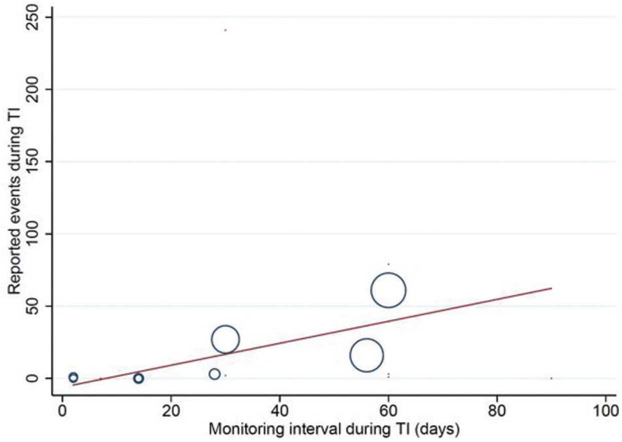

Figure 3: Effect of the monitoring interval during TI (days) on the reported adverse events. The area of circles is proportional to the sample size.

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

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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Background. Unmet needs among hospitalized patients with HIV may prevent engagement in HIV care leading to worse clinical outcomes. Our aim was to examine the role of unmet subsistence needs (e.g., housing, transportation, food) and medical needs (e.g., mental health, substance abuse treatment) as barriers for retention in HIV care and viral load (VL) suppression.

Methods. We utilized data from the Mentor Approach for Promoting Patients' Self-Care intervention study, the enrolled hospitalized HIV-patients at a large publicly funded hospital between 2010 and 2013, who were out-of-care. We examined the effect of unmet needs on retention in HIV care (attended HIV appointments within 0–30 days and 30–180 days) and viral load suppression, 6 months after discharge.

Results. A total of 417 participants were enrolled, 78% reported having ≥1 unmet need at baseline, most commonly dental care (55%), financial (43%), or housing needs (34%). Participants with unmet needs at baseline, compared with those with no needs, were more likely to be African American, have an existing HIV diagnosis, and be uninsured. Among participants who completed a baseline and 3-month survey (n = 320), 45% reported a need for dental care, 42% reported financial needs, and 32% reported housing needs that were unmet at either time point (Figure 1). Having a dental care need at baseline that was met was significantly associated with higher odds of VL improvements at 6-month follow-up (OR: 2.2; 95% CI: 1.04–4.50, P = 0.03) and higher odds for retention in care (OR: 2.06; 95% CI: 1.05–4.07, P = 0.04). An unmet need for transportation was associated with lower odds of retention in care (OR: 0.5; 95% CI: 0.34–0.94, P = 0.03), even after adjusting for other factors. Compared with participants with no need, those who reported ≥3 unmet subsistence needs were less likely to demonstrate viral load improvement (OR: 0.51; 95% CI: 0.28–0.92; P = 0.03) and to be retained in care (OR: 0.52; 95% CI: 0.28–0.95; P = 0.03).

Conclusion. An important and novel finding in our study is that the number of unmet subsistence needs had a significant effect on retention in care and VL suppression. Broader access to programs that can assist in meeting subsistence needs among hospitalized patients could have significant individual and public health benefits.

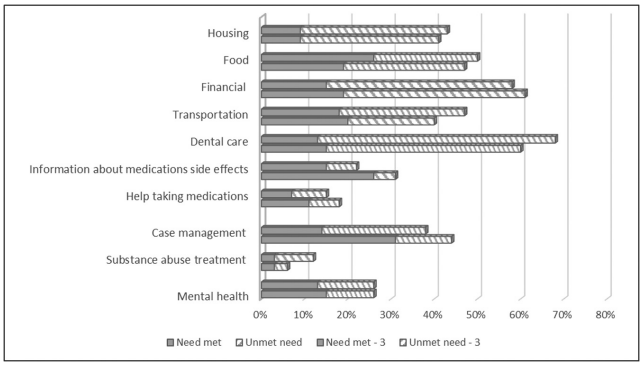

Figure 1. Percentage of participants with a specific need that was met or unmet at baseline (n=417), top bar, and the percentage of participants with a specific need that was met at both time points or unmet at either time point at 3-month follow-up, bottom bar (n = 320).

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

1771. Gut Resistome Changes in Response to Prophylactic Antibiotic Administration During Chemotherapy in Children With Acute Lymphoblastic Leukemia

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Background. Antibiotic resistance harbored in gut microbiome contributes to the emergence of multi–drug-resistant organisms (MDRO). Pediatric leukemia patients typically receive extensive antibiotics and are at higher risk for infection due to MDRO.

Methods. A prospective cohort of children (n = 242) with acute lymphoblastic leukemia self-collected stool samples at diagnosis and after induction chemotherapy. A third of patients (n = 69) underwent protocol-driven antibiotic prophylaxis: Levofloxacin (LV) given once neutropenia develops. With neutropenic fever patients on prophylaxis stopped LV and all patients received cefepime. Using metagenomic sequencing, we identified bacterial community composition and after alignment to the Comprehensive Antibiotic Resistance Database were able to determine the presence of bacterial resistance genes in 168 stool samples from 49 patients.

Results. Expected changes in the community composition were discovered with LV prophylaxis, including the loss of many *Enterobacteriaceae* and *Enterococcaceae* species, offset by increases in *Bacteroides* species. Unexpectedly, LV prophylaxis reduced the acquisition of VanA cluster of vancomycin resistance genes and did not increase acquisition of β-lactamase or fluoroquinolone (FQ) resistance gene families.

Conclusion. LV prophylaxis during leukemia treatment imparts predictable changes in gut bacterial communities but counter intuitively decreases antibiotic resistance in the gut microbiome reservoir. The reduction in VanA cluster of genes is likely due to depletion of *Enterococcaceae* species via direct killing or loss of synergistic partners. The lack of increase in target (FQ) or off-target resistance suggests that prophylaxis altered community selective pressures or prophylaxis drug concentrations were sufficient to limit the outgrowth of resistant mutants.

Disclosures. **J. Wolf**, Karius Inc.: Investigator, Research support.

1772. Vancomycin-Resistant Enterococcus Alters the Gastrointestinal Microbiome in Critically Ill Patients

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Background. In critically ill patients, rectal colonization with VRE is associated with an increased risk for nosocomial infection or death. In mice, fecal transplantation of *Blautia producta* directly inhibits VRE growth and leads to clearance of VRE. We performed a prospective, intensive care unit (ICU)-based study to evaluate the relationship between *B. producta* and VRE. We also sought to determine the relationship between VRE, MRSA, and other common MDR bacteria.

Methods. This study included 97 adults newly admitted to the ICU between February 2015 and June 2016. Rectal swabs were obtained at time of ICU admission and 72 hours later. VRE rectal colonization status was determined categorically for each sample by culture on selective media. Specimens were also cultured for methicillin-resistant *Staphylococcus aureus* (MRSA) and for MDR Gram-negatives, defined as those with nonsusceptibility to 3 or more antibiotic classes. 16S rRNA gene sequencing was performed and the relative abundance was calculated for *B. producta*. Differentially abundant bacteria taxa between VRE positive and VRE negative specimens were assessed using linear discriminant analysis effect size (LefSe) analysis.

Results. Among the 97 patients, 7 (7.2%) were colonized with VRE at the time of ICU admission and 3 (3.3%) of the remaining patients became colonized 72 hours later. The microbiome composition differed significantly when accounting for VRE colonization status. The relative abundance of *B. producta* was 140-fold higher in VRE-negative compared with VRE-positive samples (0.0012% vs. 8.48 × 10^{-6}%, P = 0.03). On LefSe analysis, there was also significantly lower differential abundance of *B. producta* when VRE was present (LDA score 4.65). The presence of VRE in culture was significantly associated with the co-presence of MRSA (23.5% co-colonized if VRE positive vs. 8.4% if VRE negative, P = 0.046) but not with the copresence of MDR Gram-negative bacteria (29.4% if cocolonized if VRE positive vs. 34.3% if VRE negative, P = 0.68).

Conclusion. In this ICU cohort, rectal colonization with VRE was inversely associated with the putatively protective organism *B. producta*. VRE was associated with rectal co-colonization with MRSA but not with MDR Gram-negative bacteria. *B. producta* may have promise as a probiotic designed to prevent VRE colonization.

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

1773. Impact of Antibiotics Used to Treat Community Acquired Pneumonia on the Gut Microbiome and Resistome in Healthy Volunteers

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Background. Antibiotics (ABX) are frequently inappropriately used to treat non-bacterial causes of respiratory illnesses. The goal of this prospective cohort study was to characterize the impact of ABX used to treat community-acquired pneumonia (CAP) on the fecal microbiome and resistome in healthy volunteers (HV).

Methods. Twenty HVs were randomized to receive 5 days of levofloxacin (LV), azithromycin (AZ), cefpodoxime (CF), or AZ+CF. Stool was collected before, during, and after ABX, then underwent microbiologic culture and shotgun sequencing. DNA was extracted, then sequenced using the Illumina NextSeq platform. Relative abundance of bacterial taxa was estimated by MetaPhlAn and antibiotic resistance gene (ARG) composition by ShortBRED. Analysis was in R.

Results. The mean HV age was 37 (range 24–59) and 10 were female. Species diversity measured via Shannon Index and richness were significantly lower in samples taken from all HVs 3 days post-ABX (P < 0.01 for all). While nonmetric