Field efficiency of syphilis screening in antenatal care: lessons from Gutu District in Zimbabwe

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Abstract

Objectives: To determine coverage for antenatal syphilis screening in a rural area and evaluate the accuracy of on-site Rapid Plasma Reagin (RPR) tests performed by nurse-midwives.
Design: Descriptive cross sectional.
Setting: Rural Health Centres (n=23) in the Gutu District of Zimbabwe.
Subjects: Women booking for antenatal care in the district were used to determine coverage of screening. Results from women who had an RPR test performed during a nine week period were used in assessing the accuracy of tests performed by nurse-midwives.
Intervention: On-site antenatal screening for syphilis using an RPR kit with immediate results and treatment for women who tested positive.
Main Outcome Measures: Prevalence of syphilis (positive RPR) at booking and the level of agreement between three observers (RHC nurse-midwife, medical practitioner under field conditions and medical laboratory technologist).
Results: Eighty five percent of women were screened for syphilis at the first antenatal visit and 11% had a positive RPR. Almost all (97.3%) women with a positive RPR test result were treated. The accuracy of tests performed by RHC staff was poor with a sensitivity of 40% (95% CI 21.8 to 61.1) when compared to those done by the medical practitioner and 8.7% (95% CI 1.5 to 29.5) when compared to those done in a laboratory. The predictive value of a positive test was 22.7% and that of a negative test was 94.9%.
Conclusion: The coverage of screening for syphilis in pregnant women in Gutu District was good but the results were unreliable. There is need for nurse-midwives, who perform the majority of RPR tests in the RHC, to receive adequate training to ensure competence in testing and to strengthen quality control procedures.

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Introduction

Syphilis in pregnancy is associated with an increase in perinatal morbidity and mortality.[1,2] Testing for syphilis has become a standard antenatal procedure in most parts of the world. Appropriate treatment of women who have syphilis during pregnancy results in prevention of congenital syphilis and the associated neonatal/ infant morbidity.[3,4] In Zimbabwe 70% of the population live in rural areas and receive health services from Rural Health Centres (RHC) that have no laboratory facilities. In most districts the only laboratory available is at the District Hospital (DH). There are a number of logistical problems in collecting blood specimens at RHC and having tests performed at the DH that include distance/transporting, storage of specimens and transmission of results. Sometimes the women default in the antenatal appointments resulting in infected women being untreated and thus an opportunity for preventing an adverse pregnancy outcome is missed.[3] A simple test for syphilis that is performed at the first antenatal visit with an immediate result is, therefore, an essential part of antenatal care especially in areas with a high prevalence of syphilis. The advantage of a rapid test is that women with positive tests can have treatment commenced at the same visit. In Zimbabwe the national coverage for antenatal syphilis screening is unknown but a 1999 survey revealed that only 30% of women had a syphilis test result recorded on their antenatal card.[5]

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On-site screening for syphilis using an RPR kit, with immediate results and treatment for women with a positive result was introduced in Gutu District as part of an antenatal care study. In this descriptive study we evaluated the intervention in terms of coverage and accuracy using data from 23 RHCs. To determine the accuracy of results of on-site testing performed by nursing staff, women registering for antenatal care during a nine week period had RPR tests performed simultaneously by nursing staff and by a medical practitioner under field conditions. A confirmatory test Treponema Pallidum Haemagglutination Assay (TPHA) was later performed in a laboratory.

Materials and Methods

Gutu District has 25 health facilities, which include one District Hospital with laboratory facilities, a Rural Hospital located at the commercial centre of the district and 23 RHCs of various sizes, serving a population of 214 000. The RHCs had a basic staff allocation of two nurses, one of whom had midwifery training.

At the first antenatal visit a pregnant woman had a blood sample collected for haemoglobin measurement and a test for syphilis. The routine practise was for the nurse-midwife to collect the blood during the consultation and then perform the syphilis test later, necessitating a return visit for the women to collect a test result. In some situations the blood sample was sent to the DH laboratory and results were not always received on time. Women with a positive RPR were treated with either intramuscular long-acting penicillin or a three week course of oral erythromycin.

Training.

Prior to the start of the study, at least one nurse from each of the 23 RHCs received a day's training on how to perform the Rapid Plasma Reagin (RPR) test (Immutrep by Omega Diagnostics, Scotland). A medical laboratory scientist conducted the training. A day's duration of training was considered adequate based on previous reports.[6] A procedure manual with instructions on how to perform the RPR test was supplied to each RHC and posters were put up for easy reference in the consulting rooms, where tests were performed.

Testing Procedure.

Five ml of venous blood was collected and allowed to sediment in a plain test tube for one hour. A special pipette capable of dispensing 50 mml drops was supplied with the RPR test kits. One drop (50 µml) of serum was placed on a test card circle and one drop of antigen added to the serum. The test card was placed on a battery operated rotator and the result was read after eight minutes. The test card was inspected in good light. Results were reported as positive or negative. Positives displayed characteristic agglutination, ranging from slight to intense. Negative results did not exhibit the agglutination reaction but were macroscopically smooth and had an even appearance. Every set of tests included a well-characterised control serum to monitor the performance of both the operator and the reagent. Each RHC was visited at least once a month by a member of the research team who observed staff as they performed tests and made corrections wherever necessary. Initially samples that tested positive were stored in the RHC and later transported to the laboratory for confirmation. This was later abandoned due to logistical problems.

Quality Control.

The accuracy of the results of the on-site screening was assessed during a nine week period when RPR tests were performed simultaneously by the RHC staff and an observer (medical practitioner) under field conditions. Part of the test sample was stored for later analysis by a central laboratory that confirmed results using a TPHA test (Randox Laboratories Ltd, Crumlin, England). For logistical reasons a convenience sample was used for the quality control as only women with tests performed at all three levels (nursing staff, medical practitioner and laboratory) during the period were included in the quality control exercise. The medical practitioner received training in performing RPR prior to the field accuracy assessment. We suspected that test specimens deteriorated during storage and transportation to the laboratory for confirmation tests and that the best way of checking the accuracy of nurse-midwife results was through simultaneous tests performed under field conditions. We assumed that competence for performing the RPR test improved with the volume of tests performed and as the medical practitioner had performed a large number of tests under laboratory conditions prior to the fieldwork we considered her results suitable for use as the standard.

Results

There were 14 182 women who booked for antenatal care during a three year period, 12 095 (85.2%) of whom had a syphilis-screening test performed. There were no differences between women with a positive and a negative syphilis screening result in terms of age, parity and gestational age at booking. The prevalence of syphilis was 11.4% based on results obtained by RHC staff. Nearly all (97.3%) women considered syphilitic were treated. Partner notification was poor with 21.4% recorded as having been notified. The majority (83.4%) of contacted partners received treatment either at the same facility or supplied medical evidence of having been treated elsewhere.

Sensitivity of the tests performed by nursing staff was calculated using the observer as the standard. Of 25 tests interpreted as positive by the medical practitioner, the RHC staff had interpreted 10 as positive giving a sensitivity of 40% (Table I). Using the medical observer as the standard, the predictive value of a positive test performed by nurse-midwives was 22.7% and that of a negative test was 94.9%. Using the TPHA performed by the laboratory, the number of positive tests performed by nurse-midwives per case identified was four while the total number of tests per case identified was 31.

Table I: Sensitivity and specificity with 95% confidence interval of RPR tests performed by clinic staff with observer as gold standard.

		Observer +/ve	Observer -/ve	Sensitivity (95% CI)	Specificity (95% CI)	Predictive Value
	+/ve	10	34	40.0%	89.2%	10/44 (22.7%)
Clinic Staff				(21.8-61.1)	(85.1-92.3)	
	-/ve	15	280			280/295 (94.9%)

+/ve = Positive; -/ve = Negative.

We show patient flow during the nine weeks of the evaluation exercise. From 417 women tested by RHC staff, 288 (69%) had samples tested at all three levels and only two tests were positive by all three testers, thus giving a sensitivity of 8.7% (Table II). Some of the samples were not properly stored prior to transporting to the laboratory and therefore the accuracy of the laboratory results was questionable.

Figure I: Screening tests and results for women booking during the accuracy evaluation exercise.

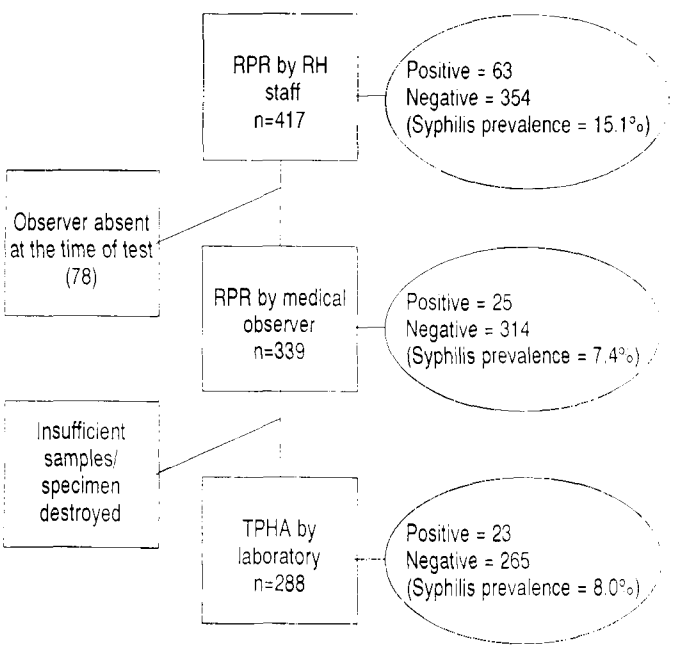

Table II: Sensitivity and specificity with 95% confidence interval (95% CI) of RPR tests performed by nurse-midwife and by observer with laboratory TPHA as the gold standard.

		Laboratory +/ve	Laboratory -/ve	Sensitivity (95% CI)	Specificity (95% CI)
Clinic Staff	Positive	2	39	8.7% (5-29.5)	85.3% (80.3-89.2)
	Negative	21	226		
Observer	Positive	2	17	8.7% (1.5-29.5)	93.6% (89.7-96.1)
	Negative	21	248		

+/ve = Positive; -/ve = Negative.

Discussion

In this report, there is need to consider coverage of antenatal screening for syphilis separately from the RPR results obtained.

The screening coverage of 85% was higher than the national average of 39% and the 70% reported from another district in the country.[5-7] The reasons for a less than 100% coverage in screening included logistics of supply of test kits and manpower constraints. The treatment rate for a presumed positive result of 97% was higher than rates reported in similar settings.[4,7]

On-site screening with immediate results and treatment of infected women has been advocated as a way of reducing perinatal morbidity and mortality from syphilis.[1,4,6-8] There are efforts to introduce on-site screening in all antenatal clinics nationally but the accuracy of RPR results in our report from a rural setting is a major source of concern. The medical observer felt that the RHC staff had problems with interpretation of the RPR result. Whenever there was doubt, nursing staff gave the result as positive and this may explain the high false positive results. There are other possible explanations for the poor sensitivity of the results and these include stability/ accuracy of the test kit under field conditions, errors in interpretation of the results by the RHC staff and poor storage of samples prior to confirmatory tests in the laboratory, and laboratory errors.

If the current rapid tests are liable to an interpretation error, efforts should be made to identify a simpler test that is reliable and easy to interpret under field conditions, probably one based on a reagent strip.

Quality control is an important part of a screening programme that needs constant attention. The clinics had supportive/supervisory visits at least monthly but still had unsatisfactory results. Concern about quality of on-site screening by nursing staff has been expressed in similar settings.[9,10] With an overall false positive rate around 12% there were many women treated unnecessarily. Most of the women were treated with intra-muscular benzathine penicillin 2.4MU. The costs of excessive treatment may be negligible since the drug is cheap, but there is a risk of adverse reactions. With a high false negative rate of 88% (95% CI 60 to 98), there were many infected women who were not correctly identified and therefore failed to receive the indicated treatment.

Control of syphilis is an important public health issue. Tracing of the partner was low in this setting but those contacted were keen to receive treatment. The prevention of congenital syphilis can only be achieved with an efficient and accurate screening programme and antenatal care offers that opportunity of identifying and treating part of the community.

Lessons Learnt.

Quality Control Strategy: When new procedures are introduced, there should be parallel introduction of a quality control mechanism. In our report, the quality control was performed 12 months after the introduction of on-site

screening for syphilis and the low sensitivity indicates poor quality of testing by RHC staff.

Constant Supportive Supervision: Frequent updates and re-training are essential components in introduction of new procedures. There was a high rate of staff turnover in the district and some of the staff in the field during the quality control exercise had not attended the initial training. The monthly visits did not achieve the aim of maintaining quality. Arrangements should have been made for new staff to be trained by the medical laboratory scientist rather than allow them to be trained by colleagues who may not have the necessary competence.

Special Personnel for Performing RPR Test: Limiting the RPR testing to a small number of personnel may have the advantage of those individuals developing competence in performing the test. The disadvantage of such a practice is that the testing system collapses when these individuals are absent. Since the staff compliment of a RHC is small, there would be benefit in ensuring that everybody receives the training for proper performance and interpretation of the RPR test.

Conclusion

As currently practised in Gutu District, the programme of screening for syphilis in pregnancy by nurses had low sensitivity and therefore failed to identify the infected women who risked producing an infected baby with the associated neonatal complications. The coverage of the programme was high, with 85% of women being screened and appropriate action being taken for a result presumed to be positive. There is need to strengthen the quality control of testing to improve on the accuracy of results.

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