UNAIDS Global Reference Group on HIV/AIDS and Human Rights

Third Meeting, Geneva, 28-30 January 2004

Issue Paper

Status: final

Ethics and Equity in Access to HIV Treatment in Context of "3 by 5"

Defining the issue

The WHO/UNAIDS 3x5 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. There is a global responsibility to support resource-limited countries to scale up ART in the face of a global public health emergency. In addition, a country-level responsibility exists to ensure treatment is made available as enunciated in human rights guidelines for HIV/AIDS.[i] 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. Most countries will use a phased approach and this will necessitate making decisions about priorities in allocating resources. Although adherence to human rights provisions is essential, none of the various human rights treaties or declarations provides criteria for setting priorities or choosing among potentially relevant principles of equity.

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 discrimination and the right to the highest attainable state of health. Policy makers will need to make decisions and various ethical principles will guide these decisions in very different ways.

Key ethical principles relevant to fair distribution of ART

- Formal principle of equity: treat like cases alike.
- Utilitarian or health maximizing principle: this calls for policies that aim at maximizing health benefits for the society as a whole
- Egalitarian principles or principles emphasizing 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 inequalities among different groups should be minimized.
- Equity as concern for the worst off, or the least advantaged
- Justice as reciprocity or compensation

Mechanisms for procedural fairness

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." Whatever ethical principles ultimately guide decision making, attention to procedural fairness will be required.

(i) Community involvement

- Involvement of communities is a prerequisite for procedural fairness.

(ii) Transparency

- Groups involved in setting priorities must use democratically developed, unambiguous criteria in making decisions about the individuals or groups to receive treatment.[ii]
- Decisions about which categories or groups should receive access to ART and the rationales for these decisions must be publicly accessible.[iii]
- 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.[iv]

(iii) 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 boards should include persons with HIV and their family members, people with different languages, cultures, educational, and class backgrounds.

(iv) Impartiality

- This criterion 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.

(v) 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[v]

(vi) Accountability

- There should be some form of accountable regulation of the process to ensure that the above conditions are met.[vi]

Steps in Policy Process for Equitable Access to ART

How should those responsible for formulating policy decide on an acceptable policy for equitable access? The following steps are relevant to fair distribution of ARV treatment services. Different ethical principles would provide alternative approaches to each step, all of which could be justified as equitable on substantive and procedural grounds.

<u>Step 1: Specifying necessary conditions for individuals to receive ART</u>

This step is relevant to setting priorities at national, local or community, and institutional levels. It requires accurately identifying groups of individuals who it is

thought will benefit most by being offered treatment. This requires meeting criteria for medical and psychosocial eligibility.

Step 2: Identifying locations and institutions where treatment is to be offered first

Two necessary conditions relating to feasibility inform this step:

(i) The existing infrastructure (established VCT programmes, skilled healthcare workers, adequate facilities for providing ART and monitoring patients). *One problem with this condition is that it excludes many locations and institutions that have not been able to offer 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 3 x 5 initiative may be given a lower priority later on, as new locations or institutions become eligible.*

(ii) Sustainability of the programme. Programmes that for economic and other reasons 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.

Step 3: Setting priorities for who shall be the first to receive ART

This is the most difficult step of all, since even after the necessary conditions noted above have been met, not all individuals in eligible groups will be able to be served. This step requires adherence to the conditions of procedural fairness noted above. The ethical approaches noted above will guide the policy process for this step in different ways. The order in which the principles of equity are applied and the weight they are given may vary in different approaches. Below are four options, each of which gives priority to some principles over others. Which approach is most equitable for a country, locality, or institution is best determined by the responsible decision makers, with attention to the mechanisms for procedural fairness.

Option 1: Setting priorities based on the application of principles of equity to the different groups and individuals within those *groups who are in need of treatment*. The steps in this option could be as follows:

(i) This option starts with individuals who have already been tested and found to be HIV positive and people with clinical manifestations of disease (justified by the utilitarian principle, or efficiency). Within this group, this approach would give first priority to subgroups (or individuals within groups) who are the least advantaged (justified by the principle of concern for the worst off). These would be

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

On a broader interpretation of 'least advantaged,' this could also include:

- Marginalized groups (MSM, sex workers, IDUs, prisoners—most discriminated against)

- Orphans and street children (most vulnerable)
- 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
- 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.

(ii) Application of the utilitarian principle to those identified as the least advantaged (the sickest who could still be helped) is applied next. This could include the following subgroups:

- Mothers with HIV identified through sites offering PMTCT
- Infected partners and children of individuals already receiving ART
- Health care workers: physicians, nurses, skilled medical laboratory technicians, counselors providing VCT, and others essential to providing medical care and treatment
- Groups that engage in high risk behavior (sex workers, MSMs, IDUs)
- Pregnant women

(iii) Application of the principle of compensatory justice is applied next. This would include (where applicable):

- People who have contracted HIV through unsafe blood collection procedures or use of unsterile medical practices
- Individuals who have been in clinical trials but are no longer receiving ART because it was not provided at the conclusion of the research

(iv) An egalitarian principle (equity as minimizing group differences) could be applied next. This could include:

- Marginalized groups (MSM, sex workers, IDUs, prisoners)
- Orphans and street children
- Other hard-to-reach groups: displaced persons and migrant workers

(v) 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.

Option 2: 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 above, ethical principles could be applied in this scheme as follows.

(i) 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.

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

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

(iv) Among all eligible individuals, an equitable distribution could be achieved among men, women, children, and the various specific groups.

This scheme would involve selecting a small enough number of healthcare institutions to enable 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.

Option 3: 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 would 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.

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

(ii) From (i) select individuals in urgent need of treatment who can still benefit from treatment

(iii) From the group identified in (ii), select skilled healthcare workers and others with special training deemed essential for the society (e.g., teachers)

(iv) Select pregnant women

(v) Select women identified as positive through PMTCT

(vi) Select partners and children of pregnant women and those identified through PMTCT

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

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

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

Option 4: 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.

(i) Decision makers could choose different starting points to begin the process of prioritization

- Location: regions, communities, urban or rural; healthcare facilities
- Patients with clinical disease
- All known HIV-positive individuals
- All individuals using healthcare facilities where screening programs exist or can be easily initiated

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

Conclusion

It is important to note that applying the different approaches and/or combinations of approaches is a complicated process and will lead to different conclusions. However, conscious attention to these different approaches is critical to informed policy making. The application of human rights norms and standards to these issues may offer a useful framework for considering these issues and the extent to which these ethical principles may help shape human rights considerations as regards equity in access should be considered by the Reference Group.

This Issue Paper was prepared by Ruth Macklin to facilitate discussion at the Reference Group's January 2004 meeting.

[i] 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).

[ii] "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).

[iii] 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.

[iv] Based on Daniels and Sabin.

[v] Based on Daniels and Sabin.

[vi] Based on Daniels and Sabin.