Efficacy and Safety of Weekly Islatravir Plus Lenacapavir in PWH at 24 Weeks: A Phase II Study

Abstract Submission Number:

208

Abstract Type:

Late Breaking Abstract

Authors:

Amy Colson[1], Gordon Crofoot[2], Peter J. Ruane[3], Moti Ramgopal[4], Alexandra W. Dretler[5], Ronald G. Nahass[6], Gary Sinclair[7], Mezgebe Berhe[8], Chris Deaton[9], Angela S. Liu[10], Eva Mortensen[10], Martin S. Rhee[10], Elizabeth G. Rhee[11], Jared Baeten[10], Joseph J. Eron[12]

Institutions:

[1]Community Resource Initiative, Boston, MA, USA, [2]Crofoot Research Center, Houston, TX, USA, [3]Ruane Clinical Research Group, Inc, Los Angeles, CA, USA, [4]Midway Immunology and Research Center, Fort Pierce, FL, USA, [5]Infectious Disease Specialists of Atlanta, Atlanta, GA, USA, [6]ID Care, Hillsborough, New Jersey, , [7]Prism Health North Texas, Dallas, TX, USA, [8]North Texas Infectious Diseases Consultants, Dallas, TX, USA, [9]Gilead Sciences, Inc, Cambridge, United Kingdom, [10]Gilead Sciences, Inc, Foster City, CA, USA, [11]Merck & Co, Inc, Palo Alto, CA, USA, [12]University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Presenting Author:

Dr Amy Colson
Other Institution (Edit Institution from Author List Page) - Community Resource Initiative

Background:

Islatravir (ISL), a nucleoside reverse transcriptase translocation inhibitor, and lenacapavir (LEN), a capsid inhibitor, have potent anti-HIV-1 activity and pharmacokinetic profiles permitting once-weekly (QW) oral dosing. We investigated efficacy and safety of ISL+LEN in virologically suppressed people with HIV-1.

Methods:

In this Phase 2, randomized, open-label, active-controlled study (NCT05052996), virologically suppressed adults on bictegravir/emtricitabine/tenofovir alafenamide fumarate (B/F/TAF) were randomized to either oral ISL 2 mg + LEN 300 mg QW or to continue daily B/F/TAF. The primary efficacy endpoint was the proportion of participants with HIV-1 RNA ≥ 50 copies/mL (FDA-defined Snapshot algorithm) at Week 24 (W24). Safety parameters, including CD4+ T-cell and absolute lymphocyte counts (ALC) and adverse events (AEs), were also evaluated.

Results:

A total of 104 participants were randomized and dosed (52/group); median age (range) was 40 (26–76) years, and 19 (18.3%) were female at birth. One (1.9%) participant in the ISL+LEN group (whose baseline HIV RNA was 251 copies/mL) had HIV-1 RNA > 50 copies/mL at W24, then suppressed on ISL+LEN (64 copies/mL at W24, < 50 copies/mL at W30); no participant in the B/F/TAF group had HIV RNA > 50 copies/mL at W24. Forty-nine (94.2%) and 48 (92.3%) participants maintained viral suppression in the ISL+LEN and B/F/TAF groups at W24, respectively; 2 (3.8%) and 4 (7.7%) participants had no data at W24 due to discontinuation or missing visits. No between-group differences were seen in changes in CD4+ T-cell counts or ALC at W24 (Table). AEs occurred in 39 participants (75.0%) on ISL+LEN and 38 (73.1%) on B/F/TAF. The most common AEs in ISL+LEN participants included diarrhea (n=7; 13.5%), upper respiratory infection (n=6; 11.5%), and arthralgia, pain in extremity, and fatigue (each n=3; 5.8%). No grade 3 or 4 AEs related to study drug were reported. Two participants discontinued ISL+LEN due to AEs unrelated to drug (large intestine perforation/renal colic; hepatitis B).

Conclusions:

In this Phase 2 study, the first QW oral ARV regimen of ISL+LEN maintained viral suppression at W24 and was well tolerated. The ISL 2 mg dose showed no clinically significant decreases in CD4+ T-cell counts or ALCs as were seen previously with higher daily, weekly, and monthly doses of ISL.

Clinical:

(G) Antiviral Therapy: Pre-Clinical Data, Randomized Trials, Efficacy, and Effectiveness Studies in HIV or SARS-CoV-2 or Mpox Virus in Adults

Search Terms:

HIV-treatment
Efficacy
Islatravir
Lenacapavir
Safety

Parameter	Median (Q1, Q3)	
	ISL+LEN (n=52)	B/F/TAF (n=52)
CD4+ T-cells/µL		
Baseline	711 (623, 862)	765 (688, 890)
W24 (change from baseline)[a]	14 (–102, 133)	–7 (–128, 67)
ALC x10^3/µL		
Baseline	1.84 (1.61, 2.25)	1.82 (1.53, 2.19)
W24 (change from baseline)[b]	0.04 (–0.22, 0.20)	0.01 (–0.22, 0.25)

ANOVA: [a]p=0.3477; [b]p=0.6301. ALC: absolute lymphocyte count;
B: bictegravir; F: emtricitabine; ISL: islatravir; LEN: lenacapavir; Q: quartile;
TAF: tenofovir alafenamide fumarate; W: week.

Efficacy, Safety, and Immunogenicity of H56:IC31 Vaccine for Prevention of Recurrent TB

Abstract Submission Number:

210

Abstract Type:

Late Breaking Abstract

Authors:

Alvaro Borges[1], Marisa Russel[2], Dereck Tait[2], Elana van Brakel[2], Andrea Cabibbe[3], Daniela Cirillo[3], Elisa Nemes[4], Thomas Scriba[4], Gavin Churchyard[5], Rodney Dawson[6], Isa Sabi[7], Andreas H. Diacon[8], Rasmus Mortensen[1], Mark Hatherill[4], for POR TB consortium

Institutions:

[1]Statens Serum Institut, Copenhagen, Denmark, [2]International AIDS Vaccine Initiative, Cape Town, South Africa, [3]IRCCS Ospedale San Raffaele, Milano, Italy, [4]South African Tuberculosis Vaccine Initiative, Cape Town, South Africa, [5]The Aurum Institute, Johannesburg, South Africa, [6]University of Cape Town, Cape Town, South Africa, [7]Mbeya Medical Research Center, Mbeya, United Republic of Tanzania, [8]TASK Applied Science, Cape Town, South Africa

Presenting Author:

Dr Alvaro Borges
Other Institution (Edit Institution from Author List Page) - Statens Serum Institut

Background:

Persons with tuberculosis (TB) who are deemed cured on completion of treatment remain at higher risk of recurrent disease. The TB vaccine candidate H56:IC31 has been shown to be safe and immunogenic in phase 1/2 studies, including in treated TB patients. Whether H56:IC31 can reduce the risk of recurrent TB is unknown.

Methods:

In a multicenter, double-blind, randomized, placebo-controlled, event-driven trial in South Africa and Tanzania, we enrolled participants aged 18-60 years, without HIV,

who were sputum smear-negative upon completion of treatment for drug-sensitive pulmonary TB. Participants were randomly assigned (1:1) to receive two doses of H56:IC31 or placebo (56 days apart) and followed up for 1 year. The primary endpoint was recurrence of culture-confirmed pulmonary TB. Vaccine efficacy (VE) estimates with 95% confidence interval (95%CI) were derived from Cox proportional hazard models. Secondary endpoints included TB relapse or reinfection as differentiated by whole genome sequencing of paired sputum samples, safety, and immunogenicity.

Results:

831 participants (mean age 34.7 years; 27.6% female; 66.1% black African; 76% from South Africa) were enrolled; 415 received H56:IC31 and 416 placebo. In the primary analysis, recurrent TB was observed in 23 (12 relapse; 8 reinfection; 3 indeterminate) of 400 participants (5.8%) in the H56:IC31 group; and 14 (6 relapse; 7 reinfection; 1 indeterminate) of 406 participants (3.4%) in the placebo group. VE for recurrence was -73.8% (95%CI:-246.9 to 9.8%; P=0.10). VE for relapse was -116.1% (-522.2 to 16.3%; P=0.11) and for reinfection VE was -21.1% (-245.3 to 56.5%; P=0.71). Participants in the H56:IC31 group reported more mild-to-moderate local injection reactions than in the placebo group. No H56:IC31-related serious adverse events were observed. Participants receiving H56:IC31 mounted robust H56-specific CD4+ T cell responses and H56-specific humoral (serum IgG) responses.

Conclusions:

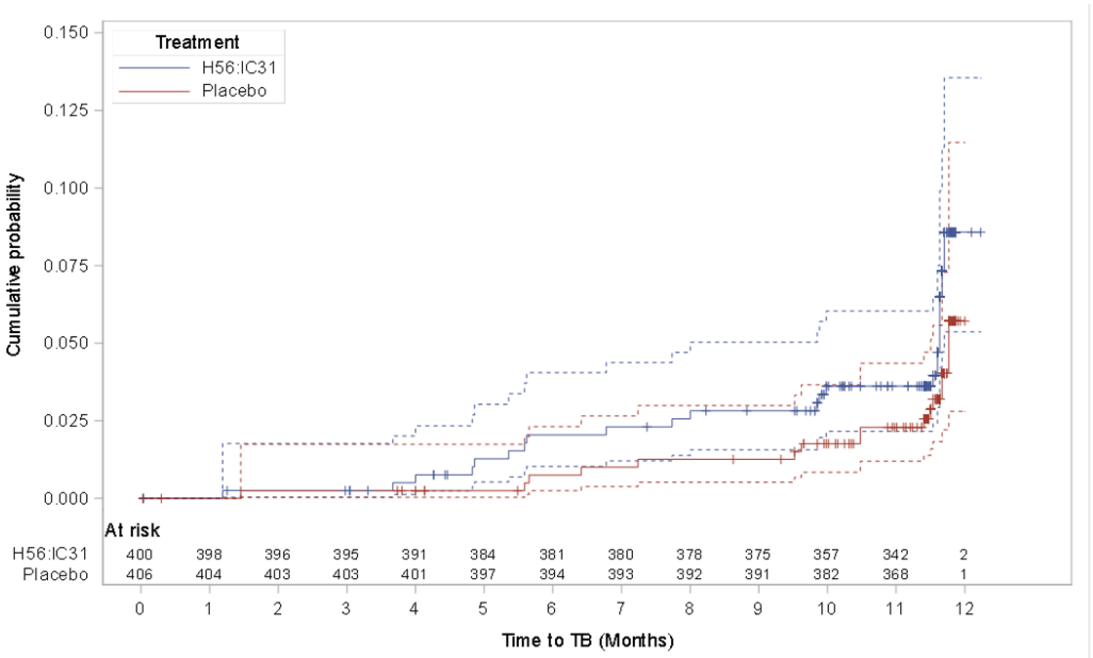
This is the first reported trial with a prevention of recurrent TB design. Vaccination with H56:IC31 upon treatment completion for pulmonary tuberculosis did not reduce the risk of recurrent tuberculosis. H56:IC31 was well-tolerated and immunogenic, but may have increased the risk of relapse by endogenous strains.

Clinical:

(N) Tuberculosis and Other Opportunistic Infections, Including the Impact of HIV or SARS-CoV-2 in Adults

Search Terms:

Clinical Trial
vaccine development
Tuberculosis
Vaccine



Dotted lines: 95% confidence bands
Trial: POR A-055

Long-Acting Injectable CAB/RPV Is Superior to Oral ART in PWH With Adherence Challenges: ACTG A5359

Abstract Submission Number:

212

Abstract Type:

Late Breaking Abstract

Authors:

Aadia I. Rana[1], Yajing Bao[2], Lu Zheng[2], Sara Sieczkarski[3], Jordan E. Lake[4], Carl J. Fichtenbaum[5], Tia Morton[6], Lawrence Fox[6], Paul Wannamaker[7], Jose R. Castillo-Mancilla[7], Kati Vandermeulen[8], Chanelle Wimbish[9], Karen T. Tashima[10], Raphael J. Landovitz[11], for the ACTG A5359 Team

Institutions:

[1]University of Alabama at Birmingham, Birmingham, AL, USA, [2]Harvard TH Chan School of Public Health, Boston, MA, USA, [3]Frontier Science & Technology Research Foundation, Inc, Amherst, NY, USA, [4]University of Texas at Houston, Houston, TX, USA, [5]University of Cincinnati, Cincinnati, OH, USA, [6]National Institute of Allergy and Infectious Diseases, Bethesda, MD, USA, [7]ViiV Healthcare, Research Triangle Park, NC, USA, [8]Janssen, Beerse, Belgium, [9]DLH, ACTG Network Coordinating Center, Bethesda, Maryland, [10]Brown University, Providence, RI, USA, [11]University of California Los Angeles, Los Angeles, CA, USA

Presenting Author:

Dr Aadia I. Rana
University of Alabama at Birmingham - University of Alabama at Birmingham (Birmingham, AL, USA)

Background:

Data from randomized clinical trials of long acting injectable treatment with cabotegravir and rilpivirine (LAI) are lacking for persons with HIV (PWH) and a history of adherence challenges.

Methods:

ACTG A5359 is a phase III, prospective, randomized, open-label trial comparing LAI vs. oral standard of care (SOC) ART in PWH in the U.S. with a history of suboptimal

adherence (persistent HIV-1 RNA >200 c/mL or loss to follow-up). Enrolled participants received conditional cash incentives for viral suppression on SOC of up to 24 weeks (Step 1). Participants achieving HIV-1 RNA ≤200 c/mL in Step 1 were randomized to monthly LAI (with/without oral lead-in) vs. continuation of SOC ART for 52 weeks (Step 2). Primary composite endpoint was the earliest occurrence of virologic failure (VF, confirmed HIV-1 RNA>200 c/mL) or treatment discontinuation. Key secondary efficacy endpoints included VF, treatment-related failure (VF or discontinuation due to adverse events, AEs) and treatment discontinuation. On Feb 12, 2024 a pre-planned interim review by an independent Data and Safety Monitoring Board recommended to stop randomization and offer LAI to all eligible participants. We present the interim results on which the DSMB recommendation was made.

Results:

As of 3 Jan 2024, 434 eligible participants were enrolled in Step 1. Median age 40 years, 70% male, 64% Black/African American, 17% Hispanic, 5% transgender, 14% current/prior injection drug use, median CD4+ cells 270/mm3, and median HIV-1 RNA 3.55 log10 c/mL. 294 eligible participants were randomized in Step 2 (LAI n=146, SOC n=148). Cumulative probability of AEs was similar in both arms. Three participants on LAI had ≥ Grade 3 injection site reactions (ISR) and one discontinued due to ISR. All efficacy endpoints favored the LAI arm (Table). Although the primary endpoint did not meet the predefined stopping criterion for this interim analysis (nominal 98.75% confidence interval excluding zero), key secondary endpoints of VF and treatment related failure met this stringent criterion, demonstrating superiority of the LAI arm vs. SOC. Two confirmed VFs in each arm had new resistance associated mutations (RAMS) including ≥2 new integrase inhibitor RAMs in both LAI participants.

Conclusions:

When considering all endpoints together, long-acting CAB/RPV demonstrated superior efficacy compared to daily oral SOC in PWH with adherence challenges.

Clinical:

(G) Antiviral Therapy: Pre-Clinical Data, Randomized Trials, Efficacy, and Effectiveness Studies in HIV or SARS-CoV-2 or Mpox Virus in Adults

Search Terms:

CAB+RPV
Long Acting Drugs
long-acting injectable antiretroviral therapy

Table: Kaplan-Meier cumulative probabilities for primary and key secondary endpoints and difference in probabilities between LAI and SOC arms

Endpoint	**CAB-LA/RPV-LA (n= 145*)**		**SOC (n=148)**		**Difference (nominal 98.75% CI)**
	Failure, n	Cumulative Probability	Failure, n	Cumulative Probability	
Primary: Regimen failure (virologic failure+ discontinuation)	28 (5+23)[#]	24.1%	47 (28+19)	38.5%	-14.4% (-29.8%, 0.8%)
Secondary: Virologic Failure	6[#]	7.2%	28	25.4%	-18.2% (-31.1%, -5.4%)
Secondary: Treatment-related failure (virologic failure + discontinuation due to AE)	9 (6+3)	9.6%	29 (28+1)	26.2%	-16.6% (-29.9%, -3.3%)
Secondary: Permanent treatment discontinuation	25	20.9%	30	24.9%	-4.1% (-18.0%, 9.8%)

* One participant with ART information pending was excluded from the interim efficacy analyses. [#] One participant assigned to LAI had treatment discontinuation as the primary endpoint but subsequently experienced VF.

Sex-Specific Innate Immune Selection in Vertical HIV Transmission and cART-Free Aviraemia in Males

Abstract Submission Number:

175

Abstract Type:

Late Breaking Abstract

Authors:

Nomonde Bengu[1], Gabriela Z. Cromhout[2], Emily Adland[3], Katya Govender[4], Nicholas Herbert[3], Nicola Cotugno[5], Paolo Palma[5], Maria C. Puertas[6], Thumbi Ndung'u[4], Edmund Capparelli[7], Mathias Lichterfeld[8], Javier Martinez-Picado[6], John Kappes[9], Moherndran Archary[2], Philip J. Goulder[3]

Institutions:

[1]Queen Nandi Regional Hospital, Empangeni, South Africa, [2]University of KwaZulu-Natal, Durban, South Africa, [3]University of Oxford, Oxford, United Kingdom, [4]Africa Health Research Institute, Mtubatuba, South Africa, [5]Bambino Gesu Children's Hospital, Rome, Italy, [6]IrsiCaixa Institute for AIDS Research, Badalona, Spain, [7]University of California San Diego, San Diego, CA, USA, [8]Ragon Institute of MGH, MIT and Harvard, Cambridge, MA, USA, [9]University of Alabama at Birmingham, Birmingham, AL, USA

Presenting Author:

Dr Gabriela Z.L. Cromhout
University of KwaZulu-Natal - University of KwaZulu-Natal

Background:

Following case reports of paediatric post-treatment control, it has been proposed that very early cART without additional interventions might achieve remission in a subset of children. To investigate this possibility, from 2015-2023 we conducted a longitudinal study of >300 mother-child pairs in KwaZulu-Natal, South Africa monitored from birth after in utero HIV transmission.

Methods:

All infants received ART at birth; 92% of infants received transplacental maternal cART pre-birth. cART adherence was assessed via history, pill-counting, pharmacy records and plasma cART concentrations determined by liquid chromatography-tandem mass spectrometry. Chimeric Gag-Protease-NL4-3 viruses were generated following viral RNA isolation and nested RT-PCR amplification of mother and child gag-pro from baseline plasma. Viral type I interferon (IFN-I) sensitivity and replicative capacity were determined using the reporter cell lines U87-snLuc/EGFP and CEM-GXR, respectively.

Results:

Despite very early cART initiation, sustained suppression of viraemia to 3yrs was observed in only 32% of children. Aviraemia was usually cART-dependent. Unexpectedly, 5 'atypical' males were identified in whom aviraemia persisted despite complete cART discontinuation for 3m-19m in 4 cases; and 17m intermittent cART in one case. By contrast, 60% of the cohort was female ($p=0.01$). Higher in utero transmission rates to female fetuses were only observed in the setting of recent maternal infection ($p=0.0005$). This was associated with transmission to females of IFN-I resistant ($p<0.0001$), low replication capacity ('fitness') virus ($p<0.0001$). HIV transmitted to male fetuses was typically IFN-I sensitive/high 'fitness'. Viruses transmitted to females by mothers who seroconverted in pregnancy were more IFN-I resistant than those not transmitted ($p=0.019$). Viruses transmitted to males were more IFN-I sensitive than those not transmitted ($p=0.02$). In sex-discordant twins where only one twin became infected, the female was infected in >90% of cases ($p=0.002$); the viruses not transmitted to the male twin were more IFN-I resistant than those transmitted to male singletons ($p=0.001$). Viruses transmitted to the 'atypical' males maintaining cART-free aviraemia had lower 'fitness' ($p<0.0001$) versus those transmitted to 'typical' males.

Conclusions:

These data indicate that early life innate immune sex differences selectively influence vertical HIV transmission and modulate post-treatment control in children living with HIV (Figure).

Basic Science:

(D) HIV Reservoirs, Latency, and Curative Strategies Including Therapeutic Vaccines and Gene Therapy

Search Terms:

Sex differences
Cure
IFN-I
Vertical transmission
Viral fitness

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Sex-Based Differences in HIV-1 Reservoir Profile in Individuals With Long-Term ART Suppression

Abstract Submission Number:

176

Abstract Type:

General Abstract Submission

Authors:

Toong Seng Tan[1], Alexander Hochroth[1], Leah Carrere[1], Sruthi Kalavacherla[1], Liliana Vela[1], Ce Gao[1], Rowena Johnston[2], Steven G. Deeks[3], Seble Kassaye[4], Phyllis Tien[3], Michael J. Peluso[3], Jeffrey Jacobson[5], Mary Carrington[6], Mathias Lichterfeld[1], Xu G. Yu[1]

Institutions:

[1]Ragon Institute of MGH, MIT, and Harvard, Cambridge, MA, USA, [2]amfAR, New York, NY, USA, [3]University of California San Francisco, San Francisco, CA, USA, [4]Georgetown University, Washington, DC, USA, [5]Case Western Reserve University, Cleveland, OH, USA, [6]Frederick National Laboratory for Cancer Research, Frederick, MD, USA

Presenting Author:

Dr Toong Seng Tan
Ragon Institute of MGH, MIT and Harvard - Ragon Institute of MGH, MIT and Harvard (Cambridge, MA, USA)

Background:

Women account for over half of people living with HIV (PLH) but they are largely underrepresented in HIV-1 cure studies. Biological sex impacts host immune responses which may lead to sex-specific selection and evolution of HIV reservoir cells. However, sex-specific differences in HIV reservoir landscapes, including proviral reservoir size, composition, and integration site profile among long-term ART-treated (LT-ART) individuals remain unclear.

Methods:

We included a total of 64 participants (34 males and 30 females, all cisgender), who remained on continuous suppressive ART for a median of 20 (range: 15 – 25) consecutive years with no more than 2 recorded plasma viremia blips (< 100

copies/mL). HIV-1 proviruses and chromosomal integration sites were analyzed using FLIP-seq and MIP-seq, as described in our previous work.

Results:

There were no significant differences in the demographic characteristics between female and male participants in the study. In total, n=4012 HIV genomes were detected in the LT-ART cohort (n=1490 in females and n=2522 in males). Frequencies of total and defective HIV-1 genomes were not different between males and females; however, we found a small trend toward higher frequencies of intact proviruses in females (0.69 vs. 0.53 median intact DNA per million PBMC, $p = 0.15$). Moreover, relative proportions of intact proviruses among total proviruses were higher in females (6.51% vs. 3.65%, $p < 0.0001$). This difference appeared to be at least partially attributable to a higher frequency of clonally-expanded intact proviruses in females compared to males (3.37 vs. 0.34 median clonal intact DNA per million PBMC, $p = 0.0029$). Intriguingly, within a total of 246 integration sites (145 intact, 101 defective) identified, we observed higher proportions of intact proviruses integrated in heterochromatin locations (including centromeric/satellite DNA, ZNF genes) and non-genic DNA in females than males (88% vs. 58%, $p < 0.0001$).

Conclusions:

Taken together, our results suggest a sex-based difference in host immune-driven proviral landscape evolution during long-term suppressive ART. Immune mechanisms responsible for viral reservoir cell selection are unclear at present but may include sex-specific immune responses. The HIV reservoir in women is associated with features of deeper latency; therefore, women may be primed to achieve a state of HIV control, and the inclusion of women in cure studies should be a priority.

Basic Science:

(D) HIV Reservoirs, Latency, and Curative Strategies Including Therapeutic Vaccines and Gene Therapy

Search Terms:

HIV reservoir
Long-term therapy
Sex difference

High Rates of Viral Suppression in Pregnancy Drop Postpartum in South African Women on TLD

Abstract Submission Number:

182

Abstract Type:

General Abstract Submission

Authors:

Elaine J. Abrams[1], Jennifer Jao[2], Elton Mukonda[3], Hlengiwe Madlala[3], Phindi Zwane[3], Jack Hu[3], Allison Zerbe[1], Justine Legbedze[2], Landon Myer[3]

Institutions:

[1]ICAP at Columbia University, New York, NY, USA, [2]Ann & Robert H Lurie Children's Hospital of Chicago, Chicago, IL, USA, [3]University of Cape Town, Cape Town, South Africa

Presenting Author:

Dr Elaine J. Abrams
ICAP at Columbia University - Columbia University (New York, NY, USA)

Background:

The global transition to 1st-line antiretroviral treatment (ART) with tenofovir+lamivudine+dolutegravir (TLD) has shown high rates of viral suppression (VS) in adults and children but little is known about pregnant and postpartum women.

Methods:

Pregnant women with HIV (PWH) already on TLD (Continuers, PWHc) or starting TLD <14 days prior to enrollment (Initiators, PWHi), were enrolled in ORCHID, an observational study of metabolic health, in Cape Town, South Africa, Sept 2021-Sept 2023. PWH were enrolled <18 weeks (wks) gestational age (GA); ART was managed by routine clinical services; viral load (VL) samples were collected at enrollment, trimester2 (T2, 24-28 wks), T3 (32-34 wks) and Q6-12wks postpartum (PP). Analyses described VS (<50 cps/mL), the incidence of major (>1000 cps/mL) and minor (50-1000 cps/mL) viremic episodes (VE) and associated factors among PWH using Poisson models.

Results:

Among 600 PWH, 450PWHc/150PWHi, median (IQR) age was 30.0 yrs (16-47), GA was 13 wks (10-16), and duration on TLD was 218 days (15-554) at enrollment [366 (149-716) and 1(0-7) for PWHc and PWHi respectively]. Median VL at enrollment was 19 cps/mL (range 19-980,148): 475 (79%) PWH had VL<50 cps/mL (89%PWHc, 49%PWHi), 76 (13%) had 50-1000 cps/mL (PWHc7.1%, PWHi29%) and 49 (8.2%) had >1000 cps/mL (PWHc3.8%, PWHi21%) [fig1]. Overall, 3142 woman-months of observation were accrued: 567 (95%) PWH had ≥1 VL <50 cps/mL; of these women 45 (8%) had ≥1 minor VE (8%C vs 7%I, p=0.8) and 39 (7%) had ≥1 major VE (4%C vs 15%I, p=<0.001). The proportion of VL measures with VS increased from enrollment (79%), was high at T2 (91%), T3 (90%), and 6wks PP (91%) but decreased thereafter. By 24wks PP, 21% of 127 VL measures were >1000cps/mL, (12%C vs 35%I, p=0.007). In multivariable analyses the incidence of VE >1000 cps/mL after VS was independently associated with decreased age [incidence rate ratio (IRR) 16-22yrs vs 34+yrs, 3.26; 95% confidence interval (CI) 1.1-10.5) and elevated VL (>1000 cps/mL) at enrollment (IRR 4.65, 95%CI: 2.0-10.5).

Conclusions:

This is among the first reports of VL in pregnant and postpartum women on TLD. We found high rates of VS in pregnant women, but postpartum viremia remains a pressing concern, particularly for younger women and those initiating ART during pregnancy.

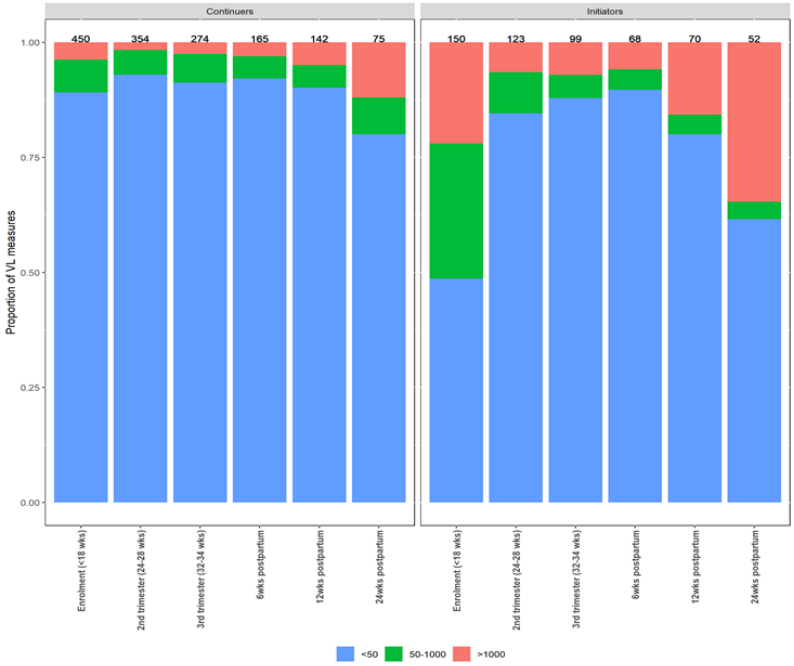
Clinical:

(O) Maternal and Fetal HIV, SARS-CoV-2, and Mpox Virus

Search Terms:

Postpartum
Pregnancy
South Africa
TLD
Viral suppression

Figure 1: Distribution of viral load test results during pregnancy and postpartum among women entering pregnancy on TLD (continuers) and initiating TLD (initiators)



ART-Free HIV-1 Remission in Very Early Treated Children: Results From IMPAACT P1115

Abstract Submission Number:

184

Abstract Type:

Late Breaking Abstract

Authors:

Deborah Persaud[1], Anne Coletti[2], Bryan S. Nelson[3], Jennifer Jao[4], Edmund Capparelli[5], Diane Costello[6], Camlin Tierney[3], Adeodata R. Kekitiinwa[7], Teacler Nematadzira[8], Boniface N. Njau[9], Jack Moye[10], Patrick Jean-Philippe[11], Yvonne Bryson[6], Ellen G. Chadwick[4], for the IMPAACT P1115 Study Team

Institutions:

[1]The Johns Hopkins University School of Medicine, Baltimore, MD, USA, [2]FHI 360, Durham, NC, USA, [3]Harvard TH Chan School of Public Health, Boston, MA, USA, [4]Northwestern University, Chicago, IL, USA, [5]University of California San Diego, San Diego, CA, USA, [6]University of California Los Angeles, Los Angeles, CA, USA, [7]Baylor College of Medicine Children's Foundation, Kampala, Uganda, [8]University of Zimbabwe, Harare, Zimbabwe, [9]Kilimanjaro Christian Medical Centre, Moshi, Tanzania, [10]National Institute of Child Health and Human Development, Bethesda, MD, USA, [11]National Institute of Allergy and Infectious Diseases, Bethesda, MD, USA

Presenting Author:

Dr Deborah Persaud
The Johns Hopkins University School of Medicine - The Johns Hopkins University School of Medicine

Background:

Very early initiation of antiretroviral therapy (ART) may limit the establishment of HIV-1 reservoirs in neonates, potentially enabling ART-free remission. We describe 6 children who received very early NVP- and PI-based ART and underwent analytical treatment interruption (ATI) in IMPAACT P1115 to assess for remission.

Methods:

Fifty-four infants with in utero HIV-1 (confirmed by 2 positive nucleic acid tests) initiated ART within 48 hours of birth and received the study regimen (NVP+2NRTIs with LPV/r added ≥42 weeks postmenstrual age) for up to 294 weeks. Eligibility criteria for ATI included sustained virologic suppression with no plasma HIV-1 RNA detected from 48 weeks onwards and no HIV-1 DNA detected in ≥850,000 PBMCs (droplet digital PCR), normal CD4, and negative HIV-1 serostatus (4th generation ELISA). Children meeting all criteria interrupted ART with frequent clinical, virologic, and immunologic monitoring; remission was defined as no confirmed plasma HIV-1 RNA above the limit of detection (LOD) of the assay for ≥48 weeks off ART. ART was resumed upon viral rebound (HIV-1 RNA confirmed ≥LOD). Plasma ARV drug levels were assessed retrospectively to confirm absence of ARV during ATI.

Results:

Six children underwent ATI at median age 5.5 years. Three of 6 achieved study-defined remission, one through 80 weeks of ATI, when viral rebound (299,538 cp/mL) occurred. The other two who achieved remission remain on ATI (>48 and >60 weeks). A fourth child remains on ATI (>44 weeks). Two children had viral rebound 3 and 8 weeks after ATI (Table). Earliest available HIV-1 RNA and DNA values ranged from 96 to >5 million cp/mL and from not detected to 130 cp/106 PBMCs. The child with 80 weeks of remission had no ARVs detected in plasma during ATI (tests pending for others). Two of 3 children with rebound (at 8 and 80 weeks) experienced acute retroviral syndrome (ARS); no other clinical or immunologic events of concern were identified during or following ATI. The children with rebound at 3 weeks (67,606 cp/mL) and 8 weeks (1801 cp/mL) had HIV-1 RNA <LOD 8 weeks and 20 weeks after resuming ART. The child with rebound at 80 weeks had HIV-1 RNA 724 cp/mL 2 weeks after resuming ART.

Conclusions:

ART-free remission for ≥48 weeks was achieved with very early treatment of in utero HIV-1. Very early treatment with durable virologic suppression may enable sustained remission in children; however, the occurrence of ARS warrants careful clinical oversight during ATI.

Clinical:

(P) Childhood and Adolescent HIV, SARS-CoV-2, or Mpox Virus

Search Terms:

Analytical Treatment Interruption
Neonatal ART
Reservoir
Remission

Table: Key Characteristics of IMPAACT P1115 Participants Who Received Very Early ART and Underwent Analytical Treatment Interruption (ATI)

Participant	Sex at Birth	Age at ART Initiation Age at ATI	Earliest HIV-1 RNA Earliest HIV-1 DNA	Earliest Age with No HIV-1 RNA Detected Earliest Age with No HIV-1 DNA Detected	Time off ART* with No HIV-1 RNA Detected	Highest DAIDS Grade Sign or Symptom of Acute Retroviral Syndrome	Time to HIV-1 RNA <LOD Duration of Follow-Up after Resuming ART
A	Female	1 day 5.6 years	>5 million copies/mL 69.8 copies/10^6 PBMCs	10 weeks 12 weeks	**80 weeks**	Grade 1	not yet determined** 2 weeks
B	Female	2 days 5.5 years	96 copies/mL 3.6 copies/10^6 PBMCs	9 weeks 12 weeks	**>60 weeks**	not applicable	Still on ATI
C	Male	1 day 5.3 years	1969 copies/mL no DNA detected	11 weeks 1 week	**>48 weeks**	not applicable	Still on ATI
D	Female	2 days 5.7 years	87 copies/mL no DNA detected	3 weeks 2 days	>44 weeks	not applicable	Still on ATI
E	Male	1 day 5.4 years	118 copies/mL 3.7 copies/10^6 PBMCs	9 weeks 25 weeks	8 weeks	not applicable	20 weeks 46 weeks
F	Female	1 day 5.5 years	15,017 copies/mL 130.4 copies/10^6 PBMCs	17 weeks 49 weeks	3 weeks	Grade 2	8 weeks 36 weeks

*Study visit week counted from initiation of ATI, duration of remission bolded. **Most recent value (2 weeks after resumption of ART) was >LOD.

Emerging Dolutegravir Resistance Among Children Being Investigated for Treatment Failure in Malawi

Abstract Submission Number:

187

Abstract Type:

Late Breaking Abstract

Authors:

George Bello[1], Sherri Pals[2], Barbara Bighignoli[1], Alinune Kabaghe[2], Jonathan Mkungudza[1], Loise Panje[1], Elliot Raizes[3], Elizabeth Kampira[4], Dumbani Kayira[4], Bilaal W. Matola[5], Stephanie Hackett[3], Duping Zheng[3], Bianca Alvarez[3], Nellie Wadonda-Kabondo[4], for the HIV Drug Resistance Surveillance Team

Institutions:

[1]International Training and Education Center for Health, Petion-Ville, Haiti, [2]US Centers for Disease Control and Prevention Windhoek, Windhoek, Namibia, [3]Centers for Disease Control and Prevention, Atlanta, GA, USA, [4]Centers for Disease Control and Prevention, Lilongwe, Malawi, [5]Government of Malawi Ministry of Health, Lilongwe, Malawi

Presenting Author:

Dr George Bello
Other Institution (Edit Institution from Author List Page) - International Training and Education Center for Health

Background:

Malawi switched from protease inhibitor- (PI) and non-nucleoside reverse transcriptase inhibitor (NNRTI)-based paediatric first- and second-line antiretroviral therapy (ART) regimens to dolutegravir-based regimens (DBR) in 2020. By 2022, over 98% of children living with HIV (CLHIV) were on DBR, requiring monitoring of dolutegravir (DTG) resistance. We evaluated the prevalence and patterns of drug resistance (DR) to DBR in children in Malawi.

Methods:

We conducted a cross-sectional survey in 19 clinics randomly selected from the 25 highest volume ART clinics in Malawi from November 2022 to March 2023. We included CLHIV aged <15 years, on a DBR ≥9 months, returning to the clinic after a previous

high viral load (VL) ≥1000 cps/ml and having completed at least 1 session of intensive adherence counselling (IAC) per national guidelines. A plasma sample was obtained for VL re-testing. Samples with VL ≥1000cps/ml were genotyped for DR using HIV-1 Genotyping kit with Integrase (ThermoFisher) and interpreted using Stanford University HIVDR Database Algorithm (version 9.4). We present weighted estimates of DR (level 3-5) with 95% confidence limits accounting for correlation within clinic using SAS.

Results:

Of the 297 CLHIV re-tested for VL, 43.1% (128/297) remained unsuppressed. Out of the 128 CLHIV that remained unsuppressed, 97.7% (125/128) were successfully genotyped for DR mutations (DRMs). For those successfully genotyped, median age was 10 years old (IQR 5-13); 58% were male, median time since ART initiation was 5.4 years (IQR 2.5-9.0); median time on DTG was 1.5 years (IQR 1.2-2.3); and 89% were ART-experienced at DTG initiation. The weighted prevalence of high-level DTG resistance among children with virological failure was 15.5% (95% CI: 6.7-24.3). The most common major DTG DRMs were R263K (10), E138K/A (5), S147G (4), and G118R (4). Resistance to any nucleoside reverse transcriptase was 41.1%, (95%CI: 27.6-54.6); to any NNRTI was 65.0%, (95%CI: 53.8-76.2); and any PI was 5.2% (95%:CI: 0.0-12.2).

Conclusions:

Among Malawian CLHIV with confirmed virological failure on DBR, DTG DRM prevalence was 15.5%, twice as high as the 8.5% found in a parallel study among Malawian adults. Prevalence of DRM to PI was rare. These collective results raise concern about effective future treatment of CLHIV, as there are no convenient alternative 2nd or 3rd line ART options currently available for this population.

Clinical:

(P) Childhood and Adolescent HIV, SARS-CoV-2, or Mpox Virus

Search Terms:

Children living with HIV
Dolutegravir
Resistance

Long-Acting Cabotegravir Plus Rilpivirine In Adolescents With HIV: Week 24 IMPAACT 2017(MOCHA) Study

Abstract Submission Number:

188

Abstract Type:

General Abstract Submission

Authors:

Aditya Gaur[1], Edmund Capparelli[2], Kristin Baltrusaitis[3], Mark Marzinke[4], Conn M. Harrington[5], Cindy McCoig[6], Herta Crauwels[7], Ellen Townley[8], Jack Moye[9], Sarah Buisson[10], Avy Violari[11], Pradthana Ounchanum[12], Chelsea Krotje[13], Carolyn Bolton[14], for the IMPAACT 2017 Team

Institutions:

[1]St Jude Children's Research Hospital, Memphis, TN, USA, [2]University of California San Diego, La Jolla, CA, USA, [3]Harvard TH Chan School of Public Health, Boston, MA, USA, [4]The Johns Hopkins University School of Medicine, Baltimore, MD, USA, [5]ViiV Healthcare, Research Triangle Park, NC, USA, [6]ViiV Healthcare, Madrid, Spain, [7]Janssen Research & Development, LLC, Pennington, NJ, USA, [8]National Institute of Allergy and Infectious Diseases, Washington, DC, USA, [9]National Institute of Child Health and Human Development, Bethesda, MD, USA, [10]FHI 360, Durham, NC, USA, [11]Chris Hani Baragwanath Hospital, Johannesburg, South Africa, [12]Chiang Rai Prachanukroh Hospital, Chiang Rai, Thailand, [13]Frontier Science & Technology Research Foundation, Inc, Amherst, NY, USA, [14]Centre for Infectious Disease Research in Zambia, Lusaka, Zambia

Presenting Author:

Dr Aditya Gaur
St Jude Children's Research Hospital - St Jude Children's Research Hospital (Memphis, TN, USA)

Background:

Long-acting (LA), intramuscular (IM) cabotegravir (CAB) + rilpivirine (RPV) constitutes the first LA combination antiretroviral treatment (ART) regimen for people with HIV-1. The goal of the ongoing IMPAACT 2017 study (MOCHA [More Options for Children and

Adolescents]; NCT03497676) is to evaluate the safety, tolerability, and pharmacokinetics (PK) of this LA combination in virologically suppressed (HIV-1 RNA < 50 c/mL) adolescents. Here we present PK and safety data through the primary Week 24 timepoint and available safety data beyond Week 24.

Methods:

In this Phase I/II, open-label, noncomparative trial, virologically suppressed adolescents (12 to <18 years of age; ≥35 kg) with HIV-1 switched from their pre-study ART to 4 weeks of daily oral CAB + RPV followed by 600 mg CAB LA and 900 mg RPV LA IM (3 mL each) in the contralateral gluteus medius per the every 2-month dosing regimen. The 1st and 2nd injections were 4 weeks apart, with subsequent injections every 8 weeks.

Results:

144 participants were enrolled at 18 sites in 5 countries. Median (min, max) age was 15 years (12, 17), body mass index 19.5 kg/m2 (16, 34), weight 48 kg (35, 101), 49% male and 74% Black or African American. Most participants received ≥1 injection (142/144) and completed the Week 24 visit (141/144); mean (standard deviation) study duration was 56 weeks (13). No deaths or adverse events (AEs) leading to study drug discontinuation occurred; no serious AEs attributable to study product occurred. Through Week 24, 16/144 (11%) had a ≥ Grade 3 AE, most common being increases in blood creatine phosphokinase (n=6) and systolic blood pressure (n=3); none of these non-injection site reaction (ISR) AEs were considered study drug related. For all safety data, 49/142 (35%) participants reported an ISR, most (86%) ISRs resolved within 7 days and were Grade 1 (91%). Two of 144 (1%) participants experienced a drug-related ≥ Grade 3 AE (injection site pain and abscess [n=1]; injection site abscess [n=1]). The outcome of the single unintended pregnancy in a study participant was a healthy live birth. There was no virologic failure through Week 24. The median (5%, 95%) Week 24 predose concentrations for CAB [2.34 µg/mL (1.11, 4.15)] and RPV [49.5 ng/mL (25.9, 78.1)] were similar to those in adults (Figure). One participant had low CAB concentration at Week 24 (0.03 µg/mL).

Conclusions:

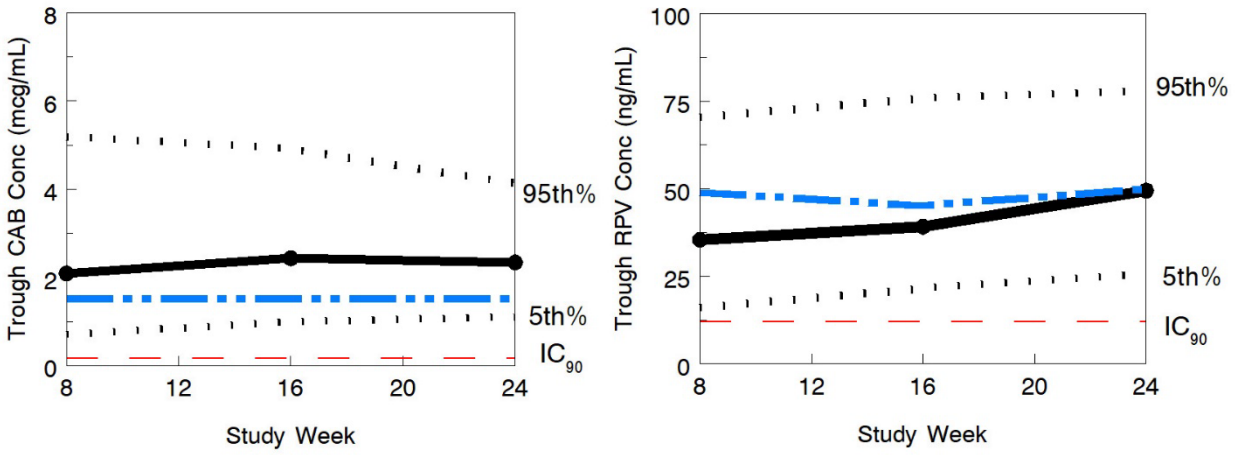
IMPAACT 2017 (MOCHA) data support using CAB-LA plus RPV-LA every 2 months in virologically suppressed adolescents.

Clinical:

(P) Childhood and Adolescent HIV, SARS-CoV-2, or Mpox Virus

Search Terms:

adolescents
Cabotegravir
Long-acting injectable
Pharmacokinetics
Rilpivirine



IMPAACT 2017 CAB and RPV troughs (Black lines - medians [solid] with 5th%-95th% [dashed]) compared to adults (Blue lines) from LATTE-2 / ATLAS-2M studies and protein adjusted IC_{90}s (Red lines)

Investigation of HIV Transmission Associated With Receipt of Vampire Facials: New Mexico, 2018-2023

Abstract Submission Number:

191

Abstract Type:

Late Breaking Abstract

Authors:

Anna M. Behar[1], Mika N. Gehre[2], Liana Atallah[3], Tegan Clarke[3], Ana-Alicia Leonso[3], Francella Jojola[4], Haoqiang Zheng[1], Hongwei Jia[1], Sheryl Lyss[1], William M. Switzer[1], Scott P. Grytdal[1], Miranda Durham[5], N. Mariam Salas[3], Marla Sievers[2], Chad Smelser[2]

Institutions:

[1]Centers for Disease Control and Prevention, Atlanta, GA, USA, [2]New Mexico Department of Health, Santa Fe, NM, USA, [3]University of New Mexico, Albuquerque, NM, USA, [4]Albuquerque Public Schools, Albuquerque, NM, USA, [5]Indian Health Service, Corrales, NM, USA

Presenting Author:

Dr Anna M. Behar
Centers for Disease Control and Prevention - Centers for Disease Control and Prevention (Atlanta, GA, USA)

Background:

HIV transmitted through cosmetic injection services via contaminated blood has not been previously documented in the United States. In summer 2018, the New Mexico Department of Health (NMDOH) was notified of a diagnosis of HIV infection in a female with no known HIV risk factors who reported exposure to needles from cosmetic platelet-rich plasma micro-needling (vampire facial) received at a spa in spring 2018.

Methods:

This report led NMDOH and CDC to investigate possible transmission of HIV through cosmetic injection services. The period of interest for active case finding was from spring 2018, when the initial case received a vampire facial, to fall 2018 when the spa closed, and on-site inspection of the spa was conducted. Names and phone numbers were compiled and cross-referenced from spa client consent forms, handwritten

appointment records, and cell phone contacts to form a list of potentially affected clients who were directly contacted to encourage testing for bloodborne pathogens. From 2018-2023, suspected cases were reported to NMDOH from clinical providers throughout the state, and blood specimens were submitted to CDC for nucleotide sequence analysis (NSA) to determine cluster association.

Results:

Active case finding identified one client with a previous diagnosis of HIV in 2012, 20 clients who received vampire facials, and 59 clients who received other injection services (e.g., Botox) during spring-fall 2018. Among the 198 former spa clients and their sexual partners tested during 2018-2023, no new HIV, Hepatitis B, or Hepatitis C infections were identified. The on-site inspection revealed several unsafe infection control practices including storage of unlabeled tubes of blood on the kitchen counter. Five suspect cases, four former spa clients plus one sexual partner of a spa client, were reported to NMDOH all of whom had HIV diagnosed during 2018–2023 and no known HIV risk factors. NSA revealed highly similar HIV strains among all cases indicating vampire facials as the likely transmission route of HIV for three cases in this cluster. The other two cases, who had previous HIV infections, were likely attributed to sexual contact. Sequences from the former client living with HIV did not cluster with any sequences from cases.

Conclusions:

This investigation underscores the importance of assessing novel sources of HIV transmission among persons with no known HIV risk factors, and adequate infection control practices at spa facilities offering cosmetic injection services.

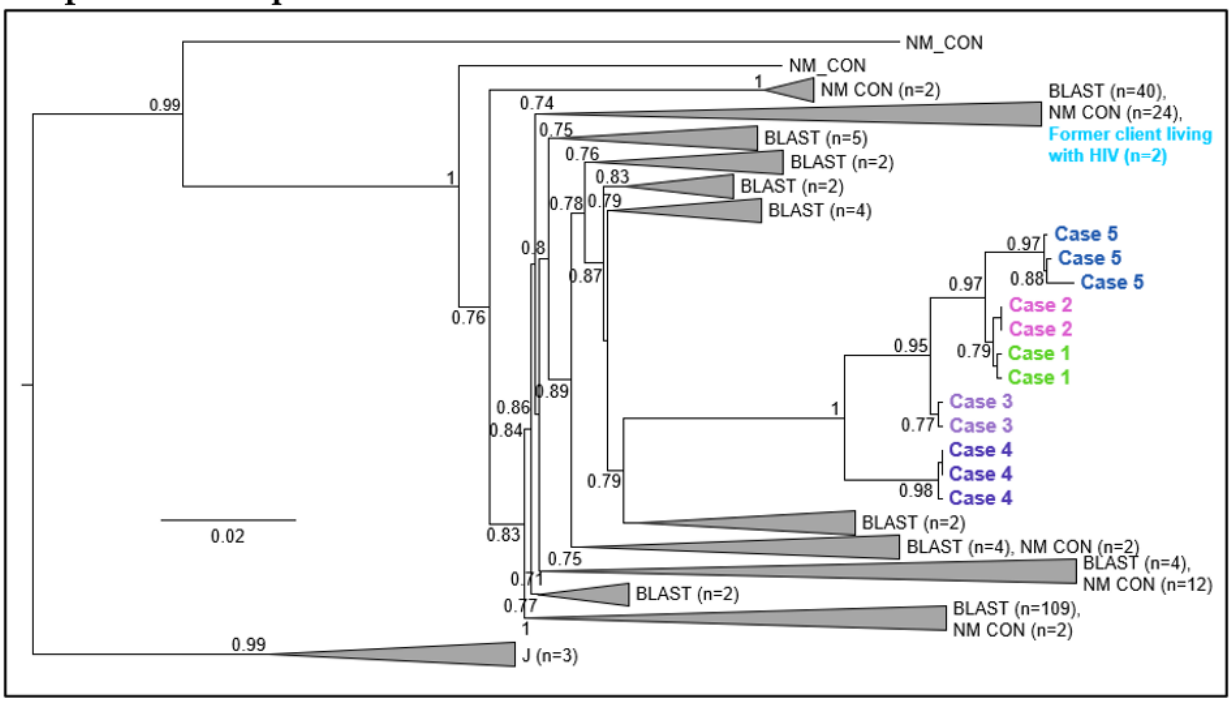
Epidemiology/Public Health:

(Q) Epidemiology of HIV, COVID-19, and Mpox

Search Terms:

Cosmetic injectibles
Investigation
Cluster
HIV
Transmission

Maximum likelihood phylogeny of HIV polymerase sequences from cluster cases compared with sequences from GenBank and local HIV surveillance databases.



Abbreviations: BLAST = Basic Local Alignment Search Tool; NM Con = New Mexico controls; J = HIV-1 subtype J reference sequences used as the outgroup.

Together TakeMeHome: Launch of a National HIV Self-Test Distribution Program, March-December 2023

Abstract Submission Number:

200

Abstract Type:

Late Breaking Abstract

Authors:

Kevin P. Delaney[1], Travis H. Sanchez[2], Robin Macgowan[1], Ruth Dana[2], Lucinda Ackah-Toffey[2], Jen Hecht[3], Emily Lilo[1], Avery Smithson[4], Revae S. Downey[1], Jessica Keralis[1], Emily Pingel[1], Natalie O. Cramer[5], Patrick S. Sullivan[2], Athena Kourtis[1], for the Together TakeMeHome Program Team

Institutions:

[1]Centers for Disease Control and Prevention, Atlanta, GA, USA, [2]Emory University, Atlanta, GA, USA, [3]Building Healthy Online Communities, San Francisco, CA, USA, [4]DLH Corporation, Newberry, MI, USA, [5]National Alliance of State and Territorial AIDS Directors, Washington, DC, USA

Presenting Author:

Dr Kevin P. Delaney
Centers for Disease Control and Prevention - Centers for Disease Control and Prevention (Atlanta, GA, USA)

Background:

HIV testing is the first step to accessing both HIV treatment and prevention services. HIV self-testing is a key strategy for overcoming barriers to HIV testing.

Methods:

The Together TakeMeHome (TTMH) program is a CDC-sponsored, direct-to-consumer, HIV self-test distribution program. CDC's Let's Stop HIV Together campaign implemented marketing on platforms including social media, dating apps, and search and display advertising. Marketing was primarily to men who have sex with men (MSM), especially Black and Hispanic MSM, Black women, and transgender women. Building Healthy Online Communities developed messages and in-app buttons in partnership with dating apps including Grindr and BLK. Persons ages 17+ in the US and

Puerto Rico were eligible to order 1-2 HIV self-tests every 90 days. Ordering wasn't restricted by prior HIV diagnosis or PrEP usage, but persons reporting ARV use were encouraged to give ordered HIV self-tests to others. A short survey was offered post-order with an opt-in for follow-up surveys. Ten- and 60-day follow-up surveys on their HIV self-test experience were conducted.

Results:

In March 2023, TTMH launched, with 181,558 orders placed in the first 9 months. Most orders (86%) were for two tests, with 337,812 total tests distributed. Most participants (109,956, 62%) came from the Grindr app. Sixty percent (108,715) of all orders contained enough information to describe participants in terms of the priority populations. Of these 61% were from men reporting male partners in the past 12 months (18% from Black MSM and 33% from Hispanic MSM), 10.7% from gender diverse persons, and 10% from Black women. Most orders (26%) were placed by persons who had never tested for HIV, or who had last tested >12 months ago (27%). Over half of participants, 86,143 (56.5%) opted into follow-up communications and as of December 11, 2023, 5,294 (6.1%) completed the 10-day survey. Among them, 109 (2.1%) reported a positive result with the HIV self-test, 6.5% sought additional STI testing, and 4.5% self-reported starting PrEP after receiving the self-test.

Conclusions:

Overall, the TTMH program has very high demand, with many persons from priority populations accessing HIV testing for the first time. Many sought additional clinical services after HIV self-testing. It is important for clinicians to be aware of the demand for HIV self-testing and how it may fit into their patient care, including preparing for discussions about HIV follow-up testing, pre-exposure prophylaxis and treatment.

Epidemiology/Public Health:

(R) Testing of HIV, COVID-19, and Mpox in Adults: New Tests, Population Studies, and Scale-Up

Search Terms:

Gay and bisexual men
Heterosexual
HIV self-testing
Transgender individuals
Women

Missed Opportunities to Prevent Congenital Syphilis in Antenatal PrEP Services in South Africa

Abstract Submission Number:

207

Abstract Type:

Late Breaking Abstract

Authors:

Dvora L. Joseph Davey[1], Aurelie Nelson[2], Kalisha Bheemraj[2], Alex de Voux[2], Rufaro Mvududu[2], Lisa Frigati[3], Landon Myer[2]

Institutions:

[1]University of California Los Angeles, Los Angeles, CA, USA, [2]University of Cape Town, Cape Town, South Africa, [3]Tygerberg Hospital, Cape Town, South Africa

Presenting Author:

Professor Dvora L. Joseph Davey
University of California Los Angeles - University of California Los Angeles (Los Angeles, CA, USA)

Background:

Pregnant women are a key population for HIV prevention through pre-exposure prophylaxis (PrEP) services and women at risk of HIV acquisition are also at risk of syphilitic infection. There is growing concern around congenital syphilis globally, yet there are few insights into the burden of syphilis in pregnant women on PrEP and their infants in Africa.

Methods:

We evaluated syphilis positivity and congenital syphilis in a cohort of pregnant women in Cape Town without HIV (>16 years) on oral PrEP in between March 2022 and December 2023. Per local standard of care, women were tested with a rapid treponemal test on site to guide treatment, followed by laboratory testing (TPHA confirmed with RPR). Maternal and infant data were abstracted from antenatal care (ANC) files, neonatal clinical records and laboratory testing data. We evaluated risk factors of maternal syphilis using logistic regression, adjusted for maternal age.

Results:

Of 500 pregnant women attending routine primary care clinics on oral PrEP, 496 (99%) were tested for syphilis at least once in ANC: median age was 25 years, median gestation was 28 weeks. At first ANC visit, 413 women received a rapid Treponemal test (83%); 26 tested positive (6.3%). Of 496 women lab tested, 51 were TPHA+ (10.3%) and 23 RPR+ (overall prevalence of current infection=4.6%, 95% CI=3.1, 6.9). After the first ANC visit, 281 women (59% of 473 who did not have prevalent syphilis) were retested at least once during pregnancy; of these, 8 had incident syphilis detected (incidence, 2.9%; 95% CI=1.5, 5.5). Overall, 31 of 496 pregnant women tested were RPR+ (6.3%, 95% CI=4.3, 8.8). In those RPR+, 16 (52%) were 'adequately treated' with 3 doses of penicillin >30 days before delivery, and 15 of 31 (48%) had 4-fold RPR titer decrease. Two congenital syphilis cases were identified (RPR titer 4x mother's RPR; 6.4% vertical transmission and 0.4% population prevalence) both with maternal diagnosis and treatment <30 days before delivery. Age-adjusted risk factors associated with maternal syphilis included younger age, reporting no sex partners, experiencing recent intimate partner violence and alcohol use (Table).

Conclusions:

These novel data demonstrate a remarkably high occurrence of syphilis in pregnancy among women enrolled in antenatal PrEP services, with half of women not fully treated in pregnancy leading to preventable congenital syphilis. There is a clear and urgent need to integrate syphilis prevention and treatment into antenatal PrEP services.

Epidemiology/Public Health:

(T) Contraception, Sexually Transmitted Infections, and Reproductive Health in Adults

Search Terms:

Pregnant women
PrEP
STI diagnosis and treatment
STI testing
Syphilis

Table 1. Baseline demographics and health characteristics among pregnant women on oral PrEP tested for syphilis during pregnancy in Cape Town, South Africa (March 2022- December 2023)

	Overall (N=500)	RPR negative (N=469, 94%)	RPR+ during pregnancy (N=31, 6.3%)	OR (95% CI)	Age adjusted OR (95% CI)
Maternal age (median, IQR) years	25 (21 - 31)	26 (21 - 31)	24 (22 - 28)	0.96 (0.90, 1.02)	-
16 – 24	224 (45%)	203 (43%)	21 (68%)	**2.75 (1.30, 6.22)**	**-**
Relationship status					
Married / cohabiting	175 (35%)	166 (35%)	9 (29%)	-	-
Not married / not cohabiting	283 (57%)	268 (57%)	15 (48%)	1.03 (0.45, 2.51)	0.88 (0.36, 2.23)
No partner	42 (8%)	35 (8%)	7 (23%)	**3.69 (1.24, 10.6)**	**3.07 (0.98, 9.22)**
Intimate partner violence (IPV) experienced in past 12m	43 (9%)	37 (8%)	6 (19%)	**2.80 (0.99, 6.87)**	**2.81 (0.99, 6.91)**
Any alcohol use in last 12m	212 (42%)	191 (41%)	21 (68%)	**3.06 (1.44, 6.91)**	**2.89 (1.35, 6.58)**

Routine Emergency Department Screening Increases Syphilis Diagnosis Among Pregnant Patients

Abstract Submission Number:

1160

Abstract Type:

Late Breaking Abstract

Authors:

Kimberly A. Stanford[1], Eleanor Friedman[1], Joseph Mason[1], Aniruddha Hazra[1], John Schneider[1]

Institutions:

[1]University of Chicago, Chicago, IL, USA

Presenting Author:

Dr Kimberly A. Stanford
University of Chicago - University of Chicago (Chicago, IL, USA)

Background:

Considering the recent surge in congenital syphilis, novel means of reaching vulnerable populations for testing and treatment are needed. The CDC recently suggested screening outside traditional prenatal care settings might be an effective strategy. As the primary source of healthcare for many communities with limited access to care, visits to the emergency department (ED) may represent a crucial opportunity for syphilis detection and congenital syphilis prevention.

Methods:

A routine, opt-out, syphilis screening program for all ED patients under age 65 was implemented in the ED of a large, urban, tertiary care hospital in Chicago. Prior to that, testing occurred at clinician discretion following the standard of care. This study retrospectively reviewed all ED encounters among pregnant people for the two-year periods before and after implementation of the screening program. Syphilis cases were defined by a combination of positive serology, rapid plasma regain (RPR) titers, and clinical history derived from chart review. Descriptive statistics were used to evaluate changes in screening and diagnosis rates, as well as demographic and clinical trends.

Results:

A total of 9,165 ED encounters involving pregnant patients were identified. In the two years before the intervention, 296 of 4,764 (6.2%) encounters included testing for syphilis, which increased almost eight-fold after the intervention, to 2,307 of 4,401 (52.4%) encounters. There were 3 (1.1% of screened population) syphilis cases identified before the intervention, which quintupled to 16 (0.7%) after the intervention. Screened patients were predominantly non-Hispanic Black (94.3% before, 92.1% after) and had public insurance (72.3% before, 72.5% after), reflecting local demographics. Notably, of all pregnant patients diagnosed with syphilis through the screening program, only 5 (31.2%) were tested for other sexually transmitted infections (STIs), 7 (43.8%) presented to the ED with abdominal or pelvic pain, and none presented with symptoms of an STI.

Conclusions:

This study found that a non-targeted screening program dramatically increased syphilis screening and diagnosis rates among pregnant patients, the majority of whom did not present with concern for STI. Implementing routine ED syphilis screening in high prevalence communities will be key to addressing the syphilis epidemic, eradicating congenital syphilis, and addressing major health care disparities.

Epidemiology/Public Health:

(T) Contraception, Sexually Transmitted Infections, and Reproductive Health in Adults

Search Terms:

congenital syphilis
Emergency department
Pregnant women
Screening
Syphilis