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

Pauline Harrington, MPH[1]; Udodirim Onwubiko, MBBS, MPH[2]; Mingli Qi, PhD, MPH[1]; David Holland, MD[2,3]; Pascale Wortley, MD, MPH[4] and Allison Chamberlain, PhD[2,3]; [1]Emory University, Atlanta, Georgia; [2]Fulton County Board of Health, Atlanta, Georgia; [3]Emory University, Atlanta, Georgia; [4]Georgia Department of Public Health, Atlanta, Georgia

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

Susanne Doblecki-Lewis, MD, MSPH[1]; Erin Kobetz, PhD[1]; John Byrne2; Stefani Butts, BA[1]; Marco Torrealba, BA[2]; Katie Klose, MSW[3]; Angela McGaugh, MD/MPH[1]; Connor Shatz[1]; Carolina Scaramutti, LMHC MPH[1]; Brian Baez Leon, AA[3]; Gilianne Narcisse, PharmD[3]; Jessica Morel, FNP-BC[3]; Patrick Whiteside[2]; Gabriel Cardenas, PhD[1]; Daniel Feaster, PhD[1] and Mario Stevenson, PhD[1]; [1]University of Miami Miller School of Medicine, Miami, Florida; [2]Prevention 305, Miami, Florida; [3]University of Miami, Miami, Florida

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

Joel V. Chua, MD[1]; Charles Davis, MD[1]; Amy Nelson, RN[1]; Ka Wing J. Lam[1]; Lydiah Mutumbi, RN[1]; Kristen A. Stafford, MPH, PhD[2]; Bruce Gilliam, MD[1]; Anthony L. DeVico, PhD[1]; George K. Lewis, PhD[1] and Mohammad M. Sajadi, MD[1]; [1]Institute of Human Virology, University of Maryland School of Medicine, Baltimore, Maryland; [2]University of Maryland, Baltimore, Baltimore, Maryland

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.

Figure 1: Structure of the Full-length Single Chain (FLSC) Vaccine.
The fusion of HIV-1 to CD4+ cells results in post-binding intermediates that involves gp120 and the CD4 receptor. The FLSC chimeric protein vaccine is a single-chain polypeptide molecule that replicates the structural, functional, and antigenic properties of this gp120-CD4 complex intermediate. Fouts TR, et al. J. Virol 2000; 74(24):11427-36.

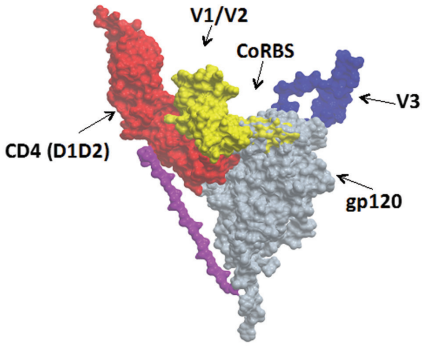
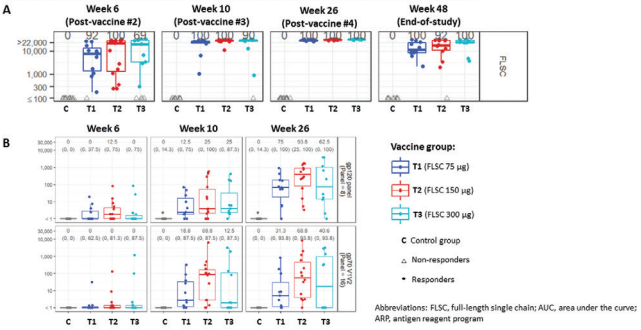


Figure 2: Immunogenicity Results
A. Binding IgG antibody response magnitude for FLSC antigen and time points, colored by group, showing durability of antibody response. B. Magnitude-breath AUC of the gp120 and gp70 V1V2.AFR breath panel by group and time points. The response rate (%) for each group and antigen is displayed.



Binding Antibody Multiplex Array (BAMA) data provided by G. Tomaras et al, Duke Human Vaccine Institute.
Statistical analyses provided by E. Chung et al, Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Fred Hutchison Cancer Research Center

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

2839. Efficacy, Pharmacokinetics (PK), and Safety Profile of Suvratoxumab (MEDI4893), a Staphylococcus aureus Alpha Toxin (AT)-Neutralizing Human Monoclonal Antibody in Mechanically Ventilated Patients in Intensive Care Units; Results of the Phase 2 SAATELLITE Study Conducted by the Public-Private COMBACTE Consortium

Bruno Francois, Physician[1]; Miguel Sánchez Garcia, MD, PhD[2]; Philippe Eggimann, MD[3]; Pierre-Francois Dequin, MD[4]; Pierre-François Laterre, MD[5]; Vincent Huberlant, MD[6]; Lucia Viña Soria, MD[7]; Thierry Boulain, MD[8]; Cédric Bretonnière, MD, PhD[9]; Jerome Pugin, MD[10]; José Trenado Álvarez, MD, PhD[11]; Ana Catalina Hernandez Padilla[12]; Frank Coenjaerts, PhD[13]; Omar Ali, PhD[14]; Kathryn Shoemaker, MS[14]; Alexey Ruzin, PhD[14]; Vadryn Pierre, PharmD[15]; Yuling Wu, PhD[16]; Susan Colbert, RN, BSN; Terramika Bellamy, MS[17]; Michael McCarthy, MD[18]; Filip Dubovsky, MD MPH[14] and Hasan S. Jafri, MD[14]; [1]CHU Dupuytren Limoges, Limoges, Limousin, France; [2]Hospital Clinico San Carlos, Madrid, Spain; [3]University Hospital and Universits of Lausanne - Switzerland, Lausanne, Vaud, Switzerland; [4]Universite Francois Rabelais Hopital Bretonneau, Tours, Centre, France; [5]St Luc University Hospital, University of Louvain, Brussels, Belgium, Brussels Hoofdstedelijk Gewest, Brussels, Belgium; [6]Centre Hospitalier Jolimont-Lobbes, Jolimont-Lobbes, Hainaut, Belgium; [7]Hospital Universitario central de Asturias, Oviedo, Asturias, Spain; [8]Centre Hospitalier Régional d'Orléans, Orléans, France, Orléans, Centre, France; [9]Institut du Thorax - CHU Nantes, Nantes, Pays de la Loire, France; [10]Hôpitaux Universitaire de Genève, Geneva, Geneve, Switzerland; [11]Hospital Universitari Mutua Terrassa, Terrassa, Catalonia, Spain; [12]Centre Hospitalier Universitaire de Limoges, Limoges, France, Limoges, Limousin, France; [13]University Medical Center Utrecht, Utrecht, Utrecht, Netherlands; [14]AstraZeneca, Gaithersburg, Maryland; [15]Astrazeneca, Columbia, Maryland; [16]Biopharma, Gaithersburg, Maryland; [17]Director, Gaithersburg, Maryland; [18]MedImmune, Gaithersburg, Maryland

Session: 293. Clinical Trials that May Change your Practice
Saturday, October 5, 2019: 2:00 PM

Background. *Staphylococcus aureus* (SA) pneumonia imposes significant morbidity and mortality in mechanically ventilated, intensive care unit (MV ICU) patients despite best clinical care. We assessed efficacy, PK, AT-neutralizing antibodies (AT NAbs), and safety of suvratoxumab (suvra) in MV ICU subjects in the placebo-controlled, randomized Phase 2 SAATELLITE study (NCT02296320; EudraCT 2014-001097-34).

Methods. Subjects with PCR-confirmed SA colonization of the lower respiratory tract were randomized to either a single intravenous infusion of 5,000 mg suvra (n = 96) or placebo (n = 100) and followed for 190 days post dose. Efficacy endpoints were Endpoint Adjudication Committee-determined relative risk reduction (RRR) of SA pneumonia incidence in suvra vs. placebo recipients within 30 days post dose (primary endpoint, tested at 2-sided $\alpha = 0.1$), incidence of all-cause pneumonia, and all-cause pneumonia or death. Serum suvra PK and levels of AT NAbs were measured through 90 days post dose and analyzed for statistical correlation. Treatment-emergent adverse events (TEAEs) and serious AEs (SAEs) were assessed through 190 days post dose.

Results. Baseline characteristics were similar between groups. Suvra provided 31.9% RRR in incidence of SA pneumonia vs. placebo (17.7% vs. 26%; $P = 0.166$), 30% RRR ($P = 0.146$) in incidence of all-cause pneumonia, and 23% RRR ($P = 0.164$) in incidence of all-cause pneumonia or death. Suvra reduced mean hospital stay and ICU duration by 3.0 and 2.4 days, resp. vs. placebo. Mean serum ± SD suvra level was 296 ± 131 µg/mL at 30 days post dose. Serum AT Nab ± SD levels reached 156.03 ± 72.48 IU/mL at 2 days post dose, declining slowly to 33.74 ± 16.04 IU/mL by 90 days post dose. AT NAbs correlated with PK ($r^2 = 0.7$), thereby confirming functional activity of suvra over time. Proportion of subjects with TEAEs or SAEs was similar between groups: ≥1 TEAE (93.8% suvra; 93.0% placebo); ≥1 serious; and/or ≥grade 3 severity SAE (66.7% suvra; 58.0% placebo).

Conclusion. A single intravenous dose of suvra produced a trend toward reduced incidence of SA pneumonia, health resource savings, sustained functional exposure in serum, and an acceptable safety profile. These results support continued development of suvra in MV ICU patients.

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

2840. Long-term Efficacy, Safety, and Durability of CAB and RPV as Two Drug Oral Maintenance Therapy: LATTE Week 312 Results

David Margolis, MD, MPH[1]; Kenneth Sutton, MA[1]; Jerome De Vente, MD[2]; Roger LeBlanc, MD[3]; Edwin DeJesus, MD[4]; Graham Smith, MD, MSc[5]; Anthony Mills, MD[6]; Jean-Guy Baril, MD[7]; Marty St. Clair[1]; Britt Stancil, BS in Statistics[8]; Peter Williams, PhD[9] and William Spreen, PharmD[1]; [1]ViiV Healthcare, Research Triangle Park, North Carolina; [2]Long Beach Education and Research Consultants, Long Beach, California; [3]Clinique OPUS INC., Montreal, QC, Canada; [4]Orlando Immunology Center, University of Central Florida College of Medicine, Orlando, Florida; [5]Maple Leaf Medical Clinic, Toronto, ON, Canada; [6]Men's Health Foundation, Los Angeles, California; [7]Clinique Medicale Quartier Latin, Montreal, QC, Canada; [8]GSK, Fuquay Varina, North Carolina; [9]Janssen Research and Development, Beerse, Antwerpen, Belgium

Session: 293. Clinical Trials that May Change your Practice
Saturday, October 5, 2019: 2:15 PM

Background. Cabotegravir (CAB), an INI, is under development in both oral and long-acting (LA) injectable formulations. LATTE (NCT01641809) was designed to select a daily oral dose of CAB and evaluate a two-drug ART regimen with rilpivirine (RPV), as suppressive maintenance therapy. Results enabled the LATTE-2 (NCT02120352) study to evaluate CAB LA + RPV LA dosed once every 1 or 2 months.

Methods. Phase 2b, multicentre, partially blinded dose-ranging study in ART-naïve HIV infected adults, randomized 1:1:1:1 to the induction regimen of once-daily oral CAB 10, 30, or 60 mg or efavirenz (EFV) 600 mg with TDF/FTC or ABC/3TC through W24. CAB patients with VL <50 c/mL immediately prior to W24 discontinued NRTIs and began RPV 25 mg as a two-drug oral maintenance regimen through W96. No change was made to the EFV arm. After W96, at the start of the open-label (OL) phase, all patients randomized to CAB were given the option to continue and switch to the sponsor-selected dose of oral CAB 30 mg. EFV patients completed the study at W96. The OL phase was completed at W312 (288 weeks on CAB + RPV). Successful CAB + RPV patients transitioned to the POLAR study (NCT03639311).

Results. A total of 243 patients were randomized and initiated treatment (ITT-E). Of those randomized to CAB (n = 181), 160 patients began CAB + RPV (W24) and 138 continued into OL phase (W96). One hundred and ten patients successfully completed the study (W312). Among patients who began CAB + RPV at W24, 66% maintained <50 c/mL, 9% had HIV-1 RNA ≥ 50 c/mL, and 25% were categorized as "No Virologic Data" by Snapshot at W312 (ITT-ME). There were 11 protocol-defined virologic failures (PDVF) on CAB; only 2 occurring after W144. Six patients developed treatment emergent (TE) resistance to one or both agents during the study; of which 4 patients developed TE major INI resistance mutations, 3 after W96. The median increase in CD4+ cell count from Baseline was 393 cells/mm^3 (−174 to 1118). During the maintenance and OL phases, 4% of CAB patients reported drug-related AEs ≥ Grade 2; SAEs occurred in 9% of CAB patients (none drug related); 3% of CAB patients withdrew due to AEs. 43% of CAB patients who entered maintenance phase reported TE lab abnormalities ≥ Grade 3.

Conclusion. As maintenance therapy in virologically suppressed patients, the 2DR CAB + RPV provided durable viral suppression through W312. Through 7 years of study, CAB + RPV continues to be generally safe and well tolerated.