PLHIV vs non-PLHIV, respectively. PCV13, PCV15/non-PCV13, and PCV20/non-
PCV15 serotypes comprised 21.5%, 11.2% and 16.5% of IPD in PLHIV.
IPD incidence rates among adults aged ≥19 years old by serotype group in PLHIV,
2008–2018

Conclusion. IPD rates declined significantly in both PLHIV and non-PLHIV during the study period due to reductions in PCV13-type IPD; however, IPD rates remained 17-fold higher in PLHIV compared to non-PLHIV, mainly due to non-
PCV13 types. Higher-valent pneumococcal conjugate vaccines provide opportunities to reduce some of the remaining IPD burden in PLHIV.

Disclosures. William Schaffner, MD, VBI Vaccines (Consultant) Lee Harrison,
MD, GSK, Merck, Pfizer, Sanofi Pasteur (Consultant)

71. Increasing Trends in Multimorbidity and Polypharmacy Over a 5-Year Period in People Living with HIV in the United States
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Session: O-15. HIV Co-infections and Co-morbidities

Background. Advances in antiretroviral therapies (ART) have resulted in people living with HIV (PLWH) living longer with higher risk for age-related comorbid conditions and polypharmacy. The aim of this study was to describe trends in comorbidity and comedications burden in PLWH over a 5-year time period.

Methods. A retrospective analysis of commercial and Medicare Advantage enrollees from the Optum Research Database was conducted. Annual cohorts of PLWH were constructed for each calendar year from 2014-2018 and included adults (≥ 18 years) with ≥ 2 medications filled for ART (oral antiretroviral medication) and at least 6 months of continuous health plan enrollment of 1 pharmacy claim for an ART or medical claim with an HIV/AIDS diagnosis code (index date=earliest claim date in each calendar year). Multimorbidity was defined as ≥ 2 non-HIV conditions and a Charlson Comorbidity Index (CCI) > 0.5. Comedications were identified using ICD-9/10 diagnosis codes from medical claims during baseline period and comedications from pharmacy/medical claims in the 90-days prior to index date=earliest claim date in each calendar year). Continuous health plan enrollment of 1 pharmacy claim for an ART or medical claim with an HIV/AIDS diagnosis code (index date=earliest claim date in each calendar year). Comorbidities were identified using ICD-9/10 diagnosis codes from medical claims during baseline period and comedications from pharmacy/medical claims in the 90-days prior to index date=earliest claim date in each calendar year).

Results. The study included 20,249 PLWH who were enrolled in commercial (80.7%-73.0%) or Medicare Advantage (19.3%-14.3%) plans were identified in 2014-2018 calendar years. Notable trends in demographics of PLWH were observed across years, including increases in mean age (48.9 to 52.4 years), proportion of females (17.2% to 20.3%) and Black race (25.9% to 29.9%), all p-trend< 0.001. Mean CCI scores increased across years (0.72 to 0.93), p-trend< 0.001. Multimorbidity (≥ 2 non-HIV conditions) and polypharmacy (≥ 5 non-ART medications) prevalence increased over 5 years (Figure 1). Hypertension, hyperlipidemia, neuropsychiatric conditions and Type 2 diabetes mellitus were the most prevalent comorbid conditions with statistically significant upward trends in prevalence across years (Figure 1).

Conclusion. Multimorbidity and polypharmacy are common in PLWH and have been increasing in prevalence over the past 5 years. Study findings highlight the importance of an individualized approach to care for a diverse PLWH population, in order to minimize drug-drug interactions and adverse events and thereby improve patient outcomes.

Figure 1. Comorbidity and Comedication Trends by Index Year among People Living with HIV

72. Massive Weight Gain in People with HIV (PWH) Starting Initial Antiretroviral Therapy (ART): Risk Factors and Predictive Ability of Early Weight Gain
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Session: O-15. HIV Co-infections and Co-morbidities

Background. Using a clinic cohort of ART naive PWH, we sought to understand factors associated with massive weight gain as well as to assess if early weight gain could help predict massive weight gain at two years.

Methods. This was a retrospective cohort study of PWH from a large, urban clinic initiating first ART from January 2005 through March 2019, who had 21 – 27 months follow-up without ART changes, and were suppressed (HIV RNA < 200 cps/ml) during that time. We defined massive weight gain as the top 20% of weight gainers at two years measured by percent (%) gain compared to baseline. Using bivariate and multivariate logistic regression (including factors in bivariate analysis with p< 0.20), we assessed the association of demographics, ART regimen, baseline CD4 count, HIV viral load, and body mass index (BMI) with weight gain at 2 years. We also assessed early weight gain (between 4 and 12 wks) and its association with massive weight gain at two years.

Results. Of 266 PWH included (table1), the median age was 36 years (IQR 29 - 45), 9% were women, 14% black, and 43% Latino. Overall, median % weight gain at 2 years was 4% (-1.1 - 11.6). In bivariate analyses, baseline factors significantly associated with massive weight gain included lower CD4 count, higher viral load, and lower baseline BMI. In multivariate analysis the odds of having massive weight gain were higher with lower CD4 count, adjusted odds ratio (aOR) 0.8 (95% CI 0.6 - 0.9) per 100 cells/ul increase and higher viral load, aOR 2.6 (95% CI 1.4 – 4.6) per 1 log increase. Early weight gains were available for 217 individuals at a median of 56 days (IQR 44 - 63) after ART initiation. Early weight gain correlated with % weight gain at 2 years (R=0.58). Individuals with ≤ 3% early weight gain represented 66% of the population and had a 10% risk (14 of 144) of having massive weight gain at 2 years. In contrast, 43 individuals had > 5% early weight gain and their risk of massive weight gain at 2 years was 56% (24 of 43).

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Conclusions. In this real-world dataset, drug class or specific NRTI use was not associated with massive weight gain which was primarily dependent on baseline CD4 count and HIV viral load. There was a moderate correlation between early weight gain and massive weight gain at 2 years which can help with patient counseling and interventions aimed at slowing weight gain in this population.

Disclosures. All Authors: No reported disclosures

73. Interim Resistance Analysis of Long-Acting Lenacapavir in Treatment-Naïve People with HIV at 28 Weeks
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Session: O-16. HIV Treatment

Background. Lenacapavir (LEN) is a first-in-class HIV-1 capsid (CA) inhibitor in clinical development for treatment and prevention of HIV-1 infection. CALIBRATE is an ongoing, phase 2 clinical study evaluating subcutaneous (SC) or oral LEN, in combination with other antiretrovirals, in treatment-naïve people with HIV-1. High rates of virologic success (HIV-1 RNA < 50 copies/mL) were achieved with LEN-based regimens by FDA Snapshot analysis at Week 28. Here, we present interim resistance analyses through Week 28.

Methods. Participants were randomized (2:2:2:1) to treatment groups (TG): (Figure): SC LEN + oral daily emtricitabine/tenofovir alafenamide (F/TAF); at Week, participants Switch F/TAF to oral TAF (TG-A) or becivgravir (B, BIC) (TG-B); oral daily LEN + F/TAF (TG-C), or oral daily B/F/TAF (TG-D). Genotypic analyses (population sequencing) of HIV-1 reverse transcriptase and integrase, and genotypic (deep sequencing) phenotypic analyses for CA were performed at screening; genotypic and phenotypic analyses were conducted at confirmed virologic failure.

Figure. CALIBRATE Study Design

Table 1: Birth Defaul Outcome of Pregnant Women Exposed to DTG-Related Prophylaxis Case with Follow-Up Closed through 31 January 2021

Table 2: Neural Outcomes (among Singleton, Live Births without Birth Defects) Prophylaxis Registry Case with Follow-Up Closed through 31 January 2021

Results. 182 participants were randomized and dosed in TG-A to D (n=52, 53, 52, 25). Most participants had subtype B HIV-1 (92.9%). Sequence analysis of baseline samples found 65% of amino acid residues were conserved with <1% variation across CA overall, and 55% of residues were fully conserved. No mutations were detected at 6 positions in CA associated with reduced susceptibility to LEN in vitro; residues were fully conserved at 5 positions (L56, M66, Q67, K70, N74), and <2% variation was observed at 1 position (T107). Three participants met the criteria for resistance analysis: 2 participants resuppressed to <50 copies/mL while continuing treatment. One participant on SC LEN + F/TAF developed emergent resistance to LEN (Q67H+K70R) and emtricitabine (M184I), followed by resuppression after starting dolutegravir, zidovudine + lamivudine, tenofovir disoproxil fumarate.

Conclusion. Emergence resistance to LEN was uncommon in treatment-naïve participants receiving SC or oral LEN (0.6%, 1/157). These interim resistance findings support the ongoing evaluation of LEN for treatment and prevention of HIV.

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