

Pediatric HIV/AIDS Cohort Study (PHACS)
AMP(PH200)/AMP Up (PH300)/AMP Up Lite (PH400)
Annual Administrative Report

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1 Enrollment and Demographic Characteristics

1.1 Enrollment

Table 1 - Table 3 show enrollment by cohort and quarter into AMP, AMP Up and AMP Up Lite, respectively. AMP first enrolled youth living with perinatally-acquired HIV (YPHIV) in the first quarter of 2007 and youth who were perinatally HIV-exposed but without perinatally-acquired (YPHEU) in the second quarter of 2007. Enrollment into AMP ended in 2009 with 451 YPHIV and 227 YPHEU; AMP follow-up ended in February 2020. AMP Up enrolls young adults with PHIV (YAPHIV) and PHEU (YAPHEU) previously enrolled in AMP and from participating sites – enrollment began in the second quarter of 2014 and is ongoing. AMP Up Lite only enrolls YAPHIV who have not participated in the AMP and AMP Up studies - the enrollment was started in the third quarter of 2017 and is ongoing. **Table 4 - Table 6** show enrollment by cohort and site into AMP, AMP Up and AMP Up Lite, respectively.

Table 7 summarizes prior participation in approved IMPAACT and other network protocols among AMP participants. **Table 8** shows the number of AMP Up participants who were previously enrolled in AMP and other protocols. AMP Up Lite did not collect information on the participants' prior participations into PHACS or non-PHACS studies.

1.2 Demographic Characteristics

Demographic characteristics and consent information of the participants in AMP, AMP Up and AMP Up Lite are summarized in **Table 9 - Table 11**, respectively.

1.3 Entry Visit and Current Status

The number of entry visits in AMP, AMP Up and AMP Up Lite are shown by PHIV status in **Table 12**. Of the participants enrolled in AMP, 448 of 451 (99%) YPHIV and 226 of 227 (99.6%) YPHEU reported an entry study visit. Of the participants enrolled in AMP Up, 631 of 635 (99%) YAPHIV and 130 of 130 (100%) YAPHEU have reported an entry study visit. Of the participants enrolled in AMP Up Lite, 313 of 313 (100%) YAPHIV have reported an entry study visit.

Table 13 shows the study status of AMP participants and enrollment into AMP Up for those who have reached 18 years-of-age. Of the AMP participants age 18 and older (N=645), 522 (81%) completed the study, 123 (19%) were lost to follow-up, and no children were still on study. Of those 18+ who completed the study, 395 (75%) have already enrolled in AMP Up. Of the 18+ lost to follow-up, 29 (24%) enrolled in AMP Up. In addition, **Table 13** shows the study status of AMP Up participants. Three AMP Up participants were inadvertently taken off study and hope to be brought back on for V2.0. Finally, **Table 13** shows the study status of AMP Up Lite participants. Out of 313 participants, 9 withdrew consent.

1.4 Select Follow-up Characteristics as of Last Clinic Visit

Selected follow-up characteristics of all enrolled participants with an entry visit as of last clinic visit are summarized by study (AMP, AMP Up vs AMP Up Lite), PHIV status and sex in **Table 14**. Such characteristics include age, pregnancy measures (ever been pregnant and the number of completed

pregnancies), HIV seroconversion and death. Completed pregnancies include live births, spontaneous/elective abortions and still births. No AMP YPHEU participants seroconverted to HIV, but one male AMP Up YAPHEU participant seroconverted to HIV. Of 209 male and 239 female AMP YPHIV participants, 3 and 2 have died, respectively. Of 244 male and 387 female AMP Up YAPHIV participants, 6 and 16 have died, respectively. Of 115 male AMP Up Lite YAPHIV participants, 2 have died, no female AMP Up Lite YAPHIV participants have died.

2 Characteristics of Participants Still on Study

2.1 Age and HIV Clinical Characteristics

All AMP participants are now off the AMP study and thus only the age (by PHIV status) of AMP Up and AMP Up Lite participants still on study at their last clinic visit is shown in **Table 15** and **Table 16**, respectively. **Table 17** shows HIV clinical characteristics and ARV regimens at the last visit of YAPHIV of AMP participants. **Table 18** shows HIV clinical characteristics and ARV regimens at the last visit of YAPHIV AMP Up and AMP Up Lite participants still on study.

2.2 ARV Use in the AMP and AMP Up Studies

Table 19 and **Table 20** show the frequencies of ARV drugs among YAPHIV AMP Up and AMP Up Lite participants, still on study used at the entry visit, respectively. **Table 21** and **Table 22** show the frequencies of ARV drugs at the last clinical visit among YAPHIV AMP Up and AMP Up Lite participants still on study, respectively. **Table 23** shows the frequencies of lifetime exposure of AMP participants to ARV classes and individual ARV drugs based on reported regimens. A participant is counted as having taken a drug if any of their reported regimens included the drug.

Figure 1 through **Figure 5** display ARV use among participants with PHIV in AMP/AMP Up (treated as a single study) between 1993 and the first quarter of 2021. For each calendar year, lines indicate the percent exposed among the AMP/AMP Up participants born that year or previously. Participants who were off AMP/AMP Up are included through the year of the date on their final ARV medication form or the date they became off study, whichever was earlier. Participants who were still on study were included through the year of the date on their most recent ARV medication form up to April 1, 2021. Participants may be exposed to more than one regimen during a calendar year and contribute to any line indicating a regimen/drug to which they were exposed. **Figure 1** shows ARV regimen trends for AMP/AMP Up participants with the following hierarchical ARV groupings: cART with INSTI/EI/FI > cART with PI > cART with NNRTI > other ART > 1 or 2 NRTIs > No ART. For instance, if a participant was exposed to any INSTI, disregarding whether or not he was exposed to PI or NNRTI, his ARV exposure would be grouped as cART w/ INSTI/EI/FI. No ART indicates a drug holiday of more than 2 months (greater than 56 days). **Figure 2** through **Figure 5** show the frequencies of exposure to ARV drug classes and individual ARV drugs.

Figure 6 - Figure 10 display ARV use among AMP Up Lite participants between 2017 and the fourth quarter of 2021. For each calendar year, lines indicate the percent exposed during that year. Participants who were off AMP Up Lite are included through the year of the date they became off study. Participants who were still on study were included from their study entry up to April 1, 2022. Participants may be exposed to more than one regimen during a calendar year and contribute to any line indicating a regimen/drug to which they were exposed. **Figure 6** shows ARV regimen trends for AMP Up Lite participants with the same hierarchical ARV groupings as the AMP/AMP Up participants. **Figure 7** through **Figure 10** show the frequencies of exposure to ARV drug classes and individual ARV drugs.

3 Tables and Figures

Table 1: AMP - Study Enrollment by Cohort and Quarter

	Enrollment quarter	Cohort		
		Caregiver (N=588)	PHIV (N=451)	PHEU (N=227)
	2007 Q1	8 (1%)	9 (2%)	0 (0%)
	2007 Q2	51 (9%)	52 (12%)	3 (1%)
	2007 Q3	64 (11%)	61 (14%)	12 (5%)
	2007 Q4	74 (13%)	66 (15%)	14 (6%)
	2008 Q1	46 (8%)	33 (7%)	24 (11%)
	2008 Q2	45 (8%)	38 (8%)	14 (6%)
	2008 Q3	53 (9%)	54 (12%)	17 (7%)
	2008 Q4	21 (4%)	12 (3%)	22 (10%)
	2009 Q1	39 (7%)	18 (4%)	39 (17%)
	2009 Q2	77 (13%)	53 (12%)	38 (17%)
	2009 Q3	66 (11%)	42 (9%)	44 (19%)
	2009 Q4	16 (3%)	13 (3%)	0 (0%)
	2010 or Later	28 (5%)	0 (0%)	0 (0%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV-exposure without perinatally-acquired HIV. Participant enrollment ended in 2009, but caregivers continue to change/enroll.

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Table 2: AMP Up - Study Enrollment by Cohort and Quarter

		Cohort	
		PHIV (N=635)	PHEU (N=130)
Enrollment quarter	2014 Q2	22 (3%)	3 (2%)
	2014 Q3	48 (8%)	13 (10%)
	2014 Q4	52 (8%)	11 (8%)
	2015 Q1	20 (3%)	4 (3%)
	2015 Q2	20 (3%)	12 (9%)
	2015 Q3	37 (6%)	5 (4%)
	2015 Q4	32 (5%)	6 (5%)
	2016 Q1	29 (5%)	8 (6%)
	2016 Q2	44 (7%)	4 (3%)
	2016 Q3	24 (4%)	4 (3%)
	2016 Q4	49 (8%)	4 (3%)
	2017 Q1	40 (6%)	1 (1%)
	2017 Q2	23 (4%)	4 (3%)
	2017 Q3	17 (3%)	2 (2%)
	2017 Q4	7 (1%)	4 (3%)
	2018 Q1	22 (3%)	6 (5%)
	2018 Q2	22 (3%)	3 (2%)
	2018 Q3	17 (3%)	5 (4%)
	2018 Q4	11 (2%)	4 (3%)
	2019 Q1	16 (3%)	5 (4%)
	2019 Q2	24 (4%)	2 (2%)
	2019 Q3	10 (2%)	4 (3%)
	2019 Q4	8 (1%)	4 (3%)
	2020 Q1	5 (1%)	1 (1%)
	2020 Q2	1 (0%)	3 (2%)
	2020 Q3	9 (1%)	1 (1%)
2020 Q4	5 (1%)	2 (2%)	
2021 Q1	4 (1%)	1 (1%)	
2021 Q2	5 (1%)	2 (2%)	
2021 Q3	3 (0%)	0 (0%)	
2021 Q4	5 (1%)	1 (1%)	
2022 Q1	4 (1%)	1 (1%)	

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV

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Table 3: AMP Up Lite - Study Enrollment by Quarter

		Cohort YAPHIV (N=313)
Enrollment quarter	2017 Q3	18 (6%)
	2017 Q4	89 (28%)
	2018 Q1	25 (8%)
	2018 Q2	17 (5%)
	2018 Q3	11 (4%)
	2018 Q4	15 (5%)
	2019 Q1	10 (3%)
	2019 Q2	35 (11%)
	2019 Q3	15 (5%)
	2019 Q4	22 (7%)
	2020 Q1	24 (8%)
	2020 Q3	1 (0%)
	2020 Q4	10 (3%)
	2021 Q1	6 (2%)
	2021 Q2	7 (2%)
	2021 Q3	2 (1%)
2021 Q4	3 (1%)	
2022 Q1	3 (1%)	

Note: YAPHIV, young adult with perinatally-acquired HIV

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Table 4: AMP - Study Enrollment by Site

Enrollment site	Cohort		
	Total (N=678)	PHIV (N=451)	PHEU (N=227)
BOSTON CHILDREN'S HOSPITAL	39 (6%)	35 (8%)	4 (2%)
ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN	40 (6%)	27 (6%)	13 (6%)
SAN JUAN RESEARCH HOSPITAL	54 (8%)	27 (6%)	27 (12%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL	41 (6%)	29 (6%)	12 (5%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	41 (6%)	21 (5%)	20 (9%)
NEW JERSEY MEDICAL CENTER	53 (8%)	46 (10%)	7 (3%)
CHILDREN'S DIAG AND TREAT CTR (S FLOR)	20 (3%)	14 (3%)	6 (3%)
BRONX/LEBANON HOSPITAL CENTER	37 (5%)	17 (4%)	20 (9%)
UNIVERSITY OF MIAMI	57 (8%)	38 (8%)	19 (8%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR)	53 (8%)	23 (5%)	30 (13%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE)	28 (4%)	23 (5%)	5 (2%)
UCSD MEDICAL CENTER	34 (5%)	17 (4%)	17 (7%)
UNIVERSITY OF MARYLAND MED CTR	31 (5%)	23 (5%)	8 (4%)
JACOBI MEDICAL CENTER	53 (8%)	37 (8%)	16 (7%)
CHILDREN'S MEMORIAL HOSPITAL OF CHICAGO	97 (14%)	74 (16%)	23 (10%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV-exposure without perinatally-acquired HIV.

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Table 5: AMP Up - Study Enrollment by Site

Enrollment site	Cohort		
	Total (N=765)	PHIV (N=635)	PHEU (N=130)
BOSTON CHILDREN'S HOSPITAL	46 (6%)	46 (7%)	0 (0%)
ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN	40 (5%)	30 (5%)	10 (8%)
SAN JUAN RESEARCH HOSPITAL	69 (9%)	54 (9%)	15 (12%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL	57 (7%)	49 (8%)	8 (6%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	59 (8%)	48 (8%)	11 (8%)
NEW JERSEY MEDICAL CENTER	75 (10%)	70 (11%)	5 (4%)
CHILDREN'S DIAG AND TREAT CTR (S FLOR)	33 (4%)	29 (5%)	4 (3%)
BRONX/LEBANON HOSPITAL CENTER	52 (7%)	34 (5%)	18 (14%)
UNIVERSITY OF MIAMI	64 (8%)	57 (9%)	7 (5%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR)	55 (7%)	34 (5%)	21 (16%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE)	34 (4%)	30 (5%)	4 (3%)
UCSD MEDICAL CENTER	36 (5%)	28 (4%)	8 (6%)
JACOBI MEDICAL CENTER	72 (9%)	61 (10%)	11 (8%)
CHILDREN'S MEMORIAL HOSPITAL OF CHICAGO	73 (10%)	65 (10%)	8 (6%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV

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Table 6: AMP Up Lite - Study Enrollment by Site

Enrollment site	Cohort	
	Total (N=313)	YAPHIV (N=313)
NYU MEDICAL CTR/BELLEVUE	48 (15%)	48 (15%)
ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN	6 (2%)	6 (2%)
UNIVERSITY OF ALABAMA AT BIRMINGHAM	20 (6%)	20 (6%)
UNIVERSITY OF SOUTHERN CALIFORNIA	36 (12%)	36 (12%)
SAN JUAN RESEARCH HOSPITAL	1 (0%)	1 (0%)
SUNY DOWNSTATE MEDICAL CENTER	55 (18%)	55 (18%)
UNIVERSITY OF FLORIDA HEALTH SCIENCE CTR	38 (12%)	38 (12%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR)	6 (2%)	6 (2%)
BOSTON MEDICAL CENTER PEDIATRIC HIV PROGRAM	29 (9%)	29 (9%)
DAVID GEFEN SCHOOL OF MEDICINE AT UCLA	8 (3%)	8 (3%)
JOHNS HOPKINS UNIVERSITY BALTIMORE	22 (7%)	22 (7%)
RUSH UNIVERSITY COOK COUNTY HOSPITAL CHICAGO	19 (6%)	19 (6%)
SUNY STONY BROOK	16 (5%)	16 (5%)
UNIVERSITY OF WASHINGTON CHILDRENS HOSPITAL SEATTLE	9 (3%)	9 (3%)

Note: YAPHIV, young adults with perinatally-acquired HIV

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Table 7: AMP - Enrollment by Previous Protocol Participation

Protocol group	Studies	PHIV (N=451)	PHEU (N=227)
No Previous Protocol	None	87 (19%)	64 (28%)
219/219C Only	219/219C	292 (65%)	97 (43%)
	219	5 (1%)	5 (2%)
	Total	297 (66%)	102 (45%)
219/219C + Other	219C+ACTG 316	1 (0%)	0 (0%)
	219/219C+WITS	17 (4%)	7 (3%)
	Total	18 (4%)	7 (3%)
WITS Only	WITS	0 (0%)	33 (15%)
Other PACTG/IMPAACT	P1057	1 (0%)	0 (0%)
	ACTG 353	0 (0%)	2 (1%)
	ACTG 326	0 (0%)	1 (0%)
	ACTG 316	0 (0%)	6 (3%)
	ACTG 185	2 (0%)	0 (0%)
	Total	3 (1%)	9 (4%)
Other	FACTS HOPE	0 (0%)	11 (5%)
	LEGACY	46 (10%)	0 (0%)
	257	0 (0%)	1 (0%)
	Total	46 (10%)	12 (5%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV-exposure without perinatally-acquired HIV.

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Table 8: AMP Up - Enrollment by Previous Protocol Participation

Protocol group	Studies	PHIV (N=635)	PHEU (N=130)
No Previous Protocol	None	90 (14%)	0 (0%)
AMP Only	PH200	81 (13%)	37 (28%)
AMP + Other	PH200+P219/P219C	184 (29%)	16 (12%)
	PH200+P219/P219C+P1074	5 (1%)	0 (0%)
	PH200+P219/P219C+PH100	21 (3%)	48 (37%)
	PH200+PH100	8 (1%)	24 (18%)
	Total	218 (34%)	88 (68%)
P219/P219C Only	P219/P219C	32 (5%)	0 (0%)
P219/P219C + Other	P219/P219C+P1074	97 (15%)	0 (0%)
	P219/P219C+P1074+PH100	25 (4%)	0 (0%)
	P219/P219C+PH100	29 (5%)	5 (4%)
	Total	151 (24%)	5 (4%)
P1074 Only	P1074	30 (5%)	0 (0%)
P1074 + Other	P1074+PH100	4 (1%)	0 (0%)
PH100 Only	PH100	29 (5%)	0 (0%)

Note: PHIV: perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV

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Table 9: AMP - Enrollment Demographics and Consent Information

		Cohort		
		Total (N=678)	PHIV (N=451)	PHEU (N=227)
Sex	Male	328 (48%)	210 (47%)	118 (52%)
	Female	350 (52%)	241 (53%)	109 (48%)
Age at enrollment (yrs)	Median (Q1, Q3)	11 (9, 14)	12 (10, 14)	10 (8, 12)
	7-9	229 (34%)	118 (26%)	111 (49%)
	10-12	235 (35%)	154 (34%)	81 (36%)
	13-15	214 (32%)	179 (40%)	35 (15%)
Race	Asian	6 (1%)	2 (0%)	4 (2%)
	Black or African American	454 (67%)	316 (70%)	138 (61%)
	White	173 (26%)	98 (22%)	75 (33%)
	American Indian	3 (0%)	3 (1%)	0 (0%)
	More than One Race	13 (2%)	9 (2%)	4 (2%)
	Participant does not want to report	17 (3%)	15 (3%)	2 (1%)
	Participant does not know	8 (1%)	6 (1%)	2 (1%)
	Race not available to clinic	4 (1%)	2 (0%)	2 (1%)
Ethnicity	Hispanic or Latino	189 (28%)	109 (24%)	80 (35%)
	Not Hispanic or Latino	485 (72%)	341 (76%)	144 (63%)
	Participant does not want to report	4 (1%)	1 (0%)	3 (1%)
Consent to share IMPAACT, WITS, or medical rec data?	No	4 (1%)	4 (1%)	0 (0%)
	Unknown	12 (2%)	6 (1%)	6 (3%)
	Yes	662 (98%)	441 (98%)	221 (97%)
Permission to store specimen in repository	No	6 (1%)	5 (1%)	1 (0%)
	Yes	672 (99%)	446 (99%)	226 (100%)
Permission includes genetic studies	No	9 (1%)	8 (2%)	1 (0%)
	Yes	669 (99%)	443 (98%)	226 (100%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV-exposure without perinatally-acquired HIV

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Table 10: AMP Up - Enrollment Demographics and Consent Information

		Cohort		
		Total (N=765)	PHIV (N=635)	PHEU (N=130)
Sex	Male	308 (40%)	244 (38%)	64 (49%)
	Female	457 (60%)	391 (62%)	66 (51%)
Age at enrollment (yrs)	Median (Q1, Q3)	20 (18, 24)	21 (18, 25)	18 (18, 19)
	Min, Max	18, 39	18, 39	18, 25
	18-19	338 (44%)	231 (36%)	107 (82%)
	20-21	134 (18%)	117 (18%)	17 (13%)
	22-23	80 (10%)	76 (12%)	4 (3%)
	24-25	73 (10%)	71 (11%)	2 (2%)
	26-27	55 (7%)	55 (9%)	0 (0%)
	28-29	20 (3%)	20 (3%)	0 (0%)
	30 or Older	65 (8%)	65 (10%)	0 (0%)
Race	Asian	4 (1%)	1 (0%)	3 (2%)
	Native Hawaiian or other Pacific Islander	2 (0%)	2 (0%)	0 (0%)
	Black or African American	506 (66%)	425 (67%)	81 (62%)
	White	198 (26%)	157 (25%)	41 (32%)
	American Indian	4 (1%)	4 (1%)	0 (0%)
	More than One Race	17 (2%)	14 (2%)	3 (2%)
	Unknown	34 (4%)	32 (5%)	2 (2%)
Ethnicity	Hispanic or Latino	224 (29%)	180 (28%)	44 (34%)
	Not Hispanic or Latino	533 (70%)	450 (71%)	83 (64%)
	Unknown	8 (1%)	5 (1%)	3 (2%)
Permission to store specimen in repository	Yes	753 (99%)	623 (99%)	130 (100%)
	No	4 (1%)	4 (1%)	0 (0%)
	Not asked during re-consent	1 (0%)	1 (0%)	0 (0%)
	Unknown	7	7	0
Permission includes genetic studies	Yes	749 (99%)	621 (99%)	128 (98%)
	No	8 (1%)	6 (1%)	2 (2%)
	Not asked during re-consent	1 (0%)	1 (0%)	0 (0%)
	Unknown	7	7	0

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV

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Table 11: AMP Up Lite - Enrollment Demographics and Consent Information

		Cohort YAPHIV (N=313)
Sex	Male	115 (37%)
	Female	198 (63%)
Age at enrollment (yrs)	Median (Q1, Q3)	25 (22, 28)
	Min, Max	18, 40
	18-19	36 (12%)
	20-21	40 (13%)
	22-23	51 (16%)
	24-25	46 (15%)
	26-27	49 (16%)
	28-29	36 (12%)
	30 or Older	55 (18%)
Race	Asian	4 (1%)
	Black or African American	205 (65%)
	White	78 (25%)
	American Indian	1 (0%)
	More than One Race	5 (2%)
	Unknown	20 (6%)
Ethnicity	Hispanic or Latino	70 (22%)
	Not Hispanic or Latino	238 (76%)
	Unknown	5 (2%)
Permission to use samples for future general tests	Yes	258 (83%)
	No	54 (17%)
	Unknown	1
Permission to use samples for future special studies	Yes	250 (80%)
	No	62 (20%)
	Unknown	1

Note: YAPHIV, young adults with perinatally-acquired HIV

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Table 12: AMP, AMP Up and AMP Up Lite - Entry Visit Status

		Study and HIV Status				
		AMP PHIV (N=451)	AMP PHEU (N=227)	AMP Up PHIV (N=635)	AMP Up PHEU (N=130)	AMP Up Lite PHIV (N=313)
Entry visit status	Visit reported	448 (99%)	226 (100%)	631 (99%)	130 (100%)	313 (100%)
	No visit reported	3 (1%)	1 (0%)	4 (1%)	0 (0%)	0 (0%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV

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Table 13: AMP, AMP Up and AMP Up Lite - Study Status

		Cohort		
		Total	PHIV	PHEU
AMP study status	Completed study	522 (77%)	342 (76%)	180 (79%)
	Enrollment error / eligibility failure	1 (0%)	0 (0%)	1 (0%)
	Death of participant/parent/guardian	5 (1%)	5 (1%)	0 (0%)
	Withdrawal / loss to follow-up	123 (18%)	84 (19%)	39 (17%)
	Site closure	25 (4%)	18 (4%)	7 (3%)
	Other reason	2 (0%)	2 (0%)	0 (0%)
Ever AMP, age 18+	Completed study	522 (81%)	342 (80%)	180 (82%)
	Lost to follow-up	123 (19%)	84 (20%)	39 (18%)
Ever AMP, age 18+, completed study	Enrolled in AMP Up	395 (76%)	271 (79%)	124 (69%)
	Not enrolled	127 (24%)	71 (21%)	56 (31%)
Ever AMP, age 18+, lost to follow-up	Enrolled in AMP Up	29 (24%)	28 (33%)	1 (3%)
	Not enrolled	94 (76%)	56 (67%)	38 (97%)
AMP Up study status	Still on study	689 (90%)	567 (89%)	122 (94%)
	Compl protocol V1.0, not yet in V2.0	3 (0%)	3 (0%)	0 (0%)
	Death of participant	22 (3%)	22 (3%)	0 (0%)
	Severe debilitation, unable to continue	1 (0%)	1 (0%)	0 (0%)
	Participant incarcerated	8 (1%)	6 (1%)	2 (2%)
	Participant withdrew consent	10 (1%)	7 (1%)	3 (2%)
	PT/parent not willing to adhere to reqs	8 (1%)	8 (1%)	0 (0%)
	Site unable to contact participant/parent	21 (3%)	18 (3%)	3 (2%)
	Other reason	3 (0%)	3 (0%)	0 (0%)
AMP Up Lite study status	Participant withdrew consent	9 (3%)	9 (3%)	0 (.%)
	Active on protocol	304 (97%)	304 (97%)	0 (.%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV-exposure without perinatally-acquired HIV

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Table 14: AMP/AMP Up/AMP Up Lite Select Follow-up Characteristics of All Enrolled Participants with an Entry Visit as of Last Clinic Visit

Characteristic		AMP PHIV (N=448)		AMP PHEU (N=226)		AMP Up PHIV (N=631)		AMP Up PHEU (N=130)		AMP Up Lite PHIV (N=313)	
		Male (N=209)	Female (N=239)	Male (N=118)	Female (N=108)	Male (N=244)	Female (N=387)	Male (N=64)	Female (N=66)	Male (N=115)	Female (N=198)
Age at last visit (years)	Median	17	18	17	17	26	26	23	23.50	28	27
	Q1, Q3	16, 19	17, 18	16, 18	17, 18	23, 28	24, 30	21, 24	22, 25	24, 32	24, 31
	15-17	81 (39%)	75 (31%)	66 (56%)	55 (51%)						
	18-21	96 (46%)	123 (51%)	34 (29%)	36 (33%)	31 (13%)	44 (11%)	24 (38%)	14 (21%)	13 (11%)	22 (11%)
	22-25	2 (1%)	5 (2%)			87 (36%)	118 (30%)	32 (50%)	39 (59%)	25 (22%)	50 (25%)
	26-30					87 (36%)	136 (35%)	8 (13%)	13 (20%)	39 (34%)	73 (37%)
	31-35					36 (15%)	75 (19%)			33 (29%)	41 (21%)
	36-40					3 (1%)	12 (3%)			5 (4%)	10 (5%)
	41 or older					0 (0%)	2 (1%)			0 (0%)	2 (1%)
	7-14		30 (14%)	36 (15%)	18 (15%)	17 (16%)					
Ever been pregnant as of last visit*	Yes	.	15 (6%)	.	15 (14%)	.	172 (44%)	.	31 (47%)	.	33 (17%)
	No	.	185 (77%)	.	80 (74%)	.	205 (53%)	.	34 (52%)	.	165 (83%)
	Unknown	.	39 (16%)	.	13 (12%)	.	10 (3%)	.	1 (2%)	.	
Number of completed pregnancies as of last visit	0	.	225 (94%)	.	94 (87%)	.	216 (56%)	.	34 (52%)	.	165 (83%)
	1	.	9 (4%)	.	9 (8%)	.	90 (23%)	.	15 (23%)	.	29 (15%)
	2	.	5 (2%)	.	4 (4%)	.	46 (12%)	.	12 (18%)	.	2 (1%)
	3	.		.	1 (1%)	.	19 (5%)	.	3 (5%)	.	2 (1%)
	4	.		.		.	8 (2%)	.	1 (2%)	.	
	5	.		.		.	6 (2%)	.	1 (2%)	.	
	6	.		.		.	2 (1%)	.		.	
		.		.							
Seroconverted to HIV as of last visit	No	209 (100%)	239 (100%)	118 (100%)	108 (100%)	244 (100%)	387 (100%)	63 (98%)	66 (100%)	115 (100%)	198 (100%)
	Yes							1 (2%)	0 (0%)		

Characteristic		AMP PHIV (N=448)		AMP PHEU (N=226)		AMP Up PHIV (N=631)		AMP Up PHEU (N=130)		AMP Up Lite PHIV (N=313)	
		Male (N=209)	Female (N=239)	Male (N=118)	Female (N=108)	Male (N=244)	Female (N=387)	Male (N=64)	Female (N=66)	Male (N=115)	Female (N=198)
Death	No	206 (99%)	237 (99%)	118 (100%)	108 (100%)	238 (98%)	371 (96%)	64 (100%)	66 (100%)	113 (98%)	198 (100%)
	Yes	3 (1%)	2 (1%)			6 (2%)	16 (4%)			2 (2%)	0 (0%)

**For AMP/AMP Up, this is based on chart abstraction. Completed pregnancies include live births, spontaneous/elective abortions, and stillbirths. For AMP Up Lite, this is based on form PH5803, Q1 and the report reasons had to be non-missing*

Note: PHIV, perinatally-acquired HIV; PHEU: perinatal HIV exposure but without perinatally-acquired HIV

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Table 15: AMP Up - Age as of Last In-person Visit or Chart Abstraction Date of Participants Still on Study

		Study and HIV Status	
		AMP Up PHIV (N=567)	AMP Up PHEU (N=122)
Age (years)	Median	26.48	23.42
	Q1, Q3	23.98, 29.94	21.41, 24.87
	18-21	67 (12%)	40 (33%)
	22-25	185 (33%)	64 (52%)
	26-30	211 (37%)	18 (15%)
	31-35	88 (16%)	0 (0%)
	36-40	11 (2%)	0 (0%)
	41 or older	2 (0%)	0 (0%)
	No entry visit reported	3 (1%)	0 (0%)

Notes:

(1) PHIV: perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV. Age is based on the date of last in-person visit or chart abstraction date

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Table 16: AMP Up Lite - Age as of Last In-person Visit or Chart Abstraction Date of Participants Still on Study

		YAPHIV (N=304)
Age (years) at last visit*	Median	28
	Q1, Q3	24, 31
	18-21	34 (11%)
	22-25	72 (24%)
	26-30	111 (37%)
	31-35	70 (23%)
	36-40	15 (5%)
	41 or older	2 (1%)

Note: PHIV: perinatally-acquired HIV; All participants are on study

* last visit: last in-person visit or chart abstraction date

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Table 17: AMP - Clinical Characteristics as of Last In-person Visit or Chart Abstraction Date of Participants Living with Perinatal HIV

		Study AMP (N=448)
CDC Category	N/A/B	335 (75%)
	C	113 (25%)
CD4 count (copies/mm ³) ⁽³⁾	Median	627
	0-250	48 (11%)
	251-500	102 (23%)
	501-750	134 (30%)
	751-1000	85 (19%)
	1001+	63 (14%)
	Unknown	16 (4%)
CD4 percent ⁽³⁾	Median	34
	< 15%	45 (10%)
	15-25%	61 (14%)
	25% or more	325 (73%)
	Unknown	17 (4%)
HIV-1 RNA (copies/mL) ^(3, 4)	≤75	239 (53%)
	76 - 200	20 (4%)
	201 - 400	14 (3%)
	401 - 5000	69 (15%)
	5001 - 50,000	60 (13%)
	50,000+	26 (6%)
	Unknown	20 (4%)
ARV regimen	cART with INSTI/EI/FI	108 (24%)
	cART with PI	203 (45%)
	cART with NNRTI	91 (20%)
	Other ARV	15 (3%)
	No ARV	31 (7%)

Notes:

- (1) HIV-1 RNA viral load measurements less than 400 copies/mL are treated as equal to 400 copies/mL when calculating the median. Clinical characteristics are based on last recorded measurement.
- (2) ARV regimen categories are hierarchical.
- (3) To determine the CD4 count/percent and HIV-1 viral load, only CD4/HIV-1 data within 12 months prior to the most recent in-person visit or chart abstraction date were considered.
- (4) Six YPHIV participants with HIV-1 RNA viral loads below detection limit but above 75 copies/mL were classified as HIV-1 RNA level ≤75 copies/mL.
- (5) 3 PHIV participants did not have entry visits and thus were excluded

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Table 18: AMP Up/AMP Up Lite - Clinical Characteristics as of Last In-person Visit or Chart Abstraction Date of Participants Living with Perinatal HIV Still on Study

		Study	
		AMP Up (N=567)	AMP Up Lite (N=304)
CDC Category	N/A/B	419 (74%)	216 (71%)
	C	148 (26%)	86 (28%)
	Unknown	0 (0%)	2 (1%)
CD4 count (copies/mm ³) ⁽³⁾	Median	551.50	514
	0-250	43 (8%)	28 (9%)
	251-500	84 (15%)	41 (13%)
	501-750	76 (13%)	38 (13%)
	751-1000	60 (11%)	26 (9%)
	1001+	29 (5%)	14 (5%)
	Unknown	275 (49%)	157 (52%)
	CD4 percent ⁽³⁾	Median	32
< 15%		37 (7%)	26 (9%)
15-25%		55 (10%)	33 (11%)
25% or more		197 (35%)	88 (29%)
Unknown		278 (49%)	157 (52%)
HIV-1 RNA (copies/mL) ⁽³⁾	≤75	207 (37%)	122 (40%)
	76 - 200	8 (1%)	8 (3%)
	201 - 400	8 (1%)	3 (1%)
	401 - 5000	26 (5%)	12 (4%)
	5001 - 50,000	22 (4%)	11 (4%)
	50,000+	14 (2%)	6 (2%)
	Unknown	282 (50%)	142 (47%)
ARV regimen	cART with INSTI/EI/PI	397 (70%)	217 (71%)
	cART with PI	50 (9%)	30 (10%)
	cART with NNRTI	50 (9%)	30 (10%)
	Other ARV	27 (5%)	11 (4%)
	No ARV	28 (5%)	9 (3%)
	Missing ARV information	15 (3%)	7 (2%)

Notes:

(1) HIV-1 RNA viral load measurements less than 400 copies/mL are treated as equal to 400 copies/mL when calculating the median. Clinical characteristics are based on last recorded measurement.

(2) ARV regimen categories are hierarchical.

(3) To determine the CD4 count/percent and HIV-1 viral load, only CD4/HIV-1 data within 12 months prior to the most recent in-person visit or chart abstraction date were considered.

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Table 19: AMP Up - Individual ARV Drugs at Entry

Class Drug	Label	N	Percent
NRTI ftc	FTC/Coviracil	369	59.7
NRTI tdf	Tenofovir/TDF	253	40.9
NRTI taf	Tenofovir Alafenamide (TAF)	131	21.2
NRTI _3tc	3tc/Epivir/Lamivudine	120	19.4
NRTI abc	Abacavir	96	15.5
NRTI zdv	ZDV/AZT	37	6.0
NRTI ddi	Didanosine/Videx/DDI	13	2.1
NRTI d4t	Stavudine/d4T	9	1.5
NNRTI rpv	Rilpivirine/TMC-278	102	16.5
NNRTI etr	Etravirine/TMC-125	38	6.1
NNRTI efv	Efavirenz/Sustiva/DMP-266	34	5.5
NNRTI nvp	Nevirapine/Viramune/NVP	5	0.8
PI rtvboost	Ritonavir/Norvir/RTV (Boost)	201	32.5
PI drv	Prezista/Darunavir/TMC-114	173	28.0
PI atv	Atazanavir/ATV	65	10.5
PI kal	Kaletra	32	5.2
PI nfv	Nelfinavir/Viracept/NFV	9	1.5
PI sqv	Saquinavir/Invirase/Fortovase/SQV	3	0.5
PI tpv	Tipranavir	2	0.3
PI fpv	Fosamprenavir	1	0.2
FI/EI mvc	Maraviroc	11	1.8
FI/EI enf	T-20/Pentafuside/Enfuvirtide/ENF	3	0.5
INSTI dtg	Dolutegravir/GSK-1349572	137	22.2
INSTI evg	Elvitegravir/GS-9137	78	12.6
INSTI ral	Raltegravir/Isentress	69	11.2
INSTI bic	Bictegravir	23	3.7
BOOSTER cob	Cobicistat	126	20.4

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Table 20: AMP Up Lite - Individual ARV Drugs at Entry

Class	Drug Label	N	Percent
NRTI	ftc FTC/Coviracil	244	78.5
NRTI	taf Tenofovir Alafenamide (TAF)	177	56.9
NRTI	tdf Tenofovir/TDF	76	24.4
NRTI	_3tc 3tc/Efavirenz/Lamivudine	25	8.0
NRTI	abc Abacavir	23	7.4
NRTI	zdv ZDV/AZT	6	1.9
NRTI	ddi Didanosine/Videx/DDI	2	0.6
NNRTI	rpv Rilpivirine/TMC-278	44	14.1
NNRTI	etr Etravirine/TMC-125	15	4.8
NNRTI	efv Efavirenz/Sustiva/DMP-266	11	3.5
NNRTI	nvp Nevirapine/Viramune/NVP	2	0.6
NNRTI	dor Doravirine	1	0.3
PI	drv Prezista/Darunavir/TMC-114	67	21.5
PI	rtv Ritonavir/Norvir/RTV	48	15.4
PI	atv Atazanavir/ATV	28	9.0
PI	kal Kaletra	2	0.6
PI	sqv Saquinavir/Invirase/Fortovase/SQV	1	0.3
FI/EI	mvc Maraviroc	4	1.3
INSTI	dtg Dolutegravir/GSK-1349572	91	29.3
INSTI	evg Elvitegravir/GS-9137	68	21.9
INSTI	bic Bictegravir	34	10.9
INSTI	ral Raltegravir/Isentress	18	5.8
BOOSTER	cobi Cobicistat	106	34.1

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Table 21: AMP Up - Individual ARV Drugs at Last Clinical Visit for Participants Still On Study

Class Drug	Label	N	Percent
NRTI ftc	FTC/Coviracil	396	69.7
NRTI taf	Tenofovir Alafenamide (TAF)	343	60.4
NRTI _3tc	3tc/Efavir/Lamivudine	81	14.3
NRTI abc	Abacavir	71	12.5
NRTI tdf	Tenofovir/TDF	65	11.4
NRTI zdv	ZDV/AZT	11	1.9
NRTI d4t	Stavudine/d4T	1	0.2
NRTI ddi	Didanosine/Videx/DDI	1	0.2
NNRTI rpv	Rilpivirine/TMC-278	91	16.0
NNRTI etr	Etravirine/TMC-125	16	2.8
NNRTI efv	Efavirenz/Sustiva/DMP-266	6	1.1
PI drv	Prezista/Darunavir/TMC-114	141	24.8
PI rtvboost	Ritonavir/Norvir/RTV (Boost)	63	11.1
PI atv	Atazanavir/ATV	28	4.9
PI kal	Kaletra	6	1.1
PI nfv	Nelfinavir/Viracept/NFV	1	0.2
PI sqv	Saquinavir/Invirase/Fortovase/SQV	1	0.2
FI/EI mvc	Maraviroc	8	1.4
INSTI dtg	Dolutegravir/GSK-1349572	168	29.6
INSTI bic	Bictegravir	134	23.6
INSTI evg	Elvitegravir/GS-9137	97	17.1
INSTI ral	Raltegravir/Isentress	34	6.0
BOOSTER cob1	Cobicistat	183	32.2

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Table 22: AMP Up Lite - Individual ARV Drugs at Last Clinical Visit for Participants Still On Study

Class	Drug Label	N	Percent
NRTI	ftc FTC/Coviracil	255	83.9
NRTI	taf Tenofovir Alafenamide (TAF)	211	69.4
NRTI	tdf Tenofovir/TDF	50	16.4
NRTI	_3tc 3tc/Epivir/Lamivudine	20	6.6
NRTI	abc Abacavir	18	5.9
NRTI	zdv ZDV/AZT	2	0.7
NNRTI	rpv Rilpivirine/TMC-278	45	14.8
NNRTI	etr Etravirine/TMC-125	10	3.3
NNRTI	efv Efavirenz/Sustiva/DMP-266	6	2.0
NNRTI	dor Doravirine	4	1.3
PI	drv Prezista/Darunavir/TMC-114	66	21.7
PI	rtv Ritonavir/Norvir/RTV	37	12.2
PI	atv Atazanavir/ATV	23	7.6
FI/EI	mvc Maraviroc	3	1.0
INSTI	dtg Dolutegravir/GSK-1349572	90	29.6
INSTI	bic Bictegravir	76	25.0
INSTI	evg Elvitegravir/GS-9137	52	17.1
INSTI	ral Raltegravir/Isentress	13	4.3
INSTI	cab Cabotegravir	1	0.3
BOOSTER	cobi Cobicistat	93	30.6

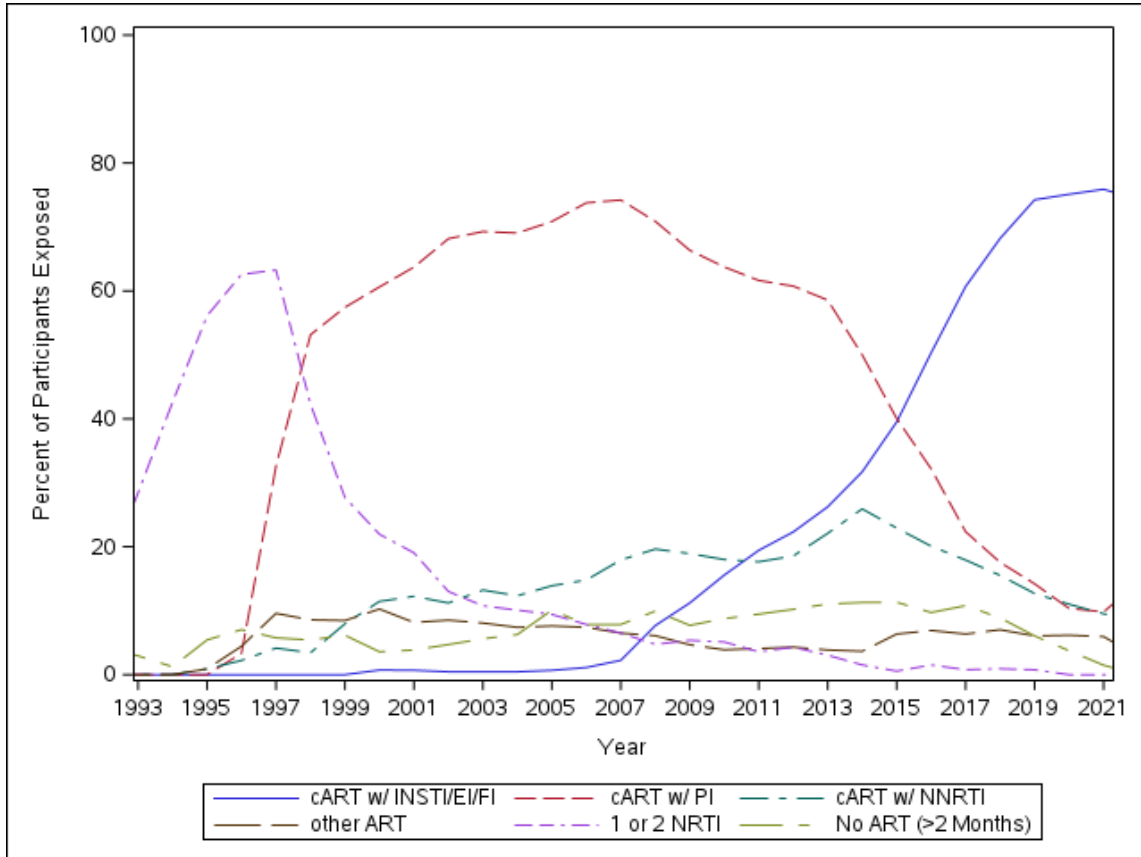
Created by: /home/phacs/actgPH400/monitoring/programs/current_arv.sas on April 26, 2022

Table 23: AMP - Lifetime Exposure to ARV Drug Classes and Individual Drugs, From Reported Regimens

Class/Drug	Total (N = 448)
Any NRTI	446 (100%)
Tenofovir/TDF	270 (60%)
FTC/Coviracil	253 (56%)
3tc/Epivir/Lamivudine	418 (93%)
Abacavir	228 (51%)
ZDV/AZT	378 (84%)
Didanosine/Videx/DDI	306 (68%)
Stavudine/d4T	344 (77%)
Zalcitabine/DDC	16 (4%)
Tenofovir Alafenamide	28 (6%)
Any NNRTI	335 (75%)
Efavirenz/Sustiva/DMP-266	205 (46%)
Etravirine/TMG-125	34 (8%)
Nevirapine/Viramune/NVP	157 (35%)
Delavirdine/DLV	2 (0%)
Rilpivirine/TMC-278	50 (11%)
Any PI	407 (91%)
Ritonavir/Norvir/RTV (Only)	139 (31%)
Ritonavir/Norvir/RTV (Boost)	335 (75%)
Kaletra	255 (57%)
Atazanavir/ATV	141 (31%)
Prezista/Darunavir/TMC-114	98 (22%)
Nelfinavir/Viracept/NFV	265 (59%)
Saquinavir/Invirase/Fortavase/SQV	50 (11%)
Amprenavir/APV	30 (7%)
Tipranavir	13 (3%)
Fosamprenavir	15 (3%)
Indinavir/Crixivan/IDV	28 (6%)
Any FI/EI	26 (6%)
Maraviroc	13 (3%)
T-20/Pentafuside/Enfuvirtide/ENF	13 (3%)
Any INSTI	127 (28%)
Raltegravir/Isentress	88 (20%)
Dolutegravir/GSK-1349572	33 (7%)
Elvitegravir/GS-9137	20 (4%)
Bictegravir	

Created by: /home/phacs/actgPH200/monitoring/detlprogs/arv_figures.sas on April 1, 2022

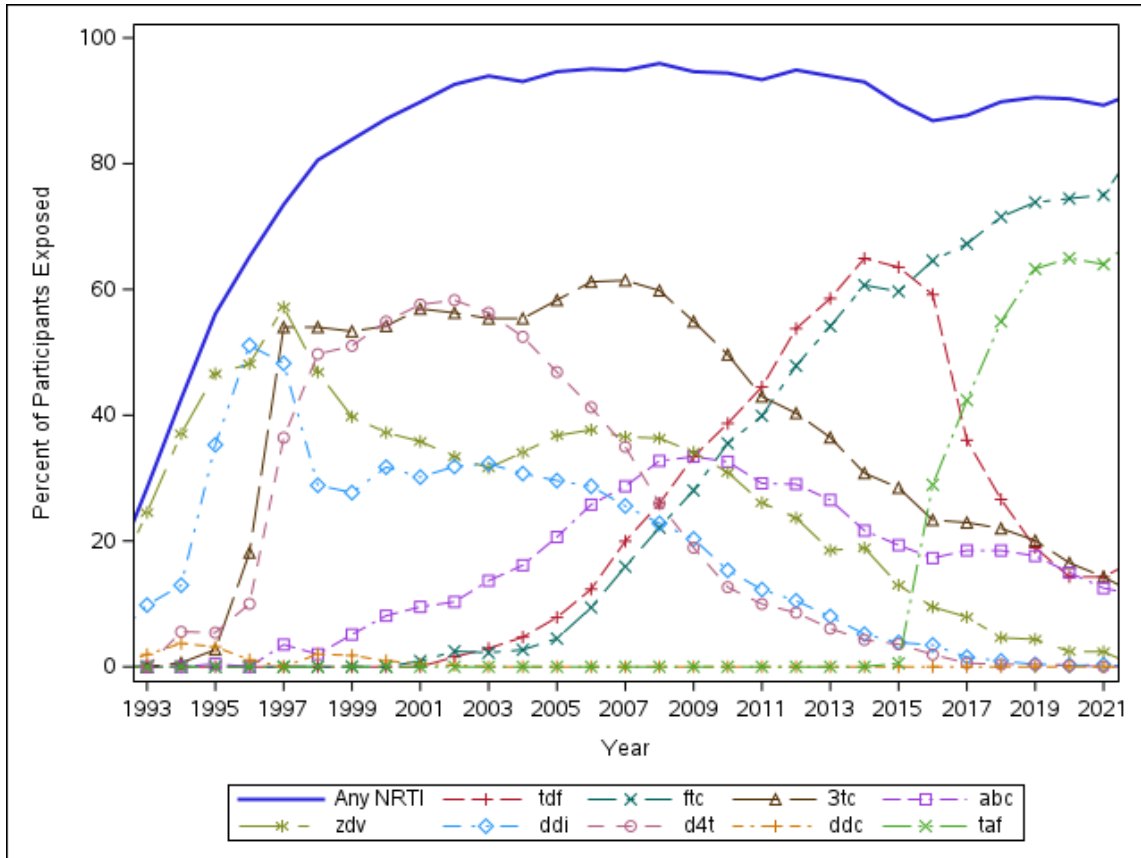
Figure 1: AMP/AMP Up - ARV Trends Over Time



Note: No ART indicates a drug holiday of >56 days.

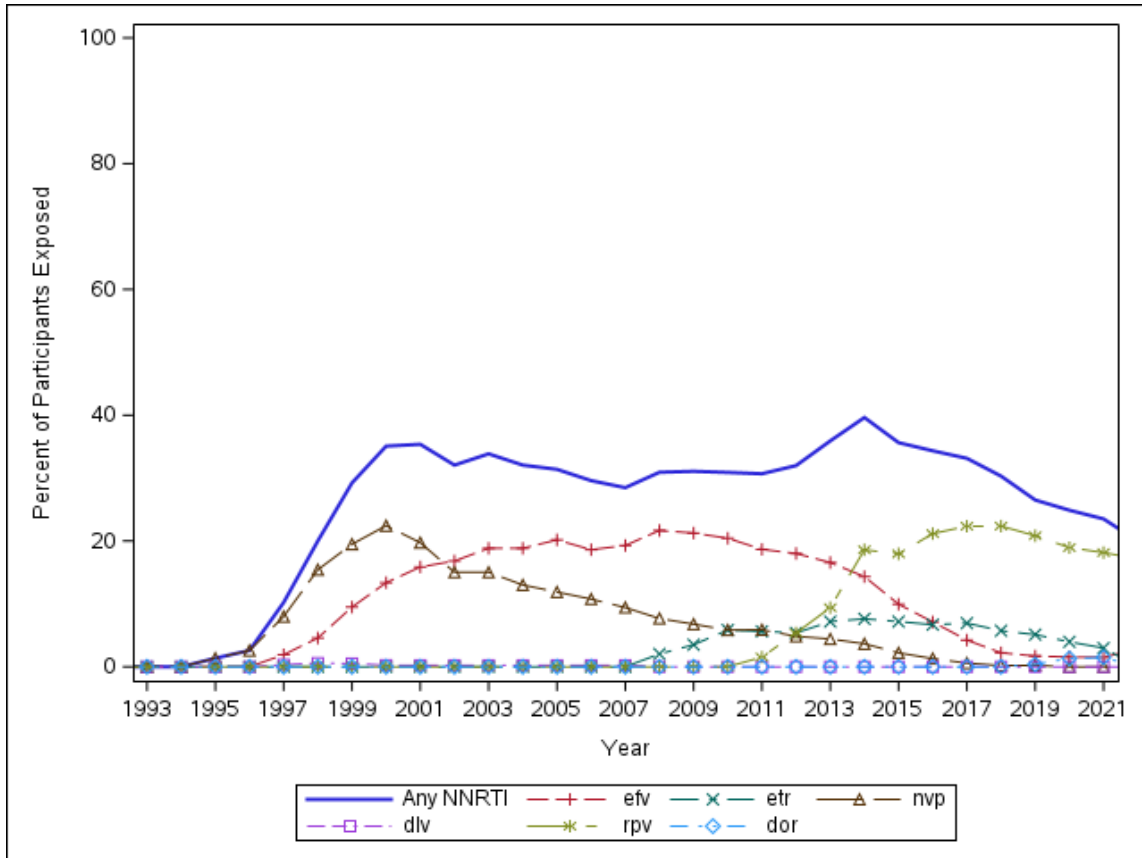
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Figure 2: AMP/AMP Up - NRTI Use, 1993 - 2022



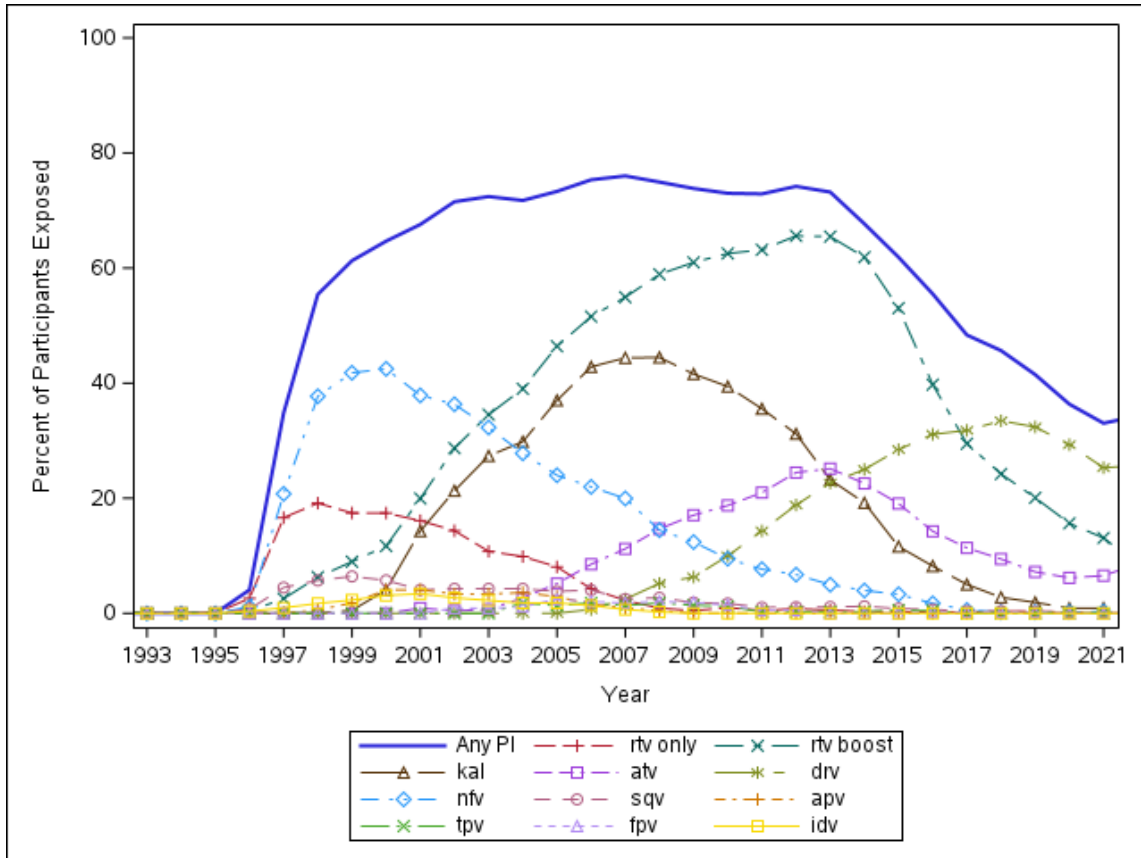
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Figure 3: AMP/AMP Up - NNRTI Use, 1993 - 2022



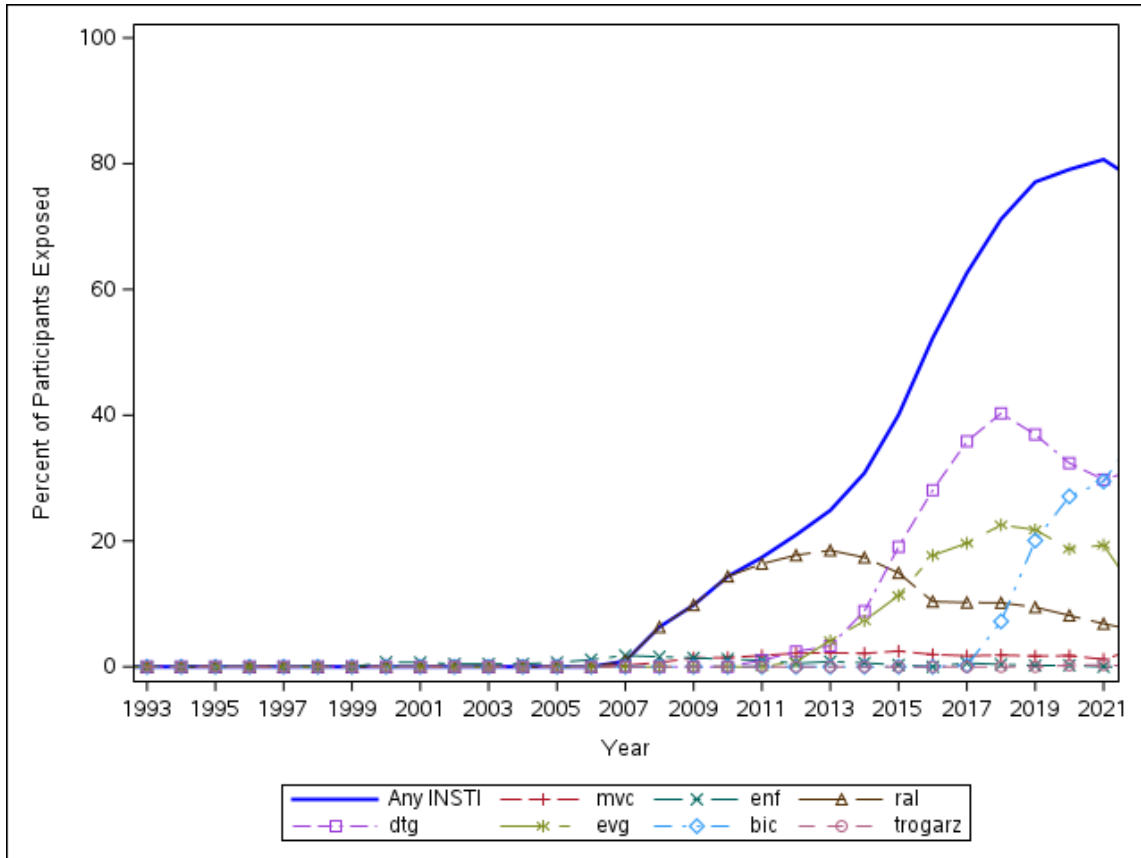
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Figure 4: AMP/AMP Up - PI Use, 1993 - 2022



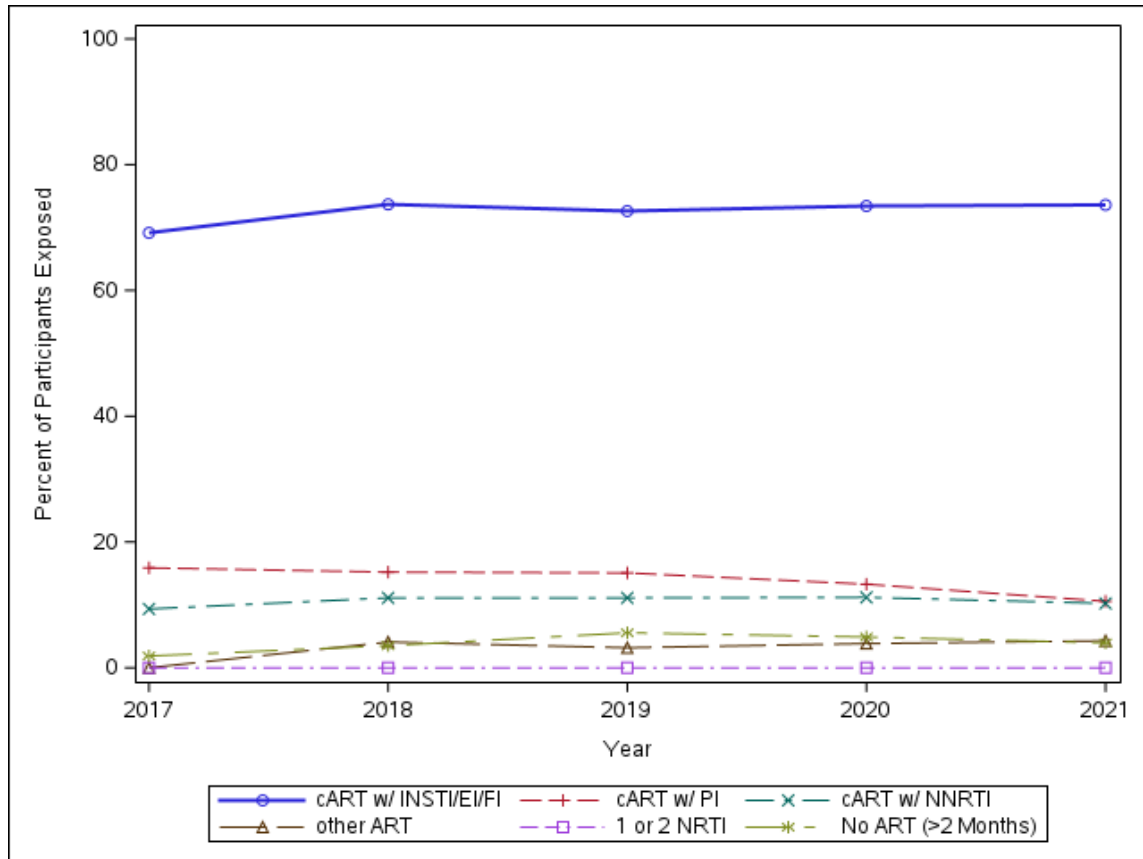
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Figure 5: AMP/AMP Up - FI/EI and INSTI Use, 1993 - 2022



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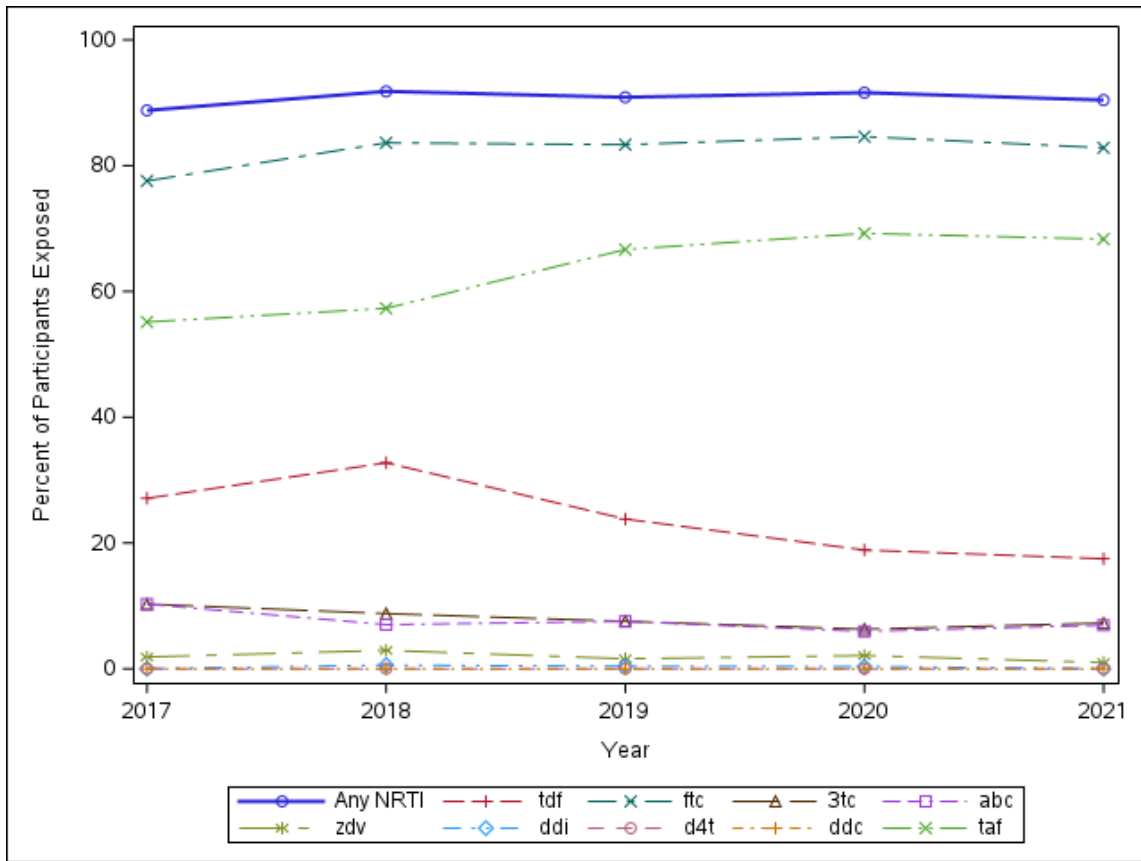
Figure 6: AMP Up Lite - ARV Trends Over Time



Note: No ART indicates a drug holiday of >56 days.

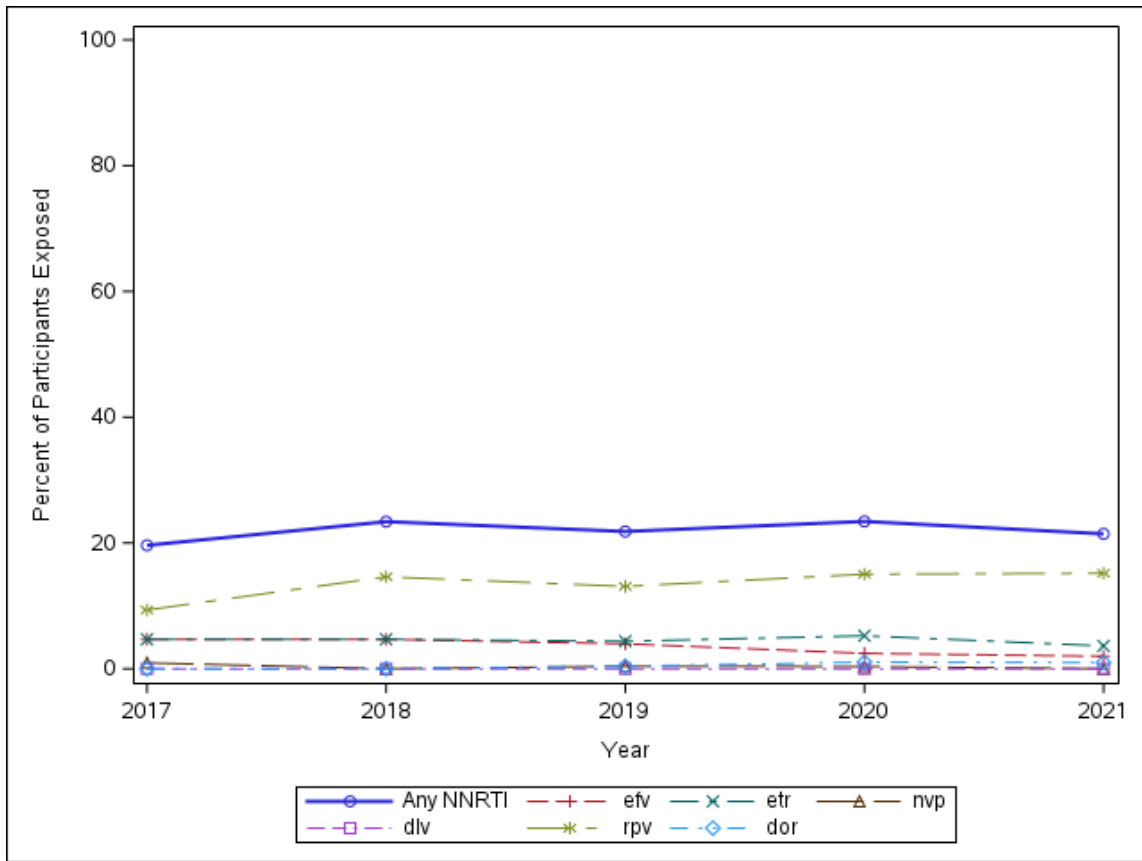
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Figure 7: AMP Up Lite - NRTI Use, 2017 - 2021



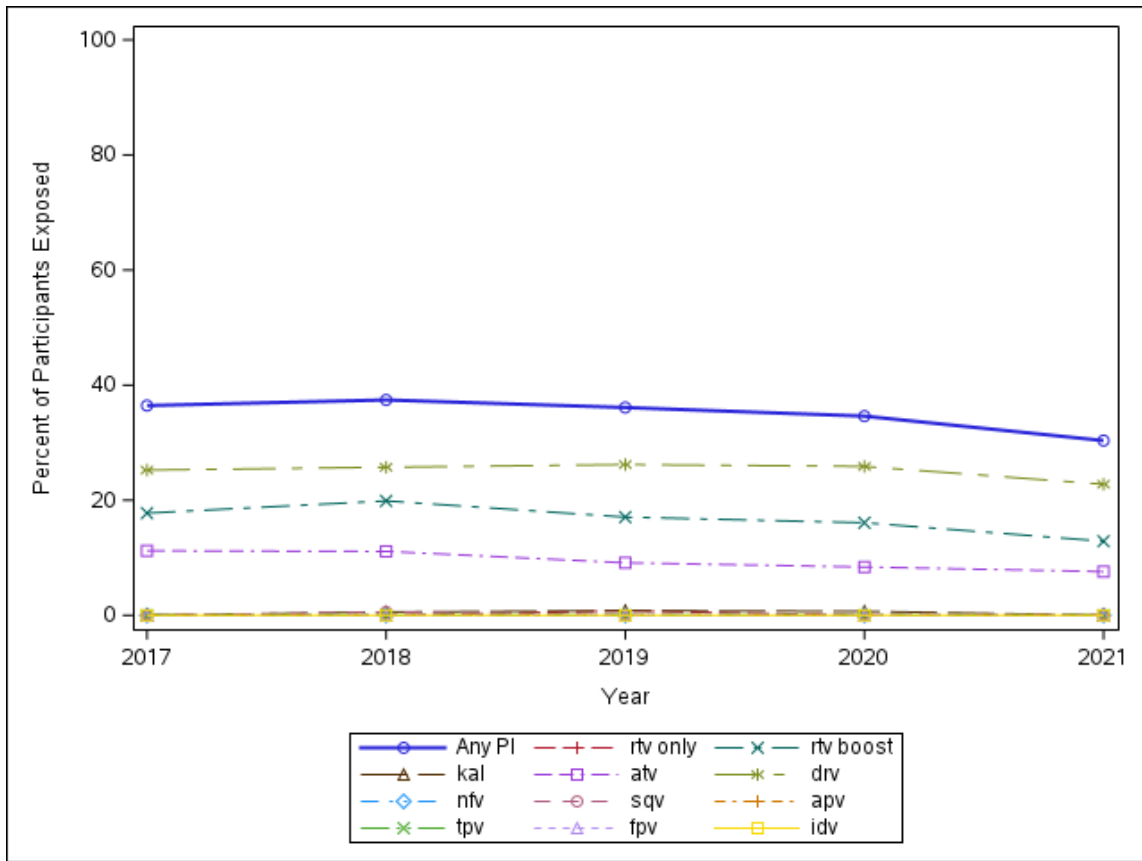
Created by: /home/phacs/actgPH400/monitoring/programs/arv_figures_auplite.sas on April 11, 2022

Figure 8: AMP Up Lite - NNRTI Use, 2017 - 2021



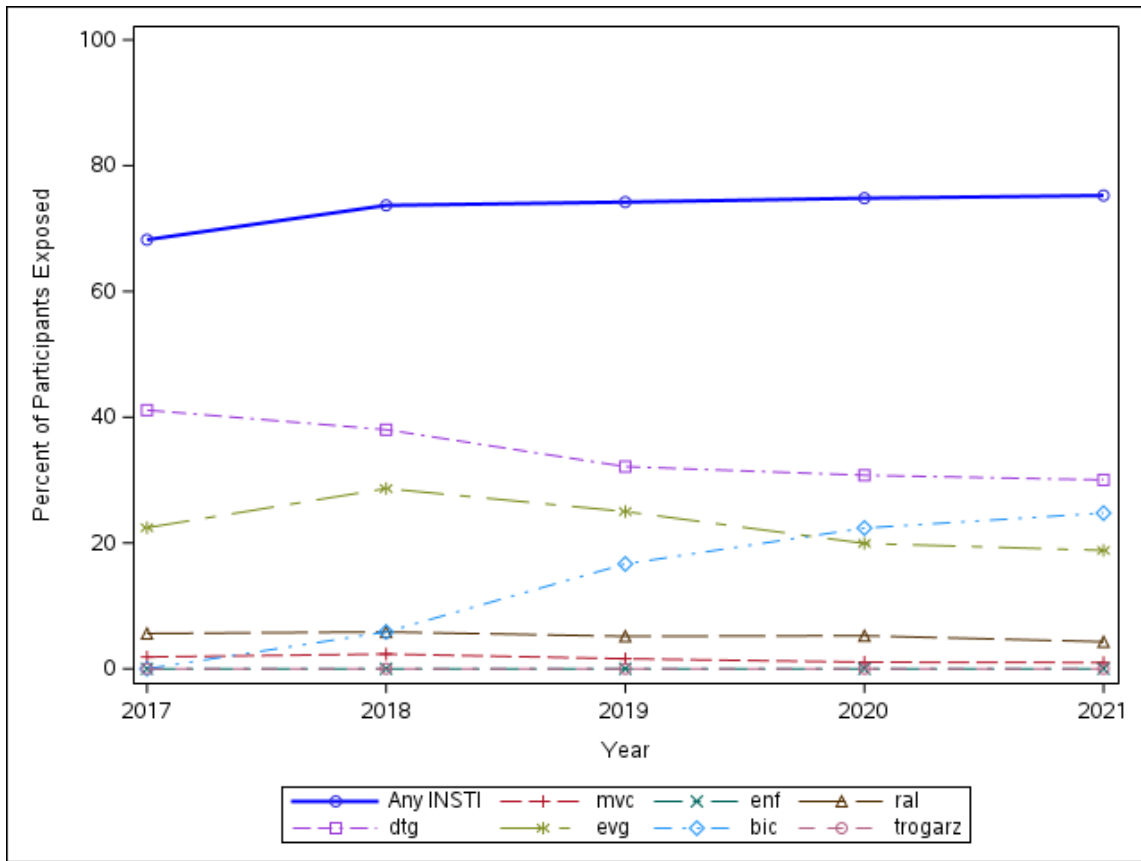
Created by: /home/phacs/actgPH400/monitoring/programs/arv_figures_auplite.sas on April 11, 2022

Figure 9: AMP Up Lite - PI Use, 2017 - 2021



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Figure 10: AMP Up Lite - FI/EI and INSTI Use, 2017 - 2021



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