



GUIDANCE ON **ETHICS** AND **EQUITABLE** ACCESS TO **HIV TREATMENT** AND **CARE**

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ISBN 92 4 159258 3



Joint United Nations Programme on HIV/AIDS
UNAIDS
UNHCR • UNICEF • WFP • UNDP • UNFPA
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World Health Organization

2004

Guidance on ethics and equitable access to HIV treatment and care.

1.HIV infections-drug therapy 2.Anti-retroviral agents-supply and distribution
3.Ethics, Clinical 4.Patient rights 5.Social justice 6.Health services accessibility
- ethics 7.Guidelines I.World Health Organization e. II.Consultation on Ethics
and Equitable Access to Treatment and Care for HIV/AIDS (2004 : Geneva,
Switzerland).

ISBN 92 4 159258 3

(NLM classification: WC 503.7)

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Printed in Switzerland

ACKNOWLEDGEMENTS

The creation of the present guidance document would not have been possible without the participation of numerous experts.

The document grew out of a global consultation on Ethics and Equitable Access to Treatment and Care for HIV/AIDS held in Geneva on 26-27 January 2004, under the auspices of UNAIDS and three WHO departments: Ethics, Trade, Human Rights and Health Law; MDGs, Health and Development Policy; and HIV/AIDS. They are grateful to the following participants for their contributions at the meeting as well as their comments on drafts of the present document: **Antoine Augustin** (Haiti), **Godfrey Banyuy Tangwa** (Cameroon), **Dan W. Brock** (USA), **John Broome** (UK), **Edgar Carrasco** (Venezuela), **Alex Coutinho** (Uganda), **Norman Daniels** (USA), **Mandeep Dhaliwal** (United Kingdom), **Ndella Diakhate** (Senegal), **Virginie Ettiegne-Traoré** (Côte d'Ivoire), **Dirceu Greco** (Brazil), **Anand Grover** (India), **Safia Houmed Houssein** (Djibouti), **Keith Joseph** (USA), **Mohamed Ali Kamil** (Djibouti), **Julia Kemp** (Malawi), **Rene Loewenson** (Zimbabwe), **Ruth Macklin** (USA), **David McCoy** (South Africa), **Mitra Motamedi** (Islamic Republic of Iran), **Thabale Jack Ngulube** (Zambia), **Charles Ngwena** (South Africa), **El Khair Osman** (Sudan), **Praphan Phanuphak** (Thailand), **Igor Ptchelina** (Russian Federation), and **Ruotao Wang** (China). In addition to members of the WHO and UNAIDS Secretariats, a number of organizations were actively represented in the meeting, including **David James Alnwick** (UNICEF), **Marie-Claude Chartier** (ILO), **Janet Fleischman** (UNAIDS Global Coalition on Women and AIDS), **Sofia Gruskin** (UNAIDS Global Reference Group on HIV/AIDS and Human Rights), **Srdan Matic** (WHO/EURO), **Lisa Oldring** (OHCHR), and **Elhadj Sy** (Global Fund). As rapporteur, **Susan Timberlake** not only prepared the meeting report but also contributed to the initial drafting of this document, as did Mandeep Dhaliwal, who served as one of the co-chairs for the consultation.

Preparation of the document rested with an interdepartmental team, led by the Department of Ethics, Trade, Human Rights and Health Law, with the UNAIDS Secretariat. The process was directed by **Alex Capron**, with principal responsibility resting on **Andreas Reis**, assisted by **Jason Sigurdson**. Other members of the writing team were **Julian Fleet**, **Claudia Garcia-Moreno**, **Ian Grubb**, **Sonali Johnson**, **Alaka Singh**, and **Yves Souteyrand**. The final document was strengthened by contributions and critiques from **Katherine Allen**, **Andrew Ball**, **Nikola Biller-Andorno**, **Samantha Bolton**, **Marie-Charlotte Bouésseau**, **Siobhan Crowley**, **Rebecca Feinberg**, **Sarah Galbraith**, **Charlie Gilks**, **Amine Kébé**, **Naisiadet Mason**, **Thierry Mertens**, **Helena Nygren-Krug**, **Carla Makhlof Obermeyer**, **Chen Reis**, **Françoise Renaud-Théry**, **Aaron Shakow**, **Marcus Stahlhofer**, **Richard Steen**, **Eugenio Villar**, **Marco Vitoria**, and **Peter Weis**. The patient assistance of **Anne Newson** and **Francine Renard**, as well as the editorial guidance of **Andrea Firley**, are gratefully acknowledged.

Drafts of the guidance document were sent for feedback to scores of institutional and organizational partners, including specialists in WHO regional and country offices and participants from UNAIDS. Drafts were also presented at numerous conferences and workshops on AIDS and equity, among others in Kinshasa, Durban, Bangkok, and Frankfurt. WHO and UNAIDS thank all those who provided written and oral comments and suggestions on the drafts, especially EQUINET, the German Technical Cooperation (GTZ), Human Rights Watch, the International Community of Women Living with HIV/AIDS, and Physicians for Human Rights.

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ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral (drug)
HIV	human immunodeficiency virus
IDU	injecting drug user
ILO	International Labour Organization
NGO	nongovernmental organization
OECD	Organization for Economic Cooperation and Development
OI	opportunistic infection
PMTCT	prevention of mother-to-child transmission
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VCT	voluntary counselling and testing
WHO	World Health Organization

EXECUTIVE SUMMARY

An estimated six million people living with HIV in developing countries are in need of antiretroviral therapy (ART). However, only 8% have access to such therapy. Even with increased efforts to scale up the care and treatment of people living with HIV, such as the 3 by 5 Initiative, not everyone in need can gain access to ART immediately. This situation requires difficult choices in priority-setting, poses serious ethical issues and imposes on governments the obligation to scale up programmes in ways that are ethically sound and as fair, beneficial and sustainable as possible. These approaches to scaling-up must respond to local needs, be locally legitimate and accord with human rights norms.

The number of patients who, according to WHO criteria, are in clinical need of ART and accompanying treatment greatly exceeds current resources and capacity in many countries. Additional criteria and procedures may be necessary in order to specify who should have priority in accessing the life-saving treatment. Decision-makers should establish clear policies on whether specific population groups should be prioritized, so as to avoid decision-making based on subjective or arbitrary criteria that may lead to discrimination. Special care has to be taken to ensure and monitor access for the most vulnerable, poor and marginalized populations and for women.

The principles of fair process, which should always guide decision-making, are especially important here because they can make decisions more broadly acceptable and legitimate even when people disagree about how to scale up ART programmes. The process of setting priorities and policies should be transparent and should include all stakeholders, especially people living with HIV. The rationales for the priorities should rest on relevant principles and evidence and should be made publicly available. The process should allow decisions to be revised in the light of new evidence and arguments, and should include an appeals procedure at appropriate levels of decision-making.

Recent advances in treatment technologies mean that ART can be provided successfully in settings where basic health services are weak. Special measures are necessary, however, to ensure that the scale-up of HIV/AIDS programmes strengthens primary care and health systems as a whole. Even modest charges for ART at the point of service can be an obstacle to equitable access. Decision-makers should carefully design policies that address financial and other barriers and secure access for the poor and marginalized while supporting essential health services.

The purpose of this document is to provide guidance for government officials, programme managers at various levels, community-based and nongovernmental organizations, groups of people living with HIV, international organizations, and donor agencies. For all, the central issue is how to achieve progressive realization of the human right to treatment in a manner that respects ethical principles both in substance and process and hence meets the legitimate expectations within each country and proves durable over time. This document is intended to raise awareness of the ethical issues and to help with the planning and implementation of the scale-up of ART and other HIV-related treatment and care programmes in an equitable fashion. It focuses on the issue of access to ART and leaves other ethical issues in providing care for people living with HIV/AIDS, such as informed consent, confidentiality, controlled clinical trials and trade barriers, to other guidance documents.

RECOMMENDATIONS

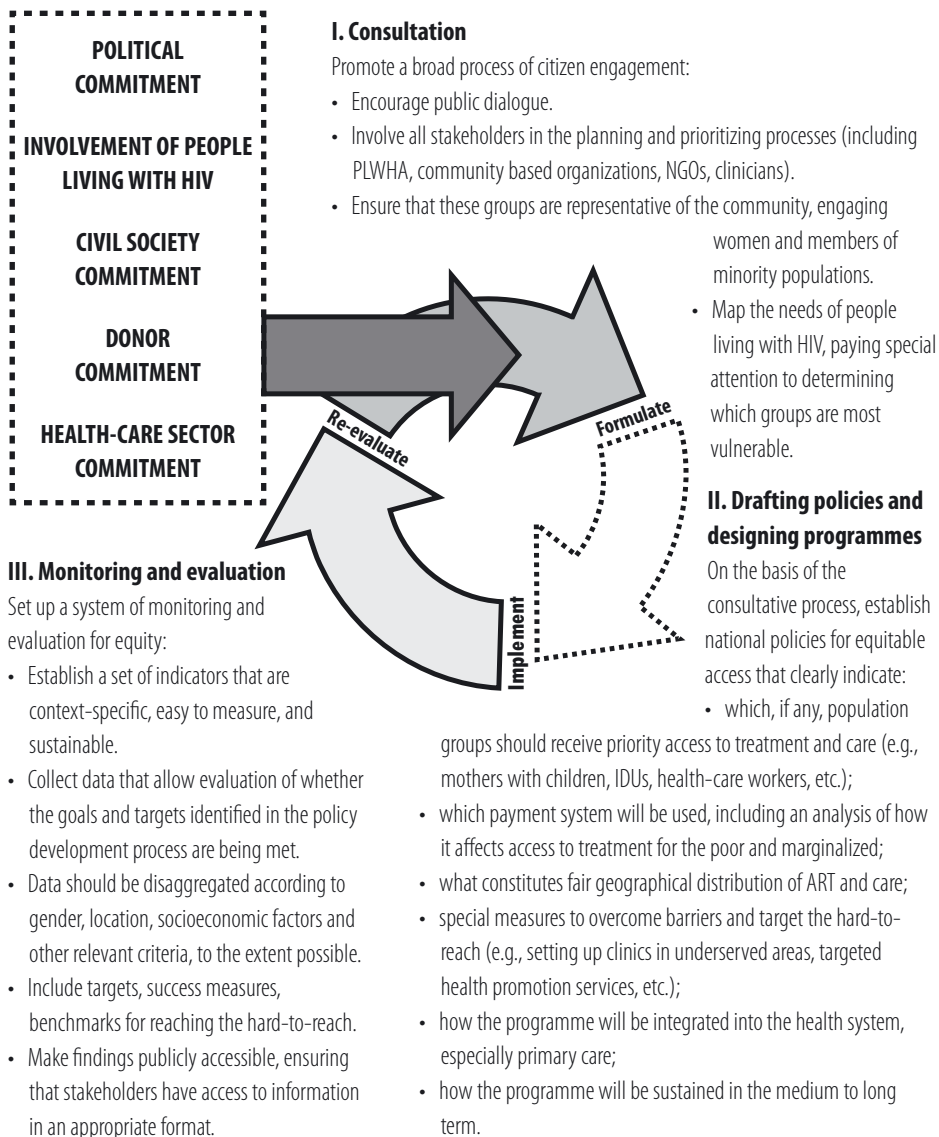
Equity—or fairness—in access to HIV treatment and care, as well as other health and social services, has long been a preoccupation of WHO and UNAIDS. In January 2004, WHO and UNAIDS convened a joint consultation on ethics and equitable access to treatment and care for HIV/AIDS, which provided valuable insights and advice for this guidance document. Because equity can sometimes appear to be an abstract concept, WHO and UNAIDS have identified a number of concrete measures that can be taken in countries and communities to promote fairness in scaling up HIV care, in particular antiretroviral treatment (ART) and related services.

WHO and UNAIDS recommend that national policy makers, programme managers, representatives of civil society, and other partners at national and local levels undertake **the following measures** to promote equity in the distribution of HIV care in resource-limited settings:

1. Mobilize without delay a wide range of partners to **scale up HIV treatment and care**. Scale-up is not only an urgent public health and development priority but also *an ethical and human rights imperative* within the framework of a comprehensive response to AIDS.
2. Establish a broadly representative **ethics advisory body** (including people living with HIV) linked to the national AIDS programme or council to plan, promote, and monitor equity in the scale-up and distribution of HIV treatment and care services. The membership of this advisory body, and in particular its leader, must be highly respected for qualities of fairness, openness, and both personal and professional integrity.
3. **Create opportunities for public dialogue on equitable access to HIV treatment and care**. These may include media events and communications, public hearings, and both national and community meetings appropriate to the circumstances. Such events should aim to allow a wide range of stakeholders to provide their views and expertise as well as to be involved in making plans and setting priorities for equitable scale-up of HIV treatment.
4. **Develop policies for scaling up HIV treatment that are firmly based in human rights and ethical principles**. A main role of the ethics advisory body is to ensure that policy makers and programme implementers balance efficiency and utility goals with due attention to equity. In the absence of clear policies, the risk is great that access to care for people living with HIV will be based on arbitrary criteria, and will disadvantage particular individuals, especially members of vulnerable populations, in violation of human rights norms.

5. **Identify vulnerable, marginalized, or other potentially underserved populations.** Depending upon the local context, these groups may include women, children, the poor, rural populations, sex workers, injecting drug users, men who have sex with men, refugees, and migrants.
6. Consider the need for **special policies and outreach programmes to prioritize these groups and to overcome barriers to their accessing care.** The rationale for such prioritization should be clearly stated and the measures for facilitating access for these groups should be indicated.
7. The ethics body should help to ensure that a **fair process** is established for setting priorities in the distribution of HIV treatment. This process should include the following central elements:
 - a **public mechanism** for setting priorities that is transparent, broadly inclusive of stakeholders, and whose principles, procedures, and priorities are widely publicized to stakeholders and the public at large;
 - **relevant reasons, principles, evidence, and information** that are widely viewed by stakeholders as appropriate and pertinent to fair decision-making about policies and priorities;
 - an **appeals mechanism** that permits the reconsideration and revision of decisions and priorities concerning the equitable scale-up of HIV treatment services;
 - an **enforcement mechanism** which uses consistent criteria to monitor scale-up and which enforces adherence to equity-related principles. This enforcement mechanism must ensure that the fair process is public and inclusive, has an appeals process, and has other elements or conditions that the ethics body may deem necessary.
8. **Define or adopt a set of five to seven measurable indicators** to monitor the fairness of HIV treatment scale-up at the national and community level. Current monitoring and evaluation systems should be adapted to collect relevant information. Such indicators should allow monitoring not only of the policies adopted but also the processes by which policies are designed and programmes are implemented. Monitoring of the general health care system will reveal the extent to which the scaling-up of HIV programmes has an impact on the health infrastructure, the migration of personnel, health care financing, and the delivery of health care generally. At least one or two indicators should ensure that access by vulnerable, marginalized, or other potentially underserved populations, including women, is monitored.
9. Responsible officials, including the ethics advisory body, should use **monitoring and evaluation data to ensure that HIV programmes are producing equitable results.** These data should also be publicly available so that all stakeholders can contribute to decisions regarding necessary adjustments in HIV policies and programmes.

The scaling-up of treatment programmes needs to start now, building on existing capacities in the health system. An ongoing policy-design and programme-evaluation mechanism should be included as part of the scaling-up effort. This process starts with broad political and social commitment to creating equitable access to treatment and care for people living with HIV/AIDS and engages the community in setting priorities and monitoring results to ensure that fair opportunity and equitable outcomes are being achieved.



Box 1: Steps to equitable access - the policy development cycle at a glance

1. INTRODUCTION

1.1 THE CHALLENGE

Some 40 million people are living with HIV and it is estimated that 6 million of them in developing countries are urgently in need of antiretroviral therapy (ART) in order to stay alive.¹ However, fewer than 8% of those who need antiretroviral drugs (ARVs) are receiving them. This dire lack of access to life-saving treatment has been declared a global health emergency by WHO and UNAIDS. WHO, UNAIDS, and many other partners are working to realize the target of providing ART for 3 million people living with HIV in developing countries by the end of 2005 (the 3 by 5 target).

Efforts to reach this target by the rapid scaling-up of ART provide hope that millions of lives will be saved in the coming years and that one of the greatest human tragedies of our time can be addressed. However, even if ART is delivered to 3 million people by 2005, only half the people in need of life-saving HIV/AIDS treatment and care will gain access to it by then. This target is only an urgent first step in efforts that must be sustained for the lifetime of the people receiving the treatment and for the duration of the epidemic—at least a matter of decades.

Where the need and demand for ART exceed the current ability to deliver it, some people will receive treatment and others will die. Such a situation poses serious ethical issues for governments, international agencies, nongovernmental organizations (NGOs), associations of people living with HIV, and health care institutions and workers. The most compelling of these issues involve choices that will affect the lives and deaths of millions. There are also serious ethical concerns about the potential diversion of resources from other health and social needs and about the possible effects of scaling up ART on fragile health systems, communities, and families. These circumstances impose powerful ethical obligations on all the actors involved to deliver treatment in ways that are as fair, beneficial, and sustainable as possible.

1.2 THE AIM OF THESE GUIDELINES

This document provides guidance on the ethical issues that arise in the scale-up of ART and other HIV-related treatment and care programmes. It aims to help the people concerned with planning and implementing these programmes to:

- a. have a frame of reference for public discussion of the programmes;
- b. design policies and programmes through a process that is fair to all;
- c. achieve results that are ethically sound and meet human rights obligations.

The goal is to create ART programmes that produce the greatest possible good and the least possible harm and that distribute benefits equitably.

This document is intended to be useful for government officials, programme administrators at the district and local levels, community-based organizations, NGOs, people living with HIV, international organizations, and donor agencies. It is not intended as a guide for bedside decision-making by individual clinicians but for people who set the policies and procedures that shape such decision-making. It reflects the current state of knowledge in a quickly evolving field. Because experience and information concerning the many implications of scaling up treatment and care for people living with HIV is limited, this document will be revised periodically in the light of emerging evidence. Feedback will therefore be very welcome. Further discussion of the ethical and operational issues arising from the scale-up of HIV treatment can be found in:

- ▶ *Consultation on equitable access to treatment and care for HIV/AIDS. Summary of issues and discussion.* Geneva: WHO/UNAIDS; 2004.
(<http://www.who.int/ethics>)
- ▶ *Treating 3 million by 2005. Making it happen. The WHO strategy.* Geneva: WHO/UNAIDS; 2003.
(<http://www.who.int/3by5/publications/documents/isbn9241591129/en/>)

2. FRAMEWORK

2.1 WHY IS HIV/AIDS A HIGH PRIORITY?

Various factors have combined both to compel and to enable a major global effort on treatment for HIV. Some 40 million people live with HIV and 8000 people die every day of treatable AIDS-related disease. The epidemic has reduced life expectancy by more than 10 years in a number of countries. But HIV is not just a public health problem. Sickness and death not only burden individual lives but threaten the social, economic and political fabrics of some nations. In the places most severely affected by the epidemic, social and health systems are being devastated by the burden of untreated AIDS, even as the ranks of available care personnel are reduced by the disease itself and by the migration of physicians and nurses to other regions. The epidemic has created large numbers of orphans and exacerbated poverty and inequality. Even without ARVs, annual basic care and treatment for a person with AIDS can be two or three times the per capita gross domestic product (GDP) in the poorest countries. HIV has already caused a measurable fall in annual per capita growth in the hardest-hit countries of Sub-Saharan Africa and threatens to erase the development achievements of the past 50 years.²

Fortunately, a dramatic expansion of treatment has become possible as ARVs have become more affordable, funding for HIV-related activities has increased, and ART programmes have been successfully mounted in resource-poor settings. These circumstances have provided the political will and the operational possibility for greatly increasing treatment and care for people living with HIV, thereby extending many lives, decreasing the number of new HIV infections and strengthening health systems. These developments in turn provide benefits to society as a whole, staving off the collapse of hospitals and clinics and thereby indirectly benefiting people with other illnesses.

2.2 THE OBLIGATION OF GOVERNMENTS TO ENSURE UNIVERSAL ACCESS TO ARV TREATMENT

In 2001, the United Nations General Assembly adopted the Declaration of Commitment on HIV/AIDS which affirmed the commitment to human rights as an essential element of the global response to HIV and AIDS. This element had already been addressed in a number of UN Commission on Human Rights resolutions³ and the *International Guidelines on HIV/AIDS and Human Rights* published by UNAIDS and OHCHR in 1998.⁴ In 2002, Guideline 6 on access to prevention, treatment, care, and support was revised to reflect recent developments in the medical treatment of HIV and applicable international law.⁵ Guideline 6 states that universal access to HIV prevention, treatment, care, and support is necessary to respect, protect and fulfil human rights related to health, including the

right to enjoy the highest attainable standard of health. A country's obligations with regard to universal access are a function both of the commitments it has made under the international human rights treaties and of its national laws and regulations.

In some countries, such as Brazil and Venezuela, the courts have found that the government has a legal obligation to provide universal access to ARV treatment.^{6,7} In other countries, governments have chosen to address coverage decisions at the political and policy level, providing treatment through the public health system and taking steps towards the realization of the goal of universal access. The progressive realization of the right to health "imposes an obligation to move as expeditiously and effectively as possible toward the goal" of full realization.⁸ In the present context, it means that governments have an obligation to make plans that outline specific time frames for meeting specific treatment targets (i.e. a benchmarking process), and then to take concrete steps towards reaching those targets. This includes, among other health objectives, ensuring that ART is offered to every person needing it. WHO considers the 3 by 5 target to be a powerful motivating force in an urgent effort to achieve such access to treatment and care, and regards universal access to be the only ethically acceptable goal.

Under international law, countries that are party to the International Covenant on Economic, Social and Cultural Rights have an obligation to ensure and protect the right to the highest attainable standard of health. This right includes access to care, including treatment for HIV. The right to health is an economic, social and cultural right subject to the obligation of each country "to undertake steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization" of the right. Achieving the 3 by 5 target requires a partnership in which the international community works together with governments in order to realize one particular aspect of the right to health, namely the treatment and care of persons living with HIV. Human rights mechanisms provide an important institutional and legal framework that sets the stage for decision-making and programme planning. Ethical analysis is both useful and necessary to guide the deliberation of policy choices on questions of prioritization as countries move towards realizing the goal of universal access to care. In this way, human rights norms and ethical analysis are complementary.

2.3 WHY IS ETHICS IMPORTANT IN SCALING UP ART PROGRAMMES?

For some time ahead, unfortunately, in many countries resources will not be sufficient to provide treatment and care for everyone in need, even if the 3x5 targets are met. As more and more people seek treatment, difficult choices have to be made about who should receive treatment and care first, and how and where to deliver ART in ways that do not harm other HIV programmes or health systems more generally.

Ethical analysis uses principles to assess the various possibilities and consequences of choices. These ethical principles are particularly useful in relation to difficult decisions that involve balancing competing priorities and the possibility of harm or benefit. [The concept of “prioritization” is discussed in Box 9.]

The principles of utility, efficiency, and fairness are useful for guiding efforts to select the people who will receive ART on a priority basis and to determine where and how ART programmes will be conducted⁹. Broadly, the use of these principles will lead to policies and programs that:

- a. maximize benefits by distributing available resources to provide the greatest total benefit (including but not limited to health benefits);
- b. distribute these benefits in a way that is fair;
- c. compensate people who have been harmed (e.g. through negligent blood transfusion) or who have taken particular risks in the context of HIV (e.g. through participation in clinical trials);
- d. address, in particular, the needs of the worst-off people or those most in need.

The principle of utility holds that one should act so as to produce the greatest good; although this was classically expressed by utilitarians as “the greatest happiness for the greatest number”, the benefits that are summed up can be of any type. A classic criticism of relying solely on this principle is that it would prefer a programme that brought very great good to a small number of people even if it was not fairly distributed, over a programme that produced a smaller total good which was equally divided among a very large number of people.

The principle of efficiency favours minimizing the use of resources needed to produce an objective, or maximizing the total impact from a given level of resources. Although an act must be efficient to satisfy the principle of utility, not all efficient acts maximize total welfare. For example, in choosing among alternative policies to provide treatment to a particular group within a population, one policy could be selected as the most efficient even though none of the alternatives satisfy the utility principle by maximizing overall benefits to the population as a whole.

The principle of fairness is met when people are treated justly, which is often expressed as treating like cases alike; plainly, in such a formulation, the determination of which characteristics will be compared is the crucial issue, which in turn translates into the question of how a neutral, disinterested view can be achieved. An act that discriminates against a person on a basis that is irrelevant to the decision at hand would violate this principle.

Sometimes all these principles are satisfied simultaneously, but acts and policies often accord with one principle but not the others.¹⁰

Box 2: Principles important in policy-making on ART programmes

2.4 ETHICAL PRINCIPLES HELP TO GUIDE CHOICES IN IMPLEMENTATION

Ethical principles can be used to select and justify actions or policies designed to protect people's rights, maximize their welfare, and avoid harming them. Depending on the weight given to these principles, various groups can be chosen to benefit from the early provision of ART. Likewise, ethical considerations can enter into decisions about which sites and systems are chosen first for the delivery of ART. Persons and societies give various weights to ethical principles and can therefore be expected to reach various decisions, any of which, however, may be defensible in ethical terms. Addressing these issues by means of ethical analysis helps to promote policies and programmes that are ethically defensible and, in consequence, are more likely to be broadly acceptable and to stand up to the criticism that arises in any highly charged field. [For a more detailed discussion of ethical principles and their application, see Box 11.]

2.5 WHAT KINDS OF POLICIES AND PROCEDURES WILL BE THE MOST EFFECTIVE AND FAIR?

In order to promote scale-up that is as effective and fair as possible, policies and procedures should be:

- clear (precise and easily understood by all);
- simple (easily applied);
- efficient (maximizing benefits);
- equitable (treating people fairly);
- non-discriminatory (having no invidious categories);
- legitimate (fairly promulgated);
- progressive (leading towards universal access);
- measurable (allowing attainment to be monitored);
- sustainable (having a reasonable basis of long-term financing);
- legal (consistent with national law and international human rights norms).

Adopting policies that fulfil these characteristics will be a challenge in many circumstances, particularly when the pursuit of one goal conflicts with achieving another.

2.6 THE RIGHT TO NON-DISCRIMINATION GUIDES THE IMPLEMENTATION OF SCALE-UP PROGRAMMES

In most societies certain groups suffer some form of discrimination, one result of which is denial of a fair and equal opportunity to obtain health care. The International Covenant on Economic, Social and Cultural Rights allows for progressive realization of rights and acknowledges that this realization may be constrained by the limits of available resources. States Parties' obligation to guarantee that people can exercise their rights without discrimination of "any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status" is not subject to this limitation.

To clarify the scope and content of individual rights and the obligations of States Parties, treaty bodies issue non-binding interpretations known as "General Comments". In 2000, the Committee on Economic, Social and Cultural Rights adopted General Comment 14 which further expanded on the grounds of non-discrimination in access to health care and the underlying determinants of health as well as to means and entitlements for their procurement. The Committee proscribed discrimination on the grounds of "...physical or mental disability, health status (including HIV/AIDS), sexual orientation, civil, political, social or other status, which has the intention or effect of nullifying or impairing the equal enjoyment or exercise of the right to health". It also noted that "health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact, without discrimination on any of the prohibited grounds".

Offering treatment can have many secondary benefits. The possibility of treatment gives people a new incentive to be tested. Those who test negative can obtain information on how to avoid infection while those who test positive can be counselled on treatment options and the prevention of further transmission. Treatment may reduce the risk of transmitting HIV as well, by reducing transmission on a population level.¹¹ Also, the availability of treatment should diminish the stigma and discrimination surrounding AIDS, to the extent it is attributable to the perception that it is a deadly disease beyond the reach of medicine. Offering treatment not only saves the lives of those who are sick but reduces the stigma that stands in the way of mounting ART programmes and reaching out to aid people living with HIV.

Box 3: Secondary benefits: increased prevention and reduced stigmatization

Some of the points made in this guidance document can be seen in the following case study of citizen engagement in the development of a **national position paper on equitable access to treatment and care** in Malawi

In July 2003, Malawi's National AIDS Commission presented a technical paper on equity in health sector responses to HIV/AIDS at a special consultation with key national-level stakeholders. Based on the recommendations of this consultation, which also addressed access to ART, the Commission initiated a broad consultative process to engage the general public in a dialogue on the issue of equity in access to ART. The process involved: a series of radio and television programmes; consultative meetings with different groups of people and organizations; and commissioned studies in selected districts. Based on Malawi's National HIV/AIDS Policy and the findings and recommendations of the various consultations, a national consensus has emerged on the issue of equitable access to treatment and care. The following policy principles have been proposed to guide the development of treatment and care programmes.

ELIGIBILITY FOR TREATMENT The Government will progressively provide access to affordable, high-quality ART and prophylaxis to prevent opportunistic infections, to adults and children who have tested HIV-positive, understand implications of ARV therapy and are medically deemed to be in need of this drug therapy.

RELATIONSHIPS WITH EXTERNAL PARTNERS ART will be provided to the private sector at the subsidized rate of 20% of the actual cost (currently MK500) (inclusive of drug costs, logistics, and monitoring activities).

To receive ART at subsidized rates, private sector providers will be trained, will understand the implications of ART, and will participate in national monitoring activities.

PUBLIC PROVISION:

SITING ART will be provided simultaneously in at least one public sector site in all districts.

FINANCING ART will be free of charge at the point of delivery in the public health sector.

PRIORITIZING At the point of delivery in the public sector, ART enrolment will be on an open, first-come, first-served basis.

Box 4: Illustration of priority-setting: the case of Malawi¹²

**ADDRESSING
BARRIERS TO
TREATMENT AND
CARE**

Targeted gender-sensitive health promotion of ART will be made to groups of people considered to be in strategic or vulnerable situations. These groups will be identified by using the following principles:

- a. situations of moral obligation to treat (e.g. mothers receiving PMTCT to prevent HIV transmission to their children);
- b. essential human resources in key frontline services (e.g. health workers, teachers, and civil protection workers);
- c. maximum multiplier effect for society, whereby treating a strategic group may encourage more people to speak openly of HIV/AIDS, seek HIV testing, and early access to care (e.g. people living positively with HIV/AIDS);
- d. principles of non-discrimination and pro-poor measures (e.g. orphans, remote rural dwellers, sex workers, prisoners);
- e. cost-effectiveness maximization in existing public health interventions (e.g. TB patients).

Implementers will be encouraged to overcome specific geographical barriers to access for remote populations. In the unexpected event that demand for ART outstrips supply, priority consideration will be given to people already on ART, pregnant women, and young children.

**COMMITMENT TO
STRENGTHENING
HEALTH SYSTEMS**

ART provision will support the provision of essential health services, particularly within the public health sector.

**COMMITMENT TO
MONITORING AND
EVALUATION**

Equity monitoring (including disaggregation by sex and age) will be conducted as part of the ART scale-up.

2.7 SHOULD CONCERN OVER ETHICAL ISSUES DELAY THE SCALING-UP OF ART PROGRAMMES?

Policy-makers and programme administrators have to grapple with the ethical issues inherent in developing ART programmes that, at least for some time ahead, can reach only some of the people in need. Yet the risk that programmes will not be perfectly fair should not be used as an excuse to delay action. Those responsible for launching or expanding ART programmes must ensure that their processes are transparent, accountable, and inclusive of all affected communities and stakeholders, and that they demonstrably take account of the relevant ethical principles and the opinions of concerned people. Of course, this cannot guarantee a programme that is beyond criticism or improvement, but should produce one that is ethically defensible and charts a fair path towards universal access to appropriate treatment and care.

2.8 WHY CONSIDER UNIVERSAL ACCESS WHEN MOST COUNTRIES ARE FAR FROM ACHIEVING IT?

The AIDS epidemic demonstrates that the supposedly impossible can become possible. Ten years ago, no one would have believed that there would be affordable HIV-related drugs that saved lives, that simplified treatment guidelines would exist, that there would be examples of successful delivery of ART in resource-poor settings, and that there would be significant political will and funding for the treatment and care of people living with HIV. These realities now mean that the capacity exists to save millions of lives. By turning AIDS from a death sentence into a chronic disease, ART can restore people to being fully functioning members of society. They are able to work and support themselves and their families. When this happens the impact of the epidemic is greatly reduced. Its crushing effects on individuals, families, communities, health systems, education, agriculture, production, security, and development are significantly mitigated. This means that a failure to act is a greater wrong than acting imperfectly. Action has to be taken urgently, rather than waiting for some ideal situation to arise.

3. DESIGNING FAIR POLICIES

3.1 MAKING ETHICAL CHOICES ON WHOM, WHEN, HOW, AND WHERE TO TREAT REQUIRES COMMITMENT TO FAIR PROCESS

Because reasonable people may disagree on which groups, if any, should be given priority and/or which sites should be established for the delivery of ART, decisions regarding who should receive ART, and when, how and where this should happen, should be guided by ethical principles.^{13, 14} One frequently cited set of principles, which align closely with human rights norms, are called “fair process” principles. Fair processes are public, transparent, inclusive, and revisable; they are also bound by the principle of non-discrimination. They help to ensure that decisions on the implementation of ART programmes are equitable and that they are regarded as legitimate by the people affected by them, even if these people express disagreement. Fair process should be conducted at various levels in a country and should involve representatives of all stakeholders, including health care workers, community members, representatives of marginalized groups typically neglected by governments, and particularly people living with HIV. Women should be adequately represented. In addition to making it possible to reach legitimate and acceptable decisions, the use of fair process should go a long way towards helping to educate people about ART, generating demand for HIV prevention and care services, mobilizing people around health as a right, and increasing transparency and public accountability.

Efforts to achieve “fair process” should not delay the expansion of ART...

...but neither should fears of delay result in the implementation of ART programmes in ways that are inequitable, serve only the privileged or discriminate against certain groups. Because fair process is critical to mobilizing communities and to giving legitimacy to the decisions taken, it should be initiated as soon as possible and wherever possible. While taking steps to expand ART on an immediate basis in some places, governments should also begin to implement fair process. This involves planning, training, workshops, development of indicators, and support for research on fair processes themselves.

Box 5: “Fair process” and delays in scaling up

3.2 THE ROLE OF PEOPLE LIVING WITH HIV AND AFFECTED COMMUNITIES

People living with HIV are the most important stakeholders in ART scale-up. They comprise the essential resource for input, involvement, and cooperation if programmes are to meet ethical and human rights standards. Decision-makers should go to great lengths to tap into, understand, and support the realities of people living with and affected by HIV. Such efforts will have the further advantage of:

- a. generating demand for testing, treatment and care;
- b. promoting adherence and avoiding the development of resistance to ART;
- c. preventing the further transmission of HIV.

With regard to demand, every effort must be made to overcome stigma and discrimination and to rally communities in support of programmes for people living with HIV. The professional and lay support for people on treatment necessarily involves family members and friends of those being treated as well as community-based organizations and NGOs. Support for people living with HIV and affected communities must be an integral part of programme design because in the hardest-hit communities, traditional support networks have already been overwhelmed or destroyed. In order for this support to be effective it must address gender and other factors that are linked to social exclusion. As treatment coverage expands the aggregate impact of people regaining their health will lead to the strengthening of families and communities.

3.3 THE ELEMENTS OF FAIR PROCESS

A fair process for setting priorities on the distribution of ART has the following central requirements or features.

- **Publicity:** The process must be transparent and involve publicly available rationales for the priorities that are set.
- **Relevance:** Stakeholders affected by the decisions must agree that the rationales rest on reasons, principles, and evidence which they view as relevant to fair decision-making about priorities. Community and stakeholder participation and voice must vary in an appropriate way with the institutional context.
- **Revisability and appeals mechanisms:** The process must allow for revisiting and revising decisions in the light of new evidence and arguments, and for an appeals process that protects those who have legitimate reasons for being exceptions to the policies adopted.
- **Enforcement or regulation:** There must be a mechanism ensuring that the three previous conditions are met.

[For a detailed list of questions on fair process that should be addressed in the national and subnational decision-making process, see the Annex.]

The German Technical Cooperation (GTZ), together with the National AIDS Control Programme, the Tanzanian Ministry of Health, and the WHO Country Office in Tanzania, have undertaken a comprehensive analysis of the decision-making processes in the scaling-up of ART and of the effects on equity. The use of the fair process framework highlights the need to recognize issues in the scaling-up of ART which can lead to controversies on moral and ethical grounds rather than on purely technical grounds. The analysis elaborates on selected issues that have given rise to some disagreement on the basis of value judgments.¹⁵

Box 6: Fair process in scaling up: the case of Tanzania

3.4 HOW SHOULD THE IMPLEMENTATION OF ART PROGRAMMES BE INITIATED?

Scaling up access to ART requires that many services currently provided only at the central or district level be progressively and quickly expanded to the health centre level and to community settings, where expertise already exists and can be rapidly built on with appropriate resources and training. It is widely agreed that ART should be initiated in facilities at all levels of the formal health system as soon as certain minimum conditions are available. These include an uninterrupted supply of drugs, HIV testing and counselling, personnel trained and certified to prescribe ART and to undertake clinical follow-up, and a secure and confidential patient record system. Adherence support and community mobilization and education with respect to ART should be introduced at the time of—or, better yet, prior to—the commencement of treatment programmes.¹⁶

These operational recommendations recognize that there is an ethical imperative to offer treatment as soon as possible to those people identified as being HIV-positive and eligible for treatment, based on the local treatment protocol, in as many settings as possible. At the same time, it must be recognized that, in many cases, people already accessing health services may be at an advantage, and that people without access to services typically face broader social and economic exclusion. For this reason, although implementation should start with known eligible cases, simultaneous efforts should be made to develop and implement strategies for the identification of new and hard-to-reach cases and for bringing them into the health care system. These efforts to expand access to treatment and care need to include transportation assistance, communications programmes aimed at encouraging people to present for testing and counselling, and outreach to marginalized populations such as the poor, women, children, migrants, men who have sex with men, sex workers, IDUs, and people with disabilities. In ethical terms there is a need to balance the desire for short-term efficiency with the long-term need for greater equity and capacity to serve broader health needs. The development of simplified treatment guidelines, as well as the growing involvement of community members and people living with HIV in treatment initiatives, makes this increasingly possible.¹⁷

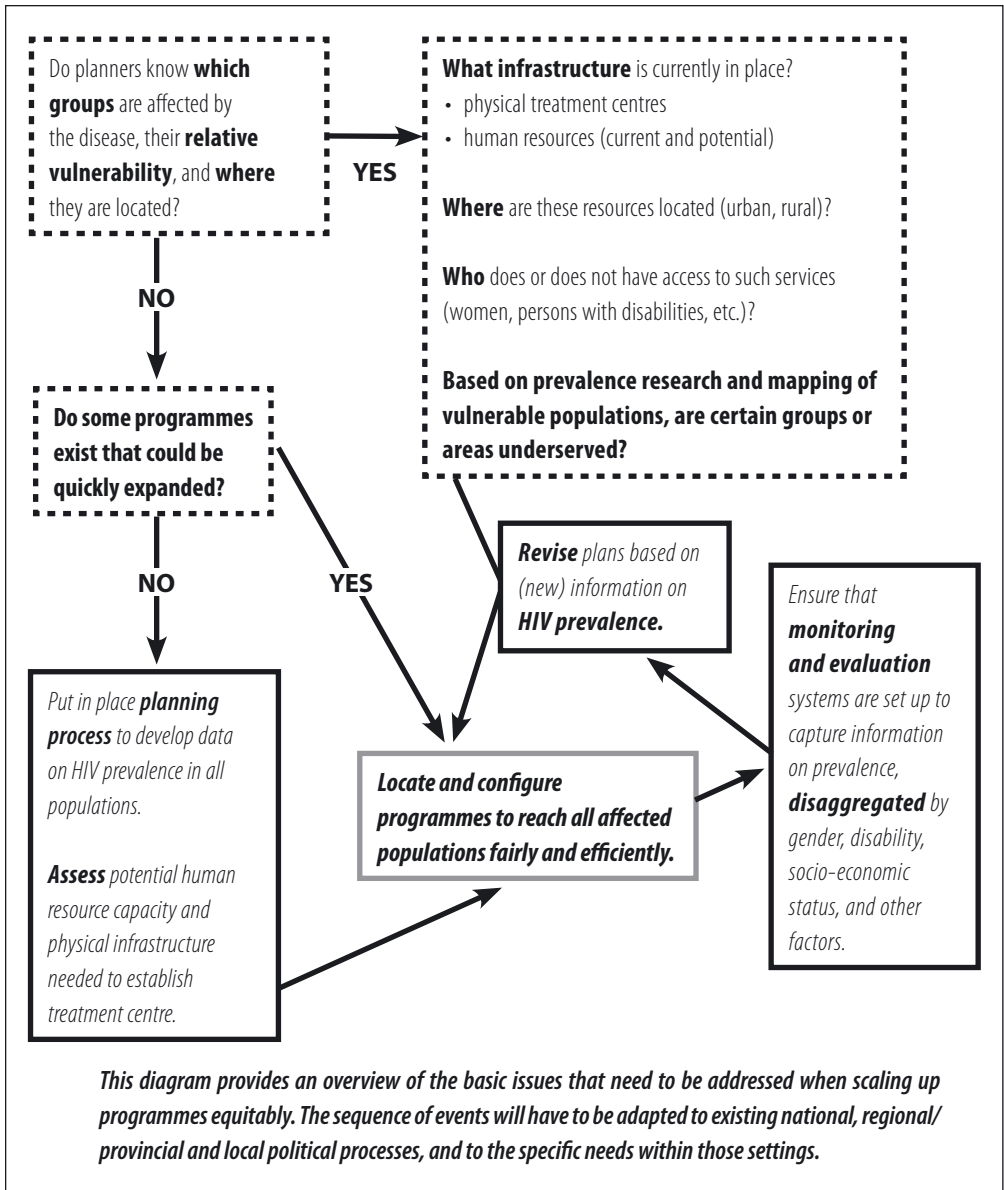
3.5 INCREASING THE COMMUNITY'S ROLE IN TREATMENT IN AN ETHICAL AND EQUITABLE WAY

Simplified treatment guidelines have made it possible to treat increasing numbers of people living with HIV within the community. "Task shifting" has meant that a broader range of cadres of health care workers can be engaged in treatment and care. Programmes must take care to ensure that all health personnel become fully familiar with and respect patients' rights, including privacy and confidentiality. The failure to do so could erect an added barrier to treatment if people fear seeking it lest their HIV status or other personal data become known without their permission.

The community, including people living with HIV/AIDS, plays an essential role in supporting treatment and care. It is important that decisions about the role of the community actively involve community members, engaging both women and men in discussions about new ways of sharing caregiving responsibilities and supporting treatment. The scaling-up of community-based treatment programmes must not increase the disproportionate caregiving burden experienced by women.

3.6 ENSURING THAT SCALING-UP EFFORTS MAKE HEALTH SYSTEMS STRONGER

The integration of HIV treatment and care with other health services has been an important feature of programme development in a number of countries, Botswana and Brazil being notable examples.¹⁸ Scaling-up efforts that take place without an analysis of existing health systems, particularly their human resources capacity, may draw away resources that are necessary to serve people with other health needs or to provide other forms of care to persons living with HIV. Ethical programme design requires that efforts be made to ensure that the scaling-up of ART programmes complements and strengthens the capabilities of existing health systems. This could entail utilizing established infrastructure and entry points, including tuberculosis, antenatal, and drug-dependence services. Where HIV treatment programmes will operate vertically, it may include monitoring the overall impact of such programmes on health systems and mitigating negative effects. Programme designers should remember that a comprehensive, coordinated, and sustainable response to the AIDS epidemic is most likely to be provided by a strong health system.



Box 7: Making decisions where to site treatment programmes

3.7 MONITORING AND EVALUATION ARE ESSENTIAL FOR DETERMINING THE EXTENT TO WHICH PROGRAMMES REACH PEOPLE IN NEED OF TREATMENT

Monitoring and evaluation should be developed as integral parts of an ART programme.¹⁹ It is necessary to understand HIV prevalence rates in various segments of the population. In order to carry out an equity analysis of treatment programmes, data from treatment sites and the district hospital level can reveal the number of people in those segments who are receiving treatment. For example, data should be disaggregated by sex, age, geographical factors, and socioeconomic status. Efforts should be made to capture information on ethnicity and linguistic minority status where these factors may represent a potential barrier to care, and to monitor the coverage of marginalized populations, such as intravenous drug users and sex workers. Efforts should also be made to track how many people without the ability to pay for treatment are receiving ART.

Monitoring and evaluation activities, in addition to tracking the extent to which treatment programmes reach people needing treatment, should cover the procedural aspects of policy design and implementation. Information should be available on the following points:

- Has a national policy on equitable access to treatment for people living with HIV been developed and made public?
- Who was involved in the policy development process and did they participate as individuals or as representatives of a group or institution?
- How were they recruited and selected?
- What was their mandate?
- Were there regular meetings of the participants and/or was there correspondence between them?
- What information, training or other resources were made available to them?
- What method was used to arrive at the final policies?
- How were these policies disseminated publicly?

The use of fair process is a growing area of public policy and academic interest. Qualitative data should be collected to give an insight into how the use of fair process affects the legitimacy of the decision-making process, as perceived by members of the community, different groups of people living with HIV, and their families and support networks of their members. Because participatory approaches to policy development are a means of engaging the community and increasing health literacy, evaluation activities may include measures of preconsultation and postconsultation understanding of HIV/AIDS and its impact on the community.

3.8 WHAT IF THE SUSTAINABILITY OF AN HIV PROGRAMME CANNOT BE ENSURED AT PRESENT?

The chronic nature of the disease, when properly treated, implies a lifetime commitment to and by patients. It is consequently essential to find ways to sustain the financing of treatment programmes for many years, until research on preventive and curative interventions stems the epidemic.

In many countries commitment to lifetime treatment will probably entail significant support from external donors for the foreseeable future. Decision-makers may be in a difficult situation if donor support for programmes covers short periods, especially when national fiscal forecasts are uncertain at best. Governments and the international community have an obligation to deliver known and available treatments to people who need them now because this can save lives and restore the well-being of families and entire communities. They also have the obligation to develop a *sustainable* response to a crisis that will continue for years.

All parties involved in the response to the AIDS epidemic have an ethical obligation to ensure the sustainability of care that is provided to people living with HIV. Uncertainty is inevitable when planning the scale-up of programmes, but the possibility that ART may become unavailable for some patients in the future is not a good reason for not starting them on it now. Reluctance to mount an ART programme may arise from the sense that starting treatment would amount to a wrong against patients who would lose access to treatment if support for the programme were to run out later. Yet the extra days, months, or years of life experienced by these patients, free from the symptoms of AIDS, refutes this concern.

Reluctance to scale up ART programmes may also stem from worries over the political or social repercussions for governments and other ART providers if programmes are discontinued for lack of funds. Three responses can be offered to such worries. First, successful ART programmes have been shown to reduce the total economic burden of AIDS. Such programmes are likely to be sustained because doing so is less costly and provides greater net benefits to society than halting them. Second, this very reality—and the precious lives saved by successful programmes—will provide high-burden countries with a strong argument to persuade external donors to continue their support. Finally, to those who might criticize a health ministry for having begun an ART programme that eventually had to be scaled back or halted, the reply will be: “Look at the patients who have been treated. Would you rather that we let them all die back then, when we could have saved them?” Programmes to provide care and treatment to persons living with HIV need careful planning, including attention to their long-term stability and equity. Yet these considerations should not paralyze the planning and policy-making process, for the failure to start without further delay, with an eye to providing treatment for as long as possible, would be the greater wrong.

3.9 IS IT ACCEPTABLE TO CHARGE PATIENTS FOR ART?

It has been shown that cost is the biggest barrier to accessing ART and adhering to treatment.²⁰ The goal of universal access cannot be met if the fees charged for ART are a barrier for the people in need, who are disproportionately poor to begin with. Health systems employ a wide variety of approaches to financing their costs; available resources and the social and political structures in which they are situated differ markedly. Where the resource base and political support for free HIV treatment for everyone needing it are insufficient, policy-makers have to make choices about how to finance programmes in ways that restrict access to the smallest possible extent. Ethical analysis can be useful for making difficult decisions of this sort.

- **Equal access for HIV care vs. consistency in health financing policy**

One ethical principle—the principle of formal justice—holds that like cases should be treated alike. In a health systems context, this might mean ensuring that similar diseases are treated similarly, or that individuals and groups facing similar disease or disability burdens receive similar levels of care. Many health systems try to recover the cost of treatment through fees charged to patients at the point of service. In such systems, would it be unfair to favour HIV patients by providing them with medication free of charge? Or might such a difference in financing be justified by other goals, such as efficiency and universal access? Are there better ways of financing ART sustainably at the country level without point-of-service cost recovery, including risk pooling strategies such as social insurance? There is strong evidence that fee-for-service financing models create serious obstacles to access. If so, then imposing user fees for HIV/AIDS treatment would not only be a failure to fulfil the right to health care, but in some cases, a death sentence. Exalting formal equality by insisting on consistent fee structures while sacrificing the needs of people living with HIV is neither appropriate nor fair. Moreover, creating policies that move towards universal access to HIV care can stimulate the development of more equitable policies for financing the health system generally.

- **Maximization of benefits vs. promoting equitable access**

Utilitarian principles favour policies that achieve the greatest good for the greatest number. Charging patients according to their ability to pay for care might thus be defended as a means of expanding the available resources and allowing more people the opportunity to be treated. Although theoretically attractive in utilitarian terms, financing based on cost recovery is problematic. Difficulties arise in determining who cannot pay, and the administration of sliding scale programmes can itself be costly, inefficient, and subject to corruption. For many people, even low charges for drugs create an insurmountable barrier to the commencement of treatment.

Furthermore, people who have started therapy may discontinue it, often quite soon or precipitately, once the fees can no longer be afforded.²¹ Rather than imposing fees, policy-makers concerned with equity should consider the significant costs associated with following a treatment regimen, including travel expenses, lost wages attributable to time spent away from paid employment, and the need to pay or compensate alternative care providers. They should, if possible, find means to overcome these less visible barriers.

In Brazil, health care was declared a right in the Federal Constitution of 1988. In 1996 a federal law granted free ARVs to all HIV-infected patients with a medical indication for treatment. The Brazilian AIDS Programme established clinical centres, a laboratory infrastructure providing free viral load and CD4 counts, condom distribution and outreach programmes. In the first year, ART was received by 2000 people and by 2004 there were 140 000 on ART. Fifteen drugs are available, seven of them being locally produced by public laboratories. It is estimated that the total expenditure on ARVs from 1996 until 2002 was approximately US\$ 2 billion. There was some criticism that this was excessive but it has been estimated that, besides the social gains (better quality of life and reduced morbidity and mortality), a net saving of approximately US\$ 200 million during this period was attributable to the implementation of the HIV care policy. AIDS-related deaths fell by 90 000, 60 000 new AIDS cases were prevented, and 600 000 hospital admissions were avoided.²²

Box 8: Free access to ART: the case of Brazil

As the experience in Brazil suggests [see Box 8], systems that have succeeded in reaching priority groups with ART have substantially subsidized treatment and care, usually providing it free through public financing or donor assistance. Where external funding is not sufficient to support the provision of free treatment and where tax revenues are not a viable source of additional funding, many decision-makers can be expected to consider redistributing public sector funds to respond to the challenges posed by HIV. Such prioritizing exercises at the macro level can benefit from ethical analysis. As mentioned previously in connection with the verticality of programmes, scaling-up efforts that take place without an analysis of the social context may draw away important resources that serve other populations by providing essential public goods. This has to be avoided. Ethical programme design requires that investments in the scaling-up of HIV programmes complement and strengthen other social endeavours, including the provision of other health services. Given the severity of the crisis, its broad impact on communities and key social institutions, and the potential for the type of economies found in the Brazil example, some reallocation of resources within the public sector may be justified in the short run so as to combat this health emergency more broadly. Policy processes, however, should identify and evaluate the impact of the decisions made and the results should be communicated to the public.

As illustrated elsewhere, the introduction of new financial resources for HIV care can provide an opportunity to strengthen a range of social institutions, and this includes national and regional social insurance mechanisms. Within these institutions, ART becomes a vital and accessible insured health care service. Where national governments are driving the scale-up of programmes by redistributing health system budgets, ethical analysis can help to inform the prioritization and resource allocation process. Participatory policy development processes described in this document can be adapted as a means of helping to guide some decision-making at the macro level.

3.10 WHAT OTHER BARRIERS TO ART SHOULD BE ADDRESSED?

Other barriers to ART access include discrimination against marginalized populations, harmful gender norms and cultural practices, corruption of officials, inadequate information about ART, and ethnic or geographical isolation. HIV status itself can represent a potential source of discrimination. Indeed, discrimination against people living with HIV by health care workers is widespread and erects a significant barrier to treatment and care. However, short and relatively inexpensive awareness training programmes for health care workers have been shown to improve their attitudes.²³

In order to meet the specific needs of certain groups of people living with HIV, specialized interventions are necessary which address the barriers they often face. These groups include the poor (financial barriers to treatment), young people (lack of information, barriers to providing legally valid informed consent), women and girls (discrimination, disproportionate burden of caregiving activities, threat of violence, harmful cultural practices), rural populations (geographical isolation), refugees and internally displaced people (conflict, isolation, lack of social order and services), migrants (discrimination, language, mobility), IDUs, sex workers, men having sex with men (legal status, social isolation, police abuse, discrimination in health services), prisoners (prison conditions and policies), and people with disabilities (physical isolation). Programmes for scaling up treatment and care for HIV should involve referral to and support for services that address the human rights abuses and other challenges faced by the members of these groups.

4. REACHING EVERYBODY IN NEED

4.1 CHOOSING SPECIFIC POPULATION GROUPS FOR PRIORITY DELIVERY OF ART

WHO has made clear clinical recommendations regarding when ART should begin in HIV-infected adolescents and adults.²⁴ Due to the lack of testing services, many people are not aware that they are HIV-positive. As these services become increasingly available, however, the number of patients in need according to clinical criteria, will often greatly exceed the availability of ART. Additional criteria as to whom should be given priority in treatment therefore need to be considered.

Since resources are limited, countries should determine whether the priority provision of ART to specific population groups achieves ethically sound goals, such as spreading the benefits widely and efficiently, increasing fairness and equity among groups and geographical locations, strengthening primary health care, and benefiting health care and society at large. The analysis should be based on the ethical principles described as well as on the realities of the local epidemic and the practical feasibility of favouring specific groups. Special attention should be paid to the gender dimension of the epidemic and the choices made should not exacerbate the existing inequities magnified by HIV and AIDS.

Depending on these factors, such choices and their justification in some countries have included prioritizing the following (in no particular order):

- a. health care workers, because they are necessary for the delivery of ART;
- b. mothers/fathers identified through PMTCT, because they are already in the system and there is a need to avoid orphaning children;
- c. people close to death from AIDS, because they are the most unwell and the most in need;
- d. people already identified as positive through HIV testing and counselling services;
- e. people who engage in high-risk behaviour, because they may pass on HIV infection;
- f. people who have participated in HIV-related research, because they have taken risks for the benefit of others;
- g. people who have been infected as a consequence of negligent blood transfusion;
- h. people who provide essential social services (e.g. teachers, farmers, police).

In particular contexts it may be that other groups should have priority or that the above groups should have priority for different reasons. In the absence of clear policies on whether specific population groups should be prioritized, decisions are inevitably ad hoc and based on subjective criteria. This opens the possibility for discriminatory practices. In order to avoid these problems, clear guidelines indicating whether specific groups are to receive priority should be established by decision-makers. This should be done in accordance with the principles of fair process. Giving priority to certain groups must not be used as a cover for discrimination against other, disfavoured groups.²⁵

In the context of ART, “prioritization” may describe different things. The simplest connotes that the targeting of educational campaigns and outreach activities, location of treatment programmes, and similar policies aim to ensure that particular groups have access to treatment in the early stages of scaling up ART, while treatment capacity and resources are being increased to universal coverage. The purpose of prioritization is to increase the proportion of people in the prioritized group who actually receive care and treatment for HIV. The ethical acceptability of such prioritization depends not only on the process used to set the policy but on the rationale for targeting the groups in question. For example, prioritizing groups such as the poor, women, or others who may be missed by programs aimed at the general public would be more defensible than prioritizing groups that already have good access to ART. Programmes that prioritize in this first sense still accept all eligible patients for whom they are able to provide treatment whether or not such persons are members of a priority group.

“Prioritization” can also describe a policy of selecting from a waiting list those people who are members of a priority group, rather than basing selection on “first-come, first-served,” a lottery, or any other method independent of group membership. For example, a programme to treat health care workers—in order to establish a base for treating the wider community—might move members of this group to the head of the queue. A third, more extreme form of prioritization would be to exclude from the list people who are not members of the priority group. In the second case, these people might get treatment (if that is possible after accommodating those given priority), but in the third situation they would not.

All policies on ART—from the location of programmes to education and outreach efforts to the management of the lists of people awaiting treatment—need to be equitable and non-discriminatory. Therefore, the more a policy advantages “priority groups”, the greater the need to ensure that the policy has not become a disguised means of discrimination, by excluding disfavoured groups, particularly those most stigmatized or marginalized in society.

Box 9: What does it mean to “prioritize” a population for ART?

4.2 THE RATIONALE FOR PROVIDING TREATMENT TO THE MOST VULNERABLE IN SOCIETY

UNAIDS broadly defines vulnerability as realities or characteristics over which a person or group has little control and which make the person or group more likely to experience harm or not receive a benefit.²⁶ This includes such factors as: social, economic, educational, employment, or legal status; discrimination against women; and geographical, political, or cultural isolation. The “maximin principle” requires preference be given to the people who are worst-off or least advantaged (most vulnerable) so as to bring them to a state of being equal to others. Its application requires that implementers choose the criteria by which to judge who is worst-off. With regard to the scaling-up of ART the most vulnerable or worst-off people might be (a) the most unwell, i.e. those with the worst health, for whom ART is most urgently indicated on medical grounds, and/or (b) those whose access to health services and to ART is blocked for some reason. In the implementation of scale-up programmes, special efforts should be made to reach these vulnerable groups.

Besides the ethical basis, there is a public health argument that underlines the crucial importance of ensuring access for vulnerable populations. Reaching them with effective services is vital for slowing down the spread of HIV. Failure to do this means further increasing their vulnerability to HIV and fuelling the spread of the epidemic.²⁷

4.3 SPECIAL EFFORTS ARE REQUIRED TO ENSURE ACCESS TO ART FOR THE POOR

Particular efforts are necessary in order to enable the poor and other vulnerable groups to gain access to treatment. Poverty is defined in this context in the broadest sense, beyond income poverty and including social and political exclusion.²⁸ A pro-poor approach is necessary to:

- a. enable the poor to gain access to treatment (better-off people can gain access with their own resources);
- b. make the process of selection of patients as egalitarian as possible;
- c. move towards greater equity between rich and poor.

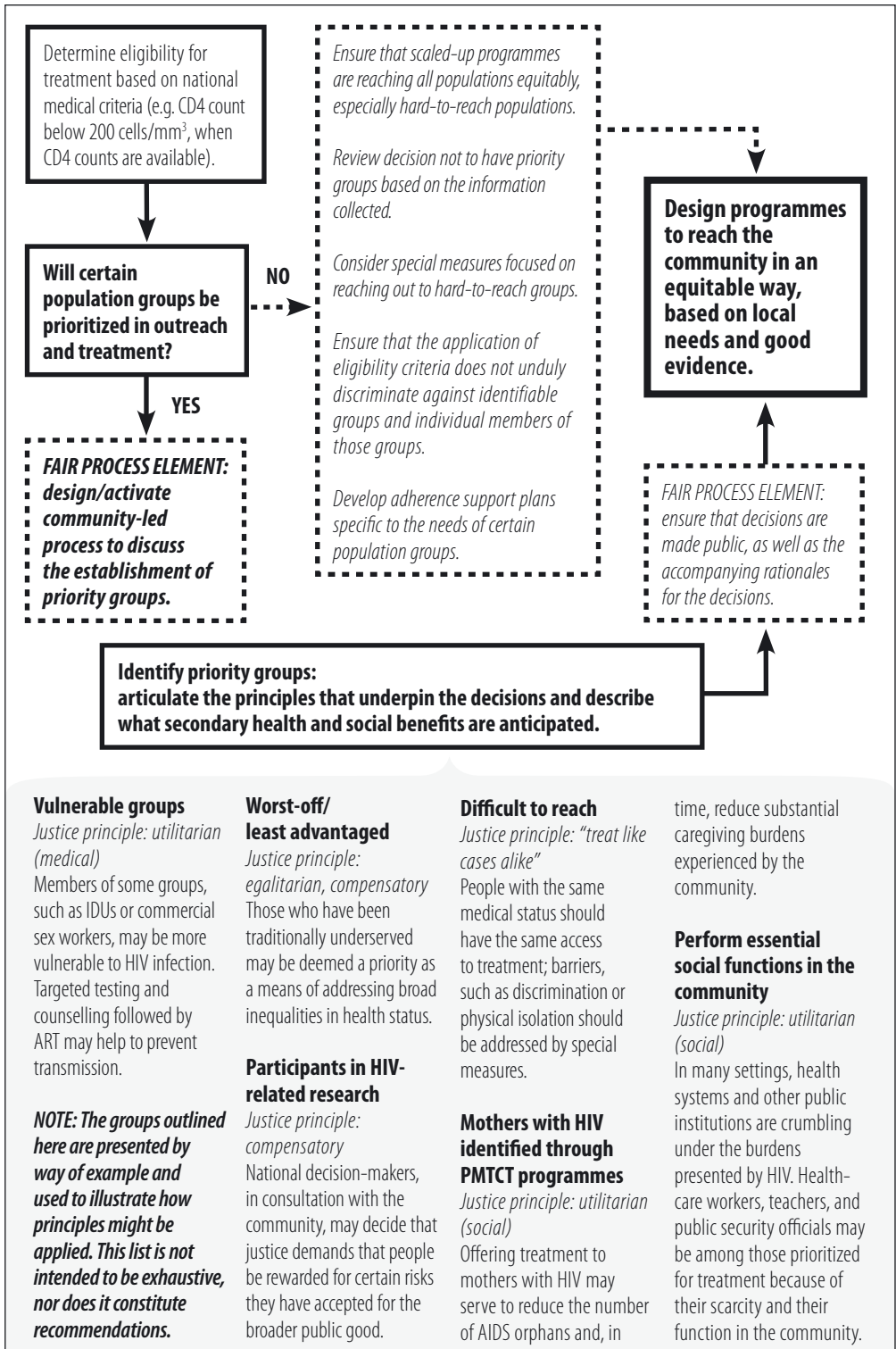
People who cannot afford ART should receive it free at the point of delivery. Furthermore, any time costs and the ability to pay should be assessed, and all the costs of accessing treatment and care should be taken into account apart from the cost of drugs and services. The costs include those of transportation, child care, and time away from income-generating activities, all of which are serious barriers for the poor. With respect to ART regimens that have to be adhered to over a lifetime,

these costs also represent serious barriers to adherence. In an effort to increase the likelihood of the poor and others taking up services, a wide range of these should be accessible in primary care facilities, possibly available outside regular working hours. The services should be child-friendly or there should be some possibility of accessing childcare services. Consideration should also be given to subsidies for transportation and nutritional supplements for patients and their families.

4.4 PRESUMED ADHERENCE SHOULD NOT BE A CRITERION FOR PRIORITIZING PATIENTS

Adherence to the ARV regimen is the single most important determinant of clinical outcome.²⁹ Supporting all patients to adhere to treatment is a fundamental component of any ART programme. Spending resources on non-adherent patients can reduce the benefit, in terms of health outcomes, produced by an ART programme. Moreover, poor adherence may promote the development and spread of drug-resistant HIV strains.³⁰ However, making presumptions about patients' inability to adhere to treatment and then denying them access to ART is ethically problematic because denials based on unreliable predictions amount to unfair discrimination and non-adherence is associated with conditions of greatest need.

It is unjust to make decisions to exclude patients using criteria that have not been established. Predictions of non-adherence are unreliable because they are subjective and based on unsupported generalizations. First, adherence to treatment is a dynamic process influenced by such changeable factors as depression, psychological stress, unstable housing, lack of social support, the quality of the clinician-patient relationship, the treatment regimen, and the clinical setting.³¹ Second, it has been shown that physicians perceive certain groups as being more likely to adhere to treatment—for example women, patients under 30 years of age, people who were not IDUs, and people with biological markers suggesting a healthy status—even though these criteria for selection do not prove to be good predictors of adherence.³² Another study found that physicians believe IDUs are always less adherent to complex regimens than other populations and were usually less likely to recommend ART for this group.^{33, 34} However, there is no evidence which demonstrates that these criteria, or any others, anticipate adherence with any reliability. Likewise, studies have demonstrated that socioeconomic status does not necessarily have an impact on adherence, and that social instability has a more significant impact.³⁵ All of these studies show that predictors of adherence are difficult to determine. Even if predictions could be made about certain social groups, additional studies have shown that these predictors cannot be extrapolated to individual adherence.³⁶ In the absence of evidence-based criteria for future adherence, decisions to exclude prospective patients from ART programmes based on “predicted non-adherence” are subject to discriminatory practices and unconscious bias.



Box 10: Reaching all people who need treatment

Policy-makers wanting to make choices that are beneficial and fair for all will find that ethical principles can contribute to achieving their goal. As regards ART programmes, the ethical principles most commonly invoked are utility and fairness. The first evaluates the rightness of an act based on the extent to which it maximizes benefits for society as a whole; the second evaluates the rightness of an act (procedural justice) and its consequences (distributive justice) based on fairness to the population.

UTILITY: How desirable benefits are characterized—in terms of both primary and secondary effects—will be crucial in selecting policies. Primary benefit, for example, could be defined in terms of improved health outcomes of individuals receiving treatment for HIV, or it could be measured in terms of relative effectiveness in saving lives. The definition adopted in turn affects which policy is chosen. The former definition of benefit would support prioritizing those groups most likely to respond well to treatment, whereas the latter would prioritize people who are worst off and closest to dying.

Utilitarian calculations can also take into account any broader, secondary benefits, such as those that accrue to the community as a whole beyond solely the physical health of treated persons. For example, providing ART to physicians and nurses living with HIV may enable these individuals to be healthy enough to continue working. The essential services they can provide are often in short supply, so restoring their health may be an important step in enabling the health system to overcome the crippling effects of the AIDS epidemic. The secondary benefits would include the health and longer lives of people who receive care that would otherwise be unavailable were these healthcare workers lost. This calculation could go on to include the benefits to families and co-workers from the survival of these patients, and so forth.

Efforts to maximize total welfare are constrained, however, by other ethical and human rights norms, including the right to non-discrimination. Suppose, for example, that an ART programme sought to maximize the number of people treated by employing coercive or intrusive means that would violate the principles of privacy and autonomy (which are not the focus of the present guidelines). Likewise, an ART programme may not invoke the justification of “utility” to follow policies which, considered as a whole, deprive women, ethnic minorities, persons with disabilities, or other vulnerable groups of a fair opportunity to get treatment and care for HIV.

FAIRNESS: This principle is often put formally as “treat like cases alike and different cases differently”. Determining what makes two situations alike and what forms of difference are relevant in various situations is crucial. For example, the right to non-discrimination usually requires that certain types of difference (gender,

Box 11: Working with ethical principles in the selection of priority groups

ability, ethnicity, and similar characteristics) not be used as a basis for excluding people from medical care. Conversely, some group differences may be relevant to the extent they are linked to increased vulnerability and necessitate special interventions (i.e., different treatment) in order to create fairness. Because the principle of fairness does not state the criteria for treating cases alike or differently, it is worthwhile to consider substantive ethical principles, in particular egalitarian, “maximin”, and justice-as-compensation principles.

Egalitarianism means equalizing specific aspects of individuals’ condition relative to other people with similar needs or to other members of the community at large. In designing policies on ART, the question would be whether to equalize health status (by prioritizing the worst off, to bring up the bottom) or to make the accessibility of services truly equal (by focusing on hard-to-reach populations). Formal equality could also be achieved by giving each person an equal share of the healthcare budget, but such a policy would leave some sick people with inadequate care, while healthy people got treatment they did not need.

The maximin principle gives preference to those who are worst-off or least advantaged. Again, choices will turn on the criteria used to judge what it means to be “worst-off”. Many alternatives are possible: the people with the worst health overall, those who will fare least well if not treated, the poorest, the most vulnerable or generally marginalized in society, or those with the least access to health services? The chosen characteristics then become central in shaping outreach and treatment programmes.

Fairness can also be described in terms of reciprocity or compensation, that is, rewarding people for what they have done, or attempting to restore them to the state they would have been in had they not endured a certain type of harm. For example, this might mean giving ART priority to groups that participated in HIV-related clinical trials (to recognize the risk they took for the benefit of the community) or to those who were infected by unsafe medical practices such as blood donation programmes that reused syringes.

VALUES IN CONFLICT: The two policy goals—maximizing overall benefits and giving everyone a fair chance—are sometimes at odds. “Doing the ethical thing” may thus mean deciding whether to limit overall benefits in order to achieve greater fairness, or deferring full equity in distribution in order to scale up ART more rapidly. Other times, however, the two principles reinforce one another, so increasing equitable access to treatment and care maximizes benefits, now and in the long term. The responsibility of those leading the policymaking process, then, is to clearly identify trade-offs where they are unavoidable and to engage the community in resolving them in an open and explicit fashion.

Even if it were assumed that future adherence could be accurately determined, the exclusion of patients with predicted problems of adherence would be questionable because this would exacerbate existing inequities. Circumstances which are typically used in predicting that certain patients will not follow their treatment plans, such as poverty, homelessness, lack of family support, and substance use and dependence, also bring into play a principle of fairness, namely that the people in greatest need should receive the greatest attention. Fairness to the least well-off would require special measures in order to improve adherence among all patients with difficulties rather than excluding them from ART.

Case management for people on ART can be effective in helping them to adhere to this lifelong treatment regimen. For example, case management for IDUs and methadone substitution treatment for heroin users have both been effective in increasing adherence in these groups. Moreover, it has been demonstrated that HIV-infected IDUs who receive comprehensive assistance with respect to drug dependence, mental health, and HIV infection, usually adhere to their ART regimens as well as other patients.^{38, 39} More generally, adherence can be encouraged by counselling, education, and peer support, with appropriate involvement from family and community members. Any individual is capable of high or low adherence, depending on the wide range of social factors that affect the ability to follow a treatment regimen. The provision of services in support of adherence recognizes that every patient has the ability to adhere to treatment.

4.5 THE IMPORTANCE OF A SPECIAL FOCUS ON EQUITABLE ACCESS FOR WOMEN

Over the past 20 years there have been significant epidemiological shifts in patterns of HIV transmission, which have led to new understandings of risk and vulnerability. Whereas in the early stages of the epidemic, HIV infection was predominantly among men in many industrialized and some developing countries, by the end of 2002 almost 50% (19.2 million) of the 38.6 million adults living with HIV were women. In sub-Saharan Africa, 58% of HIV-positive adults are women, and infection rates among women aged 15–24 years are many times higher than those among young men.

The increase in HIV infection among women is attributable to the combination of biological vulnerability to STIs, including HIV, and to various social, cultural, economic, legal, and political factors that reflect inequality, such as women's lesser access to education, health services, income, property ownership, protection under the law, and political representation. As studies from diverse settings have shown, these and other factors (e.g. gender-based violence) create an environment in which women find it more difficult to protect their health resulting in an increased vulnerability to HIV infection. The issues affecting the uptake and experience of health services among women and girls, including those related to HIV, can vary across contexts

and within populations. This often creates different barriers for adolescent girls, female migrant workers, rural women, households headed by females, female sex workers, and so on. These guidelines focus on issues that are often observed among women and influence their access to treatment programmes including ART. The issues surrounding specific subpopulations and specific contexts, which are not separately addressed here, will need to be considered when setting national policies and designing ART programmes.

4.6 SPECIFIC BARRIERS TO HIV TREATMENT FOR WOMEN

The tendency of women to delay seeking treatment when they are ill is most often attributed to their dual workload (income generation and household labour in combination with looking after small children and other family members who are unwell). Other factors that affect women's access to health services include the need for permission from husbands or senior household members, fear of domestic violence, restriction on physical mobility outside the home, and the cost, distance, opening times, and other service-related issues, e.g. lack of privacy in examination settings and the sex of health care providers.

In many countries, women and girls may lack basic knowledge about reproductive processes, sexual health, and STIs. Many women do not consider themselves to be at high risk because they are faithful to one partner, and consequently they are unlikely to seek HIV testing until they develop AIDS symptoms or their partner becomes ill. In addition to the fear of violence and/or ostracism by family members when a positive HIV result is revealed, women's experiences of health centres are shaped by moralistic attitudes towards sex that are reflected in negative or judgemental attitudes of health staff. These act as a major deterrent to women seeking information on or treatment for HIV.

Although the cost of HIV treatment is an issue for both men and women, the latter often face additional problems, e.g. a lack of control over family expenditure, a requirement to obtain permission, and the relative poverty of households headed by females. Women's economic dependence on their husbands is reinforced by the legal discrimination they suffer in property, inheritance, and divorce laws in many countries. Such matters are of concern in relation to ensuring equitable access to ART. Moreover, where access to treatment is tied to formal employment, e.g. through health insurance provided in the workplace, men's greater participation in the formal sector may provide them with greater access to ARVs. Recently, HIV-positive women and others in both southern Africa and in Asia have expressed concerns that their husbands might send them to obtain ARVs from a treatment centre and then take the drugs themselves rather than risk being seen to need them.

4.7 TACKLING THE BARRIERS AND ENSURING EQUITABLE ACCESS OF WOMEN TO CARE AND TREATMENT

In order to ensure equal access to treatment and care, it is necessary to have an understanding of the biological and social differences and the differing needs of men and women. Sociocultural inequalities that disproportionately affect women cannot be dealt with in the context of health alone. They also require a supportive environment promoting, among other things, equal protection under the law, equal access to education, and opportunity and the ability to earn a living. Links between health services and organizations working on issues with a bearing on HIV/AIDS would be very beneficial in helping to provide a supportive referral network. Examples are legal protection, assistance with property and inheritance rights, literacy programmes, jobs and skills training, microcredit programmes, and women's shelters.

Intervention: training curriculum

In South Africa, RADAR (Rural AIDS and Development Action Research programme; www.wits.ac.za/radar) has developed a one-week VCT training curriculum for nurses which merges approaches taken from domestic violence training materials with more traditional VCT training methodology. Role playing and other interactive methods explore how gender roles, gender inequalities, and domestic violence increase women's vulnerability to HIV infection. An HIV-positive facilitator was instrumental in conceptualizing and implementing the curriculum. Her own disclosure during the training was designed to sensitize nurses to the importance of confidentiality and the benefits and risks women face in disclosing their HIV status. Because referral services for domestic violence were not available, the training emphasized the provision of a non-judgmental and supportive approach to women in abusive relationships and the need for women themselves to make decisions on the safety and feasibility of disclosure to partners. The evaluation of the programme included a review of services, in-depth interviews with trained nurses, and the use of mock clients to evaluate VCT from the client's perspective. Integrating domestic violence issues into VCT training also heightened nurses' perceptions of HIV risk. This type of training has the potential to raise awareness about both the risks and benefits of disclosure for women and to improve the quality of VCT service delivery. In settings where women are known to be at high risk of both domestic violence and HIV, such training approaches may be particularly relevant.⁴¹

Box 12: Addressing gender and domestic violence: the case of South Africa

The following are some recommendations for improving women's access to HIV-related services and increasing their uptake of HIV/AIDS treatment.

- ▶ **Involvement of women's groups**

It is critical that local groups of women living with HIV be involved at the local, national, and global levels in the design and roll-out of treatment so that issues of access to treatment which affect such women can be identified and addressed.

- ▶ **Expanding provision of ART outside PMTCT**

As important as it is to provide ART to HIV-positive mothers in the context of PMTCT programmes, it is also critical to provide HIV-related services outside the prenatal context. The goal is to reach women who are not pregnant, and, in particular, adolescents (an especially vulnerable group), and women who are past childbearing age (frequently the main carers of orphaned grandchildren). Potential entry points include primary health care clinics, family planning services, home-based care initiatives, and other non-conventional loci through which women and girls connect, such as religious groups, HIV-positive women's self-help groups, local YWCA, Girl Guides groups, other youth centres, and women's income-generating associations. The creation of an enabling local environment would be very beneficial for women, permitting them to access treatment in their own neighbourhoods rather than having to travel long distances, something that is often very difficult. Such initiatives may be particularly effective in reaching rural women.

- ▶ **Integration of HIV services with reproductive health services**

Just as ART needs to be part of the continuum of HIV prevention, testing, and care in order to avoid disjointed services and failed follow-up, the full range of HIV services should be integrated into reproductive health services, including family planning. Such integration is part of a comprehensive response to the multiple needs of women and helps remove the stigma of stand-alone HIV services. Where the integration of services is not possible, referral systems can be created that link primary care, including antenatal, family planning, and general outpatient clinics, to HIV testing and other relevant services. In addition, where appropriate, the provision of services can be undertaken in a targeted manner for hard-to-reach populations, such as sex workers, rural women, and refugee women, without creating or reinforcing prejudice against them.

- ▶ **Provision of counselling and referral in relation to gender-based violence**

Counselling is not only important in helping people to deal with a positive HIV result but can also help to maintain adherence to treatment programmes and identify additional support through community initiatives such as AIDS service organizations. Apart from trained counsellors, it is critical that all other health staff be trained in gender and HIV/AIDS issues, in provider-client interaction and counselling techniques in order to provide a confidential

and non-judgemental environment. The training of health providers should cover gender-based violence and the provision of appropriate advice on potential disclosure-related violence by counselling services, together with information on referral services as appropriate. Mediated disclosure to partners can also be explored if the women concerned are in agreement. Many health providers may be concerned about their own HIV status but may not wish to discuss the matter with their peers for fear of losing their jobs. Training in sensitivity awareness with respect to disclosure issues should therefore be conducted throughout the health service.

- **Provision of gender-sensitive health communication**

Communication on all aspects of HIV and AIDS, including treatment options, is essential, so that both men and women are aware of the mechanisms of HIV transmission and know where to go for testing and treatment. Health promotion programmes should be designed for men and women in appropriate settings. For example, information on HIV prevention, testing, and care can be made available in places to which women have good access, such as markets. When illiteracy, particularly among women, is high, written materials such as pamphlets and brochures will not convey information effectively. Other communication media, such as drama and radio programmes, can be used. In addition, specific outreach may be necessary for certain groups, including adolescents.

- **Developing more sensitive health-financing mechanisms**

Women are less likely to be able to afford user fees and drug costs because of their limited access to income and other productive resources. Where provision of care without charge is not possible or available, careful attention must be paid to the impact on women's access to services, to the inclusion of gender issues in poverty assessments, and to eligibility criteria (e.g. households headed by females) for free and subsidized therapy.

- **Ensuring that drug-adherence programmes are gender-sensitive**

Factors that may affect women's ability to maintain and continue treatment include opposition by husbands, the misconception that drugs can harm a fetus, time constraints, and breaches of privacy or confidentiality. Therefore, in addition to providing full information on treatment options, programmes should identify methods of treatment support and follow-up that are acceptable to the people involved. Women are the main providers of HIV-related care, but male involvement should also be encouraged in caregiving activities, including child care.

4.8 SPECIAL NEEDS OF ADOLESCENTS

The additional barriers to care for HIV faced by some adolescents and young adults illustrate the need for special action aimed at avoiding an inequitable distribution of ART. Some of the barriers arise from policies, others from a failure to adjust programmes to the particular needs and characteristics of this group.

Real and perceived legal standards can prevent adolescents from being tested for HIV and accessing the treatment and care that they need. In many jurisdictions the ability of minors to provide legally valid informed consent is not clearly defined, or the age at which they can consent and/or be tested or treated without information being disclosed to a parent or guardian is 18 years or older. Confidentiality is essential if adolescents are to decide to seek treatment. Whether because of stigma or a threat to their safety, if a positive status becomes known, an inappropriate insistence on parental consent may in effect amount to a denial of treatment and care. Even when the law allows confidential testing or treatment at a younger age for certain conditions, this authority may be poorly understood by health care providers. Moreover, physicians and nurses may have to make assessments of young persons' capacities to make decisions on the basis of informed consent but may not feel adequately prepared to do this.

These barriers to providing care to adolescents may result in HIV programmes that are not always sufficiently adapted to the special needs of this group. For example, communications need to take account of adolescents' sense of invulnerability and their frequent alienation from social institutions. Furthermore, a lack of understanding about HIV not only places this group at greater risk but leaves them unaware of the availability of services, including ARV treatment. To be effective, education needs to start early and to use age-appropriate messages. The programmes need to convey the importance of knowing one's HIV status and provide information on how to access counselling and testing services as well as education on rights.

Reaching young people effectively requires programmes both to be located in places that are easy to access and to be available at convenient times. Special attention must be paid to young people who are particularly hard to reach, such as those who are outside the school system, without housing, or in unsafe home environments. Engaging young people and representative groups in decision-making about programme design is an important way of gaining an improved understanding of their needs and helps towards the creation of more responsive programmes. Efforts to engage citizens in decision-making and priority-setting should include young people, making them full partners in establishing equitable access to treatment and care for persons living with HIV.

With respect to the needs of HIV-positive children orphaned by AIDS, the legal requirements for informed consent can present barriers that result in a denial of care. Legislation presently under review in South Africa would address this in part by allowing caregivers to consent to treatment. Up to now, however, consent has been sought from the courts on a case-by-case basis. Legal counsel working with the AIDS Law Project (ALP) in South Africa sought to create a precedent and raise the public profile of this issue through three cases brought before the courts in 2003.

The third of these cases increased the ability of HIV-positive children without parents or legal guardians to access testing and treatment. An urgent application was heard by the Johannesburg High Court on 5 December 2003, brought on behalf of the University of Witwatersrand Paediatric HIV Working Group, whose members provide treatment and care to children at paediatric HIV clinics at the Chris Hani Baragwanath Coronation and Johannesburg General Hospitals. The applicants requested permission to treat eight children who required ART and to test three children for HIV. They also asked the court for permission to test and treat other unnamed children in similar positions by obtaining consent from their caregivers, even though the law did not permit this. The court ruled in favour of the children receiving treatment and HIV tests. In addition, the court also permitted the Paediatric HIV Working Group to rely on the permission of caregivers who had certified that treatment and/or HIV testing was in the best interests of the child concerned, in the absence of a legal guardian who could give permission.

The order granted by the court made an impact on the ability of health care workers affiliated to the Witwatersrand Paediatric HIV Working Group to provide treatment to orphaned children but did not affect children in other provinces. Proposed legislative reforms under review by the South African Portfolio Committee on Social Development, however, would change this by defining a caregiver who would be able to consent to treatment in the absence of a parent or legal guardian.⁴²

Box 13: Informed consent for AIDS orphans: the case of South Africa

While this group has certain common needs and characteristics, the range of factors that make some young people particularly vulnerable needs to be kept in mind. Poverty affects the conditions under which young people live and learn. This in turn determines access to information and services, as well as the ability to make important life choices without coercion. The burden of HIV on families may place heavy caregiving responsibilities on some young people, making it more difficult for them to access services for themselves. Finally, gender is a compounding factor. Where HIV is transmitted predominantly by heterosexual relations, the incidence of infection is higher—and often much higher—in girls than in boys of the same age. This vulnerability is further compounded when females have less practical and legal independence than males in a particular culture.

For young people, especially adolescents, to be treated equitably, laws and regulations will need to be in place that will enable this group to obtain care under appropriate circumstances. Health care providers will also need to understand how to apply these guidelines in practice and ART programmes will have to provide information and services in an accessible fashion.

4.9 BARRIERS TO CARE FOR CHILDREN

Children often face special technical barriers to ART. Diagnosis is often difficult before the age of 12–15 months because the necessary specialized virological testing equipment is unavailable in many settings. Access to age-appropriate treatment regimens is also lacking. Generic WHO guidance indicates which ART drugs and regimens should be used in first-line treatment, but these are often unavailable in formulations that are usable, palatable, or acceptable to younger children. Even if the formulations are available in-country, they are usually significantly more expensive than the equivalent treatments designed for adults. Technical capacity for monitoring in children is also limited. For children under 6 years of age, monitoring is best based on the CD4 percentage, but commercially available CD4 machines frequently do not provide this information.

The inability to obtain legally valid informed consent for the treatment of HIV-positive children may also pose a barrier to care. HIV has had a dramatic impact on entire communities, leaving many children orphaned and without legal guardians. By 2001, AIDS had killed the mothers or both parents of 10.4 million children under the age of 15 years (the vast majority in Africa), and UNICEF estimates that this number could double by 2010.⁴³

Children orphaned by AIDS may already be HIV-positive themselves. Even if they are not, they are often forced into situations that increase their vulnerability to HIV infection. Policy-makers should develop preventive responses to address the factors that increase vulnerability to infection, together with treatment responses that overcome barriers to care for children living with HIV. This includes designing and publicizing informed consent requirements that recognize the many situations in which parents have died and no legal guardians or active surrogate caregivers are available to give informed consent for testing and treatment. If they exist at all, state-run social service and child protection mechanisms are overwhelmed in many settings and may be unavailable to intervene and assess a child's best interests with regard to testing and treatment. The informed consent of a parent or guardian is an ethical requirement designed to protect the interests of children, but excluding children from access to life-saving care because a parent or guardian is unavailable is a greater wrong. Practical and accessible alternative measures should be developed in order to respond legally to the health needs of children and protect their interests in the broadest sense.

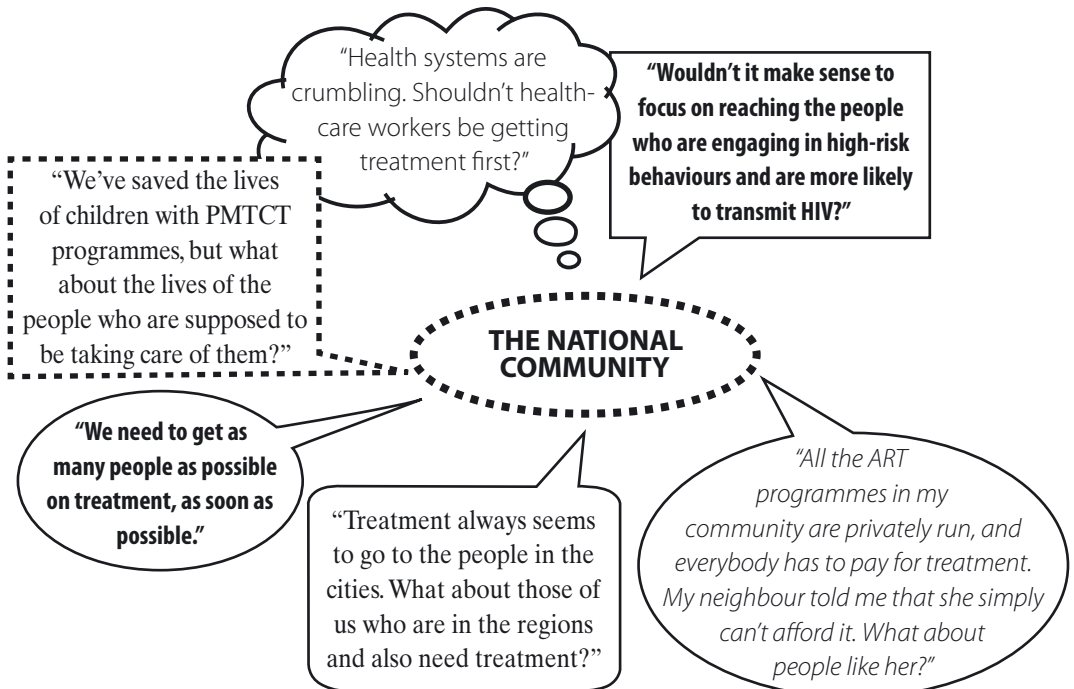
MOVING FROM CITIZEN PREFERENCES TO POLICIES AND PROGRAMMES BUILT ON EVIDENCE AND CITIZEN VALUES

The citizen engagement process is essential for satisfying two of the four elements of fair process:

Publicity: The process must be transparent and involve publicly available rationales for the priorities that are set.

Relevance: Stakeholders affected by the decisions must agree that the rationales rest on reasons, principles, and evidence which they view as relevant to making fair decisions about priorities; community and stakeholder participation and voice must vary in an appropriate way with the institutional context.

Citizens will probably have different ideas about what an equitable response to the epidemic looks like. These understandings will have a variety of sources, ranging from personal experiences to the experiences of friends, family, neighbours and colleagues, and to formal professional training in healthcare, economics, human rights, and other disciplines. These understandings form the starting point for a deliberative priority-setting process.



Fair process is an essential part of decision-making as it helps citizens to understand each other and the foundations of each other's values and preferences.

Deliberative forums allow for the sharing of both technical information and information on human rights norms and obligations. Through dialogue, policy decisions can be developed on the basis of reasons, principles, and evidence which are relevant and responsive to the needs of the community.

Box 14: Building a deliberative decision-making model

In the deliberative process, positions need to be articulated in terms of responsiveness to a need (which is evidence-based), and the rationale for the decision must be provided. Ethical principles can be helpful when articulating the rationale in terms of duties and impacts upon the community.

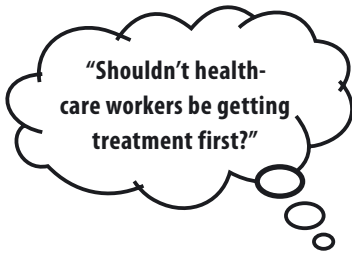
A position expressed as a preference or opinion...

becomes

...one based on evidence...

- snapshot of health systems human resource needs.
- number of beds closed because of lack of health care workers.
- number of people who would receive care if those beds were open.
- number of health-care workers with HIV/AIDS (and as percentage of health sector workforce).
- number of people in the community who are living with HIV/AIDS and who would be able to return to work if they responded well to treatment.
- etc.

For example:



...and values/ethical principles

- UTILITARIAN PRINCIPLES: because health-care workers perform a valuable function in the community by improving the health and well-being of others, and because the health system is under pressure because of the relative scarcity of health-care workers, giving priority to health-care workers living with HIV/AIDS will allow them to perform a valuable social function. (Result: maximization of social utility through anticipated secondary benefits.)
- COMPENSATORY PRINCIPLES: because some health-care workers have been infected by HIV/AIDS while performing their professional duties, and because employers were unable to provide adequate protection, justice demands that treatment programmes be provided on the basis of the risks endured for the sake of a community benefit.

Rationales for policy positions are in turn expressed in terms of both their ethical dimension and their evidence base

- The impact of health-care workers' contribution to the public good can, for example, be expressed as the number of people cared for during a certain period of time. The secondary benefit of this care can also be accounted for.
- A programme designed to offer treatment to present and former health-care workers living with HIV/AIDS will reach a certain number of professionals, resulting in an expectation that a certain number of people will either be able to continue working or return to work.
- The programme will help to fill a certain number of empty positions in the health system, resulting in a certain number of beds being created or reopened.
- The programme will respond to a certain number of cases of HIV which were acquired by professionals while performing their duties.
- etc.

Proposed programmes are then compared for their abilities to reach people equitably and effectively

- Treatment programmes for health-care workers
→ cost, reach, equity implications.
- Expansion of treatment programme in university hospital
→ cost, reach, equity implications.
- Programme to treat IDUs
→ cost, reach, equity implications.
- etc.

Equitable access to treatment and care for HIV-positive children depends on research and development which yield safe and effective drug regimens in addition to diagnostic equipment which meet children's needs. In research trials involving children, informed consent should be obtained from the parents or guardians of the participants in accordance with national legislation and ethical guidelines. Children should be involved in the decision-making process, including decisions on treatment, to the extent that they are capable.⁴⁴ At the programme level, leaders must be committed to ensuring that health care providers have the medications required to treat children, the appropriate equipment, legal environment, and skills necessary for testing, monitoring, and care.

ANNEX

IMPLEMENTATION OF FAIR PROCESS

The following questions are intended to serve as concrete examples of what it means to adhere to fair process criteria in defining policies. In so far as possible these questions should be addressed during the national and subnational decision-making process (the discussion of fair process draws on the work of Prof. Norman Daniels).⁴⁵

Publicity

- Do the decision-makers provide public access to the full rationale for their decisions and not simply to their recommendations?
 - Do they hold public hearings during the process of arriving at the recommendations?
 - Are the rationales as accessible as the recommended requirements?
 - Are the rationales presented in ways comprehensible to people who are interested in understanding them?
 - Are the stakeholders who are involved in deliberation about these rationales free to discuss their arguments outside the deliberative process?
 - Are complaints that are brought by decision-makers from the national and subnational levels made public so that the responses to the proposals are also publicly accessible?
- Do they distinguish empirical issues from ethical issues so that values are not submerged within technical conclusions by a narrow range of experts?
 - Do they consult with and welcome to the deliberation a broad range of stakeholders affected by the decisions? Are the stakeholders from all relevant groups? Are they from the appropriate levels (national, regional, local) at which the effects of recommendations will be felt?
 - Do they support the stakeholders during the deliberative process by facilitating access to information and providing them with an opportunity to understand the evidence and interact with others engaged in the deliberative process?
 - Do they treat disagreements with respect and patience and seek to reconcile differing views?
 - Do they empower the stakeholders to be—and to see themselves as—true rather than token participants? Is the involvement of the stakeholders valued by other experts or merely tolerated?
 - Do they make an effort to organize the results of stakeholder deliberation so that everybody can see the framework for different positions as clearly as possible and understand what is at issue in cases of disagreement?
 - Do they discuss and deliberate about the process for resolving disagreements so that people feel the process to be fair and genuinely respectful of them?
 - Do they develop rationales that are inclusive of points of disagreement so that others can see the careful nature of the deliberation?

Relevant reasons

- Do decision-makers undertake a careful comprehensive gathering of relevant evidence bearing on the empirical background to the various ethical issues that have to be addressed?
- Do they expand this evidence as new arguments are raised which involve empirical assumptions?

- Do they make recommendations about priorities and rationales which are appropriately respectful of local discretion and authority?

Do the stakeholders involved at each level of decision-making:

- pay careful attention to fair process in deliberation at other levels and consider arguments and resulting rationales in their own deliberations;
- formulate their rationales so that they guard against charges of favouritism, especially where priorities among special groups are at issue;
- concentrate on arguments that all stakeholders can see as relevant, affirming a common interest in solutions that produce fair outcomes for the community and all of its members?

Revisability

- Do decision-makers at the national and subnational levels invite disagreements raised by decision-makers at other levels and revisit policies in the light of these disagreements?
- Do they consider that decisions are best reached through an iterative process in which new evidence and arguments are welcomed as an opportunity to improve quality? Are the results of routine monitoring and evaluation of progress fed back and used to revise policies?
- Do they assure decision-makers that they have an opportunity and responsibility to raise objections at levels other than their own and to request reconsideration?
- Do they ensure that appropriate stakeholders are involved in the careful deliberation about revision and that they are treated and supported in the ways described earlier, especially if they were left out of the initial process?

- Is there a mechanism for making appeals against decisions, including the grounds for complaints, matters of public record in addition to the decisions themselves?

- Is the responsiveness to appeals and other complaints seen as part of a quality improvement process or is it dismissed as rebelliousness or obstructionism?

Enforcement

Do decision-makers:

- make themselves accountable to lower levels of decision-making for having carried out a fair process in their deliberations;
- challenge decisions made in response to their recommendations on the grounds that the decisions were not made in accordance with fair process;
- seek international agreements or national regulations on the elements of fair process which should be involved in such priority-setting decisions;
- seek agreements about components of fair process among decision-makers at each level so that standards are clear and departures from them can be challenged?

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