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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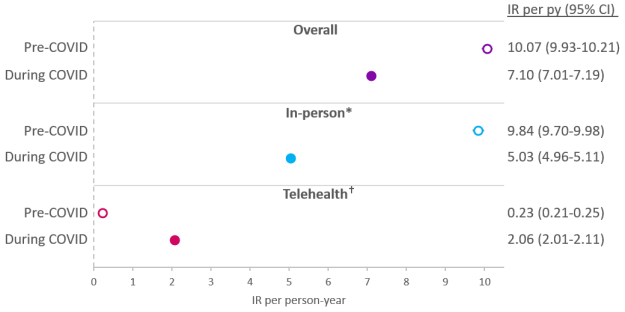
Session: P-51. HIV: Treatment

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.

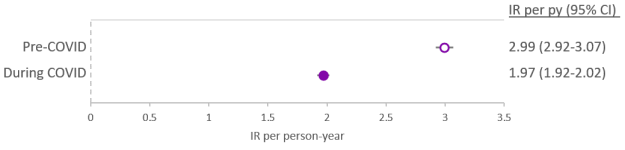
Figure 1. Incidence rates for overall, in-person, and telehealth visits during the pre-COVID (open circle) and the COVID (filled circle) study periods



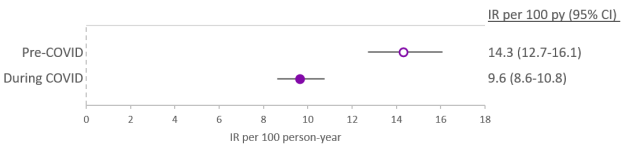
*Any scheduled or walk-in outpatient, inpatient, or emergency with a nurse or physician, or laboratory visits

†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.

Disclosures. **Gerald Pierone, MD**, **Epividian** (Board Member) **Jennifer S. Fusco, BS**, **Epividian, inc** (Employee) **Laurence Brunet, PhD**, **Epividian, inc** (Employee)

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887. Implementation of Long-acting Injectable Cabotegravir/Rilpivirine for HIV-1 Treatment at a Ryan White-funded Clinic in the U.S. South

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Session: P-51. HIV: Treatment

Background. In January 2021, the first ever long-acting injectable (LAI) antiretroviral therapy (ART), cabotegravir/rilpivirine (CAB/RPV), was approved for maintenance HIV-1 treatment in select patients with virologic suppression. LAI-ART has the potential to improve ART adherence, reduce HIV stigma, and promote equity in care outcomes, however, implementation in real-world settings has yet to be evaluated.

Methods. We launched a pilot LAI-ART program at the largest Ryan White-funded HIV clinic in the Southeast. From 4/14/21 to 5/14/21, providers referred patients interested and willing to switch to LAI-CAB/RPV who met screening criteria. Our interdisciplinary LAI team (Clinician-Pharmacy-Nursing) verified clinical eligibility (HIV-1 < 200 c/ml ≥6 months and no history of virologic failure, resistance to either drug, or chronic HBV infection) and pursued medication access for 28-day oral lead-in and monthly injectable CAB/RPV. We describe demographic and clinical variables of referred PWH and early outcomes in accessing LAI-ART.

Results. Among 42 referrals, median age was 40.5 (Q1-Q3, 32-52) years, 83% were men, and 76% Black. Payor source distribution was 26% Private, 19% Medicare, 10% Medicaid, and 45% ADAP. At the time of referral, median CD4 count was 583 (Q1-Q3, 422-742) cells/mm^3 and median sustained HIV-1 RNA < 200 c/ml was 1427 (Q1-Q3, 961-2534) days. A total of 35 patients (74%) met clinical eligibility for LAI-CAB/RPV, including 4 patients who required a transition off proton pump inhibitor therapy to accommodate oral RPV. Ineligible PWH were excluded due to evidence of RPV resistance (n=5), possible RPV hypersensitivity (n=1), and HIV non-suppression (n=1). The table summarizes the process of pursuing LAI-ART access for the initial 10 enrollees by insurance status.

Table. Summary of medication access pursuit for patients enrolled in long-acting injectable (LAI) cabotegravir/rilpivirine (CAB/RPV) pilot program for HIV-1 treatment.

Patient	Prescription drug coverage	Initial insurance claim disposition	If initial claim rejected, PA disposition	If PA denied, appeal disposition	Additional comments	Time since medication access pursued to current disposition	Current disposition
1	Private	Approved	- - -	- - -	Pending insurance verification by ViiV, given patient required to pay entire cost out-of-pocket	29 days+	CAB/RPV not started
2	Private	Rejected	Denied (same day)	Denied (9d later)	Benefit investigation submitted and awaiting response from ViiV (16 days+)	29 days+	CAB/RPV not started
3	Private	Rejected	Denied (same day)	Pending (29 days+)	N/A	29 days+	CAB/RPV not started
4	Private	Rejected	Denied (6d later)	Pending (14 days+)	N/A	29 days+	CAB/RPV not started
5	Medicare	Approved	- - -	- - -	PAP required for oral lead-in approved by ViiV (14d later)	15 days	CAB/RPV oral lead-in day 15/28
6	Medicare	Approved	- - -	- - -	PAP required for oral lead-in submitted and awaiting response from ViiV (9 days+)	16 days+	CAB/RPV not started
7	Medicare	Approved	- - -	- - -	PAP required for oral lead-in submitted and awaiting response from ViiV (1 days+)	5 days+	CAB/RPV not started
8	Medicaid	Rejected	Pending (for 5d+)	- - -	N/A	5 days+	CAB/RPV not started
9	ADAP	CAB/RPV not covered; PAP required			PAP required for oral lead-in and injectable submitted and awaiting response from ViiV (9 days+)	16 days+	CAB/RPV not started
10	ADAP	CAB/RPV not covered; PAP required			PAP required for oral lead-in and injectable submitted and awaiting response from (9 days+)	14 days+	CAB/RPV not started

(+) = status still pending at time of abstract submission
Abbreviations: ADAP = AIDS Drug Assistance Program; d = days; PA = Prior Authorization; PAP = Patient Assistance Program

Conclusion. Our experience implementing LAI-ART at a Ryan White-funded HIV clinic in the Southern U.S. has been challenged by substantial human resource capital to attain drug, delayed therapy initiation due to insurance denials, and patient ineligibility primarily due to concern for potential RPV resistance. These barriers may perpetuate disparities in ART access and virologic suppression among PWH and need to be urgently addressed so that LAI-ART can be offered equitably.

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888. *In Vitro* Forgiveness of INSTI-Containing Regimens at Drug Concentrations Simulating Variable Adherence

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Session: P-51. HIV: Treatment

Background. The integrase strand transfer inhibitor (INSTI)-based regimens bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF), dolutegravir (DTG)+FTC/TAF, DTG/lamivudine (3TC), and DTG/rilpivirine (RPV) are all used for treatment of HIV-infected patients. Here, relative time to *in vitro* viral breakthrough (VB) and resistance barrier using simulated human drug exposures at either full or suboptimal treatment adherence to each regimen were compared.

Methods. Wild-type HIV-1 (IIIb)-infected MT-2 cells were exposed to the combinations of BIC+FTC+TAF, DTG+FTC+TAF, DTG+3TC, or DTG+RPV for up to 35 days or until VB. Fixed drug concentrations were the human plasma-free adjusted clinical trough concentrations (C_{min}) or fixed at simulated C_{min} after missing 1 to 4 consecutive doses (C_{min}-1 to -4), with many replicates. Drug resistance was studied by next-generation sequencing at ≥2% frequency.

Results. At drug concentrations corresponding to full adherence and 1 missed dose (C_{min} and C_{min}-1), no VB occurred with any regimen (Table). At C_{min}-2, only DTG+3TC had VB, with some emergent resistance to both drugs. At C_{min}-3, all regimens had VB: by day 12, 100% of DTG+3TC wells had VB; for BIC+FTC+TAF, DTG+FTC+TAF, and DTG+RPV, < 15% of wells had VB which began after day 14. Emergent RT or IN resistance was seen for DTG+RPV and DTG+3TC but not for BIC+FTC+TAF or DTG+FTC+TAF. At C_{min}-4, all DTG+3TC and DTG+FTC+TAF wells had VB by day 12, while DTG+RPV had 94% VB by day 25 and BIC+FTC+TAF had 50% VB by day 35. Emergent C_{min}-4 drug resistance was seen for all regimens but at differing frequencies; DTG+RPV had the most wells with resistance. Cumulatively, emergent RT and/or IN resistance was found in 1.3% BIC+FTC+TAF, 2.5% DTG+FTC+TAF, 7.9% DTG+3TC, and 8.8% DTG+RPV cultures.

Summary of Forgiveness and Barrier to Resistance of INSTI-Containing Regimens

In Vitro Drug Concentration	Breakthrough Frequency (Resistance Development)							
	BIC+FTC+TAF		DTG+FTC+TAF		DTG+3TC		DTG+RPV	
	VB (n/N; %) [first day of VB]	With Resistance, n[a]	VB (n/N; %) [first day of VB]	With Resistance, n[a]	VB (n/N; %) [first day of VB]	With Resistance, n[a]	VB (n/N; %) [first day of VB]	With Resistance, n[a]
C_{min}	0/60; 0 [na]	0	0/48; 0 [na]	0	0/60; 0 [na]	0	0/48; 0 [na]	0
C_{min}-1	0/36; 0 [na]	0	0/48; 0 [na]	0	0/36; 0 [na]	0	0/48; 0 [na]	0
C_{min}-2	0/60; 0 [na]	0	0/48; 0 [na]	0	41/60; 68 [14]	13; RT: M184V/I (4), V75I (3) *IN: G140E/R (2), E157K (2), L74M (1), S153F (1)*	0/48; 0 [na]	0
C_{min}-3	3/36; 8 [21]	0	1/48; 2 [25]	0	36/36; 100 [7]	3; RT: None *IN: L74M (2), V72A (1), S153F (1)*	7/48; 15 [14]	1; RT: M230I *IN: None*
C_{min}-4	18/36; 50 [15]	3; RT: M184I (2) *IN: G163R (1)*	48/48; 100 [11]	6; RT: M184V (1), K219R (1) *IN: Q148R (2), Q95R (1), H51Y (1), S153F (1)*	36/36; 100 [5]	2; RT: None *IN: R263K (2), L74M (1)*	45/48; 94 [8]	20; RT: E138K (8), K101E (3), M230I (2), V90I (2), V106I (1), Y181C (1), H221Y (1) *IN: H51Y (2), R263K (1), M50I (1), Q95R (1), A128T (1), S153F (1), G163R (1)*

na = not applicable
a. Reverse transcriptase (RT) substitutions are shown in plain text. *Integrase (IN) substitutions are shown in italics.*

Conclusion. Regimen forgiveness and resistance barrier are important factors in long term treatment. These INSTI-based regimens had high *in vitro* forgiveness and resistance barriers with concentrations simulating high adherence. When multiple missed doses were simulated *in vitro*, BIC+FTC+TAF had the highest forgiveness and barrier to resistance. When compared to DTG+3TC and DTG+FTC+TAF, DTG+RPV had higher forgiveness but lower resistance barrier after several simulated missed doses.

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889. Early Discontinuations and Adverse Events Among Treatment-Naïve Patients Initiating Integrase Inhibitors in a Real-world Setting

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Session: P-51. HIV: Treatment

Background. Cohort studies suggest higher rates of discontinuations (DCs) and adverse events (AEs) with integrase inhibitors (INSTIs) than is reported in clinical trials. Here, we assess DC of different INSTIs in combination with one of two tenofovir prodrugs in the first year following initiation defined as "early DC" in a real-world cohort of treatment-naïve patients.

Methods. This analysis evaluated treatment-naïve patients at a single center initiating raltegravir (RAL), elvitegravir/cobicistat (EVG/c), dolutegravir (DTG) or bictegravir (BIC) in combination with emtricitabine/tenofovir alafenamide (F/TAF) or emtricitabine/tenofovir disoproxil fumarate (F/TDF) between 10/2007-1/2020. Eligible patients had a minimum follow-up of 1 year. The primary endpoint was incidence of early INSTI DC. Secondary endpoints included AEs and risk factors for early INSTI DC and treatment-related AEs.

Results. 331 patients were included. Median age was 32 years, 89% were male, 43% were non-White, 8% started RAL-based therapy, 46% started EVG/c-based