ISSUE PAPER FOR THE SESSION:
The UNAIDS Treatment Initiative

Background

The Reference Group has regularly considered human rights issues related to scaling up HIV treatment, most recently at a session during the fourteenth Reference Group meeting in December 2012.

During that session, Dr Badara Samb, UNAIDS, presented on what was then a draft plan for a 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 the draft document about the initiative prepared by UNAIDS Secretariat and sent to Reference Group members in advance of the meeting. In particular, Reference Group members repeated concerns already expressed earlier on during the meeting about the UNAIDS' messaging on the state of the epidemic, suggesting that UNAIDS, and particularly the Secretariat, has to be much more balanced between achievements/"end of AIDS" messages and the very hard issues that need to be, and are not being, addressed in order for treatment to be scaled up. Members felt that UNAIDS Secretariat, as well as others involved in supporting treatment scale up, such as WHO, should not shy away from, and indeed has an obligation with regard to, conveying hard messages, including that:

- further scaling up access to HIV treatment 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;
- those who are not yet on treatment include marginalized and often criminalized populations; thus, new ways to reach them and to overcome discrimination and other human rights violations 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

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1 Everyone. The UNAIDS Treatment Agenda for Reaching 15 Million People Living with HIV with Antiretroviral Treatment by 2015. Internal draft.
third-line antiretroviral therapy (see also Issue Paper 1, on Intellectual Property, Access to Medicines and Human Rights, prepared for this meeting).

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 is 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.

Members emphasized that, to reach the next half (and more, once treatment guidelines will have changed), things will have to be done differently by UNAIDS, governments and civil society. They urged UNAIDS Secretariat to flesh out these challenges and corresponding actions, rather than portraying 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 message of political accountability as do human rights.

Members emphasized that treatment expansion is the human rights imperative of the epidemic and said that it was right and critical for the Secretariat and Cosponsors 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 issued a number of recommendations, including:

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 sustain 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 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.
   - 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, to health and to non-discrimination. Any new treatment initiative should defend treatment as a human right.

- 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, key populations and other marginalized groups; stigma and discrimination in health care systems; and punitive laws and law enforcement that impact treatment and/or promote low self-esteem, stigma, discrimination, retaliation, 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 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.\(^2\) 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 talk in explicit terms about unjust application of criminal law and its consequences on treatment expansion. … 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.

3.5 UNAIDS and partners need to address children’s (lack of) access to treatment more forcefully.

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 is putting out. UNAIDS should try to make real the lives of those not on treatment (and are either dying or threatened with death) as well as depict the experience of those who are on treatment but experience huge burdens of travel, money and time commitments to get short stocks of drugs; discrimination at point of delivery; lack of nutrition support; continuing stock outs; requirement to “pay” even where treatment is supposed to be free of charge at point of delivery; and 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 not able at all 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.

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\(^2\) UNAIDS. Key programmes to reduce stigma and discrimination and increase access to justice in national HIV responses. Guidance note. 2012.
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 UNAIDS Secretariat should collaborate and coordinate closely with WHO treatment efforts and UNDP intellectual property efforts. ...

After the meeting, the Reference Group provided more detailed comments on the draft UNAIDS Secretariat treatment agenda.³

Developments since the fourteenth Reference Group meeting

New WHO guidelines
In June 2013, WHO issued new guidelines recommending that adults or adolescents living with HIV with 350-500 CD4 initiate ART, but that ART should be “a priority” for adults or adolescents with fewer than 350 CD4. The guidelines state:⁴

- As a priority, ART should be initiated in all individuals with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and individuals with CD4 count ≤350 cells/mm³ (strong recommendation, moderate quality evidence).
- ART should be initiated in all individuals with HIV with a CD4 count >350 cells and ≤500/mm³ regardless of WHO clinical stage (strong recommendation, moderate-quality evidence).
- ART should be initiated in all individuals with HIV regardless of WHO clinical stage or CD4 cell count in the following situations:
  - Individuals with HIV and active TB disease (strong recommendation, low-quality evidence).

³ Comments on “Everyone” (UNAIDS Treatment Agenda) by the UNAIDS Reference Group on HIV and Human Rights. 25 January 2013
⁵ There is insufficient evidence and/or favourable risk–benefit profile to support initiating ART at a CD4 cell count >500 cells/mm³ or regardless of CD4 cell count or WHO clinical stage in the following situations: individuals with HIV older than 50 years, individuals with HIV-1 infected or coinfected with HIV-2, individuals with HIV coinfected with HCV and key populations with HIV with a high risk of transmission (such as people who inject drugs, men who have sex with men, transgender people and sex workers). ART initiation in these populations should therefore follow the same principles and recommendations as for other adults with HIV.
- Individuals coinfected with HIV and HBV with evidence of severe chronic liver disease (*strong recommendation, low-quality evidence*).

- Partners with HIV in serodiscordant couples should be offered ART to reduce HIV transmission to uninfected partners (*strong recommendation, high-quality evidence*).

- Pregnant and breastfeeding women with HIV.

With the new guidelines, an estimated 26 million people are clinically eligible for treatment (compared to 17 million under the previous guideline), with nearly 9.7 million of them receiving it, leaving a **gap of 16.3 million**. 1.6 million people began treatment between 2011-2012, 4/5 of them in sub-Saharan Africa.

**UNAIDS’ Treatment Initiative: Treatment 2015**
On July 13, at the Abuja+12 summit of the African Union, UNAIDS launched its treatment initiative, *Treatment 2015*,⁶ to accelerate access to antiretroviral treatment for 15 million people. The framework includes three main concepts:

- **speed** (i.e. this would require treating another 5 million people in 2 years);
- **focus** (i.e. optimal use of resources for populations mostly in need, linked to the “location” concept); and
- **innovation** (i.e. in HIV testing).

It relies on three pillars:
- **demand** (i.e. the right to know one’s status and be treated)
- **invest** (i.e. resources and innovation)
- **deliver** (i.e. improve delivery systems).

According to the document:

*Treatment 2015* provides a results-driven framework to expedite and greatly expand coverage. With less than 1000 days before the end of 2015, much work remains to be done. The WHO’s new 2013 guidelines on The Use of Antiretroviral Drugs for Treating and Preventing HIV Infection recommend a CD4 threshold of 500 for initiation of HIV treatment. As an important step towards getting to zero AIDS-related deaths, countries should be encouraged to prioritize immediate efforts to ensure that all people eligible for HIV treatment have access to it.

**Issues for consideration by the Reference Group**
Both the WHO guidelines and the UNAIDS framework are based on evidence of the public health benefits of a rapid extension of antiretroviral treatment coverage. While the final version of *Treatment 2015* takes some of the

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comments made by the Reference Group on the previous draft into account, many, if not all, of the recommendations issued at the fourteenth meeting, noted above, remain relevant.

UNAIDS is forming a steering group for Treatment 2015 and convening a meeting in December to develop a process for setting new targets by June 2014. The initiative includes 30 priority countries where UNAIDS believes it can make the biggest difference; for example, UNAIDS will advocate for a large allocation from the Global Fund in Nigeria and in the Democratic Republic of Congo. The human rights team has been tasked with developing recommendations on what can be done in human rights terms to reach the new targets.

The revised OHCHR/UNAIDS Guidelines on HIV and Human Rights state the following (in summary) in respect of HIV prevention, treatment and care:

- States should enact legislation to provide for the regulation of HIV-related goods, services and information, so as to ensure widespread availability of quality prevention measures and services, adequate HIV prevention and care information, and safe and effective medication at an affordable price.

- States should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of quality goods, services and information for HIV prevention, treatment, care and support, including antiretroviral and other safe and effective medicines, diagnostics and related technologies for preventive, curative and palliative care of HIV and related opportunistic infections and conditions.

- States should take such measures at both the domestic and international levels, with particular attention to vulnerable individuals and populations.

Questions for discussion

1. Do they new guidelines change the content of the human right to treatment? Specifically, is there a human right to treatment regardless of clinical stage of infection if someone has a CD4 count of less than 500, given the evidence of the individual and public health benefits of initiating treatment at this stage? What would be the implications of calling this a human right?

2. From a human rights point of view, how might we formulate a new definition of “universal access” given shifting criteria? Is a rights-based definition of universal access 26 million people on treatment? How do we balance quantity and quality from a human rights perspective? Is it enough for people to initiate treatment, which is what UNAIDS currently
reports on, or from a human rights point of view must they be successfully on treatment, i.e. virally suppressed?

3. What is the link between the revised WHO guideline and HIV-related stigma and discrimination? Is the prospect of being non-infectious if virally suppressed through treatment sufficient to change attitudes towards people living with HIV? Could that have an impact on willingness to come forward for HIV testing? Is such optimism inappropriate given the reality of lack of treatment access in poor countries?

4. How can UNAIDS and the Reference Group continue to develop the human rights content of the right to treatment? Should this be the subject of a global dialogue or e-consultation? Should there be country-specific dialogues? Should an analytical document be developed or commissioned? Should a further revision of Guideline 6 of the OHCHR/UNAIDS International Guidelines on HIV and Human Rights be considered?

5. As noted above, UNAIDS’ human rights team has been tasked with developing recommendations on what can be done in human rights terms to reach the new targets. What, in addition to the recommendations it made on this issue at its fourteenth meeting, does the Reference Group recommend be done?

Issues related to HIV testing will be discussed in a separate session.

Related background documents

1. WHO. When to start ART in adults and adolescents. Consolidated ARV guidelines, June 2013.

This issue paper was prepared by Jonathan Cohen and 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.