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STI & HIV 2023 World Congress Abstract Submissions

Prevalence and incidence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* among pregnant women in a high HIV prevalence setting in South Africa

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Background
Sexually transmitted infections (STIs) among pregnant women in South Africa have been reported to be more common among women living with HIV (WLHIV) than among HIV-negative women. The objectives of this study were to investigate the prevalence and incidence of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) and their associations with HIV infection in pregnancy.

Methods
CT/NG testing was implemented in an ongoing cohort study about STIs in pregnancy in a primary healthcare clinic in East London, South Africa. At the baseline antenatal care visit before 27 weeks of gestation and between 30-34 weeks, an HIV rapid test was done, and a nurse-collected vaginal swab was tested using the GeneXpert CT/NG assay. Women with positive results were offered treatment. We calculated percentages, relative risks (RR) and incidence rates per 100 woman-years (with 95% confidence intervals, CI).

Results
From March 2021 to November 2022, we tested 215 women at baseline and at 30-34 weeks gestation. At baseline, 43 women were CT and/or NG-positive; CT 40/215 (19%, CI 14-25), NG 9/215 (4%, CI 2-8) (6 CT and NG), and 57/215 were WLHIV (27%, CI 21-33). The risk of CT/NG was 12% (7/57) in WLHIV and 23% (36/158) in HIV-negative women (RR 0.5, CI 0.3-1.1). CT/NG appeared to be less common in women reporting condom use at last intercourse (RR 0.38, CI 0.1-1.5) and more common among women reporting >1 partner in the last 6 months (1.4, CI 0.7-3.0). Most women with positive results (41/43) returned for treatment. At the 30-34 week visit, 16 (7%) women were CT-positive and 1 (0.5%) was NG-positive. CT/NG incidence for women with baseline negative results (10 women, 9 CT and 1 NG) was 0.1 (CI 0.01-0.7) per 100 woman-years. Of 7 women with repeat positive CT results, 2/7 (29%) were WLHIV and 5/36 (14%) were HIV-negative (RR 2.0, CI 0.5-8.6).

Conclusion
CT and NG were highly prevalent in this cohort. Compared with HIV-negative women, WLHIV appeared less likely to have CT/NG at baseline. Over half of the positive results at 30-34 weeks were new infections, highlighting the need for prevention and treatment of incident CT/NG in late pregnancy.

Prevalence and incidence of *Trichomonas vaginalis* in pregnant women in South Africa

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Background
Trichomonas vaginalis (TV) is the most common curable sexually transmitted infection (STI). It is associated with adverse pregnancy outcomes and increased risk of HIV transmission. We aimed to determine the incidence and prevalence of TV at two time-points during pregnancy.

Methods
Women attending their first antenatal care visit were enrolled in an implementation-effectiveness study of STI screening strategies in East London, South Africa. Inclusion criteria were women ≥18 years and <27 gestational weeks, irrespective of HIV-infection status. Trained research nurses performed physical examination and vaginal swab collection. Screening included onsite testing at baseline and at 30-34 gestational weeks using the GeneXpert TV assay. Women with positive results were treated with 7 days of metronidazole 400mg twice daily and offered partner notification slips. Data were collected on treatment adherence, partner notification and treatment.

Results
From March 2021 to November 2022, we tested 171 women at baseline and 30-34 gestational weeks. TV test at baseline was positive for 17 (10%, 95% confidence interval, CI 6-16%); all were treated. TV infection was more common among women living with HIV compared to women without (9/46 (20%, CI 10-34) versus 8/125 (6%, CI 3-13), p=0.01). Self-reported adherence data were available for 11/17 (65%) of positive women; all reported to have finished the full course of treatment provided. Ten women informed their partner of their STI diagnosis; 5 partners were reportedly treated. At the 30-34 week visit, 5/171 (3%) women tested positive for TV, of which 4 had been positive at baseline (i.e. 4 of 17 (24%) of those with positive TV test at baseline) and 1 had a new infection after previous negative test. The incidence rate for baseline negative participants was 0.013 per 100 woman-years (CI 0.00- 0.09).

Conclusion
TV was prevalent among pregnant women in our setting, and more common among HIV infected women. Incident infection was low at the repeat visit at 30-34 weeks suggesting once off diagnostic testing may be sufficient. However, when previously treated, repeat TV test positivity was high at 30-34 weeks despite reported excellent treatment adherence.

Preparedness of pregnant women to wait for same-day results of sexually transmitted infections

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Project
We are conducting studies about sexually transmitted infections (STIs) in pregnancy in 5 primary healthcare clinics in East London, South Africa. At antenatal visits, research nurses collect a vaginal swab for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis* testing on the GeneXpert platform. Women with any positive result are offered same-day treatment. Women who do not wait are telephonically requested to return for treatment. A subset was asked about their preparedness to wait for their results.

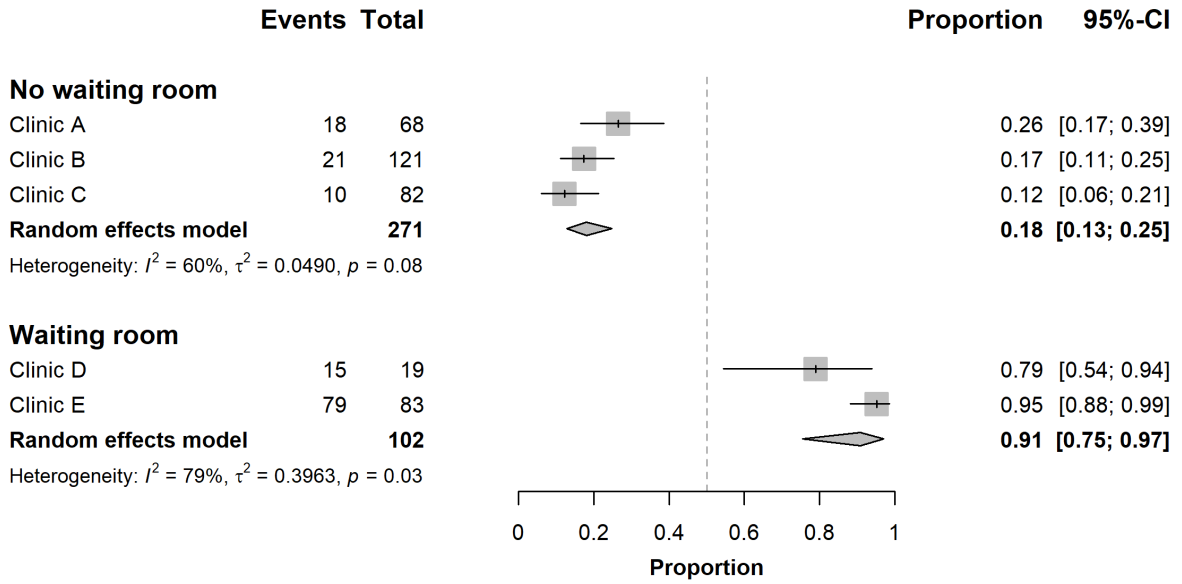
Issue
Ensuring treatment for STIs in resource-limited settings is challenging. Introduction of diagnostic testing for STIs is imperative. The GeneXpert system provides the opportunity for same-day treatment as STI test results are available within 90 minutes. However, it is not clear whether same-day treatment is feasible in clinics. In our study clinics, 2 have a designated waiting area and 3 do not.

Results
We tested 1194 pregnant women for STIs from March 2021 to December 2022, of whom 282 (24%, 95% confidence interval, CI 21-26) had positive results for any STI. Of these, 116/282 (41%) received same-day treatment, 92/282 (33%) returned within 1 week, 53/282 (19%) within 2-11 weeks, and 21 (7%) did not return. The concordance of the intention to wait/not to wait and if participants effectively waited, was 70% (99/141) among 141 women who answered additional questions. The most common reasons not to wait were (1) need to get back to family (42/121, 35%), (2) need to get to work (33/121, 27%), and (3) hunger (18/121, 15%). Combining data from all participants in random effects meta-analysis stratified by clinic (Figure 1), 91% (CI 75-97%, I^2 79%) waited in clinics with a waiting room compared with 18% (CI 13-25%, I^2 60%) in clinics without.

Lessons Learned
Same-day treatment for pregnant women with STIs was possible and more likely at clinics with a designated waiting area. The intention of women to wait is not a reliable indicator of actual waiting,

suggesting that the intention can be modified. We have since built waiting rooms in 2 of the 3 clinics that did not have them and are studying the outcomes of this intervention on same-day STI treatment.

Figure 1. Meta-analysis of participants waiting for their result at 5 antenatal clinics, stratified by waiting room availability



STI testing and treatment in pregnancy may be limited by re-infection from untreated partners

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Background
Chlamydia trachomatis (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) are associated with adverse pregnancy outcomes. Sexually transmitted infection (STI) testing followed by pathogen-directed treatment would optimize treatment compared with syndromic management. We aimed to determine STI treatment outcomes among pregnant women in South Africa.

Methods
Pregnant women at 4 healthcare clinics in East London, South Africa were included in an implementation-effectiveness study. Eligibility criteria included <27 gestational weeks and attendance at their first antenatal care visit. Nurse-collected vaginal specimens were tested on-site using the GeneXpert CT/NG and TV molecular assays. In one study arm, women with positive STI result(s) received pathogen-directed treatment, partner notification slips, and a test-of-cure (TOC) visit was scheduled at 21days post-treatment; visits were allowed up to 35 days. At TOC, sexual behaviour and partner treatment data were collected, and CT, NG, and TV STI testing were repeated; cure was defined as a negative result on repeat testing.

Results
We tested 361 eligible women in one study arm between March 2021 and November 2022. Of these, 93 (26%) tested positive for any STI and 86 (93%) received treatment within study arm timeline (51 for CT, 15 for NG, and 34 for TV); 70/93 (75%) were asymptomatic and 28/93 (30%) were HIV-positive. TOC visit was attended by 55/86 (64%, 95% confidence interval, CI 53-74) women within the appropriate window of time; 9/55 (16%, CI 8-29) had a positive repeat STI test (4/32 (13%) for CT, 5/22 (23%) for TV, and 0/11 (0%) for NG) (Table 1). Most women (98%; 54/55) reported disclosure of their STI to their partner however only 45% (25/55) reported that their partner received treatment. Of the 9 women with repeat positive testing at TOC, only 1/9 (11%, CI 0.6-49) reported that her partner received treatment compared with 24/46 (52%, CI 37-67) of cured participants (Fisher Exact p=0.03).

Conclusion
Primarily asymptomatic STIs were common among this cohort of pregnant women in South Africa. However, the potential benefits of STI testing and treatment in pregnancy may be limited by re-infection from untreated partners. Improving partner treatment should be prioritised.

Table 1. STI treatment outcomes among pregnant women attending test-of-cure visit

Infection	Women positive and treated at baseline, n	Women attended TOC, n	Women cured, n (%)	Women with persistent or recurrent infection, n (%)
CT	41	25	22 (88%)	3 (12%)
NG	6	4	4 (100%)	0
TV	25	16	11 (69%)	5 (31%)
CT + NG	5	4	4 (100%)	0
CT + TV	5	3	2 (67%)	1 (only CT) (33%)
NG + TV	4	3	3 (100%)	0

Could Vaginal pH Testing Reduce Excess Antibiotic Use Among Pregnant Women with Vaginal Discharge Syndrome?

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Background. *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) are common curable sexually transmitted infections (STIs). Syndromic management of vaginal discharge syndrome (VDS), the current standard-of-care in resource-constrained settings, results in substantial antibiotic overtreatment. In view of increasing antimicrobial resistance, novel strategies to reduce antibiotic use are urgently needed.

Methods. Data were obtained from pregnant women with VDS (observed and/or reported abnormal vaginal discharge with or without other urogenital symptoms) in an ongoing randomized controlled trial of STI screening strategies in South Africa, wherein women were tested for abnormal vaginal pH (pH > 4.5 - rapid test strips, multiple manufacturers), and STIs (GeneXpert CT/NG and TV; Cepheid, Sunnydale, California). We determined (1) the sensitivity and specificity of abnormal pH for CT or NG, and TV, and (2) hypothetical over or undertreatment with pH-guided therapy (treating those with abnormal pH) versus syndromic management (treating everyone).

Results. Among 118 pregnant women with VDS, 74 (62.7%) had abnormal vaginal pH. Of those 118, 42 (35.6%) tested positive for any STI. By STI, positivity was CT, 26 (22.0%), NG, 8 (6.8%), CT or NG, 32 (27.2%), and TV, 15 (12.7%).

Abnormal vaginal pH (Table) had a sensitivity of 71.4% (95% CI 55.4%–84.3%) and specificity of 42.0% (95% CI 31.0%–54.0%) for any STI. The sensitivity was 68.8% (95% CI 50.1%–83.9%) and specificity 40.0% (95%CI 29.2%–50.7%) for CT or NG, and the sensitivity was 80.0% (95% CI 51.9%–95.7%) and specificity 39.8% (95%CI 30.3%–49.9%) for TV.

Based on STI positivity (Table), pH-guided therapy would reduce overtreatment from 76 (64.4%) to 44 (37.3%) women with no STI; 86 (72.9%) to 52 (44.1%) women without CT or NG, and 103 (87.3%) to 62 (52.5%) women without TV. Conversely, pH-guided therapy would undertreat 12 (10.2%) women with any STI; 10 (8.5%) with CT or NG, and 3 (2.5%) with TV.

Conclusion. Abnormal pH showed moderate sensitivity for CT or NG, high sensitivity for TV, but low specificity for any STI. Although pH-guided therapy would considerably reduce antibiotic overtreatment in pregnant women with VDS, there is potential for missed treatment. Further research into benefit versus harm, including strategies to complement vaginal pH-guided therapy, is necessary.

Table. Sensitivity and Specificity of abnormal vaginal pH for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), or *Trichomonas vaginalis* (TV) infection in 118 pregnant women with abnormal vaginal discharge in East London, South Africa.

	CT, NG, or TV present	CT, NG, or TV absent	
Abnormal pH (>4.5)	30	44	74
Normal pH (≤4.5)	12	32	44
	42	76	118
Sensitivity = 71.4% (95% CI 55.4% to 84.3%), Specificity = 42.0% (95% CI 31.0% to 54.0%)			
	CT or NG present	**CT or NG absent**	
Abnormal pH (>4.5)	22	52	74
Normal pH (≤4.5)	10	34	44
	32	86	118
Sensitivity = 68.8% (95% CI 50.1% to 83.9%), Specificity = 40.0% (95% CI 29.2% to 50.7%)			
	TV present	**TV absent**	
Abnormal pH (>4.5)	12	62	74
Normal pH (≤4.5)	3	41	44
	15	103	118
Sensitivity = 80.0% (95% CI 51.9% to 95.7%), Specificity = 39.8% (95% CI 30.3% to 49.9%)			

Title: Chlamydial Ophthalmia Neonatorum: Case Series from Gaborone, Botswana

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Abstract

Background: Ophthalmia neonatorum is acute conjunctivitis occurring usually within the first month of life. It carries significant risk of corneal ulceration, corneal perforation, and blindness. We describe a case series of chlamydial ophthalmia neonatorum. The data presented in the case series were obtained from the “Maduo” study, a prospective

cluster-controlled study of the relationship between curable sexually transmitted infections in pregnancy and adverse neonatal outcomes.

Methods: We recruited pregnant women from four antenatal clinics in Gaborone, Botswana. Chlamydial ophthalmia neonatorum cases were confirmed with GeneXpert® diagnostic testing. Our exposure of interest was *C. trachomatis* infection in the mother. Our outcome of interest was the diagnosis of chlamydial conjunctivitis in the infant.

Results: Our study population consisted of 29 infants born to mothers who were recruited at their first antenatal visit (February 2021 - April 2022) and tested positive for *C. trachomatis* within 8 weeks of delivery. Chlamydial ophthalmia neonatorum was diagnosed in twelve (41%) of twenty-nine exposed infants. Eight cases were confirmed with GeneXpert® diagnostic testing while four were identified as probable cases based on high suspicion from clinical history and presentation. Nine had clinical signs of conjunctivitis, while three were asymptomatic. Four infants had signs suggestive of chlamydial pneumonia. All but one infant had received ocular tetracycline 1% prophylaxis at birth. Four had been managed for chlamydial conjunctivitis or pneumonia at a different health facility. Two of five symptomatic cases who completed the prescribed course of erythromycin had lingering symptoms. Case findings are summarized in the Table.

Conclusions: Our findings affirm that current prophylaxis modalities for chlamydial ophthalmia neonatorum may be inadequate. To the extent feasible in low- and middle-income healthcare settings, we recommend implementation of routine *C. trachomatis*

screening and treatment in pregnant women to prevent chlamydial ophthalmia neonatorum.

Table 1: The 12 Cases of Chlamydial Ophthalmia Neonatorum, Gaborone Botswana, Identified by Postnatal Visit (October 2022)

	CASE 1	CASE 2	CASE 3	CASE 4	CASE 5	CASE 6	CASE 7	CASE 8	CASE 9	CASE 10	CASE 11	CASE 12
PERINATAL CHARACTERISTICS AND HISTORY PRIOR TO THE POSTNATAL VISIT												
Sex at birth	Male	Male	Female	Female	Female	Female	Female	Male	Female	Male	Female	Female
Mode of delivery [a]	SVD	SVD	SVD	SVD	SVD	SVD	SVD	SVD	SVD	SVD	SVD	SVD
Born preterm (<37 weeks' gestation)	No	No	No	No	No	No	No	No	No	No	Yes	Yes
Had a low birth weight (< 2500g)	No	No	No	No	No	No	No	No	No	No	Yes	Yes
Mother lives with HIV	No	No	No	No	No	No	No	No	No	Yes	Yes	No
Mode of feeding since birth	Breastfed	Breastfed	Breastfed	Breastfed	Breastfed	Breastfed	Breastfed	Breastfed	Breastfed	Breastfed	Replacement	Breastfed
Ocular tetracycline hydrochloride (1%) administered at birth	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Management for Chlamydia infection between birth and postnatal visit	Received unspecified prior treatment for pneumonia at a different facility	None	Received unspecified prior treatment for conjunctivitis at a different facility	None	None	None	None	Erythromycin was previously prescribed for conjunctivitis. Course completion could not be ascertained	Received unspecified prior treatment for conjunctivitis at a different facility	None	None	None
CLINICAL PRESENTATION, DIAGNOSIS, MANAGEMENT, AND FOLLOW UP												
Age in days at presentation	49	58	40	44	45	45	126	51	67	46	42	44
Confirmed [b] **or Probable** [c] **case**	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Confirmed	Probable	Probable	Probable	Probable
Ocular swab positive for *C. trachomatis* (GeneXpert®)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	No	No
Nasopharynx swab positive for *C. trachomatis*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
Eye sign at presentation	Eyelid swelling	Eyelid swelling	None	None	Eyelid swelling & Purulent discharge	Purulent eye discharge	Watery eye discharge	None	Purulent eye discharge	Eyelid swelling	Purulent eye discharge	Eyelid swelling
Chest sign at presentation	None	None	None	None	Chest congestion	Chest congestion	Cough	None	None	Cough	None	None
Erythromycin prescribed	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Mothers encouraged to seek care at local facility if symptoms persisted	Mothers encouraged to seek care at local facility if symptoms persisted	Mothers encouraged to seek care at local facility if symptoms persisted	Mothers encouraged to seek care at local facility if symptoms persisted
Completed erythromycin course	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No follow up required	No follow up required	No follow up required	No follow up required
Lingering symptoms after treatment	Itchy eyes	None	None	None	None	None	Cough	None	No follow up required	No follow up required	No follow up required	No follow up required

[a] SVD: spontaneous vaginal delivery
[b] Confirmed case: GeneXpert® *C. trachomatis*-positive ocular and/or nasopharyngeal swab in an infant who has eye signs OR a positive ocular swab result in an infant with asymptomatic infection
[c] Probable case: High clinical suspicion based on presence of eye signs at clinical evaluation, with or without history of prior management for chlamydia conjunctivitis
[d] Case management: Mothers of infants with probable infection were encouraged to seek care at a local facility. Botswana syndromic care guidelines currently recommend erythromycin (50mg/kg/day for 14 days) for suspected chlamydial conjunctivitis in the newborn

Title: Impacts of COVID-19 Pandemic and Lockdowns on Sexual Health and Livelihoods of Sex Workers in India

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ABSTRACT TEXT

Background: The COVID-19 pandemic has undermined HIV prevention efforts globally, with dire consequences for key populations in low- and middle-income countries. We aimed to understand the impacts of the COVID-19 pandemic on the livelihoods of sex workers in India as well as their sexual behaviors and HIV-related service utilization.

Methods: From June to September 2022, we conducted a survey (N=279) and in-depth interviews (N=40) with female, male, and transgender sex workers in West Bengal, India regarding their experiences before and during the COVID-19 pandemic. Frequency distributions for sexual health, HIV/STI testing, service utilization, and income-related variables were compared pre- and post- pandemic using chi-squared tests. Interview transcripts were thematically coded and analyzed using an inductive approach.

Results: No significant changes in condom use were observed before versus during the pandemic. HIV testing and service utilization declined sharply during the first lockdown in India from March to May 2020 but rebounded following the lifting of restrictions in June 2020. However, most respondents reported significant or total declines in the number of weekly clients during the first lockdown from a mean of 13 to 1 clients/week, which have yet to return to pre-pandemic levels (current mean=10 clients/week). Furthermore, 92% of respondents reported no rate increases to compensate for the lower number of clients. As a result, the majority of respondents experienced significant loss of income (25-30%) sustained over two years. Participants described how inability to maintain stable income has led to severe financial strain, food insecurity, reliance on external support, emotional distress and isolation, and exploitation.

Conclusion: Our findings indicate that the COVID-19 pandemic has contributed to significant financial losses among sex workers in India. Although self-reported condom use behaviors were maintained consistently throughout the pandemic and HIV/STI testing frequency rebounded following the first lockdown, the prolonged economic impacts of the pandemic plunged many sex workers into debt. Over the long-term, these structural conditions may subject sex workers to increased exploitation or lead to sexual risk-taking, such as engaging in condomless sex for additional income, which may consequently heighten the potential for HIV and STI transmission.

Title: Alcohol Use Disorders and Inconsistent Condom Use Among Sex Workers in India

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ABSTRACT TEXT

Background: HIV prevalence in India has declined over the last 20 years, most notably among female sex workers. However, HIV prevalence and incidence remain high among men who have sex with men and transgender people engaged in sex work. We conducted a survey among female sex workers (FSWs), male sex workers (MSWs), and transgender sex workers (TGSWs) in India to elucidate the relationship between alcohol use disorders and condom use behaviors.

Methods: From 2019-2020, we surveyed 233 sex workers recruited by the Durbar Mahila Samanwaya Committee (DMSC), a community-led structural intervention in West Bengal, India. Hazardous drinking was measured using the Alcohol Use Disorders Identification Test (AUDIT-C). Chi-squared tests and multiple logistic regression were utilized to evaluate associations between alcohol use disorders indicated by AUDIT-C scores ≥5 and inconsistent condom use.

Results: Alcohol use disorders were more common among all three groups sampled compared to the general population in India. Alcohol use disorders were significantly higher among TGSWs with 80% having an AUDIT-C score ≥5 compared to FSWs (21%) and MSWs (27%). Alcohol use disorders were significantly associated with self-reports that alcohol or drugs impaired consistent condom use (AOR: 7.078, 95% CI: 3.626-13.818, $p<0.001$). In total, 69% of respondents who reported difficulty with consistent condom use due to alcohol or drugs were classified as having an alcohol use disorder. Further, 41% of MSWs and 37% of TGSWs reported that alcohol or drugs made it difficult to use condoms consistently, a rate more than 3 times higher than among FSWs.

Conclusion: Alcohol use disorders were identified as a strong predictor of inconsistent condom use among sex workers in India. Alarmingly high prevalence of alcohol use disorders was found among TGSWs, which may undermine HIV and STI prevention efforts with this highly impacted group. Our findings underscore the importance of improving access to PrEP among sex workers with alcohol use disorders in India, particularly among MSWs and TGSWs who report less consistent condom use than FSWs. The findings also highlight the continued need for condom promotion programs, as consistent condom use remains the primary mode of preventing STIs among sex workers.

Table 1. Alcohol, Substance Use, and Condom Use Among Female, Male, and Transgender Workers in West Bengal, India (N=233), 2019-2020									
		Female Sex Workers (FSW, N=133)		Male Sex Workers (MSW=49)		Transgender Sex Workers (TGSW=51)		Chi2Test	
Variable	**Responses**	**n**	**%**	**n**	**%**	**n**	**%**	**χ2**	**p-value**
Have you consumed any of these substances in the last 30 days? (Choose all that apply)	1 = Alcohol	57	42.9	37	75.5	45	88.2	38.0201	<0.001
	2 = Guthka (chewing tobacco)	17	12.8	14	28.6	24	47.1	24.8666	<0.001
	3 = Cigarettes	25	18.8	41	83.7	41	80.4	91.9265	<0.001
	4 = Marijuana	4	3.0	9	18.4	15	29.4	26.6746	<0.001
	5 = Injectable (heroin)	0	0.0	0	0.0	0	0.0		
	6 = Other (specify)	0	0.0	0	0.0	0	0.0		
	7 = No substance use in last 30 days	61	45.9	3	6.1	2	3.9	47.0104	<0.001
	8 = I can't remember	1	0.8	0	0.0	0	0.0	0.7551	0.686
Are you currently addicted to any of these substances? (Choose all that apply)	1 = Alcohol	52	39.1	5	10.4	1	2.0	33.9801	<0.001
	2 = Guthka (chewing tobacco)	15	11.3	11	22.9	24	47.1	27.9815	<0.001
	3 = Cigarettes	23	17.3	21	43.8	13	25.5	13.3514	0.001
	4 = Marijuana	3	2.3	3	6.3	0	0.0	3.9692	0.137
	5 = Injectable (heroin)	0	0.0	0	0.0	0	0.0		
	6 = Other (specify)	0	0.0	0	0.0	0	0.0		
	7 = No substance use in last 30 days	63	47.4	6	12.5	16	31.4	19.2529	<0.001
	8 = I can't remember	2	1.5	0	0.0	0	0.0	1.5017	0.472
Have you ever been treated for drug or alcohol use?	0 = No	50	37.6	45	91.8	50	98.0	84.0062	<0.001
	1 = Yes	20	15.4	4	8.2	1	2.0		
	88 = Not Applicable	63	47.4	0	0.0	0	0.0		
AUDIT-C Score (Categorical)	<5, No misuse indicated (alcohol)	104	79.4	36	73.5	10	20.0	58.1361	<0.001
	≥5, Misuse indicated (alcohol)	27	20.6	13	26.5	40	80.0		
AUDIT-C Score (Mean, IQR)	Continuous (Range: 0-11)	1.9	(0-4)	2.9	(1-5)	5.6	(5-7)	F=36.17	<0.001
Have using drugs or alcohol ever made it difficult for you to use condoms?	0 = No	54	40.6	22	44.9	29	56.9	45.8916	<0.001
	1 = Yes	16	12.0	20	40.8	19	37.3		
	88 = Not Applicable	63	47.4	7	14.3	3	5.9		

Title: Knowledge Gaps Regarding PrEP and STI Prevention Among Sex Workers in India

Authors: Sabrina Navarro, Alexander Moran, Bijan Hosseini, Suchith Kumar, Toofan Pradhan, Protim Ray, Dallas Swendeman, Anne E. Fehrenbacher

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ABSTRACT TEXT

Background: Sex workers are disproportionately impacted by HIV in India. Compared to the general population, HIV prevalence is more than 9 times higher among female sex workers (FSW), 16 times higher among male sex workers (MSW), and 18 times higher among transgender sex workers (TGSW). Our study evaluated how PrEP acceptability and condom use preferences are affected by PrEP knowledge among sex workers.

Methods: From August 2019 to February 2020, we conducted a survey (N=233) and seven focus groups (N=45) with sex workers recruited by the Durbar Mahila Samanwaya Committee in West Bengal, India. PrEP knowledge was assessed by a sum score from a six-item scale. Associations between PrEP knowledge, acceptability, and condom use preferences were evaluated with chi-squared tests and linear regression. Focus group transcripts were inductively coded using thematic analysis.

Results: Participants had high PrEP knowledge, with higher scores among MSW (mean=5.4) versus TGSW (mean=4.8) and FSW (mean=4.7). Approximately 73% of TGSW and 68% of FSW responded incorrectly about whether PrEP protects against both HIV and STIs, compared to 12% of MSW. Despite higher PrEP knowledge, 20% of MSW reported that they would have condomless sex if they took PrEP, versus 5% of FSW and 2% of TGSW. PrEP knowledge scores were not associated with PrEP acceptability nor condom use preferences. In focus groups, MSW and TGSW provided many reasons for preferring condomless sex with PrEP use, including dual costs of PrEP and condoms, monetary incentives for condomless sex, and fear of losing clients. FSW did not express these concerns because free condoms are provided to them by targeted interventions, which have normalized condom use in brothel settings where FSW predominantly work but have had limited reach among MSW and TGSW who work in more diverse settings.

Conclusion: We identified an important PrEP knowledge gap among sex workers in India. While condoms protect against both HIV and STIs, PrEP only prevents HIV. Misconceptions regarding PrEP may increase risk of STI transmission. Understanding the structural and social factors impacting condom use preferences among sex workers is critical for maximizing the effectiveness of both PrEP promotion and STI prevention programs.

Title: PrEP Method Preferences and Anticipated Stigmas Among Female, Male, and Transgender Sex Workers in India

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ABSTRACT TEXT

Background: India has the second largest HIV epidemic worldwide with more than 2.3 million people living with HIV. However, PrEP uptake lags far behind countries with comparable epidemics. India's first PrEP demonstration project completed in 2018 in Karnataka and West Bengal indicated feasibility, safety, high adherence, and willingness to continue on daily oral PrEP among urban female sex workers (N=1,325). The current study is the first to characterize determinants of PrEP method preferences among a gender-diverse sample of sex workers in both urban and rural India.

Methods: From August 2019 to February 2020, we surveyed 133 female sex workers (FSW), 49 male sex workers (MSW), and 51 transgender sex workers (TGSW) and conducted seven focus

groups with sex workers in West Bengal, India. Confirmatory factor analysis was used to construct and validate a novel 7-item PrEP Acceptability Scale (Cronbach's alpha=0.73), which was highly correlated with a single item on willingness to take oral PrEP (r=0.60). Multiple linear regression was used to model determinants of PrEP acceptability. Conditional logistic regression with a gender by stigma interaction term was used to assess preferences for long-acting injectable versus oral PrEP.

Results: Although most participants (87%) reported willingness to take PrEP as a daily oral pill, 90% of MSW and 88% of TGSW were worried that their partners might think they already have HIV if they started PrEP, and 61% and 71%, respectively, did not want their partners to know if they started PrEP. In contrast, <30% of FSW reported either stigma concern. As such, preference for injectable PrEP was higher among TGSW (75%) and MSW (76%) than FSW (39%). When stratifying by gender, odds of preferring injectable PrEP were 30 times higher among MSW and 21 times higher among TGSW who reported both stigma concerns.

Conclusion: Our findings highlight the importance of offering a variety of PrEP products to meet the needs of specific key populations. Gender transformative interventions to combat PrEP stigma among sex workers in India should be prioritized to ensure that high PrEP acceptability is translated into uptake and adherence, particularly among MSW and TGSW, who bear a disproportionate burden of HIV.

Abstract Title: Does Genital Herpes Symptom History Predict Herpes Simplex Virus Type 2 Antibody Positivity?

ABSTRACT PREVIEW: DOES GENITAL HERPES SYMPTOM HISTORY PREDICT HERPES SIMPLEX VIRUS TYPE 2 ANTIBODY POSITIVITY?

Does Genital Herpes Symptom History Predict Herpes Simplex Virus Type 2 Antibody Positivity?

Abstract ID: **1439030**

ABSTRACT Category: **Abstract Submission**

Abstract Status: **Complete**

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Track

Epidemiology & Monitoring

Focus of Study:

- Diagnostics: Serology
- Population health

Type of Study

- Epidemiology/Screening

Pathogen of research

- Herpes Viruses

Geographic Region of Research

- America/Latin

What is your preferred format for this abstract? (please put oral presentation, poster, or no preference)

Poster

Abstract (350 words maximum)

Background: Herpes simplex infections are common and cause substantial morbidity and mortality. There is no national strategy to control herpes simplex infections. The positive predictive value of current HSV-2 antibody tests is a concern. The US Centers for Disease Control and Prevention recommends serologic screening for HSV-2 in individuals with a history of genital herpes symptoms. However, no validated symptom screening tool currently exists. We developed and evaluated a genital herpes symptom screening tool to predict HSV-2 antibody positivity among STI clinic patients in Lima, Peru.

Methods: We recruited and enrolled participants visiting public STI clinics who agreed to complete a tablet-based survey of prior genital herpes symptoms (anogenital ulcers, genital, or inguinal pain, burning, itchiness or tingling or constitutional symptoms with one or more other symptoms). For this analysis, individuals reporting current genital herpes symptoms were excluded to focus on asymptomatic screening. Survey findings were compared with semi-quantitative HSV-2 serological test results (Anti-HSV-2 (gG2) ELISA IgG (Euroimmun, Germany)). Sera with optical density index values < 0.80 were considered anti-HSV-2 negative, between 0.80 and 2.9 were considered anti-HSV-2 equivocal, and ≥3.0 were considered anti-HSV-2 positive.

Results: We enrolled 131 participants between July-October 2022. We found that 21.2% of patients were anti-HSV-2 positive, 39.4% were anti-HSV-2 equivocal, and 39.4% were anti-HSV-2 negative. Anti-HSV-2 positivity among asymptomatic participants reporting no prior genital herpes symptoms was 18% while 26% in those with at least one prior symptom. Positivity increased to 33% in those with 4 or more symptoms. There was a 1.47-fold (95% CI 0.77 - 2.83) increase in anti-HSV-2 positivity in those with any prior genital herpes symptoms compared to those with none.

Conclusion: Testing only those with a history of any prior genital symptoms might increase the likelihood of identifying HSV-2 infected individuals and improve the positive predictive values of current HSV-2 antibody tests. However, the 18% with no prior genital herpes symptoms would be missed using this testing strategy. The high number of equivocal tests is an additional issue that requires attention, resolution of equivocal values with Western blot testing is underway.

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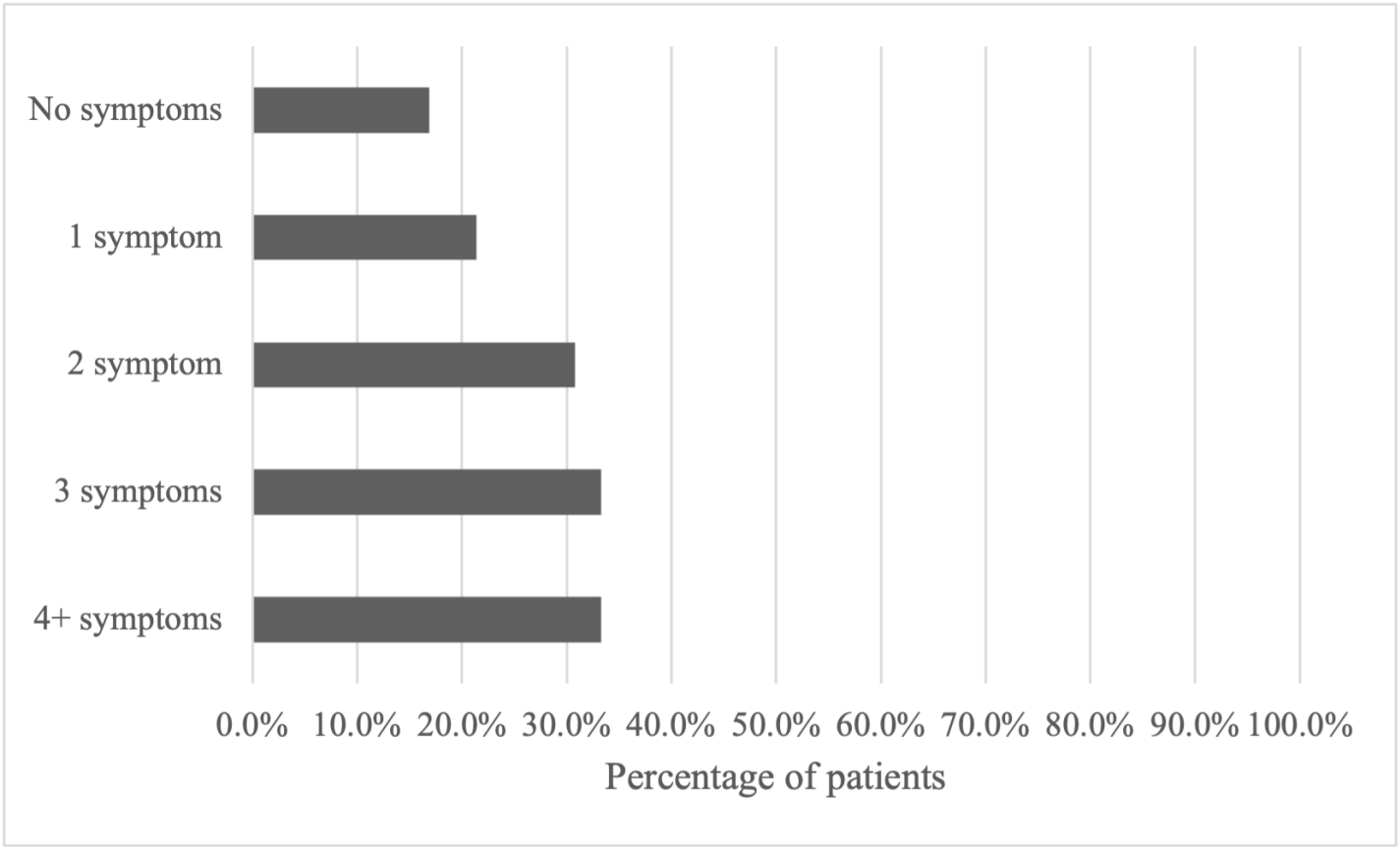

Frequency of anti-HSV-2 positivity by number of prior genital herpes symptoms reported
The chart shows the percentage of patients testing positive for anti-HSV-2 by the number of prior genital herpes symptoms patients reported in the survey. 17.9% of patients reported no prior genital herpes symptoms, 21.4% reported 1 symptom, 30.8% reported 2 symptoms, 33.3% reported 3 symptoms, and 33.3% reported 4 or more symptoms. Anti-HSV-2 positivity increased when patients reported an increased number of genital herpes symptoms.

STIHIV_herpes abstract_figure.png

Young Investigators and Scholarships

Do you need a scholarship?
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If yes, please provide the date of completion of your highest degree:

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If yes, please provide the start date for your graduate degree or clinical training:
2021-08-02

Are you the presenting author for the abstract you have submitted to the 2023 STI & HIV World Congress?
Yes

If you are applying for a scholarship, in 100 words or less, please describe why you need a scholarship to attend ISSTDR 2023 in Chicago. Please note that you MUST complete this section only if you are applying for a scholarship.
I need a scholarship to attend ISSTDR as I am a medical student from California with increasing loans and few funds to be able to afford registration, make the trip to Chicago and pay for accommodations. I would appreciate any assistance as an economically disadvantaged student with the desire to disseminate my research and gain important knowledge and career experience at ISSTDR.

Gender?
cis-female

ABSTRACT PREVIEW: ANALYSIS OF MUTATIONS ASSOCIATED WITH TETRACYCLINE RESISTANCE AND MOLECULAR TYPING OF TREPONEMA PALLIDUM STRAINS FROM SYPHILIS PATIENTS IN LIMA, PERU

Analysis of mutations associated with tetracycline resistance and molecular typing of Treponema pallidum strains from syphilis patients in Lima, Peru

Abstract ID: **1439444**

ABSTRACT Category: **Abstract Submission**

Abstract Status: **Complete**

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Abstract

Track

Epidemiology & Monitoring

Focus of Study:

Antimicrobial resistance

Type of Study

- Epidemiology/Genomic

Pathogen of research

- Treponema pallidum

Geographic Region of Research

- America/Latin

What is your preferred format for this abstract? (please put oral presentation, poster, or no preference)

poster

Abstract (350 words maximum)

Background

The analysis of genetic diversity of *Treponema pallidum* subspecies *pallidum* (TP) strains is a pivotal tool to investigate syphilis molecular epidemiology, transmission dynamics and mutations possibly associated with antibiotic resistance. Among currently used genotyping methods is the Enhanced CDC

typing scheme (ECDCT). In parallel, assessing the presence and prevalence of mutations possibly associated with resistance to second-line antibiotics can help decide on viable treatment options. Here, we report on the distribution of TP strain types in samples from Peruvian active syphilis patients and on genetic polymorphisms that could be associated with tetracycline resistance.

Methods

We analyzed DNA extracted from 87 lesion swab samples. The presence of TP DNA was assessed by amplification of three TP-specific genes, namely *tp0548*, *tp0574,* and *polA* (*tp0105*) genes. Typing of positives samples was performed by detecting the number of repeats in the *arp* gene, analysis of the *tprE/G/J* RFLP pattern, and sequence of a fragment of the *tp0548* gene. The possibility of a strain genetically resistant to tetracycline was assessed among 22 samples by sequencing of a specific region of the 16S rRNA gene to search for mutations at gene positions 965 and 1058. Positivity was defined as a sample with any of the point mutations.

Results

Of the 51 samples with TP-DNA, 15 (29.4%) samples yielded complete genotypes, while 16 (31.3%) could be partially genotyped, and 20 (39.3%) could not be genotyped. Among the fully-typed samples, strain type 14d/g was the most prevalent (4/15; 27%), followed by strain types 14d/d (2/15; 13%), and 12d/g (2/15; 13%). None of the 22 TP-positive samples exhibited the mutations in the 16S rRNA gene.

Conclusions

The ECDCT methodology allows us to improve the still limited knowledge of molecular types of TP in Peru, despite the small number of fully typable samples. Mutations associated with decreased susceptibility to tetracycline were not detected, supporting that resistance to this antibiotic has not started to emerge in this pathogen. Hence, tetracycline continues to be useful for syphilis treatment and can be considered as preventive treatment for pre- or post-exposure prophylaxis given the recent results in doxyPrEP and doxyPEP studies.

Young Investigators and Scholarships

Do you need a scholarship?
Yes

Are you an early-career investigator?
Yes

If yes, please provide the date of completion of your highest degree:
2018-08-15

If not, are you currently a student, post-doctoral trainee, or clinical trainee?
No

If yes, please provide the start date for your graduate degree or clinical training:

Are you the presenting author for the abstract you have submitted to the 2023 STI & HIV World Congress?
Yes

If you are applying for a scholarship, in 100 words or less, please describe why you need a scholarship to attend ISSTDR 2023 in Chicago. Please note that you MUST complete this section only if you are applying for a scholarship.
I am currently working as a researcher collaborator for an NIH-funded syphilis grant conducted in

Peru with PI Dr. Klausner, in conjunction with Dr. Caceres at my institution, UPCH. We are currently in the final year of the study and eager to present our results. This scholarship would provide me the opportunity to attend the conference and participate actively in scholarly exchange of ideas with regard to syphilis immunology, which will support my work moving forward. This will be a great opportunity for me to meet potential collaborators and strength ties with existing collaborators to work towards future projects.

Gender?
cis-female

STI & HIV 2023 WORLD CONGRESS
CHICAGO, IL USA 24-27 JULY 2023

ABSTRACT PREVIEW: HIV INFECTION MODIFIES THE ASSOCIATION BETWEEN PRIOR TREPONEMA PALLIDUM INFECTION AND CLINICAL PRESENTATION OF EARLY SYPHILIS AMONG PATIENTS FROM STI CLINICS IN PERU

HIV infection modifies the association between prior Treponema Pallidum infection and clinical presentation of early syphilis among patients from STI clinics in Peru

Abstract ID: **1427132**

ABSTRACT Category: **Abstract Submission**

Abstract Status: **Active**

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Abstract Title: HIV infection modifies the association between Treponema pallidum infection and clinical presentation of early syphilis among patients from STI clinics in Peru

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Abstract

Track

Clinical Science

Abstract Title: HIV infection modifies the association between prior Treponema Pallidum infection and clinical presentation of early syphilis among cases enrolled from STI clinics in Peru

Focus of Study:

- Diagnostics: Serology
- Sexual minorities

Type of Study

- Clinical research

Pathogen of research

- Human Immunodeficiency Virus
- Treponema pallidum

Geographic Region of Research

- America/Latin

What is your preferred format for this abstract? (please put oral presentation, poster, or no preference)

no preference

Abstract (350 words maximum)

Background: The role of prior Treponema Pallidum (TP) infection on the clinical presentation of early syphilis may be different when comparing people by HIV status. We aim to evaluate the association of prior TP infection on clinical presentation of early syphilis stratified by HIV status; additionally, we explored the association of prior TP infection on lesion manifestations.

Methods: We used data from the baseline and four-week visits from the PICASSO cohort conducted in Peruvian STI clinics from 2019-2022. We included patients diagnosed with early syphilis by serology (current RPR ≥1:8 and 2-fold increase from previous RPR) and/or clinical exam (lesion compatible with syphilis), who also had previous RPR and/or TP rapid tests (TPrt) results to determine prior TP infection. Prior TP infection status was categorized as reinfection (previous RPR ≥1:8 or positive TPrt) or first infection (negative TPrt within 12 months). HIV status was determined by HIV rapid testing at enrolment. Logistic regression models were used to calculate adjusted prevalence ratios (aPR) of clinical presentation by prior TP infection status, stratified by HIV status (see Table 1 footnote on included variables). Primary and secondary lesions were each compared by prior TP infection status using Fisher's exact tests.

Results: We included 145 cis-gender men and transgender women. TP first infection was positively associated with symptomatic (primary/secondary syphilis) clinical presentation at diagnosis (unadjusted PR=1.94; p=0.014). When stratified by HIV status, this association was significant among HIV-uninfected individuals (aPR=6.63; p=0.001), but not among those living with HIV (aPR=1.38; p=0.458) (See Table 1). Regarding lesion manifestations, among secondary syphilis cases (n=16), all cases with TP re-infection improved within one week, while only 29% of first TP exposure cases improved in this timeframe (p=0.045). Among primary syphilis cases (n=25), all lesions improved within one week. No differences were found by body distribution, pain or lesion number in primary or secondary syphilis cases.

Conclusion: The association between symptomatic early syphilis presentation and first TP exposure is more pronounced among patients without HIV. Furthermore, prior TP infection was associated with faster-perceived healing of secondary lesions. Our findings indicate the complexity of the host immune response to TP infection.

Abstract Title: HIV infection modifies the association between prior Treponema Pallidum infection and clinical presentation of early syphilis among patients from STI clinics in Peru

Uploaded File(s)

Upload Table or Figure

	Total	n	%	PR	IC	P	aPR*	IC	P
HIV negative									
TP first infection	50	19	38%	5.45	1.72-17.26	**0.004**	6.63	2.15-20.45	**0.001**
TP reinfection	43	3	7%						
HIV positive									
TP first infection	11	5	45%	1.33	0.61-2.91	0.473	1.38	0.59-3.25	0.458
TP reinfection	41	14	34%						
*Adjusted by age, time elapsed since last syphilis test, and RPR change since the last test									

Table 1. Association between symptomatic early syphilis presentation (primary or secondary syphilis) and prior TP exposure status, stratified by HIV status

Table 1 without title.jpg

Young Investigators and Scholarships

Do you need a scholarship?
Yes

Are you an early-career investigator?
Yes

If yes, please provide the date of completion of your highest degree:
2021-04-15

If not, are you currently a student, post-doctoral trainee, or clinical trainee?

If yes, please provide the start date for your graduate degree or clinical training:

Are you the presenting author for the abstract you have submitted to the 2023 STI & HIV World Congress?
Yes

If you are applying for a scholarship, in 100 words or less, please describe why you need a scholarship to attend ISSTDR 2023 in Chicago. Please note that you MUST complete this section only if you are applying for a scholarship.
I am an early-career Peruvian physician and researcher and am very interested in contributing to the improvement of sexual health in my country. This scholarship would provide me with an excellent opportunity to share the work of my interdisciplinary research group regarding the clinical manifestations of syphilis in new and repeat infections. I would also have the opportunity to be in contact with researchers around the world in the field of STI epidemiology. It would be an honor and a privilege to have this opportunity to discuss our results and new research ideas that could improve syphilis management in Peru.

Gender?
cis-male

Abstract Title: HIV infection modifies the association between prior Treponema Pallidum infection and clinical presentation of early syphilis among patients from STI clinics in Peru

STI & HIV 2023 WORLD CONGRESS
CHICAGO, IL USA 24-27 JULY 2023

ABSTRACT PREVIEW: LABORATORY EVALUATION OF ORAL FLUID FOR SYPHILIS SCREENING, LIMA, PERU

Laboratory Evaluation of Oral Fluid for Syphilis Screening, Lima, Peru

Abstract ID: **1434407**

ABSTRACT Category: **Abstract Submission**

Abstract Status: **Complete**

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Abstract Title: Laboratory Evaluation of Oral Fluid for Syphilis Screening, Lima, Peru

Abstract

Track

Basic & Translational Science

Focus of Study:

- Diagnostics: Novel Methods
- Diagnostics: Rapid Tests/Point of Care

Type of Study

- Basic Science

Pathogen of research

- Treponema pallidum

Geographic Region of Research

- America/Latin

What is your preferred format for this abstract? (please put oral presentation, poster, or no preference)

Poster

Abstract (350 words maximum)

Background:
Syphilis remains a curable bacterial sexually transmitted infection (STI), with a global burden of 7.1 million new cases during 2020. Serological tests for syphilis require equipment unavailable in many health centers; however, point-of-care testing has allowed rapid screening using finger-prick whole blood samples. A further improvement could be the use of oral fluid. We evaluated the performance of treponemal antibody point-of-care testing for syphilis screening using oral fluid samples.

Methods:
Individuals who routinely attended STI clinics in Lima, Peru, were recruited. We collected oral fluid using the OraSure collection device (OraSure Technologies Inc., USA) according to manufacturer's instructions and serum from each participant. Oral fluid and serum were analyzed using the SD Bioline Syphilis 3.0 rapid test (Standard Diagnostics Inc., Korea). Oral fluid was processed using 30µL + 2 drops of sample diluent, while serum was processed using 10µL + 4 drops of sample diluent; serum were also tested using RPR (RPR slide test, Wiener Laboratorios SAIC, Argentina) and TPPA (Serodia, Fujirebio Diagnostics Inc., Japan). We assessed oral fluid rapid test overall percent agreement, sensitivity, and specificity against the following comparators: (1) serum SD Bioline Syphilis, (2) serum TPPA, and (3) both TPPA and RPR reactive or both TPPA and RPR non-reactive.

Results:

Among 324 participants, median age was 31.5 years (IQR: 11.5) and 71.6% were male. Nearly half (51.3%) reported prior syphilis and 30.6% were living with HIV. The overall percent agreement, sensitivity, and specificity of oral fluid was 71.0% (95% CI: 65.7% – 75.9%), 78.2% (71.3% – 83.8%), and 63.5% (55.8% – 70.6%), respectively, versus serum SD Bioline Syphilis; similar results were obtained versus serum TPPA. The overall percent agreement and sensitivity increased when using the third comparator (74.6% [68.8% – 79.8%] and 86.6% [78.9% – 92.3%], respectively). When limiting the sample to TPPA-reactive with RPR titer ≥ 1:8, the sensitivity increased to 88.1% (75.0% – 94.8%), but the percent agreement decreased to 70.4% (63.3% – 76.9%).

Conclusions:
We observed a good performance of the rapid treponemal test using oral fluid. Further investigations are needed to improve the specificity of oral fluid as a potential sample for accurate syphilis screening.

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Upload Table or Figure

Table 1. Performance of the use of oral fluid in the treponemal antibody rapid test for syphilis screening. table.pdf

Young Investigators and Scholarships

Do you need a scholarship?
Yes

Are you an early-career investigator?
Yes

If yes, please provide the date of completion of your highest degree:
2020-11-25

If not, are you currently a student, post-doctoral trainee, or clinical trainee?
No

If yes, please provide the start date for your graduate degree or clinical training:

Are you the presenting author for the abstract you have submitted to the 2023 STI & HIV World Congress?
Yes

If you are applying for a scholarship, in 100 words or less, please describe why you need a scholarship to attend ISSTDR 2023 in Chicago. Please note that you MUST complete this section only if you are applying for a scholarship.
My name is Jazmin Qquellon, I am from Peru, and I have a Master of Science degree in Epidemiology Research. My research focuses on the development of diagnostic alternatives that allow timely and proper coverage of HIV and STI screening in vulnerable populations. Since 2020, I have been investing my salary in family members who depend on me, so I do not have enough financial savings to cover all the

expenses to attend this prestigious event. However, I know that these lectures will positively impact my professional training, as well as expand my professional network.

Gender?

cis-female

Abstract Title: Rapid Plasma Reagin (RPR) sero-reversion after treatment and its association with Prior Treponema Pallidum infection: analysis from the PICASSO cohort among people with early syphilis in Peru

ABSTRACT PREVIEW: RAPID PLASMA REAGIN (RPR) SERO-REVERSION AFTER TREATMENT AND ITS ASSOCIATION WITH PRIOR TREPONEMA PALLIDUM INFECTION: ANALYSIS FROM THE PICASSO COHORT AMONG PEOPLE WITH EARLY SYPHILIS IN PERU

Rapid Plasma Reagin (RPR) sero-reversion after treatment and its association with Prior Treponema Pallidum infection: analysis from the PICASSO cohort among people with early syphilis in Peru

Abstract ID: **1432307**

ABSTRACT Category: **Abstract Submission**

Abstract Status: **Complete**

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Abstract

Track

Clinical Science

Focus of Study:

Diagnostics: Serology

Type of Study

- Clinical research

Pathogen of research

- Treponema pallidum

Geographic Region of Research

- America/Latin

What is your preferred format for this abstract? (please put oral presentation, poster, or no preference)

No preference

Abstract (350 words maximum)

Background: Prior *Treponema Pallidum* (TP) infection may alter host response to treatment in future infections. We aim to evaluate the association of TP reinfection status and time to Rapid Plasma Reagin (RPR) sero-reversion after treatment, among people with early syphilis from cohort in Peru.

Methods: We use data from the PICASSO cohort, conducted in Peru from May 2019 to August 2022. For this analysis, we included people with early syphilis (having ≥2-fold RPR titer increase from previous RPR within 12 months, or being diagnosed with primary syphilis) and a baseline RPR titer of ≥1:8. Individuals also had to have prior RPR and/or TP rapid-test (TPrt) results to differentiate "TP reinfections" (previous RPR ≥1:8 or positive TPrt) from "TP first-infections" (negative TPrt within 12 months prior to diagnosis). The main outcome was time to RPR sero-reversion, defined as time to first non-reactive RPR result after baseline treatment. Cox regression models were used to estimate unadjusted and adjusted Hazard Ratios (aHRs) by TP reinfection status, adjusting by HIV infection status and baseline RPR titer.

Results: We included 143 early syphilis cases with a median age of 29 years, 35% were HIV-infected (40% with viral load< 200 copies/ml), and 58% were "TP reinfections" cases. Participants were follow for a median of 272 days (interquartil interval: 175-366 days), and 28% (n=40) reached a non-reactive RPR after treatment (sero-reversion). Mean time to sero-reversion was lower among the TP first-infection compared to Reinfections (349 vs 528 days, p-value: < 0.001) (see Figure 1). Lower time to RPR sero-reversion was positively associated with lower baseline RPR titer (1:8 vs >1:32; HR:2.65, p=0.027), and being HIV-uninfected (HR:4.14, p=0.003). No association was found with age or syphilis clinical stage. In the adjusted model, less time to RPR sero-reversion was positively associated with TP first-infection (aHR: 4.89; p< 0.001).

Conclusion: Prior TP infection increases the time to RPR sero-reversion after treatment, which should be taken into consideration to prevent unnecesary overtreatment. Our findings provide insight to understand the complex host-immunity response to TP infection and emphasize the need for further research to improve tools for diagnosis treatment control.

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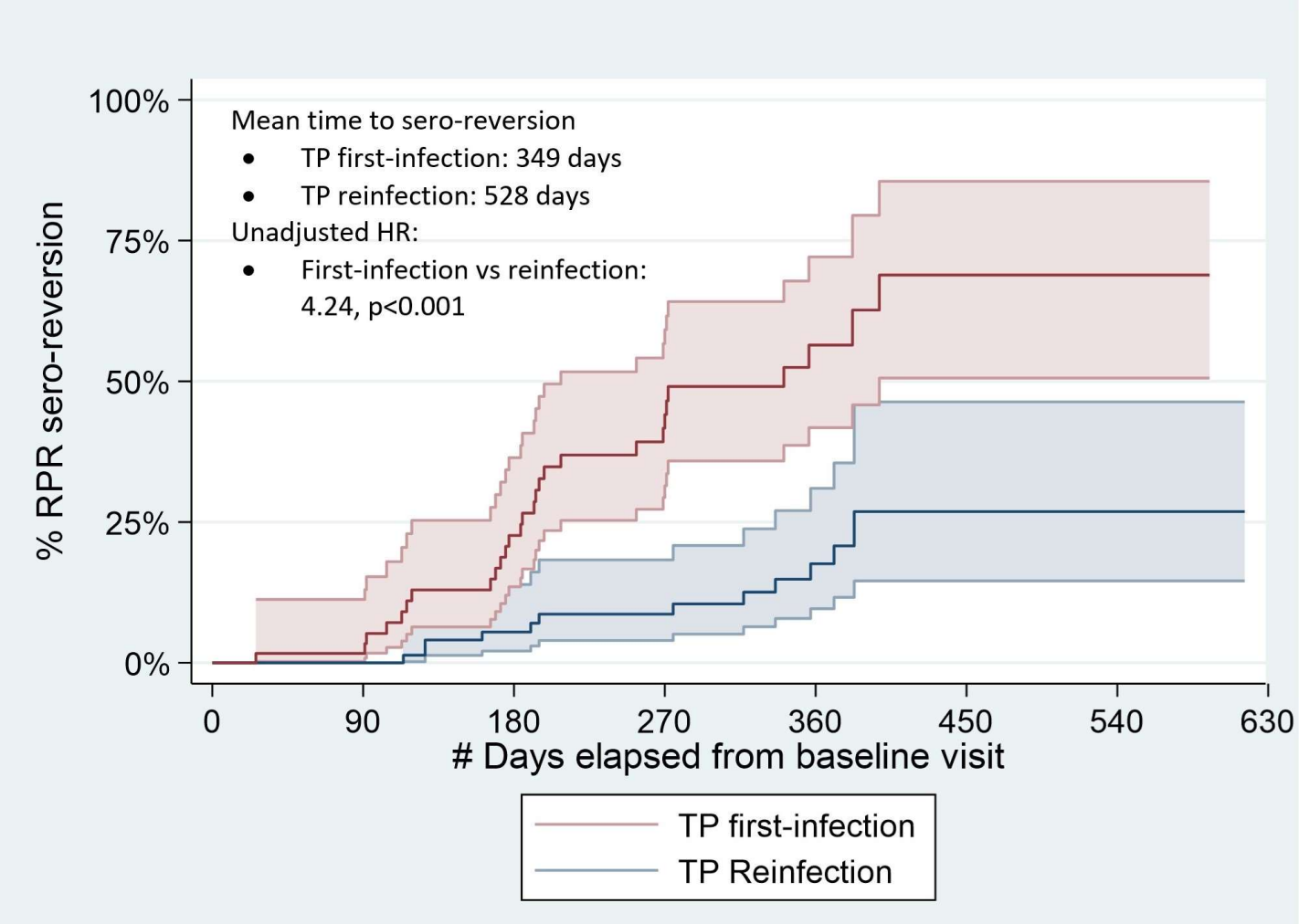

Figure 1: Unadjusted time to RPR sero-reversion among patients with early syphilis

Figure 1 Unadjusted time to RPR seroreversion_notitle.jpg

Young Investigators and Scholarships

Do you need a scholarship?
Yes

Are you an early-career investigator?
No

If yes, please provide the date of completion of your highest degree:
2015-12-25

If not, are you currently a student, post-doctoral trainee, or clinical trainee?
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If yes, please provide the start date for your graduate degree or clinical training:
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Are you the presenting author for the abstract you have submitted to the 2023 STI & HIV World Congress?

Yes

If you are applying for a scholarship, in 100 words or less, please describe why you need a scholarship to attend ISSTDR 2023 in Chicago. Please note that you MUST complete this section only if you are applying for a scholarship.

Talking about sex has never being an issue for me, which has helped me as I have made STI research my daily job. I am currently working in a syphilis research group. Attending the HIV&STI 2023 conference, would provide a remarkable platform to share with colleagues and experts our results about the role of repeated syphilis on serologic response to treatment, adding more evidence to the discussion of the complex host immunology of syphilis. This is very important as we need to improve currents tools for prevention and diagnosis to control its spread among high-risk populations.

Gender?

cis-male

Abstract Title: Cytokine levels seven days post treatment among patients with active syphilis in Peru

ABSTRACT PREVIEW: CYTOKINE LEVELS SEVEN DAYS POST TREATMENT AMONG PATIENTS WITH ACTIVE SYPHILIS IN PERU

Cytokine levels seven days post treatment among patients with active syphilis in Peru

Abstract ID: **1450594**

ABSTRACT Category: **Abstract Submission**

Abstract Status: **Active**

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Role:

Co-author

Abstract

Track

Epidemiology & Monitoring

Focus of Study:

- Immune response
- Diagnostics: Serology

Type of Study

- Research

Pathogen of research

- Treponema pallidum

Geographic Region of Research

- America/Latin

What is your preferred format for this abstract? (please put oral presentation, poster, or no preference)

no preference

Abstract (350 words maximum)

Background: Laboratory diagnosis of syphilis requires detection of treponemal and non-treponemal antibodies; however, these serologic biomarkers may not always inform disease activity or treatment response. Selected cytokines are used for diagnosing other infectious diseases (e.g., tuberculosis interferon-gamma release assays) and have demonstrated associations with syphilis. We measured previously syphilis-associated cytokines Eotaxin-Rantes-Leptin and IL1ra-Trail-CD40L in active syphilis cases pre-and-post treatment to explore cytokine response by syphilis stage, history and by HIV-infection status.

Methods: From July to December 2020, we enrolled individuals with active syphilis (RPR titer ≥1:8) from STI clinics in Lima, Peru. Cases also had to have prior RPR and/or *Treponemal pallidum* (TP) antibody rapid-test results to differentiate cases with past syphilis from "first-infections" (negative TP antibodies within 12 months prior to diagnosis). Serum samples were collected the day of treatment and at 7 days post-treatment. Mean Fluorescent Index (MFI) values of Eotaxin-Rantes-Leptin and IL1ra-Trail-CD40L cytokines were analyzed using a Luminex Flex3D-H2 instrument (Thermo Fisher, Waltham, MA). We used Wilcoxon signed-rank test to compare each cytokine MFIs medians between visits and Mann-Whitney U test to evaluate associations with other covariates.

Results: Among 31 individuals with active syphilis, 41% (13/31) were people living with HIV-infection; 16 (51.6%) had syphilis previously, 10 (32.3%) had a first infection and 5 (16.1%) had an unknown syphilis history. Additionally, 10 had primary syphilis, 3 had secondary syphilis, 17 had early latent, and 1 late latent syphilis. When comparing pre- and post-treatment levels of Eotaxin-Rantes-Leptin and IL1ra-Trail-CD40L, no MFIs differences were found for Eotaxin, Leptin, Trail and CD40L (p-values >0.1), but median MFIs differed for Rantes (10073.3 [IQR: 7465] vs 14697.3 [IQR: 5604.8] and IL1ra (28.5 [IQR: 11.3] vs 23 [IQR: 6.8]) (p-values < 0.001). Pre-and-post treatment median MFIs differed for Eotaxin, IL1ra and CD40L when analyzed by HIV-infection status, (p-values < 0.05). No differences in cytokine levels between visits were found by syphilis history or stage.

Conclusion: Certain cytokines measured in syphilis cases at pre and post treatment did change but not differ by syphilis history or stage but by HIV-infection status. Further research in additional populations and with other

cytokines may be needed.

Young Investigators and Scholarships

Do you need a scholarship?
Yes

Are you an early-career investigator?
No

If yes, please provide the date of completion of your highest degree:

If not, are you currently a student, post-doctoral trainee, or clinical trainee?
Yes

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2017-03-07

Are you the presenting author for the abstract you have submitted to the 2023 STI & HIV World Congress?
Yes

If you are applying for a scholarship, in 100 words or less, please describe why you need a scholarship to attend ISSTDR 2023 in Chicago. Please note that you MUST complete this section only if you are applying for a scholarship.
The conference will be an amazing opportunity for me to share my work, learn from leading experts in the field about innovations in HIV and STI laboratory methods and build a network with other researchers. There will be presentations related to syphilis immunology and vaccine development. Additionally, I am interested in updates about antibiotic resistance in N. gonorrhoeae, an area of substantial importance to me and my country. These topics may help us us to implement novel and interesting interventions headed by my research unit in order to track these public health issues not currently addressed in my country

Gender?
cis-male

Abstract Title: Detection of treponemal tp47 and tp0548 genes in oral, anal and genital lesion samples from syphilis patients

STI & HIV 2023 WORLD CONGRESS
CHICAGO, IL USA 24-27 JULY 2023

ABSTRACT PREVIEW: DETECTION OF TREPONEMAL TP47 AND TP0548 GENES IN ORAL, ANAL AND GENITAL LESION SAMPLES FROM SYPHILIS PATIENTS

Detection of treponemal tp47 and tp0548 genes in oral, anal and genital lesion samples from syphilis patients

Abstract ID: **1437191**

ABSTRACT Category: **Abstract Submission**

Abstract Status: **Complete**

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Abstract Title: Detection of treponemal tp47 and tp0548 genes in oral, anal and genital lesion samples from syphilis patients

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CC

Carlos F, Caceres, MD, PhD (he/him/his)

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Professor

Organization:
Universidad Peruana Cayetano Heredia

Role:

Co-author

Abstract Title: Detection of Treponema pallidum genes in oral, anal and genital lesion samples from syphilis patients

JK

Jeffrey D. Klausner, MD MPH (he/him/his)

Position:
Clinical Professor

Organization:
University of Southern Californiia

Role:
Co-author

Abstract

Track

Basic & Translational Science

Focus of Study:

- Diagnostics: Novel Methods
- Diagnostics: Nucleic Acid Amplification Tests

Type of Study

- Basic Science

Pathogen of research

- Treponema pallidum

Geographic Region of Research

- America/Latin

What is your preferred format for this abstract? (please put oral presentation, poster, or no preference)

Poster

Abstract (350 words maximum)

Background
Painless chancres are common symptoms of syphilis and are present in about one-third infected individuals; extra genital locations as well as hidden rectal or vaginal chancres could cause misdiagnosis. Treponema pallidum (TP) DNA detection based on polymerase chain reaction (PCR) assays is commonly performed in lesion samples using tp47 and polA genes, with sensitivities over 80%. We evaluated the performance of using two gene targets tp47 and tp0548 for TP DNA detection in anal, oral and lesion swabs samples from active syphilis cases.

Methods
Between 2019 and 2022, participants diagnosed with active syphilis using laboratory (rapid reagin plasmatic [RPR] of ≥1:8 and ≥2-fold titer increase from previous RPR) or clinical criteria (having syphilitic chancre) from STI clinics in Peru were enrolled in a cohort study. We collected samples three different types for TP DNA detection: oral mucosa, anal mucosa and urogenital lesions. Samples were collected and stored in a vial with 500ul lysis buffer. DNA was extracted by columns (Zymo research, USA) and assessed using specific primers for conventional PCR to amplify tp47 and tp0548 target genes. We calculated the proportion of TP DNA detected for each target in all oral, anal and lesion samples and compared the positivity by syphilis stage.

Results
Overall 258 oral, 116 anal, and 87 lesion swabs samples were collected. We detected tp47 and tp058 targets in 10/258 (3.9%) and 13/258 (5.0%) in oral swab specimens, respectively; tp47 and t0548 targets in 45/116 (38.8%) and 18/116 (15.5%) anal swab specimens, respectively; and tp47 and tp0548 in lesion swab samples 21/87 (24.1%) and 42/87 (48.3%), respectively. We

Abstract Title: Detection of treponemal tp47 and tp0548 genes in oral, anal and genital lesion samples from syphilis patients

detected tp47 in 34.6%, 50.0%, 18.7% and 21.7% cases of primary, secondary, early latent and late latent syphilis respectively. In addition, we detected tp0548 in 51.8%, 40.9%, 11.2% and 4.3% cases of primary, secondary, early latent, and late latent syphilis, respectively.

Conclusion
Using tp47 and tp0548 genes in combination improves the detection of TP DNA in different types of samples from patients with syphilis. Using both PCR targets for screening of anal and oral samples may facilitate detection of syphilis cases when genital lesions are absent.

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Table 1. TP DNA detected by PCR in anatomical sites from syphilis cases
Abstract_Detection of treponemal tp47 and tp0548 genes _table.pdf
TP: Treponema pallidum; PCR: Polymerase chain reaction; DNA: deoxyribonucleic acid; Pos: Positive

Young Investigators and Scholarships

Do you need a scholarship?
Yes

Are you an early-career investigator?
No

If yes, please provide the date of completion of your highest degree:

If not, are you currently a student, post-doctoral trainee, or clinical trainee?
Yes

If yes, please provide the start date for your graduate degree or clinical training:
2019-10-02

Are you the presenting author for the abstract you have submitted to the 2023 STI & HIV World Congress?
Yes

If you are applying for a scholarship, in 100 words or less, please describe why you need a scholarship to attend ISSTDR 2023 in Chicago. Please note that you MUST complete this section only if you are applying for a scholarship.
I am a master's student and I am currently doing my thesis at STI. I am very interested in attending the ISSTDR congress as it will allow me to acquire new knowledge and share experiences with professionals related to my area. I believe I deserve this scholarship because I could use the knowledge learned during the congress and use it to improve research in my country. In addition, I am applying for the scholarship due to my financial limitations since I am the only financial support for my family. I am very grateful for the opportunity to apply.

Gender?
cis-female

Abstract Title: Detection of treponemal tp47 and tp0548 genes in oral, anal and genital lesion samples from syphilis patients

Title: Implementing routine culturing and antimicrobial susceptibility testing for *Neisseria gonorrhoeae* within a HIV pre-exposure prophylaxis program in Hanoi, Vietnam

Authors: Paul C. Adamson[1], Hao TM Bui[2], Hai Ha Long Le[3,4], Loc Q Pham[2], Thanh C Nguyen[2], Jeffrey D Klausner[5], Giang Minh Le[2]

Affiliations: [1]University of California, Los Angeles, David Geffen School of Medicine, [2] Center for Training and Research on Substance Abuse and HIV, Hanoi Medical University, Hanoi, Vietnam, [3]National Hospital for Dermatology and Venereology, Hanoi, Vietnam, [4]Hanoi Medical University, Hanoi, Vietnam [5]University of Southern California, Keck School of Medicine, Los Angeles, CA

Background: Antimicrobial resistance (AMR) in *Neisseria gonorrhoeae* (NG) is an urgent global health issue. Patients on HIV pre-exposure prophylaxis (PrEP) have high rates of NG infections and routine testing is recommended. The objectives of this study were to implement routine testing and culturing of NG infections within a PrEP program in Vietnam in order to determine the prevalence of NG, NG culture-positivity, and to describe the patterns of AMR in NG.

Methods: From January through November 2022, participants in the PrEP program at the Sexual Health Promotion Clinic in Hanoi, Vietnam were enrolled. A survey collecting demographic, behavioral, and clinical characteristics was administered. Participants self-collected urine, rectal, and pharyngeal specimens for nucleic-acid amplification testing (NAAT). Those receiving same-day NG treatment also had swabs for NG culture collected. Participants NAAT-positive for NG were recalled for treatment and had specimens collected for culture and antibiotic susceptibility testing (AST).

Results: In total, 506 participants were enrolled. The median age was 24.9 years (IQR: 21.7–29.6). All were male and reported having sex with men in the prior 12 months. The median number of sex partners in the prior month was 1 (IQR: 1 – 2). Symptoms within the prior week were reported by 41.7% (211/506). The overall prevalence of NG infections by NAAT was 14.8% (75/506); there were 16 (3.2%) urethral, 36 (7.1%) rectal, and 60 (11.9%) oropharyngeal NG infections. Among those with NG, 93.3% (70/75) returned for treatment and culturing, with a median of 7 days after initial collection. NG culture positivity was 35.7% (5/14) for urethral, 10.0% (3/30) for rectal, and 3.6% (2/56) for oropharyngeal. All NG isolates were susceptible to cefixime, ceftriaxone, and spectinomycin, while 40.0% (4/10) were non-susceptible to azithromycin.

Conclusions: A high prevalence of NG infections, was observed among MSM in a PrEP program in Hanoi, Vietnam. NG culture positivity was low, highlighting difficulties in culturing NG, particularly from extragenital sites. While many NG infections were asymptomatic, NAAT and culture positivity were higher among those reporting symptoms. AST of NG is important for AMR surveillance and optimization of NG culturing within PrEP program settings can enhance these efforts.

Table 1. Nucleic acid amplification testing and culturing of *Neisseria gonorrhoeae* among 506 men who have sex with men in a PrEP program in Hanoi, Vietnam, from January to November 2022.

	Anatomic Site	**Specimens Collected for NAAT**	**NG Positive NAAT-specimens**	**Specimens Collected for NG Culture**	**NG positive Culture-Specimens**	**NG Culture Recovery (%)**
All (n = 506)						
	Urethral	506	16 (3.2%)	14	5	35.7
	Rectal	495*	36 (7.3%)	30	3	10.0
	Oropharyngeal	506	60 (11.9%)	56	2	3.6
Symptoms within prior 7 days (n = 211)						
	Urethral	211	14 (6.6%)	13	5	38.5
	Rectal	204	20 (9.8%)	17	2	11.8
	Oropharyngeal	211	34 (16.1%)	32	1	3.1
No symptoms (n = 295)						
	Urethral	295	2 (0.7%)	1	0	0
	Rectal	291	16 (5.5%)	13	1	7.7
	Oropharyngeal	295	26 (8.8%)	24	1	4.2
Culture same day (n=8)						
	Urethral	-	8	8	4	50.0
	Rectal	-	2	2	0	0
	Oropharyngeal	-	4	4	0	0
Culture Day 1 – 7 (n=31)						
	Urethral	-	1	1	1	100
	Rectal	-	12	12	2	16.7
	Oropharyngeal	-	26	26	2	7.7
Culture Day > 7 (n=31)						
	Urethral	-	5	5	0	0
	Rectal	-	16	16	1	6.3
	Oropharyngeal	-	26	26	0	0

*11 participants refused collection of rectal specimens
Abbreviations: NAAT - nucleic acid amplification testing, NG – *N. gonorrhoeae*

Title: *Mycoplasma genitalium* infections among men who have sex with men in an HIV pre-exposure prophylaxis program in Hanoi, Vietnam

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Word count: 342

Background *Mycoplasma genitalium* (MG) primarily causes nongonococcal urethritis (NGU) and relates to antimicrobial resistance (AMR), which is a major concern. Pharyngeal and rectal infections can also occur, which are mostly asymptomatic. Screening for MG is not typically performed and data on prevalence are limited. We explored the prevalence of MG among men who have sex with men (MSM) in an HIV pre-exposure prophylaxis (PrEP) program in Hanoi, Vietnam.

Methods From January to December 2022, MSM in the PrEP program at the Sexual Health Promotion Clinic in Hanoi, Vietnam were enrolled in a study testing for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG). A survey collecting demographic, behavioral, and clinical characteristics was administered. A retrospective analysis of MG results from self-collected urine, rectal, and pharyngeal specimens was performed using the Alinity m STI Assay (Abbott Molecular, USA).

Results In total, specimens from 303 participants with a median age of 25.1 (21.7-29.5) years underwent MG testing. Among them, 51.8% had two or more sex partners in the last month, while 12.9% participated in group sex and 50.8% reported sexualized drug use in the last 6 months. The prevalence of MG infections was 7.3% (19/261), 1.4% (4/291), and 3.1% (9/295) at rectum, pharynx and urethra, respectively, and 9.6% (29/303) were positive for MG at any site. MG co-infections with NG and CT occurred among 17.2% (5/29) and 6.9% (2/29), respectively; those with MG infections were at a significantly lower level than those without MG in CT infections (96.9% and 3.1%, p=0.04). Among those reporting urethral and pharyngeal symptoms, but without CT or NG, no MG infections were detected; 4 rectal MG infections were detected among 86 participants reporting rectal symptoms, but without CT or NG.

Conclusions We observed nearly 10% prevalence of MG infections among MSM in a PrEP program in Hanoi, Vietnam. The prevalence was highest among rectal specimens and most infections were asymptomatic. The clinical utility of testing for MG outside of NGU is not known. Additional studies are needed to better understand the risk factors and AMR related to MG, and cost-effectiveness of MG testing and treatment in Vietnam.

Table 1. Demographic, behavioral, and clinical characteristics of 303 MSM PrEP users with specimens tested for *M. genitalium*

Characteristics	Overall (N=303)	MG negative (N=274)		MG positive (N=29)		p value*
	n	n	%	n	%	
Median age (IQR)	25.1 (21.7-29.5)	25.6 (21.7-29.9)		25.4 (20.9-27.3)		0.27
Age, years						0.58
16-24	140	128	91.4	12	8.6	
≥ 25	163	146	89.6	17	10.4	
Highest education						0.31
Up to high school	28	23	82.1	5	17.9	
In vocational training/ college/university	88	78	88.6	10	11.4	
Finished vocational training/college/university	153	141	92.1	12	7.8	
Post-graduation training	34	32	94.1	2	5.9	
Monthly income						0.11
Up to $300	107	99	92.5	8	7.5	
More than $300	152	139	91.5	13	8.5	
Can't remember	44	36	81.8	8	18.2	
Sexual practice in the last 6 months						
Any group sex	39	35	89.7	4	10.3	0.88
Any sexualized drug use	154	140	90.9	14	9.1	0.77
Sex with male partners met via mobile apps	186	170	91.4	16	8.6	0.47
Number of sex partners in the last month						0.35
0	41	39	95.1	2	4.9	
1	105	96	91.4	9	8.6	
≥ 2	157	139	88.5	18	11.5	
Any STI symptoms in the last week						
Genitourinary symptoms	41	39	95.1	2	4.9	0.27
Pharyngeal symptoms	72	64	88.9	8	11.1	0.61
Rectal symptoms	51	45	88.2	6	11.8	0.49
No symptoms	175	157	89.7	18	10.3	0.62
Current STI infections						
N. gonorrheae	42	37	88.1	5	11.9	0.58
C. trachomatis	64	62	96.9	2	3.1	**0.04**
No co-infections	212	190	89.6	22	10.4	0.47
Used antibiotic in the last 6 months						0.34
No	191	176	92.2	15	7.8	
Yes	81	70	86.4	11	13.6	

Unsure	31	28	90.3	3	9.7	
Episodes of antibiotic use in the last 6 months						0.19
None	191	176	92.2	15	7.8	
1	77	66	85.7	11	14.3	
2	16	13	81.3	3	18.7	
3 – 5	16	16	100.0	0	0	
More than 5	3	3	100.0	0	0	

Neisseria gonorrhoeae and *Chlamydia trachomatis* positivity by symptom status and anatomic site of infection among men who have sex with men in a Human Immunodeficiency Virus Pre-exposure Prophylaxis program in Hanoi, Vietnam

Authors: Hao TM Bui[1], Paul C. Adamson[2], Thanh C. Nguyen[1], Loc Q. Pham[1], Giang M. Le[1], Jeffrey D. Klausner[3]

Affiliations

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Word count: 350

Current: 319

Background: Routine screening for sexually transmitted infections (STIs) is recommended for patients using human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) due to high rates of asymptomatic bacterial STIs. However, in Vietnam, as in many other low-resource settings, management of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) infections is primarily syndromic due to limited resources for testing. The study objectives were to evaluate CT and/or NG test positivity at three anatomic sites among symptomatic and asymptomatic participants in an HIV PrEP program in Vietnam.

Methods: From January-December 2022, participants in the HIV PrEP program at the Sexual Health Promotion Clinic in Hanoi, Vietnam were enrolled. Study participants completed a survey collecting demographic, behavioral and clinical characteristics. Participants self-collected urine, rectal, and pharyngeal specimens for nucleic-acid amplification testing. Participants positive for CT and/or NG were recalled for treatment.

Results: In total, 529 participants were enrolled. All were male and reported having sex with men in the prior 12 months; the median age was 25.1 years (IQR: 21.7– 29.65). The overall prevalence of CT or NG infection was 29.3% (155/529). The prevalence was 20.5% (108/529) for CT and 14.6% (77/529) for NG. By anatomic site, there were 34 (6.4%) urethral, 95 (18.0%) rectal, and 83 (15.7%) pharyngeal CT or NG infections. Among the 155 participants with CT or NG infections at any site, more than half (56.1%; 87/155) had no urethral, rectal or pharyngeal symptoms in the prior week. CT or NG test positivity among those reporting symptoms was 9.8% for urethral, 18.6% for rectal and 19.5% for pharyngeal. Positivity rate among asymptomatic participants was 4.1%, 17.5% and 13.1% for urethral, rectal, and pharyngeal respectively.

Conclusion: Through routine screening at three anatomic sites, we observed a high prevalence of CT and NG infections among MSM in a PrEP program in Hanoi, Vietnam. While more than half of the infections occurred among those asymptomatic, test positivity was consistently higher among those with symptoms.

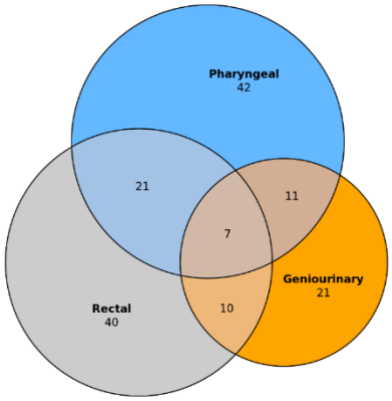
Table 1. Neisseria gonorrhoeae and Chlamydia trachomatis positivity by symptom status and anatomic site of infection of 529 men who have sex with men enrolled in a PrEP program and undergoing CT/NG testing.

	Overall N=529	**Any Symptoms n = 215**		**Asymptomatic n = 314**		**P value***
		n	%	**n**	%	
Any STIs symptoms in the past week						
Genitourinary symptoms	38 (17.7%)	38	100			
Pharyngeal Symptoms	126 (58.6%)	126	100			
Rectal symptoms	51 (23.7%)	51	100			
CT infection by Anatomic Site						
Urethral	23 (4.3%)	11	5.1	12	3.8	0.47
Rectal	73 (13.8 %)	30	14.0	43	13.7	0.93
Oropharyngeal	30 (5.7%)	15	7.0	15	4.8	0.28
Any site	108 (20.4%)	47	21.9	61	19.4	0.50
NG infection by Anatomic Site						
Urethral	16 (3.0%)	14	6.5	2	0.6	<0.001
Rectal	38 (7.2%)	21	9.8	17	5.4	0.06
Oropharyngeal	62 (11.7%)	33	15.3	29	9.2	0.03
Any site	77 (14.6%)	40	18.6	37	11.8	0.03
CT and NG infection by Anatomic Site						
Urethral	5 (0.9%)	4	1.9	1	0.3	0.16
Rectal	16 (3.0%)	11	5.1	5	1.6	0.02
Oropharyngeal	9 (1.7%)	6	2.8	3	1.0	0.17
Any site	26 (4.9%)	17	7.9	9	2.9	0.008
CT or NG infection by Anatomic Site						

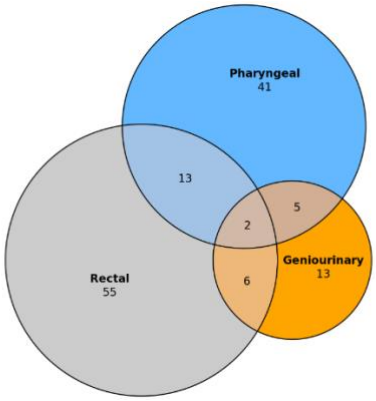
Urethral	34 (6.4%)	21	9.8	13	4.1	0.009
Rectal	95 (18.0%)	40	18.6	55	17.5	0.75
Oropharyngeal	83 (15.7%)	42	19.5	41	13.1	0.04
Any site	155 (29.3%)	68	31.6	87	27.7	0.33

Figure 1: Venn diagrams of *N. gonorrhoeae* or *C. trachomatis* infections by anatomic site and symptom status

In participants who reported symptoms within the prior week



In participants without reported symptoms in the prior week



Title: Preliminary Results from a Clinical Trial Comparing the Efficacy of Cefixime Versus Penicillin G for the Treatment of Early Syphilis

Authors: Kori Keith[1], Chrysovalantis Stafylis[1], Kelika Konda[1], Michael Reyes-Diaz[2], Jeffrey D. Klausner[1]

Affiliations:

[1] Department of Population and Public Health Sciences, University of Southern California Keck School of Medicine, Los Angeles, California, USA

[2] Center for Interdisciplinary Studies in Sexuality, AIDS and Society, Universidad Peruana Cayetano Heredia, Lima, Peru

Background: Syphilis has reemerged as a global health concern globally. The treatment recommendation for syphilis at all stages is injectable benzathine penicillin G. Cefixime is proposed as an alternative to penicillin as it is a widely available, oral, low cost and safe in pregnancy. A previous pilot study showed that cefixime was likely efficacious for the treatment of early syphilis. The goal of this study is to evaluate the effectiveness of cefixime compared to benzathine penicillin G.

Methods: We are conducting a randomized, multisite, open-label, non-inferiority clinical trial to evaluate the effectiveness of cefixime (400mg, orally, twice a day, for 10 days) compared to benzathine penicillin G (2.4 million units, intramuscularly), in patients with and without human immunodeficiency virus (HIV) infection. The trial seeks to enroll 400 participants from 10 clinical sites in the United States and Peru. Patients return at 3, 6, and 9 months for clinical evaluation and rapid plasma reagin (RPR) testing. The primary outcome is serological response by 3- or 6- months post-treatment, defined as 4-fold or greater RPR titer decrease from baseline.

Results: As of January 5th, 2023, 56 participants have been enrolled. Of those, the majority are HIV infected (85.7%) and men who have sex with men (85.7%). Currently, 34 participants have returned for 3-month evaluation, and 28 participants have returned for 6-month evaluation. To date, 93.3% (14/15) of cefixime participants and 92.3% (12/13) of penicillin participants achieved a 4-fold or greater RPR titer decrease by 3 or 6-months after treatment.

Conclusion: Efficacy appears similar between both treatment arms. Enrollment and data collection is ongoing. The anticipated study completion date is June 2025.

Word Count: 269

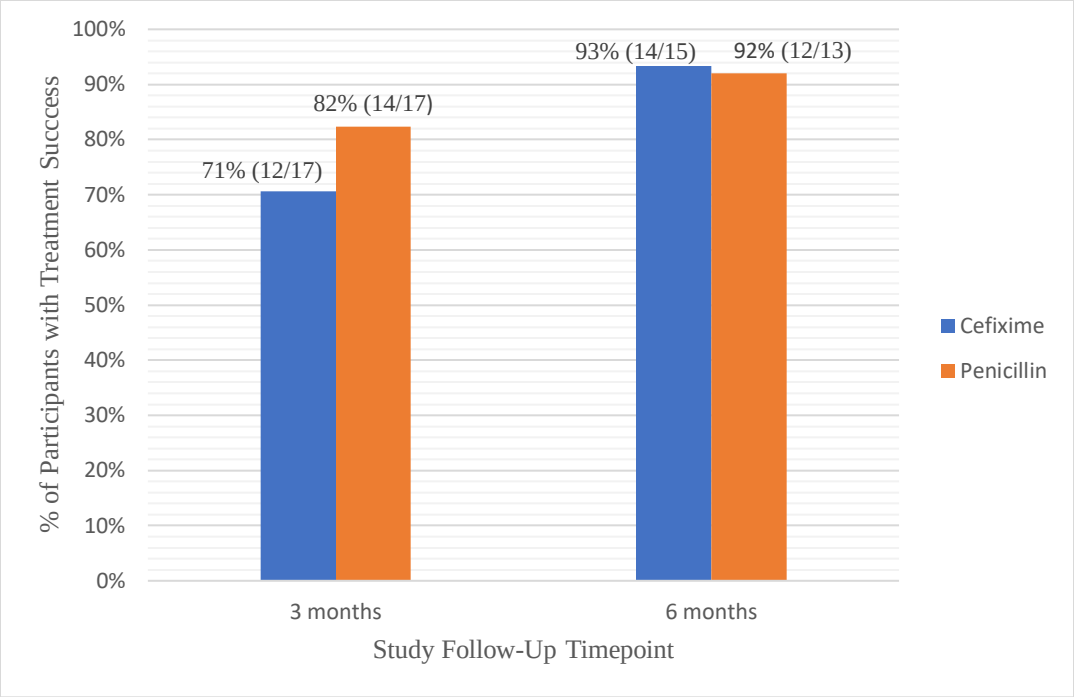


Figure 1. Treatment response by 3- or 6-months after treatment initiation among cefixime and penicillin participants.

Title: Rapid Plasma Reagin Titer Changes Between Dates of Diagnosis and Treatment

Authors: Kori Keith[1], Chrysovalantis Stafylis[1], Kelika Konda[1], Michael Reyes-Diaz[2], Jeffrey D. Klausner[1]

Affiliations:

[1] Department of Population and Public Health Sciences, University of Southern California Keck School of Medicine, Los Angeles, California, USA

[2] Center for Interdisciplinary Studies in Sexuality, AIDS and Society, Universidad Peruana Cayetano Heredia, Lima, Peru

Background: Syphilis has reemerged as a global health concern. Per the US Centers for Disease Control and Prevention guidelines, physicians should re-test patients on the date of syphilis treatment. We evaluated the change in syphilis rapid plasma reagin titer from the date of a reactive screening test to the date of treatment.

Methods: In an ongoing clinical trial of the effectiveness of cefixime in participants with and without HIV infection we screened patients for syphilis utilizing historical and screening rapid plasma reagin (RPR) titers. Participants titers were repeated on the day of treatment as the baseline for study outcomes. We compared RPR titer results from study participants on the day of initial diagnosis and the day of treatment. Percentages of participants with two-fold or greater titer changes were calculated. We categorized results by the time interval between titers <6 days, 7-14 days, or 14+ days, and whether the observed change was an increase or decrease in RPR.

Results: As of January 5th, 2023, we enrolled 56 participants. The median duration between the day of diagnosis and day of treatment is 7 (range 0-90) days. Among participants with 0-6 days between diagnosis and treatment, 15.4% (8/13) had an increased RPR and 46.2% (6/13) had a decreased RPR. Among participants with 7-14 days between diagnosis and treatment 29.0% (9/31) had an RPR increase and 35.5% (11/31) had an RPR decrease. In cases with 14+ days between diagnosis and treatment, 22.2% (2/9) and 44.4% (4/9) had increases and decreases, respectively. Fifteen (44.1%) of the 34 participants with changed titers had 4-fold or higher titer changes.

Conclusion: Our results support repeat RPR titer testing the day of treatment for patients with syphilis. Repeat testing may help avoid treatment response misinterpretation due to changes in titers that occur between the time of diagnosis and the time of treatment.

Word Count: 303

Abstract Title: A Scoping Review of Linezolid Safety in Pregnancy

STI & HIV 2023 WORLD CONGRESS
CHICAGO, IL USA 24-27 JULY 2023

ABSTRACT PREVIEW: A SCOPING REVIEW OF LINEZOLID SAFETY IN PREGNANCY

A Scoping Review of Linezolid Safety in Pregnancy

Abstract ID: **1448651**

ABSTRACT Category: **Abstract Submission**

Abstract Status: **Complete**

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Abstract

Track

Clinical Science

Focus of Study:

- Health inequalities
- Key population-led interventions
- Treatment: New Therapies

Type of Study

- Systematic review / meta analysis

Pathogen of research

- Treponema pallidum

Geographic Region of Research

What is your preferred format for this abstract? (please put oral presentation, poster, or no preference)

Poster

Abstract (350 words maximum)

Background: Syphilis is a serious global health problem, with nearly one million cases among pregnant women resulting in over 350,000 adverse birth outcomes annual. Due to benzathine penicillin shortages and its high cost, alternative syphilis treatments are needed. Linezolid 600 mg daily or twice daily is clinically used for skin infections and drug-resistant tuberculosis. Linezolid has shown high efficacy against syphilis in animal models. Common side effects of prolonged use include neuropathy and thrombocytopenia. As a low-cost, widely available antibiotic, linezolid has the potential to be an alternative syphilis treatment.

Methods: We conducted a scoping review to investigate the safety of linezolid during pregnancy. We reviewed the publicly available FDA materials submitted for the New Drug Application 021130 Pfizer (Zyvox-linezolid) 2000-2021. We also searched PubMed and Embase for reports published between May 3,

Abstract Title: A Scoping Review of Linezolid Safety in Pregnancy

1999, to June 10, 2022, using keywords "linezolid" and "pregnancy". We reviewed linezolid dosage, duration of treatment, disease of interest, and animal, fetal and maternal toxicities to assess the safety of linezolid treatment.

Results: We identified 171 studies and included thirteen with data on animal or human outcomes. Of the six animal studies, no teratogenic effects from linezolid (at an equivalent dose for 60 kg adult) were observed in 311 mice, rats, or rabbits. Fetal and maternal toxicity in 56 animals occurred at human equivalent dosages of 486 to 2,187 mg daily (typical human dose 600 to 1200 mg daily) for 11-12 days, including increased litter loss and decreased survival and fertility of pups. Among 31 reported cases of linezolid exposure in pregnant women, linezolid was given to 30 with drug-resistant tuberculosis and one with *Staphylococcus aureus* infection. Thirty of 31 pregnant women experienced no fetal or maternal toxicity. Polyneuropathy was reported in one case after 5 months of long-term use.

Conclusion: Our scoping review found no teratogenic effects of linezolid. Adverse effects in animals appeared at dosages close to typical human dose, but no adverse events were reported in a small number of women. Further research may be needed to determine the safety of linezolid in pregnancy.

Uploaded File(s)

Upload Table or Figure

Animal Study	Animal	Animal Dose (mg/kg/day)	Human Equivalent Dose for 60 kg adult (mg)	Sample Size	Teratogenic effects in fetus (abnormal fetal development)	Non-teratogenic effects in fetus	Maternal Toxicity and adverse events
Investigational New Drug	Mice	0, 50, 150, 450	0, 243.2, 729.7, 2189.2	25 mice/group (1:1:1:1)	None	At animal dose 450 mg/kg/day: Total litter loss (8/25 mice)	None
Investigational New Drug	Mice	5	24.3	-	None	None	None
Study 95-207	Rat	0, 2.5, 15, 50	0, 24.3, 145.9, 486.5	24 rats/group (1:1:1:1)	None	At animal dose 50 mg/kg/day: Decreased survival and fertility	None
Segment I of Study 95-207	Rat	0, 2.5, 15, 50	0, 24.3, 145.9, 486.5	24 rats/group (1:1:1:1)	None	At animal dose 50 mg/kg/day: Delayed auditory response and locomotor reflexes	None
Daniel et al.	Rat	0, 15, 50, 100	0, 145.9, 486.5, 973	25 rats/group (1:1:1:1)	None	None	None
Investigational New Drug	Rabbit	15	291.9	-	None	None	None
Clinical Study	**Disease/Condition**	**Therapeutic Dose (mg)**	**Duration of Treatment**	**Sample Size**	**Teratogenic effects in fetus (abnormal fetal development)**	**Non-teratogenic effects in fetus**	**Maternal Toxicity and adverse events**
Acquah et al.	Multi-drug resistant tuberculosis	-	-	4	None	None	None
Alene et al.	Multi-drug resistant tuberculosis	-	-	3	None	None	None
Loveday et al.	Multi-drug resistant tuberculosis	-	-	20	None	None	None
Jaspard et al.	Multi-drug resistant tuberculosis	600 once daily	3 weeks	1	None	None	None
Mercieri et al.	Community-acquired methicillin-resistant staphylococcus aureus	600 twice daily	4 weeks	1	None	None	None
Van Kampenhout et al.	Multi-drug resistant tuberculosis	300 twice daily	26 weeks (6.5 months)	1	None	None	Polyneuropathy
Zhu et al.	Anti-tuberculosis drug-induced acute liver failure	600 once daily	4 weeks	1	None	None	None

Table 1 - Linezolid Safety in Pregnancy Results

Table 1 - Linezolid Safety in Pregnancy Results.png

Young Investigators and Scholarships

Abstract Title: A Scoping Review of Linezolid Safety in Pregnancy

Do you need a scholarship?
Yes

Are you an early-career investigator?
Yes

If yes, please provide the date of completion of your highest degree:
2022-12-14

If not, are you currently a student, post-doctoral trainee, or clinical trainee?

If yes, please provide the start date for your graduate degree or clinical training:

Are you the presenting author for the abstract you have submitted to the 2023 STI & HIV World Congress?
Yes

If you are applying for a scholarship, in 100 words or less, please describe why you need a scholarship to attend ISSTDR 2023 in Chicago. Please note that you MUST complete this section only if you are applying for a scholarship.
As the first person in my family to pursue higher education in research, I would highly benefit from a scholarship to attend ISSTDR 2023 in Chicago. The scholarship will not only help me financially, but allow me to network with prominent researchers and learn about the latest research in sexually transmitted diseases worldwide. The experience I would gain from the ISSTDR Conference in Chicago will be beneficial as I start medical school in Fall 2023 and hopefully pursue a medical career in infectious diseases and health equity.

Gender?
cis-female

Title: PrEPTECH: Clinical Results from a Telehealth Platform for HIV Pre-Exposure Prophylaxis

Conference Name: STI & HIV 2023 World Congress

Authors: Thuan-Huong P Doan[1]; Rebecca K Erenrich[2]; Rebecca Braun[2]; Jeffrey D Klausner[3]

Affiliations

[1]University of California, Los Angeles, Los Angeles, CA, United States; [2] ETR Associates, Scotts Valley, CA, United States; [3]Keck School of Medicine, University of Southern California, Los Angeles, CA, United States

Deadline: January 13, 2023

Body Word Limit: 350 Words

Body Word Count: 339 Words

Background:

Young men who have sex with men (MSM) and transgender women (TW) experience a high incidence of Human Immunodeficiency Virus (HIV) and barriers to obtaining HIV PrEP. Telehealth platforms could reduce those barriers. We present the preliminary clinical results of an ongoing randomized-controlled trial of PrEPTECH, an integrated telehealth model for HIV PrEP delivery.

Methods:

We recruited MSM and TW between 18-27 years through social media and dating apps. Participants underwent online risk assessment and requested home self-collection test kits for anorectal *Chlamydia trachomatis*/*Neisseria gonorrhoeae*, syphilis, hepatitis B surface antigen, HIV infection and creatinine (myLAB Box©, California, USA). After review of laboratory

results, participants were mailed an initial 1-month (for MSM) or 3-month (for TW) supply emtricitabine/tenofovir df 200 mg/300 mg. Participants were followed-up at 30 and 90 days.

Results:

As of January 2023, of 116 participants who requested test kits, 59 (51%) completed self-testing: 1 (1.8%) of 56 anorectal *N. gonorrhoeae* tests and 0 *C. trachomatis* tests were positive. Fifty-three (89.8%) of 59 syphilis tests were nonreactive, 1 (1.7%), equivocal, 4 previously treated and 1 newly diagnosed. One (1.7%) of 59 hepatitis B surface antigen results was positive. All HIV infection results were non-reactive. Creatinine test results were all normal (< 1.21 mg/dL). Fifty-eight participants (98.3%) were mailed medication. Of those (median age 24 years, 74% people of color), 50 (86.2%) reported at least 2 male anal sex partners within the past 6 months, 56 identified as MSM, and 2, as TW. Among the 38 (66.7%) of 57 time-eligible participants who completed 30-day follow-up, 18 (47.4%) reported no adverse events, 6 reported 1 adverse event (15.8%), and 14 (36.8%) reported at least 2, including sore throat, fever, fatigue, or stomach pain. Of the 4 (8.5%) of 47 time-eligible participants who completed 90-day follow-up, 3 reported no adverse events and 1 reported 2 adverse events.

Conclusion

Among these telehealth PrEP initiators, we observed few baseline STIs and no renal parameters that would prohibit starting PrEP. Online PrEP programs may facilitate access to PrEP for young MSM and TW.

Title: Knowledge and Barriers to HIV Pre-Exposure prophylaxis in Southern California

Conference Name: International Society for Sexually Transmitted Diseases Research (ISSTDR)

Authors: Gilbert A. Orta Portillo, MPH[1]; Chrysovalantis Stafylis MD, MPH[1]; Yara Tapia, BA[1] Jeffrey D. Klausner MD, MPH[1]

[1]Keck School of Medicine of the University of Southern California, Department of Population and Public Health Sciences, Los Angeles, CA, USA

Background:

Pre-exposure prophylaxis (PrEP) has greatly enhanced HIV prevention, yet disparities in PrEP uptake remain among gay and bisexual men of color when compared to their White counterparts. Our aim was to investigate knowledge and attitudes among non-using PrEP residents at risk for HIV infection in a semi-urban, two-county region in Southern California.,.

Methods:

We recruited adults between September 2022 to January 2023, using geolocation-focused online advertisements on social media and dating apps along with palm cards with QR codes distributed by local clinics and organizations. Eligible participants were: 1) male 2) over the age of 18 years; 3) reported sex with men; 4) residents of San Bernardino or Riverside counties, California; 5) HIV-uninfected; and 6) currently not taking PrEP. Descriptive analyses (mean, standard deviations, frequencies, and proportions) were performed.

Results:

Our sample included 84 males, with median age of 32 years, with a majority of Hispanic/Latinx (51.2%) and White (62.3%) participants. Most individuals reported having sex with men only (77.1%), having public (50.6%) or private medical insurance (30.1%), had ever engaged in oral sex (73.8%), receptive anal sex (57.1%) and group sex (50.0%). On average, participants used condoms in 22.5% of their sexual encounters during the past 6 months. Most had read or heard about PrEP (77.4%) and felt familiar with PrEP (63.8%), have seen information on PrEP via social media (48.8%) and dating sites or apps (45.2%).

Nearly half (49.4%) of participants were unaware that you can obtain PrEP if uninsured. Most participants were comfortable potentially taking PrEP (57.0%) and potentially engaging sexually with someone on PrEP (76.2%). Participants reported support from their LGBGTQI+ community (33.3%) and social networks (51.2%) in taking PrEP. Most traveled 5 to 10 miles for medical care (34.5%). Participants felt comfortable discussing sexual behaviors with their provider (50.0%). In addition, participants reported that local providers understood their culture (51.2%) and they could communicate in their preferred language (67.4%).

Conclusion:

This study underscored that non-PrEP using gay and bisexual men in the San Bernardino-Riverside County area are informed and knowledgeable of PrEP and that health care providers were generally culturally competent with LGBTQI+ sexual health behaviors.

Title: Group sex and behavior changes among men who have sex with men in Southern California

Conference Name: International Society for Sexually Transmitted Diseases Research (ISSTDR)

Authors: Chrysovalantis Stafylis MD, MPH[1]; Gilbert A. Orta Portillo, MPH[1]; Yara Tapia, BA[1]; Jeffrey D. Klausner MD, MPH[1]

[1]Keck School of Medicine of the University of Southern California, Department of Population and Public Health Sciences, Los Angeles, CA, USA

Background: The Monkeypox (Mpox) epidemic (May 2022 - September 2022) disproportionately affected sexually active gay, bisexual, and other men who have sex with men. To understand community-level changes in sexual behavior, we surveyed individuals in a semi-urban area in Southern California.

Methods: We recruited adults between October 2022 to January 2023, using geolocation-focused online advertisements on social media and dating apps along with palm cards with a QR code distributed by local clinics and organizations. Eligible participants were: 1) male, 2) over the age of 18 years; 3) reported sex with men; 4) residents of San Bernardino or Riverside counties, California; 5) HIV-uninfected; and 6) currently not taking PrEP. Descriptive analyses (mean, standard deviations, frequencies, and proportions) were performed.

Results: Our sample included 64 males with median age of 36.2 years (range 18-70 years). The majority were Hispanic/Latinx (50%) and White (36%). Most participants reported sex with men only (78.1%), with 50% having participated in group sex in the past year. On average, participants used condoms 37.2% of their sexual encounters during the past 6 months.

Forty-two percent reported that they changed their sexual behavior during the Mpox epidemic.

Among those who participated in group sex before the outbreak (n=32), 53.1% participated in group sex at least once a year and 21.9% 2-4 times/year. The average number of partners during group sex was 3.4. During the outbreak, 44% (14/32) reported they participated in group sex and the average number of partners was 3.6. Among them, 57% (8/14) reported 2-4 instances of group sex. To reduce the risk of Mpox infection, group sex participants reported that they limited

the number of sex partners (34.4%), used condoms during anal sex (12.5%), avoided crowded places (9.4%) and asked their partners about Mpox symptoms before sex (9.4%).

Conclusion: Survey participants reported modest sexual behavior changes in response to the Mpox outbreak. Since group sex is a sex behavior that increases the risk for Mpox, HIV and other sexually transmitted infections, public health messages should include specific discussion of safer group sex practices in sexual health promotion.

Title: Real-world Performance versus Regulatory Data of Herpes Simplex Virus Type-2 Antibody Tests

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Background: Herpes Simplex Virus (HSV) is a common and prevalent sexually transmitted infection affecting 6 billion people globally. Serological screening for HSV in asymptomatic individuals is not recommended because of suboptimal test performance characteristics. We reviewed the performance of serologic screening in real-world populations, which included symptomatic and asymptomatic individuals, and compared findings to publicly available product package insert data in currently used US Food and Drug Administration (FDA) cleared HSV-2 serologic tests.

Methods: Applying no date or geographical restrictions, we searched PubMed and Google Scholar to identify human studies reporting performance of Herpes Simplex Type-2 antibody tests compared to the University of Washington Western Blot HSV-2 assay. We reviewed regulatory data, which included data from the US FDA 510(k) premarket submissions from test manufacturers reported in package inserts.

Results: We identified 12 published studies relevant to the research question (N=8087 test results). Assays evaluated included ELISA (enzyme-linked immunoassay) and immunoblot.

Real-world performance values compared to the UW HSV-2 Western Blot for the Focus HerpeSelect HSV-2 ELISA ranged in sensitivity from 91.9% to 100.0% and specificity 41.0% to 97.8%. For the Biokit HSV-2 Rapid ELISA, sensitivity was 66.0% and specificity 90.9%. For the Virotech Line Immunoblot, sensitivity was 98.1% and specificity 100.0%

In comparison, package insert data for the Focus HerpeSelect HSV-2 ELISA had sensitivity of 96.1% and specificity of 97.0%, Biokit HSV-2 Rapid ELISA 92.2% and 87.0%, and Virotech Line Immunoblot 91.6% and 94.9%.

In 7 studies including African populations (N=5293 test results), Focus HerpeSelect sensitivity ranged from 98.0% to 100.0% and specificity from 41.0% to 97.5%. In 5 studies that excluded African populations (N=2794 test results), Focus HerpeSelect performance ranged from

sensitivity of 91.9% to 100.0% and specificity of 57.4% to 100.0%. One study was excluded to account for bias. In the remaining 4 studies that excluded African populations (N=1930 test results), the Focus HerpeSelect specificity ranged from 89.0% to 100.0%.

Conclusion: HSV-2 serological test performance demonstrated discrepancies between real-world studies and reported data in manufacturers' package inserts. Test performance may vary by study populations. Larger, independent, and more robust studies of HSV-2 antibody test performance are needed.