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

10-11 October 2012  
Geneva, Switzerland

WHO Library Cataloguing-in-Publication Data

WHO/UNAIDS consultation on the ethics of PrEP and early initiation of ART for prevention.  
How should countries reach a decision?

I. World Health Organization.

ISBN 978 92 4 150718 9

Subject headings are available from WHO institutional repository

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## ACKNOWLEDGEMENTS

This report was facilitated by the excellent quality of the presentations made by the speakers at this meeting. Isabelle de Zoysa captured the essence of these presentations and the discussion they stimulated in this report. Other participants at the meeting commented extensively on earlier drafts and helped refine the text and the thinking it presented. This meeting was organized by Barbara de Zalduando of the Office of the Deputy Director, UNAIDS, Andreas Reis of the Department of Ethics, Equity, Trade and Human Rights and by Kevin O'Reilly, Yves Souteyrand and Florence Koechlin McGillivray of the HIV Department at the World Health Organization. Generous funding was provided by the Bill and Melinda Gates Foundation. .

## 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 objectives of the meeting were to lay out the principles and processes that countries can use to make policy choices about the use of ARVs for HIV prevention that are both fair and sustainable in their own particular context.

This report summarizes the group's deliberations and recommendations. It is intended to clarify ethical issues related to the strategic use of new ARV-based prevention interventions and lay the foundations for a country-owned approach to setting priorities. It will also contribute to the development of comprehensive guidance on the clinical, operational and programmatic aspects related to the use of ARVs for the treatment and prevention of HIV and AIDS.

### 3. ARV-BASED PREVENTION AS PART OF COMBINATION PREVENTION

Current knowledge and experience in the use of ARV-based prevention options is evolving rapidly. WHO has now issued recommendations on the use of pre-exposure oral prophylaxis of HIV for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV in the context of demonstration projects (WHO, 2012b). These projects are intended to shed light on a number of context-specific implementation issues, including how to provide safe and effective delivery of pre-exposure prophylaxis to key populations, and how to support adherence and minimize the risk of drug resistance.

At the same time, the discovery that antiretroviral therapy (ART) can radically reduce the risk of HIV transmission from infected to uninfected sexual partners has led to a reconsideration of the question of when to begin treatment. Early initiation of ARVs for prevention, sometimes known as Treatment as Prevention or TasP, would warrant commencing such treatment sooner than might be indicated given the clinical status of the HIV positive individual. The clinical benefits of early initiation of treatment are not yet clearly demonstrated, and the growing body of evidence and experience on this matter is currently under review. However, given the large impact of such early treatment on transmission within serodiscordant couples, WHO has recently published guidelines recommending that HIV-positive partners with a CD4 count >350 in serodiscordant couples should be offered ART to reduce HIV transmission to uninfected partners (WHO, 2012a). Furthermore, people with HIV in serodiscordant couples and who are started on ART for their own health should be advised that treatment is also recommended to reduce HIV transmission to uninfected partners.

There is wide agreement that the strategic use of ARVs for prevention purposes offers unique opportunities to revitalize HIV prevention. Reaching out to populations in need with an expanded menu of prevention options should result in higher prevention coverage and improved programme effectiveness. ARV-based prevention also offers opportunities to bridge prevention and treatment, through careful targeting and planned transitions between various uses of ARVs. For example, modelling of intervention modalities in serodiscordant couples suggests that specific sequencing patterns of pre-exposure prophylaxis of the uninfected partner followed by early use of ARVs by the infected partner will maximise prevention benefits, with a later transition to ART for the infected partner. There are no universal solutions, however, and countries should decide what modalities work best in their particular circumstances, taking into account a range of technical, programmatic and ethical issues.

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. It is therefore up to national policymakers to make challenging decisions about what HIV treatment and prevention strategies to adopt and prioritise, how to do so, and when to do so, based on their local context and after careful analysis of their epidemic and identification of people most at risk, and after taking stock of current programme limitations, such as low levels of knowledge of serostatus, poor coverage with various prevention and treatment interventions, and high levels of stigma and discrimination.

## 4. COUNTRY EXPERIENCES

A number of participants commented on their own country or region's experiences. They described a huge range of possible trajectories for the introduction and implementation of ARV-based prevention, and underlined that decisions can only be made at country level, taking into account local realities and contexts.

Epidemiological patterns of infection and disease vary enormously, and different population groups are affected, both between and within countries. In general, high levels of HIV transmission continue to be found among key populations, including sex workers, men who have sex with men and transgender women, and people who inject drugs. These groups face high levels of stigma and discrimination, including within the health services, and remain poorly covered with HIV prevention and treatment services. In some countries with generalized epidemics, such as Nigeria and Uganda, policy-makers have identified the need for specific strategies to reduce transmission among partners in stable relationships who, until recently, were labelled "low risk." In other countries, such as South Africa, there is concern about high incidence rates among adolescent girls, and the many legal, social and programmatic challenges in reaching them.

Countries continue to struggle with programme deficiencies, including low coverage of HIV testing and counselling services and low rates of disclosure to partners, so most people do not know whether they, or their partners, are infected or not. Thus, ART tends to be provided to people when they present with advanced disease. Some country representatives mentioned the overarching need to scale up ART and work to improve quality of care, including support for ART adherence, which should also bring in prevention benefits. At the same time, established high impact HIV prevention interventions are still not reaching those most at risk. Representatives from Eastern Europe, South Asia and Latin America highlighted significant policy challenges in taking key interventions to scale (such as opiate substitution treatment for people who inject drugs, and comprehensive HIV prevention services for sex workers and men who have sex with men).

Countries have signed on to ambitious HIV prevention and treatment goals but struggle to make progress with limited and unpredictable resources, often linked to donor priorities. In the short-term, difficult trade-offs between programme areas will be made. Concerns about shrinking resources over time make politicians and policy makers nervous about taking on new strategies, yet they recognize that significant "game changers" are required for success.

Initial consultations in countries around possible demonstration projects for pre-exposure prophylaxis and early initiation of ARVs for prevention have elicited genuine interest, but also highlighted widespread concerns and many misconceptions among different constituencies. A common difficulty is identifying how biomedical HIV prevention measures might interact with other prevention approaches. Anxiety persists in many circles over issues of demand for and adherence to early initiation of ARVs (given that the motivation is altruistic, to prevent on-going transmission to others). Both strategies elicit concerns about possible risk compensation and potential message confusion or distraction from behavioural risk reduction including condom use. In some settings, there is resistance to what is perceived as the medicalization of prevention, especially where the supply of affordable medicines is already a challenge, and has even at times fuelled suspicions that pharmaceutical companies may promote ARV-based prevention for

business reasons.

Nonetheless, the added value of such interventions in specific circumstances was emphasized by participants, for example in sex work settings (especially for female sex workers who remain at a disadvantage in negotiating condom use with their clients), or in societies that value fertility (for seronegative women who seek pregnancy). Communities of women and people living with HIV also welcome the fact that pre-exposure prophylaxis addresses the need for a female-controlled preventive measure that can be used without a male partner's consent. Women tend to have insufficient power to negotiate safe sex, and in high prevalence settings are exposed to high risks of HIV. Some community groups see PrEP as an opportunity to take charge of themselves in terms of prevention. They also recognize that more effective prevention strategies will decrease the number of new people needing ART, and thus possible competition for treatment. Another circumstance where providing ARVs for prevention was seen to have special merit is post-trial provision of ARVs for pre-exposure prophylaxis clinical trial participants and in the communities and countries that hosted these trials.

It is clear that resource allocation for HIV prevention and HIV treatment will have to be ramped up in nearly all 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 (UNAIDS, 2012). 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, resulting in "implicit rationing" (Bennett and Chanfreau, 2005). This approach may lead to outright discrimination against vulnerable groups, which tend to be most at risk and affected by HIV. Thus, since there is no universal solution to the best use of ARVs for prevention, the challenge is to support countries to reach the best decisions for their populations through a fair and transparent process.

## 5. ETHICAL PRINCIPLES AND HUMAN RIGHTS CONSIDERATIONS

Participants reviewed the values, ethical principles and human rights obligations that should be considered and brought into balance in the process of priority setting and use of ARVs for prevention and treatment. They took note of earlier guidance on ethics and equitable access to ART (WHO, 2004), and considered how ethical and human rights considerations might play out in decision-making about ART-based prevention.

### 5.1 Ethical principles

The leading ethical principles that could be applied to the use of ARVs for prevention or treatment considerations were discussed as follows.

The most widely used principle in formulating health policy is one of **utility**. This principle is open to different interpretations, but the key is its focus on determining the best balance of beneficial over harmful outcomes. Its proper use requires the specification of consequences that are considered significant (e.g., preventing new infections, preventing deaths, or preventing suffering). This in turn will depend upon access to relevant data about the population/s in question, including their ARV needs, predictions about the future nature of HIV in that population, and an assessment of the efficiency or cost-effectiveness of various policy options.

Different results will emerge depending on salient goals, the data that are available and used, and implementation circumstances (Sinnott-Armstrong 2012). In thinking about utility, there are significant choices to be made about what shall be considered relevant. For example, if the focus is on clinical impact, the application of utility may give priority to treating those who are already HIV positive. It might also result in the exclusion of candidates who are not expected to adhere to or be retained in treatment, or candidates with very advanced HIV disease who may not respond so well to treatment. In a public health context, utility considerations might provide reason to give priority to prevention, with the aim of having the greatest overall impact upon a population by seeking to prevent the largest number of new infections and thereby saving more lives in the longer-term. It might also support prioritising HIV prevention services for those groups most at risk of HIV, if this would result in the greatest benefit to the whole population in terms of reduction in new infections.

In practice, utility will tend to support using whatever mix of ARV-based interventions for treatment and prevention will produce the greatest balance of health benefits over harms. However, a focus on utility can be indifferent to fair distribution within the population, and may even lead to injustice, by, for example, leaving out the hard-to-reach. Some have argued that other principles are needed to ‘temper’ the utility goal (Macklin & Cowan 2012). However, defenders of utility point out that the theory is quite robust and open to many modifications to include other important considerations (Sinnott-Armstrong 2012).

**Equity** requires ensuring a fair distribution of health benefits among people with different degrees of need, with the aim of securing equal choices, chances or outcomes for all. The goal is to reduce unfair disparities in health status among different groups. It is generally agreed that all medically eligible people should have a fair chance of accessing ART, on equity grounds, although this is difficult to achieve in the context of limited resources. The required efforts to

facilitate access to ART for people who are not currently reached by health services, including poor or rural or excluded populations, are often neglected, though not always with an explicit reasoning.

One problem is that it is not always clear what it is that needs to be equalized. Different results may arise depending on whether the focus is on resources for health, access to health services or health status. For example one focus concerns the fair distribution of health resources across the population, while a focus on equitable health outcomes would draw increased attention to reducing HIV risk among key populations and enhancing health services for those with other conditions (such as tuberculosis or drug dependency). A focus on equitable outcomes might in fact require spending more resources on hard-to-reach populations.

In general, the equity principle will mandate due consideration of vulnerable individuals and groups, which include uninfected partners in serodiscordant couples, most at risk populations, and vulnerable or least advantaged people such as people in poverty, undocumented migrants and those engaged in illegal activities.

Other principles, including urgent need, the rule of rescue, and prioritarianism, may be needed to “temper” the utility principle (Macklin & Cowen, 2012). **Urgent need** suggests that, where life-saving responses are available, priority ought to be given to treatment services for those who are sick and debilitated, and in imminent risk of death. This implies that sick people have a greater priority for services than healthy individuals, even those at high risk. This definition of “urgent need” runs the risk of prioritising those individuals who are known to be eligible for treatment today over those who are likely to acquire HIV and require treatment in the future. The urgent need principle can also be used to argue that health services should prioritize those at highest risk over those at lower risk. For example, the principle has been used to draw attention to the perilous situation that is faced by uninfected partners in serodiscordant couples. This principle justifies concern over the frequent observation that high-risk populations remain under-served, or even excluded from the prevention and treatment services that they need. Finally, risk remains a more abstract concept than severity of disease and there always will be difficulty in addressing equally urgent needs that give rise to equal moral claims.

Somewhat related to the ethical principle of urgent need is the **rule of rescue**, which refers to the ethical imperative to save individual lives in acute danger, even when resources might be more efficiently spent to prevent deaths in the larger population. This principle mandates immediate ART for those who are very sick who would otherwise die (Macklin and Cowan, 2012). It is in direct conflict with the interpretation of utility that mandates saving the most lives, which may well be through focusing treatment services on those who are likely to respond best, or through averting future HIV infections. The rule of rescue principle is often cited in emergency settings, such as helicopter rescues of lone mountaineers. There is some disagreement whether it should be a guiding principle for priority setting at a public health level.

**Prioritarianism** gives preference to the worst off or the least advantaged. The interpretation of this principle in the context of HIV/AIDS varies. It may be applied to people defined as worst off in terms of health status, or socio-economic status, or access to health services, and these three dimensions often do not coincide. This principle may be linked to the principle of equity, as those who are economically disadvantaged or socially excluded are often vulnerable and may be at increased risk of HIV, yet underserved. The prioritarian principle is problematic for guiding allocations to HIV treatment and prevention. Both those in need of ART and those at high risk of

acquiring HIV who would benefit most from prevention can be considered to be “worst off” in their respective categories of people with HIV infection and people free of HIV.

Other important considerations are what we might call collective moral values, that are often at the core of public health ethics, and which complement the focus of bioethics on individuals. For example, it can be argued that public health involves **common goods and values** such as **fairness** and **solidarity** (Dawson 2011a). For example, we each have a joint interest in trying to keep infectious disease as low as possible in our communities. Rights-based policies that enhance prevention, particularly at the population level, contribute to the common good of a low HIV prevalence in that particular community (Dawson 2011b).

Similarly, values such as solidarity might provide the grounds for prioritizing allocation of resources to PrEP and other prevention strategies. Solidarity may manifest as a shared strategy to combat a threat of harm, or as a function of the values, meanings and identities that a community shares (Dawson and Verweij 2012). The principle of solidarity helps explain why HIV has so often been deemed more than an individual risk, but rather, something that affects a community, and which therefore catalyses a collective response.

## 5.2 Human rights considerations

Human rights considerations are grounded in the kinds of values and ethical principles described above. Furthermore, human rights are entitlements defined in international law and provide a legal framework to determine the obligations of states, and mechanisms to hold them accountable for progress. This is important, in view of weak governance structures in many settings and the common failure of governments to take significant decisions that are satisfactory both with regard to content and process.

The majority of states recognize minimum core obligations, defined under the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1976). These require the provision of both treatment and prevention interventions to those in urgent need thereof, in a reasonable, fair, and incrementally sustainable manner.

In practice, it is often challenging to determine whether or not these minimum core obligations have been met, as there are no agreed standards. However, stubborn or rising HIV prevalence in many settings suggest that inadequate HIV policies are in place, and therefore that a country is not meeting its minimum core obligations in relation to HIV programme implementation. As inadequate policies do not meet the standard of reasonableness, they require revision.

An important feature of human rights law is the concept of progressive realization. This recognizes that resource limitations may impede the full realization of all rights in the immediate future. Each state party is nevertheless obliged to take the necessary steps, including the adoption of legislative measures, to the maximum of its available resources, to work towards targets in an incremental and sustainable way, so that the right can be realized over time.

Using the above principles as guidance, a government’s minimum core obligation in relation to managing HIV includes both the provision of treatment and prevention interventions. This means that in high HIV-burden settings where programmatic treatment rollout has commenced, progressive incremental treatment scale-up toward universal access should continue concurrent to focused effort to fairly identify and provide for marginalised and high-risk populations who are in

urgent need of novel HIV prevention interventions.

Human rights considerations also draw attention to the importance of dignity and of placing equal value on all individuals, so that none can be considered underserving or be disregarded on social, moral, legal or economic grounds. These considerations point to the legal obligations of governments and also constitute entitlements, which individuals and groups can claim through legal procedures. The pressure on governments to meet their obligations and address entitlements can serve as a source of activism and a stimulus to the empowerment of underprivileged groups and participation of civil society more broadly. The focus is both on outcomes and processes towards outcomes, which must be non-discriminatory, participatory, inclusive and consensual and address the needs of the most marginalized. This however requires capacity building and support, particularly for the meaningful participation of civil society, which is usually insufficiently resourced.

### 5.3 Balancing key principles

Ethical principles can provide justification for choosing one or another scheme for the fair allocation of limited resources to implement ARV-based prevention and treatment services. However, ethical principles can conflict requiring balancing of competing concerns. In particular, the two main goals sought in public health -- health maximisation and equity -- can be in direct conflict. While there is broad agreement among ethicists on leading ethical principles, no consensus exists on which ethical principle should take precedence over another, or how different principles ought to be weighted. Thus it is crucial to have a fair process for decision-making in place (see section 6) to debate and decide these issues at country level.

Progressive realization of health goals should respect the ethical principles of health benefit maximization and fairness in the distribution of health benefits from treatment and prevention. All intervention programmes should respect the principles of patient autonomy, non-discrimination and protection of marginalized groups, who suffer compounding disadvantages. Special attention must also be paid to gender issues and to ensuring that choices made do not exacerbate existing gender inequities magnified by HIV/AIDS.

Some policies may have different distributional impact for different groups, and principles of distributive justice are needed to assess such policies. An example was presented at the meeting, comparing a policy for ART provision that could lead to many lives or healthy life years saved now for persons at high mortality risk, and another policy for ARV-based prevention that could save more future lives or healthy life-years for groups at lower mortality risk. If distributional impact is assessed according to individual expected risk (so called ex-ante egalitarianism), the first policy that saves many lives now for those at highest risk will be judged as most fair. If distributional impact is assessed according to actual outcomes (so called ex-post egalitarianism), the policy that saves most lives over all will be judged as the most fair. In the latter case, both the principle of health benefit maximization and the equity principle stipulating fair distribution of health benefits are satisfied. This example highlights the importance of clarifying core values and agreeing on key objectives to be achieved, including their time frame.

## 6. THE PROCESS TO INFORM DECISION-MAKING

While the principles may be clear, there are no simple answers to the ethical and human rights challenges of decision-making regarding pre-exposure prophylaxis and the early initiation of ARVs for prevention. People may differ in their interpretation of the scientific evidence at hand, given its rapidly evolving nature and the importance of context, and there is no universal formula on which ethical principle should take precedence to inform policy under such circumstances. Depending on the social, economic and epidemiological context and local setting, countries might reach different conclusions. It is therefore important that national strategic resource allocation decisions for ARV-based prevention are made through an inclusive process that is transparent, evidence-informed, and seen and accepted as legitimate by the public.

**BOX: Features of fair process** (Daniels, 2005)

- **Publicity** (the process must be transparent and the rationale for priority setting decisions must be publicly available)
- **Relevance** (the stakeholders affected by these decisions must agree that the rationale rests on reasons, principles, and evidence that the view as relevant)
- **Revisability and appeals** (there must be an avenue for revisiting and revising decisions in the light of new evidence and arguments and there is a process to protect individuals who have legitimate reasons for being an exception to policies adopted)
- **Enforcement** (there must be some means, either voluntary or regulatory, of ensuring that the first three conditions are met).

Participants emphasized the importance of a sound, country-based procedural approach that meets the conditions identified by Daniels (2005). These key conditions were included in recommendations for a fair process to distribute ART services in the 3 by 5 initiative (WHO, UNAIDS, 2004) and remain relevant for decision-making in relation to ARV-based prevention. In practice, strategic decisions should be justified with reference to key ethical principles, evidence about people at risk, evidence about the effectiveness and cost-effectiveness of implementation approaches, and evidence about their distributional impact. 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. Decisions once made should be open to review in the light of evolving evidence, the experience of implementation, and legitimate requests to revisit the appropriate balance of principles. Such a process should be transparent and the result made public.

These conditions require investment of time and resources, and they may be difficult to meet in all settings. Government officials have primary responsibility to facilitate consultative processes and should be held accountable for results. However, governance structures are not strong in all settings, and transparency and accountability may be difficult to secure. Furthermore, the implementation of fair process procedures does not guarantee that fair solutions will be identified and adopted. Nevertheless, where fair process can be incorporated in the decision-making, it will add legitimacy to decisions that could otherwise be challenged as unfair.

## 7. PRACTICAL APPLICATIONS

Meeting participants then considered how countries might handle international recommendations on early initiation of ARVs for people with HIV infection or pre-exposure prophylaxis in specific circumstances, which will be issued in the future. This led to a more in-depth discussion of the ethical considerations that might influence the decision making process, the consultative processes that could be put into place, and how discussions would take into account the epidemiological, social, economic and political environment.

### 7.1 Science-based decision-making

An important first step is to bring together the evidence required to inform the discussions, as good ethics rest on good science and evidence. The participants pointed out the pitfalls of policy-making that is insufficiently science-based and becomes vulnerable to pressure from public opinion, powerful politicians or donors. For example, the utilitarian premise that prevention strategies should reflect epidemiological patterns and should focus on populations at higher risk of HIV is largely disregarded in many settings. In addition, available evidence on the potential impact and cost-effectiveness of different prevention strategies needs to be mustered. Ideally, analyses will be conducted using local data to better understand the implications of various policy choices and implementation scenarios. These should consider relevant factors, such as access to, and coverage with key interventions in different populations. The use of data that is made publicly available provides the necessary basis for shared knowledge on which to ground discussions, and makes space to adapt international guidelines in line with country needs and realities. It also allows biases to be challenged. For example, presumed adherence levels should not be a criterion for prioritizing people for ARV-based services, as presumptions may be incorrect, and could amount to unfair discrimination against persons whose needs may be greatest (such as the poor, mobile populations, or people who inject drugs). A more appropriate response would be provisions to support improved adherence among those who face difficulties in accessing services, or who suffer other conditions.

### 7.2 Overarching principles

Those responsible for making decisions should of course weigh technical information, but also take into consideration all ethical principles and ensure that human rights provisions are respected, promoted and fulfilled. The principles of utility (effectiveness and cost-effectiveness) must therefore be reconciled with considerations of equity, urgent need, and common good. At times, these principles align. For example, sex workers are at high risk of acquiring or transmitting HIV, and the utilitarian principle would therefore support specific ARV-based prevention services in sex work settings. As sex workers are also marginalized and subject to discrimination and violence, equity and urgent need principles would also apply. When sex workers are supported to avert new infections this benefits their clients, their clients other partners, and the community at large. Often, however, it is necessary to balance divergent interests and concerns.

Ethical considerations do not only apply in relation to the development of broad strategies, but also in relation to how the strategies are applied. The provision of services has to respect human rights and principles of medical ethics. So for example it is necessary that the intended

beneficiaries be provided the information they need to take decisions, and the option to decline services, including HIV testing and ARV treatment or prophylaxis. The necessary measures also must be taken to protect their confidentiality and to ensure that health services and health providers do not discriminate, for example on the basis of sexual orientation or social group or profession. Guidelines on complex issues, such as partner counselling, should be followed.

### 7.3 Fair process

The discussion about fair processes highlighted that various approaches are possible depending on local context. For example, discussions about policy shifts may take place as part of regular strategic planning, including the mobilisation of well-established country-level consultative processes. In some large countries such planning may be decentralized to provincial or local levels. Similarly, there are no blueprints in terms of the stakeholders to be included. An important rule is to ensure that the key populations that are most affected by the issue to be debated are represented at the table. For example, people living with HIV, sex work organizations, women's groups, and people who use drugs, need to be fully engaged in discussions about pre-exposure prophylaxis, which could be implemented in sex work or drug use settings or offered to discordant couples. This, however, requires that sufficient resources are set aside to support meaningful consultations within sex work, drug use, and women's networks.

Participants identified a number of useful resources to guide the consultation process at county level. In particular, they recommended the use of the "3AQ framework" (availability, acceptability, affordability, quality) for assessing whether the right to health is being met (Gruskin & Tarantola, 2008). They also reviewed experience in other domains with the use of a checklist of questions to guide the assessment of the impact of various policies on equity considerations (Norheim, personal communication). They also considered the materials prepared on "good participatory practice" in biomedical HIV prevention trials (UNAIDS, AVAC, 2011).

### 7.4 The importance of the regulatory and legal environment

HIV programmes are often implemented in difficult political contexts, in which stigma and discrimination against key populations are rife, and certain groups or behaviours are criminalized. It is important not to aggravate the vulnerability of most at risk groups through mishandling of data or insensitive labelling and targeting. This raises the importance of addressing factors that may constrain or support the participation of affected groups in the consultation process as well as their access to planned interventions. Making progress requires more attention to critical enablers (e.g., through the implementation of stigma reduction, law reform, community mobilization, legal services) in each national context in order to eliminate the social and policy barriers related to HIV and to promote non-discriminatory access to services. Also, the potential legal and policy barriers to reaching out to and engaging adolescents and children in specific programmes need to be carefully managed when planning new ARV-based HIV prevention strategies.

In general, affected groups should no longer be considered as passive recipients of services but instead as active participants in intervention design and implementation, signalling a major mind shift in many settings. Unfortunately, discussions about resourcing ARV-based prevention interventions tend to focus on the need to procure commodities and there is too little attention to the resources needed for supportive, protective, and enabling interventions.

## 7.5 Need for capacity-building

A final, but critical point concerns the need to actively build the knowledge and skills of those who will deliver the new ARV-based services for HIV prevention, and those who will take them up. Misinformation and misconceptions about early initiation of treatment, pre-exposure prophylaxis and ARVs for prevention abound. These may need to be dispelled before constructive discussions can be held on their potential contribution to combination HIV prevention. Ethics-, human rights- and legal-literacy also need to be strengthened, not only among representatives of civil society, but also among policy-makers and experts, health service providers, and among judges and law enforcement. Further training and support to programme managers and health providers are required on approaches to protect non-discrimination, informed consent, and confidentiality in the health services. Finally, the capacity of civil society to mobilize in solidarity with people most affected, and to build accountability mechanisms needs attention and investment, so that all parties are willing and able to measure and report inequity, discrimination and coercion.

## 8. CONCLUSIONS AND NEXT STEPS

HIV prevention is a dynamic and rapidly changing field. The development of novel ARV-prevention tools is timely as worldwide, over 2 million of people are still acquiring HIV every year. New ARV prevention tools offer the opportunity to diversify the prevention basket, respond to specific needs, and strengthen 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.

The information generated in this meeting will be incorporated within the WHO/UNAIDS guidance on the use of ARVs for both treatment and prevention, which is under development. Meeting participants recommended that WHO, UNAIDS and partners should consider developing practical tools that will support countries to take decisions that are ethically sound both in substance and process, within the context of demonstration projects or otherwise. For example, materials are needed that help to clarify goals and specify choices that need to be made and provide guidance on what evidence needs to be gathered, who participates in the analysis, what is made of the evidence and how uncertainties are handled. A checklist was called for that specifies priority-setting criteria and outlines questions to assist the evaluation of possible options according to these criteria, as a useful input to deliberations about fair and efficient priority setting.

Decisions about when and how to implement such tools need to be made firmly at the country level, and addressed in a manner that meets ethical principles and human rights considerations as well as the local social, economic and political context. There are no simple answers, and different countries will make different decisions based on their own context. It is hoped that the advice generated in the meeting will provide pointers for countries to build consensus around policy options that are suitable for their own settings.

## AGENDA

TIME	Topic	Chair/ Speakers
<b>10 October</b>		
9:00	<ul style="list-style-type: none"> <li>Welcome and introductions (15 min.)</li> <li>Context and objectives of the meeting (15 min.)</li> <li>Update on scientific basis (15 min.)</li> <li>Discussion (15 min.)</li> </ul>	<b>Chair:</b> Yves Souteyrand  Gottfried Hirnschall  Barbara de Zalduondo/ Andreas Reis  Kevin O'Reilly
10:00	Evolution of ethical debate in HIV over the last decade (15 min.) Discussion	Ruth Macklin
10:30	<b>Break</b>	
11:00	Panel discussion: Perspectives from the field <ul style="list-style-type: none"> <li>Nigeria</li> <li>Kenya</li> <li>India</li> <li>Community</li> <li>South Africa</li> <li>Peru</li> </ul> Discussion (30 min.)	<b>Chair:</b> Ron Bayer  John Idoko George Githuka Samarajit Jana Anna Zakowicz Fareed Abdullah Carlos Caceres
12:30	<b>Lunch</b>	
13:30	Update on cost-effectiveness and modelling studies of ARV-based prevention (15 min.) Discussion	<b>Chair:</b> Suzanne Leclerc- Madlala  Timothy Hallett
14:00	<ul style="list-style-type: none"> <li>Ethical concepts of priority setting of the use of ARVs (20 min.)                Discussion</li> <li>Equity and cost-effectiveness: key criteria (20 min.)                Discussion</li> </ul>	Angus Dawson  Ole Norheim
15:30	<b>Break</b>	
16:00		<b>Chair:</b> Gabriela Calazans

	<ul style="list-style-type: none"> <li>• Progressive realization and prioritization of ARVs (15 min.) Discussion</li> <li>• Fair process in decision-making (15 min.) Discussion</li> <li>• Community involvement in decision-making (15 min.) Discussion</li> <li>• Tying principles to practice</li> </ul>	<p>Jerome Singh</p> <p>Anant Bhan</p> <p>Johannes Mokgethi-Heath</p> <p>Joint comments : Mark Dybul &amp; Ron Bayer</p>
17:30	End of Day 1	
18:00	Reception	

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Meeting report  
10-11 October 2012  
Geneva, Switzerland

ISBN 978 92 4 150718 9



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