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ETHICS AND EQUITY IN ACCESS TO HIV TREATMENT — 3 BY 5 INITIATIVE

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Table of Contents

A. Background.....	1
B. Description and analysis of issues.....	3
1. Eligibility criteria for individuals to receive ART.....	3
1.1 Medical eligibility	
1.2 Psychosocial criteria	
2. Key ethical principles for fair distribution of ART.....	3
2.1 Formal principle of equity	
2.2 Substantive (material) principles of equity	
2.2.1 Utilitarian	
2.2.2 Egalitarian	
2.2.3 Maximin (concern for the worst off)	
2.3 Justice as reciprocity or compensation	
3. Categories that may be considered priorities.....	6
3.1 Individuals who are already infected	
3.1.1 Mothers identified through PMTCT	
3.1.2 HIV positive infants of mothers with HIV	
3.1.3 People enrolled in vaccine and microbicide and behavioural prevention trials	
3.1.4 People screened for preventive HIV vaccine trials	
3.1.5 People who have been in epidemiological studies	
3.1.6 Individuals who have been in clinical trials	
3.1.7 People who have contracted HIV through unsafe blood collection procedures or use of unsterile medical practices	
3.2 Infected partners and children of individuals receiving ART	
3.3 Health care workers	
3.4 Teachers and other essential human resources	
3.5 Marginalized groups at high risk of having HIV	
3.6 Children	
3.7 Orphans and street children	
3.8 Women	
3.9 Pregnant women	
3.9.1 Individuals with TB	
3.9.2 Individuals needing post exposure prophylaxis	
3.9.3 Others that might be chosen through the implementation of fair procedural mechanisms	
4. Selection of locations for ART programmes.....	10
4.1 Infrastructure and personnel requirements	
4.2 Urban or rural health facilities	
4.3 Public hospitals providing primary care	
4.4 Private health facilities or employer based services	
4.5 Specialized medical facilities	
4.5.1 Antenatal and family planning clinics	

4.5.2	STI clinics	
4.5.3	Injection drug treatment programmes	
5.	The level of policy formulation and implementation.....	11
5.1	National level (Ministry of Health)	
5.2	Local or district level (appropriate geopolitical unit)	
5.3	Facility level	
6.	Mechanisms for procedural fairness.....	12
6.1	Community involvement	
6.2	Transparency	
6.3	Inclusiveness	
6.4	Impartiality	
6.5	Due process	
6.6	Accountability	
C.	Alternative options for equitable access to ART.....	14
D.	Conclusions.....	18

A. Background

This document¹ is designed to provide ethical guidance on the issues countries must address in order to ensure fair distribution of health resources in scaling up ART in the 3x5 Initiative. This WHO/UNAIDS initiative aims to reach those in need of treatment and to identify those who are hard to reach, especially in populations that have not had access to services. WHO and UNAIDS have identified three core principles that underlie the effort: urgency, equity and sustainability.² Among other guiding principles for the initiative is one that emphasizes the relationship between treatment and human rights.³ A global responsibility exists to support resource-limited countries to scale up ART in the face of a global public health emergency. In addition, there is an accompanying country-level responsibility to fulfill the right to treatment as enunciated in human rights guidelines for HIV/AIDS.⁴ It will not be possible to reach everyone in need as the 3x5 Initiative begins, so it is necessary to work progressively towards universal access as a human right. Most countries will use a phased approach and this will necessitate making decisions about priorities in allocating resources. It is important to emphasize that treating three million people by the end of 2005 is a *target*, not an ultimate goal. The eventual goal is to provide universal access to ARV treatment for all who need it.

In the interim, when not all persons in need of HIV treatment can be served, distribution of HIV treatment services should be guided by principles of equity or fair distribution and considerations of human rights, including the right to freedom from discrimination⁵ and the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.⁶ The right to health embodies entitlements: the right to a system of health protection. In turn, the system of health protection must provide “equality of opportunity for people to enjoy the highest attainable standard of health.”⁷ Although adherence to human rights provisions is essential, none of the various human rights treaties or declarations provides specific criteria for setting priorities or choosing among potentially

relevant principles of equity.

Ideally, the 3x5 Initiative would provide ARV treatment free of charge through public health-care institutions. This would ensure not only that the poor will not be excluded from the scaling up of ART, but also that priority will be given to the large numbers of people in developing countries for whom existing treatments have not been affordable and who would continue to be excluded if they had to pay out-of-pocket for ART. Although not everyone agrees that the poor should be given preference in scaling up ART, an argument in favor of giving preference to the poor is supported by a leading ethical principle (see 2.2.3 below). Moreover, on a practical level evidence from existing programmes in which people in developing countries have had to pay for some or all of the cost

(1) I am grateful to Reidar Lie, Norman Daniels, Dan Brock, John Broome, Praphan Phanuphak, Dirceu Greco, Charles Ngwena, and Angela Ballantyne for their comments and helpful suggestions on earlier drafts of this paper.

(2) WHO/UNAIDS. *Treating 3 Million by 2005: Making it happen* (WHO 2003), p. 1.

(3) “The Initiative will advance the United Nations goals of promoting human rights as codified in the Universal Declaration of Human Rights, as expressed in the WHO Constitution in seeking the attainment of the highest possible standards of health, and clarified in the Declaration of Commitment of the United Nations General Assembly Special Session on HIV/AIDS in 2001.” WHO/UNAIDS. *Treating 3 Million by 2005: Making it happen*, p. 10.

(4) Office of the United Nations High Commissioner for Human Rights and the Joint United Nations Programme on HIV/AIDS, *HIV/AIDS and Human Rights: International Guidelines, Revised Guideline 6* (United Nations: New York and Geneva, 2002).

(5) “Non-discrimination: 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.” *General Comment No. 14* (2000), Committee on Economic, Social and Cultural rights, Economic and Social Council, e/c.12/2000/4, 11 August 2000.

(6) Article 25, paragraph 1, of the *Universal Declaration of Human Rights*; Article 25, paragraph 1, of the *Universal Declaration of Human Rights*; Article 24 of the *Convention on the Rights of the Child*; and Article 12 of the *Convention on the Elimination of All Forms of Discrimination against Women*.

(7) *General Comment No. 14* (2000), Committee on Economic, Social and Cultural rights, Economic and Social Council, e/c.12/2000/4, 11 August 2000.

of ARVs demonstrates an array of negative medical and social consequences (interruption of therapy, deteriorating health status, poor adherence, and development of drug resistance).⁸

Even if people from middle and low income groups can afford to pay something to start on treatment, it is unlikely that they will be able to continue in the longer term with what is essentially treatment of a chronic illness. There are many examples across Asia and Africa of people becoming impoverished because they have sold all their assets to meet healthcare costs. Requiring patients to pay for at least a portion of their treatment has been justified by the claim that it would guarantee better adherence to therapy; but there is no empirical evidence showing that providing free treatment results in lesser adherence to the drug regimen. At this time, the issue of providing ART free of charge has not yet been resolved by WHO. However, there is agreement that economic status should not be a barrier to access to ART.

This document will not discuss the complex issue of co-payments or user charges. One option would be to introduce a “means” test that identifies those who are able to pay out of pocket, followed by a sliding scale for the amount each individual would have to pay. Evidence from other areas of health care delivery has shown that it is difficult to design a fair and efficient system of means testing. Although it might be fair that those who can afford treatment should be required to pay for it, it is likely that money would be wasted on administrative costs, con-

(8) Kathy Attawell and Jackie Mundy. *Scaling up the Provision of Antiretroviral Therapy in Resource-Poor Countries: A Review of Experience and Lessons Learned*. DFID Health Systems Resource Center. Prepared for the UK Department for International Development in collaboration with WHO (August 2003).

(9) WHO/UNAIDS. *Treating 3 Million by 2005: Making it happen*, p. 10.

(10) *General Comment No. 14* (2000), Article 12, para. 19.

joined with the possibility of deceptive and corrupt schemes.

The design of a fair system of means is beyond the scope of this paper. An underlying assumption, however, is that every country and community should ensure that the lowest socioeconomic classes and the poorest individuals are given a high priority for access to ART, consistent with other eligibility criteria for treatment. This is in accordance with the guiding principle of equity as stipulated in the 3x5 Initiative: “The Initiative will make special efforts to ensure access to antiretroviral therapy for people who risk exclusion because of economic, social, geographical or other barriers.”⁹ Ensuring that the poor receive treatment also follows from human rights obligations: “States have a special obligation to provide those who do not have sufficient means with the necessary health insurance and health-care facilities.”¹⁰

The 3x5 Initiative will necessitate making some hard choices. Some governmental authorities may be reluctant to make decisions about who should be first to gain access to ART in their country or district because of fear of criticism and the charge that some groups have been left out or given unfair priority. But what is the alternative? Not to make explicit, careful decisions justified by principles of ethics and equity is likely to be irresponsible. If the international community fails to address these challenges of priority, then the probable outcome will be a perpetuation of existing inequalities.

The structure of this guidance document is as follows. Section B provides a brief explication or analysis of the items listed in the accompanying Table of Contents. Section C lays out alternative schemata for fair distribution of ARV treatment services, from among which decision makers may choose based on the justifications provided. Section D contains a few concluding remarks.

B. Description and analysis of issues

1. Eligibility criteria for individuals to receive ART

1.1 Medical eligibility

This is a necessary but not sufficient condition for receiving ARV treatment. Fulfilling medical criteria for ART, as defined by WHO (CD4 count below 200) is a threshold condition that must be met before proceeding to other criteria for selecting individuals or groups to receive ARVs. This criterion results in beginning ART at a later point in the disease process than the guideline followed in some industrialised countries (CD4 count below 350). The decision of whether to treat patients with CD4 counts above 200 is left to national programmes. However, it is evident that if the higher CD4 count is chosen, more patients will be initially eligible for treatment and a smaller percentage of those who are eligible will be able to be treated.

1.2 Psychosocial criteria

1.2.1 Adherence to treatment regimen (a utilitarian criterion; see 2.2.1 below)

Individuals already receiving ART or other medications (e.g., for TB) will normally have demonstrated adherence or lack of adherence to a treatment regimen. All patients should receive treatment preparedness education and be assigned a treatment supporter (either a health worker or family/friend trained in treatment support). Treatment preparedness and treatment support include support for adherence, but also involve ongoing prevention activities and psychosocial support for the person beginning ART. It is a requirement of both ethics and human rights to avoid a priori discrimination that would exclude individuals or groups in the absence of convincing evidence that they are or would be nonadherent. Prejudicial judgments have been made in the past regarding the capability of adherence on the part of some individuals or groups. For example, evidence exists that some individuals who habitually use intoxicating substances have a lessened capability for adherence; but other evidence from harm reduction programs has shown that drug injection users can be highly adherent to ART.

1.2.2 Family or social supports

Selecting individuals who have family or other social supports has been used as an eligibility criterion for receiving ARVs. However, that could discriminate against unmarried individuals or those lacking social supports, especially members of marginalized groups. At the same time, application of this eligibility criterion could result in including people antecedently suspected of being nonadherent (such as those who use drugs or alcohol), since the family or other social supports would be likely to improve their prospects for adherence. At its three HIV/AIDS clinics in Khayelitsha, South Africa, Médecins Sans Frontières (MSF) gives preference to individuals based on the number of their dependents, health status, income, and other social criteria.¹¹ Each of these criteria must be analyzed separately to determine whether they unfairly discriminate against some individuals or groups and also whether they justify giving priority to individuals with these characteristics.

2. Key ethical principles for fair distribution of ART

As noted above, one of the guiding principles of the 3x5 Initiative is equity. Several general ethical principles, in addition to specific principles of equity, are potentially relevant and can provide justifications for choosing one or another scheme for fair access to ART. These principles point to criteria or concerns that must be considered; but the principles can conflict, and it then becomes necessary to balance competing concerns. There is no uniquely correct way of doing this balancing. Moreover, there is no consensus on how the different principles ought to be weighted, or on how the goal of maximizing health should be weighted against other social goods. Different people often have different weightings. For these reasons, leading commentators have urged that emphasis has to be placed on fair processes.¹² To the extent that

(11) Attawell and Mundy.

(12) Norman Daniels and James E. Sabin. *Setting Limits Fairly* (New York: Oxford University Press, 2002).

decision makers in each country can agree on principled ways to set priorities among the various individuals and groups eligible for ART, the following principles can be used to justify their decisions. Even given such agreement, the use of fair procedures remains necessary since equity demands adherence to both substantive and procedural aspects of ethics.

2.1 Formal principle of equity: treat like cases alike

This is a purely formal principle, and is the basis for the requirement of non-discrimination in the right to health. No one should be denied health care on the basis of arbitrary or non-relevant criteria. However, this formal principle does not state what the relevant and non-arbitrary criteria are. Therefore the analysis must proceed by using substantive or material principles, that is, principles that provide criteria for choosing among individuals or groups that are relevantly similar. It is, however, appropriate to invoke this formal principle in order to prevent discrimination against some infected individuals or groups.

2.2 Substantive (material) ethical principles

2.2.1 Utilitarian ethical principle

Utilitarian principles can take several forms. In its most general form, the utilitarian principle calls for maximizing overall societal benefits. Utility is sometimes understood as efficiency in reaching the goal of maximizing societal benefits. Applied specifically to health policy, the principle aims at maximizing health benefits for the society as a whole. The best policy would be one that embodies a mix of health care services that produces the greatest overall health effects. Although the utilitarian principle has been understood to embrace considerations of justice¹³, it does not, strictly speaking, provide a basis for choosing among eligible groups in the most equitable manner.

(13) This is the position of John Stuart Mill, one of the foremost expositors of utilitarianism.

(14) Dan W. Brock. "Fairness and Health." Chapter 14.3 in *Summary Measures of Population Health*, ed. Chris Murray et al. (Geneva: WHO, 2002).

In the context of scaling up ART, a utilitarian approach could call for treating the greatest number of people, even if some (e.g., the sickest) could benefit only temporarily before their overall health status worsens. On this view, health benefits would be maximized even though the sickest people would receive a small amount of benefit. On a different and more widely accepted interpretation, maximizing health benefits would mean giving priority to people whose medical condition is such that they respond better to treatment and are likely to survive for the longest time. Adhering to this second interpretation of the utilitarian principle would therefore exclude patients whose HIV disease has progressed to a point where only a temporary health benefit can be expected. This is an example of the "fair chances versus best outcome" problem.¹⁴ Some would argue that equity requires giving everyone a fair chance at treatment, even if that option would not result in the best overall health outcome.

Although the principle of health maximization has widespread support in the public health literature, there are disagreements and uncertainties within the principle itself that need to be addressed and that have specific policy implications. Which benefits should be counted? Only the medical benefits of treatment for the individuals? Or other benefits, as well? For example, treating health care personnel or teachers has the additional benefit of ensuring that needed personnel are available for treatment and health promotion, which produces additional health benefits for society as a whole. Similarly, treating factory workers rather than children or unemployed people produces economic benefits for the country, which in turn could be used to increase treatment access. However, giving priority to the more productive members of society would perpetuate the exclusion of individuals and groups who have historically lacked access to health care. There is no agreement about the appropriateness of taking these types of considerations into account. There is, however, agreement that social worth measured in terms financial wealth or social promi-

nence is not acceptable as a criterion for giving first priority to individuals or groups. In addition, individuals or groups should not be denied access based on perceptions of their lack of social worth. If certain groups are given priority, it is important to ensure that the reason for this is the anticipated secondary health or social goods that are produced, and not the inherent worth of the chosen groups.

Implications:

- a. Exclusive use of this principle could result in ignoring specific claims for priority of access on the part of vulnerable or marginalized groups;
- b. It implies the use of a triage system designed to maximize medical utility.

2.2.2 Egalitarian principle of equity

Egalitarian theories call for distributing resources equally among persons, or distributing goods, such as health care services, or health, equally among different groups. This could mean either that everyone should receive the same amount of resources for health care; or that everyone should receive the same amount of health care services; or that insofar as possible, health status among different groups should be minimized. This principle is the basis for schemes that emphasize health equity over health maximization. The goal is to reduce disparities in health status among different groups or strata in society: the poor, women, people living in rural areas, ethnic or racial minorities, and others.

Within this approach there are also ambiguities and disagreements, primarily with regard to what should be equalized: resources for health, health status, or access to health care. Because health needs differ widely among people and groups, the choice has important policy consequences. Giving everyone the same resources will produce different outcomes because health care needs vary. This illustrates how providing equal amounts of resources can be inequitable. For example, groups that have TB or malaria in addition to HIV/AIDS have greater health

needs than PLWHAs without other diseases. Aiming at equalizing health status will potentially divert resources to interventions that produce very small benefits for people who require enormous resources to obtain any benefit at all.

Implications:

This principle is relevant to providing equitable access to ART for groups that have been underserved by the health system or denied care altogether, and therefore suffer generally worse health status. There is some overlap with the “maximin” principle, concern for the worst off (see 2.2.3 below), since the economically least advantaged classes in every society have generally been underserved, have had less access to health care, and have a worse health status than more affluent groups. However, specific groups such as women and racial or ethnic minorities have been underserved in some societies even when they are not among the least advantaged economically. Moreover, in some societies, marginalized groups such as IDUs, sex workers, and MSMs have either been denied access to ART or have had difficulty gaining access. This principle calls for ensuring that all groups and categories of persons have equal access to ARVs; but taken by itself, it does not imply that these groups should be given priority over others with the same medical needs. Additional considerations are needed to make the case for determining priority of access.

2.2.3 Concern for the worst off or the least advantaged (the maximin principle¹⁵)

“Maximin” means “it matters morally that we help those that are least well off.” This principle calls for giving preference to those who are worst off in some relevant respect, but its status as a principle of equitable selection is open to debate. In the context of health care delivery, this is usually understood to refer to those who are worst off in terms of health status, but it could also apply to a) the poorest; b) the lowest socioeconomic class; c) the most vulnerable (for

(15) Sarah Marchand, Daniel Wikler, and Bruce Landesman. ‘Class, Health, and Justice,’ *The Milbank Quarterly*, 76 (1998), 449-467: 460.

example, children, especially orphans); d) groups that are marginalized or most discriminated against (in many societies, IDUs, sex workers, MSMs); or e) those who live in remote areas with poor access to any type of health services. Since, as already noted, the highest priority in general terms should be given to the least economically advantaged individuals and groups, the 'least advantaged' in this guidance document refers primarily to the sickest individuals and groups c), d), and e).

On one interpretation, we can consider the least advantaged to be those who are the sickest, irrespective of how much they would benefit from ART. This would mean that if patients in an advanced stage of clinical AIDS can still benefit from ART, they should be among the first treated. The consequence of this would be to divert resources away from people who could potentially benefit more from treatment; the result would be in direct conflict with a health maximization principle. This is, again, the fair chances-best outcome problem described above in 2.2.1.

On another interpretation, concern for the worst off would mean giving priority to those most in need, where need is understood as how badly off people would be if not treated (this can be referred to as urgent need). According to this view, preference should be given to patients in urgent need of ART on the basis of how much they can benefit individually, treating the most needy first. Using this principle would result in treatment of comparatively fewer patients than using a straightforward utilitarian principle.

There is no clear or obvious way of determining how much weight should be given to a principle that calls for giving priority to the sickest. On the assumption that giving first priority to the

(16) Dan W. Brock, "Ethical Issues in the Use of Cost Effectiveness Analysis for the Prioritization of Health Care Resources." In *Bioethics: A Philosophical Overview*, eds. George Khushf and H. Tristram Englehardt, Jr. (Dordrecht: Kluwer Publishers, forthcoming 2004). Also in *Ethical Foundations of Health Equity*, eds. Sudhir Anand and Amartya Sen (Oxford: Oxford University Press, forthcoming 2004).

(17) WHO/UNAIDS. *Treating 3 Million by 2005: Making it happen*, p. 10.

sickest is a reasonable ethical principle, the problem becomes how much aggregate health benefits should be sacrificed in order to treat the sickest first. Furthermore, with respect to who are the "worst off," "most vulnerable," or "least advantaged" according to other criteria, there is likely to be considerable variation among different countries as well as disagreements within a given society. Nevertheless, as stipulated in the Initiative's guiding principle, Treatment and Human Rights, "Under 3x5, special attention will be given to protecting and serving vulnerable groups in prevention and treatment programmes."¹⁷

2.3 Justice as reciprocity or compensation

A different yet relevant category identifies fairness with the concepts of reciprocity and compensation. Justice as reciprocity calls for providing something in return for contributions that people have made. One example might be individuals who have participated in HIV-related research: participants in AIDS treatment trials, and those in epidemiologic or preventive vaccine trials discovered to be HIV positive. These people undertook the risks or inconvenience of serving as research subjects without a guarantee of receiving any direct benefit. More controversial, however, is selection of individuals or groups who have contributed to society in other ways, unrelated to HIV/AIDS research. Rewarding people with life-saving medications in response to their past contributions to society has both supporters and opponents.

Compensatory justice could apply to individuals who were harmed as a result of substandard medical practices such as blood collection, use of unsterile needles, etc.

3. Categories or groups of people that decision makers may consider to be priorities for ART services

Giving first priority to any individuals or groups will be highly controversial. Only a subset of principles used to set priorities for specific groups are properly considered principles of

equity. Other ethical principles may be relevant, and selection might also be made using criteria that are primarily pragmatic (for example, all infected members of a family). Equity or fairness may actually oppose giving priority to certain groups that, if selected, are likely to produce the greatest overall benefits to society.

Two general subgroups could initially be eligible to receive treatment. The first subgroup comprises individuals who already know their HIV positive status, and those who have a clinical diagnosis of advanced stage HIV infection. The second general subgroup comprises individuals who will be identified as HIV positive through targeted screening programs not yet established. The point of distinguishing between these two general subgroups is that the principle of utility (understood as efficiency) could dictate giving first priority to individuals already identified as HIV positive. However, other considerations of equity militate against using efficiency as the sole criterion for priority setting (see 3.1 below).

Within both of these general groups, several specific subgroups might be considered appropriate for first priority for ART services. Some of these latter groups and the reasons that can justify why they might (or might not) be given priority are noted below. Even though there might be reasons in favor of a particular group, there might be equally good reasons in favor of other groups, so decision makers should consider all these reasons for providing access to one group or another before deciding on a particular policy.

3.1 Individuals who have already been tested and know their HIV-positive status, and those who have a clinical diagnosis of advanced stage HIV infection

Giving priority to this group in general can be justified primarily by the principle of utility maximization, since additional resources are not needed for VCT. Although this approach would be more efficient from an economic standpoint, it would be unfair to those individuals who have not yet been tested and found to be HIV posi-

tive, but who are eligible and have an equal need for treatment.

Within this first subgroup, another well-known principle is potentially applicable: first come, first served. This refers to the order in which people were tested and learned that they were HIV-positive. As in any queue, those who came first, and therefore waited longest, might be considered the first ones to be served. However, use of this principle exclusively would have unfair consequences according to other principles of equity. For example, if in one location most of those tested first were men, fewer women would then have access to treatment in early stages of the initiative and that would violate gender equity. If the first to be tested in another location were pregnant women in PMTCT programmes, it would be unfair to nonpregnant women, men, and children who learned of their HIV-positive status at a later time. The first come, first served principle must therefore be balanced and constrained by the additional ethical principles that may apply to the following subgroups.

3.1.1 Mothers with HIV identified through sites offering PMTCT¹⁸

Priorities for these women can be justified on grounds of a) equity and b) social utility.

- a) Their infants were given the opportunity to avoid acquiring HIV through the PMTCT program, but the women were given only AZT or Nevarapine—a medication that could prevent transmission but would not benefit the women themselves. Fairness could dictate that these women should be given priority for treatment, on a par with the benefit offered to their infants.
- b) Social utility is increased by the existence of fewer AIDS orphans. Treating HIV positive mothers promotes this goal.

3.1.2 HIV positive infants of mothers who are HIV positive

Infants who become HIV positive in spite of the preventive treatment provided in PMTCT pro-

(18) In Zambia, immediate priority will be given to mothers with HIV identified through sites offering PMTCT, their partners and infants born with HIV.

grams already had one chance that might have prevented HIV infection. Arguably, it would be unfair to give these infants treatment because it would provide a second chance for a healthy life, whereas other HIV-positive infants had not had a first chance. Nevertheless, infants—like all children—are vulnerable because they lack autonomy and the capacity to act independently and seek treatment on their own behalf.

3.1.3 People enrolled in vaccine and microbicide and behavioural prevention trials who become HIV positive during the trial

The principle of justice as reciprocity could justify giving priority to this group, based on fair compensation for their contribution to the vaccine trial. (Providing access to vaccine trial participants has already been endorsed by the HVTN.) In the absence of a cohort of subjects who become HIV-positive during preventive trials, there could be no meaningful results of such trials. On the other hand, some might argue that the prevention research itself provided an opportunity to avoid HIV infection, so these groups, too, would be given a second chance to preserve their health before others have received a first chance. The strength of these competing considerations depends on the projected efficacy of the preventive methods.

3.1.4 People screened for vaccine, microbicide, and behavioural prevention trials and excluded because they were found to be positive

Although this group did not contribute to the clinical trials, the fact that they are already identified as HIV positive and have undergone VCT would make them appropriate on utilitarian grounds but not justified by a principle of equity.

3.1.5 People who have been in epidemiologic studies and identified as HIV positive

The rationale is the same as that in 3.1.4.

(19) In April 2003, China started to provide free ARVs to people in rural provinces who contracted HIV through government-approved blood collection stations, through county, township and village health facilities.

(20) In Botswana, HIV positive women and their spouses and infants will be targeted initially.

3.1.6 Individuals who have been in clinical trials but are no longer receiving ART because it was not provided at the conclusion of the research

This group might deserve high priority because they have been left worse off following their trial participation than they were during the research. Giving preference to this group could not be justified on grounds of equity, since they have already received some therapeutic benefit. Indeed, one argument is that having already received some benefits in terms of improved quality and prolongation of life, it would be unfair to provide more such benefits when other groups have not yet received any. However, an overriding public health consideration justifies continuing ART for those already receiving treatment: withdrawing ARVs may contribute to an increase in drug-resistant strains. In addition, when ART has already been provided to participants in clinical trials, the necessary infrastructure is already in place to begin to provide wider access to others. The utilitarian principle supports this approach.

3.1.7 People who have contracted HIV through unsafe blood collection procedures or use of unsterile medical practices¹⁹

This group deserves a high priority in accordance with the principle of compensatory justice. They are owed just compensation for lack of diligence or failure to adhere to proper medical practices in the healthcare system.

3.2 Infected partners and children of individuals already receiving ART²⁰

Priority for infected family members can be justified on grounds of medical and social utility, but not on grounds of fairness. The prospect of sharing ARVs among family members when only one is granted access to treatment militates against treating some but not all infected members of immediate families. Sharing medications within the family can lead to inefficacious treatment as well as drug-resistant strains. Some argue further that based on the traditional, social importance of the family in all cultures, it is the family rather than the individual that

should be considered the relevant unit for ARV treatment.

3.3 Health care workers: physicians, nurses, skilled medical laboratory technicians, counselors providing VCT, and others essential to providing medical care and treatment

The utilitarian principle, especially as applied to health maximization, justifies according priority of access to this group. The maximin principle (concern for the worst off) may also apply indirectly, since treatment of the sickest and most vulnerable populations could not succeed unless health workers are given priority. In general, it would appear that giving priority to health workers is supported by both principles. However, a decision to give priority to health workers depends on empirical facts: whether there is a shortage of health care workers and an urgency in treating those who are infected. For example, in some countries there may not be as great a need in urban areas where there is a greater proportion of health workers.

3.4 Teachers, high-level government employees²¹, and other human resources who make essential contributions to the viability and stability of society

The utilitarian principle applies to this group the same as to medical personnel; but there are no considerations of equity or fairness that justify giving preference to teachers and other essential personnel. However, there is likely to be considerable uncertainty and disagreement concerning which groups are most essential and therefore should be given priority. This is one of the issues that would have to be determined by policy makers in accordance with mechanisms of fair procedures (see section 6 below).

3.5 Marginalized groups at high risk of having HIV (MSMs, sex workers, IDUs)

These groups could be given priority of access on grounds of medical utility. Since they engage in high risk behaviors, VCT followed by ARV treatment can aid in efforts to prevent the spread of HIV. In addition, appeal to the principle of compensatory justice could argue for

providing treatment to groups that have traditionally been marginalised and excluded from medical care. These groups may also be considered among the “least advantaged” because of stigmatisation and marginalisation in many societies.

3.6 Children

Children are a vulnerable group, unable to advocate or seek treatment for themselves. They also constitute the future of every society. It is likely that the majority of HIV positive children will be identified as a result of a parent having been tested and found to be positive; alternatively, some children will manifest clinical disease. As members of a family receiving ART (in accordance with 3.2 above), these children should be given the same priority for treatment as the other family members.²² In addition, the human rights treaty that deals with children specifies their right to the highest attainable standard of physical and mental health.²³

3.7 Orphans and street children

These groups are doubly vulnerable: not only are they children, but they lack homes, parents, or other ongoing caregivers. Unlike children likely to receive treatment because they are in families where one or both parents receive ART (see 3.6), these children would not otherwise be identified as HIV positive and given access to treatment. The maximin principle could justify selection of orphans and street children, as they are likely to be among the worst off in society.

3.8 Women

In some societies, women and girl children receive medical treatment only after male members of the family are treated. Discrimination against women continues in many developing

(21) It was reported at one consultation that in countries in southern Africa, posts in the government are vacant because of illness. In one country, 45 % of positions are vacant.

(22) The Indian government plans to give free AIDS drugs to all HIV positive children under 15. (Free drugs for HIV+ kids, mothers - [13-11-2003] - Hindustan-Times.com.htm).

(23) Article 24, *Convention on the Rights of the Child*.

countries in clear violation of the human rights treaty, Convention for the Elimination of All Forms of Discrimination Against Women (CEDAW). In line with the provisions of that treaty, women must have access to ART equal to that of men. Although women in general should not be considered vulnerable, in societies in which they are oppressed and subjected to decisions made by husbands and fathers, women can properly be thought of as vulnerable.

3.9 Pregnant women²⁴

Pregnant women could constitute a high priority group for access on grounds of medical and social utility, but not specifically on grounds of equity. Programmes that provide VCT for pregnant women exist in antenatal clinics even where PMTCT programmes are not yet in place. Therefore, giving priority to this group would maximize the efficient use of resources (social utility) and also serve the social goal of lowering the rate of maternal to child transmission of HIV.²⁵ However, giving priority to pregnant women would be unfair to nonpregnant women. In societies that discriminate against women generally but place a high value on women only when they are pregnant, gender equity would not be served by giving pregnant women preference for treatment over nonpregnant women. An additional concern voiced by some is that if

(24) Kenya's proposal to the GFATM explicitly targets pregnant women who are HIV positive.

(25) Botswana has made pregnant women a priority target group for the national treatment programme.

(26) This group is being targeted initially in Botswana.

(27) Kenya's proposal to the GFATM explicitly targets individuals needing post exposure prophylaxis, including victims of sexual assault and health workers exposed at work.

(28) Most existing or proposed programs appear to have selected sites—regions, districts, hospitals—but have not set priorities for groups who would receive ARVs first. Countries taking, or planning to take, a district approach to delivery include Brazil, China, Lesotho, Mozambique, Rwanda, and Zambia. Most countries, especially in sub-Saharan Africa, are taking a phased approach to the introduction or scale up of ART through the public sector, starting initially with provision through selected provincial or regional hospitals. (Reported in Attawell and Mundy, "Scaling up the Provision of Antiretroviral Therapy in Resource-Poor Countries: A Review of Experience and Lessons Learned," August 2003).

pregnant women are given priority for treatment, women who know their HIV status will become pregnant in order to receive ART.

3.9.1 HIV positive individuals who have presented with TB.²⁶

Medical and social utility, but not equity, could justify giving priority to this group.

3.9.2 Individuals needing post exposure prophylaxis.²⁷

This group includes but is not limited to health-care workers who are exposed to HIV in caring for patients. The same considerations that justify giving priority to healthcare workers apply here.

3.9.3 Others that might be chosen through the implementation of fair procedural mechanisms

4. Criteria for selecting locations where ART programmes are to be introduced²⁸

Decision makers at the country level and possibly also at regional levels will have to decide where to establish treatment programs beyond those that already exist. All of the locations or facilities mentioned below should meet the criterion of sustainability for ART programmes. It is widely recognized that sustainability is a necessary condition for initiating a treatment program, especially because of the development of drug-resistant strains among individuals in whom treatment is begun and then withdrawn, but also for ethical reasons. Sustainability is one of the core principles identified by WHO and UNAIDS in undertaking the 3x5 Initiative.

4.1 Infrastructure and personnel requirements

In the initial roll-out of ART programmes, adequate infrastructure, including clinical care, laboratory and pharmacy facilities, and skilled personnel already in place constitute a necessary condition for providing safe and effective treatment.²⁹ These requirements are justified by the utilitarian ethical principle. It is true, unfortunately, that a focus on localities and institutions

where adequate facilities and personnel are already in place results initially in failure to provide ART in heretofore neglected areas. In order to provide wider access to treatment, the building of adequate infrastructure in those places should take place simultaneously with the introduction of the 3x5 Initiative in areas or institutions that are already well prepared to provide efficacious treatment. Changes in programmes can and should occur as capacity to provide ART is developed in places where the infrastructure is currently inadequate.

4.2 Urban or rural health facilities

A fair distribution of ART programmes requires scale up in both urban and rural areas. This is subject to the constraints noted in 4.1 above. However, even in those countries or regions where fewer people would be served in rural than in urban areas, an equitable geographic distribution calls for instituting programmes in places where there may be fewer candidates for ART so that the minority in need of treatment will not be neglected. This is a situation in which the utilitarian principle (maximize overall utility) conflicts with the egalitarian principle (minimize differences among different groups).

One selection criterion could be those areas where clinical trials (preventive vaccine or treatment trials) are ongoing or soon to be initiated. This selection would have the advantage of identifying individuals and groups who are HIV positive without the need to institute new VCT programmes prior to establishing ART programmes.

4.3 Public hospitals providing primary care

Aside from specialized health centers where free ARV treatment can be provided, general public hospitals are likely to be one of the main sites of treatment. Since these hospitals care for a wide range of patients, an equitable distribution in terms of age, gender, and other patient characteristics can readily be achieved.

4.4 Private health facilities or employer based services

It is to be hoped that these institutions will continue to provide the services already in place, including free ART or insurance-based programmes.

4.5 Specialized medical facilities

4.5.1 Antenatal and family planning clinics

4.5.2 STI clinics

4.5.3 Injection drug treatment programmes

The above facilities are appropriate sites for selection on grounds of utility, and in some cases, also on grounds of equity. VCT and PMTCT are already in place at many antenatal clinics, so it would be efficient to initiate ARV treatment programs there. Sex workers are likely to seek care at STI clinics, thereby providing equitable access to ART for this marginalized group. And IVDUs who attend drug treatment programmes can also have access at those sites. Initiating free ART at all of these sites could have the consequence of encouraging use of these facilities for their primary medical purpose, thereby maximizing health benefits in general.

5. The level at which policies for equitable access might be formulated

5.1 At the national level (Ministry of Health)

Decisions at this level involve the regions of the country where the first programmes will be introduced or existing programs expanded. Equity calls for a fair balance between rural and urban areas, and between those areas where there is a high rate of HIV infection and a lower rate, given the constraints noted in 4.1. The national level has the appropriate authority for establishing a prioritization policy for the 3x5 Initiative in the country as a whole. However, in some countries individual states can formulate and implement policies.³⁰ Policy making at the

(29) Attawell and Mundy.

national level should also take account of new developments and improvements in the infrastructure, thereby enabling the addition of new sites for ARV as the programme proceeds. Some countries have already chosen categories or groups of individuals to receive priority as the programme is initiated (see notes).

According to one view, decisions about which groups will receive first priority should be made at the national level. On this view, fairness in the country as a whole demands that “like cases be treated alike.” An alternative view might consider the local or institutional level to be more appropriate for setting these priorities, based on other considerations of equity (see, for example, 3.3 above and 5.3 below).

5.2 At the local or district level (appropriate geopolitical unit)

Decisions at this level can include an array of items, including urban-rural balance and equitable selection of institutions where ART programmes are to be introduced. At this level also, policies could be formulated that would seek to minimize group differences in access in accordance with the egalitarian principle.

5.3 At the facility level (hospital, clinic, or other healthcare center)

It is at this level that decisions invariably focus on a fair selection of individuals or groups to

(30) An example is the state of Kerala, in India, which announced a plan in January 2004 to provide ART free of charge to all AIDS patients in the state. In the beginning, the drug would be distributed through all the medical college hospitals and subsequently at all the government hospitals. (Asianet News Agency.)

(31) Atawell and Mundy; Paul Farmer, “Community-based approaches to HIV treatment in resource-poor settings,” *The Lancet*, Vol. 358 (2001), 404-409.

(32) “Public accountability in the form of open, democratic processes is a fundamental requirement of justice because people must understand what principles and reasoning are used in choices that affect their basic well-being.” (Norman Daniels, Donald W. Light, and Ronald L. Caplan, *Benchmarks of Fairness for Health Care Reform*, New York: Oxford University Press, 1996, p. 57).

(33) Based on criteria for legitimacy and fairness specified in Norman Daniels and James E. Sabin, “Last Chance Therapies and Managed Care: Pluralism, Fair Procedures, and Legitimacy,” *The Hastings Center Report*, Vol. 28, No. 2 (March-April 1998), 27-41: 36.

receive ARV. With knowledge of the health status of individuals who come for care at the particular facility, decision makers can use a combination of maximin principles of equity, utilitarian ethical principles, and an egalitarian principle (“treat like cases alike”) to set priorities for people in need of ART.

6. Mechanisms for procedural fairness

Just as the selection of individuals or groups to receive priority for ART requires a justification using principles of equity, so also must procedural mechanisms be justified as fair. Fairness in this domain requires that the process of decision making for equitable access be transparent, inclusive, impartial, ensure due process, and be accountable. Although the decision making process will involve different groups at each of the three main levels—national, local or community, and institutional—the same criteria for procedural fairness apply to all levels. Relevant stakeholders should be involved in a central and meaningful way, either as direct decision makers or as members of an advisory body that is not mere “window-dressing.” Procedural fairness includes different types of elements.

6.1 Community involvement

Involvement of communities is a prerequisite for procedural fairness. In addition, a growing body of evidence demonstrates that tangible benefits result from community involvement as ART is introduced. These benefits include education of the community, mobilization, and high level of adherence to treatment regimens.³¹

6.2 Transparency

*6.2.1 Groups involved in setting priorities must use democratically developed, unambiguous criteria in making decisions about the individuals or groups to receive treatment.*³²

*6.2.2 Decisions about which categories or groups should receive access to ART and the rationales for these decisions must be publicly accessible.*³³

6.2.3 *The rationale for choices of target groups and other priorities should be “reasonable” in the sense that it appeals to reasons and principles that are accepted as relevant by the stakeholders.*³⁴

6.3 Inclusiveness

Those involved in the decision making process at all levels should include a wide range of individuals and groups. Policymakers and members of advisory board should include persons with HIV and their family members, people with different languages, cultures, educational, and class backgrounds. A list that has been proposed of different types of stakeholders relevant to scaling up ARV treatment is as follows.

- People with HIV
- Healthcare workers
- Governments
- Non-governmental organizations
- Community based organizations
- Faith based organizations
- Medical associations
- Drug regulatory authorities
- Private sector
- Donors
- Academic institutions

Although most or all of the above stakeholders may be relevant in a variety of contexts related

to scaling up ARV treatment, some may have to be excluded in some situations because of conflicts of interest. In addition, care is needed in selecting faith-based organizations as some are demonstrably discriminatory towards MSMs, sex workers, IDUs, and methods of prevention (e.g. condom distribution) that should go hand-in-hand with scaling up treatment.

6.4 Impartiality

This criterion for procedural fairness is required to avoid conflicts of interest. For example, stakeholders should not be involved in the decision making process that sets priorities for their own group to receive ART.

6.5 Due process

There should be a mechanism for challenge and revision of the chosen scheme, including the opportunity for revising decisions about priorities in light of further evidence and changing circumstances.³⁵

6.6 Accountability

There should be some form of accountable regulation of the process to ensure that the above conditions are met.³⁶

(34) Based on Daniels and Sabin.

(35) Based on Daniels and Sabin.

(36) Based on Daniels and Sabin.

C. Alternative options for equitable access to ART

The 3x5 Initiative has as one of its guiding principles Ethical Standards: “The Initiative will identify options for an ethical approach to meeting 3 by 5 targets.”³⁷ Accordingly, given all the considerations outlined above, and given the often conflicting reasons that might exist for giving priorities to particular groups of people or particular locations or areas in a country, how might those responsible for formulating policy decide on an acceptable policy for equitable access?

1. The first step is to specify the necessary conditions for individuals to receive ART. As described above, these require meeting the criteria for

- 1.1 medical eligibility (B.1.1) and
- 1.2 psychosocial criteria (B.1.2).

This step is relevant to setting priorities at all three levels: national, local or community, and institutional. It requires accurately identifying groups of individuals who will benefit the most by being offered treatment. The focus at this stage is on the individual medical benefit an individual would receive from treatment

2. A second step in initiating ART programmes would require identifying locations and institutions where treatment is to be offered first. Two necessary conditions relating to feasibility inform this step:

- 2.1 The existing infrastructure (established VCT programmes, skilled healthcare workers, adequate facilities for providing ART and monitoring patients); and
- 2.2 Sustainability of the programme. Programmes that are not able to be sustained will have the ethically unacceptable consequence of withdrawing ART from people who have been receiving the benefits of treatment. A guiding principle of the 3x5 Initiative is Life-Long Care: “Once started,

antiretroviral therapy is for life. The world community has a responsibility to ensure uninterrupted medicine supply once antiretroviral therapy has been started.”³⁸

One problem with condition C.2.1 is that it would exclude many locations and institutions that have not been able to offer any ARV treatments to date. This has the result of perpetuating lack of equitable access to treatment for populations in those locations or institutions. A remedy for this is for policy makers to ensure that in the process of scaling up, some resources are allocated to building the necessary infrastructure in places where they do not now exist. In subsequent phases as the programme is rolled out, these locations or institutions can then be given priority on grounds of the earlier lack of access (compensatory justice). This implies that criteria of fairness may shift on a temporal basis. Those locations or institutions given first priority at the outset of the 3x5 Initiative may be given a lower priority later on, as new locations or institutions become eligible. The conditions for procedural fairness specified in B.6.5 can help to identify such shifts in priority.

3. A third step would be to set priorities for who shall be the first to receive ART. This is the most difficult process of all, since even after the necessary conditions in C.1.1 and 1.2 above have been met, not all individuals in the groups identified earlier (section B.3) will be able to be served. This step requires adherence to the conditions of procedural fairness described in section B.6 above. At each level of policy making, the conditions outlined in B.6.1 through 6.6 should be in place.

Clearly, a variety of national and local circumstances will determine what is the best policy choice. The same circumstances will not obtain in different countries or even in regions of the same country. Some countries have already initiated ART programs on a national or regional level. Obviously, those programs should be continued as the 3x5 Initiative is rolled out. Failing to do so will inevitably be perceived as unfair by groups who have already been given

(37) WHO/UNAIDS. *Treating 3 Million by 2005: Making it happen*, p. 10.

(38) WHO/UNAIDS. *Treating 3 Million by 2005: Making it happen*, p. 10.

priority for treatment. However, since some existing programs require that people receiving ART pay for part of the cost of treatment, instituting a programme in which free treatment is provided in public healthcare institutions will still involve setting new priorities for access to ART.

It could be that the most acceptable scheme for setting priorities is the one that employs the greatest number of ethical principles in choosing among all the groups and individuals eligible for ART. A congruence of principles leading to the same choices may indicate that there is less disagreement in how various competing factors should be weighted. Nevertheless, there is no guarantee that this will yield the most equitable scheme. The order in which the principles are applied and the weight they are given may vary in different approaches. Each of the following options gives priority to some principles over others. Which approach is most equitable for a country, locality, or institution will best be determined by the responsible decision makers complying with mechanisms for procedural fairness.

3.1 One candidate for the most equitable system would be a plan that sets priorities based on the application of principles of equity to the different groups and individuals within those groups who are in need of treatment. This option starts with individuals who have already been tested and found to be HIV positive (justified by the utilitarian principle), and people with clinical manifestations of disease.

Within that group, this plan would then give first priority to subgroups (or individuals within groups) who are the least advantaged (justified by the maximin ethical principle of concern for the worst off and those who are most vulnerable). These would be

3.1.1 The sickest individuals who are still able to be helped by ARV treatment

On the broader interpretation of 'least advantaged,' this would also include

3.1.2 Marginalized groups (MSM, sex workers, IDUs, prisoners—most discriminated

against)

3.1.3 Orphans and street children (most vulnerable)

3.1.4 Individuals (especially women and children) living in rural and remote areas who have least access to health care generally and treatment for HIV/AIDS, in particular

3.1.5 Other hard-to-reach populations, e.g., displaced persons and migrant workers.

However, it would not seem fair to select any of these groups for ART if they were in less urgent need of treatment than the other groups listed below.

3.2 Application of the utilitarian principle to those identified who have been determined to be least advantaged (the sickest who could still be helped) could include the following subgroups

3.2.1 Mothers with HIV identified through sites offering PMTCT

3.2.2 Infected partners and children of individuals already receiving ART

3.2.3 Health care workers: physicians, nurses, skilled medical laboratory technicians, counselors providing VCT, and others essential to providing medical care and treatment

3.2.4 Groups that engage in high risk behavior (sex workers, MSMs, IDUs)

3.2.5 Women

3.3 Application of the principle of compensatory justice would include (where applicable)

3.3.1 People who have contracted HIV through unsafe blood collection procedures or use of unsterile medical practices

3.3.2 Individuals who have been in clinical trials but are no longer receiving ART because it was not provided at the conclusion of the research

3.4 An egalitarian principle (equity as minimizing group differences) could be applied

next and could include

3.4.1 Marginalized groups (MSM, sex workers, IDUs, prisoners)

3.4.2 Orphans and street children

3.4.3 Other hard-to-reach groups: displaced persons and migrant workers

If the successive application of principles of equity still results in a larger number of people in need of ART than can be initially served, then a randomization procedure (e.g., a lottery) for selection of individuals could be employed. As resources for ARV treatment increase, more individuals could then be included in each treatment group.

3.5 A different option for setting priorities could focus initially on applying principles of equity to healthcare institutions that provide healthcare services to individuals and groups likely to be HIV-infected. These would include both urban and rural health facilities, general public hospitals, and specialized clinics or facilities such as STI clinics, antenatal clinics, and treatment of IDUs. Consistent with the necessary conditions specified in C.2.1 and 2.2, ethical principles could be applied in this scheme as follows.

3.5.1 Selection of facilities could be based on an egalitarian principle, providing equitable access to the widest geographic area and the most diverse types of healthcare institutions.

3.5.2 A subset of all eligible institutions could then be chosen randomly, again in accordance with an egalitarian principle.

3.5.3 Within the institutions selected on that basis, all eligible individuals in each institution would be considered candidates for ART.

3.5.4 Among all eligible individuals, an equitable distribution should be achieved among men, women, children, and the various specific groups.

This scheme would involve selecting a small enough number of healthcare institutions to en-

able treatment of all medically eligible individuals who also meet the psychosocial criteria. It is the most egalitarian scheme possible, since there would be no distinctions or priorities among all users of the same facility. Based on inclusion of all relevant types of health care facility, it also ensures that members of all relevant groups will gain access to ARVs: pregnant women at antenatal clinics, sex workers and MSMs at STI clinics, IDUs at drug treatment centers, and the general population at general public hospitals. Although this scheme does not specifically favor the least advantaged, given the geographic distribution it is likely to include substantial numbers of groups that are the least advantaged in the categories described earlier.

Decision makers might prefer the scheme in 3.5 that begins with the selection of institutions over the scheme outlined in 3.1 – 3.4, which requires that specific groups be given priority. It may be more ethically acceptable, all things considered, to offer treatment to everyone using a given health care institution, especially when fair procedures are used to select the institutions.

3.6 A third option would apply the principle of utility in order to achieve health maximisation under the constraint of ensuring ARV treatment for the least advantaged. Under this scheme, it will be necessary to calculate the expected aggregate health benefits in the whole population under various treatment strategies. All things being equal, the strategy that produces the highest expected population health benefit should be chosen. This approach could involve steps such as the following, or other alternatives empirically determined to be most likely to achieve health maximization for the country as a whole.

3.6.1 Begin by identifying all individuals with clinical AIDS and those known to be HIV-infected

3.6.2 From 3.6.1 select individuals in urgent need of treatment who can still benefit from treatment

3.6.3 From the group identified in 3.6.2,

select skilled healthcare workers and others with special training deemed essential for the society (e.g., teachers)

3.6.4 Select pregnant women

3.6.5 Select women identified as positive through PMTCT

3.6.6 Select partners and children of pregnant women and those identified through PMTCT

3.6.7 Select groups engaging in high risk behavior and therefore more likely to spread infection (IDUs, sex workers, MSMs)

3.6.8 Select individuals with TB, first treating the TB and then choosing those in urgent need of ART

3.6.9 Use VCT for individuals with TB not known to be HIV-infected, provide immediate treatment for TB and ART when needed

3.7 Options involving combinations of the above alternatives

Policymakers and advisory bodies responsible for setting priorities may seek to combine features of the above allocation schemes in light of

priorities that have already been established, the total numbers of HIV-infected individuals living in the country or locality, the proportion of infected individuals in the various subgroups, the degree of readiness of the existing infrastructure and trained healthcare personnel available to roll out the programme, and other factors.

3.7.1 Decision makers could choose different starting points to begin the process of prioritization

3.7.1.1 Location

- *Regions, communities, urban or rural*
- *Healthcare facilities*

3.7.1.2 Patients with clinical disease

3.7.1.3 All known HIV-positive individuals

3.7.1.4 All individuals using healthcare facilities where screening programs exist or can be easily established

3.7.2 Decision makers may choose which principle of equity should take precedence and how other relevant principles should be weighted

D. Conclusions

Whatever options are selected for setting priorities, and whichever ethical principles are chosen as most equitable for the country, community, or institution, those responsible for making decisions should take into consideration all relevant ethical principles and must ensure that all human rights obligations are respected, protected, and fulfilled.

Whichever principles of ethics and equity are chosen as most appropriate, and even if all of the elements of fair procedures are scrupulously followed, there is bound to be disappointment and resentment on the part of individuals and groups that are not among the first to receive ART. This suggests the desirability of taking into account geographic proximity in selecting individuals and groups as treatment programmes are initiated. The same rationale that justifies treating all eligible members of the same family could apply also in a village or a closely knit urban neighborhood. Evidence from situations in which some people have to be denied treatment or face delays in receiving treatment attests to the difficulty this causes for caregivers or others who must confront the unlucky patients. In one Médecins Sans Frontières project, a Selection Committee meets once a month to decide which patients, among those found to be eligible under the MSF criteria for treatment, will receive ART. According to one account, members of this committee are reluctant to deny treatment to anyone who meets the eligibility criteria. Moreover, when patients meet some but not all of the designated criteria, committee members are inclined to help those patients to fulfill the remaining criteria. The result is a tendency to “approve” and “select” for treatment virtually every patient they consider, and to avoid “de-selecting” anyone.³⁹

National authorities and local decision makers will have to determine how much epidemiologic research and data gathering is necessary before initiating a treatment programme. To begin a programme with insufficient data risks missing

individuals most in need of treatment and hard-to-reach marginalized groups (see C.3.1.1 and C.3.1.2). In addition, needed information about the existing infrastructure and trained personnel in various locations and institutions may be lacking (see C.2.1). These gaps may result in failure to comply with principles of equity that have been selected to guide the programme. However, lengthy and costly data gathering will delay implementation of the programme and possibly also divert funds that could be used to finance treatment for a larger number of people. For example, should there be an attempt to calculate how much the costs and benefits not directly associated with treatment provision contribute to expected benefits? These include costs of developing new infrastructure in rural areas, or benefits of enabling health care workers to return to work and contribute to further increased access to treatment, treatment of workers who are essential for favorable economic conditions of a country, etc. On the one hand, such information appears to be necessary for economic efficiency. On the other hand, it would require personnel and resources to make the necessary calculations.

These considerations suggest that the advisory committees established in accordance with the mechanisms for procedural fairness should include individuals with relevant knowledge and expertise. One of the first tasks of these committees could be to ascertain how much and what information is already available, and determine what critical information needs to be gathered before initiating the treatment programme.

It is essential that principles of ethics, equity, and human rights be in the forefront as the 3x5 Initiative is rolled out. Those responsible for making decisions face hard choices, but ones that can be justified by the application of these principles.

(39) This information was provided to me by Renee Fox, personal communication.



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