

# Content Validation of a Modified PozQoL for Assessing HIV Therapies

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## Conclusions

- There is a need for modernisation of patient-reported outcome measures to accompany advancements in HIV therapeutics, including HIV cure-related interventions
- The results of this study support the content validity of the modified PozQoL and its suitability and practicality in HIV cure-related clinical trial settings that include a complex regimen phase along with an analytical treatment interruption**
- An additional Round 2 interview is planned in order to meet sample size goals
- The modified PozQoL will be considered for use in future HIV studies, and its psychometric properties will be assessed using trial data

## Plain Language Summary

- For clinical trials that test new ways of managing HIV, it is important to understand how people who participate in the trials believe that their quality of life has changed
- Researchers developed the PozQoL questionnaire to measure the quality of life of people with HIV
- A review of the PozQoL identified that it was a promising measure to use in participants who may be taking HIV medicines and those who hypothetically may stop taking their HIV medicines
- In this study, the PozQoL was modified for use in HIV cure-related clinical trials, tested in people with HIV, and refined based on their feedback
- People with HIV found that the modified version was easy to understand
- The final version of the PozQoL was determined to be an acceptable questionnaire to use for measuring quality of life in people with HIV during a clinical trial
  - Relevance of the items will be further evaluated when the measure is administered in HIV cure-related trials and undergoes further psychometric evaluation

## Introduction

- HIV cure-related clinical trials typically require analytical treatment interruptions (ATIs)
- It is hypothesised that the absence of regular adherence to medication during the ATI may improve quality of life by decreasing the burden associated with daily treatment
- Patient-reported outcome measures are essential tools for capturing patient perspectives on health status and quality of life<sup>1</sup>
- The PozQoL is a 13-item questionnaire that assesses psychological, social, health, and functional concepts for people with HIV (PWH)<sup>2</sup>

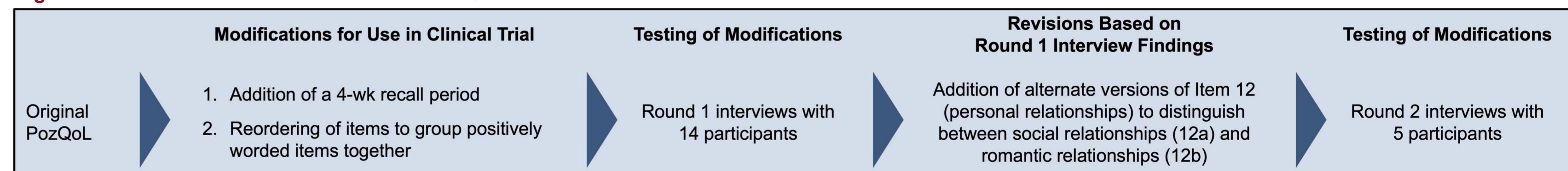
## Objective

- To evaluate a modified version of the PozQoL that incorporated revisions from the research team, external clinical experts from France and the United States, and a PWH advocate to ensure its suitability and practicality for use in HIV cure-related clinical trials that include a complex regimen phase along with an ATI

## Methods

- We modified the PozQoL so that positively worded items were grouped together and a 4-week recall period was added to the instructions (Figure 1)
- We conducted a set of hybrid concept elicitation and cognitive debriefing interviews with 14 PWH in the United States currently on antiretroviral therapy to assess the content validity of the modified PozQoL (Round 1)
- To be eligible for the study, individuals must have been aged  $\geq 18$  years; able to read, write, and comprehend US English; willing and able to participate in a 90-minute interview via videoconferencing or telephone; diagnosed with HIV; and receiving antiretroviral therapy for HIV for  $\geq 12$  months
  - Individuals were excluded if they were previously diagnosed with AIDS or unable to understand the nature, scope, and possible consequences of the study
- We analysed interview transcripts for issues with content, language, and structure/format in the modified PozQoL
- Based on feedback from Round 1, we revised the modified PozQoL again and underwent further cognitive debriefing interviews with an additional 5 PWH to ensure its comprehensibility, clarity, and relevance (Round 2)

Figure 1. Overview of Modifications to the PozQoL



## Results

### Study Population

- At the time of this analysis, recruitment goals across Rounds 1 and 2 were met for all demographics except gender and multiple age groups; these goals were partially met (Table 1)

Table 1. Study Population Characteristics

Characteristic	Recruitment Goal (%)	Actual n (%) for Round 1 (N = 15) <sup>a</sup>	Actual n (%) for Round 2 (N = 19) <sup>a</sup>	Total (N = 34)
Sex assigned at birth				
Male	$\geq 50.0$	9 (60.0)	14 (73.7)	23 (67.6) <span style="color: green;">✓</span>
Female	$\geq 25.0$	6 (40.0)	5 (26.3)	11 (32.4) <span style="color: green;">✓</span>
Gender				
Nonbinary/transgender	$\geq 10.0$	1 (6.7)	1 (5.3)	2 (5.9) <span style="color: orange;">□</span>
Age, y				
18-24	$\geq 10.0$	1 (6.7)	1 (5.3)	2 (5.9) <span style="color: orange;">□</span>
25-34	$\geq 30.0$	4 (26.7)	5 (26.3)	9 (26.5) <span style="color: orange;">□</span>
35-44	$\geq 20.0$	3 (20.0)	3 (15.8)	6 (17.6) <span style="color: orange;">□</span>
$\geq 45$	$\geq 20.0$	7 (46.7)	10 (52.6)	17 (50.0) <span style="color: green;">✓</span>
Race				
African American	$\geq 40.0$	8 (53.3)	8 (42.1)	16 (47.1) <span style="color: green;">✓</span>
White	$\geq 30.0$	7 (46.7)	10 (52.6)	17 (50.0) <span style="color: green;">✓</span>
Ethnicity				
Hispanic/Latino(a)	$\geq 15.0$	3 (20.0)	6 (31.6)	9 (26.5) <span style="color: green;">✓</span>
Highest level of educational achievement				
High school diploma or less	$\geq 20.0$	3 (20.0)	6 (31.6)	9 (26.5) <span style="color: green;">✓</span>
Treatment burden <sup>b</sup>				
VS on a single-tablet regimen	$\geq 33.0$	12 (80.0)	12 (63.2)	24 (70.6) <span style="color: green;">✓</span>
VSTE on a complex regimen	$\geq 10.0$	3 (20.0)	2 (10.5)	5 (14.7) <span style="color: green;">✓</span>
HTE	$\geq 6.7$	1 (6.7)	2 (10.5)	3 (8.8) <span style="color: green;">✓</span>

Key: ✓, goal met; □, goal partially met.

<sup>a</sup>Due to time constraints, only 14 of 15 Round 1 participants and 5 of 9 Round 2 participants were able to debrief the modified PozQoL. <sup>b</sup>Treatment burden categories VSTE and HTE were defined by criteria provided by Gilead Sciences, Inc.; participants could be counted in multiple treatment burden categories.

HTE, heavily treatment experienced; VS, virally suppressed; VSTE, virally suppressed treatment experienced.

### Cognitive Debriefing

- During Round 1, the modified PozQoL was cognitively debriefed with 14 PWH, and potential clarity issues were identified for 3 items (lack a sense of belonging [Item 6], worn out due to HIV management [Item 11], and HIV limits my personal relationships [Item 12]) by 2 participants for each item
- For the Round 2 interviews (n = 5), no changes in the modified PozQoL were implemented for Items 6 and 11
- However, 2 alternate versions of Item 12 were added to differentiate between social and romantic relationships

► Across Rounds 1 and 2 (n = 19),  $\geq 80\%$  of PWH interpreted each of the items on the modified PozQoL as intended (Table 2)

- Additionally,  $\geq 80\%$  of PWH reported that each of the items, including the new Alternate Items 12a and 12b, was clear (Table 2)
- Despite some relevancy issues with certain items, 7 of the 13 original items were relevant to  $\geq 80\%$  of PWH in the past 4 weeks (Table 2)

Table 2. Overview of Cognitive Debriefing Results<sup>a</sup>

Instructions/Item	Statement	Interpretation	Clarity	Response Option Interpretation/Clarity	Relevance
Instructions	N/A	✓	✓	N/A	N/A
Item 1 <sup>b</sup>	I am enjoying life.	✓	✓	✓	✓
Item 2 <sup>b</sup>	I feel good about myself as a person.	✓	✓	✓ <sup>c</sup>	✓
Item 3 <sup>b</sup>	I feel in control of my life.	✓	✓	✓ <sup>c</sup>	✓
Item 4 <sup>b</sup>	I am optimistic about my future.	✓	✓	✓ <sup>c</sup>	✓
Item 5 <sup>d</sup>	I worry about my health.	✓	✓	✓ <sup>c</sup>	✓
Item 6 <sup>e</sup>	I lack a sense of belonging with people around me.	✓	✓	✓ <sup>c</sup>	<span style="color: red;">✗</span>
Item 7 <sup>f</sup>	I feel that HIV prevents me from doing as much as I would like.	✓	✓	✓ <sup>c</sup>	<span style="color: red;">✗</span>
Item 8 <sup>f</sup>	Having HIV limits my opportunities in life.	✓	✓	✓ <sup>c</sup>	<span style="color: red;">✗</span>
Item 9 <sup>d</sup>	I worry about the impact of HIV on my health.	✓	✓	✓ <sup>c</sup>	✓
Item 10 <sup>e</sup>	I am afraid that people may reject me when they learn I have HIV.	✓	✓	✓ <sup>c</sup>	<span style="color: orange;">□</span>
Item 11 <sup>f</sup>	Managing HIV wears me out.	✓	✓	✓ <sup>c</sup>	<span style="color: red;">✗</span>
Item 12 <sup>e</sup>	I feel that HIV limits my personal relationships.	✓	✓	✓ <sup>c</sup>	<span style="color: red;">✗</span>
Alternate Item 12a <sup>b</sup>	I feel that HIV limits my social relationships.	✓	✓	✓ <sup>c</sup>	<span style="color: red;">✗</span>
Alternate Item 12b <sup>b</sup>	I feel that HIV limits my romantic relationships.	✓	✓	✓ <sup>c</sup>	✓
Item 13 <sup>d</sup>	I fear the health effects of HIV as I get older.	✓	✓	✓ <sup>c</sup>	✓

Key: ✓, misinterpreted or reported as unclear by  $\leq 20\%$  of participants who provided evaluable data; □, misinterpreted or reported as unclear by  $20\%$  to  $30\%$  of participants who provided evaluable data; ✗, misinterpreted or reported as unclear by  $>30\%$  of participants who provided evaluable data.

<sup>a</sup>Due to time constraints, only 14 of 15 Round 1 participants and 5 of 9 Round 2 participants were able to debrief the modified PozQoL. <sup>b</sup>Items 1 through 4 are categorised under the "psychological" domain of well-being. <sup>c</sup>The response options for Items 1 to 13 were the same, so the response options were debriefed once at first mention (Item 1). <sup>d</sup>Items 5, 9, and 13 are categorised under the "health concerns" domain of well-being. <sup>e</sup>Items 6, 10, 12, 12a, and 12b are categorised under the "social" domain of well-being. <sup>f</sup>Items 7, 8, and 11 are categorised under the "functional" domain of well-being.

N/A, not applicable.

References: 1. Weldring T, Smith SMS. *Health Serv Insights*. 2013;6:61-8.

2. Brown G, et al. *BMC Public Health*. 2018;18:527.

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► The difference in relevancy results by recall period may reflect how participants in this study had their HIV well under control and therefore may not have recently had quality of life-related concerns

- Based on these findings, no further modifications beyond those made prior to Round 1 will be made; the modified PozQoL will retain positive grouping of items and a 4-week recall period
  - Further assessment of relevancy will be considered during psychometric validation of the modified PozQoL

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