The Real-World Impact of Pre-Exposure Prophylaxis (PrEP) Prescription Uptake and Dispensing Status on HIV Infection Risk in the US

Poster 1557

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Li Tao, Juan Yang, Woodie Zachry, Joshua Gruber, and Dylan Mezzio Gilead Sciences, Inc., Foster City, CA, US

Key Findings

- Increased HIV incidence among those who had difficulty accessing pre-exposure prophylaxis (PrEP) suggests that removing barriers associated with dispensing may lower HIV risk in people who could benefit from PrEP (PWBP) in real-world settings
- In this analysis of prescription claims data, any delay beyond same-day dispensing of PrEP was associated with a significantly higher risk of acquiring HIV in the United States
- Specific populations that could benefit most from the removal of barriers include transgender men and women, and individuals with sexually transmitted infections (STIs) contracted within the last 12 months, in whom higher increases in new HIV diagnoses were seen

Conclusions

- Open-source large prescription-claims database studies can provide insight into the impact of PrEP access on real-world HIV prevalence and incidence
- Our findings demonstrate that rejected claims for PrEP were linked to an overall ~2 times increased risk for new HIV diagnoses and any delay in time to first dispensed claim was associated with higher risk of acquiring HIV
- This underscores the need to
- Reduce the impact insurance rejection may have on patient disengagement
- Remove barriers that prevent immediate same-day PrEP access
- HIV incidences were highest among transgender individuals who had a PrEP prescription dispensing status of non-dispensed rejected (ND-R) or non-dispensed abandoned (ND-A)
- This highlights the importance of eliminating insurance rejection barriers for transgender individuals to reduce HIV incidence rates
- This also highlights the need for further investigation of reasons for PrEP abandonment (e.g., stigma) in the transgender community
- The highest rate of new HIV diagnosis (8.1%) was observed in individuals with STIs who had rejected claims for PrEP
- Rejection of PrEP claims in these individuals with behaviors considered high risk for HIV acquisition led to a higher chance of HIV diagnosis
- Increased incidence among those who did not access PrEP suggests that initiatives to remove barriers associated with dispensing may lower HIV-infection risk in PWBP

Background

- The use of PrEP has been significantly associated with a decline in new HIV-1 diagnoses in the United States¹
- Despite being an effective HIV prevention strategy, disparities in the uptake and persistence of PrEP exist²
 In 2021, the Centers for Disease Control (CDC) and Prevention found that only ~30% of PWBP in the United States were prescribed it, with large disparities in uptake by race, ethnicity, gender, and geography³
- Both the International AIDS Society (IAS)-USA and the CDC guidelines support the use of same-day PrEP:
- IAS-USA does not recommend delaying PrEP⁴
- The CDC outlines procedures for same-day PrEP and notes that safely shortening the time to initiation of PrEP may be useful, as some PWBP report behaviors that put them at risk of acquiring HIV between the time of evaluation for PrEP and PrEP prescription³
- Barriers to the effective use of PrEP include inaccessibility of PrEP services, social stigma, lack of awareness about PrEP, concerns around PrEP side effects/medication interactions, provider bias/distrust of healthcare systems, financial implications, and insurance or payer rejections²
- These barriers may have different effects on specific populations of PWBP²
- Addressing the barriers to PrEP access could improve the equitable uptake and consistent use of PrEP

Objective

• To evaluate the impact of PrEP access on HIV incidence by exploring potential associations between PrEP prescription access experience, dispensing status, and HIV incidence rates in the United States

Methods

Population (Figure 1)

- Individuals receiving prescriptions for cabotegravir (CAB), emtricitabine/tenofovir disoproxil fumarate (F/TDF), or emtricitabine/tenofovir alafenamide (F/TAF) as PrEP between January 2019–February 2023 were selected from a de-identified prescription-claims database (IQVIA Longitudinal Access and Adjudication Dataset [IQVIA LAAD])
- Use of these regimens for HIV or hepatitis B treatment, or HIV post-exposure prophylaxis (PEP) was excluded
- Individuals who had any PrEP claims within the wash-out window (6 months prior to the index date) were also excluded

PrEP prescription status

 Individuals were categorized into three groups according to PrEP prescription dispensing status: dispensed (DISP) (Figure 1)

References: 1. Sullivan PS, et al. *Ann Epidemiol.* 2018;28:833–840. 2. Mayer KH, et al. *Adv Ther.* 2020;37:1778–1811.

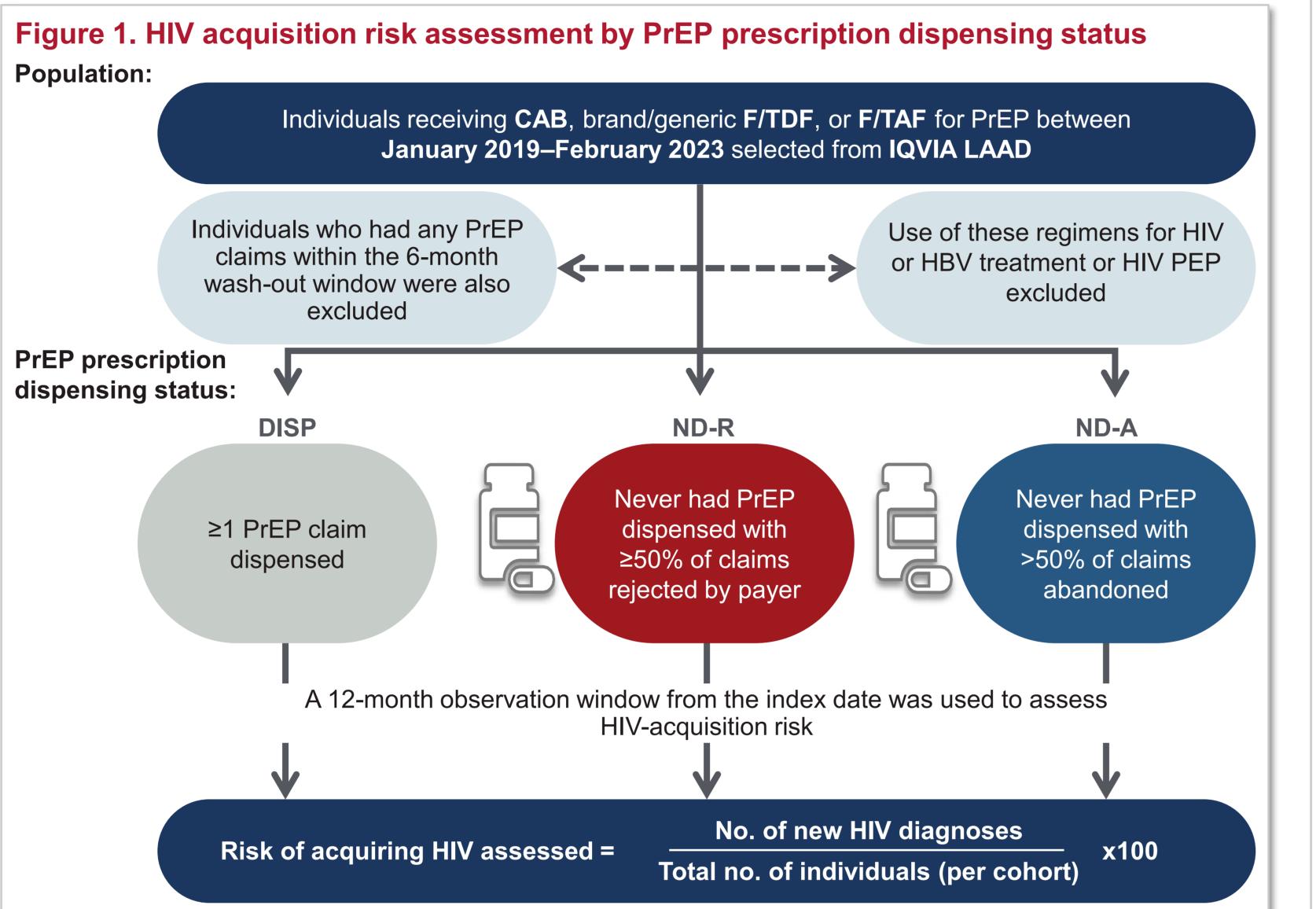
3. Centers for Disease Control and Prevention. PrEP for HIV Prevention in the US. Available at: https://www.cdc.gov/nchhstp/newsroom/fact-

sheets/hiv/prep-for-hiv-prevention-in-the-us-factsheet.html. (Accessed October 2023). 4. Gandhi RT, et al. JAMA. 2023;329:63–84.

 An abandoned claim occurred when the prescription was approved by the payer, but later reversed by the pharmacist when the prescription was not collected within 14 days

HIV diagnoses

- New HIV diagnoses were calculated as outlined in Figure 1
- Logistic regression was used to calculate odds ratios (OR) and 95% confidence intervals (CIs) of HIV infection by PrEP prescription dispensing status and time to dispense
- In the DISP cohort, time to dispense was defined as the number of days between initial claim submission and the first instance of claim dispensing



HIV, human immunodeficiency virus; F/TAF, emtricitabine/tenofovir alafenamide; F/TDF, emtricitabine/tenofovir disoproxil fuma rate; HBV. hepatitis B virus: LAAD. Longitudinal Access and Adjudication Dataset; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis.

Subgroup analysis

- Across the three PrEP-prescription dispensing status groups, cumulative HIV incidence was analyzed overall, and in the following subgroups:
- Gender; region; individuals with any STIs in their medical history (defined as infections with a predominantly sexual mode of transmission; ICD: A50-A64); insurance type

Results

PrEP prescription dispensing status

- Among 522,273 individuals, 88% were in the DISP cohort, 7% were ND-R, and 5% were ND-A (Figure 2)
- The most common reasons given for rejection of claims were as follows (% of claims made):
- Product/service not covered 22%; prior authorization required 11%; refilled too soon 10%; non-matched cardholder ID 9%; dispensed after coverage terminated 6%
- The distribution of gender by cohorts is shown in Figure 2/Table 1
- In the observation window, there were 12,119 new HIV diagnoses, representing an overall cumulative incidence of ~2%
- Compared with those in the DISP cohort (Figure 3)
- Individuals in the ND-R cohort had a 95% (~2-fold) higher risk of new HIV diagnosis (cumulative incidence ~4%)
 Those in the ND-A cohort were 38% more likely to acquire HIV (cumulative incidence ~3%)

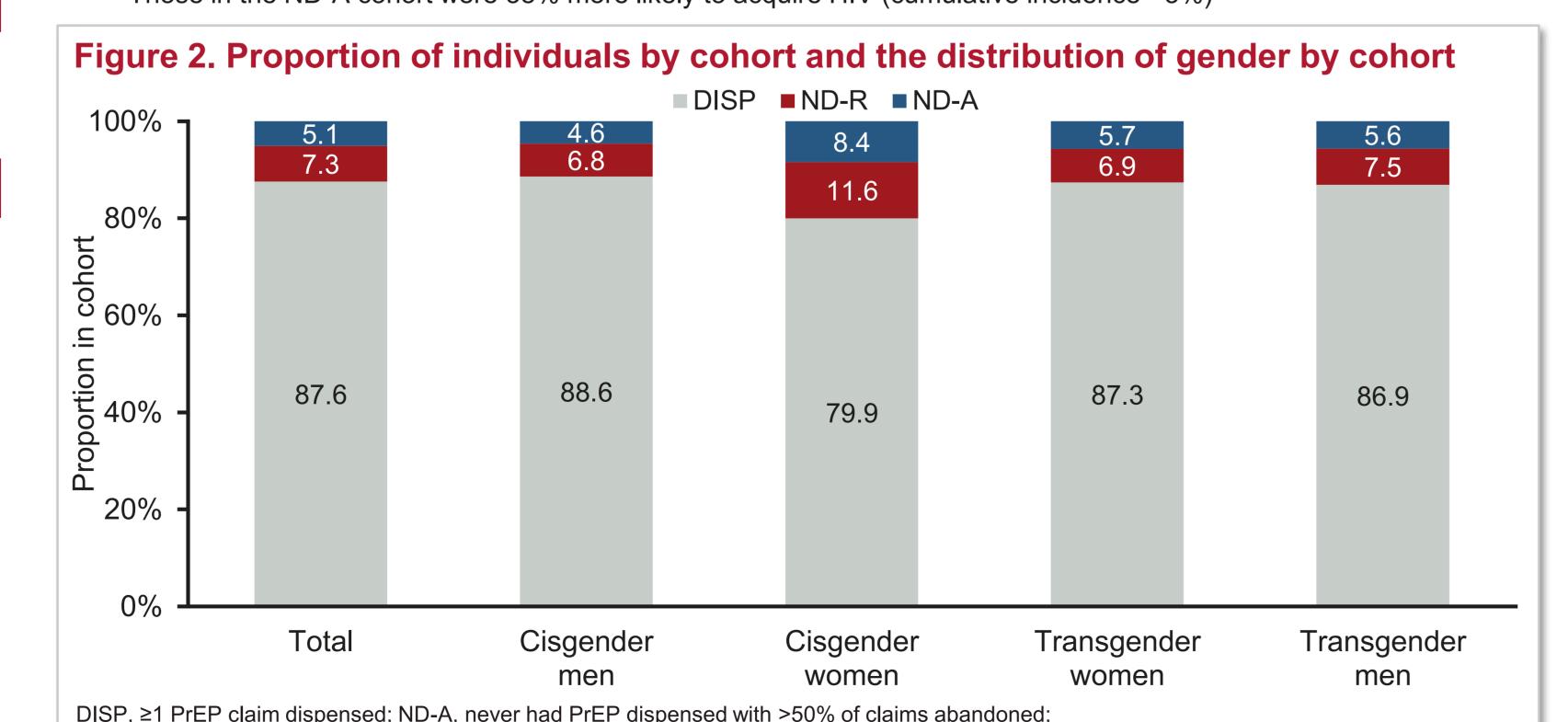


Table 1. Subgroup analysis of HIV cumulative incidence*

government to provide free local health coverage counseling to people with Medicare.

| | DICD | | | 110101 11441 121 410 0011004 | | | | | | |
|------------------------------------|-----------|---------|----------------------|------------------------------|---------|----------------------|-----------|---------|----------------------|--|
| | DISP | | | ND-R | | | ND-A | | | |
| | Total (N) | HIV (n) | HIV incidence (%) | Total (N) | HIV (n) | HIV incidence (%) | Total (N) | HIV (n) | HIV incidence (%) | |
| All | 457,561 | 9,780 | 2.1 | 38,311 | 1,565 | 4.1 | 26,401 | 774 | 2.9 | |
| Gender | | | | | | | | | | |
| Cisgender men | 404,109 | 8,373 | 2.1 | 30,789 | 1,261 | 4.1 | 21,039 | 585 | 2.8 | |
| Cisgender women | 45,785 | 1,185 | 2.6 | 6,668 | 276 | 4.1 | 4,822 | 163 | 3.4 | |
| Transgender women | 4,494 | 152 | 3.4 | 357 | 16 | 4.5 | 295 | 18 | 6.1 | |
| Transgender men | 2,717 | 66 | 2.4 | 233 | 9 | 3.9 | 175 | 8 | 4.6 | |
| Had STI | 56,014 | 2,121 | 3.8 | 3,801 | 306 | 8.1 | 2,578 | 139 | 5.4 | |
| Region [†] | | | | | | | | | | |
| West | 115,625 | 2,363 | 2.0 | 9,025 | 365 | 4.0 | 7,245 | 196 | 2.7 | |
| Midwest | 60,865 | 1,251 | 2.1 | 4,672 | 199 | 4.3 | 4,279 | 117 | 2.7 | |
| Northeast | 92,610 | 2183 | 2.4 | 6,647 | 316 | 4.8 | 4,826 | 147 | 3.1 | |
| South | 181,804 | 3836 | 2.1 | 16,097 | 600 | 3.7 | 9,506 | 297 | 3.1 | |
| Insurance type | | | | | | | | | | |
| Commercial | 243,433 | 4,978 | 2.0 | 25,886 | 1,015 | 3.9 | 14,841 | 435 | 2.9 | |
| Medicaid | 48,750 | 1,799 | 3.7 | 6,961 | 366 | 5.3 | 2,927 | 119 | 4.1 | |
| Medicare | 8,805 | 436 | 5.0 | 735 | 58 | 7.9 | 1,185 | 39 | 3.3 | |
| Assistance Program [‡] | 53,668 | 1,088 | 2.0 | 3,161 | 83 | 2.6 | 6,940 | 173 | 2.5 | |

Never had PrEP dispensed

DISP, ≥1 PrEP claim dispensed; HIV, human immunodeficiency virus; ND-A, never had PrEP dispensed with >50% of claims abandoned; ND-R, never had PrEP dispensed with ≥50% of claims rejected by payer; PrEP, pre-exposure prophylaxis; STI, sexually-transmitted infection.

Figure 3. OR and 95% CI for the relationship between prescription dispensing status and HIV-infection risk within

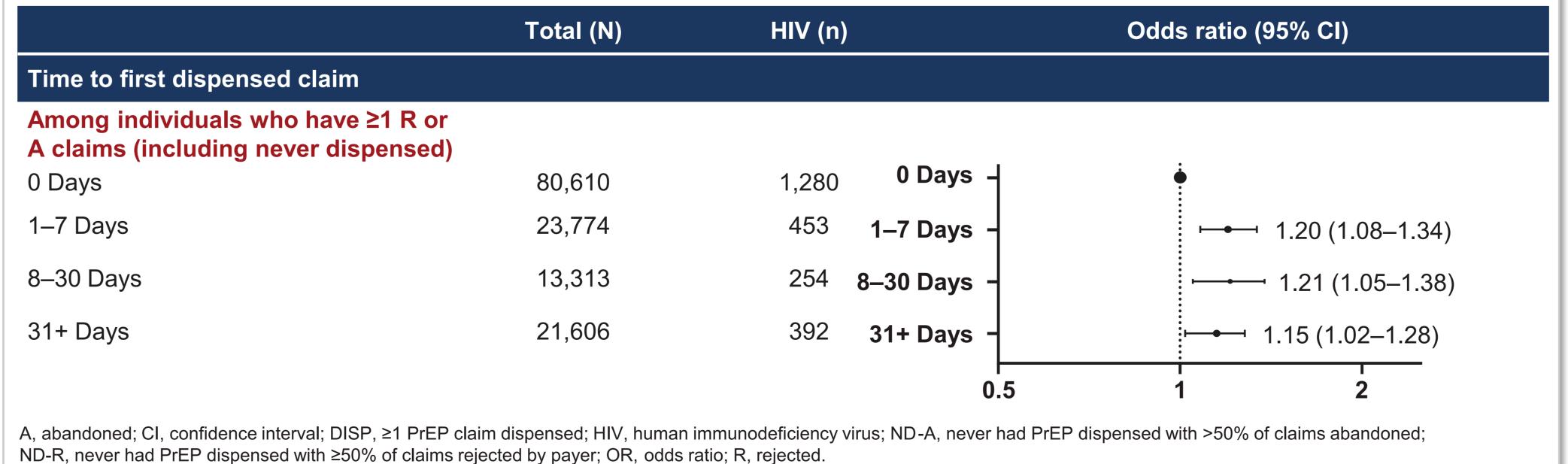
*A significance test of HIV incidence was performed between the DISP cohort vs ND-A and ND-R (p<0.05). †Missing removed (n=9,072). ‡A state program that gets funding from the federal

| | Total (N) | HIV (n) | | Odds ratio (95% CI) |
|--------------|-----------|---------|--------|---------------------|
| Claim status | | | | |
| DISP | 457,561 | 9,780 | DISP - | |
| ND-R | 38,311 | 1,565 | ND-R - | + 1.95 (1.85–2.06) |
| ND-A | 26,401 | 774 | ND-A | 1.38 (1.28–1.49) |
| | | | 0.5 | 1 2 |

Time to dispensing

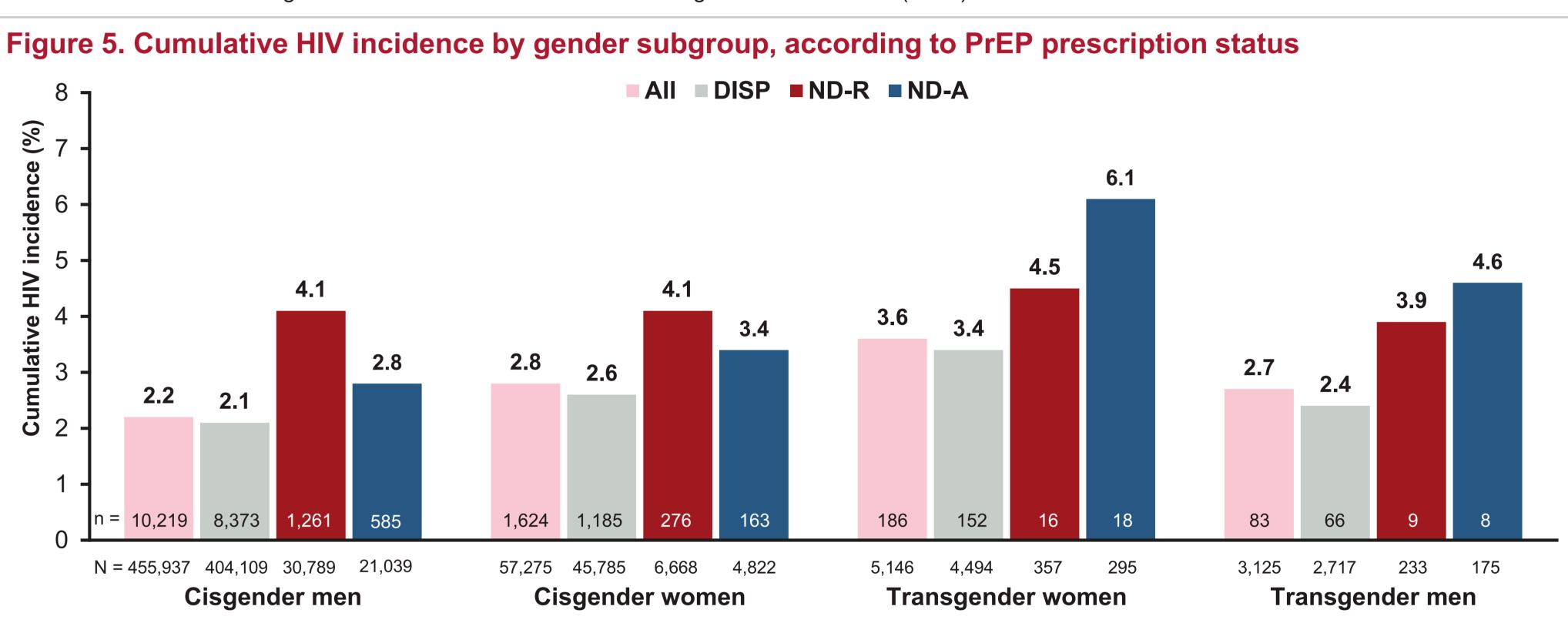
- In the DISP cohort, for individuals who had at least one abandoned or rejected claim, ≥1 day delayed time to dispensing was associated with
 increased risk of acquiring HIV when compared to those who were dispensed PrEP the same day (Figure 4)
- The increased HIV-infection risk remained at a similar level, irrespective of the time to first PrEP dispensing

Figure 4. OR and 95% CI for the relationship between time to first PrEP dispensing and HIV-infection risk within 12 months of first PrEP claim



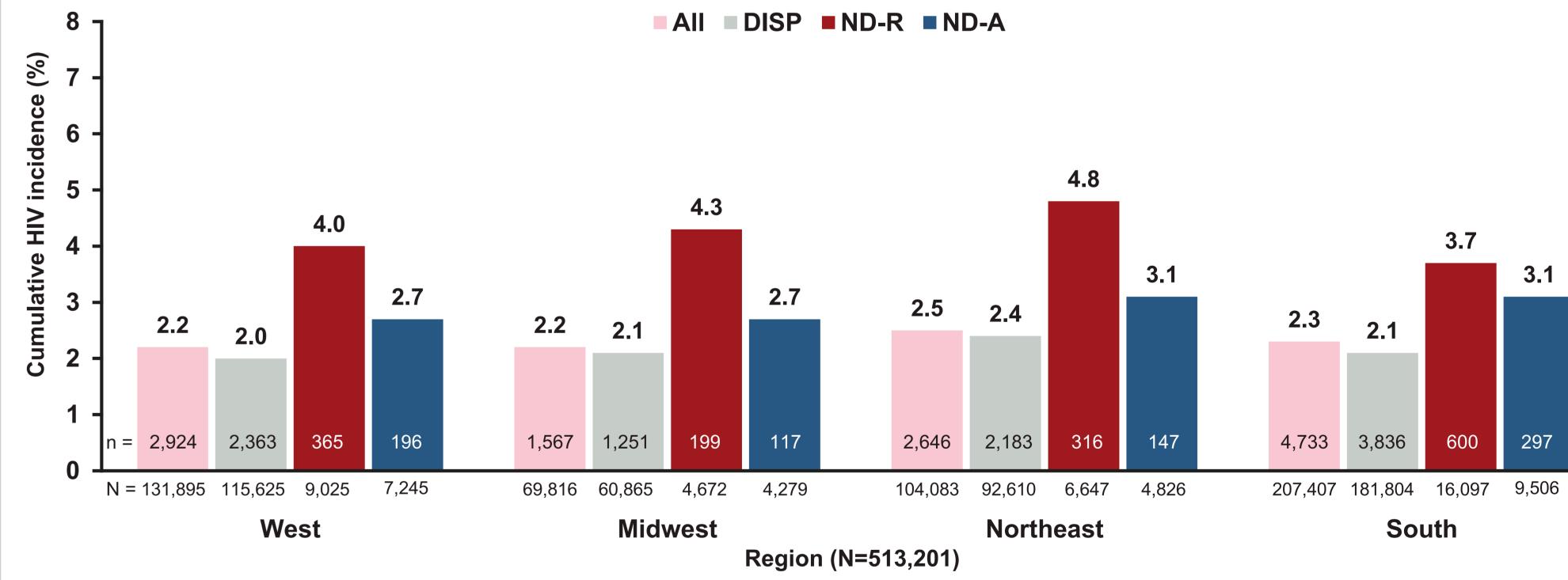
HIV incidence by subgroups

- Subgroup analyses of cumulative HIV incidence showed that:
- Across gender subgroups, HIV incidence was lowest in cisgender men (2.2%) and highest in transgender women (3.6%) (Figure 5)
- When considering PrEP prescription dispensing status among gender subgroups, new HIV diagnoses were lowest in cisgender men who received a
 dispensed claim (2.1%), and highest in transgender men and women in the ND-A cohort (4.6% and 6.1%, respectively)
- For cisgender individuals, HIV incidence was highest in the ND-R group
- For transgender individuals, HIV incidence was highest in the ND-A and ND-R groups
- HIV incidence was similar across different regions (Figure 6)
- Individuals from the Northeast region in the ND-R cohort had the highest HIV incidence (4.8%)
- Overall, HIV incidence in individuals with STIs was nearly twice as high as that in the overall population (~4% versus ~2%, respectively)
 New HIV diagnoses were highest in those individuals with STIs in the ND-R and ND-A cohorts (8.1% and 5.4%, respectively)
- HIV incidence was higher in patients receiving Medicaid or Medicare than those using other insurance types (Figure 7)
- Individuals receiving Medicare in the ND-R cohort had the highest HIV incidence (7.9%)

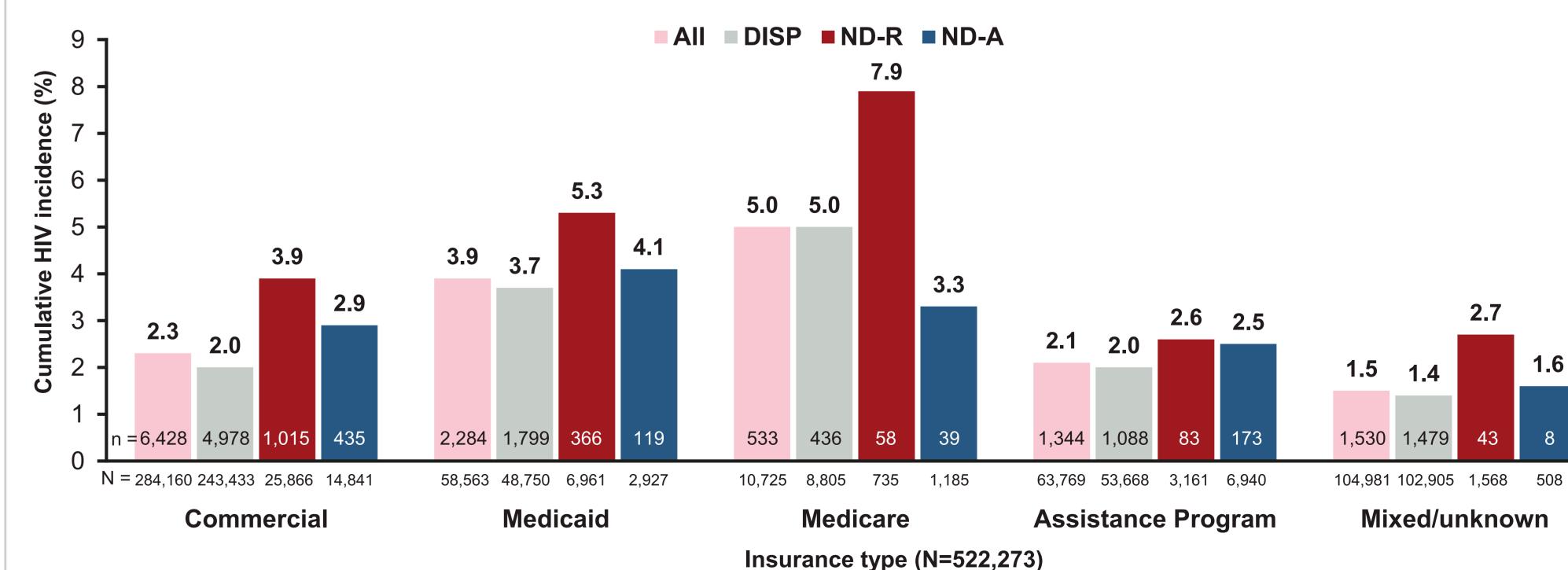


Gender subgroups (N=522,273)

Figure 6. Cumulative HIV incidence by region, according to PrEP prescription status







DISP, ≥1 PrEP claim dispensed; HIV, human immunodeficiency virus; ND-A, never had PrEP dispensed with >50% of claims abandoned; ND-R, never had PrEP dispensed with ≥50% of claims rejected by payer; PrEP, pre-exposure prophylaxis.

Correspondence: li.tao@gilead.com

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ND-R, never had PrEP dispensed with ≥50% of claims rejected by payer; PrEP, pre-exposure prophylaxis