



CONCEPT NOTE

Background

Despite success in increasing access to life-saving antiretroviral therapy (ART), global investment in combating the HIV/AIDS pandemic has had less impact on HIV prevention. Globally, an estimated 33 million people were living with HIV at the end of 2007. Some 2.7 million new infections occurred in 2007, approximately 4 million people were on ART at the end of 2008, of the estimated 9.5 million in immediate need of treatment. There is increasing acceptance that universal access to HIV/AIDS treatment and care, as well as the health-related Millennium Development Goals, will not be achieved without reduction of HIV incidence, especially in the most affected countries of the world.

Recent biomedical research on HIV prevention has yielded mixed results. In settings with generalized HIV epidemics, randomized controlled trials of HIV vaccines, suppressive therapy for herpes simplex type 2, cervical diaphragms, and sexually transmitted infection control have not shown protective benefit. Behavioural interventions have demonstrated some success in reduction of risk behaviours but appear insufficient to eliminate HIV transmission. Male circumcision can reduce adult transmission by about 40% at the overall population level in generalized epidemic settings, but implementation of this surgical intervention is challenging. A recent Thai vaccine study encouragingly reports a modestly effective vaccine (31% reduction). There is increasing acknowledgment of the need to intensify prevention interventions for most at risk populations in generalized as well as concentrated epidemic settings, and to expand programmes for female sex workers and their clients, injecting drug users and men who have sex with men. A major barrier to efforts to expand treatment and prevention is that just over 40% of the 33 million living with HIV in low and middle income countries are aware of their HIV status.

Current prevention efforts may reduce new infections but are unlikely to rapidly reduce HIV incidence in settings with severe generalized HIV epidemics. Evaluation of the role of ART for HIV prevention has emerged as a key priority in these settings. Guidance already exists concerning use of antiretrovirals (ARVs) for post-exposure prophylaxis (PEP) and intense research is on-going on pre-exposure prophylaxis (PREP), with results from randomized controlled trials expected in the near to mid-term future. The greatest prevention impact, however, is likely to come from the effect of ART on suppressing viral load, and therefore infectiousness, of persons already infected with HIV.

In industrialized countries, mother-to-child transmission of HIV has almost been eliminated by universal voluntary HIV testing of mothers and preventing transmission through the use of anti-retroviral drugs, accompanied by elective caesarean section and the use of replacement infant feeding. There is observational evidence that ART may reduce sexual transmission of HIV, however current recommendations for the use of ART are aimed at reducing the risk of disease progression and death for the individual, and are not premised on rendering persons with HIV non infectious. Emerging data confirm that ART reduces transmission within discordant couples, but modelling suggests this is insufficient to dramatically reduce incidence. Although there is increasing emphasis on 'positive prevention' and provider-initiated HIV testing and counselling, there have been no large-scale studies of the effect of diagnosing all HIV-positive people early, and treating them immediately.

A recent paper by WHO scientists presented a theoretical mathematical model of the potential impact of universal voluntary HIV testing and counselling followed by immediate ART for all those with HIV, irrespective of clinical stage or CD4 count. The results of the modelling exercise suggested that in a generalized heterosexual epidemic of southern African severity, a 95% reduction of HIV incidence might be achievable within 10 years, and that this approach might



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be cost-saving in the medium term. Universal voluntary HIV testing and immediate ART, combined with current prevention approaches, could potentially offer a new strategy for controlling severe, generalized HIV epidemics.

Evaluation of the feasibility and acceptability of this modeled and of other approaches using HIV treatment for prevention needs to be undertaken. Specifically, further consultation is needed to guide ongoing and planned research efforts and to assess the feasibility, acceptability and to explore human rights and ethical considerations. WHO will therefore convene a meeting of researchers, clinicians, prevention experts, social and biomedical scientists, human right specialists and ethicists, government officials, modellers, donors and community representatives, including people living with HIV, to discuss the modelled approach and the optimal use of ART for HIV prevention.

Purpose

A two and a half day meeting to explore the feasibility, acceptability, implications and research needs related to the use of ART for HIV prevention, including the modelled approach.

Specific objectives

1. To review scientific data and experience on use of ART for prevention of HIV transmission.
2. To explore individual, community, human rights, ethical and public health implications.
3. To explore operational elements.
4. To clarify the research agenda required to examine the potential impact of a variety of approaches on use of ART to prevent HIV transmission.
5. To explore the role of key stakeholders including WHO.

Expected Outcomes

1. Key experience and scientific evidence relevant to ART and its impact on HIV transmission reviewed.
2. Issues around individual, community, human rights, ethical and public health implications identified
3. Operational implications identified.
4. Research agenda to evaluate ART for prevention and other HIV treatment approaches to reduce HIV transmission defined.
5. Roles of stakeholders including WHO, in the evolving agenda on ART for prevention identified