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Cohort Profile: The STOP HIV/AIDS Program Evaluation (SHAPE) Study in British Columbia, Canada

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Cohort Profile: The STOP HIV/AIDS Program Evaluation (SHAPE) Study in British Columbia, Canada

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Abstract

Purpose: The STOP HIV/AIDS Program Evaluation (SHAPE) study is a longitudinal cohort developed to monitor the progress of an HIV testing and treatment expansion program across the province of British Columbia (BC). The study considers how socio-structural determinants such as gender, age, sexual identity, geography, income, and ethnicity influence engagement in HIV care.

Participants: Between January 2016 and September 2018, 644 BC residents who were at least 19 years old and diagnosed with HIV were enrolled in the study and completed a baseline survey. Participants will complete two additional follow-up surveys (18-months apart) about their HIV care experiences, with clinical follow-up ongoing.

Findings to date: Analyses on baseline data have found high levels of HIV care engagement and treatment success among SHAPE participants, with 95% of participants receiving antiretroviral therapy and 90% having achieved viral suppression. However, persistent disparities in HIV treatment outcomes related to age, injection drug use, and housing stability have been identified and require further attention when delivering services to marginalized groups.

Future plans: Our research will examine how engagement in HIV care evolves over time, continuing to identify barriers and facilitators for promoting equitable access to treatment and care among people living with HIV. A qualitative research project, currently in the formative phase, will compliment quantitative analyses by taking a strengths-based approach to exploring experiences of engagement and re-engagement in HIV treatment among individuals who have experienced delayed treatment initiation or treatment interruptions.

Strengths and limitations of this study

- The SHAPE study collects in-depth data concerning the experiences and perspectives of people living with HIV in order to improve understanding of barriers and facilitators to linkage and retention in care. Findings will be used to inform policy and interventions for addressing inequities in HIV health care.
- Community-engaged research methods are integrated throughout the study. For example, peer research associates are involved in all phases of research from planning to data collection, analysis and knowledge dissemination.
- Purposive sampling was employed to obtain a sample that is representative of key sociodemographic characteristics of people living with HIV in the province of BC, however, challenges were experienced in reaching certain recruitment targets such as targets for young adults and mid-higher income groups.
- SHAPE participants were overwhelmingly engaged in HIV care at baseline, which may reflect sampling bias. Individuals who face the greatest barriers to accessing HIV care are likely to experience similar barriers to involvement in research, and therefore, to be underrepresented in our cohort.

Introduction

Modern treatment for HIV, antiretroviral therapy (ART), has been shown to greatly reduce HIV-related morbidity and mortality (1-3). The public health benefit of ART uptake and sustained adherence was first recognized in 2006 with the publication of mathematical models indicating that reduction in community viral load would prevent transmission and, subsequently, new cases of HIV(4). Since then mounting evidence based on clinical trials, cohort and population-based studies has led to widespread, international support for the concept of HIV Treatment as Prevention(5-8).

In 2010, the Seek and Treat for Optimal Prevention of HIV/AIDS (STOP HIV/AIDS) Program was initiated as a pilot intervention by the BC Ministry of Health and the BC Centre for Excellence in HIV/AIDS. In order to implement the principles of Treatment as Prevention in public health practice, the pilot intervention aimed to expand access to HIV testing and treatment to all clinically eligible individuals in two cities disproportionately impacted by the HIV/AIDS epidemic in the province of BC: Vancouver and Prince George. In 2013, the STOP HIV/AIDS Program was expanded throughout the province (9, 10). As the STOP HIV/AIDS program expands access to ART in BC, it is critical to monitor and evaluate socio-structural determinants of HIV health outcomes and respond to disparities in engagement in care; failure to do so could reinforce health inequities among people living with HIV (PLWH).

Despite availability of fully subsidized HIV health care and the optimization of treatment and testing since 2010 in BC, inequities in treatment access and retention persist, particularly among structurally marginalized populations. Women, Indigenous peoples, people who inject drugs, and youth have been found to have lower levels of ART adherence and engagement in HIV care (11-14). Hence, there is a need to improve strategies for linking and retaining individuals in HIV care by considering socio-demographic, economic and behavioural vulnerabilities.

Rationale and objectives

The STOP HIV/AIDS Program Evaluation (SHAPE) study was initiated in 2016 to monitor progress of the provincial program to optimize testing, treatment, and prevention of HIV. The SHAPE study examines determinants of progression along the HIV cascade of care to generate information for addressing ongoing barriers to HIV health care. This information will be used to strengthen the implementation of BC's program for ART expansion. Funding is provided by the BC Centre for Excellence in HIV/AIDS and the BC Ministry of Health. Specific objectives of the SHAPE study are:

- i. To monitor the proportion of key groups (Indigenous peoples, youth, people who inject drugs and women) who are at different stages along the cascade of care (receiving care, receiving ART, adherent to ART and virologically suppressed) in the context of expanded HIV testing, treatment and care throughout the province.
- ii. To identify clinical, social and structural determinants of progression along the cascade of care.

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- iii. To assess the impact of community-based organizations, peer support and other supportive services on individuals' HIV-care experiences.
 - iv. To assess the impact of exposure to the STOP HIV/AIDS program among PLWH in BC.
 - v. To assess the beliefs, attitudes and behaviours associated with HIV treatment and care among PLWH in BC and how this impacts their experience in the cascade of care.

Cohort description

Between January 2016 and September 2018, PLWH who were BC residents, at least 19 years of age, able to provide informed consent and complete surveys in English were eligible to enrol in the SHAPE study. Purposive sampling was employed in order to obtain a sample that was representative of key sociodemographic characteristics including age, gender, Indigenous ethnicity¹, geography, sexual identity, and hepatitis C co-infection. Recruitment targets were developed by proportionally allotting a subsample size according to rates seen in the population of PLWH across the province. Estimates of the distribution of these characteristics were derived from the Drug Treatment Program (DTP), which distributes ART to all medically eligible residents of BC and serves as a longitudinal clinical database of all individuals who have been linked to HIV care. Recruitment remained open until there was adequate representation and appropriate power for analytical purposes.

Characteristics of SHAPE participants compared to the population of eligible non-respondents are shown in **Table 1**. Eligible non-respondents were defined as those who (a) accessed HIV care in the DTP during SHAPE's enrolment period (January 1 2016 – September 1 2018); (b) were at least 19 years of age on or before September 1 2018; (c) ever received ART from the DTP; and (d) did not participate in SHAPE.

Recruitment methods

Participants were recruited using a combination of strategies including the following:

- i. Community association driven recruitment involved developing partnerships with AIDS service organizations (ASOs) that offer essential resources for PLWH. Outreach and support services provided by ASOs typically relate to medication management, counseling and peer navigation, which are particularly important among individuals who are recently diagnosed and those who face structural barriers to accessing traditional health care services. Staff and volunteers at ASOs provided recruitment assistance by promoting the study among their clients

¹ The term 'Indigenous' is used here to describe participants who self-identified as Indigenous in the baseline survey instrument. 'Indigenous' is used to collectively describe the Indigenous peoples of Canada, inclusive of those who identify as 'Aboriginal' or First Nations, Métis and Inuit. This term is used while acknowledging the diversity of cultures, languages and traditions that exist among Indigenous Canadians.

- through word-of-mouth, advertising on their websites, and displaying posters and postcards in their common spaces.
- ii. In order to reach individuals who do not utilize ASOs, posters and postcards were placed at clinics that specialize in HIV health care across BC, as well as public locations such as notice boards in community centres, coffee shops, and libraries. Health clinics serving a large number of PLWH were informed about the study and their staff encouraged to invite eligible patients to participate. Postcards were also included in HIV prescription refill packages that are picked up by patients at pharmacies throughout the province.
 - iii. A study website was developed to provide information about the study to participants, health workers and ASO staff. The website includes information on participant eligibility, research aims, data collection procedures, ethics and consent processes, contact information and study results. Participants may access the study surveys via a secure link on the website.
 - iv. Paid online advertisements were placed on Craigslist and social networking websites and mobile apps including Facebook, Grindr, and Scruff.

Cohort characteristics

A total of 644 eligible participants were recruited, of whom 139 (22%) identified as female; 101 (16%) self-reported Indigenous ethnicity; 368 (57%) identified as gay, bisexual or other men who have sex with men (gbMSM); and 273 (42%) reported a history of injection drug use (IDU), see **Table 1**. The median age of SHAPE participants at time of study enrolment was 51 (Q1-Q3: 43-57). Participants had been diagnosed with HIV for a median of 15 years prior to study enrolment (Q1-Q3: 8-21), and median years from first ART date to enrolment was 7 (Q1-Q3: 4-12). SHAPE participants and eligible non-respondents did not vary significantly by age at ART initiation, the proportion of gbMSM, or hepatitis C co-infection.

Table 1 Comparison of SHAPE cohort participants with eligible non-respondents who were enrolled in the DTP

Variable	SHAPE participants (n=644)	Eligible non-respondents (n=7737)	P-value
Demographic Variables			
Age when initiating ART, median (Q1-Q3)	39 (32-47)	39 (32-47)	0.26
Gender, n (%)			<0.001
Woman	139 (22%)	1294 (17%)	
Man	496 (77%)	6394 (83%)	
Other	9 (1%)	49 (1%)	
Ethnicity, n (%)			<0.001
Caucasian	467 (73%)	3012 (63%)	
Indigenous	101 (16%)	674 (14%)	
Asian	18 (3%)	429 (9%)	
African, Caribbean and Black	4 (1%)	240 (5%)	
Other	54 (8%)	428 (9%)	

<i>Missing value</i>	-	2954	
History of injection drug use, n(%)	273 (42%)	2080 (33%)	<0.001
<i>Missing value</i>	96	1382	
Gay, bisexual or other MSM, n(%)	368 (57%)	3089 (52%)	0.010
<i>Missing value</i>	-	1776	
Age at baseline*, median (Q1-Q3)	50.5 (43-57)	53 (43-59)	<0.001
Clinical Variables			
Hepatitis C co-infection, n (%)	215 (33%)	2362 (32%)	0.499
<i>Missing value</i>	-	376	
Years since HIV diagnosis*, median (Q1-Q3)	15 (8-21)	13 (6-20)	<0.001
Viral load testing rate (tests/year during year prior to baseline*), median (Q1-Q3)	4 (3-5)	3 (2-4)	<0.001
Years on ART*, median (Q1-Q3)	7 (4-12)	9 (4-14)	<0.001
ART interruption ever*†, n (%)	319 (50%)	3244 (42%)	<0.001
<i>Missing value</i>	10	47	

*As of study enrolment date for SHAPE participants; as of September 1st 2018 for eligible non-respondents.
 †ART interruption defined as 90 days or longer off ART among individuals who have ever initiated treatment. A limitation of this assessment is that we lack information concerning clinical trial status of SHAPE participants and non-respondents, which may inflate the appearance of treatment interruptions in our data.

As shown in Figure 1, SHAPE participants were enrolled from each health authority in the province. Health authorities are responsible for delivering health services to the population residing within corresponding geographic regions of the province. Although the majority of PLWH in the province reside in Vancouver Coastal Health (VCH) Authority, where the urban setting of Vancouver is located, individuals residing outside of VCH may encounter unique barriers to accessing HIV services. Emerging research indicates that PLWH who reside in nonurban areas face increased vulnerability at each stage of the HIV cascade of care (15). Hence, it was a priority for the SHAPE research team to engage participants in regions of BC that have previously been under-represented in research.

(Insert Figure 1 here)

Figure 1 SHAPE cohort composition by BC health authority vs. total population of PLWH in BC*

*Based on those enrolled in the DTP who met the SHAPE cohort eligibility criteria, but were not enrolled in the study.

Data collection and follow-up

Participants completed a baseline survey and throughout the course of the study will complete two follow-up surveys, 18-months apart, collecting information concerning their HIV care experiences. Each survey takes approximately one hour to complete, and participants are compensated \$30 per survey for their time and expertise. Participants are offered the option of completing an online self-administered survey, or being interviewed by a peer research associate (PRA) by phone or in-person. These options were established

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3 to minimize financial, physical and social barriers to participation for individuals across
4 the province.
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6 7 **Surveys**

8 The SHAPE baseline survey is comprised of the following sections: (i) sociodemographics,
9 (ii) current health and medical history, (iii) HIV testing and diagnosis experiences, (iv)
10 linkage to care, (v) treatment, (vi) retention in care and resiliency, and (vii) awareness and
11 experience of the STOP HIV/AIDS program. Development of the survey tool involved a
12 literature review for the purpose of identifying key topic areas as well as variables and
13 validated scales for inclusion in the survey. Selected scales include: the Household Food
14 Security Survey Module (16), Short Form-6D for measuring health-related quality of life
15 (17), Drug Abuse Screening Test (DAST-10) (18, 19), Alcohol Use Disorders
16 Identification Test (AUDIT-C) (20, 21), Centre for Epidemiologic Studies Depression
17 Scale (CES-D 10) (22, 23), Everyday Discrimination Scale (24, 25), HIV Stigma Scale
18 (26, 27), HIV Treatment Adherence Self-Efficacy Scale (28), Antiretroviral Medication
19 Attitude Scale (29), Continuity of Care Scale (30), and Medical Outcomes Study Social
20 Support Survey (31-33). Follow-up surveys also examine resiliency and HIV disclosure
21 concerns using the Resilience Scale (RS-14) (34, 35) and disclosure sub-scale of
22 HIV/AIDS Quality of Life Scale (36, 37), respectively.
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26 Surveys were pre-tested and improved upon with the expertise of PRAs, followed by a
27 pilot phase in which additional community members assessed the survey for
28 appropriateness and sensitivity. Participants are encouraged to provide feedback so that
29 further improvements can be made to future surveys.
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32 **Linkages to clinical data**

33 The SHAPE study benefits immensely from data linkage with the DTP. Anyone prescribed
34 ART in the province of BC is automatically enrolled in the DTP, thereby enabling
35 longitudinal follow-up of health records and laboratory results related to HIV treatment
36 and virologic outcomes. Through the DTP database, the SHAPE study is able to link
37 participant survey responses with routine clinical data collection such as CD4 cell counts,
38 viral load testing, specific ART regimen and changes, adherence and the provincial vital
39 statistics registry. This linkage also enables the SHAPE research team to compare
40 demographics and clinical indicators between SHAPE participants and non-participants.
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43 Prior to enrolling in the study, participants consent to having their survey data linked to
44 clinical records that are held by the BC Ministry of Health, and to being contacted at a later
45 date for follow-up or for clarification regarding any missing survey information.
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48 Ethical approval for the SHAPE study was obtained from the University of British
49 Columbia/Providence Health Care research ethics board (REB number: H15-01807).
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51 **Patient and public involvement**

52 In accordance with GIPA/MIPA (Greater/Meaningful involvement of people living with
53 HIV) principles, PLWH are meaningfully involved in all phases of the SHAPE study from
54 planning to data collection, analysis and knowledge dissemination (49, 50). PRAs, who
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share lived experiences with study participants and are trained in research methods, facilitate recruitment and interview study participants. While past studies in the field of HIV have at times been limited by lower levels of community involvement outside of the process or data collection phase (50, 51), SHAPE PRAs are involved in identifying research priorities and questions, developing and evaluating data collection tools, analyzing data, and sharing findings. Knowledge dissemination strategies prioritize bringing findings back to communities and fostering dialogue that may guide research direction and further enhance collaboration.

Findings to date

The SHAPE study collects comprehensive data on social determinants of health and individual attitudes, experiences and behaviours that may impact HIV treatment outcomes. Table 2 depicts the SHAPE cohort by socio-demographic, health and behavioural characteristics.

Table 2 Characteristics of SHAPE participants (n=644) at time of study enrolment

Variable	Count, n(%) or median (Q1-Q3)
Education level	
Less than high school	147 (23%)
Completed high school	193 (30%)
Greater than high school	302 (47%)
Sexual orientation	
Heterosexual	240 (37%)
Gay or lesbian	315 (49%)
Other	89 (14%)
Annual income for year prior to enrolment (\$)	16,800 (13,200-30,720)
Currently employed	292 (45%)
Food insecure*	326 (51%)
Currently receiving housing subsidy	232 (36%)
Incarceration history	
Incarcerated within the past year	19 (3%)
Yes, but not within the past year	209 (32%)
Never incarcerated	416 (65%)
History of homelessness	
Currently homeless	27 (4%)
Yes, in the past year but not now	65 (10%)
Yes, but not in the past year	231 (36%)
Never homeless	321 (50%)
Mental illness diagnosis, ever	341 (53%)
CES-D 10 (depression) score	9 (5-16)
Significantly depressed†	312 (48%)
MOS-SSS (social support) score‡	65 (42-86)
AUDIT-C (alcohol use) score	2 (0-5)
Hazardous alcohol use§	47 (7%)

HIV stigma score	48 (33-63)
Use of supportive services since HIV diagnosis	
Peer navigation	225 (37%)
ASOs	451 (71%)
Food bank/meal program	269 (44%)
Other	221 (36%)

*Food insecure was defined as often or sometimes unable to afford to eat balanced meals in the past 12 months.

†The CES-D 10 measures depressive symptomology using a shortened 10-item scale that has been validated for use among PLWH in BC (22). The possible range is 0-30 with scores ≥ 10 indicating the presence of significant depressive symptoms.

‡This is an overall support index calculated by transforming scores from a 19-item scale to have a range of 0-100; higher scores indicate greater social support. Instructions for scoring and interpreting the MOS-SSS are available at www.rand.org/health-care/surveys_tools/mos/social-support.html

§This validated and shortened version of the AUDIT scale has a possible range of 0-12 with scores > 8 indicating hazardous alcohol use.

||HIV stigma scores have been reparametrized to have arrange of 0-100 with higher scores indicating higher levels of perceived stigma. Scores are calculated based on a shortened and validated 10-item version of the scale, which includes items from all four sub-scales of the original 40-item scale: personalized stigma, disclosure concerns, negative self-image, and concern with public attitudes (27).

Since the SHAPE cohort completed enrolment in September 2018, several studies have been initiated to examine social determinants of progression along the cascade of care. One recently presented analysis used baseline survey responses in conjunction with longitudinal clinical data to assess the relationship between social support, which was self-reported using the MOS-SSS (33), and engagement in HIV treatment. Results from multivariable logistic regression modelling demonstrated that social support is protective against interruptions in ART. After adjustment for known confounders, each 10% increase in MOS-SSS score was found to reduce the likelihood of experiencing ART interruptions by 16% (38). Other recent studies include characterization of the distribution of HIV-related stigma among individuals accessing ART, and a prospective analysis of changes in clinical outcomes – including viral rebound, ART interruption, and sustained ART adherence – since study enrolment. Respective results indicated that age, city size, IDU experience, violence and mental health disorder diagnosis are independently associated with HIV-related stigma (39), and that despite few occurrences of viral rebound or less the optimal ART adherence among SHAPE participants, disparities exist based on key characteristics related to age, ethnicity, geography, socio-economic status and incarceration, among other facets of structural marginalization (40).

In addition, preliminary findings disseminated via conference presentations describe prevalence and predictors of viral suppression in the SHAPE cohort. Our research indicates that despite high levels of engagement along the cascade of care among SHAPE participants (Figure 2), inequities in treatment outcomes persist among certain vulnerable groups. Among PLWH in BC, younger adults, individuals with a history of IDU and those who are currently homeless are at greater risk for failing to achieve viral suppression (41). Moreover, age and HIV risk type were identified as determinants of time to suppression, with younger age and identification with a risk group other than gbMSM predicting longer time between initiation of ART and viral suppression (42). These findings corroborate

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3 previous research on determinants of viral suppression (43-48), and suggest the need for
4 targeted supports to address health disparities among PLWH in BC.
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7 (Insert Figure 2 here)

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9 **Figure 2** HIV cascade of care among SHAPE participants at time of study
10 enrolment(n=644)
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12 Future research will seek to quantify differences in clinical outcomes and experiences of
13 accessing HIV care between SHAPE participants who were diagnosed with HIV prior to
14 and during the era of the STOP HIV/AIDS program. Studies will also continue to examine
15 how engagement in care evolves over time and to identify barriers and facilitators for
16 promoting equitable access to HIV treatment and care. These quantitative analyses will be
17 complimented by a qualitative research project, which is currently in the formative and
18 planning stage. Qualitative work will consist of two components: (1) semi-structured
19 interviews of health care providers and PLWH that take a strength-based approach to
20 examining experiences of engagement and re-engagement in HIV treatment; and (2)
21 supporting the development of an Indigenous-led research program that explores the
22 knowledge and experiences of Indigenous peoples living with HIV.
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26 Knowledge dissemination strategies utilized by the SHAPE research team include
27 traditional avenues such as academic conferences and manuscripts, and community-based
28 knowledge translation and exchange activities. Methods of bringing research back to
29 communities include presentations and discussions held at our research sites, and
30 producing plain language summaries; newsletters and information sheets.
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33 **Strengths and limitations**

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35 The SHAPE cohort provides a unique source of information on HIV care experiences
36 among PLWH in BC. The comprehensive survey tool allows for quantitative assessment
37 of behaviours, beliefs and attitudes related to HIV testing, treatment and care, which is
38 further contextualized by social, structural and medical factors reported by participants.
39 Moreover, linkage of survey responses with longitudinal clinical data allows for analysis
40 of the impact of HIV care experiences on long-term cascade of care outcomes, such as
41 experiences of HIV treatment interruptions, changes in ART regimens, sustained viral
42 suppression or viral rebound.
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46 Purposive sampling methods were used to ensure that findings would be representative of
47 the experiences of PLWH throughout BC who have diverse sociodemographic and clinical
48 characteristics. An important strength of the study is the representativeness that was
49 achieved by geographic region, which was defined by Health Authority of residence.
50 However, challenges were experienced in reaching certain enrolment targets. Younger
51 adults aged 19-29 and mid-higher income groups were difficult to recruit. Moreover,
52 SHAPE is a sample of individuals with high levels of engagement in care at the time of
53 baseline interview; therefore, PLWH who face the most pervasive barriers to accessing
54 HIV treatment and care may be underrepresented.
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Collaboration

For further information on the SHAPE study, please contact the principal investigator, Dr. Rolando Barrios (rbarrios@cfenet.ubc.ca) or the study coordinator, Andrea Bever (abever@cfenet.ubc.ca). We welcome feedback and ideas, including proposals for collaboration on data analyses or knowledge translation and exchange activities.

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Contributors: RB conceptualized and established the SHAPE study. AB conceptualized and drafted the present manuscript with contributions from PS, LW, BB, KS, DM, TW and CT. SG and TW collected data, and LW conducted statistical analyses. All authors critically reviewed and approved the manuscript.

Conflicts of interest: None to declare.

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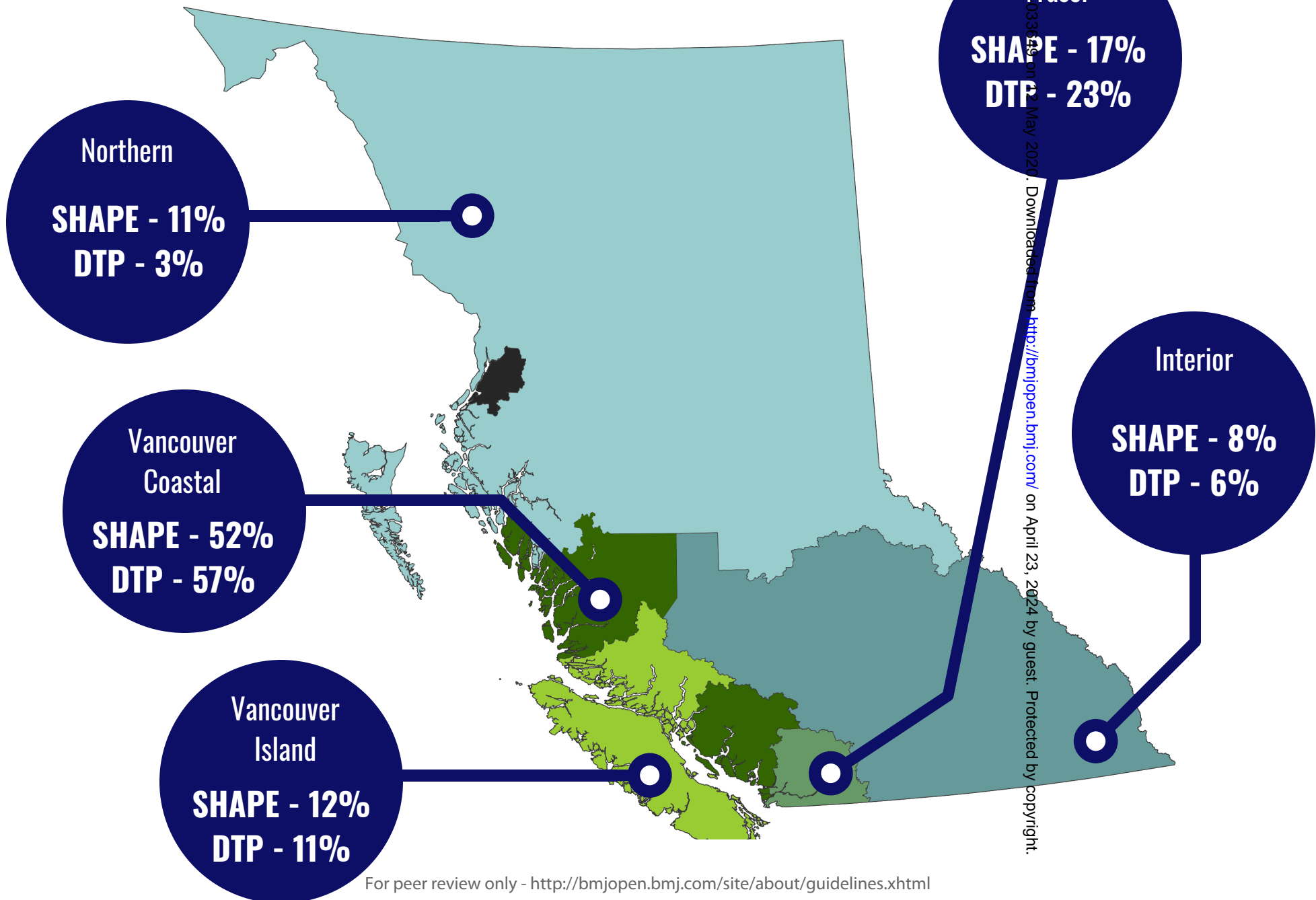
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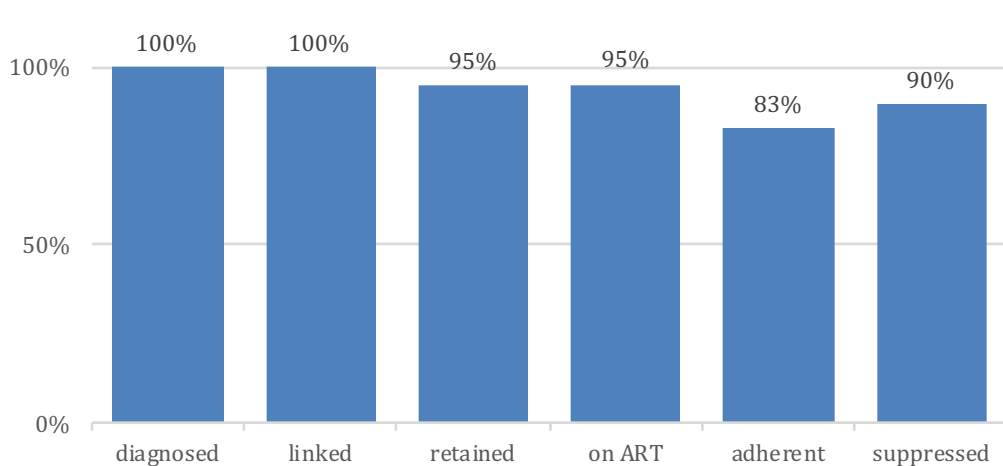
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■ % of participants in each stage of care

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Cohort Profile: The STOP HIV/AIDS Program Evaluation (SHAPE) Study in British Columbia, Canada

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Abstract

Purpose: The STOP HIV/AIDS Program Evaluation (SHAPE) study is a longitudinal cohort developed to monitor the progress of an HIV testing and treatment expansion program across the province of British Columbia (BC). The study considers how socio-structural determinants such as gender, age, sexual identity, geography, income, and ethnicity influence engagement in HIV care.

Participants: Between January 2016 and September 2018, 644 BC residents who were at least 19 years old and diagnosed with HIV were enrolled in the study and completed a baseline survey. Participants will complete two additional follow-up surveys (18-months apart) about their HIV care experiences, with clinical follow-up ongoing.

Findings to date: Analyses on baseline data have found high levels of HIV care engagement and treatment success among SHAPE participants, with 95% of participants receiving antiretroviral therapy and 90% having achieved viral suppression. However, persistent disparities in HIV treatment outcomes related to age, injection drug use, and housing stability have been identified and require further attention when delivering services to marginalized groups.

Future plans: Our research will examine how engagement in HIV care evolves over time, continuing to identify barriers and facilitators for promoting equitable access to treatment and care among people living with HIV. A qualitative research project, currently in the formative phase, will compliment quantitative analyses by taking a strengths-based approach to exploring experiences of engagement and re-engagement in HIV treatment among individuals who have experienced delayed treatment initiation or treatment interruptions.

Strengths and limitations of this study

- The SHAPE study collects in-depth data concerning the experiences and perspectives of people living with HIV in order to improve understanding of barriers and facilitators to linkage and retention in care. Findings will be used to inform policy and interventions for addressing inequities in HIV health care.
- Community-engaged research methods are integrated throughout the study. For example, peer research associates are involved in all phases of research from planning to data collection, analysis and knowledge dissemination.
- Purposive sampling was employed to obtain a sample that is representative of key sociodemographic characteristics of people living with HIV in the province of BC, however, challenges were experienced in reaching certain recruitment targets such as targets for young adults and mid-higher income groups.
- SHAPE participants were overwhelmingly engaged in HIV care at baseline, which may reflect sampling bias. Individuals who face the greatest barriers to accessing HIV care are likely to experience similar barriers to involvement in research, and therefore, to be underrepresented in our cohort.

Introduction

Modern treatment for HIV, antiretroviral therapy (ART), has been shown to greatly reduce HIV-related morbidity and mortality (1-3). The public health benefit of ART uptake and sustained adherence was first recognized in 2006 with the publication of mathematical models indicating that reduction in community viral load would prevent transmission and, subsequently, new cases of HIV(4). Since then mounting evidence based on clinical trials, cohort and population-based studies has led to widespread, international support for the concept of HIV Treatment as Prevention (5-8).

In 2010, the Seek and Treat for Optimal Prevention of HIV/AIDS (STOP HIV/AIDS) Program was initiated as a pilot intervention by the British Columbia (BC) Ministry of Health and the BC Centre for Excellence in HIV/AIDS. At this time, it was estimated 11 700 individuals living in BC were living with HIV, with 6.6 new HIV diagnoses per 100 000 population (300 cases) (9). In order to implement the principles of Treatment as Prevention in public health practice, the pilot intervention aimed to expand access to HIV testing and treatment to all clinically eligible individuals in two cities disproportionately impacted by the HIV/AIDS epidemic in the province of BC: Vancouver and Prince George. In 2013, the STOP HIV/AIDS Program was expanded throughout the province (9, 10). As the STOP HIV/AIDS program expands access to ART in BC, it is critical to monitor and evaluate socio-structural determinants of HIV health outcomes and respond to disparities in engagement in care; failure to do so could reinforce health inequities among people living with HIV (PLWH).

Despite availability of fully subsidized HIV health care and the optimization of treatment and testing since 2010 in BC, inequities in treatment access and retention persist, particularly among structurally marginalized populations. Women, Indigenous peoples, people who inject drugs (PWID), and youth have been found to have lower levels of ART adherence and engagement in HIV care (11-14). For example, previous studies have discovered that women and individuals <30 years old had higher attrition rates between successive stages of HIV treatment and care (14), younger PWID were less likely to receive ART (12), and up to 50% of PWID discontinued ART prematurely (13). Hence, there is a need to improve strategies for linking and retaining individuals in HIV care by considering socio-demographic, economic and behavioural vulnerabilities.

Rationale and objectives

The STOP HIV/AIDS Program Evaluation (SHAPE) study was initiated in 2016 to monitor progress of the provincial program to optimize testing, treatment, and prevention of HIV. The SHAPE study examines determinants of progression along the HIV cascade of care to generate information for addressing ongoing barriers to HIV health care. This information will be used to strengthen the implementation of BC's program for ART expansion. Funding is provided by the BC Centre for Excellence in HIV/AIDS and the BC Ministry of Health. Specific objectives of the SHAPE study are:

- i. To monitor the proportion of key groups (Indigenous peoples, youth, people who inject drugs and women) who are at different stages along the cascade of care

- (receiving care, receiving ART, adherent to ART and virologically suppressed) in the context of expanded HIV testing, treatment and care throughout the province.
- ii. To identify clinical, social and structural determinants of progression along the cascade of care.
 - iii. To assess the impact of community-based organizations, peer support and other supportive services on individuals' HIV-care experiences.
 - iv. To assess the impact of exposure to the STOP HIV/AIDS program among PLWH in BC.
 - v. To assess the beliefs, attitudes and behaviours associated with HIV treatment and care among PLWH in BC and how this impacts their experience in the cascade of care.

Cohort description

Between January 2016 and September 2018, PLWH who were BC residents, at least 19 years of age, able to provide informed consent and complete surveys in English were eligible to enrol in the SHAPE study. Purposive sampling was employed in order to obtain a sample that was representative of key sociodemographic characteristics including age, gender, Indigenous ethnicity¹, health authority of residence, sexual identity, and hepatitis C co-infection. Recruitment targets were developed by proportionally allotting a subsample size according to rates seen in the population of PLWH across the province. Estimates of the distribution of these characteristics were derived from the Drug Treatment Program (DTP), which distributes ART to all medically eligible residents of BC and serves as a longitudinal clinical database of all individuals who have been linked to HIV care. Recruitment remained open until there was adequate representation and appropriate power for analytical purposes.

Characteristics of SHAPE participants compared to the population of eligible non-respondents are shown in **Table 1**. Eligible non-respondents were defined as those who (a) accessed HIV care in the DTP during SHAPE's enrolment period (January 1 2016 – September 1 2018); (b) were at least 19 years of age on or before September 1 2018; (c) ever received ART from the DTP; and (d) did not participate in SHAPE.

Recruitment methods

Participants were recruited using a combination of strategies including the following:

- i. Community association driven recruitment involved developing partnerships with AIDS service organizations (ASOs) that offer essential resources for PLWH. Outreach and support services provided by ASOs typically relate to medication management, counseling and peer navigation, which are particularly important

¹ The term 'Indigenous' is used here to describe participants who self-identified as Indigenous in the baseline survey instrument. 'Indigenous' is used to collectively describe the Indigenous peoples of Canada, inclusive of those who identify as 'Aboriginal' or First Nations, Métis and Inuit. This term is used while acknowledging the diversity of cultures, languages and traditions that exist among Indigenous Canadians.

among individuals who are recently diagnosed and those who face structural barriers to accessing traditional health care services. Staff and volunteers at ASOs provided recruitment assistance by promoting the study among their clients through word-of-mouth, advertising on their websites, and displaying posters and postcards in their common spaces.

- ii. In order to reach individuals who do not utilize ASOs, posters and postcards were placed at clinics that specialize in HIV health care across BC, as well as public locations such as notice boards in community centres, coffee shops, and libraries. Health clinics serving a large number of PLWH were informed about the study and their staff encouraged to invite eligible patients to participate. Postcards were also included in HIV prescription refill packages that are picked up by patients at pharmacies throughout the province.
- iii. A study website was developed to provide information about the study to participants, health workers and ASO staff. The website includes information on participant eligibility, research aims, data collection procedures, ethics and consent processes, contact information and study results. Participants may access the study surveys via a secure link on the website.
- iv. Paid online advertisements were placed on Craigslist and social networking websites and mobile apps including Facebook, Grindr, and Scruff.

Cohort characteristics

A total of 644 eligible participants were recruited, of whom 139 (22%) identified as female; 101 (16%) self-reported Indigenous ethnicity; 368 (57%) identified as gay, bisexual or other men who have sex with men (gbMSM); and 273 (42%) reported a history of injection drug use (IDU), see **Table 1**. The median age of SHAPE participants at time of study enrolment was 51 (Q1-Q3: 43-57). Participants had been diagnosed with HIV for a median of 15 years prior to study enrolment (Q1-Q3: 8-21), and median years from first ART date to enrolment was 7 (Q1-Q3: 4-12). P-values evaluated differences between SHAPE participants and eligible non-respondents in the DTP. Chi-square and Fisher's Exact test were used for categorical variables and Wilcoxon Rank-Sum test for continuous variables.

Table 1 Comparison of SHAPE cohort participants with eligible non-respondents who were enrolled in the DTP

Variable	SHAPE participants (n=644)	Eligible non-respondents (n=7737)	P-value
Demographic Variables			
Age at baseline*, n (%)			<0.001
<30	25 (4%)	313 (4%)	
30 to <40	92 (14%)	1078 (14%)	
40 to <50	184 (29%)	1718 (22%)	
≥ 50	343 (53%)	4628 (60%)	
Gender, n (%)			<0.001
Woman	139 (22%)	1294 (17%)	
Man	496 (77%)	6394 (83%)	

Other	9 (1%)	49 (1%)	
Ethnicity, n (%)			<0.001
Caucasian	467 (73%)	3012 (63%)	
Indigenous	101 (16%)	674 (14%)	
Asian	18 (3%)	429 (9%)	
African, Caribbean and Black	4 (1%)	240 (5%)	
Other	54 (8%)	428 (9%)	
Missing value	-	2954	
History of injection drug use, n (%)	273 (42%)	2080 (33%)	<0.001
Missing value	96	1382	
Gay, bisexual or other MSM, n (%)	368 (57%)	3089 (52%)	0.010
Missing value	-	1776	

*As of study enrolment date for SHAPE participants; as of September 1st 2018 for eligible non-respondents.

As shown in Figure 1, SHAPE participants were enrolled from each health authority in the province. Health authorities are responsible for delivering health services to the population residing within corresponding geographic regions of the province. The majority of PLWH in the province reside in Vancouver Coastal Health (VCH) Authority, where BC's most populous city, Vancouver, is located. Health authorities outside of VCH include both urban and non-urban communities, but tend to be less densely populated and have a lower concentration of HIV-related services. Based on emerging research indicating that PLWH who reside in nonurban areas face increased vulnerability at each stage of the HIV cascade of care (15), we hypothesized that individuals outside of VCH may encounter unique barriers to accessing HIV services. Hence, it was a priority for the SHAPE research team to engage participants throughout BC, and in particular, to ensure representativeness of regions that have previously been under-represented in research.

(Insert Figure 1 here)

Figure 1 SHAPE cohort composition by BC health authority vs. total population of PLWH in BC*

*Based on those enrolled in the DTP who met the SHAPE cohort eligibility criteria, but were not enrolled in the study.

Data collection and follow-up

Participants completed a baseline survey and throughout the course of the study will complete two follow-up surveys, 18-months apart, collecting information concerning their HIV care experiences. Each survey takes approximately one hour to complete, and participants are compensated \$30 per survey for their time and expertise. Participants are offered the option of completing an online self-administered survey, or being interviewed by a peer research associate (PRA) by phone or in-person. These options were established to minimize financial, physical and social barriers to participation for individuals across the province.

Most participants (60.3%) chose to complete the baseline survey online, whereas 34.8% completed the survey in-person and 5.0% completed the survey over the phone. Of

participants that responded to a supplemental question regarding their recruitment into the study (n=198), 39.9% were recruited through AIDS Service Organizations (ASOs) and peer navigators, 20.7% heard about the study from physicians or health care workers, 13.1% responded to an informational postcard received with their HIV medication prescription, and the remainder were recruited via clinic bulletin boards, social media, or friends and family.

Prior to enrolling in the study, and before commencing each follow-up survey, participants consented to use of their anonymized survey data and linked clinical records, held by the BC Ministry of Health, for SHAPE research. Those who self-administered the survey online provided consent electronically via the study website. For phone and in-person interviews, consent was given verbally or in writing with assistance from a PRA or other study staff member. Participants also agreed to being contacted at a later date for follow-up or for clarification regarding any missing survey information.

Ethical approval for the SHAPE study was obtained from the University of British Columbia/Providence Health Care research ethics board (REB number: H15-01807).

Surveys

The SHAPE baseline survey is comprised of the following sections: (i) sociodemographics, (ii) current health and medical history, (iii) HIV testing and diagnosis experiences, (iv) linkage to care, (v) treatment, (vi) retention in care and resiliency, and (vii) awareness and experience of the STOP HIV/AIDS program. Development of the survey tool involved a literature review for the purpose of identifying key topic areas as well as variables and validated scales for inclusion in the survey. Selected scales include: a partial Household Food Security Survey Module (16), Short Form-6D for measuring health-related quality of life (17), Drug Abuse Screening Test (DAST-10) (18, 19), Alcohol Use Disorders Identification Test (AUDIT-C) (20, 21), Centre for Epidemiologic Studies Depression Scale (CES-D 10) (22, 23), Everyday Discrimination Scale (24, 25), 10-item Berger HIV Stigma Scale (26, 27), HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES) (28), Antiretroviral Medication Attitude Scale (29), Continuity of Care Scale (30), and Medical Outcomes Study Social Support Survey (MOS-SSS) (31-33). Follow-up surveys also examine resiliency and HIV disclosure concerns using the Resilience Scale (RS-14) (34, 35) and disclosure sub-scale of HIV/AIDS Quality of Life Scale (36, 37), respectively.

Surveys were pre-tested and improved upon with the expertise of PRAs, followed by a pilot phase in which additional community members assessed the survey for appropriateness and sensitivity. Participants are encouraged to provide feedback so that further improvements can be made to future surveys.

Linkages to clinical data

The SHAPE study benefits immensely from data linkage with the DTP. Anyone prescribed ART in the province of BC is automatically enrolled in the DTP, thereby enabling longitudinal follow-up of health records and laboratory results related to HIV treatment and virologic outcomes. Through the DTP database, the SHAPE study is able to link participant survey responses with routine clinical data collection such as CD4 cell counts,

viral load testing, specific ART regimen and changes, adherence and the provincial vital statistics registry. This linkage also enables the SHAPE research team to compare demographics and clinical indicators between SHAPE participants and non-participants.

Patient and public involvement

In accordance with GIPA/MIPA (Greater/Meaningful involvement of people living with HIV) principles, PLWH are meaningfully involved in all phases of the SHAPE study from planning to data collection, analysis and knowledge dissemination (38, 39). PRAs, who share lived experiences with study participants and are trained in research methods, facilitate recruitment and interview study participants. While past studies in the field of HIV have at times been limited by lower levels of community involvement outside of the process or data collection phase (39, 40), SHAPE PRAs are involved in identifying research priorities and questions, developing and evaluating data collection tools, analyzing data, and sharing findings. Knowledge dissemination strategies prioritize bringing findings back to communities and fostering dialogue that may guide research direction and further enhance collaboration.

Findings to date

The SHAPE study collects comprehensive data on social determinants of health and individual attitudes, experiences and behaviours that may impact HIV treatment outcomes. Table 2 depicts the SHAPE cohort by socio-demographic, health and behavioural characteristics.

Table 2 Characteristics of SHAPE participants (n=644) at time of study enrolment

Variable	Count, n(%) or median (Q1-Q3)
Education level	
Less than high school	147 (23%)
Completed high school	193 (30%)
Greater than high school	302 (47%)
Sexual orientation	
Heterosexual	240 (37%)
Gay or lesbian	315 (49%)
Other	89 (14%)
Annual income for year prior to enrolment (\$)	16,800 (13,200-30,720)
Currently employed	292 (45%)
Food insecure*	326 (51%)
Currently receiving housing subsidy	232 (36%)
Incarceration history	
Incarcerated within the past year	19 (3%)
Yes, but not within the past year	209 (32%)
Never incarcerated	416 (65%)
History of homelessness	
Currently homeless	27 (4%)
Yes, in the past year but not now	65 (10%)

Yes, but not in the past year	231 (36%)
Never homeless	321 (50%)
Mental illness diagnosis, ever	341 (53%)
CES-D 10 (depression) score	9 (5-16)
Significantly depressed†	312 (48%)
MOS-SSS (social support) score‡	65 (42-86)
AUDIT-C (alcohol use) score	2 (0-5)
Hazardous alcohol use§	247 (38%)
HIV stigma score	48 (33-63)
Use of supportive services since HIV diagnosis	
Peer navigation	225 (37%)
ASOs	451 (71%)
Food bank/meal program	269 (44%)
Other	221 (36%)
Clinical Variables	
Hepatitis C co-infection, n (%)	215 (33%)
Missing value	-
Years since HIV diagnosis^, median (Q1-Q3)	15 (8-21)
Viral load testing rate (tests/year during year prior to baseline^), median (Q1-Q3)	4 (3-5)
Years on ART^, median (Q1-Q3)	7 (4-12)
ART interruption ever^~, n (%)	319 (50%)
Missing value	10

*Food insecure was defined as often or sometimes unable to afford to eat balanced meals in the past 12 months.

†The CES-D 10 measures depressive symptomology using a shortened 10-item scale that has been validated for use among PLWH in BC (22). The possible range is 0-30 with scores ≥ 10 indicating the presence of significant depressive symptoms.

‡This is an overall support index calculated by transforming scores from a 19-item scale to have a range of 0-100; higher scores indicate greater social support. Instructions for scoring and interpreting the MOS-SSS are available at www.rand.org/health-care/surveys_tools/mos/social-support.html

§This validated and shortened version of the AUDIT scale has a possible range of 0-12 with scores > 8 indicating hazardous alcohol use.

||HIV stigma scores have been reparametrized to have a range of 0-100 with higher scores indicating higher levels of perceived stigma. Scores are calculated based on a shortened and validated 10-item version of the scale, which includes items from all four sub-scales of the original 40-item scale: personalized stigma, disclosure concerns, negative self-image, and concern with public attitudes (27).

^As of study enrolment date for SHAPE participants; as of September 1st 2018 for eligible non-respondents.

~ART interruption defined as 90 days or longer off ART among individuals who have ever initiated treatment. A limitation of this assessment is that we lack information concerning clinical trial status of SHAPE participants and non-respondents, which may inflate the appearance of treatment interruptions in our data.

Since the SHAPE cohort completed enrolment in September 2018, several studies have used baseline survey data to examine social determinants of progression along the cascade of care. One recently presented preliminary analysis used baseline survey responses in conjunction with longitudinal clinical data to assess the relationship between social support, which was self-reported using the MOS-SSS (33), and engagement in HIV treatment. Results from multivariable logistic regression modelling demonstrated that

social support is protective against interruptions in ART. After adjustment for known confounders, each 10% increase in MOS-SSS score was found to reduce the likelihood of experiencing ART interruptions by 16% (41). Other recent studies include characterization of the distribution of HIV-related stigma among individuals accessing ART, and a prospective analysis of changes in clinical outcomes – including viral rebound, ART interruption, and sustained ART adherence – since study enrolment. Respective results indicated that age, city size, IDU experience, violence and mental health disorder diagnosis are independently associated with HIV-related stigma (42), and that despite few occurrences of viral rebound or less the optimal ART adherence among SHAPE participants, disparities exist based on key characteristics related to age, ethnicity, geography, socio-economic status and incarceration, among other facets of structural marginalization (43).

In addition, preliminary findings disseminated via conference presentations describe prevalence and predictors of viral suppression in the SHAPE cohort. Our research indicates that despite high levels of engagement along the cascade of care among SHAPE participants (>80% of participants at each stage) (Figure 2), inequities in treatment outcomes persist among certain vulnerable groups. Among PLWH in BC, younger adults, individuals with a history of IDU and those who are currently homeless are at greater risk for failing to achieve viral suppression (44). Moreover, age and HIV risk type were identified as determinants of time to suppression, with younger age and identification with a risk group other than gbMSM predicting longer time between initiation of ART and viral suppression (45). These findings corroborate previous research on determinants of viral suppression (46-51), and suggest the need for targeted supports to address health disparities among PLWH in BC.

(Insert Figure 2 here)

Figure 2 HIV cascade of care among SHAPE participants at time of study enrolment (n=644).

‘Diagnosed’: first instance of detectable viral load, a reported AIDS-defining illness, or ART dispensation.

‘Linked’: first instance of HIV-related service (viral load/CD4 test or ART dispensation) ≥ 30 days following HIV diagnosis date.

‘Retained’: viral load/CD4 test or at least two ART dispensations ≥ 3 months apart within 12 months prior to baseline survey.

‘On ART’: at least two ART dispensations ≥ 3 months apart within 12 months prior to baseline survey.

‘Adherent’: > 80% adherence within 12 months prior to baseline survey.

‘Suppressed’: undetectable viral load (<200 copies/ml) ≥ 3 months within 12 months prior to baseline survey.

Future research will seek to quantify differences in clinical outcomes and experiences of accessing HIV care between SHAPE participants who were diagnosed with HIV prior to and during the era of the STOP HIV/AIDS program. Studies will also continue to examine how engagement in care evolves over time and to identify barriers and facilitators for

1
2
3 promoting equitable access to HIV treatment and care. These quantitative analyses will be
4 complimented by a qualitative research project, which is currently in the formative and
5 planning stage. Qualitative work will consist of two components: (1) semi-structured
6 interviews of health care providers and PLWH that take a strength-based approach to
7 examining experiences of engagement and re-engagement in HIV treatment; and (2)
8 supporting the development of an Indigenous-led research program that explores the
9 knowledge and experiences of Indigenous peoples living with HIV.
10
11

12 Knowledge dissemination strategies utilized by the SHAPE research team include
13 traditional avenues such as academic conferences and manuscripts, and community-based
14 knowledge translation and exchange activities. Methods of bringing research back to
15 communities include presentations and discussions held at our research sites, and
16 producing plain language summaries; newsletters and information sheets.
17
18

19 **Strengths and limitations**

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21
22 The SHAPE cohort provides a unique source of information on HIV care experiences
23 among PLWH in BC. The comprehensive survey tool allows for quantitative assessment
24 of behaviours, beliefs and attitudes related to HIV testing, treatment and care, which is
25 further contextualized by social, structural and medical factors reported by participants.
26 Moreover, linkage of survey responses with longitudinal clinical data allows for analysis
27 of the impact of HIV care experiences on long-term cascade of care outcomes, such as
28 experiences of HIV treatment interruptions, changes in ART regimens, sustained viral
29 suppression or viral rebound.
30
31

32 Purposive sampling methods were used to ensure that findings would be representative of
33 the experiences of PLWH throughout BC who have diverse sociodemographic and clinical
34 characteristics. An important strength of the study is the representativeness that was
35 achieved by geographic region, which was defined by Health Authority of residence.
36 However, challenges were experienced in reaching certain enrolment targets. Younger
37 adults aged 19-29 and mid-higher income groups were difficult to recruit. Moreover,
38 SHAPE is a sample of individuals with high levels of engagement in care at the time of
39 baseline interview; therefore, PLWH who face the most pervasive barriers to accessing
40 HIV treatment and care may be underrepresented.
41
42
43

44 **Collaboration**

45
46 For further information on the SHAPE study, please contact the principal investigator, Dr.
47 Rolando Barrios (rbarrios@cfenet.ubc.ca) or the study coordinator, Clara Tam
48 (ctam@cfenet.ubc.ca). We welcome feedback and ideas, including proposals for
49 collaboration on data analyses or knowledge translation and exchange activities.
50
51

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1
2
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10
11

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13 and drafted the present manuscript with contributions from PS, LW, BB, KS, DM, TW
14 and CT. SG and TW collected data, and LW conducted statistical analyses. All authors
15 critically reviewed and approved the manuscript.
16
17

18 **Data sharing statement:** The data for this study cannot be made available due to
19 restrictions from research ethics and contractual obligations.
20
21

22 **Conflicts of interest:** None to declare.
23

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26
27

28 **References**

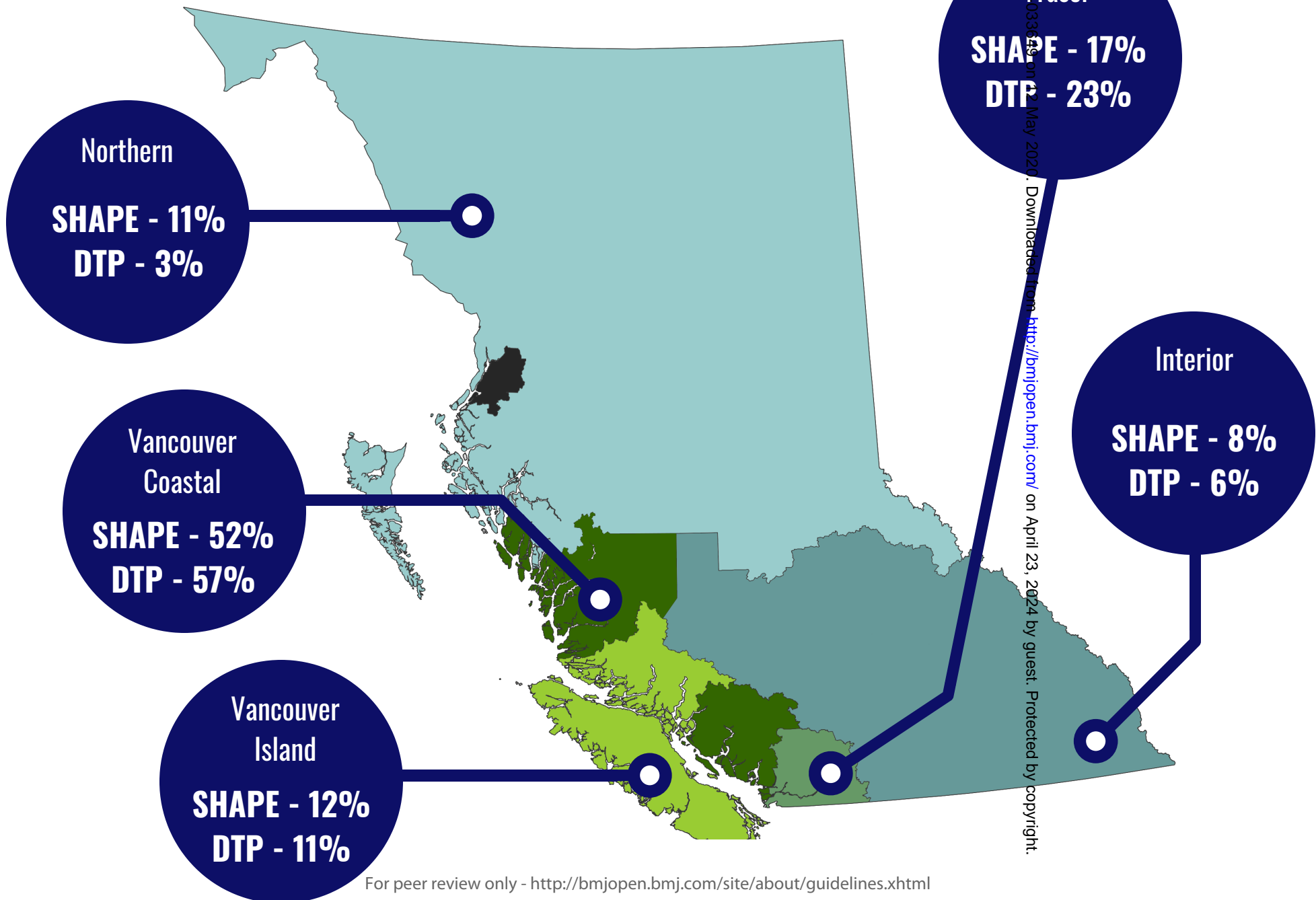
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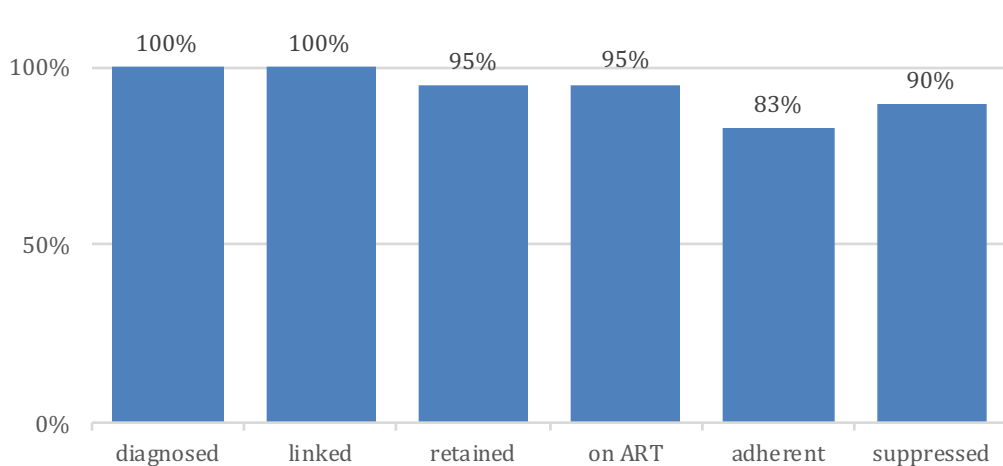
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■ % of participants in each stage of care