

Figure 1. Summary of Univariate Logistic Regression Model

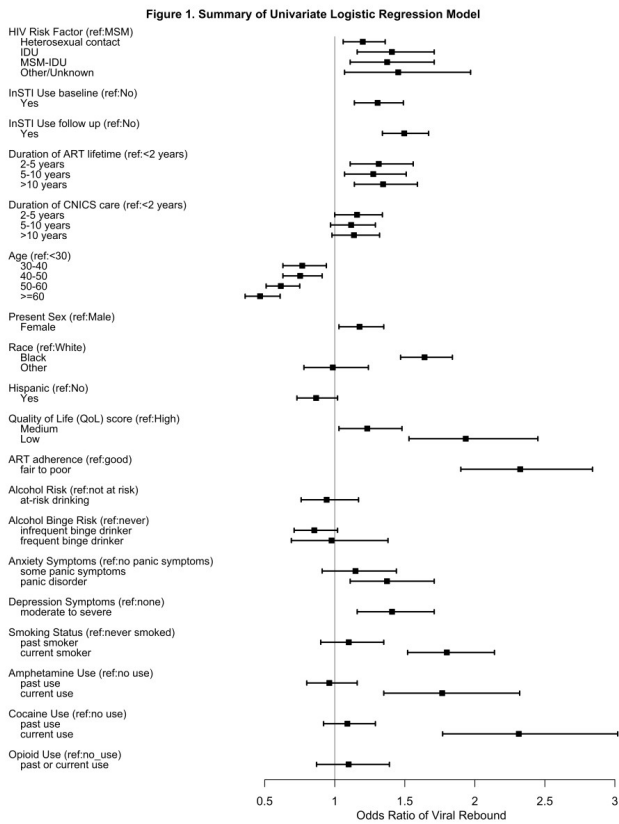
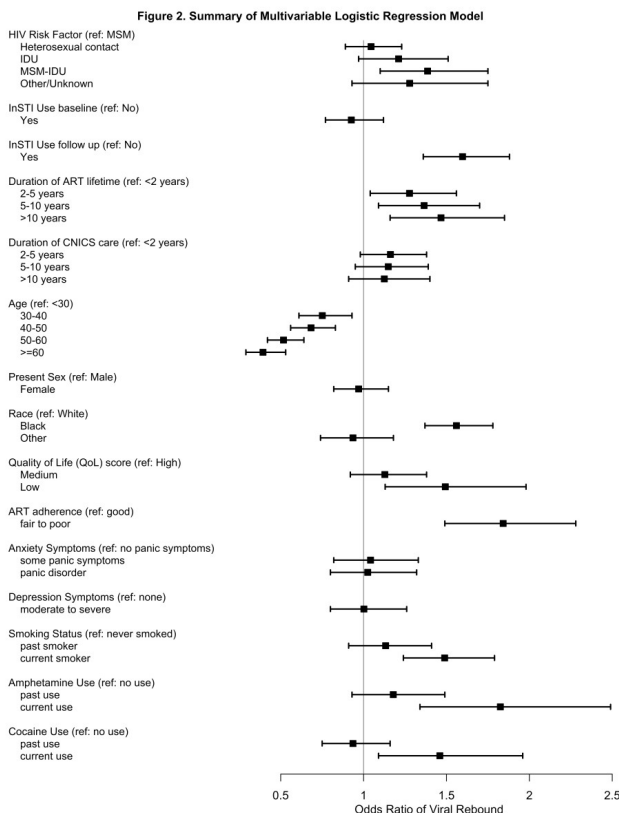


Figure 2. Summary of Multivariable Logistic Regression Model



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.

Disclosures. Edward Cachay, MD, MAS, Gilead (Consultant, Grant/Research Support) Merck Sciences (Grant/Research Support) Heidi Crane, MD, MPH, ViiV (Grant/Research Support) Benigno Rodriguez, MD, Gilead (Speaker's Bureau) ViiV (Speaker's Bureau)

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

Thomas Campbell, MD¹; Amanda Clarke, MD²; Benoit Trottier, MD³; Christoph C. Carter, MD⁴; Yongwu Shao, PhD⁵; Ramin Ebrahimi, MS⁶; Moupali Das, MD⁷; Diana M. Brainard, MD⁸; Jay Gladstein, MD⁹; ¹University of Colorado, Denver, CO; ²Brighton & Hove Sexual Health, Brighton, England, United Kingdom; ³Clinique de Médecine Urbaine du Quartier Latin, Montreal, QC, Canada; ⁴Gilead Sciences Inc., Foster City, CA; ⁵Gilead Sciences Inc, Foster City, California; ⁶APLA 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 β 2M 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)	
Hispanic/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
β 2M: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 (%)	3.9	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 Cockcroft-Gault; β 2M, 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.

Disclosures. Thomas Campbell, MD, Gilead Sciences Inc. (Scientific Research Study Investigator) Amanda Clarke, MD, Gilead Sciences Inc. (Consultant, Scientific Research Study Investigator, Other Financial or Material Support, Conference attendance

sponsorship) **Viiv Healthcare** (Consultant, Other Financial or Material Support, Conference travel sponsorship) **Benoit Trottier, MD, AbbVie** (Grant/Research Support, Other Financial or Material Support, Personal fees) **Bristol-Myers Squibb** (Grant/Research Support, Other Financial or Material Support, Personal fees) **Gilead Sciences Inc.** (Grant/Research Support, Scientific Research Study Investigator, Other Financial or Material Support, Personal fees) **Janssen** (Grant/Research Support, Other Financial or Material Support, Personal fees) **Merck** (Grant/Research Support, Other Financial or Material Support, Personal fees) **Viiv Healthcare** (Grant/Research Support, Other Financial or Material Support, Personal fees) **Christoph C. Carter, MD, Gilead Sciences Inc.** (Employee, Shareholder) **Yongwu Shao, PhD, Gilead Sciences Inc.** (Employee, Shareholder) **Ramin Ebrahimi, MSc, Gilead Sciences Inc.** (Employee, Shareholder) **Mouपालi Das, MD, Gilead Sciences Inc.** (Employee, Shareholder) **Diana M. Brainard, MD, Gilead Sciences** (Employee) **Jay Gladstein, MD, Gilead Sciences Inc.** (Scientific Research Study Investigator)

996. The Potential for Reducing Opioid and Analgesic Prescriptions Via Herpes Zoster Vaccination

Jean-Etienne Poirrier, PhD, MBA¹; Justin Carrico, BS²; Jessica K. DeMartino, PhD¹; Katherine A. Hicks, MS, BSPH²; Jeffrey J. Stoddard, MD³; Saurabh P. Nagar, MS²; Juliana Meyers, MA²; ¹GSK, Philadelphia, Pennsylvania; ²RTI Health Solutions, Research Triangle Park, North Carolina ³Janssen, Raritan, New Jersey

Session: P-46. HIV: Prevention

Background. Herpes zoster (HZ), or shingles, is a common neurocutaneous disease caused by the reactivation of latent varicella zoster virus that often includes rash and neuropathic pain that may last for months. Opioids and other analgesics may be prescribed. Recombinant zoster vaccine (RZV) is preferentially recommended for the prevention of HZ in adults aged 50 years and older. This study aimed to assess the impact of RZV vaccination on opioid and other analgesic prescription-related outcomes.

Methods. Estimates of analgesic prescription rates (opioids, benzodiazepines, and other analgesics) among HZ cases were established using Truven claims data from 2012-2018 for adults aged 50 years and older. HZ case avoidance with RZV vaccination was calculated using a previously published cost-effectiveness model. This data was included in a calculator assessing the impact of RZV vaccination on analgesic prescription-related outcomes (compared to no vaccination).

Results. Between 24.4% and 28.0% of HZ cases in the observed claims had at least one opioid prescription, dependent on age group (4.5%-6.5% and 8.6%-19.6% for benzodiazepines and other analgesics, respectively). The mean number of opioid prescriptions per person in each age group with at least one opioid prescription was between 1.7 and 1.9 (1.7-2.3 and 1.7-2.0 prescriptions for benzodiazepines and other analgesics, respectively). Assuming a 1-million-person population and 65% RZV coverage, the calculator predicts RZV vaccination will prevent 75,002 cases of HZ and will prevent 19,311 people from being prescribed at least 1 HZ-related opioid, 4,502 people from being prescribed benzodiazepines, and 12,201 people from being prescribed other analgesics. Additionally, 34,520 HZ-related opioid prescriptions will be avoided (9,413 benzodiazepine prescriptions; 22,406 other analgesic prescriptions).

Conclusion. HZ is associated with high levels of opioid, benzodiazepine, and other analgesic use. Primary prevention of HZ by vaccination could potentially reduce opioid and other medication exposure.

Disclosures. Jean-Etienne Poirrier, PhD, MBA, The GSK group of companies (Employee, Shareholder) Justin Carrico, BS, GlaxoSmithKline (Consultant) Jessica K. DeMartino, PhD, The GlaxoSmithKline group of companies (Employee, Shareholder) Katherine A. Hicks, MS, BSPH, GlaxoSmithKline (Scientific Research Study Investigator, GSK pays my company for my contractual services.) Saurabh P. Nagar, MS, RTI Health Solutions (Employee) Juliana Meyers, MA, GlaxoSmithKline (Other Financial or Material Support, This study was funded by GlaxoSmithKline.)

997. The Purview Paradox: PrEP Utilization at a Major Southern California County Teaching Hospital and Affiliated Clinics

Stephanie Clavijo, MPH¹; Matthew Herrmann, MD²; Katya Corado, MD²; ¹UCLA/CDU, Los Angeles, California; ²Harbor-UCLA Medical Center, Sherman Oaks, California

Session: P-46. HIV: Prevention

Background. According to the Centers for Disease Control (CDC), PrEP coverage in the United States was approximately 18% in 2018 and 21.9% in California. We predict that PrEP prescription is lower at Harbor-UCLA Medical Center (HUMC) and affiliated clinics within Los Angeles County Department of Health Services.

Methods. A retrospective chart review of HIV-negative patients with ICD-10 coded diagnoses of sexually transmitted infections (STIs) or high-risk sexual behavior was performed across various medical specialties at HUMC and affiliated clinics in 2018. Documentation of sexual behavior risk reduction counseling, PrEP discussion and prescription was reviewed from electronic medical records for each encounter. Descriptive statistics and analysis were completed in STATA Version 16.1, StataCorp LLC.

Results. The sample included 250 individual patients, all with indications for PrEP. Of those, 47.2% identified as Latinx and 27.2% Black. Table 1 shows 74% of patients identified as heterosexual whereas 9.2% identified as gay, and 4.4% bisexual. Of the 250 individual patients, 87 (34.8%) returned for a 2nd visit, 35 (14.0%) for a third, and 9 (3.6%) for a 4th visit, for a total of 381 encounters. Of the total encounters, 49.3% had sexual behavior risk reduction counseling, 7.3% had discussions about PrEP with their provider, and only 2.1% were newly prescribed PrEP (Table 2). Of the 2.1% new PrEP prescriptions, 1.8% were prescribed by family medicine providers with no new prescriptions by OB/GYN or acute care providers. Only 25% of new PrEP prescriptions were female patients. A positive test for an STI occurred in 45.1% of total encounters while high risk sexual behavior was identified in 54.9% of encounters (Table 3).

Table 1: First Encounter Demographics (N=250 Individual Patients)

Table 1: First Encounter Demographics (N=250 Individual Patients)	
	Individual Patients (N=250)
Mean Age	32.4
Gender	
Male	101 (40.4%)
Female	147 (58.8%)
Non-Binary	2 (0.8%)
Race/ Ethnicity	
Asian/ PI	15 (6.0%)
Black	68 (27.2%)
European	19 (7.6%)
Latinx	118 (47.2%)
Mixed Race	7 (2.8%)
Other	23 (9.2%)
Sexual Orientation	
Bisexual	11 (4.4%)
Heterosexual	185 (74.0%)
Gay	23 (9.2%)
Unspecified	31 (12.4%)
Provider Type	
Physician	120 (48.0%)
Nurse Practitioner	116 (46.4%)
Physician Assistant	3 (1.2%)
Medical Student	9 (3.6%)
Other	2 (0.8%)
Specialty	
Family Medicine	88 (35.2%)
Internal Medicine	16 (6.4%)
Ob/Gyn	89 (35.6%)
Emergency Medicine	32 (12.8%)
Urgent Care	25 (10.0%)
Insurance	
Self-Pay	40 (16.0%)
Medicaid	168 (67.2%)