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)*

**Principal Investigator:**

<table>
<thead>
<tr>
<th>Title Dr.</th>
<th>Name: Kelly O’Brien</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department (or organization if not affiliated with U of T):</td>
<td>Department of Physical Therapy</td>
</tr>
<tr>
<td>Mailing address:</td>
<td>500 University Ave, Room 160, Toronto, ON, Canada, M5G 1V7</td>
</tr>
<tr>
<td>Phone:</td>
<td>416-978-0565</td>
</tr>
<tr>
<td>Institutional e-mail:</td>
<td><a href="mailto:kelly.obrien@utoronto.ca">kelly.obrien@utoronto.ca</a></td>
</tr>
</tbody>
</table>

**Co-Investigators:**

**Are co-investigators involved?** Yes ☒ No ☐

<table>
<thead>
<tr>
<th>Title Dr.</th>
<th>Name: Kristine Erlandson</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Colorado Denver</td>
<td></td>
</tr>
<tr>
<td>Institutional e-mail:</td>
<td><a href="mailto:kristine.erlandson@ucdenver.edu">kristine.erlandson@ucdenver.edu</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title Dr.</th>
<th>Name: Soo Chan Carusone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casey House</td>
<td></td>
</tr>
<tr>
<td>Institutional e-mail:</td>
<td><a href="mailto:schancarusone@caseyhouse.on.ca">schancarusone@caseyhouse.on.ca</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title Dr.</th>
<th>Name: Colm Bergin</th>
</tr>
</thead>
<tbody>
<tr>
<td>St. James’s Hospital</td>
<td></td>
</tr>
<tr>
<td>Institutional e-mail:</td>
<td><a href="mailto:cbergin@stjames.ie">cbergin@stjames.ie</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title Dr.</th>
<th>Name: Steve Hanna</th>
</tr>
</thead>
<tbody>
<tr>
<td>McMaster University</td>
<td></td>
</tr>
<tr>
<td>Institutional e-mail:</td>
<td><a href="mailto:hannahs@mcmaster.ca">hannahs@mcmaster.ca</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title Dr.</th>
<th>Name: Richard Harding</th>
</tr>
</thead>
<tbody>
<tr>
<td>King’s College London, Cicely Saunders Institute</td>
<td></td>
</tr>
<tr>
<td>Institutional e-mail:</td>
<td><a href="mailto:Richard.harding@kcl.ac.uk">Richard.harding@kcl.ac.uk</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title Dr.</th>
<th>Name: Aileen Davis</th>
</tr>
</thead>
<tbody>
<tr>
<td>University Health Network, Toronto Western Hospital</td>
<td></td>
</tr>
<tr>
<td>Institutional e-mail:</td>
<td><a href="mailto:adavis@uhnresearch.ca">adavis@uhnresearch.ca</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title Dr.</th>
<th>Name: Patty Solomon</th>
</tr>
</thead>
<tbody>
<tr>
<td>McMaster University, School of Rehabilitation Science</td>
<td></td>
</tr>
<tr>
<td>Institutional e-mail:</td>
<td><a href="mailto:solomon@mcmaster.ca">solomon@mcmaster.ca</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title Dr.</th>
<th>Name: Ahmed Bayoumi</th>
</tr>
</thead>
<tbody>
<tr>
<td>St. Michael’s Hospital</td>
<td></td>
</tr>
<tr>
<td>Institutional e-mail:</td>
<td><a href="mailto:ahmed.bayoumi@utoronto.ca">ahmed.bayoumi@utoronto.ca</a></td>
</tr>
</tbody>
</table>

**Location:** 1) University of Toronto, Casey House, Toronto Ontario; 2) University of Colorado Infectious Diseases Group Practice Clinic, University of Colorado Denver, United States, 3) St James’s Hospital Department of GU Medicine and Infectious Diseases (GUIDE Clinic), HRB Clinical Research Facility (CRF) at St James’s Hospital and Trinity College Dublin. This study will require REB approval at each of the 3 sites.

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 (UofI 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.
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

Data sharing and communication among investigators. The ‘SF-HDQ Steering Committee’ (Drs. O’Brien, Erlandson and site leaders, 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.

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

**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.

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

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.

Date Last Revised: February 13, 2022
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

**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 (e.g. 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).

**Sensitivity 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.

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

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 J) 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.

Date Last Revised: February 13, 2022
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

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.

Date Last Revised: February 13, 2022
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 (e.g. 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 Erlanson, 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...
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

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.

Date Last Revised: February 13, 2022

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
Supplemental File 1
Assessing the Sensitivity 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

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 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.

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

**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.

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

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 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. 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