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Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

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ABSTRACT

Objectives: The Short-Form HIV Disability Questionnaire (SF-HDQ) was developed to measure the presence, severity and episodic nature of health challenges across six domains. Our aim was to assess the sensibility, utility and implementation of the Short-Form HIV Disability Questionnaire (SF-HDQ) in clinical practice.

Design: Mixed methods study design involving semi-structured interviews and questionnaire administration.

Participants: We recruited adults living with HIV and HIV clinicians in Canada, Ireland, and the United States.

Methods: We electronically administered the SF-HDQ followed by a sensibility questionnaire (face and content validity, ease of usage, format) and conducted semi-structured interviews to explore utility and implementation of the SF-HDQ in clinical practice. The threshold for sensibility was a median score of ≥5/7 (adults living with HIV) and ≥4/7 (HIV clinicians) for ≥80% of items. Qualitative interview data were analyzed using directed content analysis.

Results: Median sensibility scores were ≥5 (adults living with HIV; n=29) and ≥4 (HIV clinicians; n=16) for 18/19 (95%) items. Interview data indicated that the SF-HDQ represents the health-related challenges of living with HIV and other concurrent health conditions; captures the daily episodic nature of HIV; and is easy to use. Clinical utility included measuring health challenges and change over time, guiding referral to specialists and services, setting goals, facilitating communication, and fostering a multi-disciplinary approach to care. Considerations for implementation included flexible, person-centered approaches to administration, and communicating scores based on personal preferences.

Conclusions: The SF-HDQ possesses sensibility and utility for use in clinical settings with adults living with HIV and HIV clinicians in three countries.

KEY WORDS

HIV, disability evaluation, questionnaires, sensibility, measurement, reliability and validity, interview

STRENGTHS & LIMITATIONS OF THIS STUDY

- Our mixed methods approach involving qualitative and quantitative approaches ensured a comprehensive assessment of sensibility, utility and implementation of the Short-Form HIV Disability Questionnaire (SF-HDQ) in clinical practice.
- Our multi-site approach spanning three different clinical contexts with both adults living with HIV and health care practitioners spanning three different clinical contexts enabled us to assess the utility of the electronic mode of SF-HDQ administration, and examine considerations for implementation across three different healthcare contexts.
- This study draws on a strong conceptual foundation of episodic disability (Episodic Disability Framework) and measurement of disability (Short Form-HIV Disability Questionnaire).
- Given our SF-HDQ assessment was focused on electronic administration, this limited participation to adults living with HIV who had access to, and comfort with, the use of technology to complete the questionnaires and participate in the interview in a web-based format.

INTRODUCTION

In developed countries such as Canada, Ireland and the United States, HIV is now experienced as a chronic illness.[1] In 2018, an estimated 51% of Americans living with HIV were aged 50 and older[2] and similar trends are forecast in other countries such as Canada and the United Kingdom (UK) with access to treatment.[3 4] Individuals with HIV can reach life expectancies similar to the general population. However, more individuals are living longer with the health consequences of HIV. People living with HIV can experience chronic conditions at higher rates compared to the general aging population[5 6] such as cardiovascular disease[7], bone and joint disorders[8 9], diabetes[10], frailty[11], neurocognitive disorders[12 13], and some forms of cancer.[14] This multimorbidity can increase the severity and complexity of health consequences of those aging with HIV[15-18], collectively referred to as disability.[17 19]

Disability is defined by people living with HIV as any physical, cognitive, mental-emotional symptoms, difficulties with day-to-day activities, challenges to social inclusion, and uncertainty about future health [17]. Disability including fatigue, pain, challenges engaging in employment, and age-related issues of frailty; coupled with poor access to services, stigma, and poverty can pose barriers to remaining engaged in care for people living with HIV.[20]

Standardized patient reported outcome measures (PROMs) developed to capture the nature and extent of disability and its fluctuation over time are critical to identify health priorities for those aging with HIV, to guide the provision of timely and appropriate care, and to determine the effectiveness of interventions.[21-23] We developed a 69-item PROM, the HIV Disability Questionnaire (HDQ) to measure the presence, severity and episodic nature of disability experienced by people living with HIV.[24] Derived from the *Episodic Disability Framework,* the HDQ measures disability across 69-items grouped into six domains: i) physical, ii) mental-emotional, and iii) cognitive symptoms and impairments, iv) difficulties with day-to-day activities, v) challenges to social inclusion and vi) uncertainty about future health.[25] The HDQ addresses gaps in previously existing health status measures to capture uncertainty (e.g. worrying about the future) and challenges to social inclusion (e.g. work, parental roles, relationships)[26] and possesses

sensibility, reliability and validity for use among people living with HIV in Canada, United Kingdom, United States and Ireland.[27-29]

To date the HDQ has been used primarily as a paper-based tool in research-focused settings, with little uptake in clinical practice due to concerns about the time it takes to complete. We recently revised the HDQ using Rasch analysis to a short-form version of the questionnaire (SF-HDQ) to enhance the feasibility for use in clinical practice.[30] To date, the development and structural validity of the SF-HDQ primarily have been established in Canada.[30] However the sensibility, specifically the comprehensiveness, clarity, ease of usage and format for use of the SF-HDQ in clinical settings is unknown.[31-33]

Our aims were to (i) assess the sensibility (face and content validity, ease of usage, format) of the SF-HDQ, (ii) explore perspectives on the utility of the electronic SF-HDQ in clinical practice, and (iii) identify implementation considerations for administration and communicating scores of the SF-HDQ in clinical practice in Canada, Ireland and the United States from the perspectives of adults living with HIV and HIV health care practitioners.

METHODS

Study Design

We conducted a mixed methods study with a convergent design using quantitative (questionnaire) and qualitative (interview) methods of data collection.

Study Setting

This study was conducted at three clinical settings in three countries: Canada (Casey House, Toronto), Ireland (Department of Genitourinary Medicine and Infectious Diseases (GUIDE), St. James's Hospital, Dublin), and the United States (The UCHealth Infectious Disease/Travel Clinic, University of Colorado). The UCHealth Infectious Disease/Travel Clinic is located in Aurora, Colorado, and provides care to people living with HIV in the Denver metropolitan area, and henceforth is referred to as the 'Denver site'. The Dublin and Denver sites are HIV outpatient clinics and the Toronto site is a specialty HIV hospital

including an inpatient and day health program for people living with HIV. We received ethics approval at the three sites: University of Toronto (Protocol #38152), University of Colorado (Protocol #19-1895) and St. James's Hospital (Protocol #2019-12) (Supplemental File 1).

Patient and Public Involvement

This research builds on a longstanding academic-clinical-community partnership among people ageing with HIV, researchers, and clinicians who identified measurement of disability as a key research priority in HIV, aging and rehabilitation as part of the Canada-International HIV and Rehabilitation Research Collaborative (CIHRRC).[34] Community members living with HIV were involved in the development of the original HIV Disability Questionnaire (HDQ) and the refinement of the SF-HDQ.

Participants

Adults Living with HIV: We recruited adults (18 years of age or older) living with HIV from each site using a recruitment poster asking interested individuals to contact the local study investigator (by email or telephone). We used purposive sampling to obtain diversity in the sample based on age (≥50 years, <50 years) and clinical site.

HIV Health Care Practitioners: We recruited health care practitioners working in HIV care at each site who self-identified as having a role in addressing disability due to HIV, aging and multi-morbidity. We emailed a targeted sample of HIV health care practitioners including (but not limited to) physicians, rehabilitation professionals (occupational therapy, physiotherapy), social workers, and nurses requesting their participation in the study.

We obtained written or verbal consent from all participants prior to the scheduled administration of the questionnaires and interview.

Data Collection

Adults living with HIV completed the electronic version of the SF-HDQ[30], a global rating scale of disability, a Sensibility Questionnaire and a demographic questionnaire using the web-based software

Qualtrics[35] (either via tablet at the clinical site or remotely via an email link) followed by a one-to-one semi-structured interview (either in person or via Zoom). Health care practitioners were asked to review the electronic version of the SF-HDQ and complete the Sensibility Questionnaire (via Qualtrics) prior to participating in the semi-structured interview. Team members in Canada (RA), Ireland (NOS) and the United States (MB) (all female) conducted the interviews and questionnaire administration. None had a prior relationship with participants.

Questionnaires

Short-Form HIV Disability Questionnaire: The SF-HDQ is a 35-item outcome measure developed to describe the health-related challenges experienced living with HIV or other health conditions across six areas; physical, cognitive and mental-emotional symptoms and impairments, uncertainty or worry about the future; difficulties with day-to-day activities; and challenges to social inclusion.[30] Participants are asked to rate the presence and severity of each health-related challenge and to indicate whether it fluctuated in the past week. The SF-HDQ possesses structural validity for use with adults living with HIV.[30]

Sensibility: Using Feinstein's sensibility criteria[31] comprised of 19 statements (7-point response scale ranging from highly disagree to highly agree), participants living with HIV and health care practitioners were asked about perspectives on face and content validity, mode of administration, format, and ease of usage of the SF-HDQ.[27] See Supplemental File 2 for the Sensibility Questionnaire.

To describe characteristics of the sample, participants living with HIV were asked to rate their health-related challenges (or disability) as minimum, moderate or severe and complete a demographic questionnaire comprised of items including age, gender, concurrent health conditions, living situation, antiretroviral use and overall perception of health.

Interviews

Sensibility and Utility: We asked about the utility of the SF-HDQ in practice and participants' experiences with completing or perspectives on potentially administering the SF-HDQ. We also asked about perceived

facilitators and challenges related to administering the SF-HDQ in a clinical setting and considerations related to administration including feasibility, format (electronic or paper), when to administer, who should administer, how often to administer and whether and how to communicate SF-HDQ score reports with patients. See Supplemental File 3 for the Interview Guide.

Interviews were conducted by one interviewer in Canada, one in Ireland and two interviewers in the United States. Due to restrictions of the COVID-19 pandemic, most interviews were conducted using the video platform Zoom. All interviews were audio recorded, transcribed verbatim and de-identified for analysis. Data collection and analysis were done concurrently. We refined the interview guide twice over the course of the study, adding probing questions based on the analysis of earlier interviews.

Participants in Toronto, Ontario and Denver, Colorado were given a $30 CAD (or equivalent) gift card as a token of appreciation. Participants in Dublin, Ireland were not given a token of appreciation in keeping with the research procedures at St. James's Hospital.

Analysis

SF-HDQ Scoring: We calculated median (interquartile ranges (IQR)) of SF-HDQ scores. Severity domain scores were calculated using the algorithm developed through Rasch analysis.[30] Presence and episodic scores included a simple sum transformed on scale of 0-100 with higher scores indicating a greater presence, severity and episodic nature of disability.

Sensibility Questionnaire: Each sensibility item was rated on an ordinal scale of 1 (highly disagree) to 7 (highly agree). Participants selected the numeric response on the scale for each item. We calculated median scores for each of the items. We considered the SF-HDQ sensible if median scores were ≥5/7 for adults living with HIV and ≥4/7 for health care practitioners for at least 80% of the items, and if no items had median scores of ≤3.[27]

Interview Data: We analyzed interview transcripts using content analytical techniques.[36] For sensibility assessment, we used directed content analysis, using initial coding categories derived from Feinstein's Sensibility Framework.[31] For utility and implementation considerations, we used a conventional content analytical approach.[36] Transcripts from participants living with HIV and HIV health care practitioners were analyzed collectively using the same coding scheme. The core qualitative team (MS, KKO, PS) met three times. They initially reviewed two transcripts independently and met to develop, by consensus, a preliminary list of codes and categories based on the interview guide and the two transcripts. The lead analyst (MS) coded five additional transcripts using the preliminary list of codes and then selected three transcripts for the core team to review and discuss. After all the transcripts were coded, the core team reviewed an additional three transcripts and coding reports from the full dataset. At this meeting, the relationships between coding categories were discussed and key themes were identified. Finally, the larger full team met to review, interpret and finalize the themes in relation to our study objectives. NVivo V11.0 QSR International software was used for data management.[37]

Sample size

Our goal was to recruit a total of 30 adults living with HIV (10 per site) and 15 health care practitioners (5 per site) for a total of 45 participants. Based on our previous sensibility work, we anticipated this sample was sufficient to provide perspectives of utilization across sites.[27 38]

RESULTS

We conducted 45 interviews (29 with adults living with HIV and 16 with HIV health care practitioners) between March 3, 2020 and February 2021, each approximately 45 minutes in duration. Sixteen interviews were held in-person (5 participants living with HIV in Toronto; and 5 people living with HIV and 6 health care practitioners in Dublin), and 29 interviews were conducted online through Zoom.

Participant Characteristics

See Table 1 for characteristics of the participants living with HIV. Eight participants in Toronto described having past experiences with the longer version of the HDQ, whereas no participants in Dublin or Denver had any prior experiences with the HDQ. Thirteen participants (46%) reported having minimum, 11 (39%) moderate and 4 (14%) severe health-challenges.

Table 1: Characteristics of Participants Living with HIV

Characteristic	Total Sample (n=29)	Toronto (n=10)	Colorado (n=10)	Dublin (n=9)
Age (in years) (median, 25-75th percentile)	57 (51, 63)	60 (55, 66)	49 (37,63)	57 (53,63)
Gender				
Woman	10 (35%)	2 (20%)	5 (50%)	3 (33%)
Man	19 (66%)	8 (80%)	5 (50%)	6 (67%)
Partnership status				
Single, Separated or Divorced, or Widowed	15 (66%)	10 (100%)	5 (50%)	5 (56%)
Married, common-law, partner or relationship	8 (28%)	0 (0%)	5 (50%)	3 (33%)
Has children	12 (41%)	3 (30%)	5 (50%)	4 (44%)
Living alone	14 (48%)	7 (70%)	3 (30%)	4 (44%)
Employed (full time or part time)	7 (24%)	1 (10%)	4 (40%)	3 (33%)
Highest level of education				
Completed university or post graduate education	6 (21%)	2 (20%)	4 (40%)	0 (0%)
Median year of HIV diagnosis (25-75th percentile)	1996 (1986, 2004)	1990 (1986, 2003)	2002 (1994, 2005)	1991 (1987, 2011)
Antiretroviral therapy use	27 (93%)	9 (90%)	10 (100%)	8 (89%)
Undetectable viral load (<50 copies/mL)	26 (90%)	10 (100%)	10 (100%)	6 (67%)
Median number of concurrent health conditions (25-75th percentile)	7 (4, 10)	10 (6,14)	7 (5,8)	4 (2,11)
Common concurrent health conditions (*≥30% of sample)*				
Mental Health Condition	17 (59%)	8 (80%)	5 (50%)	4 (44%)
Trouble sleeping	16 (55%)	6 (60%)	5 (50%)	5 (56%)
Chronic pain (joint)	15 (52%)	7 (70%	5 (50%)	3 (33%)
High blood pressure	12 (41%)	6 (60%)	3 (30%)	3 (33%)
High cholesterol	11 (38%)	4 (40%)	5 (50%)	2 (22%)
Osteopenia or osteoporosis	10 (35%)	0 (0%)	4 (40%)	6 (67%)
Chronic pain (muscle)	9 (31%)	5 (50%)	3 (30%)	1 (11%)
Cognitive decline	9 (31%)	5 (50%)	1 (10%)	3 (33%)
Gastrointestinal conditions	9 (31%)	3 (30%)	4 (40%)	2 (22%)
General Health Status				
Excellent	9 (31%)	3 (30%)	3 (30%)	3 (33%)
Very good	7 (24%)	3 (30%)	3 (30%)	1 (11%)
Good	7 (24%)	3 (30%)	2 (20%)	2 (22%)
Fair	3 (10%)	0 (0%)	1 (10%)	2 (22%)
Poor	2 (7%)	1 (10%)	1 (10%)	0 (0%)

Characteristics reported for 28 of 29 participants (1 participant from Dublin site did not complete).

Across the sample of adults living with HIV (n=29), the highest SF-HDQ presence and severity scores were in the cognitive (median score: 67) and mental-emotional (median score: 37) domains; and the highest episodic scores were in the mental-emotional and physical domains (median score: 20). The majority of participants (93%) considered themselves as having a 'good day' on the day they completed the SF-HDQ in relation to their overall health (Table 2).

Table 2: Short-Form HIV Disability Questionnaire (SF-HDQ) Scores for Participants living with HIV (n=29)

SF-HDQ Domains	**Entire Sample (n=29)** Median (25-75th percentile)	**Toronto (n=10)** Median (25-75th percentile)	**Colorado (n=10)** Median (25-75th percentile)	**Dublin (n=9)** Median (25-75th percentile)
Presence Domain Scores				
Physical	40 (30, 80)	65 (30, 90)	40 (30, 50)	50 (25, 70)
Cognitive	67 (33, 100)*	100 (50, 100) *	33 (25, 75)	67 (17, 100)*
Mental-Emotional	60 (30, 90)	70 (35, 100)	60 (15, 85)	60 (30, 80)
Uncertainty	60 (40, 80)	40 (20, 85)	80 (40, 85)*	60 (30, 90)
Day to Day Activities	40 (10, 100)	80 (40,100)	30 (0, 100)	20 (20, 60)
Social Inclusion	29 (14, 57)	36 (14, 64)	29 (0, 50)	29 (7, 57)
Severity Domain Scores				
Physical	28 (20, 50)	44 (23, 53)	22 (20, 34)	28 (18, 44)
Cognitive	20 (11, 35)	35 (15, 37)	11 (8, 26)	28 (6, 35)
Mental-Emotional	37 (14, 51)*	46 (16,56)*	37 (8, 44)*	26 (14, 43)
Uncertainty	30 (17, 46)	33 (15, 46)	30 (17, 43)	30 (17, 47)*
Day to Day Activities	21 (4, 39)	29 (15,41)	11 (0, 41)	15 (8, 28)
Social Inclusion	21 (8,34)	30 (13,41)	18 (0,32)	21 (7, 36)
Episodic (fluctuating in the past week) Domain Scores				
Physical	20 (0, 40)*	30 (8, 70)	20 (0, 25)*	10 (0, 40)
Cognitive	0 (0, 67)	34 (0, 75)*	0 (0, 50)	0 (0, 84)
Mental-Emotional	20 (0, 70)*	30 (0, 65)	0 (0, 85)	40 (0, 60)*
Uncertainty	0 (0, 40)	20 (0, 40)	0 (0, 65)	0 (0, 40)
Day to Day Activities	0 (0, 40)	30 (0,40)	0 (0, 25)	20 (0, 50)
Social Inclusion	0 (0, 14)	7 (0,14)	0 (0, 7)	0 (0, 0)
Good Day-Bad Day Item "In terms of your overall health, are you having a good day or bad day today?"				
Good day	27 (93%)	10 (100%)	10 (100%)	7 (89%)
Bad day	2 (7%)	0 (0%)	0 (0%)	2 (22%)

n=29 participants completed the SF-HDQ; Score range: 0-100

*Highest scores across domains.

Sixteen HIV health care practitioners participated in Toronto (n=5), Denver (n=5) and Dublin (n=6). They included physicians (n=5), social workers (n=3), nurses (n=3), physiotherapists (n=2), a physiotherapy resident (n=1), massage therapist (n=1), and pharmacist (n=1).

Sensibility, Utility and Implementation Considerations of the SF-HDQ

We describe sensibility findings derived in combination from the sensibility questionnaire and interview data. Results pertaining to utility and implementation considerations were drawn from the interview data. We reference quotations with each participant number (P), the target population: participant living with HIV (PLWH) or health care practitioner (HCP); and country: Canada (CAN), Ireland (IRE) or United States (US).

A – SENSIBILITY

Collectively, results from the sensibility questionnaire and interviews indicate that the SF-HDQ possesses face and content validity and is easy to use with adults living with HIV. Sensibility questionnaire results indicate the SF-HDQ met our criterion for sensibility with adults living with HIV (Table 3) but not health care practitioners, because one item had a median score ≤3 (item 9 – *There were items missing in this questionnaire that should be included*) (Table 4).

Table 3: Sensibility Questionnaire for Adults living with HIV

Sensibility Item – Adults Living with HIV	Entire Sample (n=28 to 29) Median (25-75th percentile)	Toronto (n=10) Median (25-75th percentile)	Colorado (n=10) Median (25-75th percentile)	Dublin (n=8 to 9) Median (25-75th percentile)
Face Validity				
1. I was able to answer all of the questions.	7 (7,7)	7 (7,7,)	7 (7,7)	7 (5,7)
2. The instructions were clear and easy to understand.	7 (6,7)	7 (7,7)	7 (5,7)	7 (5,7)
3. The questions were clear and easy to understand.	7 (7,7)	7 (7,7)	7 (6,7)	7 (6,7)
4. The overall questionnaire makes sense.	6 (5,7)	7 (6,7)	7 (5,7)	5 (5,6)
5. The response categories (or options) for the questions were adequate.	6 (5, 7)	6 (4,7)	7 (5,7)	5 (5,6)
Content Validity				
6. The questionnaire captured all elements of my disability.	5 (4,7)	7 (4,7)	6 (4,7)	5 (3,5)
7. The questionnaire included important items that are necessary to describe my disability.	6 (5,7)	7 (5,7)	7 (6,7)	5 (4,5)
8. The questionnaire included items that were repetitive or redundant.*	5 (4,5)	5 (5,5)	5 (5,6)	4 (3,5)
9. There were items missing in this questionnaire that should be included.*	4 (3,5)	4 (2,5)	5 (4,6)	4 (3,5)
10. Some of the questions seemed out of order.*	5 (4,7)	5 (3,7)	6 (4,7)	6 (5,7)
11. I was able to find my answer in the list of possible answers to the questions.	6 (4,7)	7 (3,7)	7 (5,7)	5 (4,6)
Format and Ease of Usage				
12. I felt uncomfortable answering some of the questions because I did not want to have anyone know my answers.*	7 (5,7)	7 (5,7)	7 (5,7)	7 (5,7)
13. I felt that the questions made me think about things that I would have preferred not to have thought about.*	5 (5,7)	5 (5,7)	7 (5,7)	6 (5,7)
14. I felt that answering the questions helped me in some way.	5 (4,5)	5 (4,7)	4 (4,5)	5 (2,5)
15. The questionnaire took too long for me to complete.*	6 (5,7)	5 (5,7)	6 (5,7)	5 (5,7)
16. The questionnaire required too much effort to complete.*	7 (5,7)	6 (5,7)	7 (6,7)	6 (5,7)
17. The questionnaire was easy to complete using the electronic tablet.	7 (5,7)	7 (5,7)	7 (6,7)	5 (5,7)
18. I would like to receive a summary of my HDQ questionnaire scores right after completing the questionnaire to help understand the areas (or domains) where I might experience health challenges.	5 (4,7)	5 (5,7)	6 (4,7)	5 (4,5)
19. Overall, this questionnaire is useful in describing disability experienced by adults living with HIV.	5 (5,7)	5 (5,7)	6 (5,7)	5 (4,5)

Sample size: n=29 for items #1-5; n=28 for items #6-19. One participant from Dublin site did not complete items 6-19 for the sensibility questionnaire. *indicates questionnaire responses were reversed for median scoring purpose.

Table 4: Sensibility Questionnaire for HIV Health Care Practitioners

Sensibility questionnaire items for health care practitioners	**Entire Sample (n=15)** Median (25-75th percentile)	**Toronto (n=5)** Median (25-75th percentile)	**Colorado (n=5)** Median (25-75th percentile)	**Dublin (n=5)** Median (25-75th percentile)
Face Validity				
1. My clients would be able to answer all of the questions.	7 (6,7)	7 (7,7)	7 (6,7)	7 (4,7)
2. The instructions were clear and easy to understand.	6 (5, 7)	7 (6,7)	7 (6,7)	5 (5,7)
3. The questions were clear and easy to understand.	7 (5,7)	7 (6,7)	7 (6,7)	5 (4,7)
4. The overall questionnaire makes sense.	6 (5,7)	7 (6,7)	6 (5,7)	5 (4,7)
5. The response categories (or options) for the questions were adequate.	5 (5,7)	7 (5,7)	5 (5,7)	5 (4,7)
Content Validity				
6. The questionnaire captured all elements of my clients' disability.	5 (5,7)	6 (4,7)	4 (3,6)	4 (3,6)
7. The questionnaire included important items that are necessary to describe my clients' disability.	5 (4,7)	7 (6,7)	5 (4,6)	4 (4,6)
8. The questionnaire included items that were repetitive or redundant.*	5 (4,6)	5 (3,7)	6 (4,7)	5 (5,6)
9. There were items missing in this questionnaire that should be included.*	**3 (3,6)**	**3 (2,6)**	4 (2,6)	**3 (2,5)**
10. Some of the questions seemed out of order. *	6 (5,7)	7 (5, 7)	6 (4,7)	6 (5,7)
11. My clients would be able to find their answer in the list of possible answers to the questions.	6 (5,7)	7 (6,7)	6 (5,7)	5 (4,6)
Format and Ease of Usage				
12. My clients would feel uncomfortable answering some of the questions because they may not want to have anyone know their answers.*	5 (3,7)	4 (3,6)	5 (4,7)	6 (3,7)
13. My clients would feel that the questions made me think about things that they would have preferred not to have thought about.*	4 (3,5)	5 (3,6)	4 (2,6)	4 (3,5)
14. My clients would feel that answering the questions helped them in some way.	5 (5,6)	6 (5,7)	6 (5,7)	5 (5,5)
15. The questionnaire would take too long for my clients to complete.*	5 (4,7)	5 (2,6)	5 (4,7)	5 (5,7)
16. The questionnaire would required too much effort to complete.*	5 (4,7)	5 (2,6)	5 (4,7)	5 (5,7)
17. The questionnaire would be easy to complete using the electronic tablet.	6 (5,7)	7 (5,7)	7 (6,7)	5 (4,6)
18. My clients would like to receive a summary of their HDQ questionnaire scores right after completing the questionnaire to help understand the areas (or domains) where they might experience health challenges.	5 (4,7)	5 (5,6)	4 (3,6)	6 (5,7)
19. Overall, this questionnaire is useful in describing disability experienced by adults living with HIV.	6 (5,7)	6 (6, 7)	6 (5,7)	5 (5,7)

Sample size: 15 participants (n=1 participant Dublin site did not complete the sensibility questionnaire) *indicates questionnaire responses reversed for median scoring purpose; **bolded** indicates items that did not meet criterion for sensibility scoring ≤3.

However, the interview findings indicate that the SF-HDQ is comprehensive, represents health related challenges (disability) living with HIV, adequately captures the episodic nature of disability and captures disability related to other conditions. Participants indicated that the SF-HDQ was easy to complete and that the items were easy to understand (ease of usage) and that the format was easy to use (adequate length, adequate response options). When asked about items missing from the SF-HDQ, a few participants commented on the importance of considering HIV stigma, HIV disclosure, addiction and substance use when measuring disability living with HIV. Participants also provided reflections on disability terminology.

SF-HDQ Items Represent Health-Related Challenges (Disability) Living with HIV: Participants agreed that the items in the SF-HDQ capture the disability experienced living with HIV, indicating the questionnaire possesses face and content validity. Participants remarked that the SF-HDQ was "*very comprehensive"* (CAN-PLWH-P20, IRE-HCP-P11), and that "*more or less, it covers everything*" (IRE-PLWH-P10). Similarly, a health care practitioner described: *"I think almost all of [the items] capture something important that a lot of our clients' experience."* (CAN-HCP-P2).

This was supported by responses on the sensibility questionnaire data, where participants indicated that the SF-HDQ captures all of the important elements of disability and is useful in describing disability experienced by adults living with HIV (Table 3; Table 4).

Importance of Capturing the Episodic Nature of Disability: Both groups of participants indicated the importance of measuring the episodic nature of HIV in the SF-HDQ. One participant living with HIV noted that asking about how health related challenges fluctuated in the past week was "*probably one of the best questions."* Health care practitioners (HCPs) also believed the questions about fluctuations were important. As one HCP noted:

> *I think it needs to be understood that there is an episodic nature to HIV so that people can be more supportive of people when they say I'm just really not feeling up to coming and not getting frustrated or angry with them or punishing them for that. I think that kind of information needs to be documented.* (CAN-HCP-P1).

A range of viewpoints emerged on the ideal timeframe for measuring fluctuations with health challenges. One participant living with HIV reflected, "*Sometimes a week is not enough and sometimes it's too much. But when you're dealing with stuff, it fluctuates constantly."* (CAN-PLWH-P5). Similarly, a HCP noted: "*I like that there's a difference between like last week and this week, what's happened. But it also changes from the beginning of the month to the end of the month for some of our clients."* (CAN-HCP-P3).

SF-HDQ Captures Disability Related to Other Health Conditions: Some participants indicated that health challenges captured in the SF-HDQ were not always HIV-related. For instance, one participant living with HIV indicated that while struggling to maintain safe and stable housing was a prominent challenge, it was not attributed to their HIV status as stated in the item wording. "*What do you mean I'm worried about my financial and my security living with HIV? What does that have to do with anything? What does HIV have to do with any type of financial anything?"* (US-PLWH-P11).

Similarly, participants described how living with uncertainty or worrying about the future was an important aspect of their health but explained that it related to aging or living with other chronic conditions. Others attributed uncertainty to the COVID-19 pandemic, as this participant living with HIV explained:

> *…uncertainty, you know I answered that quite a bit because so many things are uncertain…I was kind of basing it on right now with COVID and everything you know. But it kept stressing right now today and that's also why I answered some of the things about kind of being lonely and stuff and social inclusion my answer to those because I would have answered those differently if it wasn't COVID.* (US-PLWH-P20).

Ease of Usage and Format: Participants reported positive experiences completing the SF-HDQ. Most described how the questionnaire was easy to complete, stating: "*the questions were pretty much straightforward."* (US-PLWH-P12) and *"the options are pretty easy to choose."* (US-HCP-P21). The majority described language in the SF-HDQ as easy to understand and "*pretty accessible."* (IRE-HCP-P11). One participant explained:

> *I think the wording on it was really good and you know being able to read it without saying 'can you help me' with this or whatever was really good. That's what I like is the fact that you know don't give me these very big words … I was able to understand this survey without having to ask you 'what does this mean?* (US-PLWH-P11).

Most participants living with HIV thought that the length of the SF-HDQ was appropriate, describing how "*It wasn't too long and it wasn't too short. In my opinion it was just right in the middle*" and "*it didn't take much time at all.*" (US-PLWH-P12). These interview findings are supported by responses to the sensibility questionnaires demonstrating that participants found the SF-HDQ easy to understand and complete, has reasonable length and possesses adequate response options (Table 3; Table 4).

Disability Terminology: A few participants reflected on the term 'disability' as used to describe health-related challenges in the context of the SF-HDQ. A HCP reflected:

> *It's a label. It's essentially calling someone disabled and especially in a world where we're trying to move from you know living with HIV is no longer a disability.* (US-HCP-P20).

Some participants similarly did not view themselves as disabled, as described by this participant: "*I haven't lost my hand or anything like that. I am not disabled. I'm not disabled through HIV or whatever.*" (IRE-PLWH-P5).

B - UTILITY

Interview data on utility of the SF-HDQ reflected two themes: 1) clinical use of the SF-HDQ, and 2) activities facilitated by the process of completing the SF-HDQ.

Clinical Use of the SF-HDQ

The majority of participants believed the SF-HDQ would be useful in clinical practice, specifically describing health challenges, assessing change in disability over time, and guiding referrals to health services and support.

Participants living with HIV and health care practitioner participants described how the SF-HDQ could be used in a clinical setting to provide a snapshot at a point in time: "*It gives you a basic understanding of what people with HIV are going through, what challenges they have.*" (US-PLWH-P15). One participant living with HIV reflected on how, *"I think it can get to help to get to know somebody. Those questions they can probably get some sort of sense on what*

their day-to-day life is." (US-PLWH-P12). Similarly, one HCP said, "*I think it's quite useful to get an idea from their patient about how HIV impacts on their day to day lives."* (IRE-HCP-P15).

Participants noted that the SF-HDQ could be useful for assessing change or stability of disability over time. One participant living with HIV noted, "*I would use it … maybe before the first visit or on a continuing basis to see how it changes.*" (US-PLWH-P15). Similarly, a HCP participant described how administering the SF-HDQ once a year would be "*good just to track how they are during the course of having HIV."* (IRE-HCP-P11). The same HCP noted that the SF-HDQ might be useful "*if the patient states that they are in a bad place, it might be a useful tool to do it straight away just to see where they actually are comparatively and to the previous visit."* (IRE-HCP-P11).

Activities Facilitated by the Process of Completing the SF-HDQ

Although the SF-HDQ is an outcome measure developed to describe health challenges living with HIV and other concurrent conditions, participants indicated that the process of completing the questionnaire can inform goal setting, facilitate communication (between patients and HCPs and between different HCPs), foster a multi-dimensional approach to care, and facilitate self-reflection about one's own health living with HIV.

Informing Goal Setting: Participants described the SF-HDQ as a tool to inform the process of goal setting. One participant living with HIV referred to the SF-HDQ as a tool to *"create a roadmap on how to treat this individual to get to an optimal outcome.*" (US-PLWH-P19). A HCP participant identified how, *"… it would be a good one for goal setting which was from a physiotherapy perspective as well.*" (IRE-HCP-P11). A HCP articulated how the SF-HDQ could facilitate goal setting beyond impairment-related treatment goals to more broadly considering social participation, *"I think to develop further goals that would be more to a participation level and more to a community level."* (CAN-HCP-P1). Another health practitioner explained how SF-HDQ results could be used to identify areas in which to focus on goals:

> *If you're using it for an annual physical as something to do a global assessment, to look at the overall wellness of the patient and identify things to work on through the next year … that could be you know like a useful thing for the team to have access to, to identify goals for the patient to work on.* (CAN-HCP-P4).

Facilitating Communication: Both HCPs and participants living with HIV referred to how the SF-HDQ can "*open up a conversation"* (IRE-PLWH-8) (US-HCP-P23) and how *"it opens a door. It gives the health practitioner information of things that they need to ask about or deal with."* (CAN-PLWH-P5). One HCP described how the SF-HDQ *"gives you the foundation to develop a conversation around all those items needed"* (IRE-HCP-P11), and how the SF-HDQ can identify areas to target interventions and referrals to services. One participant living with HIV reflected:

> *It can be used to maybe start a conversation towards something that maybe they didn't realize was there. So, it might be able to help a doctor or a physician to say 'hey we also have these other programs that might help you because it seems like you have a little more anxiety'. So, I think it would be beneficial in that way.* (US-PLWH-P13).

Some participants noted that the SF-HDQ could facilitate communication between clinicians. A HCP described, "*It definitely would be helpful for communication like if we could fax it back with a referral or something as part of [the patient's] treatment plan and things like that."* (CAN-HCP-P2).

Some participants identified the SF-HDQ as a tool for encouraging self-reflection of one's health living with HIV which can facilitate discussions with one's health care practitioner and possibly between practitioners. One participant living with HIV explained, *"I liked it because it just really brings out the fact that wait, am I feeling lonely. It made me think about some things but actually I thought it was really good."* (US-PLWH-P11). Another person living with HIV shared, *"some of the questions I never even really thought about. So it helps me to think about them. So they were good for me to look at."* (US-PLWH-P13). Similarly, a HCP noted:

> *It is a benefit I think because it'll highlight things that maybe the patient hasn't thought to bring up with the clinician they saw. Always it's good for them maybe to think about things that maybe are impacting their life or their quality of life.* (IRE-HCP-P13).

Fostering a Multi-Disciplinary Approach to Care: Participants described how the SF-HDQ went beyond biomedical issues and highlighted the multi-dimensional nature of health and approach to care. One participant living with HIV believed that the SF-HDQ could be used *"for people to really see how they feel, how they are, instead of just getting medication and take your medication … that is it."* (US-PLWH-P8). Similarly, a HCP noted how the questionnaire *"could help us identify the needs of the patients outside of their actual physical needs as in their blood pressure, their bloods and things like that. So, the greater needs, you know the full holistic needs of the patient."* (IRE-HCP-P14). Another HCP from Toronto explained:

> *I think it's great that it's so comprehensive in a sense because it raises your awareness to issues that you know you may not be aware of for certain patients right because the nature of family practice is people come in and they have a complaint of the day. Often with HIV it's all focused on meds and med adherence and side effects and you know counts and stuff and it's less focused on peoples' overall wellness. I like it because it reminds us of the importance of the overall wellness and that taking the time to think outside the box … to think less about health counts and cell counts and more about peoples' kind of lived experience every day.* (CAN-HCP-P4).

C - IMPLEMENTATION CONSIDERATIONS

Considerations for implementation of the electronic SF-HDQ spanned administration and communication of questionnaire scores in clinical practice.

Administration

Considerations pertaining to administration included burden of administration (time, conundrum of identifying health challenges with limited resources to address them, logistical issues of security, internet, space), and the importance of person-centered approaches for tailoring the mode of administration (use of technology, literacy, cognition) and offering flexible options for modes of processes of administration (format, location, timing, and persons involved in administration).

Table 5 includes participants' quotes related to perspectives on the burden of administration and the need for person-centred approaches for administration of the electronic SF-HDQ in a clinical setting.

Table 5: Implementation Considerations of the Electronic SF-HDQ in Clinical Practice: Administration

Implementation Consideration	Administration Consideration	Description / Example Quotations
Burden of administration	Time to administer and complete the SF-HDQ in clinical practice	• *I don't think anyone in the clinic will or has time to do anything extra.* (US-HCP-P20) • *How would you do it in a post-COVID world when you're trying to reduce waiting time?* (IRE-HCP-P15)
	Conundrum of identifying health challenges with limited resources to address then	• *It's a great questionnaire but the problem is there's no way that we can address the issues after it's done and we have the information.* (CAN-HCP-P23) • *Well, I think if we're going to ask all those questions, we need to have strategies in place to deal with all the answers and I'm not sure that we have at the moment.* (IRE-HCP-P15)
	Logistical issues (security of tablets for electronic administration, internet, space)	• *Gadgets tend to walk out the door.* (IRE-HCP-P15) • *To get a room and a computer…it's challenging in a resource-stretched and starved environment.* (IRE-HCP-P13)
Person-centered approaches for tailoring mode of administration	Use of technology - familiarity and comfort	• *I still find with a lot of our patients, particularly the over 50 group, that their IT skills might not what is required for this and that they might now have a computer and they might not have WIFI access.* (IRE-HCP-P15) • *Technology challenges definitely. I think most people with a tablet would go through it fairly quickly but there are probably people who are technologically challenged and it might be a little more difficult.* (CAN-PLWH-P15)
	Literacy of disability and health challenge terminology in the questionnaire	• *I think [the wording] might be beyond the reach of some of the patients you want to capture. So, people who maybe haven't had the chance to finish school, and we have a lot of them, or patients who are you know refugees, or you know English is not their first language.* (IRE-HCP-P16) • *I can think there might be, you know, depending on the education level of a participant, they might have trouble with some of the verbiage.* (US-PLWH-P18)
	Cognitive health challenges that may influence ability to complete the questionnaire	• *Because of the very real kind of neuro features of the HIV, especially with the long-term survivors."* (CAN-HCP-P5) • *I guess it would come down to their problems with their cognitive impairment and thought you know because people seem to have an awful lot of cognitive impairment problems that I've seen with HIV.* (CAN-PLWH-03)
Flexible options for modes and processes of administration	Format (electronic or paper based)	• *I think electronic I would prefer. But there are going to be people that need paper.* (CAN-HCP-01) • *It's a lot easier than say a pen and paper.* (US-PLWH-P12) • *It was really easy to fill out online.* (US-PLWH-P2)

Implementation Consideration	Administration Consideration	Description / Example Quotations
	Location of administration (home or clinic)	• *I would not want to do this during a clinic visit. … if you do it on the computer, that's good. … Let's say I'm going to have a visit tomorrow and you send it to me the day before. I can fill it out and send it and then not have to worry about it. Like I said, I would not want to go into a visit because I'm going into a visit to do whatever, get checked and I want to be gone. Then those that don't have a computer, maybe send the questionnaire in the mail and you know put their please fill out before visit and then have them bring it in with them.* (US-PLWH-11) • *I prefer that [completing the questionnaire with a clinician in clinic] because if I am with her or him one by one, then I can ask a question, then you can answer me or you can ask me a question, then I can answer. If I heard her answer and I can ask an explanation.* (CAN-PLWH-04)
	Timing of administration (prior to or after clinic appointment)	• *I think like either during the appointment or after … if there's a wait time before the client has to come in, then it's a great time to take care of the survey because then they feel like no time is being wasted if they have something to do.* (US-PLWH-13) • *I think before an appointment because I feel like after an appointment, you're ready to go. So, I think before an appointment would be ideal. Unfortunately, too because it may help bring out things that they forgot to talk about during their appointment. So, if they're taking it beforehand it might help them think of things that they may have forgotten about. (CAN-PLWH-P16)*
	Person to administer (self-, practitioner-, or administratively administered)	• *I think it should come from your primary care doctor.* (US-PLWH-14) • *It could be that we do an intake and then sort of get an administrative person to meet with them before their next visit. Yeah, I think either of those options could work.* (CAN-HCP-P2)

US - United States; Denver Colorado; CAN – Canada; Toronto, Ontario; IRE – Ireland; Dublin, Ireland
HCP – Health care practitioners; PLWH –person living with HIV; P - participant

Communication of Scores

Participants had mixed preferences about communicating SF-HDQ scores among patients and practitioners. Interview findings highlighted the importance of considering personal preferences for communicating SF-HDQ scores among persons living with HIV and their health care practitioners, and the importance of explaining and interpreting SF-HDQ scores with persons living with HIV (Table 6).

Table 6: Implementation Considerations of the Electronic SF-HDQ in Clinical Practice: Communicating Scores

Implementation Consideration	Description / Example Quotations
Consider personal preferences of patients when communicating scores among patients and health care practitioners	**Participants Living with HIV** • *Personally, I would like to get my score because that would give me some insight into my overall, you know, how I'm feeling overall.* (CAN-PLWH-P2) • *I don't know if I'd want to know [my scores] or not to be quite truthful. I think that's more for the clinician to know. So, I think you might make yourself worry too much about some things where I think you've got more problems than maybe you do. It could be negative to you."* (CAN-PLWH-P3) • *It [seeing my score] would make me feel uncomfortable and I'd probably stay on topic too long on ones than another, you know, why is this so high and why is that so low…. I honestly don't want to see it because you don't want to feel like a failure after.* (CAN-PLWH-P3) • ***Communicating Questionnaire Scores with Health Care Practitioner Team:*** *I think it's important because they'd see what's actually going on with you. Again, they'd direct you to the right people like if you need to see a psychiatrist or you know, whatever or something else that may be going on in your health that you may not be really aware that's a larger problem than it is. I may be thinking oh it's nothing and they're going we've got to deal with this. So it's important they see it.* (CAN-PLWH-P3). **Health Care Practitioners** • *I would have a preference to share because I think if the patients have answered it themselves, I think they should be able to know what their results are or what they have answered about themselves or what the scoring would be.* (IRE-HCP-P14) • *I think it's beneficial because sometimes people may not think that they have a problem like a physical problem or a mental emotional. Maybe they think that it's part of the way you're supposed to feel.* (IRE-HCP-P21) • *I'm not sure they would completely understand the nuances of it unless say someone has a disability score of 90. But is that discouraging them and they're doing okay or does that make them feel entitled that they deserve more? I mean I don't know. I'm just throwing this out there. Medicine has a lot of nuances.* (US-HCP-P23)
Importance of Explaining the Meaning of Scores	• *I think seeing them and knowing what they mean are two different things. I'd be happy to see them if I knew what they meant." (US-PLWH-P2).* • *…if they [persons living with HIV] are very depressed and they don't have adequate support to help them process this than I think that it could be harmful. But that doesn't mean that they shouldn't have access to it because I think it's their right to have access to their information. But that's why I would give it with adequate explanation only… I think it's okay [to give the patient a printout of their scores] only if it's given with some explanation because like we've talked about there are varying levels of disability that we're expressing. So, you want to make sure that you've given them all they need to process it. (US-HCP-P22)*

US - United States; Denver, Colorado; CAN – Canada; Toronto, Ontario; IRE – Ireland; Dublin, Ireland
HCP – Health care practitioners; PLWH –person living with HIV; P - participant

DISCUSSION

Overall, the SF-HDQ appears to demonstrate sensibility for use with adults living with HIV across the three healthcare contexts. The SF-HDQ was considered to possess utility for describing health-related challenges across health dimensions, identifying areas for follow-up or intervention, facilitating goal setting, and guiding referrals. The process of completing the SF-HDQ was described by participants as facilitating communication (including encouraging reflections on one's health), and fostering a multi-dimensional approach to care.

Results from the interviews highlight the need to person-centered tailored approaches to administration, specifically providing options for mode of administration (i.e., electronic- and paper-based methods), timing of administration (i.e., before, during, following an appointment), and considerations for how to communicate scores and score interpretations with patients, to account for differences between clinical settings and individuals.

Interview data indicate that participants felt the items in the SF-HDQ captured their experiences with disability. Overall, most participants described the language in the SF-HDQ as easy to understand and found the length of the questionnaire appropriate and feasible to complete. Many participants commented positively on how the SF-HDQ asked if challenges had fluctuated or changed in the past week, as they felt this was relevant to their experiences living with HIV.

Collectively the questionnaire and interview findings suggest that the SF-HDQ possesses sensibility for use with adults living with HIV. Despite participants indicating items were missing that should be included in the SF-HDQ on the sensibility questionnaire (item 9), both groups indicated the SF-HDQ captured all elements of disability (item 6) (table 3; table 4). These questionnaire results may be attributed to participants commenting in the interviews on the importance of considering HIV stigma, HIV disclosure, as well as addiction and substance use in the context of disability living with HIV. We recognize the importance of these concepts as they relate to disability.[19] However, as intrinsic or extrinsic

factors that can influence dimensions of disability, they are beyond the scope of disability and the SF-HDQ. Nevertheless, these findings highlight the benefit, need and importance, of administering the SF-HDQ in combination with other patient-reported outcome measures to fully understand the context in which disability may be experienced among adults living with HIV.

Some items in the SF-HDQ refer to HIV as the source of the challenge including: worrying about the future, worrying about finances, worrying about housing and concern around specific HIV blood tests. Participants questioned the need to specifically reference HIV in items related to uncertainty and social inclusion and items related to finance and housing, questioning the relevance of HIV specificity of items. Uncertainty and worrying about the future can be attributed to other factors (for example, the COVID-19 pandemic) and not solely HIV.[39] Attributing specific health challenges to HIV can be difficult for an individual as the challenge may not be directly from HIV but from consequences of HIV such as treatment or concurrent health conditions experienced when aging with HIV. Health challenges can also be compounded by certain factors affecting risk acquisition such as socioeconomic status or personal health.[20] Results suggest revisiting the need for HIV specificity of items in the SF-HDQ. Future research should explore the refinement of the questionnaire, focused on measuring episodic disability as a health-related consequence of a health condition regardless of the source of disability. This has the potential to broaden the applicability of the questionnaire for use with other health conditions.

The term 'disability' was negatively perceived by some participants in the study. Some participants from the United States disliked the term, whereas Canadian participants were more familiar with the term 'disability' as used in the context of rehabilitation, and some were familiar with the HDQ. In the SF-HDQ preamble, we explain the concept of 'disability' as a description of health challenges, and that the term is not meant to label individuals who complete the questionnaire. Nevertheless, a few participants referred to how they do not consider themselves disabled citing concerns of negative connotations with 'disability' terminology. Changing the terminology of the SF-HDQ would mean changing the concept of interest

measured, which has implications given the tool was grounded in conceptual foundation of the Episodic Disability Framework which was derived from the perspectives of adults living with HIV.[17 19] We recommend revising the preamble of the questionnaire to remove references to the term 'disability' and to rename the questionnaire the Episodic Disability Questionnaire (EDQ), to reflect the episodic nature of health challenges, while remaining grounded within the original conceptual foundation derived from the HIV community.

Participants had mixed preferences about completing the questionnaire at home on their own, or at the clinic on their own, or with a HCP. Brief and comprehensive PROMs administered on the same day as a clinic visit can improve completion rates, provide immediate feedback on disability, enhance patient-practitioner communication and facilitate person-centered care.[40-42] However, discomfort with technology and lack of access to web-based platforms can limit electronic questionnaire administration.[42] SF-HDQ administration will be dependent on the context and characteristics of the population served which may differ within and across clinical settings. Future SF-HDQ guidance on SF-HDQ administration should consider what is important for standard (consistent) mode administration to ensure validity and reliability, and what aspects of administration may be flexible depending on the environment (menu of options).

Participants living with HIV had variable preferences about personally receiving their scores after completion of the SF-HDQ. Some participants noted that scores may provoke anxiety without clarity of the meaning of the scores, whereas the majority of HCP participants believed scores should be communicated and clearly interpreted with their patients. Future guidance on SF-HDQ administration should include details of communicating scores with patients and their interpretation. While results suggest that reviewing scores can help understand where health challenges occur across the six domains and facilitate a dialogue about specific areas someone may be struggling with, ultimately the interpretability of the SF-HDQ scores is unknown. Future work should assess the interpretability of SF-HDQ scores.

While health practitioners positively commented on the utility of the SF-HDQ, some expressed hesitancy to use the SF-HDQ to identify health challenges that they may not have the resources to be able to address in the clinic setting. Despite the barriers and limited access to rehabilitation, the SF-HDQ can play a role in the pathway of care with value in measuring and identifying health challenges in order to gain knowledge on the need for rehabilitation and other health or supportive services.[11 43] Furthermore, in the absence of what health care practitioners feel they are unable to address, utilization of the SF-HDQ may foster space to listen to patients' concerns, acknowledge their experiences, share their narratives in therapeutic dialogue with their practitioner.[44 45]

Overall, results provide key considerations for SF-HDQ administration across three clinical settings in different countries highlighting the importance of tailoring implementation to the individual, cultural and clinical context. Strengths of our study included our mixed methods multi-site approach with 45 participants, involving both patient and practitioner perspectives practitioners spanning three different clinical contexts, which enabled us to assess the utility of the electronic mode of SF-HDQ administration, and examine considerations for implementation across three different healthcare contexts. Measurement properties are specific to the context and population in which the tool is assessed, highlighting the importance of considering the characteristics of the participants living with HIV and clinical sites in this study. The Toronto sample also demonstrated greater presence, severity and episodic scores of disability compared with the other two sample populations (Table 2). Our aim was not to compare sensibility and utility across sites, nor between adults living with HIV and HIV health care practitioners, rather collectively assess the SF-HDQ sensibility and utility across a diversity of sites and perspectives. Results highlight the need for personalized tailoring of administration dependent on personal preferences and context.

Given our SF-HDQ assessment was focused on electronic administration, this limited participation to individuals living with HIV who had access to and comfort with the use of technology in order to complete the questionnaires and, if the interview was conducted remotely, participate in a Zoom interview.

Results highlight the importance of offering flexible options for SF-HDQ administration in the clinic setting including a paper-based option for those with barriers to electronic administration. Findings from this study will inform the development of a guidance document to guide administration and scoring of the SF-HDQ in clinical settings and increase knowledge about the intended utility of the questionnaire.

CONCLUSIONS

The SF-HDQ possessed sensibility and utility for use with adults living with HIV across the three clinical settings in Canada, Ireland and the United States. Clinical utility of the SF-HDQ included measuring health challenges and its change over time, guiding referrals to clinical specialists and services, informing goal setting, facilitating communication, and fostering multi-disciplinary approaches to HIV care. Considerations for implementation included flexible, person-centered approaches to mode and processes of administration, and communicating scores based on personal preferences among persons living with HIV and HIV clinicians. Future work should consider refinement of the SF-HDQ for implementation across different clinical and cultural contexts and future measurement property assessment.

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AUTHORS' CONTRIBUTIONS

KKO and KME co-led the conceptualization of the study objectives and design, and drafted the protocol, led the application for acquisition of funding, and are the co-lead investigators on the study who led the implementation of the study. KKO, KME, CB, SCC are country and site leads on the research team, and were involved in the conceptualization of the study design, development of the protocol, acquisition of funding, and implementation of the study. PS, AMD, AMB, SEH, and RH are co-investigators and were involved in the conceptualization of the study design and contributed to the development of the protocol, acquisition of funding, and implementation of the study. KKO, PS, AMD, SCC, MS, and RA were involved in the data analysis and interpretation. KKO, PS, AMD, and MS drafted the manuscript. DAB, JHV, NSS, and MBof were involved in guiding study implementation and participated in data interpretation. RA, NOS, CM, and MB were involved in participant recruitment and data collection. BT assisted with manuscript preparation. Authors possess expertise in HIV and rehabilitation (KKO, KME, CB, SCC, PS, AMD, AMB, RH, DAB, JHV, NSS, MBof, RA, BT, NOS, CM, MB), with methodological expertise in measurement (KKO, AMD, RH, SEH) and qualitative research (PS, SCC, AMD, MS). All authors were involved in reviewing prior drafts of the manuscript. All authors have read and approved the final manuscript.

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COMPETING INTERESTS

None declared.

ETHICS APPROVAL

This study received research ethics approval from the University of Toronto (Protocol #38152), University of Colorado (Protocol #19-1895) and St. James's Hospital (Protocol #2019-12).

DATA AVAILABILITY STATEMENT

The data supporting the conclusions of this article are included within the article and its additional files. The data used and/or analysed during the current study are available from the corresponding author on reasonable request.

SUPPLEMENTAL FILES

Supplemental File 1: Original Protocol and Research Ethics Board Approval

Supplemental File 2: Sensibility Questionnaire

Supplemental File 3: Interview Guide

REFERENCES

1. Deeks SG, Lewin SR, Havlir DV. The end of AIDS: HIV infection as a chronic disease. *Lancet* 2013;382(9903):1525-33. doi: 10.1016/S0140-6736(13)61809-7 [published Online First: 2013/10/25]

2. Centers for Disease Control. HIV Among People Aged 50 and Over. 2018. https://www.cdc.gov/hiv/group/age/olderamericans/index.html.

3. Yin Z, Brown AE, Hughes G, et al. Over half of people in HIV care in the United Kingdom by 2028 will be aged 50 years or above (HIV in the United Kingdom 2014 Report: data to end 2013). *Public Health England, London* 2015

4. Surveillance and Epidemiology Division, Professional Guidelines and Public Health Practice Division, Centre for Communicable Disease and Infection Control, et al. Summary: Estimates of HIV incidence, prevalence and Canada's progress on meeting the 90-90-90 HIV targets, 2016. 2021. https://www.canada.ca/en/public-health/services/publications/diseases-conditions/summary-estimates-hiv-incidence-prevalence-canadas-progress-90-90-90.html.

5. Kendall CE, Wong J, Taljaard M, et al. A cross-sectional, population-based study measuring comorbidity among people living with HIV in Ontario. *BMC public health* 2014;14(1):161. doi: 10.1186/1471-2458-14-161 [published Online First: 2014/02/15]

6. Hasse B, Ledergerber B, Furrer H, et al. Morbidity and aging in HIV-infected persons: the Swiss HIV cohort study. *Clin Infect Dis* 2011;53(11):1130-9. doi: 10.1093/cid/cir626 [published Online First: 2011/10/15]

7. Guaraldi G, Orlando G, Zona S, et al. Premature age-related comorbidities among HIV-infected persons compared with the general population. *Clin Infect Dis* 2011;53(11):1120-6. doi: 10.1093/cid/cir627 [published Online First: 2011/10/15]

8. Balogun JA, Kaplan MT, Miller TM. The effect of professional education on the knowledge and attitudes of physical therapist and occupational therapist students about acquired immunodeficiency syndrome. *Physical Therapy* 1998;78(10):1073-82.

9. Brown TT, Qaqish RB. Antiretroviral therapy and the prevalence of osteopenia and osteoporosis: a meta-analytic review. *AIDS* 2006;20(17):2165-74. doi: 10.1097/QAD.0b013e32801022eb00002030-200611140-00005 [pii] [published Online First: 2006/11/07]

10. Vance DE, Mugavero M, Willig J, et al. Aging With HIV: A Cross-Sectional Study of Comorbidity Prevalence and Clinical Characteristics Across Decades of Life. *J Assoc Nurses AIDS Care* 2011;22(1):17-25. doi: S1055-3290(10)00064-6 [pii]10.1016/j.jana.2010.04.002

11. Erlandson KM, Schrack JA, Jankowski CM, et al. Functional impairment, disability, and frailty in adults aging with HIV-infection. *Curr HIV/AIDS Rep* 2014;11(3):279-90.doi: 10.1007/s11904-014-0215-y

12. Heaton RK, Clifford DB, Franklin DR, Jr., et al. HIV-associated neurocognitive disorders persist in the era of potent antiretroviral therapy: CHARTER Study. *Neurology* 2011;75(23):2087-96. doi: 75/23/2087 [pii]10.1212/WNL.0b013e318200d727 [published Online First: 2010/12/08]

13. Valcour V, Shikuma C, Shiramizu B, et al. Higher frequency of dementia in older HIV-1 individuals: the Hawaii Aging with HIV-1 Cohort. *Neurology* 2004;63(5):822-7. doi: 63/5/822 [pii] [published Online First: 2004/09/15]

14. Shiels MS, Pfeiffer RM, Gail MH, et al. Cancer Burden in the HIV-Infected Population in the United States. *J Natl Cancer Inst* 2011;103(9):753-62. doi: djr076 [pii]10.1093/jnci/djr076 [published Online First: 2011/04/13]

15. Antiretroviral Therapy Cohort Collaboration. Survival of HIV-positive patients starting antiretroviral therapy between 1996 and 2013: a collaborative analysis of cohort studies. *The Lancet HIV* 2017;4(8):e349-e56. doi: 10.1016/S2352-3018(17)30066-8

16. Willard S, Holzemer WL, Wantland DJ, et al. Does "asymptomatic" mean without symptoms for those living with HIV infection? *AIDS Care* 2009;21(3):322-8. doi: 909441524 [pii] 10.1080/09540120802183511 [published Online First: 2009/03/13]

17. O'Brien KK, Bayoumi AM, Strike C, et al. Exploring disability from the perspective of adults living with HIV/AIDS: development of a conceptual framework. *Health Qual Life Outcomes* 2008;6:76. doi: 1477-7525-6-76 [pii] 10.1186/1477-7525-6-76 [published Online First: 2008/10/07]

18. Erlandson KM, Allshouse AA, Jankowski CM, et al. Relationship of physical function and quality of life among persons aging with HIV infection. *AIDS* 2014;28(13):1939-43. doi: 10.1097/QAD.0000000000000384

19. O'Brien KK, Davis AM, Strike C, et al. Putting episodic disability into context: a qualitative study exploring factors that influence disability experienced by adults living with HIV/AIDS. *J Int AIDS Soc* 2009;12(1):5. doi: 1758-2652-2-5 [pii] 10.1186/1758-2652-2-5 [published Online First: 2009/11/11]

20. Bulsara SM, Wainberg ML, Newton-John TRO. Predictors of Adult Retention in HIV Care: A Systematic Review. *AIDS Behav* 2018;22(3):752-64. doi: 10.1007/s10461-016-1644-y [published Online First: 2016/12/19]

21. Cooper V, Clatworthy J, Harding R, et al. Measuring quality of life among people living with HIV: a systematic review of reviews. *Health Qual Life Outcomes* 2017;15(1):220. doi: 10.1186/s12955-017-0778-6 [published Online First: 2017/11/17]

22. Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. *Jama* 1995;273(1):59-65.

23. Harding R, Clucas C, Lampe FC, et al. What factors are associated with patient self-reported health status among HIV outpatients? A multi-centre UK study of biomedical and psychosocial factors. *AIDS Care* 2012;24(8):963-71. doi: 10.1080/09540121.2012.668175 [published Online First: 2012/04/24]

24. O'Brien KK, Bayoumi AM, King K, et al. Community engagement in health status instrument development: experience with the HIV disability questionnaire. *Progress in community health partnerships : research, education, and action* 2014;8(4):549-59. doi: 10.1353/cpr.2014.0071 [published Online First: 2014/01/01]

25. O'Brien KK, Bayoumi AM, Stratford P, et al. Which dimensions of disability does the HIV Disability Questionnaire (HDQ) measure? A factor analysis. *Disabil Rehabil* 2015;37(13):1193-201. doi: 10.3109/09638288.2014.949358

26. O'Brien KK, Solomon P, Bayoumi AM. Measuring disability experienced by adults living with HIV: assessing construct validity of the HIV Disability Questionnaire using confirmatory factor analysis. *BMJ open* 2014;4(8):e005456. doi: 10.1136/bmjopen-2014-005456 [published Online First: 2014/09/03]

27. O'Brien KK, Bayoumi AM, Bereket T, et al. Sensibility assessment of the HIV Disability Questionnaire. *Disabil Rehabil* 2013;35(7):566-77. doi: 10.3109/09638288.2012.702848 [published Online First: 2012/07/24]

28. O'Brien KK, Solomon P, Bergin C, et al. Reliability and validity of a new HIV-specific questionnaire with adults living with HIV in Canada and Ireland: the HIV Disability Questionnaire (HDQ). *Health Qual Life Outcomes* 2015;13:124. doi: 10.1186/s12955-015-0310-9

29. Brown DA, Simmons B, Boffito M, et al. Evaluation of the psychometric properties of the HIV Disability Questionnaire among adults living with HIV in the United Kingdom: A cross-sectional self-report measurement study. *PloS one* 2019;14(7):e0213222. doi: 10.1371/journal.pone.0213222 [published Online First: 2019/07/11]

30. O'Brien KK, Dzingina M, Harding R, et al. Developing a short-form version of the HIV Disability Questionnaire (SF-HDQ) for use in clinical practice: a Rasch analysis. *Health Qual Life Outcomes* 2021;19(1):6. doi: 10.1186/s12955-020-01643-2 [published Online First: 2021/01/08]

31. Feinstein AR. The theory and evaluation of sensibility. In: Feinstein AR, ed. Clinimetrics. Westford, MS: Murray Printing Company 1987:141-66.

32. Feinstein AR. Benefits and obstacles for development of health status assessment measures in clinical settings. *Med Care* 1992;30(5 Suppl):MS50-6. [published Online First: 1992/05/01]

33. Burns KE, Duffett M, Kho ME, et al. A guide for the design and conduct of self-administered surveys of clinicians. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne* 2008;179(3):245-52. doi: 10.1503/cmaj.080372 [published Online First: 2008/07/30]

34. O'Brien KK, Ibanez-Carrasco F, Solomon P, et al. Research priorities for rehabilitation and aging with HIV: a framework from the Canada-International HIV and Rehabilitation Research Collaborative (CIHRRC). *AIDS Res Ther* 2020;17(1):21. doi: 10.1186/s12981-020-00280-5 [published Online First: 2020/05/21]

35. Qualtrics [program]. Provo, Utah, USA, 2017.

36. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res* 2005;15(9):1277-88. doi: 15/9/1277 [pii]10.1177/1049732305276687 [published Online First: 2005/10/06]

37. NVivo qualitative data analysis software. Version 11. [program], 2017.

38. Hennink MM, Kaiser BN, Marconi VC. Code Saturation Versus Meaning Saturation: How Many Interviews Are Enough? *Qual Health Res* 2017;27(4):591-608. doi: 10.1177/1049732316665344 [published Online First: 2016/09/28]

39. Brown DA, O'Brien KK, Josh J, et al. Six Lessons for COVID-19 Rehabilitation From HIV Rehabilitation. *Phys Ther* 2020;100(11):1906-09. doi: 10.1093/ptj/pzaa142 [published Online First: 2020/08/02]

40. Edwards TC, Fredericksen RJ, Crane HM, et al. Content validity of Patient-Reported Outcomes Measurement Information System (PROMIS) items in the context of HIV clinical care. *Qual Life Res* 2016;25(2):293-302. doi: 10.1007/s11136-015-1096-2 [published Online First: 2015/08/08]

41. Fredericksen RJ, Tufano J, Ralston J, et al. Provider perceptions of the value of same-day, electronic patient-reported measures for use in clinical HIV care. *AIDS Care* 2016;28(11):1428-33. doi: 10.1080/09540121.2016.1189501 [published Online First: 2016/05/31]

42. Cella D, Hahn EA, Jensen SE, et al. Patient-reported outcomes in performance measurement. Research Triangle Park, NC: RTI International, 2015.

43. Brown D, Nelson M, Bower M, et al. Presence of complex comorbidity and functional disability when ageing with HIV; review of referrals to specialist HIV outpatient physiotherapy in the UK. *HIV Medicine Abstracts of the 22nd Annual Conference of the British HIV Association (BHIVA)* 2016;17(1):14-71.

44. Rushforth A, Ladds E, Wieringa S, et al. Long Covid - The illness narratives. *Soc Sci Med* 2021;286:114326. doi: 10.1016/j.socscimed.2021.114326 [published Online First: 2021/08/24]

45. Dhairyawan R. The medical practice of silencing. *Lancet* 2021;398(10298):382-83. doi: 10.1016/S0140-6736(21)01659-7 [published Online First: 2021/08/02]

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Human Participant Research Ethics Protocol Worksheet
University of Toronto

Title: **Advancing Assessment of Episodic Disability to Enhance Healthy Aging among Adults Living with HIV: Developing a Short-Form HIV Disability Questionnaire (SF-HDQ) for use in Clinical Practice**

Protocol adapted to reflect relevant objective for study objective in manuscript (objective 1)

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Date Last Revised: February 13, 2022

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

This research has undergone scholarly review by peer review committee or some other equivalent: **NIH Scholarly Review (NIH Review Committee) and NIH Council Review.** This protocol builds on a foundation of previous HDQ development and validation work done in Canada and Ireland (UofT Protocol Reference #27456 (Ireland HDQ validation study); #27563 (HIV Health and Rehabilitation Survey).

Potential Conflicts – This section will ask for information pertaining to any potential conflicts of interest, restrictions on information, researcher relationships, collaborative decision making and terms of reference**.**

Where relevant, please explain any pre-existing relationship between the researcher(s) and the researched (e.g., instructor-student; manager-employee; clinician-patient; minister-congregant). Please pay special attention to relationships in which there may be a power differential – actual or perceived.

Participants may include persons whom Kelly O'Brien, Soo Chan Carusone, Kristine Erlandson, Colm Bergin, Ahmed Bayoumi, Patty Solomon, or Aileen Davis, have worked with as a colleague in a community-based research or educational capacity. Study investigators or the research coordinator at each site, who have no relationship with the potential participant, will obtain consent. Interested participants will be invited to contact the study co-investigators or research coordinator who has no relationship with the potential participants, who will discuss the study in detail and if applicable, will obtain consent.

(d) Please describe the decision-making processes for collaborative research studies. If Terms of Reference exist, attach them. Collaborative research studies include those where a number of sites (e.g. other universities, non-TAHSN hospitals, etc.) are involved, as well as those that involve community agencies.

This research involves an international academic-clinical partnership between Canada (University of Toronto, Casey House, McMaster University, St. Michael's Hospital, University Health Network), United States (University of Colorado Denver), Ireland (St. James's Hospital (Dublin), and the United Kingdom (King's College London (UK)). Data collection will occur at three sites (Toronto, Dublin, Denver).

Process for making decisions on scientific direction and allocation of resources. The SF-HDQ Team is a diverse virtual team with members from multiple clinical and academic institutions, multiple disciplines, different countries, time zones, health systems and cultural backgrounds. We are committed to a co-creation approach to collaborating, communicating and governing. As Co-PIs, Drs. O'Brien and Erlandson will meet via Skype or telephone biweekly to discuss project progress and overall management and administrative responsibilities. We will establish a 'SF-HDQ Steering Committee' comprised of Drs. O'Brien and Erlandson as well as Site Lead Co-Investigators in Toronto (Dr. Chan Carusone) and Dublin (Dr. Bergin) who will meet via teleconference monthly. They will work together to discuss progress of recruitment, data collection, and any issues arising that pertain to the study. Other members of the team may be invited to join these meetings when applicable. This Committee will be responsible for monitoring progress of the research at the sites, including timelines, mechanisms for data collection, storage and transfer, ensuring adherence to institutional site IRBs, and providing oversight and vision to knowledge translation and dissemination activities. These meetings will be held via teleconference. Decisions will be made by consensus. Drs. O'Brien and Erlandson will continue to communicate on an ad hoc basis as needed in between formal meetings via Skype or telephone as needed.

Fiscal and management coordination. Dr. O'Brien will be responsible for overall administration of the project. Together, Drs. O'Brien and Erlandson will manage the oversight and coordination of project management, research administration, fiscal oversight, publications and data sharing, and integration of all resources needed for the project. Dr. O'Brien will oversee decisions on minor changes in research direction and have the authority to reallocate funds and resources between project components if needed.

Data sharing and communication among investigators. The 'SF-HDQ Steering Committee' (Drs. O'Brien, Erlandson and site leads, Drs. Bergin and Chan Carusone) will meet monthly. These meetings will also be used to review progress toward the aims of recruitment, data collection and facilitate the transfer of data and ideas, outline objectives and plans for the forthcoming year and prepare the yearly progress report to the funding agency. Bimonthly, these meetings will morph into a 'Full SF-HDQ Team' meeting with the entire team, including co-investigators, research coordinators and other personnel involved in the study. Much of the work of the SF-HDQ Team will be conducted virtually, and thus strong internal communication mechanisms will be critical to our viability and productivity. We will balance our communication mechanisms in terms of social presence (through our Year 1 face-to-face meeting) and information richness (through frequent videoconferencing and use of collaborative online tools). For the annual SF-HDQ Team meeting, we will leverage opportunities such as the Canadian Association for HIV Research (CAHR) Conference, International Workshop on HIV and Aging, or CIHRRC International Forums on HIV and Rehabilitation Research to disseminate research and meet in person while reducing travel costs. To support dissemination of our research through peer-reviewed publications, the 'SF-HDQ Steering Committee' will establish an authorship policy in accordance with the International Committee of Medical Journal Editors Authorship Guidelines [http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html]

Procedures for resolving conflicts. We will adopt a proactive and collaborative approach to conflict resolution. Being proactive will allow us to anticipate conflict based on resources limitations (e.g. time, skills, and finances). A collaborative approach will ensure we provide opportunities for input from all team members that will include adequate internal communications, comprised of collaboration, accommodation, and compromise. If conflicts arise, we will seek resolution by focusing on the fact-based content of the interpersonal interactions, explicitly discussing and debating decisions reached in a respectful manner. As Co-Principal Investigators, unresolved conflicts will be resolved by the Drs. O'Brien and Erlandson. If this approach does not lead to resolution, or if conflict persists, we will consult an arbitration committee consisting of three impartial senior faculty members at the University of Toronto for ultimate resolution. No members of the arbitration committee will be directly involved in the research grant or disagreement. We will review and evaluate our team process, productivity, communication, and governance structure at each meeting. We will invite input from all team members to evaluate our progress on collaboration, communication, and knowledge translation throughout the study.

Distribution of Resources

The University of Toronto will be the primary lead institution for this study, followed by the University of Colorado Denver, St. James's Hospital, Trinity College Dublin, and King's College London who will have specific budgetary resources allocated to sites and investigators according to project and institutional requirements. Dr. Erlandson (University of Colorado) and Dr. Bergin (St. James's Hospital, Trinity College Dublin) will oversee the budget allocated to their respective sites. Because Casey House is affiliated with the University of Toronto, the budgetary requirements to conduct recruitment and data collection at Casey House will be overseen by Drs. O'Brien and Chan Carusone. Casey House will invoice University of Toronto for their research services accordingly. King's College London is not a study site, however Dr. Harding (King's College London) will draw salary for his contributions to the study.

Community Advisory Committee. This research is also informed by an HIV Community Advisory Committee that Kelly O'Brien (principal investigator) works with part of a larger program of research (HIV Disability Questionnaire). The decision making process will be shared among the members of the research team who will inform and guide all aspects of this research. Given the international nature of this research, the Community Advisory Committee expanded to include further international representation to inform the research process at each of the sites. This international expert Community Advisory Committee (comprised of ~9 members including people living with HIV, representative from community organizations, and clinicians who work in HIV care) will advise on SF-HDQ content, administration, scoring and usage. This will ensure the SF-HDQ is meaningful, relevant and practical for use in the real-world clinical setting.

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Project Summary

Rationale

Describe the purpose and scholarly rationale for the project:

With advances in combination antiretroviral therapy, HIV is now considered a chronic illness where individuals can reach life expectancies similar to the general population. However, more individuals are living longer with the health consequences of HIV, multimorbidity and aging known as disability. Disability is defined by people living with HIV (PLWH) as any physical, cognitive, mental-emotional symptoms, difficulties with day-to-day activities, challenges to social inclusion, and uncertainty about future health. Disability including fatigue, pain, challenges engaging in employment, and age-related issues of frailty; coupled with poor access to services, stigma, and poverty can pose barriers to PLWH remaining engaged in care.

Standardized patient reported outcomes (PROs) designed to capture the nature and extent of disability and its fluctuation over time are critical to guide the provision of timely care and to determine the effectiveness of interventions for adults aging with HIV. While a multitude of health status instruments exist, they do not capture the breadth and depth of disability, the fluctuating nature of HIV, and lack items related to social inclusion and uncertainty, identified as critical to people aging with HIV. To fill this gap, we developed a 69-item Patient Reported Outcome (PRO), the **HIV Disability Questionnaire (HDQ) (Appendix A)** to measure the presence, severity and episodic nature of disability experienced by people living with HIV. We demonstrated that the HDQ possesses sensibility, reliability and validity among adults living with HIV in Canada and Ireland. However, to date the HDQ has been used primarily in the context of research, with little uptake in clinical practice due to concerns of time restrictions. There is a critical need for a brief, yet comprehensive assessment of disability for adults aging with HIV that can be routinely administered across health system settings and clinical practice. **The purpose of the proposed study is to develop and pilot the implementation of a new short-form HIV-specific disability questionnaire to identify disability across clinical settings in order to promote healthy aging among adults aging with HIV.**

Our primary objective is to develop and assess the utility of a new short form HIV-specific disability questionnaire (SF-HDQ) across multiple clinical practice settings with adults aging with HIV.

The HDQ has potential for use in community practice with PLWH in the following ways: 1) as a screening tool to describe and better understand health-related challenges (or disability) and to help target timely and appropriate referrals to services; 2) as a component of client-centered care, facilitating discussion between clients, clinicians, and community to describe health-challenges, and assist with goal-setting; 3) to promote communication across clinical and community sites; and 4) to evaluate change in disability and effectiveness of interventions.

Outcomes will lead to the first known short form HIV-specific disability PRO developed through international and academic-community collaboration to assess prevalence and impact of episodic disability. This study will provide a foundation for future assessment of the extent to which the SF-HDQ can inform and facilitate referrals to services, goal setting, and patient-provider communication. Future universal measurement of disability over time may contribute to databases that facilitate ongoing clinical management, specifically tracking of episodic disability trends and evaluation of interventions to inform future allocation of resources to better promote healthy aging with HIV.

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Methods

Describe formal/informal procedures to be used:

STUDY DESIGN:

We will use a descriptive sequential mixed methods study design using quantitative (questionnaires) and qualitative (interviews) to assess sensibility (purpose, face and content validity, ease of usage, format), challenges and feasibility of administration, and to explore perspectives on how the SF-HDQ may be utilized in clinical practice (why used, by who, how and when it should be administered, and how it should be scored, and interpreted) to optimize healthy aging with HIV. We will use a cross-sectional pilot study to examine the implementation of the SF-HDQ and assess its psychometric properties in the 'real world' clinical practice across three health system sites (Toronto, Dublin, Denver).

STUDY SETTING (3 Sites: Canada, United States and Ireland):

Casey House, Toronto, Canada: Casey House is a 14-bed sub-acute HIV hospital in downtown Toronto providing in-patient and community programs for adults living with HIV. In 2017, Casey House launched a new Day Health Program (DHP) to allow people aging with HIV to experience better overall health and quality of life, by improving their access to interdisciplinary care while remaining in their homes and communities. The DHP offers a time limited, goal focused program for individuals living with HIV and complex health issues, with a capacity of 250 clients. Recently, physiotherapy was integrated into the DHP. The HDQ is used to assess disability among incoming clients to the program.

The University of Colorado Infectious Diseases Group Practice Clinic, University of Colorado Denver, United States: The University of Colorado Infectious Diseases Group Practice Clinic is a large HIV clinical program is a University affiliated, Ryan White supported, clinic which includes both in-patient and out-patient care at the University of Colorado Hospital (UCH) through Infectious Diseases Group Practice (IDGP).

Department of GU Medicine and Infectious Diseases (GUIDE), St. James's Hospital, Dublin, Ireland: The GUIDE Clinic is the largest HIV, Infectious Diseases and sexual health service in Ireland. The clinic serves ~3000 adults living with HIV in Ireland (~60% of people living with HIV in the Irish Republic). The clinic provides care and treatment for people living with HIV by a multidisciplinary team. In 2012, Kelly O'Brien collaborated with Colm Bergin to validate the HDQ for use with people living with HIV in Ireland.

METHODS:

Objective 1: To assess the utility of a new short-form HIV-specific disability questionnaire across multiple clinical practice settings with adults aging with HIV.

We will use a combination of quantitative (questionnaires) and qualitative (interviews) with 30 adults aging with HIV and 15 HIV health providers in 3 sites in Canada (Casey House) the United States (University of Colorado) and Ireland (St. James's Hospital) to assess sensibility (face and content validity, ease of usage), utility, and optimal use of the SF-HDQ in clinical practice. Outcomes will include an administration, scoring, and interpretation guide for clinical practice.

Clinicians who administered the SF-HDQ will complete a one-time questionnaire to describe the purpose they used the SF-HDQ, strengths and challenges of use, if and how they used the scores to guide clinical decisions, and recommendations to revise the guidance document for utilization.

RESEARCH PROCEDURES:

Objective 1) Assessing the Utility of the SF-HDQ
We will administer the **SF-HDQ** using electronic (tablet) methods of administration at each of the 3 sites.

We will then meet with participants to assess:
Sensibility: Using Feinstein's criteria, we will administer a self-reported questionnaire comprised of 18 statements (7 point response scale ranging from highly disagree to highly agree) asking about perspectives on face, content validity, method of administration, format, and ease of usage of the SF-HDQ (**Appendix B**). We will specifically ask participants to identify items that should be added or removed related to context (country). We will also electronically administer a demographic questionnaire comprised of items including but not limited to age, sex, gender, ethnicity, and multimorbidity (**Appendix C**).

Utility: Following the questionnaire administration, we will conduct semi-structured interviews with adults aging with HIV (n~10 each site), and HIV health providers who administered the HDQ (n~5 each site). We will ask about the utility of the SF-HDQ in practice, (e.g. assessing disability, facilitating communication, goal-setting, guiding referrals), experience with completing/administering the SF-HDQ, strengths and challenges, feasibility, how it should be administered (electronic, paper), when to administer (prior to or during a clinical visit), who should administer (type of health provider), and how often (to capture episodic nature of disability) (**Appendix D**).

Interpretability: We will administer a global rating scale (GRC) asking participants whether they consider themselves living with minimal, moderate or severe forms of disability (**Appendix E**) followed by a discussion about how scores might inform clinical decision making (e.g. referrals, discharge planning, interventions) and whether any specific considerations to context (country), age or gender exist.

All interviews will be audio recorded and transcribed verbatim. Upon analysis, we will meet as a team to identify recommendations that should comprise a clinical guidance document to facilitate SF-HDQ clinical use.

DATA ANALYSIS:

Objective 1) Assessing the Utility of the SF-HDQ
SF-HDQ Scoring: We will score the HDQ using the algorithm developed through Rasch Analysis (see Objective 1a).

Sensibility Questionnaire: We will calculate median scores for each of the items. We will consider the HDQ sensible if median scores were ≥5 for PLWH and ≥4 HIV health providers (7 point ordinal scale) for at least 80% of the items and if no items had median scores of ≤3 in either group, similar to criteria used in our earlier HDQ sensibility assessment.

Interview Data: We will analyze interviews using content analytical techniques and a team based approach to qualitative analysis. Our coding scheme will include the following areas: i) purpose of using SF-HDQ, ii) experience completing/administering the HDQ, iii) strengths, iv) challenges, iv) feasibility, v) method, timing and frequency of administration, vi) recommendations to guide administration, scoring, and interpretation of the SF-HDQ in practice, and vii) specific considerations related to context (country, older vs younger age, gender). We will use NVivo software for data management.

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Participants and Data – This section will ask for information pertaining to sample size, vulnerability, recruitment and compensation.

Describe the participants to be recruited, or the individuals about whom personally identifiable information will be collected. List the inclusion and exclusion criteria. Where the research involves extraction or collection of personally identifiable information, please describe where the information will be obtained, what it will include, and how permission to access said information is being sought.

STUDY PARTICIPANTS:

Adults aging with HIV (≥18 years) and *Health Providers who work in HIV care* who self-identified as having a role in addressing disability aging with HIV (which may include but are not limited to disciplines of medicine, rehabilitation, social work, and nursing).

Inclusion criteria:

Adults Living with HIV

Adults (18 years of age or older) living with HIV willing and able to provide written informed consent to participate in the study. ***Sampling:*** We will use purposive sampling to obtain diversity among participants with HIV in the sample based on age (≥50 years, <50 years), ethnicity, gender (men, women, transgender), and clinical site (US, Ireland and Canada). We chose to include adults at any age (rather than specifically older adults ≥50 years) as disability assessment is critical to consider in the context of multimorbidity prevention and healthy aging at any age over the lifespan.

HIV Health Providers

Health Providers who work in HIV care in Toronto, Canada, Aurora Colorado, and Dublin, Ireland who self-identify as having a role in addressing disability due to HIV, aging and multimorbidity. This may include (but is not limited to) physicians, rehabilitation professionals (occupational therapy, physiotherapy), social workers, and nurses. We chose to retain broad inclusion criteria for health providers given clinical teams may differ across sites. This broad inclusion criterion will allow us to explore diversity of perspectives and multidisciplinary approaches to disability assessment for adults aging with HIV in different health system clinical settings.

RECRUITMENT

Assessing the Utility of the SF-HDQ

Adults Living with HIV

We will recruit and enroll 10 adults (18 years or older) living with HIV and 5 HIV health providers who work in HIV Care in Aurora, CO, United States (University of Colorado), Toronto, Canada (Casey House) and Dublin, Ireland (St. James's Hospital) for a total of 45 participants (30 adults living with HIV and 15 health providers). We will specifically aim to recruit at least 50% of participants ≥50 years in each of the sites to over represent older adults living with HIV to account for the increasing prevalence of older adults with HIV in Canada, the United States, and Ireland. We will aim to recruit 25% women.

Participants who are interested will be asked to contact study investigators (by email or telephone) to discuss the study, and if they consent to arrange an appointment for data collection (**Appendix L**). The research team will provide a hard copy (or email) of the information letter and consent form (**Appendix J1**) and discuss the contents of the consent form (in person or by telephone) to individuals who are eligible and interested in participating in the study.

The individual will be informed of the purpose and rationale of the study, inclusion criteria, potential medical and social risks of participation, the voluntary nature of the study and their right to withdraw at any time, and compensation. We will also provide further information regarding the types of questions they will be asked. We may send up to two reminders to potential participants after providing the information sheets and consent forms if needed (**Appendix L**). Participants who indicate that they are not interested or do not respond after these two requests, will not be further approached about participation. Signed consent will occur in person prior to the time of scheduled administration of questionnaires and interview. We will send a reminder email or phone call (based on preferred mode of communication) the day prior to the interview (**Appendix N**).

HIV Health Providers

We will recruit health providers (n~5 each site) working in HIV care at each site (University of Colorado, Casey House and St. James's Hospital) using targeted recruitment of key informants.

An initial recruitment will occur via email to the targeted sample of key informant health providers working in HIV care at the three sites (Casey House, University of Colorado, St. James's Hospital). Initial contact with potential participants will be made via email; in the email we will provide information about the study such as the purpose statement, research objectives and proposed impact of results (**Appendix M1**). We will provide them with the information letter and consent form, which includes additional information such as participation requirements (i.e. the interview process) and contact information of the research team (**Appendix J2**). Interested individuals will be asked to contact the Research Coordinator at their given site by email or telephone to discuss the eligibility and details associated with the study.

SAMPLE SIZE:

Objective 1) Assessing the Utility of the SF-HDQ

Based on our previous sensibility work, we anticipate a sample of 45 (30 adults living with HIV +15 providers) will be sufficient to provide perspectives of utilization across sites. The University of Colorado Infectious Diseases Group Practice Clinic is a University-affiliated, Ryan White supported, clinic serving over 2500 adults with HIV in the Denver metro area, representative of an urban population aging with HIV, as approximately half are ≥50 years. Casey House is a specialty hospital in Toronto that recently launched a new day health program for PLWH and complex multimorbidity. Casey House currently serves 250 clients of which an estimated 50% are ≥50 years. The GUIDE Clinic at St. James's Hospital serves 3000 PLWH in Ireland, of which 495 (21%) are estimated ≥50 years.

COMPENSATION

Assessing Utility of SF-HDQ

Participants will be provided with a $30 CAD (Toronto Site), $20 USD (Colorado Site) gift card token of appreciation for taking part in the initial pilot administration and follow up interview on the experiences with the SF-HDQ. Participants at the Ireland site will not be provided an honorarium as this is in keeping with their research procedures at St. James's Hospital. HIV Health Providers will receive a $30 CAD (Toronto) and $20 USD (Colorado) gift card token of appreciation for taking part in each of the Objective 1 and Objective 2 interviews. Participants at the Ireland site will not be provided an honorarium as this is in keeping with their research procedures at St. James's Hospital.

VULNERABILITY

Group vulnerability of adults with HIV is medium as participants have a pre-existing health condition (HIV) with potentially other concurrent health conditions including mental health, addictions which may affect them psychologically, or socioeconomically.

Supplemental File 1
Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Participants may include persons whom members of the research team, have worked with as a colleague in a community-based research or educational capacity. Study investigators or the research coordinator at each site, who have no relationship with the potential participant, will obtain consent. Interested participants will be invited to contact the study co-investigators or research coordinator who has no relationship with the potential participants, who will discuss the study in detail and if applicable, will obtain consent.

Given our target population of adults living with HIV may experience cognitive impairment influencing their capacity to consent. This possibility will be addressed at the recruitment stage as researchers will include the capacity to consent as inclusion criteria for consideration by staff at the sites (Casey House, University of Colorado Hospital and St James's Hospital). We will continually assess participant capacity throughout communication leading up to participation, by asking potential participants to reiterate in his/her own words their understanding of the study, what is involved with participation and the risks/benefits of participating.

Group vulnerability of health providers is low.

Investigator Experience

Please describe the community members research team status (eg. employees, volunteers, or participants). What training will they receive?

The research team is comprised of researchers and clinicians from Canada, Ireland and the United States. We will strike a Community Advisory Committee (n~9) comprised of people living with HIV and representatives from AIDS Service Organizations in Canada, such as Toronto PWA Foundation, Realize; in the United States such as Treatment Education Network, Empowerment and Brother John; and in Ireland such as HIV Ireland and Positive Now. Many of the team members have been involved in the original development and validation of the HDQ.

Investigator Experience with this type of research

Please provide a brief description of the previous experience for this type of research by the applicant, the research team, and any persons who will have direct contact with the applicants. If there is no previous experience, how will the applicant and research team be prepared?

Our team has a strong history of collaboration and success in forming partnerships, comprised of people living with HIV, researchers, clinicians and community stakeholders with knowledge of HIV, aging and rehabilitation, implementation science, and knowledge transfer and exchange.

Nominated Principal Investigator, **Kelly O'Brien**, is a physical therapist and Associate Professor at the Department of Physical Therapy, University of Toronto and Canada Research Chair in Episodic Disability and Rehabilitation. As the Principal Investigator of the CIHR-funded study to develop and validate the original HIV Disability Questionnaire (HDQ), and the HIV Health and Rehabilitation Survey (HHRS) she is well versed in the development and property assessment of patient reported outcomes (PROs) and evaluation of their utilization. Co-Principal Investigator, **Kristine Erlandson,** is a Medical Doctor and Assistant Professor at the Division of Infectious Diseases, Division of Geriatric Medicine, University of Colorado Denver who's research is focused on understanding the mechanisms of successful aging in HIV-infection. She will oversee the implementation of the study at the University of Colorado Denver site. Co-Principal Investigator, **Soo Chan Carusone** is the Director of Research at Casey House**.** As the site lead at Casey House and a member of the core SF-HDQ team, she will collaborate with Dr. O'Brien to facilitate recruitment and data collection at Casey House. Co-Investigator **Colm Bergin** is a Consultant Physician at St. James's Hospital and Clinical Professor at Trinity College Dublin. As the Ireland site lead, he will oversee the implementation of the study at St. James's Hospital/Trinity College Dublin/ Clinical Research Facility Site. Co-investigator, **Patty Solomon** is a Professor at McMaster University, is an original developer of the HDQ, and an expert in HIV and Rehabilitation. She will be will provide expertise with the

qualitative inquiry and overall guidance in the implementation, data collection and analysis of the data. Co-investigator, **Steven Hanna,** is Professor at McMaster University, who possesses statistical expertise in factor analysis and structural equation modeling. Dr. Hanna will provide expertise in relation to statistics, factor analysis when assessing the properties of the SF-HDQ. Co-Investigator, **Richard Harding** is a Professor at King's College London. He will provide his expertise in relation to measurement, implementation, and evaluation of clinical practice for adults living with HIV and chronic illness. Co-investigator, **Ahmed Bayoumi** is a General Internist and Scientist at the Centre for Research on Inner City Health at St. Michael's Hospital and is an original developer of the HDQ, and a clinician working in HIV care. Dr. Bayoumi will provide expertise with the quantitative inquiry and overall guidance in the implementation, data collection and analysis of the data, translation of the findings, and inform the relevance of this work specifically to successful aging with HIV in Canadian clinical settings. Co-investigator, **Aileen Davis** is a Professor at the University of Toronto and Senior Scientist in the Division of Health Care and Outcomes Research Unit at the University Health Network. She will be involved in all aspects of this study, specifically providing methodological and psychometric expertise as it relates to Rasch analysis and development and assessment of the SF-HDQ.

Possible Risks and Benefits

Possible Risks – (Complete as Applicable)

Psychological/Emotional Risks:

It is possible that some adults living with HIV may find some of the questions on the questionnaires or in the interviews to be personal or sensitive in nature. Participants can choose not to answer questions and may end the interview at any time. If the participants find themselves becoming very upset during this study, the investigators will recommend discussing their feelings with their health care professional (e.g. physician), qualified counselor, or services at the specific site (Casey House, University of Colorado Hospital or St. James's Hospital). If the participants have difficulty contacting a health care professional, qualified counselor or local community health center, they may contact the principal investigator /site lead for further assistance. In this situation, the study team will facilitate linkages to supportive services at the specific site of study for the given participant.

Physical Risks:

There is no physical risk from taking part in this study.

Social Risks:

Adults living with HIV: There is no known social risk for participants. Participants will be completing the SF-HDQ in the study as part of their regular clinic or day health program visit as part of the pilot implementation. Participants will be reminded that all findings will be presented in a way that maintains participant anonymity.

HIV Health Providers: Health Provider participants are at low-risk. However, some participants may feel pressured to participate and/or uncomfortable speaking honestly when the findings may be reported back to their colleagues and superiors. To mitigate this risk, potential participants will be informed that their choice to participate will not be shared with anyone outside of the research team and will have no impact on their employment now or in the future. Participants will also be reminded that all findings will be presented in a way that maintains participant anonymity.

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Legal Risks:

Not applicable.

Potential Benefits

Benefit Description:

Taking part in this study will not give the participants any health benefits or give them any treatment, experimental or otherwise. However, it may help to develop a new measure of disability and advance knowledge about the disability that adults living with HIV experience. Many of the patients who decide to take part in these studies do so for altruistic reasons. They have a genuine concern about the HIV epidemic and understand that they might be contributing to a potential solution for this complicated medical illness.

Date Last Revised: February 13, 2022

Consent

Consent Process Details:

Objective 1b) Assessing the utility of the SF-HDQ

Adults Living with HIV

Initial contact with potential participants who are adults living with HIV will be made via a study poster (**Appendix I**) at recruitment locations or directly via health care professionals who may have invited their clients to participate. After the study investigators have made the initial in person contact in the clinic setting to determine the eligibility, a copy of the information sheet and consent form (**Appendix J1**) to individuals who are eligible and interested in participating will be sent out by email or provided in person.

Participants may consent in person upon initial determination of eligibility or those who are interested can ask to be contacted by study investigators (by email) to arrange an appointment at which written consent will be obtained. The research team will reach out to the participants (**Appendix L**) and will attach the information letter and consent form (by email) (**Appendix J1**) or discuss the contents of the consent form by phone or in person to individuals who are eligible and interested in participating in the study. The individual will be informed of the purpose and rationale of the study, inclusion criteria, potential medical and social risks of participation, the voluntary nature of the study and their right to withdraw at any time, and compensation (**Appendix J1**). We will also provide further information regarding the types of questions they will be asked. We may send up to two reminders to potential participants after sending copies of the information sheets and consent forms. Participants who indicate that they are not interested or do not respond after these two requests, will not be further approached about participation. Signed consent will occur in person prior to the time of scheduled administration of questionnaires and interview.

Participants may choose to withdraw from the study at any point in time for any reason. For example, if participants appear too uncomfortable with the questions being asked in the interview or on the questionnaires, they may withdraw at any time and still receive the token of appreciation (if applicable). Furthermore, if the interviewer or (questionnaire administrator) feels that participants are too uncomfortable with the questions asked, he/she may also stop the interview / questionnaire administration. If participants choose to withdraw before the completion of the interview or questionnaire administrations, participants will have the opportunity to withdraw their information from the study, otherwise investigators may use information collected up to the point before participants withdrew.

HIV Health Providers

An initial recruitment will occur via email to the targeted sample of key informant health providers working in HIV care at the three sites (Casey House, University of Colorado, St. James's Hospital). Initial contact with potential participants will be made via email; in the email we will provide information about the study such as the purpose statement, research objectives and proposed impact of results (**Appendix M1**). We will provide them with the information letter and consent form (**Appendix J2**), which includes additional information such as participation requirements (i.e. the interview process) and contact information of the research team.

Interested individuals will be asked to contact the Research Coordinator at their given site by email or telephone to discuss the eligibility and details associated with the study. Signed consent will occur in person prior to the time of scheduled administration of questionnaires and interview.

Supplemental File 1
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Capacity/Competency Assessment Process

Process Details by which Capacity/Competency will be assessed and alternate sources of consent:

Given our target population of adults living with HIV may experience cognitive impairment influencing their capacity to consent. This possibility will be addressed at the recruitment stage as researchers will include the capacity to consent as inclusion criteria for consideration by staff at the sites (Casey House, University of Colorado Hospital and St James's Hospital). We will continually assess participant capacity throughout communication leading up to participation, by asking potential participants to reiterate in his/her own words their understanding of the study, what is involved with participation and the risks/benefits of participating.

Assent Process

Participant Assent Process Details:

Not applicable.

Debriefing and Dissemination

Information Feed Back Details following completion of a participant's participation in the project:

In collaboration with the Community Advisory Committee, we will implement a KT plan including presentations at academic conferences, community organizations at each of the sites, development of a fact sheet summary for broad distribution at the sites and via the Canada-International HIV and Rehabilitation Research Collaborative (CIHRRC); drafting manuscripts for peer-reviewed publication in open access journals. We will specifically email a copy of a fact sheet summary of the study findings to all participants.

Procedural details which allow participants to withdraw from the project:

After the study investigators make initial contact, a copy of the information sheet and consent form (Appendix J1 & Appendix J2) will be discussed in person or by phone to individuals who are eligible and interested in participating. On the information sheet and consent form, details about participants' right to withdraw are clearly presented. Participants will be reminded of their right to withdraw from the project verbally prior to administration of the SF-HDQ and interview.

Participants may choose to withdraw from the study at any point in time for any reason. For example, if participants appear too uncomfortable with the questions being asked in the interview or on the questionnaires, they may withdraw at any time and still receive their compensation.
Furthermore, if the interviewer or (questionnaire administrator) feels that participants are too uncomfortable with the questions asked, he/she may also stop the interview / questionnaire administration.

When ensuring the capacity to consent, the individual will be asked to communicate his/her understanding of his/her right to withdraw from the study at any time. The participant will also be reminded of this right if he/she appears distressed with administration of the SF-HDQ or by the interview/or expresses a desire to stop the administration of the SF-HDQ or the interview. Potential participants will be informed that participation in the study is voluntary and that they have the right to withdraw at any time with no negative consequences.

For the adults living with HIV who are accessing services at one of the three sites (Casey House, St. James's Hospital, University of Colorado Hospital), withdrawal will not affect the services that they receive. If participants choose to withdraw before the completion of the interview or questionnaire administrations, investigators may use information collected up to the point before participants withdrew, unless the participant wishes to have it removed. Participants have the right to refrain from answering questions on the SF-HDQ or in the interview that they do not feel comfortable with.

Supplemental File 1
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What happens to a participant's data and any known consequences related to the removal of said participant?

Participants will be informed that choosing to withdraw from the study will not compromise the care they receive (at Casey House, St James's Hospital or University of Colorado Hospital) or their employment, nor will it disqualify them from receiving the token of appreciation, if applicable. In the event of a withdrawal from the study, the participant will be asked if they will permit the use of data obtained up until that point; if they decline, all data associated with the participant will be destroyed.

List reasons why a participant cannot withdraw from the project (either at all or after a certain period of time):

Not Applicable

Confidentiality and Privacy

Data Protection

Describe how the data will be protected through the research phase and subsequent dissemination of results:

All participant study records (individual interview transcripts, demographic questionnaires, SF-HDQ) will be identified by a coded number to maintain participant confidentiality. A master list of participants with their respective codes along with contact information of participants (email; telephone number if applicable) will be stored on a password protected computer file at the site location. Hard copy consent forms will be stored in a locked cabinet at the University of Toronto, St James's Hospital and University of Colorado Denver in a secure office / lab location.

All questionnaire responses will be downloaded from Qualtrics, an online secure e-survey software that uses Transport Layer Security (TLS) encryption, at their respective site and later transferred to the University of Toronto using Sharefile, a password protected and encrypted transfer system and stored on a secure server at the University of Toronto. We will establish data sharing agreements between the University of Toronto, University of Colorado Denver and St. James's Hospital to facilitate the transfer and sharing of anonymized data.

Electronic data will be stored on a password-protected computer in a locked office at the University of Toronto and University of Colorado Denver, accessible only to investigators and research coordinators. Electronic files will be shared among investigators on a secured file share system, ShareFile (http://www.sharefile.com/about//).

All information will remain strictly confidential and available only to study investigators and research staff, members of the IRBs that reviewed the protocol, and other regulatory authorities for the purpose of monitoring this study, unless required by law. All study data will be held at the respective site in which it were collected (University of Colorado Denver, Casey House, St. James's Hospital) according to the institutional privacy protocols (e.g. in a locked cabinet inside a secured office; on a password protected computer) and then transferred to the University of Toronto for storage and analysis.

We will keep all email communications strictly between participants and the research team. The information letter and consent form will also include email and telephone contact details at the Episodic Disability and Rehabilitation Lab. The voice mailbox will be accessible only to the site PI (Kelly O'Brien, Kristen Erlandson, Colm Bergin) and the designated research coordinator.

Date Last Revised: February 13, 2022

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Describe how the data will be retained, and its final disposal or storage. Please provide reason if data will be stored for an indefinite length of time.

Only the research team will have access to the data including questionnaires, audio files and transcripts. All questionnaire responses will be downloaded from Qualtrics, an online secure e-survey software that uses Transport Layer Secuirty (TLS) encryption, at their respective site and later transferred to the University of Toronto using Sharefile, a password protected and encrypted transfer system and stored on a secure server at the University of Toronto. accessible only to the investigators. Any quotations from transcripts attributed in the final written report of the study will be anonymous.

Upon completion of the interviews, we will immediately upload audio files to Sharefile, a secure sharing and encrypted storage system, recordings will be deleted from the recording device and identification numbers will replace participant identifiers on corresponding data. We will ensure anonymity by storing the excel file containing the identification numbers linked with participant names on a password- protected computer located in a locked office at the University of Toronto, St James's Hospital and University of Colorado Denver. Only members of the research team will have access to Sharefile. The researchers will use the password-protected and encrypted Qualtrics account to transfer data. The password for Sharefile will be electronically stored separately from the data obtained.

Printed transcripts and field notes from the interviews and consent forms will be stored in a locked filing cabinet in the office of the primary investigator the University of Toronto, St James's Hospital and University of Colorado Denver. The document that links the name of each participant to their assigned numeric code will be stored on a password protected computer file at the University of Toronto, St James's Hospital and University of Colorado Denver.

No identifying information will be included when compiling and disseminating results. In the event that we want to include specific quotes, participant ID numbers will be used.

Length of Time to Retain Data

Following the completion of the study, printed and electronic data (excluding audio recorded data) will be retained for 5 years in the same location that it was stored throughout the study. Audio files will be destroyed immediately following publication. Files containing personal contact information will be deleted after publication. All remaining electronic and hard copy data and information related to the study will be retained for 5 years after the completion of the study and then destroyed by Kelly O'Brien (Toronto), Kristine Erlandson (Denver) or Colm Bergin (Dublin).

Level of Risk and Research Ethics Board

Explanation/Justification details for the group vulnerability and research risk listed above:

Research is low risk as it involves collection of self-reported questionnaire data about health challenges and verbal data (via interviews). The subject matter of the interviews and demographic and HDQ questionnaires is not sensitive in nature. As such there is a low probability that participants will be harmed and the magnitude of harm should it occur would be low.

Group vulnerability of adults with HIV is medium as participants have a preexisting health condition (HIV) with potentially other concurrent health conditions including mental health, addictions which may affect them psychologically, or socioeconomically.

Group vulnerability and research risk of health providers is low.

Date Last Revised: February 13, 2022

UNIVERSITY OF TORONTO

OFFICE OF THE VICE-PRESIDENT, RESEARCH AND INNOVATION

RIS Protocol Number: 38152

Approval Date: 21-Aug-19

PI Name: Miss Kelly O'Brien

Division Name:

Dear Miss Kelly O'Brien:

Re: Your research protocol application entitled, " SF-HDQ Study: Advancing Assessment of Episodic Disability to Enhance Healthy Aging among Adults Living with HIV: Developing a Short-Form HIV Disability Questionnaire (SF-HDQ) for use in Clinical Practice"

The HIV REB has conducted a Full Board review of your application and has granted approval to the attached protocol for the period 2019-08-21 to 2020-08-20.

Please note that this approval only applies to the use of human participants. Other approvals may be needed.

Please be reminded of the following points:

- An **Amendment** must be submitted to the REB for any proposed changes to the approved protocol. The amended protocol must be reviewed and approved by the REB prior to implementation of the changes.
- An annual **Renewal** must be submitted for ongoing research. You may submit up to 6 renewals for a maximum total span of 7 years. Renewals should be submitted between 15 and 30 days prior to the current expiry date.
- A **Protocol Deviation Report** (PDR) should be submitted when there is any departure from the REB-approved ethics review application form that has occurred without prior approval from the REB (e.g., changes to the study procedures, consent process, data protection measures). The submission of this form does not necessarily indicate wrong-doing; however follow-up procedures may be required.
- An **Adverse Events Report (AER)** must be submitted when adverse or unanticipated events occur to participants in the course of the research process.
- A **Protocol Completion Report** (PCR) is required when research using the protocol has been completed. For ongoing research, a PCR on the protocol will be required after 7 years, (Original and 6 Renewals). A continuation of work beyond 7 years will require the creation of a new protocol.
- If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.

OFFICE OF RESEARCH ETHICS
McMurrich Building, 12 Queen's Park Crescent West, 2nd Floor, Toronto, ON M5S 1S8 Canada
Tel: +1 416 946-3273 ● Fax: +1 416 946-5763 ● ethics.review@utoronto.ca ● http://www.research.utoronto.ca/for-researchers-administrators/ethics

University Research
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
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UCD Anschutz Medical Campus | UCD Downtown Denver Campus | University of Colorado Health | Denver Health and Hospitals | Colorado Prevention Center | Children's Hospital Colorado | Colorado School of Mines | VA Eastern Colorado Health Care System

Certificate of Approval

06-Sep-2019

Title:	Developing a Short-Form Version of the HIV Disability Questionnaire (HDQ)
Subject:	COMIRB Protocol 19-1895 Initial Application
Investigator:	Kristine Erlandson
Sponsor(s):	National Institute on Aging/NIH/DHHS~
Effective Date:	06-Sep-2019
Expedited Category:	7

Submission ID: APP001-2

SUBMISSION DESCRIPTION:

APP001-2: Response to request for minor modifications.

APP001-1: Initial application for Expedited chair review.

This study was reviewed and approved under the “2018 Requirements” of the Federal Policy for the Protection of Human Subjects.

If continuing review is required for your research, your submission is APPROVED until the expiration date listed above. The investigator will need to submit this research for Continuing Review at least 30 days prior to the expiration date. If a study's approval expires, investigators must stop all research activities immediately (including data analysis) and contact the COMIRB office for guidance

If your study has not been assigned an expiration date continuing review is not required for your research.

Regardless of continuing review, you are required to submit changes to your research for approval prior to implementing those changes. You are required to report unanticipated problems and serious or continuing noncompliance to COMIRB. When your research is complete you must report the study closure to COMIRB.

Your responsibilities as Principal Investigator are posted here:
http://www.ucdenver.edu/research/Research%20Administration%20Documents/Responsibilities-of-Investigators.docx

REVIEW DETAILS– Please read carefully:

Dr. Erlandson:

Thank you for your responses to the requested minor modifications. It can now be approved but there is one other thing you should be aware of and that will need clarification. Because one of your data collection sites is Ireland, the General

Data Protection Regulation (GDPR) of the European Union comes into play. If you're not familiar with the GDPR, they are a set of very strict regulations on data privacy with very heavy penalties for violation, primarily aimed as internet business but which includes research. While this is primarily a concern for the lead site (Toronto) and the Irish site, the fact that, it appears, you will have access to the data brings CU into the picture. Please contact COMIRB Director, John Heldens (john.heldens@CUAnschutz.edu) who can help you determine the appropriate path.
Minimal Risk: This research poses no more than minimal risk as defined in 45 CFR 46.102(i) [and/or] 21 CFR 56.102(i). This submission was reviewed under Expedited procedures and the following determinations were made.
Affiliated Site:
University of Colorado Health
Informed consent is required.

All criteria for waiving of documentation of consent were met for Aim 2.
HIPAA: This study is subject to HIPAA. A waiver of Authorization was granted [for screening]. All criteria for waiving HIPAA authorization were met.
Certificate of Confidentiality: [If NIH or CDC-funded, or if PI has requested a CoC] This study must be conducted under the terms of a certificate of confidentiality. More details regarding the terms of CoCs can be found on the NIH and CDC websites.
The following documents have been reviewed as part of this approval :
AIM1BConsent v 09.03.19
Aim2Consent(patient) v 09.03.19
AIM2ProviderConsent v 09.03.19
Appendix M-- Provider Emiail v 08.07.19
Appendix-A-HDQ-Version-2017-Ver-10-7-Jun-28-19-CLEAN-Aug-7-19
Appendix-B-Sensibility-Questionnaire-Aug-7-19
Appendix-C-SFHDQ-Demographic-Questonnaire-Aug-20-19
Appendix-D-Sensibility-Interview-Guide-REVISED-Aug-20-19
Appendix-E-Global-Disability-Rating-Scale-Aug-7-19
Appendix-F-Criterion-Measures-WHODAS-PHQ8-MOS-SSS-Aug-7-19
Appendix-G-HCPs-PreInterivew-Questionnaire-Objective2-Aug-7-19
Appendix-H-Obj2-Health-Provider-Interview-Guide-REVISED-Aug-20-19
Appendix-N-Reminder-Email-SFHDQ-PLWH-HCPs-Aug-7-19
Application Form v 08.20.19
CF-260_Advertising_Components_Form
cover letter (no date)
FINAL-OBrien-NIH-APPLICATION-ALL-SUBMITTED-DEC-19-18
Personnel eForm v 09.03.19
portal clearance v 08.20.19
Protocol-Template v 08.20.19
Qualtrics-Security-Document-Aug-2019
Response Submission Cover Letter v 08.20.19
SF-HDQ-Version-Possible short form (as an example) v 05.24.19
UofT-REB-Comments-Aug-20-19
UofT-REB-SFHDQ-Study-Approval-Letter-Aug-21-19

If red-line changes were made, the tracked changes and clean versions have been uploaded into eRA (InfoEd). If the PI disagrees with these changes, submit a change form to COMIRB with the revised documents.

Click here to your submission: Submission Page

Study personnel are approved to conduct the research as described in the above documents approved by COMIRB

Information on how to submit changes (amendments) to your study, reports of unanticipated problems, and request for study closure to COMIRB can be found on the COMIRB website
http://www.ucdenver.edu/research/comirb/submissions/Pages/default.aspx

For the duration of this research the investigator must:

- Submit any change in the research design, investigator, and any new or changed study documents (including new/changed consent forms, questionnaires, advertisements, etc.) to COMIRB and receive approval before implementing the changes
- Use only a copy of the COMIRB-approved, stamped Consent and/or Assent Form. The investigator bears the responsibility for obtaining Informed Consent from all subjects as required by COMIRB prior to the start of study procedures. COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form after it is signed.
- Inform COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policies and Procedures.
- Remain actively engaged in the conduct of the research. The investigator must ensure that all enrolled participants are appropriate for the study prior to study procedures beginning.

As part of this review it was determined that for this research:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, §46.116.
5. Informed consent will be appropriately documented in accordance with, and to the extent required by, §46.117.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Appropriate safeguards are in place to protect potentially vulnerable populations from coercion and undue influence.

Please reply to the email containing this letter, contact the COMIRB Help Desk at COMIRB@ucdenver.edu or call 303-724-1055 if you have questions or concerns.

Sincerely,

UCD Panel S

Tallaght University Hospital | Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

SJH/TUH Research Ethics Committee Secretariat
email: researchethics@tuh.ie

Prof Colm Bergin,
St James's Hospital,
James' Street,
Dublin 8

09th January 2020

REF: Advancing Assessment of Episodic Disability to Enhance Healthy Aging among Adults Living with HIV: Developing a Short-Form HIV Disability Questionnaire (HDQ) for use in Clinical Practice

REC: 2019-12 Chairman's Action (1)
(Please quote reference on all correspondence)

Date of Valid Submission to REC: 04.09.2019
Date of Ethical Review: 03.12.2019
Research and Innovation Application Number: PLEASE SUBMIT

Dear Prof Bergin,

The REC is in receipt of your recent request to TUH/SJH Research Ethics Committee in which you queried ethical approval for the above named study.

The Chairman, Prof. Richard Dean, on behalf of the Research Ethics Committee, has reviewed your correspondence given **full approval** for this study to proceed. However, please submit the Research and Innovation Number to the JREC, please also submit the approval od the DPIA from the DPO as data is going to Canada.

Applicants must submit an annual report for ongoing projects and an end of project report upon completion of the study. It is the responsibility of the researcher/research team to ensure all aspects of the study are executed in compliance with the General Data Protection regulation (GDPR), Health Research Regulations and the Data Protection Act 2018. ***Additionally, please note for documents submitted for GDPR purposes that the REC and the Chair are not confirming that you're documents are GDPR compliant, they are approving the document from an ethical perspective.***

Yours sincerely,

Sadhbh O'Neill

REC Officer – Dr Sadhbh O'Neill
SJH/TUH Research Ethics Committee

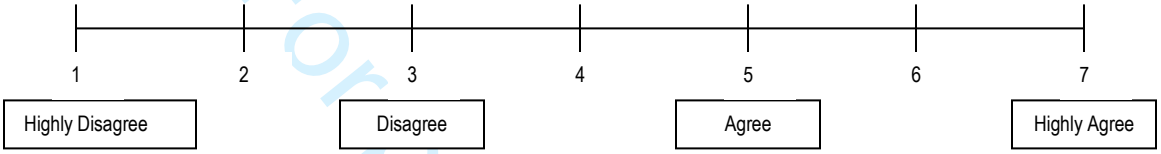
The SJH/TUH Joint Research and Ethics Committee operates in compliance with and is constituted in accordance with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 & ICH GCP guidelines.

Supplemental File 2
Sensibility Questionnaire (Adults Living with HIV Version Example)

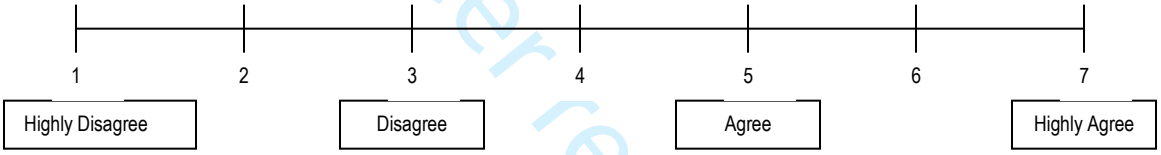
You have just completed (or reviewed) the new Short-Form HIV Disability Questionnaire (SF-HDQ). The goal of the questionnaire is to describe disability experienced by adults living with HIV. We would like to get your feedback on its use in the clinic setting. There is no right or wrong answers. Please circle the most appropriate numeric answer on the scale in response to each of the following statements pertaining to the Short-Form HIV Disability Questionnaire.

Face Validity

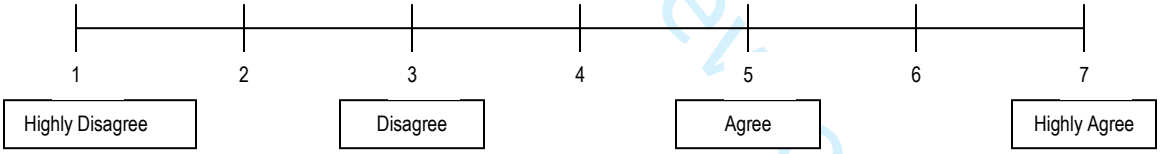
1. I was able to answer all of the questions.



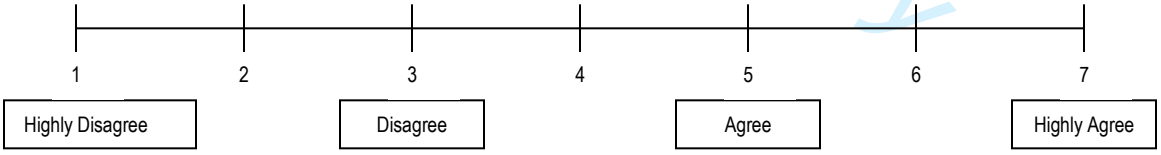
2. The instructions were clear and easy to understand.



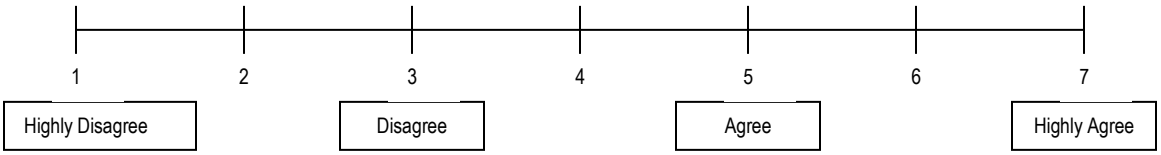
3. The questions were clear and easy to understand.



4. The overall questionnaire makes sense.



5. The response categories for the questions were adequate.

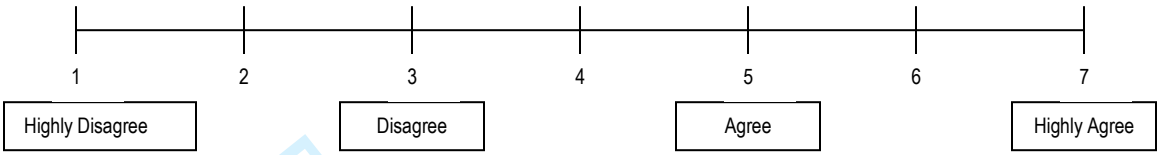


Date Last Revised: February 13, 2022

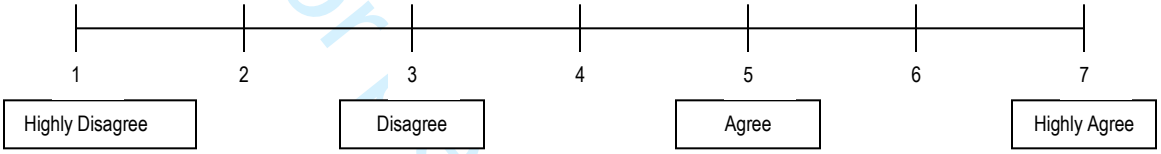
Supplemental File 2
Sensibility Questionnaire (Adults Living with HIV Version Example)

Content Validity

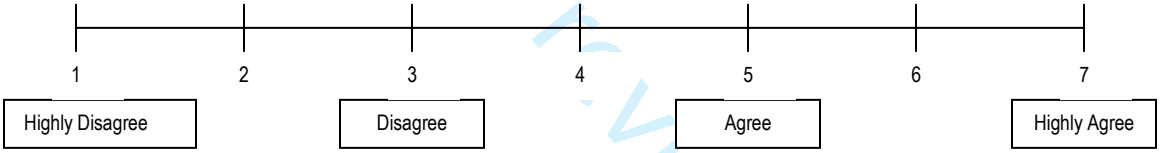
6. The Short-Form HIV Disability Questionnaire was intended to capture disability which has been defined by adults living with HIV as: symptoms / impairments, difficulties with day-to-day activities, challenges to social inclusion and uncertainty. The questionnaire captured all elements of my disability.



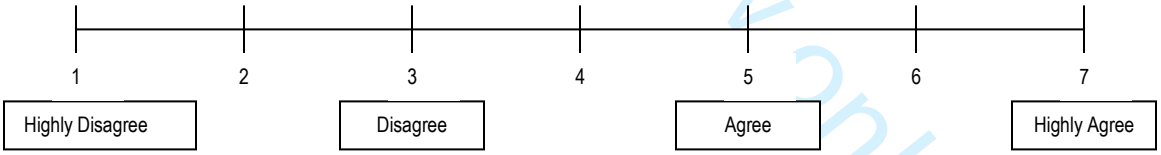
7. The questionnaire included important items that are necessary to describe my disability.



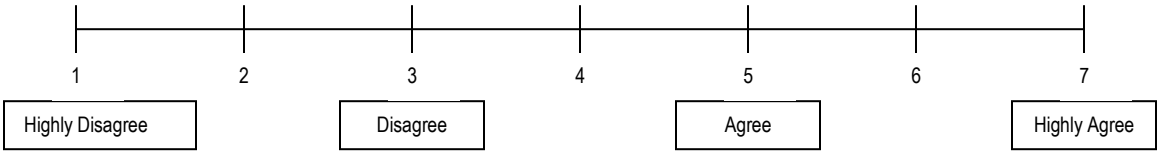
8. The questionnaire included items that were repetitive or redundant.



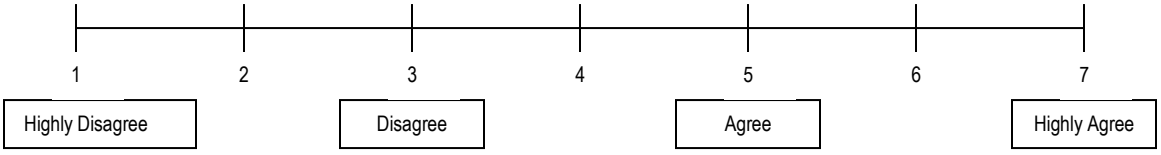
9. There were items missing in this questionnaire that should be included.



10. Some of the questions seemed out of order.



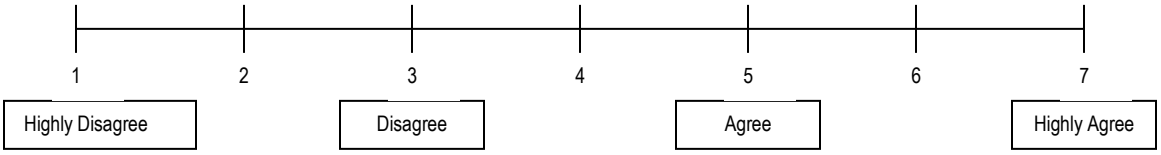
11. I was able to find my answer in the list of possible answers to the questions.



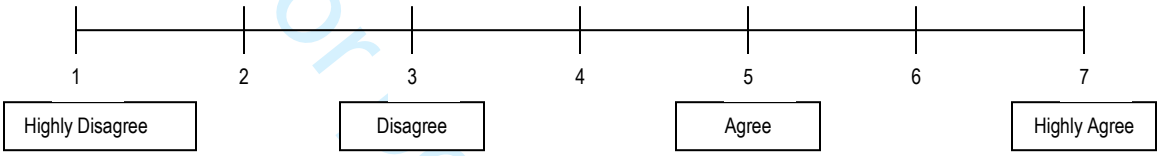
Supplemental File 2
Sensibility Questionnaire (Adults Living with HIV Version Example)

Format and Ease of Usage

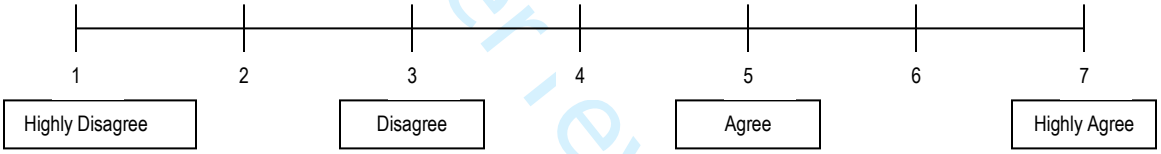
12. I felt uncomfortable answering some of the questions because I did not want to have anyone know my answer.



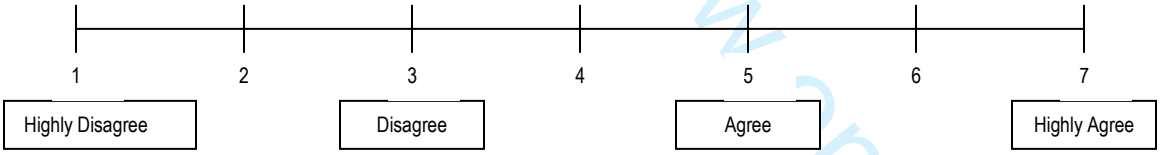
13. I felt that the questions made me think about things that I would have preferred not to have thought about.



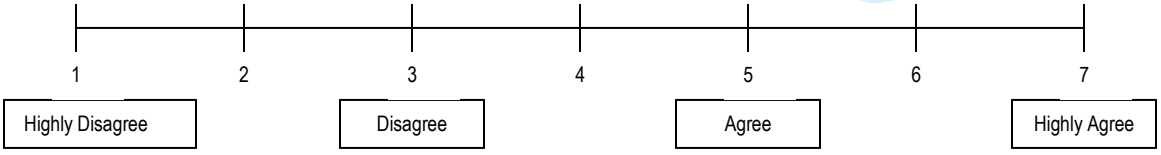
14. I felt that answering the questions helped me in some way.



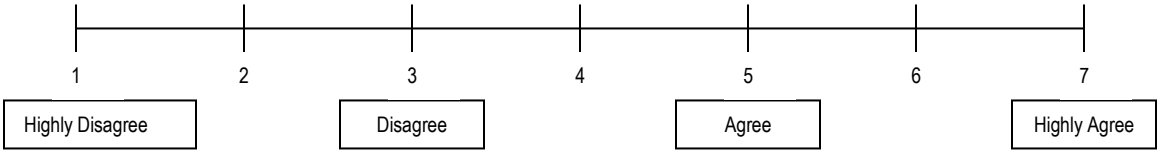
15. The questionnaire took too long for me to complete.



16. The questionnaire required too much effort to complete.

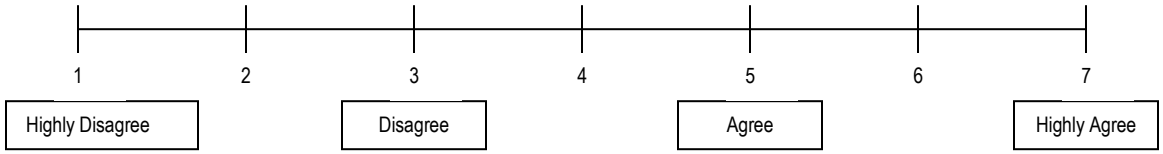


17. The questionnaire was easy to complete using the electronic tablet.

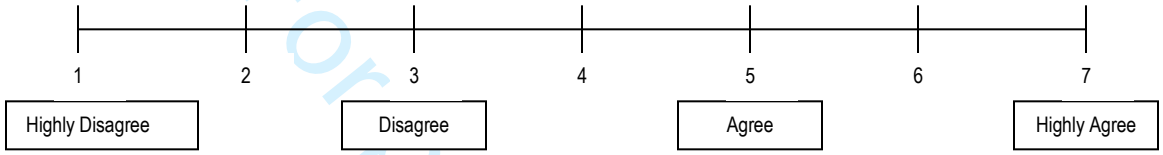


Supplemental File 2
Sensibility Questionnaire (Adults Living with HIV Version Example)

18. I would like to receive a summary of my HDQ scores right after completing the questionnaire to help understand the areas (or domains) where I might experience health challenges.



19. Overall, this questionnaire is useful in describing disability experienced by adults living with HIV.



Supplemental File 3
Interview Guide (Adults Aging with HIV & Health Care Practitioners)

Thank you for agreeing to participate in this study. As you know, our aim is to establish a short-form version of the HDQ. I am meeting with you to try to get your feedback on the questionnaire items you just completed (or reviewed) related to disability. Disability is defined as any symptoms or impairments, difficulties with day-to-day activities, challenges to social inclusion and uncertainty that you may experience living with HIV, its conditions or treatments that can fluctuate on a daily basis and over the entire course living with HIV. I am interested in learning whether you think the short form version of this questionnaire adequately captures the types of health related challenges (or disability) that you (or your patients) might experience living with HIV. I am also interested in learning about your thoughts on the ways in which the SF-HDQ can be used in the clinical setting. As a reminder, this interview is being audio-recorded. You can refuse to answer any questions you are not comfortable or do not wish to answer. Do you have any questions before we begin?
**Note – question delivery will be adapted according to the target population (adult living with HIV who completed the SF-HDQ versus health care providers that will review the SF-HDQ)*

Past Experience

1. *What are your past experiences with the HDQ? (i.e. any involvement with HDQ prior to today?)*

Probes:

- Health Provider Participants
  - Have you administered the HDQ in your work previously?
  - Have you been given feedback about the HDQ from patients/ clients who have completed the HDQ?
    - If so, what was the feedback?
- PLWH Participants– have you completed the HDQ as a client, patient, or study participant, previously?

Current Experience (as of Today)

2. *Can you describe your overall experience completing (or administering) the SF-HDQ?*

3. *What went well? What didn't go well?*

Date Last Revised: February 13, 2022

Supplemental File 3
Interview Guide (Adults Aging with HIV & Health Care Practitioners)

Face and Content Validity

4. What are your overall thoughts on the short-form HDQ questionnaire items?

Probes:

How well do you think the items captured the disability you (or your patients) experience living with HIV?

- symptoms or impairments (physical, cognitive, mental-emotional)
- difficulties carrying out day-to-day activities (e.g. shopping, meal preparation)
- challenges to social inclusion (e.g. work, personal relationships, parenting)
- uncertainty (e.g. worrying about the future living with HIV)

5. Do you feel there were any items that especially captured the types of disability you (or your patients) experience? (were really good at capturing your (your patients') disability?)

Probes:

If yes, what were those important questions?

[If vague can ask participants to identify which items were the really important ones?]

6. Do you feel the response options were sufficient to allow you (your patients) to adequately answer the question to best describe your disability experience?

Probes:

If yes, what did you like about the response options?

If no, what would you change about the response options?

Item Generation

7. Do you feel there were any items missing from the questionnaire?

Probes:

If yes, what types of questions would you like to see put back (or added) into the SF-HDQ?

- symptoms or impairments (pain, fatigue, body composition changes)
- difficulties carrying out day-to-day activities (e.g. shopping, meal preparation)
- challenges to social inclusion (e.g. work, personal relationships, parenting)
- uncertainty (e.g. worrying about the future living with HIV)

How might you word those questions on a questionnaire?

Supplemental File 3
Interview Guide (Adults Aging with HIV & Health Care Practitioners)

Item Wording

8. What do you think about the wording of the questions in the questionnaire?

Item Reduction

9. Do you think there were any questions that were redundant or repetitive? (meaning, do you think the SF-HDQ could be made even shorter?)

Probes:

If yes, what were those questions?
Do you think that these items could be removed from the questionnaire and it still adequately capture your (your patients') experience?

Ease of Usage

10. What did you think of the length of time it took you (or will take your patients) to complete the questionnaire?

Probes:

Was the time it took to complete the questionnaire too long?
Could you (your patients) have completed a longer questionnaire?

Utility / Overall Purpose

11. How might the SF-HDQ be used in clinical practice? What ways do you think the SF-HDQ might be used in clinical practice?

Probes:

- Assessing or describing disability experienced by adults aging with HIV?
- Helping with communication about disability experienced between patients and providers?
- Goal-setting?
- Identifying areas to target interventions?
- Identifying challenges that might help guide referrals to other services or providers?

12. How might you envision the SF-HDQ being used in your clinical practice? What would be the optimal way to use it?

Date Last Revised: February 13, 2022

Supplemental File 3
Interview Guide (Adults Aging with HIV & Health Care Practitioners)

13. Do you see the SF-HDQ as a benefit for use in clinical practice? IF so, how?

Probes:

- Instant feedback of disability scores to care providers and patients / identifying domains with challenges?
- See above.

14. Do you see any challenges with using the SF-HDQ in clinical practice? IF so, how?

Probes:

- Burden of time?
- Lack of technology literacy (tablet format)?
- Concerns of data privacy?

Administration

*15. What did you think of completing the questionnaire on the **electronic tablet**?*

Probes:

What did you like? Not like? Did you have any problems with the tablet format? (or do you think that your patients might have any problems with the tablet?)

*16. Who do you think is the **ideal person to administer** the SF-HDQ in clinic?*

Probes:

Type of health provider? Administrative personnel? Does it matter?

*17. When do you think would be the **ideal time to administer** the SF-HDQ in clinic? How often?*

Probes:

Prior to attending the clinic? At the clinic but before your appointment with health provider? Explain.

Scoring

The SF-HDQ is scored on a scale from 0-100 with higher scores indicating greater presence, severity and episodic nature of disability: (Provide an example of what SF-HDQ score sharing might look like – SF-HDQ item responses; domain summary numeric scores, and visual bar graph)

Supplemental File 3
Interview Guide (Adults Aging with HIV & Health Care Practitioners)

*18. What do you think about **seeing / sharing SF-HDQ scores immediately** after you complete / administer the questionnaire?*

Probes:

What about sharing the **domain scores** (6 domain scores) each for severity, presence, and episodic nature of disability?

What about seeing / sharing **specific SF-HDQ item responses for all 35 questions?**

What do you think would be the best **FORMAT** to share scores (e.g. numeric, bar graph, items, domain scores, etc)?
What might the PROCESS of sharing scores look like (e.g. discussion with patient and provider)?

*19. What might be some **reasons behind your preferences** to receive (share) / not receive (not share) domain scores or item responses?*

Probes:

What might be some **strengths of seeing / sharing scores**?
What might be some **concerns or limitations?**

*20. How might **patients use the SF-HDQ scores** (summary scores; individual item responses)?*

*21. How might **clinicians use them?** (aka – what would we do with the numbers?)*

*22. In summary, how might you **recommend SF-HDQ scores be shared with patients / used by clinicians?***

Episodic Nature of Disability

23. What do you think about the way in which the SF-HDQ asks about fluctuations in health related challenges?

Probes:

Can you think about what is a good day for you and what is a bad day for you – have you experienced both a good day and a bad day within the last week? Last 2 weeks? Last month?

Supplemental File 3
Interview Guide (Adults Aging with HIV & Health Care Practitioners)

How often do your episodes occur? *Do you think that it is possible to capture the episodic nature of disability on this questionnaire? If so, please explain how this might occur? Timeline – 1 week episodes ups and downs? 2 weeks for the episodes? Should we ask about the last month for the episodic nature? How can we capture that in a questionnaire?*

Summary

Do you have anything else you wish to say about the questionnaire that you completed today in relation to the way it captures disability?

Do you have any other suggestions for how this questionnaire can better capture and describe disability experienced by adults living with HIV?

Thank you very much for participating in this interview today. Your responses will help to refine this future measure of disability.

For Adult Living with HIV Participants: If you feel that today's discussion has raised any difficult issues for you, or if you wish to pursue support or want to talk more about any of the topics discussed today, feel free to talk to the staff at _____ for more support.

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	9
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1-3
Occupation	3	What was their occupation at the time of the study?	1-3
Gender	4	Was the researcher male or female?	9
Experience and training	5	What experience or training did the researcher have?	31
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	9
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	9
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	9
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	7; 9-11
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	8
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	8
Sample size	12	How many participants were in the study?	11
Non-participation	13	How many people refused to participate or dropped out? Reasons?	NA
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	10-11
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	9
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	11-13
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	10; SuppFile2;
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	NA
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	10
Field notes	20	Were field notes made during and/or after the inter view or focus group?	10
Duration	21	What was the duration of the inter views or focus group?	11
Data saturation	22	Was data saturation discussed?	NA
Transcripts returned	23	Were transcripts returned to participants for comment and/or	NA

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	11
Description of the coding tree	25	Did authors provide a description of the coding tree?	11
Derivation of themes	26	Were themes identified in advance or derived from the data?	11
Software	27	What software, if applicable, was used to manage the data?	11
Participant checking	28	Did participants provide feedback on the findings?	NA
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	17-25
Data and findings consistent	30	Was there consistency between the data presented and the findings?	17-25
Clarity of major themes	31	Were major themes clearly presented in the findings?	17-25
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	17-25

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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BMJ Open

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

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Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

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ABSTRACT

Objectives: The Short-Form HIV Disability Questionnaire (SF-HDQ) was developed to measure the presence, severity and episodic nature of health challenges across six domains. Our aim was to assess the sensibility, utility and implementation of the Short-Form HIV Disability Questionnaire (SF-HDQ) in clinical practice.

Design: Mixed methods study design involving semi-structured interviews and questionnaire administration.

Participants: We recruited adults living with HIV and HIV clinicians in Canada, Ireland, and the United States.

Methods: We electronically administered the SF-HDQ followed by a sensibility questionnaire (face and content validity, ease of usage, format) and conducted semi-structured interviews to explore utility and implementation of the SF-HDQ in clinical practice. The threshold for sensibility was a median score of ≥5/7 (adults living with HIV) and ≥4/7 (HIV clinicians) for ≥80% of items. Qualitative interview data were analyzed using directed content analysis.

Results: Median sensibility scores were ≥5 (adults living with HIV; n=29) and ≥4 (HIV clinicians; n=16) for 18/19 (95%) items. Interview data indicated that the SF-HDQ represents the health-related challenges of living with HIV and other concurrent health conditions; captures the daily episodic nature of HIV; and is easy to use. Clinical utility included measuring health challenges and change over time, guiding referral to specialists and services, setting goals, facilitating communication, and fostering a multi-disciplinary approach to care. Considerations for implementation included flexible, person-centered approaches to administration, and communicating scores based on personal preferences.

Conclusions: The SF-HDQ possesses sensibility and utility for use in clinical settings with adults living with HIV and HIV clinicians in three countries.

KEY WORDS

HIV, disability evaluation, questionnaires, sensibility, measurement, reliability and validity, interview

STRENGTHS & LIMITATIONS OF THIS STUDY

- Our mixed methods study involving qualitative and quantitative approaches ensured a comprehensive assessment of sensibility, utility and implementation of the Short-Form HIV Disability Questionnaire (SF-HDQ) in clinical practice.
- Our multi-site approach spanning three different clinical contexts with both adults living with HIV and health care practitioners enabled us to assess the utility of the electronic mode of SF-HDQ administration, and examine considerations for implementation across three different healthcare contexts.
- This study draws on a strong conceptual foundation of episodic disability (Episodic Disability Framework) and measurement of disability (Short Form-HIV Disability Questionnaire).
- Given our SF-HDQ assessment was focused on electronic administration, this limited participation to adults living with HIV who had access to, and comfort with, the use of technology to complete the questionnaires and participate in the interview in a web-based format.

INTRODUCTION

In developed countries such as Canada, Ireland and the United States, HIV is now experienced as a chronic illness.[1] In 2018, an estimated 51% of Americans living with HIV were aged 50 and older[2] and similar trends are forecast in other countries such as Canada and the United Kingdom (UK) with widespread access to treatment.[3 4] Individuals with HIV can reach life expectancies similar to the general population. Thus, more individuals are living longer with the health consequences of HIV. People living with HIV can experience chronic conditions at higher rates compared to the general aging population[5 6] such as cardiovascular disease[7], bone and joint disorders[8 9], diabetes[10], frailty[11], neurocognitive disorders[12 13], and some forms of cancer.[14] This multimorbidity can increase the severity and complexity of health consequences of those aging with HIV[15-18], collectively referred to as disability.[17 19]

Disability is defined by people living with HIV as any physical, cognitive, mental-emotional symptoms, difficulties with day-to-day activities, challenges to social inclusion, and uncertainty about future health [17]. Disability including fatigue, pain, challenges engaging in employment, and age-related issues of frailty; coupled with poor access to services, stigma, and poverty can pose barriers to remaining engaged in care, for people living with HIV.[20]

Standardized patient reported outcome measures (PROMs), developed to capture the nature and extent of disability and its fluctuation over time, are critical to identify health priorities for those aging with HIV, to guide the provision of timely and appropriate care, and to determine the effectiveness of interventions.[21-23] We developed a 69-item PROM, the HIV Disability Questionnaire (HDQ) to measure the presence, severity and episodic nature of disability experienced by people living with HIV.[24] Derived from the *Episodic Disability Framework,* the HDQ measures disability across 69-items grouped into six domains: i) physical, ii) mental-emotional, and iii) cognitive symptoms and impairments, iv) difficulties with day-to-day activities, v) challenges to social inclusion and vi) uncertainty about future health.[25] The HDQ addresses gaps in previously existing health status measures to capture uncertainty (e.g. worrying about the future) and challenges to social inclusion (e.g. work, parental roles, relationships).[26] In addition, the HDQ

possesses sensibility, reliability and validity for use among people living with HIV in Canada, United Kingdom, United States and Ireland.[27-29]

To date the HDQ has been used primarily as a paper-based tool in research-focused settings, with little uptake in clinical practice due to concerns about the time it takes to complete. We recently revised the HDQ using Rasch analysis to a short-form version of the questionnaire (SF-HDQ) to enhance the feasibility for use in clinical practice.[30] To date, the development and structural validity of the SF-HDQ primarily have been established in Canada.[30] However the sensibility, specifically the comprehensiveness, clarity, ease of usage and format for use of the SF-HDQ in clinical settings is unknown.[31-33]

Our aims were to (i) assess the sensibility (face and content validity, ease of usage, format) of the SF-HDQ, (ii) explore perspectives on the utility of the electronic SF-HDQ in clinical practice, and (iii) identify implementation considerations for administration and communicating scores of the SF-HDQ in clinical practice in Canada, Ireland and the United States from the perspectives of adults living with HIV and HIV health care practitioners.

METHODS

Study Design

We conducted a mixed methods study with a convergent design using quantitative (questionnaire) and qualitative (interview) methods of data collection.

Study Setting

This study was conducted at three clinical settings in three countries: Canada (Casey House, Toronto), Ireland (Department of Genitourinary Medicine and Infectious Diseases (GUIDE), St. James's Hospital, Dublin), and the United States (The UCHealth Infectious Disease/Travel Clinic, University of Colorado). The UCHealth Infectious Disease/Travel Clinic is located in Aurora, Colorado, and provides care to people living with HIV in the Denver metropolitan area, and henceforth is referred to as the 'Denver site'. The Dublin and Denver sites are HIV outpatient clinics and the Toronto site is a specialty HIV hospital

including an inpatient and day health program for people living with HIV. We received ethics approval at the three sites: University of Toronto (Protocol #38152), University of Colorado (Protocol #19-1895) and St. James's Hospital (Protocol #2019-12) (Supplemental File 1).

Patient and Public Involvement

This research builds on a longstanding academic-clinical-community partnership among people ageing with HIV, researchers, and clinicians who identified measurement of disability as a key research priority in HIV, aging and rehabilitation as part of the Canada-International HIV and Rehabilitation Research Collaborative (CIHRRC).[34] Community members living with HIV were involved in the development of the original HIV Disability Questionnaire (HDQ) and the refinement of the SF-HDQ.

Participants

Adults Living with HIV: We recruited adults (18 years of age or older) living with HIV from each site using a recruitment poster asking interested individuals to contact the local study investigator (by email or telephone). We used purposive sampling to obtain diversity in the sample based on age (≥50 years, <50 years) and clinical site.

HIV Health Care Practitioners: We recruited health care practitioners working in HIV care at each site who self-identified as having a role in addressing disability due to HIV, aging and multi-morbidity. We emailed a targeted sample of HIV health care practitioners including (but not limited to) physicians, rehabilitation professionals (occupational therapy, physiotherapy), social workers, and nurses requesting their participation in the study.

We obtained written or verbal consent from all participants prior to the scheduled administration of the questionnaires and interview.

Data Collection

Adults living with HIV completed the electronic version of the SF-HDQ[30], a global rating scale of disability, a Sensibility Questionnaire and a demographic questionnaire using the web-based software

Qualtrics[35] (either via tablet at the clinical site or remotely via an email link) followed by a one-to-one semi-structured interview (either in person or via Zoom). Health care practitioners were asked to review the electronic version of the SF-HDQ and complete the Sensibility Questionnaire (via Qualtrics) prior to participating in the semi-structured interview. Team members in Canada (RA), Ireland (NOS) and the United States (MB) (all female) conducted the interviews and questionnaire administration. None had a prior relationship with participants.

Questionnaires

Short-Form HIV Disability Questionnaire: The SF-HDQ is a 35-item outcome measure developed to describe the health-related challenges experienced when living with HIV or other health conditions across six areas; physical, cognitive and mental-emotional symptoms and impairments, uncertainty or worry about the future; difficulties with day-to-day activities; and challenges to social inclusion.[30] Participants were asked to rate the presence and severity of each health-related challenge and to indicate whether it fluctuated in the past week. The SF-HDQ possesses structural validity for use with adults living with HIV.[30]

Sensibility: Using Feinstein's sensibility criteria[31] comprised of 19 statements (7-point response scale ranging from highly disagree to highly agree), participants living with HIV and health care practitioners were asked about perspectives on face and content validity, mode of administration, format, and ease of usage of the SF-HDQ.[27] See Supplemental File 2 for the Sensibility Questionnaire.

To describe characteristics of the sample, we administered a global rating scale of disability whereby participants living with HIV were asked to check the box (minimum, moderate or severe) that best described how they would rate their health-related challenges (or disability) that day. Participants were also asked to complete a demographic questionnaire comprised of items including age, gender, concurrent health conditions, living situation, antiretroviral use and overall perception of health.

Interviews

Sensibility and Utility: We asked about the utility of the SF-HDQ in practice and participants' experiences with completing or perspectives on potentially administering the SF-HDQ. We also asked about perceived facilitators and challenges related to administering the SF-HDQ in a clinical setting and considerations related to administration including feasibility, format (electronic or paper), when to administer, who should administer, how often to administer and whether and how to communicate SF-HDQ score reports with patients. See Supplemental File 3 for the Interview Guide.

Interviews were conducted by one interviewer in Canada, one in Ireland and two interviewers in the United States. Due to restrictions of the COVID-19 pandemic, most interviews were conducted using the video platform Zoom. All interviews were audio recorded, transcribed verbatim and de-identified for analysis. Data collection and analysis were done concurrently. We refined the interview guide twice over the course of the study, adding probing questions based on the analysis of earlier interviews.

Participants in Toronto, Ontario and Denver, Colorado were given a $30 CAD (or equivalent) gift card as a token of appreciation. Participants in Dublin, Ireland were not given a token of appreciation in keeping with the research procedures at St. James's Hospital.

Analysis

SF-HDQ Scoring: We calculated median (interquartile ranges (IQR)) of SF-HDQ scores. Severity domain scores were calculated using the algorithm developed through Rasch analysis.[30] Presence and episodic scores included a simple sum transformed on scale of 0-100 with higher scores indicating a greater presence, severity and episodic nature of disability.

Sensibility Questionnaire: Each sensibility item was rated on an ordinal scale of 1 (highly disagree) to 7 (highly agree). Participants selected the numeric response on the scale for each item. We calculated median scores for each of the items. We considered the SF-HDQ sensible if median scores were ≥5/7 for adults

living with HIV and ≥4/7 for health care practitioners for at least 80% of the items, and if no items had median scores of ≤3.[27]

Interview Data: We analyzed interview transcripts using content analytical techniques.[36] For sensibility assessment, we used directed content analysis, using initial coding categories derived from Feinstein's Sensibility Framework.[31] For utility and implementation considerations, we used a conventional content analytical approach.[36] Transcripts from participants living with HIV and HIV health care practitioners were analyzed collectively using the same coding scheme. The core qualitative team (MS, KKO, PS) met three times. They initially reviewed two transcripts independently and met to develop, by consensus, a preliminary list of codes and categories based on the interview guide and the two transcripts. The lead analyst (MS) coded five additional transcripts using the preliminary list of codes and then selected three transcripts for the core team to review and discuss. After all the transcripts were coded, the core team reviewed an additional three transcripts and coding reports from the full dataset. At this meeting, the relationships between coding categories were discussed and key themes were identified. Finally, the larger full team met to review, interpret and finalize the themes in relation to our study objectives. NVivo V11.0 QSR International software was used for data management.[37]

Sample size

Our sample size estimation was based on our qualitative approach using interviews to assessing sensibility and utility. Based on our previous sensibility assessment of the original (long-form) HIV Disability Questionnaire (involving interviews with 22 adults living with HIV and 5 clinicians in one country)[27] and the estimated number of interviews required to achieve an understanding of interview data (16-24 interviews),[38] we anticipated a total of 30 adults living with HIV (10 per site) and 15 health care practitioners (5 per site) for a total of 45 participants was sufficient to provide perspectives of sensibility and utility across sites.

RESULTS

We conducted 45 interviews (29 with adults living with HIV and 16 with HIV health care practitioners) between March 3, 2020 and February 2021, each approximately 45 minutes in duration. Sixteen interviews were held in-person (5 participants living with HIV in Toronto; and 5 people living with HIV and 6 health care practitioners in Dublin), and 29 interviews were conducted online through Zoom.

Participant Characteristics

See Table 1 for characteristics of the participants living with HIV. Eight participants in Toronto described having past experiences with the longer version of the HDQ, whereas no participants in Dublin or Denver had any prior experiences with the HDQ. Thirteen participants (46%) reported having minimum, 11 (39%) moderate and 4 (14%) severe health-challenges.

Table 1: Characteristics of Participants Living with HIV

Characteristic	Total Sample (n=29)	Toronto (n=10)	Colorado (n=10)	Dublin (n=9)
Age (in years) (median, 25-75th percentile)	57 (51, 63)	60 (55, 66)	49 (37,63)	57 (53,63)
Gender				
Woman	10 (35%)	2 (20%)	5 (50%)	3 (33%)
Man	19 (66%)	8 (80%)	5 (50%)	6 (67%)
Partnership status				
Single, Separated or Divorced, or Widowed	15 (66%)	10 (100%)	5 (50%)	5 (56%)
Married, common-law, partner or relationship	8 (28%)	0 (0%)	5 (50%)	3 (33%)
Has children	12 (41%)	3 (30%)	5 (50%)	4 (44%)
Living alone	14 (48%)	7 (70%)	3 (30%)	4 (44%)
Employed (full time or part time)	7 (24%)	1 (10%)	4 (40%)	3 (33%)
Highest level of education				
Completed university or post graduate education	6 (21%)	2 (20%)	4 (40%)	0 (0%)
Median year of HIV diagnosis (25-75th percentile)	1996 (1986, 2004)	1990 (1986, 2003)	2002 (1994, 2005)	1991 (1987, 2011)
Antiretroviral therapy use	27 (93%)	9 (90%)	10 (100%)	8 (89%)
Undetectable viral load (<50 copies/mL)	26 (90%)	10 (100%)	10 (100%)	6 (67%)
Median number of concurrent health conditions (25-75th percentile)	7 (4, 10)	10 (6,14)	7 (5,8)	4 (2,11)
Common concurrent health conditions (*≥30% of sample*)				
Mental Health Condition	17 (59%)	8 (80%)	5 (50%)	4 (44%)
Trouble sleeping	16 (55%)	6 (60%)	5 (50%)	5 (56%)
Chronic pain (joint)	15 (52%)	7 (70%	5 (50%)	3 (33%)
High blood pressure	12 (41%)	6 (60%)	3 (30%)	3 (33%)
High cholesterol	11 (38%)	4 (40%)	5 (50%)	2 (22%)
Osteopenia or osteoporosis	10 (35%)	0 (0%)	4 (40%)	6 (67%)
Chronic pain (muscle)	9 (31%)	5 (50%)	3 (30%)	1 (11%)

Characteristic	Total Sample (n=29)	Toronto (n=10)	Colorado (n=10)	Dublin (n=9)
Cognitive decline	9 (31%)	5 (50%)	1 (10%)	3 (33%)
Gastrointestinal conditions	9 (31%)	3 (30%)	4 (40%)	2 (22%)
General Health Status				
Excellent	9 (31%)	3 (30%)	3 (30%)	3 (33%)
Very good	7 (24%)	3 (30%)	3 (30%)	1 (11%)
Good	7 (24%)	3 (30%)	2 (20%)	2 (22%)
Fair	3 (10%)	0 (0%)	1 (10%)	2 (22%)
Poor	2 (7%)	1 (10%)	1 (10%)	0 (0%)

Characteristics reported for 28 of 29 participants (1 participant from Dublin site did not complete).

Across the sample of adults living with HIV (n=29), the highest SF-HDQ presence and severity scores were in the cognitive (median score: 67) and mental-emotional (median score: 37) domains; and the highest episodic scores were in the mental-emotional and physical domains (median score: 20). The majority of participants (93%) considered themselves as having a 'good day' on the day they completed the SF-HDQ in relation to their overall health (Table 2).

Table 2: Short-Form HIV Disability Questionnaire (SF-HDQ) Scores for Participants living with HIV (n=29)

SF-HDQ Domains	**Entire Sample (n=29)** Median (25-75th percentile)	**Toronto (n=10)** Median (25-75th percentile)	**Colorado (n=10)** Median (25-75th percentile)	**Dublin (n=9)** Median (25-75th percentile)
Presence Domain Scores				
Physical	40 (30, 80)	65 (30, 90)	40 (30, 50)	50 (25, 70)
Cognitive	67 (33, 100)*	100 (50, 100) *	33 (25, 75)	67 (17, 100)*
Mental-Emotional	60 (30, 90)	70 (35, 100)	60 (15, 85)	60 (30, 80)
Uncertainty	60 (40, 80)	40 (20, 85)	80 (40, 85)*	60 (30, 90)
Day to Day Activities	40 (10, 100)	80 (40,100)	30 (0, 100)	20 (20, 60)
Social Inclusion	29 (14, 57)	36 (14, 64)	29 (0, 50)	29 (7, 57)
Severity Domain Scores				
Physical	28 (20, 50)	44 (23, 53)	22 (20, 34)	28 (18, 44)
Cognitive	20 (11, 35)	35 (15, 37)	11 (8, 26)	28 (6, 35)
Mental-Emotional	37 (14, 51)*	46 (16,56)*	37 (8, 44)*	26 (14, 43)
Uncertainty	30 (17, 46)	33 (15, 46)	30 (17, 43)	30 (17, 47)*
Day to Day Activities	21 (4, 39)	29 (15,41)	11 (0, 41)	15 (8, 28)
Social Inclusion	21 (8,34)	30 (13,41)	18 (0,32)	21 (7, 36)
Episodic (fluctuating in the past week) Domain Scores				
Physical	20 (0, 40)*	30 (8, 70)	20 (0, 25)*	10 (0, 40)
Cognitive	0 (0, 67)	34 (0, 75)*	0 (0, 50)	0 (0, 84)

Mental-Emotional	20 (0, 70)*	30 (0, 65)	0 (0, 85)	40 (0, 60)*
Uncertainty	0 (0, 40)	20 (0, 40)	0 (0, 65)	0 (0, 40)
Day to Day Activities	0 (0, 40)	30 (0,40)	0 (0, 25)	20 (0, 50)
Social Inclusion	0 (0, 14)	7 (0,14)	0 (0, 7)	0 (0, 0)
Good Day-Bad Day Item "In terms of your overall health, are you having a good day or bad day today?"				
Good day	27 (93%)	10 (100%)	10 (100%)	7 (89%)
Bad day	2 (7%)	0 (0%)	0 (0%)	2 (22%)

n=29 participants completed the SF-HDQ; Score range: 0-100

*Highest scores across domains.

Sixteen HIV health care practitioners participated in Toronto (n=5), Denver (n=5) and Dublin (n=6). They included physicians (n=5), social workers (n=3), nurses (n=3), physiotherapists (n=2), a physiotherapy resident (n=1), massage therapist (n=1), and pharmacist (n=1).

Sensibility, Utility and Implementation Considerations of the SF-HDQ

We describe sensibility findings derived in combination from the sensibility questionnaire and interview data. Results pertaining to utility and implementation considerations were drawn from the interview data. We reference quotations with each participant number (P), the target population: participant living with HIV (PLWH) or health care practitioner (HCP); and country: Canada (CAN), Ireland (IRE) or United States (US).

A – SENSIBILITY

Collectively, results from the sensibility questionnaire and interviews indicate that the SF-HDQ possesses face and content validity and is easy to use with adults living with HIV. Sensibility questionnaire results indicate the SF-HDQ met our criterion for sensibility with adults living with HIV (Table 3) but not health care practitioners, because one item had a median score ≤3 (item 9 – *There were items missing in this questionnaire that should be included*) (Table 4).

Table 3: Sensibility Questionnaire for Adults living with HIV

Sensibility Item – Adults Living with HIV	Entire Sample (n=28 to 29) Median (25-75th percentile)	Toronto (n=10) Median (25-75th percentile)	Colorado (n=10) Median (25-75th percentile)	Dublin (n=8 to 9) Median (25-75th percentile)
Face Validity				
1. I was able to answer all of the questions.	7 (7,7)	7 (7,7,)	7 (7,7)	7 (5,7)
2. The instructions were clear and easy to understand.	7 (6,7)	7 (7,7)	7 (5,7)	7 (5,7)
3. The questions were clear and easy to understand.	7 (7,7)	7 (7,7)	7 (6,7)	7 (6,7)
4. The overall questionnaire makes sense.	6 (5,7)	7 (6,7)	7 (5,7)	5 (5,6)
5. The response categories (or options) for the questions were adequate.	6 (5, 7)	6 (4,7)	7 (5,7)	5 (5,6)
Content Validity				
6. The questionnaire captured all elements of my disability.	5 (4,7)	7 (4,7)	6 (4,7)	5 (3,5)
7. The questionnaire included important items that are necessary to describe my disability.	6 (5,7)	7 (5,7)	7 (6,7)	5 (4,5)
8. The questionnaire included items that were repetitive or redundant.*	5 (4,5)	5 (5,5)	5 (5,6)	4 (3,5)
9. There were items missing in this questionnaire that should be included.*	4 (3,5)	4 (2,5)	5 (4,6)	4 (3,5)
10. Some of the questions seemed out of order.*	5 (4,7)	5 (3,7)	6 (4,7)	6 (5,7)
11. I was able to find my answer in the list of possible answers to the questions.	6 (4,7)	7 (3,7)	7 (5,7)	5 (4,6)
Format and Ease of Usage				
12. I felt uncomfortable answering some of the questions because I did not want to have anyone know my answers.*	7 (5,7)	7 (5,7)	7 (5,7)	7 (5,7)
13. I felt that the questions made me think about things that I would have preferred not to have thought about.*	5 (5,7)	5 (5,7)	7 (5,7)	6 (5,7)
14. I felt that answering the questions helped me in some way.	5 (4,5)	5 (4,7)	4 (4,5)	5 (2,5)
15. The questionnaire took too long for me to complete.*	6 (5,7)	5 (5,7)	6 (5,7)	5 (5,7)
16. The questionnaire required too much effort to complete.*	7 (5,7)	6 (5,7)	7 (6,7)	6 (5,7)
17. The questionnaire was easy to complete using the electronic tablet.	7 (5,7)	7 (5,7)	7 (6,7)	5 (5,7)
18. I would like to receive a summary of my HDQ questionnaire scores right after completing the questionnaire to help understand the areas (or domains) where I might experience health challenges.	5 (4,7)	5 (5,7)	6 (4,7)	5 (4,5)
19. Overall, this questionnaire is useful in describing disability experienced by adults living with HIV.	5 (5,7)	5 (5,7)	6 (5,7)	5 (4,5)

Sample size: n=29 for items #1-5; n=28 for items #6-19. One participant from Dublin site did not complete items 6-19 for the sensibility questionnaire. *indicates questionnaire responses were reversed for median scoring purpose.

Table 4: Sensibility Questionnaire for HIV Health Care Practitioners

Sensibility questionnaire items for health care practitioners	**Entire Sample (n=15)** Median (25-75th percentile)	**Toronto (n=5)** Median (25-75th percentile)	**Colorado (n=5)** Median (25-75th percentile)	**Dublin (n=5)** Median (25-75th percentile)
Face Validity				
1. My clients would be able to answer all of the questions.	7 (6,7)	7 (7,7)	7 (6,7)	7 (4,7)
2. The instructions were clear and easy to understand.	6 (5, 7)	7 (6,7)	7 (6,7)	5 (5,7)
3. The questions were clear and easy to understand.	7 (5,7)	7 (6,7)	7 (6,7)	5 (4,7)
4. The overall questionnaire makes sense.	6 (5,7)	7 (6,7)	6 (5,7)	5 (4,7)
5. The response categories (or options) for the questions were adequate.	5 (5,7)	7 (5,7)	5 (5,7)	5 (4,7)
Content Validity				
6. The questionnaire captured all elements of my clients' disability.	5 (5,7)	6 (4,7)	4 (3,6)	4 (3,6)
7. The questionnaire included important items that are necessary to describe my clients' disability.	5 (4,7)	7 (6,7)	5 (4,6)	4 (4,6)
8. The questionnaire included items that were repetitive or redundant.*	5 (4,6)	5 (3,7)	6 (4,7)	5 (5,6)
9. There were items missing in this questionnaire that should be included.*	**3 (3,6)**	**3 (2,6)**	4 (2,6)	**3 (2,5)**
10. Some of the questions seemed out of order. *	6 (5,7)	7 (5, 7)	6 (4,7)	6 (5,7)
11. My clients would be able to find their answer in the list of possible answers to the questions.	6 (5,7)	7 (6,7)	6 (5,7)	5 (4,6)
Format and Ease of Usage				
12. My clients would feel uncomfortable answering some of the questions because they may not want to have anyone know their answers.*	5 (3,7)	4 (3,6)	5 (4,7)	6 (3,7)
13. My clients would feel that the questions made me think about things that they would have preferred not to have thought about.*	4 (3,5)	5 (3,6)	4 (2,6)	4 (3,5)
14. My clients would feel that answering the questions helped them in some way.	5 (5,6)	6 (5,7)	6 (5,7)	5 (5,5)
15. The questionnaire would take too long for my clients to complete.*	5 (4,7)	5 (2,6)	5 (4,7)	5 (5,7)
16. The questionnaire would required too much effort to complete.*	5 (4,7)	5 (2,6)	5 (4,7)	5 (5,7)
17. The questionnaire would be easy to complete using the electronic tablet.	6 (5,7)	7 (5,7)	7 (6,7)	5 (4,6)
18. My clients would like to receive a summary of their HDQ questionnaire scores right after completing the questionnaire to help understand the areas (or domains) where they might experience health challenges.	5 (4,7)	5 (5,6)	4 (3,6)	6 (5,7)
19. Overall, this questionnaire is useful in describing disability experienced by adults living with HIV.	6 (5,7)	6 (6, 7)	6 (5,7)	5 (5,7)

Sample size: 15 participants (n=1 participant Dublin site did not complete the sensibility questionnaire) *indicates questionnaire responses reversed for median scoring purpose; **bolded** indicates items that did not meet criterion for sensibility scoring ≤3.

However, the interview findings indicate that the SF-HDQ is comprehensive, represents health related challenges (disability) living with HIV, adequately captures the episodic nature of disability and captures disability related to other conditions. Participants indicated that the SF-HDQ was easy to complete and that the items were easy to understand (ease of usage) and that the format was easy to use (adequate length, adequate response options). When asked about items missing from the SF-HDQ, a few participants commented on the importance of considering HIV stigma, HIV disclosure, addiction and substance use when measuring disability living with HIV. Participants also provided reflections on disability terminology.

SF-HDQ Items Represent Health-Related Challenges (Disability) Living with HIV: Participants agreed that the items in the SF-HDQ capture the disability experienced living with HIV, indicating the questionnaire possesses face and content validity. Participants remarked that the SF-HDQ was "*very comprehensive"* (CAN-PLWH-P20, IRE-HCP-P11), and that "*more or less, it covers everything*" (IRE-PLWH-P10). Similarly, a health care practitioner described: *"I think almost all of [the items] capture something important that a lot of our clients' experience."* (CAN-HCP-P2).

This was supported by responses on the sensibility questionnaire data, where participants indicated that the SF-HDQ captures all of the important elements of disability and is useful in describing disability experienced by adults living with HIV (Table 3; Table 4).

Importance of Capturing the Episodic Nature of Disability: Both groups of participants indicated the importance of measuring the episodic nature of HIV in the SF-HDQ. One participant living with HIV noted that asking about how health related challenges fluctuated in the past week was "*probably one of the best questions."* Health care practitioners (HCPs) also believed the questions about fluctuations were important. As one HCP noted:

> *I think it needs to be understood that there is an episodic nature to HIV so that people can be more supportive of people when they say I'm just really not feeling up to coming and not getting frustrated or angry with them or punishing them for that. I think that kind of information needs to be documented.* (CAN-HCP-P1).

A range of viewpoints emerged on the ideal timeframe for measuring fluctuations with health challenges. One participant living with HIV reflected, "*Sometimes a week is not enough and sometimes it's too much. But when you're dealing with stuff, it fluctuates constantly."* (CAN-PLWH-P5). Similarly, a HCP noted: "*I like that there's a difference between like last week and this week, what's happened. But it also changes from the beginning of the month to the end of the month for some of our clients."* (CAN-HCP-P3).

SF-HDQ Captures Disability Related to Other Health Conditions: Some participants indicated that health challenges captured in the SF-HDQ were not always HIV-related. For instance, one participant living with HIV indicated that while struggling to maintain safe and stable housing was a prominent challenge, it was not attributed to their HIV status as stated in the item wording. "*What do you mean I'm worried about my financial and my security living with HIV? What does that have to do with anything? What does HIV have to do with any type of financial anything?"* (US-PLWH-P11).

Similarly, participants described how living with uncertainty or worrying about the future was an important aspect of their health but explained that it related to aging or living with other chronic conditions. Others attributed uncertainty to the COVID-19 pandemic, as this participant living with HIV explained:

> *…uncertainty, you know I answered that quite a bit because so many things are uncertain…I was kind of basing it on right now with COVID and everything you know. But it kept stressing right now today and that's also why I answered some of the things about kind of being lonely and stuff and social inclusion my answer to those because I would have answered those differently if it wasn't COVID.* (US-PLWH-P20).

Ease of Usage and Format: Participants reported positive experiences completing the SF-HDQ. Most described how the questionnaire was easy to complete, stating: "*the questions were pretty much straightforward."* (US-PLWH-P12) and *"the options are pretty easy to choose."* (US-HCP-P21). The majority described language in the SF-HDQ as easy to understand and "*pretty accessible."* (IRE-HCP-P11). One participant explained:

> *I think the wording on it was really good and you know being able to read it without saying 'can you help me' with this or whatever was really good. That's what I like is the fact that you know don't give me these very big words … I was able to understand this survey without having to ask you 'what does this mean?* (US-PLWH-P11).

Most participants living with HIV thought that the length of the SF-HDQ was appropriate, describing how "*It wasn't too long and it wasn't too short. In my opinion it was just right in the middle*" and "*it didn't take much time at all.*" (US-PLWH-P12). These interview findings are supported by responses to the sensibility questionnaires demonstrating that participants found the SF-HDQ easy to understand and complete, has reasonable length and possesses adequate response options (Table 3; Table 4).

Disability Terminology: A few participants reflected on the term 'disability' as used to describe health-related challenges in the context of the SF-HDQ. A HCP reflected:

> *It's a label. It's essentially calling someone disabled and especially in a world where we're trying to move from you know living with HIV is no longer a disability.* (US-HCP-P20).

Some participants similarly did not view themselves as disabled, as described by this participant: "*I haven't lost my hand or anything like that. I am not disabled. I'm not disabled through HIV or whatever.*" (IRE-PLWH-P5).

B - UTILITY

Interview data on utility of the SF-HDQ reflected two themes: 1) clinical use of the SF-HDQ, and 2) activities facilitated by the process of completing the SF-HDQ.

Clinical Use of the SF-HDQ

The majority of participants believed the SF-HDQ would be useful in clinical practice, specifically describing health challenges, assessing change in disability over time, and guiding referrals to health services and support.

Participants living with HIV and health care practitioner participants described how the SF-HDQ could be used in a clinical setting to provide a snapshot at a point in time: "*It gives you a basic understanding of what people with HIV are going through, what challenges they have.*" (US-PLWH-P15). One participant living with HIV reflected on how, *"I think it can get to help to get to know somebody. Those questions they can probably get some sort of sense on what*

their day-to-day life is." (US-PLWH-P12). Similarly, one HCP said, "*I think it's quite useful to get an idea from their patient about how HIV impacts on their day to day lives."* (IRE-HCP-P15).

Participants noted that the SF-HDQ could be useful for assessing change or stability of disability over time. One participant living with HIV noted, "*I would use it … maybe before the first visit or on a continuing basis to see how it changes.*" (US-PLWH-P15). Similarly, a HCP participant described how administering the SF-HDQ once a year would be "*good just to track how they are during the course of having HIV."* (IRE-HCP-P11). The same HCP noted that the SF-HDQ might be useful "*if the patient states that they are in a bad place, it might be a useful tool to do it straight away just to see where they actually are comparatively and to the previous visit."* (IRE-HCP-P11).

Activities Facilitated by the Process of Completing the SF-HDQ

Although the SF-HDQ is an outcome measure developed to describe health challenges living with HIV and other concurrent conditions, participants indicated that the process of completing the questionnaire can inform goal setting, facilitate communication (between patients and HCPs and between different HCPs), foster a multi-dimensional approach to care, and facilitate self-reflection about one's own health living with HIV.

Informing Goal Setting: Participants described the SF-HDQ as a tool to inform the process of goal setting. One participant living with HIV referred to the SF-HDQ as a tool to *"create a roadmap on how to treat this individual to get to an optimal outcome.*" (US-PLWH-P19). A HCP participant identified how, *"… it would be a good one for goal setting which was from a physiotherapy perspective as well.*" (IRE-HCP-P11). A HCP articulated how the SF-HDQ could facilitate goal setting beyond impairment-related treatment goals to more broadly considering social participation, *"I think to develop further goals that would be more to a participation level and more to a community level."* (CAN-HCP-P1). Another health practitioner explained how SF-HDQ results could be used to identify areas in which to focus on goals:

> *If you're using it for an annual physical as something to do a global assessment, to look at the overall wellness of the patient and identify things to work on through the next year … that could be you know like a useful thing for the team to have access to, to identify goals for the patient to work on.* (CAN-HCP-P4).

Facilitating Communication: Both HCPs and participants living with HIV referred to how the SF-HDQ can "*open up a conversation"* (IRE-PLWH-8) (US-HCP-P23) and how *"it opens a door. It gives the health practitioner information of things that they need to ask about or deal with."* (CAN-PLWH-P5). One HCP described how the SF-HDQ *"gives you the foundation to develop a conversation around all those items needed"* (IRE-HCP-P11), and how the SF-HDQ can identify areas to target interventions and referrals to services. One participant living with HIV reflected:

> *It can be used to maybe start a conversation towards something that maybe they didn't realize was there. So, it might be able to help a doctor or a physician to say 'hey we also have these other programs that might help you because it seems like you have a little more anxiety'. So, I think it would be beneficial in that way.* (US-PLWH-P13).

Some participants noted that the SF-HDQ could facilitate communication between clinicians. A HCP described, "*It definitely would be helpful for communication like if we could fax it back with a referral or something as part of [the patient's] treatment plan and things like that."* (CAN-HCP-P2).

Some participants identified the SF-HDQ as a tool for encouraging self-reflection of one's health living with HIV which can facilitate discussions with one's health care practitioner and possibly between practitioners. One participant living with HIV explained, *"I liked it because it just really brings out the fact that wait, am I feeling lonely. It made me think about some things but actually I thought it was really good."* (US-PLWH-P11). Another person living with HIV shared, *"some of the questions I never even really thought about. So it helps me to think about them. So they were good for me to look at."* (US-PLWH-P13). Similarly, a HCP noted:

> *It is a benefit I think because it'll highlight things that maybe the patient hasn't thought to bring up with the clinician they saw. Always it's good for them maybe to think about things that maybe are impacting their life or their quality of life.* (IRE-HCP-P13).

Fostering a Multi-Disciplinary Approach to Care: Participants described how the SF-HDQ went beyond biomedical issues and highlighted the multi-dimensional nature of health and importance of a multi-disciplinary approach to care. One participant living with HIV believed that the SF-HDQ could be used *"for people to really see how they feel, how they are, instead of just getting medication and take your medication … that is it."* (US-PLWH-P8). Similarly, a HCP noted how the questionnaire *"could help us identify the needs of the patients outside of their actual physical needs as in their blood pressure, their bloods and things like that. So, the greater needs, you know the full holistic needs of the patient."* (IRE-HCP-P14). Another HCP from Toronto explained:

> *I think it's great that it's so comprehensive in a sense because it raises your awareness to issues that you know you may not be aware of for certain patients right because the nature of family practice is people come in and they have a complaint of the day. Often with HIV it's all focused on meds and med adherence and side effects and you know counts and stuff and it's less focused on peoples' overall wellness. I like it because it reminds us of the importance of the overall wellness and that taking the time to think outside the box … to think less about health counts and cell counts and more about peoples' kind of lived experience every day.* (CAN-HCP-P4).

C - IMPLEMENTATION CONSIDERATIONS

Considerations for implementation of the electronic SF-HDQ spanned administration and communication of questionnaire scores in clinical practice.

Administration

Considerations pertaining to administration included burden of administration (time, conundrum of identifying health challenges with limited resources to address them, logistical issues of security, internet, space), and the importance of person-centered approaches for tailoring the mode of administration (use of technology, literacy, cognition) and offering flexible options for modes of processes of administration (format, location, timing, and persons involved in administration).

Table 5 includes participants' quotes related to perspectives on the burden of administration and the need for person-centred approaches for administration of the electronic SF-HDQ in a clinical setting.

Table 5: Implementation Considerations of the Electronic SF-HDQ in Clinical Practice: Administration

Implementation Consideration	Administration Consideration	Description / Example Quotations
Burden of administration	Time to administer and complete the SF-HDQ in clinical practice	• *I don't think anyone in the clinic will or has time to do anything extra.* (US-HCP-P20) • *How would you do it in a post-COVID world when you're trying to reduce waiting time?* (IRE-HCP-P15)
	Conundrum of identifying health challenges with limited resources to address then	• *It's a great questionnaire but the problem is there's no way that we can address the issues after it's done and we have the information.* (CAN-HCP-P23) • *Well, I think if we're going to ask all those questions, we need to have strategies in place to deal with all the answers and I'm not sure that we have at the moment.* (IRE-HCP-P15)
	Logistical issues (security of tablets for electronic administration, internet, space)	• *Gadgets tend to walk out the door.* (IRE-HCP-P15) • *To get a room and a computer…it's challenging in a resource-stretched and starved environment.* (IRE-HCP-P13)
Person-centered approaches for tailoring mode of administration	Use of technology - familiarity and comfort	• *I still find with a lot of our patients, particularly the over 50 group, that their IT skills might not what is required for this and that they might now have a computer and they might not have WIFI access.* (IRE-HCP-P15) • *Technology challenges definitely. I think most people with a tablet would go through it fairly quickly but there are probably people who are technologically challenged and it might be a little more difficult.* (CAN-PLWH-P15)
	Literacy of disability and health challenge terminology in the questionnaire	• *I think [the wording] might be beyond the reach of some of the patients you want to capture. So, people who maybe haven't had the chance to finish school, and we have a lot of them, or patients who are you know refugees, or you know English is not their first language.* (IRE-HCP-P16) • *I can think there might be, you know, depending on the education level of a participant, they might have trouble with some of the verbiage.* (US-PLWH-P18)
	Cognitive health challenges that may influence ability to complete the questionnaire	• *Because of the very real kind of neuro features of the HIV, especially with the long-term survivors."* (CAN-HCP-P5) • *I guess it would come down to their problems with their cognitive impairment and thought you know because people seem to have an awful lot of cognitive impairment problems that I've seen with HIV.* (CAN-PLWH-03)
Flexible options for modes and processes of administration	Format (electronic or paper based)	• *I think electronic I would prefer. But there are going to be people that need paper.* (CAN-HCP-01) • *It's a lot easier than say a pen and paper.* (US-PLWH-P12) • *It was really easy to fill out online.* (US-PLWH-P2)

Implementation Consideration	Administration Consideration	Description / Example Quotations
	Location of administration (home or clinic)	• *I would not want to do this during a clinic visit. … if you do it on the computer, that's good. … Let's say I'm going to have a visit tomorrow and you send it to me the day before. I can fill it out and send it and then not have to worry about it. Like I said, I would not want to go into a visit because I'm going into a visit to do whatever, get checked and I want to be gone. Then those that don't have a computer, maybe send the questionnaire in the mail and you know put their please fill out before visit and then have them bring it in with them.* (US-PLWH-11) • *I prefer that [completing the questionnaire with a clinician in clinic] because if I am with her or him one by one, then I can ask a question, then you can answer me or you can ask me a question, then I can answer. If I heard her answer and I can ask an explanation.* (CAN-PLWH-04)
	Timing of administration (prior to or after clinic appointment)	• *I think like either during the appointment or after … if there's a wait time before the client has to come in, then it's a great time to take care of the survey because then they feel like no time is being wasted if they have something to do.* (US-PLWH-13) • *I think before an appointment because I feel like after an appointment, you're ready to go. So, I think before an appointment would be ideal. Unfortunately, too because it may help bring out things that they forgot to talk about during their appointment. So, if they're taking it beforehand it might help them think of things that they may have forgotten about. (CAN-PLWH-P16)*
	Person to administer (self-, practitioner-, or administratively administered)	• *I think it should come from your primary care doctor.* (US-PLWH-14) • *It could be that we do an intake and then sort of get an administrative person to meet with them before their next visit. Yeah, I think either of those options could work.* (CAN-HCP-P2)

US - United States; Denver Colorado; CAN – Canada; Toronto, Ontario; IRE – Ireland; Dublin, Ireland
HCP – Health care practitioners; PLWH –person living with HIV; P - participant

Communication of Scores

Participants had mixed preferences about communicating SF-HDQ scores among patients and practitioners. While most participants indicated preferences for health care practitioners to receive SF-HDQ of their patients, participants living with HIV preferences varied regarding their receipt of personal scores. For instance, some participants living with HIV did not want to know their SF-HDQ scores, in order to prevent them from worrying about their health or the meaning of the scores. Alternatively, some participants living with HIV expressed their interest in receiving their scores to provide further insights

into and to help identify any changes in their overall health. Interview findings highlighted the importance of considering personal preferences for communicating SF-HDQ scores among persons living with HIV and their health care practitioners, and the importance of explaining and interpreting SF-HDQ scores with persons living with HIV (Table 6).

Table 6: Implementation Considerations of the Electronic SF-HDQ in Clinical Practice: Communicating Scores

Implementation Consideration	Description / Example Quotations
Consider personal preferences of patients when communicating scores among patients and health care practitioners	**Participants Living with HIV** • *Personally, I would like to get my score because that would give me some insight into my overall, you know, how I'm feeling overall.* (CAN-PLWH-P2) • *I don't know if I'd want to know [my scores] or not to be quite truthful. I think that's more for the clinician to know. So, I think you might make yourself worry too much about some things where I think you've got more problems than maybe you do. It could be negative to you."* (CAN-PLWH-P3) • *It [seeing my score] would make me feel uncomfortable and I'd probably stay on topic too long on ones than another, you know, why is this so high and why is that so low…. I honestly don't want to see it because you don't want to feel like a failure after.* (CAN-PLWH-P3) • ***Communicating Questionnaire Scores with Health Care Practitioner Team:*** *I think it's important because they'd see what's actually going on with you. Again, they'd direct you to the right people like if you need to see a psychiatrist or you know, whatever or something else that may be going on in your health that you may not be really aware that's a larger problem than it is. I may be thinking oh it's nothing and they're going we've got to deal with this. So it's important they see it.* (CAN-PLWH-P3). **Health Care Practitioners** • *I would have a preference to share because I think if the patients have answered it themselves, I think they should be able to know what their results are or what they have answered about themselves or what the scoring would be.* (IRE-HCP-P14) • *I think it's beneficial because sometimes people may not think that they have a problem like a physical problem or a mental emotional. Maybe they think that it's part of the way you're supposed to feel.* (IRE-HCP-P21) • *I'm not sure they would completely understand the nuances of it unless say someone has a disability score of 90. But is that discouraging them and they're doing okay or does that make them feel entitled that they deserve more? I mean I don't know. I'm just throwing this out there. Medicine has a lot of nuances.* (US-HCP-P23)
Importance of Explaining the Meaning of Scores	• *I think seeing them and knowing what they mean are two different things. I'd be happy to see them if I knew what they meant." (US-PLWH-P2).* • *…if they [persons living with HIV] are very depressed and they don't have adequate support to help them process this than I think that it could be harmful. But that doesn't mean that they shouldn't have access to it because I think it's their right to have access to their information. But that's why I would give it with adequate explanation only… I think it's okay [to give the patient a printout of their scores] only if it's given with some explanation because like we've talked about there are varying levels*

	of disability that we're expressing. So, you want to make sure that you've given them all they need to process it. (US-HCP-P22)

US - United States; Denver, Colorado; CAN – Canada; Toronto, Ontario; IRE – Ireland; Dublin, Ireland
HCP – Health care practitioners; PLWH –person living with HIV; P - participant

DISCUSSION

Overall, the SF-HDQ appears to demonstrate sensibility for use with adults living with HIV and HIV health care practitioners across the three healthcare contexts. The SF-HDQ was considered to possess utility for describing health-related challenges across health dimensions, identifying areas for follow-up or intervention, facilitating goal setting, and guiding referrals. The process of completing the SF-HDQ was described by participants as facilitating communication (including encouraging reflections on one's health), and fostering a multi-dimensional approach to care.

Results from the interviews highlight the need to person-centered tailored approaches to administration, specifically providing options for mode of administration (i.e., electronic- and paper-based methods), timing of administration (i.e., before, during, following an appointment), and considerations for how to communicate scores and score interpretations with patients, to account for differences between clinical settings and individuals.

Interview data indicate that participants felt the items in the SF-HDQ captured their experiences with disability. Overall, most participants described the language in the SF-HDQ as easy to understand and found the length of the questionnaire appropriate and feasible to complete. Many participants commented positively on how the SF-HDQ asked if challenges had fluctuated or changed in the past week, as they felt this was relevant to their experiences living with HIV.

Collectively the questionnaire and interview findings suggest that the SF-HDQ possesses sensibility for use with adults living with HIV. Despite participants indicating items were missing that should be included in the SF-HDQ on the sensibility questionnaire (item 9), both groups indicated the SF-HDQ captured all elements of disability (item 6) (table 3; table 4). These questionnaire results may be attributed

to participants commenting in the interviews on the importance of considering HIV stigma, HIV disclosure, as well as addiction and substance use in the context of disability living with HIV. We recognize the importance of these concepts as they relate to disability.[19] However, as intrinsic or extrinsic factors that can influence dimensions of disability, they are beyond the scope of disability and the SF-HDQ. Nevertheless, these findings highlight the benefit, need and importance, of administering the SF-HDQ in combination with other patient-reported outcome measures (e.g. HIV Stigma Scale[39], HIV Social Support Scale[40]) to fully understand the context in which disability may be experienced among adults living with HIV.

Some items in the SF-HDQ refer to HIV as the source of the challenge including: worrying about the future, worrying about finances, worrying about housing and concern around specific HIV blood tests. Participants questioned the need to specifically reference HIV in items related to uncertainty and social inclusion and items related to finance and housing, questioning the relevance of HIV specificity of items. Uncertainty and worrying about the future can be attributed to other factors (for example, the COVID-19 pandemic) and not solely HIV.[4139] Attributing specific health challenges to HIV can be difficult for an individual as the challenge may not be directly from HIV but from consequences of HIV such as treatment or concurrent health conditions experienced when aging with HIV. Health challenges can also be compounded by certain factors affecting risk acquisition such as socioeconomic status or personal health.[20] Results suggest revisiting the need for HIV specificity of items in the SF-HDQ. Future research should explore the refinement of the questionnaire, focused on measuring episodic disability as a health-related consequence of a health condition regardless of the source of disability. This has the potential to broaden the applicability of the questionnaire for use with other health conditions.

The term 'disability' was negatively perceived by some participants in the study. Some participants from the United States disliked the term, whereas Canadian participants were more familiar with the term 'disability' as used in the context of rehabilitation, and some were familiar with the HDQ. In the SF-HDQ

preamble, we explain the concept of 'disability' as a description of health challenges, and that the term is not meant to label individuals who complete the questionnaire. Nevertheless, a few participants referred to how they do not consider themselves disabled citing concerns of negative connotations with 'disability' terminology. Changing the terminology of the SF-HDQ would mean changing the concept of interest measured, which has implications given the tool was grounded in conceptual foundation of the Episodic Disability Framework which was derived from the perspectives of adults living with HIV.[17 19] We recommend revising the preamble of the questionnaire to remove references to the term 'disability' and to rename the questionnaire the Episodic Disability Questionnaire (EDQ), to reflect the episodic nature of health challenges, while remaining grounded within the original conceptual foundation derived from the HIV community.

Participants had mixed preferences about completing the questionnaire at home on their own, or at the clinic on their own, or with a HCP. Brief and comprehensive PROMs administered on the same day as a clinic visit can improve completion rates, provide immediate feedback on disability, enhance patient-practitioner communication and facilitate person-centered care.[42-43] However, discomfort with technology and lack of access to web-based platforms can limit electronic questionnaire administration.[44] SF-HDQ administration will be dependent on the context and characteristics of the population served which may differ within and across clinical settings. Future SF-HDQ guidance on SF-HDQ administration should consider what is important for standard (consistent) mode administration to ensure validity and reliability, and what aspects of administration may be flexible depending on the environment (menu of options).

Participants living with HIV had variable preferences about personally receiving their scores after completion of the SF-HDQ. Some participants noted that scores may provoke anxiety without clarity of the meaning of the scores, whereas the majority of HCP participants believed scores should be communicated and clearly interpreted with their patients. Future guidance on SF-HDQ administration should include details of communicating scores with patients and their interpretation. While results suggest that reviewing scores can help understand where health challenges occur across the six domains and

facilitate a dialogue about specific areas someone may be struggling with, ultimately the interpretability of the SF-HDQ scores is unknown. Future work should assess the interpretability of SF-HDQ scores.

While health practitioners positively commented on the utility of the SF-HDQ, some expressed hesitancy to use the SF-HDQ to identify health challenges that they may not have the resources to be able to address in the clinic setting. Despite the barriers and limited access to rehabilitation, the SF-HDQ can play a role in the pathway of care with value in measuring and identifying health challenges in order to gain knowledge on the need for rehabilitation and other health or supportive services.[11 45] Furthermore, in the absence of what health care practitioners feel they are unable to address, utilization of the SF-HDQ may foster space to listen to patients' concerns, acknowledge their experiences, share their narratives in therapeutic dialogue with their practitioner.[46 47]

Overall, results provide key considerations for SF-HDQ administration across three clinical settings in different countries highlighting the importance of tailoring implementation to the individual, cultural and clinical context. Strengths of our study included our mixed methods multi-site approach with 45 participants, involving both patient and practitioner perspectives practitioners spanning three different clinical contexts, which enabled us to assess the utility of the electronic mode of SF-HDQ administration, and examine considerations for implementation across three different healthcare contexts. Measurement properties are specific to the context and population in which the tool is assessed, highlighting the importance of considering the characteristics of the participants living with HIV and clinical sites in this study. The Toronto sample also demonstrated greater presence, severity and episodic scores of disability compared with the other two sample populations (Table 2). Our aim was not to compare sensibility and utility across sites, nor between adults living with HIV and HIV health care practitioners. Furthermore, given the heterogeneity across clinical contexts and target populations, we did not expect (nor was it a goal) to achieve saturation of themes. Rather, our aim was to obtain meaningful information through the exploration of the categories generated during the interviews, which could then be used to inform the SF-

HDQ sensibility and utility across a diversity of sites and perspectives. Results highlight the need for personalized tailoring of administration dependent on personal preferences and context.

Given our SF-HDQ assessment was focused on electronic administration, this limited participation to individuals living with HIV who had access to and comfort with the use of technology in order to complete the questionnaires and, if the interview was conducted remotely, participate in a Zoom interview. Results highlight the importance of offering flexible options for SF-HDQ administration in the clinic setting including a paper-based option for those with barriers to electronic administration. Findings from this study will inform the development of a guidance document to guide administration and scoring of the SF-HDQ in clinical settings and increase knowledge about the intended utility of the questionnaire.

CONCLUSIONS

The SF-HDQ possessed sensibility and utility for use with adults living with HIV across the three clinical settings in Canada, Ireland and the United States. Clinical utility of the SF-HDQ included measuring health challenges and its change over time, guiding referrals to clinical specialists and services, informing goal setting, facilitating communication, and fostering multi-disciplinary approaches to HIV care. Considerations for implementation included flexible, person-centered approaches to mode and processes of administration, and communicating scores based on personal preferences among persons living with HIV and HIV clinicians. Future work should consider refinement of the SF-HDQ for implementation across different clinical and cultural contexts and future measurement property assessment.

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AUTHORS' CONTRIBUTIONS

KKO and KME co-led the conceptualization of the study objectives and design, and drafted the protocol, led the application for acquisition of funding, and are the co-lead investigators on the study who led the implementation of the study. KKO, KME, CB, SCC are country and site leads on the research team, and were involved in the conceptualization of the study design, development of the protocol, acquisition of funding, and implementation of the study. PS, AMD, AMB, SEH, and RH are co-investigators and were involved in the conceptualization of the study design and contributed to the development of the protocol, acquisition of funding, and implementation of the study. KKO, PS, AMD, SCC, MS, and RA were involved in the data analysis and interpretation. KKO, PS, AMD, and MS drafted the manuscript. DAB, JHV, NSS, and MBof were involved in guiding study implementation and participated in data interpretation. RA, NOS, CM, and MB were involved in participant recruitment and data collection. BT assisted with manuscript preparation. Authors possess expertise in HIV and rehabilitation (KKO, KME, CB, SCC, PS, AMD, AMB, RH, DAB, JHV, NSS, MBof, RA, BT, NOS, CM, MB), with methodological expertise in measurement (KKO, AMD, RH, SEH) and qualitative research (PS, SCC, AMD, MS). All authors were involved in reviewing prior drafts of the manuscript. All authors have read and approved the final manuscript.

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COMPETING INTERESTS

None declared.

ETHICS APPROVAL

This study received research ethics approval from the University of Toronto (Protocol #38152), University of Colorado (Protocol #19-1895) and St. James's Hospital (Protocol #2019-12).

DATA AVAILABILITY STATEMENT

The data supporting the conclusions of this article are included within the article and its additional files. The data used and/or analysed during the current study are available from the corresponding author on reasonable request.

SUPPLEMENTAL FILES

Supplemental File 1: Original Protocol and Research Ethics Board Approval

Supplemental File 2: Sensibility Questionnaire

Supplemental File 3: Interview Guide

REFERENCES

1. Deeks SG, Lewin SR, Havlir DV. The end of AIDS: HIV infection as a chronic disease. *Lancet* 2013;382(9903):1525-33. doi: 10.1016/S0140-6736(13)61809-7 [published Online First: 2013/10/25]

2. Centers for Disease Control. HIV Among People Aged 50 and Over. 2018. https://www.cdc.gov/hiv/group/age/olderamericans/index.html.

3. Yin Z, Brown AE, Hughes G, et al. Over half of people in HIV care in the United Kingdom by 2028 will be aged 50 years or above (HIV in the United Kingdom 2014 Report: data to end 2013). *Public Health England, London* 2015

4. Surveillance and Epidemiology Division, Professional Guidelines and Public Health Practice Division, Centre for Communicable Disease and Infection Control, et al. Summary: Estimates of HIV incidence, prevalence and Canada's progress on meeting the 90-90-90 HIV targets, 2016. 2021. https://www.canada.ca/en/public-health/services/publications/diseases-conditions/summary-estimates-hiv-incidence-prevalence-canadas-progress-90-90-90.html.

5. Kendall CE, Wong J, Taljaard M, et al. A cross-sectional, population-based study measuring comorbidity among people living with HIV in Ontario. *BMC public health* 2014;14(1):161. doi: 10.1186/1471-2458-14-161 [published Online First: 2014/02/15]

6. Hasse B, Ledergerber B, Furrer H, et al. Morbidity and aging in HIV-infected persons: the Swiss HIV cohort study. *Clin Infect Dis* 2011;53(11):1130-9. doi: 10.1093/cid/cir626 [published Online First: 2011/10/15]

7. Guaraldi G, Orlando G, Zona S, et al. Premature age-related comorbidities among HIV-infected persons compared with the general population. *Clin Infect Dis* 2011;53(11):1120-6. doi: 10.1093/cid/cir627 [published Online First: 2011/10/15]

8. Balogun JA, Kaplan MT, Miller TM. The effect of professional education on the knowledge and attitudes of physical therapist and occupational therapist students about acquired immunodeficiency syndrome. *Physical Therapy* 1998;78(10):1073-82.

9. Brown TT, Qaqish RB. Antiretroviral therapy and the prevalence of osteopenia and osteoporosis: a meta-analytic review. *AIDS* 2006;20(17):2165-74. doi: 10.1097/QAD.0b013e32801022eb00002030-200611140-00005 [pii] [published Online First: 2006/11/07]

10. Vance DE, Mugavero M, Willig J, et al. Aging With HIV: A Cross-Sectional Study of Comorbidity Prevalence and Clinical Characteristics Across Decades of Life. *J Assoc Nurses AIDS Care* 2011;22(1):17-25. doi: S1055-3290(10)00064-6 [pii]10.1016/j.jana.2010.04.002

11. Erlandson KM, Schrack JA, Jankowski CM, et al. Functional impairment, disability, and frailty in adults aging with HIV-infection. *Curr HIV/AIDS Rep* 2014;11(3):279-90.doi: 10.1007/s11904-014-0215-y

12. Heaton RK, Clifford DB, Franklin DR, Jr., et al. HIV-associated neurocognitive disorders persist in the era of potent antiretroviral therapy: CHARTER Study. *Neurology* 2011;75(23):2087-96. doi: 75/23/2087 [pii]10.1212/WNL.0b013e318200d727 [published Online First: 2010/12/08]

13. Valcour V, Shikuma C, Shiramizu B, et al. Higher frequency of dementia in older HIV-1 individuals: the Hawaii Aging with HIV-1 Cohort. *Neurology* 2004;63(5):822-7. doi: 63/5/822 [pii] [published Online First: 2004/09/15]

14. Shiels MS, Pfeiffer RM, Gail MH, et al. Cancer Burden in the HIV-Infected Population in the United States. *J Natl Cancer Inst* 2011;103(9):753-62. doi: djr076 [pii]10.1093/jnci/djr076 [published Online First: 2011/04/13]

15. Antiretroviral Therapy Cohort Collaboration. Survival of HIV-positive patients starting antiretroviral therapy between 1996 and 2013: a collaborative analysis of cohort studies. *The Lancet HIV* 2017;4(8):e349-e56. doi: 10.1016/S2352-3018(17)30066-8

16. Willard S, Holzemer WL, Wantland DJ, et al. Does "asymptomatic" mean without symptoms for those living with HIV infection? *AIDS Care* 2009;21(3):322-8. doi: 909441524 [pii] 10.1080/09540120802183511 [published Online First: 2009/03/13]

17. O'Brien KK, Bayoumi AM, Strike C, et al. Exploring disability from the perspective of adults living with HIV/AIDS: development of a conceptual framework. *Health Qual Life Outcomes* 2008;6:76. doi: 1477-7525-6-76 [pii] 10.1186/1477-7525-6-76 [published Online First: 2008/10/07]

18. Erlandson KM, Allshouse AA, Jankowski CM, et al. Relationship of physical function and quality of life among persons aging with HIV infection. *AIDS* 2014;28(13):1939-43. doi: 10.1097/QAD.0000000000000384

19. O'Brien KK, Davis AM, Strike C, et al. Putting episodic disability into context: a qualitative study exploring factors that influence disability experienced by adults living with HIV/AIDS. *J Int AIDS Soc* 2009;12(1):5. doi: 1758-2652-2-5 [pii] 10.1186/1758-2652-2-5 [published Online First: 2009/11/11]

20. Bulsara SM, Wainberg ML, Newton-John TRO. Predictors of Adult Retention in HIV Care: A Systematic Review. *AIDS Behav* 2018;22(3):752-64. doi: 10.1007/s10461-016-1644-y [published Online First: 2016/12/19]

21. Cooper V, Clatworthy J, Harding R, et al. Measuring quality of life among people living with HIV: a systematic review of reviews. *Health Qual Life Outcomes* 2017;15(1):220. doi: 10.1186/s12955-017-0778-6 [published Online First: 2017/11/17]

22. Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. *Jama* 1995;273(1):59-65.

23. Harding R, Clucas C, Lampe FC, et al. What factors are associated with patient self-reported health status among HIV outpatients? A multi-centre UK study of biomedical and psychosocial factors. *AIDS Care* 2012;24(8):963-71. doi: 10.1080/09540121.2012.668175 [published Online First: 2012/04/24]

24. O'Brien KK, Bayoumi AM, King K, et al. Community engagement in health status instrument development: experience with the HIV disability questionnaire. *Progress in community health partnerships : research, education, and action* 2014;8(4):549-59. doi: 10.1353/cpr.2014.0071 [published Online First: 2014/01/01]

25. O'Brien KK, Bayoumi AM, Stratford P, et al. Which dimensions of disability does the HIV Disability Questionnaire (HDQ) measure? A factor analysis. *Disabil Rehabil* 2015;37(13):1193-201. doi: 10.3109/09638288.2014.949358

26. O'Brien KK, Solomon P, Bayoumi AM. Measuring disability experienced by adults living with HIV: assessing construct validity of the HIV Disability Questionnaire using confirmatory factor analysis. *BMJ open* 2014;4(8):e005456. doi: 10.1136/bmjopen-2014-005456 [published Online First: 2014/09/03]

27. O'Brien KK, Bayoumi AM, Bereket T, et al. Sensibility assessment of the HIV Disability Questionnaire. *Disabil Rehabil* 2013;35(7):566-77. doi: 10.3109/09638288.2012.702848 [published Online First: 2012/07/24]

28. O'Brien KK, Solomon P, Bergin C, et al. Reliability and validity of a new HIV-specific questionnaire with adults living with HIV in Canada and Ireland: the HIV Disability Questionnaire (HDQ). *Health Qual Life Outcomes* 2015;13:124. doi: 10.1186/s12955-015-0310-9

29. Brown DA, Simmons B, Boffito M, et al. Evaluation of the psychometric properties of the HIV Disability Questionnaire among adults living with HIV in the United Kingdom: A cross-sectional self-report measurement study. *PloS one* 2019;14(7):e0213222. doi: 10.1371/journal.pone.0213222 [published Online First: 2019/07/11]

30. O'Brien KK, Dzingina M, Harding R, et al. Developing a short-form version of the HIV Disability Questionnaire (SF-HDQ) for use in clinical practice: a Rasch analysis. *Health Qual Life Outcomes* 2021;19(1):6. doi: 10.1186/s12955-020-01643-2 [published Online First: 2021/01/08]

31. Feinstein AR. The theory and evaluation of sensibility. In: Feinstein AR, ed. Clinimetrics. Westford, MS: Murray Printing Company 1987:141-66.

32. Feinstein AR. Benefits and obstacles for development of health status assessment measures in clinical settings. *Med Care* 1992;30(5 Suppl):MS50-6. [published Online First: 1992/05/01]

33. Burns KE, Duffett M, Kho ME, et al. A guide for the design and conduct of self-administered surveys of clinicians. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne* 2008;179(3):245-52. doi: 10.1503/cmaj.080372 [published Online First: 2008/07/30]

34. O'Brien KK, Ibanez-Carrasco F, Solomon P, et al. Research priorities for rehabilitation and aging with HIV: a framework from the Canada-International HIV and Rehabilitation Research Collaborative (CIHRRC). *AIDS Res Ther* 2020;17(1):21. doi: 10.1186/s12981-020-00280-5 [published Online First: 2020/05/21]

35. Qualtrics [program]. Provo, Utah, USA, 2017.

36. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res* 2005;15(9):1277-88. doi: 15/9/1277 [pii]10.1177/1049732305276687 [published Online First: 2005/10/06]

37. NVivo qualitative data analysis software. Version 11. [program], 2017.

38. Hennink MM, Kaiser BN, Marconi VC. Code Saturation Versus Meaning Saturation: How Many Interviews Are Enough? *Qual Health Res* 2017;27(4):591-608. doi: 10.1177/1049732316665344 [published Online First: 2016/09/28]

39. Reinius M, Wettergren L, Wiklander M, et al. Development of a 12-item short version of the HIV stigma scale. *Health and Quality of Life Outcomes.* 2017;15; 115. doi: https://doi.org/10.1186/s12955-017-0691-z

40. Sherbourne CD, Stewart AL. The MOS social support survey. *Soc Sci Med.* 1991;32(6):705-714.

41. Brown DA, O'Brien KK, Josh J, et al. Six Lessons for COVID-19 Rehabilitation From HIV Rehabilitation. *Phys Ther* 2020;100(11):1906-09. doi: 10.1093/ptj/pzaa142 [published Online First: 2020/08/02]

42. Edwards TC, Fredericksen RJ, Crane HM, et al. Content validity of Patient-Reported Outcomes Measurement Information System (PROMIS) items in the context of HIV clinical care. *Qual Life Res* 2016;25(2):293-302. doi: 10.1007/s11136-015-1096-2 [published Online First: 2015/08/08]

43. Fredericksen RJ, Tufano J, Ralston J, et al. Provider perceptions of the value of same-day, electronic patient-reported measures for use in clinical HIV care. *AIDS Care* 2016;28(11):1428-33. doi: 10.1080/09540121.2016.1189501 [published Online First: 2016/05/31]

44. Cella D, Hahn EA, Jensen SE, et al. Patient-reported outcomes in performance measurement. Research Triangle Park, NC: RTI International, 2015.

45. Brown D, Nelson M, Bower M, et al. Presence of complex comorbidity and functional disability when ageing with HIV; review of referrals to specialist HIV outpatient physiotherapy in the UK. *HIV Medicine Abstracts of the 22nd Annual Conference of the British HIV Association (BHIVA)* 2016;17(1):14-71.

46. Rushforth A, Ladds E, Wieringa S, et al. Long Covid - The illness narratives. *Soc Sci Med* 2021;286:114326. doi: 10.1016/j.socscimed.2021.114326 [published Online First: 2021/08/24]

47. Dhairyawan R. The medical practice of silencing. *Lancet* 2021;398(10298):382-83. doi: 10.1016/S0140-6736(21)01659-7 [published Online First: 2021/08/02]

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Human Participant Research Ethics Protocol Worksheet
University of Toronto

Title: **Advancing Assessment of Episodic Disability to Enhance Healthy Aging among Adults Living with HIV: Developing a Short-Form HIV Disability Questionnaire (SF-HDQ) for use in Clinical Practice**

Protocol adapted to reflect relevant objective for study objective in manuscript (objective 1)

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Date Last Revised: February 13, 2022

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

This research has undergone scholarly review by peer review committee or some other equivalent: **NIH Scholarly Review (NIH Review Committee) and NIH Council Review.** This protocol builds on a foundation of previous HDQ development and validation work done in Canada and Ireland (UofT Protocol Reference #27456 (Ireland HDQ validation study); #27563 (HIV Health and Rehabilitation Survey).

Potential Conflicts – This section will ask for information pertaining to any potential conflicts of interest, restrictions on information, researcher relationships, collaborative decision making and terms of reference**.**

Where relevant, please explain any pre-existing relationship between the researcher(s) and the researched (e.g., instructor-student; manager-employee; clinician-patient; minister-congregant). Please pay special attention to relationships in which there may be a power differential – actual or perceived.

Participants may include persons whom Kelly O'Brien, Soo Chan Carusone, Kristine Erlandson, Colm Bergin, Ahmed Bayoumi, Patty Solomon, or Aileen Davis, have worked with as a colleague in a community-based research or educational capacity. Study investigators or the research coordinator at each site, who have no relationship with the potential participant, will obtain consent. Interested participants will be invited to contact the study co-investigators or research coordinator who has no relationship with the potential participants, who will discuss the study in detail and if applicable, will obtain consent.

(d) Please describe the decision-making processes for collaborative research studies. If Terms of Reference exist, attach them. Collaborative research studies include those where a number of sites (e.g. other universities, non-TAHSN hospitals, etc.) are involved, as well as those that involve community agencies.

This research involves an international academic-clinical partnership between Canada (University of Toronto, Casey House, McMaster University, St. Michael's Hospital, University Health Network), United States (University of Colorado Denver), Ireland (St. James's Hospital (Dublin), and the United Kingdom (King's College London (UK)). Data collection will occur at three sites (Toronto, Dublin, Denver).

Process for making decisions on scientific direction and allocation of resources. The SF-HDQ Team is a diverse virtual team with members from multiple clinical and academic institutions, multiple disciplines, different countries, time zones, health systems and cultural backgrounds. We are committed to a co-creation approach to collaborating, communicating and governing. As Co-PIs, Drs. O'Brien and Erlandson will meet via Skype or telephone biweekly to discuss project progress and overall management and administrative responsibilities. We will establish a 'SF-HDQ Steering Committee' comprised of Drs. O'Brien and Erlandson as well as Site Lead Co-Investigators in Toronto (Dr. Chan Carusone) and Dublin (Dr. Bergin) who will meet via teleconference monthly. They will work together to discuss progress of recruitment, data collection, and any issues arising that pertain to the study. Other members of the team may be invited to join these meetings when applicable. This Committee will be responsible for monitoring progress of the research at the sites, including timelines, mechanisms for data collection, storage and transfer, ensuring adherence to institutional site IRBs, and providing oversight and vision to knowledge translation and dissemination activities. These meetings will be held via teleconference. Decisions will be made by consensus. Drs. O'Brien and Erlandson will continue to communicate on an ad hoc basis as needed in between formal meetings via Skype or telephone as needed.

Fiscal and management coordination. Dr. O'Brien will be responsible for overall administration of the project. Together, Drs. O'Brien and Erlandson will manage the oversight and coordination of project management, research administration, fiscal oversight, publications and data sharing, and integration of all resources needed for the project. Dr. O'Brien will oversee decisions on minor changes in research direction and have the authority to reallocate funds and resources between project components if needed.

Data sharing and communication among investigators. The 'SF-HDQ Steering Committee' (Drs. O'Brien, Erlandson and site leads, Drs. Bergin and Chan Carusone) will meet monthly. These meetings will also be used to review progress toward the aims of recruitment, data collection and facilitate the transfer of data and ideas, outline objectives and plans for the forthcoming year and prepare the yearly progress report to the funding agency. Bimonthly, these meetings will morph into a 'Full SF-HDQ Team' meeting with the entire team, including co-investigators, research coordinators and other personnel involved in the study. Much of the work of the SF-HDQ Team will be conducted virtually, and thus strong internal communication mechanisms will be critical to our viability and productivity. We will balance our communication mechanisms in terms of social presence (through our Year 1 face-to-face meeting) and information richness (through frequent videoconferencing and use of collaborative online tools). For the annual SF-HDQ Team meeting, we will leverage opportunities such as the Canadian Association for HIV Research (CAHR) Conference, International Workshop on HIV and Aging, or CIHRRC International Forums on HIV and Rehabilitation Research to disseminate research and meet in person while reducing travel costs. To support dissemination of our research through peer-reviewed publications, the 'SF-HDQ Steering Committee' will establish an authorship policy in accordance with the International Committee of Medical Journal Editors Authorship Guidelines [http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html]

Procedures for resolving conflicts. We will adopt a proactive and collaborative approach to conflict resolution. Being proactive will allow us to anticipate conflict based on resources limitations (e.g. time, skills, and finances). A collaborative approach will ensure we provide opportunities for input from all team members that will include adequate internal communications, comprised of collaboration, accommodation, and compromise. If conflicts arise, we will seek resolution by focusing on the fact-based content of the interpersonal interactions, explicitly discussing and debating decisions reached in a respectful manner. As Co-Principal Investigators, unresolved conflicts will be resolved by the Drs. O'Brien and Erlandson. If this approach does not lead to resolution, or if conflict persists, we will consult an arbitration committee consisting of three impartial senior faculty members at the University of Toronto for ultimate resolution. No members of the arbitration committee will be directly involved in the research grant or disagreement. We will review and evaluate our team process, productivity, communication, and governance structure at each meeting. We will invite input from all team members to evaluate our progress on collaboration, communication, and knowledge translation throughout the study.

Distribution of Resources

The University of Toronto will be the primary lead institution for this study, followed by the University of Colorado Denver, St. James's Hospital, Trinity College Dublin, and King's College London who will have specific budgetary resources allocated to sites and investigators according to project and institutional requirements. Dr. Erlandson (University of Colorado) and Dr. Bergin (St. James's Hospital, Trinity College Dublin) will oversee the budget allocated to their respective sites. Because Casey House is affiliated with the University of Toronto, the budgetary requirements to conduct recruitment and data collection at Casey House will be overseen by Drs. O'Brien and Chan Carusone. Casey House will invoice University of Toronto for their research services accordingly. King's College London is not a study site, however Dr. Harding (King's College London) will draw salary for his contributions to the study.

Community Advisory Committee. This research is also informed by an HIV Community Advisory Committee that Kelly O'Brien (principal investigator) works with part of a larger program of research (HIV Disability Questionnaire). The decision making process will be shared among the members of the research team who will inform and guide all aspects of this research. Given the international nature of this research, the Community Advisory Committee expanded to include further international representation to inform the research process at each of the sites. This international expert Community Advisory Committee (comprised of ~9 members including people living with HIV, representative from community organizations, and clinicians who work in HIV care) will advise on SF-HDQ content, administration, scoring and usage. This will ensure the SF-HDQ is meaningful, relevant and practical for use in the real-world clinical setting.

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Project Summary

Rationale

Describe the purpose and scholarly rationale for the project:

With advances in combination antiretroviral therapy, HIV is now considered a chronic illness where individuals can reach life expectancies similar to the general population. However, more individuals are living longer with the health consequences of HIV, multimorbidity and aging known as disability. Disability is defined by people living with HIV (PLWH) as any physical, cognitive, mental-emotional symptoms, difficulties with day-to-day activities, challenges to social inclusion, and uncertainty about future health. Disability including fatigue, pain, challenges engaging in employment, and age-related issues of frailty; coupled with poor access to services, stigma, and poverty can pose barriers to PLWH remaining engaged in care.

Standardized patient reported outcomes (PROs) designed to capture the nature and extent of disability and its fluctuation over time are critical to guide the provision of timely care and to determine the effectiveness of interventions for adults aging with HIV. While a multitude of health status instruments exist, they do not capture the breadth and depth of disability, the fluctuating nature of HIV, and lack items related to social inclusion and uncertainty, identified as critical to people aging with HIV. To fill this gap, we developed a 69-item Patient Reported Outcome (PRO), the **HIV Disability Questionnaire (HDQ) (Appendix A)** to measure the presence, severity and episodic nature of disability experienced by people living with HIV. We demonstrated that the HDQ possesses sensibility, reliability and validity among adults living with HIV in Canada and Ireland. However, to date the HDQ has been used primarily in the context of research, with little uptake in clinical practice due to concerns of time restrictions. There is a critical need for a brief, yet comprehensive assessment of disability for adults aging with HIV that can be routinely administered across health system settings and clinical practice. **The purpose of the proposed study is to develop and pilot the implementation of a new short-form HIV-specific disability questionnaire to identify disability across clinical settings in order to promote healthy aging among adults aging with HIV.**

Our primary objective is to develop and assess the utility of a new short form HIV-specific disability questionnaire (SF-HDQ) across multiple clinical practice settings with adults aging with HIV.

The HDQ has potential for use in community practice with PLWH in the following ways: 1) as a screening tool to describe and better understand health-related challenges (or disability) and to help target timely and appropriate referrals to services; 2) as a component of client-centered care, facilitating discussion between clients, clinicians, and community to describe health-challenges, and assist with goal-setting; 3) to promote communication across clinical and community sites; and 4) to evaluate change in disability and effectiveness of interventions.

Outcomes will lead to the first known short form HIV-specific disability PRO developed through international and academic-community collaboration to assess prevalence and impact of episodic disability. This study will provide a foundation for future assessment of the extent to which the SF-HDQ can inform and facilitate referrals to services, goal setting, and patient-provider communication. Future universal measurement of disability over time may contribute to databases that facilitate ongoing clinical management, specifically tracking of episodic disability trends and evaluation of interventions to inform future allocation of resources to better promote healthy aging with HIV.

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Methods

Describe formal/informal procedures to be used:

STUDY DESIGN:

We will use a descriptive sequential mixed methods study design using quantitative (questionnaires) and qualitative (interviews) to assess sensibility (purpose, face and content validity, ease of usage, format), challenges and feasibility of administration, and to explore perspectives on how the SF-HDQ may be utilized in clinical practice (why used, by who, how and when it should be administered, and how it should be scored, and interpreted) to optimize healthy aging with HIV. We will use a cross-sectional pilot study to examine the implementation of the SF-HDQ and assess its psychometric properties in the 'real world' clinical practice across three health system sites (Toronto, Dublin, Denver).

STUDY SETTING (3 Sites: Canada, United States and Ireland):

Casey House, Toronto, Canada: Casey House is a 14-bed sub-acute HIV hospital in downtown Toronto providing in-patient and community programs for adults living with HIV. In 2017, Casey House launched a new Day Health Program (DHP) to allow people aging with HIV to experience better overall health and quality of life, by improving their access to interdisciplinary care while remaining in their homes and communities. The DHP offers a time limited, goal focused program for individuals living with HIV and complex health issues, with a capacity of 250 clients. Recently, physiotherapy was integrated into the DHP. The HDQ is used to assess disability among incoming clients to the program.

The University of Colorado Infectious Diseases Group Practice Clinic, University of Colorado Denver, United States: The University of Colorado Infectious Diseases Group Practice Clinic is a large HIV clinical program is a University affiliated, Ryan White supported, clinic which includes both in-patient and out-patient care at the University of Colorado Hospital (UCH) through Infectious Diseases Group Practice (IDGP).

Department of GU Medicine and Infectious Diseases (GUIDE), St. James's Hospital, Dublin, Ireland: The GUIDE Clinic is the largest HIV, Infectious Diseases and sexual health service in Ireland. The clinic serves ~3000 adults living with HIV in Ireland (~60% of people living with HIV in the Irish Republic). The clinic provides care and treatment for people living with HIV by a multidisciplinary team. In 2012, Kelly O'Brien collaborated with Colm Bergin to validate the HDQ for use with people living with HIV in Ireland.

METHODS:

Objective 1: To assess the utility of a new short-form HIV-specific disability questionnaire across multiple clinical practice settings with adults aging with HIV.

We will use a combination of quantitative (questionnaires) and qualitative (interviews) with 30 adults aging with HIV and 15 HIV health providers in 3 sites in Canada (Casey House) the United States (University of Colorado) and Ireland (St. James's Hospital) to assess sensibility (face and content validity, ease of usage), utility, and optimal use of the SF-HDQ in clinical practice. Outcomes will include an administration, scoring, and interpretation guide for clinical practice.

Clinicians who administered the SF-HDQ will complete a one-time questionnaire to describe the purpose they used the SF-HDQ, strengths and challenges of use, if and how they used the scores to guide clinical decisions, and recommendations to revise the guidance document for utilization.

RESEARCH PROCEDURES:

Objective 1) Assessing the Utility of the SF-HDQ
We will administer the **SF-HDQ** using electronic (tablet) methods of administration at each of the 3 sites.

We will then meet with participants to assess:
Sensibility: Using Feinstein's criteria, we will administer a self-reported questionnaire comprised of 18 statements (7 point response scale ranging from highly disagree to highly agree) asking about perspectives on face, content validity, method of administration, format, and ease of usage of the SF-HDQ (**Appendix B**). We will specifically ask participants to identify items that should be added or removed related to context (country). We will also electronically administer a demographic questionnaire comprised of items including but not limited to age, sex, gender, ethnicity, and multimorbidity (**Appendix C**).

Utility: Following the questionnaire administration, we will conduct semi-structured interviews with adults aging with HIV (n~10 each site), and HIV health providers who administered the HDQ (n~5 each site). We will ask about the utility of the SF-HDQ in practice, (e.g. assessing disability, facilitating communication, goal-setting, guiding referrals), experience with completing/administering the SF-HDQ, strengths and challenges, feasibility, how it should be administered (electronic, paper), when to administer (prior to or during a clinical visit), who should administer (type of health provider), and how often (to capture episodic nature of disability) (**Appendix D**).

Interpretability: We will administer a global rating scale (GRC) asking participants whether they consider themselves living with minimal, moderate or severe forms of disability (**Appendix E**) followed by a discussion about how scores might inform clinical decision making (e.g. referrals, discharge planning, interventions) and whether any specific considerations to context (country), age or gender exist.

All interviews will be audio recorded and transcribed verbatim. Upon analysis, we will meet as a team to identify recommendations that should comprise a clinical guidance document to facilitate SF-HDQ clinical use.

DATA ANALYSIS:

Objective 1) Assessing the Utility of the SF-HDQ
SF-HDQ Scoring: We will score the HDQ using the algorithm developed through Rasch Analysis (see Objective 1a).

Sensibility Questionnaire: We will calculate median scores for each of the items. We will consider the HDQ sensible if median scores were ≥5 for PLWH and ≥4 HIV health providers (7 point ordinal scale) for at least 80% of the items and if no items had median scores of ≤3 in either group, similar to criteria used in our earlier HDQ sensibility assessment.

Interview Data: We will analyze interviews using content analytical techniques and a team based approach to qualitative analysis. Our coding scheme will include the following areas: i) purpose of using SF-HDQ, ii) experience completing/administering the HDQ, iii) strengths, iv) challenges, iv) feasibility, v) method, timing and frequency of administration, vi) recommendations to guide administration, scoring, and interpretation of the SF-HDQ in practice, and vii) specific considerations related to context (country, older vs younger age, gender). We will use NVivo software for data management.

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Participants and Data – This section will ask for information pertaining to sample size, vulnerability, recruitment and compensation.

Describe the participants to be recruited, or the individuals about whom personally identifiable information will be collected. List the inclusion and exclusion criteria. Where the research involves extraction or collection of personally identifiable information, please describe where the information will be obtained, what it will include, and how permission to access said information is being sought.

STUDY PARTICIPANTS:

Adults aging with HIV (≥18 years) and *Health Providers who work in HIV care* who self-identified as having a role in addressing disability aging with HIV (which may include but are not limited to disciplines of medicine, rehabilitation, social work, and nursing).

Inclusion criteria:

Adults Living with HIV

Adults (18 years of age or older) living with HIV willing and able to provide written informed consent to participate in the study. ***Sampling:*** We will use purposive sampling to obtain diversity among participants with HIV in the sample based on age (≥50 years, <50 years), ethnicity, gender (men, women, transgender), and clinical site (US, Ireland and Canada). We chose to include adults at any age (rather than specifically older adults ≥50 years) as disability assessment is critical to consider in the context of multimorbidity prevention and healthy aging at any age over the lifespan.

HIV Health Providers

Health Providers who work in HIV care in Toronto, Canada, Aurora Colorado, and Dublin, Ireland who self-identify as having a role in addressing disability due to HIV, aging and multimorbidity. This may include (but is not limited to) physicians, rehabilitation professionals (occupational therapy, physiotherapy), social workers, and nurses. We chose to retain broad inclusion criteria for health providers given clinical teams may differ across sites. This broad inclusion criterion will allow us to explore diversity of perspectives and multidisciplinary approaches to disability assessment for adults aging with HIV in different health system clinical settings.

RECRUITMENT

Assessing the Utility of the SF-HDQ

Adults Living with HIV

We will recruit and enroll 10 adults (18 years or older) living with HIV and 5 HIV health providers who work in HIV Care in Aurora, CO, United States (University of Colorado), Toronto, Canada (Casey House) and Dublin, Ireland (St. James's Hospital) for a total of 45 participants (30 adults living with HIV and 15 health providers). We will specifically aim to recruit at least 50% of participants ≥50 years in each of the sites to over represent older adults living with HIV to account for the increasing prevalence of older adults with HIV in Canada, the United States, and Ireland. We will aim to recruit 25% women.

Participants who are interested will be asked to contact study investigators (by email or telephone) to discuss the study, and if they consent to arrange an appointment for data collection (**Appendix L**). The research team will provide a hard copy (or email) of the information letter and consent form (**Appendix J1**) and discuss the contents of the consent form (in person or by telephone) to individuals who are eligible and interested in participating in the study.

The individual will be informed of the purpose and rationale of the study, inclusion criteria, potential medical and social risks of participation, the voluntary nature of the study and their right to withdraw at any time, and compensation. We will also provide further information regarding the types of questions they will be asked. We may send up to two reminders to potential participants after providing the information sheets and consent forms if needed (**Appendix L**). Participants who indicate that they are not interested or do not respond after these two requests, will not be further approached about participation. Signed consent will occur in person prior to the time of scheduled administration of questionnaires and interview. We will send a reminder email or phone call (based on preferred mode of communication) the day prior to the interview (**Appendix N**).

HIV Health Providers

We will recruit health providers (n~5 each site) working in HIV care at each site (University of Colorado, Casey House and St. James's Hospital) using targeted recruitment of key informants.

An initial recruitment will occur via email to the targeted sample of key informant health providers working in HIV care at the three sites (Casey House, University of Colorado, St. James's Hospital). Initial contact with potential participants will be made via email; in the email we will provide information about the study such as the purpose statement, research objectives and proposed impact of results (**Appendix M1**). We will provide them with the information letter and consent form, which includes additional information such as participation requirements (i.e. the interview process) and contact information of the research team (**Appendix J2**). Interested individuals will be asked to contact the Research Coordinator at their given site by email or telephone to discuss the eligibility and details associated with the study.

SAMPLE SIZE:

Objective 1) Assessing the Utility of the SF-HDQ

Based on our previous sensibility work, we anticipate a sample of 45 (30 adults living with HIV +15 providers) will be sufficient to provide perspectives of utilization across sites. The University of Colorado Infectious Diseases Group Practice Clinic is a University-affiliated, Ryan White supported, clinic serving over 2500 adults with HIV in the Denver metro area, representative of an urban population aging with HIV, as approximately half are ≥50 years. Casey House is a specialty hospital in Toronto that recently launched a new day health program for PLWH and complex multimorbidity. Casey House currently serves 250 clients of which an estimated 50% are ≥50 years. The GUIDE Clinic at St. James's Hospital serves 3000 PLWH in Ireland, of which 495 (21%) are estimated ≥50 years.

COMPENSATION

Assessing Utility of SF-HDQ

Participants will be provided with a $30 CAD (Toronto Site), $20 USD (Colorado Site) gift card token of appreciation for taking part in the initial pilot administration and follow up interview on the experiences with the SF-HDQ. Participants at the Ireland site will not be provided an honorarium as this is in keeping with their research procedures at St. James's Hospital. HIV Health Providers will receive a $30 CAD (Toronto) and $20 USD (Colorado) gift card token of appreciation for taking part in each of the Objective 1 and Objective 2 interviews. Participants at the Ireland site will not be provided an honorarium as this is in keeping with their research procedures at St. James's Hospital.

VULNERABILITY

Group vulnerability of adults with HIV is medium as participants have a pre-existing health condition (HIV) with potentially other concurrent health conditions including mental health, addictions which may affect them psychologically, or socioeconomically.

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Participants may include persons whom members of the research team, have worked with as a colleague in a community-based research or educational capacity. Study investigators or the research coordinator at each site, who have no relationship with the potential participant, will obtain consent. Interested participants will be invited to contact the study co-investigators or research coordinator who has no relationship with the potential participants, who will discuss the study in detail and if applicable, will obtain consent.

Given our target population of adults living with HIV may experience cognitive impairment influencing their capacity to consent. This possibility will be addressed at the recruitment stage as researchers will include the capacity to consent as inclusion criteria for consideration by staff at the sites (Casey House, University of Colorado Hospital and St James's Hospital). We will continually assess participant capacity throughout communication leading up to participation, by asking potential participants to reiterate in his/her own words their understanding of the study, what is involved with participation and the risks/benefits of participating.

Group vulnerability of health providers is low.

Investigator Experience

Please describe the community members research team status (eg. employees, volunteers, or participants). What training will they receive?

The research team is comprised of researchers and clinicians from Canada, Ireland and the United States. We will strike a Community Advisory Committee (n~9) comprised of people living with HIV and representatives from AIDS Service Organizations in Canada, such as Toronto PWA Foundation, Realize; in the United States such as Treatment Education Network, Empowerment and Brother John; and in Ireland such as HIV Ireland and Positive Now. Many of the team members have been involved in the original development and validation of the HDQ.

Investigator Experience with this type of research

Please provide a brief description of the previous experience for this type of research by the applicant, the research team, and any persons who will have direct contact with the applicants. If there is no previous experience, how will the applicant and research team be prepared?

Our team has a strong history of collaboration and success in forming partnerships, comprised of people living with HIV, researchers, clinicians and community stakeholders with knowledge of HIV, aging and rehabilitation, implementation science, and knowledge transfer and exchange.

Nominated Principal Investigator, **Kelly O'Brien**, is a physical therapist and Associate Professor at the Department of Physical Therapy, University of Toronto and Canada Research Chair in Episodic Disability and Rehabilitation. As the Principal Investigator of the CIHR-funded study to develop and validate the original HIV Disability Questionnaire (HDQ), and the HIV Health and Rehabilitation Survey (HHRS) she is well versed in the development and property assessment of patient reported outcomes (PROs) and evaluation of their utilization. Co-Principal Investigator, **Kristine Erlandson,** is a Medical Doctor and Assistant Professor at the Division of Infectious Diseases, Division of Geriatric Medicine, University of Colorado Denver who's research is focused on understanding the mechanisms of successful aging in HIV-infection. She will oversee the implementation of the study at the University of Colorado Denver site. Co-Principal Investigator, **Soo Chan Carusone** is the Director of Research at Casey House**.** As the site lead at Casey House and a member of the core SF-HDQ team, she will collaborate with Dr. O'Brien to facilitate recruitment and data collection at Casey House. Co-Investigator **Colm Bergin** is a Consultant Physician at St. James's Hospital and Clinical Professor at Trinity College Dublin. As the Ireland site lead, he will oversee the implementation of the study at St. James's Hospital/Trinity College Dublin/ Clinical Research Facility Site. Co-investigator, **Patty Solomon** is a Professor at McMaster University, is an original developer of the HDQ, and an expert in HIV and Rehabilitation. She will be will provide expertise with the

qualitative inquiry and overall guidance in the implementation, data collection and analysis of the data. Co-investigator, **Steven Hanna,** is Professor at McMaster University, who possesses statistical expertise in factor analysis and structural equation modeling. Dr. Hanna will provide expertise in relation to statistics, factor analysis when assessing the properties of the SF-HDQ. Co-Investigator, **Richard Harding** is a Professor at King's College London. He will provide his expertise in relation to measurement, implementation, and evaluation of clinical practice for adults living with HIV and chronic illness. Co-investigator, **Ahmed Bayoumi** is a General Internist and Scientist at the Centre for Research on Inner City Health at St. Michael's Hospital and is an original developer of the HDQ, and a clinician working in HIV care. Dr. Bayoumi will provide expertise with the quantitative inquiry and overall guidance in the implementation, data collection and analysis of the data, translation of the findings, and inform the relevance of this work specifically to successful aging with HIV in Canadian clinical settings. Co-investigator, **Aileen Davis** is a Professor at the University of Toronto and Senior Scientist in the Division of Health Care and Outcomes Research Unit at the University Health Network. She will be involved in all aspects of this study, specifically providing methodological and psychometric expertise as it relates to Rasch analysis and development and assessment of the SF-HDQ.

Possible Risks and Benefits

Possible Risks – (Complete as Applicable)

Psychological/Emotional Risks:

It is possible that some adults living with HIV may find some of the questions on the questionnaires or in the interviews to be personal or sensitive in nature. Participants can choose not to answer questions and may end the interview at any time. If the participants find themselves becoming very upset during this study, the investigators will recommend discussing their feelings with their health care professional (e.g. physician), qualified counselor, or services at the specific site (Casey House, University of Colorado Hospital or St. James's Hospital). If the participants have difficulty contacting a health care professional, qualified counselor or local community health center, they may contact the principal investigator /site lead for further assistance. In this situation, the study team will facilitate linkages to supportive services at the specific site of study for the given participant.

Physical Risks:

There is no physical risk from taking part in this study.

Social Risks:

Adults living with HIV: There is no known social risk for participants. Participants will be completing the SF-HDQ in the study as part of their regular clinic or day health program visit as part of the pilot implementation. Participants will be reminded that all findings will be presented in a way that maintains participant anonymity.

HIV Health Providers: Health Provider participants are at low-risk. However, some participants may feel pressured to participate and/or uncomfortable speaking honestly when the findings may be reported back to their colleagues and superiors. To mitigate this risk, potential participants will be informed that their choice to participate will not be shared with anyone outside of the research team and will have no impact on their employment now or in the future. Participants will also be reminded that all findings will be presented in a way that maintains participant anonymity.

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Legal Risks:

Not applicable.

Potential Benefits

Benefit Description:

Taking part in this study will not give the participants any health benefits or give them any treatment, experimental or otherwise. However, it may help to develop a new measure of disability and advance knowledge about the disability that adults living with HIV experience. Many of the patients who decide to take part in these studies do so for altruistic reasons. They have a genuine concern about the HIV epidemic and understand that they might be contributing to a potential solution for this complicated medical illness.

Date Last Revised: February 13, 2022

Consent

Consent Process Details:

Objective 1b) Assessing the utility of the SF-HDQ

Adults Living with HIV

Initial contact with potential participants who are adults living with HIV will be made via a study poster (**Appendix I**) at recruitment locations or directly via health care professionals who may have invited their clients to participate. After the study investigators have made the initial in person contact in the clinic setting to determine the eligibility, a copy of the information sheet and consent form (**Appendix J1**) to individuals who are eligible and interested in participating will be sent out by email or provided in person.

Participants may consent in person upon initial determination of eligibility or those who are interested can ask to be contacted by study investigators (by email) to arrange an appointment at which written consent will be obtained. The research team will reach out to the participants (**Appendix L**) and will attach the information letter and consent form (by email) (**Appendix J1**) or discuss the contents of the consent form by phone or in person to individuals who are eligible and interested in participating in the study. The individual will be informed of the purpose and rationale of the study, inclusion criteria, potential medical and social risks of participation, the voluntary nature of the study and their right to withdraw at any time, and compensation (**Appendix J1**). We will also provide further information regarding the types of questions they will be asked. We may send up to two reminders to potential participants after sending copies of the information sheets and consent forms. Participants who indicate that they are not interested or do not respond after these two requests, will not be further approached about participation. Signed consent will occur in person prior to the time of scheduled administration of questionnaires and interview.

Participants may choose to withdraw from the study at any point in time for any reason. For example, if participants appear too uncomfortable with the questions being asked in the interview or on the questionnaires, they may withdraw at any time and still receive the token of appreciation (if applicable). Furthermore, if the interviewer or (questionnaire administrator) feels that participants are too uncomfortable with the questions asked, he/she may also stop the interview / questionnaire administration. If participants choose to withdraw before the completion of the interview or questionnaire administrations, participants will have the opportunity to withdraw their information from the study, otherwise investigators may use information collected up to the point before participants withdrew.

HIV Health Providers

An initial recruitment will occur via email to the targeted sample of key informant health providers working in HIV care at the three sites (Casey House, University of Colorado, St. James's Hospital). Initial contact with potential participants will be made via email; in the email we will provide information about the study such as the purpose statement, research objectives and proposed impact of results (**Appendix M1**). We will provide them with the information letter and consent form (**Appendix J2**), which includes additional information such as participation requirements (i.e. the interview process) and contact information of the research team.

Interested individuals will be asked to contact the Research Coordinator at their given site by email or telephone to discuss the eligibility and details associated with the study. Signed consent will occur in person prior to the time of scheduled administration of questionnaires and interview.

Supplemental File 1
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Capacity/Competency Assessment Process

Process Details by which Capacity/Competency will be assessed and alternate sources of consent:

Given our target population of adults living with HIV may experience cognitive impairment influencing their capacity to consent. This possibility will be addressed at the recruitment stage as researchers will include the capacity to consent as inclusion criteria for consideration by staff at the sites (Casey House, University of Colorado Hospital and St James's Hospital). We will continually assess participant capacity throughout communication leading up to participation, by asking potential participants to reiterate in his/her own words their understanding of the study, what is involved with participation and the risks/benefits of participating.

Assent Process

Participant Assent Process Details:

Not applicable.

Debriefing and Dissemination

Information Feed Back Details following completion of a participant's participation in the project:

In collaboration with the Community Advisory Committee, we will implement a KT plan including presentations at academic conferences, community organizations at each of the sites, development of a fact sheet summary for broad distribution at the sites and via the Canada-International HIV and Rehabilitation Research Collaborative (CIHRRC); drafting manuscripts for peer-reviewed publication in open access journals. We will specifically email a copy of a fact sheet summary of the study findings to all participants.

Procedural details which allow participants to withdraw from the project:

After the study investigators make initial contact, a copy of the information sheet and consent form (Appendix J1 & Appendix J2) will be discussed in person or by phone to individuals who are eligible and interested in participating. On the information sheet and consent form, details about participants' right to withdraw are clearly presented. Participants will be reminded of their right to withdraw from the project verbally prior to administration of the SF-HDQ and interview.

Participants may choose to withdraw from the study at any point in time for any reason. For example, if participants appear too uncomfortable with the questions being asked in the interview or on the questionnaires, they may withdraw at any time and still receive their compensation.
Furthermore, if the interviewer or (questionnaire administrator) feels that participants are too uncomfortable with the questions asked, he/she may also stop the interview / questionnaire administration.

When ensuring the capacity to consent, the individual will be asked to communicate his/her understanding of his/her right to withdraw from the study at any time. The participant will also be reminded of this right if he/she appears distressed with administration of the SF-HDQ or by the interview/or expresses a desire to stop the administration of the SF-HDQ or the interview. Potential participants will be informed that participation in the study is voluntary and that they have the right to withdraw at any time with no negative consequences.

For the adults living with HIV who are accessing services at one of the three sites (Casey House, St. James's Hospital, University of Colorado Hospital), withdrawal will not affect the services that they receive. If participants choose to withdraw before the completion of the interview or questionnaire administrations, investigators may use information collected up to the point before participants withdrew, unless the participant wishes to have it removed. Participants have the right to refrain from answering questions on the SF-HDQ or in the interview that they do not feel comfortable with.

Supplemental File 1
Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

What happens to a participant's data and any known consequences related to the removal of said participant?

Participants will be informed that choosing to withdraw from the study will not compromise the care they receive (at Casey House, St James's Hospital or University of Colorado Hospital) or their employment, nor will it disqualify them from receiving the token of appreciation, if applicable. In the event of a withdrawal from the study, the participant will be asked if they will permit the use of data obtained up until that point; if they decline, all data associated with the participant will be destroyed.

List reasons why a participant cannot withdraw from the project (either at all or after a certain period of time):

Not Applicable

Confidentiality and Privacy

Data Protection

Describe how the data will be protected through the research phase and subsequent dissemination of results:

All participant study records (individual interview transcripts, demographic questionnaires, SF-HDQ) will be identified by a coded number to maintain participant confidentiality. A master list of participants with their respective codes along with contact information of participants (email; telephone number if applicable) will be stored on a password protected computer file at the site location. Hard copy consent forms will be stored in a locked cabinet at the University of Toronto, St James's Hospital and University of Colorado Denver in a secure office / lab location.

All questionnaire responses will be downloaded from Qualtrics, an online secure e-survey software that uses Transport Layer Security (TLS) encryption, at their respective site and later transferred to the University of Toronto using Sharefile, a password protected and encrypted transfer system and stored on a secure server at the University of Toronto. We will establish data sharing agreements between the University of Toronto, University of Colorado Denver and St. James's Hospital to facilitate the transfer and sharing of anonymized data.

Electronic data will be stored on a password-protected computer in a locked office at the University of Toronto and University of Colorado Denver, accessible only to investigators and research coordinators. Electronic files will be shared among investigators on a secured file share system, ShareFile (http://www.sharefile.com/about//).

All information will remain strictly confidential and available only to study investigators and research staff, members of the IRBs that reviewed the protocol, and other regulatory authorities for the purpose of monitoring this study, unless required by law. All study data will be held at the respective site in which it were collected (University of Colorado Denver, Casey House, St. James's Hospital) according to the institutional privacy protocols (e.g. in a locked cabinet inside a secured office; on a password protected computer) and then transferred to the University of Toronto for storage and analysis.

We will keep all email communications strictly between participants and the research team. The information letter and consent form will also include email and telephone contact details at the Episodic Disability and Rehabilitation Lab. The voice mailbox will be accessible only to the site PI (Kelly O'Brien, Kristen Erlandson, Colm Bergin) and the designated research coordinator.

Date Last Revised: February 13, 2022

Supplemental File 1

Assessing the Sensibility and Utility of a Short-Form Version of the HIV Disability Questionnaire in Clinical Practice Settings in Canada, Ireland and the United States: A Mixed Methods Study

Describe how the data will be retained, and its final disposal or storage. Please provide reason if data will be stored for an indefinite length of time.

Only the research team will have access to the data including questionnaires, audio files and transcripts. All questionnaire responses will be downloaded from Qualtrics, an online secure e-survey software that uses Transport Layer Secuirty (TLS) encryption, at their respective site and later transferred to the University of Toronto using Sharefile, a password protected and encrypted transfer system and stored on a secure server at the University of Toronto. accessible only to the investigators. Any quotations from transcripts attributed in the final written report of the study will be anonymous.

Upon completion of the interviews, we will immediately upload audio files to Sharefile, a secure sharing and encrypted storage system, recordings will be deleted from the recording device and identification numbers will replace participant identifiers on corresponding data. We will ensure anonymity by storing the excel file containing the identification numbers linked with participant names on a password- protected computer located in a locked office at the University of Toronto, St James's Hospital and University of Colorado Denver. Only members of the research team will have access to Sharefile. The researchers will use the password-protected and encrypted Qualtrics account to transfer data. The password for Sharefile will be electronically stored separately from the data obtained.

Printed transcripts and field notes from the interviews and consent forms will be stored in a locked filing cabinet in the office of the primary investigator the University of Toronto, St James's Hospital and University of Colorado Denver. The document that links the name of each participant to their assigned numeric code will be stored on a password protected computer file at the University of Toronto, St James's Hospital and University of Colorado Denver.

No identifying information will be included when compiling and disseminating results. In the event that we want to include specific quotes, participant ID numbers will be used.

Length of Time to Retain Data

Following the completion of the study, printed and electronic data (excluding audio recorded data) will be retained for 5 years in the same location that it was stored throughout the study. Audio files will be destroyed immediately following publication. Files containing personal contact information will be deleted after publication. All remaining electronic and hard copy data and information related to the study will be retained for 5 years after the completion of the study and then destroyed by Kelly O'Brien (Toronto), Kristine Erlandson (Denver) or Colm Bergin (Dublin).

Level of Risk and Research Ethics Board

Explanation/Justification details for the group vulnerability and research risk listed above:

Research is low risk as it involves collection of self-reported questionnaire data about health challenges and verbal data (via interviews). The subject matter of the interviews and demographic and HDQ questionnaires is not sensitive in nature. As such there is a low probability that participants will be harmed and the magnitude of harm should it occur would be low.

Group vulnerability of adults with HIV is medium as participants have a preexisting health condition (HIV) with potentially other concurrent health conditions including mental health, addictions which may affect them psychologically, or socioeconomically.

Group vulnerability and research risk of health providers is low.

Date Last Revised: February 13, 2022

UNIVERSITY OF TORONTO

OFFICE OF THE VICE-PRESIDENT, RESEARCH AND INNOVATION

RIS Protocol Number: 38152

Approval Date: 21-Aug-19

PI Name: Miss Kelly O'Brien

Division Name:

Dear Miss Kelly O'Brien:

Re: Your research protocol application entitled, " SF-HDQ Study: Advancing Assessment of Episodic Disability to Enhance Healthy Aging among Adults Living with HIV: Developing a Short-Form HIV Disability Questionnaire (SF-HDQ) for use in Clinical Practice"

The HIV REB has conducted a Full Board review of your application and has granted approval to the attached protocol for the period 2019-08-21 to 2020-08-20.

Please note that this approval only applies to the use of human participants. Other approvals may be needed.

Please be reminded of the following points:

- An **Amendment** must be submitted to the REB for any proposed changes to the approved protocol. The amended protocol must be reviewed and approved by the REB prior to implementation of the changes.
- An annual **Renewal** must be submitted for ongoing research. You may submit up to 6 renewals for a maximum total span of 7 years. Renewals should be submitted between 15 and 30 days prior to the current expiry date.
- A **Protocol Deviation Report** (PDR) should be submitted when there is any departure from the REB-approved ethics review application form that has occurred without prior approval from the REB (e.g., changes to the study procedures, consent process, data protection measures). The submission of this form does not necessarily indicate wrong-doing; however follow-up procedures may be required.
- An **Adverse Events Report (AER)** must be submitted when adverse or unanticipated events occur to participants in the course of the research process.
- A **Protocol Completion Report** (PCR) is required when research using the protocol has been completed. For ongoing research, a PCR on the protocol will be required after 7 years, (Original and 6 Renewals). A continuation of work beyond 7 years will require the creation of a new protocol.
- If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.

OFFICE OF RESEARCH ETHICS
McMurrich Building, 12 Queen's Park Crescent West, 2nd Floor, Toronto, ON M5S 1S8 Canada
Tel: +1 416 946-3273 ● Fax: +1 416 946-5763 ● ethics.review@utoronto.ca ● http://www.research.utoronto.ca/for-researchers-administrators/ethics

University Research
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

Colorado Multiple Institutional Review Board, CB F490
University of Colorado, Anschutz Medical Campus
13001 E. 17th Place, Building 500, Room N3214
Aurora, Colorado 80045

303.724.1055 [Phone]
303.724.0990 [Fax]
COMIRB Home Page [Web]
comirb@ucdenver.edu [E-Mail]
FWA00005070 [FWA]

UCD Anschutz Medical Campus | UCD Downtown Denver Campus | University of Colorado Health | Denver Health and Hospitals | Colorado Prevention Center | Children's Hospital Colorado | Colorado School of Mines | VA Eastern Colorado Health Care System

Certificate of Approval

06-Sep-2019

Title:	Developing a Short-Form Version of the HIV Disability Questionnaire (HDQ)
Subject:	COMIRB Protocol 19-1895 Initial Application
Investigator:	Kristine Erlandson
Sponsor(s):	National Institute on Aging/NIH/DHHS~
Effective Date:	06-Sep-2019
Expedited Category:	7

Submission ID: APP001-2

SUBMISSION DESCRIPTION:

APP001-2: Response to request for minor modifications.

APP001-1: Initial application for Expedited chair review.

This study was reviewed and approved under the “2018 Requirements” of the Federal Policy for the Protection of Human Subjects.

If continuing review is required for your research, your submission is APPROVED until the expiration date listed above. The investigator will need to submit this research for Continuing Review at least 30 days prior to the expiration date. If a study's approval expires, investigators must stop all research activities immediately (including data analysis) and contact the COMIRB office for guidance

If your study has not been assigned an expiration date continuing review is not required for your research.

Regardless of continuing review, you are required to submit changes to your research for approval prior to implementing those changes. You are required to report unanticipated problems and serious or continuing noncompliance to COMIRB. When your research is complete you must report the study closure to COMIRB.

Your responsibilities as Principal Investigator are posted here:
http://www.ucdenver.edu/research/Research%20Administration%20Documents/Responsibilities-of-Investigators.docx

REVIEW DETAILS– Please read carefully:

Dr. Erlandson:

Thank you for your responses to the requested minor modifications. It can now be approved but there is one other thing you should be aware of and that will need clarification. Because one of your data collection sites is Ireland, the General

Data Protection Regulation (GDPR) of the European Union comes into play. If you're not familiar with the GDPR, they are a set of very strict regulations on data privacy with very heavy penalties for violation, primarily aimed as internet business but which includes research. While this is primarily a concern for the lead site (Toronto) and the Irish site, the fact that, it appears, you will have access to the data brings CU into the picture. Please contact COMIRB Director, John Heldens (john.heldens@CUAnschutz.edu) who can help you determine the appropriate path.
Minimal Risk: This research poses no more than minimal risk as defined in 45 CFR 46.102(i) [and/or] 21 CFR 56.102(i). This submission was reviewed under Expedited procedures and the following determinations were made.
Affiliated Site:
University of Colorado Health
Informed consent is required.

All criteria for waiving of documentation of consent were met for Aim 2.
HIPAA: This study is subject to HIPAA. A waiver of Authorization was granted [for screening]. All criteria for waiving HIPAA authorization were met.
Certificate of Confidentiality: [If NIH or CDC-funded, or if PI has requested a CoC] This study must be conducted under the terms of a certificate of confidentiality. More details regarding the terms of CoCs can be found on the NIH and CDC websites.
The following documents have been reviewed as part of this approval :
AIM1BConsent v 09.03.19
Aim2Consent(patient) v 09.03.19
AIM2ProviderConsent v 09.03.19
Appendix M-- Provider Emiail v 08.07.19
Appendix-A-HDQ-Version-2017-Ver-10-7-Jun-28-19-CLEAN-Aug-7-19
Appendix-B-Sensibility-Questionnaire-Aug-7-19
Appendix-C-SFHDQ-Demographic-Questonnaire-Aug-20-19
Appendix-D-Sensibility-Interview-Guide-REVISED-Aug-20-19
Appendix-E-Global-Disability-Rating-Scale-Aug-7-19
Appendix-F-Criterion-Measures-WHODAS-PHQ8-MOS-SSS-Aug-7-19
Appendix-G-HCPs-PreInterivew-Questionnaire-Objective2-Aug-7-19
Appendix-H-Obj2-Health-Provider-Interview-Guide-REVISED-Aug-20-19
Appendix-N-Reminder-Email-SFHDQ-PLWH-HCPs-Aug-7-19
Application Form v 08.20.19
CF-260_Advertising_Components_Form
cover letter (no date)
FINAL-OBrien-NIH-APPLICATION-ALL-SUBMITTED-DEC-19-18
Personnel eForm v 09.03.19
portal clearance v 08.20.19
Protocol-Template v 08.20.19
Qualtrics-Security-Document-Aug-2019
Response Submission Cover Letter v 08.20.19
SF-HDQ-Version-Possible short form (as an example) v 05.24.19
UofT-REB-Comments-Aug-20-19
UofT-REB-SFHDQ-Study-Approval-Letter-Aug-21-19

If red-line changes were made, the tracked changes and clean versions have been uploaded into eRA (InfoEd). If the PI disagrees with these changes, submit a change form to COMIRB with the revised documents.

Click here to your submission: Submission Page

Study personnel are approved to conduct the research as described in the above documents approved by COMIRB

Information on how to submit changes (amendments) to your study, reports of unanticipated problems, and request for study closure to COMIRB can be found on the COMIRB website
http://www.ucdenver.edu/research/comirb/submissions/Pages/default.aspx

For the duration of this research the investigator must:

- Submit any change in the research design, investigator, and any new or changed study documents (including new/changed consent forms, questionnaires, advertisements, etc.) to COMIRB and receive approval before implementing the changes
- Use only a copy of the COMIRB-approved, stamped Consent and/or Assent Form. The investigator bears the responsibility for obtaining Informed Consent from all subjects as required by COMIRB prior to the start of study procedures. COMIRB REQUIRES that the subject be given a copy of the consent and/or assent form after it is signed.
- Inform COMIRB immediately of any Unanticipated Problems that are unexpected and related to the study in accordance with COMIRB Policies and Procedures.
- Remain actively engaged in the conduct of the research. The investigator must ensure that all enrolled participants are appropriate for the study prior to study procedures beginning.

As part of this review it was determined that for this research:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, §46.116.
5. Informed consent will be appropriately documented in accordance with, and to the extent required by, §46.117.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Appropriate safeguards are in place to protect potentially vulnerable populations from coercion and undue influence.

Please reply to the email containing this letter, contact the COMIRB Help Desk at COMIRB@ucdenver.edu or call 303-724-1055 if you have questions or concerns.

Sincerely,

UCD Panel S

Tallaght University Hospital | Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

SJH/TUH Research Ethics Committee Secretariat
email: researchethics@tuh.ie

Prof Colm Bergin,
St James's Hospital,
James' Street,
Dublin 8

09th January 2020

REF: Advancing Assessment of Episodic Disability to Enhance Healthy Aging among Adults Living with HIV: Developing a Short-Form HIV Disability Questionnaire (HDQ) for use in Clinical Practice

REC: 2019-12 Chairman's Action (1)
(Please quote reference on all correspondence)

Date of Valid Submission to REC: 04.09.2019
Date of Ethical Review: 03.12.2019
Research and Innovation Application Number: PLEASE SUBMIT

Dear Prof Bergin,

The REC is in receipt of your recent request to TUH/SJH Research Ethics Committee in which you queried ethical approval for the above named study.

The Chairman, Prof. Richard Dean, on behalf of the Research Ethics Committee, has reviewed your correspondence given **full approval** for this study to proceed. However, please submit the Research and Innovation Number to the JREC, please also submit the approval od the DPIA from the DPO as data is going to Canada.

Applicants must submit an annual report for ongoing projects and an end of project report upon completion of the study. It is the responsibility of the researcher/research team to ensure all aspects of the study are executed in compliance with the General Data Protection regulation (GDPR), Health Research Regulations and the Data Protection Act 2018. ***Additionally, please note for documents submitted for GDPR purposes that the REC and the Chair are not confirming that you're documents are GDPR compliant, they are approving the document from an ethical perspective.***

Yours sincerely,

Sadhbh O'Neill

REC Officer – Dr Sadhbh O'Neill
SJH/TUH Research Ethics Committee

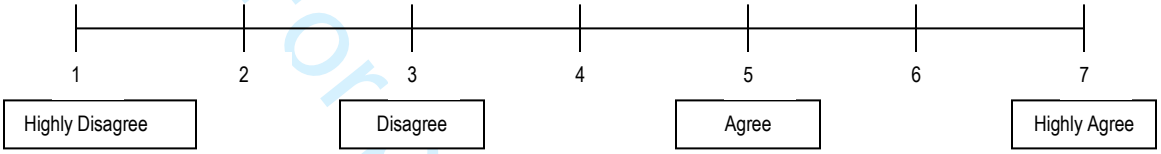
The SJH/TUH Joint Research and Ethics Committee operates in compliance with and is constituted in accordance with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 & ICH GCP guidelines.

Supplemental File 2
Sensibility Questionnaire (Adults Living with HIV Version Example)

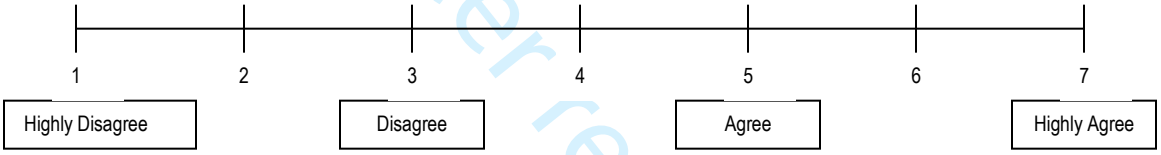
You have just completed (or reviewed) the new Short-Form HIV Disability Questionnaire (SF-HDQ). The goal of the questionnaire is to describe disability experienced by adults living with HIV. We would like to get your feedback on its use in the clinic setting. There is no right or wrong answers. Please circle the most appropriate numeric answer on the scale in response to each of the following statements pertaining to the Short-Form HIV Disability Questionnaire.

Face Validity

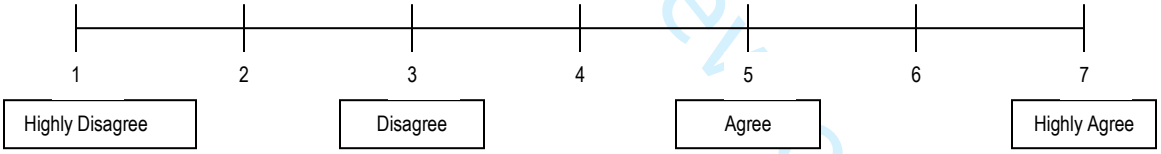
1. I was able to answer all of the questions.



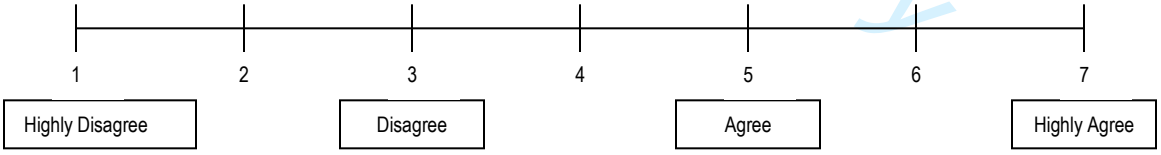
2. The instructions were clear and easy to understand.



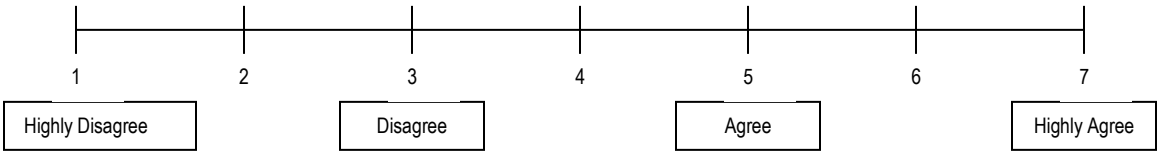
3. The questions were clear and easy to understand.



4. The overall questionnaire makes sense.



5. The response categories for the questions were adequate.

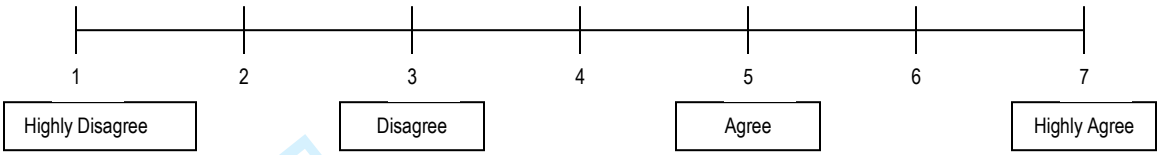


Date Last Revised: February 13, 2022

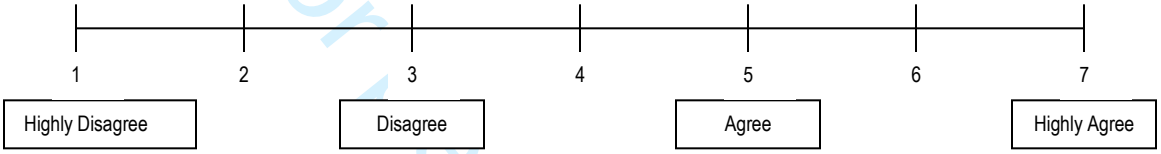
Supplemental File 2
Sensibility Questionnaire (Adults Living with HIV Version Example)

Content Validity

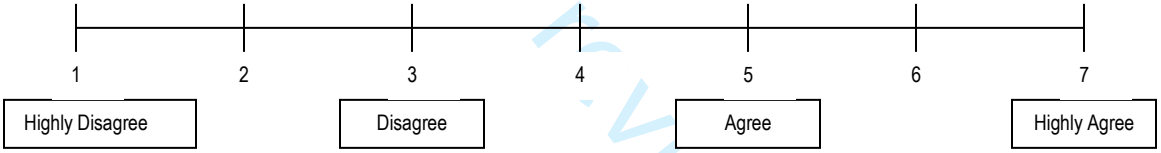
6. The Short-Form HIV Disability Questionnaire was intended to capture disability which has been defined by adults living with HIV as: symptoms / impairments, difficulties with day-to-day activities, challenges to social inclusion and uncertainty. The questionnaire captured all elements of my disability.



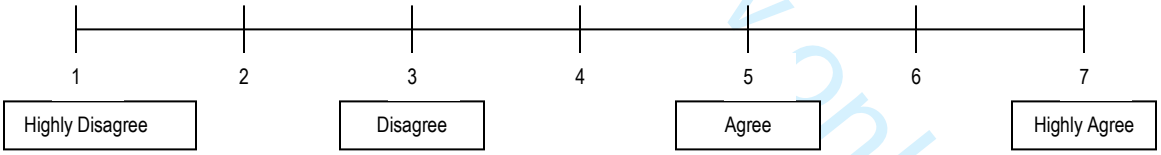
7. The questionnaire included important items that are necessary to describe my disability.



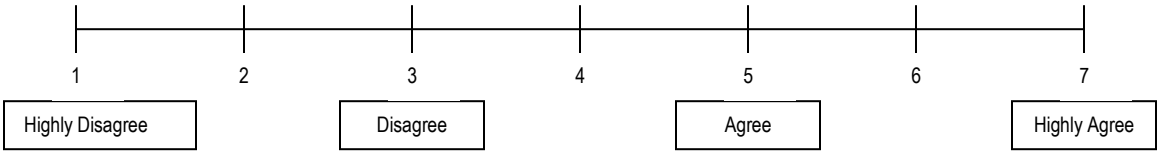
8. The questionnaire included items that were repetitive or redundant.



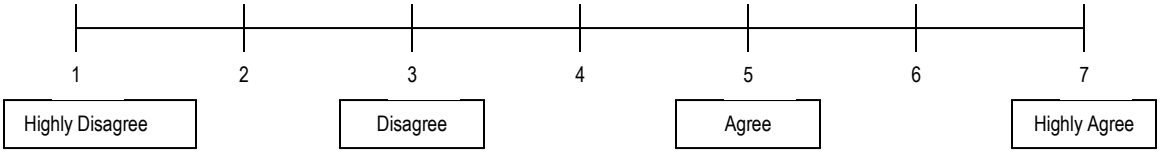
9. There were items missing in this questionnaire that should be included.



10. Some of the questions seemed out of order.



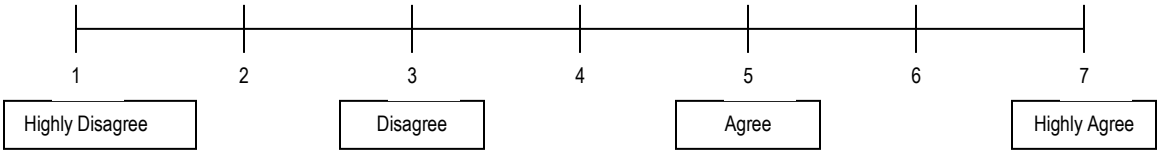
11. I was able to find my answer in the list of possible answers to the questions.



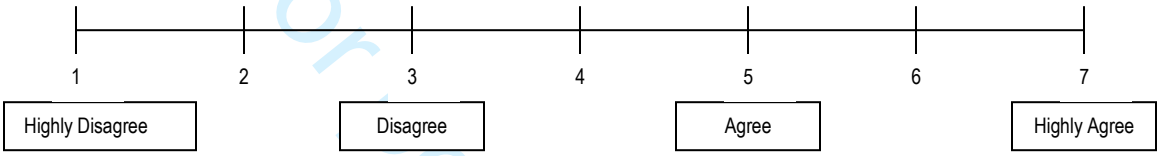
Supplemental File 2
Sensibility Questionnaire (Adults Living with HIV Version Example)

Format and Ease of Usage

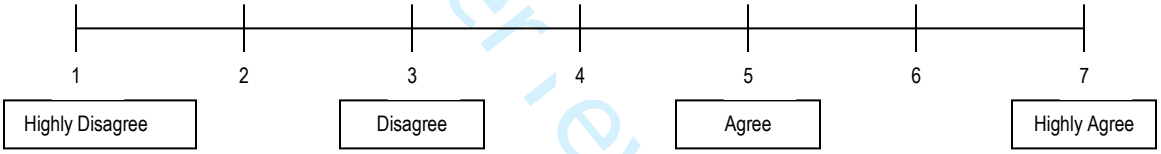
12. I felt uncomfortable answering some of the questions because I did not want to have anyone know my answer.



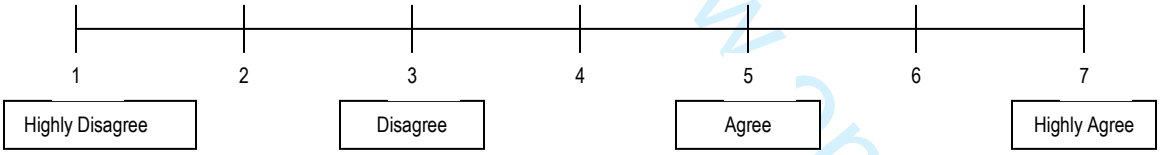
13. I felt that the questions made me think about things that I would have preferred not to have thought about.



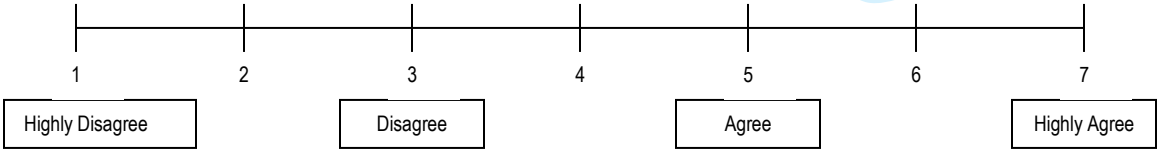
14. I felt that answering the questions helped me in some way.



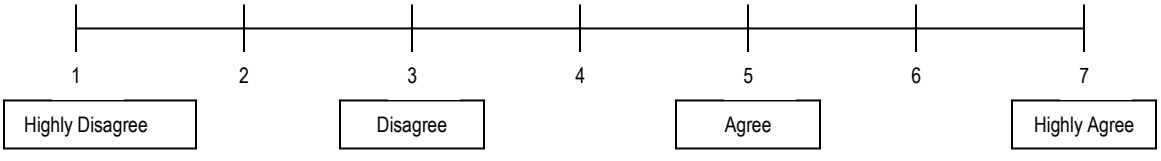
15. The questionnaire took too long for me to complete.



16. The questionnaire required too much effort to complete.

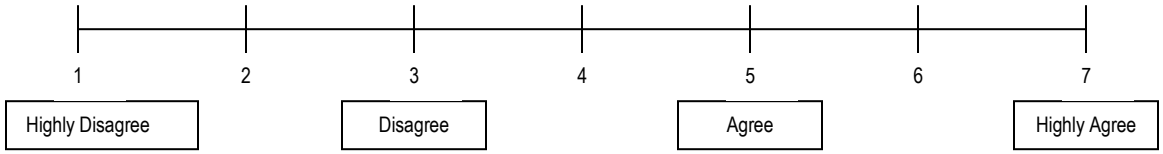


17. The questionnaire was easy to complete using the electronic tablet.

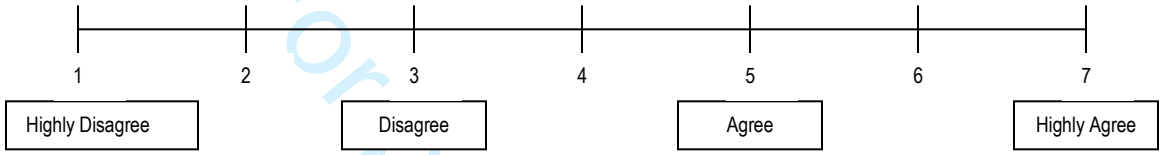


Supplemental File 2
Sensibility Questionnaire (Adults Living with HIV Version Example)

18. I would like to receive a summary of my HDQ scores right after completing the questionnaire to help understand the areas (or domains) where I might experience health challenges.



19. Overall, this questionnaire is useful in describing disability experienced by adults living with HIV.



Supplemental File 3
Interview Guide (Adults Aging with HIV & Health Care Practitioners)

Thank you for agreeing to participate in this study. As you know, our aim is to establish a short-form version of the HDQ. I am meeting with you to try to get your feedback on the questionnaire items you just completed (or reviewed) related to disability. Disability is defined as any symptoms or impairments, difficulties with day-to-day activities, challenges to social inclusion and uncertainty that you may experience living with HIV, its conditions or treatments that can fluctuate on a daily basis and over the entire course living with HIV. I am interested in learning whether you think the short form version of this questionnaire adequately captures the types of health related challenges (or disability) that you (or your patients) might experience living with HIV. I am also interested in learning about your thoughts on the ways in which the SF-HDQ can be used in the clinical setting. As a reminder, this interview is being audio-recorded. You can refuse to answer any questions you are not comfortable or do not wish to answer. Do you have any questions before we begin?
**Note – question delivery will be adapted according to the target population (adult living with HIV who completed the SF-HDQ versus health care providers that will review the SF-HDQ)*

Past Experience

1. *What are your past experiences with the HDQ? (i.e. any involvement with HDQ prior to today?)*

Probes:

- Health Provider Participants
  - Have you administered the HDQ in your work previously?
  - Have you been given feedback about the HDQ from patients/ clients who have completed the HDQ?
    - If so, what was the feedback?
- PLWH Participants– have you completed the HDQ as a client, patient, or study participant, previously?

Current Experience (as of Today)

2. *Can you describe your overall experience completing (or administering) the SF-HDQ?*

3. *What went well? What didn't go well?*

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Face and Content Validity

4. What are your overall thoughts on the short-form HDQ questionnaire items?

Probes:

How well do you think the items captured the disability you (or your patients) experience living with HIV?

- symptoms or impairments (physical, cognitive, mental-emotional)
- difficulties carrying out day-to-day activities (e.g. shopping, meal preparation)
- challenges to social inclusion (e.g. work, personal relationships, parenting)
- uncertainty (e.g. worrying about the future living with HIV)

5. Do you feel there were any items that especially captured the types of disability you (or your patients) experience? (were really good at capturing your (your patients') disability?)

Probes:

If yes, what were those important questions?

[If vague can ask participants to identify which items were the really important ones?]

6. Do you feel the response options were sufficient to allow you (your patients) to adequately answer the question to best describe your disability experience?

Probes:

If yes, what did you like about the response options?

If no, what would you change about the response options?

Item Generation

7. Do you feel there were any items missing from the questionnaire?

Probes:

If yes, what types of questions would you like to see put back (or added) into the SF-HDQ?

- symptoms or impairments (pain, fatigue, body composition changes)
- difficulties carrying out day-to-day activities (e.g. shopping, meal preparation)
- challenges to social inclusion (e.g. work, personal relationships, parenting)
- uncertainty (e.g. worrying about the future living with HIV)

How might you word those questions on a questionnaire?

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Item Wording

8. What do you think about the wording of the questions in the questionnaire?

Item Reduction

9. Do you think there were any questions that were redundant or repetitive? (meaning, do you think the SF-HDQ could be made even shorter?)

Probes:

If yes, what were those questions?
Do you think that these items could be removed from the questionnaire and it still adequately capture your (your patients') experience?

Ease of Usage

10. What did you think of the length of time it took you (or will take your patients) to complete the questionnaire?

Probes:

Was the time it took to complete the questionnaire too long?
Could you (your patients) have completed a longer questionnaire?

Utility / Overall Purpose

11. How might the SF-HDQ be used in clinical practice? What ways do you think the SF-HDQ might be used in clinical practice?

Probes:

- Assessing or describing disability experienced by adults aging with HIV?
- Helping with communication about disability experienced between patients and providers?
- Goal-setting?
- Identifying areas to target interventions?
- Identifying challenges that might help guide referrals to other services or providers?

12. How might you envision the SF-HDQ being used in your clinical practice? What would be the optimal way to use it?

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13. Do you see the SF-HDQ as a benefit for use in clinical practice? IF so, how?

Probes:

- Instant feedback of disability scores to care providers and patients / identifying domains with challenges?
- See above.

14. Do you see any challenges with using the SF-HDQ in clinical practice? IF so, how?

Probes:

- Burden of time?
- Lack of technology literacy (tablet format)?
- Concerns of data privacy?

Administration

*15. What did you think of completing the questionnaire on the **electronic tablet**?*

Probes:

What did you like? Not like? Did you have any problems with the tablet format? (or do you think that your patients might have any problems with the tablet?)

*16. Who do you think is the **ideal person to administer** the SF-HDQ in clinic?*

Probes:

Type of health provider? Administrative personnel? Does it matter?

*17. When do you think would be the **ideal time to administer** the SF-HDQ in clinic? How often?*

Probes:

Prior to attending the clinic? At the clinic but before your appointment with health provider? Explain.

Scoring

The SF-HDQ is scored on a scale from 0-100 with higher scores indicating greater presence, severity and episodic nature of disability: (Provide an example of what SF-HDQ score sharing might look like – SF-HDQ item responses; domain summary numeric scores, and visual bar graph)

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*18. What do you think about **seeing / sharing SF-HDQ scores immediately** after you complete / administer the questionnaire?*

Probes:

What about sharing the **domain scores** (6 domain scores) each for severity, presence, and episodic nature of disability?

What about seeing / sharing **specific SF-HDQ item responses for all 35 questions?**

What do you think would be the best **FORMAT** to share scores (e.g. numeric, bar graph, items, domain scores, etc)?
What might the PROCESS of sharing scores look like (e.g. discussion with patient and provider)?

*19. What might be some **reasons behind your preferences** to receive (share) / not receive (not share) domain scores or item responses?*

Probes:

What might be some **strengths of seeing / sharing scores**?
What might be some **concerns or limitations?**

*20. How might **patients use the SF-HDQ scores** (summary scores; individual item responses)?*

*21. How might **clinicians use them?** (aka – what would we do with the numbers?)*

*22. In summary, how might you **recommend SF-HDQ scores be shared with patients / used by clinicians?***

Episodic Nature of Disability

23. What do you think about the way in which the SF-HDQ asks about fluctuations in health related challenges?

Probes:

Can you think about what is a good day for you and what is a bad day for you – have you experienced both a good day and a bad day within the last week? Last 2 weeks? Last month?

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How often do your episodes occur? *Do you think that it is possible to capture the episodic nature of disability on this questionnaire? If so, please explain how this might occur? Timeline – 1 week episodes ups and downs? 2 weeks for the episodes? Should we ask about the last month for the episodic nature? How can we capture that in a questionnaire?*

Summary

Do you have anything else you wish to say about the questionnaire that you completed today in relation to the way it captures disability?

Do you have any other suggestions for how this questionnaire can better capture and describe disability experienced by adults living with HIV?

Thank you very much for participating in this interview today. Your responses will help to refine this future measure of disability.

For Adult Living with HIV Participants: If you feel that today's discussion has raised any difficult issues for you, or if you wish to pursue support or want to talk more about any of the topics discussed today, feel free to talk to the staff at _____ for more support.

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	9
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1-3
Occupation	3	What was their occupation at the time of the study?	1-3
Gender	4	Was the researcher male or female?	9
Experience and training	5	What experience or training did the researcher have?	31
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	9
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	9
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	9
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	7; 9-11
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	8
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	8
Sample size	12	How many participants were in the study?	11
Non-participation	13	How many people refused to participate or dropped out? Reasons?	NA
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	10-11
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	9
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	11-13
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	10; SuppFile2;
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	NA
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	10
Field notes	20	Were field notes made during and/or after the inter view or focus group?	10
Duration	21	What was the duration of the inter views or focus group?	11
Data saturation	22	Was data saturation discussed?	NA
Transcripts returned	23	Were transcripts returned to participants for comment and/or	NA

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	11
Description of the coding tree	25	Did authors provide a description of the coding tree?	11
Derivation of themes	26	Were themes identified in advance or derived from the data?	11
Software	27	What software, if applicable, was used to manage the data?	11
Participant checking	28	Did participants provide feedback on the findings?	NA
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	17-25
Data and findings consistent	30	Was there consistency between the data presented and the findings?	17-25
Clarity of major themes	31	Were major themes clearly presented in the findings?	17-25
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	17-25

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.