Approaches to rationing antiretroviral treatment: ethical and equity implications
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Abstract Despite a growing global commitment to the provision of antiretroviral therapy (ART), its availability is still likely to be less than the need. This imbalance raises ethical dilemmas about who should be granted access to publicly-subsidized ART programmes. This paper reviews the eligibility and targeting criteria used in four case-study countries at different points in the scale-up of ART, with the aim of drawing lessons regarding ethical approaches to rationing. Mexico, Senegal, Thailand and Uganda have each made an explicit policy commitment to provide antiretrovirals to all those in need, but are achieving this goal in steps — beginning with explicit rationing of access to care. Drawing upon the case-studies and experiences elsewhere, categories of explicit rationing criteria have been identified. These include biomedical factors, adherence to treatment, prevention-driven factors, social and economic benefits, financial factors and factors driven by ethical arguments. The initial criteria for determining eligibility are typically clinical criteria and assessment of adherence prospects, followed by a number of other factors. Rationing mechanisms reflect several underlying ethical theories and the ethical underpinnings of explicit rationing criteria should reflect societal values. In order to ensure this alignment, widespread consultation with a variety of stakeholders, and not only policy-makers or physicians, is critical. Without such explicit debate, more rationing will occur implicitly and this may be more inequitable. The effects of rationing mechanisms upon equity are critically dependent upon the implementation processes. As antiretroviral programmes are implemented it is crucial to monitor who gains access to these programmes.

Keywords Antiretroviral therapy, Highly active/ethics/utilization; Health care rationing/ethics/methods/organization and administration; Health services accessibility/ethics; Eligibility determination/utilization; Patient selection/ethics; Health policy; Policy making; Health expenditures; Socioeconomic factors; Mexico; Senegal, Thailand, Uganda (source: MeSH MeSH).

Introduction
The emerging global commitment to providing antiretroviral therapy (ART) to people living with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) in low-income countries, as exemplified by The world health report 2004 (1), heralds a new era in the AIDS pandemic. However, the increased availability of subsidized antiretroviral (ARV) treatments in low-income countries raises complex ethical issues. Although analysts have considered the issues from a global perspective (2, 3), the ethical and equity issues surrounding access to ART within a particular country context are just beginning to be addressed. The world health report 2004 acknowledged that “Special attention must be paid to questions of fairness as programmes get under way, since more people need treatment than will receive it” (1), but offers little concrete guidance to countries. Rationing of access to ART is a subject that is generally extremely politically sensitive, and also potentially divisive:

“If treatment were available for only a minority, the processes of determining criteria for treatment and selecting treatment candidates would challenge the most cohesive and organized society” (2).
Many developing countries are committed to providing universal access to ARVs; however, the limitations on the current capacity of health systems and availability of funding require a step-by-step approach to scale-up. For example, a phased ART expansion process moving from operational research, to consolidation in a limited number of facilities, to final expansion was proposed in the Malawian application to the Global Fund (4). Until nationwide expansion is achieved, difficult decisions must be made about who will gain access to life-saving therapies, and who will have to wait, or potentially never receive such care.

This paper provides a brief overview of rationing, followed by the description of the rationing process in four case-studies which reflect different phases of ARV scale-up:

- A relatively small pilot programme in Senegal;
- A draft national ARV policy for Uganda, which is in the consolidation phase;
- The Thai national policy where scale-up is quite advanced; and
- The national policy in Mexico, which has moved close to universal access.

Our primary concern is the rationing of ARV drugs for treatment purposes rather than for prophylactic purposes, although in practice prophylaxis may be closely linked to care. Our study aims to assist policy development in developing countries where there is a high prevalence of HIV/AIDS, and where need outstrips the current supply of treatment. Building upon the case-studies and experiences elsewhere, conclusions are drawn about appropriate approaches to the rationing of highly active ART (HAART).

An anatomy of rationing

Rationing is the controlled distribution of scarce goods or services. Government (or other suppliers) may choose to ration services when demand outstrips supply and when it is inappropriate for access to the service to be determined by the willingness of individuals to pay for it. Although in some countries where the prevalence of HIV/AIDS is high, the demand for HAART has been less than anticipated, the first condition potentially applies in many settings, and the second is a widely agreed principle.

Policy-makers in developing countries have generally preferred to talk of “targeting priority recipients” for ARVs rather than of rationing. Clearly this term is softer, and also suggests that in the future ARVs will be available to all. Although government has expressed a commitment to universal access, for many people this will come too late. In practice, the current prioritization of specific population groups for treatment with ARVs takes exactly the same form as rationing.

There is a substantial literature on approaches to rationing in the health sector (5). Rationing may occur through a variety of mechanisms and be based on different sorts of criteria. For example, rationing occurs if certain services are excluded from a benefit package, or it may occur through the development of clinical guidelines or through queuing. For rationing ARVs, only a certain subset of rationing mechanisms are feasible; such a mechanism needs to be able to identify which individuals gain access to services (as opposed, for example, to which services will be offered). This problem most closely resembles that of rationing of organ transplants or certain extremely expensive therapies (6, 7).

Explicit rationing occurs when defined and widely understood criteria (such as age-related or insurance-related criteria) are used to determine access. By contrast, implicit rationing lacks any overarching plan or clearly defined criteria, but rather depends on subtle decisions, many of which are made by health-care providers (8, 9). The implicit criteria used by health-care providers to allocate services may be similar to those that would be adopted if explicit criteria were developed. However the fact that implicit criteria have not been discussed and agreed, and are not clear and widely understood, gives them a fundamentally different nature.

Although explicit rationing criteria are more likely to be developed as part of national policies, and implicit criteria are more likely to be applied by individual providers, this is not always the case. Implicit rationing may occur due to macro-level policy decisions which, for example, mean that ARV services are not available in certain parts of a country. Conversely, explicit rationing criteria may be discussed and agreed at the community level.

Certain rationing mechanisms are difficult to classify. For example, queueing does not explicitly deny treatment to patients, but rather awards some patients lower priority than others in accessing services. Queue management may be explicit (based for example upon defined indicators of severity of the clinical condition) or implicit (based for example upon physician referral practices) (10). The relative advantages and disadvantages of implicit and explicit rationing criteria have been debated (11). In practice, the decision on who receives ARVs will depend upon a complex interaction between broader systemic constraints, and explicit and implicit rationing criteria.

Rationing mechanisms in practice: Mexico, Senegal, Thailand and Uganda

The national governments of Mexico, Senegal, Thailand and Uganda have all made a clear commitment to expanding the ARV programme to achieve universal access to care. However, the case-studies presented reflect different phases in the scale-up process.

Pilot phase in Senegal

The ISAARV (Initiative Sénégalaise d’Accès aux ARV) was an applied research programme that provided ARV therapy to 339 patients from August 1998 to November 2001 in a limited number of facilities in Senegal, with an element of cost-sharing for the patient. Building upon the ISAARV initiative, ART was gradually scaled up, and finally expanded so that it was available nationwide, free of charge, in December 2003. The patient selection process in the ISAARV initiative is shown in Fig. 1.

In the ISAARV initiative, the first criterion was the patient’s residency. Residency was chosen rather than citizenship to avoid the sensitive issue of discrimination in a multi-ethnic country. Being a non-resident was “the only social criterion of programme exclusion” (12).

The second criterion was the patient’s clinical status. Biomedical data were reviewed by a Technical Medical Committee to determine the patient’s eligibility for ARV therapy. In the third step of patient selection, the “social profile” of the candidate was reviewed to assess the patient’s capacity to adhere to treatment and the patient’s ability to pay for ARV drugs. These two aspects were intimately linked: likely adherence to treatment was assessed not only on the basis of the patient’s...
personal commitment to taking the drugs but also on his or her ability to bear the future costs of treatment. The information collected through these steps was submitted to the Eligibility Committee. If a patient consented to meeting the cost of ARV therapy at the level proposed by the social assessment then the Eligibility Committee granted that patient access to ART.

A report on the ISAARV initiative noted that during the period when subsidies were low, and prices to patients relatively high, doctors tended to discuss ARVs with, and refer only those patients whom they believed could afford to pay (12). This implicit form of rationing appeared particularly prevalent before November 2000, when all patients (except health workers and active members of the People Living With HIV/AIDS (PLWHA) National Coalition who were exempt) were required to pay something for services.

Consolidation phase in Uganda
In June 2003 the Ugandan Government, through a process involving a wide range of stakeholders at national and subnational levels, developed a draft policy to guide the consolidation phase of ART expansion. This expansion phase built upon previous pilot programmes including the Joint Clinical Research Center (initiated in 1992) and the subsequent Drug Access Initiative (1998).

The draft policy defines selection criteria to determine who gains access to ARV treatment in the short term, as part of the longer process of expanding access to all in need. Those granted access to ARV treatment in the short term are said to receive “priority eligibility”. Others who are assigned “ordinary eligibility” will receive access to free HAART in the future.

The draft national policy states that clinically eligible patients will be counselled to inform them fully about ART including its benefits and limitations, and at the same time the likelihood of their adherence to treatment will be assessed. Counsellors may involve family members or community members in assessing the likely adherence of a patient.

Priority groups for access to ART are shown in Fig. 2. The identification of groups i and ii is driven by prevention issues. The prioritization of children infected with HIV/AIDS appears to be driven by moral concerns (the innocence of the children), whereas prioritizing HIV/AIDS activists recognizes the important role that these individuals have played in the fight against AIDS. The inclusion of mothers who had previously participated in the prevention of mother-to-child transmission (PMTCT) programme may be justified on several grounds:

- its effectiveness in promoting the use of preventive strategies (i.e. PMTCT) by rewarding those who do seek testing;
- on ethical grounds in terms of the difficulties of denying mothers further treatment after they have given birth; and
- for social reasons given the great number of AIDS orphans in Uganda.

Expansion of antiretroviral therapy in Thailand
After many years of small-scale provision of ART, the Thai Government launched its Access to Care Initiative in 2000 to begin to scale up service provision. In December 2001 a Universal Coverage policy was adopted, which was to be implemented in a phased manner. By 2004 about 50 000 people were receiving ARVs, i.e. 60–70% of those in need. Prior to the universal coverage policy, patient enrolment was carried out locally by a panel of government officials, staff of nongovernmental organizations, and representatives of communities and PLWHA groups, based upon the official criteria reflected in Fig. 3.

Unlike the policies of other countries, the policy in Thailand did not present a hierarchical process for determining who gained access to care, but simply presented a number of inclusion and exclusion criteria (13). Hospitals were given quotas (referred to as “targets” after the adoption of the universal access policy) for the number of patients to be treated. However there appears to have been considerable variation between areas in the degree to which the formal criteria were applied and ultimately the final decisions were made by health professionals (14). Like some other countries, Thailand prioritized those who had made a contribution to society; however the national criteria were vague as to how such individuals would be identified. This criterion was deleted in 2002. Thailand also excluded intravenous drug users (IDUs) from ART, but the policy noted that “these patients should be treated for the addiction before commencing ART”. In this sense, the exclusion was not used as a treatment barrier. This criterion was deleted in 2003, although the adherence criteria could still potentially be used to justify the exclusion of IDUs.

Approaching universal coverage in Mexico
The Ministry of Health in Mexico has consistently stated it as a priority to ensure access to those who cannot otherwise afford ARVs. In August 2003, the Mexican President made a commitment to extend provision of free ARV drugs to all AIDS patients (15). To achieve this goal the Seguro Popular, which provides health insurance for those unable to formally enter
the social security system, recently extended its coverage to include ART. Fig. 4 illustrates the overall schema that defined who gained access to ART in 2003 with a focus on the Ministry of Health programme for free care.

Although the clinical eligibility criteria applied to everyone, the insurance status of the patient was the next major factor affecting access; distinct patterns of access were seen for the insured and the uninsured. Of the uninsured who met the explicit selection criteria, those who had previously been treated (typically people who were formerly insured), were awarded priority access so as to ensure their uninterrupted treatment and prevent the emergence of drug resistance. Those who had not previously received ARVs were considered of lower priority and were placed on a waiting list. Separate waiting lists were compiled for each state within Mexico. Highest priority was given to those patients on the waiting list whose disease was at a more acute stage as measured by low CD4 cell counts, high viral loads and symptoms of advanced disease progression.

Anecdotal evidence suggests that in addition to the explicit rationing and queuing criteria in Mexico, further rationing took place due to inadequate funding. For example ARV drugs were sometimes out of stock at Ministry of Health hospitals, in which case patients were expected to pay for the drugs themselves (16). Also as individual states were allowed to contribute extra funding for the care of patients within their state, considerable differences in coverage rates of the uninsured emerged between different states, and between rural and urban areas.

**Rationing criteria used in antiretroviral therapy programmes**

In three out of four of the case-studies there is a hierarchical process with the number of persons eligible for treatment being reduced by the incremental application of explicit rationing criteria.

In all case-studies, two sets of core technical criteria, namely, clinical eligibility criteria and adherence criteria were applied. Although clinical eligibility criteria may appear scientifically based and relatively “value neutral”, in developing countries the empirical basis for determining best practices with respect to ART management is weak, especially in terms of the appropriate point at which to start treatment. Thus, for example, Malawi’s proposal to the Global Fund (4) suggests that all patients in clinical stage III or IV of the disease will be entitled to treatment with ARVs, without requiring CD4 counts. This policy reflects a particular interpretation of the scientific evidence (distinct from WHO guidelines) and implies a different access pattern than would exist if CD4 counts were required. Given the lack of scientific evidence, clinical guidelines for ART can involve value judgements and should be inspected and understood in this light (17).

In the case-studies, prospects for adherence to treatment were primarily assessed through the patient’s stated willingness to comply with treatment. There are also examples of the use of proxy indicators for adherence: the Uganda Cares initiative in Masaka requires that patients “come from a stable social network or family” (18). Whereas evidence from industrialized countries suggests that lack of social or family support is associated with poor adherence (19), this is not proven in developing countries and the application of this criterion would have a
negative effect on access to care for the vulnerable. Adherence to treatment is critical, but may be better addressed in the programme design rather than by using it as an eligibility criterion.

After the application of the technical criteria, additional rationing criteria were applied to reduce the gap between the need for ART and the supply. Prevention-driven rationing criteria aimed to use access to ARVs to increase demand for testing and counselling for HIV/AIDS, and thus reduce transmission rates. In Uganda, women who had previously participated in the PMTCT programme were given priority for receiving HAART. In Botswana pregnant women and their qualifying partners were priority groups (20). In Brazil, which has a policy of universal access to free ART (21), certain groups such as IDUs are targeted by ART programmes (22). As mentioned above, the former Thai policy required that such patients be treated for their addiction prior to receiving ARVs.

Other factors used in rationing reflect the social and economic benefits derived from keeping certain subgroups of the population healthier for longer due to the broader benefits for society associated with their employment or social roles, for example giving priority to health workers, mothers or activists. Policies describe such criteria with varying degrees of specificity. Ethical arguments may also be employed, for example to give priority to the poor, children or vulnerable populations. Children appear particularly likely to be prioritized (as, for example, in Botswana and Uganda).

Financial factors such as ability to pay for treatment appear less likely to be applied as explicit rationing factors, although this did occur in the early phase of ISAARV.

Mexico used waiting lists to assign priority among those deemed eligible for care. Waiting lists may be more effective during the later stages of scale-up when those placed on these lists stand a good chance of receiving care.

**Conclusions**

The policies of Mexico, Senegal, Thailand and Uganda illustrate the range of criteria that can be used to determine who should have access to ARVs. Some explicit criteria, such as assessment of ability to pay, or linking treatment to participation in prophylactic programmes (such as PMTCT), or prioritizing those groups who play a key role in society (such as health workers) focus on utilitarian concerns about how to maximize the benefit from a fixed supply of ART. Other explicit rationing criteria, such as prioritizing access for the vulnerable, give greater weight to egalitarian arguments.

Decisions about who should gain access to ARVs should reflect societal values (23). Stakeholder consultations and debate about explicit criteria for rationing are needed in order for policy-makers to appreciate the values that ARV policies need to reflect, and to create support and consensus around policies developed. Such a process occurred in Uganda where widespread consultative meetings with a range of stakeholders were undertaken as part of the policy development process. Elsewhere, community participation processes have been used to determine access to care, for example, in Khayelitsha, South Africa (24). Although community-based rationing may work well during the pilot phase, it is unlikely to be workable as treatment is scaled up, because patients would move from one facility to another in the hope of qualifying for treatment.

If debates about, and explicit decisions regarding rationing do not occur, or if rationing criteria are left vague and poorly defined, then allocation is more likely to be driven by implicit rationing, whereby individual decision-makers use their own values or professional judgements to determine who gains access to care. Implicit rationing is less likely to be consistent and fair, and is certainly less transparent and open to societal review than explicit rationing. The country case-studies illustrated situations in which explicit rationing criteria did not bring demand and supply into alignment and implicit rationing occurred. In Senegal, during the pilot phase, information about the programme was not widely disseminated, only certain physicians were informed and able to refer patients — thus patients’ ability to access ARV services depended upon which physician they happened to see. In Mexico the lack of funds for providing ARV to those without insurance translated into different patterns of access for the insured and uninsured groups regardless of explicit rationing criteria. In Thailand the quota system and the vague criteria sometimes led to decisions on rationing being made by physicians.

The equity and ethical implications of explicit rationing criteria will also depend significantly on how the rationing mechanisms are implemented. For example, in the Senegal pilot programme, the sliding payment scale was adopted to promote equity, but given budget constraints and the high price of pharmaceuticals at the time, the sliding scale was relatively steep.
so that few patients were able to access the programme free of charge. Furthermore, health workers assessing clinical eligibility appear to have begun to incorporate their understanding of the cost-sharing arrangements informally into the screening process, so that patients who appeared unlikely to be able to afford their share of the costs were not referred for treatment (12). In Thailand, although the criterion excluding IDUs was dropped, adherence criteria may still negatively affect the access of this group to ART.

Unless there is substantial growth over time in the budget of an ART programme and the capacity of a health system to deliver services, a significant number of those receiving treatment will be identified early on and will require continued financial support over future years, preventing new ART recipients participating in any large number. It is therefore critical that scale-up strategies give consideration from the outset to the question of rationing. Rationing criteria will need to change over time, not only in response to changing societal values, but also as countries move through different phases of scaling up, so that progressively greater numbers of people receive treatment.

Public debate and consensus building about approaches to rationing ARVs are critical to developing the sustainability and equity of ARV programmes; without some degree of societal consensus on this issue ARV programmes will be contentious and socially divisive. Furthermore, as rationing policies are developed and implemented, resources must also be employed to monitor the extent to which the chosen policies are reaching the people whom they seek to target and achieving societal objectives.

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Résumé

Rationnement des traitements antirétroviraux : incidences aux plans de l’éthique et de la justice sociale
Malgré le souci croissant, à l’échelle mondiale, d’améliorer l’accès aux traitements antirétroviraux, les traitements disponibles resteront vraisemblablement en deçà des besoins. Ce déficit pose un dilemme éthique, à savoir qui doit bénéficier des programmes de traitements antirétroviraux subventionnés par les pouvoirs publics. Pour en tirer des enseignements au sujet des approches éthiques du rationnement, le présent article examine les critères appliqués dans quatre pays ayant fait l’objet d’études de cas concernant le droit au bénéfice du traitement et le ciblage des bénéficiaires à différents stades du processus d’amélioration de l’accès aux traitements antirétroviraux. Le Mexique, le Sénégal, la Thaïlande et l’Ouganda se sont chacun officiellement engagés à assurer l’accès aux traitements antirétroviraux à toutes les personnes qui en ont besoin, mais ils procèdent par étapes – l’accès aux soins, dans un premier temps, étant officiellement rationné. Les études de cas et l’expérience d’autres pays ont permis de dégager différentes catégories de critères de rationnement officiels : facteurs biomédicaux, observance du traitement, facteurs axés sur la prévention, avantages sociaux et économiques, facteurs financiers et facteurs reposant sur des arguments éthiques. Les critères utilisés, en général, pour déterminer le droit au bénéfice du traitement, sont d’abord des critères cliniques joints à une évaluation des chances d’observance des traitements, suivis de plusieurs autres facteurs. Les mécanismes de rationnement s’appuient sur plusieurs théories éthiques, les fondements éthiques des critères de rationnement officiels devant pour leur part tenir compte des valeurs sociales. Une telle concordance passe nécessairement par de vastes consultations, non seulement avec des responsables politiques et des médecins, mais aussi avec un éventail de parties intéressées. Sans ces échanges officiels, un rationnement implicite, peut-être plus inéquitable, s’instaurera. Les effets des mécanismes de rationnement sur la justice sociale dépendent entièrement de la manière dont ces mécanismes sont mis en œuvre. Au fur et à mesure de l’application des programmes de traitement antirétroviral, il est indispensable de surveiller à qui ces programmes bénéficient.

Resumen

Criterios de racionamiento de la medicación antirretroviral: implicaciones éticas y en materia de equidad
Pese al creciente compromiso mundial para suministrar terapia antirretroviral (TAR), la disponibilidad de esta medicación tiende a ser aún inferior a las necesidades. Este desequilibrio plantea el dilema ético de determinar a quién se debe otorgar acceso a los programas de TAR que gozan de subvenciones públicas. En este artículo se examinan la elegibilidad y los criterios de focalización usados en cuatro países donde se han realizado estudios de casos en diferentes momentos de la expansión de la TAR, a fin de extraer conclusiones respecto a los criterios éticos para racionar los medicamentos. México, el Senegal, Tailandia y Uganda han asumido un compromiso de política explícito para proporcionar antirretrovirales a todos los necesitados, pero están persiguiendo esa meta por etapas, empezando por un racionamiento explícito del acceso a asistencia. Sobre la base de los estudios de casos y de experiencias de otros lugares, se han identificado categorías de criterios explícitos de racionamiento, que comprenden factores biomédicos, el cumplimiento del tratamiento, factores motivados por la prevención, beneficios sociales y económicos, factores financieros y factores motivados por argumentos éticos. Los criterios iniciales para determinar la elegibilidad suelen ser criterios clínicos y una evaluación de las perspectivas de cumplimiento, seguidos de otros factores. Los mecanismos de racionamiento reflejan varias teorías éticas subyacentes, y la base ética de los criterios explícitos de racionamiento debe reflejar los valores sociales. Para garantizar esa concordancia, es fundamental la consulta generalizada con diversos interesados directos, no...
sólo con los formuladores de políticas y los médicos. Sin un debate explícito de esa naturaleza, los casos de racionamiento implícito serán más frecuentes, y ello entrañará un mayor riesgo de inequidad. Los efectos de los mecanismos de racionamiento en la equidad dependen de forma decisiva del proceso de implementación. A la hora de llevar a la práctica los programas de tratamiento antirretroviral, es crucial controlar quiénes consiguen acceder a esos programas.

References