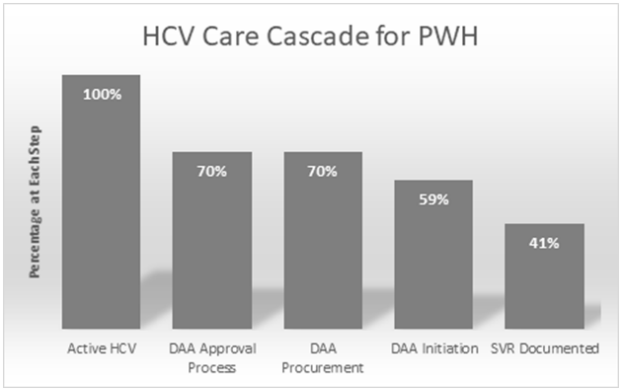
Methods. This retrospective review evaluated patients receiving care at a Ryan White-funded clinic from 07/2018 to 12/2020. Patients were eligible if HCV diagnosed ≥1 year and receiving HIV care. The primary endpoint was to compare the prevalence HCV before and after a pharmacy initiative to target the remaining patients at the clinic not treated during first 3 ½ year period of oral DAA therapy availability. Secondary analysis was to identify barriers to care, measure the proportion of patients in each step of the HCV care cascade, and determine predictors of SVR. Among barriers to care, inconsistent engagement was defined as patients with habitual missed appointments. Logistic regression and Chi-square tests were performed.

Results. 46 of 1,100 PWH had active HCV for ≥1 year. Median age, years since HIV and HCV diagnoses were 58.5 years of age, 17 years, and 11.5 years, respectively. Most patients were male (70%), Black (61%), Latinx (28%), HCV genotype 1 (90%), had an HIV RNA < 200 copies/mL (72%), & had Medicaid (87%). 32/46 patients agreed to therapy, with all getting insurance approval and DAAs delivered. Glecaprevir/pibrentasvir (73%) was the preferred by payors, followed by sofosbuvir/velpatasvir (15%). Eight remained with active HCV and 19 achieved SVR. The prevalence rate dropped from 4.2% to 0.7% (P < 0.0001). Active drug use, inconsistent engagement, mental health disorder and nonadherence were initial barriers to care. After multivariate analysis, patients with inconsistent engagement continued to be less likely achieve SVR compared to those we remained consistently in care (aOR: 0.062, 95 CI: 0.009-0.421).

HCV care cascade in PWH within a Ryan White-funded clinic



Active HCV includes 46 patients with chronic HCV infection receiving HIV in care at clinic, DAA approval process describes patients agreeing to HCV treatment along a continuum of pending laboratory results or pending prior authorization requests, DAA procurement depicts patients that have received approval and delivery of medications, DAA initiation describes patients who started treatment (27 patients), and SVR documented defines patients with an undetectable HCV RNA 12 weeks after therapy (19 patients).

Conclusion. Pharmacists can impact the burden of HCV among PWH receiving care. The HCV care cascade remains tied to the HIV continuum of care, with disengagement from care remaining an important rate-limiting step impeding micro-elimination.

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

832. Body Mass Index and Quality of Life in People Living With HIV

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Session: P-46. HIV: Complications and Co-infections

Background. Weight gain among people living with HIV (PLWH) on antiretroviral therapy (ART) may lead to obesity. This study evaluated association between body mass index (BMI) and health-related quality of life (HRQoL) from the patient's perspective.

Methods. A cross-sectional study using self-reported data from the 2018 and 2019 US National Health and Wellness Survey (NHWS), a nationally representative online survey of ~75,000 adults was conducted. Respondents self-reporting a physician diagnosis of and prescription use for treatment of HIV were included. HRQoL was assessed using Short-Form 36-Item Health Survey Version 2 [Mental and Physical Component Summary scores (MCS and PCS)] and EQ-5D-5L [dimension responses: "no" vs "any problems"/"yes"); EQ-Visual Analogue Scale (VAS) score]. Bivariate analyses (chi-square tests for categorical and ANOVA for continuous variables) compared patient characteristics and HRQoL outcomes across BMI (kg/m^2) categories: normal weight (NW; 18.5-< 25), overweight (OW; 25-< 30) and obese (OB; ≥30). Multivariable models analyzed each outcome as a function of BMI, controlling for age, sex, race, and Charlson Comorbidity Index (CCI; excluding HIV/AIDS).

Results. A total of 566 respondents were analyzed. Majority were aged ≥50 years (58%) and male (87%). The OB (vs NW) group had higher proportion of respondents who were female (22% vs 10%), Black (37% vs 24%), residing in the South (46% vs 33%), and higher mean CCI score (1.28 vs. 0.97) (Table 1). A higher proportion of OB (vs NW) respondents reported having pain/discomfort and problems with mobility and usual activities but not self-care. Anxiety/depression was reported less in OB vs NW groups (Table 1) However, self-reported use of prescription medications for anxiety (19% vs 20%) and depression (34% vs 25%) was similar in OB and NW groups. PCS and EQ-VAS scores were lower in OB vs OW and NW, but no difference in MCS score was observed (Table 1). Lower PCS and EQ-VAS scores were associated with higher BMI (both p=0.01) but not MCS (p=0.68) in multivariate models.

Conclusion. PLWH with higher BMI have poorer physical and general HRQoL. Impact of potential adverse weight gain and transition to higher BMI on humanistic and clinical outcomes should be considered when selecting ART regimens.

Table 1. Comorbidity Burden and Quality of Life in People Living with HIV by BMI Categories.

	Normal Weight (n=223)	Overweight (n=195)	Obese (n=148)
CCI score, mean (SD)	0.97 (2.77)	0.71 (1.11)	1.28 (1.62)*
EQ-5D-5L			
Mobility-any problems, n (%)	87 (39.0%)	69 (35.4%)	85 (57.4%)*
Usual activities-any problems, n (%)	102 (45.7%)	73 (37.4%)	77 (52.0%)*
Self-care-any problems, n (%)	40 (17.5%)	35 (16.9%)	33 (22.3%)
Pain/discomfort-yes, n (%)	145 (65.0%)	123 (63.1%)	117 (79.1%)*
Anxiety/depression-yes, n (%)	141 (63.2%)	99 (50.8%)	82 (55.4%)*
EQ-VAS score, mean (SD)	69.3 (24.1)	69.4 (26.6)	63.5 (25.9)*
SF-36			
MCS score, mean (SD)	43.4 (12.4)	46.1 (12.3)*	44.3 (12.5)
PCS score, mean (SD)	48.7 (9.6)	48.6 (10.0)	43.9 (10.7)*

CCI=Charlson Comorbidity Index; EQ-VAS=EQ Visual Analogue Scale; MCS=Mental Component Score; PCS=Physical Component Score; SD=Standard deviation; *p-value ≤0.05 compared to NW in bivariate analysis

Disclosures. **Jennifer Ken-Opurum, PhD**, **Kantar Health** (Employee) **Girish Prajapati, M.B.B.S., MPH** , **Merck & Co., Inc.** (Employee, Shareholder) **Joana E. Matos, PhD**, **Kantar Health** (Employee) **Princy N. Kumar, MD**, **AMGEN** (Other Financial or Material Support, Honoraria)**Eli Lilly** (Grant/Research Support)**Gilead** (Grant/Research Support, Shareholder, Other Financial or Material Support, Honoraria)**GSK** (Grant/Research Support, Shareholder, Other Financial or Material Support, Honoraria)**Merck & Co., Inc.** (Grant/Research Support, Shareholder, Other Financial or Material Support, Honoraria)

833. Efficacy and Safety of Long-Acting Cabotegravir + Rilpivirine in Participants with HIV/HCV Co-infection: ATLAS-2M 48-Week Results

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Session: P-46. HIV: Complications and Co-infections

Background. The phase IIIb ATLAS-2M study demonstrated non-inferiority of long-acting (LA) cabotegravir (CAB) + rilpivirine (RPV) dosed every 8 weeks (Q8W) compared with every 4 weeks (Q4W) for maintenance of virologic suppression. Hepatitis C virus (HCV) co-infection occurs in ~6% of people with HIV due to shared modes of transmission. We report efficacy and safety of CAB + RPV LA in participants with HIV/HCV co-infection in ATLAS-2M.

Methods. Participants with HIV-1 RNA < 50 c/mL receiving CAB + RPV LA Q4W (transitioned from ATLAS [NCT02951052]) or oral comparator ART were randomized 1:1 to receive CAB + RPV LA Q4W or Q8W. Baseline HCV RNA was assessed by polymerase chain reaction. Participants with symptomatic chronic HCV infection requiring treatment within 12 months or liver enzymes not meeting entry criteria were excluded. Week 48 assessments included proportion with HIV-1 RNA ≥50 and < 50 c/mL (Snapshot algorithm), general and hepatic safety, and pharmacokinetics.

Results. HIV/HCV co-infection was present in 10 (1%) of 1045 participants, 60% of whom were female at birth. At Week 48, 9/10 (90%) and 972/1035 (94%) participants with HIV/HCV co-infection and HIV mono-infection, respectively, had HIV-1 RNA < 50 c/mL (adjusted difference, 4.1; 95% CI, −14.5 to 22.6). No participants with HIV/HCV co-infection had HIV-1 RNA ≥50 c/mL (vs 14/1035 [1%] with HIV mono-infection) or confirmed virologic failure through Week 48 (vs 10 [1%] with HIV mono-infection); 1/10 (10%) discontinued for reasons other than adverse events (AEs). Excluding injection site reactions (ISRs), AEs and serious AEs were reported in 4 (40%) and 0 participants with HIV/HCV co-infection, respectively; the only AE reported in >1 participant was injection site pain (n=5; 50%). In participants with HIV/HCV co-infection, all ISRs were grade 1/2; none led to withdrawal. No hepatic laboratory abnormalities were reported in participants with HIV/HCV co-infection through Week 48; rates were low in those with HIV mono-infection (Table). Plasma CAB and RPV concentrations were similar between groups.

Table. Hepatic Safety Parameters in Participants with HIV/HCV Co-infection and HIV Mono-infection Receiving CAB + RPV LA Q4W or Q8W through Week 48 in ATLAS-2M

Liver abnormality, n (%)	HIV/HCV co-infection (N=10)	HIV mono-infection (N=1035)[a]
ALT ≥3 × ULN	0	18 (2)
ALT ≥3 × ULN, BIL ≥2 × ULN, and ALP <2 × ULN	0	3 (<1)
Hepatocellular injury[b]	0	15 (1)
Hepatocellular injury and BIL ≥2 × ULN	0	3 (<1)
Liver stopping event	0	4 (<1)[c]

ALP, alkaline phosphatase; ALT, alanine aminotransferase; BIL, bilirubin; CAB, cabotegravir; HCV, hepatitis C virus; LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; RPV, rilpivirine; ULN, upper limit of normal.
[a]N=1031 for laboratory abnormalities. [b]Defined as ([ALT/ALT ULN]/[ALP/ALP ULN]) ≥5 and ALT ≥3 × ULN. ALT and ALP must be measured on the same day. [c]All liver stopping events occurred after treatment started. Events included acute hepatitis B virus infection (n=2; both participants withdrew from the study), acute hepatitis E virus infection (n=1; continued CAB + RPV LA dosing), and acute hepatitis C virus infection (n=1; continued CAB + RPV LA dosing; not resolved).

Conclusion. CAB + RPV LA was effective and well tolerated in this small cohort of participants with HIV and asymptomatic HCV co-infection.

Disclosures. **Ronald D'Amico, DO, MSc**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Paul Benn, MB ChB FRCP**, **ViiV Healthcare** (Employee) **Shanker Thiagarajah, MB ChB**, **GlaxoSmithKline** (Employee, Shareholder) **Susan L. Ford, PharmD**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Eileen Birmingham, MD, MPH**, **Janssen Research and Development** (Employee, Shareholder) **Ojesh R. Upadhyay, MPH, MBA**, **GlaxoSmithKline** (Employee) **Louise Garside, PhD**, **GlaxoSmithKline** (Employee) **Rodica Van Solingen-Ristea, MD**, **Janssen Research and Development** (Employee)**ViiV Healthcare** (Employee) **Kati Vandermeulen, M.SC.**, **Janssen Research and Development** (Employee) **William Spreen, PharmD**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee)

834. Characterization of Heavily Treatment Experienced HIV-1 Infected Clinical Trial Participants Infected with SARS-CoV-2 COVID 19: Fostemsavir BRIGHTE Phase 3 Clinical Trial

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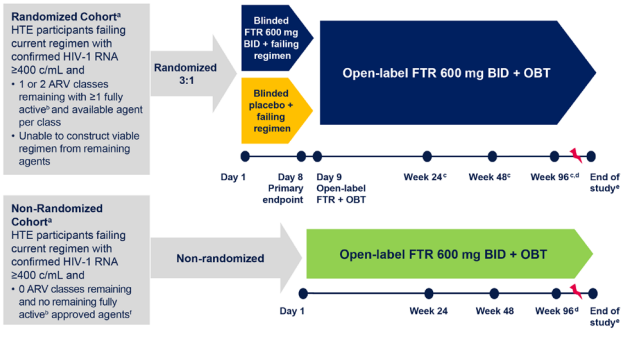
Session: P-46. HIV: Complications and Co-infections

Background. BRIGHTE is an ongoing global study evaluating the gp120 attachment inhibitor fostemsavir (FTR) in heavily treatment-experienced (HTE) adults with multidrug resistant (MDR) HIV-1 unable to form a viable antiretroviral (ARV) regimen. An estimated 2 million people living with HIV-1 have been infected with SARS-CoV-2. Those with HIV viremia and/or low CD4+ counts are at increased risk of serious adverse outcome. We describe the reported COVID cases in a clinical trial population of people living with MDR HIV and immune suppression.

Methods. At the start of the COVID pandemic, all ongoing BRIGHTE subjects had achieved ≥ 192 weeks on FTR and optimized background ARVs; results through Week 96 were presented previously. Investigators used WHO guidelines for COVID diagnosis and reported exposure, testing results and symptom presence.

Figure 1. BRIGHTE Study Design



[a]There were no screening TMR IC_{95} criteria. [b]Fully active = no current or historical evidence of resistance and the participant is tolerant of, eligible for, and willing to take (in the case of enfuvirtide) the ARV. [c]Measured from the start of open-label FTR 600 mg BID + OBT. [d]Week 96 database lock August 14, 2018. [e]The study is expected to be conducted until an additional option, rollover study, or marketing approval is in place. [f]Use of investigational agents as part of OBT was permitted.
Bolt symbol, onset of COVID-19 pandemic; ARV, antiretroviral; BID, twice daily; HTE, heavily treatment experienced; OBT, optimized background therapy.

Results. 371 subjects [272 Randomized Cohort (RC), 99 Non-Randomized Cohort (NC)] were enrolled; 44% were ≥ 50 years of age and 86% had an AIDS history. Median CD4+ count at study start of was 80 cells/mm^3 (IQR 11–202); 30% with ≤ 20 cells/mm^3. 250 subjects remained in BRIGHTE at pandemic start. By April 2021, 17 subjects (14 RC, 3 NC) had confirmed COVID infection (positive PCR test). Severity was Grade 1-3, all cases resolved with no deaths. Six subjects were hospitalized (Table 1); most recent CD4+ count prior to COVID were 293-1641 cells/mm^3 and 5/6 subjects were virologically suppressed. Treatments often included prophylactic anticoagulants and supplemental oxygen; no cART changes were made. The remaining 11/17 confirmed cases were managed outpatient. Five more subjects had suspect COVID not confirmed by PCR and 2 subjects had negative PCR tests.

Table 1. Characterization of Participants with Serious AEs of Confirmed COVID-19 Infections – All Hospitalizations

Participant/ Treatment Cohort	Demographics and Baseline Age (years) / Gender / Race Country CD4+ (cells/mm^3) / HIV-1 RNA (c/mL)	COVID Case Positive COVID Test Date / Event Duration / Severity Grade / Outcome Relevant medical history or known exposure risks Pre COVID CD4+ (cells/mm^3) and HIV-1 RNA (c/mL) Reported Treatment
00376/ Randomized Cohort	54 / Female / Black Brazil 75 cells/mm^3, 82,270 c/mL	15 Apr 2020 / 16 days / Grade 3 / Recovered HIV-1, diabetes, systemic arterial hypertension, no known exposure 823 cells/mm^3, <40 c/mL ceftriaxone IV, azithromycin, oseltamivir, cefuroxime, enoxaparin, supplemental oxygen via nasal catheter
00631/ Randomized Cohort	47 / Male / Other (Mestizo) Peru 196 cells/mm^3, 25,694 c/mL	24 May 2020 / 19 days / Grade 3 / Recovered HIV-1, systemic arterial hypertension, obesity, recent exposure in community 293 cells/mm^3, <40 c/mL Orphenadrine, acetaminophen, enoxaparin, albuterol, ipratropium
00626/ Randomized Cohort	38 / Male / White Argentina 131 cells/mm^3, 373,289 c/mL	07 Jul 2020 /19 days / Grade 2 / Recovered HIV-1, smoker, no known exposure 876 cells/mm^3, <40 c/mL Enoxaparin, omeprazole
00312/ Randomized Cohort	71 / Male / Black Belgium 207 cells/mm^3, 2,395 c/mL	26 Oct 2020 /15 days / Grade 3 / Recovered HIV-1, chronic renal failure/dialysis, recent visit to healthcare facility 310 cells/mm^3, <40 c/mL Dexamethasone, enoxaparin, aspirin, tramadol, movicol, furosemide, bilastine, darbepoetin alfa, valproic acid, potassium, sodium bicarbonate, calcium carbonate, supplemental oxygen via nasal canula
00524/ Randomized Cohort	55 / Male / Other (Mulatto) Brazil 7 cells/mm^3, 112,343 c/mL	12 Feb 2021 /17 days / Grade 3 / Recovered HIV-1, systemic arterial hypertension, recent exposure in community 563 cells/mm^3, 117 c/mL Ceftriaxone, ciprofloxacin, dexamethasone, enoxaparine, loperadmide, oxygen support
00449/ Randomized Cohort	55 / Female / White Brazil 368 cells/mm^3, 54,925 c/mL	09 Mar 2021 /43 days / Grade 2 / Recovered HIV-1, asthma, recent exposure in community + visit to healthcare facility 1641 cells/mm^3, <40 c/mL Dexamethasone, oxygen support

Conclusion. A total of 22/250 COVID-19 cases (17 confirmed, 5 unconfirmed) have been reported in BRIGHTE. Outcomes were reassuring with no deaths or known persistent sequelae, despite having advanced HIV and comorbid diseases at baseline associated with poorer COVID outcomes. Outcomes may have benefitted from immunologic improvement during the trial.

Disclosures. **Shiven Chabria, MD**, **Viiv Healthcare** (Employee) **Stephane De Wit, MD**, **Gilead** (Grant/Research Support)**Janssen** (Grant/Research Support)**Merck Sharpe & Dohme** (Grant/Research Support)**ViiV Healthcare** (Grant/Research Support) **Amy Pierce, BS**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Bronagh M. Shepherd, PhD**, **GlaxoSmithKline** (Employee, Shareholder) **Michael Warwick-Sanders, BM BSc DPM MFPM**, **GSK** (Employee) **Marcia Wang, PhD**, **GlaxoSmithKline** (Employee, Shareholder) **Andrew Clark, MD**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Peter Ackerman, MD**, **GSK/ViiV Healthcare** (Employee, Shareholder)

835. Improvement in Diet Attenuates Antiretroviral Therapy (ART) Associated Weight Gain in Persons with Human Immunodeficiency Virus (PWH)

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Session: P-46. HIV: Complications and Co-infections

Background. Weight gain among PWH on ART is a growing clinical concern. We explore factors associated with weight gain at The Ohio State University Wexner Medical Center Infectious Diseases Clinic.

Methods. This was a single-center, retrospective, cohort study of adult PWH on ART for at least 3 months seen at our clinic from 1/1/2015 to 1/1/2019. Patients with CD4+ T cell count < 200 cells/mm^3, viral load >200 copies/mL, history of malignancy, or pregnancy were excluded. 870 patients met criteria. Patient demographics, lifestyle factors, medical co-morbidities, concurrent medications, and ART regimens were documented during the study period. The primary outcome was percent weight change over the follow up period. Secondary outcome was the odds of > 5kg weight gain over the study period. The effects of concurrent medications, medical comorbidities, ART combinations, and self-reported lifestyle behaviors on these outcomes were modeled using mixed effect linear and logistic regression analysis.

Results. At baseline, 83.6% were male, 29.2% were African American, and 65.6% had a body mass index ≥ 25 kg/m. Over a mean follow up of 1.86 years, the study population gained a mean percent weight of 2.12 ± 0.21% (p< 0.001) with an odds of weight gain >5kg of 0.293 (p< 0.001). Male sex and increasing age were significantly associated with a decrease in percent weight over the study period as reflected in the table below. Diet was also significantly associated with a decrease in percent weight change over the study period of -1.99 ± 0.47 %, p= < 0.001 and a lower odds of > 5kg of weight gain (OR= 0.70, 95% CI= 0.50 – 0.97, p=0.03). In regression models, combination therapy with tenofovir alafenamide (TAF) and integrase strand transfer inhibitor (INSTI) containing regimens were significantly associated with an increase in percent weight over the study period. Other significant factors including demographics and ART regimens are noted in Table 1.