Consultation on ethics and equitable access to treatment and care for HIV/AIDS

Summary of issues and discussion
26-27 January 2004
Geneva
World Health Organization and Joint United Nations Programme on HIV/AIDS
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This publication provides an account of the points discussed at a global consultation on Ethics and Equitable Access to Treatment and Care for HIV/AIDS held in Geneva on 26-27 January 2004. The meeting was convened by UNAIDS and WHO's ETH, HDP and HIV departments. This report presents the views of the consultants, not necessarily those of the sponsoring organizations. It has, however, been indispensable in the process of preparing guidance material on this topic for WHO Member States, and we are very grateful to all the consultants, particularly to Professors Ruth Macklin and Norman Daniels who wrote background papers.

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The “Treat 3 Million by 2005 Initiative” – the “3 by 5 initiative”, launched by the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) – provides additional hope that millions of people with HIV/AIDS will have access to life-saving treatment in the coming years. However, even if antiretroviral therapy (ART) is delivered to three million people in developing countries by 2005, this accounts for only half the number of people in need of life-saving HIV/AIDS treatment and care. Furthermore, the “3 by 5 target” represents only an urgent first step in an effort that will have to be sustained for the lifetime of those receiving the treatment and for the duration of the epidemic – at least a matter of decades. In response to the serious ethical and operational challenges presented by this situation, WHO and UNAIDS convened an international consultation on Ethics and Equitable Access to Treatment and Care for HIV/AIDS to clarify the ethical principles and concerns that should be addressed in the progressive scaling up of ART programmes. The following is a summary of the conclusions reached during the meeting.

The 3 by 5 initiative specifically – and expansion of access to ART in general – is about people living with and affected by HIV/AIDS. They comprise the essential resource for input, involvement and cooperation if the 3 by 5 target is to be reached. In order to generate demand and ensure adherence, every effort must be made to overcome stigma and discrimination and to support the mobilization of communities and people living with HIV/AIDS. A holistic approach to the scaling up of ART, locating it firmly in a comprehensive response to the epidemic and in the primary health care context, will go a long way towards achieving the broad goals of HIV prevention and care, alleviating the impact of the epidemic, and benefiting health systems in general.

Human rights, laws and ethical principles provide guidance on expanding access to ART in a just and equitable manner. The human rights to life, health, equality and nondiscrimination oblige states to provide HIV-related treatment and care without discrimination to all those who need it. Guided by ethical principles and human rights, the ultimate goal is universal access to HIV/AIDS treatment and care. Towards this end, governments and donors should develop practical and sustainable strategies and plans that include timetables and benchmarks as part of their commitment to the progressive realization of the right to health, including the right to ART and other aspects of care for people with HIV/AIDS.

The principles of utility, efficiency, fairness and sustainability are the critical ethical principles that should guide efforts to select those who will have priority for receiving ART and to determine where and how ART will be provided. Broadly, these principles seek to:

- maximize all benefits (including, but not limited to, health benefits) that stem from the use of limited resources;
- distribute these benefits in a way that is fair, and
- where appropriate, compensate those who have been harmed or who have taken particular risks related to HIV/AIDS, such as participants in research.

Depending on the weight given to these principles, various groups could be chosen to benefit from the early provision of ART. In no particular order of priority, these include those close to death from AIDS, health care workers, parents, pregnant women, the poor, sex workers, injecting drug users, men who have sex with men, people who have participated in HIV-related research and people who were infected because of negligent blood transfusion.

Because reasonable people may disagree on which groups should be given priority based on ethical considerations, fair processes are needed for discussions and decisions about who should get ART, when, how and where. Public, transparent, inclusive and revisable processes will help to ensure that the decisions regarding who receives ART are equitable, and are acceptable to those affected by them. Such processes should be conducted at various levels within a country and should involve all stakeholders, including people living with HIV/AIDS and other marginalized groups. Implementation of a fair process will help to educate people about ART, generate demand for HIV prevention and care services, mobilize people around health as a right, and increase transparency and public accountability. It is recommended that fair process be implemented as soon as possible, wherever possible, and that initial steps should involve planning, training, workshops, development of indicators and research regarding fair process.

Immediate steps can be taken to provide ART to those with advanced AIDS-related disease who report for treatment where the infrastructure is already in place to support ART using simplified treatment guidelines. Governments should make efforts to build infrastructure where there is none and, simultaneously, to reach out to marginalized groups in other ways, such as through public information and education campaigns and social marketing of testing, counselling, treatment and care.
The goal of universal access means that cost and/or economic status must not be a barrier to access to treatment and care, and particular efforts should be made to enable the poor to gain access to treatment. Strategies should be developed to provide ART free at the point of delivery to those who cannot afford it. In systems where health care is partially or totally financed on a private basis, cost recovery for ART could involve a mixture of public and private schemes to cater for different income groups – free to those who cannot pay and have no health insurance, payment by insurance schemes for those in the formal workforce, and payment out of pocket by those wealthy enough to do so. However, if cost recovery schemes prove inefficient or obstructive to access, free delivery to all should be considered. In addition to poverty, there are other barriers to equity that must be addressed. These include stigma and discrimination; harmful gender norms; lack of governance, transparency and accountability; corruption; and ethnic, educational and/or geographical isolation. Women represent a large group who may be denied access for reasons other than lack of wealth, such as discrimination.

In addition to the provision of the drugs themselves, the integration of ART into health services provides a critical opportunity to improve national health overall and to strengthen primary health care systems. To seize this opportunity, the necessary steps must be taken to integrate ART delivery into local primary care networks; avoid vertical programmes; improve systems for the procurement of essential drugs and their distribution and monitoring; set up sustainable government financial systems; address the human resource crisis in health care through adequate salaries, incentives, and training; and involve and support communities, social services and associations of people living with HIV/AIDS. It will be necessary to develop indicators and systems by which to monitor and evaluate the efficiency and fairness of ART delivery, the extent to which a fair process has been achieved, and the overall effects of ART on national health systems and the delivery of health care.

The challenges involved in the equitable provision of HIV/AIDS treatment and care are undeniably huge. However, with sufficient commitment to appropriate ethical principles, to a comprehensive and primary health care approach, and sustained national and international solidarity, expanding access to ART holds the promise of saving the lives of millions of people living with HIV/AIDS, on an equitable basis, while supporting health systems for all.
1. Inequities in health care have meant that many people worldwide have suffered disease and death from preventable or treatable conditions because they could not access the necessary treatment and care. Since the introduction of ART in 1996, the HIV/AIDS epidemic has cast a glaring light on these inequities, as millions of people have died, and continue to die, because they could not afford this treatment. Of around 40 million people now living with HIV/AIDS, it is estimated that six million are urgently in need of ART to avoid death within about 2 years. However, although the prices of antiretrovirals have dropped dramatically in least developed countries, and there is unprecedented political commitment and financing for treatment, fewer than 7% of those in developing countries who need antiretrovirals are receiving them.

2. On 22 September 2003, LEE Jong-Wook (Director-General of the World Health Organization) and Peter Piot (Executive Director of the Joint United Nations Programme on HIV/AIDS) declared this dire lack of access to life-saving treatment and care a global health emergency. In response, WHO and UNAIDS launched the Treat 3 million by 2005 initiative — the 3 by 5 Initiative. The target of this mobilizing effort is to ensure the provision of ART to three million people living with HIV/AIDS in poor countries by the end of 2005. In addition to being a public health imperative, the need to provide ART is founded on the obligations of states to ensure the human rights to life, health, equality and nondiscrimination. The 3 by 5 target is considered to be the first step in an urgent effort to achieve universal access to ART for all those who need it. The core principles governing the implementation of the 3 by 5 initiative include urgency, equity and sustainability.

3. The provision of ART to three million people by 2005 is a daunting, but achievable, challenge. However, this target accounts for only half of those presently in need of ART. The fact that the need for ART exceeds the current ability to deliver it means that some will receive treatment and others will die. Such a situation poses grave ethical issues for the governments, international agencies, nongovernmental organizations, institutions and health care workers working to scale up access to ART. The most compelling of these ethical dilemmas involve choices that will affect the life and death of millions of people. However, other serious ethical concerns surround the potential diversion of resources from other health and social needs, as well as the possible effects of vertically-implemented ART programmes on fragile health systems, communities and families.

4. In an effort to help ensure the ethical distribution of treatment and care for those with HIV/AIDS, WHO and UNAIDS convened an international consultation on Ethics and Equitable Access to Treatment and Care for HIV/AIDS. The consultation was organized by the WHO Department of Ethics, Trade, Human Rights and Health Law, in collaboration with the Department of MDGs, Health and Development and the Department of HIV/AIDS along with the UNAIDS Secretariat. The objectives of the meeting were as follows:

- To elucidate issues of ethics and equity that might arise in the course of implementation and scaling up of ART programmes.
- To lay the groundwork for the formulation of guidance to help governments and other partners to implement ART programmes in an ethical and equitable manner.
- To consider indicators by which equity in implementation and distribution can be monitored.

5. The participants at the consultation included treatment providers, physicians and other health care workers; ethicists, lawyers and human rights advocates; and representatives of governments, international agencies, nongovernmental organizations, academia, and groups of people living with HIV/AIDS (see Annex 1 for list of participants). The participants reviewed three background papers at the meeting:

- Ethics and equity in access to HIV treatment: “3 by 5” initiative, by Dr Ruth Macklin.
- How to achieve fair distribution of ARTs in “3 by 5”:
  - fair process and legitimacy in patient selection, by Dr Norman Daniels.
- “3 by 5”, priority in treatment and the poor, POV/HDP/SDE/WHO.

6. A summary of the major issues raised and of the discussion about them that took place at the meeting is provided in this document. The insights gained from this meeting have been used by WHO and UNAIDS to develop guidance intended to assist in ensuring the equitable distribution of ART, and standards and procedures by which to monitor and evaluate equitable implementation of ART programmes.

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7. Throughout the meeting, participants discussed the nature of the ethical guidance that would be useful to countries and other bodies that are scaling up ART programmes. Dr Thierry Mertens (WHO) in his presentation entitled *What guidance to offer on achieving fair access to ART* emphasized that the debate concerning equity in the provision of ART must be considered within the changing context and time frame of the 3 by 5 initiative. This context is characterized by uncertainty in the estimates and forecasts of:

- the number of people living with HIV/AIDS, taking into account the estimate that some 80% of these people do not know their HIV status; and
- the number of people who will need ART over the next few years (possibly from 6 to 12 million people).

Producing estimates is complicated by the fact that even when people do know that they are HIV positive, they might not come forward for reasons of stigma and discrimination. Indeed, one of the greatest initial challenges is to create demand for treatment (see also paragraphs 70 and 71).

8. Equity must be considered in terms of various dimensions, such as socioeconomic status, geographical location, age, gender, severity and duration of infection, and vulnerability. In the light of other rampant diseases and widespread undernourishment, governments have voiced concern about favouring HIV/AIDS patients, in particular with regard to providing ARTs free at the point of service while other HIV/AIDS-related care and treatment for other diseases, has to be paid out of pocket. Dr Mertens stressed that scaling up ART should serve to strengthen health systems through improvements in drug procurement policies, financing, a sufficient number of trained health staff, health information systems, logistics systems, public–private partnerships and community partnerships. He gave a critical appraisal of the issue of subsidies and emphasized the need to build up social security systems to ensure sustainability. The difficult question is how to include the excluded, particularly in the light of the knowledge that targeting strategies have so far proven very difficult to implement.

9. Dr Michel Jancloes (WHO) spoke of the particular challenges in providing technical assistance to government officials and others who will be implementing ART programmes. He gave examples of actual issues that will be faced by those in country:

- How can ART be justified when primary health care is not being provided?
- How can ART be provided free of charge when the same patients must pay out of pocket for malaria care?
- How can the authorities ensure that a health centre has a balanced budget to deal with patients who are not infected by HIV as well as those who are?
- How will funding be sustained?
- Should governments start programmes where there is minimal capacity or where there might be greatest impact?
- How can the appropriate balance between HIV prevention and care be achieved?
- What should be the policy of governments towards private HIV/AIDS clinics?

The politics of equity form the backdrop in considering all of these questions; it is “ethics in action”.

10. Dr Jancloes urged that the meeting should not result in a generic document on ethics and equity that would not be useful to those in country. Rather, the participants at the meeting should assist WHO and others in offering ongoing, practical advice on the kinds of questions faced by implementers. Towards this end, countries need:

- context-specific advice for health care implementers, as well as for those working with various branches of government, donors, the press, the private sector, etc.;
- access to best ethical practice, especially that of neighbouring countries; and
- assistance in building capacity in policy analysis and development which includes ethical considerations.

11. In this context, the participants urged that ethical guidance produced by WHO and UNAIDS should be both grounded in intellectual and academic knowledge, and practical so as to address the actual issues being faced by governments and others. It was pointed out that the task of developing guidance on equitable access to HIV/AIDS care is extremely important because such guidance could serve as a standard of equity in care for other health programmes. The participants at the meeting felt that guidance should be able to lead implementers from little or no
Nature of ethical guidance

access to universal access to HIV-related treatment and care, based on a consensus that universal access is the only truly ethical outcome.

12. The participants at the meeting discussed the nature of the guidance that would be most useful to governments and to others trying to implement ART programmes. In particular, participants discussed whether WHO/UNAIDS should provide specific advice on issues about which countries might disagree, leave room for decentralized decision-making, and/or provide guidance only as to process. One participant raised the issue of the need to find a balance between offering principles alone, which would be “too soft”, and issuing directives, which would be too strong. Another participant felt that it would not be possible to be prescriptive beyond requiring that relevant considerations be taken into account through a fair process. Recognizing that guidelines that work in one country may not work in another, a number of participants felt that the most that could be achieved would be to define the relevant questions and let countries develop their response in a context-specific manner. The participants generally agreed that models for guidance should include some version of three broad components:

- a list of ethical issues to be resolved;
- ethical principles and an acceptable process by which to consider the relevant issues; and
- indicators for monitoring and evaluation.

13. Various participants urged that guidance on the ethical delivery of ART be contextualized as far as possible. In this regard, some participants suggested that generic guidelines should be supplemented with specific case studies based on real conditions and actual experience, including lessons learned from such countries as Brazil, Cambodia and Malawi. This might also be done through a pragmatic rapid feedback approach by which policies and guidelines are continually revised in the light of experience obtained. Other participants suggested that WHO produce hypothetical case studies that describe how ideal and ethically-guided plans for the expansion of ART might look under different political, economic, social and health systems, circumstances and conditions. One participant suggested that WHO provide countries with evaluations, in terms of equity and ethics, of their national plans for the equitable delivery of ART.

14. The participants at the meeting urged that the guidance not be over “medicalized”, but that it should also include reference to non-health interventions that should be a part of efforts to expand access to ART, particularly those that would make greater access a reality for vulnerable groups. Such guidance would encourage the delivery of HIV treatment and care in a way that is sustainable and that supports society through a practical process of referrals to services that deal with the social and economic realities that underpin the epidemic.

15. Representatives from WHO confirmed that, whatever guidelines were produced, they would be subject to further consideration and iteration, based on dialogue and the reported experience of countries. It was intended that guidance would be clear (easily understood by all), simple (easily applied), congruent (based on medically relevant criteria), equitable (ethically sound), non-discriminatory (no invidious categories), legitimate (fairly promulgated), progressive (leading toward universal access) and measurable (attainment can be monitored).
16. The participants at the meeting discussed the role of human rights and the utility of adopting a human rights approach to the equitable distribution of AIDS treatment and care. Participants stressed that principles of human rights comprise powerful sources of obligation, as well as guidance, concerning the provision of ART. In this regard, they noted the critical relevance to the implementation of treatment programmes of the rights to life, health, equality and nondiscrimination, as well as the concept of progressive realization.

17. The participants at the meeting affirmed the right to treatment and care for people with HIV and AIDS as a part of the right to health. Furthermore, they discussed how under human rights jurisprudence, the goal is substantive equality which requires eradication of structural inequality across all diseases, not only HIV/AIDS, and is based on equal access to health services and equal outcomes. Therefore, special efforts to reach the poor and marginalized were considered valid means by which to attain this equity.

18. The participants at the meeting discussed the concept of “progressive realization” of economic, social and cultural rights, including the right to health and access to health care and treatment. It was recognized that progressive realization is an accepted norm in human rights principles. However, it was also pointed out that many countries have not been willing and/or able to realize the right to health, among other rights, progressively over time. In this context, the participants urged that governments, and those supporting them, develop strategies with practical timetables, benchmarks and targets for real and expeditious movement towards full realization of the right to health, including universal access to ART and other aspects of HIV/AIDS care. Participants recognized that meeting this target will be inherently difficult in countries where social, political and/or health systems are on the point of collapse.

19. Some participants felt that the use of the human rights discourse is the most comprehensive and inclusive approach for achieving equity in access to ART. Other participants noted, however, that the content of human rights is often not sufficiently specific to provide guidance on many of the particular issues raised in the context of ART implementation. It was pointed out that in some countries human rights are considered supplementary to national law whereas in others, human rights are expressed in constitutional law, and litigation has compelled governments to implement programmes that guarantee universal access to ART.

20. The participants at the meeting urged the development of as much synergy as possible between ethical guidance, on the one hand, and obligations under human rights and law, on the other. It was also urged that jurisprudence regarding human rights, including their interpretation in General Comments and the recommendations of treaty bodies, be used as sources of guidance and articulations of states’ obligations. General principles based on solidarity, respect for human dignity and a collective response were also considered key to guidance on ethics and equity in implementation of ART.
21. The participants at the meeting discussed the ethical dilemmas surrounding the provision of HIV/AIDS treatment in light of other equally compelling needs and conditions, and asked whether the drive to expand access to ART was a case of inappropriate “AIDS exceptionalism”. The participants stressed that finding an appropriate balance between the responses to HIV/AIDS and to other pressing health and social needs is one of the most critical ethical challenges for those working on the 3 by 5 initiative and other programmes. For this reason, they urged that any scaling up of delivery of ART should be done with due consideration of the impact it would have on the ability of governments and health systems to meet other needs. Such concerns reflect the ethical obligation to implement ART in such a way that health systems and overall health and social development, not only the HIV/AIDS situation, will benefit (for further discussion of this issue, see paragraphs 62–66).

22. Representatives from WHO and UNAIDS acknowledged the ethical dilemmas, but described the factors that have come together to compel a major global initiative on HIV/AIDS treatment and care. These include the following:

- The impact of HIV is likely to cause the collapse of a number of countries within two generations.
- Health systems are already collapsing under the weight of untreated AIDS.
- A dramatic expansion of ART coverage has become more feasible as the medicines and diagnostics have become more affordable in low income countries, funding for AIDS care has increased, treatment with ART has been shown to be possible in resource-poor settings and simplified treatment guidelines have been developed.
Relevant ethical principles

23. Dr Ruth Macklin gave a presentation based on her paper, *Ethics and equity in access to HIV treatment: “3 by 5” initiative*, in which she outlined the ethical principles that are useful in selecting those who might be given priority in receiving ART. She pointed out that these ethical principles can conflict, as people can hold different opinions as to how much weight should be given to each principle. This leads to a need for a balancing of competing concerns. The two major relevant approaches to ethical principles are utility and fairness. The first evaluates the rightness of an act based on its ability to result in maximum benefit for the population in question; the second evaluates the justice of an action and its consequences.

24. The utilitarian principle calls for policies that maximize health and/or other benefits for society as a whole in the most efficient manner. In the case of access to ART, applying this principle to the medical criteria for selection of patients to receive ART would result in giving priority to people living with HIV and AIDS whose medical condition is such that they would respond better to treatment than those people who are so ill that any health benefit would be unlikely or limited. Criteria that would determine those who might receive priority based on grounds of efficiency, maximization of utility and of other social benefits might include those who already know their status and have a diagnosis of advanced AIDS, those identified as HIV-positive in epidemiological studies, HIV-positive mothers identified through centres offering programmes for prevention of mother-to-child transmission, infected partners and children of those already receiving ART, health care workers essential to providing care and treatment, and teachers and other groups providing essential social services.

25. The principle of fairness is often expressed in a formal fashion: “Treat like cases alike; different cases differently”. However, because this principle does not state the criteria for treating cases alike or differently, it is necessary to consider substantive ethical principles, in particular, egalitarian, “maximin”, and “justice as compensation” principles.

26. The egalitarian principle seeks to achieve equal distribution of resources, and in the case of access to ART, would seek to reduce disparities in the health status of those living with HIV/AIDS. When using this principle it would be necessary for implementers to choose what is to be equalized when priority for access ART is given to certain groups. In other words, should resources for health, health status, or access to health services be equal?

27. The “maximin” principle gives preference to those who are “worst off” or least advantaged. Its application requires implementers to choose the criteria by which to judge who is “worst off”. Should they choose those whose health is the worst, those who are poorest, those who are the most vulnerable or marginalized, or those who have the least access to health services? Implementers could also choose to give priority to the sickest or to those in most urgent need of treatment, that is, those “worst off if not treated”. Priority based on the egalitarian and/or maximin principles could be given to groups who are marginalized, at high risk of having HIV/AIDS, and/or those who do not have access to health or HIV/AIDS care, such as women, children, the poor, migrants, rural and ethnic populations, internally displaced people and refugees, sex workers, men who have sex with men and injecting drug users.

28. Another ethical principle is that which seeks justice in the form of reciprocity or compensation, that is, rewarding people for something they have done (e.g. those who have participated in HIV trials, those who have been willing to come forward to be tested for HIV, or those who have disclosed their status through public advocacy) or compensating people for a harm that has been done to them (e.g. those who have been victims of unsafe medical practices or blood transfusion).

29. In the discussion of these principles and their application, the participants at the meeting pointed out that there are two broad moral concerns:

- to maximize all the benefits, not only health benefits, that are gained by use of limited resources – a principle of efficiency – with any losses being justified; and
- to distribute benefits in a way that is fair, i.e. all in need of the benefit have a fair chance of receiving it – a principle of equity or fairness.

30. In the context of rolling out ART programmes or of establishing the criteria for assigning priority among possible recipients of ART, overall benefits may be maximized by using one strategy or set of criteria whereas equity would favour a different strategy or set of priorities. For example, the participants at the consultation recognized that in many settings the fastest way to reach the largest number of patients would be to scale up an ART programme at the centres that now serve the most patients (who tend to be the better educated and relatively affluent people living in urban areas and receiving care at university hospitals or similar institutions); yet this could result in ignoring – or at best, indefinitely postponing – actions to address the needs of people whose needs are more difficult to meet (i.e. those in remote locations, those who are members of marginalized groups, and those who are unaware of their HIV status, often because they lack access to relevant HIV
Relevant ethical principles

educational and testing programmes). Likewise, social utility would argue for selection criteria that prioritized groups such as HIV-positive mothers of infants (i.e. having intervened to prevent infection in the infant, the mothers should also be protected), affected family member(s) of those already receiving ART (to prevent ART being shared between family members which can render the therapy ineffective and increase the risk of drug-resistant viral strains emerging), and health care workers (i.e. because they are needed for the success of the ART programme). Yet considerations of fairness would not necessarily be met by such selection criteria. Furthermore, although medical and overall benefit would argue in favour of continuation of ART once someone has started it, notions of fairness would dictate against giving some people lifelong treatment if that meant that others received no treatment at all.

31. Thus, the two general concerns – maximizing overall social benefits and giving everyone a fair chance – are often in opposition. The question becomes one of how much in overall benefits implementers should be willing and able to sacrifice to meet specific goals of fairness. It was pointed out that in times of emergency, such as the present global health emergency, efforts to obtain the greatest utility – to the detriment of fairness – can best be achieved. For these reasons, it was felt that margins of difference should be allowed between states, and that the process by which decisions are reached becomes critical to ensure the acceptance and legitimacy of the choices made (see paragraphs 36–42).

32. The participants agreed that delivery of ART must involve considerations of both utility and fairness. But it was clear from the discussion that those present gave different weight to different factors. The following groups were suggested by individual participants as being deserving of priority in part for the reasons given:

- those who were tested first (because they are “first in the queue” and may have shown courage in being willing to be tested in the face of possible stigmatization).

Some participants also suggested that those likely to adhere well to the treatment regime would deserve priority (so as to avoid development of drug-resistance). It was noted, however, that adherence is a dynamic process and that there is no evidence that the likelihood of adherence can be anticipated with any certainty.

33. The participants at the meeting acknowledged that it is very difficult, if not impossible, to reach agreement on how benefits should be weighed against fairness, or how equitable access to treatment can best be achieved. For these reasons, it was felt that margins of difference should be allowed between states, and that the process by which decisions are reached becomes critical to ensure the acceptance and legitimacy of the choices made (see paragraphs 36–42).

34. Because human rights call for universal access, some participants were uncomfortable with the selection of particular groups to receive priority and with the “positive discrimination” involved in such selection. In addition to the difficulty of agreeing on who was “most in need” or “most vulnerable”, one participant felt that some governments might misuse guidance that called for the selection of priority groups to allow them to practise discrimination against particular groups and/or exclude them from ART. For these reasons, a number of participants emphasized the critical importance of keeping universal access as the stated goal, with an obligation on governments to demonstrate how they intended to achieve it over time.

35. It was pointed out during the meeting that almost all current programmes for scaling up the provision of ART utilize some sort of social criteria for patient selection. These include a history of regular reporting to health facilities, adherence and the existence of some sort of treatment support. The use of such criteria was not discussed in detail. However, it was suggested that WHO and UNAIDS should evaluate the arguments and evidence for and against the use of such criteria.
Dr Norman Daniels presented an overview of his paper entitled How to achieve fair distribution of ART in “3 by 5”: fair process and legitimacy in patient selection. Dr Daniels reiterated the lack of agreement on principles specific enough to determine fair distribution of ART, noting in particular the ethical controversies surrounding issues of eligibility, siting of services and priorities. He argued that, in the absence of agreement on fair principles, the implementers of ART programmes should rely on fair process (“procedural justice”) to determine what is acceptable in a particular context and to provide legitimacy to the decisions taken.

The elements of fair process would include: publicity (transparency); relevance as judged by appropriate stakeholders; revisability in light of new evidence, arguments or appeals; and enforceability. Steps toward the implementation of fair process would involve clarifying institutional levels of decision-making, developing institutional structures to address decisions at each level, training to develop competence in fair process, learning from experience and improving process through training and research, and developing mechanisms for enforcement. To become effective in this context, further research and training about fair process may be needed as part of ART scale-up.

Dr Daniels pointed out that there would be certain constraints to fair process. Human rights dictate against certain unacceptable outcomes, such as the use of invidious categories. Furthermore, societies with undemocratic systems would have difficulty in accepting or implementing fair process. However, Dr Daniels urged that, even in environments hostile to fair process, efforts should be made to introduce fair process and to improve it, wherever possible. Dr Daniels enumerated a number of benefits beyond the provision of HIV treatment that should result from the implementation of fair process, such as the introduction of standards that would serve as models for other decision-making regarding health systems, greater accountability and democratic empowerment.

Some participants at the meeting expressed concern about the investment in time and money that fair process would require, particularly in the light of the emergency need for ART. The view was expressed that some stakeholders (e.g. government ministries, international institutions, nongovernmental organizations and activists) would be neither willing nor able, especially in countries on the point of social collapse, to take the time to implement fair process before beginning the roll-out of ART. At least one participant was uncomfortable with making fair process a condition for national scaling up. Another participant pointed out that some countries already have political institutions and procedures in which they use all the elements of fair process, but still arrive at the wrong outcomes and/or exclude or ignore the most vulnerable. In such situations, fair process would not necessarily result in ethical choices.

While acknowledging these concerns about fair process, the participants embraced it as a critical means by which to establish legitimate and ethical priorities in the provision of ART and to make these priorities acceptable to those affected by them. Participants also felt that the use of fair process would help to achieve important goals beyond 3 by 5. In particular, the use of fair process would offer an opportunity to enhance transparency, equity and governance mechanisms in all aspects of health, including the improved ability of civil society to hold governments and donors to account in terms of health and new and better structures to inform decision-making.

The participants at the meeting agreed that a focus on fair process should not delay a response to the emergency which is at the root of the 3 by 5 initiative. Nor should governments be allowed to use the development of fair process as an excuse to delay taking action. The participants at the meeting recognized that it might not be possible or desirable in some settings to implement fair process as an initial condition, but they felt that efforts to implement fair process at the international, national and local levels should be undertaken as early as possible in the implementation process. In terms of the acceptance of fair process by people living with HIV/AIDS, it was felt that it would be acceptable to them as long as they believed that, when they are clinically eligible and it’s their turn for treatment, ART will be available.

The participants at the meeting urged that early efforts to implement fair process should include the following:

- research on fair process;
- the development of training materials;
- workshops focused on training in fair process; and
- the development of indicators by which to monitor and evaluate fair process and decision-making in the context of the scaling up of ART.

The participants at the meeting stressed that an important challenge would be to guarantee meaningful participation of relevant stakeholders in fair process and it was suggested that a research agenda be developed to investigate this issue.
Dr Eugenio Villar presented a paper entitled “3 by 5”, *priority in treatment and the poor*. Dr Villar stressed that the pandemic of HIV/AIDS is not only a health emergency, but is also about human suffering and the failings of development, including widespread poverty, weak health systems with poor and inequitable health outcomes, and it has a devastating impact on, among other things, health systems and human resources. Nevertheless, in light of the political momentum surrounding the scaling up of ART, the financial assistance earmarked for this purpose, and the broader context of achieving the Millennium Development Goals, the 3 by 5 initiative is also an important opportunity to address some of the needs of the poor and to strengthen health systems through a pro-poor approach. “Poverty” is defined to include not only economic poverty, but also the social and political dimensions of poverty.

Lessons learned from local and national successes in the provision of ART indicate the importance of the following factors: strong political support, planning based on effective disease surveillance, public finance mechanisms to protect the poor, uninterrupted supply of drugs to facilities, legislation to guarantee low cost of drugs, health care networks anchored at the lowest level of care with an effective upward referral system, outreach programmes, home care and community participation involving community workers, and resources for advocacy and demand stimulation. Furthermore, any scaling up of ART should be achieved through an overall primary health care approach.

Many of the participants at the meeting felt a pro-poor approach to be critical to the ethical implementation of ART programmes. These participants felt that, unless a systematic, concerted effort is made to reduce disparities and inequities in health care and to ensure that the poor benefit, the “better off” will be the ones who receive ART first. It was felt that a pro-poor approach would be necessary to:

- enable the poor to gain access to treatment (whereas the wealthy are able to gain access with their own resources);
- make the process of selecting beneficiaries as egalitarian as possible; and
- move towards greater equity in health care between the rich and the poor.

Furthermore it was pointed out that the relationship between poverty and stigma is being increasingly recognized. Offering treatment to the poor will help to change the dynamics of that relationship and overcome stigma.

The participants at the meeting urged, however, that care must be taken with regard to the definition, use and implications of the term “poor”. It was pointed out that there is great variability within and between countries concerning who is classified as poor. Furthermore, use of the term “poor” often masks the denial of human rights, including injustice meted out to certain sectors of the population because they are different; the failure of government and leaders to meet their social and economic obligations; and the diversity among those classified as “poor”.

The participants at the meeting further noted that the goal of equity would not be entirely attained by a pro-poor approach. Depending on the nature of the epidemic in a particular country, the poor might not necessarily be those in the greatest need of access to ART. Furthermore, in many countries, barriers to equity stem from factors not associated with wealth or poverty. These barriers include gender; lack of governance, transparency and accountability; corruption; stigma and discrimination; educational and/or geographical isolation. Thus, there is a need not only to focus on the poor, but also to focus on those marginalized by factors other than poverty.

Some participants were uncomfortable with the focus on the poor. One participant wanted to clarify the justification for giving the poor priority asking whether it was to compensate for other harms done to them because they were poor. Another participant felt that a focus on the poor was redundant since the countries in which the burden of disease is highest are also by and large the poorest countries, and within these countries, HIV/AIDS generally correlates with poverty.
49. The participants at the meeting did not agree on whether provision of ART should be free for all at point of delivery or be subject to cost recovery for those with the means to pay. The participants, however, did agree that cost should not be a barrier to access for anyone needing treatment. Some participants felt that the decision on whether or not to provide ART free at point of delivery to all must be left to individual countries based on the realities pertaining in each. To do otherwise might result in the disruption of existing systems.

50. A number of participants felt strongly that ART should be provided free at point of delivery to all who needed it. It was noted that:

- It is difficult to determine ability to pay, and costly and inefficient to administer “sliding scale” programmes.
- Even low costs for drugs constitute an insurmountable barrier for many of the people wanting to start treatment.
- Evidence shows that even when drugs are inexpensive, some patients who have started therapy discontinue it when they can no longer afford it, or do not purchase their drugs regularly.
- Where services are free, it still costs people a significant amount of money just to come in for treatment.

In the light of this knowledge, every effort should be made to enable people to feel confident enough to become connected and stay connected to health services. Any effort to recover costs would have the opposite effect, and would therefore constitute a serious barrier to equity and achievement of the eventual goal of universal access.

51. Other participants, however, noted that cost recovery was entrenched in many systems. It would be difficult to exempt ART from cost recovery when patients are required to pay for other health services and medications, particularly if the provision of ART is well integrated into the health care system. Some participants expressed the view that, where resources are limited, it would be unethical for governments to provide ART free to those who can afford it. Such a policy could reduce the pool of people to whom ART could be provided and/or reduce the sustainability of the programme. Thus, they urged that only the poor should be offered free delivery of ART.

52. A number of participants felt that cost recovery for ART could involve a mixture of public and private schemes with different delivery mechanisms for different segments of the population – free to those who cannot pay and have no insurance; payment by insurance schemes for those in the formal workforce; and payment out of pocket by those wealthy enough to do so.
The participants at the meeting discussed both the “emergency” nature of the 3 by 5 initiative and the “long-term” nature of ART itself, and the implications of characterizing the scaling up of treatment in either of those ways. The need for urgency is self-evident: several thousand people are dying each day from a treatable and preventable disease. This has been the case for many years, even though the treatment gap was not declared a global health emergency until September 2003. On the other hand, the treatment gap arises from a number of factors, including deep, ongoing structural problems and reflects a long-term crisis that is likely to last for decades.

Thus, the participants at the meeting recognized that the 3 by 5 initiative calls for responses that are not only urgent and immediate, but that will also be sustainable throughout the lives of those receiving treatment, as well as over the course of the epidemic. In particular, donor governments and private funding agencies will have to make decisions about funding that will need to continue for many years to come. Also, donors and governments respond very differently to emergencies and to long-term structural issues and private funders often make grants only in the short term.
Participants discussed the context in which the 3 by 5 initiative is operating. Although many of the countries involved have national plans and have approached and/or received funding from the Global Fund, the World Bank’s Multi-Country AIDS Program and the US President’s Emergency Plan for AIDS Relief, few of these countries have had experience with a public health challenge of this magnitude. Furthermore, many countries are trying to implement ART under conditions of poverty, political and social breakdown, corruption, and/or collapse of health systems.

In this regard, participants urged that incentives are needed to encourage governments to act responsibly and meet their international and national obligations in the provision of health care and the fulfilment of other human rights. Transparency, accountability and the participation of civil society should become critical components of implementation.

It was pointed out that many national plans for the provision of treatment and care for people with HIV/AIDS are mostly technical, do not address equity issues (or do so in a medicalized manner), and are only just beginning to incorporate targets commensurate with those called for by the 3 by 5 initiative. The participants at the meeting urged that the scaling up of ART should be within the contexts of:

- broader development goals;
- a comprehensive response to HIV/AIDS; and
- primary health care delivery, to the degree possible.

Furthermore, national plans for scaling up should involve:

- a detailed road map for universal access;
- ways to strengthen governmental financial and health care systems;
- a workable strategy based on multisectoral support;
- strong involvement of local communities; and
- methods by which to monitor the process.

The participants at the meeting discussed the practical issue of where to start. There was general agreement that immediate efforts should be made to treat people already identified as being HIV-positive, in need of treatment, and reporting for care, based on the ethical imperative to offer treatment as soon as possible. Some participants argued that in this group of people, the principle of a queue – first come, first served – should be applied.

It was recognized, however, that the majority of those already in the health system are likely to be those better served (“better off”) than many others and that this group does not always include the people who should receive priority treatment. Furthermore, investment in people already in the system could have opportunity costs for those not in the system. For these reasons, it was stressed that, although implementation should start with known eligible cases, simultaneous efforts should be made to develop and implement strategies for the identification of new and hard-to-reach cases and for bringing them into the system. These efforts would involve expansion of testing and counseling, and outreach to underserved or marginalized populations, such as the poor, women and children, migrants, men who have sex with men, sex workers and intravenous drug users.

There was also discussion as to where the programmes providing ART should be located. The discussion illustrated the complexity of the competing and overlapping concerns of efficiency and equity. Short-term efficiency dictates that provision of ART should begin in areas where the necessary infrastructure is already in place, whereas both equity and long-term efficiency dictate investment in infrastructure in rural and underserved areas so as to eventually serve broader health needs.

The participants at the meeting felt that overcoming barriers to health care (in terms of health-seeking behaviour, and of cultural, social and geographical barriers) and reaching underserved people are among the most important challenges of ART scale-up. Thus, participants felt that, if it was necessary for immediate scaling up, provision of ART could ethically begin where present capacity allows it (often in capital cities and university hospitals), provided that steps were taken simultaneously to plan for and implement programmes in rural areas and among marginalized groups.
Citing the example of Brazil, one participant described the dynamics of scaling up the provision of care in the context of achieving universal access. In Brazil, health care was declared a right in the Federal Constitution of 1988. In 1996, a federal law was approved granting free ART to all HIV-infected patients who have medical indications for treatment. The Brazilian AIDS Program established clinical centres, laboratory infrastructure (providing free viral load and CD4 counts), condom distribution and outreach programmes. In the first year, two thousand people were receiving ART and by 2004, 130 000 were on ART. Sixteen drugs are available, eight of which are produced locally by public laboratories. It is estimated that the total expenditure on ART (1996–2002) was around US$ 2.4 billion and, in response to criticism that these costs were too high, the government reported that besides the social gains (better quality of life, and reductions in morbidity and mortality) there was actually an estimated saving of US$ 2.2 billion in this period (as a result of the reduction by 90 000 in the number of AIDS-related deaths, prevention of over 58 000 new cases of AIDS and avoidance of 400 000 hospital admissions).
There was strong consensus among the participants at the meeting concerning the centrality of health systems and the need to scale up ART in ways that would strengthen health systems overall. Thus, the participants urged that the equity analysis consider not only questions of individual access to treatment, but also about means of delivery that will not harm health systems. Participants noted the many forces that are currently undermining health systems. These include: increasing privatization and segmentation of health care delivery into separate systems for the poor, middle-class and rich; the diminishing role of central government resulting from devolution to local authorities; concentration on acute care as opposed to care for chronic conditions; erosion of basic sanitation and nutrition; and the impact of the HIV epidemic on human and other health resources.

The participants at the meeting noted two sets of opportunity costs that would be a part of the implementation of ART: those related to other services due to the focus on HIV, and those related to health systems as a result of a vertical implementation of ART programmes. Participants stressed the need to be aware of these costs and to decide how best to manage them. One participant pointed out that these issues were in part related to speed. The greater the speed in rolling out ART the greater the potential for verticality, the creation of parallel health services, reduced integration and support to primary health care, and the diversion of human and other resources from other areas. Thus, the goal becomes to scale up as fast as possible, while avoiding the negative costs associated with speed.

The participants at the meeting noted that the movement to expand access to ART represents one of the few areas in which there is significant political will, commitment and resources with which to improve public health on a global level. As such, it provides a unique opportunity to strengthen health systems. It was agreed that ART should be delivered in such a way that resources are utilized to support essential health services. The participants agreed that the best way to strengthen health systems would be to use the primary health care approach.

Practical examples of ways of improving health systems through the scale-up of ART include supporting strong local networks for primary care; setting up systems for procurement of essential drugs and for their distribution and monitoring; strengthening government financial systems that support health; addressing the human resource crisis through providing treatment, incentives and salaries for health care workers; increasing public accountability; and supporting community involvement and the social networks that are so important in ensuring success against the epidemic. It was felt that the provision of ART would be able to set the stage for advocacy for other diseases and health systems, and for this reason the 3 by 5 initiative should have a strong advocacy component.

Though it was recognized that providing ART cannot “fix” everything, some of the participants felt that 3 by 5 could be used as a means to accelerate the achievement of broad health and social goals. Steps to support these goals could include: allocating sufficient and sustainable resources for health care; designing health systems in a way that responds to various social claims for greater inclusion; creating models of finance based on collective social responsibility; and building capacity to deliver comprehensive health care, including treatment for chronic conditions. Some participants urged WHO to reclaim moral authority in the discussion of health and health systems by moving beyond the creation of normative positions on access to treatment for individuals and engaging in an active pursuit of these goals. One participant suggested that the campaign for access to ART be coupled with efforts to attain equity and fairness in the globalization process so as to build capacity at the macro level for sustained global investment in health infrastructure and for dealing with future epidemics. Some participants also felt that efforts under the 3 by 5 initiative should tackle other global constraints, such as those resulting from patent laws, debt repayment requirements and trade barriers.
Partnerships

67. The participants at the meeting stressed the centrality of the participation of a broad range of actors in the scale-up of HIV/AIDS programmes, including the provision of ART. This would include civil society, international agencies, the private sector and the relevant sectors of governments. Consistent with the multisectorial approach of UNAIDS, the participants urged WHO to broaden its contacts to include those outside of ministries of health. In particular, WHO should be prepared to work directly with the private sector, nongovernmental organizations and associations of people living with HIV/AIDS. Concern was expressed that in many developing countries there is very little real contribution or involvement from civil society. Such involvement must be strongly encouraged and supported.

68. Representatives of WHO reiterated that 3 by 5 is not a target that can be reached by the efforts of WHO alone, but requires the involvement of many partners and stakeholders, including WHO, other UNAIDS Cosponsors and the Secretariat, governments, people living with HIV/AIDS, funding agencies, and the private sector, including businesses, private health care providers and pharmaceutical companies. How to make participation of all groups meaningful is still a question that requires an answer. With regard to the 3 by 5 initiative, WHO has been exploring how processes that involve all the partners can be brought to bear in different places and at different levels in different countries.
69. The participants at the meeting noted the human tragedy of thousands of individuals continuing to die of a treatable disease, as well as the continuing toll of stigma, discrimination and indifference at the hands of communities, governments and health systems. The stigma attached to HIV/AIDS continues to distort the response of governments and communities, including taking the form of “blaming” certain groups according to how they became infected. Although networks of people living with HIV/AIDS are achieving important goals through organization and advocacy, it was agreed that the lack of a strong voice of people infected and affected is a major issue in many countries. Some participants argued that citizens should be empowered to recognize that they should receive ART as a right. The international community can help out, but communities themselves must mobilize to claim the human right to receive treatment.

70. The participants at the meeting noted that currently there may actually be more supply than demand for ART therapy. This may mean that the greatest initial challenge will be recruiting sufficient numbers of people to receive treatment, not deciding who will get it. Pointing out that need and demand were two different things, some participants asked whether a country-by-country estimate had been made of the number of people likely to come forward for treatment under the initiative. It was also pointed out that both need and demand would increase leading, over time, from a 3 by 5 scenario to scenarios of “5 by 6” and “9 by 7”. Participants urged implementers to plan ahead for this cumulative demand.

71. The participants at the meeting stressed that ethical considerations require that demand for ART be generated by ART literacy and health-seeking empowerment so that efforts are not limited to those already in the health system and/or otherwise privileged. As discussed in the previous point, specific efforts have to be made to reach those who are not willing or able to seek treatment. Participants emphasized that people living with HIV/AIDS are the primary stakeholders and should be involved from the outset to help to identify and overcome the barriers to health-seeking behaviour and access, e.g. stigma, discrimination, lack of voluntary testing and counselling (VCT), gender, geography, poverty and criminalization. Establishing a fair process at all levels, as discussed above, was cited as one of the best ways to create equity and ART literacy and demand.
The participants at the meeting recognized the critical importance of gender in an epidemic where women now account for almost half of all adults living with HIV/AIDS worldwide, and for 58% of those living with HIV/AIDS in sub-Saharan Africa (see Report on the global HIV/AIDS epidemic. Geneva, UNAIDS, 2002). It was stressed that those implementing ART should pay attention to the need for comprehensive integration of gender issues — addressing the needs of all women and girls. In this regard, it was urged that not only should the needs of pregnant and other women who attend targeted programmes be met, but also that ART programmes address the needs of other vulnerable women who may not normally be reached.

In particular, HIV/AIDS treatment programmes will need to address the barriers faced by women in getting access to preventive measures, VCT and other forms of treatment. These barriers include discrimination in the social, economic, political, education and health spheres, violence against women, and harmful traditions and practices. These problems are compounded for women living with HIV/AIDS. One participant pointed out that questions of access to treatment are decided at the family level, and for many women and girls, such decisions result in their being denied access to treatment.

The participants at the meeting urged that ART programmes reach out to women and girls and assist in providing access to other social services that would help them to address systemic factors that lead to inequality and oppression. These might include services that address discrimination and stigma; legal assistance in matters relating to property ownership, credit, divorce, custody and inheritance; shelter from violence; and economic and educational empowerment. Funding should be targeted to those governmental and nongovernmental entities that provide these social services so that they actually provide sufficient help to women and girls. It was also urged that indicators be sure to capture the gender dimensions of equity in implementation of ART programmes.
Monitoring and evaluation

75. Dr Catherine Hankins gave a presentation entitled *What indicators will be useful in measuring fair access?* She pointed out that there has been an “epidemic” of HIV/AIDS-related indicators which has resulted in the need for harmonization to reduce the reporting burden on countries and to ensure comparability. In the context of the issues of equity and access to ART, verifiable indicators might include:

- publication and use of guidelines on ethics and equity;
- programme monitoring that includes the collection of data on gender, age, socioeconomic status and marginalization;
- national targets being set; and
- the number of community-based organizations and organizations of people living with HIV/AIDS that are participating.

Outcome indicators would include the number of men, women and children with advanced infection receiving ART. Other efforts could involve monitoring fair process so that lessons learned could be used to improve outcomes; monitoring implementation of decisions on patient selection; mapping baseline access and setting targets, such as those related to gender; and developing strategies to reach targets.

76. In the light of the view that those implementing ART should be concerned both with equity within the specific context of treatment programmes and in a broader health context, the participants at the meeting stressed the need to monitor how ART is contributing to improvements in:

- access to treatment within a comprehensive response to HIV/AIDS;
- the overall HIV/AIDS situation;
- health systems; and
- delivery of health care generally.

It was recognized that indicators may differ from one country to another depending on problems of equity and access, including the actual experience of people receiving the ART. A further suggestion was the inclusion of relevant national or international baselines and indicators in addition to the local ones, reflecting for example, migration of personnel from country to country, or within a country and from region to region.

77. The participants at the meeting also stressed that indicators should be developed and used to monitor and evaluate decision-making, as well as other elements of fair process, at various levels in the implementation of ART. This could be a part of a broader effort by governments and others to examine accountability and other governance issues in health systems. It was recognized that it will be necessary to develop and implement a research agenda around issues of fair process as a way to allow it to be effectively implemented and monitored.
## Annex 1

### List of participants

<table>
<thead>
<tr>
<th>Name</th>
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Annex 2
List of background papers

The three papers prepared for the consultation are available for download from the WHO ethics and health web site, www.who.int/ethics/.


- Pro-Poor Health Policy Team (POV/HDP/SDE/WHO), *“3 by 5”, priority in treatment and the poor* (2003)