Background

Progress in access to HIV treatment has been impressive. By the end of 2010, 6.6 million people were receiving ART, compared with only 30,000 in 2003. As a result, AIDS mortality has decreased in many high-burden countries. The number of new HIV infections is also decreasing. ART rollout has been a great success – a health and human rights victory. Yet, over half of those requiring treatment in resource-poor countries still do not have access; and ART is still mainly being provided to people who are already symptomatic.

UNAIDS and WHO, supported by scientists and treatment activists have been proposing a new way of thinking: ART is a smart global health investment; it should be started early in the course of disease; it is inextricably linked to prevention; and it can – and must – be radically simplified. As noted below, the prevention benefits of ART were confirmed by data released in May 2011 indicating that early initiation of ART reduces sexual transmission by 96 percent compared to later initiation.

Because of evidence that ART should be started earlier in the course of HIV disease, WHO changed its treatment guidelines in 2010. The 4 key messages are: (1) start ART earlier when CD4 count is less than 350, before becoming vulnerable to sickness; (2) use less toxic drugs as fixed dose combinations; (3) start ART in all persons living with HIV who have active TB and chronic Hepatitis B disease irrespective of CD4 cell count; (4) use laboratory monitoring such as CD4 and viral load to improve efficiency and quality of HIV treatment and care. While the overall clinical benefit to the HIV-positive individual of earlier treatment initiation continues to be discussed, leaving unresolved the question around when best to start treatment, a number of guidelines for high-income settings, e.g. International AIDS Society-United States of America and the United States Department of Health and Human Services (US-DHHS) guidelines now go further than the WHO guidelines, recommending that treatment be initiated at CD4 < 500.

The challenges and implications of implementing even the WHO recommendations in developing countries are significant, much as it is a human rights imperative to do so. As the number of treatment-eligible people goes up with the revised CD4 threshold, coverage decreases and waiting lists are lengthened. At least initially, it can be expected that treatment costs will increase, although long-term benefits may balance that out. The need for community engagement and task-shifting is profound, especially but not exclusively for marginalized groups who face human rights abuses

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3 A number of guidelines for high-income settings, e.g. International AIDS Society-United States of America and the United States Department of Health and Human Services (US-DHHS) guidelines now recommend that treatment be initiated at CD4 < 500.

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This issue paper was prepared to facilitate discussion at the thirteenth meeting (December 2011) of the UNAIDS Reference Group on HIV and Human Rights. It was revised after the meeting to include a summary of the discussion at the meeting and the Reference Group recommendations. It does not necessarily reflect the views of the Reference Group, the UNAIDS Secretariat or the Cosponsors of UNAIDS.
in the formal health system. Human resources demands will be increased at all levels. Last but not least, there will need to be a much more proactive approach to early diagnosis, taking into consideration the many structural and human-rights barriers to scale-up of HIV testing and counselling.

This is why UNAIDS and WHO started a “Treatment 2.0” initiative and called for a “radically simplified treatment platform that’s also good for prevention”. The argument behind it is that, to reach the millions of people still in need, HIV treatment must be simplified and costs brought down.

**Issues discussed at the March 2011 Reference Group meeting**

At its 12th meeting in March 2011, the UNAIDS Reference Group on HIV and Human Rights (Reference Group) considered the human rights issues related to “Treatment 2.0”. It welcomed Treatment 2.0 as a human rights imperative to help remedy the differential and inequitable standard of HIV care in high-income and low-income countries; and emphasized that in order for the Treatment 2.0 agenda to succeed, UNAIDS and WHO must provide strong leadership on three “make-or-break” factors: **community mobilization, an enabling human rights environment, and affordability of first and second-line medicines**. The Reference Group appreciated that UNAIDS and WHO staff strongly agreed with these factors during the meeting, and welcomed the invitation to provide ongoing input and suggest concrete language as UNAIDS and WHO continue to develop messaging and strategy for Treatment 2.0 and related issues, including the investment framework that was under development at the time of the meeting. Among other things, the Reference Group recommended that “UNAIDS and WHO should issue a strong statement that Treatment 2.0 is a human rights imperative that will not succeed without an enabling environment in which basic human rights relating to HIV are respected, and should revise its documents and activities and work plans on Treatment 2.0 to place human rights, community mobilization and affordability of medicines on an equal footing as necessary pre-conditions for the success of Treatment 2.0”; and that “UNAIDS and WHO should consider adding an additional institutional partner with a strong track record on human rights to the Treatment 2.0 Working Group.”

Finally, the Reference Group urged UNAIDS and WHO to move away from a sole focus on the need to do things “differently” and “more efficiently” at this time in the epidemic, to also emphasizing the need for, and the moral and human rights imperative of, ongoing assistance to low-income countries. In its recommendation brief, the Reference Group emphasized that “[i]t is necessary, but insufficient, to do things differently and more efficiently. Both high-income and low-income countries have human rights obligations to which they must be held accountable.”

**Scientific developments since the March 2011 Reference Group meeting**

Since the March meeting, results from several clinical trials on the use of antiretroviral drugs (ARVs) for HIV prevention have changed the landscape in HIV prevention and raised new questions and opportunities on how to optimize the use of

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4 UNAIDS. Treatment 2.0. Is this the future of treatment? Geneva: July 2010. UNAIDS defines Treatment 2.0 as follows: “Treatment 2.0 is a new approach to simplifying the way HIV treatment is currently provided and to scale up access to life-saving medicines. Using a combination of efforts, it could reduce treatment costs, make treatment regimens simpler and smarter, reduce the burden on health systems and improve the quality of life for people living with HIV and their families.”
ARVs for both HIV treatment and prevention. The following is a brief summary of the key developments.5

Treatment as prevention of HIV and TB
The efficacy of early ART in preventing sexual transmission of HIV among serodiscordant couples was confirmed when HPTN 052, a randomized controlled clinical trial of 1763 serodiscordant couples that took place in 13 sites in Botswana, Brazil, India, Kenya, Malawi, South Africa, Thailand, the United States and Zimbabwe, announced its results in May 2011 after an efficacy rate of 96 percent was shown in the early treatment arm of the trial (CD4 350-550 cells/mm3).5 This trial confirmed earlier data from observational studies.7

Lawn et al showed that earlier initiation of ART before TB diagnosis can significantly reduce the risk of developing active TB, and plays a significant role in preventing morbidity, transmission and mortality due to TB, particularly in high TB burden settings.6

Antiretroviral pre-exposure prophylaxis (PrEP)
In July 2010, the first trial to report on topical PrEP (vaginal tenofovir gel) to prevent HIV acquisition in women reported an overall 39 percent effectiveness.9 In November 2010, the iPrex trial, a multinational trial of daily oral PrEP administering tenofovir (TDF)/emtricitabine (FTC) tablets among men who have sex with men, showed that PrEP was 44 percent effective in preventing HIV acquisition.10 In April 2011 the FEM-PrEP trial, assessing the effectiveness of oral TDF/FTC among women in Kenya, South Africa, and Tanzania, was discontinued when an interim analysis revealed that the trial would not be able to find a difference in risk reduction, if there were any, between the treatment and the placebo arms.11

More recently, since the March 2011 Reference Group meeting, two trials among heterosexual men and women reported encouraging results. One was Partners PrEP carried out in Kenya and Uganda among serodiscordant couples. It compared two oral PrEP formulations, TDF alone and TDF/FTC, to a placebo control. In this trial, there was a 62 percent reduction in the risk of HIV acquisition among those taking TDF and a 73 percent reduction in the group taking TDF/FTC. The trial was stopped

5 The summary is a shortened and adapted version of the concept note for the WHO Informal Consultation: Strategic Use of Antiretroviral Drugs, 14-16 November 2011, Geneva. On file with Reference Group Secretariat.
early following an interim review because of the evident effectiveness of PrEP. TDF2, a smaller study among heterosexual men and women in Botswana, reported similar results with TDF/FTC reducing the risk of acquiring HIV by 63 percent overall.

The WHO “Informal Consultation” on Strategic Use of Antiretroviral Drugs

WHO held a consultation in Geneva on 14–16 November 2011 to review this new evidence, discuss potential implications for programme implementation and research, and identify evidence gaps. Participants included global scientific and policy leadership, senior clinical researchers, senior national AIDS programme managers, social researchers, an ethicist, a representative of the Reference Group, and civil society representatives. The objectives of the consultation were to advise WHO on best ways for the provision of guidance on the use of ARVs to treat and prevent HIV (clinical, operational, programmatic); and to identify key areas where additional research, additional modelling and demonstration projects (to assess operational considerations and feasibility) are needed. A meeting report is being prepared, but was not yet available at the time of writing this paper. Participants briefly talked about, but did not discuss in detail, many ethical and human rights issues raised by the strategic use of ARVs for treatment and prevention. Ultimately, the recommendations of the consultation will be presented to the WHO HIV Strategic and Technical Advisory Group in 2012 and a white paper will be presented at the International AIDS Conference 2012 in Washington D.C.

Other developments since the March 2011 Reference Group meeting

The current economic crisis and dwindling international resources have reduced the financial resources made available for the AIDS response. At the end of 2010 about US$ 15 billion was available. International assistance has declined from US$ 8.7 billion in 2009 to US$ 7.6 billion in 2010.

In June 2011, at the UN General Assembly High Level Meeting on AIDS, member states committed to an ambitious set of goals including a 50 percent reduction in new sexual transmissions, elimination of vertical transmission, and a total of 15 million people on ART by 2015. They further committed to making at least US$ 22–24 billion available for the global HIV response annually by 2015. According to UNAIDS, “[t]his level of resourcing is critical if the new global goals are to be achieved. Even more critical is that these resources are invested wisely in order to maximise return, to achieve value for money

A new UNAIDS Investment Framework, first published in The Lancet just before the High Level Meeting by Bernard Schwartlander and colleagues, is meant to provide a roadmap for such an approach, tying investments to concrete results. The Investment Framework starts with the premise that, while there have been tremendous gains in the global response to HIV, a systematic effort to match

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investment to needs has so far been largely lacking. According to UNAIDS, the "resulting mismatch has stretched scarce resources too thinly over too many objectives".16

The framework has four aims:
- Maximizing the benefits of the HIV response
- Using country-specific epidemiology to ensure rational resource allocation
- Encouraging countries to implement the most effective programmes based on local context
- Increasing efficiency in HIV prevention, treatment, care and support.

According to UNAIDS, a more strategic and programmatically targeted approach to spending would achieve “extraordinary results”,17 averting 12.2 million new HIV infections and 7.4 million AIDS-related deaths between 2011 and 2020 compared with a continuation of current approaches. UNAIDS continues by saying that "[v]alue for money is best obtained when national AIDS responses make timely investments that are in the right places; utilize the right strategies; increase efficiency, reduce costs and promote innovation."18 This approach has since been adopted by the new strategy of the Global Fund to Fight AIDS, Tuberculosis and Malaria, and has also been taken up by the HIV prevention strategy issued by the US President’s Emergency Fund for AIDS Relief.

The Investment Framework calls for the rational allocation of resources to six basic programme activities:
1. focused interventions for key populations at higher risk (particularly sex workers and their clients, men who have sex with men, and people who inject drugs);
2. elimination of new HIV infections among children;
3. behaviour change programmes;
4. condom promotion and distribution;
5. treatment, care and support for people living with HIV;
6. voluntary medical male circumcision in countries with high HIV prevalence and low rates of circumcision.

In addition, the Investment Framework calls for investment in so-called “critical enablers”. According to UNAIDS,19

Critical enablers can be divided into two categories: social enablers that create environments conducive to rational HIV responses; and programme enablers that create demand for programmes and improve their performance. Critical enablers vary greatly according to context, and the evidence base supporting them is less consistent – results are so often locally determined – but they are crucial to overcoming the barriers to effective programmes. Examples of social enablers are outreach for HIV testing, stigma reduction, human rights, addressing the fear of violence addressing gender inequality in access to information and services, advocacy and community mobilization. Programme enablers include strategic planning, programme management and capacity-

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17 Ibid.
18 Ibid.
building for community-based organizations. These organizations can foster innovation and community approaches in the long term can bring down costs and ensure sustainability.

The Investment Framework provides for substantial up-front investment in critical enablers, with essential resources amounting to US$ 5.9 billion in 2011 and US$ 3.4 billion projected for 2015.

Key issues for consideration by the Reference Group

According to the concept note for the recent WHO meeting on the strategic use of ARVs for treatment and prevention,

Countries with limited resources will ultimately have to determine how best to use ARVs and allocate resources for those who need treatment for their own health and for prevention of HIV, TB, and PMTCT. In light of new evidence it is important to reconsider how ARVs can be used most effectively and strategically to help turn the HIV epidemic around. We need to determine the role, acceptability and feasibility of the use of ARVs for earlier treatment and prevention of HIV in combination with core programmatic activities and critical enablers identified by the Investment Framework Study Group.

Barr, Amon and Clayton have recently articulated a rights-based approach to HIV treatment and prevention, suggesting, among other things, a few basic principles that could drive the development of attempts to realise the impact of ART on prevention:

- Guidelines determining the optimal time to start ART in the course of HIV disease must be based on what is best for the individual patient. People living with HIV should not be expected to begin therapy for the primary purpose of preventing HIV transmission. The primary purpose of treatment is treatment. Patients should not be compelled to risk earlier development of antiretroviral drug resistance and/or suffer drug-related side effects unless there is clear evidence that earlier use of ART can be beneficial for the patient in prolonging life and improving the quality of life.
- If resources are limited, decisions about who should receive ART must be based on the need to treat the sickest patients first and not based on perceived opportunities to prevent new infections. The best way to address this is to ensure that all those meeting current treatment guidelines have adequate access to ART and other health care services.
- The choice to use ART remains a personal choice. Patients have the right to decide not to take ART.
- The availability of second- and third-line treatment combinations is essential to long-term use of ART. This will be especially important as earlier treatment is considered to maximize both treatment and prevention benefits of ART.

These principles are consistent with those outlined in a document prepared by the International Treatment Preparedness Coalition (ITPC), based on community consultations on Treatment 2.0.\(^1\) In addition, the ITPC document contains the following additional principles:

- **Access to HIV testing and linkage to care are human rights.** A reframing of the discussion about testing is needed in which early initiation of treatment, and thus testing, is recognized as a right. The role of communities is to remove the barriers that act as impediments to realizing that right.
- **Access to information about the benefits and availability of treatment is also a human right.** There has been reluctance in many countries to raise awareness about the availability and benefits of treatment. Meeting participants speculated that this is because governments do not want to increase demand that they do not have the resources to meet. However, increased awareness about the benefits of treatment should be seen, not only as a right to information, but as an important incentive to increase the use of testing and health services.

However, at least some of these principles are controversial. At the WHO meeting on the strategic use of ARVs for treatment and prevention, some participants argued that, under certain circumstances, the public health benefits of treating people (or providing PrEP to certain high-risk individuals) could outweigh the interests of sick people needing treatment.

Other issues raised at the WHO meeting included human rights barriers to early diagnosis and the lack of adequate financial resources.

**Summary of the discussion at the thirteenth Reference Group meeting**

At the meeting, the Reference Group first briefly reviewed the scientific and other developments since the twelfth meeting of the Reference Group in March 2011 (see above). With regard to the scientific developments, it noted that results from several clinical trials on the use of antiretroviral drugs (ARVs) for HIV prevention had changed the landscape in HIV prevention and raised new questions and opportunities on how to optimize the use of ARVs for both HIV treatment and prevention. The Reference Group welcomed the results of these studies, which confirm that treatment is prevention. It emphasized that this further strengthens the public health and human rights arguments for vastly increased scale-up of HIV testing and counselling, with strong linkages to care, support and treatment for people testing HIV positive. The Reference Group noted that the reasons for, and benefits of, rapid expansion of ART have never been more compelling – yet this is happening exactly at the time that the economic crisis and dwindling international resources have reduced the financial resources made available for the AIDS response. This lack of resources, which is itself a human rights issue, may force countries to make extremely difficult resource allocation decisions – potentially

\(^1\) ITPC. Treatment 2.0.: The next phase of HIV treatment and prevention scale-up: A community-based response.
pitching the needs of sick individuals against the public health benefits of providing treatment to individuals with higher CD4 counts, or even to uninfected individuals.

The Reference Group concluded that it would be extremely important to analyse, in depth, the many difficult ethical and human rights issues raised by the strategic use of ARVs for treatment and prevention. One of these issues, which has been of perennial concern to the Reference Group, is how to eliminate or at least reduce human rights barriers to early diagnosis. In this context, the Reference Group noted that expanding access to treatment would require further massive scale-up of HIV testing and counselling, which must mean both greater access to various forms of HIV testing and counselling, and also greater action to remove the many barriers to HIV testing and counselling. According to the Reference Group this will in turn require vastly increased resources and commitment devoted to addressing the stigma and human rights violations that impede early diagnosis. An additional, critical human rights issue is loss to follow-up and the unknown extent to which that might be caused by human-rights issues. Finally, Reference Group members critiqued the concept of “community mobilization” as a solution to early diagnosis and loss to follow-up, noting that community mobilization sometimes manifests as mass HIV testing campaigns without respect for human rights. In this context, the recent HIV testing campaign in South Africa, in which the 18-step protocol was violated in 95 percent of cases, needs to be closely studied by UNAIDS.

The Reference Group suggested that WHO could work closely with the Reference Group to identify relevant ethical and human rights questions and analyse them, in a transparent and consultative process, with the ultimate goal of providing WHO/UNAIDS guidance to countries on these issues. In particular, the Reference Group offered to undertake a consultation process on the human rights issues related to the strategic use of ARVs for treatment and prevention, with consultation questions agreed upon with WHO and the UNAIDS Secretariat.

The Reference Group asked UNAIDS for an opportunity to provide input into the further development of the new UNAIDS Investment Framework, particularly its “critical enablers” components. The Reference Group regretted that it had had, until the time of its thirteenth meeting, no opportunity to provide input into what constitutes one of UNAIDS’ major initiatives, with potentially huge human rights benefits, but also some potential risks that require further analysis.

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22 The Reference Group heard about the consultation on the strategic use of ARVs held by WHO in Geneva on 14–16 November 2011. Participants at that consultation briefly talked about, but did not discuss in detail, the many ethical and human rights issues raised by the strategic use of ARVs for treatment and prevention.


Recommendations

1. As part of the efforts to provide guidance to countries on the strategic use of ARVs for treatment and prevention, WHO, working closely with UNAIDS Secretariat and the Reference Group, should conduct a broad consultation to analyse ethical and human rights issues related to the strategic use of ARVs, and provide guidance on these issues.

2. The Reference Group urges UNAIDS to ensure adequate attention to the further development and eventual implementation, as part of countries’ HIV programmes, of the critical enablers component of the Investment Framework.

3. The Reference Group asks UNAIDS for an opportunity to provide input into the further development of the UNAIDS Investment Framework and any related documents or statements.

4. The Reference Group recognizes the need to further increase access to HIV testing and counselling, but urges 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.

This issue paper was prepared by the Reference Group Secretariat to facilitate discussion at the Reference Group’s December 2011 meeting. It was revised after the meeting to include a summary of the discussion at the meeting and the Reference Group recommendations.