

HATiP

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Treatment equity in practice: how scarce resources for treatment are being used, and the ethical dilemmas that need to be debated

Criteria for rationing treatment

[With thanks to Dr Siobhan Crowley of WHO for her input to this article]

The goal of treating 3 million patients with HIV in the developing world by the end of this year is an ambitious one, but even should that target be met, millions more in the developing world will still be waiting for antiretroviral therapy (ART). In some resource-limited settings, it will take years to develop the infrastructure, and marshal the human and financial resources to meet the demand for first-line treatment. Access to expensive second line treatments will be even more limited.

In the meantime, rationing of access to treatment will be inevitable and is already occurring implicitly in most settings - even where treatment is being doled out on a first come first serve basis, or to those able to commute to the clinic. But is this really the most rational and ethical basis for allocating treatment?

In a [December 2004 commentary](#) in *The Lancet*, researchers from the United States and South Africa suggest that where rationing occurs, criteria need to be transparent and need to be openly debated by civil society, donors and other stakeholders. The commentary is available [online in pdf form](#).

WHO recently published 'Guidance on ethics and equitable access to HIV treatment and care' (see http://www.who.int/ethics/resource_allocation/en/), the result of an international expert consultation in January 2004.

The key recommendations of the guidance are:

- 1 Scale up HIV treatment and care, as it is an ethics and human rights imperative
- 2 Establish broadly representative ethics advisory bodies
- 3 Create opportunities for public dialogue on equitable access to HIV treatment and care
- 4 Develop policies for scaling up HIV treatment that are firmly based in human rights and ethical principles
- 5 Identify vulnerable, marginalized or other potentially underserved populations
- 6 Consider the need for special policies and outreach programmes to prioritize these groups and to overcome barriers to their accessing care
- 7 Establish a fair process for setting priorities in the distribution of HIV treatment
- 8 Define or adopt a set of five to seven measurable indicators to monitor the fairness of HIV treatment scale up at the national and community level.
- 9 Use monitoring and evaluation data to ensure that HIV programmes are producing equitable results.

Currently, efforts towards dissemination and country work are under way. The goal is to raise awareness among policy makers for distributive justice and equity in HIV/AIDS, to promote best practice

in conducting fair consultative processes, and to facilitate the formulation of national policy papers on the topic. In addition, equity indicators for monitoring and evaluation of these policies under severe resource constraints are being developed. (See: <http://www.who.int/hiv/pub/advocacy/guidelines/en/>)

Equity in practice

But what does equity mean in practice? When health care is in short supply, a multitude of criteria can be applied to decide who receives what level of care. Although based on apparently neutral clinical criteria that appear 'common-sense' to clinicians, all clinical guidelines imply value judgements about who is most needy, or how scarce resources can be most equitably distributed.

For example, countries such as Botswana have prioritised the sickest to receive ARVs first. Although this is a practical consideration - if they don't receive ARV treatment they will die or tie up health care worker time in the treatment of serious illnesses - an ethical consideration is also implicit here. These people are the most needy of immediate care, and as a global society we generally agree in the abstract that those most in need should receive scarce resources first.

However, when talking about scarcity, we often talk about how scarce resources can be put to the best use (utility). Those who believe in this 'greatest good of the greatest number' approach to health care would argue that it is better to prioritise those who will respond better to treatment and live longer - generally not the sickest patients. This approach also argues for the prioritisation of less sick patients because they will require less health care worker time, thus allowing more patients to be enrolled, and quicker too.

Arguments about utility and ethics often raise the question of whether the benefit of treatment should be calculated solely in terms of the benefit to an individual or to the wider society. For example, an individualist or non-consequentialist approach would be to say that a woman deserves priority in treatment because women have poorer access to health care in general. A social utilitarian approach would be to argue that women should also be treated in order to reduce mother to child transmission and the burden of HIV-infected children and orphans, and that these may be more important justifications for prioritising this group of patients in the long run.

Access to treatment is also determined by decisions about the siting of treatment facilities. Those who argue for all due speed and efficiency tend to advocate using existing centres of excellence to spearhead treatment roll out. Critics of this approach say that it further entrenches existing inequities of health care distribution within countries, and risks squandering the transformative potential for the health care system of new resources from bodies such as the Global Fund to Fight AIDS. In particular, it risks further entrenching the gap between rural and urban populations and reinforcing the division between hospital-based and primary care.

In some programmes, rationing is implicit, for example, treatment is limited to those with access to the ART-dispensing clinic. Most facilities probably will treat everyone who is medically eligible on a first-come, first-served basis until they run out of drugs or expertise.

Systems based on queuing may be biased in favour of those who are free to wait in a queue: those with jobs, child-care responsibilities, or other obligations may never get to the front.

While queuing may be a one-time ordeal to get on the ART waiting list, at some sites in Africa, patient waiting times (in general) are extraordinarily long (4+ hours). Patients without emergencies are often turned away and told to come back on another day.

Queuing also depends on who gets tested at a particular site, if, for example, women do not come forward for testing due to concerns about stigma at one particular site, a first come first served allocation of treatment will pay little attention to gender equity. If on the other hand testing and treatment for mothers and families is prioritised at another site, "it would be unfair to nonpregnant women, men and children who learned of their HIV-positive status at a later time," observed Ruth Macklin of New York's Albert Einstein College of Medicine in a discussion paper prepared for the 2004 WHO consultation on equitable access to treatment.

She also notes: "Giving priority to pregnant women would be unfair to nonpregnant women. In societies that discriminate against women generally but place a high value on women only when they are pregnant, gender equity would not be served by giving pregnant women preference for treatment over non-pregnant women."

Other criteria for rationing treatment

Other programmes use explicit socio-economic criteria to define the populations that have priority.

Examples include:

- Mothers of new infants (to prevent mother-to-child transmission)
- Skilled workers, health care workers, teachers, bureaucrats, armed forces - to preserve to social order/and or the country's economic viability. Uganda has recently announced that it will provide free ART to its healthcare workers who qualify for treatment, see <http://www.aidsmap.com/en/news/2B975DAF-4A42-4402-860A-46DDFF159489.asp>
- The poor or any individual who cannot afford treatment - again, here demand is likely to outstrip supply. However, in some countries such as South Africa, it is a constitutional mandate that any large public health programme should be equitable.

In contrast, other programmes have chosen to require co-payments from patients in order to receive treatment - essentially rationing by income. At least some of Uganda's patients receive treatment through a fee-for-service model:

<http://www.aidsmap.com/en/news/AFB128B5-AEF7-4FAF-9A0B-E0322C3BA99F.asp> .

Other programmes employ geographical rationing, in which some regions have preferential access to treatment, either because of the nature of available infrastructure or explicit decisions made on epidemiological or political grounds.

Hard choices are unavoidable

"Different ways to ration antiretroviral therapy will have different social and economic consequences for African populations. Understanding these outcomes is important if the decisions made about resource allocation and programme design are to help a nation accomplish its goals for fighting HIV/AIDS and sustaining economic development", say the authors of *The Lancet* commentary.

"Hard choices are unavoidable." The authors warn that at each decision-making level, from international donors, though governments and local health services, there will be a temptation to use implicit systems of rationing rather than to make and enforce hard choices.

They conclude: "African governments can ration deliberately, on the basis of explicit criteria, or they can allow implicit rationing to prevail. Without analysis and debate about public policy, people will

make arbitrary decisions about access to treatment, and implicit rationing will foster both inequity and inefficiency."

"We believe that governments that make deliberate choices about rationing antiretroviral therapy, and then explain and defend those choices to their constituencies, are more likely to sustain economic development and social cohesion and secure a socially desirable return from the large investments now being made."

Commentary

When discussing treatment rationing, a distinction should be made between:

- vanguard programmes piloting antiretroviral therapy (ART) in various settings, and
- national programmes that are responsible for providing antiretroviral care within a country (or province/region).

Small pilot ART programmes manage their limited resources with patient selection or eligibility criteria. Naturally the criteria varies depending upon the purpose of the programme - such as the programme that Chris Green mentions that provides ART to treatment advocates (see below).

Another example is Columbia University's MTCT+ Initiative, which provides care and support to women, children, and their family members at a number of sites in different countries. There are programmatic criteria that limit resources to women, children, partners and household members, and then there are clinical criteria for treatment. However, the initiative devolves responsibility to each site regarding how to define "households" and other criteria - using community boards to reach decisions.

But national programmes rarely devolve responsibility for treatment rationing to local community boards. In most settings, responsibility is devolved down to the provincial or district level - but it rarely goes much further than that. This varies by setting. In Uganda, for example, as Dr. Henry Barigye points out (see below), there is a mix of programmes/funders, so there will be a variety of rationing/selection criteria).

But how do national programmes with a mission to provide comprehensive care to their citizens with HIV honestly tackle treatment rationing and equity? During start-up, most national programmes have little choice but to employ geographical rationing because the healthcare delivery infrastructure is initially limited to the clinics already in operation.

This likely reinforces longstanding inequities in healthcare (between rich and poor, urban and rural) but it makes sense to first rollout ART in established centres. How ART programmes expand from there is another matter.

An issue that the *Lancet* article didn't really touch on is that ART cannot be divorced from the delivery of a basic package of primary care and the need to improve the health care structure in general - otherwise overburdened health care systems could buckle under the weight of the roll-out. (On the other hand, it could be argued that healthcare systems are already buckling under the increased burden of illness associated with HIV itself - and that the rollout will reduce that burden).

Nonetheless, in most developing countries, the resources available to primary care are insufficient to cope with both the volume of patients and the provision of even the most basic primary care package. Resources being directed to managing HIV could improve healthcare infrastructure and improve equity in healthcare. But if managed poorly, the introduction of ART could increase rationing of other general healthcare services due to the human resource and time commitments required to run ART programmes.

This is one of the reasons why monitoring and evaluation is so important. It might be possible to reach 3x5 targets in terms of numbers of patients put on treatment, and yet fail to measurably improve the general health outcomes of people living in resource limited settings.

(Part Two of this article follows in a second email).

Advisory panel feedback

HATIP asked the members of its Advisory Panel whether there are explicit criteria for treatment rationing at their sites? If so, how were these chosen? Has their programme chosen to prioritise treatment of mothers or families?

Was triage part of their approach? Should available care be directed only to those with some hope of survival or a good chance of responding? How does patient "readiness" or ability to be "trained" for treatment affect decisions?

Panel responses reveal a wide range of views and practices already developing in the field.

Dr Francois Venter

Esselen Street Project, Hillbrow, Johannesburg

Our explicit criteria in South Africa are entirely based on medical need - CD4 <200 or AIDS-defining disease, and then willing to come for several adherence visits. There are plenty of hidden details - everything from geographical location to the number of adherence visits.

In SA, it's a function of where you live, how motivated you are to access the site, and whether you can cope with the queues.

SA's constitution does not allow discrimination on basis of demographics, [so allocation of treatment by the state on the grounds of profession or employment, or to pregnant women, would be considered discriminatory] and is thus not a subject of debate.

I desperately tried to come up with some criteria, but I'm afraid I couldn't. In my clinic, we've managed to cut waiting times to a week, so it's not an issue yet. Before that, we just pushed people into a simple queue, and hoped they lived long enough to get to the front. Brutal but simple, and I don't know of any better system at present. But mine is certainly not one I'd want to defend.

The only venture, I guess, is to debate whether people with incurable malignancies, such as KS or poorly responsive lymphoma, should not be considered. Then, I guess you could look at 'high consuming' diseases - things which are very expensive to diagnose/treat. MAI, and CMV leap to mind. But I don't like that. I think there are such disparities in the health system in SA, that asking for a rational debate ONLY in HIV seems ridiculous.

Dr Henry Barigye

Mildmay Centre, Kampala, Uganda

The rationing criteria are not uniform in Uganda. I will mention one centre I am conversant with - The Mildmay Centre. As part of the PEPFAR programme, patients are invited on the basis of who registered first (patients were previously attending for treatment of OIs), whether they are clinically eligible and whether they have a treatment supporter. They follow a family approach. So, if a client has children or spouse(s), they are invited to test and would also benefit if they qualify. They will continue recruiting until they reach the 1000 [patients], which PEPFAR is willing to take on.

However there is also another category of people who pay for their treatment. These will start treatment as long as they clinically qualify and they do not need to have treatment supporters.

As you can see even in one institution they are combining various methods. The same is true for the whole country. I feel that no single method will be adopted, but a combination of different approaches. I disagree that queuing is biased against those who are not free to wait in a queue. What queuing should mean is that treatment is given on the basis of first to present to the treatment centre. Surely any system will include some form of queuing. There is no way one will wait for some one who "strongly" deserves but is yet to present him or her self. Finally there is need to consider the contradiction that patients who get medicines for free usually undergo different steps and procedures than those who just purchase them out of pocket.

Dr Halima Dawood

King Edwards Hospital, KZN South Africa

The King Edward site was one of the few sites in KZN that had patients with CD4 counts documented and hence was most prepared to commence the ARV programme. About 3-4 months into the programme other sites came on board and the decision was taken by the team to refer patients to their nearest site. This I believe was implicit rationing as patients choose their site for a variety of reasons: stigma being a significant factor.

Initially the goal of the programme was to attain numbers in order to get funds and hence build infrastructure. Currently there is no assessment of the programme at this site.

I believe [that while] clinical criteria are essential to commencement of HAART, the patient "buy-in" to the treatment plan is essential. This will significantly impact on adherence and hence the success of the programme. Placing patients on ARVs solely because they are HIV-infected, should not be the only reason to commence ARVs. We [also] try to get families on board

Chances of survival in HIV infection may be difficult to predict as great heterogeneity in treatment response has been demonstrated. The most ill patients may not be the best candidates for treatment, but I have treated patients who are extremely ill and are brought in by family members who provide tremendous support. This has resulted in treatment success. Once again being HIV-positive should not be the sole criteria as HIV therapy is different from other chronic diseases in that the effects of non-treatment or non-compliance are not manifested acutely. We need a paradigm shift in our thinking of managing a chronic disease that goes beyond just medical therapy.

Chris Green

Treatment Educator for the Spiritia Foundation, Jakarta, Indonesia

We have given considerable thought to this since we started a fund to provide therapy to activists in our network.. A number of basic elements show how we approached this:

1. Clinical criteria must be the basic entry point
2. There must be consideration of ability to adhere. For this reason, the recipient must have revealed status to at least one supporter, who must also agree to accept this role. Both must agree to learn about the importance of adherence.
3. There needs to be a committee who will decide on candidates. Preferably this should not include doctors or nurses who are caring for the candidate.
4. Priorities must be clear. This may include pregnant women, families with young children, and (in our case) activists - we can justify this because it is a principle of the fund.

We discussed this topic at our recent Treatment Educators' course. One major concern in our environment (not yet perhaps in

Africa) is the fact that many who need treatment are drug users, either active or liable to relapse. The point is made that drug users are among the most adherent to their own regimen - they have to get their fix on time - but there is no doubt that active drug use does make adherence more difficult. But should we send active users to the end of the queue?

There is also the topic of subsidy. There are still many who believe that adherence is enhanced if people have to contribute to the cost of treatment, even though most studies fail to support this. The more people who contribute, the more people we can support. But should those who are willing to contribute go to the top of the queue? And what do we do if someone who agrees to contribute fails to do so, either for good or bad reasons?

As for triage, priority is given to those most likely to survive post treatment. This would suggest that we DON'T give priority e.g. to those with CD4s in single digits with TB. On the other hand, most such candidates don't consume the limited supplies for very long - and if they do, then you could say we've been successful.

One other point that rarely gets raised: we are effectively rationing by diagnosis. Currently less than 5000 people in Indonesia are aware that they are infected, out of an estimated 130,000. Our national objective in line with 3 by 5 is to treat 10,000 people by the end of this year. But we can't treat people who are not aware they are infected. And it's most unlikely we'll find enough this year - some estimates are that we'll need to test 500,000-1 million people to find the 10,000, and there's no way we can scale up VCT that fast. I suspect that similar situations apply in many parts of Africa. When I visited Khayalitsha, MSF noted that their waiting list was not very long, but nor was it getting longer. We need to work much harder on promoting the availability of ART, and scaling up VCT.

On the other hand, we need to be aware (or hope?) that prices will come down. There is no reason why first-line ART should be more expensive than TB treatment - we'll see prices below \$50 per year well before 2010. What is going to be much more concerning is how we ration second-line and salvage therapies, which, like treatment for MDR-TB will remain very expensive. But if this therapy is needed because of lack of adherence, the chances are it will rapidly fail as well. Would this be throwing good money after bad? How do we allocate funding between first- and second-line?

Finally, we talk of the need for transparency, accountability and enforcement. Great, but... let's be realistic. These are not qualities for which our countries are well-known. We ask for policies to be made, yet many of our countries HATE to develop clear policies, since these limit the flexibility which allow priority to be given to 'certain' people. We need to be very pragmatic, and not aim for perfect systems, but provide communities with the skills to monitor what happens - yet be aware that they are equally open to 'bias'.

In the end, while we should aim (generally) for 'equity', this is pie in the sky. If we had real equity, people in the US and Europe would have the same access as those in Burundi. Some people will be treated, others not. The aim must be universal access as soon as possible, and in the meantime, well life just isn't fair.

BTW, I remember some time back a newspaper editor somewhere in Africa proposed that those who receive free therapy should be prepared to do something in return, particularly to speak out openly. Not sure that I fully agreed, but it is a valid point.

Dr Douglas Wilson

Edendale Hospital, KwaZulu-Natal, South Africa:

Equity: a: justice according to natural law or right; specifically: freedom from bias or favouritism b: something that is equitable [Merriam-Webster's Collegiate Dictionary]

To me the key phrase is 'natural law or right' which suggests that superhuman standards aren't needed to achieve equity - doing the best one can under the circumstances is OK.

At the Edendale ARV Clinic we insist that patients who meet the rollout's entry criteria attend the clinic to book their first appointment - this shows us that the patient is motivated enough and mobile enough to attend the adherence training and routine follow-up appointments. Patients also need to bring their treatment supporter with them to the three training session (which increases the transport costs for the patient). The booking system works well. Thereafter, in less than 2 weeks the patient will be on ARVs. Pregnant women have their own ARV clinic run by the obstetricians, but still need to jump through the same hoops. Very ill patients, including those with malignancies, are not 'fast-tracked' through the system, and still need to complete adherence training with their supporter.

Part of my job at Edendale is to expand and improve the diabetic service - there are not enough experienced clinicians to be able to divide up the work. How should I best be spending available time: trying to improve services for HIV-infected patients or for diabetics? Inevitably one makes compromises, and tries to achieve some degree of equity between the two groups of patients. These issues have never been publicly debated, and [yet] a consensus has been reached. We are left to make the best decisions we can, and are always vulnerable to criticism that we are not doing enough.

Paul Roux

Senior Pediatrician and Head of Pediatric HIV/AIDS service, Groote Schuur Hospital, South Africa

I have some 'big picture' thoughts on the issue of rationing, mainly to argue against those who believe that African countries have inevitably to ration access to ARVs.

An 'inclusive' view of HIV/AIDS - particularly in children - (or any other affliction, or congenital disability) is that it is society which 'has' HIV/AIDS, not the individuals who are affected. Infection of children with HIV, given the prevalence, is regarded as 'normal'.

Infected children are an inevitable part of the population. This formulation recognises infection as inherent to social structure: The pathology lies in society that has to be fixed, rather than something wrong with the individual that needs fixing. (See Herr SS, Gostin LO, Koh HH, Eds 'The human rights of persons with intellectual disabilities.' Oxford University Press 2003. (ISBN 0-19-826779-7).

The infected child is not merely a 'patient' or locus of infection, but a moral person and a participant member of society. On the argument of inclusivity, any society which 'has' HIV/AIDS, has no grounds upon which to impose rationing against individuals.

A practical formulation of the concept of equality based on well-being as an outcome - rather than a simple equal treatment formulation (which still warrants unequal treatment for those who are 'different') - contains the premise that all humans, in spite of their differences, are entitled to consideration and respect as equals. This formulation takes into account the fact that some 'different', possibly less well placed individuals may need special accommodation to benefit from treatment and care. This 'special accommodation' extends the ambit of 'responsibility for care' to extend access to treatment to those for whom economic and other social constraints (including for example orphanhood, parental

substance abuse and homelessness in the case of children) would otherwise put it out of reach.

In the case of many developing countries, 'special accommodation' means that the affected society would have to improve primary health care in general, since gaps there will lead to rationing through lack of diagnosis (as pointed out in your article) on the one hand and a lack of health maintenance services for those on treatment on the other.

This formulation of equality requires the opposite of treatment rationing - and would obviously cost more. The inclusive view would indicate that the additional cost of this 'special accommodation' must be carried by the society in which the infection inheres. HIV/AIDS is a global disease, hence 'society' in this case means all of humanity. Where 'Pathologies of Power' (see Paul Farmer's book of this title) have contributed to the extent of the epidemic, those wielding such global power must be called to account.

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about HATIP

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