

RESPONSE

Challenges confronting the WHO/UNAIDS 3x5 Initiative

RUTH MACKLIN

Department of Epidemiology and Population Health, Albert Einstein College of Medicine, 1300 Morris Park Avenue, Bronx, New York 10461, USA.
email: macklin@aecom.yu.edu

Efforts such as the World Health Organization's 3x5 Initiative bring with them new challenges, along with the hope and promise of expanding access to antiretroviral treatment (ART) in developing countries. Some challenges are practical or technical: Will a sufficient number of volunteers undergo HIV tests to determine their eligibility for treatment? Will there be enough rapid test kits available for all the people who will have to be tested? Equally challenging are questions of ethics and equity.

The editorial in the July–September 2004 issue of the Journal (1) describes some of the ethical challenges this initiative faces in India. This includes the ongoing discrimination against people living with HIV/AIDS in both public and private sectors, the injustice evident in the selection of the sites where free access to ART will be offered, and the potential for corruption due to bribery in rejecting or selecting patients for free treatment. Although these and other ethical challenges are not unique to India, they are based on evidence from current and past discriminatory practices and unjust distribution of health care resources.

The editorial asks, 'How can the selection process be impartial and objective if the profession that is supposed to implement it has shown discriminatory behaviour?' The only way to accomplish this is to adhere to *procedural fairness* while selecting both the sites where free ART will be available and the individuals who will be eligible to receive the treatment. Elements necessary for achieving procedural fairness are discussed below.

Community involvement

Involvement of communities is a prerequisite for procedural fairness.

Transparency

Groups involved in setting priorities must use democratically developed, unambiguous criteria in taking decisions about the individuals or groups that will receive treatment. '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(2).'

Decisions about which categories or groups should have access to ART and the rationale for these decisions should be 'reasonable' in that it should appeal to reasons and principles that are accepted as relevant by the stakeholders. Such decisions must be publicly accessible(3).

Inclusiveness

Those involved in the decision-making process at all levels should include a wide range of individuals and groups. Policy-makers and members of advisory boards should include persons with HIV infection and their family members, people from different backgrounds—language, cultural, educational and class.

Impartiality

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

Due process

There should be a mechanism for challenge and revision of the chosen scheme, including the opportunity for revising decisions about priorities in the light of further evidence and changing circumstances (3).

Accountability

There should be some form of accountable regulation of the process to ensure that the above conditions are met (3). In addition to embodying elements of procedural fairness, implementation of the 3x5 Initiative must also respect human rights and adhere to substantive principles of ethics and equity. Although adherence to human rights provisions in scaling up treatment programmes is essential, none of the various human rights treaties or declarations provide specific criteria for setting priorities or choosing among potentially relevant principles of equity. As treatment programmes are rolled out, it will not be possible for every eligible person to be treated at once. What criteria should decision-makers use to set

priorities for access? Are there ethically acceptable grounds for choosing special groups, such as health care workers, to ensure effective implementation of treatment programmes? Can giving preference to children or pregnant women be ethically justified? There is no clear and uncontroversial way of determining which groups in a population should be given the priority when all cannot be treated at the outset.

Ideally, the 3x5 Initiative should provide ART 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 number 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. Moreover, practically, evidence from existing programmes in which people in developing countries have had to pay for some or all the cost of antiretroviral drugs reveals an array of negative medical and social consequences, including interruption of therapy, deterioration of health status, poor adherence, and development of drug resistance.

An argument in favour of giving priority to the poor is supported by a leading ethical principle: concern for the worst off or the least advantaged. 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 the poorest members of society; the lowest socioeconomic class; the most vulnerable (for example, children, especially orphans); or groups that are marginalised or most discriminated against. The principle that favours the least advantaged and the most vulnerable groups does not, however, call for giving strict priority to these groups.

Other ethical principles are potentially relevant and can provide justifications for choosing one or the other scheme for access to ART. The *utilitarian* principle, applied specifically to health policy, aims at maximising *health benefits* for society as a whole. For example, treating health care personnel or teachers would have the additional benefit of ensuring that needed personnel are available for providing treatment and for health promotion, which produces additional health benefits for society. 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.

An *egalitarian* principle of equity in this context would call for distributing resources equally among persons, or distributing health care services equally among different groups. This principle is the basis for schemes that emphasise health equity over health maximisation. There is thus a conflict with the utilitarian approach. 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.

The three principles described here point to criteria or concerns that must be considered, but the principles can lead to conflict, and it then becomes necessary to balance competing concerns. There is no unique, correct way of achieving this balance. For this reason, leading commentators have urged that the emphasis has to be on fair processes (4). The aforementioned principles can serve to justify the decisions to the extent that decision-makers in each country can agree on principled ways to set priorities for equitable access among those eligible for ART.

A different option for setting priorities could focus initially on applying principles of equity to institutions that provide health care services to individuals and groups likely to be HIV-infected. These would include both urban and rural health facilities, general public hospitals, and specialised clinics or facilities. Whichever approach is chosen, the use of the fair procedures described earlier remains necessary, since equity demands adherence to both substantive and procedural aspects of ethics.

This article is adapted from a background paper prepared for a WHO consultation on Ethics and Equity in the 3x5 Initiative, Geneva, Switzerland, January 26–27, 2004. The background paper, Ethics and Equity in Access to HIV Treatment—3 by 5 Initiative, can be accessed at <http://www.who.int/ethics/en/background-macklin.pdf>.

References

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3. *Last chance therapies and managed care: Pluralism, fair procedures, and legitimacy*, *The Hastings Center Report*. 1998;28:27–41. (Based on criteria for legitimacy and fairness specified in Daniels N, Sabin JE.
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