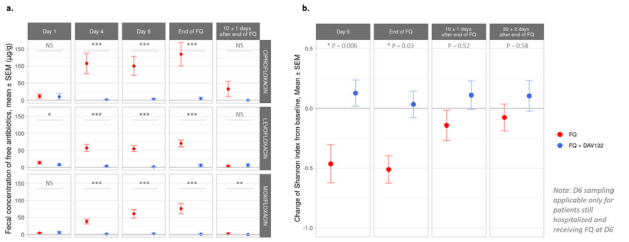

Conclusion. DAV132 was well tolerated in elderly hospitalized patients with comorbidities. It neither altered antibiotic plasma levels nor elicited changes in concomitant drugs regimens. Intestinal microbiota diversity was protected and resistance to colonization by Cd was preserved. DAV132 is a promising, novel product to prevent antibiotic-induced intestinal dysbiosis.

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LB-6. Increased Diagnoses of Acute HIV Infection through Routine ED Screening and Rapid Linkage to Care and initiation of HAART During the COVID-19 Pandemic

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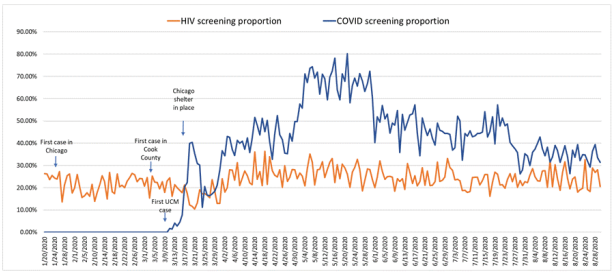
Session: LB1. Late Breaking Abstracts
Saturday, October 24, 2020: 10:40 AM

Background. The COVID-19 pandemic has negatively impacted routine HIV screening in healthcare settings. This has serious implications, especially for patients with acute HIV infection (AHI) presenting with symptoms suggesting COVID-19 infection. This is a high priority population for rapid linkage to care (LTC) and initiation of HAART.

Methods. We reviewed data from our eXpanded HIV Testing and LTC (X-TLC) Program, a collaboration effort between 13 healthcare centers on the South and West Sides of Chicago. Since 2016, most sites had 4th or 5th generation HIV Ag/Ab testing available.

Results. Most sites experienced reductions in HIV screens during the COVID-19 pandemic. Advanced planning by our ED incorporated blood draws for HIV screens as part of COVID-19 evaluations. UCM performed 19,111 HIV screens (11,133 in the ED) between 1/1/20 and 8/17/20, along with 100,635 COVID PCRs (14,754 in ED) between 3/17/20 and 8/17/20. Nine patients were diagnosed with AHI after the first case of COVID-19 in Chicago (1/24/20), and 7 were diagnosed after the first case of community transmission in Cook County (3/8/20). All cases of AHI were diagnosed in the ED. The rate of AHI was significantly higher in 2020 versus the prior 4 years (14.4 vs 6.8 per year, $p < 0.05$). AHI patients comprised 25.7 % (9/35) of all new diagnoses, the highest percent ever. There were 7 men (6 identified as MSM) and 2 cis-gender women, median age of 25 years (21 to 28 years). The median viral load was 6 million (115,000 to > 6 million) copies/mL. Eight of 9 patients presented with an illness indistinguishable from COVID-19, including 1co-infected patient. All were LTC and started on HAART from time of PCR result within a median of 1 day (0–38), but 3 days (range 1–41) from sample collection as a result of delayed reflex PCR confirmatory testing due to high demands on lab personnel and scarcity of reagents due to COVID-19 PCR volumes (since resolved).

HIV Screening and COVID-19 Testing in the ED During COVID-19



Conclusion. Continued HIV screening in our ED during the COVID-19 pandemic identified an increased number of patients with AHI. These individuals may be more likely to present for care due to fear of COVID-19 infection. We achieved rapid LTC and initiation of HAART without any incremental increases in resources. All HIV screening programs should incorporate blood-based HIV screening into their COVID-19 testing programs.

Disclosures. **Moira McNulty, MD, MS**, **Gilead Sciences** (Grant/Research Support)

LB-7. Weight Change in Suppressed People with HIV (PWH) Switched from Either Tenofovir Disoproxil Fumarate (TDF) or Abacavir (ABC) to Tenofovir Alafenamide (TAF)

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Background. Weight gain in PWH occurred in both naïve and switch studies and is linked to use of integrase inhibitors (INSTIs) with varying associations with nucleoside reverse transcriptase inhibitors (NRTIs). One hypothesis is that gain associated with TAF when switching from TDF is a result of cessation of TDF-induced weight suppression.

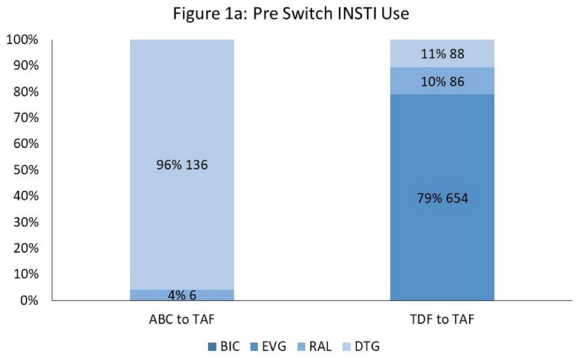
Methods. The study evaluated weight change in suppressed PWH on INSTI+NRTIs switched from ABC or TDF to TAF. Eligible pts had HIV, were ≥ 18 yrs at index (date of switch), treatment-experienced with known prior regimen, suppressed at index (-12 to +1 mo) and 1 yr, ≥ 6 mo pre-index history, with weight measures at index and 1 yr, no current or pre-index use of protease inhibitor or non-nucleoside reverse transcriptase inhibitor. Univariate comparisons were performed using X^2 for categorical and t-test for continuous variables; negative binomial model with log link function evaluated risk of gain ≥ 3% of body weight between groups accounting for age, gender, race, body mass index (BMI), CD4. Linear mixed effects model was used to estimate mean weight at index and 1 yr post switch.

Results. Of 970 pts, 828 (85%) switched from TDF to TAF and 142 (15%) from ABC to TAF. Groups were balanced by race, gender, index BMI [Table 1]. Figures 1a-b describe pre- and post-switch INSTI use. At 1 yr, mean unadjusted weight change was 1.4 kg in TDF and 0.2 in ABC group p=0.039. TDF to TAF had higher proportion of PWH with gain ≥ 3% vs ABC to TAF (40% vs 27% p=0.003); differences in gain ≥ 5% and ≥ 10% were not statistically significant (26% vs 22% p=0.323 and 10% vs 6% p=0.220). Pts who gained ≥ 3% were younger, with greater proportion of females, non-obese, with 1 prior regimen, and prior elvitegravir (EVG) use. In adjusted analysis TDF to TAF had higher risk of gain ≥ 3% vs ABC to TAF [Figure 2]. In sensitivity analysis accounting for EVG or dolutegravir (DTG) use, TDF to TAF also had higher risk of ≥ 3% gain vs ABC to TAF: adjusted risk ratio (aRR)= 1.38 [1.01–1.89] and aRR= 1.42 [1.02–1.97].

Table 1. Baseline (index) characteristics.

Treatment-experienced suppressed switches from INSTI+NRTI: ABC to TAF and TDF to TAF		A: ABC to TAF n=142	B: TDF to TAF n=828		C: Gained≥ 3%	D: Lost or gained < 3%	
only p-values<0.05 are shown		n (%)	n (%)	A v B			C v D
Age <50		55 (39)	532 (64)	<0.001	242 (66)	345 (57)	0.009
Gender	Male	112 (79)	647 (78)		275 (75)	484 (80)	0.038
	Female	19 (13)	134 (16)		69 (19)	84 (14)	0.047
	Other	0 (0)	3 (0)		1 (0)	2 (0)	
	Unknown	11 (8)	44 (5)		23 (6)	32 (5)	
Race	White	85 (60)	454 (55)		194 (53)	345 (57)	
	Black or African American	38 (27)	237 (29)		111 (30)	164 (27)	
	Other	11 (8)	81 (10)		38 (10)	54 (9)	
	Unknown	8 (6)	56 (7)		25 (7)	39 (6)	
Baseline BMI	Underweight	5 (4)	38 (5)		23 (6)	20 (3)	0.031
	Normal	44 (32)	263 (32)		132 (36)	175 (30)	0.026
	Overweight	52 (38)	267 (33)		107 (30)	212 (36)	0.049
	Obese	36 (26)	250 (31)		100 (28)	186 (31)	
Baseline CD4 count <200 cells/ml		8 (6)	23 (3)		22 (6)	47 (8)	0.049
Prior regimens	1	43 (30)	473 (57)	<0.001	211 (57)	305 (51)	0.043
	2	43 (30)	203 (25)		84 (23)	162 (27)	
	3 or more	56 (39)	152 (18)	<0.001	73 (20)	135 (22)	
INSTI Post switch	RAL	0 (0)	27 (3)	N/A	10 (3)	17 (3)	
	DTG	23 (16)	94 (11)		49 (13)	68 (11)	
	BIC	74 (52)	48 (6)	<0.001	40 (11)	82 (14)	
	EVG	45 (32)	659 (80)	<0.001	269 (73)	435 (72)	
INSTI Pre Switch	Prior RAL	6 (4)	86 (10)	0.021	31 (8)	61 (10)	
	Prior DTG	136 (96)	88 (11)	<0.001	73 (20)	151 (25)	
	Prior BIC	0 (0)	0 (0)	N/A	0 (0)	0 (0)	
	Prior EVG	0 (0)	654 (79)	N/A	264 (72)	390 (65)	0.025

Figures 1a-b. Distribution of pre switch and post switch INSTI use.



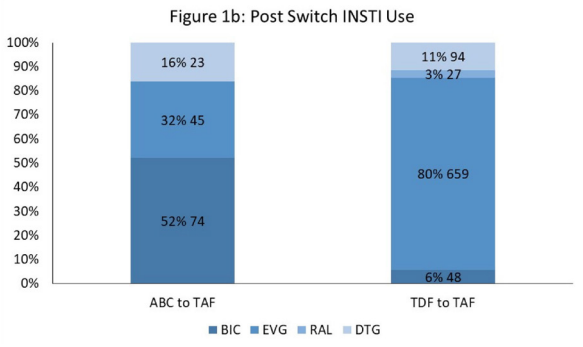
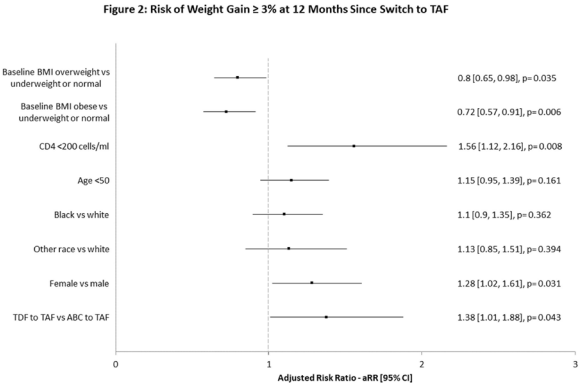


Figure 2. Risk of weight gain ≥ 3% of body weight at 1 year post switch accounting for age, gender, race, index BMI, and CD4.



Conclusion. Switching from TDF to TAF in INSTI-based regimens had a greater risk of weight gain vs ABC to TAF. This difference persisted when accounting for impact of the INSTI agent in the current regimen. These data suggest that differences in weight gain between TAF and TDF are driven by removal of TDF-associated weight suppression.

Disclosures. **Paul Sax, MD**, **Gilead** (Consultant, Research Grant or Support)**Janssen** (Consultant)**Merck** (Consultant, Research Grant or Support)**ViiV Healthcare** (Consultant, Research Grant or Support) **Keri N. Althoff, PhD, MPH**, **Gilead** (Advisor or Review Panel member) **Keri N. Althoff, PhD, MPH**, All of Us Study (NIH) (Individual(s) Involved: Self): Consultant; MedIQ (Individual(s) Involved: Self): Consultant; TrioHealth (Individual(s) Involved: Self): Advisor or Review Panel member **Todd T. Brown, MD, PhD**, **Gilead** (Consultant)**Merck** (Consultant)**Theratechnologies** (Consultant)**ViiV Healthcare** (Consultant) **Janna Radtchenko, MBA**, **Trio Health** (Employee) **Helena Diaz Cuervo, PhD**, **Gilead Sciences** (Employee) **Steven Santiago, MD**, **Gilead** (Advisor or Review Panel member, Speaker's Bureau)**Janssen** (Speaker's Bureau) **Graeme Moyle, MD**, **Theratechnologies** (Consultant) **Karam Mounzer, MD**, **Epividian** (Advisor or Review Panel member)**Gilead** (Advisor or Review Panel member, Research Grant or Support, Speaker's Bureau)**Janssen** (Advisor or Review Panel member, Research Grant or Support, Speaker's Bureau)**Merck** (Advisor or Review Panel member, Research Grant or Support, Speaker's Bureau)**ViiV Healthcare** (Advisor or Review Panel member, Research Grant or Support, Speaker's Bureau) **Richard Elion, MD**, **Gilead** (Advisor or Review Panel member, Research Grant or Support, Speaker's Bureau)**Janssen** (Speaker's Bureau)**Proteus** (Research Grant or Support)**ViiV Healthcare** (Advisor or Review Panel member, Research Grant or Support)

LB-8. Summary of COVID-Related Impact on Cabotegravir and Rilpivirine Long-Acting (CAB+RPV LA) Dosing Across the Six Ongoing Global Phase IIb and IIIb Clinical Trials

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Background. SARS-CoV-2 (COVID-19) has disrupted healthcare service delivery globally. CAB+RPV LA is a novel, long-acting antiretroviral therapy (ART) currently in development and is administered intramuscularly monthly or every 2 months by a healthcare provider. COVID-19 and the resultant restrictions on access to some clinical trial sites presents challenges to the continuous delivery ('implementation fidelity') of CAB+RPV LA during a pandemic.

Methods. Descriptive analyses were conducted using aggregated data from ongoing CAB+RPV LA clinical trials (LATTE-2, ATLAS, ATLAS-2M, FLAIR, POLAR, and CUSTOMIZE) to evaluate impact of COVID-19 on LA dosing. Data through 15 July 2020 were aggregated, categorized, and summarized to show trends. Data collection is continuously ongoing.

Results. As of 15 July 2020, 1831 participants are currently on CAB+RPV LA across these clinical studies. As of 15 July, 113 (6%) participants had injection visits that were impacted by COVID-19. LA dosing was interrupted in 51 (45%) participants due to clinic closure or staffing constraints, 9 (8%) for self-quarantine, 11 (10%) for confirmed or suspected COVID-19, and 42 (37%) for other reasons. Among participants impacted, 64 (58%) were from N. America, 29 (26%) Europe, 14 (13%) S. Africa, and 3 (3%) Latin America. Majority of participants were male (87, 79%), white (74, 65%), with median age 35 years. Mitigation strategies included short-term oral therapy with CAB+RPV (78, 69%), short-term standard of care ART (28, 25%), and rescheduling of LA injections (6, 5%). Although some are still receiving oral therapy, current median duration of oral therapy has been 45 days. To date, 65 (58%) have restarted LA and viral load data collection is ongoing. No suspected or confirmed virologic failure was observed for any participant impacted by COVID-19 to date.

Conclusion. In the midst of the global pandemic, no treatment interruptions were seen across the ongoing CAB+RPV LA clinical studies. Missed visits were manageable and successfully mitigated, primarily by temporary transition to oral therapy with no resultant virologic failure or emerging resistance through 15 July 2020. CAB+RPV LA is a new HIV-1 treatment modality that has demonstrated implementation fidelity across clinical studies during the current COVID-19 pandemic.

Disclosures. **Ronald D'Amico, DO, MSc**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Paul Benn, MB ChB FRCP**, **ViiV Healthcare** (Employee, Shareholder) **Cynthia C. McCoig, MD**, **ViiV Healthcare** (Employee) **Cynthia C. McCoig, MD**, ViiV Healthcare (Individual(s) Involved: Self): Employee **Sandy Griffith, PharmD**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Krischan J. Hudson, PhD, MPH**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Kenneth Sutton, MA**, **GlaxoSmithKline** (Shareholder)**ViiV Healthcare** (Employee) **Kenneth Sutton, MA**, GlaxoSmithKline (Individual(s) Involved: Self): Shareholder; ViiV Healthcare (Individual(s) Involved: Self): Employee **Conn M. Harrington, BA**,