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 alter 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%). 60% had a history of arrest or incarceration. Of 281 clients diagnosed with HIV due to testing during pregnancy and 17% during routine screening. Sexual exposure was the most 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 sexuality. Seven pregnancies occurred while on dolutegravir, three were prior to the warning, once 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) antiretroviral therapy (ART) engagement, 2) ART regimens, 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 clinical trials dolutegravir plus etravirine 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 during 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 re-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 impacted ART and MOUD 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 (TMBl-311)
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Session: P-47. HIV: Treatment
Background. The primary 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) retroviral therapy (ART) 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 (unnecessary 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 log₁₀ 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 was observed regardless of VL, suggesting IBA can be therapeutically effective 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.
Disclosures. Princy Kumar, MD, Gilead Sciences Inc. (Scientific Research Study Investigator) Jason Leider, MD, PhD, THERA (Speaker’s Bureau) R Brandon Cash, PharmD (Employee) Steven Weinheimer, PhD, TaiMed Biologics USA (Employee) Pedro Mesquita, PhD, Therapeutics, Inc. (Employee)

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 at 24 weeks.
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 treatment. 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...