69. Incidence of metabolic complications among treatment-naïve adults living with HIV-1 randomized to B/F/TAF, DTG/ABC/3TC or DTG+F/TAF after 144 Weeks

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Session: O-15. HIV Co-infections and Co-morbidities

Background. Metabolic comorbidities including diabetes (DM) and dyslipidemia pose challenges to the long-term care of people with HIV (PWH). Incidence of cardiovascular disease and DM are reported at higher rates in PWH than the general population. Obesity is broadly prevalent in both the general population and PWH, and higher body mass index (BMI) can contribute to metabolic complications. Here we present longer-term follow up on incidence of DM, hypertension (HTN), BMI categorical shifts, and lipid changes over 144 weeks of blinded treatment from two trials of PWH initiating antiretroviral therapy.

Methods. We assessed incidence of metabolic complications in adult PWH in Study 1489: bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) vs dolutegravir/abacavir/ lamivudine (DTG/ABC/3TC) and Study 1490: B/F/TAF vs DTG+F/TAF. Treatment-emergent (TE) metabolic comorbidities were defined by standard MedDRA search lists. CDC-defined BMI categories were compared from baseline (BL) to Week 144. Analyses by sex at birth and race were performed, as well as for lipid changes.

Results. Among 1,274 total participants, median (range) age was 33 years (18-77), 90% men, 33% black. In study 1489, BL prevalence of DM and HTN was 4.5 and 12.1% with TE DM and HTN in B/F/TAF being 0.7% and 10%, and for DTG/ABC/3TC 1.3% and 6.9%, respectively. In study 1490, BL prevalence of DM and HTN was 6.8 and 18.8% with TE DM and HTN in B/F/TAF being 2.1 and 5.8%, and for DTG+F/TAF 2.3 and 6.5%, respectively. BMI shift from Normal to Obese: B/F/TAF 0%, DTG/ABC/3TC 3.2%, p=0.12 (1489) (Table 1); B/F/TAF 2.5%, DTG+F/TAF 2.9% p=1.00 (1490) (Table 2). Subgroup analyses by gender/race showed similar findings for TE DM, HTN, and BMI changes. Median changes from BL fasted lipids were small (Table 1).

Table 1§. Studies 1489 and 1490: Metabolic Outcomes from Baseline to Week 144

Table 2±. Shift Table of BMI Category at Week 144 by Baseline BMI Category – Overall

Conclusion. Through over 144 weeks of follow up, PWH randomized to initiate B/F/TAF, DTG/ABC/3TC or DTG+F/TAF had low rates of incident DM or HTN-related AEs, with no statistically significant differences by treatment group. BMI changes/categorical shifts from BL did not significantly differ by regimen, and no clinically significant change or difference by regimen in lipids were observed. While data are limited by three years of follow up, they are strengthened by randomized study design of three widely used initial ART regimens.

Disclosures. **Eric Daar, MD**, **Bristol-Myers Squibb** (Consultant)**Gilead Sciences Inc.** (Consultant, Scientific Research Study Investigator, Advisor or Review Panel member, Research Grant or Support)**Janssen** (Consultant, Advisor or Review Panel member, Research Grant or Support)**Merck** (Consultant, Advisor or Review Panel member, Research Grant or Support)**Teva** (Consultant, Advisor or Review Panel member)**ViiV Healthcare** (Consultant, Advisor or Review Panel member, Research Grant or Support) **Chloe Orkin, MD**, **Gilead Sciences Inc.** (Grant/Research Support, Scientific Research Study Investigator, Other Financial or Material Support)**Janssen** (Research Grant or Support, Other Financial or Material Support)**Merck** (Research Grant or Support, Other Financial or Material Support)**ViiV** (Research Grant or Support, Other Financial or Material Support) **Paul Sax, MD**, **Gilead Sciences** (Consultant, Grant/Research Support)**Janssen** (Consultant)**Merck** (Consultant, Research Grant or Support)**ViiV** (Consultant, Research Grant or Support) **Jeffrey L. Stephens, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator, Research Grant or Support) **Ellen Koenig, MD**, **Gilead Sciences Inc.** (Scientific Research Study Investigator) **Amanda Clarke, MD**, **Gilead Sciences Inc.** (Consultant, Scientific Research Study Investigator, Other Financial or Material Support, Conference attendance sponsorship)**ViiV Healthcare** (Consultant, Other Financial or Material Support, Conference travel sponsorship) **Axel Baumgarten, MD**, **AbbVie** (Advisor or Review Panel member, Speaker's Bureau)**Bristol-Myers Squibb** (Advisor or Review Panel member, Speaker's Bureau)**Gilead Sciences Inc.** (Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau)**Janssen** (Speaker's Bureau)**Merck** (Advisor or Review Panel member) **Cynthia Brinson, MD**, **Abbvie** (Scientific Research Study Investigator)**BI** (Scientific Research Study Investigator)**Gilead Sciences Inc.** (Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau, Personal fees)**GSK** (Scientific Research Study Investigator)**Novo Nordisk** (Scientific Research Study Investigator)**ViiV Healthcare** (Scientific Research Study Investigator, Advisor or Review Panel member, Speaker's Bureau) **Moti Ramgopal, MD FIDSA**, **Abbvie** (Scientific Research Study Investigator, Speaker's Bureau)**Gilead** (Consultant, Scientific Research Study Investigator, Speaker's Bureau)**Janssen** (Consultant, Scientific Research Study Investigator, Research Grant or Support, Speaker's Bureau)**Merck** (Consultant, Scientific Research Study Investigator)**ViiV** (Consultant, Scientific Research Study Investigator, Speaker's Bureau) **Hailin Huang, PhD**, **Gilead Sciences Inc.** (Employee, Shareholder) **Terry Farrow, MD**, **Gilead Sciences Inc.** (Employee, Shareholder) **Jared Baeten, MD, PHD**, **Gilead Sciences Inc.** (Employee, Shareholder) **Jason Hindman, PharmD**, **Gilead Sciences Inc.** (Employee, Shareholder) **Hal Martin, MD, MPH**, **Gilead Sciences Inc.** (Employee, Shareholder) **Kimberly Workowski, MD**, Nothing to disclose

70. Changes in Invasive Pneumococcal Disease among Adults Living with HIV Following Introduction of 13-Valent Pneumococcal Conjugate Vaccine, 2008–2018

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**Session:** O-15. HIV Co-infections and Co-morbidities

Background. People living with HIV (PLHIV) are at increased risk of invasive pneumococcal disease (IPD). The 13-valent pneumococcal conjugate vaccine (PCV13) was recommended for children in 2010, and for immunocompromised adults (including PLHIV) in series with 23-valent polysaccharide vaccine (PPSV23) in 2012. We evaluated changes in IPD incidence in adults ≥19 years old by HIV status after PCV13 introduction and proportion of remaining IPD due to serotypes included in the 15- (PCV15) and 20-valent (PCV20) conjugate vaccines expected to be licensed in 2021.

Methods. IPD cases were identified through CDC's Active Bacterial Core surveillance (ABCs). HIV status was obtained from medical records. Isolates were serotyped by Quellung reaction, or whole-genome sequencing and grouped into PCV13-types, PPV11-types (unique to PPSV23), or non-vaccine types. We estimated IPD incidence (cases per 100,000 people) using national projections of ABCs cases as numerators and national case-based HIV surveillance (PLHIV) or US census data (non-PLHIV) as denominators. We compared IPD incidence in 2011–12 and 2017–18 to pre-PCV13 baseline (2008–09) by serotype groups. We assessed the proportion of IPD due to serotypes included in PCV15 and PCV20.

Results. Overall IPD incidence at baseline was 306.7 for PLHIV and 15.2 for non-PLHIV. From baseline to 2017–18, IPD incidence declined in PLHIV (-40.3%; 95% CI: -47.7, -32.3%) and non-PLHIV (-28.2%; 95% CI: -30.9, -25.5%). The largest reductions were in PCV13-type IPD during both periods (-44.2% for PLHIV and -42.2% for non-PLHIV in 2011–12; -72.5% for PLHIV and -62.2% for non-PLHIV in 2017–18) compared to baseline (Figures 1, 2). In 2017–2018, overall IPD and PCV13-type rates were 16.8 (95% CI: 15.1, 18.5) and 12.6 (95% CI: 9.9, 15.3) times as high in

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
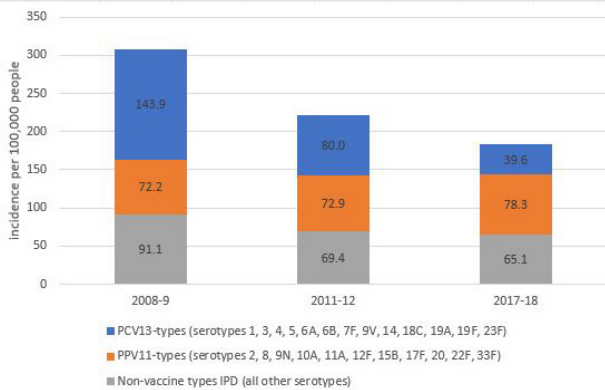
IPD incidence rates among adults aged ≥19 years old by serotype group in non-PLHIV, 2008–2018
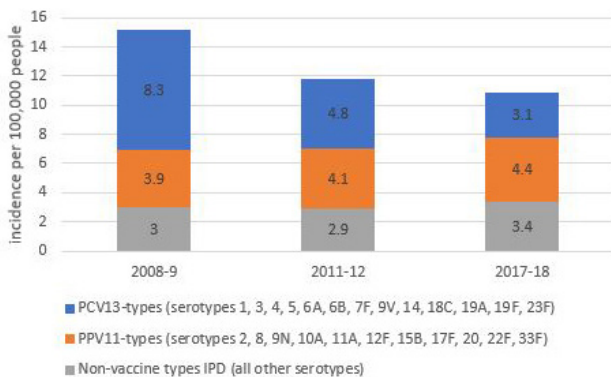
Conclusion. IPD rates declined significantly in both PLHIV and non-PLHIV during the study period due to reductions in PCV13-type IPD; however, IPD rates remained 17-fold higher in PLHIV compared to non-PLHIV, mainly due to non-PCV13 types. Higher-valent pneumococcal conjugate vaccines provide opportunities to reduce some of the remaining IPD burden in PLHIV.

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 comedication burden in PLWH over a 5-year time period.
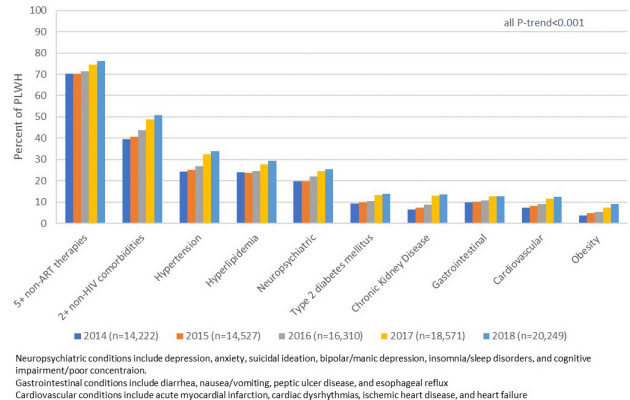
Methods. A retrospective analysis of commercial and Medicare Advantage enrollees from the Optum Research Database was conducted. Annual cohorts of PLWH were constructed for each calendar year from 2014-2018 and included adults (≥ 18 years) with ≥ 1 pharmacy claim for an ART or medical claim with an HIV/AIDS diagnosis code (index date=earliest claim date in each calendar year). Continuous health plan enrollment of 12 months prior to (baseline), and 30 days after index date was required for each annual cohort. 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 using National Drug Codes. Charlson Comorbidity Index (CCI) was computed excluding HIV/AIDS. P-for-trend values accounting for clustering by patients across calendar years were assessed.

Results. Overall, 14,222 - 20,249 PLWH who were enrolled in commercial (80.7%-65.4%) or Medicare Advantage (19.3%-34.6%) 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 29.0%), 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

Neuropsychiatric conditions include depression, anxiety, suicidal ideation, bipolar/manic depression, insomnia/sleep disorders, and cognitive impairment/poor concentration.
Gastrointestinal conditions include diarrhea, nausea/vomiting, peptic ulcer disease, and esophageal reflux
Cardiovascular conditions include acute myocardial infarction, cardiac dysrhythmias, ischemic heart disease, and heart failure

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 naïve 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 weights 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).