

HD. After week (W) 96, participants transitioned to daily B/F/TAF to assess whether efficacy and safety would be maintained on this STR that is guidelines-recommended for PLWH with eGFR > 30 mL/min.

**Methods.** Virologically suppressed adult PLWH with ESRD on chronic HD who completed W96 on E/C/F/TAF enrolled in the B/F/TAF extension for 48 weeks. Efficacy was assessed as the proportion of participants with virologic suppression (HIV RNA < 50 copies/mL). Safety was assessed throughout the study, PK was assessed using sparse sampling at W4, 24 and 48.

**Results.** 55 enrolled, 36 completed E/C/F/TAF, 10 entered the B/F/TAF extension. The median age was 55 yrs (range 34-63); median time on HD was 4 yrs (range 2-16). All ten participants on B/F/TAF had HIV-1 RNA < 50 c/mL (95% CI 69%, 100%) at W48. All participants had at least 1 adverse event (AE); most were grade 1 or 2 in severity. One participant had a grade 3 AE and 3 had serious AEs; none were considered related to study drug by the investigator. One participant had AEs attributed to study drug (malaise grade 1 and nausea grade 2), which resolved and did not lead to discontinuation of study drug. There were no clinically relevant changes in fasting lipids. In participants with evaluable data (n=2-5 per timepoint), mean bictegravir trough concentrations were lower compared to PLWH not on HD but remained 4- to 7-fold higher than the established protein-adjusted 95% effective concentration (paEC<sub>95</sub>) of 162 ng/mL against wild-type virus.

**Conclusion.** A once daily regimen of B/F/TAF maintained virologic suppression in PLWH on chronic HD. B/F/TAF was well-tolerated with no discontinuations. B/F/TAF may be an effective, safe and convenient once daily STR and ameliorate the need for dose adjustment in appropriate PLWH who require chronic HD.

**Disclosures.** Joseph J. Eron, MD, Gilead Sciences (Consultant, Research Grant or Support) Janssen (Consultant, Research Grant or Support) Merck (Consultant) ViiV Healthcare (Consultant, Research Grant or Support) Aimee Wilkin, MD, MPH, Gilead Sciences Inc. (Grant/Research Support, Scientific Research Study Investigator, Advisor or Review Panel member) GlaxoSmithKline (Grant/Research Support) Janssen (Grant/Research Support, Scientific Research Study Investigator, Advisor or Review Panel member) Pfizer (Grant/Research Support) Moti Ramgopal, MD FACP FIDSA, AbbVie (Speaker's Bureau) Allergan (Speaker's Bureau) Gilead Sciences Inc. (Consultant, Scientific Research Study Investigator, Speaker's Bureau) Janssen (Speaker's Bureau) Merck (Consultant) ViiV Healthcare (Consultant) Olayemi Osiyemi, M.D., GlaxoSmithKline (Advisor or Review Panel member, Speaker's Bureau) ViiV Healthcare (Advisor or Review Panel member, Speaker's Bureau) Jihad Slim, MD, AbbVie (Speaker's Bureau) Gilead (Speaker's Bureau) Janssen (Speaker's Bureau) Merck (Speaker's Bureau) ViiV (Speaker's Bureau) David Asmuth, MD, Gilead Sciences Inc. (Scientific Research Study Investigator) Edwin DeJesus, MD, Gilead Sciences (Advisor or Review Panel member) Polina German, PharmD, Gilead Sciences (Employee) Christiana Blair, MS, Gilead Sciences (Employee, Shareholder) Christoph C. Carter, MD, Gilead Sciences Inc. (Employee, Shareholder) Diana M. Brainard, MD, Gilead Sciences (Employee) Sean E. Collins, MD, MS, Gilead Sciences (Employee) Hal Martin, MD, MPH, Gilead Sciences Inc. (Employee, Shareholder)

### 1003. BIC/FTC/TAF Maintains Viral Suppression in Patients with Documented M184V/I Mutations: A Real World Experience

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Session: P-47. HIV: Treatment

**Background.** The M184V/I mutation is a common mutation in treatment-experienced patients with HIV and confers high-level resistance to lamivudine and emtricitabine. Our objective is to assess the effectiveness of bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF) in a real-world setting in achieving and maintaining viral suppression in patients with documented M184V/I mutations.

**Methods.** This case series is comprised of treatment-experienced HIV-positive patients with documented historical or newly-identified M184V/I mutations who were placed on BIC/FTC/TAF as a switch strategy or as therapy for patients who had failed a prior regimen. Patients with any resistance to tenofovir or bictegravir were excluded. Our primary outcome was sustained viral suppression at 12 months after initiation of BIC/FTC/TAF.

**Results.** We included 33 patients (94% black, 52% male, median age 49, range 36-63) with an M184V/I mutation. The majority (91%) showed sustained viral suppression at 12 months of treatment. Non-adherence to medication was the common factor in all three cases of treatment failure. One patient developed an R263K mutation while on therapy, which conferred low-level resistance to bictegravir. There were no other instances of newly-acquired resistance to any of the components of BIC/FTC/TAF.

**Conclusion.** Our results demonstrate high success rates of BIC/FTC/ATF in achieving and maintaining viral suppression in patients with documented M184V/I mutations who adhere to medications in a real-world setting with a single instance of new treatment-emergent resistance to bictegravir. These findings are congruent with reported sub-group analysis in clinical trial data and support the use of BIC/FTC/ATF in patients with M184V/I mutations.

**Disclosures.** Leandro A. Mena, MD, MPH, Binx Health (Grant/Research Support) Evofem (Grant/Research Support) Gilead Science (Consultant, Grant/Research Support, Speaker's Bureau) GSK (Grant/Research Support) Janssen (Grant/Research Support) Merck (Consultant, Grant/Research Support) Roche Molecular (Consultant, Grant/Research Support) SpeedDx (Grant/Research Support) ViiV Healthcare (Consultant, Grant/Research Support, Speaker's Bureau)

### 1004. Clinical Decision Support System Alerts for HIV Retention in Care – A Pilot Implementation Research Study

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Session: P-47. HIV: Treatment

**Background.** Clinical decision support system (CDSS) alerts may help retain people living with HIV (PLWH) in care. A system of CDSS alerts utilizing the CHORUS™ portal was developed to identify PLWH at risk of being lost to care. To evaluate feasibility for a larger scale study, a before and after implementation research pilot study was implemented in the OPERA Cohort at three clinic sites in a southeastern US city.

**Methods.** Periods without intervention (*before*) or with CDSS alerts (*after*) were followed by 3 months of follow up. The study population consisted of PLWH with ≥ 1 electronic health record entry in the 2 years prior to, or during, the *before* or *after* period (Fig 1). To support clinicians through a discrete implementation strategy, alerts warning of suboptimal patient attendance were generated daily for the eligible PLWH at each site; providers or other clinic staff could respond to the alerts (Fig 2). Alerts, responses, and visits (i.e., meeting with provider or HIV lab measurement) were characterized. The proportion of PLWH with ≥ 1 visit in the *before* and *after* periods were compared at each site by Pearson's Chi-square.

Figure 1. Pilot study timeline

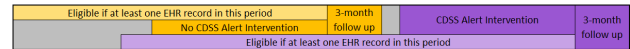
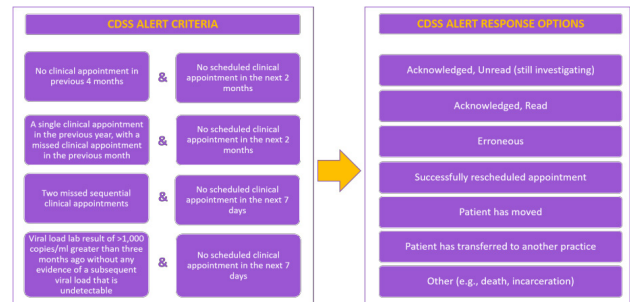


Figure 2. CDSS alert criteria and response options



**Results.** A total of 12,230 PLWH were eligible (sites A: 11,271; B: 733; C: 1,344 PLWH), with > 75% in both the *before* and *after* periods. The ratio of alerts to responses was 11.9 at site A (2,245 alerts to 189 responses in 309 days; Fig 3A), and comparatively lower at sites B (756 alerts to 334 responses in 352 days, ratio=2.2; Fig 3B) and C (1,305 alerts to 896 responses in 246 days, ratio=1.5; Fig 3C). Responses to alerts were sporadic at sites A and B and consistent at site C. After the intervention, the proportion of PLWH with ≥ 1 visit stayed the same at site A (46% in both periods; p=0.47), decreased at site B (91% to 80%; p< 0.01), and increased at site C (72% to 81%; p< 0.01).