

# HIV Incidence Among AIDSVAX<sup>®</sup> B/B Vaccine Trial Participants in Montreal, Toronto and Vancouver

**Keith Chan<sup>1</sup>**, Lampinen T<sup>1</sup>, Logue K<sup>3,4</sup>, Vincelette J<sup>2</sup>,  
Willoughby B<sup>5</sup>, Linnen K<sup>3,4</sup>, Roy JL<sup>2</sup>, McLean N<sup>1</sup>, Gallagher  
L<sup>5</sup>, Popovic V<sup>6</sup>, Fikre M<sup>3</sup>, Young J<sup>6</sup>, Hogg RS<sup>1</sup>, Remis RS<sup>3</sup>.

1. BC Centre for Excellence in HIV/AIDS, Vancouver, BC.; 2. Centre hospitalier de  
l'Universite de Montreal, Montreal, PQ; 3. University of Toronto, Toronto, Ontario; 4.  
cascAIDS Research Inc., Toronto, Ontario; 5. Virion Health, Vancouver, BC.; 6. VaxGen  
Inc., Brisbane, CA, USA.



# Objectives:

- Estimate HIV incidence at 36 months among Canadian trial participants in the first phase III HIV preventive vaccine efficacy trial
- Determine sexual risk behaviours associated with HIV seroconversion



# Methods:

## CANVAC Consortium:

- Examine behavioural determinants and epidemiological aspects related to the vaccine trial
- Focus was trends in sexual behaviours, loss to follow-up, comparisons with findings from other studies of men who have sex with men



## Vaccine Trial:

- Randomized, double-blind, placebo-controlled 3-year study
- Evaluate efficacy of the bivalent rgp120/HIV-1 vaccine (AIDSVAX<sup>®</sup> B/B).
- Sites in Canada were Montreal, Toronto and Vancouver
- Enrollment took place from July-October 1999



- Eligible were HIV- men who had a male anal sex partner in the previous 12 months
- Injection drug users and men in a monogamous relationship were ineligible
- Vaccinated in a 2:1 ratio of vaccine: placebo at 0, 1, 6, 12, 18, 24 and 30 months
- At each study visit, risk reduction counseling was provided and a questionnaire about risk behaviours in the previous 6 months was administered



## Statistical Analysis:

- HIV incidence: number of infections / follow-up time
- 95% Confidence Intervals based on Poisson distribution
- Risk factors for seroconversion, including site, age and sexual behaviours, were examined using Cox Proportional Hazards model with time dependent covariates



# Results:

## Enrollment and Final Disposition of Participant

	No. Participants	Seroconverters	Lost to Follow-up
Overall	291	19 (7%)	42 (14%)
Montreal	99	3(3%)	5 (12%)
Toronto	87	6(7%)	22 (25%)
Vancouver	105	10 (10%)	15( 14%)



## HIV Incidence at 36 months

	Average Follow-up (months)	Incidence (%ppy)	95% CI
Overall	31.9	2.45	1.35-3.56
Montreal	35.2	1.03	0.00-2.20
Toronto	29.0	2.86	0.57-5.14
Vancouver	31.3	3.65	1.39-5.91



## Risk for Seroconversion: univariate results

Variable	Hazard Ratio	95% CI	p-value
Montreal	1.00	-	-
Toronto	3.05	0.75-12.44	0.120
Vancouver	3.65	1.03-13.84	0.045
Age	0.95	0.91-1.01	0.074



## Risk for Seroconversion: HIV+ Partners

Variable	Hazard Ratio	95% CI	p-value
Unprotected anal insertive intercourse			
No	1.00	-	-
Yes	2.58	0.89-7.48	0.081
Unprotected anal receptive intercourse			
No	1.00	-	-
Yes	1.87	0.42-8.19	0.406
Any unprotected anal intercourse			
No	1.00	-	-
Yes	2.25	0.78-6.46	0.132



3 separate models, site adjusted

## Risk for Seroconversion: HIV? Partners

Variable	Hazard Ratio	95% CI	p-value
Unprotected anal insertive intercourse			
No	1.00	-	-
Yes	4.48	1.81-11.10	0.001
Unprotected anal receptive intercourse			
No	1.00	-	-
Yes	9.22	3.59-23.70	<0.001
Any unprotected anal intercourse			
No	1.00	-	-
Yes	5.62	2.24-14.08	<0.001



3 separate models, site adjusted

## Risk for Seroconversion: HIV+ or ? Partners

Variable	Hazard Ratio	95% CI	p-value
Unprotected anal insertive intercourse			
No	1.00	-	-
Yes	3.32	1.33-8.27	0.010
Unprotected anal receptive intercourse			
No	1.00	-	-
Yes	6.23	2.51-15.46	<0.001
Any unprotected anal insertive intercourse			
No	1.00	-	-
Yes	4.19	1.63-10.72	0.003



3 separate models, site adjusted

## Risk for Seroconversion: HIV- Partners

Variable	Hazard Ratio	95% CI	p-value
Unprotected anal insertive intercourse			
No	1.00	-	-
Yes	0.46	0.11-1.99	0.297
Unprotected anal receptive intercourse			
No	1.00	-	-
Yes	1.35	0.45-4.07	0.599
Any unprotected anal receptive intercourse			
No	1.00	-	-
Yes	1.43	0.54-3.76	0.473



3 separate models, site adjusted

## Risk for Seroconversion: Adjusted Model

Variable	Hazard Ratio	95% CI	p-value
Montreal	1.00	-	-
Toronto	3.47	0.83-14.63	0.090
Vancouver	4.54	1.14-18.15	0.033
Unprotected anal receptive intercourse (HIV? partner)			
No	1.00	-	-
Yes	8.54	3.30-22.06	<0.001
Unprotected anal insertive intercourse (HIV+ partner)			
No	1.00	-	-
Yes	2.08	0.70-6.17	0.190



# Conclusion:

- Overall seroincidence of 2.45% per person year
- Significant site differences (Montreal < Toronto < Vancouver)
- These differences may reflect underlying difference in the method of recruitment, sexual behaviours and networks or the differential impact of HIV prevention strategies in these cities



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