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Full Length Research Paper

Criteria used for selecting patients for antiretroviral therapy in Uganda: A qualitative study

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Limited resources in low income countries still prevent HIV patients from accessing treatment and necessitate the rationing of anti retroviral therapy. This paper aims to describe the criteria used in actual patient selection so as to develop evidence based recommendations for improving fairness in patient selection in Uganda and similar contexts. Qualitative interviews (n = 37) from six AIDS treatment units in Uganda; review of policy and clinic documents; and group discussions (n = 47) people living with AIDS. Practitioners identified both medical criteria (need, CD4 count, WHO staging, Absence of severe co-infections, patient readiness, and ART naivety) and social criteria (economic status, social support, treatment buddy, disclosure, duration with organization, distance, alcohol consumption, relatives of clients on ART, first-in- first- out, vulnerability and activism). There was congruence around the medical criteria across institutions and the national guidelines; and variations around the social criteria. The variations around the social criteria necessitate more explicit debate. Commonly used and accepted criteria could be considered for explicit inclusion in the national guidelines. Disputed criteria should be debated to identify an acceptable set of criteria for ART rationing. These criteria should be publicized to facilitate on-going revisions, ensure consistency, and contribute to fair patient selection.

Key words: HIV/AIDS, anti-retroviral treatment, Uganda, rationing, criteria.

INTRODUCTION

Antiretroviral therapy (ART) has the potential to reverse the natural course of the HIV infection and improve the quality of life for people living with AIDS. While there are global efforts to ensure universal access to ART, coverage in Eastern and southern Africa still remains low-estimated at 32% (http://www.aidsuganda.org; WHO, 2008, Mangi, Talle, Juma and Klepp, 2009). For example in Uganda, of the 350,000 people eligible for ART, only 180,000 (40%) have access to this life saving treatment (Basudde, 2009). In such contexts, difficult rationing decisions must be made about which patients should have access to the limited ART. Such limit-setting decisions have been found to be value-laden and may be perceived as unfair by the people who may be denied access. Some argue that, for limit-setting decisions to be fair, they must be based on criteria and reasons that are perceived by fair-minded people (People who in principle seek to cooperate with others on terms they can justify to each other. They accept the rules of the game that promote the game's essential skills and the excitement their use produces (Daniels and Sabin, 2002)) to be relevant to the decisions. Furthermore, the rationales and the decisions must be publicized and there must be mechanisms to appeal against decisions as well as an internal or external mechanism to ensure adherence to the prior conditions (Daniels and Sabin, 2002). There has been emphasis on the need for explicit criteria that relevant stakeholders, including people living with Aids (PLWAs), can consider relevant (Daniels, 2005; http://www.aidsuganda.org; WHO, 2008; Johansson et al., 2008).

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Box 1. Previously described Patient selection criteria in Uganda.

Meets medical eligibility criteria
Meets adherence criteria
Priority to the following persons:
Pregnant women on Nevirapine
Post- exposure prophylaxis (health workers and rape victims)
HIV-infected family members
Children
HIV/AIDS activists
Participants in research projects already on ART

Source: http://www.aidsuganda.org. Accessed May, 2008.

The World Health Organization (WHO) has developed clinical staging and patient selection guidelines to assist national governments to develop criteria for selecting patients for ART. Member governments (such as the government of Uganda), and non-governmental organisations have used the WHO guidelines directly or as basis for developing national ART treatment guidelines and eligibility criteria (Wendo, 2004; UNAIDS, 2004; Deslaux et al., 2002; Okero et al, 2003) (Table 1).

Benett and Chanfreau (2006) evaluated four national-level ART policies, identifying some of the key criteria used in patient selection. These included medical eligibility, adherence to treatment, prevention, social and economic benefits, financial and ethical criteria. In a review of criteria used in low-income countries, McCough et al. (2005) found the most common criteria to be: the WHO HIV clinical staging, adherence, expected compliance, age, and occupation. Additional criteria cited in different papers include: number of dependants (mothers vs. single men), income, regularity of attendance to HIV clinics, likely work status after treatment, disclosure and activism, social/family support structures, and geographical stability (Chequer et al., 2002; Desclaux, Ciss et al., 2003; Diomande et al., 2003; Kenyon et al., 2003; Rosen et al., 2005; Macklin, 2006).

Most of the literature on criteria for selecting patients has focused on criteria recommended in the national-level policies. However, the people involved in the development of the national-level criteria are thought to be somewhat far removed from the realities that practitioners face at the bedside (Kapiriri and Martin, 2007). As a result, practitioners often modify the national criteria, or introduce additional criteria to ration scarce drugs (Bayer, Oppenheimer, 2007; Jitta et al., 2003). What do the practitioners consider when making ART rationing decisions at the service delivery level? To the best of our knowledge, the only study reporting the criteria used to select patients for ART in Uganda was based on a review of the national policy documents (Bennett and Chanfreau, 2005). Uganda published a national ART policy in 2003 and developed national guidelines on ART in accordance to the WHO guidelines (Wendo, 2004) (Table 1). However, there is a dearth of information about how the national guidelines have been interpreted and used by clinicians at the patient level; and what criteria clinicians actually consider when selecting patients to receive ART. Moreover, the studies that have described criteria for rationing ART (medical eligibility, adherence, and priority to specific groups), summarised in Box 1 were conducted before Uganda's attempt to achieve universal access to ART (Wendo, 2004, Bennett and Chanfreau, 2005).

This paper describes the criteria used by Ugandan practitioners to select patients for antiretroviral therapy. The findings from this study provide basis for facilitating public discussions with regards to the acceptable criteria, and improving transparency and fairness in patient selection.

METHODS

Settings

We conducted a qualitative study in 2007 in Uganda. Respondents were recruited from five ART treatment institutions in Kampala and Mbale districts. Interview sites included: one private-not-for-profit hospital, two treatment centres at the national teaching and referral hospital, a private AIDS treatment hospital and the treatment arm of The AIDS Support Organization (TASO), in both districts. All units try to adhere to the national treatment guidelines which recommend the first-line of ART treatment to be either; 1) Zidovudine/ Lamivudine + Efavirenz (or niverapine); or 2) Stavudine/ Lamivudine + nevirapine (WHO/UNAIDS, 2003).

Data collection

Three strategies of data collection were employed: document review, interviews with key informants and focus group discussions.

Document review: We reviewed policy documents and clinic records. We obtained the policy documents on guidelines for patient selection at the national, district and hospital levels. We also asked our key informants to give us any relevant unpublished literature. These documents were reviewed to obtain the recommended criteria for patient selection at the different levels. We reviewed clinic records to establish the criteria actually used in patient selection as reflected by the patients being treated. Using a checklist, we collected information on patient's age, gender, WHO staging of the disease and CD4 from the registers at four treatment centres. In each centre, we sampled every third record from the patient's register entered between the period of January, 2004 and December, 2006. This provided information on the demographic and medical characteristics of the patients who are actually accessing ART at these centres. Incomplete entries were excluded. The documents were reviewed by the investigators who were not involved in the data collection to minimize bias in the data collection.

In- depth interviews: We identified people who were involved in the development of the guidelines for the selection of patients for ART at the national-level or in their institution and/ or in their health institution.

Sampling: We sampled respondents from Kampala and Mbale. At the national level, our initial respondents were members of the

Table 1. Uganda national guiding principles for ART.

Guiding principles for good ART	Not to start ART too soon (when CD4 cell count is close to normal) or too late (when the immune system is irreversibly damaged)
	Efficacy of the chosen drug regimens
	Freedom from serious adverse effects
	Ease of administration
	Affordability and availability of drugs and drug combinations
	Ongoing support of the patient to maintain adherence
Recommended criteria for initiating ART	Primary Criteria
	WHO Stage IV disease irrespective of CD4 cell count
	Advanced WHO Stage III disease including persistent or recurrent oral thrush and invasive bacterial infections irrespective of CD4 cell count or total lymphocyte count.
	When CD4 testing is available, ART can be started for patients in WHO stage I, II or III with CD4 cell counts ≤200/mm.
	Tuberculosis (TB) and a CD4 cell count between 200-350/mm^3
	Patient-specific factors
	Interest and motivation in taking therapy
	Presence of co-morbidities especially tuberculosis. Treatment of co-existing infection takes priority over starting ART.
	Psychosocial barriers
	Financial barriers
	Potential for adherence (willingness to participate in ARV educational sessions and peer support ARV groups, and to complete a personal adherence plan with a counsellor)
	Patient's informed consent to taking ART.

Source: Whyte SR. et al. 2004.

National AIDS Program, and the ministry of health. We asked them to identify other relevant informants. We sampled both technical and non-technical people (such as patient representative groups) to capture any variations in opinion. We also sampled representatives from the key donors such as United States Agency for International Development (USAID) and Centre for Disease Control and prevention, and lead None Government Organizations (NGO) like PLAN international. Within the treatment facilities, snowball sampling was used: the initial respondent was the person in charge of the ART clinic, and he or she identified subsequent respondents. Sampling ended when no new information emerged from the interviews (thematic saturation). We interviewed a total of 37 respondents (including nurses, doctors and counsellors involved in HIV patient care and treatment). All interviews were audio-recorded with consent from the respondents.

Interviews lasted an average of 45 min and were conducted by two trained interviewers. We used a pre-tested, open-ended interview guide. The guide was used with flexibility to allow the interviewers to pursue any relevant emerging themes.

Focus group discussions: We conducted five group discussions (with about 9 participants per group), using a pre-tested discussion guide, with People Living with AIDS (PLWAs), most of whom were on ART. We held two female-only, two male-only, (this was done to facilitate maximum participation for the women) and one gender-mixed group. Group discussions began with an introduction of the purposes of the study, followed by participants' self introductions after which, the main topics for discussion were introduced and discussed. Each group discussion had a facilitator and a note-taker. Discussions were audio-recorded with permission from the participants. The discussions lasted an average of 60 - 80 min.

Data analysis

Data were analysed by all research team members. The recorded interviews were transcribed and the focus groups (which were conducted in vernacular) were translated. The team members who were not involved in the data collection read through the transcripts and identified the major themes related to patient selection criteria. A list of themes was created and refined; criteria for applying these themes to passages were then developed. Next, major codes expressing each of these themes were assigned to the transcripts. The process was then repeated for sub-categories (criteria) within each theme, resulting in transcripts annotated with major and minor codes. Subsequently, a code sheet was drawn up for each major code. Further analysis involved grouping the identified criteria under larger categories namely, medical eligibility criteria, socio-economic criteria, adherence criteria, ethical/fairness criteria, and other. Further analysis involved comparing the identified criteria between the treatment institutions and against the national and WHO guidelines.

Validity: Validity was ensured in three ways. Firstly, we triangulated sources of information by interviewing a variety of respondents including practitioners and patients, and reviewing documents and patients' records to describe the criteria used in patient selection (Strauss and Cobin, 1998). Secondly, we documented all research activities to allow for critical appraisal of the methods. Thirdly, data were analysed by two independent researchers and the final results presented to the people who collected the data (who were also knowledgeable about the context) to verify if our interpretation of the results were reasonable. Furthermore, the final elements were compared to the interview transcripts to ensure consistency (Kvale, 1999).

Research ethics

The proposal was reviewed and approved by the Western regional research ethics review board of Norway and the Uganda National council for Science and Technology. Verbal consent was obtained from all respondents and focus group participants prior to their participation. All data were anonymize prior to publication.

RESULTS

Many respondents recognised that ART rationing decisions depended on the complex interaction between broad 'institutional' constraints such as resource scarcity and national guidelines, erratic drug supply and the specific criteria used. Respondents from all units except the private treatment centre reported that although it was inevitable to ration ART, rationing of such life saving treatment was unfair. While they recognised the improvement in the availability of ART through international organisations such as the Global Fund and the President's Emergency Plan for AIDS Relief (PEPFAR), national-level respondents reported that ART was still inadequate. They also identified related increasing constraints with regards to human resources and infrastructure, especially in rural districts. Within these constraints, respondents explained that they try to adapt the Ministry of Health's guidelines in patient selection, as one respondent explained:

> "We still respect the Ministry of Health (MOH) guidelines, but maybe somewhere we have to make it a little bit more applicable because MOH guidelines are quite broad (Practitioner-Public unit)."

The rest of the paper is organized in two main sections. First, we describe the criteria and the reasons why the criteria are used and second, we compare the identified criteria across treatment centres and between treatment centres and the national and WHO guidelines.

Description of the identified criteria

This section is organized according to the two categories under which the described criteria fit: the medical criteria and the Social criteria. For each criterion, we report reasons given for or against its use (summarised in Table 3).

Medical criteria

The medical criteria included patient's health need, patient's CD4 count, WHO staging, potential to benefit, patient readiness presence/absence of co- infections, and ART naivety (patients who have never been on ART). We discuss these in detail.

Need: Respondents from all centres identified "need" as an important criterion for patient selection. "Need" was interpreted in terms of severity of the disease. For example, The AIDS Support Organization (TASO) units sometimes exempted very ill patients from other priority rules. Severity of disease was assessed by the CD4 count and/or WHO staging, explained below. Respondents thought it fair that severely ill patients were prioritized.

CD4 count: This criterion was articulated in all centres. Respondents reported that patients were eligible for ART only if their CD4 count was less than 200, but the public unit had temporarily lowered the cut-off (50) and the private unit had a higher cut-off (250). This was consistent with the reviewed patient records. In all units, <80% of the recorded patients on ART had a CD4 count of <200. However, 60% (47 - 48% for the rest of the units) of the recorded patients in the public unit had a CD4 count of <100 (Table 2). The reasons behind the CD4 criterion were that it was recommended in the national guidelines and was scientifically sound. However, respondents from the private treatment centre who reported they recruited patients with CD4 counts up to 250, reasoned that this cut-off was consistent with that used in developed countries; and recognised that within limits, the higher the cut-off the better the treatment outcomes. Respondents from the publicly-funded unit recognized that the temporarily lowered cut-off to 50 could give worse treatment outcomes-selecting those with least potential to benefit (discussed below) but still prioritised them because they are often very ill and in dire need of the ART.

Potential to benefit: Respondents from all units identified patient's potential to benefit as an important criterion, especially in view of the scarcity of ART. However, consistent use of this criterion was contradicted by respondents who reported that sometimes very sick patients are prioritised despite the knowledge that patients may not benefit as much as others from the treatment.

"(…) only those patients whose CD4 is below 50, because it is like saying for sure, we know that you are in danger.... let us at least be daring to take on those ones, because it is possible I may not see them tomorrow."(Practitioner-Public unit)

Others identified this as a dilemma:

> "(…) even if you start them (CD4 50) on drugs a majority don't live for up to one year, you would rather give the one of 150 [CD4 count]" (Practitioner- Private unit).

WHO disease stage: Respondents from all units reported that they consider the WHO disease staging as criterion for patient selection. This was corroborated with the patients' records whereby >80% of the patients were

Table 2. Characteristics of patients receiving antiretroviral therapy identified from the review of the clinic records**.

	TASO-rural N (%)	TASO- urban* N (%)	Faith-based N (%)	Public N (%)	Total N (%)
Age					
30 yrs and below	146 (17)	0	404 (30)	134 (26)	684 (25)
31-40	358 (41)	4 (33)	563 (42)	213 (42)	1138 (42)
41-50	278 (32)	8 (66)	282 (21)	112 (22)	680 (25)
51 and above	100 (11)	0	92 (9)	47 (9)	239 (9)
Total	882	13	1341	506	2742
Sex					
Male	236 (27)	47 (32)	460 (34)	200 (39)	943 (33)
Female	646 (73)	100 (68)	881 (66)	312 (61)	1939 (66)
Total	882	147	1341	512	2882
WHO Staging					
1	72 (8)	11 (8)	160 (12)	19 (6)	262 (10)
2	449 (51)	38 (28)	535 (40)	87 (26)	1109 (41)
3	321 (36)	68 (50)	436 (33)	176 (52)	1001 (37)
4	40 (5)	20 (15)	210 (16)	58 (17)	328 (12)
Total	882	137	1341	340	2700
CD4 Count					
0-100	411 (47)	71 (48)	628 (47)	240 (60)	1350 (49)
101- 200	460 (52)	53 (36)	495 (37)	131 (33)	1139 (41)
201- 350	8 (1)	18 (12)	139 (10)	23 (6)	188 (7)
351- 500	1 (0.1)	5 (3)	46 (3)	7 (2)	59 (2)
>500	2 (0.2)	0	30 (2)	0 (0)	32 (1)
Total	882	147	1338	401	2768

**Not all 6 units provided documents. The subtotals and totals differ with each characteristic; we collected the data we could from all records-some of which were lacking in some variables, hence the variations.

either WHO stage II or III. According to the respondents, patients who are assessed as stages 3 or 4 were prioritised to access ART. They explained that in cases of lack of access to a laboratory to assess the CD4 count, the WHO staging is useful for monitoring progression of the disease.

Co- infections: Respondents from the TASO units, the faith-based and public units identified presence of severe co- infections as a criterion for delaying the initiation of ART. For these patients, priority is given to treating the co- infections before starting them on ART. For example, patients with severe TB are first treated for TB before they are considered for ART. This was in line with the national ART treatment guidelines, and was thought to improve patients' treatment outcomes.

This criterion was also identified by some of the group discussants, who recognised that it is for the benefit of the patient if any severe co- infections were treated first.

Patient readiness: Respondents from all units and all group discussants identified patient readiness as a relevant criterion. Patient readiness was assessed at two fronts: the physiological and psychological readiness (assessed by individual patient's consent to treatment). Physiological readiness was linked to the medical criteria-whereby patients are assessed to ensure that their vital organs can metabolise the HIV drugs.

Psychological readiness was said to be determined by the counsellors and often involved assessment of the patients' emotional status (they should not be depress-sed), and the patient should have completed 3 - 4 home visits and 4 - 5 counselling sessions. They should also show that they understand how to take the ART and that treatment was life-long. At the end of the counselling and home visits, patients are asked to give a written consent saying that they understand the implications of initiating ART, and will comply. Only patients who consent are started on treatment. Patient readiness was also identified by the patients in the group discussions.

"Psychosocially if the person is not ready---then even if clinically he is ready, they will not put that person on ARVs" (Practitioner- TASO)

"But still first I had to get informed about the drugs to be given. They could not give me the drugs there and then even when I was badly off. They cannot give the drugs which you do not understand..." (Patient- FGD).

Table 3. Criteria for patient selection as identified by our respondents from different treatment centres.

Treatment centre criteria	TASO-Rural	TASO-Urban	Faith-based	Public	Public- Research	Private
Biological:						
Need	+	+	+	+	+	+
CD4 count	<200	<200 (50)	<200	<200	< 200	<250
Potential to Benefit	+	+	+	+	+	+
WHO stage 3 & 4	+	+	+	+	+	+
Absence of severe Co-infections	+	+	+	+	-	-
Patient readiness	+	+	+	+	+	+
ART naive	-	-	+	-	+	+
Social:						
Economic status	+	-	-	+	+	-
Treatment buddy	+	+	+	+	+	+
Disclosure	+	+	+	+	+	+
Duration with organisation	+	+	+	-	+	+
Distance	+	120 km	21 km	+	+	60 km
Alcohol consumption	-	-	-	+	-	-
Close relatives of client on ART	+	+	-	-	-	-
First in, first out (FIFO)	+	+	+	+	+	+
Vulnerable populations						
a) The poor	-	-	+	-	-	-
b) Children	-	-	-	-	+	+
c) Women	+	+	-	-	-	-
Activism:						
i) Member of staff	+	+	+	-	+	-
ii) Peer educator	+	+	-	-	+	-
iii) Client representative,	+	+	-	-	-	-
iv) Participants in clinical trials	-	-	-	-	+	-

Key: + = Criterion identified in respective institution, - = Criterion not identified in the respective institution.

ART naivety: Respondents from the two TASO units and the public unit identified ART naivety as one of the criteria that was used in the initial stages of implementing the ART program when drugs were extremely scarce. The main rationale for using this criterion was to avoid resistance to first-line drugs since second line drugs are more expensive.

"(…) the reason why we wanted those ARVs naive because we did not want to start with resistance already because we thought those have been on other drugs and they can be resistant."(Practitioner- Public unit)

While it was still considered in some of the sampled units, several key informants argued that it may not be a fair criterion to use in prioritizing patients.

Social criteria

The social criteria included; patient's economic and employment status, having social support, a treatment buddy, HIV status disclosure, duration with the organization, distance, alcohol consumption, being a close relative to a patient on ART, First-in-first- out (FIFO), vulnerable populations and activism. We discuss these in detail.

Economic status: Three of the six sampled treatment centres prioritized patients who demonstrated that they could afford to sustain un-interrupted ART and a healthy diet. Affordability was assessed by the patients' employment status in some centres, while other centres required patients to prove that they can afford to buy the drugs for at least two weeks (by demonstrating that they have a regular source of income or a social network who would provide them with the necessary resources), before they are started on the treatment. This was thought to be relevant because: the supply of free ART can be erratic, and when not available, patients are encouraged to purchase the drugs from the open market so that they do not interrupt the regimen. Furthermore, best treatment outcomes are associated with a healthy diet, which requires the patient to have some resources

to purchase/ access the recommended food.

This criterion was not well articulated by the patient group discussants although they alluded to the evaluation of their ability to maintain a healthy diet as criterion.

Adherence criteria: This criterion related to the patients' ability to sustain uninterrupted uptake of the recommended ART regimen. This was thought to be crucial in avoiding resistance to the first-line treatment of choice in Uganda (see methods section)-which is relatively more affordable. Non-adherence may lead to resistance, which would necessitate the introduction of second-line drugs which are not readily available and are more expensive. Factors used to assess patients' ability to adhere to treatment included: having a treatment buddy, disclosure, duration with support organisation (where relevant), distance from health unit, alcohol consumption, psychological readiness and patient's consent. A treatment buddy was a formally recognised status in all the units. Buddies were described as people that lived with the patient, who formally consent to becoming treatment buddies after understanding what the role entails (making sure the patient takes their drugs and keeps the clinic appointments). Both key informant and group discussants recognised the relevance of treatment buddies, as was expressed by the group discussants;

> "I found this treatment supporter (buddy) a very good idea to help us.....If you do not bring a supporter you will be ruining you. Because this person is to help you alone" (Women's FGD)

Disclosure (identified in all units) was relevant in terms of patients' 'freedom' to take the drugs. When patients do not disclose their HIV status especially to the people they live with, it is difficult to consistently take their drugs for fear of being 'caught'-which leads to poor adherence. Distance from the clinic was also used, in all units, to assess if a patient will adhere to treatment. However, the cut off distance varied from 21 Km (in the faith based unit), to 120 Km (in TASO-urban unit). Respondents reasoned that patients were likely to adhere to the regimen and clinical visit requirements (especially when very ill), if they lived within a reasonable distance from the clinic. "Reasonable" distances are also convenient for the clinic should the social workers need to visit and monitor the patient. Another predictor of adherence (only identified by respondents from the public unit) is whether the patients consumed alcohol. Respondents reasoned that alcohol consumption affects both treatment outcomes (by compromising vital organs such as the liver) and patient's adherence (when drunk, patients might forget to take their drugs, and to keep clinic appointments). Lastly, to encourage proper compliance with ART regiment, close relatives/ friends of patients on ART are also prioritised in both TASO units. This is because there is fear that patients might share their drugs, and fail to take the regimen as recommended.

First-in-first-out (FIFO): This criterion was identified in all the sampled units. Duration with the organisation was used as criterion, whereby the faithful long standing patients who had been with the organization for at least one year were prioritised. They reasoned that such patients had demonstrated their ability to adhere by virtue of their having been faithful to coming to the unit prior to the availability of ART. Hence initially these units never recruited first-time visitors and patients were prioritised in order of how long they had been with the clinic.

> "What we do, to avoid confusion in this centre and all the branches in the other regions, the procedure is first come first served" (Practitioner- TASO).
> "Because, when the therapy came on board there were many people who had waited as far as back as the 1980s, 90s, and it would look unfair to start with people who had just registered"(Practitioner- Public unit).

While some respondents thought FIFO was a fair selection criterion, others felt otherwise. Moreover, some respondents reported that this criterion seems to have changed recently. These observed that sometimes, severely ill patients and relatives of patients on ART are prioritized in spite of the order in which they came,

> "(…) our issue of looking at the family, you imagine, a child or an adult in this home we discover they are positive and one of their members is on ARV don't you think they will take those drugs and swallow them?"(Policy maker).

Special population groups: Respondents identified vulnerable groups of people that would be prioritized in order to achieve equity in access to ART. Given the costs of ART, the faith-based unit reported that they endeavour to prioritize the poor-those people who cannot afford to buy the drugs from the open market. In addition, the public research unit and private unit made an effort to prioritise children by reserving a quota of the treatment slots for the children. Both TASO units reported that they prioritised pregnant and breast feeding women, especially those who received nevirapine to prevent mother to child HIV transmission. This was consistent with the reviewed records. Furthermore, respondents from the research unit reported that often patients who participate in clinical trials are prioritized (Table 3).

Activism: Some specific groups of people, by virtue of their involvement with the HIV/AIDS programs, were dentified as priority candidates for ART. These included staff members (In both TASO units, the public and the

private units), client representatives, board members, members of the drama groups (that conduct peer education and mobilization that is both TASO units). These people were prioritised by virtue of their commitment to the HIV cause, their lack of fear to disclose their HIV status, and their willingness to help others with HIV.

> "(…) so we got the drama groups first, because those are our advocates, then we go to the client councils also for ARVs and then we went to those who registered with TASO first.....(Practitioner- TASO).

DISCUSSION

We have presented empirical findings from a study describing criteria actually used in patient selection in six HIV/AIDS treatment centres in Uganda. The criteria identified by our respondents can be summarised under the medical and social categories. There was marked overlap of the criteria used across treatment centres and also between the treatment centres and the national guidelines. However, scarcity sometimes forces local practitioners to modify existing criteria and use additional criteria. For example, the widespread use of FIFO rule is not recommended in WHO and national guidelines.

Most of these criteria have been identified in reports elsewhere. Medical eligibility criteria, adherence, prevention- driven, social and economic benefits, ethical arguments, financial factors and waiting lists were identified as criteria in scaling up ARVs in countries such as Mexico, Senegal, Uganda and Thailand (Bennett and Chanfreau, 2005; Macklin, 2006). In describing actual patient selection in South Africa, similar criteria were also identified, although some of the criteria such as residence requirements were used with flexibility with increasing ART availability (Fox and Goemaere, 2006). However, a CD4 count cut-off of 50 has not been reported before.

Comparison of criteria between the treatment centres and the national guidelines

In comparing the selection criteria between the treatment centres, there was more agreement around the medical criteria and less agreement around the social criteria (Table 3). The agreement around the medical criteria may be explained in two ways. First, the treatment centres, in order to qualify for free ART, should abide with the national guidelines. Since the Ministry of Health provided details of relevant medical considerations, it is not surprising that the centres are in agreement with regards to these criteria. This was not the case with the social criteria where the ministry provided only a framework but left individual treatment centres to determine the details. That may explain why some criteria (such as alcohol consumption and considering the poor) are used by only a few centers. Failure to articulate explicit criteria would contribute to these variations (Mechanic, 1995; Kapiriri and Norheim, 2004).

The second explanation relates to the inherent values operating in the different provider contexts. TASO is one of the oldest AIDs support organizations in Uganda whose members became activists and disclosed their status even before ART was available. It is not surprising that they are the only units that identified activism and FIFO as important criteria (TASO Uganda, 2009). Another example of inherent values impacting the rationing criteria is the finding that only the faith- based treatment centre prioritized the poor. The vision of this unit is; '…to provide quality medical care to all at minimum cost without compromising the economically disadvantaged…' While this may reflect the core values of the treatment centre; it conflicts with some of the criteria used in the other units who require patients to prove that they can sustain ART in order to prevent interruption in treatment and resistance to drugs.

The provider reports provided minimal information including the patients' age, sex, WHO staging and CD4 count. Age and sex are standard demographic data which is routinely collected. However, WHO staging and the CD4 count are additional data that is collected from each patient. No records articulated the social characteristics of the patient. This may be a reflection of the importance providers place on these criteria. Conversely, it may reflect the required reporting standards, whereby the records on the social criteria are kept separately or only kept in the patients' files which we did not review.

The national guidelines on criteria for patient selection specify two major categories - the primary criteria which is predominantly medical eligibility, and the patient-specific 'factors' which are mainly social criteria (see Table 1). In comparison to the identified criteria, there was agreement with regards to both WHO stage/CD4 count and patient readiness. However, while the document review revealed variations in the CD4 count cut off (ranging from <50 - 250), it was difficult to determine if those patients with a higher CD4 count than was recommended were either started on treatment based on the WHO stage or they had Tuberculosis (Table 1). Furthermore, the social criteria- where there was marked variation between units-were not explicitly articulated in the national guidelines. For example, the guidelines identify financial barriers as one of the patient specific criteria. It is apparent from our findings that this criterion was interpreted differently in different units. While some units used it to "eliminate" those who could not sustain the treatment; others used it to justify prioritising those who could not afford the market ART. Some of the respondents who participated in developing the national guidelines clarified that the national level personnel were mandated to develop explicit medical criteria while the

treatment units were delegated the authority to develop the specific social criteria. It was beyond the scope of this study to explore the development of the guidelines at the unit level but our respondents alluded to the fact that they had developed detailed guidelines on both the medical and social criteria.

The rationales behind the criteria

Most of the reasons given for the different criteria were consistent with current knowledge, although some of the rationales were questionable. For example, the rationales behind the cut-off of CD4 count at <200 although previously accepted in guidelines for distributing ART in low and middle income countries, were questioned. It is known that late start of treatment as much as earlier start may not benefit patients, moreover, a higher cut-off is recommended in high income countries (Ford, Mills et al, 2009; USDHHS, 2006). Hence, while there are good reasons to expect better outcomes from earlier treatment, it may be a discussion of social justice why lower thresholds are used in low-income countries (Phillips et al, 2003).Furthermore, while respondents used co-infections as a reason to delay initiation of ART, there is evidence that suggests that starting antiretrovirals immediately in a person with an acute opportunistic infection lowers the risk of AIDS progression and death compared with delaying antiretrovirals until the opportunistic infection is controlled (Zolopa, Andersen et al, 2008). From a medical and ethical perspective: should there be standard criteria for all patients in spite of where they live? This may relate to the discussion on global health ethics and resource allocation, which is beyond the scope of this paper (Daniels, 2005).

Although the rationales behind the social criteria may seem reasonable that is to ensure adherence, minimise ad hoc treatment and chances of developing resistance which may be perceived as unfair to people who are concerned with prioritizing the vulnerable-a value held by some of the Ugandan population (Fox and Goemaere, 2006; Kapiriri and Martin, 2007). Poor people may not afford to purchase drugs, food or live in the vicinity of a treatment centre (Bennett and Chanfreau, 2005). However, concern for the poor while ensuring adherence and preventing development of resistance would require dealing with the structural barriers that may prevent poor people from accessing ART.

Other rationales behind criteria such as activism and FIFO may be more difficult to justify. The rationale behind prioritising activists seems reasonable; however, it may also be unfair to people who for some reasons-social, economic or otherwise-are unable to work as activists. Activists were among the initial people who presented themselves at the units-even before the treatment was available. In most of the units, these people were part of the teams that developed the guidelines for patient selection. It is thus, not surprising that they supported FIFO. This may also partly explain why in some units providers reported that they treat patients with very low CD4 counts, despite knowing that they might not have good outcomes and hence, less cost-effective to treat. Furthermore, the rationales behind FIFO may also be contested by people interested in equity. Arguably, activism may necessitate a certain type of person who may not be representative of especially the vulnerable poor patients in rural areas-since these lack an enabling environment, lack access to information and other necessary resources (Kapiriri et al., 2003), and are unlikely to have been among the first to present at the units. Using these criteria may marginalise such people vulnerable people-and this may partly explain why some units are increasingly considering other criteria beyond the FIFO.

Limitations

To the best of our knowledge, this is one of the few empirical studies that examine the criteria actually used by clinicians in rationing ART. However, we recognize some limitations to our study. First, we relied on what our respondents described and did not observe actual patient selection. However, our study is strengthened by using different sources of data. Second, this paper limited its discussion to patient selection criteria, and did not emphasise the selection process. These results are presented in another paper (Sofaer et al., 2008). Third, we cannot claim that our findings are generalizable to all treatment centres but maintain that they provide insight into the criteria that is currently used in selecting patients to access ART in the institutions we have studied-and are hence useful for understanding and guiding policy.

Conclusion

This paper describes the criteria used to ration ART in Uganda. Practitioners recognised the need to ration ART given the resource constraints-a reality some perceived as unfair. Scarcity sometimes forced local practitioners to modify existing criteria and to use additional criteria. Practitioners from six ART treatment units identified both medical and social criteria used to ration ARTs. There was an overlap between medical criteria used by the treatment centres we studied and the national recommendations (where the guidelines are more explicit); and variations with regards to the social criteria (where the national guidelines are less explicit). These findings highlight the need for more explicit criteria to ensure consistence, and hence fairness in rationing across treatment centres. Criteria which have been adopted by all treatment centres could be considered for explicit inclusion in the national guidelines. Criteria where there are wide variations should be publicly debated, considering the uniqueness of each specific treatment centre

and their clientele, so as to develop an acceptable set of criteria for rationing ART. These criteria should be publicized to facilitate on-going revisions. The acceptable set of criteria would be an invaluable input to a fair patient selection process.

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