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Pediatric HIV/AIDS Cohort Study (PHACS) Adolescent Master Protocol (AMP / PH200) and AMP Up (PH300) Annual Administrative Report

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Use:

This report is intended primarily for generating data analysis concept sheets and substudy proposals for PHACS. Information contained in the report also may be used in presentations and published manuscripts with acknowledgement or citation.

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1 Enrollment and Demographic Characteristics

1.1 Enrollment

Table 1 and **Table 2** show enrollment by cohort and quarter into AMP and AMP Up, respectively. AMP first enrolled HIV-infected (HIV+) participants in the first quarter of 2007 and HIV-exposed, uninfected (HEU) participants in the second quarter of 2007. Enrollment into AMP ended in 2009 with 451 HIV+ and 227 HEU participants; caregivers continue to change/enroll. AMP Up first enrolled HIV+ and HEU participants in the second quarter of 2014 and is ongoing. **Table 3** and **Table 4** show enrollment by cohort and site into AMP and AMP Up, respectively.

Table 5 summarizes prior participation in approved IMPAACT and other network protocols among AMP participants. **Table 6** shows the number of AMP Up participants who were previously enrolled in AMP and other protocols.

1.2 Demographic Characteristics

Demographic characteristics and consent information of the participants in AMP and AMP Up are summarized in **Table 7** and **Table 8**, respectively.

1.3 Entry Visit and Current Status

The number of entry visits in AMP and AMP Up are shown by HIV status in **Table 9**. Of the participants enrolled in AMP, 448 of 451 (99%) HIV+ and 226 of 227 (99.6%) HEU reported an entry study visit. Of the participants enrolled in AMP Up, 570 of 576 (99%) HIV+ and 110 of 110 (100%) HEU have reported an entry study visit.

Table 10 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=603), 490 (81%) completed the study, 109 (18%) were lost to follow-up, and 4 (1%) were still on study. Of the 18+ that completed the study, 368 (75%) have already enrolled in AMP Up. Of the 18+ lost to follow-up, 28 (26%) have already enrolled in AMP Up. In the last row, **Table 10** also shows the study status of AMP Up participants.

2 Characteristics of Participants Still on Study

2.1 Age and HIV Clinical Characteristics

The age of AMP and AMP Up participants at their last clinical visit is shown by HIV status in **Table 11**. **Table 12** shows HIV clinical characteristics and ARV regimens at the last visit of HIV+ AMP and AMP Up participants still on study.

2.2 ARV Use in the AMP Study

Table 13 shows the frequencies of ARV drugs used at the last clinical visit among HIV+ AMP participantsstill on study, with combination drugs broken into their individual components.**Table 14** and **Table 15**show the frequencies of ARV drugs among HIV+ AMP Up participants still on study used at the entry and

last clinical visit, respectively. **Table 16** 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 HIV+ participants in AMP between 1993 and 2017. For each calendar year, lines indicate the percent exposed among the AMP participants born that year or previously. Participants are included through the year of their last clinical visit. 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 participants with the following ARV groupings: cART with PI, cART without PI, 3 NRTIs, 1 or 2 NRTIs, other ART, or No ART. 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.

3 Follow-Up

The median duration of follow-up in AMP was 9.99 years among HIV+ and 10.08 years among HEU participants. In AMP Up the median duration of follow-up was 3.04 years among HIV+ and 3.47 years among HEU. The follow-up time is based on the assumption that a subject is still on study as of the last data retrieval date unless known to have discontinued. It is not based on their last study visit.

4 Tables and Figures

			Cohort	
		Caregiver (N=588)	Infected (N=451)	Uninfected (N=227)
Enrollment quarter	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%)

Table 1: AMP - Study Enrollment by Cohort and Quarter

Note: Participant enrollment ended in 2009, but caregivers continue to change/enroll.

			C	ohort
			Infected (N=576)	Uninfected (N=110)
Enrollment quarter	2014 (ຸ22	22 (4%)	3 (3%)
	2014 (23	48 (8%)	13 (12%)
	2014 (24	52 (9%)	11 (10%)
	2015 (Q1	20 (3%)	4 (4%)
	2015 (ຸລ2	20 (3%)	12 (11%)
	2015 (23	37 (6%)	5 (5%)
	2015 (ຊ4	32 (6%)	6 (5%)
	2016 (Q1	29 (5%)	8 (7%)
	2016 (ຸ22	44 (8%)	4 (4%)
	2016 0	23	24 (4%)	4 (4%)
	2016 (ຊ4	49 (9%)	4 (4%)
	2017 (Q1	40 (7%)	1 (1%)
	2017 (ຸ22	23 (4%)	4 (4%)
	2017 (23	17 (3%)	2 (2%)
	2017 (ຊ4	7 (1%)	4 (4%)
	2018 (Q1	22 (4%)	6 (5%)
	2018 0	ຸ22	22 (4%)	3 (3%)
	2018 0	23	17 (3%)	5 (5%)
	2018 0	ຊ4	11 (2%)	4 (4%)
	2019 (Q1	16 (3%)	5 (5%)
	2019 (Q2	24 (4%)	2 (2%)

Table 3: AMP - Study Enrollment by Site

		Cohort		
	Total (N=678)	Infected (N=451)	Uninfected (N=227)	
Enrollment site 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%)	

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Table 4: AMP Up - Study Enrollment by Site

		C	ohort
	Total (N=686)	Infected (N=576)	Uninfected (N=110)
Enrollment site BOSTON CHILDREN'S HOSPITAL	38 (6%)	38 (7%)	0 (0%)
ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN	37 (5%)	27 (5%)	10 (9%)
SAN JUAN RESEARCH HOSPITAL	65 (9%)	51 (9%)	14 (13%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL	51 (7%)	45 (8%)	6 (5%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	49 (7%)	39 (7%)	10 (9%)
NEW JERSEY MEDICAL CENTER	74 (11%)	69 (12%)	5 (5%)
CHILDREN'S DIAG AND TREAT CTR (S FLOR)	32 (5%)	28 (5%)	4 (4%)
BRONX/LEBANON HOSPITAL CENTER	44 (6%)	33 (6%)	11 (10%)
UNIVERSITY OF MIAMI	52 (8%)	45 (8%)	7 (6%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR)	41 (6%)	24 (4%)	17 (15%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE)	30 (4%)	27 (5%)	3 (3%)
UCSD MEDICAL CENTER	34 (5%)	26 (5%)	8 (7%)
JACOBI MEDICAL CENTER	69 (10%)	60 (10%)	9 (8%)
CHILDREN'S MEMORIAL HOSPITAL OF CHICAGO	70 (10%)	64 (11%)	6 (5%)

Protocol group	Studies	Infected (N=451)	Uninfected (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	PACTS HOPE	0 (0%)	11 (5%)
	LEGACY	46 (10%)	0 (0%)
	257	0(0%)	1 (0%)
	Total	46 (10%)	12 (5%)

Table 5: AMP - Enrollment by Previous Protocol Participation

Table 6: AMP Up - Enrollment by Previous Protocol Participation

Protocol group	Studies	Infected (N=576)	Uninfected (N=110)
No Previous Protocol	None	62 (11%)	0 (0%)
AMP Only	PH200	79 (14%)	35 (32%)
AMP + Other	PH200+P219/P219C	180 (31%)	15 (14%)
	PH200+P219/P219C+P1074	4 (1%)	0 (0%)
	PH200+P219/P219C+PH100	16 (3%)	40 (36%)
	PH200+PH100	7(1%)	20 (18%)
	Total	207 (36%)	75 (68%)
P219/P219C Only	P219/P219C	27 (5%)	0(0%)
P219/P219C + Other	P219/P219C+P1074	93 (16%)	0(0%)
	P219/P219C+P1074+PH100	25 (4%)	0 (0%)
	P219/P219C+PH100	26 (5%)	0 (0%)
	Total	144 (25%)	0(0%)
P1074 Only	P1074	27 (5%)	0(0%)
P1074 + Other	P1074+PH100	4 (1%)	0(0%)
PH100 Only	PH100	26 (5%)	0 (0%)

			Col		
		Total (N=678)	Infected (N=451)	Uninfected (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%)	

Table 7: AMP - Enrollment Demographics and Consent Information

			Cohort	
		Total (N=686)	Infected (N=576)	Uninfected (N=110)
Sex	Male	275 (40%)	223 (39%)	52 (47%)
	Female	411 (60%)	353 (61%)	58 (53%)
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	292 (43%)	203 (35%)	89 (81%)
	20-21	126 (18%)	110 (19%)	16 (15%)
	22-23	66 (10%)	63 (11%)	3 (3%)
	24-25	69 (10%)	67 (12%)	2 (2%)
	26-27	54 (8%)	54 (9%)	0 (0%)
	28 or Older	79 (12%)	79 (14%)	0 (0%)
Race	Asian	4 (1%)	1 (0%)	3 (3%)
	Native Hawaiian or other Pacific Islander	2 (0%)	2 (0%)	0 (0%)
	Black or African American	446 (65%)	380 (66%)	66 (60%)
	White	181 (26%)	144 (25%)	37 (34%)
	American Indian	4 (1%)	4 (1%)	0 (0%)
	More than One Race	16 (2%)	14 (2%)	2 (2%)
	Unknown	33 (5%)	31 (5%)	2 (2%)
Ethnicity	Hispanic or Latino	205 (30%)	167 (29%)	38 (35%)
	Not Hispanic or Latino	473 (69%)	404 (70%)	69 (63%)
	Unknown	8 (1%)	5 (1%)	3 (3%)
Permission to store specimen in repository	Yes	673 (99%)	563 (99%)	110 (100%)
	No	4 (1%)	4 (1%)	0 (0%)
	Unknown	9	9	0
Permission includes genetic studies	Yes	670 (99%)	562 (99%)	108 (98%)
	No	7 (1%)	5 (1%)	2 (2%)
	Unknown	9	9	0

Table 8: AMP Up - Enrollment Demographics and Consent Information

Table 9: AMP and AMP Up - Entry Visit Status

		Study and HIV Status			
		AMP Infected (N=451)	AMP Uninfected (N=227)	AMP Up Infected (N=576)	AMP Up Uninfected (N=110)
Entry visit status	•	()	226 (100%)	`` '	110 (100%)
	No visit reported	3 (1%)	1 (0%)	6 (1%)	0 (0%)

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Table 10: AMP and AMP Up - Study Status and AMP Up Enrollment

		Cohort		hort
		Total	Infected	Uninfected
AMP study status	Still on study	31 (5%)	10 (2%)	21 (9%)
	Completed study	491 (72%)	332 (74%)	159 (70%)
	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	490 (81%)	331 (80%)	159 (83%)
	Lost to follow-up	109 (18%)	80 (19%)	29 (15%)
	Still on study	4 (1%)	1 (0%)	3 (2%)
Ever AMP, age 18+, completed study	Enrolled in AMP Up	368 (75%)	259 (78%)	109 (69%)
	Not enrolled	122 (25%)	72 (22%)	50 (31%)
Ever AMP, age 18+, lost to follow-up	Enrolled in AMP Up	28 (26%)	27 (34%)	1 (3%)
	Not enrolled	81 (74%)	53 (66%)	28 (97%)
AMP Up study status	Still on study	660 (96%)	551 (96%)	109 (99%)
	Compl protocol: No follow-up required	1 (0%)	1 (0%)	0 (0%)
	Unexpctd closure of study: compld reqs	1 (0%)	1 (0%)	0 (0%)
	Death of subject	10 (1%)	10 (2%)	0 (0%)
	Subject incarcerated	7 (1%)	6 (1%)	1 (1%)
	Subject withdrew consent	4 (1%)	4 (1%)	0 (0%)
	PT/parent not willing to adhere to reqs	1 (0%)	1 (0%)	0 (0%)
	Site unable to contact participnt/parent	2 (0%)	2 (0%)	0 (0%)

	Study and HIV Status			
	AMP Infected (N=10)	AMP Uninfected (N=21)	AMP Up Infected (N=551)	AMP Up Uninfected (N=109)
Median	16.45	17.04	24.61	21.31
Q1, Q3	16.06, 17.45	16.48, 17.23	22.12, 27.66	19.99, 22.88
15-17	10 (100%)	21 (100%)	0 (0%)	0 (0%)
18-21	0 (0%)	0 (0%)	133 (24%)	65 (60%)
22-25	0 (0%)	0 (0%)	209 (38%)	41 (38%)
26-30	0 (0%)	0 (0%)	152 (28%)	3 (3%)
31-35	0 (0%)	0 (0%)	48 (9%)	0 (0%)
36-40	0 (0%)	0 (0%)	4 (1%)	0 (0%)
	Q1, Q3 15-17 18-21 22-25 26-30 31-35	Infected (N=10) Median 16.45 Q1, Q3 16.06, 17.45 15-17 10 (100%) 18-21 0 (0%) 22-25 0 (0%) 26-30 0 (0%) 31-35 0 (0%)	AMP Infected (N=10) AMP Uninfected (N=21) Median 16.45 17.04 Q1, Q3 16.06, 17.45 16.48, 17.23 15-17 10 (100%) 21 (100%) 18-21 0 (0%) 0 (0%) 22-25 0 (0%) 0 (0%) 26-30 0 (0%) 0 (0%) 31-35 0 (0%) 0 (0%)	AMP Infected (N=10)AMP Uninfected (N=21)AMP Up Infected (N=551)Median16.4517.0424.61Q1, Q316.06, 17.4516.48, 17.2322.12, 27.6615-1710 (100%)21 (100%)0 (0%)18-210 (0%)0 (0%)133 (24%)22-250 (0%)0 (0%)209 (38%)26-300 (0%)0 (0%)152 (28%)31-350 (0%)0 (0%)48 (9%)

Table 11: AMP and AMP Up - Age as of Last Visit of Participants Still on Study

Note: Age is based on the date of last scheduled visit or last contact.

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 Table 12: AMP and AMP Up - Clinical Characteristics as of Last Visit of HIV-Infected Participants

 Still on Study

		Stu	ıdy
		AMP (N=10)	AMP Up (N=551)
CDC Category	N/A/B	9 (90%)	400 (73%)
	С	1 (10%)	151 (27%)
CD4 (cells/mm ³)	Median	724	591.50
	0-250	0 (0%)	100 (19%)
	251-500	1 (10%)	110 (21%)
	501-750	5 (50%)	165 (31%)
	751-1000	4 (40%)	91 (17%)
	1001+	0 (0%)	66 (12%)
CD4 Percent	Median	39	30
	< 15%	0 (0%)	86 (16%)
	15-25%	0 (0%)	110 (21%
	25% or more	10 (100%)	334 (63%
HIV-1 RNA (copies/mL)	Median	400	400
	0-400	9 (90%)	383 (72%
	401-5000	1 (10%)	51 (10%)
	5001-50000	0 (0%)	73 (14%)
	50001+	0 (0%)	28 (5%)
ARV regimen	cART with INSTI/EI/FI	5 (50%)	320 (58%
	cART with PI	3 (30%)	70 (13%)
	cART with NNRTI	1 (10%)	68 (12%)
	Other ARV	1 (10%)	46 (8%)
	No ARV	0 (0%)	30 (5%)
	Missing ARV information	0 (0%)	17 (3%)

Note: 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.

Note: ARV data for some AMP Up participants who were not enrolled in AMP are not yet included. ARV regimen categories are hierarchical.

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Class Drug	Label	Ν	Percent
NRTI ftc	FTC/Coviracil	7	70
NRTI taf	Tenofovir Alafenamide (TAF)	6	60
NRTI _3tc	3tc/Epivir/Lamivudine	3	30
NRTI zdv	ZDV/AZT	2	20
NRTI abc	Abacavir	1	10
NRTI tdf	Tenofovir/TDF	1	10
NNRTI rpv	Rilpivirine/TMC-278	1	10
PI atv	Atazanavir/ATV	4	40
PI rtvboost	Ritonavir/Norvir/RTV (Boost)	4	40
PI kal	Kaletra	2	20
INSTI dtg	Dolutegravir/GSK-1349572	3	30
INSTI evg	Elvitegravir/GS-9137	3	30
cobi	Cobicistat	5	50

Table 13: AMP - Individual ARV Drugs at Last Clinical Visit for Children Still On Study

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Table 14: AMP Up - Individual ARV Drugs at Entry

Class Drug	Label	NI	Percent
NRTI ftc	FTC/Coviracil	321	58.7
NRTI tdf	Tenofovir/TDF	254	46.4
NRTI _3tc	3tc/Epivir/Lamivudine	121	22.1
NRTI abc	Abacavir	88	16.1
NRTI taf	Tenofovir Alafenamide (TAF)	86	15.7
NRTI zdv	ZDV/AZT	43	7.9
NRTI d4t	Stavudine/d4T	26	4.8
NRTI ddi	Didanosine/Videx/DDI	26	4.8
NNRTI rpv	Rilpivirine/TMC-278	96	17.6
NNRTI etr	Etravirine/TMC-125	43	7.9
NNRTI efv	Efavirenz/Sustiva/DMP-266	39	7.1
NNRTI nvp	Nevirapine/Viramune/NVP	7	1.3
PI rtvboos	t Ritonavir/Norvir/RTV (Boost)	208	38.0
PI drv	Prezista/Darunavir/TMC-114	163	29.8
PI atv	Atazanavir/ATV	67	12.2
PI kal	Kaletra	40	7.3
PI nfv	Nelfinavir/Viracept/NFV	16	2.9
PI sqv	Saquinavir/Invirase/Fortovase/SQV	5	0.9
PI fpv	Fosamprenavir	2	0.4
PI tpv	Tipranavir	2	0.4
FI/EI mvc	Maraviroc	12	2.2
FI/EI enf	T-20/Pentafuside/Enfuvirtide/ENF	4	0.7
INSTI dtg	Dolutegravir/GSK-1349572	123	22.5
INSTI ral	Raltegravir/Isentress	72	13.2
INSTI evg	Elvitegravir/GS-9137	64	11.7
INSTI bic	Bictegravir	5	0.9
BOOSTER cobi	Cobicistat	103	18.8

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Class Drug	Label	NI	Percent
NRTI ftc	FTC/Coviracil	332	60.3
NRTI taf	Tenofovir Alafenamide (TAF)	240	43.6
NRTI tdf	Tenofovir/TDF	112	20.3
NRTI _3tc	3tc/Epivir/Lamivudine	105	19.1
NRTI abc	Abacavir	88	16.0
NRTI zdv	ZDV/AZT	24	4.4
NRTI d4t	Stavudine/d4T	19	3.4
NRTI ddi	Didanosine/Videx/DDI	17	3.1
NNRTI rpv	Rilpivirine/TMC-278	99	18.0
NNRTI etr	Etravirine/TMC-125	32	5.8
NNRTI efv	Efavirenz/Sustiva/DMP-266	16	2.9
NNRTI nvp	Nevirapine/Viramune/NVP	3	0.5
PI drv	Prezista/Darunavir/TMC-114	164	29.8
PI rtvboost	Ritonavir/Norvir/RTV (Boost)	119	21.6
PI atv	Atazanavir/ATV	41	7.4
PI kal	Kaletra	22	4.0
PI nfv	Nelfinavir/Viracept/NFV	8	1.5
PI sqv	Saquinavir/Invirase/Fortovase/SQV	4	0.7
PI fpv	Fosamprenavir	2	0.4
FI/EI mvc	Maraviroc	12	2.2
FI/EI enf	T-20/Pentafuside/Enfuvirtide/ENF	1	0.2
INSTI dtg	Dolutegravir/GSK-1349572	168	30.5
INSTI evg	Elvitegravir/GS-9137	103	18.7
INSTI ral	Raltegravir/Isentress	51	9.3
INSTI bic	Bictegravir	28	5.1
BOOSTER cobi	Cobicistat	173	31.4

Table 15: AMP Up - Individual ARV Drugs at Last Clinical Visit for Participants Still On Study

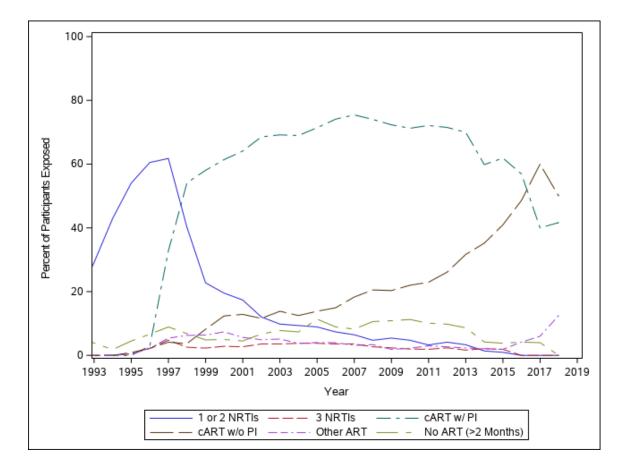
Created by: /home/phacs/actgPH300/monitoring/det/progs/current_arv.sas on July 31, 2019

 Table 16: AMP - Lifetime Exposure to ARV Drug Classes and Individual Drugs, From Reported Regimens

Class/Drug		Total (N=448)
Any NRTI	1	446 (100%)
Tenofovir/TDF	1	272 (61%)
FTC/Coviracil	1	255 (57%)
3tc/Epivir/Lamivudine	1	418 (93%)
Abacavir	1	228 (51%)
ZDV/AZT	1	381 (85%)
Didanosine/Videx/DDI	1	306 (68%)
Stavudine/d4T	1	344 (77%)
Zalcitabine/DDC	1	16 (4%)
Tenofovir Alafenamide	1	30 (7%)
Any NNRTI	1	336 (75%)
Efavirenz/Sustiva/DMP-266	1	206 (46%)
Etravirine/TMG-125	1	34 (8%)
Nevirapine/Viramune/NVP	1	158 (35%)
Delavirdine/DLV	1	2 (0%)
Rilpivirine/TMC-278	1	50 (11%)
Any PI	1	408 (91%)
Ritonavir/Norvir/RTV (Only)	1	140 (31%)
Ritonavir/Norvir/RTV (Boost)	1	337 (75%)
Kaletra	1	255 (57%)
Atazanavir/ATV	1	142 (32%)
Prezista/Darunavir/TMC-114	1	99 (22%)
Nelfinavir/Viracept/NFV	1	266 (59%)
Saquinavir/Invirase/Fortavase/SQV	1	50 (11%)
Amprenavir/APV	1	31 (7%)
Tipranavir	1	13 (3%)
Fosamprenavir	1	15 (3%)
Indinavir/Crixivan/IDV	1	28 (6%)
Any FI/EI	1	25 (6%)
Maraviroc	1	12 (3%)
T-20/Pentafuside/Enfuvirtide/ENF	1	13 (3%)
Any INSTI	1	131 (29%)
Raltegravir/Isentress	1	88 (20%)
Dolutegravir/GSK-1349572	1	33 (7%)
Elvitegravir/GS-9137	1	25 (6%)
Bictegravir	1	1 (0%)

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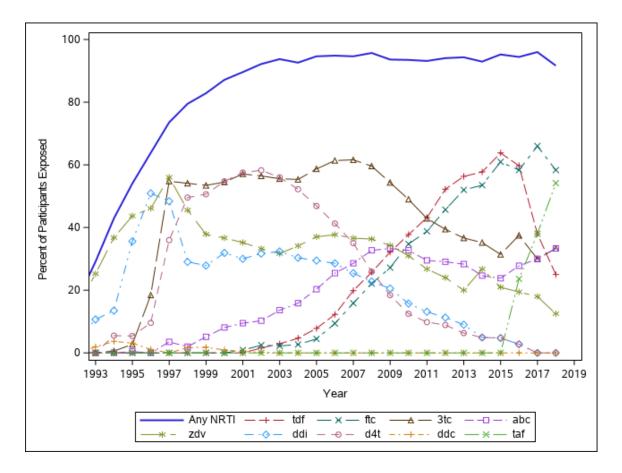
Figure 1: AMP - ARV Trends Over Time



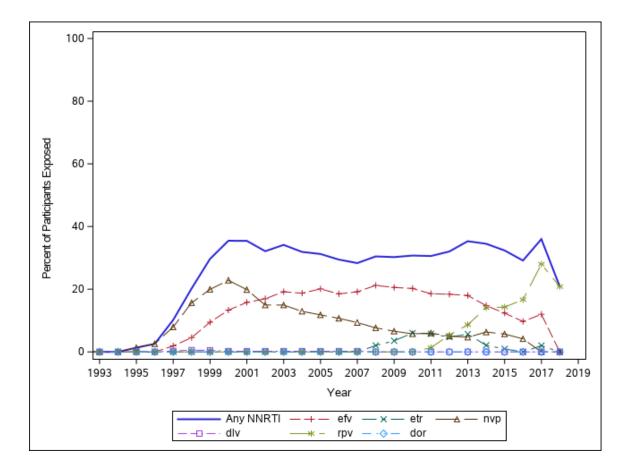
Note: No ART indicates a drug holiday of >56 days.

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Figure 2: AMP - NRTI Use, 1993 - 2018

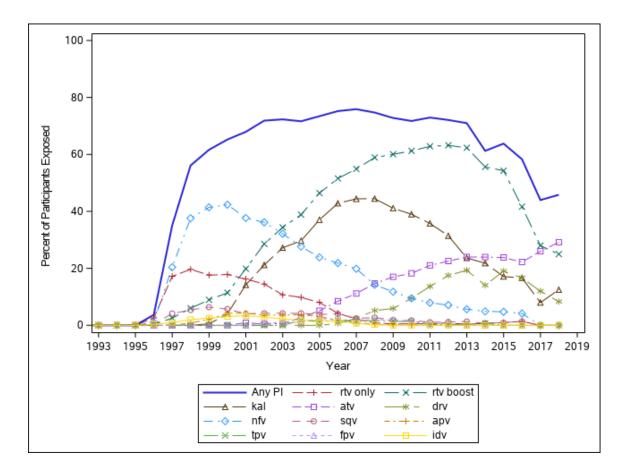


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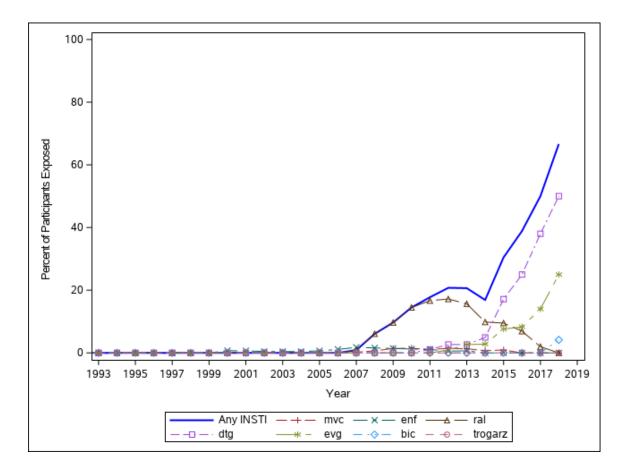
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Figure 4: AMP - PI Use, 1993 - 2018



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Figure 5: AMP - FI/EI and INSTI Use, 1993 - 2018



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