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Session: 263. HIV: ART Resistance and Adherence
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Background. HIV therapy has been moving toward smaller size, once a day regimens in hopes of improved adherence. Surprisingly, few publications characterize HIV patient's pill preferences. To evaluate HIV-negative or treatment-naïve pill preference, we conducted a prospective randomized study at the Infectious Diseases Clinic at Henry Ford Hospital in Detroit, MI.

Methods. Fifty patients were recruited, receiving questionnaires regarding factors influencing the ease of swallowability, medication habits, pill preferences and adherence while being randomized to receive placebo pills representing currently FDA approved combination antiretrovirals DTG/ABC/3TC and BIC/FTC/TAF. Statistical analyses presented are descriptive.

Results. Patients preferred pills or tablets (84%) as their preferred form of medication. Patient's ideal pill length size was reported between 4–9 millimeters (96%), with no responses > 13 mm. The most important factors for ease of swallowability were stated as size (40%) and smoothness (38%). Interestingly, 80% of participants then reported that size and shape of the pills was only "some or less" important to them for their pills; however, 32% of participants stated that size, and shape (16%), could make them not want to take a pill daily. When offered the choice of regimens, patients preferred taking more, smaller pills (42%) vs. fewer larger pills (36%) or liquids (14%). Three most common factors indicated as making medication adherence difficult included taking multiple doses daily (38%), large pills (16%), and multiple pills per dose (14%). When given free response, pills having a smooth coating was reinforced by 10 of the 25 (40%) participants who commented.

Conclusion. Patient preferences for medications are varied and nuanced, but carry implications on patients self-reported likelihood to remain adherent to a regimen. Care should be taken in a clinical setting, such as HIV, to take pill characteristics into account when selecting antiretroviral regimens for patients.

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

2512. Decreasing Adherence to Antiretroviral Therapy over 4 Years of Follow-up in a Commercially-Insured Population of Patients with HIV

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Background. This study compared yearly and longer term antiretroviral (ARV) adherence among HIV patients overall and by single-tablet regimens (STRs) vs. multi-tablet regimens (MTRs).

Methods. A retrospective study using Optum Clinformatics US-based claims data was conducted. Patients with an HIV-1 diagnosis during 2011–2017, age ≥ 18 years at index (date of first complete ARV regimen during the study period), and continuous enrollment for ≥ 3 months before index (baseline) and ≥ 12 months after index (observation) were included. MTRs were required to be comprised of 3 or more agents across at least 2 classes. Adherence was measured as the proportion of days covered (PDC) and compared using a Chi-square test. PDC was examined in the 1-year observation period for the overall analysis, and each year following index among patients with at least 4 years of continuous data. A subgroup analysis was conducted among patients with index during 2014–2016 to evaluate modern ARV adherence.

Results. Among the 15,153 included patients, median age was 45 years, the majority were male (88%), and 53% were in the South. At baseline, 58% (n = 8,715) were receiving an STR and 43% (n = 6,438) an MTR. Compared with STR patients, MTR patients had higher prevalence of hyperlipidemia (36% vs. 29%), cardiovascular disease (27% vs. 21%), and hypertension (25% vs. 20%). During year 1, the proportion of patients with PDC ≥ 0.90 was 63% overall (Table 1), and greater for STR than MTR (67% vs. 58%, P < .001). Among patients with at least 4 years of observation, PDC ≥ 0.90 decreased over time (from 67% in year 1 to 53% in year 4). In the subgroup of patients with index during 2014–2016 (Table 2), similar but slightly worse trends were observed, with PDC ≥ 0.90 for 57% of patients overall, and decreasing over time for those patients with at least 3 years of observation (59% in year 1 to 42% in year 3).

Conclusion. Adherence in this population of patients with HIV showed room for improvement in the first year of observation overall and in the modern ARV era, with those receiving STRs having higher adherence when compared with those receiving MTRs. For the patients with 4 years of follow-up, adherence tended to decrease year on year. Maintaining high rates of ARV adherence is a critically important aspect of therapy for patients with HIV.

Table 1. Adherence among all patients and among subset of patients with ≥ 4 years of follow-up.

	Overall N = 15,153	STR n = 8,715	MTR n = 6,438	P value
All patients				
PDC during 1 year follow-up				
PDC ≥ 0.90, n (%)	9,117 (60.8%)	5,794 (66.5%)	3,723 (57.8%)	< .001
Among patients with ≥ 4 years of follow-up[1]				
PDC (1st year)				
n (%)	3,811 (25.2%)	1,916 (22.4%)	1,837 (28.8%)	
PDC ≥ 0.90, n (%)	2,586 (67.8%)	1,394 (71.3%)	1,172 (63.1%)	< .001
PDC (2nd year)				
n (%)	3,707 (24.5%)	1,923 (22.1%)	1,784 (27.7%)	
PDC ≥ 90%, n (%)	2,119 (57.2%)	1,203 (62.6%)	916 (51.3%)	< .001
PDC (3rd year)				
n (%)	3,552 (23.4%)	1,894 (21.7%)	1,658 (25.8%)	
PDC ≥ 0.90, n (%)	2,004 (56.4%)	1,162 (61.4%)	842 (50.8%)	< .001
PDC (4th year)				
n (%)	3,419 (22.6%)	1,869 (21.4%)	1,550 (24.1%)	
PDC ≥ 0.90, n (%)	1,809 (52.9%)	1,088 (58.2%)	714 (46.1%)	< .001

MTR Multi-tablet regimen; PDC proportion of days covered; STR Single-tablet regimen
[1] If a patient switched from an MTR to an STR (or vice versa), they were excluded from the subsequent years' PDC calculations.

Table 2. Adherence among all patients with index year between 2014 and 2016 and among subset of patients with ≥ 3 years of follow-up.

	Overall N = 5,314	STR n = 3,646	MTR n = 1,668	P value
All patients				
PDC during 1 year follow-up				
PDC ≥ 90%, n (%)	3,052 (57.4%)	2,251 (61.7%)	801 (48.0%)	< .001
Among patients with ≥ 3 years of follow-up[1]				
PDC (1st year)				
n (%)	810 (15.2%)	488 (13.4%)	322 (19.3%)	
PDC ≥ 90%, n (%)	476 (58.8%)	313 (64.1%)	163 (50.6%)	< .001
PDC (2nd year)				
n (%)	771 (14.5%)	478 (13.1%)	293 (17.6%)	
PDC ≥ 90%, n (%)	353 (45.8%)	252 (52.7%)	101 (34.5%)	< .001
PDC (3rd year)				
n (%)	721 (13.6%)	464 (12.7%)	257 (15.4%)	
PDC ≥ 90%, n (%)	305 (42.3%)	229 (49.4%)	76 (29.6%)	< .001

MTR Multi-tablet regimen; PDC proportion of days covered; STR Single-tablet regimen
[1] If a patient switched from an MTR to an STR (or vice versa), they were excluded from the subsequent years' PDC calculations.

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

2513. The Effect of Treatment Supporter Interventions on ART Adherence in Eastern and Southern Africa: a systematic review and meta-analysis

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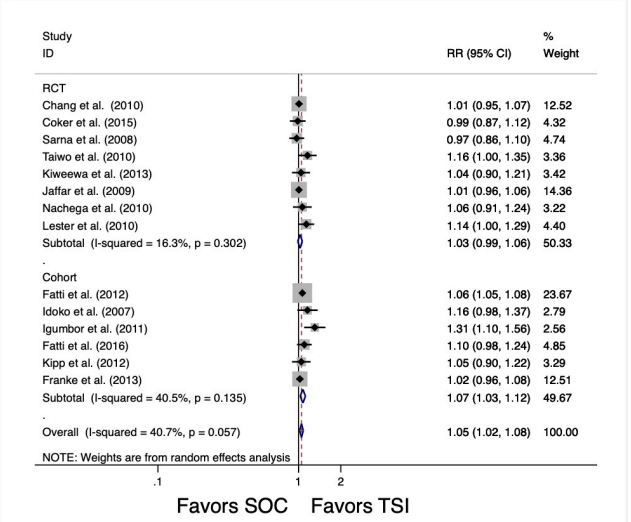
Session: 263. HIV: ART Resistance and Adherence
Saturday, October 5, 2019: 12:15 PM

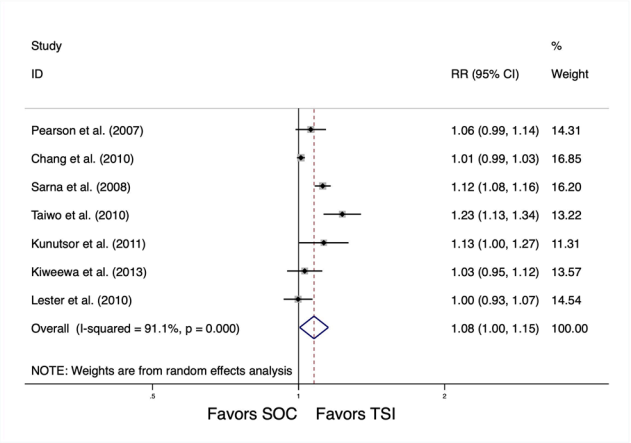
Background. Access to ART has significantly reduced morbidity and mortality and improved quality of life in people living with HIV (PLWH). Treatment supporter interventions (TSIs) utilize patient or facility selected individuals to increase optimal ART adherence through home visits, peer support and medication management. This aim of this meta-analysis is to evaluate the effectiveness of TSIs in improving optimal ART adherence among PLWH in SSA using process- and outcome-oriented measures.

Methods. We searched PubMed, EMBASE, SCOPUS, Web of Science (WOS), Cochrane Library, and ClinicalTrials.gov for randomized controlled trials or cohort studies comparing treatment supporter interventions to the standard of care conducted in Eastern and Southern Africa. The primary outcomes were ART adherence measured by pill counts and virologic suppression. Pooled risk ratios with 95% confidence intervals were calculated using random-effects models. Stratified analyses and meta-regression were conducted to determine the effect of study type and patient nomination of treatment supporters on ART adherence.

Results. Sixteen studies, 10 RCTs and 6 cohort studies, were selected for inclusion. Virologic suppression was reported in 14 studies with 12,457 individuals in TSIs and 23,592 receiving the standard of care. Optimal ART adherence was reported in 7 RCTs only (2,185 individuals in TSI and 1,545 receiving SOC). Optimal ART adherence was 7.6% higher in TSIs compared with SOC (pooled RR 1.076, 95% CI 1.005–1.151, p = 0.035). Heterogeneity of these studies was high (I^2 = 91.1%). Virologic suppression was 5% higher in TSIs compared with the standard of care (pooled RR 1.05, 95% CI 1.019–1.081, P = 0.001). Meta-regression demonstrated that virologic suppression did not significantly vary by study type (b = −0.042, 95% CI −0.09–0.001, P = 0.057) and patient selection of the treatment supporter (b = 0.026, 95% CI −0.07–0.12, P = 0.554).

Conclusion. Optimal ART adherence is marginally higher in treatment supporter interventions compared with the standard of care. Patient-nominated supporters achieve similar rates of virologic suppression to facility-selected supporters, and could play a critical role in addressing disparities in health outcomes among PLWH.





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

2514. Real-time Antiretroviral Electronic Adherence Monitoring In Young African American Men Who Have Sex With Men

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Session: 263. HIV: ART Resistance and Adherence
Saturday, October 5, 2019: 12:15 PM

Background. Antiretroviral therapy adherence remains a challenge, particularly for young African American men who have sex with men (YAAMSM). We enrolled 40 YAAMSM for 3 months of electronic adherence monitoring (EAM). These data may be useful in developing an antiretroviral EAM intervention that responds to missed doses with real-time text messages.

Methods. YAAMSM (age 18–34 years) living with HIV and taking ART participated in a quantitative and qualitative study that included ART adherence monitoring with a Wisepill electronic monitoring device for up to 3 months. Interviews were performed during April 2017–April 2019 at baseline and follow-up. Monitoring data were reviewed to determine timing and patterns of missing their first true adjudicated miss for durations of 1 dose, 3 consecutive days, and 7 consecutive days. Follow-up qualitative interviews included exploring acceptability of monitoring.

Results. The median age was 28 years and median participant observation time was 90 days (interquartile range 88–90 days) (n = 40 participants). Among those with at least 2 weeks follow-up and adjudication (n = 32), 100% missed at least 1 day. Most (82%) of these participants were <80% adherent in at least one of their monitored months. One dose and 3-day misses did not cluster (e.g., no disproportion on weekends). Most (88%) first missed doses occurred during the first 9 days monitored and most (69%) of the 13 who missed 3 consecutive days missed within the first monitored month. Four participants missed 7 consecutive days. Among 31 with a follow-up interview, 28 (90%) felt receiving a text because of device monitoring would affect their medication taking in the future. Illustrative quotes included, "It made me more responsible" and "…it makes you want to do it right."

Conclusion. Most YAAMSM living with HIV in this study had adherence below the target threshold of >80%. These data support development of a text message responsive real-time electronic adherence monitoring intervention approach.

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

2515. Clinical Relevance of Immune Non-Response Among Virally Suppressed Adults Living with HIV in Africa and the United States

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Background. Immune non-response (INR) for people living with HIV (PLWH) is the inability to regain healthy CD4 counts despite viral suppression (VS) on antiretroviral therapy (ART). We identified factors associated with INR in two methodologically similar but demographically diverse cohorts with open access to care and assessed the relationship between INR and incident serious non-AIDS event (SNAE).

Methods. The US Military HIV Natural History Study (NHS) and the African Cohort Study (AFRICOS) are multisite, open cohort studies enrolling PLWH. Participants with 2 years of VS < 400 copies/mL on ART were evaluated for INR, defined as CD4 < 350 cells/μL at 2 years VS. Logistic regression was used to estimate adjusted odds ratios (aOR) and 95% confidence intervals (CI) for factors associated with INR. Cox proportional hazards regression produced adjusted hazard ratios (aHR) and 95% CIs for factors associated with incident SNAE (first non-AIDS cancer, cardiovascular, gastrointestinal, genitourinary, liver, musculoskeletal or respiratory event) after 2 years of VS.

Results. 10.8% of the 1,784 NHS and 25.8% of the 984 AFRICOS subjects had INR. The AFRICOS cohort was older and had a higher proportion of females. In both cohorts, immune non-responders were significantly older and had a significantly lower CD4 at ART initiation. Those with INR also took longer to reach 2 years of VS since starting ART. Odds of INR decreased by over 60% for every 100 cell increase in baseline CD4 in both cohorts (NHS aOR = 0.31 [95% CI 0.26, 0.37]; AFRICOS aOR = 0.36 [95% CI 0.21, 0.86]). In the NHS, hazard of incident SNAE was 61% higher for those with INR (aHR = 1.61 [95% CI 1.12, 2.33]). Probability of SNAE-free survival at 15 years since 2 years of VS was approximately 20% lower comparing those with and without INR; nearly equal to the differences observed by 15-year age groups.

Conclusion. INR was common in two diverse cohorts with open access to care and treatment. The association with SNAEs suggests early identification of and interventions to prevent or reverse INR may improve clinical outcomes, but further study is needed. The clinical relevance of INR highlights the value of early HIV identification and treatment, and suggests CD4 monitoring at ART initiation and post-VS is important in settings where INR is prevalent.

Table 1. Comparison of baseline demographic and clinical characteristics in the NHS and AFRICOS [a]

Characteristic	NHS (n=1,784)			AFRICOS (n=984)		
	INR (n=193)	No INR (1,591)	p-value [b]	INR (n=254)	No INR (n=730)	p-value
Age (years) (IQR)	37.1 (31.9,42.5)	33.9 (28.3, 40.0)	<0.001	40.0 (34.2, 47.1)	36.3 (30.3,42.9)	<0.001
Females (%)	6.7	6.9	0.95	38.2	63.5	<0.001
Smokers (%) [c]	22.3	19.4	0.44	4.3	2.7	0.21
"At-risk" drinkers (%) [c]	15.0	15.5	0.55	N/A	N/A	N/A
BMI (kg/m²) (%)			0.21			0.052
Underweight (≤18.5)	1.6	0.6		12.2	8.4	
Overweight (>25)	52.3	58.8		23.2	29.6	
History of hypertension (%)	29.5	18.5	<0.001	12.6	14.1	0.54
History of diabetes (%)	11.4	3.5	<0.001	12.6	11.1	0.52
History of depression (%)	27.5	19.1	0.0062	18.1	17.8	0.92
History of chronic HBV (%)	5.8	2.6	<0.001	3.4	4.5	0.49
History of HCV (%)	6.7	3.9	0.15	1.7	1.1	0.51
History of AIDS event (%)	35.2	8.4	<0.001	20.9	15.1	0.033
History of poor ART adherence (%) [d]	33.3	25.8	0.027	10.2	10.0	0.92
Baseline CD4 (cells/μL) (IQR)	161.0 (59.5, 229.5)	374.0 (277.0, 488.0)	<0.001	112.5 (54.0, 191.0)	208.0 (112.0, 294.0)	<0.001
Baseline viral load (log_{10} copies/ml) (IQR)	4.6 (3.8, 5.2)	4.5 (3.8, 4.9)	0.012	2.6 (1.6, 5.2)	3.3 (0.0, 5.0)	0.70
Time to ART start (years) (IQR)	4.7 (3.8, 5.2)	1.6 (0.2, 5.4)	<0.001	0.2 (0.1, 0.8)	0.5 (0.1, 2.3)	<0.001
Time from ART start to 2 years VS (years) (IQR)	3.2 (2.3, 8.4)	2.5 (2.3, 3.8)	<0.001	4.3 (2.3, 6.5)	5.0 (2.5, 7.6)	0.005

[a] Baseline was defined as time of ART initiation.
[b] Chi-squared and Wilcox-Mann-Whitney tests were utilized to look for significant differences by INR status for categorical and continuous variables, respectively.
[c] Approximately 50% of baseline smoking and drinking data were missing from the NHS and therefore excluded from further analyses. AFRICOS history of drinking data was not available.
[d] In the NHS, poor adherence was defined as <95% days covered with ART between treatment initiation and 2 years VS. In the AFRICOS, poor adherence was defined as at least 1 self-reported missed dose in the last month.

Table 2. Unadjusted and adjusted logistic regression results for predictors of INR in the NHS and AFRICOS

Characteristic	Crude OR [a] (95% CI)	p-value	Adjusted OR [b] (95% CI)	p-value
NATURAL HISTORY STUDY				
Baseline viral load [c] (log_{10} copies/ml)	1.21 (1.01, 1.45)	0.035	0.64 (0.52, 0.79)	<0.001
History of hypertension (reference group=no)	1.84 (1.32, 2.57)	<0.001	1.69 (1.06, 2.70)	0.027
Baseline CD4 (cells/μl) (per 100 cells)	0.36 (0.31, 0.41)	<0.001	0.31 (0.26, 0.37)	<0.001
AFRICAN COHORT STUDY				
Baseline age (years)	1.04 (1.03, 1.06)	<0.001	1.04 (1.02. 1.06)	<0.001
Gender (reference group=male)	0.35 (0.26, 0.48)	<0.001	0.52 (0.37, 0.72)	0.001
Baseline CD4 (cells/μl) (per 100 cells)	0.39 (0.27, 0.89)	<0.001	0.36 (0.21, 0.86)	<0.001

[a] Crude ORs were calculated for all factors with significant differences by immune response status as per chi-squared and Wilcox-Mann-Whitney tests for categorical and continuous variables, respectively (p<0.05).
[b] Stepwise selection was used to create the adjusted logistic regression model. Factors significant in the crude analyses that were not significant in the adjusted models included: baseline age (NHS); time from HIV+ to ART start (both cohorts); time from ART start to 2 years VS (both cohorts); history of depression (NHS); history of diabetes (NHS); history of chronic HBV (NHS); poor ART adherence (NHS); history of AIDS event (both cohorts) and history of SNAE before 2 years VS (NHS).
[c] Baseline was defined as time of ART initiation.