Methods. ART-naïve adults, initiating a DTG- or EVG-based regimen and meeting all study eligibility criteria (Figure 1) were identified in the OPERA® Observational Database, a collaboration of HIV caregivers following 100,000+ people living with HIV (PLWH) through electronic medical records. PLWH were followed from the date of first prescription until DTG- or EVG discontinuation, death, or study end (July 31, 2018). The primary outcome was verified (2 consecutive viral load (VL) ≥200 copies/mL or 1 VL ≥200 copies + discontinuation) virologic failure (VF), defined as either failure to achieve suppression (<50 copies/mL) prior to 36 weeks or failure to maintain suppression once achieved. Survival analyses were conducted with Kaplan–Meier methods and multivariate Cox Proportional Hazards modeling.

Results. A total of 1,688 (DTG) and 2,537 (EVG) met all eligibility criteria. Median (IQR) length of follow-up in the DTG users was 21 months (14–30), in the EVG users was 20 (14–32) months. Figure 2 characterizes baseline demographic/clinical characteristics. Figures 3 and 4 depict Kaplan–Meier curves and Cox model results, respectively. VF was experienced by 8.2% DTG and 10.9% EVG initiators at a rate (95% CI) per 1,000 person-years of 40.2 (33.8, 47.8) and 51.3 (45.3, 58.1), respectively. Younger age (18–25), being African American, having a baseline CD4 count ≤ 200, or having a government-based payer (ADAP, Ryan White, Medicaid, or Medicare) at baseline were associated with a significant ($P < 0.05$), increased hazard of VF. Initiating on DTG or initiating therapy with a lower baseline VL was associated with a significant, reduced hazard of VF. Compared with DTG, the adjusted hazard ratio for VF was 1.29 (95% CI: 1.02, 1.63) for EVG.

Conclusion. Among ART-naïve patients, DTG users were significantly less likely to experience virologic failure than EVG users after adjustment for important baseline covariates.

Figure 1. Study Inclusion/Exclusion Criteria

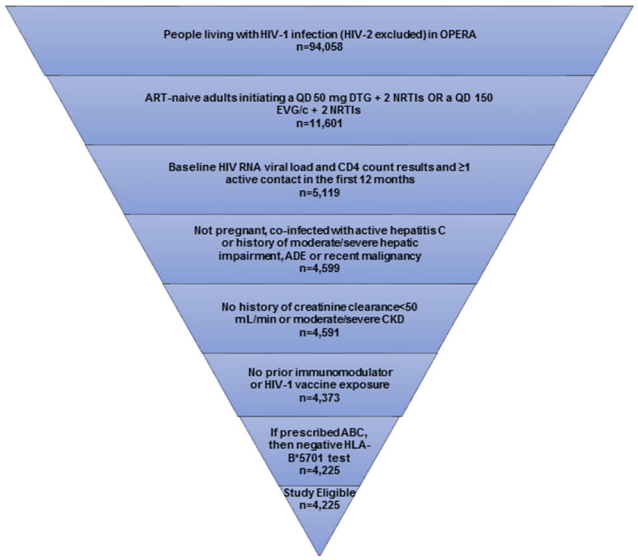


Figure 2: Demographic & Clinical Characteristics of Study Population

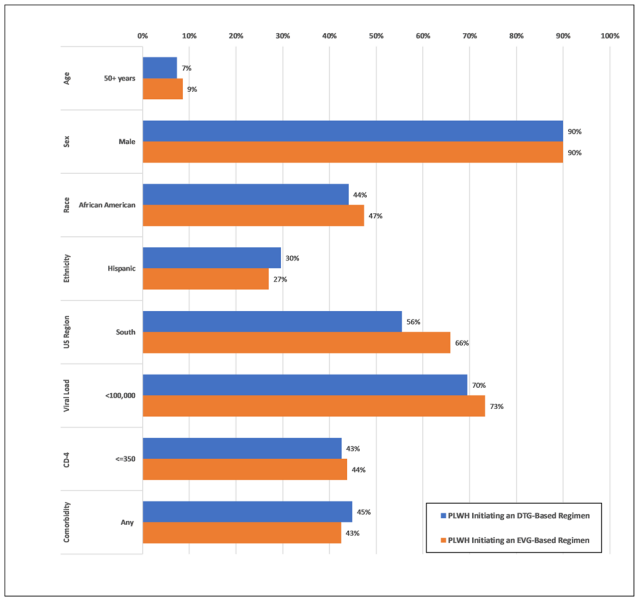


Figure 3. Unadjusted Cumulative Probability of Virologic Failure over Time on Core Agent

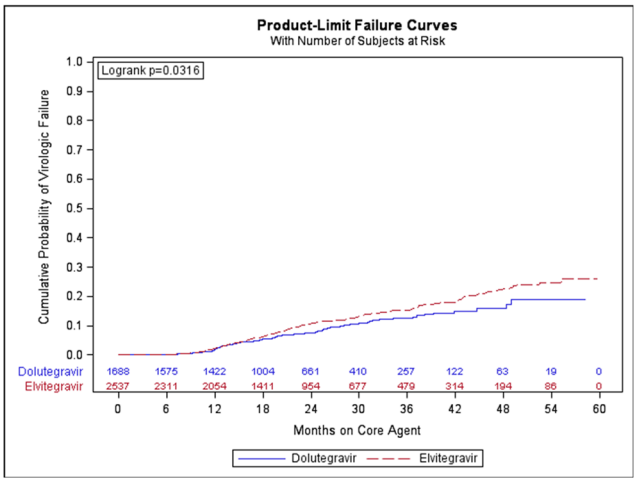
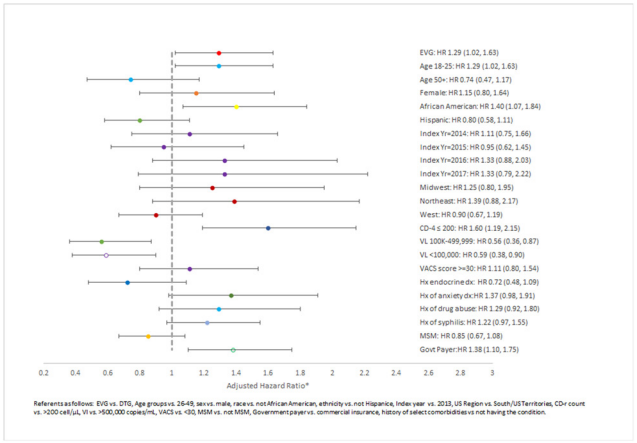


Figure 4. Virologic Failure, Cox Model Results



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

2489. Adverse Events with Biktarvy: Post-Marketing Study

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Background. Bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF) was FDA approved in February 2018. There are no published post-marketing data evaluating safety and efficacy. After large uptake of BIC/FTC/TAF at our institution, reports of rash prompted a real-world review. The purpose of this study was to assess one year post-marketing safety and tolerability of BIC/FTC/TAF.

Methods. This retrospective, observational, pharmacoepidemiologic study was conducted one year post-approval of BIC/FTC/TAF, between February 2018 and March 2019 at the University of South Carolina Immunology Center. Adults receiving BIC/FTC/TAF were included. Drug discontinuation and treatment-related adverse effects were evaluated. Baseline demographics and serial laboratory data were collected.

Results. A total of 201 patients were assessed. Of those, the majority were treatment experienced (181, 90%), African American (137, 68%) males (132, 65%) with a mean age of 46 years (range 20–76 years). Four patients were transgender. 135 (67%) had a BMI of ≥ 25 kg/m^2 and 77 (38%) had a BMI of ≥ 30 kg/m^2. At baseline, 146 (72.6%) had virologic suppression (VS) (< 200 copies/mL) with a mean CD4 count of 529 cells/mm^3 (range < 35–1573 cells/mm^3). VS was maintained in 145/146 and subsequently reached in 47/55 (85.5%) at first follow-up. Of the 201, 18 (8.9%) patients reported adverse drug events (ADEs) for a total of 19 events (10 rash, 2 dizziness, 1 nausea/vomiting, 1 headache, 1 diarrhea, 1 loss of appetite, 1 weight gain, 1 fatigue, 1 insomnia). Eleven (5%) patients discontinued therapy; nine (4%) due to ADEs (7 rash, 1 insomnia and loss of appetite, and 1 feeling unwell). One patient with high AST/ALT at baseline increased from 129/243 U/L to 234/394 U/L, respectively. No other laboratory abnormalities were reported.

Conclusion. In a southern, predominantly African American overweight population, our results demonstrate low discontinuation rates associated with BIC/FTC/TAF, with rash being the predominate cause. Overall, 4% discontinued BIC/FTC/TAF due to ADEs compared with 1% as reported in the package insert. VS rates were high throughout the evaluation period. Ongoing post-marketing evaluation is important for early recognition of unexpected adverse outcomes.

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

2490. Longer-Term Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide in Virologically Suppressed Adults Living With HIV and End-Stage Renal Disease on Chronic Hemodialysis

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Background. HIV treatment for individuals with end-stage renal disease (ESRD) on hemodialysis (HD) has previously required complex dose-adjusted regimens. We evaluated the safety and efficacy of single-tablet, once-daily elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) in people living with HIV (PLH) and ESRD on chronic HD.

Methods. Virologically suppressed adult PLH with ESRD on chronic HD for ≥ 6 months were switched to open-label E/C/F/TAF 150/150/200/10 mg once daily for 96 weeks. Efficacy was assessed as the proportion of participants who maintained virologic suppression (HIV RNA < 50 copies/mL) using the snapshot algorithm. Safety and participant satisfaction were assessed throughout the study.

Results. We enrolled 55 participants with median age 51 years (range 23–64) with median time on HD 6 years (range 1–17). In the per protocol analysis set, virologic suppression was maintained in 30 of 31 participants (96.8%, 95% CI [83.3%, 99.9%]) at week 96. In the full analysis set, virologic suppression was maintained in 30 of 55 participants (54.5%; 95% CI [40.6%, 68.0%]); one discontinued therapy due to lack of efficacy, and W96 data were unavailable for 24. Of the 24 participants lacking W96 data, 17 discontinued study drug early and 7 had missing data while on study drug; all had HIV RNA < 50 copies/mL at the last pre-week 96 check. Treatment-emergent AEs occurred in 53 (96.4%) participants, and study-drug-related AEs occurred in 7 (12.7%). Treatment-emergent AEs leading to premature study drug discontinuation occurred in 4 (7.3%) participants; two were considered study-drug-related (allergic pruritus and peripheral neuropathy in one participant each). No study-drug-related serious AEs were observed. 85.7% (30/35) of responding participants reported they were 'much more satisfied' with their regimen.

Conclusion. Single-tablet, once-daily E/C/F/TAF was effective in maintaining virologic suppression in PLH on chronic HD over 96 weeks of follow-up. E/C/F/TAF was well tolerated and was associated with improved participant satisfaction. These data demonstrate that E/C/F/TAF is a safe and effective alternative to more complicated regimens in PLH on chronic HD, with the potential to improve patient satisfaction and quality of life.

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

2491. Virologic Response of Switching Tenofovir Disoproxil Fumarate (TDF)-Based Regimen to Abacavir (ABC)-Based Regimen vs. Lopinavir/Ritonavir(LPV/r) Plus Lamivudine(3TC) in HIV-Infected Patients with TDF-Induced Nephrotoxicity at 24 Weeks: A Prospective, Open-Label, Randomized, Controlled Trial

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Background. Tenofovir disoproxil fumarate (TDF)-induced nephrotoxicity is a well-recognized complication and one of the reasons for treatment switching in HIV-infected patients. Salvage regimens in renal impairment such as abacavir(ABC)-based regimen or two-drug regimens such as boosted protease inhibitor (PI) plus lamivudine (3TC) are the options for switching. However, ABC is contraindicated in patients with a high risk for cardiovascular disease. In resource-limited setting, only some PIs such as lopinavir and atazanavir are available options.

Methods. We conducted a prospective, open-label, randomized controlled trial in a tertiary center in Bangkok. We recruited HIV-infected adults who had viral suppression, with TDF-induced proximal tubulopathy and/or a significant decrease in estimated glomerular filtration rate(eGFR). The patients were randomized to receive ABC/3TC plus efavirenz (ABC-based regimen) or LPV/r+3TC. The primary outcome was the proportion of patients with viral suppression at 24 weeks. The secondary outcomes were the immunologic response, recovery of eGFR, proximal tubular function and change in lipid profile at 24 weeks.

Results. Between August 2018 - February 2019, we screened 87 patients and enrolled 24 patients were randomly assigned to the ABC-based regimen and 23 patients to LPV/r+3TC regimen. In the intention-to-treat population, virologic response at 24 weeks was noted in 21 (87.5%) patients assigned to ABC-based regimen and 19 (82.6%) patients assigned to LPV/r+3TC regimen ($P = 0.635$). There were no differences in the improvement of the percentage change of eGFR, fractional excretion of phosphate, renal tubular reabsorption of phosphate (TmP/GFR), fractional excretion of uric and UPCI at 24 weeks. Triglyceride levels were significantly increased in LPV/r+3TC regimen compared with ABC-based regimen at 24 weeks (91.32% vs. 20.46%; $P = 0.001$).

Conclusion. Our study showed no difference in virologic suppression after switching to ABC-based regimen or LPV/r+3TC regimen in patients with TDF-induced nephrotoxicity. There was no difference in percentage change of eGFR, recovery of proximal tubular function in both arms after discontinuation of TDF. There was a significant change in triglyceride levels in LPV/r +3TC regimen.

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

2492. Differences between Individuals Currently Taking Integrase Inhibitor (INSTI)-based Therapy and Those Not Taking INSTIs in the Era of INSTIs as Recommended First-line Therapy

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Background. Agents from the integrase inhibitor (INSTI) therapeutic class only are recommended as initial therapy for most patients with HIV. Clinicians now face a decision when treating ART-experienced patients on non-INSTI regimens: continue current therapy or switch to INSTI. Multiple factors may be considered in this decision: clinician/patient preference, comorbidities, tolerability, and resistance history. The objective of this analysis was to examine patient factors associated with currently taking an INSTI-based regimen.

Methods. We used data from the DC Cohort, a longitudinal observational cohort of patients receiving HIV care at 14 clinics between 2011–2018. Participants in the sample had ≥ 1 encounter between 4/1/17 and 3/1/18, were aged ≥ 18 years and were ART experienced. Participants were classified as currently, previously, or never on an INSTI. Independent variables included demographics, clinical characteristics, alcohol/tobacco use, HBV/HCV status and HIV-related variables (recent CD4 and HIV RNA, presence of resistance mutations). Multivariable multinomial logistic regression was used to identify factors associated with INSTI use status.

Results. Among 4584 participants (58.2% aged 50+ years; 69.4% male; 2.5% transgender; 80.3% Black; 36% MSM), most (65.0%) were current INSTI users; however, a sizeable proportion (28.3%) were never users and 6.7% were former users. Current and previous INSTI users were more likely to have a major NRTI, NNRTI or PI mutation compared with never users (see Table 1). Transgender participants (compared with males), were less likely to be current (vs. never) users (adjusted odds ratio (aOR) 0.48, 95% CI 0.32, 0.72). Younger participants (18–24 vs 50+ years) were more likely current users (aOR 1.90, 95% CI 1.18, 3.06), as were Hispanic participants (aOR 1.39, 95% CI 1.05, 1.84).

Conclusion. The majority of active DC Cohort participants were using INSTI-based therapy. Transgender and older individuals were less likely to be on INSTIs, indicating that they are more likely to be on PI-based or NNRTI-based therapy or not on therapy. Further research should explore whether this is detrimental for long-term HIV outcomes in these patient groups. Additionally, these results suggest resistance history as an important driver of INSTI prescription.

Table 1. Presence of Major Resistance Mutations among Individuals on ART in the DC Cohort, 2017-2018, N=4584

	Currently on INSTI (n=2,978)	Previously on INSTI (n=307)	Never on INSTI (n=1,299)	p-value
	N (%)	N (%)	N (%)	
Major NRTI mutation present	628 (21.1)	76 (24.8)	120 (9.2)	<0.0001
Major NNRTI mutation present	625 (21.0)	68 (22.1)	135 (10.4)	<0.0001
Major PI mutation present	277 (9.3)	29 (9.4)	65 (5.0)	<0.0001
Major INSTI mutation present	52 (1.7)	7 (2.3)	16 (1.2)	0.3111

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