



HPTN Study Operations Report

December 2011

PTN Executive Summary Report
14 December 2011
Enrollment Summary

Protocol	Site	Date of First Enrollment	Target Number	Total Enrolled	% Target Enrollment	Months of Enrollment	Cumulative Enrollment Per Month	% Enrollment Period
046 V2 (Mothers)	Uganda – Mulago Hospital	08Feb2007	190	190	100%	8.2	23.2	completed
	Zimbabwe – Harare/Chitungwiza	09Mar2007	157	157	100%	7.8	20.1	completed
	Total		347	347	100%	8.8	39.4	
046 V2 (Infants)	Uganda – Mulago Hospital	08Feb2007	190	193	102%	8.2	23.5	completed
	Zimbabwe – Harare/Chitungwiza	09Mar2007	157	156	99%	7.8	20	closed
	Total		347	349	101%	8.8	39.7	
046 V3 (Mothers)	South Africa – Durban – Prince Mshiyeni Hospital	22Jul2008	400	408	102%	18	22.7	completed
	Tanzania – Dar Es Salaam	28Jan2009	270	218	81%	10	21.8	closed
	Uganda – Mulago Hospital	23Jun2008	500	545	109%	19.2	28.4	completed
	Zimbabwe – Harare/Chitungwiza	14May2008	500	507	101%	20.5	24.7	completed
	Total		1670	1678	100%	20.5	81.9	
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	22Jul2008	400	409	102%	18	22.7	completed
	Tanzania – Dar Es Salaam	28Jan2009	270	219	81%	10	21.9	closed
	Uganda – Mulago Hospital	23Jun2008	500	562	112%	19.2	29.3	completed
	Zimbabwe – Harare/Chitungwiza	14May2008	500	510	102%	20.5	24.9	completed
	Total		1670	1700	102%	20.5	82.9	
052 Run-in (Indexes)	US – Boston – Fenway Community Health Center	24Oct2005	6	2	33%	11.5	0.2	closed
	Brazil – Porto Alegre	30Jan2006	5	5	100%	3.3	1.5	completed
	Brazil – Rio de Janeiro	22Sep2005	15	15	100%	2.2	6.8	completed
	India – Chennai – YRGCare	10Nov2005	10	10	100%	1.3	7.7	completed
	India – Pune	01Jul2005	10	10	100%	2.2	4.5	completed
	Malawi – Blantyre – Queen Elizabeth Central	25Aug2005	10	10	100%	6.9	1.4	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	12Apr2005	10	10	100%	1.2	8.3	completed
	Thailand – Chiang Mai	24Jun2005	10	10	100%	2.3	4.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	09Jan2006	10	10	100%	2.4	4.2	completed
Total		86	82	95%	18	4.6		
052 Run-in (Partners)	US – Boston – Fenway Community Health Center	24Oct2005	6	2	33%	11.5	0.2	closed
	Brazil – Porto Alegre	30Jan2006	5	5	100%	3.3	1.5	completed
	Brazil – Rio de Janeiro	22Sep2005	15	15	100%	2.2	6.8	completed

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	India – Chennai – YRGCare	10Nov2005	10	10	100%	1.3	7.7	completed
	India – Pune	01Jul2005	10	10	100%	2.2	4.5	completed
	Malawi – Blantyre – Queen Elizabeth Central	25Aug2005	10	11	110%	6.9	1.6	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	12Apr2005	10	10	100%	1.2	8.3	completed
	Thailand – Chiang Mai	24Jun2005	10	10	100%	2.3	4.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	09Jan2006	10	10	100%	2.4	4.2	completed
	Total		86	83	97%	18	4.6	
052 Full Study (Indexes)	Botswana – Gaborone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	85	101%	28.9	2.9	completed
	Brazil – Rio de Janeiro	14Nov2007	168	171	102%	29.4	5.8	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	60	102%	6	10	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	220	100%	27.3	8.1	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	241	241	100%	26.5	9.1	completed
	South Africa – Johannesburg – Witwatersrand	20May2008	44	46	105%	23.4	2	completed
	South Africa – Soweto	11Jun2009	49	50	102%	10.2	4.9	completed
	Thailand – Chiang Mai	11Oct2007	98	96	98%	30.1	3.2	closed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1681	101%	34.7	48.4	
052 Full Study (Partners)	Botswana – Gaborone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	88	105%	28.9	3	completed
	Brazil – Rio de Janeiro	14Nov2007	168	175	104%	29.4	6	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	60	102%	6	10	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	221	101%	27.3	8.1	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	241	245	102%	26.5	9.2	completed
	South Africa – Johannesburg – Witwatersrand	20May2008	44	46	105%	23.4	2	completed
	South Africa – Soweto	11Jun2009	40	50	125%	10.2	4.9	completed
	Thailand – Chiang Mai	11Oct2007	98	97	99%	30.1	3.2	closed

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	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1694	102%	34.7	48.8	
057 (Mothers)	Brazil – Belo Horizonte	08Aug2007	12	12	100%	40	0.3	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	10	125%	28.7	0.3	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	15	100%	38.9	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	13	163%	29.2	0.4	completed
	Malawi – Blantyre – Queen Elizabeth Central	26Dec2006	71	72	101%	43.4	1.7	completed
	Total		114	122	107%	47.8	2.6	
057 (Infants)	Brazil – Belo Horizonte	08Aug2007	12	12	100%	40	0.3	completed
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	10	125%	28.7	0.3	completed
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	15	100%	38.9	0.4	completed
	Brazil – Rio de Janeiro	17Apr2008	8	13	163%	29.4	0.4	completed
	Malawi – Blantyre – Queen Elizabeth Central	27Dec2006	71	72	101%	43.4	1.7	completed
	Total		114	122	107%	47.7	2.6	
058	China – Guangxi – Heng County	24Dec2008	480	408	85%	33.6	12.1	closed
	China – Nanning	19May2010	263	161	61%	16.6	9.7	closed
	China – Xinjiang	23Dec2008	555	477	86%	34.1	14	closed
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	1248	83%	53.2	23.5	
061	US – Atlanta	26Feb2010	201	109	54%	7	15.6	closed
	US – Boston	17Jul2009	403	237	59%	15.3	15.5	closed
	US – Decatur	16Sep2009	202	183	91%	12.2	15	closed
	US – Los Angeles	30Sep2009	403	283	70%	12.3	23	closed
	US – NY – Harlem Prevention Center	08Jan2010	201	154	77%	6.3	24.4	closed
	US – NY – New York Blood Center	01Oct2009	202	156	77%	10.7	14.6	closed
	US – San Francisco	13Aug2009	403	204	51%	13.6	15	closed
	US – Washington DC	28Jul2009	403	227	56%	14.2	16	closed
	Total		2418	1553	64%	15.3	101.5	
062	Malawi – Lilongwe – Lilongwe Central Hospital	26Apr2010	46	28	61%	19.9	1.4	90%

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	Total		46	28	61%	19.9	1.4	
063 (Part 1)	Thailand – Chiang Mai	01Apr2010	61	61	100%	3	20.3	completed
	Total		61	61	100%	3	20.3	
063 (Part 2)	Brazil – Rio de Janeiro	06Apr2011	300	130	43%	8.4	15.5	65%
	Thailand – Chiang Mai	21Feb2011	239	147	62%	9.9	14.8	68%
	Zambia – Lusaka – Matero Clinic	28Apr2011	200	112	56%	7.7	14.5	63%
	Total		739	389	53%	9.9	39.3	
064 (Women)	US – Atlanta	22Oct2009	200	215	108%	7	30.7	completed
	US – Baltimore	05Aug2009	200	210	105%	8.7	24.1	completed
	US – Chapel Hill	26May2009	200	210	105%	8.7	24.1	completed
	US – Decatur	27Aug2009	200	211	106%	11.1	19	completed
	US – NY – Bronx–Lebanon Hospital Center	16Jun2009	200	210	105%	8.4	25	completed
	US – NY – Harlem Prevention Center	26Oct2009	200	210	105%	7.4	28.4	completed
	US – Newark	05Jun2009	400	420	105%	10.5	40	completed
	US – Raleigh	11Aug2009	200	210	105%	5.7	36.8	completed
	US – Washington DC	17Jun2009	200	211	106%	10.3	20.5	completed
	Total		2000	2107	105%	14.2	148.4	
064 (Men)	US – Decatur	10Mar2010	30	47	157%	4.9	9.6	completed
	US – NY – Bronx–Lebanon Hospital Center	30Sep2009	30	54	180%	6.7	8.1	completed
	US – Raleigh	29Apr2010	30	37	123%	3.2	11.6	completed
	US – Washington DC	02Apr2010	30	40	133%	2.8	14.3	completed
	Total		120	178	148%	10.3	17.3	
066	US – Baltimore	28Feb2011	16	19	119%	3.5	5.4	completed
	US – Chapel Hill	07Feb2011	16	19	119%	6.8	2.8	completed
	Total		37	38	103%	6.8	5.6	
067	South Africa – Cape Town	12Sep2011	180	52	29%	3.1	16.8	40%
	Thailand – Bangkok	–	180	–	–	0	–	pending
	Total		360	52	14%	3.1	16.8	

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068	South Africa – Bushbuckridge – MRC/Wits	05Mar2011	2900	1936	67%	9.5	203.8	94%
	Total		2900	1936	67%	9.5	203.8	

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Retention Summary

Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
046 V2 (Mothers)	Uganda – Mulago Hospital	190	1140	1057	1071	93%	94%
	Zimbabwe – Harare/Chitungwiza	157	942	821	885	87%	94%
	Total	347	2082	1878	1956	90%	94%
046 V2 (Infants)	Uganda – Mulago Hospital	193	2123	1997	2015	94%	95%
	Zimbabwe – Harare/Chitungwiza	156	1727	1611	1639	93%	95%
	Total	349	3850	3608	3654	94%	95%
046 V3 (Mothers)	South Africa – Durban – Prince Mshiyeni Hospital	408	2448	2105	2298	86%	94%
	Tanzania – Dar Es Salaam	218	1308	1145	1228	88%	94%
	Uganda – Mulago Hospital	545	3270	3088	3070	94%	94%
	Zimbabwe – Harare/Chitungwiza	507	3042	2800	2856	92%	94%
	Total	1678	10068	9138	9453	91%	94%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	409	4499	4183	4268	93%	95%
	Tanzania – Dar Es Salaam	219	2409	2185	2285	91%	95%
	Uganda – Mulago Hospital	562	6182	6018	5864	97%	95%
	Zimbabwe – Harare/Chitungwiza	510	5610	5291	5322	94%	95%
	Total	1700	18700	17677	17739	95%	95%
052 Combined (Indexes)	Botswana – Gaborone	77	780	757	765	97%	98%
	Brazil – Porto Alegre	90	1251	1222	1214	98%	97%
	Brazil – Rio de Janeiro	184	2787	2738	2695	98%	97%
	India – Chennai – YRGCare	250	3675	3267	3558	89%	97%
	India – Pune	175	2555	2521	2472	99%	97%
	Kenya – Kisumu	60	535	531	526	99%	98%
	Malawi – Blantyre – Queen Elizabeth Central	230	2918	2722	2839	93%	97%
	Malawi – Lilongwe – Lilongwe Central Hospital	251	3318	3060	3223	92%	97%
	South Africa – Johannesburg – Witwatersrand	46	553	529	540	96%	98%
	South Africa – Soweto	50	461	448	453	97%	98%
	Thailand – Chiang Mai	106	1570	1553	1517	99%	97%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	3074	2891	2989	94%	97%
	Total	1759	23477	22239	22791	95%	97%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
052 Combined (Partners)	Botswana – Gabarone	77	780	710	765	91%	98%
	Brazil – Porto Alegre	93	1251	1130	1214	90%	97%
	Brazil – Rio de Janeiro	188	2787	2280	2695	82%	97%
	India – Chennai – YRGCare	250	3675	2919	3558	79%	97%
	India – Pune	175	2555	2461	2472	96%	97%
	Kenya – Kisumu	60	535	513	526	96%	98%
	Malawi – Blantyre – Queen Elizabeth Central	232	2918	2317	2839	79%	97%
	Malawi – Lilongwe – Lilongwe Central Hospital	255	3318	2626	3223	79%	97%
	South Africa – Johannesburg – Witwatersrand	46	553	487	540	88%	98%
	South Africa – Soweto	50	461	409	453	89%	98%
	Thailand – Chiang Mai	107	1570	1406	1517	90%	97%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	3074	2514	2989	82%	97%
	Total		1773	23477	19772	22791	84%
057 (Mothers)	Brazil – Belo Horizonte	12	72	72	70	100%	97%
	Brazil – Porto Alegre – Conceicao	10	60	58	58	97%	97%
	Brazil – Porto Alegre – Santa Casa	15	89	86	86	97%	97%
	Brazil – Rio de Janeiro	13	78	78	75	100%	97%
	Malawi – Blantyre – Queen Elizabeth Central	72	432	421	417	97%	97%
	Total		122	731	715	706	98%
057 (Infants)	Brazil – Belo Horizonte	12	84	84	81	100%	96%
	Brazil – Porto Alegre – Conceicao	10	70	68	67	97%	96%
	Brazil – Porto Alegre – Santa Casa	15	104	101	100	97%	96%
	Brazil – Rio de Janeiro	13	91	91	87	100%	96%
	Malawi – Blantyre – Queen Elizabeth Central	72	504	488	484	97%	96%
	Total		122	853	832	819	98%
058	China – Guangxi – Heng County	408	1047	855	927	82%	89%
	China – Nanning	161	170	135	157	79%	92%
	China – Xinjiang	477	1186	978	1050	82%	88%
	Thailand – Chiang Mai University	202	1063	925	897	87%	84%
	Total		1248	3466	2893	3030	83%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
061	US – Atlanta	109	218	182	201	83%	92%
	US – Boston	237	454	340	418	75%	92%
	US – Decatur	183	346	249	318	72%	92%
	US – Los Angeles	283	512	412	471	80%	92%
	US – NY – Harlem Prevention Center	154	298	276	274	93%	92%
	US – NY – New York Blood Center	156	284	240	261	85%	92%
	US – San Francisco	204	388	304	357	78%	92%
	US – Washington DC	227	434	364	399	84%	92%
	Total	1553	2934	2367	2701	81%	92%
062	Malawi – Lilongwe – Lilongwe Central Hospital	28	245	229	240	93%	98%
	Total	28	245	229	240	93%	98%
064 (Women)	US – Atlanta	215	392	358	362	91%	92%
	US – Baltimore	210	411	398	378	97%	92%
	US – Chapel Hill	210	323	299	300	93%	93%
	US – Decatur	211	346	309	320	89%	93%
	US – NY – Bronx–Lebanon Hospital Center	210	328	315	304	96%	93%
	US – NY – Harlem Prevention Center	210	362	323	335	89%	92%
	US – Newark	420	821	789	756	96%	92%
	US – Raleigh	210	411	387	379	94%	92%
	US – Washington DC	211	337	315	312	93%	93%
	Total	2107	3731	3493	3446	94%	92%
066	US – Baltimore	19	126	110	125	87%	99%
	US – Chapel Hill	19	133	129	132	97%	99%
	Total	38	259	239	257	92%	99%
067	South Africa – Cape Town	52	211	200	210	95%	99%
	Thailand – Bangkok	–	–	–	–	–	–
	Total	52	211	200	210	95%	99%

MEMORANDUM

DATE:	19 APR 2006
TO:	Study Operations Group
FROM:	Deborah Donnell
RE:	Summary of HPTN and MTN Enrollment and Recruitment
CC:	

These tables are based on the same data as the protocol specific enrollment and retention reports routinely sent out by SCHARP to each of the protocol teams.

Enrollment Summary

The Enrollment Summary describes the number of participants enrolled in each study based on the data received and entered at SCHARP. The report lists the date of **First Enrollment**, the **Target Number** of participants, and the **Total Number** enrolled to date for each site in each study. The percentage of target already enrolled is:

$$\text{Target Enrollment} = \frac{\text{Total Enrolled}}{\text{Target Number}}$$

As a guide to the sites' progress in enrollment, the percentage **Enrollment Period** elapsed is calculated - this is the elapsed proportion of the accrual period specified in the protocol.

Retention Summary

The Retention Summary is based on study visits. The table reports the number of **Expected Visits** for each site on each protocol - this is a calculation of all visits that should have occurred to date assuming no missed visits or loss to followup. **Completed Visits** are the number of these expected visits that have actually occurred (based on data received and entered at SCHARP). **Protocol Expectations** calculates the number of visits that should have occurred to date assuming the protocol specified acceptable loss to followup rate. Currently the report uses a retention standard of 10% annual loss to followup for HPTN035, HPTN037, and HPTN039 (i.e., Phase IIb and III trials), and 0% for the safety run-in phase of HPTN052.

Retention is simply the proportion of expected visits that have been completed:

$$\text{Retention} = \frac{\text{Completed}}{\text{Expected}}$$

As a guide for performance, the **Protocol Expected Standard** is calculated as the percentage of **Protocol Expected** visits that have occurred:

$$\text{Protocol Expected Standard} = \frac{\text{Protocol Expected}}{\text{Expected}}$$

The network evaluation committee has defined adequate performance as within 90% of the protocol expected standard.

Questions about this report may be directed to Deborah Donnell (deborah@scharp.org; (206) 667-5661).

HPTN Network Laboratory Update December 2011

I. HPTN 046

A. General Comments

1. Protocol Version - 3.0 dated 26 Sept, 2007
2. SSP version – 5.0 dated 09 April 2008
3. Enrollment Status - Closed
4. Date of last SMC call – 17 May 2010
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - None
6. Lab-related notes to file/deviations issued since preparation of SMC report
 - a. Dar es Salaam – Note to File (NTF) issued 19 May describing the delay in the testing of one sample for DNA PCR--resolved.
 - b. Dar es Salaam – Protocol Deviation form issued 26 May 2010 describing that a cell pellet storage was not requested by the clinic BOTH PREVIOUSLY REPORTED June study ops
 - c. Dar es Salaam – Protocol Deviation form issued 26 May 2010 describing that plasma and DBS storage were not requested by the clinic. PREVIOUSLY REPORTED June study ops
 - d. Dar es Salaam – 8 Protocol Deviation forms received on 30 June 2010 They describe the failure of the physician to request DBS or breast milk storage. Discovered during retrospective chart reviews. PREVIOUSLY REPORTED August study ops
 - e. UZ-UCSF – NTF issued 22 September describing the movement of the DBSCards from the laboratory (temperature monitored) to a storage area for the laboratory. The lab recently started monitoring temperatures in the area. A list of PTIDs involved is still pending.
 - f. UZ-UCSF - Pending NTF regarding another power problem that affected the freezers at the off site location
 - g. UZ-UCSF – NTF regarding outage of WB kits in October delaying resulting of 1 participant.

B. Site Specific

1. Harare – Follow-up at this site is complete.
2. Kampala - Follow-up at this site is complete.
3. Durban - Follow-up at this site is complete
4. Dar es Salaam – Follow-up at this site is complete

C. Shipping / QA Status

1. Shipping lists for resistance testing samples have been sent to the sites. All samples have now been received at the NL.
2. Mark Mirochnick and SCHARP have selected samples required for PK studies. Lists have been sent to the sites for shipping to the NL. Samples from all sites were received at the HPTN Network Lab and have been forwarded to a non-Network-affiliated lab (Dr Caparelli) for testing.

II. HPTN 052

A. General Comments

1. Protocol Version - 3.0 dated 20 November 2006
2. SSP version - 1.6 dated 9 January 2009
3. Enrollment Status - closed
4. Date of last SMC call – November 2011
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - None

6. Lab-related NTFs/deviations issued since preparation of SMC report
 - a. COM Blantyre – NTF regarding serum aliquots were indicated on the LDMS tracking sheet but were never stored. The clinic and NL were not notified.
 - b. COM Blantyre – NTF regarding incorrect hematology reference ranges submitted with results to the clinic. Reference ranges provided by the lab manager to DCLOT did not match reference ranges on file at SCHARP.
 - c. Botswana – NTF--Participant sample was brought to the lab but not processed for the required plasma storage.

B. Site Specific

1. Pune/NARI – The site has started performing testing at Model Colony. Have submitted their LDMS reconciliations late, have not submitted their QC for review, but have submitted their inventory.
2. Harare - Pending an update on their ordering / inventory SOP. Site is working on the validation of a new chemistry analyzer. Have submitted their LDMS reconciliations late, have not submitted their QC for review, and submitted their inventory.
3. Chennai – Have submitted their LDMS queries, did not submit their QC for review, but submitted their inventory
4. Blantyre – Have submitted their LDMS reconciliations, did submit their QC for review, and submitted their inventory
5. Porto Alegre - Have submitted their LDMS reconciliations, submitted their QC for review, and did not submitted their inventory.
6. Rio sites – Have submitted their LDMS reconciliations late, have submitted their QC for review, and did submit their inventory.
7. Lilongwe - Have submitted their LDMS reconciliations, submitted their QC for review, and have not submitted their inventory.
8. Chiang Mai – Did not have any LDMS reconciliations, submitted their QC for review, and submitted their inventory
9. Johannesburg--WITs – Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and WITS have not submitted their inventory
10. Soweto – Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and Soweto have not submitted their inventory
11. Botswana - Have submitted their LDMS reconciliations, have not submitted their QC for review, and have not submitted their inventory
12. Kenya – Have submitted their LDMS reconciliations, have not submitted their QC for review, and have submitted their inventory

C. Shipping / QA Status

Pending shipments of seroconverting plasma and serum aliquots from several sites

III. HPTN 057

A. General Comments

1. Protocol Version - 2.0 dated 28 October 2009
2. SSP version - 4.0 lab section dated 11 March 2010
3. Enrollment Status - Fully enrolled
4. Date of last SMC call – 21 February 2008.
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - Clarification memo issued 15 July2010 clarifying that CK total protein and glucose are not required in HPTN 057 (they had been indicated in section Appendix 1B) PREVIOUSLY REPORTED ON STUDY OPS REPORT
6. Lab-related notes to file/deviations issued since preparation of SMC report - None

B. Site Specific

1. Blantyre – Follow-up at this site has been completed.
2. Santa Casa Porto Alegre - No outstanding issues. Site are completing LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.
3. UFMG - No outstanding issues. Site are completing LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.
4. HSE Rio – Follow-up at this site has been completed.
5. HNSC Porto Alegre - Site are completing LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.

C. Shipping / QA Status

All requested shipments have been received.

IV. HPTN 058

A. General Comments

1. Protocol Version – 2.0 dated 16 September 2008
2. SSP Version – 2.0 dated 05 December 2008
3. Enrollment status – Closed. Study to be closed due to decision of the DSMB.
4. Date of last SMC call – 02 September 2011
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - None
6. Lab-related NTFs/deviations issued since preparation of SMC report - None

B. Site Specific

1. Thailand - Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and submitted their inventory.
2. Xinjiang Site - Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and have not submitted their inventory.
3. Guangxi - Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and have not submitted their inventory.

C. Shipping / QA Status

No outstanding shipments or requests.

V. HPTN 061

A. General Comments

1. Protocol Version – Version 2.0, 02 April 2009
2. SSP Version – Section 11 Version 5.0 09 December 2010.
3. Enrollment status – All sites have completed enrollment
4. Date of last SMC call – 30 March 2011
5. Communiqués/Notification of change to SSP issued since preparation of last SMC report - EAC convened and had call on 25 October 2011 to review QA testing discrepant results. Data communiqué 9 issued on 05 May 2011. Appendix D of SSP released for procedures for co-enrolled 061 participants with HVTN 505.
6. Lab-related NTFs/deviations issued since preparation of SMC report:
 - a. Atlanta - NTF received for mislabeled rectal swab. PREVIOUSLY REPORTED
 - b. Atlanta - NTF received for PID for which a tube was received with no rectal swab in it. PREVIOUSLY REPORTED.
 - c. Atlanta - NTF received for rectal swab misplaced by lab (later it was noted that it was not misplaced but mislabeled). PREVIOUSLY REPORTED.
 - d. Atlanta - NTF received for 2 PIDs, one who did not return for 2nd WB; one who did after 4 weeks at 6 month visit.

- e. Decatur – PREVIOUSLY REPORTED. NTF received for 3 PIDs who did not return for 2nd WB.
- f. Decatur - PREVIOUSLY REPORTED. NTF received for PID who was so difficult to stick no blood obtained only rectal swab and urine collected.
- g. Decatur - PREVIOUSLY REPORTED. NTFs received for 2 PIDs who are lost to follow since enrollment and have not completed syphilis confirmatory testing, 2 PIDs who completed syphilis confirmatory testing at visit 2.0 and for 9 PIDs who only had one WB per SCHARP's report (3 had completed and CRF were being refaxed)
- h. Fenway – PREVIOUSLY REPORTED. NTF received for 5 PIDs plasma storage QNS.
- i. Fenway - PREVIOUSLY REPORTED. NTF received for PID who returned for interim visit and HIV testing but no plasma was stored.
- j. Fenway - PREVIOUSLY REPORTED. NTF received for 3 PIDs that have not had their 2nd WB as yet and are outside the 4 week window.
- k. GWU - PREVIOUSLY REPORTED. NTF for flood in Ross Hall and freezer move still pending.
- l. GWU - PREVIOUSLY REPORTED. Protocol Deviation received for PID enrolled who was under age.
- m. GWU - NTFs received for 2 PIDs who have refused HIV testing but allowed syphilis testing and plasma storage.
- n. GWU - PREVIOUSLY REPORTED. NTF received for 2 PIDs; one 2nd WB collected after 4-week window, one outside 4-week window not yet collected.
- o. NYBC – NTF received for PID who did not return for 2nd WB. Protocol deviation pending for PID who did return but site did not collect 2nd WB or required VL.
- p. NYBC - NTF and a requested protocol deviation awaiting response from site. PREVIOUSLY REPORTED--None.
- q. UCLA - PREVIOUSLY REPORTED. Two NTFs received for 2 PIDs who refused sample collection.
- r. UCLA - PREVIOUSLY REPORTED. NTF received for freezer downtime as freezer was being repaired.
- s. UCLA - PREVIOUSLY REPORTED. NTFs received for 3 PIDs for whom a 2nd WB was not completed.
- t. Harlem – PREVIOUSLY REPORTED--None
- u. San Francisco - PREVIOUSLY REPORTED. NTF received for PID who was difficult stick, no plasma stored.
- v. San Francisco - NTF received for plasma storage specimens left out over weekend, discarded and participant redrawn.
- w. San Francisco - PREVIOUSLY REPORTED. NTF received for PID due to difficult stick at 2 visits had no plasma stored.
- x. San Francisco - PREVIOUSLY REPORTED. Protocol Deviation submitted for specimen mix-up with a HVTN 505 participant and a HPTN 061 participant. PREVIOUSLY REPORTED.
- y. San Francisco - NTF received for PID who did not have 2nd WB within the 4-week window and no plasma stored at visit 2.0.
- z. San Francisco - PREVIOUSLY REPORTED. 5 NTFs received, two for which no plasma was stored, one the confirmatory syphilis testing was not done, one for QNS plasma storage and one for specimens for plasma storage left out over 3 day weekend and had to be redrawn.

B. Site Specific

1. Fenway - No new updates
2. George Washington University - Waiting on response from site for November LDMS reconciliation report.
3. San Francisco - No new updates
4. Harlem - No new updates
5. Atlanta/Decatur - No new updates
6. New York Blood Center - No new updates
7. UCLA - No new updates

C. Shipping / QA Status

1. NL investigating discrepant QA results from 2nd set of QA done at Harlem and Fenway, still on going.
2. Shipping lists generated by SCHARP were sent out to sites by NL, for 100% enrollment QA.
3. Specimens in process of being shipped from sites to NL for 100% enrollment QA

VI. HPTN 063**A. General Comments**

1. Protocol Version - Version 1.0 dated 15 September 2008
2. SSP version - Version 1.1 dated 04 August 2011
3. Enrollment Status - All sites enrolling.
4. Date of last SMC call - None
5. Communiqués/Notifications of Change to SSP issued since preparation of last SMC report - None
6. Lab-related notes to file (NTF)/deviations issued since preparation of SMC report:
 - a. Zambia - PREVIOUSLY REPORTED. Protocol deviation received for lab SOP and SSP not being followed for plasma processing.

B. Site Specific**C. Shipping / QA Status**

Shipping list requested from SCHARP for list of specimens to be shipped from Thailand site.

VII. HPTN 064**A. General Comments**

1. Protocol Version - 1.0 dated 09 July 2008
2. SSP Version - 2.0 dated 12 May 2010
3. Enrollment Status - All sites have completed enrollment.
4. Date of last SMC call - 01 November 2010
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - None
6. Lab-related notes to file (NTF)/deviations issued since preparation of SMC report:
 - a. Johns Hopkins University - NTF received; confirmatory WB was sent to the incorrect lab and was not completed. PREVIOUSLY REPORTED April study ops. NTF received; plasma wasn't stored for a participant due to a lab accident. PREVIOUSLY REPORTED November study ops.
 - b. Emory - NTF received; plasma wasn't stored within the allotted timeframe. PREVIOUSLY REPORTED. NTF and Protocol Deviation received; site enrolled a participant who used falsified information. PREVIOUSLY REPORTED December study ops.

- c. Harlem - NTF received for incorrect PID and VID entered into LDMS on two participants. PREVIOUSLY REPORTED March study ops.
- d. GWU - NTF regarding the flood in Ross Hall and the freezer move is pending. NTF received for 6 month participant was mistakenly extended to 12 month. PREVIOUSLY REPORTED April study ops.

B. Site Specific

- 1. Bronx - No new updates.
- 2. Harlem - No new updates.
- 3. Newark - No new updates.
- 4. Johns Hopkins University - No new updates.
- 5. George Washington University - No new updates.
- 6. University of North Carolina - No new updates.
- 7. Emory - No new updates.

C. Shipping / QA Status

- 1. All enrollment QA testing has been completed and the data forwarded to SCHARP.
- 2. All endpoint and incidence testing has been completed and the data has been forwarded to SCHARP.

VIII. HPTN 066

A. General Comments

- 1. Protocol Version - 2.0 dated 29 November 2010
- 2. SSP version – Version 1.0
- 3. Enrollment Status – Enrollment and follow-up are now completed.
- 4. Date of last SMC call – None
- 5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - Lab Communique #1 issued 08 March 2011 stating that if possible, the blood sample on Day 35 needs to be drawn according to the following criteria: 1) As close as possible to the same time of day as the prior dose of study drug. 2) Within 3 hours of the tissue/luminal sample collection.
- 6. Lab-related notes to file (NTF)/deviations issued since preparation of SMC report - None
- 7. Miscellaneous - PBMCs in this study are being used for PK analysis and will follow an SOP developed specifically for this purpose. This study is not storing viable PBMCs and will not follow the Cross-Network PBMC Processing SOP

B. Site Specific

- 1. UNC - None
- 2. JHU - None.

C. Shipping / QA Status

- 1. QA lists for the JHU site has been prepared by SCHARP. The JHU site is preparing to transfer these samples to the HPTN NL for testing.
- 2. Specimens for QA have been received at the NL. Results have been submitted to SCHARP.
- 3. A list of all available samples at the JHU site and at the UNC site have been submitted to Dr Hendrix.

IX. HPTN 067

A. General Comments

- 1. Protocol Version – 2.0 dated 18 February 2011
- 2. SSP version – 1.0 dated 24 October 2011
- 3. Enrollment Status – enrolling in Capetown
- 4. Date of last SMC call –

5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - None
6. Lab-related notes to file (NTF)/deviations issued since preparation of SMC report -
 - a. Capetown – NTF regarding storage of urine samples at screening. Samples were removed from LDMS and destroyed

B. Site Specific

C. Shipping / QA Status

X. HPTN 068

A. General Comments

1. Protocol Version – 1.0 dated 06 October 2010
2. LoA Version - 1.0 dated 06 October 2011
3. SSP version – 1.0 dated 01 February 2011
4. Enrollment Status – Enrolling
5. Date of last SMC call – 30 September 2011
6. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - None
7. Lab-related notes to file (NTF)/deviations issued since preparation of SMC report:
 - a. NTF previously requested for invalid rapid results that weren't documented.

B. Site Specific

Samples are now being collected at the site rather than the schools.

C. Shipping / QA Status

The Network Laboratory requested 100% QC of all samples collected. The samples were received in the Network Laboratory and are currently being tested

XI. HPTN 069

A. General Comments

1. Protocol Version – 1.0 dated 04 October 2011
2. SSP version – Draft
3. Enrollment Status – Not yet open
4. Date of last SMC call – None
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report - None
6. Lab-related notes to file/deviations issued since preparation of SMC report - None

B. Site Specific

1. Case – None
2. Cornell – None
3. Fenway – None
4. GW – Site are working with IQA to have their PBMC lab certified.
5. JHU (Intensive Tissue Cohort) - None
6. UPITT – None
7. UPR – None
8. UCSF – None
9. UPENN (Intensive Tissue Cohort) - None
10. UW – None
11. UCLA (Intensive Tissue Cohort) - None
12. UNC (Intensive Tissue Cohort) - None

C. Shipping / QA Status

1. None

NL updates

The NL is working on the incidence testing for both HPTN 043 and the domestic trials.

Travel Updates

Estelle is planning a visit to the Malawi and Kenya sites in January and the Brazil sites in late February.

Implementations Issues and Problems Summary December 2011

058

On October 17, 2011 HPTN announced that HPTN 058 is being closed to new enrollment, and a phase-out of the study was initiated.

063

Sites identified challenges recruiting men into HPTN 063 for various reasons but primarily because men are significantly less likely to report sexual risk behavior during the pre-screening/screening visits. During the full team meeting at the 2011 HPTN Annual Meeting, the sites and protocol team explored different avenues of recruiting men in HPTN 063 and have proposed new recruitment methods. The protocol team has increased calls to bi-monthly with each site to monitor recruitment and evaluate the newly proposed recruitment methods. The HPTN 063 Protocol Team has incorporated changes to the protocol to modify the eligibility criteria in order to be more inclusive of various degrees of sexual risk in Version 2.0. Additionally, weekly screening and enrollment reports, as well as monthly accrual graphs are distributed to the full protocol team and closely monitored. Members of CORE and SCHARP performed a site assessment visit the last week in September at the Brazil site to provide training assistance to new staff and also help strengthen their recruitment plans. Members from the CORE and NL traveled to Zambia November 9-11, 2011 for an assessment visit to review lab management and also strategize about male recruitment.

067

The Cape Town site had previously identified that participants were having trouble completing the CASI due to problems with the Xhosa translation. In discussions with the site team it was determined that the translation was no longer a problem. The earlier participants had trouble understanding certain terms which are now explained by counselors in advance and with computer literacy which the counselors are working to improve.

Report for HPTN Study Operations Group

HPTN 046

A phase III trial to determine the efficacy and safety of an extended regimen of nevirapine in infants born to HIV-infected women to prevent vertical transmission during breastfeeding

Based on data available through: 9 December 2011

Participating Study Sites:

- CAPRISA Umlazi; Durban, South Africa
- Muhimbili Hospital; Dar es Salaam, Tanzania
- Mulago Hospital; Kampala, Uganda
- Chitungwiza Clinics; Chitungwiza, Zimbabwe

Study Implementation Status:

Follow-up to protocol Version 3.0 was completed on 30 July 2011

Accrual Status:

Accrual to protocol Version 3.0 was completed in January 2010. 1678 mother-infant pairs were enrolled across 4 countries.

Status of Intervention Delivery:

N/A

Retention Status:

N/A

Implementation Issues and Problems:

N/A

Changes to Trial Design

Version 1.0 of the study protocol was never implemented due to significant revisions prior to its release to sites. Under Version 2.0, infants were randomized at birth to receive either extended NVP or placebo from birth through age six months. With publication of findings which demonstrated efficacy of daily NVP in reducing breastfeeding HIV-1 transmission through six weeks of age, Version 2.0 accrual was closed, and all enrolled infants under six weeks of age were offered open-label NVP through age six weeks. The protocol was amended to Version 3.0 to provide all study infants with daily NVP from birth through six weeks of age and to then randomize those who were HIV-1-uninfected to either extended NVP or placebo through six months of age, and the trial was re-initiated.

N/A

HPTN 046 Accepted Publications and Presentations Table

Title	Type	Conference/Reference	Authors/Presenters	Status
Maternal Disease Progression in the First Year after Delivery among HIV infected African Women followed in the HPTN 046 Clinical Trial, A Randomized Placebo Controlled Trial of Infant NVP from 6 weeks to 6 months.	Abstract	CROI 2012	Mary Glenn Fowler, Elizabeth Brown, Bonnie Maldonado, Tsungai Chipato, Karim Manji, Kathy George, Susan Eshleman, Sheryl Zwierski, Jerry Coovadia and Heather Watts for the HPTN 046 Team.	Accepted
Efficacy and Safety of an Extended Nevirapine Regimen in Breastfeeding Infants of HIV-1-Infected Women for Prevention of Postnatal HIV Transmission: Results of the Randomized, Double-Blind, Placebo-Controlled HPTN 046 Trial	Manuscript	The Lancet Journal	Hoosen M. Coovadia MD, Elizabeth R. Brown, Mary Glenn Fowler, Tsungai Chipato, Dhayendre Moodley, Karim Manji, Philippa Musoke, Lynda Stranix-Chibanda, Vani Chetty, Wafaie Fawzi, Clemensia Nakabiito, Lindiwe Msweli, Roderick Kisenge, Laura Guay, Anthony Mwatha, Diana J. Lynn, Susan H. Eshleman, Paul Richardson, Kathleen George, Philip Andrew, Lynne M. Mofenson, Sheryl Zwierski, and Yvonne Maldonado for the HPTN 046 Protocol Team	Accepted Under Final Review
Under Protocol Version 2.0: Extended prophylaxis with Nevirapine and Cotrimoxazole among HIV Exposed Uninfected Infants is Safe	Manuscript	AIDS Journal	J. Azire M.G Fowler, Jing Wang, et al.	Pending Publication

HPTN 046 Manuscript Bibliography
New since last report, highlight in yellow

None

HPTN 046 Presentation Bibliography
New since last report, highlight in yellow

Under Protocol Version 2.0:

1. J. Azire. Extended prophylaxis with Nevirapine and Cotrimoxazole among HIV Exposed Uninfected Infants is Safe (Oral Presentation). 2nd International Workshop on HIV Pediatrics; 16-17 July 2010, Vienna, Austria (abstract O_24).
2. J. Azire. Extended prophylaxis with Nevirapine and Cotrimoxazole among HIV Exposed Uninfected Infants is Safe (Poster Presentation). XVIII International AIDS Conference; 18-23 July 2010, Vienna, Austria (abstract MOPE0281).
3. J. Azire. Extended prophylaxis with Nevirapine and Cotrimoxazole among HIV Exposed Uninfected Infants is Safe (Oral Presentation). 4th National Paediatric HIV/AIDS Conference, September 2010, Kampala, Uganda.
4. J. Azire. United States Division of AIDS (DAIDS) Toxicity Tables Overestimate Neutropenia among African HIV Exposed Uninfected Infants (Poster Presentation). 3rd International Workshop on HIV pediatric; 15-16 July 2011 in Rome, Italy.
5. J. Azire. United States Division of AIDS (DAIDS) Toxicity Tables Overestimate Neutropenia among African HIV Exposed Uninfected Infants (Poster Presentation). 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention, 17-20 July 2011, in Rome, Italy.

Under Protocol Version 3.0:

None

Report for HPTN Study Operations Group

HPTN 052

A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 In Serodiscordant Couples

Based on available data through: 9 December 2011

Participating Study Sites:

- Gaborone, Botswana
- Porto Alegre and Rio de Janeiro, Brazil
- Chennai, India
- Pune, India
- Blantyre, Malawi
- Lilongwe, Malawi
- Johannesburg, South Africa
- Soweto, South Africa
- Chiang Mai, Thailand
- Harare, Zimbabwe
- Kisumu, Kenya

Study Implementation Status:

All sites listed above are operating under Version 3.0 of the protocol. Enrollment is closed as of April 2010. Follow-up is on-going.

The HPTN 052 DSMB met 28 April 2011 and issued the following recommendations:

1. The Board recommends that the results of the trial be announced as soon as possible.
2. The Board congratulates the team for a very well-done trial that definitively shows that immediate ART reduces transmission of HIV.

In response to the above recommendations, LoA#5 to V. 3.0, a "Dear Participant" letter, and the DSMB summary and recommendations have been provided to the study sites. The sites have submitted these documents to their IRBs/ECs for approval, and are providing the "Dear Participant" letter to the study participants. It should be noted that the "Dear Participant" letter offers study-provided ART to all Index Cases on the delayed arm.

The status of IRB/EC approvals, as well as the response by the participants to the "Dear Participant" letter are being tracked.

The team is discussing an amendment to the study for continued follow up of currently enrolled couples. Details are being considered.

Refer to the Network Laboratory report for any issues and problems related to the clinical site laboratories.

HPTN 052 Accepted Publications and Presentations Table

Title	Type	Conference/Reference	Authors/Presenters	Status
n/a (9 December 2011) *				

*other manuscripts have been submitted but not yet accepted at the time of this report, and some are still in development but not submitted

HPTN 052 Manuscript Bibliography
New since last report, highlight in yellow

1. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011; 365(6):493-505.
2. Eshleman SH, Hudelson SE, Redd AD, Wang L, Debes R, Chen YQ, et al. Analysis of Genetic Linkage of HIV From Couples Enrolled in the HIV Prevention Trials Network 052 Trial. *J Infect Dis* 2011.

HPTN 052 Presentation Bibliography
New since last report, highlight in yellow

1. Godbole, S., et al. Antiretroviral Therapy to Prevent the Sexual Transmission of HIV-1: Initial Results from HPTN 052. Poster presented at IAS, 19 February 2008. Abstract# TUPE0046.
2. Kumarasamy N., et al. Antiretroviral Therapy to Prevent the Sexual Transmission of HIV-1 and Reduce HIV Associated Morbidity and Mortality: Baseline Data from HPTN 052. Poster presented at IAS, 19 July 2010. Abstract# MOPE0398.
3. Cohen, M.S., et al. Antiretroviral treatment to prevent the sexual transmission of HIV-1: results from the HPTN 052 multinational randomized controlled trial. Oral presentation at IAS, July 2011. Abstract# MOAX0102.
4. Grinsztejn, B., et al. Effects of early versus delayed initiation of antiretroviral therapy (ART) on HIV clinical outcomes: results from the HPTN 052 randomized clinical trial. Oral presentation at IAS, July 2011. Abstract# MOAX0105.
5. Hughes, J., et al. Analysis of genetic linkage of HIV from couples enrolled in the HIV Prevention Trials Network (HPTN) 052 trial. Oral presentation at IAS, July 2011. Abstract# MOAX0103.
6. Hosseinipour, M.C., et al. Immunologic and virologic disease progression and responses to ART across geographic regions: outcomes from HPTN 052 study. Oral presentation at IAS, July 2011. Abstract# MOAX0104.

Report for HPTN Study Operations Group

HPTN 057

A Phase I Open Label Trial of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-1 Infected Pregnant Women and their Infants

Based on data available through: December 12, 2011

Participating Study Sites:

- Queen Elizabeth Central Hospital, Blantyre Malawi (QECH)
- Federal University of Minas Gerais, Belo Horizonte (UFMG)
- Irmandade Santa Casa de Misericordia de Porto Alegre, Porte Alegre (Santa Casa)
- Hospital dos Servidores do Estado – Servico de Doencas Infecciosas, Rio de Janeiro (HSD)
- Hospital Nossa Senhora da Conceicao Servico de Infectologia, Porte Alegre (Conceicao)

Study Implementation Status:

Enrollment was completed in November 2011. Follow-up is for 1 year. The expected study completion date is December 2011. Safety and pk analysis for Cohorts 1 – 3 is complete. Analysis of cohort 4 pk data is underway and is expected to be completed in 1st quarter 2012.

Accrual Status: Complete.

Site	# Evaluable Mother/Infant Pairs Enrolled			
	Cohort 1	Cohort 2	Cohort 3	Cohort 4
Queen Elizabeth Central Hospital, Blantyre Malawi	24	16	15	15
Santa Casa, Porte Alegre Brazil	3	4	4	2
University of Minas Gerais, Belo Horizonte Brazil	3	1	2	3
Conceicao, Porte Alegre Brazil	-	-	4	5
Hospital do Servidores, Rio de Janeiro Brazil	-	-	5	6
Total	30	21	30	31

Status of Intervention Delivery: Not Applicable

Retention Status: Two mother/infant pairs for Cohorts 1 – 3 have been lost to follow-up.

Implementation Issues and Problems: None

**HPTN 057 Accepted Publications and Presentations Table
(Publications/Presentations in process)**

None

**HPTN 057 Manuscript Bibliography
(Published)**

New since last report, highlight in yellow

None

**HPTN 057 Presentation Bibliography
(Previously presented)**

New since last report, highlight in yellow

1. Karin Nielsen-Saines. Bone Age and Mineral Density Assessments Using Plain Roentgenograms in Tenofovir (TDF) exposed infants in Malawi and Brazil Enrolled in HPTN 057 (Poster Presentation). American Pediatric Society/Society for Pediatric Research Annual Meeting; May 1-4, 2010, Vancouver, Canada.
2. M. Mirochnick. Tenofovir Disoproxil Fumarate (TDF) Pharmacokinetics (PK) with Increased Doses in HIV-1 Infected Pregnant Women and their Newborns (HPTN 057) (Oral Presentation). 11th International Workshop on Clinical Pharmacology of HIV Therapy; April 7-9, 2010, Sorrento, Italy.
3. Mark Mirochnick. Pharmacokinetics (PK) of Tenofovir Disoproxil Fumarate (TDF) After Administration to HIV-1 Infected Pregnant Women and their Newborns (Poster Presentation). The 16th Conference on Retroviruses and Opportunistic Infections (CROI 2009); February 8-11, 2009, Montreal, Canada.

Report for HPTN Study Operations Group

HPTN 058

A Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection and death among opiate dependent injectors

Based on data available through 10 December 2011

Participating Study Sites:

- Xinjiang Uighur Autonomous Region, Centers for Disease Control and Prevention, Xinjiang, China
- Guangxi Zhuang Autonomous Region, Centers for Disease Control and Prevention, Heng County, Guangxi, China
- Guangxi Zhuang Autonomous Region, Centers for Disease Control and Prevention, Nanning, Guangxi, China
- Research Institute for Health Sciences, Chiang Mai, Thailand

Study Implementation Status:

Enrollment is ended early due to feasibility concerns for the primary endpoint raised by the DSMB. Overall, 1,252 participants were enrolled out of the planned 1,500 with 202 in Chiang Mai, 478 in Xinjiang, 411 in Heng County and 161 in Nanning.

Accrual Status:

	Chiang Mai	Nanning	Heng County	Xinjiang
Date First Screened	11-Apr-07	6-May-10	19-Dec-08	19-Dec-08
Date First Enrolled	30-May-07	19-May-10	24-Dec-08	21-Dec-08
# Individuals Screened	281	366	863	874
# Individuals Enrolled	202	161	411	478

Status of Intervention Delivery:

Study drug has been generally well tolerated.

Retention Status:

All Sites	
Week 26	89%
Week 52	83%
Week 78	85%
Week 104	81%
Week 130	73%
Week 156	83%

Implementation Issues and Problems:

On October 17, 2011 HPTN announced that HPTN 058 is being closed to new enrollment, and a phase-out of the study was initiated.

**HPTN 058 Accepted Publications and Presentations Table
(Publications/Presentations in process)**

None

**HPTN 058 Manuscript Bibliography
(Published)**

New since last report, highlight in yellow

1. Sugarman, J.; Corneli, A.; Donnell, D.; Liu, T. Y.; Rose, S.; Celentano, D.; Jackson, B.; Aramrattana, A.; Wei, L.; Shao, Y.; Liping, F.; Baoling, R.; Dye, B.; & Metzger, D. (2011). Are there adverse consequences of quizzing during informed consent for HIV research? *Journal of Medical Ethics* 37 (11):693-697
2. Lucas, G.; Beauchamp, G.; et. al. (2011). Short-term safety of buprenorphine/naloxone in HIV-seronegative opioid-dependent Chinese and Thai drug injectors enrolled in HIV Prevention Trials Network 058. *International Journal of Drug Policy*

**HPTN 058 Presentation Bibliography
(Previously presented)**

New since last report, highlight in yellow

1. Greg Lucas, Deborah Donnell, David Metzger. Short-term safety of BUP/NX in a planned subset of opioid-dependent, HIV seronegative, Chinese and Thai injection drug users enrolled in HPTN 058. Poster presented at NIDA International Forum June 11-15, 2010
2. Carin Busch, Shuaifeng Liu, et al. Improvement of Quality Assurance/Quality Control Process for HPTN 058 trial in Guangxi, China. Poster presented at HPTN Annual Meeting June 6-10, 2010
3. Apinun Aramrattana. Oral Abstract presenting HPTN 058 and most recent safety data on first 50 participants. Oral presentation at Chiang Mai University Annual Research Conference Dec 8-10, 2008
4. Xinjiang Team. Progress and Challenges of HPTN 058 in Urumqi. Poster presented at HPTN Annual Meeting June 6-10, 2010
5. Chiang Mai Team. HPTN 058 mobile operations for improving recruitment and retention of opiate injection participants in northern Thailand remote areas. Poster presented at HPTN Annual Meeting June 6-10, 2010
6. Jianhua Huang, Shuaifeng Liu, et. al.. Recruitment Strategies in HPTN 058 trial in Guangxi, China. Poster presented at HPTN Annual Meeting June 6-10, 2010
7. Tساناي Vongchak, Umpava Timpan, Marisa Guptarak, et. al. Using Mobile operations to improve retention of opiate injecting participants living in remote areas of northern Thailand in HPTN 058. Poster presented at 19th Annual Meeting on NIDA SPR International Poster Session (May 31- June 3, 2011)
8. Tساناي Vongchak, Umpava Timpan, Kanungnit Nugate, et. al. Counseling Outcomes in BUP/NX Treatment Program. Presented at Harm Reduction 2011: IHRA's 22nd International Conference: April 3-7, 2011 in Beirut, Lebanon

9. Jun Ma. HPTN 058 in Xinjiang, China. Poster presented at HPTN Annual Meeting June 2011
10. J.J. Chen, J.B. Chen, Y. Chen, B.H. He, J.H. Huang, C.H. Lei, S. Liu, Y.L. Long, W. Liu- Guangxi Center for Disease Control and Prevention, M. Abbott, S. Bolton, J. Ko, M. Motevalli, J. B. Jackson. Retention: Strategies and their Effectiveness in the HPTN 058 Trial in China (Heng County). Poster presented at HPTN Annual Meeting June 2011
11. Guangxi Team. A Comprehensive Tracking System for Outreach Activities in a Clinical Trial; HPTN 058 Study in China (Guangxi)
12. L. Yu, K. Cai, Y. Chen, X. Deng¹, N. Guo, F. Liang, S. Liu¹, C. Li, R. Li, K. Wei, F. Zhong, J. Mo, W. Liu. Recruitment in HPTN 058 Clinical Trial, Nanning, Guangxi, China. Poster presented at HPTN Annual Meeting June 2011

Report for HPTN Study Operations Group

HPTN 061

Feasibility Study of a Community-level, Multi-component Intervention for Black Men who have Sex with Men in Preparation for a Community-level Randomized Trial to Test the Efficacy of the Intervention in Reducing HIV Incidence Among Black Men who have Sex with Men

Based on data available through: 02 December 2011

Participating Study Sites:

- Ponce de Leon Center CRS (site 5802) and Hope Clinic CRS (site 31440) in Atlanta and Decatur, Georgia, respectively
- San Francisco Vaccine and Prevention CRS in San Francisco, California (site 30305)
- New York Blood Center (NYBC)/Union Square CRS (site 31605) and Harlem Prevention Center CRS (site 30276) in New York City, New York
- University of California at Los Angeles (UCLA) Vine Street CRS (site 31607) in Los Angeles, California
- The Fenway Institute CRS (site 31602) in Boston, Massachusetts
- George Washington University CRS (site 31608) in Washington, D.C.

Study Implementation Status:

All sites for the HPTN 061 protocol have finished enrolling and are following participants.

Site	Date of Activation	Date of First Enrollment	Date of Completion of Community Recruitment
The Fenway Institute	06 July 2009	17 July 2009	29 Sept 2010
George Washington University	20 July 2009	28 July 2009	28 Sept 2010
San Francisco Vaccine and Prevention CRS	11 August 2009	13 August 2009	29 Sept 2010
New York Blood Center	24 August 2009	01 October 2009	27 July 2010
Hope Clinic CRS	04 September 2009	16 September 2009	16 Sept 2010
UCLA	25 September 2009	29 September 2009	29 Sept 2010
Ponce de Leon CRS	09 October 2009	26 February 2010	16 Sept 2010
Harlem Prevention Center	05 January 2010	08 January 2010	17 June 2010

Final Site-Reported Total Enrollment:

Fenway	GWU	Emory: Ponce + Hope	San Fran	UCLA	NYBC	Harlem	TOTAL
237	227	292	204	283	156	154	1,553

Status of Intervention Delivery:

All sites will cease follow up by 09 December

Recruitment Status:

All recruitment has been completed. Total enrollment was 1553.

Retention Status:

Retention for the 6 month visit is at 81%.

Retention for the 12 month (exit) visit is at 80%

Implementation Issues and Problems:

No notable issues or problems

**HPTN 061 Accepted Publications and Presentations Table
(Publications/Presentations in process)**

None

**HPTN 061 Manuscript Bibliography
(Published)**

New since last report, highlight in yellow

**HPTN 061 Presentation Bibliography
(Previously presented)**

New since last report, highlight in yellow

1. Jonathan Lucas, Georgette King, Chadwick Campbell, Christopher Watson. Mobilizing United States' Diverse Black MSM Population: The revolutionary leadership and community engagement strategies of HPTN 061, the BROTHERS study. Workshop conducted at Faces of Urban Health Forum on October 26, 2010
2. Sheldon D. Fields, PhD, RN., Jonathan Lucas, MPH., Christopher C. Watson, BS., Gregory A. Victorienne, BA., Benjamin Perkins, MA, M.Div., Craig Hutchinson, MPH., Jermel Wallace, MHS., Irvin Parker, Michael Arnold, PhD., and HPTN 061 Black Caucus. Where are the brothers? Successes and challenges of Retaining Black MSM in Clinical Research Studies. Workshop conducted at NAESM meeting on January 18, 2011.
3. Justin Hardick, Nicole Quinn, Susan Eshleman, Estelle Piwowar-Manning, Vanessa Cummings, The HPTN 061 Study Team, Charlotte Gaydos. Multi-Site Screening for Lymphogranuloma venereum (LGV) in the United States. Presented during the ISSTD conference ISSTD Conference July 10-13, 2011.
4. Leo Wilton, Chauncey Watson, Lawrence Bryant, Jonathan Lucas, Gregory Victorienne, Sheldon Fields, Darrell Wheeler, and HPTN 061 Black Caucus. The Development of a Black Caucus in a Community Level HIV Prevention Intervention for Black MSM in Six Cities in the US. Presented during CDC HIV Prevention Conference August 14-17, 2011.
5. Christopher Watson, Christopher Hucks-Ortiz, Sheldon D. Fields, Leo Wilton, and HPTN 061 Black Caucus. Mobilizing the United States' Diverse African American MSM population: Engagement, Recruitment and Retention Strategies of HPTN 061, the BROTHERS Project. Poster presented during the APHA Conference October 31, 2011.
6. Sheldon Fields, Christopher Watson, Gregory Victorienne, Jonathan Lucas, and HPTN 061 Black Caucus. Lessons Learned from a Retreat on Retention of Black MSM in the BROTHERS Study. Presented at the 2011 National HIV Prevention Conference, Atlanta, GA. 15-Aug-11.

Report for HPTN Study Operations Group

HPTN 062

Feasibility and Acceptability Study of an Individual-Level Behavioral Intervention for Individuals with Acute and Early HIV-Infection

Based on data available through: 06 December 2011

Participating Study Sites:

- University of North Carolina Project, Kamuzu Central Hospital, Lilongwe, Malawi

Study Implementation Status:

Lilongwe site was activated on 24 February 2010 and began enrolling in April 2010. Enrollment is dependent on identifying acutely infected people in the CHAVI 001 study, hence enrollment is sporadic. As of December 2011, CHAVI 001 will cease identifying acutely infected individuals; therefore, recruitment for 062 will also cease in late December.

A Publication Plan has been written and the team has discussed potential papers; six papers are planned as of now. A qualitative analysis workshop will be conducted at the site to allow local staff the opportunity to contribute to those potential papers.

Accrual Status (completed at all sites):

Twenty-seven participants have been enrolled to date (excluding one participant that was an enrollment error and was un-enrolled in 062). CHAVI 001 screening for acutely infected individuals has ceased, and hence, no further enrollments are possible for 062.

Status of Intervention Delivery:

Most study visits have been completed on time; retention is high. The last participant visit is scheduled for March 2012.

Retention Status:

See the SCHARP report.

Implementation Issues and Problems:

None.

Publications/Presentations

None

Report for HPTN Study Operations Group

HPTN 063 Preparing for International Prevention Trials Involving HIV-Infected Individuals in Care Settings

Based on data available through: 09 December 2011

Participating Study Sites:

- Matero Clinic CRS; Lusaka, Zambia
- Chiang Mai University AIDS Prevention CRS; Chiang Mai, Thailand
- Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS; Rio de Janeiro, Brazil

Study Implementation Status:

Version 1.0 of the protocol was approved on 16 September 2008 and distributed to sites upon notification of approval (17 September 2008). Letter of Amendment (LoA) #1 (Zambia only) dated 12 May 2010, was approved by DAIDS on 18 May 2010. LoA #2, dated 7 December 2010, was approved by DAIDS on 9 December 2010. LoA #3, dated 6 July 2011, was approved by DAIDS on 20 July 2011.

Version 2.0 of the protocol dated 04 November 2011 was distributed to sites upon notification of approval (07 November 2011).

The Thai site was activated on 26 March 2010 and enrolled their first participant on 01 April 2010. Enrollment was paused on 22 June 2010 due to ACASI issues discussed during the 2010 HPTN Annual Meeting. The Thai site received DAIDS approval to resume screening/enrollment activities on 08 February 2011 after the ACASI was revised. Screening and enrollment activities resumed in Thailand on 14 February 2011. The Thai site successfully completed enrollment of women on 16 September, 2011. The site closed enrollment on 18 November, 2011. An extension was granted on their enrollment period and all IRB approvals were received on 8 December 2011. The site will resume enrollment activities on 12 December 2011.

The Brazil site was activated on 30 March 2011 and enrolled their first participant on 01 April 2011.

The Zambia site was activated on 19 April 2011 and enrolled their first participant on 20 April 2011.

Accrual Status:

Below is site-reported screening and enrollment data ending 04 October 2011. Refer also to the SCHARP enrollment summary.

Retention Status:

Refer to the SCHARP retention summary

HPTN-063 Cumulative Screening and Enrollment Report

Based on Site-Reported Information

November 25, 2011

Site (Quantitative Participants)	Date of First Screening	Date of First Enrollment	No. Pre- Screened	No. Report No Unprotect ed Sex	No. Not Receiving Care	Total No. Screened	Total No. Enrolled
Brazil: Rio de Janeiro (IPEC CRS)	01-Apr-11	01-Apr-11					
Women			465	83	2	146	46
Heterosexual Men			319	36	2	56	18
MSM			247	56	0	116	47
Thailand: Chiang Mai	01-Apr-10	01-Apr-10					
Women			1227	4	0	107	100
Heterosexual Men			1943	5	0	76	66
MSM			292	0	0	43	42
Zambia: Lusaka (Metero Clinic CRS)	20-Apr-11	20-Apr-11					
Women			278	144	2	76	75
Heterosexual Men			123	64	0	42	35
TOTAL	N/A	N/A	4984	392	6	662	429

Thailand (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders	MSM	Thailand (Focus Groups)	Date of Focus Group	No. of participant
Date of Interview	17-May-10	22-Jul-10	1-Oct-10	17-May-10	Session 1	17-Jun-10	8
	22-Jul-10	15-Sep-10	6-Oct-10	19-May-10	Session 2	27-Jan-11	11
	10-Sep-10	20-Apr-11	19-Oct-10	5-Aug-10	Session 3		
	20-Sep-10	14-Jul-11	17-Nov-10	18-Mar-10	Session 4		
	24-Mar-10		2-Dec-10	31-May-11	TOTAL	2	19
	21-Apr-11			26-Jun-11			
	12-May-11			3-Aug-11			
	23-Aug-11						
	23-Sept-11						
	30-Sept-11						
TOTAL	10	4	5	7			

Brazil (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders	MSM	Brazil (Focus Groups)	Date of Focus Group	No. of participants
Date of Interview	27-Sep-11	20-Sep-11		18-Jul-11	Session 1	27-Oct-11	9
	7-Oct-11	5-Oct-11		3-Oct-11	Session 2		
	14-Oct-11	25-Oct-11		18-Oct-11	Session 3		
	21-Oct-11			19-Oct-11	Session 4		
	21-Oct-11			21-Oct-11	TOTAL	0	9
				21-Oct-11			
				25-Oct-11			
				27-Oct-11			
				31-Oct-11			
	TOTAL	5	3	0	9		

Zambia (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders	Zambia (Focus Groups)	Date of Focus Group	No. of participants
Date of Interview	10-May-11			Session 1		
				Session 2		
				Session 3		
				Session 4		
				TOTAL	0	0
TOTAL	1	0	0			

Implementation Issues and Problems:

Sites identified challenges recruiting men into HPTN 063 for various reasons but primarily because men are significantly less likely to report sexual risk behavior during the pre-screening/screening visits. During the full team meeting at the 2011 HPTN Annual Meeting, the sites and protocol team explored different avenues of recruiting men in HPTN 063 and have proposed new recruitment methods. The protocol team has increased calls to bi-monthly with each site to monitor recruitment and evaluate the newly proposed recruitment methods. The HPTN 063 Protocol Team has incorporated changes to the protocol to modify the eligibility criteria in order to be more inclusive of various degrees of sexual risk in Version 2.0. Additionally, weekly screening and enrollment reports, as well as monthly accrual graphs are distributed to the full protocol team and closely monitored. Members of CORE and SCHARP performed a site assessment visit the last week in September at the Brazil site to provide training assistance to new staff and also help strengthen their recruitment plans. Members from the CORE and NL traveled to Zambia November 9-11, 2011 for an assessment visit to review lab management and also strategize about male recruitment.

Publications/Presentations

None

**Report for HPTN Study Operations Group
HPTN 064
Women's HIV SeroIncidence Study (ISIS)**

Based on data available through: 04 November 2011

Participating Study Sites:

- Emory University, Atlanta, Georgia (Ponce de Leon Center CRS and Hope Clinic CRS)
- Johns Hopkins Adult AIDS CRS, Baltimore, Maryland
- University of North Carolina-Chapel Hill, North Carolina (UNC AIDS CRS and Wake County Health and Human Services CRS)
- Columbia University, New York, New York (Bronx-Lebanon Hospital Center CRS and Harlem Prevention Center CRS)
- New Jersey Medical School Adult Clinical Trials Center, Newark, New Jersey
- George Washington University School of Public Health and Health Services, Washington D.C.

Study Implementation Status:

HPTN 064 successfully completed enrollment July 26, 2010, enrolling 2099 women. All study visits were completed on February 28, 2011.

Study close out, data analysis and laboratory assessments are currently underway.

Please see the attached form for a listing of study abstracts and publications.

Accrual Status:

Completed.

Status of Intervention Delivery:

N/A

Retention Status:

Completed. Please see SCHARP Retention Report.

Implementation Issues and Problems: N/A

HPTN 064 Accepted Publications and Presentations Table

Title	Type	Conference/Reference	Authors/Presenters
HIV Incidence in Women at Risk for HIV Acquisition in the US: The HPTN 064 (ISIS Study)	Poster Presentation	Conference on Retroviruses and Opportunistic Infections (CROI 2012) March 5-8, 2012	Hodder S, Justman J, Hughes J, Wang J, Haley D, Adimora A, Del Rio C, Soto-Torres L, Eshleman S, and El Sadr W for the HIV Prevention Trials Network (HPTN) 064 Study Team
Use of a Multifaceted Approach for Analysis of HIV Incidence in the Women's HIV Seroincidence Study (HPTN 064)	Poster Presentation	Conference on Retroviruses and Opportunistic Infections (CROI 2012) March 5-8, 2012	Eshleman S, Hughes J, Laeyendecker O, Johnson-Lewis L, Wang J, Vallari A, Haley D, Soto-Torres L, Justman J, and Hodder S for the HPTN 064 Study Team
HPTN 064 (ISIS): Identifying and Retaining US Women at Increased Risk of HIV Infection	Oral Presentation	National HIV Prevention Conference August 15, 2011	Haley DF, Lucas JP, Waller HC, DiNenno EA, Soto Torres LE, Justman JE, Hodder SL.
Multilevel determinants of women's HIV risk in the United States: Qualitative implications for intervention development from the HIV Prevention Trial Network's (HPTN) Women's HIV SeroIncidence Study (ISIS)	Oral Presentation	International Aids Society July 19, 2011	Frew PM, del Rio C, Kuo I, O'Leary A, Chege W, Justman J, Golin CE, Haley DF, Root C, Waller H, Jones L, Lancaster K, Amsterdam A, Lucas J, and Hodder SL for the HIV Prevention Trials Network Women's HIV SeroIncidence Study (ISIS) Team

Male attitudes toward HIV Testing among Men in 4 US Cities	Poster	International Aids Society July 17-20, 2011	Golin C, Haley DF, Frew P, Kuo I, Soto-Torres L, Justman J, Waller H, Amola O, Jones L, Amsterdam A, Adimora A, Fogel CI, Amola A, Smith J, Lancaster K, Lucas JP, O'Leary A and Hodder SL on behalf of the HIV Prevention Trials Network (HPTN) 064, HIV SeroIncidence (ISIS) Team
Condom use among U.S. women at high risk for HIV infection—implications for HIV prevention	E-Poster (CD)	International Aids Society July 17-20, 2011	Kuo I, O'Leary A, Justman J, Frew P, Golin CE, Haley DF, Amsterdam A, Lancaster K, Waller H, Jones L, Lucas JP, Soto-Torres L and Hodder SL, for the HIV Prevention Trials Network (HPTN) Women's HIV SeroIncidence Study (ISIS) Team
Contextual factors associated with low condom use among women at high risk for HIV/AIDS	Oral Presentation	VOICES May 22, 2011	Merchant S, Waller H, Jones L, Cokley C, Shabazz-El W, Kuo I, O'Leary A, Justman J, Frew P, Golin CE, Haley DF, Amsterdam A, Lancaster K, Lucas J, Soto-Torres L for the HIV Prevention Trials Network (HPTN) 064 Women's HIV SeroIncidence Study (ISIS) Team

HPTN 064 Manuscript Bibliography
New since last report, highlight in yellow

HPTN 064 Presentation Bibliography
New since last report, highlight in yellow

1. Haley DF, Lucas JP, Waller HC, DiNenno EA, Soto Torres LE, Justman JE, Hodder SL. **HPTN 064 (ISIS): Identifying and Retaining US Women at Increased Risk of HIV Infection, An Iterative Approach.** In: 2011 National HIV Prevention Conference, Atlanta Ga, August 14-17, 2011
2. Frew PM, del Rio C, Kuo I, O'Leary A, Chege W, Justman J, Golin CE, Haley DF, Root C, Waller H, Jones L, Lancaster K, Amsterdam A, Lucas J, and Hodder SL for the HIV Prevention Trials Network Women's HIV SeroIncidence Study (ISIS) Team (Oral Presentation). **Multilevel determinants of women's HIV risk in the United States: Qualitative implications for intervention development from the HIV Prevention Trial Network's (HPTN) Women's HIV SeroIncidence Study (ISIS).** In: 2011 International AIDS Society Annual Meeting, Rome, Italy, July 17-20, 2011
3. Golin C, Haley DF, Frew P, Kuo I, Soto-Torres L, Justman J, Waller H, Amola O, Jones L, Amsterdam A, Smith J, Lancaster K, Lucas JP, O'Leary A and Hodder SL on behalf of the HIV Prevention Trials Network (HPTN) 064, HIV SeroIncidence (ISIS) Team (Poster). **Male attitudes toward HIV Testing among Men in 4 US Cities.** In: 2011 International AIDS Society Annual Meeting, Rome, Italy, July 17-20, 2011
4. Kuo I, O'Leary A, Justman J, Frew P, Golin CE, Haley DF, Amsterdam A, Lancaster K, Waller H, Jones L, Lucas JP, Soto-Torres L and Hodder SL, for the HIV Prevention Trials Network (HPTN) Women's HIV SeroIncidence Study (ISIS) Team (E-Poster). **Condom use among U.S. women at high risk for HIV infection—implications for HIV prevention.** In: 2011 International AIDS Society Annual Meeting, Rome, Italy, July 17-20, 2011
5. Merchant S, Waller H, Jones L, Cokley C, Shabazz-EI W, Kuo I, O'Leary A, Justman J, Frew P, Golin CE, Haley DF, Amsterdam A, Lancaster K, Lucas J, Soto-Torres L for the HIV Prevention Trials Network (HPTN) 064 Women's HIV SeroIncidence Study (ISIS) Team. **Contextual factors associated with low condom use among women at high risk for HIV/AIDS.** In: 2011 Voices Conference, Arlington, VA, May 21-24, 2011.

Report for HPTN Study Operations Group

HPTN 065

TLC-Plus: A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus Treat Approach for HIV Prevention in the United States

Based on available data through: 8 December 2011

Participating Study Sites:

HPTN 065 includes two intervention communities (Washington, D.C. and the Bronx, New York) and four comparator communities (Miami, Florida; Philadelphia, Pennsylvania; Chicago, Illinois; and Houston, Texas). A total of 77 sites (38 test sites and 39 care sites) located in Washington, D.C. and the Bronx, New York are actively participating in the study.

Bronx:

Nineteen test sites (including 9 hospitals) and 20 care sites are participating in the study. (Note that two hospitals have been combined into one entity for randomization.)

Washington, DC:

Nineteen test sites (including 7 hospitals) and 19 care sites are participating in the study.

Study Implementation Status:

Expansion of HIV testing:

- Social Mobilization: The first social mobilization ads began on November 19, 2010 in DC on social networking and dating websites and in print. The NY social mobilization campaign began on April 1, 2011. Ads have been placed on dating sites, community blogs, and printed in magazines that target MSM.
 - Posters in both English and Spanish were developed for distribution in the Bronx. Sites have placed ads in their clinics and around the Bronx.
 - Appointment cards to encourage testing twice a year have been developed by the ad agency in DC and will be distributed by the DC DOH. As well, promotional water bottles have been ordered and will be distributed to sites by the DC DOH.
- Expanded Testing in Hospitals: February 1, 2011 marked the official start of the Expanded Testing component in hospitals. All DC (7) and Bronx (9) hospitals have begun submitting HIV testing data for the study via an Atlas-based data collection tool. Calls and/or site visits are being held with hospitals on an as-needed basis.
 - Monthly baseline rates for offering an HIV test (1st 6 months) range from 2% to 63% (mean = 22%, median = 18%) in the inpatient setting and 0% to 43% (mean = 11%, median = 7%) in the ED setting.
 - All hospitals are receiving an additional sum of money provided via an Inter-agency Agreement with the CDC to scale-up testing in in-patient admissions. As part of these efforts, a webinar for lab staff on HIV testing is being organized in conjunction with the CDC, and a technical assessment of lab involvement in HIV testing is currently being developed.

Linkage-to-Care (L2C) and Viral Suppression (VS):

- The Linkage-to-Care component began on April 1, 2011 for DC and Bronx test sites. To date, all test sites in DC and the Bronx have been activated; 90% of Bronx test sites and 100% of DC test sites have begun dispensing coupons. All care sites in the Bronx and DC have been activated to redeem coupons for gift cards.
- The Viral Suppression component began at 10 DC care sites on February 1, 2011. The VS component began on March 1, 2011 at one Bronx care site and on April 1, 2011 at the remaining DC and Bronx care sites. To date, all DC and Bronx care sites have been activated, and all have begun dispensing gift cards.

Prevention for Positives (PfP):

- A subset of 12 care sites (6 in NY and 6 in DC) have been invited and officially agreed to participate in the PFP study component. The team is proceeding with contract and IRB approval processes for the 12 sites. To date, 5 sites in DC and 4 sites in the Bronx have received IRB approval for this component. Six sites in DC and no sites in the Bronx have signed contracts.
- The study team has decided to move forward with a brief patient acceptability test of the CARE+ program with a small sample of patients from 3-4 participating PfP sites in DC and the Bronx. The anticipated start date of the patient acceptability test is January, 2011. The anticipated field date for the PFP component is late first quarter, 2012, after the acceptability test has been completed.

Patient and Provider Surveys:

- The Provider Survey closed on May 2, 2011. The final response rate for this baseline survey was 60%, 53% in the Bronx and 71% in DC. A draft manuscript presenting these data is currently being reviewed by the study team.

Site and DOH Surveys:

- All test and care sites have been trained on how to enter data into Atlas, and all sites except for 1 Bronx site (due to an IRB issue) have received an invitation to take the annual site survey. To date 10 out of 19 test sites (52%) in DC and 12 out of 19 test sites (63%) in the Bronx have completed the test site survey. Thirteen out of 19 care sites (68%) in DC and 12 out of 20 care sites (60%) in the Bronx have completed the care site survey.
- SCHARP is in the process of developing a fillable pdf version of the DOH survey to send to DOHs. DOH surveys will be implemented on a rolling basis once the document is finalized.

Training Update

- The study team is providing refresher trainings for sites and new staff members via phone or in person, as needed or requested.

Investigator of Record (IoR) Calls

- The study chair and co-chair are holding grouped calls with all IoRs at all study sites in order to give a comprehensive update on the status of the study. There will be two calls for D.C. sites and 2 calls for Bronx sites. The calls are planned for the week of Dec. 12th.

Reviews:

- The first SMC and DSMB reviews are tentatively scheduled for Feb/March 2012 (the exact date is still to be determined).
- Membership for the SMC has been confirmed. Members include: Jono Mermin, Tom Coates, and Grant Colfax

Publications: The table on the next page outlines the HPTN 065 manuscripts and presentations and their current status.

Accrual Status: N/A

Retention Status: N/A

Implementation Issues and Problems:

None

**HPTN 065 Accepted Publications and Presentations
(Publications/Presentations in process)**

Title	Type	Conference/Reference	Authors/Presenters	Status
Use of HIV Case Surveillance System to design and evaluate site-randomized interventions in an HIV prevention study: HPTN 065	manuscript	N/A	Deborah J Donnell, Irene Hall, Theresa Gamble, Geetha Beauchamp, Angelique B. Griffin, Lucia V. Torian and Bernard Branson	Accepted by The Open AIDS Journal

**HPTN 065 Manuscript Bibliography
(Published)**

New since last report, highlight in yellow

1. El-Sadr WM, Affrunti M, Gamble T, Zerbe A. Antiretroviral therapy: a promising HIV prevention strategy? J Acquir Immune Defic Syndr 2010 Dec; 55 Suppl 2: S116-21.

**HPTN 065 Presentation Bibliography
(Previously presented)**

New since last report, highlight in yellow

1. Hall HI. Test and Linkage to Care Study (Oral Presentation). In: 2010 Council of State and Territorial Epidemiologists (CSTE) Pre-conference HIV Surveillance Workshop. Portland, OR; June 6, 2010.
2. King G, and Lucas, JP. Exploring the TLC-Plus research study: Is a community-wide test and link to care strategy the key to curbing the HIV epidemic among Black men who have sex with men? 2011 National African American MSM Leadership Conference on HIV/AIDS and Other Health Disparities. Brooklyn, NY; January 21, 2011.
3. Donnell D, Hall HI, Jia Y, Griffin AB, Brady KA, Grigg RL, Sayegh MA, Torian LV and Wafaa El Sadr. Using HIV Surveillance Data to Evaluate Outcome of Site Randomized Interventions in the TLC-Plus Study. 2011 National HIV Prevention Conference. Atlanta, GA; August 15, 2011.
4. El-Sadr W, Branson BM, Donnell D, Hall HI, and King GM. TLC-Plus: Design and Implementation of a Community-focused HIV Prevention Study in the U.S. 2011 National HIV Prevention Conference. Atlanta, GA; August 17, 2011.

Report for HPTN Study Operations Group

HPTN 066

Dose-Proportionality And Intra-Individual Variability Of Intracellular Tenofovir Diphosphate And Emtricitabine Triphosphate In Healthy Volunteers

Based on data available through: 6 December 11

Participating Study Sites:

- Johns Hopkins University (JHU), Baltimore MD; USA
- University of North Carolina at Chapel Hill (UNC), Chapel Hill NC; USA

Study Implementation Status:

Version 2.0 of the protocol was granted final approval on 29 November 2010 and was distributed to the sites 1 December 2010. Letter of Amendment (LoA) #1 to HPTN 066, Version 2.0 was approved by DAIDS on 16 December 2010. Clarification Memo #1 to HPTN 066, Version 2.0 was approved by DAIDS on 15 June 2011.

32 evaluable participants completed the study; 13 from JHU and 19 from UNC. Accrual and follow-up activities have ended at both sites. The final participant completed follow-up at UNC on 20 October.

Accrual Status:

	UNC	JHU
Date First Screened	24-Jan-2011	21-Feb-2011
Date First Enrolled	7-Feb-2011	28-Feb-2011
# Individuals Screened	27	31
# Individuals Enrolled	19	19
Final # of evaluable participants	19	13

Status of Intervention Delivery:

Not applicable

Retention Status:

Refer to the SCHARP retention summary.

Implementation Issues and Problems:

None at this time.

Publications/Presentations

None

Report for HPTN Study Operations Group

HPTN 067

The ADAPT study:

A Phase II, Randomized, Open-Label, Pharmacokinetic and Behavioral Study of the Use of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis (PrEP)

Based on data available through December 9, 2011

Participating Study Sites:

- The Thailand Ministry of Public Health–United States (U.S.) Centers for Disease Control (CDC) collaboration (TUC) Silom Community Clinic in Bangkok, Thailand (31681)
- The Emavundleni Centre, The Desmond Tutu HIV Foundation in Cape Town, South Africa (30346)

Study Implementation Status:

The Cape Town site activated on 29 August and enrolled their first participant on 12 September 2011. Protocol team members Bonnie Dye (Clinical Research Manager) and Rivet Amico (Behavioral Scientist) traveled to the site in mid-November to provide booster trainings on counseling and performing weekly interviews. They also conducted an early site assessment visit.

The Bangkok site training was held 13-16 September 2011. The Thai ERC granted approval for Protocol Version 1.0. The CDC IRB reviewed the protocol 8 September and comments were received by the team 23 September 2011. Version 3.0 will need to be reviewed by the CDC and Thai ERC IRBs. Approval for Version 3.0 by both bodies is anticipated in early 2012.

Version 3.0 dated December 1, 2011 was approved and distributed to the team on 7 December 2011. This version includes changes requested during regulatory reviews and recent results from other PrEP trials.

The Site Selection Committee is in the process of selecting and confirming the addition of a US site.

Accrual Status:

	Cape Town	Bangkok
Date First Screened	30-Aug-2011	
Date First Enrolled	12-Sept-2011	
# Individuals Screened	92	
# Individuals Enrolled	50	
# Individuals Randomized	22	

Status of Intervention Delivery:

A total of 22 women have been randomized in Cape Town and have begun the 24 week self-administered phase. The weekly calls and data from the Electronic Drug Monitoring device are running smoothly.

Retention Status:

Week	4	10	18	30	34
Cape Town	32/33 (97%)	NA	NA	NA	NA
Bangkok	NA	NA	NA	NA	NA

Implementation Issues and Problems:

The Cape Town site had previously identified that participants were having trouble completing the CASI due to problems with the Xhosa translation. In discussions with the site team it was determined that the translation was no longer a problem. The earlier participants had trouble understanding certain terms which are now explained by counselors in advance and with computer literacy which the counselors are working to improve.

Publications/Presentations

None

Report for HPTN Study Operations Group

HPTN 068 Effects of Cash Transfer for the Prevention of HIV in Young South African Women

Based on data available through: 9 December 2011

Participating Study Sites:

- MRC/Wits Rural Public Health and Health Transitions Research Unit (Agincourt)

Study Implementation Status:

Through 33 weeks of enrollment the site has enrolled 1,936 young women. 61 young women have been found to be HIV positive and 93 are HSV-2 positive.

The site implemented a self-imposed enrollment pause in preparation for their first PPD in mid-November (14-16). The report has been posted to the DAIDS ES system.

They will continue with weekend camp enrollment on January 28-29.

The Data and Safety Monitoring Board convened on 24 October. The final report was distributed on November 11. The Board's recommendations are being considered by the team.

Accrual Status:

1,936 of 2,900 enrolled. 2,660 negative young women need to be enrolled onto the study.

Status of Intervention Delivery:

No issues. The cash transfers are properly being made to the accounts of the young women and their parents.

Retention Status:

Not applicable.

Implementation Issues and Problems:

The CTU and the Operations Center have decided on an oversight plan for the study which involves a series of visits for assessment of the site.

Publications/Presentations

None

Report for HPTN Study Operations Group

HPTN 069

A Phase II Randomized, Double-Blind, Study of the Safety and Tolerability of Maraviroc (MVC), Maraviroc + Emtricitabine (MVC+FTC), Maraviroc + Tenofovir disoproxil fumarate (MVC+TDF), or Tenofovir disoproxil fumarate + Emtricitabine (TDF+FTC) for Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission in At-Risk Men Who Have Sex with Men

Based on data available through: 9 December 2011

Participating Study Sites:

- Case CRS
- Cornell Clinical Research Site
- Fenway Health
- George Washington University
- JHU General Clinical Research Center
- San Francisco Department of Public Health
- UCLA Care Center
- UNC CTU
- University of Pennsylvania
- University of Pittsburgh
- University of Puerto Rico
- University of Washington

Study Implementation Status:

Version 1.0 of the protocol, dated October 4, 2011, was distributed to sites on October 18, 2011. The FDA 30-day review was completed and the FDA cleared the study on November 14, 2011 (under IND 113,655).

The Clinical Trials Agreement (CTA) with Gilead is final, and the CTA with ViiV Healthcare is pending.

Sites are in the process of submitting the protocol to their respective IRBs. HPTN Operations Office, SDMC (SCHARP), and the Network Laboratory are working with each site regarding site activation requirements.

Accrual Status:

N/A

Status of Intervention Delivery:

N/A

Retention Status:

N/A

Implementation Issues and Problems:

N/A

Publications/Presentations:

None

Appendix: HPTN Protocols and INDs

Protocol #		IND	IND Sponsor	Study Status
HPTN 052	A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy Plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 in Serodiscordant Couples	68,535	DAIDS	Closed to Accrual
HPTN 058	A Phase III randomized controlled trial to evaluate the efficacy of drug treatment and death in prevention of HIV infection and death among opiate dependent injectors	73,797	DAIDS	Enrolling
HPTN 067	A Phase II, Randomized, Open-Label, Pharmacokinetic and Behavioral Study of the Use of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis (PrEP)	71,589	DAIDS	Enrolling
HPTN 069	Phase II Randomized, Double-Blind, Study of Safety and Tolerability of Maraviroc, Maraviroc + Emtricitabine, Maraviroc + Tenofovir or Tenofovir + Emtricitabine for PreExposure Prophylaxis to Prevent HIV Transmission in At-Risk Men Who Have Sex with Men	TBD	TBD	In Development