Statistical Analysis Plan

Official Title: Effect of a Navigator Program on Post-Hospital Outcomes for Homeless Adults: A Pragmatic Randomized Controlled Trial

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1 Study Design and Research Questions

1.1 Summary of Design

The Navigator study is a pragmatic randomized controlled trial (RCT) conducted at an urban academic teaching hospital (St. Michael's Hospital) and an urban community teaching hospital (St. Joseph's Health Centre) in Toronto, Canada. Recruitment began in October 2021 and total recruitment is estimated to be completed by December 2024.

Eligible patients must be 18 years of age or older, be admitted to any medical or surgical service (excluding psychiatry and obstetrics), and be identified as experiencing homelessness (as per the Canadian definition of homelessness) at the time of admission or anytime during the hospital admission. Patients will not be eligible if they are unable to provide informed consent or were connected with a Homeless Outreach Counsellor (HOC) prior to the initiation of the RCT and have received services from the HOC within 90 days preceding their current admission

Participants are randomized by a third-party randomization service (randomize.net). This service will assign participants to either the intervention or the usual care arm using permuted-block randomization, with a 1:1 allocation ratio and random permuted block sizes of 6 or 8. This process will maintain balanced group sizes between the intervention and usual care arms at intermediate points in the recruitment process and minimize the possibility of the research team predicting study allocation.

Participants randomized to the intervention arm are assigned to a HOC, who connects with participants as early as possible during the admission and provides support for 90 days after hospital discharge (or beyond 90 days for certain patients, if the HOC deems this to be necessary and/or appropriate). HOCs activities include (1) making connections and referrals to community-based providers, (2) supporting and advocating for patients during the hospital stay and discharge process, (3) supporting patients with health-related matters during the post-discharge period, (4) supporting patients with social-related matters during the post-discharge period, and (5) transferring patient-related information to other healthcare and community-based providers.

Participants in the usual care arm are discharged without support from a HOC. However, all participants still receive standard supports from Care Transition Facilitators (CTFs) and/or social workers. Although CTFs and social workers help patients during their hospital stay to arrange discharge plans and make follow-up arrangements, they do not typically work with patients after hospital discharge.

It is not possible to blind participants, HOCs, or healthcare teams given the active and collaborative nature of the intervention. However, data collectors and data analysts are blinded to the allocation of participants. The research team member who performs study allocation for a participant will not be involved in the 30-day follow-up interview for that participant.

1.2 Primary Research Question

Among adults experiencing homelessness admitted to any medical or surgical service (excluding psychiatry and obstetrics), does the Navigator Program increase follow-up visit rates with a primary care provider [PCP] (physician or nurse practitioner) within 14 days of hospital discharge, as compared with usual care?

1.3 Secondary Research Questions

Among adults experiencing homelessness admitted to any medical or surgical service (excluding psychiatry and obstetrics), what are the effects of the Navigator Program on the number of emergency department visits and the composite of hospital re-admission or all-cause mortality following hospital discharge, as compared with usual care?

1.4 Exploratory Research Questions

Among adults experiencing homelessness admitted to any medical or surgical service (excluding psychiatry and obstetrics), what are the effects of the Navigator Program on their care transition experience, number of days in hospital post-discharge, time to re-admission or death, difficulties meeting subsistence needs, visit rates to non-PCP providers, medication adherence, rates of connection to community-based case managers, rates of leaving against medical advice, and overall health status and quality of life following hospital discharge, as compared with usual care?

2 Outcomes

2.1 Primary Outcome

The primary outcome is follow-up with a PCP (physician or nurse practitioner) within 14 days of hospital discharge. This outcome was chosen given the unique and substantial barriers to primary care access faced by the homeless population and the fact that timely access to primary care after hospitalization is associated with better outcomes. In-person visits, virtual encounters, and phone calls will all be considered. The primary outcome will be ascertained using three data sources: a) through participant self-report at the 30-day interview; b) phone calls to PCP offices, and c) verification in the OHIP and Community Health Center Databases at ICES. **PCP follow-up documented in any of the three data sources will be considered sufficient to meet the primary outcome criterion.** Definitions, self-reported measures, and scoring algorithms of the primary outcome and all other outcomes are described in Appendices 1 and 2.

2.2 Secondary Outcomes

The secondary outcomes are listed below, collected using administrative databases at ICES. For participants who cannot be linked to databases at ICES, administrative data will be obtained from St. Michael's Hospital and St. Joseph's Health Centre.

1. Number of emergency department visits within 30 days post-discharge
2. Number of emergency department visits within 90 days post-discharge
3. Composite measure of any re-admission or all cause-mortality within 30 days post-discharge
4. Composite measure of any re-admission or all cause-mortality within 90 days post-discharge

2.3 Exploratory Outcomes

Exploratory outcomes will be collected using hospital discharge summaries, participant self-report at the 30-day interview, and ICES or other administrative databases

2.3.1 Hospital Discharge Summaries

1. Participant leaving against medical advice (during the initial hospitalization during which they are randomized)

2.3.2 Participant's Self-Report at 30-Day Interview

1. Self-reported quality of care transition (3-item Care Transitions Measure, CTM-3) after hospital discharge at the time of the 30-day interview
2. Self-reported change in difficulties meeting subsistence needs (Competing Priorities measure from RAND Course of Homelessness Study) at the time of the 30-day interview relative to baseline
3. For participants who did not previously report contact with a case manager in the 30 days prior to the baseline interview, connection to a case manager in the community at the time of the 30-day interview
4. Medication adherence (eight-item Morisky Medication Adherence Scale, MMAS-8) at the time of the 30-day interview
5. Change in health status (EQ-5D-3L; European Quality of Life – Five Dimension - Three Levels) at the time of the 30-day interview relative to baseline
6. Change in quality of life (EQ-5DVisual Analogue Scale) at the time of the 30-day interview relative to baseline

2.3.3 ICES or Other Administrative Databases

1. Total number of days spent in hospital(s) after index admission within 90 days post-discharge
2. Total number of days spent in hospital(s) after index admission within 180 days post-discharge
3. Time in days to all-cause re-admission or mortality after discharge (up to 180 days post-discharge)
4. Attendance of any non-PCP healthcare appointment made at the time of discharge (up to 180 days post-discharge)

3 Analysis Sets

3.1 Intention-to-treat sample

All analyses will follow the intention-to-treat principle. All randomized participants who are discharged alive contribute outcome data to the analysis based on their randomized group, regardless of compliance.

The primary outcome can only occur in patients who are discharged alive. Thus, participants will be excluded from the analysis if:

(a) they die during the initial hospitalization during which they are randomized, or
(b) they are never discharged from hospital and remain hospitalized 30 days after the final study participant is randomized

4 Statistical Methods

4.1 Sample Size Justification

We assumed that the 14-day PCP follow-up rates after hospital discharge among people experiencing homelessness receiving usual care would be approximately 2/3 that of low-SES patients in a study conducted at two urban academic hospitals (=2/3 of 48%=32%). Sample sizes of 256 participants per study arm achieve 80% power to detect an absolute difference between the two arms of 12%, equivalent to a 37.5% increase in relative rate of follow-up with a PCP within 14 days of discharge. Given an estimated 20% attrition rate based on past studies in this population and setting, a total of 640 participants (320 per arm) were recruited for this study. Additional participants will be recruited and randomized to replace previously randomized participants who die during their hospitalization or who are never discharged from the hospital, since they will contribute no post-baseline data, including the primary outcome. The number of additional participants will be consistent with maintaining group balance using permuted block-randomization (i.e., 1 or more blocks of size 6 or 8, depending on number of participants required).

4.2 Interim Analyses

No interim analyses will be performed

4.3 Statistical analyses

All analyses will follow the intention-to-treat principle.

The detailed statistical analysis plan for using ICES administrative data will be developed on a separate document per institutional requirements, but the analyses are summarized in this document as well.

4.3.1 Descriptive Statistics

Baseline participant characteristics by study arm will be summarized with counts and proportions for binary and categorical variables, and means and standard deviations, and medians and interquartile ranges, where appropriate. No statistical testing of baseline differences between the study arms will be performed, as recommended in the CONSORT statement and other publications [Moher, Senn, Pocock].

Descriptive statistics will also characterize the distribution of outcomes according to baseline characteristics by intervention arm.

We will also construct graphs to explore relationships and estimate correlations and associations between participant baseline characteristics and outcomes, overall and by subgroups.

To evaluate the magnitude of missing data from the baseline and 30-day interviews, the proportion of missing data for all outcomes and baseline variables by intervention arm will be also calculated.

4.3.2 Primary Outcome Analyses

The primary analysis of the primary outcome will be performed using the $\chi 2$ test to compare two independent proportions of 14-day PCP follow-up. The difference in proportions (risk difference) with 95% confidence interval (CI) will be estimated using the Wald method.

Secondary analyses of the primary outcome include estimating unadjusted effects of the intervention. The unadjusted risk ratio with 95% confidence interval (CI) will be estimated using the modified Poisson regression model including only the intervention arm indicator. The unadjusted odds ratio with 95% CI will be estimated from the logistic regression model including only the intervention arm indicator.

4.3.3 Secondary and Exploratory Outcomes Analyses

For secondary and exploratory outcomes, Table 1 and Table 2 display the statistical model and intervention effects according to outcome type (binary, continuous, time to event).

For binary outcomes, logistic regression models will be used to estimate odds ratios with 95% CIs. For count outcomes, Poisson or negative binomial regression models (if overdispersion is suggested by the data) will be used to estimate rate ratios with 95% CIs.

For continuous outcomes, linear (or another more outcome-specific distribution) regression models will be built.

For change in continuous outcomes from baseline to 30-days post-discharge, we will consider analysis of covariance (ANCOVA), adjusting for the baseline outcome value.

For time in days to re-admission or all-cause mortality after discharge, a survival analysis will be performed. Cumulative event rates will be calculated with the Kaplan-Meier method, with event or censoring times calculated from the date of discharge. Differences in Kaplan-Meier survival curves between the study arms will be assessed using the log-rank test. The Cox proportional hazards model will estimate the hazard ratio with 95% CI.

Multiple testing correction for p-values will be applied in the analyses of secondary outcomes using the Holm method.

For exploratory outcomes, in addition to 95 % CIs, we will also report p-values, since we agree with Pocock et al. (2021) that such p-values, although mostly characterized as being a form of descriptive statistics, can "help the reader focus on potentially important exploratory findings."

Table 1. **Secondary Outcomes, Statistical Models and Measures of Intervention Effect by Outcome Type**

Secondary Outcome	Outcome Type	Model	Intervention Effect (Unadjusted)
Number of ED visits within 30 days post-discharge	Count ≥0	Poisson or negative binomial regression including intervention arm indicator	Rate ratio with 95% CI, and p-value*
Number of ED visits within 90 days post-discharge	Count ≥0	Poisson or negative binomial regression including intervention arm indicator	Rate ratio with 95% CI, and p-value*
Composite of re-admission or all-cause mortality within 30 days post-discharge	Binary, 0/1	Logistic regression including intervention arm indicator	Odds ratio with 95% CI, and p-value*
Composite of re-admission or all-cause mortality within 90 days post-discharge	Binary, 0/1	Logistic regression including intervention arm indicator	Odds ratio with 95% CI, and p-value*

CI: confidence interval; ED: emergency department
*Multiple testing correction for p-values will be applied using the Holm method.

Table 2. **Exploratory Outcomes, Statistical Models and Measures of Intervention Effect by Outcome Type**

Exploratory Outcome	Outcome Type	Model	Intervention Effect (Unadjusted)
Leaving against medical advice at discharge	Binary, 0/1	Logistic regression	Odds ratio with 95% CI, and p-value
Self-reported quality of care transition after hospital discharge (CTM-3) at the time of the 30-day interview	Continuous, range 0-100, unknown distribution	Linear regression or appropriate model for specific distribution type	Mean difference with 95% CI, and p-value
Self-reported change in difficulties meeting subsistence needs total score (Competing Priorities) at the 30-day interview post discharge relative to baseline, total score	Continuous, range 0-15	ANCOVA on change in total scores, with baseline value as covariate	Mean difference with 95% CI, and p-value
For participants who did not previously report contact with a case manager in the 30 days prior to the baseline interview, connection to a case manager in the community at the time of the 30-day interview	Binary, 0/1	Logistic regression	Odds ratio with 95% CI, and p-value
Medication adherence (MMAS-8) at the time of the 30-day interview	Continuous, range 0-8	Linear regression or appropriate model for specific distribution type	Mean difference with 95% CI, and p-value
Change in health status EQ-5D-3L at the time of the 30-day interview relative to baseline	Continuous, range -0.340 to 1.0 at each time point	ANCOVA on change in total scores, with baseline value as covariate	Mean difference with 95% CI, and p-value
Change in quality of life EQ-5D VAS at the time of the 30-day interview relative to baseline	Continuous, potential range 0-100	ANCOVA on change in total scores, with baseline value as covariate	Mean difference with 95% CI, and p-value
Days spent in hospital post-discharge within 90 days post-discharge	Count ≥0	Poisson or negative binomial regression including intervention arm indicator	Rate ratio with 95% confidence interval, and p-value

Days spent in hospital post-discharge within 180 days post-discharge	Count ≥0	Poisson or negative binomial regression including intervention arm indicator	Rate ratio with 95% confidence interval, and p-value
Time in days to re-admission or all-cause mortality after discharge, within 180 days post-discharge.	Time to event	Kaplan Meier curves with log-rank test Cox proportional hazards model	Hazard ratio with 95% CI, and p-value
Attendance of any non-PCP healthcare appointment within 180 days post-discharge	Binary, 0/1	Logistic regression	Odds ratio with 95% CI, and p-value

PCP: primary care physician; VAS: visual analog scale; ANCOVA: analysis of covariance; CI: confidence interval

4.3.4 Subgroup Analyses: For whom does the intervention work best?

To evaluate which patient subgroups may most benefit from the intervention with respect to the primary outcome, multivariable logistic regression models will estimate odds ratios with 95% confidence intervals to explore potential subgroup effects. Models will include each of the following pre-specified baseline covariates, in addition to the intervention arm indicator, one-at-a-time, and the corresponding interaction term with the intervention arm: age, sex, racial or ethnic identity, time of enrollment relative to study initiation (first or second half), self-reported current illicit drug use, self-reported current high-risk alcohol use, Charlson Comorbidity Index score (from ICES), and prior acute care utilization for a mental health reason (from ICES).

4.3.5 Sensitivity Analyses

For the primary outcome, we will evaluate whether a sensitivity analysis needs to be performed excluding the 16 patients who were asked the 3 original questions about visiting a PCP within 14 days. Determination will depend on whether, for these cases, the only indicator of the visit was by self-report.

For the Competing Priorities exploratory outcome, we will also compare groups using 3 alternative scoring methods. The first method calculates, for each participant, the mean score across all 5 items, range 1-4 (each item is scored on a 1–4 scale, with Never = 1; Rarely = 2; Sometimes = 3; and Usually = 4). The second method dichotomizes the mean score to participants with frequent (>3) versus infrequent (≤3) competing priorities. The third method classifies participants as having competing priorities if they responded ‘‘Usually’’ to any of the 5 items. For the first method, we will fit an analysis of variance (ANOVA) model. For the binary outcomes, we will fit generalized estimating equations, for the binomial distribution with logit link. Models will include the intervention arm indicator, time (30-day versus baseline interview), and the interaction of intervention arm by time. A significant interaction will indicate that the change from baseline is different between the study groups.

The total MMAS-8 score can also be categorized into three levels of adherence: high adherence (score = 8), medium adherence (score of 6 to < 8), and low adherence (score< 6). We will compare the groups using the Cochran-Armitage test for trend.

For binary outcomes outlined in Tables 1 and 2, and subgroup analyses, we will also fit modified Poisson regression models to estimate risk ratios with 95% CIs. All analyses will be conducted using R, STATA, and SAS. All statistical tests will be two-sided and a p-value of 0.05 or less will indicate statistical significance.

4.4 Handling of Incomplete Data

Missing data in outcomes may lead to biased estimates of the intervention effect and/or loss of power to test the intervention effect. In general, if rates of missingness per variable are low (< 5% overall), we may consider complete case analysis (Graham, 2009).

4.4.1 Missing Data for the Primary Outcome, Mortality, and Healthcare Utilization Outcomes

We expect that there will be no missing data for our primary outcome, since we are using 3 sources of data. We expect likewise for all secondary outcomes and for exploratory outcomes related to death or healthcare utilization.

4.4.2 Missing Data for Baseline Variables and 30-Day Interview Self-Reported Exploratory Outcomes

The main reasons for missing data at baseline include "do not know" responses or refusal to answer survey questions.

Missing data reasons at the 30-day interview include the same reasons as at baseline, but also may be due to patients dying after discharge and before the interview, being lost to follow-up, refusing the interview, or being too medically unwell to participate in interviews.

For most of the exploratory outcomes, missing data may be missing not at random (MNAR). This occurs when the distribution of missing data depends on unobserved characteristics of the individuals, in particular, the outcomes themselves (i.e., missing because of lower medication adherence, lower quality of life, leaving against medical advice, etc.). For data that are missing at random (MAR), the probability of missingness depends only on observed data but not on the data that are missing (Austin, 2018). That is, after controlling for or stratifying by observed variables, missingness is random. There is general consensus that the greater the number of observed variables that can be assumed to capture reasons for (or associated with) missingness and can be incorporated in the multiple imputation process, the more plausible the MAR assumption becomes (Collins et a., 2001, Graham, 2012, White, 2010). The traditional approach for handling missing data is multiple imputation, and multiple imputation can handle MAR and specific MNAR scenarios (van Buuren, 2018).

4.4.3 Multiple Imputation

In addition to complete case analysis of exploratory self-reported outcomes, we will use the R package MICE to perform multiple imputation and analyze multiple imputed datasets. A specific plan for implementing the multiple imputation method will be developed once all data are available.

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Appendix 1. Outcome Definitions

1 Primary Outcome

The primary outcome will be determined **using participant self-report at the 30-day interview, PCP office confirmation, and administrative databases**

Participant self-report at the 30-day interview was originally determined using the following 3 questions:

Q1 “Do you have a regular family doctor?” By family doctor, we mean a family doctor, GP, or a nurse practitioner who is familiar with you.
Q2 If Yes: Have you seen your primary care provider since you were discharged from St. Michael’s Hospital or St. Joseph’s Hospital on [DATE]?
Q3 If Yes: What was the date of the first visit with your primary care provider after discharge?

These 3 previous questions were only asked for the first 16 participants, and then were revised as follows and retained until the end of the study:

Q1 Have you seen any doctor or nurse practitioner since you were discharged from St. Michael’s Hospital or St. Joseph’s Hospital on [DATE]?
Q2 If Yes: Have you seen a family doctor or nurse practitioner since you were discharged from St. Michael’s Hospital or St Joseph's Hospital on [DATE]?
Q3 If Yes: What was the date of the first visit with the family doctor or nurse practitioner after discharge?

The primary outcome uses participant self-report at the 30-day interview, which will be defined as follows:

If the interval between discharge date and date of first visit with primary care provider, family doctor, or NP is less than or equal to 14 days then follow-up with a PCP within 14 days of hospital discharge is equal to 1 (Yes). Otherwise, it is equal to 0 (No).

2 Secondary Outcomes

Secondary outcomes will be determined **using administrative databases**

1. Number of emergency department visits within 30 days post-discharge
2. Number of emergency department visits within 90 days post-discharge
3. Composite measure of any re-admission or all cause-mortality* within 30 days post-discharge
4. Composite measure of any re-admission or all cause-mortality* within 90 days post-discharge

*Readmissions and days in hospital (i.e., acute care utilization) outcomes will not include labour and delivery visits, and planned readmissions.

Transfers within and between hospitals may count as single admission events, but will be determined on a case-by-case situation. For example, if a patient is transferred between services within the hospital, the entire hospital stay will be treated as a single admission.

Counting the number of transfers will be formalized after careful review of the literature and based on the frequency of inter- vs intra-hospital transfers.

3 Exploratory Outcomes

Exploratory outcomes will be collected using 3 sources: hospital discharge summaries, participant self-report at the 30-day interview, and administrative databases.

3.1 Hospital Discharge Summaries

1. Indicator of participant leaving against medical advice at discharge

3.2 Participant Self-Report at 30-Day Interview

1. Self-reported quality of care transition (3-item Care Transitions Measure, CTM-3) after hospital discharge at the time of the 30-day interview
2. Self-reported change in difficulties meeting subsistence needs (Competing Priorities measure from RAND Course of Homelessness Study) at the time of the 30-day interview relative to baseline
3. For participants who did not previously report contact with a case manager in the 30 days prior to the baseline interview, connection to a case manager in the community at the time of the 30-day interview
4. Medication adherence (eight-item Morisky Medication Adherence Scale, MMAS-8) at the time of the 30-day interview
5. Change in health status (EQ-5D-3L; European Quality of Life – Five Dimension - Three Levels) at the time of the 30-day interview relative to baseline

6. Change in quality of life (EQ-5DVisual Analogue Scale) at the time of the 30-day interview relative to baseline

3.3 Administrative Databases

1. Total number of days spent in hospital (s) post-discharge within 90 days post-discharge
2. Total number of days spent in hospital (s) post-discharge within 180 days post-discharge
3. Time in days to all-cause re-admission or mortality after discharge (up to 180 days post-discharge)
4. Attendance of any non-PCP healthcare appointment made by the time of discharge* within 180 days post-discharge

   *Only non-PCP appointments made by the time of discharge and documented in the discharge summary will be assessed for attendance

A summary of outcome domains and study instruments and detailed descriptions of study instruments are provided in Liu et al, 2022 and its online supplemental file 3.

Appendix 2 Self-Reported Measures and Scoring Algorithms

Details of the instruments used to evaluate exploratory self-reported outcomes are described below:

1 CTM-3: Three-Item Care Transitions Measure

The CTM-3 is a measure designed to evaluate the extent to which patients believe the healthcare team accomplished essential care processes in preparing them for discharge and participating in post-hospital self-care activities. This measure was endorsed by The National Quality Forum (www.qualityforum.org).

Each of the three items is scored on a 1–4 scale, with Strongly Disagree=1; Disagree=2; Agree=3; and Strongly Agree=4. For each participant, the mean score is calculated by summing up the responses across the 3 items and dividing by the number of items answered (https://mhdo.maine.gov/_pdf/NQF_CTM_3_%20Specs_FINAL.pdf).

The mean score (mean_ctm3) is then re-scaled to a 0-100 score (CTM3_score) using the following formula:

CTM3_score=(new_max - new_min) / (old_max - old_min) * (mean_ctm3 - old_min) + new_min,

where new_max=100; new_min=0; old_max=4; old_min=1.

Higher scores indicate better care transition experiences. This continuous variable has been used in a variety of studies.

2 Competing Priorities

This measure is a validated 5-item measure of frequency of difficulty in meeting the following needs over the past 30 days: shelter, food, clothing, a place to wash, and access to a bathroom (Koegel et al, 1996; Gelbert et al, 1997).

Each item is scored on a 1–4 scale, with Never=1; Rarely=2; Sometimes=3; and Usually=4. There is no consensus on how to best score this instrument. We are aware of four scoring methods.

The first method calculates, for each participant, the mean score across all 5 items (Koegel et al, 1996, range 1-4).

The second method dichotomized the mean score to participants with frequent (>3) versus infrequent (≤3) competing priorities (Gelbert et al, 1997).

The third method classifies participants as having competing priorities if they responded ‘‘Usually” to any of the 5 items (Hwang et al, 2010).

The fourth method, re-scales items to a range of 0 to 3, and calculates the total score as their sum (Baggett et al, 2018, range 0-15).

3 MMAS-8: Eight-Item Morisky Medication Adherence Scale (purchased license to use)

The MMAS-8 is a validated self-reported measure of medication adherence that has been validated among disadvantaged patient populations and those with chronic illnesses. The MMAS-8 consists of 8 items, 7 of which are yes/no questions, coded as 1 if indicating adherence or 0 if otherwise. The last item has a five-point Likert-scale rating, with Never/Rarely=1; Once in a while=0.75; Sometimes=0.50; Usually=0.25; and All the time=0.

For each participant, the total score is calculated as the sum of all items (range 0-8). Higher scores indicate greater adherence. The total score can also be categorized into three levels of adherence: high adherence (score = 8), medium adherence (score 6 to < 8), and low adherence (score<6).

4 EQ-5D: EuroQoL-5D

The EQ-5D instrument was originally developed to include two parts to measure health status and quality of life: the 3L and the visual analog scale (VAS).

The EQ-5D-3L is a generic measure of health-related quality of life that has been widely used among homeless populations. The EQ-5D-3L includes five items concerning mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, which are coded as 1, 2, or 3 ordered according to problem/disability level. The scoring for the 3L portion is unique to each country based on the "value" ascribed to that health state by a representative sample of the population. We will use the validation for Canada

The combination of values from all items are scaled into a value according to Table A1 [range -0.340 (33333) to 1 (11111).

Table A1. **List of values for all health states derived from EQ5D-L in Canada***

Health state	Value	Health state	Value	Health state	Value
11111	1.000	21111	0.843	31111	0.567
11112	0.826	21112	0.780	31112	0.504
11113	0.609	21113	0.563	31113	0.286
11121	0.844	21121	0.799	31121	0.522
11122	0.781	21122	0.736	31122	0.459
11123	0.564	21123	0.518	31123	0.242
11131	0.591	21131	0.546	31131	0.269
11132	0.528	21132	0.483	31132	0.206
11133	0.311	21133	0.265	31133	-0.011
11211	0.817	21211	0.771	31211	0.495
11212	0.754	21212	0.708	31212	0.432
11213	0.537	21213	0.491	31213	0.214
11221	0.772	21221	0.727	31221	0.450
11222	0.709	21222	0.664	31222	0.387
11223	0.492	21223	0.446	31223	0.170
11231	0.519	21231	0.474	31231	0.197
11232	0.456	21232	0.411	31232	0.134
11233	0.239	21233	0.193	31233	-0.083
11311	0.784	21311	0.738	31311	0.461
11312	0.720	21312	0.675	31312	0.398
11313	0.503	21313	0.458	31313	0.181
11321	0.739	21321	0.693	31321	0.417
11322	0.676	21322	0.630	31322	0.354
11323	0.459	21323	0.413	31323	0.136
11331	0.486	21331	0.440	31331	0.164
11332	0.423	21332	0.377	31332	0.101
11333	0.206	21333	0.160	31333	-0.117
12111	0.819	22111	0.773	32111	0.496
12112	0.755	22112	0.710	32112	0.433
12113	0.538	22113	0.493	32113	0.216
12121	0.774	22121	0.728	32121	0.452
12122	0.711	22122	0.665	32122	0.389
12123	0.494	22123	0.448	32123	0.171
12131	0.521	22131	0.475	32131	0.199
12132	0.458	22132	0.412	32132	0.136
12133	0.241	22133	0.195	32133	-0.082
12211	0.746	22211	0.701	32211	0.424
12212	0.683	22212	0.638	32212	0.361
12213	0.466	22213	0.420	32213	0.144
12221	0.702	22221	0.656	32221	0.380
12222	0.639	22222	0.593	32222	0.316
12223	0.421	22223	0.376	32223	0.099
12231	0.449	22231	0.403	32231	0.127
12232	0.386	22232	0.340	32232	0.063
12233	0.168	22233	0.123	32233	-0.154
12311	0.713	22311	0.668	32311	0.391
12312	0.650	22312	0.604	32312	0.328
12313	0.433	22313	0.387	32313	0.111
12321	0.669	22321	0.623	32321	0.346
12322	0.605	22322	0.560	32322	0.283

12323	0.388	22323	0.343	32323	0.066
12331	0.416	22331	0.370	32331	0.093
12332	0.352	22332	0.307	32332	0.030
12333	0.135	22333	0.090	32333	-0.187
13111	0.665	23111	0.620	33111	0.343
13112	0.602	23112	0.557	33112	0.280
13113	0.385	23113	0.339	33113	0.063
13121	0.621	23121	0.575	33121	0.298
13122	0.557	23122	0.512	33122	0.235
13123	0.340	23123	0.295	33123	0.018
13131	0.368	23131	0.322	33131	0.045
13132	0.304	23132	0.259	33132	-0.018
13133	0.087	23133	0.042	33133	-0.235
13211	0.593	23211	0.548	33211	0.271
13212	0.530	23212	0.484	33212	0.208
13213	0.313	23213	0.267	33213	-0.010
13221	0.549	23221	0.503	33221	0.226
13222	0.485	23222	0.440	33222	0.163
13223	0.268	23223	0.223	33223	-0.054
13231	0.296	23231	0.250	33231	-0.027
13232	0.232	23232	0.187	33232	-0.090
13233	0.015	23233	-0.030	33233	-0.307
13311	0.560	23311	0.514	33311	0.238
13312	0.497	23312	0.451	33312	0.174
13313	0.279	23313	0.234	33313	-0.043
13321	0.515	23321	0.470	33321	0.193
13322	0.452	23322	0.407	33322	0.130
13323	0.235	23323	0.189	33323	-0.087
13331	0.262	23331	0.217	33331	-0.060
13332	0.199	23332	0.154	33332	-0.123
13333	-0.018	23333	-0.064	33333	-0.340

*Source: Bansback N, Tsuchiya A, Brazier J, Anis A. Canadian valuation of EQ-5D health states: preliminary value set and considerations for future valuation studies. PLoS One. 2012;7(2):e31115.