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Development of a core patient-reported outcome set for use in HIV care at the individual patient level in Montreal: protocol for a two-phased multimethod project

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ABSTRACT

Introduction There is international interest in using patient-reported outcome measures in HIV care to improve the well-being of people with HIV, but the prioritisation of specific outcomes and measures remains unclear. This project's objective is to engage both people with HIV and healthcare, social and community service providers to develop a French and English-language core set of patient-reported outcomes and measures for use in HIV care at the patient level in Montreal (Canada).

Methods and analysis This multimethod project will follow guidance from the Core Outcome Measures in Effectiveness Trials Initiative and involve two phases. Phase 1 will see the selection of the core set of outcomes (ie, the health concepts to target) and include a rapid scoping review to inform a Delphi study with a panel of 50 people with HIV and providers in Montreal. It will end with a multidisciplinary consensus meeting to make final decisions on the outcomes. Phase 2 will be devoted to choosing the measures to assess the selected outcomes. It will include a systematic search for instruments, an appraisal of the quality and feasibility of the identified instruments and a consensus meeting for the final selection.

Ethics and dissemination Research ethics board (REB) approval was obtained on 9 December 2024, from the institutional REB of the Research Institute of the McGill University Health Centre (reference number: 2024-9695). Findings will primarily be disseminated to (1) healthcare and social service providers through academic rounds and a provincial continuing education programme for HIV clinicians; (2) to people with HIV through partner community organisations and (3) a range of stakeholders at local, national and international conferences and through peer-reviewed publications.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This multimethod project will develop a patient-reported outcome measure-specific core outcome set for individual HIV patient care in Montreal, Quebec.
⇒ It follows guidance for core outcome set development.
⇒ It involves a formal rapid scoping review and continuous engagement of patients and other stakeholders with committees and consensus-based approaches.
⇒ It is limited by the exclusion of some people with HIV in vulnerable situations, including those who have insufficient knowledge of English or French.

INTRODUCTION

The utility of patient-reported outcome measures for HIV care

There is international interest in the integration of patient-reported outcome measures (PROMs) into HIV care towards improving the long-term well-being of people with HIV, with some emphasising the evaluation of health-related quality of life and the identification of symptoms or other potential problems (eg, social issues and undiagnosed comorbidities).[1] PROMs are tools that capture direct, unfiltered patient reports of their perspective on their health (eg, questionnaires).[2] In HIV clinical practice, PROM use is found to be highly acceptable and valuable to both patients and providers and evidence supports such benefits as improved patient–provider communication, priority setting during consultations, and detection and monitoring of health issues (eg, symptoms and health behaviours).[3]

Limited but varied PROM use in HIV care

PROM use in routine HIV clinical care is not standard practice. For instance, in Canada, where the present project is based, we are aware of few published accounts, specifically, those of the PROgress study involving a Toronto site[4 5] and our team's pilot study in Montreal.[6] Internationally, across initiatives,

the targeted outcomes can vary. For instance, among the numerous PROs captured by the QuaLiv (France),[7] PROgress (USA, Canada),[5] Positive Outcomes (UK)[8] and AmbuFlex PRO system projects (Denmark),[9] the only common outcomes seem to be drug use, alcohol use and symptoms of depression. Hence, local considerations and needs may drive which PROs are emphasised and be crucial to their uptake in these HIV care settings. However, agreeing on which patient-reported outcomes (ie, health aspects) and measures (ie, instruments) are essential could help expedite and simplify PROM integration into HIV care.

One solution: a core patient-reported outcome set for individual HIV patient care

A core outcome set (COS) is an agreed on, standardised collection of outcomes for a particular health condition, treatment or intervention that should minimally be measured and reported, typically in clinical trials.[10] Using a COS designed for clinical trials in a given area can facilitate the synthesis, application, transparency, relevance and utility of results obtained.[10] However, COSs are also developed for clinical practice.[10 11] They can be used for routine monitoring of individual patients,[12] to inform medical decision-making, to drive quality improvement and to support patient-focused care.[11]

The development of COS is embryonic in HIV relative to other health conditions (eg, rheumatic diseases and[13] cancer[14]). To our knowledge, only one COS applicable to high-income countries for use in adult HIV care has been published, the HIV360.[15] Designed for worldwide application,[15] it includes a mix of patient-reported, clinician-reported and administratively reported outcomes. Its PROs are health-related quality of life, depression and sexual health (function and engagement with testing for sexually transmitted infections) and are all core outcomes (no supplementary PROs are mentioned). However, the primary aim of this COS appears to be to generate data for aggregation and/or research, notably, to inform quality improvement, HIV care evaluation, benchmarking and the identification of best practices.[15] Hence, its choice of core outcomes (eg, a PROM of sexual function as a 'proxy for sexual health') and 'risk adjustment variables' (eg, drug use and smoking) seems consistent with this.[15]

We are aware of no PRO-specific COS for HIV that aims to prioritise and standardise these outcomes for purposes of sharing this information with a patient's provider, as a part of their routine clinical care. The selection of patient-reported outcomes and instruments can differ based on whether the purpose is situated at the micro (individual), meso (organisation) or macro (system) levels of use.[16] Similarly, a core set's composition can be expected to vary based on its focus,[17] whether healthcare quality monitoring, trial reporting or in our case, the screening and monitoring of individual patients. Hence, a distinct COS seems justified. Furthermore, it was essential for us to identify peripheral PROs/PROMs which may offer HIV care environments more flexibility to adapt or expand PROM use (eg, in line with patient needs, available services) and to report how stakeholder group differences were addressed in COS development.

With PROs, differences between the perspectives of patients and healthcare providers may be especially important to consider. Research investigating preferences for PROs in HIV care has shown divergences between these groups. In one study, patients (n=206) and providers (n=17) from five US cities were surveyed to identify their priority PRO domains for routine HIV care visits.[18] While both agreed on the importance of depression, medication adherence, HIV treatment/symptoms and sexual risk behaviour, the top-eight PROs of patients included social issues (ie, HIV stigma and social support), while that of providers emphasised behavioural issues (ie, substance abuse, alcohol abuse and tobacco use). Furthermore, in Montreal (Quebec),[19] a needs-assessment survey of people with HIV (n=114) and providers (n=31) indicates that, across groups, interest was greatest for patient-reported measures for use in care on the experience of healthcare (people with HIV: 96%, providers: 97%), HIV self-management (people with HIV: 92%, providers: 97%) and the experience of antiretroviral treatment (people with HIV: 90%, providers: 90%). However, a greater proportion of providers than people with HIV deemed 10 of the 12 outcome categories of interest, with the greatest divergences seen in sexual/reproductive health (people with HIV: 73%, providers: 94%), disability (people with HIV: 62%, providers: 81%) and psychological challenges (people with HIV: 81%, providers: 94%). The one category more highly endorsed by patients was quality of life (people with HIV: 89%, providers: 77%), the second lowest rated category by providers. While the representativeness of the study samples can be questioned, this research nevertheless argues for a transparent accounting of differences in stakeholder perspectives and how they are integrated into PRO selection for HIV care. Indeed, some have questioned to what extent PRO rankings in some standard sets represent the patient perspective.[20] This is critical, as PRO sets are meant to capture outcomes that are most relevant to patients.[10]

Necessarily, creating a COS involves potentially difficult decisions about which outcomes to include and exclude. Stakeholder valuation of PROs may be influenced by a wide variety of factors, including the preferred number of outcomes, concerns for patient/provider burden, as well as perceived healthcare setting resources for administration and addressing flagged problems.[21] On the issue of COS breadth, an efficient PRO-based COS for care could arguably represent numerous domains with relatively few items and demands on patients or providers. This is illustrated well by the PROgress Study 'Build your own PRO assessment' tool.[22] Furthermore, some have argued for using a collection of single-item patient-reported measures in clinical care,[23] as opposed to multi-item measures, perhaps exemplified by the Positive Outcomes PROM, with its selection of over 20 individually actionable items for HIV care.[24] It thus seems relevant to consider

stakeholder views on pragmatic considerations such as these in this COS' development as well as efficiency.

For these reasons, our team aims to (1) create a core set specifically of PROs for use in HIV care at the individual patient level, that offers peripheral PROs for customisation; (2) limit its scope to the city of Montreal (Quebec), for greater specificity and flexibility (eg, in the choice of PROs/PROMs); (3) transparently document and account for differences in HIV stakeholder group priorities in PRO selection and how they are addressed and (4) consider efficiency while taking account of stakeholder preferences for the COS and its implementation (eg, preferred number of outcomes, instrument items) within COS decision-making.

Scope of the proposed core outcome set

The proposed COS will be developed for routine use in HIV clinical practice settings in the metropolitan area of Montreal (Quebec) with adults living with HIV (ie, 18 years of age and older). The COS will be limited to patient-reported outcomes, including those PROs and aspects of patient experience that are deemed by both HIV care/service providers and people with HIV to be important to address in HIV care. The COS will mainly be for use at the individual patient level to support clinical patient management.[16] Its primary function will be to help screen for and monitor the chosen outcomes. The COS' possible use at the aggregate level to support other goals will be discussed with stakeholders (eg, performance evaluation, healthcare delivery planning, quality improvement and patient-oriented research).[16]

The COS will differentiate between core (essential) and peripheral outcomes. It will take account of the diversity of patients seen in the urban centre of Montreal (eg, migrants, women, men who have sex with men, ageing and multimorbid patients, transgendered persons, injection drug users) and the medical treatments received via HIV care (eg, antiretroviral therapy). The stakeholders of this COS within the area will include people with HIV, HIV-specialised healthcare, social and community service providers, as well as HIV care centre administrators and decision-makers.

The pursuit of a COS specific to Montreal does not exclude its adaptation or application to other localities. For instance, in a subsequent step, we expect to initiate a parallel project in Paris with the goal of a common or overlapping COS. This is justifiable in terms of similarities between the two cities in general healthcare delivery (such that there is a mutual recognition agreement in Quebec and France of the professional qualifications of physicians),[25] the HIV populations treated, the HIV care provided and the cities' official language (ie, French). Furthermore, in both Montreal and Paris, patients and providers have reported interest in using PROMs in HIV care[19 26] and pilot projects are planned to implement their electronic administration, one of which is currently underway in Montreal.[5]

Nevertheless, barriers to implementing the proposed COS into routine care include well-documented challenges to the clinical uptake of PROMs administration, such as concerns about its value, purpose, complexity and detrimental impacts on workload, workflow and the quality of patient care, including the patient–provider relationship.[27] Several facilitators of implementation will be built into our methods, including necessarily choosing PROs and corresponding measures which are perceived as relevant and appropriate, as well as involving stakeholders, and considering their needs and resources.[28]

METHODS AND ANALYSIS

This evidence-based COS-development project will be conducted in two phases, following the Core Outcome Measures in Effectiveness Trials (COMET) Initiative handbook,[10] the Core Outcome Set-STAndards for Development recommendations[29] and the Core Outcome Set-STAndardised Protocol Items Statement[30] (figure 1). The project began with early protocol and funding proposal development in the spring of 2022 and was formally registered in the COMET initiative open-access public repository of COS projects on 22 September 2023 (https://comet-initiative.org/Studies/Details/2798). The project is still in phase 1. Its projected end date is December 2025.

Phase 1: select the outcomes

The objective of phase 1 is to decide what PROs to measure. Phase 1 has two steps. Step 1 is complete. Its goal was to produce a list of outcomes, organised by domain, for consideration. To do so, several empirical sources of PROs were synthesised with content analysis. The main empirical material considered was that of a now published rapid scoping review specially conducted by our team as a part of step 1.[31] It was designed drawing on recommendations for both rapid[32] and scoping reviews[33 34] and registered on the Open Science Framework on 27 April 2022 (https://osf.io/fupzv). Based on published work from 2005, it identified initiatives to administer PROMs for individual HIV patient care. Four databases were searched on 4 May 2022 (Medline, Embase, the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and PsychINFO), with guidance from a university librarian. All records were examined by an experienced reviewer, with a subset (at least 10%) screened by another. From the retained documents, verbatim information was extracted on (1) the PROs used in HIV care (eg, the health issues measured by patient report); (2) their measurement (eg, the implemented instruments) and (3) details of their administration and use in HIV care. Data extraction and synthetisation were done by a single reviewer with at least 10% of the work verified by another. This review identified over 60 distinct outcomes, within 14 domains.[31] The list of outcomes produced was supplemented by a relevant generic PRO taxonomy (the adult self-reported health framework of the Patient-Reported Outcomes Measurement Information System)[35] and an American

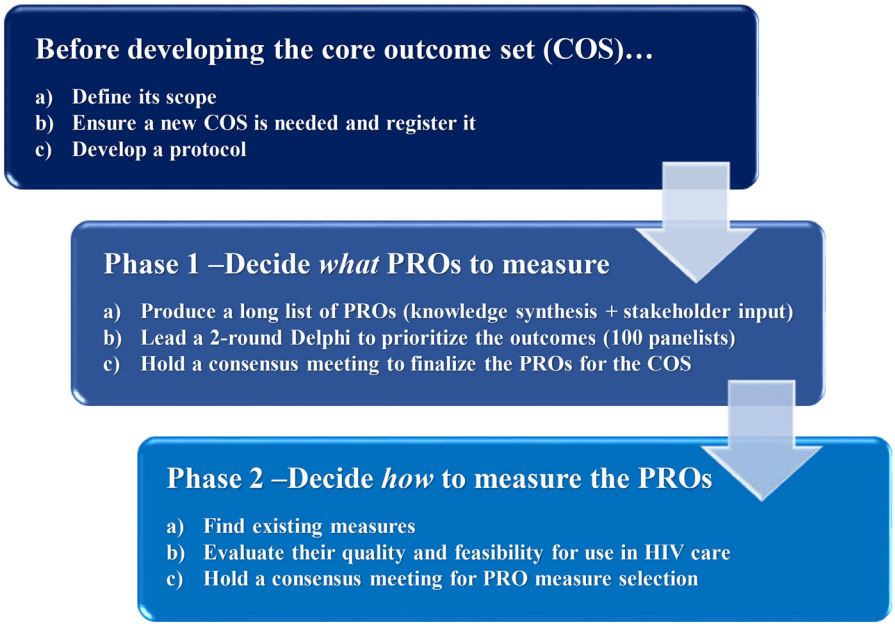

Figure 1 Core patient-reported outcome set development project design. COS, core outcome set; PROs, patient-reported outcomes.

study on outcome preferences among people with HIV and providers for HIV care.[18] The prefinal synthesis of all these sources was presented for feedback to people with HIV to help ensure that the taxonomy of PROs used (ie, the labels of outcomes and their corresponding domains) was not only comprehensive but comprehensible to end-users.

With the finalised list of PROs (of step 1), we will consult stakeholders in step 2 with a modified Delphi to agree on essential and peripheral outcomes for the PRO set. The Delphi will have two distinct panels for comparison (one of people with HIV and one of providers), as differences are expected. Panellists will be recruited with a variety of methods, including flyers, email invitations and word-of-mouth, from participating private and public HIV healthcare settings in Montreal. The Delphi will be characterised by two rounds of online survey questionnaires, administered using Research Electronic Data Capture (REDCap), a secure, web-based software platform designed to support data collection for research studies.[36] Panel members will be purposefully sampled to attain at least 25 participants per major stakeholder group with attention to diversity. The minimum goal is 50 panellists. To participate, people with HIV must be engaged in HIV care in the Montreal area, aged 18 or older, and able to complete the Delphi surveys in either English or French. No specific quota sampling for diversity or vulnerability factors[37] will be applied beyond the goal of at least 30% inclusion of cis-gender women on the panel. Despite this, significant representation of migrant people with HIV is expected, consistent with the growing proportion of new infections in Quebec among people from countries where HIV is endemic[38] and one of the recruitment site's being Immigration Canada's primary referral centre for people with HIV in Montreal (ie, the Chronic Viral Illness Service of the McGill University Health Centre). Given the inherent demands (eg, linguistic, cognitive) of participating in the Delphi and our staff's limited resources to accommodate panel members in highly vulnerable situations, for the present purposes, we will rely on the perspective of providers (eg, healthcare professionals, community organisation staff) to represent those in the most vulnerable situations, which will be a limitation of this project. Providers will require at least 5 years of experience treating or serving people with HIV. To maximise response rates, panellists will be compensated after each round.

At both rounds, panellists will be asked to rate the level of importance of outcomes on a 3-point scale. While the most common response format used among patient participants in Delphi surveys to develop COS are 9-point scales,[39 40] during cognitive testing of the Delphi round 1 questionnaire with a 9-point scale, both interviewed people with HIV wished for a scale with fewer response options (ie, 3 or 5). This coincides with the results of Lange *et al*[41] who evaluated patient preferences for different scales in a Delphi study; the largest proportions of patients preferred the 5-point and 3-point scales (36% and 23%, respectively); the fewest preferred the 9-point scale (16%), leaving 24% with no preference among the scales presented. In Delphi studies, the choice of response scale and thresholds for consensus can dramatically impact results.[40 41] While in COS development, a 3-point scale relative to a 9-point scale may lead to the retention of fewer outcomes,[40] a 3-point scale has shown similar reliability to 5-point and 9-point scales and can offer a pragmatic advantage, when its interpretation is straightforward.[41] Hence, our team opted for use of a 3-point scale, similar to that of De Meyer *et al*,[40] where 1='not important enough'; 2='important but not critical'

and 3='critical, should be included' in the COS. The results of both Delphi rounds will be analysed for patterns of missing data. Their presence and any methods used to address them will be reported.

At round 1, panellists will also be asked to rate each outcome domain's level of importance with the 3-point response scale and to identify their top-five priority domains. With open questions, panellists will be able to propose additional outcomes. If three or more panellists suggest an outcome that was not previously included, it will be added for consideration in round 2. Additional questions will ask about preferences as to the number of outcomes in the COS and pragmatic aspects of PRO assessment (eg, format, administration, length). Panellists will also rate their agreement with several common expectations of PRO assessments on a 5-point scale, from (1) 'strongly disagree' to (5) 'strongly agree'.

With the round 1 results, the following consensus criteria will be applied to outcomes measured on the 3-point scale. Given recommendations to use a combination of such criteria,[40] an outcome will be considered for inclusion as core if (a) at least 70% of panellists give it a score of 3 and (b) 15% or fewer rate it '1', in both stakeholder groups. Likewise, if at least 70% of each group rates an outcome '1' and no more than 15%, as '3', then the outcome will be considered for exclusion. All outcomes not meeting these criteria will be reevaluated at round 2.

Panellists will receive a report with summary statistics of the round 1 results of each main stakeholder group (people with HIV, providers) prior to the round 2 questionnaire. At round 2, they will rate the outcomes that did not reach consensus, as defined. They will also indicate their interest in participating in live consensus meetings to decide on the final set of outcomes and select related instruments. To limit participant attrition at round 2, REDCap will be programmed to send automatic reminders at 10-day intervals to non-responders (for 20 days).

With the round 2 data, additional consensus criteria to that for round 1 will be applied: Outcomes that meet the combined 70% (rated 3) and 15% (rated 1) thresholds in only one stakeholder group will be discussed at the consensus meeting. If more than 50% of both stakeholder groups rate any of the other outcomes '3', then they too will be discussed at the consensus meeting. Outcomes discussed at the consensus meeting will be considered for inclusion in the core set (with those identified at round 1) or as secondary outcomes or alternatively for elimination. All remaining outcomes will be excluded, barring unforeseen problems such as dramatic differences in stakeholder group ratings, inequitable representation of group interests, and/or concerning inconsistencies of retained outcomes with other data collected (eg, on preferences for the number of outcomes in the set). Should exceptions be made for any outcome, these will be transparently reported. Panellist attrition from round 1 to round 2 will be addressed by comparing the characteristics of those who dropped out to those who remained (eg, sociodemographics), for patterns and reporting the results.

All statistical analyses for the Delphi will be performed with R.[42] Descriptive statistics, such as proportions, means and SD, will be generated (eg, on panellist characteristics, all outcomes considered and threshold attainment). The scores of major groups will be compared (eg, people with HIV with providers, women with men, Francophones with Anglophones, Immigrant with native-born respondents) using appropriate statistics. This will help ensure the interests of specific groups are considered in the selection of the COS. As done for our team's previous Delphi,[43] we will perform proportion comparisons with a Pearson's χ^2 test for 2×2 contingency tables, to assess the null hypothesis of no difference between two proportions. If over 20% of the cells of a contingency table have expected frequencies less than 5, a Fisher's exact test will be used. Notably, comparisons will consider the proportion of groups meeting (and not meeting) consensus criteria for outcome inclusion in the core set. For continuous variables (eg, age in years), Student's t-tests will be used to test the null hypothesis that the observed means are equal between subgroups (eg, participants of both rounds vs those who only participated in round 1). The p values of the conducted tests will be reported, with a significance level of 5%, acknowledging that this may encompass borderline results.

Following the Delphi, as suggested, the results will be presented during a half day consensus meeting with members of the steering committee and other invited stakeholders to discuss the proposed core set of PROs. A target of 10–15 participants is set. This meeting will be led by experienced facilitators. They will promote equitable participation by explaining the goal of hearing from everyone and the value of diverse perspectives and seeking to guide the meeting accordingly.[44] Following Munblit *et al*,[45] the pros and cons of each outcome of uncertain status will be discussed systematically and then members will vote in real time on its final classification. Voting will further support equitable participation by ensuring all participants are heard.[44] As proposed by De Meyer *et al* for final decisions,[40] we will use the previously described 3-point rating scale. At least 70% of all members must rate the outcome as critical (3) for inclusion as core. If not meeting this criterion, it must be rated by 70% of members as at least a 2 (important), to be considered a secondary outcome. All other outcomes will be excluded.

Phase 2: select the measures

Measurement selection during phase 2 for essential outcomes will follow the conjoint guidance of the COMET initiative and the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) in this regard.[46] This will mainly involve finding existing generic or HIV-specific measures, evaluating their quality and feasibility, respecting minimum quality criteria, selecting one measure per outcome and using consensus procedures with stakeholders to agree

on the final selection. We will begin by leading a targeted search for candidate PROMs for each essential outcome, with independent literature reviews in Medline (Ovid), using the PROM search filter designed by COSMIN.[47] We will also consider instruments identified by past reviews of PROMs administered to people with HIV[31 48 49] and through COSMIN's database of systematic reviews of outcome measurement instruments.[50] The psychometric properties of candidate instruments will be collected and considered, prioritising content validity, followed by internal structure, and finally, other measurement properties, in accordance with COMET-COSMIN guidance.[46] These will then be weighed against feasibility considerations, including those identified by the phase 1 Delphi (eg, respondent preferences for the number of questions in the core set, patient completion time, time needed for healthcare professionals to review the results). Among candidate instruments, we will also search the literature for evidence of their implementation and effectiveness in clinical practice, for added consideration. When this is complete, like for phase 1, a consensus meeting with a target sample of up to 15 stakeholders will conclude phase 2. During this meeting, the information collected and synthesised on each candidate instrument, per essential outcome, will be presented and discussed. Respondents will then vote on their preferred instrument for each outcome. Our goal is at least 70% endorsement of one instrument per outcome. This meeting will also include a discussion of strategies to encourage uptake of the COS.

Patient and public involvement

Patient Advisory Committee

An experienced Montreal-based patient advisory committee[51] composed of diverse people with HIV will participate periodically throughout this project to provide recommendations and the patient perspective, notably on the content to be presented in the Delphi surveys and during consensus meetings to help verify relevance, comprehensiveness and comprehensibility to people with HIV. The committee was created to include representation of the main epidemiological groups affected by HIV in the city. A goal of at least four people with HIV for advisory committee involvement is set. In this project, as mentioned, patients will also participate in the Delphi as well as the consensus meetings, further contributing to decision-making. All patients engaged in this project will be compensated.

Study management

The steering committee

A multidisciplinary steering committee will guide this project and convene as needed for decision-making. Its membership will include the expertise of people with HIV and of those knowledgeable in PROs and their measurement, stakeholder engagement, HIV research coordination, HIV-specialised healthcare and social service delivery and HIV centre administration. Some members of the steering committee will be part of the study management group which is responsible for the daily management of the project and will meet more frequently.

ETHICS AND DISSEMINATION

This project received conditional approval on 9 August 2023 and final approval on 9 December 2024, from a Research Ethics Board of the Research Institute of the McGill University Health Centre, Montreal, Quebec, Canada (reference #2024-9695).

Informed consent will be collected online from all potential panellists prior to beginning the first Delphi survey online and the project will be conducted in accordance with the applicable Health Canada regulations, the International Conference on Harmonisation guidelines on current Good Clinical Practice and the Declaration of Helsinki.

For Delphi panellists who wish to participate in the consensus meetings, there will be a separate informed consent process.

All personal data collected from participants will remain confidential, to the extent possible by applicable laws and regulations.

The findings of this project will be disseminated when key results from each phase are available. In phase 2, knowledge translation will mainly concern the final core outcome set including instrument selection through traditional channels such as national and international conferences and peer-reviewed journals. More locally, we will seek to transfer the knowledge gained with and for people with HIV in collaboration with community-based organisations with whom we have existing partnerships to ensure the content delivered is adapted to the audience and reaches people with HIV. Involvement of engaged people with HIV in the presentation of results will be compensated yet entirely voluntary and respectful of disclosure concerns. Knowledge translation targeted to healthcare professionals will occur through academic rounds at local HIV care services and a Quebec continuing education programme for HIV clinicians.

The development of this core outcome set, which will be conjointly created in both English and French, could facilitate the integration of PROMs in HIV care in Montreal, with potential improvements in care quality and the well-being of thousands of people with HIV. It is particularly relevant considering recent recommendations by the European AIDS Clinical Society to administer PROMs annually to all people with HIV in clinical care.[52] As an indication of possible initial reach and impact, in the province of Quebec, rates of HIV diagnoses are higher than the national average,[53] with most new cases concentrated in Montreal.[54] Indeed, over 6300 people with HIV are treated at four major HIV care centres in Montreal (L'Actuel Medical Clinic, Quartier Latin Urban Medical Clinic, Clinique d'infectiologie virale chronique of the University of Montreal Health Centre (CHUM) and the Chronic Viral Illness Service of the McGill University Health Centre).[55]

Our COS could also apply to similar care settings with possible further benefits. The uptake of this COS offers opportunities for both patient-oriented HIV care and research. Indeed, PROs are a critical component of patient-centred outcomes research[2] which aims to evaluate questions and outcomes that are relevant to patients and their caregivers,[56] towards more informed healthcare decisions. Secondarily, at the aggregate level and possibly combined with clinical data, the data generated by implementing the COS in HIV care, could enable 'real-world' treatment comparisons and care quality evaluations.[2]

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