

Acceptability of Oral-fluid rapid HIV 1 and 2 antibody test among selected key populations in Sri Lanka

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Abstract

Introduction: Oral-fluid rapid HIV 1 and 2 antibody test is recommended by WHO to be used as a “test for triage” to support expanding community-based HIV testing services among Key populations (KPs) for HIV infection such as Men who have sex with men (MSM), Beach boys (BB), Female sex workers (FSW) and Drug users (DUs)


Objective: The aim of this study was to ascertain the acceptability of oral fluid rapid HIV 1/2 antibody test (OraQuick®) among key populations receiving services under the Global Fund HIV prevention project during 2013-2015 in Sri Lanka.

Methods: Out of the total registered members of KPs (21,014), a purposive sample of 614 (MSM-185, BB-128, FSW-155, DU-146) was studied. Data collected by WHO certified community testers using three tools, i). interviewer administered questionnaire, ii) confidential oral fluid rapid HIV test and recording, iii), a self-administered feedback form.

Results: Mean age of the sample was 34 years (Mdn=32.7 years). Males, females and transgender people were 68.9%, 30.6%, 0.5% respectively. Further, 40.7% were single, 36.5% married, 11.7% living together and 11% were separated. It seems that these groups prefer both community testing (49%) as well as outreach testing by STD staff (49%). However, going to an STD clinic was preferred only by 10%. Majority preferred oral-fluid testing (88%) and finger prick testing preferred by 10.2%. Majority expected test report just after the test (88.3%). The overall satisfaction of the oral-fluid rapid HIV test by KPs was MSM 97%, BB-99%, FSW-99%, DU-99%.

Conclusions: Members of KP groups show high level of acceptability for the oral-fluid rapid HIV 1 and 2 antibody test. This type of “test for triage” approach can be used to improve the community based HIV testing in Sri Lanka.

Key words: HIV, oral fluid test, Acceptability, Sri Lanka

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Full article

Introduction

Sri Lanka is a country with low level of HIV epidemic. HIV prevalence has not consistently exceeded 5% in any of the key populations such as female sex workers (FSW), men who have sex with men (MSM), and drug users (DU). A cumulative total of 2308 HIV positive persons have been reported up to end 2015. During 2015, total of 235 HIV cases reported to the National STD/AIDS Control Programme (NSACP). In general, an estimate of 10.5 new infections occurs per week out of which, only about 4.5 new cases are reported to the NSACP. HIV prevalence in the general population is 0.02%. (1)

Sri Lanka has completed a phase of HIV prevention project from 2013 through 2015 under the support of Global Fund. During this period, HIV prevention interventions were mainly targeted at key populations (KP). The intervention included a delivery of HIV prevention package (HPP) to men who have sex with men (MSM), beach boys (BB), female sex workers (FSW), and drug users (DU). The services in the HPP is shown in Box 1.

Box 1: HIV prevention package (HPP)

1. Provision of STI knowledge,
2. Provision of HIV knowledge,
3. Provision of key population tailored leaflets,
4. Condom/dildo demonstration,
5. Provision of condoms and
6. Escorting of peers to STD clinic for HIV testing.

Those who received all 1 to 5 services in the HPP are defined as “reached”. Once the reached person is escorted to a STD clinic, they are defined as “escorted”.

This HPP was delivered to KPs through peer educators (PE) scattered in selected districts in the country. Each PE has regular contact with another 6-15 peers forming a peer group (PG). Total of 1,284 peer groups (PG) were operational at the end of 2015 (MSM 382, BB 116, FSW 374, DU 412).

However, in this model, approximately 60% of key populations in the project do not take the

escorting step for HIV testing. In this background, a national steering committee was formed to introduce an oral-fluid rapid HIV antibody test as a community based testing model to Sri Lanka. The committee decided to test its acceptability in a research model among those currently in the peer group intervention.

In the recently released WHO consolidated Guidelines on HIV Testing Services introduces a strategy to support expanding community-based HIV testing services (HTS), particularly to reach higher risk populations who may not otherwise test for HIV and link to prevention, treatment and care. (2) **Test for triage** is an approach to support community-based HTS provided by lay community providers. In this approach, trained and supported lay providers conduct an HIV rapid diagnostic test (RDT) and if reactive, the individual is promptly linked to a facility for further HIV testing where the validated national testing algorithm is performed. (2)

Therefore, the objective of the study is to ascertain the acceptability of Oral-fluid rapid HIV 1/2 antibody test (OraQuick) among key populations receiving services under GFATM HIV prevention project in Sri Lanka

Methods

Study design: descriptive cross sectional study among selected members of key population groups in Sri Lanka

Study setting: Sri Lanka has completed a phase of HIV prevention activity plan under the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) during 2013 to 2015 period which is currently continued for another 3-years under the New Funding Model (2016–2018) of GFATM.

The Family Planning Association of Sri Lanka as the non-governmental principal recipient of the GFATM grant is currently carrying out HIV prevention interventions for KPs through peer groups. Under this model, peer educators, who were persons identified as having knowledge and leadership qualities, were trained and a monthly allowance was given to

maintain an average of 8 peers (range, 1-26) forming a peer group and the model was supervised and coordinated by the other staff of the project

There were total of 1,284 peer groups (MSM 382, BB 116, FSW 374, DU 412) scattered in 13 districts in Sri Lanka covering a total peer population of 21,014.

Population: All the peers of key populations over 18 years of age and registered under the Global Fund HIV prevention project (2013-2015) and those received services were included as the population. (table 1)

Sample: A purposive sampling method was used to take sub-set of peer population. Table 1, shows the different population sizes under each key population groups and the size of the purposive sample.

Table 1. Distribution of population sizes and samples by key population groups

Category	MSM	BB	FSW	DU	Total
Peer population	4,746	2,047	5,392	8,829	21,014
Sample size	185	128	155	146	614

Data collection: Data collection for the study was done using following three tools

- **Interviewer administered questionnaire;** Questionnaire was developed in English in consultation with community groups and experts and then translated to local languages Sinhala and Tamil and pre-tested among a group of key populations.
- **Performance of oral-fluid rapid HIV test;** for this OraQuick® HIV-1/2 rapid antibody test was used, it is a qualitative immunochromatographic test for the detection of HIV 1 and 2 antibodies (Manufactured in Thailand for OraSure Technologies, Inc.). It has sensitivity of 100% and specificity of 99.87% (3)
- **Self administered feedback form;** was also developed using literature, and in consultation with subject and community experts in English language and then translated to local language Sinhala and

Tamil. Feedback form was pre-tested among a group of KPs.

Data were collected from- 10th August, 2016 to 28th October, 2016 by trained research assistants representing both community and non-community groups.

Training of research assistants: A Mixed group of individuals representing community and non-community groups were trained in a three day residential programme. All were trained to become WHO certified community testers. The training programme was conducted by an international consultant with the help of local consultants.

Data collection process: First, the study information sheet was given to study participants to read and understand or was read to participants who were illiterate. Then, informed consent was taken for the questionnaire and the oral-fluid HIV test. Participants were interviewed in a private and a confidential setting to complete the questionnaire. Then oral-fluid rapid HIV test was performed by gently swiping the test swab along upper and lower gums. Then the swab was inserted to a test tube provided with the test pack and results were read in 20 minutes and recorded. Participants were given pre- and post HIV test counseling. After the HIV test, participants were given a self administered feedback form as the final step of the data collection process.

Data analysis: All the qualitative variables were analyzed for frequencies and percentages for individual peer type (FSW, MSM, BB, DU). Percentages for the whole sample were adjusted by calculating weighted averages proportionate to the size of the population. Quantitative variables were analyzed for central tendency and variability (Range or Standard Deviation). The stakeholders wanted to have one summary measure for all four key populations. In this context, weighted average of four estimates was considered as a more reliable estimate for all key populations. Weights were given

considering the size of the peer population (MSM – 4746, BB-2047, FSW-5392, DU-8829).

Ethical considerations

Ethics clearance was taken from the Ethical Review Committee (ERC) of the Faculty of Medicine, University of Peradeniya on 21.07.2016 (project No. 2016/EC/31)

All the potential participants completed the questionnaire and the oral-fluid rapid HIV test and no withdrawals reported during the phase of the completion of the study.

Sample characteristics: Table 2 indicates the sample characteristics by different type of peer groups of key populations studied.

Results

Table 2: Sample characteristics

Mean and Median age by peer type										
		MSM		BB		FSW		DU		Total (ADJ)
Age (Years)	Mean (SD)	29.78 (9.09)		30.88 (11.84)		36.36 (10.64)		36.41 (11.84)		34.36
	Median (Range)	28 (18-68)		28 (18-69)		35 (18-65)		35 (18-67)		32.74
Socio-demographic characteristics										
Category	Level	MSM		BB		FSW		DU		Total (ADJ) (%)
		No	%	No	%	No	%	No	%	
Gender	Male	172	93%	127	99%	0	0%	127	88%	68.9%
	Female	1	1%	0	0%	152	98%	17	12%	30.6%
	Transgender	11	6%	1	1%	3	2%	1	1%	0.5%
	Total	184	100	128	100	155	100	145	100	100%
Sexual Orientation	Heterosexual	14	8%	78	63%	143	96%	110	79%	65.8%
	Homosexual	97	54%	13	11%	0	0%	7	5%	15.4%
	Bisexual	67	37%	32	26%	5	3%	20	14%	17.9%
	Other	1	1%	0	0%	1	1%	2	1%	0.9%
	Total	179	100	123	100	149	100	139	100	100%
Current marital status	Single	129	71%	60	48%	26	18%	53	37%	40.7%
	Living together	13	7%	19	15%	21	14%	17	12%	11.7%
	Married	27	15%	37	29%	68	46%	63	44%	36.5%
	D/S/W	13	7%	10	8%	33	22%	10	7%	11.0%
	Other	0	0%	0	0%	0	0%	0	0%	0.0%
	Total	182	100	126	100	148	100	143	100	100%
Employment status	Student	11	6%	0	0%	0	0%	1	1%	1.7%
	Not employed	29	16%	25	20%	78	52%	34	24%	28.7%
	Self-employed	63	35%	31	25%	27	18%	61	42%	32.7%
	Employed	63	35%	46	37%	38	25%	40	28%	29.6%
	Retired	2	1%	24	19%	2	1%	2	1%	3.0%
	Other	12	7%	0	0%	6	4%	6	4%	4.3%
	Total	180	100%	126	100%	151	100%	144	100%	100%
Level of education	Pre-school	3	2%	1	1%	3	2%	3	2%	1.8%
	Primary 1-5	11	6%	13	10%	29	19%	15	11%	11.7%
	Completed 6-10	77	42%	66	53%	72	47%	76	54%	49.3%
	Passed OL	41	22%	23	18%	35	23%	33	23%	22.5%
	Passed AL	42	23%	20	16%	11	7%	13	9%	12.4%
	Diploma	5	3%	1	1%	1	1%	1	1%	1.2%
	Degree	5	3%	0	0%	1	1%	0	0%	0.8%
	Other	1	1%	1	1%	0	0%	0	0%	0.2%
Total	185	100%	125	100%	152	100%	141	100%	100%	
District mostly lived during the previous year	Anuradhapura	26	15%	0	0%	12	8%	13	9%	9.2%
	Colombo	78	44%	24	19%	66	44%	69	49%	43.4%
	Galle	34	19%	49	40%	5	3%	15	11%	13.4%
	Gampaha	32	18%	22	18%	32	21%	35	25%	21.6%
	Hambantota	1	1%	0	0%	0	0%	0	0%	0.1%
	Kalutara	7	4%	20	16%	1	1%	0	0%	2.6%
	Kandy	0	0%	1	1%	0	0%	0	0%	0.1%
	Kurunegala	1	1%	0	0%	3	2%	0	0%	0.6%
	Matara	0	0%	0	0%	1	1%	0	0%	0.2%
	Puttlam	0	0%	8	6%	3	2%	0	0%	1.1%
	Ratnapura	0	0%	0	0%	26	17%	10	7%	7.4%
	Missing data	0	0%	0	0%	1	1%	0	0%	0.2%
Total	179	100%	124	100%	150	100%	142	100%	100%	

ADJ=Adjusted summary measure for all the groups

Multiple answer questions were used to describe the preferred method of access for an HIV test, preferred biological sample and preferred turnaround time for the test results. It shows that these groups generally prefer

community testing, testing by outreaching STD clinic staff and outreaching healthcare workers.

However, accessing to a STD clinic for an HIV test is preferred only by 10% of respondents. Most preferred sampling methods were oral-fluid test and finger prick tests. Majority preferred to receive the test result just after the test. (Table 4)

Oral-fluid HIV test results: All the study participants were offered the oral-fluid rapid

HIV test and overall 98.5% accepted the test. The prevalence of reactive test results in the sample was 1.3% (7 cases or reactive tests). Individuals with reactive HIV test results were referred to the nearest STD clinic to undergo the series of HIV test in the national algorithm for HIV diagnosis. Out of the seven reactive test results, one was found to be confirmed positive for HIV. (Table 5)

Oral-fluid rapid HIV test identified 7 reactive patients and sent them to STD clinic for HIV confirmation. However, only one was confirmed to have HIV infection among the MSM group.

Table 4: Preferred method of access for an HIV test, preferred biological sample and preferred turnaround time by the type of peer group

Variable	Variable level	MSM	BB	FSW	DU	Total sample
		(n=185)	(n=128)	(n=155)	(n=146)	
		No (%)	No (%)	No (%)	No (%)	(ADJ)
Preferred method of access for an HIV test	Going to an STD clinic	18 (10%)	13 (10%)	13 (8%)	18 (12%)	10.5%
	STD clinic staff visiting our place	92 (50%)	58 (45%)	92 (59%)	63 (43%)	49.0%
	Testing by an outreach healthcare worker	58 (31%)	29 (23%)	42 (27%)	40 (27%)	27.8%
	HIV testing in a community friendly centre	34 (18%)	9 (7%)	19 (12%)	23 (16%)	14.6%
	Testing by the Peer Educator at your place	63 (34%)	81 (63%)	68 (44%)	83 (57%)	49.0%
	Other (Specify)	11 (6%)	2 (2%)	1 (1%)	1 (1%)	1.9%
Not answered or missing values		6 (3%)	1 (1%)	3 (2%)	2 (1%)	1.8%
Preferred method of sampling	Testing by drawing a sample of blood	16 (9%)	2 (2%)	6 (4%)	12 (8%)	6.6%
	Testing by finger prick	26 (14%)	17 (13%)	12 (8%)	13 (9%)	10.2%
	Testing by using oral fluid	159 (86%)	108 (84%)	144 (93%)	127 (87%)	88.0%
	Other (Specify)	1 (1%)	1 (1%)	0 (0%)	4 (3%)	1.3%
	Not answered or missing values	8 (4%)	2 (2%)	5 (3%)	2 (1%)	2.5%
When would you prefer to get the result of the test	Within 1 week	3 (2%)	4 (3%)	10 (7%)	5 (3%)	3.9%
	Within 2-3 days	13 (7%)	16 (13%)	12 (8%)	10 (7%)	7.9%
	Just after testing	159 (91%)	104 (84%)	128 (85%)	130 (90%)	88.3%
	Total	175 (100%)	124 (100%)	150 (100%)	145 (100%)	100 (100%)

Table 5: Results of the oral-fluid rapid HIV test

Category	MSM		BB		FSW		DU		Total (ADJ)	
	No.	%	No.	%	No.	%	No.	%		
Oral-fluid rapid HIV test result	Number tested	180	97%	128	100%	151	97%	145	99%	98.4%
	Reactive	3	2%	1	1%	0	0%	3	2%	1.3%
	Non-reactive	175	97%	127	99%	151	100%	142	98%	98.4%
	Invalid	2	1%	0	0%	0	0%	0	0%	0.3%
Total	180	100%	128	100%	151	100%	145	100%		
Number confirmed with HIV	1	1%	0	0%	0	0%	0	0%	0.1%	

Acceptability of oral-fluid rapid HIV test (OraQuick) among different KP groups

The following table describes the study participants' feedback on the level of satisfaction towards the oral fluid rapid HIV testing process. The feedback given to individual statements showed that participants were satisfied with the oral-fluid

rapid test. However, some respondents had felt a pressure to get the test done (18%) and another 13% still complained that they had to wait too long even for the oral-fluid rapid test. Furthermore, about 6% did not like the test. About one fourth of MSM (28%) and BB (27%) believed that this type of HIV test is a barrier to receive other services from STD clinics. (Table 6)

Table 6: Acceptability of oral-fluid rapid HIV test

Acceptability of oral fluid-rapid HIV test										
Statement	Agree/ Disagree	MSM (n=185)		BB (n=128)		FSW (n=155)		DU (n=146)		Total sample (ADJ)
		No	%	No	%	No	%	No	%	
I would recommend this test to others as a good test	Agree	183	99%	128	100%	153	99%	145	99%	99.1%
	Disagree	0	0%	0	0%	1	1%	0	0%	0.2%
I was satisfied with the test that I received today	Agree	183	99%	128	100%	152	98%	145	99%	99.0%
	Disagree	0	0%	0	0%	1	1%	1	1%	0.5%
I felt pressured into getting the HIV test today	Agree	58	31%	30	23%	26	17%	14	10%	17.7%
	Disagree	120	65%	98	77%	128	83%	131	90%	81.0%
I do not like this type of HIV test	Agree	30	16%	5	4%	6	4%	4	3%	6.2%
	Disagree	151	82%	122	95%	147	95%	140	96%	92.3%
I had to wait too long for my HIV test result	Agree	37	20%	12	9%	22	14%	13	9%	12.8%
	Disagree	147	79%	116	91%	131	85%	133	91%	86.7%
This HIV test is a barrier to receive other services from the STD clinic	Agree	51	28%	34	27%	14	9%	20	14%	16.9%
	Disagree	131	71%	94	73%	139	90%	124	85%	81.8%
Overall, I felt that the test done today was private and confidential	Agree	165	89%	122	95%	148	95%	133	91%	92.2%
	Disagree	18	10%	5	4%	6	4%	13	9%	7.3%
I felt that my HIV test result was told to me in a private way	Agree	179	97%	127	99%	152	98%	146	100%	98.7%
	Disagree	5	3%	1	1%	1	1%	0	0%	0.9%
I understand the meaning of my HIV test result	Agree	184	99%	128	100%	154	99%	146	100%	99.7%
	Disagree	0	0%	0	0%	0	0%	0	0%	0.0%
The information I was given about HIV testing was satisfactory	Agree	183	99%	127	99%	154	99%	146	100%	99.5%
	Disagree	1	1%	0	0%	0	0%	0	0%	0.1%

Overall satisfaction of the oral fluid rapid HIV test

As the final evaluation on the level of satisfaction, respondents were asked to rate the overall satisfaction of the oral-fluid rapid HIV test. Following table shows the ratings

given by peer type. Overall satisfaction about the oral-fluid rapid HIV test had been rated "Good", "Very good" or "Excellent" by over 97% of respondents.

Table 7: Overall satisfaction

Satisfaction										
	Levels	MSM		BB		FSW		DU		Total (ADJ)
		No	%	No	%	No	%	No	%	
Overall, how is your satisfaction about this oral fluid HIV test (OraQuick test)	Poor/Fair	5	3%	1	1%	1	1%	1	1%	1.2%
	Good	35	19%	24	19%	47	31%	15	10%	18.5%
	Very Good	88	48%	21	17%	39	26%	50	34%	33.6%
	Excellent	55	30%	80	63%	65	43%	79	54%	46.8%
	Total	183	100%	126	100%	152	100%	145	100%	100%

Discussion

The national steering committee formed to introduce the oral-fluid rapid HIV antibody test wanted to look at the acceptability of the test among key populations before being introduced as a community based test (CBT). Test sensitivity and specificity was a major concern at the beginning. However, the Thailand version of this oral-fluid test (OraQuick) has 100% sensitivity and 99.87% specificity according to the manufacturers brochure enclosed with the product package. There were no results of any validation in the country. This study’s main target was not to detect new cases but to comprehend the acceptability of the oral-fluid HIV test as a community based test among key populations, which can mainly be introduced at community settings such as drop-in centres and other forms of community locations in order to reduce the testing gap.

Different types of Oral-fluid rapid HIV tests are available and its technologies are evolving. Therefore, the steering committee mainly focused at assessing the acceptability of the test hoping to replace high quality oral-fluid test in future in the country as a community based HIV test. The study showed high acceptability for an oral-fluid test of this nature and over 97% expressed satisfaction regarding the test and the testing procedure done by the trained community testers. Furthermore, participants expressed their willingness to undergo the test done by both community testers and out-reaching healthcare workers. In contrast, the access to

a STD clinic is accepted only by 10%, which reflects the need for an alternative method of testing. In this high acceptable situation, the test can also be introduced as a self-test of HIV.

Conclusion

Majority of members of the key populations has accepted oral-fluid rapid HIV test. Rating of satisfaction as good, very good and excellent were taken as expression of satisfaction and 97% of MSMs and 99% of BB, 99% of FSW and 99% of DUs were overall satisfied with the test. However, some respondents had felt a pressure to get the test done (18%) and another 13% still complained that they had to wait too long even for the oral-fluid rapid test. Furthermore, about 6% did not like the test. About one fourth of MSM (28%) and BB (27%) believed that this type of HIV test is a barrier to receive other services from STD clinics. The oral-fluid rapid HIV test can be introduced to key populations as a community based HIV test based on the acceptability and satisfaction expressed.

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