ORIGINAL RESEARCH ARTICLE

Simultaneous triple point-of-care testing for HIV, syphilis and hepatitis B virus to prevent mother-to-child transmission in India

N P Pai MD MPH PhD*, **J Kurji** MSc†**, **A Singam** MD‡**, **R Barick** MD‡, **Y Jafari**§, **M B Klein** MD MSc*, **S Chhabra** MD‡ **and P Shivkumar** MD‡

*Division of Clinical Epidemiology & Division of Infectious Diseases, McGill University Health Center, Montreal; †Dala Lana School of Public Health, University of Toronto, Toronto, Canada; ‡Mahatma Gandhi Institute of Medical Sciences, Sevagram, India; §Department of Epidemiology, Biostatistics & Occupational Health, McGill University, Montreal, Canada

Summary: An innovative simultaneous triple point-of-care (STPOC) screening strategy for syphilis, hepatitis B and HIV with Determine® tests was offered to pregnant women presenting for antenatal care and evaluated for feasibility and preference in rural India. Of 1066 participants approached, 1046 consented, of which 1002 (96.0%) completed the strategy. Only 9% reported any history of testing in their current pregnancy. With STPOC screening, 989 women (98.7%) tested negative and 13 had preliminary positive results for infection. The total time taken was 45 minutes per participant. Mothers and infants were provided prophylaxis/treatment for HIV, syphilis and hepatitis B, with interventions initiated within 3–5 days. STPOC was preferred by 99.3% (95%CI: 98.8–99.8%) of participants, facilitated early simultaneous screening for the three infections, timely initiation of prophylaxis/treatment and was feasible in this rural setting. These data suggest that multiplexed STPOC screening for syphilis, hepatitis B and HIV in pregnancy would be desirable for women in rural India.

Keywords: HIV, syphilis, hepatitis B, point-of-care test, screening, pregnancy, antenatal care, rural, India

INTRODUCTION

HIV, syphilis and hepatitis B virus (HBV) are the three infections that contribute most to maternal–infant morbidity and mortality. Worldwide, an estimated 33.3 million adults are infected with HIV,[1] about 80 million with syphilis and about 350 million individuals are chronically infected with HBV.[2] Universal screening programmes for these three infections (HIV, HBV and syphilis, or 'triple screening') in developed settings have been effective in reducing mother-to-child transmission.[3–5] In contrast, public health screening programmes for these infections using point-of-care (POC) tests (HIV, HBV and syphilis) have not been reported from resource-limited countries except for Guatemala.[6,7] Data on combined HIV/syphilis screening programmes have been reported from Ethiopia, China, Nigeria and Ghana.[8–12] In India, although HIV prevalence has declined, the absolute number of HIV infections remains high at 2.27 million.[1] To date, only two studies have determined seroprevalence of HIV, HBV, hepatitis C (HCV) and syphilis in at-risk populations,[13,14] and to our knowledge there is limited reporting of triple screening for infections in pregnant women.[6] Current non-treponemal serological assays for syphilis have suboptimal sensitivity and specificity and although HIV, HBV and syphilis infections are known to be prevalent, inconsistent irregular screening leads to inevitable loss to follow-up of patients in public health settings. This can be averted by provision of on-site POC testing.

HIV, HBV and syphilis also contribute to infant morbidity. Untreated syphilis in pregnancy can cause congenital infection, stillbirths or death shortly after delivery.[15] Viral hepatitis, the commonest liver disease in pregnancy, causes fetal morbidity[16] while HIV can be transmitted in pregnancy, labour, delivery and breastfeeding.[16] Although triple screening is not in place for pregnant women in public health settings, subsidized or free prophylaxis/treatment for HIV are readily available. Penicillin is inexpensive and effective in treating syphilis but timely administration early in pregnancy is essential. HBV vaccine and immunoglobulin are also available in many resource-limited global settings. Furthermore, despite the recommendations and the availability of prevention of mother-to-child transmission (PMTCT) interventions for HIV, as of 2008, only 26% of pregnant women in low- and middle-income countries received HIV testing and only 45% of those with HIV received antiretroviral therapy.[17] Although

Correspondence to: Assistant Professor N P Pai, Division of Clinical Epidemiology, Department of Medicine, Royal Victoria Hospital, McGill University Health Center, V Building, 687 Pine Avenue West, Montreal, Quebec, Canada H3A1A1.
Email: nitika.pai@mcgill.ca

**Contributed equally

the Sexually Transmitted Diseases Diagnostics Initiative of the World Health Organization recommends universal screening for syphilis by the second trimester of pregnancy to prevent perinatal transmission, a survey of 22 sub-Saharan African countries reported that only 38% of pregnant women were screened for syphilis.[18,19]

Timely detection of triple infections is hampered by the lack of on-site laboratory facilities;[15] test results are not available for days to weeks and irregular follow-up obstructs quality clinical management.[7] There is anecdotal evidence that a vast majority of women in rural areas present for care only during delivery and labour, thereby missing opportunities for effective PMTCT.[20] Inexpensive singleton POC tests for HIV, HBV and syphilis are available and offer the potential of rapid same-day screening with the added benefit of preventing non-return of patients, and flagging them for treatment and care. Nonetheless, the potential of triple screening women for the prevention of PMTCT in resource-limited settings is relatively unexplored.[7,15,21,22] Thus, in the light of renewed initiatives and to align enhanced detection and treatment for HIV and sexually transmitted infections with Maternal and Child Health programmes in view of the Millennium Development Goals (MDG),[4–6] we proposed an innovative screening strategy using available POC tests:[20,23] the simultaneous triple point-of-care screening strategy (STPOC) for HIV, HBV and syphilis infections in pregnancy. We report the feasibility, acceptability, along with prevalence and impact of this strategy in pregnant women presenting for antenatal care in a tertiary care hospital in rural India.

METHODS

Setting

Between December 2008 and July 2009, we conducted a prospective cross-sectional study in the outpatient clinics of the Department of Obstetrics and Gynaecology at the Mahatma Gandhi Institute of Medical Sciences (MGIMS). MGIMS is a tertiary-care teaching hospital in Sevagram with an estimated 3500 deliveries each year, serving as a high-risk obstetric centre to several villages in the Wardha district in rural central India. The study was jointly approved by the ethics committees based at McGill University Health Centre, Montreal, Canada, and MGIMS, Sevagram, India.

Objectives

The primary objective of the study was to evaluate the feasibility of implementation of an STPOC for HIV, HBV and syphilis in rural pregnant women in a resource-limited setting. The secondary objectives were: (a) to evaluate the preference for the strategy as compared with existing strategies, (b) to examine patient experience with the strategy, (c) to determine the prevalence of HIV, HBV and syphilis in the study population and (d) to assess impact.

Study population, sampling and eligibility

Women aged 18 years or older, pregnant at any gestational age, willing to provide informed consent and presenting with unknown or poor documentation of triple testing were deemed eligible. Women with medical obstetric emergency conditions or with mental health problems that precluded informed consent were excluded. Patients were identified through the daily registration roster by the physician-in-charge and recruited using a consecutive sampling methodology. All eligible participants were approached by the study manager/clinical research coordinator for informed consent, and consenting participants were offered STPOC.

Study procedure

The STPOC strategy consisted of: (A) pretest combined counselling for HIV, HBV and syphilis; (B) simultaneous triple screening with POC tests; (C) post-test combined counselling; and (D) linkages and referral for treatment/prophylaxis. Simultaneous triple screening was conducted using three Determine® POC tests for HIV1/2, HBV and syphilis (Determine® HIV-1/2, Determine® HBsAg, Determine® Syphilis TP; Inverness Medical Diagnostics, Ontario, Canada).[24] The three Determine® tests were performed simultaneously according to the manufacturer's instructions. Each test required a single finger stick specimen of blood (50 μL) that was collected by a special retractable lancet (Unistix3 lancets, Safe-Tec Clinical Products, Inc, Ivyland, PA, USA)[25]. Three 50-μL aliquots of blood were sampled one after another using three marked capillaries and placed on the three colour-coded test strips for HIV, HBV and syphilis. The assay time was recorded with a timer. Preliminary rapid test results were made available within 30–35 minutes and results declared in a post-test combined counselling session conducted immediately after triple screening. Venous blood was collected for those with preliminary reactive test result for confirmatory testing. Preliminary non-reactive participants reporting risky behaviours were encouraged to return for repeat testing prior to delivery. Confirmatory test results were made available within 1–3 days from ISO-9001-2000 (International Organization for Standardization)-certified private laboratories. Confirmatory test results were compared for concordance with HIV rapid test results through the parallel Government-sponsored HIV PMTCT programme. Triage of confirmed-positive women to early treatment was done within 3–5 days upon receipt of confirmatory test results. Positive women were flagged for treatment and their infants were prophylaxed/treated and referred soon after delivery.

The POC tests were conducted by counsellors in two rooms attached to the outpatient clinic. One served as the testing room and the other as the pre/post-test counselling room. The testing room was equipped with all necessary equipment and counsellors wore thick latex gloves. The counsellors had experience with a prior study conducted at the site two years ago, and were trained in the conduct of rapid testing, universal safety precautions for infection control and quality control and quality assurance.

Confirmatory test

A preliminary reactive Determine® HIV-1/2 test result was confirmed by dual ELISA (enzyme-linked immunosorbent assay): ELISA 1 (Immunocomb HIV 1 & 2 CombFirm; Orgenics, Courbevoie, France) and ELISA 2 (Vironostika® HIV Uni-form II Ag/Ab Plus O; Biomerieux, Marcy l'Etoile, France), with discrepant results confirmed by Western blot (Qualicode HIV 1/2 Kit; Immunetics technologies, Boston,

MA, USA). Preliminary reactive Determine® HBsAg test results were confirmed by conventional serological testing for HBsAg enzyme immunoassay (EIA) (HBSAg; Biomerieux, Boxtel, Netherlands) and further by HBV DNA (Abbott RealTime HBV PCR; Abbott Molecular Diagnostics, Wiesbaden, Germany). Preliminary reactive Determine® Syphilis TP tests were confirmed by the toluidine red unheated serum test kit (TRUST; Span Diagnostics Ltd, Surat, India) and *Treponema pallidum* haemagglutination assay (TPHA; Immunotrep; Omega Diagnostics, Alloa, Scotland, UK). Infants were tested with HIV DNA PCR tests (Roche Amplicor HIV1 DNA v1.5 Kit; Roche Diagnostics Systems Inc, Branchburg, NJ, USA) at birth, two and six months post-partum; seronegative status was confirmed by HIV ELISA testing (Vironostika HIV Uniform II Ag/Ab Plus O; Organon Teknika Corp, NC, USA) at 18 months postdelivery.

Quality assurance and quality control

About 15–20 random samples of participants were sent out every month for quality control and independently tested for concordance by an ISO 9001–2000[26]-certified private laboratory. Counsellors were trained on simultaneous conduct of rapid tests for one month in 50 patients in a pilot before study recruitment was initiated. Readers of the index tests and reference standards were blinded to the results of the other test. CDC guidelines on rapid testing quality assurance and quality control were followed to ensure quality in rapid test conduct.[27]

Statistical analysis

Data were analysed using STATA version 11 (STATA Corp, College Station, TX, USA). Proportions were computed with 95% confidence intervals (CI). Our sample size was computed using the primary outcome of feasibility, in particular completion rate defined as the proportion of consenting participants who underwent STPOC. At an assumed completion rate of 95%, with a 99% CI, a sample of 788 would achieve the required precision for the study. Feasibility of study conduct was also documented by recruitment rate defined as the proportion of participants approached who were recruited in the study. Uptake was defined as the increase in number of women screened for triple infections over and above screening rates for any triple infection documented at baseline. At baseline, documentation of self-reported screening was done by asking participants about their experience with any testing for HIV, HBV and syphilis in their current pregnancy. Preference was defined as the proportion that preferred STPOC over other testing strategies in place. Preference was assessed by asking participants to compare the STPOC with singleton rapid (HIV) and conventional (phlebotomy) testing and which strategy they preferred. Period prevalence in the study sample was defined as the proportion of those who completed the study procedure and tested positive for a specific infection in the sample in the defined study period. Impact outcomes were defined as clinical outcomes (i.e. initiation of treatment and referral linkages in women and documentation of reduction in perinatal transmission in their infants with testing at delivery, 2 and 6 months). Regular follow-up of infants occurred at 18 months of age to document the absence of infection.

RESULTS

The flow of participants is demonstrated in Figure 1. Table 1 shows demographic and risk profile characteristics of the study participants. Seropositive is defined as positive for one or more of the tests for HIV antibody/antigen, syphilis (treponemal and non-treponemal tests) and HBsAg and DNA.

Feasibility

Feasibility was investigated by completion rates, consent and recruitment rates, uptake and time for conduct. During the study period, 1066 pregnant women were deemed eligible and approached for participation; 1046 (98%) women consented to testing. Reasons for refusing consent ($n = 20$) were not documented. Of 1046 that were recruited, 44 did not complete the entire study procedure, but a majority of women, 96% (1002/1046), completed the strategy. The total time taken for STPOC testing was 25 minutes (range 21–27) and the time taken for the strategy was 45 minutes (range 40–47) per participant. The median time between STPOC and receipt of confirmatory test results was 1–3 days, and from STPOC to action (i.e. initiation of treatment and referral for HIV and syphilis and diagnostic work-up for HBV) was 3–5 days. At baseline, only 90 (8.98% [95% CI: 7.21–10.75%]) women reported being screened for all three infections in their current pregnancy. In the study, with 96% of women screened as a result of the strategy, the uptake of STPOC over and above the baseline screening was 86%.

Preference

995 women (99.3% [95% CI: 98.8–99.8%]) preferred 3-in-1 (STPOC) testing to singleton rapid testing and conventional strategies, and also reported recommending the STPOC strategy to their pregnant friend.

Patient experience

Patient experience with the STPOC strategy was documented in face-to-face interviews. Three hundred and eleven women (31.0% [95% CI: 28.2–33.9%]) reported having a fear of being pricked with a lancet while 322 women (32.1% [95% CI: 29.2–35.0%]) reported pain while being pricked. Of the 1022 women, 857 (85% [95% CI: 83.3–87.7%]) were pricked once, 117 (11.7% [95% CI: 9.7–13.7%]) were pricked twice and 28 (2.7% [95%CI: 1.7–3.7%]) were pricked three times or more. Due to unknown duration of exposure, all infections were assumed to be prevalent infections.

Period prevalence

Period prevalence of HIV in the study sample was 0.6% [95% CI: 0.12–1.07%], HBV was 0.5% [95% CI: 0.06–0.94%] and syphilis was 0.2% [95% CI: 0–0.48%].

Impact

At POC, a majority (98.7%) of study participants were found to be seronegative, while 13 tested positive: six women were HIV infected, five were HBV infected and two were syphilis infected.

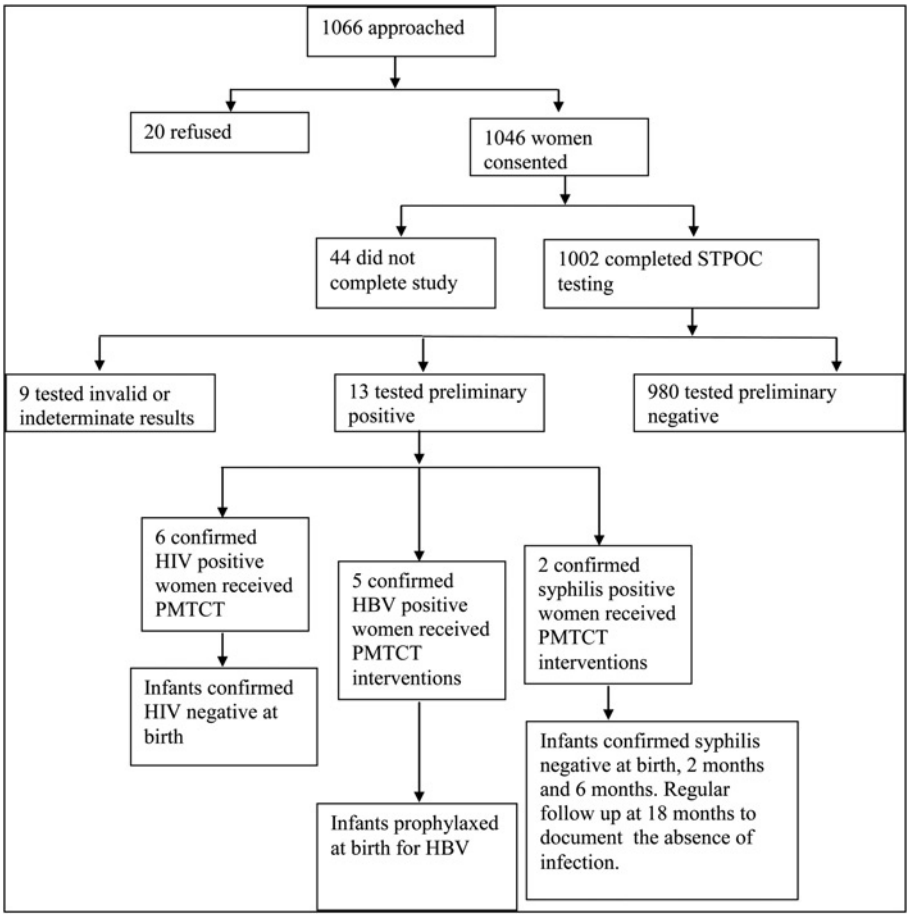

Figure 1 **Flow of participants through the study**

No woman was found to be co-infected. For the purpose of the study, confirmatory testing was expedited within 1–3 days. Participants found preliminary positive were flagged by the study team as 'awaiting confirmatory test results' and were triaged to referral pathways within 3–5 days. Participants were flagged for antiretroviral therapy (ART) and PMTCT interventions, and received immediate treatment for syphilis. Diagnostic work-up and referral to hepatologists for HBV were also initiated. Referral, care and follow-up of women and their infants were done by the Department of Obstetrics and Gynaecology and the Department of Paediatrics as part of the standard of care at the hospital. Infants were documented to be free of HIV, HBV and syphilis infections at birth and at 18 months post-delivery.

DISCUSSION

In this rural resource-limited setting, STPOC determined serostatus for three infections at the point-of-care and was feasible to conduct with a completion rate of 96%. This strategy allowed for an uptake of 86% over and above baseline screening for mono-infections in pregnancy. The total time taken to implement this strategy using rapid POC tests was 45 minutes or less per participant and the median turnaround time to confirmatory test results and referral for prophylaxis/treatment was 1–5 days. Although current HIV screening with rapid HIV tests is effective in flagging preliminary positive patients to ART and CD4 staging, routine screening for syphilis with laboratory-based non-treponemal assays is ineffective due to inaccuracy and loss to follow-up of patients. In addition, there is no provision for free confirmatory treponemal tests (e.g. TPHA) and tests conducted by private facilities are expensive (US$10). Furthermore, first-line HBV screening (HBsAg) is also expensive (US$10–20) and is therefore not offered routinely, unless clinically indicated. In such a situation, a screening strategy with three cheaper POC tests with accuracy parameters (sensitivity >92–99%, specificity >98%) offers a suitable first-line potential alternative to those who may never get screened for these infections. A positive result from the laboratory will often get communicated to the attending physician only at the next patient visit (which could be in three weeks or more), with incumbent possibility of non-return of the patient or loss to follow-up to another private provider or facility. Thus, the STPOC strategy's added value is the opportunity to screen and flag patients for confirmatory testing and prophylaxis/treatment, providing timely care with fewer losses of positive participants.

STPOC was preferred by 99% of participants to other singleton rapid tests and conventional testing strategies. Acceptability and preference for POC strategies have been high at this hospital setting.[20,23] STPOC was executed by study counsellors with no laboratory training by optimizing the available PMTCT platform for care. A run-in pilot period of one month was required for training. The participants in our study had a high literacy rate. Educated women make informed choices – this fact could be optimized for dissemination of written information.

Table 1 **Demographic details and risk factors in seronegative women and seropositive women**

		Serostatus			
Risk factors	**Categories**	**Positive**	**95% CI**	**Negative**	**95% CI**
Marital Status	Married	100% (13/13)		99.8% (987/989)	(99.5, 100)%
Age (mean, range)		24.2 (21.7, 26.6)		23.8 (23.6, 24.1)	
Education	No School	0% (0/13)		1.3% (13/989)	(0.6, 2.0)%
	Primary School	7.7% (1/13)	(0, 22.8)%	1.9% (19/989)	(1.1, 2.8)%
	Middle School	7.7% (1/13)	(0, 22.8)%	6.8% (67/989)	(5.2, 8.3)%
	High School	53.8% (7/13)	(25.6, 82.1)%	61.5% (608/989)	(58.4, 64.5)%
	Diploma/Bachelor	23.1% (3/13)	(0, 46.9)%	22.0% (218/989)	(19.5, 24.6)%
	Professional	7.7% (1/13)	(0, 22.8)%	6.2% (61/989)	(4.7. 7.7)%
	Other	0% (0/13)	(0, 0)%	0.1% (1/989)	(0, 0.3)%
	No Answer	0% (0/13)	(0, 0)%	0.2% (2/989)	(0, 0.5)%
Income	Rs 1–2,500	38.5% (5/13)	(10.9, 66.0)%	19.8% (196/989)	(17.3, 22.3)%
	Rs 2,501–5,000	33.3% (4/13)	(5.4, 6.1)%	43.6% (431/989)	(40.5, 46.7)%
	Rs 5,001–7,500	8.3% (2/13)	(0, 24.7)%	19.9% (197/989)	(17.4, 22.4)%
	Rs 7,5000–10,000	16.7% (2/13)	(0, 38.7)%	9.2% (91/989)	(7.4, 11.0)%
	Rs >10,000	0% (0/13)	(0,0)%	4.6% (45/989)	(3.2, 5.9)%
	No answer/do not know	0% (0/13)	(0,0)%	2.9% (29/989)	(1.9, 4.0)%
Occupation (self)	Labourer/field worker	30.8% (4/13)	(4.6, 56.9)%	7.4% (73/989)	(5.7, 9.0)%
	Farmer (Own)	7.7% (1/13)	(0,22.8)%	10.5% (104/989)	(8.6, 12.4)%
	Housewife	53.8% (7/13)	(25.6, 82.1)%	75.7% (749/989)	(73.1, 78.4)%
	Business	0% (0/13)	(0,0)%	0.8% (8/989)	(0.2, 1.4)%
	Teacher/bank employee	7.7% (1/13)	(0, 22.8)	1.6% (16/989)	(0.8, 2.4)%
	Student	0% (0/13)	(0,0)%	1.1% (11/989)	(0.5, 1.8)%
	Other	0% (0/13)	(0,0)%	2.8% (28/989)	(1.8, 3.9)%
Current STI symptoms	No symptoms	53.8% (6/13)	(25.6 82.1)%	68.6% (678/989)	(65.7, 71.4)%
	Vaginal discharge	38.5% (5/13)	(10.9, 66.0)%	23.0% (227/989)	(20.3, 25.6)
	Burning during urination	30.7% (4/13)	(4.6, 56.9)%	10.0% (99/989)	(8.1, 11.9)%
	Pelvic pain	0% (0/13)	(0,0)%	2.9% (29/989)	(1.9, 4.0)%
	Genital sores/ulcer	0% (0/13)	(0,0)%	1.2% (12/989)	(0.5, 1.9)%
Past blood transfusion	Yes	0% (0/13)		4.5% (44/989)	(3.2, 5.7)%
	No	100% (13/13)		95.2% (942/989)	(93.9, 96.6)%
	No answer	0% (0/13)		0.3% (3/989)	(0, 0.6)%
Tested for STIs (current pregnancy)	Yes	7.7% (1/13)	(0, 22.8)%	9.0% (89/989)	(7.2, 10.8)%
	No	92.3% (11/13)	(77.2, 100)%	90.3% (893/989)	(88.4, 92.1)%
	No answer	0% (0/13)		0.7% (7/989)	(0.2, 1.2)%
Spouse with TB	Yes	0% (0/13)		0.8% (8/989)	(0.2, 1.4)%
	No	100% (13/13)		99.0% (979/989)	(98.4, 99.6)%
	No answer	0% (0/13)		0.2% (2/989)	(0,0.5)%

STI, sexually transmitted infections; TB, tuberculosis

Our study had some limitations: (a) *Attrition bias*: 20 women refused to consent and 24 did not complete the study procedures and were lost to follow-up. Documentation of non-completion by the study counsellor suggests that loss to follow-up was due to the fact that waiting times for attending physicians were long and upon being seen by an attending physician, the participants failed to return to complete the post-test counselling and follow-up. These women were similar to participants except for their marital status – of 24 women, six (25%) were single/unmarried. (b) *Preliminary tests*: nine invalid/indeterminate test results occurred with POC tests in our study and were later confirmed to be negative. The manufacturer's sensitivity and specificity claims for Determine® tests in whole blood specimens are: HIV – 100% and 100%; HBV – 98.36% and 100%; syphilis – 100% and 92.3%. Thus, false-positive tests were likely to occur in our study. However, we also recently independently reviewed the global evidence and pooled accuracy parameters for POC tests used worldwide for syphilis and HBV infection.[28] We found that in serum, triple infection POC tests report high specificities (>99%) but sensitivities were in the range of 98.4–99.9%. Thus, even with the currently available test sensitivities, the potential of POC tests for syphilis and HBV to help screen women inexpensively is far greater than what is currently available at publicly-funded hospitals. (c) *Impact assessment*: Due to the low prevalence of HIV, HBV and syphilis infections (<0.05%) and the use of an observational study design, we could not effectively document nor evaluate impact outcomes. (d) *Selection bias*: Participants were a convenient sample of outpatient clinic attendees that raise the potential for selection bias. Testing and prophylaxis were provided free of charge to the participants, and prophylaxis offered to their infant for HBV and for prevention of syphilis motivated women to participate in the study. The possibility that this may have resulted in more high-risk women attending the clinic cannot be ruled out. (e) *Partial verification bias*: Differential algorithms were utilized for positives and negatives with a potential for partial verification bias. (f) *Historical control comparisons*: The comparisons with historical controls were also limited in that screening for syphilis and HBV was performed at this hospital on clinical suspicion with incomplete documentation. Complete follow-up data were available on few symptomatic cases that showed up in the next visit from the hospital's electronic database.

In summary, this pilot study evaluated whether the STPOC strategy was feasible to conduct in a resource-limited setting. If the STPOC strategy is incorporated within the existing PMTCT pathways, it will cost one to two additional counsellor consultations, 3 POC tests (in all) and one special lancet for each patient; we were limited in conducting formal cost-effectiveness analyses. As part of the National Rural Health Mission initiative,

this strategy could be offered by the health-care workers in a primary care setting with a training period of one month.[29]

The proposed strategy is a step-up to optimize the existing pathways towards eliminating congenital syphilis and HBV and HIV transmission in infants. Although triple screening with rapid POC tests has been performed in laboratories and blood banks in sera and blood specimens,[30,31] to the best of our knowledge this is the first report in pregnant women. This observational pilot study helped explore the optimization of the PMTCT platform towards providing an integrated care package for simultaneous triple testing that is in line with achieving MDG 3, 4 and 5.[20] Our observational study was limited in assessing impact; therefore, future intervention studies should aim to compare conventional strategy of symptomatic screening versus routine screening for triple infection to help establish the impact on infant transmission. We feel that the STPOC strategy worked well and is a precursor to future multiplexed POC testing initiatives in pregnant women.

ACKNOWLEDGEMENT

Dr Pant Pai acknowledges the current support of CIHR New Investigator Award and CIHR Operating grants CIHR HBF 103210 and CIHR KRS 102067. We also acknowledge our study counselors, staff and study participants at MGIMS, Sevagram for their time and efforts spent on the CTN SP243 study. The study was approved by the Institutional Review Boards at McGill University, Montreal, and Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharastra, India. The study sponsors had no role in the conception, design and conduct of the study. The investigators independently designed, executed, conducted the study and wrote the manuscript. Inverness Diagnostics played no role in the design, funding, conduct and analyses, nor interpretation of the study and its results.

REFERENCES

1 UNAIDS. UNAIDS Report on the Global AIDS Epidemic. Joint United Nations Programme on HIV/AIDS (UNAIDS), 2010
2 WHO Media Centre. *Hepatitis B*. 2008. See http://www.who.int/mediacentre/factsheets/fs204/en/ (last accessed 3 May 2012)
3 Op de Coul EL, Hahné S, van Weast YW, *et al.* Antenatal screening for HIV, hepatitis B and syphilis in the Netherlands is effective. *BMC Infect Dis* 2011;**11**:185
4 Spada E, Tosti ME, Zuccaro O, *et al.* Evaluation of the compliance with the protocol for preventing perinatal hepatitis B infection in Italy. *J Infect* 2011;**62**:165–71
5 Frischknecht F, Sell W, Trummer I, Brühwiler H. Serological testing for infectious diseases in pregnant women: are the guidelines followed? *Swiss Med Wkly* 2011;**140**:w13138
6 Samayoa B, Anderson MR, Pacheco KPA, *et al.* Seroprevalence of HIV, hepatitis B, and syphilis among pregnant women at the general hospital, Guatemala City, 2005–2009. *J Int Assoc Physicians AIDS Care (Chic)* 2010;**9**:313–7
7 WHO/TDR. *Use of Rapid Syphilis Tests.* The Sexually Transmitted Diseases Diagnostics Initiative 2006. See http://whqlibdoc.who.int/hq/2006/TDR_SDI_06.1_eng.pdf (last accessed 3 May 2012)
8 Chi BH, Vwalika B, Killam WP, *et al.* Implementation of the Zambia electronic perinatal record system for comprehensive prenatal and delivery care. *Int J Gynaecol Obstet* 2011;**113**:131–6
9 Olokoba AB, Salawu FK, Danburam A, *et al.* Hepatitis B virus infection amongst pregnant women in North-eastern Nigeria – a call for action. *Niger J Clin Pract* 2011;**14**:10–3
10 Ramos JM, Toro C, Reyes F, *et al.* Seroprevalence of HIV-1, HBV, HTLV-1 and Treponema pallidum among pregnant women in a rural hospital in Southern Ethiopia. *J Clin Virol* 2011;**51**:83–5
11 Zhang RL, Luo Y, Xie JX, *et al.* [A correlation analysis between the rate of vertical transmission of HBV and HBsAg-positive father to infant and the rate of neonatal cord blood HBV-DNA.]. *Zhonghua Liu Xing Bing Xue Za Zhi* 2010;**31**:159–62
12 Chan OK, Lao TT, Suen SS, *et al.* Knowledge on hepatitis B infection among pregnant women in a high endemicity area. *Patient Educ Couns* 2011;**85**:516–20
13 Kosaraju K, Padukone S, Bairy I. Co-infection with hepatitis viruses among HIV-infected individuals at a tertiary care centre in South India. *Trop Doct* 2011;**41**:170–1
14 Jindal N, Arora U, Singh K. Prevalence of human immunodeficiency virus (HIV), hepatitis B virus, and hepatitis C virus in three groups of populations at high risk of HIV infection in Amritsar (Punjab), Northern India. *Jpn J Infect Dis* 2008;**61**:79–81
15 Peeling RW. Evaluating diagnostics: STI. *Nature Reviews Microbiology* 2006;**4(S1)**
16 Bacq Y. Hepatitis B and pregnancy. *Gastroenterol Clin Biol* 2008;**32(Part 2)**:S12–9
17 WHO. Mother-to-child transmission of HIV data and statistics. 2010. See http://www.who.int/hiv/topics/mtct/data/en/index.html (last accessed 10 August 2010)
18 Herring A, Ballard R, Mabey D, Peeling RW. Evaluation of rapid diagnostic tests: syphilis. *Nat Rev Microbiol* 2006;**4(Suppl)**:S33–40
19 Goh BT, Thornton AC. Antenatal screening for syphilis. *Sex Transm Infect* 2007;**83**:345–6
20 Pai NP, Barick JP, Tulsky JP, *et al.* Impact of round-the-clock, rapid oral fluid HIV testing of women in labor in rural India. *PLoS Med* 2008;**5**:e92
21 Schackman BR, Fontain SN, Nolte C, Joseph P, Pape JW, Fitzgerald DW. Cost-effectiveness of rapid syphilis screening in prenatal HIV testing programs in Haiti. *PLoS Med* 2007;**4**:e183
22 WHO. *Prevention of mother to child transmission of syphilis*. 2006. See http://www.who.int/reproductive-health/publications/standards/prevention_mtct_syphilis.pdf (last accessed 3 May 2012)
23 Pant Pai N, Joshi R, Dogra S, *et al.* Evaluation of diagnostic accuracy, feasibility and client preference for rapid oral fluid-based diagnosis of HIV infection in rural India. *PLoS One* 2007;**2**:e367
24 Determine A. *Inverness Medical*. All rights reserved., London: I.M. UK, 2007
25 Mumford O. *Unistik 3 Lancing Devices*. 2011. See: http://www.owenmumford.com/us/range/40/unistik-3.html (last accessed 24 October 2011)
26 ISO. International Standards for Business, Government and Society. See http://www.iso.org/iso/home.htm (last accessed 2 May 2012)
27 CDC. *Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988*. 2007. See http://www.cdc.gov/hiv/topics/testing/resources/guidelines/pdf/QA_Guidlines.pdf (last accessed 3 May 2012)
28 Pant Pai N. *Diagnostic Performance of Rapid Tests for HIV and Related Co-Infections in Vulnerable Populations*. Ottawa, ON: Canadian Institute for Health Research, 2010
29 Ministry of Health and Family Welfare. *ASHA Training Module Book 1*, 2005–2012
30 Allain JP, Bianco C, Blajchman MA, *et al.* Protecting the blood supply from emerging pathogens: the role of pathogen inactivation. *Transfus Med Rev* 2005;**19**:110–26
31 Allain JP, Lee H. Rapid tests for detection of viral markers in blood transfusion. *Expert Rev Mol Diagn* 2005;**5**:31–41

(Accepted 24 October 2011)