

Module 1

Basic information on HIV/AIDS and HIV testing & counselling

Sub module 1: Introduction and orientation

Sub module 2: Epidemiology and implications for VCT

Sub module 3: Overview of HIV

Sub module 4: HIV testing

Sub module 5: Role of VCT in HIV prevention and care

Module 1

Sub module 1: Introduction and orientation

Session objectives



At the end of the training session, the trainer will have:

Orientated trainees to the training programme

Established the baseline knowledge of trainees

Time to complete sub module



1 hour 30 minutes

Training materials



Question box

Pre- and post-training knowledge questionnaire for trainees

Pre- and post-training knowledge questionnaire answer sheet

Pre- and post-training knowledge questionnaire result sheet

Session instructions

1. Housekeeping issues

- Welcome trainees. Discuss per diems, meals, transportation arrangements, course timings and remind people to be prompt
- Acknowledge that there may be HIV positive people in the course or people who have had a family member who is HIV positive. Indicate that the course may raise issues for these people and provide all group members with a telephone counselling contact number or means of debriefing privately with one of the trained facilitators in private

2. Establish “group norms”

- Brainstorm what should be the guiding principles for the group and only put down what the group has agreed upon and trainees commit to respect

3. Group members and training team introductions

- Introduce facilitators – ask for brief self-introductions
- Each trainee introduces himself or herself by stating their name, professional backgrounds and current role in counselling

4. Question in a box

- Ask trainees to write down on a piece of paper any questions they have about any aspect of the course material that they feel uncomfortable to ask in front of others. They may submit questions throughout the course and these will be addressed at the close of each day
- Instruct them to place the paper in the box when complete

5. Pre-training knowledge questionnaire

- Explain that the questionnaire is to assess the trainees' level of knowledge at the beginning of the course so that the facilitators know what areas need to be emphasised. It is also a useful tool for training evaluation
 - Ask trainees to close their folders
 - Pass around the pre-training knowledge questionnaire
 - Give trainees a code number on a piece of paper and ask him or her to record this number on their questionnaire. Then ask them to file this number in their folder so they can record it on their post-training questionnaire when conducted at the end of the course. Reassure trainees that as a result of this they will not be identifiable as individuals
6. Explain that there will be two types of course evaluation. An anonymous session evaluation will provide the facilitator with feedback. An anonymous course evaluation will be conducted at the end of the course.

Module 1

Sub module 2: Epidemiology and implications for VCT

Session objectives



At the end of the training session, trainees will be able to:

Discuss HIV transmission modes, risk behaviour and the relationship with epidemiological data

Appreciate the relationship between sexually transmitted infections and HIV transmission

Discuss why VCT is a key intervention of HIV/AIDS public health programmes

Time to complete sub module



1 hour

Training materials



PowerPoint presentation (**PPT01**)

(To be updated once yearly from the website:

<http://www.unaids.org/publications/graphics/index.html>)

AIDS epidemic update 2003

(To be updated once yearly from web site:

<http://www.unaids.org/hivaidsinfo/documents.html>)

Handout (**H01**), including regional HIV/AIDS data (to be updated once yearly requesting information from respective WHO Regional Office <http://www.who.searo.org>)

Question box

Evaluation form collection box

Content



Global and regional HIV situation

HIV transmission modes

Behavioural patterns related to HIV transmission and implications

STIs and HIV transmission

VCT and HIV/AIDS public health programmes

Session instructions

1. Activity:

- Role-play – ‘The HIV transmission game’
 - Objective: To help trainees understand how quickly HIV can spread
 - Time: Approximately 15 minutes
 - What to do:
 - Prepare slips of paper, enough to provide one for each student and one for yourself: 25% marked with '+' (plus sign), 75% marked with '-' (minus sign)
 - Ask each trainee to take a slip of paper from a box or hat. Keep one for yourself too, making sure it is one with a '+' sign on it. Emphasise that no one should look at their slips of paper until the end of the exercise
 - Ask the trainees to move freely about the room, stopping to greet participants. Do this yourself also
 - After each person has greeted four or five friends, stop the activity and ask everyone to look at their slip of paper
 - Ask all those who have a '+' (plus sign) on their paper to come forward. Explain that this game is pretending that these people are HIV positive. Reinforce the point that there is no risk of catching HIV through normal social greeting—this is a game to show how fast HIV can spread
 - Then ask all trainees who greeted anyone with a '+' (plus sign) slip of paper to come forward to join their friends. Explain that this game is pretending that these people are at high risk of being infected with the HIV virus
 - Next, look to see who is left. Explain that this game is pretending that the status of these people is unknown. They may have made friends with those infected before they had become infected; but in any case they are at risk
 - Finally ask, according to this game:
 - How many people were originally infected with the HIV virus?
 - How many are at high risk of being infected?
 - How many others are at risk of being infected?
 - How many remain uninfected?
 - What does this tell us about the spread of HIV in our community?
2. Lecture with PowerPoint presentation (**PPT01**). During the presentation ask participants questions to keep them involved actively in the presentation. *e.g. prior to showing patterns of infection amongst vulnerable sub groups, ask the participants which groups they think are the most vulnerable to HIV infection.*
3. Ask the group if they have any questions and remind them about the “question box”.
4. Ask trainees to complete an evaluation form and place in the “evaluation form collection box”.

Module 1

Sub module 2: Epidemiology and implications for VCT



Session objectives

At the end of the training session, trainees will be able to:

Discuss HIV transmission modes, risk behaviour and epidemiological data

Appreciate the relationship between STIs and HIV transmission

Discuss why VCT is a key intervention of HIV/AIDS public health programmes

What is HIV?

Human immunodeficiency virus (HIV) is the virus that causes AIDS. HIV belongs to the family of retroviruses.

A person infected with HIV is infectious for life. Most people living with HIV remain asymptomatic (without signs and symptoms of disease) for long periods of time and may not know that they are infected. However, even those without symptoms can still transmit the virus to others.

HIV transmission modes

HIV is transmitted by sexual contact, through blood, and from mother- to- child during pregnancy, delivery, or breastfeeding.

Sexual

Heterosexual transmission is the predominant route of transmission around the world. Sexual transmission occurs during heterosexual (male-female) intercourse and homosexual (male-to-male) intercourse. Sexual intercourse refers to penetrative vaginal, anal, and oral sexual contact between two individuals. Of highest risk is unprotected penetrative vaginal or anal intercourse with an infected individual. Direct oral sexual contact (mouth to penis or mouth to vagina) is generally considered to present a low risk for HIV transmission. Level of risk is dependent upon the presence of an appropriate exit and entry point for the virus; such as cuts/sores on the mouth, bleeding gums/gum disease and/or cuts/sores on the genital organs.

Exposure to infected blood, blood products, or transplanted organs or tissues

Exposure to contaminated blood may occur as a result of the transfusion of blood not screened for HIV-antibodies; the re-use of contaminated syringes and needles; or contaminated medical utensils. Exposure to infected blood or blood products can occur in health care settings, traditional healing rituals e.g. scarification, and through intravenous drug use. Exposure to HIV-infected organs and tissues can occur in health care settings.

Mother-to-child HIV transmission

The majority of HIV infections in children occur from the HIV-infected mother passing the virus to her infant before, during, or after birth. The risk of transmission without any intervention is variable from one country to another and is generally estimated between 25 and 40% in developing countries and between 16 and 20% in Europe and North-America.

How HIV is not transmitted

It is important to note that HIV is NOT transmitted by casual person-to-person contact such as shaking hands, hugging, touching or kissing. There is NO evidence that HIV can be transmitted through toilets, swimming pools, sharing eating or drinking utensils, or insects (such as mosquitoes).

Global HIV/AIDS situation

As the world enters the third decade of the AIDS epidemic, the evidence of its impact is undeniable. Wherever the epidemic has spread unchecked, it is robbing countries of the resources and capacities on which human security and development depend. In some regions, HIV/AIDS, in combination with other crises, is driving an increasing number of countries towards destitution.

In 2002 the AIDS epidemic claimed more than three million lives and an estimated five million people acquired HIV—bringing to 40 million the number of people globally living with the virus. Among those, 37 million were adults of whom 50% were women) and 2.5 million children under 15 years of age. About 95% of new infections occurred in toward middle income countries.

In most parts of the world, the majority of new infections occur in young people between 15 and 24 years, sometimes younger. Not only do these new infections cluster among youth who are just becoming sexually active, but up to 60% of all infections in females occur by the age of 20. Given that the period between initial HIV infection and the onset of HIV-related disease can be lengthy, it is clear that adolescence is a critical period for potential exposure to HIV.

Best current projections suggest that an additional 45 million people will become infected with HIV in 126 low and middle-income countries (currently with concentrated or generalised epidemics) between the years 2002 and 2010—unless the world succeeds in mounting a drastically expanded, global prevention effort. More than 40% of those infections would occur in Asia and the Pacific.

Regional HIV/AIDS situations

Sub-Saharan Africa, which is by far the worst-affected region globally, is now home to 29.4 million people living with HIV/AIDS (PLWHA). This region has the highest mean HIV prevalence (9%), with 12 countries having an estimated HIV prevalence of more than 10% in the 15-49 year old population. Four countries (Botswana, Lesotho, Swaziland, and Zimbabwe) have HIV prevalence of over 30%. Heterosexual HIV transmission predominates in this region.

The Asia and Pacific region is a vast geographic area that together includes close to 60% of the total world population. Thus, even low HIV infection rates in this region would contribute millions of additional PLWHA and deaths to the already staggering global toll of AIDS. Asia and the Pacific region, with estimated 7.4 million PLWHA as of the end of 2003, ranks second after sub-Saharan Africa.

The numbers in South-East Asia are dominated by India (estimated close to 4.6 million adult infections or about 80 % of this sub-regional total) and high HIV prevalence in Thailand, Cambodia, and Myanmar.

HIV prevalence in this large and diverse region ranges from lows of less than 0.1 % (Bhutan) to highs of 2.1% and 1.8% (Hanzanmar and Thailand). Heterosexual transmission predominates, but there are significant areas of HIV transmission in injecting drug user (IDU) groups in North-East India, Indonesia, Myanmar, Nepal, Vietnam, Pakistan and Thailand.

HIV/AIDS numbers in East Asia and the Pacific are dominated by China (estimated nearly 1 million HIV infections – about 95% of this sub-regional total). Without China, HIV prevalence in other countries of this sub-region is 0.018% or about 1/5000. HIV prevalence ranges from a low of less than 0.01% (DPR Korea) to a high of 0.7% (Papua New Guinea). A large proportion (about 90 percent) of HIV infections in China are attributed to transmission in IDU and to faulty plasma collection from paid plasma donors that occurred during the early to mid-1990s.

In several Asian countries that are experiencing the early stages of the epidemic, significant economic and social changes are giving rise to conditions and trends that favour the rapid spread of HIV—for example, commercial sex, injecting drug use, limited access to basic services and increased migration.

HIV/AIDS numbers in Eastern Europe and Central Asia are dominated by Ukraine (250,000 HIV infections) and Russia (700,000 HIV infections) – about 95% of the region's total. Without Ukraine and Russia, HIV prevalence in all of the other countries in this region is 0.05%. Most HIV infections have been attributed to IDU transmission, with subsequent heterosexual transmission from infected IDU to their regular sex partner(s).

Other regions in the world have low HIV prevalence.

HIV surveillance

The most common measure of the HIV/AIDS epidemic is the prevalence of HIV infections among a country's adult population—in other words, the percentage of the adult population living with HIV. These data are estimated from sentinel surveillance data collection among defined populations of interest - for example pregnant women attending antenatal care, STI patients, intravenous drug users, sex workers, and men who have sex with men (MSM). Additional information can be obtained to monitor specific behaviours among defined populations of interest.

UNAIDS/WHO HIV epidemic definitions

- | | | |
|-----------------|---|--|
| 1. Low level | - | below 1% in the general population, under 5% in high-risk groups |
| 2. Concentrated | - | below 1% in the general population, over 5% in high risk groups |
| 3. Generalised | - | over 1% in the general population. |

Countries are grouped according to the status of the HIV epidemic for purposes of surveillance. This typology recognises that a country may shift from one state to another.

1. **Generalised HIV epidemic:** e.g. Cambodia*, parts of India, Myanmar, and Thailand*
2. **Concentrated HIV epidemic:** e.g. parts of China, Indonesia, Malaysia, Nepal and Vietnam
3. **Low level HIV epidemic:** e.g. Bangladesh, Bhutan, Laos, Maldives, Philippines, Republic of Korea and Sri Lanka
4. **No reported HIV:** e.g. DPR Korea

* HIV prevalence is decreasing in the general population and in some high-risk groups

Vulnerability across Asia

The majority of HIV transmission occurs only as a result of those human behaviour(s) that place an individual at significant risk of an HIV infection. The primary risk behaviours that place a person at significant risk of acquiring or transmitting an HIV infection include having unprotected sexual intercourse (vaginal or anal) with multiple and concurrent sex partners, and/or sharing drug injecting equipment.

Behavioural surveillance tracks risk behaviours that provide warning signs for the spread of HIV. Main behaviours that have a high risk for HIV transmission are sexual and drug-taking behaviours including:

Sexual behaviours

- Lack of consistent condom use
- Having multiple sexual partners
- Frequent visits to commercial sex workers

Drug-taking behaviours

- Sharing injecting equipment
- Inadequate cleaning of injecting equipment before sharing

As HIV transmission generally involves certain behaviours that some in the community perceive to be socially unacceptable (or illegal), stigma and discrimination can be a significant issue for people with HIV/AIDS.

The predominant mode of HIV transmission in Asia is from commercial sex workers to their clients. HIV prevalence of over 40% among commercial sex workers were documented in some countries.

Extensive and/or explosive HIV epidemics in IDUs who share injecting equipment with other IDUs have occurred in about 100 areas throughout the world. Currently this is the primary mode of HIV transmission in many countries of Asia and Eastern/Southern Europe.

Sexually transmitted infections and HIV transmission²

STIs represent a major public health problem in developing countries. In South-East Asia alone there are nearly 50 million STIs occurring annually. Incidence of curable STIs in these countries varies from 7 to 9 cases per 100 women in the reproductive age. The public health importance of STIs has risen even more since it is known that STIs enhance the sexual transmission of HIV infection.

At the individual level, STIs increase the susceptibility of HIV negative individuals for HIV infection. STIs also increase the infectiousness of HIV positive persons. At the population level, STIs seem to be one of the key factors that drive the HIV pandemic in developing countries. The proportion of new HIV infections in a population due to bacterial STIs is particularly high in early and moderately advanced HIV epidemics when HIV prevalences are still rising.

Transmission of STIs is associated with the same behaviours that put individuals at risk for HIV, such as multiple sex partners, high-risk partners, and lack of consistent condom use.

Prevention of STIs prevents transmission of HIV!

HIV prevention strategies

Targeted interventions

The most efficient way to contain the spread of HIV in the whole population is to target populations with high HIV case reproduction number, e.g. those with the most sexual partners.³ Among the range of measures with immediate impact in decreasing HIV transmission are condom use, and treatment of STIs.^{4, 5, 6} Thailand has shown the effectiveness of the “100% condom programme” targeting CSWs and their clients in brothels on a national scale.⁷

It is well known that the HIV epidemic started in IDU populations in several Asian countries and then spread to other risk groups and the general population. Harm reduction through provision of sterile injecting equipment and maintenance treatment have been proven effective in preventing HIV transmission among IDUs.⁸

Prevention of mother-to-child transmission (MTCT) of HIV

Numerous clinical trials have shown that the use of antiretroviral drugs can reduce MTCT effectively in non-breastfeeding and breastfeeding populations in the short-term, and to a less, extent, after prolonged breastfeeding. The number of HIV infections in children born to HIV infected women in the developed world has dramatically decreased as a result of rapid implementation of interventions to prevent MTCT. Several developing countries in Africa, Latin America, Central and Eastern Europe and South-East Asia have implemented interventions to prevent MTCT by administering abbreviated antiretroviral regimens.

VCT during the antenatal period is the entry point for pregnant women and their children to prevent MTCT. VCT also benefits HIV negative women by providing advice on how to remain negative. Countries that include prevention of MTCT in a comprehensive package of HIV prevention and care will observe a decrease in HIV infections in infants and young children.⁹

Ensuring safe blood supply

Priority control strategies include promotion of safe injecting behaviour, mobilisation of voluntary remunerative blood donation, promotion of rational use of blood by health care workers and ensuring screening for HIV of all donated blood prior to transfusion.

HIV prevention works. Some examples of successful HIV prevention programmes are available through the UNAIDS Best Practice collection.

VCT as a public health strategy

High quality VCT not only enables and encourages people with HIV to access appropriate care but has been demonstrated to be effective for HIV prevention.¹⁰ People who attend VCT typically reflect deeply on their values and sexual practices and a negative or positive diagnosis is often associated with reduced risk behaviours.¹¹

VCT services can be utilised to assess individual risk behaviour and to inform about HIV prevention. Clients should learn about major modes of HIV transmission, safe sex (condom use) and harm reduction for injecting drug users (clean injecting equipment). Counsellors should explain the relationship between STIs and HIV transmission and refer clients to STI services for STI screening. The distribution of free condoms at VCT centres has been introduced in many countries.

VCT is a key component of HIV programmes in industrialised countries, but until recently it has not been a major strategy for low and middle income countries.¹² However, the importance of its role in HIV prevention and improving access to care means that VCT services are being more widely promoted and developed.

Reference

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- ³ Over M, Piot P. HIV infection and sexually transmitted diseases. In: Jamison DT, Mosley WH, Meashe m AR, Bobadilla JL, eds. Disease control priorities in developing countries. New York: Oxford University Press, 1993.
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- ⁹ Lo Y. Prevention of mother-to-child transmission of HIV-1. *Journal of Health Management*. In press.
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Module 1

Sub module 3: Overview of HIV

Session objectives



At the end of the training session, trainees will be able to:

Demonstrate improved knowledge of HIV disease

Appreciate the relationship between TB and HIV and the implications for the implementation of VCT

Discuss the current and proposed scaling up of HIV/AIDS care including antiretroviral treatment

Time to complete sub module



1 hour 30 minutes

Training materials



PowerPoint presentation (**PPT02**)

Activity sheet (case studies) (**AS01**)

Handout (**H02**) (To be updated once yearly)

WHO SEARO 1999. Guidelines for preventing HIV, HBV and other infections in the health care setting.

Question box

Evaluation form collection box

Content



HIV/AIDS disease

TB and HIV

HIV/AIDS care including antiretroviral treatment

Session instructions

1. Ask trainees if they have ever seen an HIV-infected person and if yes, what feelings were there.
2. Ask trainees to answer the clinical management quiz and instruct them to self review their answers as the lecture progresses.
3. Lecture with PowerPoint presentation (**PPT02**)
4. Activity: Interactive case discussions.
 - Ask the trainees to read each of the cases and then guide a large group discussion by asking the group for responses to the questions that appear on the case studies (**AS01**)
5. Ask the group if they have any questions and remind them about the “question box”.
6. Ask trainees to complete an evaluation form and place in the “evaluation collection box”.

Case study 1

A 30-year-old man goes to his local hospital for a health check-up. While waiting to see the doctor, he asks if he can see a counsellor to talk about some problems with his family. He tells you, the counsellor, that he found out he was HIV positive three years ago when he applied for a visa to work overseas. He is not currently taking any medicines. He says that he has had a productive cough for three weeks. He has lost weight and he also sweats excessively in bed at night.

Questions for discussion

What do you think might be wrong with the client?

What specific information in the case are you basing this on?

What are the treatment, care and referral options for the client in your setting?

Case study 2

A 36-year-old male went to the hospital and had his CD4 count measured. He reports that the doctor said it was so low that he needed to start taking medicine. The doctor appears to have given him antiretroviral treatment (a combination of d4T, 3TC and nevirapine). He has been taking the medicine for two weeks. He reports that he has a rash all over his body and doesn't feel well.

Questions for discussion

What are the possible explanations for the rash?

What are the treatment, care and referral options for the client in your setting?

Module 1

Sub module 3: Overview of HIV



Session objectives

At the end of the training session, trainees will be able to:

Demonstrate improved knowledge of HIV disease

Appreciate the relationship between TB and HIV and the implications for VCT

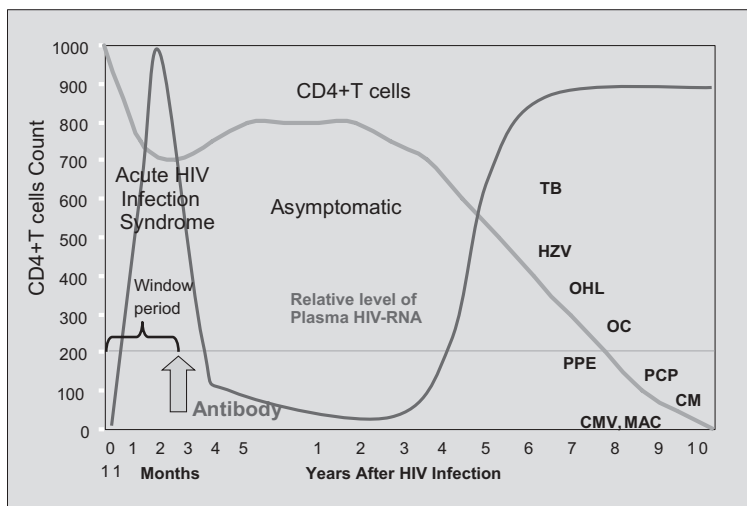
Discuss the current and proposed scaling-up of HIV/AIDS care including antiretroviral treatment

HIV/AIDS disease

AIDS stands for acquired immune deficiency syndrome. “Acquired” means neither innate nor inherited but transmitted from person-to-person; “immune” is the body’s system of defence; “deficiency” means not working to the appropriate degree; and “syndrome” means a group of signs and symptoms. AIDS is the advanced stage of HIV infection. It is a disabling and deadly disease caused by HIV. Because HIV progressively destroys the immune system, without any treatment most people, particularly in resource-constrained settings, will die within a few years of the first signs of AIDS.

Natural history

Figure 1: Natural course of HIV infection and common diseases



- TB= Tuberculosis
- OHL=Oral hairy cell leukoplakia
- OC=Oral candidiasis
- PPE=Papular pruritic eruption
- PCP = Pneumocystis carinii pneumonia
- CM= Cryptococcal meningitis
- CMV= Cytomegalovirus retinitis
- MAC= Mycobacterium avium infection

After the HIV virus enters a person's body, it infects and starts to replicate in the person's cells (essentially CD4 T cells and macrophages). HIV induces the body's immune system to produce antibodies specific to HIV. The period between the acquisition of the infection and the production of HIV detectable antibodies is called the "window period". The window period can last for 2-12 weeks. During this period the person is highly infectious but may not test positive on common HIV antibody tests. Up to 30-50% of people have a recognisable acute illness at the time of infection, characterised by fever, lymphadenopathy (enlargement of lymph nodes), night sweats, skin rash, headache, and cough.

HIV-infected people may remain asymptomatic for periods as long as 10 years or more. People in this phase potentially play an important role in the transmission of HIV as they remain infectious and can be identified only by screening their serum for HIV antibodies. After a period of time that varies from one individual to another, viral replication resumes and is accompanied by a destruction of CD4 lymphocytes and other immune cells resulting in a progressive immunodeficiency syndrome. The progression depends on the type and factors such as age that may cause faster progression (children less than 5 years of age and those over 40 years of age stand at greater risk), other infections, and possibly genetic (hereditary) factors.

Opportunistic infections (OIs), diseases and malignancies occur among HIV-infected individuals. These are correlated with the degree of immune suppression such as TB, oral hairy cell leukoplakia, oral candidiasis, papular pruritic eruption, *pneumocystis carinii* pneumonia, cryptococcal meningitis, cytomegalovirus retinitis, and *mycobacterium avium* infection (**Figure 1**).

Clinical staging

WHO proposed an interim clinical staging system for HIV infection and disease in adults and adolescents in 1989 in four clinical stages. In addition to the signs, symptoms and diseases, physical activity was added to the framework using the performance scales, a modification of the Eastern Cooperative Oncology Group score. Patients are classified according to the presence of the clinical condition, or performance score, belonging to the highest stage. The staging system is hierarchic: once a stage is reached, the patient cannot revert to a lower stage—he/she can only progress to a higher one. A laboratory axis measuring CD4 count was introduced in 1991 (**Figures 2-4**).

Rates of progression to AIDS are influenced by plasma viral load and CD4 T cell count. The higher the viral load (the amount of virus in the body) the lower the CD4 count and the higher the chances of progressing to AIDS and death. Death may be due to HIV, opportunistic infections (OIs) or malignant diseases.

HIV/AIDS care and treatment

Since AIDS was first recognised 20 years ago, remarkable progress has been made in improving the quality and duration of life for HIV-infected persons in the industrialised world. During the first decade of the epidemic, this improvement occurred because of improved recognition of opportunistic disease processes, improved therapy for acute and chronic complications, and introduction of chemoprophylaxis against key opportunistic pathogens. The second decade of the epidemic has witnessed extraordinary progress in developing combined antiretroviral therapies (ART) as well as continuing progress in preventing and treating OIs. ART has reduced the incidence of OIs and extended life substantially.

Opportunistic infections

The three most commonly reported OIs in South-East Asia are TB, *Pneumocystis carinii* pneumonia and extrapulmonary cryptococcosis (usually meningitis).

Figures 2-4: WHO staging system for HIV infection in adults and adolescents > 13 years

<p>Clinical Stage I</p> <ul style="list-style-type: none"> ● Asymptomatic ● Persistent generalised lymphadenopathy (PGL) <p>Performance scale 1: Asymptomatic, normal activity</p>	<p>Clinical Stage II</p> <ul style="list-style-type: none"> ● Weight loss, <10% of body weight ● Minor mucocutaneous manifestations (seborrheic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular cheilitis) ● Herpes zoster, within the last five years ● Recurrent upper respiratory tract infections (i.e. bacterial sinusitis) <p>and/or performance scale 2: symptomatic, normal activity</p>
<p>Clinical Stage III</p> <ul style="list-style-type: none"> ● Weight loss, >10% of body weight ● Unexplained chronic diarrhoea, > 1 month ● Unexplained prolonged fever (intermittent or constant) > 1 month ● Oral candidiasis (thrush) ● Oral hairy leukoplakia ● Pulmonary tuberculosis, within the past year ● Severe bacterial infections <p>and/or performance scale 3: bedridden, < 50% of the day during the last month</p>	
<p>Clinical Stage IV</p> <ul style="list-style-type: none"> ● HIV wasting syndrome, as defined by CDC a ● <i>Pneumocystis carinii</i> pneumonia ● Toxoplasmosis of the brain ● Cryptosporidiosis with diarrhoea, > 1 month ● Cryptococcosis, extrapulmonary ● Cytomegalovirus (MCV) disease of an organ other than liver, spleen or lymph nodes ● Herpes simplex virus (HSV) infection, mucocutaneous >1 month, or visceral any duration ● Progressive multifocal leukoencephalopathy (PML) ● Any disseminated endemic mycosis (i.e. histoplasmosis, coccidioidomycosis) ● Candidiasis of the oesophagus, trachea bronchi or lungs ● Atypical mycobacteriosis, disseminated ● Non-typhoid Salmonella septicaemia ● Extrapulmonary tuberculosis - Lymphoma ● Kaposi's sarcoma (KS) ● HIV encephalopathy, as defined by CDC b <p>and/or performance scale 4: bedridden, < 50% of the day during the last month</p>	

a HIV wasting syndrome: Weight loss of > 10% of body weight, plus either unexplained chronic diarrhoea (> 1 month), or chronic weakness and unexplained prolonged fever (> 1 month).

b HIV encephalopathy: Clinical findings of disabling cognitive and/or motor dysfunction interfering with activities of daily living, progressing over weeks to months, in the absence of a concurrent illness or condition other than HIV infection that could explain the findings.

The prevention and treatment of OIs has a beneficial impact on the progression of HIV infection.

HIV and TB^{1,2}

HIV fuels the TB epidemic in several ways.³ It promotes progression to active TB both in people with recently acquired⁴ and with latent⁵ *M. tuberculosis* infections. HIV is the most powerful known risk factor for reactivation of latent TB infection to active disease.⁶ The annual risk of developing TB in a person living with HIV/AIDS (PLWHA) who is co-infected with *M. tuberculosis* ranges from 5-15%. Up to 60% of people with HIV/AIDS develop active TB during their lifetime compared to about 10% of HIV-negative people. HIV increases the rate of recurrent TB⁷ which may be due to either endogenous reactivation (true relapse) or exogenous re-infection.⁸

Increasing TB cases in PLWHA pose an increased risk of TB transmission to the general community, whether or not HIV-infected. About a third of the 42 million PLWHA worldwide at the end of 2000 were co-infected with *M. tuberculosis*. The countries most severely affected by TB/HIV are those in sub-Saharan Africa, where HIV prevalence is highest.

HIV services can help detect more TB cases. This involves intensified case-finding in settings where there are many HIV-infected people. People attending health services including centres for VCT⁹ should be assessed for their risk of TB. Those clients who have had respiratory symptoms (e.g. cough > 3 weeks), have been in prison,¹⁰ are health care workers¹¹ or who have household contacts with HIV positive index infectious TB cases¹² are more likely to be at risk of having TB infection.

ARTⁱ

The recent introduction of combination ART has reduced HIV/AIDS morbidity and mortality by 60 to 90% and improved the quality and duration of life of PLWHA.^{13, 14, 15, 16} The aim of antiretroviral treatment in general is to prolong and improve the quality of life by maintaining maximal suppression of HIV replication for as long as possible. Reductions in plasma viraemia achieved with ART account for much of the clinical benefits associated with ART.¹⁷ The choice of regimen depends on a number of factors. These include amongst others, cost of therapy, availability and medium/long term affordability, convenience and likelihood of adherence, regimen potency, tolerability and adverse effect profile, possible drug interactions, and potential for alternate treatment options in the event that the initial drug regimen fails.

Antiretroviral therapy with single or dual drug regimen is not recommended due to the rapid emergence of drug resistance. Monotherapy with zidovudine is recommended only for the prevention of mother-to-child transmission of HIV.^{18, 19} Monotherapy with nevirapine is also only recommended for this purpose.²⁰ The use of a protease inhibitor with two nucleoside reverse transcriptase inhibitors (NsRTI) has shown potent and durable suppression of viral replication.^{21, 22, 23, 24} Combination of non-nucleoside reverse transcriptase inhibitors (NNRTI) with 2 NsRTI also produces viral suppression and immunological improvements which are at least comparable to those seen in combinations that include protease inhibitors.^{25, 26} Currently, several regimens with acceptable antiviral potency are available. These regimens are composed of three or four drugs. Two NsRTI generally form the backbone of most combinations.

WHO guidelines on the use of ART in resource constrained countries have been published in 2003 and include information such as when to start ART and which regimen to use.^{27, 28}

ⁱ Antiretroviral refers to a substance that stop or inhibits the replication of a retrovirus such as HIV.

ART is a life-long commitment. Adherence to treatment is the most important factor to suppress HIV replication and avoid the emergence of drug resistance.

HIV/AIDS care continuum

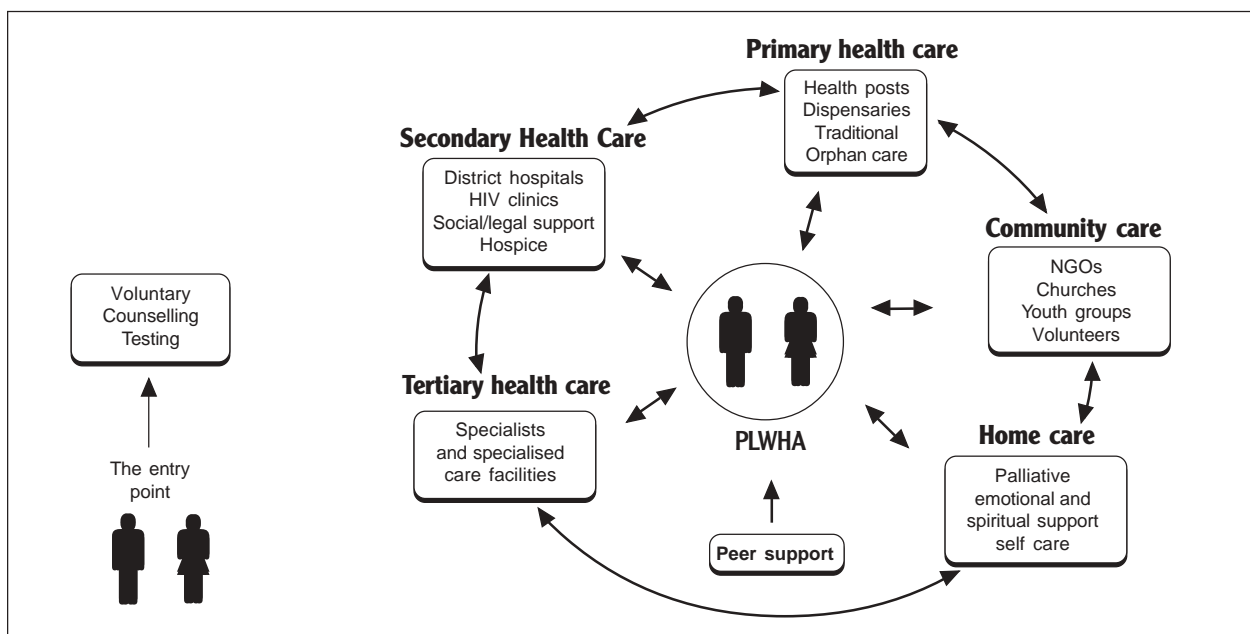
Management of OIs and ART cannot be seen in isolation. HIV-infected patients, including those with active TB, should benefit from additional care needs, including clinical and nursing care in particular for the prevention and treatment of OIs, ongoing psychosocial support and counselling, financial and employment support, assistance for housing and living in enabling environment, legal assistance, and care and support for orphans as promoted by WHO SEARO. Experiences from several countries have demonstrated that a continuum of care from hospital to home is the optimum to provide care and support to those affected. WHO SEARO is also promoting a continuum of care which includes an adequate referral and collaborative care network from hospital to the community and home (Figure 5).²⁹

Scaling-up of HIV/AIDS care including antiretroviral treatment

More than seven million PLWHA in Asia and the Pacific WHO regions and an increasing number of PLWHA are in need and are demanding access to comprehensive HIV/AIDS care including ART. The burden of AIDS cases on health services is particularly high in Cambodia, China, India, Myanmar, Vietnam, and Thailand and will further increase during the coming years. Comprehensive HIV/AIDS care as defined by WHO includes medical treatment, nursing care, counselling, and psychosocial support for PLWHA, their families and dependants.³⁰

WHO estimates that approximately 800,000 people (5%) are taking ART worldwide, of whom 500,000 live in high income countries. It is estimated that 5-6 million adults are currently in need of ART. Brazil, an exceptional case due to a programme of free and expanded access, accounts for over one-third of those taking ART in resource limited settings. The duration of survival increased from five months to 58 months during 1989 to 2001. Common HIV opportunistic infections such as PCP, toxoplasmosis and TB decreased significantly in reported AIDS cases in Brazil.

Figure 5: HIV/AIDS continuum of care



In order to successfully scale up ART in resource constrained settings there needs to be commitment, not only from the governments concerned, but also commitment from the global community. In 2001 there was a special session on AIDS held by the United Nations. This session produced the “United Nations Special Session on AIDS Declaration of Commitment and Further Actions”.

- The UN declared HIV/AIDS a health, developmental and security challenge
- UN General Assembly Special Session was held on 25-27 June 2001, New York
- The UN Declaration of Commitment on HIV/AIDS (Resolution A/RES/S-26-2) was unanimously adopted by the Special Session on HIV/AIDS (UNGASS) of the UN General Assembly in June 2001
- Resource requirements of 7-10 billion dollars / year were estimated

The international commitment to strengthen national capacities to respond to the HIV/AIDS epidemic, consistent with the goals of UNGASS, resulted in the establishment of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) in 2001 which makes available resources to mitigate the impact caused by HIV/AIDS, TB and malaria. The organisation is unique in that it is a public-private partnership which is a financial instrument and not an implementing agency. It is the largest global fund of its kind with over USD \$2 billion currently committed to national programmes.

In June 2001 the United National General Assembly Special Session on HIV/AIDS set the following targets:

- By the year 2003, ensure that national strategies supported by regional and international strategies, are developed in close collaboration with the international community, including governments and relevant intergovernmental organisations, as well as with civil society and the business sector, to strengthen health-care systems and address factors affecting the provision of HIV-related drugs, including ART
- By 2005 develop and make significant progress in implementing comprehensive care strategies including providing access to affordable medicines (Declaration of Commitment on HIV/AIDS; United Nations General Assembly Special Session on HIV/AIDS, 25-27 June 2001)

WHO has recently set the target of providing ART to three million people in developing countries globally by the year 2005. This will be ten times the present figure. Countries in Asia should set national targets for the number of PLWHA to be receiving ART by 2005, in proportion to the agreed global goal.

Counselling and ART

For an effective ART it is absolutely critical that all prescribed medicines are taken regularly and at the same time of the day. Some drugs require special instructions, as they are to be taken before or after a meal and with a certain amount of fluid. The counsellor plays an important role in assessing readiness for ART, treatment literacy and adherence.

All antiretroviral medicines have side effects. The counsellor should refer to a physician with ART experience to decide if treatment can continue or should be interrupted.

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Module 1

Sub module 4: Introduction to HIV testing

Session objectives



At the end of the training session, trainees will be able to:

Define laboratory diagnosis of HIV infection

Discuss the different requirements for different HIV antibody assays

Understand assay characteristics: sensitivity; specificity; predictive value; false positive and false negative results

Understand counselling issues relating to provision of results cognisant of test characteristics (See above)

Understand different testing algorithms, in particular serial versus parallel testing

Understand the limitations of HIV antibody assays and alternative assays which can be used to diagnose HIV infection

Discuss the meaning of confidential and anonymous testing

Define the concepts of confidentiality and informed consent

Understand principles involved in the maintenance of the quality of HIV testing services.

Time to complete sub module



1 hour

Training materials



PowerPoint presentation (**PPT03**)

Handout (**H03**)

Activity sheet (**AS02**)

Question box

Evaluation collection box

Content



Laboratory diagnosis of HIV infection

Window period

Types of HIV tests

Screening tests—ELISA and HIV rapid tests

WHO testing algorithm—ELISA and HIV rapid tests

External quality assurance (proficiency test) of test performance

Paediatric testing

Issues in testing – linked testing, linked anonymous testing, unlinked anonymous testing

Session Instructions

1. Lecture with PowerPoint presentation **PPT03**: During the presentation ask trainees questions to keep them involved actively in the presentation, e.g., ask trainees to write a list of what they perceive are the strengths and weaknesses of rapid tests for VCT in their cultural and workplace settings. Review in large group discussion, calling on volunteers from the group to discuss their responses.
2. Ask the group if they have any questions and remind them about the “question box”.
3. Ask trainees to complete an evaluation form and place in the “evaluation collection box”.

Module 1

Sub module 4: Introduction to HIV testingⁱ



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Understand different testing algorithms, in particular serial versus parallel testing

Understand the limitations of HIV antibody assays and alternative assays which can be used to diagnose HIV infection

Discuss the meaning of confidential and anonymous testing

Define the concepts of confidentiality and informed consent

Understand principles involved in the maintenance of the quality of HIV testing services.

Laboratory diagnosis of HIV infection

The diagnosis of HIV infection is based on the detection of HIV antibodies in the blood of infected persons.

Different HIV antibody assays

A variety of HIV antibody assays are available. These assays can be broadly classified into three groups: Enzyme Linked Immunosorbent Assay (ELISA); western blot assay; and rapid tests. These assays use different methodologies that are described below. Most current HIV antibody tests are capable of detecting antibodies to both HIV -1 and HIV -2.

- **ELISA:** HIV antibodies in the test serum are detected using an antibody sandwich capture technique. Essentially, HIV antibodies, if present, in the test serum are 'sandwiched' between HIV antigen, which is fixed to the test well, and to 'enzymes' that are added to the test well following addition of the test serum. The test well is washed thoroughly to remove any unbound enzyme. A colour reagent is then added to the well. Any bound enzyme will catalyse a change in colour in this reagent. The presence of HIV antibodies is thus inferred from the change in colour.

ⁱ This document has been adapted from the PSI "New Start " Zimbabwe VCT training package. The document has been updated and reviewed for use in South Asia by Dr Ruangpung Sutthent from Mahidol University, Thailand, Dr Mark Kelly and Kathleen Casey of the International Health Services Unit Albion Street Centre, Sydney Australia.

Some of the more recent ELISAs have the capacity to detect both HIV antibodies and HIV antigen (See below).

- **Western blot:** HIV antibodies in the test serum are detected by reacting to a variety of viral proteins. The viral proteins are initially separated into bands according to their molecular weight on an electrophoresis gel. These proteins are then transferred or 'blotted' to nitrocellulose paper. The paper is then incubated with the patient's serum. HIV antibodies to specific HIV proteins bind to the nitrocellulose paper at precisely the point to which the target protein migrated. Bound antibodies are detected by colourimetric techniques.
- **Rapid tests:**^{1, 2, 3} A variety of rapid tests are available, which employ a variety of techniques including particle agglutination; lateral flow membrane; through flow membrane and comb or dipstick-based assay systems. Rapid tests are most appropriate for the smaller health institutions where only a few samples are processed each day. Rapid tests are quicker and do not require specialised equipment. Rapid tests, by definition, take up to 10 minutes. Most are dot-blot immunoassays or agglutination assays requiring no instrumentation or specialised training and take 10-20 minutes to perform. Most rapid tests have sensitivities and specificities of over 99% and 98% respectively. Only 'WHO recommended' tests should be used to ensure a high level of sensitivity and specificity. The major advantage of the rapid HIV test is that it allows results to be given on the same day as testing thus reducing the number of visits made by the clients. There is also an increased likelihood of clients receiving test results as opposed to the numbers who may not return when same day testing regimes are not used. A further benefit is that subjects are more likely to receive their results from the same health care worker who performed pre-test counselling.

Different requirements for different antibody assays⁴

There is a variety of situations where HIV antibody assays are used. The choice of the test used will be determined by three factors: the objective of the test; the sensitivity and specificity of the test; and the prevalence of HIV in the population being tested.

There are three main objectives for which HIV antibody assays are used :

- Transfusion and transplant safety (for the safety of the recipient). It should be stated that WHO policy is to prevent the blood transfusion service from becoming a defacto HIV diagnosis service in the absence of effective clinical testing services. The tests (or algorithms) used by transfusion service may not necessarily be the best test for HIV clinical diagnosis (see below)
- Surveillance (for the knowledge of the population)
- Voluntary diagnostic testing (VDT) - testing of persons with clinical signs or symptoms of HIV infection in clinical settings. Voluntary counselling and testing - is a primary prevention strategy, offered in either community or clinical settings, often to persons who are aware they have engaged in transmission risk behaviour and wish to learn their HIV status. Often people presenting for VCT are without signs and symptoms.

Test characteristics

Biological assays are not accurate 100% of the time. Each biological assay has the potential to give false positive or false negative results. A working understanding of these concepts is important when giving test results or developing testing programmes.

- **Sensitivity:** This describes the capacity of a test to accurately define a 'true case'. A highly sensitive test will give very few false negative results. Highly sensitive tests are used when there

is absolute need to have very few false negatives such as in the case of testing blood for a transfusion service.

- **Specificity:** This describes the capacity of a test to accurately define a ‘true non-case’. A highly specific test will give very few false positive results. Highly specific tests are used when there is an absolute need to have few false positive results such as in the case of clinically diagnosing an individual with HIV infection.
- **Predictive value (Box 1):** The probability that a particular assay will accurately determine the infection status of an individual varies with the prevalence of the infection within a population. False negative results will be less common in low prevalence populations whereas false positive results will be more common in low prevalence populations. Correspondingly, false negative results will be more common in high prevalence countries whereas false positive results are less common in high prevalence countries. In other words, in high prevalence populations a person who tests positive has a greater likelihood of actually being truly infected. Conversely, in low prevalence countries a person who tests negative is more likely to be truly negative.

These relationships are mathematically expressed in the table below.

Box 1. Calculating the accuracy of HIV tests ⁵

Test results	Actual HIV status		
	HIV infected	HIV uninfected	Total
Positive	A	B	A+B
Negative	C	D	C+D
Total	A+C	B+D	

- A= people with HIV who test positive (**true positive**)
- B= people without HIV who test positive (**false positive**)
- C= people with HIV who test negative (**false negative**)
- D= people without HIV who test negative (**true negative**)
- A+C = all people who truly are infected with HIV
- B+D = all people who truly are not infected with HIV

- **Sensitivity** - Probability of a positive test in people infected with HIV, expressed as a percentage $A/A+C$
- **Specificity** - Probability of a negative test in people uninfected, expressed as a percentage $D/B+D$
- **Positive predictive value** - Probability the person is HIV-infected when the test is positive, expressed as a percentage $A/A+B$
- **Negative predictive value** - Probability the person is uninfected when the test is negative, expressed as a percentage $D/C+D$

WHO recommended minimum standards for sensitivity and specificity are 99 and 95% respectively.

Testing algorithms/strategies^{3,4}

The accuracy of a result is increased if two HIV antibody assays are used, as false positive results are possible for any assay. The gains in accuracy of repeat HIV testing must be weighed up against the increased cost. UNAIDS and WHO recommend three testing strategies to maximise accuracy while minimising cost.

- **Strategy one:** All blood is tested with one ELISA or rapid antibody assay. All positive results are considered infected and all negative results are uninfected. This strategy is employed in two main settings: transfusion/transplant service and surveillance. In the former setting the particular assay used should be a combined HIV-1/HIV-2 assay which is highly sensitive. Units of blood which return reactive or intermediate results must be considered infectious and discarded. When using this strategy for surveillance the assay employed need not be as sensitive as the transfusion and transplant safety as outlined above.
- **Strategy two:** All blood is tested first with one ELISA or rapid test. Any serum found to be reactive with the first test will be tested by the second test which should differ from the first test in that it uses different methodologies and/or targets different peptides. Serum that is reactive in both assays is considered HIV infected while serum which is non-reactive on both assays is considered negative. Discordant results (i.e. first assay tested positive and second assay tested negative) should be repeated with the same assays. If, however, the results remain discordant after repeat testing the serum should be considered indeterminate. This strategy is predominantly employed for the clinical diagnosis of HIV disease (**Figure 1**). However it may also be used for surveillance programmes in low prevalence populations. Repeat testing strategies are recommended for surveillance in low prevalence countries due to the low positive predictive value of a single test. All samples for surveillance programmes that remain discordant after repeat testing are considered indeterminate. The indeterminate results should be reported and analysed separately in the annual surveillance reports.
- **Strategy three:** This is similar to 'strategy two' except that a third test is performed on all positive samples which have been detected. Therefore all concordant positive specimens and all discordant specimens are retested using a third assay. The three tests employed in this strategy should be based on different antigen preparation and methodologies. Any sample which results in an indeterminate results with the third test will be considered indeterminate.

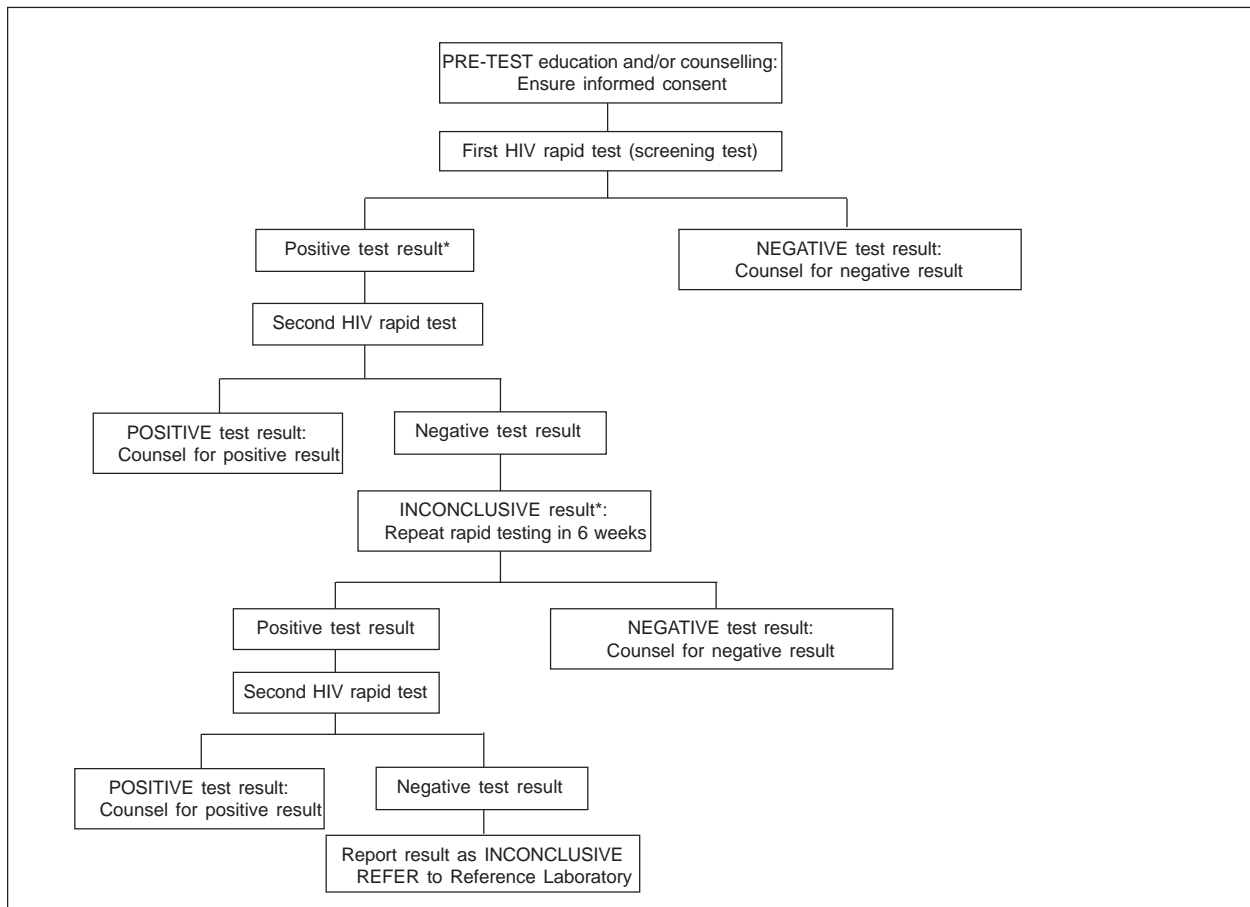
In selecting which tests to employ in these strategies in general, the most sensitive test should be used first followed by the more specific tests.

Serial versus parallel testing algorithms

Most testing strategies employ serial testing patterns. In this way a second test is not performed if the first assay indicates a negative result. As a highly sensitive assay is employed as the initial assay in serial testing algorithms false negatives are extremely unlikely. However, false negatives would be expected to increase in high prevalence cohorts.

Parallel testing on the other hand routinely uses two HIV assays on each sample tested. The first assay should be the more sensitive and the second assay should be the more specific. The assays differ in the antigenic targets, methodology and sensitivities and specificities. In the case of a discordant result the assay is repeated using a different third test known as the 'tie-breaker'. For quality control

Figure 1: WHO algorithm for the use of HIV Rapid Tests in Testing and Counselling Services ⁶



NOTE: If a first positive (reactive) and a second negative (non-reactive) test result occurs in more than 5% of cases, test processes should be reviewed.

purposes (See later) the ‘tie-breaker’ result may be confirmed by Western blot assay (or ELISA if three rapid tests have been used) at a later time-point.

While parallel testing is more expensive than serial testing it is associated with a less complex pathway to follow in the event of discordant results than those outlined for serial testing. Other advantages include a reduction in the risk of false negative results; need for only one finger-stick; favourable perception that ‘two tests are better than one’; reduces the stigma associated with the patient being called back for a second test.

WHO is currently promoting the use of HIV rapid tests for VCT services using a serial testing algorithm (See above). **(Figure 1)**

In low prevalence settings a parallel testing algorithm may offer superior testing accuracy

Situations when HIV antibody assays cannot be used to diagnose HIV infection

There are recognised clinical situations in which HIV infection cannot be diagnosed by standard HIV antibody assays. Two such situations include the window period of acute infection and diagnosis of HIV in the newborn.

Window period of acute infection

The window period represents the period of time between initial infection with HIV and the time when HIV antibodies can be detected in the blood stream. During this period, when HIV replicates in the blood and lymph nodes, the subject is highly infectious and may be symptomatic but the patient's blood will test negative for HIV antibody. The window period can last up to 12 weeks and may vary between different assays using different methodologies. Very sensitive ELISAs have shorter window periods. HIV infection cannot be diagnosed during this period using antibody-based assays. Assays which detect part of the virion (as opposed to the antibody of the infected host) are employed in this situation. The tests most commonly used in this situation are the p24 antigen and the proviral HIV DNA assays. The p24 antigen assay detects the viral protein p24. The assay has high specificity (>95%) but its sensitivity is low at 80%. The proviral DNA detects the presence of HIV DNA which is integrated into the host genes in peripheral blood lymphocytes. This assay is based on polymerase chain reaction (PCR) technology and is both highly specific and highly sensitive (98% and >99% respectively). The performance of this test in detection of HIV-1 and non-HIV-1 subtypes has not been determined. The HIV DNA assay is available only in the research setting. HIV RNA PCR tests are not recommended for the diagnosis of acute HIV infection because of significant rates false positive results (10%). Typically true positive results are greater than 100,000 copies/mL whereas false positive results are generally less than one thousand copies/mL.

Diagnosis of HIV in the newborn

HIV antibody assays cannot be used to diagnose HIV infection in the neonate secondary transmission of maternal antibodies via the placenta or breast milk. Maternal antibodies may be present in the neonate for up to 18 months. Neonates will test HIV antibody positive whether they have HIV infection or not during this period. Antenatal diagnosis is confirmed at 18 months of age by a persistently positive HIV antibody test. HIV can be diagnosed in the newborn before this time-point by using a variety of non-antibody based assays. These assays include HIV p24 antigen, viral culture (of peripheral blood cells) or by the detection of HIV viral load tests detecting either HIV RNA or HIV DNA. The sensitivities of these assays range from 8-32%, from 95-100% and to >99% respectively. Detailed discussion of the diagnosis of HIV infection in the newborn is beyond the scope of this review.

Counselling issues relating to HIV antibody result provision

Counsellors should have a good appreciation of the possibility of false negative and false positive HIV antibody results in order to advise patients accurately on the interpretation of their test results.

- **False positive results:** Currently available HIV antibody tests are extremely sensitive and false positive rates are appreciable, particularly in low prevalence populations. All clinical HIV testing strategies require repeated HIV antibody assays to be undertaken. A false positive on one assay is unlikely to also test positive on the second assay. Potential reasons for false positives include technical error; serological cross reactivity; repeat thawing and freezing of sample.
- **False negative results:** A false negative result reports that the sample is not HIV infected when in fact it is infected. The most common reason for a false negative HIV antibody result is that the patient is recently infected with HIV and is currently within the window period as described above. Therefore accurate HIV risk assessment during the period must be undertaken.

Confidential and anonymous HIV testing

Most people with HIV infection are asymptomatic. They have no symptoms that clinically suggest a decreased immune function, and therefore, a laboratory test is required to make the diagnosis of HIV. A client may request an HIV test because of their self-perceived risk or for other reasons. A health care provider may also recommend a test based on a patient's behavioural history and/or clinical findings such as STDs or OIs. Regardless of the circumstances in which a person seeks HIV testing, **HIV antibody testing and counselling should always be voluntary and confidential.** HIV testing must be voluntary in that the client gives informed consent for the test to be undertaken after pre-test counselling and in the absence of coercion.

Information about the individual and his or her sexual partners must be kept strictly confidential. Confidentiality will help obtain a client's trust and avoid stigmatisation and discrimination. Careful record management is a prerequisite for confidentiality.

There are three general methods to label blood samples to ensure confidentiality:

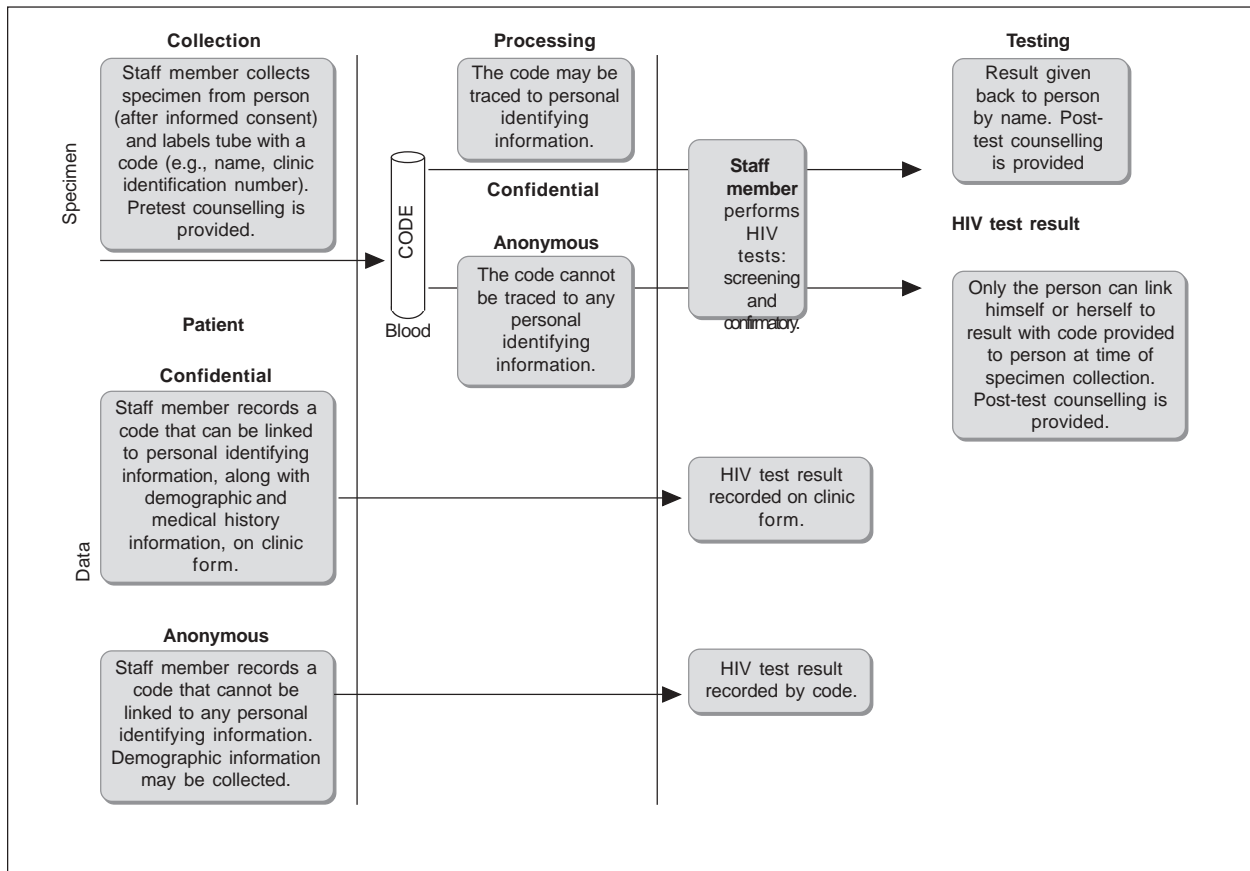
- Linked-anonymous testing
- Linked testing
- Unlinked anonymous

In **linked-anonymous testing**, no names or other identifiers from the client are recorded. The client receives a unique number, in no way linked to any medical records that matches the number placed on the blood sample sent to the laboratory. The result from the laboratory for the specific number is reported back to the clinic/counselling site. The individual must come to the clinic/site with the correct number to be informed of the result. In this procedure, no record is kept of the clients who provided blood for the samples and there is no way to find the client if she or he does not return for the results.

In **linked testing**, the blood sample sent for HIV testing has an identifier on it, such as a name or a Centre number, which links the sample to the individual client. To ensure maximum confidentiality for clients, samples sent for HIV testing should not be identified with a name but with some other identifier such that laboratory scientists and other people with access to laboratory records will not be able to identify the client. Sometimes HIV test request forms will have sequential numbers printed on them whereby the laboratory gets copies of the request only with a number and the Centre retains copies with the number and the client information.

Unlinked, anonymous testing is often performed on blood samples obtained for other reasons (for example, syphilis serology in antenatal clinics or blood donations). In this testing procedure, all identifiers are removed from the blood and it is tested for HIV antibody. In this context, unlinked, anonymous screening means that a test result cannot be traced back to the client who provided the blood specimens and that no record is kept of the clients who provided blood specimens for the sample. Epidemiologists and ministries of health use unlinked, anonymous screening to monitor trends in HIV infection in different geographic areas and populations and to further our understanding of the natural history of HIV infection.

Figure 2: Linked confidential and anonymous HIV testing



Ensuring quality of HIV testing in VCT services ^{5,6}

It is important that all VCT services develop a Quality Assurance programme.

Quality assurance (QA)

Quality assurance is defined as the set of planned and systematic activities to provide adequate confidence that requirements for quality will be met.

It is critical that each facility performing HIV testing establishes and implements a QA programme to monitor and evaluate all functions and services throughout the total testing process i.e. from the client entering the service, through the counselling and testing steps, through the provision of the test result, and possible referral.

Quality control (QC)

Quality control refers to those measures that must be included to verify that the test is working, and that must be taken to monitor the validity of the technical aspects of the test procedure, e.g. were all reagents at room temperature before starting the test procedure; was the control line of the test clearly visible. Quality control includes the testing of samples with known results to verify that the testing procedure and materials are working properly. When quality control specimens that are analysed

daily produce acceptable results, and all other conditions related to the test kit performance have been met, then test results on the samples from clients may be accepted as valid.

External Quality Assessment (EQA)

Every testing facility must be able to demonstrate and document its competence in performing all HIV tests. External Quality Assessment (EQA) is part and parcel of an testing QA program. The focus of EQA is on the identification of laboratories or testing sites that perform below standard so that additional training and/or other measures can be instituted to improve performance. There are three complementary ways in which the quality of testing services can be assessed by an external authority:

a. On-site Audit

Having on-site audit is necessary to review that all SOPs are adhered to, including quality control, record keeping, and observation of test performance. Additionally, on-site audit is an opportunity to directly administer a proficiency test to each individual performing testing. A program of on-site auditing should include a standard checklist of testing service indicators. Auditors, inspectors and supervisors should be trained to perform consistent reviews of testing sites. Standard checklists and evaluation methods allow for the collection and comparison of consistent information from multiple sites.

b. Proficiency Testing (PT) or external quality assessment schemes (EQAS)

Proficiency testing or EQAS involves the distribution of small panels of well characterised test samples (6-10 specimens) by the EQAS organiser (e.g., the National Reference Laboratory or another organiser) to all testing sites. Laboratories administering proficiency testing panels should strive to adhere to international guidelines, e.g., ISO Guide 43. The limitations of PT/EQAS are that they are spot checks in time – they represent the upper performance level, they usually involve a small number of samples, and there are a limited number of assessments per year. Often, the test results may not represent the routine test performance.

c. Blinded Rechecking

Retesting a selected sample of specimens in a reference or referral laboratory may also be an option to assess the quality of testing. This can be accomplished by forwarding all positive and 5-10% of negative specimens for re-testing when a serum or plasma specimen is available.

Alternatively, dried blood spots (DBS) can be used for blinded rechecking in situations where it is impractical to refer specimens for additional testing (e.g. whole blood finger prick tests). The dried blood spots are collected at the time of patient testing on filter paper and transported to a reference laboratory. The use of this method requires a reference laboratory that has demonstrated proficiency with eluting the specimens and performing standard EIA methods. Additional concerns include the logistics and methods of collecting dried blood spots in the testing protocol. Although a sample of specimens re-tested by dried blood spots may be desirable, this may be difficult to implement in the flow of testing and counselling of patients. Additionally, testing a percentage of specimens, such as 10% may be problematic. Countries may consider random sampling of dried blood spots, e.g., bimonthly, or at a given time or day. Further development of dried blood spots protocols is necessary to assist with the expansion of rapid testing for testing and counselling services, especially at remote sites.

Factors in influencing quality ⁶

1) *Pre-analytical factors*

- Training of laboratory technician and health care workers
- Laboratory safety
- Specimen collection, labelling and transport conditions
- Number of specimens tested
- Selection of test kits
- Availability of test kits
- Expiry dates of test kits (use before expiry dates)
- Storage of test kits according to manufacturer's guidelines

2) *Analytical factors*

- Written procedures manual
- Testing performance
- Correct use of reagents (if any)
- Inclusion of internal quality control in test kits
- Quality control monitoring procedure

3) *Post-analytical factors*

- Interpreting results
- Transcribing results, e.g. recording results on the forms using the correct identifier code
- Entering data into the tracking system (computer and/or hardcopy)
- Maintaining records
- Reviewing quality control

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Module 1

Sub module 5: Role of VCT in HIV prevention and care

Session objectives



At the end of the training session, trainees will be able to:

Define the aims and objectives of VCT

Discuss the enhanced efficacy of VCT over mandatory testing

Discuss the evidence for the enhanced efficacy of anonymous VCT over name-based testing

Discuss the evidence that VCT reduces HIV transmission

Discuss the evidence that VCT facilitates client behaviour change

Appreciate the role of VCT in partner disclosure

Time to complete sub module



1 hour 30 minutes

Training materials



PowerPoint presentation (**PPT04**)

Handout (**H04**)

Activity sheet (**AS03**)

Question box

Evaluation form collection box

Content



What is voluntary counselling and testing?

Evidence for action: Mandatory versus voluntary testing

Evidence for action: Anonymous versus name-based testing

Evidence for action: Reduction in HIV transmission

Evidence for actions: Behaviour change

Evidence for action: Partner disclosure

Session instructions

1. Lecture with PowerPoint presentation (**PPT04**).
2. Activity (**AS03**).
 - Ask trainees to break into three small groups and nominate a spokesperson for the group. Each group has only 10 minutes to prepare and not more than 10 minutes to present to the larger group.
 - Hand out the activity sheet (**AS03**) and provide each group with the following tasks:
 - Group 1** – You are asked by your hospital to justify why VCT is important. The Director of the hospital has asked you to make a short 10 minute presentation at the staff meeting. The Director does not see any reason why testing cannot proceed as it already does in the hospital where blood is collected and the patient is told that they must have an HIV test. The Director also says that they will provide health information about HIV in a brochure.
 - Group 2** – You have been asked to provide a briefing paper for an advertising company that is going to market VCT to the community. You will need to think about how to explain to the general public about what VCT is and why they may want to attend VCT. They will also need to know about privacy and confidentiality.
 - Group 3** – Many VCT services have difficulty attracting men. How could we market VCT to men? Before you decide what to do it may be useful to discuss the reasons why men may not request or attend VCT services.
3. Ask the group if they have any questions and remind them about the “question box”.
4. Ask trainees to complete an evaluation form and place in the “evaluation form collection box”.

Module 1

Sub module 5: Role of VCT in HIV prevention and careⁱ



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Discuss the evidence that VCT reduces HIV transmission

Discuss the evidence that VCT facilitates client behaviour change

Appreciate the role of VCT in partner disclosure

HIV testing - HIV testing is performed for a number of different reasons

Surveillance – This is anonymous and unlinked serological testing which is used to develop epidemiological data that assists in HIV prevention and service planning.

Blood screening – Donated blood is screened for HIV to ensure the safety of clinical blood supplies.

Voluntary individual testing – Individuals voluntarily choose to test in order to learn their HIV status.

Diagnostic testing – This testing is conducted when clients present for management of an illness. This diagnosis forms part of the clinical management of the client. This should always be conducted with the patient's knowledge and consent. Counselling should still be conducted prior to testing and at the time of the provision of results.

United Nations policy on VCT

VCT is based on the requirement that testing for HIV be based on the informed consent on the person being tested. HIV testing must always be the individual's informed decision. The UN does not support mandatory testing. There is no evidence that mandatory testing is effective.

ⁱ This document was prepared on behalf of WHO by Dr Rachel Baggaley and adapted for inclusion in this training package by Kathleen Casey.

The necessary pre-conditions for effective VCT services

Irrespective of the approach used for delivery or the model of VCT selected for implementation, a number of minimum requirements must be met if VCT services are to be considered truly ethical and beneficial.^{1, 2, 3, 4} Principal among these requirements are:

Informed consent

Counselling and testing must be truly voluntary and individuals should be able to opt out or refuse counselling or testing if they do not think that it is in their best interest.

It is recommended that testing always be accompanied by counselling. If a client declines counselling, it is advisable to try to raise the essential issues which are normally addressed in pre-test counselling. It should be emphasised that this form of information provision is not a substitute for counselling.

It is important that health workers present pre-test information to clients in such a way that they can clearly understand the benefits of counselling. Ideally, written consent should be obtained before testing takes place. If testing is conducted in an anonymous clinic the signed consent can be separately filed.

Confidentiality

It is imperative that governments develop the necessary legislative and policy infrastructure to support confidential HIV counselling and testing, and such frameworks should include provision for penalties where confidentiality is breached.

It is important that counselling and testing centres develop policies to protect the confidentiality of clients. All levels of staff should be briefed on the policy and the rationale for the existence of the policy. It is advisable when sharing information for referral purposes to obtain the written consent of the client. This consent should include specific information as to what information is to be shared and with whom it is to be shared. Although there are advantages of sharing information about HIV status, those being tested must be assured of the confidentiality of their test results. The risks and benefits need to be discussed and weighed.

The decision to share or involve anyone else must be made by the person undergoing VCT. Anonymous testing protects the identity of clients. In clinics doing anonymous testing codes, rather than patient names, codes are allocated to the client and attached to the medical record and blood samples. Reporting of a positive HIV test result to a central data registry may also be done using a coding system. Many countries have adopted this strategy for national HIV registries.

Legislation and public education to prevent discrimination

Community education programmes, legislation and public health policies which are respectful of human rights can assist in reducing the discrimination experienced by HIV-positive persons. Health workers may also require education with regard to discrimination, and all health services should have policies in place which prevent discrimination toward patients by health workers. VCT uptake may be limited by the fear of discrimination. Fear of discrimination may also reduce the rate at which people return to collect their results.

Quality control

It is essential that the quality of both testing and counselling can be assured with appropriate monitoring and evaluation as a key and planned component of interventions. Counsellors and other health workers involved in VCT must have adequate training and clinical supervision to ensure that a quality service is provided.

The counselling component of VCT

Counselling is a confidential dialogue between a person and a care provider aimed at enabling the person to cope with stress and make personal decisions related to HIV/AIDS. The counselling process includes an evaluation of personal risk of HIV transmission and facilitation of preventive behaviour.⁵

VCT is used to denote any intervention that includes a minimum of pre- and post- test counselling associated with HIV testing, while acknowledging that many VCT services also offer longer term ongoing and supportive counselling.

Rationale for VCT

1. HIV prevention

High quality and voluntary HIV counselling and testing is an effective (and cost-effective) component of prevention approaches, which promote sexual behaviour change to reduce HIV transmission.⁶ People who attend VCT typically reflect deeply on their values and sexual practices and a diagnosis (whether negative or positive) is often associated with reduced risk behaviour.⁷ VCT offers couples a way of finding out each other's HIV status and plan accordingly. The UN also proposes a model to assist counsellors in managing situations where a partner refuses to disclose their status. Counselling can assist in reducing HIV transmission between serodiscordant couples.^{8,9} Although there are many examples of high quality VCT services in developing countries, these are often on a small scale, and are therefore unavailable to the vast majority of people, particularly in high prevalence developing countries.

2. An entry point to HIV treatment and care

The value of VCT as an entry point for appropriate medical and supportive care is also being increasingly recognised.^{10,11} With the development of safe and effective interventions for the prevention of mother-to-child transmission of HIV, the national implementation of VCT services has become more urgent in many countries. It is hoped that a wide range of feasible, affordable and effective treatments (including antiretroviral drug combinations) will also become much more widely available in the near future. To ensure the safety and efficacy of all these interventions, access to VCT will be essential.

In addition to such public health gains, VCT is also regarded as a human rights imperative because HIV infection has so many serious and long-term implications for health and well-being, including for the reproductive, sexual and family life of individuals, and for their social and productive life within their communities.

VCT is already a key component of HIV programmes in developed countries, but until recently has not been a major strategy for developing countries¹². However, its importance for HIV prevention and for improving access to care means that VCT services are being more widely promoted and developed, particularly in sub-Saharan Africa. Many countries are gradually instituting VCT as part of their primary health care package.¹³ For example, in South Africa, access to care, counselling and support for HIV/AIDS and STIs is one of the top 10 national health priorities.

ART much more widely available for PLWHAs in developing countries²⁶. This will necessitate the development of VCT services where they are currently not available. It will increase demand at VCT sites, as ARTs becomes accessible

- Reducing stigma and denial and promoting normalisation are major factors in HIV-prevention efforts, and it has been proposed that the wider availability of VCT (thus increasing the numbers of people who are aware of their HIV status) can make a major contribution towards these goals.²⁷
²⁸ In Uganda, AIDS Information Centres in Kampala and elsewhere have counselled and tested approximately half a million people and are thought to have contributed towards the reductions in HIV infection that are now being observed.²⁹ In Thailand it has also been accepted that the availability of VCT is an important component in challenging stigma and preventing HIV infections³⁰
- Voluntary HIV counselling and testing as a human right: This is important because it is more difficult for people to make decisions about their sexual behaviour and about having children without knowing their HIV status; access to VCT could be seen as part of a basic right to health care
- HIV prevention for injecting drug users: In many parts of the world injecting drug use is the major driving force behind the HIV epidemic. Unless large-scale comprehensive HIV prevention programmes (incorporating safe injection/needle exchange, drug treatment and VCT) can be implemented, the prevalence of HIV infection among injecting drug users will rise and may increase in the general population as a result
- Advances in HIV testing technology. As simpler and cheaper rapid HIV diagnostic tests become available, VCT will become more practical and economical and more people may wish to know their status. However, in any VCT service the personnel costs associated with counselling and support outweigh the diagnostic costs of testing and this should be taken into account in planning and budgeting

VCT and ethical partner notification

In the context of HIV/AIDS, UNAIDS and WHO encourage beneficial disclosure of HIV/AIDS status.³¹ This is disclosure that is voluntary; respects the autonomy and dignity of the affected individuals; maintains confidentiality as appropriate; leads to beneficial results for the individual, their sexual and drug-injecting partners, and family; leads to greater openness in the community about HIV/AIDS; and meets ethical imperatives so as to maximise good for both the uninfected and the infected.

In order to encourage beneficial disclosure, an environment should be created in which more people are willing and able to get tested for HIV, and are empowered and encouraged to change their behaviour according to the results. This can be done by: (1) establishing more VCT services; (2) providing incentives to get tested in the form of greater access to community care and support, and examples of positive living; and (3) removing disincentives to testing and disclosure by protecting people from stigma and discrimination.

Though the epidemic is over 15 years old and though HIV prevalence is very high in many communities, HIV/AIDS continues to be denied at the national, social and individual levels; to be highly stigmatised; and to cause serious discrimination based on HIV/AIDS status. There are many reasons for the stigma, denial, discrimination and secrecy that surround HIV/AIDS, and these differ from culture to culture. The partner notification strategies that are proposed as integral component of VCT programmes are designed to assist in reducing the denial, stigma and discrimination associated with the disease.

Requirements for successful VCT implementation

- Realistic training and support of counsellors
- Social marketing and community mobilisation
- Referral networks and support services
- Appropriate facilities — time, privacy, confidential information management, accessibility
- Effective and responsive monitoring and evaluation

Public health challenges

- Gender and sexual negotiation
- Men's control over VCT decision-making
- Men's control over sexual behaviour decisions
- Men need to be engaged in VCT (Botswana, Rwanda)
- Quality of counselling
- Access to VCT and uptake of results
- Making VCT youth-friendly
- New testing technologies — rapid tests
- Increasing access to care
- Ethical cost-effective models of counselling and VCT
- Group information-giving
- Targeting services to users
- Provision of VCT outreach services
- Telephone counselling – important for less mobile clients and those who live in areas with limited services (rural areas)

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The need to scale up VCT

Despite all these factors and recent developments, the numbers of people who know their HIV status remains relatively low (approximately 5% of the world's population). This needs to be substantially increased to multiply the impact of prevention approaches and to bring those in need of care and treatment into the health care system. Low coverage characterises most of sub-Saharan Africaⁱ, and the expansion of VCT services has followed the same pattern as other HIV prevention and care projects – a gradual, piecemeal and often unplanned re-invention of services. If this approach continues, access to quality VCT will remain limited.

The recent United Nations Declaration of Commitment on HIV/AIDS contains a commitment to the rapid scaling-up of VCT services in generalⁱⁱⁱ, with a particular emphasis on accelerating access to PMTCT interventions^{iv} and antiretroviral treatment, necessitating the rapid development of VCT to serve as an entry point for these interventions.^v The first international VCT technical consultation was convened by WHO and UNAIDS in Harare, Zimbabwe, in July 2001. Its primary purpose was to share the experiences of VCT delivery in all regions. The challenges and advantages of employing various approaches to VCT to serve different populations were also explored, as were the benefits and problems of integrating VCT with other health interventions. It was acknowledged that there was great political and international will to develop and expand VCT services, particularly in high-prevalence developing countries.

Evidence for VCT as an effective HIV prevention and care strategy

Evidence of the importance of promoting VCT is now accumulating in many parts of the world and in many areas of activity. Examples of the clear potential benefits include:

- Many studies have demonstrated that VCT can help people change their sexual behaviour to prevent HIV transmission¹⁴. Furthermore, a recent multi-centre study in Africa demonstrated that VCT can be a cost-effective intervention to prevent sexual transmission of HIV¹⁵
- Cheap and effective interventions are available for the prevention of mother-to-child transmission of HIV (PMTCT)^{16,17,18,19,20,21}. The majority of these rely on identifying pregnant women with HIV so that they and their infants can benefit from these interventions. There are currently many research projects, pilot projects and some national PMTCT programmes offering VCT to pregnant women
- Increased access to treatment and care for people living with HIV/AIDS (PLWHA) – co-trimoxazole prophylaxis^{22, 23} and tuberculosis preventive therapy^{24, 25} are relatively cheap and easy to administer. They have been shown to reduce morbidity in PLWHA and several projects are currently successfully implementing these interventions following VCT. As ART becomes cheaper, more effective and available, early knowledge of HIV status and thus access to VCT become more important. Several countries have initiated ART access projects and there is increasing political pressure to make

ⁱ For example Lesotho (with an antenatal seroprevalence rate of 25 –35%) has no VCT services at all. WHO Office Lesotho. Personal communication. 2001.

ⁱⁱ United Nations General Assembly Special Session. Declaration of Commitment on HIV/AIDS. June 2001, page 19: "...recognizing that care, support and treatment can contribute to effective prevention through an increased acceptance of voluntary and confidential counselling and testing, and by keeping PLWHA and vulnerable groups in close contact with health-care systems and facilitating their access to information, counselling and preventive supplies."

^{iv} Ibid page 54: "by 2005, reduce the proportion of infants infected with HIV by 20 percent, and by 50 percent by 2010, by ensuring that 80 percent of pregnant women accessing antenatal care have information, counselling and other HIV-prevention services available to them, increasing the availability of and providing access for HIV-infected women, including voluntary counselling and testing, access to treatment, especially antiretroviral therapy and, where appropriate, breast-milk substitutes and the provision of a continuum of care."

^v Ibid page 52: "by 2005, ensure: that a wide range of prevention programmes which take account local circumstances, ethics and cultural values, is available in all countries, particularly the most affected countries, including information, education and communication, in languages most understood by communities and respectful of cultures, aimed at reducing risk-taking behaviour and encouraging responsible sexual behaviour, including abstinence and fidelity; expanded access to essential commodities, including male and female condoms and sterile injecting equipment; harm-reduction efforts related to drug use; expanded access to voluntary and confidential counselling and testing; safe blood supplies; and early and effective treatment of sexually transmittable infections."

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