Sexual behavior following acute HIV diagnosis in men who have sex with men and in transgender women in the *Sabes* study in Lima, Peru

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Abstract

Sexual behavior following a diagnosis of acute HIV in men who have sex with men and in transgender women in the *Sabes* study in Lima, Peru

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Objectives: To determine the impact of early antiretroviral therapy (ART) on risky sexual behavior practices during the acute period of human immunodeficiency virus (HIV) infection and compare the ability of different survey modalities to capture these risky sexual behavior practices.

Methods/Study Population: Our study looked at a cohort of 83 individuals, a subset of *Sabes* participants, who were either men who have sex with men (MSM) or transgender women (TW) living in Lima, Peru and observed their sexual behavior patterns over a year following diagnosis of acute HIV. Participants had been randomly assigned to initiate ART either immediately or after six months. We followed self-reported behavior and sexually transmitted infection (STI) diagnosis to determine if ART had an impact on an individual's sexual behavior patterns. We collected information about sexual behavior practices using both computer-assisted self-interviewing (CASI) and in-person interviewing, and biologic data from testing for gonorrhea and chlamydia at specified intervals.

Results: Our results indicate that during the acute period of HIV, when chances for transmission to a seronegative partner are the highest, individuals with HIV continue to practice risky sexual behavior which occurs regardless of ART use and continues even up to 48 weeks after known diagnosis. Individuals in our study, however, were not consistent with their reporting of condomless sex through either CASI or in-person interviewing and many documented STIs did not have corresponding reports of condomless sex by participants.

Discussion/Significance of Impact: Our study is significant in its use of both biologic and survey data on sexual behavior over 48 weeks in a defined cohort of newly diagnosed individuals. Through understanding the behavior patterns during acute HIV, we can design better interventions aimed at these behaviors to reduce onward transmission and population-level incidence.

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Introduction

Currently, there are an estimated 37 million individuals living with human immunodeficiency virus (HIV) globally, with an estimated 2 million new cases in 2015 (UNAIDS, 2016). In Peru, there are an estimated 66,000 (95% CI 56,000-79,000) individuals living with HIV with a prevalence of 0.3% (95% CI .3-0.4) in adults aged 15 to 49 (UNAIDS, 2015). These numbers show that HIV remains a pandemic despite increasing funds and interventions aimed at curtailing transmission.

Antiretroviral therapy (ART) has been widely accepted as long-term treatment for the management of HIV and the growing trend of "treatment as prevention" (TasP) has encouraged placing individuals with high CD4 counts on treatment for their own health as well as to decrease transmission to others (Rodger et al., 2014). The period of acute HIV infection, immediately after acquisition, is important due to the high viral load during this time and the corresponding increased likelihood of onward transmission (Miller et al., 2010; Attia et al., 2009). The high risk of transmission to others and studies showing personal benefit from early ART led WHO to recommend universal treatment for all HIV-infected individuals (WHO, 2015). Countries have varied in the timing of adoption of this treatment standard but, overall, they are adopting earlier treatment guidelines based on economic feasibility and the robustness of their health system. In Peru, standards in 2012 at the initiation of our study were to treat HIV-infected individuals when their CD4 count

was 350 or less, or when an AIDS-defining illness occurred (UNAIDS, 2012).

Both men who have sex with men (MSM) and transgender women (TW) in Lima, Peru have consistently been shown to have a high prevalence of HIV as well as other STIs (Sanchez et al., 2007; Sanchez et al., 2009; Perez-Brumer et al., 2013) compared to the general population. Several studies show the prevalence of HIV was over 10% among MSM and over 20% among TW living in Lima, Peru (UNGASS, 2014; Castillo et al., 2015, Sanchez et al., 2011). Studies on gonorrhea and chlamydia have estimated the prevalence to be around 2.1% and 4.1%, respectively (Perez-Brumer et al., 2013) in MSM. Disturbing findings from previous studies include the observation that in the acute period of HIV, when an individual is most likely to transmit to another individual, risky sexual behavior continues to occur, as indicated by individual self-report and biological data (Malek et al., 2015; Cope 2014). A number of studies have shown that participant responses to surveys can be inaccurate, based on their failure to disclose risk of HIV acquisition, in the underreporting of the number of partners, or a discrepancy between biomarkers and survey responses (Kelly et al., 2014; Gallo et al., 2013; Bernstein et al., 2008; Lyss et al., 2007; Wu et al., 2015). This limits the applicability of survey-collected data, yet survey-collected data has the capacity to be a rich source of information. Studies have shown participants report a decrease in risky sexual behavior post-diagnosis (Pettifor et al., 2015) as well as reporting seropositioning (using knowledge of each partner's HIV status to choose sexual positions less likely to transmit HIV) to reduce their risk of onward transmission (Snowden et al., 2014;

Vallabhaneni et al., 2013). Comprehensive studies looking at the validity of survey data compared to biological markers have been limited to cross-sectional approaches and none of them have captured longitudinal data specifically following individuals diagnosed during acute HIV infection (Gallo et al., 2013; Kelly et al., 2014).

Looking at incidence of new HIV infections in Lima, Peru, we see that new infections are discovered both by routine testing and by the expansion of new testing strategies to individuals not previously tested (Sanchez et al., 2009). Models have suggested that acute HIV infection in MSM and TW is an important driver of onward HIV infection (Goodreau et al., 2012) and behavior shortly after diagnosis can have a significant impact on prevalence (Khanna et al., 2014). Understanding which risky behaviors occur during acute HIV is essential for planning interventions that will be effective. Interestingly, dynamic mathematical models looking at the TasP approach predict that ART alone cannot eliminate HIV transmission (Wu et al., 2014), and concurrent interventions, such as targeted community education to reduce behaviors associated with HIV transmission, may be required in addition to ART to effectively reduce incidence (Wilson et al., 2012). Our study aimed to analyze the effect, if any, that initiation of ART had on sexual behavior, through a randomized trial of time to ART initiation in MSM/TW with acute HIV infection. This study is timely in its contribution to understanding the ramifications of immediate ART initiation due to new WHO recommendations for all individuals to begin ART as soon as possible after diagnosis.

Our study is unique in a number of ways. First, it is a cohort study looking at the acute period of HIV diagnosis, rather than a cross-sectional study, which would have limitations for drawing inference of cause and effect. Second, it collected both biologic data and self-reported survey data to get the most accurate picture of sexual activity after HIV diagnosis. Third, it was done at a unique time in which randomization to ART was consistent with the standard of treatment, so we can accurately quantify the ramifications ART initiation had on sexual behavior.

Objectives

This analysis of a subset of participants in the *Sabes* study sought to:

- Determine the prevalence of certain sexually transmitted infections at and following HIV diagnosis during the acute infection period (generally accepted as 1 to 4 weeks following HIV acquisition)
- Investigate whether the initiation of ART, either immediately after diagnosis or delayed for six months, influences risky sexual practices
- Compare the use of computer and in-person interviewing to collect behavioral information on individuals during the acute period of HIV diagnosis, using sexually transmitted infections as a marker for risky sexual behavior (i.e., condomless sex)

Methods

a. *Study design*

This study was part of a larger project, referred to as *Sabes*, in Lima, Peru that began in July 2012. In the first step of this study, approximately 3,200 MSM and TW with unknown HIV status, who were at risk of acquisition, were screened for HIV infection. Participants who tested HIV-negative were then followed at monthly visits during step two with HIV testing, education, and prevention counseling. At each monthly visit, testing for new HIV infection was done using tests that detect HIV antibodies and HIV ribonucleic acid (RNA). Because participants were tested monthly using tests that detected HIV soon after acquisition, it was possible to detect very early infection. All participants were offered enrollment into our 48-week trial in which they were randomly assigned to begin ART immediately or six months after diagnosis. ART was a standard one-pill daily treatment to avoid unnecessary burden to participants. Stribilid® (elvitegravir/cobicistat/emtricitabine/tenofovir) or Atripla® (emtricitabine/tenofovir/efavirenz) were first-line treatments. Newly diagnosed HIV-infected individuals were tested for other STIs (gonorrhea and chlamydia) within 3 months of HIV acquisition and given a questionnaire asking about their sexual behavior and drug/alcohol use during the last thirty days. It is worth noting that the main project of *Sabes* enrolled more than 200 newly HIV-infected participants; however our analysis was done just for those 83 individuals who had completed the 48-week follow-up visit as of January 2016. This consisted of 41

individuals who had been randomly assigned to the immediate ART group and 42 individuals who had been randomly assigned to the delayed ART group for a total of 83 participants.

Step 1	Screening of MSM and TW unaware of HIV status and at high-risk of acquisition
Step 2	High-risk HIV-uninfected MSM and transgender women tested at variable intervals (~monthly) for HIV status
Step 3	Individuals with incident HIV infection detected during Step 1 and Step 2 enrolled in 48-week randomized trial

Figure 1. Overall study design

b. *Data Collection*

During follow-up of the newly-diagnosed HIV-infected participants, frequent study visits (at least once every three months) were conducted during which data was collected on sexual behavior practices, drug and alcohol use before sex, and acquisition of new STIs. This was done using timeline follow back (TFB) questionnaires with an in-person interviewer and computer-assisted self-interviewing (CASI), and biological testing for STIs.

Data Collection Type	**Frequency**
Timeline Follow Back	Every month
Computer Assisted Self Interviewing	Every three months
Sexually Transmitted Infections	Every three months or when symptomatic

Figure 2. Data collection type and frequency of use

CASI is a reliable survey tool for collecting information that participants may otherwise feel inhibited to share (Langhuag et al., 2010; Gnambs et al., 2015). Sexual behavior questions specifically focused on positioning (insertive, receptive,

versatile), the number of partners, whether a condom was used, and whether drugs or alcohol were used before or during the sexual encounter (questionnaires shown in Appendix 1). Condom use questions were separated by whether the sexual act was with a main partner, casual partner, or with an individual when money or drugs were given in compensation for sex (transactional sex). The question asked what percent of the time a condom was used and participants indicated whether, in each of these categories, they used condoms always, most of the time, half the time, sometimes or never. The question did not address condom breakage or what amount of time, during individual sexual acts, the condom was worn.

Monthly TFB questionnaires also collected 30-day participant recall during a face-to-face interview on alcohol use and sexual encounters. TFB is an established and reliable method of detecting use of illicit substances in those with substance use disorder (Hjorthøj et al., 2012) and assessing sexual behavior (Weinhardt et al., 1998). For each sexual encounter, participants were asked the identity of the partner (or anonymous), their role (receptive or insertive) and whether a condom was used. The TFB data was pooled for each interval and analyzed after each participant had completed the 48-week trial.

At the first post-diagnosis visit and for each of the following quarterly visits, participants were screened for both urethral and rectal gonorrhea and chlamydia. These samples were analyzed at an outside laboratory. Of note, supply shortages affected the ability to conduct universal screening of participants for STIs at certain clinics, but these circumstances affected both treatment groups equally and were

taken into account during analysis. Treatment of infections was done promptly upon diagnosis with standard treatment regimens. CASI surveys and TFB interviews were conducted in Spanish in Lima, Peru by personnel employed at the respective research sites.

c. *Data Preparation*

Questionnaire and biologic data were first analyzed separately and were then compared to determine the degree of correlation between the two, which we would expect would be high if participants accurately reported sexual behaviors.

Data were separated into three analytical time periods. The first was the baseline analysis of the cohorts, which was done using data collected at enrollment immediately after HIV diagnosis. The next analytical time period was from this enrollment visit up to and including the 24-week visit. This time period is important because the two groups (delayed and immediate) differ on whether or not the participants were on ART. The third time period begins immediately after the 24-week visit and continues until the end of the study period at 48 weeks. During this time period, the participants are all on ART, regardless of whether they were initially assigned to the immediate or delayed group.

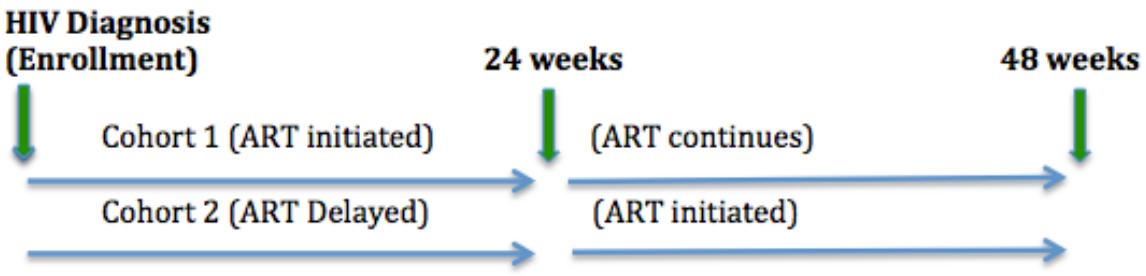

Figure 3. Timing of ART in relation to HIV diagnosis, in those initiated immediately on ART and those delayed to begin ART at six months

Throughout the analysis, a laboratory test that indicated an STI diagnosis of "equivocal" was regarded as a negative test and an individual having two infections (e.g., both rectal chlamydia and urethral chlamydia) was counted in each subset as separate infections. Because initial STI specimens were tested in batches, we did not count an STI observed at weeks 12 and 24 as a new STI if the same STI was observed at the preceding visit and we could not verify that the preceding results had been returned in time to allow treatment. Additionally, when an individual was found to have a positive STI test with no previously negative STI test to confirm the infection was new, the STI was not counted as a new infection.

The average number of sexual interactions that had the ability to transmit HIV (i.e., anal intercourse without a condom) was determined for each individual over each analytical period (baseline, up to and including 24 week visit, post 24 week visit) for each survey method. For timeline follow back, any act of anal intercourse (insertive, receptive or both) without a condom during our designated time period was coded as the ability to transmit HIV and other STIs. For our CASI survey, any indication less than "always used" condoms were coded as the ability to transmit HIV. We did this to ensure that having a diagnosed STI and reported condom use were biased towards agreement.

d. Data Analysis

For STIs diagnosed in each time period, we calculated an odds ratio using Fisher's exact test due to the small numbers of STIs in some categories. Our 2 x 2 tables

were set up with the immediate initiation of antiretroviral treatment being the intervention and the presence of an STI being the outcome measured. To obtain pooled estimates, we used the Cochran Mantel-Haenszel method across the two intervals (baseline to the 24 week visit and 25 to 48 weeks) or the two randomization arms. The analysis was done on an individual level and based on whether an individual had any STIs during the specified time period (so, for example, an individual having multiple infections within the 25 to 48 week period was only counted once). We also report the number of STIs as a function of the number of tests, allowing an individual to be counted more than once if they have multiple infections.

For the timeline follow back data, we performed a multiple linear regression to determine if ART had any effect on condom use or role (insertive or receptive). We also wanted to determine whether starting ART immediately vs. delaying initiation for 24 weeks had any effect on individuals' reported use of condoms, controlling for positioning during sex and the amount of time during the study period. For the CASI data, we performed a logistic regression on the odds of condomless anal intercourse using reported condom use (i.e. with a main partner, casual partner, or during transactional sex) as the outcome and ART group (immediate or delayed) as the predictor, controlling for reported drug and alcohol use. Fourteen participants in the study provided no information on their condom adherence and one individual's CASI data was not available for analysis.

We analyzed the consistency of each individual's reporting of sexual behavior data

on the two surveys and the results of their biological STI testing. We would expect that an individual who engaged in a condomless sex act would indicate this via both the TFB (by specifying the specific day it happened) and via CASI survey (indicating **any** designation less than "always" using condoms). An individual having an incident STI would, by our understanding of disease process, have at least one condomless sex act reported during that same period on both surveys. We calculated a percent agreement and kappa test to determine the amount of agreement between the two survey modalities in each time period. We also analyzed whether diagnosed STIs had corresponding reports of condomless sex on either CASI or TFB.

Results

A. Sexually Transmitted Infections

Although more STIs were detected among participants in the delayed arm, the two cohorts were not statistically significantly different in prevalence of STIs shortly after enrollment into the step 3 study which is consistent with our trial being randomized. Table 1 shows the itemization of infections by both site (rectal or urethral) and type of infection (gonorrhea or chlamydia), which was used to calculate the prevalence at baseline and corresponding p-values (note some individuals had more than one infection). At enrollment, 15 individuals had an STI in addition to HIV: 10 in the delayed group, and 5 in the immediate group.

	Immediate	Prevalence	Delayed	Prevalence	Significance (p-value)
Gonorrhea	**2**	**4.88%**	**6**	**14.29%**	**0.15**
Rectal	2		5		
Urine	0		1		
Chlamydia	**4**	**9.76%**	**7**	**16.67%**	**0.35**
Rectal	4		6		
Urine	0		1		
TOTAL	**6**		**13**		

Table 1. Sexually transmitted infections used to calculate baseline prevalence, by site and type of infection. Note some individuals had more than one infection and the numbers in this table represent each infection, not each individual who was found to have an STI.

The proportion of participants with STIs by treatment arm is shown in Table 2 (where it is calculated on an individual basis). Note the numbers in Table 1 and Table 2 differ because some individuals had multiple infections.

	Immediate	Proportion	Delayed	Proportion
Baseline (Prevalent)	5	12%	10	24%
1 to 24 Weeks (Incident)	8	20%	12	29%
25 to 48 Weeks (Incident)	7	17%	8	19%
Total in Cohort (with and w/o STIs)	41		42	

Table 2. Number and proportion of individuals with rectal and/or urethral gonorrhea and/or chlamydia, at baseline (prevalent infections) and 24, 48 weeks (incident infections)

In both groups, STIs continue to occur after diagnosis of acute/early HIV infection during the 48 week follow-up period. This indicates that even after participants know they have HIV and can transmit it to other individuals, they continue to have condomless sex.

To determine if being on ART had any effect on the amount of risky sexual behavior, we calculated odds ratios based on STIs for each of the three time periods. Tables 3-

5 show the corresponding odds ratios, calculated using Fisher's exact test. The analysis was done using individuals as the unit of analysis.

Baseline	STI	No STI	
Immediate	5	36	41
Delayed	10	32	42
	15	68	

Odds ratio= .45 (95% CI .11 to 1.63), 2-sided Fisher's exact p = 0.25

Table 3. Calculation of prevalence odds ratio at baseline (first post-diagnosis visit)

1 to 24 weeks	STI	No STI	
Immediate	8	33	41
Delayed	12	30	42
	20	63	

Odds ratio= .6 (95% CI .22, 1.68), 2-sided Fisher's exact p= 0.44

Table 4. Calculation of odds ratio for 1 to 24 weeks

25 to 48 weeks	STI	No STI	
Immediate	9	32	41
Delayed	9	33	42
	18	65	

Odds ratio= 1.03 (95% CI .36, 2.93) 2-sided Fisher's exact p = 1.0

Table 5. Calculation of odds ratio for 25 to 48 weeks

Using the Cochran Mantel-Haenszel method to estimate the pooled OR for STIs across the 2 strata (time intervals), we get a pooled odds ratio of 0.67 (95% CI .36 to 1.24) with a p-value of 0.20, indicating there is no significant difference in the odds of STIs in the immediate vs. delayed arms after controlling for time of assessment.

B. Self-reported behaviors, CASI

At enrollment, participants reported an average of 5.57 sex partners in the three months prior to diagnosis (range 0 to 55 sex partners). Out of the 38 individuals who stated they had a main sexual partner, the majority of them (23 out of 38 participants) reported role versatility with their main partner. Ten of them reported giving or receiving money, alcohol, drugs or other things in exchange for the sexual acts with that partner. Eighteen individuals (21.7%) reported having any partner, main or otherwise, in the last three months in which sex was traded for goods. Eleven participants (13.3%) stated they had exchanged sex for goods within the last thirty days, with the average number of transactions in the last thirty days being 8.8. In the last thirty days, two individuals reported being forced to have sex when they didn't want to.

Fourteen individuals (16.9%) in our cohort reported using drugs or alcohol right before sex with a partner in the previous thirty days before enrollment, with alcohol being the most commonly reported drug (all 14 participants), followed by marijuana (2 participants). Crack and cocaine 'paste' were each only reported by only one participant.

At enrollment, 29 out of the 41 participants in the immediate group (70.7%) and 24 individuals out of the 42 in the delayed group (57.1%) admitted to inconsistent condom use in the last three months. Table 6 provides a summary of participant responses at baseline.

	Main Partner	Casual Partner(s)	Transactional Sex Partner(s)
Never (Nunca)	13	4	1
Occasionally (Ocasionalmente)	3	7	1
Half the time (La mitad de tiempre)	6	6	2
Most (La major parte)	6	14	6
Always (Siempre)	10	15	8

Table 6. Self-reported condom use at baseline, CASI responses; number of individuals who identified with each category

Participants who responded were more likely to not use a condom during sex with a main partner and condom use was the highest, proportionally, with transactional sex partners at baseline.

Tables 7 and 8 provide a summary of participant responses during the period from baseline to 24 weeks, and 25 weeks to completion, respectively. As most participants filled out the survey twice during each time period, the table below includes the answer which indicated less condom use if the answers on the two surveys differed.

	Immediate			**Delayed**		
	Main Partner	Casual Partner(s)	Transactional Sex Partner(s)	Main Partner	Casual Partner(s)	Transactional Sex Partner(s)
Never	1	2	0	3	0	0
Occasionally	1	1	0	0	0	0
Half the time	3	2	1	4	2	0
Most	4	3	1	2	2	3
Always	14	20	2	11	18	6

Table 7. Self-reported condom use during the first 24 weeks of the study, CASI responses; number of individuals who identified with each category

	Immediate			Delayed		
	Main Partner	Casual Partner(s)	Transactional Sex Partner(s)	Main Partner	Casual Partner(s)	Transactional Sex Partner(s)
Never	2	5	3	4	2	3
Occasionally	1	0	1	1	0	0
Half the time	1	2	1	2	1	0
Most	1	2	1	1	3	2
Always	21	15	9	15	22	12

Table 8. Self-reported condom use during the second 24 weeks of the study, CASI responses; number of individuals who identified with each category

In the first 24 weeks of the study, participants in the immediate and delayed study arms had an average of 3 and 5 partners per three-month interval, respectively. The number of individuals indicating anything less than "always" using a condom with any kind of partner (main, casual or transactional) over our study period is summarized in Table 9. As in previous tables, if an individual gave two different answers during a particular period (i.e. baseline to week 12 and week 13-24) we selected the report of lower condom use, so the tables reflect the highest estimates of possible sexual exposures.

	Immediate	Delayed
Baseline	26	24
Baseline to 24 weeks	14	13
25 weeks to completion	11	12

Table 9. Condomless sex acts reported via CASI, by individual

We performed a logistic regression with the CASI data in Period 1 (Baseline to 24 weeks) to determine the effect of ART initiation on condom use (ART was used by those in the immediate but not deferred arms during this interval). ART use was determined to have no effect on condom use when looked at for main partner (p= 0.79), casual partner (p=0.40), transactional partner (p=0.57) or for condomless sex

with any partner type (p=0.90). When controlling for alcohol or drug use, which was rarely reported in the first 24 weeks of the study, the effect of ART use on condom use was still not significant (p=0.71).

C. Self-reported behaviors, TFB

At enrollment, 63 individuals reported having sex in the previous 30 days: 27 of those individuals (12 immediate, 15 delayed) reporting at least one act of condomless sex. The number of individuals in each cohort reporting condomless sex acts over time by treatment arm is shown in Table 10.

	Immediate	Delayed
Baseline	12	15
Baseline to 24 weeks	6	10
25 weeks to completion	6	4

Table 10. Number of individuals reporting condomless sex acts via TFB

We performed a multiple linear regression with the TFB data to determine the effect of ART initiation on condom use, controlling for sexual role and week of the study. ART timing was determined to have no effect on condom use (p=0.97).

D. Correlation between CASI and TFB

We analyzed the CASI data and TFB data at the time of participant enrollment to determine the amount of condomless sex that was reported with each method. The prevalence of condomless sex reported by each method is reported in Table 11 for enrollment.

	Immediate (+|tested)	Prevalence %	Delayed (+|tested)	Prevalence %	Overall %
CASI	29/41	70.73%	24/42	57.14%	**63.86%**
Timeline Follow Back	11/41	26.83%	15/42	35.71%	**31.33%**

Table 11. Reporting of condomless sex using computer vs. in-person interviewing, by individual participant (at baseline)

We performed a kappa test to determine the amount of agreement between CASI and TFB. Since this was at enrollment, we calculated the agreement for the overall group rather than each treatment cohort separately. Percent agreement was 54.9%, with an expected agreement of 44.8% under independence. This provided us with a kappa of 0.18 (95% CI .02 to 0.35), indicating slight agreement (Landis et al., 1977). Discordance was more likely to reflect reports of condomless sex on CASI but not TLFB (Table 12).

	CASI		
TFB	Y	N	Total
Y	20	5	25
N	32	25	57
Total	52	30	82

Table 12. Agreement on reported condomless sex reported by CASI (last thirty days) and TFB (last thirty days), at enrollment

Lastly, we determined what percent of diagnosed STIs had a condomless sex act reported on either CASI or TFB during the time period in which the STI was diagnosed. For the 15 participants (Table 2) with diagnosed gonorrhea or chlamydia at baseline, eight of these patients reported condomless sex on either CASI or TFB.

Four of these were captured by both CASI and TFB, and four were captured by either CASI or TFB, but not both (two on CASI and two on TFB).

In order to compare CASI and TFB after enrollment, we used only TFB data that was collected on the same days as the CASI, so that we didn't overestimate the amount of condomless sex that was reported on TFB vs. CASI (as TFB was collected every month and CASI was collected every three months, inquiring about the last 30 days).

	Immediate		Delayed	
	CASI		CASI	
TFB	Y	N	Y	N
Y	3	2	4	3
N	9	21	9	14

Table 13. Agreement between condomless sex reported on CASI and TFB for the interval from baseline to 24 weeks

In the immediate group, agreement between CASI and TFB was 68.6%, with an expected agreement of 61.2%. This gave us a kappa of .19 indicating only slight agreement (Landis et al., 1977). In the delayed group, agreement between CASI and TFB was 60%, with an agreement expected by chance of 53.6%. This gave us a kappa of .14, also indicating slight agreement (Landis et al., 1977).

Using the Cochran Mantel-Haenszel equation controlling for randomization arm (immediate or delayed) gives us an overall OR of 2.59 (95% CI 0.69 to 9.72) for agreement vs. non-agreement, with a p-value of 0.70, telling us there is a low likelihood of agreement in responses to the two questionnaires in the study population during the first time period.

	Immediate		Delayed	
	CASI		CASI	
TFB	Y	N	Y	N
Y	6	1	3	1
N	5	23	9	22

Table 14. Agreement between condomless sex reported on CASI and TFB for the interval 25 weeks to completion

In the immediate group, agreement between CASI and TFB was 82.9%, with an expected agreement of 61.1%. This gave us a kappa of 0.56 indicating moderate agreement (Landis et al., 1977). In the delayed group, agreement between CASI and TFB was 71.4%, with an expected agreement of 62.1%. This gave us a kappa of 0.25, indicating fair agreement (Landis et al., 1977). Table 15 provides a summary of the kappa statistics and magnitude based on Landis and Koch's guidelines (Landis et al., 1977).

	Immediate	Delayed
Baseline	.18 (Slight)	
Initiation to 24 weeks	.19 (Slight)	.14 (Slight)
25 weeks to completion	.56 (Moderate)	.25 (Fair)

Table 15. Summary of kappa statistics for CASI and TFB with corresponding magnitude over time

Again using the Cochran Mantel-Haenszel equation controlling for group (immediate or delayed) gives us an overall pooled OR of 14.6 (95% CI 2.30 to 92.13), with a p-value of 0.49 telling us there is low (but slightly better) agreement in responses to the two questionnaires by the study population during the second time period.

E. Correlation between TFB and STIs

Table 16 shows the number of individuals who were diagnosed with an STI in each treatment group and the corresponding number and percent of those individuals who reported any act of condomless sex on TFB.

	Immediate			Delayed		
	Diagnosed	Reported	%	Diagnosed	Reported	%
Baseline	5	2	40%	10	4	40%
1 to 24 Weeks	8	2	25%	12	0	0%
25 to 48 Weeks	7	1	14%	8	1	13%

Table 16. Correlation between STIs and condomless sex acts reported by TFB, over time, by individual

At no point in time did the number of individuals with an STI infection who disclosed condomless sex on TFB reach a proportion greater than 40%. Overall, incident STIs remained stable over time with the disclosure of condomless sex decreasing over time. This trend was observed in both the immediate and deferred treatment arms. The presence of an incident STI without any disclosure on TFB indicates that participants were sexually active without disclosing this information to the interviewers.

F. Correlation between CASI and STIs

Table 17 shows the number of individuals who were diagnosed with an STI in each treatment group and the corresponding number and percent of those individuals who reported any act of condomless sex on CASI.

	Immediate			Delayed		
	Diagnosed	Reported		Diagnosed	Reported	
Baseline	5	3	60%	10	3	30%
1 to 24 Weeks	8	4	50%	12	3	25%
25 to 48 Weeks	7	1	14%	8	1	13%

Table 17. Correlation between CASI and STIs, over time, by individual

Over time we see the same trend from Table 16 in that the proportion of reported STIs decreases over time. We can also observe that more individuals diagnosed with an STI reported unprotected sex on CASI compared to TFB at baseline and in the first 24 weeks, when the two groups differed with respect to ART.

Discussion

Our study shows that populations of men who have sex with men and transgender women in Lima, Peru, despite receiving a diagnosis of HIV, continue to exhibit risky sexual behavior that provides the opportunity to further transmit HIV. This was shown through both biological testing for STIs and through survey modalities using both in-person and computer-based interviewing. Our study is unique in that we were able to identify individuals in the acute/early phase of HIV infection and follow them for 48 weeks after diagnosis. We did not observe that early ART initiation had any effect on an individual's reported condom use or likelihood of acquiring an STI. This was true both during the first 6 months of our study, when the two groups differed in whether or not they were on ART, and in the second 6 months when both groups had started ART. Our study indicates that initiating ART immediately, rather than delaying for six months, will not lead to an increase in STIs. Interestingly, we

observed that participant's reporting of condomless sex varied by which survey modality we used, with more condomless sex reported on CASI than TFB. Agreement between the two survey methods was very low throughout the study, indicating that at no time were participants consistent in their responses to the two surveys. It also supports the use of biological testing to confirm survey responses, especially when the responses are collected with in-person interviewing.

Previous studies have supported the use of ART in the acute/early phase of HIV for the benefits to both the individual and their partners. Early ART initiation has been shown to lower the probability of progression to later stages of HIV (Herout et al., 2015) and decrease sequelae of HIV infection including cardiovascular disease, non-AIDS-defining cancer and tuberculosis (Insight Start Study Group, 2015; Siegfried et al., 2010). Recent studies have also shown that early ART initiation does not increase negative social consequences, such as HIV-related discrimination or lack of HIV disclosure (Jean et al., 2016). The decrease in an individual's viral load through the use of ART will also decrease onward transmission, which leads to a lower incidence within a community (Eshleman et al., 2016; Rodger et al., 2016; McClelland et al., 2015; Solomon et al., 2016). Studies specifically looking into sexual behavior following ART initiation have generally shown a decrease in sexual activity following ART initiation when using questionnaires for data collection (Jean et al., 2015; Peltzer et al., 2015). A meta-analysis on sexual behavior post-ART initiation, using studies published prior to 2010, found that when using STI diagnosis as a marker of sexual activity, ART was protective against having an STI. The same meta-

analysis, when looking at reported behavior, also showed a decrease in unprotected sex when individuals were on ART (Doyle et al., 2014). Our study builds upon these previous ones in its study design as a randomized trial and by employing both biological testing and participant survey methods. The integration of these methods allows us to analyze commonalities and discrepancies between them, which was not possible in previous studies. We contribute to the growing body of evidence that "risk disinhibition," the idea that being initiated on ART will make individuals more likely to engage in condomless sex due to a perceived protective benefit, is not a reason to delay treatment.

Participants having incident STIs without corresponding disclosure of condomless sex points out an important limitation of many survey-based studies, and a strength of our study which used multiple avenues to ascertain whether participants were having condomless sex. Had our study been conducted without any biological STI testing, we would have severely underestimated the amount of risky sexual behavior. Still, survey-based data remains an extremely important component of our research study and provides rich information. Discrepancies in participant responses to TFB and CASI may be due to participants being unwilling to report data during in-person interviewers, but also may be due to the way in which questions were asked. With TFB, an interviewer provided a calendar of the previous 30 days and asked individuals to identify specific days on which sexual acts occurred. For CASI, participants were asked about a specific type of partner (main, trading sex or casual) and asked what percent of the time they used a condom with this partner.

While previous questions in the survey specified a time period of the last 30 days, participants may easily have differed in their responses based on whether they interpreted the question to also refer to the last 30 days versus their overall sexual activity with the specific partner. If participants answered the question based on overall sexual activity, rather than last 30 days, the data could under- or over-report the participant's condom use. This would lead to a discrepancy between CASI and TFB that is not due to participant preference for disclosure of sensitive information. That being said, our data analysis was biased towards agreement between the questionnaires and the biological STI measurements by coding **any** indication of less than 100% condom use as having the potential to transmit STIs. In this way, even if a participant misinterpreted the CASI question to indicate overall condom use, CASI and TFB should agree because an act of condomless sex (either in the last 30 days or at any time) would be coded the same way. We feel that this partly ameliorated the differences in questions and methods of collecting the data. Other limitations of our study include the small sample size, lack of geographical diversity of participants, and lack of biological testing to confirm use or non-use of drugs and alcohol. We feel these limitations do not undermine the results of our study. While we would have liked to analyze serosorting behavior and investigate any relationships in being on ART and a participant's sexual positioning with partners, there were not enough participants who responded to questions on these topics and responses were not very consistent. Frequent drug and alcohol testing, while being a way to validate aspects of our data, influences cost and participants' willingness to participate.

Our study's strengths lie in its abundance of information about type of sexual partners, drug and alcohol use before sex, and condom use. In addition, the randomized design reduces bias that is difficult to eliminate in non-randomized study designs. Lastly, our study looks at individuals during a unique period of HIV infection, the acute phase, and follows them for a year after diagnosis to get an in-depth and longitudinal view of sexual behavior.

The finding of continuing risky sexual activity, despite receiving a diagnosis of HIV, is concerning for efforts aimed at ending the HIV epidemic and provides necessary information for designing public health interventions. Future studies looking into ART initiation and sexual behavior may not have the ability to randomize, but could still get important information about the correlation between STI diagnose and self-disclosure. It would be ideal to perform a study in which individuals are surveyed with a 30-day recall method (such as TFB) both by an in-person interviewer and then on a computer; so that any difference between the surveys can be distinctly attributed to the modality and not the way questions are asked. It would be best to still allow a diversity of information to be collected in this manner, such as the number of partners, kind of sexual partner (main, casual, transactional), and drug and/or alcohol use prior to sex. In addition, future studies could expand upon our results by testing in other populations such as heterosexual men and women and individuals of other ethnicities outside of Peru. The most important thing to address in future investigations is which community interventions, if any, decrease risky sexual behavior during acute HIV infection, regardless of whether or not the

individual is on ART.

Overall, our study has made an important contribution to the field in its ability to show, through biologic testing and participant surveys, that ART does not have an effect on an individual's sexual behavior after HIV diagnosis. In addition, it showed that the survey method being used should be carefully considered when drawing conclusions about individuals' sexual behavior. Our results support the growing body of evidence that ART should be initiated as soon as possible following HIV diagnosis, without concern that doing so will lead to an increase in risky sexual behavior that transmits HIV onward into the community.

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Abbreviations and Symbols

ART- Antiretroviral therapy
CASI- Computer-assisted self-interviewing
CD4- Cluster of differentiation 4
CI- Confidence interval
HIV- Human immunodeficiency virus
MSM- Men who have sex with men
PrEP- Pre-exposure prophylaxis
RNA- Ribonucleic acid
STI- Sexually transmitted infection
TasP-Treatment as prevention
TFB- Timeline follow back
TW-Transgender women
UNAIDS- United Nations Program on HIV/AIDS
UNGASS- United Nations General Assembly Special Session
WHO- World Health Organization

Appendix

CASI Questionnaire related to HIV risk behaviors and drug/alcohol use in relation to sex (translated from Spanish)

Overall Partners
How many people have you had sex with in the last 3 months?
In the last 30 days, how many times were you forced to have sex when you did not want to?
During the past 30 days, did you use drugs or alcohol just before or during sex with any partner?
(Alcohol, marijuana, crack, cocaine, cocaine paste, other (please specify))

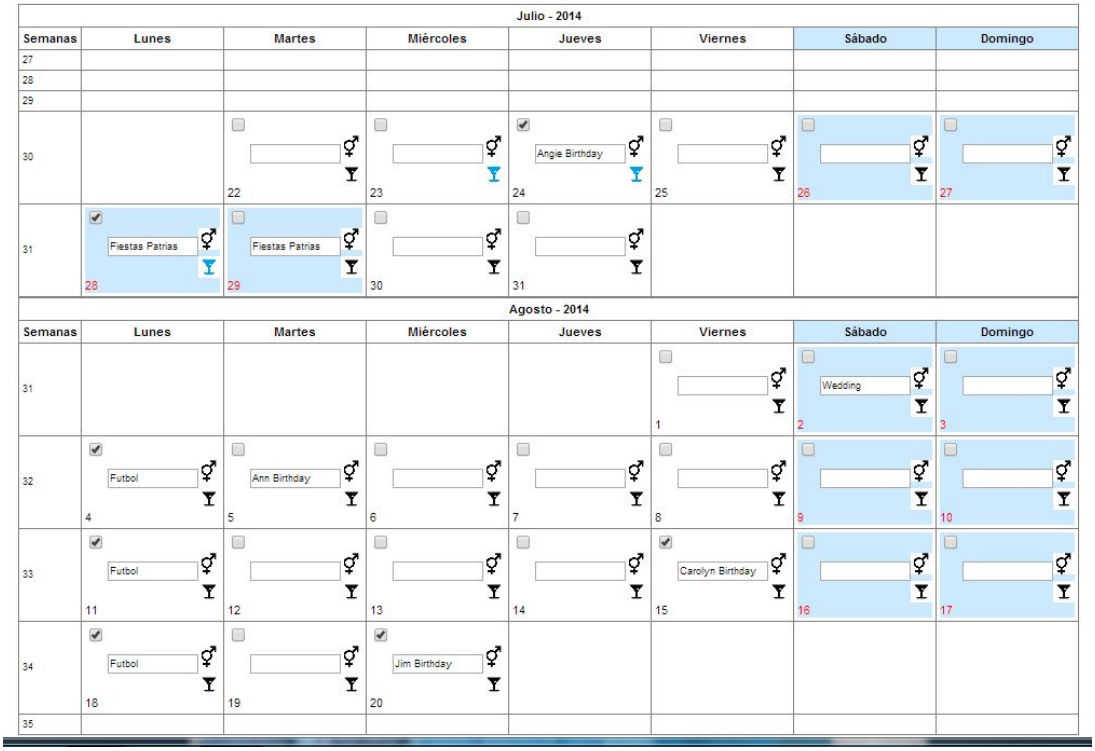
Trading Sex
Have you ever had sex to receive money, alcohol, drugs, or other things from this main partner?
Have you ever given money, alcohol, drugs, or other things to this main partner for sex?
Have you ever traded anal sex for drugs, money, food, clothing, shelter, or any other goods?
How many times during the past 30 days did you have anal sex to get money, drugs, or a place to stay?
Of those times you traded for anal sex, what percent of the time did you use a condom?
About what fraction of your anal sex with your trading partner(s) were you receptive?

Main Partner
In the last 30 days, did you have a person that you considered a main partner?
As far as you know, has this main partner ever been tested for HIV?
What were their last HIV test results?
What percent of the time have you used a condom when you have had anal sex with this main partner?
About what fraction of your anal sex with this main partner were you receptive?
Have you ever had sex to receive money, alcohol, drugs, or other things from this main partner?
Have you ever given money, alcohol, drugs, or other things to this main partner for sex?

Casual Partner
In the past 30 days, did you have anal sex with one or more casual partners?
How many times in the last month did you have anal sex with casual partners?
Of those times you had anal sex with a casual partner, what percent of the time did you use a condom?
About what fraction of your anal sex with your casual partner(s) were you receptive?

Timeline Follow Back Questionnaire

Monthly View



Day View