Conclusion. Lack of power makes meaningful interpretation of the results for the primary objective difficult. However, several of the prespecified secondary objectives and subgroup analyses demonstrated clinically significant results related to increased weight gain or BMI category changes with INSTI-, PI-, and tenofovir-based regimens. Checking the patient's weight at every appointment is considered standard practice at IU Health clinics, but missing values despite qualifying encounters were observed. Further commitment to standardized weighing practices should be a priority at clinics caring for patients living with HIV.

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1006. Contraception, Pregnancy and ART in Women of Child-Bearing Years

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Session: P-47. HIV: Treatment

Background. Simpler anti-retroviral (ART) regimens with less pill burden and fewer side effects can improve adherence and clinical outcomes. Warnings about dolutegravir possibly causing neural tube defects (NTD) are alarming and have the potential to limit ART options for women of child-bearing years. A recent preliminary analysis from an observational study group in Botswana prompted a warning from the US Department of Health and Human Services (DHHS), released in May 2018, about the use of dolutegravir during conception.

Methods. At a large urban HIV clinic in New Orleans, a retrospective chart review was performed on adult women up to age 40 who were seen in clinic in 2018 to assess for dolutegravir use, as well as discussion of NTD and pregnancy.

Results. 132 woman in the age range were seen in 2018, the mean age was 33 years (range 19 to 40). Average age of HIV diagnosis was 26. Most were African-American (83%) and 81% had Medicaid or no insurance. Eleven percent were diagnosed with HIV due to testing during pregnancy and 17% during routine screening. Sexual exposure was the main reported risk factor for HIV (69%) and 48% had another STD. Only 61% had a documented discussion of contraception and pregnancy plans. Over their treatment at the clinic, 47 pregnancies occurred. Most of the women were on integrase regimens (65%), although 14% were on protease inhibitor regimens and 20% were on other regimens or combination regimens. Forty two percent of the women were ever on dolutegravir and 12 had NTD discussed, resulting in 3 regimen changes. The main reason it was not discussed was permanent sterilization, change to a different ART regimen prior to the warning, long-term contraception, or no sexual activity. Seven pregnancies occurred while on dolutegravir, three were prior to the warning, one after the first trimester, and one ended in abortion. None had an NTD reported.

Conclusion. Dolutegravir is very commonly used due to its tolerability and simplicity. While recent reports show the risk of NTD to be lower than previously thought, it is still elevated compared to other ART and a more open discussion of pregnancy plans, contraception, and NTD if applicable, needs to occur in women living with HIV.

Disclosures. **All Authors**: No reported disclosures

1007. Criminal Justice Involvement Negatively Impacts Engagement in Treatments for HIV and Opioid Use Disorder in Vietnam

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Session: P-47. HIV: Treatment

Background. People living with HIV (PLWH) and opioid use disorder (OUD) commonly experience criminal justice involvement (CJI). We sought to estimate the impact of CJI on 1) HIV care engagement, 2) antiretroviral therapy (ART) prescription rates, and 3) receipt of medications for opioid use disorder (MOUD), among PLWH and OUD in Vietnam.

Methods. Participants were PLWH enrolled in a 12-month MOUD treatment trial of HIV clinic-based buprenorphine vs. methadone referral in Vietnam. We compared those with CJI (arrest, incarceration, or compulsory "06" drug rehabilitation) during the first 9 months of the study to those with no CJI. To ensure participants with CJI had the opportunity to re-engage in treatment, only those who were released before their 9-month study visit were included; participants still incarcerated at 9 months were excluded. Logistic regression models estimated the association between CJI and HIV care engagement (≥ 1 visit), ART prescription, and receipt of MOUD between 9 and 12 months, controlling for demographics, substance use, past CJI, and HIV history.

Results. At baseline, 234 of 281 participants (83.6%) had a history of arrest/incarceration, and 172 (61.2%) reported prior 06 detention. During their first 9 months of study participation, 14 participants (5.0%) were arrested and 14 participants (5.0%) were sent to compulsory 06 rehabilitation. Being arrested (OR=0.04, 95% CI= (0.007, 0.25)), sent to compulsory 06 rehabilitation (OR=0.08, 95% CI= (0.02, 0.38)), or either (OR=0.07, 95% CI= (0.02, 0.24)), were negatively associated with receipt of MOUD. CJI involvement was also negatively associated with HIV clinic engagement after release (OR=0.20, 95% CI= (0.05, 0.84)). A similar negative association was noted for ART prescription, though it did not reach statistical significance (OR=0.17, 95% CI= (0.03, 1.22)).

Conclusion. Arrest, incarceration, and compulsory 06 rehabilitation negatively impact HIV and OUD care among people with HIV and OUD in Vietnam. Policies that decrease incarceration, and the impacts of incarceration, for people with OUD and HIV may improve care outcomes in Vietnam and elsewhere.

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1008. Disease Severity Impact on Long-Term Virologic Response to Ibalizumab in Expanded Access Protocol (TMB-311)

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Session: P-47. HIV: Treatment

Background. The principal goal of antiretroviral therapy (ART) is durable suppression of HIV RNA. In treatment-experienced (TE) patients, ongoing viremia can lead to further accumulation of drug resistance, increased morbidity and mortality. ART efficacy often depends on HIV disease severity; therefore, we sought to assess its impact on long-term virologic suppression in patients treated with Ibalizumab (IBA), the first long-acting, post-attachment inhibitor approved for multi-drug resistant (MDR) HIV-1 treatment.

Methods. In TMB-301, a Phase 3 study, 40 TE patients with viral load (VL) >1000 copies/mL (c/mL) received an intravenous (IV) loading dose of IBA (2000mg) followed by maintenance doses (800mg IV) every 2 weeks combined with an optimized background regimen. Patients who completed TMB-301 in the US (n=27) continued to an expanded access protocol TMB-311. To determine the impact of baseline (BL) disease on long-term virologic response, we conducted an on-treatment analysis stratified by BL VL and CD4 count up to week 96. Differences in the proportion of suppressed (< 50 c/mL) individuals among the strata were assessed by Fisher's exact test.

Results. Median BL VL and CD4 count were 35,350 c/mL and 73 cells/mL, respectively. The number of patients in the VL strata were 11, 17 and 12 for VL < 10,000, 10,000-70,000, and >70,000 c/mL, respectively. There were 12, 10, 5 and 13 patients in the subgroups with CD4 count < 10, 10-100, >100-200 and >200 cells/μL. Population disease severity was reflected by four deaths (unrelated to study drug). Overall, the proportion of suppressed patients increased from 55% at week 24 (n=31) to 75% for patients remaining on treatment for 96 weeks (n=20). Median VL decrease was 2.9 $\log_{10}$ c/mL. Notably, no statistically significant differences were found across groups. Among patients with advanced HIV disease, 66.7% with CD4 count < 10 cells/mL and 71.4% with VL >70,000 c/mL at BL remained fully suppressed at week 96.

Conclusion. In TE patients with advanced HIV disease, maximal viral suppression with IBA was observed regardless of BL CD4 or VL strata if patients remained on treatment. This demonstrates that TE patients across the spectrum of HIV disease, can achieve viral suppression by using drugs with a new mechanism of action.

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1009. Dolutegravir and Doravirine in Combination: When Standard Antiretroviral Regimens are Unacceptable

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Session: P-47. HIV: Treatment

Background. A drug-drug interaction study between dolutegravir and doravirine in healthy volunteers found no evidence of untoward interaction. Whilst we hypothesize that the combination would be safe and effective, there is no supportive clinical data. We aimed to assess the rationale for use of dolutegravir and doravirine in combination and clinical outcomes among persons with HIV infection (PWH) receiving care at the Washington DC VAMC.

Methods. A quality improvement initiative utilized the clinical case registry to identify all PWH receiving both dolutegravir and doravirine. We conducted chart review to examine (a) the reasons for switch from other ART to dolutegravir and doravirine, and comorbidities, HIV resistance mutations or drug interactions precluding the use of standard ART, (b) adverse events or side effects and (c) achievement of virologic suppression.

Results. A case registry search revealed 21 individuals receiving combination dolutegravir doravirine from 2018–2020 (Table 1 and Figure 1). Side effects were not noted except one patient developed mild diarrhea that improved with continuation of therapy. Four patients were hospitalized during the follow-up period for reasons unrelated to the medications. One patient who was admitted to the ICU with shock and multi-organ failure was switched on admission but died four days later and therefore

was not included in the analysis of viral outcome (Table 2). One patient had cardiac arrest following missed dialysis, hyperkalemia and rectal hemorrhage from metastatic rectal cancer.

Table 1: Patient Demographics.

Mean Age (Range)	
	61.8 years (50-74)
Gender	
	Male: 90.5% (19/21)
	Female: 9.5% (2/21)
Race	
	African-American: 95.2% (20/21)
	Caucasian: 4.8% (1/21)
Comorbidities	
	Hypertension 61.0% (13/21)
	Coronary artery disease: 19.0% (4/21)
	Diabetes Mellitus, Type 2: 19.0% (4/21)
	Chronic Kidney Disease: 28.6% (6/21)
	Cancer: 14.3% (3/21)
	Active Hepatitis B: 9.5% (2/21)
	Hepatitis C: 33% (7/21)
	Cirrhosis: 23.8% (5/21)
	Peptic Ulcer Disease: 19.0% (4/21)
	Lower GI Bleed: 14.3% (3/21)
	Seizure disorder: 14.3% (3/21)
	Peripheral Neuropathy or Radiculopathy: 28.6% (6/21)
	Dementia or Cognitive Impairment: 19.0% (4/21)
	Psychiatric Disorders: 47.6% (10/21)
Antiretroviral Therapy Regimen	
	Dolutegravir/Doravirine alone: 66.7% (14/21)
	Dolutegravir/Doravirine + Lamivudine: 14.3% (3/21)
	Dolutegravir/Doravirine + Emtricitabine: 4.8% (1/21)
	Dolutegravir/Doravirine + Tenofovir: 4.8% (1/21)
	Dolutegravir/Doravirine + Cobicistat-boosted Darunavir: 4.8% (1/21)
	Dolutegravir/Doravirine + Emtricitabine/Tenofovir: 4.8% (1/21)
Mean Duration of Follow-Up (Range)	
	10 months (3-17)

Figure 1: Reasons for Switching to Dolutegravir with Doravirine.

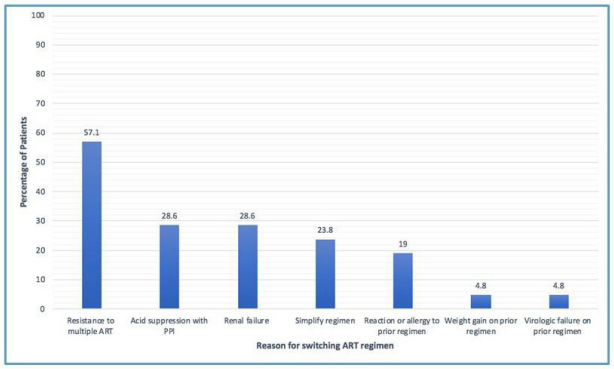

Table 2: Virologic Control Before and After Switching to Dolutegravir with Doravirine.

	Virologic control in 12 months prior to switch (all patients)	Virologic control post-switch (>12 months follow-up)	Virologic control post-switch (all patients)
Undetectable VL (<50), % (n)	61.9% (13)	66.7% (6)	70% (14)
VL 50 to 200, % (n)	14.3% (3)	22.2% (2)	15% (3)*
VL>200, % (n)	14.3% (3)	22.2% (2)	10% (2)
No VL data, % (n)	9.5% (2)	-	5% (1)
Mean CD4	513	561	560
CD4 <200	14.3% (3)	22.2% (2)	15% (3)
No CD4 data	9.5% (2)	-	15% (3)
Total number of persons included	21	9	20

*One with preexisting V106A mutation

Conclusion. In an era of abundant ART options, we identified a subset of older PWH whose treatment options are defined by extensive comorbidities, viral resistance, and medication interactions or toxicities. Doravirine is attractive for this population as it can be used in renal impairment, moderate hepatic impairment, is unaffected by timing of meals, and (unlike rilpivirine) has no interaction with proton pump inhibitors. Dolutegravir is included in NRTI-sparing regimens that HHS guidelines suggest should be considered in older PWH, especially with CKD. We found that dolutegravir with doravirine is well tolerated, and achieves virologic suppression in the majority of PWH, indicating this combination is useful when other ART options cannot be used.

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1010. Effective Management of HIV in Rural Georgia Using Telemedicine

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Session: P-47. HIV: Treatment

Background. The increasing incidence of HIV and lack of care in rural areas contributes to the ongoing epidemic. The dearth of specialized health services within remote communities and access of this population to available services poses a challenge to HIV care. Telemedicine (TM) is a potential tool to improve HIV care in these remote communities, but little is known about its effectiveness when compared to traditional (face-to-face) (F2F) care. The objective of this study is to examine the effectiveness of HIV care delivered through TM, and compare to F2F care.

Methods. This is a retrospective chart review of all HIV positive patients who attended either the F2F clinic (Augusta, GA) or the TM clinic (Dublin, GA) between May 2017 to April 2018. Data extracted included demographics, CD4 count, HIV PCR, co-morbidities, dates of clinic attendance, HIV resistance mutations and ART changes. Viral suppression and gain in CD4 counts were compared. T-test was conducted to test differences in characteristics and outcomes between the two groups.

Results. 385 cases were included in the study (52.5% black, 82% females, F2F=200, TM=185). Mean CD4 count in the TM group was statistically higher (643.9 cells/mm^3) than the F2F group (596.3 cells/mm^3) ($p< 0.001$). There was no statistically significant difference in mean HIV viral load (F2F= 416.8 cp/ml, TM=713.4 cp/ml, p=0.3) and rates of year-round viral control (F2F= 73% vs TM = 77% p= 0.54). 38 patients achieved viral suppression during the study period (F2F= 24, TM =14) with a mean change of -3.34 x 10^4 vs -1.24 x 10^4, respectively. The difference in mean change was not statistically significant by Snedacor's W Statistics. This indicates there was no significant difference between the two populations in terms of mean viral suppression among patients who were otherwise not suppressed before the study period.

Conclusion. To achieve an HIV cure, HIV care is required to extend to rural areas of the country and the world. Through delivery of care using TM, trained specialists can target communities with little or no health care. Moreover, use of TM achieves target outcome measures comparable to F2F clinics. Increase in the use of TM will improve the access to specialty HIV care and help achieve control of HIV in rural communities.

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1011. Efficacy and Safety of Doravirine in Treatment-Naïve Adults ≥50 Years Old With HIV-1

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Session: P-47. HIV: Treatment

Background. Nearly 50% of people living with HIV in the US are ≥50 years old. Older people are more likely to have late-stage HIV infection at diagnosis, greater risk for cardiovascular disease and certain cancers, and concurrent medications for common age-related conditions. Doravirine (DOR) is a next-generation NNRTI with activity against first-generation NNRTI-associated mutations, a neutral impact on lipids, and few drug-drug interactions with commonly used medications.

Methods. We compared Week 96 results from DOR Phase 2 and Phase 3 trials (P007, P018, and P021) in treatment-naïve adults ≥50 vs < 50 years old. 855 participants received DOR 100mg +2 NRTIs in P007 & P018 or fixed combination DOR/3TC/TDF in P021; 383 participants received ritonavir-boosted darunavir (DRV) +2 NRTIs in P018; and 472 received efavirenz (EFV) 600mg +FTC/TDF in P007 or fixed combination EFV/FTC/TDF in P021. Participants who took ≥1 dose of study drug were included; the Observed Failure approach was used for missing efficacy data. All analyses were done by descriptive statistics.

Results. Of 1710 participants, 187 (11%) were 50-70 (median 54) years old at study entry. Baseline characteristics and treatment outcomes are summarized below for participants < 50 vs ≥50 years old. The older cohort had more women, more participants with AIDS, and lower median CD4+ T-cell counts than the younger cohort, whereas baseline HIV-1 RNA was similar between age cohorts. Hypertension and use of analgesics were more common in older participants. In each treatment group, the older cohort had a higher proportion of participants with HIV-1 RNA< 50 copies/mL at week 96 and fewer discontinuations due to lack of efficacy than the younger cohort. Mean change in CD4+ T-cell count was similar between age cohorts in the DOR and DRV groups and was lower for older participants in the EFV group. Rates of drug-related AEs and serious drug-related AEs were similar between age cohorts across all treatment groups. Discontinuations due to drug-related AEs were similar between age cohorts in the DOR group and were slightly higher for older participants in the DRV and EFV groups.