

AN ANALYSIS OF THE PROTOCOLS FOR SYPHILIS SCREENING IN PREGNANT
WOMEN AROUND THE WORLD

By

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Abstract

Syphilis is the second leading cause of preventable stillbirth worldwide, preceded only by malaria (WHO publishes new estimates on congenital syphilis 2019). Maternal syphilis leads to congenital syphilis in over half of affected pregnancies. Congenital syphilis can cause stillbirth, miscarriage, and other complications in pregnancy, yet has been under-diagnosed in pregnant women. Newly developed point-of-care Rapid Syphilis Tests (RST) allow for same-day treatment and have been proven to be more cost-effective in comparison to standard Rapid Plasma Reagin (RPR) testing. Successful introduction of new health technology requires healthcare worker acceptance, effective training, quality monitoring and robust health systems. The objective of this study is to determine if pregnancy clinics around the world are testing and treating for syphilis during pregnancy. These results will then allow us to investigate potential reasons why syphilis may not be diagnosed and treated during pregnancy. Questionnaires were administered through Qualtrics, a secure database to distribute surveys and analyze responses, to pregnancy clinics in various countries around the world. Pregnancy clinics were selected from personal contacts, contacts of Obstetrics and Gynecology department at the University of Arizona, and through an internet search of OB/GYN's through Doctors without Borders and Médecins Sans Frontières. Using a conceptual framework, we explored syphilis testing and treatment acceptance and usability. Both qualitative and quantitative data were analyzed using descriptive statistics. We hypothesized that diagnosis and treatment of syphilis during pregnancy will be greater in developed countries compared to developing countries due to the latter's limited financial means, limited training, and limited resources, which are all factors that affect universal healthcare. Limitations to this study include low response rate (possibly due to

perceived legal implications), technology barriers, and language barriers. A conclusion drawn from this study is that majority of pregnancy clinics around the world test and treat for syphilis during pregnancy. Of the few clinics that do not test for syphilis, reasons were given which could be further analyzed in future studies to close the gap in testing and treatment.

Introduction

Syphilis is a sexually transmitted disease caused by the transmission of the spirochete *Treponema pallidum* (*T. pallidum*). Syphilis is spread by direct contact with a syphilis lesion during vaginal, anal, or oral sex, as well as spread from an infected mother to her unborn baby, known as congenital syphilis. Congenital syphilis is caused by the release of *T. pallidum* straight into the blood stream of the fetus causing spirochetemia which spreads to most organs. The WHO STI guideline recommends screening all pregnant women for syphilis during the first antenatal care visit for standard care.

Screening tests for syphilis include the Venereal Disease Research Laboratory Test (VDRL), Rapid Plasma Regain Test (RPR), Rapid Immunochromatographic Test, and Rapid Syphilis Test (RST). If there is a positive screening result from one of the above tests, then additional tests are used to confirm a syphilis infection including Enzyme Immunoassay (EIA) test, Fluorescent Treponemal Antibody Absorption (FTA-ABS) test, *Treponema Pallidum* Particle Agglutination Assay (TPPA), Darkfield Microscopy, and Micro-Hemagglutination Assay (MHA-TP) (WHO Guideline on Syphilis Screening and Treatment for Pregnant Women 2017).

WHO states that the most ideal treatment for syphilis during pregnancy is a prompt treatment with benzathine penicillin G 2.4 million units once intramuscularly before 24 weeks gestation in order to prevent transmission to the fetus. In cases where penicillin cannot be used (e.g. due to penicillin allergy where penicillin desensitization is not possible) or are not available (e.g. due to stock-outs), the WHO STI guideline suggests using with caution, erythromycin 500 mg orally

four times daily for 14 days or ceftriaxone 1 g intramuscularly once daily for 10-14 days or azithromycin 2 g once orally (WHO Guideline on Syphilis Screening and Treatment for Pregnant Women 2017).

Congenital syphilis significantly increases the risk of infant death and has been responsible for 305,000 perinatal deaths worldwide annually, with a dramatic rise in cases since 2013 (STDs Continue to Rise in the U.S. Press Release 2019). Syphilis in pregnancy is the second leading cause of preventable stillbirth globally, with the first being malaria, mainly due to lack of proper prenatal care or receiving incomplete treatment. Syphilis during pregnancy can result in miscarriage (loss of fetus before 20 weeks gestation), premature birth (<37 weeks gestation), fetal growth restriction, low birthweight (<5 lbs, 8 oz), stillbirth (loss of fetus after 20 weeks gestation) (Rac 2013). While congenital syphilis can cause severe illness and fetal demise, most neonates born with congenital syphilis are asymptomatic at birth. Untreated infants' clinical manifestations usually appear by three months of age and commonly include hepatomegaly, jaundice, rhinitis, generalized lymphadenopathy, and/or rash (WHO Guideline on Syphilis Screening and Treatment for Pregnant Women 2017).

Multiple studies have demonstrated cost-effectiveness of syphilis screening at the initiation of prenatal care. These studies have shown that screening with RST is feasible, successful, acceptable, and cost-effective in underserved populations with high incidence of congenital syphilis. The introduction of RST catalyzed improvements in the quality of care and has become National policy in some of the countries introduced (Mahomed 2013). Despite the presence of screening and treatment for syphilis during pregnancy for more than 70 years, it remains a

significant health concern. Widespread consistent use of these screening and treatment options will help prevent against perinatal deaths worldwide, which is why it is crucial for pregnancy clinics to follow the standard of care guidelines. The purpose of the research is to discover whether or not pregnancy clinics around the world are following the standard of care by testing and treating syphilis during pregnancy. An additional objective of this study is to discover possible reasons and implications behind the lack of testing and treatment of syphilis during pregnancy.

Methods

This was a retrospective study of congenital syphilis testing and treatment implementation in prenatal clinics globally. A 19-question formal survey was constructed using Qualtrics, an online data software program licensed by the University of Arizona. The survey questions were designed to gather information on the use of known syphilis screening tools as well as to discover reasons behind the potential lack of syphilis screening and treatment during pregnancy. Determining whether or not pregnancy clinics are screening and treating syphilis is a reasonable starting point for exploring reasons behind the increase in global congenital syphilis cases.

Demographic questions were asked to provide the logistics of the clinics and underline differences between each pregnancy clinics in terms of funding, location, size, profit, and services provided. The survey proceeds to gather information on whether the pregnancy clinic screens or treats for syphilis during their patient's pregnancy. If the clinic responds "No" to testing syphilis during their patient's pregnancy, the survey directs them to follow up questions to gather information on why the pregnancy clinic does not test or treat syphilis. If the clinic responds "Yes" to testing syphilis during their patient's pregnancy, the survey directs them to follow up questions to gather information about the types of screening tools used, type of treatment prescribed or offered, how treatment is paid for, and when testing is completed during the patient's pregnancy.

The formal survey was sent out to pregnancy clinics around the world between January 18th, 2021 and March 1st, 2021. The survey was sent through The Office of Global Women's Health

email list by Dr. Lynn Coppola at University of Arizona OB/GYN Department. Additionally, the survey was sent to contacts at HEARTFIRE Missions Organization and Birmingham's Women and Children's Fetal Medicine Centre. Lastly, the survey was sent to various Medecins Sans Frontieres locations and Global Women's Health Fellowship programs around the United States.

Results

We received 140 responses to the survey sent between January 18th and March 1st of 2021. Of these responses, 9 countries were represented. These countries included the United Kingdom, United States, New Zealand, Canada, Zambia, Ghana, Malawi, Philippines, and Cameroon. The number of clinics responding per country is shown in Table 1.

Out of the 140 clinics who responded, 138 clinics reported that they test their patients for syphilis during pregnancy and 2 clinics reported that they do not test their patients for syphilis during pregnancy. One of the clinics that does not test patients for syphilis was a specialized maternal fetal medicine clinic located in the United States that was not-for-profit, in an urban location, and sees more than 100 patients in a month. The clinic reported that they do not provide syphilis screening for their patients because they are a specialized clinic. The other clinic that did not screen for syphilis was located in the Philippines. This clinic was for-profit, rural, privately funded and sees 0-25 patients in a month. The reason this clinic does not screen for syphilis during pregnancy is because it “causes a financial burden for the patient who has to pay for testing”.

Table 1: The table shows each of the responding clinics country’s economic classifications as well as the number of clinics responding from each country. Additionally, the table displays the percentage of clinics surveyed in the country that reported “yes” for syphilis testing.

Country:	Country’s Economic Classification:	Number of Responses:	Number of clinics that reported “yes” to screening for syphilis:
United Kingdom	Developed	3	3
United States	Developed	130	129
New Zealand	Developed	1	1
Canada	Developed	1	1
Zambia	Developing	1	1
Ghana	Developing	1	1
Malawi	Least developed country	1	1
Philippines	Developing	1	0
Cameroon	Developing	1	1

Of the 138 clinics that stated they test patients for syphilis during pregnancy, only 130 clinics stated that they test 100% of their patients for syphilis during pregnancy. Six clinics stated they test 75%-100% of their patients for syphilis, 1 clinic stated they test between 50%-75% of their patients for syphilis, and 1 clinic stated they test less than 25% of their patients for syphilis. The demographics for the clinics who test less than 100% of their patients for syphilis during pregnancy include: developed economic classification (both the United States or the United Kingdom), urban setting, greater than 100 patients in a month, both not-for-profit and for-profit, and both government and privately funded.

Table 2: This table shows the percentage of patients tested for syphilis during pregnancy by each clinic.

Percentage of patients tested for syphilis during pregnancy at the clinic:	Number of clinics:
100%	130
75%-100%	6
50%-75%	1
25%-50%	0
Less than 25%	1 (Three total if including the two clinics who do not test for syphilis at all)

The 138 clinics that responded “yes” to testing their patients for syphilis during pregnancy were asked additional questions about treatment for patients who test positive. Question 13 of the survey asked clinics how they treat positive syphilis cases in pregnant women at their clinic. 96 clinics stated that the clinic prescribes or administers medicine, 28 clinics refer patients to other resources, and 10 clinics responded “other” to the question. Of the 10 clinics that responded “other” to question 13, 8 clinics stated they refer positive patients to the health department, infectious disease services, or genitourinary medicine (GUM services), 1 clinic stated they refer positive patients to the hospital to provide treatment, and 1 clinic stated that they did not know how they would provide treatment because they had never experienced a positive syphilis case at their clinic. Lastly, 4 clinics that responded “yes” to testing for syphilis during pregnancy did not respond to question 13 of the survey.

Discussion

Congenital syphilis is caused by a mother with syphilis passing the infection to her baby during pregnancy. Cases of congenital syphilis have nearly quadrupled in the past few years. In 2019 the number of congenital syphilis cases was the highest since 1995. This information is important because of the effect congenital syphilis has on the outcome of a baby's health and longevity. Up to 40% of babies born from women with untreated syphilis may be stillborn or die from the infection (STD Facts – Congenital Syphilis 2017). Syphilis can be tested for and treated during pregnancy, yet the cases continue to rise despite the ability to prevent pregnancy complications. This study aimed to analyze possible factors behind the rise in syphilis cases during pregnancy. The factor we chose to study that could affect the number of syphilis cases was whether women are receiving testing and treatment during their prenatal care. Therefore, the objective of this study was to determine if pregnancy clinics around the world are testing and treating for syphilis during pregnancy.

Our results showed that not all clinics around the world are testing and treating for syphilis during pregnancy. Of the clinics that reported they do not test for syphilis during pregnancy, one clinic stated that they do not test because they are a specialized fetal medicine clinic. This raises the question, why does the specialized clinic not screen for syphilis, a question we did not ask in the survey. A second clinic that does not test for syphilis stated that they do not provide testing because of the financial burden it places on the patients. This statement raises the question of why wouldn't the clinic at least offer the syphilis test and explain the negative outcomes associated with congenital syphilis. Additionally, we discovered that out of the clinics that test

for syphilis, not every clinic tests 100% of their pregnant patients. We also discovered that the treatment of syphilis is not the sole responsibility of the clinics. Although majority of clinics administer and prescribe treatment for positive syphilis cases, some clinics are required to refer to other resources such as the Health Department or Infectious Disease Services, adding another possible factor to the increase in untreated syphilis cases. Due to the limited number of responses to the survey we cannot conclude that these findings are a significant factor in the rise in syphilis cases during pregnancy, but it does provide insights into the complexity of the issue.

Another aspect of this study was to examine the potential reasons behind the lack of syphilis testing and treatment by pregnancy clinics. We hypothesized that testing and treatment of syphilis was correlated to the county's economic classification (developed or developing). In our study, results indicated that there was no relationship between economic classification and syphilis testing and treatment, although our range of surveyed clinics was limited.

The original design of this study was to analyze if syphilis testing and treatment was a significant factor of the current rise in congenital syphilis cases. Due to limitations of our data, we were unable to statistically analyze significance in data. The limitations included language barriers, technology barriers, lack of resources to survey every clinic globally, and low response rate due to possible perceived legal implications. If this study could be conducted again, we would find country representatives to help with survey distribution as well as evaluating whether the survey is more easily understood by different cultures than others due to the varying healthcare policies. The largest response rate occurred 1-3 days after the survey was sent out, therefore if we were able to complete this study again we would send the survey out multiple times. Partnering with

country representatives and strategies aimed at increasing their response rate would increase the sample size and provide a statistical answer. Lastly, even though the survey was anonymous, in the future we would use some form of a tracker such as an IP address to observe if individuals complete the survey more than once and if there were differences in the responses. Additionally, there was suspicion that individuals may work at clinics in more than one country and therefore a tracking device on each response would help us analyze the number of clinic representatives responding on behalf of two clinics.

Conclusion

In summary, our study showed that not all prenatal clinics around the world test and treat for syphilis during pregnancy. Additionally, of the clinics that do test for syphilis during pregnancy, not every clinic tests 100% of their patients. We did not find a close relationship between a country's economic classification and the percentage of clinics that screen for syphilis.

We did discover that 1 clinic out of 140 clinics does not test for syphilis do to the lack of financial support, leading to the idea that there might be other clinics around the world with similar restraints. Further research with a larger sample size would need to be completed to discover if there is a significance between location and resources available and percentage of clinics that screen 100% of their patient population for syphilis.

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Appendix

An Analysis of the Protocols for Syphilis Screening for Pregnant Women around the World

Survey Flow

Standard: Block 1 (1 Question)

Block: Default Question Block (18 Questions)

Page Break

Start of Block: Block 1

Thank you for taking the time to answer the questions of this survey. This survey is aiding in a research study at the University of Arizona to develop an understanding challenges faced in following World Health Organization (WHO) recommendations on the testing and treatment of syphilis during pregnancy. The purpose of this survey is to investigate potential reasons why syphilis may not be detected and treated during pregnancy. Your responses to the questions are for research purposes only and are not legally binding. Thank you again for your time.

End of Block: Block 1

Start of Block: Default Question Block

Q1 In which country is the pregnancy center you are representing located?

Q2 Is the pregnancy center you are representing not-for-profit or for-profit?

Not-for-profit: Not required to pay property tax, state or federal income tax, or sales tax. In exchange for this tax-free existence, non-profit hospitals are expected to distribute any additional capital back into their surrounding communities. Rely on funding from donors, minor investments, the community, and government grants.

For-profit: Are investor-owned or the shareholders of a publicly-traded company. For-profit hospitals and healthcare clinics are funded by investors or shareholders.

Not-for-profit (1)

For-profit (2)

Q3 Is the pregnancy center you are representing located in a urban or rural setting?

- Urban (1)
 - Rural (2)
-

Q4 How many patients does the pregnancy center you are representing see in a month?

- 0 - 25 patients (1)
 - 26 - 50 patients (2)
 - 51 - 75 patients (4)
 - 76 - 100 patients (5)
 - More than 100 patients (6)
-

Q5 Is the pregnancy center you are representing government funded and/or privately funded?

- Government funded (1)
 - Privately funded (2)
 - Both government funded and privately funded (4)
 - Other (please explain) (5) _____
-

Q6 Which of the following services does the pregnancy center you are representing provide? (Select all that apply)

- Qualitative Urine Pregnancy Test (1)
- Ultrasounds (2)
- Prenatal care throughout entire pregnancy (3)
- Routine On-site or referred off-site blood work (4)
- Group B Strep Test (5)

Skip To: Q7 If Q6 = Routine On-site or referred off-site blood work

Skip To: Q8 If Q6 != Routine On-site or referred off-site blood work

Q7 What testing is included in the routine initial blood work?

Q8 Does the pregnancy center you are representing screen patients for syphilis during pregnancy?

- Yes (1)
- No (2)

Skip To: Q10 If Q8 = Yes

Skip To: Q9 If Q8 = No

Q9 If the pregnancy center that you are representing does not screen patients for syphilis during pregnancy, which of the following are reasons why syphilis screening during pregnancy is not done? (Select all that Apply)

- Lack of health provider training despite available equipment (such as RST) (1)
 - Lack of laboratory/laboratories for local off-site testing (2)
 - Lack of supplies for testing (3)
 - Lack of financial support for testing supplies (4)
 - Not able to treat patient if there is a positive result (5)
 - Clinic does not feel that it is necessary to screen for syphilis during pregnancy. (6)
 - Other (please explain below) (7)
-

Skip To: End of Survey If Condition: If the pregnancy center tha... Is Greater Than or Equal to 1. Skip To: End of Survey.

Q10 What percent of patients that are seen by the pregnancy center you are representing are screened for syphilis during pregnancy?

- Less than 25% (1)
 - Less than 50% but more than 25% (2)
 - Less than 75% but more than 50% (3)
 - Less than 100% but more than 75% (4)
 - 100% (5)
-

Q11 At what stage in pregnancy does the pregnancy center you are representing screen for syphilis? (Select all that apply)

Patient's first visit (1)

1st Trimester (2)

2nd Trimester (3)

3rd Trimester (4)

Q12 How does the pregnancy center you are representing screen for syphilis during pregnancy? (Select all that apply)

Patients are referred to off-site laboratory testing (1)

On-site rapid syphilis test (RST) testing (2)

On-site rapid plasma regain (RPR) testing (3)

Other (please explain below) (4)

Q13 How does the pregnancy center you are representing treat positive syphilis screening results during pregnancy?

- Clinic does not have the ability to treat patients (1)
 - Clinic refers patient to other resources for treatment (2)
 - Clinic prescribes or administers medication (3)
 - Other (please explain below) (4)
-

Skip To: Q16 If Q13 = Clinic prescribes or administers medication

Skip To: Q15 If Q13 = Clinic refers patient to other resources for treatment

Skip To: Q14 If Q13 = Clinic does not have the ability to treat patients

Q14 Why does the pregnancy center you are representing not have the ability to treat patients for a positive syphilis screening during pregnancy?

Skip To: End of Survey If Condition: Why does the pregnancy cent... Is Empty. Skip To: End of Survey.

Skip To: End of Survey If Condition: Why does the pregnancy cent... Is Not Empty. Skip To: End of Survey.

Q15 If the pregnancy center you are representing refers patients to other resources for treatment of positive syphilis screening, please describe what this option entails.

Skip To: End of Survey If Condition: If the pregnancy center you... Is Not Empty. Skip To: End of Survey.

Skip To: End of Survey If Condition: If the pregnancy center you... Is Empty. Skip To: End of Survey.

Q16 Which form of medication does your clinic use to treat positive syphilis results?

Q17 How does the patient receive the medication for a positive syphilis screen during pregnancy? (Select all that apply)

- Prescription is filled on-site (1)
 - Prescription is filled off-site (2)
 - Other (please explain below) (3)
-

Q18 If a patient is prescribed medication for a positive syphilis result during pregnancy how is the cost paid? (Select all that apply)

- Medication is covered by insurance (1)
 - Patient pays out of pocket for medication (2)
 - There is no cost to the patient for medication (3)
 - The pregnancy center you are representing reimburses or covers the cost of the medication (4)
 - Medication is covered by governmental funds (5)
 - Other (please explain below) (6)
-

End of Block: Default Question Block

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