

## **Comments on the draft document “Guidance on Provider-initiated HIV Testing and Counselling in Health Facilities”**

**Submitted by the UNAIDS Reference Group on HIV and Human Rights<sup>1</sup>  
to WHO and UNAIDS**

Please find below consolidated comments<sup>2</sup> of the members of the UNAIDS Reference Group on HIV and Human Rights on the draft WHO/UNAIDS document “Guidance on Provider-initiated HIV Testing and Counselling in Health Facilities” (27 November 2006).

### ***General Comments***

1. The UNAIDS Reference Group on HIV and Human Rights would like to commend the drafters of the guidelines for a number of improvements made since the first draft of July 2006. These include strengthened provisions on the importance of informed consent prior to HIV testing. The document also makes useful distinctions between generalized, concentrated and low prevalence epidemics, and its recommendations are tailored to the specific characteristics of national and local epidemics. Despite improvements, however, the Reference Group is of the opinion that the draft document still leaves a number of important issues inadequately addressed.

### **Clearly articulate that PITC is only one component of making HIV testing and other prevention and care services more widely available**

2. The Reference Group recognises that the guidelines involve a significant change in policy for the WHO/UNAIDS, namely that PITC may occur even where there is no or limited access to ART. This is based on the recognition that both asymptomatic and symptomatic persons can benefit from earlier diagnosis -- even if ART is not available. However, we would urge that the final version of the guidance document explicitly mention that implementation and expansion of PITC should occur concomitantly with expansion of access to ART and that resources should not be diverted to PITC at the expense of ART rollout.
3. Although the draft guidelines are concerned with PITC only, the document should more strongly emphasise that HIV testing does, and needs to, occur outside health settings, through various models of VCT. In this context, PITC is only one component of a comprehensive strategy to make HIV testing more widely available. Other contexts which the document should refer to and emphasize as important involve, for example, VCT, mobile testing facilities, voluntary testing among marginalised populations (men who have sex with men, sex workers, drug users, prisoners).

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<sup>1</sup> The UNAIDS Reference Group on HIV and Human Rights was established in 2002 to advise the Joint United Nations Programme on HIV/AIDS on all matters relating to HIV and human rights. The Reference Group is comprised of advocates, jurists, ethicists, people living with HIV, and people working in NGOs, the community sector, and in academia. The views of the Reference Group do not necessarily reflect the views of the UNAIDS Secretariat or those of the UNAIDS Co-sponsors.

<sup>2</sup> These comments draw upon submissions on the Guidelines provided by individual members of the Reference Group, as well as on work done by Reference Group members in related contexts. In particular, the comments draw on work done by Reference Group member, Ralf Jürgens, for the Open Society Institute which was circulated to and supported by RG members.

4. The Guidelines should make it clear that in all contexts (PITC in health care facilities and HIV testing and counselling offered outside health facilities) HIV testing and counselling should be conducted only with full adherence to the Three Cs – informed consent, confidentiality and counselling. There is a significant risk that, without this clarification, this guidance document may be inappropriately adapted for use in other settings, such as prisons, in ways that involve human rights abuses and result in negative impacts.

### **Acknowledge the limitations of PITC and the barriers to uptake affecting all models of testing**

5. The Reference Group supports increased access to HIV testing and notes that there may be a number of good reasons for initiating or expanding PITC, including quality of care, increased access to treatment, persistent low knowledge of HIV status, and possible role of PITC in supporting HIV prevention efforts. However, the introduction of PITC should not be justified by the “limitations of the current approaches”, as the document suggests. The document implies that VCT in itself is a limitation and fails to acknowledge that in many settings VCT services have only recently been scaled up, and often do not receive adequate support and funding.
6. Furthermore, as the objective of introducing PITC is to “substantially expand knowledge of HIV status”, the barriers to increase the uptake of testing should be more clearly identified, as well as the necessary actions to address them. The draft guidance document identifies “fear of stigma and discrimination, user fees, and limited access to health services in general” as barriers to the uptake of VCT. These barriers are, however, not applicable to VCT only, but also to PITC and HIV testing in general.
7. To achieve the goal of a substantial increase in the knowledge of HIV status, the draft guidance document should emphasize that PITC should be implemented in parallel with a scaling up of VCT services inside and outside health settings, as well as testing services targeting vulnerable groups e.g. sex workers, drug users, and men who have sex with men. These populations require other sources of HIV testing that are not provider-initiated and are offered in a peer-driven and non-judgmental manner,

### **Clarify use of opt-in and opt-out terminology**

8. The focus on the use of an “opt-out” approach in the PITC, and the dichotomy between “opt-in” and “opt-out” is misleading. In both client-initiated and provider-initiated testing situations, a client can opt-in by confirming his or her desire to take the test once counselling has been received, or the client can opt-out if circumstances do not lead the client to express such willingness. Enabling an individual to opt-in or opt-out, based on full information about risks and benefits, respects that individual’s right to informed consent. Whether one characterises the decision as “opting in” or “opting out”, the ultimate decider as to whether the HIV test will be performed or not in both client-initiated and provider-initiated HIV testing is the individual,.
9. By associating a provider-initiated approach to testing with a so-called “opt-out” strategy, the guidelines may create a foundation for abuses, particularly in the form of imposed testing, that the document claims to prevent<sup>3</sup>. The draft guidance needs to clearly emphasize its opposition to compulsory testing, and underline the need for informed consent before any test can be initiated.

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<sup>3</sup> For example, in cases where HIV testing is considered “routine”, as with antenatal attendees or pre-operative patients, a study from Pune in India shows that patients are not informed that they are being tested (Datye et al., 2005).

10. The implementation of PITC needs to be carefully monitored and evaluated to ensure that, in practice, providers offer and recommend testing with sufficient information and give patients an explicit opportunity to decline the test.

### **Elaborate guidance to ensure truly informed consent**

11. As noted above, the Reference Group appreciates that the draft guidelines emphasise the central role of informed consent prior to testing for HIV. However, the Group would also point to some concerns related to informed consent and an opt-out approach to HIV testing.
12. The adoption of an opt-out approach, as recommended in the draft document, may in practice result in people being tested without their informed and truly voluntary consent. True voluntariness requires that an individual realises that they can say no to an HIV test and that they have the confidence and power to make that choice. In settings where there is a significant power imbalance between test provider and client, the voluntary nature of HIV testing may be compromised. Clients may feel compelled to consent to the provider's offer, especially if the offer is communicated with the information that the test will be performed unless the client refuses. There is concern that prevailing gender norms in many settings will particularly disadvantage women in the context of PITC, notably those women who are poor, uneducated and possess limited ability to negotiate.
13. The use of verbal informed consent rather than written consent as indicated in this draft guidance document would be appropriate as long as the monitoring system allows for the retrospective assessment of regularity and quality of the consent process. Further, it should be emphasized that the signed consent of patients on admission to a health facility to procedures and treatment does not supersede the need for verbal or written informed consent to testing.
14. Guidance is needed in relation to obtaining informed consent from pregnant women in labour, as they may be unable to provide informed consent to undergoing HIV testing and the consent cannot be assumed. In some cases this can be ensured by providing pre-test information and counselling and obtaining informed consent to HIV testing as an integrated part of the pre-natal examinations. Also, the requirement for post-test counselling of women who were tested during labour needs to be elaborated.

### **Prepare a communications strategy for the new Guidelines**

15. It is strongly recommended that WHO and UNAIDS carefully prepare for the release of the final version of the guidance and make sure that the communications highlight the need for a vast scale-up of HIV testing, but equally highlight that HIV testing remains voluntary and that PITC will not be enough. These issues are mentioned in the current draft of the guidance, but often are not sufficiently elaborated, and risk being forgotten in practice as countries and funders support and implement PITC.

### **Remove references to "HIV screening"**

16. The Reference Group finds the use of the term "HIV screening" problematic. The term does not make sense either from a public health or a human rights perspective in the way the guidelines use it and raises more problems than the "routinely offered" terminology. The draft guidance document states that "HIV screening aims to identify unrecognized or unsuspected HIV infection". It refers to HIV testing for persons attending health facilities *who do not have obvious HIV-related symptoms or signs*, but who would benefit from knowing their HIV status in order to receive specific preventive and/or therapeutic services." (page 19). It only states that

people will be tested, but fails to mention the voluntariness of the test. Such use of the term “HIV screening” is both inappropriate and misleading. The Reference Group is of the view that it should be replaced by “routine offer” or “systematic offer”, which, while not perfect, highlights that the *offer* is routine, not the test itself. The Reference Group recommends that the document speak only about provider-initiated testing, undertaken for different purposes, and avoids the terminology “diagnostic HIV testing” and “HIV screening.”

### **Strengthen guidance to address risks faced by women and girls**

17. The guidance document should acknowledge the risks that women and girls face when seeking testing for HIV and disclosing their status. The document should avoid speaking of “majorities” and “minorities” when describing the benefits of knowing one’s status and the negative consequences associated with it. The fact that a significant minority of women are facing violence, discrimination and other negative consequences of disclosure requires urgent action. Furthermore, there is still insufficient knowledge on the full range of adverse consequences of testing and disclosure. Some studies have reported higher levels of violence than the example given in the draft guidance document (see e.g. Semrau et. Al, 2005).
18. It is recommended that the guidance document describes the risks involved in disclosure and provides direction to providers on how to identify who may be at risk of adverse consequences, and what support is necessary to enable these individuals to avoid or minimize these risks.

### **Address training and support needs of health personnel**

19. The PITC guidance needs to underscore the importance of providing effective and thorough information and support to all health professionals when implementing the policy. The knowledge and skills of health providers with regards to obtaining informed consent, and providing counselling, has direct implications for patients and the respect of their right to confidentiality, informed consent and privacy. Thus, training, as well as development of “codes of conduct”, emphasizing the rights of the client/patient and the responsibilities and duties of the health professional, must be a standard and resourced part of the implementation and expansion of PITC.
20. Training and guidance should also address how to respond to the needs of members of marginalised populations, and how to ensure that their rights are respected, as these groups have limited access to health systems and may otherwise avoid seeking assistance in the health system if HIV testing policies prove to be coercive. PITC guidance should affirm that members of marginalised populations will receive adequate treatment and care irrespective of their HIV status or belonging to certain marginalised populations in the society (rights to non-discrimination and health). If the voluntary nature of testing as well as the principles of dignity, respect and non-discrimination are not fully understood and embraced by health professionals, then the proposed policy risks deterring people from seeking health services when needed<sup>4</sup>.

### **Include explicit support for community mobilisation, education and engagement**

21. The role of community mobilisation should be addressed separately as it could provide an effective means to encourage people to seek testing, to know they have the right to say yes or no to an offer of an HIV test, and to know what type of care is available and they are entitled to.

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<sup>4</sup> A recent population-based study in Botswana, 43% of respondents believed that the HIV testing policy would lead people to avoid going to the doctor for fear of testing, suggests that many do not fully understand the voluntary nature of testing (Weiser et al., 2006). Preliminary data from another study, undertaken in Kinshasa, Democratic Republic of the Congo, show that 41 percent of TB nurses and HIV counsellors believed it would be difficult for patients to opt-out of an offer of routine testing, as did 33 percent of patients (Corneli et al., 2005).

Such clarity is important if communities implementing PITC are to address the risk that people stay away from health facilities for fear that they will be tested without their consent.

22. Formal engagement of community-based groups may also be the best and most cost-effective way to both monitor the provision of PITC and ensure positive outcomes (see section on Monitoring below). Health-care facilities can partner with community-based groups giving them the explicit role of checking that patients were not abused through PITC, supporting them to remain connected to health care, and helping them to access and remain on treatment and/or receive other forms of supports, such as legal assistance.
23. In the short-term, testing policies that encompass support to community mobilisation, education and engagement, among other measures, may be more costly than simply providing routine, opt-out testing. These supports should be seen, however, as essential elements of a comprehensive policy that is protective of rights. Provisions should be made to cost and implement them. With regards to the specific capacities of health systems, they must be strengthened both to respect people's right to consent to a medical procedure that has great consequences in their lives, and to give them as much information as possible to protect themselves from abuses and other adverse consequences that may accompany the knowledge of their HIV status. Such programmatic action is not, and should not be seen as, discretionary. These elements are essential to an effective AIDS response, and are human rights obligations of governments. 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.

### **Go beyond “supportive policy and legal framework” and address related services**

24. A supportive policy and legal framework is a necessary backdrop to the implementation of PITC. It should be recognized, however, that the mere existence of a supportive legal framework does not in itself address important issues such as stigma, discrimination or violence. The guidance should make reference to necessary programmes and services to protect groups who may face disproportionate risks in certain settings (e.g. women who face risks of domestic violence, men who have sex with men who face discrimination or violence). The State, with support of the international community, should invest in human rights education and information, as well as services (e.g. legal aid and social support) for clients to seek redress for human rights violations they have experienced.

### **Monitor implementation of the policy**

25. In addition to monitoring the implementation of the PITC guidelines with regards to the issues above (e.g. quality of informed consent, adverse events), the policy needs to be monitored for its impact on access to treatment, care, and support, as well as prevention. Thus, monitoring and evaluation should form an essential and ongoing part of programmes to implement PITC. It should be emphasized that the number of people tested should not be the goal in itself, nor the measure of success. Rather the success should be measured in terms of: numbers of positive people who then access services and treatment; rates of voluntary disclosure and its outcomes; numbers of negative people who are fully counselled on how to stay negative; the numbers of people who voluntarily request HIV testing at health services and VCT centres. This information could surely be traced through setting up a number of sentinel surveillance sites in countries/regions/institutions that adopt PITC. UNAIDS and WHO should be willing to advocate for the funding of such surveillance as well as for funding and implementation of adequate patient tracking/monitoring systems which currently do not exist in many highly affected locales.

## Specific comments

### Page 10, section on limitations of current approaches

26. The barriers to the uptake of VCT cited in the draft WHO/UNAIDS guidance document are “fear of stigma and discrimination, user fees, and limited access to health services in general”. These barriers are not only applicable to VCT but also to PITC and HIV testing generally. There are reports from places where provider initiated testing has been implemented, e.g. among pregnant women in Malawi, some women are shunning hospitals “fearing that they will be forced to undergo and HIV test” (Kumwenda, 2006). User fees do represent a barrier to uptake of VCT services, but they are not an inherent limitation of VCT since they can (and should) be removed. If resources can be found to implement widespread provider-initiated testing, resources should also be found to remove user fees at VCT sites. It would be useful to identify approaches to addressing the barriers to HIV testing in a systematic way.
27. The section cites one report and two articles to support the statement that “even with rapid scale-up of these [VCT] programmes, the people most at risk for HIV may be the least likely to use VCT services.” This fails to acknowledge that there is a large body of research showing how practical obstacles to testing and counselling can be reduced, including for people most at risk. It also fails to acknowledge that for many of those who need testing the most – underserved and socially marginalized communities – PITC is also unlikely to work precisely because they rarely access the health system. For sex workers, people who use drugs, or gay 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. Rather than promoting opt-out PITC for these populations, 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 counselling options for them<sup>5</sup>.
28. The section highlights that “numerous studies show considerable gaps between willingness to consider testing and counselling, and completing the process” and that “when rapid tests are not used, a certain proportion of patients does not return to receive test results.” Again, this is not a limitation of current approaches, as studies have shown that these problems continue even when PITC is implemented<sup>6</sup>. For example, a randomized trial undertaken in Kenya

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<sup>5</sup> A more promising route than PITC might be to reach them with mobile clinics (see, e.g., Liang et al., 2005) or “where they are at” (see, e.g., 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 centres, or through outreach programs, which may require changes to laws and policies in order to allow such practice. For prisoners, it should mean being able to access 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. See Jürgens, “‘Routinizing’ HIV testing in low- and middle-income countries”.

<sup>6</sup> A study of antenatal clinics in Francistown in Botswana 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, 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). While rapid testing may indeed increase the likelihood that people will receive their test results, this alone may not be a sufficient achievement. See Jürgens, “‘Routinizing’ HIV testing in low- and middle-income countries”.

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 peri-natal HIV interventions between the women: significantly fewer HIV-positive women who received rapid testing accepted referral for peri-natal 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”<sup>7</sup>.

29. Another concern is the low HIV-serostatus disclosure rates to sexual partners. 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 share HIV test results with a partner. The most salient barrier to disclosure described by women is fear of partner’s reaction and 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 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).

Page 12, section 1.3 on “rationale for new approaches”

30. Most of the studies cited as arguments for new approaches actually do not speak to the need for new approaches to HIV testing and counselling, but to how obstacles to VCT services can be reduced and uptake of VCT increased. These studies are not a rationale for a new approach, but a rationale for putting into practice lessons about how to improve VCT services learnt from a large number of studies.

Pages 13 to 16, section 1.4 on “experience with provider-initiated testing and counselling

31. In the third paragraph, it is said: “With “opt-in” approaches, individuals have to specifically request an HIV test or affirmatively agree to the test being performed. With “opt-out” approaches, the test is recommended as a standard part of a client’s medical care and individuals must specifically decline the test if they do not want it to be performed.” This is not an entirely correct characterization of the difference between an opt-in and an opt-out approach to PITC. Opt-in approaches can (and should) include a recommendation that the test

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<sup>7</sup> More broadly, this study and many other studies showing low rates of uptake of perinatal HIV interventions, suggest that policies that may increase uptake of testing may not necessarily lead to increased uptake of perinatal HIV interventions. “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 & Behets, 2006, at 54). See Jürgens, “Routinizing’ HIV testing in low- and middle-income countries”.

be undertaken. The only relevant difference between opt-in and opt-out approaches is that, under opt-in approaches, testing proceeds only if the patient expressly agrees to the test, while under an opt-out approach people are tested unless they expressly decline to be tested.

32. The summary of evidence about opt-out approaches to PITC is problematic. Attention is required with regards to the following in particular:

a) It should have been mentioned that, although there is a growing number of studies, evidence about opt-out approaches to PITC outside the prenatal context remains very limited. In particular, only a few studies in resource-poor countries have examined PITC with an opt-out approach.

b) Three of the studies cited on page 14 as evidence of the fact that opt-out approaches in resource-poor settings show results similar to those obtained in the U.S., Canada, or the United Kingdom (at 14, notes 39, 42 and 43), and “cause less anxiety for women than an ‘opt-in approach’ (at 14, note 42), are not studies about opt-out approaches at all. Instead, two of the studies analyzed the acceptability of forms of testing under which the *offer* of HIV testing became a part of routine antenatal care, but women were tested only after group *and* individual counselling and if they opted *in* to testing (Etiebet et al., 2004), or after counselling 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 of suggesting measures for increasing uptake (Nuwaha et al., 2002). Ultimately, only two of the studies cited on page 14 suggest that opt-out approaches may indeed lead to increased uptake of HIV testing among pregnant women in resource-poor settings:

- The study from antenatal clinics in Malawi, where under the new guidelines, women receive group pre-test counselling and are then tested for HIV unless they specifically request to not be tested (Zimba et al., 2006). However, according to newspaper reports, some women are shunning hospitals “fearing that they will be forced to undergo an HIV test” (Kumwenda, 2006).
- The study, undertaken in Zimbabwe, suggested that an opt-out strategy would be acceptable to pregnant women if it was implemented (Perez et al., 2006). However, the study 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 will be necessary.

33. On page 14, the draft guidance document states that opt-out testing and counselling did not appear to result in coercion and that most study respondents said they supported it. The paper then says that this has been documented not only for prenatal care, but also “in home-based testing where the vast majority of respondents consented to giving blood samples for HIV tests and receiving results at home in connection with Demographic Household Surveys”. It is not clear why the issue of home-based testing that is not otherwise addressed in the draft guidance document is brought up here. In addition, it should be clarified whether the home-based testing is “opt-out testing” as is suggested in the draft guidance document. Finally, two of the three qualitative studies cited on page 14 (refs 20 and 39) are not about this issue at all and cannot be used to support the statement made.

34. On page 14 it is mentioned that studies show that an “opt-out” approach to HIV testing has led to an increased uptake. It is worth mentioning that “opt-in” approaches to HIV testing can show

results that are comparable to those resulting from “opt-out” approaches, if the offer of HIV testing and counselling is integrated into routine antenatal services<sup>8</sup>.

35. On page 15, without providing a reference, the document suggests that “an overload of information may make clients uncomfortable and discourage them from accepting testing and counselling.” However, a study that compared various pre-test counselling 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). More 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 pre-test counselling and informed consent requirements do not necessarily pose barriers to implementation of PITC, even in resource-poor settings<sup>9</sup>.
36. It would have been worth noting that, with the exception of the studies in antenatal settings, no studies have compared opt-in and opt-out approaches to PITC.
37. The statement that “the evidence about the consequences of disclosure is limited and contradictory” is problematic. More research is needed to investigate whether relaxing counselling requirements and changing the informed consent procedure 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 (Weiser et al., 2006, Semrau et. Al 2005, Medley et al., 2004).
38. Although it may be statistically accurate to state that “a small minority of cases (around 5%)” involve violence or other adverse consequences (page 15), such a statement seems inappropriate in the light of the seriousness of the acts reported. Furthermore, summarizing the available evidence this way – as minority/majority or as an average – risks hiding the fact that in some of the studies reported levels of violence were much higher than 5%<sup>10</sup>.
39. It may be worthwhile noting that 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. Women who are tested at antenatal clinic sites may be less likely to have a chance to think about

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<sup>8</sup> Experience in one jurisdiction in Canada that has not adopted an opt-out approach – preferring to offer and recommend an HIV test to all pregnant women, but to test only if they opt-in – shows that such an approach can result in uptake rates that are comparable to those reached in jurisdictions using an opt-out approach (Schietinger, 2006). This has also been the case in resource-poor countries, where studies in a number of countries have shown that when the offer of HIV testing and counselling is integrated into routine antenatal services, up to 97 percent of women accept the offer and *opt in* to HIV testing (see, e.g., Malonza et al., 2003; Etiebet et al., 2004; Shankar et al., 2003; Kiarie et al., 2000).

<sup>9</sup> 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 pre-test counselling message and made a routine component of prenatal care with little additional burden on providers. They point out that it may take longer than what some providers currently provide in terms of pre-test counselling, but is shorter than what is required by many existing counselling 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 counselling 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 provide people with information that will help them make an informed decision.

<sup>10</sup> In a more recent study in Zambia, 28 percent of women who tested HIV-positive reported adverse social events, including physical violence, verbal abuse, divorce or separation (Semrau et al., 2005).

testing or prepare themselves or their partners for testing. Therefore they may be both less likely to disclose results to their partners and more likely to be victims of violence when they do (Amon, 2006b)<sup>11</sup>.

40. The guidance document needs to go beyond a review of available evidence on adverse consequences of finding out or disclosing one's status. In its present form, the document trivialises the risk of negative outcomes. Guidance is needed on how to identify, implement, and evaluate strategies for the scale up of HIV testing "that will allow women to maximize on the beneficial outcomes and minimize the harmful aspects of disclosing their HIV sero-status" (ibid). There are four specific opportunities to integrate a focus on violence and/or fear of violence within HIV testing and counselling, including addressing:
  - Violence as a barrier to women accessing HIV testing and counselling services;
  - Violence as a barrier to women disclosing HIV test results to their sexual partners;
  - Violence as a barrier for women to negotiate HIV risk reduction with partners and
  - The post-test support needs of women living in violent relationships (WHO, 2006, at 36).
41. It has been suggested that "awareness about gender and violence" be incorporated into testing and counselling for HIV (Heise, 2006) and that some screening of women most at risk of negative outcomes of disclosure – as well as targeted, intensive counselling 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). Such measures should be recommended by the guidance document.
42. It is recommended that the guidance document provides an objective summary of findings arising from studies, describe the risks involved in disclosure and provides directions on how to minimize these risks.

Page 17, section 2 on "objectives"

43. At the end of the first paragraph on page 17, the draft guidance document says: "This document does not address voluntary counselling and testing, for which guidance already exists." The document refers to two WHO documents, a manual for training of trainers by the WHO Regional Office for South-East Asia, and a guideline on VCT by the WHO Regional Office for Africa. While these are important and valuable documents, they are not nearly as authoritative as the final version of the guidance on PITC in health facilities will be. At a minimum, the PITC guidance document needs to include more than just a few statements saying that efforts are also needed to expand VCT and that PITC should be seen as only one of several potential components in an overall strategy to increase uptake of HIV testing. Simply concluding that scaling up PITC "should not exclude scaling up other HIV testing and counselling models as well, including VCT" (at 43) is not enough. The clear focus of current efforts to increase access to HIV testing is on PITC, and there is concern that VCT might not receive enough support and funding if resource-poor countries and funders continue shifting

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<sup>11</sup> In a survey of women in Tanzania three months after they received testing and counselling, 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 of their HIV-positivity. 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" (ibid, at 24). However, "women who currently disclose do so selectively, choosing to whom they disclose and when to disclose, likely based on how they anticipate that their partner will 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." (ibid)

their emphasis to PITC. This would be of particular concern in countries where access to voluntary HIV testing and counselling remains limited, the epidemic is concentrated among marginalized populations, and few of those most at risk access health services. For a number of reasons, scaling up access to HIV testing and counselling should not only “not exclude” scaling up VCT, but has to include a greater emphasis on also scaling up VCT.

44. The document should include a section explaining why, in addition to implementing PITC, scaling up access to VCT is important – recognizing that, 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, or belong to vulnerable communities. It should note that if governments want to maximize the usefulness of testing as a 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 counselling easily accessible to them. Finally, as mentioned above, it should note that for many of those who need testing the most – underserved and socially marginalized communities – PITC is also unlikely to work precisely because they rarely access the health system.

Page 19, section 3 on “Terminology”

45. The descriptions of client-initiated VCT and provider-initiated testing and counselling are not entirely accurate. First, the document states that in client-initiated VCT, “guidance from the counsellor about the desirability of taking a test is often neutral.” While this may sometimes be the case, this is not an inherent component of VCT and in practice, many counsellors in VCT programmes have shifted to recommending the test since the benefits of testing have increased, and depending on the circumstances revealed in counselling. Second, the decision to use the term “HIV screening” is unfortunate (see comment on page 3).

Page 22, section 4.1 on “Diagnostic HIV testing in all epidemic types”

46. The reference to HIV screening of surgical patients in all epidemic settings when “patients may require diagnostic HIV testing for diagnosis and management of conditions potentially associated with HIV”, is unnecessary as this would apply for all patients attending health care facilities. It is further mentioned that “HIV testing of surgical patients is not justified simply for knowledge of HIV status by service providers”, which also applies to all patients and not only the ones undergoing surgery. It is thus recommended to delete the section on surgical patients, and include a section to emphasize universal precautions in all situations where accidental exposure to HIV may occur.

Page 23, section 4.2.1 on “Recommendation to implement in all health facilities”

47. The draft guidance document mentions, in relation to HIV-screening in generalized epidemics, that “all adults and adolescents seen in health facilities should be offered an HIV-test”, and further it states that this “applies to medical and surgical services, public and private facilities, and inpatient and outpatient settings.” It should be clarified what is meant by inpatient and outpatient settings, to ensure that the guidelines will only be applied where intended. In its present formulation, the guidance risks being overly broad.

Page 23, section 4.2.2 on “STI services”

48. STI services are identified as a health facility that could provide PITC (on page 23 and 27). Linking STI services and HIV-testing seems logical and reasonable, but it might add to the

stigma related to HIV as caused by sexual “misbehaviour” and it might also negatively influence the uptake of STI services. It is therefore recommended that caution is applied, and preferable that the approach is pilot tested before implementing it through PITC.

Page 24, section 4.2 on “Health services for most-at-risk populations”

49. There is 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. The draft guidance (page 24) recognizes that “[s]pecial efforts may be needed to ensure that HIV screening does not contribute to stigmatization and discrimination against these groups or lead to involuntary HIV testing”. However, the document recommends that HIV screening “be considered” in specific health services, such as STI, acute care and drug dependence treatment services, “as a component of an overall strategy to increase knowledge of HIV status and access to prevention, treatment, care and support for most-at risk populations”. Introducing PITC with an opt-out approach for such marginalized populations in such settings could lead to negative consequences, e.g. that these groups to not seek the care and treatment they need.
50. Speaking about most-at-risk populations, the document says: “A range of strategies may be needed to increase overall utilization of health care services ...as well as developing peer-based services, mobile VCT services and social mobilization programmes.” This paragraph should be worded more strongly and make clear recommendations, as it is clear that PITC will not be enough and that a range of strategies will be needed to increase access to HIV testing for most-at-risk populations.

Page 26, section 4.2.2 on “Priorities for implementation”

51. Adolescents are defined as 10 -18 years old people. The definition should be provided with a reference, as WHO and other UN agencies have used alternative definitions of adolescents, e.g. 10 – 19 years old.
52. Some guidance on offering HIV testing following sexual abuse of children, adolescents and adults should be inserted.

Page 29, section 5 on “Ensuring an enabling environment”

53. In the draft guidance document page 29, it is recognized that “disclosure-related violence does occur...and steps must be taken to prevent it”. The document continues by saying that “[p]ositive outcomes are most likely when HIV testing and counselling is confidential and is accompanied by counselling and informed consent, staff are adequately trained, the person undergoing the test is offered or referred to appropriate follow-up services and an adequate policy and legal framework is in place to prevent discrimination”. Therefore, according to the draft guidance, “at the same time as provider-initiated testing is implemented, equal efforts must be made to put in place protections against compulsory testing and unauthorized disclosure and to mitigate the potential negative outcomes of knowing one’s HIV status”. This is an important statement, but when it comes to protection of women and girls, programmes to reduce stigma and provide psychosocial support in low-income countries are currently non-existent, under-funded, overburdened or in the design-phase (Rennie and Behets, 2006). In the current circumstances, routine opt-out HIV-testing policies could therefore expose women and girls to risks of significant harm.
54. For the reasons mentioned above, the document should not say that disclosure-related violence occurs “in a small minority of cases” but instead say that, while studies show that a majority of women will experience support after disclosure, an alarming number of women report negative outcomes, including violence, and detail the steps that should be taken to

prevent it, rather than simply referring to an unpublished document that most people will not be able to access.

Page 30, section 5.1 on “HIV-related services”

55. The list of basic care services for HIV-positive individuals (page 30) is useful and helps signal what services should be available when implementing PITC, even where ART is not available. However, some issues merit further consideration.

- The importance of ensuring sustained engagement with the health system and HIV-related services in the community should be made more explicit in the guidelines, including treatment and programmes to support treatment literacy. The guidelines should present approaches to addressing the issue of sustained engagement, possibly in the context of addressing obstacles to increasing the uptake of HIV testing. Ensuring access to testing alone is not enough to ensure that all the benefits of testing are realised.
- While positive that the list of basic care services is quite detailed, it is suggested that guidance with regards to prioritising the expansion of services be included.
- A mechanism needs to be suggested for how to decide when PITC should not be implemented due to the unavailability of critical HIV-related services. Such mechanisms are particularly important in settings where ART and other forms of treatment and care are not widely available.

Page 31, section 5.2.1 on “An ethical process for obtaining informed consent”

56. The document states that “codes of conduct should be developed to guide health care workers in obtaining informed consent.” It is suggested that WHO and UNAIDS develop a model code of conduct and minimum standards for training and accrediting trainers, and assist countries in implementing such a code and in training health care personnel in the process of obtaining informed consent. In order to increase the capacity of health systems to deliver counselling, changes to scopes of practice may be necessary to enable lay counsellors to perform HIV counselling and testing, after receiving adequate training.

Page 32, section 5.2.2 on “Additional measures”

57. It is not made sufficiently clear what the concept of “beneficial disclosure” entails, e.g. that it is voluntary, respects the autonomy and dignity of the affected individuals, maintains confidentiality as appropriate etc, and it is also not made clear how it is distinct from partner notification.

Page 34, section 6 on “Process and elements”

58. The fact that the guidance specifies minimum requirements for pre-test information sessions is a welcome development. However, the final version of the guidance should mention that other, additional information may have to be provided during pre-test information or counselling sessions, depending on the circumstances of the jurisdictions that adopt PITC policies. For example, in countries that have legislation criminalizing exposure to HIV and/or transmission of HIV, it is essential that people understand that, if they test positive, disclosing their status to their sexual or drug using partner and/or taking precautions to prevent transmission may be required by law. Similarly, as has been discussed above, 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 counselling 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.

59. In the guidelines (page 35 and 38), it is mentioned that clients during the pre-test counselling should be informed that in the case of a positive test, they would be encouraged to inform

other persons, and on page 38, it is mentioned that disclosure should be discussed in the post-test counselling. It is important to consider safeguards to ensure that this does not lead coercion to disclose or disclosure of status without consent.

Page 36, section 6.1.5 and 6.1.6 on “special considerations for adolescents” and “Follow-up where a test is declined”

60. It is suggested that a paragraph is added, stating that an HIV test may be performed in “the best interests of the child”, even in the presence of parental objection, when required for the purposes of urgent medical treatment. Such a decision should involve the child, according to his or her evolving capacities (i.e. he or she is given an opportunity to consent, or assent, to the test.) Procedural safeguards and due process must be observed in order to protect the interests of the child.

Page 38, section 6.2.1 on “Post-test counselling for HIV-negative persons”

61. The document states that counselling for those who test HIV-negative should include an explanation of the test result, and “advice on methods to prevent the acquisition of HIV and provision of condoms.” It is not entirely clear what this means. Should counselling include (1) provision of advice on methods to prevent the acquisition of HIV and (2) provision of condoms, or provision of advice on methods to prevent the acquisition of HIV, including condoms (and clean injecting equipment)?

Page 44, section 8 on “Programmatic considerations”

62. Most-at-risk populations are identified as particular important groups in relation to expanded access to HIV testing. However, there is need for further guidance on identifying and working with these groups, as well as strengthening the capacity of health systems to respond to their needs and promote their rights. While it is acknowledged that “most-at-risk” will vary according to the dynamics of local epidemics, it would be beneficial if reference could be made to processes to be followed when adapting the policy to local circumstances. It is recommended that representatives from most-at-risk populations -- including, but not limited to, people living with HIV – are involved in the process of adapting the guidelines to the local context.

Page 45, section 9 on “Monitoring and evaluation”

63. It is strongly recommended that monitoring and evaluation guidelines are made available when the guidance document is formally released, addressing critical human rights and gender issues outlined above.

Page 46, on “Appendix”

64. The working papers and recommendations on HIV testing of the UNAIDS Reference Group on HIV and human rights should be made publicly available and referred to in this appendix.

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