HIV oral self-screening test among HIV/STD/TB clinic attendees: A mixed-method pilot investigation examining merit for larger evaluation

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Background & objectives: Globally, several countries consider HIV self-test as an important element in the toolbox to end AIDS by 2030. Against this background, the present investigation was conducted to pilot test the performance of an indigenous HIV oral self-test (HIVOST) and explore its acceptability. The overall purpose was to examine if this kit could serve as a promising tool and merit future larger clinical evaluation.

Methods: A concurrent mixed-method investigation was undertaken during March-October 2019. One hundred and thirty two consecutive HIV/sexually transmitted diseases/tuberculosis clinic attendees were invited for participation; of whom, 100 were enrolled, and among them, 40 provided consent for qualitative in-depth interviews. The HIVOST kit assessed for its performance served as the ‘index test’, which worked on the principle of lateral flow chromatography. The results of the HIVOST were interpreted independently by the study physicians and participants at 20 min. HIVOST kit performance was assessed against the HIV confirmatory blood test result based on the national algorithm (3 rapid test or 1 ELISA and 2 rapid test) serving as the ‘reference’. Sensitivity, specificity, positive predictive value, negative predictive value and inter-rater agreement were estimated. The voices and concerns of the study participants were coded followed by identification of qualitative themes and ideas.

Results: The sensitivity and specificity of the index test at the end of 20 min as interpreted by the participants were 83.3 per cent [95% confidence interval (CI): 69.8 to 92.5] and 98 per cent (95% CI: 89.4 to 99.5), respectively. Study physicians and participants independently interpreted HIVOST results with substantial inter-rater agreement (kappa value 0.88; 95% CI: 0.78-0.97). All HIVOST test strips were valid. Majority of the participants preferred saliva over blood for HIV self-test. ‘Comfort’, ‘confidentiality’ and ‘convenience’ were the perceived advantages of HIVOST. Some of the participants wished the package inserts contained ‘how-to-do instructions in local languages’, ‘expiry date (if any)’ and ‘contact helpline number’. A few of them highlighted the need for a confirmatory HIV result following oral self-test. Concerns of the participants revolved around potential self-harm following HIVOST-positive result and safe disposal of kits.

#Equal contribution
The global goal of ending AIDS by 2030 is pivoted on achieving the targets of 95-95-95. This means, 95 per cent of the people living with HIV (PLHIV) would know their HIV status of which at least 95 per cent would be on antiretroviral therapy (ART) and 95 per cent of those on ART would attain adequate viral load suppression. To achieve the aforementioned population level targets, it is important to implement innovative testing strategies and link newly identified PLHIV to ART facilities. As one of the means to achieve the aforementioned goal, the World Health Organization (WHO) disseminated HIV self-testing guidelines in 2016 for its use as screening test. Noticeably, HIV self-test is a process in which a person collects his or her own specimen (oral fluid or blood) and then performs a test and interprets the result, often in a private setting, either alone or with someone he or she trusts.

The National AIDS Control Programme (NACP), India, established in 1992 is committed to the worldwide initiative of AIDS elimination. The challenge, however, rests with the existing reach of NACP, which is witnessing the ‘last mile coverage’ as difficult. Currently, of the estimated 2.14 million PLHIV in India, 1.58 million (74%) have been detected, and of these, only 56 per cent are on ART.

The International Centre for AIDS Care and Treatment Program (ICAP; Columbia University, New York, USA) highlighted the importance of various testing strategies around social network, provider’s initiative, index client paired with partner notification services, new-borns and HIV self-testing. It maintains that HIV self-screening, as a tool, would have the potential to promote uptake of a subsequent confirmatory diagnostic test. Nevertheless, different country-specific programmes are in different stages of acceptance of HIV self-test, and India is yet to make such an approach integral to the NACP.

Currently, HIV self-test kits are not commercially available in India. To date, only a few studies have been conducted among the general population in the country using OraQuick Rapid HIV-1/2 (OraSure Technologies Inc, USA) test as point-of-care testing for HIV. This has received approval by the United States Food and Drug Administration. Two studies, conducted in Maharashtra, used OraQuick ADVANCE Rapid HIV-1/2 Antibody Test (OraSure Technologies Inc, USA) among inpatient and outpatient attendees, as well as women in active labour. The stated objectives of these studies were (i) impact of introducing the kit, (ii) client preference for oral fluid-based testing, and (iii) diagnostic accuracy of the kit. These investigations highlighted the preference for oral fluid over finger-prick blood as the test specimen among the study participants.

Against this backdrop, the current pilot study was conducted to assess the performance and acceptability of an indigenous HIV oral-self-test (HIVOST) kit. The manufacturer developed this tool as a screening test, based on lateral flow chromatography as elaborated below. An initial assessment report shared by the manufacturer with the current investigation team claimed that a small group of all known HIV-seropositive as well as seronegative individuals were detected appropriately with the kit. The present study therefore examined if the kit performed well while being assessed through a blinded pilot procedure and could merit a larger clinical evaluation.

**Material & Methods**

We conducted a mixed-method investigation. The performance assessment of the indigenous HIVOST was conducted as a small-scale pilot study through quantitative inquiry. A concurrent qualitative investigation explored the perception around and acceptability of the HIVOST (the guides and probes used are provided in the online supplementary file) among study participants. Approval from the Institutional Ethics Committee of the ICMR-National AIDS Research Institute (ICMR-NARI), Pune, India was obtained before recruitment of the study participants.

**Study setting and participants:** This investigation was conducted in the district of Pune in the western State of
Maharashtra, India. Three clinics, one located within the premise of ICMR-NARI, the other at Aundh Chest Hospital (ACH) and the third at Dr Kotnis Municipal dispensary-Gadikhana (GDK), served as recruitment sites. Participants were attendees of HIV, sexually transmitted diseases and tuberculosis (HIV/STD/TB) clinics. Consecutive adult clinic attendees, aged 18 yr or above, were invited for participation and were recruited following written informed consent. A total of 132 participants were included in the study; of whom, only 100 could be enrolled from March to October 2019. The enrolment algorithm is presented in Figure 1.

**Participant recruitment and data collection:** The present pilot investigation involved a small sample size as it was an initial exploration of the utility and merit of the HIVOST kit. This study followed a patient-control approach in a setting where attendees would be suspected of having the disease or the absence of it (binary outcome) based on a valid test strip result. Consecutive adult clinic attendees, aged 18 yr or above, were invited for participation and were recruited following written informed consent. A total of 132 participants were included in the study; of whom, only 100 could be enrolled from March to October 2019. The enrolment algorithm is presented in Figure 1.

Of the above mentioned study participants, 40 clinic attendees (20 HIV-seroreactive and 20 HIV-seronegative) were invited for face-to-face qualitative in-depth-interviews (IDIs) as well. Apart from a male and a female study physician (trained in community medicine), the rest of the research team had three male and two female members. The entire team was trained on the applicable research methodology. The study physicians, along with the participants, remained blinded about confirmatory HIV blood test results while reading and interpreting HIVOST strips. The operational definition of acceptability, used by us, referred to determining how well an intervention would be received by the target population and the extent to which the new intervention might meet the needs of the target population and organizational settings.

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**Fig. 1.** Enrolment algorithm of the participants. ACH, Aundh Chest Hospital; GDK, Gadikhana Clinic; HIVOST, HIV oral self-test; ICMR-NARI, ICMR-National AIDS Research Institute.
Study tools: The IDI guide, used for qualitative investigation, was finalized based on inputs obtained through pilot testing and team discussions. Interviews conducted before the HIV self-test explored various issues such as health-seeking behaviour, prior HIV test experience, preference for HIV self-test specimen (blood vs. saliva), advantages of HIV self-test and apprehensions. Other issues comprised various aspects of the HIVOST kit such as packaging and presentation, information to go with the kit, procedure and place, preferred kit outlets and cost, potential misuse and potential social harms.

Index test: The HIV oral self-screening test named Morcheck, a product of Morsef Life Sciences LPP, Mumbai and manufactured by Bhat Bio-tech India (P) Ltd., Bangaluru, India assessed during this investigation, was based on the principle of lateral flow chromatography. The kit had an oral brush to collect saliva by swabbing the upper and lower gums. The saliva-soaked brush was inserted in a test tube containing a buffer solution, in which it was moved up and down 6-8 times. The fluid from the oral brush was squeezed by pressing it against the inner wall of the test tube following which the brush was removed. Next, the test strip was vertically inserted in the test tube as indicated by arrow marks pointing downwards. The result on the strip was interpreted at 20 min and not later than 45 min (as instructed in the package insert). While appearance of a control (C) line on the strip would indicate that the test was valid, HIV seroreactivity would be indicated by appearance of another line termed as test (T) line. In case of non-appearance of the C-line, a strip would be considered invalid regardless of the presence or absence of a T-line.

Reference test: The national HIV test confirmation guideline was followed by the clinic counsellors. This required using either (i) three rapid tests or (ii) one enzyme-linked immunosorbent assay (ELISA) and two rapid tests for the detection of HIV-1 and HIV-2 antibodies in the blood13. Each of these assays employed different antigenic principles for antibody capture. Each participant had provided blood specimen for confirmatory HIV test earlier to participation in the present investigation.

Study implementation: Since most of the individuals willing to know about their HIV status would consider healthcare workers as someone trustworthy2; index test results were read independently but simultaneously at the end of 20 min by both participants and study physicians. As the maximum time limit for test strip result read out was mentioned in the package insert as 45 min, the study physicians assessed if the performance of the test kit changed by any considerable extent while interpreted at the longest permissible time interval. On the other hand, the participants attended the study clinics to receive a confirmatory HIV blood test result and were scheduled for counselling sessions. Therefore, they were not withheld for longer time period observations. After reading HIVOST strip at 20 min, participants moved on to receive confirmatory HIV blood test results and counselling. Among 100 individuals participating in index test assessment, 40 were willing to participate in qualitative IDIs. Data saturation was achieved with these interviews14, which were conducted in local languages (Hindi or Marathi). Each of these IDIs lasted for approximately one hour and 20 min and was conducted before and after HIVOST procedure by a participant. The IDIs were audio taped following a written informed consent from the study participants and later transcribed to exact verbatim and then translated into English. Quality check was conducted periodically by the interviewers (study physicians) and the study supervisor.

Data analysis: Descriptive statistics were used to present participants’ profiles and to estimate the sensitivity, specificity, positive and negative predictive values of the index test. Quantitative data were analyzed using Microsoft Excel (Microsoft Corp., USA) and Statistical Package for the Social Sciences (SPSS) Version 15.0 (SPSS for Windows, IBM® , USA).

Qualitative data were first coded and then aggregated to create appropriate major or minor categories (themes), which in turn were synthesized into ideas. This was carried out by the two study physicians with assistance from the research supervisor. Team meetings were held at regular intervals to resolve coding discrepancies between research team members. In vivo coding followed by content analysis helped in capturing the voices and concerns of the study participants. N-vivo software (version 11, QSR International, Australia) was used for qualitative data management.

Results

Participants undergoing HIV oral-self-test (HIVOST): The mean and median age of the study participants was 35 and 34 yr, respectively (standard deviation ± 10.7;
minimum 20 yr, maximum 65 yr); 56 per cent (56/100) were male. Twelve per cent of the participants never attended a school and a third were not involved in any income generating activity.

**Index test interpretation by study participants:** All HIV self-test strips used for the assessment were valid as indicated by the appearance of C-line. Two of the clinic attendees could not comprehend the test procedure, and descriptive statistics were therefore generated from the results obtained from 98 participants (48 confirmed HIV seroreactive and 50 sero-negative). The index test at 20 min in the hand of the participants (Table) had a sensitivity of 83.3 per cent (95% CI: 69.8-92.5) and specificity of 98 per cent (95% CI: 89.4-99.5). Positive predictive value (PPV) of the index test at 20 min was estimated to be 95.2 per cent (95% CI: 83.6-98.7) and negative predictive value (NPV) was 85.7 per cent (95% CI: 76.1 to 91.9).

**Index test assessment by physicians:** HIVOST strip results interpreted by the study physicians at 20 min were contrasted against the confirmatory HIV blood test results (Table). Of the confirmed 48 HIV-seroreactive individuals, three were interpreted as negative by HIVOST, resulting in a sensitivity of 93.8 per cent (95% CI: 82.8 to 98.7). All 50 confirmed HIV-seronegative clinic attendees were detected as negative on HIVOST strip by the study physicians, giving rise to an estimated specificity of 100 per cent (95% CI: 92.9 to 100). Inter-rater reliability between participants and study physicians on index test results was high (kappa = 0.88; 95% CI: 0.78 to 0.97). The PPV of the index-test at 20 min at the hand of physicians was estimated to be 100 per cent and the NPV was 94.3 per cent (95% CI: 84.8 to 98.0). While the study physicians interpreted each HIVOST strip at the end of 45 min, the sensitivity of the index test increased to 95.8 per cent (95% CI: 85.8 to 99.5; 46/48), as the test line took time to be visible on one of the used strips and specificity remained unchanged at 100 per cent. Since the study participants were scheduled for post-test counselling, they were not withheld for observation at the end of longer time interval.

**Qualitative investigation:** The age of IDI participants ranged from 22 to 59 yr; 65 per cent (26/40) of the interviewees were male. At the time of this investigation, two-third of the IDI participants were married, 12 unmarried and three were widows. Most of the interviewees (32/40) had some income-generation activities such as farming, driving, working as a security guard and engagement in private companies. Half of the women participants were homemakers. Eagerness to receive information about a new HIV test approach prompted most of them to take part in this investigation.

**Prior HIV test experience vis-a-vis self-test:** Facility-based prior HIV test experience had a bearing on the perception of participants about HIV self-test; fear of getting identified, lack of confidence in the way things were handled (syringe and needles, report management) and delay in obtaining results at government facilities reflected some of the concerns. Non-availability of pre- and post-HIV test counselling services at private clinics was highlighted as a deficiency by a few of the participants.
‘It (HIVOST) is so simple... do these steps and you will get the result then and there; and your health is in your hand...this slogan can be put up there’, (NARI 010, 59 yr, male).

‘There is only one flaw, the required time that is there...20 min ...that is too much ...that (HIVOST) should give you result in two minutes’, (NARI 010, 59 yr, male).

Although the perception about ease of undertaking HIV self-test did not change following actual experience, contrasting it with urine pregnancy test, two of the participants found HIVOST cumbersome.

‘Like a pregnancy kit, when two lines are seen, it is positive, and when one line is there, it is negative. So, if it is like this, then a person can understand’, (NARI 005, 25 yr, female).

Choice of specimen: Ease of using saliva compared to blood, quick result, ability to do the test by self and fear associated with a needle were behind the preference of some of the participants for saliva over blood. Those who preferred a test with blood as a test specimen over saliva did so considering blood as the body tissue where HIV resided and the scope for conducting additional investigations with blood. A few of the participants added that (i) confirmatory blood test would be required following HIVOST, and (ii) a negative result may lead to a false sense of security and increased risk taking.

‘No... I think blood test would be better than the one with saliva...we will trust blood, right...it is for sure... virus is in the blood’, (NARI 064, 26 yr, male).

‘Blood test will be the simple one, means we can check it just by one prick. It will give you proper result...it would be simple...normally, we do the same for sugar test also, and we can do it for this as well’, (NARI 014, 26 yr, male).

Some of the study participants who thought that blood would be better for HIV self-test than saliva, however, changed their opinions after undertaking HIVOST as they found it convenient.

Kit-related reflections: On presentation of the HIVOST kits, participants were encouraged to reflect on the four domains during IDIs: (i) information to go with the kit and packaging, (ii) preferred place to do HIV self-test, (iii) appropriate kit outlet, and (iv) cost considerations. Most of them considered it as a screening test and cited examples of self-test for pregnancy and diabetes during discussion. They also mentioned about the need for undertaking a confirmatory test. The importance of creating awareness around HIV self-test was highlighted by a few and some others suggested to have information on the ‘expiry date’ written on the kit. Counselling services, 24 h help line and opportunity for face-to-face interaction following a positive HIV self-test result were also suggested.

‘It should mention validity (expiry) date, etc...if at all there is any’, (NARI 003, 24 yr, male).

‘Um...service meaning...what you can do here is that you can write a note saying “these are not the final results”...the kit...I mean, the way it is for results - I mean SSC (secondary school certificate, 10th standard examination) results that we check online, SSC-HSC (higher secondary certificate, 12th standard examination) results... and if it is not there, it does not say “you have failed”... it says that you should contact your college’, (NARI 004, 25 yr, male).

‘Yes, information means where to go... there should be a helpline number to contact’, (GDK 004, 47 yr, female).

Majority of the participants raised concern around the word ‘HIV’ written on the kit and felt that it should have been masked. The necessity of using local language with the kit was also highlighted. Other suggestions included ‘step-by-step pictorial instruction’, ‘advertisement’, ‘videos on social media’, ‘live demonstration in health camps’ and ‘face-to-face interaction’.

‘Like the advertisement of condom was there...then, how have they done marketing? Asking for condom is difficult... so just ask for KS (Kama Sutra), so people, the guy will understand and you will also get what you want... right? So, asking for it...Sir please give me this HIV kit...that is asking for... that is very difficult... but, for example, if you give a simple name like xxxx...it will be easy...right?’, (NARI 012, 31 yr, male).

‘If I understand it (how to do HIVOST), I can explain it to others, and then, the other person can also do it (to others)’, (NARI 002, 29 yr, male).

‘Visual and reading instructions...I mean there should be some symbols and some written instructions to visualize, as if we are reading any food recipe...do this, then do that, etc...that type would be of great help’, (NARI 007, 24 yr, male).
Being asked about the preferred kit outlets, the participants kept ‘comfort’, ‘convenience’ and ‘commonly visited places’ as key considerations. Most of them mentioned medical shops and government hospitals as the place of choice for procurement of HIVOST; ‘colleges’, ‘vending machines’ and ‘shopping malls’ were other innovative suggestions around kit outlets.

‘That time people make mistakes (sexual activity) because of their immaturity…therefore, it is necessary to make it available in the colleges’,
(NARI 005, 25 yr, female).

‘Government hospital will be the first priority… but after that there are anganwadi centres (rural child care centre in India) and places where due to government programmes people from low socio-economic groups go’,
(ACH 006, 33 yr, female).

‘When you put five rupees coin, means in the machine…if such machine is there in small government dispensary… it will be beneficial… or at bus stop’,
(ACH 014, 26 yr, male).

Being asked about an acceptable cost for oral HIV self-test kit, the participants mentioned that poor would benefit if it were given free of cost. However, some of them highlighted that if the kits were made available free of cost, then people would not value it. We also encountered a rare point of view from a participant who mentioned

“Because they (manufacturers) are producing it, they must make some profit out of it, isn’t it”,
(NARI002, 29 yr, male).

Most of them suggested a price tag ranging from INR 50 to INR 150 (US$ 0.66 to $2).

The abstraction matrix (Fig. 2) presents voices of participants pertaining to different domains such as service needs (perceived as necessary), apprehensions and suggestions for future improvements. In addition, we also captured their post-HIVOST experience.

**Discussion**

The Gap Report published by the Joint United Nations Program on HIV/AIDS (UNAIDS) highlighted that globally about half of the PLHIV were unaware of their HIV status. In India, this estimate is about 20 per cent of the total estimated number of PLHIV.
in the country. Furthermore, the declining trend of new HIV infections detected every year in India has now halted\(^{16}\). Meanwhile, the narratives around rights to health have underlined the access to HIV tests as one of the core service components\(^{17}\). Against such background, the present investigation has generated important public health evidence. The uniqueness of this study rests with its concurrent mixed-method approach. We juxtaposed data generated on the performance of an indigenous HIVOST next to the voices of people, who could be its potential users.

The major challenge for India in achieving the goal of ending AIDS by 2030 is to encourage and assist people in knowing their HIV status so that those who are infected and yet unaware could in turn be linked with ART services, which in turn would help in achieving adequate suppression of viral load and eventually break the chain of transmission. Studies on the acceptability and accuracy of HIVOSTs from India are sparse. Most of the investigations\(^{9,18}\) used OraQuick, a point-of-care test, manufactured by OraSure technology, which was evaluated in other developing and developed country settings as well\(^{19,20}\).

In the current study, HIV/STD/TB clinic attendees undertook the HIVOST, and majority of them considered it to be a useful screening tool. Such findings were in line with another study conducted in Pune where a prototype HIVOST kit was presented to the truckers and young adults (18-24 yr) to facilitate interactions\(^{21}\). A study on HIVOST kit also underlined similar acceptability among peer educators and female sex workers in the red-light area of Pune, India; no prototype HIVOST kit was placed in front of the participants during this inquiry and HIV self-test concept was rather explained verbally to them\(^{22}\).

The observed difference in sensitivity and specificity derived from the interpretation of test results by the participants vis \(a\) \(v\) study physicians in the present investigation could probably be explained by the prevailing anxiety among the study participants, which might have influenced their ability to read test strips. A study conducted in Ethiopia for the evaluation of an oral fluid-based OraQuick HIV self-test kit (OraSure Technologies Inc., USA) revealed that 399 out of 400 participants could interpret the results\(^{23}\).

In the present study, the first HIV self-test experiences of the participants were explored during the IDIs. Comfort of private space, convenience, ability to do the HIV test by oneself and quick results were some of the perceived advantages of HIVOST. Saliva was preferred by most of the participants compared to blood, while a few others focussed on the accuracy of the test rather than the type of specimen to be used. Similar findings emerged from a teaching hospital-based investigation, where 74 per cent of the women in active or early labour located in the district of Wardha, Maharashtra, preferred saliva over blood\(^{7}\).

Most of the clinic attendees wished to have pictorial instructions, video clipping-based explanation or physical assistance with the HIV self-test. After using index HIVOST, some of the participants, however, changed their opinions about it as they found it easy to use and interpret and felt that no assistance would be required to take this test by oneself. A mixed-method study conducted among pregnant women registered at Kasturba Hospital, Maharashtra, echoed similar expressions while OraQuick HIV self-test (OraSure Technologies Inc., USA) was used\(^{24}\).

Chemist shops, hospitals and clinics were cited as potential kit outlets by the study participants during the present investigation. Vending machines in college premises and online availability featured as two rare but innovative suggestions in this regard. In Brazil, internet-based facilitation of HIV testing was found acceptable among men having sex with men\(^{25}\). The preferred cost of the kit which suggestively emerged through the present study was between US$ 0.6 to 2, which was similar to the findings from South Africa and Kenya\(^{26,27}\).

HIV self-test was brought to the centre stage of discussion by UNAIDS nearly a decade ago\(^{28}\). However, many countries including India are still weighing the pros and cons of its introduction in their respective national programmes. Arguments contributing to such quandary around HIV self-test comprise (i) accuracy of the results, (ii) probable psychological impact following testing without counselling, (iii) difficulty in referral for treatment and care, (iv) unethical use of HIV self-test, (v) concerns around kit disposal, and (vi) justification for unprotected sex\(^{17}\). We came across some of these issues raised by the participants during the current study. In an earlier investigation, similar apprehensions were expressed by the transgender population and men having sex with men in Pune\(^{29}\) all of whom provided rich inputs for appropriate intervention planning. On a different note, with the prevailing COVID-19 pandemic and the number of attendees at the integrated counselling and testing centres and
targeted intervention sites dwindling, United States Center for Disease Control has encouraged those at risk to undertake HIV self-test and subsequently link them for confirmatory diagnostic tests followed by treatment and care services\textsuperscript{29}. As indicated by the evidence generated through this small-scale pilot investigation on the indigenous HIVOST, a future large-scale evaluation is merited. Noticeably, this index kit was earlier assessed for its acceptability among most at risk population groups\textsuperscript{21,29} in India. The small sample size of the current pilot investigation is its major limitation. Hence, a larger evaluation with adequate power to determine if this kit could be considered relevant for the national programme is necessary. The findings of the qualitative component of this investigation cannot be generalized across all population groups as it was specific to the clinic attendees in Pune.

Overall, the present investigation revealed a high inter-rater agreement in interpretation of HIVOST results between the participants and study physicians, which was reassuring. However, the maximum time interval of 45 min for read-out should be underlined as the waiting time before interpreting HIVOST results. Majority of the participants in the current investigation found HIV self-test acceptable. This and the earlier investigation findings around the index test underline the necessity for a larger clinical evaluation and subsequently examining relevance of it for the NACP in India. Furthermore, creation of a supporting environment to facilitate evaluation of various HIV self-screening test kits in the country would be helpful.

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**Conflicts of Interest:** None.

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Supplementary material

Interview Guides

In-Depth Interview Guide for clinic attendees

Site ___________ Gatekeeper organization________________ Location ________

Date DD MM YYYY

Start Time

End Time

“Can I seek your permission to switch on the tape-recorder for recording our conversations so that I don’t miss out on anything and play it later to listen to our conversations and learn from them.

(ENCIRCLE BELOW THE RESPONSE FOR RECORDING AS APPROPRIATE)

Yes

No

Start Recorder if permitted and Read Introduction:

My name is _________________ (Name of the moderator) and his / her name is __________________ (Name of the note-taker). We will conduct your interview together and keep notes in addition to recording your responses.

Before we begin we would appreciate it, if you could please share something about yourself:

• How old are you? …… (Age in completed years)
• Have you ever attended school? -----------------
• Which class did you pass in school ? ----------------
• What do you do for a living ? ______
• How much money do you make in a month (in Rupees)? __________
• How long have you been staying in the location where you currently reside? ______

We are interested in knowing your views about issues that will be asked. Please note that there is no wrong or right response. If there are any apprehensions that you would like to talk about you may bring them up even if we haven’t asked them. If there is any question that you would like to ask I would take a note of them and answer them after this interview. If we are unable to answer any of the questions we would refer them to an appropriate person.

As mentioned earlier, the main goal of this discussion is to understand acceptability of oral HIV self-test. We want to remind you that what we discuss here will be kept confidential, and that we will not share your personal information or responses with anyone outside of the study.

(ENCIRCLE BELOW THE RESPONSE FOR RECORDING AS APPROPRIATE)

1. YES
2. NO

If he say “NO” may I know your reasons for declining__________________________

Thank you for your response
| IDI Guide (for clinic attendees) |
|---------------------------------|
| **1. How comfortable were you in accepting my invitation for participation in this study?**  |
| **Probes**                      |
| Why do you feel it was important for you to participate? |
| What benefits do you see of participating? |
| **2. Where do you currently go to seek health care services?**  |
| **Probe**                       |
| Which facility do you go to? Why? |
| Please elaborate the reasons for preferring this facility/these facilities |
| Did you ever take an HIV test before? |
| If ‘yes’, do you think that had an HIV self-test have been available at the time when you took the HIV test for the first time it would have been useful -please elaborate |
| If ‘no’ why did you not take an HIV test |
| How useful do you think an HIV self-test would be to you? |
| **3. Did you know about HIV self-test earlier than today’s discussion-how did you come to know?**  |
| **Probes**                      |
| Do you think that making an HIV self-test available would be of any help to people? |
| Please elaborate why do you think so? |
| What problems do you think people would face to go and take an HIV test from a government facility? |
| What is the fear in it? |
| **4. (You said an HIV test would be valuable)-IF SAID IT WOULD NOT BE VALUABLE OR USEFUL DURING DISCUSSION AROUND GUIDE 2 ABOVE-DO NOT ASK THIS- which one would be more acceptable-blood based or oral fluid based?**  |
| **Probe**                       |
| -Why do you say so? |
| **5. If any HIV self-test is made available (show the kit) will you take the test and do it yourself? )-IF SAID IT WOULD NOT BE VALUABLE OR USEFUL-DO NOT ASK THIS**  |
| **Probes**                      |
| Please help me understand your concerns |
| What is the fear? |
| What would you require for taking such a test? |
| **6. Would you like someone to show how to use the HIV self-test, which I am talking about?**  |
| **Probes**                      |
| Why do you ask for such assistance? |
| What type of assistance would you like - picture, mobile clipping, and individual showing you how to do it? |
| How could this method be improved? |
| **7. Where do you think you or your friends would like to take the test? IF SAID IT WOULD NOT BE VALUABLE OR USEFUL DURING DISCUSSION AROUND GUIDE 2 ABOVE -DO NOT ASK THIS**  |
| **Probe**                       |
| Why do you think such a place would be preferred? |
| **8. If you think this test is made available in the market, where would you like them to be available?**  |
| **Probe**                       |
| Please tell me the reasons- why did you say what you said? |
| **9. What are your concerns regarding this test?**  |
| **Probe**                       |

*Contd...*
| IDI Guide (for clinic attendees) |
|----------------------------------|
| Do you think there would be any difficulty in reading the result? |
| Do you think other support services would be necessary (please elaborate)? |
| Do you foresee any individual risk (please elaborate)? |
| Do you foresee any social harm (please elaborate)? |
| Do you think, some people could use this test in a wicked way? |
| **10. If this test is made available, do you think there should be a cost attached to it?** |

**Probe**

What do you think should be an appropriate cost per test kit?

---

This is an oral HIV self-test kit which is now available to you free of cost. I would now like to introduce you to a study team member who will demonstrate and assist you to use the oral HIV self-test. Are you willing to try this test out here?

(ENCIRCLE BELOW THE RESPONSE FOR RECORDING AS APPROPRIATE) Date __________

1. Yes
2. No
3. If ‘yes’ start the time of HIV self-test ------------------
4. End time ------------------
5. Interpretation of the HIVOST result by the participant ------------------
6. Interpretation of the HIVOST by the person accompanying the participant ------------------

If ‘No’ (can you please tell me the reasons for not taking this test)
Did you ever use an HIV self-test before (if yes what type of test -please describe)

1. Did you find this test useful
   Probes
   - How did you feel?
   - What are the advantages you felt?
   - Is there any disadvantage – Why so ?
   - Was it necessary to show you how to use the test?

2. What were the difficulties faced by you while doing this test ?
   Probes
   Do you think other support services would be necessary ?
   Do you foresee any personal risk ?
   What type of assistance you think one would require ?

3. Was there any difficulty in interpreting the results of this test?
   Probes
   Why do you say so?
   What type of assistance you think one would require ?

4. Do you have any suggestions for improvement in this?
   Probes
   Anything else ?
   Who do you think should do such things?

5. What is your overall concerns around this test?
   Probes
   Do you foresee any danger ?

6. How were the photos explaining the test on the page that came in the packet?
   Probes
   Any scope for improvement
   Would a different method be helpful
   Please explain

7. Would you recommend this HIV self to any of your family members?
   Probes
   - If “yes” when are you going bring/refer……
   -Do you want me to call you for this extended help…
   -If “yes” when should I call you ------------------(at which number-----------------------------)

8. Would you recommend this HIV self to any of your family members?
   Probes
   - If “yes” when are you going bring/refer…..
   -Do you want me to call you for this extended help…
   -If “yes” when should I call you ------------------(at which number-----------------------------)

9. Would you like to say anything to me that you did not say earlier during our conversation

10. Date of receiving HIV blood test result _______

11. Date of linking the person with HIV treatment facility (as needed)_______