Scaling up access to HIV treatment: human rights issues and considerations

Background

Last year, UN Member States adopted the 2011 United Nations Political Declaration on HIV and AIDS, agreeing to take specific steps to dramatically reduce AIDS-related morbidity and mortality and reduce HIV transmission rates by 2015.\(^1\) These ambitious targets include reducing sexual HIV transmission by 50%, reduced transmission among people who use drugs by 80%, elimination of vertical transmission, reducing HIV-related tuberculosis deaths by 50%, elimination of HIV-related stigma and discrimination, and the provision of anti-retroviral (ARV) treatment to 15 million people.

The UNAIDS 2012 Global Report\(^2\) documents many accomplishments made toward reaching these goals, including:

- Antiretroviral therapy reached 8 million people by the end of 2011 – a 20-fold increase since 2003. Since 1995, antiretroviral therapy has added 14 million life-years in low- and middle-income countries, including 9 million in sub-Saharan Africa. More people initiated antiretroviral therapy in 2011 than in any previous year, and the number of people living with HIV receiving treatment rose by 21% compared with 2010.
- In 2011, the number of people dying from AIDS-related causes continued to decline. Approximately 1.7 million people died from AIDS-related causes worldwide - a 24% decline in AIDS-related mortality compared with 2005.
- Worldwide, the number of people newly infected continues to fall: an estimated 2.5 million people (adults and children) acquired HIV infection in 2011, 20% fewer than in 2001. In 39 countries, the incidence of HIV infection among adults fell by more than 25% between 2001 and 2011. In sub-Saharan Africa, an estimated 1.8 million people acquired HIV infection in 2011, 25% fewer than in 2001.
- In 2011, about 330 000 children acquired HIV infection, a 43% decline since 2003 and a 24% drop since 2009. More than 90% of the children infected with HIV in 2011 live in sub-Saharan Africa. There, the number of children newly infected fell by 24% from 2009 to 2011.

Advances in the understanding of how ARV treatment and prophylaxis can prevent HIV infection provide important new tools to reach the 2015 goals of reduced transmission rates. It is now well established that ART significantly reduces both sexual and vertical transmission rates.

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transmission. HIV treatment access, together with a full array of evidenced-based HIV prevention interventions, including condom use, syringe exchange and substitution therapy, voluntary male circumcision and behavioral change, provides an effective armamentarium for HIV prevention for the first time in the history of the epidemic.

Better understanding of the prevention impact of treatment scale up is emerging through observational studies and modeling. In South Africa, a study shows that when treatment uptake is high (i.e. more than 30% of people are receiving it), the odds of acquiring HIV drop by 40%. For every 10% increase in the share of people getting ART in the study, HIV incidence decreased by 17%. Reductions in community viral load indicate decreased HIV incidence rates in studies of people who use drugs in Vancouver, men who have sex with men in San Francisco and in Taiwan.

Additional advances in science are needed, most notably a vaccine and a cure for HIV disease along with improved ARV treatment and prophylaxis regimens. However, many of the primary scientific challenges in HIV have been addressed to the point that the 2012 International AIDS Conference was abuzz with the prospect of “ending AIDS.” However, significant challenges remain to make these lofty aspirations a reality. These include (a) improved mechanisms to implement effective treatment and prevention approaches, (b) protection of human rights and reduction of HIV-related stigma, and (c) securing the political will to implement a comprehensive and equitable HIV response, particularly for key affected populations.

Regional trends underscore the gap between the rhetoric and reality of “ending AIDS.” Since 2001, the number of people newly infected in the Middle East and North Africa has increased by more than 35% to 37,000. The incidence of HIV infection in Eastern Europe and Central Asia began increasing in the late 2000s after having remained relatively stable for several years. This is now the fastest growing HIV epidemic. These regions are also seeing a rise in AIDS-related deaths. The countries in which HIV infections are increasing are those with concentrated epidemics primarily affecting men who have sex with men (MSM), people who use drug, sex workers and people in prisons and other forms of detention —populations who, not coincidentally, endure criminalization and high rates of violence by police and other actors. The 2012 UNAIDS Global Report presents the stark reality of HIV in the lives of key affected populations and women:

- The HIV prevalence among MSM in capital cities is consistently higher than that in the general population. The prevalence of HIV infection among men who have sex with men in surveys in capital cities is on average 13 times higher than that in the

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4 Tanser F et al. Effect of ART coverage on rate of new HIV infections in a hyper-epidemic, rural population: South Africa.
9 UNAIDS Global Report 2012
country’s general population. Some evidence indicates that the global prevalence of HIV infection among men who have sex with men may have increased from 2010 to 2012.

- In 49 countries with available data, the prevalence of HIV infection is at least 22 times higher among people who inject drugs than for the population as a whole, with prevalence at least 50-fold higher in 11 countries.\(^\text{10}\)
- In countries with generalized epidemics, HIV prevalence is consistently higher among sex workers in the capital city than among the general population, with a median of 23%. A recent review of available data from 50 countries, which estimated the global HIV prevalence among female sex workers at 12%, found that female sex workers are 13.5 times more likely to be living with HIV than other women.\(^\text{11}\)
- Prevention programs rarely address the specific vulnerability of transgender people. In 2012, only 43% of countries reported that their national AIDS strategies address transgender people. Forty per cent of countries report that government provides programs and services to less than 25% of transgender people.\(^\text{12}\)

### Implementing effective and rights-based HIV treatment and prevention

Despite the urgent need for expanded services for key affected populations, recent data show that services for these populations continue to be severely lacking. People who inject drugs have accounted for between two thirds and three quarters of all reported HIV cases in Eastern Europe and Central Asia for the past decade;\(^\text{13}\) and yet data from 18 countries in Eastern Europe and Central Asian show that fewer than 10% of people who inject drugs in need of treatment were receiving ART in 2010. Research findings in China, Malaysia and Viet Nam point to similar patterns.\(^\text{14}\) Less than one third of pregnant women who needed ART for their own health in 2011 were receiving it. Fewer than half (45%) of pregnant women known to be living with HIV were assessed for their eligibility to receive ART in 2010\(^\text{15}\). For MSM and sex workers, little data on treatment coverage is available.

Prevention coverage remains inadequate for men who have sex with men. Globally, the median prevention coverage measured in surveys in capital cities is 55%, with a majority of countries reportedly achieving at least 40% coverage for men who have sex with men\(^\text{16}\). Country reports to UNAIDS indicate that the scale of syringe exchange programmes is also inadequate, with most countries indicating that programmes annually provide fewer than 100 needles per person who injects drugs. A separate 2010

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\(^\text{16}\) UNAIDS Global Report 2012
study estimated that, globally, two needle-syringes were distributed monthly per person who injects drugs per month.\textsuperscript{17}

Key populations are also inadequately served with HIV counseling and testing\textsuperscript{18}. The median proportion of men who have sex with men who received an HIV test in the last 12 months is 38%, with fewer than 1 in 3 men being tested in the past 12 months in South and South-East Asia and Western and Central Europe. HIV testing services are also failing to reach many people who inject drugs, with a median of 39% of people who inject drugs reporting that they had received an HIV test in the previous 12 months.

The HIV treatment and care cascade

To be successful, a continuum of HIV interventions is needed that links counseling and testing (HTC) to treatment and prevention services, enrolls people living with HIV into care and prevention services, refers people living with HIV to social support organisations and programmes, provides assessment for treatment eligibility, initiates treatment in a timely manner, and ensures life-long effective utilization of ART and other health and social services. Eliminating stigma and discrimination in healthcare settings – in addition to being a human rights imperative – is also essential to programme retention and supporting adherence.

Figure 1: The four steps of HIV care across the continuum of care

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
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<tbody>
<tr>
<td>HIV Testing to enrolment into care</td>
<td>HIV Enrolment to ART eligibility</td>
<td>Eligibility to ART initiation</td>
<td>ART initiation to long-term ART</td>
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</table>

Engaging people in HIV care - and sustaining that engagement over many years - is a major challenge. As the table below indicates, HIV programmes need to ensure those enrolled in care are retained at every step of the “leaky cascade” across the continuum of care. As one expert has put it, “the arrows are more important than the boxes” in the continuum, as that is where people drop out. While this table focuses on a group of patients in Mozambique, data from sub-Saharan Africa, Asia and the United States all show similar, disturbing patterns.\textsuperscript{19}

\textsuperscript{18} UNAIDS Global Report 2012
\textsuperscript{19} See, for example, Egger et al CROI 2012, or El Sedar, CROI, 2012
Some of the challenges faced at each stage of the HIV care cascade are:

**Step 1: HIV testing and counselling**
HIV testing and counselling (HTC) is an entry point for HIV prevention, care and treatment. It is currently estimated that close to half of the 33 million people living with HIV know their HIV status and that up to 80% of persons with HIV may be lost to follow up between testing and initiation of ART (Rosen S, 2011). It will not be possible to meet 2015 treatment and prevention targets unless demand for and use of HTC increases significantly. This requires an understanding of barriers to HIV testing that goes beyond the debate about informed consent.

**Step 2: Linkage to and retention in pre-ART care**
This step in the cascade has the highest rate of loss to follow-up. For instance, a study in Malawi looking at retention in care for patients in pre-ART care showed 25% retention at one month, 11% at two months, and 4% at six months. In contrast, retention in care for patients initiated on ART was 99% at one month, 97% at two months, and 90% at 6 months. (Tayler-Smith K, 2010).

**Step 3: Initiation of ART**
Most patients present in health care settings at advanced stages of HIV infection resulting in less than optimal outcomes on ART. Studies from sub-Saharan Africa have shown that the following characteristics lead to higher attrition: being male, living in an urban environment, not receiving cotrimoxazole prophylaxis, presenting with WHO stage IV defining conditions, low body weight, and accessing treatment at district or mission hospitals. (Zimbabwe ART Evaluation Report, 2012; Mozambique (Auld et al., 2011); Zambia (Stringer et al., 2006); South Africa (Klausner et al., 2011); Rwanda (Lowrance et al., 2009); and West Africa (Ekouevi et al., 2010)). Because little data is available measuring treatment uptake among key affected populations, it is difficult to know the
factors that lead to their attrition, but well-documented stigma and discrimination within health care settings and the fear of disclosure can be assumed to be important factors. In an era of treatment as prevention, it is worth asking whether people who are diagnosed with HIV are sufficiently aware that treatment can render them essentially sexually non-infectious, as that could affect treatment initiation decisions as well as self-stigma.

Step 4: Retention in care and treatment adherence

The aggregate retention rates at 12, 24 and 36 months based on routine national programme data for 22 countries in sub-Saharan Africa were 75.2%, 66.8% and 65.6%, respectively (Tassie JM et al., 2010). Significant levels of loss to follow-up have been documented to occur during the first two years of treatment, largely due to death and “silent” (undocumented) transfers (Lawn et al. 2008; Fox and Rosen 2010). Earlier studies indicate relatively high levels of adherence in sub-Saharan Africa compared to the United States and Europe.

Retention in HIV care and treatment adherence is essential to maximize HIV treatment outcomes, and by extension treatment-as-prevention outcomes. Therefore, it is crucial to demonstrate and document the impact of cost-effective, efficient and sustainable interventions to support HIV treatment scale-up, retention in HIV care, and treatment adherence. Many of the most effective interventions are community-centered and informed by a human rights-based approach. More information is needed to understand the “root cause” challenges that impact the ability of people to seek out and consistently utilize health services, including cost/transport barriers, judgmental healthcare providers, lack of peer/social support, lack of food security, fear of negative repercussions of a positive result and breach of confidentiality and internal stigma.

The role of affected communities in rights-based HIV service delivery

A coordinated approach to chronic HIV care requires partnership among patients/their families, community-level interventions, and health care providers each playing complementary roles. The role of community-based organizations and networks of people living with HIV has long been recognized as important in the comprehensive and rights-based response to HIV. Communities have important roles to play in supporting healthcare delivery, partly because they represent people living with HIV and those affected by the epidemic. Additionally, healthcare delivery systems are often overstretched to meet the demand created by the epidemic, and too often are places of abuse and judgmentalism. In this context, trusted community-based organizations and networks of people living with HIV and their caregivers have assumed a central role in responding to the crisis.

The Treatment 2.0 Initiative, the HIV Investment Framework and the Global Fund’s Community-Systems Strengthening framework (CSS) recognize the role of community mobilization in the response to HIV. To understand and maximize this role, significantly more must be done to support, document and scale-up community-based interventions and to measure their impact. The link between community-based interventions and human rights-based programming (the latter recently defined by UNAIDS) also needs to be articulated.
In 2011, the International Treatment Preparedness Coalition (ITPC) organized a series of community consultations to support the Treatment 2.0 Initiative. ITPC’s consultations produced a list of services and activities that community-based providers are uniquely placed to deliver:

### Table 1. HIV services and activities that community-based providers are uniquely placed to deliver

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Prevention</th>
<th>Advocacy</th>
</tr>
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<tbody>
<tr>
<td>* Adherence support</td>
<td>* Prevention of vertical transmission</td>
<td>* Monitoring and accountability (health systems, government responses, rights abuses, quality of services)</td>
</tr>
<tr>
<td>* Testing and counselling</td>
<td>* Harm reduction services (syringe exchange, opioid substitution therapy [OST], etc.)</td>
<td>* Quality assurance of health services</td>
</tr>
<tr>
<td>* Treatment literacy</td>
<td>* Sexuality education</td>
<td>* Anti-stigma, anti-discrimination, and decriminalization efforts (legal support, law reform, lobbying)</td>
</tr>
<tr>
<td>* Linkage to care/support services</td>
<td>* Sexual and reproductive health and rights awarenesses</td>
<td></td>
</tr>
<tr>
<td>* Linkages to harm reduction services</td>
<td>* Condom distribution</td>
<td></td>
</tr>
<tr>
<td>* Management of health and psycho-social needs following testing</td>
<td>* PrEP (pre-exposure prophylaxis) education</td>
<td></td>
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<tr>
<td>* Disclosure support</td>
<td>* Education on TB infection control</td>
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<tr>
<td>* Treatment delivery (a treatment extension role for community organisations)</td>
<td>* Client notification, collectivization, peer outreach skills for sex workers</td>
<td></td>
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<tr>
<td>* Case management</td>
<td>* Promotion of male circumcision</td>
<td></td>
</tr>
<tr>
<td>* Nutritional support</td>
<td>* Post-exposure prophylaxis (PEP) for sexual assault survivors</td>
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</tbody>
</table>

WHO recently co-sponsored two consultations to better understand the role of affected communities in providing HIV services, which brought together over 100 community advocates and service providers from around the world. Meeting the needs of key affected populations was of particular concern. Key overarching recommendations from these consultations are summarised below:

- Ensure that psychosocial, legal, and, nutritional support programmes and advocacy and human rights training efforts are considered integral to treatment optimisation and funded accordingly.
- Directly involve key affected populations in the design, implementation, and evaluation of testing, care, and treatment programmes.
- Scale up testing and treatment simultaneously, to ensure that every individual that is tested has access to treatment, care, and support.
- Integrate HIV testing and treatment with screening and treatment for TB, HCV, STIs, HPV, and harm reduction services.
- Tailor interventions to the specific needs, lifestyles, and behaviours of key affected populations.
- Support communities to develop clinically sound treatment literacy education modules that are easy-to-understand, in community-appropriate language (local dialects, slang, vernacular), and provided in community settings.

One positive development in 2012 was the creation and implementation of the Robert Carr Civil Society Network Fund, a community-driven funding mechanism that supports global and regional HIV networks and which is funded by the government of the U.S., Norway and the United Kingdom, along with the Bill and Melinda Gates Foundation. This innovative funding approach will provide approximately US$5 million in its first year of funding, a good start, but not enough to sustain the work of these networks. Aside from the fragmented efforts of private and government donors, no global mechanism to support community-based human rights and community mobilization work currently exists.

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20 Reports from both consultations can be found at [www.HIVtreatmentoptimization.org](http://www.HIVtreatmentoptimization.org)
Defining rights-based approaches to HIV service delivery

Stigma, discrimination and human rights violations continue to be a major obstacle to success in HIV treatment and prevention. In the epidemic’s fourth decade, nearly 4 in 10 countries worldwide still lack any specific legal provisions to prevent or address HIV-related discrimination. Little progress has been made in reforming laws that discriminate against people living with HIV and other key populations at higher risk. According to the UNAIDS Global Report 2012, nongovernmental informants in 70% of countries and national governments in 60% reported the existence of laws, regulations or policies that present obstacles to effective HIV prevention, treatment, care and support for key populations and vulnerable groups.

As of 2012, about 60 countries have adopted laws that specifically criminalize HIV transmission, with some 600 convictions reported in 24 countries.\(^{21}\) According to a 2012 global review, more than 40% of United Nations Member States (78 of 193 countries) criminalize same-sex relations, with some jurisdictions permitting imposition of the death penalty for convictions under such laws.\(^{22}\) Similarly, a 2011 review\(^{23}\) found that punitive policies pertaining to drug use – including criminalization of those dependent on drugs, compulsory drug detention or prohibiting syringe and needle programmes and other harm-reduction measures – undermine efforts to deliver life-saving HIV services for people who use drugs. Laws deeming some aspect of sex work to be illegal are in place in the majority of countries and are often used to justify harassment, extortion and violence against sex workers by police and clients, which places them at increased risk of HIV infection.\(^{24}\)

There is potential for human rights violations at every stage of the HIV care cascade. Efforts to create enabling human rights environments for people living with and affected by HIV must be central to the response to HIV and the treatment optimization framework. The role of community-based and oriented service delivery in creating such an environment is paramount. The lack of sufficient investment in strong health and social systems, including community-based organizations and advocacy, represents a failure in addressing the human rights challenges that hinder effective HIV outcomes.

An enabling environment includes, among other things:

- The repeal and non-enforcement of punitive laws such as those that criminalize consensual sex between men, sex work, and drug use.

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• The enactment and enforcement of legislation that strengthens a rights-based approach to HIV, including anti-discrimination laws.
• Access to justice for key affected populations.
• The repeal of HIV-specific laws that criminalize transmission of HIV when there is no intent to transmit.
• Legal protections for women, including against violence, unequal access to property and inheritance, and other gender-based determinants of HIV risk and vulnerability.
• The availability of methods to criticize and seek redress for inappropriate and/or poor quality care including mechanisms to support civil society monitoring of service quality.
• Opportunities for dialogue between networks of people living with HIV and affected populations with district and national health officials to improve the quality and equity of care delivery.

Entrenched social inequality such as discrimination and violence against women, men who have sex with men, transgender people, sex workers, people who use drugs, and migrants must also be addressed in efforts to scale-up HIV treatment.

For example, discrimination has a direct effect on women’s ability to embark upon and remain in the HIV care cascade. In several settings, women are particularly at risk of infection because of unequal status in society, their vulnerability to sexual violence, and lack of power to negotiate safer sex practice, including condom use. This in turn reduces their ability to access counseling, testing, and treatment, leading to negative health outcomes.

Moving forward, implementation science is needed to model and evaluate effective approaches to service delivery that will increase demand for and retention in care and protect human rights. There is clear overlap between these approaches and the community-based interventions above, and communities play a natural role in protecting and promoting human rights in the context of HIV.

Applying the HIV Investment Framework
As described in more detail in Issue Paper 2: Human Rights and the Investment Framework, the HIV Investment Framework provides a structure for prioritization in National AIDS Strategies to improve health outcomes at reduced costs, by utilizing a set of evidence-based treatment and prevention services supported by a set of critical enabling services. Many pieces must fall into place for the Investment Framework to be successfully applied. One of the most important is increased and sustained involvement by civil society and communities. Community engagement is a main theme in regards to both programme and social enablers, the two parts of the framework that address what should be done and how it should be done. “Community mobilization” is specified as an important social enabler and “community-centered design and delivery” is similarly prioritized as a program enabler.

To be effective, these services must be provided using rights-based approaches and coupled with monitoring and advocacy to ensure that laws, policies and practices reflect

human rights principles to improve public health. In 2012, UNAIDS produced “Investing for results. Results for people”\textsuperscript{26}, which describes processes for countries to better understand their current HIV investments and how to apply the Investment Framework toward a fully optimized AIDS response. To date, at least 29 countries have used this process to analyze their HIV investments in preparation of revised National AIDS Plans.

In 2012, UNAIDS organized two consultations to describe the Investment Framework to community-based advocates and service providers and get input from them about what further information is needed to strengthen the Framework as well as recommend strategies for application of the Framework at country levels. These recommendations include:

- Both human rights and community mobilization underpin the entire model and should be considered basic programme activities.
  - Within any context, human rights based approaches and actions to ensure human rights are not optional. They must not be seen as discretionary or context specific. For concentrated epidemics, human rights and community mobilization are even more important and should be part of the main programme activities as well as critical enablers.
  - Community mobilization should be intrinsic to the investment approach. Community mobilization is more than outreach, patient support and referral. There is an urgent need to provide guidance on what community mobilisation means and how to ensure appropriate levels and quality in the application of investment approaches.
  - Responses to concentrated epidemics focus mainly on key affected populations and the structural changes that are required for effective programme delivery. Legal reform must be at the centre of the response in countries with concentrated epidemics. Recognizing the rights of key populations will translate to improved health care for people who use drugs, sex workers, MSM, transgender people and people living with HIV.

\textbf{The impact of funding trends on key affected populations}

Meeting the targets set in the 2011 Political Declaration on AIDS will require the political will of UN member states to provide sufficient resources and enact policies that further, rather than impede, public health and human rights objectives. Two key areas are how the HIV response is funded and how policies for drug access are developed and implemented. Current trends in funding the HIV response raise significant human rights concerns in that key affected populations are in danger of losing resources targeting their needs.

HIV spending increased by 11\% in 2011 compared to 2010, including a 15\% rise in HIV expenditures by low- and middle-income countries, with domestic spending accounting for a majority of all HIV expenditure for the first time. However, total global HIV investment in 2011 was US$ 16.8 billion, considerably less than the global goal of US$ 22 billion to US$ 24 billion in annual HIV spending by 2015\textsuperscript{27}. In 2012, six months after

\textsuperscript{26}www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2359_investing-for-results_en.pdf
\textsuperscript{27}UNAIDS Global Report 2012
the UN Member States issued the Political Declaration, the Global Fund for AIDS, TB and Malaria cancelled a round of grant making for the first time in its history due to insufficient funds. The cancellation of Round11 is not mentioned in the UNAIDS Global Report for 2012, nor is its impact on 2015 targets discussed.

Donor contributions continue to play an essential role in AIDS funding, especially in low- and middle- income countries. Many middle-income countries, including many upper-middle-income countries, are still not fully assuming the responsibility of funding HIV services, with half of upper-middle-income countries relying on external donors for funding 50% or more of their HIV programmes for key populations at higher risk28.

International donors are increasingly focused on support for “high-burden, low income countries” to achieve the greatest impact and make progress toward meeting treatment targets. Notably, the New Funding Model adopted by the Global Fund Board in November will allocate the largest share of resources to high burden countries with the least ability to pay. While special considerations and mechanisms will address the needs of key affected populations, it remains unclear whether resource levels will be sufficient to meet these needs. Among other things, the Global Fund has yet to determine what share of funds will be available to countries whose epidemics are concentrated among criminalized populations, as well as whether critical enablers such as community mobilization and human rights programmes will be deemed a priority need for core support.

Donors are reluctant to provide funding to middle and lower-middle income countries whose government’s have the ability, but often not the willingness, to contribute to an increasing share of their AIDS responses. While it is critically important to channel resources to poor countries, especially those with a high disease burden, the negative impact of these funding trends is felt severely by key affected populations. Their governments’ failure to provide adequate funding for HIV treatment and prevention is directly related to the kinds of people who are infected, thus placing human rights concerns at the center of the HIV funding debate. Upper-middle income countries with concentrated epidemics, such as those in Eastern Europe and the Middle East, are some of the places where the Global Fund has had its most profound impact, including by opening up space for dialogue about taboo subjects of sex and drugs, and civil society groups in these regions perceive recent trends at the Fund as “punishing success.”

As described above, many countries with concentrated epidemics are not considered “high burden”, but the incidence and prevalence of HIV among key populations in these countries is often very high, and directly linked to severe human rights abuses suffered by these populations. Thus again, structuring HIV resources around the overall burden of infection in a country neglects the human rights issues that are fueling concentrated epidemics.

Access to HIV services for key populations continues to fall way short of need, and international donors foot the bill for many of these services, as the UNAIDS 2012 Global Report illustrates:

28 Ibid.
• Although countries are increasingly recognizing the need to address HIV among men who have sex with men, recent increases in resources for HIV programs for men who have sex with men have primarily resulted from the efforts of international donors. In 2010–2011, international funding accounted for 92% of all spending on MSM HIV programmes. Among 58 countries reporting expenditures for MSM programming, 45 relied primarily on external sources, including 19 of 21 upper-middle-income countries.
• 91% of total spending on HIV programmes for sex workers in 2010–2011 came from international donors.
• Similarly, funding for HIV prevention programs for people who inject drugs has increased – doubling between 2006–2007 and 2010–2011 in 18 countries – but most of this increase results from the efforts of international donors, which accounted for 92% of total HIV spending on people who inject drugs in 2010–2011.
• Many private foundations, who have traditionally provided key support for advocacy and community mobilization have either significantly reduced their support for HIV-related work (such as the Ford Foundation) or have limited their HIV work to “high burden countries” (such as the Bill and Melinda Gates Foundation).
• The percentage of Global Fund grants that include activities addressing stigma and human rights rose from 13% in Round 8 to 62% in Round 10, although such activities are frequently not integrated into grant work plans, budgets and performance frameworks. 29 A Global Fund review in July 2012 30 found “only feeble advances in improvement of the human rights environment as concerns disease outcomes”.

Access to medicines
Policy to ensure consistent access to safe, efficacious, low-cost HIV treatment also continues to impede scale up and threaten the sustained use of ART. Issues on intellectual property and TRIPS flexibilities are discussed in detail in an issue paper on “Intellectual Property, Universal Access and the MDGs” prepared for the Reference Group’s eleventh meeting in April 2010. At the time, the Reference Group:
• expressed its deep concern about the long term funding of HIV treatment, an issue which is a central component of UNAIDS’ mandate to support countries towards universal access;
• called on UNAIDS to act with urgency in response to the anticipated crisis in the funding of medicines;
• recommended that the UNAIDS Executive Director and the UNDP Administrator, together with the other UN System principals, express serious concern in public for a and directly with heads of State, Ministers of Trade and Ministers of Health, about the insistence of high-income countries on including “TRIPS plus” provisions in bilateral trade agreements;
• called particular attention to the vulnerability of children and their need to sustained access to treatment, and recommended that UNICEF play an increasingly active role in advocacy and support to governments on issues of intellectual property and access to medicines.

Over the past two years, advocacy to ensure access to affordable treatment has grown significantly in Asia, Eastern Europe, Latin America and Africa. The Treatment 2.0 Initiative calls for the availability of simpler, easy-to-use ARV regimens as a key component of treatment scale up. However, the cost of many new drugs and new fixed-dose combinations remains prohibitive and patent and trade laws continue to impede progress.

Over the past year, there have been small price reductions for the newer ARVs recommended by WHO in its 2010 guidelines for first-line therapy, like tenofovir. Greater reductions and a reform of the global intellectual property regime and enforcement agenda are needed to support further scale-up. Further, middle-income countries are no longer offered standardized price discounts by originator companies and, instead must negotiate ARV price reductions on a case-by-case basis. Although voluntary measures by companies to broaden drug access have increased over the past year, these require close scrutiny, with many countries still paying exorbitant prices. In India, long regarded as the world’s pharmacy before it became subject to WTO intellectual property rules, intellectual property disputes continue in India and the world is awaiting the outcome of important court decisions there.

There has been progress in moving away from d4T based regimens, with many countries now using either TDF or AZT for new patients starting treatment. In a survey of 16 countries conducted by MSF, all had removed d4T from their national protocol as the preferred first-line ARV, with eight having chosen TDF, five AZT and three choosing either of the two as the alternative.

The move away from d4T has been slowed by the higher cost of these alternative regimens. The price of TDF-based regimens is now nearly the same (when combined with nevirapine), or lower (when combined with efavirenz), than AZT-based regimens, for countries that can access generic versions. But for countries faced with patent barriers or excluded from the scope of voluntary licences, the prices remain consistently high. For example, the fixed-dose combination of TDF/FTC/EFV (produced by Merck/BMS/Gilead), which is an adherence-friendly one pill a day, has remained priced at $613 and $1033 per patient per year (ppy) for lower-income and lower-middle-income countries, respectively, for the last five years. For some middle-income countries, prices can be even higher.

Meanwhile, second- and third-line ARVs remain priced many times higher than first-line drugs. A key development for second-line therapy over the past year was the tentative approval granted by the US Food and Drug Administration (US FDA) of the first-ever fixed-dose combination of atazanavir/ritonavir (ATV/r) in November 2011. This finally provides an alternative boosted protease inhibitor to lopinavir/ritonavir (LPV/r).

Demand for second-line treatment is growing fast: in 2011, it was estimated that almost

31 See, for example, www.itpglobal.org
34 Ibid.
half a million people would need second-line medicines by 2012.\textsuperscript{35} As WHO considers changing its treatment guidelines to recommend earlier initiation of ART as a prevention intervention, the availability of second-line therapy – of lack of it – becomes a key consideration in determining whether to start treatment or not.

The cost of today’s most affordable second-line regimen (AZT/3TC + ATV/r) has decreased over the past year to $399 ppy\textsuperscript{36}. But this is still three times more than the most affordable first-line regimen. For countries where generic versions cannot be used because of patent barriers or because they are excluded from the geographical scope of the voluntary licences, the price can be many times higher.

Newer ARVs remain prohibitively expensive, partially because demand for some of them is still small. This is unlikely to change since patents have prevented the broad and open generic competition that will drive prices down. This means that in middle-income countries much higher prices are paid. In Russia, an upper middle-income country, raltegravir, darunavir and etravirine combined was procured at over $27,000 ppy. This does not even include ritonavir, which would be needed in addition to complete the regimen. For those people already failing on their second-line combination, the high price will mean they almost certainly will be left without effective treatment options.

Key issues for consideration by the Reference Group

WHO Consolidated Guidelines for 2013 – WHO is developing a consolidated set of HIV guidelines slated for release in 2013. These guidelines will update the 2010 treatment guideline and consolidate and update the guidelines for key affected populations, children, vertical transmission, TB integration and sero-discordant couples. It will include clinical, operational and programmatic components and have an important impact on the approaches toward scale up of HIV prevention and treatment at country-level. As such, these guidelines provide an important platform for the articulation of rights-based approaches to HIV counseling and testing, treatment and care, and prevention.

Human rights principles and practices and community-based interventions should be incorporated throughout the HIV Consolidated Guidelines as the most effective way to meet public health goals, including embedding them in the following issues:

- Initiation of ART – The WHO will consider whether to recommend earlier initiation of ART based on (1) whether data shows a treatment benefit to the patient, and/or (2) whether earlier initiation can prevent HIV transmission. It will be important to ensure that patients have a choice as to whether and when to initiate treatment and that they have access to comprehensive information to make informed choices. The risks and benefits of earlier use of ART are still unclear. What are the human rights and ethical implications of recommending treatment primarily as a prevention intervention given a) the potential that treatment might cause harm to the patient taking the


\textsuperscript{36} Untangling the Web of Antiretroviral Price Reductions, July 2012, www. MSFaccess.org
medication, b) the equal right to treatment for those who may not present a high risk of onward transmission (e.g. children), and c) the human right to treatment in itself?

- If earlier initiation of ART is recommended, the availability and affordability of second line regimens should be a key consideration by countries in determining whether to adopt this approach.
- The programmatic guidelines will provide a decision making process for countries for determining their capacity for treatment scale up. If limited by resource constraints – whether financial, structural or human – providing treatment to those who need it first based on clinical criteria should be a key recommendation. The human rights imperative of providing treatment to all who need it should also be emphasized.
- The effectiveness of treatment as prevention creates the risk that countries will divert resources from other prevention measures—including condoms, needle and syringe programs, methadone, and outreach for key populations—on the grounds that treatment is a “magic bullet.” The guidelines should be clear that treatment-as-prevention has only ever worked in the context of access to a comprehensive package of prevention programs which bring patients into the health-care system, and that pitting treatment against other forms of prevention is a mistake.
- To meet 2015 targets, the demand for and use of HIV testing and counseling needs to increase drastically. In their zeal to increase HTC rates, countries and international agencies should recognize that a) HTC is only a valuable tool if the information obtained can be put to use by the person being tested, and b) human rights is a tool, not a hindrance, in increasing access to and uptake of testing. That requires a high quality of information, rights-based HTC approaches, stigma-free environments, elimination of human rights-based barriers to testing (e.g. the fact that knowing one’s status can expose him or her to criminalization for non-disclosure; the reality of involuntary disclosure of confidential HIV test results by state agencies; the imposition of arbitrary costs for HIV tests), and the assurance of linkage from testing to care. The Guidelines provide an important opportunity to set effective and rights-based principles for HTC scale up.  

Funding for community mobilization and service delivery - While the UNAIDS Strategic Plan, the UN General Assembly Political Declaration, the Global Fund Strategy, the Investment Framework and the recently released PEPFAR Blueprint all cite the need for community mobilization and scale up of community-based services as key components to meeting 2015 targets and “ending AIDS”, none have proposed a strategy for adequately resourcing that work. The Global Fund is still unable to provide data on its funding for community-based services and advocacy. The scale up of community-based services and advocacy will require funding, technical support, and evaluation. How will multi-lateral agencies support these efforts?

Implementation Science, the treatment cascade and development of TasP implementation approaches – Improving utilization and programme effectiveness at each point of the treatment cascade is a key challenge in meeting HIV goals. The first 8 million people to start ART did so at later stages of AIDS and when they were already  

symptomatic. Treatment restored their health and their ability to resume work and life activities. The majority of the next 8 million that will start ART are at earlier stages of HIV disease. Many, if not most of these people are asymptomatic and have never felt ill from HIV. A much better understanding is needed about how to motivate and engage asymptomatic people in HIV testing, care, treatment and prevention approaches. An implementation science agenda needs to be developed and resourced, asking such questions as:

- How can HTC approaches be tailored to meet the needs of specific populations to increase demand? What are the best means to link people to care and support?
- What are the social support mechanisms most needed to retain asymptomatic people in care and support treatment adherence? What treatment literacy approaches are effective in helping people make and follow through on treatment decisions? What is the role of peers and people living with HIV in providing counseling, treatment literacy and adherence support services? How can we stimulate the development of treatment options that are easier to adhere to (e.g. taking pills weekly rather than daily)?
- How can efforts to stem gender-based violence, which is an impediment to HIV treatment adherence, be integrated with HIV treatment delivery?
- How does the prevention impact of treatment change perceptions about people living with HIV as well as people willingness to engage in testing and treatment? Is TasP a motivator into testing and/or care for asymptomatic people (i.e. by reducing the stigma and reality of infectiousness)? What are the most effective ways of disseminating information about TasP?
- Do rights-based approaches to service delivery produce better health outcomes?

Issues discussed at the December 2012 Reference Group meeting
At its 13th meeting in December 2012, the Reference Group heard from UNAIDS about a planned, new UNAIDS initiative on access to treatment. Reference Group members generally welcomed an initiative to re-energize efforts to provide access to treatment to everyone in need, but expressed many concerns about what was being proposed concretely in the draft document about the initiative prepared by the UNAIDS Secretariat and sent to Reference Group members in advance of the meeting. In particular, members expressed concerns about UNAIDS messaging on the state of the epidemic, suggesting that UNAIDS, and particularly the Secretariat, should be much more balanced between achievements and “end of AIDS” messages and the very hard issues that still need to be addressed as we move forward. Members felt that the UNAIDS Secretariat should not shy away from, and indeed has an obligation with regard to, conveying hard messages, including that:

- further scaling up access to HIV testing requires addressing the fear, discrimination, social exclusion, discrimination, punitive laws and injustices that keep people from taking up testing, as well as the lack of mechanisms and support to move people from testing to treatment in a timely fashion;

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• those who are not yet on treatment include marginalized and often criminalized populations – new ways to reach them and to overcome political and legal discrimination against them will have to be found to expand treatment;
• insufficient resources, both from donors and from implementing countries, are being made available to achieve the rapid treatment scale-up required to ensure everyone in need can access treatment;
• many people on treatment are dropping off, for reasons that require serious and concerted action;
• developments regarding intellectual property are going to impede treatment access, particularly for people who will require second- and third-line antiretroviral therapy.

Members requested that UNAIDS keep the focus on these difficult issues, rather than playing them down and pretending that we could “end AIDS” without addressing them, if we are to reach the millions currently without access to treatment across multiple barriers, including human rights violations and injustice.

The Reference Group urged UNAIDS to advocate strongly and strategically for serious and sustained financial support for civil society, including groups taking on human rights issues. It further urged UNAIDS to ensure that its staff at country level are fully apprised of barriers to treatment access, are in contact with those in need of treatment who are not getting it and are acting as their vocal champions.

Reference Group members expressed concern about the fact that access to treatment for marginalized populations in certain settings, such as Eastern Europe and the Middle East, remains “shockingly low”, and that at the same time as people in desperate need are denied treatment, mandatory testing proposals are creeping back onto government agendas. They questioned the focus on attempts to massively increase the number of people tested for HIV, when data clearly show that so many of those tested fail to be linked to care or, if they are, fail to be retained in care. Members emphasized that, to reach the next half (and more when treatment guidelines change), things will have to be done differently by UNAIDS, governments and civil society. They urged the UNAIDS Secretariat to flesh out these challenges and corresponding actions, rather than painting a “rosy picture” of the epidemic. In this context, they urged UNAIDS to continue defending treatment as a human right, rather than characterizing it as a “pathfinder for social justice”. While members recognized that social justice is an important concept, they also pointed out that it carries with it no legal obligation or political punch as do human rights.

The Reference Group also expressed concern about the fact that there does not appear to be sufficient collaboration, joint strategizing and clear messaging on shared issues regarding treatment in general and intellectual property in particular among the UNAIDS Secretariat, WHO and UNDP.

In conclusion, the Reference Group appreciated and applauded the willingness of UNAIDS and UNDP to have serious dialogue with the Group and its members, as well as other partners, on efforts to scale up HIV treatment and, in particular, a new UNAIDS initiative that would support and bolster such efforts. Among other things, members expressed concern about the up-to-3.5-times increase in cost as people move from first-
to second-line treatment, and the up-to-23-times increase in cost for people requiring third-line treatment; the generally very high prices of drugs in Eastern Europe, Latin America and the Caribbean and the enormous disparity in pricing of the same drug in different countries; and barriers to treatment access beyond intellectual property, including corruption and lack of competition. They noted that, as more and more middle-income countries in Eastern Europe and Latin America become ineligible for support from the Global Fund, a strategy for ensuring greater access to treatment in those regions urgently needs to be developed.

Members emphasized that treatment expansion is the human rights imperative of the epidemic and said that it was right and critical for the UNAIDS Secretariat and co-sponsors to make treatment expansion a priority. They highlighted that UNAIDS can and should offer to this effort the ability to be bold, direct, challenging and concrete about the serious challenges that need to be addressed. Members concluded by urging UNAIDS to provide such leadership and committed to providing more detailed comments on the draft UNAIDS Secretariat treatment agenda in writing before the end of January 2013.39

Beyond the issue of pricing, Reference Group members were concerned about the fact that the current intellectual property regime fails to adequately stimulate innovation for antiretroviral (and many other) drugs. They challenged the UNAIDS Secretariat, WHO and UNDP to move forward quickly and strategically on the recommendations related to access to medicines in the Global Commission’s report, noting that putting a reconfiguration of the intellectual property regime on the global agenda will be a huge, but critical, task.

Recommendations

3.1 The Reference Group strongly advises the UNAIDS Secretariat to rethink its messaging and communications strategy to be much more balanced between achievements and the difficult work that remains to be done. This will be critical to sustaining support and engagement in the AIDS response. In particular, the Reference Group strongly calls upon the UNAIDS Secretariat to speak out about the hard issues (and the actions needed to address them) that stand in the way of treatment access for all. Such leadership is the Secretariat’s niche, comparative advantage and raison d’être. In short, the UNAIDS Secretariat and any documents on scaling up treatment access need to engage in much more “plain speaking” and express articulation of the human rights necessities of the epidemic.
  o This should start by expressly recognizing and affirming as vital, not only in their own right but as essential strategies to inform the work necessary for an effective response, the human rights to life, health and non-discrimination. Any new treatment initiative should defend treatment as a human right.
  o Specifically, UNAIDS needs to take on intellectual property issues; stock outs; inequitable and inadequate delivery; state-level denial and discrimination against people living with HIV and other key populations and marginalized groups; stigma and discrimination in

39 Comments on “Everyone” (UNAIDS Treatment Agenda) by the UNAIDS Reference Group on HIV and Human Rights. 25 January 2013
health care systems; and punitive laws and law enforcement that impact treatment and/or promote low self-esteem, stigma, discrimination, retaliation, and risks of violence and imprisonment suffered by people living with HIV who are marginalized and criminalized. Any new treatment initiative should spell out concretely what the UNAIDS Secretariat plans to do about these issues.

3.2 **UNAIDS should do more to promote key programmes to support human rights which will also support treatment.** UNAIDS made a significant breakthrough in recent years by capturing in a practical list the seven key programmes that can dramatically improve the likelihood of scaling up HIV services from a human rights perspective: stigma reduction, legal aid, law reform, legal/human rights literacy, human rights sensitization of police, human rights training of health care workers, and reduction of harmful gender norms and violence against women. The expansion of such programmes at country level will help a great deal to address the fundamental exclusion and inequities faced by exactly those populations that make the remaining scale-up of testing and treatment so challenging. The expansion of such programmes also serves to direct sufficient funding to civil society groups who are no longer receiving it.

3.3 **UNAIDS should speak in explicit terms about the unjust application of criminal law and its consequences on treatment expansion.** Unjust application of criminal law to sex- and drug-related behaviours is a major barrier to testing and treatment access in many parts of the world. UNAIDS should explicitly recognize this, and any treatment initiative should include recommended actions addressing this.

3.4 **UNAIDS should be explicit, and serious, about the problems with the patent system.** A large part of the problems related to access to and affordability of drugs stems from the patent system steering research and development not towards medicines with important therapeutic applications for under-served needs like HIV and co-infections, but towards the ever-greening of existing block-buster medicines. UNAIDS needs to provide leadership and take an active role on this, in particular by pushing for some of the structural and potentially long-lasting solutions proposed in the Report of the Global Commission on HIV and the Law, including innovation prize funds, a binding international treaty on research and development and open source drug discovery. In addition, any treatment initiative should attend also to preventing and reversing some of the developments on intellectual property that we know are going to impede treatment access. As a minimum, UNAIDS should support efforts by people in low- or middle-income countries (LMICs) who are calling for their governments to incorporate, and where necessary, use TRIPS flexibilities to increase and sustain treatment. Countries considering passing legislation that may restrict treatment access (e.g., so-called anti-counterfeiting legislation) should be pressured not to do so. Countries that have already passed such legislation should repeal it, or amend it to ensure that access to affordable and sustainable treatment is not impeded. LMICs involved in bilateral, regional or multilateral negotiations should not agree to TRIPS-plus commitments or to provisions that may restrict their ability to

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40 UNAIDS. Key programmes to reduce stigma and discrimination and increase access to justice in national HIV responses. Guidance note. 2012.
use TRIPS flexibilities. UNAIDS and UNDP should support the proposal by Haiti, currently before the WTO TRIPS Council, to exempt all least developed countries (LDCs) from having to apply the TRIPS Agreement as long as they remain LDCs.

3.5 **UNAIDS and partners need to address children’s (lack of) access to treatment more forcefully.** The disparity of treatment between adults and children is a major human rights issue. UNAIDS and its partners should take this on as a priority.

3.6 **UNAIDS should highlight the fact that many are still dying of AIDS.** They have become a “lost group” without a voice, including in the many reports that UNAIDS has been issuing. UNAIDS should try to recognize the reality of the lives of those not on treatment (and who are either dying or threatened with death), as well as depict the experience of those who are on treatment but experience (i) huge burdens of travel, money and time commitments to get short stocks of drugs; (ii) discrimination at point of delivery; (iii) lack of nutrition support; (iv) continuing stock outs; (v) requirement to “pay” even where treatment is supposed to be free of charge at point of delivery; and (vi) pressures by family members to share drugs. UNAIDS should propose to expand treatment based on the real experience of those without treatment and of those barely able or completely unable to remain on treatment. An important part of UNAIDS’ role and that of its staff at country level is to find, work with, advocate for, support the engagement of, and identify solutions with those without treatment and those unable to sustain treatment. UNAIDS staff should be seen as their champions and the “go to” people in the UN.

3.7 UNAIDS should strongly affirm that civil society action and engagement has been a crucial driver of the response. Such civil society engagement is not dying for lack of interest or need, but is being threatened by less and less funding being made available to continue good and vitally needed work. This is a major crisis that threatens the entire response, including treatment expansion. **UNAIDS should champion the specific forms of political and financial support that civil society needs to enable it to advocate for policy and legal changes and adjustments in government spending, as well as to provide patient support, community mobilization and service delivery.**

3.8 **The UNAIDS Secretariat should collaborate and coordinate closely with WHO treatment efforts and UNDP intellectual property efforts.** The Reference Group urges the UNAIDS Secretariat, WHO and UNDP to work together closely to present a solid, united, rights-based and strategic front on the political, technical and funding challenges presented by treatment expansion.

This issue paper was prepared by David Barr for the Reference Group Secretariat to facilitate discussion at the Reference Group’s December 2012 meeting. It was revised by the Reference Group Secretariat after the meeting to include a summary of the discussion at the meeting and the Reference Group recommendations.