

Estimating Genital Herpes Prevalence and Treatment Patterns Among US Healthcare-Engaged Individuals: Insights From Claims Data

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Background

- Genital herpes (GH), caused by herpes simplex virus types 1 and 2 (HSV-1 and HSV-2), is a prevalent sexually transmitted infection in the US and is associated with considerable morbidity, psychosocial impact, and elevated risk of HIV acquisition¹⁻³
- Traditional surveillance methods (serological surveys, self-reported data) have limitations
 - Underestimation due to asymptomatic infections
 - Underreporting due to stigma and recall bias
- Claims-based analysis provides real-world insights into diagnosed GH cases, healthcare utilization, and treatment patterns
- Understanding GH prevalence and treatment patterns can inform better disease management strategies

Objective

- To assess symptomatic GH prevalence, recurrence, and treatment patterns in the US using claims-based data from individuals actively engaged in the healthcare system

Methods

- Study design**
 - Retrospective observational study using Forian's hybrid claims ecosystem, CHRONOS, consisting of data from open-source and closed-source claims linked at the anonymized patient level, and an electronic health record (EHR) database
 - Study period: 1 Jan 2021 to 31 Dec 2023
 - Data scope: 2021–2022 data were used for historical context; 2023 is the primary analysis year
- Study population**
 - Cohort size: 40,248,823 individuals with semi-annual medical and quarterly pharmacy claims
- GH case identification (2023) required at least one ICD-10-CM code**
 - Directly coded GH: at least one GH ICD-10-CM code (A60%) in 2023
 - HSV diagnosis with GH symptoms: HSV (B00%) code + GH-specific symptoms (abnormal bleeding, abscess, blisters, dysuria, inflammation, itching, lesions, pain, ulcer in the urogenital area) in 2023
 - Prior GH history: directly coded GH or HSV diagnosis with GH symptoms in 2021–2022 + evidence of care seeking (HSV antiviral prescription claim, GH-specific symptoms, or HSV ICD-10-CM code) in 2023
 - HSV with EHR confirmation: HSV (B00%) cases where EHR notes confirm GH diagnosis in 2023
- Cases stratified by demographics (age, sex, race)**
- Recurrent GH definition**
 - Filling ≥90 days of an annual antiviral supply, including acyclovir, valacyclovir, or famciclovir, consistent with suppressive therapy; having ≥2 GH-related care episodes, including a GH, HSV, or GH symptom ICD-10-CM code; or antiviral treatment separated by ≥28 days in 2023
- Treatment pattern definitions**
 - Chronic suppressive therapy: having filled ≥180 days of antiviral supply in 2023
 - Intermittent suppressive therapy: having filled 90–179 days of antiviral supply, indicating partial adherence to suppressive therapy
 - Episodic therapy: having filled <90 days of antiviral supply, consistent with episodic treatment for outbreak management rather than suppressive therapy
- Extrapolation to the US population**
 - Crude prevalence rates were calculated using a subset of 40,248,823 patients from Forian's database, which includes individuals with semi-annual medical and quarterly pharmacy claims in 2023, as the denominator
 - Age- and sex-specific prevalence rates from this subset were applied to US Census Bureau population estimates to extrapolate the total population of patients with GH at the national level

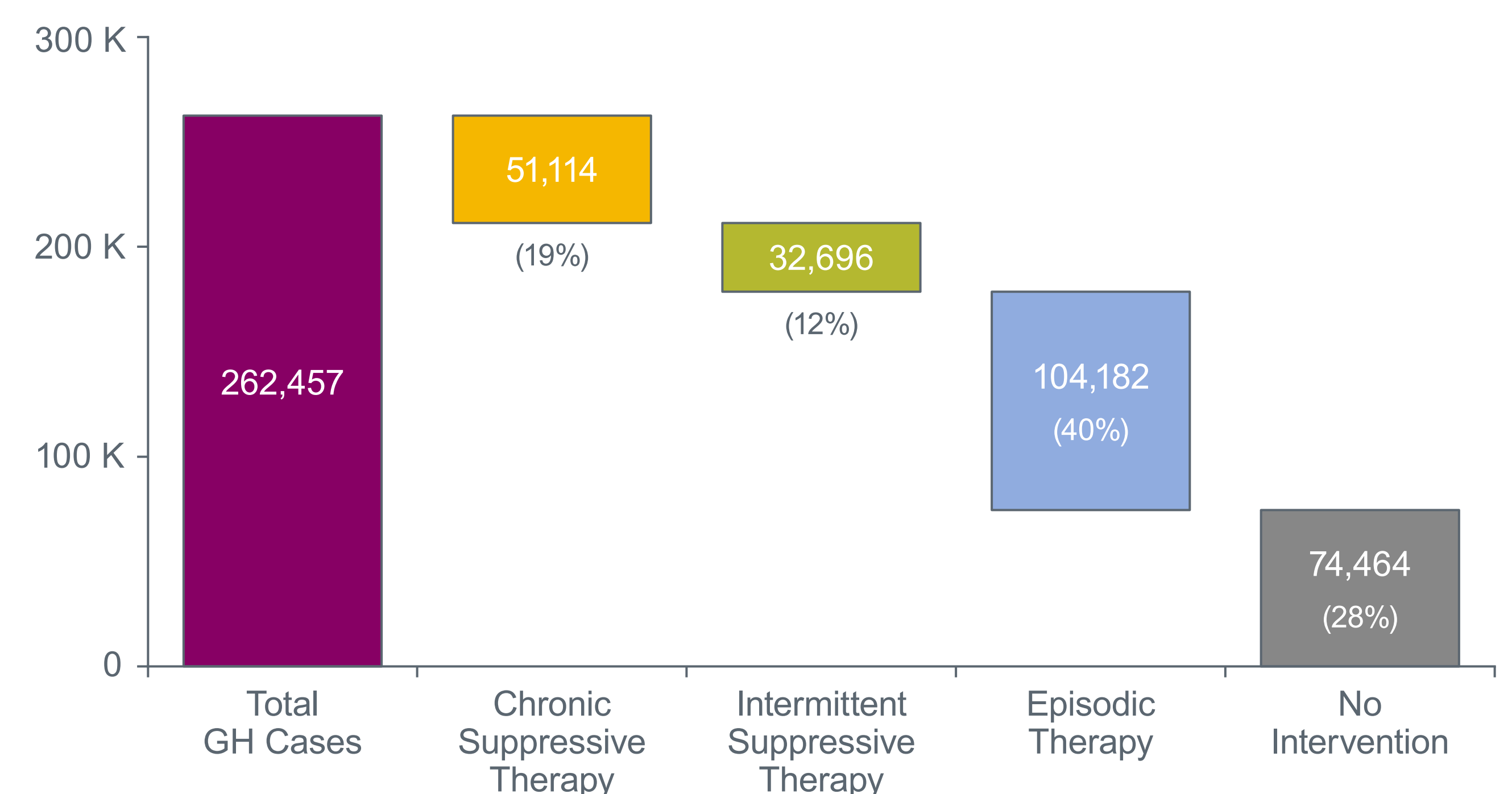
Results

Table 1. Demographic Characteristics of Genital Herpes Cases Identified Among the Study Sample in 2023

Characteristics	n = 262,457
Sex	
Female	202,092 (77)
Male	60,365 (23)
Age, years	
Mean	40
0–17	10,498 (4)
18–39	136,478 (52)
40–49	44,618 (17)
50–59	34,119 (13)
60–69	23,621 (9)
70–79	10,498 (4)
80+	2625 (1)
Race/ethnicity^a	
White/other	107,155 (74)
Black/African American	18,349 (13)
Hispanic/Latino	16,504 (11)
Asian/Pacific Islander	3062 (2)

Genital herpes prevalence was assessed from 1 January 2023 to 31 December 2023. Data are presented as n (%) unless indicated otherwise. ^aPercentages are out of n = 145,070 patients who had available race/ethnicity information.

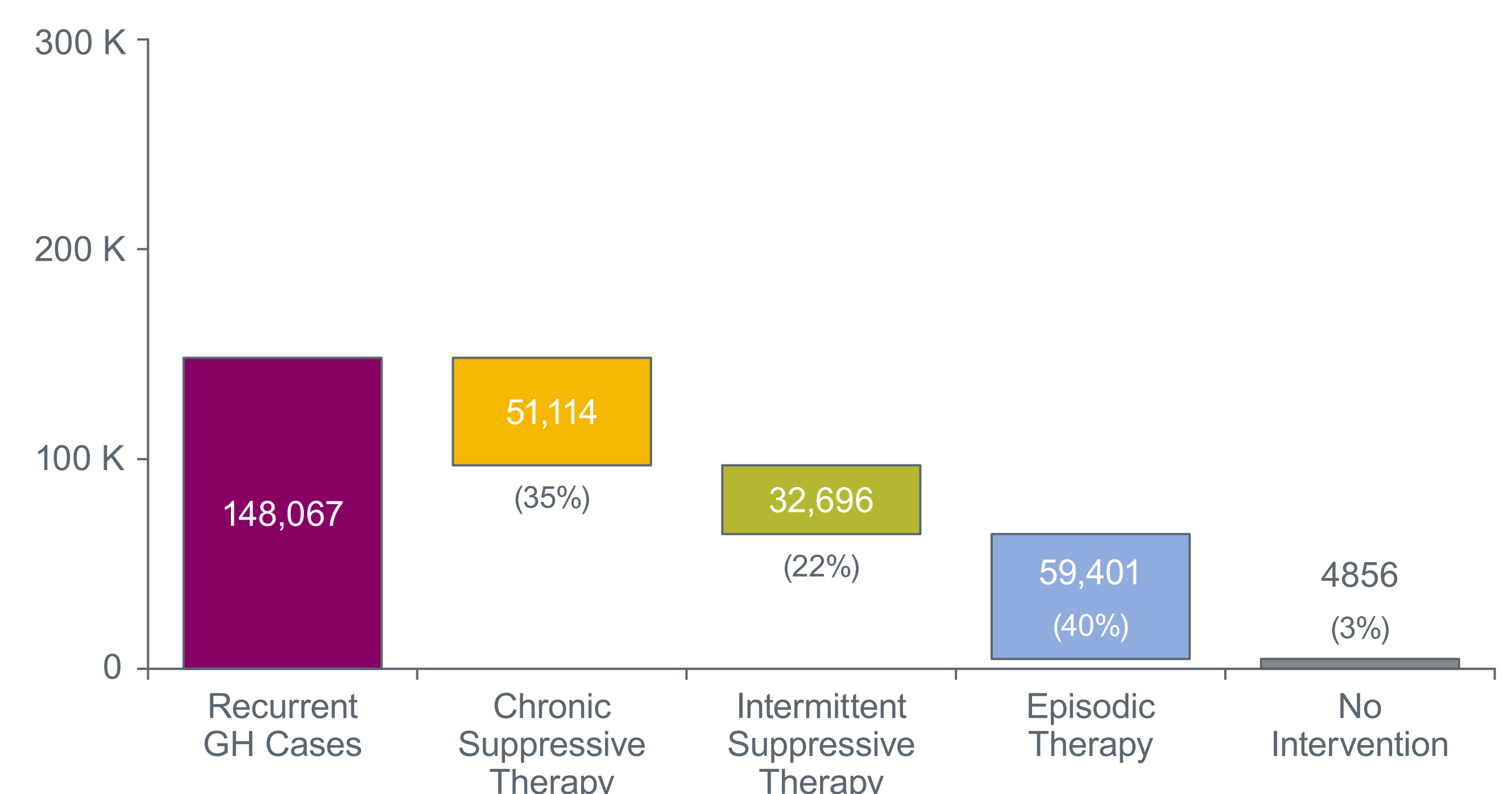
Figure 1. Total GH Cases in 2023 Stratified by Antiviral Treatment Duration



GH, genital herpes.

- Total GH cases**
 - In 2023, a total of 262,457 cases were observed (Figure 1), with the highest prevalence identified among patients who were female, aged 18 to 39 years, or White (Table 1)
 - Among all patients with GH, 32% (83,810) received suppressive therapy, including 51,114 on chronic suppressive therapy and 32,696 on intermittent suppressive therapy; 40% (104,182) received episodic therapy, while 28% (74,464) received no antiviral treatment (Figure 1)
 - The standardized prevalence rate was 714 per 100,000 person-years (95% confidence interval [CI]: 703–725). Extrapolated to the US population, an estimated 2.39 (95% CI: 2.35–2.43) million individuals sought care for GH in 2023

Figure 2. Recurrent GH Cases in 2023 Stratified by Antiviral Treatment Duration



GH, genital herpes.

- Recurrent GH cases**
 - In 2023, 148,067 cases were classified as recurrent GH (Figure 2)
 - Among the patients classified as having recurrent GH, 97% received pharmacologic treatment, with 57% on suppressive therapy and 40% on episodic therapy (Figure 2)
 - The standardized prevalence rate for recurrent GH was 408 per 100,000 person-years (95% CI: 402–415). Extrapolated to the US population, approximately 1.35 (95% CI: 1.33–1.37) million individuals experienced recurrent GH, with 864,260, stratified by age and sex, receiving suppressive therapy, either on a chronic or an intermittent regimen

Conclusions

- This analysis highlights the substantial burden of GH in the US, with wide variability in antiviral treatment patterns likely reflecting differences in disease severity, patient adherence, and healthcare access
- The true burden of GH is likely underestimated due to undiagnosed cases, nonspecific (or inaccurate) ICD-10-CM coding, and a lack of engagement in the healthcare system
- Among patients with recurrent GH, nearly half (43%) did not access suppressive therapy, suggesting that better treatment strategies are needed to enhance chronic disease management

REFERENCES

1) Looker KJ, et al. *Lancet Infect Dis.* 2020;20(2):240-9. 2) Corey L, et al. *Ann Intern Med.* 1983;98:958-72. 3) Catotti DN, et al. *Sex Transm Dis.* 1993;20:77-80.

ACKNOWLEDGMENTS

This analysis was conducted by Clearview Analytics, with contributions from Lian Liu and Eric Partida-Trautman, and was funded by Assembly Biosciences, Inc. Writing and editorial support were provided by Sylvia Stankov, PhD, of Red Nucleus, with funding from Assembly Biosciences, Inc.

DISCLOSURES

LL is an employee of ClearView Healthcare Partners and reports research funding from Assembly Biosciences, Inc. CJ reports research funding from GSK and Moderna, and consulting fees from Assembly Biosciences, Inc., and Pfizer. MS reports consulting fees from Assembly Biosciences, Inc., and Tune Therapeutics. KK, AG, and JD are employees and stockholders of Assembly Biosciences, Inc.