

Is it Feasible to Use an Oral-Fluid Based Rapid Test Facilitated by Frontline Workers to Improve HIV Screening of Pregnant Women in Indian Rural Settings?

Pankhuri Sharma^{1*}, Simi Khan¹, Jagannath Behera¹, Archana Sarkar¹, Sunil Mehra¹ and Poonam Verma Shivkumar²

¹Research and Innovation Unit, Mamta Health Institute of Mother and Child, New Delhi, India

²Department of Obstetrics and Gynecology, Mahatma Gandhi Institute of Medical Sciences, Wardha, Maharashtra, India

Abstract

Objectives: The importance of knowing HIV status is a key strategy for HIV response and effective treatment services. The present study aimed to assess feasibility of using oral-fluid based rapid HIV test aided by Frontline-Health workers (FLWs) of pregnant women in rural districts of India.

Methods: A feasibility study, using cross sectional design was carried-out in two rural districts of India. Overall, 900 pregnant women were screened using OraQuick® test, an oral-fluid based rapid HIV test facilitated by trained FLWs and subsequently, all participants were tested at in existing government center for confirmatory HIV testing. The data were collected from three aspects: i) the results of OraQuick® HIV test and confirmatory test ii) the perspectives of FLWs through in-depth interviews and iii) information on the acceptability of oral-fluid based HIV testing from 479 pregnant women, through a structured questionnaire. The descriptive statistics was used to analyse the quantitative data and thematic content analysis to analyse the qualitative in-depth interviews.

Results: Of the 947 pregnant women who were offered HIV screening using OraQuick® saliva based test, 95% (n=900) accepted to undergo the test. Of the total 479 pregnant women interviewed, 91.2% liked the OraQuick® kit for HIV screening. The key motivators of accepting the test are easy procedure (43%), non-invasiveness (29%) and quick access to results (18%). Out of 900 pregnant women screened by OraQuick®, nine women were found to be HIV positive, which corresponded with confirmatory test results. Qualitative data provided insights into FLWs to understand their views regarding current situation on HIV testing and services available to the pregnant women.

Conclusion: With an urgent need to improve access to HIV screening at the grass root level, an oral based HIV rapid testing mechanism can provide a plausible solution for improving early detection of HIV among pregnant women.

Keywords: Oral-fluid based HIV rapid test; Pregnant women; Frontline health workers; Feasibility; Acceptability; Non-invasive

Introduction

Early HIV testing is the first step to prevention, treatment and linkages to care services for HIV. Studies have suggested that numerous times the infection is detected during the later stages of the disease and many of those tested for HIV are not aware of their test results [1]. The importance of knowing HIV status is a key strategy for HIV response and development of effective treatment services. To achieve, the UN 90–90–90 global targets, it is crucial to reach the first 90, which is diagnosis of HIV [2]. Challenge remains in reaching the unreached vulnerable group where there is limited access and uptake of HIV testing services.

In developing countries, 90% of new infections among children are due to Mother-to-child transmission (MTCT) [3]. WHO have identified India among the top 10 priority countries, which accounts for 75% of the global prevention of mother to child transmission (PMTCT) service need [4]. In India, of all reported cases of HIV infection, 5.4% were due to MTCT and around 49,000 pregnant women are living with HIV [5]. In spite of all efforts by government, less than half of pregnant women (47%) have received PMTCT services [6]. This can be attributed to poor availability and accessibility to antenatal care and PMTCT services for pregnant women particularly in rural India. Multiple factors related to individual (such as inadequate knowledge on PMTCT); socio-cultural (such as stigma associated with HIV and little spouse support) and structural (such as poor transportation for HIV testing center) have been found to hinder the accessibility to HIV testing [7,8]. Another challenge for low rates of HIV testing in India is the inadequate provision of equipment essential for HIV testing including laboratory technicians and facilities [9,10].

To address these challenges, use of varied HIV testing approaches such as rapid testing has been a key development [11]. Accumulating evidence have found that introduction of rapid HIV testing in community settings is a feasible approach for reaching out to people potentially at risk for HIV infection and thus further enhances the chances of proper care and treatment [12].

To enhance the coverage in rural India, national guidelines have emphasised on including universal HIV screening as an integral part of routine antenatal (ANC) check-up. Shifting the task of HIV testing services aided by FLWs have potential for increased coverage and uptake of HIV screening among pregnant women. As these FLWs are village-level functionaries, they can reach pregnant women even in remote areas and they are culturally competent [13]. For prevention of mother to child transmission of HIV, it is pivotal introduce a mechanism to increase the outreach and coverage of HIV screening among pregnant

***Corresponding author:** Pankhuri Sharma, Research and Innovation Unit, Mamta Health Institute of Mother and Child, Greater Kailash Enclave II, New Delhi-110048, India, Tel: 011 2922 0210; E-mail: pankhurishrm10@gmail.com

Received February 23, 2018; **Accepted** March 20, 2018; **Published** March 30, 2018

Citation: Sharma P, Khan S, Behera J, Sarkar A, Mehra S, et al. (2018) Is it Feasible to Use an Oral-Fluid Based Rapid Test Facilitated by Frontline Workers to Improve HIV Screening of Pregnant Women in Indian Rural Settings? HIV Curr Res 3: 127. Doi: [10.4172/2572-0805.1000127](https://doi.org/10.4172/2572-0805.1000127)

Copyright: © 2018 Sharma P, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

women. Hence, the current study aimed to explore the feasibility and acceptability of rapid oral fluid-based HIV testing using the OraQuick® kits conducted by FLWs, particularly auxiliary nurse midwives (ANMs) among pregnant women living in rural districts in India.

Methodology

Study setting

This study was conducted as a part of the project on Preventing Parent to Child Transmission (PPTCT) of HIV through early identification, care and support of pregnant women for improving maternal health outcomes in two districts of India. The project was implemented by institutes in India (names hidden for blind review), and funded by International HIV/AIDS Alliance. The implementation districts were Nagpur and Adilabad in states Maharashtra and Telangana respectively. These were selected based on HIV Sentinel Surveillance conducted by National AIDS Control Organization (NACO), India; and inhabited by a sizable tribal population. Both Nagpur and Adilabad districts have presence of HIV risk factors and these districts had more than 1% ANC prevalence [14].

Study design

From March 2014 to September 2015, a cross-sectional study was carried out among pregnant women in rural settings. Data was collected from pregnant women and FLWs using quantitative and qualitative approach. Standard guidelines were followed for data collection (STROBE [15] and COREQ [16]). A multi-stage cluster sampling process was adopted to recruit participants in the study. Two blocks were selected from each study districts, the villages under the selected blocks were divided into ten proximal geographic clusters of villages. Through the process of random sampling, 5 clusters were selected from each block and a target was set to select 50 women from each selected cluster.

Study population and participant recruitment

In total, 947 pregnant women aged 18 years and above agreed to be part of the study, of which 900 pregnant women gave final consent for HIV screening by OraQuick® kit. Before conducting the tests, the FLWs known as Auxiliary Nurse Midwife (ANM) were oriented on providing pre-test and post-test counselling as per the national guidelines. They were trained on the stepwise procedures of conducting oral fluid based HIV screening test through OraQuick® kits and other related operational procedures as explained in published work by the authors [14]. For this study, trained 60 FLWs approached pregnant women from their respective clusters, informed them about the study objectives and obtained their study participation consent. Following this, a convenient time and date was taken from each consented participant for conducting HIV screening at village level health center. HIV status screened through the OraQuick® kits were interpreted and recorded by FLWs. All existing relevant national protocols were followed to counsel the participants, maintaining the confidentiality of the HIV status and linking them to treatment and care services. All pregnant women who underwent HIV screening through OraQuick® were taken for confirmatory HIV test at government center for matching the results of OraQuick® HIV test kit with standard HIV test for confirmation. Each participant was given a unique identity number, which was linked to government testing center database to match results for all participants. All pregnant women over 18 years of age were included in the study. The exclusion criteria included pregnant women with bleeding gums, oral ulcers affecting the process of oral-fluid based testing and pregnant women with any other complication impeding informed consent.

Data collection

The data was collected on the following aspects: a) Results of OraQuick® test conducted and interpreted by FLWs for 900 pregnant women; b) the perspectives on assisting the screening of HIV through OraQuick® test and its feasibility was also captured from 20 FLWs who were available at the time of in-depth interview and agreed to participate; c) From the subset of 900, pregnant women, on the basis of their availability and willingness to participate, 479 pregnant women were interviewed using a structured questionnaire administered verbally by the outreach worker in participants' preferred language to obtain information on the acceptability of the oral fluid based HIV testing. The qualitative data was collected through in-depth interviews with FLWs to understand their experiences, feasibility and challenges of conducting oral fluid based HIV testing at community level.

Operational definitions

Acceptability was computed as the percentage of the uptake of the oral fluid-based HIV test, where the numerator was the number of pregnant women who underwent HIV screening test, and the denominator was the number of participants who were offered to testing. Acceptability was also corroborated through a structured questionnaire to understand the factors influencing the acceptability of the test among pregnant women. Accuracy was defined by sensitivity and specificity parameters of OraQuick® HIV kit results matched with established HIV test for confirmation. Index test was an OraQuick® HIV kit result as interpreted by FLW. Reference standard tests were the confirmatory tests done for HIV at government facility using the standard national algorithm of three rapid HIV test kits [17]. Feasibility of oral fluid HIV rapid test was assessed through in-depth interviews with FLWs on testing procedures including ease of performance and interpretation of the oral fluid based HIV rapid test and challenges for future utilization.

Sample size

In the present study, it was assumed that 50% of pregnant women will be tested by FLWs using rapid oral fluid based HIV test, with 95% confidence interval and 10% margin of error to obtain the minimum sample size. The minimum sample size calculated was 384 each from two districts. A cushion of 10% for non-response, unusable data, and rounding off the figures generated a sample of 422. Hence, in our study a sample size of 900 participants presents a true representation of the sample from two districts.

Analysis

Descriptive statistics was computed related pregnant women's experiences regarding HIV oral fluid based testing. Test kit sensitivity and specificity were computed from tests results identified by FLWs compared with confirmatory test results conducted at government testing centres. All statistical analysis was executed using IBM SPSS Statistics v.22.

Inductive approach was used to analyse the in-depth interviews. The responses were first coded and then grouped manually into different thematic areas. Themes were taken from the codes identified through the interview sheets and were categorized into major and minor themes based on the respondent's perspectives and experiences [18].

Ethical consideration

All tenets of ethical principles involving human participants were followed for this study [19]. Informed written consent was obtained from all the participants (pregnant women and FLWs). The pre-and post-test counselling was given to all pregnant women who underwent HIV test. Those who were tested positive for HIV were linked to

existing HIV treatment and care services of government. Institutional Ethical approvals were obtained from both the institutes prior to the implementation of this study.

Results

The results of this study was focussed on assessing the feasibility (reference) of an oral fluid based HIV rapid test among pregnant women performed by FLWs at community level in low resource settings. The acceptability (reference) component was defined as the percentage of consenting pregnant women up taking the oral fluid-based HIV test. The motivators were also captured from the pregnant women to corroborate with the acceptability component. Of the 947 pregnant women who were offered to get screened for HIV using OraQuick® saliva based test, 95% (n=900) accepted to undertake the test. Of the total 479 pregnant women interviewed, 91.2% liked the OraQuick® kit for HIV screening. A total of 42 pregnant women did not like test, reasons reported were non-reliability on the accuracy of results (n=22), discomfort in giving saliva sample (n=6), confidentiality issues (n=4) and the test is not confirmatory (n=10). The main motivator of liking the test (Figure 1) was reported as easy procedure (43%).

Of the total, 900 pregnant women screened by rapid HIV test-OraQuick®, nine women were found to be HIV positive, which later corresponded with confirmatory test results. All the results interpreted by FLW for OraQuick® test matched with the confirmatory results conducted at government health centre (Table 1).

Qualitative data provided further insights into the FLWs to understand their views regarding the current situation on HIV testing as well as the services available to the pregnant women (Table 2). Each interview took 35-40 minutes time. The analysis suggested some specific thematic areas pertaining to the knowledge of PPTCT program, feasibility and compliance to use OraQuick® test and potential challenges for mainstreaming HIV point of care test. Some of the issues reflected by FLWs through these in-depth interviews were lack of awareness among pregnant women regarding HIV testing services and status, need for more quality trainings on PPTCT and innovative test and fear of HIV status disclosure in the community. The FLWs shared their experiences regarding OraQuick® test and the convenience with respect to easy and non-invasive procedure and acceptance by pregnant women. The need for mechanisms to ensure confidentiality and encourage husbands for HIV screening was also highlighted.

Discussion and Conclusion

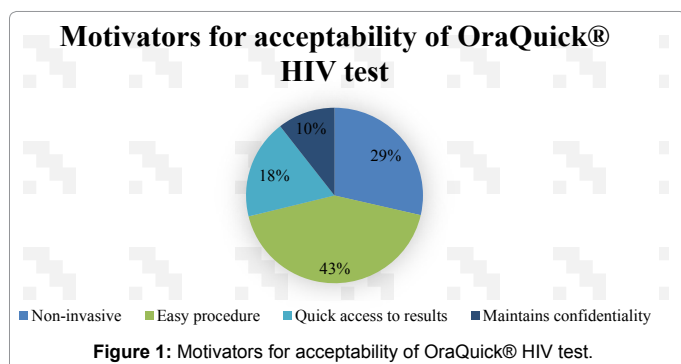
The present study demonstrates that HIV screening using a non-invasive oral-fluid based rapid test- OraQuick® kit is feasible among the pregnant women in rural and remote areas, assisted by FLW with respect to both acceptability and accuracy. The study emphasised that the frontline workers known as Auxiliary mid-wives) in Indian health system were effectively able to conduct this community based

testing strategy using non-invasive, oral-fluid based test owing to its easy procedure, non-invasiveness and results accuracy. The FLWs are the interphase between the community and healthcare services and are easily accessible as they are the part of the communities. They are from the communities and can easily reach pregnant women in remote settings. Our results clearly indicates towards the acceptance of pregnant women in rural settings for this test with uptake as 95%, which is higher than reported in other studies on oral fluid based rapid tests (83-85%) [20]. This concord with other studies conducted among rural women indicating for the preference of oral fluid-based tests over blood-based tests [21]. The reasons behind the higher acceptability was assistance by FLWs, convenient to perform [22] and lack of fear of blood draw, or pain of needle stick etc. [9].

A review among pregnant women suggested that the overall sensitivity and specificity of blood-based rapid tests was high compared with oral rapid tests [23]. Although our study conducted in low-prevalence setting indicates high accuracy (100% sensitivity and 100% specificity) of OraQuick® HIV kits when used to screen 900 pregnant women by FLWs at village level health center. The nine pregnant women found to be positive as tested by both oral based testing and confirmatory test were linked to care and treatment as per the national guidelines. Earlier studies in rural India, relating to the accuracy of oral-based tests have also reported high accuracy of oral -based kits [9,24]. Although it is recognised that sensitivity and specificity can be affected by prevalence and user errors [23].

Qualitative data provided insights from FLWs on the knowledge for HIV testing services, barriers for HIV testing, their experiences on using oral based HIV test and facilitators for point of care test. The results of this study, which utilized FLWs rather than formally trained staff nurses and doctors, demonstrate that coverage of HIV testing through oral-fluid based rapid method can be improved in India and other similar settings in which a lack of adequate trained human resources impedes access to HIV testing. FLWs reflected the low awareness on HIV transmission from mother-to-child among community which was also highlighted in another study among pregnant women in India [25]. For strengthening of PPTCT services, even lowest level of health functionaries need trainings support and supervision in providing counselling services to community. This was also highlighted in the qualitative data collected from FLWs. The United Nations task force meeting report on prevention of mother-to-child transmission have also emphasized on frequent trainings of primary health care workers on integrated MNCH and HIV services to counsel and support pregnant and lactating women [26]. The findings from systematic review reflected that task shifting from higher health care providers to frontline health workers can lead to increased accessibility of HIV testing services [27]. Our study results corroborates to these findings and showed that shifting the task of HIV testing to lower health cadre increases the uptake and compliance to HIV testing. The proposed strategy have the advantage of using a frontline healthcare functionary, who is readily available in the village, and can extend support for HIV screening services to the pregnant women in remote villages where government testing centers are not accessible. This has cost benefit too as it reduces the travel cost incurred by the women and the load on personnel (one counselor who provides counselling and a lab-technician performs rapid HIV test), thereby reducing the human resource cost for screening services.

One of the barriers to getting HIV test results in existing health system is high burden of clients, most of the times women wait for hours for receiving their results. Thus, the major advantage oral-fluid based rapid tests provides an opportunity for improving the likelihood that clients will receive timely results. The non-invasive technique can



Women HIV test results (1% women were HIV positive)		ICTC results		
		Positive	Negative	Total
Ora-quick results	Positive	9	0	9
	Negative	0	891	891
Total		9	891	900

Table 1: Accuracy of HIV test results (OraQuick® saliva based test).

Coding	Themes	
	Major	Minor
PPTCT	Lack of Awareness Capacity building of primary health care providers	PPTCT programme is not known widely. Importance of knowing one's own HIV status Importance of undergoing HIV testing during every pregnancy Require more comprehensive trainings for ANMs
OraQuick® HIV rapid test	Feasibility Decentralization of HIV testing services	Easy compliance by pregnant women Non-invasive test and has easy procedure Can be done in health centre at village level by FLWs Saves the travelling time for pregnant women
Challenges	Confidentiality Male partner testing	Fear of doing HIV test due to possibility of positive results Assuring non-disclosure of results Mechanisms to encourage husbands for HIV testing

Table 2: Emerging themes from In-depth with ANMs.

be scaled up by providing knowledge for early HIV testing and PPTCT among pregnant women, ensuring their timely access to health services; strong links to pre-and post-counselling services and treatment; skilled FLWs and the systems necessary to regulate the availability and use of good-quality test kits, which is critical to minimise erroneous results.

Findings should be inferred in respect to the limitations of this study. The low prevalence of HIV in the study population might have limited the extrapolation of the outcomes regarding the sensitivity and specificity of the OraQuick® tests for the wider population. Another limitation of the study was the use of purposive sampling which may have led to a bias selection of participants for qualitative data collection. However, the in-depth interviews were crucial in providing substantial perspectives and well corroborating the quantitative data findings. Further future research, could explore the cost-effectiveness of this strategy.

With an urgent need to improve access to HIV screening at the grass root level where the pregnancy load is high, and infrastructure and workforce for HIV testing are inadequate, an oral based HIV rapid testing mechanism can provide a plausible solution for strengthening PPTCT services and reducing the missed opportunities of early detection of HIV among pregnant women.

Acknowledgements

The authors thank all the study participants and field staff. The guidance from Dr. Gitau Mburu on overall project implementation is highly acknowledged. We sincerely thank Dr. Ritu Dargan for her technical consultation. We are grateful to Pallavi Bhandarkar and Ravi for coordinating the study at field.

Author Contribution

PS carried out interpretation of the data, contributed majorly in drafting of manuscript and carrying out qualitative interviews. SK was involved in the literature review, statistical analysis, and drafting of manuscript. JB made substantial contributions to the design and methods of the study, development of tools and data monitoring. AS, PVS and SM majorly contributed in the conceptualization, implementation of the study, providing technical inputs and the final approval of the version to be submitted. All authors read and approved the final manuscript.

Declaration of Interest

None

Funding

The project was funded by International HIV/AIDS Alliance

Ethical Approval

Ethical approvals were obtained for this study from the Ethics Committee of the institutes (MGIMS/IEC/OBGY/99/2013) and (MERB/Dec 2013/001).

References

- Lee VJ, Tan SC, Earnest A, Seong PS, Tan HH, et al. (2007) User acceptability and feasibility of self-testing with HIV rapid tests. *J Acquir Immune Defic Syndr* 45: 449-453.
- Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, et al. (2011) Prevention of HIV-1 Infection with Early Antiretroviral Therapy. *N Engl J Med* 365:493-505.
- De Cock KM, Fowler MG, Mercier E, De Vincenzi I, Saba J, et al. (2000) Prevention of mother-to-child HIV transmission in resource-poor countries: Translating research into policy and practice. *JAMA* 283: 1175-1182.
- Avert Global information and education on HIV and AIDS (2017) Prevention of Mother-To-Child Transmission (PMTCT) of HIV.
- Madhivanan P, Krupp K, Kulkarni V, Kulkarni S, Vaidya N, et al. (2014) HIV testing among pregnant women living with HIV in India: are private healthcare providers routinely violating women's human rights? *BMC Int Health Hum Rights* 14: 7.
- National AIDS Control Organisation (2013) Prevention of Parent to Child Transmission (PPTCT) of HIV using Multi Drug Anti-retroviral Regimen in India: Department of AIDS Control Basic Services Division, Ministry of Health & Family Welfare, Government of India.
- Rogers A, Meundi A, Amma A, Rao A, Shetty P, et al. (2006) HIV-related knowledge, attitudes, perceived benefits, and risks of HIV testing among pregnant women in rural Southern India. *AIDS Patient Care and STDs* 20: 803-811.
- Sinha G, Dyalchand A, Khale M, Kulkarni G, Vasudevan S, et al. (2008) Low utilization of HIV testing during pregnancy: What are the barriers to HIV testing for women in rural India? *J Acquir Immune Defic Syndr* 47: 248-252.
- Pai NP, Barick R, Tulsy JP, Shivkumar PV, Cohan D, et al. (2008) Impact of round-the-clock, rapid oral fluid HIV testing of women in labor in rural India. *PLoS Med* 5: e92.
- Steinbrook R (2007) HIV in India-the challenges ahead. *N Engl J Med* 356: 1197-1201.
- Branson BM, Viall A, Marum E (2013) Expanding HIV testing: Back to the future. *J Acquir Immune Defic Syndr* 63: S117-121.
- Bowles KE, Clark HA, Tai E, Sullivan PS, Song B, et al. (2008) Implementing rapid HIV testing in outreach and community settings: Results from an advancing HIV prevention demonstration project conducted in seven U.S. cities. *Public Health Rep* 123: 78-85.

13. World Health Organization (2016) Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: Recommendations for a public health approach.
14. Sarkar A, Mburu G, Shivkumar PV, Sharma P, Campbell F, et al. (2016) Feasibility of supervised self-testing using an oral fluid-based HIV rapid testing method: A cross-sectional, mixed method study among pregnant women in rural India. *J Int AIDS Soc* 19: 20993.
15. Erik von E, Altman DG, Egger M, Pocock SJ, Gotsche PC (2007) Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies. *BMJ* 335: 806-808.
16. Tong A, Sainsbury P, Craig J (2007) Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. *Int J Qual Health Care* 19: 349-357.
17. National AIDS Control Organisation (2015) National guidelines for HIV testing national AIDS. Ministry of Health & Family Welfare of India, New Delhi
18. World Medical Association (2013) World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 310: 2191-2194.
19. Ann J Melvin, Alarcon J, Velasquez C, Rodriguez C, Piscocoya J, et al. (2004) Rapid HIV Type 1 Testing of Women Presenting in Late Pregnancy with Unknown HIV Status in Lima, Perú. *AIDS Res Hum Retroviruses* 20: 1046-1052.
20. Pai NP, Bhargava M, Joseph L, Sharma J, Pillay S, et al. (2014) Will an unsupervised self-testing strategy be feasible to operationalize in Canada? Results from a pilot study in students of a large Canadian university. *AIDS research and treatment*.
21. Figueroa C, Johnson C, Verster A, Baggaley R (2015) Attitudes and acceptability on HIV self-testing among key populations: A Literature Review. *AIDS Behav* 19: 1949-1965.
22. Pai NP (2007) Rapid oral fluid-based point-of-care HIV testing: Applicability in developing countries. *Indian J Med Res* 126: 171-173.
23. Pai NP, Joshi R, Dogra S, Taksande B, Kalantri S, et al. (2007) Evaluation of diagnostic accuracy, feasibility and client preference for rapid oral fluid-based diagnosis of HIV infection in rural India. *PLoS one* 2: e367.
24. Kumar A, Singh B, Kusuma YS (2015) Counselling services in prevention of mother-to-child transmission (PMTCT) in Delhi, India: An assessment through a modified version of UNICEF-PPTCT tool. *J Epidemiol Glob Health* 5: 3-13.
25. UNAIDS, UNICEF, UNFPA, WHO (2010) The 7th Asia-Pacific United Nations Prevention of Mother-to-Child Transmission Task Force Meeting.
26. Kennedy C, Yeh P, Johnson C, Baggaley R (2017) Should trained lay providers perform HIV testing? A systematic review to inform World Health Organization guidelines. *AIDS care* 29: 1473-1479.