# Development of Two Versions of a Patient Preference Questionnaire for Evaluating Potential HIV Cure–Related and Other HIV Interventions

PCR63

**Karine Dubé[1], Sorana Segal-Maurer[2,3], Martin Duracinsky[4], Martha Gauthier[5], Kathy Vong[5], Harlow Sharp[5], Blaise Cureg[5], Imani Weeks[5], Kwanza Price[3], Caroline Burk[3], James Jarrett[3]**

[1]Division of Infectious Diseases and Global Public Health, School of Medicine, University of California San Diego, San Diego, CA, USA; [2]The Dr James J Rahal Jr Division of Infectious Diseases, NewYork-Presbyterian Queens, Flushing, NY, USA; [3]Gilead Sciences, Inc., Foster City, CA, USA; [4]Patient-Reported Outcomes Research (PROQOL), Health Economics Clinical Trial Unit (URC-ECO), Hôtel-Dieu Hospital, Assistance Publique - Hôpitaux de Paris (AP-HP), Paris, France; [5]Lumanity Patient-Centered Outcomes, Boston, MA, USA



## Conclusions

- Second-round cognitive debriefing results indicated that the HIV Intervention Preference Questionnaire is a clear and relevant patient-reported outcome measure to assess patient preferences regarding HIV cure–related research interventions and analytical treatment interruptions
- **Overall, people with HIV interpreted both versions of the questionnaire as intended, and 1 revision to the questionnaire order was identified to improve clarity**
- Psychometric evaluation of both versions is planned to confirm the robustness and accuracy in capturing the preferences of people with HIV during an HIV cure–related research intervention or analytical treatment interruption

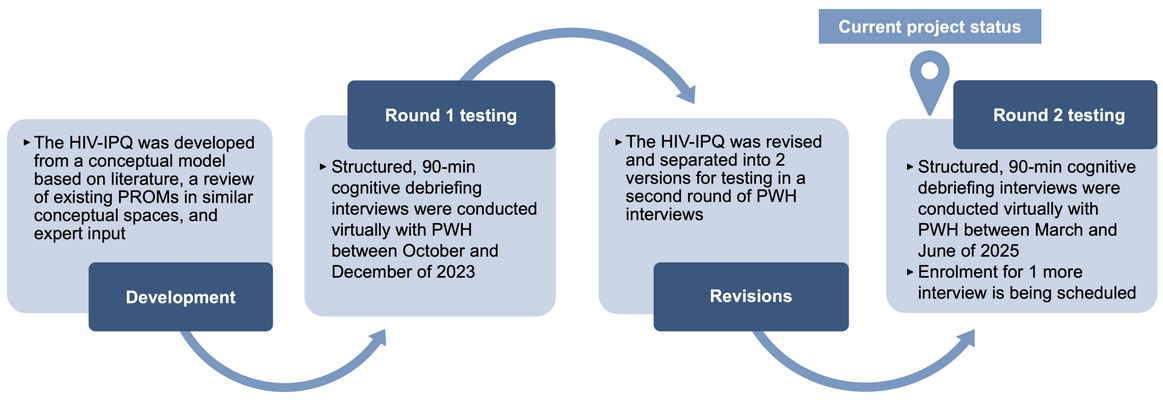
## Plain Language Summary

- Studies focused on an HIV cure or treatment-free HIV control might include a planned break from HIV medicine, which is known as an “analytical treatment interruption”
- While analytical treatment interruptions are important to assess HIV cure–related research interventions, they may also increase levels of HIV in participants, which can increase the chance of transmission, as well as have emotional, mental, and physical impacts
- The HIV Intervention Preference Questionnaire is being developed to better understand the preferences for and psychosocial impacts of different HIV control plans during a clinical study and during a period when HIV medicines are stopped
- This study looked at whether people with HIV found the questions and instructions in the HIV Intervention Preference Questionnaire easy to understand and whether they interpreted them as intended
- Most people with HIV understood the questions as intended and provided feedback to help improve the questionnaire before it is tested further

## Introduction

- Analytical treatment interruptions (ATIs) are important in the evaluation of potential HIV cure–related regimens to assess sustained viral suppression in the absence of antiretroviral therapy[1]
  - While important, ATIs can pose risks, such as viral rebound and psychosocial impacts, that may deter people with HIV (PWH) from participating in clinical trials with ATIs[1,2]
- To better understand the HIV control plan preferences of PWH before and during a clinical study intervention or ATI period, the HIV Intervention Preference Questionnaire (HIV-IPQ) was developed as a patient-reported outcome measure[3] (**Figure 1**)
- An initial round of qualitative interviews with 13 PWH in the United States taking antiretroviral therapy was conducted to confirm the appropriateness of the HIV-IPQ and evaluate its clarity[3]
  - Based on these results, the HIV-IPQ was revised and separated into 2 versions, requiring additional testing with PWH
  - Results from Round 2 testing are presented in this poster

**Figure 1. Development of the HIV-IPQ**




HIV-IPQ, HIV Intervention Preference Questionnaire; PROM, patient-reported outcome measure; PWH, people with HIV.

## Objective

- To assess 2 versions of the HIV-IPQ focusing on the intervention (HIV-IPQ-I) and ATI (HIV-IPQ-ATI) phases of hypothetical clinical trials using qualitative cognitive debriefing interviews

## Methods

- We developed 2 versions of the HIV-IPQ to separately focus on the intervention (HIV-IPQ-I) and ATI (HIV-IPQ-ATI) phases of hypothetical clinical trials (**Table 1**)
- PWH ≥18 years of age who were receiving antiretroviral therapy in the United States participated in virtual, structured, 90-minute cognitive debriefing interviews between March and June of 2025
  - We recruited PWH to ensure diversity in age, sex, gender, race/ethnicity, education, and treatment experience
- Interviewers used a conversational, think-aloud method, in which they encouraged PWH to verbalise their thoughts while completing the HIV-IPQ to assess comprehensibility and clarity, as well as whether the recall period and response options were appropriate
- We analysed transcripts of completed interviews using MAXQDA (v22.6.0 or higher) to identify potential issues with the content, language, structure, and format of the HIV-IPQ
- This process was aligned with the US Food and Drug Administration patient-focused drug development guidelines[4]

**Table 1. HIV-IPQ at a Glance[a]**

| HIV-IPQ-I | HIV-IPQ-ATI |
|---|---|
| **Objective:** to understand the preference of PWH between the treatment they were using prior to the clinical study and the **HIV clinical study intervention period** | **Objective:** to understand the preference of PWH between the treatment they were using prior to the clinical study and the **HIV clinical study ATI period** |
| **Instructions:** for the following questions, please pick the answer that best describes your experience with the HIV treatment that you were using before starting this clinical study compared with your experience during the new **HIV clinical study intervention period** | **Instructions:** for the following questions, please pick the answer that best describes your experience with the HIV treatment that you were using before starting this clinical study compared with your experience during the **HIV medication–free period of this clinical study** |
| **Item 1 concept and response options:**<br>Overall preference<br>❑ Treatment before the study<br>❑ **Study intervention**<br>❑ No preference | **Item 1 concept and response options:**<br>Overall preference<br>❑ Treatment before the study<br>❑ **HIV medication–free period**<br>❑ No preference |
| **Item 2 concept and response options:**<br>Specific areas of preference (eg, convenience, mental burden of taking/receiving medication, emotional impact)<br>❑ Very much prefer treatment before the study<br>❑ Somewhat prefer treatment before the study<br>❑ No preference<br>❑ Somewhat prefer **study intervention**<br>❑ Very much prefer **study intervention** | **Item 2 concept and response options:**<br>Specific areas of preference (eg, convenience, mental burden of managing HIV, emotional impact)<br>❑ Very much prefer treatment before the study<br>❑ Somewhat prefer treatment before the study<br>❑ No preference<br>❑ Somewhat prefer **HIV medication–free period**<br>❑ Very much prefer **HIV medication–free period** |

[a]Bolding denotes differences between the HIV-IPQ-I and HIV-IPQ-ATI.
ATI, analytical treatment interruption; HIV-IPQ, HIV Intervention Preference Questionnaire; HIV-IPQ-ATI, HIV Intervention Preference Questionnaire (Analytical Treatment Interruption); HIV-IPQ-I, HIV Intervention Preference Questionnaire (Intervention); PWH, people with HIV.

## Results

### Study Population

- Characteristics of PWH who participated in the cognitive debriefing interviews are summarised in **Table 2**
- At the time of data analysis, recruitment goals were met for all demographics except gender and age groups <45 years of age

**Table 2. Characteristics of PWH**

| Characteristic, n (%) | Recruitment Goal (%) | PWH (N = 19)[a] |
|---|---|---|
| **Sex assigned at birth** | | |
| Male | ≥50 | 14 (73.7) ✓ |
| Female | ≥25 | 5 (26.3) ✓ |
| **Gender** | | |
| Nonbinary/transgender | ≥10 | 1 (5.3) ⚐ |
| **Age, y** | | |
| 18-24 | ≥10 | 1 (5.3) ⚐ |
| 25-34 | ≥30 | 5 (26.3) ⚐ |
| 35-44 | ≥20 | 3 (15.8) ⚐ |
| ≥45 | ≥20 | 10 (52.6) ✓ |
| **Race** | | |
| African American | ≥40 | 8 (42.1) ✓ |
| White | ≥30 | 10 (52.6) ✓ |
| **Ethnicity** | | |
| Hispanic/Latino(a) | ≥15 | 6 (31.6) ✓ |
| **Highest education level** | | |
| High school diploma or less | ≥20 | 6 (31.6) ✓ |
| **Treatment burden[b]** | | |
| VS on a single-tablet regimen | ≥33 | 12 (63.2) ✓ |
| VSTE on a complex regimen | ≥10 | 2 (10.5) ✓ |
| HTE | ≥6.7 | 2 (10.5) ✓ |

Key: ✓, goal met; ⚐, goal partially met.
[a]Due to time constraints, 9 PWH completed and 1 PWH partially completed the cognitive debriefing interview for the HIV-IPQ-I, and 8 PWH completed the cognitive debriefing interview for the HIV-IPQ-ATI.
[b]Treatment burden categories VSTE and HTE were defined by criteria provided by Gilead Sciences, Inc.; participants could be counted in multiple treatment burden categories.
HIV-IPQ-ATI, HIV Intervention Preference Questionnaire (Analytical Treatment Interruption); HIV-IPQ-I, HIV Intervention Preference Questionnaire (Intervention); HTE, heavily treatment experienced; PWH, people with HIV; VS, virally suppressed; VSTE, virally suppressed treatment experienced.

### Overview of Cognitive Debriefing Results

- Among the 19 PWH who participated in the cognitive debriefing interviews, 9 fully debriefed the HIV-IPQ-I, 1 partially debriefed the HIV-IPQ-I, and 8 fully debriefed the HIV-IPQ-ATI

▶ All instructions and most items from both versions of the HIV-IPQ were interpreted as intended and clear (**Table 3** and **Figure 2**)

- Only Item 1 (treatment plan preference) in the HIV-IPQ-I was reported as unclear by >20% of PWH with evaluable data; 2 of 10 PWH (20%) who interpreted the item as intended noted that the item’s wording was unclear and could be simplified to be more direct (**Table 3**)

▶ Since the majority of PWH interpreted the treatment plan preference item as intended and found it clear, there was no proposed revision for this item

**Table 3. Interpretation and Clarity of the HIV-IPQ-I and HIV-IPQ-ATI**

| Instructions/Item | HIV-IPQ-I | | HIV-IPQ-ATI | |
|---|---|---|---|---|
| | Interpretation | Clarity[a] | Interpretation | Clarity[a] |
| **Instructions** | ✓ | ✓ | ✓ | ✓ |
| **Item 1 (treatment plan preference)** | ✓ | ⚐ | ✓ | ✓ |
| **Item 2 (arrow instructions)** | ✓ | ✓ | ✓ | ✓ |
| **Item 2a (fits with lifestyle)** | ✓ | ✓ | ✓ | ✓ |
| **Item 2b (convenience)** | ✓ | ✓ | ✓ | ✓ |
| **Item 2c (ease of following plan)** | ✓ | ✓ | ✓ | ✓ |
| **Item 2d (ease of accessing plan)** | ✓ | ✓ | ✓ | ✓ |
| **Item 2e (ease of remembering to take/receive treatment)** | ✓ | ✓ | – | – |
| **Item 2e/2f (mental impacts)** | ✓ | ✓ | ✓ | ✓ |
| **Item 2f/2g (emotional impacts)** | ✓ | ✓ | ✓ | ✓ |
| **Item 2g/2h (physical impacts)** | ✓ | ✓ | ✓ | ✓ |
| **Item 2h/2j (confidence HIV is well managed)** | ✓ | ✓ | ✓ | ✓ |
| **Item 2i (method of administration)** | ✓ | ✓ | – | – |
| **Item 2i/2k (relationship with partner)** | ✓ | ✓ | ✓ | ✓ |

Key: ✓, misinterpreted or reported as unclear by <20% of PWH who provided evaluable data; ⚐, misinterpreted or reported as unclear by 20% to 30% of PWH who provided evaluable data.
[a]Clarity was only queried if PWH had interpreted the item as intended.
HIV-IPQ-ATI, HIV Intervention Preference Questionnaire (Analytical Treatment Interruption); HIV-IPQ-I, HIV Intervention Preference Questionnaire (Intervention).

**Figure 2. Representative Feedback Confirming the Content Validity of the HIV-IPQ (Both Versions)**

**Item**

**Item 2a (fits with lifestyle)**
*Fits with your lifestyle or daily routine*

**PWH feedback**

9 of 9 PWH (100%) with evaluable data interpreted as intended, and 8 of 9 (89%) reported as clear

**Representative PWH quotations**

*“Will I have the time to do the study? Will I have—will I—will it—**will I be able to fit it into my time schedule** or yeah, can I fit it in during my day?”*

*“If—well, if I was off the HIV medications, I could—**the daily routine would be different because I wouldn’t have to take the medication in the morning**. I would just take my multivitamin and that’s it. And **then 1 less trip to the pharmacist** and—but it would be a relief that **I wouldn’t have to take it or remember have to take it**.”*

*“Very **clear**.”*

HIV-IPQ, HIV Intervention Preference Questionnaire; PRO, patient-reported outcome; PWH, people with HIV.

- All 5 PWH with evaluable data (100%) reported that they preferred the overall preference question to be positioned at the end of the questionnaire (**Figure 3**)
  - Based on this feedback, the overall preference question will be moved to the end of the questionnaire

**Figure 3. Summary of Feedback on and Revisions to the HIV-IPQ**

**Item**

**Item 1 (treatment plan preference)**

**HIV-IPQ-I:** *Thinking about the treatment you were using before the study compared with the study intervention, which do you prefer?*

**HIV-IPQ-ATI:** *Thinking about the treatment you were using before the study compared with the HIV medication–free period, which do you prefer?*

**PWH feedback**

**HIV-IPQ (both versions):** 5 of 5 PWH (100%) with evaluable data preferred the overall preference question at the end of the questionnaire

**Proposed revision**

Move treatment plan preference question (currently Item 1 in Table 3) to the end of the questionnaire (after Item 2i/2k in Table 3)

**Representative PWH quotation**

*“I think it should **be asked at the end** because, once going through all of the other questions, I think at the end you’ll have a better—well, I’ll say me—**I’ll have a better idea of what I would prefer after going through everything else**.”*

HIV-IPQ, HIV Intervention Preference Questionnaire; HIV-IPQ-ATI, HIV Intervention Preference Questionnaire (Analytical Treatment Interruption); HIV-IPQ-I, HIV Intervention Preference Questionnaire (Intervention); PRO, patient-reported outcome; PWH, people with HIV.

**References: 1.** Julg B, et al. *Lancet HIV*. 2019;6:e259-68. **2.** Dubé K, et al. Presented at: International Society for Pharmacoeconomics and Outcomes Research (ISPOR); 13-16 May 2025; Montreal, QC, Canada. Poster PCR126. **3.** Duracinsky M, et al. Presented at: International Society for Pharmacoeconomics and Outcomes Research (ISPOR); 5-8 May 2024; Atlanta, GA, USA. Poster PCR136. **4.** US Food and Drug Administration. Patient-focused drug development: collecting comprehensive and representative input. Accessed 23 October 2025. https://www.fda.gov/media/139088/download.

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**Correspondence:** Karine Dubé, kdube@health.ucsd.edu

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