our current practice alleviates nPEP interruption due to potential insurance issues and pick-up delays, follow-up and adherence are not assured. The significant cost-savings with a shorter supply at the outset may encourage more robust follow-up and adherence.

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993. Risk Factors for Periconception Non-Suppression Among Women Living with HIV in Kisumu, Kenya

Ephrat Fisseha, BS[1]; Karen Hampanda, PhD, MPH[2]; Patrick Oyaro, MBChB, MPH[3]; Evelyn Brown, BSc[4]; Irene Mukui, MBChB, MPH[5]; Beryne Odeny, MBChB, MPH, PhD(c)[6]; Rena Patel, MD[6]; Lisa Abuogi, MD, MS[2]; [1]University of Colorado School of Medicine, Denver, Colorado; [2]University of Colorado, Aurora, Colorado; [3]Health Innovations Kenya, Kisumu, Nyanza, Kenya; [4]University of Washington Kenya, Kisumu, Nyanza, Kenya; [5]Kenya Ministry of Health, Nairobi, Nairobi Area, Kenya; [6]University of Washington, SEATTLE, Washington

Session: P-46. HIV: Prevention

Background. Pregnant and postpartum women living with HIV (WLHIV) are a priority population for virologic monitoring and efforts to ensure viral suppression to reduce the risk for vertical-transmission and poor maternal health outcomes. Few studies have examined the role of parity on viral suppression during periconception in WLHIV.

Methods. We present data from the ongoing Opt4Mamas study which enrolled pregnant women with HIV on antiretroviral therapy between March and November 2019 attending antenatal care in five public health facilities in Kisumu County, Kenya. We evaluated associations between various sociodemographic and psychosocial factors and periconception viral suppression (< 40 copies/mL) within 12 months of study enrollment. We conducted univariate and multivariate logistic regressions, calculating odds ratios (OR) and 95% confidence intervals (CI).

Results. Among 497 women enrolled, mean age 29.9 years, 301 (61%) had viral load results available within 12 months of study enrollment. Viral loads were available a median of 18 days from conception (interquartile range 71 days before to 90 days after conception), and 237 women (79%) were virally suppressed. The majority (90%) of women were on a non-nucleoside reverse transcriptase inhibitor and 23 (9%) were on a protease inhibitor-containing regimen. In univariate analysis, women younger than 25 and primigravida women were less likely to be virally suppressed (OR 0.31, 95% CI [0.16 - 0.60] and OR 0.25, 95% CI [0.11 - 0.61] respectively; Table 1). The relationship between primigravida and periconception viral suppression is modified by age and duration on ART. Primigravida women who were younger than 25 years or who had less than 1 year of ART had significantly reduced odds of achieving viral suppression in the past year compared to primigravida women who were older or who had more experience taking ART (OR 0.09, 95%CI [0.03-0.31] and OR 0.09, 95%CI [0.02-0.48] respectively; Table 2).

Table 1: Comparison of Pregnant Women with HIV by Periconception Viral Suppression

Characteristic	Variables	Non-suppressed (VL>40 copies/mL) n=64	Suppressed (VL<40 copies/mL) n=237	Total	OR (95% CI)
Age					
	<25 years	20 (31%)	29 (12%)	49 (16%)	0.31*** (0.16-0.60)
	>24 years	44 (69%)	207 (88%)	251 (84%)	1.0 (ref)
Marital Status					
	Not married	11 (17%)	30 (13%)	41 (14%)	1.0 (ref)
	Married	52 (83%)	207 (87%)	259 (86%)	1.46 (0.67 - 3.10)
Polygamous Relationship					
	No	48 (89%)	168 (82%)	216 (83%)	1.0 (ref)
	Yes	6 (11%)	38 (18%)	44 (17%)	1.81 (0.72 - 4.53)
Completed Primary School					
	No	13 (21%)	46 (19%)	59 (20%)	1.0 (ref)
	Yes	50 (79%)	191 (81%)	241 (80%)	1.08 (0.54 - 2.15)
Does your household have electricity?					
	No	25 (40%)	87 (37%)	112 (37%)	1.0 (ref)
	Yes	38 (60%)	149 (63%)	187 (63%)	1.13 (0.64 - 1.99)
Gravida					
	Primigravida	11 (17%)	12 (5%)	23 (8%)	0.25* (0.11 - 0.61)
	Multigravida	52 (83%)	224 (95%)	276 (92%)	1.0 (ref)
Parity					
	Mean (SD)	2.7 (1.6)	2.6 (1.4)	2.7 (1.4)	0.97 (0.79 - 1.2)
WHO stage at time of enrollment					
	Stage I	28 (52%)	107 (51%)	135 (52%)	1.0 (ref)
	Stage II	7 (13%)	39 (19%)	46 (17%)	1.44 (0.58 - 3.57)
	Stage III	4 (7%)	17 (8%)	21 (8%)	1.10 (0.34 - 3.53)
	Stage IV	1 (2%)	1 (1%)	2 (1%)	0.26 (0.02 - 4.28)
	Missing	14 (26%)	43 (21%)	57 (22%)	-
Duration on ART					
	<1 year	9 (17%)	18 (9%)	27 (11%)	0.49 (0.20-1.15)
	>1year	44 (83%)	181 (91%)	225 (89%)	1.0 (ref)
ART Regimen					
	NNRTI based	48 (87%)	189 (91%)	237 (90%)	2.63 (0.97 - 7.17)
	PI based	7 (13%)	16 (8%)	23 (9%)	1.0 (ref)
	Other	0 (0%)	2 (1%)	2 (1%)	1.71 (0.67 - 4.35)
Disclosure to Primary Sexual Partner					
	No	7 (11%)	18 (8%)	25 (8%)	1.0 (ref)
	Yes	56 (89%)	219 (92%)	275 (92%)	1.52 (0.61 - 3.82)
Male Partner Status					
	Positive	33 (53%)	140 (59%)	173 (58%)	1.0 (ref)
	Negative	21 (33%)	71 (30%)	92 (31%)	1.31 (0.75 - 2.29)
	Don't Know	9 (14%)	26 (11%)	45 (11%)	-
Male Partner Support					
	Did not attend ANC	38 (60%)	149 (63%)	182 (62%)	0.89 (0.50 - 1.57)
	Attended ANC	25 (40%)	87 (37%)	112 (38%)	1.0 (ref)
Moderate Depression					
	No	59 (94%)	225 (95%)	284 (95%)	1.0 (ref)
	Yes	4 (6%)	11 (5%)	15 (5%)	0.72 (0.22 - 2.35)

ART- antiretroviral treatment, NNRTI- non-nucleoside reverse transcriptase inhibitor, PI- protease inhibitor, ANC- antenatal care

* p<0.05 **p<0.01 ***p<0.001

Table 2: Interaction Effects with Primigravida Status

Characteristic	Variables	OR (95% CI)
Age		
	Multigravida, young age	0.47 (0.21-1.03)
	Primigravida, older age	0.83 (0.17-4.04)
	Primigravida, younger age	0.09*** (0.03-0.31)
	Multigravida, older age	1 (ref)
Duration on ART		
	Multigravida, <1 year ART	0.91 (0.29-2.96)
	Primigravida, >1 year ART	0.36 (0.11-1.17)
	Primigravida, <1 year ART	0.09* (0.02-0.48)
	Multigravida, >1 year ART	1 (ref)

* p<0.05 **p<0.01 ***p<0.001

Conclusion. Risk factors for non-suppression around the time of conception in WLHIV include primigravida status, which is modified by age and duration on ART. Interventions targeting viral suppression among WLHIV leading up to their first pregnancy are needed, particularly among those who are newly initiated onto ART or younger age.

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994. Risk for Viral Rebound in the Era of U=U; A CNICS Analysis

Blake Hansen, ScM[1]; Tao Liu, PhD[1]; Lauri Bazerman, MS[2]; Mari-Lynn Drainoni, PhD[3]; Fizza S. Gillani, Ph.D[4]; Edward Cachay, MD, MAS[5]; Katerina Christopoulos, MD, MPH[6]; Heidi Crane, MD, MPH[7]; Mari Kitahata, MD, MPH[7]; Kenneth H. Mayer, MD, MPH[8]; Richard Moore, MD[9]; Sonia Napravnik, PhD, MPH[10]; Aadia Rana, MD[11]; Benigno Rodriguez, MD[12]; Curt Beckwith, MD[13]; [1]Brown University, Providence, Rhode Island [2]The Miriam Hospital, Providence, Rhode Island [3]Boston University, Boston, Massachusetts; [4]Brown University/The Miriam Hospital/Lifespan, Providence, Rhode Island [5]University of California, San Diego, San Diego, California; [6]University of California San Francisco, San Francisco, California; [7]University of Washington, Seattle, Washington; [8]Harvard Medical School/Fenway Research Institute, Boston, MA; [9]Johns Hopkins University, Baltimore, MD; [10]University of North Carolina at Chapel Hill, Chapel Hill, NC; [11]University of Alabama-Birmingham School of Medicine, Birmingham, Alabama; [12]Case Western Reserve University, Cleveland, Ohio; [13]Brown University School of Medicine, Providence, RI

Session: P-46. HIV: Prevention

Background. The "Undetectable equals Untransmittable (U=U)" HIV prevention campaign is a cornerstone of HIV prevention. However, there are few recommendations to guide patients and providers in U=U implementation and limited data on risk factors for viral rebound among persons eligible for U=U.

Methods. We conducted a retrospective multi-center study using data from the CNICS HIV research network to identify risk factors for viral rebound among persons with established viral suppression [two viral loads (VL) and all VLs of < 200 copies/ul within a one-year period (U=U eligible)]. Demographics, patient-reported outcomes, and longitudinal clinical data from 21,359 persons with HIV were analyzed. To include missing data in the analysis, they were treated as a separate category. The primary outcome of viral rebound was defined as any VL > 200 copies/ul within two years after U=U eligibility. A univariable logistic regression model was conducted to identify predictors of viral rebound. Significant variables (p< 0.05) were included in a multivariable logistic regression model. Predictive values of individual variables were captured by adjusted odds ratios (aORs).

Results. From 2011-2019, 12,150 patients met criteria for U=U eligibility and had two years of follow up data. The median age was 46 (IQR: 38-53); 68% male; 51% were white, 39% black. 1544 (13%) experienced viral rebound during follow-up. Forest plot summaries of univariable and multivariable logistic regression models are in Figures 1&2. In multivariable analysis, Black race (aOR=1.56, p< 0.001); MSM-IDU risk (aOR=1.38, p=0.006); lower QoL score (aOR=1.49, p=0.005); poorer ART adherence (aOR=1.84, p< 0.001); duration of lifetime ART [aOR=1.47 (10+yrs), = 1.37 (5-10 yrs); and = 1.28 (2-5 yrs), p< 0.001]; use of InSTIs after eligibility (aOR=1.60, p< 0.001); current smoker (aOR=1.49, p< 0.001), current amphetamine (aOR=1.83, p< 0.001) or cocaine use (aOR=1.46, p=0.012), were associated with viral rebound. In both analyses, older age was protective against viral rebound.

Figure 1. Summary of Univariate Logistic Regression Model

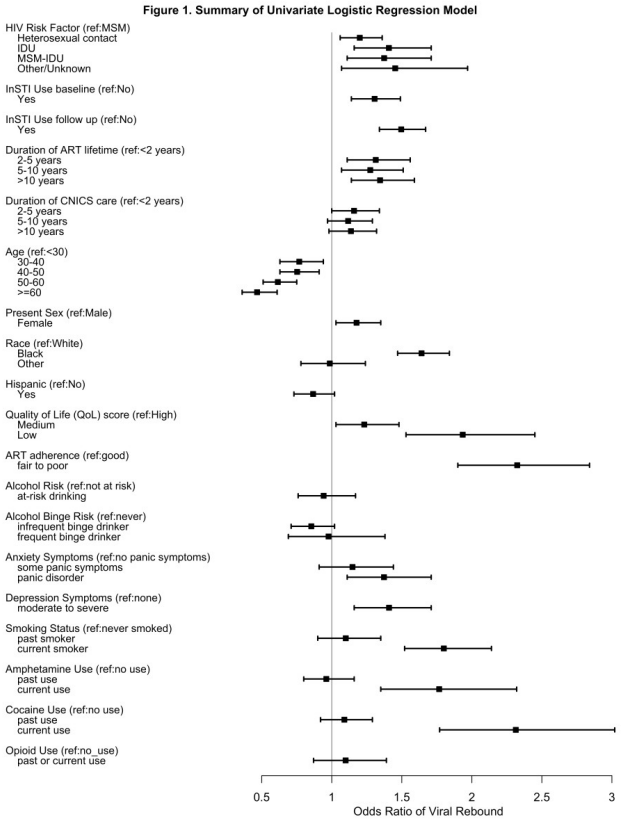
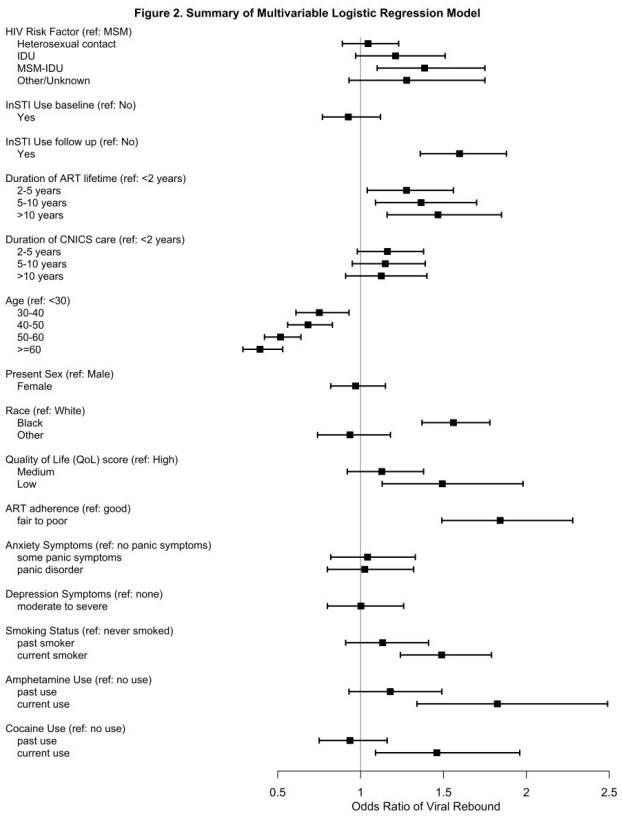


Figure 2. Summary of Multivariable Logistic Regression Model



Conclusion. We identified multiple risk factors for viral rebound among PWH with viral suppression. Further research is needed to identify synergistic risk factors that increase probability of viral rebound to inform optimal implementation of U=U.

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995. Safety and Efficacy of F/TAF and F/TDF for PrEP in DISCOVER Participants Taking F/TDF for PrEP at Baseline

Thomas Campbell, MD[1]; Amanda Clarke, MD[2]; Benoit Trottier, MD[3]; Christoph C. Carter, MD[4]; Yongwu Shao, PhD[5]; Ramin Ebrahimi, MSc[4]; Moupali Das, MD[4]; Diana M. Brainard, MD[4]; Jay Gladstein, MD[6]; [1]University of Colorado, Denver, CO; [2]Brighton & Hove Sexual Health, Brighton, England, United Kingdom; [3]Clinique de Médecine Urbaine du Quartier Latin, Montreal, QC, Canada; [4]Gilead Sciences Inc., Foster City, CA; [5]Gilead Sciences Inc, Foster City, California; [6]APLA Health, Los Angeles, California

Session: P-46. HIV: Prevention

Background. DISCOVER is an ongoing trial comparing emtricitabine plus tenofovir alafenamide (F/TAF) or tenofovir disoproxil fumarate (F/TDF) for HIV pre-exposure prophylaxis (PrEP). DISCOVER included some participants already taking F/TDF for PrEP at baseline (BL) creating a unique opportunity to study outcomes after switching from F/TDF to F/TAF.

Methods. Men who have sex with men and transgender women at risk of HIV were randomized to receive blinded daily F/TAF or F/TDF and followed for at least 96 weeks; participants taking BL F/TDF for PrEP could enroll without a washout period. Laboratory assessments included estimated glomerular filtration rate (eGFR), markers of renal proximal tubular function (RBP and β2M to creatinine ratios), and fasting cholesterol levels; these were analyzed by 2-sided Wilcoxon rank sum test. Bone mineral density (BMD) was assessed in a subset of participants and analyzed by ANOVA.

Results. 905 of 5387 (16.8%) participants were on BL F/TDF for PrEP for a median duration of 399 days; baseline characteristics are found in Table 1. There was one HIV infection among BL PrEP users, in a participant randomized to F/TDF who had intermittent low adherence. Participants on BL PrEP randomized to F/TAF had improvements in eGFR and markers of proximal tubular function compared to F/TDF. Median change in BMD was not statistically different for BL PrEP users assigned to F/TAF vs F/TDF, however *de novo* F/TAF participants had improved BMD profiles compared to F/TDF. BL PrEP users in the F/TAF arm had increases in LDL cholesterol (median +6mg/dL) compared to F/TDF, while changes in HDL and total:HDL ratio were similar. Lipid-modifying agent (LMA) initiation in BL PrEP users was more frequent in the F/TAF arm, while LMA initiation in *de novo* PrEP participants was similar between arms (Table 2).

Table 1. Characteristics of DISCOVER participants

	Baseline PrEP (N=905)	No Baseline PrEP (N=4482)	p value
N (safety analysis set)	905	4482	-
Duration of PrEP, median days (IQR)	398.5 (148, 763)	-	
Age, median (IQR)	36 (30, 45)	34 (27, 43)	<0.001
Transgender women, N (%)	6 (0.7)	68 (1.5)	0.044
Race N (%)			0.79
White	770 (85.3)	3741 (83.6)	
Black	69 (7.6)	405 (9.0)	
Asian	39 (4.3)	194 (4.3)	
Hispanix/Latinx ethnicity, N (%)	154 (17.1)	1164 (26.0)	<0.001
Sexuality (self-reported), N (%)			0.009
Gay/Homosexual	850 (94.1)	4045 (90.8)	
Bisexual	44 (4.9)	341 (7.7)	
Straight/Heterosexual	3 (0.3)	38 (0.9)	

PrEP, pre-exposure prophylaxis; IQR, interquartile range

Table 2. Efficacy and safety results

	Baseline PrEP			No Baseline PrEP		
	F/TAF (N=465)	F/TDF (N=437)	P value	F/TAF (N=2229)	F/TDF (N=2253)	P value
Duration of PrEP, median days (IQR)	383 (141, 764)	406 (166, 763)	-	-	-	-
HIV infection						
HIV infections, N	0	1	-	8	14	-
HIV rate per 100 PY (95% CI)	0 (-, 0.413)	0.119 (0.003, 0.662)	-	0.193 (0.084, 0.381)	0.333 (0.182, 0.558)	-
Renal biomarkers						
eGFR*	3 (-7.1, 12.8)	-2.6 (-12.6, 6.6)	<0.001	-1.2 (-11.4, 8.9)	-4.4 (-13.7, 5)	<0.001
β2M:Cr ratio†	-35.5 (-65.5, -1.3)	-11.4 (-46.3, 53.2)	<0.0001	-10.8 (-39.5, 28.8)	17.3 (-22.8, 108.3)	<0.0001
RBP:Cr ratio†	-10.3 (-38.1, 18.6)	5.5 (-25.2, 64.6)	<0.0001	2.9 (-24.8, 39.4)	24.5 (-11.5, 76.1)	<0.0001
Bone mineral density						
N (BMD analysis subset)	20	16	-	124	122	-
BMD Spine†	1.682 (0.252, 3.756)	0.446 (-5.284, 1.847)	0.1295	0.729 (-1.493, 2.735)	-1.434 (-3.465, 0.636)	<0.0001
BMD Hip†	1.561 (-0.924, 5.125)	0.573 (-0.368, 2.67)	0.7457	0.15 (-1.296, 1.733)	-1.109 (-2.913, 0.404)	<0.0001
Cholesterol‡						
LDL*	6 (-9, 19)	0 (-11, 9)	0.011	-2 (-16, 12)	-8 (-22, 5)	<0.001
HDL*	1 (-5, 6)	-1 (-5, 6)	0.65	-2 (-8, 4)	-5 (-11, 1)	<0.001
Total:HDL ratio	0.1 (-0.3, 0.5)	0 (-0.4, 0.4)	0.12	0.1 (-0.3, 0.5)	0 (-0.4, 0.4)	0.29
LMA initiation (%)	3.0	0.9	0.03	1.3	1.0	0.27

*median change (interquartile range). Units are mL/min for eGFR and mg/dL for cholesterol.
†median percent change (interquartile range)
‡Cholesterol laboratory data include participants with both baseline and week 96 fasting levels, and excludes participants on LMAs.
PrEP, pre-exposure prophylaxis; F/TAF, emtricitabine/tenofovir alafenamide; F/TDF, emtricitabine/tenofovir disoproxil fumarate; IQR, interquartile range; PY, person-years; DBS, dried blood spot tenofovir diphosphate concentration; eGFR, estimated glomerular filtration rate by Cockroft-Gault; β2M, β-2-microglobulin; Cr, creatinine; RBP, retinol binding protein; BMD, bone mineral density by dual energy x-ray absorptiometry; LDL, low density lipoprotein; HDL, high density lipoprotein; LMA, lipid modifying agent.

Conclusion. HIV incidence was low in participants taking BL PrEP. Participants who switched from F/TDF to F/TAF had improvements in renal biomarkers. There was no statistical difference in BMD among BL PrEP users, although numbers were small. The observed lipid changes in BL PrEP users are consistent with the LDL and HDL suppressive effect of TDF, and the small but higher rate of LMA initiation with F/TAF is likely related to withdrawal of this effect.

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