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Conclusions

- Results of this cross-sectional survey revealed that many individuals picking up an initial HIV-1 oral pre-exposure prophylaxis (PrEP) prescription encountered obstacles that were associated with delayed or no pickup
- Cost concerns and insurance coverage issues were significantly more prevalent among individuals who did not pick up their first PrEP prescription within 14 days of when their healthcare provider first prescribed it versus those that did pick up their prescription within 14 days
- Overall, 21% of individuals were told their prescription could not be processed properly, nearly half (43%) of whom were not given a reason; among those given a reason, lack of insurance coverage and the need for prior authorization (PA) were the most commonly reported
- These findings suggest that efforts to address barriers to PrEP at the pharmacy level should target reducing out-of-pocket (OOP) costs and streamlining medical authorization processes to further encourage PrEP initiation

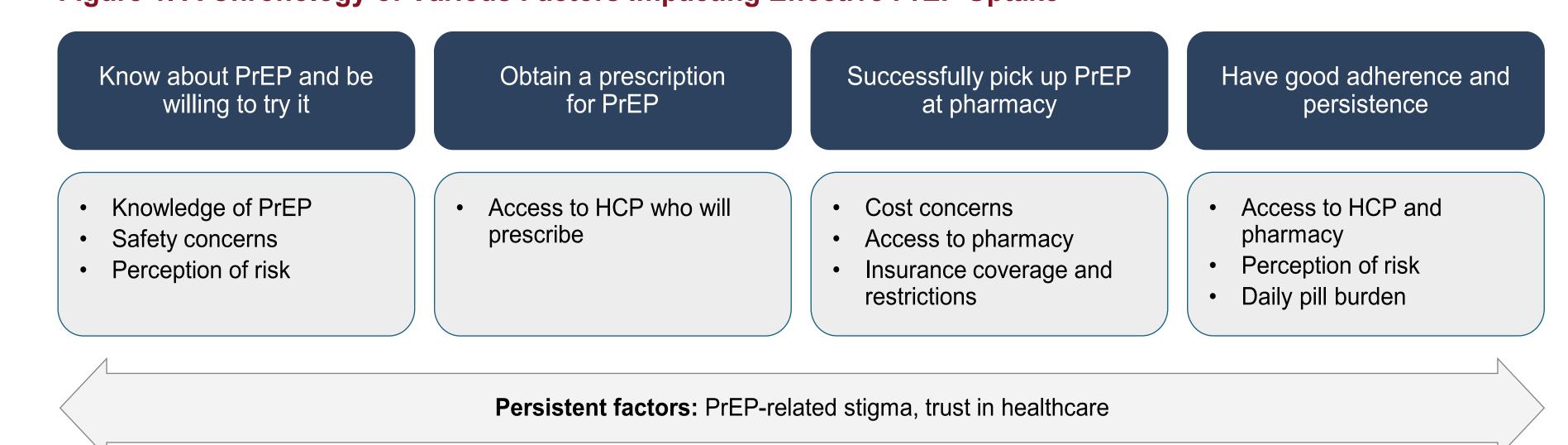
Plain Language Summary

- Medications that prevent HIV, also called "PrEP". are available in the USA. But some people who need or want to take PrEP have problems getting it
- Most insurance plans cover PrEP. However, coverage amounts vary, and some plans ask for healthcare providers to get "prior authorization" - special approval from the insurance company before they pay for the medicine
- We asked people picking up their first PrEP prescription about what they knew about PrEP, how they felt about taking it, and any costs or problems they faced at the pharmacy
- Researchers compared answers between people who picked up their PrEP within 14 days of their healthcare provider prescribing it and those who did not
- Many people had problems when trying to pick up their prescription at the pharmacy, such as insurance not covering it or needing prior authorization from their healthcare provider
- People who did not pick up their prescription within 14 days were more likely to have issues with cost, insurance coverage, and their overall budget
- To help more people take PrEP in the USA, we need to make it easier and less expensive to pick up a first prescription – especially for those worried about money

Background

- The Ending the HIV Epidemic (EHE) initiative, introduced by the US Department of Health and Human Services in 2019, targets a 90% reduction in new HIV-1 cases in the US by 2030¹
- The US Preventive Services Task Force (USPSTF) provided a Grade A recommendation in 2019 that PrEP be made available to any person at high risk of HIV-1 acquisition, and in 2023, to any person at increased risk^{2,3}
- Under the Affordable Care Act (ACA), most private health insurance plans are required to cover USPSTF Grade A and B recommendations with zero OOP costs and no PA⁴
- Between 2023 to 2024, PrEP use in the US increased by 17% to 591,475 PrEP users; uptake, however, remains disproportionately low in individuals who are young, female, Black or Hispanic/Latine, and who live in the South⁵ - Barriers to PrEP uptake include a lack of PrEP awareness, concerns about side effects, stigma, limited geographic access,
- and costs⁶ (**Figure 1**) Despite USPSTF recommendations and ACA insurance coverage requirements, OOP costs and PA vary widely across plans^{7,8}
- There is a lack of research on the barriers to PrEP perceived by individuals picking up their first PrEP prescription
- We previously reported the results of a pilot study identifying cost and insurance coverage problems as the most reported issues associated with delays in picking up an initial PrEP prescription9
- Here we present the final results of this survey study

Figure 1. A Chronology of Various Factors Impacting Effective PrEP Uptake



HCP, healthcare provider; PrEP, pre-exposure prophylaxis

Objective

 To describe factors associated with failure to pick up a first PrEP prescription within 14 days among people prescribed PrEP for the first time

Methods

Survey Design

- Adults with an initial PrEP prescription and without evidence of an HIV-1 infection were invited to complete an electronically-deployed, IRB-approved survey in **English or Spanish**
 - Eligible individuals had a first prescription for PrEP at a Walgreens pharmacy in the USA ≤7 months prior to being invited to participate in the pilot phase (March–April 2024) or final study phase (July–December 2024) of the survey
- Individuals were contacted by text, email, or both. consented to participate, and were compensated upon survey completion
- A prescreener questionnaire assessed respondent eligibility and collected additional respondent information Eligibility information included age, prior HIV-1 diagnosis, and indication and timing of first
- PrEP prescription Information on insurance type, cost of PrEP, and state where dispensing pharmacy was located were obtained retrospectively from the pharmacy
- The survey comprised 35 multiple choice and Likert scale questions on topics including attitudes toward PrEP, OOP expenses at pickup, and prescription fill
- Responses to Likert scale questions were dichotomized to increase statistical power

Data Analysis

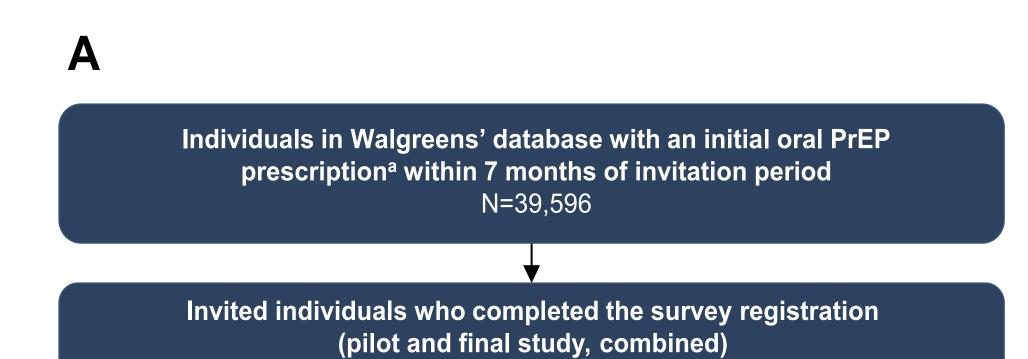
- Data were combined across the pilot and final survey No major differences were found between study phases in question content, data collection, or distribution
- Responses were compared between respondents who picked up their prescription within 14 days of when the order was first received at the pharmacy (prompt pickup [PP]) and those who did not pick up within 14 days (delayed/no pickup [D/NP]) using Chi-square/Fisher's exact tests (significance
- Survey responses were grouped into five key topics: Demographics and health-related social needs, PrEP attitudes and stigma, self-efficacy, healthcare experience, and cost and coverage of PrEP
- Univariate logistic regression analysis was used to calculate odds ratios (OR) and confidence intervals (CI) for the association between pickup status and predictor variables OR values indicate the odds of observing a predictor
- variable among those with PP versus D/NP, where OR>1 favors PP and OR<1 favors D/NP Results were considered statistically significant when
- the 95% CI excluded a value of 1.0 Associations were also assessed with a multivariate logistic regression model, adjusted for age, sex, race, payer type, and pharmacy region

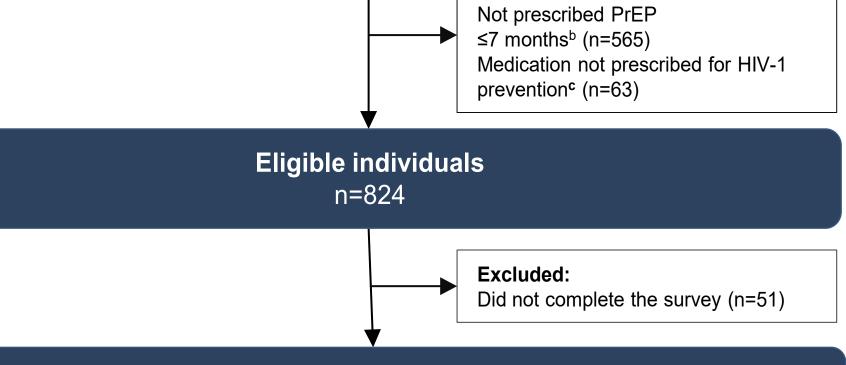
Results

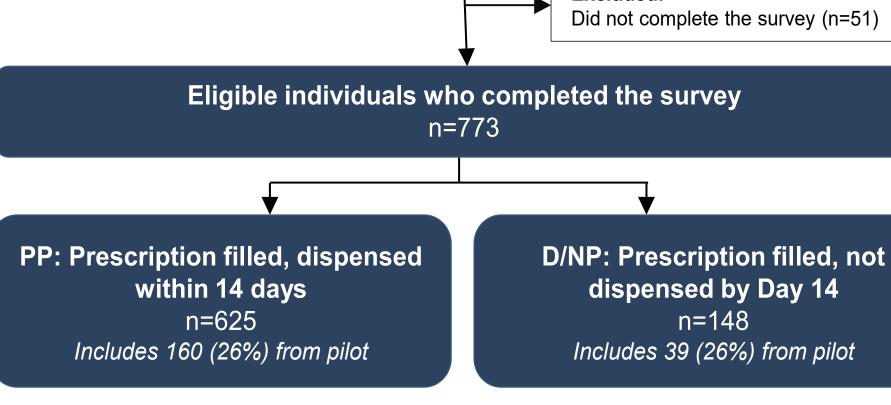
(Figure 2A)

- registered (4%) to participate; of these, 824 (58%) individuals were eligible for inclusion and 773 (54%) completed the survey
- Among respondents, 199 (26%) participated in the pilot and 574 (74%) in the final study
- In total, 625 (81%) respondents picked up promptly and 148 (19%) had delayed or no pickup
- Individuals who registered for the survey most often used a pharmacy in the South (34%), followed by the Midwest (29%), and West (22%), and least often in the Northeast (14%) (Figure 2B)
- 49% of respondents' pharmacies were located in a state with a PrEP drug assistance program (DAP) (Figure 2B)

Figure 2. Respondent Overview (A) and Geographic Locations of Walgreens Pharmacies (B)







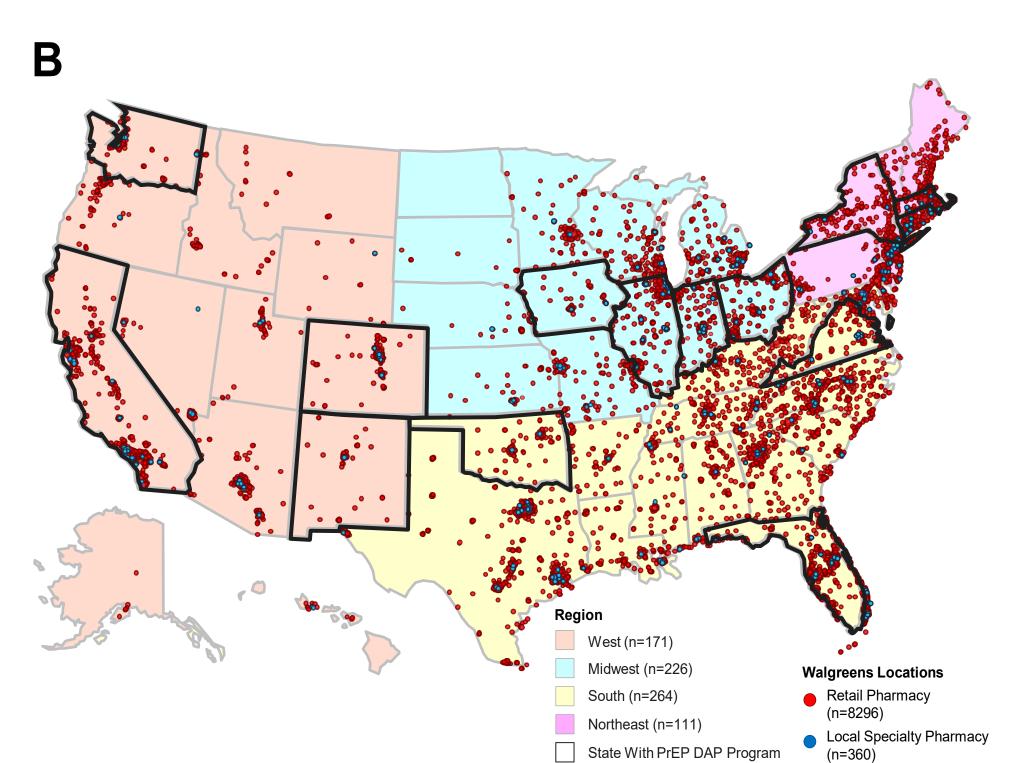


Figure B shows the US states and number of survey respondents in each region; states boxed in black have ^aExclusion items were not mutually exclusive. ^bGPI codes specific for PrEP medications (including F/TDF and F/TAF) were used to identify individuals for survey invitation: GPI codes specific to antiretroviral treatment were used to exclude individuals with prior HIV-1 treatment. ^cMedication prescribed for post-exposure prophylaxis or treatment of HIV-1 or hepatitis B virus DAP, drug assistance program; D/NP, delayed/no pickup; F/TAF, emtricitabine/tenofovir alafenamide fumarate; F/TDF, emtricitabine/tenofovir disoproxil fumarate; GPI, generic product identifier; PP, prompt pickup; PrEP, pre-exposure prophylaxis.

Study Population (Table 1)

- Respondent characteristics were similar between groups, with the exception of OOP costs
 - 84% of PP respondents had \$0 OOP costs for PrEP compared with 47% of D/NP respondents 46% of D/NP respondents had no cost data, primarily due to no
- pickup and thus no charge data, compared with 2% of PP The frequency of respondents using a pharmacy in a state without a
- PrEP DAP was slightly higher in the D/NP group (57%) than the PP
- No differences in region of pharmacy were observed between dispensation groups

Table 1. Characteristics of Survey Respondents by PrEP Dispensation Group, USA, March–December, 2024

aracteristic, n (%)		Total (N=773)	Prompt pickup (n=625)	Delayed/no pickup (n=148)
e (y)	<25	99 (12.8)	79 (12.6)	20 (13.5)
	25–34	248 (32.1)	190 (30.4)	58 (39.2)
	35–44	227 (29.4)	188 (30.1)	39 (26.4)
	45–54	103 (13.3)	91 (14.6)	12 (8.1)
	55–65	63 (8.2)	57 (9.1)	6 (4.1)
	>65	33 (4.3)	20 (3.2)	13 (8.8)
logical sex	Male	626 (81.0)	505 (80.8)	121 (81.8)
	Female	133 (17.2)	110 (17.6)	23 (15.5)
	Othera	14 (1.8)	10 (1.6)	4 (2.7)
ce	Asian	39 (5.0)	28 (4.5)	11 (7.4)
	Black	79 (10.2)	58 (9.3)	21 (14.2)
	Hispanic/Latine	91 (11.8)	71 (11.4)	20 (13.5)
	White	452 (58.5)	384 (61.4)	68 (45.9)
	Multiple races	96 (12.4)	75 (12.0)	21 (14.2)
	Otherb	16 (2.1)	9 (1.4)	7 (4.7)
ucational level	High school or less	98 (12.7)	77 (12.3)	21 (14.2)
	1–3 y college	250 (32.3)	202 (32.3)	48 (32.4)
	≥4 y college	415 (53.7)	338 (54.1)	77 (52.0)
	Prefer not to answer	10 (1.3)	8 (1.3)	2 (1.4)
yer type ^c	Commercial	489 (63.3)	407 (65.1)	82 (55.4)
	Government funded	200 (25.9)	162 (25.9)	38 (25.7)
	Cash	0 (0)	0 (0)	0 (0)
	Discount card, PAP, or other	81 (10.5)	56 (9.0)	25 (16.9)
gion	Northeast	111 (14.4)	91 (14.6)	20 (13.5)
	Midwest	226 (29.2)	178 (28.5)	48 (32.4)
	South	264 (34.2)	216 (34.6)	48 (32.4)
	West	171 (22.1)	140 (22.4)	31 (20.9)
EP DAP Stated	PrEP DAP	379 (49.0)	315 (50.4)	64 (43.2)
	Non-PrEP DAP	394 (51.0)	310 (49.6)	84 (56.8)
EP OOP cost	\$0	591 (76.5)	522 (83.5)	69 (46.6)
	>\$0 to ≤\$10	46 (6.0)	40 (6.4)	6 (4.1)
	>\$10 to ≤\$25	23 (3.0)	21 (3.4)	2 (1.4)
	>\$25 to ≤\$100	31 (4.0)	29 (4.6)	2 (1.4)
	>\$100 to ≤\$500	3 (0.4)	3 (0.5)	0 (0)
	No datae	79 (10.2)	10 (1.6)	69 (46.6)
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المامة Massachusetts. New Mexico. New York. Ohio, Oklahoma, Virginia, and Washington State. ^eCost data unavailable du to no pickup within 30 days or otherwise missing data. DAP, drug assistance program; OOP, out-of-pocket; PAP, patient assistance program; PrEP, pre-exposure

PrEP Costs and Financial Burdens (Table 2)

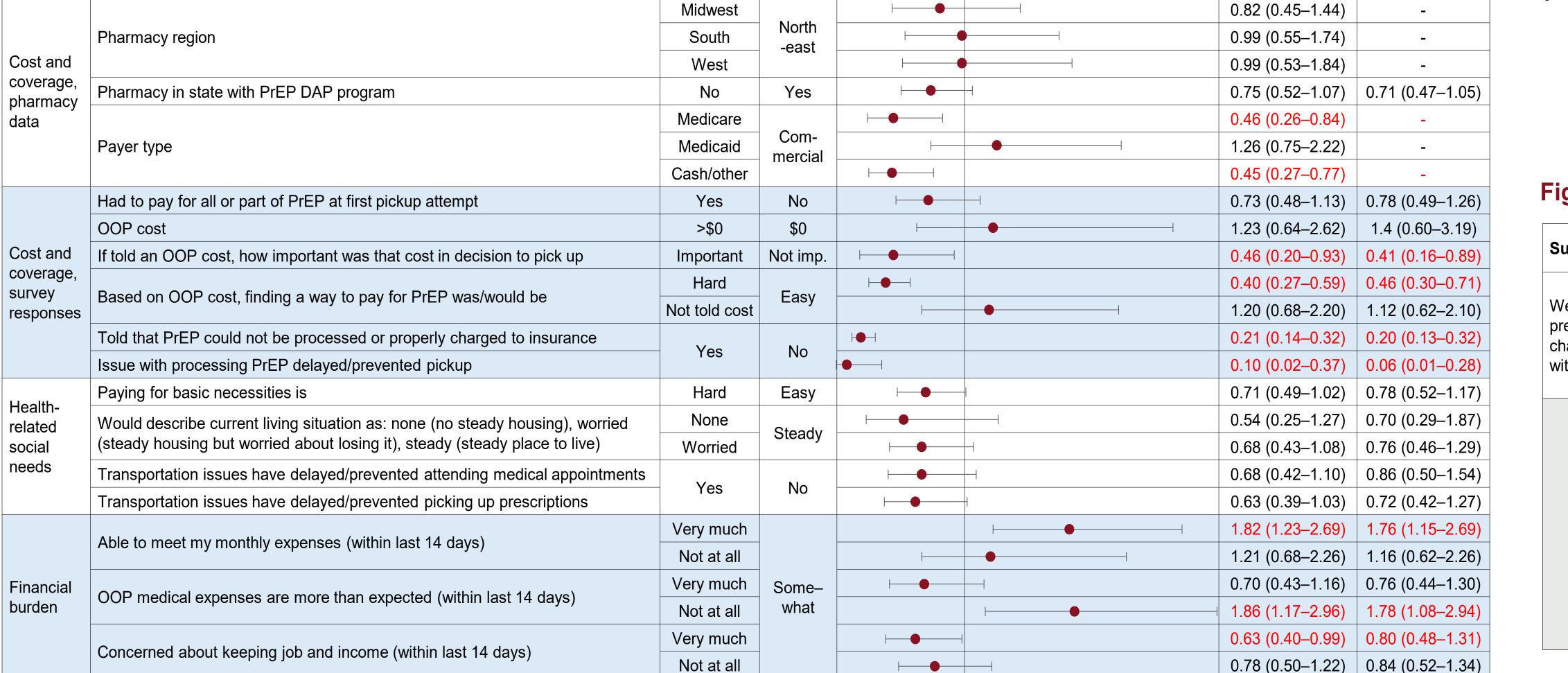
- Prompt pickup was significantly *less likely* for individuals who: Reported that the cost of PrEP was important in their decision to pick up (OR, 0.46) or was difficult to pay (OR, 0.40) Had high versus moderate concern about their job and income
- Prompt pickup was significantly more likely when individuals: Were "very much" versus "somewhat" able to meet their monthly
- expenses (OR, 1.82) Reported their OOP general medical costs as "not at all" versus "somewhat" more than expected (OR, 1.86)

Insurance Coverage and Claims Issues (Table 2)

- Prompt pickup was significantly less likely for individuals who: Were covered under Medicare (OR, 0.46) or who used cash/other means (OR, 0.45)
- Encountered insurance processing issues (OR, 0.21) and reported experiencing delays due to those issues (OR, 0.10)

Table 2. Relationship Between Prompt PrEP Dispensation and PrEP Cost, Insurance Coverage, and Health-Related Social





Statistical significance indicated by red text ^aAdjusted by age, sex, race, paver type, pharmacy region. OR (95% CI CI, confidence interval; DAP, drug assistance program; OOP, out-of-pocket cost; OR, odds ratio; PrEP, pre-exposure prophylaxis.

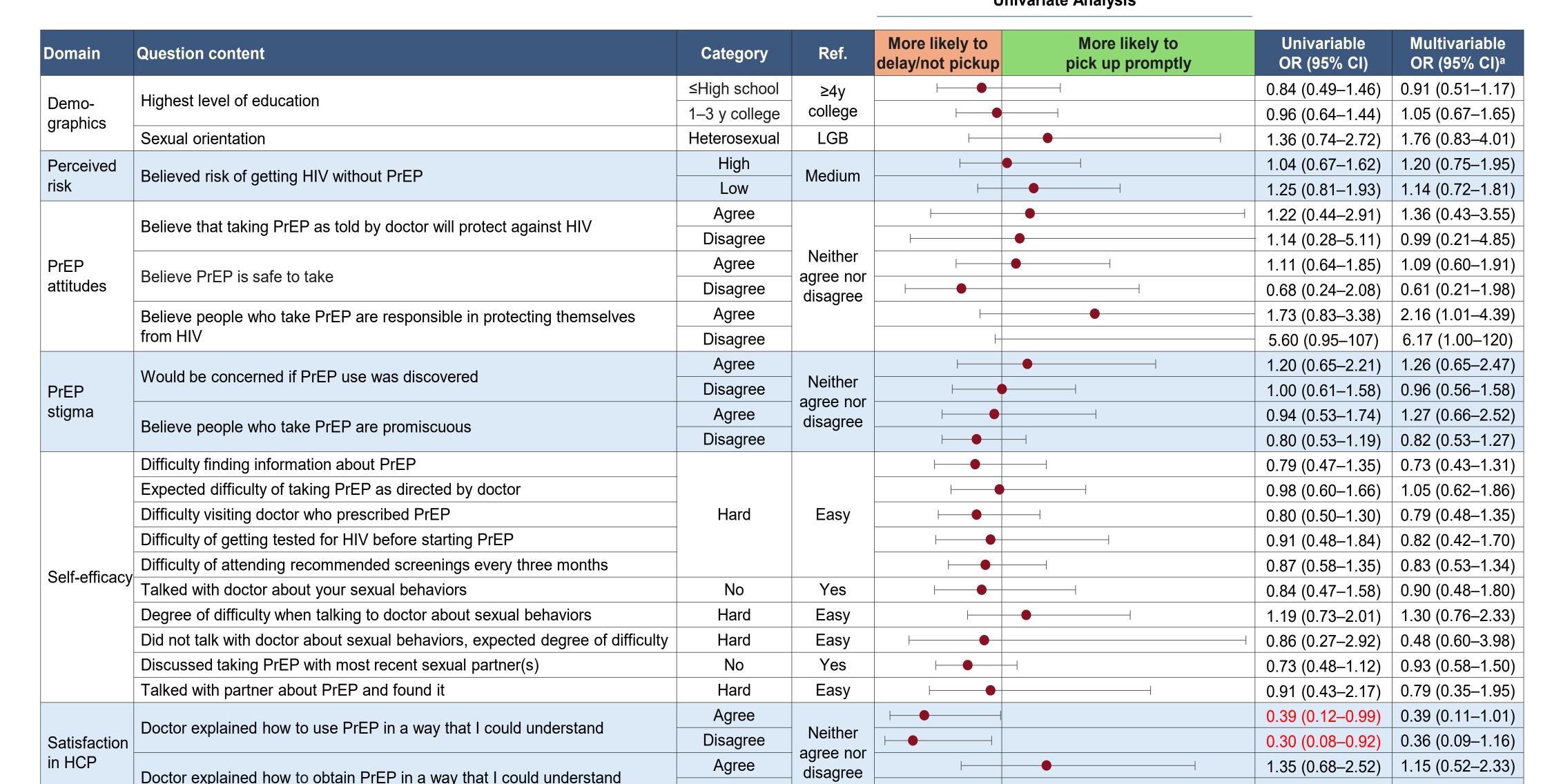
Health-Related Social Factors (Table 2)

Statistical significance indicated by red text.

^aAdjusted by age, sex, race, payer type, pharmacy region.

- The likelihood of prompt pickup was consistently lower, but non-statistically significant, for individuals with unsteady housing, transportation barriers, and higher-than-expected OOP medical expenses in general versus respondents without these concerns Other Assessed Factors
- No significant associations were found between pickup group and respondent demographics, perceived risk, PrEP attitudes, HIV-1 stigma, self-efficacy, and satisfaction in healthcare provider (Table 3)
- For all factors, directionality of multivariate logistic regression results were consistent with univariate logistic regression results (Tables 2 and 3)

Table 3. Relationship Between Prompt PrEP Dispensation and Other Assessed Variables, USA, March-December, 2024

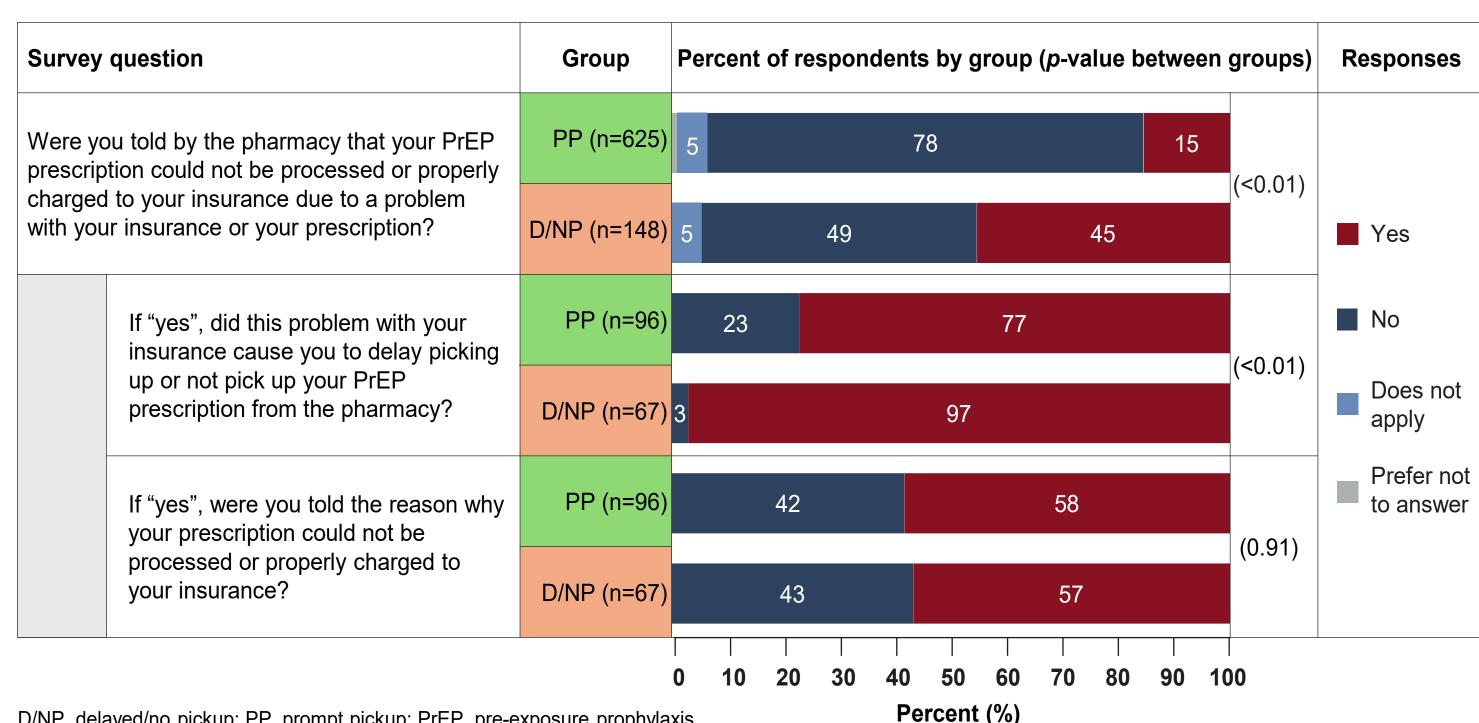


CI, confidence interval; DAP, drug assistance program; HCP, healthcare provider; LGB, lesbian, gay, or bisexual; OR, odds ratio; PrEP, pre-exposure prophylaxis; y, years.

Claims Processing Issues (Figure 3)

- Overall, 163 (21%) respondents reported encountering a claims processing issue
- Among these respondents,139 (85%) reported experiencing delays in pickup
- Many respondents (n=69, 42%) were not told why they encountered a processing issue
- Claims processing issues were reported significantly more often (p<0.01) in the D/NP group (n=67, 45%) than the PP group (n=96, 15%)
- These issues caused pickup delays in both groups, but delays were significantly more frequent (p<0.01) in the D/NP group (n=65, 97%) than the PP group (n=74, 77%)
- No differences were observed between pickup groups in the proportion of respondents given a reason for the processing issue

Figure 3. Claims Processing Issues by PrEP Pickup Group, USA, March–December, 2024

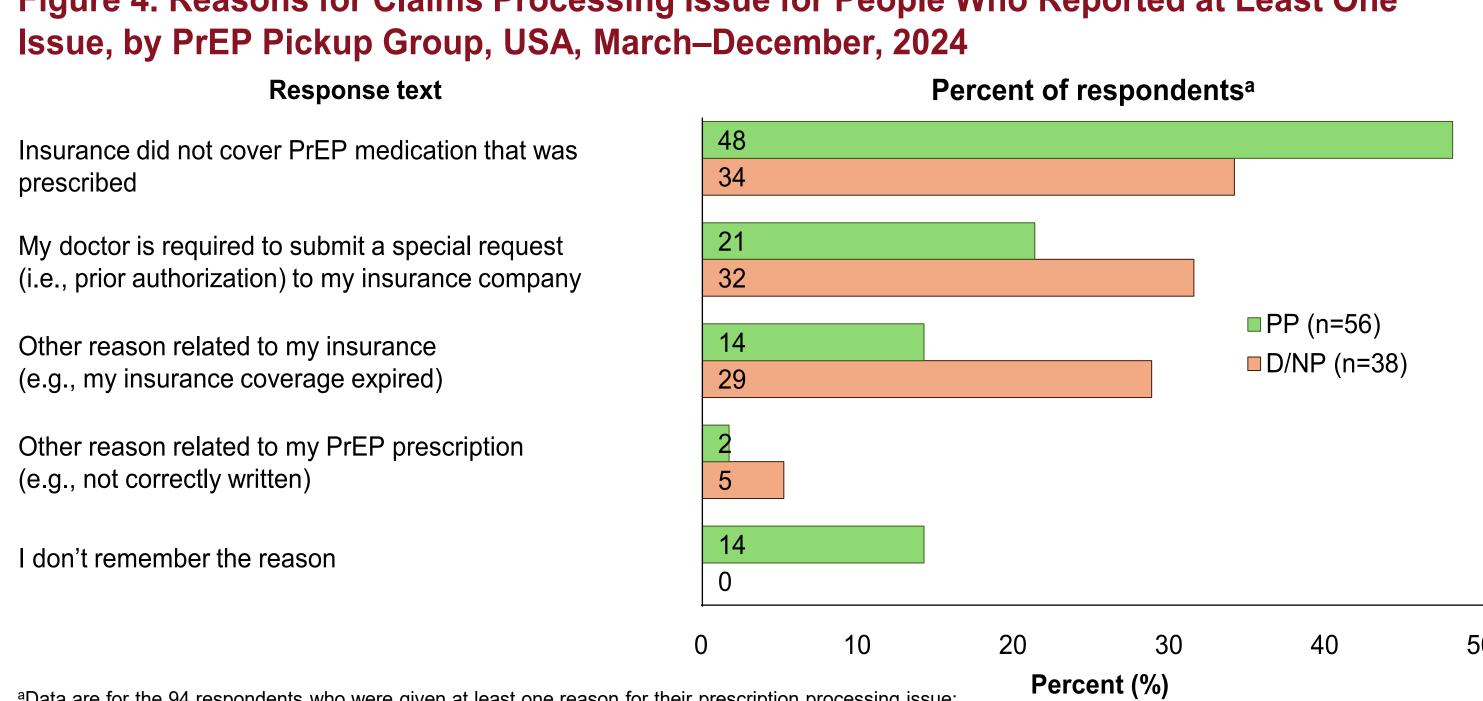


D/NP, delayed/no pickup; PP, prompt pickup; PrEP, pre-exposure prophylaxis

Self-Reported Claims Issue Reasons (Figure 4)

- Among the 139 respondents with a claims processing issue, 94 (68%) respondents were given at least one reason, including 56 with prompt pickup and 38 with delayed/no pickup
- For the respondents with claims issues who were given a reason, self-reported prescription fill rejection reasons differed significantly (p<0.01) between pickup groups
- Respondents in the D/NP group compared with the PP group more often reported encountering the need for PA (32% versus 21%) and other insurance-related issues (34% versus 16%)
- Among 9% of PP respondents who encountered a claims issue and reported a reason, 48% reported being told their PrEP medication was not covered by insurance, compared with 34% in

Figure 4. Reasons for Claims Processing Issue for People Who Reported at Least One Issue, by PrEP Pickup Group, USA, March-December, 2024



Data are for the 94 respondents who were given at least one reason for their prescription processing issu responses were mutually exclusive. D/NP, delayed/no pickup; PP, prompt pickup; PrEP, pre-exposure prophylaxis

Limitations

in the survey

- Possible biases due to the uneven distribution of Walgreens pharmacies, an unrepresentative sample due to non-participation, reliance on self-reported data, and inclusion of subjective questions may limit the generalizability of results to a broader population
- The cross-sectional survey design does not allow for the evaluation of factors that vary with time Barriers to PrEP dispensation are complex with interacting drivers that might not be identifiable 0.77 (0.30–1.98) | 0.79 (0.27–2.25)
 - Causal inferences cannot be drawn from this descriptive study, because many factors may contribute to variation between groups

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Conflicts of Interest: KP and JC are current or former employees and shareholders of Walgreens Co. IS was an employee of Walgreens at the time of the study. JCC, AH, MB, and WZ are employees and shareholders of Gilead Sciences, Inc. PSS has received research grants and speaker fees from Gilead Sciences Inc. He has also received research grants from Merck and ViiV Healthcare.