

VCT TOOLKIT

Voluntary Counseling and Testing for HIV: A Strategic Framework

September 2003

Family Health International



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ACKNOWLEDGEMENTS

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INTRODUCTION

The HIV epidemic continues to spread at an alarming rate, with over 14,000 new infections per day. While the epidemic is now spreading rapidly in some parts of Asia and Latin America and Caribbean, sub-Saharan Africa continues to bear the greatest burden of disease. HIV prevalence exceeds 30 percent among sexually active adults in some African cities, and AIDS is the leading cause of death in major cities within sub-Saharan Africa.

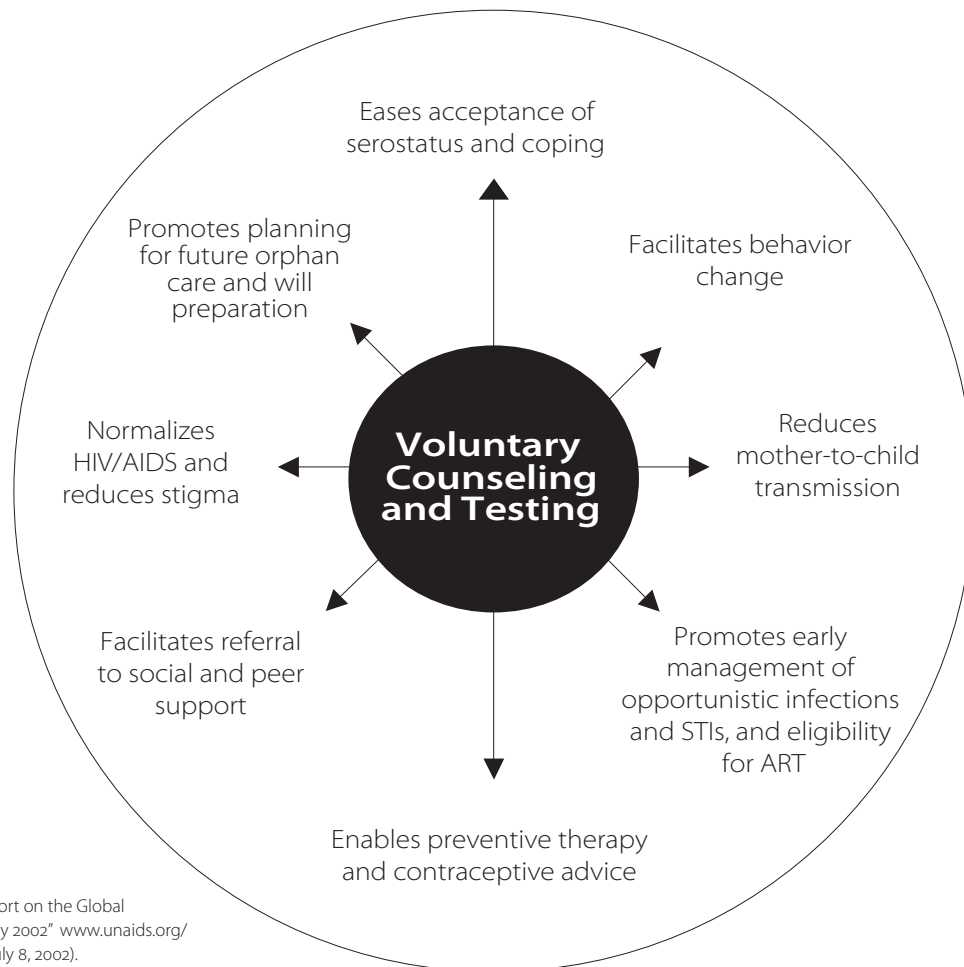
More than 90 percent of the estimated 42 million persons living with HIV/AIDS (PLHA) around the world live in resource-constrained countries in Africa, Asia, Latin America and Caribbean. But despite the very high number of people already living with HIV/AIDS, it is estimated that less than 10 percent are aware they are infected, mainly because of the limited availability, access, and use of voluntary counseling and testing (VCT) for HIV. This fact greatly hinders efforts to respond to the AIDS epidemic, as people have to know if they are infected if they are to access services. Figure 1 shows

the benefits of VCT as an entry point to prevention and care services.

HIV VCT has long been a component of HIV prevention and care efforts among affected communities in developed countries, and is now increasingly being implemented in resource-constrained countries. In the presence of a high prevalence and growing awareness of HIV, several governments have included VCT services as a major component of their national HIV prevention and care programs.

Because of the recognized importance of HIV VCT in national AIDS control programs, HIV VCT services are in various stages of development in many resource-constrained countries. Where available (these services tend to be of limited quality and coverage) they are implemented by nongovernmental organizations (NGOs) and some public and private health centers, clinics, and hospitals.

Figure 1



Source: UNAIDS, "Report on the Global HIV/AIDS Epidemic-July 2002" www.unaids.org/ Barcelona, accessed July 8, 2002).

STATE OF THE ART

Several observational studies were first to suggest the feasibility and effectiveness of HIV VCT. For example, in 1991, a study conducted among 149 discordant couples (one HIV-infected and the other HIV-negative) in Kinshasa, Congo, demonstrated a marked increase in condom use among these couples, from less than 5 percent before the HIV VCT intervention to 70 percent following the intervention [Kamenga et al., 1991]. Another study—carried out in Rwanda on the impact of HIV VCT among a cohort of women—reported an increase in condom use from only 7 percent having ever used condom before the intervention to 16 percent among HIV-seronegative and 35 percent among HIV-seropositive women after the intervention [Allen et al., 1992]. Finally, an analysis of data from 3,000 clients receiving HIV VCT at the AIDS Information Center in Uganda demonstrated substantial reduction in risk behaviors at three and six months following the intervention [Campbell et al.].

Findings from the above observational studies have been confirmed by a controlled study conducted by FHI in collaboration with the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO). This multi-center (including Kenya, Tanzania, Trinidad and Tobago) randomized controlled study coordinated by the Center for AIDS Prevention Studies documented a 43 percent reduction in the occurrence of unprotected sex among those who received HIV VCT [the voluntary HIV-1 Counseling and Testing Study Group]. In addition to the behavioral data, this study demonstrated that HIV VCT is highly cost-effective. The cost per disability adjusted life year saved (DALY) was US\$12.77 in Kenya and US\$17.78 in Tanzania. This compares favorably to other health interventions in resource-poor settings, and the cost-effectiveness can be significantly improved by targeting couples and populations most at risk for HIV infection [Sweat et al.].

Based on this existing data and evidence, there is currently a consensus about the efficacy and cost-effectiveness of the HIV VCT intervention for HIV prevention and care. HIV VCT has become or is being advocated as a major component of any comprehensive national AIDS control program in many countries. Major roles recognized for HIV VCT include:

- Enabling HIV VCT clients to cope and make personal decisions related to HIV/AIDS;

- Assisting HIV VCT clients to initiate and maintain preventive behaviors;
- Serving as an early referral and entry point to HIV care and support services, and to other prevention services, including family planning;
- Helping to combat stigma and discrimination in the community.

FHI GOALS AND OBJECTIVES

FHI's goal on HIV VCT is to help reduce HIV transmission through behavior change, especially among populations most at risk for HIV infection, and help meet the care and support needs of PLHA, their families, and communities. Specific objectives of our HIV VCT efforts are to:

- Improve the local capacity to provide HIV VCT;
- Improve/promote availability and use of HIV VCT services;
- Promote functional linkages between HIV VCT services and other care and support services (AIDS care and the continuum of care services);
- Promote strategies aimed at reducing stigma and discrimination;
- Contribute to the improvement of the quality of VCT services.

FHI'S TECHNICAL AND PROGRAMMATIC APPROACHES

Guiding Principles

FHI recognizes that counseling is a culturally sensitive and complex intervention. We therefore support working with in-country counterparts and the community, including PLHA, to develop culturally appropriate VCT services based on the client-centered* approach to counseling.

Beyond the counseling sessions and testing of specimens (if desired by the client), HIV VCT is an important entry point to many other care and support services. Therefore, expanding and promoting HIV VCT services must be done with special care to ensure that the needs of those using the promoted services will be met to the extent possible. For example, massive promotion of HIV VCT not coordinated with the development and/or strengthening of other care and support services and referral networks may result in poor

* A client in the context of VCT is any person—young or adult, feeling healthy or sick—who seeks a service where one receives HIV counseling and learns of his/her HIV serostatus.

quality services and fall short of meeting the needs of PLHA. For HIV VCT to fully play its role in HIV/AIDS prevention and care, it must be of the best quality, available, and easily accessible to those who need such service. The existence of effective referral systems between HIV VCT and other care and support services—either in the same health facility or in the community—is critical in responding to the needs of people infected or affected by HIV/AIDS.

Quality assurance of both HIV testing and counseling is critical to the success of HIV VCT services. FHI contributes to quality assurance by developing standard operating procedures, training, supervision and support of staff, and establishing both internal and external quality control systems.

FHI's Approaches

The increasing availability of and access to antiretroviral therapy (ART), interventions to prevent mother-to-child transmission on HIV (PMTCT), and other prevention and care interventions dictate that individuals' knowledge of HIV status be increased as most of these interventions require knowing one's HIV serostatus. FHI supports the need to tailor innovative approaches to HIV counseling and testing to this changing context of the HIV/AIDS epidemic.

Counseling Approaches

To respond to this imperative, FHI supports efforts to develop VCT approaches that are cost-effective, pragmatic, ethical, and adaptable to various needs and settings. To achieve large-scale implementation of HIV VCT, FHI supports the notion—espoused by WHO and other international organizations—that it is critical to move beyond the idea of VCT as a package always to be provided in the exact way in all circumstances. Rather, VCT services must be adapted to respond to varying needs and contexts. HIV counseling and testing currently occur in three major contexts:

- For those who want to know their serostatus. This is "traditional" VCT, offered for behavior change in the prevention of HIV;
- Where it is medically indicated in the context of clinical care for diagnosis purposes;
- For PMTCT.

To respond to these different circumstances, pre-test counseling might be adapted. For example, in the context of clinical diagnosis for the medically indicated, less emphasis might be put on risk assessment during pre-test

counseling to focus more on disclosure of HIV status and care and support. In the context of PMTCT, in antenatal (ANC) clinics with heavy workloads, women may be seen in groups for pre-test counseling. While group pre-test information sessions can be employed at VCT service sites with heavy client flow to reduce the length of individual/pre-test counseling and reduce the burden on counselors, these should not be seen as a replacement to pre-test counseling.

FHI emphasizes the requirement that regardless of the VCT approach used, there remain a number of minimum standards which remain critical – the voluntary nature of HIV testing, the need to obtain informed consent, confidentiality of the process, and access to high-quality supportive counseling. The process of obtaining informed consent must ensure that sufficient information is provided, that the information is understood, and that an informed choice is made by the individual offered the HIV test under each circumstance.

In addressing those who want to know their serostatus (traditional VCT), FHI tailors the design and implementation of HIV VCT services to the unique epidemiological, behavioral, and economic context of each country and setting to maximize their effectiveness and cost-effectiveness. We pay particular attention to the choice of HIV VCT service delivery models in each country and setting. Both self-standing and integrated HIV VCT services have advantages and disadvantages. Selecting one approach over the other or going for a mix of both self-standing and integrated models must be done carefully, considering such factors as: choice of local authorities, target populations, level of stigma and discrimination in the community, management and administration ease, potential for linkages, existing demand and likelihood of service utilization, equity issues, feasibility, ability to be replicated, etc. Whatever the model of service delivery, every effort must be made to ensure that the counseling provided remains of the highest quality possible.

Testing Approaches

Choice of the HIV testing protocol must consider the local HIV epidemiology, the locally existing laboratory infrastructure, the volume of HIV testing (namely, number of people to be tested daily), the quality assurance capacity, the clients' preference, the impact of the chosen protocol on provision of the service, and the cost implications of the chosen protocol. Various protocols and strategies can be considered, and it is normally the responsibility

of government regulatory bodies — ministries of health, national AIDS control programs, national reference laboratories — to develop the most feasible testing strategies (standard testing algorithm) for the country.

FHI supports current WHO recommendations of three testing strategies, depending on HIV prevalence in the population, the sensitivity and specificity of the antibody tests being used, and whether the objective is blood screening, surveillance, or diagnosis (Appendix 1 describes the three testing strategies.)

The wide availability of high-quality, rapid HIV tests has helped VCT programs overcome one of their main problems — patients' failure to return for test results. Using ELISA-based technology, VCT clients must typically wait at least 72 hours for their results. Experience in most VCT centers suggests that 20-40 percent of those tested do not return for their test results. In settings where service utilization has been low, introducing rapid tests has increased access to VCT services significantly. Rapid HIV assays have recently been found to have important applications for HIV prevention, as well as for care and support interventions. For those who test negative, results can be communicated on the same day, providing an additional avenue for prevention strategies. Those who test positive can be referred early to clinical care and support services. Some view the waiting period for test results using ELISA technology as a time for reflection, giving pre-test counseling a greater impact. This can be accomplished with rapid testing by ensuring time between the pre-test and blood-draw or finger-prick stage.

The sensitivity and specificity of rapid tests currently on the market are comparable to those of ELISA. Studies looking at specific combinations of two or more different rapid HIV tests have provided results as reliable as those from ELISA and Western Blot combinations, even in low-prevalence settings. Therefore, FHI suggests that the choice between rapid tests and standard ELISA and Western Blot be made with the following advantages and disadvantages of each option in mind.

The advantages of rapid tests include: speed of the test (less than 30 minutes), client is informed of test result during the same visit, require less or no sophisticated infrastructure, do not require highly trained staff. But they have the following disadvantages: people do not always believe in their accuracy, less time for the counselor and the client to prepare for test results, especially positive results.

The advantages of ELISA include: capacity to run large numbers of samples at once, perceived better accuracy by clients, cost declines once initial investment in equipment made. On the negative side, ELISA has the following disadvantages: samples have to be transported to a centralized location for testing, requires highly trained staff, waiting period of several days depending on volume of testing, and requires sophisticated infrastructure.

The advent of rapid test technologies, especially those that use whole blood instead of serum, has also increased the options for testing protocols and procedures to accommodate different service settings and client preferences. These options are serial testing and parallel testing.

- Serial testing: In serial testing, all persons are tested with a rapid HIV test. If the test is positive, a second, different rapid HIV test is performed. Discordant test results are further tested with a third type of rapid HIV test. The tests are performed in series.
- Parallel testing: In parallel testing, all persons are tested using two tests simultaneously (in parallel). If the tests are discordant — which is estimated to occur less than one percent of the time — a third type of rapid test is used as “tiebreaker.”

See Appendix 2 for a discussion of the relative advantages and disadvantages of parallel and serial testing, and for an illustrative costing exercise comparing the two approaches in different settings.

Implementation

While it is imperative that any client who requests HIV testing receives it, in low-prevalence settings (less than 1 percent) where the population is not at increased risk for HIV, HIV counseling and testing must be targeted to maximize cost-effectiveness. It is important to make special efforts to avail VCT services to particular groups (youth, couples, pre-marital couples, men who have sex with men, sex workers, injecting drug users, etc.) that may greatly benefit from such service. Of particular interest are adolescents. Given the declining age of onset of first sexual activity, investing in youth-friendly VCT services must be a priority for many nations, especially within sub-Saharan Africa.

FHI's programmatic approach includes the following planning and implementation steps:

- Support baseline analysis, including identifying and meeting with stakeholders, gathering background

information on existing VCT services, conducting an inventory of care and support services, and exploring needs and expectations of potential VCT clients;

- Support project design using information gathered in bullet one above;
- Support implementation of HIV VCT services;
- Provide appropriate assistance with quality assurance and monitoring and evaluation.

FHI supports countries in the following specific areas:

Policy

- Advocating for HIV VCT services to policymakers, and leaders at various levels;
- Developing national guidelines on HIV counseling and testing;
- Developing standardized HIV counseling training curricula;
- Developing appropriate HIV VCT training materials;
- Involving the community to promote acceptability of HIV VCT services, acceptance of PLHA, and reduction of stigma and discrimination.

Service Promotion

- Using appropriate media to advertise and promote HIV VCT services to increase demand for HIV VCT.

VCT Services

- Assessing the availability, quality, and use of existing HIV VCT services;
- Designing, implementing, and scaling up high-quality HIV VCT services;
- Training counselors in risk-reduction counseling and in personal emotional support techniques;
- Training laboratory personnel;
- Supporting quality assurance (for example, quality control for HIV testing; supervision and quality control for HIV counseling);
- Developing a directory of care and support services to facilitate referrals both to services within the health facility (for integrated VCT services) and within the greater community;
- Establishing/promoting linkages between HIV VCT services and other care and support services as appropriate.

Research and Evaluation

- Providing ongoing technical assistance to improve implementation, monitoring, and evaluation of HIV VCT services;
- Supporting the development of a limited number of HIV VCT sites as learning centers and using experience gained there to expand HIV VCT services in the country;
- Supporting collection and dissemination of lessons learned.

INTERVENTION-LINKED RESEARCH

Many operational questions related to implementation of HIV VCT in resource-constrained countries remain unanswered. FHI strives to conduct well-designed, intervention-linked research as part of our HIV VCT-supported activities to improve HIV VCT service design and implementation.

Intervention-linked research questions include:

- What is the impact of support groups on the long-term sustainability of behavior change achieved through HIV VCT?
- What is the community impact of HIV VCT?
- How can HIV VCT be integrated efficiently and affordably (inexpensively) in sexually transmitted infection (STI), family planning, and PMTCT services?
- Are certain HIV VCT service delivery models more cost-effective than others?
- What is the added value of parallel HIV testing on serial testing as recommended by WHO?

MONITORING AND EVALUATION

Monitoring and evaluation (M&E) is a critical component for successfully implementing HIV VCT services. Well-designed and -conducted M&E of HIV VCT helps identify and correct potential problems on an ongoing basis and provides feedback during planning, design, and implementation of HIV VCT programs.

M&E activities should address two relevant areas for service providers and policymakers:

- Service delivery — how well HIV VCT is provided;
- Program effectiveness — the intermediate outcomes and long-term impact that HIV VCT may have on the population receiving the service.

Illustrative indicators include:

Process indicators: service delivery/program output

- Proportion of people in the community who know about the HIV VCT services;
- Number of people counseled and tested at the HIV VCT site (per month, per year);
- Proportion of people counseled and tested who have returned to receive their test results;
- Proportion of people testing HIV positive who have been referred to appropriate care and support services;
- Proportion of people counseled and tested who state that they intend to inform their partners;
- Proportion of people counseled and tested who have informed their partners (partner notification).

Effectiveness indicators: intermediate program outcomes

- Changes in HIV/STI-related risk behaviors among HIV VCT clients and their partners;
- Changes in behavior among people stating that they know their serostatus (collected through behavioral surveillance surveys, for example);
- Changes in STI trends in sub-populations reached by the HIV VCT program;
- Reduced stigmatization of, and discrimination against, people in the community affected by HIV/AIDS;
- Increased community support for PLHA.

Effectiveness indicators: expected program impact (long-term effects)

- Changes in trends in HIV incidence/prevalence in the population or sub-populations served by HIV VCT programs;
- Reduced mother-to-child transmission of HIV in women of childbearing age targeted by the HIV VCT programs;
- Sustained changes in societal norms in the community reached by the HIV VCT programs.

LINKAGES AND PARTNERSHIPS

FHI recognizes the importance of linkages between HIV VCT and our other prevention and care activities. HIV VCT is an important component of our prevention activities

for risk reduction and is used as an entry point for our care activities such as tuberculosis (TB) prophylaxis and treatment, medical care, PMTCT, establishment of support networks, etc. For example, in Kenya, HIV VCT is used as an entry point to treatment and prophylaxis activities for TB. Our HIV VCT expertise is also used to support ongoing activities to prevent mother-to-child transmission of HIV in Kenya and Rwanda.

In addition, FHI collaborates with NGOs, community-based organizations (CBOs), and other national and international organizations involved in HIV VCT activities. It is in this context that we collaborated with WHO, UNAIDS, the Center for AIDS Prevention Studies, the Kenya Association of Professional Counselors, the Muhimbili University College of Health Sciences (Tanzania), and the Queens Park Counseling Center (Trinidad) in conducting a multi-center randomized study of the efficacy of HIV VCT. We are currently working with Population Services International/AIDSMARK in Zimbabwe and collaborating with the Centers for Disease Control and Prevention (CDC) in Kenya and Côte d'Ivoire.

ILLUSTRATIVE ACTIVITIES

Following are illustrative FHI undertakings related to VCT:

Global and Regional Activities

- FHI staff serve on WHO expert committees on VCT. This gives FHI an opportunity to share field experience directly with global policymaking groups and to rapidly report back to the field the results of technical debates and discussions.
- FHI has produced a comprehensive VCT "Tool Kit" to help programs assemble sound VCT services. The Tool Kit includes modules on counselor training, standard operating procedures for VCT sites, commodities management for VCT, monitoring and evaluation, and quality assurance.

Country Activities

West Africa (Burkina Faso, Cameroon, Cote d'Ivoire, Togo):

Through its regional office in Abidjan and with funding from USAID's West Africa Regional Program (WARP), FHI supported the training of 50 VCT counselors from 20 institutions in Burkina Faso, Cameroon, and Cote d'Ivoire. IMPACT is helping implement standards and guidelines for VCT in these three countries.

Cambodia: Through collaboration with the Gorgas Memorial Institute and the Government of Cambodia, FHI

is establishing VCT centers as access points for inhalation preventive therapy for TB in persons with HIV. This pilot project, with other examples provided here, points to the diverse array of services that can be built around VCT as a nexus between prevention and care.

China: FHI is conducting VCT activities as part of the China-United Kingdom HIV/AIDS Prevention and Care Project. This national project is located in the Chinese Center for Disease Control and Prevention. FHI is also helping to establish pilot VCT model clinics in Yunnan and Sichuan (VCT clinic with anonymous testing), primarily targeting injection drug users.

Dominican Republic: In collaboration with the National AIDS Control Program and the National AIDS Council, through Fund Genesis (a local NGO) FHI is helping the government develop a VCT model that can be replicated in high-priority locations. FHI is linking VCT with participants of the 2002 Demographic Health Survey (DHS) in 75 locations.

Egypt: FHI is helping the Government of Egypt establish two model VCT sites in Cairo. In collaboration with the Egyptian Ministry of Health and Population (MOHP), FHI is developing standard operating procedures for VCT, Arabic guides for counselors, and a national VCT policy.

Eritrea: In close collaboration with the Eritrea Ministry of Health, FHI helped develop national VCT training guidelines, and has helped train counselors, trainers, and counseling supervisors. FHI has also helped establish pilot stand-alone VCT clinics.

Ethiopia: In July 2002, the Addis Ababa Health Bureau asked FHI to provide technical assistance for establishing VCT services in government health centers in the Addis Ababa Administrative Region. FHI and CDC staff worked together in November and December 2002 to train 40 counselors from 21 centers in the Addis Ababa Health Bureau.

Ghana: To help develop comprehensive care, including provision of ART, FHI trained 25 VCT counselors and two counselor supervisors (clinical psychologists). FHI is supporting development of national VCT guidelines and national M&E tools, including a data/information management system for the Ministry of Health as part of Global AIDS Fund grant preparation. FHI/IMPACT helped create a VCT center at the Ghana Police Hospital in Accra in December 2002. As part of FHI's *Start* initiative to introduce triple antiretroviral (ARV) drug therapy, two VCT centers were established at St. Martins Hospital

and Atua Government Hospital in Manya Krobo District, Eastern Region of Ghana. Refresher trainings have since been offered, and a psychologist supports counselors on a regular basis.

Jordan: FHI/IMPACT provides technical support to the Jordanian National Aids Program (NAP) for its Counseling and Hotline Center. With FHI/IMPACT support, the Center developed a promotional brochure to advertise its services and a counseling manual in Arabic. FHI conducted a counselor-training workshop for 20 health educators from Jordan's 12 governorates. Designed primarily to enhance counseling skills, the workshop also focused on strengthening service delivery and referral networks. Preparing for ART provision and condom distribution, a day clinic was established in the counseling center. This will allow medical monitoring and treatment of HIV-positive persons in a non-judgmental environment.

Kenya:

- With funds from USAID/Kenya, FHI currently supports more than 50 VCT clinics in Nairobi, Coast, Western, and Rift Valley provinces.
- National VCT guidelines have been developed, and a national VCT task force formed under NASCOP with all partners.
- One hundred eighty four counselors have been trained to offer VCT services, and more than 22,000 clients have been served.
- FHI's Institute for Family Health is conducting a costing study on integrating family planning services into VCT sites in Nairobi.
- Rapid scale-up has been achieved in less than one year. Most VCT sites are integrated in health care services, and some are linked with TB prophylaxis therapy, home-based care, and PMTCT projects.
- A quality assurance curriculum and system for HIV testing and counseling has been established.

Rwanda:

- With funds from USAID and CDC, FHI supports 21 VCT sites, primarily integrated in health centers and district hospitals. In 2002 alone, 72,000 clients agreed to be tested at the 19 functioning VCT sites.
- Prophylaxis for TB and other opportunistic infections (OI) was integrated in two of the VCT sites, while MTCT is integrated in five sites. ART was introduced at two VCT sites in early 2003.

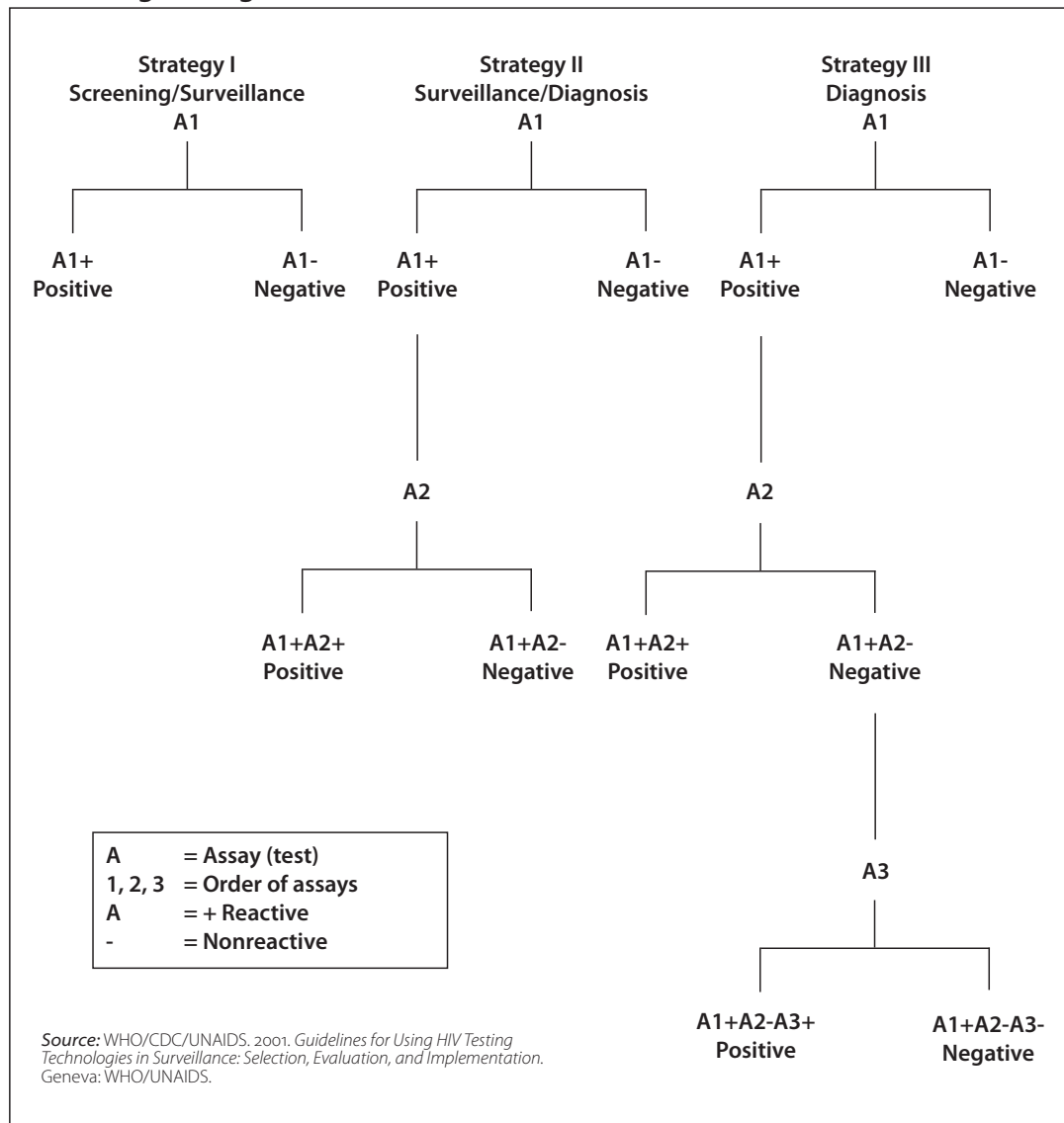
- Rwanda is spearheading a model for comprehensive care and support for PLHA. For example, the Biryogo Medical and Social Center offers VCT and MTCT; in March 2003, the Center introduced OI prophylaxis and treatment, as well as ART. The Center has strong links with the community-based association of PLHA, Ihumure, and employs some of its members. To complement center-based medical care for PLHA, IMPACT is piloting home-based care and a micro-credit program targeting Ihumure membership. Under the micro-credit program, PLHA will be paired with HIV-negative family or community members to ensure sustainability of the enterprise even if the PLHA is too sick to work.
- FHI has been instrumental in developing the national VCT guidelines, HIV testing algorithms, and counselor training curriculum for the Ministry of Health.
- FHI has helped to scale-up VCT in Rwanda and increase access and coverage for VCT services by introducing full-time individual, anonymous, and same-day counseling and testing services.
- FHI has helped the Centre d'Information Rwandais sur le SIDA (CRIS), a free-standing VCT public sector site in Kigali, to improve and computerize its client record-keeping system, which has subsequently been adopted by all VCT sites in Rwanda.

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APPENDIX 1

HIV Testing Strategies



A = Assay (test)
1, 2, 3 = Order of assays
A = + Reactive
- = Nonreactive

Source: WHO/CDC/UNAIDS. 2001. *Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation*. Geneva: WHO/UNAIDS.

Strategy I

- Requires one test
- For use in diagnostic testing in populations with an HIV prevalence greater than 30 percent among persons with clinical signs or symptoms of HIV infection
- For use in blood screening for all prevalence rates
- For use in surveillance testing populations with an HIV prevalence greater than 10 percent (e.g., unlinked anonymous testing for surveillance among pregnant women at prenatal clinics); no results are provided to the persons tested

Strategy II

- Requires up to two tests
- For use in diagnostic testing in populations with an HIV prevalence of 30 percent among persons with clinical signs or symptoms of HIV infection or greater than 10 percent among asymptomatic persons
- For use in surveillance testing in populations with an HIV prevalence of 10 percent (e.g., unlinked anonymous testing for surveillance among patients at prenatal clinics or STI clinics); no results are provided to the persons tested

Strategy III

- Requires up to three tests
- For use in diagnostic testing in populations with an HIV prevalence of 10 percent among asymptomatic persons

Source: WHO/CDC/UNAIDS. 2001. *Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation, and Implementation*. n.p.: UNAIDS/WHO.

APPENDIX 2

PARALLEL VS. SERIAL HIV RAPID TESTING PROTOCOL

Definitions:

Parallel testing: Two different tests are used for each client. If the two initial test results are concordant (either HIV-positive or HIV-negative), the result is reported to the client. If the initial results are discordant, a third test is used as a tiebreaker.

Serial testing: One screening test is first used on each client, followed by a different test for all samples that initially tested HIV-positive. In case of discordance of results between the first and the second tests, a third test is used as a tiebreaker.

Pros and Cons of Each Approach

	Pros	Cons
Parallel Testing	<ul style="list-style-type: none"> Shorter waiting time may lessen time taken from work, resulting in a lower cost to the client and less anxiety while waiting for results. Having only one finger stick reduces the potential for stigma Clients perception that two tests are better than one, reducing shopping around, and winning public trust Blood samples taken by finger prick are suited for conditions in the field (e.g. mobile clinics, remote areas, doctor's offices etc.) <p><i>Note:</i> The last three may be applicable to serial testing depending on how the service is organized</p>	<ul style="list-style-type: none"> Several published studies report that there is no significant increase in accuracy with parallel testing rather than serial testing: <ol style="list-style-type: none"> 1) Wilkinson et al. AIDS 1997;11:337-381 2) Anderson et al. AIDS 1997; 11; 1815-1822 More expensive than serial testing (can be more than 50 % more expensive depending on the HIV prevalence as shown in illustration below) Using finger prick makes it difficult to organize quality control. May require to additional blood collection from selected clients for quality control.
Serial Testing	<ul style="list-style-type: none"> Currently recommended protocol by both WHO (Weekly Epidemiological Record #12, Mar 1997) and CDC (Mar 27, 1998 Morbidity and Mortality Weekly Report) Several published studies have demonstrated that serial testing using rapid tests yield highly accurate test results (predictive values). The results are equivalent, and in some cases better than the standard algorithm of EIA followed by Western blot. Drawing of a venipuncture sample makes it possible to have extra samples that can be archived for quality assurance purposes as well as avoiding the necessity for recalling patient for a second test. Less cost, increasing chances for sustainability, freeing up funding for other interventions or for wider reach of VCT. 	<ul style="list-style-type: none"> Possibility of longer waiting time for clients that test positive on first test. However, this can be minimized through an appropriate clients' flow. Additionally, this time can be used to provide health information and to minimize anxiety; video or other distractions may be provided. Potential for stigmatizing clients who test positive. However, this can be handled by organizing patient flow so that all patients are handled in a similar fashion (same waiting time, one veni-puncture) Might require EDTA test tube, which will add to cost. However, the cost of US 7 cents per one EDTA tube is less than adding another test. <p><i>Previous recommendations were based on serum and plasma based tests and not whole blood tests. However, this protocol can easily be evaluated in any country</i></p>

Scenario I

Assumptions: Population of 28000 with 30 percent HIV prevalence

Scenario I-A: Percent agreement of 99 percent for parallel and serial testing

	Cost per test in US dollars	Parallel Testing (1% discordance)		Serial Testing (10% discordance)		Percent Cost Difference
		Number of tests	Total Cost	Number of tests	Total Cost	
Test A	1.5	28,000	42,000	28,000	42,000	
Test B	2.2	28,000	61,600	5,600	12,320	
Test C	2.2	280	616	560	1,232	
Total Cost			104,216		55,552	46.7%

Scenario I-B: Percent agreement of 99 percent for parallel and 90 percent for serial testing

	Cost per test in US dollars	Parallel Testing (1% discordance)		Serial Testing (1% discordance)		Percent Cost Difference
		Number of tests	Total Cost	Number of tests	Total Cost	
Test A	1.5	28,000	42,000	28,000	42,000	
Test B	2.2	28,000	61,600	2,800	6,160	
Test C	2.2	280	616	28	62	
Total Cost			104,216		48,222	53.7%

Scenario II

Assumptions: Population of 28,000 with 20 percent HIV prevalence

Scenario II-A: Percent agreement of 99 percent for parallel and serial testing

	Cost per test in US dollars	Parallel Testing (1% discordance)		Serial Testing (1% discordance)		Percent Cost Difference
		Number of tests	Total Cost	Number of tests	Total Cost	
Test A	1.5	28,000	42,000	28,000	42,000	
Test B	2.2	28,000	61,600	8,400	18,480	
Test C	2.2	280	616	84	185	
Total Cost			104,216		60,665	41.8%

Scenario II-B: Percent agreement of 99 percent for parallel and 90 percent for serial testing

	Cost per test in US dollars	Parallel Testing (1% discordance)		Serial Testing (10% discordance)		Percent Cost Difference
		Number of tests	Total Cost	Number of tests	Total Cost	
Test A	1.5	28,000	42,000	2,800	42,000	
Test B	2.2	28,000	61,600	8400	18,480	
Test C	2.2	280	616	840	1,848	
Total Cost			104,216		62,665	39.9%

Scenario III

Assumptions: Population of 28,000 with 10 percent HIV prevalence

Scenario III-A: Percent agreement of 99 percent for parallel and serial testing

	Cost per test in US dollars	Parallel Testing (1% discordance)		Serial Testing (1% discordance)		Percent Cost Difference
		Number of tests	Total Cost	Number of tests	Total Cost	
Test A	1.5	28,000	42,000	2,800	42,000	
Test B	2.2	28,000	61,600	5,600	12,320	
Test C	2.2	280	616	56	124	
Total Cost			104,216		54,444	47.8%

Scenario III-B: Percent agreement of 99 percent for parallel and 90 percent for serial testing

	Cost per test in US dollars	Parallel Testing (1% discordance)		Serial Testing (10% discordance)		Percent Cost Difference
		Number of tests	Total Cost	Number of tests	Total Cost	
Test A	1.5	28,000	42,000	28,000	42,000	
Test B	2.2	28,000	61,600	2,800	6,160	
Test C	2.2	280	616	280	616	
Total Cost			104,216		48,776	52.7%

Note: Based on the above scenarios, the cost per HIV-infection identified varies from **\$7.2-\$17.4** when using serial testing as compared to **\$12.4-\$37.2** when using parallel testing.

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