
WHO/UNAIDS CONSULTATION ON THE ETHICS OF PREP AND EARLY INITIATION OF ART FOR PREVENTION: HOW SHOULD COUNTRIES REACH A DECISION?

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EXECUTIVE SUMMARY

Two new HIV prevention strategies based on ARVs are being considered in the development of comprehensive guidance on the strategic use of ARVs for the treatment and prevention of HIV and AIDS. The first consists of pre-exposure prophylaxis (PrEP), or the use of ARVs by high-risk HIV-uninfected people to avoid the acquisition of HIV infection. The second entails the early initiation of ARVs in individuals with HIV infection, at an earlier time than recommended for treatment purposes, in order to decrease transmission to uninfected sexual partners. The use of ARVs for HIV prevention offers the opportunity to diversify the prevention basket, respond to specific needs, and bolster combination prevention approaches. ARV-based prevention also offers opportunities to bridge prevention and treatment, and to reinvigorate efforts to redress current programme insufficiencies and widespread inequities, and to have a significant impact on population health.

Countries face a number of complex ethical issues in making strategic allocations of financial and programmatic resources for HIV prevention and treatment. Overall resources will need to be ramped up in countries to achieve the ambitious goals set out in the 2006 Political Declaration of Commitment on HIV/AIDS and the 2011 High Level Meeting on HIV/AIDS. In the meantime, priority setting is inevitable in most settings, and should be conducted in ways that will reduce inequities and maximize health benefits for the whole population. The failure to devise a rational and transparent plan could result in inequitable distribution of resources, including money, services and medicines, as otherwise allocations are likely to be driven by subjective or arbitrary criteria to determine who gains access to care. This approach may lead to outright discrimination against vulnerable groups, which tend to be most at risk and affected by HIV.

Research findings and the patchwork of experiences gained to date on the ground suggest that the expected benefits of ARV-based prevention will be highly context-specific. Decisions about the introduction and implementation of ARV-prevention need to be made firmly at the country level, based on a careful assessment of local epidemiological, social, economic and political conditions. Policy choices at country level should be guided by explicit ethical principles and human rights considerations. Human rights obligations require the scaling up of both treatment and prevention interventions to those in need, in a reasonable, fair, and incrementally sustainable manner. Ethical principles can support the fair identification of those who are in urgent need of novel HIV prevention interventions and the strategic allocation of programme resources.

There are no simple solutions, however, as ethical principles can conflict and there is no agreement on which ethical principles should take precedence to inform policy under such circumstances. Depending on local realities, different countries might take different approaches in weighing competing concerns and might reach different conclusions. It is therefore important that policy decisions on ARV-based prevention are made through a fair and transparent process. The process should be inclusive with broad stakeholder involvement, and convincing mechanisms to ensure that the voices of affected communities are heard, including most at risk populations, and people living with HIV. Genuine efforts should be made to build trust and seek common ground among stakeholders.

Making progress requires more attention to address the social and policy barriers related to HIV and to promote non-discriminatory access to services. This however requires capacity building and support, particularly for the meaningful participation of civil society, which is usually insufficiently resourced.

KEY MESSAGES

1. Countries must work towards the progressive realization of their High Level Meeting commitments with regard to scaling up ART, intensifying HIV prevention and eliminating stigma and discrimination. Treatment scale-up toward universal access should continue concurrent to the engagement of stakeholders to fairly identify marginalised and high risk populations who are in urgent need of novel HIV prevention interventions.
2. The strategic use of ARVs for prevention purposes in both HIV-positive and HIV-negative persons offers unique opportunities to revitalize prevention and improve the impact of ARVs on population health, through expanding prevention options, especially for certain vulnerable and marginalized groups with specific needs, and to strengthen combination prevention approaches.
3. Decisions about when and how to implement ARV-based prevention interventions need to be addressed in a manner that meets ethical principles and human rights considerations, both in substance and in process, along with technical and programmatic considerations.
4. The selection of policy options and the strategic allocation of resources for ARV-based interventions for treatment and prevention should be done at the national and local levels, through a fair and transparent process, with the full engagement of relevant stakeholders, including people living with HIV and groups most likely to be vulnerable to and exposed to HIV. There are no simple answers, and different countries will make different decisions based on their own context.
5. Tools and resources should be made available by international organizations and development partners to facilitate and support the process of decision-making and build the capacity of all those involved.

ACRONYMS AND ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
HIV	human immunodeficiency virus
ICESCR	International Covenant on Economic, Social and Cultural Rights
PrEP	pre-exposure prophylaxis
TasP	treatment as prevention
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

1. INTRODUCTION

Recent trials demonstrate that the antiretroviral (ARV) drugs currently used to treat people living with HIV can also serve for prevention purposes. Two new HIV prevention strategies based on ARVs are now under consideration. The first consists of pre-exposure prophylaxis (PrEP), or the use of ARVs by high-risk HIV-uninfected people to avoid the *acquisition* of HIV infection. The second entails the early initiation of ARVs in individuals with HIV infection, at an earlier time than recommended for treatment purposes, in order to decrease *transmission* to uninfected sexual partners.

Recent advances in our scientific understanding of how ARV drugs work and what they can do have delivered exciting new HIV prevention options and altered the landscape of policy discussions about the control of the pandemic. This is very good news, but raises some hard questions. In addition to implementation and cost issues, a number of ethical considerations need to be addressed. For example, how can countries balance the public health objective to prevent the most overall deaths from HIV and AIDS, and the ethical principles and human rights obligations to provide treatment for those who might die without it? On what grounds could ARVs for prevention be offered to some people and not to others? National AIDS programs and the global community need to address these questions in settings that differ significantly in terms of HIV incidence and prevalence, populations most affected, prevention and treatment achievements, and financial and health systems resource constraints, as well as social, political and legal structures. In addition to the individual and family benefits of avoiding new HIV infections and AIDS related deaths, all people benefit from low HIV rates in their society, and in the world, so we also have a collective interest in trying to achieve and maintain an AIDS-free generation.

2. SCOPE AND OBJECTIVES OF THE MEETING

This meeting was held as part of a larger body of work led by WHO on the strategic use of ARVs for the treatment and prevention of HIV and AIDS. The meeting agenda and list of participants are provided in Attachments 1 and 2. A number of scientists, ethicists, human rights advocates, representatives of communities of people living with HIV, policy-makers and program implementers came together to consider the ethical dimensions of the use of ARVs for HIV prevention, specifically pre-exposure prophylaxis and early initiation of antiretroviral treatment (ART) for prevention purposes. Participants were asked to connect established ethical principles with the diverse practical challenges and experiences that countries bring to their consideration of whether and how to incorporate the use of ARVs in their prevention priorities. The specific

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