Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2011;365:493-505. DOI: 10.1056/NEJMoa1105243.

HPTN 052: Supplementary Appendix

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The table below outlines all associated Institutional Review Boards/Ethics Committees for each clinical research site. In some cases, a local site partnered with a US institution to conduct HPTN 052; therefore, a US IRB also had a responsibility to review and approve the research. The table also includes non-US regulatory bodies that reviewed the study (for example local Ministries of Health, Poisons Boards, etc).

IRBs/ECs and Other Regulatory Bodies by Site

Site	Affiliated IRBs/ECs and Regulatory Bodies
Porto Alegre, Brazil	• UCLA Office for Protection of Research Subjects: Medical Institutional Review Board • Brazil Ministério da Saúde: CONEP: Comissão Nacional de Ética em Pesquisa • Gerencia de Ensino e Pesuisa: Comitê de Ética em Pesquisa do Grupo Hospitalar Conceição-GHC
Rio de Janeiro, Brazil	• UCLA Office for Protection of Research Subjects: Medical Institutional Review Board • Instituto de Pesquisa Clínica Evandro Chagas: Comitê de Ética em Pesquisa • Brazil Ministério da Saúde: CONEP: Comissão Nacional de Ética em Pesquisa • Grupo Hospitalar Conceição-GHC: Comitê de Ética em Pesquisa
Boston, MA, USA	• Fenway Community Health Center: Fenway Community Health Center Institutional Review Board
Chennai, India	• Fenway Community Health Center: Fenway Community Health Center Institutional Review Board • YRG CARE Institutional Review Board • University of California, San Diego: Human Research Protections Program • Health Ministry Screening Committee (India)
Pune, India	• National AIDS Research Institute (ICMR): National AIDS Research Institute (NARI) Ethics Committee • Johns Hopkins University School of Medicine: Johns Hopkins Medicine Institutional Review Board • Health Ministry Screening Committee (India)
Chiang Mai, Thailand	• Johns Hopkins Bloomberg School of Public Health Institutional Review Boards • Human Experimentation Committee, Research Institute for Health Sciences, Chiang Mai University • Research Ethics Committee, Faculty of Medicine, Chiang Mai University • Ethical Review Committee for Research in Human Subjects Ministry of Public Health, Thailand
Kisumu, Kenya	• Kenya Medical Research Institute: KEMRI National Ethical Review Committee • CDC Atlanta: CDC National Center for HIV/AIDS, Viral Hepatitis, STDs and TB Prevention IRB • Kenya National Pharmacy and Poisons Board (PPB)

Site	Affiliated IRBs/ECs and Regulatory Bodies
Harare, Zimbabwe	• University of California at San Francisco: Committee on Human Research, Office of Research Administration • Medical Research Council of Zimbabwe: Medical Research Council of Zimbabwe (MRCZ) Institutional Review Board • Medicines Control Authority of Zimbabwe (MCAZ) • Research Council of Zimbabwe (RCZ)
Blantyre, Malawi	• University of Malawi College of Medicine: College of Medicine Research & Ethics Committee (COMREC) • Johns Hopkins University Bloomberg School of Public Health: Institutional Review Board
Lilongwe, Malawi	• Malawi Ministry of Health & Population: National Health Sciences Research Committee • University of North Carolina School of Medicine: Committee on the Protection of the Rights of Human Subjects
Gaborone, Botswana	• Botswana Ministry of Health: Health Research and Development Committee • Harvard School of Public Health: Human Subjects Committee
Johannesburg, South Africa	• University of Witwatersrand: Human Research Ethics Committee: Medical • Medicines Control Council (South Africa)
Soweto, South Africa	• University of Witwatersrand: Human Research Ethics Committee: Medical • Medicines Control Council (South Africa)

Full Inclusion/Exclusion Criteria

HPTN 052 Study Inclusion Criteria

Couple	Index Case (HIV-infected)	Partner (HIV-uninfected)
• Men and women age $\geq$ 18 years. • Willing to disclose HIV test results to partner. • Not intending to relocate out of the area for the duration of study participation and does not have a job or other obligations that may require long absences from the area. • Plans to maintain a sexual relationship with the person who is enrolled in the study with them. • Reports having sex (vaginal or anal) with partner at least 3 times in the last 3 months (reports separately and not in front of each other).	• Positive HIV serology obtained within 60 days prior to enrollment • Willing to be randomized if pregnant or breast feeding ▪ CD4+ cell count of 350-550 cells/mm^3 ▪ Hemoglobin $\geq$ 7.5 g/dL; platelet count $\geq$50,000/µL; AST (SGOT), ALT (SGPT), and alkaline phosphatase $\leq$ 5 x ULN; total bilirubin $\leq$ 2.5 x ULN; calculated creatinine clearance $\geq$ 60 mL/min; absolute neutrophil count $\geq$ 750 mm^3 or 0.750 x 10^9/L	• Negative HIV serology within 14 days prior to enrollment.

HPTN 052 Study Exclusion Criteria

Couple	Index Case (HIV-infected)
• Reports a history of injection drug use within the last five years. • Previous and/or current participant in an HIV vaccine study. • Any condition that, in the opinion of the site investigator, would make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives. • Incarceration in a correctional facility, prison, or jail; and involuntary incarceration in a medical facility for psychiatric or physical (*e.g.* infectious disease) illness	• Current or previous AIDS-defining illness • Current or previous use of any ART drugs (some exceptions apply) • Documented or suspected acute hepatitis within 30 days prior to enrollment, irrespective of AST (SGOT) and ALT (SGPT) values. • Acute therapy for serious medical illnesses, in the opinion of the site investigator, within 14 days prior to enrollment. Candidates with chronic, acute, or recurrent infections that are serious, in the opinion of the site investigator, who must continue with chronic (maintenance) therapy (*e.g.*, TB), must have completed at least 14 days of therapy prior to study entry and be clinically stable. • Radiation therapy or systemic chemotherapy within 45 days prior to enrollment.NOTE:Anticipated need for systemic chemotherapy while on study is not permitted. • Any immunomodulator or other investigational therapy within 30 days prior to enrollment. • Active drug or alcohol use or dependence that, in the opinion of the site investigator, would interfere with adherence to study requirements. • Vomiting or inability to swallow medications due to an active, pre-existing condition that prevents adequate swallowing and absorption of study medication. • Need for a prohibited medication • Allergy/sensitivity to any study drugs or their formulations.

Note: There are no explicit exclusion criteria for HIV-1 uninfected participants (partners)

Overview of Study Procedures

Procedure	Index Case (HIV-infected)	Partner (HIV-uninfected)
Sexual History Assessment	Enrollment, Quarterly, Annual	Enrollment, Quarterly, Annual
HIV testing (includes pre and post-test counseling)	N/A	Quarterly, Annual
Adherence Assessment[1]	Week 2*, Monthly**, Quarterly, Annual	N/A
Couples Counseling	Enrollment, Week2*, Monthly**, Quarterly, Annual	Enrollment, Week 2*, Monthly**, Quarterly, Annual
Adherence Counseling[1]	Enrollment, Week 2*, Monthly**, Quarterly, Annual, Virologic Failure	Enrollment, Week 2*, Monthly**, Quarterly, Annual, Virologic Failure
Quality of Life Assessment	Enrollment, Quarterly, Annual	N/A
Physical exam (includes medical history)[2]	Enrollment, Week 2*, Monthly**, Quarterly, Annual	Enrollment, Quarterly, Annual, Seroconversion
Chest x-ray	Enrollment	N/A
Genital exam	Enrollment, Annual	Enrollment, Annual, Seroconversion
Circumcision status[3]	Enrollment, Annual	Enrollment, Annual
Pelvic exam	Enrollment, Annual, Seroconversion	Enrollment, Annual, Seroconversion
Provide study medications[4]	Enrollment, Week 2*, Monthly**, Quarterly, Annual	N/A
Pregnancy test	Enrollment, Monthly**, Quarterly, Annual	N/A
GC, CT, TV, BV, candida	Enrollment, Annual	Enrollment, Annual
HIV EIA/Western blot/IFA	N/A	Quarterly, Annual
CBC, Blood chemistry, LFTs	Enrollment, Week 2* Monthly**, Quarterly, Annual	Seroconversion
CD4 cell count	Enrollment, Quarterly, Annual	Seroconversion
Blood plasma HIV-1 RNA	Enrollment, Monthly***, Quarterly, Annual, Seroconversion, Virologic Failure	Seroconversion
Syphilis serology	Enrollment, Annual	Enrollment, Annual
HIV genotyping	Enrollment, Seroconversion, Virologic Failure	Seroconversion
Plasma sample storage	Enrollment, Quarterly, Annual, Seroconversion, Virologic Failure	Enrollment, Quarterly, Annual, Seroconversion
Serum sample storage	Enrollment, Quarterly, Annual	Enrollment, Annual, Seroconversion
Whole blood sample storage	Enrollment	Enrollment
PBMCs sample storage	Enrollment, Quarterly, Annual, Seroconversion	Enrollment, Quarterly, Annual, Seroconversion
Genital secretions storage	Enrollment, Annual, Seroconversion	Seroconversion

N/A = not applicable

*The Week 2 visit occurs after the Index Case initiated ART for a short interval clinical follow-up.

**Monthly visits take place first three months of the study and after the Index Cases in the delay arm initiate ART.

***For Arm 1, performed at one monthly visit following enrollment. For Arm 2, one monthly visit following initiation of ART. Thereafter, per the table above (*i.e.* at quarterly, annual, seroconversion, and virologic failure visits).

[1] Adherence assessments and counseling take place for couples in which the Index Case was on ART.

[2] Includes collection of concomitant medications information.

[3] Circumcision status (men only) is not collected once positive circumcision is established.

[4] Study medications are generally dispensed at quarterly visits; a subset of participants are dispensed ART at monthly visits for closer adherence monitoring.

Enrollment of HIV-Serodiscordant Couples by Site

Site	Enrollment (Number of Couples)
Porto Alegre, Brazil	90
Rio de Janeiro, Brazil	186
Boston, MA, USA	2
Chennai, India	250
Pune, India	175
Chiang Mai, Thailand	106
Kisumu, Kenya	60
Harare, Zimbabwe	240
Blantyre, Malawi	230
Lilongwe, Malawi	251
Gaborone, Botswana	77
Johannesburg, South Africa	46
Soweto, South Africa	50

Baseline Characteristics of the Participants at Enrollment by Treatment Arm.

Characteristics	HIV-1 infected Participants*		HIV-1 uninfected Participants*	
	Early (N=886)	Delayed (N=877)	Early (N=893)	Delayed (N=882)
Demographic				
Female sex	432 (49%)	441 (50%)	441 (49%)	418 (47%)
Age group				
18-25	145 (16%)	161 (18%)	154 (17%)	174 (20%)
26-40	556 (63%)	547 (62%)	537 (60%)	526 (60%)
>40	185 (21%)	169 (19%)	202 (23%)	182 (21%)
Education level				
No schooling	101 (11%)	69 (8%)	112 (13%)	77 (9%)
primary schooling	360 (41%)	347 (40%)	317 (35%)	344 (39%)
Secondary schooling	346 (39%)	388 (44%)	373 (42%)	367 (42%)
Post-secondary schooling	79(9%)	72 (8%)	91 (10%)	93 (11%)
Missing	0 (0%)	1 (<1%)	0 (0%)	1 (<1%)
Marital Status				
Single	49 (6%)	38 (4%)	53 (6%)	43 (5%)
Married/living w/partner	833 (94%)	833 (95%)	834 (93%)	833 (94%)
Widowed/separated/divorced	4 (<1%)	6 (1%)	6 (1%)	6 (1%)
Region				
North/South America	142 (16%)	136 (16%)	145 (16%)	139 (16%)
Asia	267 (30%)	264 (30%)	268 (30%)	264 (30%)
Africa	477 (54%)	477 (54%)	480 (54%)	479 (54%)
Sexual Activity				
Any unprotected sex in last week	37 (6%)	51 (8%)	49 (8%)	53 (8%)
No. of sex partners in last 3 months				
0-1	831 (94%)	833 (95%)	863 (97%)	844 (96%)
2-4	48 (5%)	41 (5%)	29 (3%)	36 (4%)
>4	7 (1%)	2 (<1%)	1 (<1%)	1 (<1%)
Missing	0 (0%)	1 (<1%)	0 (0%)	1 (<1%)
No. of sex acts in last week				
0	246 (28%)	225 (26%)	253 (28%)	240 (27%)
1-2	430 (49%)	438 (50%)	410 (46%)	433 (49%)
3-4	156 (18%)	158 (18%)	180 (20%)	151 (17%)
>4	54 (6%)	55(6%)	50 (6%)	57 (6%)
Missing	0 (0%)	1 (<1%)	0 (0%)	1 (<1%)
Clinical				
CD4 counts				
Median (IQR)*	442 (373-522)	428 (357-522)	-	-
Plasma RNA				
<400	54 (6%)	43 (5%)	-	-
400-1,000	24 (3%)	33 (4%)	-	-
1,001-10,000	212 (24%)	183 (21%)	-	-
10,001-100,000	407 (46%)	432 (49%)	-	-
100,001-1,000,000	186 (21%)	186 (21%)	-	-

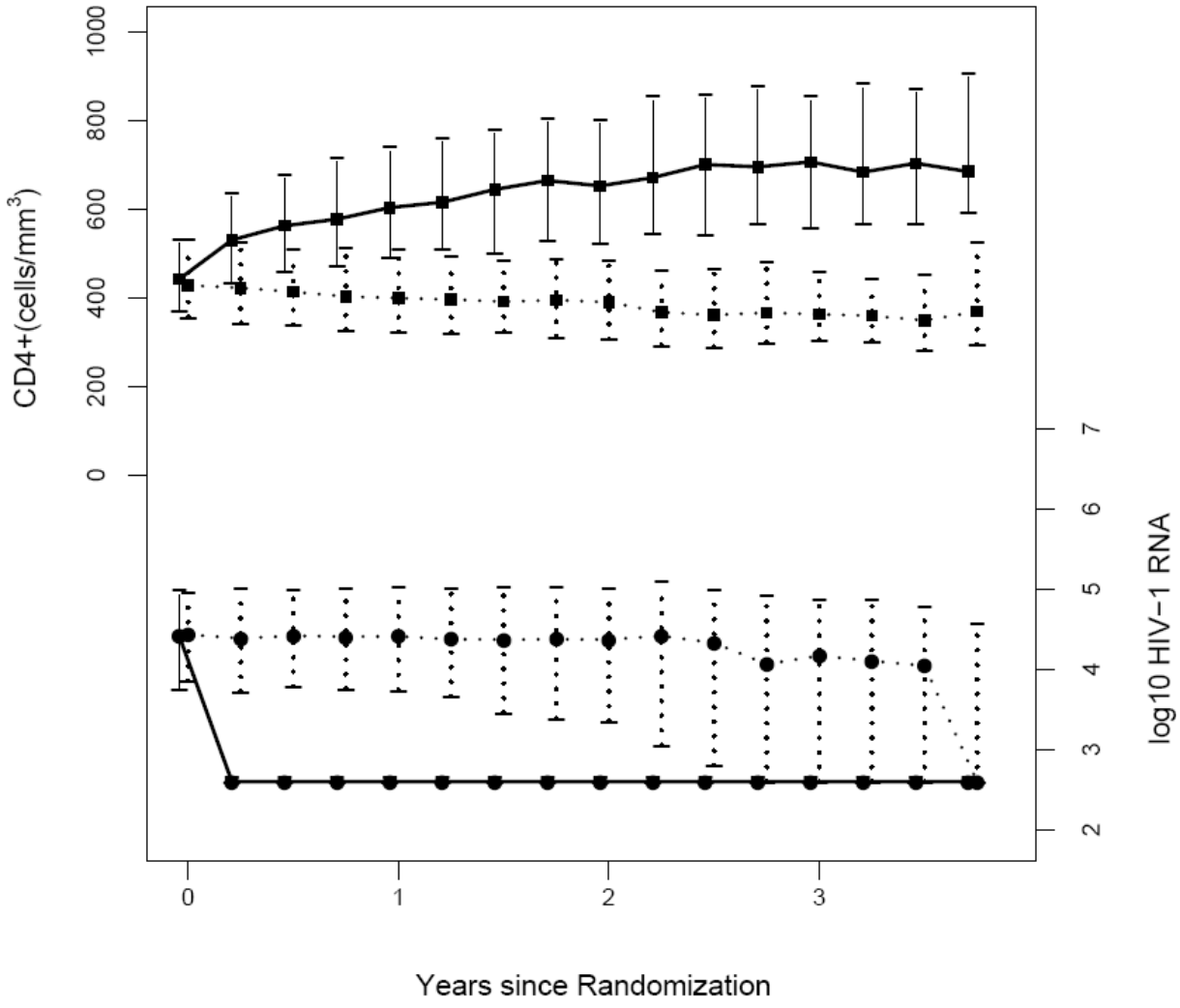
Characteristics	HIV-1 infected Participants *		HIV-1 uninfected Participants *	
	Early (N=886)	Delayed (N=877)	Early (N=893)	Delayed (N=882)
Missing	3 (<1%)	4 (<1%)	-	-
Women reporting prior ART use for PMTCT‡	115/432 (27%)	119/441 (27%)	-	-
STIs				
Hepatitis B	46 (5%)	45 (5%)		
Syphilis	29 (3%)	32 (4%)	27 (3%)	18 (2%)
Gonorrhea	13 (1%)	9 (1%)	10 (1%)	8 (1%)
C. trachomatis	20 (2%)	14 (2%)	14 (2%)	21 (2%)
Women only				
Bacterial Vaginosis	75/432 (17%)	70/441 (16%)	46/441 (10%)	43/418 (10%)
Trichomonas	22/432 (5%)	24/441 (5%)	17/441 (4%)	14/418 (3%)
Couple type at enrollment				
	Early		**Delayed**	
Male (HIV+) Female (HIV-)	436 (49%)		417 (48%)	
Female (HIV+) Male (HIV-)	431 (49%)		441 (50%)	
Male (HIV+) Male (HIV-)	18 (2%)		19 (2%)	
Female (HIV+) Female (HIV-)	1 (0%)		0 (0%)	

* Summary statistics are shown in number (%), or specified otherwise

† IQR, inter-quartile range, lower limit is 25th-percentile and upper limit is 75th-percentile

‡ Denominator is the number of eligible women in each arm

Follow-up CD4+, HIV RNA, and Their Respective IQRs by Arm



Lines are shown for median follow-up CD4 counts and viral loads of two trial arms during the study period. Solid lines are for the early arm, and dotted lines for the delayed arm. Also shown are inter-quartile ranges. In the early arm, mean follow-up CD4 count increases from 449 cells/mm^3 at enrollment to 742 cells/mm^3 at month 45 visit, and percentage of follow-up VL<400 increases from 6% at enrollment to 97% at month 45 visit. In the delayed arm, mean follow-up CD4 count decreases from 449 cells/mm^3 at enrollment to 400 cells/mm^3 at month 45 visit, and percentage of follow-up VL<400 increases from 5% at enrollment to 24% at month 30 visit but decreases to a range of 0-5% between month 33 and month 45 visits.

Incidence of Transmission and Clinical Events by Region

Incidence Rates and 95% Confidence Intervals for Linked HIV-1 Transmissions, All HIV-1 Transmissions, Clinical Events, and Composite Event

Region/Sites*	Linked Transmission		All Transmission		Clinical Event		Composite Event	
	Incidence	95% CI	Incidence	95% CI	Incidence	95% CI	Incidence	95% CI
African	**1.6**	**[1.0, 2.4]**	**2.3**	**[1.6, 3.2]**	**3.1**	**[2.3, 4.1]**	**3.8**	**[2.9, 4.9]**
Gaborone, Botswana	1.1	[0.0, 6.1]	2.2	[0.3, 7.9]	3.2	[0.7, 9.4]	4.2	[1.1, 10.7]
Kisumu, Kenya	0.0	[0.0, 6.7]	0.0	[0.0, 6.7]	3.5	[0.4, 12.8]	0.0	[0.0, 6.4]
Blantyre, Malawi	2.9	[1.4, 5.3]	3.2	[1.6, 5.7]	1.8	[0.7, 3.6]	3.8	[2.2, 6.3]
Lilongwe, Malawi	2.4	[1.2, 4.4]	3.4	[1.8, 5.7]	3.8	[2.2, 6.1]	5.2	[3.3, 7.8]
Johannesburg, South Africa	0.0	[0.0, 5.2]	0.0	[0.0, 5.2]	4.2	[0.9, 12.2]	0.0	[0.0, 4.8]
Soweto, South Africa	0.0	[0.0, 7.8]	2.1	[0.1, 11.8]	4.1	[0.5, 14.6]	4.0	[0.5, 14.5]
Harare, Zimbabwe	0.5	[0.1, 1.9]	1.0	[0.3, 2.7]	3.2	[1.7, 5.4]	3.4	[1.8, 5.6]
Asia	**0.2**	**[0.0, 0.6]**	**0.3**	**[0.1, 0.8]**	**4.0**	**[2.9, 5.3]**	**2.6**	**[1.8, 3.7]**
Chennai, India	0.2	[0.0, 1.1]	0.2	[0.0, 1.1]	6.3	[4.3, 8.8]	3.4	[2.0, 5.3]
Pune, India	0.0	[0.0, 0.9]	0.0	[0.0, 0.9]	2.5	[1.2, 4.6]	2.3	[1.0, 4.3]
Chiang Mai, Thailand	0.4	[0.0, 2.4]	0.9	[0.1, 3.2]	1.6	[0.4, 4.2]	1.6	[0.4, 4.2]
South America	**0.5**	**[0.1, 1.5]**	**0.5**	**[0.1, 1.5]**	**1.9**	**[1.0, 3.3]**	**1.9**	**[1.0, 3.3]**
Porto Alegre, Brazil	0.5	[0.0, 3.0]	0.5	[0.0, 3.0]	1.1	[0.1, 3.8]	1.6	[0.3, 4.6]
Rio de Janeiro, Brazil	0.5	[0.1, 1.7]	0.5	[0.1, 1.7]	2.3	[1.1, 4.2]	2.0	[0.9, 3.9]

*Data for the two couples enrolled at the site in Boston, MA, USA are not included as the enrollment was so low and follow-up time so short that incidence rate estimates are imprecise.

Adherence Counseling Checklists

HPTN 052 Adherence Counseling Checklist: Initial Visit

A **physician or clinician** conducting the following items:

____ **Discussion of the importance of good doctor-patient communication**

- Reinforce that successful HIV treatment relies on good doctor-patient communication
- Assure the participants that they can ask any question at any time throughout the study

____ **Education about HIV medications and adherence**

- Explain the concepts of viral replication, mutation, and resistance
- Emphasize that poor adherence can lead to resistance and that 95-100% adherence is optimal
- Explain the concept of viral load and how it will be used to monitor health and resistance
- Warn against sharing ART with others

____ **Introduction of ART regimen**

- Show the participants each pill, teach its name, and explain what it does
- Discuss the dosing of each pill (when and how many) and any food restrictions

____ **Review of side effects**

- Review the side effects of each component of the index case's particular regimen
- Explain the importance of adherence regardless of side effects
- Emphasize that many side effects will decrease automatically or can be treated

An **adherence counselor** conducting the following items:

____ **Build rapport**

- Discuss living with HIV, health maintenance, and the reasons the couple joined the study
- Emphasize that they can ask any questions at any time throughout the study

____ **Define medication adherence**

- Explain that adherence is the degree to which a person sticks to the prescribed regimen
- Emphasize the collaborative process and taking an active role in one's treatment

____ **Education about HIV medications and adherence (repeat of information from clinician)**

- Review association of nonadherence to the potential for medication resistance

____ **Review of side effects (repeat of information from clinician)**

- Review the expectations about side effects, and that generally they can get better over time.
- Emphasize the importance about continued communication about side effects

____ **Discussion of good doctor-patient communication (repeat of information from clinician)**

- Review the need to always ask questions so that the best decisions can be made about medicines.

____ **Introduction of ART regimen (repeat information from clinician)**

- Review regimen
- Ask the participants to articulate the information and correct any misunderstandings

____ **Create a simple and concrete daily medication schedule (participant's adherence plan)**

- Finalize a concrete, simplified adherence plan using any appropriate tools (*e.g.* pill boxes)
- Discuss when the doses will be taken in different circumstances (*e.g.*, at home, at work)
- Review food restrictions and ensure that the plan accommodates specific medications

____ **Develop reminder strategies**

- Specifically address the involvement of the partner and/or other support people
- Suggest and discuss over reminder strategies (*e.g.*, watch, timer, notes)

____ **Discussion of family, community, social support, and privacy**

- Discuss who knows the index case's HIV status and how they can help with adherence
- Strategize how the participant can keep their HIV status private and still maintain adherence

____ **Address additional potential barriers to adherence**

- Brainstorm about potential barriers to adherence and ways to overcome such obstacles

____ **Address handling slips (missed doses)**

- Emphasize that although the goal is optimal adherence, no one is perfect
- Discuss ways to get back on track as soon as possible after a missed dose

____ **Attending appointments and contact information**

- Discuss how the participant will get to future appointments, if necessary, strategize about potential barriers to attendance (*e.g.*, transportation)
- Make sure that the participants have contact information for questions or emergencies

____ **General review**

- What questions do you have about your regimen?

HPTN 052 Adherence Counseling Checklist: Follow-up Visit

An **adherence counselor** conducting the following items:

____ **Continue to build rapport**

- Encourage the participants to start the sessions with their concerns or questions
- Emphasize that participants can ask any questions at any time throughout the study

____ **Review the concept of medication adherence**

- Confirm that the participants understand the concept of medication adherence
- Answer any questions and correct any misunderstandings, consult a clinician if necessary

____ **Review information about HIV medications and adherence**

- Confirm that the participants understand the relationship between adherence and resistance
- Emphasize that ART should not be shared with others

____ **Review of side effects**

- Ask the participants what questions they have about side effects
- Assist the participants in eliminating or reducing side effects, consult a clinician if necessary

____ **Review the status of the participants' doctor-patient communication**

- Ensure that participants are still comfortable talking to the clinicians about treatment issues
- If problems exist, assist participants in improving communication

____ **Review the participant's ART regimen**

- If the participant is still unfamiliar with the regimen or the ART has changed, review the particulars of each drug – what it looks like, its name, what it does, and how it is taken
- Answer any questions related to the ART regimen, consult a clinician if necessary

____ **Review the participant's concrete daily medication schedule (participant's adherence plan)**

- Determine the usefulness of the various components of the participant's adherence plan
- Make adjustments to the adherence plan as necessary

____ **Review reminder strategies**

- Ask about the usefulness of the reminder strategies being used, including partner support
- Suggest alternatives and new approaches as appropriate

____ **Review the role of family, community, social support, and privacy**

- Discuss how the participants' family and friends are helping or hindering adherence
- Determine if privacy issues are negatively influencing adherence
- Suggest alternatives and new approaches as appropriate

____ **Review additional potential barriers to adherence**

- Determine if any new barriers to adherence have arisen, help address these issues

____ **Address handling slips (missed doses)**

- Ask the participants how they have handled missed doses
- Discuss ways to handle similar situations in the future, consult a clinician if necessary

____ **Attending appointments and contact information**

- If participants are having trouble coming to their appointments, discuss alternative strategies
- Make sure that the participants have contact information for questions or emergencies

Most Frequently Used Initial Primary Regimens by Arm

	Early Arm	Delayed Arm	Total
N initiated primary regimen	886	184	1070
(AZT/3TC)/EFV	641 (72%)	129 (70%)	770 (72%)
(AZT/3TC)/ATV	88 (10%)	13 (7%)	101 (9%)
(FTC/TDF)/EFV	80 (9%)	21 (11%)	101 (9%)
(AZT/3TC)/(LPV/RTV)	60 (7%)	3 (2%)	63 (6%)
Other	17 (2%)	18 (10%)	35 (3%)

Most Frequently Used Primary Regimen by Site and by Arm

Initial Primary Regimen, by Site – Early Arm (Americas and Asia)

	Total	North/South America			Asia		
		Porto Alegre, Brazil	Rio de Janeiro, Brazil	Boston, US	Chennai, India	Pune, India	Chiang Mai, Thailand
N index enrolled	886	47	95	0	125	89	53
N initiated primary regimen	886 (100%)	47 (100%)	95 (100%)	0 (-%)	125 (100%)	89 (100%)	53 (100%)
(AZT/3TC)/EFV	641 (72%)	27 (57%)	77 (81%)	0 (-%)	121 (97%)	68 (76%)	31 (58%)
(AZT/3TC)/ATV	88 (10%)	19 (40%)	16 (17%)	0 (-%)	0 (0%)	13 (15%)	9 (17%)
(FTC/TDF)/EFV	80 (9%)	1 (2%)	2 (2%)	0 (-%)	4 (3%)	3 (3%)	6 (11%)
(AZT/3TC)/(LPV/RTV)	60 (7%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)	4 (4%)	4 (8%)
(AZT/3TC)/ATV/RTV	8 (1%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
3TC/TDF/EFV	6 (1%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)	0 (0%)	3 (6%)
(AZT/3TC)/ATV/RTV-generic	1 (<1%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)	1 (1%)	0 (0%)
(LPV/RTV)/(FTC/TDF)	1 (<1%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)
3TC/ATV/d4T	1 (<1%)	0 (0%)	0 (0%)	0 (-%)	0 (0%)	0 (0%)	0 (0%)

Initial Primary Regimen, by Site – Early Arm (Africa)

	Total	Africa						
		Gaborone, Botswana	Kisumu, Kenya	Blantyre, Malawi	Lilongwe, Malawi	Johannesburg, South Africa	Soweto, South Africa	Harare, Zimbabwe
N index enrolled	886	38	30	115	126	24	25	119
N initiated primary regimen	886 (100%)	38 (100%)	30 (100%)	115 (100%)	126 (100%)	24 (100%)	25 (100%)	119 (100%)
(AZT/3TC)/EFV	641 (72%)	0 (0%)	13 (43%)	95 (83%)	86 (68%)	8 (33%)	18 (72%)	97 (82%)
(AZT/3TC)/ATV	88 (10%)	0 (0%)	14 (47%)	2 (2%)	11 (9%)	0 (0%)	0 (0%)	4 (3%)
(FTC/TDF)/EFV	80 (9%)	36 (95%)	1 (3%)	8 (7%)	6 (5%)	6 (25%)	5 (20%)	2 (2%)
(AZT/3TC)/(LPV/RTV)	60 (7%)	2 (5%)	1 (3%)	10 (9%)	22 (17%)	2 (8%)	2 (8%)	13 (11%)
(AZT/3TC)/ATV/RTV	8 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	8 (33%)	0 (0%)	0 (0%)
3TC/TDF/EFV	6 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (3%)
(AZT/3TC)/ATV/RTV-generic	1 (<1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(LPV/RTV)/(FTC/TDF)	1 (<1%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)
3TC/ATV/d4T	1 (<1%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Initial Primary Regimen, by Site - Delayed Arm (Americas and Asia)

	Total	North/South America			Asia		
		Porto Alegre, Brazil	Rio de Janeiro, Brazil	Boston, US	Chennai, India	Pune, India	Chiang Mai, Thailand
N index enrolled	877	43	91	2	125	86	53
N initiated primary regimen	184 (21%)	10 (23%)	37 (41%)	1 (50%)	27 (22%)	23 (27%)	22 (42%)
(AZT/3TC)/EFV	129 (70%)	7 (70%)	26 (70%)	0 (0%)	25 (93%)	14 (61%)	13 (59%)
(FTC/TDF)/EFV	21 (11%)	0 (0%)	7 (19%)	1 (100%)	2 (7%)	2 (9%)	2 (9%)
(AZT/3TC)/ATV	13 (7%)	2 (20%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	7 (32%)
(AZT/3TC)/NVP	9 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (26%)	0 (0%)
(AZT/3TC)/(LPV/RTV)	3 (2%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
NVP/3TC/d4T	3 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
3TC/EFV/d4T	2 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
(FTC/TDF)/ATV/RTV	1 (1%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(LPV/RTV)/(FTC/TDF)	1 (1%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
3TC/TDF/EFV	1 (1%)	1 (10%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
NVP/(FTC/TDF)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Initial Primary Regimen, by Site - Delayed Arm (Africa)

	Total	Africa						
		Gaborone, Botswana	Kisumu, Kenya	Blantyre, Malawi	Lilongwe, Malawi	Johannesburg, South Africa	Soweto, South Africa	Harare, Zimbabwe
N index enrolled	877	39	30	115	125	22	25	121
N initiated primary regimen	184 (21%)	1 (3%)	2 (7%)	15 (13%)	21 (17%)	4 (18%)	1 (4%)	20 (17%)
(AZT/3TC)/EFV	129 (70%)	0 (0%)	2 (100%)	12 (80%)	17 (81%)	1 (25%)	0 (0%)	12 (60%)
(FTC/TDF)/EFV	21 (11%)	1 (100%)	0 (0%)	2 (13%)	0 (0%)	3 (75%)	1 (100%)	0 (0%)
(AZT/3TC)/ATV	13 (7%)	0 (0%)	0 (0%)	0 (0%)	2 (10%)	0 (0%)	0 (0%)	1 (5%)
(AZT/3TC)/NVP	9 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (15%)
(AZT/3TC)/(LPV/RTV)	3 (2%)	0 (0%)	0 (0%)	1 (7%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)
NVP/3TC/d4T	3 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (15%)
3TC/EFV/d4T	2 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (5%)
(FTC/TDF)/ATV/RTV	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(LPV/RTV)/(FTC/TDF)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
3TC/TDF/EFV	1 (1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
NVP/(FTC/TDF)	1 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)

ART Adherence by Pill Count by Arm

	Total	Early Arm	Delayed Arm
N index on ART	1149	881*	268**
Summary of Adherence			
Missing	7 (1%)	2 (<1%)	5 (2%)
Adherence>105%	42 (4%)	28 (3%)	14 (5%)
Evaluated	1100 (96%)	851 (97%)	249 (93%)
Adherence>=75%	1053 (96%)	812 (95%)	241 (97%)
Adherence>=95%	855 (78%)	671 (79%)	184 (74%)
% Mean (SD)	95 (13)	95 (14)	95 (9)
% Median	99	99	99
% Min, Max	0, 105	0, 105	35, 104
% Q1, Q3	96, 100	96, 100	95, 100

* Five HIV-infected participants in the early arm were dispensed ART at enrollment, but never returned for follow-up; therefore, no pill count data are available for these participants.

** The number of people in the delayed arm on ART includes 84 participants who took ART for the prevention of vertical HIV transmission during pregnancy.

Clinical Endpoints by Arm

Clinical Endpoints*, by Arm – HIV-1 Infected Participants

	Total	Early Arm	Delayed Arm
Total Number of Events [1]	**129**	**53**	**76**
Mycobacterium tuberculosis, pulmonary [2]	30	14	16
Bacterial infections, severe	27	16	11
Death	23	10	13
Mycobacterium tuberculosis, extrapulmonary	20	3	17
Herpes simplex, chronic	10	3	7
Bacterial pneumonia, recurrent, severe	4	2	2
Oesophageal candidiasis	4	2	2
Cervical carcinoma, invasive, confirmed by biopsy	2	0	2
Kaposi's sarcoma	2	1	1
Wasting syndrome due to HIV associated with either chronic diarrhea or chronic weakness and documented fever >= 1 month	2	0	2
Cryptococcosis, extrapulmonary including meningitis	1	1	0
Encephalopathy, HIV-related	1	0	1
Lymphoma, Burkitt, immunoblastic, primary central nervous system/cerebral, B cell non Hodgkin	1	0	1
Pneumocystis pneumonia	1	0	1
Septicemia, recurrent, including non-typhoidal Salmonella	1	1	0

*The clinical endpoints include WHO stage 4 events, mycobacterium tuberculosis pulmonary or severe bacterial infections.

[1] A total of 105 participants had at least one clinical event; 15 participants had two or more distinct clinical events. If a participant had multiple events during study follow-up, then all events are counted in this table.

[2] Thirteen (13) people in the early arm had 14 cases of pulmonary TB, and 15 people in the delayed arm had 16 cases of pulmonary TB.

HIV-1 Infected Participants with Two or More Distinct Clinical Events

	Total	Early Arm	Delayed Arm
Combination of Events (Total)	**15**	**7**	**8**
Bacterial infection, severe / TB	3	3	0
Bacterial infection, severe / extrapulmonary TB	1	0	1
Bacterial infection, severe / Bacterial pneumonia, recurrent, severe / TB	1	0	1
Bacterial infection, severe / Bacterial pneumonia, recurrent, severe / Oesophageal candidiasis	1	1	0
Bacterial infection, severe / Septicemia, recurrent	1	1	0
Bacterial infection, severe / Death	2	1	1
Herpes simplex, chronic / TB / Death	1	1	0
Lymphoma, Burkitt, immunoblastic, primary central nervous system/cerebral, B cell non Hodgkin / extrapulmonary TB	1	0	1
TB / Death	2	0	2
Bacterial pneumonia, recurrent, severe / TB / Death	1	0	1
Encephalopathy, HIV-related / extrapulmonary TB	1	0	1

*See Footnote # 2 in the "Clinical Endpoints by Arm – HIV-1 Infected Participants" table above, indicating that two individuals had two cases of pulmonary TB over time; those cases are not counted in this table as they are the same event.

Graded Lab Abnormalities by Arm

Graded Lab Abnormalities, by Arm – HIV-1 Infected Participants

	Early Arm (N=881)		Delayed Arm (N=872)	
	Grade 3	**Grade 4**	**Grade 3**	**Grade 4**
ALT (SGPT)	16 (1%)	5 (<1%)	10 (1%)	5 (<1%)
AST (SGOT)	16 (1%)	10 (1%)	15 (1%)	5 (<1%)
Albumin	3 (<1%)	0 (0%)	9 (1%)	0 (0%)
Alkaline Phosphatase	0 (0%)	0 (0%)	1 (<1%)	0 (0%)
Creatinine	0 (0%)	0 (0%)	4 (<1%)	1 (<1%)
Hemoglobin	9 (1%)	12 (1%)	6 (<1%)	10 (1%)
Neutrophils	77 (8%)	18 (2%)	37 (4%)	9 (1%)
Phosphate	58 (6%)	1 (<1%)	53 (6%)	1 (<1%)
Platelets	5 (<1%)	2 (<1%)	8 (<1%)	7 (<1%)
Potassium	3 (<1%)	0 (0%)	2 (<1%)	1 (<1%)
Sodium	4 (<1%)	0 (0%)	1 (<1%)	1 (<1%)
Total Bilirubin	48 (5%)	9 (1%)	7 (<1%)	1 (<1%)
WBC	2 (<1%)	1 (<1%)	2 (<1%)	0 (0%)

Incidence of Adverse Events by MedDRA Body System by Arm

	Total		Early Arm		Delayed Arm	
N HIV-1 Infected Participants Enrolled	1763		886		877	
N HIV-1 Infected Participants with One or More AEs*	246	(14%)	127	(14%)	119	(14%)
MedDRA Body System						
Blood and lymphatic system disorders	2	(<1%)	0	(0%)	2	(<1%)
Cardiac disorders	1	(<1%)	0	(0%)	1	(<1%)
Congenital, familial and genetic disorders	1	(<1%)	0	(0%)	1	(<1%)
Ear and labyrinth disorders	4	(<1%)	3	(<1%)	1	(<1%)
Gastrointestinal disorders	27	(2%)	12	(1%)	15	(2%)
General disorders and administration site conditions	16	(<1%)	10	(1%)	6	(<1%)
Hepatobiliary disorders	2	(<1%)	2	(<1%)	0	(0%)
Immune system disorders	2	(<1%)	0	(0%)	2	(<1%)
Infections and infestations	91	(5%)	42	(5%)	49	(6%)
Injury, poisoning and procedural complications	8	(<1%)	8	(<1%)	0	(0%)
Investigations	1	(<1%)	1	(<1%)	0	(0%)
Metabolism and nutrition disorders	30	(2%)	16	(2%)	14	(2%)
Musculoskeletal and connective tissue disorders	6	(<1%)	3	(<1%)	3	(<1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	(<1%)	2	(<1%)	1	(<1%)
Nervous system disorders	29	(2%)	20	(2%)	9	(1%)
Pregnancy, puerperium and perinatal conditions	23	(1%)	9	(1%)	14	(2%)
Psychiatric disorders	34	(2%)	26	(3%)	8	(<1%)
Renal and urinary disorders	6	(<1%)	3	(<1%)	3	(<1%)
Reproductive system and breast disorders	16	(<1%)	8	(<1%)	8	(<1%)
Respiratory, thoracic and mediastinal disorders	8	(<1%)	1	(<1%)	7	(<1%)
Skin and subcutaneous tissue disorders	7	(<1%)	6	(<1%)	1	(<1%)
Vascular disorders	9	(<1%)	4	(<1%)	5	(<1%)

*Primary Clinical events (death, WHO stage 4 events, pulmonary TB, and severe bacterial infection) are excluded from the table. Other potential HIV/AIDS related events are included. Laboratory abnormalities are also excluded and reported in a separate table.

Death Summary

Death Summary – HIV-1 Infected Participants

Cause of Death	ART at time of death	Most recent CD4 prior to death	Most recent viral load prior to death
Early Arm			
Suicide, unknown cause	EFV, FTC/TDF	500	<400
Gastroenteritis	3TC/ZDV, EFV	469	<400
Miliary tuberculosis	3TC/ZDV, EFV	318	<400
Suicide (hanging)	EFV, 3TC, TDF	800	<400
Unknown, alcohol history	3TC/ZDV, EFV	525	<400
Meningococcal sepsis	EFV, 3TC, d4T	578	<400
Unknown	EFV, 3TC, d4T	Missing	92,371
Suicide (poisoning)	EFV, FTC/TDF	419	<400
Unknown	EFV, 3TC, d4T	353	133,000
Leptospirosis	EFV, 3TC, d4T	482	<400
Delayed Arm			
Adenocarcinoma of stomach	EFV, d4T, 3TC	81	<400
Unknown, recent empyema	3TC/ZDV, EFV	197	<400
Tuberculosis	not on ART	31	187,486
Unknown	not on ART	421	215,909
Motor vehicle accident	3TC/ZDV, EFV	396	<400
Unknown	not on ART	372	57,600
Pneumococcal sepsis; probably meningitis	not on ART	480	56,550
Unknown	not on ART	495	757,539
Unknown	not on ART	351	23,300
Unknown, alcohol history	not on ART	504	53,200
Motor vehicle accident	not on ART	382	302,000
Tuberculosis	not on ART	303	368,000
Cerebral vascular accident	not on ART	364	252,000

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