

Community-based point-of-care testing to identify new HIV infections

A cross-sectional study from Pune, India

Megha Mamulwar, MD^{a,*}, V. Sam Prasad, MBBS, MAPP^b, Amit Nirmalkar, MPhil^a, Sarita Goli, MSW^a, Sachin Jadhav, MSW^a, Shamali Kumbhar, MSc, DMLT^a, Varsha Kale, MSc^a, Elizabeth Michael, MA^b, Teresa Marie Ford^b, Denys Nazarov, MA^b, Lyle Honig, BBA^b, Raman Gangakhedkar, MPH^a, Madhuri Thakar, PhD^a

Abstract

The World Health Organization recommends point-of-care testing (POCT) to detect human immunodeficiency virus (HIV) infected individuals in the community. This will help improve treatment coverage through detection of HIV infection among those who are unaware of their status.

This study was planned with an objective to investigate the feasibility and acceptability of POCT for HIV in the community.

A community-based cross-sectional study was conducted in rural and peri-urban areas of Pune, India. These sites were selected based on the distance from the nearest HIV testing center. Testing locations were identified in consultation with the local stakeholders and grass-root health workers to identify and capture the priority population. The POCT was performed on blood samples collected by the finger-prick method.

The proportion of participants seeking HIV tests for the first time was 79.6% that signifies the feasibility of POCT. The acceptability in the peri-urban and rural areas was 70.2% and 69.7%, respectively. POCT was performed at construction sites (24.9%), nearby industries (16.1%) and parking areas of long-distance trucks (8.1%) in the peri-urban area. Three newly diagnosed HIV-infected participants (0.1%) were detected from the peri-urban areas but none from the rural areas. Two of the newly diagnosed participants and their spouses were linked to care.

There was a high acceptability of POCT and wider coverage of priority population with a strategy of testing at places preferable to the study population. Therefore, we believe that community-based POCT is a promising tool for improving HIV testing coverage even in low prevalence settings with the concentrated HIV epidemic.

Abbreviations: ART = antiretroviral therapy, ARTC = antiretroviral therapy center, ANM = auxiliary nurse midwife, ASH = accredited social health activist, AWW = Anganwadi Worker/government appointed preschool teacher, ELISA = enzyme linked immunosorbent assay, FSW = female sex worker, HIV = human immunodeficiency virus, HTS = HIV testing services, ICTC = integrated counselling and testing centers, LHV = lady health volunteer, MPW = multi-purpose worker, MSM = men having sex with men, NACP = National AIDS Control Program, NFHS = national family health survey, PHC = primary health center, PLHIV = people living with human immunodeficiency virus, POCT = point-of-care testing, TG = transgender.

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^a ICMR National AIDS Research Institute, Bhosari, Pune, India, ^b AIDS Healthcare Foundation, New Delhi, India.

* Correspondence: Megha Mamulwar, ICMR National AIDS Research Institute, 73, 'G'-Block, MIDC, Post Box No: 1895, Bhosari, Pune 411 026, India (e-mail: mmamulwar@nariindia.org).

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1. Introduction

Globally 35 million people are infected with human immunodeficiency virus (HIV) and only 48% of these are aware of their HIV status.^[1] In view of the 95-95-95 goal set for 2030, there is a need to improve HIV testing coverage that would be a gateway to care and treatment.^[2] Community-based HIV point-of-care testing (POCT) along with the facility-based testing has been recommended to reach out and identify 52% of people living with HIV (PLHIV), unaware of their HIV status globally. The World Health Organization guidelines on HIV testing services recommend use of community-based HIV POCT, along with linkage to care, particularly for the at-risk groups.^[3]

POCT has the advantage of providing test reports within few minutes as compared to the standard integrated counselling and testing center (ICTC) based approach.^[4,5] The performance of POCT is comparable with enzyme linked immunosorbent assay (ELISA), which has good sensitivity and specificity. It does not require any skilled person to perform the test, thereby enhancing access to HIV testing in resource-limited settings.^[6] A highly mobile population such as long-distance truckers are known to prefer free POCT along the roadside.^[7] This test is useful for the

detection of new HIV-infected cases especially in an area with limited coverage of clinic-based HIV testing.^[8] The distance from the testing center, time and cost of these tests should be minimum for its successful offer to the high-risk groups.^[9,10] Knowledge about HIV testing availability plays an important role in accessing HIV testing services.^[11]

Almost ~2.1 million (1.7–2.7 million) PLHIV in India.^[1] The National AIDS Control Program (NACP) offers HIV testing services (HTS) through facility-based and a few mobile ICTC.^[12] Community-based testing was not part of the NACP during the implementation phase of this study.^[13] The people undergoing HIV tests at ICTC can be of 2 types; a self-motivated person voluntarily coming for HIV testing and a person with HIV test prescription by a clinician. This type of HIV testing service structure leads to missed opportunities in the detection of HIV infection in the priority population. The “priority population” is a group of people that practice high-risk sexual behavior but do not access HTS voluntarily.^[13,14]

HIV status is not known to the 23% of people infected with HIV in India.^[1,16] This is largely due to varying proportion of HIV testing coverage among the priority population. The HIV testing coverage (around 10%) and linkage to antiretroviral treatment center (ARTC) (62.3%) for truckers and migrant workers is low in India.^[17] Migrants and truckers constitute an important “bridge” population for transmission of HIV from high-risk to low-risk groups. These issues underscore the need for expansion of HIV testing services beyond the clinical settings as the undiagnosed PLHIV contributes significantly to the HIV transmission.^[18–21] Various studies conducted across the world have revealed that community-based testing could be a useful strategy to reach high risk groups such as female sex workers (FSW), men having sex with men (MSMs), and transgenders (TGs) those were unreached by any prevention and care services.^[15,18,22–25]

The National AIDS Control Program has adopted the “Test and Treat policy” in 2017 in India and has prioritized identifying those who are infected with HIV infection and link them to ARTC as a key strategy.^[26] Initiation of antiretroviral therapy (ART) to PLHIV immediately after the HIV diagnosis, not only reduces morbidity and mortality but also an important prevention strategy to stop the further transmission of HIV.^[27,28] Improving HIV testing coverage beyond clinical setting has the potential to reach the unreached PLHIVs of India. There was no data available on the feasibility and acceptability of POCT in India. Therefore, this study was planned to assess the feasibility and acceptability of POCT in rural as well as peri-urban areas of Pune city in India.

2. Methodology

This was a community-based cross-sectional study conducted from August 2016 to May 2017. After obtaining the state government approval, a primary health center (PHC) was identified for the study. Two sub-centers were selected from the PHC, based on the distance from the nearest ICTC (Fig. 1). The distance of HTS from the beneficiary is an important factor in the utilization of services.^[7,8]

The sample size estimation was based on the “priority population” for community-based POCT that has an unmet need for HIV testing.^[3] This population includes individuals with multiple sexual partners, their spouses, and unregistered pregnant women for whom HIV testing was not done during

their antenatal care visits. Infants, children, and adolescents were not included in this study. The estimated sample size was 900 study participants that was computed with 5% level of significance and 90% power to detect the difference.

The study team approached 3881 individuals in the community of which 2685 (69.1%) individuals came forward voluntarily for POCT. Risk assessment for all the participants was done using a structured questionnaire to categorize them as “priority population”. After this assessment 909 (23.4%) were found to fall in the priority population group (Fig. 1).

2.1. Community mobilization for POCT

A 1-day orientation training program for all the grass root health workers involved in this research study such as Accredited Social Health Activist (ASHA), lady health volunteer (LHV), Anganwadi Worker (AWW)/government-appointed preschool teacher, multi-purpose worker (MPW), and Auxiliary Nurse Midwife (ANM) was conducted, explaining them about the study objectives, methodology, and their job responsibilities for the study. The messages to be given to the community during the awareness campaigns were explained to them in detail in this training session.

Awareness campaigns about the POCT specifying the date, time, and location of testing were carried out by these grass-root health workers at least 5 to 7 days in advance. In addition to the testing details, the community was informed that a similar testing facility is also available in the nearby government hospital. The study team and grass-root health workers disseminated these messages uniformly in the community before organizing POCT activity. The POCT on a particular location continued till the point of saturation. The local stakeholders such as hotel owners, company managers, and supervisors were involved in the process of community mobilization after emphasizing the importance of voluntary participation.

2.2. Strategies for selection of locations for POCT

The preparatory field activities with local stakeholders, were useful in developing different community out-reach strategies. Testing locations were identified in consultation with the local stakeholders and grass-root health workers to identify and capture the priority population. In the rural sub-center, the POCT was offered in the premises of government schools, temples, and public gathering sites after a house-to-house community mobilization for HIV testing by the study team along with the grass-root health workers. The study team organized POCT at the worksite for the laborers working at poultry farms, poly houses, brick kilns, and weekly market areas of these villages to enhance access to the priority population.

In the peri-urban sub-center, community youth groups voluntarily extended their support for identifying and organizing POCT at different locations such as weekly market areas, hotels, railway stations, sports grounds, and national highways. POCT was also offered to the small-scale industry workers at their worksite with prior permission from the employer. The employers were intimated through a formal letter that the test results will only be disclosed individually to the person undergoing the test.

The study team approached long-distance truckers for HIV testing at the parking area. Common parking areas for private and public transport vehicles were also considered as one of the locations for HIV testing.

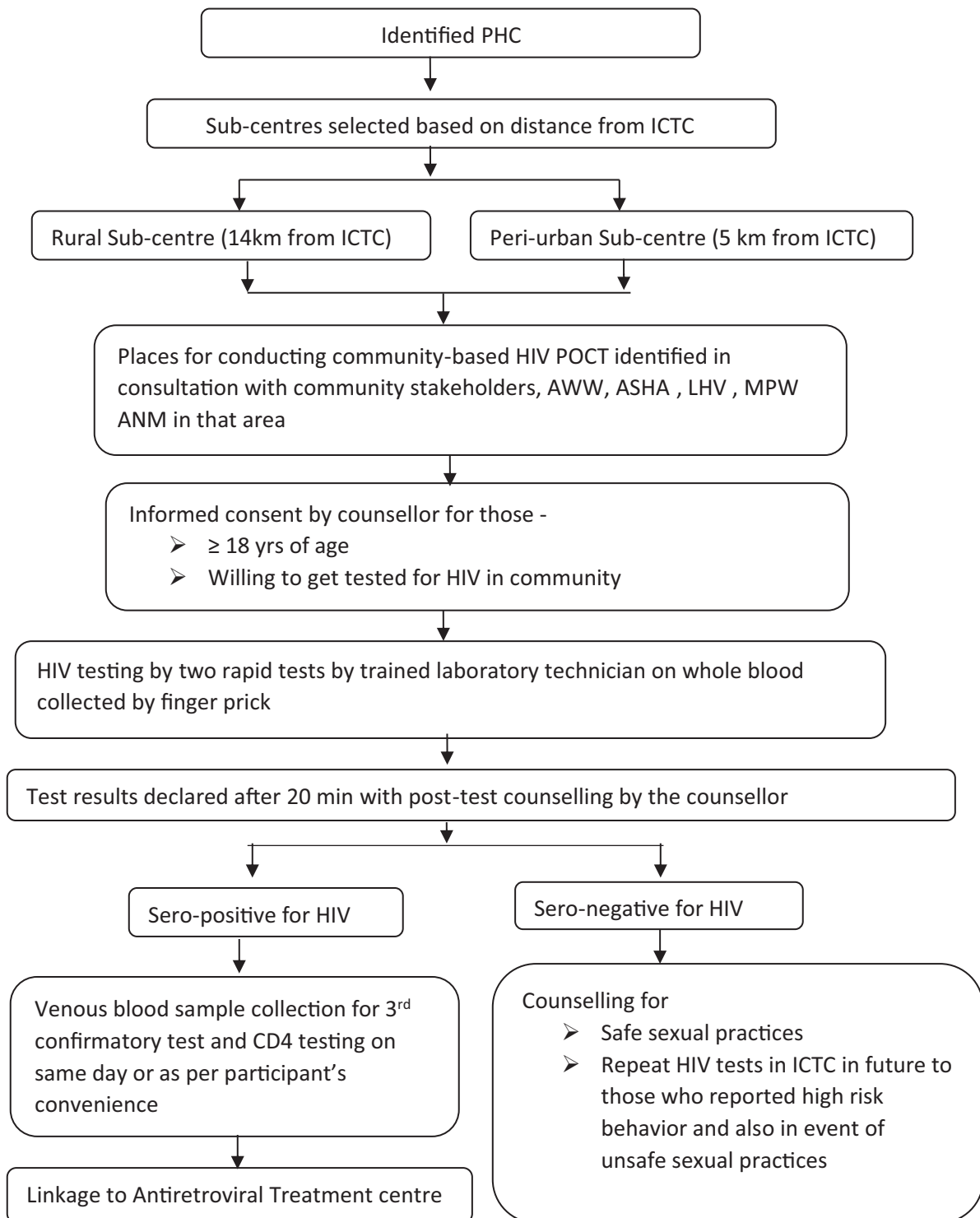


Figure 1. The study procedures for community-based POCT in both the sub-centers. ANM = auxiliary nurse midwife, ASHA = Accredited Social Health Activist, AWW = Anganwadi Worker/government appointed preschool teacher, HIV = human immunodeficiency virus, ICTC = integrated counselling and testing centers, LHV = lady health volunteer, MPW = multi-purpose worker, PHC = primary health center, POCT = point-of-care testing.

2.3. Community-based POCT for HIV

A pre-test counselling was offered after obtaining written informed consent from the study participants. A trained laboratory technician performed the POCT for HIV. Two rapid HIV test kits (SD Bioline HIV 1/2 3.0, SD Biostandard Diagnostics Pvt Ltd, Gurgaon Haryana, and Meriscreen HIV

1-2 Whole Blood (Meri Diagnostics Pvt Ltd, Vapi Gujarat) were used. Blood was collected by finger prick method using a disposable lancet and tested by both rapid kits simultaneously following the manufacturer's instructions. The minimum time required for a participant to know about his/her HIV status by undergoing POCT was 20 minute. The participants were

informed of their test results maintaining confidentiality along with post-test counselling, thereafter.

The participants who were found to be HIV-reactive by both tests and those having discordant test results were referred to the nearest ARTC. A trained laboratory technician confirmed the diagnosis using a third HIV test at the ARTC.^[3] If the third test was found to be reactive, blood sample was obtained on the same day for CD4 count estimation and the individual was linked to ARTC. In case of negative results for both rapid tests, the participant was declared as negative and was asked to repeat the test after 6 months.

We estimated the feasibility of community-based HIV POCT by determining the proportion of participants undergoing HIV tests for the first time signifying the ease with which POCT can be arranged in the field in a low prevalence setting.^[22] The proportion of people accepting the test; out of all those to whom the test was offered, was considered as acceptability of POCT for this study.^[22]

2.4. Ethical considerations

The study (protocol number NARI/EC - 2016-04) was approved by the institutional ethical committee. Written informed consent was obtained from all the study participants who were willing to undergo POCT.

2.5. Data collection and statistical analysis

The field investigators administered a structured questionnaire to obtain socio-demographic information, awareness about HIV and HIV care services, risk assessment, views on community-based testing and partner notification.

Data were entered in Microsoft Excel and were analyzed using SPSS statistical software package version 15.0 (SPSS Inc; Chicago, IL, USA). Chi-square was used to test the association between the covariates. The statistical significance was considered at $P \leq .05$.

3. Results

3.1. Socio-demographics characteristics

The study team approached 3881 individuals during the community visits. They could conduct 2685 POCT revealing

69.2% acceptability of POCT in the study area. The proportion of participants seeking HIV tests for the first time, which signifies the feasibility of POCT was 79.6%.

Majority (55.2%) of the study participants were in the age group of 18 to 29 years with a mean age of 30.7 (range: 18-65) years. The proportion of male study participants (62.9%) was more as compared to the females (36.9%) and TG (0.2%) who agreed to HIV testing ($P < .001$). POCT was accepted by 82.8% of females when it was offered at their door step. The proportion of pregnant women tested was 2.1%. The participants who completed 10 years of education were 55% of the study population, 71.3% were married and 56.1% were skilled workers by occupation.

3.2. Strategies used for POCT

The proportion of people undergoing POCT by house-to-house community mobilization was 43.4% and about 47.8% refused to undergo testing. The proportion of people accepting POCT when it was offered at work site (construction site [24.9%], small scale industries [16.1%], parking area of long-distance truckers, and private and/or public vehicles [8.1%]) was higher as compared to the acceptability of POCT at public places (3.4%) (Table 1).

3.3. Characteristics of peri-urban and rural testing sites

The acceptability of POCT in peri-urban areas was 70.2% which was similar to that observed in the rural area (69.7%). The area of residence of a participant does not have an impact on the acceptability of testing. The overall proportion of study participants reporting high-risk behavior was 22% in the total study population whereas it was 88.4% in peri-urban and 11.6% in the rural sub-center. The proportion of migrant population tested was 32.8%. The majority (43.4%) of POCTs were performed by community mobilization through door-to-door visits.

3.4. HIV risk assessment

A large proportion of participants with high-risk behavior were tested at construction sites (31.1%), small-scale industries (19.9%) and parking areas (12.9%) as compared to door-to-

Table 1
Different strategies used to reach the community for POCT.

Strategy	Place of POCT	Number approached (3881) [†]	Number tested (2686)	Number refused (1291)	HIV infection detected (3)	Sub-center		Risk behavior	
						Peri-urban (2194)	Rural (491)	Present (909)	Absent (1776)
POCT at door step	POCT by door-to-door visits for community mobilization	1785	1165 (43.4) [‡]	619 (47.8)	–	703 (32)	462 (94.1)	208 (22.9)	957 (53.9)
POCT at work site	Construction site	858	668 (24.9)	190 (14.7)	–	668 (30.4)	0	283 (31.1)	385 (21.7)
	Hotel/bar/roadside eateries	165	111 (4.1)	54 (4.2)	–	101 (4.6)	10 (2)	63 (6.9)	48 (2.7)
	Small scale industries	522	431 (16.1)	91 (7)	1 [*]	431 (19.6)	0	181 (19.9)	250 (14.1)
	Parking area for long distance trucks/private hire vehicles like taxi etc	122	218 (8.1)	–	2 [*]	199 (9)	19 (3.9)	117 (12.9)	101 (5.7)
POCT at public places	Public places like railway station, weekly market, crowded streets	429	92 (3.4)	337 (26.3)	–	92 (4.2)	0	57 (6.8)	35 (2)

HIV = human immunodeficiency virus, POCT = point-of-care testing.

^{*} Partner notification, testing and linkage to treatment was done for the migrant working in industry and 1 truck driver.

[†] N.

[‡] Column percentage.

door visits (22.9%) (Table 1). Young men in the age group of 18 to 29 years who reported having multiple sexual partners were 31.4%. In the age group of ≥ 30 years, 36.2% reported having multiple sexual partners and 48.2% of these were from the bridge population. The study reports that MSM were 0.9% in the age group of 18 to 29 years. History of blood transfusion was reported by 9.5% of women as against 2.2% among males. The POCT was also accepted by participants from high risk group such as FSW (0.3%), MSM (0.7%), and TGs (0.2%). One of the study participants reported use of injecting drug use.

3.5. First time and repeat HIV testing

HIV testing was done for the first time by 90.2% of participants who reported high-risk behavior. First time HIV testing was significantly more among males (72%) as compared to repeat testing (26.6%) ($P = .01$) whereas in females repeat testing was more (73%) ($P = .01$). The first time HIV testing in peri-urban sub-center was 79.7% and was 20.3% in rural sub-center.

3.6. Awareness about HIV testing and treatment centers

Awareness about HIV testing centers (73.8%) and treatment centers (57.2%) was higher among the residents of peri-urban as compared to those from rural sub-center. The awareness about HIV testing (97.9%) and treatment center (97.3%) was higher among the literate study participants as compared to those who were illiterate ($P = .01$).

3.7. HIV positivity

In this study, we found 3 newly diagnosed HIV infected participants (0.1%) through POCT. All 3 participants were confirmed later by the third rapid test in accordance with the 3 test algorithms recommended by the national program. We could link 2 of these PLHIVs (1 migrant and 1 long distance truck driver) to anti-retroviral treatment on the day of diagnosis and the third PLHIV who was a long-distance truck driver was not willing to visit ARTC for the lack of time. The availability of POCT in the community helped in participant linkage to ARTC. Partners of both these PLHIV who were found to be HIV infected were brought under the care by partner notification, testing, and linkage.

4. Discussion

This is the first study in India reporting the feasibility and acceptability of POCT in peri-urban and rural areas. The findings from this study suggest that POCT in the community is feasible and acceptable in the study area. A larger proportion (90.2%) of participants following high-risk sexual behavior underwent HIV testing for the first time. This indicates that the community-based POCT could reach hitherto unreached priority population, which is comparable to other studies.^[22,23] The present study has reported HIV positivity among the bridge population with their wider HIV testing coverage. Currently, this population has lesser HIV testing coverage under the umbrella of facility-based HIV testing offered through the National AIDS Control Program in India. Based on the findings of this study, community-based POCT will be a useful strategy to enhance access to HTS in these population groups. Similar findings are reported from different parts of the world.^[9,24,25]

A study conducted in North India has reported the delays in diagnosis of HIV infection among partners of HIV infected migrants, deferring early initiation of ART.^[2,3] Our study reveals that community-based POCT has the potential to facilitate early partner notification and testing. This facilitates the linkage of partner to HIV care and treatment, preventing further transmission of HIV.

A higher proportion of first time testing as reported in our study will be crucial from a programmatic point of view, as a new HIV case diagnosis is frequently associated with the first HIV test.^[8] Early detection through POCT should be followed by linkage to the free ART program.^[28] This will also serve as an important milestone for the NACP given the “test and treat” strategy based on the use of ART for prevention of HIV transmission.^[11,29]

Identification of sites for community-based POCT involving local stakeholders is important for reaching a higher proportion of the priority population. This method of selection of sites, yields higher priority population coverage which may not get covered by the ICTC.^[13,14,27]

A study from Italy has reported that 19% of people who refused POCT gave multiple reasons for the refusal (35% prior testing and 20% no risk behavior).^[18] The most common reasons for refusal of POCT in the present study were lack of time, fear of needle prick, fear of stigma, HIV test is done in recent past and no health problems for which the HIV test could be advised. The stigma attached to HIV in Indian community has led to the refusal of community-based POCT at public places.

The majority of males accepted POCT in this study that corroborate findings from other studies.^[8,30] The proportion of females undergoing POCT was higher as compared to males when it was offered door-to-door. We have not explored the influence of family members present in the household on uptake of the test and this could be a limitation of the study. A larger proportion of repeat testing among females was noted that could be indicative of higher antenatal HIV testing coverage in the area as a part of national health program for antenatal care. A larger proportion of early infant diagnosis of HIV can be achieved if community-based testing is extended to this age group.^[31]

The study has revealed a larger proportion of young adults (18-29 years) reporting high-risk behavior such as multiple sexual partners. A study based on the National Family Health Survey NFHS-3 (2005-06) and NFHS-4 (2015-16) has confirmed the rising trend of high-risk sexual behavior among adolescent boys (15-19 years) and young men (20-24 years).^[32] The declining age of sexual debut (less than 15 years) among young adults in India increases their risk of acquiring HIV infection.^[33] They have limited access to accurate information about safe sexual practices.^[34] Routine use of POCT will address issues related to young adults who are less likely to access care at ICTC due to fear of disclosure.^[8,35]

This study data reiterates the fact that increasing awareness about HIV testing facilities and free ART programs in the community will be helpful in improving the utilization of these services.^[11,21] The literacy status of participants and the distance between the area of residence and ICTC played an important role in the awareness about HIV testing and treatment center.

HIV infection was observed among migrants and truckers in the peri-urban area. It indicates the need for POCT in the priority population such as migrants and long-distance truckers at the nearest possible place. The barriers in the implementation of

POCT such as the availability of individuals to undergo a test, the distance of the testing facility should also be taken into account while planning POCT. If these barriers are addressed appropriately, it will enhance the outreach for test & treat strategy.^[36] This will ensure the prevention of transmission of HIV through early diagnosis and treatment.

5. Conclusion

Community-based POCT will be an acceptable and feasible strategy to reach the “priority population” in India. The wider coverage, early detection of HIV infection, linkage to care and facilitation of partner notification are important pointers from the current study. These pointers will be crucial for reducing the further transmission of HIV, on the way to achieve 95-95-95 goal. Therefore, we believe that community-based POCT is a promising strategy for improving HIV testing and control, even in low prevalence settings with concentrated HIV epidemic.

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Author contributions

Conceptualization: MM, VSP, MT, RG.

Field investigation and data curation: SG, SJ, SK.

Formal analysis: AN.

Funding: EM, TMF, DN, LH.

Methodology: MM, VSP, RG, MT.

Validation: VK.

Writing – original draft: MM, VSP, RG and MT.

Writing – review & editing: MM, VSP, AN, EM, TNF, DN, LH and MT.

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