882. Use of Tenofovir Disoproxil Fumarate Shows Weight Loss vs Placebo: A Meta-Analysis of 7 Clinical Trials in 19,359 HIV-negative Individuals

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Background. Recent clinical trials have shown weight gain associated with newer antiretrovirals. It is unclear how the nucleoside reverse transcriptase inhibitor backbone affects weight. Recent evidence suggests greater weight gain with tenofovir alafenamide (TAF) compared to tenofovir disoproxil fumarate (TDF). However, it is not fully understood whether TDF contributes to weight suppression or weight loss.

Methods. A systematic search of PubMed, Embase and clinicaltrials.gov was conducted to identify all randomised control trials comparing TDF/FTC or TDF to control in HIV-negative individuals. The primary endpoint included the number of events of '5% weight loss' or 'abnormal loss of weight'. The Mantel-Haenszel test with random-effects modelling was used to calculate the odds ratio (OR) and 95% confidence intervals (95% CI). Further analyses of gastrointestinal (GI) adverse events (AEs) were undertaken, including the number of reported adverse events of nausea, vomiting, loss of appetite and diarrhoea.

Results. Seven PrEP trials: PARTNERS, VOICE, TDF-2, Bangkok PrEP, iPrEX, FEM-PrEP and HPTN 084 were included in the analysis of weight loss, with a total sample size of 19,359. One study (HPTN 084) compared TDF/FTC to cabotegravir (CAB). The remaining compared either TDF or TDF/FTC or placebo. HIV-negative individuals taking TDF were more likely to experience weight loss compared to control (OR 1.44 95% CI 1.12 – 1.85 p = 0.005 (table 1)). In a separate analysis of GI AEs, exposure to TDF was also linked to greater odds of vomiting (OR 1.81 95% CI (1.20, 2.73) p < 0.005). There were no increased odds of nausea, diarrhoea, or loss of appetite.

Weight loss events in PrEP trials.

	Number of events (weight loss)					
	TDF or TDF/FTC	**TOTAL**	**Placebo (PBO) / non-TDF arm**	**TOTAL**	**Odds Ratio (95% CI)**	**Weight loss definition**
VOICE (TDF or TDF/FTC vs PBO)	49	2010	17	1009	1.46 (0.84, 2.54)	Abnormal loss of weight
TDF-2 (TDF/FTC vs PBO)	113	611	72	608	2.07 (1.52, 2.83)	>5% weight loss
FEM-PrEP (TDF/FTC vs PBO)	1	1025	0	1033	2.57 (0.10, 63.26)	> 5% Weight loss
BKK (TDF vs PBO)	140	1204	135	1209	1.05 (0.81, 1.35)	>5% weight loss
PARTNERS (TDF or TDF/FTC vs PBO)	13	3163	6	1584	1.09 (0.41, 2.86)	>5% weight loss
iPREX (TDF/FTC vs PBO)	34	1251	19	1248	1.81 (1.03, 3.19)	>5% weight loss
HPTN 084 (TDF/FTC vs CAB)	101	1610	78	1614	1.32 (0.97, 1.79)	Abnormal loss of weight
Total	**470**	**11054**	**327**	**8305**	**1.44 (1.12, 1.85)**	

Conclusion. There is evidence in HIV-negative individuals that TDF may be associated weight loss when compared to placebo. Further research should be carried out in HIV positive individuals, and clinical trials of TDF/FTC should publish weight data to widen the evidence base

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883. Qualitative Patient-Participant Perspectives on Implementation of Monthly Cabotegravir and Rilpivirine Long Acting (CAB+RPV LA) Injectable in the United States (CUSTOMIZE)

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Session: P-51. HIV: Treatment

Background. CAB+RPV LA administered monthly for HIV treatment is non-inferior to daily oral ART at maintaining viral suppression and preferred by most participants in clinical trials over daily ART. CUSTOMIZE, an implementation-effectiveness study, evaluated facilitators and barriers to clinic implementation of CAB+RPV LA from the patient perspective.

Methods. 115 participants were enrolled across 8 HIV clinics. Semi-structured phone interviews were conducted with a randomized subgroup of 3-6 participants per site, prior to the 1st (Baseline [BL], N=34) and 12th CAB+RPV LA injections (Month 12 [M12], N=31). Consolidated Framework for Implementation Research-guided interviews were recorded, transcribed, and coded using ATLAS.ti.

Results. At BL, 97% (n=33) of those interviewed indicated ≥1 challenge taking daily oral ART, including concerns about adherence (n=19; 56%), dosing frequency (n=13; 38%) and side effects (n=12; 35%). Twenty-seven (79%) reported anticipated challenges of CAB+RPV LA such as worry about side effects (n=15; 44%) and discomfort from injections (n=14; 41%). Participants reported at BL that CAB+RPV LA may help with adherence (n=17; 50%) or reduce fears of HIV status disclosure (n=10; 29%). At M12, 35% (n=11) reported some pain/discomfort from injections, but 87% (n=27) reported satisfaction with CAB+RPV LA, most commonly due to preferring the monthly regimen over the daily pill (n=15; 48%). Facilitators reported by participants as most helpful during early implementation were verbal education by clinic staff (14%), reminder texts/calls (13%), and an educational video about the regimen (6%). Most (n=25; 81%) indicated clinic hours were not a barrier, but 19% (n=6) noted taking time off work for the visits. Many participants (n=21; 68%) described positive aspects of going to the clinic each month, none complained about visit length, and 94% (n=29) reported intent to continue CAB+RPV LA after the study.

Conclusion. Interviewed participants reported several challenges with daily oral ART that monthly CAB+RPV LA may help overcome. Some initial concerns about receiving CAB+RPV LA were reported at BL, but most participants were satisfied with the regimen after one year and plan to continue receiving CAB+RPV LA following the study.

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884. Title: Factors Associated with Lack of Viral Suppression Among Women Living with HIV in the United States: An Integrative Review

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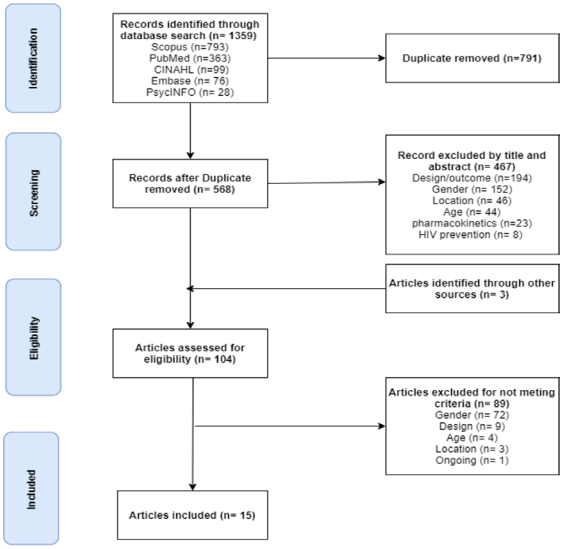
Session: P-51. HIV: Treatment

Background. Women account for 19% of new HIV cases in the United States (US). Transgender women are 49 times more likely than other groups to be diagnosed with HIV. HIV is one of the top ten causes of death among women between 25 to 44 years. Adherence to antiretroviral therapy (ART) and consequent viral suppression (VS) are keys to preventing sexual transmission, risk of drug resistance, and improving health outcomes. Hence, it is essential to identify factors behind VS in women living with HIV (WLWH).

Methods. This review identified and synthesized peer-reviewed studies describing reasons for lack of VS among WLWH in the US. : Using the PRISMA model, we searched CINAHL, PubMed, Embase, Scopus, and PsycINFO, then selected US studies published from 2010 to April 2021. Studies that included men, non-adults, ongoing studies, and foreign studies were excluded. 1,359 studies were assessed and screened for duplicate and eligibility.

PRISMA Model



Results. 15 studies were eligible for review; 8 included all WLWH, 5 focused on pregnant WLWH, 1 included only African American WLWH and 1 included only transgender WLWH. Based on study participants and findings, results were divided into pregnancy and non-pregnancy-related factors. *Pregnancy-related factors:* Early ART initiation and group prenatal care improved care retention and VS. WLWH in cities were more likely to be virally suppressed at delivery than those in rural regions. Intimate partner violence (IPV) was associated with poor ART adherence and time to achieve stable VS. Also, being postpartum was associated with high viral load regardless of ART. *Non-pregnancy-related factors*: The most reported common factors were substance use and IPV. Other factors included social determinants of health, age, race, health insurance, income, number of pills, and regimen. Transgender-specific factors were stress, race, age, relationship, transphobic experiences, gender satisfaction, and adherence to hormone therapy.

Conclusion. Substance use, income, mental health, health insurance, race, and ART regimen were the most common factors associated with VS in WLWH. There was paucity of data on transgender-specific VS factors. More research is needed to explore VS and treatment adherence amongWLWH, especially transgender women.

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885. Pregnancy Outcomes and Pharmacokinetics in Pregnant Women Living with HIV Exposed to Long-Acting Cabotegravir and Rilpivirine in Clinical Trials

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Session: P-51. HIV: Treatment

Background. Limited data exist among women living with HIV who become pregnant while exposed to long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV). We report outcomes in pregnant participants and LA pharmacokinetic (PK) tail data in pregnant women exposed to CAB+RPV with live births.

Methods. Women of reproductive potential exposed to ≥ 1 dose of CAB+RPV (oral/LA) from ViiV-sponsored Phase 2/3/3b clinical treatment studies and the compassionate use program were included in this analysis and pregnancies identified. Per protocol, upon identification of pregnancy, CAB+RPV was discontinued and an alternative regimen initiated, with continued quarterly PK sampling for 52 weeks post last injection during long-term safety follow-up (LTFU). Descriptive characteristics of pregnant women and birth outcomes and available CAB and RPV PK during pregnancy for those with live births are summarized.

Results. As of March 31, 2021, 26/325 women of reproductive potential (age 18–49 years) became pregnant while exposed to CAB+RPV (5 oral, 21 LA [including 3 following LA discontinuation]). There were 11 live births (1 oral, 10 LA), of which 10 had no reported congenital abnormalities and 1 had reported congenital ptosis, in a pre-term infant with intrauterine growth restriction. There were 9 elective terminations and 6 miscarriages (5 in first 9 weeks of gestation). Ten women exposed to intramuscular CAB+RPV LA became pregnant with subsequent live birth outcomes, including 3 infants conceived during the PK tail in LTFU. All women were virologically suppressed at time of pregnancy identification. In women becoming pregnant on LA dosing, plasma CAB and RPV concentrations during pregnancy were within the range of expected concentrations in non-pregnant women. Two of 10 women with live births exposed to CAB+RPV LA continued LA therapy during pregnancy (compassionate use program participants).

Conclusion. Pregnancy outcomes in women exposed to CAB+RPV at conception are consistent with earlier findings. There was 1 reported congenital anomaly among 11 live births. CAB and RPV PK tail in pregnancy was within the expected range for non-pregnant women. Ongoing monitoring of birth defects within the antiretroviral pregnancy registry and pregnancy surveillance within the treatment program continues.

Disclosures. **Parul Patel, PharmD**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Susan L. Ford, PharmD**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Mark Baker, PhD**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Claudia Meyer, MBChB, MRCP, MSc, FRCPath, DTM&H**, **GlaxoSmithKline** (Employee, Shareholder) **Louise Garside, PhD**, **GlaxoSmithKline** (Employee) **Ronald D'Amico, DO, MSc**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Rodica Van Solingen-Ristea, MD**, **Janssen Research and Development** (Employee)**ViiV Healthcare** (Employee) **Herta Crauwels, PhD**, **Janssen** (Employee) **Joseph Polli, PhD, FAAPS**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Ciara Seal, BS**, **GlaxoSmithKline** (Employee, Shareholder) **Shanker Thiagarajah, MB ChB**, **GlaxoSmithKline** (Employee, Shareholder) **Eileen Birmingham, MD, MPH**, **Janssen Research and Development** (Employee, Shareholder) **William Spreen, PharmD**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Bryan Baugh, MD**, **Janssen, Johnson & Johnson** (Employee, Shareholder) **Matthew Bosse, DO**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Vani Vannappagari, MBBS, MPH, PhD**, **ViiV Healthcare Limited** (Employee)

886. The Impact of the COVID-19 Pandemic on Clinical Follow-Up, Monitoring and Regimen Discontinuation for People Living with HIV in the US

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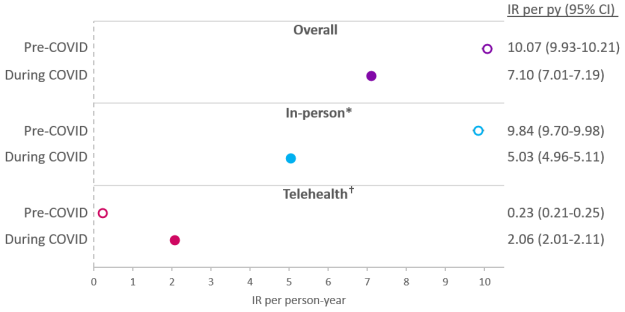
Session: P-51. HIV: Treatment

Background. The COVID-19 pandemic has disrupted health care services for people living with HIV (PLWH). This study aimed to compare rates of clinical visits, viral load monitoring and antiretroviral therapy (ART) regimen discontinuation among virally suppressed PLWH in the US before and during the COVID pandemic.

Methods. The study population consisted of ART-experienced PLWH ≥18 years of age and active in care in the OPERA cohort within 2 years prior to 31OCT2020. Virally suppressed PLWH (i.e., viral load < 200 copies/mL) were included if they switched to either dolutegravir/lamivudine or a dolutegravir- or bictegravir-based 3-drug regimen between 01MAY2019 and 30APR2020. The study periods spanned from 01MAY2019 to 28FEB2020 (pre-COVID) and 01MAR2020 to 31OCT2020 (during COVID). Incidence rates of clinical visits, viral load measurements and regimen discontinuation were estimated using univariate Poisson regression for both study periods. In-person visits comprised any scheduled or walk-in outpatient, inpatient, emergency or laboratory visit. Telehealth visits comprised any phone or video encounters.

Results. The study included 4806 PLWH in the pre-COVID and 4992 in the COVID period. Rates of in-person visits were reduced almost 2-fold during COVID, while telehealth visits increased almost 9-fold, resulting in an overall reduction in any visits rates from 10.07 visits per person-year (95% CI: 9.93, 10.21) pre-COVID to 7.10 (95% CI: 7.01, 7.19) during COVID [Fig 1]. Rates of viral load measurements dropped from 2.99 viral loads per person-year (95% CI: 2.92, 3.07) pre-COVID to 1.97 (95% CI: 1.92, 2.02) during COVID [Fig 2]. Regimen discontinuation rates were also reduced from 14.3 discontinuations per 100 person-years pre-COVID (95% CI: 12.7, 16.1) to 9.6 (95% CI: 8.6, 10.8) during COVID [Fig 3]. In both study periods, virologic failures were detected in < 1% of PLWH with ≥ 1 viral load.

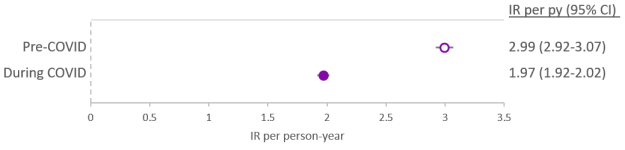
Figure 1. Incidence rates for overall, in-person, and telehealth visits during the pre-COVID (open circle) and the COVID (filled circle) study periods



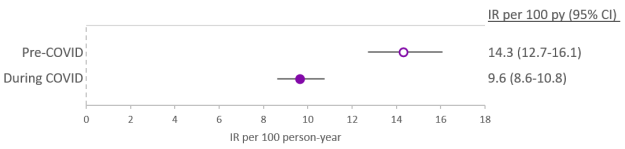
*Any scheduled or walk-in outpatient, inpatient, or emergency with a nurse or physician, or laboratory visits

†Any telephone encounters, virtual visits, telehealth, and video encounters

Incidence rates for viral load measurements during the pre-COVID (open circle) and the COVID (filled circle) study periods



Incidence rates for regimen discontinuation during the pre-COVID (open circle) and the COVID (filled circle) study periods



Conclusion. The COVID pandemic has led to an important reduction in the frequency and type of clinical follow-up visits and viral load monitoring among virally suppressed PLWH in the US. A reduction in regimen discontinuation rates was also observed, presumably associated to less frequent follow-up. The long-term impact of the pandemic on HIV care remains uncertain.

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