalizations
- *After Diagnosis*
 - 75% received prophylactic treatment
 - 80% took medications all of the time
 - 15% most of the time
 - 5% some of the time
 - 86.5% reported good or excellent control of symptoms with medication

Conclusions:

- Findings suggest control of HAE improved after diagnosis in adults with HAE within underrepresented racial/ethnic groups, but patients continued to experience challenges with disease management.

Claims Data

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³University of California San Diego, Department of Medicine, Division of Allergy and Immunology, La Jolla, CA, USA; ⁴Inovalon Insights, Bowie, MD, USA; ⁵Takeda Pharmaceuticals USA, Inc., Lexington, MA, USA

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- Few studies have investigated the effects of SDOH on outcomes (treatment patterns, emergency department (ED) visits, and hospitalization) in patients with HAE.

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FIGURE 1: SDOH INVESTIGATED IN PATIENTS WITH HAE



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Patient population

- A total of 1209 individuals with HAE from the claims database met the criteria for inclusion; 960 patients had information about their race/ethnicity, 1102 had information about income, and 1101 had information about their rurality.
- Baseline demographics and clinical characteristics are shown in Table 2.
- Median patient age was highest among African American individuals and lowest among Hispanic individuals, with no notable differences by income and rurality.
- The proportion of patients on Medicaid was highest among Hispanic individuals and lowest among White individuals, and higher among individuals in the lower income group (Figure 2). There was no notable difference by rurality.

FIGURE 2: PROPORTION OF PATIENTS ON MEDICAID

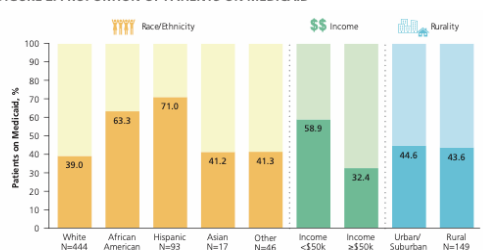


TABLE 1: HAE MEDICATIONS

Acute/STP therapies	LTP therapies
C1 esterase inhibitors (Berinert, Cinryze,* Haegarda,* Ruconest), ecallantide, FFP, icatibant	C1 esterase inhibitor (Cinryze), C1 esterase inhibitor (Haegarda), lanadelumab, antifibrinolytics, androgens* (methyltestosterone, danazol, or oxandrolone)

*Cinryze and Haegarda were considered short-term prophylaxis (STP) if ≤14 days of continuous days' supply was dispensed. *Antifibrinolytics and androgens were not considered HAE-specific medications for patient inclusion criteria.

TABLE 2: BASELINE DEMOGRAPHICS AND CLINICAL CHARACTERISTICS

	All patients N=1209	All patients N=1209
Female, n (%)	742 (61.4)	
Race/Ethnicity, %		
White	46.3	45.2
African American	37.5	40.0
Hispanic	9.7	14.9
Asian	1.8	
Other	4.8	
Median age	49.0	
Median age by race/ethnicity, years		
White	52.0	23.2
African American	55.0	24.6
Hispanic	34.0	21.1
Asian	36.0	17.8
Other	44.0	13.3
Median age by income, %		
<\$50K / ≥\$50K	53.0 / 47.0	
Median age by rurality, %		
Urban/Suburban	48.0	
Rural	53.0	2.3
Insurance type, %		
Managed Medicaid		45.2
Commercial		40.0
Medicare Advantage		14.9
Index year, %		
2017		23.2
2018		24.6
2019		21.1
2020		17.8
2021		13.3
US geographic region, %		
South		38.0
Midwest		25.7
West		18.5
Northeast		15.4
Unknown		2.3

Patients treated with LTP therapy

- LTP was used by 26.0% of patients overall, of whom 17.4% had an allergist/immunologist as their dedicated treatment specialist. African Americans, those on lower incomes, and those in rural areas had the lowest relative proportions of LTP therapy use, which correlated with having a lower proportion of allergist/immunologists as their specialist (Figure 3).

Patients treated with FFP

- FFP treatment was used by 51.3% of patients overall. African Americans, those on lower incomes, and those in rural areas were the groups with the highest proportions of FFP use (Figure 4).

ED visits and hospitalizations

- The proportions of individuals who had an ED visit are shown in Figure 5. Among the highest proportions were for African Americans, those on lower incomes, and those in rural areas.
- Asians had the highest proportion of hospitalizations, with no notable differences in the proportions of patients with hospitalizations by income or rurality (Table 3).

FIGURE 3: PROPORTION OF PATIENTS WITH A CLAIM FOR LTP TREATMENT

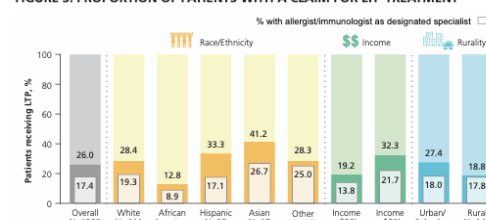


FIGURE 4: PROPORTION OF PATIENTS WITH A CLAIM FOR FFP TREATMENT

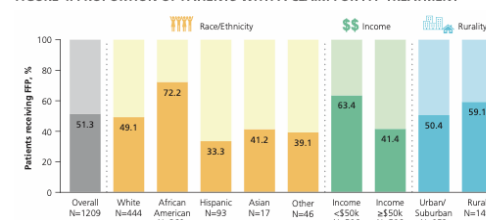
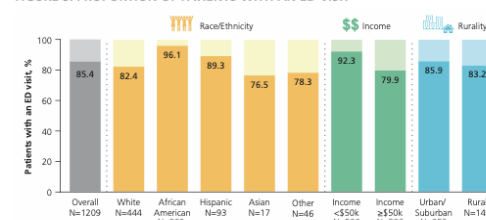


FIGURE 5: PROPORTION OF PATIENTS WITH AN ED VISIT



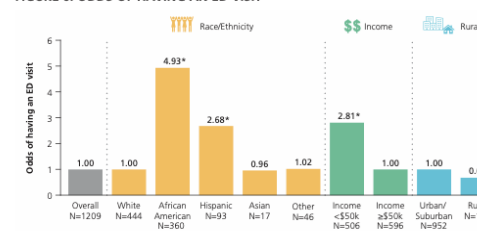
CONCLUSIONS

- Findings from this study indicate variability in healthcare utilization for patients with HAE in the United States, according to race/ethnicity, income, and rurality determinants.
- Traditionally underserved communities, such as African American and Hispanic populations, those on lower incomes, and those who resided in rural areas had lower LTP therapy use and more ED visits relative to other groups.
- These results warrant further evaluation, with strategies needed to reduce healthcare disparities among individuals with HAE in the United States.
- In multivariable models, African American patients and Hispanic patients had significantly higher odds of having an ED visit compared with White patients (odds ratio [OR], 4.93; 95% CI, 2.72–8.93 and OR, 2.68; 95% CI, 1.29–5.54, respectively, Figure 6).
- In addition, individuals with lower incomes had significantly higher odds of an ED visit (OR, 2.81; 95% CI, 1.90–4.15) compared with patients on higher incomes.

TABLE 3: PROPORTION OF PATIENTS REQUIRING HOSPITALIZATION

Race/Ethnicity	Hospitalization, %
White	33.6
African American	33.3
Hispanic	31.2
Asian	58.8
Other	28.3
Income	
<\$50K	29.4
≥\$50K	27.2
Rurality	
Urban/Suburban	30.7
Rural	36.3

FIGURE 6: ODDS OF HAVING AN ED VISIT



*Statistically significant.

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DISCLOSURES

A.P. Baptist has research relationships with BioCryst, Ionis Pharmaceuticals, Pharvaris, and Takeda, and works as a consultant for BioCryst and Takeda. J.A. Meadows has been a speaker for Amgen, AstraZeneca, Pfizer, Regeneron, Sanofi, and Teva Pharmaceuticals; advisory board member for Bryn Pharma, Merck Sharp & Dohme, and Teva Pharmaceuticals; and consultant for Adhion, Takeda, and Teva Pharmaceuticals. M.A. Riedl has received research support from BioCryst, BioMarin, CSL Behring, Ionis Pharmaceuticals, Kalvista Pharmaceuticals, Pharvaris, and Takeda; has served as a consultant for Astra Therapeutics, BioCryst, BioMarin, CSL Behring, Cyle Pharm, Intellia Therapeutics, Kalvista Pharmaceuticals, Ono Pharmaceutical, Pfizer, Pharvaris, and Takeda; and provided speaker presentations for CSL Behring, Pharming, and Takeda. K. Sing and B.G. Schultz are employees of Takeda Pharmaceuticals USA, Inc., and hold stock options in Takeda Pharmaceutical Company Limited. T. Davis, S.B. Robinson, and Y. Huang are employees of Inovalon Insights, which was contracted by Takeda Pharmaceuticals USA, Inc. to perform this analysis.

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DISCLAIMER

This poster is intended for healthcare professionals only.

Claims Data

FIGURE 3: PROPORTION OF PATIENTS WITH A CLAIM FOR LTP TREATMENT

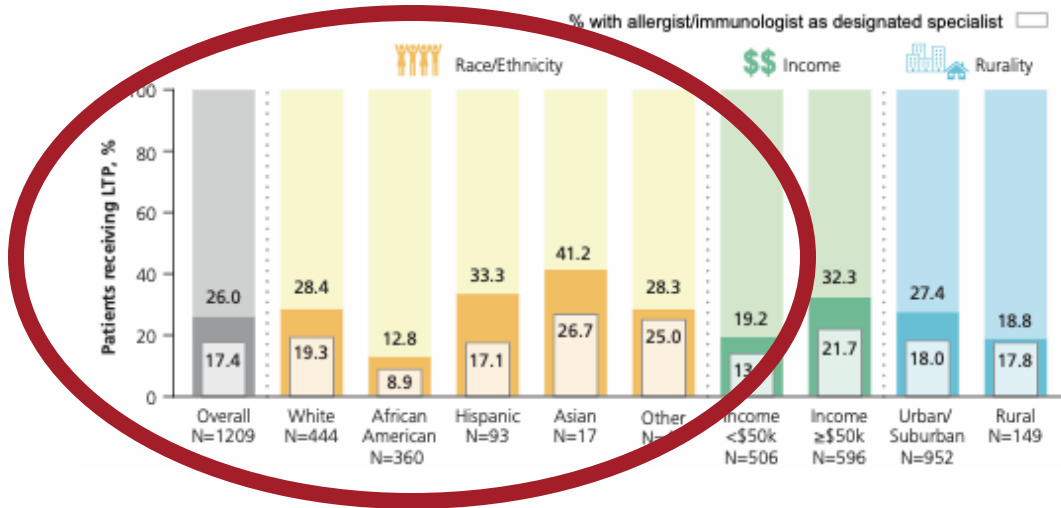


FIGURE 4: PROPORTION OF PATIENTS WITH A CLAIM FOR FFP TREATMENT

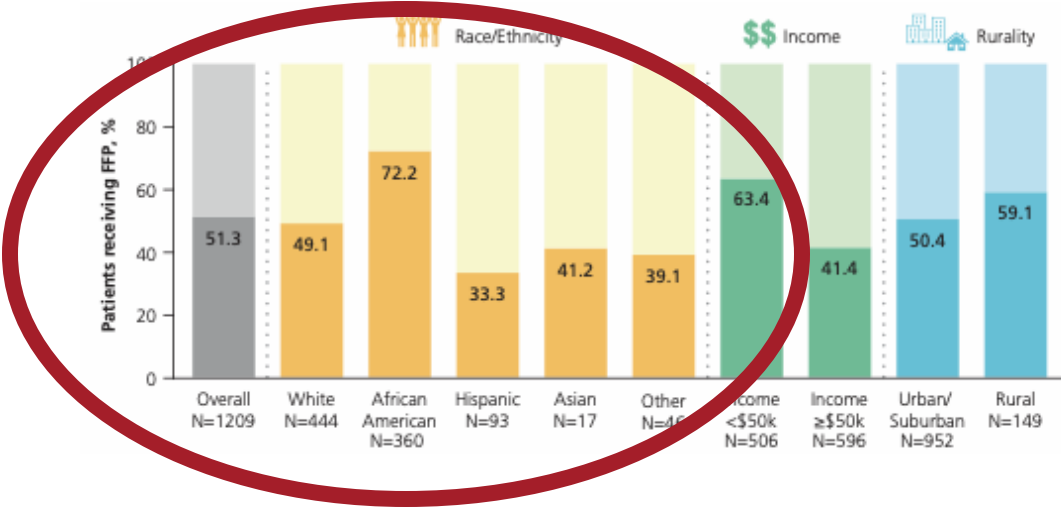


FIGURE 5: PROPORTION OF PATIENTS WITH AN ED VISIT

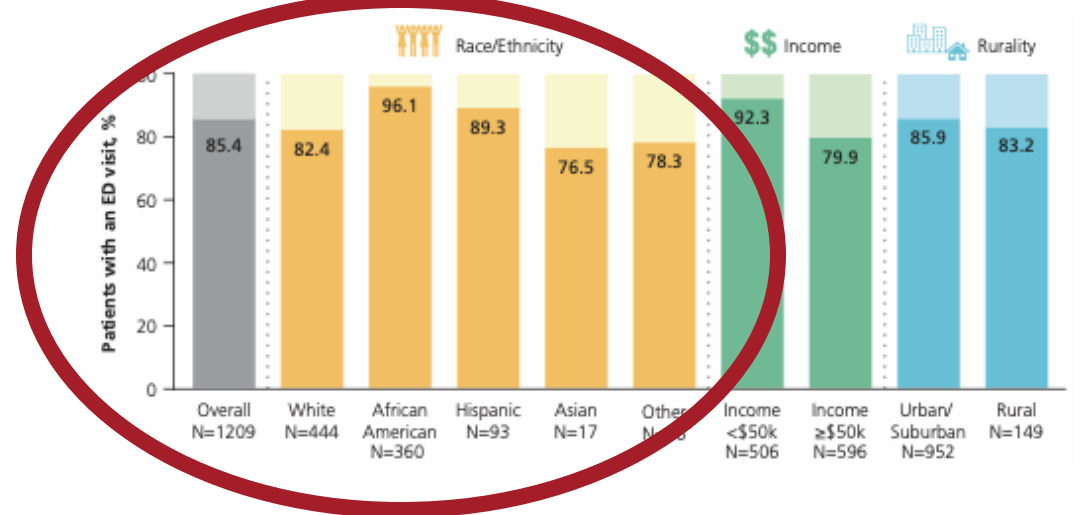
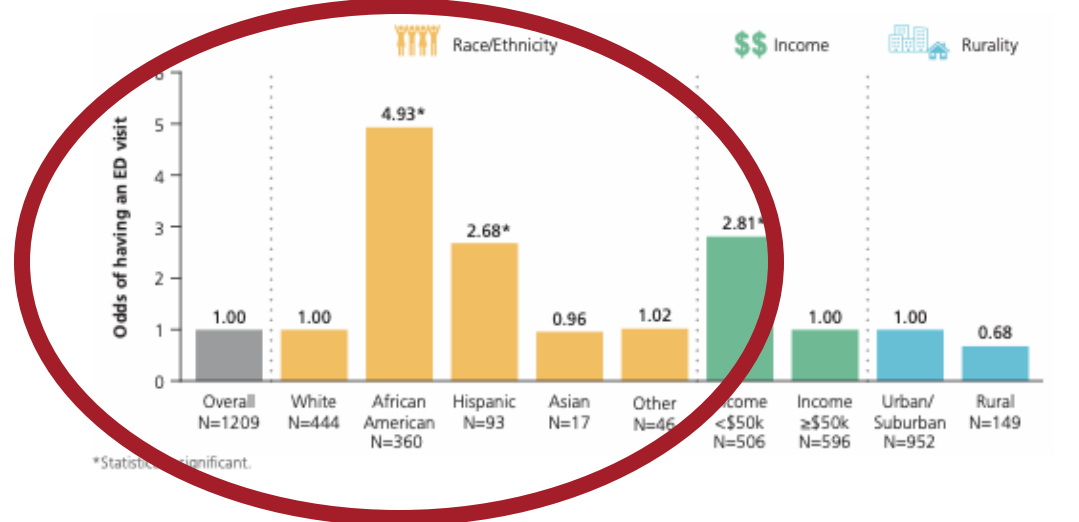


FIGURE 6: ODDS OF HAVING AN ED VISIT



*Statistically significant.

Addressing the Problems

- Understand the racial/ethnic inequalities
- Patient education
- HCP education
- Team approach to care
- Other solutions