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Acceptability and feasibility of dual HIV and syphilis point-of-care testing for early detection of infection among pregnant women in China: a prospective study

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ABSTRACT

Objective To assess the feasibility and acceptability of using WHO prequalified combined dual HIV/syphilis rapid diagnostic tests (RDT) for same-day results in antenatal care (ANC) clinics.

Methods This is a pragmatic implementation study using quantitative approach to evaluate outcomes. Antenatal clinic attendees from 21 rural and urban township hospitals in two provinces of China were offered with free dual RDTs testing that included HIV and syphilis, in addition to the routine blood tests. Study outcomes included testing uptake before and during dual RDT use, test feasibility and acceptability among pregnant women. Regression model was used to assess acceptance of RDT testing.

Results In total, 1787 out of 1828 pregnant women attending ANC received the RDT testing. Testing uptake among pregnant women in their first and second trimester increased from 76.0% (2438/3269) using standard blood testing to 90.1% (1626/1787) with concurrent RDT use (χ^2=197.1, p<0.001). Among 1787 pregnant women who received RDT tests, 98.3% (1757/1787) participants were given test result the same day. Positive proportions of HIV and syphilis screened with RDT were 0.06% (1/1787) and 1.0% (18/1787), respectively. Regression analysis indicated that women who did not receive syphilis or HIV testing before were less likely to accept dual RDT (OR 0.28, 95% CI 0.10 to 0.75). Acceptance for dual RDT testing at second or third antenatal visit was lower compared with the first visit (OR 0.37, 95% CI 0.15 to 0.94).

Conclusion Combined dual HIV/syphilis RDT with same-day results increased uptake of HIV and syphilis testing among pregnant women at primary healthcare facilities. Given the diversity of testing capacities among health services especially in rural areas in China, the dual RDT kit is feasible tool to improve testing uptake among pregnant women.

Strengths and limitations of this study

- The study included a very large sample of women attending antenatal clinics at primary care level, the representative of services for women in China.
- With the focus on real-world implementation, we used quantitative methods to understand the feasibility and outcomes of using a new technology (dual rapid diagnostic test) to test HIV and syphilis. The application lends strength to the study and interpretation of results.
- The limitation includes that clinics were purposively selected, based on the willingness of hospital administration to participate in the study. This may have introduce some degree of positive bias.

INTRODUCTION

Eliminating HIV and syphilis as public health threats by 2030 is an ambitious global health goal articulated by WHO to support the health targets of the 2030 Agenda for Sustainable Development Goals.[1] The syndemics of HIV and syphilis among pregnant women is one of the greatest challenges in public health and maternal health globally. The burden among pregnant women is substantial. In 2013, there were more than 1.4 million pregnant women living with HIV in low-income and middle-income countries, with an estimated 240 000 children newly infected with HIV.[2] In 2012, an estimated 930 000 maternal syphilis infections caused 350 000 adverse pregnancy outcomes including 143 000 early fetal deaths and stillbirths, 62 000 neonatal deaths, 44 000 preterm or low weight births and 102 000 infected infants worldwide.[3]

In the last decade, notable improvements have been achieved in advancing services for HIV and sexually transmitted infections. The increase in numbers of pregnant women screened for HIV and syphilis, together with increased access to treatment help underline the feasibility of dual elimination of mother-to-child transmission (EMTCT) of HIV and

syphilis.[1] In China, testing and counselling are the primary intervention steps in the package of essential services for prevention of MTCT (PMTCT). PMTCT interventions include provision of free antiretroviral (ARV) treatment and diagnosis for exposed infants.[4]

WHO and The Joint United Nations Programme on HIV/AIDS recommend a dual strategy for EMTCT of HIV and syphilis.[2] Global and regional initiatives for dual EMTCT of HIV and syphilis were launched in 2011. China initiated the free integrated PMTCT (iPMTCT) of HIV, syphilis and HBV programme in 2011 which included universal coverage of HIV, syphilis and hepatitis B antenatal testing. Early detection and timely intervention are critical components. As public health interventions, antenatal syphilis screening and treatment are proved to be cost saving in moderate and high-prevalence settings and cost-effective even when prevalence is less than 1%.[5–7] In China, HIV MTCT decreased from an estimated 34.8% in 2004 to 6.1% in 2014 after expansion of universal access to HIV antenatal screening for all pregnant women and free ARV prophylaxis for HIV-infected pregnant women with replacement feeding for HIV-exposed infants.[8] Reported congenital syphilis increased from 25.5 per 100 000 live births in 2005 to 60.8 per 100 000 live births in 2009. The situation possibly related to increasing access to syphilis diagnosis.[4] Apparently, to achieve the goal of dual EMTCT of HIV and syphilis, early diagnosis and timely intervention are key steps in the cascade of interventions then to reduce new infections among infants.

Worldwide, access to quality-assured diagnosis and treatment services is restricted or absent in many resource-limited settings across low-income and middle-income countries, like Mongolia, Ghana and China.[5 9 10] In order to improve the number of women tested and treated, innovative strategies are imperative. A number of single rapid diagnostic tests (RDTs) for HIV or syphilis have been developed and scaled up across the world.[8 11] A combination of these two rapid point-of-care diagnostic test kit enables syphilis and HIV testing to be offered concurrently at any antenatal care (ANC) setting. These dual RDTs have shown great prospect based on sensitivity and specificity assessments conducted in laboratory evaluation, and are low cost and commercially available.[12–16] Dual RDTs can concurrently test antibodies to HIV and *Treponema pallidum* antigens, also ensuring the test to be conducted in a single visit with provision of results within the same day. This approach offers opportunities to improve testing uptake among pregnant women and thus achieve the aim of EMTCT of HIV and syphilis.[16 17]

The current universal antenatal testing strategy in the national PMTCT programme in China for HIV and syphilis is based mainly on the use of the HIV enzyme immunoassay and rapid plasma reagin non-treponemal test for syphilis. These tests require venous blood samples and may take several days until the results return. In addition, the tests are technically demanding and require laboratory equipment, which is not widely available in many resource-limited settings, especially in rural or hard-to-reach regions in the country. These conditions impede equitable access of HIV and syphilis tests to all pregnant women in China. The application of dual HIV and syphilis RDTs could be helpful to relieve these problems.

This study aims to evaluate the feasibility and acceptability of dual HIV and syphilis rapid diagnostics for early testing among pregnant women in comparison to routine assay tests in primary care facilities in China.

METHODS

Study design

This pragmatic implementation study used quantitative approach to evaluate outcomes. Quantitative data were collected from pregnant women attending ANC clinics.

Study setting, participants and public involvement

Pregnant women attending the Yuantan township hospital (Guangdong Province) and the Funan township hospital (Anhui province) in China from February to July in 2015 were invited to enrol. Baseline data were collected from the past 3 months from the ANC registry of these two sites from October 2014 to January 2015.

The following inclusion and exclusion criteria were used to recruit pregnant women for the feasibility study. (1) Inclusion criteria: women attending the antenatal clinic at the study sites and unaware of their HIV and syphilis status when they were enrolled into the study. (2) Exclusion criteria: women less than 16 years of age, unable to provide informed consent, had already been tested and aware of their HIV and/or syphilis status or with prior participation of the evaluation study.

Patients were not involved in the design, conduct or analysis of the study. The preliminary results summary was collated and presented on propaganda posters within two township hospitals, and also passed by the ANC lectures in prenatal health education programmes.

Variables and data resources

The number and percentage of women attending ANC, the number and percentage of women tested for HIV using the routine tests (ELISA; chemiluminescence immunoassay, CLIA; particle agglutination assay, PA) and the number and percentage of women tested for syphilis with both treponemal and non-treponemal antibodies testing were collected. All enrolled pregnant women provided informed consent before they were interviewed or tested with RDT.

At the time of introduction of the dual RDTs, all ANC attendees were provided HIV, syphilis testing and counselling, which included RDT-related information as well as information on the routine HIV or syphilis testing method in the participating sites. At the same time, all ANC attendees were surveyed to collect basic information on sociodemographic characteristics, partner testing, self-reporting previous history of pregnancy, HIV and

syphilis testing and treatment, and current HIV and syphilis testing and treatment management.

Sample size

To estimate a single proportion with an adequate level of precision, we assumed a 95% CI for the proportion and assumed that the unknown proportion to be 0.50 with a precision of no wider than 0.05 (ie, m≤0.025). With the formula: n≥(2/m)2×p×(1 p), we estimated that a total of at least 1600 pregnant women were needed for study.

Dual HIV and syphilis tests

All consenting ANC attendees were offered with dual HIV/syphilis RDT kits. The dual tests were conducted with finger stick sample, unless the venous blood was collected for other obstetric blood testing. A total of 1633 out of 1787 (91.1%) pregnant women provided finger-prick blood samples, and the other 154 (0.09%) provided only venous blood samples. Test results were recorded in the questionnaires (online supplementary material). Reference tests such as ELISA, CLIA or PA for RDT results comparison were conducted at the ANC laboratory in the clinic or hospital. Positive results using RDT tests were revaluated by routine national protocols, which required confirmation by the National Reference Laboratory of National Center for AIDS Prevention and Control. All attendees were notified of results and offered treatment if the confirmed test results were positive.

Statistical analysis

Data collected via the questionnaires (online supplementary material) were entered in Epidata V.3.0 and were checked by staff. We used SAS V.19.0 to measure the outcomes and compare the outcome indicators (willingness for RDT, early testing coverage) at the baseline and after introduction of the dual RDTs. χ^2 tests were used to examine the change in early testing coverage before and after implementing RDT among pregnant women.

Acceptability was defined as a pregnant woman actually receiving dual RDT testing. Acceptability of dual HIV/syphilis RDTs by ANC attendees was independently tested against the following factors: age, sociodemographic characteristics, history of pregnancy, HIV and syphilis testing and treatment, willingness to test and distance to ANC. A multivariate logistic model was used to determine predictors of acceptability of RDT among pregnant women while adjusting for confounding factors. Variables with p<0.10 in the univariate analyses were eligible for inclusion in the multivariate model. Variables were retained in the final model only if they were statistically significantly associated (p<0.05) with the outcome or deemed to be of a priori importance. A backward approach was used to select variables for the final model. The adjusted ORs with 95% CI were reported. P values were used to measure strength of association and identify statistically significant results. A p<0.05 was considered as a statistically significant association.

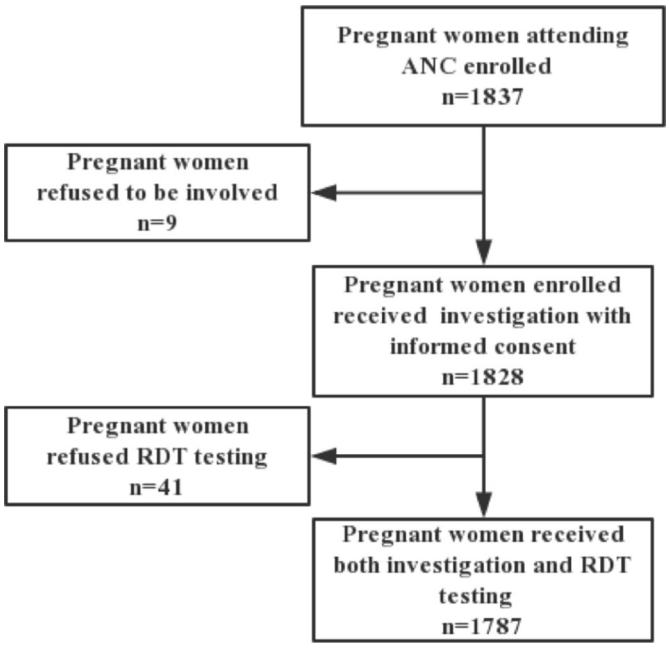

Figure 1 Study of acceptability and feasibility of dual HIV and syphilis point-of-care testing for early detection of infection among pregnant women in China sample enrolment flow chart. ANC, antenatal care; RDT, rapid diagnostic test.

RESULTS

Demographic characteristics of pregnant women

Between February and July 2015, a total of 1828 pregnant women eligible for the study were offered with RDT tests and also completed questionnaires (figure 1). Same like RDTs, 6 of them were found infected with HIV and 17 were tested positive for syphilis infection with reference tests. The median age of the cohort was 23 years (range 18–47 years). Local residents accounted for 96.9% (1772/1828) (table 1). The majority of the participants (88.0% (1607/1828)) had education of senior middle school or above and 6.5% (119/1828) received junior middle school education or below. More than half of participants (65.5% (1196/1828)) were farmers, and 33.4% (606/1828) of pregnant women were in their first pregnancy and 56.0% (1010/1811) had already gave birth to at least one child. The average gestational age of pregnancy at enrolment was 20.4 weeks (range 8–43 weeks).

Accessibility to ANC clinics

Participants took a median time of 34.5 min (range 5 min to 4 hours) to travel to ANC clinics. The majority of pregnant women (60.0% (1083/1817)) took motor or autobikes, 32.7% (589/1817) travelled by bus to clinics and 7.3% (137/1871) walked to ANC clinics.

Uptake of dual HIV and syphilis rapid testing

In total, testing uptake among pregnant women in their first and second trimester increased from 76.0% (2438/3269) using standard blood testing to 90.1% (1626/1787) with concurrent HIV and syphilis RDT test kit (χ^2=197.1, p<0.001).

Table 1 Univariate analysis for acceptability of RDT for early testing among pregnant women in China

Indicators	All	Accepted		Unaccepted		χ^2	P values
		n	%	n	%		
Demographic characteristics							
Hukou							0.29*
Local resident	1771	1718	97.0	53	3.0		
Temporary resident	27	24	92.3	3	7.7		
Migration people	19	18	94.7	1	5.3		
Other	11	11	100	0	0		
Age							0.81*
<25	1029	994	96.9	35	3.4		
25-29	608	592	97.4	16	2.6		
30-34	139	134	96.4	5	3.6		
35-39	42	41	97.6	1	2.4		
>40	10	10	100	0	0		
Education							0.88*
Primary	119	117	98.3	2	1.7		
Junior	1607	1554	96.7	53	3.3		
Senior	61	60	98.4	1	1.6		
College	39	38	97.4	1	2.6		
Other	2	2	100	0	0		
Occupation							0.24*
Farmer (peasant-worker)	1585	1536	96.9	49	3.1		
Unemployed	156	153	98.1	3	1.9		
Other	86	81	94.2	5	5.8		
First ANC visit							0.02*
Yes	898	880	98.0	18	2.0		
No	922	887	96.2	35	3.8		
First pregnancy						1.65	0.44
Yes	606	584	96.4	22	3.7		
No	1208	1174	97.2	34	2.8		
Other	14	13	92.9	1	7.1		
History of delivery						1.13	0.56
Yes	1023	994	97.2	29	2.8		
No	790	763	96.6	27	3.4		
Other	15	14	93.3	1	6.7		
History of abortion						4.5	0.10
Yes	291	287	98.6	4	1.4		
No	1507	1456	96.6	51	3.4		
Other	30	28	93.3	2	6.7		
Having children						12.7	<0.001
Yes	1010	983	97.3	27	2.7		
No	801	774	96.6	27	3.4		
Other	14	14	82.4	3	17.6		
gestational weeks						30.2	<0.001
~12	578	561	97.1	17	2.9		
13–27	669	656	98.1	13	1.9		

Continued

Table 1 Continued

Indicators	All	Accepted n	Accepted %	Unaccepted n	Unaccepted %	χ^2	P values
28~	565	542	95.9	23	4.1		
Other	16	12	75.0	4	25.0		
Preference of delivery place							0.11*
Township level	976	937	96.0	39	4.0		
County level	703	690	98.2	13	1.8		
City level	64	62	96.9	2	3.1		
Private hospitals	11	11	100	0	0		
No idea	74	71	96.0	3	4.0		
Time from home to ANC							0.09*
~30 min	1323	1280	96.9	43	3.1		
~60 min	350	343	98.0	7	2.0		
~120 min	141	136	96.5	5	3.5		
120 min and above	14	12	85.7	2	12.3		
HIV testing before						2.00	0.37
Yes	717	700	97.7	17	2.3		
No	190	182	95.8	8	4.2		
Other	213	206	96.7	7	3.3		
Syphilis testing before						2.9	0.23
Yes	695	680	97.8	15	2.2		
No	184	177	96.2	7	3.8		
Other	225	216	96.0	9	4.0		

*Fisher accurate χ^2.
ANC, antenatal care; RDT, rapid diagnostic test.

In 1828 pregnant women who were enrolled in the study, 1787 underwent RDT testing. Positive RDT screening results for HIV and syphilis were 0.06% (1/1787) and 1.0% (18/1787), respectively. RDT results were 100% correspond to national confirmatory tests.

Among those who had previously been pregnant, 64.3% (699/1087) and 63.1% (677/1037) of them self-reported having received HIV and syphilis tests during their first pregnancy. Among these women previously been tested, two were positive for HIV and six for syphilis.

Willingness to accept HIV/syphilis RDT dual testing

Among 1828 participants who were offered with RDT tests, 1794 (95.3%) expressed willing to undergo rapid tests at once and 34 (4.7%) were reluctant. Before the RDT administered, participants received pretest education and filled in questionnaires (online supplementary material). These participants still tested via routine screening tests for HIV and syphilis. In total, 1771 pregnant women received RDT testing and 23 refused rapid testing. Of the 23 refusals, 13 stated that they had been tested previously and 10 wanted their blood samples to be taken during the third trimester rather than the first.

Associated factors with RDT testing acceptability

Regression analysis indicated that demographic characteristics, pregnancy history, gestational week, distance to ANC or preference of delivery place did not affect the acceptability of RDT test among participating pregnant women (table 1). Acceptability of RDT testing was statistically lower in women who had not received HIV or syphilis testing before compared with those who had previously tested (OR 0.28; 95% CI 0.10 to 0.75). Acceptance of dual RDT testing at the second or third antenatal visits was lower compared with those were at their first visit (OR 0.37, 95% CI 0.15 to 0.94) (tables 1 and 2).

Feasibility of dual HIV and syphilis rapid testing for early testing among pregnant women

Among 1787 pregnant women who received RDT testing, 98.3% (1757/1787) of participants were given back their test results on the same day. Among those who did not received RDT testing result on the same day, 65.6% (20/30) did not return to ANC for test results. Six (18.8%) pregnant women left ANC before RDT testing results were provided, and 14.1% (4/30) thought the test results would be provided later. Among 1757 pregnant women received RDT testing results, 54.9% (965/1757)

Table 2 Regression analysis and factors associated with rapid diagnostic test acceptability (n=1828)

Indicator	Intercept	SE	Wald	P values	OR	95% OR Lower	95% OR Upper
Intercept	3.31	1.78	3.47	0.06			
HIV testing before no/yes	0.95	0.54	3.12	0.08	2.59	0.90	7.44
Syphilis testing before no/yes	−1.29	0.51	6.33	0.01	0.28	0.10	0.75
First antenatal care no/yes	−0.99	0.47	4.34	0.04	0.37	0.15	0.94

receiving their RDT results within 30 min, 20.7% (364/1757) received results within 30–60 min and 428 (24.4%) received results longer than 1 hour later.

DISCUSSION

This study showed good feasibility of use of dual RDTs for early HIV and syphilis testing among pregnant women. We noted marked improvements in uptake of HIV and syphilis testing with use of RDTs in China. This is an important finding because in some countries, despite the majority of pregnant women having access to ANC, only a small proportion undergo HIV and/or syphilis screening.[10 12] In 2012, more than 60% of pregnant women in Nigeria received ANC, but only 33% were screened for syphilis, and in Northeast areas of the country only less than 10% of pregnant women were screened.[2] China's iPMTCT programme reached 13.1 million pregnant women in 2013. Pregnant women HIV antibodies testing showed an increase in testing rates from 85.4% in 2009 to 97.3% in 2013. However, HIV, syphilis and HBV testing coverage in pregnancy varies tremendously in different regions of China.[12] In Sichuan, Yunnan and Xinjiang provinces, HIV, syphilis and HBV testing during pregnancy was 79.4%, 68.4% and 69.9%, respectively.[12 13] In some counties in Guangdong province where the overall prevalence of HBV is high, the three-disease testing rates during pregnancy was found to be low.[14]

Several studies in China have reported that lack of HIV or syphilis testing during pregnancy and labour, and inadequately equipped laboratories with trained personnel. These are major barriers to testing uptake.[13 18 19] Therefore, new approaches to HIV and syphilis screening should be adopted and promoted. Point-of-care tests can accelerate access to testing and subsequent connection to treatment and care services by shortening the time to result in a group of women and their families who are in close contact with health services.[17]

The standard test methods require traditional assays and well-equipped laboratories with trained personnel, which impedes testing uptake and interventions. Timely diagnosis for HIV-infected pregnant women enables provision of ARVs to reduce risk of transmission to their infants, and the effectiveness of these interventions has been demonstrated in China.[20] Our study indicated testing uptake among pregnant women in their first and second trimester increased by 14% compared with baseline survey. This dual test is particularly timely given WHO and UNAIDS recommendations for a dual strategy for the prevention of HIV and syphilis as well as WHO policy on sexually transmitted infections testing for key populations.[1 18 21]

It is worth to be noticed that the acceptance of dual RDT testing at the second or third antenatal visit was lower compared with that of the first visit. This is consistent with previous findings.[10] Punguyire *et al* found pregnant women HIV testing uptake differed according to maternal healthcare.[10] Similar findings have been reported by other studies in China.[12–14 20] Receiving HIV or syphilis testing previously also affected RDT acceptance among pregnant women. This is probably because knowledge of one's status would decrease their requirement to have another test.

The limitations of this survey include that the study was conducted in purposively selected township clinics, according to the willingness of hospital administration to participate in the study. This may introduce some degree of positive bias. However, the objective was to assess real-world pragmatic field scenarios and as the study included a large number of participating sites and pregnant women, we opined that the results faithfully reflect the actual experience of providers and women.

In summary, our study showed that dual RDTs with same-day results are acceptable by pregnant women and feasible to promote in China. Dual RDTs use at decentralised healthcare facilities were feasible. It simplifies the access to diagnosis, the critical first step to the cascade of PMTCT care for those who are infected.[22 23] Moreover, in order to achieve the goal of dual EMTCT, reaching high coverage of testing among all pregnant women is essential.[24 25] Thus, RDTs would also be useful approaches to expand access to combined HIV/syphilis diagnosis among hard to reach populations and geographical areas in China as well as other countries. The next step planned for the scale up of RDT testing in the national programme is to promote the use of quality-assured diagnostics across the country, particularly in decentralised health facilities. Some township hospitals of pilot areas without well-equipped laboratories have already begun

procuring dual or triple rapid testing kits for routine use. Moreover, widespread introduction of RDT tests could accelerate the scale up of screening for HIV and syphilis among pregnant women throughout China.

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Contributors QW, LMN, X-SC and A-LW conceived and designed the study, reviewed and revised manuscript. QW and P-LC performed the study, supervised data collection, analysed the data, drafted the initial manuscript and revised the manuscript. L-XD, X-YW, Y-PQ, XJ and MS contributed to data collection and analysis, and reviewed the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Ethical clearance was provided by the Institutional Review Board of the Center for National Women and Children's Health at the China Center for Disease Control. The study protocol was approved by the CenterCentre for National Women and Children's Health (IRB Number:FY-2014–001).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Original data are available and can be accessed by contacting A-LW. Review Board of Center for National Women and Children's Health within China Center for Disease Control conducted the participant deidentification. All participants permitted this research-oriented data usage of their blood sample.

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