Looking back over the past decades, one of the most spectacular successes has to be the increase in access to life-saving HIV treatment—13-fold in the past 6 years—largely in sub-Saharan Africa. I worry however, for the future. At current costs, treatment will not be available for all in need. The UNAIDS agenda—Treatment 2.0—charts out the new direction the global community has to take. Smarter and more efficient treatment regimens are needed, as are simple-to-use diagnostics.

This will need us to look beyond the current configuration of drug development, production and supply; broaden private and public partnerships that include the south and north; cut out narrow interests; and open the door to new ideas, new insights and deeper understanding. This agenda also has to address the additional HIV-associated health needs of people living with HIV such as cancer, lymphomas, cardiovascular complications and ageing-related diseases.

- Michel Sidibé, Letter to Partners (2011), at 17-18

Background
Progress in access to HIV treatment has been impressive. Preliminary data indicate that, by the end of 2010, more than 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; ART is still mainly being provided to people who are already symptomatic; and some argue that it is too complicated and expensive and therefore “not sustainable” in the long term. Indeed, some have argued that The Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), the US President’s Emergency Plan for AIDS Relief, and other funders have been investing too much in HIV treatment, to the detriment of HIV prevention and other health issues.

UNAIDS and WHO, supported by scientists and treatment activists are now 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. Treatment benefits have been clear for many years. The Global Fund and partners have estimated that effective treatment has saved over three million lives since it has become available. But now we know that earlier treatment also benefits prevention efforts, for both HIV and TB. It has been estimated that the number of persons newly infected with HIV each year could be reduced by 1 million if all those who need antiretroviral therapy, based upon current WHO treatment guidelines recommending treatment initiation at 350 CD4 cells or fewer, received it. In addition, treatment reduces disability and morbidity, reduces costs for management of opportunistic infections and cancer, reduces

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1 G Hirnschall, B Schwartlaender. Treatment 2.0: catalyzing the next phase of scale-up. The Lancet, published online February 25, 2011.
orphan-hood, improves maternal and child outcomes, reduces stigma and human rights violations against people living with HIV, and increases work force productivity.

Because of the evidence that ART should be started earlier in the course of HIV disease, WHO changed its treatment guidelines in 2010.³ The 4 key messages are: (1) start ART earlier (before becoming vulnerable to sickness when CD4 count is less than 350); (2) reduce the risk of adverse events and improve adherence by using 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. Although they have represented the standard of care in developed nations for some time, far from all resource-poor countries are using the new WHO recommendations.

The challenges and implications of implementing 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 do not feel comfortable accessing 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 have started the “Treatment 2.0” initiative and called for a “radically simplified treatment platform that's also good for prevention”,⁴ as one major component of the new UNAIDS strategy aimed at getting to zero AIDS-related deaths and zero new infections. The argument behind it is that, to reach the millions of people still in need, HIV treatment must be simplified and costs brought down.

**What are the components of Treatment 2.0?**

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. Modelling suggests that, compared with current treatment approaches, Treatment 2.0 could avert an additional 10 million deaths by 2025.*⁵

UNAIDS, together with WHO and other partners, has defined five pillars or work streams within which advances are necessary in order to realize Treatment 2.0 and achieve universal access goals. In UNAIDS’ 2011-2015 strategy, they have been described as follows:

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**Optimise drug regimens:** UNAIDS calls for the development of new pharmaceutical compounds that will lead to a "smarter, better pill" that will be less toxic, longer-acting and easier to use. Combined with dose optimisation and improved sequencing of first and second line regimens this will simplify treatment protocols and improve efficacy. Optimising HIV treatment will also result in other health benefits, including much lower rates of TB and malaria among people living with HIV.

**Provide access to point-of-care diagnostics:** Monitoring treatment requires complex equipment and specialised laboratory technicians. Simplifying diagnostic tools in order to provide viral load and CD4 cell counts at the point of care could help to reduce the burden on health systems. Such a simplified treatment platform could defray costs and increase people's access to treatment.

**Reduce costs:** Despite drastic reductions in drug pricing over the past decade, the costs of antiretroviral therapy programmes continue to rise. While drugs must continue to be made more affordable—including first- and second-line regimens—potential gains are highest in reducing the non-drug-related costs of providing treatment, such as diagnostics, hospitalisation, monitoring treatment, and out-of-pocket expenses. These costs are currently twice the cost of the drugs themselves.

**Adapt delivery systems:** Simpler diagnostics and treatment regimens will also allow for further decentralising and integrating of service delivery systems, thereby reducing redundancy and complexity, and facilitating a more effective continuum of treatment, care and support. Task-shifting and strengthening procurement and supply systems will be important elements of this change.

**Mobilise communities:** Treatment access and adherence can be improved by involving the community in managing treatment programmes and by promoting scale-up of voluntary testing and confidentiality and reducing stigma and discrimination in health care settings and communities. Strengthening the demand and uptake for testing and treatment will both improve treatment coverage and help to reduce costs for extensive outreach. Greater involvement of community-based organisations in treatment maintenance, adherence support and monitoring will reduce the burden on health systems.

Human rights issues are not discussed in earlier Treatment 2.0 documents, but internal documents now explicitly recognize that “important barriers to HIV treatment uptake and retention have been insufficiently addressed: in particular stigma associated with HIV infection, and discrimination and human rights violations towards people living with HIV.” Specifically, the “mobilize communities” pillar is supposed to help advance human rights as “community-based approaches can build trust, protect human rights, empower people, and can increase the willingness of PLHIV to access HIV services...”

With support from UNAIDS and the Open Society Foundations (OSF), the International Treatment Preparedness Coalition (ITPC) is “developing policy and catalyzing action to ensure that community mobilization and service delivery is...”

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6 UNAIDS. Treatment 2.0: Rational, Work Streams and Partners. Draft working paper.
7 Ibid.
supported as a central strategy of the Treatment 2.0 agenda. On 24-25 January 2011, ITPC convened a Planning Committee of experts in the fields of HIV/AIDS service delivery, HIV policy, community organizing, and human rights (including Reference Group members Joe Amon and Jonathan Cohen) to create a conceptual framework for this project. Participants identified the following human rights activities that communities can, and do, undertake that could contribute to the realization of the prevention benefits of treatment and Treatment 2.0 more broadly:

- **Addressing factors outside the health system that impede access to care** such as police violence, violence in the home, pervasive stigma, and fear and discrimination in employment.
- **Playing an educational role in changing attitudes of police, healthcare workers, and religious leaders.**
- **Holding global funding institutions** like PEPFAR and the Global Fund **accountable for their roles funding governments whose AIDS policies violate human rights.**
- **Documenting rights violations against PLWHA and key populations.**
- **Mobilizing demand for the right to health.**

Participants also stressed that an “opportunity of the Treatment 2.0 agenda is not only to support communities to monitor the human rights environment in the context of treatment scale-up, but to redouble efforts to hold governments accountable to their human rights commitments in the context of AIDS”. The ITPC planning meeting will be followed up by regional consultations in Bangkok, Brazil and Cape Town in the first half of 2011.

**Key issues for consideration by the Reference Group**

In many ways, Treatment 2.0 has the potential to result in significant treatment, prevention and human rights benefits. Human rights activists should strongly support the thinking behind it and ally with those advocating for a strong role for communities in its scale-up.

However, realizing the Treatment 2.0 agenda will require not only major changes in drug therapy, diagnostics, drug costs, particularly for second-line treatments, delivery costs, and health and community systems, but also in the following issues of perennial concern to human rights advocates:

- **Human rights barriers to early diagnosis:** Treatment 2.0 will require massive scale-up of HIV testing and counseling, 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 counseling. This will in turn require vastly increased resources and commitment devoted to addressing the stigma and human rights violations that impede early diagnosis.

- **Drug pricing:** Treatment 2.0 cannot be realized as long as simplified regimens are subject to monopoly prices. Its success hinges on the ability of governments to utilize TRIPS flexibilities to stimulate generic competition to reduce the price of drugs, particularly second-line regimens.

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9 Ibid, at 5.
Communities: Communities play a critical role at every point in the chain from diagnosis to initiation to adherence. They also play a key role in holding governments accountable to their commitments to scale-up testing and treatment. The success of Treatment 2.0 will depend on vastly increased resources and capacity for communities who have always been the make-or-break factor in the HIV response.

As Global Fund Executive Director Michel Kazatchkine said in remarks at AIDS 2010 in Vienna,

*I am excited by what we could achieve [with Treatment 2.0]. But we have to do it right. This is not only about the science, it is also about the people and about resources. Sometimes, it is too easy to forget that we are asking people to get tested for HIV regularly, in environments where people living with HIV still suffer a great deal of abuse and discrimination and where they may even be criminalized, because they are gay, use drugs, are sex workers. People will only get on, and stay on, treatment if we devote much greater attention to human rights, community mobilization, and creating an enabling environment. .... [W]e need to devote much greater attention to human rights ... if we want to successfully scale up treatment and prevention and tackle the HIV epidemic. In practice, this means eliminating laws that create barriers to testing and treatment, such as laws that deny women the right to property or inheritance, laws criminalizing drug use and/or possession, and laws criminalizing same-sex activity or sex work. It means including human rights programs into national AIDS plans and applications to the Global Fund.... Treatment 2.0 simply will not work without this.*

At the level of civil society, there is recognition and dialogue about the importance of and synergy between the three elements—human rights, drug pricing, and communities—that are the make-or-break factors of Treatment 2.0. Yet this is not yet reflected in UNAIDS strategy. A group of human rights activists (including Jonathan Cohen, Michaela Clayton, Joe Amon and Ralf Jürgens) who met with Michel Sidibé in Vienna during AIDS 2010 expressed (in a letter sent to Sidibé after the meeting) strong support for “Treatment 2.0” (and, in particular, renewed UNAIDS leadership on access to generic medicines) and on the need for a “Prevention Revolution”. However, they expressed concern about the fact that the strategy on Treatment 2.0, outlined by UNAIDS in *Treatment 2.0 – Is this the Future of Treatment?* is lacking a pillar on human rights and, more importantly, does not analyse community mobilization, human rights and drug pricing as overlapping yet distinct issues in their own right. The activists strongly urged UNAIDS to revise the document (and all future work on “Treatment 2.0”) accordingly.

Despite the strong plea by the activists (and follow-up by the Reference Group secretariat, which has repeated these points in correspondence to both UNAIDS and WHO, as the Reference Group was providing comments on the new UNAIDS and WHO strategies), all three of the above issues—human rights, drug pricing, and communities—continue to be neglected, although the third is the most prominent on paper. The Reference Group now needs to consider how it can strongly support Treatment 2.0, while at the same time continuing to push for greater attention to human rights in the Treatment 2.0 agenda. This is part of a broader risk that human rights issues continue to be marginalized, as part of a separate pillar of UNAIDS’ new strategy, rather than being integrated also in the work on treatment and prevention.
Potential key messages and recommendations

1. The Reference Group strongly supports Treatment 2.0 as a human rights imperative to reduce the differential standard of care in rich and poor countries.

2. As part of the Treatment 2.0 agenda, UNAIDS and WHO must provide strong leadership on human rights, access to affordable medicines and community mobilization as the make-or-break factors in Treatment 2.0’s success.

3. The Reference Group is concerned that the strategy on Treatment 2.0, outlined by UNAIDS in Treatment 2.0 – Is this the Future of Treatment?, the new UNAIDS strategy, and Michel Sidibé’s Letter to Partners does not recognize human rights, drug pricing and community mobilization as equally important and overlapping considerations in the success of Treatment 2.0.

4. The Reference Group urges UNAIDS and WHO to ensure adequate attention to human rights advocacy, leadership and programming as the Treatment 2.0 agenda will be operationalized. This could be done either by adding a separate, sixth work stream on human rights, or by explicitly referring to human rights in the “mobilizing communities” work stream and adding specific human rights activities under that work stream.

5. More broadly, the Reference Group urges UNAIDS to ensure greater integration of the three pillars of the new UNAIDS strategy. Human rights issues are not separate, but intimately linked to the success of the prevention and treatment pillars. This means that efforts to articulate the content and direction of Treatment 2.0 and the Prevention Revolution need to include sufficient acknowledgement of the critical importance of a protective, not punitive, legal and human rights environment. Human rights concerns, as well as a strong focus on people living with HIV, must figure prominently in efforts to take forward both Treatment 2.0 and the Prevention Revolution.

6. The Human Rights Reference Group would like to provide ongoing input as UNAIDS continues to develop messaging and strategy for Treatment 2.0 and the Prevention Revolution.

7. Strong links need to be established between the Reference Group, the Prevention Commission, and the Commission on AIDS and the Law.

Questions for discussion

1. Are any key issues missing from the paper?
2. Bearing in mind the huge number of human rights barriers to Treatment 2.0, what do Reference Group members think are the priority human rights actions for ensuring Treatment 2.0’s success?
3. How can the Reference Group best combine our efforts with those advocating for affordable medicines and a strong role for communities in Treatment 2.0?
4. Do members agree with the key issues and draft recommendations?
5. How should the Reference Group be communicated and disseminated, particularly since they involve not only UNAIDS Secretariat, but also WHO?

This issue paper was prepared by the Reference Group Secretariat to facilitate discussion at the Reference Group’s March 2011 meeting.

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