

Consultation on Antiretroviral Treatment for Prevention of HIV Transmission

Meeting Report

2-4 November 2009
World Health Organization
Geneva, Switzerland

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ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
ANRS	Agence Nationale de Recherches sur le Sida et les Hépatitides Virales
ART	antiretroviral therapy
ARV	antiretroviral
DALY	disability-adjusted life year
HIV	human immunodeficiency virus
MDG	Millennium Development Goal
NGO	nongovernmental organization
NIAID	National Institute of Allergy and Infectious Disease (USA)
NIH	National Institutes of Health (USA)
PEPFAR	(US) President's Emergency Plan For AIDS Relief
PHAC	Public Health Agency, Canada
PITC	provider-initiated testing and counselling
START	Strategic Timing of Antiretroviral Treatment (study)
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

EXECUTIVE SUMMARY

Background

At the end of 2008, an estimated 33.4 million people were living with the human immunodeficiency virus (HIV). By the end of 2008, 4 million people were on treatment. While 1 million people were started on treatment in 2008, there were 2.7 million new infections in that year alone. Universal access thus remains a dream for millions of people. Without significant improvement in prevention, it is unlikely that universal access targets will be met, including the growing demand for antiretroviral treatment (ART).

Antiretroviral treatment (ART) for the prevention of HIV transmission has emerged as a potentially significant component of HIV prevention strategies. The scientific evidence of the effect of ART on prevention of HIV transmission includes studies which show that viral load suppression significantly decreases the risk of sexual transmission in serodiscordant couples and virtually eliminates mother-to-child transmission in settings that use ART or triple antiretroviral prophylaxis. Community-based studies from a number of settings suggest that increasing ART coverage is associated with a decreased incidence of HIV. Building on this growing body of scientific evidence and previous modelling efforts, in November 2008, a team of scientists from the World Health Organization (WHO) released the results of a modelling exercise that examined the potential impact of ART on transmission of HIV. Although further evidence is needed on the role of ART in preventing HIV transmission, including that from ongoing and planned randomized controlled trials, the available evidence suggests that lowering the viral load has a significant impact on HIV transmission.

Implementing WHO recommendations for earlier initiation of ART will obviously require increased access to HIV testing and counselling. This calls for expanded service provision, high levels of adherence, strong community engagement, a human rights framework, and minimal development and transmission of resistance. Attaining universal access targets for expansion of coverage with ART within the current WHO guidelines of initiating ART at a CD4+ count of ≤ 350 cells/cmm should have a significant prevention benefit for individuals, their families and the community. Expansion beyond the current guidelines could provide added health and prevention benefits, but the first priority is to reach those who are the most severely immunocompromised. A prevention-centered expansion of the use of ART beyond current recommendations would be demanding and require further operational, feasibility, acceptability, human rights and ethical exploration, as well as clarification on research priorities. ART at WHO-recommended levels has considerable treatment and prevention benefits, and its role as a potential key element of HIV and tuberculosis (TB) prevention strategies needs to be considered.

To further explore the potential use of ART to prevent HIV transmission and to define a research agenda, a three-day consultation was hosted by the WHO HIV/AIDS department in November 2009. This meeting was immediately followed by a technical meeting in which over seventy global experts focused on modelling and research issues. The initial consultation drew one hundred and five experts, including representatives of national governments, specialists in HIV research and modelling; multilateral

agencies and civil society; and people living with HIV. The consultation examined the evidence base for using ART for HIV prevention, and explored unanswered research questions, concerning the identification of optimal strategies to increase the uptake of HIV testing and counselling, optimal timing of ART initiation for improved individual and public-health outcomes, and the potential role of ART for prevention in low-level and concentrated epidemics. Other issues that were examined included costing, the need to pilot test increased access to HIV testing and using ART for prevention, ethical and human rights considerations, national and community experiences, and the feasibility of using ART for HIV prevention. The importance of expanding access to ART to meet universal access goals, with prevention benefits for HIV and TB, was also emphasized. There was consensus that ART should not be seen as a replacement for existing prevention strategies but as part of a multifaceted, integrated prevention approach. In conclusion, the meeting participants agreed that there was a need to test assumptions regarding the implementation of ART for prevention and build the evidence base through field trials that would measure the impact of ART on HIV transmission among individuals as well as at the population level.

Research priorities

Selected research issues that emerged from the meeting

- Optimal timing of ART initiation for improved individual and public health outcomes
- Feasibility, acceptability and effectiveness of expanding coverage with ART to universal access at a CD4+ count of ≤ 350 cells/cmm and to all those who test HIV positive, irrespective of CD4+ count
- Assessment of the short- and long-term efficacy of ART in preventing HIV transmission
- Effects on acquired and transmitted drug resistance of expanding ART coverage to universal access at a CD4+ count of ≤ 350 cells/cmm and to everyone irrespective of CD4+ count
- Measurement of ART coverage, adherence levels and community impact of ART provision
- Modelling and studies of ART for prevention in low-level and concentrated epidemics
- Cost and cost-effectiveness of ART for prevention of HIV transmission in various scenarios for expanding access to ART
- Optimal strategies to increase uptake of HIV testing and counselling and ART
- Positive or negative impact on stigma of expanding access to universal HIV testing and counselling and ART
- Positive and negative impact on social and human rights of expanding access to HIV testing and counselling and ART

Next steps for WHO

WHO committed to;

- facilitate a constructive and inclusive dialogue among key partners;
- make materials from the consultation widely available;
- examine model assumptions including more detailed exploration of costs and economic analyses with a focus on both costs and benefits, impact on TB, and human rights issues;
- monitor the status and progress of research in this area;
- ensure the involvement of people living with HIV and affected communities in discussions regarding the use of ART in prevention;
- assist Member States in reviewing studies and evaluating issues related to the use of ART in prevention;

- include considerations on the use of ART in preventing HIV and TB as part of the routine guidelines revision process of the WHO Guidelines Review Committee;
- develop simple communication tools on the use of ART in prevention;
- convene follow-up policy and technical discussions with stakeholders in this area.

CONSULTATION ON ANTIRETROVIRAL TREATMENT FOR HIV PREVENTION

1. Background

Despite a 10-fold increase in access to antiretroviral treatment (ART) between 2003 and 2008, the HIV epidemic continues to outpace the response of national and international health agencies. Globally, an estimated 33.4 million people were living with HIV as of December 2008, including 2.7 million who were newly infected that year. Without substantial reductions in the incidence of HIV, especially in the most affected countries, it is unlikely that universal access to HIV/AIDS treatment can be achieved. This, in turn, would prevent the achievement of the health-related Millennium Development Goals (MDGs). Scientific evidence from observational studies and secondary outcomes from ongoing prevention trials shows that the provision of ART reduces the risk of HIV transmission, and has an impact on lowering individual viral load and transmission among couples with a discordant serostatus. In addition, programme data from some communities suggest that expanding access to ART and lowering community viral load is associated with a decrease in HIV transmission. Proof of concept can also be found from the use of antiretrovirals (ARVs) for the prevention of mother-to-child transmission of HIV, with some areas reporting virtual elimination. Models using the available data have come to mixed conclusions regarding ART for prevention, with most experts agreeing that the outcomes depend on the assumptions that are used in the models.

2. Scope and objectives of the consultation

2.1 Scope

The WHO HIV/AIDS department convened an international consultation on 2–4 November 2009 to explore the use of ART for the prevention of HIV transmission. A second meeting that focused on technical issues regarding modelling and research immediately followed the larger stakeholder meeting. In evaluating the feasibility and acceptability of expanding coverage of ART to meet universal access targets, the first consultation considered the implications of, and research needs related to, using ART for HIV prevention. Discussions included issues related to expanding to universal access for those with CD4+ counts ≤ 350 cells/cmm and above this cut-off as a potential strategy for eliminating HIV transmission (for simplicity, provision of ART to those with CD4+ cell counts > 350 cells/cmm is hereinafter referred to as “ART irrespective of CD4+ count”). Working groups focused on various aspects of the use of ART for prevention of HIV transmission and made recommendations for future directions (*see* Appendix A, Consultation agenda).

The consultation was attended by one hundred and five participants (*see* Appendix B, List of participants). Experts included representatives of national governments, those in the field of HIV research and modelling, multilateral agencies and civil society and people living with HIV. The second technical meeting had more than seventy participants.

2.2 Objectives

1. To review the scientific data on and experience with the use of ART for prevention of HIV transmission.
2. To explore the individual, community, human rights, ethical and public health implications of the use of ART for prevention.
3. To investigate operational/programmatic elements.
4. To clarify the research agenda regarding the use of ART for prevention.
5. To define the role of key stakeholders including WHO.

2.3 Purpose of the consultation report

This report summarizes the proceedings of the first consultation on ART for prevention of HIV transmission, Geneva, 2–4 November 2009, focusing primarily on the highlights, areas of consensus and areas where consensus could not be achieved. More detailed information regarding opinions, data and the agenda are available at <http://www.who.int/hiv/events/artprevention/day1/en/index.html>.

The second technical meeting on modelling the impact of ART on TB and HIV was attended by members of the Informal Working Group, and was held on 4–6 November 2009, in Geneva. It considered the technical issues that arise in relation to modelling, assessing the costs, engaging with the community, related human rights considerations, and carrying out field trials on the impact of universal voluntary HIV testing and immediate treatment on HIV and TB. The presentations and agenda can be found at http://www.who.int/hiv/topics/artforprevention/modelling_meeting/en/index.html.

3. ART for prevention: the current evidence

Scientific evidence increasingly supports the view that ART is effective in reducing the risk of HIV transmission.

A growing body of clinical evidence suggests that starting ART earlier is beneficial for people living with HIV. The WHO guidelines promote early treatment for those with CD4+ counts ≤ 350 cells/cmm; however, in many areas, patients continue to present extremely late for diagnosis. The scientific evidence of the effect of ART on the prevention of HIV transmission is derived from studies which show that ART suppresses viral load and that viral load suppression significantly decreases the risk of sexual transmission in serodiscordant couples and virtually eliminates mother-to-child-transmission of HIV in settings that use ART or triple antiretroviral (ARV) prophylaxis. Evidence from community-

based studies in concentrated epidemic settings such as Vancouver, British Columbia and Taiwan suggest that increasing ART coverage is associated with a decline in HIV incidence. Although further evidence is needed on the role of ART in preventing HIV transmission, including that from ongoing and planned randomized controlled trials, study findings suggest that ART has a significant impact on HIV transmission.

Although modelling does not represent scientific evidence, it can be used to explore potential scenarios and elaborate what further evidence would be useful for making public health policy decisions. Modelling efforts over the past ten years have examined the potential impact of ART on the prevention of HIV with mixed results. For example, a modelling exercise undertaken in a 10-block area of Vancouver, Canada, suggested that declines in community viral load stemming from widespread use of ART were helping to drive reductions in HIV incidence among injecting drug users. Renewed consideration of the prevention potential of ART was, in part, prompted by the publication of a 2008 modelling exercise by WHO scientists, which used available research data and previous results of modelling. It evaluated the prevention benefits of universal access to ART for those with a CD4+ count ≤ 350 cells/mm and annual universal voluntary HIV testing and immediate initiation of ART (or “ART irrespective of CD4+ count”). Taking into account evidence from South Africa, which indicates that a person living with HIV infects seven people during the 10 years that they live on average with HIV infection, the model suggested that universal access for those with a CD4+ count ≤ 350 cells/cmm would substantially reduce the incidence of and mortality from HIV infection, but not eliminate HIV. Expanding access to “ART irrespective of CD4+ count” would reduce HIV transmission by 100-fold. Assuming full coverage by 2015, the model concluded that new infections would be virtually eliminated by 2020, although it would require an additional forty years for the complete elimination of all HIV infection (defined as one case per 1000). The model also suggested that expansion to universal access and “ART irrespective of CD4+ count” would result in a sharp fall in the incidence of TB in high-prevalence settings, although eventual elimination of TB transmission associated with HIV infection would require the actual elimination of HIV itself.

In summary, emerging scientific evidence and recent modelling work suggest that the expansion of ART coverage could be a powerful strategy to reduce HIV-associated morbidity and mortality and HIV incidence. There is also a need to continue expanding coverage with ART as part of universal access for those eligible, based on their current treatment needs. Further research is clearly needed on when to start ART and its prevention benefits.

4. Overall research and investigative needs

Many experts agreed that the use of ART for prevention should be considered as an important HIV prevention strategy. A need was also expressed to test assumptions through field trials that would measure the effect of ART at an individual and population level. Others expressed serious reservations about the value of ART for preventing HIV transmission and voiced concerns regarding the potential for

generating large-scale HIV drug resistance, acute phase transmission that would render ART ineffective, transmission due to the virus remaining in the genital secretions, ethical issues and stigma.

Selected research issues that emerged from discussions included;

- the epidemiological role of acute HIV infection in HIV transmission,
- the human rights and community support issues, including issues around achieving universal access to ART for those with a CD4+ count ≤ 350 cells/cmm and above within a human rights framework, while avoiding coercive approaches to expanding access to testing and ART,
- the optimal approaches to scaling up HIV testing and counselling,
- the effect of initiating complex medical regimens in individuals who may not need ART, and of increased and longer utilization of ART,
- the regimens for optimal clinical and prevention effect,
- the extent of residual HIV transmission, and frequency and magnitude of viral rebound for those on long-term ART,
- the monitoring of ARV toxicity and drug resistance associated with earlier initiation of ART,
- the adherence rates of people started on ART at higher CD4+ counts,
- the magnitude and durability of viral load suppression resulting from earlier initiation of ART,
- the financial requirements and economic impact of expanding ART,
- the effect of stigma on the feasibility and effectiveness of expanding access to ART.

5. Specific scientific and technical considerations

Important areas related to ART for prevention were when to start and the role of acute and early HIV infection in HIV transmission.

5.1 When to start

In a session devoted to scientific and technical issues relating to the use of ART for prevention, the draft WHO ART guidelines for adults and adolescents were discussed. At the time of the consultation, WHO was poised to issue new guidelines recommending earlier initiation of ART, with the new eligibility criterion of starting treatment once the patient's CD4+ count falls to or below 350 cells/cmm. To date, no randomized trials have definitively addressed the optimal time to initiate therapy, although a growing body of evidence supports earlier rather than later initiation of therapy. Participants raised the issue that a number of studies that aim to shed light on this question are ongoing, including the HPTN 052 (initiation of ART at a CD4+ count of 250–350 compared to 350–550 cells/cmm) and START (Strategic Timing of Antiretroviral Treatment, CD4+ count >500 cells/cmm) studies.

5.2 Acute and early HIV infection

The acute phase and early infection is of considerable importance to prevention efforts. Empirical results from ecological and population-based studies and several short-term observational studies involving serodiscordant heterosexual couples suggest that ART reduces the rate of HIV transmission.

A multinational, randomized controlled trial (National Institutes of Health HPTN052) that examines the reliability and durability of ART for the prevention of transmission in HIV status-discordant couples is under way. This study and others also consider the effects of ART on sexual risk-taking behaviour, and the transmission of HIV-resistant variants when ART is used for the prevention of HIV transmission.

The importance of the acute phase for HIV transmission was discussed. Experts raised the Miller et al. paper which suggests that as many as 48% of incident HIV infections in some settings may stem from acute infection, which could potentially affect assumptions regarding the protective benefit of lowering community viral load.¹ However, it was also argued that the actual surveillance data regarding the doubling time of the epidemic in South Africa and elsewhere do not reflect this high level of transmission in the acute phase (doubling time would be much shorter). It was recognized that this is an area of uncertainty and more data would help to further delineate the importance of the acute phase in transmission dynamics.

Important technical areas that merit further consideration include;

- the cost, cost-effectiveness and cost-benefits of expanding access to ART for those with CD4+ counts ≤ 350 cells/cmm and to everyone, irrespective of CD4+ count,
- the incidence of resistance and adverse events with earlier initiation of ART at ≤ 350 cells/cmm and for all irrespective of CD4+ count,
- the strategies to improve treatment adherence for those who are initiated on ART, with a particular emphasis on those who start when they are asymptomatic,
- the approaches to increase access to HIV testing and counselling including universal voluntary counselling and testing,
- the relationship between the stage of infection and efficiency of transmission,
- the potential issue of behavioural disinhibition associated with strategies that envisage expanding access to those with CD4+ counts > 350 cells/cmm,
- the degree of therapeutic benefit to the individual with immediate initiation of ART at CD4+ levels > 350 cells/cmm.

Field trials

A number of field trials are in progress. It was noted that in the United States of America (USA), the Federal Government is planning pilot projects of "Test and Treat" in Washington, DC and in the Bronx in New York City. In San Francisco, the relationship between very high HIV testing levels and ART coverage, and a reduction in HIV transmission is being evaluated. A similar programme is also under way in the Canadian province of British Columbia. Modelling and programme data suggest that declines in community viral load as a result of ART are driving sharp reductions in HIV incidence in Vancouver, British Columbia, Canada. An ongoing cohort study in Botswana is trying to address community HIV incidence after intervention with ART and the Agence Nationale de Recherche sur le Sida et les Hépatitides Virales (ANRS) is planning work with collaborators in South Africa to design and implement a large cluster randomized study on ART for prevention.

¹ Miller WC et al. Role of acute and early HIV infection in the sexual transmission of HIV. *Current Opinion in HIV and AIDS*, 2010, 5:277–282.

5.3 HIV testing and counselling

Scientific evidence was presented on HIV testing and counselling and its potential relevance to expanding access to ART, including reaching everyone irrespective of CD4+ count. HIV testing technologies have evolved considerably over the course of the epidemic. Systematic reviews of the evidence regarding the association between HIV testing and behavioural change show that there are minor changes in the number of sexual partners and frequency of unprotected sex. The findings of these studies, however, are undermined by methodological weaknesses. Conducting cohort studies of voluntary counselling and testing with HIV incidence as an outcome has proven to be challenging. In considering the applicability of the available evidence for projecting likely results from universal test and treat, it is important to bear in mind that individuals who seek voluntary HIV testing and counselling tend to be highly motivated, whereas those reached through initiatives for the expansion of access to ART may be somewhat less motivated to learn their HIV serostatus and to act on their results. Preliminary results from a multisite study sponsored by the USA National Institutes of Mental Health found a higher uptake of HIV testing in community-based venues than in clinical settings, although clinical settings yielded a higher percentage of positive results. Community-based HIV testing and counselling is feasible and a number of studies and programmes in sub-Saharan Africa have provided access to HIV testing and counselling for over 80% of the target population. The counselling encounter continues to be a powerful intervention for engagement in health interventions of people at risk and those who are HIV positive when provided within a context of continuum of care. Although the presentations primarily focused on the technical aspects and benefits of testing and counselling, the point was made that testing and counselling should not be considered alone and should be implemented within a strong human rights framework that protects the Three Cs: confidentiality, consent and counselling.

5.4 Couples' counselling and testing

In some parts of Africa, a large majority of new HIV infections are acquired unknowingly from spouses. When both partners know each other's HIV serostatus, risk reduction interventions can be carefully tailored and motivation to avoid transmission is high. Studies in various African settings indicate that half or more of HIV-positive married adults have HIV-uninfected partners. Studies in Rwanda and Zambia suggest that focused couples' counselling and testing could avert a majority of new HIV infections, at a cost per infection averted that is substantially lower than what would be required for expansion of ART coverage. It was argued that embarking on expanded coverage of ART beyond the current guidelines could raise thorny issues regarding resource allocation. Experts argued for couples' counselling and HIV testing as a significant and less expensive intervention than providing ART above the current guidelines. One expert raised the spectre of treating eighteen million asymptomatic people with HIV. This would require expenditure amounts that are more than twice as high as the entire foreign assistance budget of the USA. The concern was raised that under the current fixed budget for ART, extending therapy to the asymptomatic might mean that a significant number of people who need ART would be unable to obtain it. The need to further explore the economic impact of ART, including both costs and benefits, was mentioned as being particularly important, given the current resource constraints.

6. Ethical, human rights and gender considerations

Substantial time was devoted to ethical and human rights considerations of the use of ART for prevention.

A South African civil society representative observed that expanding access to those with a CD4+ count ≤ 350 cells/cmm and to everyone irrespective of CD4+ count would be implemented in low-income settings where ART sites are already overburdened. Given the current difficulties in many resource-limited settings of reaching agreed treatment targets, questions were raised regarding the financial and operational challenges that would be associated with initiating ART as soon as an individual tests HIV positive, regardless of the patient's disease stage. Resource shortfalls for ART scale-up have already been exacerbated by cutbacks resulting from the ongoing global financial and economic crisis.

Numerous precedents exist in public health practice for providing medical interventions to people in order to achieve both broader community as well as individual benefits. However, participants questioned the clinical premise that early HIV infection should be treated early, and the ethical basis for providing ART to individuals who are asymptomatic when millions of patients who are symptomatic and currently need therapy cannot obtain it. It was agreed that the expansion of ART coverage should be focused on those who are most ill; it is urgent to move beyond the current access levels of around 40% of those eligible under the prevailing guidelines (i.e. CD4+ count ≤ 200 cells/cmm). Reaching higher levels of coverage with ART while expanding eligibility will obviously require increased access to HIV testing and counselling.

The common and genuine concerns about individual autonomy, treatment adherence and confidentiality, which have long been part of debates regarding HIV/AIDS treatment, care and prevention, were addressed in relation to expanding access to "ART irrespective of CD4+ count". Ethical considerations, such as respect for the individual, beneficence and justice were raised, and participants asked whether the risks associated with "ART irrespective of CD4+ count" outweighed its theoretical individual and community treatment and prevention benefits. It was suggested that "ART irrespective of CD4+ count" would be acceptable if major advances occurred in the realm social and human rights, including but not limited to assurances that interventions would not be coercive, and if local infrastructures had been first expanded and strengthened substantially to ensure long-term access to ART and health services. Underscoring the concerns of people living with HIV and other community advocates, participants cited an HIV testing bill under parliamentary consideration in Uganda. The proposed legislation would subject individuals found to have exposed another person to HIV to life imprisonment, and would impose criminal penalties on HIV-positive people who fail to heed recommendations on HIV prevention and treatment. It was suggested that the bill represented an effort to put "ART irrespective of CD4+ count" into effect and was a possible example of how the approach could inadvertently exacerbate the stigma and discrimination associated with HIV.

A lively interchange occurred on the relationship between human rights and public health practice. While one speaker urged human rights advocates to support efforts to increase knowledge of HIV serostatus and access to ART as a fundamental human right, others cautioned against pitting human rights and public health principles against one another. Additional research was proposed to better discern the degree to which human rights considerations affect the testing decisions of individuals at risk for HIV infection, and on ways to expand access to life-saving ART within a human rights framework. The role of the community in designing, delivering and evaluating expanded access to HIV testing and counselling, ART and other HIV services was emphasized as a precondition for improved public health.

Speakers also urged that the gender dimensions of the HIV epidemic be taken into account when “ART irrespective of CD4+ count” is considered for adoption. Access to ART for women and their partners is particularly important, and special consideration should be given to women who are in serodiscordant relationships with a partner who is infectious but not eligible for treatment. It was observed that while the model focused on the possible elimination of HIV transmission in generalized heterosexual epidemics, HIV is not driven by heterosexual transmission in all settings. A number of participants asked whether the use of ART for prevention would be viable in concentrated epidemics and whether it might have adverse effects on populations most at risk. However, some experts did not think it would, and described plans to expand ART to drug users, men who have sex with men and others in the hope of reducing HIV incidence.

7. Economic and health systems considerations

Estimations of resource needs by the Joint United Nations Programme on HIV/AIDS (UNAIDS)/WHO to achieve universal access showed that by increasing the number of people on ART and expanding access to ART for everyone eligible, i.e. those with CD4+ counts ≤ 350 cells/cmm and to everyone testing HIV positive irrespective of CD4+ count, would require significant new financial outlays. Achieving and sustaining universal access to HIV prevention, treatment, care and support for those with CD4+ counts ≤ 350 cells/cmm would require an annual expenditure of US\$ 36 billion in 2015. Altering treatment guidelines to recommend initiation of ART at a CD4+ count of 350 cells/cmm rather than at 200 cells/cmm would increase treatment costs by 57%, while starting ART at a CD4+ count of 500 cells/cmm would require a 71% increase in resources. Expansion of ART irrespective of CD4+ count would increase financial requirements by 121%, excluding the increased costs associated with expanding voluntary HIV counselling and testing.

Significant additional work would be required to strengthen health systems to make universal test and treat feasible. According to a desk review of data commissioned by WHO, an additional US\$ 251 billion would be required between 2009 and 2015 to deliver the health interventions required to ensure achievement of the health-related Millennium Development Goals (MDGs) in 49 countries.

The session on operational considerations took into account the policies and plans of leading funders of

ART services. A strong scientific and strategic consensus would be required before the Global Fund to fight AIDS, Tuberculosis and Malaria could begin supporting countries to implement ART for prevention. The US President's Emergency Plan for AIDS Relief (PEPFAR) planned to intensify its focus on current HIV prevention initiatives as a result of the continuing increase in HIV treatment costs.

Most costing efforts are focused on inputs and do not examine the potential economic benefits of expanded access to ART. Using data from South Africa, efforts have been made to project costs associated with universal test and treat, taking into account the increased costs associated with HIV testing and provision of ART, along with anticipated reductions in HIV-related hospital admissions. The scenarios for which costs were estimated include (1) ART not being available, (2) initiating ART at a CD4+ count ≤ 200 cells/cmm, (3) initiating ART at a CD4+ count ≤ 350 cells/cmm, (4) initiating ART at a CD4+ count ≤ 500 cells/cmm, and (5) ART irrespective of CD4+ count. HIV prevalence is reduced over time in each of these scenarios, with prevalence trends shifting further downwards when ART is combined with enhanced HIV prevention interventions. Although the scenario of ART irrespective of CD4+ count provides the maximum access to ART and has higher short-term costs, it results in lower long-term costs. In other words, ART irrespective of CD4+ count lowers the long-term need for ART by optimally reducing the number of new HIV infections (other scenarios also reduce new HIV infections but to a lesser degree). Using data from Kenya, the economic model indicates that expanding access to ART irrespective of CD4+ count would cost less per disability-adjusted life year (DALY) saved than initiating ART at CD4+ levels recommended by current guidelines.

In contrast to evaluations focusing largely on upfront costs, this WHO-led work on the economic impact of ART pointed out the possibility that a significant front-loaded investment to expand access to ART would not only avert millions of new infections but also save hundreds of millions of dollars over the long term. Although the assumptions in modelling efforts are open to debate, the economic impact of ART expansion in the South African presentation emphasized the importance of a balanced economic analysis that includes both costs and benefits.

8. Country perspectives

Country experiences and opinions were solicited systematically during the course of the consultation.

Malawi

Malawi has roughly 1 million people living with HIV, or an adult HIV prevalence of 12%, with half or fewer of HIV-infected adults knowing their HIV serostatus. In 2001, Malawi began implementing rapid HIV testing, and expanded the approach countrywide in 2003. In its efforts to promote HIV testing, Malawi uses a range of approaches, including provider-initiated testing and counselling (PITC), static sites for voluntary HIV counselling and testing, mobile testing services, home-based door-to-door outreach, and a national campaign to change social norms on HIV testing. Important steps have been taken to integrate HIV testing into the diagnostic management of a number of diseases. Since 2006, Malawi has also sponsored an annual, nationwide, week-long HIV testing campaign, involving collaborative efforts

among diverse partners to deliver HIV testing and counselling services. The annual number of HIV tests administered in Malawi increased from 149 540 in 2002 to 1.7 million in 2008, with the number of static HIV testing sites growing from 70 to 713 during this period. Nationwide efforts have been undertaken to train HIV counsellors and laboratory technicians, and extensive resource materials on HIV testing are now available for service providers. Challenges encountered include periodic stock-outs of HIV test kits, lack of timely transmission of testing data from the districts to the national level, and low uptake of HIV testing services by males and couples. Based on its successful experience in increasing the uptake of HIV testing, Malawi recommends efforts to strengthen supply chain management of HIV test kits, use of innovative approaches to increase HIV testing, and focused efforts to improve training, monitoring and evaluation at subnational levels.

Feasibility of expanded access to HIV testing and counselling

Countries such as Malawi and Kenya have demonstrated the feasibility of dramatically scaling up the utilization of HIV testing and counselling services.

Malawi has implemented a combination of energetic strategies to increase knowledge of HIV serostatus. The number of HIV tests administered in the country has risen from 149 450 in 2002 to 1.7 million in 2008.

In Kenya, community-based efforts, including home-based couples' counselling and testing, have shown considerable promise. In a district in western Kenya, a private sector company in collaboration with local nongovernmental organizations (NGOs), the Centers for Disease Control Kenya, and Ministry of Health was able to test 41 040 people, or 80% of the men and women aged between 15 and 49 years during a seven-day campaign.

Kenya

Kenya's success in bringing ART to scale and in lowering HIV prevalence has been cited widely. In July 2009, more than 290 000 people in Kenya were receiving ART and national HIV prevalence has declined by half over the past decade. Scale-up of ART has been facilitated by the promulgation of national ART guidelines, extensive training of health workers in administering ARVs, decentralized service provision, and a significant increase in the number of clinical sites providing ART. Inadequate knowledge of HIV serostatus remains a major impediment to scale-up; surveys in Kenya indicate that more than 80% of people living with HIV are unaware of their HIV serostatus. Among Kenyans who are aware of their HIV infection and have a CD4+ count <350 cells/cmm, 81% are on ART. Emerging challenges in national efforts to further increase ART coverage include a loss of funding associated with the global economic downturn, the need to shift to less toxic but more expensive ARVs, inadequate health system infrastructure, weak patient monitoring systems, persistent stigma and discrimination, and a lack of experience of the health system in delivering chronic care.

Representatives of other countries were invited to share their national perspectives on issues relating to ART for prevention. Because many of the countries represented at the consultation have low-level or concentrated epidemics, there was considerable discussion as to whether the model could have potential applicability to less severe epidemics. In Ukraine, for example, a lower–middle-income country with relatively low ART coverage, it was suggested that care should be taken to ensure that drug users and other marginalized groups are not further disadvantaged by public health approaches that purport to limit

individual freedom for the benefit of the society at large. Brazil, an upper–middle-income country that finances its ART programme through national revenues, is experiencing a financial burden as an increasing number of patients require more expensive second-line ARVs. Although there is strong national political commitment to the AIDS response and a vibrant civil society in Thailand, it was reported that a notable share of people living with HIV still fail to receive ART because they do not know their HIV serostatus or are deterred from seeking services as a result of enduring HIV-related stigma. Although impressive progress has been made in scaling up HIV testing services in South-East and South Asia, it is estimated that less than 20% of people living with HIV are aware of their HIV serostatus.

9. Key research questions and methodologies to assess the use of ART for prevention

In an effort to elucidate the research needed to advance the study of using ART for prevention, attendees at the consultation broke up into six working groups and reported their recommendations back to the full group. Focus areas for the respective groups included (i) research priorities in settings with generalized epidemics, (ii) research priorities in low-prevalence areas with concentrated epidemics, (iii) human rights and ethical issues in areas with generalized epidemics, (iv) human rights and ethical issues in settings with concentrated epidemics, (v) operational research in areas with generalized epidemics, and (vi) operational research in areas with concentrated epidemics. Discussions focused on the following research issues and areas.

The use of ART for prevention involves potentially sensitive social and human rights considerations, and studies to assess this approach will potentially raise complex ethical issues. International ethical standards oblige sponsors of research on human subjects to minimize the risk to participating individuals, to ensure that the benefits of research (including benefits to others) outweigh the risks (including social as well as physical harm), and to select research participants fairly. Some of the innovative study designs under consideration to evaluate the use of ART for prevention may present novel ethical questions; for example, cluster-randomized trials may raise questions regarding the necessity of individual informed consent. Two particular complications were pointed out: one, that considerations of research ethics may conflict with rules and norms on fair access to treatment (especially when “ART irrespective of CD4+ count” is seen as competing for resources with the provision of ART for treatment according to current or expanded guidelines). The second complication mentioned was that research standards and expectations may differ between the sponsoring countries and the countries where research on “ART irrespective of CD4+ count” is carried out, with ethical review and approval required from both.

Having reviewed the available data, perspectives and key issues relating to the use of ART for prevention, the consultation focused on examining an optimal approach to research to build a sufficient evidence base for public health action. The feasibility, acceptability, effectiveness, cost and potential adverse events associated with the use of ART for prevention have yet to be established. Careful evaluation will be required before policy-makers have a sufficient basis to implement this approach.

Several key areas of research need to be explored. Considerable investigation is needed in the field of HIV testing, including studies to identify the most acceptable, feasible, effective and cost-effective methods for providing expanded access to HIV testing in ways that satisfy fundamental ethical concerns. Other questions that need to be answered include the optimal strategies to maximize the uptake of HIV testing, how best to diagnose and address acute HIV infection, how to maximize efficiency in the delivery of HIV testing services, and whether other prevention interventions may be incorporated into HIV testing initiatives.

HIV treatment will also need to be the focus of extensive scientific study. Research would be needed to identify optimal treatment regimens, the best strategy for monitoring individuals who are on ART, and the effects of immediate treatment on clinical prognosis. Substantial health systems research will be required to identify the most appropriate approach to treatment provision (e.g. whether a vertical or horizontal approach would be more effective, whether universal test and treat might result in adverse effects on other health services). Economic studies will also be needed to estimate the total costs associated with expanding to universal access at a CD4+ count ≤ 350 cells/cmm and to “ART irrespective of CD4+ count”, the potential economic benefits, and ascertain the acceptability of “ART irrespective of CD4+ count” in different settings and among different populations.

Well-designed studies will be required to determine the impact on HIV transmission of expanding access to ART including “ART irrespective of CD4+ count”. Research should also focus on quantifying the relative contribution to HIV incidence of different stages of HIV infection. Data will be needed on the levels of ART coverage and adherence required to obtain a population-level prevention benefit. The cost-effectiveness of various approaches to the use of ART for prevention should also be ascertained. Research should also be conducted on the behavioural impact of expanding provision of ART to universal access levels and beyond, including “ART irrespective of CD4+ count” (e.g. risk compensation), and evaluating the impact of using ART for prevention on stigma and discrimination.

Field studies on the use of ART for prevention will be large, expensive and complicated, and it was agreed that large-scale trials should only go forward if pilot tests suggest that ART offers promise as a prevention tool and merits further examination. A multicountry study could be a suitable approach for large trials, as it would provide information on diverse settings and populations. The absence to date of an assay that can reliably estimate HIV incidence in diverse settings may complicate efforts to derive clear findings from studies, underscoring the urgent need for further investment in research to develop such an assay. Innovative research approaches exist to limit the size and expense associated with some of the needed research, although such designs are likely to have sufficient power only to identify a clear effect. In the meantime, while pilot studies are considered, research should immediately go forward on other important issues related to the use of ART for prevention, such as optimal intervention strategies for serodiscordant couples and for individuals with acute HIV infection.

10. Current and ongoing research

A number of ongoing studies are likely to shed light on some of the issues discussed above. Potentially useful findings could emerge from ongoing or planned trials, including HPTN 043 (impact of community-based provision of voluntary testing and counselling), CTN00032 (HIV rapid testing and counselling in drug use treatment programmes in the USA), long-term follow up of serodiscordant couples, PopART (a planned research project in Uganda and Zambia to examine the population effect of ART by a UK consortium) and TasP (a planned French-sponsored study in South Africa to inform planning for the use of ART as prevention and determine the origins of incident HIV infections). Other pertinent studies include HTPN 052 (a study randomizing the infected partner in serodiscordant couples to immediate or deferred therapy), pilot studies in Washington, DC and the Bronx borough of New York City (USA) to evaluate expanded HIV testing and prompt initiation of ART, START, TasP 1 (a planned cluster-randomized trial by French researchers to determine if expanded access to ART lowers HIV incidence), and a planned trial in the Canadian province of British Columbia to measure the impact of expanded HIV testing and ART on HIV incidence.

11. Conclusion: the way forward

With five new HIV infections for every two individuals started on ART, it was agreed that momentum towards universal access was waning and that the HIV epidemic has not been contained in spite of the availability of effective interventions.

In light of our commitment to achieving universal access and the health-related MDGs, the significant treatment and prevention benefits of ART need to be considered as key elements of HIV prevention strategies.

The prevention aspects of expanding ART coverage to meet universal access targets and beyond would be demanding and require further operational, feasibility, acceptability, human rights and ethical exploration, as well as clarification on research priorities. However, the treatment and prevention benefits of ART suggest that we should not be discouraged in our efforts to expand access to life-saving services within a human rights-supportive framework.

The consultation was considered “a very good beginning”, and recognized that ART is useful for both treatment and prevention. WHO pledged to convene meetings among partners and other key stakeholders to advance the research agenda on the use of ART for prevention. Although consensus was not achieved on many aspects of the use of ART for prevention of HIV transmission, many stakeholders supported the conclusion that ART should be considered a central component of HIV prevention interventions and emphasized the importance of monitoring the prevention benefits of expanding coverage of ART to universal access targets and beyond. It was also agreed that any effort to expand access to ART including its use for prevention must be done within a human rights framework and must not exacerbate stigma or

discrimination. Above all, strengthening HIV prevention must never compromise treatment access for those in immediate need of therapy.

Participants acknowledged that there is uncertainty regarding the magnitude of the prevention benefits of ART and it was agreed that appropriate steps should be expeditiously taken to address the important gaps in the knowledge base on the use of ART for prevention, as well as the feasibility, efficacy and acceptability of universal test and treat and other ART for prevention options.

Next steps for WHO

WHO committed to:

- facilitate a constructive and inclusive dialogue among key partners,
- make materials from the consultation widely available,
- examine model assumptions including more detailed exploration of costs and economic analyses with a focus on costs and benefits, impact on TB, and human rights issues,
- monitor the status and progress of research in this area,
- ensure the involvement of people living with HIV and affected communities in discussions regarding the use of ART in prevention,
- assist Member States in reviewing studies and evaluating issues related to the use of ART in prevention,
- include considerations on the use of ART in preventing HIV and TB as part of the routine guidelines revision process of the WHO Guidelines Review Committee,
- develop simple communication tools on the use of ART in prevention,
- convene follow-up policy and technical discussions with stakeholders in this area .

Appendix A: Agenda

DAY 1

2 November 2009

OPENING SESSION	
09.00	Welcome and opening remarks <i>Hiroki Nakatani</i>
09.15	Background <i>Teguest Guerma</i> Meeting objectives, expected outcomes and working methods <i>Siobhan Crowley</i>
09.30	Universal voluntary HIV testing and counselling and immediate ART: results of a modelling exercise <i>Brian Williams & Reuben Granich - Discussion (20')</i>
SCIENTIFIC AND TECHNICAL CONSIDERATIONS Chair: Kevin M. De Cock	
11.00	Universal voluntary testing and treatment: when to start and other research issues <i>Carl Dieffenbach (20')</i> Scientific evidence for the use of ART for HIV prevention <i>Julio Montaner (15')</i> Commentary <i>Myron Cohen (5')</i> Discussion
12.00	Scientific evidence on HIV testing and counselling to prevent HIV transmission and increase access to prevention, treatment and care <i>Michael Sweat, Susan Allen (30')</i> Discussion
ETHICAL, HUMAN RIGHTS AND COMMUNITY CONSIDERATIONS Chair: Beri Hull	
14.00	Community engagement and acceptance of ART for HIV prevention <i>Nonkosi Khumalo (10')</i> People living with HIV perspectives on ART for HIV prevention <i>Kevin Moody (10')</i> Human rights and ART for prevention <i>Lucy Cheshire (10')</i> Gender perspectives on ART for HIV prevention <i>Mariangela Simao (10')</i> Ethics of ART for HIV prevention as a public health intervention <i>Khoudia Sow (10')</i> Discussion

OPERATIONAL CONSIDERATIONS – ECONOMIC AND HEALTH SYSTEMS ISSUES	
Chair: Wafaa El-Sadr	
16.30	<p>UNAIDS/WHO assumptions, methods and estimation of resource needs to achieve universal access <i>UNAIDS, Carlos Avila (15)'</i></p> <p>Costs of scaling up and the current financial landscape <i>Tessa Edejer (15)'</i></p> <p>Detailed programme costing of seek and immediately treat approaches in a hyperendemic setting <i>Jim Kahn (20)'</i></p> <p>Commentary: The Global Fund perspective – <i>Rifat Atun (5)'</i> The PEPFAR perspective – <i>Eric Goosby (5)'</i></p> <p>Discussion</p>

DAY 2

3 November 2009

09.00 Welcome and orientation to Day 2	
OPERATIONAL CONSIDERATIONS – COUNTRY PERSPECTIVES	
<i>Chair: Rowland Swai</i>	
	<p>Scaling up HIV testing and counselling Malawi -- <i>Mtemwa Nyangulu (15')</i></p> <p>Scaling up access to ART Kenya – <i>Mohammed Ibrahim (15')</i></p> <p>Discussion</p>
RESEARCH AGENDA	
<i>Chair: Jean-François Delfraissy</i>	
11.00	<p>What are the key research questions and research methodologies to assess ART use for HIV prevention? <i>Richard Hayes (15')</i></p> <p>Ethical aspects of the research agenda <i>Alex Capron (15')</i></p> <p>Introduction to ongoing or planned trials <i>François Dabis (15')</i></p> <p>Discussion</p>
GROUP WORK	
13.30	<p>Introduction to group work and logistics</p> <p>Groups on:</p> <ul style="list-style-type: none"> Defining the research agenda (A+B) Human rights and ethical issues (C+D) Operational considerations (E+F)

DAY 3**4 November 2009**

09.00 Welcome and orientation to Day 3	
GROUP WORK FEEDBACK Chair: Carl Dieffenbach	
09.10	<p>Group work presentations</p> <p>Group A+B: Research agenda</p> <p>Group C+D: Human rights and ethical issues</p> <p>Group E+F: Operational considerations</p> <p>Discussion</p>
11.00	<p>Panel discussion: Enacting the research agenda – roles, responsibilities and expectations</p> <p>Chair: Michel Kazatchkine</p> <p><i>(5' comments each, on own agency/institution role and responsibilities vis-à-vis the research agenda)</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> ANRS – <i>Brigitte Bazin</i> <input type="checkbox"/> Bill and Melinda Gates Foundation – <i>Steve Becker/Renee Ridzon</i> <input type="checkbox"/> Community – <i>Mark Harrington</i> <input type="checkbox"/> DfID – <i>Malcolm McNeil</i> <input type="checkbox"/> IAS – <i>Robin Gorna</i> <input type="checkbox"/> NIH – <i>Carl Dieffenbach</i> <input type="checkbox"/> PEPFAR – <i>Eric Goosby</i> <input type="checkbox"/> PHAC – <i>Howard Njoo</i>
NEXT STEPS Chair: <i>Teguest Guerma</i>	
12.00	<p>Synthesis</p> <p><i>Siobhan Crowley and Brian Williams</i></p> <p>Reflections from UNAIDS</p> <p><i>Paul De Lay, UNAIDS</i></p> <p>Next steps</p> <p><i>Teguest Guerma</i></p>
13.15	Meeting closes

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