Feasibility of supervised Self-Testing using an Oral Fluid-based HIV Rapid Testing method among pregnant women in Rural India

Archana Sarkar, Gitau Mburu, Poonam Shivkumar, Pankhuri Sharma, Fiona Campbell, Jagannath Behera, Ritu Dargan, Surendra Mishra, Sunil Mehra

MAMTA Health Institute for Mother and Child, New Delhi, India

Mahatma Gandhi Institute of Medical Sciences, Wardha

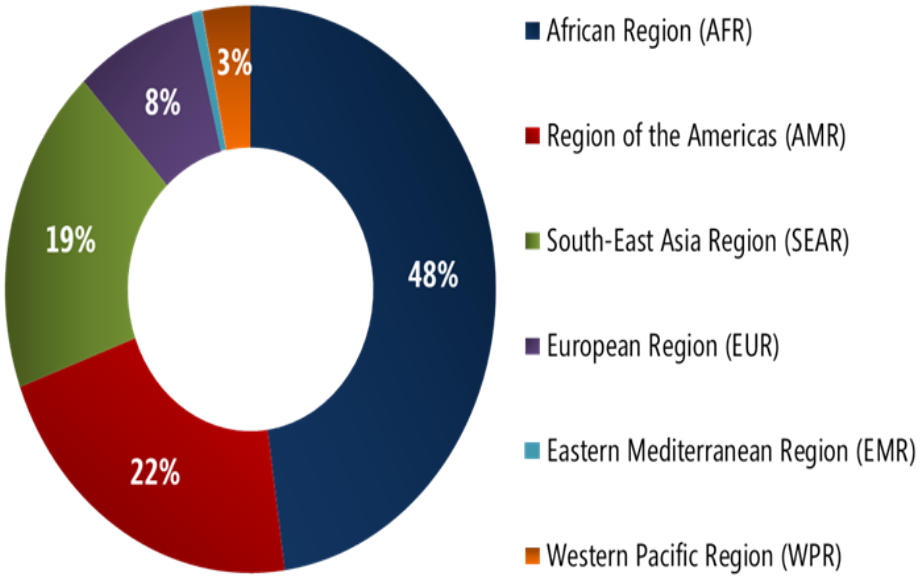
International HIV/AIDS Alliance, Brighton, United Kingdom

`

Webinar on Getting to the First 90: Engaging Men & Self-Testing

Where are we with HIV testing?

Between 2010 and 2014, 600 million adults (ages 15+) received HIV testing in 122 LMICs..

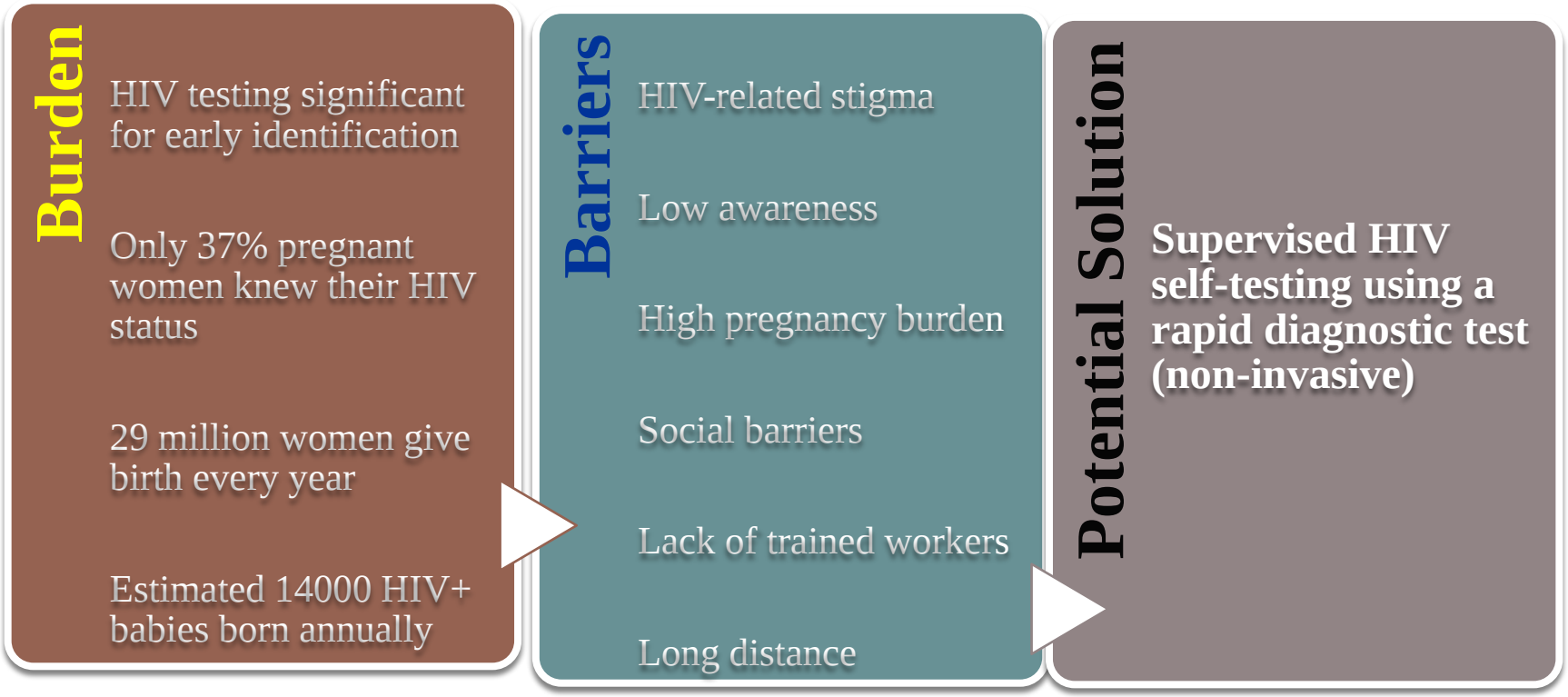


Reaching the first "90" is the most problematic: Too few taking the test

- **Half of people with HIV unaware of status**
- **Only 44% pregnant women take the test in low and middle-income countries**
- **Feasibility studies are required on new testing approaches**

Source: GARPR (WHO, UNAIDS, UNICEF) 6 July 2015.

HIV Testing: Pregnant Women In India



Objectives of the Study

To conduct supervised HIV self-testing using OraQuick® HIV antibody test among pregnant women in rural hospital settings of India to assess:

- Acceptability
- Concordance
- Feasibility of self-testing supervised by community health workers (CHWs)

Methodology

Study design: Cross-sectional study, conducted between August 2014 and January 2015

Study setting: Kasturba Rural Hospital, Mahatma Gandhi Institute of Medical Sciences, Wardha

Study Procedures

- **Orientation of Healthcare workers:** Objectives, protocol and procedures for OraQuick® test by the instruction guide
- **Recruitment:**
  - **Inclusion Criteria**

    Pregnant women (>18 years of age)

    First trimester of pregnancy and Registered for ANC with the hospital

    Informed Consent
  - **Exclusion Criteria**

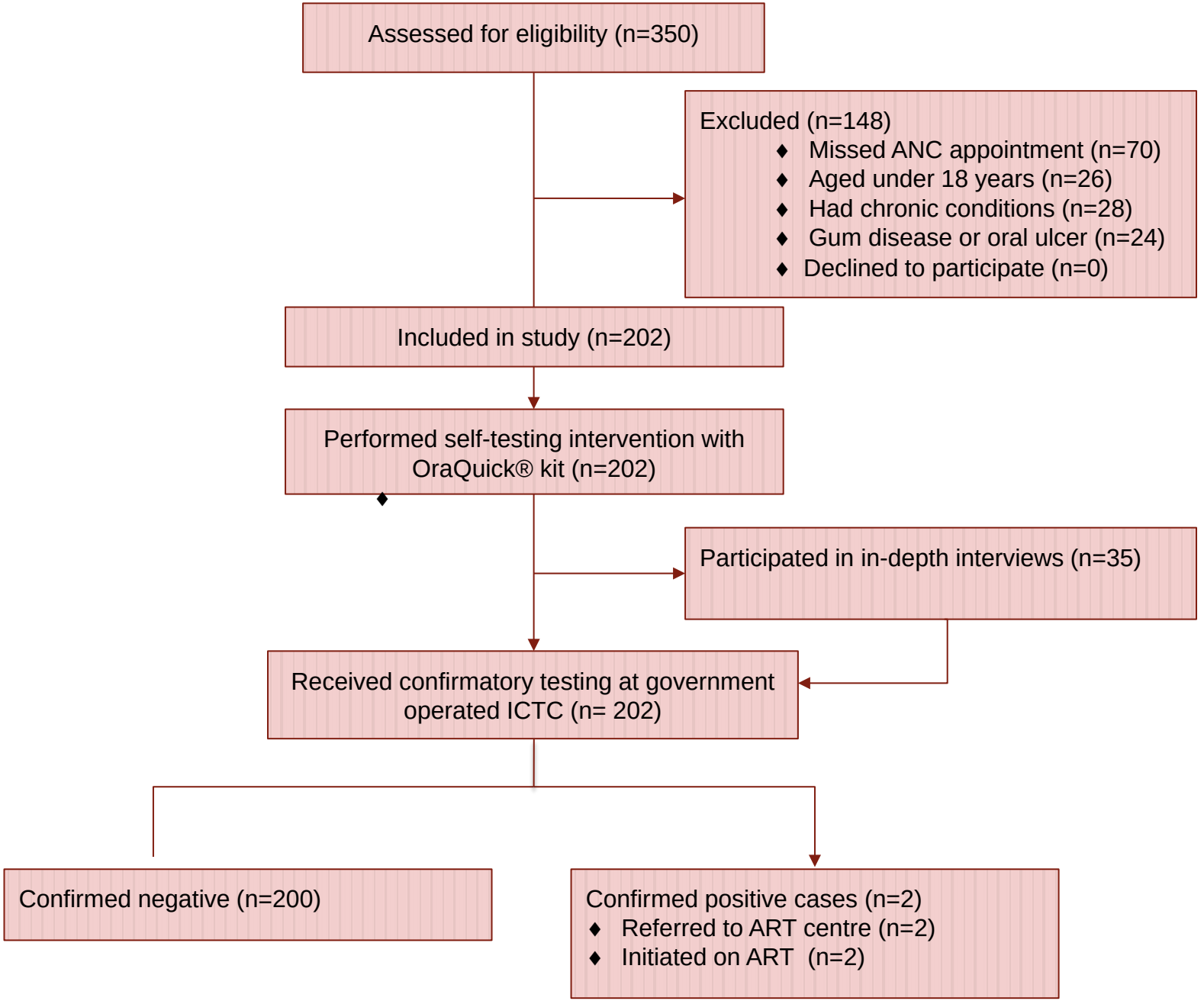
    Bleeding gums/periodontal diseases

    Abnormal vital signs

    Incapacitation to give consent

- **Pre-& Post Test Counselling:** Consenting women provided pre and post test counselling

Recruitment of Participants



Procedure of Supervised Self-Testing:

- Self-testing by OraQuick® kit explained by CHW using pictorial representation
- Women performed test under supervision of CHW
- Test results observed and interpreted first by participants and then by CHW independently
- Results confirmed by government-run Integrated Counselling and Testing Centres (ICTC) at the hospital
- Post-test counselling and linkage to appropriate care

Data Collection and Analysis

Ethical consideration

- Ethical approval obtained
- Privacy and confidentiality were maintained

Data collection

- Semi-Structured questionnaire
- Observation schedule (for the health workers)
- In-depth interviews

Analysis

- Statistical analyses: IBM SPSS Statistics V.22
- Qualitative data translated and transcripts analyzed through an inductive approach

Operational definitions

Acceptability

Proportion of uptake (%) =

$$\frac{\text{no. of those who chose to self-test}}{\text{no. of those who were offered to testing}}$$

Sensitivity and specificity parameters

Index test: Self-test result interpreted by CHW

Reference standard test: Confirmatory tests done for HIV at the ICTC

Concordance

Agreement between the test result interpretation by participant and a CHW

Quantified as percentage agreement and with the Cohen's Kappa (k) inter-rater agreement

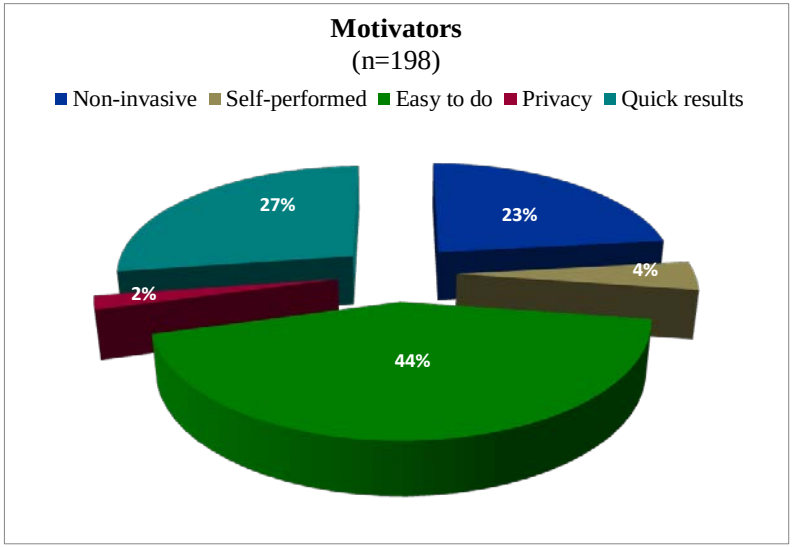
Feasibility

Assessed by the 'documented completion of self-testing and counselling processes

Results: Acceptability

- 100% pregnant women accepted the test
- 83.7% preferred oral compared to blood-based HIV tests
- 96% reported to recommend this test to other people
- 96% thought the test kits should be sold in public outlets

Main reason for liking the test (n=198)



"I liked the test as it took little time for the testing process and it gave result very quickly" (**Interview, 23-year-old pregnant woman, Parvani village**)

"I didn't have to give blood for testing, which reduced my fear and trouble" (**Interview, 23-year-old pregnant woman, Pula village**)

Concordance

- 98% concordance
- Kappa; k= 0.566, p<0.001

Inter-rater agreement between users and supervisors

Inter-rater agreement		Supervisor result			Total
		Positive	Negative	Invalid	
User result	Positive	2	0	0	2
	Negative	0	197	1	198
	Invalid	0	2	0	2
Total		2	199	1	202

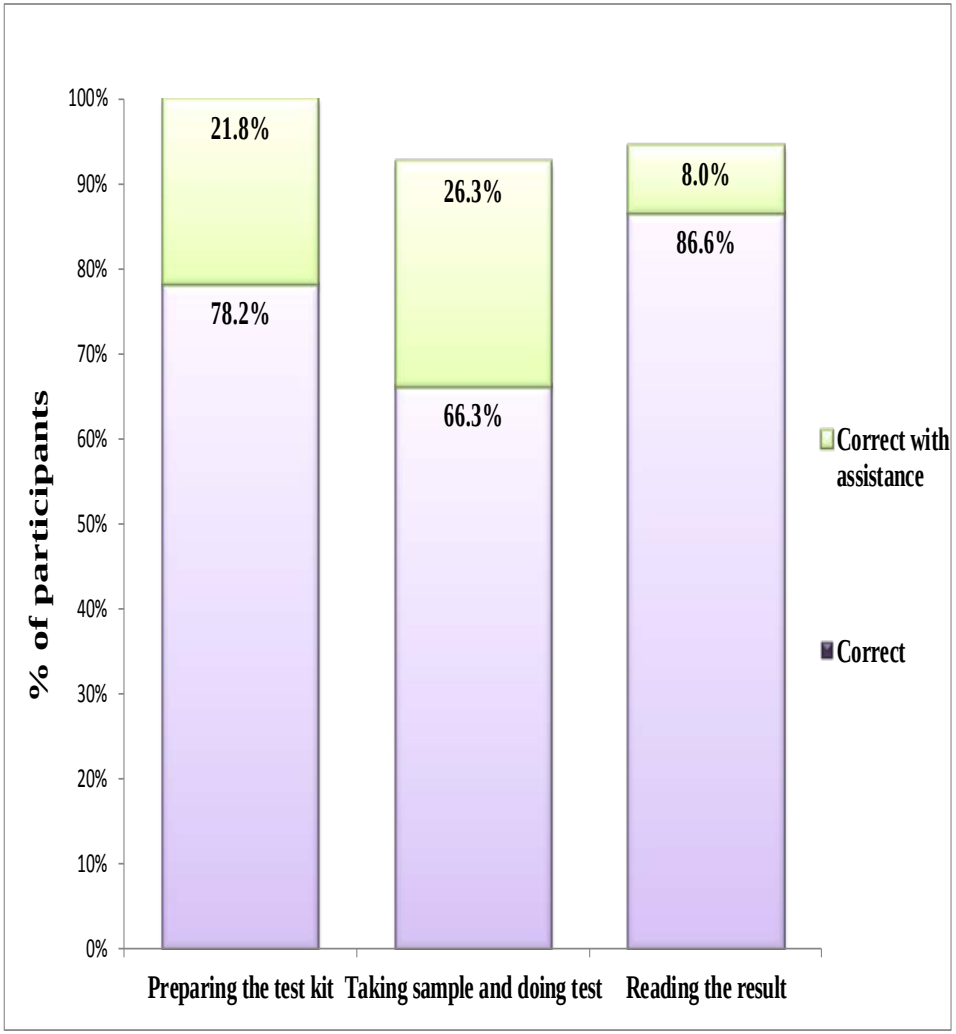
Sensitivity and Specificity

- 100% sensitivity and specificity for 201 tests
- As per CHW interpretation, two HIV positive and 199 HIV negative
- Results confirmed by ICTC
- One oral test deemed invalid by the supervisor and excluded

Feasibility

- All participants prepared test kit correctly with assistance
- 92.6% took the sample and did the test correctly
- 15% required assistance in swabbing gums; 3 did incorrectly
- 94.6% read and interpreted results correctly
- 95.5% participants reported being confident of performing test correctly

Correct test performance (n=202)



Qualitative Findings:Themes and Implications for Programming

Issue/coding concept	Major theme	Minor theme	Implications for program and research
Understanding self-testing the procedure	Clarity of test instructions	Literacy levels	Catering for illiterate populations e.g. use of pictorials
Acceptance and performance of the test	Time-efficiency	Availability of self-test kits	Some participants did not wait for required 20 minutes
	Non-invasiveness		
	Convenience	Pain less	
Interpreting the result	Clarity of instructions	Visual aids	Interventions focussing on invalid and other incorrect results
Barriers to and fear of self-testing	Fear of incorrect results		Emphasis that oral testing is a screening test critical in increasing uptake

Conclusion

- → Oral Fluid-based HIV Rapid Testing is Acceptable and Feasible
- → May provide a viable solution in resource constrained settings
- →Can utilize CHWs, rather than formally trained staff nurses
- →Ora-Quick has concordance with ICTC results in field settings
- →May strengthen implementation of Option B+ Strategy
- →Can be a useful strategy for screening in high pregnancy burden settings
- →Policy restrictions on HIV supervised self-testing
- →Further evidence needed to scale-up programmes

Way Forward.....

New HIV testing services guidelines launched in July 2015

New recommendations

1. Trained lay providers testing (*new recommendation*)

2. HIV self-testing (*implementation and monitoring*)

Currently, we are exploring use of rapid oral fluid based HIV testing by Community Health Workers (CHWs) among pregnant women as 'point of care' screening