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Authors

Shannon, Chelsea Lee
Bristow, Claire
Hoff, Nicole
et al.

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Short Report: Acceptability and Feasibility of Rapid Chlamydial, Gonococcal, and Trichomonal Screening and Treatment in Pregnant Women in Six Low-to-Middle Income Countries

CL Shannon, BA[1], **CC Bristow, PhD**[2], **NA Hoff, PhD**[3], **A Wynn, PhD**[1], **M Nguyen, MS**[4], **A Medina-Marino, PhD**[5], **J Cabeza, MD, MPH**[6], **AW Rimoin, PhD**[3], and **JD Klausner, MD, MPH**[1]

[1]Division of Infectious Diseases, Department of Medicine, University of California Los Angeles, CA, USA

[2]Division of Global Public Health, Department of Medicine, University of California San Diego, La Jolla, CA, USA

[3]Department of Epidemiology, Fielding School of Public Health, University of California Los Angeles, CA, USA

[4]Department of Epidemiology, Hanoi Medical University, Hanoi, Vietnam

[5]Research Unit, Foundation for Professional Development, Pretoria, South Africa

[6]South American Program in HIV Prevention Research, David Geffen School of Medicine, University of California Los Angeles, CA, USA

Abstract

Background—*Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) infections during pregnancy are linked with adverse birth outcomes. However, few countries have prenatal CT, NG, or TV screening programs. In this study, we aimed to evaluate the acceptability and feasibility of CT, NG, and TV screening and treatment among pregnant women across six low-to-middle income countries.

Methods—A total 1,817 pregnant women were screened for CT, NG, and TV in Botswana, the Democratic Republic of Congo (DRC), Haiti, South Africa, and Vietnam. An additional 640 pregnant women were screened for CT in Peru. Screening occurred between December 2012 and October 2017. Acceptability of screening was evaluated at each site as the proportion of eligible women who agreed to participate in screening. Feasibility of treatment was calculated as the proportion of women who tested positive that received treatment.

Results—Acceptability of screening and feasibility of treatment was high across all six sites. Acceptability of screening ranged from 85–99%, and feasibility of treatment ranged from 91–100%.

Corresponding Author: Chelsea Shannon, 10290 Wilshire Blvd, Suite 350, Los Angeles, CA 90024, Phone: (310) 748-9794 Fax: (310) 794-8297, cshannon@mednet.ucla.edu.

Conflicts of Interest: None

Discussion—The high acceptability of screening and treatment for CT, NG, and TV among pregnant women supports further research to evaluate the cost-effectiveness of prenatal CT, NG, and TV screening programs.

Keywords

STD screening; STD treatment; acceptability; feasibility; international STDs

Introduction

Every year, there are an estimated 349 million new infections with *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) globally.[1] In pregnant women, those infections can be linked to serious adverse birth outcomes, including premature labor and birth and low birth weight infants.[2, 3, 4] Furthermore, maternal CT or NG infection during birth can cause mother-to-child CT or NG transmission in 30–70% of cases.[5, 6, 7] Neonatal CT infection can cause chlamydial opthalmia neonatorum as well as chlamydial pneumonia. Neonatal NG infection can cause gonococcal opthalmia neonatorum, which, if untreated, may lead to blindness. Finally, maternal infection with CT, NG, or TV may be associated with an increased chance of acquiring HIV infection and an increased likelihood of mother-to-child HIV transmission.[8, 9]

Currently, maternal diagnostic screening for CT, NG, and TV is only done in a limited number of countries.[10] Diagnostic screening typically involves nucleic acid amplification tests that are expensive and take multiple days to receive results. Due to the limited access to laboratory testing and the lack of cost-effectiveness data, the World Health Organization (WHO) only recommends symptom-based management of CT, NG, and TV.[11] However, as most of those infections are asymptomatic, the syndromic management approach leaves many sexually transmitted diseases (STDs) undiagnosed and untreated, and thus may contribute to a large number of attributable adverse birth outcomes. A recent study in Australia showed that prenatal CT screening and treatment reduced the risk of adverse birth outcomes on a population level.[12, 13]

Many rapid diagnostic tests for CT, NG, and TV are in development or newly available.[14] Such tests will increase the accessibility of prenatal STD screening globally by increasing access to testing. However, STD screening is often viewed as stigmatizing, and specimen collection through pelvic examination or self-collected vaginal swabs might be considered invasive.[15] As rapid diagnostic tests become more readily available, it is critical to evaluate the acceptability and feasibility of prenatal screening programs for CT, NG, and TV. Understanding the acceptability and feasibility is a key step in informing the development of policy recommendations.

The World Health Organization (WHO) defines acceptability as the extent to which an intervention is considered to be reasonable among those receiving, delivering, or affected by the intervention. Feasibility is defined as the likelihood that an intervention can be properly carried out or implemented in a given context.[16] Studies have shown prenatal syphilis screening to be acceptable and feasible.[17, 18] A study done in Australia used qualitative methods to assess acceptability of rapid CT and NG testing among primary care providers in

remote settings.[19] The study found high acceptability of testing among primary care providers delivering the intervention. In this study, we aimed to evaluate the acceptability and feasibility of prenatal CT, NG, and TV screening and treatment among pregnant women in low-to-middle income countries. To do this, we compiled acceptability and feasibility data from CT, NG, and TV screening and treatment projects conducted by our study team in 6 different low-to-middle income countries.

Materials and Methods

Over the past 5 years, we have conducted STD screening studies among pregnant women in six distinct settings. A total of 1,817 pregnant women were recruited for CT, NG, and TV screening at prenatal clinics in Botswana, the Democratic Republic of Congo (DRC), Haiti, South Africa, and Vietnam.[20, 21 , 22] Additionally, 640 pregnant women were recruited for CT screening at prenatal clinics in Peru.[23] In Haiti, screening occurred at the Haitian Study Group for Kaposi's Sarcoma and Opportunistic Infections (GHESKIO) clinics in Port-au-Prince clinic from October 2015 to January 2016. In Peru, screening took place from December 2012-January 2013 at the Instituto Nacional Materno Perinatal (INMP) and Hospital Nacional Arzobispo Loayza (HNAL). In Vietnam, women were screened at the Ha Dong Hospital in Hanoi from September to December 2016. In Botswana, screening occurred at the maternal and child health clinic in Princess Marina Hospital, Gaborone from July 2015 to March 2016. In DRC, women were screened at the Kintanu, Ngeba, Ngamba, and Lemfu clinics in the Kisantu Health Zone, Bas Congo Province from October 2016 to March 2017. In South Africa, screening took place at two clinics in the Soshanguve Township and one clinic in the Mamelodi Township in Tshwane District from September 2016 to October 2017.

In Botswana, DRC, Haiti, South Africa, and Vietnam, eligible women were pregnant, age 18 years or older, and less than 35 weeks pregnant. Eligible women in Peru were age 16 years or older and less than 41 weeks pregnant. Samples were obtained via self-collected vaginal swabs in Botswana, Haiti, Peru, South Africa, and Vietnam. In DRC, samples were collected by the physician during the prenatal visit. Testing in Botswana, DRC, Haiti, South Africa, and Vietnam was conducted using the GeneXpert ® CT/NG and TV tests (Cepheid, Sunnyvale, California). In Peru, testing was done using the Aptima Combo2 ® system (Hologic, San Diego, California). Study protocols were approved by in-country institutional review boards / research ethics committees and the University of California Los Angeles, as well as local health departments and participating hospitals.

Women that tested positive for an STD were treated with 1 gm of oral azithromycin for CT infection, with 250 mg injection of ceftriaxone plus 1 gram of oral azithromycin for NG infection, or with 2 gms of oral metronidazole for TV infection. However, in DRC, women with NG infection were treated with 1 gram of oral azithromycin without ceftriaxone, per local recommendations. For HIV-infected participants, the dosage of metronidazole was 400 mg orally twice daily for 7 days. Patients were asked to return to clinic in three to six weeks for a test of cure. Women typically received same day treatment in South Africa and Botswana, while patients returned to the clinic for treatment in Haiti, DRC, Peru, and

Vietnam. Women who tested positive for CT, NG, or TV were given antibiotics to bring to their partner or asked to bring their partner in for treatment.

We assessed acceptability of screening by measuring the uptake of screening among eligible pregnant women. We measured feasibility of treatment by measuring the proportion of pregnant women who tested positive that received treatment. We calculated 95% confidence intervals for acceptability of screening and feasibility of treatment using the binomial method. We calculated percent acceptability overall weighted by the sample size. We also used a full Bayesian method for bivariate random-effects meta-analysis to calculate pooled estimates of acceptability of screening and feasibility of treatment with SAS (v9.4, Cary, NC) PROC MCMC.[24] By using quantitative metrics, we were able to compare results between countries and determine overall acceptability and feasibility of prenatal CT, NG, and TV screening and treatment among the six sample populations.

Results

Acceptability of CT, NG, and TV screening among pregnant women was consistently high, with values ranging from 85–99%. Feasibility of treatment was also high, ranging from 91–100%. Specific values for the acceptability of screening and feasibility of treatment are shown in the table.

Discussion

Prenatal CT, NG, and TV screening and treatment was acceptable and feasible among pregnant women across all six study populations. Despite the stigma associated with STD testing, nearly all pregnant women were willing to participate in screening, and nearly all who tested positive successfully received treatment. The high acceptability of screening and treatment among pregnant women, in conjunction with previously found high acceptability among primary care providers, indicates an overall high acceptability of prenatal screening programs for CT, NG, and TV among various populations.[19] Furthermore, the successful treatment of prenatal STDs across multiple settings indicates the feasibility of identifying and treating prenatal STDs in countries that traditionally rely on syndromic management. Those findings should be used to inform the development of screening policies for STDs in pregnancy.

We evaluated acceptability and feasibility of CT, NG, and TV screening and treatment using quantitative measures: uptake of screening and the proportion of women who tested positive that received treatment. By using those measures, we were able to quantitatively compare results by country, specimen collection method, and treatment practice. We were also able to avoid response biases that can occur with interviews or surveys.

Despite such advantages, our method of evaluation had a few limitations. Most notably, we have limited information on specific reasons for accepting or declining screening or treatment. In the Botswana, Peru, and DRC studies, the primary reason for non-acceptance of screening was lack of time. It was rare that testing was refused due to screening methods.[20, 21] However, without qualitative measures at every site, we cannot infer why different sites had varying levels of acceptability and feasibility, and we cannot determine how

acceptability and feasibility might be improved. Notably, acceptability of screening was lowest in DRC, which was the only site that used physician-collected samples instead of self-collected samples. Additionally, feasibility of treatment was slightly higher at sites that provided same-day treatment than sites that did not, likely due to the fact that patients did not have to return to clinic to receive treatment.

Another limitation stems from the fact that, while each country had very similar protocols, there were differences from site to site, ranging from differences in staff to differences in clinic set up. It is possible that such differences may have influenced acceptability and feasibility rates from site to site. However, those differences also reflect the reality of implementing STD screening and treatment programs in diverse real world settings, and support the generalizability of our findings.

Finally, data were only collected from one or two clinical settings per country. The results do not reflect the acceptability rates of entire regions or countries, and may not reflect all socioeconomic or demographic groups.

Moving forward, well-powered trials to evaluate the effectiveness of prenatal CT, NG, and TV screening programs to prevent adverse birth outcomes are urgently needed. It is also essential to evaluate other aspects of feasibility, such as outcomes of partner treatment, cure rates, and rates of re-infection. Ultimately, program sustainability will depend on updating WHO guidelines and adoption on the country level.

Understanding the acceptability and feasibility of prenatal STD screening in low-to-middle income country settings is an important step towards implementing such programs. The high acceptability of screening and feasibility of treatment suggest that women are willing to provide self-collected vaginal swabs, undergo screening, and receive treatment. Given the increasing accessibility of rapid diagnostic STD tests and the high acceptability and feasibility of screening and treatment, the data support further programmatic evaluation of prenatal CT, NG, and TV screening programs.

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Short Summary

Prenatal *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* screening and treatment had high levels of acceptability and feasibility among pregnant women in six low-to-middle income countries around the world.

Table

Acceptability of Screening and Feasibility of Treatment of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) Infections Among Pregnant Women in 6 Low-to-Middle Income Countries

	Number of Eligible Women	Number of Women who Agreed to Screening	Acceptability of Screening* (%)	Number of Women with CT, NG, or TV Infection	Number of Women who Received Treatment	Feasibility of Treatment* (%)	Specimen Collection Method	Treatment Timeline
Botswana	225	200	88.9% (95% CI: 84.0, 92.7)	30	30	100.0% (95% CI: 88.4, 100.0)	Self-collected	Same-day treatment
Democratic Republic of Congo	432	368	85.2% (95% CI: 81.5, 88.4)	66	64	97.0% (95% CI: 89.5, 99.6)	Provider-collected	Return to clinic for treatment
Haiti	322	300	93.2% (95% CI: 89.8, 95.7)	133	122	91.7% (95% CI: 85.7, 95.8)	Self-collected	Return to clinic for treatment
Peru	640	600	93.8% (95% CI: 91.6, 95.5)	60	59	98.3% (95% CI: 91.1, 100.0)	Self-collected	Return to clinic for treatment
South Africa	442	430	97.3% (95% CI: 95.3, 98.6)	174	174	100.0% (95% CI: 97.9, 100.0)	Self-collected	Same-day treatment
Vietnam	403	400	99.3 % (95% CI: 97.8, 99.8)	33	31	93.9 % (95% CI: 79.8, 99.3)	Self-collected	Return to clinic for treatment
Pooled (random effects model) **			**94.2% (95% CI: 86.2, 98.3)**			**97.9% (95% CI: 92.6, 99.9)**		
Overall (weighted by sample size)			**93.3% (95% CI: 92.2%, 94.2%)**			**96.77% (95% CI: 94.8%, 98.2%)**		

*Acceptability of screening was calculated as the proportion of uptake of screening among eligible women. Feasibility of treatment was calculated as the proportion of women who tested positive for an STI that received treatment. 95% confidence intervals were calculated using the binomial method.

**Random Effects Model run using SAS PROC MCMC

The table shows the acceptability of screening and feasibility of treatment of *Chlamydia trachomatis, Neisseria gonorrhoeae,* and *Trichomonas vaginalis* infections among pregnant women in Botswana, Democratic Republic of Congo, Haiti, Peru, South Africa, and Vietnam.