

OPEN REPORT

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.

1.2 Demographic Characteristics

Demographic characteristics of the participants in AMP and AMP Up are summarized in **Table 7** and **Table 8**, respectively. Consent information for AMP participants is also shown in **Table 7**.

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, 413 of 417 (99%) HIV+ and 75 of 75 (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=474), 384 (81%) completed the study, 80 (17%) were lost to follow-up, and 10 (2%) were still on study. Of the 18+ that completed the study, 282 (73%) have already enrolled in AMP Up. Of the 18+ lost to follow-up, 18 (23%) 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 participants still on study, with combination drugs broken into their individual components. **Table 14** shows the frequencies of lifetime exposure 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 2016. 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 6.49 years among HIV+ and 7.29 years among HEU participants. In AMP Up the median duration of follow-up was 1.49 years among HIV+ and 1.95 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

Table 1: AMP - Study Enrollment by Cohort and Quarter

		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%)

Note: 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	
		Infected (N=417)	Uninfected (N=75)
Enrollment quarter	2014 Q2	22 (5%)	3 (4%)
	2014 Q3	48 (12%)	13 (17%)
	2014 Q4	52 (12%)	11 (15%)
	2015 Q1	20 (5%)	4 (5%)
	2015 Q2	20 (5%)	12 (16%)
	2015 Q3	37 (9%)	5 (7%)
	2015 Q4	32 (8%)	6 (8%)
	2016 Q1	29 (7%)	8 (11%)
	2016 Q2	44 (11%)	4 (5%)
	2016 Q3	24 (6%)	4 (5%)
	2016 Q4	49 (12%)	4 (5%)
	2017 Q1	40 (10%)	1 (1%)

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Table 3: AMP - Study Enrollment by Site

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

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Table 4: AMP Up - Study Enrollment by Site

Enrollment site	Cohort		
	Total (N=492)	Infected (N=417)	Uninfected (N=75)
BOSTON CHILDREN'S HOSPITAL	26 (5%)	26 (6%)	0 (0%)
ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN	27 (5%)	20 (5%)	7 (9%)
SAN JUAN RESEARCH HOSPITAL	55 (11%)	43 (10%)	12 (16%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL	40 (8%)	34 (8%)	6 (8%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	27 (5%)	20 (5%)	7 (9%)
NEW JERSEY MEDICAL CENTER	60 (12%)	56 (13%)	4 (5%)
CHILDREN'S DIAG AND TREAT CTR (S FLOR)	11 (2%)	10 (2%)	1 (1%)
BRONX/LEBANON HOSPITAL CENTER	32 (7%)	27 (6%)	5 (7%)
UNIVERSITY OF MIAMI	37 (8%)	33 (8%)	4 (5%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR)	23 (5%)	12 (3%)	11 (15%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE)	23 (5%)	20 (5%)	3 (4%)
UCSD MEDICAL CENTER	27 (5%)	21 (5%)	6 (8%)
JACOBI MEDICAL CENTER	50 (10%)	43 (10%)	7 (9%)
CHILDREN'S MEMORIAL HOSPITAL OF CHICAGO	54 (11%)	52 (12%)	2 (3%)

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Table 5: AMP - Enrollment by Previous Protocol Participation

Protocol group	Studies	Infected	Uninfected
		(N=451)	(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%)

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Table 6: AMP Up - Enrollment by Previous Protocol Participation

		Cohort		
		Total (N=492)	Infected (N=417)	Uninfected (N=75)
Enrollment From AMP	No	192 (39%)	192 (46%)	0 (0%)
	Yes	300 (61%)	225 (54%)	75 (100%)

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Table 7: AMP - Enrollment Demographics and Consent Information

		Cohort		
		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%)
	Subject does not want to report	17 (3%)	15 (3%)	2 (1%)
	Subject does not know	8 (1%)	6 (1%)	2 (1%)
	Race not available to clinic	4 (1%)	2 (0%)	2 (1%)
Ethnicity	Hispanic or Latino	188 (28%)	109 (24%)	79 (35%)
	Not Hispanic or Latino	485 (72%)	341 (76%)	144 (63%)
	More than one ethnicity	1 (0%)	0 (0%)	1 (0%)
	Subject 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%)

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Table 8: AMP Up - Enrollment Demographics

		Cohort		
		Total (N=492)	Infected (N=417)	Uninfected (N=75)
Sex	Male	201 (41%)	170 (41%)	31 (41%)
	Female	291 (59%)	247 (59%)	44 (59%)
Age at enrollment (yrs)	Median (Q1, Q3)	20 (18, 24)	21 (19, 25)	18 (18, 19)
	Min, Max	18, 39	18, 39	18, 23
	18-19	191 (39%)	134 (32%)	57 (76%)
	20-21	110 (22%)	95 (23%)	15 (20%)
	22-23	51 (10%)	48 (12%)	3 (4%)
	24-25	51 (10%)	51 (12%)	0 (0%)
	26-27	41 (8%)	41 (10%)	0 (0%)
	28 or Older	48 (10%)	48 (12%)	0 (0%)
Race	Asian	2 (0%)	1 (0%)	1 (1%)
	Native Hawaiian or other Pacific Islander	1 (0%)	1 (0%)	0 (0%)
	Black or African American	318 (65%)	273 (65%)	45 (60%)
	White	133 (27%)	106 (25%)	27 (36%)
	American Indian	4 (1%)	4 (1%)	0 (0%)
	More than One Race	11 (2%)	9 (2%)	2 (3%)
	Unknown	23 (5%)	23 (6%)	0 (0%)
Ethnicity	Hispanic or Latino	154 (31%)	126 (30%)	28 (37%)
	Not Hispanic or Latino	333 (68%)	287 (69%)	46 (61%)
	Unknown	5 (1%)	4 (1%)	1 (1%)

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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=417)	AMP Up Uninfected (N=75)
Entry visit status	Visit reported	448 (99%)	226 (100%)	413 (99%)	75 (100%)
	No visit reported	3 (1%)	1 (0%)	4 (1%)	0 (0%)

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

		Total	Cohort	
			Infected	Uninfected
AMP study status	Still on study	150 (22%)	70 (16%)	80 (35%)
	Completed study	384 (57%)	275 (61%)	109 (48%)
	Enrollment error / eligibility failure	1 (0%)	0 (0%)	1 (0%)
	Death of subject/parent/guardian	5 (1%)	5 (1%)	0 (0%)
	Withdrawal / loss to follow-up	111 (16%)	81 (18%)	30 (13%)
	Site closure	25 (4%)	18 (4%)	7 (3%)
	Other reason	2 (0%)	2 (0%)	0 (0%)
Ever AMP, age 18+	Completed study	384 (81%)	275 (79%)	109 (87%)
	Lost to follow-up	80 (17%)	65 (19%)	15 (12%)
	Still on study	10 (2%)	8 (2%)	2 (2%)
Ever AMP, age 18+, completed study	Enrolled in AMP Up	282 (73%)	208 (76%)	74 (68%)
	Not enrolled	102 (27%)	67 (24%)	35 (32%)
Ever AMP, age 18+, lost to follow-up	Enrolled in AMP Up	18 (23%)	17 (26%)	1 (7%)
	Not enrolled	62 (78%)	48 (74%)	14 (93%)
AMP Up study status	Still on study	485 (99%)	410 (98%)	75 (100%)
	Death of subject	5 (1%)	5 (1%)	0 (0%)
	Subject incarcerated	1 (0%)	1 (0%)	0 (0%)
	Subject withdrew consent	1 (0%)	1 (0%)	0 (0%)

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

		Study and HIV Status			
		AMP Infected (N=70)	AMP Uninfected (N=80)	AMP Up Infected (N=410)	AMP Up Uninfected (N=75)
Age (years)	Median	16.32	15.79	22.85	19.87
	Q1, Q3	15.35, 17.01	15.02, 16.41	20.75, 25.58	19.07, 21.64
	13	2 (3%)	0 (0%)	0 (0%)	0 (0%)
	14	12 (17%)	19 (24%)	0 (0%)	0 (0%)
	15	18 (26%)	28 (35%)	0 (0%)	0 (0%)
	16	20 (29%)	23 (29%)	0 (0%)	0 (0%)
	17	18 (26%)	10 (13%)	0 (0%)	0 (0%)
	18	0 (0%)	0 (0%)	29 (7%)	16 (21%)
	19	0 (0%)	0 (0%)	38 (9%)	24 (32%)
	20	0 (0%)	0 (0%)	42 (10%)	11 (15%)
	21	0 (0%)	0 (0%)	42 (10%)	8 (11%)
	22	0 (0%)	0 (0%)	58 (14%)	7 (9%)
	23	0 (0%)	0 (0%)	43 (11%)	7 (9%)
	24	0 (0%)	0 (0%)	33 (8%)	2 (3%)
	25	0 (0%)	0 (0%)	30 (7%)	0 (0%)
	26	0 (0%)	0 (0%)	25 (6%)	0 (0%)
	27	0 (0%)	0 (0%)	17 (4%)	0 (0%)
	28	0 (0%)	0 (0%)	10 (2%)	0 (0%)
	29	0 (0%)	0 (0%)	15 (4%)	0 (0%)
	30	0 (0%)	0 (0%)	9 (2%)	0 (0%)
	31	0 (0%)	0 (0%)	6 (1%)	0 (0%)
	32	0 (0%)	0 (0%)	3 (1%)	0 (0%)
	33	0 (0%)	0 (0%)	3 (1%)	0 (0%)
	35	0 (0%)	0 (0%)	2 (0%)	0 (0%)
	39	0 (0%)	0 (0%)	1 (0%)	0 (0%)

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

		Study	
		AMP (N=70)	AMP Up (N=410)
CDC Category	N/A/B	60 (86%)	302 (74%)
	C	10 (14%)	108 (26%)
CD4 (cells/mm ³)	Median	749.50	547
	0-250	2 (3%)	61 (15%)
	251-500	16 (23%)	119 (30%)
	501-750	17 (24%)	107 (27%)
	751-1000	23 (33%)	68 (17%)
	1001+	12 (17%)	42 (11%)
CD4 Percent	Median	38	29
	< 15%	1 (1%)	57 (14%)
	15-25%	5 (7%)	101 (25%)
	25% or more	64 (91%)	239 (60%)
HIV-1 RNA (copies/mL)	Median	400	400
	0-400	57 (81%)	256 (64%)
	401-5000	8 (11%)	56 (14%)
	5001-50000	3 (4%)	67 (17%)
	50001+	2 (3%)	18 (5%)
ARV regimen	cART with PI	34 (49%)	167 (41%)
	cART without PI	32 (46%)	157 (38%)
	Other ARV	4 (6%)	45 (11%)
	No ARV	0 (0%)	27 (7%)
	Missing	0 (0%)	14 (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.

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

Class Drug	Label	N	Percent
NRTI tdf	Tenofovir/TDF	37	52.9
NRTI ftc	FTC/Coviracil	36	51.4
NRTI _3tc	3tc/Efavir/Lamivudine	26	37.1
NRTI abc	Abacavir	19	27.1
NRTI zdv	ZDV/AZT	18	25.7
NRTI d4t	Stavudine/d4T	1	1.4
NRTI ddi	Didanosine/Videx/DDI	1	1.4
NRTI ddc	Zalcitabine/DDC	0	0.0
NNRTI rpv	Rilpivirine/TMC-278	11	15.7
NNRTI efv	Efavirenz/Sustiva/DMP-266	7	10.0
NNRTI dlv	Delavirdine/DLV	0	0.0
NNRTI etr	Etravirine/TMC-125	0	0.0
NNRTI nvp	Nevirapine/Viramune/NVP	0	0.0
PI rtvboost	Ritonavir/Norvir/RTV (Boost)	28	40.0
PI atv	Atazanavir/ATV	17	24.3
PI kal	Kaletra	9	12.9
PI drv	Prezista/Darunavir/TMC-114	7	10.0
PI nfv	Nelfinavir/Viracept/NFV	2	2.9
PI sqv	Saquinavir/Invirase/Fortovase/SQV	1	1.4
PI apv	Amprenavir/APV	0	0.0
PI fpv	Fosamprenavir	0	0.0
PI idv	Indinavir/Crixivan/IDV	0	0.0
PI justrtv	Ritonavir/Norvir/RTV (Only)	0	0.0
PI tpv	Tipranavir	0	0.0
FI/EI enf	T-20/Pentafuside/Enfuvirtide/ENF	0	0.0
FI/EI mvc	Maraviroc	0	0.0
II dtg	Dolutegravir/GSK-1349572	13	18.6
II ral	Raltegravir/Isentress	7	10.0
II evg	Elvitegravir/GS-9137	2	2.9

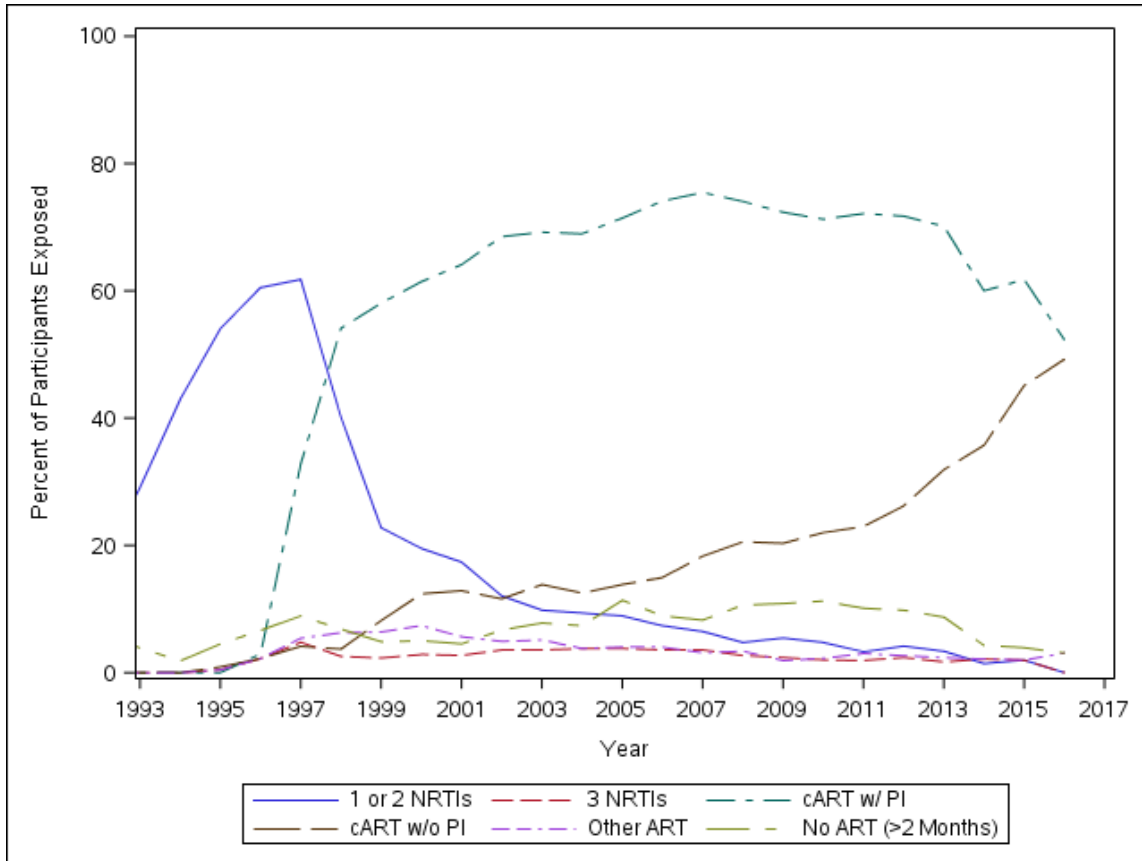
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Table 14: AMP - Lifetime Exposure to ARV Drug Classes and Individual Drugs, From Reported Regimens

Class/Drug	Total (N=448)
Any NRTI	446 (100%)
Tenofovir/TDF	270 (60%)
FTC/Coviracil	248 (55%)
3tc/Epivir/Lamivudine	418 (93%)
Abacavir	226 (50%)
ZDV/AZT	381 (85%)
Didanosine/Videx/DDI	306 (68%)
Stavudine/d4T	344 (77%)
Zalcitabine/DDC	16 (4%)
Any NNRTI	334 (75%)
Efavirenz/Sustiva/DMP-266	205 (46%)
Etravirine/TMG-125	33 (7%)
Nevirapine/Viramune/NVP	158 (35%)
Delavirdine/DLV	2 (0%)
Rilpivirine/TMC-278	47 (10%)
Any PI	408 (91%)
Ritonavir/Norvir/RTV (Only)	140 (31%)
Ritonavir/Norvir/RTV (Boost)	337 (75%)
Kaletra	255 (57%)
Atazanavir/ATV	142 (32%)
Prezista/Darunavir/TMC-114	95 (21%)
Nelfinavir/Viracept/NFV	266 (59%)
Saquinavir/Invirase/Fortavase/SQV	50 (11%)
Amprenavir/APV	31 (7%)
Tipranavir	13 (3%)
Fosamprenavir	15 (3%)
Indinavir/Crixivan/IDV	28 (6%)
Any FI/EI	25 (6%)
Maraviroc	12 (3%)
T-20/Pentafuside/Enfuvirtide/ENF	13 (3%)
Any II	120 (27%)
Raltegravir/Isentress	87 (19%)
Dolutegravir/GSK-1349572	25 (6%)
Elvitegravir/GS-9137	16 (4%)

Created by: /home/phacs/actgPH200/monitoring/detlprogs/arv_figures.sas on April 19, 2017

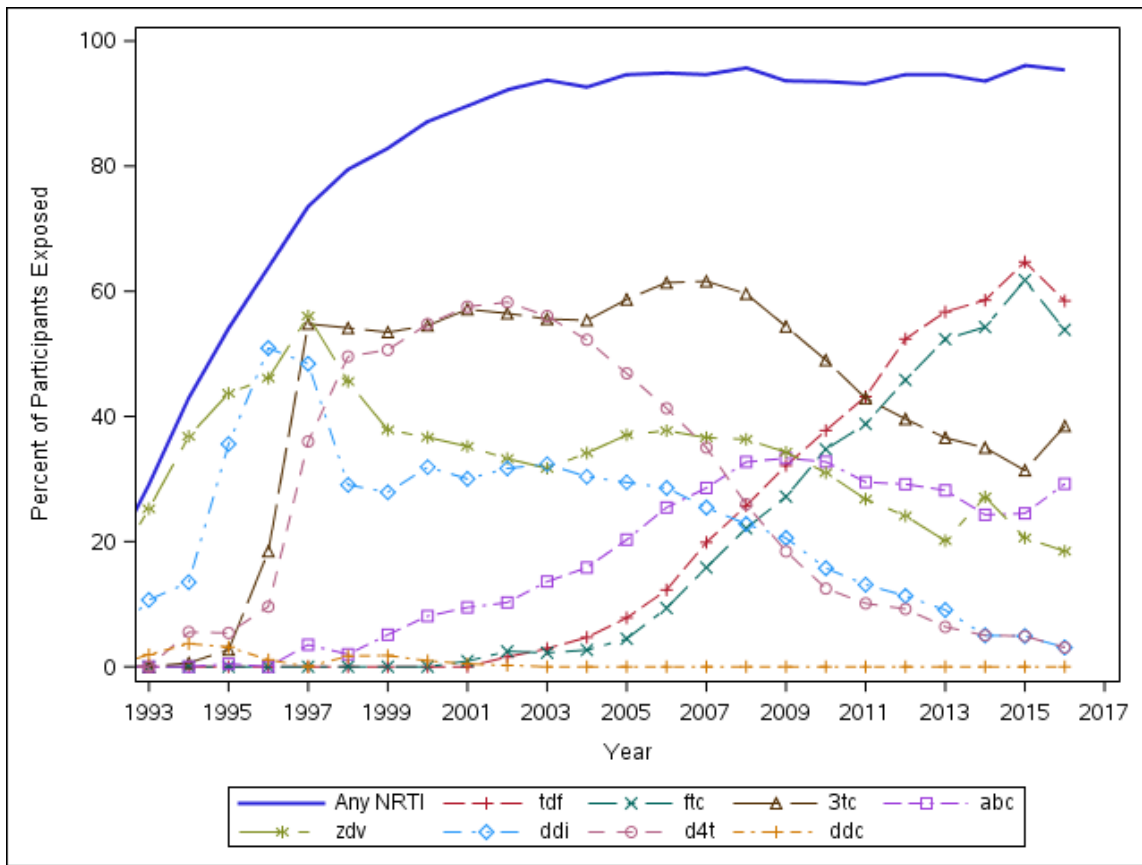
Figure 1: AMP - ARV Trends Over Time



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

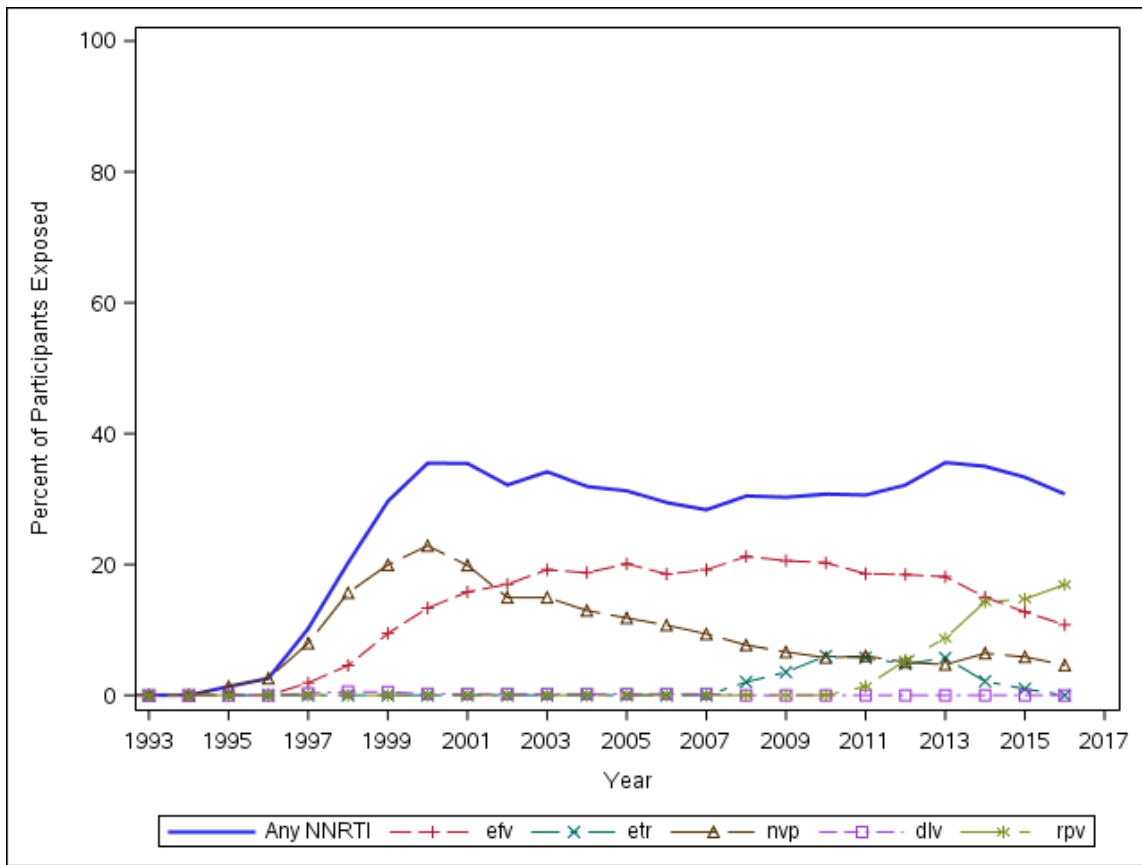
Created by: /home/phacs/actgPH200/monitoring/det/progs/arv_figures.sas on April 19, 2017

Figure 2: AMP - NRTI Use, 1993 - 2016



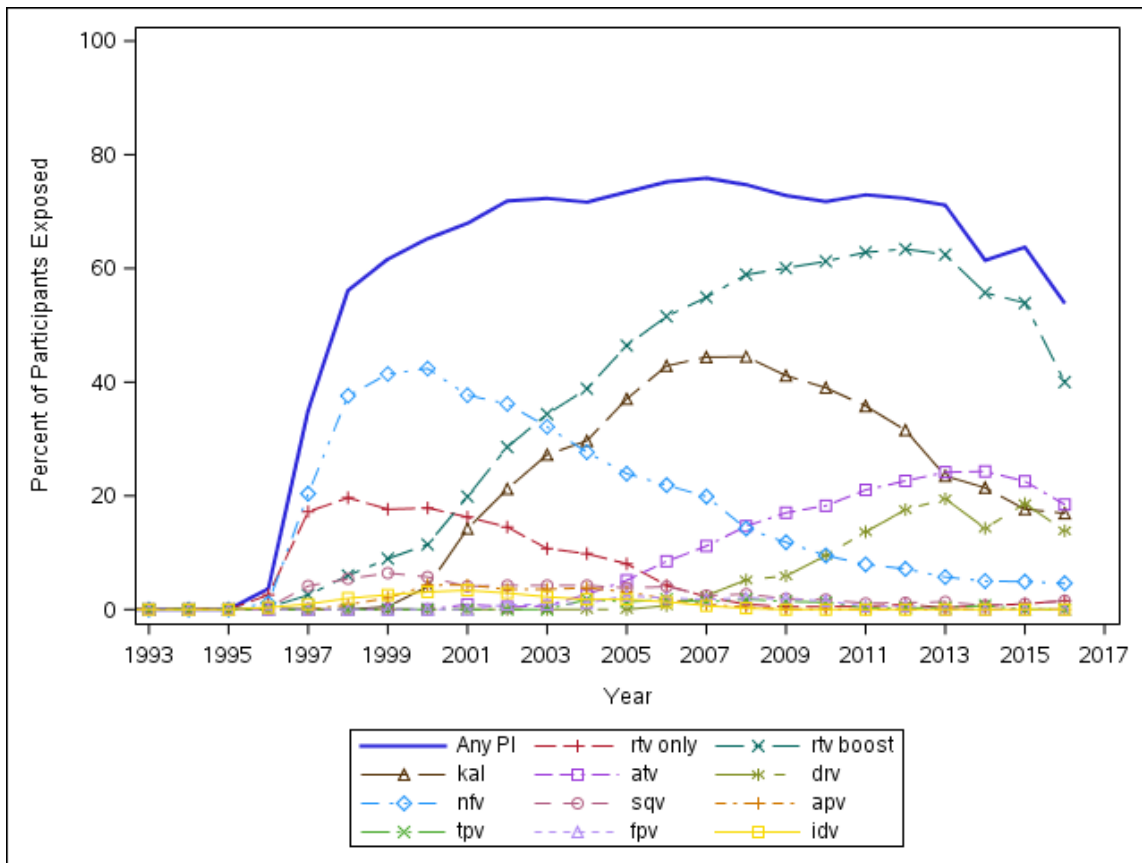
Created by: /home/phacs/actgPH200/monitoring/det/progs/arv_figures.sas on April 19, 2017

Figure 3: AMP - NNRTI Use, 1993 - 2016



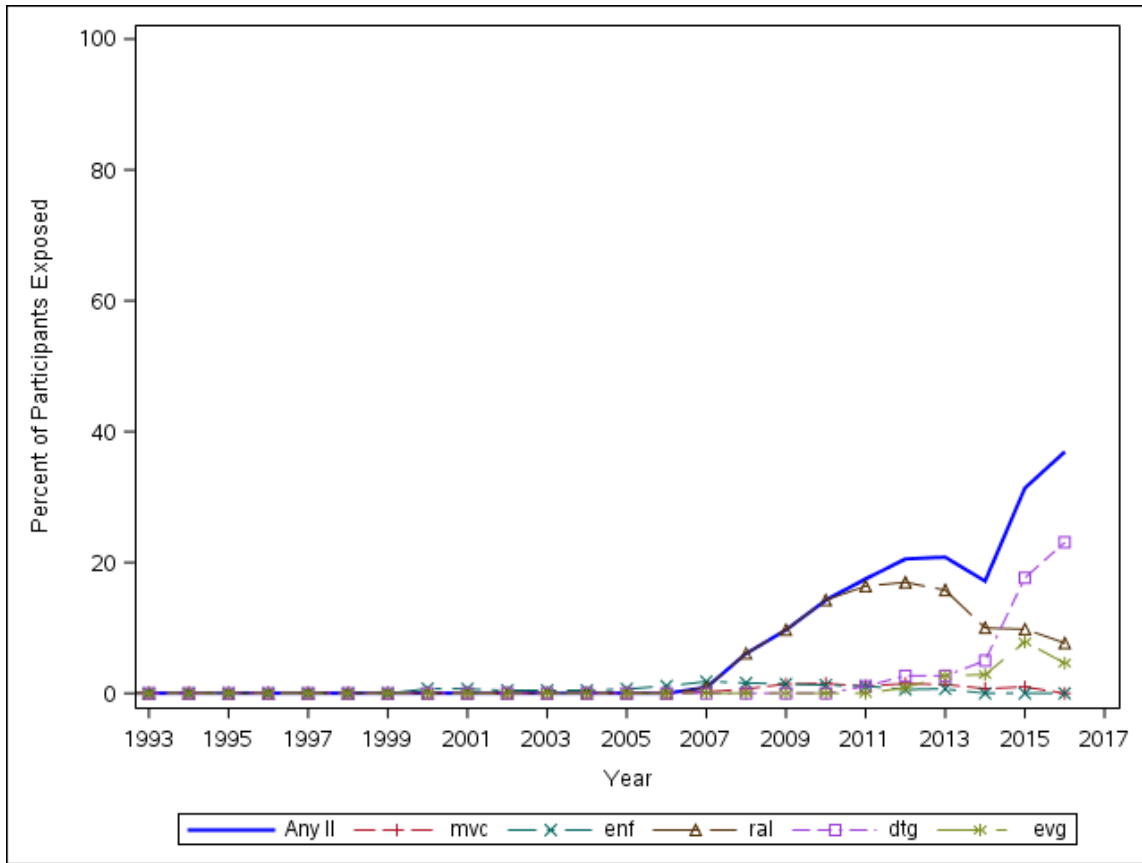
Created by: /home/phacs/actgPH200/monitoring/det/progs/arv_figures.sas on April 19, 2017

Figure 4: AMP - PI Use, 1993 - 2016



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Figure 5: AMP - FI/EI and II Use, 1993 - 2016



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