VALIDATING A SELF-REPORT MEASURE FOR ASSESSING VIRAL SUPPRESSION IN OBSERVATIONAL STUDIES: AN ANALYSIS OF LINKED SURVEY AND CLINICAL DATA FROM THE CANADIAN HIV WOMEN'S SEXUAL AND REPRODUCTIVE HEALTH COHORT STUDY

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BACKGROUND

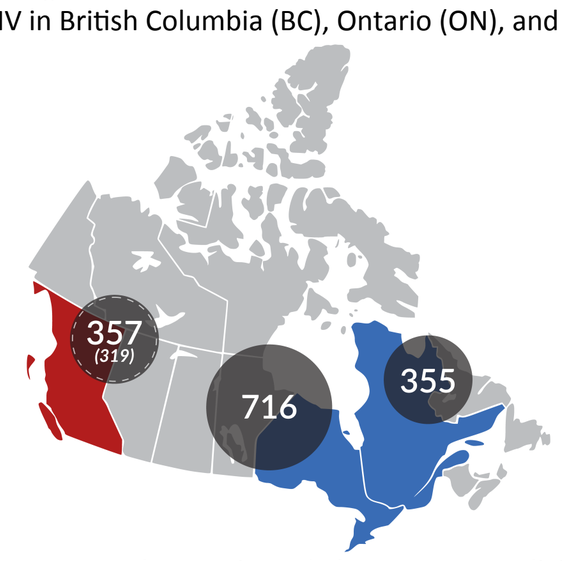
Treatment as Prevention (TasP) seeks to reduce HIV morbidity, mortality, and transmission by providing treatment in people living with HIV to suppress their viral load (VL). This is an important component of the UNAIDS 90-90-90 goal (90% diagnosed, 90% on treatment, 90% virally suppressed) to reduce the burden of HIV/AIDS worldwide.

Assessment of viral suppression is essential towards evaluating progress on achieving TasP-related goals. Laboratory technologies are undoubtedly the gold standard for measuring VL in clinical practice. However, in the absence of linkage to clinical data, observational studies rely on self-report in surveys and it is unclear whether this is a valid method for assessment.

Study objective: We assessed the validity of a self-reported measure of undetectable VL to assess viral suppression among women living with HIV.

METHODS

The **Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS)** is a longitudinal community-based research study enrolling over 1,400 women living with HIV in British Columbia (BC), Ontario (ON), and Québec (QC), Canada.



BC, ON, and QC are the three provinces with the largest number of people living with HIV in Canada.

To date, our cohort includes 357 women living with HIV from BC, 716 from ON, and 355 from QC.

This analysis included BC participants enrolled between Aug 27, 2013 and Mar 13, 2015 (n=340). After exclusions, final sample size was 319.

Peer Research Associates (who are women living with HIV) administer a comprehensive, online questionnaire to participants (≥16 years) at baseline and every 18-months, collecting socio-demographic, behavioral, and clinical information including VL data.

In this analysis:

- **Study Population:** Baseline survey data were analyzed for participants enrolled in BC, the only study province where linkage to clinical data was possible through the Drug Treatment Program at the BC Centre for Excellence in HIV/AIDS (a population-based registry capturing 100% of VL in BC).
- **Outcome:** Self-reported undetectable VL was assessed by the survey question: "What was your most recent viral load, undetectable (i.e. below 50 copies/mL) or detectable (i.e. over 50 copies/mL)?" Laboratory measurements of VL < 50 copies/mL (closest to and before the study visit) were the gold standard criterion for validity analyses.
- **Statistical Analysis:** We measured positive and negative predictive values (PPV, NPV) and likelihood ratios (LR+, LR–) of self-reported undetectable VL.

RESULTS

Of 340 BC participants enrolled at the time of analysis, 99% were linked to BC-CfE clinical data. Those remaining unlinked (n=2), missing self-report VL (n=18), or both (n=1) were excluded. Among the remaining 319 women included in this analysis:

- 99% self-reported accessing HIV medical care in the past year
- 91% self-reported currently taking antiretroviral therapy
- 85% self-reported having undetectable VL
- 82% had laboratory data indicating viral load < 50 copies/mL

Table 1. Participant Characteristics at Baseline (n=319)

	n(%)
Age, median (IQR)	45 (IQR: 37-51)
Gender identity	
Woman	311(97)
Trans woman/Two-spirited/Gender Queer/Other	8(3)
Ethnicity	
Indigenous	143(45)
Caucasian	116(36)
African/Caribbean/Black Canadian	26(8)
Other	34(11)
Sexual orientation	
Heterosexual	262(82)
Lesbian/Gay/Queer/Two-spirited/Bisexual/Questioning	44(14)
Other	13(4)
>=High School Education (Yes)	252(79)
<$20,000 Annual Household Income (Yes)	201(76)
Incarcerated in past 12 months (Yes)	31(10)
Illicit drug use in past 3 months (Yes)	112(35)
Patient at Oak Tree Clinic (an HIV specialty clinic for women) (Yes)	125(49)

RESULTS (CONTINUED)

Table 2. Predictive values and likelihood ratios of self-reported undetectable VL

a. Overall

		Laboratory-confirmed VL (from BC-CfE)[1]		PPV (95% CI)	NPV (95% CI)	LR+ (SE)	LR- (SE)
		VL <50 copies/mL	VL >=50 copies/mL				
Self-report VL (from CHIWOS)	Undetectable (i.e. <50 copies/mL)	252	18	93.3 (89.7-96)	77.6 (63.4-88.2)	0.20 (0.06)	12.4 (3.2)
	Detectable (i.e. >50 copies/mL)	11	38				

1. Gold Standard (True diagnosis)

b. Stratified by population

	PPV (95% CI)	NPV (95% CI)	LR+ (SE)	LR- (SE)
Ethnicity				
Indigenous	93.1(86.9-97.0)	**85.2 (66.3-95.8)**	0.16 (0.07)	**12.35 (4.33)**
Caucasian	93 (86.1-97.1)	**68.8 (41.3-89.0)**	0.34 (0.12)	**9.82 (3.94)**
African/Caribbean/Black	90.9 (70.8-98.9)	**75 (19.4-99.4)**	0.28 (0.24)	**8.25 (6.05)**
Other	96.9 (83.8-99.9)	**50 (1.3-98.7)**	0.52 (0.37)	**16 (19.39)**
Education				
< High school	94.6 (84.9-98.9)	**66.7 (34.9-90.1)**	0.35 (0.14)	**12.22 (7.30)**
>=High school	93.0 (88.8-96.0)	**81.08 (64.8-92.0)**	0.20 (0.069)	**11.62 (3.04)**
Illicit drug use in past 3 months				
Yes	90.4 (81.9-95.8)	**79.3 (60.3-92.0)**	0.23 (0.08)	**9.23 (2.87)**
No	96.2 (91.3-98.7)	**73.3 (44.9-92.2)**	0.28 (0.12)	**19.01 (8.87)**
HIV Clinic				
Oak Tree Clinic	96.1 (90.3-98.9)	**87.0 (66.4-97.2)**	0.13 (0.07)	**22.17 (11.01)**
Non-Oak Tree Clinic	94.8 (89.0-98.1)	**58.8 (32.9-81.6)**	0.43 (0.13)	**11.27 (5.03)**

Interpreting Predictive Values:

- Overall, the PPV reveals that 93% of women who self-reported being undetectable truly were.
- Overall, the NPV reveals that 77.6% who reported being detectable truly were.
- No significant differences in PPV were observed by population groups, suggesting our self-report measure is a valid method of assessment of undetectable VL among diverse women living with HIV, in settings where true prevalence of VL suppression is high (i.e., 82% were virally suppressed as measured through laboratory data). In contrast, variations in NPV were observed by population groups.

Interpreting Likelihood Ratios:

- Likelihood ratios tell us **how much we should shift our suspicion** for a particular self-report.
- **LR+** (=sensitivity/1-specificity) indicates how much more likely is self reporting undetectable in a person **with** suppression (true positives), compared to a person **without** suppression (false positives). In other words, LR+ corresponds to the clinical concept of "ruling-in disease", and **tells us how much to increase the probability of suppression if the self-report is positive (undetectable).**
- **LR-** (=1-sensitivity/specificity) indicates how much more likely is self-reporting detectable in a person **with** suppression (false negatives), compared to a person without suppression (true negatives). In other words, **LR-** corresponds to the clinical concept of "ruling-out disease", and **tells us how to much to decrease the probability of suppression if the self-report is negative (detectable).**
- **In this study:** LR+ is low (0.1-0.5), providing minimal increase in the likelihood of suppression. This is because the true rate of viral suppression is so high (82%). However, LR- is high (9-22), providing a large and conclusive decrease in the likelihood of suppression. In other words, if a participant reports being detectable, we can be fairly certain that she is *not* supressed (i.e., we can confidently "rule-out" suppression).

CONCLUSIONS

A brief self-reported measure assessing undetectable VL strongly predicted true viral suppression among a cohort of women living with HIV in BC with a high prevalence of laboratory-confirmed viral suppression**.** Information provided by a self-report of detectable was much more informative to ruling in or out suppression. This measure can be used in research settings without laboratory data to assess TasP-related goals.

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Étude sur la santé sexuelle et reproductive des femmes vivant avec le VIH au Canada
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