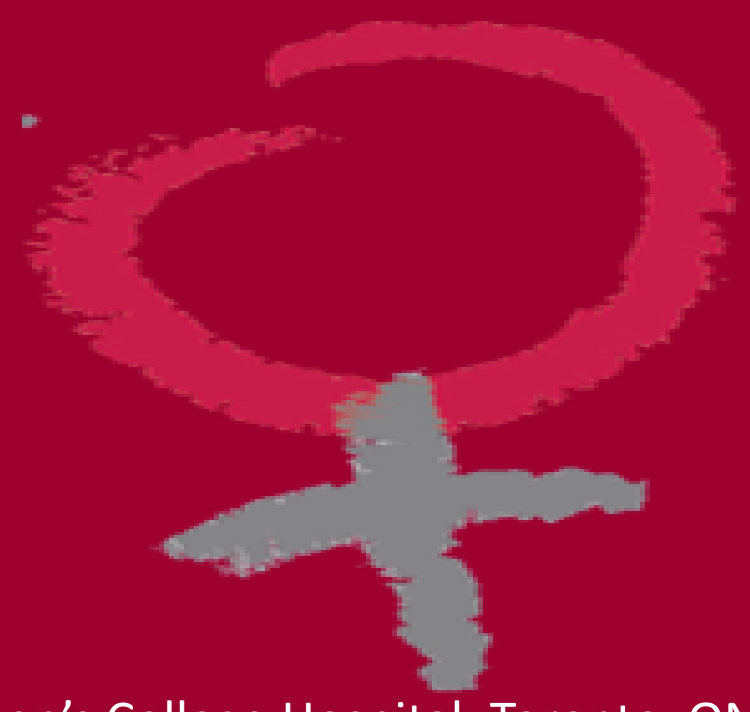# Validation of self-reported combination antiretroviral therapy (cART) regimens in a multi-site Canadian cohort of women living with HIV

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BACKGROUND

- Most observational studies reporting specific combination antiretroviral therapy (cART) regimens among people living with HIV use **self-reported data**

- **Objective:** To assess the validity of self-reported cART regimens, CD4 counts and HIV viral loads among women living with HIV in British Columbia (BC) and Quebec (QC), Canada

METHODS

- Questionnaire data from Wave 1 (2013-2015) of the **Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS)** was linked with clinical databases from the the British Columbia Centre for Excellence in HIV/AIDS and the Réseau Informatique du SIDA du Québec, for BC and QC respectively

- The primary outcome was self-reported cART, which was assessed by asking: "Which antiretrovirals are you currently taking?"

- We measured sensitivity, specificity, and positive and negative predictive values (PPV, NPV) of self-reported values for each antiretroviral agent, and the accuracy of self-reported cART, most recent CD4 counts (<200, 200-500, or >500 cells/mm^3) and viral loads (<50, >50 copies/mL) according to clinical databases

RESULTS

- Of 1422 CHIWOS participants, we excluded women:
  - From Ontario (n=490)
  - Not currently on cART (n=247)
  - Who did not know their cART regimens (n=71)
  - Who could not be linked to clinical databases (BC n=2/356; QC n=163/353)
  - → **N = 449** for analyses (n=146/449 (32.5%) from QC; n=303/449 (67.5%) from BC)

Table 1: Characteristics of study population at 1st CHIWOS questionnaire

Data from clinical databases		Total	Percentage (%)
Current CD4 cell count (cells/mm^3)	<200	41	9.1
	200-500	173	38.5
	>500	235	52.3
VL < 50 copies/mL	Yes	391	87.1
	No	58	12.9
Number of active agents in cART regimen	2	1	0.2
	3	407	90.7
	4	37	8.2
	5	4	0.9
Number of pills/day in cART regimen	1	91	20.3
	2	185	41.2
	3	99	22.1
	4	31	6.9
	5	38	8.5
	6	4	0.8
	7	1	0.2

- 20% reported taking a single-tablet regimen, 41% two-pill, 22% three-pill, and 17% >four-pill regimens
- 91% of cART regimens had three active agents

Table 2: Accuracy of self-reported CD4 count, HIV viral load and cART regimen

	Accuracy of self-reported data compared to clinical databases	
	Percentage (%)	95% confidence interval
Current CD4 category	80.8	76.6 – 84.5
By CD4 category of clinical database		
<200 cells/mm^3	66.7	49.8 – 80.9
200-500 cells/mm^3	73.4	65.7 – 80.2
>500 cells/mm^3	88.9	83.9 – 92.9
Current HIV viral load category	92.4	89.5 – 94.7
By HIV viral load category of clinical database		
<50 copies/mL	97.9	95.9 – 99.1
≥50 copies/mL	51.9	37.6 – 66.0
Complete ART regimen	78.8	74.8 – 82.5
By number of agents in cART regimen (excluding boosters)		
2 to 3	88.7	85.3 – 91.6
4 or more	68.3	51.9 – 81.9
By number of pills per day in cART regimen		
1	94.5	87.6 – 98.2
2 to 3	89.8	85.7 – 93.1
4 or more	73.0	61.4 – 82.7

- The accuracy of self-reported CD4 counts and viral loads were 80.8% and 92.4%, respectively

- 78.8% (95% CI 74.8-82.5) self-reported their complete cART regimen accurately

- Accuracy **decreased** with a higher number of active agents and pill burden

- The **overall sensitivity, specificity, PPV and NPV** per cART agent were 91.3% (95% CI 89.9-92.6), 98.1% (95% CI 97.7-98.4), 92.4% (95% CI 91.0-93.6) and 97.8% (95% CI 97.4-98.1), respectively

CONCLUSIONS

- Self-reported antiretroviral agents strongly predicted accurate cART regimens among Canadian women living with HIV

- Accuracy of self-reported CD4 counts and viral loads was also very good

- Self-reported cART, CD4 counts and viral loads are valid measurement methods in research when clinical or laboratory data are unavailable

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