PEOPLE LIVING WITH HIV IN STOP THE SPREAD OTTAWA: IMMUNE RESPONSE TO SARS-CoV-2 VACCINATION

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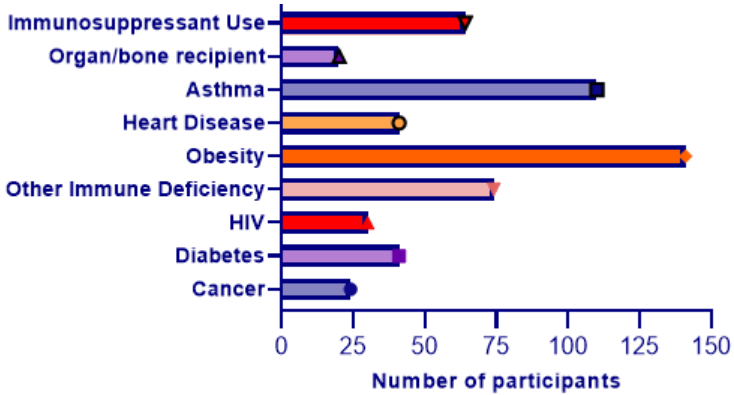
Contact: ecollins@ohri.ca Conflict of interest disclosure: I have no conflicts of interest

BACKGROUND

- Individuals with immunocompromising conditions may not elicit sufficient immune response to vaccination.
- Data on SARS-CoV-2 vaccine immunogenicity in people living with HIV (PLWH) remains sparse.
- Stop the Spread Ottawa (SSO) is a 1000-member cohort study on SARS-CoV-2 immune response in participants at risk of exposure and/or severe disease. PLWH (n=31) comprise an important subgroup.
- Since October 2020, all participants submit monthly blood and saliva samples for 10 months.

Figure 1. Health conditions of participants in Stop the Spread Ottawa (n=1032)



AIMS

1) Describe the PLWH subgroup in Stop the Spread Ottawa.

2) Present results from interim analysis: IgG anti-spike response post SARS-CoV-2 vaccination in people living with HIV and other immunocompromising conditions

Study Design

Baseline blood draw

For 10 months: 1) All participants submit monthly dried blood spot and saliva samples. 2) Participants with previous infection attend monthly bloodwork.

Participants who test positive or are vaccinated for COVID-19 during the study are asked to attend monthly bloodwork.

End of 10 month study: 300 participants will extend for 2 years

People living with HIV in Stop the Spread Ottawa

Table 1: Baseline characteristics of participants with HIV in Stop the Spread Ottawa (n=31)

Age, years	Sex, male	Years living with HIV	Current antiretroviral therapy	Fully suppressed viral load	Obesity	Current smokers
Median (IQR): 60 (10.8) Range: 32-71	N(%): 27 (87.1)	Median (IQR): 15 (19) Range: 5-40	N(%): 31 (100)	N(%): 30 (96)	N(%): 3 (9.7)	N(%): 4 (12.9)

INTERIM ANALYSIS: IgG anti-spike response following SARS-CoV-2 vaccination in immunocompromised patients

- **Bayesian logistic regression** was used to measure the association between immunocompromising condition(s) **(HIV, cancer, other immune deficiency, and/or use of immunosuppressants)**, and seronegative (IgG anti-Spike) rate ≥ 14 days post SARS-CoV-2 vaccination.
- Included participants with ≥ 1 dried blood spot (DBS) result available ≥ 14 days post-vaccination **(n=285).**
- **Propensity score matching** was used to balance potential confounders identified a priori.
- **Multiple imputation** was used for missing data.

Hypothesis: ≥ 10% participants with immunocompromising conditions will have ≥ 1 seronegative result post-vaccination for SARS-CoV-2.

H0: $\theta<0.10$ vs HA: $\theta \geq 0.10$

Model:

$Y \sim$ binomial $(285,\theta)$

$\theta \sim$ beta $(16.83, 93.84)$

$\theta \sim$ normal $(-1.76, 0.266)$

Table 2: Baseline characteristics of participants included in interim analysis, by pre-vaccine immune status, prior to matching (n=285)

	Controls (n=234)	Immunocompromising condition(s) (n=51)
Mean age, years (SD)	42.35 (12.74)	57.02 (12.51)
Sex, male (%)	53 (22.7)	23 (45.1)
Race, white (%)	206 (88.4)	46 (90.2)
Type of immune deficiency, (%) Cancer HIV Other immune deficiency Immune suppressant use	 --- --- --- ---	 10 (19.6) 9 (17.6) 30 (58.8) 26 (53.1)
Days between DBS collection date and date of 2nd SARS-CoV-2 vaccine dose	55.52 (35.59)	66.96 (33.23)
Days between 1st and 2nd SARS-CoV-2 vaccine doses	50.42 (24.41)	48.35 (22.42)
ELISA serology results Mean anti-s IgG scaled luminescent value, (SD) Mean anti-s IgG scaled to cut-off (SCO), (SD)	 1.84 (0.56) 10.03 (3.75)	 1.38 (0.8) 8.7 (5.16)
Participants with ≥1 anti-S IgG seronegative result, (%)	13 (5.6)	7 (13.7)

CONCLUSIONS

1) Adjusting for confounders, participants with immunocompromising conditions were **2.14 [0.374, 12.22]** times more likely to have ≥ 1 seronegative dried blood spot result ≥ 14 days post-vaccination.

2) There is evidence to support rejecting the null of <10% seronegative prevalence post SARS-CoV-2 vaccination among participants with immunocompromising conditions.

FUTURE DIRECTIONS

1) Analysis will be repeated when more results are available.

2) Combined analyses with similar studies is underway.

3) Subgroup analyses will compare seronegativity rate between groups with different immunocompromising conditions.

4) The 24-month extension for 300 participants will maximize opportunities to characterize SARS-CoV-2 immune and vaccine efficacy, and detect emerging variants.

LIMITATIONS

- Reliance on self-reported data.
- Limited results available.
- Results driven by prior.

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HALTE À LA PROPAGATION STOP THE SPREAD OTTAWA