

# **Increasing Access to HIV Testing and Counseling while Respecting Human Rights**

August 2007

**Background Paper**

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400 West 59<sup>th</sup> Street  
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[www.soros.org](http://www.soros.org)

For more information, contact:  
Public Health Program  
Open Society Institute  
[www.soros.org/health](http://www.soros.org/health)

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## Executive Summary

Since the beginning of the AIDS epidemic, public health and human rights experts have debated whether individual rights to informed consent, confidentiality of HIV test results, and pre- and post-test counseling ought to be relaxed in order to maximize the number of people tested for HIV. This debate reached its apex in 2002, when prominent health experts began calling for a move away from the traditional client-initiated voluntary counselling and testing (VCT) model toward an approach that makes testing more routine within health facilities. Anticipating objections from human rights groups, some commentators went as far as to suggest that human rights-based approaches to HIV testing might have reduced the role of public health and social justice in HIV policy. This paper, however, shows that HIV testing can and should be expanded without disregard for human rights.

There is consensus among AIDS and human rights activists, public health officials, and policymakers in favor of vastly scaled up access to affordable and high-quality HIV testing. Greater access to HIV testing and counseling is not only a public health imperative but an element of the human right to the highest attainable standard of health.

Evidence from both high-income and low- and middle-income settings suggests that many opportunities to diagnose and counsel individuals at health facilities are missed when systems rely solely on clients to initiate VCT. Increasing access to HIV treatment can go a long way toward addressing this challenge. However, introducing some form of provider-initiated HIV testing and counselling (PITC) can also help to facilitate diagnosis and access to HIV-related services. This means that in addition to the traditional model of client-initiated VCT, new approaches to HIV testing and counseling should be implemented.

In order to make it feasible for health care providers to offer HIV testing and counseling to all their patients, in some settings it may be justified to relax pretest counseling requirements. Human rights and public health do not require cumbersome procedures for pretest counseling. They do require, however, that people, regardless of whether they initiate or are offered an HIV test, can seek and receive sufficient information to enable them to give informed and truly voluntary consent to testing. They also require that people receive post-test counseling and that confidentiality of test results and of the fact of seeking a test are guaranteed.

Although informed consent is difficult to achieve under any system, adoption of an opt-out approach to testing, under which people are tested unless they specifically decline the test, creates a legitimate concern that more people will be tested without their informed and voluntary consent than under a client-initiated system. This makes it essential to ensure that introduction of provider-initiated testing is combined with careful monitoring and with training of health workers.

The optimal balance between public health and human rights may lie in routinely *offering and recommending* HIV testing and counseling, but requiring that clients specifically agree (“opt-in”) to the test, rather than having to decline it. Experience has shown that where implementation of a provider-initiated opt-in approach is adequately supported, it can be as successful in increasing the number of people who test for HIV as an opt-out approach. Opt-in PITC also has the potential to have an impact on access to care and treatment, prevention, and stigma similar to that of PITC using an opt-out approach.

Efforts to scale up access to HIV testing and counseling, which currently focus on PITC in formal health settings, also need to devote greater attention to how client-initiated VCT

services can be improved and scaled-up. VCT is particularly important because large numbers of people do not use formal health services and may need other ways to gain access to HIV testing and counseling. This is especially true for people living in rural areas poorly served by the health care system, mobile populations, and vulnerable communities such as sex workers, gay, bisexual and transgender persons, and people who use drugs who face stigma and discrimination in health settings.

Efforts to scale up access to HIV testing and counseling must be coordinated and integrated with increased efforts to scale up access to antiretroviral treatment and to evidence-based prevention; and must go hand in hand with establishing strong and enforceable legal frameworks for protection against HIV-related discrimination and abuse, particularly for women, children and adolescents, sex workers, men who have sex with men, people who use drugs, and prisoners.

Finally, mandatory and compulsory HIV testing continues to occur in many countries and contexts, in violation of ethical principles and basic rights of consent, privacy, and bodily integrity. There is concern that making testing more routine and adopting “opt-out” approaches may in practice result in even more instances of HIV testing without consent, particularly in countries with a history of mandatory testing. This makes it more important than ever for countries to review laws, policies, and practices to explicitly prohibit mandatory testing and to implement measures to ensure such prohibitions are enforced.

# Report Synopsis

## General Background

At the end of 2006, an estimated 39.5 million people were living with HIV. High numbers of new HIV infections continue to occur throughout the world. Sub-Saharan Africa remains the hardest-hit region, with 24.7 million people living with HIV. Epidemics in Eastern Europe and Asia continue to grow.

In recent years, global action to combat the HIV pandemic has increased markedly. In the United Nations Millennium Declaration and during the UN General Assembly Special Session on HIV/AIDS in 2001, the world made an unprecedented commitment to halting and reversing the epidemic by 2015. At the 2005 UN World Summit and at the 2006 UN High Level Meeting on AIDS, world leaders committed “to pursuing all necessary efforts ... towards the goal of universal access to comprehensive prevention programmes, treatment, care and support by 2010.” At the same time, increased resources have been committed to fighting the epidemic.

By the end of 2006, more than 2 million people living with HIV in low- and middle-income countries were receiving life-prolonging antiretroviral treatment (ART), compared to 1.3 million people at the end of 2005 and less than 500,000 people in 2003.

One of the conditions for achieving the aim of universal access to treatment by 2010 for all who need it is an expansion of HIV testing and counseling. The World Health Organization (WHO) estimates that only about 10 percent of persons living with HIV/AIDS in low- and middle-income countries know their HIV status. In many of these countries, access to HIV testing remains limited. Many high-income countries also estimate that a significant number of people living with HIV are not aware of their HIV status.

## The Debate about HIV Testing and Counseling

In recent years, an international consensus has emerged that access to HIV testing must be scaled up urgently and that, in addition to the traditional model of client-initiated voluntary counseling and testing (VCT), new approaches to HIV testing and counseling must be implemented in more settings and on a much larger scale than has so far been the case.

In 2006, WHO and UNAIDS developed a draft guidance on provider-initiated HIV testing and counseling (PITC) in health facilities and solicited feedback from experts in the fields of HIV testing and counseling, prevention, treatment, and care, as well as human rights experts and HIV activists. On May 30, 2007, the final version of the guidance was launched. Of all the documents on HIV testing and counseling released over the last few years, the WHO/UNAIDS guidance is likely to have the biggest impact in shaping HIV testing policy and practice in low- and middle-income countries.

The debate about how to increase access to HIV testing is not occurring in a vacuum. Rather, it is taking place in an environment where evidence-based and human rights-based policies and programs are being widely undermined. At the same time, even as vastly increased funding for the fight against HIV has become available, those people most vulnerable to HIV and its impact continue to receive the least access to HIV prevention, care, and treatment services.

## **Methodology and Scope**

The Open Society Institute's (OSI) Public Health Program commissioned this paper in order to inform discussions about an OSI position on HIV testing. The paper was presented for discussion in October 2006 at a meeting of OSI's Global Health Advisory Committee. The paper was first revised in December 2006, following the release of the draft WHO/UNAIDS guidance. At the time, this paper was widely disseminated and served as the basis for extensive comments provided by OSI and others to the WHO and UNAIDS on the draft guidance. The paper was revised again after the release of the final version of the WHO/UNAIDS guidance.

The paper is based upon a review of the literature and upon extensive consultations with people providing services to, and/or shaping policy for, populations vulnerable to HIV in Sub-Saharan Africa, Asia, Eastern Europe, Latin America, and North America. It focuses on the issues raised by proposals to make HIV testing more routine in low- and middle-income countries. This paper does not deal in detail with other important and controversial issues, such as pre-marital testing or testing of minors, because these issues are neither central to the current debate about making HIV testing more routine nor the motivation for OSI's decision to develop a position on this question.

Most of the literature and policymaking around HIV testing has concerned itself primarily with Sub-Saharan Africa or the "hidden epidemic" in high-income countries. This paper is significant, however, because it also seeks to address how this debate affects vulnerable populations in other parts of the world where the nature of the epidemic is often very different.

## **Main Conclusions**

### **1. Increasing access to HIV testing and counseling is essential.**

It is undisputed that access to quality HIV testing is essential for an effective global response to HIV/AIDS, and there is complete consensus among AIDS and human rights activists, public health officials, and policymakers in favor of vastly scaled up access to affordable and high-quality HIV testing. Greater access to HIV testing and counseling is both a public health and a human rights imperative.

It will be important to increase efforts to improve and better support VCT, but there is agreement that this alone will not be sufficient to achieve vastly scaled-up access to HIV testing and counseling. The experience of ART roll-out has shown that when VCT and treatment are available and the community is mobilized around HIV testing, people do come forward voluntarily in larger numbers for testing. Nevertheless, for countries with a generalized HIV epidemic, there is consensus about the need to make testing more routinely available and to combine scaled-up VCT with some form of PITC. There is also consensus that efforts to increase access to HIV testing should not be limited to countries with a generalized epidemic, but that certain forms of PITC should also be introduced in countries with low-level or concentrated HIV epidemics.

While there is consensus that HIV testing should be more routinely available, there is lack of agreement about a number of other issues concerning PITC and, more generally, about making testing more routine. This paper focuses on these issues.

## **2. Stepping up the fight against compulsory and mandatory testing is necessary.**

Many of the persons consulted for this paper and for developing a position for OSI strongly recommended that compulsory and mandatory HIV testing be addressed as well. Mandatory and compulsory HIV testing occurs in many countries and contexts, in violation of ethical principles and basic rights of consent, privacy, and bodily integrity. With the exception of HIV screening for blood, blood products, and before all procedures involving transfer of bodily fluids or body parts, compulsory or mandatory testing is also ineffective for public health purposes. There is concern that making testing more routine—particularly by adopting approaches under which people are tested unless they specifically decline the test—may result in even more instances of HIV testing without consent. In particular, official endorsement of such approaches by WHO and UNAIDS could be understood by some as an endorsement of a generally more coercive approach to HIV testing.

In the final version of their guidance, WHO and UNAIDS stress that they “do not support mandatory or compulsory testing of individuals on public health grounds.” In addition, they should undertake concrete activities to fight policy and practice requiring or permitting mandatory testing.

## **3. In increasing access to HIV testing, it is necessary to protect human rights and require counseling, informed consent, and confidentiality.**

In the early years of the HIV/AIDS epidemic, aggressive calls for punitive, forcible testing sparked widespread concern about the effects of such strategies on individual rights and the spread of the epidemic. Eventually, members of affected communities and public health professionals recognized that HIV testing must be voluntary and that informed choice was central to creating a climate of confidence and trust between the person being tested and the service providers. Three underpinning principles of HIV testing (the “three Cs”) were established as norms: *counseling* and information about HIV/AIDS before and after the test; *consent* to be tested given in an informed, specific, and voluntary way by the person to be tested; and *confidentiality* of test results and of the fact of seeking a test.

Central to the debate about scaling up access to HIV testing is whether and, if so, to what extent, these conditions should be relaxed. Some proponents of more routine forms of testing have gone so far as to dismiss the ethical and human rights requirement that testing be voluntary. Some have argued that the protections afforded by the three Cs treated HIV/AIDS as exceptional, because it was exceptional in the early years of the epidemic, but that “the world has changed,” stigma has decreased, and treatment is now “widely available.”

Arguments in favor of models of HIV testing that eliminate or minimize specific, informed consent and counseling often do not adequately take into account the link between these elements and human rights:

- Informed consent protects the human right to security of the person as well as the right to receive information.
- Pretest counseling contributes to the protection of these same human rights.
- Post-test counseling also imparts information to which people have a right.
- Confidentiality of test results and of the fact of seeking an HIV test is part of protecting and respecting the right to privacy.

- Beyond the components of the testing process itself, governments have a responsibility to ensure that HIV testing is not offered or provided in a way that discriminates against any person or group of people.
- Finally, the right to be free of discrimination and the right to security of the person also require that in setting HIV testing policy and overseeing its practice, governments take into account the outcomes of HIV testing for people and do all they can to prevent human rights violations associated with HIV testing.

Under international law, any public health action by the state that limits human rights must be justified by demonstrating that it is rationally connected to achieving a pressing objective; that it infringes upon human rights as little as possible; and that the benefits achieved are proportional to the harm done to individual human rights.

The question therefore is whether the conditions exist, particularly in countries with generalized HIV epidemics, to justify limiting or infringing upon human rights by relaxing the informed consent and counseling requirements of testing. Different conditions and populations may yield a different analysis.

#### **4. Some relaxation of counseling and informed consent requirements can be justified, but...**

In the context of the current debate, the main questions are: whether it is justified to replace pre-test counseling with so-called pretest information and whether it is justified to adopt an informed right-of-refusal approach, under which people are presumed to consent to HIV testing unless they explicitly withhold consent or “opt out” of testing.

Those who answer this question in the affirmative generally argue that new approaches to testing that incorporate these elements are justified because they are necessary to increase the number of people being tested, and ultimately the number of people who contribute to prevention and treatment goals by changing their behavior and by seeking treatment. They also assume that few human rights abuses and other negative consequences will result from this approach. Finally, they assume that less rights-restricting alternatives, such as increased VCT and/or PITC with an opt-in approach, will not achieve these objectives.

#### **Increasing uptake**

There is no question that introducing PITC in health facilities leads to increased uptake of HIV testing. A number of studies, particularly in antenatal settings, but also in STI or TB clinics and other settings, have shown that making the offer of HIV testing and counseling routine and recommending testing makes patients more likely to undergo testing. There is also evidence from a small number of studies, particularly in resource-rich countries, that in *antenatal settings* adoption of an opt-out approach leads to particularly high rates of HIV testing uptake. However, studies in a number of countries have shown that opt-in approaches can result in uptake rates that are comparable to those reached in jurisdictions using an opt-out approach.

With the exception of a few studies in antenatal settings, no studies have compared opt-in and opt-out approaches to PITC. Generally, studies suggest that, whether an opt-in or an opt-out approach to PITC is adopted, most people will accept the offer if providers recommend and encourage HIV testing. Studies also suggest that pretest counseling and informed consent

requirements do not necessarily pose barriers to implementation of PITC, even in resource-poor settings.

Finally, while efforts to increase uptake of HIV testing are important, many studies suggest that more tests alone are not a sufficient achievement. For example, studies have shown that many of the pregnant women who accept HIV testing in antenatal settings in resource-poor settings do not obtain their results or take up perinatal HIV interventions. This suggests a need to link HIV testing policies with technologies that allow rapid testing, as well as a need to address the reasons why women do not get their results or face barriers to take up perinatal interventions. Another concern is low HIV-serostatus disclosure rates to sexual partners. Women often face greater difficulty than men in making the decision to test and share HIV test results with a partner. Efforts to increase access to, and uptake of, HIV testing therefore need to be accompanied by efforts to increase HIV-serostatus disclosure rates and support those persons, particularly women, who test positive through the HIV-serostatus disclosure process. In this context, it is worth studying whether some form of enhanced VCT that incorporated rapid testing and support with disclosure might result in higher rates of learning and disclosing one's HIV status than the model of simplified PITC currently being proposed.

### **Facilitating access to treatment**

One important benefit of scaled-up testing is the opportunity to identify people with HIV at an earlier stage. Where ART is available, maximum benefit in terms of reduced morbidity and mortality is obtained when HIV infection is diagnosed before end-stage immunodeficiency. Even in the absence of ART, when an HIV diagnosis is made earlier in the course of the disease, health benefits can accrue. Therefore, according to the 2007 WHO/UNAIDS guidance on PITC in health facilities, access to ART “should not be an absolute prerequisite” for the implementation of PITC. At the same time, there “should at least be a reasonable expectation that it will become available within the framework of a national plan to achieve universal access to antiretroviral therapy for all who need it.”

### **Assisting HIV prevention**

There is evidence that people who seek voluntary testing, find out they are HIV-positive, and receive counseling are more likely to take precautions to protect their partners than people who do not know their serostatus. There is also evidence that the nature and duration of prevention counseling might influence its effectiveness. But there is no evidence specifically about the value of pretest counseling for prevention, and no studies have been concluded where testing provided with pretest counseling was compared with testing without pretest counseling or simplified pretest counseling.

In general, the existing evidence supports greater emphasis on efforts to increase the number of people who are aware of their HIV infection so that they can be counseled and supported to take precautions to reduce the spread of HIV to their sexual partners. However, a key question remains. Will the reductions in risk behaviors observed in the studies of people who have initiated VCT themselves be replicated among people who accept PITC, but may be less ready or motivated to disclose their status and change their behavior than people who initiate testing themselves? This is an important question as simply increasing uptake of testing may not be enough to effect changes in behavior absent efforts to make it possible for people testing positive to safely disclose their HIV status and take up prevention and treatment options. At the same time, access to evidence-based prevention measures needs to be scaled up, recognizing that

many people, particularly in most-at-risk populations, are denied access to HIV prevention tools whether or not they test positive.

### **Reducing stigma and discrimination**

Making testing more routinely available may help reduce the *stigma related to HIV testing*. However, this does not necessarily justify relaxing counseling and informed consent requirements. A policy of routinely offering and recommending opt-in testing may lessen the stigma of being tested as much as a policy of routine opt-out testing, as under both policies, testing is offered to everyone.

Widespread testing may also contribute to reducing the *stigma and discrimination related to HIV/AIDS*, particularly if it is accompanied by widespread access to HIV treatment. Once HIV is perceived as a chronic but treatable condition, one of the factors that amplifies stigma—fear of contagion and inevitable death—is lessened. However, stigma is much more than fear of contagion. It is also related to the perception that HIV infection results from “immoral” behavior such as extra-marital sex, homosexuality, prostitution, or injection drug use. Testing and treatment may thus be one component in helping overcome stigma and discrimination, but only further research will be able to tell the extent to which they can contribute to lessening stigma.

### **Routine testing without sufficient counseling and genuinely informed consent will lead to human rights abuses and other negative consequences.**

People who argue for more routine forms of HIV testing with reduced emphasis on pretest counseling and informed consent assume that few human rights abuses and other negative consequences will result from this approach—or in any case that the benefits of HIV testing outweigh the prospect of such abuse. While more research will be needed to establish whether relaxing informed consent and counseling requirements affects people’s experiences of abuse or other negative outcomes as a result of testing HIV-positive, the research that does exist suggests that concern about negative outcomes may be justified. With regard to potential negative outcomes for women, studies show that most HIV-positive women report positive outcomes with disclosure of their HIV status, but that a significant minority of women report negative outcomes, including blame, abandonment, violence, anger, stigma, and depression. Other populations most at-risk of HIV transmission, such as men who have sex with men, injecting drug users, sex workers, and prisoners, are also more susceptible to coercion, discrimination, violence, abandonment, incarceration or other negative consequences upon disclosure of an HIV-positive test result.

### **Conclusion**

Scaling up access to HIV testing and providing some form of PITC (in addition to scaled-up VCT services) is likely to have many benefits, particularly if people testing positive can benefit from treatment, including ART, and have access to evidence-based prevention measures that enable them to reduce the risk of transmission to their partners; and if the social and legal environment is such that people with or at risk of HIV:

- feel comfortable about seeing a health worker and about getting tested for HIV;
- can learn how to maintain their HIV-free status or start working on keeping their health despite their HIV-positive status;

- can disclose their status without recrimination or discrimination; and
- can live and work without discrimination for being HIV-positive or being at risk of it.

Making testing more available might also help reduce the stigma related to HIV testing and ultimately contribute to reducing the stigma and discrimination related to HIV/AIDS—although reducing the stigma related to HIV testing does not automatically reduce the stigma against people and behaviors associated with HIV.

In order to make it feasible for health care providers to offer HIV testing to all their patients, in some settings it may also be justified to relax, to some extent, pretest counseling requirements. Human rights and public health do not require cumbersome procedures for pretest counseling. But human rights and public health imperatives require that regardless of whether persons are routinely offered an HIV test in a health care setting or whether they initiate HIV testing themselves, they are able to give informed and truly voluntary consent to testing. Established practice in HIV testing provides good models for obtaining informed consent without undue burden.

WHO and UNAIDS, in their guidance on PITC, say that patients must be able to make a voluntary and informed decision about whether to be tested or not, and specify the “minimum information for informed consent” that health care providers should provide patients when recommending HIV testing and counseling.

However, a concern remains that adoption of an opt-out approach to testing, as recommended by WHO and UNAIDS, may in practice result in people being tested without their informed and voluntary consent. In settings where there is a power imbalance between the test provider and the client, the voluntary nature of HIV testing may be compromised, as the client may feel compelled to consent to the provider’s offer, particularly when the offer is communicated with the information that the test will be performed unless the client refuses. Careful monitoring and training of health workers administering opt-out testing is essential to addressing this concern.

One way of rapidly scaling up access to HIV testing that may be as effective as a matter of public health and more respectful of human rights would be to routinely offer and recommend opt-in HIV testing and counseling, rather than opt-out testing. Experience has shown that where implementation of such a policy is adequately supported, it can be as successful in increasing the number of people who test for HIV as adopting an opt-out approach. It also has the potential to have an impact on access to care and treatment, prevention, and stigma similar to that of PITC using an opt-out approach.

Ultimately, any form of PITC—whether opt-in or opt-out—needs to be carefully monitored and evaluated to ensure that, in practice, providers offer and recommend testing, but that patients give informed and voluntary consent to the test.

Finally, scaling up HIV testing must be adequately monitored and evaluated and accompanied by research. Many discussions of HIV testing and counseling have occurred and continue to occur in the absence of empirical data, either from studies or from monitoring of existing programs. Outside the prenatal context, evidence about the impact of PITC remains limited and deeper research questions beyond simply the numbers of people getting tested have not been adequately addressed.

## **5. Much greater attention needs to be devoted to how client-initiated VCT services can be expanded, particularly for most-at-risk populations.**

Efforts to scale up access to HIV testing and counseling, which currently focus on PITC in formal health settings, need to devote greater attention to how client-initiated VCT services can be improved and scaled-up, particularly for socially marginalized groups.

A large body of research demonstrates the effectiveness of VCT as part of comprehensive prevention, treatment and care strategies. VCT services that are responsive and sensitive to the communities served need to be adequately supported by resources and promoted and scaled up. Research studies undertaken in many countries and settings suggest ways in which uptake and acceptability of VCT can be increased.

Scaling up access to VCT is particularly important because large numbers of people do not use formal health services and may need other ways to gain access to HIV testing and counseling, especially if they live in rural areas poorly served by the health care system, are mobile, or belong to vulnerable communities who face stigma and discrimination in health settings. For many of those who need testing the most—underserved and socially marginalized communities—PITC is unlikely to work precisely because they rarely use the health system. For sex workers, people who use drugs, or gay men, for example, health systems can be notoriously forbidding places.

In their guidance document, WHO and UNAIDS do recognize that “strategies are needed to increase access to and uptake of HIV testing and counselling” for most at-risk populations, “particularly through innovative client-initiated approaches such as services delivered through mobile clinics, in other community settings, through harm reduction programmes or through other types of outreach.” However, they also recommend that “consideration ... be given to recommending HIV testing and counselling to all patients who attend [specific health services, such as acute care, STI or drug dependence treatment services] if this is epidemiologically appropriate and socially acceptable.”

There is a concern that implementation of PITC in such settings may lead some people to avoid seeking care. In many countries, people belonging to most-at-risk populations have been routinely subject to abuse in health care settings and may not feel that they have the power to decline a recommendation to be tested, because they may feel that they would suffer negative consequences if they did. The WHO/UNAIDS guidance recognizes these concerns and makes several recommendations aimed at addressing them, including that “additional discussion” take place in these settings of the right to decline HIV testing, of the risks and benefits of HIV testing and disclosure, and about social support needs. The guidance concludes that “an ‘opt-in’ approach to informed consent may merit consideration for highly vulnerable populations” and suggests that where PITC is implemented, most-at-risk populations and their advocates should be involved in the development of HIV testing and counseling protocols and in the monitoring and evaluation of PITC programs.

Nevertheless, concerns remain that, unless dedicated financial and technical resources are devoted to ensuring that these recommendations can be implemented in practice, members of most-at-risk populations will continue avoiding health services or experiencing abusive treatment. Therefore, WHO and UNAIDS should provide more detailed guidance about the training and supervision required by health care providers in these settings, and specify what exactly the “additional discussion” of the right to decline HIV testing should entail. Pilot projects incorporating these elements should be funded and monitored and evaluated. Ultimately, efforts

to scale up HIV testing and counseling for most-at-risk populations should continue to focus on strategies to increase access to and uptake of HIV testing and counseling through innovative client-initiated VCT services.

## **6. HIV testing cannot be considered in isolation.**

For the last 20 years, important barriers to HIV testing have included stigma, lack of access to or investment in VCT, lack of HIV treatment and care, and a belief held by patients and health care providers alike that it was better “not to know” because of the lack of treatment and pervasive discrimination. Streamlining PITC within formal health settings does not address all of these barriers. Contrary to what some have claimed, it was not the entrenching of the right to informed consent that caused low HIV testing uptake, but the poor implementation of VCT, and the fact that treatment options were limited and stigma and discrimination rampant. In recent years progress has been made on these fronts, but a move toward increasing access to HIV testing that is genuinely grounded in human rights and promotes public health demands that these issues now be addressed tangibly and urgently.

HIV testing is never a goal in itself, but clearly linked to larger prevention and care, treatment, and support goals. Consequently, the efficacy of testing policies and programs is, in turn, codetermined by the availability of effective prevention and care, treatment, and support programs. This means that testing programs and programs to scale up access to ART and to evidence-based prevention need to be coordinated and integrated.

In addition, increasing testing and counseling must go hand in hand with much greater investment in real protection—in practice, and not just on paper—from HIV-related discrimination and abuse, particularly for women, children and adolescents, sex workers, men who have sex with men, people who use drugs, and prisoners. In their guidance on PITC, WHO and UNAIDS recognize that in addition to expanding access to HIV testing, “equal efforts must be made to ensure that a supportive social, policy and legal framework is in place to maximize positive outcomes and minimize potential harm to patients.” But in practice, there have been few efforts to cost, budget, and implement national programs that would secure legal and human rights protections for people living with, affected by, or vulnerable to HIV and AIDS. Despite vastly increased funding for global HIV and AIDS programs, there has been little investment in basic human rights initiatives. If the scaling up of HIV testing is to reach its goals, HIV-related human rights must become a much higher priority.

# Definitions

The definition and interpretation of various terms used in the debate about making HIV testing more routine vary widely. It is therefore important to present first the most widely used terms and be clear about their meaning.

## HIV Testing and Counseling

### **Client-initiated counseling and testing (also called voluntary counseling and testing, or VCT)**

VCT involves individuals actively seeking HIV testing and counseling services. It has been the dominant, recommended model for HIV counseling and testing among individuals without symptoms of AIDS. VCT is conducted in a wide variety of settings, including health facilities, stand-alone facilities outside health institutions, through mobile services, in community-based settings, and even in people's homes.

The VCT approach rests on: (a) governments and other care providers making HIV counseling and testing services available; (b) public awareness of that availability; (c) an individual's decision to seek out a facility providing VCT services; and (d) the individual's subsequent conscious choice to return to receive test results along with associated post-test counseling and referral. Significantly, in a traditional VCT approach, it is the individual—not the health system—that initiates action; she or he receives counseling and testing services only after having made an active decision to seek out a VCT service and be tested. VCT is especially oriented to self-empowerment for the person seeking the test and the provision of prevention counseling tailored to the test result.

### **Provider-initiated testing and counseling (PITC)**

PITC refers to HIV testing and counseling that is initiated by health care providers for persons attending health care facilities. According to the WHO/UNAIDS guidance on PITC in health facilities, guidance from health care providers is not neutral but recommends HIV testing and counseling "as a standard component of medical care."(WHO/UNAIDS, 2007) "The major purpose of such testing is to enable specific clinical decisions to be made and/or specific medical services to be offered that would not be possible without knowledge of the person's HIV status." (id.)

PITC encompasses two scenarios in which health care providers in clinical settings initiate HIV testing and counseling:

- In the case of persons who present themselves to health facilities *with symptoms or signs of illness that could be attributable to HIV*, health care providers recommend HIV testing and counseling as part of the patient's routine clinical management. This includes recommending HIV testing and counseling to tuberculosis patients and persons suspected of having tuberculosis.

- Provider-initiated HIV testing and counseling also aims to identify unrecognized or unsuspected HIV infection in persons attending health facilities. Health care providers may therefore recommend HIV testing and counseling to patients in some settings even if they *do not have obvious HIV-related symptoms or signs*. In such circumstances, HIV testing and counseling is recommended by the health care provider “as part of a package of services provided to all patients during all clinical interactions in the health facility.”(id.)

WHO and UNAIDS are seeking to replace the term “**routine offer of testing**,” which they had employed in their 2004 policy statement on HIV testing and counseling (UNAIDS/WHO, 2004),<sup>1</sup> and also avoid terminology such as “HIV screening” and “routine recommendation” in favor of “provider-initiated HIV testing and counseling.” The two agencies emphasize that PITC is voluntary. They also highlight that PITC “is neither mandatory nor compulsory” and add that they “do not support mandatory or compulsory testing of individuals on public health grounds.” (WHO/UNAIDS, 2007, at 20)

Provider-initiated testing can be done using either an “opt-out” approach or an “opt-in” approach.

- With an “**opt-out approach**,” testing is initiated by the provider of some (health) service and people are tested unless they clearly opt out and refuse to be tested. Some add other elements to the definition, saying that in opt-out testing regimes clients or patients receive only essential information about HIV, and there is greater emphasis on post-test, rather than pre-test, counseling (See, for example, De Cock, 2005, at 33). This is what is proposed in the WHO/UNAIDS guidance on PITC in health facilities, which—with some exceptions—recommends an “opt-out approach ... including simplified pre-test information.” (WHO/UNAIDS, 2007, at 5). What taking an opt-out approach to testing means in practice will vary widely. WHO and UNAIDS stress that, “when recommending HIV testing and counselling, service providers should always aim to do what is in the best interest of the individual patient. This requires giving individuals sufficient information to make an informed and voluntary decision to be tested (id., at 6). In contrast, the New York City health department recommends that physicians say to their patients, in advising them about all the blood tests that will be performed, ‘I am going to ... do an HIV test. Do you have any questions?’” (New York City Department of Health and Mental Hygiene, 2006)
- With an “**opt-in approach**,” testing is initiated by the provider, who *offers* an HIV test as a routine part of discussions with all patients in a given setting or meeting certain criteria (e.g., all pregnant women, all patients using STI health services), but the client must specifically agree to the test, rather than having to decline it. With “opt-out,” the default is testing; with “opt-in,” the default is no testing.

It should be noted that the terms “opt-in” and “opt-out” are generally avoided in the WHO/UNAIDS guidance, despite the fact that the document acknowledges that in some circumstances, such as in health facilities that serve highly vulnerable populations, “opt-in” approaches “merit consideration.” (WHO/UNAIDS, 2007, at 20) Significantly, the document states that, “[w]hether patients “opt-in” or “opt-out,” the end result should be the same: an

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<sup>1</sup> The 2004 policy statement will be updated to reflect the terminology used in the 2007 guidance.

informed decision by the patient to accept or decline the health care provider’s recommendation of an HIV test.” (id.)

### **Other terms**

In addition to these, other terms have often been used to describe more routine or involuntary forms of HIV testing, often without clearly stated definitions.

**Routine testing** implies that everyone in a given setting or circumstance is tested without regard to individual consent.

“**Routine offer of testing**” should, if used correctly, mean that everyone in a given setting or circumstance is routinely *offered* an HIV test; the test is done only if the offer is accepted by the patient.

Some authors have used the term “routine testing” carelessly and sometimes interchangeably with “routine offer of testing” (e.g., Metz, 2005), or with “opt-out testing” (e.g. Weiser, et al., 2006), even though there are important differences. It often becomes necessary to determine as best as possible from the context what a particular author means.

**Compulsory testing**, also known as involuntary testing, is defined as testing without a voluntary element—i.e., without informed consent, at the behest of someone or some institution other than the person tested and, sometimes, with neither the fact of having been tested nor the result communicated to the person tested (Canadian HIV/AIDS Legal Network, Center for Health and Gender Equity, Gay Men’s Health Crisis, 2006).

**Mandatory testing** is defined as testing that would occur *as a condition for some other benefit*, such as donating blood or bodily tissues, immigrating to certain countries, getting married, joining the military or as a precondition of other kinds of employment.

The words “**compulsory**” and “**mandatory**” are often used, albeit inaccurately, as interchangeable terms. Often people refer to “mandatory” testing when what they are really talking about is compulsory testing, and the intended meaning has to be deduced from the context.

## **Types of HIV Epidemics**

WHO and UNAIDS define different types of HIV epidemics as follows:

### **Generalized HIV epidemics**

HIV is firmly established in the general population. Although sub-populations at high risk may contribute disproportionately to the spread of HIV, sexual networking in the general population is sufficient to sustain an epidemic independent of sub-populations at higher risk of infection. Numerical proxy: HIV prevalence consistently over 1 percent in pregnant women (WHO/UNAIDS, 2007).

### **Concentrated HIV epidemics**

HIV has spread rapidly in one or more defined sub-populations, but is not well-established in the general population. The future course of the epidemic is determined by the frequency and nature of links between the sub-populations with high rates of HIV and the general population. Numerical proxy: HIV prevalence is consistently over 5 percent in at least one defined subpopulation but is below one percent in pregnant women in urban areas (id.).

### **Low-level HIV epidemics**

HIV has never spread to significant levels in any sub-population. Recorded infection is largely confined to individuals with higher risk behavior, e.g., sex workers, people who inject drugs, and men who have sex with men. Numerical proxy: HIV prevalence has not consistently exceeded five percent in any defined sub-population (id.).

## Methodology and Scope

This background paper was commissioned by OSI's Public Health Program to inform discussions about an OSI position on HIV testing. It was presented for discussion at a meeting of OSI's Global Health Advisory Committee in October 2006. It was first revised in December 2006 following the release of the draft WHO/UNAIDS Guidance on Provider-initiated HIV Testing and Counselling in Health Facilities (WHO/UNAIDS, 2006). At the time, the paper was widely disseminated and served as the basis for extensive comments provided by OSI and others to WHO and UNAIDS on the draft guidance. The paper was revised again after the release of the final version of the WHO/UNAIDS guidance.

Research included a review of existing materials—reports, position statements, policy documents, studies, critiques, advocacy materials, journal articles, and news clippings—on the issue of expanding HIV testing. A search of the published scientific literature was carried out using electronic databases. Conference abstracts were reviewed, and searches of the Internet were conducted. Attempts were made to obtain as much information as possible from low- and middle-income countries, particularly those that have been left out of the discussion on scaling up HIV testing. The “gray” literature was reviewed via a variety of sources including professional contacts, direct contact with known researchers and research centers and the Internet.

In addition, the author worked with staff from OSI and the Soros foundations network to identify the implications of routine testing for OSI's work, and to survey existing policy and practice on HIV testing in the countries in which OSI operates, with a focus on marginalized groups, such as people who use drugs and sex workers. In order to do this, the author interviewed people from within and outside the OSI and Soros foundations network in a number of low- and middle-income countries, and obtained written comments from others. Informants were not compensated for their participation, and their names were sometimes withheld on request.

A first draft of both this background paper and the position paper were peer reviewed by experts in the field, and both documents were revised taking their comments into account.

The focus of both papers is on scaling up HIV testing in low- and middle-income countries, in the context of recent calls by the World Health Organization and other major opinion leaders on making HIV testing more routine. Policies, however, are also in transition in high-income countries, as evidenced in particular by the issuing of new recommendations on HIV testing and counseling in the United States and France during the drafting of the papers. While developments in high-income countries are not the focus of the papers, they are nevertheless included inasmuch as they affect developments in low- and middle-income countries. In addition, much of the analysis in the papers also applies to high-income countries.

The papers do not deal in detail with some other important and controversial issues, such as pre-marital testing or testing of minors, as they are neither central to the current debate about making HIV testing more routine nor the motivation for OSI's position paper.

# General Background

## Key points

- Global action to combat the HIV pandemic has increased markedly, with world leaders having committed to “pursuing all necessary efforts ... towards the goal of universal access to comprehensive prevention programmes, treatment, care and support by 2010.”
- By the end of 2006, more than 2 million people living with HIV in low- and middle-income countries were receiving life-prolonging antiretroviral treatment, compared to 1.3 million people at the end of 2005 and fewer than 500,000 people in 2003.
- However, evidence-based and human rights-based policies and programs are being widely undermined. At the same time, those persons most vulnerable to HIV and its impact continue to receive the least access to HIV prevention, care, and treatment services.

At the end of 2006, an estimated 39.5 million people were living with HIV. Large numbers of new HIV infections continue to occur throughout the world. Sub-Saharan Africa remains the hardest-hit region, with 24.7 million people living with HIV. Epidemics in Eastern Europe and Asia continue to grow (UNAIDS/WHO, 2006).

In recent years, global action to combat the HIV pandemic has increased markedly. In the United Nations Millennium Declaration (2000) and during the United Nations General Assembly Special Session on HIV/AIDS in 2001, the world made an unprecedented commitment to halting and reversing the epidemic by 2015. There has been global acknowledgement of the HIV/AIDS pandemic as not only a public health crisis but also a threat to societies and international security. The world’s leaders endorsed a set of specific global targets in combating HIV/AIDS (United Nations General Assembly, 2001). More recently, first in 2005 at the meeting of the “Group of Eight” nations and at the World Summit (United Nations General Assembly, 2005), and then at the 2006 High Level Meeting on AIDS, world leaders committed “to pursuing all necessary efforts ... towards the goal of universal access to comprehensive prevention programmes, treatment, care and support by 2010.”(United Nations General Assembly, 2006)

As part of this effort, increased resources have been committed to fighting the epidemic. In 2001, the Global Fund to Fight HIV/AIDS, TB and Malaria (GFATM) was created. Three years later, the United States Leadership against AIDS, Tuberculosis and Malaria Act of 2003 (the United States Global AIDS Act), which authorized the President’s Emergency Plan for AIDS Relief (commonly known as PEPFAR), was enacted. The same year, WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS), and the GFATM launched the Treat 3 Million by 2005 Initiative (3 by 5), partly out of the recognition that HIV/AIDS was exacerbating inequities between rich and poor countries, and the conviction that the human rights to health and life should not be dependent on ability to pay for medicines (WHO and UNAIDS, 2003). At its heart, 3 by 5 was a public health initiative, but it also aimed to lessen the inequity that exists in access to medicines between First and Third Worlds (Heywood, 2004). Although the ambitious target of 3 by 5 was not reached, by the end of 2005, an estimated 1.3 million people living with HIV in low- and middle-income countries were receiving ART, which was more than a three-fold increase in the number of people on ART two years previously

(WHO/UNAIDS, 2006b).<sup>2</sup> Within a few years, the question “should AIDS treatment programs be implemented in low-income countries?” was replaced with a new question: “How can the ambitious and costly global AIDS treatment programmes be implemented in ways that are swift, affordable, feasible, efficient *and* ethically sound in the resource-poor countries most burdened by HIV/AIDS?” (Rennie and Behets, 2006, at 52)

At the same time, however, evidence-based and human rights-based HIV/AIDS policies and programs are being widely undermined, impeding efforts to scale up both HIV treatment and prevention. In the last 25 years, it has been shown time and again that HIV programs are most effective when based on people’s voluntary, informed and, open engagement with health services. Such services should inform and educate people about HIV, support them to engage in behavior change, and offer them a variety of prevention and care options that will fit in with the realities of their lives and allow them to choose what is most effective (Amon, 2006; Csete, 2005; Heywood, 2004). However, at the same time as the world witnesses a global regression in commitment to human rights more generally—as seen in political rhetoric and policies on terrorism, trade, migration, freedom of expression, etc.—there has been a recent trend to resort to punitive and coercive attempts at “HIV control.”

- In many countries, governments are resorting to coercive methods of HIV prevention, such as criminalization of “intentional” HIV transmission and mass HIV testing without informed consent (Amon, 2006; see also the many reports released by Human Rights Watch’s HIV/AIDS & Human Rights program, available via [www.hrw.org](http://www.hrw.org)). Such policies have the potential to promote stigmatization of people living with HIV and to deter these and other people from coming forward for needed health services.
- In many countries that have fought hard to establish access to comprehensive and effective HIV-related services, there has been pressure, based on political or ideological orientation, to implement only one or two narrow approaches (e.g., an exclusive or predominant emphasis on abstinence-based HIV-prevention programs). This results in young people being denied access to sexual and life-skills education; young women being denied access to information about and control over their own sexuality; and people being denied access to comprehensive HIV information, condoms, and certain reproductive and sexual health services.
- Even though commercial sex is a context in which vulnerability to HIV infection can be high for both sex workers and clients (depending on the conditions of work for sex workers), in many countries police confiscate condoms from sex workers and use them as evidence of illegal prostitution, and sex workers are deterred from seeking health services by the fear of forced HIV testing and prejudicial treatment by health workers. In 2003, the United States Congress passed a law requiring all recipients of United States global HIV/AIDS funding to adopt an explicit policy “opposing” prostitution—a requirement that had a chilling effect on

*The push for more routine approaches to HIV testing is happening in a larger political context ... which includes the undermining of evidence-based prevention measures, impediments to scaling up treatment, and coercive and punitive responses to AIDS. Other policy shifts could occur following the move to making HIV testing more routine, such as more coercive approaches to partner notification.*  
- Canadian HIV/AIDS Legal Network, Center for Health and Gender Equity, Gay Men’s Health Crisis, 2006

<sup>2</sup> By the end of 2006, more than two million people living with HIV in low- and middle-income countries were receiving treatment, an increase of 54 percent since the end of 2005 (WHO, UNAIDS, UNICEF, 2007).

efforts to work respectfully with sex workers to prevent the transmission of HIV and provide care and treatment to sex workers.

- There has been pressure by a small minority of countries on the United Nations and others to withdraw support from needle and syringe programs, despite incontrovertible evidence of the effectiveness of such programs for HIV prevention (WHO, 2004; National Academy of Sciences, 2006). Some proven methods of preventing HIV among people who inject drugs—needle and syringe programs and opioid substitution therapies (WHO, 2005c)—remain restricted by law or policy in many countries. Even where these programs are legal, people who use drugs sometimes fear that turning to these programs means running the risk of arrest for possession of drug paraphernalia or controlled substances. Criminal laws and police practices that drive people who use drugs away from HIV and other health services, or into prison, have been shown to be counterproductive to efforts to respond to the HIV epidemic within this population (see, for example, Wood, et al., 2003; International Harm Reduction Association, 2007).
- In prisons, where HIV spreads rapidly through sex and injecting drug use, access to condoms, sterile injecting equipment, and opioid-substitution therapy remains restricted in many countries (Jürgens, Betteridge, 2005; WHO, 2007). Access to HIV treatment is also often limited (Jürgens, 2006; WHO, 2007b). Such restrictions effectively exclude an entire segment of the population from HIV services, making the goal of universal access impossible to attain. They also represent unsound public health policy, given the links between prisoner health and broader community health.

Ironically, human rights advocates have sometimes been blamed for the lethargic response of governments, particularly in adopting effective HIV prevention policies—the same human rights advocates who have been saying “for 25 years that we must have information, we must be protected from violence and property rights abuses, we must have condoms, clean needles and methadone,”(Amon, 2006) and who have also been fighting for increased access to HIV testing and counseling and to treatment (Heywood, 2004; Heywood, 2005). As Amon has put it: “These are demands that are based both in human rights and in effective, science-based prevention, and the reason that we don’t have these things is not because activists haven’t been asking for them. It is because governments have refused to provide them.”

# The Debate about HIV Testing and Counseling: A Brief History

## Key points

- In recent years, there has been a call for a large expansion of HIV testing services and for moving away from a sole reliance on the voluntary counseling and testing (VCT) model, particularly in high-prevalence countries, but also in some high-income countries.
- The current move to expanded HIV testing has been endorsed by a number of prominent leaders and is attributable to three main factors: (1) advances in ART have dramatically improved the clinical outcome of HIV infection, strengthening one objective of HIV testing: to make care available to HIV-positive people; (2) increasing the number of people who know they are HIV-positive may have a positive impact on prevention efforts; (3) some believe that a change in testing strategies will contribute to the “normalization” of HIV.
- Of all the documents released over the last years, the 2007 WHO/UNAIDS *Guidance on Provider-Initiated HIV Testing and Counselling in Health Facilities* will likely have the biggest impact in shaping HIV testing policy and practice in low-and middle-income countries.
- The guidance recommends an opt-out approach to provider-initiated testing and counseling, but also strongly supports the continued scale up of client-initiated VCT.

## Background

HIV testing has long been a focal point of concern for those committed to the struggle against HIV/AIDS (Canadian HIV/AIDS Legal Network, Center for Health and Gender Equity, Gay Men’s Health Crisis, 2006). In the early years of the epidemic, aggressive calls for punitive, forcible testing sparked widespread concern about the effects of such strategies on individual rights and the spread of the epidemic. Members of affected communities and public health professionals recognized that HIV testing must be voluntary and that informed choice was central to creating a climate of confidence and trust between the person being tested and service providers. The pressures that existed at the time to make HIV testing compulsory or mandatory were curbed, as most public health professionals came to understand that VCT was the most effective and rights-based approach to HIV testing (Gruskin, 2005). HIV/AIDS, unlike some other infectious diseases, disproportionately affected populations who were already marginalized and created deep social stigma that made traditional public health approaches unworkable.

The pursuit of public health goals led to the HIV/AIDS epidemic being treated, for good reason, in ways different from previous public health emergencies—an approach later called “HIV exceptionalism.”(Bayer, 1991; Bayer and Fairchild, 2006)

Three underpinning principles of HIV testing (the “three Cs”) were established as norms, namely:

- *counseling* and information about HIV/AIDS before and after the test;
- *consent* to be tested given in an informed, specific and voluntary way by the person to be tested; and
- *confidentiality* of test results and of the fact of seeking a test.

In recent years, however, HIV testing policies have started shifting. There has been a call for a large expansion of HIV testing services and for moving away from a sole reliance on the VCT model, particularly in high-prevalence countries (De Cock, Mbori-Ngacha, Marum, 2002; De Cock, Marum, Mbori-Ngacha, 2003; De Cock, Bunnell, Mermin, 2006). Some suggest that VCT is too slow or inefficient to help prevent the relentless spread of HIV, while others argue that client-initiated VCT will always have an important role to play in the response to HIV/AIDS but that it needs to be supplemented by some form of provider-initiated testing.

At the same time, there have been calls in some high-income countries, including the United Kingdom (Manavi and Welsby, 2005) and France (Conseil National du Sida, 2006), but particularly the United States (Frieden, 2005; Feinberg, 2006; Bozzette, 2005; Beckwith, et al., 2005; Bazell, 2006; Rietmeijer and Thrun, 2006; Koo, et al., 2006; Simmons, et al., 2006), for a revision of standard approaches, in an effort to identify a higher proportion of those people living with HIV who do not know their status—the so-called “hidden epidemic.”(Schieteringer, 2006) The call for a new paradigm in testing is being taken up in many countries by political authorities. In some cases, AIDS experts who previously supported the idea that HIV testing was always to be completely voluntary and feature informed consent and pretest counseling are now supporting measures that do not necessarily preserve these conditions. The proponents of this new paradigm often argue that AIDS should no longer be treated as an exceptional disease with respect to human rights protections in testing (see, for example, Cameron, 2005; Cameron, 2006).

The current move to expanded HIV testing is attributable to a number of factors (see, for example, Schieteringer, 2006; Gruskin, 2005):

*Firstly*, advances in ART have dramatically improved the clinical outcome of HIV infection, particularly when it is initiated before people develop physical symptoms of HIV disease. This has strengthened one objective of HIV testing and counseling: to make care available to people who are seropositive. Yet, even in countries in which ART has been available since 1996, a significant proportion of people who live with HIV do not know their HIV status—30 to 35 percent in Western Europe, 25 to 35 percent in Oceania, and 25 to 30 percent in North America (Schieteringer, 2006, with reference to Archibald, 2004; Branson, 2006). In developing countries, where treatment is finally starting to become more readily available, the percentage of people who are aware of their HIV status is even lower and has been estimated to be no higher than 10 percent (UNAIDS and WHO, 2004). Surveys in 12 high-burden countries in sub-Saharan Africa showed that a median of just 12 percent of men and 10 percent of women in the general population had been tested for HIV and received the results (WHO, UNAIDS, UNICEF, 2007; see also Corbett, et al., 2006, with reference to Measure DHS, 2006). This is one of the reasons why, even as ART becomes increasingly available, initial uptake has been slow—many individuals who might qualify for treatment simply do not know their HIV status. Without knowing who is infected, however, programs are unable to provide people with appropriate care, treatment, counseling, and support. Access to ART is unlikely to be successfully scaled up without a parallel expansion of HIV testing.

The identification of each HIV-positive person generally requires testing a much larger number of persons. In 2003, WHO estimated that, in the period after 2005, up to 180 million people would need HIV testing and counseling every year (WHO, 2003, at 12). Consequently, rapid expansion of effective HIV testing and counseling capacity has become a pressing

operational and policy priority in many programs and countries (Nieburg, Cannell, Morrison, 2005).

The push to extend ART has also fuelled calls for more aggressive testing measures, including “routine” testing of, or routine offers of HIV testing to, pregnant women in order to enable the optimum use of tools to prevent mother-to-child transmission (Dabis, et al., 2000; Chou, et al., 2005b; Fennelly and Charles, 2006).

Some argue that expanded HIV testing is justified and needed even when ART is not available, calling for “routine testing wherever basic HIV care and prevention are available.”(De Cock, Bunnell, Mermin, 2006) According to them, this would allow infected persons to receive care such as cotrimoxazole prophylaxis, which is within the reach of even the poorest countries. Of course, in addition to a change in testing strategies, other preconditions of successful testing scale-up include availability of affordable test kits and competent health care staff (Vermund and Wilson, 2002).

**Secondly**, there is some evidence that people who know they are HIV-positive are more likely to take precautions to protect their partners than people who do not know their serostatus (Marks, 2005; Weinhardt, 1999). The importance of this for HIV prevention is enhanced in settings where ART is available, given the value of ART in reducing a person’s viral load.

**Thirdly**, some believe that a change in testing strategies is needed as part of a larger effort to make the treatment of HIV similar to that of other diseases, and thereby contribute to the “normalization” of HIV and reduce HIV-related stigma (see, for example, Cameron, 2006).

According to WHO, knowing their HIV status enables *individuals* to initiate or maintain behaviors to prevent acquisition or further transmission of HIV, gain early access to HIV-specific care, treatment and support, access interventions to prevent transmission from mothers to their infants, better cope with HIV infection, and plan for the future. HIV testing also helps communities to reduce the denial, stigma, and discrimination that surround HIV/AIDS and mobilize support for appropriate responses (WHO, 2003b).

## **Chronology of a Shifting Debate**

The following is a brief summary of some of the main events since 2001 that have influenced the discussion about making HIV testing more routine.

### **2001**

In December 2001, WHO held a consultation to begin to explore new approaches to delivering HIV testing and counseling services (WHO, 2002). At that consultation, participants endorsed the standard model of VCT as an effective way to address certain needs in certain settings. However, the participants also recognized the need for a greater variety of models in the provision of testing and counseling services that could be rapidly scaled up. They concluded that new models of HIV testing and counseling should retain their commitment to voluntariness and informed consent; should be adapted to different populations and service delivery settings; and should be capable of rapid expansion.

## 2002

In 2002, through a widely cited paper, Kevin De Cock (then with the Centers for Disease Control and Prevention in Kenya, and since March 2006 director of WHO's HIV/AIDS department) and colleagues called for "routine HIV testing [that] should not require specific consent or pre-test counselling" and claimed that "human-rights based approaches to HIV/AIDS prevention might have reduced the role of public health and social justice." (DeCock, et al, 2002) In their view, particularly in high-prevalence settings, HIV testing should be the routine or default practice in health facilities, with people having the possibility to opt out of testing. In November, WHO convened another, larger consultation to consider strategies to increase access to HIV testing and counseling. Those at the consultation reconfirmed the commitment to voluntary HIV testing and counseling and explored new modalities by which to ensure informed consent. Participants urged that HIV testing and counseling be offered as standard best practice in the provision of prevention, care, and treatment services whenever testing and counseling can benefit the health of those affected by HIV/AIDS.

## 2003

In 2003, the United States Centers for Disease Control and Prevention (CDC) began a new program (Advancing HIV Prevention) that included routinely encouraging HIV testing in certain health care settings as a part of medical care (Janssen, et al., 2003).

## 2004

In the course of 2004, the charge toward a "new approach" to HIV testing gathered supporters and momentum internationally. Botswana implemented a new policy of routine HIV testing under which all people in Botswana would automatically be offered an HIV test when they utilized health services. People receive a pretest information session, have the right to "opt-out" of testing, and those who are tested receive post-test counseling (Kenyon, 2005; Ministry of Health, 2004; Stegling, 2004; Weiser, et al., 2006). Similar initiatives have since been under active discussion, or have been adopted, in a number of other countries (Alcorn, 2006).

In February 2004, the Global Business Coalition on HIV/AIDS, Tuberculosis and Malaria (GBC), a corporate membership advocacy organization, launched its global "opt-out" campaign calling for dramatic scale up of HIV testing and counseling. The campaign was initiated by Richard Holbrooke (GBC president and CEO) and Dr. Richard Furman, MD, (Founder, World Medical Mission) when they published an opinion piece in the *New York Times* arguing that "international policy on testing must be changed, not only in Africa but also in every nation that is threatened, including India, China and Russia and countries in the Caribbean." They proposed redesignating VCT "as something like 'Confidential and Recommended [or Routine] Counseling and Testing.'" But their recommendations went even further: "We believe that, at a minimum, testing should *be required* at three specific moments in a person's life: at marriage, before childbirth and upon any visit to a hospital. At these moments (and, we hope, others), public health criteria legitimately take priority over the desire of an individual." Finally, they proposed that "part of international and American financing for AIDS programs be set aside specifically to encourage and carry out testing; that new technologies, like a quick, cheap and reliable saliva swab test, be widely distributed in Africa and other highly affected areas; and that all public education programs be reoriented to stress the importance of testing." (Holbrooke and

Furman, 2004). Following the *New York Times* article, the GBC “worked aggressively to make the shift in HIV testing policy a reality”(GBC website, accessed on 15 September 2006; see also Global Business Coalition on HIV/AIDS, 2004); and Richard Holbrooke and the GBC have continued arguing strongly for a change in testing policy (see, for example, Holbrooke, 2005; Holbrooke, 2006). Most recently, at the XVI International AIDS Conference in Toronto in August 2006, newly appointed GBC Executive Director John Tedstrom said that “it was impossible to engage in appropriate prevention, counselling and treatment programmes if millions of people carrying the virus had not been identified.” (BBC News, 2006)

Later in 2004, UNAIDS and WHO, partly in response to Botswana’s initiative and to concerns raised about that initiative, issued a policy statement reasserting the importance of maintaining “the three C’s” for all voluntary counseling and testing, but advocating for scaled-up HIV testing services, changes in the delivery of provider-initiated testing and counseling, and for the use of new testing technologies. One recommendation was that pretest counseling be provided in group settings with individual follow-up in order to streamline the counseling process. Another recommendation was to use rapid test technologies. A third recommendation was to offer the HIV test to all patients in certain clinical settings along with pretest counseling that is less involved than the standard counseling session recommended in VCT. A fourth recommendation was to have patients opt-out of provider-initiated testing rather than opt-in (UNAIDS and WHO, 2004). In a plenary presentation at the XV International AIDS Conference in Bangkok, Jim Kim, then director of WHO’s department of HIV/AIDS, stated:

With the possibility of treatment, we feel it is critical to routinely offer testing and counseling in all health care settings. Knowing your HIV status is one of the most powerful forces for behavior change and we have to be ambitious in our efforts to make testing and counseling widely available in every country. Of course, the more routine offer of HIV testing cannot come at the expense of human rights. It can only work with counseling, consent, confidentiality, community involvement and an aggressive effort to fight stigma and discrimination. (Kim, 2004)

## 2005

In October 2005, prominent South African judge Edwin Cameron joined those calling for changes to HIV testing policy and practice, suggesting that the “legal protections burdening HIV testing require reconsideration and reform.”(Cameron, 2005) He later clarified that, in his view, the diagnosis of HIV should be “re-medicalised,” by “making it a normal part of medical treatment, subject only to a patient’s *deliberate and express* refusal to be tested,” under three conditions: ART must be available for offer to the patient; there must be assurance that the consequence of diagnosis will not be discrimination and ostracism; and the patient must be secure in the confidentiality of the testing procedure and its outcome (Cameron, 2006). He admitted that these conditions are still rare in Africa, but said that “where they do exist, we must move urgently to normalise the treatment and diagnosis of AIDS.” Cameron’s approach was criticized by Mark Heywood, head of the AIDS Law Project, South Africa, who said that while people should be encouraged to test for HIV, Cameron was “trying to de-exceptionalise, when HIV remains an exception. For most people, HIV diagnosis remains full of dangers and access to treatment is far from guaranteed.”(Beresford, 2006)

In October 2005 persons living with HIV, representatives of AIDS service organizations, clinicians, researchers, and representatives of development organizations and international agencies working on AIDS attended the Symposium on HIV Testing and Human Rights in

Montréal, Canada. Participants considered the human rights and public health implications of HIV testing approaches that depart from traditional client-initiated VCT, as well as measures that may enhance human rights protections in all forms of HIV testing. They also assessed the practical feasibility of these measures, and articulated research and policy needs related to these questions. They concluded that forms of HIV testing that omit or significantly curtail informed consent, counseling, and confidentiality are not acceptable as a matter of ethics and human rights (Canadian HIV/AIDS Legal Network, Center for Health and Gender Equity, Gay Men's Health Crisis, 2006).

On December 1, 2005, the Ministry of Health of Lesotho and the WHO announced a village-to-village campaign to test every resident of Lesotho aged twelve and older for HIV by the end of 2007 (WHO, 2005; Mills and Chong, 2006). The Lesotho operational plan for universal access to HIV testing states that "every household will be offered an HIV test" and that "communities will choose how HIV testing and counseling will be carried out for [their] members." Independent oversight "to guarantee the rights of community members" will be provided by a three-person committee in each health center catchment area, with each center providing "at least a biannual written report." (Lesotho Ministry of Health and Social Welfare, 2005) The government is also creating a national telephone hotline. The government budgeted \$11.7 million for testing, but only a small amount for post-test referral (Amon, 2006b, with reference to Lesotho Ministry of Health and Social Welfare, 2005). In practice, the door-to-door campaign to offer HIV testing began in July 2006 in certain regions and is currently being rolled out. Approximately 100,000 people have been tested since the launch of the campaign, not only as part of the door-to-door testing initiative, but also in facility-based outreach testing (Richter, 2006). Doctors working in Lesotho have expressed concern about the program, as there is currently a grave lack of medical personnel who can administer ART in Lesotho and insufficient support and infrastructure (Richter, 2006).

## **2006**

In April 2006, former United States President Bill Clinton endorsed Lesotho's program and suggested other countries and companies should launch extensive efforts to diagnose HIV. Clinton said he might support programs that went still further, explicitly requiring compulsory testing and even disclosure of positive HIV results to the partners of those found to be infected. Asked about the ethics of such compulsion, he argued that it could be justified in countries with high infection rates, on condition that measures to guarantee diagnosis, treatment, and anti-discrimination were in place. "In a population with extremely high rates of infection, [compulsory testing] overcomes other reservations," he said (Financial Times, 2006).

In July 2006, as part of the country's goal of testing one million people by the end of 2007, Malawi began a weeklong nationwide HIV testing campaign, expected to reach 50,000 people between 14 and 49 years of age (Agence France Presse, 2006). More than 240 testing sites, staffed by about 1,000 counselors, were designated for HIV testing throughout the week. The campaign followed the revelation that only 15 percent of the country's 12 million people have sought testing for HIV.

Also in July 2006, WHO and UNAIDS held a consultation meeting to obtain initial feedback on a first draft of recommendations for PITC in health facilities (WHO/UNAIDS, 2006a).

On August 14, 2006, during the XVI International AIDS Conference in Toronto, WHO and UNAIDS issued a statement on HIV testing and counseling that says that PITC “must be implemented in a manner that is consistent with human rights principles” and that “[a]ppropriate policy and legal frameworks to protect against stigma and discrimination must be in place before provider-initiated testing is implemented.”(WHO/UNAIDS, 2006c)

On September 22, 2006, the United States CDC issued new recommendations for testing in health care settings in the United States. Many aspects differ from previous recommendations (CDC, 2006, at 8):

- “Opt-out screening” is recommended in all health care settings for patients aged 13 to 64 years. It is defined as “performing HIV screening after notifying the patient that (1) an HIV test will be performed and (2) the patient may elect to decline or defer testing.”
- Consent may be assumed unless the patient expressly declines testing, and specific signed consent for HIV testing should not be required. General consent for medical care should be considered sufficient to encompass informed consent for HIV testing.
- Persons at high risk for HIV should be tested for HIV at least annually.
- HIV test results should be provided in the same manner as results of other diagnostic or screening tests.
- Prevention counseling should not be required as a part of HIV screening programs in health-care settings.

*The idea of making testing a routine part of medical care is clearly the thing to do, so long as we make sure to accompany that with care, treatment, and counseling.*

Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health (NIH), November 30, 2006

These recommendations go even further than those of WHO and UNAIDS (see below), because among other things they envisage opt-out testing in *all* health care settings, not only “where there is a high HIV prevalence.”<sup>3</sup> The recommendations have been criticized by a number of organizations and individuals, including the American Civil Liberties Union (ACLU, 2006), the National Association of People with AIDS (NAPWA, 2006), and the New York State health commissioner, but were supported in many editorials and opinion pieces published in the week following their release (see, *Kaiser Daily HIV/AIDS Report*, September 29, 2006) and by many of the participants at a CDC-sponsored meeting on November 29, 2006 (*Kaiser Daily HIV/AIDS Report*, November 30, 2006). While supporting CDC’s objective of increasing the number of people tested for HIV, the ACLU, NAPWA, and other organizations and individuals deplored the abandonment of the requirements of written consent and pretest counseling and called on public health officials to develop and pilot new models to expedite and improve VCT services (see also Hilton Fisher, Hanssens and Schulman, 2006). New York State Health Commissioner Antonia Novello, MD, a

<sup>3</sup> It should be noted that the U.S. Preventive Services Task Force, while strongly recommending that primary care clinicians screen all pregnant women as well as all adults and adolescents with identifiable risk factors for HIV, in 2005 had made no recommendation for or against screening other patients, leaving the decision of whether to screen these individuals to the discretion of the primary care clinician. The Task Force had estimated that as many as 11,000 non-high risk patients would have to be screened to prevent one clinical progression or death over three years (Chou, et al., 2005c). It concluded that “[g]iven the competing demands, the limited duration of the average primary care visit, and the very small likelihood that any one clinician would provide health benefits to an otherwise-undetected seropositive patient, the physician should consider whether this time might be better spent providing other preventive services ... that carry the potential to improve outcomes for more patients.” (Calonge and Petitti, 2005)

former U.S. Surgeon General, rejected the CDC's recommendation as unwise. In an op-ed, Novello argued that increased HIV testing "must not occur at the expense of adding problems to those who, unaware of their status, or in denial about their behavior, or in a situation where language barriers impede their comprehension, or in a situation where they fear violence or deportation, might not be able to cope with the newly acquired diagnosis." (Novello, 2006) Health care providers in India have also expressed "serious apprehensions" over the CDC recommendations, stating that they cannot be automatically adopted for India because of the prevalence of stigma and because "diagnosis, treatment and care are grossly inadequate." (Vijay, 2006)

The CDC recommendations are similar to those offered earlier in 2006 by San Francisco City health agencies (Allday, 2006) and the New York City health department, which recommended that the requirements for pretest counseling and written informed consent be eliminated and replaced with a requirement for consent with the right to opt out. In a circular about informed consent, the New York City health department recommends that physicians say to their patients, in advising them about all the blood tests that will be performed, "I am going to ... do an HIV test. Do you have any questions?" (New York City Department of Health and Mental Hygiene, 2006)

On October 13, 2006, an editorial entitled "AIDS Tests, Everywhere" in the *New York Times* called upon UNAIDS and WHO to "move quickly to endorse opt-out testing." (Editorial, 2006b)

Also in October 2006, the Department of Health of South Africa released a draft of a new national policy on HIV counseling and testing which makes provision for the offer of counseling and testing to "any person motivated to know their HIV status who is 14 years of age and above." (Department of Health, 2006) The draft policy signifies a clear change from the policy on HIV testing South Africa has followed since 2000, which is based almost exclusively on the VCT model. In particular, the draft policy provides that "[h]ealth providers recommend HIV counselling to all clients on a routine basis to ensure that all clients who would benefit from counselling and testing receive these services." Groups that will be targeted by the routine offer also include clients diagnosed with or at risk of STIs or TB, "sexually active men and women with one or more sexual partners," "vulnerable groups like pregnant women, commercial sex workers, migrant workers, substance users and long distance truck drivers and prisoners," and "women or couples considering pregnancy or concerned about transmission of HIV to their unborn child." According to the draft, "counselling must always precede and follow testing," "all clients should be given a choice to test or not to test," and it is "highly recommended" to obtain a written consent before testing for HIV (Department of Health, 2006, at 10). A discussion paper by the AIDS Law Project, released on October 31, supports the department's move toward "a more proactive and wide-ranging form of HIV testing" and states that "it is vital that the Department finalises the draft policy as a priority, but with wide consultation (Richter, 2006).

On November 23, 2006, the French National AIDS Council released a report recommending changes to the "HIV testing paradigm." (Conseil National du Sida, 2006) In particular, the report suggests that the offer of an HIV test become routine in certain settings, including health facilities in some regions of France where HIV prevalence is high, and that physicians be able to offer HIV testing without undertaking counseling "whenever counseling is a barrier to HIV testing." (id., at 8)

On November 28, 2006, six months after the meeting at which a first draft was discussed, a revised draft of the WHO/UNAIDS *Guidance on Provider-initiated HIV Testing and Counselling in Health Facilities* was released (WHO/UNAIDS, 2006). WHO and UNAIDS sought further input before finalizing the guidance. The draft guidance elaborated upon the 2004 joint policy statement on HIV testing and counseling (UNAIDS/WHO, 2004). Consistent with that statement, it recommended an opt-out approach to PITC in health facilities, but provided more detailed guidance on approaches to the implementation of PITC in generalized, concentrated, and low-level HIV epidemics (see the definitions section above for more information about the different types of epidemics), with options for phased implementation in priority settings where there are resource and capacity constraints. An HIV test was “recommended as a standard part of medical care for all patients attending health facilities in generalized HIV epidemics, and in certain settings in concentrated and low-level epidemics.”(id., at 4) These settings included STI services, health services for most-at-risk populations, and antenatal, childbirth, and postpartum services (id., at 27). The guidance recognized that PITC is voluntary and the “three Cs” “must be observed” for PITC (id., at 5), but stated that individuals must specifically decline the HIV test if they do not want it to be performed” (id., at 4) and replaced pretest counseling with “simplified pretest information” to obtain consent. It emphasized, however, that this “requires giving individuals sufficient information to make an informed and voluntary decision to be tested, including an opportunity to decline the test” (id.), and specified minimum requirements for information that health care providers should give to patients as part of “pretest information.” In addition, although it said that “access to antiretroviral therapy should not be an absolute prerequisite” for the implementation of PITC, the draft guidance document said that PITC “should be accompanied by a minimum set of HIV-related prevention, treatment, care, and support services and implemented within the framework of a national plan to achieve universal access to antiretroviral therapy for all who need it.”(id., at 6) Contrary to the first draft of the document, the “minimum set of prevention services” now included not only HIV prevention counseling for individuals and couples, promotion and provision of male and female condoms, and interventions to prevent mother-to-child transmission for pregnant women, but also “needle and syringe exchange (where permitted) and other harm reduction interventions for injecting drug users.”(id., at 30) In addition, the draft guidance said that, at the same time as PITC is being implemented, “efforts must be made to put in place a supportive policy and legal framework to maximize positive outcomes and minimize potential risks to the patient,” and that “national plans to achieve universal access to HIV prevention, treatment, care and support for all who need it should also address ... broad social measures to protect the human rights of people living with HIV/AIDS and at risk of exposure to HIV.”(id., at 7) As a result, contrary to the first draft, the guidance was consistent with the 2004 UNAIDS/WHO policy statement on HIV testing, which had been careful to link increased access to testing with access to prevention, care, and treatment and to the creation of a more supportive legal and policy environment. The guidance concluded with a discussion of available testing technologies and of monitoring and evaluation of PITC.

WHO and UNAIDS received approximately 170 sets of comments on the draft guidance, including from OSI, based on the extensive research undertaken for this paper.

## 2007

In June 2007, the final draft of the WHO/UNAIDS guidance document was released (WHO/UNAIDS, 2007). Of all the different documents released over the last several years, the WHO/UNAIDS guidance will likely have the biggest impact in shaping HIV testing policy and practice in low- and middle-income countries. Among the many changes made to the document, the most significant are the following:

- WHO and UNAIDS emphasize that VCT contributes significantly to helping people learn their HIV status, and that PITC programs are meant to complement, not replace, VCT. The document states that WHO and UNAIDS “strongly support the continued scale up of client-initiated VCT.”
- The document recognizes that innovative client-oriented approaches “such as services delivered through mobile clinics, in other community settings, through harm reduction programmes or through other types of outreach” are needed to increase access to and uptake of HIV testing and counseling for most-at-risk populations. In addition, it states that “consideration should ... be given to recommending” HIV testing and counseling to members of most-at-risk populations at specific health services, such as acute care, STI or drug-dependence treatment services. It acknowledges that an opt-in approach to informed consent “may merit consideration” for highly vulnerable populations.
- The document no longer neglects concern for the risk of negative outcomes of HIV testing and disclosure, particularly for women; instead, it recognizes that these concerns need to be taken seriously.
- The document states unequivocally that PITC “is neither mandatory nor compulsory” and that WHO and UNAIDS “do not support mandatory or compulsory testing of individuals on public health grounds.”
- The document recognizes that the evidence base for scaling up PITC is more limited than had been suggested in the draft guidance, and emphasizes the need for monitoring and evaluation.

# Compulsory and Mandatory HIV Testing

## Key points

- Compulsory and mandatory HIV testing occurs in many countries and contexts, in violation of ethical principles and basic rights of consent, privacy, and bodily integrity.
- There is concern that making testing more routine—particularly by adopting approaches under which people are tested unless they explicitly decline the test—may in practice result in even more instances of HIV testing without consent. In particular, official endorsement of such approaches by WHO and UNAIDS could be understood by some as an endorsement of a generally more coercive approach to HIV testing.
- In the final version of their guidance, WHO and UNAIDS stress that they “do not support mandatory or compulsory testing of individuals on public health grounds.” In addition, they should undertake concrete activities to fight policy and practice requiring or permitting compulsory or mandatory testing.

While the focus of this paper is on the current calls for making HIV testing more routine, many of those consulted in the course of drafting the paper and the position for OSI strongly recommended that compulsory and mandatory HIV testing be addressed as well. When asked what an OSI position on HIV testing should include, New York City’s commissioner of health, Thomas Frieden, said that, first and foremost, in the context of the countries in which OSI operates and the populations it works with, the statement should “strongly oppose mandatory testing.”(Interview on September 14, 2006) Generally, people consulted raised two concerns:

- First, they said that, for many of the populations they work with, mandatory or compulsory testing is a reality, whether they seek drug-dependence treatment and are tested without their consent upon admission (and often rejected if they test positive), whether they are imprisoned and undergo compulsory testing upon incarceration, whether they work in the sex trade (and are subsequently criminalized further if they test positive), or whether they are listed for surgical procedures—and denied the procedures if they test positive (Malavade, et al., 2002). Sometimes, such testing occurs because of policies or laws requiring it; but often it occurs surreptitiously, without the knowledge of the person being tested, in order to exclude people with HIV from access to certain services, or to impose restrictions on them.
- Second, they expressed a concern that making testing more routine, particularly by adopting “opt-out” models, would in practice result in even more instances of HIV testing without consent. They feared that official endorsement of opt-out PITC by WHO and UNAIDS would be understood by many as an endorsement of a generally more coercive approach to HIV testing. They said that, without a requirement for specific consent, testing would in effect become compulsory in many countries and in many situations.

Others have cited similar concerns. In a recent press release, Human Rights Watch provided examples from around the world of existing or proposed HIV testing programs that violate

individual rights and do not contribute to HIV prevention and treatment goals. For example, in India, the state government of Goa has proposed mandatory premarital testing despite opposition by women's groups and AIDS activists who recognize that empowering women to negotiate condom use and discuss AIDS with their partners and spouses is more important for their protection, before and during their marriage. In Saudi Arabia, testing is mandatory for foreign workers, who are then confined to locked hospital rooms and deported if found to be HIV positive. Human Rights Watch also pointed to proposals in the last few years in Malawi and Sierra Leone to test all journalists; in China to test all workers in the tourism sector and beauty parlors in the city of Guiyang; in Botswana to test all students applying for scholarships; and in India, to test all individuals wishing to obtain or retain a driver's license in Punjab state (Human Rights Watch, 2006).

In addition, many countries continue to apply universal HIV testing to people in certain institutions such as the military or prisons, or those undergoing certain evaluations, such as medical examinations when applying to immigrate or for insurance. For example, on October 26, 2006, the Indian armed forces announced that HIV testing would become mandatory for those entering the armed forces (Anonymous, 2006).

Crewe and Viljoen (2005) expressed a concern "that if 'emergency' measures such as routine opt-out or opt-in testing fail to reach the desired number of people, the next logical step under utilitarian principles might be to call for compulsory testing, either of selected groups (such as "high risk" groups) or for the population more generally." An example of this slippery slope is evident in Zambia, where the National AIDS Council called for compulsory testing in hospitals and clinics as part of the program to place at least 100,000 people on ART by 2005 (Crewe and Viljoen, 2005, with reference). Other factors, such as inadequate training and intolerant attitudes of health care workers, may also see opt-out testing become compulsory in practice. "Faced with mounting pressure to treat large numbers of people with ARVs, policymakers or health care workers might confuse a call for increased HIV testing with a relaxation of the human right to consent."(id.)

As mentioned above, two of the most prominent and vocal proponents of changes to HIV testing policies, Richard Holbrooke and Bill Clinton, have already recommended widespread compulsory or mandatory testing, at least in some circumstances. Another proponent, Kevin De Cock, has stopped short of endorsing compulsory or mandatory testing. After providing many examples of how, in Africa, compulsory and mandatory HIV testing is widely practiced, he stated that "some of these examples of mandatory testing probably reduce HIV transmission, others yield little public health benefit but might further marginalise people infected with HIV." He concluded that:

if mandatory testing is practised, it should be based on scientifically supported rationales that apply to other infectious diseases, and should adhere to the same standards of provision of information, assurance of confidentiality, and referral for services and support as in voluntary testing. With a few exceptions, mandatory testing is likely to contribute fairly little to HIV prevention. (De Cock, Mbori-Ngacha, Marum, 2002, at 69)

However, De Cock did endorse premarital testing, saying: "Unfortunately, premarital testing in industrialised countries did not have much effect, which has led to it being ignored in Africa's high prevalence, heterosexual epidemic. For ethical and public health purposes, people should be strongly encouraged to learn the HIV status of prospective sex partners, undergo premarital

testing, and notify their partners.”(id., at 70) Calls for laws or guidelines to enforce mandatory HIV testing before marriage are becoming louder in some African countries and in practice, some religious leaders are asking people intending to get married to provide proof that they have had an HIV test (Opinion, 2006). In October 2006, Francois Venter, MD, head of the South African HIV Clinicians Society, argued that South Africa should institute mandatory HIV tests through employers, banks, and medical insurance programs, saying that all employers should insist on proof of an HIV test—but not the result—before offering a candidate a job, and that people should also be required to show proof of an HIV test to open a bank account, apply for a government grant, or deal in any way with bureaucracy (Quinn, 2006).

According to the *International Guidelines on HIV/AIDS and Human Rights* drafted in 1996, “public health legislation should ensure that HIV testing of individuals should only be performed with the specific informed consent of that individual. Exceptions to voluntary testing would need specific judicial authorization, granted only after due evaluation of the important considerations involved in terms of privacy and liberty.”(OHCHR and UNAIDS, 2006, at 27) International agencies working on HIV and public health authorities continue to reject compulsory or mandatory testing as unethical and a violation of human rights and as ineffectual in public health terms (WHO, 2003, at 9; UNAIDS and WHO, 2004). The one exception is HIV screening for blood, blood products, and before all procedures involving transfer of bodily fluids or body parts, such as artificial insemination, corneal grafts, and organ transplant, which is recommended by UNAIDS/WHO and is commonly required in national HIV policies, often legislatively.

The August 2006 WHO and UNAIDS statement on HIV testing and counseling emphasizes that “provider-initiated testing and counseling should not be confused with mandatory testing” and that “testing must be voluntary and patients must retain the right to decline the test.”(WHO/UNAIDS, 2006c) The WHO/UNAIDS guidance on PITC in health facilities also stresses that PITC “is neither mandatory nor compulsory” and that “WHO and UNAIDS do not support mandatory or compulsory testing of individuals on public health grounds.”(WHO/UNAIDS, 2007, at 20)

Such statements should be welcomed. In addition, international agencies, particularly UNAIDS and WHO, need to demonstrate leadership on this issue by detailing what concrete activities will be undertaken to fight policy and practice requiring or permitting such testing, including:

- developing model legislation that prohibits compulsory and mandatory testing;
- assisting governments to revise existing laws or policies requiring such testing;
- promoting government investment in scaling up accessible testing services, particularly for those most in need; and
- developing a model code of conduct for health care providers and assisting with training test and health care providers on HIV, human rights, and ethical practice, and promoting the *International Guidelines on HIV/AIDS and Human Rights*. (OHCHR/UNAIDS, 2006)

# No Controversy: The Need to Scale Up Access to HIV Testing

## Key points

- There is complete consensus among AIDS activists and policymakers in favor of vastly scaled-up access to affordable and high-quality HIV testing.
- Efforts to increase access are an important part of the legal obligation of countries to take steps to realize progressively every person's human right to the highest attainable standard of health.
- The real question is not *whether* HIV testing should be scaled up, but *how* it can best be scaled up to meet the needs of different populations in different parts of the world and define what the right to health demands in terms of the testing services themselves.

Today, it is undisputed that access to quality HIV testing is essential for an effective global response to HIV/AIDS, and there is complete consensus among AIDS activists and policymakers in favor of vastly scaled up access to affordable and high-quality HIV testing. In his plenary speech at the XVI International AIDS Conference in Toronto in August 2006, Anand Grover of the Lawyers Collective HIV/AIDS Unit in India expressed this consensus as follows:

*Testing and counselling should be accessible to all and free of charge. This should be the central policy goal.*  
- Canadian HIV/AIDS Legal Network, Center for Health and Gender Equity, Gay Men's Health Crisis, 2006

Undoubtedly the vast majority of the people living with HIV do not know that they are HIV- positive. It is in their interest to know that they are indeed HIV-positive so that they can protect themselves by taking appropriate treatment and also protect others. Therefore scaling up of testing is of the utmost necessity. There can be no two opinions on this proposition. (Grover, 2006)

Commentators have argued that the human right to enjoy the “highest attainable standard” of health, which essentially means the highest attainable standard of health information, goods, and services,<sup>4</sup> underscores the need to increase access to HIV testing and counseling, as do the rights to non-discrimination, education, information and participation and the right to enjoy the benefits of scientific progress and its applications. According to Csete and Elliott:

The authoritative comment on the right to health, from the UN committee that monitors governments' progress on attaining this right, suggests that the right to health includes basic services, including HIV/AIDS-related health services, that are “scientifically and medically appropriate and of good quality,” as well as respectful of culture and medical ethics.<sup>5</sup> We take this to include HIV testing. (Csete and Elliott, 2006)

<sup>4</sup> International Covenant on Economic, Social and Cultural Rights. United Nations General Assembly Res. 2200A, December 16, 1966, article 12(1). See also interpretation of this right in UN Committee on Economic, Social and Cultural Rights. General Comment No. 14: The right to the highest attainable standard of health: Art 12 E/C.12/2000/4, August 11, 2000.

<sup>5</sup> General Comment No. 14 at pars 12c and 12d.

WHO has stated:

The right to health obligates governments to take legislative, budgetary and administrative steps towards the progressive realization of this right. The right to health includes the right to knowledge about one's health status—in this case, knowledge of one's HIV status through HIV testing and counselling. The right to health also includes the right to comprehensive care, treatment and support for health conditions, including for HIV/AIDS, and the medicines necessary to treat them. Since HIV testing is an essential first step to accessing such care, treatment and support, greater access to HIV testing should form a part of governments' obligations to realize progressively the right to health. (WHO, 2003)

While there is consensus on the need to scale up access to HIV testing, there are differing views on the essential elements of HIV testing and on the means by which greater access to HIV testing should be achieved. The real question is not *whether* HIV testing should be scaled up. The key issues now are *how* testing can best be scaled up to meet the needs of different populations in different parts of the world and define what the right to health demands in terms of the testing services themselves.

The *General Comment on the Right to Health* sets out the following conditions that should be applied to HIV testing as they are to any other form of health care:

- a. *Availability*—sufficient quantity of sites, trained health professionals, testing kits etc.
- b. *Accessibility*—no discrimination in access (rural populations, marginalized populations such as people who inject drugs, prisoners, migrants, youth, sex workers, men who have sex with men, etc.), physically accessible, safe, affordable (if not cost free), impartial information
- c. *Acceptability*—respects medical ethics (including the right to confidentiality), sensitive to cultures, gender etc., information in local languages
- d. *Quality*—reliable testing technology, quality of counseling

Those interviewed in the process of writing this paper stressed that, while scale-up is needed everywhere, the discussion about scale-up has so far been driven primarily by the needs of countries in Sub-Saharan Africa most affected by the epidemic, countries where there is also a real, concerted effort to scale up access to ART. They emphasized that what may be ethical and work there may not be ethical and may not work in other countries, particularly in countries where the epidemic is concentrated among certain segments of the population that are often at the margins of society and often have the least access to ART and other treatment and care, as well as to evidence-based HIV prevention methods.

# Making Testing More Routinely Available: Agreements and Disagreements

## Key points

- For countries with a generalized HIV epidemic, there is consensus about the need to make testing more routinely available, and to combine scaled-up VCT with some form of PITC.
- There is also consensus that efforts to increase access to HIV testing should not be limited only to countries with a generalized epidemic, but that certain forms of PITC should also be introduced in countries with low-level or concentrated HIV epidemics.
- However, there is lack of agreement about a number of other issues concerning PITC and, more generally, making testing more routine. In particular, there is a lack of agreement about whether and, if so, to what extent, the three underpinning principles of HIV testing (counseling, consent, and confidentiality) need to be relaxed in an effort to increase HIV testing rates.

## Agreements

While it will be important to continue—and scale up—efforts to improve and better resource VCT (see, below, the chapter on voluntary counseling and testing services), this alone will not be sufficient to achieve vastly scaled-up access to HIV testing and counseling and, ultimately, universal access to prevention, care, treatment and support.

The experience of ART roll out has shown that when VCT and treatment are available *and the community is mobilized around HIV testing*, people do come forward voluntarily in larger numbers for testing. One widely cited example is the Médecins Sans Frontières pilot project in Khayelitsha, South Africa, where, upon the widespread provision of ART, the number of people getting tested has also risen dramatically (Global HIV Prevention Working Group, 2004). Although in an earlier study, which preceded widespread availability of ART, only 14 percent of participants indicated they would be more likely to access VCT if ART became available (Day, et al., 2003), more recent research in South Africa has confirmed a correlation between an increase in the uptake of VCT services and the availability of ART (Mfundisi, et al., 2005). During a presentation at the XVI International AIDS Conference, Heywood referred more generally to the success of South Africa's VCT scale up. Health facilities providing VCT have more than doubled from 1,500 in 2002/03 to 3,700 in 2004/05. The number of people counseled for testing in the public sector rose from 413,000 in 2002/03 to 691,000 in 2003/04 and 1.3 million in 2004/05, and the total number of people tested rose from 247,287 in 2002/03 to 511,843 in 2003/04 (Heywood, 2006). "Dramatically increased" demand for VCT has also been reported in settings such as Dar es Salaam, Tanzania (Maman, et al., 2003; Maman, et al., 2001).

Nevertheless, for countries with a generalized HIV epidemic, there is consensus about the need to make testing more routinely available, and to combine scaled-up VCT with some form of PITC. There is also a consensus that efforts to increase access to HIV testing should not be limited only to countries with a generalized epidemic, but that certain forms of PITC should also be introduced in countries with low-level or concentrated HIV epidemics. As Heywood has

stated (2005), a “commitment to the routine offer of testing has ... become necessary because in most developing countries easy access to counseling, an HIV test, and information about AIDS in health facilities has been as scarce as access to anti-retroviral drugs.” Making HIV testing more routinely available can be expected to increase substantially the number of people who obtain HIV tests relative to approaches that rely on VCT alone (Metz, 2005).

## **Disagreements**

However, while there is consensus that HIV testing should be more routinely available, there is lack of agreement about a number of other issues concerning PITC and more generally, making testing more routine. In particular, there is lack of agreement about:

- whether or not pretest counseling should be eliminated and replaced by some form of “simplified pretest information”;
- what type of information provision is adequate to constitute informed consent;
- whether or not PITC should be implemented using an “opt-in” or “opt-out” approach;
- the extent to which scale-up of testing and counseling needs to be linked to availability of treatment, including ART, and evidence-based prevention information and tools;
- the extent to which scale-up of HIV testing needs to be linked to efforts to reduce stigma and discrimination, to protect women from gender-based violence, and to create supportive legal and social environments; and
- the extent to which HIV/AIDS should be “normalized” and treated like other diseases and the role that expanding HIV testing can play in this, as well as the debate about whether making HIV testing more routine might reduce HIV-related stigma.

# Human Rights and the Three Cs: Counseling, Informed Consent, and Confidentiality

## Key points

- In the early years of the epidemic, three underpinning principles of HIV testing (the “three Cs”) were established as norms.
- Some argue that the protections afforded by the three Cs are no longer justified and advocate for models of HIV testing that eliminate or minimize specific, informed consent and counseling. Often, they do not adequately take into account the link between these elements and human rights.
- In particular, informed consent has a clear foundation in ethics and in human rights law. International human rights law recognizes the individual right to withhold consent to medical treatment, including diagnostic tests. Under international law, restrictions on rights can be justified, if certain conditions are met.
- The question, therefore, is whether the conditions exist, particularly in countries with generalized HIV epidemics, to justify limiting or infringing the human rights protections provided by counseling and informed consent. Different conditions and populations may yield a different analysis. The burden of proof is on those who propose modifications to, or elimination of, the three Cs.

As described above, in the early years of the HIV/AIDS epidemic, aggressive calls for punitive, forcible testing sparked widespread concern about the effects of such strategies on individual rights and the spread of the epidemic. In response, three underpinning principles of HIV testing—counseling, consent, and confidentiality—were established as norms. Central to the debate about making HIV testing more routine is whether and, if so, to what extent, these three principles should be relaxed.

## The Approach Taken in the WHO/UNAIDS Guidance

As mentioned above, the WHO/UNAIDS guidance on PITC in health facilities states that, “as in the case of client-initiated HIV testing and counselling, provider-initiated HIV testing and counselling is voluntary and the ‘three Cs’—informed consent, counselling and confidentiality—must be observed.”

(WHO/UNAIDS, 2007, at 19)

The guidance specifies that:

When recommending HIV testing and counselling, service providers should always aim to do what is in

*The emphasis on counselling around HIV diagnosis is unique in infectious diseases and merits discussion. Awareness of HIV/AIDS is now high in Africa, and evidence that more extensive pretest counselling is necessary for HIV than for other infections is lacking. What seems most necessary is to make access to information for HIV testing and prevention easily available, remove artificial barriers to testing, and provide appropriate information and medical and social support to infected people.*

-De Cock, Mbori-Ngacha, Marum, 2002

the best interests of the individual patient. This requires giving individuals sufficient information to make an informed and voluntary decision to be tested, maintaining patient confidentiality, performing post-test counselling and making referrals to appropriate services. (id., at 6)

Nevertheless, the guidance recommends “simplified pretest information” instead of pretest counseling, and uses an informed “right-of-refusal” or “right-to-decline” approach to obtaining consent under which consent is assumed unless the patient expressly refuses or declines the test (i.e., “opt-out” routine testing). This is similar to the CDC’s revised recommendations on HIV testing in health-care settings (CDC, 2006).

However, in a welcome development, WHO and UNAIDS have specified minimum requirements for “simplified pretest information.” The guidance says:

When recommending HIV testing and counselling to a patient, the health care provider should at a minimum provide the patient with the following information:

- The reasons why HIV testing and counselling is being recommended.
- The clinical and prevention benefits of testing and the potential risks, such as discrimination, abandonment or violence.
- The services that are available in the case of either an HIV-negative or an HIV-positive test result, including whether antiretroviral treatment is available.
- The fact that the test result will be treated confidentially and will not be shared with anyone other than health care providers directly involved in providing services to the patient.
- The fact that the patient has the right to decline the test and that testing will be performed unless the patient exercises that right.
- The fact that declining the test will not affect the patient’s access to services that do not depend upon knowledge of HIV status.
- In the event of an HIV-positive test result, encouragement of disclosure to other persons who may be at risk of exposure to HIV.
- An opportunity to ask the health care provider questions. (WHO/UNAIDS, 2007, at 36)

The guidance adds that patients “should also be made aware of relevant laws in jurisdictions that mandate the disclosure of HIV status to sexual and/or drug injecting partners.”(id.) As mentioned above, it recognizes that “additional measures to ensure informed consent may be appropriate” for “some patient groups, such as populations most at-risk of HIV transmission and women.”(id., at 37)

In addition, the guidance states that “[a]t the same time as provider-initiated HIV testing and counseling is implemented, equal efforts must be made to ensure that a supportive social, policy and legal framework is in place to maximize positive outcomes and minimize potential harms to patients.”(id., at 32) It continues by saying that the implementation of PITC is likely to require a major investment in training and ongoing supervision of health care personnel in the processes of obtaining informed consent, maintaining confidentiality, counseling referral, and treating patients decently and without discrimination due to HIV status or perceived risk behaviors.

One of the “basic elements” of the social, policy, and legal framework required to support PITC is “an ethical process for obtaining informed consent.” The guidance states that

Guidance and ongoing supervision must be provided to health care providers on the process of obtaining informed consent. Patients must receive adequate information on which to base a personal and voluntary

decision whether or not to consent to the test, and be given an explicit opportunity to decline a recommendation of HIV testing and counselling without coercion. (id., at 33)

## **Proposals to Further Relax or Abandon Counseling and Informed Consent**

In contrast to the WHO/UNAIDS guidance, the CDC recommendations for HIV testing in health care settings in the United States say only that “patients should be informed orally or in writing that HIV testing will be performed unless they decline” and that “oral or written information should include an explanation of HIV infection and the meaning of positive and negative test results, and the patient should be offered an opportunity to ask questions and to decline testing.”(CDC, 2006, at 7-8) Going even further, in a circular about informed consent, the New York City health department recommends that physicians say to their patients, in advising them about all the blood tests that will be performed, “I am going to ... do an HIV test. Do you have any questions?”(New York City Department of Health and Mental Hygiene, 2006) The French National AIDS Council seems to propose a similar approach, suggesting that in certain circumstances, if counseling is a barrier to testing because physicians do not have the time or the training necessary to undertake it, HIV testing may be offered without any counseling (Conseil National du Sida, 2006, at 8, 21). It is not clear whether any form of pretest information would still be required.

Some proponents of routine testing have gone so far as to dismiss the ethical and human rights requirement that testing be voluntary: in 2004, before the recent changes to U.S. policy, Holbrooke and Furman asserted that “current United Nations and United States policy on testing simply does not work” and that “it is time to abandon this ethnocentric Western rhetoric, born in the 1980s in the United States under different circumstances, that led to the ‘V’ in V.C.T.”(2004) Others have argued that the protections afforded by the three Cs treated HIV/AIDS as exceptional, because it was exceptional in the early years of the epidemic, but that “the world has changed,” stigma has decreased, and treatment is now “widely available.” They suggest that, where treatment is available, “the exceptionalisation of HIV infection in the healthcare setting may be impeding its effective management” and that the “exceptional protections for HIV testing” in the health care setting should be relaxed (Cameron, 2006). With regard to the requirements of express and specific consent and pretest counseling, Cameron states:

These safeguards are intended for the protection of people with HIV; but today I suggest that they also serve to reinforce the inner fears and dread—the inner sense of self-contamination—of those who suspect they may have HIV... People shy away from being tested because the requirements relating to consent and counselling accentuate the differentness and distinctness and horror of AIDS. They emphasise to the patient that this disease is exceptional, abnormal, unusual. As a result, rather than consenting to testing, many shy away. They prefer to ascribe their symptoms to causes other than HIV, when all too often the routine administration of a test will confirm the opposite, and will open the way to effective management of their condition. (Cameron, 2006)

In a 2006 article, Csete and Elliott summarized the arguments made by proponents of relaxing or abandoning counseling and informed consent requirements as follows:

- VCT, especially with counseling and informed consent, is too slow and costly to be a useful tool for a public health emergency on the scale of HIV/AIDS, especially in high-prevalence countries.
- Pretest counseling has dissuaded physicians from offering the test because of the amount of time it takes and because it forces them to raise issues they may not feel comfortable discussing with their patients.
- Pretest counseling has dissuaded clients from taking an HIV test or created a barrier or impediment to testing when it provides an overload of information.
- HIV/AIDS awareness is already very high in most high-prevalence countries, and therefore there is less need for counseling (De Cock, Mbori-Ngasha, Marum, 2002).
- The exceptional human rights protections related to HIV testing compared to those of other infectious diseases only add to stigma; normalizing HIV testing and less insistence on confidentiality or anonymity of testing will reduce stigma.
- VCT actually may undermine social justice in that it restricts people's access to testing, which is essential to treatment and care. (Csete and Elliott, 2006)

Some proponents of making HIV testing more routine argue that safeguards to protect human rights must be part of the universal offer of testing and counseling, but warn that procedures that safeguard a patient's autonomy at the expense of his or her health and well-being undermine the moral and logical basis of human rights themselves (Heywood, 2005, at 15, with reference to Nieburg, et al., 2005). According to Heywood,

*Instead of arguing that the requirement of informed consent has not been raised to an unjustifiably high level for HIV care ("AIDS exceptionalism"), we should assert that it has been tolerated at a low level for other communicable diseases ...*  
 – Heywood, 2005

This argument artificially pits a person's right to autonomy against his or her right to health and well-being—as if the two can be separated. It leads down a dangerous road—away from the principle that a human rights approach will complement and strengthen a public health approach. (Heywood, 2005)

Indeed, as was pointed out above, HIV testing and counseling are properly seen as an aspect of the human right to the highest attainable standard of health. Heywood also points out that, contrary to what some have argued (e.g., Cameron, 2006) the requirement of informed consent has not been raised to an unjustifiably high level for HIV care. Rather, it could be said that it has been tolerated at an unjustifiably low level for other communicable diseases (Heywood, 2005).

## **The Link between the Three Cs and Human Rights**

Arguments in favor of models of HIV testing that eliminate or minimize specific, informed consent and counseling often do not adequately take into account the link between these elements and human rights. As Rennie and Behets (2006) have put it, "the difficulties and complexities associated with a genuine consideration of human rights, particularly in resource-poor countries, are often downplayed by advocates of the new routine testing policies."

Central to the human rights calculus related to HIV testing is the notion of informed consent. Informed consent is defined as "a process of communication between a patient and

physician that results in the patient's authorization or agreement to undergo a specific medical intervention.”(American Medical Association, 1998) What constitutes sufficient information to ensure that consent is informed is contextual, determined by the nature and complexity of the condition at issue and the consequences of the diagnosis, and subsequent care and treatment that may be available. The patient should have an opportunity to ask questions for a better understanding of the treatment or procedure to allow an informed decision to proceed or to refuse a particular course of medical intervention.

Informed consent has a clear foundation in ethics and in human rights law. International human rights law recognizes the individual right to withhold consent to medical treatment, including diagnostic tests.<sup>6</sup> This right derives from the principle of individual autonomy, which has its roots in the inherent dignity of every individual<sup>7</sup> and recognizes that an individual has the right and ability to make decisions on his or her person and private information, as opposed to a paternalistic approach in which the physician has the right and duty to make such decisions on behalf of the patient. Testing for HIV without informed consent represents an involuntary intrusion into bodily integrity, which is protected by the right to liberty and security of the person in article 9 of the International Covenant on Civil and Political Rights (ICCPR).<sup>8</sup>

The ICCPR also protects the right to seek and receive information, which is central to informed consent.<sup>9</sup> Pretest counseling contributes to the fulfilment of these same human rights. Post-test counseling also imparts information to which people have a right. Confidentiality of test results and of the fact of seeking an HIV test is part of respecting and protecting the right to privacy.<sup>10</sup> Finally, each of these rights should be viewed as part of appropriate and quality health care, which is protected under the right to the highest attainable standard of health in the International Covenant on Economic, Social and Cultural Rights.

Beyond the components of the testing process itself, governments have a responsibility to ensure that HIV testing, like all other essential health services, is not offered or provided in a way that discriminates against any person or group of people.<sup>11</sup> The right to be free of discrimination and the right to security of the person, also require that in both HIV testing policy and practice, governments take into account the outcomes of HIV testing for people—including stigma, discrimination, violence and other abuse—and do all that they can to prevent human rights violations associated with this health service. As Csete, Schleifer, and Cohen have stated:

AIDS-related human rights concerns encompass subordination of women and girls, stigma and discrimination faced by people living with HIV/AIDS and those at high risk, the right of all people to HIV/AIDS information and services, and the right to health of newborn children. Informed consent and confidentiality are linked to all these other rights, particularly in settings where HIV/AIDS still carries a deep stigma, and should not be considered in isolation. (Csete, Schleifer, and Cohen, 2004)

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<sup>6</sup> See UN Committee on Economic, Social and Cultural Rights, *The Right to the Highest Attainable Standard of Health: CESCR General Comment 14*, UN Doc. E/C.12/2000/4 (November 8, 2000), para 8 “The right to health contains both freedoms and entitlements. The freedoms include the right to control one’s health and body, including ... the right to be free from interference, such as the right to be free from ... non-consensual medical treatment and experimentation.”

<sup>7</sup> Universal Declaration of Human Rights arts 1 and 3.

<sup>8</sup> International Covenant on Civil and Political Rights. United Nations General Assembly Res. 2200A, December 16, 1966, article 9(1).

<sup>9</sup> *Id.*, at article 19(2).

<sup>10</sup> *Id.*, at article 17(1).

<sup>11</sup> International Covenant on Economic, Social and Cultural Rights, article 2(2).

Restrictions on these rights can, of course, be justified. In 1985, a UN human rights body suggested conditions under which it may be justifiable for a society, including public health authorities, to limit or infringe upon human rights to some degree. Among the conditions identified are the following:

- when the limitation on human rights “responds to a pressing public or social need,” “pursues a legitimate aim and is proportionate to that aim”;
- when the limitation represents “no more restrictive means than are required for the achievement of the purpose of the limitation”;
- when the limitation is not applied in an arbitrary or discriminatory manner;
- when the limitation is provided for by law; and
- when the limitation does not violate “non-derogable” rights, which include the right to life and freedom from medical or scientific experimentation without free consent.<sup>12</sup>

The question therefore becomes whether the conditions exist, particularly in countries with generalized HIV epidemics and for most-at-risk populations in countries with low-level and concentrated HIV epidemics, to justify limiting or infringing upon human rights by relaxing the informed consent and counseling requirements of testing. Different conditions and populations may yield a different analysis.

The burden of proof is on those who propose modifications to, or elimination of, the three Cs, to build a body of evidence showing that new models of HIV testing that relax the counseling and informed consent requirements do not violate the human rights of persons tested in the proposed testing process or contribute, in ways that could be avoided or minimized, to subsequent human rights violations experienced by people who get tested (Tarantola, 2005; Canadian HIV/AIDS Legal Network, Center for Health and Gender Equity, Gay Men’s Health Crisis, 2006).

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<sup>12</sup> UN Economic and Social Council, UN Sub-Commission on Prevention of Discrimination and Protection of Minorities. Siracusa Principles on the Limitation and Derogation of Provisions in the International Covenant on Civil and Political Rights (Annex). UN Doc E/CN.4/1984/4 (1984), articles I.A., II.D.

## **Can Relaxation or Elimination of Counseling and Informed Consent Requirements Be Justified?**

Is it justified to replace pretest counseling with so-called pretest information, and is it justified to adopt an informed right-of-refusal approach, under which people are tested unless they opt out of testing?

Those who answer this question in the affirmative generally argue that new approaches to testing that incorporate these elements are justified because they are necessary to increase the number of people being tested, and ultimately the number of people who contribute to prevention and treatment goals by changing their behavior and seeking treatment. They also assume that few human rights abuses and other negative consequences will result from this approach. Finally, they assume that less rights-restricting alternatives such as increased VCT and/or PITC with an opt-in approach will not achieve these objectives.

These arguments have been made with regard to countries with generalized HIV epidemics, and with regard to high-income countries with “hidden HIV epidemics,” specifically the United States, the United Kingdom, and France. In the WHO/UNAIDS guidance on PITC in health facilities, they have been expanded implicitly to most-at-risk populations in countries with low-level or concentrated epidemics, while recognizing that special protections may be needed to ensure that members of these populations do not suffer adverse consequences. The following sections examine these assumptions.

## Increasing Uptake of HIV Testing

### Key points

- Many studies have shown that making the offer of HIV testing and counseling routine and recommending testing makes patients more likely to undergo testing. However, with the exception of a few studies in antenatal settings, no studies have compared opt-in and opt-out approaches to PITC.
- Studies also suggest that pretest counseling and informed consent requirements do not necessarily pose barriers to implementation of PITC, even in resource-poor settings.
- Many studies suggest that more tests alone are not a sufficient achievement. For example, studies have shown that many of the pregnant women who accept HIV testing in antenatal settings in resource-poor settings do not obtain their results or take up perinatal HIV interventions. Another concern is low HIV-serostatus disclosure rates to sexual partners.

An increasing number of studies, the vast majority undertaken in prenatal settings, have shown that various forms of making HIV testing and counseling more routine do yield high rates of testing.

### Experience in high-income countries

#### Prenatal settings

Studies in high-income countries have shown that PITC in prenatal settings leads to high numbers of women being tested. Opt-out PITC (with the right to decline) has been associated with the highest proportions of individuals tested (Anderson, 2005; CDC, 2002; Jayaraman, et al., 2003; Walmsley, 2003; Mossman, 2002; Bitnun, et al., 2004).

Several factors appear to influence HIV testing rates. One randomized trial undertaken in the United Kingdom in 1996/97 found that prenatal testing rates were significantly higher when women were offered testing (35 percent) than when they did not receive a direct offer (6 percent), independent of whether a comprehensive or minimal pretest counseling protocol was used; but uptake varied widely between individual providers offering the test (Simpson, et al., 1998). Testing rates were generally higher in places that used an “opt-out” approach (Chou, et al., 2005b). While in Ontario, Canada, the opt-in testing and counseling policy for pregnant women delivers results comparable to most opt-out policies (Schietinger, 2006; Remis, et al., 2003; Remis, et al. 2004; Remis, et al., 2006), in studies in the United Kingdom and the United States, the proportion of pregnant women undergoing prenatal HIV testing increased from 33 to 74 percent with the “opt-in” strategy to 81 to 88 percent with the “opt-out” strategy (Stringer, et al., 2001; Simpson, et al., 1998; Simpson, et al., 1999a; Simpson, et al., 1999b; Blott, et al., 1999; CDC, 2002). In part, this increase may be explained by evolving attitudes among both women and providers, owing to increasing knowledge about effective treatment and considerable media exposure. In Alberta, Canada, the implementation of an “opt-out” prenatal HIV testing policy also resulted in a “dramatic” increase in the number of women tested (Jayaraman, et al., 2003). However, even with the “opt-out” approach, many women may decline testing if their provider does not recommend and encourage HIV testing, suggesting that education and training about the importance of recommending the test must be delivered to all prenatal care providers

(Anderson, et al., 2005). A number of studies confirm that strong provider endorsement of testing increases the number of pregnant women getting tested for HIV (Lindsay, et al., 1991; Royce, et al., 2001).

A small number of studies explored what pregnant women think about the HIV test. In one study, most women (87.7 percent) answered yes to the question, “Do you think the HIV test should be a routine test like all the other blood tests during pregnancy (i.e., it’s done unless you say you don’t want it)?” (Simpson, et al., 1999a) A small qualitative study suggested that routine testing would cause less anxiety to pregnant women because it would eliminate the stigma of saying yes to testing (Boyd, et al., 1999). Other studies showed that policy and practice may differ greatly with respect to pretest counseling and informed consent (Leonard, et al., 2002; Leonard, et al., 2001; Leonard, 2001; Leonard and Shap, 1999; Howard Research and Instructional Systems, Inc., 2001). In these studies, many pregnant women reported that they did not experience the offer to test as voluntary and did not feel that they had given their informed consent to be tested. Some women thought that HIV testing in pregnancy was mandatory, or that there were good reasons for not “making a fuss” about the testing offer before them, and most women went along with prenatal HIV testing in absence of any meaningful pre-test discussion (Csete and Elliott, 2007, with references).

### **Outside the prenatal setting**

Outside the prenatal setting, a small number of studies have indicated that a high proportion of patients find PITC an acceptable intervention.

- In a sexually transmitted infection clinic in the United States, HIV was added to the list of tests offered to all patients, who were informed at registration and given a consent form to read and sign (Campos-Outcalt, 2006). Each person who signed the form was provided counseling during the clinical encounter (which consisted of answering the patient’s questions regarding the test and providing general prevention information). Sixty-eight percent of patients accepted testing, and 5.6 percent of those tested were seropositive.
- In a small study, 72 hospitalized patients in the United States were asked about how they would feel about an unsolicited HIV test. Only 11 percent had an unfavorable response (Greenwald, 2006).
- Studies of routine testing at genitourinary clinics in the United Kingdom also demonstrated that many patients will accept HIV testing and counseling when it is offered (Lee, 2005; Jones, Peterson, and Watson, 2005) and that the uptake increases when an “opt-out” testing policy is adopted (Day, et al., 2004).

### **Experience in resource-poor settings**

A number of studies have been undertaken in African countries to compare HIV testing uptake under different testing strategies and to assess what other factors affect uptake of HIV testing. Many of these studies were undertaken in prenatal settings, but some focused on uptake of testing in other settings, such as TB clinics or workplaces; others examined uptake of testing at free-standing or clinic-based VCT centers. The results of these studies have been summarized as follows:

Direct offer of HIV testing in a convenient location usually leads to high uptake in both health-care settings and community settings. Acceptance of provider-initiated testing can exceed 90% for antenatal clinic attendees and patients presenting with opportunistic infections, but with rates of return of only 45%–75% when a repeat visit is required. However, only a minority of African adults will make unsolicited visits to free-standing or clinic-based VCT centres. Major disincentives include fear of being seen, fear of breach of confidentiality, inability to cope or adverse life events if found to be positive, and a sense of futility if testing is not linked to HIV care. Accessibility and cost are also important. Making counselling and receipt of results available through home visits increased uptake of community-based VCT from 10%–12% to 37%–87% in four different African studies. Thus, the consistent finding is that relatively minor differences in accessibility translate into major differences in acceptability of [testing and counseling] in Africa. (Corbett, et al., 2006, with many references)

WHO and UNAIDS also note that evidence from resource-poor settings “indicates that the uptake of testing increases when testing is routinely discussed and offered, and when it is well-integrated into prenatal care.”(WHO/UNAIDS, 2007, at 16, with many references) They continue by saying:

Findings from a growing number of studies in settings other than pre-natal care are also encouraging. Comparisons of data collected before and after the introduction of provider-initiated HIV testing and counselling consistently show significantly higher uptake, as documented in post-partum wards in Botswana; pediatric wards in Zambia; tuberculosis clinics as well as Ugandan pediatric wards, maternity wards and STI clinics. In Mbarara hospital in Uganda, increased uptake of HIV testing appeared to be associated with clinical benefits for patients. People diagnosed HIV-positive after provider-initiated HIV testing and counselling were introduced were at an earlier clinical stage and had higher CD4 counts than those identified beforehand, and were therefore more likely to be referred to treatment at an appropriate time. (id.)

However, while there are studies about various forms of HIV testing, including PITC with an opt-in approach, only a few studies examine PITC with an opt-out approach. Three studies have been cited as evidence that opt-out approaches in resource-poor settings show results similar to those obtained in the United States, Canada, or the United Kingdom (WHO/UNAIDS, 2006, at 14, notes 39, 42 and 43), and that opt-out approaches “cause less anxiety for women than an ‘opt-in approach’ (at 14, note 42); but actually these are not studies about opt-out approaches at all. Two of the studies analyzed the effect of testing approaches in which the *offer* of HIV testing became a part of routine antenatal care. In one of the studies, women were tested only after group *and* individual counseling and only after if they opted *in* to testing (Etiebet, et al., 2004); in the other, women were tested after counseling and accepting the HIV test (Shankar, et al., 2003). The third study analyzed factors influencing acceptability of VCT in a district of Uganda with a view to suggesting measures for increasing uptake (Nuwaha, et al., 2002). Only a few studies suggest that opt-out approaches may indeed lead to increased uptake of HIV testing among pregnant women in resource-poor settings:

- A study presented at the XVI International AIDS Conference in Toronto in August 2006 showed that in Malawi, during the nine months between April and December 2005, 14,495 (98.3 percent) women at prenatal clinics were counseled and 14,491 (98.3 percent) were tested after the government adopted new guidelines recommending an opt-out strategy in antenatal clinics—compared to 15,343 women who came to clinics in the nine months between July 2004 and March 2005, of whom 11,689 (76.2 percent) were counseled and 11,674 (76.1 percent) were tested. Under the new guidelines, women receive group pretest

counseling and are then tested for HIV unless they specifically request to not be tested (Zimba, et al., 2006).<sup>13</sup>

- A study, undertaken in Zimbabwe, suggested that an opt-out strategy would be acceptable to pregnant women if it was implemented (Perez, et al., 2006). It warned that the “possible negative impacts in the implementation of this strategy should not be neglected” and suggested that close monitoring of issues such as whether such a strategy would deter women from seeking prenatal care or result in fewer women returning for their test results would be necessary. Preliminary results from the pilot phase of the implementation of the new strategy showed a significant increase in counseling and testing rates in both urban and rural settings (99.9 percent of antenatal clinic bookings tested versus 65 percent under the traditional VCT model and 95 percent versus 54 percent, respectively). At the same time, the introduction of routine testing did not seem to have any negative effects on post-test counseling rates or the delivery of ARV prophylaxis (Miller, et al, 2006).

However, studies in a number of countries have shown that opt-out approaches may not be necessary to obtain high uptake of HIV testing. When the offer of HIV testing and counseling was integrated into routine antenatal services, up to 97 percent of women accepted the offer and *opted in* to HIV testing (see, for example, Malonza, et al., 2003; Etiebet, et al., 2004; Shankar, et al., 2003; Kiarie, et al., 2000). (More information on these studies and other studies undertaken in low- and middle-income countries outside Africa can be found in Appendix 1.)

Information about the only *country-wide program* of PITC using an opt-out approach, introduced in Botswana in 2004, also remains limited. However, it is known that the number of people tested for HIV in Botswana has increased substantially since the program was introduced and that most people express support for the program:

- It has been reported that the number of people tested for HIV increased by 134 percent in 2005; that only 10 percent of those who were offered the test did not go ahead with it; and that 41 percent of those tested were HIV-positive (Alcorn, 2006; Steen, et al., 2007; Rajaraman and Surender, 2006).
- A study of antenatal clinics in Francistown showed that in the first three months of routine opt-out testing, 90.5 percent of pregnant women were tested for HIV, compared with 75.3 percent during the final four months of opt-in testing (Seipone, et al., 2004). Attendance at antenatal clinics remains high at more than 95 percent (Steen, et al., 2007). However, the success of the policy was mitigated by the fact that many of the women who were tested failed to return for their results—29.4 percent during the opt-in period and 33 percent during the first three months of routine testing (a statistically insignificant difference: Seipone, et al., 2004).
- A population-based study in Botswana indicated that most people (81 percent) reported being extremely or very much in favor of routine testing (Weiser, et al., 2006). It should be noted that almost half of the people interviewed in the study had never heard about the routine testing policy and responded to questions about routine testing after the policy was explained to them by the researchers. In addition, only 15 percent of those tested had actual experience with routine testing.

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<sup>13</sup> According to newspaper reports, however, some women are shunning hospitals “fearing that they will be forced to undergo an HIV test” (Kumwenda, 2006).

## **Increasing uptake: Summary and discussion**

The research about uptake of HIV testing can be summarized as follows:

- There can be no question that introducing PITC in health facilities leads to increased uptake of HIV testing. Studies, particularly in antenatal settings, but also in STI or TB clinics and other settings, have shown that making the offer of HIV testing and counseling routine and recommending testing makes patients more likely to undergo testing.
- There is also evidence from a small number of studies, particularly in resource-rich settings, that in *antenatal settings* adoption of an opt-out approach leads to particularly high rates of HIV testing uptake. However, studies in a number of countries—both in high-income countries and resource-poor settings—have shown that opt-in approaches can result in uptake rates that are comparable to those reached in jurisdictions using an opt-out approach.
- With the exception of the studies in antenatal settings, no studies have compared opt-in and opt-out approaches to PITC.
- Generally, studies on PITC suggest that, whether an opt-in or an opt-out approach to PITC is adopted, most people will accept the offer if providers recommend and encourage HIV testing.

Studies also suggest that pretest counseling and informed consent requirements do not necessarily pose barriers to implementation of PITC, even in resource-poor settings. In fact, in many of the studies, these requirements were not relaxed. High HIV testing uptake rates were found in settings where group pre-test information was provided, in settings where both group and individual pretest counseling were provided, in settings where consent to testing was assumed unless the patient expressly refused the test, and in settings where people had to sign written consent forms. A study that compared various pretest counseling protocols found that “neither anxiety nor dissatisfaction increased with the amount of information given, lending no support to previous suggestions that comprehensive discussion may have an adverse impact.”(Simpson, et al., 1998)

One study found that HIV testing acceptance rates of pregnant women who are routinely offered HIV testing can be further increased when women understand the modes of vertical transmission and the role of medication in preventing transmission, believe that prenatal identification of HIV infection can promote the health of the mother and child, and perceive their providers as strongly endorsing prenatal testing (Fernandez, et al., 2000). According to the authors, these points can be woven into a pretest counseling message and made a routine component of prenatal care with little additional burden on providers. They point out that it may take more time than what some providers currently provide for pretest counseling, but that it involves less time than what is required by many existing counseling and testing guidelines and that it would also provide a foundation for a pregnant women who tests HIV-positive to accept treatment for herself and her baby (Fernandez, et al., 2000, at 468). The study suggests that pre-test counseling requirements may be somewhat relaxed, but that it would be counterproductive and ultimately reduce the number of people who take up HIV testing if that relaxation goes too far and if providers fail to give people information that will help them make an informed decision. As Fisher, Hanssens, and Schulman (2006) point out, “health care providers committed

to increasing HIV testing can do so efficiently and effectively while respecting their patients' fundamental right to informed consent."<sup>14</sup> They continue by saying:

Nearly all people offered HIV testing in a thoughtful, careful way—even people in the midst of a medical trauma—accept the offer. The few who do not accept it typically have good reason not to at that particular time; skilled counselling could ensure they return to test when the time is right for them. State legislatures can be assured that there is no basis to abandon the fundamental legal right of patients to informed consent in order to make HIV testing more “routine.” (id.)

### **Increasing uptake of HIV testing is not enough**

Efforts to increase uptake of HIV testing are important, but many studies suggest that more tests alone are not a sufficient achievement.

*Just the fact of having been tested may not necessarily be a positive outcome if the extra margin of people who are routinely tested includes a significant number who were not well prepared for testing, who do not have adequate information to understand what their test result means for their lives and those around them, who may have irrational fears of HIV because they have had little information about the disease, or who may not know how to begin to disclose their status to sexual or drug-using partners.*

Csete and Elliott, 2006, at 6-7

### **Uptake of HIV interventions**

Importantly, although 75 to 97 percent of pregnant women in sub-Saharan Africa accept HIV testing in antenatal settings offering counseling and testing, between 25 and 55 percent of women who consent to the test do not obtain their results (Cartoux, et al., 1998). From a public health perspective, this suggests a need to link HIV testing policies with technologies that allow rapid testing (in which people can learn their test results on the spot), as well as a need to address the reasons why women do not get their results. A randomized trial undertaken in Kenya demonstrated that pregnant women randomly assigned to rapid HIV testing were more likely to obtain their results than women randomly assigned to conventional ELISA testing (96 versus 73 percent: Malonza, et al., 2003). However, although rapid testing was associated with a significantly increased rate of obtaining results, there was no significant difference in the overall uptake of perinatal HIV interventions between the women in the two groups: significantly fewer HIV-positive women who received rapid testing accepted referral for perinatal HIV interventions than women who received conventional testing. According to Malonza, et al.:

women may have been unable to cope with the HIV/AIDS information on the same day as receiving their HIV-1 test results. With rapid HIV-1 testing, there may be limited time for women to comprehend the implications of a positive diagnosis and to decide on what action to take. In contrast, conventional testing provides ample time for women to decide on their readiness to receive HIV-1 results, and those who

<sup>14</sup> Fisher, Hanssens, and Schulman (2006) describe a pilot program to increase HIV testing of pregnant women by offering counseling and rapid HIV tests to women in active labor who did not have HIV tests already in their records, implemented in the American state of Illinois since 2005 (Collins and Haufle, 2005). One year after the program began, the percentage of women accepting HIV testing rose from 86.7 percent to 97.1 percent. By early 2006, that percentage had risen to 97.9 percent (Garcia, et al., 2006; Collins and Haufle, 2005). They continue by saying: “Similar results have been obtained in similar programs in other states, such as California. In fact, contrary to the CDC’s and others’ interpretation that the U.S. perinatal testing experience demonstrates that informed consent prior to HIV testing is dispensable, perinatal transmission of HIV has been all but eliminated in this country *with* informed consent in most states. Data from the Perinatal Guidelines Project further supports the experience of Illinois—i.e., that the vast majority of women accept HIV testing if it is recommended by their health care provider”.

choose to get their results are prepared to accept the diagnosis, the implications of a positive test, and referral for perinatal HIV-1 interventions. (Malonza, et al., 2003)

More broadly, this and many other studies showing low rates of uptake of perinatal HIV interventions (see Appendix 2) suggest that policies that may increase uptake of testing may not be enough to ensure increased uptake of perinatal HIV interventions—despite preliminary evidence from the pilot phase of the introduction of routine HIV testing in antenatal clinics in Zimbabwe, which resulted in “increases in the percentages of HIV-infected women and their infants receiving ARV prophylaxis in the majority of health facilities.”(Miller, et al., 2006) “Girls and women may feel intimidated or obliged to comply with the health care providers’ request to be tested, but at the same time perceive too many risks in actually learning their status and in acting upon that knowledge.”(Nieburg, Cannell, Morrison, 2005, at 13) Ultimately, “one wonders whether the women ... who failed to return for their test results were committed to knowing their HIV status, or whether they were channelled into testing.”(Rennie and Behets, 2006, at 54)

### **Rates of HIV-serostatus disclosure**

Low rates of HIV-serostatus disclosure to sexual partners represent another concern. In sub-Saharan Africa, reported rates of serostatus disclosure to sexual partners vary widely. Studies have found that between 16.7 and 86 percent of HIV-positive individuals share HIV test results with their sexual partners (Maman, et al., 2003, with further references). Women face greater difficulty than men in making the decision to test and in sharing HIV test results with a partner. The most salient barrier to disclosure described by women is fear of a partner’s reaction and a partner’s negative attitudes toward HIV testing (Maman, et al., 2001). The lowest rates of HIV serostatus disclosure are reported in studies among pregnant women (Kilewo, et al., 2001; Anterman, et al., 2001).

The discrepancy in disclosure rates between populations of women who are tested in VCT clinics and those tested within the context of antenatal care in the same city at the same time may be explained by the fact that women who come to VCT clinics to test for HIV typically think about HIV testing for a long period of time, often talk to their partner about their decision to test, and often have a high perception of risk for HIV that motivates them to seek VCT services (Maman, et al., 2001). In contrast, women who are offered HIV testing within the context of antenatal care may not have had time to psychologically prepare themselves for HIV testing and may not have had a chance to talk to their partner before deciding to test for HIV, and so the barriers to disclosure they face may be more formidable (Maman, et al., 2003).

The low rates of disclosure seen in many of the studies have many implications (Medley, et al., 2004):

- First, disclosure of HIV status between women and their sexual partners is necessary to initiate discussions about HIV/AIDS that raise both partners’ awareness of the risk of infection and may ultimately lead to behavior change to reduce HIV risk.
- Second, disclosure plays an important role in women’s uptake of prevention of mother-to-child transmission (PMTCT) programs and in their participation in treatment and care and support programs. In order to benefit from interventions that can reduce HIV perinatal transmission, women must be willing to be tested for HIV, and if they are HIV-positive they must be willing to accept and adhere to PMTCT prophylaxis. The optimal uptake and

adherence to PMTCT programs is difficult for women whose partners are either unaware or not supportive of their participation.

- Finally, it has been well documented in Africa that women often lack the power to make independent decisions with regard to their own health care and that of their children (Medley, et al., 2004, with reference to Molyneux, et al., 2002; Guinan and Leviton, 1995; Manhart, et al., 2000). It is therefore difficult for HIV-positive women to seek social and medical support from care and treatment programs for themselves and their infants without first disclosing their HIV status to their partners.

Efforts to increase access to, and uptake of, HIV testing therefore need to be accompanied by efforts to increase HIV-serostatus disclosure rates and support those who test positive, particularly women, through the HIV-serostatus disclosure process. Great caution needs to be taken to ensure that new, more routine forms of testing result not only in increased uptake of HIV testing, but also in increased disclosure rates. Moreover, it is worth studying whether some form of enhanced VCT that incorporated rapid testing and support with disclosure might result in higher rates of learning and disclosing one's HIV status than the model of simplified PITC currently being proposed.

In this context, it is of concern that current proposals de-emphasize pretest counseling. Studies have suggested that new HIV counseling approaches to support women through the testing and HIV-serostatus disclosure process are needed (Maman, et al., 2003), and that, in order to increase rates of HIV-serostatus disclosure to sexual partners, repeated opportunities for counseling on disclosure should be used in HIV testing programs.

DeRosa and Marks (1998) found that rates of disclosure among clients in the United States increased with the number of times that a health official at the HIV clinic where they received care discussed the issue of HIV disclosure. It has therefore been suggested that, "at a minimum, raising the issue of disclosure during both the HIV pretest and the post-test counseling session is necessary in order to address the barriers and plan for disclosure to sexual partners." (Maman, et al., 2003) Multiple opportunities for discussion of disclosure are also important from the counselors' perspective in order to assess whether clients have the social support they need to cope with the diagnosis (id.). Medley, et al., also concluded that standard protocols for HIV testing and counseling do not dedicate sufficient time to considering the challenges of HIV status disclosure that are faced by many clients, particularly women. They suggested that "standard counselling protocols need to be enhanced for HIV-infected women, concentrating on barriers to partner notification, and additional counselling needs to focus on helping women identify the pros and cons of disclosure." (Medley, et al., 2004)

## Enough Awareness of HIV/AIDS?

### Key points

- Another of the arguments used to justify relaxing pretest counseling and informed consent requirements is that awareness of HIV is now high, at least in Africa, which reduces the need for extensive pretest counseling.
- However, this argument fails to take into account the fact that awareness is not the same as knowledge and understanding, much less behavior change.

Another of the arguments used to justify relaxing pretest counseling and informed consent requirements is that awareness of HIV is now high, at least in Africa, reducing the need for extensive pre-test counseling (De Cock, Mbori-Ngacha, Marum, 2002, at 69). However, this argument fails to take into account the fact that awareness is not the same as knowledge and understanding, much less behavior change. Heywood points out:

High levels of HIV/AIDS awareness are often accompanied by high levels of misunderstanding, myth, and denial. High awareness does not lead to health-seeking behaviour—and the deterrent is not the human rights approach. It is important to understand pre-test counselling as both a public health intervention intended to transfer knowledge about HIV to the patient and an ethical and human rights obligation compelling the health worker to respect patient autonomy. (Heywood, 2004, at 9)

Heywood also notes that in South Africa, which has some of the continent's largest and most expensive HIV-prevention campaigns, there is evidence that these campaigns may create awareness of an ephemeral existence of HIV, but not of one's own risk. A survey carried out by the Reproductive Health Research Unit (RHRU) of the University of the Witwatersand found that 85 percent of the nearly 12,000 young people surveyed were aware of HIV. But, the survey also found:

Among sexually active young people 67% continue to think of themselves as being at low risk for HIV infection. 54% of young people who indicated never using a condom with their last sexual partner feel that they are at low risk of HIV infection.... Despite the high prevalence of HIV in this young age group (10.2%), the vast majority of HIV positive youth do not know that they are infected as 67% reported that they had never been tested. (Pettifor, et al., 2004, at 56-57)

According to Heywood,

the RHRU's findings beg the question why so-called at-risk populations are not seeking HIV testing—which brings us back to the issue of human rights and stigma! If anything, this emphasizes the importance of counselling rather than the opposite. (Heywood, 2004)

Some of the persons consulted for this paper suggested that knowledge and understanding of HIV is even lower in many other countries, particularly in Asia, Eastern Europe, and the former Soviet Union. They pointed out that misconceptions about HIV and AIDS remain high, and that many people do not know the difference between HIV and AIDS, know little if anything about ART, and have rarely received adequate prevention information.

In addition, they pointed out that, contrary to UN policy recommendations (UNAIDS, 2002b) and the *International Guidelines on HIV/AIDS and Human Rights* (OHCHR and UNAIDS, 2006, Guideline 4), countries continue to introduce specific criminal penalties against the deliberate and intentional transmission of HIV, or even against failing to take reasonable steps to prevent HIV transmission to one's partner—a trend that must be taken into account in the context of expanded HIV testing with simplified counseling. In practice, this means that as soon as a person finds out that he or she is positive, they have to tell their partner or face criminal penalties.

In this context, it is important to note that women, who are more likely to be tested for HIV than men under an approach that makes HIV testing a more routine part of using health services, may be disproportionately exposed to the risk of criminalization in instances of not disclosing to a sexual partner and not using precautions—when it is precisely because women too often lack autonomy in their sexual relations as a result of violence, cultural norms, and/or economic subordination that they may be unable to disclose or to negotiate safer sex.

“For testing to be part of a comprehensive, effective and human rights-based prevention effort, it should provide the people tested the opportunity to understand and ask questions about HIV/AIDS transmission and care and treatment and to get help on the difficult matter of disclosing their HIV status.”(Csete and Elliott, 2006, at 7) As noted in the WHO/UNAIDS guidance (2007, at 36), testing should be accompanied by counselling for people about potential legal liability for not disclosing HIV-positive status to their partners, as well as other legal issues such as protection from HIV-related violence and discrimination. While there is “no doubt that the absence of qualified counsellors has been a bottleneck at various times, particularly in heavily affected communities,” this is “a question of resources and program priorities,” and “many low-income countries have shown that relatively rapid training of HIV counsellors is possible when resources are available.”(id.)

## Facilitating Access to ART

### Key points

- One important benefit of wider testing is the opportunity to identify people with HIV at an earlier stage. This has led to debate over whether ART availability should be a precondition for making HIV testing more routine, or whether this is unwarranted given that HIV testing has health benefits short of ART.
- According to the WHO/UNAIDS guidance, access to ART “should not be an absolute prerequisite” for the implementation of PITC, but there “should at least be a reasonable expectation that it will become available within the framework of a national plan to achieve universal access to antiretroviral therapy for all who need it.”
- There is increasing evidence that a shortage of medical staff, rather than low uptake of HIV testing, is hindering rapid scale-up of treatment, at least in some resource-poor settings.

Proponents of relaxing pretest counseling and informed consent requirements have argued that some curtailment of the right to informed consent may be justified to ensure that new medical advances, particularly ART, will reach people living with HIV on a large scale. This was the main justification for the Botswana program, which stated that “earlier identification through routine testing of HIV-positive patients will allow earlier [ART] enrolment.” The Botswana minister of health justified routine testing with reference to the right of access to care, referring to a “right not to die before your time because a doctor did not perform relevant tests and diagnostics.”(Crewe and Viljoen, 2005, with reference) In a population-based study in Botswana undertaken 11 months after the introduction of routine testing, 93 percent of participants believed that this policy would increase access to ART, but 43 percent also believed that it would lead people to avoid going to the doctor for fear of being tested without consent (Weiser, et al., 2006).

One important benefit of wider testing is the opportunity to identify people with HIV sooner after infection. Where ART is available, maximum benefit in terms of reduced morbidity and mortality is obtained when HIV infection is diagnosed before end-stage immunodeficiency. In the absence of PITC, many people start treatment very late when they are already experiencing wasting, and very advanced disease and low body mass index are repeatedly associated with poor response to ART in African studies. Researchers in Uganda looked at the effects of introducing “routine testing” on the clinical profile of HIV-positive patients in their care, and found that over the course of a year, routine testing shifted the profile strongly toward asymptomatic patients who needed less intensive clinical management when they started treatment. Prior to “routine testing,” 65 percent of patients had CD4 counts below 200 and three-quarters were symptomatic. After routine testing was introduced, the proportion with CD4 counts below 200 fell to 45 percent and the proportion that were symptomatic fell to 55 percent. Although the clinic that shifted to “routine testing” had more patients under care as a result of “routine testing,” these patients were likely to have a better chance of success when they began treatment (Alcorn, 2006, with reference to Andia, et al., 2006).

Crewe and Viljoen (2005) suggest that the “goal of greater access to ARV medicines is unimpeachable,” but “the assumption that earlier identification of HIV cases through routine testing will achieve that goal, or is necessary to achieve that goal, is debatable.” While routine

testing may indeed identify more asymptomatic patients, the reality is that in most low- or middle-income countries, there is far from a guarantee that the tested person will receive ART, due to the unavailability or unaffordability of these medications in many settings. In most countries, treatment rollout programs are not nearly universal, often with more coverage in urban areas and little or no coverage in rural settings. Often, some of the most vulnerable populations, such as people who inject drugs, prisoners, and children, have little or no access to ART (WHO, UNAIDS, UNICEF, 2007). Even where ART is widely available, the general requirement is that usually only HIV-positive people with a CD4 count of less than 200 qualify for ART; and therefore a positive test does not necessarily mean immediate access to treatment. Finally, in some resource-poor settings at least, there is increasing evidence that shortage of medical staff, rather than low uptake of HIV testing, is hindering rapid scale-up of treatment (Médecins sans Frontières, 2007). Current testing and treatment scale-up campaigns often neglect to make this clear:

Often the uninformed person living with HIV may find themselves in a place of having to deal with an unexpected load of repeated testing and challenges that they were initially not fully aware of as a result of the simplified counselling. One lady in Botswana expressed the view that had she been fully informed of the implications of HIV testing before testing she would probably have opted out as knowing her status has caused her more anxiety than not knowing.<sup>15</sup>

While some people clearly indicate that ART availability should be a necessary precondition for making HIV testing more routine (e.g., Cameron, 2006), others have advocated that the use of routine testing should not be restricted to settings in which ART is available (De Cock, Bunnell, Mermin, 2006). They say that routine testing would be justified “wherever basic HIV care and prevention are available” and that this “would improve efforts at prevention, allow infected persons to receive care such as cotrimoxazole prophylaxis, and normalize HIV testing.”(id.) According to the WHO/UNAIDS guidance on PITC in health facilities, access to ART “should not be an absolute prerequisite” for the implementation of PITC, but there “should at least be a reasonable expectation that it will become available within the framework of a national plan to achieve universal access to antiretroviral therapy for all who need it.”(WHO/UNAIDS, 2007, at 8) In addition, the guidance states that PITC “should be accompanied by a recommended set of HIV-related prevention, treatment, care and support services,” including

education, psychosocial and peer support for management of HIV; periodic clinical assessment and clinical staging; management and treatment of common opportunistic infections; co-trimoxazole prophylaxis; tuberculosis screening and treatment when indicated, preventive therapy when appropriate; malaria prevention and treatment, where appropriate; STI case management and treatment; palliative care and symptom management; advice and support on other prevention interventions, such as safe drinking water; nutrition advice; infant feeding counselling; and *antiretroviral treatment, where available.* (id., at 31)

There is no question that, when an HIV diagnosis is made earlier in the course of the disease, health benefits can accrue for persons testing HIV positive even in the absence of ART. But, as Rennie and Behets (2006) say, treatment availability “cannot be used as an argument in favour of implementing routine testing in African or Asian countries where antiretroviral treatment

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<sup>15</sup> PLWHA in Botswana speaking at Press Conference ARASA/BONELA Consultative meeting on HIV Testing Gabarone Botswana, March 13, 2006.

coverage is currently dismal, and where it may take years before accessible and appropriate treatment, care and other services become widely available.” Mentioning the example of the Democratic Republic of Congo, where only two percent of patients with symptoms of AIDS have access to ART (WHO/UNAIDS, 2005b), they ask:

How should the issue of routine HIV-testing policies be approached in such circumstances? With little prospect of treatment, would a VCT approach be ethically more appropriate, even in areas of high prevalence, despite the known shortcomings of VCT? To what extent does access to treatment have to be “assured” (nationally, regionally or locally) before a routine HIV-testing policy is justified on human rights grounds? (Rennie and Behets, 2006)

According to Metz (2005), only policies of routinely offering HIV testing with an opt-in approach, but not opt-out approaches, are ethically justified when testing does not serve as a gateway to treatment and when ART “is unaffordable or otherwise unavailable.”

Those consulted in the course of writing the paper agreed with WHO and UNAIDS that access to ART should not be an absolute prerequisite for the implementation of PITC, but highlighted that, even if there is a reasonable expectation that ART will become available in a particular country, some populations may be left out. Speaking about people who inject drugs, Kasia-Malinowska Sempruch, director of OSI’s International Harm Reduction Program, referred to WHO’s own statistics according to which in Eastern Europe and Central Asia, people who inject drugs account for more than 70 percent of HIV cases but represent only about 24 percent of the people receiving ART (WHO/UNAIDS, 2006b). She added: “The reality is that if people who use drugs are tested, it often happens against their will or even without their knowledge. And it is not done to benefit them, but to exclude them. Those people who are on drugs who do receive treatment are the first to suffer if there are interruptions in the supply of medications—they are the bottom of everyone’s priorities.”

## Assisting HIV Prevention

### Key points

- There is evidence that people who seek voluntary testing, who learn they are HIV-positive, and who receive counseling are more likely to take precautions to protect their partners than people who do not know their serostatus.
- There is also evidence that the nature and duration of prevention counseling might influence its effectiveness. But there is no evidence specifically about the value of pretest counseling for prevention, and no studies have been undertaken where testing provided with pretest counseling was compared with testing without pretest counseling or abbreviated pretest counseling.
- It is not known whether the reductions in risk behaviors observed in the studies of people who have initiated VCT themselves will be replicated among people who accept PITC. It is also self-evident that HIV testing cannot be an effective gateway to prevention unless people who test positive can safely disclose their HIV status and gain access to a full range of prevention options.

Proponents of relaxing pretest counseling and informed consent requirements also argue that it is justified because, as more people learn their HIV status, this will assist HIV prevention efforts.

### Review of the evidence

#### Reducing the risk of HIV in infants

ART combined with HIV and infant-feeding counseling is highly effective in reducing the risk of HIV in infants (Chou, 2005b). Although combination ARV regimens, given during pregnancy, labor, and in the postpartum are most effective, in resource-limited settings, ARV prophylaxis at the time of labor and/or to the infant shortly after delivery has also been shown to reduce mother-to-child transmission (MTCT) (WHO/UNAIDS, 2006; Jackson, et al., 2002). With these interventions and through safe infant feeding measures, new HIV infections in children are becoming increasingly rare in several parts of the world. These advances in the prevention of MTCT have increased the benefits of HIV testing during pregnancy, leading many to recommend routine opt-out testing for all pregnant women (Institute of Medicine, 1999; American Academy of Pediatrics and American College of Obstetricians and Gynecologists, 1999; CDC, 2006).

#### The impact on HIV testing and counseling on HIV transmission rates

There is also some evidence that people who know they are HIV-positive are more likely to take precautions to protect their partners than people who do not know their serostatus (Weinhardt, et al., 1999; Wolitski, et al., 1997; Higgins, et al., 1991; *The Voluntary HIV-1 Counseling and Testing Efficacy Study Group*, 2000; Glick, 2005, with further references), thus limiting the number of secondary infections compared to individuals who are unaware of their HIV serostatus. The importance of this for HIV prevention is enhanced when factoring in the value of ART in reducing a person's viral load. Because viral load is the chief biological predictor of HIV transmission (Quinn, et al., 2000; Tovanabutra, et al., 2002; Castilla, et al., 2005; Pedraza, et al., 1999), reduction in viral load through timely initiation of HAART might reduce transmission even for HIV-infected patients who do not change their risk behavior (Sanders, et al., 2005).

These findings have supported the recent focus on identifying people who are not yet aware of their HIV infection and on developing prevention programs for people who are HIV-positive (Schieter, 2006).

Weinhardt, et al. (1999) conducted a meta-analysis of 27 published studies of HIV counseling and testing interventions promoting reductions in sexual risk behavior. Consistent with the findings of Wolitzki, et al. (1997), they concluded that HIV counseling and testing can facilitate behavior change among individuals found to be seropositive as well as among serodiscordant couples, but is not an effective primary prevention strategy for uninfected participants (Weinhardt, 1999). This has more recently been confirmed by studies in Africa (Motovu, et al., 2005). Those who were seropositive and discordant couples reported more behavior change (reduced unprotected intercourse and increased condom use) than those who learned they were HIV-negative. In fact, HIV-negative participants reported no more change in sexual behavior than participants who were not tested at all.

More recently, it was reported that VCT has been associated with a reduction in non-regular partner numbers and an increase in condom use over six months of follow-up, especially among HIV-positive individuals, among a sample of 5200 individuals who had undergone VCT in Rwanda. Condom use doubled with non-regular partners (Mukabarisi, et al., 2006). Finally, Marks, et al. conducted a meta-analysis of studies in the United States comparing high-risk sexual behavior among people who are either aware or unaware that they are infected with HIV. They found that the prevalence of unprotected anal or vaginal intercourse with uninfected partners was on average 68 percent lower for HIV-positive persons who were aware of their status than it was for HIV-positive persons who were unaware of their status. They did note a number of methodological limitations of the primary studies (Marks, et al., 2005). Most importantly, the studies used self-reported sexual behavior. Self-reports are open to socially desirable responding, and some HIV-positive persons may underreport unprotected sex with at-risk partners (Catania, et al., 1990). Glick (2005) notes further limitations: follow-up periods in many studies are too short—often just several months—to gauge long-term impacts; and study results may reflect self-selection into VCT of individuals who are predisposed to make behavior changes, suggesting the need to interpret the results of the studies “with a good deal more caution than has been the case.” Glick concludes:

Reductions in risk behaviors reported in these studies may have limited relevance for inferring the outcomes from a scaled-up program that attempts to achieve broad coverage. Even individual-level randomized trials may have low external validity, and hence they may not provide meaningful estimates of behavioral outcomes under an expanded program. A key problem is that expansion is likely to be associated with significantly reduced costs (broadly defined) to using the service, and this will draw in new participants who are likely to respond differently than existing ones who presumably value the service more highly. (Glick, 2005)

No clinical trials have evaluated the impact on transmission rates of testing and counseling compared with no testing and counseling on HIV transmission rates. One prospective U.S. study of 144 serodiscordant heterosexual couples who received counseling and reported reduced risky behaviors found no seroconversion after 193 couple-years of follow-up (Padian, et al., 1993). A prospective African study found that the rate of seroconversion among uninfected female partners of HIV-positive men was 6 to 9 per 100 person-years, compared with 22 per 100 person-years in women with untested partners (Allen, et al., 1992). Two observational studies found that testing plus counseling was associated with a moderate (about 33 percent) decrease in

sexually transmitted diseases among those who tested positive but that it increased the risk among those who tested negative (relative risk, 1.27 to 2; Chou, 2005b with reference to Otten, et al, 1993; Chamot, et al., 1999). Two randomized trials found that more interactive counseling was more effective than standard counseling in reducing sexually transmitted disease rates among HIV-positive women (Wingood, et al., 2004) and seronegative heterosexual persons (Kamb, et al., 1998b), although there were too few new HIV infections to detect differences in HIV rates. However, the first randomized trial to report HIV incidence under different VCT strategies in Africa found no significant difference in HIV incidence among HIV-negative employees under two randomly allocated, workplace-based VCT strategies, despite a major difference in acceptability and the fact that VCT acceptors received counseling with personalized risk reduction planning (Corbett, et al., 2007).

Finally, a number of cross-sectional studies found that HIV-positive people who use drugs report less risky behaviors than untested or HIV-negative people who use drugs (Desenclos, 1993; Schlumberger, 1999; Celentano, 2001), but one randomized trial (Calsyn, et al., 1992) and one prospective study (McCusker, et al., 1994) found that testing plus counseling was not associated with decreased risk behaviors among people who use drugs (Chou, et al., 2005b).

Despite evidence that knowledge of HIV-positive status reduces some high-risk behaviors, the United States Preventive Services Task Force concluded that “there is insufficient evidence with which to accurately estimate the effects on transmission rates.”(Chou, et al., 2005, at 66) However, in a widely cited study, Marks, Crepaz, and Janssen estimated that sexual transmission of HIV in the United States from persons who are unaware of their infection is 3.5 times higher than among persons who are aware of their infection (Marks, Crepaz, and Janssen, 2006). They concluded that, if all people unaware of their infection could learn of their serostatus, and the prevalence of unprotected anal or vaginal intercourse with at-risk partners declined by 57 percent (based on the data from their earlier meta-analysis: Marks, et al., 2005), then the overall number of new sexual HIV infections in the United States could, theoretically, be reduced by 31 percent per year (Marks, Crepaz, and Janssen, 2006). Baggaley, et al. (2006) modeled the impact of ART use in resource-poor settings, concluding that “HIV epidemics in sub-Saharan Africa are not amenable to control through treatment, regardless of the extent of roll-out, and must be integrated with prevention methods. In the absence of substantial behaviour change of treated patients through extensive counselling, prevalence is likely to increase.”

### **The call for making testing more routine in the context of prevention**

De Cock and colleagues have argued that in high prevalence settings, especially in Africa, “a stated goal for prevention should be for every citizen, including sexually active adolescents, to know their HIV status, and for repeat testing to occur at regular intervals, and in case of risky behaviour or impending life decisions.”(De Cock, Mbori-Ngacha, Marum, 2002, at 70) According to them, “this approach would demystify HIV/AIDS, place the responsibility for avoidance of acquiring or transmitting HIV on every individual, and empower the community to take charge of its own health.” One of the motivations of the routine HIV testing program in Botswana was that it would “identify the HIV-negative population, which will help to target prevention strategies better and help people stay negative.”(Crewe and Viljoen, 2005, with reference)

Clearly, the fact that the majority of HIV-positive people in low- and middle-income countries do not know their HIV status and may transmit HIV sexually (or through sharing of injecting equipment) to their partner(s) raises the issue of whether more routine forms of testing are justified to protect those who are uninfected. One person consulted for this paper put the question in the following terms: “We have always protected the right of the person to refuse testing, but don’t those who are not infected have a right to health or not to be infected?”

However, while implementing more routine forms of HIV testing would likely increase the number of people aware of their HIV status, some have speculated that HIV testing that includes neither quality pre-test counseling nor truly informed consent may lose at least some of its power as a prevention tool. For example, Crewe and Viljoen (2005) have said that it is “striking that routine testing proposals de-emphasize the one thing that is likely to assist people in adopting safer sex practices ..., full pre-test counselling and information.” They conclude that, for testing to succeed as a prevention strategy, information and counseling are essential, and that there is scant likelihood that a routine opt-out testing approach that de-emphasizes counseling will have a more beneficial impact on HIV prevention than increased access to VCT programs. Similarly, Kenyon says that:

behavioral change is the product of understanding and ownership of one’s health and a sense of responsibility to protect the health of others. These changes occur not from the act of testing blood alone, but from the pre-test counselling, the information given, and the informed and voluntary consent that accompany them. For RHT [routine HIV testing] to be successful in Botswana and elsewhere in its public health goals, it must not dilute the participation of patients in their own health care or neglect individuals’ rights to autonomy, dignity, and information. (Kenyon, 2005, at 22)

According to Koo, et al. (2006), however, “a close look at published studies evaluating combined counseling and testing programs challenges the belief in a benefit of pretest counseling [for prevention].” They point out that finding out one is HIV positive reduces risk behaviors, while finding out one is negative does not necessarily result in the same outcome—despite the fact that pretest counseling is offered in both cases. They speculate that this “suggests that discovering one is HIV-infected and the subsequent counseling around this diagnosis explains the reduced risk behavior, rather than pretest counseling.” They continue by saying that “pretest counseling is not risk-reduction counseling but rather informational counseling with a focus on assessing readiness to test” and conclude that “counseling might best be conducted after the patient knows their status, allowing for tailored messages dependent on serostatus.”

According to a recent systematic review of the literature (Chou, et al., 2005), some randomized trials (Rotheram-Borus, et al., 2004; Rotheram-Borus, et al., 2001; Wingood, et al., 2004; Fogarty, et al., 2001; Kalichman, et al., 2001; EXPLORE Study Team, 2004), but not all (Coates, et al., 1989; Cleary, et al., 1995; Patterson, Shaw, and Semple, 2003; Richardson, et al., 2004) found that more-intensive counseling or counseling tailored to participant needs was associated with greater reductions in risky behaviors than less-intensive or standard counseling. Counseling methods varied greatly across the trials, however, and it was therefore difficult to draw definitive conclusions about the added value of pretest counseling for prevention.

More generally, Wolitski, et al., observed that “motivating individuals to change their HIV risk behaviours is best achieved by comprehensive efforts that provide for repeated intervention contacts across multiple settings using a range of intervention strategies and messages” and that the “ultimate goal of these efforts should be to change the behaviours and norms of entire communities in a manner that will perpetuate the reinforcement of HIV risk-reduction and help-

seeking practices of at-risk community members.”(Wolitski, et al., 1997, 65) A systematic review of studies of HIV-prevention interventions for people living with HIV (Schietinger, with reference to Crepaz, 2006) determined that the interventions associated with reducing sexual risk behaviors:

- were based on behavioral theory
- were specifically focused on HIV transmission risk behaviors (more than 2/3 of sessions)
- provided skills building (e.g., correct condom use, problem-solving)
- were delivered by health care providers or professional counselors
- were delivered to individuals on a one-to-one basis
- were delivered in an intensive manner (more than 10 sessions or 20 hours total)
- were delivered over a long duration (greater than 3 months)
- were delivered in settings where people with HIV receive services
- addressed a myriad of issues related to coping with one’s serostatus, medication adherence, and HIV risk behavior.

## **Conclusion**

There is evidence that people who seek voluntary testing, find out they are HIV-positive, and receive counseling are more likely to take precautions to protect their partners than people who do not know their serostatus. There is also evidence that the nature and duration of prevention counseling might influence its effectiveness. But there is no evidence specifically about the value of *pretest* counseling for prevention, and no studies have been undertaken where testing provided without pretest counseling (or simplified pretest counseling) was compared with testing with pretest counseling. There are also no studies that have isolated client versus provider initiation or opt-in versus opt-out PITC approaches as variables affecting prevention/behavior change.

In general, the existing evidence supports greater emphasis on efforts to increase the number of people who are aware of their HIV infection so that they can be counseled and supported to take precautions to reduce the spread of HIV to their sexual partners. However, a number of questions remain.

One of them is whether the reductions in risk behaviors observed in the studies of people who have initiated VCT themselves will be replicated among people who accept PITC, but may be less ready or motivated to disclose their status and change their behavior than people who initiate testing themselves (Glick, 2005). More broadly, this relates to the fact that—as discussed above—increasing uptake of testing is not enough, and efforts need to focus equally on making it possible for people testing positive to safely disclose their HIV status and take up prevention and treatment options.

Indeed, even knowledge and disclosure of HIV status does not begin to address the range of structural and human rights issues that affect individuals’ ability to protect themselves and others from HIV—issues that must be factored into the costs and benefits of relaxing requirements of consent and counseling for HIV testing. People interviewed for this paper cautioned against overstating the value of testing and counseling for HIV prevention in settings where other barriers may exist that make it difficult if not impossible for people to disclose their HIV status and/or change their behaviors once they find out that they are HIV-positive. This is especially true for women. Evelyn Serima, HIV/AIDS technical specialist, ILO Sub Regional Office for Southern Africa, said:

In the African context, where women are often denied any rights, how often will a woman who finds out she is HIV-positive feel safe to disclose to her partner or insist on taking precautions? Simply testing people will make little difference, particularly if we don't counsel them and support them appropriately at the time of testing.

During studies in Papua New Guinea, Jamaica, and India, women reported that bringing up the issue of condom use, with its inherent implication that one partner or the other has been unfaithful, can result in violence (Gupta, 2002, with reference to George and Jaswal, 1995; Jenkins, 1995; Wyatt, et al., 1992). Gupta says:

To protect women from HIV infection we must find ways to empower them. This means implementing policies and programmes that increase women's access to education and information and to productive resources, such as land, income, and credit. It also means providing women with HIV prevention technologies that they themselves can control. ... We must also increase social support for women by facilitating their opportunities to meet in groups and organise, allowing them to draw strength from numbers and to derive practical solutions from each other. Simultaneously, we must promote sexual and family responsibility among young boys and men and enable them to examine the damaging effects of prevalent notions of masculinity and male power. Finally, we must recognise that violence against women is a gross violation of women's rights that has important implications for the health of women and communities. If we are to contain the HIV epidemic, we must tackle its root cause—gender inequality. (Gupta, 2002; see also Gupta, 2000; American Foundation for AIDS Research, 2005)

Discussing a different context, people from Eastern Europe and Central Asia interviewed for this paper highlighted that the vast majority of injecting drug users in countries in the region do not even have access to clean injecting equipment and to drug treatment. They pointed out that in theory HIV testing may help prevention, but that most people in the region who test positive cannot even get access to the prevention tools that would enable them to protect their injecting partners—and that those who live where there is one of the few needle exchange programs risk being arrested because police regularly harass them if they go to such a program.

Another context in which people are often denied access to any HIV-prevention tools, even including condoms, is prisons. A recent WHO report acknowledges that “[k]nowledge of HIV status alone is not sufficient to prevent HIV transmission when the means that would enable a person to take steps to reduce that risk, short of being able to stop the behaviour that creates the risk, are not accessible in prison.”(WHO, UNODC, UNAIDS, 2007)

Generally, there is a concern that discussions about making HIV testing more routine do not sufficiently take into account the often disempowering context in which people have to deal with information about their HIV status, a context that may be characterized by poverty, patriarchy, prejudice, stigma, and/or homophobia (Crewe and Viljoen, 2005); as well as a concern that the emphasis on HIV testing could eclipse prevention programs that have proven their worth but have not been introduced in many settings or scaled up appropriately in others (Rietmeijer and Thrun, 2006). While one could argue that HIV testing is equally important to these interventions, the point is that the effectiveness of testing should not be assumed when weighing the costs and benefits of relaxing consent and counselling requirements.

Finally, as discussed above, if governments want to maximize the usefulness of testing as an HIV prevention strategy, focusing on mainstreaming testing within clinical settings may have relatively limited impact. During early infection (the two-and-a-half month period after HIV seroconversion), the average rate of HIV transmission via heterosexual intercourse is five- to

twelve-fold higher than during established infection. More than 40 percent of people with newly acquired HIV infection transmit it to their partners within approximately five months (Wawer, et al., 2005; see also Pilcher, et al., 2004). Specific efforts need to be made to identify primary HIV infection in order to reduce the spread of HIV that might otherwise occur during the acute phase of HIV disease. Many of the people who have sex or inject drugs rarely, if ever, see health care providers. This means that for prevention purposes, it would be a mistake to focus on PITC without also scaling up interventions outside the health system. Rather, it will be important to find ways to encourage sexually active people, particularly men, to be tested, and to make testing and counseling easily accessible to them, for example by providing mobile VCT units at work settings and places where sex, alcohol, or cigarettes are sold and served.

## Reducing Stigma and Discrimination

### Key points

- Making testing more routinely available may help reduce the *stigma related to HIV testing*. However, a policy of routinely offering and recommending opt-in testing may lessen the stigma of being tested as much as a policy of routine opt-out testing—because, under both policies, testing is offered to everyone.
- Testing may also contribute to reducing the *stigma and discrimination related to HIV*, particularly if treatment is accessible and HIV is increasingly perceived as a chronic but treatable condition. However, this is unlikely to change the perception that HIV infection results from “immoral” behavior such as extra-marital sex, homosexuality, prostitution, or injecting drug use.
- Testing and treatment may thus be one component in helping overcome certain forms of stigma and discrimination, but only further research will be able to tell the extent to which they can contribute to lessening stigma overall.

Those who support more routine forms of HIV testing and propose relaxing the counseling and informed consent requirements also argue that this is justified because when testing and counseling is offered to everyone, individuals do not feel singled out as “at risk” for HIV. Thus, the stigma of being tested will be lessened if everyone is offered the test and many people are tested (Schietinger, 2006, at 61). This is borne out in the population study undertaken in Botswana 11 months after introduction of the routine opt-out testing program, in which 60 percent of respondents felt that routine testing reduces the stigma of getting tested (Weiser, et al., 2006). Interviews with most persons tested anonymously in a mobile VCT program in marketplaces in Zimbabwe mentioned the stigma of being tested as a factor discouraging HIV testing (Morin, 2006). However, this does not necessarily justify relaxing counseling and informed consent requirements, as suggested by those favoring a policy of routine opt-out testing. A policy of routinely offering and recommending opt-in testing may lessen the stigma of being tested as much as a policy of routine opt-out testing—under both policies, testing is offered to everyone.

Proponents of routine testing also suggest that with widespread testing more people learn their HIV status and can access ART, and that HIV/AIDS will then come to be perceived as yet another chronic, manageable illness (Castro and Farmer, 2005). In this sense, proponents of routine testing depart from the school of AIDS “exceptionalism,” which argues that AIDS is a uniquely stigmatized disease requiring specific human rights protections. In the words of the Botswana minister of health, “[i]n a highly infected society ... there is simply no place for exceptionalism that feeds stigma, induces fear, and curtails standard diagnostic care.” (Crewe and Viljoen, 2005, with reference) However, as stated by Csete and Elliott,

Whether routine testing without consent or counselling would reduce stigma and discrimination by treating HIV/AIDS more like other diseases is an empirical question that has not been tested in research. It would be difficult to test such a hypothesis in ethical ways. In countries where certain categories of people—such as all people who enter military service, all prisoners, or all immigrants—are subjected to mandatory or compulsory HIV testing, there is no evidence that suggests that the routinization of testing reduces stigma and discrimination. (Csete and Elliott, 2006)

HIV/AIDS does remain exceptional among infectious diseases in the degree to which it is associated with severe, even demonizing, stigma in the public mind and with abusive responses from individuals and communities. There remains relatively little investment in most countries in real protection from HIV-related discrimination and abuse.

It is true that once HIV is perceived as a chronic but treatable condition, one of the factors that amplifies stigma—fear of contagion and inevitable death—is lessened. However, stigma is much more than fear of contagion. It is also related to the perception that HIV infection results from “immoral” behavior such as extra-marital sex, homosexuality, prostitution, or injecting drug use (Crewe and Viljoen, 2005). It is a tool used by cultures to exclude those felt to have broken extant rules. The dominant stereotype of people living with HIV is a stigmatizing one that casts them as immoral (Stanley, 1999). While downgrading HIV to the status of a “manageable disease” may go some distance toward addressing HIV/AIDS-related stigma, it is unlikely on its own to alter deeply rooted perceptions of the moral stature of people living with AIDS (Furber, et al., 2004).

Testing and treatment may thus be one component in helping overcome stigma and discrimination, but only further research will be able to tell the extent to which they can contribute to lessening stigma. In the population-based study undertaken in Botswana, Wolfe, et al., (2006) found that perceived access to ART was strongly and significantly related to not holding stigmatizing attitudes and to not having “anticipated stigma” (belief that adverse social consequences would arise should they test positive and disclose their status to others). On the other hand, they found significant ongoing stigmatizing attitudes and anticipated stigma, suggesting that treatment access may be a necessary, but not sufficient, part of stigma reduction. The fact that there is still significant HIV stigma in countries where there is good access to treatment also suggests that access to treatment is not enough to eliminate stigma. Testing and treatment cannot be expected to end the stigma that is deeply located in social structures, in the history of the response to the HIV/AIDS pandemic, in the ways in which health systems are structured, and in the ways in which health care workers often behave toward people living with HIV (Chingore, forthcoming). In order to effectively reduce stigma, as research increasingly shows, it is necessary to engage with institutions, attitudes, culture, and beliefs (UNAIDS, 2002/03; Burris, 2002).

## Human Rights Abuses and Other Negative Consequences Following Testing

### Key points

- People who argue for more routine forms of HIV testing with reduced emphasis on pretest counseling and informed consent assume that few human rights abuses and other negative consequences will result from this approach—or in any case that the benefits of HIV testing outweigh the prospect of such abuse.
- More research will be needed to investigate this, but the research that does exist suggests that concern about negative outcomes may be justified.
- With regard to potential negative outcomes for women, studies show that a significant minority of women tested for HIV report negative outcomes with disclosure of their HIV status, including blame, abandonment, violence, anger, stigma, and depression.
- In many countries, populations most at risk of HIV transmission are also more susceptible to coercion, discrimination, violence, abandonment, incarceration or other negative consequences upon disclosure of an HIV-positive test result.

People who argue for more routine forms of HIV testing with reduced emphasis on pretest counseling and informed consent assume that few human rights abuses and other negative consequences will result from this approach—or in any case that the benefits of HIV testing outweigh the prospect of such abuse. For example, while De Cock and colleagues (2002) recognized that some women refuse HIV testing because of “stigma, discrimination, and potential consequences such as domestic violence, abandonment, or murder,” they noted that the frequency of these events is uncertain. In response, Csete, Schleifer, and Cohen pointed out that:

Indeed, the frequency of domestic violence in particular will always be uncertain since it is a hidden crime and is aggressively prosecuted in very few places. But our work and that of other investigators indicate that women frequently face spousal violence when they reveal that they are HIV positive or even show interest in learning their status or obtaining care. Such violence is deeply rooted and underpinned in many societies by inequitable laws on property, inheritance, and divorce that keep women economically dependent on their spouses and limit their choices in leaving dangerous unions. To trivialise or minimise HIV/AIDS-linked violence and abuse against women only risks perpetuating this abuse and also the stigma associated with AIDS, which is itself a major impediment to fighting the epidemic. (Csete, Schleifer, and Cohen, 2004, with reference to Human Rights Watch, 2003)

Clearly, more research is needed to investigate whether relaxing informed consent and counseling requirements affects people’s experiences of abuse or other negative outcomes as a result of testing HIV-positive. The existing research suggests that concern about negative outcomes may be justified. In the population-based survey in Botswana, 14 percent of participants believed that the policy of routine opt-out testing could increase gender-based violence related to testing. Among participants who had been tested, 2 percent of those tested at VCT centers, but 6 percent of those tested by routine testing reported poor treatment from others related to testing (Weiser, et al., 2006). A review of 17 studies from Africa and Southeast Asia

concluded that 4 to 28 percent of women reported negative outcomes following the disclosure of their status, including blame, abandonment, violence, anger, stigma, and depression (Medley, et al., 2004). Of these women, between 2.5 percent and 14.6 percent reported having faced violence as a reaction to disclosure of their HIV status. In another, more recent study in Zambia, 28 percent of women who tested HIV-positive reported adverse events, including physical violence, verbal abuse, divorce or separation (Semrau, et al., 2005).

The highest rates of negative outcomes have been reported by women tested in antenatal clinics, and the lowest rates by women tested at VCT sites. It has been suggested that women who are tested at antenatal clinic sites are less likely to have a chance to think about testing or prepare themselves or their partners for testing; therefore they are both less likely to disclose results to their partners and more likely to be victims of violence when they do (Amon, 2006b).

In a survey of women in Tanzania three months after they received testing and counseling, the women who were HIV-positive reported more violence from their current partners than the women who were HIV-negative (Maman, 2002).

Studies thus show that a significant minority of women report negative outcomes following disclosure that they are HIV-positive. At the same time, they show that the majority of HIV-positive women surveyed report positive outcomes with disclosure of their HIV status, including less anxiety, fewer symptoms of depression, increased social support and, in many cases, a strengthening of the relationship with their partners (USAID/Synergy, 2004). This finding may suggest “that the considerable scaling up of counseling and testing programs now underway may pose a lower risk of negative outcomes of disclosure for HIV positive women—and suggest that there will be greater support for women—than expected, even by the women themselves.”(id., at 24) However, the study says:

Women who currently disclose do so selectively, choosing to whom they disclose and when to disclose, likely based on how they anticipate their partner to react. While a relatively small proportion of women report negative outcomes, this may represent a large absolute number of women as more women learn that they are HIV positive and disclose their status to others. (id.)

Thus, the study concluded, it will be important not to trivialize the risk of negative outcomes and instead find strategies for the scale up of HIV testing “that will allow women to maximize the beneficial outcomes and minimize the harmful aspects of disclosing their HIV serostatus.”(id.) It will also be critical to compare negative outcomes among women who test positive in a VCT setting with the negative outcomes among women who test positive in an opt-out PITC setting.

There are four specific reasons to integrate a focus on violence within HIV testing and counseling:

- violence acts as a barrier to women seeking HIV testing and counseling services;
- violence acts as a barrier to women disclosing HIV test results to their sexual partners;
- violence acts as a barrier for women to negotiate HIV risk reduction with partners; and
- violence in women’s relationships is likely to add to their post-test support needs.(WHO, 2006, at 36)

It has been suggested that “awareness about gender and violence” be incorporated into testing and counseling for HIV (Heise, 2006) and that some screening of women most at risk of negative outcomes of disclosure—as well as targeted, intensive counseling to help such women,

especially those already exposed to domestic violence and sexual coercion—could help women minimize abuse following disclosure (Medley, et al., 2004, at 305). Other researchers have noted that if the two partners in a sexual relationship can be counseled together—which costs more in outreach time and is not always possible—abusive situations may be effectively defused (*Voluntary HIV-1 Counseling and Testing Efficacy Study Group*, 2000). However, a number of studies point to a strong reluctance on the part of many persons to test with their partners (Glick, 2005, at 348). Typically, few couples come in for testing, despite efforts to encourage couples to test. One barrier to more couple testing may be that many women who would like to have themselves and their partners tested lack the power to get their partners to go along. In addition, in a recent study, there were no significant differences in reported adverse social events between women counseled as individuals or as part of a couple (Semrau, et al., 2005).

In almost all low- and middle-income countries, unequal gender relations are reflected in the HIV epidemic. Women and teenage girls are infected at higher rates than men and have significantly less social and economic power to take measures to protect themselves from infection (Gupta, 2002). They are also frequently blamed for the infection of their partners and suffer from extreme forms of retribution. In many cases, they have no inheritance rights, are subjected to wife inheritance and other forms of oppression, and generally carry the main responsibility for care and support of family members who are living with HIV and AIDS. As stated by Crewe and Viljoen, the

ways in which routine testing can further disadvantage women must be recognized.... Far from being a means of “empowerment,” routine testing and possible disclosure may make the position of women much more precarious. Not only is confidentiality of test results often breached, but as women are more likely than men to come into contact with the health system (largely because of antenatal services), routine testing may reinforce stereotypes about women being the principal bearers of HIV infection. Women may thus suffer very greatly from routine testing—emotionally, physically and economically. Unless tests are offered in an environment of establishing first what ongoing support the woman will need, what kind of support it is possible the woman may have and, in the absence of family or community support, who she will be able to turn to—the basic fundamentals of good pretest counselling—she should not be offered the test. In addition, for many women the option to “opt out” of HIV testing in the face of pressure from a medical professional will not be realistic. (Crewe and Viljoen, 2005)

In their guidance on PITC in health facilities, WHO and UNAIDS acknowledge the concern that “in some settings increased knowledge and disclosure of HIV status may be accompanied by increased stigma, discrimination, abandonment and violence.”(WHO/UNAIDS, 2007, at 16) According to them, these concerns “underscore the importance of adequate training and supervision for health care providers, particularly in the processes of counselling, obtaining informed consent and maintaining confidentiality of HIV test results.”(id., at 17) In addition, “close monitoring and evaluation, especially in the implementation stages, will be needed to ensure that provider-initiated HIV testing and counselling is implemented in a way that minimizes adverse outcomes and maximizes benefits for patients.” (id.)

Generally, Csete and Elliott comment:

While measures may be taken to mitigate negative outcomes of HIV testing, it is clear that even where the three Cs are respected as a matter of policy, access to such measures is bound to be limited. In addition, for some people, such as women in violent relationships, the only action that may reduce the

harm they face from being known to be HIV-positive may be leaving the relationship, which may be impeded by factors that counselling and information cannot address. (Csete and Elliott, 2006)

As Rennie and Behets point out, “there should be a sober recognition that while needs have been identified and policies have been formulated, many programmes to reduce stigma and provide psychosocial support for women and girls in low-income countries are currently non-existent, in the design phase, overburdened or underfunded (2006, at 55). They conclude that in the current circumstances, routine opt-out HIV-testing policies could expose women and girls to risks of significant harm.

People interviewed for this paper expressed particular concern about abuses that sex workers, men who have sex with men, people who use drugs, and prisoners could suffer in many countries if those countries were to implement PITC with an opt-out approach. WHO and UNAIDS recognize these concerns, saying that “populations most at-risk of HIV transmission may be more susceptible to coercion, discrimination, violence, abandonment, incarceration or other negative consequences upon disclosure of an HIV-positive test result.”(WHO/UNAIDS, 2007, at 25) As discussed in more detail below, they further recognize that innovative *client-initiated* approaches are needed to increase access to and uptake of HIV testing and counseling for these populations, such as services delivered through mobile clinics or in community settings. While they say that “consideration should ... be given to recommending” HIV testing and counseling to all patients attending specific health services for most-at-risk populations, such as acute care, STI or drug dependence treatment services, they also suggest that

- health care providers “will usually require special training and supervision to uphold standards of informed consent and confidentiality for these populations”;
- “additional discussion of the right to decline HIV testing, of the risks and benefits of HIV testing and disclosure, and about social support needs may be required”; and
- an opt-in approach to informed consent “may merit consideration for highly vulnerable populations.”(id.)

Persons consulted for this paper said that introducing PITC with an opt-out approach for such marginalized populations in such settings would be “the wrong priority” and could lead to unintended, negative consequences. They were concerned that this would be just another reason for them to stay away from the care they need. Mariya Savchuk, public health program director at the International Renaissance Foundation in Ukraine, added: “With all the abuse they already suffer in so-called care settings, making it even easier for people to test them without their consent is not the way to go. We need to find ways to encourage IDUs to seek VCT, in settings they know and trust. We need to allow nurses to work at needle exchanges and drop-in centers to do tests—currently the law in our country does not permit that, but it would be the best way to get people to know their status.” Raminta Stuiyte, director of the Central and Eastern European Harm Reduction Network, said that it would send out the wrong message to prison authorities if routine opt-out testing was recommended: “Often, [prisoners] have no access to VCT during incarceration—the prisons say they have neither the funds nor the staff. That is the problem. That’s what [WHO and UNAIDS] should be calling for, not for routine opt-out testing that would turn into automatic testing of all prisoners.” She was also concerned about what this would mean for sex workers, who are already often subjected to testing without their consent. “It

would mean even more involuntary testing, even greater barriers to the care and treatment they need to stay healthy—and to protect their customers.”

## Conclusions

Making testing more routinely available is likely to have many benefits, particularly if people testing positive can benefit from treatment, including ART, have access to prevention measures that enable them to reduce the risk of transmission to their partners, and the social and legal environment is such that people with or at risk of HIV:

- feel comfortable about seeing a health worker and about getting tested for HIV;
- can learn how to maintain their HIV-free status or start working on keeping their health despite their HIV-positive status;
- can disclose their status without recrimination or discrimination; and
- can live and work without discrimination on the grounds of being HIV-positive or being at risk of it.(Buchanan, 2005).

Making HIV testing more available may in some contexts also help reduce the stigma related to HIV testing and ultimately contribute to reducing the stigma and discrimination related to HIV/AIDS, though this needs to be carefully studied. In order to vastly increase the number of people who have access to HIV testing, it will be necessary to move toward a model of HIV testing that combines VCT with some form of PITC.

In order to make it feasible for health care providers to offer HIV testing to all their patients, in some settings it may also be justified to relax, to some extent, pretest counseling requirements. Human rights and public health do not require “cumbersome procedures for pretest counseling and *written* informed consent.”(Gostin, 2006) But human rights—and public health imperatives—do require that regardless of whether persons are routinely offered an HIV test in a health care setting or whether they initiate HIV testing themselves, they are able to give informed and truly voluntary consent to testing.

### **Scaling up access to HIV testing while retaining informed consent**

Great caution needs to be taken to ensure that even simplified forms of pre-test counseling allow people to understand the benefits and risks associated with HIV testing, as well as its voluntary nature, and that the actual practice of how providers go about offering the test allows people to give informed and truly voluntary consent. What it means to provide an “opportunity to refuse” a test should be clearly outlined in a code of conduct for health workers and implemented with thorough training and oversight.

This is particularly important in settings where the benefits of testing are still limited because access to ART is not guaranteed or even unlikely in the near future, necessary prevention measures are scarce or unavailable, or negative consequences or human rights abuses are widespread and protection against discrimination not provided by legislation or unenforceable in practice. But even in resource-rich countries, the risks and benefits of HIV testing remain complex and health providers need to secure specific consent for HIV testing – general consent by definition covers only those procedures whose risks and benefits are generally well known.

### Obtaining informed consent without undue burden

Established practice in HIV testing provides good models for obtaining informed consent without undue burden. Recommendations to forgo specific informed consent for HIV tests rest primarily on “a critical faulty assumption: that the process of securing informed consent presents a substantial barrier to busy health care professionals who would otherwise offer HIV testing to their patients.”(Hilton Fisher, Hanssens, Schulman, 2006) It may be more convenient for providers to undertake testing without counseling. However, experience in many settings shows that health care providers committed to increasing uptake of HIV testing, and supported by policy and professional guidelines, can do so efficiently and effectively while respecting their patients’ fundamental right to informed consent. For example, in Cape Town, a number of STI clinics offer HIV testing to all people who attend the clinic and require written consent from the patient, but have reduced the amount of time spent on counseling. Data from the first quarter of 2006 show a major increase in the number of people who test for HIV at the clinics (Richter, 2006).

Those who mischaracterize the informed consent requirement as a dated response to a past time, when stigma and the lack

*When I got pregnant at 16 I knew nothing. I didn't know I had a choice not to be tested. You can't just 'opt-out'.*  
Member of the International Community of Women Living with HIV/AIDS (ICW) from South Africa. ICW press release, XVI International AIDS Conference

of effective treatment warranted “special treatment” for HIV, seem to forget that the informed consent requirement is not a response to HIV but an established tenet of ethical and quality health care that emerged *long before* the appearance of HIV/AIDS. Ultimately, counseling and informed consent requirements

do more than merely reflect the past and continuing reality of HIV stigma and its practical consequences. They incorporate the evolving understanding of a patient’s right to information and autonomy in making treatment decisions, a right undermined by proposals for a reversion to the outdated “doctor knows best — you don’t need to know” approach. (id.)

Acknowledging that patients need to be able to make a voluntary and informed decision about whether to be tested or not, WHO and UNAIDS, in their guidance on PITC in health facilities, specify the “minimum information for informed consent” that health care providers should provide patients when recommending HIV testing and counseling (WHO/UNAIDS, 2007, at 36). They add that, depending on the local conditions, pre-test information can be provided in the form of individual information sessions or in group health information talks; and that “verbal communication is normally adequate for the purpose of obtaining informed consent.”(id.) In addition, they recommend that, at the same time as PITC is implemented, health facilities should develop codes of conduct for health care providers and methods of redress for patients whose rights are infringed and that “consideration should be given to the appointment of an independent ombudsman or patient advocate to whom breaches of HIV testing and counselling protocols and codes of conduct can be reported.”(id., at 34)

The fact that the guidance specifies minimum requirements for pre-test information sessions is a welcome development, as is the recommendation to develop codes of conduct and

methods of redress. Yet, whether these minimum requirements are sufficient to ensure true informed consent remains to be seen.

WHO and UNAIDS should develop a model code of conduct for health care providers undertaking HIV testing and counselling; guidance on the content of training on informed consent, confidentiality and counselling; and minimum standards for training and accrediting trainers. In addition, they should assist countries in implementing and overseeing such a code, in training health care personnel, and in securing the resources necessary for the training and implementation of the code of conduct.

In order to increase the capacity to undertake testing and counseling, countries should review and, if necessary, amend policies, laws and regulations in order to allow: (a) task-shifting in health facilities; and (b) lay personnel to carry out HIV testing and counseling, after receiving adequate training.

In addition, when countries considering the implementation of PITC adapt the WHO/UNAIDS guidance document to local conditions, they should acknowledge that additional information may have to be provided during pre-test information or counseling sessions. In particular, as has been discussed above and recommended elsewhere, in some settings it will be important to incorporate awareness about gender and violence into pre-test sessions, and to undertake some screening of women most at risk of negative outcomes of disclosure, as well as targeted, intensive counseling, including referral to legal services, to help such women. Finally, while group sessions may be adequate to provide some of the basic pre-test information, people should be given an opportunity to ask questions not only in the group, but also individually.

### **Could adoption of an opt-out approach to testing result in more people being tested without informed consent?**

Ultimately, a legitimate concern remains that adoption of an opt-out approach to testing, as recommended by WHO and UNAIDS, may *in practice* result in people being tested without their informed and truly voluntary consent, unless they realize they can say no to an HIV test *and* have the confidence and power to make that choice.

In settings where there is a power imbalance between test provider and client, the voluntary nature of HIV testing may be compromised, as the client may feel compelled to consent to the provider's offer, particularly when the offer is communicated with the information that the test will be performed unless the client refuses. The recent population-based study in Botswana, in which 68 percent of participants who were tested (either by VCT or by routine testing) responded that they believed that they could not refuse the HIV test, and 43 percent of respondents believed that the HIV testing policy would lead people to avoid going to the doctor for fear of testing, also suggests that many may not fully understand the voluntary nature of testing (Weiser, et al., 2006). Evelyn Serima, one of the people interviewed for this paper, said: "In Botswana, most of the people don't understand what the policy is. Because the president said that people should be tested, they don't think they can opt out from testing."

Preliminary data from another study, undertaken in Kinshasa, Democratic Republic of the Congo, indicate that most nurses, HIV counselors and TB patients prefer routine, opt-out HIV testing at TB clinics over opt-in HIV testing with referrals onsite or offsite. But 41 percent of TB nurses and HIV counselors and 33 percent of patients believed it would be difficult for patients to opt-out of an offer of routine testing (Corneli, et al., 2005). A study of private practitioners' communications with patients about HIV testing in Pune, India, showed that "in the majority of cases, pre-test communication is extremely limited and informed consent practically non-

existent.”(Datye, et al., 2006) In cases where HIV testing is considered “routine,” as with antenatal attendees or pre-operative patients, patients are not informed that they are being tested. Generally, “communication with their patients around HIV is prescriptive rather than shared, and falls considerably short of best-practice standards around consent, counselling and confidentiality as upheld in national guidelines.”(Datye, et al., 2006)

Another person interviewed for this paper, Claude Cahn, Programs Director, European Roma Rights Centre, also said health-care providers in many countries do not ask what patients want, or even tell patients what they do. He said that patients in many countries would most likely not be able to opt out of HIV testing: “Very few people in Central and Eastern Europe decide freely about their medical care. The attitude of providers is so paternalistic.” In his presentation at the XVI International AIDS Conference, Anand Grover (2006) cautioned that “if opt-out routine testing is recommended globally the clear message for all the medical fraternity in the developing world would be to test all persons without consent, i.e., mandatory testing.”

Just how serious this concern needs to be taken was shown by a letter published on 6 December 2006 by Russian physicians in the *Annals of Internal Medicine* (Vlassov and Denisov, 2006). The letter points out that “Russia inherited from the USSR the system of extensive testing of citizens without a barrier of consent: blood donors, pregnant women, all inpatients, etc.” It suggests that the “efficacy of the Russian ... system was de-facto recognized by the U.S. Centers for Disease Control and Prevention recommendations calling for routine HIV testing without specific consent.” It concludes by saying that the United States recommendation “is mimicking the Russian style” and that “WHO recently is also supporting the Russian style system by its recommendation of provider-initiated testing.” While the letter gets most of the facts wrong, it nevertheless highlights the danger that support for more routine forms of testing may be misinterpreted.

*[Some of the proponents of routine opt-out testing] create an artificial and unwarranted polarity between human rights, social justice, and public health. They claim to find a new AIDS paradox in their assertion that human rights advocates deter HIV testing by insisting on autonomy via informed consent, and they conclude that ‘failure to prevent HIV transmission constitutes an infringement of human rights that hampers Africa’s human and social development.’*

*Contrary to what [they] suggest, human rights both encompass and demand social justice and public health. The problem is that bad or corrupt governance by First and Third World governments prioritizes neither social justice nor public health in many developing countries. This is manifest in the fact that it is the lack of access to health care services, including voluntary counselling and testing (VCT), and prophylactic or curative medicines that is the greatest deterrent to health seeking behaviour. As recognized by the WHO, community mobilization around HIV/AIDS is necessary to demand the supply of VCT and other HIV-related services, as well as to create the demand in the community. Although [the proponents of routine opt-out testing] would not believe it, the reality is that the human rights principles of confidentiality and informed consent are still widely ignored in health settings in Africa – and are therefore not the kind of obstacles they are claimed to be.*

– Heywood, 2004, with reference to De Cock, Mbori-Ngacha, Marum, 2002)

### **The alternative: Routinely offering and recommending opt-in HIV testing**

One way of rapidly scaling up access to HIV testing that may be as effective as a matter of public health and more respectful of human rights would be to routinely offer and recommend opt-in HIV testing and counseling, rather than opt-out testing, in clinical settings. While generally recommending an opt-out approach to PITC in health facilities, WHO and UNAIDS

acknowledge that an opt-in approach “may merit consideration for highly vulnerable populations.”(2007, at 5)

Routinely offering and recommending opt-in HIV testing and counseling would recognize that providers should do more than just offer the HIV test to their patients. It would place emphasis upon how providers go about offering the test in order to allow people to give informed and truly voluntary consent. Experience has shown that, where implementation of such a policy is adequately supported, it can be as successful in increasing the number of people who test for HIV as adopting a “right-of-refusal” approach (Schietinger, 2006)—particularly, if accompanied by other necessary efforts to remove barriers to HIV testing, such as provision of adequately supported VCT services, social mobilization campaigns to encourage people to seek testing and to combat stigma and discrimination, as well as legislative and policy reforms to eliminate existing discrimination and other barriers to health services and to protect against such denial of human rights. It may also result in fewer people avoiding going to seek health care for fear of being unable to decline testing. It has the potential to have an impact on access to care and treatment, prevention, and stigma similar to that of routine opt-out testing. Finally, it takes into account that knowledge and understanding of HIV often remain low even where awareness of HIV is high, emphasizing the importance of providing people with the information they need, allowing them to ask questions, and preparing them for the result of the test.

Admittedly, if a doctor “recommends” something, it could be difficult for patients, particularly women (especially given likelihood of gender and/or class differences between the female patient and the physician), to decline the test—so in effect it risks being similar to an opt-out system, unless care is taken to respect and ensure patients’ autonomy. But at the same time providers should not simply offer an HIV test to their patients, but explain the potential benefits of testing and recommend testing, regardless of whether or not patients consider themselves at risk or not.

According to WHO and UNAIDS, “whether patients ‘opt-in’ or ‘opt-out,’ the end result should be the same: an informed decision by the patient to accept or decline the health care provider’s recommendation of an HIV test.”(2007, at 20) Ultimately, any form of PITC needs to be carefully monitored and evaluated to ensure that, in practice, providers offer and recommend testing, but that patients give informed consent to the test. In addition, community mobilization efforts should be undertaken to encourage people to seek testing, while clearly explaining the policy so that people do not stay away from health facilities for fear that they will be tested without their consent.

In the short-term, testing policies that encompass these elements may be more costly than simply providing routine, opt-out testing, and it will require scaling up of the capacity of health systems both to respect people’s right to consent to a medical procedure that has great consequences in people’s lives, and to give them as much information as possible to protect themselves from abuses that may accompany the knowledge of their HIV status. But these elements are essential to an effective HIV/AIDS response, and are human rights obligations of governments (Csete, Elliott, 2006, at 9). It is a positive duty of the state and the international community to provide the resources and personnel for scaling up HIV testing that incorporates these elements.

## **The need for more research**

The research undertaken for this paper has clearly demonstrated that deeper research issues beyond simply the numbers of people getting tested are not being addressed enough. In order to be able to assess whether increased uptake of testing allows countries to achieve prevention and treatment goals, more information is needed about the number of people who:

- obtain their test results;
- disclose their HIV status;
- ultimately change their sexual and/or drug using behaviors; and
- access care and treatment, including ART.

Research is also needed to capture the experience of HIV testing and that of people who may be at risk of adverse outcomes. Questions such as the following should be addressed:

- What is the experience of people being tested as a result of approaches in which HIV testing is more routine? In particular, to what extent do people still experience counseling and testing as voluntary, and how will a shift away from “voluntariness” affect responses to prevention messages?
- Would more routine forms of HIV testing under which people are tested unless they opt out lead to a greater chance of negative consequences including human rights abuses, particularly against women, than forms of HIV testing under which testing is routinely offered and recommended, but people have to opt in to testing?
- Would such forms of HIV testing “normalize” HIV and reduce HIV-related stigma to a greater extent than forms of HIV testing under which people are offered the test, but tested only if they opt in, or than massively increased investment in VCT and anti-stigma campaigns?
- Would such forms of testing result in greater uptake of ART, or might they result in lesser uptake than forms of HIV testing under which people are offered the test, but tested only if they opt in, given that they have the potential to deter people who are anxious about knowing their HIV status from seeking health care?
- Under what conditions are such forms of testing likely to deter patients seeking care (including antenatal care)?
- Would such forms of testing increase the number of people who are tested for HIV significantly more than routine offer of testing, and would this extra margin be prepared to know their HIV status, disclose it to their partner(s) and engage in positive behavior change?
- To what extent is the ability to scale up treatment currently being restricted by a “testing gap” rather than by other factors?
- Do more routine forms of testing lose some of the preventive value of testing and counseling, and would this be offset by the greater number of people who may take up testing (and find out their status)?
- What is the impact of rapid point-of-care testing on counseling and the consent process?
- Do the jurisdictions that have adopted such routine forms of testing have universal or even good access to treatment, condoms and other prevention measures? (Csete and Elliott, 2006; Schietinger, 2006; Alcorn, 2006).

The WHO/UNAIDS guidance recognizes that “monitoring and evaluation should form an essential and ongoing part” of programs to implement PITC (WHO/UNAIDS, 2007, at 47). The document recommends that routine monitoring be complemented with focused evaluations on specific aspects of implementation and encourages health facilities “to partner with non-governmental organizations and civil society groups in monitoring and evaluating provider-initiated testing and counselling to ensure service quality and acceptability, including the maintenance of high ethical standards and human rights norms.” More detailed guidance on monitoring and evaluation of HIV testing and counseling, including PITC, is being developed by WHO and will be available later in 2007.

# Voluntary Counseling and Testing Services

## Key points

- A large body of research demonstrates the effectiveness of VCT as part of comprehensive prevention, treatment and care strategies.
- Scaling up access to VCT is particularly important because large numbers of people do not use formal health services and may need other ways to gain access to HIV testing and counseling, especially if they live in rural areas poorly served by the health care system, are mobile, or belong to vulnerable communities. Vulnerable groups may be further deterred from seeking formal health care if opt-out PITC is perceived as a form of forced testing.
- The WHO/UNAIDS guidance recognizes these concerns and makes several recommendations aimed at addressing them. WHO and UNAIDS should provide more detailed guidance about the training and supervision health care providers need in these settings, specifically about vulnerable groups' "right to decline" testing.
- Efforts to scale up HIV testing and counseling for most-at-risk populations should continue to focus on strategies to increase access to and uptake of HIV testing and counseling through innovative VCT services.

Current efforts to scale up access to HIV testing and counseling focus on new models of providing counseling and testing and devote little attention to how client-initiated VCT services can be improved and scaled-up.

WHO and UNAIDS continue to promote and "strongly support" the continued scale up of VCT (WHO/UNAIDS, 2006c; WHO/UNAIDS, 2007) and point to existing guidance on VCT (WHO/UNAIDS, 2007, at 18, with reference to WHO Regional Office for South-East Asia, 2004; WHO Regional Office for Africa, 2005). Nevertheless, the clear focus of current efforts to increase access to HIV testing is on PITC, and some of the persons consulted for this paper expressed the concern that VCT might not receive enough support and funding if resource-poor countries and funders continue shifting their emphasis to PITC. According to them, this would be of particular concern in countries where access to voluntary HIV testing and counseling remains limited, the epidemic is concentrated among marginalized populations, and few of those most at risk have access to or use health services. For a number of reasons, scaling up access to HIV testing and counseling has to include a greater emphasis on also scaling up VCT.

## The Experience with VCT

There is a large body of research, including case studies,<sup>16</sup> that demonstrates the effectiveness of VCT as part of comprehensive prevention, treatment and care strategies (Voluntary HIV-1 Counseling and Testing Efficacy Study Group, 2002; UNAIDS, 2001; WHO/UNAIDS, 2001). In particular, VCT has been shown to be effective in increasing understanding of risks, providing a supportive environment in which to learn one's HIV status, encourage acceptance of and coping with HIV (TASO Uganda, 1995), facilitating behavioral change for prevention (particularly

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<sup>16</sup> See, for example, the VCT "success stories" at [http://www.usaid.gov/our\\_work/global\\_health/aids/TechAreas/voluntarycounsel/vct\\_success.html](http://www.usaid.gov/our_work/global_health/aids/TechAreas/voluntarycounsel/vct_success.html).

among serodiscordant heterosexual couples and those testing HIV-positive), and increasing access to support. When it has been widely implemented in a context of community mobilization, it has also helped to open up the epidemic; decrease stigma and discrimination; increase opportunities for counseling for couples; and involve greater numbers in the response (UNAIDS, 2002). Because it has been confidential and has been non-threatening with regard to testing, VCT has tended to attract those who might otherwise shy away from HIV intervention. From a public health perspective, VCT has therefore served to connect many people to paths related to prevention and care (WHO, 2003, at 9). VCT has been identified as one of the most cost-effective HIV/AIDS interventions in Africa (Creese, et al., 2002), including in reducing sexual transmission of HIV (Sweat, et al., 2000).

There have been many challenges in implementing VCT, and many VCT services are far from being perfect. Testing often occurs with little counseling and informed consent (see, for example, Kawichai S, et al., 2006). However, these do not add up to the “failure” of VCT. Critics of VCT often fail to acknowledge that in many settings VCT has not been adequately funded or promoted. An international survey of VCT in 11 cities in West, East and South Africa and Thailand undertaken in 1997 found that of 8 cities with more than 2 million inhabitants each, four had only one VCT center available for the entire population (Cartoux, et al., 1998). In South Africa, one of the countries hit hardest by the HIV/AIDS epidemic, it took until 2000 before the government made VCT a priority and effective implementation was initially impeded by a number of factors at the level of policies, infrastructure and provisions (Swanepoel, 2006). As Csete and Elliott (2006, with reference to Attaran and Sachs) have pointed out,

[o]ver the decade from 1988 to 1998, when sub-Saharan Africa should have been building HIV counselling and testing capacity, official development assistance for all HIV/AIDS programs, including testing, was scandalously low and actually declined on a per-HIV-positive-person basis. In this period, with so little hope of offering effective treatment for HIV/AIDS, it is unsurprising that many countries tended to invest in general education programs or promotion of condom use rather than pushing people to be tested.

As WHO and UNAIDS have pointed out, uptake of VCT “has been hampered by many of the same factors that limit uptake of other HIV-related services, including stigma and discrimination, limited access to treatment, care and health services in general, as well as gender issues.”(WHO/UNAIDS, 2007, at 14) Other factors affecting uptake of HIV testing via VCT services include:

- In many countries, VCT is available only in urban centers.
- VCT is often under-resourced, and counselors may be overworked and unable to spend sufficient time with those being tested.
- The availability of VCT is often not well publicized; in some countries, many people learn about VCT only after they have already been informed of their HIV-positive status.
- There has been a focus on creating discrete “VCT services” rather than VCT capacities integrated into prevention and care practice.(Canadian HIV/AIDS Legal Network, Center for Health and Gender Equity, Gay Men’s Health Crisis, 2006)

Some have suggested that the VCT model has not been given a fair chance, and pointed out that the VCT approach itself was not the major factor in low HIV testing uptake:

The problem was in its poor implementation and the fact that treatment options were few and inadequately applied. The prevention and management of opportunistic infections through the use of simple and cheap drugs, even before the advent of ARV therapy, had been shown to impact significantly on the duration and quality of life of people living with HIV. Yet, no developing country established such schemes on a national scale, and successful projects remained few and with limited outreach. (Tarantola, 2005)

It has been only since 2002, the year in which the debate about making HIV testing more routine picked up speed (De Cock, Mbori-Ngacha, Marum, 2002), that greater flows of HIV/AIDS assistance through mechanisms such as the GFATM have opened the possibility for large-scale building of counseling capacity as well as expansion of treatment access. As Csete and Elliott (2006) have stated, the growing hope of access to ART

should be seen as highlighting the need for urgent scale-up of counselling capacity to ensure that HIV testing has the preventive value and the strong link to treatment and care that it should have. Scale-up of testing is urgently needed and, with appropriate investment, that scale-up could minimize HIV-related abuse and encourage confidence in the health system that is needed for long-term treatment and care.

## **The Need for Supporting, Promoting, and Scaling Up VCT**

Therefore, rather than giving up on them, VCT services that are responsive and sensitive to the communities served need to be adequately supported by resources and promoted and scaled up. As Tarantola (2005) has pointed out, “to enhance this capacity is neither easy nor inexpensive, but doing so has been shown to be highly cost-effective with potential long-term public health benefits.”(Voluntary HIV-1 Counseling and Testing Efficacy Study Group, 2000; Holtgrave, Reiser, Di Francisco, 1997; Kamb, et al., 1998) Research studies undertaken in many countries and settings, summarized below, suggest ways in which uptake and acceptability of VCT can be increased. At a minimum, the delivery of VCT needs to be better coordinated with other health services and integrated in services for most-at-risk populations. Better links are required between VCT and health services such as those provided for STIs and other sexual and reproductive health, and for directly-observed therapy for TB. Consideration should be given to one-stop sexual health services—this would help to reduce stigma or at least minimize the degree to which HIV-related stigma may impede access to HIV testing and health services if these are delivered through separate, identifiable sites—and to mobile VCT services. VCT should also be included in harm reduction services and low-threshold services for other most-at-risk populations. Finally, serious investigations should continue to be undertaken to streamline VCT in order to make it less resource-intensive and time-intensive, while preserving its benefits. As stated by Alcorn, in some settings “there simply aren’t enough counsellors to scale up to do traditional VCT” and “HIV programmes may have no choice but to abandon lengthy pre-test counselling.”(Alcorn, 2006) However, it may be possible to ensure confidentiality, consent and counseling in alternative, streamlined models of VCT, rather than only seeing these components as barriers (Canadian HIV/AIDS Legal Network, Center of Health and Gender Equity, Gay Men’s Health Crisis, 2006), which is how they have too often been dismissed (e.g., DeCock, et al, 2002).

## **Maximizing Prevention Potential and Meeting the Needs of Vulnerable Communities**

Scaling up access to VCT is particularly important because – although PITC in medical facilities will clearly play a large role in identifying people who are likely to need treatment soon (due to the fact that medical facilities mainly see sick people), large numbers of people do not use formal health services and may need other ways to gain access to HIV testing, especially if they live in rural areas poorly served by the health care system, are mobile workers such as truck drivers, or belong to vulnerable communities.

If governments want to maximize the usefulness of testing as an HIV prevention strategy, waiting for people to show up in clinical settings is going to have relatively limited impact. More than 40 percent of people with newly acquired HIV infection transmit it to their partners within approximately five months (Wawer, et al., 2005). This means that it will be important to find ways to encourage those who rarely visit health facilities – young, sexually active people, particularly men – to be tested, and to make testing and counseling easily accessible to them, for example by providing mobile VCT units at places wherever sex, alcohol, or cigarettes are sold and served, but also in work settings (Akuno, et al., 2006).

For many of those who need testing the most – that is, persons in underserved and socially marginalized communities – PITC is also unlikely to work precisely because these persons rarely use the health system. For sex workers, people who use drugs, or men who have sex with men, for example, health systems can be notoriously forbidding places. These populations require other sources of HIV testing that are not provider-initiated and are offered in a peer-driven and non-judgmental manner. Concerted efforts should be undertaken to developing human-rights based policies reflecting the needs of these populations and to implementing and promoting safe, voluntary, and accessible HIV testing and counseling options for them. A more promising route than PITC might be to reach them with mobile clinics (see, for example, Liang, et al., 2005) or “where they are” (see, for example, Tsu, et al., 2002) by empowering community-based organizations to provide HIV tests to their peers—in widows’ groups and youth clubs, brothels, bathhouses (Spielberg, et al., 2003) and gay bars. For people who use drugs, VCT may be offered at needle and syringe programs, drop-in centers, or through outreach programs, which may require changes to laws and policies in order to allow such practice. For prisoners, it should mean having access to VCT at any time during incarceration, and not being pressured to submit to “voluntary,” routine, or even compulsory testing upon incarceration, recognizing that this is a particularly stressful time, that some prisoners may go through withdrawal from drugs on which they are dependent, and that prisoners should have access to testing at the time they choose.

As mentioned above, WHO and UNAIDS do recognize that “strategies are needed to increase access to and uptake of HIV testing and counselling” for most at-risk populations, “particularly through innovative client-initiated approaches such as services delivered through mobile clinics, in other community settings, through harm reduction programmes or through other types of outreach.”(WHO/UNAIDS, 2007, at 24-25) However, they also recommend that “consideration ... be given to recommending HIV testing and counselling to all patients who attend [specific health services, such as acute care, STI or drug dependence treatment services] if this is epidemiologically appropriate and socially acceptable.”(id.)

There is a concern that implementation of PITC in specific health services for most-at-risk populations may lead certain people to avoid seeking care, and that these settings are less appropriate venues for HIV testing than peer-based settings such as needle and syringe programs and drop-in centers. In many countries people belonging to these populations have been routinely subject to abuse in health care settings and may not feel that they have the power to decline a recommendation to be tested, because they may feel that they would suffer negative consequences if they did. For example, stigma and discrimination against people who use injecting drugs has been documented in health care services as well as in communities. In a study in Ireland of the experiences of hospitalized people with HIV, those who used drugs perceived more stigma and judgment from nurses than other people with HIV. Respondents reported that nurses blamed them for their illness and made disparaging remarks when they requested pain medication (Schietinger, 2006, with reference to Surlis, 2001). In Ukraine, where injecting drug use is a major factor in the spread of HIV, people who use drugs report that they frequently face police violence and abusive treatment in the health care system (HRW, 2006). Persons who use drugs report avoiding drug treatment and other services because official registration requirements can lead to being exposed to the police, losing employment, and being mistreated in hospitals; these reports are confirmed by the observations of service-providers. More often, drug treatment is simply forced. Men who have sex with men also continue to experience stigma and discrimination because of their sexual orientation, particularly in jurisdictions in which homosexuality is illegal, which creates a significant barrier to testing and counseling. Similar issues arise for other most-at-risk populations.

The WHO/UNAIDS guidance recognizes these concerns, acknowledging that “[p]opulations most at-risk of HIV transmission may be more susceptible to coercion, discrimination, violence, abandonment, incarceration or other negative consequences upon disclosure of an HIV-positive test result.”(WHO/UNAIDS, 2007, at 25) The guidance recommends that:

- plans for PITC in health services for most-at-risk populations “should prioritize the implementation of a supportive social, policy and legal framework”
- health care providers receive special training and supervision to uphold standards of informed consent and confidentiality for these populations
- “additional discussion” take place of the right to decline HIV testing, of the risks and benefits of HIV testing and disclosure, and about social support needs
- “mechanisms are in place for referral to prevention, care and support services provided by community-based organizations and civil society groups.”(id., with reference to WHO, 2005c; WHO, 2005d; WHO/UNAIDS, 2004)

The WHO/UNAIDS guidance concludes that “an ‘opt-in’ approach to informed consent may merit consideration for highly vulnerable populations” and suggests that “[i]nvolving most-at-risk populations and their advocates in the development of HIV testing and counselling protocols and in the monitoring and evaluation of provider-initiated HIV testing and counselling programmes will help to ensure that the most appropriate and acceptable practices are followed.”(id.)

These are good recommendations, but concerns remain that, unless special efforts are made to ensure they will be implemented, in practice members of most-at-risk populations will continue avoiding health services or experiencing abusive treatment. WHO and UNAIDS should provide more detailed guidance about the training and supervision of health care providers in these settings, as well as about what exactly the “additional discussion” of the right to decline HIV testing should entail. Pilot projects incorporating these elements should be undertaken and evaluated.

# HIV Testing Policies Cannot Be Considered in Isolation

## Key points

- HIV testing is never a goal in itself; it is clearly linked to larger prevention and care, treatment and support goals. Because the efficacy of testing policies and programs depends on the availability of effective prevention and care, treatment and support programs, all of these efforts must be coordinated and integrated.
- Increasing testing and counseling must go hand in hand with much greater investment in real protection from HIV-related discrimination and abuse, particularly for women, children and adolescents, sex workers, men who have sex with men, people who use drugs, and prisoners.
- Efforts to cost, budget, and implement national programs that would secure legal and human rights protections for people living with, affected by, or vulnerable to HIV and AIDS need to become a priority.

## Lessons from Botswana

When Botswana adopted its routine testing policy, it was because enrolment in its HIV treatment program was slow, which was thought to be due in part to underutilization of HIV testing (de Korte, Mazonde, Darkoh, 2004; Center for Strategic and International Studies, 2004). An October 2006 editorial in the *New York Times* said that the “simple change in the rules for AIDS testing” in 2004 allowed HIV testing rates and, ultimately, the country’s program of provision of ART to “soar” (Editorial, 2006), suggesting that it was only through making HIV testing more routine within its health system and testing everyone unless they “opt out” that Botswana was able to achieve an increased uptake of testing and ART. Botswana has since been hailed as the global model for PITC.

In fact, Botswana’s turn-around coincided with a massive investment in ART in the country. When other African nations were slow to respond to HIV/AIDS, Botswana was devoting substantial national resources to HIV and securing international funding to increase access to ART. In addition to changing its HIV testing policy, the government launched a massive community-based communications program to encourage people to be tested, both in hospitals and in VCT centers. Botswana now has 16 testing centers (called Tebelopele), operating 15 satellite clinics, and 80 percent of the country’s population live within 50 km of a testing center. In 2003 the national HIV program began using mobile testing caravans to offer testing in more remote areas, and by December 2004 had carried out 176, 805 tests. Mobile testing caravans were particularly effective at reaching people who had never tested before; over 90 percent of those who took a test at a mobile caravan were doing so for the first time, and they accounted for 14 percent of all HIV tests carried out in Botswana in 2005 (Alcorn, 2006). The country’s president, Festus Mogae, publicly speculated he might be HIV-positive and had his own blood drawn for an HIV test, breaking much of the stigma and silence that deters people from testing. All of this activity occurred in a country that enjoys the highest GNP per capita in

sub-Saharan Africa, a record of democratic governance, and a health infrastructure in which 75 percent of the population (including 95 percent of women receiving antenatal care) have regular access to health care (Nieburg, Cannell, and Morrison, 2005). A “simple change in the rules” on HIV testing does not capture this complexity. According to Alcorn,

The success of Botswana’s efforts to promote universal testing has been ascribed to strong political leadership and a strong social marketing campaign which explained the benefits of testing - and the process - to the population. Botswana have been encouraged to ‘take a loved one for testing’, but it’s important to remember that this campaign is occurring in the context of the most comprehensive roll out of treatment anywhere in Africa (Alcorn, 2006).

Indeed, the population-based study undertaken in Botswana indicates that knowledge that treatment was available was a key factor in encouraging testing for two-thirds of those tested, as was confidentiality of the test results, especially for men, and the national media advertising campaign – 69 percent of respondents said they were convinced by advertising messages of the need to test (Weiser, et al., 2006).

In addition to showing that more needs to be done to increase testing uptake than “simply changing the rules for testing,” Botswana’s experience also highlights some areas of concern, as has been highlighted by the population-based study. As mentioned above, 68 percent of participants who were tested for HIV in Botswana responded that they believed they could not refuse their HIV test, and 43 percent believed that the HIV testing policy would lead people to avoid going to the doctor for fear of testing (Weiser, et al., 2006). Parts of the Botswana legislative framework “raise questions as to whether there exists an enabling and protective environment for those living with the virus. For example, ... laws protecting women from domestic violence and marital rape have not been passed yet.”(Stegling, 2006)

The population-based study concluded that,

Whenever HIV testing policies are implemented, human rights must be protected by ensuring that patients have all the information necessary to make an informed and free decision about being tested, by providing protection for women against violence related to HIV status, and by ensuring total confidentiality. (Weiser, et al., 2006, editor’s summary)

## **Time to Act on Other Priorities**

More broadly, it is important to recognize that, for the last 20 years, important barriers to HIV testing have included stigma, lack of access to VCT, and a belief held by health-care providers and patients alike that it was better “not to know” because of the lack of treatment and pervasive discrimination. Contrary to what some authors have claimed, it was not the entrenching of the right to informed consent that caused low HIV testing uptake, but the poor implementation of VCT, and the fact that treatment options were limited and stigma and discrimination rampant. While in recent years progress has been made on these fronts, a move towards increasing access to HIV testing that is genuinely grounded in human rights and promotes public health demands that these issues now be addressed tangibly and urgently.

HIV testing is never a goal in itself, but clearly motivated by prevention and care, treatment and support goals. Consequently, the efficacy of testing policies and programs is, in

turn, also co-determined by the availability of effective prevention and care, treatment and support programs.

Even as world leaders have committed to the goal of universal access to comprehensive prevention programs, treatment, care and support by 2010, and even as vastly increased financial resources have become available, those persons most vulnerable to HIV and its impact continue to receive the least access to HIV prevention, care and treatment services:

- In many countries, young people are those who have the highest rate of infection and yet most of them do not receive sufficient information about HIV and education, including sex education, nor do they have independent access to HIV testing and counseling or to treatment.
- Children living with HIV are not receiving treatment. Most orphans do not receive the care and support they need, and they are often victims of sexual abuse, discrimination and property-grabbing by relatives.
- Women continue to provide most of the care for the ill and for the children left behind. Often, their work is not valued or remunerated.
- In many countries, people who use drugs comprise a majority of the people living with HIV but represent the smallest fraction of individuals receiving anti-retroviral treatment.
- Sex workers often cannot access HIV services due to punitive approaches to sex work and prostitution, including sexual violence and discrimination practiced against sex workers.
- Around the world, men who have sex with men face widespread violence and discrimination and often cannot access HIV services for fear of arrest, discrimination, or violence.
- Prisoners in many countries have little or no access to voluntary HIV testing and to treatment, and are often denied access to HIV prevention.

*I fear that some of the calls for routine testing see diagnosis without access to care or other services, as an end in and of itself – it's public health on the cheap. Some people are saying: let's get everyone tested, we'll worry about the rest later. ... Let's make testing easier, simpler, more routine, but let's not put "the rest" on the back burner, let's keep more women from being raped or beaten now, more kids from turning to ... heroin ...*  
Gregg Gonsalves, email to HIV testing policy discussion group, July 24, 2006

Increasing HIV testing and counseling capacity must therefore go hand in hand with increasing capacity for HIV treatment (including ART), care, and prevention, and with much greater investment in real protection – in practice, and not just on paper – from HIV-related discrimination and abuse, particularly for women, children and adolescents, sex workers, men who have sex with men, people who use drugs, and prisoners. Even proponents of more routine approaches to HIV testing accept that stigma and discrimination against people living with HIV, and human rights abuses against particularly vulnerable groups that are compounded by HIV-related stigma, remain serious challenges. Simply increasing the number of people tested will not be effective in combating the wide range of forms and instances of HIV-related discrimination and abuse. Women, in particular, continue to report negative outcomes following disclosure of their HIV status. Well-funded measures for protection of HIV-positive women and girls from abuse are needed. These include short-term measures such as emergency help-lines, safe shelters for battered women, and training of police and social service providers on AIDS-related violence

against women, and longer-term efforts such as ensuring effective prosecution of perpetrators of sexual violence, reform of legislation to criminalize marital rape, and school-based awareness programs for girls and boys (Csete, Schleifer, Cohen, 2004).

The need for some of these measures is acknowledged in the WHO/UNAIDS guidance on PITC in health facilities, which says that “at the same time as provider-initiated testing is implemented, equal efforts must be made to ensure that a supportive social, policy and legal framework is in place to maximize positive outcomes and minimize potential harms to patients.”(WHO/UNAIDS, 2007, at 9) The guidance adds that “optimal delivery of provider-initiated HIV testing and counselling in the long term requires that laws and policies against discrimination on the basis of HIV status, risk behaviour and gender are in place, monitored and enforced.”(id.)

While the guidance says that these measures “may not be prerequisites for the implementation of provider-initiated testing,” it adds that “they should be addressed as part of national plans to scale up HIV testing and counselling and to achieve universal access to HIV prevention, treatment, care and support.”(id., at 34) The fact that WHO and UNAIDS recognize that expansion of testing will require adequate resources to address these issues should be welcomed. In the past, the need for such measures has often been acknowledged on paper in national and international plans or statements, but real action and leadership to address them has continued to be missing. International financial institutions and bilateral donors must make vastly increased commitments in these areas.

# Appendices

## Appendix 1: List of People Consulted

The following people were consulted in the process of developing this paper, and provided oral and/or written comments and suggestions.

Mabel Bianco, President, Foundation for Studies and Research on Women, and Coordinator, International Women's AIDS Caucus, Argentina

Aisuloo Bolotbaeva, OSI Kyrgyzstan

Claude Cahn, Programs Director, European Roma Rights Centre, Hungary

Helen Epstein, consultant and writer specializing in public health in developing countries, United States

Thomas Frieden, New York City Health Commissioner, United States

Beri Hull, Global Advocacy Officer, International Community of Women Living with HIV/AIDS (ICW), United States

Karyn Kaplan, Director, Policy and Development, Thai AIDS Treatment Action Group (TTAG), Thailand

Dr Gayatri Palat, Program Director, Indian Palliative Care Network, India

Mariya Savchuk, Public Health Program Director, International Renaissance Foundation, Ukraine

Grace Sedio, Project Officer, International Community of Women Living with HIV/AIDS (ICW), Botswana

Evelyn Serima, HIV/AIDS Technical Specialist, ILO Sub Regional Office for Southern Africa, Zimbabwe

Meena Seshu, General Secretary, SANGRAM, India

Raminta Stuikyte, Director, Central and Eastern European Harm Reduction Network, Lithuania

Paisan Suwannawong, Director, Thai AIDS Treatment Action Group (TTAG), and Thai Drug Users Network, Thailand

Wan Yan Hai, Beijing AIZHIXING Institute of Health Education, China

## **Appendix 2: Studies on Uptake of HIV Testing and Counseling**

As mentioned above (see the chapter on “Can Relaxation or Elimination of Counseling and Informed Consent Requirements Be Justified?”), a fairly large number of studies have been undertaken, mainly in African countries, to compare HIV testing uptake under different testing strategies and to assess what other factors impact on uptake of HIV testing. The results of these studies have been summarized as follows:

Direct offer of HIV testing in a convenient location usually leads to high uptake in both health-care settings and community settings. Acceptance of provider-initiated testing can exceed 90% for antenatal clinic attendees and patients presenting with opportunistic infections, but with rates of return of only 45%–75% when a repeat visit is required. However, only a minority of African adults will make unsolicited visits to free-standing or clinic-based VCT centers. Major disincentives include fear of being seen, fear of breach of confidentiality, inability to cope or adverse life events if found to be positive, and a sense of futility if testing is not linked to HIV care. Accessibility and cost are also important. Making counselling and receipt of results available through home visits increased uptake of community-based VCT from 10%–12% to 37%–87% in four different African studies. Thus, the consistent finding is that relatively minor differences in accessibility translate into major differences in acceptability of [testing and counseling] in Africa. (Corbett, et al., 2006, with many references)

This appendix provides more information about some of the most relevant studies undertaken.

### **African Countries**

#### **Multi-country Studies**

##### **Testing of Pregnant Women**

In the first such study, Cartoux, et al. (1998) evaluated acceptability of VCT by pregnant women in the context of clinical trials assessing interventions to reduce mother-to-child transmission (MCT) of HIV in developing countries. 13 studies located in West, East and South Africa, and in Thailand were included in a cross-sectional mailing survey about the acceptability of VCT in antenatal clinics. Acceptance rate, return rate, overall acceptability of VCT (acceptance of both pre- and post-VCT sessions) were obtained using a standardized questionnaire. Seven of the 13 VCT study centers offered group counseling before testing. The mean duration of the individual pretest and post-test counseling sessions was 15 and 26 min, respectively. The acceptance rates of VCT at pretest session amongst the women who were offered VCT were high, with the exception of Malawi (median, 92 percent; range, 53 to 99.7 percent). Return rates varied widely between sites (median, 82 percent; range, 33 to 100 percent). A return rate of 100 percent was obtained in one site in Zambia where rapid test algorithms were used and HIV results were provided on the same day, before the women left the antenatal clinic. In 9 out of 13 sites, the return rates of women diagnosed as HIV-positive were below those of women found to be HIV negative. According to the authors, this suggests that HIV-positive women perceive themselves at risk of HIV infection and do not want to know their test result. The overall acceptability of VCT varied widely between sites. The median overall acceptability of VCT was 69 percent, ranging from 33 to 95 percent. Overall acceptability of VCT most frequently depended on return rates because acceptance rates of the test itself were generally high. Overall acceptability rates did not vary with HIV prevalence, basic training of counselors, specific interventions and duration or techniques of pre-test counseling. The authors pointed out that their findings

reflect the experience in research projects with optimal logistics and human resources, where VCT and intervention are offered free of charge. However, none of the interventions assessed in the trials were proven effective at the time of the study and, in programs that included a placebo group, women could not be guaranteed to benefit from the intervention. Acceptability of VCT and interventions therefore are likely to differ when interventions are implemented in a public health program with a real cost and known benefits. In sites where a particular effort in implementing VCT programs had been made, overall acceptability of HIV testing of pregnant women was high.

## **Botswana**

### **Testing of Pregnant Women**

Rakgoasi (2005) examined the extent to which women accessing antenatal-care services in Botswana were offered HIV-related information and counseling and an opportunity to take an HIV test as part of the PMTCT program, and how these women responded. Data were drawn from the Botswana AIDS Impact Survey 2001, a nationally-representative sample survey. The survey interviewed over 4,494 of 4,728 eligible women on various issues relating to HIV/AIDS at both household and individual levels. Over half (57.9 percent) of the women were offered HIV/AIDS-related information, counseling, or testing. Age, education, and residence were important predictors of being offered HIV counseling or testing. Younger and more-educated women and those residing in towns were more likely to be offered both HIV counseling and testing than older, less-educated, and rural women. Seventy-nine percent of the women who were offered HIV testing agreed to undergo the test regardless of their background characteristics. However, the number of pregnant women who underwent HIV testing during antenatal care accounted for only a fifth (21 percent) of all antenatal-care attendees in 2001. Lack of capacity to deliver VCT services to all pregnant women attending antenatal care was seen as one of the biggest challenges to increased use of VCT services.

A study of antenatal clinics in Francistown showed that in the first three months of routine opt-out testing, 90.5 percent of women were tested for HIV, compared with 75.3 percent during the final four months of opt-in testing (Seipone, et al., 2004). However, many of the women who were tested failed to return for their results—9.4 percent during the opt-in period and 33 percent during the first three months of routine testing (a statistically insignificant difference: Seipone, et al., 2004).

## **Burkina Faso**

### **Testing of Pregnant Women**

Pignatelli, et al. (2006) identified factors predicting uptake of VCT in pregnant women. All pregnant women receiving ante-natal group health education at St Camille Medical Center in Ouagadougou from May 1, 2002 to April 30, 2004 were offered VCT. If they consented, the women were pre-test counseled, tested by two rapid tests giving immediate results and post-test counseled. Less than one-fifth of pregnant women [1,216/6,639 (18.3 percent, CI 17.4-19.3 percent)] accepted VCT. The HIV prevalence rate was 10.6 percent. While the two-step approach of group education followed by VCT yielded a low uptake rate, the drop-out rate after enrolling in the program was nearly zero. The authors concluded that effective scaling-up of VCT requires a mass sensibilization campaign pointing out the program's benefits and addressing the stigma of HIV.

## **Cameroon**

### **Testing of Pregnant Women**

Welty, et al. (2005) reported about a PMTCT program implemented as part of the routine antenatal care at the Cameroon Baptist Convention Health Board. Nurses, midwives, nurse aides, and trained birth attendants counseled pregnant women, obtained risk factor data, and offered free HIV testing with same-day results. From February 2000 through December 2004, this program rapidly expanded to 115 facilities in 6 of Cameroon's 10 provinces, not only to large hospitals but to remote health centers staffed by

trained birth attendants. 690 health workers were trained in PMTCT and counseled 68,635 women, 91.9 percent of whom accepted HIV testing. Of 63,094 women tested, 8.7 percent were HIV-1-positive, and 98.7 percent of positive and negative mothers received post-test counseling. Of 5,550 HIV-positive mothers, 5,433 (97.9 percent) were counseled on single-dose NVP prophylaxis.

## **Ghana**

### **Testing of Pregnant Women**

Baiden, et al. (2005) report the results of a cross-sectional questionnaire survey undertaken in the Kassena-Nankana district of Ghana to assess the perception and attitude of 270 antenatal clinic attendants towards VCT. Although 92.6 percent of respondents indicated a willingness to get tested, only 51 percent considered HIV testing for pregnant women to be useful. Most (93.6 percent) indicated they would like their husbands (partners) to know the result of the test and 52.2 percent indicated that their husbands would be willing to accompany them to antenatal clinic (ANC) at least once during the pregnancy. The perception of the usefulness of HIV testing, the willingness to disclose test result to the husband and perceived willingness of husband to accompany wife to antenatal clinic were found to be independent predictors of a woman's willingness to get tested. The willingness to disclose test result to husband and knowledge of at least one mode of MTCT transmission were found to be independent predictors of a woman's perception that getting tested was useful. According to the authors, the results suggest that for pregnant women, the willingness to get tested for HIV does not equate with the perception of the test's usefulness, and that spouses are likely to exert strong influence on the attitude of pregnant women towards VCT. The authors suggested that couple counseling facilitated through couple-friendly ANC services be explored as a strategy for the intended VCT program in this district.

## **Ivory Coast**

### **Testing of Pregnant Women**

A PMTCT program in Ivory Coast included group counseling before HIV testing, conducted by trained social workers, followed by private sessions with social workers during which individual women accepted or refused HIV testing, and HIV testing; counseling two weeks after the test by trained social workers or program doctors; and, for women whose test results were positive, monthly follow up visits with a program midwife before starting free prophylaxis at 36 weeks' gestation; and zidovudine before and during labor. During the program's first 15 months of operations, from February 1998 to the end of May 1999, HIV testing was offered to 9,657 women, of which 6,982 (72 percent) accepted the test. Of the 884 women who tested positive, 395 (45 percent) received their test results. Only 118 women eventually started taking zidovudine. Of those who did not, 84 percent refused to return or discontinued follow up visits, and 16 percent were lost to follow up or removed from the program for a variety of reasons. At the request of the program, Painter, et al. (2004) set out to find out so many women who receive HIV-positive test results and are offered short course antiretroviral prophylaxis to prevent MTCT do not participate in necessary follow up visits. They undertook a qualitative interview study with a purposive sample of 27 women who had received HIV-positive test results and were invited to return for monthly follow up visits, but who had either refused or discontinued the visits. Most of the women explained their non-participation in follow up visits by referring to negative experiences they had had while interacting with program staff or to their views about the program. Additional reasons concerned their disbelief of HIV positive test results and personal factors. The authors concluded that training and supervision of program staff may increase the likelihood of positive interactions between staff and clients, thereby facilitating women's participation in the PMTCT program; and that outreach and community mobilization should complement these measures and contribute to increased social support for women's efforts to prevent MTCT. Painter, et al. (2005) also examined the possible effects of women's sociocultural and economic circumstances at the MTCT prevention program. Participants (n = 30) completed follow-up visits and prophylaxis. Non-participants (n = 27) refused or discontinued follow-up visits and did not begin

zidovudine. The authors found that fewer non-participants had been born in Cote d'Ivoire (67 percent vs. 97 percent) or were Ivorian nationals (48 percent vs. 77 percent); they had lived in the country for less time (21 vs. 26 median years). They were less likely to be French-literate (37 percent vs. 77 percent), and more of them reported having had Koranic education only (18 percent vs. 0). They more often reported miscarriages, stillbirths, or infant deaths (69 percent vs. 33 percent), and had partners with low-ranked jobs (63 percent vs. 30 percent). This suggested that the non-participants were more marginal socioculturally and economically in Ivorian society than participants. According to the authors, greater attention to mitigating the effects of broader structural factors on women's participation in interventions may increase the effectiveness of MTCT prevention in Africa.

Brou, et al. (2005) followed for 12 months 400 women who had tested HIV negative during pregnancy. They found that for about 60 percent of women, the HIV test allowed them to reinforce communication with their partner on issues related to STDs and AIDS. For about 20 percent, the HIV test was the occasion to start a dialogue on these issues. On the whole, communication between spouses on these questions became more frequent after the HIV test in all socio-demographic classes. Ninety percent of women asked their husband (or regular sexual partner) to use condoms in case they had sexual intercourse with other women. They used different strategies to tackle this difficult subject with their husband. Ninety seven percent of the women notified their partner they had been tested for HIV. This notification was easy because they were HIV negative. Then 94 percent of women asked their partner he should also be tested. However, only about 25 percent of the partners eventually took an HIV test. Many of them were afraid and did not want to know their HIV status. Others thought they did not need to be tested since their wife was tested and was HIV negative. One third of the couples used condoms at the resumption of sexual activity after childbirth. When the woman was instructed, condoms were more frequently used. Generally, women used the contraceptive role of the condom to convince their partner to use it. The ability of HIV negative women to adopt prevention practices in order to avoid a possible HIV infection from their husband (or regular partner) depended strongly on the quality of the conjugal relationship. Behavioral changes were easier when both partners were instructed or when the woman was financially independent.

## **Kenya**

### **TB Clinics**

For example, until recently, TB clinics did not routinely offer HIV testing or even refer TB patients to HIV services. Efforts to improve the HIV diagnosis rate in TB patients began in Nyanza province, the region with the highest HIV prevalence (around 15 percent). The program began with a pilot at Nyanza General Hospital in 2004. Patients were offered an opt-out HIV test with a same day result, and pre-test counseling emphasized the importance of diagnosing HIV infection for the patient's medical care at the TB clinic. Sixty-eight percent received counseling, of whom 83 percent chose to undergo HIV-testing. Of those who tested, 81 percent were HIV-positive. Following the pilot at Nyanza General Hospital, province-wide scale-up began in 2005. From 935 TB patients tested in the first quarter of 2005, the province scaled up to test 2,273 in the fourth quarter. All patients who test HIV-positive receive cotrimoxazole through the TB clinic and are referred for HIV care. The program also encourages TB patients to refer their partners for HIV testing, and includes HIV prevention counseling as well as condom provision. According to the researchers evaluating the program, the biggest difficulty facing it is the lack of access to ART for patients who test HIV-positive. Only 15 percent of those eligible for ART actually get it at present (Alcorn, 2006, with reference to Onyango, et al., 2006).

### **Cost of VCT**

Forsythe, et al. (2002) performed an economic evaluation of VCT services in two rural health centers and an urban health center in Nairobi. A contingent valuation study was also performed among VCT clients. The study found that integrating services into existing health centers can significantly reduce the cost of

VCT. Furthermore, it appears that some level of cost recovery from VCT clients is feasible and can contribute to sustainability, although it is very unlikely that the full cost of the service could be recovered from the clients. The national provision of VCT in all Kenyan health centers is likely to be an affordable option.

### **Testing of Pregnant Women**

Kiarie, et al. (2000) conducted an early study to evaluate HIV-1 testing acceptability and return for test results in two Nairobi city council antenatal clinics. Pregnant women attending the clinics received pre-test counseling and were offered HIV-1 testing at the time of routine syphilis and hemoglobin level testing. Only two of 399 women offered HIV-1 testing declined testing (an acceptance rate of 99.8 percent) and 379 said HIV testing should be offered to all antenatal mothers. Fifty (12.6 percent) of the 397 women tested were HIV-positive. However, only 69 percent of the women returned to collect their results. Women who did not return to collect their results were more likely to be HIV-positive (44 percent did not collect their results) and to have had a previous pregnancy. The authors felt that not returning to collect their test results was perhaps a more culturally acceptable way for the women to decline the offer of testing, and suggested that “allowing women to choose to obtain results may be an important way to maintain their autonomy.” They pointed out that at the time of the study (1994) there were no effective options to prevent perinatal transmission of HIV, and that testing may be more acceptable today.

A more recent study examined whether HIV testing using a rapid assay increases the proportion of pregnant women obtaining results and the uptake of perinatal HIV interventions (Malonza, et al., 2003). Pregnant women attending public health clinics in Nairobi were offered VCT. Consenting women were randomly assigned to receive either rapid or conventional testing. Women randomly assigned to rapid testing were allowed to receive same-day results or to return later. The results for women randomly assigned to conventional testing were available after seven days. HIV-positive women were referred for antiretroviral prophylaxis to prevent mother-to-child transmission of HIV. Of 1,282 women offered VCT, 1,249 (97 percent) accepted testing, of whom 627 were randomly assigned to rapid testing and 622 to conventional testing. The percentage receiving results was significantly higher among women who received rapid testing (96 percent) compared with conventional testing (73 percent). However, of 161 HIV-1-seropositive women, only 24 took up antiretroviral prophylaxis. Surprisingly, significantly fewer HIV-positive women who received rapid testing accepted referral for perinatal HIV interventions than women who received conventional testing. The authors suggested that women

may have been unable to cope with the HIV/AIDS information on the same day as receiving their HIV-1 test results. With rapid HIV-1 testing, there may be limited time for women to comprehend the implications of a positive diagnosis and to decide on what action to take. In contrast, conventional testing provides ample time for women to decide on their readiness to receive HIV-1 results, and those who choose to get their results are prepared to accept the diagnosis, the implications of a positive test, and referral for perinatal HIV-1 interventions.

They concluded that “thorough post-test counselling for HIV-1-infected pregnant women who receive same-day results is important for such women to understand their role in the prevention of infant HIV-1” and that “the overall uptake of perinatal HIV-1 interventions may be improved if women of reproductive age are educated about the prevention of mother-to-child transmission of HIV-1 before they become pregnant.”

Another study also documented high uptake of testing, but low uptake of perinatal HIV interventions (Temmerman, et al., 2003). At the antenatal clinic of the Coast Provincial General Hospital (CPGH) in Mombasa, health information is provided, followed by pre-test HIV voluntary counseling and testing. Out of 3564 first-visit pregnant women receiving health education, 2,516 were counseled (71 percent) and 2,483 were tested (97 percent); 348 were HIV positive (14 percent), and 106 women took nevirapine in labor.

Farquhar, et al. (2004) set out to determine effect of partner involvement and couple counseling on uptake of interventions to prevent HIV transmission. Women attending a Nairobi antenatal clinic were encouraged to return with partners for VCT and offered individual or couple posttest counseling. Nevirapine was provided to HIV-positive women and condoms distributed to all participants. Among 2104 women accepting testing, 308 (15 percent) had partners participate in VCT, of whom 116 (38 percent) were couple counseled. Thirty-two (10 percent) of 314 HIV-positive women came with partners for VCT; these women were 3-fold more likely to return for nevirapine ( $P = 0.02$ ) and to report administering nevirapine at delivery ( $P = 0.009$ ). Nevirapine use was reported by 88 percent of HIV-infected women who were couple counseled, 67 percent of those whose partners came but were not couple counseled, and 45 percent of those whose partners did not present for VCT. HIV-positive women receiving couple counseling were 5-fold more likely to avoid breast-feeding ( $P = 0.03$ ) compared with those counseled individually. Partner notification of positive results was reported by 138 women (64 percent) and was associated with 4-fold greater likelihood of condom use ( $P = 0.004$ ). The authors concluded that antenatal couple counseling may be a useful strategy to promote HIV-1 prevention interventions.

Van't Hoog, et al. (2005) implemented a pilot project to evaluate approaches to increase program uptake at health facility level at New Nyanza Provincial General Hospital, a public hospital in western Kenya, an area with high HIV prevalence. Counseling, HIV testing, and dispensing of single-dose nevirapine were integrated into routine antenatal services rather than being presented as an optional service to which pregnant women could "opt in." The proportion of clients who learned their HIV status increased from 55 percent to 68 percent. According to the authors, this improvement was "primarily the result of more comprehensive pretest counseling, from 77 percent when the pretest counseling was conducted in a separate part of the hospital to 92 percent when integrated into the examination." There was also a small improvement in the acceptance rate of HIV testing among those who received pretest counseling, from 80 to 83 percent. "Not ready" or "undecided" were the most common reasons for declining the test, given by 65 percent of the women who refused. The wish to consult the husband first or to return with the husband was expressed by 11 percent. Fear, either of the result or of the husband's reaction, was also commonly mentioned (20 percent). Less than 1 percent of partners came for partner or couples counseling, in both periods. Nevirapine uptake increased from 57 to 70 percent. The authors concluded that integration of PMCT into routine antenatal services is possible and that the way PMCT is implemented in the antenatal clinics can make a difference in uptake of counseling and testing. To improve program impact, they recommended "better patient flow to minimize inconvenience; routine HIV testing in ANC using rapid tests; repeated education concerning nevirapine administration; routine testing for women of unknown status in labor, or of their infants postnatally; expansion of PMCT Plus to improve follow-up and involve partners and families; and expansion of treatment efforts to provide HAART as a more efficacious regimen for women with low immunity."

Fenelly and Charles (2006) reported that in Kijabe hospital, a 205-bed facility located in a rural area north of Nairobi, 1,177 of 1,395 (85 percent) women newly registered for antenatal care in 2003 accepted VCT.

Finally, Delva, et al. (2006) appraised the quality and quantity of antenatal HIV counseling by observing and assessing 14 group educational sessions, 66 pre-test counseling sessions and 50 post-test counseling sessions. They concluded that, in general, "the frequency and duration of the counseling was low. Crucial topics such as window period and partner involvement and follow-up support were covered haphazardly." They suggested that "ample pre- and post-test counselling including follow-up should be pursued for optimal effectiveness of PMTCT" and proposed a number of health system interventions preceded and guided by ongoing audit.

## **Malawi**

### **Testing of TB Patients**

Zachariah, et al. (2003) undertook a study in new patients registered with TB in a rural district of Malawi in order to verify the acceptability of VCT. Patients diagnosed with TB between January and December 2000 were offered VCT and were subsequently interviewed. Of 1,049 new TB patients enrolled in the study, 1,007 (96 percent) were pre-test counseled, 955 (91 percent) underwent HIV testing and 912 (87 percent) were post-test counseled; 43 (4 percent) patients refused HIV testing. The overall HIV infection rate was 77 percent. The authors concluded that offering VCT to TB patients has a high acceptance rate and provides an opportunity to strengthen and integrate TB and HIV programs.

### **Testing of Pregnant Women**

In Malawi, in the nine months between April and December 2005, 14,495 (98.3 percent) women at prenatal clinics were counseled and 14,491 (98.3 percent) were tested after the government adopted new guidelines which advocate for an opt-out strategy in antenatal clinics—compared to 15,343 women who came to clinics in the nine months between July 2004 and March 2005, of whom 11,689 (76.2 percent) were counseled and 11,674 (76.1 percent) were tested. Under the new guidelines, women receive group pre-test counseling and are then tested for HIV unless they specifically request to not be tested. Post-test counseling is provided on an individual and confidential basis (Zimba, et al., 2006). According to newspaper reports, however, some women are shunning the hospital “fearing that they will be forced to undergo an HIV test.”(Kumwenda, 2006)

Manzi, et al. (2005) documented the uptake of VCT and follow-up interventions in a prevention of mother-to-child HIV transmission program at a hospital in rural Malawi, to determine: the acceptability of offering “opt-out” VCT; the progressive loss to follow up of HIV-positive mothers during the antenatal period, at delivery and to the 6-month postnatal visit; and the proportion of missed deliveries in the district. Of 3136 antenatal mothers, 2,996 (96 percent) were pre-test counseled, 2,965 (95 percent) underwent HIV-testing, all of whom were post-test counseled. Only 31 (1 percent) refused HIV-testing. 646 (22 percent) were HIV-positive, and were included in the PMTCT program. 288 (45 percent) mothers and 222 (34 percent) babies received nevirapine. The cumulative loss to follow up was 358 (55 percent) by the 36-week antenatal visit, 440 (68 percent) by delivery, 450 (70 percent) by the first postnatal visit and 524 (81 percent) by the 6-month postnatal visit. This left just 122 (19 percent) of the initial cohort still in the program. The authors concluded that the progressive loss to follow up of more than three-quarters of this cohort by the six-month postnatal visit demands a “different way of acting” if PMTCT is to be scaled up.

### **Acceptance and Uptake of HIV Testing**

DeGraft-Johnson, et al. (2005) examined variation in past and desired use of VCT services among 868 women and 648 men in a rural Malawi district population. Only 11 percent of men and 7 percent of women had been tested, but of those untested, 76 percent of men and 61 percent of women said they desired testing. Ninety percent of respondents willing to know their results preferred to hear them from a test site counselor and on the same day of the test. Knowledge of the behaviors of HIV prevention, knowing someone with AIDS, knowing the locations of a test site, and perceived risk of HIV infection all had a consistently significant association with past and future VCT use for men and women.

## **Mozambique**

### **Testing of TB Patients**

A pilot TB/HIV integration program was set up in Beira, a city of 600,000 people in Mozambique. HIV testing and counseling was offered on an opt-out basis at six TB clinics. Over the first seven months (September 2005 to March 2006), of 1,290 registered TB patients, 60 percent agreed to be tested, 20 percent already knew their status, and 20 percent opted out. Seventy-one percent of those who tested were

HIV positive. This represented a dramatic increase in testing at the TB sites. Before the program, about 20 TB patients in Beira were tested each month, compared to an average of 184 per month since the opt-out program began (Alcorn, 2006, with reference to Montoya, et al., 2006).

## **Nigeria**

### **Testing of Pregnant Women**

Chama, et al. (2004) reported that between July 2002 and June 2003, 262 pregnant women received VCT at the antenatal clinic of the University of Maiduguri Teaching Hospital, and 207 (79 percent) agreed to be tested. Thirty-one (11.8 percent) were HIV positive. The majority of the HIV-positive mothers received nevirapine in labor while 35 percent had combination ARV drugs in pregnancy. All the infants received nevirapine suspension within 72 hours of delivery. According to the authors, expensive and slow testing facilities, insufficient and inconsistent counselors, lack of ARV drugs for both mother and baby as well as unaffordable caesarean delivery were some of the constraints being faced at the clinic.

A number of studies were carried out among pregnant women attending antenatal clinics in different parts of the country to determine their knowledge and acceptability of VCT in pregnancy as a strategy for the prevention of MTCT of HIV. The majority of the women had good knowledge of the modes of HIV transmission, however, knowledge of specific aspects of PMTCT was poor. In one of the studies (Ekanem and Gbadegesin, 2004), almost all the women (96.1 percent) said that they were willing to undergo HIV testing in pregnancy particularly if it would assist preventing transmission of HIV to their babies; but only few said they would undergo the test if the result would be shared with relatives. In another, 13 percent of the women “disapproved” of VCT because of fear of stigmatization, isolation, and marriage security (Iliyasu, et al., 2005). All studies agreed that, as the country embarks on its PMTCT program, there is a need to “scale up health education” (Igwegbe and Ilika, 2005) in order to increase the level of knowledge, acceptability and adoption of VCT and other PMTCT strategies among pregnant women.

## **Rwanda**

### **Testing of TB Patients**

In Rwanda, in 2004, 45.5 percent of the registered TB patients were tested for HIV, and 46 percent were found to be positive. By the first quarter of 2006, 64 percent were tested, and 49 percent were HIV positive. Much of the increase in testing has been attributed to two sites, Gisenyi District Hospital and Health Center and Kicukiro Hospital, which served as models for the integration of HIV and TB services for the rest of the country. To coordinate the process at each site, they hired a TB/HIV focal point person and established multidisciplinary team meetings between the TB and HIV personnel. A simple TB screening questionnaire was piloted at the HIV clinic and the TB clinic began offering what they call “healthcare worker initiated HIV counselling and testing.” Between the 3rd and 4th quarter of 2005, and the 1st quarter of 2006, there were 206 newly registered TB patients at Gisenyi. Eighty-six (42 percent) were aware of their status at the start of TB treatment (76 percent were HIV positive). Of the 120 who did not know their status, 106 (88 percent) consented to HIV testing, and 34 (32 percent) were HIV positive. Overall, the percentage of registered TB patients with known TB status rose from 61 percent in 2004 to 92 percent during the pilot study period. Rwanda plans to roll out this model to the rest of the country (Alcorn, 2006, with reference to Gasana, et al., 2006).

## **South Africa**

### **Acceptance and Uptake of Testing**

In an early article, Pronyk, et al. (2002) described the introduction of VCT among five primary health care facilities in a rural South African setting. A baseline review of services demonstrated low levels of VCT, which were predominantly hospital-based. Twenty health workers in five primary health care facilities were trained to provide VCT using rapid-testing assays. One year after its introduction, a major

increase in the quantity of HIV testing, the proportion of clients who receive their results, and the proportion who present voluntarily was observed. The majority of those presenting were women. The quality of VCT was rated very good in mock client encounters.

Van Dyk and van Dyk (2003) set out to determine the needs, attitudes and beliefs of a sample of South Africans towards VCT, and to investigate possible barriers affecting participation in VCT programs in South Africa. A semi-structured questionnaire was used to survey the views of 1,422 people. Results indicate that while subjects were not opposed to VCT in principle, 33 percent would go to clinics where nobody would know them. The following problems with VCT services were mentioned: Logistical problems (not enough counselors, long lines, lack of privacy); no trust in the health care system or fearing a breach of confidentiality; fear of rejection; and a lack of follow-up support after diagnosis. The authors made suggestions on how to improve VCT services in South Africa.

Kalichman and Simbayi (2003) examined the relation between HIV testing history, attitudes towards testing, and AIDS stigmas. 224 men and 276 women living in a black township in Cape Town completed surveys. 47 percent had been tested for HIV. Compared to people who had been tested, individuals who were not tested for HIV demonstrated significantly greater AIDS related stigmas; ascribing greater shame, guilt, and social disapproval to people living with HIV. The authors concluded that efforts to promote VCT in South Africa require education about the benefits of testing and, perhaps more important, reductions in stigmatizing attitudes towards people living with HIV/AIDS; and suggested that structural and social marketing interventions that aim to reduce AIDS stigmas will probably decrease resistance to seeking VCT.

Hutchison and Mahlalela (2006) used data from a population-based household survey and a government clinic survey in the Eastern Cape Province of South Africa to examine attitudes towards VCT services, patterns of utilization of VCT services and the relationships between HIV/AIDS-related stigma, VCT service availability and quality and use of VCT. The household survey data were linked with clinic-level data to assess the impact of expanded VCT services and access to rapid testing on the likelihood of being tested in rural areas and on HIV/AIDS stigma. The analysis found that while overall use of VCT services is low, utilization of VCT services is positively associated with age, education, socioeconomic status, proximity to clinics, availability of rapid testing and outreach services and lower levels of HIV/AIDS stigma. Importantly, the effects of stigma appeared considerably stronger for females, while men were more heavily influenced by the characteristics of the VCT services themselves.

In a small qualitative study in a rural South African village, Mabunda (2006) found that participants knew of the availability of VCT services in the area, but did not utilize the services unless they had signs and symptoms suggesting possible HIV infection.

Finally, Swanepoel (no date) suggests that the implementation of effective VCT programs in South Africa has been impeded by a number of factors at the level of policies, infrastructure and provisions. He points out that very little research has been forthcoming on the efficacy of the communication programs that are needed to support VCT services and suggests the following questions for urgent action research:

- Why are these VCT communication interventions not effective?
- What can be done to optimize their efficacy in persuading those at risk for HIV to present themselves for VCT?

He continues by saying that VCT communication interventions can fail for a variety of reasons:

The limited impact of these interventions can be ascribed to, amongst others, the fact that their design was not supported by adequate, theory-driven empirical formative research on the contextual and personal determinants of the VCT uptake behaviour of their target audiences. To be effective, any intervention or interventions to increase the uptake of VCT would have to redress the problematic determinants (barriers) of VCT uptake behavior and support those that facilitate it. Decisions as to what these barrier and facilitating determinants are, how they relate to each other, and precisely how they are to be addressed in different kinds

of interventions cannot be left solely to the intuition of intervention designers, but must be based on *theory and theory-driven empirical research*.

The article provides such a theoretically and empirically motivated analysis of the contextual and personal determinants of VCT uptake behavior. According to the author, the analysis provided could “be considered a starting point for the formative research required for the design of effective VCT communication interventions.”

### **Cost of Testing**

McConnell, et al. (2005) set out to determine the cost per client completing VCT in an urban, church-based, non-profit organization that offers rapid-test VCT services in KwaZulu-Natal, South Africa. Six hundred and sixty-two clients completed VCT, at a cost of \$101.58 per client. Cost per client decreased over the year by 66 percent because expenses remained stable as more clients were served. The authors concluded that the cost of providing VCT services in this study was higher than previously reported, but declined with expanding scale.

### **Testing of Pregnant Women**

Coetzee, et al. (2005) aimed to estimate the field efficacy of the first program for PMTCT initiated in South Africa, in the subdistrict of Khayelitsha. The program was initiated as a pilot at two midwife obstetric units in January 1999. Lay counselors conducted pre- and post-test counseling and nurses took blood. After 17 months protocol changes aimed at eliminating weaknesses included rapid HIV testing for both mothers and infants. An initial evaluation of the program showed that VCT was highly acceptable, with individual counseling more effective than group counseling (Abdullah, et al., 2001). In 2003, the rate of acceptance for VCT attained 97 percent of the 7,314 women presenting for first antenatal visits. Coetzee, et al. identified a consecutive sample of 658 mother-infant pairs for enrolment in their study. Of the 535 mother-infant pairs (81 percent) eventually included in the study, 410 (77 percent) received an effective PMTCT intervention according to the policy at the time. The rate of transmission of HIV from mother to child was 8.8 percent. According to the authors, the results of this study demonstrate the feasibility and effectiveness of a large-scale PMTCT program in an urban public-sector setting.

Etiebet, et al. (2004) interviewed 264 women attending prenatal care in clinics in Khayelitsha. All had been offered HIV testing, and 95 percent had accepted. Women who had not been tested were four times more likely to believe that in the community families reject HIV-positive women. Of women who tested, 19 percent were HIV positive and 83 percent had told their partner that they had taken the test. HIV-positive women who had not disclosed testing to their partners were three times more likely to believe that, in the community, partners are violent towards HIV-positive women. The study concluded that routinely offering prenatal HIV testing and interventions to reduce perinatal HIV transmission is acceptable to the majority of women in Khayelitsha, despite an awareness of discrimination in the community towards HIV-positive women.

### **Testing of Adolescents**

MacPhail, et al. (2006) undertook group discussions among adolescents aged 12 to 24 years and their parents in two townships in Gauteng. The research represents the first attempt to understand the perceptions and attitudes of young people and their parents to VCT. It found that few youth have accessed VCT and that there are many perceived barriers to accessing it. These barriers primarily concern how they will be treated at the testing facility and a fear of what will result from a positive diagnosis. The authors concluded that a youth-friendly and appropriate model of VCT is required to encourage young people to learn whether or not they are HIV-positive and suggest that such a model include four components, including a community mobilization component.

## **Uptake of Workplace VCT**

Day, et al. (2003) conducted a study to identify attitudes that influence uptake of VCT amongst gold mine workers in South Africa. 105 healthy men were interviewed. The level of basic knowledge of HIV was high, but reported awareness of the extent of HIV infection in the workforce and perceived personal risk of HIV infection was low. Health issues were considered the most important indication for HIV testing and one-third had been tested. Fear of testing positive for HIV and the potential consequences, particularly stigmatization, disease and death, were the major identified barriers to VCT. Half of the participants felt workplace education programs needed to be improved to promote VCT access. Twenty-six per cent became more favorably inclined towards HIV testing in response to information on improvements that have been made to the confidentiality and convenience of the company's VCT service. Only 14 percent then indicated that they would be more likely to access VCT if ART became available. The authors concluded that a vigorous community education program is essential if the introduction of ART is to be effective in promoting uptake of VCT.

## **Tanzania**

### **Acceptance and Uptake of Testing**

In an early pilot study, Killewo, et al. (1998) assessed the acceptability of VCT in a rural village in Kagera. Village residents were prepared by their leaders and subsequently invited to health education group meetings to volunteer for the test. Of the 245 adults responding to the invitation, 137 (55.9 percent) subsequently volunteered for the HIV test and to receive the results, indicating a moderate level of acceptability.

A study by Kakoko, et al. (2006) determined the prevalence and factors associated with testing for HIV among Tanzanian teachers. It collected data through a cross-section questionnaire survey among 918 primary school teachers in Mwanza region. About 20 percent of the participants had voluntarily tested for HIV. Teachers who were younger, had easy access to HIV testing services, had a partner with tertiary education, and perceived their health status positively were significantly more likely to have tested for HIV. Teachers who had tested for HIV were significantly less likely: to perceive that it is not necessary to test for HIV in absence of vaccine or cure for HIV/AIDS; to support that only people who suspect that they are HIV infected should test for HIV; and to believe that HIV infected people are likely to die quicker if they are tested for HIV and be informed about their positive results. The authors concluded that there is a need to promote positive views of voluntary testing for HIV among Tanzanian teachers.

### **Testing of Pregnant Women**

Westheimer, et al. (2004) assessed correlates of acceptance of HIV testing in the antenatal setting in and around Dar-es-Salaam. From August 13, 2001 to November 27, 2002, 14,235 pregnant women attending antenatal clinics were offered testing for HIV infection. Pre-test counseling consisted of a one-on-one conversation with a trained nurse. It included brief discussion of the modes of transmission of HIV; options for proceeding if the test were positive or negative; and discussions of whether and how to inform one's partner of the result. Participants were asked if they would like to have their blood tested for HIV. If they agreed, they were then asked to sign a written consent form. At the post-test counseling session, HIV-positive women were given the option of enrolling in a study of antibiotic treatment to prevent chorioamnionitis-related perinatal transmission of HIV. No ART was available at that time in Tanzania. Of the women offered testing, 10,991 (77.2 percent) accepted, and 11.4 percent were found to be HIV positive. Approximately 80 percent of the women screened returned for their results.

According to the authors, the study confirms that while demographic characteristics may play some role in determining acceptance of HIV screening, counseling is by far the more important factor. One of the strongest predictors of testing acceptance was site of recruitment. The authors concluded that

the most effective methods of increasing testing acceptance need to focus on the sites and counselors themselves:

Ensuring adequate and frequent training of counselors can increase both the acceptance of testing and the return for results. In addition, ensuring that the clinics are as comfortable and as inviting as possible, with limited waiting time, should encourage women not only to accept testing for HIV but also to seek medical care earlier. Finally, any discussion of HIV in developing countries would not be complete without mentioning the need to address the enormous stigma and threat to women's well-being associated with HIV infection in these settings.

Msuya, et al. (2006) aimed to determine the predictors of failure to return for HIV posttest results among pregnant women (N = 2,654) receiving antenatal care at primary health clinics in Moshi urban district. Consenting pregnant women, who were in the third trimester of pregnancy, received individual pre-test counseling, followed by interview and screening for HIV. Post-test counseling and results were given after 1 week. A total of 182 (7 percent) failed to return for their HIV test results. Women were less likely to return for test results if their partners did not come for testing (adjusted odds ratio [AOR], 12.6; 95 percent CI, 3.1-51.4), if their partners consumed alcohol (AOR, 1.8; 95 percent CI, 1.3-2.7), and if they had never discussed reproductive health matters with their partners (AOR, 1.7; 95 percent CI, 1.1-2.7). Additionally, the site of recruitment, age, alcohol consumption, and advanced gestation age predicted failure to return for HIV test results. The authors recommended promotion of antenatal couple counseling and strengthening of community awareness of the availability of perinatal interventions, with special efforts targeting men. In addition, they suggested that the predictors for failure to collect test-results be addressed during pre-test counseling.

### **Cost-effectiveness of Free VCT**

Thielman, et al. (2006) evaluated the cost-effectiveness of fee-based and free testing strategies at a VCT program integrated into a community-based AIDS service organization in Moshi. The researchers waived the usual fee schedule during a 2-week free, advertised VCT campaign; analyzed the number of clients testing per day during pre-free, free, and post-free testing periods; and estimated the cost-effectiveness of limited and sustained free testing strategies. The number of clients testing per day increased from 4.1 during the pre-free testing interval to 15 during the free testing campaign and remained significantly increased at 7.1 after resumption of the standard fees. HIV seroprevalence (16.7 percent) and risk behaviors were unchanged over these intervals. Modeled over 1 year, the costs per infection averted with the standard fee schedule, with a 2-week free VCT campaign, and with sustained free VCT year-round were \$170, \$105, and \$92, respectively, and the costs per disability-adjusted life year gained were \$8.72, \$5.40, and \$4.72, respectively. The study concluded that the provision of free VCT enhances both the number of clients testing per day and its cost-effectiveness in resource-limited settings.

## **Uganda**

### **Acceptance and Uptake of Testing**

The AIDS Information Center (AIC) was established in Kampala, Uganda in 1990 in response to increasing interest in VCT. By 1996, over 300,000 clients had been seen. Approximately 25 percent of clients failed to learn their HIV status as a result of failure to return or late arrival of results. To address these issues, AIC carried out a pilot project using rapid HIV assays over a period of 5 working days. Three hundred and twenty-five clients were seen, all of whom left AIC knowing their HIV status and having spent less than two hours at the Center. According to the authors, the results demonstrate that "same-day" results can be provided in counseling and testing settings without compromising the quality of counseling or the accuracy of HIV testing (Downing, et al., 1998).

Nuwaha, et al. (2002) examined the factors influencing uptake of VCT in Bushenyi district with a view of suggesting measures for increased uptake. Focus group discussions were used to elicit reasons for carrying out VCT and a cross sectional survey to estimate the proportion of people who undertake VCT. 17 percent of 219 people interviewed had ever undergone HIV. The factors influencing VCT for HIV were consequences of a test result, influences from a sexual partner, cost of VCT, physical accessibility of VCT, awareness, risk of HIV infection, need for linking VCT with care (especially availability of antiretrovirals) and perceived quality of care of VCT services. The authors concluded that increased mobilization and access for VCT, reducing costs of VCT, linking of VCT with care, and emphasizing the positive consequences of VCT as well as providing high quality VCT services may increase the number of people seeking VCT.

A number of studies analyzed the experience of the Community HIV Epidemiological Research study in the rural Rakai district. Study participants were visited once every 10 months. VCT was one of the service components of the Project, and was offered free of charge to all those who provided blood and requested their HIV test results. The Project also offered condom promotion and supplies, community HIV /AIDS education, and treatment for opportunistic infections. Project counselors visited those who requested their HIV results in their homes. Motovu, et al. (2002) showed that in 1999/2000, 90 percent of those who participated in the ongoing epidemiological research study requested their HIV results, and 64.6 percent of those who requested them ultimately received them. The proportion of people receiving HIV results almost doubled between 1994 and 2000 from about 35 percent in 1994 /1995 to 65 percent in 1999 /2000. These data indicate high proportions of acceptance and receipt of VCT in this rural population-based cohort, suggesting that home delivery of VCT could offer a unique opportunity for people in the rural areas to access counseling and testing services, given adequate resources. Nyblade, et al. (2003) found that during the initial phase of the population-based free VTC program, certain high-risk groups were underrepresented among VTC recipients and concluded that there is a need to target VTC to ensure participation by high-risk individuals most in need of services. In a more recent study, Matovu, et al. (2005) found no effect of VCT acceptance on subsequent risk behaviors or on HIV incidence in HIV-negative persons. The authors concluded that their findings in this community-based VCT program in rural Uganda “suggest selective uptake of services by persons who are less likely to be HIV infected, high rates of retesting among HIV-negative persons which may be associated with a false sense of security, and a lack of impact of VCT on risk reduction and HIV incidence among initially HIV-uninfected individuals.”

Another intervention offering counseling and HIV results at home, followed by a qualitative evaluation exploring nature of demand and barriers to knowing HIV status, found that offering HIV results at home significantly increased uptake of results. Previous male advantage in uptake of test results was effectively eliminated. Focus group discussions and in-depth interviews highlighted substantial non-monetary costs of getting HIV results from high-visibility public facilities. Inconvenience, fear of stigmatization, and emotional vulnerability of receiving results from public facilities were the most common explanations for the relative popularity of home-based VCT. It was however seen as less appropriate for youth and couples with conflicting attitudes toward testing. The authors suggested that integrating VCT into other services, locating testing centers in less visible surroundings, or directly confronting stigma surrounding testing may be less expensive ways to reproduce increased uptake with home VCT (Wolff, et al., 2005).

### **Testing of Pregnant Women**

Giuliano, et al. (2006) evaluated the five-year performance of a program at St Francis Hospital Nsambya in Kampala. The program included VCT for pregnant women and administration of antiretroviral prophylaxis in the peripartum period for HIV positive women. Overall 24,133 women received counseling, 76 percent (18,384) agreed to be tested, and 2,011 (10.9 percent) were HIV positive; 1,341 (66.7 percent of the HIV positive women) were enrolled in the program and received antiretroviral drugs.

Acceptance of the test increased from 72.7 percent in 2000-2 to 79.9 percent in 2003-4, when a drug access program became available in the hospital.

Homsy, et al. (2006) evaluated the uptake of routine intrapartum testing and counseling in the maternity ward of a 200-bed hospital in rural Uganda and compared it with the uptake of “opt-out” testing and counseling in the antenatal clinic. They found that routine counseling and testing using an opt-out strategy was well received and achieved high coverage: 97 percent of 3,696 women and 97 percent of 107 male partners counseled in the antenatal clinic accepted testing. 20 percent of the men tested HIV positive, 16 of whom shared their result with their wife. Fourteen couples (13.5 percent) had discordant HIV test results. In the maternity ward, 86 percent of women and 98 percent of men counseled accepted testing. Eighty-eight percent of all women presenting with undocumented HIV status were discharged knowing their HIV status after implementing the opt-out routine intrapartum rapid HIV counseling and testing strategy, as compared with 39 percent during the seven-month period preceding the introduction of intrapartum counseling and testing. The authors concluded that PMTCT programs should promote routine opt-out counseling and testing for HIV in both antenatal clinics and maternity wards.

Finally, Andia, et al. (2006) looked at the effects of introducing routine testing at their clinic on the clinical profile of HIV-positive patients in their care. They found that over the course of a year, routine testing shifted the profile strongly towards asymptomatic patients who needed less intensive clinical management when they started treatment. Although the clinic had more patients under care as a result of routine testing, these patients were likely to have a better chance of success when they began treatment. One of the advantages for patients noted was the fact that routine testing was free; previously patients had had to pay for a test, which was a significant disincentive to testing (Alcorn, 2006, with reference to Andia, et al., 2006).

## **Zambia**

### **Acceptance and Uptake of Testing**

Fylkesnes and Siziya (2004) examined factors affecting readiness for and acceptability of VCT. Participants in a population-based HIV survey conducted in an urban population in Zambia in 1996 were offered VCT. Although 29 percent of them expressed interest in being tested (readiness), only 4 percent of this group used the services (i.e. acceptability). When the survey was repeated 3 years later, VCT was designed differently to assess acceptability. The participants were randomly allocated to VCT either at the local clinic (similar to 1996,  $n = 1,102$ ) or at an optional location ( $n = 1,343$ ). The acceptability was 11.8 percent among the group allocated to VCT at the local clinic compared with 55.8 percent for the group allocated to an optional location. The authors concluded that “a strong effect of placement on acceptability of VCT was demonstrated, indicating this barrier to be important in explaining low demands for VCT in the past. Differences in perceptions of how confidentiality is handled at the two locations might be an important underlying factor.”

### **Testing of Pregnant Women**

Stringer, et al. (2003) undertook a first study to evaluate a NVP-based perinatal HIV prevention program initiated in Lusaka in November 2001. The first 12 months cost \$221 000 and enabled 178 district health employees to be trained in VCT. 17,263 pregnant women were counseled for HIV, 12,438 (72 percent) were tested, and 2,924 (24 percent) were found to be infected with HIV. NVP has been taken by 1,654 (57 percent) mothers and 1,157 (40 percent) babies. It is estimated that at least 190 infants have been spared HIV infection (11 per 1,000 counseled women or 65 per 1,000 identified HIV-infected women). The authors concluded that “prevention of mother-to-child HIV transmission is feasible and cost effective in resource-limited settings,” but noted that “patient attrition and non-adherence represented a major source of program inefficiency, which requires to be systematically addressed.”

A more recent study by Stringer, et al. (2005) determined the population effectiveness of the city-wide perinatal HIV prevention program in Lusaka. Of 8,787 women in the surveillance population, 7,204

(82 percent) had been offered antenatal HIV testing, of which 5,149 (71 percent) had accepted, and of which 5,129 (99 percent) had received a result. Using anonymous surveillance of newborn cord blood for HIV serology and nevirapine (NVP), the study found that only 675 of 2,257 (30 percent) seropositive mother-infant pairs in the surveillance population received both a maternal and infant dose of NVP. It concluded that “successful perinatal HIV prevention requires each mother-infant pair to negotiate a cascade of events that begins with offering HIV testing and continues through adherence to the prescribed regimen. This novel surveillance demonstrates that failures occur at each step, resulting in reduced coverage and diminished program effectiveness.”

Semrau, et al. (2005) examined whether whether women counseled antenatally as part of a couple were more likely to accept HIV testing and nevirapine in a PMTCT program, and whether they would be less likely to experience later adverse social events than women counseled alone. A PMTCT program that included active community education and outreach to encourage couple counseling and testing was implemented in two antenatal clinics in Lusaka, Zambia. A subset of HIV-positive women was asked to report their experience of adverse social events six months after delivery. Couple-counseled women were compared with individual-counseled women stratified by whether or not they had disclosed their HIV status to their partners. Nine percent (868) of 9,409 women counseled antenatally were counseled with their husband. Couple-counseled women were more likely to accept HIV testing (96 percent) than women counseled alone (79 percent); however uptake of nevirapine was not improved. Six months after delivery, 28 percent of 324 HIV-positive women reported at least one adverse social event (including physical violence, verbal abuse, divorce or separation). There were no significant differences in reported adverse social events between couple- and individual-counseled women.

## **Zimbabwe**

### **Acceptance and Uptake of Testing**

Laver (2001) undertook a study among 204 adults, including 102 females, to describe rural adult preparedness to test for HIV. None of the participants had knowingly been tested for HIV prior to the study; 55.8 percent had heard about VCT and 21 percent had thought about testing. Of these, 34.8 percent (n=15) had already talked to somebody about testing. When compared with married respondents, significantly more singles expressed preparedness to test for HIV in the next six months. Only 14.2 percent of respondents expressed willingness to pay for a test. Strongly articulated fears about testing included being seen by friends at a VCT center, stigmatization, violence and stress. Women were more fearful than men about taking an HIV test. The author concluded that the study showed “some preparedness” among adults from rural communities to test for HIV. “While current strategies to promote VCT in urban areas reflect sensitivity to many of the fears of adults expressed in this study, the initiative must be expanded to embrace rural communities. There is a need to build on positive perceptions about testing and embrace a strategy that disables fear, particularly among women. The initiative must go beyond the individual as the primary target and be promoted within the broader context of the community with the assistance of credible opinion leaders. It should also link closely with other services that offer primary prevention, pilot treatment and support activities.”

Morin, et al. (2006) provided free anonymous mobile VCT using two rapid HIV tests in 12 marketplaces in Epworth and Seke. Qualitative interviews were conducted to assess motivations for and barriers to testing. A subsample of HIV testers and individuals near testing vans who declined testing (nontesters) completed a questionnaire. A total of 1,099 individuals participated in mobile VCT between March 2002 and August 2003, and 29.2 percent tested HIV-positive. Overall, 98.8 percent of participants elected to receive HIV test results the same day. Reasons for not testing previously were often logistic (eg, inconvenience of hours [25.6 percent] and location [20.7 percent] or cost [8 percent]). Those who used the same-day mobile testing services (testers vs. nontesters) perceived themselves at higher risk for HIV infection but were less likely to have known people with HIV or where to get tested. The authors concluded that “same-day HIV testing in community settings seems to be acceptable in sub-Saharan

Africa. Barriers to HIV testing are often logistic and can be overcome with community-based strategies. These strategies need to be refined to address the needs of those not using mobile testing services.”

### **Uptake of Workplace VCT**

Corbett, et al. (2006) identified businesses with occupational health clinics in Zimbabwe and divided them into two “intervention” groups. Employees at half the businesses were offered “on-site VCT”—pre-test counseling followed by same-day on-site rapid testing, results, and post-test counseling. Employees at the other businesses had the same pre-test counseling but were offered a voucher for an HIV test at an off-site testing center and a later appointment to discuss the results—so-called off-site VCT. Everyone had the same access to limited HIV care should they need it. Previous studies on VCT had indicated that the convenience of getting the test, whether the test is directly offered, and the attitude of staff supplying it are all very important. In this study, the researchers asked whether providing VCT in the workplace could improve the “uptake” of HIV testing in Africa. Half of the employees at the on-site VCT businesses took up the option of HIV testing, but only a fifth of employees at the off-site VCT businesses accepted vouchers for testing, and only one in five of these people actually used their voucher. On-site VCT resulted in about 12 times as many HIV tests as off-site VCT. The authors concluded that on-site VCT in the workplace might be one way to improve uptake of HIV testing in Africa from its current low level. Importantly, a relatively minor change in accessibility to testing can translate into a major difference in test uptake. This may hold true in non-occupational settings.

### **Testing of Pregnant Women**

Perez, et al. (2004) piloted the first program for prevention of mother to child transmission of HIV in rural Zimbabwe. VCT services were provided in the antenatal clinic of a 120-bed district hospital in Buhera district, and community mobilization was conducted. No services for prevention of mother to child transmission of HIV were available at baseline. Within 18 months, 2,298 pregnant women had received pretest counseling, and the acceptance of HIV testing reached 93 percent. Of all 2,137 women who had an HIV test, 1,588 (74.3 percent) returned to collect their result; 326 of the 437 HIV positive women diagnosed had post-test counseling, and 104 (24 percent) mother-child pairs received nevirapine prophylaxis.

Shetty, et al. (2005) assessed the feasibility and acceptability of VCT by pregnant women using community volunteers. From July 1999 to June 2001, a perinatal HIV prevention program was undertaken in two antenatal clinics. Community volunteers, recruited from local community organizations, underwent a two-week training course in VCT. Rapid HIV testing was performed after informed consent. Lay counselors conducted individual pre- and post-test counseling for HIV. A total of 35 women community volunteers were trained in VCT; 34 graduated and committed to work four hours per week in the clinic. Of the 6,051 pregnant women presenting for antenatal clinics (ANC), 1,824 (30 percent) underwent pre-test counseling, 1,547 (26 percent) were tested, and 429 (28 percent) were HIV-positive. Overall, 1,283 (83 percent) returned for their test results including 406 (95 percent) of HIV-positive women. Only 203 (50 percent) opted for ZDV prophylaxis to prevent MTCT of HIV. Over the two-year study period, two counselors died and three sought employment at other organizations. Adherence to duty roster was 97 percent and no breach of confidentiality was reported. The authors concluded that, despite many challenges, VCT delivered by community volunteers is feasible and acceptable for pregnant women aiming to reduce their risk of transmitting HIV to their infants.

In another study, Perez, et al. (2006) conducted an exploratory cross-sectional survey conducted in six PMTCT sites in rural Zimbabwe. This was among the first attempts to evaluate the acceptability of a routine opt-out strategy for HIV testing during pregnancy among women using maternal and child health services in a developing country with high HIV prevalence. Women who had attended ANC in health centers where PMTCT was provided were surveyed in postnatal services. Of 520 women sampled, 285 (55 percent) had been HIV tested during their last pregnancy. Women who had been tested were more likely to report having received group education and individual pretest counseling (81.4 percent)

than untested women (22.1 percent). When untested women were asked why they did not receive group education, the main reasons were not having booked in time or not having group counseling available the same day as the day of booking. The three most important reasons quoted for not accepting to be tested were, in order of decreasing frequency: it was never mentioned to them; they needed to talk to their partner; and they were not prepared to go through pretest counseling. Among the 235 women not HIV tested in ANC, 79 percent said they would accept HIV testing if opt-out testing was introduced; 16 percent said they would decline routine HIV testing, mainly because of their fear of knowing their HIV status and the need to have their partner's consent. Among the women already tested in ANC (n = 285), 97 percent would accept the opt-out approach. The authors concluded that the findings from their study "favor very much the adoption of the opt-out testing strategy." However, they emphasized the importance of the quality of group pretest counseling and individual post-test counseling for HIV-negative and HIV-positive women, and warned that "possible negative impacts in the implementation of this strategy should not be neglected." They suggested that there will be a need to include "interventions to raise community awareness and to develop critical attitudes concerning domestic violence when introducing the opt-out strategy"; and to monitor the implementation of routine testing to assess "how it will influence the use of prenatal care. Will it deter women from seeking prenatal care? Will it result in fewer women returning for their test results?"

## **Other Low- or Middle-Income Countries**

### **China**

#### **Testing of Pregnant Women**

Hesketh, et al. (2005) assessed knowledge and attitudes towards HIV and HIV testing among pregnant women and health professionals in Yunnan Province, to inform the introduction of VCT programs. The study design was a cross sectional survey using self completion questionnaires. It was carried out in 12 hospitals in four high prevalence areas of Yunnan Province. Questionnaires were completed under examination conditions by health professionals, and at the routine antenatal examination by pregnant women. Completed questionnaires were obtained from 840 pregnant women and 780 health professionals. Knowledge of HIV and its modes of transmission were good in health professionals but patchy in pregnant women. The weakest area in both groups was knowledge of maternal to child transmission. There was strong support for compulsory testing in pregnancy and at the premarital examination. But attitudes towards HIV/AIDS were negative: 23 percent of health professionals and 45 percent of pregnant women thought HIV was a disease of "low class and illegal" people, 48 percent of health professionals and 59 percent of pregnant women thought that HIV positive individuals should not be allowed to get married, and 30 percent of the health professionals were not willing to treat an HIV positive individual. Levels of knowledge were higher and attitudes more positive in younger health professionals and better educated pregnant women. The authors concluded that community education programs and intensive training of health workers must precede or accompany VCT programs and address negative attitudes towards people with HIV.

### **India**

#### **Cost of Testing**

Dandona, et al. (2005) obtained detailed cost and output data for the 2002-03 fiscal year from written records and interviews in 17 VCT centers in the public health system in Andhra Pradesh. They found that 32,413 clients received the complete sequence of services at the 17 VCT centers, including post-HIV test counseling. The number of clients served by each VCT center ranged from 334 to 7,802 (median 979). The overall HIV-positive rate in post-test counseled clients was 20.5 percent (range 5.4 to 52.6 percent).

The cost per client for the complete VCT sequence varied 6-fold between VCT centers (range \$2.92-17.14, median \$7.51). The cost per client was significantly lower at VCT centers with more clients, due to substantial fixed costs. Personnel made up the largest component of cost (53.7 percent). Fourteen VCT centers reported that they could serve more clients with the available personnel and infrastructure, and that inadequate demand for their services was the main hurdle towards achieving this.

### **Testing of Pregnant Women**

Shankar, et al. (2003) examined acceptability among pregnant women and their husbands of HIV testing within the antenatal clinic and delivery room of a government hospital in Pune from September 2000 to November 2001. Acceptance of HIV counseling and testing was high with 83 percent of eligible women in the antenatal clinic and 68 percent of eligible women in the delivery room getting tested on the same day. Structured interviews were conducted on 94 pregnant women in the antenatal clinic and 50 women in the delivery room, and 100 husbands who accompanied their wives in the antenatal clinic. The majority of women agreed to be tested independently, without the need for further consultation with family members, a view that was strongly supported by accompanying husbands. For delivering women who were not progressing in their labor, counseling in the delivery room allowed for individual attention to questions and concerns thereby making counseling in the delivery room feasible.

Bharucha, et al. (2005) found that 61 percent of the women admitted for normal delivery in a government hospital in Pune between April 2001 and March 2002 had been previously tested for HIV during their pregnancy. If previously seen in the hospital's affiliated antenatal clinic, the likelihood of being previously tested was 89 percent, in contrast to 27 percent of women having prenatal care elsewhere.

Nieburg, Cannell, and Morrison (2005, at 13) reported that at one prenatal testing site it was found that at one site virtually all women agreed to be tested, but few stayed to receive their results – illustrating “how girls and women may feel intimidated or obliged to comply with the health care providers’ request to be tested, but at the same time perceive too many risks in actually learning their status and in acting upon that knowledge.”

## **Jamaica**

### **Testing of Pregnant Women**

Johnson, et al., 2004 evaluated a PMTCT program in Kingston, Jamaica. Pregnant women presenting had HIV serology performed by ELISA or a rapid test after receiving group counseling. HIV-positive women were referred to high risk antenatal clinics and antiretroviral prophylaxis was given. In year one, 5,558 (40 percent) of 14,054 women who started antenatal care received group counseling and 7,383 (53 percent) received HIV testing. HIV prevalence was 2.1 percent (152/7 383). The authors reported “sub-optimal identification of the HIV-positive pregnant woman and administration of AZT chemoprophylaxis, along with issues of patient confidentiality and stigma” on the labor ward. They concluded that the program needed strengthening.

## **Thailand**

### **Testing of Pregnant Women**

Kanshana and Simonds (2002) described the development, components, and initial uptake of Thailand's national program for PMTCT. They reported that research, monitoring and evaluation of pilot projects, training, and policy-making provided the information, experience, infrastructure, and guidance to develop a PMTCT program that was implemented in all Ministry of Public Health hospitals in Thailand in 2000. A national system was established to monitor program implementation. Monitoring reports were received from 669 hospitals in 65 provinces for the period October 2000 through July 2001. During this period, 93 percent of 318,721 women who gave birth were tested for HIV; 69 percent of 3,958 HIV-positive women giving birth received zidovudine; and 86 percent and 80 percent of the 3,865 children born to HIV-

positive women received zidovudine and infant formula, respectively. The authors concluded that a national PMTCT program was successfully implemented in Thailand; that early monitoring indicates good program uptake; and that lessons learned from implementing this program include the importance of paying attention to counseling, communication, and training in the program, and using pilot projects and focused monitoring and evaluation data to guide the program development, expansion, and improvement.

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