

Megan Chen¹, Soodi Navadeh¹, Seojin Park¹, Michael Bogart¹, Danielle Altman², Zahava Rosenberg-Yunger², Jessica Baldasaro², Courtney Chatha², Kailynn Schmidt², Gerrit Vandenberg²

¹Gilead Sciences, Inc., Foster City, CA, USA; ²Modus Outcomes, a THREAD company, Cary, NC, USA

Conclusions

- This study provided a broader understanding of how people with HIV (PWH) understand treatment adherence and satisfaction and the factors that influence them
- Expert clinician interviews and qualitative interviews from PWH revealed that existing patient-reported outcomes (PROs) may not fully capture the real-world patient experience with treatment satisfaction and adherence
- Findings from this study resulted in the development of two separate conceptual models (treatment-related factors of treatment adherence and satisfaction, and individual- and health system-level factors of treatment adherence and satisfaction) to capture these experiences
- A limitation of this study was that saturation was not achieved from the qualitative interviews. This is likely due to the heterogeneity of the sample—specifically, the time since diagnosis, the length of time spent on treatment, and the various treatments taken by these individuals. As a result, there may not be full conceptual coverage shown in these models
- Given that the current PRO landscape does not explicitly address many of these concepts of treatment adherence and satisfaction that are important to PWH, future research to develop novel PROs assessing concepts of treatment adherence and satisfaction that are important to PWH is warranted

Plain Language Summary

- Treatments for people with human immunodeficiency virus (PWH) have changed and become better in recent years
- Researchers want to understand how much patients like their treatments. To do this, they use questions called “patient-reported outcomes” (PROs). PROs ask questions such as:
 - Adherence: Do you take your HIV medicine as you were told by your doctor?
 - Satisfaction: How happy are you with your HIV treatment?
- We interviewed doctors who play an important role in treatment selection and specialize in PROs in HIV outcomes, we read articles, and we interviewed PWH to find out what they thought about treatment adherence and satisfaction
- Based on what we learned, we created two images of the patient experience of HIV treatment for treatment adherence and satisfaction
 - The first image, called treatment-level factors, shows topics such as side effects, how well a treatment is working, and how easy it is to take the treatment
 - The second image, called individual- and health system-level factors, shows topics such as access to treatment, interactions with care providers, and feeling shame about HIV
- We learned that PWH may have side effects from treatments and sometimes have trouble speaking with their doctors
- Some PWH said that they are worried about friends or neighbors judging them for having HIV
- The questions that are used to understand the experiences of PWH do not specifically cover all these topics
- If we want to understand what is most important to PWH, we need more studies that ask questions about what it is like to live with HIV

Introduction

- As of 2023, there were approximately 39.9 million PWH globally, with 77% of PWH accessing antiretroviral therapy (ART).¹⁻³
- ART adherence is a significant determinant of virologic suppression.⁴ Over the past 35 years, HIV treatment has evolved from regimens with high pill burden and treatment-limiting toxicities to manageable daily and long-acting regimens, such as the approval of the combination ART pill in 2006 and an injectable in 2021.^{2,5} As the number of treatment options has increased, so has the importance of treatment preference among PWH
- PRO questionnaires, which are commonly used to measure HIV treatment adherence and satisfaction, were developed before many of these newly developed regimens existed.⁶ Furthermore, the experience of living longer with HIV and managing comorbidities that develop as part of aging with HIV may be changing how PWH view their quality of life
- There is little evidence to indicate that existing PROs provide adequate coverage of the treatment adherence and satisfaction concepts that matter to PWH who have utilized modern ARTs

Objective

- Recent improvements in treatments for PWV inspired the exploration of concepts related to treatment adherence and satisfaction with newer treatment options, including the assessment of currently available PRO measures and the development of two conceptual models
- To address this measurement gap, a three-phase study was conducted, consisting of a targeted literature review, expert consultation, and interviews with 27 PWV who have utilized ART

Methods

- This study consisted of three research phases: qualitative interviews with PWH, clinician interviews, and a targeted literature review

Interviews With PWH

- To gather patient-experience data, qualitative interviews were conducted with 27 PWH who had utilized ART
 - A saturation analysis was conducted to assess conceptual coverage
- ### Clinician Interviews
- HIV clinicians were interviewed 1:1 and were asked about the treatment landscape and factors influencing HIV treatment adherence and satisfaction, as well as their experience with relevant HIV treatment satisfaction and adherence PROs

Targeted Literature Review

- A targeted literature review using PubMed and ClinicalTrials.gov of qualitative research and PROs in PWH identified factors affecting adherence and satisfaction
- Saturation analysis was conducted to assess conceptual coverage

Conceptual Model Development

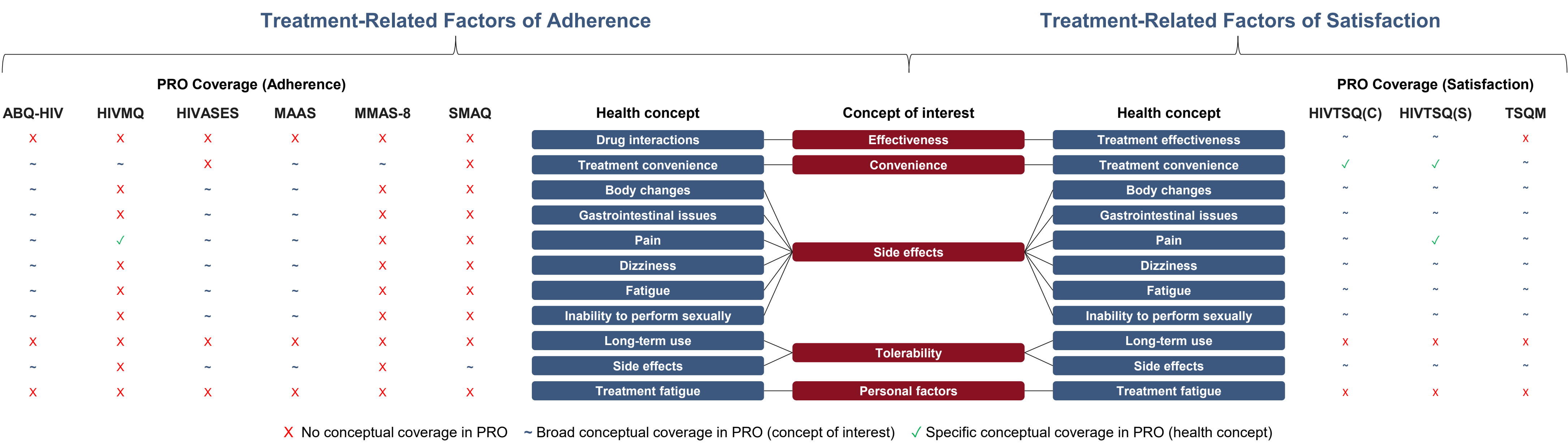
- Conceptual models were developed by grouping concepts into higher-level domains, and PRO items were then mapped to these models to assess coverage
- Item-to-concept mapping against the conceptual model was performed to infer content validity and identify gaps in the assessment of HIV treatment satisfaction and adherence (including PROs currently included in Gilead's clinical research program)

Results

Key Findings

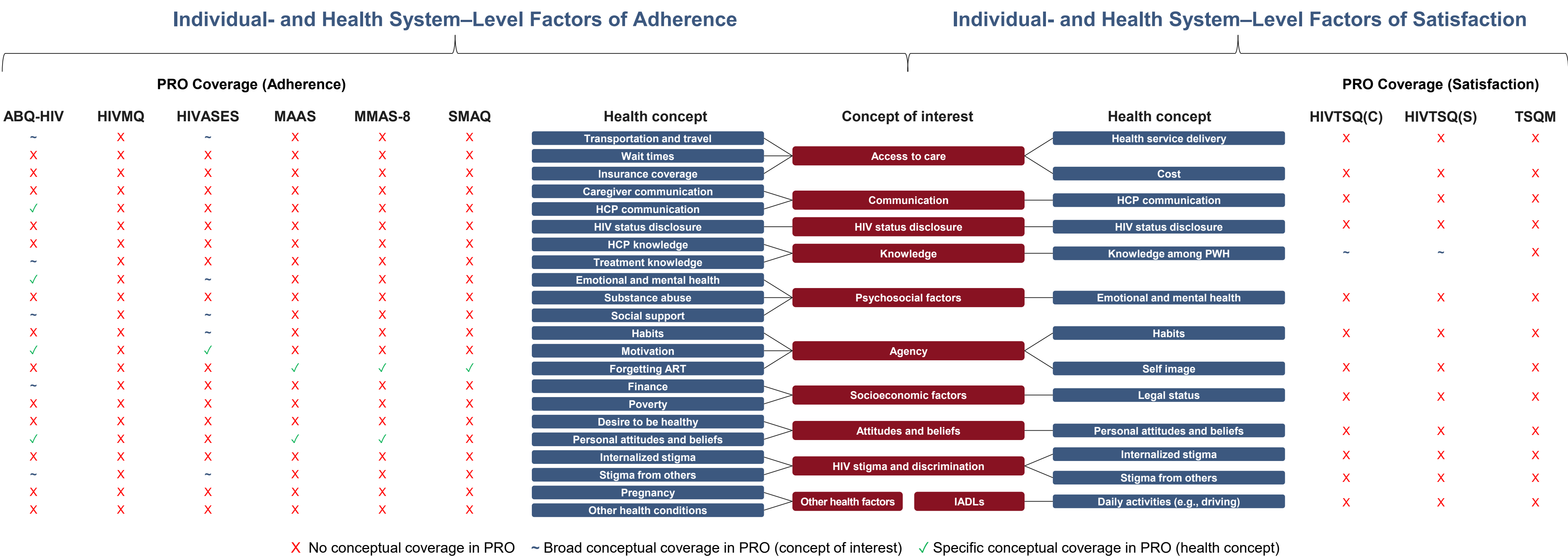
- Findings from the three research phases, which included the interviews with PWH (Table 1) resulted in the development of two separate conceptual models illustrating treatment adherence and satisfaction: treatment-related factors (5 domains - e.g., effectiveness and side effects) and individual- and health system-related factors (11 domains - e.g., access to care, interactions with providers, and HIV stigma and discrimination) (**Figures 1 and 2**)
- PWH frequently noted access to care (e.g., insurance and cost), side effects, effectiveness, communication (e.g., interactions with their healthcare providers), and HIV-related stigma as key factors affecting their treatment adherence and satisfaction
 - Although existing PROs provided coverage of some concepts, gaps related to contemporary PWH experiences with treatment adherence and satisfaction were identified, such as treatment effectiveness, access to care, HIV stigma and discrimination, and interactions with healthcare providers (**Figures 1 and 2**)

Figure 1. Conceptual Model 1 and Coverage Within PRO Assessment Tools



ABQ-HIV, Adherence Barriers Questionnaire for HIV; HIVASES, HIV Treatment Adherence Self-Efficacy Scale; HIVMQ, HIV Medications Questionnaire; HIVTSQ(C), HIV Treatment Satisfaction Questionnaire (Change); HIVTSQ(S), HIV Treatment Satisfaction Questionnaire (Status); MAAS, Medication Adherence Assessment Scale; MMAS-8, Morisky Medication Adherence Scale-8; PRO, patient-reported outcome; SMAQ, Simplified Medication Adherence Questionnaire; TSQM, Treatment Satisfaction Questionnaire for Medication.

Figure 2. Conceptual Model 2 and Coverage Within PRO Assessment Tools



ABQ-HIV, Adherence Barriers Questionnaire for HIV; ART, antiretroviral therapy; HCP, healthcare professional; HIVASES, HIV Treatment Adherence Self-Efficacy Scale; HIVMQ, HIV Medications Questionnaire; HIVTSQ(C), HIV Treatment Satisfaction Questionnaire (Change); HIVTSQ(S), HIV Treatment Satisfaction Questionnaire (Status); IADL, independent activities of daily living; MMAS, Medication Adherence Assessment Scale; MMAS-8, Morisky Medication Adherence Scale-8; PRO, patient-reported outcome; PWH, people with HIV; SMAQ, Simplified Medication Adherence Questionnaire; TSMQ, Treatment Satisfaction Questionnaire for Medication.

Table 1. Health Information of Interviewed PWH

Age, Years		Highest Education Level		Substance Use Disorder	
Median (range)	51 (27-77)	Some high school/high school/GED	2 (7.4)	Yes	6 (22.2)
Sex at Birth	n (%)	Some college	11 (40.7)	No	21 (77.8)
Female	11 (40.7)	Associate's or Bachelor's degree	9 (33.3)	Other Chronic Conditions (e.g., Diabetes)	n (%)
Male	16 (59.3)	Graduate degree	4 (14.8)	Yes	22 (81.5)
Gender	n (%)	Trade or technical school	1 (3.7)	No	5 (18.5)
Female	11 (40.7)	Employment Status	n (%)	Mental Health Diagnoses (e.g., Anxiety)	n (%)
Male	14 (51.9)	Working full time	9 (33.3)	Yes	17 (63.0)
Nonbinary	1 (3.7)	Working part time	3 (11.1)	No	10 (37.0)
Other	1 (3.7)	Retired	1 (3.7)	Stage of HIV	n (%)
Ethnicity	n (%)	Disabled	7 (26.0)	Acute	5 (18.5)
Non-Hispanic/non-Latine	23 (85.2)	Student	2 (7.4)	Chronic	6 (22.2)
Hispanic/Latine	4 (14.8)	Unemployed	2 (7.4)	AIDS	3 (11.1)
Race	n (%)	Other (e.g., caregiver)	3 (11.1)	Unsure/do not know	5 (18.5)
Asian	1 (3.7)	Time Since Diagnosis	n (%)	Undetectable	8 (29.6)
Black/African American	17 (63.0)	≤ 5 years	2 (7.4)	Mode of Current Treatment	n (%)
Biracial	2 (7.4)	6-10 years	5 (18.6)	Single tablet	18 (66.7)
White	6 (22.2)	11-20 years	8 (29.6)	Multi-tablet	3 (11.1)
Other	1 (3.7)	> 20 years	12 (44.4)	Injection	6 (22.2)

GED, General Educational Development.

Disclosures: MC, SN, SP, and MB are employees of Gilead Sciences, Inc. DA, ZR-Y, and KS were employees of Modus Outcomes, a THREAD company, at the time of their involvement. JB, CC, and GV are employees of Modus Outcomes, a THREAD company.

Correspondence: Megan Chen, megan.chen15@gilead.com.