

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 AMP and AMP Up 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**, and will be added for AMP Up participants in future reports.

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, 265 of 268 (99%) HIV+ and 63 of 64 (98%) 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=405), 333 (82%) completed the study and 64 (16%) were lost to follow-up. Of the 18+ that completed the study, 248 (74%) have already enrolled in AMP Up. Of the 18+ lost to follow-up, 14 (22%) 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 2015. 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 Retention and Follow-Up in the AMP Study

The median duration of follow-up in AMP was 78 months among HIV+ and 81 months among HEU participants. 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=587)	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	27 (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=268)	Uninfected (N=64)
Enrollment quarter	2014 Q2	22 (8%)	3 (5%)
	2014 Q3	48 (18%)	13 (20%)
	2014 Q4	52 (19%)	11 (17%)
	2015 Q1	20 (7%)	4 (6%)
	2015 Q2	20 (7%)	12 (19%)
	2015 Q3	37 (14%)	5 (8%)
	2015 Q4	32 (12%)	6 (9%)
	2016 Q1	29 (11%)	8 (13%)
	2016 Q2	8 (3%)	2 (3%)

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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=332)	Infected (N=268)	Uninfected (N=64)
BOSTON CHILDREN'S HOSPITAL	17 (5%)	17 (6%)	0 (0%)
ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN	22 (7%)	15 (6%)	7 (11%)
SAN JUAN RESEARCH HOSPITAL	37 (11%)	25 (9%)	12 (19%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL	23 (7%)	18 (7%)	5 (8%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	22 (7%)	15 (6%)	7 (11%)
NEW JERSEY MEDICAL CENTER	47 (14%)	45 (17%)	2 (3%)
CHILDREN'S DIAG AND TREAT CTR (S FLOR)	6 (2%)	5 (2%)	1 (2%)
BRONX/LEBANON HOSPITAL CENTER	15 (5%)	11 (4%)	4 (6%)
UNIVERSITY OF MIAMI	20 (6%)	18 (7%)	2 (3%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR)	14 (4%)	4 (1%)	10 (16%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE)	18 (5%)	15 (6%)	3 (5%)
UCSD MEDICAL CENTER	15 (5%)	11 (4%)	4 (6%)
JACOBI MEDICAL CENTER	32 (10%)	26 (10%)	6 (9%)
CHILDREN'S MEMORIAL HOSPITAL OF CHICAGO	44 (13%)	43 (16%)	1 (2%)

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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=332)	Infected (N=268)	Uninfected (N=64)
Enrollment From AMP	No	69 (21%)	69 (26%)	0 (0%)
	Yes	263 (79%)	199 (74%)	64 (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=332)	Infected (N=268)	Uninfected (N=64)
Sex	Male	139 (42%)	115 (43%)	24 (38%)
	Female	193 (58%)	153 (57%)	40 (63%)
Age at enrollment (yrs)	Median (Q1, Q3)	20 (18, 22)	20 (19, 23)	18 (18, 20)
	Min, Max	18, 33	18, 33	18, 23
	18-19	151 (45%)	105 (39%)	46 (72%)
	20-21	97 (29%)	82 (31%)	15 (23%)
	22-23	32 (10%)	29 (11%)	3 (5%)
	24-25	21 (6%)	21 (8%)	0 (0%)
	26-27	14 (4%)	14 (5%)	0 (0%)
	28 or Older	17 (5%)	17 (6%)	0 (0%)
	Race	Asian	1 (0%)	0 (0%)
Native Hawaiian or other Pacific Islander		1 (0%)	1 (0%)	0 (0%)
Black or African American		217 (65%)	181 (68%)	36 (56%)
White		87 (26%)	62 (23%)	25 (39%)
American Indian		2 (1%)	2 (1%)	0 (0%)
More than One Race		7 (2%)	5 (2%)	2 (3%)
Unknown		17 (5%)	17 (6%)	0 (0%)
Ethnicity	Hispanic or Latino	101 (30%)	76 (28%)	25 (39%)
	Not Hispanic or Latino	228 (69%)	190 (71%)	38 (59%)
	Unknown	3 (1%)	2 (1%)	1 (2%)

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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=268)	AMP Up Uninfected (N=64)
Entry visit status	Visit reported	448 (99%)	226 (100%)	265 (99%)	63 (98%)
	No visit reported	3 (1%)	1 (0%)	3 (1%)	1 (2%)

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

		Cohort		
		Total	Infected	Uninfected
AMP study status	Still on study	207 (31%)	96 (21%)	111 (49%)
	Completed study	333 (49%)	251 (56%)	82 (36%)
	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	105 (15%)	79 (18%)	26 (11%)
	Site closure	25 (4%)	18 (4%)	7 (3%)
	Other reason	2 (0%)	2 (0%)	0 (0%)
Ever AMP, age 18+	Completed study	333 (82%)	251 (81%)	82 (85%)
	Lost to follow-up	64 (16%)	53 (17%)	11 (11%)
	Still on study	8 (2%)	4 (1%)	4 (4%)
Ever AMP, age 18+, completed study	Enrolled in AMP Up	248 (74%)	186 (74%)	62 (76%)
	Not enrolled	85 (26%)	65 (26%)	20 (24%)
Ever AMP, age 18+, lost to follow-up	Enrolled in AMP Up	14 (22%)	13 (25%)	1 (9%)
	Not enrolled	50 (78%)	40 (75%)	10 (91%)
AMP Up study status	Still on study	329 (99%)	265 (99%)	64 (100%)
	Death of subject	2 (1%)	2 (1%)	0 (0%)
	Subject withdrw consent prior std co	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=96)	AMP Uninfected (N=111)	AMP Up Infected (N=265)	AMP Up Uninfected (N=64)
Age (years)	Median	15.92	15.35	21.47	19.17
	Q1, Q3	14.63, 16.73	14.25, 16.46	19.73, 23.37	18.35, 20.94
	12	3 (3%)	1 (1%)	0 (0%)	0 (0%)
	13	9 (9%)	14 (13%)	0 (0%)	0 (0%)
	14	16 (17%)	31 (28%)	0 (0%)	0 (0%)
	15	23 (24%)	27 (24%)	0 (0%)	0 (0%)
	16	30 (31%)	24 (22%)	0 (0%)	0 (0%)
	17	15 (16%)	14 (13%)	1 (0%)	0 (0%)
	18	0 (0%)	0 (0%)	34 (13%)	28 (44%)
	19	0 (0%)	0 (0%)	39 (15%)	11 (17%)
	20	0 (0%)	0 (0%)	36 (14%)	9 (14%)
	21	0 (0%)	0 (0%)	47 (18%)	7 (11%)
	22	0 (0%)	0 (0%)	30 (11%)	6 (10%)
	23	0 (0%)	0 (0%)	22 (8%)	2 (3%)
	24	0 (0%)	0 (0%)	18 (7%)	0 (0%)
	25	0 (0%)	0 (0%)	4 (2%)	0 (0%)
	26	0 (0%)	0 (0%)	13 (5%)	0 (0%)
	27	0 (0%)	0 (0%)	1 (0%)	0 (0%)
	28	0 (0%)	0 (0%)	4 (2%)	0 (0%)
	29	0 (0%)	0 (0%)	5 (2%)	0 (0%)
	30	0 (0%)	0 (0%)	5 (2%)	0 (0%)
	32	0 (0%)	0 (0%)	2 (1%)	0 (0%)
	33	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=96)	AMP Up (N=265)
CDC Category	N/A/B	81 (84%)	191 (72%)
	C	15 (16%)	74 (28%)
CD4 (cells/mm ³)	Median	693	586
	0-250	2 (2%)	32 (13%)
	251-500	21 (22%)	66 (27%)
	501-750	29 (31%)	80 (32%)
	751-1000	28 (29%)	40 (16%)
	1001+	15 (16%)	29 (12%)
CD4 Percent	Median	37	30
	< 15%	2 (2%)	36 (15%)
	15-25%	12 (13%)	53 (22%)
	25% or more	82 (85%)	157 (64%)
HIV-1 RNA (copies/mL)	Median	400	400
	0-400	77 (80%)	160 (65%)
	401-5000	9 (9%)	37 (15%)
	5001-50000	9 (9%)	37 (15%)
	50001+	1 (1%)	11 (4%)
ARV regimen	cART with PI	50 (52%)	107 (40%)
	cART without PI	40 (42%)	77 (29%)
	Other ARV	5 (5%)	11 (4%)
	No ARV	1 (1%)	16 (6%)
	Missing	0 (0%)	54 (20%)

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	55	57.3
NRTI ftc	FTC/Coviracil	53	55.2
NRTI _3tc	3tc/Eпивir/Lamivudine	32	33.3
NRTI abc	Abacavir	24	25.0
NRTI zdv	ZDV/AZT	20	20.8
NRTI d4t	Stavudine/d4T	3	3.1
NRTI ddi	Didanosine/Videx/DDI	3	3.1
NRTI ddc	Zalcitabine/DDC	0	0.0
NNRTI rpv	Rilpivirine/TMC-278	13	13.5
NNRTI efv	Efavirenz/Sustiva/DMP-266	10	10.4
NNRTI nvp	Nevirapine/Viramune/NVP	5	5.2
NNRTI dlv	Delavirdine/DLV	0	0.0
NNRTI etr	Etravirine/TMC-125	0	0.0
PI rtvboost	Ritonavir/Norvir/RTV (Boost)	42	43.8
PI atv	Atazanavir/ATV	22	22.9
PI kal	Kaletra	15	15.6
PI drv	Prezista/Darunavir/TMC-114	11	11.5
PI nfv	Nelfinavir/Viracept/NFV	4	4.2
PI sqv	Saquinavir/Invirase/Fortovase/SQV	1	1.0
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	13.5
II ral	Raltegravir/Isentress	8	8.3
II evg	Elvitegravir/GS-9137	5	5.2

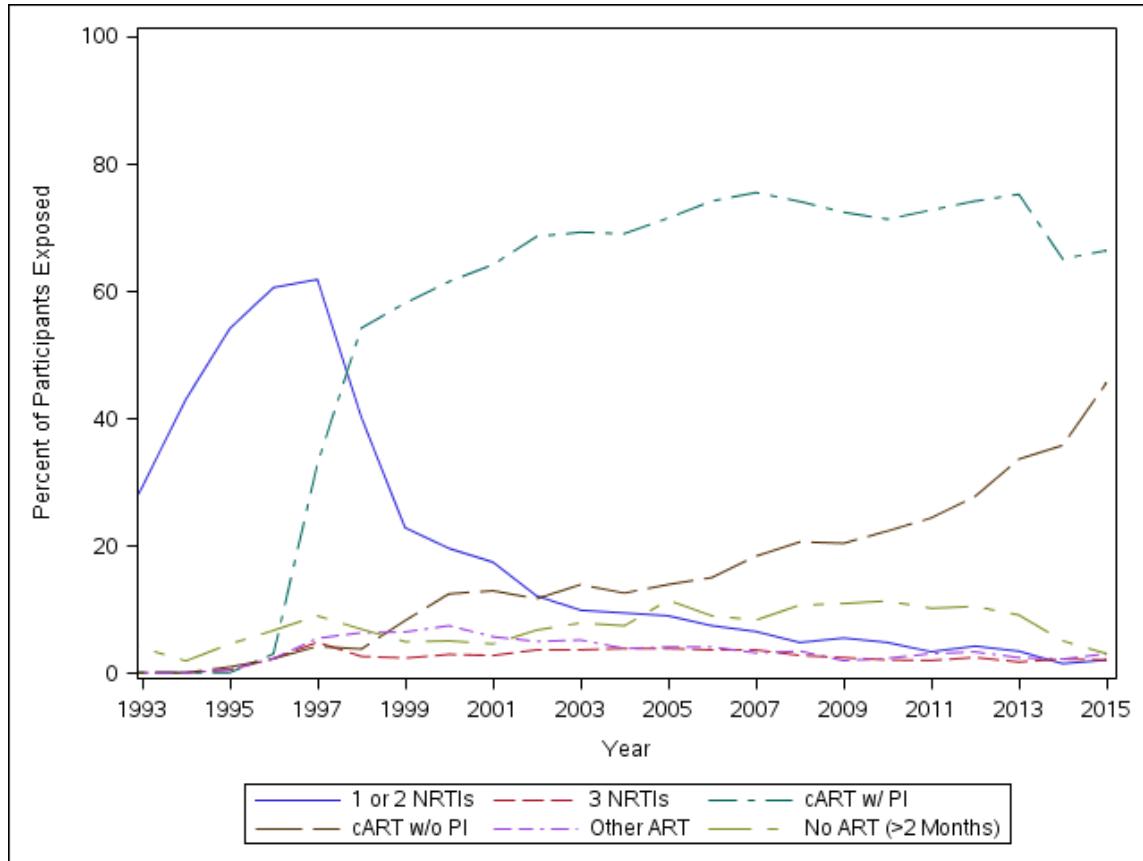
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Table 14: AMP - Lifetime Exposure to ARV Drug Classes and Individual Drugs, From Reported Regimens

Class/Drug	Total (N=448)
Any NRTI	446 (100%)
Tenofovir/TDF	271 (60%)
FTC/Coviracil	249 (56%)
3tc/Epivir/Lamivudine	419 (94%)
Abacavir	225 (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	206 (46%)
Etravirine/TMG-125	35 (8%)
Nevirapine/Viramune/NVP	158 (35%)
Delavirdine/DLV	2 (0%)
Rilpivirine/TMC-278	45 (10%)
Any PI	408 (91%)
Ritonavir/Norvir/RTV (Only)	139 (31%)
Ritonavir/Norvir/RTV (Boost)	337 (75%)
Kaletra	255 (57%)
Atazanavir/ATV	143 (32%)
Prezista/Darunavir/TMC-114	99 (22%)
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	90 (20%)
Dolutegravir/GSK-1349572	22 (5%)
Elvitegravir/GS-9137	18 (4%)

Created by: /home/phacs/actgPH200/monitoring/detlprogs/arv_figures.sas on May 16, 2016

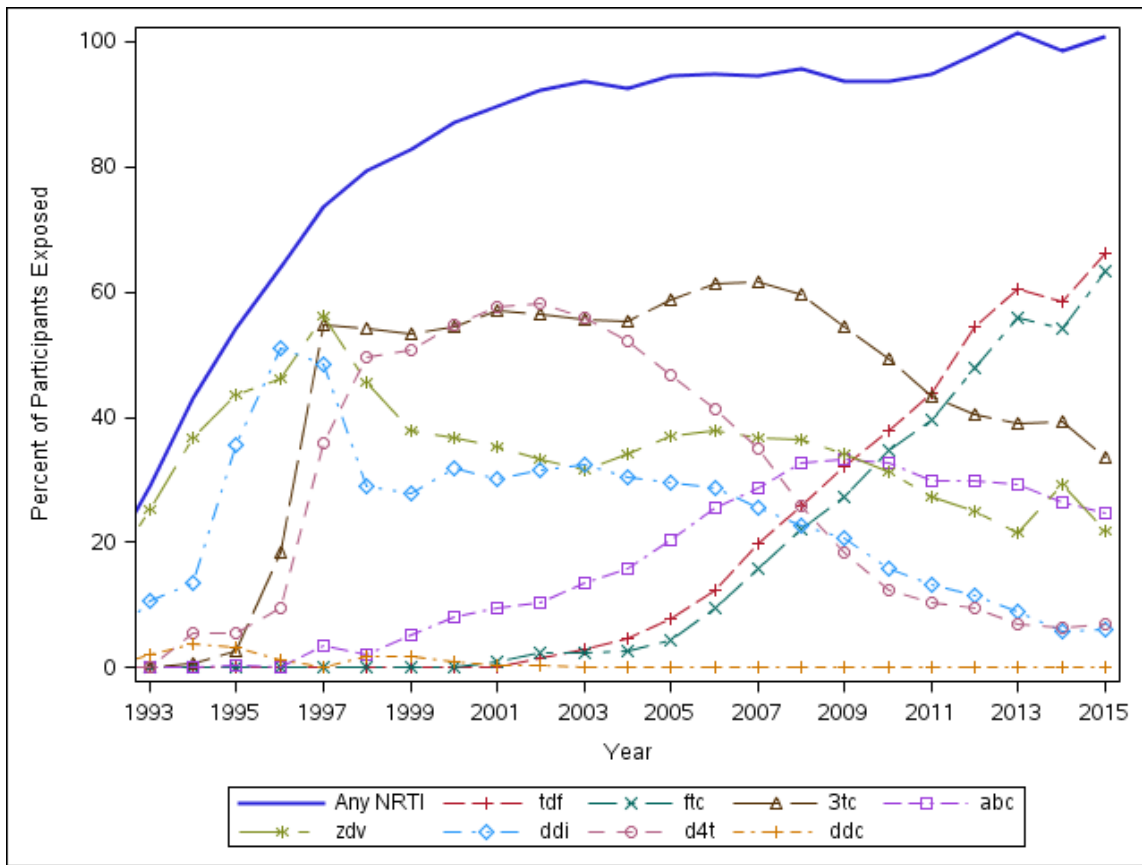
Figure 1: AMP - ARV Trends Over Time



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

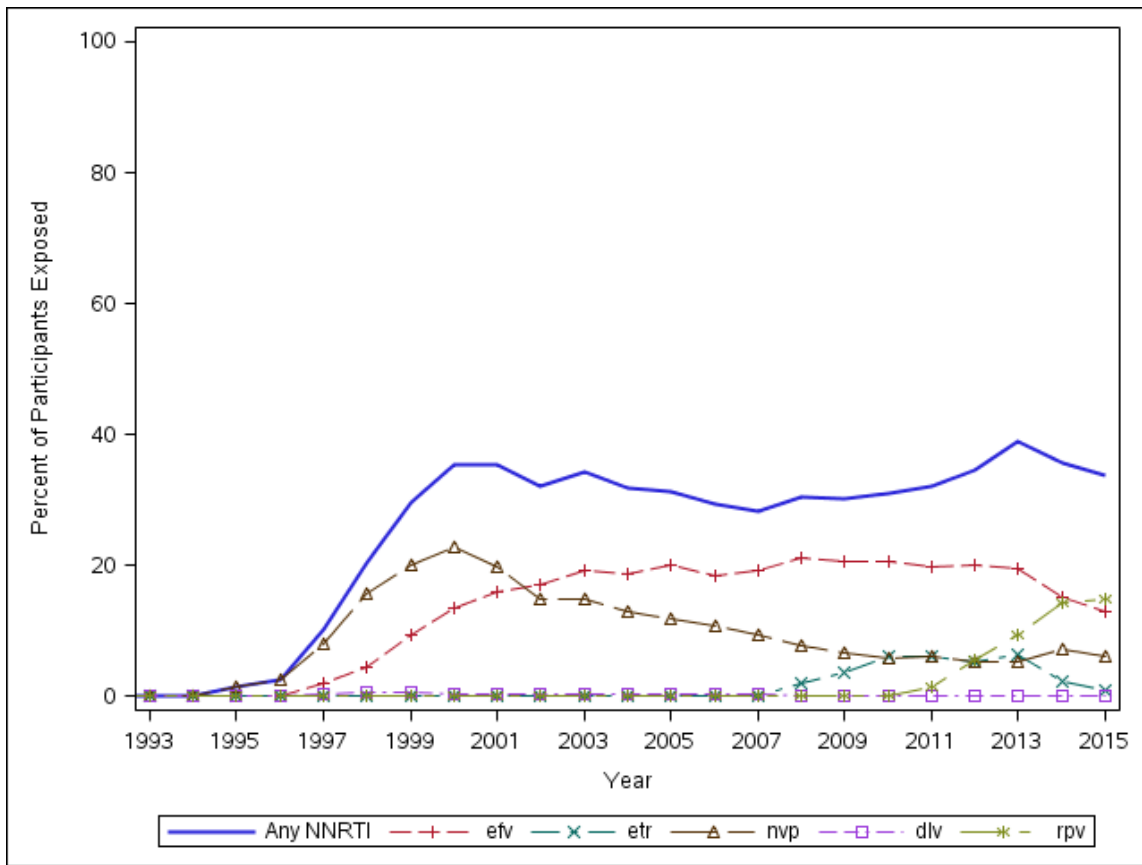
Created by: /home/phacs/actgPH200/monitoring/det/progs/arv_figures.sas on May 16, 2016

Figure 2: AMP - NRTI Use, 1993 - 2015



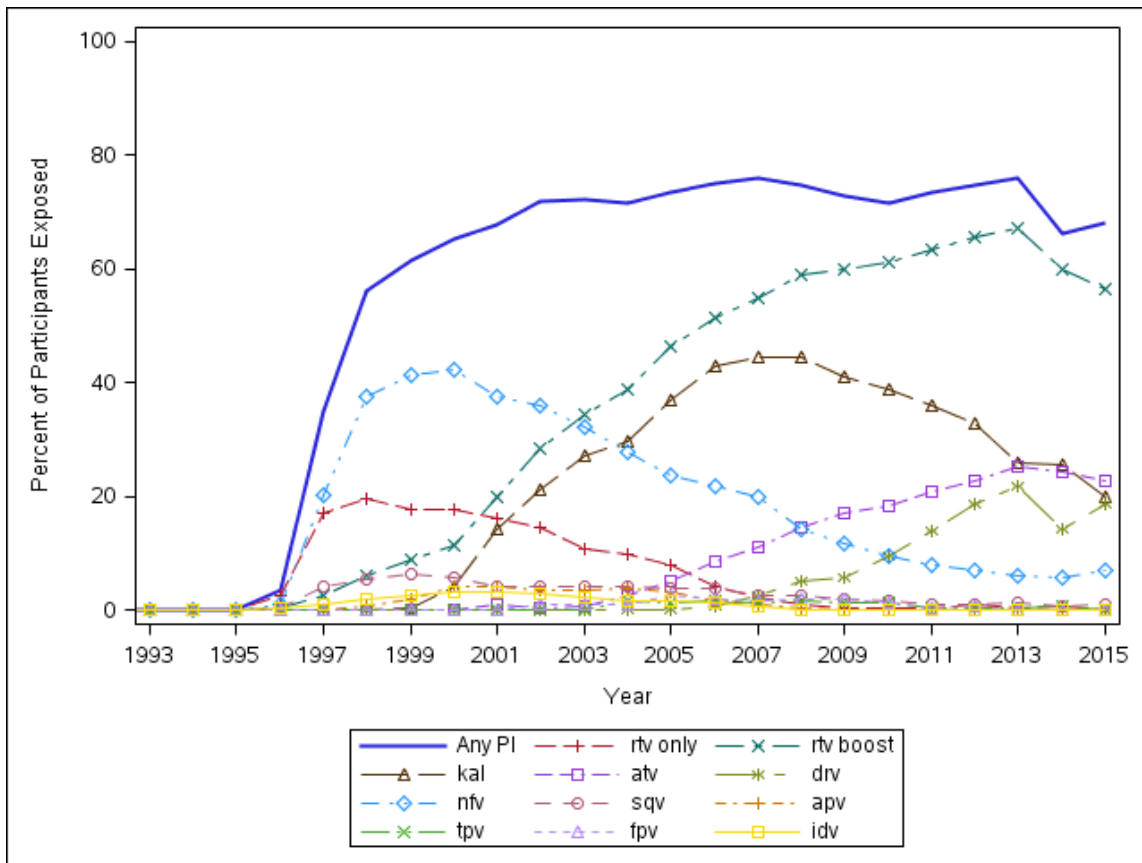
Created by: /home/phacs/actgPH200/monitoring/det/progs/arv_figures.sas on May 16, 2016

Figure 3: AMP - NNRTI Use, 1993 - 2015



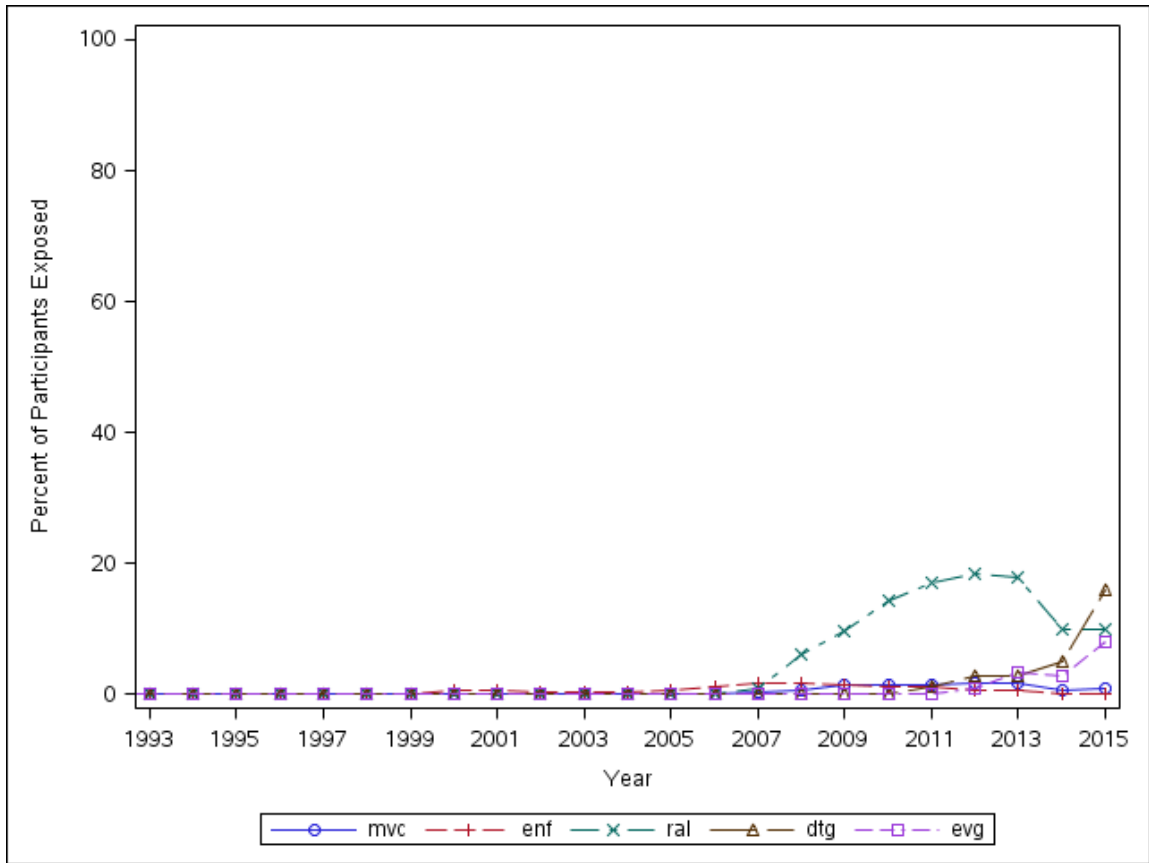
Created by: /home/phacs/actgPH200/monitoring/det/progs/arv_figures.sas on May 16, 2016

Figure 4: AMP - PI Use, 1993 - 2015



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Figure 5: AMP - FI/EI and II Use, 1993 - 2015



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