Results. 15 studies were eligible for review; 8 included all W/LWH, 5 focused on pregnant W/LWH, 1 included only African American W/LWH and 1 included only transgendeer W/LWH. 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. W/LWH in cities were more likely to receive ART than those in rural regions. Intimate partner violence (IPV) was associated with poor ART adherence and time to achieve stable VS. Also, being partnered 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, mental health, health insurance, race, and ART regimen were the most common factors associated with VS in W/LWH. There was paucity of data on transgender-specific VS factors. More research is needed to explore VS and treatment adherence among W/LWH, 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 ViV-sponsored Phase 2/3/4b clinical trial 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 to be delivered by cesarean section. Babies were born at term and had reported congenital poxitis, in a pre-term infant with intrauterine growth restriction. There were 9 elective term deliveries. In women becoming pregnant on LA exposure, there was 1 reported congenital anomaly (a pre-term infant with intrauterine growth restriction). There were 9 elective term deliveries.

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 anti-retroviral pregnancy registry and pregnancy surveillance within the treatment programs continues.

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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 OPORTA cohort within 2 years prior to 31Oct2020. Virally suppressed PLWH (i.e., viral load <200 copies/mL) were included if they switched to either delavirdine/lamivudine or a delavirdine- 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 from 10.07 visits per person-year (95% CI: 9.93, 10.21) pre-COVID to 7.10 (95% CI: 6.90, 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.

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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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 inter-disciplinary LAI team (Clinician-Pharmacy-Nursing) verified clinical eligibility (HIV-1 < 200 c/ml ≥ 3 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 PWs 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% Public, 19% Medicare, 10% Medicaid, and 45% ADAP. At the time of referral, median CD4 count was 583 (Q1-Q3, 422-742) cells/mm³ 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 PWs 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 pursued for patients enrolled in long-acting injectable (LAI CAB/RPV) program

| Patient | Prescription coverage | Insurance | Integritas CAB/RPV disposition | Partial denial | Full denial | PA approval | Additional comments | Time since medication approval | Time since medication pursued to current disposition | Current disposition |
|---------|----------------------|-----------|-------------------------------|---------------|------------|------------|-------------------|--------------------------|---------------------------------|-------------------|
| 1       | Covered               | Integritas | Approved                      | Full denial   | PA approval |           |                   | 13 days                  | 20 days                          | Approved          |
| 2       | Covered               | Integritas | Approved                      | Full denial   | PA approval |           |                   | 13 days                  | 20 days                          | Approved          |
| 3       | Covered               | Integritas | Approved                      | Partial denial| PA approval |           |                   | 13 days                  | 20 days                          | Approved          |
| 4       | Covered               | Integritas | Approved                      | Partial denial| PA approval |           |                   | 13 days                  | 20 days                          | Approved          |
| 5       | Covered               | Integritas | Approved                      | Full denial   | PA approval |           |                   | 13 days                  | 20 days                          | Approved          |
| 6       | Covered               | Integritas | Approved                      | Partial denial| PA approval |           |                   | 13 days                  | 20 days                          | Approved          |
| 7       | Covered               | Integritas | Approved                      | Full denial   | PA approval |           |                   | 13 days                  | 20 days                          | Approved          |
| 8       | Covered me              | Integritas | Approved                      | Full denial   | PA approval |           |                   | 13 days                  | 20 days                          | Approved          |
| 9       | Covered me              | Integritas | Approved                      | Partial denial| PA approval |           |                   | 13 days                  | 20 days                          | Approved          |
| 10      | Covered me              | Integritas | Approved                      | Full denial   | PA approval |           |                   | 13 days                  | 20 days                          | Approved          |

Conclusion. Our experience implementing LAI-ART at a Ryan White-funded HIV clinic in the Southeast 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/evicabacvir/tenofovir alafenamide (BIC/FTC/TAF), dolutegravir (DTG)+FTC/TAF, DTG/raltegravir (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 (HIV-1) 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 (Cmin) or fixed at simulated Cmin after missing 1 to 4 consecutive doses (Cmin,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 (Cmin,1 and Cmin,4), no VB occurred with any regimen (Table). At Cmin,2, only DTG+3TC had VB, with some emergent resistance to both drugs. At Cmin,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 Cmin,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 Cmin,4 drug resistance was seen for all regimens but at differing frequencies; DTG+RPV had the most well stimulated resistance but not for BIC+FTC+TAF or DTG+FTC+TAF. At Cmin,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 Cmin,4 drug 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

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-naive patients.

Methods. This analysis evaluated treatment-naive patients at a single center initiating raltegravir (RAL), elvitegravir/cobicistat (EVG/c), dolutegravir (DTG) or bictegravir (BIC) in combination with emtricitabine/tenofovir alafenamide (FTAF) or emtricitabine/tenofovir disoproxil fumarate (FTD/3TC) from 10/2007-10/2020. 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