

**Results:** A total of 446 patients were switched to a TAF containing regimen during the study period, and included as cases. Controls (n=162) consisted of patients who continued a regimen containing abacavir/lamivudine/dolutegravir during the study period. The control group was older (54 vs. 49 years,  $p < 0.0001$ ), had a higher proportion of black patients (17.9% vs 11.4%,  $p=0.04$ ), had a higher mean VACS score (27 vs 18,  $p < 0.0001$ ), and had fewer patients with reported physical activity (21.6% vs 30%,  $p=0.04$ ), although this was driven by a higher proportion of patients in the controls with unknown physical activity. Cases showed significantly more weight gain compared to controls at 12 months (2.01kg vs 0.77kg,  $p=0.001$ ). There was a higher percentage of increase in BMI class in the cases compared to control at 12 months (18.2% vs 9.9%,  $p=0.01$ ). Increase in weight at 12 months varied dependent on the rest of the antiretroviral regimen (Table 1). Cases had a significant increase in the number of patients with hypertension (35.9% pre vs 43.7% post,  $p=0.02$ ) and hyperlipidemia after the switch (7.8% pre and 18.4% post,  $p < 0.00001$ ), while controls only had a significant increase in hyperlipidemia (50.0% pre vs 67.9% post,  $p=0.01$ ).

Table 1: Change in weight (kg) during the study period

	Cases	Controls (n=162)	p-value
Total of all classes (n=446)			
6 months	1.54 (1.17-1.92)	0.19 (-0.47-0.86)	<b>&lt;0.0001</b>
12 months	2.01 (1.56-2.47)	0.77 (-0.04-1.57)	<b>0.001</b>
Non-INSTI to INSTI (n=96)			
6 months	1.93 (1.05-2.82)	0.19 (-0.47-0.86)	<b>0.0006</b>
12 months	2.35 (1.45-3.24)	0.77 (-0.04-1.57)	<b>0.002</b>
INSTI to INSTI (n=235)			
6 months	1.35 (0.79-1.90)	0.19 (-0.47-0.86)	<b>0.003</b>
12 months	1.50 (0.81-2.19)	0.77 (-0.04-1.57)	0.06
INSTI to non INSTI (n=6)			
6 months	-0.08 (-1.52-0.45)	0.19 (-0.47-0.86)	0.73
12 months	1.13 (-0.92- 3.18)	0.77 (-0.04-1.57)	0.85
Non-INSTI to Non-INSTI (n=109)			
6 months	1.71 (1.16-2.27)	0.19 (-0.47-0.86)	<b>0.0001</b>
12 months	2.88 (2.10- 3.65)	0.77 (-0.04-1.57)	<b>0.0002</b>

INSTI: integrase strand transfer inhibitor

**Conclusion:** Patients switched to an ARV regimen containing TAF gained significantly more weight, and had higher rates of increase in BMI category than those who stayed on a non TAF containing regimen throughout the study period.

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### 108. Selective Decay of Intact HIV-1 Proviral DNA on Antiretroviral Therapy

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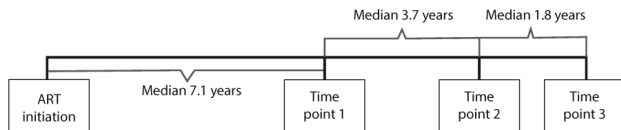
#### ACTG A5321 team

**Session:** O-21. HIV Treatment and Complications

**Background:** HIV-1 proviruses persist in people on antiretroviral therapy (ART) but most are defective and do not constitute a replication-competent reservoir. The decay of infected cells carrying intact compared with defective HIV-1 proviruses has not been well-defined in people on ART.

**Methods:** We separately quantified intact and defective proviruses (using an intact proviral DNA assay), residual plasma viremia, and markers of inflammation and activation in people on long-term ART. Longitudinal measurements were done at three timepoints: timepoint 1 was a median of 7.1 years on ART; timepoint 2 was a median of 3.7 years later; timepoint 3 was a median of 5.5 years after timepoint 1 and a median 12 years after starting ART (Figure 1).

Figure 1: Study timepoints



**Results:** Among 40 participants tested longitudinally from a median of 7.1 years to 12 years after ART initiation, intact provirus levels declined significantly over time (median half-life 7.1 years; 95% confidence interval [CI], 3.9, 18), whereas defective provirus levels did not decrease. The median half-life of total HIV-1 DNA was 41.6 years (95% CI, 13.6, 75). When we evaluated the change in proviral DNA per year, intact proviral DNA declined significantly more ( $p < 0.001$ ) than defective proviral DNA (the latter did not change) (Figure 2). The proportion of all proviruses that were intact diminished over time on ART, from about 10% at the first on-ART timepoint to about 5% at the last timepoint (Figure 3). At timepoint 1, intact provirus levels on ART correlated with total HIV-1 DNA and residual plasma viremia, but there was no evidence for associations between intact provirus levels and inflammation or immune activation.

Figure 2: Percent change in HIV-1 proviral DNA per year

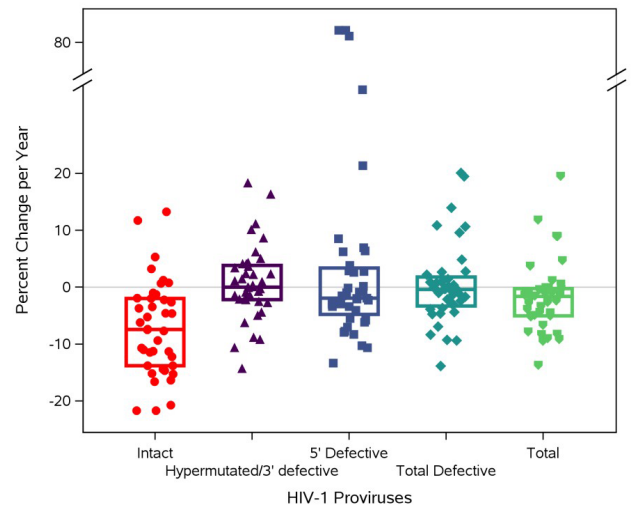
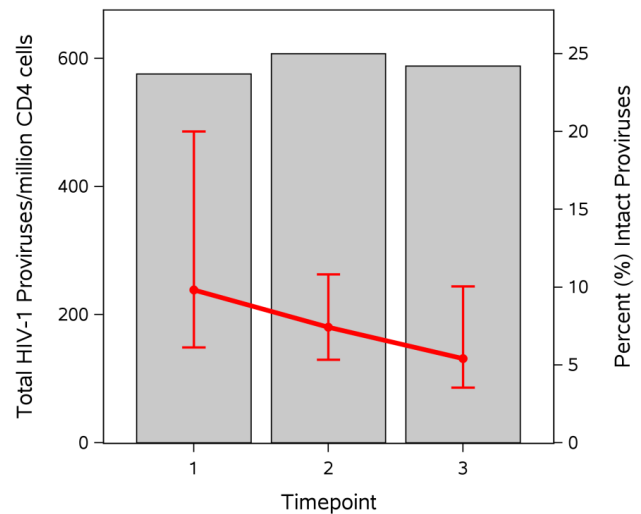


Figure 3: Total HIV-1 proviruses (grey bars) and the percentage of intact proviruses (red lines, displaying median, Q1, Q3) by timepoint.



**Conclusion:** Cells containing intact, replication-competent proviruses are selectively lost during suppressive ART. Defining the mechanisms involved should inform strategies to accelerate HIV-1 reservoir depletion.

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### 109. Preexisting Resistance and Week 48 Virologic Outcomes After Switching to B/F/TAF in African American Adults with HIV

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**Session:** O-21. HIV Treatment and Complications

**Background:** The BRAAVE 2020 study is evaluating the safety and efficacy of switching to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) among virologically suppressed Black adults with HIV. At Week (W) 24, 0.6% (2/328) on B/F/TAF vs 1.8% (3/165) who stayed on their baseline 3 drug regimen (SBR) had HIV-1 RNA  $\geq 50$  c/mL demonstrating noninferiority of B/F/TAF. Here, resistance analyses and virologic outcomes at W48 are described.

**Methods:** Enrollment criteria permitted prior treatment failure, except on an INSTI-containing regimen, and allowed documented resistance to NNRTIs, PIs and/or NRTIs, except for K65R/E/N,  $\geq 3$  thymidine analog mutations (TAMs), or T69-insertions; primary INSTI resistance (-R) was excluded. Preexisting drug resistance was assessed with historical genotypes and proviral DNA genotyping. B/F/TAF outcomes were determined by last on-treatment HIV-1 RNA through W48.

**Results:** Altogether, 495 participants enrolled (B/F/TAF n=330, SBR n=165). Preexisting primary NRTI-R, NNRTI-R, and PI-R substitutions were observed in 14% (70/495), 21% (102/495), and 13% (62/495), respectively. M184V/I and TAMs were detected in 10% (51/495) and 7% (34/495), respectively. Primary INSTI-R was detected post-randomization in 2% (11/495); all continued on study and were included in efficacy analyses. At W24, 163 in the SBR group switched to B/F/TAF (SBR to B/F/TAF). W48 outcomes were determined for 489 participants who had  $\geq 1$  post-switch HIV-1 RNA measurement: 99% (324/327) in the B/F/TAF and 100% (162/162) in the SBR to B/F/TAF groups had HIV-1 RNA < 50 copies/mL at their last study visit, including 100% (68/68) with NRTI-R (50 of whom had archived M184V/I and post-switch data), and 100% (11/11) with INSTI-R (Table). No participant had treatment emergent resistance to study drugs.

Table. BRAAVE 2020 Preexisting Resistance and Virologic Suppression at Week 48 (Last On-treatment Observation Carried Forward Analysis)

% (n/N)	B/F/TAF		SBR to B/F/TAF	
	Total	HIV-1 RNA < 50 copies/mL	Total	HIV-1 RNA < 50 copies/mL
$\geq 1$ HIV-1 RNA measurement post switch	N=327	99% (324/327)	N=162	100% (162/162)
No primary resistance (PR, RT, IN)	66% (217/327)	99% (215/217)	65% (105/162)	100% (105/105)
Any primary resistance (PR, RT, IN)	34% (110/327)	99% (109/110)	35% (57/162)	100% (57/57)
NRTI-R	13% (43/327)	100% (43/43)	15% (25/162)	100% (25/25)
M184V/I	9% (30/327)	100% (30/30)	12% (20/162)	100% (20/20)
TAMs	6% (20/327)	100% (20/20)	8% (13/162)	100% (13/13)
NNRTI-R	21% (69/327)	99% (68/69)	20% (32/162)	100% (32/32)
RPV-R <sup>1</sup>	9% (28/327)	100% (28/28)	7% (12/162)	100% (12/12)
PI-R	11% (35/327)	100% (35/35)	16% (26/162)	100% (26/26)
INSTI-R <sup>2</sup>	2% (8/327)	100% (8/8)	2% (3/162)	100% (3/3)

1. Rilpivirine associated resistance (RPV-R) defined as having  $\geq 1$  of the following substitutions in RT: L100I, K101E/F, E138A/G/K/Q/R, V179L, Y181C/I/V, Y188L, H221Y, F227C, or M320I/L  
2. INSTI-R substitutions observed: E92G (n=3), T66A (n=1), Y143C/H (n=4), Q148H/K/R (n=3)

IN = integrase; INSTI = IN strand transfer inhibitor; NNRTI = nonnucleoside RT inhibitor; NRTI = nucleoside(t)ide RT inhibitor; PI = PR inhibitor; PR = protease; -R = resistance; RT = reverse transcriptase; TAMs = thymidine analog mutations

**Conclusion:** Preexisting resistance was common among virologically suppressed Black adults in BRAAVE 2020, notably M184V/I, TAMs, and NNRTI-R. High rates of virologic suppression were maintained through 48 weeks of B/F/TAF treatment and there were no failures with de novo resistance, indicating that B/F/TAF is an effective treatment option for virologically suppressed people with HIV with or without preexisting resistance to NNRTIs, PIs, or non-tenofovir NRTIs.

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### 110. Bone Mineral Density Screening in Veterans Living with HIV

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**Session:** O-21. HIV Treatment and Complications

**Background:** Low bone mineral density (BMD) is more prevalent in people living with HIV (PLWH) than in the general population. Although no consensus exists regarding when to start screening for BMD loss in PLWH, the Infectious Diseases Society of America (IDSA) recommends dual x-ray absorptiometry (DXA) for men aged  $\geq 50$  years, postmenopausal women, and patients with a history of fragility fracture, chronic glucocorticoid treatment, or at high fall risk. The objective of this study is to evaluate how well this guideline is being carried out in a population of veterans living with HIV (VLWH).

**Methods:** We retrospectively identified VLWH seen at the Veterans Affairs Medical Center (VAMC) in Houston, TX, between 2014–2018 via the VAMC HIV Registry. We extracted demographic, laboratory, and clinical variables, as well as DXA results via this registry database and subsequent chart review.

**Results:** We identified 1,306 VLWH who received care between 2014–2018; 197 turned 50 years old during this time period. Of those, only 32 (16.2%) underwent DXA (2 women, 30 men). DXA revealed normal BMD in 17 (53.1%), osteopenia in 12 (37.5%), and osteoporosis in 3 (9.4%), as defined by traditional DXA T-score cutoffs. Average CD4 count at time of DXA was 698 cells/mm<sup>3</sup> (n=30) (average CD4 for those with normal DXA was 654 [n=16] and for those with osteopenia/osteoporosis it was 749 [n=14]; t-test p = 0.47). Thirty had HIV viral load (VL) < 100 copies/mL; the remaining 2 had VLs of 11,200 and 2,980, both with normal DXAs. Vitamin D (VD) levels were available for 1,005 (77%) VLWH in the study cohort. Of those, 278 (27.7%) were VD deficient (25-hydroxy VD level of < 20 ng/mL). VD levels were available for

31 of the 32 VLWH who had DXA after turning 50 years old; the average VD level was 22.76 (24.61 [n=16] for those with normal BMD and 20.78 [n=15] for those with osteoporosis/osteopenia; t-test p = 0.30).

**Conclusion:** Our results indicate that adherence to IDSA BMD screening guidelines in VLWH can be improved. Given that nearly half of the screened patients showed evidence of BMD loss on their initial DXA, efforts should be made to increase awareness and screening in this vulnerable population. Prevention, earlier diagnosis, and treatment of BMD loss in VLWH would likely lead to decreased morbidity associated with fractures due to low BMD in this population.

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### 111. Outcomes Related to COVID-19 Among People Living with HIV: Cohort from a Large Academic Center

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**Session:** O-22. HIV in Special Populations

**Background:** The COVID-19 pandemic has resulted in nearly 8 million cases and close to 500,000 deaths globally. Little is known about risk factors for favorable or adverse outcomes from COVID-19 among people living with HIV (PWH). Small case series have described outcomes for hospitalized PWH with COVID-19.

**Methods:** This is a retrospective chart review of PWH with confirmed diagnosis of COVID-19 from 2 HIV ambulatory clinics from March 1 to May 31, 2020 in a large urban academic center that serves a substantial proportion of underserved minorities. Data on demographics, clinical characteristics, and outcomes were abstracted using a standardized data collection tool. Bivariate analysis was performed to identify correlates of hospitalization.

**Results:** Among the clinic cohort of 1469 PWH, 94 (6.4%) were tested for SARS-CoV-2 and 40 (42.5%) were positive. Fifty-percent were women, 65% were 50 years and older, 65% were black, 65% were former or active smokers, and 40% were active alcohol or substance users. The majority (90%) were on ART and 87.5% had HIV viral suppression (< 50 copies/mL). Among comorbidities, 50% had hypertension, 42.5% chronic lung disease, 42.5% cardiovascular disease (CVD), 40% obesity, 27.5% diabetes (DM), and 20% chronic kidney disease (CKD). Hospitalization occurred in 19 patients (47.5%) and of those, 4 (21%) required escalation of care. The median length of stay was 12 days (IQR 5.5–15.5) and there was no inpatient mortality. Among the 12 PWH who had HIV viral load test during hospitalization, 11 (91.7%) maintained viral suppression and none of the 19 patients had ART interruption. Those who were hospitalized were more likely to be >50 years old (p=0.02); have CVD (p=0.003), DM (p=0.01), and CKD (p=0.02); or have multiple comorbidities (p=0.007) compared to those managed as outpatients. Furthermore, incremental numbers of comorbidities were associated with hospitalization (p=0.009). A history of AIDS, black race, obesity, smoking, and substance use disorders were not associated with hospitalization or adverse outcome.

**Conclusion:** In this initial and to our knowledge largest cohort in an urban academic center, PWH with COVID-19 had favorable short-term outcomes. The risk factors associated with hospitalization were older age and multiple non-HIV related comorbidities.

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### 112. A Quality Management Project of a Midwestern Academic HIV Clinic Operation During COVID-19: Implementation Strategy and Preliminary Outcomes

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**Session:** O-22. HIV in Special Populations

**Background:** During the COVID-19 pandemic, HIV clinics had to transform care delivery in order to ensure retention in care (RIC) for people with HIV (PWH). The objective of this quality management project is to maintain high rates of RIC and viral load suppression (VLS) during the pandemic for PWH receiving services at an academic HIV clinic in the Midwest.

**Methods:** We developed a multifaceted implementation strategy for clinic operation using a combination of telehealth and in-person visits. The strategy included: 1) assess for readiness and identify barriers and facilitators, 2) identify and prepare champions, 3) organize clinician implementation meetings, and 4) staff training. As a result, we developed an implementation blue print with criteria for telehealth vs. office visits, criteria for rescheduling patients, conducted staff training on telehealth and personal protective equipment, and changed the clinic structure to accommodate in-person visits for patients who did not meet telehealth criteria and walk-ins. We monitored VLS (defined as HIV RNA < 200 copies per mL) and RIC as measured by medical visit frequency (MVf, defined as percentage of patients who had one visit in each 6 months of the preceding 24 months with at least 60 days between visits); and gap in care (GiC, defined as no visit in the preceding 6 months).

**Results:** As of June 14, 2020, there were 1140 active PWH receiving care at the clinic. By February 29, 2020 there were 34 patients lost to care as defined as no visit within the preceding 12 months). Between March 1 and June 14, 2020 we conducted a