
COMMENTS ON WHO/UNAIDS DRAFT, “GUIDANCE ON PROVIDER INITIATED HIV TESTING
AND COUNSELING IN HEALTH FACILITIES”/SUBMISSION TO WHO
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On November 27, 2006, the World Health Organization and UNAIDS circulated a draft guidance to policy makers, health care professionals, and other interested parties around the world on routine provider-initiated HIV testing and counseling (PITC) at health care facilities. The document recommends that provider-initiated diagnostic testing, based on the “opt-out” model, be introduced in all types of epidemics, and that provider-initiated HIV testing for all adults and adolescents seen in all health care facilities be introduced in countries with generalized epidemics.¹ In other words, all adults and adolescents presenting to health care facilities in generalized epidemics will be offered an HIV test, regardless of the condition they presented with, and will be tested unless they specifically refuse the test.

The rationale behind this recommendation is the fact that the vast majority of people living with HIV are unaware of their status, and that this lack of knowledge interferes both with the ability of people to seek care and treatment in a timely fashion, as well as with HIV prevention efforts. According to WHO and UNAIDS, shifting the initiative for HIV testing from health care users to health care providers (provider-initiated testing) would dramatically increase the numbers of people who know their status, thus facilitating increased access to treatment and prevention efforts.

The draft guidance recommends that health care facilities provide pre-test counseling and obtain informed consent before the test is conducted, as well as post-test counseling. Thus,

¹ The draft guidance defines a generalized epidemic as an epidemic where HIV is firmly established in the general population and prevalence is consistently over one percent in pregnant women (page 21).

it calls for a testing model that combines the dual goals of ensuring a dramatic increase in testing and respecting the autonomy of patients accessing health care services.²

Human Rights Watch presents these comments on the draft guidance in response to WHO and UNAIDS' request for feedback. The comments are based on a review of the draft guidance, available evidence on various testing models, and Human Rights Watch's research on human rights and HIV/AIDS, including on testing and counseling practices. The conclusions of this paper can be summarized as follows:

In an era of rapidly increasing access to anti-retroviral treatment, scaled up HIV testing opportunities is both a human rights and public health imperative. But scaling up testing should not be an end in itself. It should be a vehicle to ensure that those tested adopt risk behavior changes that protect them and others from attracting the virus. For those who test positive, it is of crucial importance that HIV testing serves as the starting point for a long-term relationship based on trust between health care providers and patients. Thus, HIV testing should be conducted in a way that facilitates the goals of enhancing HIV prevention, care and treatment.

Human Rights Watch therefore welcomes WHO and UNAIDS' commitment to scaling up testing and the fact that the draft guidance embraces the principle of informed consent, an important improvement from the June 2006 version of the document. But we are concerned that, in practice, the proposed model will lead to restrictions on the principle of informed consent, including in some cases involuntary testing. Not only is there an inherent risk to authentic informed consent in the opt-out model—patients are no longer required to make a positive decision to be tested—the draft guidance's lack of direction on a number of important problems with ensuring authentic informed consent that are likely to arise with provider-initiated opt-out testing and some of the language used in the guidance exacerbate this risk. For example, the guidance is silent on how health care providers are to deal with patients who have serious health conditions that may impair their ability to give informed consent. In many low and middle-income countries, a considerable percentage of patients

² WHO, UNAIDS (2006). Provider-initiated HIV testing and counseling in clinical settings: Operational recommendations. First draft for comment, 27 June 2006.

only present to health care facilities when they are seriously ill. We are also concerned about the guidance's sweeping caution against "overload of information" as a potential factor in people declining to be tested. This caution may well encourage states to limit information provided to patients about HIV and the risks and benefits of HIV testing, yet the guidance fails to support its assertion with any evidence or even define the term.

Although restrictions on the principle of informed consent may be legitimate and permissible in certain circumstances—such restrictions must, at a minimum, respond to a pressing public or social need, pursue a legitimate aim, be proportional, and be no more restrictive than necessary—it is not clear that the opt-out testing model is the least restrictive model capable of achieving the pursued goal of dramatically increasing the number of people aware of their HIV status (and enabling them to access care and treatment services and to protect others from the virus). The guidance does not cite clear and unequivocal evidence that other forms of testing, including opt-in testing, could not be similarly effective as opt-out testing. Also, many of the reasons cited in the draft guidance for the failure, to date, of achieving much higher testing uptake through voluntary counseling and testing (VCT) expose a lack of sufficient effort on the part of states and the international community to remove barriers to testing more than fundamental flaws in the VCT model.

Human Rights Watch welcomes the strong emphasis the guidance places on the need for confidentiality of test results and on countering stigma and discrimination against people living with HIV in health care settings. We believe that considerable training efforts will be required to ensure confidentiality and professional treatment of people living with HIV.

While we welcome the fact that the draft guidance makes specific reference to the risk of adverse consequences of disclosure of HIV+ status, we are deeply concerned that it unjustifiably downplays them. It marginalizes the suffering of thousands of people from physical violence by asserting that the five percent of people who disclose their status and have faced physical violence is a "small minority," presents the available evidence of

adverse consequences incorrectly and selectively, and draws inappropriate conclusions from the evidence presented. The guidance also ignores the fact that WHO itself recognizes physical violence and violence against women in particular as a serious public health crisis.

Finally, we strongly believe that the expansion of provider-initiated testing and counseling should be part of a larger effort to dramatically increase HIV testing opportunities. PITC is one way to reach people that are currently not making use of HIV testing services. However, it is not a panacea. Certain population groups at risk of HIV in generalized epidemics, such as young men, are not likely to be frequent users of health care services and may thus still not be reached with the offer of testing.

On the basis of these observations, we make the following recommendations (more detailed recommendations can be found in the body of the paper):

- Along with provider-initiated testing and counseling, WHO and UNAIDS should make a concerted effort to expand other forms of HIV testing. Research needs to be done to determine the potential of alternative models of provider-initiated and VCT, particularly as antiretroviral treatment (ART) is rolled out and becomes a key factor in people's decision making with regard to HIV tests. UNAIDS should issue a policy brief that outlines the broader strategic framework within which the draft guidance on provider-initiated testing and counseling in health facilities was prepared;
- The draft guidance should provide considerably more direction on how states are to ensure authentic informed consent in practice, including a clear explanation that the desire for high rates of acceptance of testing should not lead to cutting corners on informed consent and recommendations for dealing with patients who are unable to make an informed decision on the test due to their physical or mental condition. Pre-test counseling should include an explicit provision to provide patients adequate time for consideration of their decision. The reference to "overload of information" should be removed or properly defined and qualified;

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- The sections on adverse consequences should be amended so as to give proper weight to the seriousness of these problems, and should properly present the available evidence and draw appropriate conclusions. The draft guidance should set out a clear strategy for identifying and addressing adverse consequences when they occur.
 - WHO and UNAIDS should fund and sponsor efforts to monitor the new policy. They should develop monitoring protocols that address the key issues including informed consent, counseling, confidentiality, and adverse consequences.

HUMAN RIGHTS STANDARDS AND HIV TESTING

Human Rights Arguments for Testing Scale Up

Some public health experts have suggested that the human rights based approaches that were adopted early in the HIV epidemic have impeded an effective public health response to this crisis.³ However, such conclusions ignore the reality that human rights norms unequivocally require states to take effective actions to counter the spread of HIV and to provide care and treatment (including, where economically feasible, ART) to those infected with the virus. Making HIV testing available and encouraging populations at risk to be tested is an integral part of an effective response, and thus required by international human rights

³ Kevin M. De Cock et al., "Shadow on the continent: public health and HIV/AIDS in Africa in the 21st century," *The Lancet*, vol. 360 (2002), pp. 67-72.

law. Indeed, human rights groups have repeatedly called on states to dramatically scale up access to testing.⁴

Two rights—the right to life and the right to health—are of particular importance with regard to the HIV epidemic. These rights are interdependent and complementary since the protection of one requires the fulfillment of the other.

The right to life includes not just an obligation for states to refrain from unlawful killing, it also requires states to take positive steps to protect the lives of people in their jurisdiction. The UN Human Rights Committee, the body that monitors implementation of the International Covenant on Civil and Political Rights and issues authoritative opinions on its interpretation, has held that

[t]he expression "inherent right to life" cannot properly be understood in a restrictive manner and the protection of this right requires that States adopt positive measures. In this connection, the Committee considers that it would be desirable for States parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics.⁵

⁴ See, for example, Physicians for Human Rights, "A Health Action AIDS Briefing Paper", July 31, 2003, <http://www.physiciansforhumanrights.org/library/statement-2003-07-31.html>; Marlise Richter, Different Models of HIV-testing: What are the Considerations in South Africa?, AIDS Law Project, October 31, 2006, www.tac.org.za/documents/FinalHIVTestingPaper.pdf; Human Rights Watch publications: Joseph Amon, "Preventing the Further Spread of HIV/AIDS: The Essential Role of Human Rights", in Human Rights Watch, *World Report 2006* (New York: Human Rights Watch, 2006); Human Rights Watch, "Unprotected: Sex, Condoms, and the Human Right to Health," Vol. 16, No. 6(C), May 2004, <http://hrw.org/reports/2004/philippines0504/index.htm>; "Test of Inequality: Discrimination against Women Living with HIV in the Dominican Republic," Vol. 16, No. 4(B), <http://hrw.org/reports/2004/dro704/>; "Suffering in Silence: Links between Human Rights Abuses and HIV Transmission to Girls in Zambia," ISBN: 1-56432-283-1, 2003, <http://www.hrw.org/reports/2003/zambia/>; "Fanning the Flames: How Human Rights Abuses are Fueling the AIDS Epidemic in Kazakhstan," Vol. 15, No. 3(D), June 2003, <http://hrw.org/reports/2003/kazako603/>; "Locked Doors: The Human Rights of People Living with HIV/AIDS in China," Vol. 15, No. 7(C), August 2003, <http://www.hrw.org/reports/2003/chinao803/>; "Policy Paralysis: A Call for Action on HIV/AIDS-Related Human Rights Abuses Against Women and Girls in Africa," December 2003, <http://www.hrw.org/reports/2003/africa1203>.

⁵ Human Rights Committee, General Comment 6, The Right to Life, Article 6, UN Doc. HRI\GEN\1\Rev.1 (1982), para. 5.

In the context of the HIV epidemic, the right to life requires states to take reasonable measures to protect people (or enable them to protect themselves) from contracting HIV and providing, to the extent feasible, health care services and treatment to people living with the virus. Thus, states have an obligation to make accurate and comprehensive information about HIV prevention available to the public, and to ensure people have access to life-saving prevention services, such as needle exchange or condoms. Where available, governments also have an obligation to provide ART to people in need of such treatment without discrimination.

The right to the highest attainable standard of health imposes a similar positive obligation on states. The Committee on Economic, Social and Cultural Rights, the independent panel of experts that monitors rights under the International Covenant on Economic, Social, and Cultural Rights (ICESCR) and provides authoritative guidance on its provisions, has interpreted the “right to prevention, treatment and control of diseases” set forth in article 12 of the ICESCR to impose a positive obligation on states parties to take steps necessary for the “prevention, treatment and control of epidemic, occupational and other diseases.” Although the right to health is subject to “progressive realization” within the pragmatic confines of each state’s financial and infrastructural resources, all states must take “deliberate, targeted, and concrete” steps toward the full implementation of the right to health.⁶

“Due Process” Criteria for Testing: Informed Consent and Confidentiality

Human rights standards set out certain “due process” criteria for the conduct of testing, such as the requirements of informed consent and confidentiality. These requirements are based on legally protected rights including those of security of person, to health, and to privacy and apply to any medical procedure, not just to HIV testing.⁷

⁶ Committee on Economic, Social, and Cultural Rights, General Comment 3, The Nature of States Parties Obligations, Article 2, U.N. Doc. HRI/GEN/1/Rev.6 (1990).

⁷ International Covenant on Civil and Political Rights (ICCPR), adopted December 16, 1966, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, entered into force March 23, 1976, Articles 9, 17 (1); International Covenant on Economic, Social and Cultural

The rights to security of person and to the highest attainable standard of health require that no medical procedures are performed without the explicit consent of the individual involved. The patient's consent must be based on an understanding of the relevant medical facts and the risks involved. In order to obtain such informed consent from the patient, health care providers must convey the details of a planned procedure or treatment, its potential benefits and serious risks, and any feasible alternatives. The person must then be given the opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.⁸

In certain cases, there may be digressions from the general rule of informed consent. Human rights law provides a specific mechanism by which it can be determined whether and to what extent rights like informed consent or confidentiality can legitimately be restricted. Under this mechanism, restrictions on these rights must, at a minimum:

- Respond to a pressing public or social need;
- Pursue a legitimate aim;
- Be proportionate to the legitimate aim pursued;
- Be no more restrictive than necessary to achieve the legitimate aim.⁹

Rights (ICESCR), adopted December 16, 1966, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3, entered into force January 3, 1976, Article 12; Beijing Declaration and Platform for Action, Fourth World Conference on Women, 15 September 1995, A/CONF.177/20 (1995), Article 108(e); Council of Europe, Convention on Human Rights and Biomedicine, adopted April 1997, CETS No.: 164, Article 5; United Nations Educational, Scientific, and Cultural Organization (UNESCO), Universal Declaration on Bioethics and Human Rights, adopted October 2005, SHS/EST/05/CONF.204/3 REV, Article 6 and 9.

⁸ American Medical Association, "Informed Consent", March 7, 2005, <http://www.ama-assn.org/ama/pub/category/4608.html> (accessed December 26, 2006); Beijing Declaration, art. 108(e); CHR.B, art.5; UDBHR, arts 6 & 9.

⁹ These criteria were developed in 1984 by a panel of thirty-one international experts who met at Siracusa, Sicily, to adopt a uniform set of interpretations of the limitation clauses contained in the ICCPR. While they do not have the force of law, they offer important, authoritative guidance as to the meaning of the terms contained in the ICCPR. "The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights," *Human Rights Quarterly*, vol. 7, no. 1 (February 1985). Apart from the criteria cited above, the Siracusa principles also require that limitations not be applied in an arbitrary or discriminatory manner and must be provided for by law. These criteria are wholly consistent with international practice in the determination of

In the case of informed consent, public health considerations play a crucial role in determining whether a pressing public or social need exists. If there is a public health imperative to take certain interventions that restrict informed consent to contain, for example, a highly contagious and lethal infection, it is highly likely that the requirement of a “pressing public or social need” is met. The interventions must obviously pursue a legitimate aim but also have to be proportional to the pressing public or social need and may not restrict the right to informed consent any more than necessary to achieve the goal.

Adverse Consequences of Testing

Human rights law puts in place an obligation on the part of states to make sure that individuals who undergo medical tests or other procedures do not face discrimination or other violations of their human rights as a result. They have an obligation to ensure that people who test positive are not stigmatized or discriminated against in health care and other government facilities, and to take effective steps to counter such abuses.¹⁰ They also have to take steps to counter so-called horizontal abuses—situations where one individual commits abuses against another individual. Thus, states must take action when people who have been tested face discrimination, violence, or other abuses in their family circle or community.¹¹

RISK OF RESTRICTIONS ON INFORMED CONSENT AND INVOLUNTARY TESTING

As mentioned above, the draft guidance seeks to combine the dual goals of ensuring a dramatic increase in testing and respecting the autonomy of patients accessing health care services.¹² Research conducted in both high and low-income settings suggests that the

legitimate restrictions and derogations which may be imposed on internationally recognized human rights.

¹⁰ ICESCR, art. 2(2).

¹¹ Declaration on the Elimination of Violence against Women, G.A. res. 48/104, 48 U.N. GAOR Supp. (no. 49) at 217, U.N. Doc. A/48/49 (1993), art. 4; International Committee on Economic, Social, and Cultural Rights, General Comment No. 14, The right to the highest attainable standard of health, U.N. Doc. E/C.12/2000/4 (2000).

¹² WHO/UNAIDS, “Provider-initiated HIV testing and counseling in clinical settings: Operational recommendations”, First draft for comment, 27 June 2006.

introduction of this routine opt-out HIV testing in health care facilities will indeed lead to a rapid increase in the number of people who are tested for HIV and become aware of their status. Thus, achieving the first goal appears likely.

It is, however, much less obvious that the second goal will be achieved. Under the draft guidance, health care providers will offer HIV tests to anyone who comes to the health care facility, irrespective of the reason for their visit, and will conduct an HIV test unless the patient specifically objects to the test. However, there is an inherent risk that such opt-out testing may result in involuntary testing in practice. After all, a person who does not express specific objections to being tested has not necessarily made a positive decision to be tested. With the opt-out model, it is harder for health care workers to determine whether a patient made an *informed* decision to be tested than in a model which requires a positive decision of the patient to be tested. Much will depend on the protocols that will be developed for opt-out testing by WHO/UNAIDS and individual countries, and on how these protocols are implemented by health care workers. These protocols will need to provide very clear criteria to counter the risk that testing will in practice become compulsory.

This inherent risk is exacerbated by the fact that the draft guidance fails to provide direction on how states are to ensure authentic informed consent and by the sweeping assertion that an “overload of information” may discourage patients from accepting testing and counseling (page 15).

First, in many countries, people only present at health care facilities when they are seriously ill. Many of these patients may be in no position to make an informed decision on an HIV test. A patient who presents to a hospital with malaria-induced high fevers may not be able to properly process the information received on an HIV test or make an informed decision. A patient who has just suffered from a traumatic event, such as rape or assault, may not be ready to be burdened with information about HIV, let alone make an informed decision to be tested or learn the test result. These patients may not only be unable to make an informed decision on an HIV test, they are also unlikely to be able to process information about HIV prevention, thus making a change in risk behaviors unlikely. Yet, the draft guidance recommends routine offer to all patients who present to health care facilities without

providing any guidance on how health care providers are to deal with such cases. Human Rights Watch believes that the guidance should address this issue, and should recommend that HIV tests are only offered to those patients who are deemed able to make an informed decision on a test and for whom it does not interfere with treatment of the condition they presented with. Although such determinations will frequently be subjective, various factors can be identified that need to be taken into consideration, including the patient's responsiveness, the level of pain he or she is in, and mental trauma.

Secondly, the draft does not provide any guidance on the amount of time health care workers should give their patients to consider whether they want to be tested. It is likely that some patients, especially those who had little (accurate) information about HIV previously before presenting to the health care facility, may need time to be able to reach an informed decision. For authentic informed consent, a patient should be able to reflect on the information received, to consult with friends or family, or seek advice or additional information (including the availability of testing from other sources, for example). Yet, the draft guidance gives the clear impression that patients are expected to make a decision on the spot. For example, under post-test counseling the guidance specifically provides for patients to be given time to consider the result of the test, whereas it is silent on this in the section on pre-test counseling. The guidance should make clear that patients need to be advised that they are under no obligation to make an immediate decision and that the HIV test will only be performed once they have made up their mind. Human Rights Watch understands that giving people time for reflection may lead to a larger number of people declining the test but testing risks becoming de facto compulsory when patients are pressured to make a decision on the spot.¹³

A related question that is not addressed in the draft concerns what happens when a patient cannot make up his or her mind. Informed consent would be compromised if health care

¹³ In cases where people must return later to collect their test results, this may actually be mitigated by the fact that people who were pressured to make an on-the-spot decision but were in fact not ready to make that decision may not collect the test result in greater numbers than those who made the decision after sufficient reflection.

workers can simply proceed with an HIV test after the pre-test counseling even if the patient may still be deliberating whether to accept or decline the test.

Finally, the draft leaves open the question what happens with the treatment of the condition with which a patient presented when the patient cannot make a decision regarding the HIV test on the spot. The draft specifically states that medical treatment should not be affected if an HIV test is declined. It may be assumed that treatment should proceed even as the patient is making up his or her mind but the draft is silent on that scenario, reinforcing the impression that patients are expected to accept or decline the test right after the pre-test counseling. It would be important to provide clear guidance on this question.

The existence of alternative testing sites would also help facilitate authentic informed consent. Some individuals who would like to know their HIV status may have legitimate reasons for not wanting to be tested at a general health care facility, including fears about confidentiality or presence of a family member when the HIV test is offered at a general health care facility. It is important that these patients are aware that they can seek HIV testing at other—equally or comparatively convenient—testing sites as well, and that they are provided with information on where other testing sites are located. Awareness of options is an important part of informed consent.

The draft guidance asserts that there is evidence that existing opt-out testing programs “did not appear to result in coercion” (page 14). However, the studies cited do not support this conclusion. Most of the studies did not in fact examine opt-out testing programs. Rather, they focused on routine offer of HIV tests with opt-in (studies mentioned in footnotes 42 and 43), different models of voluntary testing (footnotes 18, 20, 39, 44), or the hypothetical acceptability of the introduction of opt-out testing in antenatal settings (footnote 40). Thus, no conclusions can be drawn from these studies regarding the risk of coercion posed by opt-out testing. As for the two studies referenced that examined opt-out testing in antenatal settings, there is no indication that these studies specifically looked at the issue of informed consent or coercion. Furthermore, the article referenced in footnote 35 concerned experiences with opt-out testing in the United Kingdom. Even if it had specifically looked at

informed consent, it would have had little comparative value for middle and low-income countries.

In terms of counseling, Human Rights Watch generally supports the recommendation for minimum information that health care providers must offer to patients regarding HIV tests. As noted above, we are concerned about the use of language that suggests that an “overload of information may make clients uncomfortable and discourage them from accepting testing and counseling.” The way this language is presented in the draft guidance can easily be interpreted as encouraging states and health care workers to limit the provision of information to patients about HIV tests because that will result in larger numbers of patients agreeing to the test. Such practice would not be consistent with the principle of informed consent, which requires that patients are given sufficient information to make an informed decision. We are particularly troubled by the fact that the guidance makes no attempt to define the term “overload of information.” To some people, any information on HIV might be an “overload of information,” yet that does not justify providing them no information. Furthermore, this sweeping assertion is not referenced in any way. The studies cited in the paragraph do not provide any evidence to support it. Human Rights Watch therefore believes that this assertion should either be taken out of the guidance altogether, or should be clearly defined and properly referenced.

We welcome the fact that the draft guidance recommends individual counseling over group counseling. It is clear, however, that in many resource-poor settings counseling will in reality often take place in groups. While the draft guidance specifically states that in situations where pre-test counseling takes place in groups, individual risk assessment and risk reduction plans should be covered in individual post-test counseling sessions, we believe that the draft guidance should also specifically state that patients should have an opportunity to ask questions about the test in private and to consent to or decline the test in private. As the draft notes, the opportunity to ask questions about the medical procedure is part of obtaining informed consent. Yet, many patients may be reluctant to ask specific

questions in a group as that might reveal sensitive personal information and could lead to stigma.

Human Rights Watch welcomes the language in the draft guidance on the specific challenges faced in ensuring informed consent (and confidentiality) for adolescents.

Lawfulness of Restrictions on Informed Consent

The routine opt-out testing model proposed by the draft guidance thus has a clear potential of resulting in restrictions on informed consent in practice, and may result in involuntary testing practices in some settings. It is therefore important to determine in what situations such restrictions may be lawful using the above-mentioned criteria.

Existence of a Pressing Public or Social Need

There is little dispute that there is a pressing need for increased access to high-quality HIV testing. In the context of the rapidly increasing roll-out of treatment and efforts to achieve universal access by 2010, a very significant scale-up of HIV testing opportunities is crucially important. As the draft guidance notes, up to 90 percent of those infected with HIV are currently unaware of their status. These people are thus not able to access necessary medical services that help protect their health and lives, and are potentially inadvertently infecting others, putting their health and life at risk.

Legitimate Aim

The aim of the proposed testing scale up is to ensure that more people become aware of their status, gain access to ARV or other treatment and care, and change their risk behavior so as to protect themselves and others. It is important to note that from the human rights perspective—as well as from the public health perspective—the testing scale up should not be a goal in itself but rather a vehicle toward prevention, care, and treatment.

Proportionality of Potential Limitations on Informed Consent

The next question is whether the opt-out testing model proposed in the draft guidance, with its risk of restrictions on informed consent in practice, is proportionate to the legitimate aim pursued.

One of the great difficulties in assessing this question is the current paucity of evidence on different HIV testing models. The draft guidance argues strongly in favor of opt-out regimes and argues that it is considerably more effective than opt-in testing. Yet, the draft does not provide much evidence to support this assertion. It refers to two studies in low to middle-income countries that found that the opt-out model seemed to “cause less anxiety for women than an opt-in approach.” But much of the other evidence from middle and low-income countries showed merely that opt-out testing has resulted in vast increases testing uptake but did not compare this to results of opt-in programs. For example, the guidance states that studies showed “pregnant women were positively inclined to accept testing if they thought it could benefit their baby” and that “uptake increased rapidly when testing would routinely discussed and offered, and where it was well integrated into antenatal care” (page 14). These would presumably also be true for opt-in testing.

Three of the studies cited in the draft guidance as evidence of the benefits of opt-out testing in resource-poor settings are not actually studies about opt-out testing. Two of these studies examined routine offer of HIV tests in antenatal settings in South Africa and India. The third examined the acceptability of VCT in a district of Uganda with a view to recommending measures for increasing uptake.¹⁴

Evidence from some studies in high income countries suggests that opt-out leads to larger increases in the percentage of people who present to medical facilities accepting testing than opt-in strategies.¹⁵ For example, studies in the United Kingdom and United States found

¹⁴ MA Etiebet et al., “Integrating prevention of mother-to-child HIV transmission into antenatal care: learning from the experiences of women in South Africa,” *AIDS Care* Vol. 16, No. 1 (2004), pp. 37-46; F Nuwaha et al. “Factors influencing acceptability of voluntary counseling and testing for HIV in Bushenyi district of Uganda,” *East African Medical Journal*, Vol. 79, No. 12 (December 2002); AV Shankar et al, “Women’s acceptability and husband’s support of rapid HIV testing of pregnant women in India,” *AIDS Care*, Vol.15, No. 6 (2003), pp. 871-874.

¹⁵ Roger Chou et al., “Prenatal screening for HIV: A review of the evidence for the U.S. Preventive Services Task Force,” *Annals of Internal Medicine*, Vol.143, No. 1, (2005), 38-54; Elizabeth M. Stringer et al., “Evaluation of a new testing policy for human immunodeficiency virus to improve screening rates,” *Obstetrics Gynecology*, Vol. 98, No.6 (2001), p. 1104-1108; WM Simpson et al. “Uptake and

that the proportion of pregnant women undergoing prenatal HIV testing increased from 33 to 74 percent with an opt-in strategy to 81 to 88 percent with an opt-out strategy.¹⁶ At the same time, however, there is some evidence that opt-in testing strategies can achieve comparable results. For example, a study in Ontario, Canada, shows that the opt-in testing and counseling policy for pregnant women delivers results comparable to most opt-out policies.¹⁷ Other studies found that encouragement to take the test from health care providers plays an important role in the decision making process,¹⁸ suggesting that an routine opt-in approach combined with a reasoned recommendation may lead to similar results as the opt-out approach.

Furthermore, in low-income countries, a number of studies have shown that when the offer of HIV testing and counseling is integrated into routine antenatal services up to 97 percent of women accept the offer and opt in to HIV testing.¹⁹

acceptability of antenatal HIV testing: randomised controlled trial of different methods of offering the test," *British Medical Journal*, Vol. 316 (1998), pp. 262-267.

¹⁶ M Blott et al., "Routine antenatal HIV testing is acceptable to women," *British Medical Journal*, Vol. 319 (1999), pp. 1069-1070; Centers for Disease Control and Prevention, "HIV testing among pregnant women – United States and Canada 1998-2001," *Morbidity and Mortality Weekly Report*, Vol. 51 (2002), pp. 1013-1016; Simpson et al. (1998), *British Medical Journal*, 262-267; WM Simpson et al., "Antenatal HIV testing: assessment of a routine voluntary approach," *British Medical Journal*, Vol. 318 (1999), pp. 1660-1661; WM Simpson et al., "A randomised controlled trial of different approaches to universal antenatal HIV testing: uptake and acceptability" and "Annex: Antenatal HIV testing—assessment of a routine voluntary approach," *Health Technology Assessment*, Vol. 3 (1999), pp. 1-112; Stringer et al. (2001), *Obstetrics Gynecology*, 1104.

¹⁷ H Schietinger, "Reaching the Hidden Epidemic with HIV Testing and Counselling: Policies in Transition?", Research Paper written for the "International Public Health Dialogue on HIV Testing and Counselling and the Hidden Epidemic", organized by The Public Health Agency of Canada, Toronto, 17 August, 2006.

¹⁸ John E. Anderson et al., "Achieving universal HIV screening in prenatal care in the United States: provider persistence pays off," *AIDS Patient Care STDS*, Vol. 19 (2005), pp. 247-252; MK Lindsay et al., "Determinants of acceptance of routine voluntary human immunodeficiency virus testing in an inner-city prenatal population" *Obstetrics Gynecology*, Vol. 78 (1991), pp. 678-680; Rachel A. Royce et al., "Barriers to universal prenatal HIV testing in 4 US locations in 1997," *American Journal of Public Health*, Vol.91 (2001), pp. 727-733.

¹⁹ MA Etiebet et al., "Integrating prevention of mother-to-child HIV transmission into antenatal care: learning from the experiences of women in South Africa," *AIDS Care* Vol. 16, No. 1 (2004), pp. 37-46; J Kiarie et al., "HIV-1 testing in pregnancy: acceptability and correlates of return for test results," *AIDS*, Vol. 14, No.10 (2000), pp. 1468-1470; Isaac M. Malonza, et al., "The effect of rapid HIV-1 testing on uptake of perinatal HIV-1 interventions: a randomized clinical trial," *AIDS*, Vol. 17 (2003), pp. 113-118; AV Shankar et al., "Women's acceptability and husband's support of rapid HIV testing of pregnant women in India," *AIDS Care*, Vol.15, No. 6 (2003), pp. 871-874.

The potential of other testing models should also continue to be examined as HIV care and treatment become more widely available and may become an important incentive for people to seek VCT testing. Evaluation of the effectiveness of the VCT testing model may differ significantly depending on whether treatment was widely available at the relevant time. This factor was not taken into account in concluding that the VCT model has been inadequate, as stated on page 10 of the guidance.²⁰ Similarly, the lack of adequate investment in promoting VCT may hinder our assessment of the effectiveness of the model to initially attract individuals.

It would also be important to examine whether there is any difference in rates of behavior change after testing in opt-in, opt-out, and VCT settings. It is not at all inconceivable that the impact in this respect will be higher in VCT or opt-in than in opt-out settings where individuals may feel less prepared for the test or to make effective decisions with the result of the test.

In light of this conflicting evidence, Human Rights Watch is not convinced that opt-out testing is the least restrictive model for increasing the number of people who test for HIV. It is not clear that opt-in testing, which is clearly preferable from the point of view of the principle of informed consent, could not achieve a testing uptake similar to that of opt-out testing if HIV tests are routinely offered to those deemed capable of making an informed and voluntary decision regarding an HIV test, counseling on the benefits and risks of testing is provided, and health care workers encourage patients to take the test. Effectiveness of opt-in and other models of testing may also increase when states conduct aggressive and ongoing public awareness campaigns about HIV that stress the importance of testing in parallel and offer access to ART for those who test positive.

ENSURING CONFIDENTIALITY

²⁰ J Csete and R Elliot, "Scaling Up HIV Testing: Human Rights and Hidden Costs," *HIV/AIDS Policy and Law Review* Vol. 11, No. 1 (April 2006).

The draft guidance strongly emphasizes the need for confidentiality of HIV tests and calls for protections to be put in place against unauthorized disclosure, which Human Rights Watch welcomes.

Confidentiality requirements are rooted in the rights to privacy and health, which establish a clear obligation for any medical information to be treated as confidential.²¹ Human Rights Watch has repeatedly documented the widespread failure of medical professionals to maintain confidentiality.²² We have documented numerous cases in which breaches of confidentiality had serious consequences for the individuals involved, including dismissal by employers, abandonment, physical violence, and even murder.²³

Human Rights Watch believes that a significant training effort for health care providers on HIV testing and confidentiality will be crucial. As we and others have documented repeatedly in the past, breaches of confidentiality occur frequently in countries around the world in various different testing settings, and may have serious consequences.²⁴ With the rapid scale up of PITC, large numbers of health care workers with little experience working with HIV patients will begin performing HIV tests. Although these people should have received general training on professional ethics, including confidentiality principles, it is important that these people receive specific training on the special nature of the potentially serious abuses as consequence of disclosure of HIV status.

²¹ ICESCR, General Comment No. 14, paras. 12(b), 12(c), 23.

²² See, for example, Human Rights Watch, “Life Doesn’t Wait: Romania’s Failure to Protect and Support Children and Youth Living with HIV”, Vol. 18, No. 6(D), August 2006, <http://hrw.org/reports/2006/romania0806/index.htm>; “A Test of Inequality: Discrimination Against Women Living With HIV in the Dominican Republic”, Vol. 16, No. 4(B), June 2004, <http://hrw.org/reports/2004/dro704/index.htm>; *Future Forsaken: Abuses Against Children Affected by HIV/AIDS in India* (New York: Human Rights Watch, 2004), <http://hrw.org/reports/2004/india0704/index.htm>.

²³ See, for example, Human Rights Watch, “A Test of Inequality: Discrimination Against Women Living With HIV in the Dominican Republic”, Vol. 16, No. 4(B), June 2004, <http://hrw.org/reports/2004/dro704/index.htm>; “Hated To Death: Homophobia, Violence, and Jamaica’s HIV/AIDS Epidemic”, Vol. 16, No. 6(B), November 2004, <http://hrw.org/reports/2004/jamaica1104/>.

²⁴ See footnote 22, and Submission from Human Rights Watch to the United Nations Office of the High Commissioner for Human Rights In Re: Human Rights Resolution 2005/84, December 6, 2006.

Human Rights Watch also draws attention to the fact that many people visit health care facilities in the company of family members, particularly when they are seriously ill. Under the draft guidance, these people would be offered an HIV test, irrespective of whether they would be able to process information on the test or make an informed and voluntary decision. It is likely that in many such cases a relative will play a key role in the decision making process, which raises questions with regard to confidentiality of HIV test results.

POTENTIAL ADVERSE CONSEQUENCES OF TESTING

Human Rights Watch welcomes the fact that the draft guidance makes specific reference to the risk of adverse consequences disclosure of HIV+ status such as physical violence, abandonment, stigma and discrimination. But we are concerned that the information on adverse consequences is presented in a way that unjustifiably downplays these concerns.

The draft guidance states that “the evidence about the consequences of disclosure is limited and contradictory. Physical violence has been reported in a small minority of cases (around 5%).” It concludes that “on balance, the available evidence suggests that “opt-out” testing and counseling is not associated with major problems...” (page 15).

First of all, Human Rights Watch strongly objects to the trivialization of the finding that around 5 percent of people who disclose a positive test result face physical violence. Five percent may statistically speaking be “a small minority” but that does no justice to the human cost to thousands of people, most of them women. It also ignores the fact that while 5 percent may face physical violence, many more may face other, also serious, adverse consequences, such as abandonment, blame, economic deprivation, stigma, or discrimination, all of which may have devastating impacts on their lives. We also recall that WHO has characterized physical violence itself, and in particular violence against women, as

a serious health crisis.²⁵ It would be counterproductive for steps against one health crisis to feed into another.

Secondly, the draft guidance poorly presents the available evidence of the risk of adverse consequences. For example, the draft references studies in Tanzania, Kenya and Zambia (footnotes 48, 50 and 52) that it says show that opt-out testing and counseling “is not associated with major problems.” The draft bases that conclusion on the fact that these studies had found that a majority of respondents had not experienced adverse consequences of disclosure, even when they expected them. The draft, however, makes no reference whatsoever to the experiences of the minority of respondents in each of the studies. Obviously the experiences of these groups are of great importance to the question of adverse consequences.

In any case, these studies concerned the experiences of women who had accessed VCT testing and not PITC opt-out testing. Thus, the draft incorrectly draws the conclusion that these studies indicate that opt-out testing and counseling “is not associated with major problems.” In fact, there is some reason to believe that people who are tested through PITC may be more vulnerable to adverse consequences than those who are tested through VCT. The general profile of people tested through PITC is likely to be considerably different from that of people who make use of VCT services and who have made a conscious choice to seek HIV testing and may have had more discretion in choosing to disclose the test result.

Finally, the draft guidance makes no reference to a number of studies that suggest higher rates of reported physical violence following disclosure of HIV status, or to the fact that domestic violence is a hidden crime, the frequency of which is bound to be uncertain. For example, a review of seventeen studies from Africa and Southeast Asia concluded that four to 28 percent of women reported negative outcomes following disclosure of their status, including blame, abandonment, violence, anger, stigma, and depression.²⁶ Of these women,

²⁵ World Health Organization, “Violence Against Women,” June 2000, <http://www.who.int/mediacentre/factsheets/fs239/en/>, accessed January 3, 2006.

²⁶ A Medly et al., “Rates, barriers and outcomes of HIV serostatus disclosure among women in developing countries: implications for prevention of mother-to-child transmission programmes,” *Bulletin of the World Health Organization*, Vol. 82, No. 4, (2004), p. 302.

2.5 to 14.6 percent reported having faced violence as a result of disclosure of their status. A study in Zambia found that 28 percent of women who tested HIV-positive reported adverse social events, including physical violence, verbal abuse, divorce, and separation.²⁷

There is thus clear evidence that a significant minority of people who disclose their HIV status after VCT testing face physical or other abuse. There is also some reason to believe that the incidence of such abuse may be higher among people who are tested at PITC settings, especially when breaches of confidentiality occur. Human Rights Watch urges WHO and UNAIDS to make sure that the draft guidance properly presents the available evidence. We also recommend that the guidance set out a clear strategy for identifying and addressing adverse consequences when they occur.

Regarding stigma and discrimination against people living with HIV in health care settings, Human Rights Watch supports recommendations in the draft guidance for additional training of health care workers. Careful monitoring should also take place to ensure that people living with HIV or those suspected of having the virus do not face stigma and discrimination.

MONITORING AND EVALUATION

The draft guidance calls for monitoring and evaluation of the scale up effort, including coverage, quality, adverse outcomes, and other issues. Human Rights Watch welcomes this commitment. We believe that WHO, UNAIDS, and individual states should closely monitor the way the new policy is implemented to ensure that the opt-out model does not in practice lead to unlawful restrictions on informed consent, breaches of confidentiality, and adverse consequences, and that any such incidents are properly addressed.

WHO and UNAIDS should fund and sponsor efforts to monitor the implementation of the new policy. We believe that WHO and UNAIDS should develop monitoring protocols that can be

²⁷ K Semrau et al., “Women in couples antenatal HIV counseling and testing are not more likely to report adverse social events,” *AIDS*, Vol. 19, No. 6, (2005), pp. 603-609.

adapted to local situations, which should address, among others, the issues of informed consent, pre and post-test counseling, confidentiality, HIV testing options, training, adverse consequences, treatment access, and behavior change. These protocols should ensure proper stratification of data so as to facilitate a maximum understanding of the issues researched.

GENERAL COMMENTS ON TESTING SCALE UP

The draft guidance identifies the rapid expansion of provider-initiated testing and counseling at health care facilities as “one of several potential components in an overall strategy to increase uptake of HIV testing and counseling and knowledge of HIV status.” Human Rights Watch welcomes that statement but is concerned that states may understand and interpret the current guidance too narrowly as sufficient towards increasing access to HIV testing overall. Human Rights Watch urges WHO and UNAIDS to issue a policy brief that outlines the broader strategic framework within which the draft guidance on PITC in health facilities was prepared.

Human Rights Watch considers it crucially important for an effective “know your status” campaign, in addition to expanding provider-initiated testing and counseling, to bolster voluntary testing and counseling services. We also consider it important that new strategies are developed to reach populations that are unlikely to be reached through either VCT or PITC at health care facilities. The effort to scale up PITC should be part of a broader strategy to increase testing opportunities, including an effort to ensure that people have easily accessible testing alternatives so that those who, for whatever reason, do not want to be tested at a local health care facility, can get tested elsewhere. Campaigns against stigma and increased education on the rights of, and adoption and enforcement of legal protection against discrimination and abuse for individuals living with HIV, should also be a part of this effort.

Using testing as a vehicle for prevention efforts can only be effective if states actually provide comprehensive prevention information to people who get tested and provide effective prevention services. As Human Rights Watch has repeatedly pointed out in the

past, many governments around the world fail to provide comprehensive prevention information or effective services.²⁸ The important opportunities for prevention offered by testing are lost when states provide inaccurate or no information about the benefits of condom use or ban needle exchange services for injecting drug users. Human Rights Watch recommends that the draft guidance specifically points out the importance of comprehensive information and prevention services as a way to maximize the impact of expanded testing on the spread of the epidemic.

²⁸ Human Rights Watch, “No Bright Future: Government Failures, Human Rights Abuses, and Squandered Progress in the Fight Against AIDS in Zimbabwe,” Vol.18, No.5(A), July 2006, <http://hrw.org/reports/2006/zimbabwe0706/>; “Unprotected: Sex, Condoms, and the Human Right to Health,” Vol. 16, No. 6(C), May 2004, <http://hrw.org/reports/2004/philippines0504/index.htm>; “Not Enough Graves: The War on Drugs, HIV/AIDS, and Violations of Human Rights,” Vol. 16, No. 8(C), July 2004, <http://www.hrw.org/reports/2004/thailand0704/index.htm>; “Ravaging the Vulnerable: Abuses Against Persons at High Risk of HIV Infection in Bangladesh,” Vol. 15, No. 6(C), August 2003, <http://www.hrw.org/reports/2003/bangladesh0803/>.