National Guidelines Community-Led HIV Testing, 2017 NEPAL

> vernment of Nepal Ministry of Health

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Government of Nepal Ministry of Health December 2017

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Annex 6 Participants in CLT consultation workshop in Kathmandu- July 7, 2107

List of Acronyms

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-Retroviral Therapy
ARV CBT	Anti-Retroviral Drugs
CCC	Community-Based HIV Testing Community Care Center
CD4	Cluster of differentiation (of T Cells)
CHBC	Community and Home-Based Care
CIP	Community Information Point
CBO	Community-Based Organization
CST	Care, Support, and Treatment
CLT	Community-Led HIV Testing
DBS	Dried Blood Spot
DPHO	District Public Health Office
eVT	Elimination of Vertical HIV Transmission
EQAS	External Quality Assessment Scheme
FCHV	Female Community Health Volunteer
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Testing
HTS	HIV Testing Services
HTC	HIV Testing Center
KP	Key Population
M&E IRRTTR	Monitoring and Evaluation Identify, Reach, Recommend, Test, Treat and Retain
МоН	Ministry of Health
MSM	Men who have Sex with Men
NCASC	National Centre for AIDS and STD Control
NPHL	National Public Health Laboratory
NGO	Non-Governmental Organization
OI	Opportunistic Infection
OST	Opioid Substitution Therapy
PCR	Polymerase Chain Reaction
PE	Peer Educator
PEP	Post-Exposure Prophylaxis
PHC PITC	Primary Health Care
PLHIV	Provider-Initiated Testing and Counselling People Living with HIV and AIDS
PMTCT	Prevention of Mother-to-Child Transmission (also see eVT)
PEP	Post-Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
PWID	People who Inject Drugs
QA	Quality Assurance
QC	Quality Control
RDT	Rapid Diagnostic Test
RNA	Ribonucleic Acid
SCF	Save the Children Federation
SMS ²	Service Quality Monitoring System via SMS
SOP	Standard Operating Procedures
SRHR STI	Sexual and Reproductive Health Rights Sexually Transmitted Infection
SW	Sex Worker
TB	Tuberculosis
TI	Targeted Intervention
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States of America Agency for International Development
USFDA	United States of America Food and Drug Administration
VCT	Voluntary Counselling and Testing
WHO	World Health Organization

Foreword

The National HIV Strategic Plan 2016-2021 commits to Fast-Track the HIV response towards acheiving the 90-90-90 treatment targets by 2020 and ending the AIDS epidemic as a public health threat by 2030. However, inadequate uptake of testing for HIV remains a primary bottleneck fo universal access to treatment and care. HIV testing uptake among the key populations, for which the HIV prevention programme was designed, is as low as 4% among migrants, 28% among people who inject drugs and 44% among men who have sex with men. As reasons behind poor HIV testing uptake in Nepal are not clear, lessons learned from elsewhere suggest that cost of transportation, long distances to HIV testing services, fear of test results, social prejudice associated with certain behaviours, and discrimination by health service providers are major barriers to the acceptance of an HIV test. Experiences from other countries have also shown that community-based approches by lay providers have proven to yield higher coverage. Nepal's National HIV Strategic Plan (NHSP) 2016-2021 has formally introduced community-led HIV testing as one of the key strategies in improving and coverage of HIV testing services in Nepal.

The National Public Health Laboratory (NPHL) has taken a bold new approach in allowing trained and certified lay providers to perform HIV screening tests in a community setting. This strategy is promising in order to realize Nepal's ambitious target of diagnosing 90 % of all people with HIV, providing ART to 90% of people diagnosed with HIV, and achieving viral suppression among 90% of the people receiving ART by 2020.

The National Guidelines on Community-led HIV Testing in Nepal are an important tool that supplements the National HIV Testing and Treatment Guidelines, 2017. These guidelines present policy provisions, implementation modalities, and programme management aspects of community-led HIV testing services, and facilitate deployment of trained lay providers to conduct HIV screening in a community setting.

There has never been a more critical need for an optimal collaboration between NPHL, NCASC, public health offices, ART centers, non-governmental organizations, community-based organizations, donors and technical partners, to address the HIV diagnosis gap in Nepal, We thank all those who have contributed to the development of the guidelines. We also request everyone involved in the HIV programme, especially those in community-based HIV testing programmes, to make good use of these guidelines. This effort will help us reach our ambitious national goal of diagnosis 90% of all people living with HIV in Nepal by the year 2020.

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Guidelines development process:

The National Centre for AIDS and STD Control (NCASC) and the National Public Health Laboratory (NPHL) of the Ministry of Health, jointly coordinated the guidelines' development process. The guidelines were written under the guidance of the National HIV Lab Technical Working Group (LTWG). An independent consultant was hired by UNAIDS, through the UNAIDS/Save the Children Cooperation Agreement from the Global Fund HIV Grant, managed by Save the Children (SCF) Nepal. Technical oversight of the guidelines' development process was provided by the Joint UN HIV Team, led by UNAIDS.

The write-up process started on May 12, 2017. A literature review was followed by meetings with NPHL, NCASC, UNAIDS, SCF, WHO, FHI 360/LINKAGES Nepal, and AHF. Field visits were made to community-based HIV testing programmes, in Makwanpur and Kathmandu districts.

A consultation meeting among NCASC, NPHL, UN partners, FHI 360/LINKAGES Nepal, AHF, SCF, members of national key population networks, HIV testing service providers and CBOs was organized on July 7, 2017, to discuss the preliminary draft of community-led HIV testing guidelines, and build consensus on the key decisions about CLT implementation in Nepal.

A draft was electronically shared among LTWG members on August 5, 2017. A LTWG meeting held on October 17, 2017 finalized the guideline.

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List of documents reviewed during the preparation of these guidelines, is attached in Annex 4.

List of participants of the CLT consultation workshop, is attached in Annex 5.

Special thanks to Dr Vladanka Andreeva, from the UNAIDS Regional Support Team, who inspired the introduction of 'test-for-triage' in Nepal, and to Dr Bharat Rewari and Dr Mukta Sharma from WHO SEARO, for their review of the final draft.

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1.1. Introduction

Due to social and biomedical advances, and increased funding, the response to HIV globally has yielded remarkable results. There are better, improved tools for screening, diagnostics, and treatment of HIV. Community responses to HIV are also established as the cornerstone of effective, equitable and sustainable HIV programmes. People living with HIV, or at increased risk of HIV play a critical role in demanding and delivering services, supporting systems for health, and reaching those who are most vulnerable to HIV, where state facilities cannot, or are not equipped to do so.

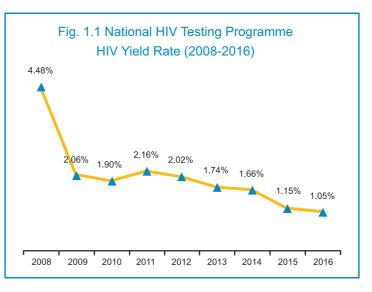
HIV testing stands central in Nepal's IRRTTR, 'Identify, Reach, Recommend, Test, Treat and Retain, case-finding/case-management continuum. This is depicted well on page 20 of 'Nepal HIVision 2020.'

People's knowledge of their HIV status through HIV testing services (HTS) is crucial to the success of any HIV response. The global 90-90-90 target, adopted by Nepal, calls for 90% of all people living with HIV to know their HIV status, by 2020. By 2020, 90% of all people with diagnosed HIV infection receiving sustained anti-retroviral therapy. By 2020, 90% of all people receiving anti-retroviral therapy having viral suppression. The first 90 - diagnosis of HIV - is essential to the second 90 - initiation of ART among people with HIV - and the ultimate outcome of the third 90 - viral load suppression among people on ART, which improves client outcomes and prevents HIV-1 transmission¹.

Approximately 150 million children and adults in 129 low- and middle-income countries reportedly received HIV testing services in 2014 with a global positivity rate at 3.4%. Available data from the 77 countries suggests that 33% more people were tested in 2013 in comparison to 2009. Much of this growth stems from the expansion of provider-initiated testing and counselling (PITC) in clinical settings, the introduction of more community-based HIV Testing Services (HTS), and the ability to provide sameday test results. While significant progress has been made, in 2013 it was estimated that 55% of people with HIV remain unaware of their status. A poor yield rate suggests that testing continues to be delivered without specifically aiming to reach those most at risk and as yet undiagnosed². In WHO's South East Asia region, only 1% of 27,844,749 people tested were tested positive for HIV³.

1.2. Nepal's HIV Testing Programme

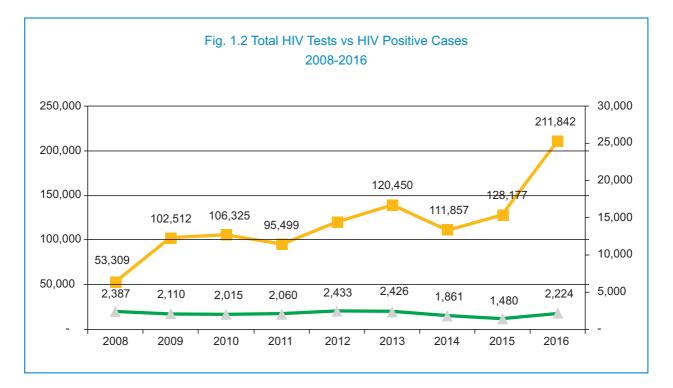
Unpublished data from NCASC suggests that there were 175 HTC sites operating in Nepal in 2016. 136 of those are managed by government and 39 are managed by NGOs, categorized as outreach-based HIV testing and counselling centers (HTC). There has been a significant reduction from 103 to 39 of such sites, operated by NGOs for key populations in recent years. 211,842 HIV tests were performed in 2016 with 2,224 HIV positive results. Annual data from 2008 to 2016 indicates that despite significant increases in the total number of HIV tests, the positivity rate has continued to decline at a steady



rate from 4.48% in 2008 to 1.05% in 2016. For a programme that invests most of its prevention resources in targeted interventions, with HIV testing as a key strategy, this is a low yield.

Among the clients of targeted interventions, as reported in the Country AIDS Report 2015, 0.7% of Migrants, 28% of PWID, and 43.8% of MSM and TG, 67.8% of MSW, and 56% of FSW took the HIV tests in 12 months prior to an interview. Despite the overall reduction, HIV prevalence among gay men and other MSM, and TG, has increased in the past decade, from 3.3% in 2007 to 6.3% in 2017. Programme data from fiscal year 2015/2016 shows that only 42% of gay men and other MSM, and TG, reached by the outreach programme were actually tested for HIV.

Though Nepal has made significant strides in increasing ART coverage among those who are diagnosed with HIV, and are eligible to receive treatment, poor case detection, problematic linkages to treatment, are impeding treatment coverage.



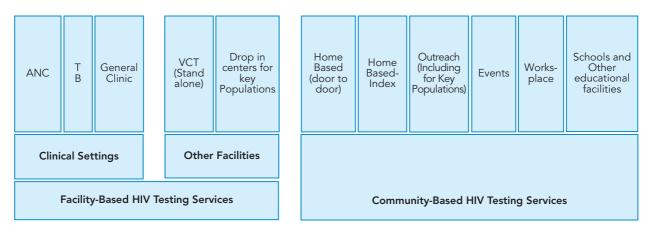
1.3. National Strategy on HIV testing in Nepal:

The 'Identify, Reach, Recommend, Test, Treat and Retain' (IRRTTR) strategy stands central in the National HIV Strategic Plan (NHSP) 2016-2021, whereby decentralized HIV testing services are specified "to identify people living with HIV as early as possible and to link them appropriately, in a timely manner, to treatment and care services."

The Plan envisions a strategic mix of HTS approaches including testing services in healthcare facilities, at standalone sites, and through a range of community-based approaches.

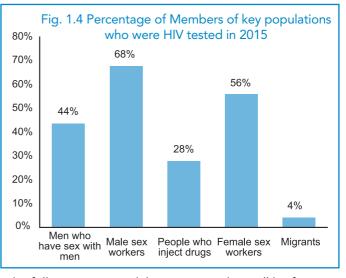
The National HIV programme aims to follow a mix of facility-based testing (FBT) and community-based testing (CBT) approaches for greater reach at the earliest stage of HIV infection. This approach is expected to reduce travel and waiting times and cost in reaching facility-based testing sites. Community-based HTS includes a number of approaches: door-to-door/home-based testing, mobile outreach to parks, bars and testing at the workplace⁴. The following table shows the available HIV testing approaches in Nepal.

Fig. 1.3 HIV Testing Approaches in Nepal



1.4. Community-Based HIV Testing Services:

Nepal started implementing communitybased HIV voluntary counselling and testing with FHI360 supported sites from early 2000, and expanded its services across the country with Global Fund resources from 2005 onwards. The programme has evolved with the introduction of provider Initiated HIV Testing and Counselling (PITC), expansion of PMTCT screening and communitybased HIV testing and counselling. Even with decades of investments in testing and counselling for key populations, an estimated 45% people with HIV still remain undiagnosed.



Among the strategic mix of testing services, the following service delivery approaches will be for community-based HIV testing and counselling services in Nepal:

Facility-based: in settings such as standalone HIV testing services through HIV Testing Centers (HTC), clinical settings, along with antiretroviral therapy sites, specialized public health laboratory, antenatal care and labor rooms, opioid substitution therapy sites, TB care sites and private clinics.

Community-based: In-reach among key populations using mobile units, entertainment sites, and hotspots for sex work and injecting drugs, use, and also focusing on remote birthing sites, and areas with higher numbers of male labor migrants and their partners. This will include community-led HIV testing, applying WHO's recommended "test-for-triage" strategy.

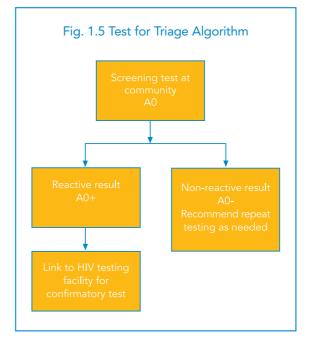
The addition of community-led HIV testing aims to complement the routine HIV testing in facilities with confirmation capacity. The approach aims to minimize client barriers and focus on delivering HIV test screening and secondary referral in a simple, accessible, and straight forward way.

Evidence shows that community-based HIV testing helps reduce prejudice and discrimination, encourages greater uptake of services and ensures greater protection of human rights. Community organizations are often better trusted by their peers and are best placed to reach those who are hard to access and are not yet accessing HIV testing in general health care settings.

1.5. Community-led HIV Testing Services (CLT):

The NHSP 2016-2021 recommends community-led HIV testing (CLT) as part of CBT, following the 'Testfor-triage strategy,' as a screening and accompanied referral approach. Directed by the NHSP, Nepal is phasing in 'Test-for-triage.' Expansion of HIV testing into the community builds on the experiences of a decade of successful implementation of CBT, among key populations. The objective of CLT is to improve uptake, increase yield, provide opportunities for early detection and care, prevent on-going transmission of HIV, and contribute in reduction of the "diagnosis gap" among key populations.

Community-led HIV testing service is an approach to expand uptake of community-based HTS among populations with higher risk of HIV, particularly those who may not otherwise test for HIV. It has been proven to improve uptake of HIV testing, and improving linkages to treatment and care - early on.



In this approach, recommended by WHO, trained lay providers conduct a screening test, using a HIV Rapid Diagnostic Test Kit (RDT), referred to in the chart as A0. If this single RDT is reactive (A0 +), the individual is accompanied to a facility for further HIV testing. At such a reference facility, confirmatory HIV testing, following the national testing algorithm is performed, beginning with A1 (see page 22 of the National HIV Testing and Treatment Guideline, 2017). If the (A1 +) is reactive, a positive HIV diagnosis is confirmed after two additional reactive tests (A2 + and A3 +), and the individual is thus diagnosed as HIV positive, and accompanied for clinical assessment and treatment. Individuals with a non-reactive test result are informed of their result, and linked to appropriate services to prevent HIV, and recommended for retesting in 3 months if they have had recent or have ongoing HIV risk. All repeated clients would be asked to retest once every 6 months.

This approach is known as the 'Test-for-triage' approach. Although it may be ideal to provide a definitive diagnosis in a community setting, correctly conducting two or three RDTs for each individual with a reactive result may be challenging for lay providers.

Nepal employs "a strategic mix of service delivery models" to achieve universal and equitable access to HIV testing and counselling for all those in need. CLT expands the choices that people have for HIV testing, and does not replace any existing testing approaches being used in the country. The test performed at the community is NOT a definitive/conclusive/confirmatory test of HIV.

Each HIV-positive diagnosis must be confirmed according to Nepal's national HIV testing algorithm as specified in Nepal HIV Testing and Treatment Guidelines, 2017 available at http://goo.gl/ptCKpA Furthermore, HIV testing needs to be repeated before starting someone on lifelong antiretroviral therapy.

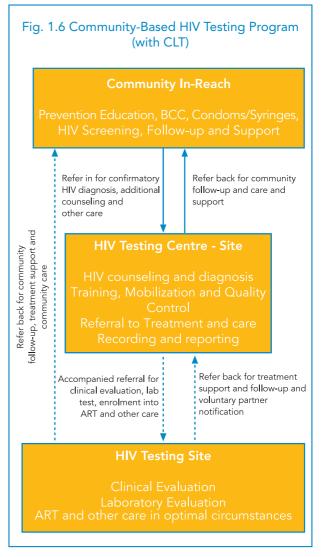
1.6. Community-led HIV Testing Services (CLT) in Nepal:

HIV Testing Centers (HTC) with HIV confirmation capacity are a necessary condition for CLT in Nepal. Such HTC will also coordinate and oversee the lay providers' recruitment, training, quality control, and monitoring; provide education on HIV and tools to prevent HIV; confirmatory HIV testing, with primary health care, and medical services, in selected sites*. Ideally, ART could be initiated at those facilities where a positive HIV diagnosis is made, as **"Point of Care Sites,"** as mentioned in the Glossary of the National HIV Testing and Treatment Guidelines, on page XVIII: "Point of Care testing is conducted in the site at which care is being provided. The test results are usually being returned rapidly so that clinical decisions can be made in a timely and cost-effective manner." Secondary site strategies are described in detail in the next section. Referral to post HIV treatment and care sites, and follow-up, are integral responsibilities of the sites, and will be routinely monitored and reported on, as key sources for evidence of success, in support of scaling up of CLT.

For providing community centric HIV testing services, this 'task sharing' model is based on peer-led in-reach to prevent HIV, provide HIV screening test services, including for eVT, recognition of opportunistic infections; support for treatment and treatment literacy, retention on ART, and linkages to other care and support services, such as TB and ANC.

The rapid screening test is performed by trained lay workers in a private area, after providing information on HIV and the HIV test, and taking verbal consent. All who are tested negative will be asked for a follow-up test in 3 months, in case this would be the first HIV test, and/or with known high risk behavior, within 3 months prior to the screening test. For repeat clients, retesting will be recommended to be taken every 6 months. All clients with a reactive test will be accompanied to an HTC for confirmatory testing, on the same day.

A Point of Care HTC uses a differential, customized approach, by providing relevant information to those who need information, HIV



testing for those who need HIV testing - including confirmatory testing, care services to those who need care, and referrals to those who need referrals. This is unlike a conventional setting, where one approach is applied to every client.

The inclusion of primary health care, STI treatment, clinical consultations on health issues, including gender specific health issues, based on SRHR are recommended in a HTC. While not considered as necessary conditions to implement CLT, those decisions will depend on the specifics of the key population(s), and available funding, including leveraging and prioritization of resources.

CL- HTS in Nepal will be guided by the following principles:

- o CLT is an HIV screening approach, whereby trained lay persons, who do not have lab training, perform a single rapid diagnostic test (RDT) in a community
- A lay provider is a person who performs functions related to health-care delivery and has been trained to deliver specific services, without a formal professional or paraprofessional certificate or educational degree.
- Lay providers who are trained and certified can independently conduct safe and effective HIV screening, using RDT in a community setting. In these guidelines they are called trained lay HIV screening test service providers.
- CLT services are placed well within the community and are ready to provide information on HIV testing, encourage people to get HIV screening test, and perform the test in a safe and secure area.

- o The lay providers need to ensure that those who are tested reactive in the screening test are accompanied to confirmatory HIV diagnosis at HIV Testing Centre (HTC) with confirmatory capacity; ideally these are point of care centres.
- In Nepal, all HIV confirmations must be performed by a trained lab technician. In these guidelines, the personnel providing HIV testing in such facilities are collectively called "lab personnel." Lab personnel can be lab assistants, lab technologists and other lab professionals who have received NPHL approved training on HIV testing.
- o Such HTCs, including the point of care sites, must have a quality-assured lab that participates in HIV EQUAS. An HTC can be part of a government hospital, stand-alone public health lab, NGO-run HTC site, or a private laboratory.
- o All HTCs, overseeing CLT, are required to comply with internal and external nationally accepted quality assurance benchmarks to continually build evidence on quality and effectiveness of HIV testing services provided by the lay providers.
- o CLT sites selection will be based on the local contexts, the nature of the epidemic at that site, cost-effectiveness and available human and financial resources. The mix needs to facilitate diagnosing as many people living with HIV as early as possible, and guaranteeing those who are diagnosed with HIV to have immediate access to antiretroviral therapy.
- o Members belonging to HIV key populations, including people living with HIV, are central to the implementation of CLT.
- National policies and protocols must explicitly permit trained and certified lay providers to conduct HIV screening services, following these Guidelines. Lay providers also need to be protected from any harm caused, within 'good faith, 'while collecting specimens; performing HIV rapid diagnostic test; interpreting reactive screening tests results; giving pre-test information; performing posttest counselling; accompanying clients to confirmatory testing sites; ensuring linkages to prevention, care and treatment services.
- o Trained lay HIV screening test service providers are not allowed to provide written results of a screening test, or of any other HIV test results.

A lay provider needs to provide following pre-test information before testing;

- o the benefits of HIV testing
- o the meaning of an HIV-positive and an HIV-negative diagnosis
- o the services available in the case of an HIV-positive diagnosis, including where ART is provided
- o a brief description of prevention options and encouragement of partner testing
- o the fact that the test result and any information shared by the client is confidential
- o the fact that the client has the right to refuse to be tested and that declining testing will not affect the client's access to HIV-related services or general medical care
- o that this test is not final and you may have to undergo more tests for confirmation

An HIV screening test is never sufficient to confirm an HIV diagnosis. Such diagnosis can only be made in a quality assured HIV testing facility, run by the Government, an NGO, or the private sector. As specified in the National HIV Testing and Treatment Guidelines 2017, any newly diagnosed HIV positive person can only start ART after a positive confirmation of HIV status at an HTC.

1.7. HIV testing services by trained lay providers - Evidence of Success:

There has been significant progress in implementing community-led HIV testing in sub-Saharan Africa and in some parts of Asia. It is noteworthy that such evidence is from countries with a high HIV prevalence, and where the health system is more willing to share its tasks, due to shortages of health workers.

The WHO's 2015 Consolidated Guidelines on HIV testing have identified the following evidence in support of HIV testing services by trained lay providers :

 HIV testing conducted by trained lay providers is accurate - as accurate as testing by laboratory staff and health-care providers.

- Clients express satisfaction and support for services delivered by trained lay providers.
- Trained lay providers can deliver various other health services, beyond HTS and HIV prevention, care and treatment, such as vaccinations, screening and testing for tuberculosis and sexually transmitted infections, and distributing bed nets for malaria prevention.
- Task sharing with trained lay providers may cost less than using other health workers to perform the same tasks. Full programme costs, cost-effectiveness and affordability vary.
- HTS can be more sensitive to the culture of the community when offered by trained lay providers. Trained lay providers may reach more people because they often are culturally competent at talking with their peers, particularly people from key populations and adolescents.

Scientific evidence from other regions on quality and effectiveness of CLT, is attached in Annex-1.

1.8. Potential challenges for the "test-for-triage" approach

A public health and human rights-based approach is important to delivering all HTS including CLT. For all HTS, regardless of approach, the actual public health benefits must always outweigh any potential harm or risk. The main reasons for testing must always be both to benefit the individuals tested and to improve health outcomes at the population level. HTS needs to be expanded not merely to achieve high testing uptake or to meet HIV testing targets, but primarily to provide access for all people in need to appropriate, quality HTS that are linked to prevention, treatment, care and support services. Thus, HIV testing for diagnosis must always be voluntary, consent must be informed by pretest information, and testing must be linked to prevention, treatment, care and support services to maximize both individual and public health benefits.

Despite the advantages of including lay providers for HIV screening is not free from risks. There must be special efforts taken to prevent any adverse events, such as breaching of confidentiality. Careful consideration needs to be given to the following challenges and limitations, while implementing CL-HTS:

- In a low prevalence setting, the rate of false reactive test result is found higher than in high prevalence settings, which without proper messaging, could lead to mistrust of services.
- It may be a challenge to maintain an uninterrupted supply of test kits to community sites.
- Lay providers may incorrectly communicate the meaning of reactive [screening] test results, resulting a client believing that a reactive test result for an HIV positive diagnosis.
- Barriers, accessing sites for additional testing to confirm HIV diagnosis may remain. Therefore, accompanied referrals to such sites would be part of CLT.
- Privacy and confidentiality of HIV testing in an informal setting is challenging.
- It may still be difficult to track and monitor clients who are [HIV screening] reactive, for a confirmatory HIV test, and linking them to HIV treatment and care. The burden to people accessing health facilities for lab services and ART, remains a challenge.
- Despite evidence that CLT yields better acceptance and uptake, such evidence is from other regions where the contexts are quite different.

CLT cannot fully address all structural, individual and social barriers to HIV testing. Offering an HIV test in the community or near the community of key populations, by people who are respectful and trustworthy, can only provide an additional choice for people to accept an HIV test.

1.9. Ensuring the '5 Cs:'

All forms of HIV testing must adhere to the 'WHO 5 Cs': Consent, Confidentiality, Counselling, Correct test results, and Connection, which is linkage to prevention, treatment and care services.

Consent: People receiving CLT services must give informed consent to be tested and counseled. Verbal consent is sufficient and written consent is not required. All clients need to be informed about the HIV testing process, including counselling, and of their right to refuse or decline testing. Age of consent for HIV test in Nepal is set at 16 years.

Confidentiality: CLT must be confidential, meaning that what the community lay provider and the client discuss cannot be disclosed to anyone else without the expressed consent of the person being tested. Confidentiality must be respected, while it must not be allowed to reinforce secrecy, self-stigma or shame. Shared confidentiality with a partner or family members - trusted others - and healthcare providers has been proven to be beneficial. Lay providers must discuss, among other issues, whom the person may wishes to inform, and how they would like this to be done.

Counselling: In a community setting, extensive pre-test counselling may not be possible. Pre-test information can be provided individually or in a group setting, and all people need to have the opportunity to ask questions in a private setting if they request it. All HIV testing in and by the community must be accompanied by appropriate post-test counselling, based on the screening test result. If a client is tested reactive in the screening test, the lay provider has to provide adequate information before linking and accompanying the client to an HIV testing site for confirmation.

Correct: Quality of HIV screening by lay providers is proven to be comparable to the quality of HIV testing provided in sites with lab technicians. Quality assurance (QA) must be built into the HIV testing by lay providers to ensure that people receive good quality pre-test counselling and screening for HIV. QA needs to include both internal and external measures, and has to receive support from a quality assured HTC. All people who receive a reactive HIV screening test need to be re-tested at a site that with lab technicians who are trained to confirm the diagnosis. Any discrepancy must be recorded, reported, and used to improve quality of the community-led HIV screening programme.

Connection: In the case-finding/case management continuum, formal linkages between services to prevent HIV, testing, treatment, and care need to include effective and appropriate follow-up, including long-term HIV prevention. All reactive persons, through screening, need to be linked with and accompanied to an HIV testing site for HIV diagnosis and, if found positive upon confirmatory testing, for further case management.

1.10. Innovative approaches to HIV testing:

Early diagnosis and prompt treatment of people living with HIV have demonstrated population level prevention benefits. Globally, innovative approaches in HIV testing are at different developmental stages. Nepal can also benefit from the available technologies and strategies that can yield better public health outcomes, by validating some of these technologies and strategies for future adoption and implementation. A few are discussed here:

1. HIV Self-test (HIVST): One of the key approaches that is being introduced in several countries, is HIV self-testing (HIVST). HIVST is a process in which an individual, who wants to know his or her HIV status, collects a specimen, performs a rapid screening test, and interprets the result by him or herself, often in private. By giving people the opportunity to test discreetly and conveniently, HIVST may increase uptake of HIV testing among people not reached by other HIV testing services. Note that every reactive HIV self-test needs to be confirmed.

WHO has issued guidelines on HIV self-testing and partner notification to support the implementation and scale-up of ethical, effective, acceptable, and evidence-informed approaches to HIVST, and assisted HIV partner notification. Benefits of HIVST are studied where this is being introduced, such as in Malawi, Zambia, Zimbabwe, and Thailand, with encouraging results. Several countries, such as Australia, China, France, Kenya and the United Kingdom, have introduced national HIV testing policies that include HIV self- testing. The forward-looking 'National HIV Testing and Treatment Guidelines 2017', present HIV self-testing as a future option in Nepal. FHI 360/LINKAGES Nepal is planning a pilot study of HIVST in Nepal, under the leadership of NPHL and NCASC.

2. HIV Testing using an oral swab: Unlike in the past when HIV test kits that use an oral swab for HIV testing had lower sensitivity and specificity, today's HIV tests, such as OraQuick® have shown very high sensitivity and specificity (>99%) in population-based surveys. The high cost of this test remains a major drawback. With lower prices foreseen, this could be a future HIV test option in Nepal, for people who want to test at home, or for those who require frequent retesting. The US FDA has approved over the counter sale of HIV self-testing kits, including test kits that use oral swabs.

3. Use of trained lay providers for HIV testing: In many countries in the Asia and the Pacific Region, lay providers belonging to key populations conduct HIV testing at both screening and confirmation facilities. In countries such as China and Vietnam, where social acceptance of certain behaviors, legal barriers, and health facility-based discrimination is a serious challenge, such an approach has been proven useful in increasing acceptance and uptake of HIV testing.

4. Use of the Internet, social media and SMS for the promotion of HIV testing: Thailand, China and other countries in the region have used online counselling and HIV testing, by providing online assistance to gay men and other men who have sex with men, with good success. Overall promotion of HIV testing, using online forums, chat groups, social media and text messaging have proven effective to improve uptake of HIV.

5. Introduction of SMS² for monitoring the quality of the CLT services from the perspective of both key populations, trained lay providers, and health care workers. With this SMS Service Quality Monitoring System, in-reach workers, and health workers at an HTC, send text messages to members of key populations who have attended CLT and HTC services, asking a few simple questions about their satisfaction with the care thy received. Using this system, trained lay providers and health care workers can also complete short SMS surveys quarterly to assess their own facility's performance and their personal performance.

Finally, please refer to table 1.5 on page 17 of the 'Nepal HIV Testing and Treatment Guidelines, 2017' that indicates the importance that **no one must be given an HIV-positive diagnosis on the basis of a single test result:**

HIV Test	Assay1 (A1)	Assay2 (A2)	Assay3 (A3)	HIV Status	Remarks
1	Non-reactive	No test needed	No test needed	Negative	
	Reactive	Non-reactive	No test needed		Repeat Assay 1 and Assay 2
2	Non-Reactive	No test needed	No test needed	Negative	
	Reactive	Non-Reactive	No test needed	Negative	
3	Reactive	Reactive	Non-Reactive	Inconclusive	Repeat the test after 14 days
4	Reactive	Reactive	Reactive	Positive	

National HIV Testing Algorithm

The full document can be found here: http://goo.gl/ptCKpA

Each HIV-positive diagnosis must be confirmed by following Nepal's national HIV testing algorithm. It is important that an HIV diagnosis is confirmed before starting someone on lifelong antiretroviral therapy. Antiretroviral therapy can be started on the same day as first HIV diagnosis provided the above criteria are met, in line with the 'National HIV Testing and Treatment Guidelines 2017', that are based on WHO recommendations.

People who are already taking antiretroviral medicines to treat HIV infection must not be retested for HIV, as they are likely to have low levels of HIV antibody and may have a false negative HIV test result.

While the means to prevent future HIV misdiagnosis are clear, WHO is still consulting on the best approach to manage people with suspected HIV misdiagnosis who are already on antiretroviral therapy - such as those started on treatment on the basis of a single positive HIV test result.

Such cases should be managed on an individual basis by specialist HIV clinicians who can assess the overall risk of underlying HIV infection such as re-testing of stored blood specimens, assessment of individual risk factors, and partner testing.

Section 2: Service Delivery of Community-Led HIV Testing Services

CLT aims to reduce structural, social, and logistical barriers to access, including transport costs, limited facility hours, and prejudice associated with testing at a facility. Task sharing by in-reach workers of key populations, who are members of their communities may help to address the needs of these key populations could are otherwise be reluctant or unable to access traditional HTS. CLT, whereby members of key populations take a lead in conducting HIV screening tests, have shown population level benefits in improving acceptance of the HIV test in other countries. The quality of test results performed by trained and certified lay providers is also found to be of acceptable quality elsewhere. Beyond providing services, lay workers, who are their clients' peers, can act as role models and offer non-judgmental and respectful support that can help reduce prejudice, facilitate access to services and improve their uptake of HIV testing. At the core of CLT programme, the following principles must be adhered to:

- Quality of HIV testing by lay providers must remain high and acceptable to nationally agreed quality benchmark.
- Adverse events e.g., coercion, inter-partner violence, psycho-social, self-harm, prejudice, discrimination must not increase due to CLT.
- The programme must ensure increased uptake of HIV testing and maintain high levels of satisfaction and quality of HIV screening and referral services.
- 100% of clients who are tested reactive to screening test must receive a confirmatory test from a quality-assured HTC.

2.1 Necessary conditions for integration of CLT in HIV testing programme:

A poorly executed testing programme or a testing programme with no clear linkages to other services can adversely affect the people taking the HIV test. Strategic and careful planning, training, implementing and regular monitoring CLT services, will minimize risks. To set-up CLT, the following minimum conditions are highly recommended:

- 1. All CLT services must be integrated into outreach and in-reach based HIV programmes, with and for key populations.
- 2. All CLT services must have a direct linkage to a HTC that can provide a confirmatory diagnosis of HIV.
- 3. All community members who are conducting HIV screening tests in the community must be trained by entities certified by NPHL, and must qualify through the Competency Framework, discussed in Section 2.4 of these Guidelines.
- 4. All HIV prevention programmes that provide CLT services must have components or links to care and support, preferably related to the same CLT service provider.

The community-led HIV test in Nepal is allowed only to be integrated into services for key populations identified in the NHSP 2016-2021. Such services can be run by NCASC, NGOs, and CBOs. The following safeguards are recommended:

- 1. Distribution of test kits for home use, or for use by un-trained person is [still] prohibited in Nepal.
- 2. Lay providers cannot give a confirmatory diagnosis of HIV, any confirmation of HIV diagnosis can only be provided by trained laboratory personnel.
- 3. CLT services must not be expanded to in areas where it is difficult to safeguard confidentiality, monitor quality of the services, and guarantee linkages to confirmatory HIV testing.

2.2 Leveraging Community readiness to increase acceptance for and participation in CLT:

In a country like Nepal, several barriers to using HIV services exist. While prejudice towards persons living with HIV continues to decrease, social prejudice, social prejudice towards certain behaviors and occupations is still common. Attention to community readiness towards HIV testing, such as knowledge, awareness, attitudes, and norms, can show how the community currently perceives HIV testing, and other follow-up services, in the continuum of case finding/ case management ('IRRTTR'); from the perspective of members of key populations, themselves. This can also reveal the extent of awareness about HIV, the value placed on HIV testing and follow-up services. Positive community perceptions will determine the potential feasibility and acceptability of a CLT programme.

Existing HTS sites are likely to expand their HIV testing through trained and certified lay providers. While these guidelines do not extensively discuss community readiness for CLT, they do provide guidance to those who are engaged in Fast-Tracking this innovative and community-led service delivery, as directed by the NHSP 2016-2021, and the 'National HIV Testing and Treatment Guidelines 2017.' These Guidelines are meant to support the CLT programme with technical assistance, and help identify and clear obstacles along the way of its phased implementation.

A community readiness assessment can also identify communities to help locate and engage key populations to access services to prevent and treat HIV; including care and social support services. Other partners for a successful CLT progamme include provincial and local public health officials, medical care providers, social services providers, business owners, government officials, educators, as well as community leaders. When, as per the 'Identify, Reach, Recommend, Test, Treat and Retain ('IRRTTR') paradigm, services to prevent HIV are linked to HIV testing at the community level, the engagement with other stakeholders, especially services providers, becomes even more important.

2.3 Confidentiality considerations:

While it is important to increase the uptake of HIV testing among key populations and offer HIV testing closer to the home, work place, hangout areas, community spaces, it is also important to make sure that HIV testing does not infringe upon the right of a client. Everyone has the right to choose to tell or not tell other people about being HIV tested; -including the results of an HIV test. That is why it is also important to ensure that the client is perfectly comfortable discussing and taking HIV test. In a community setting, allocating a private space for discussing sensitive and intimate topics may not always be possible. It is important to always ensure that the client is comfortable in a private setting, and is made comfortable discussing personal matters, related to sexualand risk-taking behaviours. While performing an HIV test, a safe, quiet, and comfortable space must be identified and agreed, in-advance, with the client.

The following confidentiality considerations are recommended for CLT:

 The contents of discussions between certified lay providers from the community and clients must not be disclosed to anyone else without the expressed consent of the person being tested.

Community Information Point (CIP)

A safe space can be highly contextual depending on the population of interest, and identifying a common community information point (CIP) is recommended in all settings.

A CIP is an informal, pre-identified space. In the current FHI 360/LINKAGES programme, a CIP acts as a connector between a community and health service providers. It is the first point of contact for key populations with in-reach workers, and is a space for discussion about HIV, STI, HIV testing and distribution of HIV prevention tools, and an information point for referral. A CIP can be used as an HIV testing site at the community level.

The location of a CIP must be strategic hotspots with and for key populations, such as cruising sites, and transit points with high mobility It is strategically positioned around 20-65 members of key populations living within a 1-2 km radius and/or 10-20 minutes walking distance from home or working area of key populations. CIPs can be co-located within a home or workplace of in-reach workers, hotels, restaurants, bars, entertainment venues, clubs, etc.

The establishment and utilization of CIPs will be workin progress, as the CLT programme identifies key populations for HTS, though in-reach. The strategic positioning of a CIP needs to be decided with the key populations, themselves. This must be a flexible process, with changes of places according to needs and preferences.

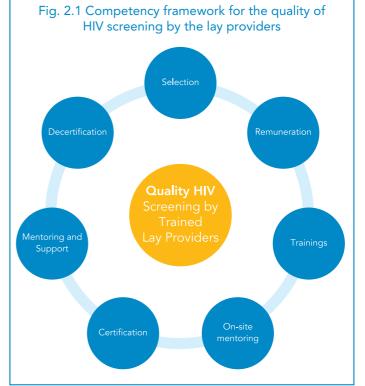
- Confidentiality must be respected, but it must not be expressed in a way that it may encourage secrecy, prejudice, and shame. Shared confidentiality with a partner, family members, trusted people, and healthcare workers is proven to be beneficial, and must be encouraged. It is important to ensure that there is no risk of adverse effects, such as violence, discrimination and social exclusion.
- Lay providers must discuss, among other issues, whom the person may wish to inform and how they would like such disclosure to be done.
- Regardless of the outcome of the screening test, all results must be kept confidential, unless the client gives permission for a disclosure procedure.

All lay providers who are trained and certified to perform HIV screening test in the community are required to provide signature of oath committing to provide confidential, non-coercive and quality services.

2.4 Competency Framework to ensure quality of HIV test by lay providers

Quality of HIV screening by trained lay provider depends on multiple factors. A competency framework that identifies key attributes that are important to ensure the quality of HIV screening is presented here, in figure 2.1. It is often difficult to ensure quality work outside of a formal facility. In the absence of direct supervision, such quality can only be achieved by investing time and resources in proper selection, training and mentoring of the lay providers, and periodically evaluating their performance, and training for continued improvement. This framework focuses on multiple facets of quality that starts from selection to training, monitoring and evaluation, and certification. Each component of this competency framework is discussed individually in the following sections.

2.4.1 Basic criteria for selection of lay HIV screening service providers:



The CLT programme must select and train lay providers who are part

of or matched to the population(s) they serve. A lay HIV screening service provider preferably belongs to one of the key populations, as identified in the NHSP. Trained lay providers must have the trust of their clients and demonstrate professional conduct, knowledge, skills and competencies in dealing with sensitive issues, respect for confidentiality, and the ability to listen - unprejudiced.

The following are the recommended basic criteria to be a lay HIV screening service provider:

- 1. Must belong to the community of interest;
- 2. Be able to read the guidance and perform basic recording and reporting;
- 3. Must be residing in the area of work for a reasonable amount of time;
- 4. Have experience in peer education, and outreach and/or in-reach work for at least 12 months;
- In areas where previous outreach or in-reach based HIV services do not exist, CLT must only be introduced after 3 to 6 months, after the implementation of an in-reach based HIV programme;

6. Not all in-reach workers would be ready to perform HIV testing from day one. A competencies and 'readiness' assessment, preferably by the NPHL or an accredited HTC, are essential, before starting HIV screening, by a lay service provider.

Whenever feasible, it would be beneficial to select and train lay providers from existing peer educators, in-reach workers, outreach workers, social mobilizers etc. In cases where there are not enough or not enough suitable candidates, additional members of key populations could be recruited and trained accordingly.

2.4.2 Selection process

A competitive selection process ensures that the selected lay providers would be the best performers. The following are the recommendations for the selection of lay providers.

- Lay providers must be competitively selected, and must meet all basic selection criteria, and further qualify based on a system where purposive allocation based on gender, geographical availability, and alignment with a key population of interest, needs to be applied. The recruitment process must be transparent.
- Not all in-reach workers would be willing to perform HIV testing. This must be a key consideration in the selection of lay providers for HIV screening.
- It is also important to note that not all peer educators and in-reach workers would be ready to independently perform the rapid diagnostic HIV screening test, from day one.

2.4.3 Remuneration

Trained lay providers may cost less than health workers with higher education, longer professional training, and experience. However, it is important that the CLT programme fairly compensates trained, certified lay providers for their work, based on, agreed upon, standardized remuneration. These workers must receive adequate wages, to avoid turnover. This needs to be decided jointly, across the CLT programme. Note that the main reason for involving lay workers is for communities to increasingly access HIV testing services, and not to reduce cost. Remuneration depends on the existing policies of an organization and also depends on the volume of work. The fair pay also means that the lay providers must not use HIV screening as a means to ask for additional pay in cases where outreach- and in-reach workers are already remunerated for their work.

2.4.4 Training of lay providers

Like other health-care providers, lay providers need training, mentoring and supervision by on-site supervisors, from those trained in laboratory procedures for HIV testing, from NPHL. Standardized training will cover HIV test procedures, including collecting specimens; performing the rapid HIV screening test; providing pre- and post-test-counselling; accompanied; daily recording of work, and periodic reporting.

As a part of the broader HIV in-reach programme, the lay providers must also be equipped with the HIV prevention, basic treatment and mitigation education, and referral skills. The following table outlines key areas to be covered during the training for the lay providers to work within the HIV in-reach programme:

Training for in-reach workers on HIV prevention and referral	Training on performing HIV screening test for lay providers
 Training for in-reach workers on HIV prevention and referral is taken from the current training module under TI programme. The module contains the following topics: HIV Basics - Epidemiology, transmissions, treatment and care Introductions to common STI, their prevention, and management Tools and skills to prevent HIV, such as the correct use of condoms, needles and syringes, eVT, and PreP HIV treatment, care and support, including ART; CHBC; CCC; OI, including Hep C, and TB-HIV Co-infection Community in-reach principles; steps; roles and responsibilities of an in-reach worker; the '9 Ds' of good quality in-reach Peer Education: Concepts and processes Communication for change concepts Communication jobservational skills; active listening Counselling types and steps of counselling; 'Do's and Don'ts'; qualities of a good counselor, counselling and communication for change Differential messaging, such as understanding clients; addressing client's barriers; providing specific information; encouraging uptake of services Counselling role play HIV testing principles, community-based testing approaches Basics of EID, eVT, CD4 and viral load principles and concepts Roles and responsibilities of in-reach workers in CBT, EID, eVT, CD4 and viral load testing 	 The following content is recommended for the training of lay providers for community HIV screening: HIV Basics, such as local epidemiology, transmission, prevention HIV epidemic and testing coverage among key populations Introduction to community-led HIV testing National HIV Testing and Treatment Guidelines, and National Community-Led Testing Guidelines' provisions and safeguards Engaging clients and providing accurate and complete information to obtain consent for an HIV screening test Explaining screening and diagnosis processes, and the differences between screening and confirmatory testing Explaining the importance of linkages to care and treatment Obtaining, preparing, carrying and safeguarding the community HIV screening test supplies Personal protection and universal precaution, biohazards and risk of Hepatitis virus transmission by contaminated blood Recording clients' ID, common errors while labeling samples and results, etc. Recording client information on the in-reach workers' HIV test register Performing tests, including procedures performed before, during and after a test o Finger prick techniques O Determine test theory and demonstration Determine test (hands on practice) Reading test results Common mistakes while conducting HIV tests and reading the test results Waste management: on-site techniques; cleaning and disinfecting test area, waste separation and disposal, transportation of infectious waste and proper disposal Interpreting and explaining test results to the clients Difference between screening result and a confirmatory HIV diagnosis Obtaining net conducting test area, waste separation and disposal, transportation of infectious waste and proper disposal Interpreting and explaining test results to the clients Difference between screening result and a confirmatory HIV diagnosis <li< td=""></li<>
	with confirmation capacity

For in-reach workers, existing training curricula of traditional peer educators and outreach workers need to be revised in order to be harmonized with and be based on the NHSP 2016-2021 and the 'National HIV Testing and Treatment Guidelines 2017.' Additional training content will include:

- Risk reduction, and scheduling a follow-up HIV test
- Accompanied referral for a reactive client
- Following up clients after confirmed HIV diagnosis
- Supporting clients in preparation of partner referral for HIV test
- Active case finding and referral for HIV [screening and confirmation] test
- Supporting HIV positive clients to access to ART and continuation of treatment
- Creating a supporting environment for HIV testing in the community

As more in-reach workers will continue to take on an HIV screening role in Nepal, the different programmes must also phase-in care and support components, as part of their scope of work. This will create the required continuum of case-finding/case management, as per NHSP (see page 20), in order for in-reach workers to support clients who are confirmed HIV positive, by providing follow-up counselling on treatment adherence, positive prevention and other care and support services.

2.4.5 On-site mentoring

Before trained lay providers are certified to perform a HIV screening test, the first 6 tests need to be directly observed by a CLT supervisor, to assess quality of information provided on HIV testing, and a lab technician for quality assessment of the actual HIV testing. The CLT supervisor and the lab technician need to observe the test process and provide feedback from each session at the end of the day. If there are issues of concern in the HIV testing process performance, either the lab technician must invite the lay provider to discuss their observations after the completion of 6 tests and point out any shortcomings in providing good quality HIV screening services, and provide hands-on assistance to correct the problems.

2.4.6 Certification

Lay providers who complete 6 observed HIV tests in the community, after their proper selection, recruitment and training are certified as "Trained Lay HIV Screening Test Provider" and are ready to perform their independent HIV screening tests at a community setting. Such certifications are annual and will be renewed based on the performance. The HTC site in coordination with the local health authorities can certify a lay provider for HIV screening tests. A sample certificate is presented in Annex-3. The following conditions are mentioned in the certificate of trained lay HIV screening service provider:

- 1. The trained HIV screening test provider is only allowed to perform HIV screening tests and is required to refer for a confirmatory HIV diagnosis to an HTC.
- 2. The trained HIV screening test provider is only allowed to perform HIV screening tests among HIV key populations and their partners in a community setting within a pre-approved area, and in a programme for and with key HIV populations.
- 3. The trained HIV screening test provider is not allowed to confirm HIV diagnosis, and issue any certification on HIV status and or result(s) of any other lab test.
- 4. The certificate provided to trained HIV screening test provider is not an approval of any lab capacity except mentioned in condition no 1. This certificate cannot be used outside of this designated CLT programme and cannot be used to obtain employment in laboratories and/or projects.

2.4.7 Mentoring and providing on-going support to the lay providers

A coordinator from an HTC and the in-reach supervisors must continually provide ongoing support and supervision to the lay providers. That supervision specifically needs to include training and follow-up on how to provide information on HIV testing, how to increase buy-in, how to conduct a quality HIV test, '5 Cs' and effective referral. At minimum, the following mentoring process must be included in the activities of CLT supervisors, lab assistants/technicians and coordinators of an HTC:

- 1. After each referral for a confirmatory HIV test, the result of all "reactive" referred client must be discussed with the lay provider who did the screening. The discussion must also focus on minimizing discordant results.
- 2. In the initial stages, proficiency panel testing must be conducted, more frequently. Lab personnel need to mentor and supervise trained lay providers at set intervals, and discuss unusual results, quality markers, universal precautions, biosafety and waste disposal.
- 3. Once a lay provider is considered experienced, for 6 months or more, proficiency testing can be scaled down, as per NPHL guidelines and recommendations.
- 4. Field monitoring of lay providers who perform HIV screening must be regular, with clear indicators to monitor the quality of work.
- 5. Formal reporting rules and mechanisms to the CLT coordinating and supporting institutions, including funding agencies, need to be established and implemented.
- 6. All participants in Nepal's CLT programme, regardless of implementing entity, must provide periodic reports to the NPHL, NCASC and other institutions, as required by the CLT governance arrangements.

2.4.8 De-certification

Since all false positive reactive results, including those at an HIV screening site, create major anxiety for clients, a lay provider with repeated false reactive referrals, needs to stop providing HIV testing services and must be re-trained. In situations when a lay provider is not improving performance after an agreed period, a lay provider can be de-certified. Such action would be the last resort, and must be taken to minimize potential harm to clients, due to repeated failure to provide a good quality HIV screening test, with trusted results. In addition to this, the following are the recommendations for de-certification of a trained lay provider:

- All trained lay providers who have not performed an HIV screening test in a period of 6 months must go through the same certification process as a new lay provider, or need to be replaced by a new lay provider.
- All trained lay providers who have not performed more than 50 tests in a 12-months period must go through the same certification process as a new lay provider.

2.5 Identifying hot spots for appropriate inclusion

As CLT is a part of a broader in-reach based HIV prevention and testing programme, based on IRRTTR, community mapping is recommended as an on-going process. Community mapping, as part of 'Identifying' needs to be undertaken periodically. For a new site starting an in-reach based HIV prevention programme with CLT, the following strategies are advised for the promotion of CLT, based on recommendations on HIV testing and retesting:

 For members of key populations with a formal work-place, such as facility-based sex-workers, or for those who frequently hangout in a specific site, place or area, promotion of HIV testing services and actual HIV screening can be done in those locations, or in a nearby CIP. For those who do not necessarily have a place of work, HIV testing can be promoted at a place of gathering, office, or even at home.

- 2. Promotion of HIV testing using social media, such as Facebook, Twitter, and hook-up apps such as Grinder and Tinder, can be used to promote community centric HIV testing; including referrals of new clients into a CLT testing programme. Online, anonymous chat rooms can also be used for reaching-in to those who are not easily accessible.
- 3. The web-based Short Message Service (SMS) developed by the USAID funded Asha project and currently being used by LINKAGES Nepal can be expanded to disseminate alert messages on benefits and importance of HIV testing and linking key populations with CIPs.

2.6 Offering HIV test:

All key populations, enrolled in HIV programmes in Nepal must be offered an HIV test once every 6 months. Clients must be provided with adequate information about benefits and risks of HIV testing, and provide their informed consent before being tested. At a minimum, it is suggested that clients will be provided with the following information:

- Overview of HIV testing, what is being tested (e.g. antibodies), testing process and procedures
- Benefits of testing
- HIV "basics" (e.g. transmission and prevention).
- Screening- versus diagnostic/confirmation testing
- Timeline for obtaining results and what a reactive and nonreactive test means.
- The 'window' period, relative to last risk and exposure.
- Verbal consent is sufficient. Age of consent for Nepal is 16 years.
 It is important to provide clients with

Benefits of HIV Testing

- Trained lab personnel, of an HTC, will confirm all HIV reactive screening test results.
- All those who test HIV negative will be retained to participate in community in-reach activities to remain negative
- In Nepal, everyone who gets tested positive for HIV immediately qualifies for life-long free anti-retroviral treatment
- Detecting HIV early makes it possible to control the infection while the immune system is still strong.
 - Early HIV diagnosis and treatment reduces negative side effects from medications and improves long-term survival rates.
- Knowing HIV status helps taking steps to prevent onward transmission of HIV to a partner, spouse, and a child.
 - Taking treatment early, and reducing the amount of viral load to an undetectable level, stops HIV transmission: Undetectable is Untransmissible: "U = U"
 - Even if an HIV infection is detectable, and a person has HIV-related symptoms, it is possible to regain a stronger immune system, by adequate treatment.
 - Detecting HIV early reduces the risk of HIV re-infection. In the case of re-infection, not only will the disease progress faster, it puts a person at risk of developing a resistant virus.

an opportunity to ask, and have answered any questions about HIV and the testing process

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Needs for information on HIV, the testing process, possible outcomes, etc. can be different among different clients.

- For those who have received HIV counselling and have been tested before, detailed introductions to HIV testing may not be required.
- Even after initial acceptance and consent, it is important to assess client's readiness to take an HIV test.
- In cases when a lay provider cannot be confident about the readiness of a client to be tested, referral to a point of care site is recommended, or testing at a later date can be negotiated.
- It is important to consider the risk of partner violence, risk of losing a job, and other securities. Those, who through pre-test counseling are found to have a significant risk to be found HIV positive, HIV screening needs to be postponed until such issues have been resolved, or refer the client to an HTC, where more advanced trained, and experienced counselors can better assess such risks.

- For infants, adolescents and people who cannot provide consent, lay providers must refer the client to a point of care site.
- Clients who are pregnant, or those who are suspected of having mental illness and those who, for any other reason seem not to be ready for an HIV test, need to be accompanied to an HTC that is better equipped to address such issues.

2.7 Ensuring consent:

Age of consent for obtaining an HIV test in Nepal, is set at 16 years. It is important to obtain consent from a client prior to performing an HIV test. Verbal consent is sufficient, written consent is not required. All consent must be given after being informed. So, the lay provider must ensure that:

- The client has fully understood the HIV test, its benefits and its risks.
- The client is clearly informed what the screening test means and how it differs from a confirmatory diagnosis.
- The client is informed about the next steps if the screening test is reactive, and where he or she will be accompanied to for confirmatory diagnosis.
- The client is informed about the benefits of HIV tests and available treatment for people who are diagnosed with HIV.
- The client must be informed about his or her right to choose for the HIV test on some other day or to get tested in a point of care HTC, or elsewhere, and also to refuse the test altogether.

2.8 Conducting HIV tests

The HIV screening test is performed by using rapid diagnostic test kits (RDT). HIV rapid tests are simple, utilize minimal equipment, and do not require sophisticated training. HIV RDT are very sensitive and specific. Experiences from other countries indicate that the use of HIV rapid tests, with counselling and same-day test-results is cost-effective, efficient and more acceptable.

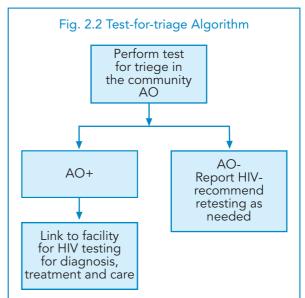
Nepal uses a serial HIV testing algorithm using 3 rapid tests. This means that the results of the first test determine whether additional testing is required. All specimens are first tested with assay One A1 (first test), and specimens that are nonreactive (A1-) are considered HIV negative. Any positive test results on first test (A1+) must be confirmed with two additional reactive positive tests (A2+ and A3+) at an HTC

2.8.1 Algorithm for CLT:

Community-led testing in Nepal is based on the WHO recommended 'test-for-triage' approach. This involves trained lay providers conducting a single HIV rapid screening test,

referred to as A0 in figure 2.2. Lay providers promptly link and accompany people with a reactive screening test result to an HTC facility for confirmatory HIV testing. Those with non-reactive test results are informed of their results, and linked to appropriate services to prevent HIV, and recommended for re-testing in 3 months if they have had recent risk, or have an ongoing HIV risk. All returning clients are advised to retest once every 6 months.

It is important to note that the screening test in the community (A0) does not replace or overlap with the national HIV testing algorithm (A1).



If the screening test in the community is reactive (A0+), the person is promptly linked to a facility for further HIV testing, where the national testing algorithm is performed, beginning with A1(see page 25 of the National HIV Strategic Plan 2016-2021). If the reactive screening test (A0+) is confirmed, and the person is given an HIV positive diagnosis, and is immediately linked to clinical assessment, and treatment.

For Nepal, Alere Determine[™] HIV-1/2, A rapid in vitro qualitative immunoassay for detection of antibodies to the Human Immunodeficiency Type (HIV-1) and Type 2 (HIV-2) is used as the screening test at the community setting.

2.8.2 Basic facts about the screening test kit:

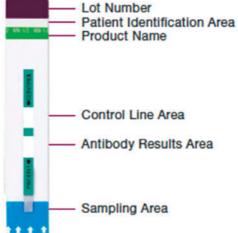
Alere Determine HIV-1/2 is an immuno-chromatographic test for the qualitative detection of antibodies to HIV-1 and HIV-2.

Description of Kit:	
Kit contents:	Serum assay contains 100 tests or 20 tests
Run time of test:	15 minutes
Storage conditions:	2-30° C
Quality control (QC):	Procedural QC is incorporated in the device
Shelf life:	Shelf life is indicated by the expiration date printed on the test package

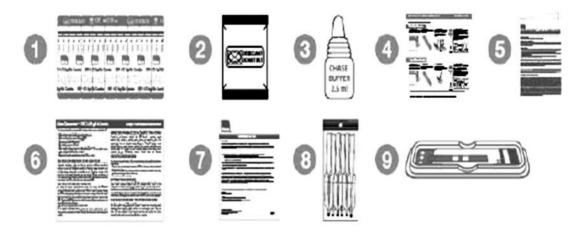
Materials provided to the lay provider

- Alere Determine[™] HIV-1/2 test strips. Each Card consists of 5 or 10 test units, which can be separated by tearing along the perforated lines. Each Test Unit has a cover that is to be removed for sample application and visualization of test results.
- 2. Desiccant Package
- 3. Chase Buffer: Containing sodium chloride, disodium preservative.
- 4. Quick Reference Guide
- 5. Package Insert
- 6. Subject Information Notices: 20 in the 20 Test Units ki
- 7. Customer Letter
- 8. Disposable Capillary Tubes: For collection and transfe





9. Disposable Workstations: 20 in the 20 Test Units kit, and 100 in the 100 Test Units kit (only in some batches, can use flat surfaces to run test if the pack insert do not include workstations).



2.8.3 Test Procedure:

It is important to ensure that the testing area is discrete as well as well lit. The available surface is flat and it is easy to open the HIV test kits. The surface must be flat, so that all the consumables can be spread out, and be easily and accessed when necessary. During a rapid HIV test, a lay provider needs to ensure the following:

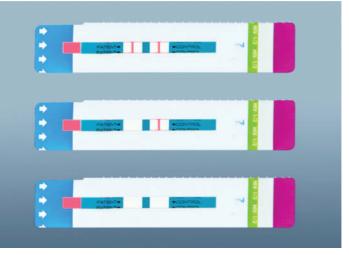
1.	Properly record the clients' identification on the client register	· Alternation
2.	Remove the desired numbers of test units from the 5- or 10-Test Unit Card by bending and tearing at the perforation. Removal of the test units should start from the right side of the Card to preserve the lot number, which appears on the left side of the Card.	
3.	Check for the expiry date of the test kit. Confirm that the text kit indeed has not expired.	
4.	Accurately label all test- with full name, client code number, date, and initials of lay providers.	
5.	Lay the Test Unit flat on the surface and remove the protective foil cover from each Test Unit. The test should be initiated within 2 hours after removing the protective foil cover from each Test Unit.	(A)
6.	Align the tip of the Capillary Tube containing the blood sample with the Sample Pad (marked by the arrow symbol) and gently squeeze the bulb. Avoid air bubbles. Wait until all the blood is transferred from the Capillary Tube to the Sample Pad. Caution: Do not lift the Capillary Tube from the Sample Pad before all the blood has been transferred - a bubble may form which will prevent the complete transfer of sample.	1
7.	After transfer of the sample apply one drop of Chase Buffer to the Sample Pad.	
8.	Read the test result between 15 and 30 minutes after the addition of the Chase Buffer. Do not read test results after 30 minutes.	

2.8.4 Reading Test Result:

In a community setting an HIV screening test, conducted by a trained lay provider, is not considered as a confirmed HIV diagnosis.

For the CLT programme in Nepal, HIV screening results are interpreted as follows:

- Preliminary Reactive (Two Bars): Pink/Red bars appear in both the control window (labeled "Control") and the patient window (labeled "Patient") of the strip. Any visible red colored bar in the patient window needs to be interpreted as reactive, even if the line is lighter or darker than the control line.
- Negative (One Bar): One pink/red bar appears in the control window of the strip



(labeled "Control"), and no red bar appears in the patient window of the strip (labeled "Patient").

Invalid (No Bar): If there is no pink/red bar in the control window of the strip, regardless
of whether a pink/red bar appears in the patient window of the strip, the result is invalid
and must be repeated. If the problem persists, lab personnel at an HTC must be consulted

Alere Determine[™] HIV-1/2 test controls must be tested prior to testing client specimens when a new test kit lot is to be used, a new shipment of test kits is received, and at periodic intervals by the lab personnel at an HTC. Controls must be tested in the same manner as during the normal screening procedure.

2.8.5 Finger prick technique:

Trained lay testers perform the finger prick technique for taking a blood sample in the community setting. These are the steps to follow for correctly performing a finger prick to collect a blood sample for a rapid diagnostic HIV test.



Massage to warm the finger and increase blood flow by gently squeezing 1. from hand to fingertip 5-6 times. Cleanse fingertip with 70% isopropyl alcohol (provided with the test kits). Using a sterile lancet, make a skin puncture just off the center of the 2. finger pad. Best locations for a finger stick are the 3rd and 4th fingers of the non-dominant hand. Make the puncture off to side of the center of the finger. NEVER use the tip or center of the finger. 3. Wipe away the first drop of blood, which tends to contain excess tissue fluid, using a sterile gauze. If necessary, apply light pressure to the surrounding tissue until another drop of blood appears. Avoid "milking". The drop of blood must be big enough to fill the strip completely. Collect the blood sample by holding the capillary tube horizontally. 4. Fill the sample up to the mark (fill-line). Filling of the capillary tube happens without the need to squeeze. 5. Align the tip of the Capillary Tube containing the blood sample with the Sample Pad, marked by the arrow symbol, and gently squeeze the bulb. Avoid air bubbles. Wait until all the blood is transferred from the Capillary Tube to the Sample Pad. Caution: Do not lift the Capillary Tube from the Sample Pad before all the blood has been transferred a bubble may form which will prevent the complete transfer of sample. 6. Add one drop of chase buffer. 7. Wait for 15 minutes to read the test results. Do not read test results after 30 minutes. 8. Dispose all the waste in a biohazard safe container.

2.9 Safety considerations and waste management:

Safety precautions are essential and must be followed from preparing for a finger prick to testing and disposal of biological waste, to minimize occupational, incidental risk of transmission, and also for environmental protection.

The following are recommended steps for the safety of lay providers and others:

- 1. Employ universal precautions: Blood and body fluids from all clients should be considered potentially infectious.
- 2. Wear gloves while pricking blood. Change when contaminated and between each client.
- 3. Wash hands when visibly contaminated and when the test process is complete.
- 4. Collect infectious waste (test kit, lancet, cotton, and gloves) in a waste disposal container and keep it for a disposal in the HTC. Each in-reach test bag has a prick proof container.
- 5. Handle sharps with caution. Do not recap, bend, or break the lancet Use caution in placing the sharps in the container.
- 6. Collect all non-infectious waste, including general waste, in a separate container.
- 7. All general waste needs to be disposed of in the community (landfill, burn, etc.).
- 8. All infectious waste must be brought to a pre-designated disposal area. It is the responsibility of an HTC to develop a waste disposal plan, with the community, such as collection frequency, disposal of sharps and method for collection of infectious waste, and for disposal of infectious waste.
- 9. All infectious waste needs to be disposed of according to the nationally recommended standards.

Safe waste disposal must be part of the training of the lay service providers and each lay provider should have clear guidance on how to dispose of infectious waste. All HTCs must develop a plan for the disposal of the used devices with each lay provider, during training.

2.10 Management of Occupational Exposure

The most common accident is the percutaneous needle prick. Sometimes exposure to blood, semen, amniotic fluid, and other blood-mixed body fluids to mucous membranes may happen. The transmission of HIV infection through occupational exposure is rare. The risk of infection via percutaneous exposure is estimated to be approximately 0.3%. Risk after a mucous membrane exposure is estimated at 0.09%.

In a case an exposure happens:

- Immediately wash the exposed part with soap and water.
- Do not squeeze the part and do not apply antiseptic, as it increases the area of trauma and may attract CD4 cells to the site of exposure.
- Immediately report the exposure to the supervisor and visit a pre-designated health center or hospital to follow post-exposure protocols.

All HTCs with a CLT programme need to have a post exposure prophylaxis protocol in place for the lay providers, and all must be adequately trained on these protocols to follow, if an accidental exposure happens. If there is an accidental exposure and a clinical evaluation ascertains that there is a risk, the lay provider must receive post exposure prophylaxis (PEP), according to the national guidelines.

2.11 Maintaining quality of CLT programmes:

The NPHL and its affiliated laboratories, at provincial and local levels will have the ultimate responsibility for maintaining the quality and safely of all HIV testing services in Nepal, including, and not limited to a 100 % compliance with the National External Quality Assurance Scheme (EQAS). For a site that is managing CLT, it is mandatory to report all discordant results to the relevant laboratory.

For CLT to be able to provide reliable, safe and good quality HIV testing the following strategies are to be applied:

- All lay providers are trained according to National Competency Standards for lay HIV testing service providers.
- Results of HIV testing at the community level are included in national reporting, and are carefully reviewed. Feedback are regularly provided to the site.
- The national laboratory authorities need to ensure that there is documented evidence in place to discuss sero-discordant results between the lay providers and the lab personnel.
- The NPHL, and the HTCs must regularly conduct testing proficiency assessments and refresher courses.
- The HTCs must also monitor community-based screening and provide feedback to lay providers.

The most crucial part of ensuring and maintaining the best quality of HIV screening at the community level is to guarantee the quality of HIV testing in the HTCs that coordinate and oversee a community-led screening programme. It is important that all laboratories at national, provincial and local levels, that provide HIV confirmatory testing, have a well-functioning internal quality assurance programme. This includes following standard operating procedures specified by the HIV test kit manufacturers. Each laboratory performing HIV testing must routinely monitor and assess the quality in the pre-analytical, analytical, and post-analytical phases of the HIV testing process. HTCs with a 100% concurrent performance in EQAS can effectively manage a community-led HIV testing programme with a good quality.

2.12 Interpreting and informing screening test results:

Reactive test:

A reactive test result means the client is likely to be HIV positive. This, however, will only be confirmed at the site.

All reactive results should be explained clearly to the client. The following strategies are recommended:

- Remind client, not to panic.
- Inform that the HIV screening test is accurate, and, according to Nepal's testing Guidelines must be confirmed at an HTC.
- Inform that everyone who has HIV will be recommended to receive free ARV medication immediately.
- Remind that it may be difficult to the client in a short term, but there is a help and in a long run and the client would be grateful that the HIV was diagnosed in time and that he or she benefited from early treatment.
- Inform that even in a developing country, people living with HIV can live as long as others in community by regularly taking medications.

It is important to reinforce that the test needs to be confirmed, and the lay provider will take the client to the confirmation site. Reassure the client that the people who work at a HTC are very considerate and friendly. There is no need to worry about anyone discriminating him or her. In HTC all information about the HIV test would be kept confidential and would not be shared with anyone without consent.

Non-reactive test:

A non-reactive test result means the client is likely to be HIV negative. This, however, will only be confirmed after looking at the window period. All non-reactive results should be explained clearly to the client.

The following strategies are recommended:

- Remind that a non-reactive result does not guarantee that he or she is HIV free
- Discuss window period and immediate risks
- Reinforce the importance of using prevention tools (condom, clean needles, etc.)

- Discuss follow up test
- Discuss network referral for HIV test
- Discuss ways he or she can promote HIV testing among peers

All clients at a community setting, with and for key populations, are encouraged to repeat the HIV screening test.

Those with non-reactive test results are informed of their results, and linked to appropriate services to prevent HIV, and recommended for re-testing in 3 months if they have had recent or have ongoing HIV risk. All repeat clients will be advised to retest once every 6 months.

While a differential approach to new and repeated tests is recommended, in cases of non-reactive test results, all clients must be educated on ways to prevent an HIV infection. This needs to be even more reinforced for returning clients. The provision of post-test HIV education, counselling and support depends on an assessment of what the client requires. For repeated tests, it is advised to ask specific risk-taking questions, reinforcing the need to stay protected. If a client requests information that an in-reach worker is not able to provide, or is unsure about the answer(s), this information must be sought from an HTC supervisor or from a reliable HIV information source, and be offered at a later time, or refer to client to such information source. In-reach workers must always refrain from providing incorrect, misleading or biased information.

2.13 Accompanied referral for confirmatory test:

For all reactive cases, an in-reach worker accompanies the client to an HTC for confirmatory diagnosis Information about such accompanied referral needs to be discussed during pre-test counseling, as part of the consent-giving process.

These are the recommended steps for companied referral - preferably to be undertaken within 24 hours of receiving a reactive screening test result:

- 1. While sharing the reactive screening test results, reinforce that all positive screening test results require confirmation at an HTC.
- 2. Inform the client where (location) and how far (distance) and when (time) the confirmatory testing will be performed.
- 3. Explain the procedures at an HTC.
- 4. Inform that the client does not have to spend any money for travel and HIV diagnosis test
- 5. Reinforce confidentiality at an HTC.
- 6. Reinforce benefits of confirmatory diagnosis and availability of free ARV treatment.
- 7. Make an appointment at the HTC and accompany the client for confirmatory testing preferably on the same day as when the reactive screening test result was given.

It is important that there is a plan on where to and when clients will be accompanied to an HTC. Such a plan must include opening and closing hours of an HTC, weekends and public holidays, mode of travel, tentative cost, etc. All lay providers must have phone numbers of a pre-identified focal person at the HTC, and an alternative focal person, to call and coordinate for confirmatory HIV diagnosis.

Sometimes a client requires and requests time to digest a reactive HIV screening test result, and would not immediately be ready or agree on going through a confirmatory diagnosis. In such cases, the lay provider must allow the client some reasonable time to make his or her decision; yet, continuously explain the importance of such follow-up testing; both to get a definite diagnosis, and to be recommended starting ART, as soon as possible - if indeed confirmed positive.

Travel to an HTC may need preparation on the part of the client, and complications may arise with family members and/or other members of the community wanting to know what such travel is all about. Shared confidentiality, with 100 percent client consent may be considered. In such cases, the in-reach worker may propose to have a trusted person additionally accompany the client to the HTC Even after multiple efforts, some clients may still refuse to be retested for a confirmatory diagnosis. It is of the utmost importance that every client who is tested reactive in a community setting, reaches an HTC for a confirmatory diagnosis. The wishes of the client need to be respected, and the lay provider would need to seek support and guidance from a supervisor. In all of this, confidentiality of the client needs to be maintained at all times.

An HTC site coordinator is responsible for arranging ART services including pre-ARV laboratory examinations, clinical care including treatment of other infections and initiation of ART. It is important that the lay provider helps facilitate this process. A lay provider is also required to facilitate linkages to other community care services.

2.14 Voluntary assisted partner notification:

All clients with a confirmed positive HIV diagnosis need to be encouraged to disclose this status to spouse, and/or sex partner(s), and strongly recommend such partner(s) to undertake an HIV screening test.

Introduction of the partner notification concept, by the lay provider, needs to start as early as during pre-counselling for HIV screening. It is important for a lay provider to communicate with and seek guidance from a professional counselor at the HTC, about ways to facilitate a partner disclosure process, once the test result comes back as positive. Lay providers can use their community knowledge and competence to encourage partner referral and voluntary opt-in for an HIV test. All this with absolute consent of the client.

While encouraging spousal or partner(s)' disclosure, counselors and lay providers need to be mindful of potential intimate partner-based aggression and violence, and other adverse effects of a positive HIV diagnosis. Disclosure is an ongoing process and may take time. It is the duty of a lay provider to continually encourage, yet never be forceful, for a client to disclose HIV status to sex partner(s), and recommend and strongly encourage such partner(s)' for HIV screening.

It is important to continuously guide individuals who do not want to disclose their HIV diagnosis to their partner(s). For such clients, an unlinked HIV test can be offered for sex partners, children, and other family members, which can be done individually. All HIV testing in the community, and elsewhere within any HIV programme, must ALWAYS be voluntary.

2.15 Community follow-up and active case finding

There is a major public health benefit of immediately offering HIV screening to sexual networks, sexual clients, and drug users networks, of a person who is newly diagnosed with HIV: The 'Index.' Active case(s) finding is a process that includes understanding of risk networks of a client. In the community of a lay provider, this could include geographical areas to be selected for more robust in-reach, and recommendations and referrals of persons belonging to a risk network, for HIV screening.

Two basic approaches are recommended.

- 1. Offering an HIV test to the "HIV transmission risk network" by encouraging a network referral. After explaining the risks, the lay provider can encourage newly diagnosed clients if they can recommend other members of their network for an HIV screening test. Such referrals have to be done confidentially and voluntarily.
- 2. Expanding in-reach around a newly diagnosed HIV positive client is can done, by recruiting newly diagnosed HIV positive persons as in-reach workers.

2.16 Maintaining records:

As in-reach workers, the trained lay-providers are expected to record and report to their HTC:

- 1. Total number of members of key populations reached for primary HIV prevention and recommending HIV screening
- 2. Total number of members of key populations screened for HIV (new and repeat)
- 3. Total number of members of non-key population screened for HIV, such as spouses, sex partners, family
- 4. Total number of clients screened reactive
- 5. Total number of clients referred for confirmatory diagnosis at an HTC
- 6. Total number of clients confirmed with HIV (of the above '5')
- 7. Total number of clients not reactive/discordant (of the above '5')

For HIV screening at the community, a lay provider is required to register the following details in their register and pass on this register to their HTC. It is expected that, over time, this reporting may be automated

Serial Number	Date	ID (Code)	New/Rrepeat	Age	Gender	Key Population	Screening result	Remarks
								Including discordant results after confirmation at the HTC; Partner notification, etc.

List of indicators for the systematic collection of data on quality and effectiveness of the community-led HIV testing programme is discussed in a later section.

2.17 Managing supplies (test kits and other commodities):

Every lay provider providing HIV screening test services in a community receives an HIV working bag. Such a bag will contain educational materials; condoms and lubricants; needles and syringes for those working in PWID programmes; HIV testing supplies and consumables; infectious waste collection container. The consumables need a continuous and timely resupply. Supply of test kits is recommended for a weekly replenishment, or as per demand. This is agreed upon with the HTC, and is based on the total number of clients tested per week; the number of test kits used, and number of test kits wasted. The HTC coordinator approves re-supply.

Contents of HIV test kit bag

- Alere Determine[™] HIV-1/2 test strips. Each Card consists of 5 test units; all lay providers should carry a pack of 20 tests in the original pack.
- 2. Lancet and lancet holders
- 3. A bottle of Chase Buffer
- 4. Quick Reference Guide of HIV test
- 5. Disposable Capillary Tubes:
- 6. Infectious waste collection container
- 7. Educational materials
- 8. Condoms and lubricants
- 9. Syringes for PWID programmes

2.18 Quality Assurance at Community-Led HIV Screening Sites and at HTCs:

The most crucial part of maintaining the quality of HIV testing at the community level is for the CLT programme to assure quality excellence of both HIV screening in the community, and HIV testing, including HIV diagnosis conformation, and other HIV-related services at an HTC.

For this:

- NPHL standard operating procedures, protocols and guidelines for HIV screening and testing must be followed and adhered to.
- All lay services providers performing HIV screening tests, doing in-reach activities to prevent HIV in their community, and providing care and treatment support, must all be recruited and trained based on selection criteria, trained and accredited by the NPHL and NCASC.
- A standardized, national CLT training curriculum will be used for training of all in-reach workers in Nepal.
- Each laboratory performing HIV testing must routinely monitor and assess the quality in the preanalytical, analytical, and post-analytical phases of the HIV testing process.
- A site with a nationally accepted concurrent performance in EQAS can effectively manage a community-led good-quality HIV testing programme.
- It is mandatory for an HTC to report all community HIV screening test discordant results to an EQAS referral laboratory.
- All HTCs providing support, overseeing and coordinating trained lay provider who screen for HIV, at minimum must have one trained and certified (NCASC) HIV counselor, and a trained and certified (NPHL) lab technician.
- All sites that are managing in-reach programmes need a work plan, budget and necessary resources to support the activities discussed in earlier sections.
- All sites performing in-reach based activities, including CLT, and initiatives to prevent HIV and conduct care programmes, must do so according to national standards.

In addition, all laboratories at national, provincial and local levels that conduct HIV testing must have a functioning internal quality assurance programme.

Special consideration for organizations that are currently providing CLT, from before these December 2017 National CLT Guidelines came into effect:

- Where public and private institutions, and NGOs, and CBOs, and Community Networks already perform community-based or community-led HIV testing, a mechanism needs to be established, within 3 months of these CLT Guidelines becoming operational, e.g. by April 2018, to select and [re]train community lay providers, according to these Guidelines and the CLT training Curriculum.
- CLT competencies of all public and private institutions, and NGOs, CBOs, and Community Networks already performing community-based or community-led HIV testing need to be reviewed, and a mutually agreed training plan needs to be put in place. Lay providers of all such sites must be certified within 9 months from these Guidelines becoming operational; e.g. by June 2018, or be deemed in-eligible to implement CLT.

1.19 Promotion of CLT:

HIV testing normalization and promotional-campaigns addressing individual, social and structural barriers must be undertaken at the national, provincial and local levels.

Obstacles to HIV testing remain, due to real or perceived social prejudice and discrimination towards people who sell sex; gay man and other men who have sex with men; people who inject drugs, and persons with alternative sexual orientations and gender identities. Prejudice and exclusion are also experienced by people who are living with HIV. A positive HIV diagnosis can be the end of means to earn a living and participate fully in society.

Community-Led HIV testing is not only about performing an HIV screening test in a community, and accompanying those who screen positive to obtain a diagnosis conformation. CLT is especially about Fast-Tracking the implementation of the full scope, scale, intensity, quality and innovation of the preventiontreatment/case finding-case management continuum of 'IRRTTR,' as illustrated on page 20 of 'Nepal HIVision 2020."

CLT needs to be introduced and promoted in communities, especially those of key populations, by leaders and members of such communities themselves; including people living with HIV. The use of social media and community events and campaigns will further increase the acceptance of uptake of HTS, including CLT.

Key HTS and CLT promotion messages

- HIV testing is good for you and your family, everyone who has been at risk for an HIV infection needs to test for HIV
- Treatment for HIV is now provided immediately after the diagnosis and is free of cost and widely available throughout Nepal.
- Better off knowing. The sooner you know you have HIV, the sooner you can get the medical care you need.
- HIV testing in Nepal is free, voluntary and confidential. You can be tested at a hospital, HTC, and even in your own community.
- HIV treatment is prevention: How HIV diagnosis helps you stay healthy and prevent onward transmission of HIV.
- Undetectable = Untransmissible
- An undiagnosed HIV infection means you are risking your own health and heath of your spouse or loved ones.
- It is normal to fear the result of an HIV test, but better to know than not to know.

2.20 Focused Monitoring and periodic Evaluation to build evidence for expansion:

Systematic collection of key indicators is recommended to monitor and document successes and failures of the CLT programme. Such systematic collection of data will build evidence for improvement and expansion on such community-led services. Integrating such reporting will be efficient and will eliminate the need separate and ad-hoc assessments, surveys and studies.

The following CLT indicators are proposed:

Area	Indicator	Measurement		
Programmatic Coverage	Proportion of members of KEY POPULATIONS reached through CLT	Numerator/ Denominator = Number of members of KEY POPULATIONS reached through in-reach services by programmes to prevent HIV/ Number of estimated members of KEY POPULATIONS in that area/community.		
Increased Uptake of HIV screening test	Proportion of members of KEY POPULATIONS who accepted a screening test at the community setting	Numerator/ Denominator = Number of members of KEY POPULATIONS who agreed to be screened for HIV in the community/ Number of members of KEY POPULATIONS reached by in-reach in that area/community		
	Proportion of new members of KEY POPULATIONS who are tested for HIV	Numerator/ Denominator = Number of ner clients belonging to KEY POPULATIONS w agreed to be screened for HIV screening ir their community / Number of members of K POPULATIONS screened in the area/community		

1. Improved seek-test-link to HIV care at the service delivery level

Area	Indicator	Measurement			
	Screening reactive rate	Numerator/ Denominator = Number of members of KEY POPULATIONS receiving a reactive screening test result/ Number of members of KEY POPULATIONS screened for HIV			
	Proportion of members of KEY POPULATIONS who are tested for HIV	Numerator/ Denominator = Number of members of KEY POPULATIONS who received a confirmatory HIV diagnosis/ Number of estimated members of KEY POPULATIONS in that area/community			
Successful referral	Proportion of members of KEY POPULATIONS referred to and HTC, for confirmatory diagnosis of HIV, and received confirmatory diagnosis	Numerator/ Denominator: Number of members of KEY POPULATIONS who are referred, by a lay provider, to obtain a confirmatory diagnosis, after a reactive screening test, who received a [HIV positive] confirmatory testing result/ Number of members of KEY POPULATIONS tested reactive at a community screening test			
Quality screening	Concurrence rate	Numerator/ Denominator: Number of screening reactive cases in the community/ Number of HIV positive diagnosis cases at the HTC			
Quality of HIV diagnosis at an HTC	External Quality concurrence rate	Numerator/ Denominator: Number of positive cases reported concurrent by the EQUAS reference laboratory/ Total number of positive cases reported as positive at the HTC, sent for quality assurance			
Linkages to care and treatment	Proportion of newly diagnosed persons with HIV, linked to HIV care	Numerator/ Denominator: Number of PLHIV linked to HIV care/ Number of members of KEY POPULATIONS newly diagnosed as HIV positive after being referred for confirmatory diagnosis by in-reach workers			
		Note: "Linked to care" is defined as PLHIV on ART, or receiving services from health workers of an ART center, or is in the process of starting ART			
Quality of HIV testing services at HTC	Proportion of sero-concurrent results with EQAS	Numerator/ Denominator: Total number of concurrent results by site/ Total number of dried blood spot samples sent by the site			

2. Satisfaction of services and SMS²

Quality and patient satisfaction with community-led testing in Nepal will be monitored through the use of a technology-based service quality monitoring system called SMS². The national programme, with catalytic funding from the Global Fund, and technical assistance from LINKAGES FHI 360, will support the phased rollout of SMS² to include patient and health provider assessments on service quality, prejudice and discrimination, and overall patient satisfaction across 3 levels of HIV testing services for key populations: national centers, HIV Testing Centers (HTC), and community-led testing sites. Feedback will be collected from both services users/clients and providers, through simple surveys via short message service (SMS), using a code that will allow anyone in the country with access to a mobile phone to take the assessment free of charge.

Resulting data will be analyzed routinely to generate national, provincial, local, and facility-specific reports to present clients' feedback on services, that will help the HTS facilities to review such feedback, identify issues and potential solutions, and track outcomes of solutions over-time. Specifically, for the community-led HIV screening sits, the trained lay service providers will be trained on how to use their mobile phone to conduct self-assessments, and review and use resulting facility reports each quarter.

Clients' user feedback will be made available to in-reach workers and HTCs.

Promotional material will be posted in community-led testing facilities, giving clear instructions to clients how to complete assessments on their own phone, after they leave the facility.

SMS² in Nepal will allow the national response to routinely monitor both patient and provider feedback on quality of community-led HIV testing - specifically as it relates to patient experience, quality of the service, and prejudice and discrimination.

3. Cost benefit of CLT:

Programmatic cost effectiveness will be analyzed periodically. The cost of inputs will be compared with other HTS without CLT. This, to ascertain if there is a value added by including CLT as part of Nepal's HTS. The cost of CLT services will be calculated by extracting cost of human resources, including training and remuneration; logistics, including accompanied referrals; maintaining commodities, locally; promotion; monitoring, etc. - and be compared with the cost of HTS with no CLT - against YIELD

Area	Indicator	Measurement
Effectiveness of the CLT programme	HIV yield rate (Service delivery level)	Numerator/ Denominator: Number of members of KEY POPULATIONS diagnosed as HIV positive, after being referred for confirmatory diagnosis by lay providers/ Number of members of KEY POPULATIONS reached through in- reach services in the community
	HIV yield rate (Programmatic level)	Numerator/ Denominator: Number of members of KEY POPULATIONS diagnosed as HIV positive being referred for confirmatory diagnosis by in-reach workers/ Number of estimated members of KEY POPULATIONS in that area/community
	Improved partner(s)' referral	Numerator/ Denominator: Number of steady partners of members of KEY POPULATIONS who are diagnosed with HIV, who were screened for HIV/ Number of members of KEY POPULATIONS diagnosed as HIV positive through the CLT programme and reported to have a steady partner

Annexes:

Annex 1	cientific evidence on the benefits of CLT
Annex 2	HIV testing and counselling recommendations, based on the National Guidelines on HIV Testing and Treatment in Nepal, 2017
Annex-3	Sample certification card for trained lay HIV screening service providers
Annex 4	Community-led testing services implementation plan
Annex 5	List of documents reviewed for preparing these CLT Guidelines
Annex 6	Participants in CLT consultation workshop in Kathmandu- July 7, 2107
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Annex -1 HIV testing and counselling recommendations based on National HIV Testing and Treatment Guideline 2017

Who to test	When to test	Where to test		
People with signs or symptoms of HIV infection, including those diagnosed with Tuberculosis, and/or Hepatitis	Integrate in healthcare encounter- provider-initiated HIV testing and counselling in health facilities, including through community in-reach	HTS centers, STI clinics, TB clinics, hospitals, Primary Health Care (PHC), health posts, other clinics, stand-alone clinics, OST sites and community settings		
Partners of people with HIV	As soon as possible after partner diagnosis. For the negative person in sero- discordant couples, offer re-testing every 6-12 months	HTS centres, TB clinics, STI clinics, hospitals, PHC, health posts, community- led HTS		
Families of index cases	As soon as possible after a family member is diagnosed	HTS centers, TB clinics, STI clinics, hospitals, PHC, health posts, community- led HTS/CLT services		
Key Populations, as defined by NHSP 2016-2021: People who inject drugs, gay men and other men who have sex with men, transgender people and sex workers	Every 6 months	HTS centers, STI clinics, community- led services for key populations and harm-reduction services, hospitals, PHC, health posts		
Pregnant women	At the first antenatal care visit- provider- initiated HIV testing and counselling	ANC settings, hospitals, PHC, health posts		
Migrant workers	On their return to place of origin and before departure to destination. If any signs and symptoms of HIV infection	n. If community-led services for key		

Annex-2 Available scientific evidence on CLT:

In a cluster -randomised controlled trial, 34 communities in four sites in Africa and 14 communities in Thailand were randomly allocated in matched pairs to receive 36 months of community-based voluntary counselling and testing for HIV (intervention group) or standard counselling and testing alone (control group) between January 2001, and December, 2011. The estimated incidence of HIV in the intervention group was 1.52% versus 1.81% in the control group with an estimated reduction in HIV incidence of 13.9%. The results were sufficiently robust, especially when taking into consideration the combined results of modest reductions in HIV incidence combined with increases in HIV testing and reductions in HIV risk behaviour, and the Project Accept approach was recommended as an integral part of all interventions (including treatment as prevention) to reduce HIV transmission at the community level. The following table summarizes the scientific evidence in support of community-based testing:

Community based	A meta-analysis of community and facility-based HIV testing to address linkage to
Community-based testing yields better results	A meta-analysis of community and facility-based HW testing to address inhage to care gaps in sub-Saharan Africa identified that Community HIV testing and counselling had high coverage and uptake and identified HIV-positive people at higher CD4 counts than facility testing. Mobile HIV testing reached the highest proportion of men of all modalities examined (50%, 95% confidence interval (CI) = 47-54%) and home with self-testing reached the highest proportion of young adults (66%, 95% CI = 65-67%). Few studies evaluated HIV testing for key populations (commercial sex workers and men who have sex with men), but these interventions yielded high HIV positivity (38%, 95% CI = 19-62%) combined with the highest proportion of first-time testers (78%, 95% CI = 63-88%), indicating service gaps. Community testing with facilitated linkage (for example, counselor follow-up to support linkage) achieved high linkage to care (95%, 95% CI = 87-98%) and antiretroviral initiation (75%, 95% CI = 68-82%). Expanding home and mobile testing, self-testing, and outreach to key populations with facilitated linkage can increase the proportion of men, young adults and high-risk individuals linked to HIV treatment and prevention, and decrease HIV burden ⁵ .
Community-based testing is feasible	A study evaluated feasibility (population reached, costs) and effectiveness (positivity rates, linkage to care) of two strategies of community-based HIV testing and counselling (HTC) in rural Swaziland. In this high HIV prevalence setting, a community-based testing programme achieved high uptake of testing and appears to be an effective and affordable way to encourage large numbers of people to learn their HIV status (particularly underserved populations such as men and young people) ⁶ .
Trained Lay providers are performing	A review of 1 RCT, 4 observational studies & 6 studies on values & preferences demonstrated that trained lay providers can perform better within HIV testing services using HIV rapid diagnostic tests. Studies identified:
quality HIV test	Increased Uptake: Uptake among ED patients was 57% (1,382/2,446) in the lay provider arm compared with 27% in the healthcare provider arm (643/2,409; RR: 2.12, 95% CI: 1.96 to 2.28)
	Quality & Accuracy equivalent to health workers with longer training: 3 observational studies report lay provider and laboratory staff test results were concordant in nearly all cases o 2 observational studies comparing lay provider and laboratory staff test results, sensitivity was calculated as 98.0% (95% CI: 96.3- 98.9%) and 99.6%, and specificity was calculated as 99.6% (95% CI: 99.4-99.7%) and 100.0%.
	Values & Preferences: General support for lay providers conducting HTS, particularly in RCT & other study measuring preferences among people who had actually undergone HTS with a lay provider.
	Cost: Cost of trained lay providers vary but are generally lower than the cost of health providers with longer training. Trained lay providers can safely and effectively perform HIV testing services using rapid diagnostic test kits.

HIV testing by Lay providers is not necessarily uncommon.	Policies in 42% of countries low and middle-income countries do permit HIV testing by lay providers, 29% are unclear and only 29 % explicitly do not permit lay providers to conduct HIV tests.
	In current national programmes misdiagnosis of HIV-positive status from programme setting and external quality assessment schemes (range: 0.7-10.5%) in Burundi, the Democratic Republic of Congo, Ethiopia, India, Malawi, Mozambique, Myanmar, Uganda, Viet Nam and Zambia. In some instances, over 2 years elapsed between misdiagnosed HIV-positive status and a subsequent retest identifying the patient as HIV-negative.
	Out of 48 national HIV testing policies reviewed by WHO in 2014-2015, only 17% adhered to WHO recommended testing strategies and only 2 included retesting before initiation of antiretroviral therapy (ART) in their national guidelines ⁷ .
Community-based testing detects more HIV cases than standard VCT services	An operational research in ten communities in Tanzania, eight in Zimbabwe, and 14 in Thailand, communities at each site were paired according to similar demographic and environmental characteristics, and one community from each pair was randomly assigned to receive standard clinic-based VCT (SVCT), and the other community was assigned to receive community-based VCT (CBVCT) plus access to SVCT.
	The proportion of clients receiving their first HIV test during the study was higher in CBVCT communities than in SVCT communities. HIV prevalence was higher in SVCT communities than in CBVCT communities, but CBVCT detected almost four times more HIV cases than did SVCT across the three study sites (952 vs 264; p=0.003). Repeat HIV testing in CBVCT communities increased in all sites to reach 28% of all those testing for HIV by the end of the intervention period ⁸ .

Evidence from the Asia and the Pacific region:

Community-based HIV testing in different forms have been implemented in the region in the past decades with mixed results. The following are a few available pieces of evidence:

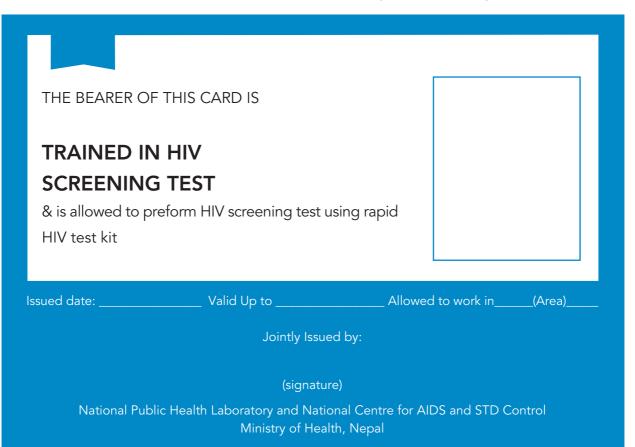
- ♦ A government-supported pilot project that authorized, trained and mobilized CBOs to recruit MSM for rapid HIV testing in China reached a large number of never-tested MSM and increased linkage to HIV care for those newly diagnosed. The intervention informed over 500 MSM of their HIV serostatus, ensured confirmatory results were received for all but one and linked over 90% of new diagnoses to care. The data supported the operational model for the effective expansion of HIV testing and linkage to care for Chinese MSM⁹.
- In a study on factors associated with PWID's willingness to access HIV testing at the drug-user-run Mitsampan Harm Reduction Centre (MSHRC) in Bangkok demonstrated that 74.2% were willing to receive HIV testing at the MSHRC suggesting potential benefits of incorporating HIV testing for IDU within peer-led harm reduction programmes¹⁰.

Cambodia CBT Model^{11,12}

HIV prevalence in Cambodia among general population adults aged 15-49 has been steadily declining over the past decade from 2.0% in 1998 and 0.9% in 2006 to 0.7% in 2013. The prevalence of HIV among female entertainment workers (FEW) has gone down from 20.8% in 2003 to 14% in 2010. The prevalence of HIV among MSM was 2.16% in 2010, 24.4% of people who inject drugs (PWID) in 2012. Along with the decline in HIV prevalence among the general population, it was noted that key populations (KP) such as entertainment workers (EW), drug users, transgender people and gay men and other men who have sex with men (MSM) remained the groups that required special programmes and services. It is noteworthy that HIV testing rate in 2013 was 68.3% among sex workers, 86.8% among men who have sex with men and 15% among PWID (data available only from 2010).

Cambodian model of providing HIV test in entertainment venue for "entertainment workers" or hang out points for MSM have been talked about in most recent forums in the region. At the time of this review, no scientific evidence was found on the effectiveness of community-based testing programme in Cambodia. Anecdotal evidence, however, suggests that the results are encouraging. The peer-provided HIV counselling and testing have increased the number of people tested from key populations from 10,000 in 2012 to 20,000 in 2014. Despite increased number of testing, the interventions have not detected a significant number of new HIV cases. In 2014, there were only about 150 confirmed cases reported in Cambodia.

Annex-3- Sample certification card for the trained lay HIV screening service provider



Conditions:

- 1. The trained and certified HIV screening test provider is only allowed to perform a Rapid Diagnostic HIV screening test
- 2. The trained HIV screening test provider is only allowed to perform an HIV screening test among key populations in an approved community facility, in a pre-approved area/community
- 3. The trained HIV screening test provider is not allowed to confirm an HIV diagnosis
- 4. All clients with a reactive HIV screening test must be accompanied to a HIV testing center (HTC) for confirmation.
- 5. A trained HIV screening test provider may never issue any certification on HIV status, or about any other lab test results, except to a client.
- 6. This certificate provided to trained HIV screening test providers is not proof of any technical capacity except what is mentioned in condition no 1.
- 7. This certificate cannot be used outside of this designated CLT programme, and cannot be used to be employed in any laboratory and/or other HIV programme.
- 8. This certificate has an annual validity and is invalid after the expiry date.

Annex 4: Community-led testing services implementation plan

As any new intervention, CL-HTS is recommended as a phase-wise trial and scale-up. A detailed implementation plan requires an assessment of current client load, the concentration of key populations and existing HTC sites capacity. The following table presents initial pilot stage for implementation of CL-HTS

District	Priority Key Pop	Current Imp partners	Estimated Key Pop Size	Current converge (prevention)	Current Coverage (HIV testing)	Target Coverage testing Y1	Target Coverage testing Y2	Target Coverage testing Y3
Banke	MSM/TG	FHI360	3696	2491	1647	67%	45%	70%
	PWID	SCI/GF	2093	1750	1371	84%	66%	75%
	FSW	FHI360	1740	1901	951	109%	55%	90%
Bara	PWID	SCI/GF	2208	1002	792	45%	36%	70%
	MSM/TG	SCI/GF	2104	3361	1727	160%	82%	90%
Bhaktapur	FSW	FHI360	4117	5231	2844	127%	69%	80%
	PWID	SCI/GF	1307	1262	979	97%	75%	80%
	MSM/TG	SCI/GF	1671	2178	1515	130%	91%	95%
Kailali	MSM/TG	FHI360	6109	3348	795	55%	13%	70%
	FSW	FHI360	3304	3147	1509	95%	46%	90%
	PWID	SCI/GF	6110	NA	NA	TBD	TBD	TBD
Kaski	FSW	FHI360	3170	1122	737	35%	23%	70%
	PWID	SCI/GF	2804	NA	NA	TBD	TBD	TBD
	MSM/TG	FHI360	4245	2034	898	48%	21%	70%
Kathmandu	FSW	FHI360	10729	8139	5410	76%	50%	70%
	MSM/TG	SCI/GF	38481	2175	1982	6%	5%	70%
	PWID	SCI/GF	2875	2113	1148	73%	40%	70%
Lalitpur	FSW	FHI360	3584	3410	1623	95%	45%	70%
Jhapa	MSM/TG	SCI/GF	2709	2543	1256	94%	46%	80%
	PWID	SCI/GF	909	NA	NA	TBD	TBD	TBD
	FSW	FHI360	741	2071	1120	279%	151%	100%
	Migrants	SCI/GF	NA	NA	NA	TBD	TBD	TBD
Rupandehi	MSM/TG	SCI/GF	5082	5686	1566	112%	31%	70%
	FSW	FHI360	2236	1926	1172	86%	52%	70%
	PWID	SCI/GF	1220	1259	1118	103%	92%	95%

Annex 5: List of documents reviewed while preparing this guideline

- 1. National HIV Strategic Plan 2016-2021, NCASC, 2017
- 2. National Consolidated Guidelines for Treating and Preventing HIV in Nepal, NCASC 2017
- 3. Guideline for implementing prevention, care and support services among key populations, LINKAGES Nepal/ FHI 360, 2016
- 4. National Protocol for External Quality Assurance System (EQAS) for HIV testing, NPHL, 2009
- 5. National Operational Guideline on Targeted Interventions: HIV Targeted Intervention Strategy for MARPS in Nepal, NCASC, 2009
- 6. National Targeted Intervention Guidelines for Injecting Drug Users NCASC, 2009
- 7. National Targeted Intervention Guidelines for Sex Workers NCASC, 2009
- 8. National Targeted Intervention Guidelines for MSM NCASC, 2009
- 9. National Targeted Intervention Guidelines for Migrants NCASC, 2009
- 10. HTC service uptake by site, unpublished document, NCASC 2017
- 11. HIV test positive yield, unpublished document NCASC 2017
- 12. Mapping and size estimation of FSW, MSM, TG, MSW, and PWID, NCASC, 2016
- 13. National VCT Guideline Nepal, NCASC 2003
- 14. Alere Determine™ HIV-1/2 Ag/Ab Combo: Quick Reference Card
- 15. Determine™ HIV-1/2 Ag/Ab Combo pack insert
- 16. Alere Determine™ HIV-1/2 test: Knowing through screening: Reference Card
- 17. Determine™ HIV-1/2 test kit pack insert
- 18. Service delivery approaches to HIV testing and counselling (HTC): a strategic HTC programme framework, WHO 2012
- Driving the HIV response: A community guide to the WHO 2013 Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection, GNP/ International HIV/AIDS Alliance and STOP AIDS NOW, 2014
- 20. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. WHO, 2014
- 21. Consolidated guidelines on HIV testing services. WHO, 2015
- 22. Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services. WHO, 2016
- 23. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. WHO, 2014, reprinted in 2016 with changes
- 24. Planning and Implementing HIV Testing and Linkage Programmes in Non-Clinical Settings, A guide for programme managers. Nation Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention. CDC (undated)
- 25. Training Manual on Innovative Approaches to Engaging Hard-to-Reach Populations Living with HIV/AIDS into Care, U.S. Department of Health and Human Services Health Resources and Services Administration. HIV/AIDS Bureau. Special Projects of National Significance Programme. 2013
- 26. Thailand's Experience on PrEP and HIV Self Testing Supabhorn Pengnonyang, Programme Coordinator, Thai Red Cross AIDS Research Centre. Power Point Presentation. 2016
- 27. Policy Brief: WHO recommends HIV testing by lay providers. WHO, 2015

Annex 6: List of participants CLT consultation workshop- July 7, 2107

- 1. Dr. Rajkumar Mahato, NPHL
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- 25. Bobby Singh, AHF Nepal
- 26. Nisha Dhaubhadel, NFWLHA
- 27. Sanjeev Raj Neupane, Save the Children
- 28. Dr. Rajya Shree Kunwar, NCASC/Save the Children
- 29. Dr. Subash Lakhe, WHO
- 30. Khagendra KC, FHI 360/ LINKAGES
- 31. Dr. Durga Bhandari, FHI 360/LINKAGES
- 32. Rishi Ojha, NEHA
- 33. Kabita Kharel, NSC

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⁸Community-based intervention to increase HIV testing and case detection in people aged 16-32 years in Tanzania, Zimbabwe, and Thailand (NIMH Project Accept, HPTN 043): a randomised study.

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¹⁰HIV testing and willingness to get hiv testing at a peer-run drop-in centre for people who inject drugs in bangkok, Thailand Lianping Ti, Kanna Hayashi, Karyn Kaplan, Paisan Suwannawong, Eric Fu, Evan Wood and Thomas Kerr. BMC Public Health BMC

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