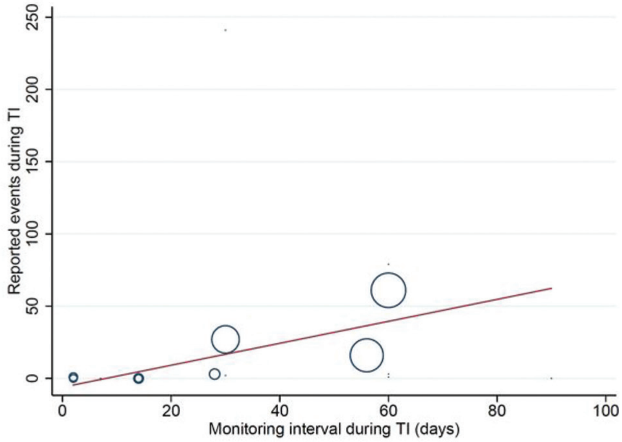

Figure 3: Effect of the monitoring interval during TI (days) on the reported adverse events. The area of circles is proportional to the sample size.

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1768. Efficacy and Safety of Switching From Boosted-Protease Inhibitors (bPI) Plus Emtricitabine/Tenofovir Disoproxil Fumarate (F/TDF) Regimens to the Once Daily (QD), Single-Tablet Regimen (STR) of Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) in Virologically Suppressed, HIV-1-Infected Adults: Week 96 Results of the Phase 3, Randomized, Non-Inferiority EMERALD Trial

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Background. The QD STR D/C/F/TAF 800/150/200/10 mg was noninferior to bPI + F/TDF at 48 weeks in EMERALD. Efficacy and safety of D/C/F/TAF through week 96 are presented.

Methods. EMERALD (NCT02269917) is a randomized, active-controlled, open-label, international, multicenter noninferiority trial. Virologically suppressed (VL<50 c/mL for ≥2 months) ART experienced (previous non-DRV VF allowed) HIV-1-infected adults were randomized (2:1) to switch to D/C/F/TAF or continue bPI + F/TDF over 48 weeks. Patients could then continue on D/C/F/TAF or switch from bPI + F/TDF to D/C/F/TAF at week 52 (Late switch, 44 weeks D/C/F/TAF exposure) in a single-arm extension phase until week 96. The percentage of patients with virologic rebound (confirmed VL ≥50 c/mL) cumulative through week 48 and week 96 were primary and secondary endpoints, respectively.

Results. Of 1141 randomized and treated patients (58% had received ≥5 previous ARVs including screening ARVs; 15% had previous non-DRV VF), 1,080 continued in the extension phase (*N* = 728 D/C/F/TAF; *N* = 352 late switch). Few patients had virologic rebound cumulative through week 96 in the D/C/F/TAF arm (3.1%, 24/763). Virologic rebound occurred in 2.3% (8/352) in the late switch arm over 44 weeks D/C/F/TAF treatment. Many rebounders (14/24 and 2/8) resuppressed by week 96. At week 96 a high percentage of patients in the D/C/F/TAF arm (90.7%, 692/763) were suppressed (VL<50 c/mL). In the late switch arm, 93.8% (330/352) maintained virologic suppression after 44 weeks of treatment. No DRV, primary PI, TFV, or FTC RAMs were seen post baseline. Few serious AEs and AE related discontinuations occurred in either arm (Table 1). Improvements in renal and bone parameters were maintained in the D/C/F/TAF arm and seen in the late switch arm (week 52–96), with a small change in TC/HDL-C ratio (Table 1).

Conclusion. Switching to D/C/F/TAF maintained high virologic suppression rates (>90%) at week 96 with no resistance development, and was well tolerated over 96 weeks with bone, renal, and lipid safety consistent with known TAF and cobicistat profiles. Efficacy and safety results in the late switch arm were consistent with week 48 results in the D/C/F/TAF arm. D/C/F/TAF combines the efficacy and high genetic barrier to resistance of DRV with the safety benefits of TAF, even in patients with a history of non-DRV VF.

Table 1: Treatment-emergent AEs and changes in renal, lipid and bone parameters at Week 96

	D/C/F/TAF arm			Late switch arm		
Treatment-emergent AEs, n (%)	D/C/F/TAF (baseline – week 48) N=763	D/C/F/TAF (baseline – week 96) N=763	P-value†‡	bPI+F/TDF (baseline – week 52) N=378	D/C/F/TAF* (week 52 –week 96) N=352	P-value†‡
AEs, any grade	630 (82.6)	690 (90.4)	ND	316 (83.6)	258 (73.3)	ND
Grade 3–4 AEs	54 (7.1)	98 (12.8)	ND	31 (8.2)	26 (7.4)	ND
Serious AEs	35 (4.6)	66 (8.7)	ND	18 (4.8)	21 (6.0)	ND
AE-related discontinuations	12 (1.6)	17 (2.2)	ND	5 (1.3)	7 (2.0)	ND
Deaths	0	3§ (0.4)	ND	0	0	ND
Median change in eGFR						
$eGFR_{cyst}$, mL/min/1.73m²	0.0	-0.9	0.018	-1.9	1.0	0.051
$eGFR_{cr}$, mL/min/1.73m²	-0.7	-1.3	<0.001	-0.6	-0.7	0.007
Median changes in renal biomarkers						
UPCR (mg/g)	-22.18	-22.23	<0.001	-7.37	-12.81	<0.001
UACR (mg/g)	-0.78	-0.63	<0.001	0.40	-0.93	<0.001
RBP:Cr (µg/g)	-27.33	-25.08	<0.001	+19.66	-39.07	<0.001
B2M:Cr (µg/g)	-66.63	-68.22	<0.001	+20.24	-110.31	<0.001
Median change in fasting lipids						
TC (mg/dL)	+19.7	+22.0	<0.001	+1.3	+22.0	<0.001
HDL-C (mg/dL)	+2.7	+3.0	<0.001	0.0	+3.3	<0.001
LDL-C (mg/dL)	+15.7	+17.0	<0.001	+1.9	+15.0	<0.001
Triglycerides (mg/dL)	+5.3	+7.0	<0.001	+4.9	+8.0	0.004
TC/HDL-C ratio	+0.20	+0.20	<0.001	+0.10	+0.20	<0.001
Changes in BMD	**N=209**	**N=209**		**N=108**	**N=105**	
Lumbar spine						
Mean % change	+1.45	+1.99	<0.001	-0.63	+2.91	<0.001
Increase by ≥3%	31.2%	36.6%	ND	9.1%	43.4%	ND
Decrease by ≥3%	7.9%	9.3%	ND	20.2%	2.0%	ND
Total hip						
Mean % change	+1.49	+1.86	<0.001	-0.27	+1.22	<0.001
Increase by ≥3%	21.0%	28.8%	ND	4.2%	24.0%	ND
Decrease by ≥3%	2.2%	3.1%	ND	8.4%	5.2%	ND
Femoral neck						
Mean % change	+0.74	+1.40	<0.001	-0.51	+0.98	0.019
Increase by ≥3%	24.2%	28.8%	ND	11.6%	29.2%	ND
Decrease by ≥3%	10.2%	8.6%	ND	17.9%	9.4%	ND

*Comprising 44 weeks of D/C/F/TAF exposure (i.e., from the switch to D/C/F/TAF at Week 52)
†Within treatment arm comparisons for change at week 96 from reference assessed by: Wilcoxon signed-rank test (eGFR, renal biomarkers and fasting lipids) and paired t-test (BMD)
‡Reference for the D/C/F/TAF arm is study baseline and for the late switchers is the last value before the switch

§Three deaths were due to metastatic pancreatic carcinoma and two cases of myocardial infarction, one of which was considered related to D/C/F/TAF in a patient who was a smoker, with a history of hypertension, coronary artery disease and obesity.

$eGFR_{cyst}$ = eGFR based on serum cystatin C (CKD-EPI formula); $eGFR_{cr}$ = eGFR based on serum creatinine (CKD-EPI formula); UPCR = urine protein: creatinine ratio; UACR = urine albumin: creatinine ratio; RBP:Cr = urine Retinol Binding Protein: creatinine ratio; B2M:Cr = urine Beta-2-Microglobulin: creatinine ratio; TC = total cholesterol; HDL-C = high-density lipoprotein-cholesterol; LDL-C = low-density lipoprotein-cholesterol; BMD = bone mineral density; ND = not determined.

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1769. Viral Suppression Among Participants of the Patient-Centered HIV Care Model Project—A Collaboration Between Community-Based Pharmacists and HIV Clinical Providers

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Background. The patient-centered HIV care model was developed to integrate community pharmacists with HIV clinical providers to deliver patient-centered HIV care. The project required 10 clinics to share, with their partnered community-based pharmacists, patients' medical histories, laboratory results, and medications. Pharmacists reviewed the clinic data and worked directly with participants and/or their partnered clinics to make recommendations and discuss potential intervention strategies for identified therapy-related problems.

Methods. We calculated the proportion of persons virally suppressed (<200 copies/mL at the last test in each of two 12-month measurement periods), pre- and post-model implementation. Included in the analysis were persons with ≥1 HIV viral load in each measurement period. McNemar's test was used to compare the proportion virally suppressed, pre- and postimplementation. Multivariable logistic regression was used to determine factors associated with viral suppression, postimplementation. Participant demographics and the proportion of days covered (PDC; a measure used to calculate adherence to medication therapy) were used as explanatory variables in the model. The PDC was modified to account for the time to the last viral load in the measurement period, and was stratified into 4 categories: ≥90%, <90–80%, <80–50%, and <50%.

Results. With 765 persons enrolled, the plurality of those included in the analysis (n = 648) were non-Hispanic black (n = 286), male (n = 470), and had a median age of 49 years (IQR=38–56). Viral suppression improved 16.3% from 73.9% to 85.9%, pre- to postimplementation (P < 0.001). Persons who had higher modified PDC (OR 1.9 per category level; 95% CI 1.4–2.6), were currently employed (OR 4.1; 1.6–12.8), or age >50 years (OR 4.7; 2.1–11.8), had greater odds of being suppressed. Non-Hispanic black persons were less likely to be suppressed (OR 0.2; 0.1–0.6); however, viral suppression among this group improved from 62.5% to 77.6%, pre- to postimplementation (P < 0.001).

Conclusion. Collaborations between community pharmacists and HIV clinic providers that seek to identify and address HIV therapy-related problems can lead to improved viral suppression among persons living with HIV.

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1770. The Association of Unmet Needs With Subsequent Retention in Care and HIV Suppression Among Hospitalized Patients With HIV Who Are Out of Care

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