HIV/AIDS Programme

SERVICE DELIVERY APPROACHES TO HIV TESTING AND COUNSELLING (HTC): A STRATEGIC HTC PROGRAMME FRAMEWORK

World Health Organization

ACTION POINTS IN THIS DOCUMENT:

1. Choose a strategic mix of service delivery models to achieve universal and equitable access to HIV testing and counselling.

2. Expand community-based options and innovate to reach beyond facilities.

3. Build strong linkages to guarantee prevention, care and treatment services after testing.

4. Use the new HIV testing strategies for high and low prevalence epidemics to assure correct test results.

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ABBREVIATIONS AND ACRONYMS

AIDS	acquired immune deficiency syndrome
ANC	antenatal care
ART	antiretroviral therapy
ARVs	antiretrovirals
CDC	U.S. Centers for Disease Control and Prevention
CHTC	couples HIV testing and counselling
CHW	community health workers
DHS	Demographic and Health Surveys
HIV	human immunodeficiency virus
HTC	HIV testing and counselling
IEC	information, education and communication
IPV	intimate partner violence
MCH	maternal and child health
M&E	monitoring and evaluation
MSM	men who have sex with men
NAT	nucleic acid testing
OST	opioid substitution therapy
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PHC	primary health care
PICO	Population / Intervention / Comparison / Outcome
PITC	provider-initiated counselling and testing
PMTCT	prevention of mother-to-child transmission of HIV
PrEP	pre-exposure prophylaxis
PWID	people who inject drugs
RCT	randomized controlled trial
RDT	rapid diagnostic test
STI	sexually transmitted infection
TasP	treatment as prevention
TB	tuberculosis
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VCT	voluntary counselling and testing
VMMC	voluntary medical male circumcision
WHO	World Health Organization

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EXECUTIVE SUMMARY

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2. Expand community-based options and innovate to reach beyond facilities.

3. Build strong linkages to guarantee prevention, care and treatment services after testing.

4. Use the new HIV testing strategies for high and low prevalence epidemics to assure correct test results.

People reach HIV treatment, care, and the full range of prevention options through the gateway of HIV testing and counselling (HTC). Currently, most people with HIV do not know that they are infected; those who do know often test late; and poor linkages from HTC to care mean that may people start antiretroviral therapy (ART) when they are already significantly immunocompromised, resulting in poor health outcomes and ongoing transmission. A successful public health response to HIV requires robust HTC services. At the same time, HTC requires successful linkages to HIV care and treatment. The value of HTC depends on linking people to services that are acceptable, accessible, and effective.

The overall goal for HTC for a national programme should be to identify as many people as possible with HIV early in their infection and link them successfully to prevention, care, and treatment services, and to link those who test negative to prevention services. This framework has been developed to support countries to select the best combination of approaches to achieve this, identifying the models of HTC delivery that are most acceptable, most cost-effective, and best reach the communities most vulnerable to HIV. Countries should set targets for HTC to assure its role in the overall response to HIV, and they should monitor the uptake and coverage of testing for the populations they seek to serve so that they can adjust ongoing programmes appropriately.

Many models of HTC services are available. Until recently, HTC has been offered largely in health-care facilities and stand-alone voluntary counselling and testing (VCT) sites. Now, new community-based approaches are developing to better serve people who otherwise lack ready access to HTC. In many settings community-based approaches may offer the greatest potential for progress toward universal access to HTC, which, in turn, supports universal access to treatment and prevention. Within these two spheres—facility-based and community-based HTC delivery models—are many variations.

How people come to be tested also has evolved. HTC began with clinic personnel recommending testing to individuals whose symptoms suggested HIV infection or whose presumed behaviour suggested exposure. When this approach proved too little and too late, VCT developed as the first programmatic form of HTC, usually provided in stand-alone facilities. Currently, most testing takes place when people visit health-care facilities (particularly antenatal care (ANC) clinics and other reproductive health services) and are tested systematically and routinely unless they decline—a strategy known as provider-initiated testing and counselling (PITC). Couples counselling offers a promising additional approach: Either couples come for testing together or one partner brings the other at a health-care provider's suggestion. Self-testing may offer opportunities for some people to learn their status even if they are unable or unwilling to seek HTC though other approaches.

A combination of strategically selected delivery models will work best. Providing HTC for all who could benefit requires a variety of approaches. No one delivery model will serve all who could benefit from HTC in a particular country or setting. Countries should choose a combination of approaches.

KEY POINTS

- There are now **many models of HTC** to choose from.
- A **combination** of delivery models will work best.
- Countries should **select delivery models strategically.**
  Key criteria are:
  - » Nature of the epidemic
  - » Cost-effectiveness
  - » Equity of access
  - » Resources available.
- To have impact, HTC requires **strong linkages** with care and treatment.
- **Rapid testing with rapid results** has been an important strategy to assure return of results and linkages with care and treatment.
- Countries need **targets** for HTC.
- In **community-based HTC** innovation can expand coverage to people previously unreached.
- In **facilities** PITC needs prioritizing beyond ANC clinics.
- Expanding **couples HTC** could have significant prevention, treatment, and social impact.
- All models of HTC must respect **human rights.** HTC must never be mandatory or tied to discrimination or criminalization.
- However HTC is delivered, **quality assurance** of both testing and counselling must be prioritized.

Important criteria for selecting approaches include:

- The ***nature of the epidemic***—generalized high prevalence, concentrated in key affected populations (such as men who have sex with men and people who inject drugs), or low level. For example, a generalized epidemic mandates prioritizing PITC in virtually all health-care contacts. In contrast, in a concentrated or low-level epidemic, PITC can focus on facilities that may attract people with HIV or exposed to HIV, such as tuberculosis (TB) clinics, services for people who inject drugs, and clinics that treat sexually transmitted infections (STIs). (See Table 1.)

- The comparative ***cost-effectiveness*** of approaches, measured by the number of infections newly identified for the number of tests performed. The cost-effectiveness of an approach varies with the nature of the epidemic. For example, door-to-door visits may be productive in high-prevalence areas, but they would find only a small percentage infected in a low prevalence setting. Combining HIV testing with other health screening and services in multi-disease campaigns may be cost-effective, offer broader health impact, and reduce stigma.

- ***Equity of access.*** As a whole, the combination of approaches should reach all areas and serve all populations that would benefit. In generalized epidemics this criterion draws attention to mobile and outreach strategies that can reach remote areas underserved by facilities. In concentrated epidemics this criterion draws attention to innovative services for key populations operating in these communities and perhaps operated by their members.

- ***Available resources.*** Different HTC models have different requirements for resources, including appropriately trained workers and infrastructure. Ideally, the combination of approaches should take maximum advantage of the resources available and at the same time work around resource gaps. Finding additional resources to scale up HTC is a crucial part of planning for overall scale-up of the response to HIV.

Countries need to set targets for HTC and monitor progress. The target-setting process for HTC takes account of the mix of HTC approaches and the populations and communities they serve. Also importantly, it helps with aligning and coordinating HTC services with prevention, treatment, care and support services. Furthermore, setting HTC targets signals the crucial role of HTC in the overall response to HIV and motivates programme staff.

To be most useful, targets should go beyond an overall numeric goal and include specific targets—for example, by HTC model, population served, and geographic area. To expand the number of people who know their HIV status, programmes should prioritize first-time testing and set targets for it. At the same time, retesting should remain readily available for those at continuing risk of infection, as are many people in key populations.

EXPANDING HTC

More can be done both in communities and in facilities.

Community-based models offer great potential to reach people and places not previously served. Also, they may identify infections earlier in their course than facility-based testing. Earlier identification makes possible earlier treatment, which in turn yields better treatment and prevention outcomes.

Different approaches suit different types of epidemics and different intended beneficiaries. Options include HTC through existing community-based health services, mobile services and outreach services set up periodically in available buildings. House-to-house visits in high prevalence areas and visits to offer testing in the households of people known to have HIV or TB can reach men, couples and adolescents unlikely to seek testing on their own. People living in prisons and other closed institutional settings need HTC in these facilities and access to follow-up services, particularly because many come from key populations.

New community-based models are emerging. There are many opportunities to adapt current approaches and to develop entirely new approaches. Monitoring, evaluating and reporting on these innovations will speed the development of effective, evidence-based approaches in communities around the world.

In facilities PITC needs broader prioritization. PITC has greatly increased the percentage of women tested in antenatal care settings. ANC services give HTC high priority because test results inform selection of appropriate strategies for preventing mother-to-child transmission of HIV and promoting the health of the mother. PITC needs prioritization in other clinical services as well. In any type of epidemic, PITC deserves high priority in services where key populations often seek care, such as TB treatment, STI clinics and, for people who inject drugs, harm reduction programmes. In generalized, high prevalence epidemics, offering PITC at every health-care contact could be the most effective approach. Couples HTC is also recommended, especially in high-burden settings.

Although self-testing for HIV is now feasible, its appropriate use remains to be determined. Many questions arise about, for example, quality of results, lack of counselling and links to follow-up services, and potential for misuse. Should programmes encourage or at least facilitate self-testing? As self-test kits become commercially available, how should programmes offer and provide post-test support?

ENSURING IMPACT AND QUALITY

The impact of HTC depends on linkage to services—and vice versa. Weak linkage between HTC and follow-up services—whether for prevention or for treatment, care and support—is the Achilles heel of many HIV programmes. The linkages need to be strong, and the follow-up services also need to be strong, in order to offer the full range of options and to be capable of tailoring their responses to individuals' and couples' specific needs. Strong linkages to high-quality prevention, treatment, and care services should be integrated into all plans to expand HTC and to introduce new HTC models. Conversely, the importance of HTC to the overall response to HIV needs further recognition at the policy level; prevention, treatment, care and support services have no benefit for people who do not reach them because they do not know their HIV status.

The options available to people through follow-up to HTC are expanding, making it even more important for people to be tested and possibly more attractive. New recommendations recognize the preventive effect of ART on HIV transmission (known as "treatment as prevention"). Such treatment offers particular benefit to serodiscordant couples, within which one partner is HIV-positive and the other is HIV-negative. Also, emerging evidence suggests that pre-exposure prophylaxis (PrEP) with antiretroviral drugs can help prevent infection, particularly for the HIV-negative partner in a serodiscordant couple and for men who have sex with men.

Technical quality is crucial. As with scale-up generally, expansion of HTC and adoption of new HTC models demand special attention to quality. Particularly in PITC settings that are not focused on HIV services (e.g. ANC services) and in community-based settings, the accuracy of testing and continuous quality assurance of testing will require thoughtful planning, implementation and review. Following the new testing strategies for high and low prevalence settings presented here will help guarantee that test results are correct.

Human rights need protection, whatever the testing model and however testing is offered. The 5Cs of good testing practices always apply: informed Consent, Confidentiality, Counselling, Correct test results and Connection to care. As community-based models develop and are expanded, extra effort may need to be put into assuring confidentiality and linkages.

Furthermore, testing must always be voluntary, never mandatory or coerced. Testing should not be promoted in situations where a positive test result could lead to discrimination or where choosing to test is treated as indicating criminalized behaviour.

Much remains to be learned. The importance of universal access to HTC is clear. How best to achieve it is not fully known, however. Close monitoring and evaluation are needed for the expansion of widely used approaches, such as PITC in facilities, and especially for the development of new community-based approaches, such as offering HTC to households. The resulting knowledge will help improve the performance of each HTC delivery model and also inform each country's choice of the optimal combination of approaches.

TABLE 1. LIKELY APPLICATIONS OF VARIOUS HIV TESTING AND COUNSELLING MODELS IN DIFFERENT EPIDEMIC SITUATIONS

HTC model	Concentrated or low-level epidemic	Generalized epidemic
Facility-based		
Clinical settings		
ANC	Cost-effectiveness needs assessment	PITC in every health-care contact
TB, STI clinics, OST, NSP	PITC in these services, which serve key populations	
General and other specific clinics	PITC in prisons and other closed institutions	
Other facilities—e.g.:		
Stand-alone VCT	Located to serve key populations	For those self-identifying as at risk who find these facilities more suitable than clinics
Drop-in centres		
Community-based		
Outreach and mobile	To key populations and high prevalence geographic areas	To key populations and remote areas
Home-based door-to-door		Where other HTC is lacking or women cannot leave home
Home-based index	To households of those known or suspected to have HIV or TB	To households of those known or suspected to have HIV or TB
Events		For general population; can reach men, youth (e.g. sports events)
Campaigns		Can address general population or specific audiences—e.g., couples, men, young people
Workplaces, schools		For working people and students whose hours do not allow clinic visits
Couples/partner testing	Couples HTC for partners of those testing HIV-positive	Couples HTC offered to all

Abbreviations: HTC = HIV testing and counselling; HIV = human immunodeficiency virus; PITC = provider-initiated testing and counselling; TB = tuberculosis; STI = sexually transmitted infections; OST = opioid substitution therapy; NSP = needle and syringe programmes

1. RATIONALE

This document builds on previous efforts to support the expansion of HIV testing and counselling (HTC) services. In 2003 and 2004 WHO defined the testing methods and principles of good HTC conduct to promote a rights-based approach (WHO 2003; WHO/UNAIDS/HIV/AIDS Alliance/GTZ, 2005). In light of missed opportunities to diagnose patients presenting to health facilities and other high-priority settings, subsequent WHO HTC efforts have sought to expand facility-based voluntary HTC. Documents produced to support these efforts include:

- *Guidance on provider-initiated testing and counselling (PITC) in health facilities* (WHO/UNAIDS, 2007)
- *Guidance on testing and counselling for HIV in settings attended by people who inject drugs: improving access to treatment, care and prevention* (WHO/SEARO/UN 2009)
- *WHO guidance on HIV testing and counselling in prisons and other closed settings* (UNODC/WHO, 2009)
- *Delivering HIV test results and messages for re-testing and counselling in adults* (WHO, 2010)
- *WHO policy requirements for HIV testing and counselling of infants and young children in health facilities* (WHO/UNICEF, 2010)
- *HIV testing in young children* (WHO, 2011)
- *Handbook for improving HIV testing and counselling services: field test version* (WHO, 2011a)
- *Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender people* (WHO, 2011b)
- *Guide for monitoring and evaluating national HIV testing and counselling programmes: field test version* (WHO, 2011c)
- *Guidance on couples HIV testing and counselling, including antiretroviral therapy for treatment and prevention in serodiscordant couples: recommendations for a public health approach* (WHO, 2012).

The last few years have witnessed an expansion of HTC service delivery models. Client-initiated stand-alone voluntary counselling and testing (VCT) and provider-initiated testing and counselling (PITC)

have continued to grow, while other HTC approaches have gained traction. Although the number of HIV tests performed annually has increased considerably over the past decade, with more than 95 million HIV tests performed in 2010 (WHO/UNAIDS/UNICEF, 2011), there are insufficient data on what populations are covered. While it is estimated that the majority of people with HIV worldwide are unaware of their infection (WHO/UNAIDS/UNICEF, 2011), country-specific data on HTC coverage are limited, and few countries have set HTC coverage targets.

HTC continues to be provided in health care facilities through the routine offer of testing (PITC), and with increasing acceptance (WHO/UNAIDS, 2007). This approach has increased uptake of HTC in clinical settings, particularly antenatal care (ANC) (Hensen et al, 2011). Still, there is need to further increase access to testing through PITC in clinical settings, especially in the higher prevalence concentrated epidemics.

Despite the additional HTC service delivery approaches, to date WHO has not provided information on or an assessment of models of HTC delivery outside of a facility setting. Such information would help countries make strategic choices about increasing HTC coverage, access, impact and acceptability. The objective of this strategic policy framework, therefore, is to define optimal combinations of HTC models and to support their expansion, based on the epidemiological context of a country or region. This framework builds on evidence obtained from reviews of published and unpublished literature and the experiences of ongoing HTC programmes.

1.1 OBJECTIVES

The objectives of this HTC policy framework are to advocate and discuss:

1. the continued effective and appropriate use of PITC in health-care settings;

2. the expansion of HTC models of service delivery beyond health care facility-based HTC to increase access and coverage of services and to maximize efficiency, impact and equity;

3. the strategic choice and implementation of a combination of HTC models of service delivery based on an analysis of epidemiological, social and programmatic context in order to maximize impact and equity;

4. providing high-quality services and adherence to the guiding principles of HTC (the 5Cs) in expanding HTC service delivery approaches;

5. establishing and measuring clear HTC targets that are linked with HIV service delivery objectives.

1.2 TARGET AUDIENCE

This document is intended for clinical and community providers of HIV, tuberculosis (TB) and other health care, programme managers and policy-makers.

2. BACKGROUND

As a "critical gateway" to services, testing is essential to the prevention and treatment of HIV (Figure 1). Still, approximately 30 years after the first HIV antibody tests became available, progress toward universal knowledge of HIV status remains inadequate.

HIV testing and counselling (HTC) empowers individuals and couples to adopt measures to prevent the transmission or acquisition of HIV infection. Furthermore, testing provides access to HIV prevention services, including prevention of mother-to-child transmission (PMTCT) and male circumcision, and it is a necessary component of emerging antiretroviral HIV prevention interventions, including pre-exposure prophylaxis (PrEP), and microbicides. Also, recent evidence of the effectiveness of early initiation of antiretroviral therapy (ART) to prevent HIV transmission in serodiscordant couples (Cohen et al, 2011), confirming previous cohort studies (Anglemeyer et al, 2011), highlights the need to expand access to testing services that reach couples. At the community level the expanded availability of HTC services may help to normalize HTC and reduce the stigma and discrimination associated with HIV and HIV testing (Khumalo-Sakutukwa et al, 2008).

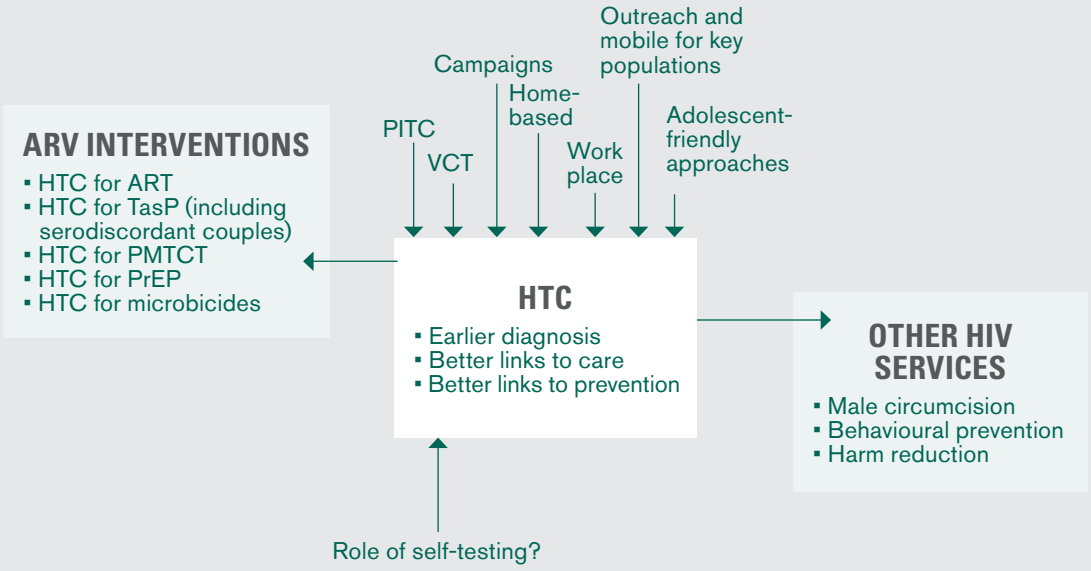
Knowledge of HIV status is also necessary for initiation of treatment. However, a significant proportion of people living with HIV, including many in high-income countries[1] (Coenen et al, 2008), remain undiagnosed until they become symptomatic, therefore presenting late for treatment (Fairall et al, 2008; Kigozi et al, 2009). Late presentation diminishes the impact of ART on morbidity and survival and delays adoption of preventive measures by persons living with HIV and their partners.

Despite widespread scale-up of client- and provider-initiated HTC services across diverse contexts, the current reach of these services remains low. In generalized epidemics the majority of people with HIV remain unaware of their HIV status. According to Demographic and Health Surveys (DHS) conducted between 2007 and 2009, a median of 33.6% of women and 17.2% of men in 18 low- and middle-income countries had ever tested for HIV (WHO/UNAIDS/UNICEF, 2011). In many settings women have greater access to HTC services due to their more frequent contact with health services; men, children and adolescents, rural and key populations vulnerable to HIV infection often have less access to needed services, and, even where services are available, these groups face barriers to access or do not find services acceptable.

In low-level and concentrated epidemics, despite high levels of testing in clinical settings, including ANC clinics for the purpose of PMTCT, key populations most at risk of infection are often not reached. Structural, operational, logistic, and social barriers—including stigma, discrimination, and punitive laws and policies—continue to limit access to existing testing services. These barriers must be reduced to maximize knowledge of HIV status and make progress toward universal access to essential services.

1 It is estimated that in the European Union about one-third of people living with HIV are unaware of their HIV status. In the United States the percentage of persons with late HIV diagnoses was 32.3% in 2007, suggesting that at least a similar proportion remained unaware of their serostatus.

FIGURE 1 UNIVERSAL HIV TESTING AND COUNSELLING FOR UNIVERSAL PREVENTION AND TREATMENT (HTC+)



Current HTC approaches have substantially increased the numbers of tests being performed. Data from 108 countries show that in 2010 more than 79 million people received HTC, up from 67.4 million reported in 100 countries in 2009 (WHO/UNICEF/UNAIDS, 2011). A sub-set of 86 countries provided data on numbers of tests in both 2009 and 2010 relative to the size of the adult population. In these countries combined, the median number of tests per 1000 adult population rose by 17%, from 47 to 55. All regions reported increases in the median number of tests per 1000 population, with the exception of the North Africa and Middle East region, where the rates remained broadly stable. Regional variability is large—from 3.6 tests per 1000 population in North Africa and Middle East to 82.0 tests per 1000 population in sub-Saharan Africa.

It is not clear, however, how much of the increase reflects first-time testing in key populations and thus an increase in the number of people who know their HIV status. Although these country reports provide the total number of people tested, they do not account for the fraction of people tested more than once during the course of the year, nor do they differentiate between first-time testers and repeat testers—the proportions of which may vary among countries. The reported increase in HTC may result partly from more repeat testing and testing of people at lower risk, rather than from improved access for people at greatest risk of HIV.

More emphasis needs to be given to prioritizing HTC approaches that are cost-effective and achieve maximum impact by identifying people who could benefit from treatment and linking people at higher risk of HIV infection with prevention interventions. To achieve this, WHO

More emphasis needs to be given to prioritizing HTC approaches that are cost-effective and achieve maximum impact.

supports the continued scale-up of facility-based HTC. At the same time, WHO recognizes the need for rapid scale-up of innovative models of HTC beyond voluntary counselling and testing (VCT) and provider-initiated testing and counselling (PITC) in health facilities. This scale-up is necessary to improve equity of coverage and access to and availability of quality services and to make possible universal knowledge of HIV status. Also to increase HTC access and equitable reach, WHO has supported the use of HIV rapid diagnostic tests, including their use by specifically trained and supervised lay counsellors in some settings. Rigorous training, supportive supervision and quality assurance must be in place to ensure the quality (i.e., the accuracy) of results. WHO supports the adoption of an effective combination of innovative HTC models and cost-effective approaches that adhere to the principles of good HTC conduct and suit local epidemiology and other context. The expansion of HTC must adhere to a rights-based approach to testing, protecting the human rights of the individual tested and adhering to ethical principles of HTC conduct (see box).

HTC GUIDING PRINCIPLES: VOLUNTARY UTILIZATION OF HTC SERVICES

Mandatory or coerced testing is never appropriate, whether that coercion comes from a health-care provider or from a partner or family member.

HTC, regardless of the model of service delivery, must adhere to the five Cs—**C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect test results and linkage to **C**are. The following are key principles that apply to all models of HTC and in all circumstances:

- Persons receiving HTC must give informed **Consent** to be tested and counselled. They should be informed of the process for HTC and of their right to decline testing.

- HTC services are **Confidential**, meaning that what the HTC provider and the person discuss will not be disclosed to anyone else without the expressed consent of the person being tested. Although confidentiality should be respected, it should not be allowed to reinforce secrecy, stigma or shame. Counsellors should raise the issue of whom else the person may wish to inform, how they would like this to be done, etc. (Shared confidentiality—with partner, family members, or others and with health care providers—is often highly beneficial.)

- HTC services must be accompanied by appropriate, high-quality pre-test information and post-test **Counselling**. Quality assurance mechanisms and supportive supervision and mentoring systems should be in place to ensure the high quality of counselling.

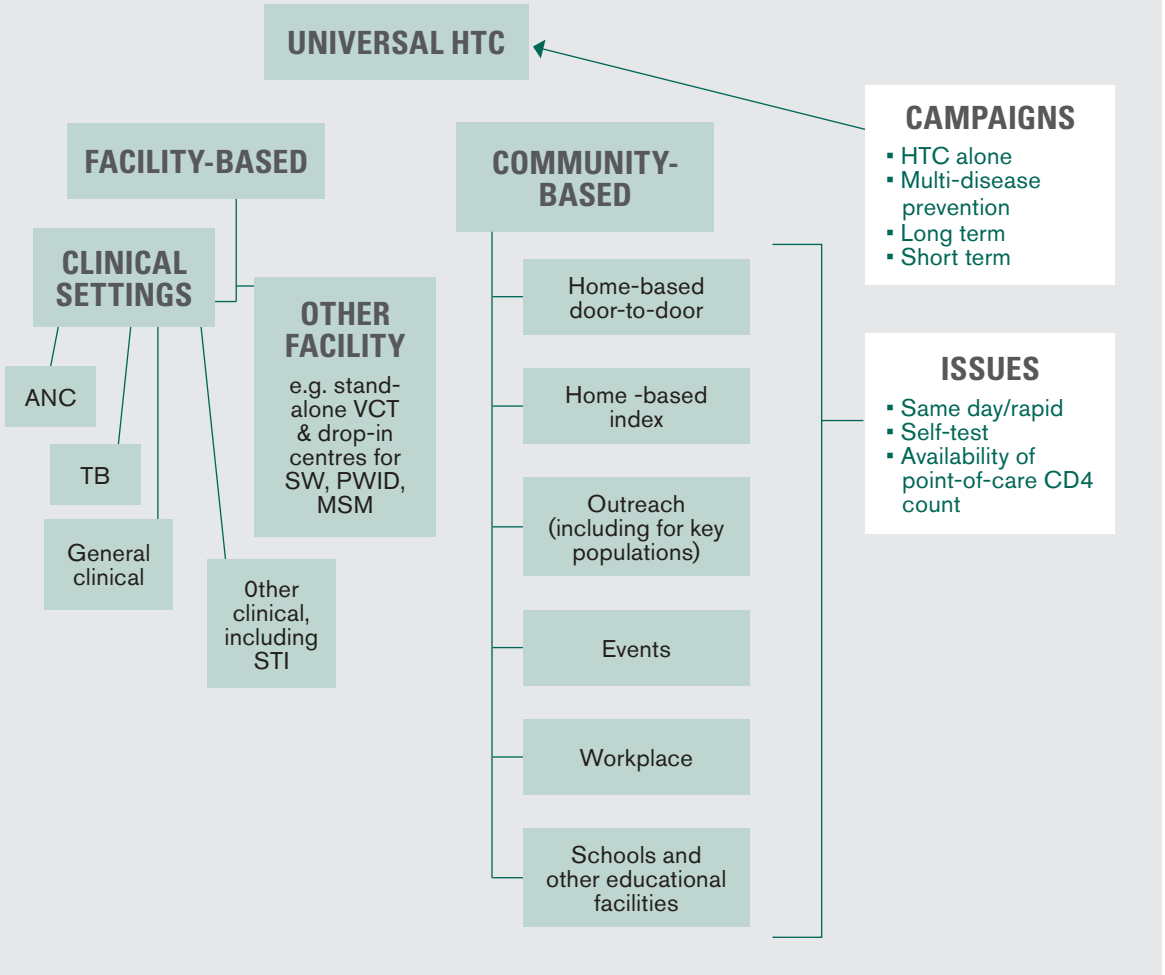
- HTC providers should strive to provide high-quality testing services, and quality assurance mechanisms should be in place to ensure the provision of **Correct test results**. Quality assurance may involve both internal and external measures and should include support from the National Reference Laboratory as needed.

- HTC should provide **Connections** to prevention, **care**, and treatment services. This includes the provision of effective referrals to follow-up services as indicated, including long-term prevention and treatment support.

3. OVERVIEW OF HIV TESTING AND COUNSELLING SERVICE DELIVERY APPROACHES

This section details the various HTC service delivery approaches, including not only VCT and PITC but also other models of HTC delivery that could be considered in expanding the availability of HTC services. The models of HTC are grouped as facility- or community-based services (Figure 2). Further details on target groups and the advantages and disadvantages of these distinct models of delivery can be found in Annex 2.

FIGURE 2 TYPOLOGY OF FACILITY-BASED AND COMMUNITY-BASED APPROACHES TO HIV TESTING AND COUNSELLING (HTC)



3.1 FACILITY-BASED APPROACHES

3.1.1 HEALTH FACILITY-BASED HIV TESTING AND COUNSELLING

Since the first antibody tests became available in 1985, HTC has been offered in clinical settings to aid clinical management. Initially, HTC was offered when a health-care provider "suspected" HIV infection in a symptomatic patient or when someone was identified as belonging to a "higher risk category". Outside clinical settings HTC was first offered more widely through client-initiated voluntary HIV counselling and testing (VCT). It became apparent, however, that health-care provider's patient risk assessment and people's own concerns were not sufficient to achieve high rates of uptake of HTC, promote early diagnosis and achieve ART coverage targets (Bayer et al, 2009). Thus, in clinical settings a more routine approach to offering HTC was adopted in many countries, particularly those with generalized HIV epidemics. Provider-initiated testing and counselling (PITC) has been promoted since 2002, following the increase in the availability of ART (Baggaley et al, 2012). In 2007 WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS), based on experience with PITC in countries and recognizing the limitations of relying solely on VCT, published guidance on the implementation of PITC in health facilities (WHO/UNAIDS, 2007). The guidance recommends scaling-up PITC in all clinical settings in generalized HIV epidemics. For concentrated epidemics the guidance recommends that implementation be guided by an assessment of epidemiological and social context, but that the scale-up of PITC be considered in ANC, sexually transmitted infection (STI), and TB clinics. In low prevalence contexts the implementation of PITC may not prove cost-effective in all clinical settings. In-country assessment will determine whether PITC is the most effective approach for identifying those with HIV who can benefit from services (WHO/UNAIDS, 2007); introducing PITC in higher prevalence areas or districts may be considered (Postma, 1999).

PITC places the onus of HTC on the health-care provider rather than the individual. It also eliminates the need for lengthy pre-test counselling and obtaining informed consent in written form, replacing these with pre-test information and the option for individuals to decide against HTC.

The routine offer of HTC seeks to normalize HIV testing and to remove the need for personal motivation to seek HTC services. Such motivation may be limited, especially where fear, stigma and discrimination are widespread. However, it is important to emphasize that although PITC involves the routine offering of HTC, it should not develop into mandatory testing or testing people without first informing them. PITC seeks to increase HTC coverage and achieve earlier diagnosis for those attending health facilities so that they can benefit from appropriate and effective services (WHO/UNAIDS, 2007).

Given the evidence that PITC is acceptable to pregnant women attending ANC, PITC should also be prioritized in other clinical settings.

Recently, in many settings PITC has been the predominant model through which individuals have learnt their HIV status and obtained access to HIV services. PITC began in ANC clinics following the finding that ARVs could reduce mother-to-child transmission (MTCT) of HIV (Hensen et al, 2011). PITC has been scaled up widely in ANC settings in both generalized and concentrated epidemics and has proved acceptable to pregnant women (Chandiserawa et al,

2007; Oosterhoff et al, 2008; Perez et al, 2006). PITC in ANC settings could be expanded to support HTC for couples (WHO, 2012).

Overall, however, implementation of PITC has been limited. Coverage levels are high in ANC settings—where policies have prioritized the routine offer of HIV testing. In other clinical settings, however, where the routine offer of HTC has not been a priority, PITC coverage is often low. Given the evidence that PITC is a strategy acceptable to pregnant women attending ANC, PITC should also be prioritized, particularly in generalized epidemics, in other clinical settings, such as TB services, STI clinics, services for key populations including opioid substitution therapy (OST) and needle syringe programmes (NSP) for people who inject drugs (PWID), and services providing male circumcision.

Even so, when facilities are concentrated in urban areas, PITC may be inaccessible to rural, hard-to-reach, and key populations. As access to HIV care, treatment and support, including ART, is being scaled up, there is a need to broaden access to HTC along with prevention services; this requires expanding HTC not only within but also beyond health facility settings. Thus, models of HTC that extend service availability and delivery beyond facility settings are particularly needed.

PITC in antenatal clinics

PITC has been implemented widely in ANC settings in various contexts to provide access to PMTCT services. The PITC approach has been demonstrated in many settings to increased access to HTC services for pregnant women beyond what VCT could achieve. In fact, reviews of published literature on PITC implementation note that PITC in ANC settings has made uptake of HTC almost universal among pregnant women in some contexts (Hensen et al, 2011) and has been an important component of successful PMTCT programmes in many countries (Matida et al, 2011).

In this framework PITC for pregnant women is considered as a strategy distinct from other PITC in health facilities.

PITC in TB, STI, OST, paediatric and other clinical settings

HTC in TB and other clinical settings has been a key component of the response to HIV, particularly in generalized epidemics. In countries with a high TB/HIV burden, diagnostic testing and counselling includes the offer of HTC to all patients with TB as a routine component of clinical care. In the Latin America and Caribbean region integrated TB/HIV HTC services have been one of the key ways of improving care and reducing loss to follow-up. WHO strongly recommends the continued scale-up of PITC in TB, STI, services for key populations such as PWID (e.g., OST and NSP) and in other clinical settings in generalized and concentrated epidemics (WHO/UNAIDS, 2007). Since immediate ART is recommended for all people with TB who are co-infected with HIV (WHO, 2012a), PITC should be routinely implemented in TB clinics.

PITC has also proved effective in paediatric care for finding previously undiagnosed cases in children who could benefit from ART. PITC can be highly acceptable in these settings (Mutanga et al, 2012).

In low-level and concentrated epidemics, an assessment of the local epidemiological and social context should guide decisions about whether and how to implement PITC in health facilities. Depending on that context, PITC may not be the most cost-effective approach in some clinical settings, particularly in low prevalence settings. WHO is currently reviewing the cost-effectiveness of PITC in low-level and concentrated epidemics.

In low-level and concentrated epidemics, PITC may be interpreted as **diagnostic testing and counselling,** in which health care providers offer HTC to individuals who show signs or symptoms consistent with HIV-related disease or AIDS. In these situations HTC serves to aid clinical diagnosis and management. This model is being refined as "indicator condition targeted HIV testing", employing checklists of key indications for the routine offer of HTC according to specific clinical criteria. This approach is important where PITC is not implemented in all health facilities, although PITC should continue to be offered to all clients in clinics where patients with a higher risk of HIV present, such as services for people with STIs or hepatitis and services for PWID.

Integrated voluntary counselling and testing (VCT), also termed client-initiated HIV counselling and testing, was the early model of HTC, designed to provide access to HIV testing for all who sought the service. Offered primarily through free-standing VCT sites (see section 3.2, Community-based testing and counselling), this approach is also integrated into some clinical settings. These VCT services have proved acceptable and effective in some clinical settings to support access to testing and to HIV prevention and treatment services. In many clinical settings, however, a more integrated routine approach (PITC) will be more cost-effective.

3.1.2 HTC IN SITES BESIDES HEALTH-CARE FACILITIES

Stand-alone voluntary counselling and testing (VCT)

While taking place in a fixed site, stand-alone VCT could be considered a community-based service. It usually does not take place in clinical settings, and the model is more closely aligned with community-based approaches. Almost by definitions, stand-alone sites usually are situated in the community and thus are more accessible to their target populations than many other health-care facilities. They often offer the more comprehensive counselling, same-day results, staffing, and linkages typical of community-based services.

In the first two decades of the HIV response, VCT was the predominant model through which individuals learnt their HIV status. The delivery model was adopted in the 1980s, following the availability of the first HIV antibody test and in the absence of effective therapeutics for HIV infection (Bayer et al, 2009; Grinstead et al, 2001). A client-initiated approach, VCT stresses the importance of voluntarism and informed consent and established standards for the ethical conduct of HTC (Bayer et al, 2009). The strategy conventionally has consisted of three primary components: individual pre- and post-test counselling, written informed consent, and measures to protect confidentiality.

VCT has ensured that millions are aware of their HIV status and has thus provided many with access to HIV prevention and care services. Nevertheless, due to barriers to VCT access, including the need for personal motivation to seek HTC, VCT is considered inadequate to increase the level of knowledge

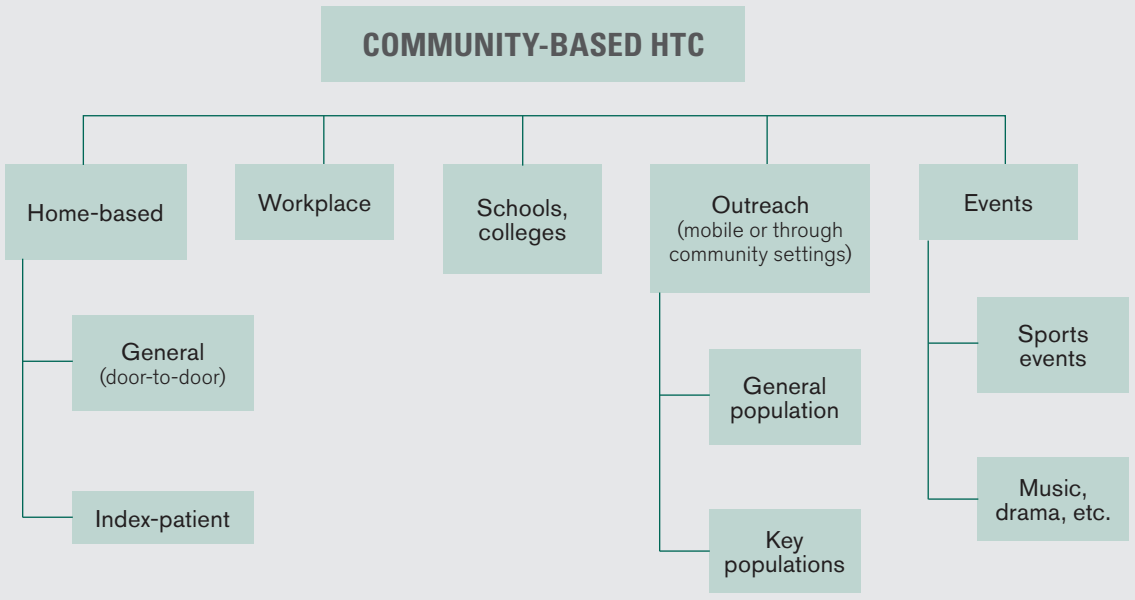
of HIV status sufficiently if it is the only community-based service available. Despite limitations, stand-alone VCT is still important in some settings and remains a key component of a comprehensive HIV prevention package. Still, the scale-up of complementary models of HTC that provide services beyond facility settings is required.

3.2 COMMUNITY-BASED TESTING AND COUNSELLING

Community-based HTC services are expected to help build public trust, protect human rights and reduce stigma and discrimination (UNAIDS, 2010). They also are expected to remove structural, logistic and social barriers to HTC, including—in the case of home-based and mobile or outreach HTC—costs associated with transportation to facility-based services. Community-based services can increase knowledge of HIV status and thus increase access to and utilization of HIV prevention and treatment services, as has been demonstrated in Brazil, China, Ukraine and Uganda (UNAIDS, 2010). Through the Treatment 2.0 platform, WHO advocates improved uptake of HTC and linkage to care and strengthened community mobilization (WHO/UNAIDS, 2010).

Community-based HTC service delivery can be implemented in a variety of settings and with various approaches (Figure 3). Details of these models of delivery and the strengths and weaknesses of each approach are listed in Annex 2.

FIGURE 3 VARIETIES OF COMMUNITY-BASED HTC



3.2.1 HOME-BASED TESTING AND COUNSELLING

Home-based HIV testing and counselling (HBHTC) provides either **door-to-door HTC services** or services to households with a known index HIV-positive or TB patient, with consent obtained from the index-patient prior to a home visit (**index-case HBHTC**). HBHTC seeks to make access to HTC more convenient and to remove structural and logistical barriers to HTC access, while also reducing the stigma associated with opting for or seeking HTC in facilities (Bateganya et al, 2010; Negin et al, 2009; USAID/AIDSTAR-One, 2009). Door-to-door HTC can serve hard-to-reach populations such as men, adolescents and rural residents and also those underserved by the formal health care system in urban areas with high HIV prevalence and low rates of HTC uptake (USAID/AIDSTAR-One, 2009). HBHTC also can support family testing and facilitate the identification of children with HIV. In low-level and concentrated epidemics, the HBHTC index-case model ensures that individuals and families at increased risk of HIV infection are offered HTC services.

HBHTC involves the training of lay counsellors or community health workers to conduct home visits, offer testing, provide counselling and perform HIV testing following consent (Negin et al, 2009). In some countries such programmes provide other health services (vaccination, routine medical check-ups, distribution of bednets and others) along with HTC to increase uptake and reduce stigma. For example, in Ethiopia health extension workers provide HTC services to the community integrated with other health services.

Evidence suggests that the strategy can be a cost-effective way to identify people with HIV who could benefit from services (Bateganya, 2010; Menzies et al 2009; Negin et al, 2009), increases testing uptake (Fylkesnes et al, 2004; Were et al, 2004; Wolff et al, 2005) and reduces inequities in access to testing services (Mutale et al, 2010). A study conducted in rural Uganda from 2004 through 2007 reports a 91% uptake of HBHTC by both men and women, with 91% of men and 89% of women testing for the first time (Tumwesigye et al, 2010). A cross-sectional study conducted in Kampala, Uganda, in 2009 reports that 69% of individuals ages 15 years and older accepted HBHTC; uptake was higher among individuals previously tested, at 85%, but 58% of individuals with no history of HTC accepted testing (Sekandi et al, 2011).

Also, HBHTC may reach ART-eligible people sooner. A study in Kenya, comparing the clinical status of individuals entering an HIV treatment programme through different HTC strategies, suggests that HBHTC may identify people with HIV earlier in the course of the infection, making possible earlier prevention, care and treatment: Among patients ages 14 years and older, those enrolled following HBHTC had higher median CD4 cell counts than those of individuals referred from VCT or from PITC—indicating an earlier point in disease progression (Wachira et al, 2012). Furthermore, HBHTC can identify a high proportion of the couples who are serodiscordant (Wachira et al, 2012).

Despite evidence of feasibility and acceptability, there is a dearth of evidence on the impact of HBHTC on access to treatment, care and support services and ART adherence following a positive test result (Negin et al, 2009). In addition, as countries continue to adopt national policies for the implementation

of HBHTC, there are concerns that, in the absence of international guidelines, HBHTC strategies lack uniform standards and hence may be of limited quality (USAID/AIDSTAR-One, 2009). Challenges associated with HBHTC include confirmation of positive results, quality assurance to ensure accurate test results, and providing linkages to other services, particularly care and PMTCT (AMPATH Kenya, 2012).

WHO and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) have developed a practical handbook on home-based HIV testing in high-prevalence countries to guide effective programme planning, implementation, and monitoring (WHO/CDC/PEPFAR/USAID/LSTM, 2012).

3.2.2 MOBILE AND OUTREACH TESTING AND COUNSELLING

HTC can be offered in a variety of settings in the community, either as outreach to community sites or through mobile vans or tents. This model of testing may set up services temporarily, but perhaps regularly, in community sites such as churches or other faith settings, places of entertainment such as bars and clubs, or schools or workplaces, and it may be linked to events, such as sporting, music, theatre, or agricultural events. In countries with low-level or concentrated epidemics—for example, in Asia—outreach is usually done in sex workers' and MSM's cruising sites, brothels, and entertainment establishment. Outreach HTC should be strongly linked to and coordinated with other outreach services and peer education. These and other approaches linked to drop-in centres for key affected populations must have systems in place to ensure that the rights of their clients are protected and they are not discriminated against or subject to criminalization (MOH/NCHADS/UNICEF, 2007). In Cambodia issues such as providing same-day/rapid test results in outreach services and ensuring confidentiality proved to be critical to providing a service acceptable to key populations.

Outreach testing has been successfully employed in Vietnam. Two days every quarter mobile HTC teams consisting of six health-care workers (three counsellors, one technician, one administrator and one porter) visits remote communes that are not easily accessible. Following pre-test counselling and informed consent, HIV testing is conducted with rapid tests. If negative, the results are returned with post-test counselling immediately. If reactive, the blood is sent to a provincial laboratory for confirmatory testing.

Outreach HTC services provided in community settings aim to improve access to and coverage of HTC services among rural and marginalized populations underserved by the formal health care system and also among key populations, particularly in low-level and concentrated epidemics. Outreach HTC also may be promoted through community events. For example, football tournaments in Lesotho, Malawi, Namibia, South Africa and Zambia provide venues for HIV prevention education, VCT and access to HIV prevention, care, and support services (Kaufman et al, 2010). One variant of outreach HTC, termed "moonlighting", provides testing services at times and locations convenient to key populations. For example, in Kenya and Uganda HTC services are offered at night to serve sex workers, their clients, bar workers, and truck drivers (WHO/UNAIDS/UNICEF, 2009).

Mobile and outreach HTC services can also provide HIV testing for pregnant women in remote areas. There are successful examples of this approach in Vietnam, where mobile teams go to community health centres to provide HTC for pregnant women who attend antenatal care. For example, mobile teams in the Quan Hoa district visit all 18 communes on a rotating basis. When a pregnant woman makes her first ANC visit, health-care staff members encourage her to make an appointment for HTC on the next date that a mobile team will come to that commune. The mobile HTC team provides pre-test counselling and facilitates informed consent, and the HIV testing is done using rapid tests. If reactive, blood specimens are sent for confirmatory testing. Counselling is provided whether the results are negative or reactive.

As with HBHTC, outreach HTC aims to remove structural, social and logistical barriers to access, including transport costs, limited facility hours and stigma associated with testing at a facility (Negin et al, 2009). Evidence from Zimbabwe, the United Republic of Tanzania and Thailand shows that mobile HTC increases testing uptake by comparison with uptake of "standard clinic-based VCT" (Khumalo-Sakutukwa et al, 2009). Evidence from Kenya suggests that mobile approaches to HTC are cost-effective at identifying people in need of services and that a high proportion of clients are first-time testers (Grabbe et al, 2010). In the design and development of outreach services, special attention must be paid to establishing effective and acceptable linkages to services, quality assurance of testing and appropriate testing strategies to confirm positive test results.

3.2.3 WORKPLACE AND EDUCATIONAL ESTABLISHMENT-BASED TESTING AND COUNSELLING

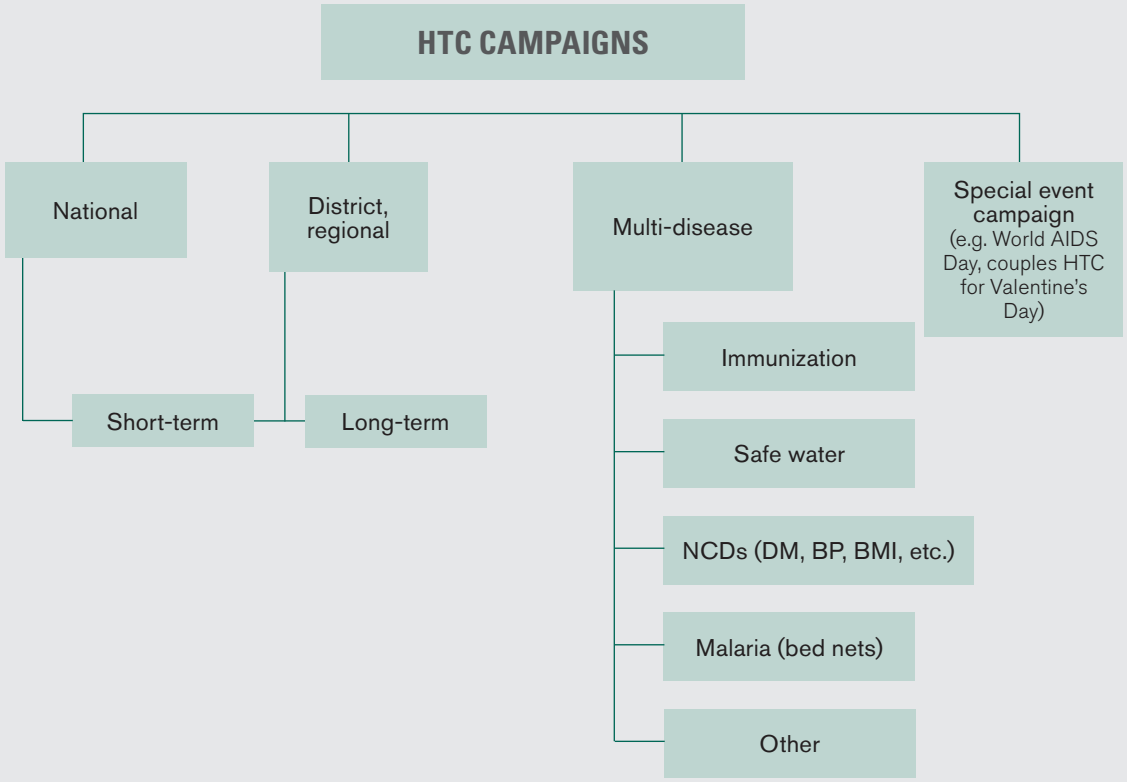
HTC services in a workplace or school seek to serve individuals—in many contexts mostly men—whose formal employment or school commitments make it hard to go to health facilities. These models of HTC provide on-site VCT to employees and their spouses or to students, with results available on the day of testing (Corbett et al, 2006). A study in Zimbabwe reported significantly higher uptake of testing associated with worksite VCT with rapid testing than with referral from the worksite to off-site VCT (Corbett et al, 2006). Since 2001 an international brewing company has offered employees and their spouses on-site HTC (van der Borght et al, 2010). Within six years 9723 individuals obtained HTC across five sub-Saharan African countries; 3.8% of these people tested HIV-positive (van der Borght et al, 2010). Workplace and school-based testing services can be integrated with clinical services already available, function as a stand-alone service, or operate as mobile or outreach HTC. Particular concerns with this delivery model are lack of confidentiality, coercion, and weaknesses in linkages to follow-up services.

School-based testing addresses sexually active youth, typically individuals ages 12 or 13 and older. In South Africa, as part of the national HTC campaign, HIV testing services are being provided to students ages 13 and older. The effort is intended to provide early access to treatment, care and support services for adolescents who test HIV-positive and to HIV prevention services for individuals who test HIV-negative (The Lancet, 2011). HTC has also been promoted in some tertiary education institutions (Adewole et al, 2004).

4. TESTING AND COUNSELLING CAMPAIGNS

National health campaigns are large-scale intensive efforts, of defined duration, that employ major communication activities to promote healthy behaviour, including uptake of health-care services. Taking many different forms, HTC campaigns seek to increase the uptake of HIV testing either by providing HTC directly as part of the campaign through, for example, mobile or outreach services or by increasing awareness of the benefits of HTC and providing information about where to obtain established HTC services. They can be general, addressing the population as a whole, or targeted, to improve access to testing for specific sub-populations. They can be national or local campaigns, can last for a finite period or stretch over years, or can be associated with a specific event. They can be specific to HIV or part of multi-disease prevention campaigns (Figure 4).

FIGURE 4 VARIETIES OF HTC CAMPAIGNS



NCD = non-communicable diseases; DM = diabetes mellitus; BP = blood pressure measurement; BMI = body mass index

National campaigns, ranging from several days to several years, have accelerated the uptake of HTC in many generalized HIV epidemic settings. In Kenya, as part of a multi-disease prevention campaign (MDP) that included insecticide-treated bednets and water filters, about 40 000 people (28 000 of them men) were tested in a seven-day period (Lugada et al, 2010). In another Kenyan MDP campaign in Nyanza, 5000 people were tested in three days, including same-day CD4 cell count results for those found to have HIV. Linkage to care during campaigns is often a major challenge. However, follow-up of 10 000 people involved in the Nyanza MDP found that the majority of those testing HIV-positive were linked to care in 10 months. In the United Republic of Tanzania three million people obtained HIV testing services in a six-month period (UNAIDS, 2010). National campaigns of a year or more have taken place in South Africa, which sought to test 15 million people over one year (SANAC, 2011), and in Lesotho, where the "Know Your Status" campaign ran in 2006 and 2007 (Lesotho MoH, 2008).

NATIONAL HTC CAMPAIGNS

National campaigns seek to increase the uptake of HTC nationwide and to make community-level HIV testing the norm (WHO/UNAIDS/UNICEF, 2011). Campaigns are a means to communicate with communities and populations, to motivate individuals and couples to seek HTC, and to mobilize communities to support and encourage testing. Campaigns have been implemented in many different ways—some providing HTC in facilities and others using a community-based approach—with differing coverage and quality. In some contexts, the lack of linkage to care and support services has been a problem.

Since 2004 Botswana has conducted annual HTC campaigns for the general population in addition to campaigns addressed specifically to students and key populations. By 2009 more than one million people had been tested (WHO/UNAIDS/UNICEF, 2011).

In Ethiopia the Ethiopian Millennium AIDS campaign, conducted from November 2006 through September 2007 (Phases I and II), reached 1.7 million people. In Phase III, from September 2007 to September 2008, 4.8 million people were tested through both community- and facility-based approaches (Ethiopia FHAPCO, M&E Department, 2007).

Lesotho launched its "Know Your Status Campaign" in 2005. The campaign increased the number of HIV tests performed fivefold over four years (WHO/UNAIDS/UNICEF, 2011). A review of the campaign noted that more than 30% of HIV tests were conducted in community settings where access to HTC services had been limited prior to the campaign (WHO AFRO, 2008).

Namibia has been conducting annual national testing days since 2008 to encourage more men to test, especially for the first time.

South Africa launched a national HTC campaign in April 2010 that encouraged 12 million sexually active individuals age 12 years or older to test for HIV over a 12-month period (Motsoaledi, 2011). The campaign, the world's largest to date, involved health facilities, stand-alone and mobile HTC services, pharmacies and universities.

Since 2004 Burkina Faso has conducted national campaigns and, with the involvement of local non-governmental organizations (NGOs), these campaigns have contributed to the rapid increase in the number of people who have tested for HIV—over one million by 2009 (WHO/UNAIDS/UNICEF, 2011).

In 2007, in Malawi's second annual HTC Awareness Week campaign, more than 186 600 people were tested, a 92% increase over the previous year's campaign. Of these, 71% learned their HIV status for the first time. Some 1367 sites offered HTC services during the week. A majority of the testing sites were mobile, reaching people in rural areas. Reaching these rural populations—historically, a difficult population to serve—was critical to the success of the HTC week (PEPFAR, 2008).

In Latin America and the Caribbean, a regional campaign, "Know your status/Hazte la prueba/Fique sabendo", on the Internet at http://www.haztelaprueba.info, offers a series of actions and provides tools that country programmes can use to increase the public's demand for HIV testing and counselling services. It seeks to enable people to make informed decisions about learning one's own HIV status while at the same time encouraging the use of health services that offer HTC.

Numeric national targets for the general population and for key populations should be considered when planning an HTC campaign. Planning should include assessment of which geographic areas have gaps in the availability of services, particularly care and treatment services, and consideration of the most appropriate models of HTC delivery. Careful planning of campaigns is key, with accurate forecasting to ensure that enough test kits and personnel are available.

During the campaign monitoring should track coverage specifically disaggregated by gender and key population groups, as well as the ratio of first-time testers to repeat testers. Monitoring the quality of the testing and the counselling, the acceptability of HTC services, and referral to and uptake of HIV prevention and care services is important in HTC campaigns, to learn not only whether increasing numbers of people are tested, but also whether those tested are effectively linked to prevention, care, treatment and support.

PEPFAR and WHO have developed an HTC events toolkit, which can guide planning, implementing and evaluation of a national HTC campaign (USAID, 2008). To share experiences of planning, implementing and evaluating campaigns, the toolkit documents country case studies of HTC campaigns in Brazil, Ethiopia and Malawi.

Some mass-media HTC campaigns focus on a particular appropriate day such as World AIDS Day or, for couples, around Valentine's Day. For example, PSI in Zimbabwe has offered free HTC services for couples for the week around Valentine's Day, and the AIDS Healthcare Foundation offers free testing and condom distribution in many countries on World Condom Day.

MULTI-DISEASE CAMPAIGNS

HTC campaigns may be linked to other disease prevention initiatives. These integrated disease prevention campaigns seek to improve coverage of a range of preventive services—for example, insecticide-treated bednets, water filters and diabetes and hypertension screening (Lugada et al, 2010). The promotion of HTC alongside other disease prevention activities not only provides a key opportunity to achieve high coverage of services, but also can be cost-effective if delivered effectively and efficiently. A cost-effectiveness and health impact model estimated that an integrated HTC, malaria and diarrhoea prevention campaign that provided HTC to over 40 000 people during a seven-day period would reduce costs associated with delivering the interventions separately and prevent 16.3 deaths per 1000 participants (Kahn et al, 2012). In western Kenya an integrated disease prevention campaign, which offered HTC, insecticide-treated bednets, male condoms and water filters, was launched in 2008. The campaign provided HTC for more than 5000 people over a three-day period and provided same-day CD4 cell count testing for those who tested HIV-positive (Granich et al, 2010). The campaign sought to reach 80% of people ages 15–49 years old. The campaign surpassed this goal: 87% of the target population were provided HTC services, and 80% of those tested were testing for the first time (Lugada et al, 2010).

5. OTHER ISSUES

5.1 MANDATORY HIV TESTING

WHO supports the mandatory screening for HIV and other bloodborne viruses of blood and blood products destined for transfusion or manufactured blood products. It is important to emphasise that this mandatory testing is on blood or blood products and not on the person who donates blood. **WHO opposes the mandatory testing of individuals.** Mandatory testing is deemed unethical and against human rights; it perpetuates stigma and discrimination and fails to have any public health impact, acting instead as a barrier to access to health services. The endorsement of PITC and the recommendation to expand HTC are **not an endorsement of mandatory or coercive HTC** of individuals. Any model of HTC must adhere to the 5Cs, which stress **voluntarism** and **informed consent**. The expansion of HTC must be supported by improved protection from stigma and discrimination for individuals who are identified as HIV-positive and by the assured provision of or referral to integrated HIV prevention and treatment services.

5.2 SELF-TESTING

Potentially, self-testing for HIV offers individuals the opportunity to test for HIV at a time and place they prefer. Also, self-testing offers complete privacy to those concerned about confidentiality (Spielberg et al, 2003a). To date, there is limited evidence on the feasibility, accuracy, and acceptability of self-testing for HIV. High levels of "informal" self-testing have been reported among health workers in sub-Saharan Africa (Namakhoma et al, 2010), and there are reports of the unregulated use for self-testing of rapid diagnostic tests, purchased through the Internet, by groups such as men who have sex with men in China (Seguy, personal communication). Self-testing is currently being explored for use by health care workers in Kenya (Napierala et al, 2011) and in communities in Malawi (Corbett, personal communication). Despite the dearth of evidence on the feasibility of self-testing at home, studies in the United States of America find that people at risk of HIV infection and people with no history of HIV testing consider the concept acceptable (Spielberg, 2003a; Speilberg, 2004).

A cross-sectional feasibility study in Malawi, which provided consenting individuals with the option of HIV self-testing followed by standard VCT or else standard VCT alone, reported that 92% of participants elected HIV self-testing (Choko et al, 2011). The accuracy of self-testing was high, with 99.2% of results concordant with subsequent repeat confirmatory HIV testing. Furthermore, 98.5% of participants said that the testing kits were "very easy" to use, and all who self-tested said that they would recommend HIV self-testing to others. Exit interviews with randomly selected individuals indicated that most would prefer self-testing in future.

SELF-TESTING

Common arguments of policy-makers and local health systems for and against self-testing

Arguments for:

+ Potential for dramatic increase in knowledge of HIV status
+ Increased confidentiality
+ Increased convenience
+ Autonomy and empowerment
+ Potential to remove the stigma surrounding HIV testing
+ Fewer resource requirements for the health-care system.

Arguments against:

– Greater potential for inaccurate results
– Psychological danger when decoupling testing from counselling
– Greater difficulty ensuring referral to treatment and care
– Potential unethical use of HIV self-testing
– Self-testing as justification for unprotected sex
– Concern for safe disposal of biohazard material.

Although the limited evidence suggests that the model is feasible, concerns exist that, in the absence of immediate post-test counselling, fewer of those who self-test positive will obtain prompt and appropriate follow-up care (Spielberg et al, 2003a). Similarly, there are concerns that this strategy would have limited preventive impact because fewer individuals would receive post-test counselling (Spielberg et al, 2003a). Furthermore, promoting self-testing could have unintended ethical or social consequences that currently are not well understood.

6. TESTING FOR SPECIFIC GROUPS

6.1 PREGNANT WOMEN

WHO strongly recommends PITC in ANC settings in countries with generalized epidemics (WHO/UNAIDS, 2007), where it has been essential to the expansion of PMTCT interventions. Testing in ANC is linked to activities for PMTCT, and the overall package is outlined in PMTCT guidelines (WHO, 2010a). Rapid HIV testing with same-day results has played an important role in increasing the uptake of PITC in many ANC settings, facilitating effective linkage to timely PMTCT interventions, provision of ART for women in need of ART for their own health and opportunities for primary prevention with those testing negative and HIV-negative partners. Couples HTC (CHTC) is recommended in ANC settings, facilitating provision of interventions including ART for prevention in serodiscordant couples.

In countries with low-level epidemics, PITC may not be the most cost-effective strategy as a national approach, although it is currently recommended and many countries in low-level and concentrated epidemics with adequate financial and health service resources currently use PITC in ANC successfully. WHO is currently working on guidance to support the most effective HTC approach for pregnant women in low-level and concentrated epidemics.

In ANC settings provider-initiated testing and counselling (PITC) has been essential to the expansion of prevention of mother-to-child transmission of HIV.

Where PITC is carried out in ANC settings, measures must be taken to prevent unintentionally or intentionally coercive testing (Hensen et al, 2011). These measures include regular mentoring and supervision of staff, retraining where necessary, and monitoring of PITC procedures to ensure their acceptability to pregnant women. Pregnant women testing HIV-positive must be linked not only to PMTCT services but also to HIV services for their own health; WHO has issued guidance on ARVs for PMTCT and for treatment of the mother's infection (WHO, 2010a). This guidance can help to support the strengthening of linkages to ART treatment and prevention services for pregnant women with HIV.

Often, pregnant women learn their HIV status before their partners learn their own status. Studies show that disclosure of HIV status to partners, relatives or friends can improve adherence to PMTCT services and infant feeding practices (Farquhar et al, 2001; Kirsten et al, 2011). WHO recommends offering couples HTC in ANC settings and wherever HTC services are available, to support mutual disclosure and development of a mutual risk reduction plan and provision of ART for prevention in serodiscordant couples (WHO, 2012) (see section 6.3, Couples). WHO views disclosure of HIV status as a process, not a single event; continuing counselling and support for disclosure are central to the standards of good-quality HTC service delivery.

In some ANC settings that have high volume, good coverage, and early attendance (before 18–24 weeks of pregnancy), PITC using laboratory-based methods such as the enzyme-linked immunosorbent assay (ELISA) is often the most appropriate model. For remote and rural clinics seeing small numbers of pregnant women, HIV testing using rapid diagnostic tests (RDTs) may be employed. Testing using RDTs is also recommended for women who present late in pregnancy, to enable them to benefit promptly from PMTCT interventions. Rapid testing can also be used to test women who present in labour or who have not received their test results prior to labour. Opportunities should be explored to connect with community-based testing, especially for those coming late to ANC or not coming to ANC and/or delivering at home.

In countries with high prevalence, generalized epidemics, because of the high vulnerability to and risk of HIV infection during pregnancy, WHO recommends retesting in the third trimester, during labour or shortly after delivery so that the infant can receive post-exposure ART if appropriate (WHO, 2010b).

Testing for HIV along with other key tests for pregnant women, including tests for syphilis, haemoglobin and hepatitis B, can be synergistic and should be considered in some settings.

6.2 INFANTS AND CHILDREN

Despite widespread implementation of PMTCT interventions, a significant number of children continue to acquire HIV during pregnancy, delivery and breastfeeding. This is because, although PMTCT interventions significantly reduce transmission to infants, transmission can still occur—especially if there are poor adherence to PMTCT regimens and high rates of loss of infants to follow-up. Furthermore, some women with HIV are not diagnosed antenatally or are not successfully linked to PMTCT programmes. HIV disease progresses rapidly in infants and children, and HIV-infected infants often die with the first episode of opportunistic infection such as pneumocystis pneumonia. Therefore, effective and efficient early diagnosis of infants and children, with links to treatment, is important. HIV-infected infants and children below age two years should be initiated on ART as soon as their HIV-positive status is confirmed, irrespective of their CD4 cell count or clinical status. HIV testing is the gateway to their survival.

HIV testing in this age group is challenging. The presence of maternal anti-HIV antibody makes it impossible to use standard rapid tests to diagnose infection in HIV-exposed infants up to 18 months of age. Instead, more costly and complex virologic tests that can detect the presence of the virus itself, such as nucleic acid testing (NAT), must be used to confirm HIV status. Details of the types of tests used and testing techniques can be found in *Recommendations on the diagnosis of HIV infection in infants and children*, at: http://www.who.int/hiv/pub/paediatric/diagnosis/en/index.html (WHO, 2010b). While virologic testing is needed for definitive diagnosis in infants, standard rapid tests may still be useful for screening infants for HIV exposure.

Most infants and children acquire HIV from their parents. Therefore, the fact that any member of a child's family—mother, father or siblings—is known to have HIV should alert health-care providers to test the child. A family-based approach can improve identification of HIV-infected children in high prevalence

settings and, more importantly, in low prevalence settings. This approach will also facilitate disclosure of HIV status in this age group. WHO guidelines on HIV disclosure counselling for children up to 12 years of age can be found at http://www.who.int/hiv/pub/hiv_disclosure/en/index.html (WHO, 2011d).

HIV testing should be offered to all infants and children born to HIV-positive women and to children from families in which a sibling or parent has HIV. PITC in clinical settings should be provided for infants and children in countries with generalized HIV epidemics. PITC provided in paediatric settings has been shown to be acceptable and effective in these settings (Mutanga et al, 2012).

Opportunities for testing young children will arise predominantly in, but should not be limited to, maternal and child health (MCH) services, child health services, in-patient wards, immunization clinics and malnutrition units. Other treatment and testing services also offer opportunities to diagnose children. For example, outreach initiatives such as home-based testing can address the whole family at the same time.

6.3 ADOLESCENTS

For many reasons, HTC services for adolescents can be highly beneficial. Among adolescents, defined as those ages 10 to 19 years of age, the main mode of HIV transmission is unprotected heterosexual sex. Adolescents are also easily exposed through injecting drug use, sex work, and male homosexual sex (UNICEF, 2010). In generalized epidemics adolescent women are particularly vulnerable to HIV infection. Early sexual debut, often with older partners, coerced sex, and low rates of condom use, combined with their biological vulnerability at that age, increase the risk of HIV infection.

Also, in generalized epidemics an increasing proportion of children entering adolescence have acquired the infection perinatally, and many remain undiagnosed, either because their mothers were not enrolled in PMTCT care or because they were not diagnosed postnatally (Ferrand et al, 2009; Ferrand et al, 2010). Some of these children are “slow progressors” and may reach adolescence unaware of their HIV-positive status. Many others will have chronic clinical and developmental problems and would benefit significantly from ART. HIV has become the most common cause of acute admission and in-hospital death among adolescents in high prevalence, generalized epidemics, and many of these adolescents were undiagnosed prior to presenting with significant morbidity (Ferrand et al, 2010a).

Current HTC approaches do not adequately meet adolescents’ needs. A study in South Africa found that a high proportion of adolescents are interested in knowing their HIV status, and yet few had ever been tested (Mathews et al, 2009; Pettifor et al, 2004). Adolescent-friendly HTC services follow the HTC guiding principles and adhere to the 5Cs (see section 10, Issues in and principles of HIV testing and counselling service delivery). Another important issue for adolescents is the lack of consensus on legal age of self-consent to HTC; consequently, the need for parental consent is a barrier for some adolescents in obtaining testing.

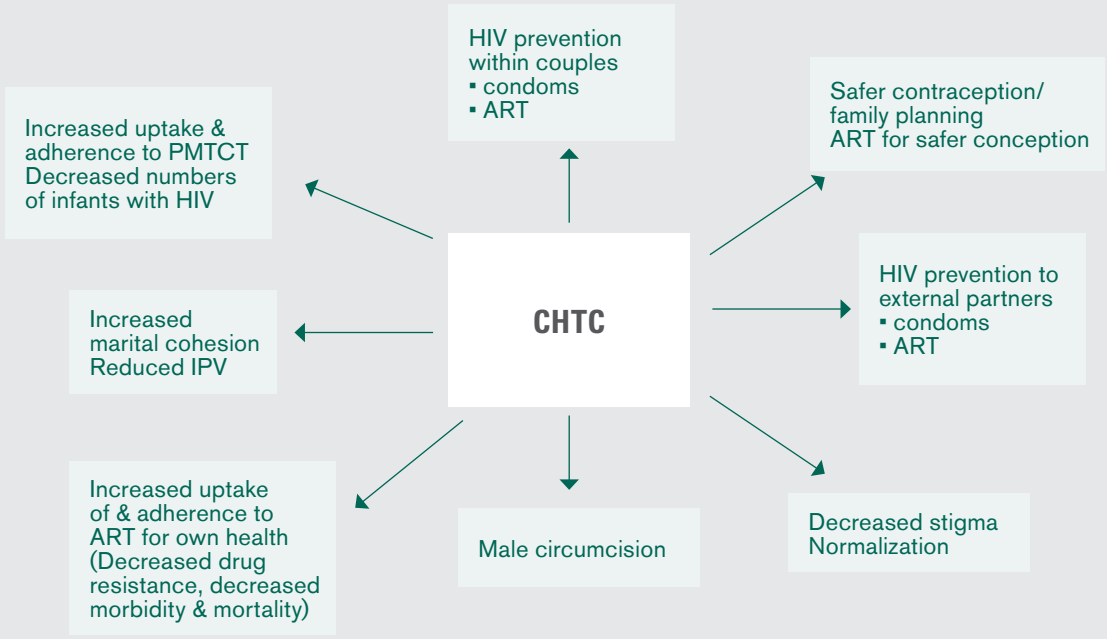
Developing and implementing HTC services that are acceptable and accessible to adolescents is a high priority. HTC should be made available, both through a PITC approach in clinical settings in generalized epidemics and particularly through community-based approaches. HTC services for adolescents must take care to provide counselling and support for disclosure to parents and sexual partners that is appropriately age-specific.

WHO's Regional Office for Africa (WHO AFRO) has developed operational guidelines on the provision of HTC services to infants, children and adolescents (WHO AFRO, 2011). Service providers in the Africa region should consult these guidelines. WHO is currently developing global HTC guidelines specifically for adolescents.

6.4 COUPLES

Approximately three-quarters of adults ages 20–49 years in sub-Saharan Africa are in cohabiting unions (Eyawo et al, 2010). Up to 50% of people living with HIV have a partner who is HIV-negative (and so are described as being in a serodiscordant union, with one partner positive, one negative) (Chemaitelly et al, 2012). Yet the vast majority of HTC is conducted with individuals, not with couples.

FIGURE 5 POTENTIAL BENEFITS OF COUPLES HTC



Couples HTC provides test results and counselling to partners simultaneously, creating an opportunity for mutual disclosure, support to couples and help developing a joint HIV risk management plan. As a public health intervention, couples HTC has many beneficial ramifications (Figure 5). Couples HTC can be provided in health facilities, including ANC, through either a client- or provider-initiated approach and through other HTC approaches.

Engagement and enrolment of male partners remains a challenge in scaling up couples services. Men are less likely than women to test for HIV (Peltzer et al., 2009; Venkatesh et al., 2011; Ziraba et al., 2011), to enrol in HIV clinical care following HIV diagnosis (Cornell et al., 2009; Parrott et al., 2011), to initiate anti-retroviral treatment (Braitstein et al., 2008; Keiser et al., 2008) and to stay in HIV clinical care (Zachariah et al., 2011). In order to bring interventions for couples to scale, efforts are clearly needed to address and specifically appeal to male partners and to link them to HIV prevention, care and treatment.

Fears about intimate partner violence (IPV) underlie some providers' reluctance to encourage couples interventions. While high levels of IPV are reported in many communities, any association with HIV testing and disclosure is unclear (WHO, 2004a). Health workers should be aware of IPV and should be trained to screen for and address IPV as part of couples counselling. Women with a history of IPV should be provided ongoing counselling and supported in making considered judgements concerning the safety and feasibility of involving their partners in testing or disclosure. Women should also be referred to community-based IPV support services where available (WHO, 2004; WHO, 2012).

WHO recommends the increased offering of voluntary HTC to couples, with support for mutual disclosure, in all settings. WHO has developed evidence-based guidelines to support these recommendations. These guidelines should be consulted in the expansion of HTC for couples (WHO, 2012).

6.5 HTC FOR PEOPLE WHO INJECT DRUGS

Decisions on how best to implement HTC in PWID settings depend upon an assessment of the situation in a particular country, including the local epidemiology; available infrastructure and financial and human resources; available HIV prevention, treatment, care and support; and the existing social, policy and legal frameworks for protection against adverse consequences of HIV testing, such as discrimination and violence. Where there are high levels of stigma and discrimination against PWID, adequate resources should be devoted to addressing these issues. In areas with concentrated HIV epidemics among PWID, consideration should be given to recommending HTC in primary care services for PWID; harm reduction services such as NST and OST; and other drug dependence treatment services as well as in STI services, TB services, and other health services for key populations (sex workers, MSM, prisoners and residents of other closed facilities including compulsory drug treatment centres). HTC can also be provided through mobile and other outreach services that offer health and other services for PWID. WHO's Regional Office for South-East Asia (SEARO) has developed guidance on HTC in settings attended by PWID (WHO/SEARO/UN, 2009).

6.6 HTC FOR MALE CIRCUMCISION

HTC is a part of the minimum services package for voluntary medical male circumcision (VMMC) (WHO/UNAIDS, 2009). Male circumcision has been adopted as an additional intervention for HIV prevention in 14 countries of eastern and southern Africa where HIV prevalence rates are high and male circumcision rates are low. The current focus is to provide "catch-up" services to males 15 to 49 years old over the next five years while, in parallel, establishing services for infants and/or adolescents. While HTC is not required for MC, it is recommended. The majority of males who have sought MC services have consented to testing—81% to 97% across four countries. According to various DHS surveys over the past five years, 57% to 91% of men in the 14 high-priority countries have never been tested for HIV. Thus, as VMMC is scaled up, a new opportunity is exists for offering testing to men (who may seldom come to health facilities), many of them for the first time.

For VMMC several countries use a mixed-service delivery model similar to approaches for HTC, including fixed-facility sites, outreach, mobile services and campaign events, particularly focusing on the school holidays. Community mobilization and HTC delivered in the community can help to generate demand for both HTC and VMMC. Several countries have conducted campaigns, including Kenya (Rapid Results Initiatives), Zimbabwe and the United Republic of Tanzania. In the United Republic of Tanzania's Iringa Region, five facilities performed 10 352 procedures in a six-week campaign in 2010, exceeding the campaign's goal by 72%. HIV testing was almost universal during the campaign (Mahler et al, 2011). A number of countries are also exploring how best to link men who test HIV-positive at VMMC services to care and treatment. In Kenya men who tested positive received vouchers, and a tracking system was used to see whether or not they obtained care; if they did not, a support member contacted the individual to encourage follow-up care. In the Lake Victoria Islands of the United Republic of Tanzania, combined VMMC and HIV testing and care campaigns are conducted. Adolescents have been particularly receptive to VMMC and HTC. Such services are beginning to identify HIV-positive adolescents who were not aware of their status and who need counselling and further care.

7. DIAGNOSTICS FOR HIV

To improve the quality of service delivery and the acceptability and uptake of HTC, for many settings WHO recommends the use of rapid diagnostic tests (RDTs) rather than conventional laboratory-based diagnostics such as enzyme immunoassay (EIA). RDTs allow quicker provision of test results and post-test counselling. Most RDTs do not require venipuncture specimen collection, but instead can be performed with simple finger-stick collection procedures. With appropriate training, support and supervision, lay counsellors or community health workers using RDTs can perform HIV testing with accuracy and reliability. Employing these workers to perform testing may be a preferred option, particularly where health care professionals are overburdened and unable to conduct HTC.

The use of RDTs is encouraged in resource-limited settings to reduce the need for and reliance on laboratory services. Such services rely on laboratory equipment that requires maintenance and skilled staff. They face problems posed by inadequate transportation of specimens to centralized laboratory services. The use of RDTs for HIV testing may increase the acceptability and, hence, the uptake of HTC and receipt of test results following HTC. However, in services where there are significant numbers of tests being carried out and patients are retained—such as in in-patient services, some ANC settings, and blood screening services—testing by laboratory-based methods such as EIA may be more cost-effective and appropriate.

Uninterrupted provision of HTC services requires a continuous supply of test kits and the necessary consumables—for example, specimen transfer devices, lancets, alcohol swabs and blood collection equipment. Stock-outs would not only affect the quality of service delivery, but also may damage clients' confidence in HTC services and thus further limit uptake. To maintain regular and consistent supplies of test kits and required consumables requires highly effective procurement and supply chain management systems that include accurate forecasting of testing needs, efficient planning and distribution of test kits and continuous post-market surveillance to report any quality problems.

Any country considering the selection and use of diagnostics for HIV testing should have:

- a national HIV testing policy, linked to the national laboratory policy and national laboratory strategic plan[1] (WHO SEARO/WPRO, 2011)

- national validated testing algorithms, with back-up options, according to the WHO testing strategies that follow, as appropriate

1 Guidance on developing a national health laboratory policy and plan can be found at: http://www.wpro.who.int/health_technology/documents/docs/Nationalhealthlab2_0F38.pdf

- quality assurance measures for testing (WHO/UNAIDS/HIV/AIDS Alliance GTZ, 2005)[1]
- accurate forecasting to avoid stock-outs of test kits and consumables (USAID/DELIVER, 2011).

7.1 HIV TESTING STRATEGIES

WHO recommends standardized testing strategies[2] to maximize the accuracy of test results while minimizing cost. Which testing strategy is most appropriate depends on the objectives of testing, the type of HIV epidemic and the prevalence of HIV in the population to be tested. The testing strategies suggested here apply equally to testing conducted in the laboratory and testing conducted outside of the conventional laboratory setting by non-laboratory technicians who are trained for this work—i.e. through task-shifting or within community settings.

These testing strategies have been developed assuming that all HIV assays used have a sensitivity of at least 99% and a specificity of at least 98%, resulting in an overall positive predictive value of 99%. The testing strategies work for all formats of HIV assays or combinations of test formats. It is essential to use HIV assays with different antigen preparations and test kit components to minimize the potential for shared false non-reactivity or false reactivity. Assays that come from different manufacturers are likely to involve different antigen preparations. Increasingly, however, manufacturers sell semi-finalized or finalized product to re-branders/re-labellers. This practice makes it difficult to determine the exact provenance of HIV assays, which is crucial to know for the selection of assays to populate the testing strategies as testing algorithms.

7.1.2 DIAGNOSIS IN HIGH PREVALENCE SETTINGS

The following testing strategy (Figure 6) applies in high prevalence settings, i.e. above 5% prevalence *in the population to be tested.* These settings may include generalized HIV epidemics and defined key sub-populations in concentrated epidemics.

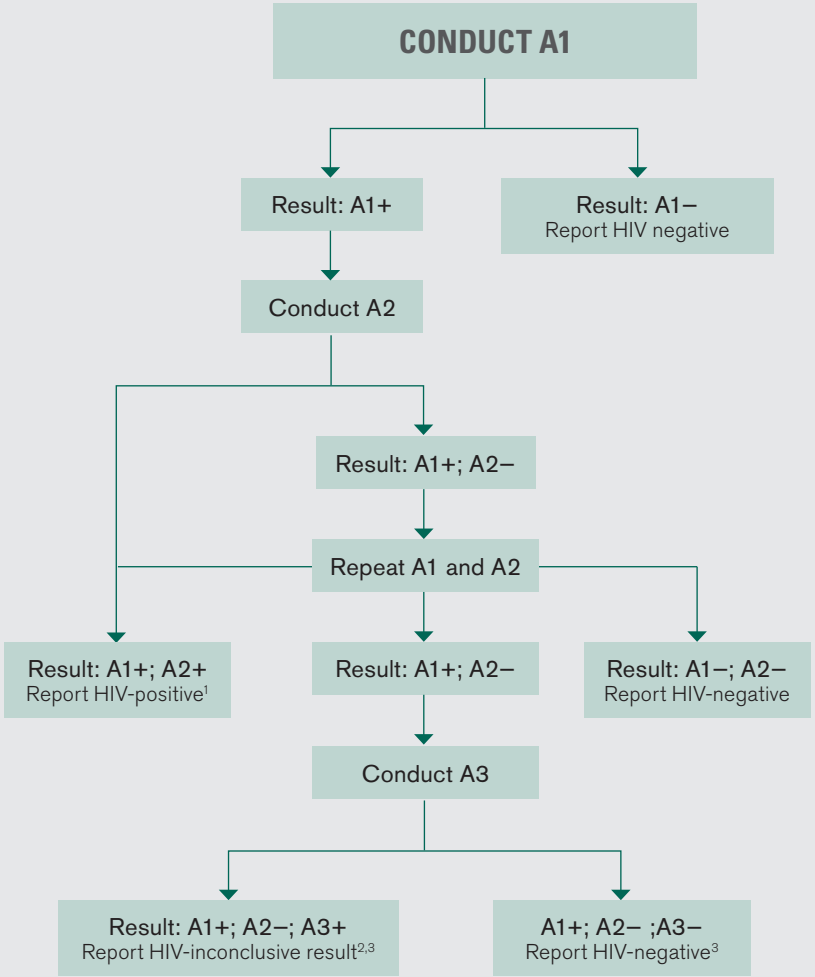
All specimens are first tested with one assay, and specimens that are non-reactive (A1–) are considered HIV-negative and reported as such. Any specimens that are reactive on the first assay (A1+) should be tested again using a different assay. For specimens that are reactive on both the first and the second assays (A1+; A2+), the result should be reported as HIV-positive. These individuals should be referred for assessment of their eligibility for treatment and entry to care, if these services are not available at the testing site. Specimens that are reactive on the first assay but non-reactive on the second assay (A1+; A2–) **should be repeated** using the same specimen (when serum/plasma) with the same two assays. When using finger-stick whole blood, a new specimen will have to be taken. Repeating the assays is usual best practice; it may eliminate discrepant results that are due to technical or clerical errors or errors inherent to the test device itself. If the results resolve to concordance (either A1+; A2+ or A1–; A2–), they may be reported as positive or negative, respectively.

1 Tools for quality assurance for testing can be found at: http://www.who.int/diagnostics_laboratory/documents/guidance/hivrttraining_overview/en/index.html; http://www.who.int/diagnostics_laboratory/documents/guidance/hivrttraining_overview/en/index.html and http://www.who.int/ihr/training/laboratory_quality/en/index.html

2 In this context a testing strategy generically describes a testing approach for a specific need (for example, blood transfusion and transplantation safety, HIV surveillance, and/or diagnosis of HIV infection in both client-initiated and provider-initiated testing and counselling), taking into consideration the presumed HIV prevalence in the population being tested. A testing algorithm describes the combination and sequence of specific HIV assays used within a given HIV testing strategy. It has been shown that combinations of EIAs or combinations of RDTs or mixed combinations of EIAs and RDTs can provide results as reliable as, and in some instances more reliable than, the conventional EIA/Western blot combination, and at much lower cost.

If the testing results remain discrepant (A1+; A2–), the specimen should be further tested using a third assay. If the third assay is non-reactive (A1+; A2–; A3–), the test result is considered negative and reported as HIV-negative. If the third assay is reactive (A1+; A2–; A3+), the test result is reported as HIV-inconclusive. The individual should be asked to return in 14 days for further testing. This situation should be rare. If the rate of HIV-inconclusive results is high, additional efforts to assure quality should be made, and the selection of assays might be reconsidered. If A1 is an antigen/antibody detection assay and A2 or A3 is an antibody-detection-only assay, re-testing should be performed with a second specimen taken after 14 days.

FIGURE 6 HIV TESTING STRATEGY FOR DIAGNOSIS IN HIGH PREVALENCE SETTINGS



Notes:
"Assay A1", "A2", "A3" represent three different assays (of any test format). "Report" = result may be reported.
[1] For newly diagnosed individuals, a positive result should be confirmed on a second specimen to rule out laboratory error.
[2] Re-testing should be performed on a second specimen taken after 14 days to rule out seroconversion.
[3] If A1 is an antigen/antibody detection assay and A2 or A3 is an antibody-detection-only assay, re-testing should be performed with a second specimen taken after 14 days.

7.1.3 DIAGNOSIS IN LOW PREVALENCE SETTINGS

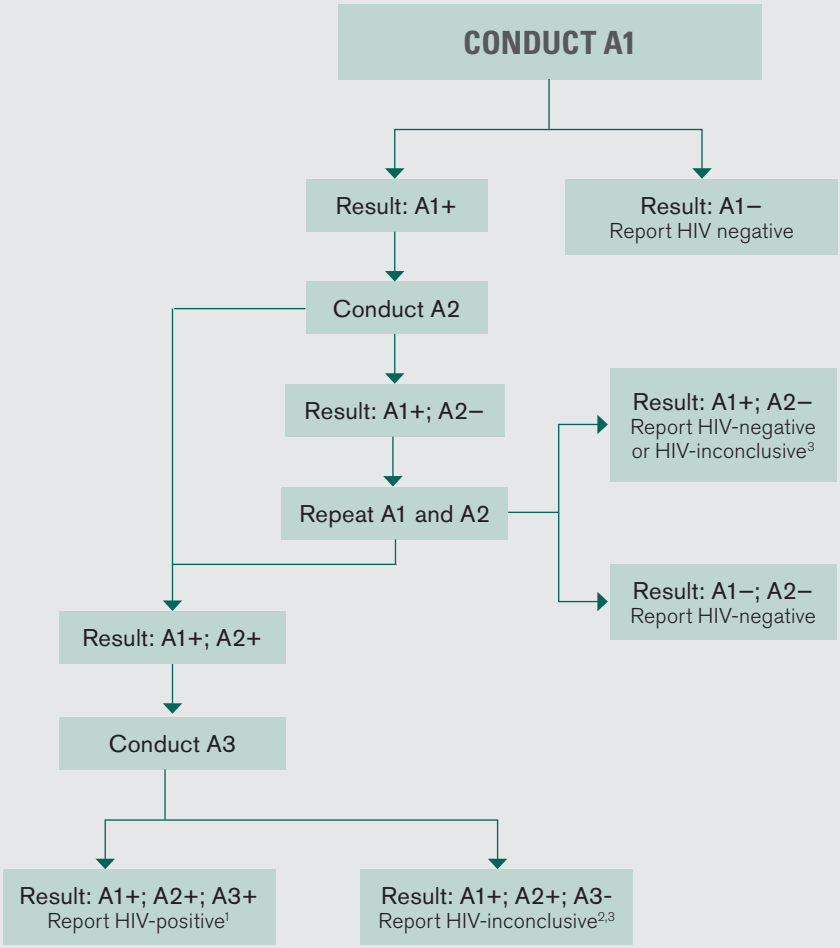
The following testing strategy (Figure 7) should be used for testing in low prevalence settings, i.e. with prevalence below 5% *in the population to be tested.* This would include settings with low-level HIV epidemics and testing of the general population in concentrated HIV epidemics.

All specimens are first tested with one assay, and specimens that are non-reactive (A1–) are considered HIV-negative and reported as such. Any specimens that are reactive on the first assay (A1+) should be retested using a second assay different from the first.

Specimens that are reactive on the first assay but non-reactive on the second assay (A1+; A2–) **should be repeated** using the same specimen (when serum/plasma) with the same two assays. When using finger-stick whole blood, a new specimen will have to be taken. Repeating the assays is usual best practice; it may eliminate discrepant results that are due to technical or clerical errors or errors inherent to the test device itself. Any specimens that are reactive on the first assay but non-reactive on the second assay (A1+; A2–) are considered HIV-negative, and results are reported as such. If A1 is an antigen/antibody detection assay and A2 is an antibody-detection-only assay, the result is inconclusive, and re-testing should be performed with a second specimen taken after 14 days.

In a low prevalence population, the positive predictive value based on two test results remains too low. Therefore, for specimens that are reactive on both the first and the second assays (A1+; A2+), a third assay should be used to confirm HIV-reactive specimens. If the third test result is also reactive (A1+; A2+; A3+), the result can be reported as HIV-positive. Such individuals should be referred for assessment of their eligibility for treatment and entry to care, if these services are not available at the testing site. If the result of the third assay is non-reactive (A1+; A2+; A3–), then the result is considered HIV-inconclusive. The individual should be asked to return in 14 days for further testing. This situation should be rare. If the rate of HIV-inconclusive results is high, additional efforts to assure quality should be made, and the selection of assays might be re-considered.

FIGURE 7 HIV TESTING STRATEGY FOR DIAGNOSIS IN LOW PREVALENCE SETTINGS



Notes:
"Assay A1", "A2", "A3" represent three different assays (of any test format). "Report" = result may be reported.
[1] For newly diagnosed individuals, a positive result should be confirmed on a second specimen to rule out laboratory error.
[2] Re-testing should be performed with a second specimen taken after 14 days to rule out potential seroconversion.
[3] If A1 is an antigen/antibody detection assay and A2 or A3 is an antibody-detection-only assay, re-testing should be performed with a second specimen taken after 14 days.

In both high and low prevalence settings, three assays may be required for diagnosis. Forecasting of stock requirements should take this into account. In low through-put facilities, it may be difficult for operators to maintain competency for performing A3, as it may rarely be performed. If competence for performance of A3 is an issue, the individual or a specimen can be referred to another, more experienced/competent testing site or laboratory for performance of A3.

7.2. SELECTION AND USE OF DIAGNOSTICS

Six to ten assays should be selected for validation of a potential testing algorithm, taking into account the considerations outlined in Table 2. One validated testing algorithm is preferable, with two additional assays as back-up options in case of stock-outs or product failures. In addition to acceptable performance characteristics, the positive and negative predictive value of the overall testing algorithm should be considered. WHO is currently developing more specific guidance on this topic.

TABLE 2 SPECIFIC CONSIDERATIONS FOR SELECTION OF HIV DIAGNOSTICS

Parameter	Considerations
Performance characteristics	
Clinical sensitivity	Set the minimum acceptable criteria e.g. ≥99% for RDTs, 100% for EIAs
Clinical specificity	Set the minimum acceptable criteria e.g. ≥98% for RDTs and EIAs
Seroconversion sensitivity	Important for blood screening and suspected highly incident populations
Inter-reader variability, if subjectively read format	Set the minimum acceptable criteria e.g. ≤5%
Invalid rate (devices/test results)	Set the minimum acceptable criteria e.g. ≤5%
Operational characteristics	
Test format	RDTs (immunochromatographic, immunofiltration) Simple (comb formats, agglutination assays) EIAs (manual plate-based EIAs, immunoanalysers) Supplemental assays (Western blot, line immunoassays) NAT (qualitative)
Specimen type	Serum/plasma, venous or capillary whole blood, oral fluid
Detection type	Discriminatory detection of HIV-1 and HIV-2 antibodies or combined detection of HIV-1/2 antibodies Simultaneous or combined detection of HIV-1 antigen and HIV-1/2 antibodies
Subtype detection	M, N, O subtypes
Time to result	Immunochromatographic: Less than 30 minutes with fewer steps Immunofiltration: Less than 5 minutes with more steps
Endpoint stability	How long is the result stable? Is longer reading time or shorter reading time desirable? (depends on service delivery model)

Ease of use	Depends on a combination of: • nature of specimen collection (finger-stick whole blood by lancet or venous whole blood by venipuncture) • number of steps in the test procedure • ease of reading the test band, line, spot • ease of interpretation of testing results • addition of procedural quality control (band appears when human specimen is added versus band appears when running buffer is added)
Degree of laboratory infrastructure required	Refrigeration for storage of test kits and/or reconstituted reagents Temperature-controlled work space Electricity/generator
Equipment/consumables required but not provided in the test kit	Lancets, alcohol swabs for finger-stick whole blood Blood collection equipment for venous whole blood Other general laboratory consumables
Specimen through-put and individual testing service delivery models	RDTs if ≤40 specimens per day per operator with limited laboratory infrastructure EIAs if ≥40 specimens per day per operator with laboratory infrastructure
Technical skill of staff conducting testing	Including both laboratory and phlebotomy skills
Availability of test kit controls and compatibility with quality control materials	Some are available but separate from test kit See also note above on procedural in-built quality control
Shelf-life of test kits	Must be negotiated as part of the procurement contract
Access to referral laboratory	Particularly important when fourth generation assays are used

7.3 OTHER FACTORS TO CONSIDER

RETESTING

More specific guidance on retesting is detailed in *Delivering HIV test results and messages for re-testing and counselling in adults* (WHO, 2010).

NEWLY DIAGNOSED HIV-POSITIVE INDIVIDUALS

It is usual best practice to obtain an additional specimen after a time interval (i.e. not the same day) to retest all newly diagnosed individuals. Retesting is usually performed as part of the clinical and laboratory-based assessment of treatment eligibility and entry to care. This procedure aims to rule out possible technical or clerical errors including specimen mislabelling and transcription errors.

DISCREPANT TESTING RESULTS

Using the testing result of A3 as a tie-breaker may not always resolve HIV status. Possible reasons for the discrepant result (A1+; A2–) could be poorer than expected specificity of A1 or early seroconversion detected by A1 but not by A2—i.e. A1 has better seroconversion sensitivity than A2.

Individuals with inconclusive overall results should be asked to attend for re-testing after 14 days. In particular, if there has been a specific incident of HIV exposure within the preceding three months, the discrepancy in the test results may be due to seroconversion, and thus testing a second specimen is advisable. If re-testing results are concordant reactive (A1+; A2+), true seroconversion is highly likely, as the antibody response will have matured and HIV-positive status can be reported. If re-testing results remain either discrepant (A1+; A2–) or resolve to both non-reactive (A1–; A2–), false reactivity is likely to have been the cause, and HIV-negative status can be reported.

Specimens from individuals with clinical signs meeting the WHO criteria for stage III or IV may show discrepant testing results due to a decrease of HIV-1/2 antibodies with advanced disease progression and impaired immune function. These instances should not be common; if observed, retesting for HIV diagnosis may not be required, but instead additional testing such as CD4 enumeration (and HIV virological testing, where available) may be carried out to guide clinical decisions.

If the percentage of discrepant test results exceeds 5% within a testing service in high prevalence settings, quality assurance procedures should be assessed for their effectiveness, and, possibly, a new testing algorithm should be validated and adopted.

FOURTH GENERATION ASSAYS FOR SIMULTANEOUS OR COMBINED DETECTION OF HIV-1 ANTIGEN AND HIV-1/2 ANTIBODIES

Newly available assays for the detection of HIV-1 p24 antigen and HIV-1/2 antibodies have the potential to identify infected individuals earlier, including individuals in the seroconversion (acute) phase. These assays are generally of superior seroconversion sensitivity to assays of earlier generations. Therefore, they should be considered as A1 assay where feasible. However, recent data show that the HIV-1 antigen detection component of some fourth generation assays may be lacking in sensitivity (Sands et al, 2012).

When fourth generation assays are used as A1 and are followed with antibody-detection-only assays as A2 and A3, due care should be taken to confirm any initial HIV-1 antigen reactivity. This may be done through re-testing of a second specimen taken 14 days later or referral of a specimen for HIV-1 antigen testing at a referral laboratory.

USE OF WESTERN BLOT AND CONFIRMATORY ASSAYS

At present a number of countries use a selection of different HIV assays in a particular order so as to minimize the number of costly confirmatory assays.[1] Confirmatory assays should be used only to resolve inconclusive testing results. Therefore, WHO suggests that countries consider testing algorithms using RDTs and/or combinations of RDT/microtitre plate EIA rather than EIA/Western blot combinations. In some countries immunofluorescence assays (IFA) are still used as a confirmatory assay, but in general these assays are less sensitive and specific than other currently available HIV assays. In some low prevalence settings, Western blot or similar confirmation assays may still be useful as A3 within the testing algorithm of a referral laboratory, given that few specimens are expected to require this additional testing.

1 That is, Western blot or similar assays based on recombinant proteins and/or synthetic peptides capable of detecting antibodies to specific HIV-1 and/or HIV-2 proteins.

WHO PREQUALIFICATION OF DIAGNOSTICS PROGRAMME

Through the WHO Prequalification of Diagnostics programme, WHO conducts an independent and impartial assessment of the quality and performance of commercially available HIV testing technologies that are best suited to limited-resource settings. The evaluations are comparative in nature. They assess technical and performance characteristics such as sensitivity and specificity using a worldwide-sourced clinical specimen reference panel and commercially acquired panels. In addition, to provide continual assurance of quality, WHO, through dossier review and site inspection, assesses the quality management system under which the product is made.

UN BULK PROCUREMENT SCHEME

HIV assays found to meet minimum standards for WHO prequalification are then eligible for United Nations (UN) procurement. The UN Bulk Procurement Scheme provides UN agencies and national programmes with access to appropriate HIV assays of good quality at reduced cost. HIV assays other than those purchased by the pooled procurement programme but meeting the minimum standards in terms of sensitivity and specificity are also suitable for use with the testing strategies.

Further information concerning the prequalification of HIV diagnostics is available on the WHO web site at http://www.who.int/diagnostics_laboratory.

8. DEVELOPING AND EXPANDING HTC MODELS BASED ON EPIDEMIOLOGICAL CONTEXT

8.1 EPIDEMIC-SPECIFIC HTC EXPANSION

Expansion of HTC should be based on the epidemiological context of a country or region. This recommendation is in line with UNAIDS guidelines that encourage countries to *"Know your epidemic, know your response"* (UNAIDS, 2007). This framework suggests combinations of models of HTC service delivery that should be considered for the following epidemics and target populations:

Generalized epidemics: Defined as settings where, although sub-populations may contribute disproportionately to the spread of HIV, HIV prevalence is consistently over 1% among pregnant women. The HTC target population in these settings is all patients (adults and children) attending health facilities; sexual partners, spouses, and children of people living with HIV; parents of children living with HIV; and key affected populations and people with high-risk behaviours and specific HIV vulnerabilities.

Concentrated epidemics: Defined as settings where HIV has spread rapidly in a sub-population but is not well established in the general population. Within one or more sub-populations, HIV prevalence is consistently above 5%, but among pregnant women in general, prevalence in urban areas is less than 1%.

Key HTC target populations are individuals in communities or populations where HIV prevalence is greater than 5%, including sex workers, MSM, PWID, and their sexual partners. The target population may also include pregnant women attending ANC facilities, delivery and postpartum services, TB and STI clinic patients, and the sexual partners of these individuals.

Low-level epidemics: HIV prevalence is below 1% among pregnant women and has not spread to higher levels in any sub-population. The HTC target populations are individuals in communities or populations where HIV prevalence may be higher than in the general population, including sex workers, MSM, and PWID, displaced populations, military or uniformed personnel, people in prison and indigenous populations.

8.2 AN ASSESSMENT OF CONTEXT

The expansion of HTC aims to increase knowledge of HIV status and to link individuals identified as HIV-positive and serodiscordant couples to HIV prevention, treatment, care, and support services. It also aims to link individuals identified as HIV-negative and seroconcordant negative couples to HIV prevention services. Prior to the selection and implementation of a combination of models of HTC, a descriptive assessment of the local context and an analysis of epidemiology and existing HTC programmes and services are required. The adoption and implementation of expanded HTC must be strategic and based on evidence from these assessments. All available data sources (i.e. population-based surveys, HTC and care and treatment programme data, surveillance data and special studies) should be utilized for the assessment.

Such assessments should cover:

- the epidemic and the geographic areas/populations with the highest burden of HIV, including geographical mapping;
- the availability (coverage/accessibility) of services, comprising the numbers of facilities providing PITC or stand-alone VCT and of HIV prevention and treatment services; Prevention and treatment services include, but are not limited to, TB, STI, PMTCT, OST, NSP, and other services attended by key populations, and male circumcision services. Also, availability through various sectors—government, private sector, NGO, community-based organizations and faith-based organizations—should be assessed.
- access for key affected populations, in all epidemic contexts;
- the utilization of available facility- and community-based HTC, prevention, treatment, care and support services, including an understanding of the barriers and facilitators to uptake of HTC, prevention, treatment, care and support;
- gaps in current coverage—an understanding of the geographic areas and populations that are not being reached by available services, including an assessment of coverage for men, adolescents and young adults, and key populations;
- the availability of resources (financial and personnel) to support sustainable HTC delivery models;
- particular social, gender and legal factors that may impede access and so need to be considered;
- ongoing monitoring and evaluation (M&E) and operational research to adjust HTC strategies according to changing epidemics and emerging evidence on models of HTC service delivery;
- assessment of the links between HTC services and other programmes—maternal and child health and sexual and reproductive health, TB, psychosocial and other support services, and outreach and peer education for values and preferences;
- policy on who can perform tests and whether point-of-care rapid testing is allowed.

The descriptive analysis of context and an assessment of need should direct the allocation of resources. Areas or populations with the greatest need for HTC access should receive priority.

8.3 STRATEGIC HTC EXPANSION AND IMPLEMENTATION BASED ON EPIDEMIOLOGICAL CONTEXT

The following framework (Table 3) provides recommendations on the combination of HTC models of delivery that should be considered based on epidemiological context.

The framework is not intended to be prescriptive; the adoption and implementation of HTC models must be based on need and supported by the availability of adequate resources and linkage to HIV treatment and prevention services (see section 8.2, An assessment of context). Annex 1 summarizes the approaches for specific contexts or populations. Details of target groups and the advantages and disadvantages of the various HTC models of delivery are provided in Annex 2.

TABLE 3 FRAMEWORK OF HTC MODELS OF DELIVERY BASED ON EPIDEMIOLOGICAL CONTEXT

Epidemic	HTC models of delivery to be considered
Generalized epidemic	**PITC.** Health-care providers should routinely offer HIV testing to all adults, adolescents, and children presenting to health facilities, if there are adequate resources, including a recommended package of (or links to) HIV prevention, treatment and care, in the context of an enabling environment. Implementation of **PITC in TB settings** should be prioritized, with an emphasis on finding co-infected patients and facilitating referral for immediate ART and TB treatment (i.e. within two weeks), which can significantly reduce mortality. Implementation of **PITC in ANC settings** should be prioritized, with an emphasis on offering HTC to couples. Repeat testing of pregnant women is recommended in the third trimester or early in the postnatal period in high prevalence generalized epidemic settings. Implementation of **PITC in STI care settings** should be prioritized, where STI services exist. STI services are a good entry point for reaching men and increasing coverage in a population likely to be at risk of HIV. Consider integrated HTC services/STI care with HTC for **key affected populations.** **HTC campaigns and multi-disease prevention campaigns** could be considered. **Home-based HIV testing.** Door-to-door testing can be offered to all households in high prevalence urban and rural settings where HTC uptake is low and access to services is inequitable. This model of delivering HTC can achieve high levels of coverage systematically. The door-to-door model with provision of HTC services to household members including partners/spouses and children of suspect or known HIV or TB index-patient (index-case model) can also be considered and can be a highly effective way to identify people with HIV, as more than half of primary sexual partners of people with HIV will also have HIV infection. **Mobile and outreach HIV testing** could be implemented in areas of high prevalence and low testing coverage or in communities and populations that are hard to reach, including those underserved by the formal health system, such as key populations and adolescents. **Workplace HIV testing** could be offered to employees on-site in areas of high prevalence where the level of testing coverage is low. **School/educational establishment**-based HTC services could be considered, although there is currently limited experience with school-based models and issues of consent, confidentiality, and linkage to prevention and care services acceptable to adolescents/young people need to be addressed. **Integrated and stand-alone VCT** may continue to be expanded where appropriate, building on models that have been successful within the country/region and with a focus on areas or populations underserved by these services. However, other HTC models should be introduced alongside stand-alone VCT.

Mixed epidemic	**PITC.** Health-care providers should recommend testing to patients in health facilities, particularly those with signs or symptoms consistent with HIV infection or TB, STI patients, and children known to have been exposed to HIV perinatally, and in services for key affected populations. Some countries may elect to provide PITC based on a geographical prioritization, providing services in districts or regions with higher HIV prevalence. Implementation of **PITC in TB settings** should be prioritized, with an emphasis on finding co-infected patients and facilitating referral for immediate ART and TB treatment (i.e. within two weeks). Implementation of **PITC in ANC settings** may also be appropriate. **Home-based HIV testing** should be useful if offered to household members and/or spouses, parents, and children of suspect or known HIV or TB index-patients (index-patient model). The door-to-door approach may also be beneficial where HIV prevalence is high but HTC uptake is low. **Mobile and outreach HIV testing.** This model of testing aims to reach key populations. Where and how this model of testing is implemented depends on the populations in need of services and the local context. WHO strongly recommends the offer of community-based testing, linked to prevention, care, treatment and support, for MSM and transgender people (WHO, 2011b). Mobile testing services should also be considered for sex workers and PWID. **Integrated and stand-alone VCT** may continue to be expanded where appropriate, building on models that have been successful within the country/region and with a focus on areas or populations underserved by these services. However, other HTC models should be introduced alongside stand-alone VCT, particularly for key populations, including MSM, transgender people, PWID, and sex workers.
Concentrated and low-level epidemics	**PITC.** In general, health-care providers should not offer HTC to all adults, adolescents and children presenting to health facilities, but instead should recommend testing to select patients, including: those with known HIV risk factors, those with signs or symptoms consistent with HIV infection, TB and STI patients, and children known to have been exposed to HIV perinatally. It is important to offer HTC sensitively and acceptably (to avoid stigma and discrimination) in settings serving key at-risk and vulnerable populations, including sex workers, MSM, transgender people, migrants and ethnic minorities. Also, PITC should be routinely offered in **drug treatment** (opioid substitution therapy) or detoxification centres, needle and syringe programmes and opioid substitution therapy programmes. Implementation of **PITC in ANC settings** may also be appropriate, particularly in settings that serve populations at higher risk. **Home-based HIV testing** services could be considered for household members and/or spouses, parents and children of suspect or known HIV or TB index-patients. **Mobile and outreach HIV testing**. This model of HTC delivery is a key element of HTC programmes in concentrated epidemics, aimed at providing accessible and acceptable services to key populations such as MSM, PWID and sex workers. It will be important to ensure that these services are not discriminatory or result in adverse outcomes for those testing and that they are linked to ongoing prevention, care, treatment and support. Services can be promoted through testing events and other innovative promotional activities. **Stand-alone VCT** may continue to be provided for key populations, building on models that have been successful within the country and focusing on areas where key populations are underserved by these services. However, other HTC models should be introduced alongside stand-alone VCT.

These models of HTC service delivery are mutually reinforcing and complementary, with each model of delivery addressing specific populations that are a priority within distinct epidemic types (see Annex 1). The strategic expansion of HTC should involve a combination of these models of delivery. Each model should be implemented strategically, where it will most effectively increase coverage and uptake by populations that are not making use of currently available services.

9. LINKAGES TO HIV PREVENTION, TREATMENT, CARE AND SUPPORT SERVICES

HTC offers limited benefit unless individuals and couples are linked to other services. Linkage to these services should be regarded as a key component of effective treatment, care and prevention. Therefore, the rapid scale-up of HTC must be accompanied by assured linkage to prevention, treatment, care and support services, including, but not limited to, pre-ART, CD4 cell count testing and services for ART, TB, STIs, PMTCT, family planning and male circumcision.

Knowledge of HIV status allows people to make informed decisions about HIV prevention and treatment. Strong linkages to effective HIV prevention, treatment, care and support services are essential if people are to carry out these decisions.

For individuals identified as HIV-negative or seroconcordant negative couples, HTC provides access to HIV prevention services, including condoms, male circumcision and, for PWID, harm reduction services (OST and NSP). In the absence of linkages to these services, HTC will have only a moderate impact on HIV prevention.

For people identified as HIV-positive, HTC provides a gateway to treatment services. It enables women and couples with HIV to access services both for themselves and to aid safer conception and prevent transmission to their infants.

For couples that are serodiscordant, HTC provides access to services to prevent HIV transmission to the uninfected partner and to HIV care, support and treatment services for the partner with HIV. It can support the uptake and effective use of PMTCT interventions and safer conception options.

Linkages ***before*** HTC can be an important way to increase HTC coverage—e.g. linkages with MCH, TB services, and outreach and peer education.

Linkage ***after*** HTC to HIV treatment and prevention is, however, generally weak, regardless of the approach to HTC, including all facility-based models of HTC delivery. For example, in a primary care clinic in Cape Town, South Africa, only 66.7% of patients eligible for ART were started on ART (Kranzer et al, 2011; Rosen et al, 2011). A review of PITC in ANC has pointed out that an average of 30% of pregnant patients living with HIV do not receive antiretroviral prophylaxis for PMTCT (Hensen et al, 2011). There is only limited evidence concerning linkages between community-based HTC and HIV treatment and prevention services, but, where reported, the linkages have been inadequate.

Connecting individuals and couples that have been tested for HIV to prevention, care and treatment services is one of the guiding principles of HTC conduct. This is the responsibility of HTC providers; to support the strengthening of linkages, HTC providers must be informed that the onus of linking their clients to the appropriate services lies with them. HTC providers must collaborate with other service providers to ensure that individuals or couples undergoing HTC are effectively linked to appropriate services. Programmes should explore appropriate interventions to maximize effective linkages, including lay accompaniers, short message service (SMS), and follow-up via mobile telephone.

It is the responsibility of HTC providers to ensure that individuals or couples are linked to appropriate prevention, treatment, care and support services.

Support groups and networks are valuable in all epidemic contexts but may play a particularly important role in low-level and concentrated epidemics. They can be central to assuring equitable access to prevention and treatment services, adherence to treatment and the prevention of loss to follow-up. Civil society organizations that facilitate access to services for people with HIV and their families must continue to be supported. HTC providers should offer individuals contact information and details of local networks that support people with HIV. In some settings peer supporters or community care providers accompany people with HIV to facilities and provide support for treatment literacy and adherence.

10. ISSUES IN AND PRINCIPLES OF HIV TESTING AND COUNSELLING SERVICE DELIVERY

The principles of the 5Cs, initially adopted in the 1980s as the 3Cs when VCT was the sole model of HTC service delivery, continue to underlie the good conduct of any HTC session. The 5Cs declare that HTC must be:

- **confidential**
- accompanied by **post-test counselling**
- performed only after obtaining **informed consent**—that is, testing should be informed and voluntary
- of high-quality: HTC providers must aim to provide high-quality testing services, and quality assurance mechanisms must be in place to support the delivery of **correct test results**. This may include the use of internal and external quality assurance indicators and should include support from the National Reference Laboratory
- provided along with **connection** to high-quality **care** for individuals and couples undergoing HIV testing as well as those who are offered HTC routinely but decline it. In other words, all individuals and couples must be **connected** to appropriate services, regardless of whether they opt to test or not.

In addition to the 5Cs, HTC services must assure that individuals identified as HIV-negative and couples that are serodiscordant or seroconcordant negative are linked to HIV prevention services.

10.1 A RIGHTS-BASED APPROACH

The dialogue concerning HTC has evolved over the past decade from a sometimes over-cautionary approach to the view that people have the right to voluntary HTC and to ongoing prevention, care and treatment. For all HTC, whether client- or provider-initiated and whether in facility or community settings, the benefits must always outweigh any potential harm or risk to individuals. Moreover, the chief reason for testing must always be to benefit the individuals tested. Thus, for example, testing must be expanded not merely to achieve high testing uptake or to meet HIV testing targets, but also to make access to appropriate, high-quality HTC services equitable and to link them to services. The expansion of HTC models of delivery must adopt a rights-based approach. Thus, HTC must always be voluntary, and consent must be informed by the offer of pre-test information. Furthermore, HTC must be linked to prevention, treatment, care and support services.

HTC, regardless of the model of service delivery, must protect, respect and fulfil human rights standards and norms. HTC must never be mandatory or coerced, nor should it be supported when people who test positive may be criminalized or discriminated against by law or administrative policy.

A human rights approach to HTC ensures adherence to an ethical process for the conduct of testing (see section 3, Overview). Individuals have a right to know their HIV status and a right to appropriate, high-quality services (UNCHR/UNAIDS, 2006). Individuals consenting to HTC must be informed of the implications of a positive test result and must be protected from stigma and discrimination, whether in health facilities, in other facility settings, including prisons, or in communities. Individuals also have a right to decline HTC, where routinely offered, and this refusal must not impede access to high-quality services that do not depend on knowledge of HIV status.

10.2 RETESTING

Unnecessary retesting of individuals who have previously been tested and know their HIV status needs to be reduced to avoid wasting resources and overburdening HTC providers. The majority of people with an HIV-negative test result do not require retesting to validate the test result. Retesting may prove important for individuals at continued risk of HIV infection, however, including the uninfected partner in a serodiscordant relationship, pregnant women, and key populations (e.g. MSM and PWID) and people in high-burden generalized epidemics. WHO has issued recommendations on retesting based on context and individual risk (WHO, 2010). These recommendations should guide the crafting of post-test counselling messaging to ensure that retesting is appropriately addressed to those who will benefit from it and unnecessary retesting of low-risk HIV-negative individuals is reduced.

A challenge encountering with retesting is that, while all counsellors are trained how to provide counselling for first-time testers, they also need the additional knowledge and skills to counsel repeat testers. HTC providers may require additional training to adapt standard post-test counselling messages concerning retesting in the window period (WHO, 2010) or to provide HTC to those who present for periodic retesting—for example, those with potential ongoing risk, such as people in serodiscordant couples or seronegative individuals taking PrEP.

10.3 IMPROVING THE QUALITY OF HTC SERVICE DELIVERY

Whether HTC services are delivered in facility or community settings, they must be of high quality, to assure that services are acceptable and therefore utilized by their intended beneficiaries. High-quality HTC is HTC that is accessible and meets the needs and demands of both clients and providers, conforms to the recognized HTC standards (the 5Cs), has measures in place to monitor the quality of the services, including external quality assurance of the testing, and is in line with national guidelines. To achieve high quality, services must be adequately and appropriately resourced, including the appropriate supplies and sufficient financial and human resources. Also, health-care providers must be supported by ongoing mentoring and supervision and, as necessary, refresher training. In some settings HIV testing is performed by lay staff. Adequate training and ongoing performance support and monitoring also are essential for all staff performing HIV testing at the community level, regardless of their level of training.

To obtain and maintain a coherent, functioning quality management system that addresses national, sub-national, facility and community concerns, it is important that quality be monitored, evaluated and improved at every level, with the active involvement of all stakeholders. A range of quality assurance (QA) and quality improvement (QI) methods have been applied in health care over the past two decades in middle- and low-income countries. Deciding which method to use for HTC will depend on the country context, the commitment of policy-makers and programme managers, and the complexity of problems that need to be addressed.

A handbook that provides practical suggestions for the improvement of HTC services is available from WHO (WHO, 2011a).

10.4 TASK-SHIFTING

The expansion of HTC, particularly in resource-limited settings, may require task-shifting of HTC to individuals with less training and fewer qualifications. Enhancing the capacity of lay counsellors, networks of people with HIV, volunteers and/or community health workers (CHW) to conduct HTC in community- and facility-based settings could strengthen the capacity of the health system to deliver HTC services and help ensure that HTC expansion is sustainable. Lay counsellors or CHW will need training in the principles of HTC conduct and on how to use RDTs, including external quality assurance. National policies will need to authorize these workers to conduct tests. These recommendations are in line with other WHO global recommendations and guidelines (WHO, 2008a). Lay counsellors can be an effective part of the workforce, provided that programmes invest in their training, supportive supervision and helpful job aids.

10.5 POLITICAL COMMITMENT, STAKEHOLDER AND COMMUNITY MOBILIZATION

The sustainable expansion of HTC requires political commitment and stakeholder and community mobilization. Political commitment in support of planning and mobilization of resources is crucial. Political commitment can ensure services are appropriately resourced and managed and can promote the reduction of stigma and discrimination. In addition, HTC expansion requires the mobilization and involvement of stakeholders, including people with HIV, NGOs, faith-based organizations, academic institutions, the private sector, health-care providers, and community and traditional leaders.

An enabling environment for HTC expansion also requires measures to prevent compulsory HTC, disclosure of status, and other potential negative outcomes of testing, including stigma and discrimination. Policies and laws that protect individuals and couples undertaking HTC may be particularly important for key populations. Similarly, policies or laws that limit or prevent key population's access to HTC must be removed.

Community mobilization is crucial to promoting increased demand for HTC services, by enabling people to appreciate the benefits of HTC. Mobilizing communities to discuss HIV and to support HTC can help reduce stigma and discrimination associated with HIV and HIV testing, thus helping to normalize HIV testing.

11. SETTING TARGETS, M&E, OPERATIONAL RESEARCH AND EVIDENCE GAPS

11.1 SETTING HTC TARGETS

Currently, most countries collect information on an annual basis on the number of people tested, and these figures are reported in the WHO universal access reports.[1] Further data are collected on the HTC coverage of pregnant women in ANC and of TB patients/suspects in TB clinics. However, most countries do not regularly collect programme statistics on HTC coverage in the general population. In some countries, however, population-based surveys such as the DHS and AIDS Indicator Surveys (AIS) periodically collect information such as the following:

- proportion of people estimated to have HIV who know their status
- percentages of women and of men ages 15–49 who have been tested for HIV in the past 12 months and received their test results the last time they were tested (DHS)
- percentages of key affected populations who have been tested for HIV in the past 12 months and received their test results the last time they were tested (DHS)
- percentage of pregnant women counselled and tested for HIV (DHS)
- percentages of women and of men ages 15–49 who have ever been tested for HIV and received their test results the last time they were tested (AIS).

To assess linkages from HTC to care, the following additional indicator has been proposed (WHO, 2011c):

- ratio of the number of new patients receiving care/pre-ART or ART services to the number of people who test positive for HIV for the first time.

Increases in the total number of tests performed or populations tested may not usefully demonstrate expanded access, particularly in countries with low and concentrated epidemics, if there are no data on what specific populations have been tested—e.g. whether access and coverage of key populations has increased. Programmes should monitor access and coverage for key at-risk and vulnerable populations. This point is relevant, as well, to tracking the number of facilities offering HTC services: An increase does not always provide a complete picture if there are no data on what populations they serve.

1 Available at http://www.who.int/hiv/topics/universalaccess/en/index.html

If countries are committed to providing universal access to treatment and prevention, they must also support universal access to testing.

If countries are committed to providing universal access to treatment and prevention, they must also support universal access to testing. Country programmes must, therefore, set targets for HTC, consider the best mix of approaches to achieve full HTC coverage, and adopt appropriate indicators to monitor the progress and evaluate the effects of implementing a strategic combination of HTC models. In low-level and concentrated epidemics, the efficiency of the HTC approaches to detect HIV-positive people is a key consideration and should be measured by the proportion of people tested who were identified as HIV-positive. The decision whether to test all pregnant women, for example, requires careful consideration of epidemiological, social, and cost-effectiveness issues.

11.2 INDICATORS AND OUTCOMES

Indicators should be SMART—specific, measurable, achievable, realistic and time-bound—and they should reflect the goals of the HTC programme. For example, programmes that seek to increase couples HTC may wish to set targets for the proportion of HTC clients who test as couples. Operational analysis should be conducted regularly to determine how the implementation of expanded models of HTC can be improved.

WHO guidelines on the monitoring and evaluation of HTC programmes are available (WHO, 2011c).

11.3 MONITORING, EVALUATION AND OPERATIONAL RESEARCH

The expansion of HTC must be accompanied by effective M&E and operational research to guide implementation and to see that efficiency, effectiveness, quality of care and acceptability are established and maintained. M&E helps ensure that services are delivered in a manner that maximizes benefits to individuals and minimizes any potentially adverse outcomes. Operational research can assess barriers and facilitators to HTC access and identify any weaknesses in the referral process and/or in linkages to services. The quality and acceptability of different models of HIV testing vary with the setting. An understanding of these aspects of HIV testing service delivery is crucial to maximizing utilization.

It is also important for countries/programmes to assess not only how well different HTC models, individually or in combination, identify people with HIV, but also how well they link them to care, treatment and support services.

11.4 ESSENTIAL STANDARDS FOR THE DELIVERY OF QUALITY HTC SERVICES

All HTC service delivery requires the same basic elements of HTC (WHO/UNAIDS, 2007). The availability and quality of each model of HTC delivery need to be monitored. These basic requirements include:

Standards of HTC service delivery

- equitable access to HTC services
- appropriate and safe space for counselling, where discussion can be confidential
- functional referral/follow-up mechanisms
- adequate trained workforce, including:
  - » counsellors, health-care workers, and peer/lay counsellors including people with HIV
  - » quality assurance and quality improvement measures to support and maintain the quality of testing
  - » quality improvement measures to support and maintain the quality of counselling.

Process of conducting HTC

- ongoing monitoring, mentoring, and supervision of the workforce to ensure that quality of service provision is maintained and the workforce is supported
- HIV testing capacity, including:
  - » adequate lab capacity (for both screening and confirmatory testing)
  - » sufficient stocks of test kits and supplies
  - » effective supply chain management system and capacity including medical waste management
  - » participation in an external quality assurance system.

Outcomes of HTC

- providing and tracking links with prevention, care and treatment services (including pre-ART, ART, PMTCT and TB)
- providing linked services, such as TB symptom screening and referral
- providing and tracking links with male circumcision, STI, family planning and MCH services
- capturing and recording testing and linkage to services, and monitoring client acceptability and any adverse outcomes.

12. GAPS IN AVAILABLE EVIDENCE

While there is evidence on the association between the models of HTC service delivery and uptake of HIV testing, there remains a dearth of evidence on:

- The cost-effectiveness and impact of **PITC in ANC** and other clinical settings, particularly in low-level and concentrated epidemics.

- **Ways to assess and increase effective linkage** of individuals to prevention, treatment, care, and support services to prevent loss to follow-up after HTC provided through the various approaches.

- The efficacy of various **approaches used by the community and community groups** to promote linkage to care after HIV diagnosis. Demonstration projects could involve health-care professionals and community groups working together to identify and remove barriers to linkage and follow-up.

- Ways to assess the **quality of community-based HTC**, including the quality of testing using point-of-care tests.

- **Factors associated with and ways to improve the uptake** of testing through the different HTC models and to provide access for hard-to-reach populations and individuals most in need of testing services, including key affected populations, adolescent, prisoners and migrant workers, men and poor, rural, and vulnerable populations.

- The **acceptability** of different models of HTC service delivery and the **motivation** to obtain HTC among different group. Although there is evidence to suggest that PITC in health facilities is acceptable to patients, there is limited evidence on the acceptability of and experiences with specific models of HTC service delivery. The relative acceptability of the various delivery models will influence access and utilization. Hence, evidence on personal perspectives and acceptability is required.

- The ratio of **new testers** to **repeat testers** for the various HTC delivery models is not known. In generalized epidemics with high incidence of HIV in the general population and for people with ongoing risk, there is benefit for people who test negative to have regular (annual) repeat tests. In many other settings, however, this is not recommended. A better analysis of the ratio of new testers to repeat testers can help programmes understand whether the increasing numbers of tests being performed mean that more people know their status or that more people are getting retested. Using the results of this analysis, programmes can adjust their HTC strategies depending on current coverage and epidemic considerations.

- **Self-testing for HIV.** There is growing interest in the potential of self-testing to increase access to testing for people who are underserved by current approaches. Self-testing may be able to offer a way to test for people unwilling or unable to attend facilities or concerned about confidentiality or stigma. There is currently little operational experience with self-testing. Pilot programmes need to be conducted and evaluated before formal recommendations can be formulated.

ANNEX 1. STRATEGIC IMPLEMENTATION OF HTC BASED ON CONTEXT AND TARGET POPULATION

The following table can be used to help determine which HTC delivery model may be most appropriate based on local epidemiological context or populations that are key and, therefore, need to be targeted specifically. The ratings provided for each category are based on a review of published and unpublished literature and the experiences of programmes.

	Populations									Lower cost	Reduced potential for stigma	Conditions for successful implementation		
Model of HTC delivery	General	Concentrated or low	Men	Young people (<24 years)	MSM	PWID	Sex workers	Rural	Urban			Super-vision	Task-shifting	Training
VCT	✓✓	✓	✓	✓	–	–	–	×	✓	–	–	✓	✓	✓
PITC1	✓✓	✓	✓	×	✓	✓	✓	–	✓	✓	✓	✓	✓	✓✓
Door-to-door HBHTC	✓✓	×	✓✓	✓✓	–	–	–	✓✓	✓	×	✓	✓✓	✓✓	✓✓
Index-patient HBHTC	✓✓	✓	✓✓	✓✓	–	–	–	✓✓	✓	×	×	✓✓	✓✓	✓✓
Mobile and outreach	✓	✓✓	✓✓	✓✓	✓✓	✓✓	✓✓	✓✓	✓	×	✓✓	✓✓	✓✓	✓✓
Workplace	✓	×	✓	×	–	–	–	✓	✓	✓	–	✓	✓	✓

MSM = men who have sex with men; PWID = people who inject drugs

1 For guidance on how and where PITC should be implemented, consult *Guidance on provider-initiated HIV testing and counselling in health facilities* (WHO/UNAIDS, 2007) and *Guidance on testing and counselling for HIV in settings attended by people who inject drugs: improving access to treatment, care and prevention* (WHO/SEARO/UN, 2009).

Key
✓ Recommended. For Conditions for implementation: Required.
✓✓ Highly recommended and should be considered a key strategy. For Conditions for implementation: Highly required.
× Not considered effective in this context/for this population. For Conditions for implementation: Not required.
Where no symbol appears, there are insufficient data or experience.

ANNEX 2. STRENGTHS AND WEAKNESSES OF VARIOUS MODELS OF HTC SERVICE DELIVERY

Model of HTC delivery	Target population	Advantages	Disadvantages
Facility-based HIV testing and counselling			
Voluntary counselling and testing (VCT)	General public, through stand-alone services	Promotes behaviour change: • RCT of VCT versus health information: individuals randomized to VCT reported less risky sexual behaviour with non-primary sexual partners (Denison et al, 2008; VCT Group, 2001) May facilitate access to HIV prevention, treatment, care and support services May facilitate access for key populations, depending on design and context Individualized attention provided Accessible to key populations Can be anonymous	Multiple barriers to access limit uptake of services: Low perceived personal risk of infection, extensive pre- and post-test counselling, negative perceptions of available services, and shortage of counsellors May attract largely the more motivated, affluent and educated clients and therefore may not reach some key populations, including adolescents
Diagnostic testing and counselling	Patients with signs or symptoms suggestive of HIV infection	Reduces missed opportunities for HIV diagnosis in health facilities Links individuals identified as HIV-positive to treatment, care and support services	Not recommended as the only strategy in concentrated epidemics, as it misses significantly more infections than does PITC Delayed HIV diagnosis: Until symptoms and signs of HIV infection develop, many individuals may not be tested, leading to many missed opportunities for HIV diagnosis Access, and hence uptake, limited to populations attending health facilities

Model of HTC delivery	Target population	Advantages	Disadvantages
Provider-initiated testing and counselling (PITC)	Patients attending health facilities—for example, ANC, TB, STI, MC, outpatient, MCH Implementation in specific facilities depending on epidemiological context	Integrated into existing health services Increases uptake of HIV testing among populations attending health facilities: • A review of PITC in ANC settings found that routine offer of voluntary HIV testing can increase uptake by 13% to 65.6% (Hensen et al, 2011) • High rates of uptake also reported in TB and STI clinics (Odhiambo et al, 2008; Weaver et al, 2008) Can normalize HIV testing, endorsing HTC as standard component of clinical care Reduces missed opportunities to diagnose HIV; earlier diagnosis and, thus, access to ART, PMTCT, TB services, and others Avoids barriers inherent in VCT access, including low motivation to seek testing, extensive pre-test counselling, need for informed consent in writing Evidence suggests acceptability in ANC and TB settings (Byamugisha et al, 2010; Corneli et al, 2008).	Access, and hence uptake, limited to populations attending health facilities Concerns over intentional and unintentional coercion, but this can be addressed through training and by providing PITC as part of the standard of care in health facilities May not be a priority to health-care staff in busy clinical settings, and, thus, implementation of PITC at clinic level may be limited unless it is prioritized May not be the most cost-effective HTC approach in low-prevalence setting
Community-based HIV testing and counselling			
All models	(Model- and context-specific)	Remove some structural, logistic and social barriers to testing Increase uptake among key, hard-to-reach populations Potential to normalize testing by reducing stigma associated with HTC	Little information available on how the distinct models of service delivery link individuals to prevention, treatment, care and support services Limited evidence currently available on the association between HTC through community-based models and behaviour change

Model of HTC delivery	Target population	Advantages	Disadvantages
National campaigns	General population or addressed to key populations; can also be delivered through a facility-based approach	Potential to reach high numbers of individuals—for example, nearly 12 million people tested in a year-long South African campaign (Motsoaledi, 2011) Can be integrated with other disease prevention campaigns. For example, Kenya's national campaign was integrated with provision of long-lasting insecticide-impregnated bednets, water purification systems and condoms (Lugada et al, 2010); in South Africa's campaign individuals are also screened for hypertension and diabetes (SANAC, 2011)	Much planning required Requires intensive management and commitment of resources, particularly in general campaigns May have limited impact in motivating first-time testers or reaching key populations and, if testing is largely through health facilities, may still reach mostly women and symptomatic individuals Quality and coverage of national campaigns can be issues May not adequately link people to prevention and care services Can lead to association of testing with campaigns, resulting in reduced demand for services following the campaigns HTC campaigns for the general population may have limited impact in low-level and concentrated epidemics, as the percentage diagnosed with HIV may be very low

Model of HTC delivery	Target population	Advantages	Disadvantages
Home-based	General population (if door-to-door) or partners, parents, children, other household members of known or suspect HIV or TB index-patients, provided consent has been obtained from the index-patient	Improves access for rural and vulnerable populations that are underserved by the formal health care system or who have limited access to services May reach people earlier in the course of infection than facility-based PITC Avoids clients' transport costs to facilities Less stigma than associated with visiting HTC facilities Provides systematic coverage High uptake: • In a study of door-to-door HTC in rural Kenya, 97.6% who consented to a home visit accepted HTC (Negin et al, 2009). In Uganda 99% of people over age 14 accepted an offer of home-based HTC (Were et al, 2006) • In Zambia a randomized trial comparing uptake of clinic- and home-based VCT reported 56% uptake of home-based HTC, compared with 12% uptake of clinic-based HTC (RR 4.7) (Fylkesnes et al, 2004) Potential to increase access for men, young people, first-time testers, those not attending facility-based services: • In a study in rural Malawi, over 75% of individuals accepted an offer of home-based HTC and immediate receipt of results (Helleringer et al, 2009). Previously, uptake of facility-based HTC among this population had been <25%. • For poorer women an offer of home-based testing removes the need to request transportation costs from their partners/husbands, which may limit their access to facility-based services (Matovu et al, 2007) The "index-patient" model achieves high coverage and can identify a high proportion of HIV-positive individuals and serodiscordant couples: • In Uganda in a study that offered HTC to household members of an index-patient initiating ART, 98.7% of men accepted HTC (Were et al, 2006) • 64.1% of married or cohabiting couples were tested as couples in a study in Uganda that offered HTC to household members of an index HIV patient. In a door-to-door component 35.9% of couples accepted (Menzies et al, 2009) The index-patient model can be used where community health workers are already visiting households to provide other services, such as TB- or ART-related care	Concerns exist for the safety of health-care providers conducting home visits Health-care providers may be expected to travel long distances Depending on time of day, home visits may not provide access to people in formal employment Ensuring quality of HIV testing is a challenge Privacy and confidentiality may be difficult to protect Possible stigmatization of homes visited by health care providers (may vary depending on epidemic setting) The index-patient model may not be cost-effective in generalized epidemics, as the majority of households are not visited—only those where someone has already been identified as having HIV

Model of HTC delivery	Target population	Advantages	Disadvantages
Mobile and outreach	Specific communities or key hard-to-reach populations, particularly in concentrated epidemics; general public	Can be promoted at sporting and other public events Provides access to hard-to-reach populations: key populations including MSM, sex workers, and PWID, rural populations underserved by the formal health care system, men, young people and first-time testers: • A randomized trial of community-based VCT in Thailand, Zimbabwe, and the United Republic of Tanzania reported greater uptake of HIV testing services among people ages 16–32 years in communities offered community-based testing than in those offered clinic-based testing services (Sweat et al, 2011) • High acceptability rates are reported. In Zimbabwe 98.8% of 1099 people using a mobile HTC service choose to receive their HIV test results on the same day (Morin et al, 2006)	Resource-intensive, particularly where services are fully mobile (Grabbe et al, 2010) May require ongoing community mobilization, including promotional activities, to continually promote the availability of the services Referrals may be difficult if referral services are distant Ensuring quality of HIV testing may be difficult Linkage to care needs special consideration
Workplace- or school-based	Populations in formal employment or in school	Provides access on-site to people with limited access to services due to employment or school commitments: • The convenience of easily accessible, on-site HIV testing services can increase testing uptake among working populations, as shown in a cluster randomized trial conducted in Zimbabwe (Corbett et al, 2006) Can also reach partners, spouses and children of employees	Concerns over confidentiality and potential for intentional or unintentional coercion Linkages to care are variable

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