Human rights issues related to “universal voluntary HIV testing and immediate ART”

Background and history of the debate

1. In late November 2008, coinciding with the ninth meeting of the Reference Group, Reuben Granich and colleagues at WHO, including then Director of the WHO HIV Department, Kevin de Cock, published an article in the Lancet regarding modelling a response to HIV that would involve universal and annual HIV testing in hyper-epidemic settings followed by the immediate provision of treatment to all those who test positive. The model by Granich et al. predicts that within 10 years of implementation, a program of universal, voluntary, annual HIV testing and immediate treatment for those who test positive could reduce HIV incidence from 20 new cases per 1,000 people per year – the current rate in places like South Africa – to less than 1 case per 1,000 per year. Further, the model predicts that this strategy, colloquially called “test and treat,” could end the pandemic within 50 years.

2. De Cock joined the Reference Group meeting on 24 November to present the mathematical model. He assured members that the purpose of the article was only to open discussion about a possible future approach to controlling HIV and even ending the epidemic, and to call for further research to test it. In this regard, he underlined that the article comprises theoretical mathematical modelling to stimulate debate and should not in any way be seen as policy or technical guidance from WHO. De Cock explained that the modelling suggests that a strategy of universal HIV testing with immediate antiretroviral therapy (ART) provision to those testing positive could lead to very good individual health and public health outcomes. He emphasized that there must be further research and that WHO would not embrace an approach unless it was based on evidence gained from such research. He also assured members that the article supports voluntary (not mandatory) testing, counselling and treatment and that it refers to various concerns that might arise during the implementation of the model, including human rights concerns.

3. In discussion with De Cock, Reference Group members welcomed the model inasmuch as it proposes the attainment of universal access to HIV treatment and HIV testing and counselling, and confirms the critical link between HIV prevention and HIV treatment. They highlighted that these are essential components of the right to health, as well as the goal of universal access to HIV prevention, treatment, care and support. However, they expressed a number of concerns, including:

   - in the public eye, the model risks being seen as representing the thinking of WHO even though it only represents the views of its authors
   - the approach appears to reduce the response to HIV to two modalities: testing and treatment, excluding attention to the political, legal, social, economic forces that underpin much of the vulnerability to infection

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the model appears to place nearly the entire burden of prevention on people living with HIV, to the detriment of empowering both the infected and non-infected to avoid HIV transmission and take mutual responsibility for their sexual health.

the costing in the model does not include costs related to social protection, including programmes and services to address HIV-related discrimination and the other adverse consequences that may occur in relation to learning one’s HIV status.

the modelling on uptake of testing and treatment does not address the vastly different social realities that people living with HIV face, including gender inequalities, criminalization, marginalization, poverty.

4. Other questions raised by the model include:

- How and whether the model would be applicable in other settings besides hyperendemic settings?
- Whether the model would result in disincentives to the funding, implementation, uptake and use of other HIV prevention modalities, as well as those relating to care and support?
- How and whether the model would extend to (or leave out) various hard to reach and marginalized populations at risk, including people who use drugs, men who have sex with men, sex workers, migrants and mobile populations, and the poor?
- Whether uptake of testing and treatment would be sufficient to achieve the results and whether voluntariness of testing and treatment could indeed be maintained in face of possible pressures. If so, how, and would necessary social protection and support measures be funded?
- How confidentiality concerning status would be maintained and how people would be protected from stigma and discrimination attached to their HIV status and/or treatment?
- Whether immediate treatment would in fact result in best possible health outcome for the individual whose immune system in not yet compromised, and whether such early treatment could result in toxicity, drug resistance and other forms of morbidity?
- What are the ethical implications, based on the risks/benefits of such immediate treatment, of the proposed model – both for the individual and in terms of the individual's possible exposure to risk for public health prevention benefits?
- Whether the model is based on serious participation/engagement of people living with HIV in its development?

5. De Cock acknowledged that these are important issues and concerns, but concluded by saying that it was time to seriously discuss and possibly implement on a pilot basis the approach proposed in the paper.

6. Following the publication of the article, Reference Group members developed a statement in response, entitled “Time for action towards universal access to prevention, treatment, care and support: Beyond theory towards practice and protection”.

The statement concludes by urging that, if any further steps are to be taken to further explore the model, they should be carried out transparently and responsibly, so as to advance knowledge without creating misperceptions and possibly confused attempts to “implement” such a model.

The Reference Group highlighted the importance of ensuring full consultation.

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with and participation by people living with HIV who are fully aware of the daily realities of stigma, violence and discrimination and who have been calling for programmes to address them since the beginning of the epidemic; and called on the modellers to include such programmes in their next round.

7. These concerns and suggestions were also summarized in a short letter by some Reference Group members, published in the Lancet in March 2009, as part of a series of letters responding to the article by Granich et al. In the letters, the authors

a. challenged some of the assumptions used in the model, or pointed out that the model’s estimated effect is based on optimistic assumptions;

b. noted that – in addition to programmatic, clinical, social, behavioural, financial, and ethical obstacles – the model underestimates the role of acute transmission;

c. claimed that the model does not adequately account for concurrency (overlapping, long-term partnerships which are likely to account for a substantial amount of HIV transmission in South Africa);

d. noted the experience of Cuba – “where extensive random testing accompanied by contact tracing of infected individuals has resulted in a high HIV detection rate” – as an alternative to implementing a universal testing programme;

e. suggested that the approach proposed by Granich et al “could strongly shift the benefits of treatment from the individual to the population” (“treating for the common good”), saying that the risks and benefits of treatment for people with CD4+ cell counts above 350 are unknown;

f. called for the development of a “robust ethical framework” to guide the use of treatment (as opposed to vaccination) as a disease elimination strategy, which is unprecedented in global public health;

g. reported the experience in Ethiopia with rapid scale-up of HIV testing and antiretroviral therapy provision, pointing out that mass testing is very resource-intensive and needs a strong health system and that, with the current health system constraints in many sub-Saharan African countries, universal testing and ART “is not really feasible”.

8. In their reply to these letters, Granich et al. said that “these comments signal that more research is needed”. Pointing to the increasing evidence of individual benefit from early initiation of ART, they noted that “[o]nly research can determine conclusively whether the modelled approach would benefit individuals by reducing HIV transmission and HIV disease, or whether drug toxicity and other considerations would outweigh advantages”. They agreed that operational challenges in implementing the model in high burden, resource-constrained settings are formidable, that “ethical and human rights issues need to be addressed”, and that “other prevention modalities would continue to have a role”. Finally, Granich et al. said that WHO will hold a meeting later in 2009 to allow discussion of many of the issues raised in the letters responding to their paper. According to them, “[a]nticipated outcomes include review and discussion of relevant research questions and methods, ethical and human rights concerns, and operational challenges, including costing”.

9. Since the publication of the article in November 2008, there have been a number of other relevant developments related to it:

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a. In an email exchange on the international treatment preparedness listserv in early December 2008, some AIDS treatment advocates expressed qualified support for the universal testing and immediate ART approach, seeing the article by Granich et al primarily as a call for HIV treatment to be considered as an HIV prevention intervention. At the same time, they rejected some of the concerns the Reference Group raised, and/or rejected its arguments as unconvincing. While treatment and human rights advocates participating in the debate eventually found quite a bit of common ground (and it should be noted that there is a lot of overlap between these two types of activists), the debate nevertheless highlighted the need for some human rights advocates to be clearer and more practical and pragmatic in their messages and statements; in particular, the Reference Group statement did not seem to resonate (enough), even with those who should be natural allies, and there is a need to refine these arguments, both for treatment activists and for public health advocates. Otherwise, there is a danger that human rights arguments will continue to be misunderstood and marginalized, as evidenced by claims – made during the email exchange on the listserv – that “the human rights community has largely stressed the dangers of HIV testing and not the central fact that HIV testing is the door into treatment and care and between life and death for anyone with HIV”. The human rights and health community was challenged to “come up with a way to scale-up testing beyond current efforts that protects rights and gets people to know their status” and to “push into new territory” and “move forward pro-actively and boldly to articulate a vision that calls for a revolution in HIV prevention, a real merger of HIV treatment and prevention efforts on the ground, a scale-up of HIV testing that respects and honors people’s human rights and gives them options for care if they are HIV+, from OI prophylaxis or TB testing to ART, or prevention if they are HIV-negative”.

Treatment and human rights advocates who participated in the debate eventually agreed on a number of points, including:

1. The human rights concerns raised in the response to the Lancet article are not specific to the recent Lancet article - they are the same concerns human rights advocates have always raised. “We raise them not only out of concern for human rights, but out of concern for the public health. Without such protections and without the services that people need to make HIV testing relevant, testing is useless if not harmful. Without human rights protections, HIV interventions don't work.”
2. If the evidence shows that ART is an effective prevention tool, “then we have a responsibility to figure out how we are going to incorporate this into our thinking.”
3. “We’re locked into approaches that simply don’t work because they don’t really address what puts people at risk of HIV, puts them in the path of epidemics. Handing out condoms and needles, providing "counseling" or telling them to "love life"

Email correspondence of 7 December 2008 by Gregg Gonsalvez (on file). ^4^ Id. ^5^ As summarized in email correspondence of 4 December 2008 by Mark Heywood (on file).
without addressing these structural factors is like handing someone a paddle on a sinking ship.”

iv. “Activists can and must show that effective HIV prevention is possible (by fighting to overcome the structural/human rights barriers), in the same way that we did with access to treatment in developing countries.” We need to “reinforce the need for other prevention strategies which have not failed because they are inherently doomed to failure (and we must not suggest this) but because they have not been given the resources or political commitment that they need, and because people continue to fear the consequences of an HIV test.”

v. “There is an unarguable (or at least very difficult to argue) median point here which is that the more HIV testing and treatment is scaled up in a responsible and respectful and programmatically manageable way, the greater the possible related and derivative benefits to HIV prevention are likely to occur due to reduction of population viral load and ultimately that this is likely to have benefits in reducing incidence and prevalence.” Therefore, “the steps ahead include trying to think through how to do this [vastly scale up access to voluntary HIV testing and immediate ART] in ways which would incorporate the concerns about coercion, cost, resistance, sustainability, changing personal behavior (for taking drugs consistently over a lifetime requires behavior changes even greater than adopting a condom from time to time), etc., etc., and thinking of different ways both to test and to adapt the model to the real world, rather than to engage in a polarizing debate about public health vs human rights…”

In his contribution to the debate, Mark Heywood pointed out that we have to address the fears of those who are disempowered and still afraid to take an HIV test “by demanding investment in dignified health systems and protection from harmful social and legal effects of their health status being known.” He went on to say that “HIV prevention must take place in the real world, and the real world is influenced by poverty-determined life choices, gender based violence, fears of discrimination and stigma”; and emphasized that the mathematical model ignores the factors that inhibit testing and treatment. He concluded: “The article, very dangerously, again juxtaposes the public health approach with a human rights-based one at a time when we need to be ever vigilant – a united front moving towards universal access, and moving fast, but getting there in a way that’s based on protecting people, not forcing them. Let’s be clear: we are all for universal access and realizing the benefits of treatment and prevention for individuals and communities. This is fundamentally about human rights.”

b. On 29 April 2009, in advance of the WHO consultation on this issue originally scheduled for 3-5 May 2009, 30 representatives of civil society organisations from Kenya, Tanzania, Uganda, Botswana, Mauritius, South Africa and Namibia met at a consultative meeting co-

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7 Email correspondence of 5 December 2008 by Mark Harrington (on file).
8 Supra, note 6.
hosted by the AIDS and Rights Alliance for Southern Africa (ARASA), the Open Society Initiative for Southern Africa (OSISA) and the Open Society Institute (OSI) to discuss the model of universal annual HIV testing and immediate antiretroviral therapy for HIV prevention and the practical application of this model to HIV programming. The participants issued a statement acknowledging the model’s potential to advance the universal access agenda, but expressing a number of “fundamental concerns about the assumptions on which the model is based, its shortcoming from a human rights perspective and its inattention to vulnerable and marginalised groups.”

The statement points out that, even if these concerns could be addressed, “the model does not address the range of human rights violations that fuel HIV vulnerability and impede access to treatment and testing in first place” and is thus fundamentally at odds with a human rights response to HIV. Participants additionally expressed frustration that WHO was vastly expanding its ambitions for universal access before interrogating why current universal access targets were not being achieved at country level. It recommends that the following be undertaken “before any further action is taken towards the piloting or implementation of this model”:

i. High level discussion of why progress towards universal access is so slow and how we can better hold governments accountable to universal access commitments

ii. The implementation of an ambitious strategy for scaling up human rights interventions that address vulnerabilities and barriers to accessing testing and treatment

iii. Additional research into the validity of assumptions on which the model is based, both those acknowledged by the authors and those that are not

iv. An analysis of what the model would look like if many of its key assumptions did not materialize, and how these projections would be balanced against the obvious human rights concerns raised

v. An inclusive and transparent process of civil society consultation, particularly in countries where the model may be piloted or introduced.

c. A WHO consultation on 6-7 May 2009, which primarily looked at community-based HIV testing and counselling, also briefly considered the “test and treat” model and came up with a list of key information and research questions concerning the model and suggested that “[w]hat is vitally important is that community and civil society joins in the debate and reflects their concerns and questions about these and the very many other issues that arise from this radical idea.”

d. In stark contrast to the tone of the statement of the Johannesburg civil society consultation, in a number of articles, prominent HIV/AIDS researchers have argued that universal HIV testing and treatment

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“now offers the best hope of controlling the HIV epidemic”.\textsuperscript{12} For example, in an article in the news magazine \textit{The Atlantic}, Haseltine recommended “that WHO, PEPFAR, and the Global Fund begin studies to assess the effectiveness of universal testing and early treatment for the prevention of HIV transmission” and concluded: "I believe that our best hope now lies in universal detection and universal treatment of all those currently HIV positive. It is time to begin. We cannot afford to wait.”\textsuperscript{13} WHO scientists have continued to emphasize that the “test and treat” approach reconciles individual and public health given increasing evidence of the individual clinical benefit of early initiation of ART.\textsuperscript{14} In the June 10 issue of the \textit{Journal of the American Medical Association}, Anthony Fauci and Carl Dieffenbach of the [US] National Institute of Allergy and Infectious Diseases (NIAID), which is part of the [US] National Institutes of Health (NIH) argued that “test and treat” potentially could represent an important public health strategy for fighting HIV/AIDS, but admitted that the model “is based on numerous assumptions that need to be tested and also raises concerns about individual rights, cost effectiveness and other critical issues that require broad public debate”.\textsuperscript{15} The authors set forth a research agenda to validate the assumptions on which the model is based and to address the concerns is raises.

e. Indeed, in addition to being on the agenda of the NIH/NIAID,\textsuperscript{16} the “test and treat” approach is attracting growing interest in the research community. A group at Imperial College London is currently actively seeking funds and support for a feasibility study of what they call the PopART (population effects of ART) approach.\textsuperscript{17} The group has “engaged with three sub-Saharan countries where we already work or where other groups are conducting HIV studies” and reports that the “approach is well received and has attracted the interest of the MoHs in some countries”.\textsuperscript{18} It says: “Human rights issues are important for us and represent one of the ethical aspects we aim to address in our feasibility study. Our consortium includes a social science component that will address these within the framework of the principles of public health ethics”.

10. Immediately after the Reference Group meeting, on 19 July 2009, a “Town Hall-style” discussion at IAS2009 in Capetown will be held on “Maximizing the benefits of treatment for individuals and communities: exploring universal voluntary HIV testing and immediate treatment”, including Reference Group members Joe Amon and Michaela Clayton. In October 2009, as part of a

\textsuperscript{13} Id.
\textsuperscript{17} Email correspondence of 23 June 2009 with Dr Roger Tatoud, Senior Programme Manager, International HIV Clinical Trials Research Mgmt Office, Imperial College London (on file). http://www1.imperial.ac.uk/medicine/about/divisions/medicine/infectious_diseases/hiv_trials/popart/
\textsuperscript{18} Id.
larger seminar on human rights in the scale-up of provider-initiated testing and counselling, the Open Society Institute will convene a one-day consensus meeting on the test-and-treat model between human rights advocates and treatment activists. There can be no doubt that the “test and treat” model will be a focus of discussion at other forthcoming meetings as well, including the AIDS 2010 conference in Vienna.

Defining the issues

11. The “test and treat” approach is yet another step towards the increasing medicalization of HIV pursued by a growing part of the AIDS establishment, including WHO, at a time when UNAIDS is getting more serious about addressing the structural factors underlying vulnerability to HIV and focuses on combination prevention and removal of punitive laws. Rather than speaking with a common voice for universal access (to HIV testing, prevention, treatment, care and support, and programmes to reduce discrimination and increase access to justice in national HIV responses), stakeholders are debating seemingly contradictory approaches.

12. The concerns raised by human rights advocates about the “test and treat” approach and, more broadly, the increasing medicalization of HIV, continue being misunderstood or minimized—including by some AIDS treatment activists. Granich et al. and those seeking to undertake feasibility studies do talk about protecting human rights in the context of the “test and treat” approach. But the main (or only) human rights intervention they envisage is training of those who would undertake universal HIV testing, in order to ensure that testing remains voluntary.

13. There is therefore an urgent need – for UNAIDS, the Reference Group on HIV and Human Rights, and for human rights advocates – to engage with the “test and treat” debate, with clear messages.

14. Linked to this is a need to discuss again the human rights issues related to “universal HIV testing” and, more specifically, provider-initiated testing and counselling and community-based HIV testing and counselling.

Questions for discussion

a) Does this paper adequately summarize the debate about the “test and treat” approach, and the main issues raised?

b) What should the Reference Group’s priority concern(s) be with regard to the “test and treat” approach?
   i. The potential for pilot research and implementation of the “test and treat” approach without due regard for human rights?
   ii. The larger issue of medicalization of HIV responses and the divergent approaches of WHO and UNAIDS?
   iii. The potential for the debate over “test and treat” to distract from more important issues such as the lack of progress toward universal access?
   iv. The need to support further debate among human rights advocates and treatment activists within civil society?

c) Based on our priority concern(s), how should the Reference Group respond to the development and implementation of the “test and treat” approach, both publicly and non-publicly, substantively and strategically?

d) What immediate recommendations related to the “test and treat” approach should the Reference Group make to the Executive Director and to WHO and other UNAIDS co-sponsors with a mandate in this area? How should these
recommendations be made? (in the form of a letter to Michel Sidibe and the heads of the other agencies, accompanied by a revised Reference Group statement?)

e) What, if any, recommendations in addition to those made in the 2007 Reference Group “Statement and recommendations on scaling up HIV testing and counselling” should the Reference Group make related to HIV testing and counselling?

Background documents
UNAIDS Reference Group on HIV and Human Rights. Statement and recommendations on scaling up HIV testing and counselling. 2007

UNAIDS Reference Group on HIV and Human Rights. Time for action towards universal access to prevention, treatment, care and support: Beyond theory towards practice and protection. 2008


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