1964. Predictive Factors for HIV Seroconversion Among Women Attending an Urban Health Clinic in the South: A Matched Case–control Study in Atlanta, GA

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Session: 229. The End of AIDS Starts with Prevention

Saturday, October 5, 2019: 11:15 AM

Background. In 2019, Fulton County, GA was named one of 48 priority "hotspots" to target in renewed efforts to end the HIV epidemic in the United States. To more accurately predict women at greatest risk for HIV, we conducted an individually matched case–control study among women who attended a Fulton County health clinic to identify risk factors associated with HIV seroconversion.

Methods. We obtained data about women who sought care at Fulton County Board of Health Sexual Health Clinic (SHC) between 2011 and 2016. Cases were women with at least one clinician-assisted visit (CAV) at the SHC prior to HIV diagnosis date. Controls were women who visited the clinic in this same period but remained HIV negative. Controls were individually matched to cases in a 2:1 matching ratio on race, age at first CAV, and date of first CAV. Conditional logistic regression was used to develop a model for predicting probability of and identifying risk factors for HIV seroconversion.

Results. Of 18,281 women who were HIV negative at their first visit to the SHC between 2011 and 2016, 110 (0.6%) seroconverted before 2018. Of these, 80 (73%) had a CAV prior to HIV diagnosis. Using these 80 cases and 160 matched controls, having a history of gonorrhea, multiple gonorrhea episodes, a history of syphilis, a greater number of sex partners in the past 2 months, anal sex, history of injection drug or crack cocaine use, a history of exchanging drugs/money for sex, and heterosexual sex with more than one sex partner in the last month were associated with HIV seroconversion in bivariate analyses. After conducting backward selection from a fully adjusted model, predictors remaining were: having a history of syphilis (OR = 4.9, 95% CI: 1.4, 16.9), anal sex (OR = 2.9, 95% CI: 1.0, 8.3), and injection drug or crack cocaine use (OR = 34.8, 95% CI: 3.7, 328.1). Women having all three risk factors were six times more likely to seroconvert compared with matched controls without these risk factors.

Conclusion. Our results offer clinical insights into which women are most at-risk for HIV and are therefore best candidates for initiating HIV prevention interventions like pre-exposure prophylaxis (PrEP) within a HIV "hotspot" in the South.

Disclosures. **All Authors:** No reported Disclosures.

1965. PrEP On the Go! Implementation Mobile PrEP, STI, and HIV Prevention Services in South Florida

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Session: 229. The End of AIDS Starts with Prevention

Saturday, October 5, 2019: 11:30 AM

Background. Pre-Exposure Prophylaxis (PrEP) can reduce HIV incidence when implemented effectively for people who are at highest risk of HIV infection. However, access to and uptake of PrEP remains suboptimal among priority populations such as black and Hispanic/Latino men who have sex with men (MSM). We established mobile HIV prevention/PrEP services delivered with cancer screening services through the Sylvester Gamechanger vehicle. We describe demographics, utilization, and early retention in PrEP care delivered through this model.

Methods. We selected four local HIV high-incidence areas where PrEP services were lacking, to locate the clinic. The vehicle, staffed by a medical provider, HIV/PrEP counselor, and cancer educator, returned to each site regularly. In addition to self-referrals, Prevention305, a community-based organization, developed focused patient recruitment through social media. Services were provided at no cost. Normative demographics, risk behavior, sexually transmitted infections (STIs), and early-maintenance-in-care data were collected. Descriptive statistics were compiled using SPSS.

Results. From October 2018 to April 2019 services were provided to 229 clients. Of these, 168 (73.7%) sought PrEP. Of PrEP clients, 125 (74.4%) identified as White/Hispanic, 6 (3.5%) as Black/Hispanic, 6 (3.5%) as White/non-Hispanic, 11 (6.5%) as Black/non-Hispanic, and 19 (11.3%) as other; 124 (73.8%) were foreign-born; 159 (94.9%) of PrEP clients identified as MSM. Six (3.5%) PrEP-seeking clients were HIV positive at baseline. Of these, 2 were identified as acute/early infections. An initial PrEP prescription was filled by 166 (98.8%). Of the 77 clients seen within the initial 3 months of operation and due for follow-up assessment, 55 (71.4%) completed a follow-up visit. Overall, 45 (26.6%) PrEP clients had positive STI results (gonorrhea, chlamydia, or syphilis) at baseline. Nine (16.3%) clients returned positive STI results at their follow-up visit.

Conclusion. Implementation of mobile HIV prevention services including PrEP is feasible and is effective in engaging Hispanic/Latino immigrant MSM. High demand for services is noted and plans are underway to increase capacity and outreach to other highly affected groups.

Disclosures. **All Authors:** No reported Disclosures.

2838. Safety and Immunogenicity of a gp120-CD4 Chimeric Subunit Vaccine: A Phase 1a Randomized Controlled Trial

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Session: 293. Clinical Trials that May Change your Practice

Saturday, October 5, 2019: 1:45 PM

Background. A primary challenge for HIV vaccine development is to raise antiviral antibodies capable of recognizing highly variable viral antigens. The full-length single chain (FLSC) gp120-CD4 chimeric protein was designed to present a highly conserved CD4-induced HIV-1 envelope structure that evokes cross-reactive humoral responses (Figure 1). IHV01 is an FLSC subunit vaccine formulated in alum adjuvant. The safety and immunogenicity of IHV01 was evaluated in this first-in-human phase 1a trial.

Methods. This randomized, double-blind placebo-controlled study involved three dose-escalating cohorts (75 µg, 150 µg, and 300 µg doses). Eligible participants were HIV-1 uninfected healthy volunteers aged 18 to 45 years. Participants in each cohort were block randomized in groups of four in a 3:1 ratio to receive either vaccine or placebo. Intramuscular injections were given on weeks 0, 4, 8, and 24. Participants were followed for an additional 24 weeks after the last immunization. Crossreactive antibody binding titers against diverse HIV envelopes and antigens and specific CD4i epitopes on gp120 were assessed.

Results. Sixty-five volunteers were enrolled—49 vaccine and 16 placebo. Majority (81%) of vaccinations with IHV01 produced no localized or systemic reactions; no different from the control group. The overall incidence of adverse events (AEs) was not significantly different between groups. Majority (89%) of vaccine-related AEs were mild in severity. The most common vaccine-related AEs were injection site pain (31%), pruritus (10%), and headache (10%). There were no vaccine-related serious AE, discontinuation due to AE, or intercurrent HIV infection. By the final vaccination, all subjects in all cohorts had developed antibodies against IHV01; all placebo recipients were negative. The antibodies induced by IHV01 reacted with envelope antigens from diverse HIV-1 strains (Figure 2).

Conclusion. IHV01 vaccine was safe, well tolerated, and immunogenic in all doses tested. The vaccine raised broadly reactive humoral responses against multiple gp120 domains, transition state structures, and CD4i epitopes.

Table 1. Study population baseline characteristics.

	Control (n=16)	FLSC 75 µg (n=15)	FLSC 150 µg (n=16)	FLSC 300 µg (n=18)	Total (n=65)
Sex					
Male	8 (50%)	8 (53%)	10 (63%)	12 (67%)	38 (58%)
Female	8 (50%)	7 (47%)	6 (38%)	6 (33%)	27 (42%)
Ethnicity					
Hispanics or Latino/a	2 (13%)	1 (7%)	0 (0%)	1 (6%)	4 (6%)
Not Hispanics or Latino/a	14 (88%)	14 (93%)	16 (100%)	17 (94%)	61 (94%)
Race					
Black or African American	11 69%)	11 (73%)	8 (50%)	13 (72%)	43 (66%)
White	4 (25%)	4 (27%)	7 (44%)	1 (6%)	16 (25%)
Asian	0 (0%)	0 (0%)	1 (6%)	2 (11%)	3 (5%)
Others	1 (6%)	0 (0%)	0 (0%)	2 (11%)	3 (5%)
Age (Years)					
18-20	1 (6%)	0 (0%)	0 (0%)	2 (11%)	3 (5%)
21-30	6 (38%)	2 (13%)	5 (31%)	6 (33%)	19 (29%)
31-40	7 (44%)	6 (40%)	7 (44%)	4 (22%)	24 (37%)
41-50	2 (13%)	7 (47%)	4 (25%)	6 (33%)	19 (29%)
Median	32.5	38.0	34.0	32.5	34.0
Range	20-47	26-43	23-45	20-45	20-47
Vaccination Frequency					
Day 0	16 (100%)	15 (100%)	16 (100%)	18 (100%)	65 (100%)
Week 4	15 (94%)	15 (100%)	15 (94%)	16 (89%)	61 (94%)
Week 8	15 (94%)	15 (100%)	15 (94%)	15 (83%)	60 (92%)
Week 24	14 (88%)	14 (93%)	14 (88%)	13 (72%)	55 (85%)

Table 3. Summary of reactogenicity by injection number. All three vaccine dosing group combined.

	Events, No. (%)							
	Vaccine #1 (Day 0)		Vaccine #2 (Week 4)		Vaccine #3 (Week 8)		Vaccine #4 (Week 24)	
	Vaccine (n=48)[1]	Control (n=15)[2]	Vaccine (n=46)[3]	Control (n=15)[2]	Vaccine (n=45)[4]	Control (n=15)	Vaccine (n=43)[5]	Control (n=14)[6]
Local reactions								
Pain								
Any	6 (12.5)	1 (6.7)	3 (6.5)	2 (13.3)	7 (15.6)	3 (20.0)	4 (9.3)	1 (7.1)
Grade 3	0	0	0	0	0	0	0	0
Erythema or induration								
Any	0	0	0	0	1 (2.2)	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Tingling or numbness								
Any	0	0	0	0	1 (2.2)	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Systemic reaction								
Headaches	2 (4.2)	1 (6.7)	3 (6.5)	1 (6.7)	1 (2.2)	1 (6.7)	1 (2.3)	0
Pruritus	1 (2.1)	1 (6.7)	0	0	2 (4.4)	0	2 (4.7)	1 (7.1)
Fever	2 (4.2)	1 (6.7)	0	0	0	0	0	0
Nausea	2 (4.2)	0	0	0	0	1 (6.7)	0	0
Fatigue	2 (4.2)	0	0	0	0	0	0	1 (7.1)
Any systemic reaction	**9 (18.8)**	**3 (20.0)**	**3 (6.5)**	**1 (6.7)**	**3 (6.7)**	**2 (13.3)**	**4 (9.3)**	**1 (7.1)**

[1]One subject removed and replaced due to incarceration.
[2]One subject lost to follow-up and replaced.
[3]One subject removed and replaced due to undisclosed exclusion criteria, and one subject discontinued vaccination and replaced due to vaccine-unrelated Bell's Palsy.
[4]One subject withdrew consent and replaced.
[5]Two subjects removed due to incarceration.
[6]One subject withdrew consent.