Background

This discussion paper has been developed in response to a request made to the Co-Chairs of the Reference Group by UNAIDS Executive Director, Michel Sidibé. He asked the Reference Group to help “normalise” and reconceptualise testing so as to remove any barriers to testing, and increase testing uptake whilst respecting and protecting human rights.

The Reference Group has actively participated in the debate about HIV testing and counselling (HTC) since its first meeting in 2003. In particular, it issued a statement in 2004 on how to ensure a human rights based approach to scaling up access to HTC and in 2007 issued a further statement and recommendations on this issue, in response to the guidance on provider-initiated testing and counselling (PITC) in health facilities issued by WHO and UNAIDS on 30 May 2007.

Whilst focusing specifically on the PITC guidance and generally expressing support for efforts to scale up access to HIV testing and counselling, the 2007 Reference Group statement emphasised that such efforts were taking place in an environment in which evidence-informed and human rights-based policies and responses to HIV were being widely undermined and that, in many countries, there were many abuses around the manner in which HIV testing and counselling was being conducted. In its statement, the Reference Group made a series of recommendations aimed at ensuring that PITC and other forms of HTC be implemented in a manner that would lead to increased benefits for human rights and public health.

In 2012, WHO and UNAIDS reaffirmed their opposition to mandatory testing in a statement issued on 28 November. Also in 2012, WHO issued “Service Delivery Approaches to HIV Testing and Counselling: A Strategic HTC

---

2 The 2007 statement is available via the Reference Group webpage, see http://www.hivhumanrights.org/category/statements/.
Framework\(^5\) which reiterates the need for human rights protection, regardless of the testing model and how testing is offered; emphasises the fact that the 5 C's (consent, confidentiality, counselling, correct test results and connection to care) of good testing practices continue to be relevant and should always be guaranteed; states that testing must always be voluntary; and notes that testing should not be promoted in situations where a positive test result could lead to discrimination or where choosing to test is treated as indicating criminal behaviour.

**What, if anything, has changed since the 2007 statement?**

**Treatment as prevention**

The results of the HPTN052 clinical trials published in August 2011,\(^6\) which examined the impact of highly active antiretroviral therapy (HAART) treatment on the transmission of HIV in sero-discordant couples, confirmed that the use of HAART decreased HIV transmission by 96%. Additionally, the study showed that starting HAART earlier was associated with more than a 40% reduction in the rate of disease progression. The findings of HPTN 052 confirmed those previously reported by Montaner, *et al.*\(^7\)

This research creates important new opportunities and public health, economic, and human rights arguments for expanded and improved integration of treatment and prevention efforts. The consequence of this understanding can be compared to historic turning-points in the past, including the development of:

- a test to detect HIV antibodies in 1985;
- anti-retroviral therapy to prevent perinatal HIV transmission in 1991; and
- highly active ART (HAART) to suppress viral replication, significantly reducing AIDS-related morbidity and mortality, in 1996.

Each of these milestones created a paradigm shift in how HIV policies and programmes were developed, prioritized, funded and implemented. The evidence regarding the impact of ART on HIV transmission presents another opportunity for a paradigm shift in the response to HIV that requires a careful examination of the scientific evidence, programmatic structure, and the important role of ensuring protection and promotion of human rights, including key principles of equity, empowerment, protection from discrimination and accountability.\(^8\)

Successful HIV prevention and use of ART, for either prevention or treatment, both depend upon the ability of individuals and affected communities to seek sources of protection, and access to quality services.

---

out services and then use those services over the course of a lifetime. While increasing rates of HIV testing utilization is one important component, it is not the numbers of tests performed that, in and of itself, will lead to increased demand for and successful use of prevention and treatment services. HIV testing is not a goal, but a tool. It is a tool that can only be valuable if the conditions are in place to put the information one receives from testing to use. Those conditions include the availability of sustained and high-quality health-care and prevention services, including ART, along with policies and programmatic approaches that connect people to services and protect them from human rights abuses.9

While testing is crucial, knowing one’s status is often not enough. Even where treatment is free, countries have reported large gaps between numbers of people who test positive and those who start, and are able to maintain, treatment. Much more needs to be done to bridge the gap between testing and treatment, and to keep people on treatment. There is still very little research on the factors that affect whether or not people choose to start treatment, but it is clear that the biomedical argument (regarding the benefit of ART in reducing morbidity and mortality) is not always sufficient motivation for people to initiate treatment. An environment of safety in which people at risk for HIV can demand and use services without fear of stigma, discrimination and abuse of their human rights is a necessary prerequisite for implementation of all HIV treatment services, including those for prevention. Without sufficient human rights protection, seeking HIV services can often be more immediately dangerous than HIV itself.10

When the Reference Group analyzed the human rights issues related to treatment as prevention at its 13th meeting in December 2011, it recognized the need to further increase access to HTC, but urged WHO and UNAIDS Secretariat “to carefully analyse the human rights risks and benefits from new approaches to testing, such as community testing and home testing.”11

A proliferation of testing settings and modalities presents opportunities for increased HIV testing uptake

There has been a proliferation of HIV testing settings and opportunities in recent years. Whilst until recently HTC has been offered largely in health care facilities and stand-alone voluntary counselling and testing sites, new community-based approaches are being developed and tested to better serve people who otherwise lack ready access to HTC. These include NGO-based anonymous testing, targeted testing in high-risk settings, community-based and workplace-based testing campaigns and events and house-to-house testing. Different testing settings and modalities raise different human rights concerns. For example, do community-based house to house testing

9 Ibid.
10 Ibid.
11 Issue paper for the session: Human rights & the strategic use of ARVs for treatment and prevention.
campaigns actually afford the opportunity for informed consent for all family members present or does the giving of consent fall on the senior, usually male, family member? Both facility-based and community-based HTC delivery models in their many variations offer the opportunity for increased uptake of HIV testing, particularly where HIV testing is integrated with other services. For example, community-based HIV testing can be integrated with malaria, iron deficiency, TB and diabetes services so that people accessing this service are not immediately labelled as presenting for an HIV test by other community members present.

Over the counter HIV self-testing (HIVST) kits will also soon be available in many places. HIVST allows people to test in private and may increase access to HIV testing. It is part of national policy in some countries including Kenya, with others considering introduction. Unregulated HIVST kits are becoming more widely available, while in 2012, the U.S. FDA approved the sale of the over-the-counter (OTC) OraQuick® In-Home HIV Test. The U.K. and France have both announced plans to approve OTC HIVST kits in 2014.12

In April 2013, the first global HIVST consultation was held in Geneva, Switzerland. Among other things, the Meeting Consensus Statement says:

- HIVST has potential to increase access to testing and meet the needs of general populations and health workers in high prevalence settings, individuals in serodiscordant relationships and other priority populations in all settings.
- Countries should actively explore HIVST as a complementary strategy to increase knowledge of status and uptake of prevention, care and treatment.
- National testing algorithms should be adapted to incorporate HIVST, regulate markets, assess accuracy and facilitate further testing following self-testing.
- The use of rapid diagnostic tests for HIVST requires a regulatory framework that ensures quality diagnostics that give accurate results in the hands of the intended users.
- Research and monitoring and evaluation are required to determine the risk of harm and adverse events associated with HIVST and rates of linkages to care. Consideration of ethical, human rights and legal issues is required.
- Governments and donors should support HIVST strategies with meaningful community engagement, as well as with monitoring the legal, ethical, gender, human rights and public health consequences of HIVST scale-up.13

---

12 Baggaley R et al. REPORT ON THE FIRST INTERNATIONAL SYMPOSIUM ON SELF-TESTING FOR HIV: THE LEGAL, ETHICAL, GENDER, HUMAN RIGHTS AND PUBLIC-HEALTH IMPLICATIONS OF HIV SELF-TESTING SCALE-UP (WHO, UNAIDS, LSTM, LSHTM & THE BROCHER FOUNDATION). Poster to be presented at ICASA.

13 Ibid.
An increase in the number of testing choices and opportunities also affords people an opportunity to decline testing in settings where and when they do not feel that it is safe, and to seek testing where and when it is. Providing a list of alternative places to test at the point where testing is being offered allows people to “save face” when declining testing — they are not saying "no" they are just saying "later" or “at another place”. This provision of alternatives is important in addressing the power differentials inherent in patient-provider interactions which often compromise informed consent. It also dispels the notion that refusal to test is a “failure.” The provision of multiple testing opportunities also addresses the fact that the limited availability of HIV testing can result in a de facto violation of the principle of consent. True consent requires that declining a procedure have no negative consequences. However, an individual who declines an HIV test because of fears of associated human rights violations and who has no other venues for testing faces undeniable negative consequences to his/her health. This person may therefore find himself forced by circumstance to accept the test even though s/he would rather decline it.

**What are the barriers to testing?**

Whilst treatment as prevention may constitute a paradigm shift in the response to HIV and whilst the proliferation of testing settings and modalities offers opportunities for increased uptake of HIV testing, the barriers to testing remain largely unchanged.

At the start of the HIV epidemic, the fear of an unknown and fatal disease led to public calls for mandatory testing and for a “right to know” others’ HIV status. Patients demanded the right to know the HIV status of their health care provider, and health care providers sought to know the status of their patients (with or without their knowledge or consent). Mandatory HIV testing programmes were proposed, and often established, for a range of different groups, including pregnant women and infants, engaged couples, employees, students, immigrants, and sex offenders. Related to this demand for forced testing and disclosure were efforts to criminalize HIV transmission and to limit the movement of HIV-infected individuals.

More than three decades later, despite greater understanding of HIV transmission, ignorance and stigma continue to drive discriminatory laws, policies and practices. These include laws that criminalise HIV transmission and populations believed to be at high risk of HIV infection, which exist in more than 160 countries.

While little quantitative evidence exists, qualitative research with diverse vulnerable populations frequently has found that fears of mandatory or coercive HIV testing and breaches in confidentiality drive individuals away from testing and treatment services.
For example, Human Rights Watch explored the issue of domestic violence and women’s and children’s vulnerability to HIV in Uganda in 2002. One woman, Alice, described the outcome of her efforts to convince her husband to go with her to test for HIV: “He said, 'if I know you’re positive I’m going to kill you.’ …I can’t even test the children because he’ll be angry and ask why.”

In China, people who use drugs reported that being tested for HIV was associated with being detained by the police and put into a drug detoxification or rehabilitation through labour (RTL) center for as long as five years. As one user put it, “[s]ometimes I’m afraid I might be sick with AIDS but I’d rather be sick and free than go to get tested, get arrested, and be sick in detox or re-education through labor [RTL].”

Men who have sex with men and sex workers are also often reluctant to seek HIV testing services because of discrimination, criminal laws and human rights abuses, including at the hands of healthcare providers and police.

Over the past decade, proposals by public health authorities to increase HIV testing utilization through routine testing (often with weakened informed consent procedures) have been met with opposition by human rights advocates seeking to protect rights to privacy, confidentiality and autonomy. This debate has often been characterized — and caricatured — as one that pits human rights against public health. This is a false dichotomy. Without sufficient human rights protection, it is not possible to meet HIV public health goals through, inter alia, increased uptake of testing. Conversely, the failure to meet public health goals represents a serious threat to the human rights of people affected by HIV. Successful responses to HIV depend upon the articulation of models that drastically increase use of HIV testing, prevention, treatment and support services and do so in ways that foster human rights protection, reduce stigma and discrimination, and encourage the sustained and supported engagement of those directly affected by HIV.

The potential impact of treatment as a prevention tool does not alter this approach. The added value of ART only heightens the need to find successful approaches to improved HIV service delivery and human rights protection.

For this to be achieved, the following issues must be addressed:

---

17 These issues are elaborated on more fully in Barr et al op cit.
- A well-defined, well-resourced and consistently applied strategy for meaningful involvement of people living with HIV and key populations in designing, implementing and monitoring testing and treatment programmes is needed. The current reality, however, is far from this — while the greater involvement of people living with HIV/AIDS (GIPA) has received much lip service, involvement of people living with HIV and communities continues to be minimal, conditional or even tokenistic.

- Law, policy and practice reform is required to create an enabling and non-discriminatory environment in which legal and policy frameworks ensure respect for and protection of the right to health (including the right to health information, access to testing and treatment, and other related socio-economic rights), as well as civil and political rights such as autonomy, privacy, the right to be protected from violence, rights to speech and assembly, and access to justice for people living with HIV and people vulnerable to HIV infection.

- Laws and policies that can act as barriers to access to HIV testing and treatment services, such as those which criminalize same sex relationships, sex work and drug use should be repealed.

- Access to justice for people whose rights have been violated must be strengthened.

- Human rights training for health care workers focusing on informed consent, confidentiality, non-discrimination, duty to treat, and universal precautions is essential, as is the training and sensitization of law enforcement agents on HIV and the human rights of vulnerable populations, particularly in terms of supporting access to services, non-discrimination, non-violence, and freedom from harassment, arbitrary arrest and detention.

- Programmes to promote the rights of women in the context of HIV are essential. These programmes include interventions to change laws, policies and practices that discriminate against women, including those that restrict women’s economic opportunities, property and inheritance rights, inadequately criminalize or redress violence against women, and perpetuate harmful and inequitable gender norms.

- Programmes to reduce stigma and discrimination are essential for the creation of a social environment which facilitates access to prevention and treatment services. These should address their underlying causes—ignorance, fear, myths and social judgment.

- Change must also be promoted from the ground up. People affected by HIV must be supported to know their rights in the context of the epidemic, to draw on them in formulating concrete demands for access to services and non-discrimination on the basis of HIV and other social status, and to
have the information and support necessary to make and follow through on testing and treatment decisions and implement behaviour change to improve health.

- There is a need to strengthen local, community-based and peer-based networks and organizations as a mechanism to support testing and treatment preparedness.

- Empowerment and mobilization approaches to service delivery are essential to the success of expanded testing and treatment access. Legal protection alone will not do away with stigma. Ultimately, the reduction of stigma will depend on the willingness and ability of individuals to seek out health services. Service provision based on principles of community mobilization and empowerment can provide the sustained engagement in care necessary for a lifetime of treatment adherence.

Is HIV testing exceptional?

Is the requirement of informed consent and confidentiality in the context of HIV testing exceptional? It is not. In fact, what is referred to by some medical ethicists as “genuine” consent — “apparent where patients can control the amount of information that they receive and what they allow to be done” — is ethically required for all medical procedures and treatment. The fact that this does not always happen when it should in the context of other medical procedures and treatment does not mean that HIV testing is exceptional. If the normalisation of HIV testing implies the weakening of ethical and human rights standards that apply to all forms of medical procedures, then normalisation is not desirable. There is, unfortunately, no magic bullet for increasing testing uptake. Instead there are myriad social, legal and structural barriers to HIV testing uptake that have to be addressed if both increased HIV testing and retention in treatment are to be achieved.

The opportunity for normalisation of HIV testing does, however, present itself with the proliferation of HIV testing settings and modalities, particularly where testing is integrated with a number of other services and the opportunity for choice between multiple testing sites and opportunities is ensured.

Potential key messages and recommendations

1. There is an ongoing need to increase access to HTC, as testing rates remain low in many settings. The RG supports such efforts unequivocally and encourages the provision of multiple HIV testing

---

18 O’Neill, Some Limits of Informed Consent, Journal of Medical Ethics, 2003:29;4-7 accessed at http://jme.bmj.com/content/29/1/4.full
settings and modalities, in particular those that integrate HIV testing with other services.

2. More than ever, however, it is clear that simply increasing the number of people tested, and/or the number of times people test, is not enough, for many reasons. Much greater efforts need to be devoted to removing barriers to testing for marginalized and criminalized populations, and to link those tested with prevention and treatment services and to retain them successfully in treatment.

This issue paper was prepared by Michaela Clayton and Joseph Amon and edited by Ralf Jürgens, to facilitate discussion at the Reference Group’s December 2013 meeting.

Please see the Summary and Recommendations report of the Reference Group’s Fifteenth Meeting for an overview of the discussion at the meeting and the Reference Group’s recommendations.