

# Screening With Patient-Reported Outcomes (PRO) Assessments to Identify Risk Factors for Suboptimal Adherence in Routine HIV Care

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# Disclosures

- Duncan Short is an employee of ViiV Healthcare and owns stock in GSK

# Adherence to ART Is Critical for Maintaining Virologic Suppression But Identifying Risk Factors for Adherence Can Be Challenging

- Modern ART regimens are highly effective at achieving virologic suppression, thereby reducing HIV-associated morbidity and mortality and increasing HRQoL among PWH<sup>1,2</sup>
- Suboptimal adherence to ART is associated with increased rates of virologic failure<sup>2,3</sup>
- Adherence to ART is associated with multiple behavioral, social, and clinical factors<sup>4-7</sup>
- However, identifying and addressing all factors potentially contributing to suboptimal ART adherence in individual patients can be challenging for healthcare providers during brief clinic visits<sup>8</sup>
- **For this analysis, we explored the relationship between self-reported adherence and risk factors obtained using PROs administered pre-consultation, as part of the larger PROgress study**

ART, antiretroviral therapy; HRQoL, health-related quality of life; PRO, patient-reported outcomes assessment; PWH, people with HIV.

1. Arts and Hazuda. *Cold Spring Harb Perspect Med*. 2012;2:a007161. 2. Altice et al. *Patient Prefer Adherence*. 2019;13:475-490. 3. Bezabhe et al. *Medicine*. 2016;95:e3361. 4. Billoro et al. *J AIDS Clin Res*. 2018;9:774. 5. Joseph et al. *AIDS Care*. 2015;27:1128-1136. 6. Lee et al. *J Acquir Immune Defic Syndr*. 2019;80:103-109. 7. Carvalho et al. *Cien Saude Colet*. 2019;24:2543-2555. 8. Suri et al. *Int J STD AIDS*. 2021;2021:9564624211032796.

# PROgress Study: Prospective, Hybrid Type 3 Implementation-Effectiveness Study

- The PROgress study evaluated **the added value of PROs** into routine HIV care at 2 outpatient HIV clinics in North America between August 2018 and July 2020
  - Eligible participants were PWH aged  $\geq 18$  years



PRO, patient-reported outcomes assessment; PWH, people with HIV.

# PROs Can Be Successfully Implemented Within Routine Care to Screen for Patient Needs, Behaviors, and Preferences to Support HIV Management

The PROgress study demonstrated that PROs<sup>1</sup>



Can be implemented into routine care without disrupting clinic flow



Were highly acceptable to patients and providers



Improved patient-provider communication



Identified otherwise hidden patient needs eg, mental health issues



May aid providers in identifying barriers to ART adherence

**Objective: examine the association between factors obtained through PROs and suboptimal ART adherence among PWH**

ART, antiretroviral therapy; PRO, patient-reported outcomes assessment; PWH, people with HIV.

1. Short et al. *AIDS Behav.* 2022;26:2409-2424.

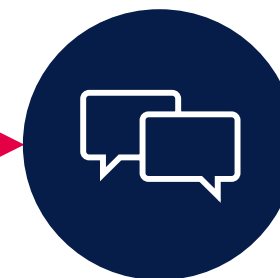
# Process for Administering PROs to PWH at Routine Care Visits in the PROgress Study



**Patient checks in and is given a PRO tablet in an appropriate location to self-administer PRO (~9 minutes)**



**Instant summary report available for provider (1 page)**



**Provider has consultation with patient**

PRO, patient-reported outcomes assessment; PWH, people with HIV.

# PROs in the PROgress Study



**ART adherence**  
Visual analog scale<sup>1</sup>



**Substance use**  
Modified ASSIST<sup>2</sup>



**Alcohol use**  
AUDIT-C<sup>3</sup>



**Smoking status**  
CNICS Smoking  
Questionnaire<sup>4</sup>



**Depression**  
Patient Health  
Questionnaire 9<sup>5,6</sup>



**Satisfaction with ART**  
Endorsement of burden or  
normal life HATQoL items<sup>7</sup>



**Difficulty meeting  
housing costs**  
Single yes/no  
question



**Intimate partner  
violence**  
Intimate Partner Violence  
4 Questionnaire<sup>8</sup>



**Risk of malnutrition**  
Canadian Nutrition  
Screening Tool<sup>9</sup>

ART, antiretroviral therapy; ASSIST, Alcohol, Smoking, and Substance Involvement Screening Test; AUDIT-C, Alcohol Use Disorders Identification Test Consumption Questionnaire; CNICS, Center for AIDS Research Network of Integrated Clinical Systems; HATQoL, HIV/AIDS-targeted quality of life; PRO, patient-reported outcomes assessment.

1. Walsh et al. *AIDS*. 2002;16:269-277. 2. Newcombe et al. *Drug Alcohol Rev*. 2005;24:217-226. 3. Bush et al. *Arch Intern Med*. 1998;158:1789-1795. 4. Cropsey et al. *J Addict Med*. 2016;10:13-19. 5. Kroenke et al. *J Gen Intern Med*. 2001;16:606-613. 6. Spitzer et al. *JAMA*. 1999;282:1737-1744. 7. Holmes and Shea. *Med Care*. 1998;36:138-154. 8. Fitzsimmons et al. ISOQOL 2019; San Diego, CA. Poster. 9. Laporte et al. *Eur J Clin Nutr*. 2015;69:558-564.

# Statistical Analyses

- Demographics and disease characteristics were obtained using chart reviews of medical records for a subset of participants
- Potential risk factors obtained from PROs and associated with suboptimal adherence of <95% and <80% were identified
- **Unadjusted analyses using univariate logistic regression models**
  - Variables that yielded  $P$  values <0.15 were included in multivariate logistic regression analyses
- **Adjusted analyses using multivariate logistic regression models**
  - Each multivariate logistic regression model included either the burden HATQoL item alone, the normal life HATQoL item alone, or both HATQoL items combined as variables
  - $P$  values <0.05 were considered statistically significant

HATQoL, HIV/AIDS-targeted quality of life; PRO, patient-reported outcomes assessment.



# Demographics and Disease Characteristics of PWH Included in Chart Reviews

Parameter, n (%)	PWH (N=596)	Parameter, n (%)	PWH (N=596)
Age, y		CD4+ cell count, cells/mm <sup>3</sup>	
<30	68 (11)	≤350	107 (18)
30 to <40	117 (20)	351 to <500	101 (17)
40 to <50	109 (18)	≥500	388 (65)
50 to <60	135 (23)	Undetectable viral load	487 (82)
≥60	165 (28)	Transmission risk category <sup>b</sup>	
Male sex at birth	409 (69)	Bisexual (either gender)	43 (7)
Race and ethnicity		Blood product transfusion	17 (3)
Black	254 (43)	Endemic area	54 (9)
White	222 (37)	Heterosexual	283 (47)
Asian	24 (4)	Injection drug user	31 (5)
Other races/Not specified <sup>a</sup>	86 (14)	Men who have sex with men	243 (41)
Ethnicity		Unknown	19 (3)
Hispanic	42 (7)		

PWH, people with HIV.

<sup>a</sup>Including aboriginal, First Nations, Middle Eastern, mixed race, and Native American. <sup>b</sup>Categories are not mutually exclusive.

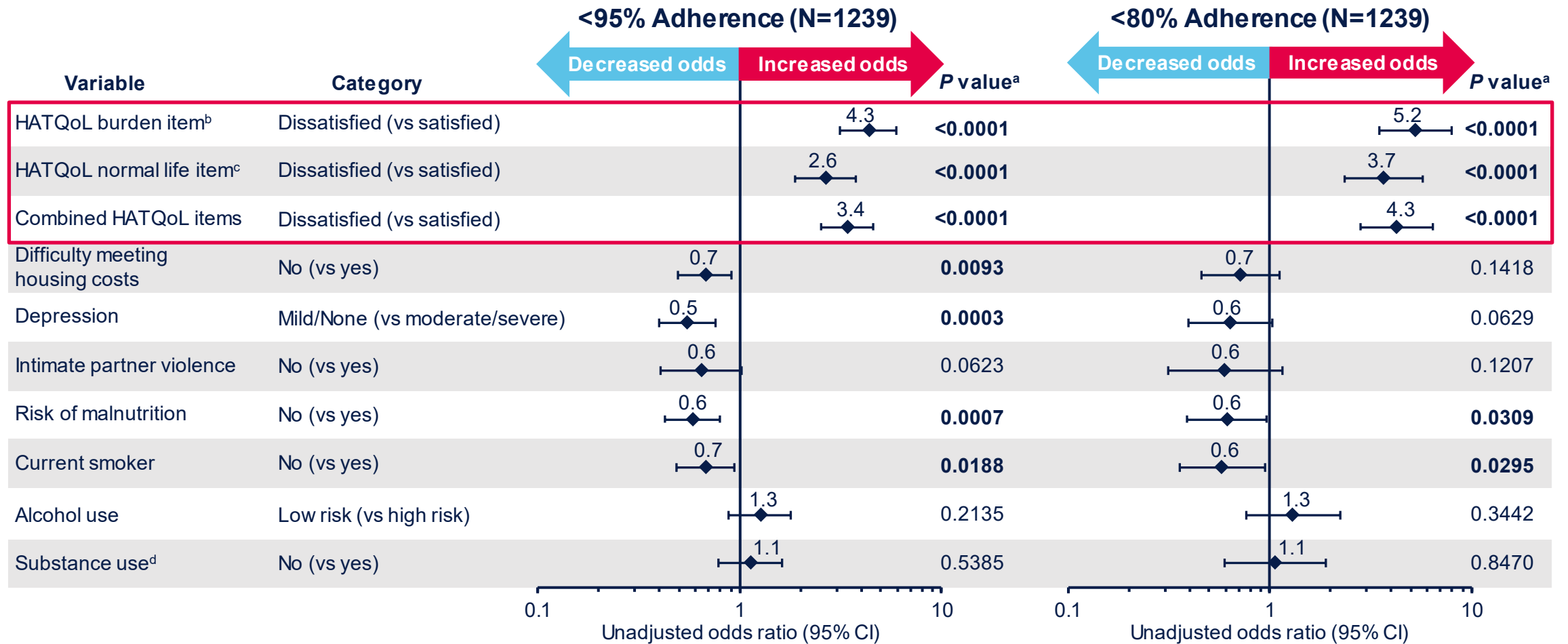
# Sociodemographic and Health-Related Characteristics of PWH Obtained From PROs

Variable	Category	Respondents, n (%) <sup>a</sup>	PWH with characteristic, n (%) <sup>b</sup>
ART adherence	<95%	1239 (76)	268 (22)
	<80%		106 (9)
HATQoL burden item <sup>c</sup>	Dissatisfied	1527 (94)	272 (18)
HATQoL normal life item <sup>d</sup>	Dissatisfied	1555 (95)	243 (16)
Combined HATQoL items	Dissatisfied	1580 (97)	354 (22)
Difficulty meeting housing costs	No	1539 (94)	561 (36)
Depression	Mild/None	1533 (94)	1235 (81)
Intimate partner violence	No	1295 (79)	1175 (91)
Risk of malnutrition	No	1608 (99)	1243 (77)
Current smoker	No	1131 (69)	747 (66)
Alcohol use	Low risk	1620 (99)	1309 (81)
Substance use (past 3 months)	No	988 (61)	373 (38)

ART, antiretroviral therapy; HATQoL, HIV/AIDS-targeted quality of life; PRO, patient-reported outcomes assessment; PWH, people with HIV.

<sup>a</sup>Percentage of the total number of PWH included in the analysis (N=1632). <sup>b</sup>Percentage of respondents for each variable. <sup>c</sup>In the past 4 weeks, taking my [HIV] medicine has been a burden. <sup>d</sup>In the past 4 weeks, taking my [HIV] medicine has made it hard to live a normal life.

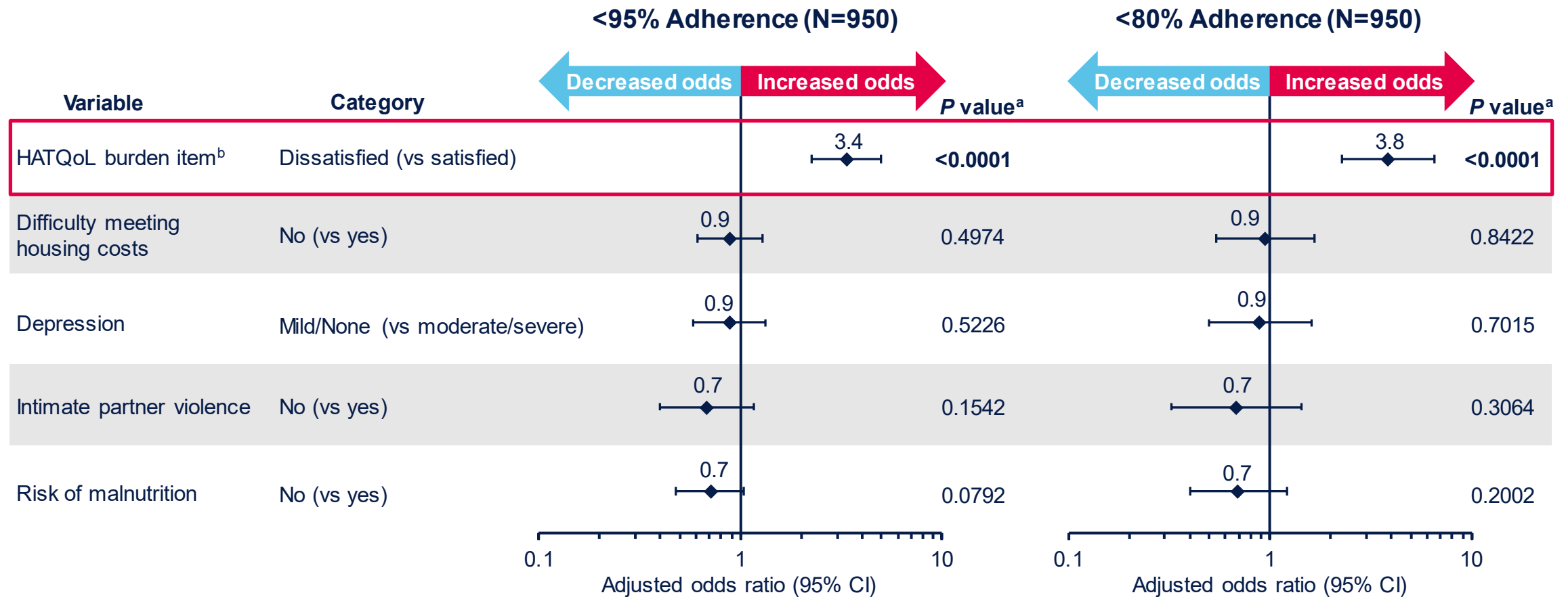
# Dissatisfaction With ART Was Significantly Associated With Suboptimal Adherence in Unadjusted Analyses



ART, antiretroviral therapy; HATQoL, HIV/AIDS-targeted quality of life.

<sup>a</sup>Bold values denote *P* values <0.05. <sup>b</sup>In the past 4 weeks, taking my [HIV] medicine has been a burden. <sup>c</sup>In the past 4 weeks, taking my [HIV] medicine has made it hard to live a normal life. <sup>d</sup>Past 3 months.

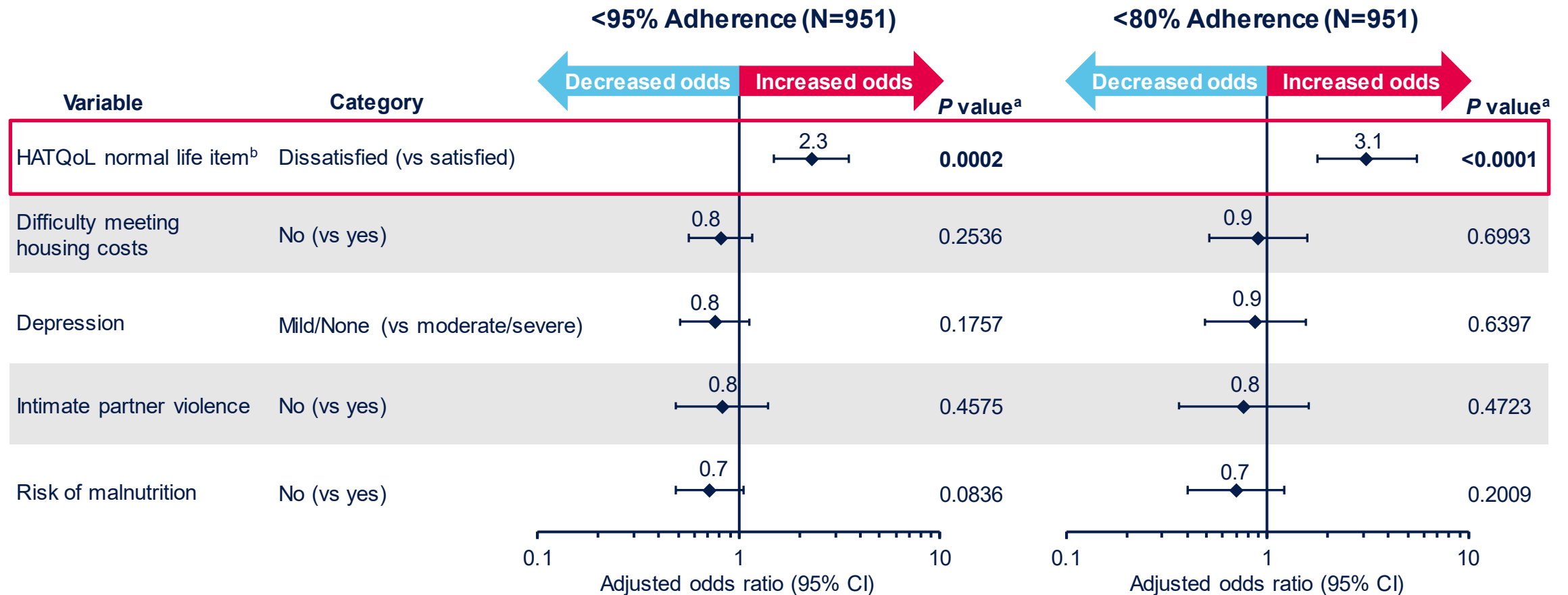
# Using 1 HATQoL Item, Dissatisfaction With ART ('Burden') Was Significantly Associated With Suboptimal Adherence in a Multivariate Model



ART, antiretroviral therapy; HATQoL, HIV/AIDS-targeted quality of life.

<sup>a</sup>Bold values denote P values < 0.05. <sup>b</sup>In the past 4 weeks, taking my [HIV] medicine has been a burden.

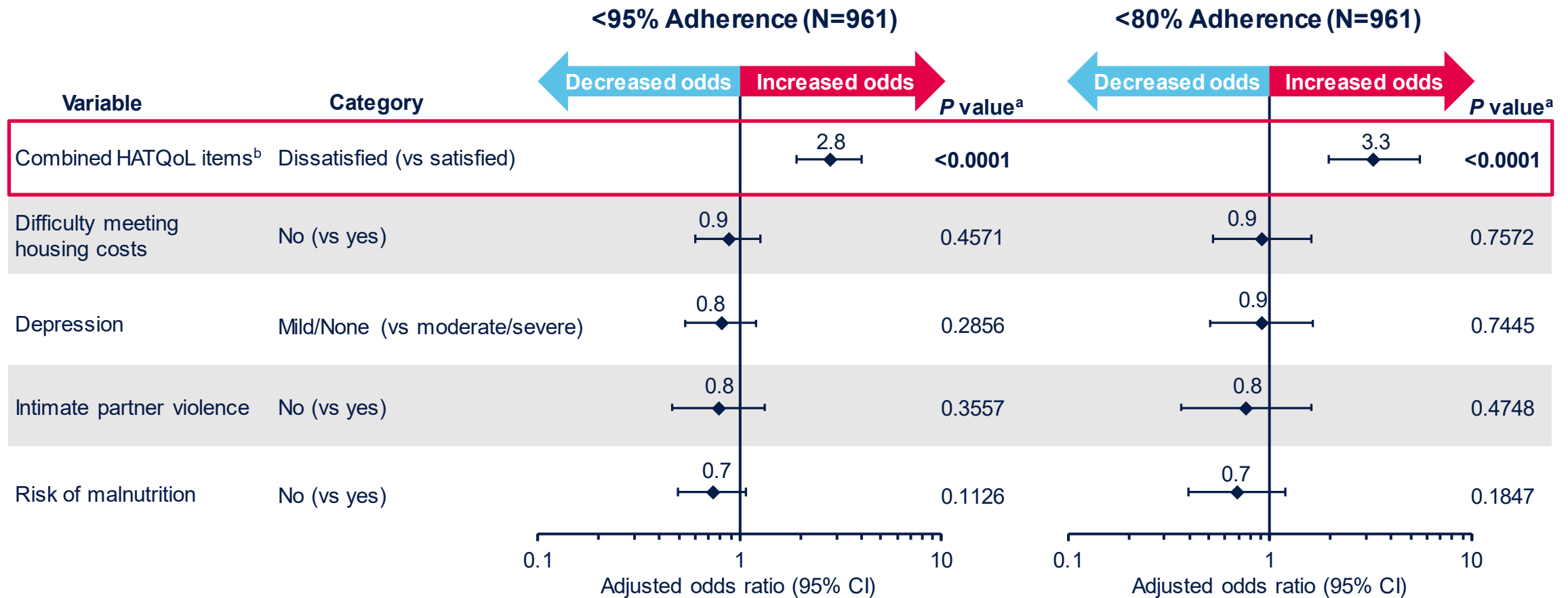
# Using 'Hard to Live a Normal Life' HATQoL Item, Dissatisfaction With ART Remained Significantly Associated With Suboptimal Adherence



ART, antiretroviral therapy; HATQoL, HIV/AIDS-targeted quality of life.

<sup>a</sup>Bold values denote P values < 0.05. <sup>b</sup>In the past 4 weeks, taking my [HIV] medicine has made it hard to live a normal life.

# Dissatisfaction With ART Was Also Significantly Associated With Suboptimal Adherence When Both HATQoL Items Were Combined



ART, antiretroviral therapy; HATQoL, HIV/AIDS-targeted quality of life.

<sup>a</sup>Bold values denote P values < 0.05. <sup>b</sup>In the past 4 weeks, taking my [HIV] medicine has (1) been a burden and (2) made it hard to live a normal life.

# Associations Observed in Analyses After Multiple Imputation and Stepwise Selection

- After multiple imputation to account for missing data due to non-responses in the multivariate logistic regression analyses
  - Dissatisfaction with ART remained significantly associated with suboptimal adherence of <95% and <80% across all 3 models ( $P<0.0001$ )
  - No risk of malnutrition was significantly associated with reduced odds of <95% adherence in the models including the normal life HATQoL item alone ( $P=0.0377$ ) or both HATQoL items combined ( $P=0.0481$ )
- Before and after multiple imputation in 3 multivariate stepwise selection models including 1 or both HATQoL items
  - Dissatisfaction with ART was significantly associated with <95% adherence ( $P<0.0001$ )
  - PWH with no risk of malnutrition were significantly less likely to have <95% adherence ( $P<0.05$ )
  - No results from stepwise multivariate analyses were available for <80% adherence because the only variables remaining after stepwise selection were HATQoL factors

ART, antiretroviral therapy; HATQoL, HIV/AIDS-targeted quality of life; PWH, people with HIV.

# Associations Observed by Study Site

- In analyses by study site,<sup>a</sup> dissatisfaction with ART was significantly associated with suboptimal adherence in several models, including
  - For **<95% adherence at St Michael's Hospital** after multiple imputation in all multivariate logistic regression and stepwise selection models
  - For **<95% adherence at Midway Specialty Care Center** before and after multiple imputation in all multivariate logistic regression models
  - For **<80% adherence at St Michael's Hospital** after multiple imputation in all multivariate logistic regression models

ART, antiretroviral therapy.

<sup>a</sup>No results were available from multivariate logistic regression models for <80% adherence or stepwise selection models for <95% or <80% adherence at Midway Specialty Care Center because HAT QoL factors were the only variables included in the model.



# Conclusions

- PROs can provide important information about a patient's adherence and related risk factors to healthcare providers in real-time
- Dissatisfaction with ART was significantly associated with suboptimal adherence in PWH who completed PROs during routine HIV care visits at 2 North American clinics
  - Using either HATQoL item or both HATQoL items combined, PWH who were dissatisfied with ART were
    - 3.1 to 3.8 times more likely to have suboptimal adherence of <80% and
    - 2.3 to 3.4 times more likely to have suboptimal adherence of <95% than those who were satisfied with their ART medications
- An association between ART dissatisfaction and suboptimal adherence was observed using a single item from the HATQoL questionnaire, indicating that valuable information can be obtained through PROs with minimal time burden for the patient
- Overall, these results suggest that screening for treatment dissatisfaction using PROs may provide value to adherence management in routine HIV care

ART, antiretroviral therapy; HATQoL, HIV/AIDS-targeted quality of life; PRO, patient-reported outcomes assessment; PWH, people with HIV.

# Acknowledgments

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- We thank the patients, providers, and staff from the 2 PROgress study clinics for their commitment to this work
- These data were published between the original conference date of July 2022 and the revised conference date of November 2022 and are available in the following publication:
  - *Short D, Wang X, Suri S, et al. Risk factors for suboptimal adherence identified by patient-reported outcomes assessments in routine HIV care at 2 North American clinics. Patient Prefer Adherence. 2022;16:2461-2472.*